FINAL RANDOMIZED BLINDED PHASE (PART A) CLINICAL STUDY REPORT

A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

PROTOCOL NUMBER
mRNA-1273-P301

Name of Test Product:	mRNA-1273
Indication:	COVID-19
ClinicalTrials.gov Identifier:	NCT04470427
Sponsor:	ModernaTX, Inc. 200 Technology Square Cambridge, MA 02139
Sponsor Signatory:	Allison August, MD VP, Clinical Development, Infectious Diseases ModernaTX, Inc. Telephone: +1-617-678-8937 E-mail: allison.august@modernatx.com
Drug Development Phase:	3
Study Initiation Date:	First participant first visit: 27 Jul 2020
Part A Analysis Cutoff Date:	Last participant visit date for Part A: 26 Mar 2021 The analyses presented in this report are based on a database lock date of 04 May 2021
Sponsor Medical Officer:	Allison August, MD
Date of Report:	05 August 2021

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

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Synopsis

Title of Study: A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

Investigators: This was a multicenter study.

Study Centers: This study was conducted at 99 study sites in the United States.

Publication (Reference): Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, et al. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. N Eng J Med. 2021;384(5):403-16.

Study Period (Part A): 27 Jul 2020 (First participant first visit) to early unblinding, study discontinuation, the Part B participant decision visit (PDV) or data cutoff date (26 Mar 2021), whichever was earlier

Drug Development Phase: 3

Background and Rationale: An outbreak of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) began in Wuhan, Hubei Province, China in December 2019 and the disease has since spread globally. On 11 Mar 2020, the World Health Organization declared COVID-19 a pandemic. Global efforts to evaluate novel antivirals and therapeutic strategies to treat severe SARS-CoV-2 infections have intensified, and there is an urgent public health need for rapid development of novel vaccines to prevent the spread of this disease. ModernaTX, Inc. (Sponsor) has used rapid response, proprietary, mRNA-based vaccine platform to develop a novel lipid nanoparticle (LNP)-encapsulated mRNA-based vaccine against SARS-CoV-2 (mRNA-1273).

Study mRNA-1273-P301 was designed as a Phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but whose occupation or location and living circumstances put them at increased risk of acquiring COVID-19 and/or SARS-CoV-2 infection. The primary goals of this Phase 3 study are to evaluate the vaccine efficacy (VE) of mRNA-1273 to prevent COVID-19, compared to placebo and to further evaluate the safety and reactogenicity profile of mRNA-1273.

This Part A clinical study report (CSR) presents the data from the randomized, placebo controlled, blinded phase (Part A) of the study based on the database lock on 04 May 2021, and includes available participant level data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier.

Objectives and Endpoints:

Objectives	Endpoints
Primary efficacy	

• To demonstrate the efficacy of mRNA-1273 to prevent COVID-19.	• The VE of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second dose of IP, where COVID-19 was defined as symptomatic disease based on the following criteria:
	  • The participant must have experienced at least TWO of the following systemic symptoms: fever (≥ 38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), OR
	  • The participant must have experienced at least ONE of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; AND
	  • The participant must have at least 1 NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR.

Primary safety	
• To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart.	• Solicited local and systemic ARs through 7 days after each dose of IP. • Unsolicited AEs through 28 days after each dose of IP. • MAAEs or AEs leading to withdrawal through the entire study period. • SAEs throughout the entire study period. • Pregnancies and perinatal outcomes.

Objectives	Endpoints
Secondary efficacy	
• To evaluate the efficacy of mRNA-1273 to prevent severe COVID-19.	• The VE of mRNA-1273 to prevent severe COVID-19, defined as first occurrence of COVID-19 starting 14 days after the second injection of IP, (as per the primary endpoint) AND any of the following: • Clinical signs indicative of severe systemic illness, respiratory rate ≥ 30 per minute, heart rate ≥ 125 beats per minute, $SpO_2 \leq 93\%$ on room air at sea level, or PaO_2/FIO_2 < 300 mm Hg, OR • Respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic BP < 90 mm Hg, diastolic BP < 60 mm Hg, or requiring vasopressors), OR • Significant acute renal, hepatic, or neurologic dysfunction, OR • Admission to an intensive care unit or death.
• To evaluate the efficacy of mRNA-1273 to prevent serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity.	• The VE of mRNA-1273 to prevent the first occurrence of either COVID-19 or SARS-CoV-2 infection starting 14 days after the second injection of IP. This endpoint includes COVID-19, as defined for the primary endpoint, and asymptomatic SARS-CoV-2 infection, determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein or a positive RT-PCR test post baseline. This endpoint was evaluated in participants who were SARS-CoV-2 negative at baseline.
• To evaluate VE against a secondary definition of COVID-19.	• The VE of mRNA-1273 to prevent the secondary case definition of COVID-19 starting 14 days after the second injection of IP. The secondary case definition of COVID-19 was defined as the presence of at least 1 of the following systemic symptoms: fever (temperature ≥ 38ºC), or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting, or diarrhea AND a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS-CoV-2 by RT-PCR.
• To evaluate VE to prevent death caused by COVID-19.	• The VE of mRNA-1273 to prevent death due to a cause directly attributed to a complication of COVID-19, starting 14 days after the second injection of IP.

Objectives	Endpoints
• To evaluate the efficacy of mRNA-1273 to prevent COVID-19 after the first dose of IP.	• The VE of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the first injection of IP.
• To evaluate the efficacy of mRNA-1273 to prevent COVID-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection.	• The VE of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second injection of IP regardless of evidence of prior SARS-CoV-2 infection (FAS analysis population).
• To evaluate the efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection.	• The VE to prevent the first occurrence of SARS-CoV-2 infection in the absence of symptoms defining COVID-19 starting 14 days after the second injection of IP. SARS-CoV-2 infection was determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 Nucleocapsid protein or a positive RT-PCR test at a scheduled visit (eg, predose on Day 29). This endpoint was evaluated in participants who were SARS-CoV-2 negative at baseline.
Secondary immunogenicity	
• To evaluate the immunogenicity of 2 doses of mRNA-1273 given 28 days apart.	• GMT of SARS-CoV-2 -specific nAb on Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759[a]. • GMFR of SARS-CoV-2-specific nAb relative to Day 1 on Day 29, Day 57, Day 209, Day 394, and Day 759[a]. • Quantified levels or GMT of S protein-specific bAb on Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759[a]. • GMFR of S protein-specific bAb relative to Day 1 on Day 29, Day 57, Day 209, Day 394, and Day 759[a].
Exploratory - The following exploratory objectives and endpoints are addressed in this CSR:	
• To evaluate the effect of mRNA-1273 on the viral infection kinetics as measured by viral load at SARS-CoV-2 infection diagnosis by RT-PCR and number of days from the estimated date of SARS-CoV-2 infection until undetectable SARS-CoV-2 infection by RT-PCR.	• The VE of mRNA-1273 on the viral infection kinetics as measured by viral load at SARS-CoV-2 infection diagnosis by RT-PCR and number of days from the estimated date of SARS-CoV-2 infection until undetectable SARS-CoV-2 infection by RT-PCR.
• To assess VE to reduce the duration of symptoms of COVID-19.	• The VE of mRNA-1273 to reduce duration of COVID-19 symptoms.
• To evaluate VE against all-cause mortality.	• The VE of mRNA-1273 against all-cause mortality.
• To assess VE against BOD due to COVID-19	• The VE of mRNA-1273 against BOD based on the post SARS-CoV-2 infection follow-up.
• To evaluate the genetic and/or phenotypic relationships of isolated SARS-CoV-2 strains to the vaccine sequence.	• The genetic and/or phenotypic relationships of isolated SARS-CoV-2 strains to the vaccine sequence.
• To conduct additional analyses related to furthering the understanding of SARS-CoV-2 infection and COVID-19, including analyses	• Additional analyses related to furthering the understanding of SARS-CoV-2 infection and

Objectives	Endpoints
related to the immunology of this or other vaccines, detection of viral infection, and clinical conduct.	COVID-19, including analyses related to the immunology of this or other vaccines, detection of viral infection, and clinical conduct.

Abbreviations: AE = adverse event; AR = adverse reaction; ARDS = acute respiratory distress syndrome; bAb = binding antibody; BOD = burden of disease; BP = blood pressure; CSR = clinical study report; ECMO = extracorporeal membrane oxygenation; FAS = Full Analysis Set; FIO_2 = fraction of inspired oxygen; GMFR = geometric mean fold rise; GMT = geometric mean titer; IP = investigational product; MAAE = medically-attended adverse event; nAb = neutralizing antibody; NP = nasopharyngeal; PaO_2 = partial pressure of oxygen; RT-PCR = reverse transcription polymerase chain reaction; SAE = serious adverse event; SpO_2 = oxygen saturation by pulse oximeter; VE = vaccine efficacy.

[a] This Part A CSR presents the immunogenicity endpoints through Day 57 for the Per-Protocol Random Subcohort for Immunogenicity.

Methodology:

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

This Part A CSR presents the data from the randomized, placebo-controlled, blinded phase (Part A) of the study based on the database lock on 04 May 2021, and includes available participant level data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier. Data from Part B, in which eligible participants were offered open-label mRNA-1273, will be included in a CSR addendum.

Part A, the Randomized, Placebo-Controlled, Blinded Phase

Part A of this study was a Phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who had no known history of SARS-CoV-2 infection but whose occupation or locations and living circumstances put them at appreciable risk of acquiring COVID-19 and/or SARS-CoV-2 infection.

Participants were randomly assigned to receive doses of either 100 µg of mRNA-1273 vaccine or placebo in a 1:1 randomization ratio. Assignment was stratified by age and health risk.

All participants were assessed for efficacy and safety endpoints. A nasopharyngeal (NP) swab sample and blood sample were obtained from each participant before the first and second dose of investigational product (IP). In addition, a series of postdose blood samples for immunogenicity

are being collected through 24 months after the second dose of IP. Efficacy assessments included surveillance for COVID-19 with reverse transcriptase polymerase chain reaction (RT-PCR) confirmation of SARS-CoV-2 infection after the first and second dose of IP.

Each participant received 2 doses of IP by 0.5 mL intramuscular (IM) injection, the first on Day 1 and the second on Day 29. An NP swab sample was collected prior to the first and second dose of IP for evaluation by RT-PCR. To preserve observer blinding, only delegated unblinded study site personnel responsible for IP preparation, administration, and/or accountability had knowledge of study IP assignment.

Participants were given an electronic diary (eDiary) to report solicited ARs for 7 days after each dose of IP and to prompt an unscheduled clinic visit for clinical evaluation and NP swab sample if a participant experienced any symptoms of COVID-19. Participants used the eDiary to report solicited ARs for the first 7 days after each dose of IP (or until resolution for solicited ARs that continued beyond 7 days) and were then followed by weekly eDiary prompts (every 7 days) to elicit an unscheduled Illness Visit if the participant experienced COVID-19 symptoms. All participants received safety calls on Day 8, Day 15, Day 22, Day 36, and Day 43 that served both to monitor for unsolicited adverse events (AEs) and to monitor for symptoms of COVID-19.

Safety telephone calls and eDiary safety prompts were performed in conjunction with surveillance for COVID-19 according to the SoEs and were intended to capture serious AEs (SAEs), medically attended AEs (MAAEs), AEs leading to withdrawal, concomitant medications associated with these events, receipt of non-study vaccinations, and pregnancy. If an eDiary prompt resulted in identification of a relevant safety event, a follow-up safety call was triggered.

Surveillance for signs and symptoms of COVID-19 is being performed through weekly contacts with the participant via a combination of telephone calls and completion of specific eDiary prompts starting at Day 1 through the end of the study. Participants with symptoms of COVID-19 lasting at least 48 hours (except for fever and/or respiratory symptoms) returned to the clinic or were visited at home by medically qualified study site personnel within 72 hours to collect an NP swab sample for RT-PCR testing for SARS-CoV-2 and other respiratory pathogens, or alternatively, if a clinic or home visit was not possible, submitted a saliva (or nasal swab) sample for SARS-CoV-2 RT-PCR testing.

All study participants who experienced COVID-19 symptoms and subsequently presented for an Illness Visit (in clinic or at home) were given an instruction card listing symptoms and severity grading system along with a thermometer, an oxygen saturation monitor, and saliva collection tubes. Study participants were contacted by the investigator (or appropriately delegated study site personnel) daily with telemedicine visits through Day 14 or until symptoms had resolved, whichever was later. During the telemedicine visit (preferably done in the evening), the

participant was asked to verbally report the severity of each symptom, their highest body temperature and lowest oxygen saturation for that day, and the investigator determined if medical attention was required due to worsening of COVID-19 symptoms. Study participants collected their own saliva (or nasal swab) sample at 3, 5, 7, 9, 14, and 21 days after the initial Illness Visit meeting criteria for COVID-19 (defined as the date of onset of symptoms and positive virologic test). Finally, a Convalescent Visit was scheduled approximately 28 days after the initial Illness Visit. At this visit, a saliva (or nasal swab) sample was collected and a blood sample was drawn for immunologic assessment of SARS-CoV-2 infection.

At each IP injection visit, participants were instructed (Day 1) or reminded (Day 29) on how to document and report solicited ARs in the eDiary provided. Solicited ARs were assessed for 7 days after each IP injection (or until resolution for solicited ARs that continued beyond 7 days), and unsolicited AEs were assessed for 28 days after each injection; SAEs, MAAEs, and AEs leading to withdrawal were assessed throughout the study.

Participants may have experienced AEs that necessitated an unscheduled visit. There may have also been situations in which the investigator asked a participant to report for an unscheduled visit following the report of an AE. Additional examinations may have been conducted at these visits as necessary to ensure the safety and well-being of participants during the study. Electronic case report forms (eCRFs) should have been completed for each unscheduled visit.

Number of Participants (Planned and Analyzed): Approximately 30,000 participants were planned to receive doses of either 100 μg of mRNA-1273 vaccine or placebo in a 1:1 randomization ratio.

In Part A, a total of 30,415 participants were randomized (Randomized Set): 15,206 in the placebo group and 15,209 in the mRNA-1273 group. Of these, 22,882 participants were ≥ 18 and < 65 years and 7,533 participants were ≥ 65 years. The number of participants included in the analysis sets used for the primary analyses of efficacy, immunogenicity, and safety are summarized as follows:

- Per-Protocol Set: 28,451 (93.5%) total (14,164 [93.1%] in the placebo group and 14,287 [93.9%] in the mRNA-1273 group)
- Per-Protocol Random Subcohort for Immunogenicity: 1,457 (4.8%) total (272 [1.8%] in the placebo group and 1,185 [7.8%] in the mRNA-1273 group)
- Safety Set: 30,346 total (15,162 in the placebo group and 15,184 in the mRNA-1273 group)

Main Criteria for Inclusion and Exclusion: Participants (males and females 18 years of age or older at time of consent), who were at high risk of SARS-CoV-2 infection, defined as adults

whose locations or circumstances put them at appreciable risk of exposure to the virus, who were heathy and had no known history of SARS-CoV-2 infection, or adults with pre-existing medical conditions who were in stable condition at screening comprised the planned target population. Additionally, potential study participants at high risk of severe COVID-19 were included based on age (65 years of age and older) and underlying medical conditions.

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

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

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

Estimands and Intercurrent Events: The estimand of the primary analysis was VE measured using 1 – HR (mRNA-1273 vs. placebo) for prevention of first occurrence of COVID-19 from 14 days after second dose of IP in adults.

Statistical Methods:

Analysis Sets: The following analysis sets were defined:

- **Randomized Set:** All participants who were randomized, regardless of the participant's treatment status in the study. Participants were analyzed according to the treatment group to which they were randomized.
- **Full Analysis Set (FAS):** All randomized participants who received at least 1 dose of IP. Participants were analyzed according to the treatment group to which they were randomized.
- **Modified Intent-to-Treat (mITT) Set:** All participants in the FAS who had no immunologic or virologic evidence of prior COVID-19 (negative SARS-CoV-2 status, ie, negative NP swab test and negative bAb against SARS-CoV-2 N-protein as measured by Roche Elecsys®) at Day 1 before the first dose of IP; ie, all FAS participants excluding those with RT-PCR and/or serology positive at baseline (Day 1 before the first dose of IP). Participants were analyzed according to the treatment group to which they were randomized.

- **PP Set:** All participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data. Participants were analyzed according to the treatment group to which they were randomized. Participants who did not receive the second injection of IP within [21, 42] days after the first injection date were excluded from the PP Set.
- **Immunogenicity Subset and Analysis Populations for Immunogenicity:** For characterizing immunogenicity of the vaccine and for assessing correlates of risk and protection, a case-cohort sampling design was used for measuring bAb and nAb data from a randomly sampled subset of study participants (the case-cohort Immunogenicity Analysis Set [ccIAS]) or immunogenicity subset. The ccIAS cohort consisted of a stratified, random sample of study participants (random subcohort) augmented with a subset or all primary endpoint cases and SARS-CoV-2 infection endpoint cases. The immunogenicity samples of the ccIAS cohort were processed and the immunogenicity data were available for the ccIAS cohort. The immunogenicity subset consisted of all participants in the ccIAS who had a valid baseline immunogenicity test result (prior to the first dose of IP) and at least 1 valid post-baseline result.
- The **Per-Protocol Random Subcohort for Immunogenicity** (PPRSI) was used as the analysis population to characterize immunogenicity of mRNA-1273. The PPRSI for immunogenicity consisted of participants in the FAS who were sampled into the random subcohort and
    a) Received both planned doses (ie, received the treatment as the participant was randomized to) with Dose 2 received within [21, 42] days after Dose 1, and
    b) No major protocol deviation that impacted critical or key data.
- **Solicited Safety Set:** All randomized participants who received at least 1 dose of IP and contributed any solicited AR data; ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The Solicited Safety Set was used for the analyses of solicited ARs, and participants were included in the treatment group corresponding to the study vaccination they actually received.

  In addition, the following Solicited Safety Set was defined for each injection separately. **The First (Second) Injection Solicited Safety Set** consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days.

Participants were analyzed according to the treatment group a participant received, rather than the treatment group to which the participant was randomized. If a participant was randomized to placebo but received any dose of mRNA-1273 vaccine at any injection, the participants were included in the mRNA-1273 group in the Solicited Safety Set.

- **Safety Set:** All randomized participants who received at least 1 dose of IP. The Safety Set was used for all analysis of safety except for the solicited ARs. Participants were included in the treatment group corresponding to the IP they actually received. For a participant who was randomized to placebo but received any dose of mRNA-1273 at any injection, the participant will be included in the mRNA-1273 group in the Safety Set.

Efficacy: The PP Set was the primary analysis population for efficacy analyses, unless otherwise specified.

Primary Efficacy Endpoint:

The number and percentage of participants who had an event (ie, the first occurrence of COVID-19 starting 14 days after the second injection) and the participants who were censored were summarized.

The non-parametric Kaplan-Meier method was used to estimate the time to first occurrence of COVID-19 curve in each treatment group.

Vaccine efficacy was defined as the percent reduction in the hazard of the primary endpoint (mRNA-1273 vs. placebo), ie, 1 – HR. The null hypothesis was:

$$H_0^{efficacy}: VE \leq 0.3$$

Equivalently, the null hypothesis was:

$$H_0^{efficacy}: HR \geq 0.7$$

A stratified Cox proportional hazard model with Efron's method of tie handling and with treatment group as covariate was used to assess the magnitude of the treatment group difference (ie, HR) between mRNA-1273 and placebo. The same stratification factors used for randomization were applied to the stratified Cox model. The VE with corresponding alpha adjusted confidence interval (CI), 95% CI, and 1-sided *p* value for testing the null hypothesis from the stratified Cox model was reported at a planned IA up to the analysis at which VE was demonstrated. After VE was demonstrated, VE and 95% CI were to be provided for subsequent analysis/updates of efficacy.

In this study, VE was demonstrated based on prespecified statistical criterion at the IA, at which, 1-sided *p* value for testing the null hypothesis of VE ≤ 0.3, 95% CI, and alpha-adjusted CI were provided from the stratified Cox model. At the primary analysis where the total number of

COVID-19 cases > 151, total target number of cases, VE, 1-sided *p* value for testing the null hypothesis of VE ≤ 0.3, and 95% CI were provided. In subsequent analysis/updates of efficacy, VE and 95% CI were provided.

The number and percentage of participants who had an event (ie, the first occurrence of COVID-19 at least 14 days after the second injection) were reported.

Sensitivity analyses were performed, with COVID-19 cases counted starting at various time points using the PP Set as follows:

- After the second injection of IP
- Fourteen days after the first injection of IP (also as primary analysis approach for the secondary efficacy objective: to evaluate the efficacy of mRNA-1273 to prevent COVID-19 after the first dose of IP).
- After randomization

Analysis of the primary efficacy endpoint based on the mITT Set was also performed using the same statistical methods used for the primary analysis. The sensitivity analyses, with COVID-19 cases counted starting at various time points were also performed using the mITT Set.

To assess consistency of VE across various subgroups, subgroup analyses of the primary efficacy endpoint were performed based on the PP Set. The primary efficacy endpoint was analyzed by each of the subgroups using the same methods described for the primary analysis (ie, stratified Cox proportional hazard model with Efron's method of tie handling with a single treatment covariate), and the estimate of VE and its 95% CI were provided within each category of the following subgroups:

- Age groups: ≥ 18 and < 65 years, ≥ 65 years
- Age groups: ≥ 18 and < 65 years, ≥ 65 years and < 75 years, ≥ 75 years
- Stratification factor at randomization: ≥ 18 and < 65 years and not at risk, ≥ 18 and < 65 years at risk, ≥ 65 years
- Sex (female, male)
- Race
- Ethnicity
- Race and ethnicity: non-Hispanic White, communities of color
- Each risk factor for severe COVID-19 illness

Secondary Efficacy Endpoints:

Similar analysis methods, as detailed for the primary efficacy endpoint, were applied to the following secondary efficacy endpoints based on the PP Set, unless otherwise specified:

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

  The analysis population for this endpoint, serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity [COV-INF], was the PP Set (primary analysis population) and the mITT Set that included participants with negative SARS-CoV-2 status at baseline. Infection [COV-INF] was defined by any post-baseline positive RT-PCR results, and/or, seroconversion due to infection defined as positive bAb specific to SARS-CoV-2 NP as measured by Roche Elecsys at post-baseline scheduled visits for participants with negative SARS-CoV-2 status at baseline (PP and mITT Sets). Both RT-PCR tests from the scheduled NP swab tests at Day 29 as well as those prompted by symptom(s) were considered. A COVID-19 case or secondary definition of COVID-19 case was always a COV-INF case.
- VE to prevent COVID-19 using a secondary definition of symptoms.
- VE to prevent death caused by COVID-19

For each of the above secondary endpoints, the following analyses were performed:

- VE was estimated with 1 – HR (mRNA-1273 vs. placebo) using a Cox proportional hazard model based on the PP Set as described for the primary efficacy endpoint. Kaplan-Meier curves of time to event were presented for each treatment group. Cases were counted starting 14 days after the second injection of IP.
- Analysis was performed using the same model based on the mITT Set as described for the primary efficacy endpoint. Kaplan-Meier curves of time to event were presented for each treatment group.
- Sensitivity analyses were performed, with cases counted starting immediately after the second injection of IP (onset date ≥ date of second injection, considering positive RT-PCR at Day 29), starting 14 days (≥ 14 days) after the first injection of IP, and immediately after randomization, respectively.
- VE and 95% CI based on the incidence were estimated with 1 – ratio of incidence rates using the exact method conditional upon the total number of cases.

For the secondary efficacy objective: VE to prevent asymptomatic SARS-CoV-2 infection

- The analysis populations for asymptomatic infection were the PP Set (primary analysis population) and mITT Set. Asymptomatic infection was COV-INF (detected by positive RT-PCR or seroconversion [bAb specific to SARS-CoV-2 NP as measured by Roche Elecsys at scheduled visits]) with absence of symptoms.

  As diseased cases (COVID-19 or secondary definition of COVID-19) were competing events for asymptomatic SARS-CoV-2 infections, competing risk method (Fine and Gray's [FG] subdistribution hazard model) was used to estimate the VE of mRNA-1273. Competing risk method was also used to estimate the cumulative incidence function, and the cumulative incidence of asymptomatic SARS-CoV-2 infections were plotted.

  In the primary approach with cases of asymptomatic SARS-CoV-2 infection counted starting 14 days after the second injection, only seroconversion at Day 57 or later was to be considered.

  As serum samples were taken at scheduled visits (eg, Day 29 [Month 1], Day 57 [Month 2]), sensitivity analyses with cases counted starting after second injection, 14 days after the first injection, after the first injection, and after randomization were the same. Only 1 set of sensitivity analysis with cases counted starting from randomization was provided. In this sensitivity analysis, asymptomatic cases detected by positive RT-PCR result at scheduled Day 29 (before the second injection), or seroconversion at time points with scheduled visits were considered. Sensitivity analysis using the mITT Set with cases counted starting from 14 days after the second injection, and from randomization were also performed.

For the secondary efficacy objective: VE to prevent COVID-19 after the first injection of IP

- This endpoint was analyzed as a sensitivity analysis of the primary efficacy endpoint with cases counted starting 14 days (≥ 14 days) after the first injection of IP.

For the secondary efficacy objective: VE to prevent COVID-19 disease regardless of prior SARS-CoV-2 infection

- VE to prevent COVID-19 disease regardless of prior SARS-CoV-2 infection was analyzed using the FAS. The same methods described for the primary efficacy endpoint were applied with cases counted starting 14 days after the second injection of IP.

Sensitivity analyses with cases counted starting immediately after the second injection, 14 days after the first injection, and after randomization were also performed. In sensitivity analysis with cases counted starting after the second injection, participants who received only the first injection and were cases, were censored at the time of COVID-19.

The VE was also estimated with 1 – the ratio of incidence rates with the 95% CI using the exact method conditional upon the total number of cases adjusting for person-time.

In addition, an exploratory analysis with the same Cox model was performed in the subgroup of the FAS whose baseline SARS-CoV-2 status was positive with cases counted starting 14 days after the second dose to assess the VE in those with positive baseline SARS-CoV-2 status, at baseline, if sample size permitted. Such analysis in the subgroup of the FAS whose baseline SARS-CoV-2 status was negative with cases counted starting 14 days after the second dose was the same as the sensitivity analysis of COVID-19 starting 14 days after the second dose in the mITT Set.

Immunogenicity: The PPRSI was used as the analysis population to characterize immunogenicity of mRNA-1273.

Data from quantitative immunogenicity assays were summarized for each treatment group using positive response rates and geometric means (GMs) with 95% CI at each time point when an assessment was performed. Data from qualitative (ie, yielding a positive or negative result) assays were summarized by tabulating the frequency of positive responses for each assay by treatment group and by baseline SARS-CoV-2 status, if applicable, at each time point that an assessment was performed.

At the time the final blinded efficacy analysis, immunogenicity analyses to characterize immunogenicity of mRNA-1273 were performed. At the time of the immunogenicity analyses, data for bAb to S (MSD, PPD-VAC65) and psVNA ID_{50} and ID_{80} titers were available. The assay by MSD to measure bAb against RBD and N-protein had not yet been validated at the time of the immunogenicity analysis; therefore, these data were not summarized/analyzed. Immunogenicity data at the prespecified time points (Baseline [Day 1], Day 29 [Month 1], and Day 57 [Month 2]) were included.

- The GMT or value with corresponding 95% CI was provided at each time point. The 95% CIs were calculated based on the *t*-distribution of the log-transformed values then back transformed to the original scale for presentation. The following descriptive statistics were also provided at each time point: the number of participants (n), median, minimum, and maximum.

- The geometric mean fold rise (GMFR) with corresponding 95% CI was provided at each post-baseline time point over pre-injection baseline at Day 1. The 95% CIs were calculated based on the *t*-distribution of the log-transformed values then back transformed to the original scale for presentation. The following descriptive statistics were also provided at each time point: the number of participants (n), median, minimum, and maximum.
- Reverse cumulative distribution function curve (RCDF) at each time point. The number and percentage of participants with fold-rise ≥ 2, fold-rise ≥ 3, and fold-rise ≥ 4 from baseline at each post-injection time point were tabulated with 2-sided 95% Clopper-Pearson CIs.
- The Ab assay of interest [bAb to spike (MSD, PPD-VAC65) and PsVNA ID_{50} and ID_{80}] are listed in the table below. For each of them, seroresponse rate was defined as the proportion of participants achieving seroresponse, defined below for each assay/test of interest. Please note that these assay-specific definition of seroresponse was an update of 'seroconversion due to vaccination' used in the protocol and relevant SAP incorporating assay-specific fold-rise criteria based on assay-specific performance characteristics. These assay-specific definitions of seroresponse were documented in a memo that became available prior to DBL.

Assay Name	Category	Test Name/ Description	Definition of Seroresponse
Pseudovirus (PsVNA)	nAb	PsVNT50 (ID_{50})	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 3.3-fold rise
		PsVNT80 (ID_{80})	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 2.3-fold rise
Anti-Spike ELISA	bAb	anti-Spike VAC65 Spike IgG Antibody	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 4.6-fold rise
MSD multiplex	bAb	anti-Spike	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 1.9-fold rise

Abbreviations: bAb = binding antibody; ELISA = enzyme-linked immunosorbent assay; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; MSD = MesoScale Discovery; nAb = neutralizing antibodies; PsVNA = pseudotyped virus neutralization assay; PsVNT50 = 50% pseudotyped lentivirus reporter test; PsVNT80 = 80% pseudotyped lentivirus reporter test.

- Number and proportion of participants achieving seroresponse were provided with 2-sided 95% Clopper-Pearson CIs at each post-baseline time point.

To assess the magnitudes of the differences between the 2 treatment groups (mRNA-1273 vs. placebo) in SARS-CoV-2-specific nAb and S protein-specific bAb, a mixed-effect model repeated measures (MMRM) using SAS PROC MIXED was used. The geometric least squares mean (GLSM) and corresponding 2-sided 95% CI for the antibody titers for each treatment

group were provided by visit. The GLSM and corresponding 95% CI results in log-transformed scale estimated from the model were back-transformed to obtain these estimates in the original scale. Geometric mean ratio (GMR), estimated by the ratio of GLSM and the corresponding 2-sided 95% CI, was provided to assess the treatment difference between the mRNA-1273 versus placebo groups at each visit. With each treatment group, within-group comparison of time points may also have been estimated using the same model.

In addition, an analysis of covariance (ANCOVA) model with the treatment group as explanatory variables, adjusting for the stratification factor at randomization, baseline value if applicable, was used to assess the treatment effect at specific time points (scheduled visits) such as Day 57. The GLSM with 95% CI for each treatment group, GMR with 95% CI for treatment difference was estimated from the ANCOVA model. The model also adjusted for minority group used to sample for the random subcohort.

It was of interest to examine the immune response in participants on mRNA-1273 with baseline SARS-CoV-2 negative status who were COVID-19 or SARS-CoV-2 infection cases. Immunogenicity data was provided in a subset of baseline SARS-CoV-2 negative participants on mRNA-1273 who were adjudicated COVID-19 cases.

Safety: Safety and reactogenicity were assessed by clinical review of all relevant parameters including solicited ARs (local and systemic), unsolicited AEs, SAEs, MAAEs, AEs leading to withdrawal from study vaccine and/or study participation, vital signs, and physical examination findings.

All safety analyses were based on the Safety Set, except summaries of solicited ARs which were based on the Solicited Safety Set. All safety analyses were provided by treatment group, unless otherwise specified.

Solicited ARs:

The number and percentage of participants who reported each individual solicited local AR and solicited systemic AR during the 7-day follow-up period (or until resolution for solicited ARs that continued beyond 7 days) after each injection were provided by severity grade. The number and percentage of participants who reported each individual solicited AR were also summarized by severity grade, days of reporting, and injection.

The number and percentage of participants experiencing fever (a temperature greater than or equal to 38.0°C/100.4°F by the oral, axillary, or tympanic route) by severity grade and the number and percentage of participants experiencing a fever of Grade 3 or higher temperature (a temperature greater than or equal to 39.0°C/102.1°F by the oral, axillary, or tympanic route) were summarized.

A 2-sided 95% exact CI using the Clopper-Pearson method was provided for the percentage of participants who reported any solicited local AR, solicited systemic AR, or any solicited AR.

The number and percentage of participants with onset of individual solicited AR were summarized by study day relative to the corresponding injection (Day 1 through Day 7). All solicited ARs that continued beyond 7 days post injection were summarized.

The above analyses of solicited ARs were summarized separately for the following subgroups:

- Age group (< 65 and ≥ 65 years)
- Sex (male, female)
- Baseline SARS-CoV-2 status
- Race and ethnicity

Unsolicited AEs:

Unsolicited TEAE summaries were provided for TEAEs up to 28 days after any injection and during Part A.

The overall summaries of unsolicited TEAEs (number and percentage) by treatment group included the following: any unsolicited TEAEs, any serious TEAEs, any unsolicited TEAEs that were MAAEs, any unsolicited TEAEs leading to discontinuation from participation in the study or study vaccine, any unsolicited severe TEAEs (severity of AEs was assessed as mild, moderate, or severe), and any unsolicited fatal TEAEs. The overviews also included a summary of participants with treatment-related TEAEs in each category.

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

- All unsolicited TEAEs
- All treatment-related unsolicited TEAEs
- All SAEs
- All treatment-related SAEs
- All unsolicited TEAEs leading to discontinuation from study vaccine
- All unsolicited TEAEs leading to discontinuation from participation in the study
- All unsolicited severe TEAEs
- All treatment-related unsolicited severe TEAEs

- All unsolicited TEAEs that were MAAEs

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

The overview of TEAEs and the TEAE summaries presented by SOC and PT were also summarized for the following subgroups: age (< 65 and ≥ 65 years), sex (male, female), and baseline SARS-CoV-2 status.

Separate listings of individual participant AE data were provided for the following: unsolicited TEAEs leading to discontinuation from study vaccine, unsolicited TEAEs leading to discontinuation from participation in the study, SAEs, treatment-related SAEs, and unsolicited treatment-related MAAEs. A listing of deaths including cause of death and a listing of TEAEs in participants who died were provided.

Other Safety:

Observed values and changes from baseline for all vital sign measurements were summarized at each visit by baseline SARS-CoV-2 serostatus and treatment group. Shift from baseline in the toxicity grades at each visit were summarized by treatment group.

Pregnancies and outcome (if available) were summarized by treatment group and a listing of pregnancies including outcome were provided.

Summary of Results:

Participant Disposition: A total of 30,415 participants were randomly assigned to study treatment: 15,206 participants in the placebo group and 15,209 in the mRNA-1273 group. Of these, 99.8% of participants overall received the first injection and 96.5% received the second injection.

A total of 531 participants (3.5%) who were randomly assigned to receive placebo and 453 participants (3.0%) who were randomly assigned to receive mRNA-1273 discontinued the study vaccine. The most common reasons for discontinuation of study vaccine were confirmed SARS-CoV-2 infection (ie, diagnosed COVID-19 by detection of SARS-CoV-2 in Day 1 NP swab or COVID-19 diagnosed prior to Day 29), other, and withdrawal of consent by participant.

A total of 2099 participants (13.8%) who were randomly assigned to receive placebo and 730 participants (4.8%) who were randomly assigned to receive mRNA-1273 discontinued the study, Part A and Part B inclusive. The imbalance of discontinuations between the placebo and mRNA-1273 groups coincided with the EUA of the Pfizer BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine.

IP Exposure in Part A: A total of 30,346 participants received the first injection: 15,162 received placebo and 15,184 received mRNA-1273. Of these, 29,362 participants (96.8%) received the second injection: 14,631 (96.5%) received placebo and 14,731 (97.0%) received mRNA-1273.

A total of 13 participants (7 participants in the placebo group; 6 participants in the mRNA-1273 group) received incorrect study vaccination per the randomization schedule.

Duration of Follow-up: Overall, the median duration of follow-up after randomization for the entire period up to the data cutoff for DBL (26 Mar 2021; inclusive of Part A and Part B) was 212 days (range, 1 to 243 days): 211 days in participants ≥ 18 to < 65 years and 214 days in participants ≥ 65 years.

The median duration of follow-up from randomization to PDV (ie, Part A) for participants who had a PDV on or before the data cutoff date was 148 days (range, 30 to 241 days): 148 days (range, 31 to 241 days) in participants ≥ 18 to < 65 years and 147 days (range, 30 to 234 days) in participants ≥ 65 years.

Demography and Baseline Characteristics: Overall, in the FAS, participant demographics and baseline characteristics were similar between the groups. A slightly higher proportion of males versus females (52.6% versus 47.4%. respectively) were enrolled. The mean age at screening was 51.4 years (range: 18 to 95 years); 75.2% of participants were ≥ 18 to < 65 years of age and 24.8% were ≥ 65 years. The majority of participants were White (79.2%) and not Hispanic or Latino (78.6%). Communities of color comprised 37.2% of the study population; the racial and ethnicity proportions observed in this study were generally representative of US demographics.

The study enrolled a total of 41.5% of participants who were considered at risk for severe COVID-19 (16.7% participants who were < 65 years and at risk, and 24.8% participants who were ≥ 65 years).

Overall, the majority of participants (82.5%) had a specified occupational risk for acquisition of SARS-CoV-2 infection; the most common occupational risks included other (31.9%) and health care workers (25.2%). A total of 83.8% of participants had a location or living circumstances risk for acquisition of SARS-CoV-2.

Efficacy Results: The results of the primary and secondary efficacy endpoint analysis are summarized for the PP Set in Table S-1 and presented graphically in Figure S-1.

Table S-1: Summary of Primary and Secondary Efficacy Endpoint Analysis Results (Per-Protocol Set)

	Placebo (N=14164)	mRNA-1273 (N=14287)
COVID-19* based on adjudication committee assessments starting 14 days after second injection		
Number of events	744	55
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.932 (0.910, 0.948)
p-value [b]		<.0001
COVID-19* starting 14 days after second injection		
Number of events	751	55
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.932 (0.911, 0.949)
Severe COVID-19* based on adjudication committee assessments starting 14 days after second injection		
Number of events	106	2
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.982 (0.928, 0.996)
Severe COVID-19* starting 14 days after second injection		
Number of events	118	3
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.976 (0.924, 0.992)
SARS-CoV-2 infection regardless of symptomatology and severity starting 14 days after second injection [c]		
Number of events	1339	280
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.820 (0.795, 0.842)
Secondary definition of COVID-19* starting 14 days after second injection		
Number of events	807	58
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.934 (0.914, 0.949)
Death caused by COVID-19 starting 14 days after second injection		
Number of events	3	0
Vaccine efficacy based on hazard ratio (95% CI) [a]		1.000 (NE, 1.000)
COVID-19* based on adjudication committee assessments starting 14 days after first injection		
Number of events	769	56
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.933 (0.911, 0.949)

	Placebo (N=14164)	mRNA-1273 (N=14287)
COVID-19* starting 14 days after first injection		
Number of events	782	58
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.931 (0.910, 0.947)
Asymptomatic SARS-CoV-2 infection starting 14 days after second injection [c]		
Number of events	498	214
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.630 (0.566, 0.685)
COVID-19* based on adjudication committee assessments starting 14 days after second injection regardless of prior SARS-CoV-2 infection, n/N [d]		
Number of events	754/15166	58/15180
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.928 (0.906, 0.945)
COVID-19* starting 14 days after second injection regardless of prior SARS-CoV-2 infection, n/N [d]		
Number of events	762/15166	58/15180
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.929 (0.907, 0.946)

Abbreviations: CI = confidence interval; RT-PCR = reverse transcription polymerase chain reaction.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[a] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. For asymptomatic SARS-CoV-2 infection, VE and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

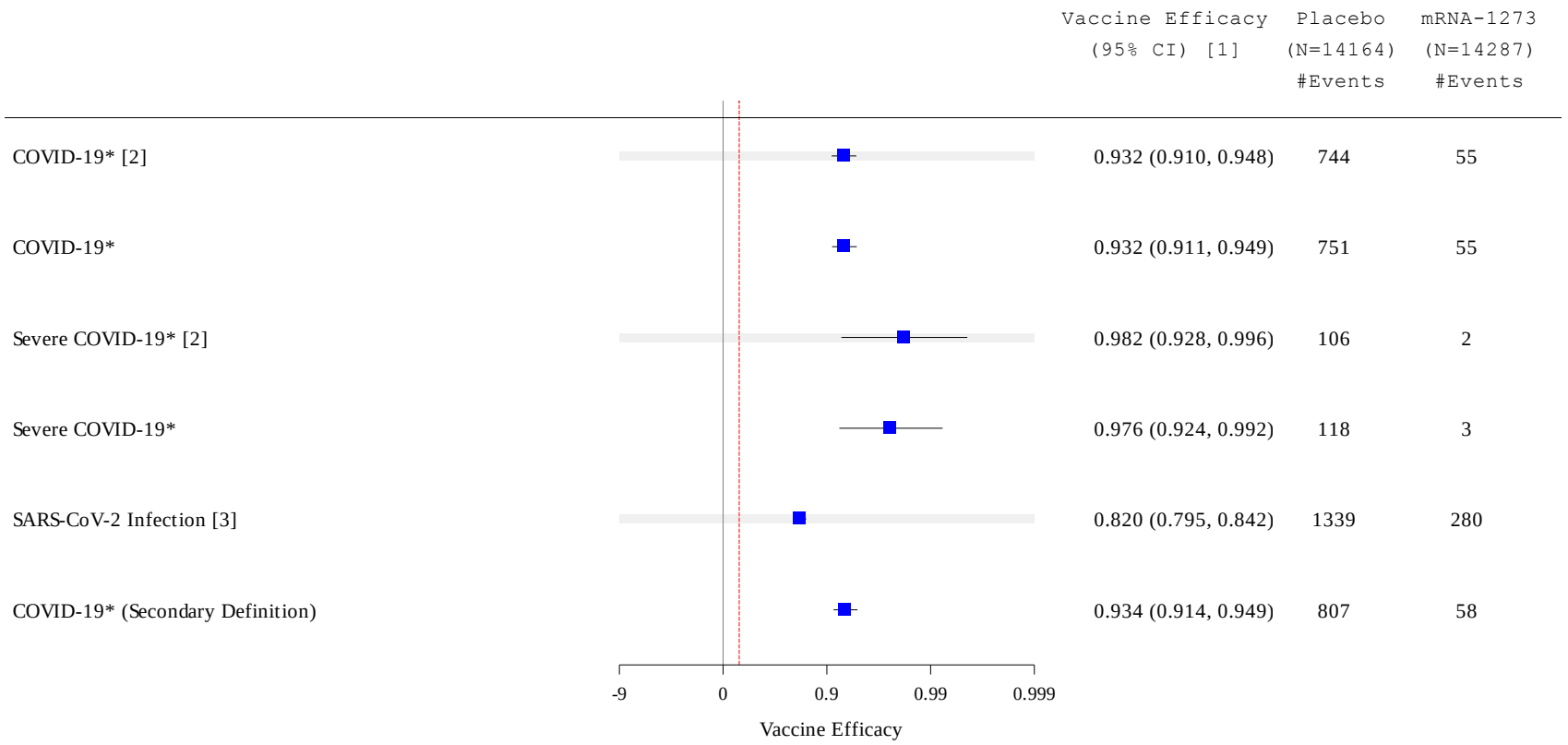
[b] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.

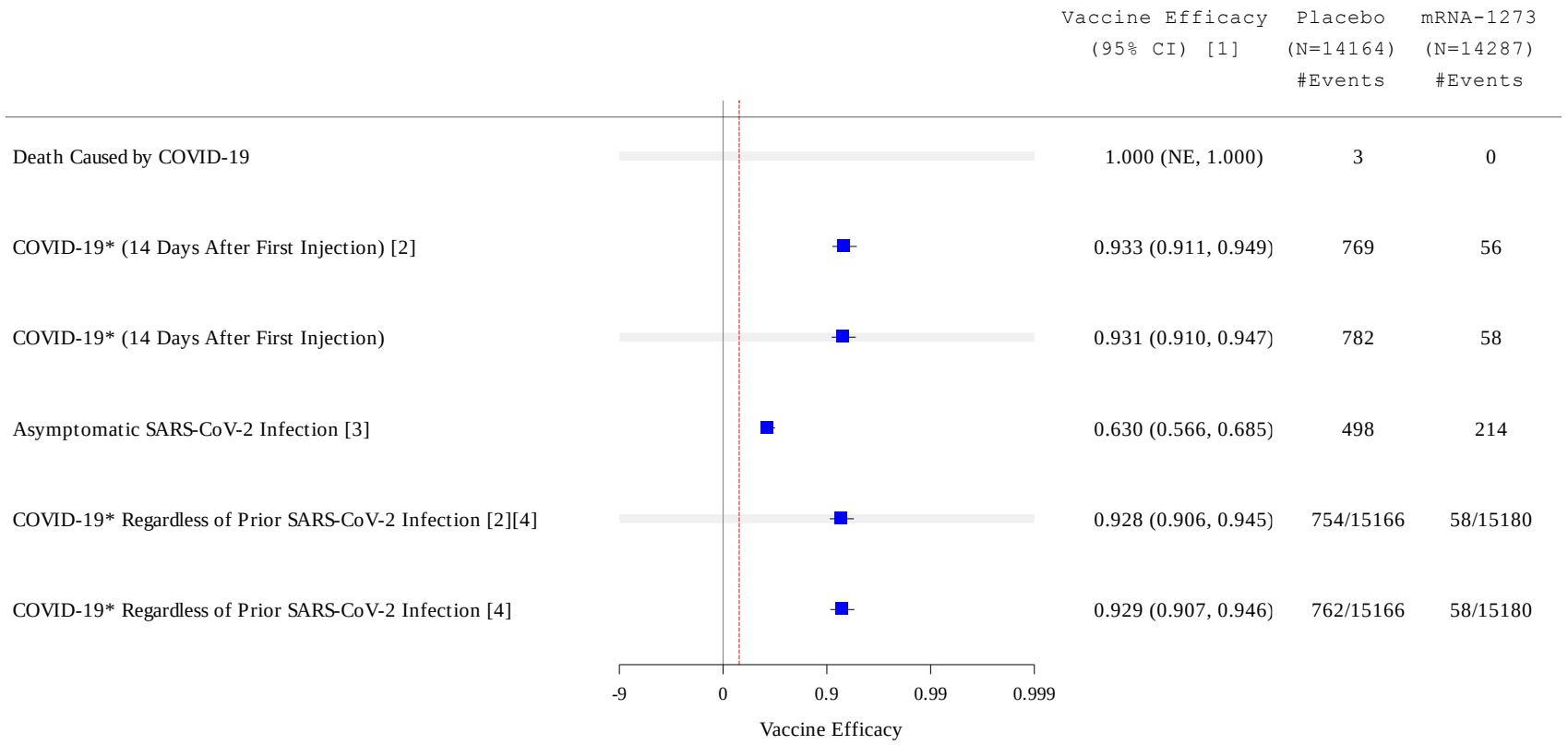
[c] Including participant decision visit.

[d] n and N are based on the number of subjects in the Full Analysis Set.

Source: Table 14.2.1.1.1.1.1.2.

Figure S-1: Forest Plot of Primary and Secondary Efficacy Endpoint Results of Cases Starting 14 Days After Second Injection (Per-Protocol Set)





Reference line indicates vaccine efficacy of 0.3.

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. For asymptomatic SARS-CoV-2 infection, VE and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] Based on Adjudication Committee assessments.

[3] Including participant decision visit.

[4] Based on the number of subjects in the Full Analysis Set.

Source: Figure 14.2.1.1.1.2.

The primary efficacy endpoint was VE of mRNA-1273 to prevent the first occurrence of adjudicated COVID-19 starting 14 days after the second dose of IP in the PP Set.

The final efficacy analysis of the primary endpoint for Part A (04 May 2021) was performed on 799 cases. The results of this analysis were consistent with the results of the interim and primary efficacy analyses, confirming persistent, high efficacy over a substantially larger case database over a longer median observation period of over 5.3 months. For the final efficacy analysis, the VE point estimate was 93.2% ($p < 0.0001$) and within the 95% CIs of the VE point estimates for the interim and primary efficacy analyses.

- Divergence of case incidence began early between mRNA-1273 and placebo groups, starting in the period from randomization up to 14 days after the first injection. Thereafter, cumulative incidence rate for the placebo group increased steadily while it remained stable and low in the mRNA-1273 group for the remainder of the observation period.
- Vaccine efficacy was consistent across subgroups for the primary efficacy endpoint.

The VE of mRNA-1273 to prevent adjudicated severe COVID-19 cases starting 14 days after second injection was consistent with the VE for the primary endpoint and was numerically higher than the VE for the primary endpoint.

- For the final analysis of efficacy for Part A, 108 participants had adjudicated severe COVID-19 starting 14 days after second injection in the PP Set (106 cases in the placebo group and 2 cases in the mRNA-1273 group); the VE point estimate based on the hazard ratio was 98.2%, confirming and extending the primary analysis of 25 Nov 2020 based on more than 3 times as many cases accrued over an approximately 2 times longer period of observation.
- Divergence of case incidence of severe COVID-19 began early between mRNA-1273 and placebo groups, starting in the period from 7 to 14 days after the first injection.
- Subgroup analyses were consistent with the primary analysis of efficacy and the point estimates of efficacy remained very high. Consistent VE point estimates were observed in subgroup analyses of participants with 1 risk factor, at last 2 risk factors, chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, and human immunodeficiency virus (HIV) infection.

The VE of mRNA-1273 to prevent SARS-CoV-2 infection, regardless of COVID-19 symptomatology and severity starting 14 days after second injection was consistent with the VE for the primary endpoint.

- Including the RT-PCR and Elecsys results from the PDV, a total of 1,619 participants had a SARS-CoV-2 infection starting 14 days after second injection in the PP Set (1,339 cases in the placebo group and 280 cases in the mRNA-1273 group); the VE point estimate based on the hazard ratio was 82.0%.
- Compared to the primary endpoint analyses, there were similar early onset of divergence in case incidence between treatment groups and similar stable and low rate of incidence rate for mRNA-1273 with increasing incidence rate in the placebo group.
- There were consistent, high VE point estimates across subgroups.

For the less restrictive secondary definition of COVID-19, the VE of mRNA-1273 was consistent with the VE for the primary endpoint, indicating that mRNA-1273 is efficacious even against mild COVID-19.

The VE to prevent asymptomatic SARS-CoV-2 infection was analyzed in the PP Set, including the RT-PCR and Elecsys results from the PDV, based on a total of 712 participants who had an asymptomatic SARS-CoV-2 infection starting 14 days after randomization (498 cases in the placebo group and 214 cases in the mRNA-1273 group). The VE point estimate based on the hazard ratio was 63.0%. This analysis confirms that vaccination with mRNA-1273 protects against asymptomatic infection (albeit at a lower VE than for symptomatic cases).

Immunogenicity Results: mRNA-1273 was highly immunogenic as measured by both bAb and nAb in both SARS-CoV-2 baseline-negative and baseline-positive individuals, as indicated by increased bAb and nAb levels 1 month after first injection (Day 29) and 1 month after second injection (Day 57).

Antibody levels at Day 29 in baseline-positive mRNA-1273 treated participants were similar to those observed at Day 57 in baseline-negative participants, indicating that the first injection of mRNA-1273 acts like a booster in participants with previous SARS-CoV-2 infection.

Among SARS-CoV-2 baseline-negative mRNA-1273 treated participants, seroresponse by bAb assay exceeded 99% at both Day 29 and Day 57, while seroresponse by nAb assay was 81.4% at Day 29 and 98.9% at Day 57.

Similar results were observed for subgroups stratified by age (≥ 18 to < 65 years and ≥ 65 years) in both SARS-CoV-2 baseline-negative and baseline-positive mRNA-1273 treated participants.

While vaccination with mRNA-1273 was highly immunogenic and protective against COVID-19, breakthrough cases occurred and there was no apparent bAb level or nAb titer through Day 57 that was predictive of the presence or absence of breakthrough COVID-19 cases.

Safety Results: In this final, randomized, blinded phase (Part A) analysis, the mRNA-1273 vaccine administered as 2 injections 28 days apart demonstrated an acceptable safety profile in the study population. This conclusion is supported by reactogenicity and key safety findings summarized here.

Solicited local and systemic adverse reactions were more frequent in mRNA-1273 than in placebo recipients, with most events considered grade 1 or 2 in severity, and most events in mRNA-1273 recipients occurring within 1 to 2 days and lasting a median of 1 to 3 days. The most common solicited local AR was pain, and the most commonly reported solicited systemic ARs were fatigue, headache, myalgia, and arthralgia. Older adults (≥ 65 years) had lower rates of solicited ARs than younger adults (< 65 years). Participants SARS-CoV-2 positive at baseline had rates of solicited ARs comparable to those among baseline negative participants. More mRNA-1273 recipients reported use of medication for pain or fever than placebo recipients, consistent with vaccine reactogenicity.

Unsolicited TEAEs in the 28 days after any injection occurred at similar rates in the mRNA-1273 and placebo groups. The higher rate of unsolicited TEAEs considered treatment-related by the investigator among mRNA-1273 participants was largely driven by events that mapped to solicited ARs but occurred beyond the solicited AR collection period or were ARs similar to solicited ARs. In addition, TEAEs were assessed for: (i) imbalances between study groups, and (ii) AEs of interest following COVID-19 vaccination or vaccinations in general. Imbalances were investigated based on the degree of imbalance and the biological plausibility and temporal occurrence relative to study treatment. An imbalance in the overall number of herpes zoster cases was noted, with more cases in the mRNA-1273 than in the placebo group; however, most cases in the mRNA-1273 group occurred more than 28 days after any dose and at an incidence expected in the general population. In contrast, most cases in the placebo group occurred within 28 days and at rates lower than expected of the general population. These findings are not supportive of relatedness to mRNA-1273.

Certain AEs are of theoretical interest for COVID-19 vaccines and were carefully assessed in the blinded study phase. mRNA-1273 vaccine was highly efficacious in preventing COVID-19 and severe COVID-19, and this efficacy has been sustained, dispelling concerns of VAERD. No significant clinical findings were identified from the SMQ/CMQ searches performed for the analyses of AEs of clinical interest for COVID-19 vaccines. A search (SMQ) for CNS vascular disorders identified a categorical imbalance, with 21 participants in the mRNA-1273 and 11 participants in the placebo group experiencing events in this SMQ, but the apparent imbalance was largely due to inclusion of 5 participants with subarachnoid hemorrhage and subdural hematoma (3 and 2 participants, respectively in the mRNA-1273 group and none in placebo) in this category. These latter events were mostly related to trauma and not to study treatment. Other

events of potential interest for COVID-19 vaccines are thrombotic and embolic events, for which no imbalance between groups was identified. Finally, assessments for TEAEs of myocarditis or pericarditis, or the symptoms suggestive of these diagnoses (including chest pain, dyspnea, and tachycardia) was performed. No events of myocarditis were identified. Pericarditis without concurrent myocarditis was reported as an SAE for 2 participants in each treatment group; the 2 events in the mRNA-1273 group occurred more than 28 days after second dose and in participants older than 55 years. Symptoms consistent with myocarditis or pericarditis were assessed, seeking patterns in grouping of symptoms or clustering in time, and only a single participant met a diagnosis of pericarditis. Assessment of events often associated with vaccination was performed, with a focus on hypersensitivity and anaphylaxis. Hypersensitivity events were more common among mRNA-1273 than placebo recipients; most of the imbalance derived from injection site urticaria and rashes. No anaphylaxis events were reported within 30 minutes after any injection.

In total, mRNA-1273 has a reactogenicity profile consistent with parenteral vaccination and generally well tolerated. Similarly, the safety profile is acceptable. No unexpected findings were identified in this final assessment of the randomized, blinded phase of the study.

Conclusions: This study was designed to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but whose occupation or location and living circumstances put them at increased risk of acquiring COVID-19 and/or SARS-CoV-2 infection.

- The final efficacy analysis of the primary endpoint for Part A (04 May 2021) included 799 cases. The results of this analysis were consistent with the results of the interim and primary efficacy analyses, confirming persistent, high efficacy over a substantially larger case database and over a longer median observation period of over 5.3 months. For the final efficacy analysis, the VE point estimate was 93.2% ($p < 0.0001$) and within the 95% CIs of the VE point estimates for the interim and primary efficacy analyses.
    - Divergence of case incidence began early between mRNA-1273 and placebo groups, starting in the period from randomization up to14 days after the first injection. Thereafter, cumulative incidence rate for the placebo group increased steadily while it remained stable and low in the mRNA-1273 group for the remainder of the observation period.
    - Vaccine efficacy was consistent across subgroups for the primary efficacy endpoint.
    - Vaccine efficacy was also consistent across the secondary endpoints characterized by high VE point estimates and tight 95% CIs, with the lower bounds of the 95% CIs well above 30%.

- mRNA-1273 was highly immunogenic as measured by both bAb and nAb in both SARS-CoV-2 baseline-negative and baseline-positive individuals, as indicated by increased bAb and nAb levels 1 month after first injection (Day 29) and 1 month after second injection (Day 57).
- mRNA-1273 demonstrated an acceptable safety profile in the participant population enrolled in this study. mRNA-1273 has a reactogenicity profile consistent with parenteral vaccination and generally well tolerated. No unexpected findings were identified in this final assessment of the randomized, blinded phase of the study.

This report is based on the data from the randomized, placebo controlled, blinded phase (Part A) of the study. Data from Part B, in which eligible participants were offered open-label mRNA-1273, will be included in a CSR addendum.

Date and Version of This Report: Final, 05 August 2021

List of Abbreviations

Abbreviation	Definition
AC	Adjudication Committee
AE	adverse event
ANCOVA	analysis of covariance
AR	adverse reaction
ART	antiretroviral therapy
bAb	binding antibody
BARDA	Biomedical Advanced Research and Development Authority
BMI	body mass index
BOD	burden of disease
BOI	burden of infection
ccIAS	case-cohort Immunogenicity Analysis Set
CDC	Centers for Disease Control and Prevention
CI	confidence interval
CIOMS	Council for International Organizations of Medical Sciences
CLIA	Clinical Laboratory Improvement Amendments
CMP	Centralized Monitoring Plan
CMQ	Custom MedDRA Query
CoV	coronavirus
COVID-19	coronavirus disease 2019
COV-INF	serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity
CRF	case report form
CSR	clinical study report
CT	cycle time
CTCAE	Common Terminology Criteria for Adverse Events
CV	coefficient of variation
DA	data analytics
DMID	Division of Microbiology and Infectious Diseases
DSMB	Data and Safety Monitoring Board
ECG	electrocardiogram
eCRF	electronic case report form
CRO	contract research organization
eDiary	electronic diary

Abbreviation	Definition
ELISA	enzyme-linked immunosorbent assay
EUA	Emergency Use Authorization
FAS	Full Analysis Set
FDA	Food and Drug Administration
FG	Fine and Gray's
FSH	follicle-stimulating hormone
GCP	Good Clinical Practice
GISAID	Global Initiative on Sharing All Influenza Data
GLSM	geometric least squares mean
GM	geometric mean
GMFR	geometric mean fold rise
GMR	geometric mean ratio
GMT	geometric mean titer
HCP	healthcare practitioner
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HR	hazard ratio
IA	interim analysis
ICF	informed consent form
ICH	International Council for Harmonisation
ID	identification
IEC	independent ethics committee
IM	intramuscular
IP	investigational product
IND	investigational new drug
IRB	institutional review board
IRT	Interactive Response Technology
ITT	intent-to-treat
LNP	lipid nanoparticle
LOCF	last observation carried forward
MAAE	medically-attended adverse event
MERS	Middle East respiratory syndrome
MI	myocardial infarction
mITT	modified intent-to-treat

Abbreviation	Definition
MMRM	mixed-effect model repeated measures
mRNA	messenger RNA
MSD	MesoScale Discovery
MSD-ECL	MesoScale Discovery-electrochemiluminescence
N	nucleocapsid
nAb	neutralizing antibodies
NCI	National Cancer Institute
NGS	Next Generation Sequencing
NHP	nonhuman primate
NIAID	National Institute of Allergy and Infectious Diseases
NOS	not otherwise specified
NP	nasopharyngeal
PD	pharmacodynamic(s)
PDV	participant decision visit
PDQTL	predefined quality tolerance limit
PP	per protocol
PPRSI	Per-Protocol Random Subcohort for Immunogenicity
PSRT	Protocol Safety Review Team
PT	preferred term
QA	quality assurance
RBD	receptor binding domain
RCDF	reverse cumulative distribution function
RP	respiratory panel
RT-PCR	reverse transcriptase polymerase chain reaction
RT-qPCR	reverse transcriptase quantitative polymerase chain reaction
SAE	serious adverse event
SAP	statistical analysis plan
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMC	safety monitoring committee
SMQ	Standardized MedDRA Query
SOC	system organ class
SOP	standard operating procedure
TEAE	treatment-emergent adverse event
USP	United States Pharmacopeia

Abbreviation	Definition
VAERD	vaccine-associated enhanced respiratory disease
VE	vaccine efficacy
VOC	variants of concern
VOI	variants of interest
WGS	Whole Genome Sequencing

1 INTRODUCTION

1.1 Background

Coronaviruses (CoVs) are a large family of viruses that cause illness ranging from the common cold to more severe diseases, such as Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome.

An outbreak of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) began in Wuhan, Hubei Province, China in December 2019 and the disease has since spread globally (WHO 2020a). On 11 Mar 2020, the World Health Organization declared COVID-19 a pandemic. As of 02 May 2021, more than 151 million cases and over 3 million deaths worldwide have been attributed to the COVID-19 pandemic (WHO 2021), and in the United States, the US Centers for Disease Control and Prevention (CDC) reported over 32 million cases of COVID-19, with 578,993 total deaths (CDC 2021). The CDC have reported that the highest risk of disease burden is in older adults (≥ 65 years old) and people of any age who have certain underlying medical conditions such as cancer, chronic kidney disease, chronic obstructive pulmonary disease, serious heart conditions, immunocompromised state, obesity, pregnancy, sickle cell disease, and type 2 diabetes mellitus; smokers are also at increased risk for severe COVID-19 (CDC 2020a).

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

ModernaTX, Inc. (Sponsor) has developed a rapid-response, proprietary vaccine platform based on a messenger RNA (mRNA) delivery system. The platform is based on the principle and observations that cells in vivo take up mRNA, translate it, and then express protein viral antigen(s) on the cell surface. The delivered mRNA does not enter the cellular nucleus or interact with the genome, is nonreplicating, and is expressed transiently. mRNA vaccines have been used to induce immune responses against infectious pathogens such as cytomegalovirus (NCT03382405), human metapneumovirus and parainfluenza virus type 3 (NCT03392389), Zika virus (NCT03325075), and influenza virus (NCT03076385 and NCT03345043).

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

Yu et al 2015; Johnson et al 2016; Chen et al 2017; Wang et al 2018; Kim et al 2019; Widjaja et al 2019).

1.2 Nonclinical Studies

Nonclinical immunogenicity, biodistribution, and safety studies were completed by the Sponsor using mRNA-1273 or similar mRNA-based vaccines formulated in SM-102–containing LNPs.

The Sponsor performed nonclinical studies of mRNA-1273 in mice, hamsters, and nonhuman primates (NHPs) to evaluate vaccine-induced immune responses, protection from high-dose SARS-CoV-2 virus challenge, and to address the theoretical concern of enhanced respiratory disease mediated by vaccine-induced antibody responses and/or Th2-directed T-cell responses observed with other vaccines against viral respiratory diseases. These studies demonstrated that mRNA-1273 is immunogenic in all species assessed, showing a dose-dependent response in IgG binding antibody titers and a strong correlation between binding antibody (bAb) and nAb activity.

Dose levels were included that were predicted to be optimal (fully protective) and suboptimal (subprotective). At higher doses, mice and NHPs were fully protected from viral replication in both lungs and nasal passages. At subprotective dose levels, animals either remained fully protected in the lungs or had reduced viral burden post-challenge versus control animals. The fact that there were no observations of increased viral load in vaccinated animals at protective or subprotective dose levels, further supports that mRNA-1273 does not drive enhanced disease.

Antigen-specific T-cell responses were observed in studies in mice and in the NHP study. Th1-directed CD4 and CD8 T-cell responses were measured post-boost in animals that were vaccinated with mRNA-1273. Direct measurement of Th1-directed responses in mice and NHPs, indirect measurement of IgG2a/c/IgG1 antibody subclasses in mice, and the high levels of neutralizing antibody in all species lessens concerns regarding disease enhancement associated with administration of mRNA-1273.

Overall, animal studies demonstrated that mRNA-1273 is immunogenic, fully protects animals from challenge at optimal dose levels, and does not drive enhanced respiratory disease at protective or subprotective dose levels.

The pivotal submission-enabling toxicology studies were conducted with 5 mRNA vaccines that encode various antigens developed with the Sponsor's mRNA-based platform using SM-102-containing LNPs (2 Zika virus vaccines: mRNA-1706 and mRNA-1893; 1 hMPV and PIV3 vaccine: mRNA-1653; and 2 CMV vaccines: mRNA-1647 and mRNA-1443). The aggregate repeat-dose toxicity profile of mRNA vaccines that were developed with the Sponsor's mRNA-based platform in rats, at intramuscular (IM) doses ranging from 8.9 to 150 µg/dose

administered once every 2 weeks for up to 6 weeks, was similar and consistent despite the fact the different mRNA constructs encode different antigens. Therefore, the Sponsor proposes that the toxicity associated with mRNA vaccines formulated in similar LNPs is driven primarily by the LNP composition, and to a lesser extent, by the biologic activity of the antigens encoded by the mRNA; therefore, the aggregate Good Laboratory Practice repeat-dose rat data are considered to be representative of mRNA vaccines formulated in the same SM-102 LNPs and support the clinical development of mRNA-1273. In addition, a developmental and reproductive toxicity study to assess potential fertility and pre and postnatal development effects of mRNA-1273 in pregnant and lactating female Sprague Dawley rats was conducted at a clinically relevant dose. Maternal administration of mRNA-1273 (100 µg) before mating (2 doses) and during gestation (2 additional doses) did not have any adverse effects on the F_0 or F_1 generations. The mRNA related non-adverse effects were limited to an increase in the number of fetuses with common skeletal variations of 1 or more rib nodules and 1 or more wavy ribs with no effect on viability or growth and development of f1 generation. Strong maternal to fetal and maternal-to-pup transfer of antibodies was observed with mRNA-1273.

1.3 Other Clinical Studies in the mRNA-1273 Development Plan

The clinical development of mRNA-1273 has been expedited to address the ongoing global public health emergency resulting from the SARS-CoV-2 pandemic (and assigned by the WHO to the highest public health emergency status). The studies were designed in accordance with both FDA general guidance on COVID-19 vaccine development (FDA 2020) and FDA product-specific guidance. These studies are also conducted in accordance with consensus ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines and applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines.

In addition to mRNA-1273-P301 (Study 301), multiple clinical studies of mRNA-1273 are ongoing to address the safety, immunogenicity, and/or efficacy of the vaccine. The initial safety and dose-finding portions of the clinical program have been completed in 3 studies (Study 20-0003, Study mRNA-1273-P201, and Study mRNA-1273-P301) and participants are continuing to be evaluated and followed for various purposes (ie, long-term safety, persistence of antibody responses, evaluation of a booster dose, etc.) No clinical studies have been completed with mRNA-1273.

Phase 1 DMID Study 20-0003 (NCT04283461) is an ongoing, dose-escalation, open-label study to assess the safety and immunogenicity of mRNA-1273 in healthy adults aged 18 years and older. Study 101 is sponsored by the Division of Microbiology and Infectious Diseases

(DMID) of the National Institute of Allergy and Infectious Diseases (NIAID). The study includes a total of 10 cohorts. Participants received 2 injections of 25 µg, 50 µg, 100 µg, or 250 µg of mRNA-1273. As a control, a panel of convalescent sera was obtained from 41 patients recovering from COVID-19 and was used as a benchmark immunogenicity comparator for antibodies induced by natural SARS-CoV-2 infection. Blood sample collection time points include baseline, Days 8, 15, 29 (prior to injection 2), 36, 43, and 57, as well as 3, 6, and 12 months after the second vaccination (Days 119, 209, and 394, respectively). Interim results from 45 participants, 18 to 55 years of age, who received 2 doses of 25, 100, and 250 µg have been published (Jackson et al 2020). Data on 40 older adults ≥ 56 years of age who received 2 doses of either 25 or 100 µg in the same Phase 1 DMID study were also published (Anderson et al 2020).

Interim results from 120 participants (age cohorts 18 to 55 years, 56 to 70 years, and ≥ 71 years; data cutoff 07 Oct 2020) showed that mRNA-1273, administered as 2 doses 28 days apart was safe and immunogenic in healthy adult participants aged ≥ 18 years. After mRNA-1273 administration, fatigue, headache, myalgia, fever, and injection site pain were the most commonly reported solicited systemic and local adverse reactions (ARs), with higher incidence noted after the second injection than after the first injection for the solicited systemic ARs. Most of the solicited ARs were mild or moderate; severe solicited ARs predominantly occurred at the highest dose (250 µg). mRNA-1273 induced robust binding antibody responses (S-2P and receptor binding domain [RBD] specific) after 2 injections. Based on the results of safety and immunogenicity at data cutoff, the 100-µg dose provides promising immunogenicity results in adults of all ages with an acceptable safety profile and was the dose selected for further evaluation in the Phase 3 clinical study. Immunogenicity and safety data through Day 209 showed that the immune responses persisted and no safety concerns were found in the healthy adult participants aged ≥ 18 years through 6 months after the second dose of mRNA-1273.

An amendment to Study 101 added an optional third mRNA-1273 vaccination to potentially enhance and extend the duration of protection provided by the 2-dose vaccination schedule of mRNA-1273 administered in the main study, and to gain an understanding of the immune responses to a third dose of mRNA-1273. Substudy subjects will receive a third mRNA-1273 vaccination, administered via an IM injection at a dosage of 100 µg (0.5 mL), given 6 to 12 months after receipt of their second vaccination in the main study. Substudy subjects will be followed for safety, reactogenicity, and immunogenicity endpoints through 12 months after the third vaccination. To be eligible to participate in the substudy, subjects must have received both the first and second mRNA-1273 vaccinations in the main study.

Phase 2a Study mRNA-1273-P201 (NCT04405076) is an ongoing, blinded, randomized, placebo-controlled dose-finding study in adults 18 years and older. The study was designed to

confirm the dose (100 µg) to be advanced into the pivotal Phase 3 study based on the observed safety profile and immunogenicity in healthy adults. Two dose levels, 50 µg and 100 µg, are being evaluated in this study, based in part on initial safety data from the Phase 1 DMID study of mRNA-1273 (Study 20-0003). The study includes 2 age cohorts: Cohort 1 with 300 participants (18 to 55 years old) and Cohort 2 with 300 participants (≥ 55 years old). A total of 600 participants received either mRNA-1273 vaccine or saline placebo control according to a 1:1:1 randomization ratio; ie, within each age cohort, 100 participants received mRNA-1273 50 µg, 100 participants received mRNA-1273 100 µg, and 100 participants received saline placebo. Two doses were administered to each participant 28 days apart. The study was started with a parallel enrollment of all 300 participants in Cohort 1 (18 to 55 years old) and a sentinel group of 50 participants in Cohort 2 (≥ 55 years old); after review of the safety data by the independent safety monitoring committee (SMC), Cohort 2 was expanded to include the remaining 250 participants.

As of 05 Nov 2020, 200 (100%) participants each in the mRNA-1273 50 µg group, mRNA-1273 100 µg group, and placebo group received the first dose, and 195 (97.5%) participants in the mRNA-1273 50 µg group, 198 (99.0%) participants in the mRNA-1273 100 µg group, and 194 (97.0%) participants in the placebo group received the second injection (mRNA-1273-P201). No protocol-specified pause rules were met during the study. Vaccination with mRNA-1273 resulted in significant immune responses to SARS-CoV-2 with an acceptable safety profile in the participant population enrolled in this study at both dose levels in 2 age cohorts: Cohort 1 (18 to 55 years old) as well as Cohort 2 (≥ 55 years old), confirming the selection of the 100-µg dose that was brought forward in the pivotal Phase 3 study. Data through Day 209 are being analyzed at the time of this report.

An amendment to the Study 201 protocol adapted the study design to include open-label interventional phases (Part B and Part C). Part B allowed unblinding of participants and offered 2 injections of mRNA-1273 in an open label manner, 28 days apart, to all participants who received placebo in Part A. Part B also offered a single booster dose of mRNA-1273 (50 µg) to participants who received 1 or 2 doses of mRNA-1273 (50 µg or 100 µg) in Part A. Part C was prompted by the need to pro-actively prepare for vaccination strategies that induce broader protection, including against emerging variants of SARS-CoV-2 such as B.1.351. Part C enrolled participants from Study 301 who received 2 doses of mRNA-1273 100 µg, 28 day apart, at least 6 months prior. Part C participants received a single injection of mRNA-1273.351 (20 µg or 50 µg) or mRNA-1273.351 mixture (50 µg total – 25 µg of 1273 and 25 µg of .351).

Phase 2/3 Study mRNA-1273-P203 (NCT04649151) is an ongoing, Phase 2/3, randomized, observer-blind, placebo-controlled study being conducted to assess the safety and immunogenicity (to infer the effectiveness) of mRNA-1273 in an adolescent population aged

12 to < 18 years. The study includes 2 arms: 100 µg of mRNA-1273 and placebo. Approximately 3,000 participants between 12 to < 18 years of age were randomly assigned in a 2:1 ratio to receive mRNA-1273 (n=2,000) or placebo (n=1,000). All participants are being monitored for 12 months following the second dose of vaccine or placebo to enable assessment of safety and immunogenicity.

Phase 2/3 Study mRNA-1273-P204 (NCT04796896) is an ongoing Phase 2/3 two-part study with an open-label, dose-escalation and age de-escalation (Part 1) and a randomized, observer-blind, placebo-controlled expansion (Part 2) to evaluate the safety, tolerability, reactogenicity, and immunogenicity (to infer the effectiveness) of mRNA-1273 in healthy children aged 6 months to < 12 years, divided into 3 age groups (6 to < 12 years, 2 to < 6 years, and 6 months to < 2 years). Enrollment of approximately 6,750 participants (1,275 participants in Part 1 and 5,700 participants in Part 2) is planned. Up to 3 dose levels of mRNA-1273 (25, 50, and 100 µg) will be evaluated in Part 1, with the highest number enrolled in the oldest age group, and the final dose level selected will be administered in 3:1 ratio (mRNA-1273:placebo) to approximately 5,700 participants (approximately 1,700 participants in the 6 to < 12 years of age group and approximately 2,000 participants in both the 2 to < 6 years and the 6 months to < 2 years age groups) in Part 2.

Phase 3b Study mRNA-1273-P304 (NCT04860297) is an ongoing Phase 3b open-label safety and immunogenicity study of mRNA-1273 in adult solid organ transplant recipients and healthy control participants who are at least 18 years of age. Approximately 240 participants (110 kidney transplant recipients, 110 liver transplant recipients, and 20 healthy adults) are planned to be enrolled and receive 2 doses of mRNA-1273 100 µg 28 days apart.

Recent data based on post-Emergency Use Authorization (EUA) experience show that solid organ transplant recipients' immune response to mRNA-based vaccination has been substantially lower than what has been reported in the general population, with antibody responses detectable in only 30-60% after 2 doses (Benotmane et al 2021; Boyarsky et al 2021, Grupper et al 2021; Marinaki et al 2021). Therefore, an amendment to Study 304 changed the study design so that all solid organ transplant recipients will be offered the opportunity to receive a third dose of 100 µg mRNA-1273 vaccine on Day 85.

1.4 Study Rationale

Study mRNA-1273-P301 was designed as a Phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but whose occupation or location and living

circumstances put them at increased risk of acquiring COVID-19 and/or SARS-CoV-2 infection. The primary goals of this Phase 3 study are to evaluate the vaccine efficacy (VE) of mRNA-1273 to prevent COVID-19, compared to placebo and to further evaluate the safety and reactogenicity profile of mRNA-1273.

The Study 301 protocol and statistical analysis plan (SAP) were designed in accordance with both FDA general guidance on COVID-19 vaccine development (FDA 2020) and FDA product-specific guidance. Study P301 data were extensively discussed with European Medicines Agency, Health Canada, as well as other agencies as part of the authorization pathway developed to expedite regulatory approval in each country. Study 301 was conducted with oversight by an independent Data and Safety Monitoring Board (DSMB) (Section 3.8.4.2) and also a clinical endpoint adjudication committee that reviewed potential cases of COVID-19 (Section 3.8.4.3). The study was conducted in accordance with consensus ethical principles derived from international guidelines including the Declaration of Helsinki and CIOMS International Ethical Guidelines and applicable ICH GCP Guidelines (Section 3.4.2).

2 STUDY OBJECTIVES AND ENDPOINTS

The study objectives and endpoints are presented in Table 2-1.

Table 2-1: Objectives and Endpoints

Objectives	Endpoints
Primary efficacy	

• To demonstrate the efficacy of mRNA-1273 to prevent COVID-19.	• The VE of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second dose of IP, where COVID-19 was defined as symptomatic disease based on the following criteria:
	  • The participant must have experienced at least TWO of the following systemic symptoms: fever (≥ 38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), OR
	  • The participant must have experienced at least ONE of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; AND
	  • The participant must have at least 1 NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR.

Primary safety	
• To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart.	• Solicited local and systemic ARs through 7 days after each dose of IP. • Unsolicited AEs through 28 days after each dose of IP. • MAAEs or AEs leading to withdrawal through the entire study period. • SAEs throughout the entire study period.

Objectives	Endpoints
Secondary efficacy	
• To evaluate the efficacy of mRNA-1273 to prevent severe COVID-19.	• The VE of mRNA-1273 to prevent severe COVID-19, defined as first occurrence of COVID-19 starting 14 days after the second injection of IP, (as per the primary endpoint) AND any of the following: • Clinical signs indicative of severe systemic illness, respiratory rate ≥ 30 per minute, heart rate ≥ 125 beats per minute, $SpO_2 \leq 93\%$ on room air at sea level, or PaO_2/FIO_2 < 300 mm Hg, OR • Respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic BP < 90 mm Hg, diastolic BP < 60 mm Hg, or requiring vasopressors), OR • Significant acute renal, hepatic, or neurologic dysfunction, OR • Admission to an intensive care unit or death.
• To evaluate the efficacy of mRNA-1273 to prevent serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity.	• The VE of mRNA-1273 to prevent the first occurrence of either COVID-19 or SARS-CoV-2 infection starting 14 days after the second injection of IP. This endpoint includes COVID-19, as defined for the primary endpoint, and asymptomatic SARS-CoV-2 infection, determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein or a positive RT-PCR test post baseline. This endpoint was evaluated in participants who were SARS-CoV-2 negative at baseline.
• To evaluate VE against a secondary definition of COVID-19.	• The VE of mRNA-1273 to prevent the secondary case definition of COVID-19 starting 14 days after the second injection of IP. The secondary case definition of COVID-19 was defined as the presence of at least 1 of the following systemic symptoms: fever (temperature ≥ 38ºC), or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting, or diarrhea AND a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS-CoV-2 by RT-PCR.
• To evaluate VE to prevent death caused by COVID-19.	• The VE of mRNA-1273 to prevent death due to a cause directly attributed to a complication of COVID-19, starting 14 days after the second injection of IP.

Objectives	Endpoints
• To evaluate the efficacy of mRNA-1273 to prevent COVID-19 after the first dose of IP.	• The VE of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the first injection of IP.
• To evaluate the efficacy of mRNA-1273 to prevent COVID-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection.	• The VE of mRNA-1273 to prevent the first occurrence of COVID-19 starting 14 days after the second injection of IP regardless of evidence of prior SARS-CoV-2 infection (FAS analysis population).
• To evaluate the efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection.	• The VE to prevent the first occurrence of SARS-CoV-2 infection in the absence of symptoms defining COVID-19 starting 14 days after the second injection of IP. SARS-CoV-2 infection was determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein or a positive RT-PCR test at a scheduled visit (eg, predose on Day 29). This endpoint was evaluated in participants who were SARS-CoV-2 negative at baseline.
Secondary immunogenicity	
• To evaluate the immunogenicity of 2 doses of mRNA-1273 given 28 days apart.	• GMT of SARS-CoV-2 -specific nAb on Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759[a]. • GMFR of SARS-CoV-2-specific nAb relative to Day 1 on Day 29, Day 57, Day 209, Day 394, and Day 759[a]. • Quantified levels or GMT of S protein-specific bAb on Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759[a]. • GMFR of S protein-specific bAb relative to Day 1 on Day 29, Day 57, Day 209, Day 394, and Day 759[a].
Exploratory - The following exploratory objectives and endpoints are addressed in this CSR:	
• To evaluate the effect of mRNA-1273 on the viral infection kinetics as measured by viral load at SARS-CoV-2 infection diagnosis by RT-PCR and number of days from the estimated date of SARS-CoV-2 infection until undetectable SARS-CoV-2 infection by RT-PCR.	• The VE of mRNA-1273 on the viral infection kinetics as measured by viral load at SARS-CoV-2 infection diagnosis by RT-PCR and number of days from the estimated date of SARS-CoV-2 infection until undetectable SARS-CoV-2 infection by RT-PCR.
• To assess VE to reduce the duration of symptoms of COVID-19.	• The VE of mRNA-1273 to reduce duration of COVID-19 symptoms.
• To evaluate VE against all-cause mortality.	• The VE of mRNA-1273 against all-cause mortality.
• To assess VE against BOD due to COVID-19	• The VE of mRNA-1273 against BOD based on the post SARS-CoV-2 infection follow-up.
• To evaluate the genetic and/or phenotypic relationships of isolated SARS-CoV-2 strains to the vaccine sequence.	• The genetic and/or phenotypic relationships of isolated SARS-CoV-2 strains to the vaccine sequence.
• To conduct additional analyses related to furthering the understanding of SARS-CoV-2 infection and COVID-19, including analyses	• Additional analyses related to furthering the understanding of SARS-CoV-2 infection and

Objectives	Endpoints
related to the immunology of this or other vaccines, detection of viral infection, and clinical conduct.	COVID-19, including analyses related to the immunology of this or other vaccines, detection of viral infection, and clinical conduct.

Abbreviations: AE = adverse event; AR = adverse reaction; ARDS = acute respiratory distress syndrome; bAb = binding antibody; BOD = burden of disease; BP = blood pressure; CSR = clinical study report; ECMO = extracorporeal membrane oxygenation; FAS = Full Analysis Set; FIO_2 = fraction of inspired oxygen; GMFR = geometric mean fold rise; GMT = geometric mean titer; IP = investigational product; MAAE = medically-attended adverse event; nAb = neutralizing antibody; NP = nasopharyngeal; PaO_2 = partial pressure of oxygen; RT-PCR = reverse transcription polymerase chain reaction; SAE = serious adverse event; SpO_2 = oxygen saturation by pulse oximeter; VE = vaccine efficacy.

[a] This Part A CSR presents the immunogenicity endpoints through Day 57 for the Per-Protocol Random Subcohort for Immunogenicity.

3 INVESTIGATIONAL PLAN

3.1 Overall Study Design and Plan

This is an ongoing 2-part Phase 3 study: Part A and Part B. Participants in Part A, the randomized, placebo-controlled, blinded phase of this study, were blinded to their treatment assignment. Given that the primary efficacy endpoint for mRNA-1273 against COVID-19 was met per the protocol-defined interim analysis (IA), Part B, the Open-Label Observational Phase of this study, was designed to offer participants who received placebo in Part A of this study and who met EUA eligibility, an option to request open-label mRNA-1273 during a Participant Decision Visit (PDV) (Figure 3-1).

All participants may have had up to 8 scheduled clinic visits, including Screening, Day 1, Day 29, Day 57, Day 209, Day 394, Day 759, and the PDV as specified in the Schedule of Events (SoE; mRNA-1273-P301 Clinical Study Protocol Table 16 [Vaccination Phase, Day 1 - Day 57], Table 17 [Surveillance Phase, Day 64 - Day 394], Table 18 [Surveillance Phase, Day 401 - Day 759], Table 19 [Convalescent Period, Starting with the Illness Visit], and Table 20 [Part B: Participant Decision Clinic Visit]; Appendix 16.1.1).

This Part A clinical study report (CSR) presents the data from the randomized, placebo-controlled, blinded phase (Part A) of the study based on the database lock on 04 May 2021, and includes available participant level data up to early unblinding, study discontinuation, the Part B PDV (Section 3.1.2) or data cutoff date (26 Mar 2021), whichever was earlier. Data from Part B, in which eligible participants were offered open-label mRNA-1273, will be included in a CSR addendum.

3.1.1 Part A, the Randomized, Placebo-Controlled, Blinded Phase

Part A of this study was a Phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who had no known history of SARS-CoV-2 infection but whose occupation or locations and living circumstances put them at appreciable risk of acquiring COVID-19 and/or SARS-CoV-2 infection.

Approximately 30,000 participants were randomly assigned to receive doses of either 100 µg of mRNA-1273 vaccine or placebo in a 1:1 randomization ratio. Assignment was stratified by age and health risk (Section 3.6.3). This was a case-driven study and thus final sample size was dependent on the actual attack rate of COVID-19.

All participants were assessed for efficacy and safety endpoints. A nasopharyngeal (NP) swab sample and blood sample were obtained from each participant before the first and second dose of

investigational product (IP). In addition, a series of postdose blood samples for immunogenicity are being collected through 24 months after the second dose of IP. Efficacy assessments included surveillance for COVID-19 with reverse transcriptase polymerase chain reaction (RT-PCR) confirmation of SARS-CoV-2 infection after the first and second dose of IP.

Each participant received 2 doses of IP by 0.5 mL intramuscular (IM) injection, the first on Day 1 and the second on Day 29. An NP swab sample was collected prior to the first and second dose of IP for evaluation by RT-PCR. To preserve observer blinding, only delegated unblinded study site personnel responsible for IP preparation, administration, and/or accountability had knowledge of study treatment assignment (Section 3.6.4).

Participants were given an electronic diary (eDiary) to report solicited ARs for 7 days after each dose of IP and to prompt an unscheduled clinic visit for clinical evaluation and NP swab sample if a participant experienced any symptoms of COVID-19. Participants used the eDiary to report solicited ARs for the first 7 days after each dose of IP (or until resolution for solicited ARs that continued beyond 7 days) and were then followed by weekly eDiary prompts (every 7 days) to elicit an unscheduled Illness Visit if the participant experienced COVID-19 symptoms. All participants received safety calls on Day 8, Day 15, Day 22, Day 36, and Day 43 that served both to monitor for unsolicited adverse events (AEs) and to monitor for symptoms of COVID-19.

Safety telephone calls and eDiary safety prompts were performed in conjunction with surveillance for COVID-19 according to the SoEs and were intended to capture serious AEs (SAEs), MAAEs, AEs leading to withdrawal, concomitant medications associated with these events, receipt of non-study vaccinations, and pregnancy (Section 3.7.1.2). If an eDiary prompt resulted in identification of a relevant safety event, a follow-up safety call was triggered.

Surveillance for signs and symptoms of COVID-19 is being performed through weekly contacts with the participant via a combination of telephone calls and completion of specific eDiary prompts starting at Day 1 through the end of the study (Section 3.7.1). Participants with symptoms of COVID-19 lasting at least 48 hours (except for fever and/or respiratory symptoms) returned to the clinic or were visited at home by medically qualified study site personnel within 72 hours to collect an NP swab sample for RT-PCR testing for SARS-CoV-2 and other respiratory pathogens, or alternatively, if a clinic or home visit was not possible, submitted a saliva (or nasal swab) sample for SARS-CoV-2 RT-PCR testing (Section 3.7.2).

All study participants who experienced COVID-19 symptoms and subsequently presented for an Illness Visit (in clinic or at home) were given an instruction card listing symptoms and severity grading system along with a thermometer, an oxygen saturation monitor, and saliva collection tubes. Study participants were contacted by the investigator (or appropriately delegated study site personnel) daily with telemedicine visits through Day 14 or until symptoms had resolved,

whichever was later. During the telemedicine visit (preferably done in the evening), the participant was asked to verbally report the severity of each symptom, their highest body temperature and lowest oxygen saturation for that day, and the investigator determined if medical attention was required due to worsening of COVID-19 symptoms. Study participants collected their own saliva (or nasal swab) sample at 3, 5, 7, 9, 14, and 21 days after the initial Illness Visit meeting criteria for COVID-19 (defined as the date of onset of symptoms and positive virologic test). Finally, a Convalescent Visit was scheduled approximately 28 days after the initial Illness Visit. At this visit, a saliva (or nasal swab) sample was collected and a blood sample was drawn for immunologic assessment of SARS-CoV-2 infection.

At each IP injection visit, participants were instructed (Day 1) or reminded (Day 29) on how to document and report solicited ARs in the eDiary provided. Solicited ARs were assessed for 7 days after each IP injection (or until resolution for solicited ARs that continued beyond 7 days), and unsolicited AEs were assessed for 28 days after each injection; SAEs, MAAEs, and AEs leading to withdrawal were assessed throughout the study.

Participants may have experienced AEs that necessitated an unscheduled visit. There may have also been situations in which the investigator asked a participant to report for an unscheduled visit following the report of an AE. Additional examinations may have been conducted at these visits as necessary to ensure the safety and well-being of participants during the study. Electronic case report forms (eCRFs) should have been completed for each unscheduled visit.

3.1.2 Part B, the Open-Label Observational Phase

The Part B Open-Label Observational Phase of the study was prompted by the authorization of a COVID-19 vaccine under EUA. Transitioning the study to Part B permitted all ongoing study participants to be informed of the availability and eligibility criteria of any COVID-19 vaccine made available under an EUA and the option to offer all ongoing study participants who request unblinding, an opportunity to schedule a PDV to know their original treatment assignment (placebo vs. mRNA-1273 vaccine). The Part B Open-Label Observation Phase also provided the opportunity for EUA-eligible study participants who previously received placebo to actively request to receive 2 doses of mRNA-1273 vaccine.

All participants in Part A were to proceed to Part B, starting with a PDV, at which time participants were given the option to be unblinded to their original group assignment.

The following participants were to continue with the original study SoEs:

- Participants who requested to not be unblinded,
- Participants who requested to be unblinded and received mRNA-1273, and

- Participants who requested to be unblinded and received placebo and choose to remain on placebo.

Participants who were unblinded, received placebo in Part A, were EUA eligible, and requested to receive mRNA-1273 are planned to have the following additional clinic visits as shown in the Supplemental SoE (mRNA-1273-P301 Clinical Study Protocol Table 21 [Appendix 16.1.1]):

- Open-Label Dose 1 (OL-D1): occurred at the PDV or at a scheduled subsequent visit.
- Open-Label Dose 2 (OL-D29): occurred 28 days after Dose 1 on OL-D1.
- Open-Label Clinic Visit (OL-D57): occurred 1 month after Dose 2 on OL-D29.

Participants who were unblinded, received only 1 dose of mRNA-1273 in Part A, were EUA eligible, and requested to receive mRNA-1273 are planned to have the following additional clinic visits as shown in the Modified Supplemental SoE (mRNA-1273-P301 Clinical Study Protocol Table 22 [Appendix 16.1.1]):

- Their second dose on OL-D1: occurred at the PDV or at a scheduled subsequent visit.
- Open-Label Clinic Visit (OL-D29): occurred 1 month after Dose 2 on OL-D1.

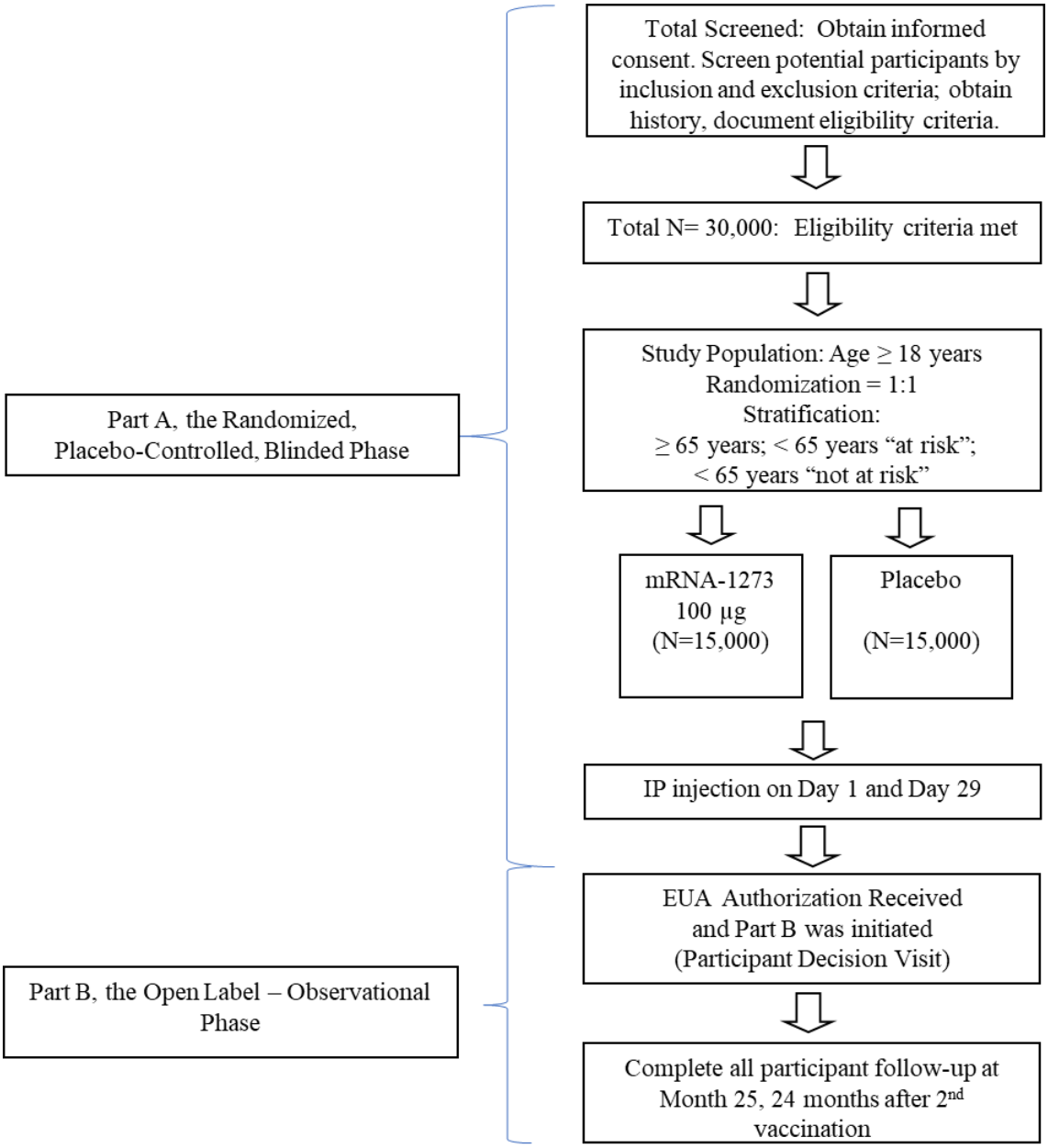
Participants receiving only 1 dose of mRNA-1273 in Part A were eligible to receive the second dose of mRNA-1273 under the following circumstances:

- They had a dosing error in Part A of the study that resulted in 1 dose of mRNA-1273 and 1 dose of placebo being administered.
- They did not have an AE that contraindicated the second dose of mRNA-1273 in Part A of the study.
- They did not withdraw consent in Part A of the study.
- They did not complete their second dose in Part A of the study for reasons other than the above.

All participants are expected to complete 24 months of follow-up after the second injection; study participants who entered the Supplemental or Modified Supplemental SoE did so in addition to their original SoE. Accordingly, all study participants are planned to complete the full study follow-up to 24 months after the second injection in Part A (mRNA-1273 or placebo).

A summary of the data from Part B, including COVID-19 cases, SAEs, AEs leading to withdrawal, MAAEs, and pregnancies will be included in a CSR addendum.

Figure 3-1: Study Flow Diagram: Part A, the Randomized, Placebo-Controlled, Blinded Phase, Followed by Part B, the Open-Label Observational Phase



Abbreviations: EUA = Emergency Use Authorization; IP = investigational product.

3.1.3 Discussion of Study Design

The mRNA-1273 vaccine is being developed to prevent COVID-19, the disease resulting from SARS-CoV-2 infection. The study was designed to primarily evaluate the clinical efficacy and safety of mRNA-1273 to prevent COVID-19 for up to 2 years after the second dose of

mRNA-1273. The immunogenicity endpoints and detection of SARS-CoV-2 infection are secondary objectives.

The design and focus of the study were dependent on the current COVID-19 pandemic, requiring identification of participant candidates at increased risk of SARS-CoV-2 infection. Adults at risk of SARS-CoV-2 infection who had no known history of SARS-CoV-2 infection were the planned target population. Potential study participants at increased risk of complications from COVID-19 were also included since it was hypothesized that these participants might benefit most from a vaccine. Participants ≥ 65 years of age, at increased risk of complications from COVID-19 due to their age, were also eligible for enrollment regardless of underlying medical conditions further increasing their risk of severe COVID-19.

Given the disproportionate disease burden of COVID-19 in racial and ethnic minorities, the study also aimed to enroll a representative sample of participants from these minority populations and adjust site selection and enrollment accordingly, per the Food and Drug Administration (FDA) Draft Guidance "Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, Enrollment Practices, and Trial Designs" (June, 2019). Study sites were also selected on the basis of SARS-CoV-2 infection risk of the local population.

The dose selected for this study (100 µg of mRNA-1273) was based on assessment of available safety and immunogenicity data from Phase 1 studies of mRNA-1647 (NCT03382405), the DMID study 20-0003 entitled "Phase I, Open-Label, Dose-Ranging Study of the Safety and Immunogenicity of 2019-nCoV Vaccine (mRNA-1273) in Healthy Adults" (NCT04283461), and the Phase 2 mRNA-1273-P201 study. The schedule (2 doses administered 28 days apart) was used in these studies.

There was no licensed SARS-CoV-2 vaccine at the time of study initiation; accordingly, 0.9% sodium chloride (normal saline) injection (USP) was used as a placebo control.

On 11 Dec 2020, the US FDA issued the first EUA to Pfizer-BioNTech for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. On 18 Dec 2020, the US FDA granted EUA for the mRNA-1273 vaccine for the prevention of COVID-19. Following EUA approval of COVID-19 vaccines, there was an increase in withdrawals of EUA-eligible participants who opted to be immunized with authorized vaccines. The clinical protocol was subsequently amended to adapt the study design to a 2-part Phase 3 study: Part A and Part B. Part A was designed to evaluate the clinical efficacy and safety of mRNA-1273 to prevent COVID-19. Part B, the Open-Label Observational Phase of the study, was prompted by the EUA and permitted all ongoing study participants to (a) be informed of the availability and eligibility criteria of any COVID-19 vaccine made available under EUA and (b) the option to offer all ongoing study participants who request unblinding an opportunity to schedule a study

visit to know their original group assignment (placebo vs. mRNA-1273 vaccine). Part B also provided the opportunity for study participants who previously received placebo to actively request to receive 2 doses of mRNA-1273 vaccine, where their participation would have otherwise denied them the opportunity to receive a COVID-19 vaccine under EUA.

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

3.2.1 Changes in the Conduct of the Study

Seven amendments were made to the original protocol, dated 15 Jun 2020. The original protocol and amendments 1 through 7 are provided in Appendix 16.1.1. The summary of major changes for each amendment is provided in Table 3-1.

Table 3-1: Summary of Major Changes Implemented With Each Protocol Amendment

Protocol Amendment	Summary of Major Changes
Protocol (15 Jun 2020)	Original
Amendment 1 (26 Jun 2020)	• Provided more intensive surveillance of symptoms and severity of cases of COVID-19 after the first dose of investigational product • Increased the frequency of telemedicine contacts during the Convalescent Period following the initial Illness Visit • Added monitoring of oxygen saturation to the Convalescent Period. • Increased the frequency of monitoring for SARS-CoV-2, using saliva as the preferred sample matrix after the Illness Visit during the Convalescent Period • Added a respiratory sample for hospitalized participants as a matrix for confirming the presence of SARS-CoV-2 • Broadened the definition for seroconversion at a participant level • Eliminated paper diaries, substituting an instruction card listing symptoms and a severity grading system to enhance the quality of data obtained by telemedicine contacts • Decreased the number of symptoms (to 1 of the 11 CDC symptoms) that would result in an Illness Visit • Expanded the scope of eDiary prompts and data collected during the Surveillance Phase

Protocol Amendment	Summary of Major Changes
Amendment 2 (31 Jul 2020)	• Provided more intensive surveillance of symptoms and severity of cases of COVID-19 after the first dose of investigational product • Added a Day 29 NP swab prior to Dose 2 • Changed the clinic visit at Month 4 to a safety call • Clarified symptom duration (> 48 hours) to trigger NP swab collection and investigator judgment whether to obtain an NP swab in the 7 days following vaccination due to overlap of solicited systemic symptoms and COVID-19 • Removed mention of continuous biometric monitoring • Removed the inclusion criterion regarding male contraception • Clarified language around influenza vaccination • Removed restriction on enrollment of participants with HIV infection • Added expedited reporting of confirmed COVID-19 cases • Added an Oversight Group • Updated description of monitoring for potential harm, including details on case counting for the purpose of harm monitoring to align with a DSMB analysis plan
Amendment 3 (20 Aug 2020)	• Added a sentence to describe the intent to enroll a representative sample of racial and ethnic minority participants in the study • Added clarification to exclusion criterion #11 to define the parameters based on screening CD4 count and viral load for exclusion of study participants • Removed “topical tacrolimus” from exclusion criterion #12 • Added HIV infection to the risk factors at Screening • Added collection of risk factors for complications of COVID-19 • Removed redundant bullet in the sample size determination • Removed safety analysis by serostatus • Removed the categories (White, non-White) from the Race Variable in the subgroup analysis • Removed “cessation of exogenous hormonal therapy” • Removed “using hormonal contraception” from postmenopausal female with high FSH levels
Amendment 4 (30 Sep 2020)	• Increased the upper limit for stratification of enrolled participants considered “at risk” at Screening to up to 50% from 40% • Updated the description of an intercurrent event (unrelated death) and its strategy
Amendment 5 (11 Nov 2020)	• Clarified the weekly schedule for eDiary prompts through Year 1 and Year 2 of follow-up • Added the Month 19 safety call

Protocol Amendment	Summary of Major Changes
Amendment 6 (23 Dec 2020)	• Added a "Participant Decision Clinic Visit" • Updated the study design to split the study into a Blinded Phase (Part A) and an Open-Label Observational Phase (Part B) • Updated the status of the ongoing clinical studies, including results of the interim analyses of this study • Added long-term efficacy analyses • Updated the benefit/risk assessment • Clarified eDiary safety prompts
Amendment 7 (10 Feb 2021)	• Clarified site unblinding at the Participant Decision Visit • Clarified requirements for Part B participants who received only 1 dose of mRNA-1273 during Part A • Updated presentation and storage conditions for vaccine • Clarified concomitant medication, eDiary, and blood sampling procedures during Part A and Part B • Removed collection of body mass index from the Participant Decision Visit • Updated maximum planned volume of blood collection for the complete study to include a range • Added suspected cases of anaphylaxis as an MAAE and requirement to report as an SAE • Clarified immunogenicity subset • Updated intercurrent events and estimands • Updated case count parameters for long-term efficacy analysis • Removed height and weight from open-label clinic visits and clarified that physical examination is symptom-directed

Abbreviations: CDC = Centers for Disease Control and Prevention; DSMB = Data and Safety Monitoring Board, eDiary = electronic diary; FSH = follicle-stimulating hormone; HIV = human immunodeficiency virus; MAAE = medically-attended adverse event; NP = nasopharyngeal; SAE = serious adverse event.

3.3 Investigators and Study Administrative Structure

ModernaTX, Inc. was the Sponsor of this clinical study. A total of 99 study sites in the United States enrolled at least 1 participant in the study. The first participant's first visit for this study was 27 Jul 2020. This study is ongoing; this Part A CSR includes available participant level data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier.

The contract research organization (CRO), PPD (Wilmington, North Carolina), was responsible for the following: biostatistics and programming (including generation of the randomization list), clinical site management, data management, data analytics, project management, safety monitoring, and medical writing and publishing.

Endpoint Clinical, Inc (San Francisco, California) managed the Interactive Response Technology (IRT) system used for participant randomization and to manage, track, order, and resupply mRNA-1273 and placebo for the study sites.

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

Medidata (Pittston, Pennsylvania) supplied eDiaries either as an application downloaded on participants' smartphone or using a device, which was used both for collection of 7-day reactogenicity and weekly eDiary prompts to elicit an unscheduled Illness Visit.

The Sponsor supplied mRNA-1273 and PPD supplied placebo to the sites.

The following laboratories were used:

PPD Central Laboratory (Highland Heights, Kentucky):

- Screening serology
- Follicle-stimulating hormone (FSH) testing, if required
- Elecsys® Anti-SARS-CoV-2 immunoassay

Viracor Eurofins Laboratories (Lee's Summit, Missouri):

- SARS-CoV-2 reverse transcriptase quantitative PCR (RT-qPCR) testing in NP swab and saliva
- BioFire® respiratory panel screening
- Spike-gene Next Generation Sequencing (NGS) and Whole Genome Sequencing (WGS) assay by RT-PCR

PPD Vaccine Laboratory (Richmond, Virginia):

- Anti-SARS-CoV-2 nucleocapsid (N)-protein enzyme-linked immunosorbent assay (ELISA)
- Anti-SARS-CoV-2 S-2P ELISA

NIH NIAID Vaccine Immunology Program (VIP; Bethesda, Maryland):

- MesoScale Discovery (MSD) electrochemiluminescence multiplex assay

Duke University (Durham, North Carolina):

- SARS-CoV-2 S pseudotyped neutralization assay

Safety monitoring committees utilized in this study included a Protocol Safety Review Team (PSRT), independent Data and Safety Monitoring Board (DSMB), and Adjudication Committee (AC); details are provided in Section 3.8.4.

A list of all investigators and clinical sites and other administrative structure/information is provided in Appendix 16.1.4.

3.4 Ethical Considerations

3.4.1 Independent Ethics Committee or Institutional Review Board

The protocol, protocol amendments, informed consent form (ICF), IB, and other relevant documents (eg, advertisements) were submitted to an institutional review board (IRB) or independent ethics committee (IEC) by the investigator and reviewed and approved by the IRB/IEC before the study was initiated.

Any amendments to the protocol required IRB/IEC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

The list of IRBs and IECs are available in Appendix 16.1.3.

3.4.2 Ethical Conduct of the Study

This study was conducted in accordance with the protocol and with the consensus ethical principles derived from international guidelines including the Declaration of Helsinki and CIOMS International Ethical Guidelines, applicable ICH GCP guidelines, and with applicable laws and regulatory requirements.

3.4.3 Participant Information and Consent

Before performing any study procedures, all potential participants signed an ICF. The informed consent document(s) must have met the requirements of 21 CFR 50; local regulations; ICH guidelines; Health Insurance Portability and Accountability Act (HIPAA) requirements, where applicable; and the IRB/IEC or study center. All consent documents were approved by the appropriate IRB/IEC. The actual ICF used at each center may have differed, depending on local regulations and IRB/IEC requirements. However, all versions must have contained the standard information found in the sample ICF provided by the Sponsor. Any change to the content of the ICF must have been approved by the Sponsor and the IRB/IEC prior to the form being used.

If new information became available that may have been relevant to the participant's willingness to continue participation in the study, this would have been communicated to him or her in a

timely manner. Such information would have been provided via a revised ICF or an addendum to the original ICF.

A participant who was rescreened was not required to sign another ICF if the rescreening occurred within 28 days from the previous ICF signature date.

Additional details of the informed consent process are provided in the mRNA-1273-P301 Clinical Study Protocol Section 11.2.6 (Appendix 16.1.1).

3.5 Selection of Study Population

3.5.1 Inclusion Criteria

Participants were eligible to be included in the study only if all the following criteria applied:

1. Adults ≥ 18 years of age at time of consent, who were at high risk of SARS-CoV-2 infection, defined as adults whose locations or circumstances put them at appreciable risk of exposure to SARS-CoV-2 and COVID-19.
2. Understood and agreed to comply with the study procedures and provided written informed consent.
3. Able to comply with study procedures based on the assessment of the investigator.
4. Female participants of nonchildbearing potential could have been enrolled in the study. Nonchildbearing potential was defined as surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy) or postmenopausal (defined as amenorrhea for ≥ 12 consecutive months prior to Screening without an alternative medical cause). An FSH level may have been measured at the discretion of the investigator to confirm postmenopausal status.
5. Female participants of childbearing potential could have been enrolled in the study if the participant fulfilled all the following criteria:
    - Had a negative pregnancy test at Screening and on the day of the first dose (Day 1).
    - Had practiced adequate contraception or had abstained from all activities that could result in pregnancy for at least 28 days prior to the first dose (Day 1).
    - Had agreed to continue adequate contraception through 3 months following the second dose (Day 29).
    - Was not currently breastfeeding

Adequate female contraception was defined as consistent and correct use of an FDA-approved contraceptive method in accordance with the product label. For example:

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

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

6. Healthy adults or adults with pre-existing medical conditions who were in stable condition. A stable medical condition was defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment.

3.5.2 Exclusion Criteria

Participants were excluded from the study if any of the following criteria applied:

1. Was acutely ill or febrile 72 hours prior to or at Screening. Fever was defined as a body temperature ≥ 38.0°C/100.4°F. Participants who met this criterion may have been rescheduled within the relevant window periods. Afebrile participants with minor illnesses could have been enrolled at the discretion of the investigator.
2. Was pregnant or breastfeeding.
3. (Part A only) Had known history of SARS-CoV-2 infection.
4. Had prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19.
5. (Part A only) Demonstrated inability to comply with the study procedures.
6. (Part A only) Had an immediate family member or household member of this study's personnel.
7. Had known or suspected allergy or history of anaphylaxis, urticaria, or other significant AR to the vaccine or its excipients.

8. Had a bleeding disorder that was considered a contraindication to IM injection or phlebotomy.
9. Had received or planned to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which was not permitted within 14 days before or after any dose of IP).
10. Had participated in an interventional clinical study within 28 days prior to the day of enrollment.
11. Had immunosuppressive or immunodeficient state, asplenia, recurrent severe infections (human immunodeficiency virus [HIV]-positive participants with CD4 count ≥ 350 cells/mm^3 and an undetectable HIV viral load within the past year [low level variations from 50-500 viral copies which did not lead to changes in antiretroviral therapy [ART] were permitted]).
12. Had received systemic immunosuppressants or immune-modifying drugs for > 14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent).
13. Had received systemic immunoglobulins or blood products within 3 months prior to the day of Screening.
14. Had donated ≥ 450 mL of blood products within 28 days prior to Screening.

3.5.3 Withdrawal of Participants From the Study or Study Treatment

3.5.3.1 Participant Withdrawal From the Study

Participants who withdrew from the study were not replaced. A “withdrawal” from the study referred to a situation wherein a participant did not return for the final visit planned in the protocol.

Participants could have withdrawn consent and withdrawn from the study at any time, for any reason, without prejudice to further treatment the participant may have needed to receive. The investigator requested that the study participant complete all study procedures pending at the time of withdrawal.

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

Information related to the withdrawal was documented in the eCRF. The investigator documented whether the decision to withdraw a participant from the study was made by the participant or by the investigator, as well as which of the following possible reasons was responsible for withdrawal:

- AE (specify)
- SAE (specify)
- Death
- Lost to follow-up
- Physician decision (specify)
- Pregnancy
- Protocol deviation
- Study terminated by Sponsor
- Withdrawal of consent by participant (specify); specify); this included participants who, at the PDV, withdrew consent from continuing in the study
- Other (specify)

Participants who were withdrawn from the study because of AEs (including SAEs) must have been clearly distinguished from participants who were withdrawn for other reasons. Investigators followed up with participants who were withdrawn from the study as result of an SAE or AE until resolution of the event.

Participants who were confirmed to have received placebo upon unblinding and intended to receive a COVID-19 vaccine under an EUA outside of this study were to be withdrawn from the study.

A participant withdrawing from the study may have requested destruction of any samples taken and not tested, and the investigator must have documented this in the site study records.

If the participant withdrew consent for disclosure of future information, the Sponsor could have retained and continued to use any data collected before such a withdrawal of consent.

The Sponsor continued to retain and use all research results that had already been collected for the study evaluation, unless the participant had requested destruction of these samples. All biological samples that had already been collected could be retained and analyzed at a later date (or as permitted by local regulations).

A participant was considered lost to follow-up if they repeatedly failed to return for scheduled visits without stating an intention to withdraw consent and they were unable to be contacted by the study site. The sites pursued multiple follow-up actions if a participant failed to return to the study site for a required study visit, as detailed in mRNA-1273-P301 Clinical Study Protocol Section 7.4 (Appendix 16.1.1).

3.5.3.2 Participant Withdrawal From Study Treatment

Every reasonable attempt was made to follow up with participants for safety throughout the entire study period, even if further IP injection was withheld or the participant missed 1 or more visits. Unless consent was withdrawn, a participant who withdrew or was withheld from receiving the second dose of IP remained in the study and completed all scheduled visits and assessments. Events that constituted contraindications to administration of IP at certain points in time are summarized in Section 3.6.1.1.

The possible reasons for withdrawal from further injection were identical to those listed in Section 3.5.3.1 for withdrawal from the study.

3.6 Study Treatment

3.6.1 Investigational Product Administered

In Part A, approximately 30,000 participants were randomly assigned in a 1:1 ratio to receive either mRNA-1273 100 µg or placebo (0.9% sodium chloride [normal saline] for injection).

Investigational product (mRNA-1273 100 µg or placebo) was administered as a 0.5 mL IM injection into the deltoid muscle (preferably the nondominant arm) on a 2-dose injection schedule (Day 1 and Day 29). The second dose of IP should have been administered in the same arm as the first dose.

At each visit when IP was administered, participants were monitored for a minimum of 30 minutes after administration. Assessments performed included vital sign measurements and monitoring for local or systemic reactions, as specified in the SoE for the Vaccination Phase, Day 1 through Day 57 (mRNA-1273-P301 Clinical Study Protocol Table 16; Appendix 16.1.1).

Eligibility for subsequent IP injection was determined per the criteria outlined in Section 3.6.1.1.

3.6.1.1 Contraindications to Subsequent Injection and Criteria for Delay of Study Treatment

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

The following events in a participant constituted absolute contraindications to any further injection of the IP to that participant. If any of these events occurred during the study, the participant should not have received additional doses of vaccine but was encouraged to continue study participation for safety through 24 months following last injection.

- (Part A Only) Diagnosed COVID-19 by detection of SARS-CoV-2 in Day 1 NP swab or COVID-19 diagnosed prior to Day 29. If COVID-19 was suspected on or prior to Day 29, further administration of IP was withheld until COVID-19 test results were available.
- Anaphylaxis or systemic hypersensitivity reaction following the administration of vaccine.
- Any SAE judged by investigator or Sponsor to be related to study vaccine.
- Any clinically significant medical condition that, in the opinion of the investigator, posed an additional risk to the participant if he or she continued to participate in the study.

The following events constituted criteria for delay of study vaccination, and if either of these events occurred at the time scheduled for administration of IP, the participant could have been injected at a later date within the time window specified in the SoE for the Vaccination Phase, Day 1 through Day 57 (mRNA-1273-P301 Clinical Study Protocol Table 16; Appendix 16.1.1), or the participant could have been discontinued from IP injection at the discretion of the investigator (Section 3.5.3):

- Acute moderate or severe infection with or without fever at the time of injection
- Fever, defined as body temperature ≥ 38.0°C (100.4°F) at the time of injection

Participants with a minor illness without fever, as assessed by the investigator, could have been administered IP. Participants with a fever of 38.0°C (100.4°F) or higher were contacted within the time window acceptable for participation and re-evaluated for eligibility. If the investigator determined that the participant's health on the day of administration temporarily precluded injection with IP, the visit was rescheduled within the allowed interval for that visit.

3.6.2 Identity of Investigational Products

The term "investigational product" refers to both mRNA-1273 vaccine and placebo administered in this study (Table 3-2). The Sponsor supplied mRNA-1273 and PPD supplied placebo to the sites.

Table 3-2: Investigational Products – Part A

Investigational Product	mRNA Concentration	Dosage Form	Packaging	Lot Numbers
mRNA-1273 vaccine	0.2 mg/mL	Sterile liquid for injection	One labeled carton, containing 1 labeled multidose vial (fill volume 5 mL)	Refer to Appendix 16.1.6
Placebo (0.9% sodium chloride injection, USP)	NA	0.9% sodium chloride (normal saline) solution for injection, USP	1 box, containing 25 single-use vials (10 mL each)	NA

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

The mRNA-1273 vaccine is an LNP dispersion of an mRNA encoding the prefusion stabilized S protein of SARS-CoV-2 combined in LNPs composed of 4 lipids (1 proprietary and 3 commercially available): the proprietary ionizable lipid SM-102; cholesterol; DSPC; and PEG2000-DMG. The mRNA-1273 vaccine was provided as a sterile liquid for injection and was a white to off white dispersion in appearance, at a concentration of 0.2 mg/mL in 20 mM Tris buffer containing 87 mg/mL sucrose and 10.7 mM sodium acetate at pH 7.5.

The placebo was 0.9% sodium chloride (normal saline) injection, which met the criteria of the United States Pharmacopeia (USP).

Unblinded study site personnel, who did not participate in any other aspect of the study during Part A, performed IP accountability procedures, dose preparation, and IP administration (Section 3.6.4). Unblinded study site personnel used a centralized IRT to manage, track, order, and resupply mRNA-1273 and placebo for the study.

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

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

mRNA-1273 vaccine for Part A was stored at 2°C to 8°C in a secure area with limited access (unblinded study site personnel only) and protected from moisture and light until it was prepared for administration. Details for mRNA-1273 vaccine storage and handling requirements are detailed in mRNA-1273-P301 Clinical Study Protocol Section 6.2.5 (Appendix 16.1.1).

The 0.9% sodium chloride injection (USP) was stored at 20ºC to 25ºC (68ºF to 77ºF) in a restricted access area.

Further description of the IP and instructions for the receipt, storage, preparation, administration, accountability, and destruction of the IP were described in the mRNA-1273-P301 Pharmacy Manual.

3.6.3 Method of Assigning Participants to Treatment Groups

In Part A, after eligibility was confirmed on Day 1, participants were randomly assigned in a 1:1 ratio to receive mRNA-1273 or placebo in a blinded manner using a centralized IRT, in accordance with pre-generated randomization schedules.

Participants were stratified by age (≥ 18 and < 65 years; or ≥ 65 years) and, if participants were < 65 years of age, on the presence or absence of risk factors for severe illness from COVID-19 based on CDC recommendation as of March 2020 (CDC 2020a). The following were the 3 strata for randomization:

- ≥ 18 and < 65 years and not at risk
- ≥ 18 and < 65 years and at risk
- ≥ 65 years

At least 25% of enrolled participants, but not exceeding 50%, were from the ≥ 65 years age group and < 65 years and at risk group.

Participants who were < 65 years old were categorized as at risk for severe COVID-19 illness if they had at least 1 of the following risk factors at Screening:

- Chronic lung disease (eg, emphysema and chronic bronchitis), idiopathic pulmonary fibrosis and cystic fibrosis), or moderate to severe asthma
- Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Severe obesity (body mass index [BMI] ≥ 40 kg/m^2)
- Diabetes (type 1, type 2, or gestational)
- Liver disease
- HIV infection

In Part A, only the unblinded study site personnel (Section 3.6.4) had controlled access to which arm the participant was randomly assigned. Access to the randomization code was strictly controlled at the pharmacy. The randomization schedule was provided to the IA review team after the database was locked for IA (Appendix 16.1.7).

3.6.4 Blinding and Unblinding

In Part A, the randomized, placebo-controlled, blinded phase of this study was observer-blind. The investigator, study staff, study participants, site monitors, and Sponsor personnel (or its designees) were to remain blinded to the IP administered until study end, with the following exceptions:

- Unblinded personnel (of limited number) were to be assigned to vaccine accountability procedures and were to prepare IP for all participants. These personnel were to have no study functions other than study vaccine management, documentation, accountability, preparation, and administration. They were not to be involved in participant evaluations and were not to reveal the identity of IP to either the participant or the blinded study site personnel involved in the conduct of the study unless the information was necessary in the case of an emergency.
- Unblinded medically qualified study site personnel were to administer the IP. They were not to be involved in assessments of any study endpoints.
- Unblinded site monitors, not involved in other aspects of monitoring, were to be assigned as the IP accountability monitors. They were to have responsibilities to ensure that sites were following all proper IP accountability, preparation, and administration procedures.
- The dosing assignment was to be concealed by having the unblinded personnel prepare the IP in a secure location that was not accessible or visible to other study staff. An opaque sleeve over the syringe used for injection maintained the blind at the time of injection, as the doses containing mRNA-1273 looked different than placebo. Only delegated unblinded site staff conducted the injection procedure. Once the injection was completed, only the blinded study staff were to perform further assessments and interact with the participants. Access to the randomization code was strictly controlled at the pharmacy.
- An unblinded statistical and programming team performed the pre-planned IAs.
- The unblinded medical monitor supported writing documents and communications with DSMB with oversight by the unblinded Sponsor clinical representative.
- An independent DSMB reviewed the interim data to safeguard the interests of clinical study participants and to help ensure the integrity of the study. The DSMB reviewed unblinded statistical outputs and IA results, provided by the independent unblinded statistician, and made recommendations to the Sponsor.

- At the initiation of Part B, the Open-Label Observational Phase of this study, site personnel who were blinded during Part A, the randomized, placebo-controlled, blinded phase, were unblinded at the participant level at the PDV.

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

In December 2020, COVID-19 vaccines started to become available under EUA as an alternative option to some participants based on evolving recommended populations by the CDC and local supply chain distribution. While all participants were encouraged to stay blinded in the study for as long as possible, their participation did not deny them the opportunity to receive a COVID-19 vaccine under EUA. Prior to implementation of Protocol Amendment 6 (23 Dec 2020; Section 3.2.1), clinical investigators could exercise discretion as to whether individual participants should have been unblinded upon request to allow them to make an informed decision regarding receipt of a COVID-19 vaccine outside of this study. Investigator judgment considered a participant's risk status under CDC recommendations, any current local public health guidance, and their access to imminently receive a COVID-19 vaccine under an EUA. Participants who were unblinded prior to Protocol Amendment 6 and determined to have received placebo, were discontinued from the study by the investigator to permit given the intention of the participant to receive vaccine under EUA. Those who received mRNA-1273 were encouraged to continue participation in an open-label manner unless the participant withdrew informed consent.

Participants who were confirmed to have received placebo upon unblinding and intended to receive a COVID-19 vaccine under an EUA outside of this study were to be withdrawn from the study at the point of unblinding.

Note: Participants who requested unblinding because of a stated imminent access to a COVID-19 vaccine under an EUA outside of this study, were withdrawn from study, and then were unable to in fact receive a COVID-19 vaccine, were permitted to re-enter the study upon reconsent to receive the mRNA-1273 vaccine once they were EUA eligible.

3.6.5 Treatment Compliance

All doses of IP were administered at the study site under direct observation of unblinded medically qualified study site personnel and appropriately recorded (date and time) in the eCRF. Unblinded study site personnel confirmed that the participant received the entire dose of vaccine or placebo. If a participant did not receive vaccine or placebo or did not receive all of the planned number of doses, the reason for the missed dose was recorded. Data were reconciled with site accountability records to assess compliance.

The required process was followed even if participants missed the second dose of IP due to noncompliance with the visit schedule and not due to a safety pause and for ensuring participants complied with the allowed study windows, as described in mRNA-1273-P301 Clinical Study Protocol Section 6.3 (Appendix 16.1.1).

3.6.6 Prior and Concomitant Medications and Therapies

3.6.6.1 Prior Medications and Therapies

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

3.6.6.2 Concomitant Medications and Therapies

A concomitant medication was defined as a medication that continued or was newly received at or after the first injection through 28 days after the last injection. A post medication was defined as a medication received more than 28 days after the last injection. At each study visit, study site personnel questioned the participant regarding any medications taken and non-study vaccinations the participant received and recorded the information in the eCRF.

In Part A only, participants were asked in the eDiary if they had taken any antipyretic or analgesic to treat or prevent fever or pain within 7 days after each IP injection, including the day of administration. Reported antipyretic or analgesic medications were recorded in the source document by the site staff during the post-injection study visits or via other participant interactions (eg, telephone calls).

The information recorded for concomitant medications, non-study vaccination, and treatment medication is described in mRNA-1273-P301 Clinical Study Protocol Section 6.4.2 (Appendix 16.1.1).

Concomitant medications and/or vaccines that did not require withdrawal of the participant from the study but may have impacted a participant's eligibility to receive a second dose or evaluability in the per-protocol (PP) analysis are listed in mRNA-1273-P301 Clinical Study Protocol Section 6.4.3 (Appendix 16.1.1). Contraindications for administration of the second dose are provided in Section 3.6.1.1.

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

All medication and interventions necessary for the appropriate care for the study participant, particularly to treat COVID-19, were administered and appropriately documented along with the AE.

3.7 Efficacy, Safety, and Immunogenicity Measurements Assessed and Schedule of Assessments

3.7.1 Study Assessments and Schedule of Events

The SoEs for all participants are presented in mRNA-1273-P301 Clinical Study Protocol Table 16 (Vaccination Phase, Day 1 - Day 57), Table 17 (Surveillance Phase, Day 64 - Day 394), Table 18 (Surveillance Phase, Day 401 - Day 759), Table 19 (Convalescent Period, Starting with the Illness Visit), and Table 20 (Part B: Participant Decision Clinic Visit) (Appendix 16.1.1).

Participants eligible for Part B open-label IP injection may have up to 3 additional scheduled clinic visits (Section 3.1.2) as specified in the mRNA-1273-P301 Clinical Study Protocol Table 21 (Supplemental Schedule of Events: Open-Label Observational Phase - Placebo Participants who request to receive mRNA-1273) and Table 22 (Modified Supplemental Schedule of Events: Open-Label Observational Phase – mRNA-1273 Participants who ONLY received 1 dose of mRNA-1273) (Appendix 16.1.1).

A participant also could have had an unscheduled visit at any time during the study. An unscheduled visit could have been prompted by Illness Visit criteria for COVID-19 or new or ongoing AEs (including vaccine reactogenicity). The site also had the discretion to make reminder telephone calls or send text messages to inform the participant about visits, review eDiary requirements, or follow up on ongoing or outstanding issues. These reminders were in addition to the protocol-specified visits.

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

3.7.1.1 Use of Electronic Diary

In Part A, the randomized, placebo-controlled, blinded phase of the study, before enrollment on Day 1, participants were instructed to download the eDiary application on their personal smartphone or were provided a Sponsor-provisioned device to record solicited ARs; the eDiary also provided prompts to elicit an unscheduled Illness Visit if the participant experienced COVID-19 symptoms (Section 3.7.2.1).

In Part A, the randomized, placebo-controlled, blinded phase of the study, at each injection visit, participants recorded data into the eDiary starting approximately 30 minutes after injection under supervision of the study site personnel to ensure successful entry of assessments. The 30-minute assessment was an opportunity for study site personnel to train the participant. The study site personnel performed any retraining as necessary. Study participants continued to record data in an eDiary after they left the study site, preferably in the evening and at the same time each day, on the day of injection and for 6 days following injection. If on Day 7 an AR persisted, the eDiary prompts and entries were continued until resolution.

In Part A, the randomized, placebo-controlled, blinded phase of the study, solicited local and systemic reactogenicity ARs, as defined in Section 3.7.4.1, were collected on the day of each IP injection, during the 7 days after IP injection (ie, the day of injection and 6 subsequent days; or until resolution for solicited ARs that continued beyond 7 days), and weekly thereafter. Any solicited AR that was ongoing beyond Day 7 was reported in an eDiary until resolution. Adverse reactions recorded in diaries beyond Day 7 were reviewed by study site personnel either during the next scheduled telephone call or at the next study site visit.

After Study Day 57, the eDiary prompted each participant weekly to surveil for potential symptoms of COVID-19. If eDiary prompts resulted in identification of relevant safety events according to the study period or symptoms of COVID-19, a follow-up safety call was triggered.

In Part A, the randomized, placebo-controlled, blinded phase of the study, at each injection visit, participants were instructed or reminded on thermometer usage to measure body temperature, ruler usage to measure injection site erythema and swelling/induration (hardness), and self-assessment for localized axillary swelling or tenderness on the same side as the injection arm.

In Part A, the randomized, placebo-controlled, blinded phase of the study, daily oral body temperature measurement was performed at approximately the same time each day using the thermometer provided by the study site.

Surveillance for signs and symptoms of COVID-19 started at Day 1 and are continuing through the entire Surveillance Phase (Day 64 to Month 25). After participants completed Part A, the weekly eDiary Safety Follow-Up Prompts were to be triggered on Day 61. Each week (ie, every 7 days) the participant received a prompt on their smartphone device to regularly surveil for signs and symptoms of COVID-19. The participant was trained on how to complete the weekly eDiary prompts at the Day 57 clinic visit and was also reminded to call the site immediately if they experienced any COVID-19 symptoms. The weekly eDiary prompt inquired about the following:

- Changes in health since the last time completing the weekly eDiary prompt or the last contact with the study site personnel
- Any known exposure to someone with SARS-CoV-2 infection or COVID-19 since the last time completing the weekly eDiary prompt or the last contact with the study site personnel
- Capture of any COVID-19 symptoms currently being experienced or experienced since the last time completing the weekly check-in as defined in Section 3.7.2.1
- Any contact with a healthcare provider that may indicate an MAAE

A positive response by the participant to these prompts resulted in a notification to both the participant and study site personnel to arrange a call. A follow-up safety call was performed to determine if an unscheduled Illness Visit for the participant was needed (defined in Section 3.7.2.2). The results of the safety call were recorded in the appropriate source documentation.

If a participant did not respond to the weekly eDiary within a 2-day window around the scheduled time point, study site personnel followed up directly with the participant via telephone call or text to confirm their health status and to remind the participant of the importance of maintaining weekly contact via the eDiary prompt.

In addition, an eDiary prompt was implemented to solicit the collection of information regarding participant's history of facial injections or dermal fillers, for cosmetic or medical indications such as migraine headaches.

3.7.1.2 Safety Telephone Call

A safety telephone call was a telephone call made to the participant by medically qualified study site personnel. Medically qualified study site personnel were those appropriately delegated individuals who were permitted to elicit verbal medical history from participants based on local regulations and local licensing requirements.

The call followed a script, which facilitated the collection of relevant safety information. The participant was interviewed according to the script about occurrence of unsolicited AEs, MAAEs, SAEs, AEs leading to study withdrawal and concomitant medications associated with those events, receipt of any non-study vaccinations, and pregnancy.

The timing of the safety telephone calls and the relevant safety information collected were indicated in the SoEs (mRNA-1273-P301 Clinical Study Protocol Section 11.1; Appendix 16.1.1).

All safety information collected from the telephone contact was documented in source documents as described by the participant and not documented on the script used for the safety telephone contact. All AEs, MAAEs, SAEs, and AEs leading to study withdrawal were recorded in the eCRF as specified in Section 3.7.4.2.

3.7.2 Efficacy Assessments

The primary and secondary efficacy endpoints are provided in Section 2.

The efficacy in this study was determined based on defined cases of COVID-19. Cases were defined as participants meeting clinical criteria based both on symptoms for COVID-19 (Section 3.7.2.1) and on RT-PCR detection of SARS-CoV-2 (Section 3.7.2.3) from samples collected within 72 hours of the study participant reporting symptoms that met the definition of COVID-19. Participants who were hospitalized for COVID-19 without the opportunity for a clinic or home visit were also considered cases, assuming that the symptomology criteria for COVID-19 were met and a respiratory sample was positive for SARS-CoV-2 by RT-PCR at a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory. Investigators were encouraged to obtain a respiratory sample during the course of hospitalization for submission to the study central laboratory, if feasible. The investigator was required to determine if the criteria for severe COVID-19 had been met. The surveillance for COVID-19 symptoms, including signs of severe systemic illness and the corresponding clinical pathways for data collection, is presented graphically in mRNA-1273-P301 Clinical Study Protocol Figure 4 (Appendix 16.1.1).

An AC, blinded to treatment assignment, reviewed potential cases (Section 3.8.4.3).

Definitions of severe COVID-19, secondary cases of COVID-19, and death attributed to COVID-19 are included in the respective defined secondary efficacy endpoints (Section 2).

3.7.2.1 Surveillance for COVID-19 Symptoms

Surveillance for COVID-19 symptoms was conducted via weekly telephone calls in Part A, Blinded Phase and Part B, Open-Label Observational Phase of the study and/or eDiary prompts as specified in Section 3.7.1.1, starting after enrollment and throughout the study. If there was no response to an eDiary prompt for 2 days, the study site personnel contacted the study participant by telephone.

According to the CDC as of 10 Jun 2020 (CDC 2020b), patients with COVID-19 have reported a wide range of symptoms ranging from mild symptoms to severe illness. Throughout the study, to surveil for COVID-19, the following prespecified symptoms that met the criteria for suspicion of COVID-19 were elicited weekly from the participant, and the presence of any one of these symptoms lasting at least 48 hours (except for fever and/or respiratory symptoms) resulted in the site arranging an Illness Visit to collect an NP swab within 72 hours:

- Fever (temperature ≥ 38ºC) or chills (of any duration, including ≤ 48 hours)
- Shortness of breath or difficulty breathing (of any duration, including ≤ 48 hours)
- Cough (of any duration, including ≤ 48 hours)
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

Importantly, some of the symptoms of COVID-19 overlap with solicited systemic ARs that are expected after vaccination with mRNA-1273 (eg, myalgia, headache, fever, and chills). During the first 7 days after IP injection, when these solicited ARs might be common, investigators used their clinical judgment and decided if an NP swab should be collected. The collection of an NP swab prior to the Day 1 and Day 29 vaccination helped ensure that cases of COVID-19 were not

overlooked. Any study participant reporting respiratory symptoms during the 7-day period after vaccination was evaluated for COVID-19.

During the course of the study, participants with symptoms of COVID-19 were asked to return within 72 hours or as soon as possible to the study site, or medically qualified study site personnel from the study site conducted a home visit as soon as possible to collect an NP swab sample (for RT-PCR), collect a blood sample for immunologic analysis of SARS-CoV-2 infection, and to evaluate for COVID-19. Both study site visits and home visits were referred to as Illness Visits (Section 3.7.2.2). The NP swab sample was also tested for the presence of other respiratory infections.

All clinical findings were recorded in the eCRF. All confirmed cases of COVID-19 were to be captured as MAAEs, along with relevant concomitant medications and details about severity, seriousness, and outcome.

3.7.2.2 Assessments During Convalescence Period, Starting at Illness Visit

All study participants who experienced COVID-19 symptoms and subsequently presented for an Illness Visit (in clinic or at home) were given an instruction card listing symptoms and severity grading system, a thermometer, an oxygen saturation monitor, and saliva collection tubes. Participants were trained on the use of the oxygen saturation monitor and how to take saliva specimens. The list of symptoms is provided in Section 3.7.2.1 and the severity scoring system is presented in mRNA-1273-P301 Clinical Study Protocol Table 3 (Appendix 16.1.1).

A study site Illness Visit may have included assessments such as medical history, physical examination, blood sampling for clinical laboratory testing, and NP swab sampling for viral PCR (including multiplex PCR for respiratory viruses including SARS-CoV-2) to evaluate the severity of the clinical case. Radiologic imaging studies may have been conducted. Blood samples were collected for potential future immunologic assessment of SARS-CoV-2 infection.

The initial Illness Visit was considered Day 1 for the Convalescent Period. Starting on Day 2 of the Convalescent Period, the investigator (or medically qualified study site personnel appropriately delegated by the investigator) contacted participants daily with telemedicine visits through Day 14 or until symptoms resolved, whichever was later. Telemedicine visits (videoconference or audio only) included participant-reported symptoms, severity of symptoms, body temperature, and oxygen saturation, as detailed in mRNA-1273-P301 Clinical Study Protocol Section 8.1.3 and Table 19 (Appendix 16.1.1). Participants were also reminded to collect their saliva sample 3, 5, 7, 9, 14, and 21 days after the initial Illness Visit and to return the sample to the study site. Immediately upon receipt of a saliva sample, the study site sent it for testing to the study central virology laboratory.

If the participant had a positive result for SARS-CoV-2 from the Day 1 Illness Visit, the participant continued the Convalescent Period; if the result was negative, the participant exited the Convalescent Period, including discontinuation of daily telemedicine visits and collection of saliva samples, and followed the respective SoE (mRNA-1273-P301 Clinical Study Protocol Table 16, Table 17, and Table 18; Appendix 16.1.1)

All participants confirmed with COVID-19 cases were scheduled for a Convalescent Visit (study site or home visit) 28 days after the initial Illness Visit. At this visit, a saliva (or nasal swab) sample was collected, and a blood sample was drawn for immunologic assessment of SARS-CoV-2 infection.

If the participant was hospitalized, medically qualified study site personnel tried to obtain medical records and SARS-CoV-2 diagnostic results and document if the criteria for COVID-19 or severe COVID-19 had been met. If the participant was later discharged from the hospital during the 28-day period following diagnosis of COVID-19, the study site personnel arranged for a resumption of a schedule for telemedicine visits and sampling for the remainder of the Convalescent Period, followed by a return to their respective study schedule.

3.7.2.3 Testing for SARS-CoV-2 Infection

3.7.2.3.1 Reverse Transcriptase-Polymerase Chain Reaction in Nasopharyngeal and Nasal Swabs Samples

Nasopharyngeal swab sample were collected for SARS-CoV-2 on Day 1 and Day 29, prior to receiving a dose of the IP, and at the PDV as specified in mRNA-1273-P301 Clinical Study Protocol Table 16 and Table 20 (Appendix 16.1.1). If COVID-19 symptoms reported lasted at least 48 hours (except for fever and/or respiratory symptoms), an Illness Visit was scheduled to collect an NP swab or nasal swab samples were obtained (Section 3.7.2.2).

Nasopharyngeal specimens collected from individuals with symptoms of COVID-19 were tested for SARS-CoV-2 infection using SARS-CoV-2 specific RT-PCR in support of primary and secondary study endpoints. Summary of RT-PCR (upper respiratory samples) method and method validation parameters (eg, sensitivity, specificity, reliability, validity) for this bioassay are presented in Appendix 16.6.

3.7.2.3.2 Elecsys Anti-SARS-CoV-2 Immunoassay in Serum and plasma samples

Elecsys Anti-SARS-CoV-2 immunoassay was used for the qualitative detection of bAb to SARS-CoV-2 N antigen in human serum and plasma. The Elecsys anti-SARS-CoV-2 aided in

identifying individuals with an adaptive immune response to SARS-CoV-2 at the time of enrollment and at subsequent time points in support of primary and secondary study endpoints.

Blood samples for immunologic assessment of SARS-CoV-2 infection were collected according to time points indicated in the SoEs (mRNA-1273-P301 Clinical Study Protocol Section 11.1 [Appendix 16.1.1]).

Summary of Elecsys Anti-SARS-CoV-2 immunoassay (ELECSYS: N-protein IgG) method and method validation parameters (eg, sensitivity, specificity, reliability, validity) for this bioassay are presented in Appendix 16.6.

3.7.2.3.3 Genotypic Analysis of SARS-CoV-2 Variants

Evaluation of genotypic/phenotypic relationship of isolated SARS-CoV-2 strains was performed using residue specimens initially collected for the qualitative detection of RNA from SARS-CoV-2 from nasal swabs (Section 3.7.2.3.1). No additional samples were collected for this analysis.

Two genotypic analysis were performed in support of exploratory endpoints:

- NGS RT-PCR based assay sequencing the whole SARS-CoV-2 S-protein genome.
- WGS RT-PCR based assay sequencing the whole SARS-CoV-2 genome.

Summary of both these sequencing methods (RT-PCR NGS and RT-PCR WGS) and method validation parameters (eg, sensitivity, specificity, reliability, validity) for both bioassays are presented in Appendix 16.6.

3.7.2.3.4 Viral Load Analysis of SARS-CoV-2 in Saliva Samples

Participants with a positive RT-PCR (NP-swabs) (Section 3.7.2.3.1) result for SARS-CoV-2 from the Day 1 Illness Visit, collected their own saliva samples (respiratory illness sample) during the telemedicine visits convalescent period on 3, 5, 7, 9, 14, and 21 days after the initial Illness Visit (mRNA-1273-P301 Clinical Study Protocol Section 11.1 [Appendix 16.1.1]).

These saliva specimens were analyzed using a SARS-CoV-2 specific RT-qPCR assay intended for quantitative detection of RNA from SARS-CoV-2 virus to analyze SARS-CoV-2 viral load over time after infection in support of exploratory endpoints.

Summary of this method (RT-qPCR [saliva sample]) and method validation parameters (eg, sensitivity, specificity, reliability, validity) are presented in Appendix 16.6.

3.7.3 Immunogenicity Assessments

The secondary and exploratory immunogenicity endpoints are provided in Section 2. Blood samples for immunogenicity assessments continue as planned at the time points indicated in the SoEs (mRNA-1273-P301 Clinical Study Protocol Section 11.1 [Appendix 16.1.1]).

In Part A, on Day 1 and Day 29, blood samples for immunogenicity assessment were collected before administration of IP. The following antigens were measured:

- Serum bAb levels against SARS-CoV-2 as measured by ligand-binding assay specific to the SARS-CoV-2 S-2P-protein (ELISA).
- Serum bAb levels against SARS-CoV-2 as measured by ligand-binding assay specific to the SARS-CoV-2 S protein (MSD).
- Serum nAb titer against SARS-CoV-2 as measured by pseudovirus neutralization assays (PsVNA).

The actual time and date of each sample collected was recorded in the eCRF, and unique sample identification was used to maintain the blind at the laboratory at all times and allowed for automated sample tracking and storage. Handling and preparation of the samples for analysis, as well as shipping and storage requirements, were described in a separate study manual.

These assays were performed in laboratories designated by the Sponsor (Section 3.3). Summaries of S-protein bAb (ELISA: S-2P protein IgG and MSD Multiples: S-protein IgG) and nAb (PsVNA) assay methodologies and method validation parameters (eg, sensitivity, specificity, reliability, validity) for each bioassay are presented in Appendix 16.6.

3.7.4 Safety Assessments

Safety assessments included monitoring and recording of the following for each participant:

- Solicited local and systemic ARs (Section 3.7.4.1) that occur during the 7 days following each injection (ie, the day of injection and 6 subsequent days; or until resolution for solicited ARs that continued beyond 7 days). Solicited ARs will be recorded daily using eDiaries (Section 3.7.1.1).
- Unsolicited AEs observed or reported during the 28 days following each dose of IP (ie, the day of injection and 27 subsequent days). Unsolicited AEs are AEs that are not included in the protocol-defined solicited ARs.
- AEs leading to discontinuation from injection and/or study participation from Day 1 through Day 759 or withdrawal from the study.

- MAAEs from Day 1 through Day 759 or withdrawal from the study.
- SAEs from Day 1 through Day 759 or withdrawal from the study.
- Abnormal vital sign measurements.
- Physical examination findings.
- Pregnancy and accompanying outcomes.
- Concomitant medications and non-study vaccinations.

3.7.4.1 Solicited Adverse Reactions (Part A, Blinded Phase Only)

The term "reactogenicity" referred to the occurrence and intensity of selected signs and symptoms (ARs) occurring after IP injection. The eDiary solicited daily participant reporting of ARs using a structured checklist. Participants recorded such occurrences in an eDiary on the day of each IP injection and for 6 subsequent days (or until resolution for solicited ARs that continued beyond 7 days).

Severity grading of reactogenicity occurred automatically based on participant entry into the eDiary according to the grading scales presented in mRNA-1273-P301 Clinical Study Protocol Table 5 (Appendix 16.1.1) modified from the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials (DHHS 2007).

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

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

- Solicited local or systemic AR that resulted in a visit to a healthcare practitioner (HCP) (MAAE)
- Solicited local or systemic AR that led to the participant withdrawing from the study or the participant being withdrawn from the study by the investigator (AE leading to withdrawal)
- Solicited local or systemic AR that lasted beyond 7 days post injection
- Solicited local or systemic AR that led to participant withdrawal from IP

- Solicited local or systemic AR that otherwise met the definition of an SAE

3.7.4.2 Adverse Events, Serious Adverse Events, and Medically Attended Adverse Events

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

The AE and SAE definitions are provided in the mRNA-1273-P301 Clinical Study Protocol Section 8.3.1 and Section 8.3.3 (Appendix 16.1.1). A TEAE was defined as any event that was not present before exposure to vaccine or any event that was already present which worsened in intensity or frequency after exposure.

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

An MAAE was an AE that led to an unscheduled visit (including telemedicine visit) to a HCP. This included visits to a study site for unscheduled assessments (eg, rash assessment, abnormal laboratory follow-up, COVID-19) and visits to HCPs external to the study site (eg, urgent care, primary care physician). Investigators reviewed unsolicited AEs for the occurrence of any MAAEs. All MAAEs were fully reported on the MAAE page of the eCRF.

All suspected cases of anaphylaxis were recorded as MAAEs and reported as an SAE, based on criteria for a medically important event, unless the event met other serious criteria. An AR was any AE for which there was a reasonable possibility that the IP caused the AE. For the purposes of investigational new drug safety reporting, “reasonable possibility” means that there was evidence to suggest a causal relationship between the IP and the AE.

At every study site visit or telephone contact, participants were asked a standard question to elicit any medically related changes, including surveillance for COVID-19 symptoms, in their well-being according to the scripts provided. Participants were also asked if they were hospitalized, had any accidents, used any new medications, changed concomitant medication regimens (both prescription and over-the-counter medications), or had any non-study vaccinations.

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

All AEs, SAEs, and MAAEs were reported in detail on the appropriate page of the eCRF and followed until resolution, stabilization, the event was otherwise explained, or the participant was lost to follow-up.

The following information on AEs was obtained:

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

Additional information on reporting and documenting AEs and SAEs as well as assessment of causality and severity are provided in the mRNA-1273-P301 Clinical Study Protocol Section 8.3 (Appendix 16.1.1).

3.7.4.3 Vital Sign Measurements

Vital signs were measured at the time points indicated in the SoEs (mRNA-1273-P301 Clinical Study Protocol Section 11.1 [Appendix 16.1.1]). The participant was seated for at least 5 minutes before all measurements were taken. On Day 1 and Day 29, vital sign measurements were collected once before IP injection and at least 30 minutes after IP injection (before participants were discharged from the study site). When applicable, vital sign measurements were performed before blood collection.

Febrile participants at Day 1 and Day 29 visits (fever defined as a body temperature ≥ 38.0°C/100.4°F) were rescheduled within the relevant window periods. Afebrile participants with minor illnesses could have received their assigned IP at the discretion of the investigator.

If any of the vital sign measurements met the toxicity grading criteria for clinical abnormalities of Grade 3 (severe) or greater, the abnormal value and grade were documented on the AE page of the eCRF (unless there was another known cause of the abnormality that resulted in an AE classification). The investigator continued to monitor the participant with additional assessments until the vital sign value reached the reference range, returned to the vital sign value at baseline,

was considered stable, or until the investigator determined that follow-up was no longer medically necessary.

3.7.4.4 Physical Examinations

A full physical examination, including vital signs, height, and weight, was performed at Screening and on Day 1, and symptom-directed physical examinations at other scheduled time points as indicated in the SoEs (mRNA-1273-P301 Clinical Study Protocol Section 11.1 [Appendix 16.1.1]). The full examination included assessment of skin, head, ears, eyes, nose, throat, neck, thyroid, lungs, heart, cardiovascular, abdomen, lymph nodes, and musculoskeletal system/extremities. Symptom-directed physical examinations may have been performed at other time points at the discretion of the investigator.

On each dosing day before injection, the arm receiving the injection was examined and the associated lymph nodes were evaluated.

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

Any clinically significant finding identified during a study visit after the first dose was reported as an MAAE.

Significant new findings that began or worsened after informed consent were recorded on the AE eCRF page.

3.7.5 Other Assessments

3.7.5.1 Other Virus/Bacteria Infection Analysis

For the RT-PCR analysis of other (not SARS-CoV-2) viral or bacterial infection, an independent NP swab sample was collected for SARS-CoV-2 on Day 1 Illness Visit and analyzed using BioFire FilmArray® Respiratory Panel (RP) assay.

The BioFire FilmArray® RP is a diagnostic multiplex PCR test performed to simultaneous detecting 20 different viruses and bacteria associated with respiratory tract infection (Adenovirus, Coronavirus 229E/HKU1/NL63/OC4, Human Metapneumovirus, Human Rhinovirus, Influenza A/A-H1/A-H1-2009/A-H3/B, Parainfluenza 1/2/3/4, Respiratory Syncytial Virus, *Bordetella pertussis/parapertussis* and *Chlamydophila/Mycoplasma pneumoniae*).

This qualitative bioassay was performed in support of exploratory endpoints. Summary of BioFire RP (RT-PCR BioFire) method and method validation parameters (eg, sensitivity, specificity, reliability, validity) are presented in Appendix 16.6.

3.7.6 Appropriateness of Measurements

Efficacy measurements used in this study were selected based on discussions with regulatory authorities and were in line with the recommendations set forth in the FDA Guidance on Development and Licensure of Vaccines to Prevent COVID-19 (DHHS 2020c). The primary endpoint was accepted, and on 18 Dec 2020, the US FDA granted EUA for the mRNA-1273 vaccine for the prevention of COVID-19 (DHHS 2021). Diagnostic testing for SARS-CoV-2 infection was performed using validated assays and/or assays authorized by the FDA under EUA (Section 3.7.2.3).

The safety measures included in this study were appropriate for a preventative vaccine for an infectious disease, including assessment of solicited ARs and unsolicited AEs.

The immunogenicity measures (quantification of neutralizing and binding antibodies) used in this study were standard and appropriate and were performed using validated assays (Section 3.7.3).

3.8 Data Quality Assurance

Data collection was the responsibility of the study site personnel at the site under the supervision of the study site investigator. The investigator was responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

- All participant data relating to the study were recorded in the eCRF unless transmitted to the Sponsor or designee electronically (eg, laboratory data). The investigator was responsible for verifying that data entries were accurate and correct by physically or electronically signing the eCRF.
- The investigators were expected to maintain accurate documentation (source data) that supported the information entered in the eCRF.
- The investigator permitted study-related monitoring, audits, IRB/IEC review, and regulatory agency inspections and provided direct access to source data documents.
- Monitoring details describing strategy (eg, risk-based initiatives in operations and quality such as Risk Management and Mitigation Strategies and Analytical Risk-Based Monitoring), methods, responsibilities and requirements, including handling of noncompliance issues and monitoring techniques (central, remote, or on-site monitoring) were provided in the study Monitoring Plan, Centralized Monitoring Plan, and Risk Management Plan.

- The Sponsor or designee was responsible for the data management of this study including quality checking of the data.
- The Sponsor assumed accountability for actions delegated to other individuals (eg, CROs).
- Study monitors performed ongoing source data verification to confirm that data entered into the CRF by authorized study site personnel were accurate, complete, and verifiable from source documents; that the safety and rights of participants were being protected; and that the study was conducted in accordance with the currently approved protocol and any other study agreements, ICH GCP, and all applicable regulatory requirements.
- Records and documents, including signed ICFs, pertaining to the conduct of this study are required to be retained by the investigator for 15 years after study completion unless local regulations or institutional policies require a longer retention period. No records may be destroyed during the retention period without the written approval of the Sponsor. No records may be transferred to another location or party without written notification to the Sponsor.

Quality assurance (QA) included all the planned and systematic actions that were established to ensure that the clinical study was performed, and the data were generated, documented (recorded), and reported according to ICH GCP and local/regional regulatory standards.

A QA representative from the Sponsor or qualified designee, who was independent of and separated from routine monitoring, periodically arranged inspections/audits of the clinical study by reviewing the data obtained and procedural aspects. These inspections may have included on-site inspections/audits and source data checks. Direct access to source documents was required for the purpose of these periodic inspections/audits.

3.8.1 Data Collection and Management

This study was conducted in compliance with ICH CGP guidelines. This study was also conducted in accordance with the most recent version of the Declaration of Helsinki.

This study used electronic data collection (to collect data directly from the investigational site using eCRFs). The investigator was responsible for ensuring that all sections of each eCRF were completed promptly and correctly and that entries could have been verified against any source data.

Study monitors performed source document verification to identify inconsistencies between the eCRFs and source documents. Discrepancies were resolved in accordance with the principles of GCP. Detailed study monitoring procedures were provided in the clinical monitoring plan.

Adverse events were coded with the most current available version of MedDRA. Concomitant medications were coded using the WHO Drug Reference List.

3.8.2 Study Monitoring

Before an investigational site entered a participant into the study, a representative of the Sponsor or its representatives visited the investigational study site to:

- Determine the adequacy of the facilities.
- Discuss with the investigator(s) and other study site personnel their responsibilities with regard to protocol adherence, and the responsibilities of Moderna or its representatives. This was documented in a Clinical Study Agreement between the Sponsor, designated CRO, and the investigator.

According to ICH GCP guideline, the Sponsor of the study was responsible for ensuring the proper conduct of the study with regard to protocol adherence and validity of data recorded on the eCRFs. The study monitor's duties were to aid the investigator and Moderna in the maintenance of complete, accurate, legible, well-organized, and easily retrievable data. The study monitor advised the investigator of the regulatory necessity for study-related monitoring, audits, IRB/IEC review, and inspection by providing direct access to the source data/documents. In addition, the study monitor explained to and interpreted for the investigator all regulations applicable to the clinical evaluation of an IP as documented in ICH guidelines.

It was the study monitor's responsibility to inspect the eCRFs and source documentation throughout the study to protect the rights of the participants; to verify adherence to the protocol; to verify completeness, accuracy, and consistency of the data; and to confirm adherence of study conduct to any local regulations. Details were outlined in the clinical monitoring plan. During the study, a monitor from Moderna or a representative are planned to have regular contacts with the investigational site, for the following:

- Provide information and support to the investigator(s).
- Confirm that facilities remain acceptable.
- Confirm that the investigational team is adhering to the protocol, that the data are being accurately recorded in the eCRFs, and that IP accountability checks are being performed.
- Perform source data verification. This includes a comparison of the data in the eCRFs with the participant's medical records at the hospital or practice, and other records relevant to the study. This will require direct access to all original records for each participant (eg, clinical charts or electronic medical record system).

- Record and report any protocol deviations not previously sent.
- Confirm AEs and SAEs have been properly documented on eCRFs and confirm any SAEs have been forwarded to the SAE Hotline, and those SAEs that met criteria for reporting have been forwarded to the IRB/IEC.

The monitor was available between visits if the investigator(s) or other study site personnel needed information or advice.

In accordance with the FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency (DHHS 2020d), investigators may have converted study site visits to telemedicine visits with the approval of the Sponsor.

3.8.3 Audits

Moderna, their designee(s), the IRB/IEC, or regulatory authorities were allowed to conduct site visits to the investigational facilities for the purpose of monitoring or inspecting any aspect of the study. The investigator agreed to allow Moderna, their designee(s), the IRB/IEC, or regulatory authorities to inspect the IP storage area, IP stocks, IP records, participant charts and study source documents, and other records relative to study conduct.

Authorized representatives of Moderna, a regulatory authority, and any IRB/IEC could visit any site to perform audits or inspections, including source data verification. The purpose of a Sponsor audit or inspection was to systematically and independently examine all study-related activities and documents to determine whether these activities were conducted, and data were recorded, analyzed, and accurately reported according to the protocol, ICH GCP E6(R2), and any applicable regulatory requirements. The investigator was required to notify Moderna immediately if contacted by a regulatory agency about an inspection.

The principal investigator obtained IRB approval for the investigation. Initial IRB approval and all materials approved by the IRB for this study, including the participant consent form and recruitment materials, were maintained by the investigator and made available for inspection.

3.8.4 Safety Monitoring Committees

3.8.4.1 Protocol Safety Review Team

A PSRT was formed to review interim and cumulative blinded safety data on a regular basis with a remit to escalate concerns to the DSMB. The PSRT was composed of the study's 3 coordinating investigators and representatives from Moderna, NIAID, Biomedical Advanced Research and Development Authority (BARDA), and the CRO. The PSRT composition, its remit, and the routine and systematic procedures for safety review and oversight of blinded

interval and cumulative data during the mRNA-1273 P301 study by the PSRT is documented in the Moderna mRNA-1273 P301 Protocol Safety Review Team Charter.

3.8.4.2 Data and Safety Monitoring Board

An independent DSMB periodically reviewed blinded and unblinded data, including both safety and cases of COVID-19 at scheduled data review meetings and at 2 planned IAs. The DSMB was a multidisciplinary group independent of the study's academic partners, Oversight Group, Sponsor, and United States Government. Members had expertise in biostatistics, clinical trials, infectious diseases, vaccine development, vaccine safety and ethics. The DSMB composition, its remit, and frequency of data review were further defined in the Moderna mRNA-1273 DSMB Charter and DSMB Analysis Plan (Appendix 16.1.13).

- In addition to blinded and unblinded review of safety data, at each data review meeting the DSMB reviewed the numbers and rate of COVID-19 cases, including rate of severe COVID-19 disease with prespecified thresholds for imbalance in the treatment groups which would have triggered halting rules.
- At the IAs, the DSMB reviewed the IA of efficacy results and made recommendations to an Oversight Group in terms of study results reporting and unblinding based on the boundaries of early efficacy. The Oversight Group was comprised of a voting member each from the Sponsor, BARDA, and NIAID.
- The DSMB monitored the study for non-efficacy at the IA. The boundary for non-efficacy was non-binding and was provided in the DSMB analysis plan.
- The DSMB also monitored the study for vaccine harm based on both COVID-19 and severe COVID-19. Continuous harm monitoring was provided for COVID-19 and severe COVID-19 separately. For harm monitoring, cases were counted starting after the first dose of study IP. Boundaries were provided based on the exact 1-sided binomial tests conditional on the total number of cases under the assumption of VE=0%. If the prespecified stopping boundary was reached for either COVID-19 or severe COVID-19, then the unblinded statisticians would have immediately informed the DSMB that the harm rules had been met.

The boundaries were considered guidelines, ie, a recommendation to modify the study would not have been based solely on statistical rules, as many other factors (ie, totality of the data from the study including additional efficacy, safety, and immunogenicity endpoints as well as data external to the study) may have been part of the decision process. In the case of a recommendation to continue the trial regardless of crossing the boundaries for efficacy or

inefficacy, the reason for disregarding the boundary must have been documented in the meeting minutes and communicated to the Sponsor.

After each data review meeting or IA, the DSMB made a recommendation to the Sponsor through an Oversight Group to take 1 of the following courses of action:

- Stop further enrollment due to meeting criteria for early efficacy or due to a safety concern.
- Pause enrollment and consider a change in study design.
- Continue enrollment and/or study conduct as planned.

The Sponsor may also have requested that the DSMB conduct ad hoc reviews of safety events from this study or other data, including new nonclinical or clinical information related to mRNA-1273 external to this study. The DSMB reviewed all available study data to adjudicate such events in accordance with the DSMB charter.

3.8.4.3 Adjudication Committee

An Adjudication Committee (AC) was assembled for the purpose of reviewing potential cases to determine if the criteria for the primary and secondary endpoints was met. The AC remained blinded to treatment assignment. The AC comprised 4 physicians (inclusive of the committee chair) who were independent of the Sponsor. The AC composition, its remit, and frequency of data review were further defined in the Moderna mRNA-1273-P301 AC Charter.

3.8.5 Risk Management

This study was conducted according to ICH E6(R2) risk and quality processes, as described by the ICH guidance documents. The predefined quality tolerance limits (PDQTLs) being monitored throughout this study include the following:

- **Parameter name:** Proportion (%) of participants enrolled that are missing the second vaccination for any reason.

  Frequency: First run when approximately 10% of participants reached Day 29. Subsequent runs at 10% increments until all participants passed Day 29.

- **Parameter name:** Proportion (%) of participants enrolled that have a study discontinuation reason of either: lost to follow-up, withdrawal of consent by participant, physician decision, or other.

Frequency: First run when approximately 10% of participants completed the End of Study/Study Discontinuation page. Subsequent runs at 10% increments until all participants completed the End of Study/Study Discontinuation page.

- **Parameter name:** Proportion (%) of participants enrolled with any blood sample for immunogenicity serologic analysis not collected up to participant completion or discontinuation

Frequency: First run when approximately 10% of participants completed Day 1. Subsequent runs when approximately 10% of participants reached the following milestones: Day 29, Day 57, and End of Study/Study Discontinuation. Thereafter, subsequent runs when approximately 20% reached End of Study/Study Discontinuation followed by 20% increments until all participants completed the End of Study/Study Discontinuation page.

3.8.6 Clinical COVID-19 Response

The following is a summary of the mitigations the study team executed to reduce and/or eliminate the impact of COVID-19 on the study, sites and participants.

- Currently, the COVID-19 pandemic impact to this study has been low and manageable.
- PPD COVID review board has approved all CRA for travel to sites that allow onsite visits as an exception to their corporate travel restrictions for this study.
- As of 2 Nov 2020, a small number of the sites have restrictions for onsite visits for unblinded and blinded monitors. We are conducting remote visits while restrictions are in place.
- Monitoring for impact across all study sites is conducted as part of the remote and onsite monitoring procedures. Contract Research Organization is responsible to poll all sites regularly on COVID-19 impact to participants and study operations.
- Protocol design accommodates the reality of the virus and was in place prior to start of enrollment.
- Routine COVID-19 site impact and travel restriction updates are captured by CRO and provided in reports to Sponsor.
- Site specific concerns are documented in Monitoring Visit Reports.

- The EOS CSR will contain all COVID-19 impacts and protocol deviations per FDA guidance.

The framework for business continuity in response to the pandemic while conducting the mRNA-1273-P301 clinical study are provided in the Clinical COVID-19 Response document.

4 STATISTICAL ANALYSIS METHODS PLANNED IN THE PROTOCOL AND DETERMINATION OF SAMPLE SIZE

4.1 Statistical Methods

All analyses were conducted using SAS software (SAS Institute, Inc, Cary, North Carolina) Version 9.4. The final mRNA-1273-P301 SAP, Version 1.0 (dated 08 Sep 2020) and Version 2.0 (dated 08 Mar 2021) are provided in Appendix 16.1.9.

4.1.1 General Considerations

Continuous variables were summarized using the number of participants (n), mean, standard deviation, median, minimum, and maximum. Categorical variables were summarized using counts and percentages.

Baseline value, unless specified otherwise, was defined as the most recent nonmissing measurement (scheduled or unscheduled) collected before the first dose of IP.

Baseline SARS-CoV-2 status was determined by using virologic and serologic evidence of SARS-CoV-2 infection on or before Day 1.

- Positive SARS-CoV-2 status at baseline was defined as a positive RT-PCR test for SARS-CoV-2, and/or a positive serology test based on bAb specific to SARS-CoV-2 N-protein (as measured by Roche Elecsys anti-SARS-CoV-2 assay) on or before Day 1.
- Negative status at baseline was defined as a negative RT-PCR test for SARS-CoV-2 and a negative serology test (as measured by Roche Elecsys anti-SARS-CoV-2 assay) at Day 1.
- The baseline SARS-CoV-2 status was defined as missing for participants with both tests missing, or with 1 test missing and 1 test negative.
- Participants with negative baseline SARS-CoV-2 status were included in the modified intent-to-treat (mITT) Set; participants with positive or missing baseline SARS-CoV-2 status were excluded from the mITT and PP Sets.

The 2 treatment groups used for summary purposes for Part A were mRNA-1273 and placebo. If a participant received any dose of mRNA-1273 at any injection, regardless of the treatment group in which the participant was randomized, the participant was included in the mRNA-1273 group as the actual treatment group received for safety analyses.

The following analysis periods and treatment groups were used for efficacy analyses for Part A:

Part A Group	Description	Blinded/Part A Analysis Period for Efficacy
mRNA-1273	Participants randomized to mRNA-1273 in the randomized, placebo-controlled, blinded phase	From randomization to earlier date of Participant Decision Visit (unblinding, study discontinuation, study completion, death, or data cutoff date for efficacy)
Placebo	Participants randomized to placebo in the randomized, placebo-controlled, blinded phase	

The following analysis period and treatment groups were used for safety analyses for Part A:

Part A Group	Description	Blinded/Part A Analysis Period for Safety
mRNA-1273	Participants received at least 1 dose of mRNA-1273 in the randomized, placebo-controlled, blinded phase	From the first dose of study investigational product (IP) to the earlier date of (study discontinuation, study completion, death, data cutoff for safety, Participant Decision Visit/unblinding) for those who did not receive study IP in Part B. For participants who received study IP in Part B, from the first dose of study IP in study to the earlier date of (data cutoff for safety, or first IP injection in Part B)
Placebo	Participants only received placebo in the randomized, placebo-controlled, blinded phase	

The above analysis period for safety analysis in Part A was also referred to as "Overall Period" in the tables and listings (hereafter referred to as "Part A" in the CSR). Within Part A, "up to 28 days after any vaccination" includes the day of each vaccination through the 27 subsequent days, or up to the day of subsequent vaccination (if applicable). This time period was used as the primary analysis period for safety analyses, including solicited AR (Day 1 through Day 7 the first and second injections) and unsolicited AE (Day 1 through Day 28 after any injection), unless specified otherwise.

4.1.1.1 Statistical Hypothesis

For the primary efficacy objective, the null hypothesis for this study was that the VE of mRNA-1273 to prevent first occurrence of COVID-19 was ≤ 30%; ie,

$$H_0^{\text{efficacy}}: VE \leq 0.3.$$

The study was considered to have met the primary efficacy objective if the confidence interval (CI) of VE ruled out 30% at either one of the IAs or at the primary analysis.

4.1.2 Determination of Sample Size

The sample size was driven by the total number of cases to demonstrate the VE (mRNA-1273 vs. placebo) to prevent COVID-19. Under the assumption of proportional hazards over time and with 1:1 randomization to vaccine:placebo, a total of 151 COVID-19 events would provide 90% power to detect a 60% reduction in hazard rate, rejecting the null hypothesis H_0:VE ≤ 30%, with 2 IAs planned at 35% and 70% of the total events using a 1-sided O'Brien-Fleming boundary for efficacy and a log-rank test statistic with a 1-sided false positive error rate of 0.025. The total number of cases pertained to the PP Set, starting 14 days after the second dose of IP. Under specified assumptions, as detailed in mRNA-1273-P301 Clinical Study Protocol Section 9.3 (Appendix 16.1.1), up to approximately 30,000 participants were planned for randomization, and the time required was expected to be approximately 5, 8, and 10 months from study start (first participant first dose) to accrue 35% (approximately 53), 70% (approximately 106), and 100% (151), respectively, of the target number of cases in the PP Set.

For the secondary objective on the VE against serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity (COV-INF), the study had ≥ 90% power to demonstrate the VE was above 30% (to reject null hypothesis VE ≤ 30%) at 1-sided alpha of 2.5% if the true VE to prevent COV-INF was 60%, because every COVID-19 disease endpoint was necessarily a COV-INF endpoint. For the secondary objective on the VE against severe COVID-19, the power depended on the number of severe COVID-19 cases (mRNA-1273-P301 Clinical Study Protocol Table 7; Appendix 16.1.1).

4.1.3 Analysis Sets

The following analysis sets were defined:

- **Randomized Set:** All participants who were randomized, regardless of the participant's treatment status in the study. Participants were analyzed according to the treatment group to which they were randomized.
- **Full Analysis Set (FAS):** All randomized participants who received at least 1 dose of IP. Participants were analyzed according to the treatment group to which they were randomized.

- **mITT Set:** All participants in the FAS who had no immunologic or virologic evidence of prior COVID-19 (negative SARS-CoV-2 status, ie, negative NP swab test and negative bAb against SARS-CoV-2 N-protein as measured by Roche Elecsys) at Day 1 before the first dose of IP; ie, all FAS participants excluding those with RT-PCR and/or serology positive at baseline (Day 1 before the first dose of IP). Participants were analyzed according to the treatment group to which they were randomized.
- **PP Set:** All participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data. Participants were analyzed according to the treatment group to which they were randomized. Participants who did not receive the second injection of IP within [21, 42] days after the first injection date were excluded from the PP Set.
- **Immunogenicity Subset and Analysis Populations for Immunogenicity:** For characterizing immunogenicity of the vaccine and for assessing correlates of risk and protection, a case-cohort sampling design was used for measuring bAb and nAb data from a randomly sampled subset of study participants (the case-cohort Immunogenicity Analysis Set [ccIAS]) or immunogenicity subset. The ccIAS cohort consisted of a stratified, random sample of study participants (random subcohort) augmented with a subset or all primary endpoint cases and SARS-CoV-2 infection endpoint cases. The immunogenicity samples of the ccIAS cohort were processed and the immunogenicity data were available for the ccIAS cohort. The immunogenicity subset consisted of all participants in the ccIAS who had a valid baseline immunogenicity test result (prior to the first dose of IP) and at least 1 valid post-baseline result.

  The analysis of characterizing immunogenicity of mRNA-1273 is provided in Section 4.2.4.
- The **Per-Protocol Random Subcohort for Immunogenicity** (PPRSI) was used as the analysis population to characterize immunogenicity of mRNA-1273. The PPRSI for immunogenicity consisted of participants in the FAS who were sampled into the random subcohort and

  a) Received both planned doses (ie, received the treatment as the participant was randomized to) with Dose 2 received within [21, 42] days after Dose 1, and

  b) No major protocol deviation that impacted critical or key data.

Details of the case-cohort sampling and analysis populations for characterizing immunogenicity of mRNA-1273 are also provided in mRNA-1273-P301 SAP Section 6.7 (Appendix 16.1.9).

- **Solicited Safety Set:** All randomized participants who received at least 1 dose of IP and contributed any solicited AR data; ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The Solicited Safety Set was used for the analyses of solicited ARs, and participants were included in the treatment group corresponding to the study vaccination they actually received.

  In addition, the following Solicited Safety Set was defined for each injection separately. **The First (Second) Injection Solicited Safety Set** consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days.

  Participants were analyzed according to the treatment group a participant received, rather than the treatment group to which the participant was randomized. If a participant was randomized to placebo but received any dose of mRNA-1273 vaccine at any injection, the participants were included in the mRNA-1273 group in the Solicited Safety Set.

- **Safety Set:** All randomized participants who received at least 1 dose of IP. The Safety Set was used for all analysis of safety except for the solicited ARs. Participants were included in the treatment group corresponding to the IP they actually received. For a participant who was randomized to placebo but received any dose of mRNA-1273 at any injection, the participant will be included in the mRNA-1273 group in the Safety Set.

4.1.4 Handling of Withdrawals of Consent, Lost to Follow-Up, and Missing Data

Imputation rules for missing or partial dates for prior and concomitant medications, non-study vaccinations, and procedures are provided in mRNA-1273-P301 SAP Appendix C, and imputation rules for missing AE dates are provided in mRNA-1273-P301 SAP Appendix D (Appendix 16.1.9).

For the secondary objective to characterize immunogenicity of mRNA-1273, for the binding and neutralizing anti-SARS-CoV-2 assays, if the laboratory results were reported as below the LLOQ (eg, < 0.1), the numeric values were imputed by 0.5 × LLOQ in the summary when treating the results as continuous variables. If the laboratory results were reported as greater than the ULOQ (eg, > 3,000), the numeric values were substituted by ULOQ in the summary when treating the

results as continuous variables. If the actual values above the ULOQ were provided by the testing laboratory, the actual values were used in the analysis and reporting.

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

4.1.5 Planned Analyses and Analyses of Efficacy Analyses That Have Been Conducted

4.1.5.1 Planned Interim Analyses and Primary Analysis

Two IAs were planned in this study: the first and second performed when approximately 35% and 70%, respectively, of the target total number of COVID-19 cases across the 2 treatment groups were observed. The primary objective of the IAs was for early detection of reliable evidence that VE was above 30%. The Lan-DeMets O'Brien-Fleming approximation spending function was used for calculating efficacy bounds and to preserve the (1-sided) 0.025 false positive error rate over the 2 IAs and the primary analysis (when the target number of cases was observed), relative to the null hypothesis ($H_0^{efficacy}$: VE ≤ 30%).

There was no intention to stop the study early if efficacy was demonstrated at any of the IAs. If efficacy was demonstrated at an IA, the subsequent IA or primary analysis was to be considered supportive in nature. The DSMB was to review the IA results and make recommendations to the Sponsor in terms of study results reporting and unblinding based on the boundaries of early efficacy as described in this section, safety data, and data external to this study. In addition to possible early efficacy at IAs, the DSMB monitored for non-efficacy and vaccine harm; the guiding principles (non-binding) is provided in Section 3.8.4.2.

The first IA was planned to occur when 35% of the total cases in the PP Set were observed. The study was to be considered positive at this IA if the 1-sided *p* value for rejecting VE ≤ 30% (hazard ratio [HR] ≥ 0.7) was less than 0.0002 based on the Lan-DeMets O'Brien-Fleming approximation spending function. This corresponded to an observed HR of approximately 0.259, or an observed VE of approximately 0.741.

The second IA was planned to occur when 70% of the total cases were observed in the PP Set. The study was to be considered positive at this IA if the *p* value for rejecting VE ≤ 30% (HR ≥ 0.7) was less than 0.0073 based on the Lan-DeMets O'Brien-Fleming approximation spending function. This corresponded to an observed HR of approximately 0.435, or an observed VE of approximately 0.565.

The primary analysis was to be performed when approximately 151 cases were observed in the PP Set. The study was to be considered positive at the primary analysis when a total of 151 cases were observed and if the 1-sided *p* value for rejecting HR ≥ 0.7 was less than 0.0227. This

corresponded to an observed HR of approximately 0.505, or observed VE of approximately 0.495.

As described in Section 3.6.4, an independent, unblinded statistics team, not involved in either study design or the regular study conduct, carried out the IAs.

4.1.5.2 Analyses of Efficacy That Have Been Conducted

4.1.5.2.1 The First Interim Analysis

The primary efficacy endpoint of mRNA-1273-P301 was based on confirmed clinical cases of COVID-19 per AC assessments (adjudicated cases), defined as the first occurrence of COVID-19 starting 14 days after the second injection.

For the primary efficacy objective, the null hypothesis of this study was that the VE of mRNA-1273 to prevent the first occurrence of COVID-19 was ≤ 30%, ie $H_0^{efficacy}$: VE ≤ 0.3.

The first IA was conducted based on a data snapshot that occurred on 11 Nov 2020 (DS1), and the data cutoff date for evaluation of efficacy was 07 Nov 2020. At the first IA, the median follow-up time was 49 days (7 weeks). The primary analysis of COVID-19 was based on the PP Set with cases starting 14 days after the second dose. The first interim efficacy analysis was performed by the independent biostatistician and the results were first reviewed by the independent external DSMB on 15 Nov 2020. The DSMB concluded that "with 63% of the expected number of the total number of adjudicated primary endpoints, the study has passed the efficacy monitoring boundary for benefit." The DSMB "encourages the study team to prepare the data for the FDA package as rapidly as possible." Based on the DSMB's recommendation, select Sponsor and CRO personnel were unblinded to prepare for regulatory submissions.

At the first IA, the total number of adjudicated COVID-19 cases starting 14 days after the second injection (ie, primary efficacy endpoint) was 95, 63% of the information fraction based on the total target number of 151 cases. Correspondingly, the nominal 1-sided alpha was 0.0047. At the first IA, the 1-sided *p* value to test the null hypothesis of VE ≤ 30% from the stratified Cox proportional hazard model was < 0.0001 and was compared to the nominal 1-sided alpha (0.0047) based on the number of cases at the first IA (95 in total). Equivalently, the lower bound of the alpha-adjusted CI of VE, the 2-sided 99.1% CI, could be compared to 30% at the first IA. The lower bound of the 2-sided 99.1% CI was above 30% at the first IA.

The VE of mRNA-1273 was demonstrated at the first IA based on the prespecified success criterion on efficacy (Section 6.1.1). Since efficacy was demonstrated at the first IA based on 95 adjudicated cases, all subsequent efficacy analyses were considered supportive or supplementary.

4.1.5.2.2 Primary Analysis of Efficacy

A second analysis was performed, that included data with a median follow-up duration for safety and efficacy of at least 2 months after completion of the full vaccination regimen. The analysis was based on a data snapshot as of 25 Nov 2020 (DS2), using a data cutoff date of 21 Nov 2020 for the evaluation of efficacy. Both safety and efficacy analyses were performed to provide additional information on the vaccine's profile. Since efficacy was demonstrated at the first IA, the primary analysis of efficacy based on DS2 was supplementary in nature.

All potential COVID-19 cases starting 14 days after the second injection confirmed by RT-PCR (central or local), were prioritized for adjudication. Corresponding available clinical data in electronic data capture as of 21 Nov 2020, were sent to the AC and were adjudicated for this analysis.

It was anticipated that the total number of adjudicated COVID-19 cases starting 14 days after the second injection in the PP Set at DS2 occurred on 25 Nov 2020 would be ≥ 151, the target total number of events at the originally planned primary analysis. At DS2, the total number of adjudicated COVID-19 cases starting 14 days after the second injection in the PP Set was 196 (Section 6.1.1). Therefore, this analysis was considered the primary analysis of efficacy including at least 151 cases, as prespecified in the protocol.

4.1.5.3 Final Analysis of Efficacy for Blinded Data (Part A)

Results from the first IA based on DS1 and the primary analysis based on DS2 were used to support the EUA application in the US and other regions of the world. The EUA was authorized for mRNA-1273 in the US on 18 Dec 2020.

The mRNA-1273-P301 Clinical Study Protocol Amendment 6 (dated 23 Dec 2020; Section 3.2.1) informed all ongoing study participants of the availability of and eligibility criteria for any COVID-19 vaccine made available under an EUA. The amendment also allowed study sites to offer participants who originally received placebo in this study the potential benefit of vaccination against COVID-19, given that the primary efficacy endpoint for mRNA-1273 against COVID-19 was met per the protocol-defined IA. Participants in this study underwent a PDV, at which they had the opportunity to be unblinded, and those originally randomized to placebo had the opportunity to receive mRNA-1273 in this study.

A final analysis of efficacy was performed when a median follow-up of at least 6 months had occurred. At this time, at least 90% of the study participants who had completed the PDV or had been unblinded or discontinued from the study provided efficacy data based on Part A, the randomized, placebo-controlled, blinded phase of the study. The final analysis of efficacy for Part A was based on database lock of 04 May 2021, and included available participant level data

up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier. Additionally, for secondary efficacy endpoints of SARS-CoV-2 infection regardless of symptomology and severity (all infection) and asymptomatic SARS-CoV-2 infection, separate analyses were performed including new positive RT-PCR results at the PDV.

4.1.6 Multiplicity Adjustments

The overall type I error rate for this study was controlled at 2.5% (1-sided). The overall type I error rate for the primary efficacy endpoint at the IAs and the primary analysis was strictly controlled at 2.5% (1-sided) based on the Lan-DeMets O'Brien-Fleming approximation spending function. The primary efficacy endpoint was considered statistically significant after consideration of the strategy for controlling the type I error as described in Section 4.1.5.1. Statistical significance of the primary efficacy endpoint can be achieved at either 1 of the IAs or at the primary analysis.

A sequential/hierarchical testing procedure was planned to control type 1 error rate over the primary efficacy endpoint and the secondary efficacy endpoints. Secondary efficacy endpoints were only tested when the primary efficacy endpoint achieved statistical significance.

If the primary efficacy endpoint achieved statistical significance at either one of the IAs or at the primary analysis, a fixed-sequence statistical strategy was used to test the following secondary efficacy endpoints in a predefined order:

1. Secondary efficacy endpoint: COVID-19 regardless of evidence of prior SARS-CoV-2 infection at the same analysis (through the same follow-up period)
2. Secondary efficacy endpoint: infection regardless of symptomatology or severity at the same analysis (through the same follow-up period)
3. Secondary efficacy endpoint: severe COVID-19 at the analysis with ≥ 20 cases, otherwise, to test at the end of the study

The sequential tests of the above 3 secondary efficacy endpoints were to be performed at 1-sided type I error rate of 0.025, if the primary efficacy endpoint achieved statistical significance at either one of the IAs or at the primary analysis. Please refer to mRNA-1273-P301 SAP Section 6.5 (Appendix 16.1.9).

A graphical overview of the testing strategy planned testing of primary and select secondary efficacy endpoints is provided in mRNA-1273-P301 SAP Figure 2 (Appendix 16.1.9).

At the IA where VE for COVID-19 was demonstrated at the prespecified statistical criterion, there were 11 total adjudicated severe COVID-19 cases starting 14 days after the second injection.

At the time of the IA and the primary analysis of efficacy, data for secondary efficacy endpoint infection regardless of symptomatology or severity were not available and were not included in these analyses.

4.1.7 Multicenter Studies

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

4.1.8 Adjustment for Covariates

Adjustments for covariates were performed for the primary efficacy analyses as described in Section 4.2.2.1 and Section 4.2.2.1.4.

4.1.9 Examination of Subgroups

Subgroup analyses of the efficacy, safety, and immunogenicity endpoints are described in Section 4.2.2, Section 4.2.3, and Section 4.2.4, respectively.

4.2 Population, Efficacy, Safety, and Immunogenicity Statistical Analyses

4.2.1 Study Population

4.2.1.1 Disposition

The number and percentage of participants in the following categories were summarized by treatment group based on the Randomized Set: Randomized Set, FAS, mITT Set, PP Set, Solicited Safety Set, and Safety Set. The denominators for the percentages were based on participants in the Randomized Set.

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

The number and percentage of randomized participants were summarized separately by stratification factor at randomization (ie, ≥ 18 and < 65 years and not at risk, ≥ 18 and < 65 years and at risk, or ≥ 65 years) based on the Randomization Set.

The number and percentage of participants in each of the following disposition categories were summarized based on the Randomized Set: received each dose of IP, prematurely discontinued before receiving the second dose of IP and the reason for discontinuation, completed study, and prematurely discontinued the study and the reason for discontinuation.

A listing was provided for participants with any inclusion and exclusion criteria violation.

4.2.1.2 Protocol Deviation

Major protocol deviations were defined as a subset of protocol deviations that significantly impacted the completeness, accuracy, or reliability of the study data or that significantly affected a participant's rights, safety, or well-being. Major protocol deviations rules were developed and finalized before database lock. The major protocol deviations are described in Section 5.4.

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

Select major protocol deviations impacted critical or key study data, and participants with such deviations were excluded from the PP Set for efficacy analyses; major protocol deviations were determined and documented by the Sponsor prior to database lock and unblinding. Reasons of exclusion from the PP Set for efficacy were summarized.

4.2.1.3 Demographics and Baseline Characteristics

Descriptive statistics were calculated for the following continuous demographic and baseline characteristics: age (years), weight (kg), height (cm), and BMI (kg/m^2). The number and percentage of participants were provided for categorical variables, such as age group, sex, race, ethnicity, randomization stratum under which the participant was randomized, and the following risk factors at screening (at least 1 of the following):

- Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Severe obesity (BMI ≥ 40 kg/m^2)
- Diabetes (type 1, type 2, or gestational)
- Liver disease
- HIV infection

The summaries were presented separately based on the FAS, Safety Set, mITT Set, and PP Set.

4.2.1.4 Medical History

Medical history data were coded by system organ class (SOC) and preferred term (PT) according to the MedDRA version 23.0.

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

4.2.1.5 Prior, Concomitant, and Post Medications

Prior and concomitant medications and non-study vaccinations were coded using the WHODrug, version March 2020.The summary of concomitant medications was based on the Safety Set. Categorization of prior, concomitant, and post medications was summarized in mRNA-1273-P301 SAP Appendix C (Appendix 16.1.9).

The number and percentage of participants who continued or newly received concomitant medications and non-study vaccinations were summarized by treatment group by PT in descending frequency in the mRNA-1273 group as follows:

- Any concomitant medications.
- Any non-study vaccine.
- Antipyretic or analgesic medications were summarized during the 7-day follow-up period of each injection and during the 28-day follow-up period after each injection (for first injection, up to second injection or 28 days after the first injection).

Prior, concomitant, and post medications and non-study vaccinations were presented in a listing.

4.2.1.6 Exposure

The number and percentage of participants who received the first and second injections were summarized by treatment group. The timing of the second injection was also summarized by treatment group.

4.2.2 Efficacy Analyses

The PP Set was the primary analysis population for efficacy analyses, unless otherwise specified. In the PP Set, mITT Set, and FAS used for all efficacy analyses, participants were included in the treatment group which they were randomized to.

COVID-19 is defined as symptomatic disease meeting clinical criteria based both on symptoms for COVID-19 and positive RT-PCR test results; mRNA-1273-P301 Clinical Study Protocol Section 8.1.1 (Appendix 16.1.1) for the eligible symptoms for COVID-19 cases. The AC, blinded to treatment assignment, reviewed potential cases and adjudicated COVID-19 and severe COVID-19 cases. The AC assessments were used in the first IA based on DS1 that occurred on

11 Nov 2020 (Section 4.1.5.2), the primary analysis based on DS2 that occurred on 25 Nov 2020 (Section 4.1.5.2.2), and the final efficacy analysis of Part A data based on database lock that occurred on 04 May 2021 (Section 4.1.5.3).

Baseline SARS-CoV-2 status (Section 4.1.1), RT-PCR test results at baseline, serology status at baseline (bAb specific to SARS-CoV-2 N-protein, as measured by Roche Elecsys anti-SARS-CoV-2 assay) were summarized by treatment group.

The mITT and PP Sets only included participants with baseline negative SARS-CoV-2 status.

The RT-PCR test results and bAb specific to SARS-CoV-2 N-protein were summarized by visit.

4.2.2.1 Analysis of the Primary Efficacy Endpoint

4.2.2.1.1 Primary Efficacy Endpoint Definition and Derivation

The primary efficacy objective is the VE of mRNA-1273 to prevent occurrence of COVID-19 starting 14 days after the second dose of IP (Section 2).

The determination of COVID-19 cases for the primary efficacy analysis is summarized in Table 4-1.

An AC blinded to treatment assignments reviewed potential cases and adjudicated COVID-19 and severe COVID-19 events, and the date of COVID-19 and severe COVID-19. Two sets of COVID-19 cases were provided:

- Based on the assessment of the AC
- Based on eligible COVID-19 symptoms (at least 2 systemic symptoms or 1 respiratory symptom) and positive RT-PCR

Table 4-1: Determination of COVID-19 Cases (Primary Efficacy Endpoint)

	COVID-19
Post-baseline PCR results at Illness Visits prompted by symptom(s)	Positive, **AND**
Systemic symptoms	At least **TWO** of the following **systemic symptoms**: fever (≥ 38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); **OR**
Respiratory symptoms	At least **ONE** of the following **respiratory** signs/symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia

Abbreviations: PCR = polymerase chain reaction.

The onset date of a documented COVID-19 case was the later date of 2 eligible systemic symptoms reported, or 1 eligible respiratory symptom reported and date of positive PCR test. The time to the first occurrence of COVID-19 was calculated as ([Date of documented COVID-19] – [Date of randomization] + 1).

In the primary analysis approach for the primary efficacy endpoint, cases were counted starting 14 days after the second injection. In the various sensitivity analyses planned to examine the onset of COVID-19, the censoring rules of cases are outlined in Table 4-2.

In Part A, there was a scheduled NP swab test at the Day 29 visit prior to the second injection of IP. In addition, serum samples for bAb against SARS-CoV-2 N-protein are being tested at Months 1, 2, 7, 13, and 25. At the IA and the primary analysis of efficacy, the RT-PCR results at Day 29 and bAb against SARS-CoV-2 N-protein at Month 1 were not considered in the determination of COVID-19 cases.

At the final blinded efficacy analysis, participants with early infection, as detected by positive RT-PCR at Day 29 or positive bAb against SARS-CoV-2 N-protein in blood samples at the scheduled visits, were censored (ie, the event did not occur for the analysis) at the time of early infection. If a participant had eligible symptom(s) within 14 days of positive RT-PCR at the scheduled Day 29 visit, the participant was considered to be a case for COVID-19.

Additional details on the primary endpoint definition and derivation are provided in the mRNA-1273-P301 SAP Section 6.3.1.1 (Appendix 16.1.9).

4.2.2.1.2 Primary Analysis Approach

The number and percentage of participants who had an event (ie, the first occurrence of COVID-19 starting 14 days after the second injection) and the participants who were censored were summarized.

The non-parametric Kaplan-Meier method was used to estimate the time to first occurrence of COVID-19 curve in each treatment group.

Vaccine efficacy was defined as the percent reduction in the hazard of the primary endpoint (mRNA-1273 vs. placebo), ie, 1 – HR. The null hypothesis was:

$$H_0^{efficacy}: VE \leq 0.3$$

Equivalently, the null hypothesis was:

$$H_0^{efficacy}: HR \geq 0.7$$

A stratified Cox proportional hazard model with Efron's method of tie handling and with treatment group as covariate was used to assess the magnitude of the treatment group difference (ie, HR) between mRNA-1273 and placebo. The same stratification factors used for randomization (Section 3.6.3) were applied to the stratified Cox model. The VE with corresponding alpha-adjusted CI, 95% CI, and 1-sided *p* value for testing the null hypothesis from the stratified Cox model was reported at a planned IA up to the analysis at which VE was demonstrated. After VE was demonstrated, VE and 95% CI were to be provided for subsequent analysis/updates of efficacy.

In this study, VE was demonstrated based on prespecified statistical criterion (Section 4.1.5) at the IA, at which, 1-sided *p* value for testing the null hypothesis of VE ≤ 0.3, 95% CI, and alpha-adjusted CI were provided from the stratified Cox model. At the primary analysis where the total number of COVID-19 cases > 151, total target number of cases, VE, 1-sided *p* value for testing the null hypothesis of VE ≤ 0.3, and 95% CI were provided. In subsequent analysis/updates of efficacy, VE and 95% CI were provided.

For the primary analysis, participants who had no documented COVID-19 were censored at the last study assessment date (Table 4-2). Participants who discontinued the study early or died due to causes unrelated to COVID-19 without documented COVID-19 were censored at the date of early discontinuation or death. Participants who experienced an early COVID-19 up to 14 days after the second injection of IP were censored at the time of documented COVID-19.

The primary analysis population for efficacy is the PP Set.

The number and percentage of participants who had an event (ie, the first occurrence of COVID-19 at least 14 days after the second injection) were reported.

Potential intercurrent events to the estimand are listed in Section 4.2.2.1.6. The primary estimand is provided in Section 4.2.2.1.6, with rationale for strategies to address intercurrent events summarized in mRNA-1273-P301 SAP Appendix F (Appendix 16.1.9).

4.2.2.1.3 Sensitivity Analyses of Primary Efficacy Endpoint

Sensitivity analyses were performed, with COVID-19 cases counted starting at various time points using the PP Set as follows:

- After the second injection of IP
- Fourteen days after the first injection of IP (also as primary analysis approach for the secondary efficacy objective: to evaluate the efficacy of mRNA-1273 to prevent COVID-19 after the first dose of IP).
- After randomization

Please note, the 2 injections were to be given 28 days apart; the PP Set included participants who received the second injection within [21, 42] days after the first injection. In the sensitivity analysis after randomization, cases that occurred up to the second dose, from the second dose to 14 days after the second dose, as well as the cases that occurred beyond 14 days after the second dose were included.

The censoring rules for analyses of the primary endpoint are summarized in Table 4-2.

Table 4-2: Censoring Rules for COVID-19

Situation	Primary Efficacy Approach (Cases ≥ 14 Days After Dose 2)	Sensitivity Analyses			
		Cases Starting After Dose 2	Cases ≥ 14 days After Dose 1	Cases Starting After Dose 1[a]	Cases Starting After Randomization
Early case from randomization up to first injection	Censored at date of case	Censored at date of case	Censored at date of case	Censored at date of case	Event
Early case from Dose 1 up to (<) 14 days after Dose 1	Censored at date of case	Censored at date of case	Censored at date of case	Event	Event
Early case from ≥ 14 days after Dose 1 up to (<) Dose 2	Censored at date of case	Censored at date of case	Event	Event	Event
Early case from Dose 2 up to (<)14 days after Dose 2	Censored at date of case	Event	Event	Event	Event
Case ≥ 14 days after Dose 2	Event	Event	Event	Event	Event
Early discontinuation or death without documentation of COVID-19	Censored at date of discontinuation/death				
Early infection as detected by: positive RT-PCR at scheduled visit (pre-Dose 2), or, positive bAb against SARS-CoV-2 nucleocapsid protein in blood samples at the scheduled visits	Censored at date of early infection				

Abbreviations: bAb = binding antibody; RT-PCR = reverse transcription polymerase chain reaction.

[a] Was to be performed if there were ≥ 10% of total cases with Dose 1 date > randomization date.

Analysis of the primary efficacy endpoint based on the mITT Set was also performed using the same statistical methods used for the primary analysis. The sensitivity analyses, with COVID-19 cases counted starting at various time points were also performed using the mITT Set.

4.2.2.1.4 Subgroup Analyses of the Primary Endpoint

To assess consistency of VE across various subgroups, subgroup analyses of the primary efficacy endpoint were performed based on the PP Set. The primary efficacy endpoint was analyzed by each of the subgroups using the same methods described for the primary analysis (ie, stratified Cox proportional hazard model with Efron's method of tie handling with a single treatment covariate), and the estimate of VE and its 95% CI were provided within each category of the following subgroups:

- Age groups: ≥ 18 and < 65 years, ≥ 65 years

- Age groups: ≥ 18 and < 65 years, ≥ 65 years and < 75 years, ≥ 75 years
- Stratification factor at randomization: ≥ 18 and < 65 years and not at risk, ≥ 18 and < 65 years at risk, ≥ 65 years
- Sex (female, male)
- Race
- Ethnicity
- Race and ethnicity: non-Hispanic White, communities of color
- Each risk factor for severe COVID-19 illness as listed in Section 3.6.3

If the number of participants in certain subgroups was too small, it may have been combined with the other subgroups for the subgroup analyses. Forest plots were provided for VE and its 95% CI for the subgroup analyses based on the PP Set. Subgroup analyses based on the mITT Set were performed.

Recently, new SARS-CoV-2 variants have emerged. COVID-19 cases were sequenced and a summary of cases genotypically distinct and genotypically similar to vaccine by treatment assignment was provided. For specific variants with sufficient number of variant cases during the blinded phase of the study, competing risk method was used to estimate the VE of mRNA-1273, specifically, Fine and Gray's (FG) sub-distribution hazard model was used. COVID-19 cases of specific variant were considered as cases, and COVID-19 cases of variant other than that of interest were considered as competing events in this analysis.

4.2.2.1.5 Supportive Analysis of the Primary Analysis Using Exact Method Based on Incidence Rate

For each treatment group, the incidence rate was calculated as the number of participants with an event (ie, first occurrence of COVID-19 at least 14 days after the second injection) divided by the number of participants at risk, adjusted by person-time. The person-time was calculated as the time from randomization to the date of the first event for participants with an event, and the time from randomization to the date of censoring for participants without an event (or who were censored). Person-time, incidence rate, and 95% CI for incidence rate were provided by treatment group.

As a supportive analysis, the VE was also estimated by 1 – the ratio of incidence rate (mRNA-1273 vs. placebo), ie, 1 – ratio of incidence rate (mRNA-1273 vs. placebo) adjusting for person-time, and the 95% CI of VE were computed using the exact method conditional upon the total number of cases adjusting for person-time.

4.2.2.1.6 Estimands and Intercurrent Events

The estimand of the primary analysis was VE measured using 1 – HR (mRNA-1273 vs. placebo) for prevention of first occurrence of COVID-19 from 14 days after second dose of IP in adults. A hypothetical strategy was used for early discontinuation (eg, withdrawal consent, deaths unrelated to COVID-19) or early COVID-19 in participants in the PP Set. Potential intercurrent events to the estimand are provided in Table 4-3. A description of the primary estimand with rationale for strategies to address intercurrent events is summarized in mRNA-1273-P301 SAP Appendix F (Appendix 16.1.9).

Table 4-3: Intercurrent Event Types

Label	Intercurrent Event Type	Comment
Intercurrent Event 1 (early discontinuation or death without confirmation of cases, ie, unrelated death)	Early discontinuation from study preventing from confirmation of COVID-19, ie, unrelated death or withdrawal consent prior to documented confirmed COVID-19	Participants in the PP Set who withdrew consent or died due to unrelated to COVID-19 without confirmation of being a case were included in primary efficacy analysis.
Intercurrent Event 2 (early COVID-19)	COVID-19 starting up to 14 days after the second dose of IP	Participants in the PP Set who experienced an early COVID-19 up to 14 days after the second dose of IP were included in primary efficacy analysis.

Abbreviations: COVID-19 = coronavirus disease 2019; IP = investigational product; PP = per protocol.

4.2.2.2 Analyses of the Secondary Efficacy Endpoints

A sequential/hierarchical testing procedure was used to control type 1 error rate over the primary efficacy endpoint and the secondary efficacy endpoints. Secondary efficacy endpoints were only tested if the primary efficacy endpoint achieved statistical significance. As required, multiplicity adjustments among the secondary efficacy endpoints were performed for secondary efficacy endpoints as described in Section 4.1.6.

The secondary efficacy endpoints and definitions of severe COVID-19, secondary cases of COVID-19, and death attributed to COVID-19 are included in Section 2.

Similar analysis methods, as detailed for the primary efficacy endpoint (Section 4.2.2.1), were applied to the following secondary efficacy endpoints based on the PP Set, unless otherwise specified:

- VE to prevent severe COVID-19; details on the determination of this endpoint are presented in mRNA-1273-P301 SAP Section 6.3.2.1.1 (Appendix 16.1.9).

- VE to prevent serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity; details on the determination of this endpoint are presented in mRNA-1273-P301 SAP Section 6.3.2.1.3 (Appendix 16.1.9).

  The analysis population for this endpoint, serologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity [COV-INF], was the PP Set (primary analysis population) and the mITT Set that included participants with negative SARS-CoV-2 status at baseline. Infection [COV-INF] was defined by any post-baseline positive RT-PCR results, and/or, seroconversion due to infection defined as positive bAb specific to SARS-CoV-2 NP as measured by Roche Elecsys at post-baseline scheduled visits for participants with negative SARS-CoV-2 status at baseline (PP and mITT Sets). Both RT-PCR tests from the scheduled NP swab tests at Day 29 as well as those prompted by symptom(s) were considered. A COVID-19 case or secondary definition of COVID-19 case was always a COV-INF case. The final analysis of efficacy for Part A included available participant level data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier. Separate analyses were also performed for SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity including new positive RT-PCR results at the PDV.

- VE to prevent COVID-19 using a secondary definition of symptoms; details on the determination of this endpoint are presented in mRNA-1273-P301 SAP Section 6.3.2.1.2 (Appendix 16.1.9).

- VE to prevent death caused by COVID-19

For each of the above secondary endpoints, the following analyses were performed:

- VE was estimated with 1 – HR (mRNA-1273 vs. placebo) using a Cox proportional hazard model based on the PP Set as described for the primary efficacy endpoint. Kaplan-Meier curves of time to event were presented for each treatment group. Cases were counted starting 14 days after the second injection of IP.

- Analysis was performed using the same model based on the mITT Set as described for the primary efficacy endpoint. Kaplan-Meier curves of time to event were presented for each treatment group.

- Sensitivity analyses were performed, with cases counted starting immediately after the second injection of IP (onset date ≥ date of second injection, considering positive RT-PCR at Day 29), starting 14 days (≥ 14 days) after the first injection of IP, and immediately after randomization, respectively.

- VE and 95% CI based on the incidence were estimated with 1 – ratio of incidence rates using the exact method conditional upon the total number of cases.

For the secondary efficacy objective: VE to prevent asymptomatic SARS-CoV-2 infection

- The analysis populations for asymptomatic infection were the PP Set (primary analysis population) and mITT Set. Asymptomatic infection was COV-INF (detected by positive RT-PCR or seroconversion [bAb specific to SARS-CoV-2 NP as measured by Roche Elecsys at scheduled visits]) with absence of symptoms.

  As diseased cases (COVID-19 or secondary definition of COVID-19) were competing events for asymptomatic SARS-CoV-2 infections, competing risk method (FG subdistribution hazard model) was used to estimate the VE of mRNA-1273. Competing risk method was also used to estimate the cumulative incidence function, and the cumulative incidence of asymptomatic SARS-CoV-2 infections were plotted.

  In the primary approach with cases of asymptomatic SARS-CoV-2 infection counted starting 14 days after the second injection, only seroconversion at Day 57 or later was to be considered. The final analysis of efficacy for Part A included available participant level data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier. Separate analyses were also performed for asymptomatic SARS-CoV-2 infection including new positive RT-PCR results at the PDV. Details on the determination of asymptomatic SARS-CoV-2 infection are provided in mRNA-1273-P301 SAP Section 6.3.2.1.4 (Appendix 16.1.9).

  As serum samples were taken at scheduled visits (eg, Day 29 [Month 1], Day 57 [Month 2], PDV), sensitivity analyses with cases counted starting after second injection, 14 days after the first injection, after the first injection, and after randomization were the same. Only 1 set of sensitivity analysis with cases counted starting from randomization was provided. In this sensitivity analysis, asymptomatic cases detected by positive RT-PCR result at scheduled Day 29 (before the second injection), or seroconversion at time points with scheduled visits were considered. Sensitivity analysis using the mITT Set with cases counted starting from 14 days after the second injection, and from randomization were also performed.

For the secondary efficacy objective: VE to prevent COVID-19 after the first injection of IP

- This endpoint was analyzed as a sensitivity analysis of the primary efficacy endpoint with cases counted starting 14 days (≥ 14 days) after the first injection of IP as described in Section 4.2.2.1.

For the secondary efficacy objective: VE to prevent COVID-19 disease regardless of prior SARS-CoV-2 infection

- VE to prevent COVID-19 disease regardless of prior SARS-CoV-2 infection was analyzed using the FAS. The same methods described for the primary efficacy endpoint (Section 4.2.2.1) were applied with cases counted starting 14 days after the second injection of IP.

  Sensitivity analyses with cases counted starting immediately after the second injection, 14 days after the first injection, and after randomization were also performed. In sensitivity analysis with cases counted starting after the second injection, participants who received only the first injection and were cases, were censored at the time of COVID-19.

  The VE was also estimated with 1 – the ratio of incidence rates with the 95% CI using the exact method conditional upon the total number of cases adjusting for person-time.

  In addition, an exploratory analysis with the same Cox model was performed in the subgroup of the FAS whose baseline SARS-CoV-2 status was positive with cases counted starting 14 days after the second dose to assess the VE in those with positive baseline SARS-CoV-2 status, at baseline, if sample size permitted. Such analysis in the subgroup of the FAS whose baseline SARS-CoV-2 status was negative with cases counted starting 14 days after the second dose was the same as the sensitivity analysis of COVID-19 starting 14 days after the second dose in the mITT Set.

4.2.2.3 Exploratory Efficacy Endpoint Analyses

Details of the analyses of exploratory objectives and endpoints included in this Part A CSR are described in the following sections.

4.2.2.3.1 Vaccine Efficacy Based on Duration and Presence/Severity of COVID-19 Symptoms

Participants reported symptoms including fever (temperature ≥ 38ºC), chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, sore throat, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, and diarrhea. The severity of these symptoms was graded according to the severity scoring system presented in mRNA-1273-P301 SAP Table 9 (Appendix 16.1.9). A score endpoint aggregating duration and presence/severity of COVID-19 symptoms were calculated as the sum of daily severity scores of all recorded symptoms across all days with symptoms. The VE of mRNA-1273 based on mean score of each treatment group was calculated as follows:

VE = [1 – Mean score of mRNA-1273 group / Mean score of placebo group] × 100%

A proportional means model including treatment group as fixed effect and stratified with stratification factor at randomization was used to assess the VE (mRNA-1273 vs. placebo) on the score aggregating duration and presence/severity of COVID-19 symptoms based on the PP Set. The score was summarized and categorized into quartiles (across the 2 groups) using 1, 2, 3, 4. The indication of the quartiles was used as the dependent variable in the proportional mean model.

4.2.2.3.2 Vaccine Efficacy Against Burden of Disease

Exploratory analysis of burden of disease (BOD) due to COVID-19 was performed. A BOD score was defined based on the post SARS-CoV-2 infection follow-up to reflect the worst severity of symptoms (0 [without COVID-19] to 3 [death]) as shown in mRNA-1273-P301 SAP Table 7 (Appendix 16.1.9).

A summary of BOD score and the number and percentage of participants with each level of BOD score was provided by treatment group using the PP Set.

To assess impact of baseline risk of severe disease on the vaccine effect regarding disease severity, summary of BOD were provided by randomization strata (ie, ≥ 65 years; < 65 years at risk; and < 65 years not at risk).

To assess the disease burden in participants with COVID-19, the summary of BOD was provided in participants with COVID-19, ie, participants with BOD score of zero were excluded from the analysis.

While transparent, the proportions in the summary table will change with increased follow-up time as more participants inevitably acquire disease. This makes comparisons across different periods of follow-up difficult. To augment this analysis, a proportional means model was used to assess the treatment effect on BOD between mRNA-1273 and placebo in terms of ratio of mean severity score. The proportional means model allowed for direct comparisons across different periods of follow-up, unaffected by differential follow-up. A proportional means model, including treatment group as fixed effect and stratified with stratification factor at randomization, was used to assess the vaccine effect on BOD. The VE for the BOD score was estimated as 1 – the ratio of means as estimated by the proportional means model and reported with 95% CIs.

4.2.2.3.3 Vaccine Efficacy Against Burden of Infection

To fully understand the impact of vaccination on disease severity, asymptomatic infections were also evaluated. Similarly, a burden of infection (BOI) score was calculated (0 [no infection] to

3 [death]) as shown in mRNA-1273-P301 SAP Table 8 (Appendix 16.1.9) and used to understand the impact.

Since asymptomatic infection was identified by seroconversion only at scheduled visits at which samples for RT-PCR test and/or serum samples were planned to be collected (eg, Months 1, 2, 7, 13, and 25), summary of BOI for relevant periods (eg, Baseline through Month 1, Month 1 through Month 2, Month 2 through Month 7, Month 7 through Month 13, and Month 13 through Month 25) was planned. With mRNA-1273-P301 Protocol Amendment 6 (Section 3.2.1), at the unblinding/PDV/OL-D1 visit, an NP swab for RT-PCR tests and serum samples was collected. The relevant periods were updated to Baseline through Month 1, Month 1 through Month 2, and Month 2 through Month 7/PDV, whichever was earlier.

A proportional means model, including treatment group as fixed effect and stratified with stratification factor at randomization, was used to assess the vaccine effect on BOI. The VE for BOI was estimated as 1 – the ratio of mean BOI scores and reported with 95% CIs.

4.2.2.3.4 Vaccine Efficacy on Viral Load

For the cohort of adjudicated COVID-19 cases, the Day 1 illness NP swab and the Days 3, 5, 6, 9, 14, 21, and 28 of illness saliva specimens were matched to assess the qualitative and quantitative result for each. Conversion from cycle time (CT) to viral copies for the quantitative RT-PCR were Log10ViralCopies=CT -40.9578)/-3.3385 for swabs (Day 1) and Log10ViralCopies = CT -41.0349)/-3.3346) for saliva (Days 3, 5, 7, 9, 14, 21, and 28). If the qualitative result was negative, the log10viral copies was assumed to be 0. A mixed-effect model repeated measures (MMRM) analysis was performed comparing absolute and change from baseline log10 viral load between vaccinated and placebo participants from the NP swab Day 1 of illness through saliva sample Days 3, 5, 7, 9, 14, 21, and 28 of illness. Only participants with a quantitative result in the Day 1 illness NP swab were included in the MMRM modeling. Any MMRM result estimate under 0 copies, was truncated at 0. There was no imputation for missing data.

4.2.2.3.5 Vaccine Efficacy to Prevent All-Cause Mortality

Vaccine efficacy to prevent all-cause mortality was analyzed using the Cox proportional hazard model (Section 4.2.2.1) based on the PP Set, mITT Set, and FAS. Death, regardless of cause, from randomization was included. Time to death was calculated as date of death – date of randomization + 1. Participants with no documented death were censored at the earliest date (last date of study participation, early discontinuation, or lost to follow-up).

4.2.3 Safety Analyses

Safety and reactogenicity were assessed by clinical review of all relevant parameters including solicited ARs (local and systemic), unsolicited AEs, SAEs, MAAEs, AEs leading to withdrawal from study vaccine and/or study participation, vital signs, and physical examination findings.

All safety analyses were based on the Safety Set, except summaries of solicited ARs, which were based on the Solicited Safety Set. All safety analyses were provided by treatment group, unless otherwise specified.

4.2.3.1 Solicited Adverse Reactions

Solicited ARs, including local and systemic ARs collected in the eDiary, are described in Section 3.7.4.1. Local and systemic solicited ARs were categorized based on the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials (DHHS 2007) as described in mRNA-1273-P301 Protocol Section 8.3.4 (Appendix 16.1.1).

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

Analyses of solicited ARs were provided by treatment group for each injection (first or second) based on the associated subset of the Solicited Safety Set, ie, First (Second) Injection Solicited Safety Set and for any injection based on the Solicited Safety Set, unless otherwise specified.

The number and percentage of participants who reported each individual solicited local AR and solicited systemic AR during the 7-day follow-up period (or until resolution for solicited ARs that continued beyond 7 days) after each injection were provided by severity grade. The number and percentage of participants who reported each individual solicited AR were also summarized by severity grade, days of reporting, and injection.

The number and percentage of participants experiencing fever (a temperature greater than or equal to 38.0°C/100.4°F by the oral, axillary, or tympanic route) by severity grade and the number and percentage of participants experiencing a fever of Grade 3 or higher temperature (a temperature greater than or equal to 39.0°C/102.1°F by the oral, axillary, or tympanic route) were summarized.

A 2-sided 95% exact CI using the Clopper-Pearson method was provided for the percentage of participants who reported any solicited local AR, solicited systemic AR, or any solicited AR.

The onset of individual solicited AR was defined as the time point after each injection at which the respective solicited AR first occurred. The number and percentage of participants with onset of individual solicited AR were summarized by study day relative to the corresponding injection (Day 1 through Day 7).

The number of days was calculated as the days that the solicited AR was reported within the 7 days after injection, including the day of injection, regardless of whether it was intermittent or continued. If the solicited AR continued beyond 7 days, the consecutive days a solicited AR was reported after 7 days was included (eg, an event that lasted 5 days in the first 7 days after injection and 3 consecutive days beyond 7 days after injection, the duration was reported as 8 [5 + 3] days).

All solicited ARs that continued beyond 7 days post injection were summarized.

The above analyses of solicited ARs were summarized separately for the following subgroups:

- Age group (< 65 and ≥ 65 years)
- Sex (male, female)
- Baseline SARS-CoV-2 status
- Race and ethnicity

4.2.3.2 Unsolicited TEAEs

Definitions and details regarding AEs are provided in Section 3.7.4.2. Unsolicited AEs were collected for up to 28 days after each IP dose; SAEs, MAAEs, and AEs leading to withdrawal were collected throughout the study.

Unsolicited AEs were coded by SOC and PT according to the MedDRA version 23.0.

All summary tables for unsolicited AEs (except for the overall summary of AEs) were presented by SOC and PT or by PT only for TEAEs with counts of participants included. All safety analyses were summarized by treatment group. Percentages were based upon the number of participants in the Safety Set within each treatment group.

Unsolicited TEAE summaries were provided for TEAEs up to 28 days after any injection and during Part A (Section 4.1.1).

For PTs with at least 7 participants in any treatment group who reported the event, rate ratio, and its 95% CI were provided as a helpful descriptive measure used in review, not a formal method for assessing the statistical significance of the between-group differences in adverse experiences. The rate ratio was calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo. The 95% CI for rate ratio was provided using the Miettinen and Nurminen method (1985). The threshold of at least 7 participants was chosen because the 95% CI for rate ratio always included one when groups of equal size each had < 7 participants reporting the event, and thus would have added little for review purpose.

The overall summaries of unsolicited TEAEs (number and percentage) by treatment group included the following: any unsolicited TEAEs, any serious TEAEs, any unsolicited TEAEs that were MAAEs, any unsolicited TEAEs leading to discontinuation from participation in the study or study vaccine, any unsolicited severe TEAEs (severity of AEs was assessed as mild, moderate, or severe), and any unsolicited fatal TEAEs. The overviews also included a summary of participants with treatment-related TEAEs in each category.

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

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

All unsolicited TEAEs were summarized by PT, sorting by frequency of the mRNA-1273 group.

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

The overview of TEAEs and the TEAE summaries presented by SOC and PT were also summarized for the following subgroups: age (< 65 and ≥ 65 years), sex (male, female), and baseline SARS-CoV-2 status. These summaries may have been provided for subgroups of select baseline characteristics.

Separate listings of individual participant AE data were provided for the following: unsolicited TEAEs leading to discontinuation from study vaccine, unsolicited TEAEs leading to discontinuation from participation in the study, SAEs, treatment-related SAEs, and unsolicited treatment-related MAAEs. A listing of deaths including cause of death and a listing of TEAEs in participants who died were provided.

4.2.3.3 Vital Sign Measurements

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

Observed values and changes from baseline for all vital sign measurements were summarized at each visit by baseline SARS-CoV-2 serostatus and treatment group. Shift from baseline in the toxicity grades at each visit were summarized by treatment group.

4.2.3.4 Pregnancies

Pregnancies and outcome (if available) were summarized by treatment group and a listing of pregnancies including outcome were provided.

4.2.3.5 Vaccine-Associated Enhanced Respiratory Disease

The DSMB continuously monitored for potential vaccine harm in this study. Potential vaccine harm was assessed based on imbalance between mRNA-1273 versus placebo for both COVID-19 and severe COVID-19 case counts using the Safety Set. For harm monitoring, participants were analyzed according to the IP that they actually received regardless of the group to which they were randomized. For harm monitoring, cases were counted starting after the first dose of study vaccination.

Cases of COVID-19 for the harm monitoring were defined as for the primary efficacy endpoint (eligible symptoms with positive RT-PCR result) but were based on the Safety Set rather than the PP Set. For harm monitoring, cases of COVID-19 were derived based on RT-PCR results and symptoms collected in the clinical database to facilitate continuous monitoring.

Details of harm monitoring are provided in the analysis plan for the DSMB. The monitoring for potential harm based on COVID-19 continued throughout the blinded phase of the study. The DSMB recommended discontinuation of the harm monitoring reports to the DSMB after the DSMB review meeting on 29 Jan 2021.

4.2.4 Immunogenicity Analyses

The secondary immunogenicity endpoints are provided in Section 2. The immunogenicity assessments performed for serum bAb level against SARS-CoV-2 spike protein and bAb level against SARS-CoV-2 N-protein, and serum nAb titer against SARS-CoV-2 are summarized in Section 3.7.3.

The PPRSI was used as the analysis population to characterize immunogenicity of mRNA-1273 (Section 4.1.3).

The following were the immunogenicity assessments (assays) used in this study:

- Serum bAb level against SARS-CoV-2 as measured by ELISA specific to the SARS-CoV-2 S protein (vaccine antigen), including tests for VAC65 spike IgG antibody.
- The MesoScale Discovery-electrochemiluminescence (MSD-ECL) multiplex assay measures bAb to antigens corresponding to S protein, RBD, and N-protein, which is not contained in mRNA-1273. Of note, data on RBD and N-protein by MSD were not available at the time of DBL and thus were not included in this CSR.
- Pseudovirus nAb assay for measuring nAb against SARS-CoV-2 S-pseudotyped viruses pseudovirus nAb ID_{50} and ID_{80} titers (PsVNT50 and PsVNT80).
- WT live virus nAb assay measuring antibody-mediated neutralization of WT live SARS-CoV-2: WT live virus MN50 titers. Of note, data on WT live virus nAb assay were not available at the time of DBL and thus were not included in this CSR.

4.2.4.1 Summary of Antibody-Mediated Immunogenicity Endpoints

Data from quantitative immunogenicity assays outlined in Section 4.2.4 were summarized for each treatment group using positive response rates and geometric means (GMs) with 95% CI at each time point when an assessment was performed. Data from qualitative (ie, yielding a positive or negative result) assays were summarized by tabulating the frequency of positive responses for each assay by treatment group and by baseline SARS-CoV-2 status, if applicable, at each time point that an assessment was performed.

At the time the final blinded efficacy analysis, immunogenicity analyses to characterize immunogenicity of mRNA-1273 were performed. At the time of the immunogenicity analyses, data for bAb to S (MSD, PPD-VAC65) and psVNA ID_{50} and ID_{80} titers were available. The assay by MSD to measure bAb against RBD and N-protein had not yet been validated at the time of the immunogenicity analysis; therefore, these data were not summarized/analyzed. Immunogenicity data at the prespecified time points (Baseline [Day 1], Day 29 [Month 1], and Day 57 [Month 2]) were included.

- The GMT or value with corresponding 95% CI was provided at each time point. The 95% CIs were calculated based on the *t*-distribution of the log-transformed values then back transformed to the original scale for presentation. The following descriptive statistics were also provided at each time point: the number of participants (n), median, minimum, and maximum.

- The geometric mean fold rise (GMFR) with corresponding 95% CI was provided at each post-baseline time point over pre-injection baseline at Day 1. The 95% CIs were calculated based on the *t*-distribution of the log-transformed values then back transformed to the original scale for presentation. The following descriptive statistics were also provided at each time point: the number of participants (n), median, minimum, and maximum.
- Reverse cumulative distribution function curve (RCDF) at each time point. The number and percentage of participants with fold-rise ≥ 2, fold-rise ≥ 3, and fold-rise ≥ 4 from baseline at each post-injection time point were tabulated with 2-sided 95% Clopper-Pearson CIs.
- The Ab assay of interest (bAb to spike (MSD, PPD-VAC65) and PsVNA ID_{50} and ID_{80}) are listed in the table below. For each of them, seroresponse rate was defined as the proportion of participants achieving seroresponse, defined below for each assay/test of interest. Please note that these assay-specific definition of seroresponse was an update of 'seroconversion due to vaccination' used in the protocol and relevant SAP incorporating assay-specific fold-rise criteria based on assay-specific performance characteristics. These assay-specific definitions of seroresponse were documented in a memo (Update on Analysis for Immunogenicity; Appendix 16.1.9) that became available prior to DBL.

Assay Name	Category	Test Name/ Description	Definition of Seroresponse
Pseudovirus (PsVNA)	nAb	PsVNT50 (ID_{50})	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 3.3-fold rise
		PsVNT80 (ID_{80})	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 2.3-fold rise
Anti-Spike ELISA	bAb	anti-Spike VAC65 Spike IgG Antibody	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 4.6-fold rise
MSD multiplex	bAb	anti-Spike	baseline <LLOQ: ≥LLOQ baseline ≥LLOQ: 1.9-fold rise

Abbreviations: bAb = binding antibody; ELISA = enzyme-linked immunosorbent assay; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; MSD = MesoScale Discovery; nAb = neutralizing antibodies; PsVNA = pseudotyped virus neutralization assay; PsVNT50 = 50% pseudotyped lentivirus reporter test; PsVNT80 = 80% pseudotyped lentivirus reporter test.

- Number and proportion of participants achieving seroresponse were provided with 2-sided 95% Clopper-Pearson CIs at each post-baseline time point.

The formula used to calculate GM titer (GMT) and GM level is provided in mRNA-1273-P301 SAP Section 6.7.4 (Appendix 16.1.9).

4.2.4.2 Analysis of Antibody-Mediated Immunogenicity Endpoints

To assess the magnitudes of the differences between the 2 treatment groups (mRNA-1273 vs. placebo) in SARS-CoV-2-specific nAb and S protein-specific bAb, a MMRM using SAS PROC MIXED was used.

For each of the SARS-CoV-2-specific nAb and S protein-specific bAb, the analysis was performed separately for participants whose SARS-CoV-2 status were negative or positive at baseline, respectively. The model included all available log-transformed antibody titers at each post-baseline visit as the dependent variable, treatment groups, visit (as a class variable), and treatment-by-visit interaction visit as fixed effects, with adjustment for stratification factor used for randomization, baseline log-transformed antibody titers if applicable, and participant as a random effect. The model also adjusted for minority group used to sample for the random subcohort. An unstructured covariance structure was used to model the within-participant errors. A Kenward-Roger approximation was used for the denominator degrees of freedom. If there was a convergence issue due to the unstructured covariance matrix, a compound symmetry covariance structure was used to model the within-participant errors. No imputation of missing data was done.

The geometric least squares mean (GLSM) and corresponding 2-sided 95% CI for the antibody titers for each treatment group were provided by visit. The GLSM and corresponding 95% CI results in log-transformed scale estimated from the model were back-transformed to obtain these estimates in the original scale. Geometric mean ratio (GMR), estimated by the ratio of GLSM and the corresponding 2-sided 95% CI, was provided to assess the treatment difference between the mRNA-1273 versus placebo groups at each visit. With each treatment group, within-group comparison of time points may also have been estimated using the same model.

In addition, an analysis of covariance (ANCOVA) model with the treatment group as explanatory variables, adjusting for the stratification factor at randomization, baseline value if applicable, was used to assess the treatment effect at specific time points (scheduled visits) such as Day 57. The GLSM with 95% CI for each treatment group, GMR with 95% CI for treatment difference was estimated from the ANCOVA model. The model also adjusted for minority group used to sample for the random subcohort.

4.2.4.3 Summary of Immunogenicity in COVID-19 Cases on mRNA-1273 With Negative SARS-CoV-2 Status at Baseline

To characterize immunogenicity of mRNA-1273, immunogenicity data (Section 4.2.4) were analyzed using the PPRSI.

It was of interest to examine the immune response in participants on mRNA-1273 with baseline SARS-CoV-2 negative status who were COVID-19 or SARS-CoV-2 infection cases. Immunogenicity data was provided in a subset of baseline SARS-CoV-2 negative participants on mRNA-1273 who were adjudicated COVID-19 cases.

4.3 Changes to the Planned Analyses

The original SAP version 1.0, was dated 08 Sep 2020. The IA and the primary analysis were performed based on SAP version 1.0. The SAP was amended after EUA, version 2.0, dated 08 Mar 2021, and the methods are described herein.

The following were clarifications or additions to the planned analyses from the SAP Version 2.0 (dated 08 Mar 2021):

- Participant discontinuation from the study by month (inclusive of Part A and Part B) was provided.
- Details of the viral load and genotyping analysis methods and results were provided in the Genotyping Report (Appendix 16.5).
- Immunogenicity analyses were performed based on the SAP version 2.0 and a memo entitled “Update on Analysis of Immunogenicity” that provided further clarification and updates on the derivation and analysis (Appendix 16.1.9).
- Available immunogenicity data was provided in mRNA-1273 participants who were adjudicated COVID-19 cases 14 days after the second injection (PP Set).
- Additional safety analyses for AEs of clinical interest were performed by using Standardized MedDRA Queries (SMQs) or Custom MedDRA Queries (CMQs).
- Analyses were performed for secondary efficacy endpoints of SARS-CoV-2 infection regardless of symptomology and severity (all infection) and asymptomatic SARS-CoV-2 infection including results at the PDV.

5 STUDY POPULATIONS

The results in this section are based on the final analysis of Part A based on a database lock of 04 May 2021, unless otherwise specified.

5.1 Disposition of Participants

A total of 30,415 participants were randomly assigned to study treatment: 15,206 participants in the placebo group and 15,209 in the mRNA-1273 group (Figure 5-1 and Table 5-1). A total of 22,882 participants were ≥ 18 and < 65 years and 7,533 were ≥ 65 years.

Overall, treatment compliance was high, with 99.8% of participants receiving the first injection and 96.5% receiving the second injection (Table 5-1).

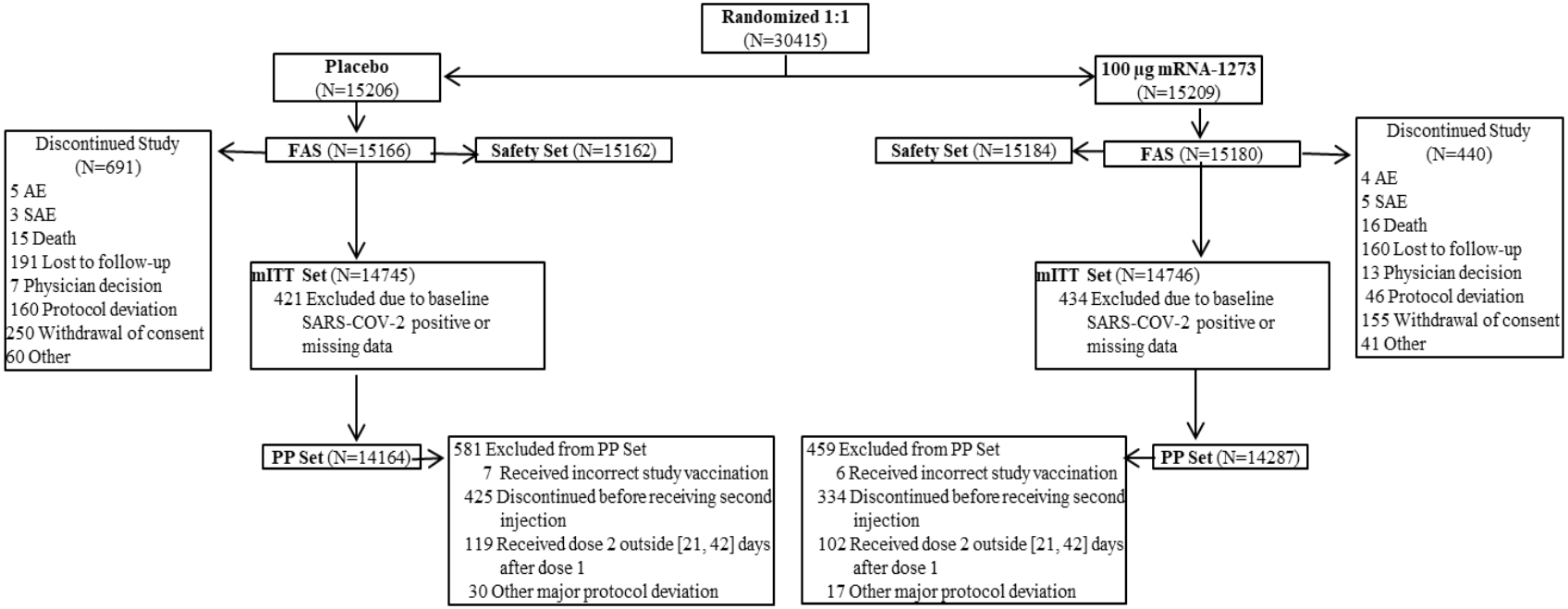
A total of 531 participants (3.5%) who were randomly assigned to receive placebo and 453 participants (3.0%) who were randomly assigned to receive mRNA-1273 discontinued the study vaccine (Table 5-1). The most common reasons for discontinuation of study vaccine were confirmed SARS-CoV-2 infection (ie, diagnosed COVID-19 by detection of SARS-CoV-2 in Day 1 NP swab or COVID-19 diagnosed prior to Day 29), other, and withdrawal of consent by participant.

A total of 691 participants (4.5%) in the placebo group and 440 participants (2.9%) in the mRNA-1273 group discontinued Part A of the study (Table 5-1). The most common reasons for discontinuation from Part A of the study were withdrawal of consent by participant, lost to follow-up, and protocol deviation. A total of 2099 participants (13.8%) in the placebo group and 730 participants (4.8%) in the mRNA-1273 group discontinued the study, Part A and Part B inclusive (Table 14.1.1.1.1.2). Figure 5-2 displays the number of discontinuations by month and shows that the imbalance of discontinuations between the placebo and mRNA-1273 groups coincided with the EUA of the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine.

A total of 29,491 participants (14,745 participants in the placebo group; 14,746 participants in the mRNA-1273 group) had a negative SARS-CoV-2 status at baseline, determined by negative RT-PCR test and negative serology test (as measured by Roche Elecsys anti-SARS-CoV-2 assay [Section 4.1.1]) (Table 14.1.1.1.1.1). All of these participants (100%) received the first injection and 28,732 participants (97.4%) received the second injection (14,320 participants [97.1%] in the placebo group; 14,421 participants [97.7%] in the mRNA-1273 group). Among participants with a negative SARS-CoV-2 status at baseline, 425 participants (2.9%) in the placebo group and 334 participants (2.3%) in the mRNA-1273 group discontinued study vaccine. The most common reason for discontinuation of study vaccine in these participants with negative SARS-CoV-2 status at baseline was withdrawal of consent by participant, reported for

102 participants (0.7%) in the placebo group and 73 participants (0.5%) in the mRNA-1273 group.

Figure 5-1: Study Disposition in the Overall Randomized Set in Part A



Abbreviations: AE = adverse event; FAS = full analysis set; mITT = modified intent-to-treat; PP = per-protocol; SAE = serious adverse event.
Source: Table 14.1.1.1.1.2.2, Table 14.1.1.1.2.2, Table 14.1.2.2, and Table 14.1.2.4.

Table 5-1: Participant Disposition by Age Group in Part A (Randomization Set)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Number of subjects									
Received first injection	11413 (99.7)	11413 (99.8)	22826 (99.8)	3753 (99.7)	3767(>99.9)	7520 (99.8)	15166 (99.7)	15180 (99.8)	30346 (99.8)
Received second injection	10966 (95.8)	11025 (96.4)	21991 (96.1)	3669 (97.5)	3702 (98.2)	7371 (97.8)	14635 (96.2)	14727 (96.8)	29362 (96.5)
Discontinued study vaccine	447 (3.9)	388 (3.4)	835 (3.6)	84 (2.2)	65 (1.7)	149 (2.0)	531 (3.5)	453 (3.0)	984 (3.2)
Reason for discontinuation of study vaccine									
Adverse event	31 (0.3)	35 (0.3)	66 (0.3)	13 (0.3)	12 (0.3)	25 (0.3)	44 (0.3)	47 (0.3)	91 (0.3)
Serious adverse event	8 (<0.1)	10 (<0.1)	18 (<0.1)	10 (0.3)	2 (<0.1)	12 (0.2)	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to follow-up	72 (0.6)	72 (0.6)	144 (0.6)	1 (<0.1)	4 (0.1)	5 (<0.1)	73 (0.5)	76 (0.5)	149 (0.5)
Physician decision	14 (0.1)	18 (0.2)	32 (0.1)	4 (0.1)	3 (<0.1)	7 (<0.1)	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	4 (<0.1)	3 (<0.1)	7 (<0.1)
Protocol deviation	30 (0.3)	26 (0.2)	56 (0.2)	7 (0.2)	11 (0.3)	18 (0.2)	37 (0.2)	37 (0.2)	74 (0.2)
Study terminated by sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of consent by participant	86 (0.8)	63 (0.6)	149 (0.7)	22 (0.6)	15 (0.4)	37 (0.5)	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	107 (0.9)	74 (0.6)	181 (0.8)	12 (0.3)	7 (0.2)	19 (0.3)	119 (0.8)	81 (0.5)	200 (0.7)
Other	91 (0.8)	84 (0.7)	175 (0.8)	13 (0.3)	10 (0.3)	23 (0.3)	104 (0.7)	94 (0.6)	198 (0.7)

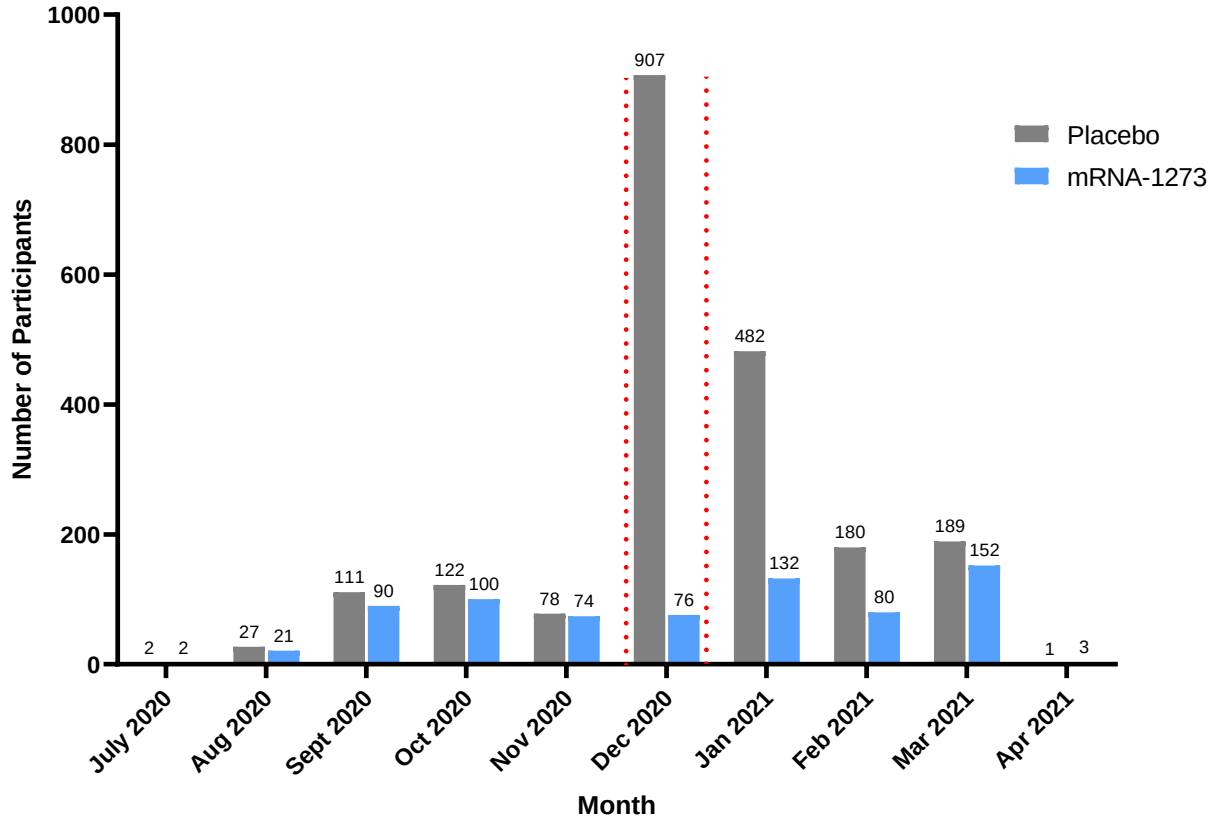
	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	**mRNA-1273 (N=11439) n (%)**	**Total (N=22882) n (%)**	**Placebo (N=3763) n (%)**	**mRNA-1273 (N=3770) n (%)**	**Total (N=7533) n (%)**	**Placebo (N=15206) n (%)**	**mRNA-1273 (N=15209) n (%)**	**Total (N=30415) n (%)**
Completed study [a]	0	0	0	0	0	0	0	0	0
Discontinued from study	591 (5.2)	392 (3.4)	983 (4.3)	100 (2.7)	48 (1.3)	148 (2.0)	691 (4.5)	440 (2.9)	1131 (3.7)
Reason for discontinuation of study									
Adverse event	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious adverse event	1 (<0.1)	4 (<0.1)	5 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	5 (<0.1)	8 (<0.1)
Death	10 (<0.1)	8 (<0.1)	18 (<0.1)	5 (0.1)	8 (0.2)	13 (0.2)	15 (<0.1)	16 (0.1)	31 (0.1)
Lost to follow-up	183 (1.6)	154 (1.3)	337 (1.5)	8 (0.2)	6 (0.2)	14 (0.2)	191 (1.3)	160 (1.1)	351 (1.2)
Physician decision	4 (<0.1)	12 (0.1)	16 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	7 (<0.1)	13 (<0.1)	20 (<0.1)
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol deviation	133 (1.2)	38 (0.3)	171 (0.7)	27 (0.7)	8 (0.2)	35 (0.5)	160 (1.1)	46 (0.3)	206 (0.7)
Study terminated by sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of consent by participant	207 (1.8)	136 (1.2)	343 (1.5)	43 (1.1)	19 (0.5)	62 (0.8)	250 (1.6)	155 (1.0)	405 (1.3)
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	49 (0.4)	37 (0.3)	86 (0.4)	11 (0.3)	4 (0.1)	15 (0.2)	60 (0.4)	41 (0.3)	101 (0.3)

Percentages are based on the number of randomized subjects.

[a] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product and have no participant decision visit or unblinding date.

Source: Table 14.1.1.1.1.2.2.

Figure 5-2 Discontinuation from Study by Month (Randomization Set)



Source: Figure 14.1.1.1.

5.2 Study Analysis Sets

Overall, the percentage of participants in each analysis set was balanced between the placebo and mRNA-1273 groups, except for the PPRST where larger number of mRNA-1273 recipients were pre-specified to be selected to characterize immunogenicity of mRNA-1273 (Table 5-2).

The Safety Set included all randomized participants who received at least 1 dose of IP (refer to Section 4.1.3 for definitions of each analysis set). The Safety Set was used for all analyses of safety except for the solicited ARs. The Solicited Safety Set included all randomized participants who received at least 1 dose of IP and contributed any solicited AR data; ie, had at least 1 post-baseline solicited safety (eDiary) assessment.

The mITT Set included all participants in the FAS who had no immunologic or virologic evidence of prior COVID-19, ie with negative SARS-CoV-2 status at baseline. A total of 855 participants (421 in the placebo group; 434 in the mRNA-1273 group) had a positive or missing baseline SARS-CoV-2 status and were excluded from the mITT Set (Table 14.1.2.4).

Table 5-3 provides a summary of positive, negative, and missing of RT-PCR test and Elecsys results at baseline.

The primary efficacy analysis was based on the PP Set, which included all participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations impacting critical or key study data. A total of 1040 participants (3.4%) including 581 participants (3.8%) in the placebo group and 459 participants (3.0%) in the mRNA-1273 group were excluded from the PP Set (Table 14.1.2.4). The most common reason for exclusion from the PP Set was participant discontinued study or study vaccination before receiving second injection (425 participants [2.8%] in the placebo group and 334 participants [2.2%] in the mRNA-1273 group). Other reasons for exclusion included participant received second injection out of window (-7/+14 days) for the PP Set (221 participants [0.7%]), received incorrect study vaccination (13 participants [< 0.1%]), and other major protocol deviation impacting critical data (47 participants [0.2%]).

A total of 29,491 participants (14,745 in the placebo group; 14,746 in the mRNA-1273 group) had a negative SARS-CoV-2 status at baseline, determined by negative RT-PCR test and negative serology test (as measured by Roche Elecsys anti-SARS-CoV-2 assay) (Table 14.1.2.1). A total of 684 participants (337 in the placebo group; 347 in the mRNA-1273 group) had a positive SARS-CoV-2 status at baseline.

The PPRST is described in Section 6.5.

Table 5-2: Number of Participants in Each Analysis Set by Age Group (Randomization Set)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	**mRNA-1273**	**Total**	**Placebo**	**mRNA-1273**	**Total**	**Placebo**	**mRNA-1273**	**Total**
Randomization set [a]	11443	11439	22882	3763	3770	7533	15206	15209	30415
Full analysis set, n (%) [a]	11413 (99.7)	11413 (99.8)	22826 (99.8)	3753 (99.7)	3767 (>99.9)	7520 (99.8)	15166 (99.7)	15180 (99.8)	30346 (99.8)
Modified Intent-to-Treat (mITT) set, n (%) [a]	11046 (96.5)	11037 (96.5)	22083 (96.5)	3699 (98.3)	3709 (98.4)	7408 (98.3)	14745 (97.0)	14746 (97.0)	29491 (97.0)
Per-protocol (PP) set, n (%) [a]	10569 (92.4)	10661 (93.2)	21230 (92.8)	3595 (95.5)	3626 (96.2)	7221 (95.9)	14164 (93.1)	14287 (93.9)	28451 (93.5)
Per-protocol random subcohort for immunogenicity, n (%) [a]	204 (1.8)	807 (7.1)	1011 (4.4)	68 (1.8)	378 (10.0)	446 (5.9)	272 (1.8)	1185 (7.8)	1457 (4.8)
Safety set [b]	11411	11415	22826	3751	3769	7520	15162	15184	30346
Solicited safety set, n (%) [b]	11408 (>99.9)	11413 (>99.9)	22821 (>99.9)	3751 (100)	3766 (>99.9)	7517 (>99.9)	15159 (>99.9)	15179 (>99.9)	30338 (>99.9)
First injection solicited safety set, n (%) [b]	11402 (>99.9)	11406 (>99.9)	22808 (>99.9)	3749 (>99.9)	3760 (99.8)	7509 (99.9)	15151 (>99.9)	15166 (99.9)	30317 (>99.9)
Second injection solicited safety set, n (%) [b]	10929 (95.8)	11000 (96.4)	21929 (96.1)	3649 (97.3)	3691 (97.9)	7340 (97.6)	14578 (96.1)	14691 (96.8)	29269 (96.5)

[a] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.

[b] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.

Source: Table 14.1.2.2.

Table 5-3: Summary of RT-PCR Test and Elecsys Anti-SARS-CoV-2 Assay Results at Baseline (Full Analysis Set)

Baseline SARS-CoV-2 Status	Baseline RT-PCR Result [a]	Baseline Elecsys Result [a]	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Positive			337 (2.2)	347 (2.3)	684 (2.3)
	Positive	Positive	61 (0.4)	50 (0.3)	111 (0.4)
	Positive	Negative/Missing	34 (0.2)	38 (0.3)	72 (0.2)
	Negative/Missing	Positive	242 (1.6)	259 (1.7)	501 (1.7)
Negative	Negative	Negative	14745 (97.2)	14746 (97.1)	29491 (97.2)
Missing			84 (0.6)	87 (0.6)	171 (0.6)
	Negative	Missing	12 (<0.1)	9 (<0.1)	21 (<0.1)
	Missing	Negative	65 (0.4)	63 (0.4)	128 (0.4)
	Missing	Missing	7 (<0.1)	15 (<0.1)	22 (<0.1)

Abbreviations: RT-PCR = reverse transcription polymerase chain reaction.

[a] Subjects with no RT-PCR result or no Elecsys result include those who were tested but had no result and those who were not tested.

Source: Table 14.2.1.2.1.

5.3 Predefined Quality Tolerance Limits Assessments

As of the database lock (04 May 2021), there have been no excursions from the PDQTLs. The team is continuing to monitor them per the plan (Section 3.8.5), and the final results will be presented in the EOS CSR.

5.4 Major Protocol Deviations

Major protocol deviations were defined as a subset of protocol deviations that could have significantly impacted the completeness, accuracy, or reliability of the study data or that may have significantly affected a participant's rights, safety, or well-being. Major protocol deviations were determined and documented by the Sponsor prior to database lock and unblinding.

Select major protocol deviations that impacted critical or key study data, and participants with such deviations were excluded from the PP Set (see Section 5.2 for exclusions from PP Set).

The most common (≥ 2% of participants) major protocol deviations in the Randomization Set were missing endpoint assessments (15.1% total; 16.3% placebo, 13.9% mRNA-1273), ICF process/timing (7.3% total; 7.4% placebo, 7.3% mRNA-1273), study treatment administration/dispensing (5.5% total; 7.3% placebo, 3.6% mRNA-1273), visit scheduling (5.5%

total; 5.9% placebo, 5.2% mRNA-1273), study procedures/assessments (4.8% total; 6.1% placebo, 3.5% mRNA-1273), and study treatment randomization (3.8% total; 4.0% placebo, 3.7% mRNA-1273) (Table 5-4).

Major protocol deviations related to concomitant medication were reported for 1.0% of participants (1.2% in the placebo group; 0.9% in the mRNA-1273 group) (Table 5-4). Concomitant vaccine use is discussed in Section 5.7.

Section 5.2 discusses reasons for exclusion from the PP Set and Table 14.1.2.4 provides a summary of reasons for exclusion from the PP Set.

Table 5-4: Major Protocol Deviations (Randomization Set)

Deviation Type	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Accidental unblinding	2 (<0.1)	3 (<0.1)	5 (<0.1)
Concomitant medication	177 (1.2)	130 (0.9)	307 (1.0)
Data privacy	73 (0.5)	19 (0.1)	92 (0.3)
Exclusion criteria	21 (0.1)	23 (0.2)	44 (0.1)
ICF process/timing	1125 (7.4)	1109 (7.3)	2234 (7.3)
Inclusion criteria	16 (0.1)	15 (<0.1)	31 (0.1)
Inv adequate resources	1 (<0.1)	1 (<0.1)	2 (<0.1)
Inv communication with ethics	29 (0.2)	4 (<0.1)	33 (0.1)
Inv oversight	3 (<0.1)	0	3 (<0.1)
Inv qualifications/agreements	8 (<0.1)	2 (<0.1)	10 (<0.1)
Inv randomization/unblinding	1 (<0.1)	2 (<0.1)	3 (<0.1)
Inv record keeping source docs	2 (<0.1)	2 (<0.1)	4 (<0.1)
Inv safety reporting (CRF)	62 (0.4)	10 (<0.1)	72 (0.2)
Inv safety rptg (reg/sponsor)	272 (1.8)	37 (0.2)	309 (1.0)
Inv subject medical care	1 (<0.1)	0	1 (<0.1)
Missing endpoint assessments	2471 (16.3)	2121 (13.9)	4592 (15.1)
Study procedures/assessments	927 (6.1)	536 (3.5)	1463 (4.8)
Study treatment admin/dispense	1108 (7.3)	551 (3.6)	1659 (5.5)
Study treatment randomization	604 (4.0)	566 (3.7)	1170 (3.8)
Visit scheduling	897 (5.9)	786 (5.2)	1683 (5.5)
Withdrawal/term criteria	3 (<0.1)	2 (<0.1)	5 (<0.1)

A subject is counted once if the subject had multiple protocol deviations within one protocol deviation type.
Source: Table 14.1.1.6.

5.5 Demographics and Other Baseline Characteristics

Overall, in the FAS, participant demographics and baseline characteristics were similar between the groups (Table 5-5). A slightly higher proportion of males versus females (52.6% versus 47.4%. respectively) were enrolled. The mean age at screening was 51.4 years (range: 18 to 95 years); 75.2% of participants were ≥ 18 to < 65 years of age and 24.8% were ≥ 65 years. The majority of participants were White (79.2%) and not Hispanic or Latino (78.6%). Communities of color comprised 37.2% of the study population; the racial and ethnicity proportions observed in this study were generally representative of US demographics.

The study planned to enroll at least 25% and up to 50% of participants most at risk for severe complications of COVID-19, including those ≥ 65 years of age or < 65 years of age with

co-morbid medical conditions such as diabetes (Type 1, Type 2, or gestational), significant cardiac disease, chronic pulmonary disease, severe obesity, liver disease, and HIV infection. The study enrolled a total of 41.5% of participants who were considered at risk for severe COVID-19 (16.7% participants who were < 65 years and at risk, and 24.8% participants who were ≥ 65 years), indicating that enrollment goals were met (Table 5-5).

Overall, the majority of participants (82.5%) had a specified occupational risk for acquisition of SARS-CoV-2 infection; the most common occupational risks included other (31.9%) and health care workers (25.2%) (Table 5-5). A total of 83.8% of participants had a location or living circumstances risk for acquisition of SARS-CoV-2.

Participant demographics and baseline characteristics in the mITT Set and PP Set were similar to those in the FAS (Table 14.1.3.3.2 and Table 14.1.3.4.2).

Participants who received only one injection of IP had a mean age at screening of 47 years (range, 18 to 90 years) (Table 14.1.3.3.4). Minorities, defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians or other Pacific Islanders comprised 47.3% of participants who received only one injection. A total of 33.4% of participants who received only one injection were considered at risk for severe COVID-19 (16.5% participants who were < 65 years and at risk, and 16.9% participants who were > 65 years).

Table 5-5: Baseline Demographics and Characteristics by Age Group (Full Analysis Set)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
Age at screening (years)									
n	11413	11413	22826	3753	3767	7520	15166	15180	30346
Mean (SD)	45.0 (12.30)	45.1 (12.35)	45.0 (12.33)	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)	51.3 (15.60)	51.4 (15.50)	51.4 (15.55)
Median	46.0	46.0	46.0	70.0	69.0	70.0	52.0	53.0	52.0
Min, Max	18, 64	18, 64	18, 64	65, 95	65, 95	65, 95	18, 95	18, 95	18, 95
Age group at screening, n (%)									
>=18 and <65 years	11413 (100)	11413 (100)	22826 (100)	0	0	0	11413 (75.3)	11413 (75.2)	22826 (75.2)
Mean (SD)	45.0 (12.30)	45.1 (12.35)	45.0 (12.33)				45.0 (12.30)	45.1 (12.35)	45.0 (12.33)
Median	46.0	46.0	46.0				46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64				18, 64	18, 64	18, 64
>=65 years	0	0	0	3753 (100)	3767 (100)	7520 (100)	3753 (24.7)	3767 (24.8)	7520 (24.8)
Mean (SD)				70.7 (4.88)	70.4 (4.66)	70.6 (4.77)	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
Median				70.0	69.0	70.0	70.0	69.0	70.0
Min, Max				65, 95	65, 95	65, 95	65, 95	65, 95	65, 95

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
Age subgroup at screening, n (%)									
>=18 and <65 years	11413 (100)	11413 (100)	22826 (100)	0	0	0	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <70 years	0	0	0	1818 (48.4)	1905 (50.6)	3723 (49.5)	1818 (12.0)	1905 (12.5)	3723 (12.3)
>=70 and <75 years	0	0	0	1194 (31.8)	1205 (32.0)	2399 (31.9)	1194 (7.9)	1205 (7.9)	2399 (7.9)
>=75 and <80 years	0	0	0	507 (13.5)	466 (12.4)	973 (12.9)	507 (3.3)	466 (3.1)	973 (3.2)
>=80 years	0	0	0	234 (6.2)	191 (5.1)	425 (5.7)	234 (1.5)	191 (1.3)	425 (1.4)
Age subgroup at screening, n (%)									
>=18 and <65 years	11413 (100)	11413 (100)	22826 (100)	0	0	0	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <75 years	0	0	0	3012 (80.3)	3110 (82.6)	6122 (81.4)	3012 (19.9)	3110 (20.5)	6122 (20.2)
>=75 and <85 years	0	0	0	692 (18.4)	616 (16.4)	1308 (17.4)	692 (4.6)	616 (4.1)	1308 (4.3)
>=85 years	0	0	0	49 (1.3)	41 (1.1)	90 (1.2)	49 (0.3)	41 (0.3)	90 (0.3)
Age and health risk for severe COVID-19, n (%) [a]									
>=18 and <65 years and not at risk	8880 (77.8)	8888 (77.9)	17768 (77.8)	2 (<0.1)	0	2 (<0.1)	8882 (58.6)	8888 (58.6)	17770 (58.6)
>=18 and <65 years and at risk	2532 (22.2)	2524 (22.1)	5056 (22.2)	3 (<0.1)	6 (0.2)	9 (0.1)	2535 (16.7)	2530 (16.7)	5065 (16.7)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
>=65 years	1 (<0.1)	1 (<0.1)	2 (<0.1)	3748 (99.9)	3761 (99.8)	7509 (99.9)	3749 (24.7)	3762 (24.8)	7511 (24.8)
Risk factor for severe COVID-19 at screening, n (%) [b]									
Chronic lung disease	504 (4.4)	473 (4.1)	977 (4.3)	245 (6.5)	239 (6.3)	484 (6.4)	749 (4.9)	712 (4.7)	1461 (4.8)
Significant cardiac disease	292 (2.6)	321 (2.8)	613 (2.7)	450 (12.0)	441 (11.7)	891 (11.8)	742 (4.9)	762 (5.0)	1504 (5.0)
Severe obesity	905 (7.9)	896 (7.9)	1801 (7.9)	153 (4.1)	174 (4.6)	327 (4.3)	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	912 (8.0)	919 (8.1)	1831 (8.0)	545 (14.5)	541 (14.4)	1086 (14.4)	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver disease	70 (0.6)	84 (0.7)	154 (0.7)	26 (0.7)	20 (0.5)	46 (0.6)	96 (0.6)	104 (0.7)	200 (0.7)
Human immunodeficiency virus infection	75 (0.7)	77 (0.7)	152 (0.7)	16 (0.4)	17 (0.5)	33 (0.4)	91 (0.6)	94 (0.6)	185 (0.6)
At risk for severe COVID-19 at screening, n (%)									
Yes	2322 (20.3)	2320 (20.3)	4642 (20.3)	1135 (30.2)	1128 (29.9)	2263 (30.1)	3457 (22.8)	3448 (22.7)	6905 (22.8)
One risk factor for severe COVID-19	1937 (17.0)	1925 (16.9)	3862 (16.9)	878 (23.4)	866 (23.0)	1744 (23.2)	2815 (18.6)	2791 (18.4)	5606 (18.5)
Two or more risk factors for severe COVID-19	385 (3.4)	395 (3.5)	780 (3.4)	257 (6.8)	262 (7.0)	519 (6.9)	642 (4.2)	657 (4.3)	1299 (4.3)
No	9091 (79.7)	9093 (79.7)	18184 (79.7)	2618 (69.8)	2639 (70.1)	5257 (69.9)	11709 (77.2)	11732 (77.3)	23441 (77.2)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
Age and risk for severe COVID-19, n (%) [c]									
>=18 and <65 years and not at risk	9091 (79.7)	9093 (79.7)	18184 (79.7)	0	0	0	9091 (59.9)	9093 (59.9)	18184 (59.9)
>=18 and <65 years and at risk	2322 (20.3)	2320 (20.3)	4642 (20.3)	0	0	0	2322 (15.3)	2320 (15.3)	4642 (15.3)
>=65 years and not at risk	0	0	0	2618 (69.8)	2639 (70.1)	5257 (69.9)	2618 (17.3)	2639 (17.4)	5257 (17.3)
>=65 years and at risk	0	0	0	1135 (30.2)	1128 (29.9)	2263 (30.1)	1135 (7.5)	1128 (7.4)	2263 (7.5)
Baseline RT-PCR results, n (%)									
Negative	11271 (98.8)	11268 (98.7)	22539 (98.7)	3724 (99.2)	3745 (99.4)	7469 (99.3)	14995 (98.9)	15013 (98.9)	30008 (98.9)
Positive	85 (0.7)	81 (0.7)	166 (0.7)	10 (0.3)	7 (0.2)	17 (0.2)	95 (0.6)	88 (0.6)	183 (0.6)
Missing	57 (0.5)	64 (0.6)	121 (0.5)	19 (0.5)	15 (0.4)	34 (0.5)	76 (0.5)	79 (0.5)	155 (0.5)
Baseline Elecsys anti-SARS-CoV-2 results, n (%)									
Negative	11124 (97.5)	11124 (97.5)	22248 (97.5)	3720 (99.1)	3723 (98.8)	7443 (99.0)	14844 (97.9)	14847 (97.8)	29691 (97.8)
Positive	274 (2.4)	276 (2.4)	550 (2.4)	29 (0.8)	33 (0.9)	62 (0.8)	303 (2.0)	309 (2.0)	612 (2.0)
Missing	15 (0.1)	13 (0.1)	28 (0.1)	4 (0.1)	11 (0.3)	15 (0.2)	19 (0.1)	24 (0.2)	43 (0.1)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
Baseline SARS-CoV-2 status, n (%) [d]									
Negative	11046 (96.8)	11037 (96.7)	22083 (96.7)	3699 (98.6)	3709 (98.5)	7408 (98.5)	14745 (97.2)	14746 (97.1)	29491 (97.2)
Positive	303 (2.7)	311 (2.7)	614 (2.7)	34 (0.9)	36 (1.0)	70 (0.9)	337 (2.2)	347 (2.3)	684 (2.3)
Missing	64 (0.6)	65 (0.6)	129 (0.6)	20 (0.5)	22 (0.6)	42 (0.6)	84 (0.6)	87 (0.6)	171 (0.6)
Sex, n (%)									
Male	5955 (52.2)	5841 (51.2)	11796 (51.7)	2102 (56.0)	2076 (55.1)	4178 (55.6)	8057 (53.1)	7917 (52.2)	15974 (52.6)
Female	5458 (47.8)	5572 (48.8)	11030 (48.3)	1651 (44.0)	1691 (44.9)	3342 (44.4)	7109 (46.9)	7263 (47.8)	14372 (47.4)
Race, n (%)									
White	8657 (75.9)	8653 (75.8)	17310 (75.8)	3344 (89.1)	3378 (89.7)	6722 (89.4)	12001 (79.1)	12031 (79.3)	24032 (79.2)
Black or African American	1316 (11.5)	1345 (11.8)	2661 (11.7)	215 (5.7)	222 (5.9)	437 (5.8)	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	662 (5.8)	589 (5.2)	1251 (5.5)	77 (2.1)	67 (1.8)	144 (1.9)	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	95 (0.8)	92 (0.8)	187 (0.8)	26 (0.7)	21 (0.6)	47 (0.6)	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or other Pacific Islander	29 (0.3)	33 (0.3)	62 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	32 (0.2)	36 (0.2)	68 (0.2)
Multiracial	284 (2.5)	287 (2.5)	571 (2.5)	35 (0.9)	32 (0.8)	67 (0.9)	319 (2.1)	319 (2.1)	638 (2.1)
Other	262 (2.3)	276 (2.4)	538 (2.4)	32 (0.9)	23 (0.6)	55 (0.7)	294 (1.9)	299 (2.0)	593 (2.0)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
Not reported	60 (0.5)	84 (0.7)	144 (0.6)	14 (0.4)	13 (0.3)	27 (0.4)	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	48 (0.4)	54 (0.5)	102 (0.4)	7 (0.2)	8 (0.2)	15 (0.2)	55 (0.4)	62 (0.4)	117 (0.4)
Ethnicity, n (%)									
Hispanic or Latino	2774 (24.3)	2767 (24.2)	5541 (24.3)	335 (8.9)	354 (9.4)	689 (9.2)	3109 (20.5)	3121 (20.6)	6230 (20.5)
Not Hispanic or Latino	8544 (74.9)	8548 (74.9)	17092 (74.9)	3377 (90.0)	3369 (89.4)	6746 (89.7)	11921 (78.6)	11917 (78.5)	23838 (78.6)
Not reported	57 (0.5)	72 (0.6)	129 (0.6)	26 (0.7)	33 (0.9)	59 (0.8)	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	38 (0.3)	26 (0.2)	64 (0.3)	15 (0.4)	11 (0.3)	26 (0.3)	53 (0.3)	37 (0.2)	90 (0.3)
Race and ethnicity group, n (%) [e]									
Minority	4070 (35.7)	4075 (35.7)	8145 (35.7)	561 (14.9)	578 (15.3)	1139 (15.1)	4631 (30.5)	4653 (30.7)	9284 (30.6)
Non-minority	7330 (64.2)	7318 (64.1)	14648 (64.2)	3179 (84.7)	3183 (84.5)	6362 (84.6)	10509 (69.3)	10501 (69.2)	21010 (69.2)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)
Race and ethnicity group, n (%) [f]									
White	6401 (56.1)	6459 (56.6)	12860 (56.3)	3067 (81.7)	3074 (81.6)	6141 (81.7)	9468 (62.4)	9533 (62.8)	19001 (62.6)
Communities of color	4999 (43.8)	4934 (43.2)	9933 (43.5)	673 (17.9)	687 (18.2)	1360 (18.1)	5672 (37.4)	5621 (37.0)	11293 (37.2)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)
Weight (kg)									
n	11353	11357	22710	3730	3738	7468	15083	15095	30178
Mean (SD)	86.75 (22.352)	86.56 (22.682)	86.66 (22.518)	83.23 (19.019)	83.11 (19.334)	83.17 (19.176)	85.88 (21.629)	85.71 (21.951)	85.79 (21.790)
Median	83.64	83.64	83.64	81.60	81.20	81.40	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4	34.8, 184.5	37.2, 165.0	34.8, 184.5	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)									
n	11352	11357	22709	3729	3739	7468	15081	15096	30177
Mean (SD)	171.16 (9.964)	170.98 (9.901)	171.07 (9.933)	170.05 (10.224)	169.97 (10.004)	170.01 (10.114)	170.88 (10.040)	170.73 (9.936)	170.81 (9.988)
Median	171.00	170.20	170.50	170.18	170.18	170.18	170.50	170.18	170.20
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0	124.5, 223.5	123.0, 208.3	123.0, 223.5	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body mass index (kg/m^2)									
n	11352	11354	22706	3729	3738	7467	15081	15092	30173
Mean (SD)	29.53 (6.904)	29.53 (7.120)	29.53 (7.012)	28.71 (5.890)	28.67 (5.851)	28.69 (5.870)	29.32 (6.677)	29.32 (6.838)	29.32 (6.757)
Median	28.27	28.25	28.26	27.75	27.86	27.79	28.13	28.13	28.13
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1	12.1, 71.1	11.2, 62.9	11.2, 71.1	10.3, 72.7	9.8, 86.1	9.8, 86.1
Body mass index subgroup, n (%)									

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
< 30 kg/m^2	6867 (60.2)	6859 (60.1)	13726 (60.1)	2436 (64.9)	2414 (64.1)	4850 (64.5)	9303 (61.3)	9273 (61.1)	18576 (61.2)
>=30 kg/m^2	4485 (39.3)	4495 (39.4)	8980 (39.3)	1293 (34.5)	1324 (35.1)	2617 (34.8)	5778 (38.1)	5819 (38.3)	11597 (38.2)
Missing	61 (0.5)	59 (0.5)	120 (0.5)	24 (0.6)	29 (0.8)	53 (0.7)	85 (0.6)	88 (0.6)	173 (0.6)
Occupational risk, n (%) [b]	10164 (89.1)	10120 (88.7)	20284 (88.9)	2387 (63.6)	2376 (63.1)	4763 (63.3)	12551 (82.8)	12496 (82.3)	25047 (82.5)
Healthcare workers	3339 (29.3)	3339 (29.3)	6678 (29.3)	504 (13.4)	467 (12.4)	971 (12.9)	3843 (25.3)	3806 (25.1)	7649 (25.2)
Emergency response	277 (2.4)	281 (2.5)	558 (2.4)	19 (0.5)	21 (0.6)	40 (0.5)	296 (2.0)	302 (2.0)	598 (2.0)
Retail or restaurant operations	882 (7.7)	857 (7.5)	1739 (7.6)	99 (2.6)	100 (2.7)	199 (2.6)	981 (6.5)	957 (6.3)	1938 (6.4)
Manufacturing and production operations	391 (3.4)	391 (3.4)	782 (3.4)	30 (0.8)	35 (0.9)	65 (0.9)	421 (2.8)	426 (2.8)	847 (2.8)
Warehouse shipping and fulfillment centers	163 (1.4)	181 (1.6)	344 (1.5)	12 (0.3)	9 (0.2)	21 (0.3)	175 (1.2)	190 (1.3)	365 (1.2)
Transportation and delivery services	419 (3.7)	434 (3.8)	853 (3.7)	61 (1.6)	50 (1.3)	111 (1.5)	480 (3.2)	484 (3.2)	964 (3.2)
Border protection and military personnel	63 (0.6)	65 (0.6)	128 (0.6)	6 (0.2)	3 (<0.1)	9 (0.1)	69 (0.5)	68 (0.4)	137 (0.5)
Personal care and in-home services	407 (3.6)	405 (3.5)	812 (3.6)	61 (1.6)	67 (1.8)	128 (1.7)	468 (3.1)	472 (3.1)	940 (3.1)
Hospitality and tourism workers	184 (1.6)	201 (1.8)	385 (1.7)	43 (1.1)	37 (1.0)	80 (1.1)	227 (1.5)	238 (1.6)	465 (1.5)
Pastoral, social or public health workers	364 (3.2)	386 (3.4)	750 (3.3)	140 (3.7)	149 (4.0)	289 (3.8)	504 (3.3)	535 (3.5)	1039 (3.4)
Educators and students	1387 (12.2)	1365 (12.0)	2752 (12.1)	170 (4.5)	186 (4.9)	356 (4.7)	1557 (10.3)	1551 (10.2)	3108 (10.2)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**
Other	3398 (29.8)	3415 (29.9)	6813 (29.8)	1432 (38.2)	1435 (38.1)	2867 (38.1)	4830 (31.8)	4850 (31.9)	9680 (31.9)
Location and living circumstances risk, n (%)[b]	9580 (83.9)	9599 (84.1)	19179 (84.0)	3109 (82.8)	3133 (83.2)	6242 (83.0)	12689 (83.7)	12732 (83.9)	25421 (83.8)
Resides in nursing home or assisted living facility	9 (<0.1)	24 (0.2)	33 (0.1)	20 (0.5)	11 (0.3)	31 (0.4)	29 (0.2)	35 (0.2)	64 (0.2)
Resides in multi-family dwelling	348 (3.0)	397 (3.5)	745 (3.3)	65 (1.7)	66 (1.8)	131 (1.7)	413 (2.7)	463 (3.1)	876 (2.9)
Resides in high density housing	1073 (9.4)	1038 (9.1)	2111 (9.2)	240 (6.4)	253 (6.7)	493 (6.6)	1313 (8.7)	1291 (8.5)	2604 (8.6)
Resides in low density, multi-family setting	1236 (10.8)	1248 (10.9)	2484 (10.9)	256 (6.8)	244 (6.5)	500 (6.6)	1492 (9.8)	1492 (9.8)	2984 (9.8)
Resides in a single family home	6148 (53.9)	6115 (53.6)	12263 (53.7)	2262 (60.3)	2283 (60.6)	4545 (60.4)	8410 (55.5)	8398 (55.3)	16808 (55.4)
Other	1647 (14.4)	1649 (14.4)	3296 (14.4)	529 (14.1)	548 (14.5)	1077 (14.3)	2176 (14.3)	2197 (14.5)	4373 (14.4)

Abbreviations: IRT = interactive response technology; Max = maximum; Min = minimum; RT-PCR = reverse transcription polymerase chain reaction; SD = standard deviation.

Percentages are based on the number of subjects in Full Analysis Set.

[a] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.

[b] Subjects could be under one or more categories, and are counted once at each category.

[c] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).

[d] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.

[e] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	**mRNA-1273 (N=11413)**	**Total (N=22826)**	**Placebo (N=3753)**	**mRNA-1273 (N=3767)**	**Total (N=7520)**	**Placebo (N=15166)**	**mRNA-1273 (N=15180)**	**Total (N=30346)**

[f] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Source: Table 14.1.3.1.2.

5.6 Medical History

The incidence of participants with any medical history was balanced between the placebo and mRNA-1273 groups (Table 5-6). The most frequently reported medical history conditions were hypertension (29.7% in the placebo group; 29.3% in the mRNA-1273 group), seasonal allergy (27.5% in the placebo group; 27.6% in the mRNA-1273 group), postmenopause (14.8% in the placebo group; 15.6% in the mRNA-1273 group), and gastroesophageal reflux disease (14.6% in the placebo group; 15.3% in the mRNA-1273 group) (Table 14.1.4.1). Among the other most common medical history conditions (≥ 10% and < 15% of participants in either group) were drug hypersensitivity, depression, anxiety, hyperlipidemia, and osteoarthritis.

Participants with a medical history of autoimmune disorder, angioedema, anaphylaxis, hypersensitivity, or dermal fillers were not excluded from the study (Table 5-6). In the mRNA-1273 group, 1152 participants (7.6%) had a history of autoimmune disorder and 3064 participants (20.2%) had a history of hypersensitivity.

Table 5-6: Summary of Medical History (Safety Set)

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of subjects with any medical history	13954 (92.0)	13999 (92.2)	27953 (92.1)
Number of subjects with at least one autoimmune disorder	1144 (7.5)	1152 (7.6)	2296 (7.6)
Number of subjects with at least one angioedema event	98 (0.6)	100 (0.7)	198 (0.7)
Number of subjects with at least one anaphylaxis event	27 (0.2)	23 (0.2)	50 (0.2)
Number of subjects with at least one hypersensitivity event	3045 (20.1)	3064 (20.2)	6109 (20.1)
Number of subjects with at least one dermal fillers event	15 (<0.1)	16 (0.1)	31 (0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Source: Table 14.1.4.1, Table 14.1.4.4, Table 14.1.4.5, Table 14.1.4.6, Table 14.1.4.7, and Table 14.1.4.8.

5.7 Prior and Concomitant Medications

Overall, concomitant medications and/or non-study vaccination throughout the study was reported for 62.3% of participants; 52.1% of participants in the placebo group and 72.5% of participants in the mRNA-1273 group (Table 14.1.5.1.1). The imbalance generally appears to be driven by antipyretic or analgesic medication use in the mRNA-1273 group during the study. A higher proportion of participants in the mRNA-1273 group (60.0%) reported any concomitant medications or non-study vaccination within 7 days post injection than participants in the placebo group (25.4%). An imbalance was also observed within 14 days post injection (62.8% in the mRNA-1273 group vs. 31.0% in the placebo group) and within 28 days post injection (72.3% vs. 51.7%, respectively).

Concomitant vaccine use throughout the study was reported for 23.5% of participants, with no notable differences between the placebo and mRNA-1273 groups (Table 14.1.5.4.1). Concomitant vaccine use within 7 days, 14 day, and 28 days post injection was reported for 0.5%, 1.7%, and 23.4% of participants, respectively, with no notable differences between the placebo and mRNA-1273 groups.

Influenza vaccine was the most frequently reported concomitant vaccine, with no notable differences between the placebo and mRNA-1273 groups (Table 14.1.5.4.2). Seasonal influenza vaccine within 14 days post injection and within 28 days post injection was reported for a total of 1.5% and 23.1% participants, respectively (Table 14.1.5.1.1). No notable differences were observed between the placebo and mRNA-1273 groups.

5.8 Exposure and Compliance

Compliance with dosing scheduling in the Randomized Set was high and is discussed in Section 5.1. In the PP Set, a total of 28,451 participants received the first and second injection (14,164 in the placebo group; 14,287 in the mRNA-1273 group) (Table 14.1.6.6.3 and Table 14.1.6.5.3).

A total of 13 participants (7 participants in the placebo group; 6 participants in the mRNA-1273 group) received incorrect study vaccination and were excluded from the PP Set (Section 5.2)

5.9 Duration of Follow-Up

The data cutoff date for DBL was 26 Mar 2021. The time on study, or duration of follow-up from randomization, is defined as the time from randomization to death/discontinuation from study, or 26 Mar 2021, whichever occurs earlier.

The median duration of follow-up after randomization for the entire period up to the data cutoff for DBL (inclusive of Part A and Part B) was 212 days (range, 1 to 243 days) (Table 5-7). The

median duration of follow-up from randomization to PDV (ie, Part A) for participants who had a PDV before the data cutoff date was 148 days (range, 30 to 241 days). The median duration of follow-up after second injection (in participants who received the second injection) for the entire period up to the data cutoff for DBL (inclusive of Part A and Part B) was approximately 6 months; 183 days (range, 1 to 218 days).

For the 2 age groups, the median duration of follow-up after randomization for the entire period up to the data cutoff for DBL (inclusive of Part A and Part B) was 211 days in participants ≥ 18 to < 65 years and 214 days in participants ≥ 65 years (Table 14.1.6.2.3). The median duration of follow-up from randomization to PDV (ie, Part A) for participants who had a PDV on or before the data cutoff date was 148 days (range, 31 to 241 days) in participants ≥ 18 to < 65 years and 147 days (range, 30 to 234 days) in participants ≥ 65 years. The median duration of follow-up after second injection (in participants who received the second injection) for the entire period up to the data cutoff for DBL (inclusive of Part A and Part B) was approximately 6 months in both age groups; 180 days (range, 1 to 218 days) in participants ≥ 18 to < 65 years and 185 days (range 8 to 218 days) in participants ≥ 65 years. In participants ≥ 18 to < 65 years, a total of 44.6% had at least 6 months of follow-up after the second injection (47.3% in the mRNA-1273 group; 42.0% in the placebo group). In participants ≥ 65 years, a total of 54.4% had at least 6 months of follow-up after the second injection (55.8% in the mRNA-1273 group; 52.9% in the placebo group).

To enhance the diversity of the trial population, an effort was made to increase enrollment in communities of color. This effort increased toward the end of the enrollment period and resulted in a slightly reduced study duration for communities of color. Across communities of color, the median study duration from second injection in participants who received the second injection was approximately 5.5 months (169 days in Black or African Americans, 165 days in Asians, 169.5 days in American Indian or Alaska Natives, 169 days in Native Hawaiian or other Pacific Islanders, and 171 days in those identified as multiple race) compared with approximately 6.2 months (185 days) for White participants (Table 14.1.6.2.5). Median study duration from second injection in subjects who received the second injection was generally balanced between the placebo and mRNA-1273 groups within all race groups.

In Hispanic or Latino participants, the median study duration from second injection in participants who received the second injection was 170 days (Table 14.1.6.2.6). In participants who were not Hispanic or Latino, the median study duration from second injection in participants who received the second injection was 185 days. Median study duration from second injection in subjects who received the second injection was balanced between the placebo and mRNA-1273 groups within these ethnicity subgroups.

Table 5-7: Summary of Study Duration (Safety Set)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Number of subjects, n (%)			
Received first injection	15162 (100)	15184 (100)	30346 (100)
Received second injection	14631 (96.5)	14731 (97.0)	29362 (96.8)
>= 49 days since first injection	14992 (98.9)	15039 (99.0)	30031 (99.0)
>= 56 days since first injection	14960 (98.7)	15023 (98.9)	29983 (98.8)
>= 2 months since first injection	14929 (98.5)	14995 (98.8)	29924 (98.6)
< 28 days since second injection	36 (0.2)	24 (0.2)	60 (0.2)
>= 28 and < 56 days since second injection	120 (0.8)	51 (0.3)	171 (0.6)
>= 28 days since second injection	14595 (96.3)	14707 (96.9)	29302 (96.6)
>= 56 days since second injection	14475 (95.5)	14656 (96.5)	29131 (96.0)
>= 2 months since second injection	14438 (95.2)	14645 (96.5)	29083 (95.8)
>= 3 months since second injection	13927 (91.9)	14595 (96.1)	28522 (94.0)
>= 4 months since second injection	13263 (87.5)	14485 (95.4)	27748 (91.4)
>= 5 months since second injection	11636 (76.7)	12861 (84.7)	24497 (80.7)
>= 6 months since second injection	6778 (44.7)	7499 (49.4)	14277 (47.0)
Study duration from randomization (days)			
Mean (SD)	198.4 (38.90)	206.1 (31.02)	202.2 (35.38)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 224.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243
Study duration from first injection (days)			
Mean (SD)	198.4 (38.91)	206.0 (31.02)	202.2 (35.39)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 224.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243
Person-years from first injection [a]	8236.9	8565.5	16802.4
Study duration from second injection (days) [b]			
Mean (SD)	165.4 (46.12)	173.7 (38.95)	169.5 (42.88)
Median	180.0	183.0	182.0
Q1, Q3	157.0, 193.0	166.0, 194.0	163.0, 194.0
Min, Max	0, 218	0, 218	0, 218

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Study duration from second injection in subjects who received second injection (days)			
n	14631	14731	29362
Mean (SD)	171.4 (34.28)	179.0 (24.65)	175.2 (30.09)
Median	180.0	184.0	183.0
Q1, Q3	161.0, 194.0	169.0, 196.0	165.0, 194.0
Min, Max	1, 218	1, 218	1, 218
Study duration from randomization to PDV/unblinding (days) [c]			
n	14307	14537	28844
Mean (SD)	144.8 (25.46)	147.5 (25.64)	146.1 (25.59)
Median	146.0	148.0	148.0
Q1, Q3	128.0, 161.0	132.0, 163.0	131.0, 162.0
Min, Max	30, 237	44, 241	30, 241
Study duration from PDV/unblinding to study discontinuation/data cutoff date (days) [c]			
n	14307	14537	28844
Mean (SD)	58.9 (23.53)	63.2 (18.73)	61.1 (21.35)
Median	67.0	66.0	67.0
Q1, Q3	52.0, 75.0	55.0, 75.0	54.0, 75.0
Min, Max	1, 205	1, 179	1, 205

Abbreviations: PDV = Participant Decision Visit; Q1=first quartile; Q3=third quartile; SD=standard deviation.

1 month = 30.4375 days.

Percentages are based on the number of safety subjects.

[a] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.

[b] Study duration from second injection is 0 day for subjects who did not receive second injection.

[c] Only include subjects who had PDV/unblinding on/before data cutoff date.

Source: Table 14.1.6.2.1.

6 EFFICACY RESULTS

6.1 Efficacy Results for Primary Endpoint

The primary efficacy endpoint was VE of mRNA-1273 to prevent the first occurrence of adjudicated COVID-19 starting 14 days after the second injection of IP in the PP Set. Vaccine efficacy was assessed at 3 different timepoints – an IA based on a data snapshot on 11 Nov 2020, the primary analysis based on a data snapshot on 25 Nov 2020, and the final analysis of Part A based on database lock of 04 May 2021.

6.1.1 Interim Analysis (11 Nov 2020) and Primary Efficacy Analysis (25 Nov 2020)

The IA of efficacy (11 Nov 2020) demonstrated formal study success based on 95 cases: the VE point estimate (95% CI) based on the hazard ratio was 94.5% (86.5, 97.8); $p < 0.0001$ (Table 6-1). The primary efficacy analysis (25 Nov 2020), which was performed on 196 COVID-19 cases, confirmed the result of the IA: the VE point estimate (95% CI) based on the hazard ratio was 94.1% (89.3%, 96.8%; $p < 0.0001$).

Source tables supporting the results of the primary endpoint for the interim and the primary efficacy analyses are provided in Section 14.2.1 and Section 14.2.2, respectively. Additional analyses of these data have been previously submitted to the applicable regulatory agencies supporting conditional use of mRNA-1273.

Table 6-1: Interim and Primary Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection (Per-Protocol Set; 11 Nov 2020 and 25 Nov 2020 Data Snapshots)

	Interim Analysis (11 Nov 2020)[a]		Primary Analysis (25 Nov 2020)	
	mRNA-1273 (N=13934)	Placebo (N=13883)	mRNA-1273 (N=14134)	Placebo (N=14073)
Number of participants with COVID-19, n (%)	5 (< 0.1)	90 (0.6)	11 (< 0.1)	185 (1.3)
Vaccine efficacy based on hazard ratio (95% CI)[b]	0.945 (0.865, 0.978)		0.941 (0.893, 0.968)	
p-value[c]	<.0001		<.0001	
Person-years[d]	2716.9	2697.5	3304.9	3273.7
Incidence rate per 1,000 person-years (95% CI)[e]	1.840 (0.598, 4.295)	33.365 (26.829, 41.011)	3.328 (1.662, 5.955)	56.510 (48.660, 65.266)
Vaccine efficacy based on incidence rate (95% CI)[f]	0.945 (0.87, 0.98)		0.941 (0.892, 0.971)	

Abbreviations: CI = confidence intervals.

[a] EUA submission (interim efficacy analysis)

[b] Vaccine efficacy is defined as 1 – hazard ratio (mRNA-1273 vs. placebo), and 95% CI was estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[c] One-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE ≤ 0.3.

[d] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[e] Incidence rate is defined as the number of participants with an event divided by the number of participants at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI was calculated using the exact method (Poisson distribution) and adjusted by person-years.

[f] Vaccine efficacy is defined as 1 – ratio of incidence rate (mRNA-1273 vs placebo). The 95% CI of the ratio was calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Source: Table 14.2.2.1.1.1.1 (11 Nov 2020) and Table 14.2.2.1.1.1.1 (25 Nov 2020)

6.1.2 Final Efficacy Analysis (04 May 2021)

The final efficacy analysis of the primary endpoint for Part A (04 May 2021) was performed on 799 adjudicated first occurrences of COVID-19 starting at least 14 days after the second injection in the PP Set (Table 6-2).

The follow-up period for the final blinded efficacy analysis provided a median of 148 days (approximately 5.3 months, where 1 month = 28 days) from randomization to the PDV for participants who completed their PDV on or before the data cut-off date (Table 14.1.6.2.1). Additionally, the median duration of follow-up from the PDV to the data cutoff was 67 days, during which time blinded follow-up continued for participants who did not complete their PDV on or before to the data cut-off. Together, these provide a total follow-up duration of approximately 7.6 months from randomization (or approximately 6.5 months from the second injection). Additional COVID-19 case information for the median 67-day period from PDV to data cutoff date will be provided in a Part B addendum to this CSR.

The results of this analysis were consistent with the results of the interim and primary efficacy analyses (Section 6.1.1), confirming persistent, high efficacy over a substantially larger case database and over the median 5.3-month blinded observation period of Part A. For the final efficacy analysis, the VE point estimate (95% CI) was 93.2% (91.0%, 94.8%; $p < 0.0001$) and the 95% CI was observed to be within the 95% CIs for the interim and primary efficacy analyses.

Table 6-2: Final Part A Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection (Per-Protocol Set; 04 May 2021 Database Lock)

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of subjects with COVID-19*, n (%)	744 (5.3)	55 (0.4)
Number of subjects censored, n (%)	13420 (94.7)	14232 (99.6)
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.932 (0.910, 0.948)
p-value [b]		<.0001
Person-years [c]	5445.2	5729.9
Incidence rate per 1,000 person-years (95% CI) [d]	136.633 (126.991, 146.814)	9.599 (7.231, 12.494)
Vaccine efficacy based on incidence rate (95% CI) [e]		0.930 (0.908, 0.948)

Abbreviations: CI = confidence intervals; RT-PCR = reverse transcription polymerase chain reaction.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[a] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[b] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.

[c] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[d] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[e] VE is defined as 1 – ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Source: Table 14.2.2.1.3.1.1.

6.1.2.1 Sensitivity Analysis Results for Final Blinded Efficacy

As a sensitivity analysis, VE of mRNA-1273 to prevent COVID-19 was analyzed and COVID-19 incidence rates were estimated in the mITT Set, which includes participants in the Randomization Set who had no evidence of prior SARS-CoV-2 infection and who received at least 1 dose of study IP. The mITT Set provides a more conservative estimate of VE of mRNA-1273 and incidence rates than the PP Set by including participants who may have received only 1 dose of IP or who might have had a major protocol deviation, thereby including a

broader population than the PP Set (refer to Section 4.1.3 for the definitions of the analysis sets). Results were consistent with those observed for the PP Set (VE point estimate [95% CI] based on the hazard ratio was 92.8% [90.6%, 94.5%]; Table 14.2.2.1.3.1.2).

Table 6-3 presents adjudicated COVID-19 cases after randomization by time period in the mITT Set, and it is apparent that the number of cases starts to diverge between placebo and mRNA-1273 groups in the time period from randomization up to 14 days after the first injection.

Table 6-3: Summary of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period (mITT Set)

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of subjects with COVID-19*, n (%)	834 (5.7)	69 (0.5)
Number of events		
From randomization up to 14 days after first injection	11	6
>=14 up to 21 days after first injection	7	1
>=21 days after first injection up to second injection	41	3
From second injection up to 7 days after second injection	11	1
>=7 up to 14 days after second injection	13	0
>=14 up to 28 days after second injection	49	4
>=28 up to 56 days after second injection	181	16
>=56 up to 84 days after second injection	230	13
>=84 up to 112 days after second injection	207	17
>=112 days after second injection	84	8

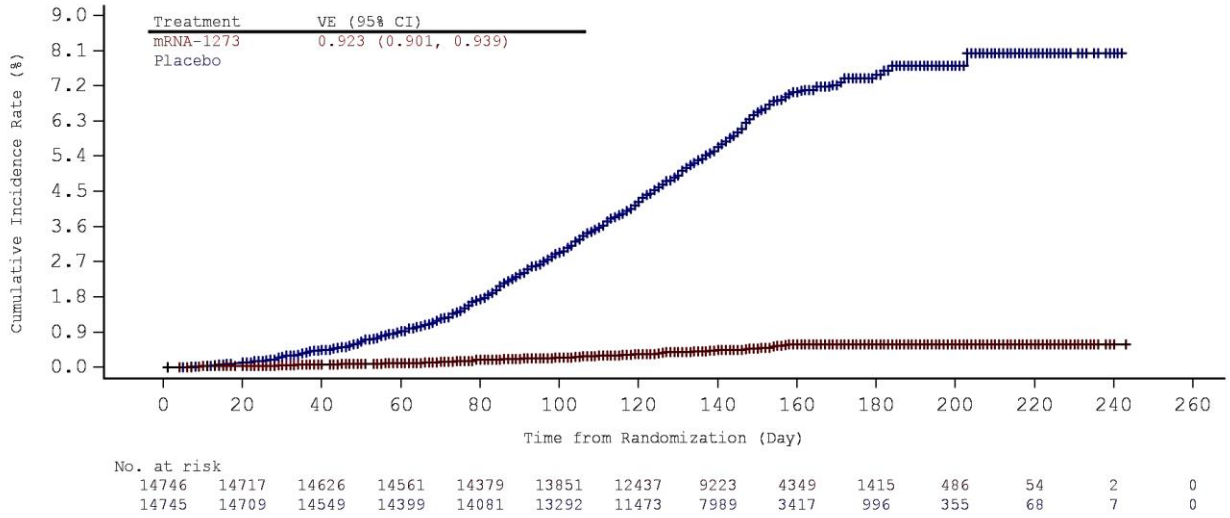
Abbreviations: RT-PCR = reverse transcription polymerase chain reaction.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Source: Table 14.2.1.1.2.1.3.4.

The cumulative incidence rate curves for adjudicated COVID-19 cases starting after randomization in the mITT Set (Figure 6-1) present a consistent picture, indicating early onset of protection. Thereafter, for the remainder of the observation period for Part A, the cumulative incidence rate for the placebo group increased steadily while it remained stable and low in the mRNA-1273 group (Table 14.2.1.1.2.1.5.2).

Figure 6-1: Cumulative Incidence Rate Curves of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization (mITT Set; 04 May 2021 Database Lock)



Abbreviations: CI = confidence interval.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Vaccine efficacy (VE) is defined as 1 – hazard ratio (mRNA-1273 vs. placebo) and 95% CI was estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Source: Figure 14.2.2.1.3.1.4.

The sensitivity analysis of the primary endpoint in the PP Set using different starting days for counting adjudicated cases of COVID-19 was performed for the following time points: after the second injection (Table 14.2.2.1.3.2.1), 14 days after the first injection (Table 14.2.2.1.3.3.1), and after randomization (Table 14.2.2.1.3.5.1). The results of these analyses were consistent with those of the primary analysis starting 14 days after the second injection. The VE of mRNA-1273 to prevent COVID-19 starting 14 days after the first injection was also a secondary objective and results are detailed in Section 6.2.3.

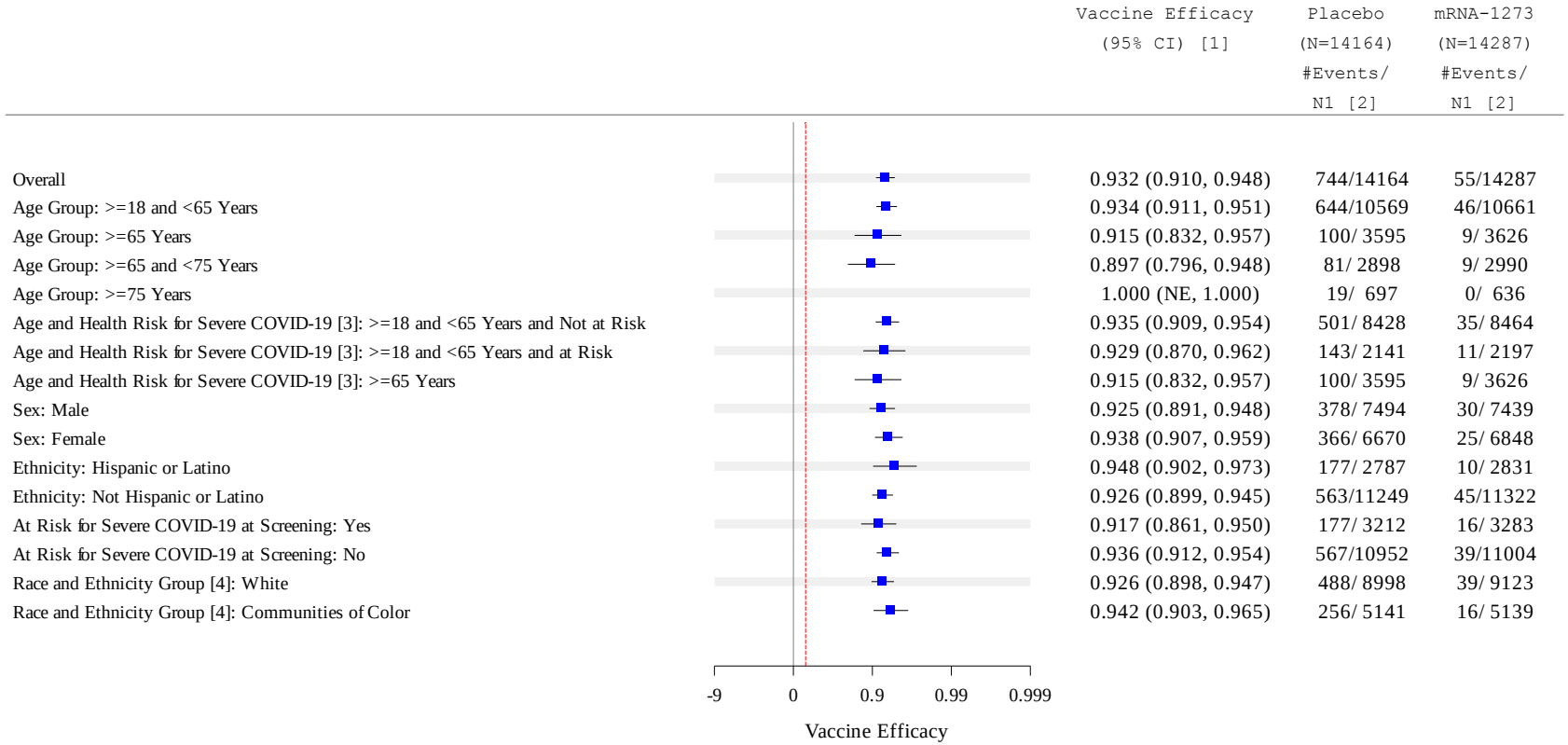
A summary of adjudicated COVID-19 cases by time period after randomization for the PP Set is provided in Table 14.2.1.1.2.1.3.1

Additional analyses were performed on the primary efficacy endpoint without adjudication; these results are presented in Section 14.2.3.

6.1.2.2 Subgroup Analysis Results for Final Blinded Efficacy

The observed efficacy in each subgroup was consistent with the high efficacy observed for the primary endpoint across the entire population, and the lower bound of the 95% CI of the individual subgroup analyses exceeded 30%, one of the success criteria for the interim efficacy analysis. A Forest Plot of subgroup analyses of VE of mRNA-1273 to prevent adjudicated COVID-19 cases starting 14 days after the second injection in the PP Set is presented in Figure 6-2. Results were consistent across subgroups (VE point estimates within the 95% CI for the overall dataset) stratified by age groups (≥ 18 to < 65 years, ≥ 65 years, ≥ 65 years to < 75 years, and ≥ 75 years); age and health risk (≥ 18 to < 65 years and not at risk, ≥ 18 to < 65 years and at risk, and ≥ 65 years), sex (male and female), ethnicity (Hispanic or Latino and not Hispanic or Latino); presence of risk for severe COVID-19 at screening; and race and ethnicity. With respect to the subgroup analysis for race and ethnicity, limited numbers of participants in each ethnic group contributed to the primary efficacy endpoint. Therefore, the race and ethnicity data were pooled into a “communities of color” group for this analysis to ensure that the subpopulations in the study would be large enough for meaningful analysis. Tables of COVID-19 case incidence and VE of mRNA-1273 for each individual race and ethnicity are presented in Section 14.2.3.

Figure 6-2: Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection (Per-Protocol Set; 04 May 2021 Database Lock)



Note: The dotted red reference line indicates vaccine efficacy of 0.3, the acceptable lower bound for the 95% CI of the primary endpoint for the interim efficacy analysis.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Based on the number of subjects in each subgroup.

[3] Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[4] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Source: Figure 14.2.2.1.3.2.3.

6.2 Efficacy Results for Secondary Endpoints

The observed efficacy for each secondary endpoint was consistent with the high efficacy observed for the primary endpoint: the VE with 95% CI is reported for each secondary endpoint. The results in this section are from the final analysis of Part A based on a database lock of 04 May 2021, unless otherwise indicated.

6.2.1 Severe COVID-19

The VE of mRNA-1273 to prevent adjudicated severe COVID-19 cases starting 14 days after second injection was consistent with the VE for the primary endpoint and was numerically higher.

In the final analysis of efficacy, 108 participants had adjudicated severe COVID-19 starting 14 days after second injection in the PP Set (106 cases in the placebo group and 2 cases in the mRNA-1273 group); the VE point estimate (95% CI) based on the hazard ratio was 98.2% (92.8%, 99.6%; Table 6-4), confirming and extending the findings of the primary analysis of 25 Nov 2020 based on a median of 148 days (final analysis) versus 78 days (primary analysis) of efficacy follow-up after randomization. Among these participants, 3 deaths in the placebo group were attributed to COVID-19 (Section 6.2.5).

Additional analyses were performed based on eligible symptoms for severe COVID-19 and positive RT-PCR without adjudication; the results were similar to those based on adjudicated cases and are presented in Section 14.2.3.

Table 6-4: Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After the Second Injection (Per-Protocol Set)

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of subjects with severe COVID-19*, n (%)	106 (0.7)	2 (<0.1)
Number of subjects censored, n (%)	14058 (99.3)	14285 (>99.9)
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.982 (0.928, 0.996)
Person-years [b]	5546.2	5737.9
Incidence rate per 1,000 person-years (95% CI) [c]	19.112 (15.648, 23.116)	0.349 (0.042, 1.259)
Vaccine efficacy based on incidence rate (95% CI) [d]		0.982 (0.932, 0.998)

Abbreviations: CI = confidence intervals; RT-PCR = reverse transcription polymerase chain reaction.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[a] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[b] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[c] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[d] VE is defined as 1 – ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Source: Table 14.2.2.2.3.1.1.

Table 6-5 presents adjudicated severe COVID-19 cases after randomization by time period in the PP Set, and it is apparent that the number of cases starts to diverge between placebo and mRNA-1273 groups in the time period of 7 to 14 days after the second injection.

Table 6-5: Summary of Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period (Per-Protocol Set)

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of subjects with severe COVID-19*, n (%)	107 (0.8)	2 (<0.1)
Number of events		
From randomization up to 14 days after first injection	0	0
>=14 up to 21 days after first injection	0	0
>=21 days after first injection up to second injection	0	0
From second injection up to 7 days after second injection	0	0
>=7 up to 14 days after second injection	1	0
>=14 up to 28 days after second injection	7	0
>=28 up to 56 days after second injection	25	0
>=56 up to 84 days after second injection	33	2
>=84 up to 112 days after second injection	28	0
>=112 days after second injection	13	0

Abbreviations: RT-PCR = reverse transcription polymerase chain reaction.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

Source: Table 14.2.1.1.2.2.3.1.

Similar results were noted for the sensitivity analysis, based on the mITT Set, of adjudicated severe COVID-19 starting 14 days after the second injection (VE point estimate [95% CI] based on the hazard ratio was 98.2% [92.8%, 99.6%]; Table 14.2.2.2.3.1.2). Sensitivity analyses using different starting days were performed for counting adjudicated severe COVID-19 cases starting after second injection, 14 days after first injection, and after randomization; these results are presented in Section 14.2.3.

An exploratory analysis of VE of mRNA-1273 to prevent severe COVID-19 starting 14 days after the first injection was carried out for participants in the mITT Set who received only 1 injection, and the results are provided in Table 14.2.2.2.4.3.2.

Subgroup analyses of VE of mRNA-1273 to prevent adjudicated severe COVID-19 were performed and the observed efficacy in each subgroup was consistent with the high efficacy observed across all cases of adjudicated severe COVID-19. Since there were only 2 cases of

adjudicated severe COVID-19 in the mRNA-1273 group, the subgroup analyses were not very informative beyond the consistently high efficacy.

The VE point estimates (95% CI) based on the hazard ratio for subgroup analysis of efficacy of participants between age ≥ 18 and < 65 years without risk (at screening) for severe COVID-19, participants between age ≥ 18 and < 65 years with risk for severe COVID-19, and participants ≥ 65 years of age who had adjudicated severe COVID-19 starting 14 days after second injection were 97.9% (84.9%, 99.7%), 100%, and 96.9% (77.1%, 99.6%), respectively (Table 14.2.2.2.3.6.3).

Subgroup analysis of efficacy by race for participants who had adjudicated severe COVID-19 starting 14 days after second injection in the PP Set consistently showed more cases in the placebo groups than in the mRNA-1273 group for all racial subgroups experiencing cases, and VE point estimates were similar between races (Table 14.2.2.2.3.6.5). Analysis of some subgroups was limited by the low number of participant in each treatment group, but for those subgroups with over 250 combined participants (White, Black or African American, Asian, Multiple, Other, or Unknown), VE point estimates based on the hazard ratio ranged from 97.8% to 100%.

Similarly, subgroup analysis of efficacy in participants grouped by risk for severe COVID-19 at screening who had adjudicated severe COVID-19 starting 14 days after second injection in the PP Set showed more cases in the placebo group than in the mRNA-1273 group for all subgroups analyzed (Table 14.2.2.2.3.6.7). As anticipated, participants at risk had a higher overall frequency of severe COVID-19 (1.4% and < 0.1% in the placebo and mRNA-1273 groups, respectively) compared with participants not at risk (0.6% and <0.1%, respectively). The VE point estimates (95% CI) based on the hazard ratio for at risk and no risk subgroups were similar at 97.9% (84.6%, 99.7%) and 98.5% (88.9%, 99.8%). Consistent VE point estimates were observed in subgroup analyses of participants with 1 risk factor, at least 2 risk factors, chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, and HIV infection.

6.2.2 SARS-CoV-2 Infection Regardless of Symptomatology and Severity

The secondary efficacy endpoint, SARS-CoV-2 infection (definition in Section 4.2.2.2) regardless of COVID-19 symptomatology and severity, includes both symptomatic COVID-19 cases and asymptomatic SARS-CoV-2 infection cases in participants with baseline negative SARS-CoV-2 status (PP Set or mITT Set). The SARS-CoV-2 infection cases in participants with baseline negative SARS-CoV-2 status were detected by positive RT-PCR tests with or without eligible symptoms or by positive bAb specific to SARS-CoV-2 N protein as measured by Roche Elecsys at scheduled visits/timepoints.

At the PDV/unblinding visit, both RT-PCR test and bAb against NP (Roche Elecsys) were performed. Including these results from the scheduled PDV visits provides a complete view of VE of mRNA-1273 to prevent SARS-CoV-2 infection, including asymptomatic infection, throughout the observation period of Part A. For the efficacy endpoints of all SARS-CoV-2 infection and asymptomatic infection, analyses including PDV visits were performed (ie, RT-PCR and Elecsys results at PDV visits were taken into consideration if the PDV visits occurred at or before the data cutoff date of 26 Mar 2021).

Including the RT-PCR and Elecsys results from the PDV, there were a total of 1,619 SARS-CoV-2 infections starting 14 days after second injection in the PP Set (1,339 cases in the placebo group and 280 cases in the mRNA-1273 group); the VE point estimate (95% CI) based on the hazard ratio was 82.0% (79.5%, 84.2%) (Table 6-6). Sensitivity analysis of VE from randomization through the PDV in the mITT Set was performed (Table 14.2.2.3.5.2.2). There were a total of 1,857 SARS-CoV-2 infections (1,522 cases in the placebo group and 335 cases in the mRNA-1273 group); the VE point estimate (95% CI) based on the hazard ratio was 80.7% (78.2%, 82.8%). These results further confirm the high and persistent efficacy of mRNA-1273 in this study.

Table 6-6: Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After the Second Injection Including Participant Decision Visit (Per-Protocol Set)

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of subjects with SARS-CoV-2 infection regardless of symptomatology and severity, n (%)	1339 (9.5)	280 (2.0)
Number of subjects censored, n (%)	12825 (90.5)	14007 (98.0)
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.820 (0.795, 0.842)
Person-years [b]	5442.4	5755.2
Incidence rate per 1,000 person-years (95% CI) [c]	246.032 (233.029, 259.572)	48.652 (43.120, 54.697)
Vaccine efficacy based on incidence rate (95% CI) [d]		0.802 (0.775, 0.827)

Abbreviations: CI = confidence intervals.

[a] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[b] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[c] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[d] VE is defined as 1 – ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Source: Table 14.2.2.3.1.1.2.

The summary of SARS-CoV-2 infection cases from randomization including the PDV by time period in the mITT Set is included in Table 6-7. The incidence of SARS-CoV-2 infection was higher in the placebo group over each time period starting in the period from randomization up to 14 days after the first injection, consistent with the corresponding primary analysis for adjudicated COVID-19 cases. The cumulative incidence rate curves for SARS-CoV-2 infection, regardless of COVID-19 symptomatology and severity starting after randomization and including the PDV in the mITT Set also shows a consistent picture (Figure 14.2.2.3.1.4.2), indicating early onset of protection. Thereafter, for the remainder of the observation period for Part A, the cumulative incidence rate for the placebo group increased steadily while it remained stable and low in the mRNA-1273 group.

Table 6-7: Summary of SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Randomization and Including Participant Decision Visit by Time Period (mITT Set)

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of subjects with SARS-CoV-2 infection regardless of symptomatology and severity, n (%)	1522 (10.3)	335 (2.3)
Number of events		
From randomization up to 14 days after first injection	11	6
>=14 up to 21 days after first injection	8	1
>=21 days after first injection up to second injection	59	8
From second injection up to 7 days after second injection	79	34
>=7 up to 14 days after second injection	13	0
>=14 up to 28 days after second injection	63	9
>=28 up to 56 days after second injection	221	29
>=56 up to 84 days after second injection	292	29
>=84 up to 112 days after second injection	318	61
>=112 days after second injection	458	158

Source: Table 14.2.1.1.2.3.4.2.

Analyses of VE of mRNA-1273 to prevent SARS-CoV-2 infection regardless of COVID-19 symptomatology and severity up to but not including PDV visits were also performed for infection cases starting 14 days after second injection in the PP Set. Sensitivity analyses with various starting points of counting cases based on the PP Set and mITT Set were performed and the results were included in Section 14.2.3. Subgroup analyses were also performed and the results in each subgroup examined were consistently high.

6.2.3 COVID-19 Starting 14 Days After the First Injection

The VE of mRNA-1273 to prevent adjudicated cases of COVID-19 starting 14 days after first injection were similar to the VE for the primary endpoint (Section 6.1.2.1). A total of 825 participants had a SARS-CoV-2 infection starting 14 days after first injection in the PP Set

(769 cases in the placebo group and 56 cases in the mRNA-1273 group); the VE point estimate (95% CI) based on the hazard ratio was 93.3% (91.1%, 94.9%; Table 14.2.1.1.1.1.1.2). Interpretation of this result is limited because more than 96% of participants received their second dose and the analysis included cases that occurred after the second dose.

Additional analyses were performed based on eligible symptoms for COVID-19 and positive RT-PCR (without adjudication); the results were similar to those from adjudicated cases and are presented in Section 14.2.3.

Similar results were noted for the sensitivity analysis based on the mITT Set (VE point estimate [95% CI] based on the hazard ratio was 92.9% [90.8%, 94.5%]; Table 14.2.2.1.3.3.2).

An exploratory analysis of VE of mRNA-1273 to prevent adjudicated COVID-19 starting 14 days after the first injection was carried out for participants in the mITT Set who received only 1 injection, and the results are provided in Table 14.2.2.1.3.3.3.

6.2.4 Secondary Definition of COVID-19

The VE of mRNA-1273 to prevent COVID-19 starting 14 days after second injection using the secondary definition for COVID-19 (only 1 symptom required from a broader list of symptoms published by the CDC; Section 2) was consistent with the VE for the primary endpoint. A total of 865 participants had a SARS-CoV-2 infection starting 14 days after second injection in the PP Set (807 cases in the placebo group and 58 cases in the mRNA-1273 group); the VE point estimate (95% CI) based on the hazard ratio was 93.2% (91.4%, 94.9%; Table 6-8).

Table 6-8: Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting 14 Days After the Second Injection (Per-Protocol Set)

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of subjects with secondary definition of COVID-19*, n (%)	807 (5.7)	58 (0.4)
Number of subjects censored, n (%)	13357 (94.3)	14229 (99.6)
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.934 (0.914, 0.949)
Person-years [b]	5433.4	5728.7
Incidence rate per 1,000 person-years (95% CI) [c]	148.525 (138.453, 159.136)	10.124 (7.688, 13.088)
Vaccine efficacy based on incidence rate (95% CI) [d]		0.932 (0.911, 0.949)

Abbreviations: CI = confidence intervals; RT-PCR = reverse transcription polymerase chain reaction.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[a] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[b] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[c] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[d] VE is defined as 1 – ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Source: Table 14.2.2.4.2.1.1

Similar results were noted for the sensitivity analysis based on the mITT Set (VE point estimate [95% CI] based on the hazard ratio was 93.1% [91.0%, 94.7%]) (Table 14.2.2.4.2.1.2).

Sensitivity analyses of COVID-19 prevention starting after randomization, based on the mITT Set and using the secondary definition of COVID-19, showed a VE point estimate based on the hazard ratio (95% CI) of 92.1% ([90.0%, 93.8%]) (Table 14.2.2.4.2.5.2).

In the mITT Set, the number of cases of COVID-19 by the secondary definition starts to diverge between placebo and mRNA-1273 groups in the time period from randomization up to 14 days after the first injection (Table 14.2.1.1.2.4.2.4), consistent with the corresponding analysis for COVID-19 cases (Table 6-3). The cumulative incidence rate curves for COVID-19 based on the

secondary definition for COVID-19 and starting after randomization in the mITT Set (Figure 14.2.2.4.2.1.4) present a picture consistent with the corresponding curves for COVID-19 based on the primary definition of COVID-19 (Figure 6-1), indicating early onset of protection.

6.2.5 Death Caused by COVID-19

Analysis of mRNA-1273 to prevent COVID-19-related death starting 14 days after the second injection showed that 3 participants died, all in the placebo group during the placebo-controlled, randomized Part A of the study. For this final analysis of efficacy for Part A, based on the PP Set, the VE point estimate (95% CI) was 100% (not estimable, 100%) (Table 14.2.1.1.1.1.1.2).

There was one death caused by COVID-19 in the mRNA-1273 group, participant US3702010. After randomization, the participant only received one dose and thus was not included in the estimates of VE of mRNA-1273 against death caused by COVID-19 14 days after the second injection. This subject is included in the listing of deaths (Listing 16.2.12) and the listing of unsolicited AEs in participants who died (Listing 16.2.7.27).

6.2.6 Asymptomatic SARS-CoV-2 Infection

Prevention of asymptomatic SARS-CoV-2 infection was analyzed using the PP Set and mITT Set and was identified by seroconversion against N protein (by the Elecsys assay) or detection by RT-PCR in the absence of symptoms. As disease cases (COVID-19 or secondary definition of COVID-19) were competing events for asymptomatic SARS-CoV-2 infections, a competing risk method (FG subdistribution hazard model) was used to estimate the VE of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection (Section 4.2.2.2). Details on the determination of asymptomatic SARS-CoV-2 infection are provided in mRNA-1273-P301 SAP Section 6.3.2.1.4 (Appendix 16.1.9). The sensitivity of the detection of asymptomatic infection was limited by the following: the frequency of assessment of seroconversion to anti nucleoprotein; the kinetics of seroconversion, which may take one to two weeks after the initial infection; and the fixed timepoints at which serum was sampled and analyzed.

At the PDV/unblinding visit, both nasal swab samples for RT-PCR test and serum samples for bAb against N protein (Roche Elecsys) were taken. Including these results at the scheduled PDV visits provides a complete view of VE of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection throughout the observation period of Part A.

Including the RT-PCR and Elecsys results at the PDV, there were a total of 712 asymptomatic SARS-CoV-2 infection cases starting 14 days after the second injection in the PP Set (498 cases in the placebo group and 214 cases in the mRNA-1273 group); the VE point estimate (95% CI) based on the hazard ratio was 63.0% (56.6%, 68.5%) (Table 6-9). Sensitivity analysis of VE to prevent asymptomatic infection from randomization and including the PDV in the mITT Set was

performed (Table 14.2.2.6.2.5.2.2). There were a total of 836 asymptomatic SARS-CoV-2 infection cases (583 cases in the placebo group and 253 cases in the mRNA-1273 group); the VE point estimate (95% CI) was 61.6% (55.5%, 66.9%) using the competing risk method. This analysis provides a complete view of VE of mRNA-1273 against asymptomatic infection and further confirms that vaccination with mRNA-1273 protects against asymptomatic infection (albeit at a lower VE than for symptomatic cases).

The cumulative incidence rate curves for asymptomatic SARS-CoV-2 infection starting after randomization in the mITT Set (Figure 14.2.2.6.2.1.6.2) are similar to the corresponding curves for COVID-19 based on the primary definition of COVID-19 starting after randomization in the mITT Set (Figure 6-1).

Table 6-9: Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting 14 Days After the Second Injection Including the Participant Decision Visit Using the Competing Risk Method (Per-Protocol Set)

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of subjects with asymptomatic SARS-CoV-2 infection, n (%)	498 (3.5)	214 (1.5)
Number of subjects with competing event, n (%)	863 (6.1)	62 (0.4)
Number of subjects censored, n (%)	12803 (90.4)	14011 (98.1)
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.630 (0.566, 0.685)
Person-years [b]	5442.1	5756.1
Incidence rate per 1,000 person-years (95% CI) [c]	91.508 (83.646, 99.909)	37.178 (32.363, 42.507)

Abbreviations: CI = confidence intervals; RT-PCR = reverse transcription polymerase chain reaction

RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition. Disease cases (COVID-19 or second definition of COVID-19) are considered as competing events for asymptomatic SARS-CoV-2 infection.

[a] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[b] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[c] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

Source: Table 14.2.2.6.2.1.1.2.

Analyses of VE of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection up to but not including PDV visits were also performed with infection cases starting 14 days after second injection in the PP Set. Sensitivity analyses with various starting points of counting cases based on the PP Set and mITT Set were performed and the results are included in Section 14.2.3.

6.2.7 COVID-19 Regardless of Prior SARS-CoV-2 Infection

The VE results of mRNA-1273 in participants with adjudicated COVID-19 regardless of prior SARS-CoV-2 infection starting 14 days after the second injection were similar to the VE for the primary endpoint. A total of 812 participants had a SARS-CoV-2 infection starting 14 days after second injection in the FAS (754 cases in the placebo group and 58 cases in the mRNA-1273

group); the VE point estimate (95% CI) based on the hazard ratio was 92.8% (90.6%, 94.5%; Table 6-10). This analysis cannot be interpreted as to the relative contribution of vaccination to the protection already afforded by prior exposure because the number of previously infected participants at baseline was too small to have an impact on the combined analysis (Table 14.1.3.2.1).

Additional analyses were performed based on eligible symptoms for severe COVID-19 and positive RT-PCR (cases not adjudicated); these results are presented in Section 14.2.3.

Table 6-10: Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After the Second Injection Regardless of Prior SARS-CoV-2 Infection (Full Analysis Set)

	Placebo (N=15166)	mRNA-1273 (N=15180)
Number of subjects with COVID-19*, n (%)	754 (5.0)	58 (0.4)
Number of subjects censored, n (%)	14412 (95.0)	15122 (99.6)
Vaccine efficacy based on hazard ratio (95% CI) [a]		0.928 (0.906, 0.945)
Person-years [b]	5768.0	6027.8
Incidence rate per 1,000 person-years (95% CI) [c]	130.721 (121.556, 140.394)	9.622 (7.306, 12.439)
Vaccine efficacy based on incidence rate (95% CI) [d]		0.926 (0.904, 0.945)

Abbreviations: CI = confidence intervals; RT-PCR = reverse transcription polymerase chain reaction.

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[a] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[b] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[c] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[d] VE is defined as 1 – ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Source: Table 14.2.2.7.3.1.

Sensitivity to different starting days for counting participants with adjudicated COVID-19 regardless of prior SARS-CoV-2 infection starting after randomization was evaluated; these results are presented in Section 14.2.3.

6.3 Efficacy Results for Exploratory Endpoints

6.3.1 Vaccine Efficacy to Reduce Duration and Presence/Severity of COVID-19 Symptoms

Participants who experienced COVID-19 symptoms and subsequently tested positive for COVID-19 during an Illness Visit were monitored daily for the duration and severity of symptoms (Section 3.7.2.2). Symptom scores aggregated over the convalescence period for adjudicated COVID-19 cases showed a higher mean total COVID-19 symptom score in the placebo group (60.6) than in the mRNA-1273 group (26.8; Table 6-11).

The VE point estimate (95% CI) of mRNA-1273 for mean of total COVID-19 symptoms score in the PP Set was 38.2% (16.5%, 54.3%), based on 1 – the ratio of the means of total COVID-19 symptoms score. This indicates meaningful protection by mRNA-1273 against symptoms over the convalescent period in participants who were adjudicated COVID-19 cases.

Table 6-11: Vaccine Efficacy of mRNA-1273 on Duration and Severity of COVID-19 Symptoms (Per-Protocol Set – Subjects with COVID-19 Based on Adjudication Committee Assessments)

	Placebo (N=770)	mRNA-1273 (N=57)
Mean of total COVID-19 symptoms score	60.6	26.8
Treatment comparison (mRNA-1273 vs. Placebo) [a]		
Ratio of the mean score		0.618
95% CI		0.457, 0.835
1 - ratio of the mean score		0.382
95% CI		0.165, 0.543

Abbreviations: CI = confidence interval.

Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.

Convalescence period: up to (<=28 days) after COVID-19 onset date.

Total symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.

Quartiles (across the two treatment groups) based on total symptom scores are used in proportional means model.

[a] Vaccine Efficacy is estimated using proportional means model including vaccination group as fixed effect and stratified with stratification factor at randomization.

Source: Table 14.2.3.3.2.

Symptom scores collected over the convalescence period for adjudicated COVID-19 cases were summarized by randomization stratum (overall, age ≥ 18 to < 65 years and not at risk, age ≥ 18

to < 65 years and at risk, and age ≥ 65 years) for number of subjects and scores per quartile, mean daily score, number of days with pre-specified symptom scores, highest temperature, and lowest oxygen saturation (Table 14.2.3.3.1). The number of placebo participants within each score quartile (based on the distribution of scores across both treatment groups) was similar, while there were relatively fewer mRNA-1273 participants in the higher quartiles (ie, above the median) than in the lower quartiles. Mean daily symptom scores, the number of days with at least 1 COVID-19 symptom score > 0, ≥ 2, or > 3, and the number of days with at least 2 COVID-19 symptom scores ≥ 2 were lower among participants receiving mRNA-1273 than among those receiving placebo. Highest temperature and lowest oxygen saturation data were similar between the 2 groups. These trends were consistent among participants age ≥ 18 to < 65 years and not at risk, age ≥ 18 to < 65 years and at risk, and age ≥ 65 years. However, the small number of participants in the mRNA-1273 groups for the latter 2 stratified groups was small (n = 12 and 7, respectively), thereby limiting the interpretation of these results.

6.3.2 Vaccine Efficacy Against Burden of Disease

The mean BOD score for the mRNA-1273 group was 0.0 versus 0.1 for the placebo group (Table 14.2.3.1.1.3). The VE point estimate (95% CI) of mRNA-1273 for BOD in the PP Set was 93.2% (91.0%, 94.8%), based on 1 – the ratio of the mean BOD scores. Although this is a statistically significant difference over the entire PP Set, the result is driven by high vaccine efficacy and the numerically dominant prevalence of mild to moderate disease.

6.3.3 Vaccine Efficacy Against Burden of Infection

The mean BOI score for the mRNA-1273 group was 0.01 versus 0.06 for the placebo group (Table 14.2.3.2.1.3). The VE point estimate (95% CI) of mRNA-1273 for BOI in the PP Set was 91.2% (89.0%, 93.0%), based on 1 – the ratio of the mean BOI score. Although this is a statistically significant difference over the entire PP Set, the result is driven by high vaccine efficacy and the numerically dominant prevalence of mild to moderate disease that was detected (especially versus asymptomatic infection).

6.3.4 Efficacy Against Viral Load

Viral load during infection was assessed in adjudicated COVID-19 cases (baseline negative, negative RT-PCR and Elecsys at Day 29, and negative Elecsys at Day 57) in the PP Set during Part A, from the Illness Visit (Day 1 of the convalescent period) through Day 28 of the convalescent period (refer to Genotyping Report [Appendix 16.5]). From Day 1 through Day 9 of the convalescent period, the mean number of viral copies detected in the placebo arm was significantly higher than those in the mRNA-1273 arm (Figure 3 of the Genotyping Report

[Appendix 16.5]), with the number being 100-fold lower among mRNA-1273 cases at Day 1 and 10-fold lower at Day 9.

6.3.5 All-Cause Mortality After Randomization

All-cause mortality after randomization was assessed in the PP Set (Table 14.2.2.8.1.1). A total of 24 participants died, 12 in each of the placebo and mRNA-1273 treatment groups.

6.4 Genotypic Analysis of Variants

The Genotyping Report is provided in Appendix 16.5.

Sequence information was obtained from all available SARS-CoV-2 PCR positive NP samples collected from July 2020 through May 2021 from participants in Part A. Sequences of the gene encoding the spike protein gene were generated from 832 different samples, corresponding to 791 trial participants (720 from placebo recipients, 71 from mRNA-1273 recipients). To assess the relative prevalence of key variant lineages detected in the clinical dataset, Pango lineages were inferred for each isolate based on amino acid mutations detected in the spike protein gene. The prevalences of selected lineages were then compared to those from a United States time-matched subset of the Global Initiative on Sharing All Influenza Data (GISAID) database. This comparison revealed that the sequences detected in adjudicated case samples were essentially a representation of the circulating strains in the US during the trial, with similar frequencies between the Part A and GISAID sample populations and D614G the predominant variant. Summaries of the number of variants by lineage in adjudicated cases starting after randomization are presented for the PP Set and mITT Set in Ad Hoc Table 14.2.1.1.2.1.4.1 and Ad Hoc Table 14.2.1.1.2.1.4.2, respectively.

6.4.1 Efficacy Against Variants

Consistent with current CDC classifications of variants and the lineages observed during Part A, exploratory analyses of VE of mRNA-1273 were conducted for variants of concern (VOC), variants of interest (VOI), and the California variants B.1.427 and B.1.429. Vaccine efficacy and 95% CIs were estimated using FG's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor. Overall, the VEs estimated in the study were driven by VE against the predominant D614G strain.

A VOC is a variant for which there is evidence of an increase in transmissibility, more severe disease (increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures. For VOC, the VE point estimate

(95% CI) based on the hazard ratio for 16 participants in the placebo group and 3 participants in the mRNA-1273 group was 82.4% (40.4%, 94.8%; Ad Hoc Table 14.2.2.6.2.1.3).

A VOI is a variant with specific genetic markers that have been associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity. For VOI, the VE point estimate based on the hazard ratio for 2 participants in the placebo group and none in the mRNA-1273 group was 100% (Ad Hoc Table 14.2.2.6.2.1.4).

An exploratory analysis of VE of mRNA-1273 was performed for California variant data combined (B.1.427 and B.1.429) using the competing risk method. The FG sub-distribution hazard model was used, and COVID-19 cases associated with variants other than the California variants were considered as competing risks. For the California variants, the VE point estimate (95% CI) based on the hazard ratio for 15 participants in the placebo group and 3 participants in the mRNA-1273 group was 81.2% (36.1%, 94.5%; Ad Hoc Table 14.2.2.6.2.1.1).

These exploratory analyses have the following limitations:

- The 100-fold lower viral shedding in the mRNA-1273 COVID-19 breakthrough cases hindered efforts to generate an unbiased sequence data set. The success rate in obtaining good quality sequences from mRNA-1273 breakthrough cases was 50% or less, while it was over 80% for cases in the placebo group.
- The sample size of variants detected was small, making it difficult to accurately assess the true proportions of viral variants and associated VEs.

6.5 Immunogenicity

A total of 1591 participants were selected for the Random Subcohort for Immunogenicity (335 participants in the placebo group; 1256 participants in the mRNA-1273 group) (Table 14.1.2.5; refer to Section 4.1.3 for definitions of the analysis sets). Of these, 1457 participants (91.6%) were included in the PP Random Subcohort for Immunogenicity (272/335 participants [81.2%] in the placebo group; 1185/1256 participants [94.3%] in the mRNA-1273 group) (Table 14.1.2.5).

A total of 134 participants (63 participants [18.8%] in the placebo group; 71 participants [5.7%] in the mRNA-1273 group) were excluded from the PP Random Subcohort for Immunogenicity Set (Table 14.1.2.5). The most common reason for exclusion was participant did not receive dose 2 per schedule (52 participants in the placebo group; 44 participants in the mRNA-1273 group), followed by HIV infection (4 participants in the placebo group; 21 participants in the mRNA-1273 group). A total of 8 participants were excluded for receiving dose 2 outside of the

window period for the PP Set (3 participants in the placebo group; 5 participants in the mRNA-1273 group); 4 participants had other major protocol deviations (3 participants in the placebo group; 1 participant in the mRNA-1273 group), and 1 participant in the placebo group was excluded for receiving the incorrect vaccination.

6.5.1 SARS-CoV-2 Spike Protein-Specific Antibodies as Measured by Binding Antibody and Pseudovirus Neutralizing Antibody Assays

The results for the immunogenicity endpoints are presented through Day 57 (Month 2).

6.5.1.1 SARS-CoV-2 Spike Protein-Specific Binding Antibodies as Measured by MesoScale Discovery Assay

As expected, the baseline GM level of SARS-CoV-2 S-protein IgG antibodies, as measured by MSD Multiplex assay, was higher at baseline in participants positive for SARS-CoV-2 (approximately 7000 AU/mL in both treatment groups) than those who were negative for SARS-CoV-2 at baseline (approximately 115 AU/mL in both treatment groups) (Table 6-12).

mRNA-1273 is highly immunogenic in both SARS-CoV-2 baseline-positive and baseline-negative participants, as indicated by increased GM levels of anti-SARS-CoV-2 S-protein IgG antibodies on Day 29 (28 days after the first injection), which were further increased on Day 57 (28 days after the second injection) (Table 6-12 and Figure 6-3).

In SARS-CoV-2 baseline-negative mRNA-1273 treated participants, the GM level (95% CI) on Day 29 was 35752.817 AU/mL (33375.81, 38299.12) (GM fold-rise [GMFR] approximately 310), with 99.1% of participants having seroresponse. Seroresponse at a subject level was defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 1.9-fold rise (critical fold rise statistically derived based on the variabilities of the MSD IgG S-protein assay at different sample dilutions; refer to Section 4.2.4.1) if baseline was equal to or above the LLOQ. On Day 57, the GM level (95% CI) increased to 316448.298 AU/mL (300071.44, 333718.95) (GMFR approximately 2737), with 99.6% of participants showing seroresponse (Table 6-12).

In SARS-CoV-2 baseline-positive mRNA-1273 treated participants, the GM levels on Day 29 were higher than those observed in baseline-negative mRNA-1273 treated participants and were similar to those observed on Day 57 in baseline-negative mRNA-1273 treated participants, indicating that the first injection of mRNA-1273 acts like a booster in participants with previous SARS-CoV-2 infection. The GM level (95% CI) was 410049.212 AU/mL (313904.05, 535642.52) on Day 29 (GMFR approximately 60) and increased to 668685.136 AU/mL

(570883.47, 783241.82) on Day 57 (GMFR approximately 96), with 97.6% of participants showing seroresponse on Day 29 and Day 57 (Table 6-12).

In the placebo group, the GM levels remained unchanged over time for baseline-negative participants (Day 57 GMFR [95% CI] of 1.10 [0.94, 1.28]) and baseline-positive participants (Day 57 0.73 [0.64, 0.83]) with only slight fluctuations (Table 6-12 and Figure 6-3).

Similar baseline results were observed for both subgroups stratified by age (≥ 18 to < 65 years and ≥ 65 years) in both SARS-CoV-2 baseline-negative and baseline-positive participants (Table 6-13 and Figure 6-4). In baseline-negative mRNA-1273 treated participants, the GM levels on Day 29 and Day 57 were lower in participants ≥ 65 years than those observed in participants ≥ 18 to < 65 years; however, seroresponse rates remained high (98.9% to 100%) across both age groups on Day 29 and Day 57. In baseline-positive mRNA-1273 treated participants, the GM levels on Day 29 were lower in participants ≥ 65 years than those observed in participants ≥ 18 to < 65 years, while Day 57 levels were similar between age groups; seroresponse rates ranged from 95.7% to 100% across both age groups on Day 29 and Day 57.

Mixed-model repeated measures and ANCOVA analyses showed consistent results (Table 14.2.4.1.1.2.3.1 and Table 14.2.4.1.1.3.3.1, respectively). These results can be found in Section 14. In addition, reverse cumulative distribution plots can be found in Section 14.

Table 6-12: Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MesoScale Discovery Assay by Baseline SARS-CoV-2 Status (Per-Protocol Random Subcohort for Immunogenicity)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline SARS-CoV-2 Status: Negative **Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)**		
Baseline (day 1)		
n [a]	139	1046
GM level	114.514	114.842
95% CI [b]	(105.36, 124.46)	(110.82, 119.01)
Median	99.820	99.820
Min, Max	99.82, 4219.35	99.82, 686841.33
Day 29		
n [a]	139	1040
GM level	117.183	35752.817
95% CI [b]	(105.96, 129.59)	(33375.81, 38299.12)
Median	99.820	38717.833
Min, Max	99.82, 12742.93	99.82, 1064384.47
N1	137	1033
GM fold-rise	1.02	309.51
95% CI [b]	(0.94, 1.12)	(287.70, 332.97)
Seroresponse [c]		
n (%) [d]	6 (4.4)	1024 (99.1)
95% CI [e]	(1.6, 9.3)	(98.4, 99.6)
>= 4-fold increase from baseline [f]		
n (%) [d]	1 (0.7)	1022 (98.9)
95% CI [e]	(0.0, 4.0)	(98.1, 99.5)
Day 57		
n [a]	141	1035
GM level	125.014	316448.298
95% CI [b]	(106.43, 146.84)	(300071.44, 333718.95)
Median	99.820	347458.394
Min, Max	99.82, 415541.60	99.82, 2020355.24
N1	139	1027
GM fold-rise	1.10	2737.08
95% CI [b]	(0.94, 1.28)	(2571.78, 2913.01)
Seroresponse [c]		
n (%) [d]	6 (4.3)	1023 (99.6)
95% CI [e]	(1.6, 9.2)	(99.0, 99.9)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
>= 4-fold increase from baseline [f]		
n (%) [d]	2 (1.4)	1021 (99.4)
95% CI [e]	(0.2, 5.1)	(98.7, 99.8)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Baseline SARS-CoV-2 Status: Positive		
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)		
Baseline (day 1)		
n [a]	128	127
GM level	7126.943	6988.940
95% CI [b]	(4898.91, 10368.28)	(4832.11, 10108.48)
Median	11824.822	9198.493
Min, Max	99.82, 3729897.61	99.82, 1373004.50
Day 29		
n [a]	127	130
GM level	5672.206	410049.212
95% CI [b]	(3955.04, 8134.92)	(313904.05, 535642.52)
Median	8387.515	656888.423
Min, Max	99.82, 1279426.90	99.82, 6557162.89
N1	126	127
GM fold-rise	0.80	60.21
95% CI [b]	(0.71, 0.90)	(45.62, 79.47)
Seroresponse [c]		
n (%) [d]	3 (2.4)	124 (97.6)
95% CI [e]	(0.5, 6.8)	(93.3, 99.5)
>= 4-fold increase from baseline [f]		
n (%) [d]	2 (1.6)	123 (96.9)
95% CI [e]	(0.2, 5.6)	(92.1, 99.1)
Day 57		
n [a]	128	130
GM level	5185.775	668685.136
95% CI [b]	(3609.31, 7450.81)	(570883.47, 783241.82)
Median	7845.081	755936.141
Min, Max	99.82, 1161989.31	435.65, 5834191.86
N1	127	127
GM fold-rise	0.73	95.78

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
95% CI [b]	(0.64, 0.83)	(68.47, 133.98)
Seroresponse [c]		
n (%) [d]	4 (3.1)	124 (97.6)
95% CI [e]	(0.9, 7.9)	(93.3, 99.5)
>= 4-fold increase from baseline [f]		
n (%) [d]	3 (2.4)	124 (97.6)
95% CI [e]	(0.5, 6.7)	(93.3, 99.5)

Abbreviations: CI = confidence intervals; Min = minimum; Max = maximum; GM = geometric mean; MSD = MesoScale Discovery.

N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

[a] Number of subjects with non-missing data at the corresponding timepoint.

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

[c] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 1.9-fold rise if baseline is equal to or above the LLOQ.

[d] Number of subjects meeting the criterion at the time point. Percentages are based on N1.

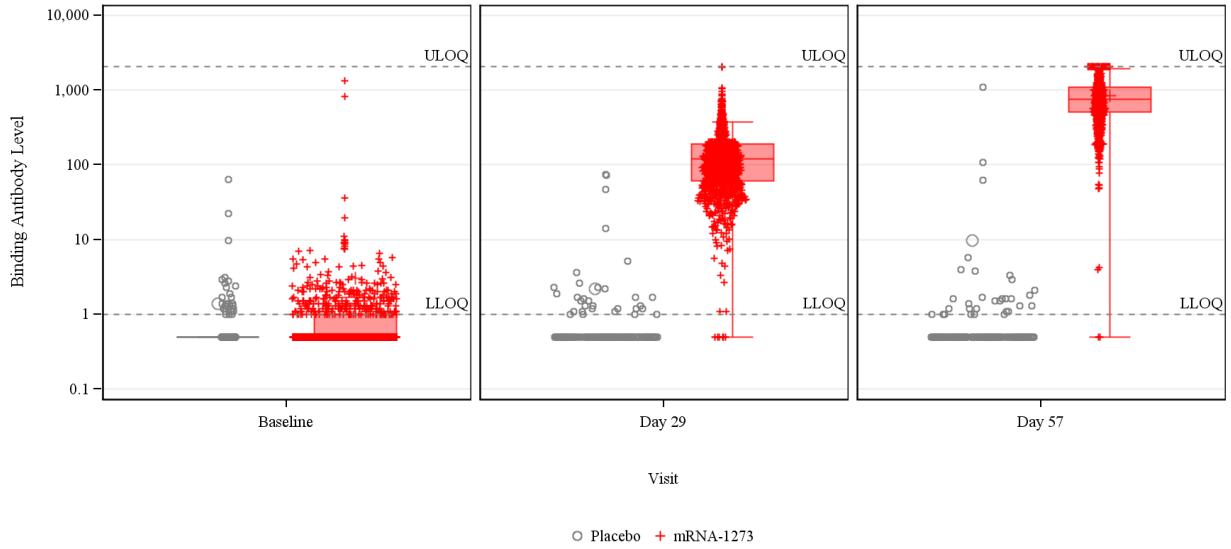
[e] 95% CI is calculated using the Clopper-Pearson method.

[f] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

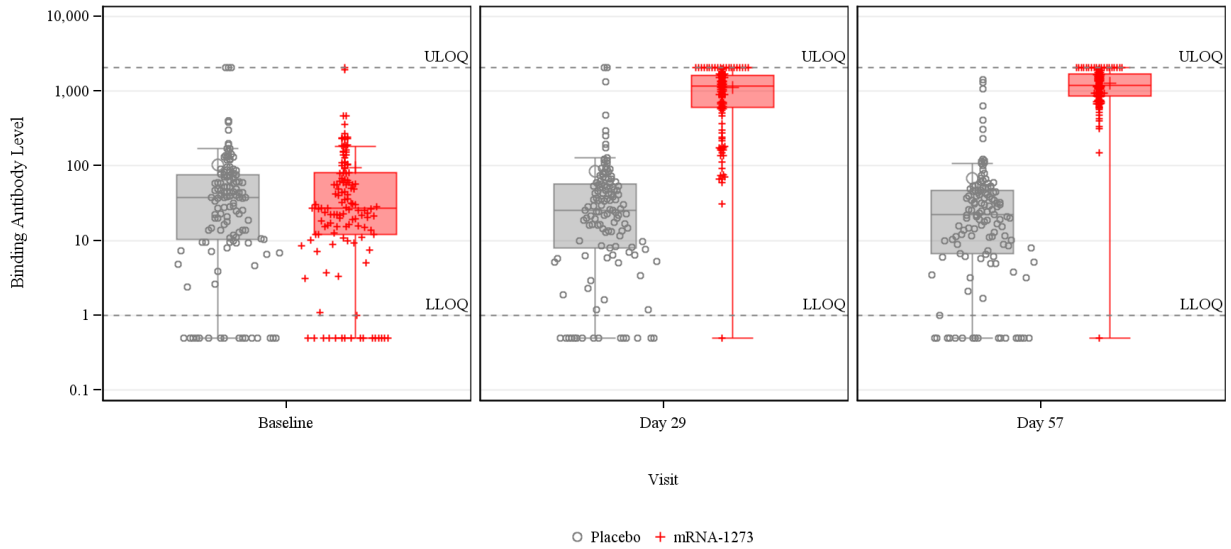
Source: Table 14.2.4.1.1.1.3.1.

Figure 6-3: Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MesoScale Discovery Assay by Baseline SARS-CoV-2 Status (Per-Protocol Random Subcohort for Immunogenicity)

Baseline SARS-CoV-2 Status: negative
Antibody: SARS-COV-2 S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



Baseline SARS-CoV-2 Status: positive
Antibody: SARS-COV-2 S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
Source: Figure 14.2.4.1.1.4.3.1.

Table 6-13: Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MesoScale Discovery Assay by Baseline SARS-CoV-2 Status and Age Group (Per-Protocol Random Subcohort for Immunogenicity)

	>=18 and <65 Years		>=65 Years	
Timepoint				
Data Category	**Placebo**	**mRNA-1273**	**Placebo**	**mRNA-1273**
Statistic	**(N=94)**	**(N=700)**	**(N=48)**	**(N=355)**
Baseline SARS-CoV-2 Status: Negative				
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)				
Baseline (day 1)				
n [a]	92	694	47	352
GM level	117.105	118.350	109.606	108.228
95% CI [b]	(104.15, 131.68)	(112.66, 124.33)	(99.79, 120.39)	(103.82, 112.82)
Median	99.820	99.820	99.820	99.820
Min, Max	99.82, 4219.35	99.82, 686841.33	99.82, 465.25	99.82, 5077.32
Day 29				
n [a]	93	689	46	351
GM level	122.075	44534.329	107.883	23231.313
95% CI [b]	(105.50, 141.25)	(41259.11, 48069.54)	(99.80, 116.62)	(20460.52, 26377.33)
Median	99.820	47750.783	99.820	26867.256
Min, Max	99.82, 12742.93	99.82, 1064384.47	99.82, 350.81	99.82, 297563.42
N1	91	685	46	348
GM fold-rise	1.05	374.32	0.98	212.89
95% CI [b]	(0.93, 1.18)	(344.23, 407.03)	(0.89, 1.09)	(186.39, 243.16)
Seroresponse [c]				
n (%) [d]	4 (4.4)	680 (99.3)	2 (4.3)	344 (98.9)
95% CI [e]	(1.2, 10.9)	(98.3, 99.8)	(0.5, 14.8)	(97.1, 99.7)
>= 4-fold increase from baseline [f]				
n (%) [d]	1 (1.1)	679 (99.1)	0	343 (98.6)
95% CI [e]	(0.0, 6.0)	(98.1, 99.7)	(0.0, 7.7)	(96.7, 99.5)
Day 57				

	>=18 and <65 Years		>=65 Years	
Timepoint				
Data Category	**Placebo**	**mRNA-1273**	**Placebo**	**mRNA-1273**
Statistic	**(N=94)**	**(N=700)**	**(N=48)**	**(N=355)**
n [a]	94	687	47	348
GM level	123.515	342705.171	128.068	270372.346
95% CI [b]	(101.23, 150.70)	(321384.23, 365440.57)	(96.41, 170.12)	(246469.00, 296593.91)
Median	99.820	367731.291	99.820	309277.361
Min, Max	99.82, 415541.60	99.82, 2020355.24	99.82, 53916.65	758.31, 1420483.52
N1	92	682	47	345
GM fold-rise	1.06	2875.38	1.17	2482.96
95% CI [b]	(0.87, 1.29)	(2658.16, 3110.35)	(0.89, 1.54)	(2244.18, 2747.15)
Seroresponse [c]				
n (%) [d]	3 (3.3)	678 (99.4)	3 (6.4)	345 (100)
95% CI [e]	(0.7, 9.2)	(98.5, 99.8)	(1.3, 17.5)	(98.9, 100.0)
>= 4-fold increase from baseline [f]				
n (%) [d]	1 (1.1)	677 (99.3)	1 (2.1)	344 (99.7)
95% CI [e]	(0.0, 5.9)	(98.3, 99.8)	(0.1, 11.3)	(98.4, 100.0)

Timepoint / Data Category / Statistic	>=18 and <65 Years		>=65 Years	
	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Baseline SARS-CoV-2 Status: Positive				
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)				
Baseline (day 1)				
n [a]	109	104	19	23
GM level	7208.447	7280.557	6676.865	5809.455
95% CI [b]	(4921.69, 10557.70)	(4977.81, 10648.57)	(1684.21, 26469.74)	(1798.02, 18770.55)
Median	11809.022	8627.384	17604.328	16337.432
Min, Max	99.82, 3729897.61	99.82, 1373004.50	99.82, 266305.31	99.82, 171363.87
Day 29				
n [a]	109	107	18	23
GM level	5761.640	460938.044	5159.526	237944.115
95% CI [b]	(3990.28, 8319.34)	(358978.97, 591856.06)	(1327.15, 20058.61)	(87695.66, 645612.37)
Median	7546.690	657850.666	17910.997	634798.316
Min, Max	99.82, 1279426.90	2174.94, 6557162.89	99.82, 151698.01	99.82, 2826194.17
N1	108	104	18	23
GM fold-rise	0.80	65.57	0.79	40.96
95% CI [b]	(0.69, 0.92)	(49.35, 87.12)	(0.69, 0.92)	(17.05, 98.42)
Seroresponse [c]				
n (%) [d]	3 (2.8)	102 (98.1)	0	22 (95.7)
95% CI [e]	(0.6, 7.9)	(93.2, 99.8)	(0.0, 18.5)	(78.1, 99.9)
>= 4-fold increase from baseline [f]				
n (%) [d]	2 (1.9)	102 (98.1)	0	21 (91.3)
95% CI [e]	(0.2, 6.5)	(93.2, 99.8)	(0.0, 18.5)	(72.0, 98.9)
Day 57				
n [a]	109	107	19	23
GM level	5145.374	659633.449	5423.756	712455.733

Timepoint	>=18 and <65 Years		>=65 Years	
Data Category	**Placebo**	**mRNA-1273**	**Placebo**	**mRNA-1273**
Statistic	**(N=110)**	**(N=107)**	**(N=20)**	**(N=23)**
95% CI [b]	(3564.96, 7426.42)	(548965.86, 792610.83)	(1402.38, 20976.61)	(534717.32, 949273.86)
Median	7170.788	735693.871	13672.267	851325.768
Min, Max	99.82, 1161989.31	435.65, 5834191.86	99.82, 766406.96	123554.67, 2016745.98
N1	108	104	19	23
GM fold-rise	0.71	90.68	0.81	122.64
95% CI [b]	(0.61, 0.83)	(63.33, 129.85)	(0.60, 1.10)	(47.13, 319.15)
Seroresponse [c]				
n (%) [d]	3 (2.8)	101 (97.1)	1 (5.3)	23 (100)
95% CI [e]	(0.6, 7.9)	(91.8, 99.4)	(0.1, 26.0)	(85.2, 100.0)
>= 4-fold increase from baseline [f]				
n (%) [d]	2 (1.9)	101 (97.1)	1 (5.3)	23 (100)
95% CI [e]	(0.2, 6.5)	(91.8, 99.4)	(0.1, 26.0)	(85.2, 100.0)

Abbreviations: CI = confidence intervals; Min = minimum; Max = maximum; GM = geometric mean; MSD = MesoScale Discovery.

N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

[a] Number of subjects with non-missing data at the corresponding timepoint.

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

[c] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 1.9-fold rise if baseline is equal to or above the LLOQ.

[d] Number of subjects meeting the criterion at the time point. Percentages are based on N1.

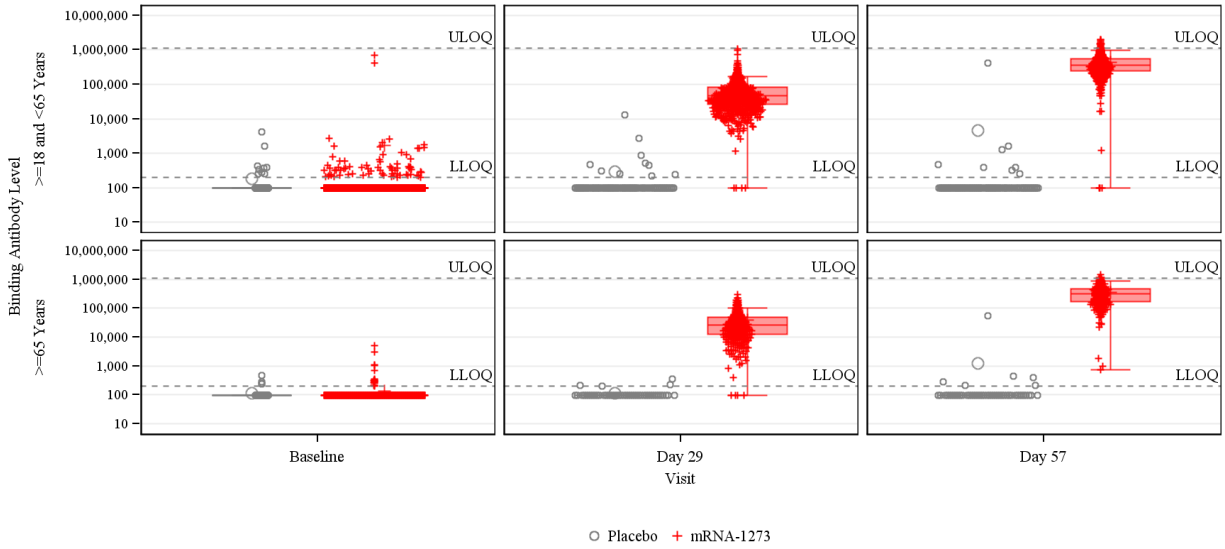
[e] 95% CI is calculated using the Clopper-Pearson method.

[f] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

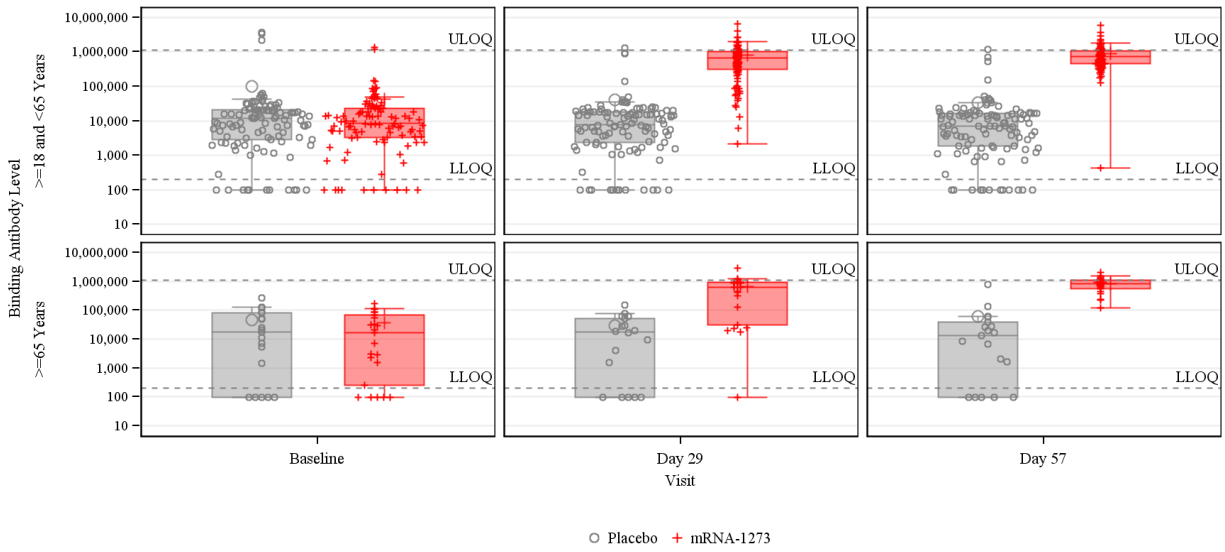
Source: Table 14.2.4.1.1.1.4.1.

Figure 6-4: Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MesoScale Discovery Assay by Baseline SARS-CoV-2 Status and Age Group (Per-Protocol Random Subcohort for Immunogenicity)

Baseline SARS-CoV-2 Status: negative
Antibody: SARS-COV-2 S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



Baseline SARS-CoV-2 Status: positive
Antibody: SARS-COV-2 S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
Source: Figure 14.2.4.1.1.4.4.1.

6.5.1.2 SARS-CoV-2 Spike Protein-Specific Binding Antibodies as Measured by ELISA

Overall, the results for SARS-CoV-2- S-2P protein IgG (VSDVAC65), as measured by ELISA assay were similar to those measured by MSD Multiplex assay (Section 6.5.1.1).

As anticipated, the baseline GM level was higher in SARS-CoV-2 baseline-positive participants (approximately 24 AU/mL in both treatment groups) than in SARS-CoV-2 baseline-negative participants (approximately 0.7 AU/mL in both treatment groups) (Table 6-14).

mRNA-1273 is highly immunogenic in both SARS-CoV-2 baseline-positive and baseline-negative participants, as indicated by increased GM levels of S-2P protein IgG on Day 29, which were further increased on Day 57 (Table 6-14 and Figure 6-5).

In SARS-CoV-2 baseline-negative mRNA-1273 treated participants, the S-2P protein IgG GM level (95% CI) on Day 29 was 106.97 AU/mL (100.64, 113.69) (GMFR approximately 149), with 99.0% of participants showing seroresponse. Seroresponse at a subject level was defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise (critical fold rise based on the similarity of variabilities of the ELISA IgG S-2P assay; refer to Section 4.2.4.1) if baseline was equal to or above the LLOQ. On Day 57, the GM level (95% CI) increased to 694.75 AU/mL (664.75, 726.10) (GMFR approximately 971), with 99.6% of participants showing seroresponse.

In SARS-CoV-2 baseline-positive mRNA-1273 treated participants, the S-2P protein IgG GM levels on Day 29 were higher than those observed in baseline-negative mRNA-1273 treated participants, and were similar to those observed on Day 57 in baseline-negative mRNA-1273 treated participants. The GM level (95% CI) was 772.15 AU/mL (628.74, 948.27) on Day 29 (GMFR approximately 32) and increased to 1097.47 AU/mL (950.57, 1267.08) on Day 57 (GMFR approximately 46), with 96.2% and 95.4% of participants showing seroresponse on Day 29 and Day 57, respectively (Table 6-14 and Figure 6-5).

In the placebo group, the S-2P protein IgG GM levels remained unchanged over time for baseline-negative participants (Day 57 GMFR [95% CI] of 1.06 [0.92, 1.23]) and baseline-positive participants (0.69 [0.62, 0.76]) with only slight fluctuations (Table 6-14 and Figure 6-5).

Similar S-2P protein IgG levels were observed for both subgroups stratified by age (≥ 18 to < 65 years and ≥ 65 years) in both SARS-CoV-2 baseline-negative and baseline-positive participants (Table 6-15 and Figure 6-6). In baseline-negative participants, the GM levels on Day 29 and Day 57 were lower in participants ≥ 65 years than those observed in participants

≥ 18 to < 65 years; however, seroresponse rates remained high (98.9% to 100%) across both age groups on Day 29 and Day 57.

In baseline-positive mRNA-1273 treated participants, the GM levels on Day 29 and Day 57 were similar between participants ≥ 65 years and ≥ 18 to < 65 years (with overlapping 95% CIs); seroresponse rates ranged from 91.3% to 97.2% across both age groups on Day 29 and Day 57.

Table 6-14: Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein Measured by Enzyme-Linked Immunosorbent Assay by Baseline SARS-CoV-2 Status (Per-Protocol Random Subcohort for Immunogenicity)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline SARS-CoV-2 Status: Negative		
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)		
Baseline (day 1)		
n [a]	141	1052
GM level	0.67	0.71
95% CI [b]	(0.60, 0.75)	(0.68, 0.75)
Median	0.50	0.50
Min, Max	0.5, 63.2	0.5, 1333.4
Day 29		
n [a]	141	1055
GM level	0.70	106.97
95% CI [b]	(0.61, 0.81)	(100.64, 113.69)
Median	0.50	121.30
Min, Max	0.5, 74.8	0.5, 2052.0
N1	140	1052
GM fold-rise	1.05	149.48
95% CI [b]	(0.94, 1.17)	(139.36, 160.34)
Seroresponse [c]		
n (%) [d]	8 (5.7)	1042 (99.0)
95% CI [e]	(2.5, 10.9)	(98.3, 99.5)
>= 4-fold increase from baseline [f]		
n (%) [d]	2 (1.4)	1038 (98.7)
95% CI [e]	(0.2, 5.1)	(97.8, 99.3)
Day 57		
n [a]	141	1053
GM level	0.71	694.75
95% CI [b]	(0.61, 0.84)	(664.75, 726.10)
Median	0.50	758.10
Min, Max	0.5, 1103.4	0.5, 2052.0
N1	140	1050
GM fold-rise	1.06	970.86
95% CI [b]	(0.92, 1.23)	(914.22, 1031.00)
Seroresponse [c]		
n (%) [d]	10 (7.1)	1046 (99.6)
95% CI [e]	(3.5, 12.7)	(99.0, 99.9)
>= 4-fold increase from baseline [f]		

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
n (%) [d]	2 (1.4)	1046 (99.6)
95% CI [e]	(0.2, 5.1)	(99.0, 99.9)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Baseline SARS-CoV-2 Status: Positive		
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)		
Baseline (day 1)		
n [a]	129	130
GM level	24.08	23.76
95% CI [b]	(17.35, 33.40)	(17.08, 33.06)
Median	38.10	27.15
Min, Max	0.5, 2052.0	0.5, 2052.0
Day 29		
n [a]	129	130
GM level	18.76	772.15
95% CI [b]	(13.66, 25.77)	(628.74, 948.27)
Median	25.40	1182.80
Min, Max	0.5, 2052.0	0.5, 2052.0
N1	128	130
GM fold-rise	0.81	32.49
95% CI [b]	(0.74, 0.88)	(25.33, 41.68)
Seroresponse [c]		
n (%) [d]	3 (2.3)	125 (96.2)
95% CI [e]	(0.5, 6.7)	(91.3, 98.7)
>= 4-fold increase from baseline [f]		
n (%) [d]	1 (0.8)	126 (96.9)
95% CI [e]	(0.0, 4.3)	(92.3, 99.2)
Day 57		
n [a]	130	130
GM level	16.09	1097.47
95% CI [b]	(11.77, 21.99)	(950.57, 1267.08)
Median	22.10	1188.60
Min, Max	0.5, 1424.9	0.5, 2052.0
N1	129	130
GM fold-rise	0.69	46.18
95% CI [b]	(0.62, 0.76)	(33.53, 63.62)
Seroresponse [c]		

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
n (%) [d]	1 (0.8)	124 (95.4)
95% CI [e]	(0.0, 4.2)	(90.2, 98.3)
>= 4-fold increase from baseline [f]		
n (%) [d]	0	126 (96.9)
95% CI [e]	(0.0, 2.8)	(92.3, 99.2)

Abbreviations: CI = confidence intervals; Min = minimum; Max = maximum; ELISA = enzyme-linked immunosorbent assay; GM = geometric mean.

N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

[a] Number of subjects with non-missing data at the corresponding timepoint.

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

[c] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise if baseline is equal to or above the LLOQ.

[d] Number of subjects meeting the criterion at the time point. Percentages are based on N1.

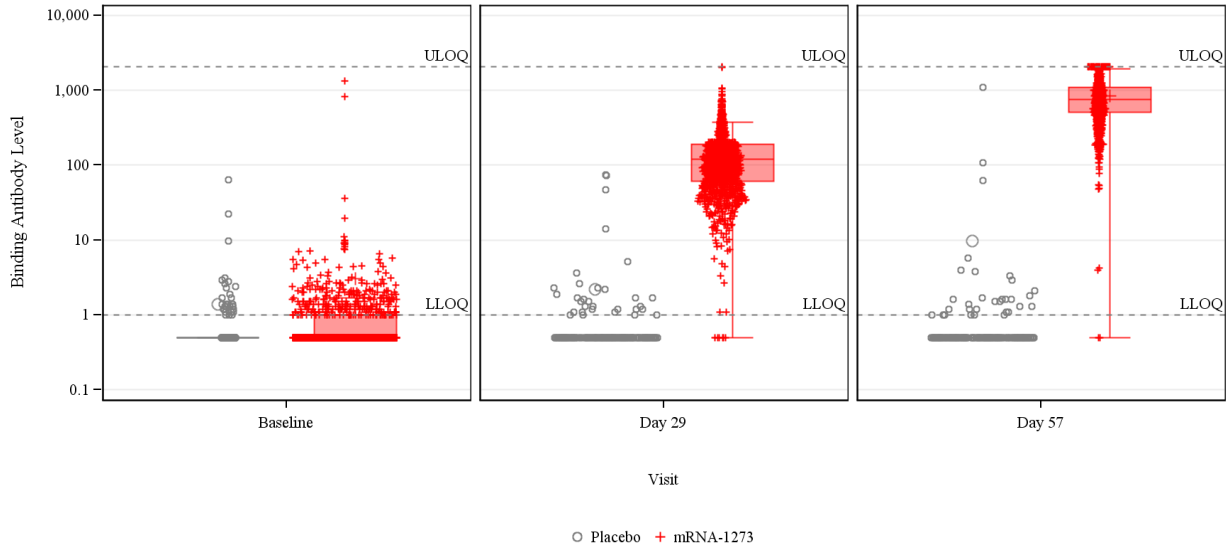
[e] 95% CI is calculated using the Clopper-Pearson method.

[f] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

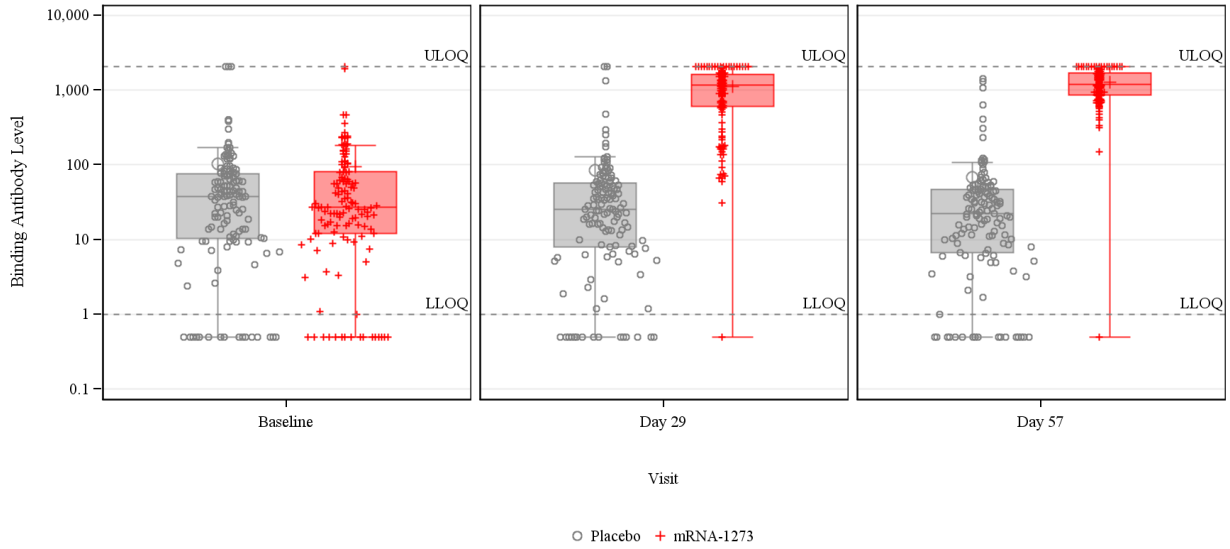
Source: Table 14.2.4.1.2.1.3.1.

Figure 6-5: Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by Enzyme-Linked Immunosorbent Assay by Baseline SARS-CoV-2 Status (Per-Protocol Random Subcohort for Immunogenicity)

Baseline SARS-CoV-2 Status: negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



Baseline SARS-CoV-2 Status: positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

Source: Figure 14.2.4.1.2.4.3.1.

Table 6-15: Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein Measured by Enzyme-Linked Immunosorbent Assay by Baseline SARS-CoV-2 Status and Age Group (Per-Protocol Random Subcohort for Immunogenicity)

	>=18 and <65 Years		>=65 Years	
Timepoint				
Data Category	**Placebo**	**mRNA-1273**	**Placebo**	**mRNA-1273**
Statistic	**(N=94)**	**(N=700)**	**(N=48)**	**(N=355)**
Baseline SARS-CoV-2 Status: Negative				
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)				
Baseline (day 1)				
n [a]	93	700	48	352
GM level	0.68	0.74	0.65	0.67
95% CI [b]	(0.60, 0.78)	(0.70, 0.78)	(0.51, 0.81)	(0.63, 0.71)
Median	0.50	0.50	0.50	0.50
Min, Max	0.5, 22.3	0.5, 1333.4	0.5, 63.2	0.5, 9.2
Day 29				
n [a]	94	700	47	355
GM level	0.68	127.94	0.75	75.16
95% CI [b]	(0.59, 0.80)	(119.47, 137.00)	(0.55, 1.02)	(67.16, 84.12)
Median	0.50	136.05	0.50	84.60
Min, Max	0.5, 47.2	0.5, 2052.0	0.5, 74.8	0.5, 746.6
N1	93	700	47	352
GM fold-rise	1.00	173.51	1.15	111.14
95% CI [b]	(0.89, 1.13)	(159.39, 188.89)	(0.92, 1.45)	(98.71, 125.13)
Seroresponse [c]				
n (%) [d]	4 (4.3)	692 (98.9)	4 (8.5)	350 (99.4)
95% CI [e]	(1.2, 10.6)	(97.8, 99.5)	(2.4, 20.4)	(98.0, 99.9)
>= 4-fold increase from baseline [f]				
n (%) [d]	1 (1.1)	691 (98.7)	1 (2.1)	347 (98.6)
95% CI [e]	(0.0, 5.8)	(97.6, 99.4)	(0.1, 11.3)	(96.7, 99.5)

Timepoint	>=18 and <65 Years		>=65 Years	
Data Category	**Placebo**	**mRNA-1273**	**Placebo**	**mRNA-1273**
Statistic	**(N=94)**	**(N=700)**	**(N=48)**	**(N=355)**
Day 57				
n [a]	93	698	48	355
GM level	0.69	740.62	0.76	612.68
95% CI [b]	(0.57, 0.84)	(702.10, 781.25)	(0.55, 1.03)	(567.34, 661.63)
Median	0.50	799.85	0.50	649.50
Min, Max	0.5, 1103.4	0.5, 2052.0	0.5, 108.8	4.0, 2052.0
N1	92	698	48	352
GM fold-rise	1.01	1003.33	1.17	909.53
95% CI [b]	(0.84, 1.22)	(928.62, 1084.06)	(0.91, 1.49)	(828.87, 998.04)
Seroresponse [c]				
n (%) [d]	4 (4.3)	694 (99.4)	6 (12.5)	352 (100)
95% CI [e]	(1.2, 10.8)	(98.5, 99.8)	(4.7, 25.2)	(99.0, 100.0)
>= 4-fold increase from baseline [f]				
n (%) [d]	1 (1.1)	694 (99.4)	1 (2.1)	352 (100)
95% CI [e]	(0.0, 5.9)	(98.5, 99.8)	(0.1, 11.1)	(99.0, 100.0)

Timepoint Data Category Statistic	>=18 and <65 Years Placebo (N=110)	>=18 and <65 Years mRNA-1273 (N=107)	>=65 Years Placebo (N=20)	>=65 Years mRNA-1273 (N=23)
Baseline SARS-CoV-2 Status: Positive				
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)				
Baseline (day 1)				
n [a]	109	107	20	23
GM level	24.83	24.32	20.35	21.35
95% CI [b]	(17.84, 34.57)	(17.30, 34.18)	(6.17, 67.08)	(7.38, 61.72)
Median	37.40	27.10	45.90	49.40
Min, Max	0.5, 2052.0	0.5, 2052.0	0.5, 401.8	0.5, 471.4
Day 29				
n [a]	110	107	19	23
GM level	19.36	845.77	15.65	505.48
95% CI [b]	(14.02, 26.74)	(708.70, 1009.36)	(4.86, 50.43)	(215.39, 1186.26)
Median	25.30	1153.90	35.10	1242.40
Min, Max	0.5, 2052.0	31.0, 2052.0	0.5, 296.3	0.5, 2052.0
N1	109	107	19	23
GM fold-rise	0.81	34.78	0.81	23.68
95% CI [b]	(0.73, 0.90)	(27.22, 44.44)	(0.70, 0.93)	(9.91, 56.60)
Seroresponse [c]				
n (%) [d]	3 (2.8)	104 (97.2)	0	21 (91.3)
95% CI [e]	(0.6, 7.8)	(92.0, 99.4)	(0.0, 17.6)	(72.0, 98.9)
>= 4-fold increase from baseline [f]				
n (%) [d]	1 (0.9)	104 (97.2)	0	22 (95.7)
95% CI [e]	(0.0, 5.0)	(92.0, 99.4)	(0.0, 17.6)	(78.1, 99.9)
Day 57				
n [a]	110	107	20	23
GM level	16.17	1056.72	15.63	1308.70

Timepoint Data Category Statistic	>=18 and <65 Years Placebo (N=110)	>=18 and <65 Years mRNA-1273 (N=107)	>=65 Years Placebo (N=20)	>=65 Years mRNA-1273 (N=23)
95% CI [b]	(11.80, 22.17)	(893.38, 1249.93)	(4.96, 49.30)	(1039.32, 1647.91)
Median	21.75	1161.10	30.15	1590.10
Min, Max	0.5, 1424.9	0.5, 2052.0	0.5, 1313.9	314.9, 2052.0
N1	109	107	20	23
GM fold-rise	0.67	43.46	0.77	61.31
95% CI [b]	(0.60, 0.76)	(30.84, 61.24)	(0.60, 0.98)	(24.65, 152.48)
Seroresponse [c]				
n (%) [d]	1 (0.9)	102 (95.3)	0	22 (95.7)
95% CI [e]	(0.0, 5.0)	(89.4, 98.5)	(0.0, 16.8)	(78.1, 99.9)
>= 4-fold increase from baseline [f]				
n (%) [d]	0	103 (96.3)	0	23 (100)
95% CI [e]	(0.0, 3.3)	(90.7, 99.0)	(0.0, 16.8)	(85.2, 100.0)

Abbreviations: CI = confidence intervals; Min = minimum; Max = maximum; ELISA = enzyme-linked immunosorbent assay; GM = geometric mean. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

[a] Number of subjects with non-missing data at the corresponding timepoint.

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

[c] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise if baseline is equal to or above the LLOQ.

[d] Number of subjects meeting the criterion at the time point. Percentages are based on N1.

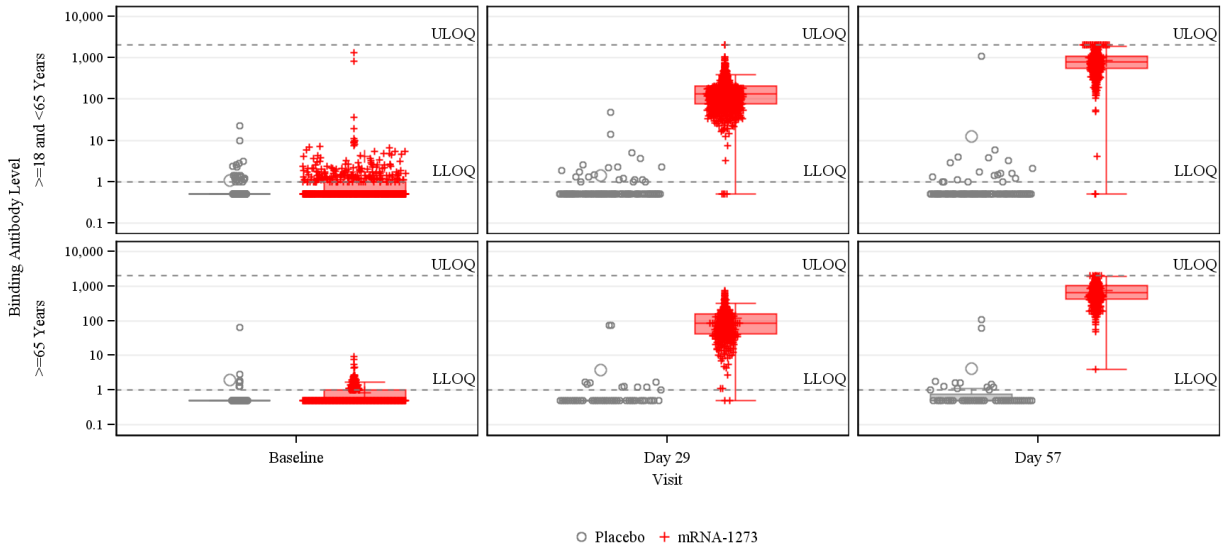
[e] 95% CI is calculated using the Clopper-Pearson method.

[f] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

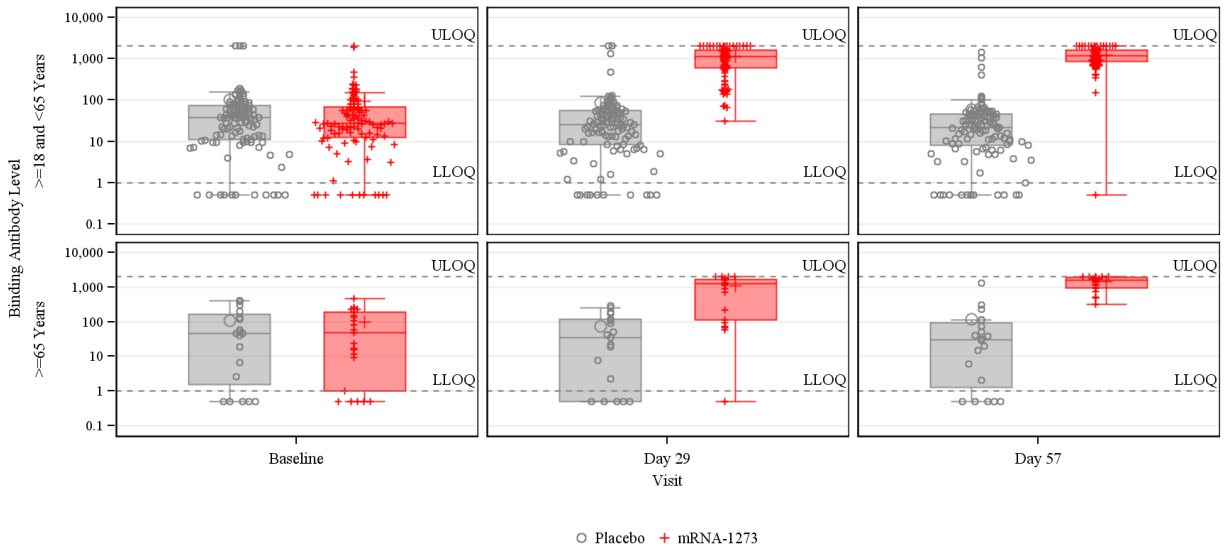
Source: Table 14.2.4.1.2.1.4.1.

Figure 6-6: Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by Enzyme-Linked Immunosorbent Assay by Baseline SARS-CoV-2 Status and Age Group (Per-Protocol Random Subcohort for Immunogenicity)

Baseline SARS-CoV-2 Status: negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



Baseline SARS-CoV-2 Status: positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

Source: Figure 14.2.4.1.2.4.4.1.

6.5.1.3 SARS-CoV-2 Spike Protein-Specific Neutralizing Antibodies as Measured by Pseudotyped Virus Neutralization Assay

As expected, the baseline GM titers for ID_{50} neutralizing antibodies against SARS-CoV-2 S-protein, as measured by PsVNA, were higher at baseline in participants who were positive for SARS-CoV-2 (approximately 83 for placebo group and 68 for mRNA-1273 treatment group) than in those who were negative for SARS-CoV-2 (approximately 9 and 10 for placebo and mRNA-1273 treatment groups, respectively; Table 6-16).

mRNA-1273 is highly immunogenic in both SARS-CoV-2 baseline-positive and baseline-negative participants, as indicated by increased ID_{50} GM titers on Day 29, which were further increased on Day 57 (Table 6-16 and Figure 6-7).

In SARS-CoV-2 baseline-negative mRNA-1273 treated participants, the GM ID_{50} titer (95% CI) on Day 29 was 54.866 (50.98, 59.04) (GMFR approximately 5.7), with 81.4% of participants showing seroresponse. Seroresponse to PsVNA ID_{50} titer at a subject level was defined as a change from below the LLOQ to equal or above the LLOQ, or at least 3.3 fold-rise (critical fold rise based on the similarity of variabilities of the PsVNA ID_{50}; refer to Section 4.2.4.1) if baseline was equal to or above LLOQ. On Day 57, the GM ID_{50} titer (95% CI) increased to 1081.124 (1019.80, 1146.14) (GMFR approximately 112.3), with 98.9% of participants showing seroresponse.

In SARS-CoV-2 baseline-positive mRNA-1273 treated participants, the ID_{50} GM titer levels on Day 29 were higher than those observed in baseline-negative participants, with titer levels that were similar to those observed on Day 57 in baseline-negative participants, supporting the observation that the first injection of mRNA1273 acts like a booster in participants with previous SARS-CoV-2 infection. The GM ID_{50} titer (95% CI) was 1478.910 (1069.60, 2044.86) on Day 29 (GMFR approximately 21.7) and increased to 3145.904 (2539.80, 3896.66) on Day 57 (GMFR approximately 46.2), with 87.7% and 94.6% of participants showing seroresponse on Day 29 on Day 57, respectively.

In the placebo group, the ID_{50} GM titers remained unchanged over time for SARS-CoV-2 baseline-negative participants (Day 57 GMFR [95% CI] of 1.07 [0.97, 1.18]) and SARS-CoV-2 baseline-positive participants on Day 57 (0.59 [0.50, 0.69]) with only slight fluctuations (Table 6-16 and Figure 6-7).

Similar results were observed for the ID_{80} titers; results and are summarized by baseline SARS-CoV-2 status in Table 6-16.

Similar baseline results were observed for both subgroups stratified by age (≥ 18 to < 65 years and ≥ 65 years) in both SARS-CoV-2 baseline-negative and baseline-positive participants

(Table 6-17 and Figure 6-8). In baseline-negative mRNA-1273 treated participants, the ID_{50} GM titers on Day 29 and Day 57 were lower in participants ≥ 65 years than those observed in participants ≥ 18 to < 65 years. The seroresponse rate was also lower in the older age group than in the younger age group on Day 29 (71.1% vs. 86.6%), with similar seroresponse rates observed in both age groups on Day 57 (99.4% vs. 98.6%). Nominal differences were observed between age groups in SARS-CoV-2 baseline-positive participants. Pseudovirus nAb ID_{80} titers are summarized by baseline SARS-CoV-2 status and age in Table 6-17.

Box plots of PsVNA ID_{80} titers by baseline SARS-CoV-2 status and age group for mRNA-1273 treated participants and placebo can be found in Section 14 (Figure 14.2.4.2.4.3.1 and Figure 14.2.4.2.4.4.1).

Table 6-16: Summary of Pseudovirus Neutralizing Antibody ID_{50} and ID_{80} Titers by Baseline SARS-CoV-2 Status (Per-Protocol Random Subcohort for Immunogenicity)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline SARS-CoV-2 Status: Negative		
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)		
Baseline (day 1)		
n [a]	142	1052
GM titer	9.250	9.624
95% CI [b]	(NE, NE)	(9.35, 9.90)
Median	9.250	9.250
Min, Max	9.25, 9.25	9.25, 18997.56
Day 29		
n [a]	142	1055
GM titer	9.515	54.866
95% CI [b]	(9.00, 10.06)	(50.98, 59.04)
Median	9.250	55.527
Min, Max	9.25, 512.90	9.25, 26386.22
N1	142	1052
GM fold-rise	1.03	5.69
95% CI [b]	(0.97, 1.09)	(5.29, 6.12)
Seroresponse [c]		
n (%) [d]	1 (0.7)	856 (81.4)
95% CI [e]	(0.0, 3.9)	(78.9, 83.7)
>= 4-fold increase from baseline [f]		
n (%) [d]	1 (0.7)	437 (41.5)
95% CI [e]	(0.0, 3.9)	(38.5, 44.6)
Day 57		
n [a]	142	1053
GM titer	9.903	1081.124
95% CI [b]	(8.99, 10.90)	(1019.80, 1146.14)
Median	9.250	1060.676
Min, Max	9.25, 2616.89	9.25, 63402.68
N1	142	1050
GM fold-rise	1.07	112.30
95% CI [b]	(0.97, 1.18)	(105.42, 119.62)
Seroresponse [c]		
n (%) [d]	2 (1.4)	1038 (98.9)
95% CI [e]	(0.2, 5.0)	(98.0, 99.4)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
>= 4-fold increase from baseline [f]		
n (%) [d]	2 (1.4)	1033 (98.4)
95% CI [e]	(0.2, 5.0)	(97.4, 99.1)
Baseline SARS-CoV-2 Status: Negative		
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)		
Baseline (day 1)		
n [a]	142	1052
GM titer	7.150	7.332
95% CI [b]	(NE, NE)	(7.18, 7.49)
Median	7.150	7.150
Min, Max	7.15, 7.15	7.15, 4341.61
Day 29		
n [a]	142	1055
GM titer	7.279	19.684
95% CI [b]	(7.03, 7.54)	(18.55, 20.89)
Median	7.150	18.282
Min, Max	7.15, 90.31	7.15, 5105.99
N1	142	1052
GM fold-rise	1.02	2.68
95% CI [b]	(0.98, 1.05)	(2.53, 2.84)
Seroresponse [c]		
n (%) [d]	1 (0.7)	663 (63.0)
95% CI [e]	(0.0, 3.9)	(60.0, 65.9)
>= 4-fold increase from baseline [f]		
n (%) [d]	1 (0.7)	182 (17.3)
95% CI [e]	(0.0, 3.9)	(15.1, 19.7)
Day 57		
n [a]	142	1053
GM titer	7.522	334.867
95% CI [b]	(7.00, 8.09)	(317.84, 352.81)
Median	7.150	365.886
Min, Max	7.15, 583.06	7.15, 6798.73
N1	142	1050
GM fold-rise	1.05	45.62
95% CI [b]	(0.98, 1.13)	(43.21, 48.17)
Seroresponse [c]		
n (%) [d]	2 (1.4)	1038 (98.9)
95% CI [e]	(0.2, 5.0)	(98.0, 99.4)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
>= 4-fold increase from baseline [f]		
n (%) [d]	2 (1.4)	1023 (97.4)
95% CI [e]	(0.2, 5.0)	(96.3, 98.3)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Baseline SARS-CoV-2 Status: Positive		
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)		
Baseline (day 1)		
n [a]	129	130
GM titer	82.519	68.117
95% CI [b]	(59.40, 114.64)	(49.88, 93.02)
Median	68.199	67.343
Min, Max	9.25, 135391.03	9.25, 258320.14
Day 29		
n [a]	129	130
GM titer	52.728	1478.910
95% CI [b]	(39.45, 70.48)	(1069.60, 2044.86)
Median	45.877	2485.351
Min, Max	9.25, 48317.06	9.25, 68671.79
N1	128	130
GM fold-rise	0.64	21.71
95% CI [b]	(0.56, 0.73)	(16.08, 29.32)
Seroresponse [c]		
n (%) [d]	1 (0.8)	114 (87.7)
95% CI [e]	(0.0, 4.3)	(80.8, 92.8)
>= 4-fold increase from baseline [f]		
n (%) [d]	0	102 (78.5)
95% CI [e]	(0.0, 2.8)	(70.4, 85.2)
Day 57		
n [a]	130	130
GM titer	47.708	3145.904
95% CI [b]	(35.41, 64.28)	(2539.80, 3896.66)
Median	37.961	3337.000
Min, Max	9.25, 49231.00	9.25, 54959.75
N1	129	130
GM fold-rise	0.59	46.18
95% CI [b]	(0.50, 0.69)	(34.10, 62.55)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Seroresponse [c]		
n (%) [d]	2 (1.6)	123 (94.6)
95% CI [e]	(0.2, 5.5)	(89.2, 97.8)
>= 4-fold increase from baseline [f]		
n (%) [d]	1 (0.8)	123 (94.6)
95% CI [e]	(0.0, 4.2)	(89.2, 97.8)
Baseline SARS-CoV-2 Status: Positive		
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)		
Baseline (day 1)		
n [a]	129	130
GM titer	29.580	24.996
95% CI [b]	(22.39, 39.09)	(19.12, 32.68)
Median	21.162	18.572
Min, Max	7.15, 42704.93	7.15, 60964.89
Day 29		
n [a]	129	130
GM titer	20.994	518.388
95% CI [b]	(16.42, 26.84)	(380.39, 706.44)
Median	15.843	776.746
Min, Max	7.15, 12132.57	7.15, 16637.72
N1	128	130
GM fold-rise	0.71	20.74
95% CI [b]	(0.64, 0.79)	(15.30, 28.10)
Seroresponse [c]		
n (%) [d]	4 (3.1)	117 (90.0)
95% CI [e]	(0.9, 7.8)	(83.5, 94.6)
>= 4-fold increase from baseline [f]		
n (%) [d]	0	99 (76.2)
95% CI [e]	(0.0, 2.8)	(67.9, 83.2)
Day 57		
n [a]	130	130
GM titer	19.228	1099.847
95% CI [b]	(15.03, 24.60)	(903.83, 1338.37)
Median	14.911	1367.157
Min, Max	7.15, 8168.14	7.15, 19222.41
N1	129	130
GM fold-rise	0.66	44.00
95% CI [b]	(0.57, 0.75)	(33.99, 56.97)
Seroresponse [c]		
n (%) [d]	3 (2.3)	125 (96.2)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
95% CI [e]	(0.5, 6.6)	(91.3, 98.7)
>= 4-fold increase from baseline [f]		
n (%) [d]	1 (0.8)	124 (95.4)
95% CI [e]	(0.0, 4.2)	(90.2, 98.3)

Abbreviations: CI = confidence intervals; Min = minimum; Max = maximum; GM = geometric mean.

N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

[a] Number of subjects with non-missing data at the corresponding timepoint.

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

[c] Seroresponse to pseudovirus neutralizing antibody ID_{50} titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 3.3-fold rise if baseline is equal to or above the LLOQ. Seroresponse to pseudovirus neutralizing antibody ID_{80} titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 2.3-fold rise if baseline is equal to or above the LLOQ.

[d] Number of subjects meeting the criterion at the time point. Percentages are based on N1.

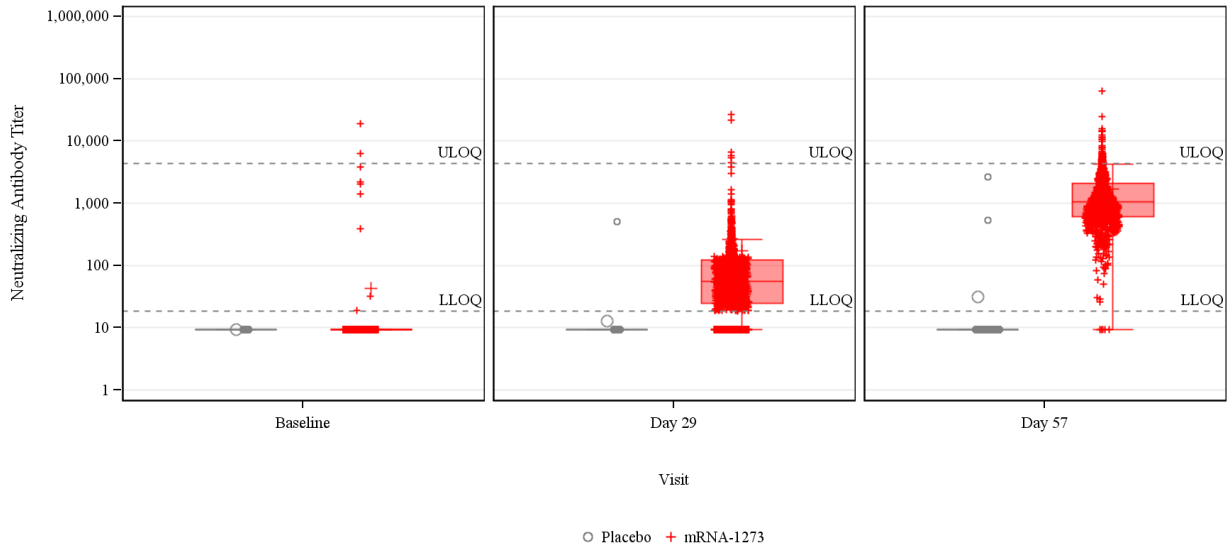
[e] 95% CI is calculated using the Clopper-Pearson method.

[f] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody titer below LLOQ, or a z-times or higher titer ratio in participants with baseline antibody titer equal to or above the LLOQ.

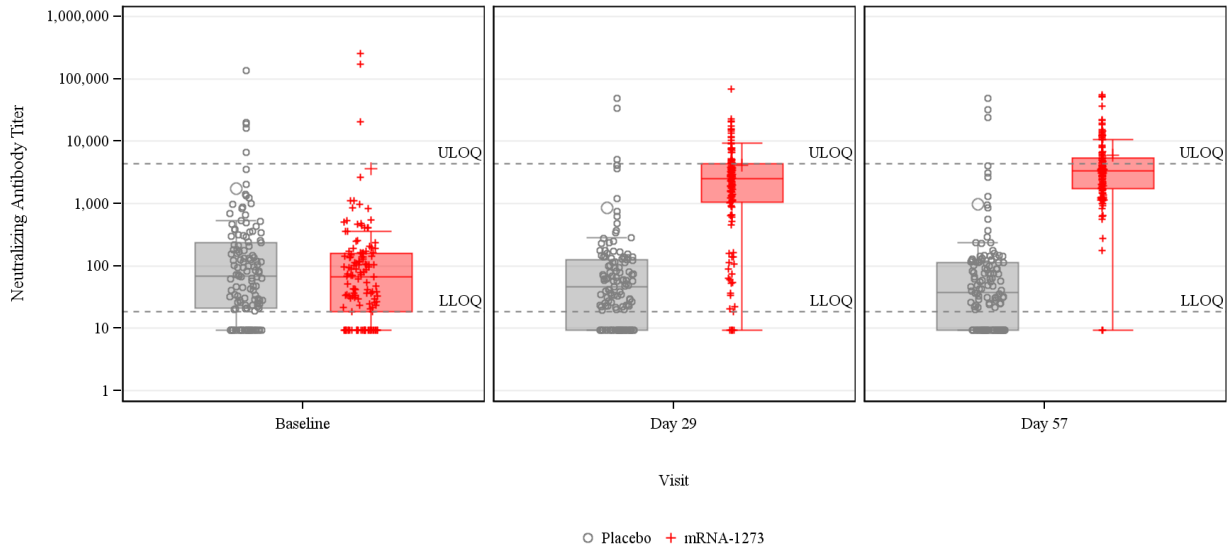
Source: Table 14.2.4.2.1.3.1.

Figure 6-7: Box Plot of Pseudovirus Neutralizing Antibody ID_{50} titers Neutralizing Specific to SARS-CoV-2 S-Protein by Pseudotyped Virus Neutralization Assay by Baseline SARS-CoV-2 Status (Per-Protocol Random Subcohort for Immunogenicity)

Baseline SARS-CoV-2 Status: negative
Antibody: Pseudovirus Neutralizing Antibody ID_{50} Titers (LLOQ: 18.5, ULOQ: 4404)



Baseline SARS-CoV-2 Status: positive
Antibody: Pseudovirus Neutralizing Antibody ID_{50} Titers (LLOQ: 18.5, ULOQ: 4404)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by ULOQ if actual values are not available.
Source: Figure 14.2.4.2.4.3.1.

Table 6-17: Summary of Pseudovirus Neutralizing Antibody ID_{50} and ID_{80} Titers by Baseline SARS-CoV-2 Status and Age Group (Per-Protocol Random Subcohort for Immunogenicity)

	>=18 and <65 Years		>=65 Years	
Timepoint **Data Category** **Statistic**	**Placebo** **(N=94)**	**mRNA-1273** **(N=700)**	**Placebo** **(N=48)**	**mRNA-1273** **(N=355)**
Baseline SARS-CoV-2 Status: Negative				
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)				
Baseline (day 1)				
n [a]	94	699	48	353
GM titer	9.250	9.767	9.250	9.348
95% CI [b]	(NE, NE)	(9.37, 10.18)	(NE, NE)	(9.16, 9.54)
Median	9.250	9.250	9.250	9.250
Min, Max	9.25, 9.25	9.25, 18997.56	9.25, 9.25	9.25, 385.04
Day 29				
n [a]	94	700	48	355
GM titer	9.250	66.828	10.057	37.188
95% CI [b]	(NE, NE)	(61.14, 73.04)	(8.50, 11.90)	(32.97, 41.94)
Median	9.250	69.063	9.250	33.600
Min, Max	9.25, 9.25	9.25, 26386.22	9.25, 512.90	9.25, 1087.16
N1	94	699	48	353
GM fold-rise	1.00	6.84	1.09	3.95
95% CI [b]	(NE, NE)	(6.26, 7.47)	(0.92, 1.29)	(3.50, 4.46)
Seroresponse [c]				
n (%) [d]	0	605 (86.6)	1 (2.1)	251 (71.1)
95% CI [e]	(0.0, 3.8)	(83.8, 89.0)	(0.1, 11.1)	(66.1, 75.8)
>= 4-fold increase from baseline [f]				
n (%) [d]	0	330 (47.2)	1 (2.1)	107 (30.3)
95% CI [e]	(0.0, 3.8)	(43.5, 51.0)	(0.1, 11.1)	(25.6, 35.4)
Day 57				

	>=18 and <65 Years		>=65 Years	
Timepoint				
Data Category	**Placebo**	**mRNA-1273**	**Placebo**	**mRNA-1273**
Statistic	**(N=94)**	**(N=700)**	**(N=48)**	**(N=355)**
n [a]	94	698	48	355
GM titer	9.823	1206.589	10.063	871.203
95% CI [b]	(8.72, 11.07)	(1125.71, 1293.28)	(8.49, 11.92)	(785.48, 966.29)
Median	9.250	1163.740	9.250	829.568
Min, Max	9.25, 2616.89	9.25, 63402.68	9.25, 526.79	9.25, 11494.25
N1	94	697	48	353
GM fold-rise	1.06	123.56	1.09	92.98
95% CI [b]	(0.94, 1.20)	(114.34, 133.53)	(0.92, 1.29)	(83.57, 103.45)
Seroresponse [c]				
n (%) [d]	1 (1.1)	687 (98.6)	1 (2.1)	351 (99.4)
95% CI [e]	(0.0, 5.8)	(97.4, 99.3)	(0.1, 11.1)	(98.0, 99.9)
>= 4-fold increase from baseline [f]				
n (%) [d]	1 (1.1)	686 (98.4)	1 (2.1)	347 (98.3)
95% CI [e]	(0.0, 5.8)	(97.2, 99.2)	(0.1, 11.1)	(96.3, 99.4)
Baseline SARS-CoV-2 Status: Negative				
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)				
Baseline (day 1)				
n [a]	94	699	48	353
GM titer	7.150	7.400	7.150	7.199
95% CI [b]	(NE, NE)	(7.18, 7.63)	(NE, NE)	(7.10, 7.30)
Median	7.150	7.150	7.150	7.150
Min, Max	7.15, 7.15	7.15, 4341.61	7.15, 7.15	7.15, 78.00
Day 29				
n [a]	94	700	48	355
GM titer	7.150	23.065	7.538	14.401
95% CI [b]	(NE, NE)	(21.40, 24.85)	(6.78, 8.38)	(13.16, 15.76)

	>=18 and <65 Years		>=65 Years	
Timepoint				
Data Category	**Placebo**	**mRNA-1273**	**Placebo**	**mRNA-1273**
Statistic	**(N=94)**	**(N=700)**	**(N=48)**	**(N=355)**
Median	7.150	20.713	7.150	7.150
Min, Max	7.15, 7.15	7.15, 5105.99	7.15, 90.31	7.15, 319.10
N1	94	699	48	353
GM fold-rise	1.00	3.12	1.05	1.99
95% CI [b]	(NE, NE)	(2.90, 3.35)	(0.95, 1.17)	(1.82, 2.18)
Seroresponse [c]				
n (%) [d]	0	497 (71.1)	1 (2.1)	166 (47.0)
95% CI [e]	(0.0, 3.8)	(67.6, 74.4)	(0.1, 11.1)	(41.7, 52.4)
>= 4-fold increase from baseline [f]				
n (%) [d]	0	142 (20.3)	1 (2.1)	40 (11.3)
95% CI [e]	(0.0, 3.8)	(17.4, 23.5)	(0.1, 11.1)	(8.2, 15.1)
Day 57				
n [a]	94	698	48	355
GM titer	7.493	373.287	7.579	270.474
95% CI [b]	(6.83, 8.22)	(351.16, 396.80)	(6.74, 8.52)	(246.15, 297.20)
Median	7.150	387.675	7.150	306.371
Min, Max	7.15, 583.06	7.15, 6798.73	7.15, 117.11	7.15, 2863.73
N1	94	697	48	353
GM fold-rise	1.05	50.45	1.06	37.40
95% CI [b]	(0.95, 1.15)	(47.28, 53.84)	(0.94, 1.19)	(33.99, 41.15)
Seroresponse [c]				
n (%) [d]	1 (1.1)	689 (98.9)	1 (2.1)	349 (98.9)
95% CI [e]	(0.0, 5.8)	(97.8, 99.5)	(0.1, 11.1)	(97.1, 99.7)
>= 4-fold increase from baseline [f]				
n (%) [d]	1 (1.1)	683 (98.0)	1 (2.1)	340 (96.3)
95% CI [e]	(0.0, 5.8)	(96.7, 98.9)	(0.1, 11.1)	(93.8, 98.0)

Timepoint Data Category Statistic	>=18 and <65 Years Placebo (N=110)	>=18 and <65 Years mRNA-1273 (N=107)	>=65 Years Placebo (N=20)	>=65 Years mRNA-1273 (N=23)
Baseline SARS-CoV-2 Status: Positive				
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)				
Baseline (day 1)				
n [a]	110	107	19	23
GM titer	83.804	69.563	75.461	61.774
95% CI [b]	(58.48, 120.09)	(49.20, 98.36)	(31.17, 182.69)	(28.63, 133.27)
Median	67.612	66.753	93.412	70.090
Min, Max	9.25, 135391.03	9.25, 258320.14	9.25, 1348.36	9.25, 1108.98
Day 29				
n [a]	110	107	19	23
GM titer	53.238	1722.766	49.868	727.067
95% CI [b]	(38.66, 73.31)	(1235.17, 2402.85)	(23.78, 104.59)	(269.07, 1964.65)
Median	43.814	2602.959	68.673	2081.484
Min, Max	9.25, 48317.06	9.25, 68671.79	9.25, 629.82	9.25, 11895.95
N1	110	107	18	23
GM fold-rise	0.64	24.77	0.69	11.77
95% CI [b]	(0.55, 0.73)	(17.93, 34.21)	(0.48, 0.98)	(5.28, 26.23)
Seroresponse [c]				
n (%) [d]	1 (0.9)	96 (89.7)	0	18 (78.3)
95% CI [e]	(0.0, 5.0)	(82.3, 94.8)	(0.0, 18.5)	(56.3, 92.5)
>= 2-fold increase from baseline [f]				
n (%) [d]	2 (1.8)	97 (90.7)	1 (5.6)	18 (78.3)
95% CI [e]	(0.2, 6.4)	(83.5, 95.4)	(0.1, 27.3)	(56.3, 92.5)
>= 3-fold increase from baseline [f]				
n (%) [d]	1 (0.9)	94 (87.9)	0	14 (60.9)

Timepoint Data Category Statistic	>=18 and <65 Years Placebo (N=110)	>=18 and <65 Years mRNA-1273 (N=107)	>=65 Years Placebo (N=20)	>=65 Years mRNA-1273 (N=23)
95% CI [e]	(0.0, 5.0)	(80.1, 93.4)	(0.0, 18.5)	(38.5, 80.3)
>= 4-fold increase from baseline [f]				
n (%) [d]	0	88 (82.2)	0	14 (60.9)
95% CI [e]	(0.0, 3.3)	(73.7, 89.0)	(0.0, 18.5)	(38.5, 80.3)
Day 57				
n [a]	110	107	20	23
GM titer	47.158	3108.874	50.846	3324.057
95% CI [b]	(34.37, 64.71)	(2432.91, 3972.65)	(20.03, 129.08)	(2142.62, 5156.94)
Median	39.899	3317.995	29.833	3359.011
Min, Max	9.25, 49231.00	9.25, 54959.75	9.25, 32343.08	276.41, 22307.78
N1	110	107	19	23
GM fold-rise	0.56	44.69	0.74	53.81
95% CI [b]	(0.48, 0.66)	(31.70, 63.00)	(0.40, 1.35)	(27.42, 105.62)
Seroresponse [c]				
n (%) [d]	1 (0.9)	101 (94.4)	1 (5.3)	22 (95.7)
95% CI [e]	(0.0, 5.0)	(88.2, 97.9)	(0.1, 26.0)	(78.1, 99.9)
>= 2-fold increase from baseline [f]				
n (%) [d]	3 (2.7)	101 (94.4)	1 (5.3)	23 (100)
95% CI [e]	(0.6, 7.8)	(88.2, 97.9)	(0.1, 26.0)	(85.2, 100.0)
>= 3-fold increase from baseline [f]				
n (%) [d]	1 (0.9)	101 (94.4)	1 (5.3)	22 (95.7)
95% CI [e]	(0.0, 5.0)	(88.2, 97.9)	(0.1, 26.0)	(78.1, 99.9)
>= 4-fold increase from baseline [f]				
n (%) [d]	0	101 (94.4)	1 (5.3)	22 (95.7)
95% CI [e]	(0.0, 3.3)	(88.2, 97.9)	(0.1, 26.0)	(78.1, 99.9)

Timepoint Data Category Statistic	>=18 and <65 Years Placebo (N=110)	>=18 and <65 Years mRNA-1273 (N=107)	>=65 Years Placebo (N=20)	>=65 Years mRNA-1273 (N=23)
Baseline SARS-CoV-2 Status: Positive				
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)				
Baseline (day 1)				
n [a]	110	107	19	23
GM titer	29.175	24.754	32.036	26.152
95% CI [b]	(21.41, 39.75)	(18.27, 33.54)	(16.33, 62.83)	(14.44, 47.35)
Median	20.189	17.341	24.358	19.802
Min, Max	7.15, 42704.93	7.15, 60964.89	7.15, 363.63	7.15, 285.67
Day 29				
n [a]	110	107	19	23
GM titer	20.672	607.318	22.956	248.180
95% CI [b]	(15.74, 27.15)	(443.66, 831.34)	(12.69, 41.53)	(94.05, 654.89)
Median	15.839	861.455	18.862	660.308
Min, Max	7.15, 12132.57	7.15, 16637.72	7.15, 219.21	7.15, 3812.03
N1	110	107	18	23
GM fold-rise	0.71	24.53	0.73	9.49
95% CI [b]	(0.63, 0.80)	(17.70, 34.01)	(0.54, 1.00)	(4.37, 20.61)
Seroresponse [c]				
n (%) [d]	3 (2.7)	99 (92.5)	1 (5.6)	18 (78.3)
95% CI [e]	(0.6, 7.8)	(85.8, 96.7)	(0.1, 27.3)	(56.3, 92.5)
>= 2-fold increase from baseline [f]				
n (%) [d]	0	94 (87.9)	1 (5.6)	17 (73.9)
95% CI [e]	(0.0, 3.3)	(80.1, 93.4)	(0.1, 27.3)	(51.6, 89.8)
>= 3-fold increase from baseline [f]				
n (%) [d]	0	93 (86.9)	1 (5.6)	15 (65.2)
95% CI [e]	(0.0, 3.3)	(79.0, 92.7)	(0.1, 27.3)	(42.7, 83.6)
>= 4-fold increase from baseline [f]				

Timepoint Data Category Statistic	>=18 and <65 Years Placebo (N=110)	>=18 and <65 Years mRNA-1273 (N=107)	>=65 Years Placebo (N=20)	>=65 Years mRNA-1273 (N=23)
n (%) [d]	0	85 (79.4)	0	14 (60.9)
95% CI [e]	(0.0, 3.3)	(70.5, 86.6)	(0.0, 18.5)	(38.5, 80.3)
Day 57				
n [a]	110	107	20	23
GM titer	18.774	1097.788	21.932	1109.478
95% CI [b]	(14.50, 24.31)	(878.34, 1372.06)	(9.82, 49.01)	(723.29, 1701.87)
Median	15.076	1301.842	7.150	1539.763
Min, Max	7.15, 8168.14	7.15, 19222.41	7.15, 7142.49	93.78, 4498.33
N1	110	107	19	23
GM fold-rise	0.64	44.35	0.73	42.42
95% CI [b]	(0.56, 0.74)	(32.98, 59.63)	(0.43, 1.23)	(25.01, 71.97)
Seroresponse [c]				
n (%) [d]	2 (1.8)	102 (95.3)	1 (5.3)	23 (100)
95% CI [e]	(0.2, 6.4)	(89.4, 98.5)	(0.1, 26.0)	(85.2, 100.0)
>= 4-fold increase from baseline [f]				
n (%) [d]	0	102 (95.3)	1 (5.3)	22 (95.7)
95% CI [e]	(0.0, 3.3)	(89.4, 98.5)	(0.1, 26.0)	(78.1, 99.9)

Abbreviations: CI = confidence intervals; Min = minimum; Max = maximum.

N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

[a] Number of subjects with non-missing data at the corresponding timepoint.

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

[c] Seroresponse to pseudovirus neutralizing antibody ID_{50} titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 3.3-fold rise if baseline is equal to or above the LLOQ. Seroresponse to pseudovirus neutralizing antibody ID_{80} titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 2.3-fold rise if baseline is equal to or above the LLOQ.

	>=18 and <65 Years		>=65 Years	
Timepoint **Data Category** **Statistic**	**Placebo (N=110)**	**mRNA-1273 (N=107)**	**Placebo (N=20)**	**mRNA-1273 (N=23)**

[d] Number of subjects meeting the criterion at the time point. Percentages are based on N1.

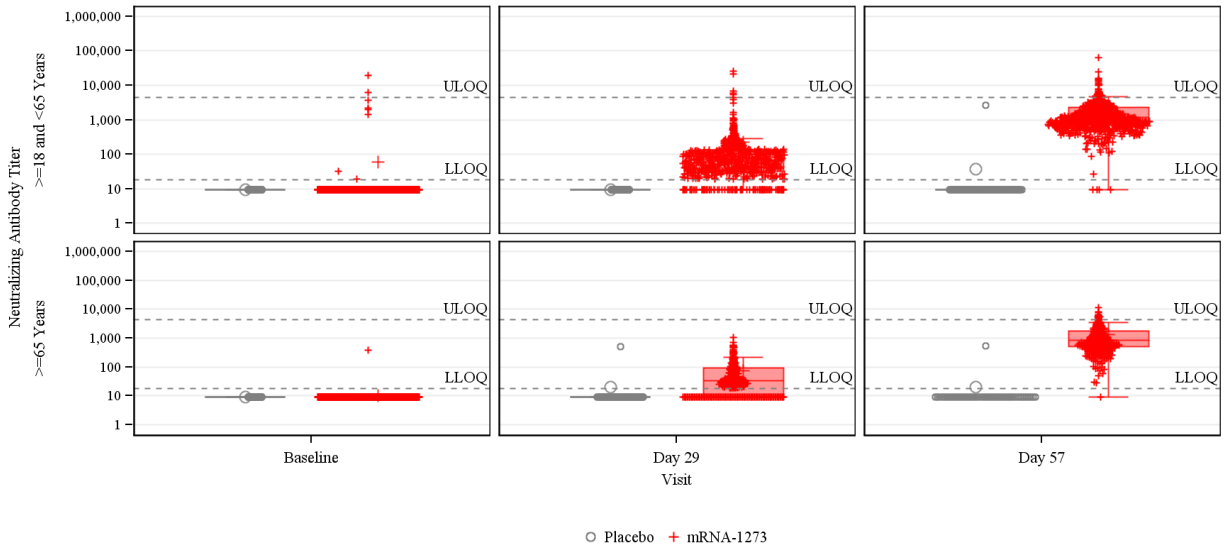
[e] 95% CI is calculated using the Clopper-Pearson method.

[f] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody titer below LLOQ, or a z-times or higher titer ratio in participants with baseline antibody titer equal to or above the LLOQ.

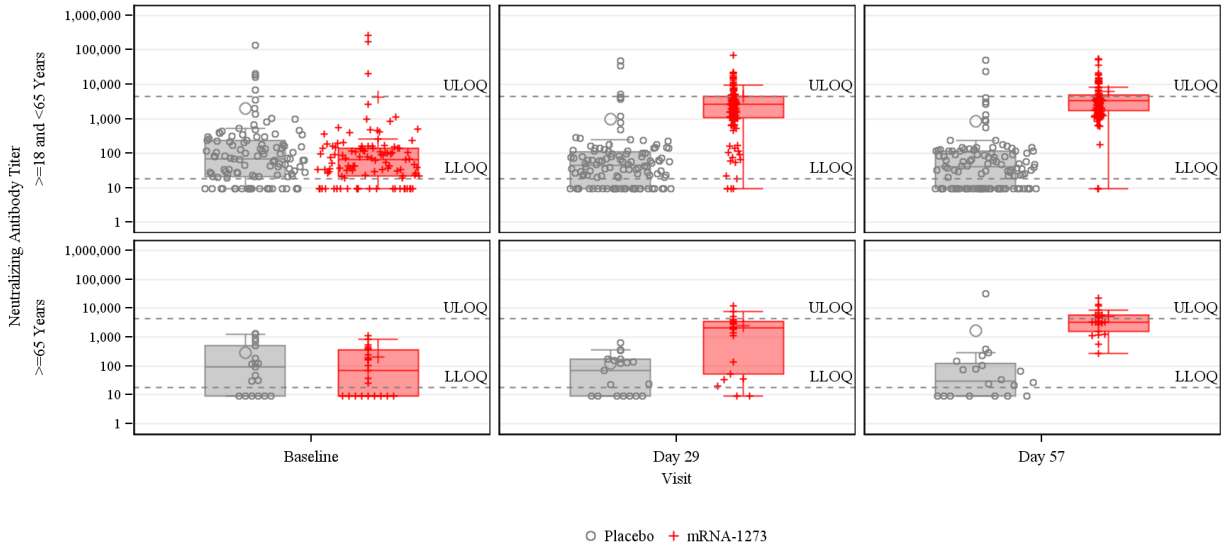
Source: Table 14.2.4.2.1.4.1.

Figure 6-8: Box Plot of Pseudovirus Neutralizing Antibody ID_{50} titers Neutralizing Specific to SARS-CoV-2 S-Protein by Pseudotyped Virus Neutralization Assay by Baseline SARS-CoV-2 Status and Age Group (Per-Protocol Random Subcohort for Immunogenicity)

Baseline SARS-CoV-2 Status: negative
Antibody: Pseudovirus Neutralizing Antibody ID_{50} Titers (LLOQ: 18.5, ULOQ: 4404)



Baseline SARS-CoV-2 Status: positive
Antibody: Pseudovirus Neutralizing Antibody ID_{50} Titers (LLOQ: 18.5, ULOQ: 4404)



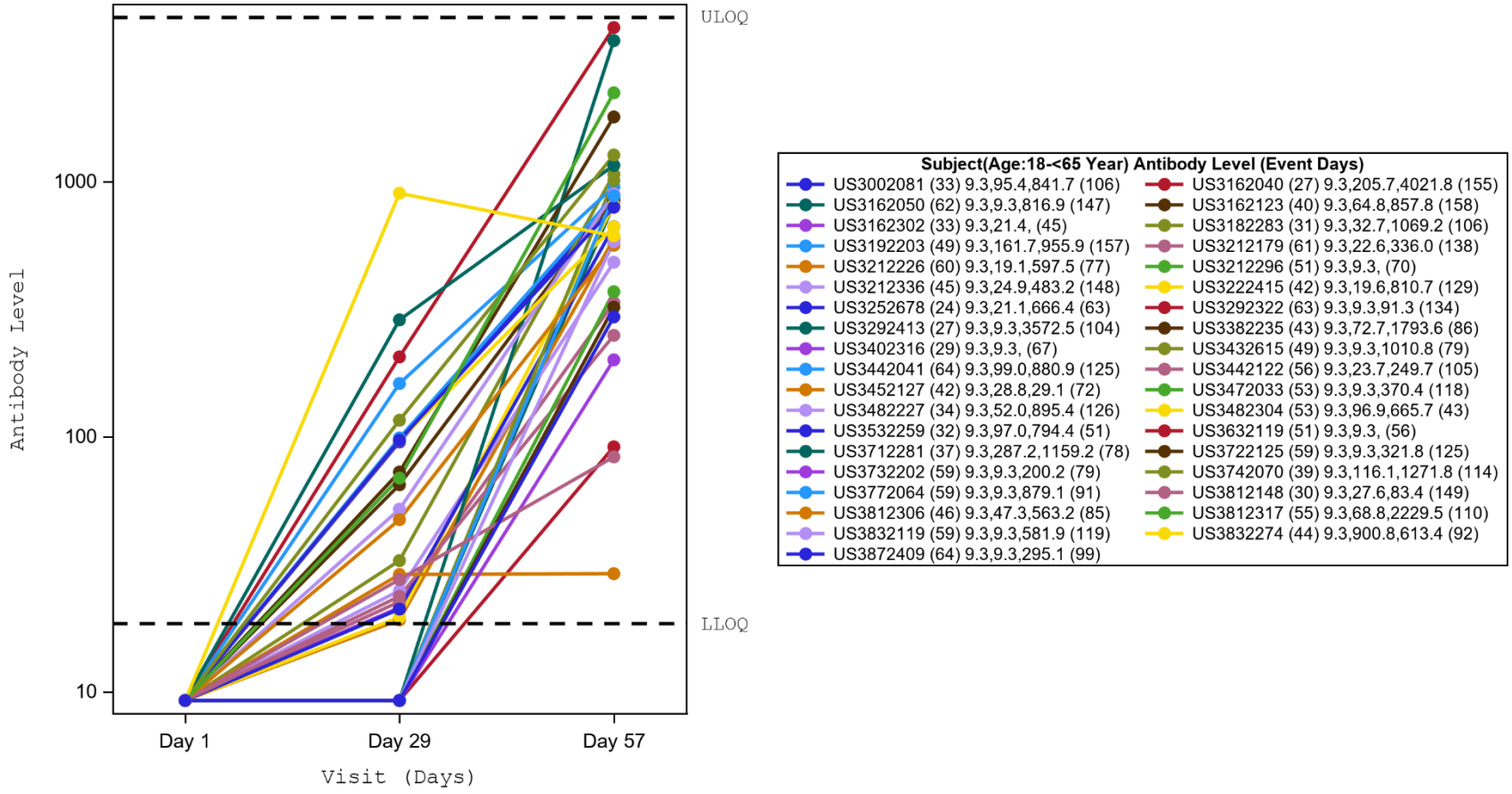
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by ULOQ if actual values are not available.
Source: Figure 14.2.4.2.4.4.1.

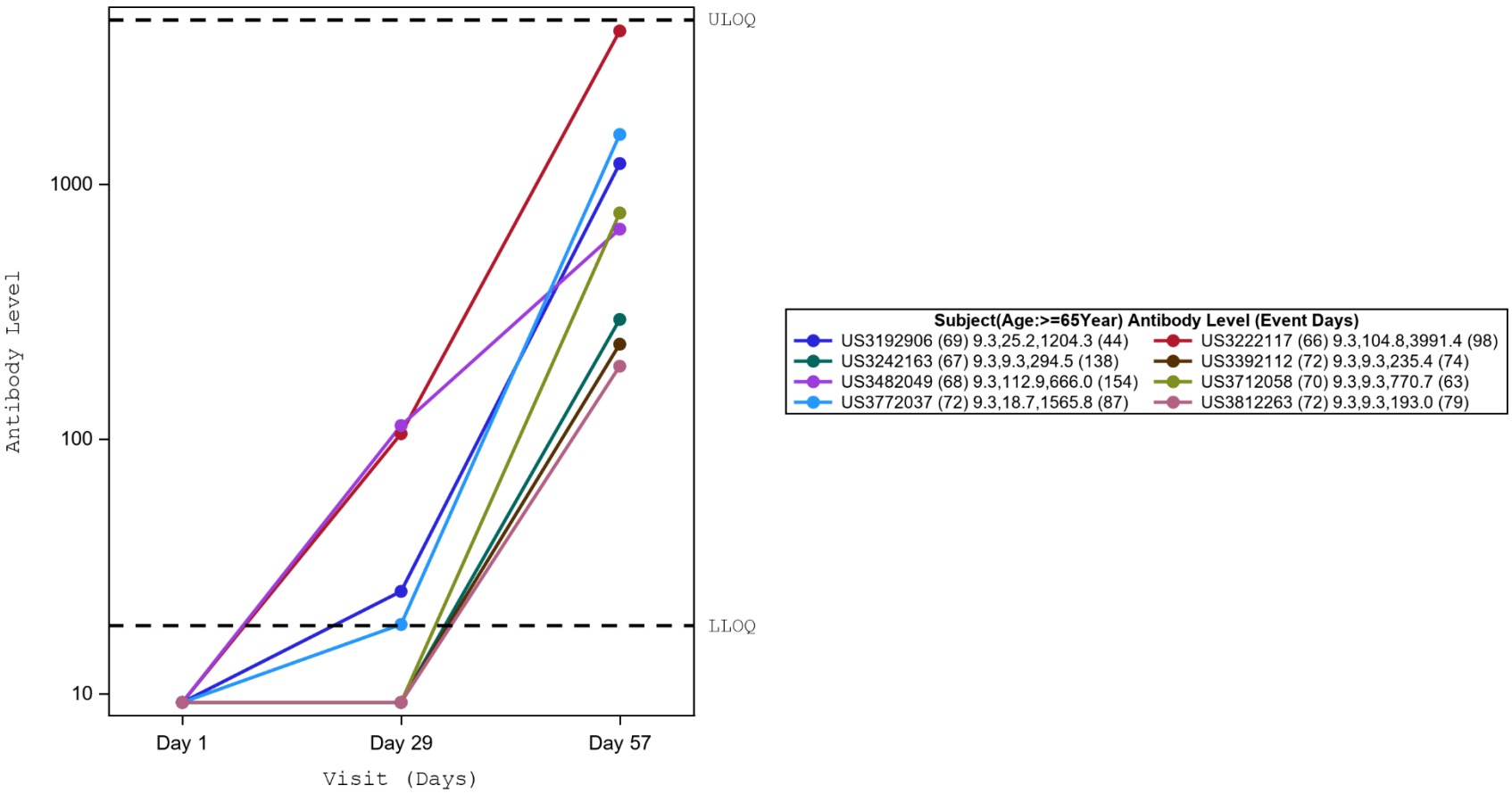
6.5.2 Analysis of Breakthrough COVID-19 Cases

Available nAb data in mRNA-1273 participants who were adjudicated COVID-19 cases starting 14 days after second injection in the PP Set are presented in Figure 6-9. These results appeared similar to those for the overall study population (Figure 6-7). Results for bAb levels as measured by MSD or ELISA assay are presented in Section 14 (Figure 16.2.2.1.3.1.1.3 and Figure 16.2.2.1.3.1.1.4, respectively).

Overall, while vaccination with mRNA-1273 was highly immunogenic and protective against COVID-19, breakthrough cases occurred and there was no apparent bAb level or nAb titer through Day 57 that was predictive of the presence or absence of breakthrough COVID-19 cases.

Figure 6-9: Plot of Pseudovirus Neutralizing Antibody ID_{50} in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection (Per-Protocol Set)





COVID-19 cases with corresponding immunogenicity data available

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Source: Figure 16.2.2.1.3.1.1.1.

6.6 Drug Dose, Drug Concentration, and Relationships to Response

Not applicable.

6.7 Drug-Drug and Drug-Disease Interaction

Not applicable.

6.8 By-Participant Displays

By-participant displays are in Appendix 16.2.

6.9 Efficacy Conclusions

6.9.1 Primary Efficacy Conclusions

The primary efficacy endpoint was VE of mRNA-1273 to prevent the first occurrence of adjudicated COVID-19 starting 14 days after the second injection of IP in the PP Set.

The final efficacy analysis of the primary endpoint for Part A (04 May 2021) included 799 cases. The results of this analysis were consistent with the results of the interim and primary efficacy analyses, confirming persistent, high efficacy over a substantially larger case database over a longer median observation period of over 5.3 months. For the final efficacy analysis, the VE point estimate was 93.2% ($p < 0.0001$) and within the 95% CIs of the VE point estimates for the interim and primary efficacy analyses.

- Divergence of case incidence began early between mRNA-1273 and placebo groups, starting in the period from randomization up to 14 days after the first injection. Thereafter, cumulative incidence rate for the placebo group increased steadily while it remained stable and low in the mRNA-1273 group for the remainder of the observation period.
- Vaccine efficacy was consistent across subgroups for the primary efficacy endpoint.

6.9.2 Secondary Efficacy Conclusions

The VE of mRNA-1273 to prevent adjudicated severe COVID-19 cases starting 14 days after second injection was consistent with the VE for the primary endpoint and was numerically higher than the VE for the primary endpoint.

- For the final analysis of efficacy for Part A, 108 participants had adjudicated severe COVID-19 starting 14 days after second injection in the PP Set (106 cases in the placebo group and 2 cases in the mRNA-1273 group); the VE point estimate based on the hazard ratio was 98.2%, confirming and extending the primary analysis of 25 Nov 2020 based on more than 3 times as many cases accrued over an approximately 2 times longer period of observation.
- Divergence of case incidence of severe COVID-19 began early between mRNA-1273 and placebo groups, starting in the period from 7 to 14 days after the first injection.
- Subgroup analyses were consistent with the primary analysis of efficacy and the point estimates of efficacy remained very high. Consistent VE point estimates were observed in subgroup analyses of participants with 1 risk factor, at least 2 risk factors, chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, and HIV infection.

The VE of mRNA-1273 to prevent SARS-CoV-2 infection, regardless of COVID-19 symptomatology and severity, starting 14 days after second injection was consistent with the VE for the primary endpoint.

- Including the RT-PCR and Elecsys results from the PDV, a total of 1,619 participants had a SARS-CoV-2 infection starting 14 days after second injection in the PP Set (1,339 cases in the placebo group and 280 cases in the mRNA-1273 group); the VE point estimate based on the hazard ratio was 82.0%.
- Compared to the primary endpoint analyses, there were similar early onset of divergence in case incidence between treatment groups and similar stable and low rate of incidence rate for mRNA-1273 with increasing incidence rate in the placebo group.
- There were consistent, high VE point estimates across subgroups.

For the less restrictive secondary definition of COVID-19, the VE of mRNA-1273 was consistent with the VE for the primary endpoint, indicating that mRNA-1273 is efficacious even against mild COVID-19.

The VE to prevent asymptomatic SARS-CoV-2 infection was analyzed in the PP Set, including the RT-PCR and Elecsys results from the PDV, based on a total of 712 participants who had an asymptomatic SARS-CoV-2 infection starting 14 days after randomization (498 cases in the placebo group and 214 cases in the mRNA-1273 group). The VE point estimate based on the hazard ratio was 63.0%. This analysis confirms that vaccination with mRNA-1273 protects against asymptomatic infection (albeit at a lower VE than for symptomatic cases).

6.9.3 Immunogenicity Conclusions

mRNA-1273 was highly immunogenic as measured by both bAb and nAb in both SARS-CoV-2 baseline-negative and baseline-positive individuals, as indicated by increased bAb and nAb levels 1 month after first injection (Day 29) and 1 month after second injection (Day 57).

Antibody levels at Day 29 in baseline-positive mRNA-1273 treated participants were similar to those observed at Day 57 in baseline-negative participants, indicating that the first injection of mRNA-1273 acts like a booster in participants with previous SARS-CoV-2 infection.

Among SARS-CoV-2 baseline-negative mRNA-1273 treated participants, seroresponse by bAb assay exceeded 99% at both Day 29 and Day 57, while seroresponse by nAb assay was 81.4% at Day 29 and 98.9% at Day 57.

Similar results were observed for subgroups stratified by age (≥ 18 to < 65 years and ≥ 65 years) in both SARS-CoV-2 baseline-negative and baseline-positive mRNA-1273 treated participants.

While vaccination with mRNA-1273 was highly immunogenic and protective against COVID-19, breakthrough cases occurred and there was no apparent bAb level or nAb titer through Day 57 that was predictive of the presence or absence of breakthrough COVID-19 cases.

7 SAFETY RESULTS

Safety analyses results are based on the final analysis of Part A based on a database lock of 04 May 2021, unless otherwise specified.

7.1 Solicited Adverse Reactions

Participants recorded solicited local and systemic ARs in the eDiary on the day of each IP injection and during the 7 days after each IP injection (Section 3.7.1.1). If ARs persisted beyond 7 days, the eDiary solicited entries until the ARs subsided.

7.1.1 Incidence and Severity of Solicited Adverse Reactions Starting Within 7 Days After Injection

Observations for solicited ARs were consistent with earlier clinical trials with the mRNA-1273 vaccine. Incidence of local and systemic ARs was higher in the mRNA-1273 group than in the placebo group, and in the mRNA-1273 group, incidence was higher after the second injection than after the first. Most solicited ARs were grade 1 to grade 2 in severity and the severity tended to increase after the second injection.

Incidence of solicited local ARs was higher in the mRNA-1273 group (84.2%) than in the placebo group (19.9%) after the first injection (Table 7-1) and after the second injection (88.7% in the mRNA-1273 group compared with 18.9% in the placebo group) (Table 7-2). Pain was the most commonly reported local AR in the mRNA-1273 group after both injections, and incidence was higher after the second injection (83.7% after the first injection and 88.3% after the second injection). In the mRNA-1273 group, grade 3 solicited local ARs were more common after the second injection (7.0%) than after the first (3.5%). Grade 3 local ARs occurred infrequently in the placebo group after either injection. Pain was the event most commonly reported grade 3 local AR in the mRNA-1273 group after both injections, and the incidence of grade 3 pain was higher after the second injection (2.7% after the first injection and 4.1% after the second injection). Grade 3 pain in the mRNA-1273 group was the only grade 3 solicited local AR reported at a frequency > 2% after either injection. No grade 4 solicited local ARs were reported.

Incidence of solicited systemic ARs was higher in the mRNA-1273 group (54.8%) than in the placebo group (42.2%) after the first injection (Table 7-1) and after the second injection (79.5% in the mRNA-1273 group compared with 36.7% in the placebo group) (Table 7-2). In the mRNA-1273 group, incidence of systemic ARs was higher after the second injection compared with after the first. In the mRNA-1273 group, fatigue (37.2%) and headache (32.6%) were the most commonly reported systemic ARs after the first and second injections (incidence was

higher for fatigue [65.4%] than for headache [58.8%]). Incidence was also higher for myalgia (58.1%), arthralgia (42.9%), and chills (44.3%) after the second injection (first injection incidence was 22.7%, 16.6%, and 8.3%, respectively). Fatigue and headache were the most commonly reported grade 3 systemic ARs in the mRNA-1273 group after the first injection (1.0% for fatigue and 1.8% for headache). This was also true after the second injection, and incidence of grade 3 fatigue (9.8%) or grade 3 headache (4.5%) were higher compared with the first injection. In addition, incidence of grade 3 myalgia (9.0%) and grade 3 arthralgia (5.3%) were higher compared with the first injection (0.6% for myalgia and 0.4% for arthralgia). In the placebo group, incidence and severity were generally not higher after the second injection compared with the first. At least one grade 4 solicited systemic AR was reported for 5 participants in the mRNA-1273 group (< 0.1%) and 6 participants in the placebo group (< 0.1%) after the first injection and for 14 (< 0.1%) and 3 (< 0.1%) participants, respectively, after the second injection. The most common grade 4 systemic AR was fever, defined as a temperature above 40°C, which was reported in 4 participants in the mRNA-1273 group and 6 participants in the placebo group after the first injection and for 13 and 3 participants, respectively, after the second injection.

Table 7-1: Summary of Participants With Solicited Adverse Reactions Starting Within 7 Days After First Injection by Grade (First Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited adverse reactions - N1	15151	15166	30317
Any solicited adverse reactions	7285 (48.1)	13317 (87.8)	20602 (68.0)
95% CI	47.3, 48.9	87.3, 88.3	67.4, 68.5
Grade 1	5134 (33.9)	9329 (61.5)	14463 (47.7)
Grade 2	1782 (11.8)	3134 (20.7)	4916 (16.2)
Grade 3	363 (2.4)	849 (5.6)	1212 (4.0)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 3 or above	369 (2.4)	854 (5.6)	1223 (4.0)
Solicited local adverse reactions - N1	15147	15162	30309
Any solicited local adverse reactions	3009 (19.9)	12765 (84.2)	15774 (52.0)
95% CI	19.2, 20.5	83.6, 84.8	51.5, 52.6
Grade 1	2842 (18.8)	10725 (70.7)	13567 (44.8)
Grade 2	89 (0.6)	1511 (10.0)	1600 (5.3)
Grade 3	78 (0.5)	529 (3.5)	607 (2.0)
Grade 4	0	0	0
Grade 3 or above	78 (0.5)	529 (3.5)	607 (2.0)
Pain - N1	15147	15162	30309
Any	2665 (17.6)	12688 (83.7)	15353 (50.7)
Grade 1	2551 (16.8)	10985 (72.5)	13536 (44.7)
Grade 2	59 (0.4)	1287 (8.5)	1346 (4.4)
Grade 3	55 (0.4)	416 (2.7)	471 (1.6)
Grade 4	0	0	0
Grade 3 or above	55 (0.4)	416 (2.7)	471 (1.6)
Erythema (redness) - N1	15147	15162	30309
Any	77 (0.5)	445 (2.9)	522 (1.7)
Grade 1	57 (0.4)	281 (1.9)	338 (1.1)
Grade 2	7 (<0.1)	122 (0.8)	129 (0.4)
Grade 3	13 (<0.1)	42 (0.3)	55 (0.2)
Grade 4	0	0	0
Grade 3 or above	13 (<0.1)	42 (0.3)	55 (0.2)
Swelling (hardness) - N1	15147	15162	30309
Any	65 (0.4)	935 (6.2)	1000 (3.3)
Grade 1	50 (0.3)	608 (4.0)	658 (2.2)

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Grade 2	9 (<0.1)	245 (1.6)	254 (0.8)
Grade 3	6 (<0.1)	82 (0.5)	88 (0.3)
Grade 4	0	0	0
Grade 3 or above	6 (<0.1)	82 (0.5)	88 (0.3)
Axillary swelling or tenderness - N1	15147	15162	30309
Any	722 (4.8)	1553 (10.2)	2275 (7.5)
Grade 1	668 (4.4)	1394 (9.2)	2062 (6.8)
Grade 2	27 (0.2)	110 (0.7)	137 (0.5)
Grade 3	27 (0.2)	49 (0.3)	76 (0.3)
Grade 4	0	0	0
Grade 3 or above	27 (0.2)	49 (0.3)	76 (0.3)
Solicited systemic adverse reactions - N1	15151	15166	30317
Any solicited systemic adverse reactions	6397 (42.2)	8316 (54.8)	14713 (48.5)
95% CI	41.4, 43.0	54.0, 55.6	48.0, 49.1
Grade 1	4334 (28.6)	5358 (35.3)	9692 (32.0)
Grade 2	1746 (11.5)	2504 (16.5)	4250 (14.0)
Grade 3	311 (2.1)	449 (3.0)	760 (2.5)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 3 or above	317 (2.1)	454 (3.0)	771 (2.5)
Fever - N1	15149	15163	30312
Any	44 (0.3)	112 (0.7)	156 (0.5)
Grade 1	28 (0.2)	73 (0.5)	101 (0.3)
Grade 2	8 (<0.1)	24 (0.2)	32 (0.1)
Grade 3	2 (<0.1)	11 (<0.1)	13 (<0.1)
Grade 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Grade 3 or above	8 (<0.1)	15 (<0.1)	23 (<0.1)
Headache - N1	15146	15162	30308
Any	4026 (26.6)	4950 (32.6)	8976 (29.6)
Grade 1	3297 (21.8)	3947 (26.0)	7244 (23.9)
Grade 2	532 (3.5)	730 (4.8)	1262 (4.2)
Grade 3	197 (1.3)	273 (1.8)	470 (1.6)
Grade 4	0	0	0
Grade 3 or above	197 (1.3)	273 (1.8)	470 (1.6)
Fatigue - N1	15146	15162	30308
Any	4133 (27.3)	5636 (37.2)	9769 (32.2)

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Grade 1	2705 (17.9)	3585 (23.6)	6290 (20.8)
Grade 2	1323 (8.7)	1899 (12.5)	3222 (10.6)
Grade 3	105 (0.7)	151 (1.0)	256 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	105 (0.7)	152 (1.0)	257 (0.8)
Myalgia - N1	15146	15162	30308
Any	2069 (13.7)	3442 (22.7)	5511 (18.2)
Grade 1	1560 (10.3)	2442 (16.1)	4002 (13.2)
Grade 2	462 (3.1)	909 (6.0)	1371 (4.5)
Grade 3	47 (0.3)	91 (0.6)	138 (0.5)
Grade 4	0	0	0
Grade 3 or above	47 (0.3)	91 (0.6)	138 (0.5)
Arthralgia - N1	15146	15162	30308
Any	1784 (11.8)	2510 (16.6)	4294 (14.2)
Grade 1	1333 (8.8)	1842 (12.1)	3175 (10.5)
Grade 2	413 (2.7)	607 (4.0)	1020 (3.4)
Grade 3	38 (0.3)	60 (0.4)	98 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	38 (0.3)	61 (0.4)	99 (0.3)
Nausea/vomiting - N1	15146	15162	30308
Any	1075 (7.1)	1262 (8.3)	2337 (7.7)
Grade 1	887 (5.9)	1047 (6.9)	1934 (6.4)
Grade 2	175 (1.2)	205 (1.4)	380 (1.3)
Grade 3	13 (<0.1)	10 (<0.1)	23 (<0.1)
Grade 4	0	0	0
Grade 3 or above	13 (<0.1)	10 (<0.1)	23 (<0.1)
Chills - N1	15146	15162	30308
Any	878 (5.8)	1251 (8.3)	2129 (7.0)
Grade 1	706 (4.7)	938 (6.2)	1644 (5.4)
Grade 2	158 (1.0)	289 (1.9)	447 (1.5)
Grade 3	14 (<0.1)	24 (0.2)	38 (0.1)
Grade 4	0	0	0
Grade 3 or above	14 (<0.1)	24 (0.2)	38 (0.1)

Abbreviations: CI = confidence intervals; N1 = number of exposed subjects who submitted any data for the event.
Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)

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

Severity grading for solicited adverse reactions is based on modified Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials (DHHS 2007).

Pain: Grade 3 = any use of prescription pain reliever/prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Erythema and Swelling: Grade 3 = >100mm/>10cm; Grade 4 = necrosis or exfoliative dermatitis.

Axillary Swelling or Tenderness: Grade 3 = any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fever: Grade 3 = ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: > 40.0°C or > 104.0°F.

Headache: Grade 3 = significant; any use of prescription pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Fatigue, Myalgia, and Arthralgia: Grade 3 = significant; prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Nausea/Vomiting: Grade 3 = prevents daily activity, requires outpatient intravenous hydration; Grade 4 = requires emergency room visit or hospitalization for hypotensive shock.

Chills: Grade 3 = prevents daily activity and requires medical intervention; Grade 4 = requires emergency room visit or hospitalization.

Source: Table 14.3.1.1.1.1.

Table 7-2: Summary of Participants With Solicited Adverse Reactions Starting Within 7 Days After Second Injection by Grade (Second Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited adverse reactions - N1	14578	14691	29269
Any solicited adverse reactions	6255 (42.9)	13556 (92.3)	19811 (67.7)
95% CI	42.1, 43.7	91.8, 92.7	67.1, 68.2
Grade 1	4346 (29.8)	4847 (33.0)	9193 (31.4)
Grade 2	1558 (10.7)	5800 (39.5)	7358 (25.1)
Grade 3	348 (2.4)	2895 (19.7)	3243 (11.1)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or above	351 (2.4)	2909 (19.8)	3260 (11.1)
Solicited local adverse reactions - N1	14577	14688	29265
Any solicited local adverse reactions	2757 (18.9)	13029 (88.7)	15786 (53.9)
95% CI	18.3, 19.6	88.2, 89.2	53.4, 54.5
Grade 1	2594 (17.8)	8789 (59.8)	11383 (38.9)
Grade 2	88 (0.6)	3217 (21.9)	3305 (11.3)
Grade 3	75 (0.5)	1023 (7.0)	1098 (3.8)
Grade 4	0	0	0
Grade 3 or above	75 (0.5)	1023 (7.0)	1098 (3.8)
Pain - N1	14577	14688	29265
Any	2486 (17.1)	12964 (88.3)	15450 (52.8)
Grade 1	2384 (16.4)	9508 (64.7)	11892 (40.6)
Grade 2	61 (0.4)	2850 (19.4)	2911 (9.9)
Grade 3	41 (0.3)	606 (4.1)	647 (2.2)
Grade 4	0	0	0
Grade 3 or above	41 (0.3)	606 (4.1)	647 (2.2)
Erythema (redness) - N1	14577	14687	29264
Any	68 (0.5)	1274 (8.7)	1342 (4.6)
Grade 1	48 (0.3)	456 (3.1)	504 (1.7)
Grade 2	5 (<0.1)	531 (3.6)	536 (1.8)
Grade 3	15 (0.1)	287 (2.0)	302 (1.0)
Grade 4	0	0	0
Grade 3 or above	15 (0.1)	287 (2.0)	302 (1.0)
Swelling (hardness) - N1	14577	14687	29264
Any	60 (0.4)	1807 (12.3)	1867 (6.4)

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Grade 1	38 (0.3)	900 (6.1)	938 (3.2)
Grade 2	10 (<0.1)	652 (4.4)	662 (2.3)
Grade 3	12 (<0.1)	255 (1.7)	267 (0.9)
Grade 4	0	0	0
Grade 3 or above	12 (<0.1)	255 (1.7)	267 (0.9)
Axillary swelling or tenderness - N1	14577	14687	29264
Any	571 (3.9)	2092 (14.2)	2663 (9.1)
Grade 1	523 (3.6)	1735 (11.8)	2258 (7.7)
Grade 2	28 (0.2)	289 (2.0)	317 (1.1)
Grade 3	20 (0.1)	68 (0.5)	88 (0.3)
Grade 4	0	0	0
Grade 3 or above	20 (0.1)	68 (0.5)	88 (0.3)
Solicited systemic adverse reactions - N1	14577	14690	29267
Any solicited systemic adverse reactions	5343 (36.7)	11678 (79.5)	17021 (58.2)
95% CI	35.9, 37.4	78.8, 80.1	57.6, 58.7
Grade 1	3519 (24.1)	3717 (25.3)	7236 (24.7)
Grade 2	1535 (10.5)	5611 (38.2)	7146 (24.4)
Grade 3	286 (2.0)	2336 (15.9)	2622 (9.0)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or above	289 (2.0)	2350 (16.0)	2639 (9.0)
Fever - N1	14573	14682	29255
Any	43 (0.3)	2276 (15.5)	2319 (7.9)
Grade 1	33 (0.2)	1363 (9.3)	1396 (4.8)
Grade 2	5 (<0.1)	697 (4.7)	702 (2.4)
Grade 3	2 (<0.1)	203 (1.4)	205 (0.7)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)
Grade 3 or above	5 (<0.1)	216 (1.5)	221 (0.8)
Headache - N1	14575	14687	29262
Any	3427 (23.5)	8637 (58.8)	12064 (41.2)
Grade 1	2740 (18.8)	4815 (32.8)	7555 (25.8)
Grade 2	522 (3.6)	3156 (21.5)	3678 (12.6)
Grade 3	165 (1.1)	666 (4.5)	831 (2.8)
Grade 4	0	0	0
Grade 3 or above	165 (1.1)	666 (4.5)	831 (2.8)
Fatigue - N1	14575	14687	29262

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Any	3418 (23.5)	9607 (65.4)	13025 (44.5)
Grade 1	2181 (15.0)	3431 (23.4)	5612 (19.2)
Grade 2	1129 (7.7)	4743 (32.3)	5872 (20.1)
Grade 3	108 (0.7)	1433 (9.8)	1541 (5.3)
Grade 4	0	0	0
Grade 3 or above	108 (0.7)	1433 (9.8)	1541 (5.3)
Myalgia - N1	14575	14687	29262
Any	1824 (12.5)	8529 (58.1)	10353 (35.4)
Grade 1	1307 (9.0)	3242 (22.1)	4549 (15.5)
Grade 2	465 (3.2)	3966 (27.0)	4431 (15.1)
Grade 3	52 (0.4)	1321 (9.0)	1373 (4.7)
Grade 4	0	0	0
Grade 3 or above	52 (0.4)	1321 (9.0)	1373 (4.7)
Arthralgia - N1	14575	14687	29262
Any	1579 (10.8)	6303 (42.9)	7882 (26.9)
Grade 1	1143 (7.8)	2809 (19.1)	3952 (13.5)
Grade 2	392 (2.7)	2719 (18.5)	3111 (10.6)
Grade 3	44 (0.3)	775 (5.3)	819 (2.8)
Grade 4	0	0	0
Grade 3 or above	44 (0.3)	775 (5.3)	819 (2.8)
Nausea/vomiting - N1	14575	14687	29262
Any	941 (6.5)	2794 (19.0)	3735 (12.8)
Grade 1	761 (5.2)	2094 (14.3)	2855 (9.8)
Grade 2	169 (1.2)	678 (4.6)	847 (2.9)
Grade 3	11 (<0.1)	21 (0.1)	32 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	11 (<0.1)	22 (0.1)	33 (0.1)
Chills - N1	14575	14687	29262
Any	813 (5.6)	6500 (44.3)	7313 (25.0)
Grade 1	629 (4.3)	2907 (19.8)	3536 (12.1)
Grade 2	167 (1.1)	3402 (23.2)	3569 (12.2)
Grade 3	17 (0.1)	191 (1.3)	208 (0.7)
Grade 4	0	0	0
Grade 3 or above	17 (0.1)	191 (1.3)	208 (0.7)

Abbreviations: CI = confidence intervals; N1 = number of exposed subjects who submitted any data for the event.
Any = Grade 1 or higher.

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)

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

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

Severity grading for solicited adverse reactions is based on modified Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials (DHHS 2007).

Pain: Grade 3 = any use of prescription pain reliever/prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Erythema and Swelling: Grade 3 = >100mm/>10cm; Grade 4 = necrosis or exfoliative dermatitis.

Axillary Swelling or Tenderness: Grade 3 = any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fever: Grade 3 = ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: > 40.0°C or > 104.0°F.

Headache: Grade 3 = significant; any use of prescription pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Fatigue, Myalgia, and Arthralgia: Grade 3 = significant; prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Nausea/Vomiting: Grade 3 = prevents daily activity, requires outpatient intravenous hydration; Grade 4 = requires emergency room visit or hospitalization for hypotensive shock.

Chills: Grade 3 = prevents daily activity and requires medical intervention; Grade 4 = requires emergency room visit or hospitalization.

Source: Table 14.3.1.1.1.2.

7.1.2 Onset of Solicited Adverse Reactions

Onset of solicited local and systemic ARs was mostly within the first 2 days after either injection. Local ARs most commonly had onset within the first day after either injection (in the mRNA-1273 group, 42.3% of participants after the first injection [Table 14.3.1.3.1.1] and 54.8% after the second injection [Table 14.3.1.3.1.2]). This was largely driven by findings for pain, which was the most commonly reported local AR. Systemic ARs most commonly had onset on Day 2 after the second injection (42.3% of participants in the mRNA-1273 group); after the first injection, onset was common on Day 1 (20.0%) and on Day 2 (18.4%). This was largely driven by findings for fatigue and headache, which were the most commonly reported systemic ARs.

7.1.3 Duration (Number of Days) of Solicited Adverse Reactions

The duration was calculated as the cumulative number of days that the solicited AR was reported, including the day of injection.

The solicited ARs in participants who received mRNA-1273 persisted for a median of 1 to 3 days after the first and second injection (Table 7-3 and Table 7-4), with no apparent difference noted between the first and second injection. Grade 3 solicited systemic ARs generally persisted for a median of 1 to 4 days, and median duration was generally similar after the first and second

injection (Table 14.3.1.4.4.1 and Table 14.3.1.4.4.2). The few grade 4 ARs reported after the first and second injection resolved within 7 days after injection.

The median duration of solicited local ARs ranged from 1 to 2 days in both the mRNA-1273 and placebo groups after the first injection (Table 7-3) and ranged from 2 to 3 days in the mRNA-1273 group vs. 1 day for all local ARs in the placebo group after the second injection (Table 7-4). In the mRNA-1273 group, with the exception of pain, the median duration of grade 3 solicited local ARs was slightly longer after the second injection (Table 14.3.1.4.4.1 and Table 14.3.1.4.4.2). No grade 4 solicited local ARs were reported after the first and second injection (Table 14.3.1.4.5.1 and Table 14.3.1.4.5.2).

The median duration of solicited systemic ARs ranged from 1 to 2 days in both mRNA-1273 and placebo groups after the first injection (Table 7-3) and after the second injection (Table 7-4). In the mRNA-1273 group, the median duration of grade 3 solicited systemic AR of nausea/vomiting was 1 day after the first injection and 3 days after the second injection; no other differences were noted for solicited systemic ARs between the first and second injections (Table 14.3.1.4.4.1 and Table 14.3.1.4.4.2). Grade 4 solicited systemic ARs were reported in both the mRNA-1273 and placebo groups after the first and second injection; all grade 4 solicited systemic ARs resolved within 7 days after injection (Table 14.3.1.4.5.1 and Table 14.3.1.4.5.2).

Table 7-3: Summary of Number of Days Reporting Solicited Adverse Reactions Starting Within 7 Days After First Injection (First Injection Solicited Safety Set)

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Solicited adverse reactions			
n	7285	13317	20602
Mean (SD)	3.3 (5.35)	3.5 (4.18)	3.4 (4.63)
Median	2.0	3.0	3.0
Min, Max	1, 189	1, 193	1, 193
Solicited local adverse reactions			
n	3009	12765	15774
Mean (SD)	2.0 (2.88)	2.7 (2.22)	2.5 (2.37)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 71	1, 71
Pain			
n	2665	12688	15353
Mean (SD)	1.7 (2.25)	2.5 (1.61)	2.3 (1.76)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 69	1, 69
Erythema (redness)			
n	77	445	522
Mean (SD)	4.2 (6.17)	2.8 (4.00)	3.0 (4.41)
Median	1.0	2.0	2.0
Min, Max	1, 28	1, 41	1, 41
Swelling (hardness)			
n	65	935	1000
Mean (SD)	6.8 (8.75)	2.2 (2.67)	2.5 (3.59)
Median	2.0	1.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary swelling or tenderness			
n	722	1553	2275
Mean (SD)	2.1 (2.86)	2.3 (3.31)	2.3 (3.18)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 69	1, 69

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Solicited systemic adverse reactions			
n	6397	8316	14713
Mean (SD)	3.3 (5.47)	3.1 (4.81)	3.2 (5.11)
Median	2.0	2.0	2.0
Min, Max	1, 188	1, 193	1, 193
Fever			
n	44	112	156
Mean (SD)	1.4 (0.62)	1.3 (0.96)	1.3 (0.88)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 8	1, 8
Headache			
n	4026	4950	8976
Mean (SD)	2.2 (2.76)	2.1 (2.36)	2.2 (2.55)
Median	1.0	1.0	1.0
Min, Max	1, 85	1, 46	1, 85
Fatigue			
n	4133	5636	9769
Mean (SD)	2.9 (4.39)	2.8 (3.90)	2.8 (4.12)
Median	2.0	2.0	2.0
Min, Max	1, 131	1, 92	1, 131
Myalgia			
n	2069	3442	5511
Mean (SD)	2.8 (3.93)	2.4 (3.58)	2.5 (3.72)
Median	1.0	1.0	1.0
Min, Max	1, 53	1, 74	1, 74
Arthralgia			
n	1784	2510	4294
Mean (SD)	3.5 (7.47)	2.9 (6.71)	3.1 (7.04)
Median	2.0	1.0	1.0
Min, Max	1, 188	1, 193	1, 193
Nausea/vomiting			
n	1075	1262	2337
Mean (SD)	1.8 (2.10)	1.7 (1.65)	1.7 (1.87)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 24	1, 35

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Chills			
n	878	1251	2129
Mean (SD)	1.7 (1.87)	1.5 (1.67)	1.6 (1.76)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 28	1, 35

Abbreviations: AR = adverse reaction; Max = maximum; Min = minimum

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.

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

Source: Table 14.3.1.4.1.1.

Table 7-4: Summary of Number of Days Reporting Solicited Adverse Reactions Starting Within 7 Days After Second Injection (Second Injection Solicited Safety Set)

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Solicited adverse reactions			
n	6255	13556	19811
Mean (SD)	3.7 (8.69)	4.2 (7.76)	4.0 (8.07)
Median	2.0	3.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited local adverse reactions			
n	2757	13029	15786
Mean (SD)	2.2 (6.40)	3.2 (3.28)	3.0 (4.02)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 154	1, 212
Pain			
n	2486	12964	15450
Mean (SD)	1.9 (4.89)	3.0 (2.47)	2.8 (3.02)
Median	1.0	3.0	3.0
Min, Max	1, 159	1, 154	1, 159
Erythema (redness)			
n	68	1274	1342
Mean (SD)	3.8 (5.28)	2.7 (2.69)	2.7 (2.88)
Median	1.0	2.0	2.0
Min, Max	1, 29	1, 39	1, 39
Swelling (hardness)			
n	60	1807	1867
Mean (SD)	4.2 (5.30)	2.5 (2.06)	2.5 (2.26)
Median	1.0	2.0	2.0
Min, Max	1, 31	1, 31	1, 31
Axillary swelling or tenderness			
n	571	2092	2663
Mean (SD)	3.0 (11.51)	2.5 (5.19)	2.6 (7.04)
Median	1.0	2.0	2.0
Min, Max	1, 212	1, 151	1, 212
Solicited systemic adverse reactions			
n	5343	11678	17021

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Mean (SD)	3.7 (8.73)	3.4 (7.91)	3.5 (8.18)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	43	2276	2319
Mean (SD)	1.4 (1.56)	1.1 (0.41)	1.1 (0.46)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 9	1, 11
Headache			
n	3427	8637	12064
Mean (SD)	2.4 (5.00)	2.4 (4.80)	2.4 (4.86)
Median	1.0	2.0	2.0
Min, Max	1, 169	1, 196	1, 196
Fatigue			
n	3418	9607	13025
Mean (SD)	3.3 (8.27)	2.8 (6.49)	2.9 (7.01)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	1824	8529	10353
Mean (SD)	3.7 (9.82)	2.2 (4.22)	2.4 (5.65)
Median	2.0	1.0	2.0
Min, Max	1, 169	1, 170	1, 170
Arthralgia			
n	1579	6303	7882
Mean (SD)	4.1 (10.02)	2.3 (4.73)	2.7 (6.20)
Median	2.0	1.0	1.0
Min, Max	1, 169	1, 185	1, 185
Nausea/vomiting			
n	941	2794	3735
Mean (SD)	2.0 (5.79)	1.7 (3.69)	1.8 (4.31)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 176	1, 176
Chills			

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
n	813	6500	7313
Mean (SD)	2.2 (7.43)	1.5 (2.27)	1.6 (3.28)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 158	1, 169

Abbreviations: Max = maximum; Min = minimum

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.

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

Source: Table 14.3.1.4.1.2.

7.1.3.1 Solicited Adverse Reactions Persisting Beyond 7 Days After Injection

Among solicited ARs that persisted beyond 7 days after the first injection, solicited local ARs were reported for 2.4% of participants in the mRNA-1273 group and 0.9% of participants in the placebo group, and solicited systemic ARs were reported for 5.7% and 5.6% of participants, respectively (Table 14.3.1.6.1.1). Findings were similar after the second injection (Table 14.3.1.6.1.2).

Most local and systemic solicited ARs that persisted beyond 7 days were grade 1 or 2 in severity after either injection. Grade 3 persistent solicited local ARs were reported for 22 participants (0.1%) in the mRNA-1273 group and 4 participants (< 0.1%) in the placebo group after the first injection; incidence was higher in the mRNA-1273 group (67 participants [0.5%]) after the second injection. Grade 3 persistent systemic ARs were reported for 97 participants in the mRNA-1273 group and 91 participants in the placebo group (0.6% each); incidence was higher in the mRNA-1273 group (231 participants [1.6%]) after the second injection. No grade 4 persistent solicited ARs were reported after either injection.

Axillary swelling or tenderness and pain were the most commonly reported persistent local ARs; axillary swelling or tenderness was more common after the first injection and pain was more common after the second. No individual solicited local AR term appeared more likely than others to occur at grade 3 after either injection.

Fatigue and headache were the most commonly reported persistent solicited systemic ARs after either injection. Persistent fever was rarely reported, occurring in only 7 participants (< 0.1%) after the first injection and 3 participants (< 0.1%) after the second injection. No individual solicited systemic AR term appeared more likely than others to occur at grade 3 after the first injection. After the second injection, fatigue was more commonly reported as a grade 3 persistent

solicited AR than other events (1.0% of participants in the mRNA-1273 group and 0.4% of participants in the placebo group).

7.1.3.2 Local Adverse Reaction With Delayed Onset Beyond 7 Days After Injection

Few participants (≤ 3.4%) in both groups had local ARs that started beyond 7 days after either injection (Table 7-5). For most participants in both groups who reported local ARs after Day 7 after either injection, the reaction had begun within the first 7 days after the injection and was still ongoing. A local AR that occurred within the first 7 days but restarted on Day 8 or later was reported for 83 participants (0.5%) in the mRNA-1273 group after the first injection and for 38 participants (0.3%) after the second injection.

In the mRNA-1273 group, the incidence of local AR with delayed onset (AR started on Day 8 or afterwards) was higher after the first injection (80 participants [0.5%]) than after the second injection (10 participants [< 0.1%]) (Table 7-5). The most common AR that was first reported on Day 8 or later was erythema, which was reported for 68 participants (0.4%) in the mRNA-1273 group after the first injection and 6 additional participants (< 0.1%) in the mRNA-1273 group after the second injection.

Table 7-5: Summary of Participants With Local Adverse Reactions That Occurs at Day 8 or Beyond of Each Injection (Solicited Safety Set)

Category	Vaccination 1		Vaccination 2	
	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)
Subjects with any local adverse reactions occurs at day 8 or beyond	158 (1.0)	514 (3.4)	199 (1.4)	356 (2.4)
Started within 7-day of the injection and continuing beyond 7 days	130 (0.9)	351 (2.3)	122 (0.8)	308 (2.1)
Had solicited AR within 7 days, and re-started on day 8 or afterwards	10 (<0.1)	83 (0.5)	20 (0.1)	38 (0.3)
No solicited AR within 7 days, and had AR started on day 8 or afterwards	18 (0.1)	80 (0.5)	57 (0.4)	10 (<0.1)
Subjects with pain occurs at day 8 or beyond	70 (0.5)	156 (1.0)	116 (0.8)	186 (1.3)
Started within 7-day of the injection and continuing beyond 7 days	56 (0.4)	102 (0.7)	58 (0.4)	155 (1.1)
Had solicited AR within 7 days, and re-started on day 8 or afterwards	6 (<0.1)	53 (0.3)	17 (0.1)	31 (0.2)
No solicited AR within 7 days, and had AR started on day 8 or afterwards	8 (<0.1)	1 (<0.1)	41 (0.3)	0
Subjects with erythema (redness) occurs at day 8 or beyond	27 (0.2)	117 (0.8)	21 (0.1)	78 (0.5)
Started within 7-day of the injection and continuing beyond 7 days	20 (0.1)	34 (0.2)	13 (<0.1)	70 (0.5)
Had solicited AR within 7 days, and re-started on day 8 or afterwards	0	15 (<0.1)	0	2 (<0.1)
No solicited AR within 7 days, and had AR started on day 8 or afterwards	7 (<0.1)	68 (0.4)	8 (<0.1)	6 (<0.1)
Subjects with swelling (hardness) occurs at day 8 or beyond	25 (0.2)	88 (0.6)	22 (0.2)	76 (0.5)
Started within 7-day of the injection and continuing beyond 7 days	22 (0.1)	33 (0.2)	16 (0.1)	70 (0.5)
Had solicited AR within 7 days, and re-started on day 8 or afterwards	0	19 (0.1)	0	2 (<0.1)
No solicited AR within 7 days, and had AR started on day 8 or afterwards	3 (<0.1)	36 (0.2)	6 (<0.1)	4 (<0.1)
Subjects with axillary swelling or tenderness occurs at day 8 or beyond	62 (0.4)	243 (1.6)	57 (0.4)	101 (0.7)
Started within 7-day of the injection and continuing beyond 7 days	54 (0.4)	223 (1.5)	48 (0.3)	90 (0.6)

Category	Vaccination 1		Vaccination 2	
	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)
Had solicited AR within 7 days, and re-started on day 8 or afterwards	5 (<0.1)	12 (<0.1)	4 (<0.1)	7 (<0.1)
No solicited AR within 7 days, and had AR started on day 8 or afterwards	3 (<0.1)	8 (<0.1)	5 (<0.1)	4 (<0.1)

Abbreviation: AR = adverse reaction.

Subjects with adverse reactions on Day 8 or beyond, independent of the start date.

Source: Table 14.3.1.21.1.4.

7.1.4 Solicited Adverse Reactions by Subgroup

7.1.4.1 Age Groups

Incidence of solicited local and systemic ARs after either injection in the mRNA-1273 group was lower among older adults (≥ 65 years) than among younger adults (≥ 18 to < 65 years) (Table 7-6 and Table 7-7), but within both age subgroups, findings were similar to those for the overall population (Section 7.1.1).

No differences were apparent between the age subgroups for duration of solicited local or systemic ARs after the first (Table 14.3.1.4.2.1) or second (Table 14.3.1.4.2.2) injections.

Table 7-6: Summary of Participants With Solicited Adverse Reactions Starting Within 7 Days After First Injection by Age Group and Grade (First Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Age Group: >=18 and <65 Years			
Solicited adverse reactions - N1	11402	11406	22808
Any solicited adverse reactions	5737 (50.3)	10262 (90.0)	15999 (70.1)
95% CI	49.4, 51.2	89.4, 90.5	69.5, 70.7
Grade 1	3993 (35.0)	6951 (60.9)	10944 (48.0)
Grade 2	1466 (12.9)	2601 (22.8)	4067 (17.8)
Grade 3	274 (2.4)	705 (6.2)	979 (4.3)
Grade 4	4 (<0.1)	5 (<0.1)	9 (<0.1)
Grade 3 or above	278 (2.4)	710 (6.2)	988 (4.3)
Solicited local adverse reactions - N1	11400	11402	22802
Any solicited local adverse reactions	2436 (21.4)	9961 (87.4)	12397 (54.4)
95% CI	20.6, 22.1	86.7, 88.0	53.7, 55.0
Grade 1	2334 (20.5)	8151 (71.5)	10485 (46.0)
Grade 2	63 (0.6)	1358 (11.9)	1421 (6.2)
Grade 3	39 (0.3)	452 (4.0)	491 (2.2)
Grade 4	0	0	0
Grade 3 or above	39 (0.3)	452 (4.0)	491 (2.2)
Pain - N1	11400	11402	22802
Any	2183 (19.1)	9908 (86.9)	12091 (53.0)
Grade 1	2116 (18.6)	8360 (73.3)	10476 (45.9)
Grade 2	44 (0.4)	1182 (10.4)	1226 (5.4)
Grade 3	23 (0.2)	366 (3.2)	389 (1.7)
Grade 4	0	0	0
Grade 3 or above	23 (0.2)	366 (3.2)	389 (1.7)
Erythema (redness) - N1	11400	11402	22802
Any	54 (0.5)	354 (3.1)	408 (1.8)
Grade 1	39 (0.3)	222 (1.9)	261 (1.1)
Grade 2	4 (<0.1)	98 (0.9)	102 (0.4)
Grade 3	11 (<0.1)	34 (0.3)	45 (0.2)
Grade 4	0	0	0
Grade 3 or above	11 (<0.1)	34 (0.3)	45 (0.2)
Swelling (hardness) - N1	11400	11402	22802
Any	42 (0.4)	766 (6.7)	808 (3.5)
Grade 1	35 (0.3)	499 (4.4)	534 (2.3)

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Grade 2	4 (<0.1)	205 (1.8)	209 (0.9)
Grade 3	3 (<0.1)	62 (0.5)	65 (0.3)
Grade 4	0	0	0
Grade 3 or above	3 (<0.1)	62 (0.5)	65 (0.3)
Axillary swelling or tenderness - N1	11400	11402	22802
Any	567 (5.0)	1322 (11.6)	1889 (8.3)
Grade 1	534 (4.7)	1180 (10.3)	1714 (7.5)
Grade 2	20 (0.2)	105 (0.9)	125 (0.5)
Grade 3	13 (0.1)	37 (0.3)	50 (0.2)
Grade 4	0	0	0
Grade 3 or above	13 (0.1)	37 (0.3)	50 (0.2)
Solicited systemic adverse reactions - N1	11402	11406	22808
Any solicited systemic adverse reactions	5063 (44.4)	6499 (57.0)	11562 (50.7)
95% CI	43.5, 45.3	56.1, 57.9	50.0, 51.3
Grade 1	3367 (29.5)	4079 (35.8)	7446 (32.6)
Grade 2	1442 (12.6)	2050 (18.0)	3492 (15.3)
Grade 3	250 (2.2)	365 (3.2)	615 (2.7)
Grade 4	4 (<0.1)	5 (<0.1)	9 (<0.1)
Grade 3 or above	254 (2.2)	370 (3.2)	624 (2.7)
Fever - N1	11400	11404	22804
Any	37 (0.3)	102 (0.9)	139 (0.6)
Grade 1	25 (0.2)	66 (0.6)	91 (0.4)
Grade 2	7 (<0.1)	22 (0.2)	29 (0.1)
Grade 3	1 (<0.1)	10 (<0.1)	11 (<0.1)
Grade 4	4 (<0.1)	4 (<0.1)	8 (<0.1)
Grade 3 or above	5 (<0.1)	14 (0.1)	19 (<0.1)
Headache - N1	11400	11402	22802
Any	3303 (29.0)	4028 (35.3)	7331 (32.2)
Grade 1	2668 (23.4)	3168 (27.8)	5836 (25.6)
Grade 2	472 (4.1)	640 (5.6)	1112 (4.9)
Grade 3	163 (1.4)	220 (1.9)	383 (1.7)
Grade 4	0	0	0
Grade 3 or above	163 (1.4)	220 (1.9)	383 (1.7)
Fatigue - N1	11400	11402	22802
Any	3281 (28.8)	4385 (38.5)	7666 (33.6)
Grade 1	2100 (18.4)	2732 (24.0)	4832 (21.2)
Grade 2	1098 (9.6)	1531 (13.4)	2629 (11.5)

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Grade 3	83 (0.7)	121 (1.1)	204 (0.9)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	83 (0.7)	122 (1.1)	205 (0.9)
Myalgia - N1	11400	11402	22802
Any	1625 (14.3)	2700 (23.7)	4325 (19.0)
Grade 1	1200 (10.5)	1874 (16.4)	3074 (13.5)
Grade 2	387 (3.4)	752 (6.6)	1139 (5.0)
Grade 3	38 (0.3)	74 (0.6)	112 (0.5)
Grade 4	0	0	0
Grade 3 or above	38 (0.3)	74 (0.6)	112 (0.5)
Arthralgia - N1	11400	11402	22802
Any	1327 (11.6)	1892 (16.6)	3219 (14.1)
Grade 1	966 (8.5)	1368 (12.0)	2334 (10.2)
Grade 2	331 (2.9)	476 (4.2)	807 (3.5)
Grade 3	30 (0.3)	47 (0.4)	77 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	30 (0.3)	48 (0.4)	78 (0.3)
Nausea/vomiting - N1	11400	11402	22802
Any	908 (8.0)	1068 (9.4)	1976 (8.7)
Grade 1	749 (6.6)	889 (7.8)	1638 (7.2)
Grade 2	151 (1.3)	173 (1.5)	324 (1.4)
Grade 3	8 (<0.1)	6 (<0.1)	14 (<0.1)
Grade 4	0	0	0
Grade 3 or above	8 (<0.1)	6 (<0.1)	14 (<0.1)
Chills - N1	11400	11402	22802
Any	730 (6.4)	1050 (9.2)	1780 (7.8)
Grade 1	584 (5.1)	780 (6.8)	1364 (6.0)
Grade 2	138 (1.2)	253 (2.2)	391 (1.7)
Grade 3	8 (<0.1)	17 (0.1)	25 (0.1)
Grade 4	0	0	0
Grade 3 or above	8 (<0.1)	17 (0.1)	25 (0.1)

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Age Group: >=65 Years			
Solicited adverse reactions - N1	3749	3760	7509
Any solicited adverse reactions	1548 (41.3)	3055 (81.3)	4603 (61.3)
95% CI	39.7, 42.9	80.0, 82.5	60.2, 62.4
Grade 1	1141 (30.4)	2378 (63.2)	3519 (46.9)
Grade 2	316 (8.4)	533 (14.2)	849 (11.3)
Grade 3	89 (2.4)	144 (3.8)	233 (3.1)
Grade 4	2 (<0.1)	0	2 (<0.1)
Grade 3 or above	91 (2.4)	144 (3.8)	235 (3.1)
Solicited local adverse reactions - N1	3747	3760	7507
Any solicited local adverse reactions	573 (15.3)	2804 (74.6)	3377 (45.0)
95% CI	14.2, 16.5	73.2, 76.0	43.9, 46.1
Grade 1	508 (13.6)	2574 (68.5)	3082 (41.1)
Grade 2	26 (0.7)	153 (4.1)	179 (2.4)
Grade 3	39 (1.0)	77 (2.0)	116 (1.5)
Grade 4	0	0	0
Grade 3 or above	39 (1.0)	77 (2.0)	116 (1.5)
Pain - N1	3747	3760	7507
Any	482 (12.9)	2780 (73.9)	3262 (43.5)
Grade 1	435 (11.6)	2625 (69.8)	3060 (40.8)
Grade 2	15 (0.4)	105 (2.8)	120 (1.6)
Grade 3	32 (0.9)	50 (1.3)	82 (1.1)
Grade 4	0	0	0
Grade 3 or above	32 (0.9)	50 (1.3)	82 (1.1)
Erythema (redness) - N1	3747	3760	7507
Any	23 (0.6)	91 (2.4)	114 (1.5)
Grade 1	18 (0.5)	59 (1.6)	77 (1.0)
Grade 2	3 (<0.1)	24 (0.6)	27 (0.4)
Grade 3	2 (<0.1)	8 (0.2)	10 (0.1)
Grade 4	0	0	0
Grade 3 or above	2 (<0.1)	8 (0.2)	10 (0.1)
Swelling (hardness) - N1	3747	3760	7507
Any	23 (0.6)	169 (4.5)	192 (2.6)
Grade 1	15 (0.4)	109 (2.9)	124 (1.7)
Grade 2	5 (0.1)	40 (1.1)	45 (0.6)
Grade 3	3 (<0.1)	20 (0.5)	23 (0.3)
Grade 4	0	0	0

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Grade 3 or above	3 (<0.1)	20 (0.5)	23 (0.3)
Axillary swelling or tenderness - N1	3747	3760	7507
Any	155 (4.1)	231 (6.1)	386 (5.1)
Grade 1	134 (3.6)	214 (5.7)	348 (4.6)
Grade 2	7 (0.2)	5 (0.1)	12 (0.2)
Grade 3	14 (0.4)	12 (0.3)	26 (0.3)
Grade 4	0	0	0
Grade 3 or above	14 (0.4)	12 (0.3)	26 (0.3)
Solicited systemic adverse reactions - N1	3749	3760	7509
Any solicited systemic adverse reactions	1334 (35.6)	1817 (48.3)	3151 (42.0)
95% CI	34.0, 37.1	46.7, 49.9	40.8, 43.1
Grade 1	967 (25.8)	1279 (34.0)	2246 (29.9)
Grade 2	304 (8.1)	454 (12.1)	758 (10.1)
Grade 3	61 (1.6)	84 (2.2)	145 (1.9)
Grade 4	2 (<0.1)	0	2 (<0.1)
Grade 3 or above	63 (1.7)	84 (2.2)	147 (2.0)
Fever - N1	3749	3759	7508
Any	7 (0.2)	10 (0.3)	17 (0.2)
Grade 1	3 (<0.1)	7 (0.2)	10 (0.1)
Grade 2	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	2 (<0.1)	0	2 (<0.1)
Grade 3 or above	3 (<0.1)	1 (<0.1)	4 (<0.1)
Headache - N1	3746	3760	7506
Any	723 (19.3)	922 (24.5)	1645 (21.9)
Grade 1	629 (16.8)	779 (20.7)	1408 (18.8)
Grade 2	60 (1.6)	90 (2.4)	150 (2.0)
Grade 3	34 (0.9)	53 (1.4)	87 (1.2)
Grade 4	0	0	0
Grade 3 or above	34 (0.9)	53 (1.4)	87 (1.2)
Fatigue - N1	3746	3760	7506
Any	852 (22.7)	1251 (33.3)	2103 (28.0)
Grade 1	605 (16.2)	853 (22.7)	1458 (19.4)
Grade 2	225 (6.0)	368 (9.8)	593 (7.9)
Grade 3	22 (0.6)	30 (0.8)	52 (0.7)
Grade 4	0	0	0
Grade 3 or above	22 (0.6)	30 (0.8)	52 (0.7)

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Myalgia - N1	3746	3760	7506
Any	444 (11.9)	742 (19.7)	1186 (15.8)
Grade 1	360 (9.6)	568 (15.1)	928 (12.4)
Grade 2	75 (2.0)	157 (4.2)	232 (3.1)
Grade 3	9 (0.2)	17 (0.5)	26 (0.3)
Grade 4	0	0	0
Grade 3 or above	9 (0.2)	17 (0.5)	26 (0.3)
Arthralgia - N1	3746	3760	7506
Any	457 (12.2)	618 (16.4)	1075 (14.3)
Grade 1	367 (9.8)	474 (12.6)	841 (11.2)
Grade 2	82 (2.2)	131 (3.5)	213 (2.8)
Grade 3	8 (0.2)	13 (0.3)	21 (0.3)
Grade 4	0	0	0
Grade 3 or above	8 (0.2)	13 (0.3)	21 (0.3)
Nausea/vomiting - N1	3746	3760	7506
Any	167 (4.5)	194 (5.2)	361 (4.8)
Grade 1	138 (3.7)	158 (4.2)	296 (3.9)
Grade 2	24 (0.6)	32 (0.9)	56 (0.7)
Grade 3	5 (0.1)	4 (0.1)	9 (0.1)
Grade 4	0	0	0
Grade 3 or above	5 (0.1)	4 (0.1)	9 (0.1)
Chills - N1	3746	3760	7506
Any	148 (4.0)	201 (5.3)	349 (4.6)
Grade 1	122 (3.3)	158 (4.2)	280 (3.7)
Grade 2	20 (0.5)	36 (1.0)	56 (0.7)
Grade 3	6 (0.2)	7 (0.2)	13 (0.2)
Grade 4	0	0	0
Grade 3 or above	6 (0.2)	7 (0.2)	13 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.

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

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

Severity grading for solicited adverse reactions is based on modified Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials (DHHS 2007).

Pain: Grade 3 = any use of prescription pain reliever/prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Erythema and Swelling: Grade 3 = >100mm/>10cm; Grade 4 = necrosis or exfoliative dermatitis.

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)

Axillary Swelling or Tenderness: Grade 3 = any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fever: Grade 3 = ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: > 40.0°C or > 104.0°F.

Headache: Grade 3 = significant; any use of prescription pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fatigue, Myalgia, and Arthralgia: Grade 3 = significant; prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Nausea/Vomiting: Grade 3 = prevents daily activity, requires outpatient intravenous hydration; Grade 4 = requires emergency room visit or hospitalization for hypotensive shock.

Chills: Grade 3 = prevents daily activity and requires medical intervention; Grade 4 = requires emergency room visit or hospitalization.

Source: Table 14.3.1.1.2.1.1.

Table 7-7: Summary of Participants With Solicited Adverse Reactions Starting Within 7 Days After Second Injection by Age Group and Grade (Second Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Age Group: >=18 and <65 Years			
Solicited adverse reactions - N1	10929	11000	21929
Any solicited adverse reactions	4921 (45.0)	10252 (93.2)	15173 (69.2)
95% CI	44.1, 46.0	92.7, 93.7	68.6, 69.8
Grade 1	3392 (31.0)	3290 (29.9)	6682 (30.5)
Grade 2	1266 (11.6)	4592 (41.7)	5858 (26.7)
Grade 3	261 (2.4)	2358 (21.4)	2619 (11.9)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Grade 3 or above	263 (2.4)	2370 (21.5)	2633 (12.0)
Solicited local adverse reactions - N1	10928	10999	21927
Any solicited local adverse reactions	2262 (20.7)	9936 (90.3)	12198 (55.6)
95% CI	19.9, 21.5	89.8, 90.9	55.0, 56.3
Grade 1	2145 (19.6)	6424 (58.4)	8569 (39.1)
Grade 2	73 (0.7)	2709 (24.6)	2782 (12.7)
Grade 3	44 (0.4)	803 (7.3)	847 (3.9)
Grade 4	0	0	0
Grade 3 or above	44 (0.4)	803 (7.3)	847 (3.9)
Pain - N1	10928	10999	21927
Any	2048 (18.7)	9893 (89.9)	11941 (54.5)
Grade 1	1978 (18.1)	6933 (63.0)	8911 (40.6)
Grade 2	48 (0.4)	2454 (22.3)	2502 (11.4)
Grade 3	22 (0.2)	506 (4.6)	528 (2.4)
Grade 4	0	0	0
Grade 3 or above	22 (0.2)	506 (4.6)	528 (2.4)
Erythema (redness) - N1	10928	10998	21926
Any	53 (0.5)	989 (9.0)	1042 (4.8)
Grade 1	36 (0.3)	358 (3.3)	394 (1.8)
Grade 2	5 (<0.1)	421 (3.8)	426 (1.9)
Grade 3	12 (0.1)	210 (1.9)	222 (1.0)
Grade 4	0	0	0
Grade 3 or above	12 (0.1)	210 (1.9)	222 (1.0)
Swelling (hardness) - N1	10928	10998	21926
Any	46 (0.4)	1399 (12.7)	1445 (6.6)
Grade 1	32 (0.3)	706 (6.4)	738 (3.4)

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Grade 2	9 (<0.1)	510 (4.6)	519 (2.4)
Grade 3	5 (<0.1)	183 (1.7)	188 (0.9)
Grade 4	0	0	0
Grade 3 or above	5 (<0.1)	183 (1.7)	188 (0.9)
Axillary swelling or tenderness - N1	10928	10998	21926
Any	474 (4.3)	1777 (16.2)	2251 (10.3)
Grade 1	435 (4.0)	1468 (13.3)	1903 (8.7)
Grade 2	27 (0.2)	262 (2.4)	289 (1.3)
Grade 3	12 (0.1)	47 (0.4)	59 (0.3)
Grade 4	0	0	0
Grade 3 or above	12 (0.1)	47 (0.4)	59 (0.3)
Solicited systemic adverse reactions - N1	10928	10999	21927
Any solicited systemic adverse reactions	4208 (38.5)	9023 (82.0)	13231 (60.3)
95% CI	37.6, 39.4	81.3, 82.7	59.7, 61.0
Grade 1	2731 (25.0)	2615 (23.8)	5346 (24.4)
Grade 2	1248 (11.4)	4458 (40.5)	5706 (26.0)
Grade 3	227 (2.1)	1938 (17.6)	2165 (9.9)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Grade 3 or above	229 (2.1)	1950 (17.7)	2179 (9.9)
Fever - N1	10925	10993	21918
Any	38 (0.3)	1909 (17.4)	1947 (8.9)
Grade 1	30 (0.3)	1112 (10.1)	1142 (5.2)
Grade 2	4 (<0.1)	600 (5.5)	604 (2.8)
Grade 3	2 (<0.1)	185 (1.7)	187 (0.9)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Grade 3 or above	4 (<0.1)	197 (1.8)	201 (0.9)
Headache - N1	10926	10998	21924
Any	2775 (25.4)	6929 (63.0)	9704 (44.3)
Grade 1	2182 (20.0)	3669 (33.4)	5851 (26.7)
Grade 2	461 (4.2)	2701 (24.6)	3162 (14.4)
Grade 3	132 (1.2)	559 (5.1)	691 (3.2)
Grade 4	0	0	0
Grade 3 or above	132 (1.2)	559 (5.1)	691 (3.2)
Fatigue - N1	10926	10998	21924
Any	2701 (24.7)	7453 (67.8)	10154 (46.3)
Grade 1	1701 (15.6)	2527 (23.0)	4228 (19.3)
Grade 2	912 (8.3)	3748 (34.1)	4660 (21.3)

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Grade 3	88 (0.8)	1178 (10.7)	1266 (5.8)
Grade 4	0	0	0
Grade 3 or above	88 (0.8)	1178 (10.7)	1266 (5.8)
Myalgia - N1	10926	10998	21924
Any	1425 (13.0)	6789 (61.7)	8214 (37.5)
Grade 1	1002 (9.2)	2415 (22.0)	3417 (15.6)
Grade 2	381 (3.5)	3258 (29.6)	3639 (16.6)
Grade 3	42 (0.4)	1116 (10.1)	1158 (5.3)
Grade 4	0	0	0
Grade 3 or above	42 (0.4)	1116 (10.1)	1158 (5.3)
Arthralgia - N1	10926	10998	21924
Any	1180 (10.8)	5010 (45.6)	6190 (28.2)
Grade 1	841 (7.7)	2111 (19.2)	2952 (13.5)
Grade 2	302 (2.8)	2249 (20.4)	2551 (11.6)
Grade 3	37 (0.3)	650 (5.9)	687 (3.1)
Grade 4	0	0	0
Grade 3 or above	37 (0.3)	650 (5.9)	687 (3.1)
Nausea/vomiting - N1	10926	10998	21924
Any	807 (7.4)	2355 (21.4)	3162 (14.4)
Grade 1	651 (6.0)	1755 (16.0)	2406 (11.0)
Grade 2	148 (1.4)	589 (5.4)	737 (3.4)
Grade 3	8 (<0.1)	11 (0.1)	19 (<0.1)
Grade 4	0	0	0
Grade 3 or above	8 (<0.1)	11 (0.1)	19 (<0.1)
Chills - N1	10926	10998	21924
Any	662 (6.1)	5357 (48.7)	6019 (27.5)
Grade 1	505 (4.6)	2316 (21.1)	2821 (12.9)
Grade 2	142 (1.3)	2877 (26.2)	3019 (13.8)
Grade 3	15 (0.1)	164 (1.5)	179 (0.8)
Grade 4	0	0	0
Grade 3 or above	15 (0.1)	164 (1.5)	179 (0.8)

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Age Group: >=65 Years			
Solicited adverse reactions - N1	3649	3691	7340
Any solicited adverse reactions	1334 (36.6)	3304 (89.5)	4638 (63.2)
95% CI	35.0, 38.1	88.5, 90.5	62.1, 64.3
Grade 1	954 (26.1)	1557 (42.2)	2511 (34.2)
Grade 2	292 (8.0)	1208 (32.7)	1500 (20.4)
Grade 3	87 (2.4)	537 (14.5)	624 (8.5)
Grade 4	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3 or above	88 (2.4)	539 (14.6)	627 (8.5)
Solicited local adverse reactions - N1	3649	3689	7338
Any solicited local adverse reactions	495 (13.6)	3093 (83.8)	3588 (48.9)
95% CI	12.5, 14.7	82.6, 85.0	47.7, 50.0
Grade 1	449 (12.3)	2365 (64.1)	2814 (38.3)
Grade 2	15 (0.4)	508 (13.8)	523 (7.1)
Grade 3	31 (0.8)	220 (6.0)	251 (3.4)
Grade 4	0	0	0
Grade 3 or above	31 (0.8)	220 (6.0)	251 (3.4)
Pain - N1	3649	3689	7338
Any	438 (12.0)	3071 (83.2)	3509 (47.8)
Grade 1	406 (11.1)	2575 (69.8)	2981 (40.6)
Grade 2	13 (0.4)	396 (10.7)	409 (5.6)
Grade 3	19 (0.5)	100 (2.7)	119 (1.6)
Grade 4	0	0	0
Grade 3 or above	19 (0.5)	100 (2.7)	119 (1.6)
Erythema (redness) - N1	3649	3689	7338
Any	15 (0.4)	285 (7.7)	300 (4.1)
Grade 1	12 (0.3)	98 (2.7)	110 (1.5)
Grade 2	0	110 (3.0)	110 (1.5)
Grade 3	3 (<0.1)	77 (2.1)	80 (1.1)
Grade 4	0	0	0
Grade 3 or above	3 (<0.1)	77 (2.1)	80 (1.1)
Swelling (hardness) - N1	3649	3689	7338
Any	14 (0.4)	408 (11.1)	422 (5.8)
Grade 1	6 (0.2)	194 (5.3)	200 (2.7)
Grade 2	1 (<0.1)	142 (3.8)	143 (1.9)
Grade 3	7 (0.2)	72 (2.0)	79 (1.1)
Grade 4	0	0	0

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Grade 3 or above	7 (0.2)	72 (2.0)	79 (1.1)
Axillary swelling or tenderness - N1	3649	3689	7338
Any	97 (2.7)	315 (8.5)	412 (5.6)
Grade 1	88 (2.4)	267 (7.2)	355 (4.8)
Grade 2	1 (<0.1)	27 (0.7)	28 (0.4)
Grade 3	8 (0.2)	21 (0.6)	29 (0.4)
Grade 4	0	0	0
Grade 3 or above	8 (0.2)	21 (0.6)	29 (0.4)
Solicited systemic adverse reactions - N1	3649	3691	7340
Any solicited systemic adverse reactions	1135 (31.1)	2655 (71.9)	3790 (51.6)
95% CI	29.6, 32.6	70.5, 73.4	50.5, 52.8
Grade 1	788 (21.6)	1102 (29.9)	1890 (25.7)
Grade 2	287 (7.9)	1153 (31.2)	1440 (19.6)
Grade 3	59 (1.6)	398 (10.8)	457 (6.2)
Grade 4	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3 or above	60 (1.6)	400 (10.8)	460 (6.3)
Fever - N1	3648	3689	7337
Any	5 (0.1)	367 (9.9)	372 (5.1)
Grade 1	3 (<0.1)	251 (6.8)	254 (3.5)
Grade 2	1 (<0.1)	97 (2.6)	98 (1.3)
Grade 3	0	18 (0.5)	18 (0.2)
Grade 4	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 3 or above	1 (<0.1)	19 (0.5)	20 (0.3)
Headache - N1	3649	3689	7338
Any	652 (17.9)	1708 (46.3)	2360 (32.2)
Grade 1	558 (15.3)	1146 (31.1)	1704 (23.2)
Grade 2	61 (1.7)	455 (12.3)	516 (7.0)
Grade 3	33 (0.9)	107 (2.9)	140 (1.9)
Grade 4	0	0	0
Grade 3 or above	33 (0.9)	107 (2.9)	140 (1.9)
Fatigue - N1	3649	3689	7338
Any	717 (19.6)	2154 (58.4)	2871 (39.1)
Grade 1	480 (13.2)	904 (24.5)	1384 (18.9)
Grade 2	217 (5.9)	995 (27.0)	1212 (16.5)
Grade 3	20 (0.5)	255 (6.9)	275 (3.7)
Grade 4	0	0	0
Grade 3 or above	20 (0.5)	255 (6.9)	275 (3.7)

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Myalgia - N1	3649	3689	7338
Any	399 (10.9)	1740 (47.2)	2139 (29.1)
Grade 1	305 (8.4)	827 (22.4)	1132 (15.4)
Grade 2	84 (2.3)	708 (19.2)	792 (10.8)
Grade 3	10 (0.3)	205 (5.6)	215 (2.9)
Grade 4	0	0	0
Grade 3 or above	10 (0.3)	205 (5.6)	215 (2.9)
Arthralgia - N1	3649	3689	7338
Any	399 (10.9)	1293 (35.1)	1692 (23.1)
Grade 1	302 (8.3)	698 (18.9)	1000 (13.6)
Grade 2	90 (2.5)	470 (12.7)	560 (7.6)
Grade 3	7 (0.2)	125 (3.4)	132 (1.8)
Grade 4	0	0	0
Grade 3 or above	7 (0.2)	125 (3.4)	132 (1.8)
Nausea/vomiting - N1	3649	3689	7338
Any	134 (3.7)	439 (11.9)	573 (7.8)
Grade 1	110 (3.0)	339 (9.2)	449 (6.1)
Grade 2	21 (0.6)	89 (2.4)	110 (1.5)
Grade 3	3 (<0.1)	10 (0.3)	13 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	3 (<0.1)	11 (0.3)	14 (0.2)
Chills - N1	3649	3689	7338
Any	151 (4.1)	1143 (31.0)	1294 (17.6)
Grade 1	124 (3.4)	591 (16.0)	715 (9.7)
Grade 2	25 (0.7)	525 (14.2)	550 (7.5)
Grade 3	2 (<0.1)	27 (0.7)	29 (0.4)
Grade 4	0	0	0
Grade 3 or above	2 (<0.1)	27 (0.7)	29 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.

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

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

Severity grading for solicited adverse reactions is based on modified Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials (DHHS 2007).

Pain: Grade 3 = any use of prescription pain reliever/prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Erythema and Swelling: Grade 3 = >100mm/>10cm; Grade 4 = necrosis or exfoliative dermatitis.

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)

Axillary Swelling or Tenderness: Grade 3 = any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fever: Grade 3 = ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: > 40.0°C or > 104.0°F.

Headache: Grade 3 = significant; any use of prescription pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fatigue, Myalgia, and Arthralgia: Grade 3 = significant; prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Nausea/Vomiting: Grade 3 = prevents daily activity, requires outpatient intravenous hydration; Grade 4 = requires emergency room visit or hospitalization for hypotensive shock.

Chills: Grade 3 = prevents daily activity and requires medical intervention; Grade 4 = requires emergency room visit or hospitalization.

Source: Table 14.3.1.1.2.1.2.

7.1.4.2 Baseline SARS-CoV-2 Status

Baseline SARS-CoV-2 status was negative for most participants. Results among participants with negative baseline status reflect those of the overall population.

Among participants with baseline SARS-CoV-2 positive status in the mRNA-1273 group, the percentage of participants who reported a grade 3 solicited local or systemic AR after the first injection was 8.4% (29/346) (Table 7-8); the percentage in the overall population was 5.6% (849/15166) (Table 7-1). This was largely driven by grade 3 solicited systemic ARs, which were reported for 6.6% (23/346) among those with positive baseline status (Table 7-8) compared with 3.0% (449/15166) for the overall mRNA-1273 group (Table 7-1). In the mRNA-1273 group, the percentages of participants with positive baseline status who had grade 3 events were higher for all systemic ARs compared with the percentages in the overall group. These differences were not observed after the second injection (Table 7-9).

No differences were apparent for this subgroup in duration of local or systemic ARs after the first (Table 14.3.1.4.3.1) or second (Table 14.3.1.4.3.2) injections or for ARs persisting beyond 7 days after the first (Table 14.3.1.6.3.1) or second (Table 14.3.1.6.3.2) injections.

Table 7-8: Summary of Participants With Solicited Adverse Reactions Starting Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade (First Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Baseline SARS-CoV-2 Status: Negative			
Solicited adverse reactions - N1	14730	14733	29463
Any solicited adverse reactions	7105 (48.2)	12976 (88.1)	20081 (68.2)
95% CI	47.4, 49.0	87.5, 88.6	67.6, 68.7
Grade 1	5015 (34.0)	9136 (62.0)	14151 (48.0)
Grade 2	1736 (11.8)	3022 (20.5)	4758 (16.1)
Grade 3	349 (2.4)	814 (5.5)	1163 (3.9)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)
Grade 3 or above	354 (2.4)	818 (5.6)	1172 (4.0)
Solicited local adverse reactions - N1	14726	14729	29455
Any solicited local adverse reactions	2934 (19.9)	12442 (84.5)	15376 (52.2)
95% CI	19.3, 20.6	83.9, 85.1	51.6, 52.8
Grade 1	2771 (18.8)	10481 (71.2)	13252 (45.0)
Grade 2	88 (0.6)	1449 (9.8)	1537 (5.2)
Grade 3	75 (0.5)	512 (3.5)	587 (2.0)
Grade 4	0	0	0
Grade 3 or above	75 (0.5)	512 (3.5)	587 (2.0)
Pain - N1	14726	14729	29455
Any	2596 (17.6)	12369 (84.0)	14965 (50.8)
Grade 1	2484 (16.9)	10735 (72.9)	13219 (44.9)
Grade 2	58 (0.4)	1232 (8.4)	1290 (4.4)
Grade 3	54 (0.4)	402 (2.7)	456 (1.5)
Grade 4	0	0	0
Grade 3 or above	54 (0.4)	402 (2.7)	456 (1.5)
Erythema (redness) - N1	14726	14729	29455
Any	74 (0.5)	429 (2.9)	503 (1.7)
Grade 1	56 (0.4)	272 (1.8)	328 (1.1)
Grade 2	7 (<0.1)	117 (0.8)	124 (0.4)
Grade 3	11 (<0.1)	40 (0.3)	51 (0.2)
Grade 4	0	0	0
Grade 3 or above	11 (<0.1)	40 (0.3)	51 (0.2)
Swelling (hardness) - N1	14726	14729	29455
Any	63 (0.4)	910 (6.2)	973 (3.3)
Grade 1	48 (0.3)	593 (4.0)	641 (2.2)

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Grade 2	9 (<0.1)	236 (1.6)	245 (0.8)
Grade 3	6 (<0.1)	81 (0.5)	87 (0.3)
Grade 4	0	0	0
Grade 3 or above	6 (<0.1)	81 (0.5)	87 (0.3)
Axillary swelling or tenderness - N1	14726	14729	29455
Any	701 (4.8)	1487 (10.1)	2188 (7.4)
Grade 1	648 (4.4)	1344 (9.1)	1992 (6.8)
Grade 2	27 (0.2)	98 (0.7)	125 (0.4)
Grade 3	26 (0.2)	45 (0.3)	71 (0.2)
Grade 4	0	0	0
Grade 3 or above	26 (0.2)	45 (0.3)	71 (0.2)
Solicited systemic adverse reactions - N1	14730	14733	29463
Any solicited systemic adverse reactions	6239 (42.4)	8053 (54.7)	14292 (48.5)
95% CI	41.6, 43.2	53.9, 55.5	47.9, 49.1
Grade 1	4234 (28.7)	5214 (35.4)	9448 (32.1)
Grade 2	1701 (11.5)	2412 (16.4)	4113 (14.0)
Grade 3	299 (2.0)	423 (2.9)	722 (2.5)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)
Grade 3 or above	304 (2.1)	427 (2.9)	731 (2.5)
Fever - N1	14729	14731	29460
Any	38 (0.3)	78 (0.5)	116 (0.4)
Grade 1	25 (0.2)	52 (0.4)	77 (0.3)
Grade 2	6 (<0.1)	14 (<0.1)	20 (<0.1)
Grade 3	2 (<0.1)	9 (<0.1)	11 (<0.1)
Grade 4	5 (<0.1)	3 (<0.1)	8 (<0.1)
Grade 3 or above	7 (<0.1)	12 (<0.1)	19 (<0.1)
Headache - N1	14725	14729	29454
Any	3917 (26.6)	4787 (32.5)	8704 (29.6)
Grade 1	3214 (21.8)	3833 (26.0)	7047 (23.9)
Grade 2	514 (3.5)	695 (4.7)	1209 (4.1)
Grade 3	189 (1.3)	259 (1.8)	448 (1.5)
Grade 4	0	0	0
Grade 3 or above	189 (1.3)	259 (1.8)	448 (1.5)
Fatigue - N1	14725	14729	29454
Any	4038 (27.4)	5466 (37.1)	9504 (32.3)
Grade 1	2646 (18.0)	3490 (23.7)	6136 (20.8)
Grade 2	1292 (8.8)	1834 (12.5)	3126 (10.6)

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Grade 3	100 (0.7)	141 (1.0)	241 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	100 (0.7)	142 (1.0)	242 (0.8)
Myalgia - N1	14725	14729	29454
Any	2011 (13.7)	3295 (22.4)	5306 (18.0)
Grade 1	1524 (10.3)	2355 (16.0)	3879 (13.2)
Grade 2	443 (3.0)	857 (5.8)	1300 (4.4)
Grade 3	44 (0.3)	83 (0.6)	127 (0.4)
Grade 4	0	0	0
Grade 3 or above	44 (0.3)	83 (0.6)	127 (0.4)
Arthralgia - N1	14725	14729	29454
Any	1735 (11.8)	2406 (16.3)	4141 (14.1)
Grade 1	1305 (8.9)	1776 (12.1)	3081 (10.5)
Grade 2	395 (2.7)	574 (3.9)	969 (3.3)
Grade 3	35 (0.2)	55 (0.4)	90 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	35 (0.2)	56 (0.4)	91 (0.3)
Nausea/vomiting - N1	14725	14729	29454
Any	1044 (7.1)	1210 (8.2)	2254 (7.7)
Grade 1	866 (5.9)	1009 (6.9)	1875 (6.4)
Grade 2	165 (1.1)	191 (1.3)	356 (1.2)
Grade 3	13 (<0.1)	10 (<0.1)	23 (<0.1)
Grade 4	0	0	0
Grade 3 or above	13 (<0.1)	10 (<0.1)	23 (<0.1)
Chills - N1	14725	14729	29454
Any	846 (5.7)	1162 (7.9)	2008 (6.8)
Grade 1	684 (4.6)	891 (6.0)	1575 (5.3)
Grade 2	149 (1.0)	250 (1.7)	399 (1.4)
Grade 3	13 (<0.1)	21 (0.1)	34 (0.1)
Grade 4	0	0	0
Grade 3 or above	13 (<0.1)	21 (0.1)	34 (0.1)

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Baseline SARS-CoV-2 Status: Positive			
Solicited adverse reactions - N1	337	346	683

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Any solicited adverse reactions	138 (40.9)	265 (76.6)	403 (59.0)
95% CI	35.7, 46.4	71.8, 81.0	55.2, 62.7
Grade 1	83 (24.6)	137 (39.6)	220 (32.2)
Grade 2	41 (12.2)	98 (28.3)	139 (20.4)
Grade 3	13 (3.9)	29 (8.4)	42 (6.1)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or above	14 (4.2)	30 (8.7)	44 (6.4)
Solicited local adverse reactions - N1	337	346	683
Any solicited local adverse reactions	60 (17.8)	250 (72.3)	310 (45.4)
95% CI	13.9, 22.3	67.2, 76.9	41.6, 49.2
Grade 1	56 (16.6)	180 (52.0)	236 (34.6)
Grade 2	1 (0.3)	56 (16.2)	57 (8.3)
Grade 3	3 (0.9)	14 (4.0)	17 (2.5)
Grade 4	0	0	0
Grade 3 or above	3 (0.9)	14 (4.0)	17 (2.5)
Pain - N1	337	346	683
Any	56 (16.6)	247 (71.4)	303 (44.4)
Grade 1	54 (16.0)	184 (53.2)	238 (34.8)
Grade 2	1 (0.3)	52 (15.0)	53 (7.8)
Grade 3	1 (0.3)	11 (3.2)	12 (1.8)
Grade 4	0	0	0
Grade 3 or above	1 (0.3)	11 (3.2)	12 (1.8)
Erythema (redness) - N1	337	346	683
Any	3 (0.9)	10 (2.9)	13 (1.9)
Grade 1	1 (0.3)	6 (1.7)	7 (1.0)
Grade 2	0	2 (0.6)	2 (0.3)
Grade 3	2 (0.6)	2 (0.6)	4 (0.6)
Grade 4	0	0	0
Grade 3 or above	2 (0.6)	2 (0.6)	4 (0.6)
Swelling (hardness) - N1	337	346	683
Any	2 (0.6)	19 (5.5)	21 (3.1)
Grade 1	2 (0.6)	10 (2.9)	12 (1.8)
Grade 2	0	8 (2.3)	8 (1.2)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or above	0	1 (0.3)	1 (0.1)
Axillary swelling or tenderness - N1	337	346	683

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Any	18 (5.3)	56 (16.2)	74 (10.8)
Grade 1	17 (5.0)	40 (11.6)	57 (8.3)
Grade 2	0	12 (3.5)	12 (1.8)
Grade 3	1 (0.3)	4 (1.2)	5 (0.7)
Grade 4	0	0	0
Grade 3 or above	1 (0.3)	4 (1.2)	5 (0.7)
Solicited systemic adverse reactions - N1	337	346	683
Any solicited systemic adverse reactions	122 (36.2)	214 (61.8)	336 (49.2)
95% CI	31.1, 41.6	56.5, 67.0	45.4, 53.0
Grade 1	70 (20.8)	108 (31.2)	178 (26.1)
Grade 2	40 (11.9)	82 (23.7)	122 (17.9)
Grade 3	11 (3.3)	23 (6.6)	34 (5.0)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or above	12 (3.6)	24 (6.9)	36 (5.3)
Fever - N1	336	346	682
Any	6 (1.8)	33 (9.5)	39 (5.7)
Grade 1	3 (0.9)	20 (5.8)	23 (3.4)
Grade 2	2 (0.6)	10 (2.9)	12 (1.8)
Grade 3	0	2 (0.6)	2 (0.3)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or above	1 (0.3)	3 (0.9)	4 (0.6)
Headache - N1	337	346	683
Any	83 (24.6)	134 (38.7)	217 (31.8)
Grade 1	60 (17.8)	89 (25.7)	149 (21.8)
Grade 2	16 (4.7)	33 (9.5)	49 (7.2)
Grade 3	7 (2.1)	12 (3.5)	19 (2.8)
Grade 4	0	0	0
Grade 3 or above	7 (2.1)	12 (3.5)	19 (2.8)
Fatigue - N1	337	346	683
Any	72 (21.4)	138 (39.9)	210 (30.7)
Grade 1	40 (11.9)	71 (20.5)	111 (16.3)
Grade 2	28 (8.3)	57 (16.5)	85 (12.4)
Grade 3	4 (1.2)	10 (2.9)	14 (2.0)
Grade 4	0	0	0
Grade 3 or above	4 (1.2)	10 (2.9)	14 (2.0)
Myalgia - N1	337	346	683
Any	47 (13.9)	128 (37.0)	175 (25.6)

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Grade 1	27 (8.0)	71 (20.5)	98 (14.3)
Grade 2	18 (5.3)	50 (14.5)	68 (10.0)
Grade 3	2 (0.6)	7 (2.0)	9 (1.3)
Grade 4	0	0	0
Grade 3 or above	2 (0.6)	7 (2.0)	9 (1.3)
Arthralgia - N1	337	346	683
Any	40 (11.9)	88 (25.4)	128 (18.7)
Grade 1	21 (6.2)	54 (15.6)	75 (11.0)
Grade 2	17 (5.0)	29 (8.4)	46 (6.7)
Grade 3	2 (0.6)	5 (1.4)	7 (1.0)
Grade 4	0	0	0
Grade 3 or above	2 (0.6)	5 (1.4)	7 (1.0)
Nausea/vomiting - N1	337	346	683
Any	25 (7.4)	43 (12.4)	68 (10.0)
Grade 1	17 (5.0)	30 (8.7)	47 (6.9)
Grade 2	8 (2.4)	13 (3.8)	21 (3.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0
Chills - N1	337	346	683
Any	27 (8.0)	81 (23.4)	108 (15.8)
Grade 1	17 (5.0)	43 (12.4)	60 (8.8)
Grade 2	9 (2.7)	35 (10.1)	44 (6.4)
Grade 3	1 (0.3)	3 (0.9)	4 (0.6)
Grade 4	0	0	0
Grade 3 or above	1 (0.3)	3 (0.9)	4 (0.6)

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Baseline SARS-CoV-2 Status: Missing			
Solicited adverse reactions - N1	84	87	171
Any solicited adverse reactions	42 (50.0)	76 (87.4)	118 (69.0)
95% CI	38.9, 61.1	78.5, 93.5	61.5, 75.8
Grade 1	36 (42.9)	56 (64.4)	92 (53.8)
Grade 2	5 (6.0)	14 (16.1)	19 (11.1)
Grade 3	1 (1.2)	6 (6.9)	7 (4.1)
Grade 4	0	0	0
Grade 3 or above	1 (1.2)	6 (6.9)	7 (4.1)
Solicited local adverse reactions - N1	84	87	171
Any solicited local adverse reactions	15 (17.9)	73 (83.9)	88 (51.5)
95% CI	10.4, 27.7	74.5, 90.9	43.7, 59.2
Grade 1	15 (17.9)	64 (73.6)	79 (46.2)
Grade 2	0	6 (6.9)	6 (3.5)
Grade 3	0	3 (3.4)	3 (1.8)
Grade 4	0	0	0
Grade 3 or above	0	3 (3.4)	3 (1.8)
Pain - N1	84	87	171
Any	13 (15.5)	72 (82.8)	85 (49.7)
Grade 1	13 (15.5)	66 (75.9)	79 (46.2)
Grade 2	0	3 (3.4)	3 (1.8)
Grade 3	0	3 (3.4)	3 (1.8)
Grade 4	0	0	0
Grade 3 or above	0	3 (3.4)	3 (1.8)
Erythema (redness) - N1	84	87	171
Any	0	6 (6.9)	6 (3.5)
Grade 1	0	3 (3.4)	3 (1.8)
Grade 2	0	3 (3.4)	3 (1.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0
Swelling (hardness) - N1	84	87	171
Any	0	6 (6.9)	6 (3.5)
Grade 1	0	5 (5.7)	5 (2.9)
Grade 2	0	1 (1.1)	1 (0.6)
Grade 3	0	0	0
Grade 4	0	0	0

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Grade 3 or above	0	0	0
Axillary swelling or tenderness - N1	84	87	171
Any	3 (3.6)	10 (11.5)	13 (7.6)
Grade 1	3 (3.6)	10 (11.5)	13 (7.6)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0
Solicited systemic adverse reactions - N1	84	87	171
Any solicited systemic adverse reactions	36 (42.9)	49 (56.3)	85 (49.7)
95% CI	32.1, 54.1	45.3, 66.9	42.0, 57.4
Grade 1	30 (35.7)	36 (41.4)	66 (38.6)
Grade 2	5 (6.0)	10 (11.5)	15 (8.8)
Grade 3	1 (1.2)	3 (3.4)	4 (2.3)
Grade 4	0	0	0
Grade 3 or above	1 (1.2)	3 (3.4)	4 (2.3)
Fever - N1	84	86	170
Any	0	1 (1.2)	1 (0.6)
Grade 1	0	1 (1.2)	1 (0.6)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0
Headache - N1	84	87	171
Any	26 (31.0)	29 (33.3)	55 (32.2)
Grade 1	23 (27.4)	25 (28.7)	48 (28.1)
Grade 2	2 (2.4)	2 (2.3)	4 (2.3)
Grade 3	1 (1.2)	2 (2.3)	3 (1.8)
Grade 4	0	0	0
Grade 3 or above	1 (1.2)	2 (2.3)	3 (1.8)
Fatigue - N1	84	87	171
Any	23 (27.4)	32 (36.8)	55 (32.2)
Grade 1	19 (22.6)	24 (27.6)	43 (25.1)
Grade 2	3 (3.6)	8 (9.2)	11 (6.4)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or above	1 (1.2)	0	1 (0.6)

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Myalgia - N1	84	87	171
Any	11 (13.1)	19 (21.8)	30 (17.5)
Grade 1	9 (10.7)	16 (18.4)	25 (14.6)
Grade 2	1 (1.2)	2 (2.3)	3 (1.8)
Grade 3	1 (1.2)	1 (1.1)	2 (1.2)
Grade 4	0	0	0
Grade 3 or above	1 (1.2)	1 (1.1)	2 (1.2)
Arthralgia - N1	84	87	171
Any	9 (10.7)	16 (18.4)	25 (14.6)
Grade 1	7 (8.3)	12 (13.8)	19 (11.1)
Grade 2	1 (1.2)	4 (4.6)	5 (2.9)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or above	1 (1.2)	0	1 (0.6)
Nausea/vomiting - N1	84	87	171
Any	6 (7.1)	9 (10.3)	15 (8.8)
Grade 1	4 (4.8)	8 (9.2)	12 (7.0)
Grade 2	2 (2.4)	1 (1.1)	3 (1.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0
Chills - N1	84	87	171
Any	5 (6.0)	8 (9.2)	13 (7.6)
Grade 1	5 (6.0)	4 (4.6)	9 (5.3)
Grade 2	0	4 (4.6)	4 (2.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.

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

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

Severity grading for solicited adverse reactions is based on modified Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials (DHHS 2007).

Pain: Grade 3 = any use of prescription pain reliever/prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Erythema and Swelling: Grade 3 = >100mm/>10cm; Grade 4 = necrosis or exfoliative dermatitis.

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)

Axillary Swelling or Tenderness: Grade 3 = any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fever: Grade 3 = ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: > 40.0°C or > 104.0°F.

Headache: Grade 3 = significant; any use of prescription pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Fatigue, Myalgia, and Arthralgia: Grade 3 = significant; prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Nausea/Vomiting: Grade 3 = prevents daily activity, requires outpatient intravenous hydration; Grade 4 = requires emergency room visit or hospitalization for hypotensive shock.

Chills: Grade 3 = prevents daily activity and requires medical intervention; Grade 4 = requires emergency room visit or hospitalization.

Source: Table 14.3.1.1.3.1.

Table 7-9: Summary of Participants With Solicited Adverse Reactions Starting Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade (Second Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Baseline SARS-CoV-2 Status: Negative			
Solicited adverse reactions - N1	14267	14378	28645
Any solicited adverse reactions	6141 (43.0)	13294 (92.5)	19435 (67.8)
95% CI	42.2, 43.9	92.0, 92.9	67.3, 68.4
Grade 1	4269 (29.9)	4739 (33.0)	9008 (31.4)
Grade 2	1524 (10.7)	5692 (39.6)	7216 (25.2)
Grade 3	345 (2.4)	2849 (19.8)	3194 (11.2)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or above	348 (2.4)	2863 (19.9)	3211 (11.2)
Solicited local adverse reactions - N1	14267	14375	28642
Any solicited local adverse reactions	2699 (18.9)	12783 (88.9)	15482 (54.1)
95% CI	18.3, 19.6	88.4, 89.4	53.5, 54.6
Grade 1	2543 (17.8)	8620 (60.0)	11163 (39.0)
Grade 2	83 (0.6)	3160 (22.0)	3243 (11.3)
Grade 3	73 (0.5)	1003 (7.0)	1076 (3.8)
Grade 4	0	0	0
Grade 3 or above	73 (0.5)	1003 (7.0)	1076 (3.8)
Pain - N1	14267	14375	28642
Any	2435 (17.1)	12722 (88.5)	15157 (52.9)
Grade 1	2337 (16.4)	9330 (64.9)	11667 (40.7)
Grade 2	58 (0.4)	2797 (19.5)	2855 (10.0)
Grade 3	40 (0.3)	595 (4.1)	635 (2.2)
Grade 4	0	0	0
Grade 3 or above	40 (0.3)	595 (4.1)	635 (2.2)
Erythema (redness) - N1	14267	14374	28641
Any	66 (0.5)	1259 (8.8)	1325 (4.6)
Grade 1	47 (0.3)	452 (3.1)	499 (1.7)
Grade 2	5 (<0.1)	527 (3.7)	532 (1.9)
Grade 3	14 (<0.1)	280 (1.9)	294 (1.0)
Grade 4	0	0	0
Grade 3 or above	14 (<0.1)	280 (1.9)	294 (1.0)
Swelling (hardness) - N1	14267	14374	28641
Any	59 (0.4)	1783 (12.4)	1842 (6.4)
Grade 1	38 (0.3)	890 (6.2)	928 (3.2)

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Grade 2	9 (<0.1)	642 (4.5)	651 (2.3)
Grade 3	12 (<0.1)	251 (1.7)	263 (0.9)
Grade 4	0	0	0
Grade 3 or above	12 (<0.1)	251 (1.7)	263 (0.9)
Axillary swelling or tenderness - N1	14267	14374	28641
Any	557 (3.9)	2047 (14.2)	2604 (9.1)
Grade 1	512 (3.6)	1704 (11.9)	2216 (7.7)
Grade 2	25 (0.2)	277 (1.9)	302 (1.1)
Grade 3	20 (0.1)	66 (0.5)	86 (0.3)
Grade 4	0	0	0
Grade 3 or above	20 (0.1)	66 (0.5)	86 (0.3)
Solicited systemic adverse reactions - N1	14266	14377	28643
Any solicited systemic adverse reactions	5241 (36.7)	11459 (79.7)	16700 (58.3)
95% CI	35.9, 37.5	79.0, 80.4	57.7, 58.9
Grade 1	3453 (24.2)	3642 (25.3)	7095 (24.8)
Grade 2	1500 (10.5)	5498 (38.2)	6998 (24.4)
Grade 3	285 (2.0)	2305 (16.0)	2590 (9.0)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or above	288 (2.0)	2319 (16.1)	2607 (9.1)
Fever - N1	14263	14370	28633
Any	42 (0.3)	2235 (15.6)	2277 (8.0)
Grade 1	32 (0.2)	1340 (9.3)	1372 (4.8)
Grade 2	5 (<0.1)	682 (4.7)	687 (2.4)
Grade 3	2 (<0.1)	200 (1.4)	202 (0.7)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)
Grade 3 or above	5 (<0.1)	213 (1.5)	218 (0.8)
Headache - N1	14265	14374	28639
Any	3363 (23.6)	8488 (59.1)	11851 (41.4)
Grade 1	2688 (18.8)	4725 (32.9)	7413 (25.9)
Grade 2	510 (3.6)	3105 (21.6)	3615 (12.6)
Grade 3	165 (1.2)	658 (4.6)	823 (2.9)
Grade 4	0	0	0
Grade 3 or above	165 (1.2)	658 (4.6)	823 (2.9)
Fatigue - N1	14265	14374	28639
Any	3344 (23.4)	9446 (65.7)	12790 (44.7)
Grade 1	2134 (15.0)	3375 (23.5)	5509 (19.2)
Grade 2	1103 (7.7)	4655 (32.4)	5758 (20.1)

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Grade 3	107 (0.8)	1416 (9.9)	1523 (5.3)
Grade 4	0	0	0
Grade 3 or above	107 (0.8)	1416 (9.9)	1523 (5.3)
Myalgia - N1	14265	14374	28639
Any	1775 (12.4)	8357 (58.1)	10132 (35.4)
Grade 1	1271 (8.9)	3166 (22.0)	4437 (15.5)
Grade 2	452 (3.2)	3886 (27.0)	4338 (15.1)
Grade 3	52 (0.4)	1305 (9.1)	1357 (4.7)
Grade 4	0	0	0
Grade 3 or above	52 (0.4)	1305 (9.1)	1357 (4.7)
Arthralgia - N1	14265	14374	28639
Any	1543 (10.8)	6181 (43.0)	7724 (27.0)
Grade 1	1115 (7.8)	2758 (19.2)	3873 (13.5)
Grade 2	384 (2.7)	2655 (18.5)	3039 (10.6)
Grade 3	44 (0.3)	768 (5.3)	812 (2.8)
Grade 4	0	0	0
Grade 3 or above	44 (0.3)	768 (5.3)	812 (2.8)
Nausea/vomiting - N1	14265	14374	28639
Any	922 (6.5)	2741 (19.1)	3663 (12.8)
Grade 1	747 (5.2)	2052 (14.3)	2799 (9.8)
Grade 2	164 (1.1)	668 (4.6)	832 (2.9)
Grade 3	11 (<0.1)	20 (0.1)	31 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or above	11 (<0.1)	21 (0.1)	32 (0.1)
Chills - N1	14265	14374	28639
Any	790 (5.5)	6384 (44.4)	7174 (25.0)
Grade 1	610 (4.3)	2854 (19.9)	3464 (12.1)
Grade 2	163 (1.1)	3340 (23.2)	3503 (12.2)
Grade 3	17 (0.1)	190 (1.3)	207 (0.7)
Grade 4	0	0	0
Grade 3 or above	17 (0.1)	190 (1.3)	207 (0.7)

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Baseline SARS-CoV-2 Status: Positive			
Solicited adverse reactions - N1	233	232	465

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Any solicited adverse reactions	82 (35.2)	187 (80.6)	269 (57.8)
95% CI	29.1, 41.7	74.9, 85.5	53.2, 62.4
Grade 1	52 (22.3)	90 (38.8)	142 (30.5)
Grade 2	27 (11.6)	68 (29.3)	95 (20.4)
Grade 3	3 (1.3)	29 (12.5)	32 (6.9)
Grade 4	0	0	0
Grade 3 or above	3 (1.3)	29 (12.5)	32 (6.9)
Solicited local adverse reactions - N1	232	232	464
Any solicited local adverse reactions	42 (18.1)	172 (74.1)	214 (46.1)
95% CI	13.4, 23.7	68.0, 79.6	41.5, 50.8
Grade 1	35 (15.1)	125 (53.9)	160 (34.5)
Grade 2	5 (2.2)	36 (15.5)	41 (8.8)
Grade 3	2 (0.9)	11 (4.7)	13 (2.8)
Grade 4	0	0	0
Grade 3 or above	2 (0.9)	11 (4.7)	13 (2.8)
Pain - N1	232	232	464
Any	36 (15.5)	169 (72.8)	205 (44.2)
Grade 1	32 (13.8)	126 (54.3)	158 (34.1)
Grade 2	3 (1.3)	36 (15.5)	39 (8.4)
Grade 3	1 (0.4)	7 (3.0)	8 (1.7)
Grade 4	0	0	0
Grade 3 or above	1 (0.4)	7 (3.0)	8 (1.7)
Erythema (redness) - N1	232	232	464
Any	1 (0.4)	9 (3.9)	10 (2.2)
Grade 1	0	2 (0.9)	2 (0.4)
Grade 2	0	4 (1.7)	4 (0.9)
Grade 3	1 (0.4)	3 (1.3)	4 (0.9)
Grade 4	0	0	0
Grade 3 or above	1 (0.4)	3 (1.3)	4 (0.9)
Swelling (hardness) - N1	232	232	464
Any	1 (0.4)	11 (4.7)	12 (2.6)
Grade 1	0	4 (1.7)	4 (0.9)
Grade 2	1 (0.4)	5 (2.2)	6 (1.3)
Grade 3	0	2 (0.9)	2 (0.4)
Grade 4	0	0	0
Grade 3 or above	0	2 (0.9)	2 (0.4)
Axillary swelling or tenderness - N1	232	232	464

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Any	11 (4.7)	32 (13.8)	43 (9.3)
Grade 1	8 (3.4)	22 (9.5)	30 (6.5)
Grade 2	3 (1.3)	8 (3.4)	11 (2.4)
Grade 3	0	2 (0.9)	2 (0.4)
Grade 4	0	0	0
Grade 3 or above	0	2 (0.9)	2 (0.4)
Solicited systemic adverse reactions - N1	233	232	465
Any solicited systemic adverse reactions	73 (31.3)	152 (65.5)	225 (48.4)
95% CI	25.4, 37.7	59.0, 71.6	43.8, 53.0
Grade 1	44 (18.9)	61 (26.3)	105 (22.6)
Grade 2	28 (12.0)	70 (30.2)	98 (21.1)
Grade 3	1 (0.4)	21 (9.1)	22 (4.7)
Grade 4	0	0	0
Grade 3 or above	1 (0.4)	21 (9.1)	22 (4.7)
Fever - N1	232	232	464
Any	1 (0.4)	31 (13.4)	32 (6.9)
Grade 1	1 (0.4)	20 (8.6)	21 (4.5)
Grade 2	0	9 (3.9)	9 (1.9)
Grade 3	0	2 (0.9)	2 (0.4)
Grade 4	0	0	0
Grade 3 or above	0	2 (0.9)	2 (0.4)
Headache - N1	232	232	464
Any	43 (18.5)	98 (42.2)	141 (30.4)
Grade 1	35 (15.1)	61 (26.3)	96 (20.7)
Grade 2	8 (3.4)	31 (13.4)	39 (8.4)
Grade 3	0	6 (2.6)	6 (1.3)
Grade 4	0	0	0
Grade 3 or above	0	6 (2.6)	6 (1.3)
Fatigue - N1	232	232	464
Any	54 (23.3)	106 (45.7)	160 (34.5)
Grade 1	31 (13.4)	42 (18.1)	73 (15.7)
Grade 2	22 (9.5)	52 (22.4)	74 (15.9)
Grade 3	1 (0.4)	12 (5.2)	13 (2.8)
Grade 4	0	0	0
Grade 3 or above	1 (0.4)	12 (5.2)	13 (2.8)
Myalgia - N1	232	232	464
Any	34 (14.7)	117 (50.4)	151 (32.5)

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Grade 1	22 (9.5)	60 (25.9)	82 (17.7)
Grade 2	12 (5.2)	46 (19.8)	58 (12.5)
Grade 3	0	11 (4.7)	11 (2.4)
Grade 4	0	0	0
Grade 3 or above	0	11 (4.7)	11 (2.4)
Arthralgia - N1	232	232	464
Any	26 (11.2)	77 (33.2)	103 (22.2)
Grade 1	19 (8.2)	37 (15.9)	56 (12.1)
Grade 2	7 (3.0)	36 (15.5)	43 (9.3)
Grade 3	0	4 (1.7)	4 (0.9)
Grade 4	0	0	0
Grade 3 or above	0	4 (1.7)	4 (0.9)
Nausea/vomiting - N1	232	232	464
Any	13 (5.6)	33 (14.2)	46 (9.9)
Grade 1	10 (4.3)	25 (10.8)	35 (7.5)
Grade 2	3 (1.3)	7 (3.0)	10 (2.2)
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Grade 3 or above	0	1 (0.4)	1 (0.2)
Chills - N1	232	232	464
Any	19 (8.2)	80 (34.5)	99 (21.3)
Grade 1	16 (6.9)	40 (17.2)	56 (12.1)
Grade 2	3 (1.3)	40 (17.2)	43 (9.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Baseline SARS-CoV-2 Status: Missing			
Solicited adverse reactions - N1	78	81	159
Any solicited adverse reactions	32 (41.0)	75 (92.6)	107 (67.3)
95% CI	30.0, 52.7	84.6, 97.2	59.4, 74.5
Grade 1	25 (32.1)	18 (22.2)	43 (27.0)
Grade 2	7 (9.0)	40 (49.4)	47 (29.6)
Grade 3	0	17 (21.0)	17 (10.7)
Grade 4	0	0	0
Grade 3 or above	0	17 (21.0)	17 (10.7)
Solicited local adverse reactions - N1	78	81	159
Any solicited local adverse reactions	16 (20.5)	74 (91.4)	90 (56.6)
95% CI	12.2, 31.2	83.0, 96.5	48.5, 64.4
Grade 1	16 (20.5)	44 (54.3)	60 (37.7)
Grade 2	0	21 (25.9)	21 (13.2)
Grade 3	0	9 (11.1)	9 (5.7)
Grade 4	0	0	0
Grade 3 or above	0	9 (11.1)	9 (5.7)
Pain - N1	78	81	159
Any	15 (19.2)	73 (90.1)	88 (55.3)
Grade 1	15 (19.2)	52 (64.2)	67 (42.1)
Grade 2	0	17 (21.0)	17 (10.7)
Grade 3	0	4 (4.9)	4 (2.5)
Grade 4	0	0	0
Grade 3 or above	0	4 (4.9)	4 (2.5)
Erythema (redness) - N1	78	81	159
Any	1 (1.3)	6 (7.4)	7 (4.4)
Grade 1	1 (1.3)	2 (2.5)	3 (1.9)
Grade 2	0	0	0
Grade 3	0	4 (4.9)	4 (2.5)
Grade 4	0	0	0
Grade 3 or above	0	4 (4.9)	4 (2.5)
Swelling (hardness) - N1	78	81	159
Any	0	13 (16.0)	13 (8.2)
Grade 1	0	6 (7.4)	6 (3.8)
Grade 2	0	5 (6.2)	5 (3.1)
Grade 3	0	2 (2.5)	2 (1.3)
Grade 4	0	0	0

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Grade 3 or above	0	2 (2.5)	2 (1.3)
Axillary swelling or tenderness - N1	78	81	159
Any	3 (3.8)	13 (16.0)	16 (10.1)
Grade 1	3 (3.8)	9 (11.1)	12 (7.5)
Grade 2	0	4 (4.9)	4 (2.5)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0
Solicited systemic adverse reactions - N1	78	81	159
Any solicited systemic adverse reactions	29 (37.2)	67 (82.7)	96 (60.4)
95% CI	26.5, 48.9	72.7, 90.2	52.3, 68.0
Grade 1	22 (28.2)	14 (17.3)	36 (22.6)
Grade 2	7 (9.0)	43 (53.1)	50 (31.4)
Grade 3	0	10 (12.3)	10 (6.3)
Grade 4	0	0	0
Grade 3 or above	0	10 (12.3)	10 (6.3)
Fever - N1	78	80	158
Any	0	10 (12.5)	10 (6.3)
Grade 1	0	3 (3.8)	3 (1.9)
Grade 2	0	6 (7.5)	6 (3.8)
Grade 3	0	1 (1.3)	1 (0.6)
Grade 4	0	0	0
Grade 3 or above	0	1 (1.3)	1 (0.6)
Headache - N1	78	81	159
Any	21 (26.9)	51 (63.0)	72 (45.3)
Grade 1	17 (21.8)	29 (35.8)	46 (28.9)
Grade 2	4 (5.1)	20 (24.7)	24 (15.1)
Grade 3	0	2 (2.5)	2 (1.3)
Grade 4	0	0	0
Grade 3 or above	0	2 (2.5)	2 (1.3)
Fatigue - N1	78	81	159
Any	20 (25.6)	55 (67.9)	75 (47.2)
Grade 1	16 (20.5)	14 (17.3)	30 (18.9)
Grade 2	4 (5.1)	36 (44.4)	40 (25.2)
Grade 3	0	5 (6.2)	5 (3.1)
Grade 4	0	0	0
Grade 3 or above	0	5 (6.2)	5 (3.1)

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Myalgia - N1	78	81	159
Any	15 (19.2)	55 (67.9)	70 (44.0)
Grade 1	14 (17.9)	16 (19.8)	30 (18.9)
Grade 2	1 (1.3)	34 (42.0)	35 (22.0)
Grade 3	0	5 (6.2)	5 (3.1)
Grade 4	0	0	0
Grade 3 or above	0	5 (6.2)	5 (3.1)
Arthralgia - N1	78	81	159
Any	10 (12.8)	45 (55.6)	55 (34.6)
Grade 1	9 (11.5)	14 (17.3)	23 (14.5)
Grade 2	1 (1.3)	28 (34.6)	29 (18.2)
Grade 3	0	3 (3.7)	3 (1.9)
Grade 4	0	0	0
Grade 3 or above	0	3 (3.7)	3 (1.9)
Nausea/vomiting - N1	78	81	159
Any	6 (7.7)	20 (24.7)	26 (16.4)
Grade 1	4 (5.1)	17 (21.0)	21 (13.2)
Grade 2	2 (2.6)	3 (3.7)	5 (3.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or above	0	0	0
Chills - N1	78	81	159
Any	4 (5.1)	36 (44.4)	40 (25.2)
Grade 1	3 (3.8)	13 (16.0)	16 (10.1)
Grade 2	1 (1.3)	22 (27.2)	23 (14.5)
Grade 3	0	1 (1.2)	1 (0.6)
Grade 4	0	0	0
Grade 3 or above	0	1 (1.2)	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.

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

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

Severity grading for solicited adverse reactions is based on modified Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventative Vaccine Clinical Trials (DHHS 2007).

Pain: Grade 3 = any use of prescription (narcotic) pain reliever/prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Erythema and Swelling: Grade 3 = >100mm/>10cm; Grade 4 = necrosis or exfoliative dermatitis.

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)

Axillary Swelling or Tenderness: Grade 3 = any use of prescription pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Fever: Grade 3 = ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: > 40.0°C or > 104.0°F.

Headache: Grade 3 = significant; any use of prescription pain reliever or prevents daily activity; Grade 4 = requires emergency room visit or hospitalization

Fatigue, Myalgia, and Arthralgia: Grade 3 = significant; prevents daily activity; Grade 4 = requires emergency room visit or hospitalization.

Nausea/Vomiting: Grade 3 = prevents daily activity, requires outpatient intravenous hydration; Grade 4 = requires emergency room visit or hospitalization for hypotensive shock.

Chills: Grade 3 = prevents daily activity and requires medical intervention; Grade 4 = requires emergency room visit or hospitalization.

Source: Table 14.3.1.1.3.2.

7.1.4.3 Race and Ethnicity

In the Safety Set, race was reported as white for 79.2% of participants overall, Black or African American for 10.2%, Asian for 4.6%, and multiracial for 2.1%; no other category was reported for > 2% of participants (Table 14.1.3.2.2). Ethnicity was reported as Not Hispanic or Latino for 78.6% of participants overall. Results among participants who reported white race and those who reported Not Hispanic or Latino ethnicity reflect those of the overall population.

Compared with those who reported white race, participants who reported Black or African American race appeared to have lower incidence of solicited local ARs overall and for all reactions except axillary swelling or tenderness after the first injection, while incidence of systemic ARs appeared to be similar between the subgroups (Table 14.3.1.1.4.1). After the second injection, participants who reported Black or African American race appeared to have lower incidence of local and systemic ARs compared with those who reported White race (Table 14.3.1.1.4.2). Other subgroups by race were too small for meaningful comparison.

No relevant differences were observed in the incidence of local or systemic ARs between participants who reported ethnicity as Not Hispanic or Latino and those who reported Hispanic or Latino ethnicity after the first (Table 14.3.1.1.5.1) or second (Table 14.3.1.1.5.2) injection.

7.1.4.4 Sex

After both the first (Table 14.3.1.1.7.1) and second (Table 14.3.1.1.7.2) injections, female participants appeared to have higher incidence of local and systemic ARs compared with male participants.

7.1.5 Medication Use for Solicited Adverse Reactions of Pain and Fever

To further characterize potential reactogenicity of mRNA-1273, analyses were performed for participant use of medications to prevent or treat pain or fever. This analysis was based on participant-recorded use in the eDiary, wherein participants entered responses in the eDiary to questions about use of medications to treat or prevent pain or fever.

After the first injection, the use of medication for pain or fever was reported for 22.0% of participants in the mRNA-1273 group and 13.2% of participants in the placebo group (Table 7-10). After the second injection, the use of medication for pain or fever was higher in the mRNA-1273 group (53.5%) compared with after the first injection, while no notable difference was observed in the placebo group (10.9%) (Table 7-11). For most participants, the medication was used to treat, rather than to prevent, pain or fever. In the mRNA-1273 group after both injections, the percentage of participants who reported use of medication for pain or fever was higher in the ≥ 18 to < 65 years age group than that observed in the ≥ 65 years age group, which is consistent with the higher observed rate of reporting solicited ARs in the younger age cohort.

Table 7-10: Summary of Medications for Pain/Fever After First Vaccination (First Injection Solicited Safety Set)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11402) n (%)	**mRNA-1273 (N=11406) n (%)**	**Total (N=22808) n (%)**	**Placebo (N=3749) n (%)**	**mRNA-1273 (N=3760) n (%)**	**Total (N=7509) n (%)**	**Placebo (N=15151) n (%)**	**mRNA-1273 (N=15166) n (%)**	**Total (N=30317) n (%)**
Medication taken for pain or fever	1523 (13.4)	2656 (23.3)	4179 (18.3)	477 (12.7)	673 (17.9)	1150 (15.3)	2000 (13.2)	3329 (22.0)	5329 (17.6)
Prevent pain or fever	257 (2.3)	396 (3.5)	653 (2.9)	124 (3.3)	162 (4.3)	286 (3.8)	381 (2.5)	558 (3.7)	939 (3.1)
Treat pain or fever	1385 (12.1)	2503 (21.9)	3888 (17.0)	414 (11.0)	595 (15.8)	1009 (13.4)	1799 (11.9)	3098 (20.4)	4897 (16.2)

Medications are collected on eDiary.

Source: Table 14.1.5.5.1.

Table 7-11: Summary of Medications for Pain/Fever After Second Vaccination (Second Injection Solicited Safety Set)

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Medication taken for pain or fever	1254 (11.5)	6307 (57.3)	7561 (34.5)	331 (9.1)	1548 (41.9)	1879 (25.6)	1585 (10.9)	7855 (53.5)	9440 (32.3)
Prevent pain or fever	223 (2.0)	1137 (10.3)	1360 (6.2)	69 (1.9)	219 (5.9)	288 (3.9)	292 (2.0)	1356 (9.2)	1648 (5.6)
Treat pain or fever	1157 (10.6)	6126 (55.7)	7283 (33.2)	290 (7.9)	1495 (40.5)	1785 (24.3)	1447 (9.9)	7621 (51.9)	9068 (31.0)

Medications are collected on eDiary.

Source: Table 14.1.5.5.2.

7.2 Unsolicited Adverse Events

Summaries of unsolicited adverse events are available for the 28-day post-injection follow-up period and with follow-up for the entire duration of Part A, which is the randomized, blinded part of the study. Summaries for Part A include all available participant level data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier, and provides accumulated safety data through a median duration of approximately 6 months after the second injection (Section 5.9).

7.2.1 Overview of Unsolicited Adverse Events

7.2.1.1 Up to 28 Days After Injection

The incidences of unsolicited TEAEs, severe TEAEs, and MAAEs regardless of relationship to the IP during the 28 days after any injection were generally similar in participants who received mRNA-1273 and those who received placebo (Table 7-12).

At least 1 TEAE that was assessed by the investigator to be treatment-related was reported in 13.6% and 8.2% of participants in the mRNA-1273 and placebo groups, respectively. These events were generally not severe and only rarely warranted discontinuation of treatment: the percentages of participants who had severe TEAEs that were assessed as treatment-related were 0.5% and 0.2%, respectively; and 20 and 14 participants, respectively, discontinued treatment in response to the event. Per protocol, solicited ARs were reported as treatment-related AEs if they started or were ongoing after 7 days after the injection, were SAEs or MAAEs, or resulted in discontinuation of treatment or withdrawal from the study (Section 3.7.4.1).

Table 7-12: Summary of Unsolicited Treatment Emergent Adverse Events up to 28 Days After Any Injection (Safety Set)

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs regardless of relationship to study vaccination			
All	4338 (28.6)	4752 (31.3)	9090 (30.0)
Serious	104 (0.7)	98 (0.6)	202 (0.7)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-attended	1940 (12.8)	1819 (12.0)	3759 (12.4)
Leading to discontinuation from study vaccine	92 (0.6)	61 (0.4)	153 (0.5)
Leading to discontinuation from participation in the study	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	233 (1.5)	258 (1.7)	491 (1.6)
Unsolicited TEAEs related to study vaccination			
All	1236 (8.2)	2067 (13.6)	3303 (10.9)
Serious	3 (<0.1)	8 (<0.1)	11 (<0.1)
Fatal	0	0	0
Medically-attended	95 (0.6)	198 (1.3)	293 (1.0)
Leading to discontinuation from study vaccine	14 (<0.1)	20 (0.1)	34 (0.1)
Leading to discontinuation from participation in the study	0	1 (<0.1)	1 (<0.1)
Severe	31 (0.2)	83 (0.5)	114 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Source: Table 14.3.1.7.1.1.

7.2.1.2 Overall Study Period in Part A

Per protocol (Protocol Section 8.3.6), TEAEs were collected to the end of the 28-day period, while SAEs, MAAEs, and TEAEs leading to study discontinued were collected throughout follow-up in Part A. Incidence of SAEs and MAAEs regardless of causality remained balanced between the groups with follow-up throughout Part A (Table 7-13). The incidence of MAAEs assessed by the investigator as related to investigational product in Part A was similar in each group to that observed in the 28-day period after each injection.

At least 1 unsolicited TEAE with a fatal outcome was reported for 17 participants in the mRNA-1273 group in Table 7-13, but death is reported for 16 participants in the mRNA-1273 group in Table 7-20. This apparent discrepancy is because there was 1 participant who had a TEAE with onset during Part A (before the PDV date and during the blinded portion) that had a fatal outcome during Part B (after unblinding at the PDV). The TEAE was first reported during Part A and its outcome is thus reported in Table 7-13, while the death, which did not occur until Part B, is not captured in Table 7-20.

Table 7-13: Summary of Unsolicited Treatment-Emergent Adverse Events in Part A (Safety Set)

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs regardless of relationship to study vaccination			
All	6513 (43.0)	6310 (41.6)	12823 (42.3)
Serious	292 (1.9)	268 (1.8)	560 (1.8)
Fatal	16 (0.1)	17 (0.1)	33 (0.1)
Medically-attended	4131 (27.2)	3468 (22.8)	7599 (25.0)
Leading to discontinuation from study vaccine	109 (0.7)	74 (0.5)	183 (0.6)
Leading to discontinuation from participation in the study	23 (0.2)	26 (0.2)	49 (0.2)
Severe	486 (3.2)	461 (3.0)	947 (3.1)
Unsolicited TEAEs related to study vaccination			
All	1288 (8.5)	2107 (13.9)	3395 (11.2)
Serious	4 (<0.1)	12 (<0.1)	16 (<0.1)
Fatal	0	0	0
Medically-attended	109 (0.7)	213 (1.4)	322 (1.1)
Leading to discontinuation from study vaccine	15 (<0.1)	20 (0.1)	35 (0.1)
Leading to discontinuation from participation in the study	0	1 (<0.1)	1 (<0.1)
Severe	34 (0.2)	88 (0.6)	122 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Source: Table 14.3.1.7.1.3.

7.2.2 Unsolicited Adverse Events by Preferred Term

The incidence of TEAEs was similar between the mRNA-1273 and placebo treatment groups in the 28-day follow-up period (31.3% and 28.6%, respectively [Table 7-12]) and in the full Part A follow-up period (41.6% and 43.0%, respectively [Table 7-13]). Unsolicited TEAEs are summarized by severity in Section 7.2.3 and by causality in Section 7.2.4. Unsolicited TEAEs with onset within 30 minutes of injection are summarized in Section 7.2.5.

The most commonly reported unsolicited TEAEs in the mRNA-1273 and placebo groups, respectively, were fatigue (5.0% vs. 4.4%) and headache (4.9% vs. 4.5%) during the 28-day follow-up period (Table 7-15) and during the Part A period (fatigue [5.8% vs. 5.3%] and headache [6.0% vs. 5.8%]) (Table 14.3.1.8.1.3).

Commonly reported adverse events were generally consistent with the solicited ARs captured to assess reactogenicity. During the 28-day follow-up period, unsolicited TEAEs that were reported for ≥ 1% of participants in the mRNA-1273 group and showed higher incidence compared with placebo were lymphadenopathy (1.7% vs. 0.8%), injection site pain (1.7% vs. 0.8%), and injection site erythema (1.0% vs. 0.3%). Other TEAEs that were reported for ≥ 1% of participants in the mRNA-1273 group and did not show higher incidence compared with the placebo group were arthralgia, myalgia, diarrhea, cough, nausea, oropharyngeal pain, nasal congestion, and hypertension (arthralgia, myalgia, and nausea were solicited systemic ARs and were only reported as TEAEs if they started on Day 8, or persisted after Day 7, after the most recent injection). Observations were similar with follow-up for the duration of Part A.

Rarer events that had a higher incidence in the mRNA-1273 group compared with the placebo group during the 28-day follow-up period included other varieties of injection site reactions and other events consistent with reactogenicity, such as injection site swelling, injection site pruritus, injection site lymphadenopathy, injection site induration, injection site macule, injection site urticaria, injection site rash, injection site papule, injection site warmth, pyrexia, and erythema (Table 14.3.1.8.1.1). Sinus headache and bursitis were also more commonly reported in the mRNA-1273 group than in the placebo group; some of the reports may have been associated with systemic ARs that have similar effects, such as headache and arthralgia, respectively. Observations were similar with follow-up for the duration of Part A, except that there was a larger number of different event terms that were reported for one or few participants (Table 14.3.1.8.1.3).

Assessment of TEAE incidence for other uncommon unsolicited TEAEs in the mRNA-1273 and placebo groups for clinically relevant differences involves evaluation of multiple comparisons without adjustment for multiplicity. Summary tables include rate ratios with 95% CIs as a descriptive measure to help review and were not a formal analysis to assess the difference.

Clinical plausibility has also not been taken into account with this analysis. Incidence was higher for some events in the mRNA-1273 group and for others in the placebo group, and this variation is likely attributable to chance.

Some events that had higher incidence in the placebo group, apparently by chance, are upper respiratory tract infection (82 participants [0.5%] in the mRNA-1273 group vs. 118 [0.8%] in the placebo group), basal cell carcinoma (10 [< 0.1%]) vs. 16 [0.1%]), seasonal allergy (33 [0.2%] vs. 47 [0.3%]), generalized anxiety disorder (0 vs. 4 [< 0.1%]), migraine (15 [< 0.1%] vs. 24 [0.2%]), presyncope (6 [< 0.1%] vs. 14 [< 0.1%]), sinus congestion (16 [0.1%] vs. 26 [0.2%]), abdominal discomfort (6 [< 0.1%] vs. 13 [< 0.1%]), contusion (20 [0.1%] vs. 29 [0.2%]), and procedural pain (18 [0.1%] vs. 31 [0.2%]) (Table 14.3.1.8.1.1). Some events that had higher incidence in the mRNA-1273 group, apparently by chance, are type 2 diabetes mellitus (21 [0.1%] vs. 11 [< 0.1%]), anxiety (52 [0.3%] vs. 38 [0.3%]), eye irritation (7 [< 0.1%] vs. 1 [< 0.1%]), respiratory tract congestion (18 [0.1%] vs. 7 [< 0.1%]), epistaxis (16 [0.1%] vs. 11 [< 0.1%]), gastroesophageal reflux disease (41 [0.3%] vs. 29 [0.2%]), abdominal pain (26 [0.2%] vs. 20 [0.1%]), and blood pressure diastolic increased (10 [< 0.1%] vs. 2 [< 0.1%]) (Table 14.3.1.8.1.1).

Review of Pericarditis and Myocarditis

In Part A, no cases of myocarditis were reported, and pericarditis was reported for 2 participants in the mRNA-1273 group and 2 participants in the placebo group (Table 14.3.1.8.1.3). The cases of pericarditis in the mRNA-1273 group occurred in (i) a 59-year old female who had nonserious chest pain, dyspnea, and fatigue on Day 4 post dose 2 that resolved within 2 days and subsequently presented with chest pain and syncope 68 days post dose 2 leading to hospitalization and a diagnosis of pericarditis and pericardial effusion, both of which resolved (the participant had received an influenza vaccination 1 month before the events), and (ii) a 65-year-old male hospitalized with a diagnosis of pericarditis 73 days post dose 2 which resolved the following day, and occurred 19 days after an SAE of myocardial infarction. These SAEs (including those in the placebo group) are described in Section 7.3.2.

Because myocarditis and pericarditis are typically rare events, Moderna assessed the clinical database for evidence of individual clinical symptoms that have been associated with these events. The randomized, blinded phase (Part A) data were assessed for TEAEs potentially associated with myocarditis or pericarditis. The TEAE data was assessed for any events mapping to PTs in the CDC working case definition diagnostic algorithm for probable and confirmed acute myocarditis and pericarditis. Using this approach, TEAEs were identified for the following 7 PTs: angina pectoris, chest discomfort, chest pain, musculoskeletal chest pain, dyspnea, palpitations, and syncope.

The TEAE database (collected for the 28 days after any injection) was assessed for the identified PTs, and the assessment further narrowed for those TEAEs occurring in temporal proximity to injection (within 7 days of any injection) based on the observed epidemiology of cases of myocarditis and pericarditis characterized from post-authorization data. As part of the study, the collection of unsolicited TEAE that are nonserious do not include narrative information but rather the verbatim entries regarding the event. All TEAEs were reviewed regardless of severity or causality (as determined by the investigator). Finally, the listing of participants reporting any of these PTs within 7 days of any injection was cross-checked to identify any participants reporting more than 1 of the targeted PT, reflecting constellations more suggestive of a possible diagnosis of myocarditis or pericarditis.

One participant reported more than 1 of the target PTs: a 71-year-old male in the mRNA-1273 group with relevant history of hyperlipidemia, hypertension, folate deficiency anemia, and constipation experienced 2 nonserious, mild, ongoing, and considered unrelated TEAEs on Days 2 and 4 post second dose, respectively, of "intermittent heart palpitations with exercising" and "intermittent chest discomfort with exercising type unknown" (verbatim terms). Other potentially relevant TEAEs reported for this participant within 7 days of these events were unrelated nonserious TEAEs of "fatigue," "generalized body aches in morning," "upper body muscle weakness," and "runny nose."

In the 28-day TEAE collection window, numerical imbalances between the mRNA-1273 and placebo groups were observed only for the PT chest pain (10 in the mRNA-1273 group and 5 in the placebo group; rate ratio 2.0 [95% CI: 0.71, 5.58]). Three of these chest pain events, all in the mRNA-1273 group, occurred within the 7-day window, one was considered related, and all resolved in 1 to 2 days. In the survey of the identified PTs in the 7-day window, imbalances in the reported PT (from the list described above) were observed for the following events:

- Dyspnea: 15 in the mRNA-1273 group and 3 in the placebo group
- Syncope: 7 in the mRNA-1273 group and 3 in the placebo group

For the PT dyspnea, 5 of the 15 events in the mRNA-1273 group were considered related, and all 18 dyspnea events resolved. For completeness, in addition to these dyspnea TEAEs, 5 participants (all in the mRNA-1273 group) reported dyspnea as an SAE, none of which were considered related and all of which occurred in participants > 50 years of age (these SAEs are described in Section 7.3.2).

For the PT syncope, 1 of the 7 events in the mRNA-1273 group was considered related, and all events resolved on the same day they occurred. For 1 of the 7 participants in the mRNA-1273 group, the syncope was an SAE: this 46-year-old Hispanic male had a previous medical history

of syncopal episodes, obesity, type 2 diabetes, and hypertension and was diagnosed with osteomyelitis during admission. The event syncope was considered not related to vaccine, and a transthoracic echocardiogram during admission showed normal cardiac function.

Overall, in this assessment of the targeted PTs, 1 participant manifested more than one of the identified PT within 7 days of any inoculation, and the events can reasonably be attributed to other comorbid conditions. For the imbalances observed for dyspnea and syncope in the 7-day window, most resolved quickly and did not cluster with other relevant TEAEs to suggest cases of myocarditis or pericarditis.

Investigation of events for which an apparent imbalance was observed or that were otherwise of interest did not suggest safety concerns with mRNA-1273, as described below.

Herpes Zoster

Incidence of herpes zoster during Part A of the study is shown in Figure 7-1. Incidence showed a larger imbalance (mRNA-1273 > placebo) over the full duration of Part A than during the 28-day follow-up period. No cases of herpes zoster were reported as SAEs, 1 case in the mRNA-1273 group was reported as severe (all other events were reported as mild or moderate), and all cases resolved, although 2 participants in the mRNA-1273 group also had events of post-herpetic neuralgia that were described as resolving.

Figure 7-1: Incidence of Herpes Zoster

Reported at any time during Part A: 73 participants	
mRNA-1273 TEAE: 50 (0.3%) MAAE: 40 (0.3%)	**Placebo** TEAE: 23 (0.2%) MAAE: 17 (0.1%)

Reported within the 28-day follow-up period after any dose: 37 participants	
mRNA-1273[1] TEAE: 22 (0.1%) (18 after Dose 1) MAAE: 17 (0.1%) Severe: 1 (< 0.1%)[2] Considered related: 2 (< 0.1%)	**Placebo** TEAE: 15 (< 0.1%) (9 after Dose 1) MAAE: 10 (< 0.1%)

Reported during Part A after the 28-day follow-up period:[3] 36 participants	
mRNA-1273 TEAE: 28 (0.1%) MAAE: 23 (0.1%)	**Placebo** TEAE: 8 (< 0.1%) MAAE: 7 (< 0.1%)

Abbreviations: MAAE = medically-attended adverse event; SAE = serious adverse event; TEAE = treatment-emergent adverse event.

1 One participant had vaccine discontinued due to herpes simplex (not included in these numbers for herpes zoster): A 44-year-old female had a moderate event reported on Day 6 after Dose 1. The event was not considered related to treatment and resolved on Day 18 (Listing 16.2.7.11).

2 A 61-year-old male had severe herpes zoster reported on Day 9 after Dose 1. The event was not considered related to treatment and resolved on Day 51 (Listing 16.2.7.7).

3 Per protocol, TEAEs were to be reported up to 28 days after any dose. After the 28-day follow-up period, only SAEs, MAAEs, and TEAEs leading to discontinuation were collected systematically.

Sources: Table 14.3.1.8.1.1, Table 14.3.1.8.1.3, Table 14.3.1.19.1.1, Table 14.3.1.19.1.3, Table 14.3.1.17.1.1, Table 14.3.1.11.1.1.

No microbiological confirmation of the presence of varicella virus was provided for any of the cases; diagnoses were based solely on clinical presentation. The cases consisted mostly of rashes; there were no reported TEAEs suggesting disseminated herpes zoster or other complications such as ophthalmic zoster or pneumonia.

Incidence of events reported under the preferred term of herpes simplex, another herpes virus that resides latent in peripheral neurons that can periodically reactivate when triggered by a variety of stimuli, was 9 participants (< 0.1%) in the mRNA-1273 group vs. 5 participants (< 0.1%) in the placebo group in 28 days of follow-up (Table 14.3.1.8.1.1) and 12 (< 0.1%) vs.

5 (< 0.1%), respectively in Part A (Table 14.3.1.8.1.3). One case resulted in the discontinuation of study treatment; a narrative for this subject is provided in Section 15.

Among participants in the mRNA-1273 group, underlying disorders considered associated with an increased risk of herpes zoster reactivation were reported in 5 participants (rheumatoid arthritis, psoriasis [receiving corticosteroids], type 1 diabetes mellitus [2 participants] (Papagianni et al 2018), and cancer [pelvic/colorectal]). One participant had herpes zoster at study entry and 2 participants had a documented previous history of herpes zoster. History of previous vaccination against herpes zoster was not systematically collected.

The incidence of herpes zoster in the US is estimated to range from 2.5 to 7.5 cases per 1000 person-years (Harpaz and Leung 2018). There is substantial variation by age, and incidence is higher in older adults. Compared with incidence of herpes zoster in individuals 50 years of age and older observed in a US population-based study (8.46 per 1000 person-years; Johnson et al 2015), the observed incidence of herpes zoster during Part A in the mRNA-1273 group (9.28 per 1000 person-years; rate ratio 1.10 [95% CI: 0.69, 1.74]) was within the expected incidence rate for the general population, while the observed incidence in the placebo group (3.45 per 1000 person-years; rate ratio 0.41 [95% CI: 0.22, 0.76]) was below the expected incidence rate (Table 7-14).

Table 7-14: Herpes Zoster Incidence per 1000 Person-Years in Part A Compared with US Expected Incidence

Treatment; Age	N	Person-years[a]	Observed		Expected[c]		Rate Ratio[d] (95% CI)[e]
			Cases	Rate[b]	Cases	Rate	
mRNA-1273	15,184	7592	50	6.59	33.9	4.47	1.47 (0.95, 2.28)
≤ 50 years	6991	3496	12	3.43	9.2	2.62	1.31 (0.55, 3.10)
> 50 years	8193	4097	38	9.28	34.7	8.46	1.10 (0.69, 1.74)
Placebo	15,162	7581	23	3.03	33.9	4.47	0.68 (0.40, 1.15)
≤ 50 years	7054	3527	9	2.55	9.2	2.62	0.97 (0.39, 2.44)
> 50 years	8108	4054	14	3.45	34.3	8.46	0.41 (0.22, 0.76)

Abbreviation: CI = confidence interval.

[a] Person-years were estimated based on the assumption of 6 months (or 0.5 years) of follow-up per participant and were calculated as (number of participants) × 0.5.

[b] The observed rate per 1000 person-years was calculated as (number of cases) / person-years × 1000.

[c] Johnson et al 2015.

[d] Incidence rate ratios were calculated as observed rate / expected rate.

[e] The 95% CIs were calculated as $_e\{\log(IRR)\pm[1.96\text{xSE}(\log(IRR))]\}$.

While the overall number of herpes zoster cases is higher in the mRNA-1273 group than the placebo group, the preponderance of herpes zoster cases reported in the mRNA-1273 group occurred more than 28 days after any dose, while in the placebo group the preponderance of events occurred within 28 days. This distribution does not support relatedness to mRNA-1273. In

addition, the observed incidence of herpes zoster in the mRNA-1273 group was within the expected incidence rate in the general population.

Other Events

- Lymphadenopathy was reported for 264 participants (1.7%) in the mRNA-1273 group and 127 participants (0.8%) in the placebo group; injection site lymphadenopathy was reported for 66 (0.4%) and 15 (< 0.1%) participants, respectively (Table 14.3.1.8.1.1); a few participants also had events that were coded as infusion site or vaccination site lymphadenopathy). Most of these events were localized/regional (ie, specified as axillary, cervical, or supraclavicular in verbatim terms) and ipsilateral to the injection site, as anticipated given the mechanism of action for this vaccine. Most events resolved within 14 days after onset. The reported characteristics of most events did not suggest generalized lymphadenopathy (ie, involving lymph nodes from multiple, distant regions). One event was reported as severe for a participant in the mRNA-1273 group; the event was described as left axillary ipsilateral lymphadenopathy, occurred 3 days after the second dose, was considered related to treatment, and resolved in 4 days. In the mRNA-1273 group, 29 participants had moderate lymphadenopathy (compared with 15 in the placebo group), and all other events were mild. Two participants in the mRNA-1273 group discontinued from vaccination in response to lymphadenopathy (Table 14.3.1.15.1): for 1 participant, the event was described as mild ipsilateral axillary lymphadenopathy, was considered related to treatment, began 5 days after dose 1, and resolved in 9 days; for another participant, the event was described as left armpit swelling, was considered related to treatment, began 4 days after dose 1, and resolved in 16 days (Listing 16.2.7.11).

- In the 28-day period, cervical radiculopathy was reported for 8 participants (< 0.1%) in the mRNA-1273 group and 1 participant (< 0.1%) in the placebo group (Table 7-15). Potentially relevant medical history was reported for 4 of the mRNA-1273 participants and included cervical radiculopathy, cervical spinal stenosis, and intervertebral disc degeneration for one participant for whom the event was reported as an SAE (moderate) and resolved in 2 days after anterior cervical discectomy and fusion; intervertebral disc compression, cervical radiculopathy, spinal stenosis, and osteoarthritis (neck and shoulders) for one participant; cervical radiculopathy for one participant; and intervertebral disc protrusion (C4-C7) for one participant. All events were mild to moderate in severity. One event was considered by the investigator to be related to study vaccine: the participant was a 70-year-old female, and mild cervical radiculopathy began and resolved on Day 2 after the second injection of mRNA-1273; the event was described as intermittent nerve pain in the neck and coincided with a moderate urinary tract

infection (which was considered not related to vaccination); the participant's medical history included osteopenia and parathyroidectomy. Seven of the participants were using concomitant pain medications. The side of the cervical radiculopathy was documented in one participant in the mRNA-1273 group; the participant had neck pain, shoulder pain, and radiculopathy contralateral to the injection site. In Part A, cervical radiculopathy was reported for 17 participants (0.1%) in the mRNA-1273 group and 2 participants (< 0.1%) in the placebo group (Table 14.3.1.8.1.3).

- In the 28-day period, facial bones fracture was reported for 4 participants in the mRNA-1273 group (1 event was an SAE in an 80-year-old participant) and no participants in the placebo group (Table 14.3.1.8.1.1). Over the duration of Part A, facial bones fracture was reported for 8 participants in the mRNA-1273 group and 1 participant in the placebo group (Table 14.3.1.8.1.3). In the mRNA-1273 group, the onset day of the event relative to the start of the study ranged from Day 14 to Day 144. All events resolved and were considered not related to study vaccine by the investigator. At least one fracture of any kind was reported for 122 participants (0.8%) in the mRNA-1273 group and 121 participants (0.8%) in the placebo group. In addition, no imbalance was observed for fall events (21 participants [0.1%] in the mRNA-1273 group and 27 participants [0.2%] in the placebo group within 28 days and 46 vs. 48 participants, respectively [0.3% in each group] during Part A) (Table 14.3.1.8.1.1 and Table 14.3.1.8.1.3).
- Vertigo or positional vertigo was reported during the 28-day follow-up for 30 (0.2%) vs. 19 (0.1%) participants in the mRNA-1273 and placebo groups, respectively. All events were nonserious and resolved (or were resolving). Vertigo was severe for one participant in the mRNA-1273 group (and occurred on the day of the second dose [at night after the injection] and resolved the following day) and severe for 3 participants in the placebo group (occurred on Day 11, 21, and 25 after the first injection). Four events in each group were assessed by the investigator to be treatment-related (Table 14.3.1.11.1.1). In the mRNA-1273 group, relative to the most recent dose, onset of vertigo events was on the day of the dose for 1 event, on Day 1 after the dose for 2 events, and on Day 3, 6, and 7 after the dose for 1 event each. Also in the mRNA-1273 group, positional vertigo occurred 3 days after the first dose for a participant with a history of positional vertigo and 4 days after the first dose for a participant who was 71 years old and had dyskinesias and was taking a semaglutide; all other events occurred between 11 and 23 days after the first or second dose. All positional vertigo events were mild to moderate in severity, nonserious, and resolved with exception of an event that was associated with Meniere's disease. During Part A, vertigo or positional vertigo was reported for 54 participants (0.4%) in the mRNA-1273 group and for 40 participants (0.3%) in the placebo group. No

imbalance was observed between the groups in the SMQ analysis for hearing and vestibular disorders (Section 7.3.3.3).

- In the 28-day period, facial paralysis was reported for 2 participants in the mRNA-1273 group (verbatim terms of Bell's palsy and left side face paralysis) and 1 participant in the placebo group (verbatim term of Bell's palsy). During Part A, facial paralysis was reported for 8 participants in the mRNA-1273 group and 3 participants in the placebo group. One event of facial paralysis (Bell's palsy) was reported as an SAE for a participant treated with mRNA-1273 (Section 7.3.2). One event in the mRNA-1273 group was reported as left facial palsy; the participant had mild viral infection at the time. All other events in both groups were reported as Bell's palsy. One participant with Bell's palsy had underlying worsening of migraine that was treated with injections of botulinum toxin. Within the mRNA-1273 group, a concomitant AE of infection was reported for 4 of the 6 Bell's palsy events. One mild event in the mRNA-1273 group was considered related to treatment. Three Bell's palsy events were reported as severe (all in the mRNA-1273 group). No notable imbalance was observed in the SMQ analysis for demyelination (Section 7.3.3.3).
- In the 28-day period, events of paresthesia, hyperesthesia, hypoesthesia, injection site paresthesia, injection site hypoesthesia, and dysesthesia were reported in the mRNA-1273 and placebo groups, respectively, as follows: paresthesia 34 (0.2%) vs. 27 (0.2%); hyperesthesia 6 (< 0.1%) vs. 0; hypoesthesia 13 (< 0.1%) vs. 9 (< 0.1%); injection site paresthesia 6 (< 0.1%) vs. 3 (< 0.1%); injection site hypoesthesia 3 (< 0.1%) vs. 1 (< 0.1%); and dysesthesia 0 vs. 3 (< 0.1%) (Table 14.3.1.8.1.1). One participant in the placebo group experienced 2 SAEs of paresthesia beginning 7 days after the first dose that were considered moderate, assessed as related to treatment, and resolved. One participant in the mRNA-1273 group who experienced paresthesia did not receive the second dose although the action taken with study vaccine was reported as "dose not changed;" 3 participants in the placebo group who experienced paresthesia did not receive the second dose; the event in the mRNA-1273 group was described as moderate "tingling in hands" that began on Day 3 after the first dose and resolved on Day 34 and was not considered related to treatment. A severe event of injection site hypoesthesia was reported for 1 participant in the mRNA-1273 group with onset on Day 3 after the first dose that was considered related to treatment and resolved on Day 5. Two severe events of paresthesia were reported for 1 participant in the placebo group with onset on Day 163 after the first dose that were not considered related to treatment (one event resolved and the other was ongoing).

Table 7-15: Participant Incidence of Unsolicited Treatment-Emergent Adverse Events (at Least 1% in Any Treatment Group or Rate Ratio 95% Confidence Interval Does Not Include 1, Based on Preferred Term) by System Organ Class and Preferred Term up to 28 Days After Any Injection (Safety Set)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of subjects reporting unsolicited adverse events	4338 (28.6)	4752 (31.3)		9090 (30.0)
Number of unsolicited adverse events	8599	9541		18140
Infections and infestations	952 (6.3)	783 (5.2)		1735 (5.7)
Upper respiratory tract infection	118 (0.8)	82 (0.5)	0.69 (0.52, 0.92)	200 (0.7)
COVID-19	156 (1.0)	22 (0.1)	0.14 (0.09, 0.22)	178 (0.6)
Cystitis	11 (<0.1)	3 (<0.1)	0.27 (0.08, 0.91)	14 (<0.1)
Tonsillitis	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)
Blood and lymphatic system disorders	148 (1.0)	292 (1.9)		440 (1.4)
Lymphadenopathy	127 (0.8)	264 (1.7)	2.08 (1.68, 2.56)	391 (1.3)
Nervous system disorders	881 (5.8)	1008 (6.6)		1889 (6.2)
Headache	687 (4.5)	744 (4.9)	1.08 (0.98, 1.20)	1431 (4.7)
Sinus headache	6 (<0.1)	20 (0.1)	3.33 (1.38, 8.05)	26 (<0.1)
Cervical radiculopathy	1 (<0.1)	8 (<0.1)	7.99 (1.30, 49.20)	9 (<0.1)
Eye disorders	67 (0.4)	70 (0.5)		137 (0.5)
Eye irritation	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Ear and labyrinth disorders	83 (0.5)	81 (0.5)		164 (0.5)
Vertigo positional	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Vascular disorders	204 (1.3)	198 (1.3)		402 (1.3)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Hypertension	161 (1.1)	153 (1.0)	0.95 (0.76, 1.18)	314 (1.0)
Respiratory, thoracic and mediastinal disorders	667 (4.4)	603 (4.0)		1270 (4.2)
Cough	165 (1.1)	177 (1.2)	1.07 (0.87, 1.32)	342 (1.1)
Oropharyngeal pain	232 (1.5)	158 (1.0)	0.68 (0.56, 0.83)	390 (1.3)
Nasal congestion	165 (1.1)	155 (1.0)	0.94 (0.75, 1.17)	320 (1.1)
Rhinorrhoea	145 (1.0)	130 (0.9)	0.90 (0.71, 1.13)	275 (0.9)
Respiratory tract congestion	7 (<0.1)	18 (0.1)	2.57 (1.10, 5.99)	25 (<0.1)
Gastrointestinal disorders	567 (3.7)	599 (3.9)		1166 (3.8)
Diarrhoea	199 (1.3)	204 (1.3)	1.02 (0.84, 1.24)	403 (1.3)
Nausea	164 (1.1)	162 (1.1)	0.99 (0.80, 1.22)	326 (1.1)
Skin and subcutaneous tissue disorders	235 (1.5)	295 (1.9)		530 (1.7)
Erythema	5 (<0.1)	15 (<0.1)	3.00 (1.13, 7.93)	20 (<0.1)
Musculoskeletal and connective tissue disorders	1017 (6.7)	1007 (6.6)		2024 (6.7)
Arthralgia	389 (2.6)	391 (2.6)	1.00 (0.87, 1.15)	780 (2.6)
Myalgia	388 (2.6)	387 (2.5)	1.00 (0.87, 1.14)	775 (2.6)
General disorders and administration site conditions	1065 (7.0)	1606 (10.6)		2671 (8.8)
Fatigue	666 (4.4)	752 (5.0)	1.13 (1.02, 1.25)	1418 (4.7)
Injection site pain	118 (0.8)	258 (1.7)	2.18 (1.76, 2.71)	376 (1.2)
Injection site erythema	39 (0.3)	157 (1.0)	4.02 (2.84, 5.69)	196 (0.6)
Pyrexia	62 (0.4)	118 (0.8)	1.90 (1.40, 2.58)	180 (0.6)
Injection site swelling	29 (0.2)	115 (0.8)	3.96 (2.64, 5.93)	144 (0.5)
Injection site pruritus	13 (<0.1)	88 (0.6)	6.76 (3.81, 12.00)	101 (0.3)
Injection site lymphadenopathy	15 (<0.1)	66 (0.4)	4.39 (2.53, 7.64)	81 (0.3)
Injection site induration	18 (0.1)	53 (0.3)	2.94 (1.73, 4.99)	71 (0.2)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injection site macule	4 (<0.1)	45 (0.3)	11.23 (4.21, 30.01)	49 (0.2)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.94 (6.58, 218.91)	39 (0.1)
Injection site rash	1 (<0.1)	24 (0.2)	23.97 (4.11, 139.71)	25 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	12.98 (2.18, 77.49)	14 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Investigations	80 (0.5)	107 (0.7)		187 (0.6)
Blood pressure diastolic increased	2 (<0.1)	10 (<0.1)	4.99 (1.23, 20.26)	12 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.8.1.1.

7.2.3 Unsolicited Adverse Events by Maximum Intensity

The incidence of severe TEAEs was similar between the mRNA-1273 and placebo treatment groups in the 28-day follow-up period (1.7% and 1.5%, respectively; Table 14.3.1.18.1.1). Hypertension was reported as severe for 28 and 34 participants, in the mRNA-1273 and placebo treatment groups, respectively (0.2% in each group); no other event was reported as severe for > 0.1% of participants in either group. Events that were reported as severe for more participants in the mRNA-1273 group than in the placebo group, respectively, were fatigue (20 vs. 9), headache (14 vs. 11), myalgia (9 vs. 4), and blood pressure increased (10 vs. 6). All except the last were among the solicited systemic ARs, which were reported as TEAEs if they persisted beyond Day 7 after any injection (in which case they are counted both with solicited ARs and with unsolicited TEAEs) or started on Day 8 or later after any injection.

The incidence of severe TEAEs assessed by the investigator as related to investigational product was higher in the mRNA-1273 group compared with the placebo group in the 28-day follow-up period (0.5% and 0.2%, respectively; Table 14.3.1.18.1.1). Events that were reported as severe and assessed by the investigator to be treatment-related for more participants in the mRNA-1273 group than in the placebo group, respectively, were fatigue (16 vs. 6) and myalgia (8 vs. 2), both of which were among the solicited systemic ARs.

7.2.4 Unsolicited Adverse Events by Relationship to Investigational Product

More participants in the mRNA-1273 group (13.6%) than in the placebo group (8.2%) had unsolicited TEAEs during the 28-day follow-up that were assessed by the investigator as related to investigational product (Table 7-16). Most of the imbalance is in events that were also solicited ARs (injection site events, headache, nausea, vomiting, pyrexia, chills) or similar to ARs (lymphadenopathy, neck pain, back pain, and musculoskeletal pain). Imbalances were also observed for less common events including diarrhea (44 vs. 32), nasal congestion (21 vs. 9), dizziness (28 vs. 13), urticaria (22 vs. 7), paresthesia (14 vs. 9), rhinorrhea (13 vs. 8), cough (13 vs. 5), rash (11 vs. 3), erythema (9 vs. 0), and insomnia (7 vs. 1).

Table 7-16: Participant Incidence of Unsolicited Treatment-Emergent Adverse Events Assessed by the Investigator as Treatment-Related by System Organ Class and Preferred Term up to 28 Days After Any Injection (Safety Set)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of subjects reporting unsolicited adverse events	1236 (8.2)	2067 (13.6)		3303 (10.9)
Number of unsolicited adverse events	2220	3704		5924
Infections and infestations	18 (0.1)	23 (0.2)		41 (0.1)
Suspected COVID-19	0	4 (<0.1)		4 (<0.1)
Viral infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Conjunctivitis	0	2 (<0.1)		2 (<0.1)
Herpes zoster	0	2 (<0.1)		2 (<0.1)
Injection site cellulitis	0	2 (<0.1)		2 (<0.1)
Oral herpes	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinusitis	0	2 (<0.1)		2 (<0.1)
COVID-19	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Gingivitis	1 (<0.1)	0		1 (<0.1)
Herpes simplex	1 (<0.1)	0		1 (<0.1)
Onychomycosis	1 (<0.1)	0		1 (<0.1)
Rhinitis	3 (<0.1)	0		3 (<0.1)
Rhinovirus infection	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	6 (<0.1)	0		6 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	99 (0.7)	225 (1.5)		324 (1.1)
Lymphadenopathy	92 (0.6)	215 (1.4)	2.33 (1.83, 2.97)	307 (1.0)
Lymph node pain	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Lymphadenitis	0	3 (<0.1)		3 (<0.1)
Anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Immune system disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Hypersensitivity	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	7 (<0.1)		10 (<0.1)
Decreased appetite	2 (<0.1)	4 (<0.1)		6 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	0	1 (<0.1)		1 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	2 (<0.1)	15 (<0.1)		17 (<0.1)
Insomnia	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Abnormal dreams	1 (<0.1)	3 (<0.1)		4 (<0.1)
Sleep disorder	0	2 (<0.1)		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Affect lability	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	343 (2.3)	525 (3.5)		868 (2.9)
Headache	302 (2.0)	439 (2.9)	1.45 (1.26, 1.68)	741 (2.4)
Dizziness	13 (<0.1)	28 (0.2)	2.15 (1.13, 4.10)	41 (0.1)
Paraesthesia	9 (<0.1)	14 (<0.1)	1.55 (0.69, 3.51)	23 (<0.1)
Dysgeusia	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Hyperaesthesia	0	5 (<0.1)		5 (<0.1)
Hypoaesthesia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Migraine	5 (<0.1)	4 (<0.1)		9 (<0.1)
Disturbance in attention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Syncope	0	3 (<0.1)		3 (<0.1)
Ageusia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)
Memory impairment	0	2 (<0.1)		2 (<0.1)
Mental impairment	0	2 (<0.1)		2 (<0.1)
Sinus headache	0	2 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	2 (<0.1)		4 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Presyncope	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sciatica	0	1 (<0.1)		1 (<0.1)
Anosmia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)
Eye disorders	4 (<0.1)	7 (<0.1)		11 (<0.1)
Vision blurred	0	2 (<0.1)		2 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Photophobia	0	1 (<0.1)		1 (<0.1)
Visual impairment	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	0	1 (<0.1)		1 (<0.1)
Eye pruritus	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	7 (<0.1)	11 (<0.1)		18 (<0.1)
Tinnitus	1 (<0.1)	5 (<0.1)		6 (<0.1)
Vertigo	4 (<0.1)	3 (<0.1)		7 (<0.1)
Deafness neurosensory	0	1 (<0.1)		1 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Vertigo positional	0	1 (<0.1)		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Ear pain	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	4 (<0.1)	9 (<0.1)		13 (<0.1)
Tachycardia	0	4 (<0.1)		4 (<0.1)
Sinus tachycardia	0	3 (<0.1)		3 (<0.1)
Angina pectoris	0	1 (<0.1)		1 (<0.1)
Palpitations	0	1 (<0.1)		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Bradycardia	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	17 (0.1)	22 (0.1)		39 (0.1)
Hypertension	12 (<0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Hot flush	3 (<0.1)	6 (<0.1)		9 (<0.1)
Flushing	1 (<0.1)	4 (<0.1)		5 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Hypotension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	42 (0.3)	55 (0.4)		97 (0.3)
Nasal congestion	9 (<0.1)	21 (0.1)	2.33 (1.09, 4.99)	30 (<0.1)
Cough	5 (<0.1)	13 (<0.1)	2.60 (0.96, 6.99)	18 (<0.1)
Rhinorrhoea	8 (<0.1)	13 (<0.1)	1.62 (0.69, 3.81)	21 (<0.1)
Oropharyngeal pain	14 (<0.1)	11 (<0.1)	0.78 (0.36, 1.69)	25 (<0.1)
Dyspnoea	4 (<0.1)	5 (<0.1)		9 (<0.1)
Throat irritation	2 (<0.1)	3 (<0.1)		5 (<0.1)
Asthma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus congestion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Tachypnoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Upper-airway cough syndrome	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Dysphonia	2 (<0.1)	0		2 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Productive cough	2 (<0.1)	0		2 (<0.1)
Rhinitis allergic	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	117 (0.8)	149 (1.0)		266 (0.9)
Nausea	57 (0.4)	78 (0.5)	1.37 (0.97, 1.92)	135 (0.4)
Diarrhoea	32 (0.2)	44 (0.3)	1.37 (0.87, 2.16)	76 (0.3)
Vomiting	17 (0.1)	22 (0.1)	1.29 (0.69, 2.41)	39 (0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Abdominal pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Abdominal pain upper	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dyspepsia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastrooesophageal reflux disease	0	3 (<0.1)		3 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	2 (<0.1)		2 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Abdominal discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Aphthous ulcer	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Dry mouth	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Toothache	0	1 (<0.1)		1 (<0.1)
Constipation	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival pain	1 (<0.1)	0		1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	0		1 (<0.1)
Paraesthesia oral	4 (<0.1)	0		4 (<0.1)
Salivary hypersecretion	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders	39 (0.3)	93 (0.6)		132 (0.4)
Urticaria	7 (<0.1)	22 (0.1)	3.14 (1.37, 7.17)	29 (<0.1)
Rash	3 (<0.1)	11 (<0.1)	3.66 (1.10, 12.19)	14 (<0.1)
Erythema	0	9 (<0.1)		9 (<0.1)
Hyperhidrosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Pruritus	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Night sweats	3 (<0.1)	6 (<0.1)		9 (<0.1)
Rash maculo-papular	0	5 (<0.1)		5 (<0.1)
Rash pruritic	2 (<0.1)	4 (<0.1)		6 (<0.1)
Rash macular	0	3 (<0.1)		3 (<0.1)
Skin burning sensation	0	3 (<0.1)		3 (<0.1)
Alopecia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angioedema	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Dermatitis atopic	0	1 (<0.1)		1 (<0.1)
Lichen planus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Rash papular	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Dermatitis contact	2 (<0.1)	0		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	398 (2.6)	458 (3.0)		856 (2.8)
Myalgia	256 (1.7)	282 (1.9)	1.10 (0.93, 1.30)	538 (1.8)
Arthralgia	257 (1.7)	267 (1.8)	1.04 (0.88, 1.23)	524 (1.7)
Pain in extremity	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Neck pain	1 (<0.1)	11 (<0.1)	10.98 (1.82, 66.17)	12 (<0.1)
Back pain	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Musculoskeletal pain	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Muscle spasms	4 (<0.1)	5 (<0.1)		9 (<0.1)
Joint range of motion decreased	0	4 (<0.1)		4 (<0.1)
Limb discomfort	0	3 (<0.1)		3 (<0.1)
Musculoskeletal stiffness	5 (<0.1)	3 (<0.1)		8 (<0.1)
Tendonitis	0	3 (<0.1)		3 (<0.1)
Bone pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Muscular weakness	1 (<0.1)	2 (<0.1)		3 (<0.1)
Axillary mass	0	1 (<0.1)		1 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flank pain	0	1 (<0.1)		1 (<0.1)
Joint stiffness	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Osteoarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Trigger finger	0	1 (<0.1)		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Muscle tightness	1 (<0.1)	0		1 (<0.1)
Muscle twitching	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	0	1 (<0.1)		1 (<0.1)
Chromaturia	0	1 (<0.1)		1 (<0.1)
Reproductive system and breast disorders	4 (<0.1)	4 (<0.1)		8 (<0.1)
Menorrhagia	0	2 (<0.1)		2 (<0.1)
Erectile dysfunction	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	0		2 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)
Menstruation irregular	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	674 (4.4)	1251 (8.2)		1925 (6.3)
Fatigue	457 (3.0)	569 (3.7)	1.24 (1.10, 1.40)	1026 (3.4)
Injection site pain	95 (0.6)	224 (1.5)	2.35 (1.86, 2.99)	319 (1.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injection site erythema	37 (0.2)	147 (1.0)	3.97 (2.77, 5.67)	184 (0.6)
Injection site swelling	28 (0.2)	111 (0.7)	3.96 (2.62, 5.97)	139 (0.5)
Chills	43 (0.3)	81 (0.5)	1.88 (1.30, 2.72)	124 (0.4)
Injection site pruritus	12 (<0.1)	80 (0.5)	6.66 (3.66, 12.10)	92 (0.3)
Pyrexia	16 (0.1)	67 (0.4)	4.18 (2.44, 7.16)	83 (0.3)
Injection site lymphadenopathy	11 (<0.1)	59 (0.4)	5.36 (2.85, 10.08)	70 (0.2)
Injection site induration	18 (0.1)	51 (0.3)	2.83 (1.66, 4.81)	69 (0.2)
Injection site macule	4 (<0.1)	39 (0.3)	9.74 (3.63, 26.15)	43 (0.1)
Injection site urticaria	1 (<0.1)	34 (0.2)	33.95 (5.87, 196.28)	35 (0.1)
Pain	10 (<0.1)	25 (0.2)	2.50 (1.22, 5.12)	35 (0.1)
Injection site rash	1 (<0.1)	21 (0.1)	20.97 (3.58, 122.74)	22 (<0.1)
Axillary pain	6 (<0.1)	19 (0.1)	3.16 (1.30, 7.69)	25 (<0.1)
Injection site papule	1 (<0.1)	12 (<0.1)	11.98 (2.00, 71.83)	13 (<0.1)
Malaise	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Injection site bruising	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Reactogenicity event	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site paraesthesia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)		6 (<0.1)
Injection site haemorrhage	1 (<0.1)	4 (<0.1)		5 (<0.1)
Peripheral swelling	2 (<0.1)	4 (<0.1)		6 (<0.1)
Chest discomfort	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site mass	1 (<0.1)	3 (<0.1)		4 (<0.1)
Non-cardiac chest pain	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vaccination site pain	0	3 (<0.1)		3 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site haematoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenderness	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Chest pain	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	0	1 (<0.1)		1 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	0	1 (<0.1)		1 (<0.1)
Asthenia	4 (<0.1)	0		4 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Investigations	7 (<0.1)	15 (<0.1)		22 (<0.1)
Body temperature increased	0	4 (<0.1)		4 (<0.1)
Blood pressure increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood pressure systolic increased	0	2 (<0.1)		2 (<0.1)
Heart rate increased	0	2 (<0.1)		2 (<0.1)
C-reactive protein increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	9 (<0.1)	5 (<0.1)		14 (<0.1)
Contusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Foot fracture	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Tooth fracture	0	1 (<0.1)		1 (<0.1)
Fall	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Wrist fracture	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.11.1.1.

7.2.5 Unsolicited Adverse Events Occurring Within 30 Minutes After Injection

Participants were to remain in the clinic for 15 minutes (or 30 minutes if they had a history of allergies) after each injection for observation because of concerns about potential anaphylaxis. No anaphylaxis was reported within 30 minutes after any injection (Table 14.3.1.19.6.3). The incidence of TEAEs, severe TEAEs, and MAAEs occurring within 30 minutes after any injection, regardless of relationship to the IP was similar in participants who received mRNA-1273 (0.8%) and those who received placebo (0.7%) (Table 7-17). Few of the events were MAAEs and/or severe, none were considered SAEs, and none led to discontinuation from the study or study vaccine in the mRNA-1273 group.

At least one unsolicited TEAE that occurred within 30 minutes after the first injection was reported for 74 participants (0.5%) and 68 participants (0.4%) in the mRNA-1273 and placebo groups, respectively (Table 14.3.1.19.5.1). Fewer participants experienced such events after the second injection (47 [0.3%] vs. 41 [0.3%] [Table 14.3.1.19.5.2]). All reported event terms were consistent with expected physiological reactions to injections. No imbalances between the groups were apparent, and no single participant had a severe TEAE within 30 minutes after both injections. Only 2 events in the placebo group led to discontinuation from study vaccine; no such events were reported in the mRNA-1273 group.

Table 7-17: Summary of Immediate Unsolicited Adverse Event Occurring Within 30 Minutes of Any Vaccination (Safety Set)

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs regardless of relationship to study vaccination			
All	105 (0.7)	118 (0.8)	223 (0.7)
Serious	0	0	0
Fatal	0	0	0
Medically-attended	14 (<0.1)	10 (<0.1)	24 (<0.1)
Leading to discontinuation from study vaccine	2 (<0.1)	0	2 (<0.1)
Leading to discontinuation from participation in the study	0	0	0
Severe	11 (<0.1)	8 (<0.1)	19 (<0.1)
Unsolicited TEAEs related to study vaccination			
All	44 (0.3)	50 (0.3)	94 (0.3)
Serious	0	0	0
Fatal	0	0	0
Medically-attended	5 (<0.1)	2 (<0.1)	7 (<0.1)
Leading to discontinuation from study vaccine	0	0	0
Leading to discontinuation from participation in the study	0	0	0
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

N = Number of participants in Safety Set who received any injection

n = Number of participants who reported AEs in specified category

Source: Table 14.3.1.19.5.3.

7.2.6 Subgroup Analyses of Unsolicited Adverse Events

7.2.6.1 Age Groups

The incidence of unsolicited TEAEs was similar in both the younger (≥ 18 to < 65 years; 29.7% of 22,826 participants) and older (≥ 65 years; 30.6% of 7520 participants) age groups; this was also true for TEAEs assessed as treatment-related by the investigator (Table 14.3.1.7.2.1.1). Further, no apparent differences in the incidence of unsolicited TEAEs were observed across the

older age subgroups: 30.5% of 6122 participants aged ≥ 65 to < 75 years, 30.9% of 1308 participants aged ≥ 75 to < 85 years, and 34.4% of 90 participants aged ≥ 85 years) (Table 7-18).

In the older age group, reported incidence was numerically higher than in the younger age group in the following SOCs: musculoskeletal and connective tissue disorders (567/7520 [7.5%] vs. 592/22826 [6.4%]); vascular disorders (144/7520 [1.9%] vs. 258/22826 [1.1%]); metabolism and nutrition disorders (77/7520 [1.0%] vs. 164/22826 [0.7%]); cardiac disorders (66/7520 [0.9%] vs. 88/22826 [0.4%]); benign, malignant, and unspecified neoplasms (including cysts and polyps) (63/7520 [0.8%] vs. 55/22826 [0.2%]); eye disorders (53/7520 [0.7%] vs. 84/22826 [0.4%]); ear and labyrinth disorders (49/7520 [0.7%] vs. 115/22826 [0.5%]); and renal and urinary disorders (45/7520 [0.6%] vs. 51/22826 [0.2%]) (Table 14.3.1.8.2.1.1). These types of events are generally consistent with expected increased frequency of TEAEs in an older population.

The most common unsolicited TEAEs by age group (≥ 2% of participants overall) were as follows:

- ≥ 18 to < 65 years (N = 22826): headache (5.1%), fatigue (4.7%), myalgia (2.6%), and arthralgia (2.4%) (Table 14.3.1.8.2.1.1).
- ≥ 65 to < 75 years (N = 6122): fatigue (4.4%), headache (3.5%), arthralgia (2.9%), and myalgia (2.4%) (Table 14.3.1.8.2.2.1).
- ≥ 75 to < 85 years (N = 1308): fatigue (4.7%), arthralgia (3.6%), headache (3.3%), and myalgia (2.7%) (Table 14.3.1.8.2.2.1).
- ≥ 85 years (N = 90): arthralgia (4.4%); myalgia and diarrhea (3.3% each); and urinary tract infection, hypertension, gastroesophageal reflux disease, and injection site pain (2.2% each) (Table 14.3.1.8.2.2.1).

The overall incidence of severe unsolicited TEAEs was higher in the older age group (2.2%) compared with the younger age group (1.4%) (Table 14.3.1.17.1.2). No difference was apparent between the age groups in the overall incidence of severe unsolicited TEAEs assessed by the investigator to be treatment-related (Table 14.3.1.18.1.2).

Analysis of unsolicited TEAEs by age group did not reveal any new clinically relevant imbalances between the mRNA-1273 and placebo groups compared with the overall population.

Table 7-18: Summary of Unsolicited Treatment-Emergent Adverse Events by Age Groups (< 65, ≥ 65 and < 75, ≥ 75 and < 85, and ≥85) up to 28 Days After Any Injection (Safety Set)

	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)
Age Group: >=18 and <65 Years			
Unsolicited TEAEs regardless of relationship to study vaccination			
All	3275 (28.7)	3515 (30.8)	6790 (29.7)
Serious	54 (0.5)	59 (0.5)	113 (0.5)
Fatal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Medically-attended	1419 (12.4)	1311 (11.5)	2730 (12.0)
Leading to discontinuation from study vaccine	70 (0.6)	49 (0.4)	119 (0.5)
Leading to discontinuation from participation in the study	3 (<0.1)	7 (<0.1)	10 (<0.1)
Severe	152 (1.3)	177 (1.6)	329 (1.4)
Unsolicited TEAEs related to study vaccination			
All	945 (8.3)	1580 (13.8)	2525 (11.1)
Serious	2 (<0.1)	6 (<0.1)	8 (<0.1)
Fatal	0	0	0
Medically-attended	78 (0.7)	161 (1.4)	239 (1.0)
Leading to discontinuation from study vaccine	8 (<0.1)	17 (0.1)	25 (0.1)
Leading to discontinuation from participation in the study	0	1 (<0.1)	1 (<0.1)
Severe	20 (0.2)	59 (0.5)	79 (0.3)

	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Total (N=6122) n (%)
Age Group: >=65 and <75 Years			
Unsolicited TEAEs regardless of relationship to study vaccination			
All	846 (28.1)	1019 (32.7)	1865 (30.5)
Serious	34 (1.1)	29 (0.9)	63 (1.0)
Fatal	0	0	0
Medically-attended	421 (14.0)	416 (13.4)	837 (13.7)
Leading to discontinuation from study vaccine	16 (0.5)	12 (0.4)	28 (0.5)

	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Total (N=6122) n (%)
Leading to discontinuation from participation in the study	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	58 (1.9)	60 (1.9)	118 (1.9)
Unsolicited TEAEs related to study vaccination			
All	228 (7.6)	396 (12.7)	624 (10.2)
Serious	0	2 (<0.1)	2 (<0.1)
Fatal	0	0	0
Medically-attended	8 (0.3)	30 (1.0)	38 (0.6)
Leading to discontinuation from study vaccine	5 (0.2)	3 (<0.1)	8 (0.1)
Leading to discontinuation from participation in the study	0	0	0
Severe	5 (0.2)	19 (0.6)	24 (0.4)

	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Age Group: >=75 and <85 Years			
Unsolicited TEAEs regardless of relationship to study vaccination			
All	201 (29.0)	203 (33.0)	404 (30.9)
Serious	13 (1.9)	10 (1.6)	23 (1.8)
Fatal	1 (0.1)	1 (0.2)	2 (0.2)
Medically-attended	93 (13.4)	86 (14.0)	179 (13.7)
Leading to discontinuation from study vaccine	5 (0.7)	0	5 (0.4)
Leading to discontinuation from participation in the study	1 (0.1)	1 (0.2)	2 (0.2)
Severe	20 (2.9)	19 (3.1)	39 (3.0)
Unsolicited TEAEs related to study vaccination			
All	57 (8.2)	85 (13.8)	142 (10.9)
Serious	1 (0.1)	0	1 (<0.1)
Fatal	0	0	0
Medically-attended	6 (0.9)	7 (1.1)	13 (1.0)
Leading to discontinuation from study vaccine	1 (0.1)	0	1 (<0.1)
Leading to discontinuation from participation in the study	0	0	0
Severe	5 (0.7)	5 (0.8)	10 (0.8)

	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
	Placebo (N=49) n (%)	**mRNA-1273 (N=41) n (%)**	**Total (N=90) n (%)**
Age Group: >=85 Years			
Unsolicited TEAEs regardless of relationship to study vaccination			
All	16 (32.7)	15 (36.6)	31 (34.4)
Serious	3 (6.1)	0	3 (3.3)
Fatal	0	0	0
Medically-attended	7 (14.3)	6 (14.6)	13 (14.4)
Leading to discontinuation from study vaccine	1 (2.0)	0	1 (1.1)
Leading to discontinuation from participation in the study	1 (2.0)	0	1 (1.1)
Severe	3 (6.1)	2 (4.9)	5 (5.6)
Unsolicited TEAEs related to study vaccination			
All	6 (12.2)	6 (14.6)	12 (13.3)
Serious	0	0	0
Fatal	0	0	0
Medically-attended	3 (6.1)	0	3 (3.3)
Leading to discontinuation from study vaccine	0	0	0
Leading to discontinuation from participation in the study	0	0	0
Severe	1 (2.0)	0	1 (1.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Source: Table 14.3.1.7.2.2.1.

7.2.6.2 Baseline SARS-CoV-2 Status

Baseline SARS-CoV-2 status was negative for most participants. Incidence of unsolicited TEAEs within 28 days after any injection among participants with negative baseline status reflect that of the overall population. In the Safety Set, 347 participants in the mRNA-1273 group and 337 participants in the placebo group had positive baseline SARS-CoV-2 status (Table 14.1.3.2.2). Among these participants, incidence of TEAEs was numerically lower in the mRNA-1273 group (22.2%) than in the placebo group (27.3%) (Table 14.3.1.7.3.1) and

compared with incidence in the overall mRNA-1273 population (31.3%) (Table 14.3.1.7.1.1). Incidence was similarly lower in the mRNA-1273 group for severe TEAEs, SAEs, MAAEs, and TEAEs considered related to treatment. The comparison is limited by the small number of baseline positive participants.

The most common TEAEs within 28 days after any injection were similar between participants with either a positive or negative baseline SARS-CoV-2 status (Table 14.3.1.8.3.1).

Table 7-19: Summary of Unsolicited Treatment-Emergent Adverse Events by Baseline SARS-CoV-2 Status up to 28 Days After Any Injection (Safety Set)

	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Total (N=29491) n (%)
Baseline SARS-CoV-2 Status: Negative			
Unsolicited TEAEs regardless of relationship to study vaccination			
All	4233 (28.7)	4652 (31.5)	8885 (30.1)
Serious	101 (0.7)	96 (0.7)	197 (0.7)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-attended	1902 (12.9)	1782 (12.1)	3684 (12.5)
Leading to discontinuation from study vaccine	84 (0.6)	54 (0.4)	138 (0.5)
Leading to discontinuation from participation in the study	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	225 (1.5)	256 (1.7)	481 (1.6)
Unsolicited TEAEs related to study vaccination			
All	1201 (8.1)	2032 (13.8)	3233 (11.0)
Serious	3 (<0.1)	8 (<0.1)	11 (<0.1)
Fatal	0	0	0
Medically-attended	90 (0.6)	197 (1.3)	287 (1.0)
Leading to discontinuation from study vaccine	14 (<0.1)	20 (0.1)	34 (0.1)
Leading to discontinuation from participation in the study	0	1 (<0.1)	1 (<0.1)
Severe	30 (0.2)	83 (0.6)	113 (0.4)

	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Baseline SARS-CoV-2 Status: Positive			
Unsolicited TEAEs regardless of relationship to study vaccination			
All	92 (27.3)	77 (22.2)	169 (24.7)
Serious	3 (0.9)	1 (0.3)	4 (0.6)
Fatal	0	0	0
Medically-attended	35 (10.4)	25 (7.2)	60 (8.8)
Leading to discontinuation from study vaccine	8 (2.4)	6 (1.7)	14 (2.0)
Leading to discontinuation from participation in the study	0	0	0
Severe	7 (2.1)	1 (0.3)	8 (1.2)
Unsolicited TEAEs related to study vaccination			
All	30 (8.9)	30 (8.6)	60 (8.8)
Serious	0	0	0
Fatal	0	0	0
Medically-attended	5 (1.5)	1 (0.3)	6 (0.9)
Leading to discontinuation from study vaccine	0	0	0
Leading to discontinuation from participation in the study	0	0	0
Severe	1 (0.3)	0	1 (0.1)

	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Baseline SARS-CoV-2 Status: Missing			
Unsolicited TEAEs regardless of relationship to study vaccination			
All	13 (15.5)	23 (26.4)	36 (21.1)
Serious	0	1 (1.1)	1 (0.6)
Fatal	0	0	0
Medically-attended	3 (3.6)	12 (13.8)	15 (8.8)
Leading to discontinuation from study vaccine	0	1 (1.1)	1 (0.6)
Leading to discontinuation from participation in the study	0	0	0
Severe	1 (1.2)	1 (1.1)	2 (1.2)

	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Unsolicited TEAEs related to study vaccination			
All	5 (6.0)	5 (5.7)	10 (5.8)
Serious	0	0	0
Fatal	0	0	0
Medically-attended	0	0	0
Leading to discontinuation from study vaccine	0	0	0
Leading to discontinuation from participation in the study	0	0	0
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects.

Source: Table 14.3.1.7.3.1.

7.2.6.3 Race and Ethnicity

The incidence of unsolicited TEAEs was similar across the race groups (Table 14.3.1.7.4.1) and ethnic groups (Table 14.3.1.7.5.1).

7.2.6.4 Sex

The observed incidence of unsolicited TEAEs during the 28-day follow-up was higher in females (35.5% of 7266 participants in the mRNA-1273 group) and lower in males (27.4% of 7918 participants in the mRNA-1273 group) (Table 14.3.1.7.7.1). The difference between the mRNA-1273 and placebo groups, respectively, was larger for females (35.5% vs. 31.6%) than for males (27.4% vs. 26.0%). The reported TEAEs were similar for both sexes and the most common TEAEs were headache, fatigue, headache, myalgia, and arthralgia (Table 14.3.1.8.7.1).

7.2.6.5 Risk Factor for Severe COVID-19

The incidence of unsolicited TEAEs in the mRNA-1273 group was 34.5% in the At Risk subgroup (3448 participants) and 30.4% in the Not At Risk subgroup (11,736 participants) (Table 14.3.1.7.6.2.1). As expected based on their medical history, serious TEAEs were reported at a higher rate in the At Risk group (1.0% in the mRNA-1273 group) compared with the Not At Risk group (0.5% in the mRNA-1273 group). There was little difference within risk subgroups

between the mRNA-1273 and placebo groups. The overall incidence of unsolicited TEAEs for the individual risk groups was similar (Table 14.3.1.7.6.3.1).

Among participants with HIV, the incidence of unsolicited TEAEs up to 28 days after any IP administration was generally similar between the mRNA-1273 group (35/94 [37.2%]) and the placebo group (38/91 [41.8%]; Table 14.3.1.7.8.1). The incidence of unsolicited TEAEs that were assessed as treatment-related was also similar between the mRNA-1273 (11/94 [11.7%]) and placebo (10/91 [11.0%]) groups.

7.2.6.6 Participants With Autoimmune Disorders

Among the 2296 participants with an autoimmune disorder reported at baseline, the incidence of unsolicited TEAEs up to 28 days after any injection was 35.0% compared with 30.0% in the overall population. However, even in this large population of participants with at least one autoimmune disorder at baseline, no difference in TEAE incidence was observed between the mRNA-1273 group (36.7% of 1152 participants) and the placebo group (33.2% of 1144 participants) (Table 14.3.1.7.9.1). Events that were assessed as treatment-related were more commonly reported by participants who received mRNA-1273 (16.8%) than by those who received placebo (9.3%), as was observed in the overall study population. This is consistent with the observed higher incidence in the mRNA-1273 group of TEAEs that were associated with reactogenicity (ARs or similar to ARs), including fatigue, injection site conditions, and arthralgia (Table 14.3.1.8.9.1). No cases of autoimmune disease exacerbations were explicitly reported.

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

7.3.1 Deaths

A total of 32 deaths were reported in Part A, including 16 participants (0.1%) in each group (Table 7-20); the table does not reflect 1 additional participant in the mRNA-1273 group who died during Part B due to a TEAE that began during Part A (Section 7.2.1.2). No trends were apparent in the timing or causes of deaths (Table 7-22). Baseline age was ≥ 65 years for 9 of the participants in the mRNA-1273 group and 6 participants in the placebo group (Listing 16.2.7.14). None of the unsolicited TEAEs leading to death were considered to be related to the IP.

COVID-19 was reported as the event leading to death for 1 participant in the mRNA-1273 group and 3 participants in the placebo group. The participant in the mRNA-1273 group was 74 years old and received dose 1 but not dose 2. No TEAEs were reported as leading to discontinuation of vaccine, but the participant is noted as having “refused second injection due to side effects

however, consented to continue study visits" (Listing 16.2.1.1). Reported TEAEs within 8 days of Day 1 were severe nausea and severe fatigue that were considered related to treatment. On Study Day 120, 119 days after the first dose, the participant began to experience symptoms of COVID-19. On Study Day 127, the participant tested positive for SARS-CoV-2 via RT-PCR. The event of COVID-19 lasted for 56 days and the participant died on Study Day 175. This participant was not included in the PP Set due to receipt of an incomplete vaccination regimen.

A listing of the deaths is presented in Listing 16.2.12 and a listing of unsolicited AEs leading to death is presented in Listing 16.2.7.14.

Case narratives for the participants who experienced a fatal TEAE are provided in Section 15.

Table 7-20: Summary of Death in Part A (Safety Set)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Number of deaths, n (%)	16 (0.1)	16 (0.1)	32 (0.1)
From randomization up to 14 days after first injection	2	0	2
>=14 up to 21 days after first injection	0	2	2
>=21 days after first injection up to second injection	1	2	3
From second injection up to 7 days after second injection	0	0	0
>=7 up to 14 days after second injection	0	0	0
>=14 up to 28 days after second injection	0	0	0
>=28 up to 56 days after second injection	2	2	4
>=56 up to 84 days after second injection	2	4	6
>=84 up to 112 days after second injection	6	3	9
>=112 days after second injection	3	3	6

Percentages are based on the number of subjects in Safety Set.

Source: Table 14.3.1.23.1.

Table 7-21: Participants With Serious Adverse Events Resulting in Death

Treatment Assignment	Preferred Term	Study Day of Death	Relationship to IP[a]
mRNA-1273	Cardiac failure congestive	145	Not related
mRNA-1273	Cardiac arrest	89	Not related
mRNA-1273	Myocardial infarction	58	Not related
mRNA-1273	Cardio-respiratory arrest	21	Not related
mRNA-1273	Hepatocellular carcinoma	107	Not related
mRNA-1273	COVID-19	175	Not related
mRNA-1273	Myocardial infarction	45	Not related
mRNA-1273	Pulmonary mass[b]	108	Not related
mRNA-1273	Cardio-respiratory arrest	155	Not related
mRNA-1273	Completed suicide	21	Not related
mRNA-1273	Death	70	Not related
mRNA-1273	Gastrointestinal haemorrhage, multiple organ dysfunction syndrome, acute respiratory failure	60	Not related
mRNA-1273	Death	138	Not related
mRNA-1273	Death	54	Not related
mRNA-1273	Head injury	37	Not related
mRNA-1273	Death	110	Not related
mRNA-1273	Coronary artery disease, diabetic complication	71	Not related
Placebo	COVID-19	64	Not related
Placebo	Gastric perforation	13	Not related
Placebo	Pancreatic carcinoma stage IV	145	Not related
Placebo	Amyotrophic lateral sclerosis	86	Not related
Placebo	Myocardial infarction	29	Not related
Placebo	Myocardial infarction	103	Not related
Placebo	Myocardial infarction	47	Not related
Placebo	Cardio-respiratory arrest	7	Not related
Placebo	Death	120	Not related
Placebo	Systemic inflammatory response syndrome	38	Not related
Placebo	COVID-19	143	Not related
Placebo	Completed suicide	87	Not related
Placebo	Myocardial infarction	86	Not related
Placebo	Death	64	Not related
Placebo	Seizure	97	Not related
Placebo	COVID-19	109	Not related

Abbreviations: IP = investigational product.

[a] Relationship is based on investigator assessment.

[b] This participant is not counted in Table 7-20 because the event began during Part A but the fatal outcome occurred during Part B (Section 7.2.1.2).

Source: Listing 16.2.7.14.

7.3.2 Other Serious Adverse Events

No difference was observed between the groups in the rates of reported SAEs during Part A (1.8% in the mRNA-1273 group [401 events] and 1.9% in the placebo group [439 events]) (Table 7-22). COVID-19 was reported as a serious TEAE for 2 (< 0.1%) participants in the mRNA-1273 group and for 40 (0.3%) participants in the placebo group. No other event was reported as an SAE in ≥ 0.1% of participants in either group. At least 1 SAE that was considered related to treatment was reported for 12 participants (< 0.1%) in the mRNA-1273 group and 4 participants (< 0.1%) in the placebo group (Table 7-23). Swelling of the face was reported as a treatment-related SAE for 2 participants in the mRNA-1273 group and 1 participant in the placebo group (further information below); no other event was reported as treatment-related for more than 1 participant in either group or overall. The other SAEs that were reported as treatment-related during Part A were B-cell small lymphocytic lymphoma, Basedow's disease, autonomic nervous system imbalance, cerebrovascular accident, multiple sclerosis, swelling of the face, nausea and vomiting, alopecia areata, angioedema, rheumatoid arthritis, and pericardial effusion and pericarditis and pleural effusion (described further below) in the mRNA-1273 group and polymyalgia rheumatica; acute myocardial infarction, hypomagnesemia, acute kidney injury, and atrial fibrillation, organizing pneumonia, and respiratory failure (single participant); swelling of the face, immunization anxiety related reaction, feeling hot, and paresthesia (single participant); and procedural hemorrhage in the placebo group. The incidence of SAEs within the 28-day follow-up period was lower in both groups than in Part A and similarly balanced (0.6% in the mRNA-1273 group [140 events] and 0.7% in the placebo group [147 events]) (Table 14.3.1.13.1.1).

Detailed information about all SAEs is available in Section 15. Notable events are briefly described here.

Dyspnea

Dyspnea was reported as an SAE for 5 participants in the mRNA-1273 group and 0 participants in the placebo group. The events were not considered related to treatment. All participants were ≥ 52 years of age at study entry and their baseline BMI was ≥ 30.0 kg/m^2. None of the events were consistent with possible myocarditis or pericarditis; the events occurred 13 days after dose 1 and 35, 81, 88, and 137 days after dose 2; and 4 of the 5 participants had pre-existing cardiac disease. Details are as follows:

- 52-year-old male: Grade 4 dyspnea had onset on Day 81 after the second dose and resolved on Day 93. It coincided with Grade 4 upper respiratory tract infection and severe abdominal pain. The participant's medical history included non-ST myocardial infarction,

cardiomyopathy, systolic congestive heart failure, pulmonary hypertension, obesity, and mitral regurgitation. The event was treated with antibiotics and resolved.

- 62-year-old female: Severe dyspnea had onset on Day 35 after the second dose and resolved on Day 50. It coincided with severe tachycardia; other events ongoing at time of onset were abdominal discomfort, discolored feces, headache, otitis media, and fatigue. The participant's medical history included heart murmur. The dyspnea was associated with possible lung infiltrates and resolved with antibiotics.
- 62-year-old male: Grade 4 dyspnea had onset on Day 13 after the first dose and resolved on Day 66. It coincided with severe paroxysmal atrial flutter and Grade 4 myocardial infarction, heart failure, acute coronary syndrome, and atrial fibrillation with rapid ventricular response. Study vaccine was discontinued in response to the myocardial infarction. The dyspnea resolved on Day 66 and was considered a sequela of the myocardial infarction. The participant's medical history included hypertension, heart murmur, irregular heart rhythm, closure of atrial septal defect, and coronary artery disease with calcified lesion.
- 62-year-old male: Grade 4 dyspnea had onset on Day 137 after the second dose and resolved on Day 140. It coincided with Grade 4 dysphasia. The participant's medical history included right ventricle dysplasia, asthma, and cardiac stents. The event was associated with a post-operative seroma after cervical discectomy.
- 64-year-old female: Severe dyspnea had onset on Day 88 after the second dose and resolved on Day 90. It was associated with fluid in the lungs and resolved with furosemide. The participant's medical history included HIV and a cancerous inguinal tumor.

Pericarditis

Pericarditis was reported as an SAE for 2 participants in the mRNA-1273 group (1 each male and female described below) and 2 in the placebo group (1 each male and female; the male participant had 3 hospitalizations for a single medical event). Another participant in the placebo group had an SAE of pericardial effusion. No cases of concomitant myocarditis were reported. Information about pericarditis events among participants who received mRNA-1273 is as follows:

- 65-year-old male: Grade 4 pericarditis had onset on Day 73 after the second dose and resolved on Day 74. The participant did not have prior history of cardiac disease but had experienced an SAE of myocardial infarction on Days 54 to 57 after the second dose and had undergone cardiac catheterization and stent placement.

- 59-year-old female: Moderate pericarditis and Grade 4 pericardial effusion had onset on Day 68 after the second dose (pericardial effusion had started at moderate severity on the previous day). Grade 4 pleural effusion began on Day 69. All 3 events were considered related to study vaccine. All 3 events resolved on Day 166 after the second dose. The participant's medical history included enlarged descending aorta and thoracic aorta ectasia. The participant had visited an emergency department with shortness of breath and chest pain on Day 5 after the second dose (grade 4 chest pain and moderate fatigue were reported as TEAEs). In addition, the participant had experienced sinus infection and received an influenza vaccination approximately 1 month before the events.

Stroke and Thrombotic Events

Cerebrovascular accident, stroke, or transient ischemic attack were reported for 10 participants in the mRNA-1273 group and 7 participants in the placebo group. Event onset occurred within 28 days after the last dose for 3 participants in the mRNA-1273 group and 2 participants in the placebo group and more than 28 days after the last dose for 7 and 5 participants in the mRNA-1273 and placebo groups, respectively. One event of cerebrovascular accident was considered by the investigator to be related to study treatment (described below). No cases were associated with thrombocytopenia. The age and sex distribution of the participants with these SAEs was similar between the groups, and all participants in both groups had at least one relevant risk factor for the event; these included previous stroke, hypertension, hypercholesterolemia, type 2 diabetes, heart failure, and congenital heart disease. Further details of events in the mRNA-1273 group are as follows:

- 68-year-old female: Severe cerebrovascular accident (right occipital lobe) had onset on Day 4 after the first dose and resolved on Day 5. The participant's medical history included sinus bradycardia and hypertension.
- 77-year-old female: Moderate embolic stroke (left frontal lobe subcortical white matter) had onset on Day 48 after the second dose and resolved on the same day. The participant's medical history included hypertension and psoriatic arthritis.
- 72-year-old male: Severe cerebrovascular accident (left middle cerebral artery lacunar stroke) had onset on Day 118 after the second dose and resolved on the same day. The participant's medical history included hyperlipidemia.
- 56-year-old male: Grade 4 cerebrovascular accident (right occipital lobe) had onset on Day 34 after the second dose and resolved on the same day. The participant's medical history included type 2 diabetes, coronary artery bypass graft, cardiac edema, coronary artery disease, stent placement, hypertriglyceridemia, hypertension,

hypercholesterolemia, myocardial infarction, hyperlipidemia, chronic obstructive pulmonary disease, tobacco and alcohol abuse and dependency, and atrial fibrillation.

- 66-year-old male: Grade 4 cerebrovascular accident (location not reported) had onset on Day 26 after the second dose and resolved on Day 28. The participant's medical history included hypertension, hyperlipidemia, type 2 diabetes, vascular stent placement. The participant had also received an influenza vaccination.
- 60-year-old female: Grade 4 cerebrovascular accident (right frontoparietal infarct) had onset on Day 93 after the second dose and did not resolve. The participant's medical history included chronic obstructive pulmonary disease, hyperlipidemia, hypertension, type 2 diabetes, carotid artery disorder, previous transient ischemic attack, previous smoking, coronary artery disease, and obesity. The cerebrovascular accident occurred after cervical spine stenosis, nerve impingement, fall, and hematoma of the neck and resultant acute respiratory failure.
- 71-year-old female: Grade 4 embolic stroke (multiple left hemisphere embolic infarct) had onset on Day 9 after the second dose (together with staphylococcal pneumonia, cervical vertebral fracture, and traumatic liver injury, all grade 4) on the day after a grade 4 road traffic accident. The participant had grade 4 carotid artery thrombosis and grade 4 acute myocardial infarction on Day 13 after the second dose, and grade 4 craniocerebral injury and grade 4 subarachnoid hemorrhage were reported on Day 23 after the second dose. None of the events was considered to be related to treatment. The outcome of the stroke was not resolved and the outcome of the carotid artery thrombosis was unknown. The participant's medical history included hypertension.
- 45-year-old male: Grade 4 transient ischemic attack (location not reported) had onset on Day 15 after the second dose and resolved on Day 16. The participant's medical history included hyperlipidemia.
- 75-year-old male: Grade 4 transient ischemic attack (right paramedian pontine infarct) had onset on Day 86 after the second dose and resolved on Day 90. The participant's medical history included high cholesterol, high blood pressure, and obesity.
- 34-year-old female: Severe cerebrovascular accident had onset on Day 67 after the first dose and resolved on Day 82. The event was considered to be related to treatment. The participant's medical history included nonserious mild COVID-19 (the participant had only received 1 dose of vaccine). Imaging showed acute left posterior inferior cerebellar artery territory infarct mass effect on the fourth ventricle. The participant had a patent foramen ovale that was surgically repaired during this same hospital admission.

In addition, a 62-year-old female had an event with the reported term of cerebrovascular accident (moderate) that was not considered an SAE but was reported based on findings in a computed tomography scan (performed after a seizure) were suggestive of subacute to remote infarction. The onset of the event was reported as Day 12 and it was described as ongoing, but the participant withdrew consent for unrelated reasons, so no further information was available.

During Part A, there were no reports of idiopathic thrombocytopenic purpura or thrombosis with thrombocytopenia syndrome (the few cases of thrombocytopenia did not occur in connection with thrombosis events) and there were no reports of cerebral venous sinus thrombosis or dural venous thrombosis. An SAE of nonarteritic ischemic optic nerve neuritis (verbatim term; preferred term was optic neuritis) together with nonserious papilledema was reported in a 66-year-old female participant treated with mRNA-1273, but there was no evidence of cerebral vasculitis, aneurysm, stenosis, or abnormal vascularity.

Deep vein thrombosis was reported as an SAE for 4 and 1 participant(s) in the mRNA-1273 and placebo groups, respectively. The event was reported as a TEAE (regardless of seriousness) for 8 and 6 participants, and no imbalance was observed in the SMQ for embolic and thrombotic events (Table 14.3.1.22.12). Among the SAEs, all events were reported in participants 55 years of age or older, occurred at least 41 days after the most recent vaccination, none were considered related to treatment, and all resolved. Among participants in the mRNA-1273 group, details are as follows: one participant had medical history including varicose veins and peroneal nerve paralysis and the deep vein thrombosis was noted incidentally during scheduled colonoscopy; one participant had medical history including hyperlipidemia and had recently had increased sedentary lifestyle; one participant had medical history including alpha thalassemia and the deep vein thrombosis occurred after the participant developed an abscess after a planned surgical procedure; and one participant had medical history including thrombophilia, thrombus, obesity, and multiple pulmonary embolisms.

A numerical imbalance was observed in the CNS vascular disorders SMQ (Section 7.3.3.3.5) due to the inclusion of subarachnoid hemorrhage and subdural hematoma that were of traumatic etiology. In the mRNA-1273 group, subarachnoid hemorrhage was reported as an SAE in 3 participants in the mRNA-1273 group and subdural hematoma was reported as an SAE in 2 participants; neither event was reported in the placebo group. None of the events were considered related to treatment and all were due to accidents. Subarachnoid hemorrhage was reported after a motor vehicle accident 7 days after the second dose for a 71-year-old female (investigator noted, “did not experience a medical condition that caused the motor vehicle accident”); after a fall in ice and snow 83 days after the second dose for a 73-year-old male; and after a fall after an episode of severe syncope (not considered related to treatment) 16 days after the second dose for a 57-year-old female whose medical history included iron deficiency anemia,

benign brain tumor excision, blurry vision, and headaches; brain imaging during hospitalization showed a Chiari malformation that was considered congenital). Subdural hematoma was reported after a head and neck injury from a fall for an 80-year-old participant and for a 65-year-old participant. One 59-year-old participant had both subarachnoid hemorrhage and subdural hematoma that were not reported as SAEs but were also due to a head injury from a fall.

Facial Swelling

An SAE of swelling face was reported as related to treatment for 2 participants in the mRNA-1273 group and 1 participant in the placebo group. None of the events required hospitalization. For a 51-year-old female, the event occurred on Day 3 after her second dose of mRNA-1273 and resolved on Day 8. The participant had received cosmetic injections including dermal fillers in both cheeks approximately 2 weeks before the second dose. For a 46-year-old female, the event was described as bilateral cheek swelling, occurred on Day 1 after the second dose of mRNA-1273, and resolved on Day 7. The participant had received dermal fillers approximately 5 and 6 months before the first and second injections, respectively. For a 41-year-old female, the event was described as swelling to the right side of the face, occurred on Day 7 after the first dose of placebo, and resolved on Day 17. The placebo participant had no reported history of dermal filler use; the event appeared to be associated with prior dental work. None of the other TEAEs within the CMQ for dermal filler reaction post vaccination were reported as SAEs, and incidence of the events did not appear to be imbalanced between the groups (Section 7.3.3.3.4).

Swelling of the face was reported as a nonserious TEAE for 3 participants in each group in the 28-day follow-up period (Table 14.3.1.8.1.1) and for 6 participants in the mRNA-1273 group and 4 participants in the placebo group in Part A (Table 14.3.1.8.1.3).

Facial Paralysis

One participant in the mRNA-1273 group had an SAE of facial paralysis that was not considered to be related to the study vaccine. The event occurred in a 67-year-old female participant, was described as Bell's palsy, occurred on Day 32 after the second dose, and resolved after approximately 7 weeks. The participant's medical history included cerebrovascular accident, hypertension, and type 2 diabetes mellitus. The participant had received an influenza vaccine approximately 2 weeks before the event. Nonserious TEAEs of facial paralysis and/or Bell's palsy are described in Section 7.2.2.

Other Events

- Seizure was reported as an SAE for 3 participants in the mRNA-1273 group and 1 participant in the placebo group. None of the events were considered related to treatment. No imbalance was evident in analyses using the SMQ for convulsions (Section 7.3.3.3).

- Nephrolithiasis was reported as an SAE for 5 participants in the mRNA-1273 group and 1 participant in the placebo group. None of the events were considered related to treatment. Among the 5 participants in the mRNA-1273 group, 4 had a history of nephrolithiasis.
- Although some autoimmune disorders were reported as SAEs in both groups, no cases of autoimmune disease exacerbations were explicitly reported, and no imbalance was evident in analyses using the CMQ for autoimmune disorders (Table 14.3.1.22.9).

Table 7-22: Participant Incidence of Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term in Part A (Safety Set)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of subjects reporting unsolicited adverse events	292 (1.9)	268 (1.8)		560 (1.8)
Number of unsolicited adverse events	439	401		840
Infections and infestations	77 (0.5)	48 (0.3)		125 (0.4)
Pneumonia	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Appendicitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Sepsis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cellulitis	0	3 (<0.1)		3 (<0.1)
Bronchitis	0	2 (<0.1)		2 (<0.1)
COVID-19	40 (0.3)	2 (<0.1)	0.05 (0.01, 0.19)	42 (0.1)
Peritonitis	0	2 (<0.1)		2 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Urosepsis	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Diverticulitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastroenteritis viral	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Septic shock	3 (<0.1)	1 (<0.1)		4 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	5 (<0.1)	1 (<0.1)		6 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
COVID-19 pneumonia	8 (<0.1)	0		8 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Localised infection	1 (<0.1)	0		1 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pyelonephritis	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.2)	27 (0.2)		51 (0.2)
Prostate cancer	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hepatocellular carcinoma	0	2 (<0.1)		2 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	3 (<0.1)	0		3 (<0.1)
Intraductal proliferative breast lesion	3 (<0.1)	0		3 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	7 (<0.1)	3 (<0.1)		10 (<0.1)
Anaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thrombocytopenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)
Immune system disorders	2 (<0.1)	0		2 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	15 (<0.1)	17 (0.1)		32 (0.1)
Dehydration	4 (<0.1)	4 (<0.1)		8 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyponatraemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypoglycaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Diabetes mellitus inadequate control	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	13 (<0.1)	13 (<0.1)		26 (<0.1)
Depression	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental status changes	1 (<0.1)	1 (<0.1)		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)
Anxiety disorder	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Major depression	2 (<0.1)	0		2 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	27 (0.2)	31 (0.2)		58 (0.2)
Cerebrovascular accident	4 (<0.1)	6 (<0.1)		10 (<0.1)
Syncope	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aphasia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Dizziness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	43 (0.3)	36 (0.2)		79 (0.3)
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Atrial fibrillation	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Cardiac failure congestive	3 (<0.1)	4 (<0.1)		7 (<0.1)
Acute coronary syndrome	0	3 (<0.1)		3 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Acute myocardial infarction	6 (<0.1)	3 (<0.1)		9 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)		6 (<0.1)
Atrial flutter	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute left ventricular failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery occlusion	0	1 (<0.1)		1 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Angina pectoris	1 (<0.1)	0		1 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)
Vascular disorders	15 (<0.1)	15 (<0.1)		30 (<0.1)
Deep vein thrombosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Haematoma	0	2 (<0.1)		2 (<0.1)
Hypertension	2 (<0.1)	2 (<0.1)		4 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Hypotension	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	35 (0.2)	25 (0.2)		60 (0.2)
Acute respiratory failure	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Dyspnoea	0	5 (<0.1)		5 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	1 (<0.1)	0.12 (0.02, 0.77)	9 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Asthma	1 (<0.1)	0		1 (<0.1)
Epistaxis	1 (<0.1)	0		1 (<0.1)
Hypoxia	3 (<0.1)	0		3 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	25 (0.2)	36 (0.2)		61 (0.2)
Colitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Gastrointestinal haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Nausea	3 (<0.1)	3 (<0.1)		6 (<0.1)
Small intestinal obstruction	3 (<0.1)	3 (<0.1)		6 (<0.1)
Abdominal pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal pain upper	0	2 (<0.1)		2 (<0.1)
Diarrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Hiatus hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Intestinal obstruction	0	2 (<0.1)		2 (<0.1)
Vomiting	2 (<0.1)	2 (<0.1)		4 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)		3 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrooesophageal reflux disease	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	0	1 (<0.1)		1 (<0.1)
Pancreatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Abdominal hernia	1 (<0.1)	0		1 (<0.1)
Abdominal pain lower	2 (<0.1)	0		2 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	5 (<0.1)	6 (<0.1)		11 (<0.1)
Cholecystitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bile duct stone	0	2 (<0.1)		2 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	28 (0.2)	24 (0.2)		52 (0.2)
Osteoarthritis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.58)	20 (<0.1)
Intervertebral disc protrusion	2 (<0.1)	3 (<0.1)		5 (<0.1)
Back pain	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Flank pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Spondylolisthesis	0	1 (<0.1)		1 (<0.1)
Vertebral foraminal stenosis	0	1 (<0.1)		1 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	11 (<0.1)	10 (<0.1)		21 (<0.1)
Acute kidney injury	6 (<0.1)	5 (<0.1)		11 (<0.1)
Nephrolithiasis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Chronic kidney disease	2 (<0.1)	1 (<0.1)		3 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abortion spontaneous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	6 (<0.1)	6 (<0.1)		12 (<0.1)
Pelvic pain	0	2 (<0.1)		2 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	12 (<0.1)	15 (<0.1)		27 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Non-cardiac chest pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Chest pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Asthenia	0	1 (<0.1)		1 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Pyrexia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)
Investigations	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	0	1 (<0.1)		1 (<0.1)
Transaminases increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	29 (0.2)	27 (0.2)		56 (0.2)
Hip fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Fall	5 (<0.1)	2 (<0.1)		7 (<0.1)
Road traffic accident	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Concussion	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Humerus fracture	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rib fracture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Skin laceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Superficial injury of eye	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Pelvic fracture	1 (<0.1)	0		1 (<0.1)
Post procedural fever	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	2 (<0.1)	0		2 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.13.1.3.

Table 7-23: Participant Incidence of Serious Treatment-Emergent Adverse Events Assessed by the Investigator as Treatment-Related by System Organ Class and Preferred Term in Part A (Safety Set)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of subjects reporting unsolicited adverse events	4 (<0.1)	12 (<0.1)		16 (<0.1)
Number of unsolicited adverse events	13	15		28
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericardial effusion	0	1 (<0.1)		1 (<0.1)
Pericarditis	0	1 (<0.1)		1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Respiratory failure	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	1 (<0.1)	0		1 (<0.1)
Acute kidney injury	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0		2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.14.1.3.

7.3.3 Other Clinically Meaningful Unsolicited Adverse Events

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

The participant incidence of unsolicited TEAEs leading to discontinuation from the study vaccine in Part A was lower in the mRNA-1273 group (0.5%; 87 events) than in the placebo group (0.7%; 123 events) (Table 7-24). The most frequently reported TEAE leading to discontinuation from the study vaccine was COVID-19 (14 participants [< 0.1%] in the mRNA-1273 group vs. 53 participants [0.3%] in the placebo group). Urticaria was reported by 5 participants who received mRNA-1273 and 2 participants who received placebo (< 0.1% each); no other unsolicited TEAE (PT) leading to discontinuation from the study vaccine was reported by more than 3 participants in either group.

The participant incidence of unsolicited TEAEs leading to discontinuation from participation in the study up to 28 days after any injection was similar between the mRNA-1273 group (< 0.1%; 9 events) and the placebo group (< 0.1%; 6 events) (Table 7-25). No unsolicited TEAE (PT) leading to discontinuation from participation in the study up to 28 days after any injection was reported by more than 1 participant in either group.

The participant incidence of unsolicited TEAEs leading to discontinuation from participation in Part A was similar between the mRNA-1273 group (0.2%; 26 events) and the placebo group (0.2%; 23 events) (Table 14.3.1.16.1.3). Myocardial infarction was reported by 2 participants in the mRNA-1273 group and 4 participants in the placebo group, and COVID-19 was reported in 1 participant in the mRNA-1273 group and 3 participants in the placebo group (< 0.1% each); no other unsolicited TEAE (PT) leading to discontinuation from participation in the study was reported by more than 2 participants in either group. In addition, events coded as “death” without further specification were reported for 4 participants in the mRNA-1273 group and 2 participants in the placebo group (Section 7.3.1).

Case narratives for participants with AEs leading to discontinuation from the study are provided in Section 15.

Table 7-24: Participant Incidence of Unsolicited Treatment-Emergent Adverse Event Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term (Safety Set)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of subjects reporting unsolicited adverse events	109 (0.7)	74 (0.5)		183 (0.6)
Number of unsolicited adverse events	123	87		210
Infections and infestations	61 (0.4)	25 (0.2)		86 (0.3)
COVID-19	53 (0.3)	14 (<0.1)	0.26 (0.15, 0.47)	67 (0.2)
Asymptomatic COVID-19	0	3 (<0.1)		3 (<0.1)
Pneumonia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes simplex	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Suspected COVID-19	0	1 (<0.1)		1 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Diverticulitis	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	3 (<0.1)		4 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymphadenopathy	0	2 (<0.1)		2 (<0.1)
Psychiatric disorders	6 (<0.1)	4 (<0.1)		10 (<0.1)
Bipolar disorder	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Anxiety	2 (<0.1)	0		2 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	6 (<0.1)	6 (<0.1)		12 (<0.1)
Ageusia	0	1 (<0.1)		1 (<0.1)
Anosmia	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Headache	2 (<0.1)	1 (<0.1)		3 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Amnesia	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	2 (<0.1)	0		2 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (<0.1)	0		2 (<0.1)
Vertigo	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	6 (<0.1)	3 (<0.1)		9 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Tachycardia	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	4 (<0.1)	4 (<0.1)		8 (<0.1)
Hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders	6 (<0.1)	3 (<0.1)		9 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0		1 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abdominal pain lower	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	4 (<0.1)	9 (<0.1)		13 (<0.1)
Urticaria	2 (<0.1)	5 (<0.1)		7 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Arthralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthritis	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Back pain	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	0		1 (<0.1)
Pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	3 (<0.1)	6 (<0.1)		9 (<0.1)
Injection site erythema	0	2 (<0.1)		2 (<0.1)
Injection site swelling	0	2 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Injection site macule	0	1 (<0.1)		1 (<0.1)
Injection site urticaria	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	1 (<0.1)		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Blood pressure increased	1 (<0.1)	0		1 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	5 (<0.1)	4 (<0.1)		9 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Product issues	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.15.1.

Table 7-25: Participant Incidence of Unsolicited Treatment-Emergent Adverse Events Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term up to 28 Days After Any Injection (Safety Set)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of subjects reporting unsolicited adverse events	6 (<0.1)	9 (<0.1)		15 (<0.1)
Number of unsolicited adverse events	6	10		16
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	0	3 (<0.1)		3 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Cardiac disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Investigations	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.16.1.1.

7.3.3.2 Medically Attended Treatment-Emergent Adverse Events

Data summarized for Part A include all available participant level data up to early unblinding, study discontinuation, the Part B PDV or data cutoff date (26 Mar 2021), whichever was earlier; the longer follow-up duration allowed more events to accumulate compared with the 28-day follow-up period.

In Part A, the participant incidence of unsolicited MAAEs was balanced between the mRNA-1273 and placebo groups (22.8% and 27.2%, respectively), with 6145 events reported in the mRNA-1273 group and 7272 events reported in the placebo group (Table 7-26). COVID-19 was the most common MAAE and was reported more frequently in the placebo group (5.9%) than in the mRNA-1273 group (0.5%). The incidence of other most common (≥ 1.0% in either group) MAAEs was balanced between the groups: upper respiratory tract infection (1.2% mRNA-1273 vs. 1.4% placebo); urinary tract infection (0.9% mRNA-1273 vs. 1.2% placebo); and hypertension (1.2% mRNA-1273 vs. 1.4% placebo).

Rate ratios were provided for events (preferred terms) that were reported for at least 7 participants in any treatment group. Events for which the 95% CI for the ratio excludes 1 were as follows (rate ratio [95% CI] for mRNA-1273 > placebo participants): herpes zoster (2.35 [1.34, 4.11]), enterovirus infection (4.99 [1.23, 20.26]), cervical radiculopathy (11.98 [2.00, 71.83]), and facial bones fracture (7.99 [1.30, 49.20]). Assessment of notable imbalances for herpes zoster, cervical radiculopathy, and facial bones fracture is provided in Section 7.2.2. Please note that because the study was not designed to evaluate for differences in the incidences of rare events, nor was any multiplicity adjustment made, the results of these statistical comparisons should be interpreted with caution.

In the 28-day follow-up period, the participant incidence of unsolicited MAAEs was balanced between the mRNA-1273 and placebo groups (12.0% and 12.8%, respectively), with 2715 events reported in the mRNA-1273 group and 2863 events reported in the placebo group (Table 14.3.1.19.1.1). COVID-19 was reported more frequently in the placebo group (0.9%) than in the mRNA-1273 group (0.1%).

Table 7-26: Participant Incidence of Unsolicited Medically-Attended Treatment-Emergent Adverse Event (at Least 5 Participants in Any Group Based on Preferred Term) by System Organ Class and Preferred Term in Part A (Safety Set)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of subjects reporting unsolicited adverse events	4131 (27.2)	3468 (22.8)		7599 (25.0)
Number of unsolicited adverse events	7272	6145		13417
Infections and infestations	2069 (13.6)	1329 (8.8)		3398 (11.2)
Upper respiratory tract infection	209 (1.4)	177 (1.2)	0.85 (0.69, 1.03)	386 (1.3)
Urinary tract infection	180 (1.2)	137 (0.9)	0.76 (0.61, 0.95)	317 (1.0)
Suspected COVID-19	96 (0.6)	113 (0.7)	1.18 (0.90, 1.54)	209 (0.7)
Viral infection	115 (0.8)	112 (0.7)	0.97 (0.75, 1.26)	227 (0.7)
Sinusitis	99 (0.7)	108 (0.7)	1.09 (0.83, 1.43)	207 (0.7)
COVID-19	892 (5.9)	79 (0.5)	0.09 (0.07, 0.11)	971 (3.2)
Rhinovirus infection	49 (0.3)	57 (0.4)	1.16 (0.80, 1.70)	106 (0.3)
Herpes zoster	17 (0.1)	40 (0.3)	2.35 (1.34, 4.11)	57 (0.2)
Tooth abscess	39 (0.3)	30 (0.2)	0.77 (0.48, 1.23)	69 (0.2)
Tooth infection	30 (0.2)	30 (0.2)	1.00 (0.61, 1.65)	60 (0.2)
Pharyngitis streptococcal	36 (0.2)	25 (0.2)	0.69 (0.42, 1.15)	61 (0.2)
Viral upper respiratory tract infection	23 (0.2)	24 (0.2)	1.04 (0.59, 1.83)	47 (0.2)
Cellulitis	28 (0.2)	23 (0.2)	0.82 (0.48, 1.41)	51 (0.2)
Ear infection	21 (0.1)	22 (0.1)	1.05 (0.58, 1.89)	43 (0.1)
Bronchitis	30 (0.2)	20 (0.1)	0.67 (0.38, 1.16)	50 (0.2)
Gastroenteritis	20 (0.1)	19 (0.1)	0.95 (0.51, 1.76)	39 (0.1)
Pharyngitis	19 (0.1)	19 (0.1)	1.00 (0.53, 1.87)	38 (0.1)
Pneumonia	33 (0.2)	19 (0.1)	0.57 (0.33, 1.00)	52 (0.2)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Otitis media	17 (0.1)	18 (0.1)	1.06 (0.55, 2.03)	35 (0.1)
Diverticulitis	19 (0.1)	15 (<0.1)	0.79 (0.41, 1.53)	34 (0.1)
Hordeolum	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Conjunctivitis	16 (0.1)	12 (<0.1)	0.75 (0.36, 1.56)	28 (<0.1)
Otitis externa	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Enterovirus infection	2 (<0.1)	10 (<0.1)	4.99 (1.23, 20.26)	12 (<0.1)
Fungal infection	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Localised infection	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Acute sinusitis	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Onychomycosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Respiratory tract infection	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Abscess limb	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Bacterial vaginosis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Herpes simplex	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Nasopharyngitis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.58)	20 (<0.1)
Paronychia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Asymptomatic COVID-19	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Cystitis	14 (<0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Gingivitis	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Skin infection	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Vulvovaginal candidiasis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Folliculitis	12 (<0.1)	6 (<0.1)	0.50 (0.19, 1.28)	18 (<0.1)
Lyme disease	0	6 (<0.1)		6 (<0.1)
Pyelonephritis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Sepsis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Appendicitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Clostridium difficile infection	0	5 (<0.1)		5 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastroenteritis viral	6 (<0.1)	5 (<0.1)		11 (<0.1)
Kidney infection	2 (<0.1)	5 (<0.1)		7 (<0.1)
Oral candidiasis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Oral herpes	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Postoperative wound infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Staphylococcal infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Staphylococcal skin infection	1 (<0.1)	5 (<0.1)		6 (<0.1)
Eye infection	6 (<0.1)	4 (<0.1)		10 (<0.1)
Vulvovaginal mycotic infection	13 (<0.1)	4 (<0.1)	0.31 (0.11, 0.89)	17 (<0.1)
Tonsillitis	11 (<0.1)	3 (<0.1)	0.27 (0.08, 0.91)	14 (<0.1)
Otitis media acute	5 (<0.1)	2 (<0.1)		7 (<0.1)
Respiratory tract infection viral	10 (<0.1)	2 (<0.1)	0.20 (0.05, 0.81)	12 (<0.1)
COVID-19 pneumonia	16 (0.1)	0		16 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	116 (0.8)	123 (0.8)		239 (0.8)
Basal cell carcinoma	28 (0.2)	22 (0.1)	0.78 (0.45, 1.36)	50 (0.2)
Prostate cancer	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Skin cancer	4 (<0.1)	6 (<0.1)		10 (<0.1)
Uterine leiomyoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Benign neoplasm of skin	2 (<0.1)	5 (<0.1)		7 (<0.1)
Malignant melanoma	5 (<0.1)	5 (<0.1)		10 (<0.1)
Squamous cell carcinoma	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Squamous cell carcinoma of skin	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Blood and lymphatic system disorders	56 (0.4)	73 (0.5)		129 (0.4)
Lymphadenopathy	29 (0.2)	38 (0.3)	1.31 (0.81, 2.11)	67 (0.2)
Anaemia	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Iron deficiency anaemia	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Immune system disorders	41 (0.3)	38 (0.3)		79 (0.3)
Seasonal allergy	25 (0.2)	23 (0.2)	0.92 (0.53, 1.61)	48 (0.2)
Drug hypersensitivity	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Hypersensitivity	5 (<0.1)	4 (<0.1)		9 (<0.1)
Endocrine disorders	33 (0.2)	33 (0.2)		66 (0.2)
Hypothyroidism	15 (<0.1)	22 (0.1)	1.46 (0.77, 2.79)	37 (0.1)
Goitre	5 (<0.1)	2 (<0.1)		7 (<0.1)
Metabolism and nutrition disorders	222 (1.5)	191 (1.3)		413 (1.4)
Hyperlipidaemia	44 (0.3)	35 (0.2)	0.79 (0.51, 1.23)	79 (0.3)
Type 2 diabetes mellitus	25 (0.2)	33 (0.2)	1.32 (0.79, 2.20)	58 (0.2)
Vitamin D deficiency	27 (0.2)	25 (0.2)	0.92 (0.54, 1.58)	52 (0.2)
Hypercholesterolaemia	30 (0.2)	21 (0.1)	0.70 (0.40, 1.21)	51 (0.2)
Diabetes mellitus	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.52)	21 (<0.1)
Glucose tolerance impaired	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Dehydration	14 (<0.1)	9 (<0.1)	0.64 (0.28, 1.45)	23 (<0.1)
Gout	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Hyponatraemia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Hypokalaemia	16 (0.1)	5 (<0.1)	0.31 (0.12, 0.82)	21 (<0.1)
Hyperglycaemia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Dyslipidaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Hypomagnesaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Psychiatric disorders	193 (1.3)	224 (1.5)		417 (1.4)
Depression	70 (0.5)	84 (0.6)	1.20 (0.87, 1.64)	154 (0.5)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Anxiety	67 (0.4)	81 (0.5)	1.21 (0.88, 1.66)	148 (0.5)
Insomnia	23 (0.2)	23 (0.2)	1.00 (0.56, 1.77)	46 (0.2)
Attention deficit hyperactivity disorder	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Bipolar disorder	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Generalised anxiety disorder	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Nervous system disorders	322 (2.1)	319 (2.1)		641 (2.1)
Headache	142 (0.9)	132 (0.9)	0.93 (0.73, 1.17)	274 (0.9)
Dizziness	25 (0.2)	18 (0.1)	0.72 (0.40, 1.31)	43 (0.1)
Migraine	19 (0.1)	18 (0.1)	0.95 (0.50, 1.78)	37 (0.1)
Sciatica	19 (0.1)	17 (0.1)	0.89 (0.47, 1.70)	36 (0.1)
Paraesthesia	13 (<0.1)	16 (0.1)	1.23 (0.60, 2.52)	29 (<0.1)
Syncope	24 (0.2)	16 (0.1)	0.67 (0.36, 1.24)	40 (0.1)
Cervical radiculopathy	1 (<0.1)	12 (<0.1)	11.98 (2.00, 71.83)	13 (<0.1)
Anosmia	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Ageusia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Nerve compression	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Cerebrovascular accident	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Facial paralysis	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Carpal tunnel syndrome	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Hypoaesthesia	5 (<0.1)	5 (<0.1)		10 (<0.1)
Lumbar radiculopathy	1 (<0.1)	5 (<0.1)		6 (<0.1)
Seizure	6 (<0.1)	5 (<0.1)		11 (<0.1)
Presyncope	5 (<0.1)	3 (<0.1)		8 (<0.1)
Restless legs syndrome	6 (<0.1)	2 (<0.1)		8 (<0.1)
Neuropathy peripheral	5 (<0.1)	0		5 (<0.1)
Eye disorders	70 (0.5)	80 (0.5)		150 (0.5)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cataract	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Dry eye	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Retinal detachment	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Glaucoma	5 (<0.1)	6 (<0.1)		11 (<0.1)
Ear and labyrinth disorders	71 (0.5)	61 (0.4)		132 (0.4)
Vertigo	13 (<0.1)	22 (0.1)	1.69 (0.86, 3.31)	35 (0.1)
Ear pain	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Tinnitus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Vertigo positional	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Meniere's disease	2 (<0.1)	5 (<0.1)		7 (<0.1)
Ear canal erythema	5 (<0.1)	1 (<0.1)		6 (<0.1)
Tympanic membrane perforation	6 (<0.1)	1 (<0.1)		7 (<0.1)
Cardiac disorders	114 (0.8)	118 (0.8)		232 (0.8)
Atrial fibrillation	27 (0.2)	25 (0.2)	0.92 (0.54, 1.58)	52 (0.2)
Palpitations	6 (<0.1)	14 (<0.1)	2.33 (0.93, 5.86)	20 (<0.1)
Ventricular extrasystoles	4 (<0.1)	10 (<0.1)	2.50 (0.83, 7.52)	14 (<0.1)
Coronary artery disease	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Angina pectoris	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Cardiac failure congestive	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Myocardial infarction	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Sinus tachycardia	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Tachycardia	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Acute myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Arrhythmia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Vascular disorders	264 (1.7)	222 (1.5)		486 (1.6)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Hypertension	218 (1.4)	176 (1.2)	0.81 (0.66, 0.98)	394 (1.3)
Haematoma	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Deep vein thrombosis	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Hypotension	6 (<0.1)	3 (<0.1)		9 (<0.1)
Respiratory, thoracic and mediastinal disorders	409 (2.7)	329 (2.2)		738 (2.4)
Cough	122 (0.8)	112 (0.7)	0.92 (0.71, 1.18)	234 (0.8)
Nasal congestion	91 (0.6)	91 (0.6)	1.00 (0.75, 1.33)	182 (0.6)
Rhinorrhoea	75 (0.5)	76 (0.5)	1.01 (0.74, 1.39)	151 (0.5)
Oropharyngeal pain	104 (0.7)	73 (0.5)	0.70 (0.52, 0.94)	177 (0.6)
Dyspnoea	46 (0.3)	41 (0.3)	0.89 (0.59, 1.35)	87 (0.3)
Asthma	28 (0.2)	20 (0.1)	0.71 (0.41, 1.26)	48 (0.2)
Chronic obstructive pulmonary disease	18 (0.1)	10 (<0.1)	0.55 (0.26, 1.18)	28 (<0.1)
Sinus congestion	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Respiratory tract congestion	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Acute respiratory failure	14 (<0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Rhinitis allergic	12 (<0.1)	7 (<0.1)	0.58 (0.24, 1.43)	19 (<0.1)
Upper-airway cough syndrome	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Sinus pain	1 (<0.1)	6 (<0.1)		7 (<0.1)
Pleural effusion	5 (<0.1)	5 (<0.1)		10 (<0.1)
Sneezing	2 (<0.1)	5 (<0.1)		7 (<0.1)
Respiratory disorder	5 (<0.1)	4 (<0.1)		9 (<0.1)
Sleep apnoea syndrome	6 (<0.1)	4 (<0.1)		10 (<0.1)
Epistaxis	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hypoxia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Pharyngeal erythema	6 (<0.1)	2 (<0.1)		8 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Wheezing	5 (<0.1)	2 (<0.1)		7 (<0.1)
Pleuritic pain	6 (<0.1)	1 (<0.1)		7 (<0.1)
Gastrointestinal disorders	371 (2.4)	382 (2.5)		753 (2.5)
Nausea	65 (0.4)	69 (0.5)	1.06 (0.76, 1.48)	134 (0.4)
Diarrhoea	60 (0.4)	61 (0.4)	1.02 (0.71, 1.45)	121 (0.4)
Gastrooesophageal reflux disease	37 (0.2)	51 (0.3)	1.38 (0.90, 2.09)	88 (0.3)
Abdominal pain	21 (0.1)	25 (0.2)	1.19 (0.67, 2.11)	46 (0.2)
Dental caries	29 (0.2)	23 (0.2)	0.79 (0.46, 1.36)	52 (0.2)
Toothache	27 (0.2)	20 (0.1)	0.74 (0.42, 1.31)	47 (0.2)
Vomiting	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Constipation	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Abdominal pain upper	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Inguinal hernia	5 (<0.1)	11 (<0.1)	2.20 (0.80, 6.05)	16 (<0.1)
Large intestine polyp	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Hiatus hernia	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Irritable bowel syndrome	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Abdominal pain lower	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Colitis	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Dyspepsia	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Gastritis	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Gastric ulcer	6 (<0.1)	5 (<0.1)		11 (<0.1)
Tooth impacted	6 (<0.1)	5 (<0.1)		11 (<0.1)
Food poisoning	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Abdominal discomfort	5 (<0.1)	2 (<0.1)		7 (<0.1)
Dysphagia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hepatobiliary disorders	17 (0.1)	27 (0.2)		44 (0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cholelithiasis	7 (<0.1)	13 (<0.1)	1.85 (0.76, 4.51)	20 (<0.1)
Cholecystitis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Skin and subcutaneous tissue disorders	180 (1.2)	155 (1.0)		335 (1.1)
Urticaria	17 (0.1)	21 (0.1)	1.23 (0.66, 2.31)	38 (0.1)
Dermatitis contact	20 (0.1)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.1)
Rash	20 (0.1)	13 (<0.1)	0.65 (0.33, 1.29)	33 (0.1)
Eczema	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Acne	17 (0.1)	9 (<0.1)	0.53 (0.24, 1.16)	26 (<0.1)
Actinic keratosis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Pruritus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Rosacea	3 (<0.1)	6 (<0.1)		9 (<0.1)
Dermatitis	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Dermal cyst	5 (<0.1)	3 (<0.1)		8 (<0.1)
Rash pruritic	6 (<0.1)	1 (<0.1)		7 (<0.1)
Musculoskeletal and connective tissue disorders	467 (3.1)	484 (3.2)		951 (3.1)
Arthralgia	65 (0.4)	68 (0.4)	1.04 (0.75, 1.46)	133 (0.4)
Back pain	73 (0.5)	62 (0.4)	0.85 (0.61, 1.19)	135 (0.4)
Osteoarthritis	57 (0.4)	52 (0.3)	0.91 (0.63, 1.32)	109 (0.4)
Myalgia	60 (0.4)	50 (0.3)	0.83 (0.57, 1.21)	110 (0.4)
Musculoskeletal pain	20 (0.1)	29 (0.2)	1.45 (0.83, 2.54)	49 (0.2)
Neck pain	14 (<0.1)	25 (0.2)	1.78 (0.94, 3.39)	39 (0.1)
Muscle spasms	25 (0.2)	22 (0.1)	0.88 (0.50, 1.55)	47 (0.2)
Pain in extremity	26 (0.2)	22 (0.1)	0.84 (0.48, 1.48)	48 (0.2)
Rotator cuff syndrome	19 (0.1)	20 (0.1)	1.05 (0.57, 1.95)	39 (0.1)
Intervertebral disc protrusion	10 (<0.1)	17 (0.1)	1.70 (0.79, 3.64)	27 (<0.1)
Bursitis	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Tendonitis	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Arthritis	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Spinal osteoarthritis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Trigger finger	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Musculoskeletal chest pain	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Periarthritis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Joint swelling	1 (<0.1)	6 (<0.1)		7 (<0.1)
Osteoporosis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Muscular weakness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Osteopenia	5 (<0.1)	5 (<0.1)		10 (<0.1)
Flank pain	5 (<0.1)	4 (<0.1)		9 (<0.1)
Intervertebral disc degeneration	5 (<0.1)	4 (<0.1)		9 (<0.1)
Exostosis	6 (<0.1)	2 (<0.1)		8 (<0.1)
Foot deformity	6 (<0.1)	2 (<0.1)		8 (<0.1)
Synovial cyst	5 (<0.1)	1 (<0.1)		6 (<0.1)
Renal and urinary disorders	78 (0.5)	71 (0.5)		149 (0.5)
Nephrolithiasis	30 (0.2)	23 (0.2)	0.77 (0.45, 1.31)	53 (0.2)
Acute kidney injury	12 (<0.1)	7 (<0.1)	0.58 (0.24, 1.43)	19 (<0.1)
Chronic kidney disease	6 (<0.1)	6 (<0.1)		12 (<0.1)
Haematuria	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Hypertonic bladder	3 (<0.1)	5 (<0.1)		8 (<0.1)
Urinary retention	4 (<0.1)	5 (<0.1)		9 (<0.1)
Reproductive system and breast disorders	100 (0.7)	85 (0.6)		185 (0.6)
Benign prostatic hyperplasia	20 (0.1)	8 (<0.1)	0.40 (0.18, 0.89)	28 (<0.1)
Ovarian cyst	6 (<0.1)	6 (<0.1)		12 (<0.1)
Prostatitis	6 (<0.1)	6 (<0.1)		12 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Breast cyst	3 (<0.1)	5 (<0.1)		8 (<0.1)
Erectile dysfunction	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Pelvic pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Prostatomegaly	5 (<0.1)	5 (<0.1)		10 (<0.1)
Breast mass	5 (<0.1)	2 (<0.1)		7 (<0.1)
General disorders and administration site conditions	240 (1.6)	265 (1.7)		505 (1.7)
Fatigue	104 (0.7)	104 (0.7)	1.00 (0.76, 1.31)	208 (0.7)
Pain	45 (0.3)	40 (0.3)	0.89 (0.58, 1.35)	85 (0.3)
Chills	34 (0.2)	29 (0.2)	0.85 (0.52, 1.39)	63 (0.2)
Pyrexia	33 (0.2)	28 (0.2)	0.85 (0.51, 1.39)	61 (0.2)
Injection site pain	6 (<0.1)	15 (<0.1)	2.50 (1.00, 6.23)	21 (<0.1)
Non-cardiac chest pain	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Chest pain	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Oedema peripheral	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Injection site lymphadenopathy	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Chest discomfort	14 (<0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Injection site erythema	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Injection site induration	0	7 (<0.1)		7 (<0.1)
Injection site rash	0	7 (<0.1)		7 (<0.1)
Injection site swelling	0	7 (<0.1)		7 (<0.1)
Peripheral swelling	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Asthenia	6 (<0.1)	4 (<0.1)		10 (<0.1)
Cyst	5 (<0.1)	3 (<0.1)		8 (<0.1)
Investigations	85 (0.6)	88 (0.6)		173 (0.6)
Blood cholesterol increased	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Blood pressure increased	17 (0.1)	8 (<0.1)	0.47 (0.21, 1.06)	25 (<0.1)
Hepatic enzyme increased	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood pressure systolic increased	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Injury, poisoning and procedural complications	425 (2.8)	392 (2.6)		817 (2.7)
Skin laceration	47 (0.3)	34 (0.2)	0.72 (0.47, 1.12)	81 (0.3)
Ligament sprain	22 (0.1)	32 (0.2)	1.45 (0.85, 2.48)	54 (0.2)
Fall	25 (0.2)	26 (0.2)	1.04 (0.60, 1.79)	51 (0.2)
Muscle strain	24 (0.2)	25 (0.2)	1.04 (0.60, 1.81)	49 (0.2)
Procedural pain	34 (0.2)	22 (0.1)	0.65 (0.38, 1.10)	56 (0.2)
Tooth fracture	30 (0.2)	22 (0.1)	0.73 (0.43, 1.26)	52 (0.2)
Foot fracture	18 (0.1)	20 (0.1)	1.11 (0.59, 2.08)	38 (0.1)
Meniscus injury	19 (0.1)	18 (0.1)	0.95 (0.50, 1.78)	37 (0.1)
Animal bite	15 (<0.1)	15 (<0.1)	1.00 (0.50, 2.01)	30 (<0.1)
Arthropod bite	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Limb injury	11 (<0.1)	13 (<0.1)	1.18 (0.54, 2.58)	24 (<0.1)
Joint injury	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Road traffic accident	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Concussion	5 (<0.1)	10 (<0.1)	2.00 (0.71, 5.58)	15 (<0.1)
Rib fracture	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Contusion	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Facial bones fracture	1 (<0.1)	8 (<0.1)	7.99 (1.30, 49.20)	9 (<0.1)
Post-traumatic pain	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Head injury	2 (<0.1)	6 (<0.1)		8 (<0.1)
Clavicle fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Corneal abrasion	5 (<0.1)	5 (<0.1)		10 (<0.1)

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Humerus fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Ligament rupture	5 (<0.1)	5 (<0.1)		10 (<0.1)
Muscle rupture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Stress fracture	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Upper limb fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Ankle fracture	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Cartilage injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Epicondylitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Skin abrasion	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Wrist fracture	6 (<0.1)	4 (<0.1)		10 (<0.1)
Arthropod sting	5 (<0.1)	3 (<0.1)		8 (<0.1)
Bone contusion	5 (<0.1)	2 (<0.1)		7 (<0.1)
Tendon rupture	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Radius fracture	6 (<0.1)	1 (<0.1)		7 (<0.1)
Wound	6 (<0.1)	1 (<0.1)		7 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.19.1.3.

7.3.3.3 Analysis of Adverse Events of Clinical Interest

Analyses for AEs of clinical interest were performed by searching the database using Standardized MedDRA Queries (SMQs) or Custom MedDRA Queries (CMQs). The SMQs for this study were anaphylactic reaction (Table 14.3.1.22.8), angioedema (Table 14.3.1.22.4), arthritis (Table 14.3.1.22.3), cardiomyopathy (Table 14.3.1.22.16), CNS vascular disorders (Section 7.3.3.3.4, Table 14.3.1.22.10), convulsions (Table 14.3.1.22.7), demyelination (Table 14.3.1.22.6), embolic and thrombotic events (Table 14.3.1.22.12), hearing and vestibular disorders (Table 14.3.1.22.13), hematopoietic cytopenias (Section 7.3.3.3.5, Table 14.3.1.22.15), hypersensitivity (Section 7.3.3.3.1, Table 14.3.1.22.2), peripheral neuropathy (Table 14.3.1.22.5), thrombophlebitis (Table 14.3.1.22.14), and vasculitis (Table 14.3.1.22.1). The CMQs were autoimmune disorders (Table 14.3.1.22.9) and dermal filler reaction post vaccination (Section 7.3.3.3.2, Table 14.3.1.22.11). The SMQ and CMQ analyses for which potential imbalances were observed are described in subsections below. Terms included in the SMQs and CMQs are provided in Appendix 16.1.13 (narrow scope terms are summarized in this report).

7.3.3.3.1 Hypersensitivity

A total of 614 participants (2.0%) reported at least one hypersensitivity event (336 participants [2.2%] in the mRNA-1273 group and 278 participants [1.8%] in the placebo group) (Table 14.3.1.22.2). Hypersensitivity events for which larger imbalances between the groups were observed were consistent with the known reactogenicity of the vaccine. Injection site urticaria was reported by 38 participants (0.3%) overall in the mRNA-1273 group vs. 1 participant (< 0.1%) in the placebo group; this imbalance was noted in the older age group but not in the younger age group. Injection site rash was reported by 25 participants [0.2%] overall in the mRNA-1273 group vs. 1 participant (< 0.1%) in the placebo group; this imbalance was noted the younger age group but not in the older age group; Table 14.3.1.22.2). No imbalance was apparent for events in the angioedema SMQ (82 vs. 71 participants [0.5% for each] in the mRNA-1273 and placebo groups, respectively [Table 14.3.1.22.4)].

7.3.3.3.2 Anaphylaxis

In the anaphylaxis SMQ, 9 events were reported for 5 participants in the mRNA-1273 group and 18 events were reported for 8 participants in the placebo group (Table 14.3.1.22.8). Anaphylactic reaction was reported in 2 participants in the placebo group on Days 11 and 10 after the first injection; one event was severe and one was grade 4 in severity; both were considered not related to IP and resolved on the same day with concomitant medications. Anaphylactic reaction of unknown cause was reported for 2 participants in the mRNA-1273 group as nonserious moderate events approximately 2 months after the second dose; both were considered not related to IP and

resolved on the same day with concomitant medications. Among the other terms in the SMQ, reported events in the mRNA-1273 group were all nonserious and described as follows: mild cough and mild eye pruritus for one participant on Day 47 after the second dose (not considered related); mild tachypnea on Day 29 after the first dose (which was reported on the day of the second dose), severe tachypnea on Day 1 after the second dose (which was the same day; event resolved on Day 64), and moderate urticaria beginning 30 minutes after the second dose and resolved in 1 hour with concomitant medication (all events considered related); and moderate dyspnea (considered related; reported as resolving) and severe swelling face (not considered related; resolving with prednisone) beginning on Day 34 after the second dose (Listing 16.2.7.28). Events in the placebo group were also nonserious and included hypotension and cough; dyspnea, hypotension, and edema; dyspnea and pruritus; hypotension and wheezing; urticaria and asthma; tachypnea (participant later had grade 4 serious anaphylactic reaction); and asthma.

7.3.3.3.3 Dermal Filler Reaction Post Vaccination

A total of 34 participants (0.1%) reported at least one TEAE in the dermal filler post-vaccination CMQ (20 participants [0.1%] in the mRNA-1273 group and 14 participants [< 0.1%] in the placebo group) and no imbalance was apparent for any individual PT (Table 14.3.1.22.11). The event was reported as an SAE for 2 participants in the mRNA-1273 group and 1 participant in the placebo group (Section 7.3.2). The event was considered related to treatment for 4 participants in the mRNA-1273 group and 3 participants in the placebo group. None of the participants who experienced this TEAE in this study had reported dermal filler reaction post vaccination in their medical history. History of dermal filler use was reported for 325 participants in the mRNA-1273 group and 234 participants in the placebo group.

7.3.3.3.4 Central Nervous System Vascular Disorders

A total of 32 participants (0.1%) experienced at least one TEAE in the CNS vascular disorders SMQ (21 participants [0.1%] in the mRNA-1273 group and 11 participants [< 0.1%] in the placebo group) (Table 14.3.1.22.10). The following events were reported for more participants in the mRNA-1273 group than in the placebo group: cerebrovascular accident (7 vs. 4), carotid artery stenosis (2 vs. 0), and embolic stroke (2 vs. 0). Further discussion of these types of events is provided in Section 7.3.2. No cases of thrombosis with thrombocytopenia syndrome were reported. For all events in the category, the difference between the mRNA-1273 and placebo groups was more pronounced among participants ≥ 65 years of age (11 vs. 4) than among participants ≥ 18 to < 65 years of age (10 vs. 7). The age distribution and the overall incidence in the mRNA-1273 group is consistent with general epidemiology of these types of vascular events, and the timing of the events is also not consistent with an attribution to mRNA-1273. Imbalances

were also noted for subarachnoid hemorrhage (4 vs. 0) and subdural hematoma (3 vs. 0), but these events were related to trauma (with precipitating events not considered related to mRNA-1273) and are thus not indicative of a vascular disorder (Section 7.3.2).

7.3.3.3.5 Hematopoietic Cytopenias

Thrombocytopenia was reported for 5 participants in the mRNA-1273 group and 1 participant in the placebo group (Table 14.3.1.22.15); these events were not associated with thrombosis and none were considered related to IP. One participant in each group had an SAE of grade 4 thrombocytopenia: the event occurred on Day 68 (approximately 40 days after the second dose) for the participant in the mRNA-1273 group [US3912024]. At the same time, the participant (who was 72 years old) had severe bacterial pyelonephritis, acute kidney failure (SAE), and nephrolithiasis (SAE). The event occurred on Day 131 for the participant in the placebo group [US3272026], who also had COVID-19 infection and cytokine storm and several other grade 4 SAEs. The nonserious thrombocytopenia TEAEs in the mRNA-1273 group were all mild and occurred on Days 25, 57, 60 (concurrent with moderate periorbital hematoma, mild periorbital hemorrhage, grade 4 serious alcohol withdrawal syndrome, and multiple other events [US3062265]), and 153. No imbalance was evident for the other terms included in the SMQ for hematopoietic cytopenias.

7.3.3.4 Vaccine-Associated Enhanced Respiratory Disease

The DSMB continuously monitored case counts of COVID-19 and severe COVID-19 based on prespecified criteria for any indication of higher disease incidence and/or severity in the mRNA-1273 group compared with the placebo group that might suggest a risk of vaccine harm in the form of vaccine-associated enhanced respiratory disease (VAERD) (Section 4.2.3.5). The prespecified criteria for enhanced disease have not been met at any time during the study. Fewer cases of severe COVID-19 (Table 6-4) or COVID-19 of any severity (Table 6-2) have been observed in participants who received mRNA-1273 than in those who received placebo. Instead of enhanced disease, participants who received mRNA-1273 and experienced COVID-19 had milder disease compared with those who received placebo (based on symptom scores during the 28 days after onset; Section 6.3.1).

7.3.4 Subgroup Analyses of Deaths, Other Serious Adverse Events, and Other Significant Unsolicited Adverse Events

7.3.4.1 Age Groups

The overall incidence of serious TEAEs in Part A was higher in older adults (≥ 65 years of age) compared to younger adults (18 to < 65 years of age) who received either mRNA-1273

(118/3769 [3.1%] vs.150/11415 [1.3%]) or placebo (124/3751 [3.3%] vs.168/11411 [1.5%]; Table 7-27). The overall incidence of serious treatment-related TEAEs in Part A were low and comparable at <0.1% for younger adults (18 to < 65 years of age) and older adults (≥ 65 years of age) who received either mRNA-1273 or placebo (Table 14.3.1.14.2.1).

Table 7-27: Participant Incidence of Serious Treatment-Emergent Adverse Events by Age Group, System Organ Class and Preferred Term in Part A (Safety Set)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Age Group: >=18 and <65 Years				
Number of subjects reporting unsolicited adverse events	168 (1.5)	150 (1.3)		318 (1.4)
Number of unsolicited adverse events	257	216		473
Infections and infestations	41 (0.4)	30 (0.3)		71 (0.3)
Pneumonia	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Sepsis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cellulitis	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Appendicitis perforated	0	1 (<0.1)		1 (<0.1)
Bronchitis	0	1 (<0.1)		1 (<0.1)
COVID-19	24 (0.2)	1 (<0.1)	0.04 (0.01, 0.24)	25 (0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Diverticulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastroenteritis viral	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Septic shock	2 (<0.1)	1 (<0.1)		3 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pyelonephritis	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (<0.1)	17 (0.1)		28 (0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Prostate cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal cell carcinoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	2 (<0.1)	0		2 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	4 (<0.1)	1 (<0.1)		5 (<0.1)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Thrombocytopenia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	2 (<0.1)	0		2 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	11 (<0.1)	8 (<0.1)		19 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hyponatraemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dehydration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Diabetes mellitus inadequate control	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	11 (<0.1)	12 (0.1)		23 (0.1)
Depression	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alcohol withdrawal syndrome	0	2 (<0.1)		2 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Anxiety disorder	1 (<0.1)	0		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Major depression	2 (<0.1)	0		2 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	19 (0.2)	18 (0.2)		37 (0.2)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Syncope	5 (<0.1)	3 (<0.1)		8 (<0.1)
Aphasia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Dizziness	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Arachnoid cyst	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	18 (0.2)	11 (<0.1)		29 (0.1)
Myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Atrial flutter	0	2 (<0.1)		2 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronary artery disease	0	2 (<0.1)		2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute myocardial infarction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atrial fibrillation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac failure acute	0	1 (<0.1)		1 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Angina pectoris	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)
Vascular disorders	11 (<0.1)	5 (<0.1)		16 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Hypertension	2 (<0.1)	0		2 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Hypotension	2 (<0.1)	0		2 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	21 (0.2)	15 (0.1)		36 (0.2)
Dyspnoea	0	5 (<0.1)		5 (<0.1)
Pulmonary embolism	5 (<0.1)	4 (<0.1)		9 (<0.1)
Acute respiratory failure	5 (<0.1)	3 (<0.1)		8 (<0.1)
Pleural effusion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	3 (<0.1)	0		3 (<0.1)
Epistaxis	1 (<0.1)	0		1 (<0.1)
Hypoxia	3 (<0.1)	0		3 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumothorax	2 (<0.1)	0		2 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	14 (0.1)	18 (0.2)		32 (0.1)
Colitis	4 (<0.1)	2 (<0.1)		6 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Hiatus hernia	0	2 (<0.1)		2 (<0.1)
Abdominal pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal pain upper	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diarrhoea	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Nausea	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vomiting	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abdominal hernia	1 (<0.1)	0		1 (<0.1)
Abdominal pain lower	2 (<0.1)	0		2 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Pancreatitis	2 (<0.1)	0		2 (<0.1)
Hepatobiliary disorders	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cholecystitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	0	3 (<0.1)		3 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	15 (0.1)	11 (<0.1)		26 (0.1)
Intervertebral disc protrusion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Osteoarthritis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Back pain	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vertebral foraminal stenosis	0	1 (<0.1)		1 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Flank pain	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Muscular weakness	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	2 (<0.1)	0		2 (<0.1)
Renal and urinary disorders	3 (<0.1)	5 (<0.1)		8 (<0.1)
Nephrolithiasis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Acute kidney injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abortion spontaneous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	4 (<0.1)	5 (<0.1)		9 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Pelvic pain	0	2 (<0.1)		2 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)		1 (<0.1)
Dysfunctional uterine bleeding	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Ovarian cyst	2 (<0.1)	0		2 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	7 (<0.1)	11 (<0.1)		18 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Chest pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Non-cardiac chest pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	18 (0.2)	13 (0.1)		31 (0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Concussion	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Head injury	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Superficial injury of eye	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Fall	3 (<0.1)	0		3 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Post procedural fever	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Rib fracture	1 (<0.1)	0		1 (<0.1)
Skin laceration	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Age Group: >=65 Years				
Number of subjects reporting unsolicited adverse events	124 (3.3)	118 (3.1)		242 (3.2)
Number of unsolicited adverse events	182	185		367
Infections and infestations	36 (1.0)	18 (0.5)		54 (0.7)
Pneumonia	3 (<0.1)	5 (0.1)		8 (0.1)
Appendicitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Bronchitis	0	1 (<0.1)		1 (<0.1)
COVID-19	16 (0.4)	1 (<0.1)	0.06 (0.01, 0.37)	17 (0.2)
Cellulitis	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Sepsis	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	4 (0.1)	1 (<0.1)		5 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	5 (0.1)	0		5 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Diverticulitis	2 (<0.1)	0		2 (<0.1)
Localised infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pyelonephritis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (0.3)	10 (0.3)		23 (0.3)
Prostate cancer	3 (<0.1)	4 (0.1)		7 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	2 (<0.1)	0		2 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thrombocytopenia	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	4 (0.1)	9 (0.2)		13 (0.2)
Dehydration	2 (<0.1)	3 (<0.1)		5 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)		1 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	0	1 (<0.1)		1 (<0.1)
Hyponatraemia	0	1 (<0.1)		1 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Type 2 diabetes mellitus	0	1 (<0.1)		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Mental status changes	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	8 (0.2)	13 (0.3)		21 (0.3)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Syncope	2 (<0.1)	2 (<0.1)		4 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)		1 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Dizziness	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	25 (0.7)	25 (0.7)		50 (0.7)
Atrial fibrillation	9 (0.2)	5 (0.1)	0.55 (0.19, 1.57)	14 (0.2)
Myocardial infarction	3 (<0.1)	3 (<0.1)		6 (<0.1)
Acute coronary syndrome	0	2 (<0.1)		2 (<0.1)
Acute myocardial infarction	4 (0.1)	2 (<0.1)		6 (<0.1)
Cardiac failure congestive	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardio-respiratory arrest	0	2 (<0.1)		2 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Coronary artery disease	3 (<0.1)	1 (<0.1)		4 (<0.1)
Coronary artery occlusion	0	1 (<0.1)		1 (<0.1)
Pericarditis	0	1 (<0.1)		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrial flutter	2 (<0.1)	0		2 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac failure acute	1 (<0.1)	0		1 (<0.1)
Vascular disorders	4 (0.1)	10 (0.3)		14 (0.2)
Deep vein thrombosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypertension	0	2 (<0.1)		2 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Hypotension	0	1 (<0.1)		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	14 (0.4)	10 (0.3)		24 (0.3)
Acute respiratory failure	5 (0.1)	4 (0.1)		9 (0.1)
Pulmonary embolism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Chronic obstructive pulmonary disease	5 (0.1)	1 (<0.1)		6 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	0	1 (<0.1)		1 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asthma	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Pleural effusion	1 (<0.1)	0		1 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders	11 (0.3)	18 (0.5)		29 (0.4)
Gastrointestinal haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Nausea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Small intestinal obstruction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal pain upper	0	1 (<0.1)		1 (<0.1)
Colitis	0	1 (<0.1)		1 (<0.1)
Diarrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Gastrooesophageal reflux disease	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Hiatus hernia	1 (<0.1)	0		1 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholecystitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	0		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	13 (0.3)	13 (0.3)		26 (0.3)
Osteoarthritis	10 (0.3)	5 (0.1)	0.50 (0.18, 1.39)	15 (0.2)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Back pain	0	1 (<0.1)		1 (<0.1)
Flank pain	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Muscular weakness	0	1 (<0.1)		1 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Spondylolisthesis	0	1 (<0.1)		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	8 (0.2)	5 (0.1)		13 (0.2)
Acute kidney injury	4 (0.1)	3 (<0.1)		7 (<0.1)
Nephrolithiasis	0	2 (<0.1)		2 (<0.1)
Chronic kidney disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	5 (0.1)	4 (0.1)		9 (0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Asthenia	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Pyrexia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	11 (0.3)	14 (0.4)		25 (0.3)
Hip fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Fall	2 (<0.1)	2 (<0.1)		4 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Humerus fracture	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Rib fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Road traffic accident	1 (<0.1)	1 (<0.1)		2 (<0.1)

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Pelvic fracture	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo; rate ratio is provided for TEAEs with at least 7 subjects in any vaccination group reporting the event. The 95% CI is calculated using the Miettinen and Nurminen method.

MedDRA version 23.0.

Source: Table 14.3.1.13.2.3.

7.3.4.2 Baseline SARS-CoV-2 Status

The overall incidence of serious treatment-related TEAEs in Part A were low and comparable at <0.1% for participants with a negative Baseline SARS-CoV-2 status who received either mRNA-1273 or placebo (Table 14.3.1.14.3.3). No serious TEAEs assessed as treatment-related were reported in participant with a positive Baseline SARS-CoV-2 status.

7.4 Clinical Laboratory Evaluation

Clinical laboratory assessments were not planned or performed.

7.5 Vital Signs and Other Observations Related to Safety

Mean vital sign measurements (diastolic blood pressure, pulse rate, respiratory rate, systolic blood pressure, and temperature) observed after dosing and through Day 209 were comparable to those observed at baseline, with no notable trends or differences across groups (Table 14.3.2.1).

The incidence of shifts from baseline to worst postbaseline for all vital sign measurements (diastolic blood pressure, pulse rate, respiratory rate, systolic blood pressure, and temperature) were comparable between the mRNA-1273 and placebo groups, with no notable trends or differences across groups (Table 14.3.2.2).

7.6 Pregnancies

As of the date of the data cutoff for this CSR, there were 9 participants (4 in the mRNA-1273 group and 5 in the placebo group) with positive results for urine pregnancy tests performed at the site during Part A (Listing 16.2.8).

According to the safety database, a total of 27 pregnancies were reported (16 in the mRNA-1273 group and 11 in the placebo group) during Part A of the study (Table 7-28). Of the outcomes known as of 04 May 2021, 1 participant in the placebo group experienced a live birth. The participant was induced at 37 weeks due to polyhydramnios and gestational diabetes and the child was noted as having congenital anomalies of bilateral talipes equinovarus and hydronephrosis. Five participants (2 in the mRNA-1273 group and 3 in the placebo group) experienced spontaneous abortion/miscarriage. These events were reported as SAEs for 4 of the participants (2 participants in each group) and were considered not related to IP; for 1 participant in the placebo group, the event was considered nonserious and causality was not reported. Two participants (1 in each group) underwent elective termination of pregnancy; there were no reported pregnancy complications for either participant.

Case narratives for the participants who experienced pregnancies are provided in Section 15.

Table 7-28: Incidence of Pregnancies Reported in Part A and Outcomes (Safety Set)

	Placebo	mRNA-1273	Total
Number of pregnancies	11	16	27
Known pregnancy outcomes	5	3	8
Live born	1[a, b]	0	1
Spontaneous abortion/miscarriage	3	2[c]	5
Elective termination	1	1	2[d]
Other maternal/gestational complications	1[a, b]	0	1
Lost to follow-up	2[e, f]	1[e]	3

[a] Baby was born at 37 weeks with congenital anomalies of bilateral talipes equinovarus and hydronephrosis.

[b] The mother of the baby with talipes equinovarus and hydronephrosis had polyhydramnios and gestational diabetes.

[c] The outcome of spontaneous abortion/miscarriage for 1 participant occurred after the Participant Decision Visit and is therefore reported as an serious adverse event in the Part B addendum to this Clinical Study Report.

[d] There were no reported pregnancy complications in either group.

[e] No response to follow up requests in 1 subject in each group with expected dates of delivery prior to data cut off of 04 May 2021.

[f] One subject was categorized as study lost to follow-up.

Source: Data in the table was generated from the safety database and case narratives for the participants who experienced pregnancies are provided in Section 15.

7.7 Safety Conclusions

In this final, randomized, blinded phase (Part A) analysis, the mRNA-1273 vaccine administered as 2 injections 28 days apart demonstrated an acceptable safety profile in the study population. This conclusion is supported by reactogenicity and key safety findings summarized here.

Solicited local and systemic adverse reactions were more frequent in mRNA-1273 than in placebo recipients, with most events considered grade 1 or 2 in severity, and most events in mRNA-1273 recipients occurring within 1 to 2 days and lasting a median of 1 to 3 days. The most common solicited local AR was pain, and the most commonly reported solicited systemic ARs were fatigue, headache, myalgia, and arthralgia. Older adults (≥ 65 years) had lower rates of solicited ARs than younger adults (< 65 years). Participants SARS-CoV-2 positive at baseline had rates of solicited ARs comparable to those among baseline negative participants. More mRNA-1273 recipients reported use of medication for pain or fever than placebo recipients, consistent with vaccine reactogenicity.

Unsolicited TEAEs in the 28 days after any injection occurred at similar rates in the mRNA-1273 and placebo groups. The higher rate of unsolicited TEAEs considered treatment related by the investigator among mRNA-1273 participants was largely driven by events that mapped to solicited ARs but occurred beyond the solicited AR collection period or were ARs similar to solicited ARs. In addition, TEAEs were assessed for: (i) imbalances between study groups, and

(ii) AEs of interest following COVID-19 vaccination or vaccinations in general. Imbalances were investigated based on the degree of imbalance and the biological plausibility and temporal occurrence relative to study treatment. An imbalance in the overall number of herpes zoster cases was noted, with more cases in the mRNA-1273 than in the placebo group; however, most cases in the mRNA-1273 group occurred more than 28 days after any dose and at an incidence expected in the general population. In contrast, most cases in the placebo group occurred within 28 days and at rates lower than expected of the general population. These findings are not supportive of relatedness to mRNA-1273.

Certain AEs are of theoretical interest for COVID-19 vaccines and were carefully assessed in the blinded study phase. As noted in Section 6, mRNA-1273 vaccine was highly efficacious in preventing COVID-19 and severe COVID-19, and this efficacy has been sustained, dispelling concerns of VAERD. No significant clinical findings were identified from the SMQ/CMQ searches performed for the analyses of AEs of clinical interest for COVID-19 vaccines. A search (SMQ) for CNS vascular disorders identified a categorical imbalance, with 21 participants in the mRNA-1273 and 11 participants in the placebo group experiencing events in this SMQ, but the apparent imbalance was largely due to inclusion of 5 participants with subarachnoid hemorrhage and subdural hematoma (3 and 2 participants, respectively in the mRNA-1273 group and none in placebo) in this category. These latter events were mostly related to trauma and not to study treatment. Other events of potential interest for COVID-19 vaccines are thrombotic and embolic events, for which no imbalance between groups was identified. Finally, assessments for TEAEs of myocarditis or pericarditis, or the symptoms suggestive of these diagnoses (including chest pain, dyspnea, and tachycardia) was performed. No events of myocarditis were identified. Pericarditis without concurrent myocarditis was reported as an SAE for 2 participants in each treatment group; the 2 events in the mRNA-1273 group occurred more than 28 days after second dose and in participants older than 55 years. Symptoms consistent with myocarditis or pericarditis were assessed, seeking patterns in grouping of symptoms or clustering in time, and only a single participant met a diagnosis of pericarditis. Assessment of events often associated with vaccination was performed, with a focus on hypersensitivity and anaphylaxis. Hypersensitivity events were more common among mRNA-1273 than placebo recipients; most of the imbalance derived from injection site urticaria and rashes. No anaphylaxis events were reported within 30 minutes after any injection.

In total, mRNA-1273 has a reactogenicity profile consistent with parenteral vaccination and generally well-tolerated. Similarly, the safety profile is acceptable. No unexpected findings were identified in this final assessment of the randomized, blinded phase of the study.

8 IMMUNOGENICITY RESULTS

Immunogenicity results are provided in Section 6.5.1.

9 PHARMACOKINETIC RESULTS

Not applicable.

10 PHARMACODYNAMIC RESULTS

Not applicable.

11 BIOMARKER ANALYSIS RESULTS

Not applicable.

12 STUDY CONCLUSIONS

This study was designed to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but whose occupation or location and living circumstances put them at increased risk of acquiring COVID-19 and/or SARS-CoV-2 infection.

- The final efficacy analysis of the primary endpoint for Part A (04 May 2021) included 799 cases. The results of this analysis were consistent with the results of the interim and primary efficacy analysis, confirming persistent, high efficacy over a substantially larger case database and over a longer median observation period of over 5.3 months. For the final efficacy analysis, the VE point estimate was 93.2% ($p < 0.0001$) and within the 95% CIs of the VE point estimates for the interim and primary efficacy analyses.
    - Divergence of case incidence began early between mRNA-1273 and placebo groups, starting in the period from randomization up to 14 days after the first injection. Thereafter, cumulative incidence rate for the placebo group increased steadily while it remained stable and low in the mRNA-1273 group for the remainder of the observation period.
    - Vaccine efficacy was consistent across subgroups for the primary efficacy endpoint.
    - Vaccine efficacy was also consistent across the secondary endpoints characterized by high VE point estimates and tight 95% CIs, with the lower bounds of the 95% CIs well above 30%.
- mRNA-1273 was highly immunogenic as measured by both bAb and nAb in both SARS-CoV-2 baseline-negative and baseline-positive individuals, as indicated by increased bAb and nAb levels 1 month after first injection (Day 29) and 1 month after second injection (Day 57).
- mRNA-1273 demonstrated an acceptable safety profile in the participant population enrolled in this study. mRNA-1273 has a reactogenicity profile consistent with parenteral vaccination and generally well tolerated. No unexpected findings were identified in this final assessment of the randomized, blinded phase of the study.

This report is based on the data from the randomized, placebo controlled, blinded phase (Part A) of the study. Data from Part B, in which eligible participants were offered open-label mRNA-1273, will be included in a CSR addendum.

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Number	Title
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Number	Title
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Number	Title
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Number	Title
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Number	Title
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Table 14.2.2.6.2.1.2.2	Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting 14 Days After Second Injection Including Participant Decision Visit Using Competing Risk Method - mITT Set
Table 14.2.2.6.2.5.1.2	Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting After Randomization Including Participant Decision Visit Using Competing Risk Method - Per-Protocol Set
Table 14.2.2.6.2.5.2.2	Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting After Randomization Including Participant Decision Visit Using Competing Risk Method - mITT Set
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Number	Title
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Number	Title
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Number	Title
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14.3 Immunogenicity Data

Number	Title
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Number	Title
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Figure 14.2.4.2.3.4.1	Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group - Per-Protocol Random Subcohort for Immunogenicity

Number	Title
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Number	Title
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14.4 Safety Data

14.4.1 Displays of Adverse Events

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Number	Title
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Number	Title
Table 14.3.1.1.4.1	Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade First Injection Solicited Safety Set
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Table 14.3.1.1.6.1.1	Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade - First Injection Solicited Safety Set
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Number	Title
Table 14.3.1.3.1.1	Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day - First Injection Solicited Safety Set
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Table 14.3.1.3.1.2	Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day - Second Injection Solicited Safety Set
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Table 14.3.1.3.5.2	Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day - Second Injection Solicited Safety Set
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Table 14.3.1.3.2.1	Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day - First Injection Solicited Safety Set
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Table 14.3.1.3.3.3	Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day - Solicited Safety Set

Number	Title
Table 14.3.1.4.1.1	Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection - First Injection Solicited Safety Set
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Number	Title
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Table 14.3.1.6.2.3	Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade - Solicited Safety Set
Table 14.3.1.6.3.1	Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade - First Injection Solicited Safety Set
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Number	Title
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Table 14.3.1.7.6.3.1	Summary of Unsolicited TEAE by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection - Safety Set
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Table 14.3.1.8.4.1	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.5.1	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.6.1.1	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.6.2.1	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.6.3.1	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.2.2.1	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.1.3	Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.8.2.1.1	Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.2.1.3	Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.8.3.1	Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.8.3.3	Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.8.13.1	Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set

Number	Title
Table 14.3.1.8.13.2	Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.10.1.1	Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection - Safety Set
Table 14.3.1.10.1.3	Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage - Safety Set
Table 14.3.1.11.1.1	Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.11.1.2	Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.11.1.3	Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set

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

Number	Title
Table 14.3.1.13.1.1	Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.13.1.3	Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.13.2.1	Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.13.2.3	Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.13.3.1	Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.13.3.3	Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage - Safety Set

Number	Title
Table 14.3.1.13.4.1	Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.14.1.1	Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.14.1.3	Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.14.2.1	Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.14.2.3	Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.14.3.1	Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.14.3.3	Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.14.5.1	Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.15.1	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term - Safety Set
Table 14.3.1.15.2	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term - Safety Set
Table 14.3.1.15.3	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term - Safety Set
Table 14.3.1.16.1.1	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set

Number	Title
Table 14.3.1.16.1.3	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.16.2.1	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.16.2.3	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.16.3.1	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.16.3.3	Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.17.1.1	Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.17.1.2	Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.17.1.3	Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.18.1.1	Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.18.1.2	Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.18.1.3	Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.19.1.1	Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set

Number	Title
Table 14.3.1.19.1.3	Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.19.2.1	Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.19.2.3	Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.19.3.1	Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.19.3.3	Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.19.4.1	Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection - Safety Set
Table 14.3.1.19.4.2	Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage - Safety Set
Table 14.3.1.19.5.1	Summary of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of 1st Vaccination - Safety Set (Dose 1)
Table 14.3.1.19.5.2	Summary of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of 2nd Vaccination - Safety Set (Dose 2)
Table 14.3.1.19.5.3	Summary of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination - Safety Set
Table 14.3.1.19.6.1	Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of First Vaccination by Preferred Term - Safety Set (Dose 1)
Table 14.3.1.19.6.2	Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Second Vaccination by Preferred Term - Safety Set (Dose 2)
Table 14.3.1.19.6.3	Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term - Safety Set

Number	Title
Table 14.3.1.21.1.3.1	Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After First Injection - Safety Set (Dose 1)
Table 14.3.1.21.1.3.2	Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After Second Injection - Safety Set (Dose 2)
Table 14.3.1.21.1.3.3	Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After Any Injection - Safety Set
Table 14.3.1.21.1.4	Summary of Subjects with Local Adverse Reactions that Occurs at Day 8 or beyond of each Injection - Solicited Safety Set
Table 14.3.1.22.1	Subject Incidence of Vasculitis [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.2	Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.3	Subject Incidence of Arthritis [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.4	Subject Incidence of Angioedema [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.5	Subject Incidence of Peripheral Neuropathy [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.6	Subject Incidence of Demyelinating Disease of Central Nervous System [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.7	Subject Incidence of Convulsions [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.8	Subject Incidence of Anaphylaxis [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.9	Subject Incidence of Autoimmune Disorder by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.10	Subject Incidence of Central Nervous System Vascular Disorders [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.11	Subject Incidence of Dermal Filler Reaction Post Vaccination by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.12	Subject Incidence of Embolic and Thrombotic Events [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.13	Subject Incidence of Hearing and Vestibular Disorders [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.14	Subject Incidence of Thrombophlebitis [1] by Preferred Term by Age Group - Safety Set

Number	Title
Table 14.3.1.22.15	Subject Incidence of Haematopoietic Cytopenias [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.22.16	Subject Incidence of Cardiomyopathy [1] by Preferred Term by Age Group - Safety Set
Table 14.3.1.23.1	Summary of Death - Safety Set

14.4.3 Displays of Laboratory Values

Not Applicable

14.4.4 Data Listings (Each Participant) for Abnormal Clinically Meaningful Laboratory Values, Vital Signs, Physical Examinations, and Other Observations Related to Safety

Number	Title
Table 14.3.2.1	Summary of Vital Signs and Change from Baseline by Visit - Safety Set
Table 14.3.2.2	Shift from Baseline in Vital Signs Toxicity Grades by Visit - Safety Set

14.4.5 Additional Safety Data

Not Applicable

Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Number of Subjects									
Received First Injection	14745 (100)	14746 (100)	29491 (100)	337 (100)	347 (100)	684 (100)	15166 (99.7)	15180 (99.8)	30346 (99.8)
Received Second Injection	14320 (97.1)	14412 (97.7)	28732 (97.4)	236 (70.0)	234 (67.4)	470 (68.7)	14635 (96.2)	14727 (96.8)	29362 (96.5)
Discontinued Study Vaccine	425 (2.9)	334 (2.3)	759 (2.6)	101 (30.0)	113 (32.6)	214 (31.3)	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine									
Adverse Event	42 (0.3)	44 (0.3)	86 (0.3)	2 (0.6)	2 (0.6)	4 (0.6)	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	16 (0.1)	11 (<0.1)	27 (<0.1)	2 (0.6)	1 (0.3)	3 (0.4)	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	0	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	69 (0.5)	62 (0.4)	131 (0.4)	4 (1.2)	11 (3.2)	15 (2.2)	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	18 (0.1)	21 (0.1)	39 (0.1)	0	0	0	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	2 (<0.1)	6 (<0.1)	0	1 (0.3)	1 (0.1)	4 (<0.1)	3 (<0.1)	7 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	35 (0.2)	33 (0.2)	68 (0.2)	0	3 (0.9)	3 (0.4)	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	102 (0.7)	73 (0.5)	175 (0.6)	6 (1.8)	4 (1.2)	10 (1.5)	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	47 (0.3)	11 (<0.1)	58 (0.2)	72 (21.4)	70 (20.2)	142 (20.8)	119 (0.8)	81 (0.5)	200 (0.7)
Other	86 (0.6)	73 (0.5)	159 (0.5)	15 (4.5)	21 (6.1)	36 (5.3)	104 (0.7)	94 (0.6)	198 (0.7)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	2009 (13.6)	654 (4.4)	2663 (9.0)	43 (12.8)	39 (11.2)	82 (12.0)	2099 (13.8)	730 (4.8)	2829 (9.3)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study									
Adverse Event	5 (<0.1)	4 (<0.1)	9 (<0.1)	0	0	0	5 (<0.1)	5 (<0.1)	10 (<0.1)
Serious Adverse Event	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	0	0	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	18 (0.1)	24 (0.2)	42 (0.1)	0	0	0	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	189 (1.3)	147 (1.0)	336 (1.1)	9 (2.7)	20 (5.8)	29 (4.2)	201 (1.3)	171 (1.1)	372 (1.2)
Physician Decision	13 (<0.1)	16 (0.1)	29 (<0.1)	0	0	0	17 (0.1)	18 (0.1)	35 (0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	650 (4.4)	147 (1.0)	797 (2.7)	12 (3.6)	3 (0.9)	15 (2.2)	664 (4.4)	152 (1.0)	816 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	410 (2.8)	249 (1.7)	659 (2.2)	15 (4.5)	14 (4.0)	29 (4.2)	448 (2.9)	279 (1.8)	727 (2.4)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.1
Subject Disposition by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	719 (4.9)	61 (0.4)	780 (2.6)	7 (2.1)	2 (0.6)	9 (1.3)	740 (4.9)	75 (0.5)	815 (2.7)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Number of Subjects									
Received First Injection	11413 (99.7)	11413 (99.8)	22826 (99.8)	3753 (99.7)	3767 (>99.9)	7520 (99.8)	15166 (99.7)	15180 (99.8)	30346 (99.8)
Received Second Injection	10966 (95.8)	11025 (96.4)	21991 (96.1)	3669 (97.5)	3702 (98.2)	7371 (97.8)	14635 (96.2)	14727 (96.8)	29362 (96.5)
Discontinued Study Vaccine	447 (3.9)	388 (3.4)	835 (3.6)	84 (2.2)	65 (1.7)	149 (2.0)	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine									
Adverse Event	31 (0.3)	35 (0.3)	66 (0.3)	13 (0.3)	12 (0.3)	25 (0.3)	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	8 (<0.1)	10 (<0.1)	18 (<0.1)	10 (0.3)	2 (<0.1)	12 (0.2)	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	72 (0.6)	72 (0.6)	144 (0.6)	1 (<0.1)	4 (0.1)	5 (<0.1)	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	14 (0.1)	18 (0.2)	32 (0.1)	4 (0.1)	3 (<0.1)	7 (<0.1)	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	4 (<0.1)	3 (<0.1)	7 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	30 (0.3)	26 (0.2)	56 (0.2)	7 (0.2)	11 (0.3)	18 (0.2)	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	86 (0.8)	63 (0.6)	149 (0.7)	22 (0.6)	15 (0.4)	37 (0.5)	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	107 (0.9)	74 (0.6)	181 (0.8)	12 (0.3)	7 (0.2)	19 (0.3)	119 (0.8)	81 (0.5)	200 (0.7)
Other	91 (0.8)	84 (0.7)	175 (0.8)	13 (0.3)	10 (0.3)	23 (0.3)	104 (0.7)	94 (0.6)	198 (0.7)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	1766 (15.4)	613 (5.4)	2379 (10.4)	333 (8.8)	117 (3.1)	450 (6.0)	2099 (13.8)	730 (4.8)	2829 (9.3)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study									
Adverse Event	4 (<0.1)	4 (<0.1)	8 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	5 (<0.1)	10 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	12 (0.1)	12 (0.1)	24 (0.1)	7 (0.2)	12 (0.3)	19 (0.3)	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	192 (1.7)	165 (1.4)	357 (1.6)	9 (0.2)	6 (0.2)	15 (0.2)	201 (1.3)	171 (1.1)	372 (1.2)
Physician Decision	13 (0.1)	16 (0.1)	29 (0.1)	4 (0.1)	2 (<0.1)	6 (<0.1)	17 (0.1)	18 (0.1)	35 (0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	539 (4.7)	116 (1.0)	655 (2.9)	125 (3.3)	36 (1.0)	161 (2.1)	664 (4.4)	152 (1.0)	816 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	368 (3.2)	234 (2.0)	602 (2.6)	80 (2.1)	45 (1.2)	125 (1.7)	448 (2.9)	279 (1.8)	727 (2.4)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2
Subject Disposition by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	636 (5.6)	61 (0.5)	697 (3.0)	104 (2.8)	14 (0.4)	118 (1.6)	740 (4.9)	75 (0.5)	815 (2.7)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2.2
Subject Disposition by Age Group in Blinded Phase
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Number of Subjects									
Received First Injection	11413 (99.7)	11413 (99.8)	22826 (99.8)	3753 (99.7)	3767 (>99.9)	7520 (99.8)	15166 (99.7)	15180 (99.8)	30346 (99.8)
Received Second Injection	10966 (95.8)	11025 (96.4)	21991 (96.1)	3669 (97.5)	3702 (98.2)	7371 (97.8)	14635 (96.2)	14727 (96.8)	29362 (96.5)
Discontinued Study Vaccine	447 (3.9)	388 (3.4)	835 (3.6)	84 (2.2)	65 (1.7)	149 (2.0)	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine									
Adverse Event	31 (0.3)	35 (0.3)	66 (0.3)	13 (0.3)	12 (0.3)	25 (0.3)	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	8 (<0.1)	10 (<0.1)	18 (<0.1)	10 (0.3)	2 (<0.1)	12 (0.2)	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	72 (0.6)	72 (0.6)	144 (0.6)	1 (<0.1)	4 (0.1)	5 (<0.1)	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	14 (0.1)	18 (0.2)	32 (0.1)	4 (0.1)	3 (<0.1)	7 (<0.1)	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	4 (<0.1)	3 (<0.1)	7 (<0.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2.2
Subject Disposition by Age Group in Blinded Phase
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	30 (0.3)	26 (0.2)	56 (0.2)	7 (0.2)	11 (0.3)	18 (0.2)	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	86 (0.8)	63 (0.6)	149 (0.7)	22 (0.6)	15 (0.4)	37 (0.5)	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	107 (0.9)	74 (0.6)	181 (0.8)	12 (0.3)	7 (0.2)	19 (0.3)	119 (0.8)	81 (0.5)	200 (0.7)
Other	91 (0.8)	84 (0.7)	175 (0.8)	13 (0.3)	10 (0.3)	23 (0.3)	104 (0.7)	94 (0.6)	198 (0.7)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	591 (5.2)	392 (3.4)	983 (4.3)	100 (2.7)	48 (1.3)	148 (2.0)	691 (4.5)	440 (2.9)	1131 (3.7)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2.2
Subject Disposition by Age Group in Blinded Phase
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study									
Adverse Event	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	5 (<0.1)	8 (<0.1)
Death	10 (<0.1)	8 (<0.1)	18 (<0.1)	5 (0.1)	8 (0.2)	13 (0.2)	15 (<0.1)	16 (0.1)	31 (0.1)
Lost to Follow-Up	183 (1.6)	154 (1.3)	337 (1.5)	8 (0.2)	6 (0.2)	14 (0.2)	191 (1.3)	160 (1.1)	351 (1.2)
Physician Decision	4 (<0.1)	12 (0.1)	16 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	7 (<0.1)	13 (<0.1)	20 (<0.1)
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol Deviation	133 (1.2)	38 (0.3)	171 (0.7)	27 (0.7)	8 (0.2)	35 (0.5)	160 (1.1)	46 (0.3)	206 (0.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	207 (1.8)	136 (1.2)	343 (1.5)	43 (1.1)	19 (0.5)	62 (0.8)	250 (1.6)	155 (1.0)	405 (1.3)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.2.2
Subject Disposition by Age Group in Blinded Phase
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11443) n (%)	mRNA-1273 (N=11439) n (%)	Total (N=22882) n (%)	Placebo (N=3763) n (%)	mRNA-1273 (N=3770) n (%)	Total (N=7533) n (%)	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	49 (0.4)	37 (0.3)	86 (0.4)	11 (0.3)	4 (0.1)	15 (0.2)	60 (0.4)	41 (0.3)	101 (0.3)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Number of Subjects			
Received First Injection	15166 (99.7)	15180 (99.8)	30346 (99.8)
Received Second Injection	14635 (96.2)	14727 (96.8)	29362 (96.5)
Discontinued Study Vaccine	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine			
Adverse Event	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)
Protocol Deviation	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	119 (0.8)	81 (0.5)	200 (0.7)
Other	104 (0.7)	94 (0.6)	198 (0.7)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	2099 (13.8)	730 (4.8)	2829 (9.3)
Reason for Discontinuation of Study			
Adverse Event	5 (<0.1)	5 (<0.1)	10 (<0.1)
Serious Adverse Event	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	201 (1.3)	171 (1.1)	372 (1.2)
Physician Decision	17 (0.1)	18 (0.1)	35 (0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	664 (4.4)	152 (1.0)	816 (2.7)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	448 (2.9)	279 (1.8)	727 (2.4)
Due to SARS-CoV-2	0	0	0
Other	740 (4.9)	75 (0.5)	815 (2.7)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8905) n (%)	mRNA-1273 (N=8909) n (%)	Total (N=17814) n (%)
Number of Subjects			
Received First Injection	8882 (99.7)	8888 (99.8)	17770 (99.8)
Received Second Injection	8535 (95.8)	8562 (96.1)	17097 (96.0)
Discontinued Study Vaccine	347 (3.9)	326 (3.7)	673 (3.8)
Reason for Discontinuation of Study Vaccine			
Adverse Event	25 (0.3)	29 (0.3)	54 (0.3)
Serious Adverse Event	5 (<0.1)	5 (<0.1)	10 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lost to Follow-Up	63 (0.7)	63 (0.7)	126 (0.7)
Physician Decision	8 (<0.1)	15 (0.2)	23 (0.1)
Pregnancy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Protocol Deviation	25 (0.3)	24 (0.3)	49 (0.3)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	62 (0.7)	54 (0.6)	116 (0.7)
Due to SARS-CoV-2	81 (0.9)	61 (0.7)	142 (0.8)
Other	73 (0.8)	69 (0.8)	142 (0.8)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8905) n (%)	mRNA-1273 (N=8909) n (%)	Total (N=17814) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	1478 (16.6)	484 (5.4)	1962 (11.0)
Reason for Discontinuation of Study			
Adverse Event	3 (<0.1)	4 (<0.1)	7 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)
Death	6 (<0.1)	5 (<0.1)	11 (<0.1)
Lost to Follow-Up	171 (1.9)	142 (1.6)	313 (1.8)
Physician Decision	11 (0.1)	12 (0.1)	23 (0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	443 (5.0)	94 (1.1)	537 (3.0)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	294 (3.3)	179 (2.0)	473 (2.7)
Due to SARS-CoV-2	0	0	0
Other	548 (6.2)	43 (0.5)	591 (3.3)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2542) n (%)	mRNA-1273 (N=2535) n (%)	Total (N=5077) n (%)
Number of Subjects			
Received First Injection	2535 (99.7)	2530 (99.8)	5065 (99.8)
Received Second Injection	2435 (95.8)	2468 (97.4)	4903 (96.6)
Discontinued Study Vaccine	100 (3.9)	62 (2.4)	162 (3.2)
Reason for Discontinuation of Study Vaccine			
Adverse Event	6 (0.2)	6 (0.2)	12 (0.2)
Serious Adverse Event	3 (0.1)	5 (0.2)	8 (0.2)
Death	0	0	0
Lost to Follow-Up	9 (0.4)	9 (0.4)	18 (0.4)
Physician Decision	6 (0.2)	3 (0.1)	9 (0.2)
Pregnancy	2 (<0.1)	0	2 (<0.1)
Protocol Deviation	5 (0.2)	2 (<0.1)	7 (0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	24 (0.9)	9 (0.4)	33 (0.6)
Due to SARS-CoV-2	26 (1.0)	13 (0.5)	39 (0.8)
Other	18 (0.7)	15 (0.6)	33 (0.6)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2542) n (%)	mRNA-1273 (N=2535) n (%)	Total (N=5077) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	288 (11.3)	129 (5.1)	417 (8.2)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	0	1 (<0.1)
Serious Adverse Event	0	0	0
Death	6 (0.2)	7 (0.3)	13 (0.3)
Lost to Follow-Up	21 (0.8)	23 (0.9)	44 (0.9)
Physician Decision	2 (<0.1)	4 (0.2)	6 (0.1)
Pregnancy	0	0	0
Protocol Deviation	96 (3.8)	22 (0.9)	118 (2.3)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	74 (2.9)	55 (2.2)	129 (2.5)
Due to SARS-CoV-2	0	0	0
Other	88 (3.5)	18 (0.7)	106 (2.1)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

	Placebo (N=3759) n (%)	mRNA-1273 (N=3765) n (%)	Total (N=7524) n (%)
Number of Subjects			
Received First Injection	3749 (99.7)	3762 (>99.9)	7511 (99.8)
Received Second Injection	3665 (97.5)	3697 (98.2)	7362 (97.8)
Discontinued Study Vaccine	84 (2.2)	65 (1.7)	149 (2.0)
Reason for Discontinuation of Study Vaccine			
Adverse Event	13 (0.3)	12 (0.3)	25 (0.3)
Serious Adverse Event	10 (0.3)	2 (<0.1)	12 (0.2)
Death	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lost to Follow-Up	1 (<0.1)	4 (0.1)	5 (<0.1)
Physician Decision	4 (0.1)	3 (<0.1)	7 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	7 (0.2)	11 (0.3)	18 (0.2)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	22 (0.6)	15 (0.4)	37 (0.5)
Due to SARS-CoV-2	12 (0.3)	7 (0.2)	19 (0.3)
Other	13 (0.3)	10 (0.3)	23 (0.3)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.1.3
Subject Disposition by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

	Placebo (N=3759) n (%)	mRNA-1273 (N=3765) n (%)	Total (N=7524) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	333 (8.9)	117 (3.1)	450 (6.0)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	1 (<0.1)	2 (<0.1)
Serious Adverse Event	3 (<0.1)	1 (<0.1)	4 (<0.1)
Death	7 (0.2)	12 (0.3)	19 (0.3)
Lost to Follow-Up	9 (0.2)	6 (0.2)	15 (0.2)
Physician Decision	4 (0.1)	2 (<0.1)	6 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	125 (3.3)	36 (1.0)	161 (2.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	80 (2.1)	45 (1.2)	125 (1.7)
Due to SARS-CoV-2	0	0	0
Other	104 (2.8)	14 (0.4)	118 (1.6)

Percentages are based on the number of randomized subjects.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.1
Subject Disposition by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Number of Subjects									
Received First Injection	14745 (100)	14746 (100)	29491 (100)	337 (100)	347 (100)	684 (100)	15166 (100)	15180 (100)	30346 (100)
Received Second Injection	14320 (97.1)	14412 (97.7)	28732 (97.4)	236 (70.0)	234 (67.4)	470 (68.7)	14635 (96.5)	14727 (97.0)	29362 (96.8)
Discontinued Study Vaccine	425 (2.9)	334 (2.3)	759 (2.6)	101 (30.0)	113 (32.6)	214 (31.3)	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine									
Adverse Event	42 (0.3)	44 (0.3)	86 (0.3)	2 (0.6)	2 (0.6)	4 (0.6)	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	16 (0.1)	11 (<0.1)	27 (<0.1)	2 (0.6)	1 (0.3)	3 (0.4)	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)	0	0	0	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	69 (0.5)	62 (0.4)	131 (0.4)	4 (1.2)	11 (3.2)	15 (2.2)	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	18 (0.1)	21 (0.1)	39 (0.1)	0	0	0	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	2 (<0.1)	6 (<0.1)	0	1 (0.3)	1 (0.1)	4 (<0.1)	3 (<0.1)	7 (<0.1)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.1
Subject Disposition by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	35 (0.2)	33 (0.2)	68 (0.2)	0	3 (0.9)	3 (0.4)	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	102 (0.7)	73 (0.5)	175 (0.6)	6 (1.8)	4 (1.2)	10 (1.5)	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	47 (0.3)	11 (<0.1)	58 (0.2)	72 (21.4)	70 (20.2)	142 (20.8)	119 (0.8)	81 (0.5)	200 (0.7)
Other	86 (0.6)	73 (0.5)	159 (0.5)	15 (4.5)	21 (6.1)	36 (5.3)	104 (0.7)	94 (0.6)	198 (0.7)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	2009 (13.6)	654 (4.4)	2663 (9.0)	43 (12.8)	39 (11.2)	82 (12.0)	2059 (13.6)	701 (4.6)	2760 (9.1)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.1
Subject Disposition by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study									
Adverse Event	5 (<0.1)	4 (<0.1)	9 (<0.1)	0	0	0	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious Adverse Event	4 (<0.1)	5 (<0.1)	9 (<0.1)	0	0	0	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	18 (0.1)	24 (0.2)	42 (0.1)	0	0	0	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	189 (1.3)	147 (1.0)	336 (1.1)	9 (2.7)	20 (5.8)	29 (4.2)	199 (1.3)	171 (1.1)	370 (1.2)
Physician Decision	13 (<0.1)	16 (0.1)	29 (<0.1)	0	0	0	13 (<0.1)	16 (0.1)	29 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	650 (4.4)	147 (1.0)	797 (2.7)	12 (3.6)	3 (0.9)	15 (2.2)	664 (4.4)	151 (1.0)	815 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	410 (2.8)	249 (1.7)	659 (2.2)	15 (4.5)	14 (4.0)	29 (4.2)	426 (2.8)	266 (1.8)	692 (2.3)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.1
Subject Disposition by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	719 (4.9)	61 (0.4)	780 (2.6)	7 (2.1)	2 (0.6)	9 (1.3)	728 (4.8)	63 (0.4)	791 (2.6)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22826) n (%)	Placebo (N=3753) n (%)	mRNA-1273 (N=3767) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Number of Subjects									
Received First Injection	11413 (100)	11413 (100)	22826 (100)	3753 (100)	3767 (100)	7520 (100)	15166 (100)	15180 (100)	30346 (100)
Received Second Injection	10966 (96.1)	11025 (96.6)	21991 (96.3)	3669 (97.8)	3702 (98.3)	7371 (98.0)	14635 (96.5)	14727 (97.0)	29362 (96.8)
Discontinued Study Vaccine	447 (3.9)	388 (3.4)	835 (3.7)	84 (2.2)	65 (1.7)	149 (2.0)	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine									
Adverse Event	31 (0.3)	35 (0.3)	66 (0.3)	13 (0.3)	12 (0.3)	25 (0.3)	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	8 (<0.1)	10 (<0.1)	18 (<0.1)	10 (0.3)	2 (<0.1)	12 (0.2)	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	72 (0.6)	72 (0.6)	144 (0.6)	1 (<0.1)	4 (0.1)	5 (<0.1)	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	14 (0.1)	18 (0.2)	32 (0.1)	4 (0.1)	3 (<0.1)	7 (<0.1)	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	4 (<0.1)	3 (<0.1)	7 (<0.1)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22826) n (%)	Placebo (N=3753) n (%)	mRNA-1273 (N=3767) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	30 (0.3)	26 (0.2)	56 (0.2)	7 (0.2)	11 (0.3)	18 (0.2)	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	86 (0.8)	63 (0.6)	149 (0.7)	22 (0.6)	15 (0.4)	37 (0.5)	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	107 (0.9)	74 (0.6)	181 (0.8)	12 (0.3)	7 (0.2)	19 (0.3)	119 (0.8)	81 (0.5)	200 (0.7)
Other	91 (0.8)	84 (0.7)	175 (0.8)	13 (0.3)	10 (0.3)	23 (0.3)	104 (0.7)	94 (0.6)	198 (0.7)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	1736 (15.2)	587 (5.1)	2323 (10.2)	323 (8.6)	114 (3.0)	437 (5.8)	2059 (13.6)	701 (4.6)	2760 (9.1)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22826) n (%)	Placebo (N=3753) n (%)	mRNA-1273 (N=3767) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study									
Adverse Event	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	12 (0.1)	12 (0.1)	24 (0.1)	7 (0.2)	12 (0.3)	19 (0.3)	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	190 (1.7)	165 (1.4)	355 (1.6)	9 (0.2)	6 (0.2)	15 (0.2)	199 (1.3)	171 (1.1)	370 (1.2)
Physician Decision	11 (<0.1)	14 (0.1)	25 (0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)	13 (<0.1)	16 (0.1)	29 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	539 (4.7)	115 (1.0)	654 (2.9)	125 (3.3)	36 (1.0)	161 (2.1)	664 (4.4)	151 (1.0)	815 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	350 (3.1)	222 (1.9)	572 (2.5)	76 (2.0)	44 (1.2)	120 (1.6)	426 (2.8)	266 (1.8)	692 (2.3)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.2
Subject Disposition by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22826) n (%)	Placebo (N=3753) n (%)	mRNA-1273 (N=3767) n (%)	Total (N=7520) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	628 (5.5)	51 (0.4)	679 (3.0)	100 (2.7)	12 (0.3)	112 (1.5)	728 (4.8)	63 (0.4)	791 (2.6)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Number of Subjects			
Received First Injection	15166 (100)	15180 (100)	30346 (100)
Received Second Injection	14635 (96.5)	14727 (97.0)	29362 (96.8)
Discontinued Study Vaccine	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine			
Adverse Event	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)
Protocol Deviation	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	119 (0.8)	81 (0.5)	200 (0.7)
Other	104 (0.7)	94 (0.6)	198 (0.7)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	2059 (13.6)	701 (4.6)	2760 (9.1)
Reason for Discontinuation of Study			
Adverse Event	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious Adverse Event	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	199 (1.3)	171 (1.1)	370 (1.2)
Physician Decision	13 (<0.1)	16 (0.1)	29 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	664 (4.4)	151 (1.0)	815 (2.7)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	426 (2.8)	266 (1.8)	692 (2.3)
Due to SARS-CoV-2	0	0	0
Other	728 (4.8)	63 (0.4)	791 (2.6)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882) n (%)	mRNA-1273 (N=8888) n (%)	Total (N=17770) n (%)
Number of Subjects			
Received First Injection	8882 (100)	8888 (100)	17770 (100)
Received Second Injection	8535 (96.1)	8562 (96.3)	17097 (96.2)
Discontinued Study Vaccine	347 (3.9)	326 (3.7)	673 (3.8)
Reason for Discontinuation of Study Vaccine			
Adverse Event	25 (0.3)	29 (0.3)	54 (0.3)
Serious Adverse Event	5 (<0.1)	5 (<0.1)	10 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lost to Follow-Up	63 (0.7)	63 (0.7)	126 (0.7)
Physician Decision	8 (<0.1)	15 (0.2)	23 (0.1)
Pregnancy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Protocol Deviation	25 (0.3)	24 (0.3)	49 (0.3)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	62 (0.7)	54 (0.6)	116 (0.7)
Due to SARS-CoV-2	81 (0.9)	61 (0.7)	142 (0.8)
Other	73 (0.8)	69 (0.8)	142 (0.8)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882) n (%)	mRNA-1273 (N=8888) n (%)	Total (N=17770) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	1455 (16.4)	463 (5.2)	1918 (10.8)
Reason for Discontinuation of Study			
Adverse Event	3 (<0.1)	3 (<0.1)	6 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)
Death	6 (<0.1)	5 (<0.1)	11 (<0.1)
Lost to Follow-Up	170 (1.9)	142 (1.6)	312 (1.8)
Physician Decision	9 (0.1)	10 (0.1)	19 (0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	443 (5.0)	94 (1.1)	537 (3.0)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	279 (3.1)	169 (1.9)	448 (2.5)
Due to SARS-CoV-2	0	0	0
Other	543 (6.1)	35 (0.4)	578 (3.3)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535) n (%)	mRNA-1273 (N=2530) n (%)	Total (N=5065) n (%)
Number of Subjects			
Received First Injection	2535 (100)	2530 (100)	5065 (100)
Received Second Injection	2435 (96.1)	2468 (97.5)	4903 (96.8)
Discontinued Study Vaccine	100 (3.9)	62 (2.5)	162 (3.2)
Reason for Discontinuation of Study Vaccine			
Adverse Event	6 (0.2)	6 (0.2)	12 (0.2)
Serious Adverse Event	3 (0.1)	5 (0.2)	8 (0.2)
Death	0	0	0
Lost to Follow-Up	9 (0.4)	9 (0.4)	18 (0.4)
Physician Decision	6 (0.2)	3 (0.1)	9 (0.2)
Pregnancy	2 (<0.1)	0	2 (<0.1)
Protocol Deviation	5 (0.2)	2 (<0.1)	7 (0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	24 (0.9)	9 (0.4)	33 (0.7)
Due to SARS-CoV-2	26 (1.0)	13 (0.5)	39 (0.8)
Other	18 (0.7)	15 (0.6)	33 (0.7)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535) n (%)	mRNA-1273 (N=2530) n (%)	Total (N=5065) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	281 (11.1)	124 (4.9)	405 (8.0)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	0	1 (<0.1)
Serious Adverse Event	0	0	0
Death	6 (0.2)	7 (0.3)	13 (0.3)
Lost to Follow-Up	20 (0.8)	23 (0.9)	43 (0.8)
Physician Decision	2 (<0.1)	4 (0.2)	6 (0.1)
Pregnancy	0	0	0
Protocol Deviation	96 (3.8)	21 (0.8)	117 (2.3)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	71 (2.8)	53 (2.1)	124 (2.4)
Due to SARS-CoV-2	0	0	0
Other	85 (3.4)	16 (0.6)	101 (2.0)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7511) n (%)
Number of Subjects			
Received First Injection	3749 (100)	3762 (100)	7511 (100)
Received Second Injection	3665 (97.8)	3697 (98.3)	7362 (98.0)
Discontinued Study Vaccine	84 (2.2)	65 (1.7)	149 (2.0)
Reason for Discontinuation of Study Vaccine			
Adverse Event	13 (0.3)	12 (0.3)	25 (0.3)
Serious Adverse Event	10 (0.3)	2 (<0.1)	12 (0.2)
Death	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lost to Follow-Up	1 (<0.1)	4 (0.1)	5 (<0.1)
Physician Decision	4 (0.1)	3 (<0.1)	7 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	7 (0.2)	11 (0.3)	18 (0.2)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	22 (0.6)	15 (0.4)	37 (0.5)
Due to SARS-CoV-2	12 (0.3)	7 (0.2)	19 (0.3)
Other	13 (0.3)	10 (0.3)	23 (0.3)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.2.3
Subject Disposition by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749) n (%)	mRNA-1273 (N=3762) n (%)	Total (N=7511) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	323 (8.6)	114 (3.0)	437 (5.8)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	1 (<0.1)	2 (<0.1)
Serious Adverse Event	3 (<0.1)	1 (<0.1)	4 (<0.1)
Death	7 (0.2)	12 (0.3)	19 (0.3)
Lost to Follow-Up	9 (0.2)	6 (0.2)	15 (0.2)
Physician Decision	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	125 (3.3)	36 (1.0)	161 (2.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	76 (2.0)	44 (1.2)	120 (1.6)
Due to SARS-CoV-2	0	0	0
Other	100 (2.7)	12 (0.3)	112 (1.5)

Percentages are based on the number of subjects in Full Analysis Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.1
Subject Disposition by Baseline SARS-CoV-2 Status
Per-Protocol Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)	Placebo (N=0) n (%)	mRNA-1273 (N=0) n (%)	Total (N=0) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Number of Subjects									
Received First Injection	14164 (100)	14287 (100)	28451 (100)	0	0	0	14164 (100)	14287 (100)	28451 (100)
Received Second Injection	14164 (100)	14287 (100)	28451 (100)	0	0	0	14164 (100)	14287 (100)	28451 (100)
Discontinued Study Vaccine	0	0	0	0	0	0	0	0	0
Reason for Discontinuation of Study Vaccine									
Adverse Event	0	0	0	0	0	0	0	0	0
Serious Adverse Event	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0
Lost to Follow-Up	0	0	0	0	0	0	0	0	0
Physician Decision	0	0	0	0	0	0	0	0	0
Pregnancy	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.1
Subject Disposition by Baseline SARS-CoV-2 Status
Per-Protocol Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)	Placebo (N=0) n (%)	mRNA-1273 (N=0) n (%)	Total (N=0) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	0	0	0	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	0	0	0	0	0	0	0	0	0
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	1736 (12.3)	455 (3.2)	2191 (7.7)	0	0	0	1736 (12.3)	455 (3.2)	2191 (7.7)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.1
Subject Disposition by Baseline SARS-CoV-2 Status
Per-Protocol Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)	Placebo (N=0) n (%)	mRNA-1273 (N=0) n (%)	Total (N=0) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Reason for Discontinuation of Study									
Adverse Event	1 (<0.1)	0	1 (<0.1)	0	0	0	1 (<0.1)	0	1 (<0.1)
Serious Adverse Event	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Death	14 (<0.1)	20 (0.1)	34 (0.1)	0	0	0	14 (<0.1)	20 (0.1)	34 (0.1)
Lost to Follow-Up	115 (0.8)	77 (0.5)	192 (0.7)	0	0	0	115 (0.8)	77 (0.5)	192 (0.7)
Physician Decision	10 (<0.1)	9 (<0.1)	19 (<0.1)	0	0	0	10 (<0.1)	9 (<0.1)	19 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	625 (4.4)	134 (0.9)	759 (2.7)	0	0	0	625 (4.4)	134 (0.9)	759 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	285 (2.0)	166 (1.2)	451 (1.6)	0	0	0	285 (2.0)	166 (1.2)	451 (1.6)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.1
Subject Disposition by Baseline SARS-CoV-2 Status
Per-Protocol Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)	Placebo (N=0) n (%)	mRNA-1273 (N=0) n (%)	Total (N=0) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	684 (4.8)	47 (0.3)	731 (2.6)	0	0	0	684 (4.8)	47 (0.3)	731 (2.6)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569) n (%)	mRNA-1273 (N=10661) n (%)	Total (N=21230) n (%)	Placebo (N=3595) n (%)	mRNA-1273 (N=3626) n (%)	Total (N=7221) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Number of Subjects									
Received First Injection	10569 (100)	10661 (100)	21230 (100)	3595 (100)	3626 (100)	7221 (100)	14164 (100)	14287 (100)	28451 (100)
Received Second Injection	10569 (100)	10661 (100)	21230 (100)	3595 (100)	3626 (100)	7221 (100)	14164 (100)	14287 (100)	28451 (100)
Discontinued Study Vaccine	0	0	0	0	0	0	0	0	0
Reason for Discontinuation of Study Vaccine									
Adverse Event	0	0	0	0	0	0	0	0	0
Serious Adverse Event	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0
Lost to Follow-Up	0	0	0	0	0	0	0	0	0
Physician Decision	0	0	0	0	0	0	0	0	0
Pregnancy	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569) n (%)	mRNA-1273 (N=10661) n (%)	Total (N=21230) n (%)	Placebo (N=3595) n (%)	mRNA-1273 (N=3626) n (%)	Total (N=7221) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	0	0	0	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	0	0	0	0	0	0	0	0	0
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	1463 (13.8)	367 (3.4)	1830 (8.6)	273 (7.6)	88 (2.4)	361 (5.0)	1736 (12.3)	455 (3.2)	2191 (7.7)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569) n (%)	mRNA-1273 (N=10661) n (%)	Total (N=21230) n (%)	Placebo (N=3595) n (%)	mRNA-1273 (N=3626) n (%)	Total (N=7221) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Reason for Discontinuation of Study									
Adverse Event	0	0	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Serious Adverse Event	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Death	11 (0.1)	10 (<0.1)	21 (<0.1)	3 (<0.1)	10 (0.3)	13 (0.2)	14 (<0.1)	20 (0.1)	34 (0.1)
Lost to Follow-Up	108 (1.0)	75 (0.7)	183 (0.9)	7 (0.2)	2 (<0.1)	9 (0.1)	115 (0.8)	77 (0.5)	192 (0.7)
Physician Decision	8 (<0.1)	7 (<0.1)	15 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)	10 (<0.1)	9 (<0.1)	19 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	506 (4.8)	101 (0.9)	607 (2.9)	119 (3.3)	33 (0.9)	152 (2.1)	625 (4.4)	134 (0.9)	759 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	235 (2.2)	137 (1.3)	372 (1.8)	50 (1.4)	29 (0.8)	79 (1.1)	285 (2.0)	166 (1.2)	451 (1.6)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.2
Subject Disposition by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569) n (%)	mRNA-1273 (N=10661) n (%)	Total (N=21230) n (%)	Placebo (N=3595) n (%)	mRNA-1273 (N=3626) n (%)	Total (N=7221) n (%)	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	594 (5.6)	35 (0.3)	629 (3.0)	90 (2.5)	12 (0.3)	102 (1.4)	684 (4.8)	47 (0.3)	731 (2.6)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Number of Subjects			
Received First Injection	14164 (100)	14287 (100)	28451 (100)
Received Second Injection	14164 (100)	14287 (100)	28451 (100)
Discontinued Study Vaccine	0	0	0
Reason for Discontinuation of Study Vaccine			
Adverse Event	0	0	0
Serious Adverse Event	0	0	0
Death	0	0	0
Lost to Follow-Up	0	0	0
Physician Decision	0	0	0
Pregnancy	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	0	0	0
Due to SARS-CoV-2	0	0	0
Other	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)	Total (N=28451) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	1736 (12.3)	455 (3.2)	2191 (7.7)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	0	1 (<0.1)
Serious Adverse Event	1 (<0.1)	1 (<0.1)	2 (<0.1)
Death	14 (<0.1)	20 (0.1)	34 (0.1)
Lost to Follow-Up	115 (0.8)	77 (0.5)	192 (0.7)
Physician Decision	10 (<0.1)	9 (<0.1)	19 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	625 (4.4)	134 (0.9)	759 (2.7)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	285 (2.0)	166 (1.2)	451 (1.6)
Due to SARS-CoV-2	0	0	0
Other	684 (4.8)	47 (0.3)	731 (2.6)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242) n (%)	mRNA-1273 (N=8271) n (%)	Total (N=16513) n (%)
Number of Subjects			
Received First Injection	8242 (100)	8271 (100)	16513 (100)
Received Second Injection	8242 (100)	8271 (100)	16513 (100)
Discontinued Study Vaccine	0	0	0
Reason for Discontinuation of Study Vaccine			
Adverse Event	0	0	0
Serious Adverse Event	0	0	0
Death	0	0	0
Lost to Follow-Up	0	0	0
Physician Decision	0	0	0
Pregnancy	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	0	0	0
Due to SARS-CoV-2	0	0	0
Other	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242) n (%)	mRNA-1273 (N=8271) n (%)	Total (N=16513) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	1236 (15.0)	281 (3.4)	1517 (9.2)
Reason for Discontinuation of Study			
Adverse Event	0	0	0
Serious Adverse Event	0	1 (<0.1)	1 (<0.1)
Death	5 (<0.1)	4 (<0.1)	9 (<0.1)
Lost to Follow-Up	98 (1.2)	62 (0.7)	160 (1.0)
Physician Decision	7 (<0.1)	5 (<0.1)	12 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	418 (5.1)	84 (1.0)	502 (3.0)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	193 (2.3)	98 (1.2)	291 (1.8)
Due to SARS-CoV-2	0	0	0
Other	514 (6.2)	26 (0.3)	540 (3.3)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331) n (%)	mRNA-1273 (N=2395) n (%)	Total (N=4726) n (%)
Number of Subjects			
Received First Injection	2331 (100)	2395 (100)	4726 (100)
Received Second Injection	2331 (100)	2395 (100)	4726 (100)
Discontinued Study Vaccine	0	0	0
Reason for Discontinuation of Study Vaccine			
Adverse Event	0	0	0
Serious Adverse Event	0	0	0
Death	0	0	0
Lost to Follow-Up	0	0	0
Physician Decision	0	0	0
Pregnancy	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	0	0	0
Due to SARS-CoV-2	0	0	0
Other	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331) n (%)	mRNA-1273 (N=2395) n (%)	Total (N=4726) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	227 (9.7)	86 (3.6)	313 (6.6)
Reason for Discontinuation of Study			
Adverse Event	0	0	0
Serious Adverse Event	0	0	0
Death	6 (0.3)	6 (0.3)	12 (0.3)
Lost to Follow-Up	10 (0.4)	13 (0.5)	23 (0.5)
Physician Decision	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	88 (3.8)	17 (0.7)	105 (2.2)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	42 (1.8)	39 (1.6)	81 (1.7)
Due to SARS-CoV-2	0	0	0
Other	80 (3.4)	9 (0.4)	89 (1.9)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591) n (%)	mRNA-1273 (N=3621) n (%)	Total (N=7212) n (%)
Number of Subjects			
Received First Injection	3591 (100)	3621 (100)	7212 (100)
Received Second Injection	3591 (100)	3621 (100)	7212 (100)
Discontinued Study Vaccine	0	0	0
Reason for Discontinuation of Study Vaccine			
Adverse Event	0	0	0
Serious Adverse Event	0	0	0
Death	0	0	0
Lost to Follow-Up	0	0	0
Physician Decision	0	0	0
Pregnancy	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	0	0	0
Due to SARS-CoV-2	0	0	0
Other	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.3
Subject Disposition by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591) n (%)	mRNA-1273 (N=3621) n (%)	Total (N=7212) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	273 (7.6)	88 (2.4)	361 (5.0)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	0	1 (<0.1)
Serious Adverse Event	1 (<0.1)	0	1 (<0.1)
Death	3 (<0.1)	10 (0.3)	13 (0.2)
Lost to Follow-Up	7 (0.2)	2 (<0.1)	9 (0.1)
Physician Decision	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	119 (3.3)	33 (0.9)	152 (2.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	50 (1.4)	29 (0.8)	79 (1.1)
Due to SARS-CoV-2	0	0	0
Other	90 (2.5)	12 (0.3)	102 (1.4)

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.4
Subject Disposition
Per-Protocol Set — Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744) n (%)	mRNA-1273 (N=55) n (%)	Total (N=799) n (%)
Number of Subjects			
Received First Injection	744 (100)	55 (100)	799 (100)
Received Second Injection	744 (100)	55 (100)	799 (100)
Discontinued Study Vaccine	0	0	0
Reason for Discontinuation of Study Vaccine			
Adverse Event	0	0	0
Serious Adverse Event	0	0	0
Death	0	0	0
Lost to Follow-Up	0	0	0
Physician Decision	0	0	0
Pregnancy	0	0	0
Protocol Deviation	0	0	0
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	0	0	0
Due to SARS-CoV-2	0	0	0
Other	0	0	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Percentages are based on the number of subjects in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.3.4
Subject Disposition
Per-Protocol Set — Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744) n (%)	mRNA-1273 (N=55) n (%)	Total (N=799) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	57 (7.7)	2 (3.6)	59 (7.4)
Reason for Discontinuation of Study			
Adverse Event	1 (0.1)	0	1 (0.1)
Serious Adverse Event	0	0	0
Death	3 (0.4)	0	3 (0.4)
Lost to Follow-Up	4 (0.5)	0	4 (0.5)
Physician Decision	0	1 (1.8)	1 (0.1)
Pregnancy	0	0	0
Protocol Deviation	18 (2.4)	1 (1.8)	19 (2.4)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	19 (2.6)	0	19 (2.4)
Due to SARS-CoV-2	0	0	0
Other	12 (1.6)	0	12 (1.5)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Percentages are based on the number of subjects in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.1
Subject Disposition by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046) n (%)	mRNA-1273 (N=11037) n (%)	Total (N=22083) n (%)	Placebo (N=3699) n (%)	mRNA-1273 (N=3709) n (%)	Total (N=7408) n (%)	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)
Number of Subjects									
Received First Injection	11046 (100)	11037 (100)	22083 (100)	3699 (100)	3709 (100)	7408 (100)	14745 (100)	14746 (100)	29491 (100)
Received Second Injection	10694 (96.8)	10758 (97.5)	21452 (97.1)	3626 (98.0)	3654 (98.5)	7280 (98.3)	14320 (97.1)	14412 (97.7)	28732 (97.4)
Discontinued Study Vaccine	352 (3.2)	279 (2.5)	631 (2.9)	73 (2.0)	55 (1.5)	128 (1.7)	425 (2.9)	334 (2.3)	759 (2.6)
Reason for Discontinuation of Study Vaccine									
Adverse Event	29 (0.3)	32 (0.3)	61 (0.3)	13 (0.4)	12 (0.3)	25 (0.3)	42 (0.3)	44 (0.3)	86 (0.3)
Serious Adverse Event	6 (<0.1)	9 (<0.1)	15 (<0.1)	10 (0.3)	2 (<0.1)	12 (0.2)	16 (0.1)	11 (<0.1)	27 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	68 (0.6)	59 (0.5)	127 (0.6)	1 (<0.1)	3 (<0.1)	4 (<0.1)	69 (0.5)	62 (0.4)	131 (0.4)
Physician Decision	14 (0.1)	18 (0.2)	32 (0.1)	4 (0.1)	3 (<0.1)	7 (<0.1)	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	2 (<0.1)	6 (<0.1)	0	0	0	4 (<0.1)	2 (<0.1)	6 (<0.1)

Percentages are based on the number of subjects in mITT set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.1
Subject Disposition by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046) n (%)	mRNA-1273 (N=11037) n (%)	Total (N=22083) n (%)	Placebo (N=3699) n (%)	mRNA-1273 (N=3709) n (%)	Total (N=7408) n (%)	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	28 (0.3)	24 (0.2)	52 (0.2)	7 (0.2)	9 (0.2)	16 (0.2)	35 (0.2)	33 (0.2)	68 (0.2)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	80 (0.7)	58 (0.5)	138 (0.6)	22 (0.6)	15 (0.4)	37 (0.5)	102 (0.7)	73 (0.5)	175 (0.6)
Due to SARS-CoV-2	44 (0.4)	9 (<0.1)	53 (0.2)	3 (<0.1)	2 (<0.1)	5 (<0.1)	47 (0.3)	11 (<0.1)	58 (0.2)
Other	75 (0.7)	65 (0.6)	140 (0.6)	11 (0.3)	8 (0.2)	19 (0.3)	86 (0.6)	73 (0.5)	159 (0.5)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	1690 (15.3)	542 (4.9)	2232 (10.1)	319 (8.6)	112 (3.0)	431 (5.8)	2009 (13.6)	654 (4.4)	2663 (9.0)

Percentages are based on the number of subjects in mITT set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.1
Subject Disposition by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046) n (%)	mRNA-1273 (N=11037) n (%)	Total (N=22083) n (%)	Placebo (N=3699) n (%)	mRNA-1273 (N=3709) n (%)	Total (N=7408) n (%)	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)
Reason for Discontinuation of Study									
Adverse Event	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	12 (0.1)	12 (0.1)	24 (0.1)	6 (0.2)	12 (0.3)	18 (0.2)	18 (0.1)	24 (0.2)	42 (0.1)
Lost to Follow-Up	180 (1.6)	143 (1.3)	323 (1.5)	9 (0.2)	4 (0.1)	13 (0.2)	189 (1.3)	147 (1.0)	336 (1.1)
Physician Decision	11 (<0.1)	14 (0.1)	25 (0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)	13 (<0.1)	16 (0.1)	29 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	526 (4.8)	111 (1.0)	637 (2.9)	124 (3.4)	36 (1.0)	160 (2.2)	650 (4.4)	147 (1.0)	797 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	334 (3.0)	205 (1.9)	539 (2.4)	76 (2.1)	44 (1.2)	120 (1.6)	410 (2.8)	249 (1.7)	659 (2.2)

Percentages are based on the number of subjects in mITT set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.1
Subject Disposition by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046) n (%)	mRNA-1273 (N=11037) n (%)	Total (N=22083) n (%)	Placebo (N=3699) n (%)	mRNA-1273 (N=3709) n (%)	Total (N=7408) n (%)	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	621 (5.6)	49 (0.4)	670 (3.0)	98 (2.6)	12 (0.3)	110 (1.5)	719 (4.9)	61 (0.4)	780 (2.6)

Percentages are based on the number of subjects in mITT set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.2
Subject Disposition by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352) n (%)	mRNA-1273 (N=279) n (%)	Total (N=631) n (%)	Placebo (N=73) n (%)	mRNA-1273 (N=55) n (%)	Total (N=128) n (%)	Placebo (N=425) n (%)	mRNA-1273 (N=334) n (%)	Total (N=759) n (%)
Number of Subjects									
Received First Injection	352 (100)	279 (100)	631 (100)	73 (100)	55 (100)	128 (100)	425 (100)	334 (100)	759 (100)
Received Second Injection	0	0	0	0	0	0	0	0	0
Discontinued Study Vaccine	352 (100)	279 (100)	631 (100)	73 (100)	55 (100)	128 (100)	425 (100)	334 (100)	759 (100)
Reason for Discontinuation of Study Vaccine									
Adverse Event	29 (8.2)	32 (11.5)	61 (9.7)	13 (17.8)	12 (21.8)	25 (19.5)	42 (9.9)	44 (13.2)	86 (11.3)
Serious Adverse Event	6 (1.7)	9 (3.2)	15 (2.4)	10 (13.7)	2 (3.6)	12 (9.4)	16 (3.8)	11 (3.3)	27 (3.6)
Death	1 (0.3)	1 (0.4)	2 (0.3)	2 (2.7)	1 (1.8)	3 (2.3)	3 (0.7)	2 (0.6)	5 (0.7)
Lost to Follow-Up	68 (19.3)	59 (21.1)	127 (20.1)	1 (1.4)	3 (5.5)	4 (3.1)	69 (16.2)	62 (18.6)	131 (17.3)
Physician Decision	14 (4.0)	18 (6.5)	32 (5.1)	4 (5.5)	3 (5.5)	7 (5.5)	18 (4.2)	21 (6.3)	39 (5.1)
Pregnancy	4 (1.1)	2 (0.7)	6 (1.0)	0	0	0	4 (0.9)	2 (0.6)	6 (0.8)

Percentages are based on the number of subjects who only received one injection in mITT Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.2
Subject Disposition by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352) n (%)	mRNA-1273 (N=279) n (%)	Total (N=631) n (%)	Placebo (N=73) n (%)	mRNA-1273 (N=55) n (%)	Total (N=128) n (%)	Placebo (N=425) n (%)	mRNA-1273 (N=334) n (%)	Total (N=759) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	28 (8.0)	24 (8.6)	52 (8.2)	7 (9.6)	9 (16.4)	16 (12.5)	35 (8.2)	33 (9.9)	68 (9.0)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	80 (22.7)	58 (20.8)	138 (21.9)	22 (30.1)	15 (27.3)	37 (28.9)	102 (24.0)	73 (21.9)	175 (23.1)
Due to SARS-CoV-2	44 (12.5)	9 (3.2)	53 (8.4)	3 (4.1)	2 (3.6)	5 (3.9)	47 (11.1)	11 (3.3)	58 (7.6)
Other	75 (21.3)	65 (23.3)	140 (22.2)	11 (15.1)	8 (14.5)	19 (14.8)	86 (20.2)	73 (21.9)	159 (20.9)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	206 (58.5)	170 (60.9)	376 (59.6)	41 (56.2)	24 (43.6)	65 (50.8)	247 (58.1)	194 (58.1)	441 (58.1)

Percentages are based on the number of subjects who only received one injection in mITT Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.2
Subject Disposition by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352) n (%)	mRNA-1273 (N=279) n (%)	Total (N=631) n (%)	Placebo (N=73) n (%)	mRNA-1273 (N=55) n (%)	Total (N=128) n (%)	Placebo (N=425) n (%)	mRNA-1273 (N=334) n (%)	Total (N=759) n (%)
Reason for Discontinuation of Study									
Adverse Event	4 (1.1)	3 (1.1)	7 (1.1)	0	1 (1.8)	1 (0.8)	4 (0.9)	4 (1.2)	8 (1.1)
Serious Adverse Event	1 (0.3)	3 (1.1)	4 (0.6)	2 (2.7)	1 (1.8)	3 (2.3)	3 (0.7)	4 (1.2)	7 (0.9)
Death	1 (0.3)	2 (0.7)	3 (0.5)	3 (4.1)	2 (3.6)	5 (3.9)	4 (0.9)	4 (1.2)	8 (1.1)
Lost to Follow-Up	71 (20.2)	66 (23.7)	137 (21.7)	1 (1.4)	2 (3.6)	3 (2.3)	72 (16.9)	68 (20.4)	140 (18.4)
Physician Decision	2 (0.6)	7 (2.5)	9 (1.4)	0	0	0	2 (0.5)	7 (2.1)	9 (1.2)
Pregnancy	0	0	0	0	0	0	0	0	0
Protocol Deviation	17 (4.8)	10 (3.6)	27 (4.3)	5 (6.8)	3 (5.5)	8 (6.3)	22 (5.2)	13 (3.9)	35 (4.6)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	95 (27.0)	65 (23.3)	160 (25.4)	26 (35.6)	15 (27.3)	41 (32.0)	121 (28.5)	80 (24.0)	201 (26.5)

Percentages are based on the number of subjects who only received one injection in mITT Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.4.2
Subject Disposition by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352) n (%)	mRNA-1273 (N=279) n (%)	Total (N=631) n (%)	Placebo (N=73) n (%)	mRNA-1273 (N=55) n (%)	Total (N=128) n (%)	Placebo (N=425) n (%)	mRNA-1273 (N=334) n (%)	Total (N=759) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	15 (4.3)	14 (5.0)	29 (4.6)	4 (5.5)	0	4 (3.1)	19 (4.5)	14 (4.2)	33 (4.3)

Percentages are based on the number of subjects who only received one injection in mITT Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Solicited Adverse Reactions - N1	3106	3119	6225
Any Solicited Adverse Reactions	1476 (47.5)	2673 (85.7)	4149 (66.7)
95% CI	45.8, 49.3	84.4, 86.9	65.5, 67.8
Grade 1	1026 (33.0)	1811 (58.1)	2837 (45.6)
Grade 2	375 (12.1)	660 (21.2)	1035 (16.6)
Grade 3	73 (2.4)	199 (6.4)	272 (4.4)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	75 (2.4)	202 (6.5)	277 (4.4)
Solicited Local Adverse Reactions - N1	3106	3119	6225
Any Solicited Local Adverse Reactions	626 (20.2)	2574 (82.5)	3200 (51.4)
95% CI	18.8, 21.6	81.1, 83.8	50.2, 52.7
Grade 1	580 (18.7)	2130 (68.3)	2710 (43.5)
Grade 2	26 (0.8)	328 (10.5)	354 (5.7)
Grade 3	20 (0.6)	116 (3.7)	136 (2.2)
Grade 4	0	0	0
Grade 3 or Above	20 (0.6)	116 (3.7)	136 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Pain - N1	3106	3119	6225
Any	546 (17.6)	2551 (81.8)	3097 (49.8)
Grade 1	511 (16.5)	2175 (69.7)	2686 (43.1)
Grade 2	21 (0.7)	285 (9.1)	306 (4.9)
Grade 3	14 (0.5)	91 (2.9)	105 (1.7)
Grade 4	0	0	0
Grade 3 or Above	14 (0.5)	91 (2.9)	105 (1.7)
Erythema (Redness) - N1	3106	3119	6225
Any	17 (0.5)	97 (3.1)	114 (1.8)
Grade 1	12 (0.4)	63 (2.0)	75 (1.2)
Grade 2	0	23 (0.7)	23 (0.4)
Grade 3	5 (0.2)	11 (0.4)	16 (0.3)
Grade 4	0	0	0
Grade 3 or Above	5 (0.2)	11 (0.4)	16 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Swelling (Hardness) - N1	3106	3119	6225
Any	10 (0.3)	196 (6.3)	206 (3.3)
Grade 1	7 (0.2)	121 (3.9)	128 (2.1)
Grade 2	1 (<0.1)	57 (1.8)	58 (0.9)
Grade 3	2 (<0.1)	18 (0.6)	20 (0.3)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	18 (0.6)	20 (0.3)
Axillary Swelling or Tenderness - N1	3106	3119	6225
Any	176 (5.7)	421 (13.5)	597 (9.6)
Grade 1	161 (5.2)	365 (11.7)	526 (8.4)
Grade 2	8 (0.3)	38 (1.2)	46 (0.7)
Grade 3	7 (0.2)	18 (0.6)	25 (0.4)
Grade 4	0	0	0
Grade 3 or Above	7 (0.2)	18 (0.6)	25 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Solicited Systemic Adverse Reactions - N1	3106	3119	6225
Any Solicited Systemic Adverse Reactions	1327 (42.7)	1727 (55.4)	3054 (49.1)
95% CI	41.0, 44.5	53.6, 57.1	47.8, 50.3
Grade 1	897 (28.9)	1081 (34.7)	1978 (31.8)
Grade 2	366 (11.8)	522 (16.7)	888 (14.3)
Grade 3	62 (2.0)	121 (3.9)	183 (2.9)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	64 (2.1)	124 (4.0)	188 (3.0)
Fever - N1	3105	3118	6223
Any	11 (0.4)	39 (1.3)	50 (0.8)
Grade 1	8 (0.3)	22 (0.7)	30 (0.5)
Grade 2	1 (<0.1)	8 (0.3)	9 (0.1)
Grade 3	0	7 (0.2)	7 (0.1)
Grade 4	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 3 or Above	2 (<0.1)	9 (0.3)	11 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Headache - N1	3106	3119	6225
Any	865 (27.8)	1031 (33.1)	1896 (30.5)
Grade 1	688 (22.2)	805 (25.8)	1493 (24.0)
Grade 2	137 (4.4)	156 (5.0)	293 (4.7)
Grade 3	40 (1.3)	70 (2.2)	110 (1.8)
Grade 4	0	0	0
Grade 3 or Above	40 (1.3)	70 (2.2)	110 (1.8)
Fatigue - N1	3106	3119	6225
Any	828 (26.7)	1154 (37.0)	1982 (31.8)
Grade 1	554 (17.8)	728 (23.3)	1282 (20.6)
Grade 2	260 (8.4)	386 (12.4)	646 (10.4)
Grade 3	14 (0.5)	39 (1.3)	53 (0.9)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	14 (0.5)	40 (1.3)	54 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Myalgia - N1	3106	3119	6225
Any	504 (16.2)	825 (26.5)	1329 (21.3)
Grade 1	380 (12.2)	570 (18.3)	950 (15.3)
Grade 2	108 (3.5)	226 (7.2)	334 (5.4)
Grade 3	16 (0.5)	29 (0.9)	45 (0.7)
Grade 4	0	0	0
Grade 3 or Above	16 (0.5)	29 (0.9)	45 (0.7)
Arthralgia - N1	3106	3119	6225
Any	409 (13.2)	585 (18.8)	994 (16.0)
Grade 1	305 (9.8)	440 (14.1)	745 (12.0)
Grade 2	93 (3.0)	128 (4.1)	221 (3.6)
Grade 3	11 (0.4)	16 (0.5)	27 (0.4)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	11 (0.4)	17 (0.5)	28 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Nausea/Vomiting - N1	3106	3119	6225
Any	257 (8.3)	305 (9.8)	562 (9.0)
Grade 1	209 (6.7)	258 (8.3)	467 (7.5)
Grade 2	46 (1.5)	42 (1.3)	88 (1.4)
Grade 3	2 (<0.1)	5 (0.2)	7 (0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	5 (0.2)	7 (0.1)
Chills - N1	3106	3119	6225
Any	229 (7.4)	342 (11.0)	571 (9.2)
Grade 1	182 (5.9)	250 (8.0)	432 (6.9)
Grade 2	41 (1.3)	78 (2.5)	119 (1.9)
Grade 3	6 (0.2)	14 (0.4)	20 (0.3)
Grade 4	0	0	0
Grade 3 or Above	6 (0.2)	14 (0.4)	20 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Solicited Adverse Reactions - N1	11909	11905	23814
Any Solicited Adverse Reactions	5737 (48.2)	10515 (88.3)	16252 (68.2)
95% CI	47.3, 49.1	87.7, 88.9	67.7, 68.8
Grade 1	4057 (34.1)	7425 (62.4)	11482 (48.2)
Grade 2	1387 (11.6)	2442 (20.5)	3829 (16.1)
Grade 3	289 (2.4)	646 (5.4)	935 (3.9)
Grade 4	4 (<0.1)	2 (<0.1)	6 (<0.1)
Grade 3 or Above	293 (2.5)	648 (5.4)	941 (4.0)
Solicited Local Adverse Reactions - N1	11905	11901	23806
Any Solicited Local Adverse Reactions	2354 (19.8)	10071 (84.6)	12425 (52.2)
95% CI	19.1, 20.5	84.0, 85.3	51.6, 52.8
Grade 1	2233 (18.8)	8486 (71.3)	10719 (45.0)
Grade 2	63 (0.5)	1173 (9.9)	1236 (5.2)
Grade 3	58 (0.5)	412 (3.5)	470 (2.0)
Grade 4	0	0	0
Grade 3 or Above	58 (0.5)	412 (3.5)	470 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Pain - N1	11905	11901	23806
Any	2093 (17.6)	10018 (84.2)	12111 (50.9)
Grade 1	2014 (16.9)	8701 (73.1)	10715 (45.0)
Grade 2	38 (0.3)	993 (8.3)	1031 (4.3)
Grade 3	41 (0.3)	324 (2.7)	365 (1.5)
Grade 4	0	0	0
Grade 3 or Above	41 (0.3)	324 (2.7)	365 (1.5)
Erythema (Redness) - N1	11905	11901	23806
Any	60 (0.5)	346 (2.9)	406 (1.7)
Grade 1	45 (0.4)	216 (1.8)	261 (1.1)
Grade 2	7 (<0.1)	99 (0.8)	106 (0.4)
Grade 3	8 (<0.1)	31 (0.3)	39 (0.2)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	31 (0.3)	39 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Swelling (Hardness) - N1	11905	11901	23806
Any	55 (0.5)	732 (6.2)	787 (3.3)
Grade 1	43 (0.4)	482 (4.1)	525 (2.2)
Grade 2	8 (<0.1)	186 (1.6)	194 (0.8)
Grade 3	4 (<0.1)	64 (0.5)	68 (0.3)
Grade 4	0	0	0
Grade 3 or Above	4 (<0.1)	64 (0.5)	68 (0.3)
Axillary Swelling or Tenderness - N1	11905	11901	23806
Any	542 (4.6)	1118 (9.4)	1660 (7.0)
Grade 1	503 (4.2)	1015 (8.5)	1518 (6.4)
Grade 2	19 (0.2)	72 (0.6)	91 (0.4)
Grade 3	20 (0.2)	31 (0.3)	51 (0.2)
Grade 4	0	0	0
Grade 3 or Above	20 (0.2)	31 (0.3)	51 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Solicited Systemic Adverse Reactions - N1	11909	11905	23814
Any Solicited Systemic Adverse Reactions	5009 (42.1)	6502 (54.6)	11511 (48.3)
95% CI	41.2, 43.0	53.7, 55.5	47.7, 49.0
Grade 1	3397 (28.5)	4219 (35.4)	7616 (32.0)
Grade 2	1360 (11.4)	1956 (16.4)	3316 (13.9)
Grade 3	248 (2.1)	325 (2.7)	573 (2.4)
Grade 4	4 (<0.1)	2 (<0.1)	6 (<0.1)
Grade 3 or Above	252 (2.1)	327 (2.7)	579 (2.4)
Fever - N1	11908	11903	23811
Any	33 (0.3)	73 (0.6)	106 (0.4)
Grade 1	20 (0.2)	51 (0.4)	71 (0.3)
Grade 2	7 (<0.1)	16 (0.1)	23 (<0.1)
Grade 3	2 (<0.1)	4 (<0.1)	6 (<0.1)
Grade 4	4 (<0.1)	2 (<0.1)	6 (<0.1)
Grade 3 or Above	6 (<0.1)	6 (<0.1)	12 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Headache - N1	11905	11901	23806
Any	3122 (26.2)	3870 (32.5)	6992 (29.4)
Grade 1	2574 (21.6)	3102 (26.1)	5676 (23.8)
Grade 2	392 (3.3)	566 (4.8)	958 (4.0)
Grade 3	156 (1.3)	202 (1.7)	358 (1.5)
Grade 4	0	0	0
Grade 3 or Above	156 (1.3)	202 (1.7)	358 (1.5)
Fatigue - N1	11905	11901	23806
Any	3261 (27.4)	4429 (37.2)	7690 (32.3)
Grade 1	2121 (17.8)	2824 (23.7)	4945 (20.8)
Grade 2	1049 (8.8)	1494 (12.6)	2543 (10.7)
Grade 3	91 (0.8)	111 (0.9)	202 (0.8)
Grade 4	0	0	0
Grade 3 or Above	91 (0.8)	111 (0.9)	202 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Myalgia - N1	11905	11901	23806
Any	1549 (13.0)	2587 (21.7)	4136 (17.4)
Grade 1	1171 (9.8)	1854 (15.6)	3025 (12.7)
Grade 2	347 (2.9)	673 (5.7)	1020 (4.3)
Grade 3	31 (0.3)	60 (0.5)	91 (0.4)
Grade 4	0	0	0
Grade 3 or Above	31 (0.3)	60 (0.5)	91 (0.4)
Arthralgia - N1	11905	11901	23806
Any	1354 (11.4)	1899 (16.0)	3253 (13.7)
Grade 1	1011 (8.5)	1381 (11.6)	2392 (10.0)
Grade 2	316 (2.7)	476 (4.0)	792 (3.3)
Grade 3	27 (0.2)	42 (0.4)	69 (0.3)
Grade 4	0	0	0
Grade 3 or Above	27 (0.2)	42 (0.4)	69 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Nausea/Vomiting - N1	11905	11901	23806
Any	809 (6.8)	946 (7.9)	1755 (7.4)
Grade 1	670 (5.6)	780 (6.6)	1450 (6.1)
Grade 2	128 (1.1)	161 (1.4)	289 (1.2)
Grade 3	11 (<0.1)	5 (<0.1)	16 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	11 (<0.1)	5 (<0.1)	16 (<0.1)
Chills - N1	11905	11901	23806
Any	645 (5.4)	893 (7.5)	1538 (6.5)
Grade 1	521 (4.4)	673 (5.7)	1194 (5.0)
Grade 2	116 (1.0)	210 (1.8)	326 (1.4)
Grade 3	8 (<0.1)	10 (<0.1)	18 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	10 (<0.1)	18 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.1.1.1.5.2
Subject Disposition by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects									
Received First Injection	11411 (100)	11415 (100)	22826 (100)	3751 (100)	3769 (100)	7520 (100)	15162 (100)	15184 (100)	30346 (100)
Received Second Injection	10964 (96.1)	11027 (96.6)	21991 (96.3)	3667 (97.8)	3704 (98.3)	7371 (98.0)	14631 (96.5)	14731 (97.0)	29362 (96.8)
Discontinued Study Vaccine	447 (3.9)	388 (3.4)	835 (3.7)	84 (2.2)	65 (1.7)	149 (2.0)	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine									
Adverse Event	31 (0.3)	35 (0.3)	66 (0.3)	13 (0.3)	12 (0.3)	25 (0.3)	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	8 (<0.1)	10 (<0.1)	18 (<0.1)	10 (0.3)	2 (<0.1)	12 (0.2)	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	72 (0.6)	72 (0.6)	144 (0.6)	1 (<0.1)	4 (0.1)	5 (<0.1)	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	14 (0.1)	18 (0.2)	32 (0.1)	4 (0.1)	3 (<0.1)	7 (<0.1)	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)	0	0	0	4 (<0.1)	3 (<0.1)	7 (<0.1)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.2
Subject Disposition by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study Vaccine (Cont.)									
Protocol Deviation	30 (0.3)	26 (0.2)	56 (0.2)	7 (0.2)	11 (0.3)	18 (0.2)	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	86 (0.8)	63 (0.6)	149 (0.7)	22 (0.6)	15 (0.4)	37 (0.5)	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	107 (0.9)	74 (0.6)	181 (0.8)	12 (0.3)	7 (0.2)	19 (0.3)	119 (0.8)	81 (0.5)	200 (0.7)
Other	91 (0.8)	84 (0.7)	175 (0.8)	13 (0.3)	10 (0.3)	23 (0.3)	104 (0.7)	94 (0.6)	198 (0.7)
Completed Study [1]	0	0	0	0	0	0	0	0	0
Discontinued from Study	1736 (15.2)	587 (5.1)	2323 (10.2)	323 (8.6)	114 (3.0)	437 (5.8)	2059 (13.6)	701 (4.6)	2760 (9.1)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.2
Subject Disposition by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study									
Adverse Event	4 (<0.1)	3 (<0.1)	7 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	12 (0.1)	12 (0.1)	24 (0.1)	7 (0.2)	12 (0.3)	19 (0.3)	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	190 (1.7)	165 (1.4)	355 (1.6)	9 (0.2)	6 (0.2)	15 (0.2)	199 (1.3)	171 (1.1)	370 (1.2)
Physician Decision	11 (<0.1)	14 (0.1)	25 (0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)	13 (<0.1)	16 (0.1)	29 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	539 (4.7)	115 (1.0)	654 (2.9)	125 (3.3)	36 (1.0)	161 (2.1)	664 (4.4)	151 (1.0)	815 (2.7)
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0
Withdrawal of Consent by Participant	350 (3.1)	222 (1.9)	572 (2.5)	76 (2.0)	44 (1.2)	120 (1.6)	426 (2.8)	266 (1.8)	692 (2.3)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.2
Subject Disposition by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reason for Discontinuation of Study (Cont.)									
Due to SARS-CoV-2	0	0	0	0	0	0	0	0	0
Other	628 (5.5)	51 (0.4)	679 (3.0)	100 (2.7)	12 (0.3)	112 (1.5)	728 (4.8)	63 (0.4)	791 (2.6)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects			
Received First Injection	15162 (100)	15184 (100)	30346 (100)
Received Second Injection	14631 (96.5)	14731 (97.0)	29362 (96.8)
Discontinued Study Vaccine	531 (3.5)	453 (3.0)	984 (3.2)
Reason for Discontinuation of Study Vaccine			
Adverse Event	44 (0.3)	47 (0.3)	91 (0.3)
Serious Adverse Event	18 (0.1)	12 (<0.1)	30 (<0.1)
Death	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lost to Follow-Up	73 (0.5)	76 (0.5)	149 (0.5)
Physician Decision	18 (0.1)	21 (0.1)	39 (0.1)
Pregnancy	4 (<0.1)	3 (<0.1)	7 (<0.1)
Protocol Deviation	37 (0.2)	37 (0.2)	74 (0.2)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	108 (0.7)	78 (0.5)	186 (0.6)
Due to SARS-CoV-2	119 (0.8)	81 (0.5)	200 (0.7)
Other	104 (0.7)	94 (0.6)	198 (0.7)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	2059 (13.6)	701 (4.6)	2760 (9.1)
Reason for Discontinuation of Study			
Adverse Event	5 (<0.1)	4 (<0.1)	9 (<0.1)
Serious Adverse Event	4 (<0.1)	5 (<0.1)	9 (<0.1)
Death	19 (0.1)	24 (0.2)	43 (0.1)
Lost to Follow-Up	199 (1.3)	171 (1.1)	370 (1.2)
Physician Decision	13 (<0.1)	16 (0.1)	29 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	664 (4.4)	151 (1.0)	815 (2.7)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	426 (2.8)	266 (1.8)	692 (2.3)
Due to SARS-CoV-2	0	0	0
Other	728 (4.8)	63 (0.4)	791 (2.6)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880) n (%)	mRNA-1273 (N=8890) n (%)	Total (N=17770) n (%)
Number of Subjects			
Received First Injection	8880 (100)	8890 (100)	17770 (100)
Received Second Injection	8533 (96.1)	8564 (96.3)	17097 (96.2)
Discontinued Study Vaccine	347 (3.9)	326 (3.7)	673 (3.8)
Reason for Discontinuation of Study Vaccine			
Adverse Event	25 (0.3)	29 (0.3)	54 (0.3)
Serious Adverse Event	5 (<0.1)	5 (<0.1)	10 (<0.1)
Death	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lost to Follow-Up	63 (0.7)	63 (0.7)	126 (0.7)
Physician Decision	8 (<0.1)	15 (0.2)	23 (0.1)
Pregnancy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Protocol Deviation	25 (0.3)	24 (0.3)	49 (0.3)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	62 (0.7)	54 (0.6)	116 (0.7)
Due to SARS-CoV-2	81 (0.9)	61 (0.7)	142 (0.8)
Other	73 (0.8)	69 (0.8)	142 (0.8)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880) n (%)	mRNA-1273 (N=8890) n (%)	Total (N=17770) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	1455 (16.4)	463 (5.2)	1918 (10.8)
Reason for Discontinuation of Study			
Adverse Event	3 (<0.1)	3 (<0.1)	6 (<0.1)
Serious Adverse Event	1 (<0.1)	4 (<0.1)	5 (<0.1)
Death	6 (<0.1)	5 (<0.1)	11 (<0.1)
Lost to Follow-Up	170 (1.9)	142 (1.6)	312 (1.8)
Physician Decision	9 (0.1)	10 (0.1)	19 (0.1)
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Protocol Deviation	443 (5.0)	94 (1.1)	537 (3.0)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	279 (3.1)	169 (1.9)	448 (2.5)
Due to SARS-CoV-2	0	0	0
Other	543 (6.1)	35 (0.4)	578 (3.3)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535) n (%)	mRNA-1273 (N=2530) n (%)	Total (N=5065) n (%)
Number of Subjects			
Received First Injection	2535 (100)	2530 (100)	5065 (100)
Received Second Injection	2435 (96.1)	2468 (97.5)	4903 (96.8)
Discontinued Study Vaccine	100 (3.9)	62 (2.5)	162 (3.2)
Reason for Discontinuation of Study Vaccine			
Adverse Event	6 (0.2)	6 (0.2)	12 (0.2)
Serious Adverse Event	3 (0.1)	5 (0.2)	8 (0.2)
Death	0	0	0
Lost to Follow-Up	9 (0.4)	9 (0.4)	18 (0.4)
Physician Decision	6 (0.2)	3 (0.1)	9 (0.2)
Pregnancy	2 (<0.1)	0	2 (<0.1)
Protocol Deviation	5 (0.2)	2 (<0.1)	7 (0.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	24 (0.9)	9 (0.4)	33 (0.7)
Due to SARS-CoV-2	26 (1.0)	13 (0.5)	39 (0.8)
Other	18 (0.7)	15 (0.6)	33 (0.7)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535) n (%)	mRNA-1273 (N=2530) n (%)	Total (N=5065) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	281 (11.1)	124 (4.9)	405 (8.0)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	0	1 (<0.1)
Serious Adverse Event	0	0	0
Death	6 (0.2)	7 (0.3)	13 (0.3)
Lost to Follow-Up	20 (0.8)	23 (0.9)	43 (0.8)
Physician Decision	2 (<0.1)	4 (0.2)	6 (0.1)
Pregnancy	0	0	0
Protocol Deviation	96 (3.8)	21 (0.8)	117 (2.3)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	71 (2.8)	53 (2.1)	124 (2.4)
Due to SARS-CoV-2	0	0	0
Other	85 (3.4)	16 (0.6)	101 (2.0)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747) n (%)	mRNA-1273 (N=3764) n (%)	Total (N=7511) n (%)
Number of Subjects			
Received First Injection	3747 (100)	3764 (100)	7511 (100)
Received Second Injection	3663 (97.8)	3699 (98.3)	7362 (98.0)
Discontinued Study Vaccine	84 (2.2)	65 (1.7)	149 (2.0)
Reason for Discontinuation of Study Vaccine			
Adverse Event	13 (0.3)	12 (0.3)	25 (0.3)
Serious Adverse Event	10 (0.3)	2 (<0.1)	12 (0.2)
Death	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lost to Follow-Up	1 (<0.1)	4 (0.1)	5 (<0.1)
Physician Decision	4 (0.1)	3 (<0.1)	7 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	7 (0.2)	11 (0.3)	18 (0.2)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	22 (0.6)	15 (0.4)	37 (0.5)
Due to SARS-CoV-2	12 (0.3)	7 (0.2)	19 (0.3)
Other	13 (0.3)	10 (0.3)	23 (0.3)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.1.5.3
Subject Disposition by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747) n (%)	mRNA-1273 (N=3764) n (%)	Total (N=7511) n (%)
Completed Study [1]	0	0	0
Discontinued from Study	323 (8.6)	114 (3.0)	437 (5.8)
Reason for Discontinuation of Study			
Adverse Event	1 (<0.1)	1 (<0.1)	2 (<0.1)
Serious Adverse Event	3 (<0.1)	1 (<0.1)	4 (<0.1)
Death	7 (0.2)	12 (0.3)	19 (0.3)
Lost to Follow-Up	9 (0.2)	6 (0.2)	15 (0.2)
Physician Decision	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pregnancy	0	0	0
Protocol Deviation	125 (3.3)	36 (1.0)	161 (2.1)
Study Terminated by Sponsor	0	0	0
Withdrawal of Consent by Participant	76 (2.0)	44 (1.2)	120 (1.6)
Due to SARS-CoV-2	0	0	0
Other	100 (2.7)	12 (0.3)	112 (1.5)

Percentages are based on the number of subjects in Safety Set.
[1] Subjects are considered to have completed the study if they complete the final visit at Day 759 (Month 25), 24 months following the last injection of investigational product.
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Table 14.1.1.2
Number of Subjects Randomized by Site
Randomization Set

Site Number	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
US300	178 (1.2)	179 (1.2)	357 (1.2)
US301	151 (1.0)	153 (1.0)	304 (1.0)
US302	147 (1.0)	146 (1.0)	293 (1.0)
US303	157 (1.0)	160 (1.1)	317 (1.0)
US304	149 (1.0)	151 (1.0)	300 (1.0)
US305	182 (1.2)	180 (1.2)	362 (1.2)
US306	154 (1.0)	156 (1.0)	310 (1.0)
US308	125 (0.8)	122 (0.8)	247 (0.8)
US309	151 (1.0)	148 (1.0)	299 (1.0)
US310	203 (1.3)	204 (1.3)	407 (1.3)
US311	229 (1.5)	227 (1.5)	456 (1.5)
US312	68 (0.4)	69 (0.5)	137 (0.5)
US313	78 (0.5)	79 (0.5)	157 (0.5)
US314	134 (0.9)	135 (0.9)	269 (0.9)
US315	252 (1.7)	251 (1.7)	503 (1.7)
US316	151 (1.0)	151 (1.0)	302 (1.0)
US317	227 (1.5)	228 (1.5)	455 (1.5)
US318	180 (1.2)	178 (1.2)	358 (1.2)
US319	455 (3.0)	457 (3.0)	912 (3.0)
US320	198 (1.3)	197 (1.3)	395 (1.3)
US321	205 (1.3)	206 (1.4)	411 (1.4)
US322	323 (2.1)	324 (2.1)	647 (2.1)
US323	86 (0.6)	87 (0.6)	173 (0.6)
US324	200 (1.3)	201 (1.3)	401 (1.3)
US325	351 (2.3)	348 (2.3)	699 (2.3)
US326	139 (0.9)	136 (0.9)	275 (0.9)
US327	181 (1.2)	183 (1.2)	364 (1.2)
US328	58 (0.4)	57 (0.4)	115 (0.4)

Percentages are based on the number of randomized subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010102.sas 21JUN2021 10:02

Table 14.1.1.2
Number of Subjects Randomized by Site
Randomization Set

Site Number	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
US329	212 (1.4)	212 (1.4)	424 (1.4)
US330	233 (1.5)	231 (1.5)	464 (1.5)
US331	280 (1.8)	281 (1.8)	561 (1.8)
US332	206 (1.4)	207 (1.4)	413 (1.4)
US333	49 (0.3)	50 (0.3)	99 (0.3)
US334	173 (1.1)	170 (1.1)	343 (1.1)
US335	290 (1.9)	291 (1.9)	581 (1.9)
US336	154 (1.0)	154 (1.0)	308 (1.0)
US337	219 (1.4)	217 (1.4)	436 (1.4)
US338	140 (0.9)	141 (0.9)	281 (0.9)
US339	176 (1.2)	174 (1.1)	350 (1.2)
US340	238 (1.6)	239 (1.6)	477 (1.6)
US341	189 (1.2)	189 (1.2)	378 (1.2)
US342	149 (1.0)	145 (1.0)	294 (1.0)
US343	316 (2.1)	316 (2.1)	632 (2.1)
US344	116 (0.8)	114 (0.7)	230 (0.8)
US345	210 (1.4)	211 (1.4)	421 (1.4)
US346	210 (1.4)	212 (1.4)	422 (1.4)
US347	64 (0.4)	62 (0.4)	126 (0.4)
US348	148 (1.0)	149 (1.0)	297 (1.0)
US349	149 (1.0)	147 (1.0)	296 (1.0)
US350	109 (0.7)	108 (0.7)	217 (0.7)
US351	152 (1.0)	152 (1.0)	304 (1.0)
US352	355 (2.3)	353 (2.3)	708 (2.3)
US353	125 (0.8)	125 (0.8)	250 (0.8)
US354	175 (1.2)	174 (1.1)	349 (1.1)
US355	219 (1.4)	221 (1.5)	440 (1.4)

Percentages are based on the number of randomized subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010102.sas 21JUN2021 10:02

Table 14.1.1.2
Number of Subjects Randomized by Site
Randomization Set

Site Number	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
US356	120 (0.8)	118 (0.8)	238 (0.8)
US357	196 (1.3)	194 (1.3)	390 (1.3)
US358	94 (0.6)	94 (0.6)	188 (0.6)
US359	123 (0.8)	124 (0.8)	247 (0.8)
US360	77 (0.5)	76 (0.5)	153 (0.5)
US361	42 (0.3)	41 (0.3)	83 (0.3)
US362	141 (0.9)	142 (0.9)	283 (0.9)
US363	76 (0.5)	76 (0.5)	152 (0.5)
US364	167 (1.1)	169 (1.1)	336 (1.1)
US365	28 (0.2)	28 (0.2)	56 (0.2)
US366	92 (0.6)	93 (0.6)	185 (0.6)
US367	200 (1.3)	203 (1.3)	403 (1.3)
US368	97 (0.6)	97 (0.6)	194 (0.6)
US369	86 (0.6)	89 (0.6)	175 (0.6)
US370	25 (0.2)	25 (0.2)	50 (0.2)
US371	123 (0.8)	125 (0.8)	248 (0.8)
US372	217 (1.4)	215 (1.4)	432 (1.4)
US373	201 (1.3)	199 (1.3)	400 (1.3)
US374	221 (1.5)	222 (1.5)	443 (1.5)
US375	200 (1.3)	200 (1.3)	400 (1.3)
US376	143 (0.9)	144 (0.9)	287 (0.9)
US377	136 (0.9)	134 (0.9)	270 (0.9)
US378	90 (0.6)	92 (0.6)	182 (0.6)
US379	50 (0.3)	49 (0.3)	99 (0.3)
US380	127 (0.8)	129 (0.8)	256 (0.8)
US381	162 (1.1)	159 (1.0)	321 (1.1)
US382	228 (1.5)	232 (1.5)	460 (1.5)

Percentages are based on the number of randomized subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010102.sas 21JUN2021 10:02

Table 14.1.1.2
Number of Subjects Randomized by Site
Randomization Set

Site Number	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
US383	134 (0.9)	135 (0.9)	269 (0.9)
US384	28 (0.2)	29 (0.2)	57 (0.2)
US385	96 (0.6)	98 (0.6)	194 (0.6)
US386	135 (0.9)	136 (0.9)	271 (0.9)
US387	247 (1.6)	245 (1.6)	492 (1.6)
US388	31 (0.2)	29 (0.2)	60 (0.2)
US389	37 (0.2)	38 (0.2)	75 (0.2)
US390	63 (0.4)	64 (0.4)	127 (0.4)
US391	96 (0.6)	96 (0.6)	192 (0.6)
US392	74 (0.5)	74 (0.5)	148 (0.5)
US393	132 (0.9)	130 (0.9)	262 (0.9)
US394	74 (0.5)	74 (0.5)	148 (0.5)
US395	92 (0.6)	90 (0.6)	182 (0.6)
US396	50 (0.3)	48 (0.3)	98 (0.3)
US397	97 (0.6)	100 (0.7)	197 (0.6)
US398	128 (0.8)	132 (0.9)	260 (0.9)
US399	62 (0.4)	64 (0.4)	126 (0.4)

Percentages are based on the number of randomized subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010102.sas 21JUN2021 10:02

Table 14.1.1.3
Number of Subjects Randomized by Stratum
Randomization Set

Stratum	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
IRT Randomization Stratum			
>=18 and <65 Years and Not at Risk	8905 (58.6)	8909 (58.6)	17814 (58.6)
>=18 and <65 Years and at Risk	2542 (16.7)	2535 (16.7)	5077 (16.7)
>=65 Years	3759 (24.7)	3765 (24.8)	7524 (24.7)
CRF Derived Stratum [1]			
>=18 and <65 Years and Not at Risk	9117 (60.0)	9115 (59.9)	18232 (59.9)
>=18 and <65 Years and at Risk	2326 (15.3)	2324 (15.3)	4650 (15.3)
>=65 Years	3763 (24.7)	3770 (24.8)	7533 (24.8)

Percentages are based on the number of randomized subjects.
[1] Stratification derived from age at screening and presence of risk factors for severe COVID-19.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010103.sas 21JUN2021 10:03

Table 14.1.1.4
Concordance of IRT Randomization Stratum and CRF Derived Stratum
Randomization Set

Treatment Group: Overall (N=30415)

	CRF Derived Stratum [1]			
IRT Randomization Stratum	>=18 and <65 Years and Not at Risk n (%)	>=18 and <65 Years and at Risk n (%)	>=65 Years n (%)	Total n (%)
>=18 and <65 Years and Not at Risk	17542 (98.5)	270 (1.5)	2 (<0.1)	17814 (58.6)
>=18 and <65 Years and at Risk	690 (13.6)	4378 (86.2)	9 (0.2)	5077 (16.7)
>=65 Years	0	2 (<0.1)	7522 (>99.9)	7524 (24.7)
Total	18232	4650	7533	30415

Percentages for the first 3 columns are based on the number in the cell on the Total column, and the percentages for Total column are based on the number in the cell on the Total row.
[1] Stratification derived from age at screening and presence of risk factors for severe COVID-19.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010104.sas 23JUN2021 02:44

Table 14.1.1.4
Concordance of IRT Randomization Stratum and CRF Derived Stratum
Randomization Set

Treatment Group: Placebo (N=15206)

	CRF Derived Stratum [1]			
IRT Randomization Stratum	>=18 and <65 Years and Not at Risk n (%)	>=18 and <65 Years and at Risk n (%)	>=65 Years n (%)	Total n (%)
>=18 and <65 Years and Not at Risk	8765 (98.4)	138 (1.5)	2 (<0.1)	8905 (58.6)
>=18 and <65 Years and at Risk	352 (13.8)	2187 (86.0)	3 (0.1)	2542 (16.7)
>=65 Years	0	1 (<0.1)	3758(>99.9)	3759 (24.7)
Total	9117	2326	3763	15206

Percentages for the first 3 columns are based on the number in the cell on the Total column, and the percentages for Total column are based on the number in the cell on the Total row.
[1] Stratification derived from age at screening and presence of risk factors for severe COVID-19.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010104.sas 23JUN2021 02:44

Table 14.1.1.4
Concordance of IRT Randomization Stratum and CRF Derived Stratum
Randomization Set

Treatment Group: mRNA-1273 (N=15209)

	CRF Derived Stratum [1]			
IRT Randomization Stratum	>=18 and <65 Years and Not at Risk n (%)	>=18 and <65 Years and at Risk n (%)	>=65 Years n (%)	Total n (%)
>=18 and <65 Years and Not at Risk	8777 (98.5)	132 (1.5)	0	8909 (58.6)
>=18 and <65 Years and at Risk	338 (13.3)	2191 (86.4)	6 (0.2)	2535 (16.7)
>=65 Years	0	1 (<0.1)	3764 (>99.9)	3765 (24.8)
Total	9115	2324	3770	15209

Percentages for the first 3 columns are based on the number in the cell on the Total column, and the percentages for Total column are based on the number in the cell on the Total row.
[1] Stratification derived from age at screening and presence of risk factors for severe COVID-19.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010104.sas 23JUN2021 02:44

Table 14.1.1.5
Reasons for Screen Failure Subjects
Subjects Screened

	Subjects Screened (N=32102) n (%)
Number of Screen Failure Subjects	1679 (5.2)
Reason for Screen Failure [1]	
Withdrew Consent	70 (4.2)
Inclusion/Exclusion	1483 (88.3)
Cohort Full	32 (1.9)
Other	94 (5.6)

Percentages are based on the number of subjects screened.
[1] Percentages are based on the number of screen failure subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010105.sas 21JUN2021 16:05

Table 14.1.1.6
Subjects with Major Protocol Deviations
Randomization Set

Deviation Type	Placebo (N=15206) n (%)	mRNA-1273 (N=15209) n (%)	Total (N=30415) n (%)
Accidental Unblinding	2 (<0.1)	3 (<0.1)	5 (<0.1)
Concomitant Medication	177 (1.2)	130 (0.9)	307 (1.0)
Data Privacy	73 (0.5)	19 (0.1)	92 (0.3)
Exclusion Criteria	21 (0.1)	23 (0.2)	44 (0.1)
ICF Process/Timing	1125 (7.4)	1109 (7.3)	2234 (7.3)
Inclusion Criteria	16 (0.1)	15 (<0.1)	31 (0.1)
Inv Adequate Resources	1 (<0.1)	1 (<0.1)	2 (<0.1)
Inv Communication with Ethics	29 (0.2)	4 (<0.1)	33 (0.1)
Inv Oversight	3 (<0.1)	0	3 (<0.1)
Inv Qualifications/Agreements	8 (<0.1)	2 (<0.1)	10 (<0.1)
Inv Randomization/Unblinding	1 (<0.1)	2 (<0.1)	3 (<0.1)
Inv Record Keeping Source Docs	2 (<0.1)	2 (<0.1)	4 (<0.1)
Inv Safety Reporting (CRF)	62 (0.4)	10 (<0.1)	72 (0.2)
Inv Safety Rptg (Reg/Sponsor)	272 (1.8)	37 (0.2)	309 (1.0)
Inv Subject Medical Care	1 (<0.1)	0	1 (<0.1)
Missing Endpoint Assessments	2471 (16.3)	2121 (13.9)	4592 (15.1)
Study Procedures/Assessments	927 (6.1)	536 (3.5)	1463 (4.8)
Study Treatment Admin/Dispense	1108 (7.3)	551 (3.6)	1659 (5.5)
Study Treatment Randomization	604 (4.0)	566 (3.7)	1170 (3.8)
Visit Scheduling	897 (5.9)	786 (5.2)	1683 (5.5)
Withdrawal/Term Criteria	3 (<0.1)	2 (<0.1)	5 (<0.1)

A subject is counted once if the subject had multiple protocol deviations within one protocol deviation type.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010106.sas 10JUN2021 10:39

Table 14.1.2.1
Number of Subjects in Each Analysis Set by Baseline SARS-CoV-2 Status
Randomization Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
Randomization Set [1]	14745	14746	29491	337	347	684	15206	15209	30415
Full Analysis Set, n (%) [1]	14745 (100)	14746 (100)	29491 (100)	337 (100)	347 (100)	684 (100)	15166 (99.7)	15180 (99.8)	30346 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	14745 (100)	14746 (100)	29491 (100)	0	0	0	14745 (97.0)	14746 (97.0)	29491 (97.0)
Per-Protocol (PP) Set, n (%) [1]	14164 (96.1)	14287 (96.9)	28451 (96.5)	0	0	0	14164 (93.1)	14287 (93.9)	28451 (93.5)
Per-Protocol Random Subcohort for Immunogenicity, n (%) [1]	142 (1.0)	1055 (7.2)	1197 (4.1)	130 (38.6)	130 (37.5)	260 (38.0)	272 (1.8)	1185 (7.8)	1457 (4.8)
Safety Set [2]	14741	14750	29491	337	347	684	15162	15184	30346
Solicited Safety Set, n (%) [2]	14738 (>99.9)	14745 (>99.9)	29483 (>99.9)	337 (100)	347 (100)	684 (100)	15159 (>99.9)	15179 (>99.9)	30338 (>99.9)
First Injection Solicited Safety Set, n (%) [2]	14730 (>99.9)	14733 (99.9)	29463 (>99.9)	337 (100)	346 (99.7)	683 (99.9)	15151 (>99.9)	15166 (99.9)	30317 (>99.9)
Second Injection Solicited Safety Set, n (%) [2]	14267 (96.8)	14378 (97.5)	28645 (97.1)	233 (69.1)	232 (66.9)	465 (68.0)	14578 (96.1)	14691 (96.8)	29269 (96.5)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010201.sas 21JUN2021 10:06

Table 14.1.2.2
Number of Subjects in Each Analysis Set by Age Group
Randomization Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total	Placebo	mRNA-1273	Total
Randomization Set [1]	11443	11439	22882	3763	3770	7533	15206	15209	30415
Full Analysis Set, n (%) [1]	11413 (99.7)	11413 (99.8)	22826 (99.8)	3753 (99.7)	3767 (>99.9)	7520 (99.8)	15166 (99.7)	15180 (99.8)	30346 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	11046 (96.5)	11037 (96.5)	22083 (96.5)	3699 (98.3)	3709 (98.4)	7408 (98.3)	14745 (97.0)	14746 (97.0)	29491 (97.0)
Per-Protocol (PP) Set, n (%) [1]	10569 (92.4)	10661 (93.2)	21230 (92.8)	3595 (95.5)	3626 (96.2)	7221 (95.9)	14164 (93.1)	14287 (93.9)	28451 (93.5)
Per-Protocol Random Subcohort for Immunogenicity, n (%) [1]	204 (1.8)	807 (7.1)	1011 (4.4)	68 (1.8)	378 (10.0)	446 (5.9)	272 (1.8)	1185 (7.8)	1457 (4.8)
Safety Set [2]	11411	11415	22826	3751	3769	7520	15162	15184	30346
Solicited Safety Set, n (%) [2]	11408 (>99.9)	11413 (>99.9)	22821 (>99.9)	3751 (100)	3766 (>99.9)	7517 (>99.9)	15159 (>99.9)	15179 (>99.9)	30338 (>99.9)
First Injection Solicited Safety Set, n (%) [2]	11402 (>99.9)	11406 (>99.9)	22808 (>99.9)	3749 (>99.9)	3760 (99.8)	7509 (99.9)	15151 (>99.9)	15166 (99.9)	30317 (>99.9)
Second Injection Solicited Safety Set, n (%) [2]	10929 (95.8)	11000 (96.4)	21929 (96.1)	3649 (97.3)	3691 (97.9)	7340 (97.6)	14578 (96.1)	14691 (96.8)	29269 (96.5)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010202.sas 10JUN2021 10:40

Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

Randomization Stratum: Overall

	Placebo	mRNA-1273	Total
Randomization Set [1]	15206	15209	30415
Full Analysis Set, n (%) [1]	15166 (99.7)	15180 (99.8)	30346 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	14745 (97.0)	14746 (97.0)	29491 (97.0)
Per-Protocol (PP) Set, n (%) [1]	14164 (93.1)	14287 (93.9)	28451 (93.5)
Per-Protocol Random Subcohort for Immunogenicity, n (%) [1]	272 (1.8)	1185 (7.8)	1457 (4.8)
Safety Set [2]	15162	15184	30346
Solicited Safety Set, n (%) [2]	15159(>99.9)	15179(>99.9)	30338(>99.9)
First Injection Solicited Safety Set, n (%) [2]	15151(>99.9)	15166 (99.9)	30317(>99.9)
Second Injection Solicited Safety Set, n (%) [2]	14578 (96.1)	14691 (96.8)	29269 (96.5)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010203.sas 21JUN2021 10:14

Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo	mRNA-1273	Total
Randomization Set [1]	8905	8909	17814
Full Analysis Set, n (%) [1]	8882 (99.7)	8888 (99.8)	17770 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	8608 (96.7)	8575 (96.3)	17183 (96.5)
Per-Protocol (PP) Set, n (%) [1]	8242 (92.6)	8271 (92.8)	16513 (92.7)
Per-Protocol Random Subcohort for Immunogenicity, n (%) [1]	129 (1.4)	448 (5.0)	577 (3.2)
Safety Set [2]	8880	8890	17770
Solicited Safety Set, n (%) [2]	8879(>99.9)	8889(>99.9)	17768(>99.9)
First Injection Solicited Safety Set, n (%) [2]	8874(>99.9)	8882(>99.9)	17756(>99.9)
Second Injection Solicited Safety Set, n (%) [2]	8507 (95.8)	8545 (96.1)	17052 (96.0)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010203.sas 21JUN2021 10:14

Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo	mRNA-1273	Total
Randomization Set [1]	2542	2535	5077
Full Analysis Set, n (%) [1]	2535 (99.7)	2530 (99.8)	5065 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	2442 (96.1)	2467 (97.3)	4909 (96.7)
Per-Protocol (PP) Set, n (%) [1]	2331 (91.7)	2395 (94.5)	4726 (93.1)
Per-Protocol Random Subcohort for Immunogenicity, n (%) [1]	75 (3.0)	359 (14.2)	434 (8.5)
Safety Set [2]	2535	2530	5065
Solicited Safety Set, n (%) [2]	2533(>99.9)	2529(>99.9)	5062(>99.9)
First Injection Solicited Safety Set, n (%) [2]	2532 (99.9)	2529(>99.9)	5061(>99.9)
Second Injection Solicited Safety Set, n (%) [2]	2426 (95.7)	2460 (97.2)	4886 (96.5)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010203.sas 21JUN2021 10:14

Table 14.1.2.3
Number of Subjects in Each Analysis Set by Randomization Stratum
Randomization Set

Randomization Stratum: >=65 Years

	Placebo	mRNA-1273	Total
Randomization Set [1]	3759	3765	7524
Full Analysis Set, n (%) [1]	3749 (99.7)	3762(>99.9)	7511 (99.8)
Modified Intent-to-Treat (mITT) Set, n (%) [1]	3695 (98.3)	3704 (98.4)	7399 (98.3)
Per-Protocol (PP) Set, n (%) [1]	3591 (95.5)	3621 (96.2)	7212 (95.9)
Per-Protocol Random Subcohort for Immunogenicity, n (%) [1]	68 (1.8)	378 (10.0)	446 (5.9)
Safety Set [2]	3747	3764	7511
Solicited Safety Set, n (%) [2]	3747 (100)	3761(>99.9)	7508(>99.9)
First Injection Solicited Safety Set, n (%) [2]	3745(>99.9)	3755 (99.8)	7500 (99.9)
Second Injection Solicited Safety Set, n (%) [2]	3645 (97.3)	3686 (97.9)	7331 (97.6)

[1] Numbers are based on planned treatment group and percentages are based on the number of randomized subjects.
[2] Numbers are based on actual treatment group and percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010203.sas 21JUN2021 10:14

Table 14.1.2.4
Summary of Reasons for Exclusion from Per-Protocol Set
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Full Analysis Set	15166	15180	30346
Baseline SARS-CoV-2 Status Positive or Missing, n (%)	421 (2.8)	434 (2.9)	855 (2.8)
Modified Intent-to-Treat (mITT) Set, n (%)	14745 (97.2)	14746 (97.1)	29491 (97.2)
Per-Protocol (PP) Set, n (%)	14164 (93.4)	14287 (94.1)	28451 (93.8)
Excluded from Per-Protocol Set, n (%)	581 (3.8)	459 (3.0)	1040 (3.4)
Reasons for Exclusion, n (%) [1]			
Received Incorrect Study Vaccination	7 (<0.1)	6 (<0.1)	13 (<0.1)
Discontinued Study or Study Vaccination before Receiving Second Injection	425 (2.8)	334 (2.2)	759 (2.5)
Received Second Injection out of Window for PP Set	119 (0.8)	102 (0.7)	221 (0.7)
Not Received Second Injection and Passed the Window for PP Set	0	0	0
Other Major Protocol Deviation Impacting Critical Data	30 (0.2)	17 (0.1)	47 (0.2)

[1] A subject who has multiple reasons for exclusion is listed under the reason that appears earliest.
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Table 14.1.2.4
Summary of Reasons for Exclusion from Per-Protocol Set
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Reasons for Exclusion Based on Protocol Deviation Review, n (%)			
Did not Receive Vaccination #2 per Schedule, Had Major Protocol Deviations	6 (<0.1)	4 (<0.1)	10 (<0.1)
Had Major Protocol Deviations, Received Vaccination #2 out of Window	0	1 (<0.1)	1 (<0.1)
Did not Receive Vaccination #2 per Schedule	419 (2.8)	330 (2.2)	749 (2.5)
Had Major Protocol Deviations	30 (0.2)	17 (0.1)	47 (0.2)
Received Incorrect Vaccination in Blinded Phase	7 (<0.1)	6 (<0.1)	13 (<0.1)
Received Vaccination #2 out of Window	119 (0.8)	101 (0.7)	220 (0.7)

[1] A subject who has multiple reasons for exclusion is listed under the reason that appears earliest.
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Table 14.1.2.5
Summary of Reasons for Exclusion from Per-Protocol Random Subcohort for Immunogenicity
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Subjects Selected for Random Subcohort	335	1256	1591
Per-Protocol Random Subcohort for Immunogenicity, n (%)	272 (81.2)	1185 (94.3)	1457 (91.6)
Excluded from Per-Protocol Random Subcohort for Immunogenicity, n (%)	63 (18.8)	71 (5.7)	134 (8.4)
Reasons for Exclusion, n (%) [1]			
Received Incorrect Vaccination	1 (0.3)	0	1 (<0.1)
Received Dose 2 out of Window for Per-Protocol Set	3 (0.9)	5 (0.4)	8 (0.5)
Did not Receive Dose 2 per schedule	52 (15.5)	44 (3.5)	96 (6.0)
Human Immunodeficiency Virus Infection	4 (1.2)	21 (1.7)	25 (1.6)
Had Other Major Protocol Deviations	3 (0.9)	1 (<0.1)	4 (0.3)

Percentages are based on the number of subjects in random subcohort.
[1] A subject who has multiple reasons for exclusion is listed under the reason that appears earliest.
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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age at Screening (Years)									
n	14745	14746	29491	337	347	684	15166	15180	30346
Mean	51.5	51.5	51.5	45.1	44.1	44.6	51.3	51.4	51.4
(SD)	(15.58)	(15.47)	(15.53)	(15.47)	(15.33)	(15.40)	(15.60)	(15.50)	(15.55)
Median	52.0	53.0	53.0	46.0	44.0	45.0	52.0	53.0	52.0
Min, Max	18, 95	18, 95	18, 95	18, 83	18, 84	18, 84	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	11046	11037	22083	303	311	614	11413	11413	22826
	(74.9)	(74.8)	(74.9)	(89.9)	(89.6)	(89.8)	(75.3)	(75.2)	(75.2)
Mean	45.0	45.2	45.1	42.1	41.0	41.5	45.0	45.1	45.0
(SD)	(12.26)	(12.32)	(12.29)	(13.17)	(12.90)	(13.03)	(12.30)	(12.35)	(12.33)
Median	46.0	46.0	46.0	44.0	42.0	43.0	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64
>=65 Years	3699	3709	7408	34	36	70	3753	3767	7520
	(25.1)	(25.2)	(25.1)	(10.1)	(10.4)	(10.2)	(24.7)	(24.8)	(24.8)
Mean	70.7	70.4	70.6	71.9	70.8	71.3	70.7	70.4	70.6
(SD)	(4.88)	(4.66)	(4.77)	(4.86)	(5.56)	(5.23)	(4.88)	(4.66)	(4.77)
Median	70.0	69.0	70.0	72.0	69.5	70.0	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95	65, 83	65, 84	65, 84	65, 95	65, 95	65, 95

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11046 (74.9)	11037 (74.8)	22083 (74.9)	303 (89.9)	311 (89.6)	614 (89.8)	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <70 Years	1795 (12.2)	1874 (12.7)	3669 (12.4)	12 (3.6)	18 (5.2)	30 (4.4)	1818 (12.0)	1905 (12.5)	3723 (12.3)
>=70 and <75 Years	1179 (8.0)	1187 (8.0)	2366 (8.0)	10 (3.0)	11 (3.2)	21 (3.1)	1194 (7.9)	1205 (7.9)	2399 (7.9)
>=75 and <80 Years	494 (3.4)	461 (3.1)	955 (3.2)	10 (3.0)	3 (0.9)	13 (1.9)	507 (3.3)	466 (3.1)	973 (3.2)
>=80 Years	231 (1.6)	187 (1.3)	418 (1.4)	2 (0.6)	4 (1.2)	6 (0.9)	234 (1.5)	191 (1.3)	425 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11046 (74.9)	11037 (74.8)	22083 (74.9)	303 (89.9)	311 (89.6)	614 (89.8)	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <75 Years	2974 (20.2)	3061 (20.8)	6035 (20.5)	22 (6.5)	29 (8.4)	51 (7.5)	3012 (19.9)	3110 (20.5)	6122 (20.2)
>=75 and <85 Years	676 (4.6)	607 (4.1)	1283 (4.4)	12 (3.6)	7 (2.0)	19 (2.8)	692 (4.6)	616 (4.1)	1308 (4.3)
>=85 Years	49 (0.3)	41 (0.3)	90 (0.3)	0	0	0	49 (0.3)	41 (0.3)	90 (0.3)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8608 (58.4)	8575 (58.2)	17183 (58.3)	236 (70.0)	263 (75.8)	499 (73.0)	8882 (58.6)	8888 (58.6)	17770 (58.6)
>=18 and <65 Years and at Risk	2442 (16.6)	2467 (16.7)	4909 (16.6)	67 (19.9)	48 (13.8)	115 (16.8)	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	3695 (25.1)	3704 (25.1)	7399 (25.1)	34 (10.1)	36 (10.4)	70 (10.2)	3749 (24.7)	3762 (24.8)	7511 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	727 (4.9)	702 (4.8)	1429 (4.8)	12 (3.6)	8 (2.3)	20 (2.9)	749 (4.9)	712 (4.7)	1461 (4.8)
Significant Cardiac Disease	722 (4.9)	745 (5.1)	1467 (5.0)	12 (3.6)	11 (3.2)	23 (3.4)	742 (4.9)	762 (5.0)	1504 (5.0)
Severe Obesity	1024 (6.9)	1041 (7.1)	2065 (7.0)	25 (7.4)	27 (7.8)	52 (7.6)	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	1423 (9.7)	1431 (9.7)	2854 (9.7)	24 (7.1)	24 (6.9)	48 (7.0)	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver Disease	95 (0.6)	102 (0.7)	197 (0.7)	1 (0.3)	1 (0.3)	2 (0.3)	96 (0.6)	104 (0.7)	200 (0.7)
Human Immunodeficiency Virus Infection	84 (0.6)	88 (0.6)	172 (0.6)	7 (2.1)	4 (1.2)	11 (1.6)	91 (0.6)	94 (0.6)	185 (0.6)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	3355 (22.8)	3375 (22.9)	6730 (22.8)	71 (21.1)	57 (16.4)	128 (18.7)	3457 (22.8)	3448 (22.7)	6905 (22.8)
One Risk Factor for Severe COVID-19	2728 (18.5)	2733 (18.5)	5461 (18.5)	62 (18.4)	43 (12.4)	105 (15.4)	2815 (18.6)	2791 (18.4)	5606 (18.5)
Two or More Risk Factors for Severe COVID-19	627 (4.3)	642 (4.4)	1269 (4.3)	9 (2.7)	14 (4.0)	23 (3.4)	642 (4.2)	657 (4.3)	1299 (4.3)
No	11390 (77.2)	11371 (77.1)	22761 (77.2)	266 (78.9)	290 (83.6)	556 (81.3)	11709 (77.2)	11732 (77.3)	23441 (77.2)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	8810 (59.7)	8776 (59.5)	17586 (59.6)	239 (70.9)	263 (75.8)	502 (73.4)	9091 (59.9)	9093 (59.9)	18184 (59.9)
>=18 and <65 Years and at Risk	2236 (15.2)	2261 (15.3)	4497 (15.2)	64 (19.0)	48 (13.8)	112 (16.4)	2322 (15.3)	2320 (15.3)	4642 (15.3)
>=65 Years and Not at Risk	2580 (17.5)	2595 (17.6)	5175 (17.5)	27 (8.0)	27 (7.8)	54 (7.9)	2618 (17.3)	2639 (17.4)	5257 (17.3)
>=65 Years and at Risk	1119 (7.6)	1114 (7.6)	2233 (7.6)	7 (2.1)	9 (2.6)	16 (2.3)	1135 (7.5)	1128 (7.4)	2263 (7.5)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Baseline RT-PCR Results, n (%)									
Negative	14745 (100)	14746 (100)	29491 (100)	238 (70.6)	258 (74.4)	496 (72.5)	14995 (98.9)	15013 (98.9)	30008 (98.9)
Positive	0	0	0	95 (28.2)	88 (25.4)	183 (26.8)	95 (0.6)	88 (0.6)	183 (0.6)
Missing	0	0	0	4 (1.2)	1 (0.3)	5 (0.7)	76 (0.5)	79 (0.5)	155 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	14745 (100)	14746 (100)	29491 (100)	34 (10.1)	38 (11.0)	72 (10.5)	14844 (97.9)	14847 (97.8)	29691 (97.8)
Positive	0	0	0	303 (89.9)	309 (89.0)	612 (89.5)	303 (2.0)	309 (2.0)	612 (2.0)
Missing	0	0	0	0	0	0	19 (0.1)	24 (0.2)	43 (0.1)
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	14745 (100)	14746 (100)	29491 (100)	0	0	0	14745 (97.2)	14746 (97.1)	29491 (97.2)
Positive	0	0	0	337 (100)	347 (100)	684 (100)	337 (2.2)	347 (2.3)	684 (2.3)
Missing	0	0	0	0	0	0	84 (0.6)	87 (0.6)	171 (0.6)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Sex, n (%)									
Male	7820 (53.0)	7678 (52.1)	15498 (52.6)	181 (53.7)	195 (56.2)	376 (55.0)	8057 (53.1)	7917 (52.2)	15974 (52.6)
Female	6925 (47.0)	7068 (47.9)	13993 (47.4)	156 (46.3)	152 (43.8)	308 (45.0)	7109 (46.9)	7263 (47.8)	14372 (47.4)
Race, n (%)									
White	11708 (79.4)	11738 (79.6)	23446 (79.5)	225 (66.8)	219 (63.1)	444 (64.9)	12001 (79.1)	12031 (79.3)	24032 (79.2)
Black or African American	1431 (9.7)	1463 (9.9)	2894 (9.8)	90 (26.7)	99 (28.5)	189 (27.6)	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	730 (5.0)	645 (4.4)	1375 (4.7)	5 (1.5)	10 (2.9)	15 (2.2)	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	119 (0.8)	113 (0.8)	232 (0.8)	2 (0.6)	0	2 (0.3)	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	31 (0.2)	36 (0.2)	67 (0.2)	1 (0.3)	0	1 (0.1)	32 (0.2)	36 (0.2)	68 (0.2)
Multiracial	316 (2.1)	310 (2.1)	626 (2.1)	2 (0.6)	5 (1.4)	7 (1.0)	319 (2.1)	319 (2.1)	638 (2.1)
Other	285 (1.9)	288 (2.0)	573 (1.9)	8 (2.4)	9 (2.6)	17 (2.5)	294 (1.9)	299 (2.0)	593 (2.0)
Not Reported	70 (0.5)	92 (0.6)	162 (0.5)	4 (1.2)	4 (1.2)	8 (1.2)	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	55 (0.4)	61 (0.4)	116 (0.4)	0	1 (0.3)	1 (0.1)	55 (0.4)	62 (0.4)	117 (0.4)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Ethnicity, n (%)									
Hispanic or Latino	2947 (20.0)	2957 (20.1)	5904 (20.0)	151 (44.8)	146 (42.1)	297 (43.4)	3109 (20.5)	3121 (20.6)	6230 (20.5)
Not Hispanic or Latino	11665 (79.1)	11650 (79.0)	23315 (79.1)	184 (54.6)	199 (57.3)	383 (56.0)	11921 (78.6)	11917 (78.5)	23838 (78.6)
Not Reported	80 (0.5)	102 (0.7)	182 (0.6)	2 (0.6)	2 (0.6)	4 (0.6)	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	53 (0.4)	37 (0.3)	90 (0.3)	0	0	0	53 (0.3)	37 (0.2)	90 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	4388 (29.8)	4408 (29.9)	8796 (29.8)	223 (66.2)	222 (64.0)	445 (65.1)	4631 (30.5)	4653 (30.7)	9284 (30.6)
Non-minority	10331 (70.1)	10312 (69.9)	20643 (70.0)	114 (33.8)	125 (36.0)	239 (34.9)	10509 (69.3)	10501 (69.2)	21010 (69.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)	0	0	0	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	9303 (63.1)	9364 (63.5)	18667 (63.3)	107 (31.8)	110 (31.7)	217 (31.7)	9468 (62.4)	9533 (62.8)	19001 (62.6)
Communities of Color	5416 (36.7)	5356 (36.3)	10772 (36.5)	230 (68.2)	237 (68.3)	467 (68.3)	5672 (37.4)	5621 (37.0)	11293 (37.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)	0	0	0	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Weight (kg)									
n	14662	14662	29324	337	346	683	15083	15095	30178
Mean	85.85	85.67	85.76	85.68	87.59	86.65	85.88	85.71	85.79
(SD)	(21.617)	(21.965)	(21.792)	(21.185)	(22.224)	(21.722)	(21.629)	(21.951)	(21.790)
Median	83.00	83.00	83.00	82.10	84.23	83.00	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4	42.7, 182.4	43.2, 179.0	42.7, 182.4	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)									
n	14660	14663	29323	337	346	683	15081	15096	30177
Mean	170.91	170.74	170.83	169.53	170.03	169.78	170.88	170.73	170.81
(SD)	(10.033)	(9.932)	(9.983)	(10.212)	(9.891)	(10.046)	(10.040)	(9.936)	(9.988)
Median	170.50	170.18	170.20	170.00	170.00	170.00	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5	142.2, 198.1	147.3, 196.0	142.2, 198.1	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	14660	14659	29319	337	346	683	15081	15092	30173
Mean	29.30	29.30	29.30	29.74	30.22	29.98	29.32	29.32	29.32
(SD)	(6.670)	(6.843)	(6.757)	(6.558)	(6.990)	(6.780)	(6.677)	(6.838)	(6.757)
Median	28.12	28.12	28.12	28.52	28.96	28.83	28.13	28.13	28.13
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1	15.7, 59.2	15.8, 60.5	15.7, 60.5	10.3, 72.7	9.8, 86.1	9.8, 86.1

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Body Mass Index Subgroup, n (%)									
< 30 kg/m^2	9059	9020	18079	201	196	397	9303	9273	18576
	(61.4)	(61.2)	(61.3)	(59.6)	(56.5)	(58.0)	(61.3)	(61.1)	(61.2)
>=30 kg/m^2	5601	5639	11240	136	150	286	5778	5819	11597
	(38.0)	(38.2)	(38.1)	(40.4)	(43.2)	(41.8)	(38.1)	(38.3)	(38.2)
Missing	85	87	172	0	1	1	85	88	173
	(0.6)	(0.6)	(0.6)		(0.3)	(0.1)	(0.6)	(0.6)	(0.6)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Occupational Risk, n (%) [2]	12173	12115	24288	306	306	612	12551	12496	25047
	(82.6)	(82.2)	(82.4)	(90.8)	(88.2)	(89.5)	(82.8)	(82.3)	(82.5)
Healthcare Workers	3757	3721	7478	67	64	131	3843	3806	7649
	(25.5)	(25.2)	(25.4)	(19.9)	(18.4)	(19.2)	(25.3)	(25.1)	(25.2)
Emergency Response	283	294	577	11	6	17	296	302	598
	(1.9)	(2.0)	(2.0)	(3.3)	(1.7)	(2.5)	(2.0)	(2.0)	(2.0)
Retail or Restaurant Operations	939	916	1855	38	34	72	981	957	1938
	(6.4)	(6.2)	(6.3)	(11.3)	(9.8)	(10.5)	(6.5)	(6.3)	(6.4)
Manufacturing and Production Operations	410	404	814	10	22	32	421	426	847
	(2.8)	(2.7)	(2.8)	(3.0)	(6.3)	(4.7)	(2.8)	(2.8)	(2.8)
Warehouse Shipping and Fulfillment Centers	162	180	342	12	9	21	175	190	365
	(1.1)	(1.2)	(1.2)	(3.6)	(2.6)	(3.1)	(1.2)	(1.3)	(1.2)
Transportation and Delivery Services	456	453	909	20	28	48	480	484	964
	(3.1)	(3.1)	(3.1)	(5.9)	(8.1)	(7.0)	(3.2)	(3.2)	(3.2)
Border Protection and Military Personnel	68	66	134	1	1	2	69	68	137
	(0.5)	(0.4)	(0.5)	(0.3)	(0.3)	(0.3)	(0.5)	(0.4)	(0.5)
Personal Care and In-Home Services	439	442	881	26	28	54	468	472	940
	(3.0)	(3.0)	(3.0)	(7.7)	(8.1)	(7.9)	(3.1)	(3.1)	(3.1)
Hospitality and Tourism Workers	208	226	434	17	11	28	227	238	465
	(1.4)	(1.5)	(1.5)	(5.0)	(3.2)	(4.1)	(1.5)	(1.6)	(1.5)
Pastoral, Social or Public Health Workers	497	520	1017	6	11	17	504	535	1039
	(3.4)	(3.5)	(3.4)	(1.8)	(3.2)	(2.5)	(3.3)	(3.5)	(3.4)
Educators and Students	1522	1514	3036	25	29	54	1557	1551	3108
	(10.3)	(10.3)	(10.3)	(7.4)	(8.4)	(7.9)	(10.3)	(10.2)	(10.2)
Other	4691	4715	9406	105	102	207	4830	4850	9680
	(31.8)	(32.0)	(31.9)	(31.2)	(29.4)	(30.3)	(31.8)	(31.9)	(31.9)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Location and Living Circumstances Risk, n (%) [2]	12322 (83.6)	12354 (83.8)	24676 (83.7)	307 (91.1)	313 (90.2)	620 (90.6)	12689 (83.7)	12732 (83.9)	25421 (83.8)
Resides in Nursing Home or Assisted Living Facility	28 (0.2)	35 (0.2)	63 (0.2)	1 (0.3)	0	1 (0.1)	29 (0.2)	35 (0.2)	64 (0.2)
Resides in Multi-Family Dwelling	396 (2.7)	448 (3.0)	844 (2.9)	13 (3.9)	14 (4.0)	27 (3.9)	413 (2.7)	463 (3.1)	876 (2.9)
Resides in High Density Housing	1240 (8.4)	1226 (8.3)	2466 (8.4)	68 (20.2)	62 (17.9)	130 (19.0)	1313 (8.7)	1291 (8.5)	2604 (8.6)
Resides in Low Density, Multi-Family Setting	1426 (9.7)	1419 (9.6)	2845 (9.6)	63 (18.7)	68 (19.6)	131 (19.2)	1492 (9.8)	1492 (9.8)	2984 (9.8)
Resides in a Single Family Home	8228 (55.8)	8205 (55.6)	16433 (55.7)	139 (41.2)	141 (40.6)	280 (40.9)	8410 (55.5)	8398 (55.3)	16808 (55.4)
Other	2113 (14.3)	2135 (14.5)	4248 (14.4)	51 (15.1)	52 (15.0)	103 (15.1)	2176 (14.3)	2197 (14.5)	4373 (14.4)

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Table 14.1.3.1.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Full Analysis Set

Percentages are based on the number of subjects in Full Analysis Set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age at Screening (Years)									
n	11413	11413	22826	3753	3767	7520	15166	15180	30346
Mean	45.0	45.1	45.0	70.7	70.4	70.6	51.3	51.4	51.4
(SD)	(12.30)	(12.35)	(12.33)	(4.88)	(4.66)	(4.77)	(15.60)	(15.50)	(15.55)
Median	46.0	46.0	46.0	70.0	69.0	70.0	52.0	53.0	52.0
Min, Max	18, 64	18, 64	18, 64	65, 95	65, 95	65, 95	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	11413 (100)	11413 (100)	22826 (100)	0	0	0	11413 (75.3)	11413 (75.2)	22826 (75.2)
Mean	45.0	45.1	45.0				45.0	45.1	45.0
(SD)	(12.30)	(12.35)	(12.33)				(12.30)	(12.35)	(12.33)
Median	46.0	46.0	46.0				46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64				18, 64	18, 64	18, 64
>=65 Years	0	0	0	3753 (100)	3767 (100)	7520 (100)	3753 (24.7)	3767 (24.8)	7520 (24.8)
Mean				70.7	70.4	70.6	70.7	70.4	70.6
(SD)				(4.88)	(4.66)	(4.77)	(4.88)	(4.66)	(4.77)
Median				70.0	69.0	70.0	70.0	69.0	70.0
Min, Max				65, 95	65, 95	65, 95	65, 95	65, 95	65, 95

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11413 (100)	11413 (100)	22826 (100)	0	0	0	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <70 Years	0	0	0	1818 (48.4)	1905 (50.6)	3723 (49.5)	1818 (12.0)	1905 (12.5)	3723 (12.3)
>=70 and <75 Years	0	0	0	1194 (31.8)	1205 (32.0)	2399 (31.9)	1194 (7.9)	1205 (7.9)	2399 (7.9)
>=75 and <80 Years	0	0	0	507 (13.5)	466 (12.4)	973 (12.9)	507 (3.3)	466 (3.1)	973 (3.2)
>=80 Years	0	0	0	234 (6.2)	191 (5.1)	425 (5.7)	234 (1.5)	191 (1.3)	425 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11413 (100)	11413 (100)	22826 (100)	0	0	0	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <75 Years	0	0	0	3012 (80.3)	3110 (82.6)	6122 (81.4)	3012 (19.9)	3110 (20.5)	6122 (20.2)
>=75 and <85 Years	0	0	0	692 (18.4)	616 (16.4)	1308 (17.4)	692 (4.6)	616 (4.1)	1308 (4.3)
>=85 Years	0	0	0	49 (1.3)	41 (1.1)	90 (1.2)	49 (0.3)	41 (0.3)	90 (0.3)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8880 (77.8)	8888 (77.9)	17768 (77.8)	2 (<0.1)	0	2 (<0.1)	8882 (58.6)	8888 (58.6)	17770 (58.6)
>=18 and <65 Years and at Risk	2532 (22.2)	2524 (22.1)	5056 (22.2)	3 (<0.1)	6 (0.2)	9 (0.1)	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)	3748 (99.9)	3761 (99.8)	7509 (99.9)	3749 (24.7)	3762 (24.8)	7511 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	504 (4.4)	473 (4.1)	977 (4.3)	245 (6.5)	239 (6.3)	484 (6.4)	749 (4.9)	712 (4.7)	1461 (4.8)
Significant Cardiac Disease	292 (2.6)	321 (2.8)	613 (2.7)	450 (12.0)	441 (11.7)	891 (11.8)	742 (4.9)	762 (5.0)	1504 (5.0)
Severe Obesity	905 (7.9)	896 (7.9)	1801 (7.9)	153 (4.1)	174 (4.6)	327 (4.3)	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	912 (8.0)	919 (8.1)	1831 (8.0)	545 (14.5)	541 (14.4)	1086 (14.4)	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver Disease	70 (0.6)	84 (0.7)	154 (0.7)	26 (0.7)	20 (0.5)	46 (0.6)	96 (0.6)	104 (0.7)	200 (0.7)
Human Immunodeficiency Virus Infection	75 (0.7)	77 (0.7)	152 (0.7)	16 (0.4)	17 (0.5)	33 (0.4)	91 (0.6)	94 (0.6)	185 (0.6)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	2322 (20.3)	2320 (20.3)	4642 (20.3)	1135 (30.2)	1128 (29.9)	2263 (30.1)	3457 (22.8)	3448 (22.7)	6905 (22.8)
One Risk Factor for Severe COVID-19	1937 (17.0)	1925 (16.9)	3862 (16.9)	878 (23.4)	866 (23.0)	1744 (23.2)	2815 (18.6)	2791 (18.4)	5606 (18.5)
Two or More Risk Factors for Severe COVID-19	385 (3.4)	395 (3.5)	780 (3.4)	257 (6.8)	262 (7.0)	519 (6.9)	642 (4.2)	657 (4.3)	1299 (4.3)
No	9091 (79.7)	9093 (79.7)	18184 (79.7)	2618 (69.8)	2639 (70.1)	5257 (69.9)	11709 (77.2)	11732 (77.3)	23441 (77.2)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	9091 (79.7)	9093 (79.7)	18184 (79.7)	0	0	0	9091 (59.9)	9093 (59.9)	18184 (59.9)
>=18 and <65 Years and at Risk	2322 (20.3)	2320 (20.3)	4642 (20.3)	0	0	0	2322 (15.3)	2320 (15.3)	4642 (15.3)
>=65 Years and Not at Risk	0	0	0	2618 (69.8)	2639 (70.1)	5257 (69.9)	2618 (17.3)	2639 (17.4)	5257 (17.3)
>=65 Years and at Risk	0	0	0	1135 (30.2)	1128 (29.9)	2263 (30.1)	1135 (7.5)	1128 (7.4)	2263 (7.5)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Baseline RT-PCR Results, n (%)									
Negative	11271	11268	22539	3724	3745	7469	14995	15013	30008
	(98.8)	(98.7)	(98.7)	(99.2)	(99.4)	(99.3)	(98.9)	(98.9)	(98.9)
Positive	85	81	166	10	7	17	95	88	183
	(0.7)	(0.7)	(0.7)	(0.3)	(0.2)	(0.2)	(0.6)	(0.6)	(0.6)
Missing	57	64	121	19	15	34	76	79	155
	(0.5)	(0.6)	(0.5)	(0.5)	(0.4)	(0.5)	(0.5)	(0.5)	(0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	11124	11124	22248	3720	3723	7443	14844	14847	29691
	(97.5)	(97.5)	(97.5)	(99.1)	(98.8)	(99.0)	(97.9)	(97.8)	(97.8)
Positive	274	276	550	29	33	62	303	309	612
	(2.4)	(2.4)	(2.4)	(0.8)	(0.9)	(0.8)	(2.0)	(2.0)	(2.0)
Missing	15	13	28	4	11	15	19	24	43
	(0.1)	(0.1)	(0.1)	(0.1)	(0.3)	(0.2)	(0.1)	(0.2)	(0.1)
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	11046	11037	22083	3699	3709	7408	14745	14746	29491
	(96.8)	(96.7)	(96.7)	(98.6)	(98.5)	(98.5)	(97.2)	(97.1)	(97.2)
Positive	303	311	614	34	36	70	337	347	684
	(2.7)	(2.7)	(2.7)	(0.9)	(1.0)	(0.9)	(2.2)	(2.3)	(2.3)
Missing	64	65	129	20	22	42	84	87	171
	(0.6)	(0.6)	(0.6)	(0.5)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Sex, n (%)									
Male	5955 (52.2)	5841 (51.2)	11796 (51.7)	2102 (56.0)	2076 (55.1)	4178 (55.6)	8057 (53.1)	7917 (52.2)	15974 (52.6)
Female	5458 (47.8)	5572 (48.8)	11030 (48.3)	1651 (44.0)	1691 (44.9)	3342 (44.4)	7109 (46.9)	7263 (47.8)	14372 (47.4)
Race, n (%)									
White	8657 (75.9)	8653 (75.8)	17310 (75.8)	3344 (89.1)	3378 (89.7)	6722 (89.4)	12001 (79.1)	12031 (79.3)	24032 (79.2)
Black or African American	1316 (11.5)	1345 (11.8)	2661 (11.7)	215 (5.7)	222 (5.9)	437 (5.8)	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	662 (5.8)	589 (5.2)	1251 (5.5)	77 (2.1)	67 (1.8)	144 (1.9)	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	95 (0.8)	92 (0.8)	187 (0.8)	26 (0.7)	21 (0.6)	47 (0.6)	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	29 (0.3)	33 (0.3)	62 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	32 (0.2)	36 (0.2)	68 (0.2)
Multiracial	284 (2.5)	287 (2.5)	571 (2.5)	35 (0.9)	32 (0.8)	67 (0.9)	319 (2.1)	319 (2.1)	638 (2.1)
Other	262 (2.3)	276 (2.4)	538 (2.4)	32 (0.9)	23 (0.6)	55 (0.7)	294 (1.9)	299 (2.0)	593 (2.0)
Not Reported	60 (0.5)	84 (0.7)	144 (0.6)	14 (0.4)	13 (0.3)	27 (0.4)	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	48 (0.4)	54 (0.5)	102 (0.4)	7 (0.2)	8 (0.2)	15 (0.2)	55 (0.4)	62 (0.4)	117 (0.4)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Ethnicity, n (%)									
Hispanic or Latino	2774 (24.3)	2767 (24.2)	5541 (24.3)	335 (8.9)	354 (9.4)	689 (9.2)	3109 (20.5)	3121 (20.6)	6230 (20.5)
Not Hispanic or Latino	8544 (74.9)	8548 (74.9)	17092 (74.9)	3377 (90.0)	3369 (89.4)	6746 (89.7)	11921 (78.6)	11917 (78.5)	23838 (78.6)
Not Reported	57 (0.5)	72 (0.6)	129 (0.6)	26 (0.7)	33 (0.9)	59 (0.8)	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	38 (0.3)	26 (0.2)	64 (0.3)	15 (0.4)	11 (0.3)	26 (0.3)	53 (0.3)	37 (0.2)	90 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	4070 (35.7)	4075 (35.7)	8145 (35.7)	561 (14.9)	578 (15.3)	1139 (15.1)	4631 (30.5)	4653 (30.7)	9284 (30.6)
Non-minority	7330 (64.2)	7318 (64.1)	14648 (64.2)	3179 (84.7)	3183 (84.5)	6362 (84.6)	10509 (69.3)	10501 (69.2)	21010 (69.2)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	6401 (56.1)	6459 (56.6)	12860 (56.3)	3067 (81.7)	3074 (81.6)	6141 (81.7)	9468 (62.4)	9533 (62.8)	19001 (62.6)
Communities of Color	4999 (43.8)	4934 (43.2)	9933 (43.5)	673 (17.9)	687 (18.2)	1360 (18.1)	5672 (37.4)	5621 (37.0)	11293 (37.2)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Weight (kg)									
n	11353	11357	22710	3730	3738	7468	15083	15095	30178
Mean	86.75	86.56	86.66	83.23	83.11	83.17	85.88	85.71	85.79
(SD)	(22.352)	(22.682)	(22.518)	(19.019)	(19.334)	(19.176)	(21.629)	(21.951)	(21.790)
Median	83.64	83.64	83.64	81.60	81.20	81.40	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4	34.8, 184.5	37.2, 165.0	34.8, 184.5	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)									
n	11352	11357	22709	3729	3739	7468	15081	15096	30177
Mean	171.16	170.98	171.07	170.05	169.97	170.01	170.88	170.73	170.81
(SD)	(9.964)	(9.901)	(9.933)	(10.224)	(10.004)	(10.114)	(10.040)	(9.936)	(9.988)
Median	171.00	170.20	170.50	170.18	170.18	170.18	170.50	170.18	170.20
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0	124.5, 223.5	123.0, 208.3	123.0, 223.5	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	11352	11354	22706	3729	3738	7467	15081	15092	30173
Mean	29.53	29.53	29.53	28.71	28.67	28.69	29.32	29.32	29.32
(SD)	(6.904)	(7.120)	(7.012)	(5.890)	(5.851)	(5.870)	(6.677)	(6.838)	(6.757)
Median	28.27	28.25	28.26	27.75	27.86	27.79	28.13	28.13	28.13
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1	12.1, 71.1	11.2, 62.9	11.2, 71.1	10.3, 72.7	9.8, 86.1	9.8, 86.1

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Body Mass Index Subgroup, n (%)									
< 30 kg/m^2	6867 (60.2)	6859 (60.1)	13726 (60.1)	2436 (64.9)	2414 (64.1)	4850 (64.5)	9303 (61.3)	9273 (61.1)	18576 (61.2)
>=30 kg/m^2	4485 (39.3)	4495 (39.4)	8980 (39.3)	1293 (34.5)	1324 (35.1)	2617 (34.8)	5778 (38.1)	5819 (38.3)	11597 (38.2)
Missing	61 (0.5)	59 (0.5)	120 (0.5)	24 (0.6)	29 (0.8)	53 (0.7)	85 (0.6)	88 (0.6)	173 (0.6)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Occupational Risk, n (%) [2]	10164	10120	20284	2387	2376	4763	12551	12496	25047
	(89.1)	(88.7)	(88.9)	(63.6)	(63.1)	(63.3)	(82.8)	(82.3)	(82.5)
Healthcare Workers	3339	3339	6678	504	467	971	3843	3806	7649
	(29.3)	(29.3)	(29.3)	(13.4)	(12.4)	(12.9)	(25.3)	(25.1)	(25.2)
Emergency Response	277	281	558	19	21	40	296	302	598
	(2.4)	(2.5)	(2.4)	(0.5)	(0.6)	(0.5)	(2.0)	(2.0)	(2.0)
Retail or Restaurant Operations	882	857	1739	99	100	199	981	957	1938
	(7.7)	(7.5)	(7.6)	(2.6)	(2.7)	(2.6)	(6.5)	(6.3)	(6.4)
Manufacturing and Production Operations	391	391	782	30	35	65	421	426	847
	(3.4)	(3.4)	(3.4)	(0.8)	(0.9)	(0.9)	(2.8)	(2.8)	(2.8)
Warehouse Shipping and Fulfillment Centers	163	181	344	12	9	21	175	190	365
	(1.4)	(1.6)	(1.5)	(0.3)	(0.2)	(0.3)	(1.2)	(1.3)	(1.2)
Transportation and Delivery Services	419	434	853	61	50	111	480	484	964
	(3.7)	(3.8)	(3.7)	(1.6)	(1.3)	(1.5)	(3.2)	(3.2)	(3.2)
Border Protection and Military Personnel	63	65	128	6	3	9	69	68	137
	(0.6)	(0.6)	(0.6)	(0.2)	(<0.1)	(0.1)	(0.5)	(0.4)	(0.5)
Personal Care and In-Home Services	407	405	812	61	67	128	468	472	940
	(3.6)	(3.5)	(3.6)	(1.6)	(1.8)	(1.7)	(3.1)	(3.1)	(3.1)
Hospitality and Tourism Workers	184	201	385	43	37	80	227	238	465
	(1.6)	(1.8)	(1.7)	(1.1)	(1.0)	(1.1)	(1.5)	(1.6)	(1.5)
Pastoral, Social or Public Health Workers	364	386	750	140	149	289	504	535	1039
	(3.2)	(3.4)	(3.3)	(3.7)	(4.0)	(3.8)	(3.3)	(3.5)	(3.4)
Educators and Students	1387	1365	2752	170	186	356	1557	1551	3108
	(12.2)	(12.0)	(12.1)	(4.5)	(4.9)	(4.7)	(10.3)	(10.2)	(10.2)
Other	3398	3415	6813	1432	1435	2867	4830	4850	9680
	(29.8)	(29.9)	(29.8)	(38.2)	(38.1)	(38.1)	(31.8)	(31.9)	(31.9)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11413)	mRNA-1273 (N=11413)	Total (N=22826)	Placebo (N=3753)	mRNA-1273 (N=3767)	Total (N=7520)	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Location and Living Circumstances Risk, n (%) [2]	9580 (83.9)	9599 (84.1)	19179 (84.0)	3109 (82.8)	3133 (83.2)	6242 (83.0)	12689 (83.7)	12732 (83.9)	25421 (83.8)
Resides in Nursing Home or Assisted Living Facility	9 (<0.1)	24 (0.2)	33 (0.1)	20 (0.5)	11 (0.3)	31 (0.4)	29 (0.2)	35 (0.2)	64 (0.2)
Resides in Multi-Family Dwelling	348 (3.0)	397 (3.5)	745 (3.3)	65 (1.7)	66 (1.8)	131 (1.7)	413 (2.7)	463 (3.1)	876 (2.9)
Resides in High Density Housing	1073 (9.4)	1038 (9.1)	2111 (9.2)	240 (6.4)	253 (6.7)	493 (6.6)	1313 (8.7)	1291 (8.5)	2604 (8.6)
Resides in Low Density, Multi-Family Setting	1236 (10.8)	1248 (10.9)	2484 (10.9)	256 (6.8)	244 (6.5)	500 (6.6)	1492 (9.8)	1492 (9.8)	2984 (9.8)
Resides in a Single Family Home	6148 (53.9)	6115 (53.6)	12263 (53.7)	2262 (60.3)	2283 (60.6)	4545 (60.4)	8410 (55.5)	8398 (55.3)	16808 (55.4)
Other	1647 (14.4)	1649 (14.4)	3296 (14.4)	529 (14.1)	548 (14.5)	1077 (14.3)	2176 (14.3)	2197 (14.5)	4373 (14.4)

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Table 14.1.3.1.2
Baseline Demographics and Characteristics by Age Group
Full Analysis Set

Percentages are based on the number of subjects in Full Analysis Set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age at Screening (Years)			
n	15166	15180	30346
Mean (SD)	51.3 (15.60)	51.4 (15.50)	51.4 (15.55)
Median	52.0	53.0	52.0
Min, Max	18, 95	18, 95	18, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	11413 (75.3)	11413 (75.2)	22826 (75.2)
Mean (SD)	45.0 (12.30)	45.1 (12.35)	45.0 (12.33)
Median	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3753 (24.7)	3767 (24.8)	7520 (24.8)
Mean (SD)	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <70 Years	1818 (12.0)	1905 (12.5)	3723 (12.3)
>=70 and <75 Years	1194 (7.9)	1205 (7.9)	2399 (7.9)
>=75 and <80 Years	507 (3.3)	466 (3.1)	973 (3.2)
>=80 Years	234 (1.5)	191 (1.3)	425 (1.4)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11413 (75.3)	11413 (75.2)	22826 (75.2)
>=65 and <75 Years	3012 (19.9)	3110 (20.5)	6122 (20.2)
>=75 and <85 Years	692 (4.6)	616 (4.1)	1308 (4.3)
>=85 Years	49 (0.3)	41 (0.3)	90 (0.3)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8882 (58.6)	8888 (58.6)	17770 (58.6)
>=18 and <65 Years and at Risk	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	3749 (24.7)	3762 (24.8)	7511 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	749 (4.9)	712 (4.7)	1461 (4.8)
Significant Cardiac Disease	742 (4.9)	762 (5.0)	1504 (5.0)
Severe Obesity	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver Disease	96 (0.6)	104 (0.7)	200 (0.7)
Human Immunodeficiency Virus Infection	91 (0.6)	94 (0.6)	185 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	3457 (22.8)	3448 (22.7)	6905 (22.8)
One Risk Factor for Severe COVID-19	2815 (18.6)	2791 (18.4)	5606 (18.5)
Two or More Risk Factors for Severe COVID-19	642 (4.2)	657 (4.3)	1299 (4.3)
No	11709 (77.2)	11732 (77.3)	23441 (77.2)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	9091 (59.9)	9093 (59.9)	18184 (59.9)
>=18 and <65 Years and at Risk	2322 (15.3)	2320 (15.3)	4642 (15.3)
>=65 Years and Not at Risk	2618 (17.3)	2639 (17.4)	5257 (17.3)
>=65 Years and at Risk	1135 (7.5)	1128 (7.4)	2263 (7.5)
Baseline RT-PCR Results, n (%)			
Negative	14995 (98.9)	15013 (98.9)	30008 (98.9)
Positive	95 (0.6)	88 (0.6)	183 (0.6)
Missing	76 (0.5)	79 (0.5)	155 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	14844 (97.9)	14847 (97.8)	29691 (97.8)
Positive	303 (2.0)	309 (2.0)	612 (2.0)
Missing	19 (0.1)	24 (0.2)	43 (0.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	14745 (97.2)	14746 (97.1)	29491 (97.2)
Positive	337 (2.2)	347 (2.3)	684 (2.3)
Missing	84 (0.6)	87 (0.6)	171 (0.6)
Sex, n (%)			
Male	8057 (53.1)	7917 (52.2)	15974 (52.6)
Female	7109 (46.9)	7263 (47.8)	14372 (47.4)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Race, n (%)			
White	12001 (79.1)	12031 (79.3)	24032 (79.2)
Black or African American	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	32 (0.2)	36 (0.2)	68 (0.2)
Multiracial	319 (2.1)	319 (2.1)	638 (2.1)
Other	294 (1.9)	299 (2.0)	593 (2.0)
Not Reported	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	55 (0.4)	62 (0.4)	117 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	3109 (20.5)	3121 (20.6)	6230 (20.5)
Not Hispanic or Latino	11921 (78.6)	11917 (78.5)	23838 (78.6)
Not Reported	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	53 (0.3)	37 (0.2)	90 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	4631 (30.5)	4653 (30.7)	9284 (30.6)
Non-minority	10509 (69.3)	10501 (69.2)	21010 (69.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	9468 (62.4)	9533 (62.8)	19001 (62.6)
Communities of Color	5672 (37.4)	5621 (37.0)	11293 (37.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)

Note: Footnotes are listed on the last page.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Weight (kg)			
n	15083	15095	30178
Mean (SD)	85.88 (21.629)	85.71 (21.951)	85.79 (21.790)
Median	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)			
n	15081	15096	30177
Mean (SD)	170.88 (10.040)	170.73 (9.936)	170.81 (9.988)
Median	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)			
n	15081	15092	30173
Mean (SD)	29.32 (6.677)	29.32 (6.838)	29.32 (6.757)
Median	28.13	28.13	28.13
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	9303 (61.3)	9273 (61.1)	18576 (61.2)
>=30 kg/m^2	5778 (38.1)	5819 (38.3)	11597 (38.2)
Missing	85 (0.6)	88 (0.6)	173 (0.6)

Note: Footnotes are listed on the last page.
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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: Overall

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Occupational Risk, n (%) [2]	12551 (82.8)	12496 (82.3)	25047 (82.5)
Healthcare Workers	3843 (25.3)	3806 (25.1)	7649 (25.2)
Emergency Response	296 (2.0)	302 (2.0)	598 (2.0)
Retail or Restaurant Operations	981 (6.5)	957 (6.3)	1938 (6.4)
Manufacturing and Production Operations	421 (2.8)	426 (2.8)	847 (2.8)
Warehouse Shipping and Fulfillment Centers	175 (1.2)	190 (1.3)	365 (1.2)
Transportation and Delivery Services	480 (3.2)	484 (3.2)	964 (3.2)
Border Protection and Military Personnel	69 (0.5)	68 (0.4)	137 (0.5)
Personal Care and In-Home Services	468 (3.1)	472 (3.1)	940 (3.1)
Hospitality and Tourism Workers	227 (1.5)	238 (1.6)	465 (1.5)
Pastoral, Social or Public Health Workers	504 (3.3)	535 (3.5)	1039 (3.4)
Educators and Students	1557 (10.3)	1551 (10.2)	3108 (10.2)
Other	4830 (31.8)	4850 (31.9)	9680 (31.9)
Location and Living Circumstances Risk, n (%) [2]	12689 (83.7)	12732 (83.9)	25421 (83.8)
Resides in Nursing Home or Assisted Living Facility	29 (0.2)	35 (0.2)	64 (0.2)
Resides in Multi-Family Dwelling	413 (2.7)	463 (3.1)	876 (2.9)
Resides in High Density Housing	1313 (8.7)	1291 (8.5)	2604 (8.6)
Resides in Low Density, Multi-Family Setting	1492 (9.8)	1492 (9.8)	2984 (9.8)
Resides in a Single Family Home	8410 (55.5)	8398 (55.3)	16808 (55.4)
Other	2176 (14.3)	2197 (14.5)	4373 (14.4)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882)	mRNA-1273 (N=8888)	Total (N=17770)
Age at Screening (Years)			
n	8882	8888	17770
Mean (SD)	43.8 (12.33)	44.0 (12.40)	43.9 (12.37)
Median	44.0	44.0	44.0
Min, Max	18, 72	18, 64	18, 72
Age Group at Screening, n (%)			
>=18 and <65 Years	8880(>99.9)	8888 (100)	17768(>99.9)
Mean (SD)	43.8 (12.33)	44.0 (12.40)	43.9 (12.36)
Median	44.0	44.0	44.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	2 (<0.1)	0	2 (<0.1)
Mean (SD)	68.5 (4.95)		68.5 (4.95)
Median	68.5		68.5
Min, Max	65, 72		65, 72
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8880(>99.9)	8888 (100)	17768(>99.9)
>=65 and <70 Years	1 (<0.1)	0	1 (<0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882)	mRNA-1273 (N=8888)	Total (N=17770)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8880 (>99.9)	8888 (100)	17768 (>99.9)
>=65 and <75 Years	2 (<0.1)	0	2 (<0.1)
>=75 and <85 Years	0	0	0
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8882 (100)	8888 (100)	17770 (100)
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	14 (0.2)	19 (0.2)	33 (0.2)
Significant Cardiac Disease	10 (0.1)	11 (0.1)	21 (0.1)
Severe Obesity	67 (0.8)	61 (0.7)	128 (0.7)
Diabetes	36 (0.4)	34 (0.4)	70 (0.4)
Liver Disease	9 (0.1)	8 (<0.1)	17 (<0.1)
Human Immunodeficiency Virus Infection	14 (0.2)	11 (0.1)	25 (0.1)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	139 (1.6)	131 (1.5)	270 (1.5)
One Risk Factor for Severe COVID-19	129 (1.5)	121 (1.4)	250 (1.4)
Two or More Risk Factors for Severe COVID-19	10 (0.1)	10 (0.1)	20 (0.1)
No	8743 (98.4)	8757 (98.5)	17500 (98.5)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882)	mRNA-1273 (N=8888)	Total (N=17770)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	8742 (98.4)	8757 (98.5)	17499 (98.5)
>=18 and <65 Years and at Risk	138 (1.6)	131 (1.5)	269 (1.5)
>=65 Years and Not at Risk	1 (<0.1)	0	1 (<0.1)
>=65 Years and at Risk	1 (<0.1)	0	1 (<0.1)
Baseline RT-PCR Results, n (%)			
Negative	8785 (98.9)	8774 (98.7)	17559 (98.8)
Positive	65 (0.7)	65 (0.7)	130 (0.7)
Missing	32 (0.4)	49 (0.6)	81 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	8660 (97.5)	8647 (97.3)	17307 (97.4)
Positive	213 (2.4)	233 (2.6)	446 (2.5)
Missing	9 (0.1)	8 (<0.1)	17 (<0.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	8608 (96.9)	8575 (96.5)	17183 (96.7)
Positive	236 (2.7)	263 (3.0)	499 (2.8)
Missing	38 (0.4)	50 (0.6)	88 (0.5)
Sex, n (%)			
Male	4628 (52.1)	4541 (51.1)	9169 (51.6)
Female	4254 (47.9)	4347 (48.9)	8601 (48.4)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882)	mRNA-1273 (N=8888)	Total (N=17770)
Race, n (%)			
White	6790 (76.4)	6757 (76.0)	13547 (76.2)
Black or African American	901 (10.1)	971 (10.9)	1872 (10.5)
Asian	579 (6.5)	503 (5.7)	1082 (6.1)
American Indian or Alaska Native	72 (0.8)	65 (0.7)	137 (0.8)
Native Hawaiian or Other Pacific Islander	20 (0.2)	26 (0.3)	46 (0.3)
Multiracial	232 (2.6)	236 (2.7)	468 (2.6)
Other	211 (2.4)	220 (2.5)	431 (2.4)
Not Reported	42 (0.5)	67 (0.8)	109 (0.6)
Unknown	35 (0.4)	43 (0.5)	78 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	2222 (25.0)	2211 (24.9)	4433 (24.9)
Not Hispanic or Latino	6588 (74.2)	6597 (74.2)	13185 (74.2)
Not Reported	42 (0.5)	58 (0.7)	100 (0.6)
Unknown	30 (0.3)	22 (0.2)	52 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	3100 (34.9)	3149 (35.4)	6249 (35.2)
Non-minority	5774 (65.0)	5725 (64.4)	11499 (64.7)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)
Race and Ethnicity Group, n (%) [6]			
White	4978 (56.0)	5004 (56.3)	9982 (56.2)
Communities of Color	3896 (43.9)	3870 (43.5)	7766 (43.7)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882)	mRNA-1273 (N=8888)	Total (N=17770)
Weight (kg)			
n	8836	8837	17673
Mean (SD)	82.29 (18.001)	82.01 (18.161)	82.15 (18.081)
Median	80.80	80.55	80.70
Min, Max	30.7, 182.4	33.3, 178.7	30.7, 182.4
Height (cm)			
n	8836	8836	17672
Mean (SD)	171.24 (9.894)	171.05 (9.893)	171.14 (9.894)
Median	171.00	170.20	170.70
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0
Body Mass Index (kg/m^2)			
n	8836	8834	17670
Mean (SD)	27.96 (5.133)	27.92 (5.255)	27.94 (5.195)
Median	27.33	27.35	27.34
Min, Max	10.3, 53.1	9.8, 57.9	9.8, 57.9
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	5978 (67.3)	5991 (67.4)	11969 (67.4)
>=30 kg/m^2	2858 (32.2)	2843 (32.0)	5701 (32.1)
Missing	46 (0.5)	54 (0.6)	100 (0.6)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8882)	mRNA-1273 (N=8888)	Total (N=17770)
Occupational Risk, n (%) [2]	7994 (90.0)	7969 (89.7)	15963 (89.8)
Healthcare Workers	2744 (30.9)	2744 (30.9)	5488 (30.9)
Emergency Response	219 (2.5)	234 (2.6)	453 (2.5)
Retail or Restaurant Operations	694 (7.8)	684 (7.7)	1378 (7.8)
Manufacturing and Production Operations	307 (3.5)	290 (3.3)	597 (3.4)
Warehouse Shipping and Fulfillment Centers	121 (1.4)	138 (1.6)	259 (1.5)
Transportation and Delivery Services	318 (3.6)	337 (3.8)	655 (3.7)
Border Protection and Military Personnel	51 (0.6)	53 (0.6)	104 (0.6)
Personal Care and In-Home Services	329 (3.7)	303 (3.4)	632 (3.6)
Hospitality and Tourism Workers	145 (1.6)	164 (1.8)	309 (1.7)
Pastoral, Social or Public Health Workers	264 (3.0)	297 (3.3)	561 (3.2)
Educators and Students	1118 (12.6)	1090 (12.3)	2208 (12.4)
Other	2606 (29.3)	2601 (29.3)	5207 (29.3)
Location and Living Circumstances Risk, n (%) [2]	7490 (84.3)	7537 (84.8)	15027 (84.6)
Resides in Nursing Home or Assisted Living Facility	6 (<0.1)	12 (0.1)	18 (0.1)
Resides in Multi-Family Dwelling	269 (3.0)	306 (3.4)	575 (3.2)
Resides in High Density Housing	877 (9.9)	842 (9.5)	1719 (9.7)
Resides in Low Density, Multi-Family Setting	958 (10.8)	945 (10.6)	1903 (10.7)
Resides in a Single Family Home	4773 (53.7)	4813 (54.2)	9586 (53.9)
Other	1313 (14.8)	1336 (15.0)	2649 (14.9)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age at Screening (Years)			
n	2535	2530	5065
Mean (SD)	49.2 (11.28)	48.9 (11.41)	49.0 (11.34)
Median	51.0	51.0	51.0
Min, Max	18, 79	18, 76	18, 79
Age Group at Screening, n (%)			
>=18 and <65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
Mean (SD)	49.1 (11.26)	48.9 (11.38)	49.0 (11.32)
Median	51.0	51.0	51.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3 (0.1)	6 (0.2)	9 (0.2)
Mean (SD)	72.0 (7.00)	67.7 (4.37)	69.1 (5.37)
Median	72.0	65.5	66.0
Min, Max	65, 79	65, 76	65, 79
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
>=65 and <70 Years	1 (<0.1)	5 (0.2)	6 (0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=80 Years	0	0	0

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
>=65 and <75 Years	2 (<0.1)	5 (0.2)	7 (0.1)
>=75 and <85 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	2535 (100)	2530 (100)	5065 (100)
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	491 (19.4)	455 (18.0)	946 (18.7)
Significant Cardiac Disease	282 (11.1)	312 (12.3)	594 (11.7)
Severe Obesity	837 (33.0)	836 (33.0)	1673 (33.0)
Diabetes	878 (34.6)	887 (35.1)	1765 (34.8)
Liver Disease	61 (2.4)	76 (3.0)	137 (2.7)
Human Immunodeficiency Virus Infection	61 (2.4)	66 (2.6)	127 (2.5)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	2185 (86.2)	2192 (86.6)	4377 (86.4)
One Risk Factor for Severe COVID-19	1810 (71.4)	1804 (71.3)	3614 (71.4)
Two or More Risk Factors for Severe COVID-19	375 (14.8)	388 (15.3)	763 (15.1)
No	350 (13.8)	338 (13.4)	688 (13.6)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	349 (13.8)	336 (13.3)	685 (13.5)
>=18 and <65 Years and at Risk	2183 (86.1)	2188 (86.5)	4371 (86.3)
>=65 Years and Not at Risk	1 (<0.1)	2 (<0.1)	3 (<0.1)
>=65 Years and at Risk	2 (<0.1)	4 (0.2)	6 (0.1)
Baseline RT-PCR Results, n (%)			
Negative	2490 (98.2)	2499 (98.8)	4989 (98.5)
Positive	20 (0.8)	16 (0.6)	36 (0.7)
Missing	25 (1.0)	15 (0.6)	40 (0.8)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	2468 (97.4)	2482 (98.1)	4950 (97.7)
Positive	61 (2.4)	43 (1.7)	104 (2.1)
Missing	6 (0.2)	5 (0.2)	11 (0.2)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	2442 (96.3)	2467 (97.5)	4909 (96.9)
Positive	67 (2.6)	48 (1.9)	115 (2.3)
Missing	26 (1.0)	15 (0.6)	41 (0.8)
Sex, n (%)			
Male	1329 (52.4)	1303 (51.5)	2632 (52.0)
Female	1206 (47.6)	1227 (48.5)	2433 (48.0)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Race, n (%)			
White	1872 (73.8)	1900 (75.1)	3772 (74.5)
Black or African American	414 (16.3)	374 (14.8)	788 (15.6)
Asian	83 (3.3)	87 (3.4)	170 (3.4)
American Indian or Alaska Native	23 (0.9)	27 (1.1)	50 (1.0)
Native Hawaiian or Other Pacific Islander	9 (0.4)	7 (0.3)	16 (0.3)
Multiracial	52 (2.1)	51 (2.0)	103 (2.0)
Other	51 (2.0)	56 (2.2)	107 (2.1)
Not Reported	18 (0.7)	17 (0.7)	35 (0.7)
Unknown	13 (0.5)	11 (0.4)	24 (0.5)
Ethnicity, n (%)			
Hispanic or Latino	553 (21.8)	557 (22.0)	1110 (21.9)
Not Hispanic or Latino	1959 (77.3)	1955 (77.3)	3914 (77.3)
Not Reported	15 (0.6)	14 (0.6)	29 (0.6)
Unknown	8 (0.3)	4 (0.2)	12 (0.2)
Race and Ethnicity Group, n (%) [5]			
Minority	970 (38.3)	927 (36.6)	1897 (37.5)
Non-minority	1560 (61.5)	1597 (63.1)	3157 (62.3)
Missing	5 (0.2)	6 (0.2)	11 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	1427 (56.3)	1458 (57.6)	2885 (57.0)
Communities of Color	1103 (43.5)	1066 (42.1)	2169 (42.8)
Missing	5 (0.2)	6 (0.2)	11 (0.2)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Weight (kg)			
n	2521	2525	5046
Mean (SD)	102.35 (28.319)	102.53 (28.881)	102.44 (28.599)
Median	98.82	99.45	99.09
Min, Max	33.5, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)			
n	2520	2526	5046
Mean (SD)	170.90 (10.199)	170.73 (9.944)	170.82 (10.071)
Median	170.35	170.18	170.18
Min, Max	123.5, 203.2	111.0, 202.8	111.0, 203.2
Body Mass Index (kg/m^2)			
n	2520	2525	5045
Mean (SD)	35.01 (9.148)	35.17 (9.520)	35.09 (9.336)
Median	33.76	33.64	33.71
Min, Max	11.6, 72.7	11.7, 86.1	11.6, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	894 (35.3)	869 (34.3)	1763 (34.8)
>=30 kg/m^2	1626 (64.1)	1656 (65.5)	3282 (64.8)
Missing	15 (0.6)	5 (0.2)	20 (0.4)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Occupational Risk, n (%) [2]	2172 (85.7)	2156 (85.2)	4328 (85.4)
Healthcare Workers	596 (23.5)	596 (23.6)	1192 (23.5)
Emergency Response	58 (2.3)	48 (1.9)	106 (2.1)
Retail or Restaurant Operations	188 (7.4)	173 (6.8)	361 (7.1)
Manufacturing and Production Operations	84 (3.3)	101 (4.0)	185 (3.7)
Warehouse Shipping and Fulfillment Centers	42 (1.7)	43 (1.7)	85 (1.7)
Transportation and Delivery Services	100 (3.9)	97 (3.8)	197 (3.9)
Border Protection and Military Personnel	12 (0.5)	12 (0.5)	24 (0.5)
Personal Care and In-Home Services	78 (3.1)	102 (4.0)	180 (3.6)
Hospitality and Tourism Workers	39 (1.5)	37 (1.5)	76 (1.5)
Pastoral, Social or Public Health Workers	102 (4.0)	90 (3.6)	192 (3.8)
Educators and Students	270 (10.7)	276 (10.9)	546 (10.8)
Other	793 (31.3)	817 (32.3)	1610 (31.8)
Location and Living Circumstances Risk, n (%) [2]	2095 (82.6)	2065 (81.6)	4160 (82.1)
Resides in Nursing Home or Assisted Living Facility	3 (0.1)	12 (0.5)	15 (0.3)
Resides in Multi-Family Dwelling	79 (3.1)	91 (3.6)	170 (3.4)
Resides in High Density Housing	196 (7.7)	196 (7.7)	392 (7.7)
Resides in Low Density, Multi-Family Setting	278 (11.0)	303 (12.0)	581 (11.5)
Resides in a Single Family Home	1380 (54.4)	1304 (51.5)	2684 (53.0)
Other	334 (13.2)	314 (12.4)	648 (12.8)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3762)	Total (N=7511)
Age at Screening (Years)			
n	3749	3762	7511
Mean (SD)	70.7 (4.90)	70.4 (4.66)	70.6 (4.79)
Median	70.0	69.0	70.0
Min, Max	40, 95	64, 95	40, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mean (SD)	40.0 (NA)	64.0 (NA)	52.0 (16.97)
Median	40.0	64.0	52.0
Min, Max	40, 40	64, 64	40, 64
>=65 Years	3748(>99.9)	3761(>99.9)	7509(>99.9)
Mean (SD)	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <70 Years	1816 (48.4)	1900 (50.5)	3716 (49.5)
>=70 and <75 Years	1192 (31.8)	1205 (32.0)	2397 (31.9)
>=75 and <80 Years	506 (13.5)	465 (12.4)	971 (12.9)
>=80 Years	234 (6.2)	191 (5.1)	425 (5.7)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3762)	Total (N=7511)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <75 Years	3008 (80.2)	3105 (82.5)	6113 (81.4)
>=75 and <85 Years	691 (18.4)	615 (16.3)	1306 (17.4)
>=85 Years	49 (1.3)	41 (1.1)	90 (1.2)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	3749 (100)	3762 (100)	7511 (100)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	244 (6.5)	238 (6.3)	482 (6.4)
Significant Cardiac Disease	450 (12.0)	439 (11.7)	889 (11.8)
Severe Obesity	154 (4.1)	173 (4.6)	327 (4.4)
Diabetes	543 (14.5)	539 (14.3)	1082 (14.4)
Liver Disease	26 (0.7)	20 (0.5)	46 (0.6)
Human Immunodeficiency Virus Infection	16 (0.4)	17 (0.5)	33 (0.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1133 (30.2)	1125 (29.9)	2258 (30.1)
One Risk Factor for Severe COVID-19	876 (23.4)	866 (23.0)	1742 (23.2)
Two or More Risk Factors for Severe COVID-19	257 (6.9)	259 (6.9)	516 (6.9)
No	2616 (69.8)	2637 (70.1)	5253 (69.9)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3762)	Total (N=7511)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 Years and Not at Risk	2616 (69.8)	2637 (70.1)	5253 (69.9)
>=65 Years and at Risk	1132 (30.2)	1124 (29.9)	2256 (30.0)
Baseline RT-PCR Results, n (%)			
Negative	3720 (99.2)	3740 (99.4)	7460 (99.3)
Positive	10 (0.3)	7 (0.2)	17 (0.2)
Missing	19 (0.5)	15 (0.4)	34 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	3716 (99.1)	3718 (98.8)	7434 (99.0)
Positive	29 (0.8)	33 (0.9)	62 (0.8)
Missing	4 (0.1)	11 (0.3)	15 (0.2)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	3695 (98.6)	3704 (98.5)	7399 (98.5)
Positive	34 (0.9)	36 (1.0)	70 (0.9)
Missing	20 (0.5)	22 (0.6)	42 (0.6)
Sex, n (%)			
Male	2100 (56.0)	2073 (55.1)	4173 (55.6)
Female	1649 (44.0)	1689 (44.9)	3338 (44.4)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3762)	Total (N=7511)
Race, n (%)			
White	3339 (89.1)	3374 (89.7)	6713 (89.4)
Black or African American	216 (5.8)	222 (5.9)	438 (5.8)
Asian	77 (2.1)	66 (1.8)	143 (1.9)
American Indian or Alaska Native	26 (0.7)	21 (0.6)	47 (0.6)
Native Hawaiian or Other Pacific Islander	3 (<0.1)	3 (<0.1)	6 (<0.1)
Multiracial	35 (0.9)	32 (0.9)	67 (0.9)
Other	32 (0.9)	23 (0.6)	55 (0.7)
Not Reported	14 (0.4)	13 (0.3)	27 (0.4)
Unknown	7 (0.2)	8 (0.2)	15 (0.2)
Ethnicity, n (%)			
Hispanic or Latino	334 (8.9)	353 (9.4)	687 (9.1)
Not Hispanic or Latino	3374 (90.0)	3365 (89.4)	6739 (89.7)
Not Reported	26 (0.7)	33 (0.9)	59 (0.8)
Unknown	15 (0.4)	11 (0.3)	26 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	561 (15.0)	577 (15.3)	1138 (15.2)
Non-minority	3175 (84.7)	3179 (84.5)	6354 (84.6)
Missing	13 (0.3)	6 (0.2)	19 (0.3)
Race and Ethnicity Group, n (%) [6]			
White	3063 (81.7)	3071 (81.6)	6134 (81.7)
Communities of Color	673 (18.0)	685 (18.2)	1358 (18.1)
Missing	13 (0.3)	6 (0.2)	19 (0.3)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3762)	Total (N=7511)
Weight (kg)			
n	3726	3733	7459
Mean (SD)	83.25 (19.025)	83.09 (19.315)	83.17 (19.169)
Median	81.60	81.20	81.40
Min, Max	34.8, 184.5	37.2, 165.0	34.8, 184.5
Height (cm)			
n	3725	3734	7459
Mean (SD)	170.04 (10.226)	169.98 (9.993)	170.01 (10.110)
Median	170.18	170.18	170.18
Min, Max	124.5, 223.5	123.0, 208.3	123.0, 223.5
Body Mass Index (kg/m^2)			
n	3725	3733	7458
Mean (SD)	28.72 (5.892)	28.66 (5.845)	28.69 (5.868)
Median	27.75	27.85	27.79
Min, Max	12.1, 71.1	11.2, 62.9	11.2, 71.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	2431 (64.8)	2413 (64.1)	4844 (64.5)
>=30 kg/m^2	1294 (34.5)	1320 (35.1)	2614 (34.8)
Missing	24 (0.6)	29 (0.8)	53 (0.7)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Randomization Stratum: >=65 Years

	Placebo (N=3749)	mRNA-1273 (N=3762)	Total (N=7511)
Occupational Risk, n (%) [2]	2385 (63.6)	2371 (63.0)	4756 (63.3)
Healthcare Workers	503 (13.4)	466 (12.4)	969 (12.9)
Emergency Response	19 (0.5)	20 (0.5)	39 (0.5)
Retail or Restaurant Operations	99 (2.6)	100 (2.7)	199 (2.6)
Manufacturing and Production Operations	30 (0.8)	35 (0.9)	65 (0.9)
Warehouse Shipping and Fulfillment Centers	12 (0.3)	9 (0.2)	21 (0.3)
Transportation and Delivery Services	62 (1.7)	50 (1.3)	112 (1.5)
Border Protection and Military Personnel	6 (0.2)	3 (<0.1)	9 (0.1)
Personal Care and In-Home Services	61 (1.6)	67 (1.8)	128 (1.7)
Hospitality and Tourism Workers	43 (1.1)	37 (1.0)	80 (1.1)
Pastoral, Social or Public Health Workers	138 (3.7)	148 (3.9)	286 (3.8)
Educators and Students	169 (4.5)	185 (4.9)	354 (4.7)
Other	1431 (38.2)	1432 (38.1)	2863 (38.1)
Location and Living Circumstances Risk, n (%) [2]	3104 (82.8)	3130 (83.2)	6234 (83.0)
Resides in Nursing Home or Assisted Living Facility	20 (0.5)	11 (0.3)	31 (0.4)
Resides in Multi-Family Dwelling	65 (1.7)	66 (1.8)	131 (1.7)
Resides in High Density Housing	240 (6.4)	253 (6.7)	493 (6.6)
Resides in Low Density, Multi-Family Setting	256 (6.8)	244 (6.5)	500 (6.7)
Resides in a Single Family Home	2257 (60.2)	2281 (60.6)	4538 (60.4)
Other	529 (14.1)	547 (14.5)	1076 (14.3)

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Table 14.1.3.1.3
Baseline Demographics and Characteristics by Randomization Stratum
Full Analysis Set

Percentages are based on the number of subjects in Full Analysis Set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age at Screening (Years)									
n	14741	14750	29491	337	347	684	15162	15184	30346
Mean	51.5	51.5	51.5	45.1	44.1	44.6	51.3	51.4	51.4
(SD)	(15.58)	(15.48)	(15.53)	(15.47)	(15.33)	(15.40)	(15.60)	(15.51)	(15.55)
Median	52.0	53.0	53.0	46.0	44.0	45.0	52.0	53.0	52.0
Min, Max	18, 95	18, 95	18, 95	18, 83	18, 84	18, 84	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	11044	11039	22083	303	311	614	11411	11415	22826
	(74.9)	(74.8)	(74.9)	(89.9)	(89.6)	(89.8)	(75.3)	(75.2)	(75.2)
Mean	45.1	45.2	45.1	42.1	41.0	41.5	45.0	45.1	45.0
(SD)	(12.26)	(12.32)	(12.29)	(13.17)	(12.90)	(13.03)	(12.30)	(12.35)	(12.33)
Median	46.0	46.0	46.0	44.0	42.0	43.0	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64	18, 64
>=65 Years	3697	3711	7408	34	36	70	3751	3769	7520
	(25.1)	(25.2)	(25.1)	(10.1)	(10.4)	(10.2)	(24.7)	(24.8)	(24.8)
Mean	70.7	70.4	70.6	71.9	70.8	71.3	70.7	70.4	70.6
(SD)	(4.88)	(4.66)	(4.77)	(4.86)	(5.56)	(5.23)	(4.88)	(4.66)	(4.77)
Median	70.0	69.0	70.0	72.0	69.5	70.0	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95	65, 83	65, 84	65, 84	65, 95	65, 95	65, 95

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11044 (74.9)	11039 (74.8)	22083 (74.9)	303 (89.9)	311 (89.6)	614 (89.8)	11411 (75.3)	11415 (75.2)	22826 (75.2)
>=65 and <70 Years	1794 (12.2)	1875 (12.7)	3669 (12.4)	12 (3.6)	18 (5.2)	30 (4.4)	1817 (12.0)	1906 (12.6)	3723 (12.3)
>=70 and <75 Years	1178 (8.0)	1188 (8.1)	2366 (8.0)	10 (3.0)	11 (3.2)	21 (3.1)	1193 (7.9)	1206 (7.9)	2399 (7.9)
>=75 and <80 Years	494 (3.4)	461 (3.1)	955 (3.2)	10 (3.0)	3 (0.9)	13 (1.9)	507 (3.3)	466 (3.1)	973 (3.2)
>=80 Years	231 (1.6)	187 (1.3)	418 (1.4)	2 (0.6)	4 (1.2)	6 (0.9)	234 (1.5)	191 (1.3)	425 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11044 (74.9)	11039 (74.8)	22083 (74.9)	303 (89.9)	311 (89.6)	614 (89.8)	11411 (75.3)	11415 (75.2)	22826 (75.2)
>=65 and <75 Years	2972 (20.2)	3063 (20.8)	6035 (20.5)	22 (6.5)	29 (8.4)	51 (7.5)	3010 (19.9)	3112 (20.5)	6122 (20.2)
>=75 and <85 Years	676 (4.6)	607 (4.1)	1283 (4.4)	12 (3.6)	7 (2.0)	19 (2.8)	692 (4.6)	616 (4.1)	1308 (4.3)
>=85 Years	49 (0.3)	41 (0.3)	90 (0.3)	0	0	0	49 (0.3)	41 (0.3)	90 (0.3)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8606 (58.4)	8577 (58.1)	17183 (58.3)	236 (70.0)	263 (75.8)	499 (73.0)	8880 (58.6)	8890 (58.5)	17770 (58.6)
>=18 and <65 Years and at Risk	2442 (16.6)	2467 (16.7)	4909 (16.6)	67 (19.9)	48 (13.8)	115 (16.8)	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	3693 (25.1)	3706 (25.1)	7399 (25.1)	34 (10.1)	36 (10.4)	70 (10.2)	3747 (24.7)	3764 (24.8)	7511 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	727 (4.9)	702 (4.8)	1429 (4.8)	12 (3.6)	8 (2.3)	20 (2.9)	749 (4.9)	712 (4.7)	1461 (4.8)
Significant Cardiac Disease	722 (4.9)	745 (5.1)	1467 (5.0)	12 (3.6)	11 (3.2)	23 (3.4)	742 (4.9)	762 (5.0)	1504 (5.0)
Severe Obesity	1024 (6.9)	1041 (7.1)	2065 (7.0)	25 (7.4)	27 (7.8)	52 (7.6)	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	1423 (9.7)	1431 (9.7)	2854 (9.7)	24 (7.1)	24 (6.9)	48 (7.0)	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver Disease	95 (0.6)	102 (0.7)	197 (0.7)	1 (0.3)	1 (0.3)	2 (0.3)	96 (0.6)	104 (0.7)	200 (0.7)
Human Immunodeficiency Virus Infection	84 (0.6)	88 (0.6)	172 (0.6)	7 (2.1)	4 (1.2)	11 (1.6)	91 (0.6)	94 (0.6)	185 (0.6)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	3355 (22.8)	3375 (22.9)	6730 (22.8)	71 (21.1)	57 (16.4)	128 (18.7)	3457 (22.8)	3448 (22.7)	6905 (22.8)
One Risk Factor for Severe COVID-19	2728 (18.5)	2733 (18.5)	5461 (18.5)	62 (18.4)	43 (12.4)	105 (15.4)	2815 (18.6)	2791 (18.4)	5606 (18.5)
Two or More Risk Factors for Severe COVID-19	627 (4.3)	642 (4.4)	1269 (4.3)	9 (2.7)	14 (4.0)	23 (3.4)	642 (4.2)	657 (4.3)	1299 (4.3)
No	11386 (77.2)	11375 (77.1)	22761 (77.2)	266 (78.9)	290 (83.6)	556 (81.3)	11705 (77.2)	11736 (77.3)	23441 (77.2)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	8808 (59.8)	8778 (59.5)	17586 (59.6)	239 (70.9)	263 (75.8)	502 (73.4)	9089 (59.9)	9095 (59.9)	18184 (59.9)
>=18 and <65 Years and at Risk	2236 (15.2)	2261 (15.3)	4497 (15.2)	64 (19.0)	48 (13.8)	112 (16.4)	2322 (15.3)	2320 (15.3)	4642 (15.3)
>=65 Years and Not at Risk	2578 (17.5)	2597 (17.6)	5175 (17.5)	27 (8.0)	27 (7.8)	54 (7.9)	2616 (17.3)	2641 (17.4)	5257 (17.3)
>=65 Years and at Risk	1119 (7.6)	1114 (7.6)	2233 (7.6)	7 (2.1)	9 (2.6)	16 (2.3)	1135 (7.5)	1128 (7.4)	2263 (7.5)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Baseline RT-PCR Results, n (%)									
Negative	14741 (100)	14750 (100)	29491 (100)	238 (70.6)	258 (74.4)	496 (72.5)	14991 (98.9)	15017 (98.9)	30008 (98.9)
Positive	0	0	0	95 (28.2)	88 (25.4)	183 (26.8)	95 (0.6)	88 (0.6)	183 (0.6)
Missing	0	0	0	4 (1.2)	1 (0.3)	5 (0.7)	76 (0.5)	79 (0.5)	155 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	14741 (100)	14750 (100)	29491 (100)	34 (10.1)	38 (11.0)	72 (10.5)	14840 (97.9)	14851 (97.8)	29691 (97.8)
Positive	0	0	0	303 (89.9)	309 (89.0)	612 (89.5)	303 (2.0)	309 (2.0)	612 (2.0)
Missing	0	0	0	0	0	0	19 (0.1)	24 (0.2)	43 (0.1)
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	14741 (100)	14750 (100)	29491 (100)	0	0	0	14741 (97.2)	14750 (97.1)	29491 (97.2)
Positive	0	0	0	337 (100)	347 (100)	684 (100)	337 (2.2)	347 (2.3)	684 (2.3)
Missing	0	0	0	0	0	0	84 (0.6)	87 (0.6)	171 (0.6)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Sex, n (%)									
Male	7819 (53.0)	7679 (52.1)	15498 (52.6)	181 (53.7)	195 (56.2)	376 (55.0)	8056 (53.1)	7918 (52.1)	15974 (52.6)
Female	6922 (47.0)	7071 (47.9)	13993 (47.4)	156 (46.3)	152 (43.8)	308 (45.0)	7106 (46.9)	7266 (47.9)	14372 (47.4)
Race, n (%)									
White	11705 (79.4)	11741 (79.6)	23446 (79.5)	225 (66.8)	219 (63.1)	444 (64.9)	11998 (79.1)	12034 (79.3)	24032 (79.2)
Black or African American	1431 (9.7)	1463 (9.9)	2894 (9.8)	90 (26.7)	99 (28.5)	189 (27.6)	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	730 (5.0)	645 (4.4)	1375 (4.7)	5 (1.5)	10 (2.9)	15 (2.2)	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	119 (0.8)	113 (0.8)	232 (0.8)	2 (0.6)	0	2 (0.3)	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	31 (0.2)	36 (0.2)	67 (0.2)	1 (0.3)	0	1 (0.1)	32 (0.2)	36 (0.2)	68 (0.2)
Multiracial	315 (2.1)	311 (2.1)	626 (2.1)	2 (0.6)	5 (1.4)	7 (1.0)	318 (2.1)	320 (2.1)	638 (2.1)
Other	285 (1.9)	288 (2.0)	573 (1.9)	8 (2.4)	9 (2.6)	17 (2.5)	294 (1.9)	299 (2.0)	593 (2.0)
Not Reported	70 (0.5)	92 (0.6)	162 (0.5)	4 (1.2)	4 (1.2)	8 (1.2)	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	55 (0.4)	61 (0.4)	116 (0.4)	0	1 (0.3)	1 (0.1)	55 (0.4)	62 (0.4)	117 (0.4)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Ethnicity, n (%)									
Hispanic or Latino	2946 (20.0)	2958 (20.1)	5904 (20.0)	151 (44.8)	146 (42.1)	297 (43.4)	3108 (20.5)	3122 (20.6)	6230 (20.5)
Not Hispanic or Latino	11662 (79.1)	11653 (79.0)	23315 (79.1)	184 (54.6)	199 (57.3)	383 (56.0)	11918 (78.6)	11920 (78.5)	23838 (78.6)
Not Reported	80 (0.5)	102 (0.7)	182 (0.6)	2 (0.6)	2 (0.6)	4 (0.6)	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	53 (0.4)	37 (0.3)	90 (0.3)	0	0	0	53 (0.3)	37 (0.2)	90 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	4387 (29.8)	4409 (29.9)	8796 (29.8)	223 (66.2)	222 (64.0)	445 (65.1)	4630 (30.5)	4654 (30.7)	9284 (30.6)
Non-minority	10328 (70.1)	10315 (69.9)	20643 (70.0)	114 (33.8)	125 (36.0)	239 (34.9)	10506 (69.3)	10504 (69.2)	21010 (69.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)	0	0	0	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	9301 (63.1)	9366 (63.5)	18667 (63.3)	107 (31.8)	110 (31.7)	217 (31.7)	9466 (62.4)	9535 (62.8)	19001 (62.6)
Communities of Color	5414 (36.7)	5358 (36.3)	10772 (36.5)	230 (68.2)	237 (68.3)	467 (68.3)	5670 (37.4)	5623 (37.0)	11293 (37.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)	0	0	0	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Weight (kg)									
n	14658	14666	29324	337	346	683	15079	15099	30178
Mean	85.85	85.67	85.76	85.68	87.59	86.65	85.88	85.70	85.79
(SD)	(21.617)	(21.965)	(21.792)	(21.185)	(22.224)	(21.722)	(21.628)	(21.951)	(21.790)
Median	83.00	83.00	83.00	82.10	84.23	83.00	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4	42.7, 182.4	43.2, 179.0	42.7, 182.4	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)									
n	14656	14667	29323	337	346	683	15077	15100	30177
Mean	170.91	170.74	170.83	169.53	170.03	169.78	170.89	170.73	170.81
(SD)	(10.032)	(9.933)	(9.983)	(10.212)	(9.891)	(10.046)	(10.039)	(9.937)	(9.988)
Median	170.50	170.18	170.20	170.00	170.00	170.00	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5	142.2, 198.1	147.3, 196.0	142.2, 198.1	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	14656	14663	29319	337	346	683	15077	15096	30173
Mean	29.31	29.30	29.30	29.74	30.22	29.98	29.33	29.32	29.32
(SD)	(6.671)	(6.842)	(6.757)	(6.558)	(6.990)	(6.780)	(6.677)	(6.837)	(6.757)
Median	28.12	28.12	28.12	28.52	28.96	28.83	28.14	28.13	28.13
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1	15.7, 59.2	15.8, 60.5	15.7, 60.5	10.3, 72.7	9.8, 86.1	9.8, 86.1

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Body Mass Index Subgroup, n (%)									
< 30 kg/m^2	9056 (61.4)	9023 (61.2)	18079 (61.3)	201 (59.6)	196 (56.5)	397 (58.0)	9300 (61.3)	9276 (61.1)	18576 (61.2)
>=30 kg/m^2	5600 (38.0)	5640 (38.2)	11240 (38.1)	136 (40.4)	150 (43.2)	286 (41.8)	5777 (38.1)	5820 (38.3)	11597 (38.2)
Missing	85 (0.6)	87 (0.6)	172 (0.6)	0	1 (0.3)	1 (0.1)	85 (0.6)	88 (0.6)	173 (0.6)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Occupational Risk, n (%) [2]	12169	12119	24288	306	306	612	12547	12500	25047
	(82.6)	(82.2)	(82.4)	(90.8)	(88.2)	(89.5)	(82.8)	(82.3)	(82.5)
Healthcare Workers	3754	3724	7478	67	64	131	3840	3809	7649
	(25.5)	(25.2)	(25.4)	(19.9)	(18.4)	(19.2)	(25.3)	(25.1)	(25.2)
Emergency Response	283	294	577	11	6	17	296	302	598
	(1.9)	(2.0)	(2.0)	(3.3)	(1.7)	(2.5)	(2.0)	(2.0)	(2.0)
Retail or Restaurant Operations	938	917	1855	38	34	72	980	958	1938
	(6.4)	(6.2)	(6.3)	(11.3)	(9.8)	(10.5)	(6.5)	(6.3)	(6.4)
Manufacturing and Production Operations	410	404	814	10	22	32	421	426	847
	(2.8)	(2.7)	(2.8)	(3.0)	(6.3)	(4.7)	(2.8)	(2.8)	(2.8)
Warehouse Shipping and Fulfillment Centers	162	180	342	12	9	21	175	190	365
	(1.1)	(1.2)	(1.2)	(3.6)	(2.6)	(3.1)	(1.2)	(1.3)	(1.2)
Transportation and Delivery Services	456	453	909	20	28	48	480	484	964
	(3.1)	(3.1)	(3.1)	(5.9)	(8.1)	(7.0)	(3.2)	(3.2)	(3.2)
Border Protection and Military Personnel	68	66	134	1	1	2	69	68	137
	(0.5)	(0.4)	(0.5)	(0.3)	(0.3)	(0.3)	(0.5)	(0.4)	(0.5)
Personal Care and In-Home Services	439	442	881	26	28	54	468	472	940
	(3.0)	(3.0)	(3.0)	(7.7)	(8.1)	(7.9)	(3.1)	(3.1)	(3.1)
Hospitality and Tourism Workers	208	226	434	17	11	28	227	238	465
	(1.4)	(1.5)	(1.5)	(5.0)	(3.2)	(4.1)	(1.5)	(1.6)	(1.5)
Pastoral, Social or Public Health Workers	497	520	1017	6	11	17	504	535	1039
	(3.4)	(3.5)	(3.4)	(1.8)	(3.2)	(2.5)	(3.3)	(3.5)	(3.4)
Educators and Students	1522	1514	3036	25	29	54	1557	1551	3108
	(10.3)	(10.3)	(10.3)	(7.4)	(8.4)	(7.9)	(10.3)	(10.2)	(10.2)
Other	4691	4715	9406	105	102	207	4830	4850	9680
	(31.8)	(32.0)	(31.9)	(31.2)	(29.4)	(30.3)	(31.9)	(31.9)	(31.9)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

	Baseline SARS-CoV-2 Negative			Baseline SARS-CoV-2 Positive			Overall		
	Placebo (N=14741)	mRNA-1273 (N=14750)	Total (N=29491)	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Location and Living Circumstances Risk, n (%) [2]	12318 (83.6)	12358 (83.8)	24676 (83.7)	307 (91.1)	313 (90.2)	620 (90.6)	12685 (83.7)	12736 (83.9)	25421 (83.8)
Resides in Nursing Home or Assisted Living Facility	28 (0.2)	35 (0.2)	63 (0.2)	1 (0.3)	0	1 (0.1)	29 (0.2)	35 (0.2)	64 (0.2)
Resides in Multi-Family Dwelling	396 (2.7)	448 (3.0)	844 (2.9)	13 (3.9)	14 (4.0)	27 (3.9)	413 (2.7)	463 (3.0)	876 (2.9)
Resides in High Density Housing	1240 (8.4)	1226 (8.3)	2466 (8.4)	68 (20.2)	62 (17.9)	130 (19.0)	1313 (8.7)	1291 (8.5)	2604 (8.6)
Resides in Low Density, Multi-Family Setting	1426 (9.7)	1419 (9.6)	2845 (9.6)	63 (18.7)	68 (19.6)	131 (19.2)	1492 (9.8)	1492 (9.8)	2984 (9.8)
Resides in a Single Family Home	8224 (55.8)	8209 (55.7)	16433 (55.7)	139 (41.2)	141 (40.6)	280 (40.9)	8406 (55.4)	8402 (55.3)	16808 (55.4)
Other	2112 (14.3)	2136 (14.5)	4248 (14.4)	51 (15.1)	52 (15.0)	103 (15.1)	2175 (14.3)	2198 (14.5)	4373 (14.4)

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Table 14.1.3.2.1
Baseline Demographics and Characteristics by Baseline SARS-CoV-2 Status
Safety Set

Percentages are based on the number of safety subjects.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age at Screening (Years)									
n	11411	11415	22826	3751	3769	7520	15162	15184	30346
Mean	45.0	45.1	45.0	70.7	70.4	70.6	51.3	51.4	51.4
(SD)	(12.30)	(12.35)	(12.33)	(4.88)	(4.66)	(4.77)	(15.60)	(15.51)	(15.55)
Median	46.0	46.0	46.0	70.0	69.0	70.0	52.0	53.0	52.0
Min, Max	18, 64	18, 64	18, 64	65, 95	65, 95	65, 95	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	11411 (100)	11415 (100)	22826 (100)	0	0	0	11411 (75.3)	11415 (75.2)	22826 (75.2)
Mean	45.0	45.1	45.0				45.0	45.1	45.0
(SD)	(12.30)	(12.35)	(12.33)				(12.30)	(12.35)	(12.33)
Median	46.0	46.0	46.0				46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64				18, 64	18, 64	18, 64
>=65 Years	0	0	0	3751 (100)	3769 (100)	7520 (100)	3751 (24.7)	3769 (24.8)	7520 (24.8)
Mean				70.7	70.4	70.6	70.7	70.4	70.6
(SD)				(4.88)	(4.66)	(4.77)	(4.88)	(4.66)	(4.77)
Median				70.0	69.0	70.0	70.0	69.0	70.0
Min, Max				65, 95	65, 95	65, 95	65, 95	65, 95	65, 95

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11411 (100)	11415 (100)	22826 (100)	0	0	0	11411 (75.3)	11415 (75.2)	22826 (75.2)
>=65 and <70 Years	0	0	0	1817 (48.4)	1906 (50.6)	3723 (49.5)	1817 (12.0)	1906 (12.6)	3723 (12.3)
>=70 and <75 Years	0	0	0	1193 (31.8)	1206 (32.0)	2399 (31.9)	1193 (7.9)	1206 (7.9)	2399 (7.9)
>=75 and <80 Years	0	0	0	507 (13.5)	466 (12.4)	973 (12.9)	507 (3.3)	466 (3.1)	973 (3.2)
>=80 Years	0	0	0	234 (6.2)	191 (5.1)	425 (5.7)	234 (1.5)	191 (1.3)	425 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11411 (100)	11415 (100)	22826 (100)	0	0	0	11411 (75.3)	11415 (75.2)	22826 (75.2)
>=65 and <75 Years	0	0	0	3010 (80.2)	3112 (82.6)	6122 (81.4)	3010 (19.9)	3112 (20.5)	6122 (20.2)
>=75 and <85 Years	0	0	0	692 (18.4)	616 (16.3)	1308 (17.4)	692 (4.6)	616 (4.1)	1308 (4.3)
>=85 Years	0	0	0	49 (1.3)	41 (1.1)	90 (1.2)	49 (0.3)	41 (0.3)	90 (0.3)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8878 (77.8)	8890 (77.9)	17768 (77.8)	2 (<0.1)	0	2 (<0.1)	8880 (58.6)	8890 (58.5)	17770 (58.6)
>=18 and <65 Years and at Risk	2532 (22.2)	2524 (22.1)	5056 (22.2)	3 (<0.1)	6 (0.2)	9 (0.1)	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)	3746 (99.9)	3763 (99.8)	7509 (99.9)	3747 (24.7)	3764 (24.8)	7511 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	504 (4.4)	473 (4.1)	977 (4.3)	245 (6.5)	239 (6.3)	484 (6.4)	749 (4.9)	712 (4.7)	1461 (4.8)
Significant Cardiac Disease	292 (2.6)	321 (2.8)	613 (2.7)	450 (12.0)	441 (11.7)	891 (11.8)	742 (4.9)	762 (5.0)	1504 (5.0)
Severe Obesity	905 (7.9)	896 (7.8)	1801 (7.9)	153 (4.1)	174 (4.6)	327 (4.3)	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	912 (8.0)	919 (8.1)	1831 (8.0)	545 (14.5)	541 (14.4)	1086 (14.4)	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver Disease	70 (0.6)	84 (0.7)	154 (0.7)	26 (0.7)	20 (0.5)	46 (0.6)	96 (0.6)	104 (0.7)	200 (0.7)
Human Immunodeficiency Virus Infection	75 (0.7)	77 (0.7)	152 (0.7)	16 (0.4)	17 (0.5)	33 (0.4)	91 (0.6)	94 (0.6)	185 (0.6)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	2322 (20.3)	2320 (20.3)	4642 (20.3)	1135 (30.3)	1128 (29.9)	2263 (30.1)	3457 (22.8)	3448 (22.7)	6905 (22.8)
One Risk Factor for Severe COVID-19	1937 (17.0)	1925 (16.9)	3862 (16.9)	878 (23.4)	866 (23.0)	1744 (23.2)	2815 (18.6)	2791 (18.4)	5606 (18.5)
Two or More Risk Factors for Severe COVID-19	385 (3.4)	395 (3.5)	780 (3.4)	257 (6.9)	262 (7.0)	519 (6.9)	642 (4.2)	657 (4.3)	1299 (4.3)
No	9089 (79.7)	9095 (79.7)	18184 (79.7)	2616 (69.7)	2641 (70.1)	5257 (69.9)	11705 (77.2)	11736 (77.3)	23441 (77.2)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	9089 (79.7)	9095 (79.7)	18184 (79.7)	0	0	0	9089 (59.9)	9095 (59.9)	18184 (59.9)
>=18 and <65 Years and at Risk	2322 (20.3)	2320 (20.3)	4642 (20.3)	0	0	0	2322 (15.3)	2320 (15.3)	4642 (15.3)
>=65 Years and Not at Risk	0	0	0	2616 (69.7)	2641 (70.1)	5257 (69.9)	2616 (17.3)	2641 (17.4)	5257 (17.3)
>=65 Years and at Risk	0	0	0	1135 (30.3)	1128 (29.9)	2263 (30.1)	1135 (7.5)	1128 (7.4)	2263 (7.5)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Baseline RT-PCR Results, n (%)									
Negative	11269	11270	22539	3722	3747	7469	14991	15017	30008
	(98.8)	(98.7)	(98.7)	(99.2)	(99.4)	(99.3)	(98.9)	(98.9)	(98.9)
Positive	85	81	166	10	7	17	95	88	183
	(0.7)	(0.7)	(0.7)	(0.3)	(0.2)	(0.2)	(0.6)	(0.6)	(0.6)
Missing	57	64	121	19	15	34	76	79	155
	(0.5)	(0.6)	(0.5)	(0.5)	(0.4)	(0.5)	(0.5)	(0.5)	(0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	11122	11126	22248	3718	3725	7443	14840	14851	29691
	(97.5)	(97.5)	(97.5)	(99.1)	(98.8)	(99.0)	(97.9)	(97.8)	(97.8)
Positive	274	276	550	29	33	62	303	309	612
	(2.4)	(2.4)	(2.4)	(0.8)	(0.9)	(0.8)	(2.0)	(2.0)	(2.0)
Missing	15	13	28	4	11	15	19	24	43
	(0.1)	(0.1)	(0.1)	(0.1)	(0.3)	(0.2)	(0.1)	(0.2)	(0.1)
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	11044	11039	22083	3697	3711	7408	14741	14750	29491
	(96.8)	(96.7)	(96.7)	(98.6)	(98.5)	(98.5)	(97.2)	(97.1)	(97.2)
Positive	303	311	614	34	36	70	337	347	684
	(2.7)	(2.7)	(2.7)	(0.9)	(1.0)	(0.9)	(2.2)	(2.3)	(2.3)
Missing	64	65	129	20	22	42	84	87	171
	(0.6)	(0.6)	(0.6)	(0.5)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Sex, n (%)									
Male	5955 (52.2)	5841 (51.2)	11796 (51.7)	2101 (56.0)	2077 (55.1)	4178 (55.6)	8056 (53.1)	7918 (52.1)	15974 (52.6)
Female	5456 (47.8)	5574 (48.8)	11030 (48.3)	1650 (44.0)	1692 (44.9)	3342 (44.4)	7106 (46.9)	7266 (47.9)	14372 (47.4)
Race, n (%)									
White	8656 (75.9)	8654 (75.8)	17310 (75.8)	3342 (89.1)	3380 (89.7)	6722 (89.4)	11998 (79.1)	12034 (79.3)	24032 (79.2)
Black or African American	1316 (11.5)	1345 (11.8)	2661 (11.7)	215 (5.7)	222 (5.9)	437 (5.8)	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	662 (5.8)	589 (5.2)	1251 (5.5)	77 (2.1)	67 (1.8)	144 (1.9)	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	95 (0.8)	92 (0.8)	187 (0.8)	26 (0.7)	21 (0.6)	47 (0.6)	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	29 (0.3)	33 (0.3)	62 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	32 (0.2)	36 (0.2)	68 (0.2)
Multiracial	283 (2.5)	288 (2.5)	571 (2.5)	35 (0.9)	32 (0.8)	67 (0.9)	318 (2.1)	320 (2.1)	638 (2.1)
Other	262 (2.3)	276 (2.4)	538 (2.4)	32 (0.9)	23 (0.6)	55 (0.7)	294 (1.9)	299 (2.0)	593 (2.0)
Not Reported	60 (0.5)	84 (0.7)	144 (0.6)	14 (0.4)	13 (0.3)	27 (0.4)	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	48 (0.4)	54 (0.5)	102 (0.4)	7 (0.2)	8 (0.2)	15 (0.2)	55 (0.4)	62 (0.4)	117 (0.4)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Ethnicity, n (%)									
Hispanic or Latino	2773 (24.3)	2768 (24.2)	5541 (24.3)	335 (8.9)	354 (9.4)	689 (9.2)	3108 (20.5)	3122 (20.6)	6230 (20.5)
Not Hispanic or Latino	8543 (74.9)	8549 (74.9)	17092 (74.9)	3375 (90.0)	3371 (89.4)	6746 (89.7)	11918 (78.6)	11920 (78.5)	23838 (78.6)
Not Reported	57 (0.5)	72 (0.6)	129 (0.6)	26 (0.7)	33 (0.9)	59 (0.8)	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	38 (0.3)	26 (0.2)	64 (0.3)	15 (0.4)	11 (0.3)	26 (0.3)	53 (0.3)	37 (0.2)	90 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	4069 (35.7)	4076 (35.7)	8145 (35.7)	561 (15.0)	578 (15.3)	1139 (15.1)	4630 (30.5)	4654 (30.7)	9284 (30.6)
Non-minority	7329 (64.2)	7319 (64.1)	14648 (64.2)	3177 (84.7)	3185 (84.5)	6362 (84.6)	10506 (69.3)	10504 (69.2)	21010 (69.2)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	6401 (56.1)	6459 (56.6)	12860 (56.3)	3065 (81.7)	3076 (81.6)	6141 (81.7)	9466 (62.4)	9535 (62.8)	19001 (62.6)
Communities of Color	4997 (43.8)	4936 (43.2)	9933 (43.5)	673 (17.9)	687 (18.2)	1360 (18.1)	5670 (37.4)	5623 (37.0)	11293 (37.2)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.3)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Weight (kg)									
n	11351	11359	22710	3728	3740	7468	15079	15099	30178
Mean	86.75	86.56	86.66	83.24	83.10	83.17	85.88	85.70	85.79
(SD)	(22.351)	(22.683)	(22.518)	(19.020)	(19.333)	(19.176)	(21.628)	(21.951)	(21.790)
Median	83.64	83.64	83.64	81.60	81.20	81.40	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4	34.8, 184.5	37.2, 165.0	34.8, 184.5	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)									
n	11350	11359	22709	3727	3741	7468	15077	15100	30177
Mean	171.16	170.98	171.07	170.05	169.97	170.01	170.89	170.73	170.81
(SD)	(9.964)	(9.902)	(9.933)	(10.223)	(10.005)	(10.114)	(10.039)	(9.937)	(9.988)
Median	171.00	170.20	170.50	170.18	170.18	170.18	170.50	170.18	170.20
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0	124.5, 223.5	123.0, 208.3	123.0, 223.5	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	11350	11356	22706	3727	3740	7467	15077	15096	30173
Mean	29.53	29.53	29.53	28.71	28.67	28.69	29.33	29.32	29.32
(SD)	(6.904)	(7.120)	(7.012)	(5.891)	(5.850)	(5.870)	(6.677)	(6.837)	(6.757)
Median	28.27	28.25	28.26	27.75	27.86	27.79	28.14	28.13	28.13
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1	12.1, 71.1	11.2, 62.9	11.2, 71.1	10.3, 72.7	9.8, 86.1	9.8, 86.1

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Body Mass Index Subgroup, n (%)									
< 30 kg/m^2	6866 (60.2)	6860 (60.1)	13726 (60.1)	2434 (64.9)	2416 (64.1)	4850 (64.5)	9300 (61.3)	9276 (61.1)	18576 (61.2)
>=30 kg/m^2	4484 (39.3)	4496 (39.4)	8980 (39.3)	1293 (34.5)	1324 (35.1)	2617 (34.8)	5777 (38.1)	5820 (38.3)	11597 (38.2)
Missing	61 (0.5)	59 (0.5)	120 (0.5)	24 (0.6)	29 (0.8)	53 (0.7)	85 (0.6)	88 (0.6)	173 (0.6)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Occupational Risk, n (%) [2]	10161	10123	20284	2386	2377	4763	12547	12500	25047
	(89.0)	(88.7)	(88.9)	(63.6)	(63.1)	(63.3)	(82.8)	(82.3)	(82.5)
Healthcare Workers	3337	3341	6678	503	468	971	3840	3809	7649
	(29.2)	(29.3)	(29.3)	(13.4)	(12.4)	(12.9)	(25.3)	(25.1)	(25.2)
Emergency Response	277	281	558	19	21	40	296	302	598
	(2.4)	(2.5)	(2.4)	(0.5)	(0.6)	(0.5)	(2.0)	(2.0)	(2.0)
Retail or Restaurant Operations	881	858	1739	99	100	199	980	958	1938
	(7.7)	(7.5)	(7.6)	(2.6)	(2.7)	(2.6)	(6.5)	(6.3)	(6.4)
Manufacturing and Production Operations	391	391	782	30	35	65	421	426	847
	(3.4)	(3.4)	(3.4)	(0.8)	(0.9)	(0.9)	(2.8)	(2.8)	(2.8)
Warehouse Shipping and Fulfillment Centers	163	181	344	12	9	21	175	190	365
	(1.4)	(1.6)	(1.5)	(0.3)	(0.2)	(0.3)	(1.2)	(1.3)	(1.2)
Transportation and Delivery Services	419	434	853	61	50	111	480	484	964
	(3.7)	(3.8)	(3.7)	(1.6)	(1.3)	(1.5)	(3.2)	(3.2)	(3.2)
Border Protection and Military Personnel	63	65	128	6	3	9	69	68	137
	(0.6)	(0.6)	(0.6)	(0.2)	(<0.1)	(0.1)	(0.5)	(0.4)	(0.5)
Personal Care and In-Home Services	407	405	812	61	67	128	468	472	940
	(3.6)	(3.5)	(3.6)	(1.6)	(1.8)	(1.7)	(3.1)	(3.1)	(3.1)
Hospitality and Tourism Workers	184	201	385	43	37	80	227	238	465
	(1.6)	(1.8)	(1.7)	(1.1)	(1.0)	(1.1)	(1.5)	(1.6)	(1.5)
Pastoral, Social or Public Health Workers	364	386	750	140	149	289	504	535	1039
	(3.2)	(3.4)	(3.3)	(3.7)	(4.0)	(3.8)	(3.3)	(3.5)	(3.4)
Educators and Students	1387	1365	2752	170	186	356	1557	1551	3108
	(12.2)	(12.0)	(12.1)	(4.5)	(4.9)	(4.7)	(10.3)	(10.2)	(10.2)
Other	3398	3415	6813	1432	1435	2867	4830	4850	9680
	(29.8)	(29.9)	(29.8)	(38.2)	(38.1)	(38.1)	(31.9)	(31.9)	(31.9)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Location and Living Circumstances Risk, n (%) [2]	9578 (83.9)	9601 (84.1)	19179 (84.0)	3107 (82.8)	3135 (83.2)	6242 (83.0)	12685 (83.7)	12736 (83.9)	25421 (83.8)
Resides in Nursing Home or Assisted Living Facility	9 (<0.1)	24 (0.2)	33 (0.1)	20 (0.5)	11 (0.3)	31 (0.4)	29 (0.2)	35 (0.2)	64 (0.2)
Resides in Multi-Family Dwelling	348 (3.0)	397 (3.5)	745 (3.3)	65 (1.7)	66 (1.8)	131 (1.7)	413 (2.7)	463 (3.0)	876 (2.9)
Resides in High Density Housing	1073 (9.4)	1038 (9.1)	2111 (9.2)	240 (6.4)	253 (6.7)	493 (6.6)	1313 (8.7)	1291 (8.5)	2604 (8.6)
Resides in Low Density, Multi-Family Setting	1236 (10.8)	1248 (10.9)	2484 (10.9)	256 (6.8)	244 (6.5)	500 (6.6)	1492 (9.8)	1492 (9.8)	2984 (9.8)
Resides in a Single Family Home	6146 (53.9)	6117 (53.6)	12263 (53.7)	2260 (60.3)	2285 (60.6)	4545 (60.4)	8406 (55.4)	8402 (55.3)	16808 (55.4)
Other	1647 (14.4)	1649 (14.4)	3296 (14.4)	528 (14.1)	549 (14.6)	1077 (14.3)	2175 (14.3)	2198 (14.5)	4373 (14.4)

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Table 14.1.3.2.2
Baseline Demographics and Characteristics by Age Group
Safety Set

Percentages are based on the number of safety subjects.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age at Screening (Years)			
n	15162	15184	30346
Mean (SD)	51.3 (15.60)	51.4 (15.51)	51.4 (15.55)
Median	52.0	53.0	52.0
Min, Max	18, 95	18, 95	18, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	11411 (75.3)	11415 (75.2)	22826 (75.2)
Mean (SD)	45.0 (12.30)	45.1 (12.35)	45.0 (12.33)
Median	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3751 (24.7)	3769 (24.8)	7520 (24.8)
Mean (SD)	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11411 (75.3)	11415 (75.2)	22826 (75.2)
>=65 and <70 Years	1817 (12.0)	1906 (12.6)	3723 (12.3)
>=70 and <75 Years	1193 (7.9)	1206 (7.9)	2399 (7.9)
>=75 and <80 Years	507 (3.3)	466 (3.1)	973 (3.2)
>=80 Years	234 (1.5)	191 (1.3)	425 (1.4)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11411 (75.3)	11415 (75.2)	22826 (75.2)
>=65 and <75 Years	3010 (19.9)	3112 (20.5)	6122 (20.2)
>=75 and <85 Years	692 (4.6)	616 (4.1)	1308 (4.3)
>=85 Years	49 (0.3)	41 (0.3)	90 (0.3)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8880 (58.6)	8890 (58.5)	17770 (58.6)
>=18 and <65 Years and at Risk	2535 (16.7)	2530 (16.7)	5065 (16.7)
>=65 Years	3747 (24.7)	3764 (24.8)	7511 (24.8)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	749 (4.9)	712 (4.7)	1461 (4.8)
Significant Cardiac Disease	742 (4.9)	762 (5.0)	1504 (5.0)
Severe Obesity	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver Disease	96 (0.6)	104 (0.7)	200 (0.7)
Human Immunodeficiency Virus Infection	91 (0.6)	94 (0.6)	185 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	3457 (22.8)	3448 (22.7)	6905 (22.8)
One Risk Factor for Severe COVID-19	2815 (18.6)	2791 (18.4)	5606 (18.5)
Two or More Risk Factors for Severe COVID-19	642 (4.2)	657 (4.3)	1299 (4.3)
No	11705 (77.2)	11736 (77.3)	23441 (77.2)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	9089 (59.9)	9095 (59.9)	18184 (59.9)
>=18 and <65 Years and at Risk	2322 (15.3)	2320 (15.3)	4642 (15.3)
>=65 Years and Not at Risk	2616 (17.3)	2641 (17.4)	5257 (17.3)
>=65 Years and at Risk	1135 (7.5)	1128 (7.4)	2263 (7.5)
Baseline RT-PCR Results, n (%)			
Negative	14991 (98.9)	15017 (98.9)	30008 (98.9)
Positive	95 (0.6)	88 (0.6)	183 (0.6)
Missing	76 (0.5)	79 (0.5)	155 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	14840 (97.9)	14851 (97.8)	29691 (97.8)
Positive	303 (2.0)	309 (2.0)	612 (2.0)
Missing	19 (0.1)	24 (0.2)	43 (0.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	14741 (97.2)	14750 (97.1)	29491 (97.2)
Positive	337 (2.2)	347 (2.3)	684 (2.3)
Missing	84 (0.6)	87 (0.6)	171 (0.6)
Sex, n (%)			
Male	8056 (53.1)	7918 (52.1)	15974 (52.6)
Female	7106 (46.9)	7266 (47.9)	14372 (47.4)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Race, n (%)			
White	11998 (79.1)	12034 (79.3)	24032 (79.2)
Black or African American	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	32 (0.2)	36 (0.2)	68 (0.2)
Multiracial	318 (2.1)	320 (2.1)	638 (2.1)
Other	294 (1.9)	299 (2.0)	593 (2.0)
Not Reported	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	55 (0.4)	62 (0.4)	117 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	3108 (20.5)	3122 (20.6)	6230 (20.5)
Not Hispanic or Latino	11918 (78.6)	11920 (78.5)	23838 (78.6)
Not Reported	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	53 (0.3)	37 (0.2)	90 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	4630 (30.5)	4654 (30.7)	9284 (30.6)
Non-minority	10506 (69.3)	10504 (69.2)	21010 (69.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	9466 (62.4)	9535 (62.8)	19001 (62.6)
Communities of Color	5670 (37.4)	5623 (37.0)	11293 (37.2)
Missing	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Weight (kg)			
n	15079	15099	30178
Mean (SD)	85.88 (21.628)	85.70 (21.951)	85.79 (21.790)
Median	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)			
n	15077	15100	30177
Mean (SD)	170.89 (10.039)	170.73 (9.937)	170.81 (9.988)
Median	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)			
n	15077	15096	30173
Mean (SD)	29.33 (6.677)	29.32 (6.837)	29.32 (6.757)
Median	28.14	28.13	28.13
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	9300 (61.3)	9276 (61.1)	18576 (61.2)
>=30 kg/m^2	5777 (38.1)	5820 (38.3)	11597 (38.2)
Missing	85 (0.6)	88 (0.6)	173 (0.6)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: Overall

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Occupational Risk, n (%) [2]	12547 (82.8)	12500 (82.3)	25047 (82.5)
Healthcare Workers	3840 (25.3)	3809 (25.1)	7649 (25.2)
Emergency Response	296 (2.0)	302 (2.0)	598 (2.0)
Retail or Restaurant Operations	980 (6.5)	958 (6.3)	1938 (6.4)
Manufacturing and Production Operations	421 (2.8)	426 (2.8)	847 (2.8)
Warehouse Shipping and Fulfillment Centers	175 (1.2)	190 (1.3)	365 (1.2)
Transportation and Delivery Services	480 (3.2)	484 (3.2)	964 (3.2)
Border Protection and Military Personnel	69 (0.5)	68 (0.4)	137 (0.5)
Personal Care and In-Home Services	468 (3.1)	472 (3.1)	940 (3.1)
Hospitality and Tourism Workers	227 (1.5)	238 (1.6)	465 (1.5)
Pastoral, Social or Public Health Workers	504 (3.3)	535 (3.5)	1039 (3.4)
Educators and Students	1557 (10.3)	1551 (10.2)	3108 (10.2)
Other	4830 (31.9)	4850 (31.9)	9680 (31.9)
Location and Living Circumstances Risk, n (%) [2]	12685 (83.7)	12736 (83.9)	25421 (83.8)
Resides in Nursing Home or Assisted Living Facility	29 (0.2)	35 (0.2)	64 (0.2)
Resides in Multi-Family Dwelling	413 (2.7)	463 (3.0)	876 (2.9)
Resides in High Density Housing	1313 (8.7)	1291 (8.5)	2604 (8.6)
Resides in Low Density, Multi-Family Setting	1492 (9.8)	1492 (9.8)	2984 (9.8)
Resides in a Single Family Home	8406 (55.4)	8402 (55.3)	16808 (55.4)
Other	2175 (14.3)	2198 (14.5)	4373 (14.4)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880)	mRNA-1273 (N=8890)	Total (N=17770)
Age at Screening (Years)			
n	8880	8890	17770
Mean (SD)	43.8 (12.33)	44.0 (12.40)	43.9 (12.37)
Median	44.0	44.0	44.0
Min, Max	18, 72	18, 64	18, 72
Age Group at Screening, n (%)			
>=18 and <65 Years	8878(>99.9)	8890 (100)	17768(>99.9)
Mean (SD)	43.8 (12.33)	44.0 (12.40)	43.9 (12.36)
Median	44.0	44.0	44.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	2 (<0.1)	0	2 (<0.1)
Mean (SD)	68.5 (4.95)		68.5 (4.95)
Median	68.5		68.5
Min, Max	65, 72		65, 72
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8878(>99.9)	8890 (100)	17768(>99.9)
>=65 and <70 Years	1 (<0.1)	0	1 (<0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880)	mRNA-1273 (N=8890)	Total (N=17770)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8878 (>99.9)	8890 (100)	17768 (>99.9)
>=65 and <75 Years	2 (<0.1)	0	2 (<0.1)
>=75 and <85 Years	0	0	0
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8880 (100)	8890 (100)	17770 (100)
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	14 (0.2)	19 (0.2)	33 (0.2)
Significant Cardiac Disease	10 (0.1)	11 (0.1)	21 (0.1)
Severe Obesity	67 (0.8)	61 (0.7)	128 (0.7)
Diabetes	36 (0.4)	34 (0.4)	70 (0.4)
Liver Disease	9 (0.1)	8 (<0.1)	17 (<0.1)
Human Immunodeficiency Virus Infection	14 (0.2)	11 (0.1)	25 (0.1)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	139 (1.6)	131 (1.5)	270 (1.5)
One Risk Factor for Severe COVID-19	129 (1.5)	121 (1.4)	250 (1.4)
Two or More Risk Factors for Severe COVID-19	10 (0.1)	10 (0.1)	20 (0.1)
No	8741 (98.4)	8759 (98.5)	17500 (98.5)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880)	mRNA-1273 (N=8890)	Total (N=17770)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	8740 (98.4)	8759 (98.5)	17499 (98.5)
>=18 and <65 Years and at Risk	138 (1.6)	131 (1.5)	269 (1.5)
>=65 Years and Not at Risk	1 (<0.1)	0	1 (<0.1)
>=65 Years and at Risk	1 (<0.1)	0	1 (<0.1)
Baseline RT-PCR Results, n (%)			
Negative	8783 (98.9)	8776 (98.7)	17559 (98.8)
Positive	65 (0.7)	65 (0.7)	130 (0.7)
Missing	32 (0.4)	49 (0.6)	81 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	8658 (97.5)	8649 (97.3)	17307 (97.4)
Positive	213 (2.4)	233 (2.6)	446 (2.5)
Missing	9 (0.1)	8 (<0.1)	17 (<0.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	8606 (96.9)	8577 (96.5)	17183 (96.7)
Positive	236 (2.7)	263 (3.0)	499 (2.8)
Missing	38 (0.4)	50 (0.6)	88 (0.5)
Sex, n (%)			
Male	4627 (52.1)	4542 (51.1)	9169 (51.6)
Female	4253 (47.9)	4348 (48.9)	8601 (48.4)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880)	mRNA-1273 (N=8890)	Total (N=17770)
Race, n (%)			
White	6788 (76.4)	6759 (76.0)	13547 (76.2)
Black or African American	901 (10.1)	971 (10.9)	1872 (10.5)
Asian	579 (6.5)	503 (5.7)	1082 (6.1)
American Indian or Alaska Native	72 (0.8)	65 (0.7)	137 (0.8)
Native Hawaiian or Other Pacific Islander	20 (0.2)	26 (0.3)	46 (0.3)
Multiracial	232 (2.6)	236 (2.7)	468 (2.6)
Other	211 (2.4)	220 (2.5)	431 (2.4)
Not Reported	42 (0.5)	67 (0.8)	109 (0.6)
Unknown	35 (0.4)	43 (0.5)	78 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	2221 (25.0)	2212 (24.9)	4433 (24.9)
Not Hispanic or Latino	6587 (74.2)	6598 (74.2)	13185 (74.2)
Not Reported	42 (0.5)	58 (0.7)	100 (0.6)
Unknown	30 (0.3)	22 (0.2)	52 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	3099 (34.9)	3150 (35.4)	6249 (35.2)
Non-minority	5773 (65.0)	5726 (64.4)	11499 (64.7)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)
Race and Ethnicity Group, n (%) [6]			
White	4977 (56.0)	5005 (56.3)	9982 (56.2)
Communities of Color	3895 (43.9)	3871 (43.5)	7766 (43.7)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880)	mRNA-1273 (N=8890)	Total (N=17770)
Weight (kg)			
n	8834	8839	17673
Mean (SD)	82.29 (18.002)	82.01 (18.160)	82.15 (18.081)
Median	80.80	80.50	80.70
Min, Max	30.7, 182.4	33.3, 178.7	30.7, 182.4
Height (cm)			
n	8834	8838	17672
Mean (SD)	171.24 (9.895)	171.05 (9.893)	171.14 (9.894)
Median	171.00	170.20	170.70
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0
Body Mass Index (kg/m^2)			
n	8834	8836	17670
Mean (SD)	27.96 (5.134)	27.92 (5.255)	27.94 (5.195)
Median	27.33	27.35	27.34
Min, Max	10.3, 53.1	9.8, 57.9	9.8, 57.9
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	5977 (67.3)	5992 (67.4)	11969 (67.4)
>=30 kg/m^2	2857 (32.2)	2844 (32.0)	5701 (32.1)
Missing	46 (0.5)	54 (0.6)	100 (0.6)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8880)	mRNA-1273 (N=8890)	Total (N=17770)
Occupational Risk, n (%) [2]	7991 (90.0)	7972 (89.7)	15963 (89.8)
Healthcare Workers	2743 (30.9)	2745 (30.9)	5488 (30.9)
Emergency Response	219 (2.5)	234 (2.6)	453 (2.5)
Retail or Restaurant Operations	693 (7.8)	685 (7.7)	1378 (7.8)
Manufacturing and Production Operations	307 (3.5)	290 (3.3)	597 (3.4)
Warehouse Shipping and Fulfillment Centers	121 (1.4)	138 (1.6)	259 (1.5)
Transportation and Delivery Services	318 (3.6)	337 (3.8)	655 (3.7)
Border Protection and Military Personnel	51 (0.6)	53 (0.6)	104 (0.6)
Personal Care and In-Home Services	329 (3.7)	303 (3.4)	632 (3.6)
Hospitality and Tourism Workers	145 (1.6)	164 (1.8)	309 (1.7)
Pastoral, Social or Public Health Workers	264 (3.0)	297 (3.3)	561 (3.2)
Educators and Students	1118 (12.6)	1090 (12.3)	2208 (12.4)
Other	2605 (29.3)	2602 (29.3)	5207 (29.3)
Location and Living Circumstances Risk, n (%) [2]	7488 (84.3)	7539 (84.8)	15027 (84.6)
Resides in Nursing Home or Assisted Living Facility	6 (<0.1)	12 (0.1)	18 (0.1)
Resides in Multi-Family Dwelling	269 (3.0)	306 (3.4)	575 (3.2)
Resides in High Density Housing	877 (9.9)	842 (9.5)	1719 (9.7)
Resides in Low Density, Multi-Family Setting	958 (10.8)	945 (10.6)	1903 (10.7)
Resides in a Single Family Home	4771 (53.7)	4815 (54.2)	9586 (53.9)
Other	1313 (14.8)	1336 (15.0)	2649 (14.9)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age at Screening (Years)			
n	2535	2530	5065
Mean (SD)	49.2 (11.28)	48.9 (11.41)	49.0 (11.34)
Median	51.0	51.0	51.0
Min, Max	18, 79	18, 76	18, 79
Age Group at Screening, n (%)			
>=18 and <65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
Mean (SD)	49.1 (11.25)	48.9 (11.38)	49.0 (11.32)
Median	51.0	51.0	51.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3 (0.1)	6 (0.2)	9 (0.2)
Mean (SD)	72.0 (7.00)	67.7 (4.37)	69.1 (5.37)
Median	72.0	65.5	66.0
Min, Max	65, 79	65, 76	65, 79
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
>=65 and <70 Years	1 (<0.1)	5 (0.2)	6 (0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=80 Years	0	0	0

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2532 (99.9)	2524 (99.8)	5056 (99.8)
>=65 and <75 Years	2 (<0.1)	5 (0.2)	7 (0.1)
>=75 and <85 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	2535 (100)	2530 (100)	5065 (100)
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	491 (19.4)	455 (18.0)	946 (18.7)
Significant Cardiac Disease	282 (11.1)	312 (12.3)	594 (11.7)
Severe Obesity	837 (33.0)	836 (33.0)	1673 (33.0)
Diabetes	878 (34.6)	887 (35.1)	1765 (34.8)
Liver Disease	61 (2.4)	76 (3.0)	137 (2.7)
Human Immunodeficiency Virus Infection	61 (2.4)	66 (2.6)	127 (2.5)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	2185 (86.2)	2192 (86.6)	4377 (86.4)
One Risk Factor for Severe COVID-19	1810 (71.4)	1804 (71.3)	3614 (71.4)
Two or More Risk Factors for Severe COVID-19	375 (14.8)	388 (15.3)	763 (15.1)
No	350 (13.8)	338 (13.4)	688 (13.6)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	349 (13.8)	336 (13.3)	685 (13.5)
>=18 and <65 Years and at Risk	2183 (86.1)	2188 (86.5)	4371 (86.3)
>=65 Years and Not at Risk	1 (<0.1)	2 (<0.1)	3 (<0.1)
>=65 Years and at Risk	2 (<0.1)	4 (0.2)	6 (0.1)
Baseline RT-PCR Results, n (%)			
Negative	2490 (98.2)	2499 (98.8)	4989 (98.5)
Positive	20 (0.8)	16 (0.6)	36 (0.7)
Missing	25 (1.0)	15 (0.6)	40 (0.8)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	2468 (97.4)	2482 (98.1)	4950 (97.7)
Positive	61 (2.4)	43 (1.7)	104 (2.1)
Missing	6 (0.2)	5 (0.2)	11 (0.2)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	2442 (96.3)	2467 (97.5)	4909 (96.9)
Positive	67 (2.6)	48 (1.9)	115 (2.3)
Missing	26 (1.0)	15 (0.6)	41 (0.8)
Sex, n (%)			
Male	1330 (52.5)	1302 (51.5)	2632 (52.0)
Female	1205 (47.5)	1228 (48.5)	2433 (48.0)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Race, n (%)			
White	1873 (73.9)	1899 (75.1)	3772 (74.5)
Black or African American	414 (16.3)	374 (14.8)	788 (15.6)
Asian	83 (3.3)	87 (3.4)	170 (3.4)
American Indian or Alaska Native	23 (0.9)	27 (1.1)	50 (1.0)
Native Hawaiian or Other Pacific Islander	9 (0.4)	7 (0.3)	16 (0.3)
Multiracial	51 (2.0)	52 (2.1)	103 (2.0)
Other	51 (2.0)	56 (2.2)	107 (2.1)
Not Reported	18 (0.7)	17 (0.7)	35 (0.7)
Unknown	13 (0.5)	11 (0.4)	24 (0.5)
Ethnicity, n (%)			
Hispanic or Latino	553 (21.8)	557 (22.0)	1110 (21.9)
Not Hispanic or Latino	1959 (77.3)	1955 (77.3)	3914 (77.3)
Not Reported	15 (0.6)	14 (0.6)	29 (0.6)
Unknown	8 (0.3)	4 (0.2)	12 (0.2)
Race and Ethnicity Group, n (%) [5]			
Minority	970 (38.3)	927 (36.6)	1897 (37.5)
Non-minority	1560 (61.5)	1597 (63.1)	3157 (62.3)
Missing	5 (0.2)	6 (0.2)	11 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	1428 (56.3)	1457 (57.6)	2885 (57.0)
Communities of Color	1102 (43.5)	1067 (42.2)	2169 (42.8)
Missing	5 (0.2)	6 (0.2)	11 (0.2)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Weight (kg)			
n	2521	2525	5046
Mean (SD)	102.36 (28.306)	102.52 (28.894)	102.44 (28.599)
Median	98.82	99.45	99.09
Min, Max	33.5, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)			
n	2520	2526	5046
Mean (SD)	170.91 (10.196)	170.73 (9.947)	170.82 (10.071)
Median	170.42	170.18	170.18
Min, Max	123.5, 203.2	111.0, 202.8	111.0, 203.2
Body Mass Index (kg/m^2)			
n	2520	2525	5045
Mean (SD)	35.01 (9.146)	35.17 (9.523)	35.09 (9.336)
Median	33.76	33.64	33.71
Min, Max	11.6, 72.7	11.7, 86.1	11.6, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	894 (35.3)	869 (34.3)	1763 (34.8)
>=30 kg/m^2	1626 (64.1)	1656 (65.5)	3282 (64.8)
Missing	15 (0.6)	5 (0.2)	20 (0.4)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2535)	mRNA-1273 (N=2530)	Total (N=5065)
Occupational Risk, n (%) [2]	2172 (85.7)	2156 (85.2)	4328 (85.4)
Healthcare Workers	595 (23.5)	597 (23.6)	1192 (23.5)
Emergency Response	58 (2.3)	48 (1.9)	106 (2.1)
Retail or Restaurant Operations	188 (7.4)	173 (6.8)	361 (7.1)
Manufacturing and Production Operations	84 (3.3)	101 (4.0)	185 (3.7)
Warehouse Shipping and Fulfillment Centers	42 (1.7)	43 (1.7)	85 (1.7)
Transportation and Delivery Services	100 (3.9)	97 (3.8)	197 (3.9)
Border Protection and Military Personnel	12 (0.5)	12 (0.5)	24 (0.5)
Personal Care and In-Home Services	78 (3.1)	102 (4.0)	180 (3.6)
Hospitality and Tourism Workers	39 (1.5)	37 (1.5)	76 (1.5)
Pastoral, Social or Public Health Workers	102 (4.0)	90 (3.6)	192 (3.8)
Educators and Students	270 (10.7)	276 (10.9)	546 (10.8)
Other	794 (31.3)	816 (32.3)	1610 (31.8)
Location and Living Circumstances Risk, n (%) [2]	2095 (82.6)	2065 (81.6)	4160 (82.1)
Resides in Nursing Home or Assisted Living Facility	3 (0.1)	12 (0.5)	15 (0.3)
Resides in Multi-Family Dwelling	79 (3.1)	91 (3.6)	170 (3.4)
Resides in High Density Housing	196 (7.7)	196 (7.7)	392 (7.7)
Resides in Low Density, Multi-Family Setting	278 (11.0)	303 (12.0)	581 (11.5)
Resides in a Single Family Home	1380 (54.4)	1304 (51.5)	2684 (53.0)
Other	334 (13.2)	314 (12.4)	648 (12.8)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747)	mRNA-1273 (N=3764)	Total (N=7511)
Age at Screening (Years)			
n	3747	3764	7511
Mean (SD)	70.7 (4.90)	70.4 (4.66)	70.6 (4.79)
Median	70.0	69.0	70.0
Min, Max	40, 95	64, 95	40, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mean (SD)	40.0 (NA)	64.0 (NA)	52.0 (16.97)
Median	40.0	64.0	52.0
Min, Max	40, 40	64, 64	40, 64
>=65 Years	3746(>99.9)	3763(>99.9)	7509(>99.9)
Mean (SD)	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <70 Years	1815 (48.4)	1901 (50.5)	3716 (49.5)
>=70 and <75 Years	1191 (31.8)	1206 (32.0)	2397 (31.9)
>=75 and <80 Years	506 (13.5)	465 (12.4)	971 (12.9)
>=80 Years	234 (6.2)	191 (5.1)	425 (5.7)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747)	mRNA-1273 (N=3764)	Total (N=7511)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <75 Years	3006 (80.2)	3107 (82.5)	6113 (81.4)
>=75 and <85 Years	691 (18.4)	615 (16.3)	1306 (17.4)
>=85 Years	49 (1.3)	41 (1.1)	90 (1.2)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	3747 (100)	3764 (100)	7511 (100)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	244 (6.5)	238 (6.3)	482 (6.4)
Significant Cardiac Disease	450 (12.0)	439 (11.7)	889 (11.8)
Severe Obesity	154 (4.1)	173 (4.6)	327 (4.4)
Diabetes	543 (14.5)	539 (14.3)	1082 (14.4)
Liver Disease	26 (0.7)	20 (0.5)	46 (0.6)
Human Immunodeficiency Virus Infection	16 (0.4)	17 (0.5)	33 (0.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1133 (30.2)	1125 (29.9)	2258 (30.1)
One Risk Factor for Severe COVID-19	876 (23.4)	866 (23.0)	1742 (23.2)
Two or More Risk Factors for Severe COVID-19	257 (6.9)	259 (6.9)	516 (6.9)
No	2614 (69.8)	2639 (70.1)	5253 (69.9)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747)	mRNA-1273 (N=3764)	Total (N=7511)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 Years and Not at Risk	2614 (69.8)	2639 (70.1)	5253 (69.9)
>=65 Years and at Risk	1132 (30.2)	1124 (29.9)	2256 (30.0)
Baseline RT-PCR Results, n (%)			
Negative	3718 (99.2)	3742 (99.4)	7460 (99.3)
Positive	10 (0.3)	7 (0.2)	17 (0.2)
Missing	19 (0.5)	15 (0.4)	34 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	3714 (99.1)	3720 (98.8)	7434 (99.0)
Positive	29 (0.8)	33 (0.9)	62 (0.8)
Missing	4 (0.1)	11 (0.3)	15 (0.2)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	3693 (98.6)	3706 (98.5)	7399 (98.5)
Positive	34 (0.9)	36 (1.0)	70 (0.9)
Missing	20 (0.5)	22 (0.6)	42 (0.6)
Sex, n (%)			
Male	2099 (56.0)	2074 (55.1)	4173 (55.6)
Female	1648 (44.0)	1690 (44.9)	3338 (44.4)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747)	mRNA-1273 (N=3764)	Total (N=7511)
Race, n (%)			
White	3337 (89.1)	3376 (89.7)	6713 (89.4)
Black or African American	216 (5.8)	222 (5.9)	438 (5.8)
Asian	77 (2.1)	66 (1.8)	143 (1.9)
American Indian or Alaska Native	26 (0.7)	21 (0.6)	47 (0.6)
Native Hawaiian or Other Pacific Islander	3 (<0.1)	3 (<0.1)	6 (<0.1)
Multiracial	35 (0.9)	32 (0.9)	67 (0.9)
Other	32 (0.9)	23 (0.6)	55 (0.7)
Not Reported	14 (0.4)	13 (0.3)	27 (0.4)
Unknown	7 (0.2)	8 (0.2)	15 (0.2)
Ethnicity, n (%)			
Hispanic or Latino	334 (8.9)	353 (9.4)	687 (9.1)
Not Hispanic or Latino	3372 (90.0)	3367 (89.5)	6739 (89.7)
Not Reported	26 (0.7)	33 (0.9)	59 (0.8)
Unknown	15 (0.4)	11 (0.3)	26 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	561 (15.0)	577 (15.3)	1138 (15.2)
Non-minority	3173 (84.7)	3181 (84.5)	6354 (84.6)
Missing	13 (0.3)	6 (0.2)	19 (0.3)
Race and Ethnicity Group, n (%) [6]			
White	3061 (81.7)	3073 (81.6)	6134 (81.7)
Communities of Color	673 (18.0)	685 (18.2)	1358 (18.1)
Missing	13 (0.3)	6 (0.2)	19 (0.3)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747)	mRNA-1273 (N=3764)	Total (N=7511)
Weight (kg)			
n	3724	3735	7459
Mean (SD)	83.26 (19.026)	83.08 (19.314)	83.17 (19.169)
Median	81.60	81.20	81.40
Min, Max	34.8, 184.5	37.2, 165.0	34.8, 184.5
Height (cm)			
n	3723	3736	7459
Mean (SD)	170.04 (10.225)	169.97 (9.994)	170.01 (10.110)
Median	170.18	170.18	170.18
Min, Max	124.5, 223.5	123.0, 208.3	123.0, 223.5
Body Mass Index (kg/m^2)			
n	3723	3735	7458
Mean (SD)	28.72 (5.893)	28.66 (5.844)	28.69 (5.868)
Median	27.75	27.85	27.79
Min, Max	12.1, 71.1	11.2, 62.9	11.2, 71.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	2429 (64.8)	2415 (64.2)	4844 (64.5)
>=30 kg/m^2	1294 (34.5)	1320 (35.1)	2614 (34.8)
Missing	24 (0.6)	29 (0.8)	53 (0.7)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Randomization Stratum: >=65 Years

	Placebo (N=3747)	mRNA-1273 (N=3764)	Total (N=7511)
Occupational Risk, n (%) [2]	2384 (63.6)	2372 (63.0)	4756 (63.3)
Healthcare Workers	502 (13.4)	467 (12.4)	969 (12.9)
Emergency Response	19 (0.5)	20 (0.5)	39 (0.5)
Retail or Restaurant Operations	99 (2.6)	100 (2.7)	199 (2.6)
Manufacturing and Production Operations	30 (0.8)	35 (0.9)	65 (0.9)
Warehouse Shipping and Fulfillment Centers	12 (0.3)	9 (0.2)	21 (0.3)
Transportation and Delivery Services	62 (1.7)	50 (1.3)	112 (1.5)
Border Protection and Military Personnel	6 (0.2)	3 (<0.1)	9 (0.1)
Personal Care and In-Home Services	61 (1.6)	67 (1.8)	128 (1.7)
Hospitality and Tourism Workers	43 (1.1)	37 (1.0)	80 (1.1)
Pastoral, Social or Public Health Workers	138 (3.7)	148 (3.9)	286 (3.8)
Educators and Students	169 (4.5)	185 (4.9)	354 (4.7)
Other	1431 (38.2)	1432 (38.0)	2863 (38.1)
Location and Living Circumstances Risk, n (%) [2]	3102 (82.8)	3132 (83.2)	6234 (83.0)
Resides in Nursing Home or Assisted Living Facility	20 (0.5)	11 (0.3)	31 (0.4)
Resides in Multi-Family Dwelling	65 (1.7)	66 (1.8)	131 (1.7)
Resides in High Density Housing	240 (6.4)	253 (6.7)	493 (6.6)
Resides in Low Density, Multi-Family Setting	256 (6.8)	244 (6.5)	500 (6.7)
Resides in a Single Family Home	2255 (60.2)	2283 (60.7)	4538 (60.4)
Other	528 (14.1)	548 (14.6)	1076 (14.3)

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Table 14.1.3.2.3
Baseline Demographics and Characteristics by Randomization Stratum
Safety Set

Percentages are based on the number of safety subjects.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=25 Years

	Placebo (N=901)	mRNA-1273 (N=878)	Total (N=1779)
Age at Screening (Years)			
n	901	878	1779
Mean (SD)	22.2 (2.16)	22.2 (2.10)	22.2 (2.13)
Median	22.0	22.0	22.0
Min, Max	18, 25	18, 25	18, 25
Age Group at Screening, n (%)			
>=18 and <65 Years	901 (100)	878 (100)	1779 (100)
Mean (SD)	22.2 (2.16)	22.2 (2.10)	22.2 (2.13)
Median	22.0	22.0	22.0
Min, Max	18, 25	18, 25	18, 25
>=65 Years	0	0	0
Mean (SD)			
Median			
Min, Max			
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	901 (100)	878 (100)	1779 (100)
>=65 and <70 Years	0	0	0
>=70 and <75 Years	0	0	0
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=25 Years

	Placebo (N=901)	mRNA-1273 (N=878)	Total (N=1779)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	901 (100)	878 (100)	1779 (100)
>=65 and <75 Years	0	0	0
>=75 and <85 Years	0	0	0
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	808 (89.7)	786 (89.5)	1594 (89.6)
>=18 and <65 Years and at Risk	93 (10.3)	92 (10.5)	185 (10.4)
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	27 (3.0)	19 (2.2)	46 (2.6)
Significant Cardiac Disease	3 (0.3)	4 (0.5)	7 (0.4)
Severe Obesity	45 (5.0)	37 (4.2)	82 (4.6)
Diabetes	6 (0.7)	11 (1.3)	17 (1.0)
Liver Disease	1 (0.1)	2 (0.2)	3 (0.2)
Human Immunodeficiency Virus Infection	1 (0.1)	2 (0.2)	3 (0.2)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	77 (8.5)	69 (7.9)	146 (8.2)
One Risk Factor for Severe COVID-19	71 (7.9)	63 (7.2)	134 (7.5)
Two or More Risk Factors for Severe COVID-19	6 (0.7)	6 (0.7)	12 (0.7)
No	824 (91.5)	809 (92.1)	1633 (91.8)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=25 Years

	Placebo (N=901)	mRNA-1273 (N=878)	Total (N=1779)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	824 (91.5)	809 (92.1)	1633 (91.8)
>=18 and <65 Years and at Risk	77 (8.5)	69 (7.9)	146 (8.2)
>=65 Years and Not at Risk	0	0	0
>=65 Years and at Risk	0	0	0
Baseline RT-PCR Results, n (%)			
Negative	885 (98.2)	860 (97.9)	1745 (98.1)
Positive	11 (1.2)	11 (1.3)	22 (1.2)
Missing	5 (0.6)	7 (0.8)	12 (0.7)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	865 (96.0)	838 (95.4)	1703 (95.7)
Positive	35 (3.9)	40 (4.6)	75 (4.2)
Missing	1 (0.1)	0	1 (<0.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	852 (94.6)	827 (94.2)	1679 (94.4)
Positive	43 (4.8)	45 (5.1)	88 (4.9)
Missing	6 (0.7)	6 (0.7)	12 (0.7)
Sex, n (%)			
Male	472 (52.4)	424 (48.3)	896 (50.4)
Female	429 (47.6)	454 (51.7)	883 (49.6)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=25 Years

	Placebo (N=901)	mRNA-1273 (N=878)	Total (N=1779)
Race, n (%)			
White	674 (74.8)	631 (71.9)	1305 (73.4)
Black or African American	82 (9.1)	84 (9.6)	166 (9.3)
Asian	82 (9.1)	85 (9.7)	167 (9.4)
American Indian or Alaska Native	7 (0.8)	4 (0.5)	11 (0.6)
Native Hawaiian or Other Pacific Islander	0	2 (0.2)	2 (0.1)
Multiracial	28 (3.1)	28 (3.2)	56 (3.1)
Other	21 (2.3)	27 (3.1)	48 (2.7)
Not Reported	3 (0.3)	10 (1.1)	13 (0.7)
Unknown	4 (0.4)	7 (0.8)	11 (0.6)
Ethnicity, n (%)			
Hispanic or Latino	261 (29.0)	283 (32.2)	544 (30.6)
Not Hispanic or Latino	636 (70.6)	591 (67.3)	1227 (69.0)
Not Reported	4 (0.4)	2 (0.2)	6 (0.3)
Unknown	0	2 (0.2)	2 (0.1)
Race and Ethnicity Group, n (%) [5]			
Minority	337 (37.4)	359 (40.9)	696 (39.1)
Non-minority	563 (62.5)	519 (59.1)	1082 (60.8)
Missing	1 (0.1)	0	1 (<0.1)
Race and Ethnicity Group, n (%) [6]			
White	462 (51.3)	404 (46.0)	866 (48.7)
Communities of Color	438 (48.6)	474 (54.0)	912 (51.3)
Missing	1 (0.1)	0	1 (<0.1)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=25 Years

	Placebo (N=901)	mRNA-1273 (N=878)	Total (N=1779)
Weight (kg)			
n	896	875	1771
Mean (SD)	79.37 (21.401)	78.48 (21.354)	78.93 (21.376)
Median	75.20	74.00	74.73
Min, Max	38.8, 167.2	44.0, 213.6	38.8, 213.6
Height (cm)			
n	896	875	1771
Mean (SD)	171.62 (9.971)	170.23 (9.589)	170.93 (9.806)
Median	171.85	170.18	170.50
Min, Max	129.5, 198.1	137.1, 205.0	129.5, 205.0
Body Mass Index (kg/m^2)			
n	896	875	1771
Mean (SD)	26.89 (6.716)	27.01 (6.803)	26.95 (6.758)
Median	25.18	25.36	25.25
Min, Max	13.6, 56.5	16.2, 86.1	13.6, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	673 (74.7)	648 (73.8)	1321 (74.3)
>=30 kg/m^2	223 (24.8)	227 (25.9)	450 (25.3)
Missing	5 (0.6)	3 (0.3)	8 (0.4)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=25 Years

	Placebo (N=901)	mRNA-1273 (N=878)	Total (N=1779)
Occupational Risk, n (%) [2]	833 (92.5)	818 (93.2)	1651 (92.8)
Healthcare Workers	212 (23.5)	205 (23.3)	417 (23.4)
Emergency Response	18 (2.0)	20 (2.3)	38 (2.1)
Retail or Restaurant Operations	150 (16.6)	117 (13.3)	267 (15.0)
Manufacturing and Production Operations	29 (3.2)	22 (2.5)	51 (2.9)
Warehouse Shipping and Fulfillment Centers	17 (1.9)	20 (2.3)	37 (2.1)
Transportation and Delivery Services	24 (2.7)	29 (3.3)	53 (3.0)
Border Protection and Military Personnel	5 (0.6)	5 (0.6)	10 (0.6)
Personal Care and In-Home Services	20 (2.2)	27 (3.1)	47 (2.6)
Hospitality and Tourism Workers	12 (1.3)	17 (1.9)	29 (1.6)
Pastoral, Social or Public Health Workers	15 (1.7)	21 (2.4)	36 (2.0)
Educators and Students	272 (30.2)	263 (30.0)	535 (30.1)
Other	222 (24.6)	216 (24.6)	438 (24.6)
Location and Living Circumstances Risk, n (%) [2]	788 (87.5)	787 (89.6)	1575 (88.5)
Resides in Nursing Home or Assisted Living Facility	1 (0.1)	0	1 (<0.1)
Resides in Multi-Family Dwelling	32 (3.6)	45 (5.1)	77 (4.3)
Resides in High Density Housing	188 (20.9)	195 (22.2)	383 (21.5)
Resides in Low Density, Multi-Family Setting	171 (19.0)	156 (17.8)	327 (18.4)
Resides in a Single Family Home	347 (38.5)	321 (36.6)	668 (37.5)
Other	145 (16.1)	156 (17.8)	301 (16.9)

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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=26 and <=50 Years

	Placebo (N=6153)	mRNA-1273 (N=6113)	Total (N=12266)
Age at Screening (Years)			
n	6153	6113	12266
Mean (SD)	39.4 (6.93)	39.2 (6.95)	39.3 (6.94)
Median	40.0	40.0	40.0
Min, Max	26, 50	26, 50	26, 50
Age Group at Screening, n (%)			
>=18 and <65 Years	6153 (100)	6113 (100)	12266 (100)
Mean (SD)	39.4 (6.93)	39.2 (6.95)	39.3 (6.94)
Median	40.0	40.0	40.0
Min, Max	26, 50	26, 50	26, 50
>=65 Years	0	0	0
Mean (SD)			
Median			
Min, Max			
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	6153 (100)	6113 (100)	12266 (100)
>=65 and <70 Years	0	0	0
>=70 and <75 Years	0	0	0
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=26 and <=50 Years

	Placebo (N=6153)	mRNA-1273 (N=6113)	Total (N=12266)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	6153 (100)	6113 (100)	12266 (100)
>=65 and <75 Years	0	0	0
>=75 and <85 Years	0	0	0
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	5034 (81.8)	4987 (81.6)	10021 (81.7)
>=18 and <65 Years and at Risk	1118 (18.2)	1126 (18.4)	2244 (18.3)
>=65 Years	1 (<0.1)	0	1 (<0.1)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	208 (3.4)	192 (3.1)	400 (3.3)
Significant Cardiac Disease	63 (1.0)	82 (1.3)	145 (1.2)
Severe Obesity	495 (8.0)	540 (8.8)	1035 (8.4)
Diabetes	327 (5.3)	319 (5.2)	646 (5.3)
Liver Disease	26 (0.4)	35 (0.6)	61 (0.5)
Human Immunodeficiency Virus Infection	41 (0.7)	37 (0.6)	78 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1001 (16.3)	1039 (17.0)	2040 (16.6)
One Risk Factor for Severe COVID-19	861 (14.0)	890 (14.6)	1751 (14.3)
Two or More Risk Factors for Severe COVID-19	140 (2.3)	149 (2.4)	289 (2.4)
No	5152 (83.7)	5074 (83.0)	10226 (83.4)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=26 and <=50 Years

	Placebo (N=6153)	mRNA-1273 (N=6113)	Total (N=12266)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	5152 (83.7)	5074 (83.0)	10226 (83.4)
>=18 and <65 Years and at Risk	1001 (16.3)	1039 (17.0)	2040 (16.6)
>=65 Years and Not at Risk	0	0	0
>=65 Years and at Risk	0	0	0
Baseline RT-PCR Results, n (%)			
Negative	6077 (98.8)	6036 (98.7)	12113 (98.8)
Positive	43 (0.7)	49 (0.8)	92 (0.8)
Missing	33 (0.5)	28 (0.5)	61 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	5989 (97.3)	5950 (97.3)	11939 (97.3)
Positive	155 (2.5)	159 (2.6)	314 (2.6)
Missing	9 (0.1)	4 (<0.1)	13 (0.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	5952 (96.7)	5903 (96.6)	11855 (96.6)
Positive	164 (2.7)	181 (3.0)	345 (2.8)
Missing	37 (0.6)	29 (0.5)	66 (0.5)
Sex, n (%)			
Male	3214 (52.2)	3198 (52.3)	6412 (52.3)
Female	2939 (47.8)	2915 (47.7)	5854 (47.7)

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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=26 and <=50 Years

	Placebo (N=6153)	mRNA-1273 (N=6113)	Total (N=12266)
Race, n (%)			
White	4552 (74.0)	4499 (73.6)	9051 (73.8)
Black or African American	703 (11.4)	724 (11.8)	1427 (11.6)
Asian	418 (6.8)	371 (6.1)	789 (6.4)
American Indian or Alaska Native	52 (0.8)	63 (1.0)	115 (0.9)
Native Hawaiian or Other Pacific Islander	16 (0.3)	15 (0.2)	31 (0.3)
Multiracial	171 (2.8)	186 (3.0)	357 (2.9)
Other	169 (2.7)	173 (2.8)	342 (2.8)
Not Reported	40 (0.7)	48 (0.8)	88 (0.7)
Unknown	32 (0.5)	34 (0.6)	66 (0.5)
Ethnicity, n (%)			
Hispanic or Latino	1619 (26.3)	1630 (26.7)	3249 (26.5)
Not Hispanic or Latino	4484 (72.9)	4426 (72.4)	8910 (72.6)
Not Reported	28 (0.5)	46 (0.8)	74 (0.6)
Unknown	22 (0.4)	11 (0.2)	33 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	2305 (37.5)	2324 (38.0)	4629 (37.7)
Non-minority	3840 (62.4)	3779 (61.8)	7619 (62.1)
Missing	8 (0.1)	10 (0.2)	18 (0.1)
Race and Ethnicity Group, n (%) [6]			
White	3259 (53.0)	3234 (52.9)	6493 (52.9)
Communities of Color	2886 (46.9)	2869 (46.9)	5755 (46.9)
Missing	8 (0.1)	10 (0.2)	18 (0.1)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=26 and <=50 Years

	Placebo (N=6153)	mRNA-1273 (N=6113)	Total (N=12266)
Weight (kg)			
n	6122	6078	12200
Mean (SD)	87.26 (22.860)	87.43 (23.525)	87.34 (23.193)
Median	83.91	84.09	84.09
Min, Max	30.7, 223.0	33.5, 236.4	30.7, 236.4
Height (cm)			
n	6122	6077	12199
Mean (SD)	171.39 (10.019)	171.41 (9.878)	171.40 (9.948)
Median	171.20	171.00	171.00
Min, Max	118.0, 205.7	111.0, 221.0	111.0, 221.0
Body Mass Index (kg/m^2)			
n	6122	6076	12198
Mean (SD)	29.61 (7.008)	29.69 (7.418)	29.65 (7.215)
Median	28.22	28.24	28.23
Min, Max	10.3, 72.7	11.2, 79.2	10.3, 79.2
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	3712 (60.3)	3657 (59.8)	7369 (60.1)
>=30 kg/m^2	2410 (39.2)	2419 (39.6)	4829 (39.4)
Missing	31 (0.5)	37 (0.6)	68 (0.6)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=26 and <=50 Years

	Placebo (N=6153)	mRNA-1273 (N=6113)	Total (N=12266)
Occupational Risk, n (%) [2]	5604 (91.1)	5557 (90.9)	11161 (91.0)
Healthcare Workers	1984 (32.2)	1981 (32.4)	3965 (32.3)
Emergency Response	181 (2.9)	185 (3.0)	366 (3.0)
Retail or Restaurant Operations	450 (7.3)	460 (7.5)	910 (7.4)
Manufacturing and Production Operations	211 (3.4)	226 (3.7)	437 (3.6)
Warehouse Shipping and Fulfillment Centers	99 (1.6)	109 (1.8)	208 (1.7)
Transportation and Delivery Services	246 (4.0)	234 (3.8)	480 (3.9)
Border Protection and Military Personnel	38 (0.6)	34 (0.6)	72 (0.6)
Personal Care and In-Home Services	227 (3.7)	209 (3.4)	436 (3.6)
Hospitality and Tourism Workers	104 (1.7)	112 (1.8)	216 (1.8)
Pastoral, Social or Public Health Workers	181 (2.9)	205 (3.4)	386 (3.1)
Educators and Students	709 (11.5)	684 (11.2)	1393 (11.4)
Other	1758 (28.6)	1772 (29.0)	3530 (28.8)
Location and Living Circumstances Risk, n (%) [2]	5162 (83.9)	5154 (84.3)	10316 (84.1)
Resides in Nursing Home or Assisted Living Facility	2 (<0.1)	11 (0.2)	13 (0.1)
Resides in Multi-Family Dwelling	213 (3.5)	249 (4.1)	462 (3.8)
Resides in High Density Housing	594 (9.7)	567 (9.3)	1161 (9.5)
Resides in Low Density, Multi-Family Setting	694 (11.3)	733 (12.0)	1427 (11.6)
Resides in a Single Family Home	3253 (52.9)	3206 (52.4)	6459 (52.7)
Other	884 (14.4)	853 (14.0)	1737 (14.2)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=50 Years

	Placebo (N=7054)	mRNA-1273 (N=6991)	Total (N=14045)
Age at Screening (Years)			
n	7054	6991	14045
Mean (SD)	37.2 (8.69)	37.1 (8.62)	37.1 (8.65)
Median	38.0	38.0	38.0
Min, Max	18, 50	18, 50	18, 50
Age Group at Screening, n (%)			
>=18 and <65 Years	7054 (100)	6991 (100)	14045 (100)
Mean (SD)	37.2 (8.69)	37.1 (8.62)	37.1 (8.65)
Median	38.0	38.0	38.0
Min, Max	18, 50	18, 50	18, 50
>=65 Years	0	0	0
Mean (SD)			
Median			
Min, Max			
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	7054 (100)	6991 (100)	14045 (100)
>=65 and <70 Years	0	0	0
>=70 and <75 Years	0	0	0
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=50 Years

	Placebo (N=7054)	mRNA-1273 (N=6991)	Total (N=14045)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	7054 (100)	6991 (100)	14045 (100)
>=65 and <75 Years	0	0	0
>=75 and <85 Years	0	0	0
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	5842 (82.8)	5773 (82.6)	11615 (82.7)
>=18 and <65 Years and at Risk	1211 (17.2)	1218 (17.4)	2429 (17.3)
>=65 Years	1 (<0.1)	0	1 (<0.1)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	235 (3.3)	211 (3.0)	446 (3.2)
Significant Cardiac Disease	66 (0.9)	86 (1.2)	152 (1.1)
Severe Obesity	540 (7.7)	577 (8.3)	1117 (8.0)
Diabetes	333 (4.7)	330 (4.7)	663 (4.7)
Liver Disease	27 (0.4)	37 (0.5)	64 (0.5)
Human Immunodeficiency Virus Infection	42 (0.6)	39 (0.6)	81 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1078 (15.3)	1108 (15.8)	2186 (15.6)
One Risk Factor for Severe COVID-19	932 (13.2)	953 (13.6)	1885 (13.4)
Two or More Risk Factors for Severe COVID-19	146 (2.1)	155 (2.2)	301 (2.1)
No	5976 (84.7)	5883 (84.2)	11859 (84.4)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=50 Years

	Placebo (N=7054)	mRNA-1273 (N=6991)	Total (N=14045)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	5976 (84.7)	5883 (84.2)	11859 (84.4)
>=18 and <65 Years and at Risk	1078 (15.3)	1108 (15.8)	2186 (15.6)
>=65 Years and Not at Risk	0	0	0
>=65 Years and at Risk	0	0	0
Baseline RT-PCR Results, n (%)			
Negative	6962 (98.7)	6896 (98.6)	13858 (98.7)
Positive	54 (0.8)	60 (0.9)	114 (0.8)
Missing	38 (0.5)	35 (0.5)	73 (0.5)
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	6854 (97.2)	6788 (97.1)	13642 (97.1)
Positive	190 (2.7)	199 (2.8)	389 (2.8)
Missing	10 (0.1)	4 (<0.1)	14 (<0.1)
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	6804 (96.5)	6730 (96.3)	13534 (96.4)
Positive	207 (2.9)	226 (3.2)	433 (3.1)
Missing	43 (0.6)	35 (0.5)	78 (0.6)
Sex, n (%)			
Male	3686 (52.3)	3622 (51.8)	7308 (52.0)
Female	3368 (47.7)	3369 (48.2)	6737 (48.0)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=50 Years

	Placebo (N=7054)	mRNA-1273 (N=6991)	Total (N=14045)
Race, n (%)			
White	5226 (74.1)	5130 (73.4)	10356 (73.7)
Black or African American	785 (11.1)	808 (11.6)	1593 (11.3)
Asian	500 (7.1)	456 (6.5)	956 (6.8)
American Indian or Alaska Native	59 (0.8)	67 (1.0)	126 (0.9)
Native Hawaiian or Other Pacific Islander	16 (0.2)	17 (0.2)	33 (0.2)
Multiracial	199 (2.8)	214 (3.1)	413 (2.9)
Other	190 (2.7)	200 (2.9)	390 (2.8)
Not Reported	43 (0.6)	58 (0.8)	101 (0.7)
Unknown	36 (0.5)	41 (0.6)	77 (0.5)
Ethnicity, n (%)			
Hispanic or Latino	1880 (26.7)	1913 (27.4)	3793 (27.0)
Not Hispanic or Latino	5120 (72.6)	5017 (71.8)	10137 (72.2)
Not Reported	32 (0.5)	48 (0.7)	80 (0.6)
Unknown	22 (0.3)	13 (0.2)	35 (0.2)
Race and Ethnicity Group, n (%) [5]			
Minority	2642 (37.5)	2683 (38.4)	5325 (37.9)
Non-minority	4403 (62.4)	4298 (61.5)	8701 (62.0)
Missing	9 (0.1)	10 (0.1)	19 (0.1)
Race and Ethnicity Group, n (%) [6]			
White	3721 (52.8)	3638 (52.0)	7359 (52.4)
Communities of Color	3324 (47.1)	3343 (47.8)	6667 (47.5)
Missing	9 (0.1)	10 (0.1)	19 (0.1)

Note: Footnotes are listed on the last page.
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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=50 Years

	Placebo (N=7054)	mRNA-1273 (N=6991)	Total (N=14045)
Weight (kg)			
n	7018	6953	13971
Mean (SD)	86.25 (22.830)	86.30 (23.450)	86.28 (23.140)
Median	82.60	82.95	82.80
Min, Max	30.7, 223.0	33.5, 236.4	30.7, 236.4
Height (cm)			
n	7018	6952	13970
Mean (SD)	171.42 (10.012)	171.26 (9.849)	171.34 (9.931)
Median	171.40	170.94	171.00
Min, Max	118.0, 205.7	111.0, 221.0	111.0, 221.0
Body Mass Index (kg/m^2)			
n	7018	6951	13969
Mean (SD)	29.26 (7.030)	29.35 (7.397)	29.31 (7.215)
Median	27.88	27.92	27.90
Min, Max	10.3, 72.7	11.2, 86.1	10.3, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	4385 (62.2)	4305 (61.6)	8690 (61.9)
>=30 kg/m^2	2633 (37.3)	2646 (37.8)	5279 (37.6)
Missing	36 (0.5)	40 (0.6)	76 (0.5)

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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Age Group: >=18 and <=50 Years

	Placebo (N=7054)	mRNA-1273 (N=6991)	Total (N=14045)
Occupational Risk, n (%) [2]	6437 (91.3)	6375 (91.2)	12812 (91.2)
Healthcare Workers	2196 (31.1)	2186 (31.3)	4382 (31.2)
Emergency Response	199 (2.8)	205 (2.9)	404 (2.9)
Retail or Restaurant Operations	600 (8.5)	577 (8.3)	1177 (8.4)
Manufacturing and Production Operations	240 (3.4)	248 (3.5)	488 (3.5)
Warehouse Shipping and Fulfillment Centers	116 (1.6)	129 (1.8)	245 (1.7)
Transportation and Delivery Services	270 (3.8)	263 (3.8)	533 (3.8)
Border Protection and Military Personnel	43 (0.6)	39 (0.6)	82 (0.6)
Personal Care and In-Home Services	247 (3.5)	236 (3.4)	483 (3.4)
Hospitality and Tourism Workers	116 (1.6)	129 (1.8)	245 (1.7)
Pastoral, Social or Public Health Workers	196 (2.8)	226 (3.2)	422 (3.0)
Educators and Students	981 (13.9)	947 (13.5)	1928 (13.7)
Other	1980 (28.1)	1988 (28.4)	3968 (28.3)
Location and Living Circumstances Risk, n (%) [2]	5950 (84.3)	5941 (85.0)	11891 (84.7)
Resides in Nursing Home or Assisted Living Facility	3 (<0.1)	11 (0.2)	14 (<0.1)
Resides in Multi-Family Dwelling	245 (3.5)	294 (4.2)	539 (3.8)
Resides in High Density Housing	782 (11.1)	762 (10.9)	1544 (11.0)
Resides in Low Density, Multi-Family Setting	865 (12.3)	889 (12.7)	1754 (12.5)
Resides in a Single Family Home	3600 (51.0)	3527 (50.5)	7127 (50.7)
Other	1029 (14.6)	1009 (14.4)	2038 (14.5)

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Table 14.1.3.2.4
Baseline Demographics and Characteristics by Age Group (>=18 and <=25, >=26 and <=50)
Safety Set — Subjects with Age >=18 and <=50 Years

Percentages are based on the number of safety subjects.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Age at Screening (Years)									
n	11046	11037	22083	3699	3709	7408	14745	14746	29491
Mean	45.0	45.2	45.1	70.7	70.4	70.6	51.5	51.5	51.5
(SD)	(12.26)	(12.32)	(12.29)	(4.88)	(4.66)	(4.77)	(15.58)	(15.47)	(15.53)
Median	46.0	46.0	46.0	70.0	69.0	70.0	52.0	53.0	53.0
Min, Max	18, 64	18, 64	18, 64	65, 95	65, 95	65, 95	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	11046 (100)	11037 (100)	22083 (100)	0	0	0	11046 (74.9)	11037 (74.8)	22083 (74.9)
Mean	45.0	45.2	45.1				45.0	45.2	45.1
(SD)	(12.26)	(12.32)	(12.29)				(12.26)	(12.32)	(12.29)
Median	46.0	46.0	46.0				46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64				18, 64	18, 64	18, 64
>=65 Years	0	0	0	3699 (100)	3709 (100)	7408 (100)	3699 (25.1)	3709 (25.2)	7408 (25.1)
Mean				70.7	70.4	70.6	70.7	70.4	70.6
(SD)				(4.88)	(4.66)	(4.77)	(4.88)	(4.66)	(4.77)
Median				70.0	69.0	70.0	70.0	69.0	70.0
Min, Max				65, 95	65, 95	65, 95	65, 95	65, 95	65, 95

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11046 (100)	11037 (100)	22083 (100)	0	0	0	11046 (74.9)	11037 (74.8)	22083 (74.9)
>=65 and <70 Years	0	0	0	1795 (48.5)	1874 (50.5)	3669 (49.5)	1795 (12.2)	1874 (12.7)	3669 (12.4)
>=70 and <75 Years	0	0	0	1179 (31.9)	1187 (32.0)	2366 (31.9)	1179 (8.0)	1187 (8.0)	2366 (8.0)
>=75 and <80 Years	0	0	0	494 (13.4)	461 (12.4)	955 (12.9)	494 (3.4)	461 (3.1)	955 (3.2)
>=80 Years	0	0	0	231 (6.2)	187 (5.0)	418 (5.6)	231 (1.6)	187 (1.3)	418 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	11046 (100)	11037 (100)	22083 (100)	0	0	0	11046 (74.9)	11037 (74.8)	22083 (74.9)
>=65 and <75 Years	0	0	0	2974 (80.4)	3061 (82.5)	6035 (81.5)	2974 (20.2)	3061 (20.8)	6035 (20.5)
>=75 and <85 Years	0	0	0	676 (18.3)	607 (16.4)	1283 (17.3)	676 (4.6)	607 (4.1)	1283 (4.4)
>=85 Years	0	0	0	49 (1.3)	41 (1.1)	90 (1.2)	49 (0.3)	41 (0.3)	90 (0.3)

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8606 (77.9)	8575 (77.7)	17181 (77.8)	2 (<0.1)	0	2 (<0.1)	8608 (58.4)	8575 (58.2)	17183 (58.3)
>=18 and <65 Years and at Risk	2439 (22.1)	2461 (22.3)	4900 (22.2)	3 (<0.1)	6 (0.2)	9 (0.1)	2442 (16.6)	2467 (16.7)	4909 (16.6)
>=65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)	3694 (99.9)	3703 (99.8)	7397 (99.9)	3695 (25.1)	3704 (25.1)	7399 (25.1)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	487 (4.4)	465 (4.2)	952 (4.3)	240 (6.5)	237 (6.4)	477 (6.4)	727 (4.9)	702 (4.8)	1429 (4.8)
Significant Cardiac Disease	279 (2.5)	309 (2.8)	588 (2.7)	443 (12.0)	436 (11.8)	879 (11.9)	722 (4.9)	745 (5.1)	1467 (5.0)
Severe Obesity	873 (7.9)	869 (7.9)	1742 (7.9)	151 (4.1)	172 (4.6)	323 (4.4)	1024 (6.9)	1041 (7.1)	2065 (7.0)
Diabetes	884 (8.0)	897 (8.1)	1781 (8.1)	539 (14.6)	534 (14.4)	1073 (14.5)	1423 (9.7)	1431 (9.7)	2854 (9.7)
Liver Disease	69 (0.6)	82 (0.7)	151 (0.7)	26 (0.7)	20 (0.5)	46 (0.6)	95 (0.6)	102 (0.7)	197 (0.7)
Human Immunodeficiency Virus Infection	68 (0.6)	72 (0.7)	140 (0.6)	16 (0.4)	16 (0.4)	32 (0.4)	84 (0.6)	88 (0.6)	172 (0.6)

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	2236 (20.2)	2261 (20.5)	4497 (20.4)	1119 (30.3)	1114 (30.0)	2233 (30.1)	3355 (22.8)	3375 (22.9)	6730 (22.8)
One Risk Factor for Severe COVID-19	1862 (16.9)	1878 (17.0)	3740 (16.9)	866 (23.4)	855 (23.1)	1721 (23.2)	2728 (18.5)	2733 (18.5)	5461 (18.5)
Two or More Risk Factors for Severe COVID-19	374 (3.4)	383 (3.5)	757 (3.4)	253 (6.8)	259 (7.0)	512 (6.9)	627 (4.3)	642 (4.4)	1269 (4.3)
No	8810 (79.8)	8776 (79.5)	17586 (79.6)	2580 (69.7)	2595 (70.0)	5175 (69.9)	11390 (77.2)	11371 (77.1)	22761 (77.2)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	8810 (79.8)	8776 (79.5)	17586 (79.6)	0	0	0	8810 (59.7)	8776 (59.5)	17586 (59.6)
>=18 and <65 Years and at Risk	2236 (20.2)	2261 (20.5)	4497 (20.4)	0	0	0	2236 (15.2)	2261 (15.3)	4497 (15.2)
>=65 Years and Not at Risk	0	0	0	2580 (69.7)	2595 (70.0)	5175 (69.9)	2580 (17.5)	2595 (17.6)	5175 (17.5)
>=65 Years and at Risk	0	0	0	1119 (30.3)	1114 (30.0)	2233 (30.1)	1119 (7.6)	1114 (7.6)	2233 (7.6)

Note: Footnotes are listed on the last page.
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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Baseline RT-PCR Results, n (%)									
Negative	11046 (100)	11037 (100)	22083 (100)	3699 (100)	3709 (100)	7408 (100)	14745 (100)	14746 (100)	29491 (100)
Positive	0	0	0	0	0	0	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	11046 (100)	11037 (100)	22083 (100)	3699 (100)	3709 (100)	7408 (100)	14745 (100)	14746 (100)	29491 (100)
Positive	0	0	0	0	0	0	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	11046 (100)	11037 (100)	22083 (100)	3699 (100)	3709 (100)	7408 (100)	14745 (100)	14746 (100)	29491 (100)
Positive	0	0	0	0	0	0	0	0	0

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Sex, n (%)									
Male	5751 (52.1)	5633 (51.0)	11384 (51.6)	2069 (55.9)	2045 (55.1)	4114 (55.5)	7820 (53.0)	7678 (52.1)	15498 (52.6)
Female	5295 (47.9)	5404 (49.0)	10699 (48.4)	1630 (44.1)	1664 (44.9)	3294 (44.5)	6925 (47.0)	7068 (47.9)	13993 (47.4)
Race, n (%)									
White	8404 (76.1)	8405 (76.2)	16809 (76.1)	3304 (89.3)	3333 (89.9)	6637 (89.6)	11708 (79.4)	11738 (79.6)	23446 (79.5)
Black or African American	1228 (11.1)	1253 (11.4)	2481 (11.2)	203 (5.5)	210 (5.7)	413 (5.6)	1431 (9.7)	1463 (9.9)	2894 (9.8)
Asian	655 (5.9)	578 (5.2)	1233 (5.6)	75 (2.0)	67 (1.8)	142 (1.9)	730 (5.0)	645 (4.4)	1375 (4.7)
American Indian or Alaska Native	93 (0.8)	92 (0.8)	185 (0.8)	26 (0.7)	21 (0.6)	47 (0.6)	119 (0.8)	113 (0.8)	232 (0.8)
Native Hawaiian or Other Pacific Islander	28 (0.3)	33 (0.3)	61 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	31 (0.2)	36 (0.2)	67 (0.2)
Multiracial	281 (2.5)	279 (2.5)	560 (2.5)	35 (0.9)	31 (0.8)	66 (0.9)	316 (2.1)	310 (2.1)	626 (2.1)
Other	253 (2.3)	265 (2.4)	518 (2.3)	32 (0.9)	23 (0.6)	55 (0.7)	285 (1.9)	288 (2.0)	573 (1.9)
Not Reported	56 (0.5)	79 (0.7)	135 (0.6)	14 (0.4)	13 (0.4)	27 (0.4)	70 (0.5)	92 (0.6)	162 (0.5)
Unknown	48 (0.4)	53 (0.5)	101 (0.5)	7 (0.2)	8 (0.2)	15 (0.2)	55 (0.4)	61 (0.4)	116 (0.4)

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Ethnicity, n (%)									
Hispanic or Latino	2620 (23.7)	2613 (23.7)	5233 (23.7)	327 (8.8)	344 (9.3)	671 (9.1)	2947 (20.0)	2957 (20.1)	5904 (20.0)
Not Hispanic or Latino	8334 (75.4)	8329 (75.5)	16663 (75.5)	3331 (90.1)	3321 (89.5)	6652 (89.8)	11665 (79.1)	11650 (79.0)	23315 (79.1)
Not Reported	54 (0.5)	69 (0.6)	123 (0.6)	26 (0.7)	33 (0.9)	59 (0.8)	80 (0.5)	102 (0.7)	182 (0.6)
Unknown	38 (0.3)	26 (0.2)	64 (0.3)	15 (0.4)	11 (0.3)	26 (0.4)	53 (0.4)	37 (0.3)	90 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	3846 (34.8)	3851 (34.9)	7697 (34.9)	542 (14.7)	557 (15.0)	1099 (14.8)	4388 (29.8)	4408 (29.9)	8796 (29.8)
Non-minority	7187 (65.1)	7166 (64.9)	14353 (65.0)	3144 (85.0)	3146 (84.8)	6290 (84.9)	10331 (70.1)	10312 (69.9)	20643 (70.0)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.4)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	6269 (56.8)	6327 (57.3)	12596 (57.0)	3034 (82.0)	3037 (81.9)	6071 (82.0)	9303 (63.1)	9364 (63.5)	18667 (63.3)
Communities of Color	4764 (43.1)	4690 (42.5)	9454 (42.8)	652 (17.6)	666 (18.0)	1318 (17.8)	5416 (36.7)	5356 (36.3)	10772 (36.5)
Missing	13 (0.1)	20 (0.2)	33 (0.1)	13 (0.4)	6 (0.2)	19 (0.3)	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Weight (kg)									
n	10986	10982	21968	3676	3680	7356	14662	14662	29324
Mean	86.72	86.54	86.63	83.24	83.09	83.17	85.85	85.67	85.76
(SD)	(22.356)	(22.709)	(22.533)	(19.007)	(19.353)	(19.180)	(21.617)	(21.965)	(21.792)
Median	83.64	83.64	83.64	81.60	81.20	81.36	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4	34.8, 184.5	37.2, 165.0	34.8, 184.5	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)									
n	10985	10982	21967	3675	3681	7356	14660	14663	29323
Mean	171.19	171.00	171.10	170.06	169.99	170.02	170.91	170.74	170.83
(SD)	(9.964)	(9.897)	(9.930)	(10.191)	(10.000)	(10.096)	(10.033)	(9.932)	(9.983)
Median	171.00	170.20	170.69	170.18	170.18	170.18	170.50	170.18	170.20
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0	124.5, 223.5	123.0, 208.3	123.0, 223.5	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	10985	10979	21964	3675	3680	7355	14660	14659	29319
Mean	29.50	29.52	29.51	28.71	28.66	28.68	29.30	29.30	29.30
(SD)	(6.906)	(7.129)	(7.018)	(5.873)	(5.859)	(5.865)	(6.670)	(6.843)	(6.757)
Median	28.25	28.24	28.25	27.73	27.85	27.78	28.12	28.12	28.12
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1	12.1, 71.1	11.2, 62.9	11.2, 71.1	10.3, 72.7	9.8, 86.1	9.8, 86.1

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Body Mass Index Subgroup, n (%)									
< 30 kg/m^2	6657	6641	13298	2402	2379	4781	9059	9020	18079
	(60.3)	(60.2)	(60.2)	(64.9)	(64.1)	(64.5)	(61.4)	(61.2)	(61.3)
>=30 kg/m^2	4328	4338	8666	1273	1301	2574	5601	5639	11240
	(39.2)	(39.3)	(39.2)	(34.4)	(35.1)	(34.7)	(38.0)	(38.2)	(38.1)
Missing	61	58	119	24	29	53	85	87	172
	(0.6)	(0.5)	(0.5)	(0.6)	(0.8)	(0.7)	(0.6)	(0.6)	(0.6)

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Occupational Risk, n (%) [2]	9822 (88.9)	9781 (88.6)	19603 (88.8)	2351 (63.6)	2334 (62.9)	4685 (63.2)	12173 (82.6)	12115 (82.2)	24288 (82.4)
Healthcare Workers	3263 (29.5)	3261 (29.5)	6524 (29.5)	494 (13.4)	460 (12.4)	954 (12.9)	3757 (25.5)	3721 (25.2)	7478 (25.4)
Emergency Response	265 (2.4)	273 (2.5)	538 (2.4)	18 (0.5)	21 (0.6)	39 (0.5)	283 (1.9)	294 (2.0)	577 (2.0)
Retail or Restaurant Operations	841 (7.6)	816 (7.4)	1657 (7.5)	98 (2.6)	100 (2.7)	198 (2.7)	939 (6.4)	916 (6.2)	1855 (6.3)
Manufacturing and Production Operations	381 (3.4)	370 (3.4)	751 (3.4)	29 (0.8)	34 (0.9)	63 (0.9)	410 (2.8)	404 (2.7)	814 (2.8)
Warehouse Shipping and Fulfillment Centers	150 (1.4)	171 (1.5)	321 (1.5)	12 (0.3)	9 (0.2)	21 (0.3)	162 (1.1)	180 (1.2)	342 (1.2)
Transportation and Delivery Services	395 (3.6)	407 (3.7)	802 (3.6)	61 (1.6)	46 (1.2)	107 (1.4)	456 (3.1)	453 (3.1)	909 (3.1)
Border Protection and Military Personnel	62 (0.6)	63 (0.6)	125 (0.6)	6 (0.2)	3 (<0.1)	9 (0.1)	68 (0.5)	66 (0.4)	134 (0.5)
Personal Care and In-Home Services	380 (3.4)	376 (3.4)	756 (3.4)	59 (1.6)	66 (1.8)	125 (1.7)	439 (3.0)	442 (3.0)	881 (3.0)
Hospitality and Tourism Workers	166 (1.5)	192 (1.7)	358 (1.6)	42 (1.1)	34 (0.9)	76 (1.0)	208 (1.4)	226 (1.5)	434 (1.5)
Pastoral, Social or Public Health Workers	358 (3.2)	373 (3.4)	731 (3.3)	139 (3.8)	147 (4.0)	286 (3.9)	497 (3.4)	520 (3.5)	1017 (3.4)
Educators and Students	1354 (12.3)	1330 (12.1)	2684 (12.2)	168 (4.5)	184 (5.0)	352 (4.8)	1522 (10.3)	1514 (10.3)	3036 (10.3)
Other	3277 (29.7)	3307 (30.0)	6584 (29.8)	1414 (38.2)	1408 (38.0)	2822 (38.1)	4691 (31.8)	4715 (32.0)	9406 (31.9)

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11046)	mRNA-1273 (N=11037)	Total (N=22083)	Placebo (N=3699)	mRNA-1273 (N=3709)	Total (N=7408)	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Location and Living Circumstances Risk, n (%) [2]	9262 (83.8)	9271 (84.0)	18533 (83.9)	3060 (82.7)	3083 (83.1)	6143 (82.9)	12322 (83.6)	12354 (83.8)	24676 (83.7)
Resides in Nursing Home or Assisted Living Facility	9 (<0.1)	24 (0.2)	33 (0.1)	19 (0.5)	11 (0.3)	30 (0.4)	28 (0.2)	35 (0.2)	63 (0.2)
Resides in Multi-Family Dwelling	333 (3.0)	383 (3.5)	716 (3.2)	63 (1.7)	65 (1.8)	128 (1.7)	396 (2.7)	448 (3.0)	844 (2.9)
Resides in High Density Housing	1004 (9.1)	985 (8.9)	1989 (9.0)	236 (6.4)	241 (6.5)	477 (6.4)	1240 (8.4)	1226 (8.3)	2466 (8.4)
Resides in Low Density, Multi-Family Setting	1175 (10.6)	1179 (10.7)	2354 (10.7)	251 (6.8)	240 (6.5)	491 (6.6)	1426 (9.7)	1419 (9.6)	2845 (9.6)
Resides in a Single Family Home	5995 (54.3)	5951 (53.9)	11946 (54.1)	2233 (60.4)	2254 (60.8)	4487 (60.6)	8228 (55.8)	8205 (55.6)	16433 (55.7)
Other	1593 (14.4)	1597 (14.5)	3190 (14.4)	520 (14.1)	538 (14.5)	1058 (14.3)	2113 (14.3)	2135 (14.5)	4248 (14.4)

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Table 14.1.3.3.2
Baseline Demographics and Characteristics by Age Group
mITT Set

Percentages are based on the number of subjects in mITT set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: Overall

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Age at Screening (Years)			
n	14745	14746	29491
Mean (SD)	51.5 (15.58)	51.5 (15.47)	51.5 (15.53)
Median	52.0	53.0	53.0
Min, Max	18, 95	18, 95	18, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	11046 (74.9)	11037 (74.8)	22083 (74.9)
Mean (SD)	45.0 (12.26)	45.2 (12.32)	45.1 (12.29)
Median	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3699 (25.1)	3709 (25.2)	7408 (25.1)
Mean (SD)	70.7 (4.88)	70.4 (4.66)	70.6 (4.77)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11046 (74.9)	11037 (74.8)	22083 (74.9)
>=65 and <70 Years	1795 (12.2)	1874 (12.7)	3669 (12.4)
>=70 and <75 Years	1179 (8.0)	1187 (8.0)	2366 (8.0)
>=75 and <80 Years	494 (3.4)	461 (3.1)	955 (3.2)
>=80 Years	231 (1.6)	187 (1.3)	418 (1.4)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: Overall

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	11046 (74.9)	11037 (74.8)	22083 (74.9)
>=65 and <75 Years	2974 (20.2)	3061 (20.8)	6035 (20.5)
>=75 and <85 Years	676 (4.6)	607 (4.1)	1283 (4.4)
>=85 Years	49 (0.3)	41 (0.3)	90 (0.3)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8608 (58.4)	8575 (58.2)	17183 (58.3)
>=18 and <65 Years and at Risk	2442 (16.6)	2467 (16.7)	4909 (16.6)
>=65 Years	3695 (25.1)	3704 (25.1)	7399 (25.1)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	727 (4.9)	702 (4.8)	1429 (4.8)
Significant Cardiac Disease	722 (4.9)	745 (5.1)	1467 (5.0)
Severe Obesity	1024 (6.9)	1041 (7.1)	2065 (7.0)
Diabetes	1423 (9.7)	1431 (9.7)	2854 (9.7)
Liver Disease	95 (0.6)	102 (0.7)	197 (0.7)
Human Immunodeficiency Virus Infection	84 (0.6)	88 (0.6)	172 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	3355 (22.8)	3375 (22.9)	6730 (22.8)
One Risk Factor for Severe COVID-19	2728 (18.5)	2733 (18.5)	5461 (18.5)
Two or More Risk Factors for Severe COVID-19	627 (4.3)	642 (4.4)	1269 (4.3)
No	11390 (77.2)	11371 (77.1)	22761 (77.2)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: Overall

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	8810 (59.7)	8776 (59.5)	17586 (59.6)
>=18 and <65 Years and at Risk	2236 (15.2)	2261 (15.3)	4497 (15.2)
>=65 Years and Not at Risk	2580 (17.5)	2595 (17.6)	5175 (17.5)
>=65 Years and at Risk	1119 (7.6)	1114 (7.6)	2233 (7.6)
Baseline RT-PCR Results, n (%)			
Negative	14745 (100)	14746 (100)	29491 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	14745 (100)	14746 (100)	29491 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	14745 (100)	14746 (100)	29491 (100)
Positive	0	0	0
Sex, n (%)			
Male	7820 (53.0)	7678 (52.1)	15498 (52.6)
Female	6925 (47.0)	7068 (47.9)	13993 (47.4)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: Overall

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Race, n (%)			
White	11708 (79.4)	11738 (79.6)	23446 (79.5)
Black or African American	1431 (9.7)	1463 (9.9)	2894 (9.8)
Asian	730 (5.0)	645 (4.4)	1375 (4.7)
American Indian or Alaska Native	119 (0.8)	113 (0.8)	232 (0.8)
Native Hawaiian or Other Pacific Islander	31 (0.2)	36 (0.2)	67 (0.2)
Multiracial	316 (2.1)	310 (2.1)	626 (2.1)
Other	285 (1.9)	288 (2.0)	573 (1.9)
Not Reported	70 (0.5)	92 (0.6)	162 (0.5)
Unknown	55 (0.4)	61 (0.4)	116 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	2947 (20.0)	2957 (20.1)	5904 (20.0)
Not Hispanic or Latino	11665 (79.1)	11650 (79.0)	23315 (79.1)
Not Reported	80 (0.5)	102 (0.7)	182 (0.6)
Unknown	53 (0.4)	37 (0.3)	90 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	4388 (29.8)	4408 (29.9)	8796 (29.8)
Non-minority	10331 (70.1)	10312 (69.9)	20643 (70.0)
Missing	26 (0.2)	26 (0.2)	52 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	9303 (63.1)	9364 (63.5)	18667 (63.3)
Communities of Color	5416 (36.7)	5356 (36.3)	10772 (36.5)
Missing	26 (0.2)	26 (0.2)	52 (0.2)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: Overall

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Weight (kg)			
n	14662	14662	29324
Mean (SD)	85.85 (21.617)	85.67 (21.965)	85.76 (21.792)
Median	83.00	83.00	83.00
Min, Max	30.7, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)			
n	14660	14663	29323
Mean (SD)	170.91 (10.033)	170.74 (9.932)	170.83 (9.983)
Median	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)			
n	14660	14659	29319
Mean (SD)	29.30 (6.670)	29.30 (6.843)	29.30 (6.757)
Median	28.12	28.12	28.12
Min, Max	10.3, 72.7	9.8, 86.1	9.8, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	9059 (61.4)	9020 (61.2)	18079 (61.3)
>=30 kg/m^2	5601 (38.0)	5639 (38.2)	11240 (38.1)
Missing	85 (0.6)	87 (0.6)	172 (0.6)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: Overall

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Occupational Risk, n (%) [2]	12173 (82.6)	12115 (82.2)	24288 (82.4)
Healthcare Workers	3757 (25.5)	3721 (25.2)	7478 (25.4)
Emergency Response	283 (1.9)	294 (2.0)	577 (2.0)
Retail or Restaurant Operations	939 (6.4)	916 (6.2)	1855 (6.3)
Manufacturing and Production Operations	410 (2.8)	404 (2.7)	814 (2.8)
Warehouse Shipping and Fulfillment Centers	162 (1.1)	180 (1.2)	342 (1.2)
Transportation and Delivery Services	456 (3.1)	453 (3.1)	909 (3.1)
Border Protection and Military Personnel	68 (0.5)	66 (0.4)	134 (0.5)
Personal Care and In-Home Services	439 (3.0)	442 (3.0)	881 (3.0)
Hospitality and Tourism Workers	208 (1.4)	226 (1.5)	434 (1.5)
Pastoral, Social or Public Health Workers	497 (3.4)	520 (3.5)	1017 (3.4)
Educators and Students	1522 (10.3)	1514 (10.3)	3036 (10.3)
Other	4691 (31.8)	4715 (32.0)	9406 (31.9)
Location and Living Circumstances Risk, n (%) [2]	12322 (83.6)	12354 (83.8)	24676 (83.7)
Resides in Nursing Home or Assisted Living Facility	28 (0.2)	35 (0.2)	63 (0.2)
Resides in Multi-Family Dwelling	396 (2.7)	448 (3.0)	844 (2.9)
Resides in High Density Housing	1240 (8.4)	1226 (8.3)	2466 (8.4)
Resides in Low Density, Multi-Family Setting	1426 (9.7)	1419 (9.6)	2845 (9.6)
Resides in a Single Family Home	8228 (55.8)	8205 (55.6)	16433 (55.7)
Other	2113 (14.3)	2135 (14.5)	4248 (14.4)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8608)	mRNA-1273 (N=8575)	Total (N=17183)
Age at Screening (Years)			
n	8608	8575	17183
Mean (SD)	43.9 (12.30)	44.1 (12.36)	44.0 (12.33)
Median	45.0	45.0	45.0
Min, Max	18, 72	18, 64	18, 72
Age Group at Screening, n (%)			
>=18 and <65 Years	8606(>99.9)	8575 (100)	17181(>99.9)
Mean (SD)	43.9 (12.29)	44.1 (12.36)	44.0 (12.33)
Median	45.0	45.0	45.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	2 (<0.1)	0	2 (<0.1)
Mean (SD)	68.5 (4.95)		68.5 (4.95)
Median	68.5		68.5
Min, Max	65, 72		65, 72
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8606(>99.9)	8575 (100)	17181(>99.9)
>=65 and <70 Years	1 (<0.1)	0	1 (<0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8608)	mRNA-1273 (N=8575)	Total (N=17183)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8606 (>99.9)	8575 (100)	17181 (>99.9)
>=65 and <75 Years	2 (<0.1)	0	2 (<0.1)
>=75 and <85 Years	0	0	0
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8608 (100)	8575 (100)	17183 (100)
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	14 (0.2)	19 (0.2)	33 (0.2)
Significant Cardiac Disease	10 (0.1)	11 (0.1)	21 (0.1)
Severe Obesity	64 (0.7)	60 (0.7)	124 (0.7)
Diabetes	36 (0.4)	33 (0.4)	69 (0.4)
Liver Disease	9 (0.1)	7 (<0.1)	16 (<0.1)
Human Immunodeficiency Virus Infection	14 (0.2)	10 (0.1)	24 (0.1)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	136 (1.6)	127 (1.5)	263 (1.5)
One Risk Factor for Severe COVID-19	126 (1.5)	117 (1.4)	243 (1.4)
Two or More Risk Factors for Severe COVID-19	10 (0.1)	10 (0.1)	20 (0.1)
No	8472 (98.4)	8448 (98.5)	16920 (98.5)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8608)	mRNA-1273 (N=8575)	Total (N=17183)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	8471 (98.4)	8448 (98.5)	16919 (98.5)
>=18 and <65 Years and at Risk	135 (1.6)	127 (1.5)	262 (1.5)
>=65 Years and Not at Risk	1 (<0.1)	0	1 (<0.1)
>=65 Years and at Risk	1 (<0.1)	0	1 (<0.1)
Baseline RT-PCR Results, n (%)			
Negative	8608 (100)	8575 (100)	17183 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	8608 (100)	8575 (100)	17183 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	8608 (100)	8575 (100)	17183 (100)
Positive	0	0	0
Sex, n (%)			
Male	4479 (52.0)	4366 (50.9)	8845 (51.5)
Female	4129 (48.0)	4209 (49.1)	8338 (48.5)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8608)	mRNA-1273 (N=8575)	Total (N=17183)
Race, n (%)			
White	6593 (76.6)	6552 (76.4)	13145 (76.5)
Black or African American	844 (9.8)	896 (10.4)	1740 (10.1)
Asian	575 (6.7)	492 (5.7)	1067 (6.2)
American Indian or Alaska Native	70 (0.8)	65 (0.8)	135 (0.8)
Native Hawaiian or Other Pacific Islander	19 (0.2)	26 (0.3)	45 (0.3)
Multiracial	229 (2.7)	229 (2.7)	458 (2.7)
Other	205 (2.4)	211 (2.5)	416 (2.4)
Not Reported	38 (0.4)	62 (0.7)	100 (0.6)
Unknown	35 (0.4)	42 (0.5)	77 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	2094 (24.3)	2074 (24.2)	4168 (24.3)
Not Hispanic or Latino	6442 (74.8)	6424 (74.9)	12866 (74.9)
Not Reported	42 (0.5)	55 (0.6)	97 (0.6)
Unknown	30 (0.3)	22 (0.3)	52 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	2930 (34.0)	2957 (34.5)	5887 (34.3)
Non-minority	5670 (65.9)	5604 (65.4)	11274 (65.6)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)
Race and Ethnicity Group, n (%) [6]			
White	4881 (56.7)	4902 (57.2)	9783 (56.9)
Communities of Color	3719 (43.2)	3659 (42.7)	7378 (42.9)
Missing	8 (<0.1)	14 (0.2)	22 (0.1)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8608)	mRNA-1273 (N=8575)	Total (N=17183)
Weight (kg)			
n	8562	8525	17087
Mean (SD)	82.30 (17.982)	81.95 (18.189)	82.13 (18.086)
Median	80.82	80.45	80.64
Min, Max	30.7, 160.4	33.3, 178.7	30.7, 178.7
Height (cm)			
n	8562	8524	17086
Mean (SD)	171.28 (9.880)	171.07 (9.887)	171.18 (9.884)
Median	171.00	170.30	170.94
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0
Body Mass Index (kg/m^2)			
n	8562	8522	17084
Mean (SD)	27.95 (5.132)	27.90 (5.259)	27.92 (5.196)
Median	27.32	27.31	27.32
Min, Max	10.3, 53.1	9.8, 57.9	9.8, 57.9
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	5793 (67.3)	5793 (67.6)	11586 (67.4)
>=30 kg/m^2	2769 (32.2)	2729 (31.8)	5498 (32.0)
Missing	46 (0.5)	53 (0.6)	99 (0.6)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8608)	mRNA-1273 (N=8575)	Total (N=17183)
Occupational Risk, n (%) [2]	7737 (89.9)	7692 (89.7)	15429 (89.8)
Healthcare Workers	2680 (31.1)	2682 (31.3)	5362 (31.2)
Emergency Response	209 (2.4)	226 (2.6)	435 (2.5)
Retail or Restaurant Operations	668 (7.8)	648 (7.6)	1316 (7.7)
Manufacturing and Production Operations	299 (3.5)	274 (3.2)	573 (3.3)
Warehouse Shipping and Fulfillment Centers	111 (1.3)	132 (1.5)	243 (1.4)
Transportation and Delivery Services	299 (3.5)	311 (3.6)	610 (3.6)
Border Protection and Military Personnel	50 (0.6)	52 (0.6)	102 (0.6)
Personal Care and In-Home Services	306 (3.6)	280 (3.3)	586 (3.4)
Hospitality and Tourism Workers	134 (1.6)	155 (1.8)	289 (1.7)
Pastoral, Social or Public Health Workers	260 (3.0)	287 (3.3)	547 (3.2)
Educators and Students	1093 (12.7)	1062 (12.4)	2155 (12.5)
Other	2518 (29.3)	2516 (29.3)	5034 (29.3)
Location and Living Circumstances Risk, n (%) [2]	7249 (84.2)	7255 (84.6)	14504 (84.4)
Resides in Nursing Home or Assisted Living Facility	6 (<0.1)	12 (0.1)	18 (0.1)
Resides in Multi-Family Dwelling	257 (3.0)	294 (3.4)	551 (3.2)
Resides in High Density Housing	825 (9.6)	792 (9.2)	1617 (9.4)
Resides in Low Density, Multi-Family Setting	914 (10.6)	886 (10.3)	1800 (10.5)
Resides in a Single Family Home	4656 (54.1)	4678 (54.6)	9334 (54.3)
Other	1272 (14.8)	1290 (15.0)	2562 (14.9)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2442)	mRNA-1273 (N=2467)	Total (N=4909)
Age at Screening (Years)			
n	2442	2467	4909
Mean (SD)	49.1 (11.29)	49.0 (11.44)	49.0 (11.36)
Median	51.0	52.0	51.0
Min, Max	18, 79	18, 76	18, 79
Age Group at Screening, n (%)			
>=18 and <65 Years	2439 (99.9)	2461 (99.8)	4900 (99.8)
Mean (SD)	49.1 (11.26)	48.9 (11.41)	49.0 (11.34)
Median	51.0	51.0	51.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3 (0.1)	6 (0.2)	9 (0.2)
Mean (SD)	72.0 (7.00)	67.7 (4.37)	69.1 (5.37)
Median	72.0	65.5	66.0
Min, Max	65, 79	65, 76	65, 79
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2439 (99.9)	2461 (99.8)	4900 (99.8)
>=65 and <70 Years	1 (<0.1)	5 (0.2)	6 (0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=80 Years	0	0	0

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2442)	mRNA-1273 (N=2467)	Total (N=4909)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2439 (99.9)	2461 (99.8)	4900 (99.8)
>=65 and <75 Years	2 (<0.1)	5 (0.2)	7 (0.1)
>=75 and <85 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	2442 (100)	2467 (100)	4909 (100)
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	474 (19.4)	447 (18.1)	921 (18.8)
Significant Cardiac Disease	269 (11.0)	300 (12.2)	569 (11.6)
Severe Obesity	808 (33.1)	810 (32.8)	1618 (33.0)
Diabetes	850 (34.8)	866 (35.1)	1716 (35.0)
Liver Disease	60 (2.5)	75 (3.0)	135 (2.8)
Human Immunodeficiency Virus Infection	54 (2.2)	62 (2.5)	116 (2.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	2102 (86.1)	2137 (86.6)	4239 (86.4)
One Risk Factor for Severe COVID-19	1738 (71.2)	1761 (71.4)	3499 (71.3)
Two or More Risk Factors for Severe COVID-19	364 (14.9)	376 (15.2)	740 (15.1)
No	340 (13.9)	330 (13.4)	670 (13.6)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2442)	mRNA-1273 (N=2467)	Total (N=4909)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	339 (13.9)	328 (13.3)	667 (13.6)
>=18 and <65 Years and at Risk	2100 (86.0)	2133 (86.5)	4233 (86.2)
>=65 Years and Not at Risk	1 (<0.1)	2 (<0.1)	3 (<0.1)
>=65 Years and at Risk	2 (<0.1)	4 (0.2)	6 (0.1)
Baseline RT-PCR Results, n (%)			
Negative	2442 (100)	2467 (100)	4909 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	2442 (100)	2467 (100)	4909 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	2442 (100)	2467 (100)	4909 (100)
Positive	0	0	0
Sex, n (%)			
Male	1274 (52.2)	1270 (51.5)	2544 (51.8)
Female	1168 (47.8)	1197 (48.5)	2365 (48.2)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2442)	mRNA-1273 (N=2467)	Total (N=4909)
Race, n (%)			
White	1816 (74.4)	1857 (75.3)	3673 (74.8)
Black or African American	383 (15.7)	357 (14.5)	740 (15.1)
Asian	80 (3.3)	87 (3.5)	167 (3.4)
American Indian or Alaska Native	23 (0.9)	27 (1.1)	50 (1.0)
Native Hawaiian or Other Pacific Islander	9 (0.4)	7 (0.3)	16 (0.3)
Multiracial	52 (2.1)	50 (2.0)	102 (2.1)
Other	48 (2.0)	54 (2.2)	102 (2.1)
Not Reported	18 (0.7)	17 (0.7)	35 (0.7)
Unknown	13 (0.5)	11 (0.4)	24 (0.5)
Ethnicity, n (%)			
Hispanic or Latino	527 (21.6)	540 (21.9)	1067 (21.7)
Not Hispanic or Latino	1895 (77.6)	1909 (77.4)	3804 (77.5)
Not Reported	12 (0.5)	14 (0.6)	26 (0.5)
Unknown	8 (0.3)	4 (0.2)	12 (0.2)
Race and Ethnicity Group, n (%) [5]			
Minority	916 (37.5)	895 (36.3)	1811 (36.9)
Non-minority	1521 (62.3)	1566 (63.5)	3087 (62.9)
Missing	5 (0.2)	6 (0.2)	11 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	1392 (57.0)	1428 (57.9)	2820 (57.4)
Communities of Color	1045 (42.8)	1033 (41.9)	2078 (42.3)
Missing	5 (0.2)	6 (0.2)	11 (0.2)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2442)	mRNA-1273 (N=2467)	Total (N=4909)
Weight (kg)			
n	2428	2462	4890
Mean (SD)	102.26 (28.488)	102.43 (28.829)	102.35 (28.658)
Median	98.64	99.25	98.80
Min, Max	33.5, 223.0	30.3, 236.4	30.3, 236.4
Height (cm)			
n	2427	2463	4890
Mean (SD)	170.90 (10.247)	170.74 (9.945)	170.82 (10.095)
Median	170.20	170.18	170.18
Min, Max	123.5, 203.2	111.0, 202.8	111.0, 203.2
Body Mass Index (kg/m^2)			
n	2427	2462	4889
Mean (SD)	34.98 (9.191)	35.14 (9.508)	35.06 (9.351)
Median	33.71	33.62	33.68
Min, Max	11.6, 72.7	11.7, 86.1	11.6, 86.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	869 (35.6)	849 (34.4)	1718 (35.0)
>=30 kg/m^2	1558 (63.8)	1613 (65.4)	3171 (64.6)
Missing	15 (0.6)	5 (0.2)	20 (0.4)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2442)	mRNA-1273 (N=2467)	Total (N=4909)
Occupational Risk, n (%) [2]	2087 (85.5)	2094 (84.9)	4181 (85.2)
Healthcare Workers	584 (23.9)	580 (23.5)	1164 (23.7)
Emergency Response	56 (2.3)	48 (1.9)	104 (2.1)
Retail or Restaurant Operations	173 (7.1)	168 (6.8)	341 (6.9)
Manufacturing and Production Operations	82 (3.4)	96 (3.9)	178 (3.6)
Warehouse Shipping and Fulfillment Centers	39 (1.6)	39 (1.6)	78 (1.6)
Transportation and Delivery Services	95 (3.9)	96 (3.9)	191 (3.9)
Border Protection and Military Personnel	12 (0.5)	11 (0.4)	23 (0.5)
Personal Care and In-Home Services	74 (3.0)	96 (3.9)	170 (3.5)
Hospitality and Tourism Workers	32 (1.3)	37 (1.5)	69 (1.4)
Pastoral, Social or Public Health Workers	100 (4.1)	87 (3.5)	187 (3.8)
Educators and Students	262 (10.7)	269 (10.9)	531 (10.8)
Other	760 (31.1)	794 (32.2)	1554 (31.7)
Location and Living Circumstances Risk, n (%) [2]	2018 (82.6)	2019 (81.8)	4037 (82.2)
Resides in Nursing Home or Assisted Living Facility	3 (0.1)	12 (0.5)	15 (0.3)
Resides in Multi-Family Dwelling	76 (3.1)	89 (3.6)	165 (3.4)
Resides in High Density Housing	179 (7.3)	193 (7.8)	372 (7.6)
Resides in Low Density, Multi-Family Setting	261 (10.7)	293 (11.9)	554 (11.3)
Resides in a Single Family Home	1344 (55.0)	1275 (51.7)	2619 (53.4)
Other	321 (13.1)	308 (12.5)	629 (12.8)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=65 Years

	Placebo (N=3695)	mRNA-1273 (N=3704)	Total (N=7399)
Age at Screening (Years)			
n	3695	3704	7399
Mean (SD)	70.7 (4.90)	70.4 (4.66)	70.6 (4.78)
Median	70.0	69.0	70.0
Min, Max	40, 95	64, 95	40, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mean (SD)	40.0 (NA)	64.0 (NA)	52.0 (16.97)
Median	40.0	64.0	52.0
Min, Max	40, 40	64, 64	40, 64
>=65 Years	3694(>99.9)	3703(>99.9)	7397(>99.9)
Mean (SD)	70.7 (4.88)	70.5 (4.66)	70.6 (4.77)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <70 Years	1793 (48.5)	1869 (50.5)	3662 (49.5)
>=70 and <75 Years	1177 (31.9)	1187 (32.0)	2364 (32.0)
>=75 and <80 Years	493 (13.3)	460 (12.4)	953 (12.9)
>=80 Years	231 (6.3)	187 (5.0)	418 (5.6)

Note: Footnotes are listed on the last page.
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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=65 Years

	Placebo (N=3695)	mRNA-1273 (N=3704)	Total (N=7399)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <75 Years	2970 (80.4)	3056 (82.5)	6026 (81.4)
>=75 and <85 Years	675 (18.3)	606 (16.4)	1281 (17.3)
>=85 Years	49 (1.3)	41 (1.1)	90 (1.2)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	3695 (100)	3704 (100)	7399 (100)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	239 (6.5)	236 (6.4)	475 (6.4)
Significant Cardiac Disease	443 (12.0)	434 (11.7)	877 (11.9)
Severe Obesity	152 (4.1)	171 (4.6)	323 (4.4)
Diabetes	537 (14.5)	532 (14.4)	1069 (14.4)
Liver Disease	26 (0.7)	20 (0.5)	46 (0.6)
Human Immunodeficiency Virus Infection	16 (0.4)	16 (0.4)	32 (0.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1117 (30.2)	1111 (30.0)	2228 (30.1)
One Risk Factor for Severe COVID-19	864 (23.4)	855 (23.1)	1719 (23.2)
Two or More Risk Factors for Severe COVID-19	253 (6.8)	256 (6.9)	509 (6.9)
No	2578 (69.8)	2593 (70.0)	5171 (69.9)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=65 Years

	Placebo (N=3695)	mRNA-1273 (N=3704)	Total (N=7399)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 Years and Not at Risk	2578 (69.8)	2593 (70.0)	5171 (69.9)
>=65 Years and at Risk	1116 (30.2)	1110 (30.0)	2226 (30.1)
Baseline RT-PCR Results, n (%)			
Negative	3695 (100)	3704 (100)	7399 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	3695 (100)	3704 (100)	7399 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	3695 (100)	3704 (100)	7399 (100)
Positive	0	0	0
Sex, n (%)			
Male	2067 (55.9)	2042 (55.1)	4109 (55.5)
Female	1628 (44.1)	1662 (44.9)	3290 (44.5)

Note: Footnotes are listed on the last page.
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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=65 Years

	Placebo (N=3695)	mRNA-1273 (N=3704)	Total (N=7399)
Race, n (%)			
White	3299 (89.3)	3329 (89.9)	6628 (89.6)
Black or African American	204 (5.5)	210 (5.7)	414 (5.6)
Asian	75 (2.0)	66 (1.8)	141 (1.9)
American Indian or Alaska Native	26 (0.7)	21 (0.6)	47 (0.6)
Native Hawaiian or Other Pacific Islander	3 (<0.1)	3 (<0.1)	6 (<0.1)
Multiracial	35 (0.9)	31 (0.8)	66 (0.9)
Other	32 (0.9)	23 (0.6)	55 (0.7)
Not Reported	14 (0.4)	13 (0.4)	27 (0.4)
Unknown	7 (0.2)	8 (0.2)	15 (0.2)
Ethnicity, n (%)			
Hispanic or Latino	326 (8.8)	343 (9.3)	669 (9.0)
Not Hispanic or Latino	3328 (90.1)	3317 (89.6)	6645 (89.8)
Not Reported	26 (0.7)	33 (0.9)	59 (0.8)
Unknown	15 (0.4)	11 (0.3)	26 (0.4)
Race and Ethnicity Group, n (%) [5]			
Minority	542 (14.7)	556 (15.0)	1098 (14.8)
Non-minority	3140 (85.0)	3142 (84.8)	6282 (84.9)
Missing	13 (0.4)	6 (0.2)	19 (0.3)
Race and Ethnicity Group, n (%) [6]			
White	3030 (82.0)	3034 (81.9)	6064 (82.0)
Communities of Color	652 (17.6)	664 (17.9)	1316 (17.8)
Missing	13 (0.4)	6 (0.2)	19 (0.3)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=65 Years

	Placebo (N=3695)	mRNA-1273 (N=3704)	Total (N=7399)
Weight (kg)			
n	3672	3675	7347
Mean (SD)	83.26 (19.012)	83.07 (19.333)	83.17 (19.173)
Median	81.60	81.20	81.36
Min, Max	34.8, 184.5	37.2, 165.0	34.8, 184.5
Height (cm)			
n	3671	3676	7347
Mean (SD)	170.05 (10.193)	169.99 (9.989)	170.02 (10.091)
Median	170.18	170.18	170.18
Min, Max	124.5, 223.5	123.0, 208.3	123.0, 223.5
Body Mass Index (kg/m^2)			
n	3671	3675	7346
Mean (SD)	28.72 (5.875)	28.65 (5.853)	28.68 (5.863)
Median	27.75	27.85	27.78
Min, Max	12.1, 71.1	11.2, 62.9	11.2, 71.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	2397 (64.9)	2378 (64.2)	4775 (64.5)
>=30 kg/m^2	1274 (34.5)	1297 (35.0)	2571 (34.7)
Missing	24 (0.6)	29 (0.8)	53 (0.7)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Randomization Stratum: >=65 Years

	Placebo (N=3695)	mRNA-1273 (N=3704)	Total (N=7399)
Occupational Risk, n (%) [2]	2349 (63.6)	2329 (62.9)	4678 (63.2)
Healthcare Workers	493 (13.3)	459 (12.4)	952 (12.9)
Emergency Response	18 (0.5)	20 (0.5)	38 (0.5)
Retail or Restaurant Operations	98 (2.7)	100 (2.7)	198 (2.7)
Manufacturing and Production Operations	29 (0.8)	34 (0.9)	63 (0.9)
Warehouse Shipping and Fulfillment Centers	12 (0.3)	9 (0.2)	21 (0.3)
Transportation and Delivery Services	62 (1.7)	46 (1.2)	108 (1.5)
Border Protection and Military Personnel	6 (0.2)	3 (<0.1)	9 (0.1)
Personal Care and In-Home Services	59 (1.6)	66 (1.8)	125 (1.7)
Hospitality and Tourism Workers	42 (1.1)	34 (0.9)	76 (1.0)
Pastoral, Social or Public Health Workers	137 (3.7)	146 (3.9)	283 (3.8)
Educators and Students	167 (4.5)	183 (4.9)	350 (4.7)
Other	1413 (38.2)	1405 (37.9)	2818 (38.1)
Location and Living Circumstances Risk, n (%) [2]	3055 (82.7)	3080 (83.2)	6135 (82.9)
Resides in Nursing Home or Assisted Living Facility	19 (0.5)	11 (0.3)	30 (0.4)
Resides in Multi-Family Dwelling	63 (1.7)	65 (1.8)	128 (1.7)
Resides in High Density Housing	236 (6.4)	241 (6.5)	477 (6.4)
Resides in Low Density, Multi-Family Setting	251 (6.8)	240 (6.5)	491 (6.6)
Resides in a Single Family Home	2228 (60.3)	2252 (60.8)	4480 (60.5)
Other	520 (14.1)	537 (14.5)	1057 (14.3)

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Table 14.1.3.3.3
Baseline Demographics and Characteristics by Randomization Stratum
mITT Set

Percentages are based on the number of subjects in mITT set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Age at Screening (Years)									
n	352	279	631	73	55	128	425	334	759
Mean	42.6	41.5	42.1	71.1	70.4	70.8	47.5	46.3	47.0
(SD)	(12.86)	(13.07)	(12.96)	(5.72)	(5.51)	(5.62)	(16.08)	(16.21)	(16.14)
Median	43.0	41.0	42.0	70.0	69.0	70.0	48.0	45.0	46.0
Min, Max	18, 64	18, 64	18, 64	65, 90	65, 87	65, 90	18, 90	18, 87	18, 90
Age Group at Screening, n (%)									
>=18 and <65 Years	352	279	631	0	0	0	352	279	631
	(100)	(100)	(100)				(82.8)	(83.5)	(83.1)
Mean	42.6	41.5	42.1				42.6	41.5	42.1
(SD)	(12.86)	(13.07)	(12.96)				(12.86)	(13.07)	(12.96)
Median	43.0	41.0	42.0				43.0	41.0	42.0
Min, Max	18, 64	18, 64	18, 64				18, 64	18, 64	18, 64
>=65 Years	0	0	0	73	55	128	73	55	128
				(100)	(100)	(100)	(17.2)	(16.5)	(16.9)
Mean				71.1	70.4	70.8	71.1	70.4	70.8
(SD)				(5.72)	(5.51)	(5.62)	(5.72)	(5.51)	(5.62)
Median				70.0	69.0	70.0	70.0	69.0	70.0
Min, Max				65, 90	65, 87	65, 90	65, 90	65, 87	65, 90

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	352 (100)	279 (100)	631 (100)	0	0	0	352 (82.8)	279 (83.5)	631 (83.1)
>=65 and <70 Years	0	0	0	32 (43.8)	30 (54.5)	62 (48.4)	32 (7.5)	30 (9.0)	62 (8.2)
>=70 and <75 Years	0	0	0	22 (30.1)	17 (30.9)	39 (30.5)	22 (5.2)	17 (5.1)	39 (5.1)
>=75 and <80 Years	0	0	0	12 (16.4)	4 (7.3)	16 (12.5)	12 (2.8)	4 (1.2)	16 (2.1)
>=80 Years	0	0	0	7 (9.6)	4 (7.3)	11 (8.6)	7 (1.6)	4 (1.2)	11 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	352 (100)	279 (100)	631 (100)	0	0	0	352 (82.8)	279 (83.5)	631 (83.1)
>=65 and <75 Years	0	0	0	54 (74.0)	47 (85.5)	101 (78.9)	54 (12.7)	47 (14.1)	101 (13.3)
>=75 and <85 Years	0	0	0	17 (23.3)	5 (9.1)	22 (17.2)	17 (4.0)	5 (1.5)	22 (2.9)
>=85 Years	0	0	0	2 (2.7)	3 (5.5)	5 (3.9)	2 (0.5)	3 (0.9)	5 (0.7)

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	272 (77.3)	234 (83.9)	506 (80.2)	0	0	0	272 (64.0)	234 (70.1)	506 (66.7)
>=18 and <65 Years and at Risk	80 (22.7)	45 (16.1)	125 (19.8)	0	0	0	80 (18.8)	45 (13.5)	125 (16.5)
>=65 Years	0	0	0	73 (100)	55 (100)	128 (100)	73 (17.2)	55 (16.5)	128 (16.9)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	14 (4.0)	10 (3.6)	24 (3.8)	10 (13.7)	5 (9.1)	15 (11.7)	24 (5.6)	15 (4.5)	39 (5.1)
Significant Cardiac Disease	4 (1.1)	5 (1.8)	9 (1.4)	15 (20.5)	5 (9.1)	20 (15.6)	19 (4.5)	10 (3.0)	29 (3.8)
Severe Obesity	25 (7.1)	16 (5.7)	41 (6.5)	8 (11.0)	0	8 (6.3)	33 (7.8)	16 (4.8)	49 (6.5)
Diabetes	27 (7.7)	11 (3.9)	38 (6.0)	14 (19.2)	4 (7.3)	18 (14.1)	41 (9.6)	15 (4.5)	56 (7.4)
Liver Disease	1 (0.3)	0	1 (0.2)	1 (1.4)	2 (3.6)	3 (2.3)	2 (0.5)	2 (0.6)	4 (0.5)
Human Immunodeficiency Virus Infection	2 (0.6)	2 (0.7)	4 (0.6)	0	1 (1.8)	1 (0.8)	2 (0.5)	3 (0.9)	5 (0.7)

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	64 (18.2)	37 (13.3)	101 (16.0)	36 (49.3)	14 (25.5)	50 (39.1)	100 (23.5)	51 (15.3)	151 (19.9)
One Risk Factor for Severe COVID-19	55 (15.6)	30 (10.8)	85 (13.5)	27 (37.0)	11 (20.0)	38 (29.7)	82 (19.3)	41 (12.3)	123 (16.2)
Two or More Risk Factors for Severe COVID-19	9 (2.6)	7 (2.5)	16 (2.5)	9 (12.3)	3 (5.5)	12 (9.4)	18 (4.2)	10 (3.0)	28 (3.7)
No	288 (81.8)	242 (86.7)	530 (84.0)	37 (50.7)	41 (74.5)	78 (60.9)	325 (76.5)	283 (84.7)	608 (80.1)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	288 (81.8)	242 (86.7)	530 (84.0)	0	0	0	288 (67.8)	242 (72.5)	530 (69.8)
>=18 and <65 Years and at Risk	64 (18.2)	37 (13.3)	101 (16.0)	0	0	0	64 (15.1)	37 (11.1)	101 (13.3)
>=65 Years and Not at Risk	0	0	0	37 (50.7)	41 (74.5)	78 (60.9)	37 (8.7)	41 (12.3)	78 (10.3)
>=65 Years and at Risk	0	0	0	36 (49.3)	14 (25.5)	50 (39.1)	36 (8.5)	14 (4.2)	50 (6.6)

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Baseline RT-PCR Results, n (%)									
Negative	352 (100)	279 (100)	631 (100)	73 (100)	55 (100)	128 (100)	425 (100)	334 (100)	759 (100)
Positive	0	0	0	0	0	0	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	352 (100)	279 (100)	631 (100)	73 (100)	55 (100)	128 (100)	425 (100)	334 (100)	759 (100)
Positive	0	0	0	0	0	0	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	352 (100)	279 (100)	631 (100)	73 (100)	55 (100)	128 (100)	425 (100)	334 (100)	759 (100)
Positive	0	0	0	0	0	0	0	0	0

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Sex, n (%)									
Male	203 (57.7)	155 (55.6)	358 (56.7)	40 (54.8)	26 (47.3)	66 (51.6)	243 (57.2)	181 (54.2)	424 (55.9)
Female	149 (42.3)	124 (44.4)	273 (43.3)	33 (45.2)	29 (52.7)	62 (48.4)	182 (42.8)	153 (45.8)	335 (44.1)
Race, n (%)									
White	244 (69.3)	199 (71.3)	443 (70.2)	65 (89.0)	46 (83.6)	111 (86.7)	309 (72.7)	245 (73.4)	554 (73.0)
Black or African American	63 (17.9)	53 (19.0)	116 (18.4)	3 (4.1)	5 (9.1)	8 (6.3)	66 (15.5)	58 (17.4)	124 (16.3)
Asian	16 (4.5)	11 (3.9)	27 (4.3)	2 (2.7)	1 (1.8)	3 (2.3)	18 (4.2)	12 (3.6)	30 (4.0)
American Indian or Alaska Native	4 (1.1)	2 (0.7)	6 (1.0)	1 (1.4)	0	1 (0.8)	5 (1.2)	2 (0.6)	7 (0.9)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0
Multiracial	9 (2.6)	5 (1.8)	14 (2.2)	1 (1.4)	0	1 (0.8)	10 (2.4)	5 (1.5)	15 (2.0)
Other	9 (2.6)	4 (1.4)	13 (2.1)	0	1 (1.8)	1 (0.8)	9 (2.1)	5 (1.5)	14 (1.8)
Not Reported	4 (1.1)	2 (0.7)	6 (1.0)	1 (1.4)	0	1 (0.8)	5 (1.2)	2 (0.6)	7 (0.9)
Unknown	3 (0.9)	3 (1.1)	6 (1.0)	0	2 (3.6)	2 (1.6)	3 (0.7)	5 (1.5)	8 (1.1)

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Ethnicity, n (%)									
Hispanic or Latino	120 (34.1)	99 (35.5)	219 (34.7)	18 (24.7)	9 (16.4)	27 (21.1)	138 (32.5)	108 (32.3)	246 (32.4)
Not Hispanic or Latino	228 (64.8)	176 (63.1)	404 (64.0)	55 (75.3)	46 (83.6)	101 (78.9)	283 (66.6)	222 (66.5)	505 (66.5)
Not Reported	3 (0.9)	2 (0.7)	5 (0.8)	0	0	0	3 (0.7)	2 (0.6)	5 (0.7)
Unknown	1 (0.3)	2 (0.7)	3 (0.5)	0	0	0	1 (0.2)	2 (0.6)	3 (0.4)
Race and Ethnicity Group, n (%) [5]									
Minority	176 (50.0)	147 (52.7)	323 (51.2)	22 (30.1)	14 (25.5)	36 (28.1)	198 (46.6)	161 (48.2)	359 (47.3)
Non-minority	175 (49.7)	131 (47.0)	306 (48.5)	51 (69.9)	41 (74.5)	92 (71.9)	226 (53.2)	172 (51.5)	398 (52.4)
Missing	1 (0.3)	1 (0.4)	2 (0.3)	0	0	0	1 (0.2)	1 (0.3)	2 (0.3)
Race and Ethnicity Group, n (%) [6]									
White	150 (42.6)	116 (41.6)	266 (42.2)	48 (65.8)	40 (72.7)	88 (68.8)	198 (46.6)	156 (46.7)	354 (46.6)
Communities of Color	201 (57.1)	162 (58.1)	363 (57.5)	25 (34.2)	15 (27.3)	40 (31.3)	226 (53.2)	177 (53.0)	403 (53.1)
Missing	1 (0.3)	1 (0.4)	2 (0.3)	0	0	0	1 (0.2)	1 (0.3)	2 (0.3)

Note: Footnotes are listed on the last page.
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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Weight (kg)									
n	348	279	627	73	55	128	421	334	755
Mean	86.36	84.93	85.72	87.10	77.15	82.82	86.49	83.65	85.23
(SD)	(22.358)	(24.180)	(23.178)	(19.548)	(17.529)	(19.280)	(21.876)	(23.373)	(22.579)
Median	84.09	80.91	83.18	85.36	74.09	81.40	84.09	79.72	82.27
Min, Max	38.2, 223.0	44.5, 213.6	38.2, 223.0	48.6, 143.0	47.7, 114.4	47.7, 143.0	38.2, 223.0	44.5, 213.6	38.2, 223.0
Height (cm)									
n	348	279	627	73	55	128	421	334	755
Mean	171.32	171.36	171.34	170.83	166.44	168.94	171.24	170.55	170.93
(SD)	(9.912)	(10.031)	(9.957)	(10.550)	(11.496)	(11.138)	(10.014)	(10.429)	(10.199)
Median	170.18	170.20	170.18	170.18	165.00	167.64	170.18	169.65	170.18
Min, Max	142.2, 205.0	149.0, 203.0	142.2, 205.0	151.0, 193.0	144.8, 191.8	144.8, 193.0	142.2, 205.0	144.8, 203.0	142.2, 205.0
Body Mass Index (kg/m^2)									
n	348	279	627	73	55	128	421	334	755
Mean	29.34	28.85	29.12	29.81	27.72	28.91	29.42	28.67	29.09
(SD)	(6.871)	(7.893)	(7.341)	(6.069)	(5.160)	(5.768)	(6.734)	(7.517)	(7.096)
Median	28.24	27.45	27.92	29.21	26.74	27.78	28.33	27.15	27.91
Min, Max	17.0, 68.8	15.5, 86.1	15.5, 86.1	19.0, 44.0	19.2, 40.3	19.0, 44.0	17.0, 68.8	15.5, 86.1	15.5, 86.1

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Body Mass Index Subgroup, n (%)									
< 30 kg/m^2	217 (61.6)	178 (63.8)	395 (62.6)	40 (54.8)	36 (65.5)	76 (59.4)	257 (60.5)	214 (64.1)	471 (62.1)
>=30 kg/m^2	131 (37.2)	101 (36.2)	232 (36.8)	33 (45.2)	19 (34.5)	52 (40.6)	164 (38.6)	120 (35.9)	284 (37.4)
Missing	4 (1.1)	0	4 (0.6)	0	0	0	4 (0.9)	0	4 (0.5)

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Occupational Risk, n (%) [2]	308 (87.5)	241 (86.4)	549 (87.0)	50 (68.5)	30 (54.5)	80 (62.5)	358 (84.2)	271 (81.1)	629 (82.9)
Healthcare Workers	75 (21.3)	61 (21.9)	136 (21.6)	11 (15.1)	6 (10.9)	17 (13.3)	86 (20.2)	67 (20.1)	153 (20.2)
Emergency Response	7 (2.0)	5 (1.8)	12 (1.9)	0	0	0	7 (1.6)	5 (1.5)	12 (1.6)
Retail or Restaurant Operations	42 (11.9)	34 (12.2)	76 (12.0)	4 (5.5)	0	4 (3.1)	46 (10.8)	34 (10.2)	80 (10.5)
Manufacturing and Production Operations	14 (4.0)	10 (3.6)	24 (3.8)	2 (2.7)	0	2 (1.6)	16 (3.8)	10 (3.0)	26 (3.4)
Warehouse Shipping and Fulfillment Centers	4 (1.1)	3 (1.1)	7 (1.1)	0	0	0	4 (0.9)	3 (0.9)	7 (0.9)
Transportation and Delivery Services	21 (6.0)	19 (6.8)	40 (6.3)	2 (2.7)	2 (3.6)	4 (3.1)	23 (5.4)	21 (6.3)	44 (5.8)
Border Protection and Military Personnel	1 (0.3)	2 (0.7)	3 (0.5)	1 (1.4)	0	1 (0.8)	2 (0.5)	2 (0.6)	4 (0.5)
Personal Care and In-Home Services	20 (5.7)	23 (8.2)	43 (6.8)	2 (2.7)	0	2 (1.6)	22 (5.2)	23 (6.9)	45 (5.9)
Hospitality and Tourism Workers	6 (1.7)	8 (2.9)	14 (2.2)	0	2 (3.6)	2 (1.6)	6 (1.4)	10 (3.0)	16 (2.1)
Pastoral, Social or Public Health Workers	10 (2.8)	10 (3.6)	20 (3.2)	0	1 (1.8)	1 (0.8)	10 (2.4)	11 (3.3)	21 (2.8)
Educators and Students	29 (8.2)	21 (7.5)	50 (7.9)	1 (1.4)	0	1 (0.8)	30 (7.1)	21 (6.3)	51 (6.7)
Other	117 (33.2)	79 (28.3)	196 (31.1)	30 (41.1)	19 (34.5)	49 (38.3)	147 (34.6)	98 (29.3)	245 (32.3)

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=352)	mRNA-1273 (N=279)	Total (N=631)	Placebo (N=73)	mRNA-1273 (N=55)	Total (N=128)	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Location and Living Circumstances Risk, n (%) [2]	314 (89.2)	238 (85.3)	552 (87.5)	63 (86.3)	49 (89.1)	112 (87.5)	377 (88.7)	287 (85.9)	664 (87.5)
Resides in Nursing Home or Assisted Living Facility	0	2 (0.7)	2 (0.3)	0	0	0	0	2 (0.6)	2 (0.3)
Resides in Multi-Family Dwelling	16 (4.5)	21 (7.5)	37 (5.9)	1 (1.4)	2 (3.6)	3 (2.3)	17 (4.0)	23 (6.9)	40 (5.3)
Resides in High Density Housing	36 (10.2)	28 (10.0)	64 (10.1)	6 (8.2)	6 (10.9)	12 (9.4)	42 (9.9)	34 (10.2)	76 (10.0)
Resides in Low Density, Multi-Family Setting	56 (15.9)	39 (14.0)	95 (15.1)	7 (9.6)	4 (7.3)	11 (8.6)	63 (14.8)	43 (12.9)	106 (14.0)
Resides in a Single Family Home	189 (53.7)	135 (48.4)	324 (51.3)	45 (61.6)	29 (52.7)	74 (57.8)	234 (55.1)	164 (49.1)	398 (52.4)
Other	47 (13.4)	34 (12.2)	81 (12.8)	9 (12.3)	9 (16.4)	18 (14.1)	56 (13.2)	43 (12.9)	99 (13.0)

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Table 14.1.3.3.4
Baseline Demographics and Characteristics by Age Group
mITT Set — Subjects Only Received One Injection

Percentages are based on the number of subjects who only received one injection in mITT set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Age at Screening (Years)									
n	10569	10661	21230	3595	3626	7221	14164	14287	28451
Mean	45.1	45.2	45.2	70.7	70.4	70.6	51.6	51.6	51.6
(SD)	(12.24)	(12.28)	(12.26)	(4.85)	(4.64)	(4.75)	(15.55)	(15.44)	(15.49)
Median	46.0	46.0	46.0	70.0	69.0	70.0	52.0	53.0	53.0
Min, Max	18, 64	18, 64	18, 64	65, 95	65, 95	65, 95	18, 95	18, 95	18, 95
Age Group at Screening, n (%)									
>=18 and <65 Years	10569	10661	21230	0	0	0	10569	10661	21230
	(100)	(100)	(100)				(74.6)	(74.6)	(74.6)
Mean	45.1	45.2	45.2				45.1	45.2	45.2
(SD)	(12.24)	(12.28)	(12.26)				(12.24)	(12.28)	(12.26)
Median	46.0	46.0	46.0				46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64				18, 64	18, 64	18, 64
>=65 Years	0	0	0	3595	3626	7221	3595	3626	7221
				(100)	(100)	(100)	(25.4)	(25.4)	(25.4)
Mean				70.7	70.4	70.6	70.7	70.4	70.6
(SD)				(4.85)	(4.64)	(4.75)	(4.85)	(4.64)	(4.75)
Median				70.0	69.0	70.0	70.0	69.0	70.0
Min, Max				65, 95	65, 95	65, 95	65, 95	65, 95	65, 95

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	10569 (100)	10661 (100)	21230 (100)	0	0	0	10569 (74.6)	10661 (74.6)	21230 (74.6)
>=65 and <70 Years	0	0	0	1748 (48.6)	1830 (50.5)	3578 (49.5)	1748 (12.3)	1830 (12.8)	3578 (12.6)
>=70 and <75 Years	0	0	0	1150 (32.0)	1160 (32.0)	2310 (32.0)	1150 (8.1)	1160 (8.1)	2310 (8.1)
>=75 and <80 Years	0	0	0	478 (13.3)	454 (12.5)	932 (12.9)	478 (3.4)	454 (3.2)	932 (3.3)
>=80 Years	0	0	0	219 (6.1)	182 (5.0)	401 (5.6)	219 (1.5)	182 (1.3)	401 (1.4)
Age Subgroup at Screening, n (%)									
>=18 and <65 Years	10569 (100)	10661 (100)	21230 (100)	0	0	0	10569 (74.6)	10661 (74.6)	21230 (74.6)
>=65 and <75 Years	0	0	0	2898 (80.6)	2990 (82.5)	5888 (81.5)	2898 (20.5)	2990 (20.9)	5888 (20.7)
>=75 and <85 Years	0	0	0	651 (18.1)	599 (16.5)	1250 (17.3)	651 (4.6)	599 (4.2)	1250 (4.4)
>=85 Years	0	0	0	46 (1.3)	37 (1.0)	83 (1.1)	46 (0.3)	37 (0.3)	83 (0.3)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Age and Health Risk for Severe COVID-19, n (%) [1]									
>=18 and <65 Years and Not at Risk	8240 (78.0)	8271 (77.6)	16511 (77.8)	2 (<0.1)	0	2 (<0.1)	8242 (58.2)	8271 (57.9)	16513 (58.0)
>=18 and <65 Years and at Risk	2328 (22.0)	2389 (22.4)	4717 (22.2)	3 (<0.1)	6 (0.2)	9 (0.1)	2331 (16.5)	2395 (16.8)	4726 (16.6)
>=65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)	3590 (99.9)	3620 (99.8)	7210 (99.8)	3591 (25.4)	3621 (25.3)	7212 (25.3)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]									
Chronic Lung Disease	463 (4.4)	449 (4.2)	912 (4.3)	229 (6.4)	226 (6.2)	455 (6.3)	692 (4.9)	675 (4.7)	1367 (4.8)
Significant Cardiac Disease	273 (2.6)	301 (2.8)	574 (2.7)	423 (11.8)	425 (11.7)	848 (11.7)	696 (4.9)	726 (5.1)	1422 (5.0)
Severe Obesity	838 (7.9)	841 (7.9)	1679 (7.9)	142 (3.9)	168 (4.6)	310 (4.3)	980 (6.9)	1009 (7.1)	1989 (7.0)
Diabetes	844 (8.0)	877 (8.2)	1721 (8.1)	519 (14.4)	525 (14.5)	1044 (14.5)	1363 (9.6)	1402 (9.8)	2765 (9.7)
Liver Disease	65 (0.6)	82 (0.8)	147 (0.7)	25 (0.7)	18 (0.5)	43 (0.6)	90 (0.6)	100 (0.7)	190 (0.7)
Human Immunodeficiency Virus Infection	66 (0.6)	70 (0.7)	136 (0.6)	16 (0.4)	15 (0.4)	31 (0.4)	82 (0.6)	85 (0.6)	167 (0.6)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
At Risk for Severe COVID-19 at Screening, n (%)									
Yes	2141 (20.3)	2197 (20.6)	4338 (20.4)	1071 (29.8)	1086 (30.0)	2157 (29.9)	3212 (22.7)	3283 (23.0)	6495 (22.8)
One Risk Factor for Severe COVID-19	1782 (16.9)	1824 (17.1)	3606 (17.0)	828 (23.0)	836 (23.1)	1664 (23.0)	2610 (18.4)	2660 (18.6)	5270 (18.5)
Two or More Risk Factors for Severe COVID-19	359 (3.4)	373 (3.5)	732 (3.4)	243 (6.8)	250 (6.9)	493 (6.8)	602 (4.3)	623 (4.4)	1225 (4.3)
No	8428 (79.7)	8464 (79.4)	16892 (79.6)	2524 (70.2)	2540 (70.0)	5064 (70.1)	10952 (77.3)	11004 (77.0)	21956 (77.2)
Age and Risk for Severe COVID-19, n (%) [3]									
>=18 and <65 Years and Not at Risk	8428 (79.7)	8464 (79.4)	16892 (79.6)	0	0	0	8428 (59.5)	8464 (59.2)	16892 (59.4)
>=18 and <65 Years and at Risk	2141 (20.3)	2197 (20.6)	4338 (20.4)	0	0	0	2141 (15.1)	2197 (15.4)	4338 (15.2)
>=65 Years and Not at Risk	0	0	0	2524 (70.2)	2540 (70.0)	5064 (70.1)	2524 (17.8)	2540 (17.8)	5064 (17.8)
>=65 Years and at Risk	0	0	0	1071 (29.8)	1086 (30.0)	2157 (29.9)	1071 (7.6)	1086 (7.6)	2157 (7.6)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Baseline RT-PCR Results, n (%)									
Negative	10569 (100)	10661 (100)	21230 (100)	3595 (100)	3626 (100)	7221 (100)	14164 (100)	14287 (100)	28451 (100)
Positive	0	0	0	0	0	0	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)									
Negative	10569 (100)	10661 (100)	21230 (100)	3595 (100)	3626 (100)	7221 (100)	14164 (100)	14287 (100)	28451 (100)
Positive	0	0	0	0	0	0	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]									
Negative	10569 (100)	10661 (100)	21230 (100)	3595 (100)	3626 (100)	7221 (100)	14164 (100)	14287 (100)	28451 (100)
Positive	0	0	0	0	0	0	0	0	0

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Sex, n (%)									
Male	5485 (51.9)	5431 (50.9)	10916 (51.4)	2009 (55.9)	2008 (55.4)	4017 (55.6)	7494 (52.9)	7439 (52.1)	14933 (52.5)
Female	5084 (48.1)	5230 (49.1)	10314 (48.6)	1586 (44.1)	1618 (44.6)	3204 (44.4)	6670 (47.1)	6848 (47.9)	13518 (47.5)
Race, n (%)									
White	8062 (76.3)	8131 (76.3)	16193 (76.3)	3211 (89.3)	3260 (89.9)	6471 (89.6)	11273 (79.6)	11391 (79.7)	22664 (79.7)
Black or African American	1154 (10.9)	1190 (11.2)	2344 (11.0)	198 (5.5)	205 (5.7)	403 (5.6)	1352 (9.5)	1395 (9.8)	2747 (9.7)
Asian	628 (5.9)	562 (5.3)	1190 (5.6)	72 (2.0)	66 (1.8)	138 (1.9)	700 (4.9)	628 (4.4)	1328 (4.7)
American Indian or Alaska Native	88 (0.8)	88 (0.8)	176 (0.8)	25 (0.7)	21 (0.6)	46 (0.6)	113 (0.8)	109 (0.8)	222 (0.8)
Native Hawaiian or Other Pacific Islander	28 (0.3)	33 (0.3)	61 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	31 (0.2)	36 (0.3)	67 (0.2)
Multiracial	270 (2.6)	270 (2.5)	540 (2.5)	34 (0.9)	30 (0.8)	64 (0.9)	304 (2.1)	300 (2.1)	604 (2.1)
Other	242 (2.3)	260 (2.4)	502 (2.4)	32 (0.9)	22 (0.6)	54 (0.7)	274 (1.9)	282 (2.0)	556 (2.0)
Not Reported	52 (0.5)	77 (0.7)	129 (0.6)	13 (0.4)	13 (0.4)	26 (0.4)	65 (0.5)	90 (0.6)	155 (0.5)
Unknown	45 (0.4)	50 (0.5)	95 (0.4)	7 (0.2)	6 (0.2)	13 (0.2)	52 (0.4)	56 (0.4)	108 (0.4)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Ethnicity, n (%)									
Hispanic or Latino	2478 (23.4)	2499 (23.4)	4977 (23.4)	309 (8.6)	332 (9.2)	641 (8.9)	2787 (19.7)	2831 (19.8)	5618 (19.7)
Not Hispanic or Latino	8004 (75.7)	8072 (75.7)	16076 (75.7)	3245 (90.3)	3250 (89.6)	6495 (89.9)	11249 (79.4)	11322 (79.2)	22571 (79.3)
Not Reported	50 (0.5)	66 (0.6)	116 (0.5)	26 (0.7)	33 (0.9)	59 (0.8)	76 (0.5)	99 (0.7)	175 (0.6)
Unknown	37 (0.4)	24 (0.2)	61 (0.3)	15 (0.4)	11 (0.3)	26 (0.4)	52 (0.4)	35 (0.2)	87 (0.3)
Race and Ethnicity Group, n (%) [5]									
Minority	3638 (34.4)	3677 (34.5)	7315 (34.5)	518 (14.4)	540 (14.9)	1058 (14.7)	4156 (29.3)	4217 (29.5)	8373 (29.4)
Non-minority	6919 (65.5)	6965 (65.3)	13884 (65.4)	3064 (85.2)	3080 (84.9)	6144 (85.1)	9983 (70.5)	10045 (70.3)	20028 (70.4)
Missing	12 (0.1)	19 (0.2)	31 (0.1)	13 (0.4)	6 (0.2)	19 (0.3)	25 (0.2)	25 (0.2)	50 (0.2)
Race and Ethnicity Group, n (%) [6]									
White	6040 (57.1)	6150 (57.7)	12190 (57.4)	2958 (82.3)	2973 (82.0)	5931 (82.1)	8998 (63.5)	9123 (63.9)	18121 (63.7)
Communities of Color	4517 (42.7)	4492 (42.1)	9009 (42.4)	624 (17.4)	647 (17.8)	1271 (17.6)	5141 (36.3)	5139 (36.0)	10280 (36.1)
Missing	12 (0.1)	19 (0.2)	31 (0.1)	13 (0.4)	6 (0.2)	19 (0.3)	25 (0.2)	25 (0.2)	50 (0.2)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Weight (kg)									
n	10514	10606	21120	3572	3598	7170	14086	14204	28290
Mean	86.69	86.54	86.61	83.17	83.17	83.17	85.79	85.69	85.74
(SD)	(22.367)	(22.647)	(22.508)	(18.993)	(19.318)	(19.156)	(21.615)	(21.901)	(21.759)
Median	83.64	83.64	83.64	81.52	81.29	81.36	82.90	83.00	83.00
Min, Max	30.7, 216.5	30.3, 236.4	30.3, 236.4	34.8, 184.5	37.2, 165.0	34.8, 184.5	30.7, 216.5	30.3, 236.4	30.3, 236.4
Height (cm)									
n	10513	10606	21119	3571	3599	7170	14084	14205	28289
Mean	171.20	170.99	171.09	170.04	170.07	170.05	170.90	170.76	170.83
(SD)	(9.971)	(9.903)	(9.937)	(10.193)	(9.953)	(10.073)	(10.040)	(9.924)	(9.982)
Median	171.00	170.20	170.69	170.18	170.18	170.18	170.50	170.18	170.20
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0	124.5, 223.5	123.0, 208.3	123.0, 223.5	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)									
n	10513	10603	21116	3571	3598	7169	14084	14201	28285
Mean	29.49	29.52	29.51	28.69	28.65	28.67	29.29	29.30	29.30
(SD)	(6.898)	(7.101)	(7.000)	(5.873)	(5.843)	(5.858)	(6.662)	(6.814)	(6.739)
Median	28.24	28.24	28.24	27.70	27.86	27.78	28.09	28.12	28.10
Min, Max	10.3, 72.7	9.8, 82.0	9.8, 82.0	12.1, 71.1	11.2, 62.9	11.2, 71.1	10.3, 72.7	9.8, 82.0	9.8, 82.0

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Body Mass Index Subgroup, n (%)									
< 30 kg/m^2	6379 (60.4)	6414 (60.2)	12793 (60.3)	2340 (65.1)	2327 (64.2)	4667 (64.6)	8719 (61.6)	8741 (61.2)	17460 (61.4)
>=30 kg/m^2	4134 (39.1)	4189 (39.3)	8323 (39.2)	1231 (34.2)	1271 (35.1)	2502 (34.6)	5365 (37.9)	5460 (38.2)	10825 (38.0)
Missing	56 (0.5)	58 (0.5)	114 (0.5)	24 (0.7)	28 (0.8)	52 (0.7)	80 (0.6)	86 (0.6)	166 (0.6)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Occupational Risk, n (%) [2]	9401 (88.9)	9456 (88.7)	18857 (88.8)	2283 (63.5)	2290 (63.2)	4573 (63.3)	11684 (82.5)	11746 (82.2)	23430 (82.4)
Healthcare Workers	3146 (29.8)	3181 (29.8)	6327 (29.8)	475 (13.2)	450 (12.4)	925 (12.8)	3621 (25.6)	3631 (25.4)	7252 (25.5)
Emergency Response	255 (2.4)	266 (2.5)	521 (2.5)	18 (0.5)	21 (0.6)	39 (0.5)	273 (1.9)	287 (2.0)	560 (2.0)
Retail or Restaurant Operations	782 (7.4)	771 (7.2)	1553 (7.3)	93 (2.6)	99 (2.7)	192 (2.7)	875 (6.2)	870 (6.1)	1745 (6.1)
Manufacturing and Production Operations	364 (3.4)	356 (3.3)	720 (3.4)	26 (0.7)	34 (0.9)	60 (0.8)	390 (2.8)	390 (2.7)	780 (2.7)
Warehouse Shipping and Fulfillment Centers	146 (1.4)	165 (1.5)	311 (1.5)	12 (0.3)	9 (0.2)	21 (0.3)	158 (1.1)	174 (1.2)	332 (1.2)
Transportation and Delivery Services	369 (3.5)	384 (3.6)	753 (3.5)	59 (1.6)	44 (1.2)	103 (1.4)	428 (3.0)	428 (3.0)	856 (3.0)
Border Protection and Military Personnel	61 (0.6)	61 (0.6)	122 (0.6)	5 (0.1)	3 (<0.1)	8 (0.1)	66 (0.5)	64 (0.4)	130 (0.5)
Personal Care and In-Home Services	356 (3.4)	351 (3.3)	707 (3.3)	57 (1.6)	66 (1.8)	123 (1.7)	413 (2.9)	417 (2.9)	830 (2.9)
Hospitality and Tourism Workers	158 (1.5)	182 (1.7)	340 (1.6)	42 (1.2)	32 (0.9)	74 (1.0)	200 (1.4)	214 (1.5)	414 (1.5)
Pastoral, Social or Public Health Workers	346 (3.3)	361 (3.4)	707 (3.3)	139 (3.9)	145 (4.0)	284 (3.9)	485 (3.4)	506 (3.5)	991 (3.5)
Educators and Students	1312 (12.4)	1292 (12.1)	2604 (12.3)	166 (4.6)	184 (5.1)	350 (4.8)	1478 (10.4)	1476 (10.3)	2954 (10.4)
Other	3130 (29.6)	3206 (30.1)	6336 (29.8)	1376 (38.3)	1380 (38.1)	2756 (38.2)	4506 (31.8)	4586 (32.1)	9092 (32.0)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10569)	mRNA-1273 (N=10661)	Total (N=21230)	Placebo (N=3595)	mRNA-1273 (N=3626)	Total (N=7221)	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Location and Living Circumstances Risk, n (%) [2]	8843 (83.7)	8952 (84.0)	17795 (83.8)	2967 (82.5)	3013 (83.1)	5980 (82.8)	11810 (83.4)	11965 (83.7)	23775 (83.6)
Resides in Nursing Home or Assisted Living Facility	9 (<0.1)	22 (0.2)	31 (0.1)	19 (0.5)	11 (0.3)	30 (0.4)	28 (0.2)	33 (0.2)	61 (0.2)
Resides in Multi-Family Dwelling	313 (3.0)	357 (3.3)	670 (3.2)	62 (1.7)	63 (1.7)	125 (1.7)	375 (2.6)	420 (2.9)	795 (2.8)
Resides in High Density Housing	959 (9.1)	948 (8.9)	1907 (9.0)	228 (6.3)	235 (6.5)	463 (6.4)	1187 (8.4)	1183 (8.3)	2370 (8.3)
Resides in Low Density, Multi-Family Setting	1107 (10.5)	1131 (10.6)	2238 (10.5)	243 (6.8)	234 (6.5)	477 (6.6)	1350 (9.5)	1365 (9.6)	2715 (9.5)
Resides in a Single Family Home	5736 (54.3)	5762 (54.0)	11498 (54.2)	2165 (60.2)	2210 (60.9)	4375 (60.6)	7901 (55.8)	7972 (55.8)	15873 (55.8)
Other	1523 (14.4)	1547 (14.5)	3070 (14.5)	503 (14.0)	523 (14.4)	1026 (14.2)	2026 (14.3)	2070 (14.5)	4096 (14.4)

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Table 14.1.3.4.2
Baseline Demographics and Characteristics by Age Group
Per-Protocol Set

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Age at Screening (Years)			
n	14164	14287	28451
Mean (SD)	51.6 (15.55)	51.6 (15.44)	51.6 (15.49)
Median	52.0	53.0	53.0
Min, Max	18, 95	18, 95	18, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	10569 (74.6)	10661 (74.6)	21230 (74.6)
Mean (SD)	45.1 (12.24)	45.2 (12.28)	45.2 (12.26)
Median	46.0	46.0	46.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3595 (25.4)	3626 (25.4)	7221 (25.4)
Mean (SD)	70.7 (4.85)	70.4 (4.64)	70.6 (4.75)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	10569 (74.6)	10661 (74.6)	21230 (74.6)
>=65 and <70 Years	1748 (12.3)	1830 (12.8)	3578 (12.6)
>=70 and <75 Years	1150 (8.1)	1160 (8.1)	2310 (8.1)
>=75 and <80 Years	478 (3.4)	454 (3.2)	932 (3.3)
>=80 Years	219 (1.5)	182 (1.3)	401 (1.4)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	10569 (74.6)	10661 (74.6)	21230 (74.6)
>=65 and <75 Years	2898 (20.5)	2990 (20.9)	5888 (20.7)
>=75 and <85 Years	651 (4.6)	599 (4.2)	1250 (4.4)
>=85 Years	46 (0.3)	37 (0.3)	83 (0.3)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8242 (58.2)	8271 (57.9)	16513 (58.0)
>=18 and <65 Years and at Risk	2331 (16.5)	2395 (16.8)	4726 (16.6)
>=65 Years	3591 (25.4)	3621 (25.3)	7212 (25.3)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	692 (4.9)	675 (4.7)	1367 (4.8)
Significant Cardiac Disease	696 (4.9)	726 (5.1)	1422 (5.0)
Severe Obesity	980 (6.9)	1009 (7.1)	1989 (7.0)
Diabetes	1363 (9.6)	1402 (9.8)	2765 (9.7)
Liver Disease	90 (0.6)	100 (0.7)	190 (0.7)
Human Immunodeficiency Virus Infection	82 (0.6)	85 (0.6)	167 (0.6)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	3212 (22.7)	3283 (23.0)	6495 (22.8)
One Risk Factor for Severe COVID-19	2610 (18.4)	2660 (18.6)	5270 (18.5)
Two or More Risk Factors for Severe COVID-19	602 (4.3)	623 (4.4)	1225 (4.3)
No	10952 (77.3)	11004 (77.0)	21956 (77.2)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	8428 (59.5)	8464 (59.2)	16892 (59.4)
>=18 and <65 Years and at Risk	2141 (15.1)	2197 (15.4)	4338 (15.2)
>=65 Years and Not at Risk	2524 (17.8)	2540 (17.8)	5064 (17.8)
>=65 Years and at Risk	1071 (7.6)	1086 (7.6)	2157 (7.6)
Baseline RT-PCR Results, n (%)			
Negative	14164 (100)	14287 (100)	28451 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	14164 (100)	14287 (100)	28451 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	14164 (100)	14287 (100)	28451 (100)
Positive	0	0	0
Sex, n (%)			
Male	7494 (52.9)	7439 (52.1)	14933 (52.5)
Female	6670 (47.1)	6848 (47.9)	13518 (47.5)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Race, n (%)			
White	11273 (79.6)	11391 (79.7)	22664 (79.7)
Black or African American	1352 (9.5)	1395 (9.8)	2747 (9.7)
Asian	700 (4.9)	628 (4.4)	1328 (4.7)
American Indian or Alaska Native	113 (0.8)	109 (0.8)	222 (0.8)
Native Hawaiian or Other Pacific Islander	31 (0.2)	36 (0.3)	67 (0.2)
Multiracial	304 (2.1)	300 (2.1)	604 (2.1)
Other	274 (1.9)	282 (2.0)	556 (2.0)
Not Reported	65 (0.5)	90 (0.6)	155 (0.5)
Unknown	52 (0.4)	56 (0.4)	108 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	2787 (19.7)	2831 (19.8)	5618 (19.7)
Not Hispanic or Latino	11249 (79.4)	11322 (79.2)	22571 (79.3)
Not Reported	76 (0.5)	99 (0.7)	175 (0.6)
Unknown	52 (0.4)	35 (0.2)	87 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	4156 (29.3)	4217 (29.5)	8373 (29.4)
Non-minority	9983 (70.5)	10045 (70.3)	20028 (70.4)
Missing	25 (0.2)	25 (0.2)	50 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	8998 (63.5)	9123 (63.9)	18121 (63.7)
Communities of Color	5141 (36.3)	5139 (36.0)	10280 (36.1)
Missing	25 (0.2)	25 (0.2)	50 (0.2)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Weight (kg)			
n	14086	14204	28290
Mean (SD)	85.79 (21.615)	85.69 (21.901)	85.74 (21.759)
Median	82.90	83.00	83.00
Min, Max	30.7, 216.5	30.3, 236.4	30.3, 236.4
Height (cm)			
n	14084	14205	28289
Mean (SD)	170.90 (10.040)	170.76 (9.924)	170.83 (9.982)
Median	170.50	170.18	170.20
Min, Max	118.0, 223.5	104.1, 221.0	104.1, 223.5
Body Mass Index (kg/m^2)			
n	14084	14201	28285
Mean (SD)	29.29 (6.662)	29.30 (6.814)	29.30 (6.739)
Median	28.09	28.12	28.10
Min, Max	10.3, 72.7	9.8, 82.0	9.8, 82.0
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	8719 (61.6)	8741 (61.2)	17460 (61.4)
>=30 kg/m^2	5365 (37.9)	5460 (38.2)	10825 (38.0)
Missing	80 (0.6)	86 (0.6)	166 (0.6)

Note: Footnotes are listed on the last page.
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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Occupational Risk, n (%) [2]	11684 (82.5)	11746 (82.2)	23430 (82.4)
Healthcare Workers	3621 (25.6)	3631 (25.4)	7252 (25.5)
Emergency Response	273 (1.9)	287 (2.0)	560 (2.0)
Retail or Restaurant Operations	875 (6.2)	870 (6.1)	1745 (6.1)
Manufacturing and Production Operations	390 (2.8)	390 (2.7)	780 (2.7)
Warehouse Shipping and Fulfillment Centers	158 (1.1)	174 (1.2)	332 (1.2)
Transportation and Delivery Services	428 (3.0)	428 (3.0)	856 (3.0)
Border Protection and Military Personnel	66 (0.5)	64 (0.4)	130 (0.5)
Personal Care and In-Home Services	413 (2.9)	417 (2.9)	830 (2.9)
Hospitality and Tourism Workers	200 (1.4)	214 (1.5)	414 (1.5)
Pastoral, Social or Public Health Workers	485 (3.4)	506 (3.5)	991 (3.5)
Educators and Students	1478 (10.4)	1476 (10.3)	2954 (10.4)
Other	4506 (31.8)	4586 (32.1)	9092 (32.0)
Location and Living Circumstances Risk, n (%) [2]	11810 (83.4)	11965 (83.7)	23775 (83.6)
Resides in Nursing Home or Assisted Living Facility	28 (0.2)	33 (0.2)	61 (0.2)
Resides in Multi-Family Dwelling	375 (2.6)	420 (2.9)	795 (2.8)
Resides in High Density Housing	1187 (8.4)	1183 (8.3)	2370 (8.3)
Resides in Low Density, Multi-Family Setting	1350 (9.5)	1365 (9.6)	2715 (9.5)
Resides in a Single Family Home	7901 (55.8)	7972 (55.8)	15873 (55.8)
Other	2026 (14.3)	2070 (14.5)	4096 (14.4)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)	Total (N=16513)
Age at Screening (Years)			
n	8242	8271	16513
Mean (SD)	44.0 (12.28)	44.2 (12.33)	44.1 (12.31)
Median	45.0	45.0	45.0
Min, Max	18, 72	18, 64	18, 72
Age Group at Screening, n (%)			
>=18 and <65 Years	8240(>99.9)	8271 (100)	16511(>99.9)
Mean (SD)	44.0 (12.27)	44.2 (12.33)	44.1 (12.30)
Median	45.0	45.0	45.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	2 (<0.1)	0	2 (<0.1)
Mean (SD)	68.5 (4.95)		68.5 (4.95)
Median	68.5		68.5
Min, Max	65, 72		65, 72
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8240(>99.9)	8271 (100)	16511(>99.9)
>=65 and <70 Years	1 (<0.1)	0	1 (<0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	0	0	0
>=80 Years	0	0	0

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)	Total (N=16513)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	8240 (>99.9)	8271 (100)	16511 (>99.9)
>=65 and <75 Years	2 (<0.1)	0	2 (<0.1)
>=75 and <85 Years	0	0	0
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	8242 (100)	8271 (100)	16513 (100)
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	13 (0.2)	18 (0.2)	31 (0.2)
Significant Cardiac Disease	10 (0.1)	11 (0.1)	21 (0.1)
Severe Obesity	64 (0.8)	59 (0.7)	123 (0.7)
Diabetes	35 (0.4)	32 (0.4)	67 (0.4)
Liver Disease	8 (<0.1)	7 (<0.1)	15 (<0.1)
Human Immunodeficiency Virus Infection	13 (0.2)	9 (0.1)	22 (0.1)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	132 (1.6)	123 (1.5)	255 (1.5)
One Risk Factor for Severe COVID-19	122 (1.5)	113 (1.4)	235 (1.4)
Two or More Risk Factors for Severe COVID-19	10 (0.1)	10 (0.1)	20 (0.1)
No	8110 (98.4)	8148 (98.5)	16258 (98.5)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)	Total (N=16513)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	8109 (98.4)	8148 (98.5)	16257 (98.4)
>=18 and <65 Years and at Risk	131 (1.6)	123 (1.5)	254 (1.5)
>=65 Years and Not at Risk	1 (<0.1)	0	1 (<0.1)
>=65 Years and at Risk	1 (<0.1)	0	1 (<0.1)
Baseline RT-PCR Results, n (%)			
Negative	8242 (100)	8271 (100)	16513 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	8242 (100)	8271 (100)	16513 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	8242 (100)	8271 (100)	16513 (100)
Positive	0	0	0
Sex, n (%)			
Male	4266 (51.8)	4200 (50.8)	8466 (51.3)
Female	3976 (48.2)	4071 (49.2)	8047 (48.7)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)	Total (N=16513)
Race, n (%)			
White	6326 (76.8)	6322 (76.4)	12648 (76.6)
Black or African American	794 (9.6)	852 (10.3)	1646 (10.0)
Asian	550 (6.7)	481 (5.8)	1031 (6.2)
American Indian or Alaska Native	66 (0.8)	62 (0.7)	128 (0.8)
Native Hawaiian or Other Pacific Islander	19 (0.2)	26 (0.3)	45 (0.3)
Multiracial	222 (2.7)	222 (2.7)	444 (2.7)
Other	197 (2.4)	207 (2.5)	404 (2.4)
Not Reported	36 (0.4)	60 (0.7)	96 (0.6)
Unknown	32 (0.4)	39 (0.5)	71 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	1983 (24.1)	1969 (23.8)	3952 (23.9)
Not Hispanic or Latino	6191 (75.1)	6230 (75.3)	12421 (75.2)
Not Reported	39 (0.5)	52 (0.6)	91 (0.6)
Unknown	29 (0.4)	20 (0.2)	49 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	2776 (33.7)	2812 (34.0)	5588 (33.8)
Non-minority	5458 (66.2)	5446 (65.8)	10904 (66.0)
Missing	8 (<0.1)	13 (0.2)	21 (0.1)
Race and Ethnicity Group, n (%) [6]			
White	4704 (57.1)	4761 (57.6)	9465 (57.3)
Communities of Color	3530 (42.8)	3497 (42.3)	7027 (42.6)
Missing	8 (<0.1)	13 (0.2)	21 (0.1)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)	Total (N=16513)
Weight (kg)			
n	8198	8221	16419
Mean (SD)	82.25 (17.989)	81.94 (18.158)	82.10 (18.074)
Median	80.73	80.45	80.60
Min, Max	30.7, 160.4	33.3, 178.7	30.7, 178.7
Height (cm)			
n	8198	8220	16418
Mean (SD)	171.27 (9.887)	171.06 (9.886)	171.16 (9.887)
Median	171.00	170.30	170.94
Min, Max	118.0, 205.7	104.1, 221.0	104.1, 221.0
Body Mass Index (kg/m^2)			
n	8198	8218	16416
Mean (SD)	27.93 (5.136)	27.90 (5.256)	27.92 (5.197)
Median	27.31	27.31	27.31
Min, Max	10.3, 53.1	9.8, 57.9	9.8, 57.9
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	5554 (67.4)	5592 (67.6)	11146 (67.5)
>=30 kg/m^2	2644 (32.1)	2626 (31.7)	5270 (31.9)
Missing	44 (0.5)	53 (0.6)	97 (0.6)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)	Total (N=16513)
Occupational Risk, n (%) [2]	7411 (89.9)	7423 (89.7)	14834 (89.8)
Healthcare Workers	2584 (31.4)	2611 (31.6)	5195 (31.5)
Emergency Response	201 (2.4)	220 (2.7)	421 (2.5)
Retail or Restaurant Operations	620 (7.5)	609 (7.4)	1229 (7.4)
Manufacturing and Production Operations	284 (3.4)	263 (3.2)	547 (3.3)
Warehouse Shipping and Fulfillment Centers	109 (1.3)	128 (1.5)	237 (1.4)
Transportation and Delivery Services	280 (3.4)	291 (3.5)	571 (3.5)
Border Protection and Military Personnel	49 (0.6)	50 (0.6)	99 (0.6)
Personal Care and In-Home Services	285 (3.5)	255 (3.1)	540 (3.3)
Hospitality and Tourism Workers	126 (1.5)	146 (1.8)	272 (1.6)
Pastoral, Social or Public Health Workers	252 (3.1)	276 (3.3)	528 (3.2)
Educators and Students	1060 (12.9)	1029 (12.4)	2089 (12.7)
Other	2409 (29.2)	2445 (29.6)	4854 (29.4)
Location and Living Circumstances Risk, n (%) [2]	6929 (84.1)	6990 (84.5)	13919 (84.3)
Resides in Nursing Home or Assisted Living Facility	6 (<0.1)	10 (0.1)	16 (<0.1)
Resides in Multi-Family Dwelling	240 (2.9)	272 (3.3)	512 (3.1)
Resides in High Density Housing	786 (9.5)	758 (9.2)	1544 (9.4)
Resides in Low Density, Multi-Family Setting	861 (10.4)	849 (10.3)	1710 (10.4)
Resides in a Single Family Home	4464 (54.2)	4521 (54.7)	8985 (54.4)
Other	1222 (14.8)	1249 (15.1)	2471 (15.0)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)	Total (N=4726)
Age at Screening (Years)			
n	2331	2395	4726
Mean (SD)	49.2 (11.22)	49.0 (11.36)	49.1 (11.29)
Median	51.0	52.0	51.0
Min, Max	18, 79	18, 76	18, 79
Age Group at Screening, n (%)			
>=18 and <65 Years	2328 (99.9)	2389 (99.7)	4717 (99.8)
Mean (SD)	49.2 (11.20)	49.0 (11.33)	49.1 (11.27)
Median	51.0	52.0	51.0
Min, Max	18, 64	18, 64	18, 64
>=65 Years	3 (0.1)	6 (0.3)	9 (0.2)
Mean (SD)	72.0 (7.00)	67.7 (4.37)	69.1 (5.37)
Median	72.0	65.5	66.0
Min, Max	65, 79	65, 76	65, 79
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2328 (99.9)	2389 (99.7)	4717 (99.8)
>=65 and <70 Years	1 (<0.1)	5 (0.2)	6 (0.1)
>=70 and <75 Years	1 (<0.1)	0	1 (<0.1)
>=75 and <80 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=80 Years	0	0	0

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)	Total (N=4726)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	2328 (99.9)	2389 (99.7)	4717 (99.8)
>=65 and <75 Years	2 (<0.1)	5 (0.2)	7 (0.1)
>=75 and <85 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=85 Years	0	0	0
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	2331 (100)	2395 (100)	4726 (100)
>=65 Years	0	0	0
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	451 (19.3)	432 (18.0)	883 (18.7)
Significant Cardiac Disease	263 (11.3)	292 (12.2)	555 (11.7)
Severe Obesity	773 (33.2)	783 (32.7)	1556 (32.9)
Diabetes	811 (34.8)	847 (35.4)	1658 (35.1)
Liver Disease	57 (2.4)	75 (3.1)	132 (2.8)
Human Immunodeficiency Virus Infection	53 (2.3)	61 (2.5)	114 (2.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	2011 (86.3)	2077 (86.7)	4088 (86.5)
One Risk Factor for Severe COVID-19	1662 (71.3)	1711 (71.4)	3373 (71.4)
Two or More Risk Factors for Severe COVID-19	349 (15.0)	366 (15.3)	715 (15.1)
No	320 (13.7)	318 (13.3)	638 (13.5)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)	Total (N=4726)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	319 (13.7)	316 (13.2)	635 (13.4)
>=18 and <65 Years and at Risk	2009 (86.2)	2073 (86.6)	4082 (86.4)
>=65 Years and Not at Risk	1 (<0.1)	2 (<0.1)	3 (<0.1)
>=65 Years and at Risk	2 (<0.1)	4 (0.2)	6 (0.1)
Baseline RT-PCR Results, n (%)			
Negative	2331 (100)	2395 (100)	4726 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	2331 (100)	2395 (100)	4726 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	2331 (100)	2395 (100)	4726 (100)
Positive	0	0	0
Sex, n (%)			
Male	1221 (52.4)	1234 (51.5)	2455 (51.9)
Female	1110 (47.6)	1161 (48.5)	2271 (48.1)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)	Total (N=4726)
Race, n (%)			
White	1741 (74.7)	1813 (75.7)	3554 (75.2)
Black or African American	359 (15.4)	338 (14.1)	697 (14.7)
Asian	78 (3.3)	82 (3.4)	160 (3.4)
American Indian or Alaska Native	22 (0.9)	26 (1.1)	48 (1.0)
Native Hawaiian or Other Pacific Islander	9 (0.4)	7 (0.3)	16 (0.3)
Multiracial	48 (2.1)	48 (2.0)	96 (2.0)
Other	45 (1.9)	53 (2.2)	98 (2.1)
Not Reported	16 (0.7)	17 (0.7)	33 (0.7)
Unknown	13 (0.6)	11 (0.5)	24 (0.5)
Ethnicity, n (%)			
Hispanic or Latino	496 (21.3)	531 (22.2)	1027 (21.7)
Not Hispanic or Latino	1816 (77.9)	1846 (77.1)	3662 (77.5)
Not Reported	11 (0.5)	14 (0.6)	25 (0.5)
Unknown	8 (0.3)	4 (0.2)	12 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	862 (37.0)	866 (36.2)	1728 (36.6)
Non-minority	1465 (62.8)	1523 (63.6)	2988 (63.2)
Missing	4 (0.2)	6 (0.3)	10 (0.2)
Race and Ethnicity Group, n (%) [6]			
White	1340 (57.5)	1392 (58.1)	2732 (57.8)
Communities of Color	987 (42.3)	997 (41.6)	1984 (42.0)
Missing	4 (0.2)	6 (0.3)	10 (0.2)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)	Total (N=4726)
Weight (kg)			
n	2320	2390	4710
Mean (SD)	102.30 (28.482)	102.39 (28.639)	102.35 (28.559)
Median	98.64	99.48	98.80
Min, Max	33.5, 216.5	30.3, 236.4	30.3, 236.4
Height (cm)			
n	2319	2391	4710
Mean (SD)	170.95 (10.256)	170.76 (9.979)	170.85 (10.116)
Median	170.50	170.18	170.20
Min, Max	123.5, 203.2	111.0, 202.8	111.0, 203.2
Body Mass Index (kg/m^2)			
n	2319	2390	4709
Mean (SD)	34.97 (9.164)	35.11 (9.411)	35.04 (9.289)
Median	33.71	33.65	33.68
Min, Max	11.6, 72.7	11.7, 82.0	11.6, 82.0
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	830 (35.6)	823 (34.4)	1653 (35.0)
>=30 kg/m^2	1489 (63.9)	1567 (65.4)	3056 (64.7)
Missing	12 (0.5)	5 (0.2)	17 (0.4)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)	Total (N=4726)
Occupational Risk, n (%) [2]	1992 (85.5)	2038 (85.1)	4030 (85.3)
Healthcare Workers	563 (24.2)	571 (23.8)	1134 (24.0)
Emergency Response	54 (2.3)	47 (2.0)	101 (2.1)
Retail or Restaurant Operations	162 (6.9)	162 (6.8)	324 (6.9)
Manufacturing and Production Operations	80 (3.4)	93 (3.9)	173 (3.7)
Warehouse Shipping and Fulfillment Centers	37 (1.6)	37 (1.5)	74 (1.6)
Transportation and Delivery Services	88 (3.8)	93 (3.9)	181 (3.8)
Border Protection and Military Personnel	12 (0.5)	11 (0.5)	23 (0.5)
Personal Care and In-Home Services	71 (3.0)	96 (4.0)	167 (3.5)
Hospitality and Tourism Workers	32 (1.4)	36 (1.5)	68 (1.4)
Pastoral, Social or Public Health Workers	96 (4.1)	86 (3.6)	182 (3.9)
Educators and Students	253 (10.9)	264 (11.0)	517 (10.9)
Other	722 (31.0)	764 (31.9)	1486 (31.4)
Location and Living Circumstances Risk, n (%) [2]	1919 (82.3)	1965 (82.0)	3884 (82.2)
Resides in Nursing Home or Assisted Living Facility	3 (0.1)	12 (0.5)	15 (0.3)
Resides in Multi-Family Dwelling	73 (3.1)	85 (3.5)	158 (3.3)
Resides in High Density Housing	173 (7.4)	190 (7.9)	363 (7.7)
Resides in Low Density, Multi-Family Setting	246 (10.6)	282 (11.8)	528 (11.2)
Resides in a Single Family Home	1277 (54.8)	1243 (51.9)	2520 (53.3)
Other	301 (12.9)	299 (12.5)	600 (12.7)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)	Total (N=7212)
Age at Screening (Years)			
n	3591	3621	7212
Mean (SD)	70.7 (4.88)	70.4 (4.64)	70.6 (4.76)
Median	70.0	69.0	70.0
Min, Max	40, 95	64, 95	40, 95
Age Group at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mean (SD)	40.0 (NA)	64.0 (NA)	52.0 (16.97)
Median	40.0	64.0	52.0
Min, Max	40, 40	64, 64	40, 64
>=65 Years	3590(>99.9)	3620(>99.9)	7210(>99.9)
Mean (SD)	70.7 (4.85)	70.5 (4.64)	70.6 (4.75)
Median	70.0	69.0	70.0
Min, Max	65, 95	65, 95	65, 95
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <70 Years	1746 (48.6)	1825 (50.4)	3571 (49.5)
>=70 and <75 Years	1148 (32.0)	1160 (32.0)	2308 (32.0)
>=75 and <80 Years	477 (13.3)	453 (12.5)	930 (12.9)
>=80 Years	219 (6.1)	182 (5.0)	401 (5.6)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)	Total (N=7212)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 and <75 Years	2894 (80.6)	2985 (82.4)	5879 (81.5)
>=75 and <85 Years	650 (18.1)	598 (16.5)	1248 (17.3)
>=85 Years	46 (1.3)	37 (1.0)	83 (1.2)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	0	0	0
>=65 Years	3591 (100)	3621 (100)	7212 (100)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	228 (6.3)	225 (6.2)	453 (6.3)
Significant Cardiac Disease	423 (11.8)	423 (11.7)	846 (11.7)
Severe Obesity	143 (4.0)	167 (4.6)	310 (4.3)
Diabetes	517 (14.4)	523 (14.4)	1040 (14.4)
Liver Disease	25 (0.7)	18 (0.5)	43 (0.6)
Human Immunodeficiency Virus Infection	16 (0.4)	15 (0.4)	31 (0.4)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	1069 (29.8)	1083 (29.9)	2152 (29.8)
One Risk Factor for Severe COVID-19	826 (23.0)	836 (23.1)	1662 (23.0)
Two or More Risk Factors for Severe COVID-19	243 (6.8)	247 (6.8)	490 (6.8)
No	2522 (70.2)	2538 (70.1)	5060 (70.2)

Note: Footnotes are listed on the last page.
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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)	Total (N=7212)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	0	0	0
>=18 and <65 Years and at Risk	1 (<0.1)	1 (<0.1)	2 (<0.1)
>=65 Years and Not at Risk	2522 (70.2)	2538 (70.1)	5060 (70.2)
>=65 Years and at Risk	1068 (29.7)	1082 (29.9)	2150 (29.8)
Baseline RT-PCR Results, n (%)			
Negative	3591 (100)	3621 (100)	7212 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	3591 (100)	3621 (100)	7212 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	3591 (100)	3621 (100)	7212 (100)
Positive	0	0	0
Sex, n (%)			
Male	2007 (55.9)	2005 (55.4)	4012 (55.6)
Female	1584 (44.1)	1616 (44.6)	3200 (44.4)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)	Total (N=7212)
Race, n (%)			
White	3206 (89.3)	3256 (89.9)	6462 (89.6)
Black or African American	199 (5.5)	205 (5.7)	404 (5.6)
Asian	72 (2.0)	65 (1.8)	137 (1.9)
American Indian or Alaska Native	25 (0.7)	21 (0.6)	46 (0.6)
Native Hawaiian or Other Pacific Islander	3 (<0.1)	3 (<0.1)	6 (<0.1)
Multiracial	34 (0.9)	30 (0.8)	64 (0.9)
Other	32 (0.9)	22 (0.6)	54 (0.7)
Not Reported	13 (0.4)	13 (0.4)	26 (0.4)
Unknown	7 (0.2)	6 (0.2)	13 (0.2)
Ethnicity, n (%)			
Hispanic or Latino	308 (8.6)	331 (9.1)	639 (8.9)
Not Hispanic or Latino	3242 (90.3)	3246 (89.6)	6488 (90.0)
Not Reported	26 (0.7)	33 (0.9)	59 (0.8)
Unknown	15 (0.4)	11 (0.3)	26 (0.4)
Race and Ethnicity Group, n (%) [5]			
Minority	518 (14.4)	539 (14.9)	1057 (14.7)
Non-minority	3060 (85.2)	3076 (84.9)	6136 (85.1)
Missing	13 (0.4)	6 (0.2)	19 (0.3)
Race and Ethnicity Group, n (%) [6]			
White	2954 (82.3)	2970 (82.0)	5924 (82.1)
Communities of Color	624 (17.4)	645 (17.8)	1269 (17.6)
Missing	13 (0.4)	6 (0.2)	19 (0.3)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)	Total (N=7212)
Weight (kg)			
n	3568	3593	7161
Mean (SD)	83.19 (18.999)	83.14 (19.298)	83.17 (19.148)
Median	81.57	81.27	81.36
Min, Max	34.8, 184.5	37.2, 165.0	34.8, 184.5
Height (cm)			
n	3567	3594	7161
Mean (SD)	170.03 (10.195)	170.07 (9.942)	170.05 (10.068)
Median	170.18	170.18	170.18
Min, Max	124.5, 223.5	123.0, 208.3	123.0, 223.5
Body Mass Index (kg/m^2)			
n	3567	3593	7160
Mean (SD)	28.71 (5.875)	28.65 (5.837)	28.68 (5.856)
Median	27.70	27.86	27.78
Min, Max	12.1, 71.1	11.2, 62.9	11.2, 71.1
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	2335 (65.0)	2326 (64.2)	4661 (64.6)
>=30 kg/m^2	1232 (34.3)	1267 (35.0)	2499 (34.7)
Missing	24 (0.7)	28 (0.8)	52 (0.7)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)	Total (N=7212)
Occupational Risk, n (%) [2]	2281 (63.5)	2285 (63.1)	4566 (63.3)
Healthcare Workers	474 (13.2)	449 (12.4)	923 (12.8)
Emergency Response	18 (0.5)	20 (0.6)	38 (0.5)
Retail or Restaurant Operations	93 (2.6)	99 (2.7)	192 (2.7)
Manufacturing and Production Operations	26 (0.7)	34 (0.9)	60 (0.8)
Warehouse Shipping and Fulfillment Centers	12 (0.3)	9 (0.2)	21 (0.3)
Transportation and Delivery Services	60 (1.7)	44 (1.2)	104 (1.4)
Border Protection and Military Personnel	5 (0.1)	3 (<0.1)	8 (0.1)
Personal Care and In-Home Services	57 (1.6)	66 (1.8)	123 (1.7)
Hospitality and Tourism Workers	42 (1.2)	32 (0.9)	74 (1.0)
Pastoral, Social or Public Health Workers	137 (3.8)	144 (4.0)	281 (3.9)
Educators and Students	165 (4.6)	183 (5.1)	348 (4.8)
Other	1375 (38.3)	1377 (38.0)	2752 (38.2)
Location and Living Circumstances Risk, n (%) [2]	2962 (82.5)	3010 (83.1)	5972 (82.8)
Resides in Nursing Home or Assisted Living Facility	19 (0.5)	11 (0.3)	30 (0.4)
Resides in Multi-Family Dwelling	62 (1.7)	63 (1.7)	125 (1.7)
Resides in High Density Housing	228 (6.3)	235 (6.5)	463 (6.4)
Resides in Low Density, Multi-Family Setting	243 (6.8)	234 (6.5)	477 (6.6)
Resides in a Single Family Home	2160 (60.2)	2208 (61.0)	4368 (60.6)
Other	503 (14.0)	522 (14.4)	1025 (14.2)

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Table 14.1.3.4.3
Baseline Demographics and Characteristics by Randomization Stratum
Per-Protocol Set

Percentages are based on the number of subjects in Per-Protocol Set.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.3.4.4
Baseline Demographics and Characteristics
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Age at Screening (Years)			
n	744	55	799
Mean (SD)	47.8 (14.31)	49.0 (14.52)	47.9 (14.32)
Median	48.0	49.0	48.0
Min, Max	18, 87	24, 74	18, 87
Age Group at Screening, n (%)			
>=18 and <65 Years	644 (86.6)	46 (83.6)	690 (86.4)
Mean (SD)	44.3 (11.74)	44.9 (12.08)	44.3 (11.75)
Median	45.0	44.5	45.0
Min, Max	18, 64	24, 64	18, 64
>=65 Years	100 (13.4)	9 (16.4)	109 (13.6)
Mean (SD)	70.9 (4.94)	70.0 (2.69)	70.8 (4.79)
Median	70.0	70.0	70.0
Min, Max	65, 87	66, 74	65, 87
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	644 (86.6)	46 (83.6)	690 (86.4)
>=65 and <70 Years	44 (5.9)	4 (7.3)	48 (6.0)
>=70 and <75 Years	37 (5.0)	5 (9.1)	42 (5.3)
>=75 and <80 Years	12 (1.6)	0	12 (1.5)
>=80 Years	7 (0.9)	0	7 (0.9)

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Table 14.1.3.4.4
Baseline Demographics and Characteristics
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Age Subgroup at Screening, n (%)			
>=18 and <65 Years	644 (86.6)	46 (83.6)	690 (86.4)
>=65 and <75 Years	81 (10.9)	9 (16.4)	90 (11.3)
>=75 and <85 Years	15 (2.0)	0	15 (1.9)
>=85 Years	4 (0.5)	0	4 (0.5)
Age and Health Risk for Severe COVID-19, n (%) [1]			
>=18 and <65 Years and Not at Risk	482 (64.8)	34 (61.8)	516 (64.6)
>=18 and <65 Years and at Risk	162 (21.8)	12 (21.8)	174 (21.8)
>=65 Years	100 (13.4)	9 (16.4)	109 (13.6)
Risk Factor for Severe COVID-19 at Screening, n (%) [2]			
Chronic Lung Disease	30 (4.0)	4 (7.3)	34 (4.3)
Significant Cardiac Disease	30 (4.0)	4 (7.3)	34 (4.3)
Severe Obesity	75 (10.1)	7 (12.7)	82 (10.3)
Diabetes	72 (9.7)	3 (5.5)	75 (9.4)
Liver Disease	5 (0.7)	1 (1.8)	6 (0.8)
Human Immunodeficiency Virus Infection	4 (0.5)	0	4 (0.5)
At Risk for Severe COVID-19 at Screening, n (%)			
Yes	177 (23.8)	16 (29.1)	193 (24.2)
One Risk Factor for Severe COVID-19	143 (19.2)	14 (25.5)	157 (19.6)
Two or More Risk Factors for Severe COVID-19	34 (4.6)	2 (3.6)	36 (4.5)
No	567 (76.2)	39 (70.9)	606 (75.8)

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Table 14.1.3.4.4
Baseline Demographics and Characteristics
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Age and Risk for Severe COVID-19, n (%) [3]			
>=18 and <65 Years and Not at Risk	501 (67.3)	35 (63.6)	536 (67.1)
>=18 and <65 Years and at Risk	143 (19.2)	11 (20.0)	154 (19.3)
>=65 Years and Not at Risk	66 (8.9)	4 (7.3)	70 (8.8)
>=65 Years and at Risk	34 (4.6)	5 (9.1)	39 (4.9)
Baseline RT-PCR Results, n (%)			
Negative	744 (100)	55 (100)	799 (100)
Positive	0	0	0
Baseline Elecsys Anti-SARS-CoV-2 Results, n (%)			
Negative	744 (100)	55 (100)	799 (100)
Positive	0	0	0
Baseline SARS-CoV-2 Status, n (%) [4]			
Negative	744 (100)	55 (100)	799 (100)
Positive	0	0	0
Sex, n (%)			
Male	378 (50.8)	30 (54.5)	408 (51.1)
Female	366 (49.2)	25 (45.5)	391 (48.9)

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Table 14.1.3.4.4
Baseline Demographics and Characteristics
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Race, n (%)			
White	631 (84.8)	48 (87.3)	679 (85.0)
Black or African American	41 (5.5)	4 (7.3)	45 (5.6)
Asian	29 (3.9)	1 (1.8)	30 (3.8)
American Indian or Alaska Native	5 (0.7)	0	5 (0.6)
Native Hawaiian or Other Pacific Islander	0	0	0
Multiracial	8 (1.1)	1 (1.8)	9 (1.1)
Other	19 (2.6)	1 (1.8)	20 (2.5)
Not Reported	5 (0.7)	0	5 (0.6)
Unknown	6 (0.8)	0	6 (0.8)
Ethnicity, n (%)			
Hispanic or Latino	177 (23.8)	10 (18.2)	187 (23.4)
Not Hispanic or Latino	563 (75.7)	45 (81.8)	608 (76.1)
Not Reported	2 (0.3)	0	2 (0.3)
Unknown	2 (0.3)	0	2 (0.3)
Race and Ethnicity Group, n (%) [5]			
Minority	220 (29.6)	14 (25.5)	234 (29.3)
Non-minority	524 (70.4)	41 (74.5)	565 (70.7)
Race and Ethnicity Group, n (%) [6]			
White	488 (65.6)	39 (70.9)	527 (66.0)
Communities of Color	256 (34.4)	16 (29.1)	272 (34.0)

Note: Footnotes are listed on the last page.
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Table 14.1.3.4.4
Baseline Demographics and Characteristics
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Weight (kg)			
n	741	55	796
Mean (SD)	89.16 (22.366)	94.22 (22.320)	89.51 (22.386)
Median	85.20	90.91	85.43
Min, Max	33.5, 182.2	59.1, 166.4	33.5, 182.2
Height (cm)			
n	741	55	796
Mean (SD)	170.92 (10.311)	172.08 (10.187)	171.00 (10.300)
Median	170.18	172.72	170.18
Min, Max	123.5, 203.2	147.3, 198.1	123.5, 203.2
Body Mass Index (kg/m^2)			
n	741	55	796
Mean (SD)	30.46 (6.996)	31.83 (6.948)	30.56 (6.997)
Median	29.19	30.53	29.24
Min, Max	11.6, 65.3	19.8, 51.8	11.6, 65.3
Body Mass Index Subgroup, n (%)			
< 30 kg/m^2	415 (55.8)	26 (47.3)	441 (55.2)
>=30 kg/m^2	326 (43.8)	29 (52.7)	355 (44.4)
Missing	3 (0.4)	0	3 (0.4)

Note: Footnotes are listed on the last page.
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Table 14.1.3.4.4
Baseline Demographics and Characteristics
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Occupational Risk, n (%) [2]	672 (90.3)	51 (92.7)	723 (90.5)
Healthcare Workers	209 (28.1)	13 (23.6)	222 (27.8)
Emergency Response	25 (3.4)	2 (3.6)	27 (3.4)
Retail or Restaurant Operations	58 (7.8)	5 (9.1)	63 (7.9)
Manufacturing and Production Operations	21 (2.8)	2 (3.6)	23 (2.9)
Warehouse Shipping and Fulfillment Centers	13 (1.7)	2 (3.6)	15 (1.9)
Transportation and Delivery Services	22 (3.0)	2 (3.6)	24 (3.0)
Border Protection and Military Personnel	3 (0.4)	0	3 (0.4)
Personal Care and In-Home Services	29 (3.9)	2 (3.6)	31 (3.9)
Hospitality and Tourism Workers	10 (1.3)	3 (5.5)	13 (1.6)
Pastoral, Social or Public Health Workers	36 (4.8)	1 (1.8)	37 (4.6)
Educators and Students	77 (10.3)	7 (12.7)	84 (10.5)
Other	237 (31.9)	23 (41.8)	260 (32.5)
Location and Living Circumstances Risk, n (%) [2]	630 (84.7)	47 (85.5)	677 (84.7)
Resides in Nursing Home or Assisted Living Facility	0	0	0
Resides in Multi-Family Dwelling	24 (3.2)	2 (3.6)	26 (3.3)
Resides in High Density Housing	41 (5.5)	5 (9.1)	46 (5.8)
Resides in Low Density, Multi-Family Setting	69 (9.3)	6 (10.9)	75 (9.4)
Resides in a Single Family Home	432 (58.1)	26 (47.3)	458 (57.3)
Other	114 (15.3)	12 (21.8)	126 (15.8)

Note: Footnotes are listed on the last page.
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Table 14.1.3.4.4
Baseline Demographics and Characteristics
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Percentages are based on the number of subjects in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.
[1] Based on stratification factor from IRT, subjects who are < 65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.
[2] Subjects could be under one or more categories, and are counted once at each category.
[3] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).
[4] Baseline SARS-CoV-2 Status: Positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.
[5] Minority is defined as: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[6] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects with Any Medical History	13954 (92.0)	13999 (92.2)	27953 (92.1)
Infections and infestations	2398 (15.8)	2411 (15.9)	4809 (15.8)
Tonsillitis	474 (3.1)	477 (3.1)	951 (3.1)
Appendicitis	345 (2.3)	362 (2.4)	707 (2.3)
Herpes simplex	189 (1.2)	188 (1.2)	377 (1.2)
Oral herpes	143 (0.9)	146 (1.0)	289 (1.0)
Diverticulitis	122 (0.8)	128 (0.8)	250 (0.8)
Pneumonia	117 (0.8)	128 (0.8)	245 (0.8)
Urinary tract infection	99 (0.7)	120 (0.8)	219 (0.7)
Sinusitis	125 (0.8)	114 (0.8)	239 (0.8)
Herpes zoster	100 (0.7)	88 (0.6)	188 (0.6)
HIV infection	81 (0.5)	81 (0.5)	162 (0.5)
Hepatitis C	55 (0.4)	59 (0.4)	114 (0.4)
Bronchitis	65 (0.4)	58 (0.4)	123 (0.4)
Onychomycosis	64 (0.4)	58 (0.4)	122 (0.4)
Hepatitis A	52 (0.3)	48 (0.3)	100 (0.3)
Chronic sinusitis	61 (0.4)	46 (0.3)	107 (0.4)
Genital herpes	59 (0.4)	38 (0.3)	97 (0.3)
Hepatitis B	24 (0.2)	36 (0.2)	60 (0.2)
Ear infection	33 (0.2)	35 (0.2)	68 (0.2)
Chronic tonsillitis	30 (0.2)	27 (0.2)	57 (0.2)
Herpes virus infection	22 (0.1)	27 (0.2)	49 (0.2)
Papilloma viral infection	26 (0.2)	27 (0.2)	53 (0.2)
Adenoiditis	27 (0.2)	25 (0.2)	52 (0.2)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Staphylococcal infection	16 (0.1)	22 (0.1)	38 (0.1)
Genital herpes simplex	21 (0.1)	20 (0.1)	41 (0.1)
Helicobacter infection	10 (<0.1)	19 (0.1)	29 (<0.1)
Cystitis	21 (0.1)	18 (0.1)	39 (0.1)
Pilonidal cyst	12 (<0.1)	17 (0.1)	29 (<0.1)
Tinea pedis	21 (0.1)	16 (0.1)	37 (0.1)
Upper respiratory tract infection	12 (<0.1)	16 (0.1)	28 (<0.1)
Fungal skin infection	17 (0.1)	14 (<0.1)	31 (0.1)
Latent tuberculosis	6 (<0.1)	14 (<0.1)	20 (<0.1)
Localised infection	5 (<0.1)	14 (<0.1)	19 (<0.1)
Folliculitis	12 (<0.1)	12 (<0.1)	24 (<0.1)
Kidney infection	19 (0.1)	12 (<0.1)	31 (0.1)
Pharyngitis streptococcal	9 (<0.1)	12 (<0.1)	21 (<0.1)
Rhinitis	17 (0.1)	12 (<0.1)	29 (<0.1)
Cellulitis	16 (0.1)	11 (<0.1)	27 (<0.1)
Clostridium difficile infection	8 (<0.1)	11 (<0.1)	19 (<0.1)
Lyme disease	11 (<0.1)	11 (<0.1)	22 (<0.1)
Tinea versicolour	6 (<0.1)	11 (<0.1)	17 (<0.1)
Poliomyelitis	4 (<0.1)	10 (<0.1)	14 (<0.1)
Appendicitis perforated	8 (<0.1)	9 (<0.1)	17 (<0.1)
Otitis media	8 (<0.1)	9 (<0.1)	17 (<0.1)
Sepsis	10 (<0.1)	9 (<0.1)	19 (<0.1)
Tuberculosis	15 (<0.1)	9 (<0.1)	24 (<0.1)
Coccidioidomycosis	6 (<0.1)	8 (<0.1)	14 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Conjunctivitis	3 (<0.1)	8 (<0.1)	11 (<0.1)
Osteomyelitis	6 (<0.1)	8 (<0.1)	14 (<0.1)
Tooth abscess	13 (<0.1)	8 (<0.1)	21 (<0.1)
Tooth infection	9 (<0.1)	8 (<0.1)	17 (<0.1)
Vulvovaginal mycotic infection	5 (<0.1)	8 (<0.1)	13 (<0.1)
Fungal infection	11 (<0.1)	7 (<0.1)	18 (<0.1)
Syphilis	6 (<0.1)	7 (<0.1)	13 (<0.1)
Body tinea	6 (<0.1)	6 (<0.1)	12 (<0.1)
Chlamydial infection	9 (<0.1)	6 (<0.1)	15 (<0.1)
Gingivitis	8 (<0.1)	6 (<0.1)	14 (<0.1)
Gonorrhoea	7 (<0.1)	6 (<0.1)	13 (<0.1)
Influenza	7 (<0.1)	6 (<0.1)	13 (<0.1)
Otitis externa	8 (<0.1)	6 (<0.1)	14 (<0.1)
Varicella	6 (<0.1)	6 (<0.1)	12 (<0.1)
Meningitis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Pharyngitis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Pharyngotonsillitis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Tinea infection	1 (<0.1)	5 (<0.1)	6 (<0.1)
Candida infection	2 (<0.1)	4 (<0.1)	6 (<0.1)
Cholecystitis infective	4 (<0.1)	4 (<0.1)	8 (<0.1)
Epididymitis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Gastrointestinal bacterial overgrowth	2 (<0.1)	4 (<0.1)	6 (<0.1)
Hordeolum	9 (<0.1)	4 (<0.1)	13 (<0.1)
Mastoiditis	2 (<0.1)	4 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Pulmonary tuberculosis	0	4 (<0.1)	4 (<0.1)
Abscess limb	3 (<0.1)	3 (<0.1)	6 (<0.1)
Acquired immunodeficiency syndrome	0	3 (<0.1)	3 (<0.1)
Acute sinusitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Dengue fever	0	3 (<0.1)	3 (<0.1)
Eye infection	3 (<0.1)	3 (<0.1)	6 (<0.1)
Herpes ophthalmic	6 (<0.1)	3 (<0.1)	9 (<0.1)
Infectious mononucleosis	7 (<0.1)	3 (<0.1)	10 (<0.1)
Labyrinthitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Malaria	6 (<0.1)	3 (<0.1)	9 (<0.1)
Measles	2 (<0.1)	3 (<0.1)	5 (<0.1)
Meningitis aseptic	1 (<0.1)	3 (<0.1)	4 (<0.1)
Meningitis viral	0	3 (<0.1)	3 (<0.1)
Nasopharyngitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Oral candidiasis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Otitis media chronic	4 (<0.1)	3 (<0.1)	7 (<0.1)
Pneumonia staphylococcal	2 (<0.1)	3 (<0.1)	5 (<0.1)
Pyelonephritis	0	3 (<0.1)	3 (<0.1)
Scarlet fever	2 (<0.1)	3 (<0.1)	5 (<0.1)
Subcutaneous abscess	3 (<0.1)	3 (<0.1)	6 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cervicitis	0	2 (<0.1)	2 (<0.1)
Chronic hepatitis B	1 (<0.1)	2 (<0.1)	3 (<0.1)
Epstein-Barr virus infection	0	2 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Furuncle	2 (<0.1)	2 (<0.1)	4 (<0.1)
Histoplasmosis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Intervertebral discitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lung abscess	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mastitis	0	2 (<0.1)	2 (<0.1)
Mycobacterium avium complex infection	4 (<0.1)	2 (<0.1)	6 (<0.1)
Myelitis	0	2 (<0.1)	2 (<0.1)
Otitis media acute	2 (<0.1)	2 (<0.1)	4 (<0.1)
Parotitis	0	2 (<0.1)	2 (<0.1)
Periodontitis	5 (<0.1)	2 (<0.1)	7 (<0.1)
Peritonitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Peritonsillar abscess	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pyelonephritis acute	0	2 (<0.1)	2 (<0.1)
Respiratory tract infection viral	0	2 (<0.1)	2 (<0.1)
Salpingitis	0	2 (<0.1)	2 (<0.1)
Sialoadenitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Streptococcal infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tinea capitis	0	2 (<0.1)	2 (<0.1)
Vulvovaginal candidiasis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Abdominal abscess	3 (<0.1)	1 (<0.1)	4 (<0.1)
Abscess intestinal	0	1 (<0.1)	1 (<0.1)
Acarodermatitis	0	1 (<0.1)	1 (<0.1)
Acute hepatitis B	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anal abscess	2 (<0.1)	1 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Anal chlamydia infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anorectal human papilloma virus infection	0	1 (<0.1)	1 (<0.1)
Arthritis viral	0	1 (<0.1)	1 (<0.1)
Ascariasis	0	1 (<0.1)	1 (<0.1)
Atypical mycobacterial pneumonia	0	1 (<0.1)	1 (<0.1)
Bacterial colitis	0	1 (<0.1)	1 (<0.1)
Bacterial infection	4 (<0.1)	1 (<0.1)	5 (<0.1)
Bacterial vaginosis	6 (<0.1)	1 (<0.1)	7 (<0.1)
Bartholin's abscess	0	1 (<0.1)	1 (<0.1)
Bartholinitis	0	1 (<0.1)	1 (<0.1)
Brain abscess	0	1 (<0.1)	1 (<0.1)
Bronchitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
COVID-19	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cellulitis pharyngeal	0	1 (<0.1)	1 (<0.1)
Cervicitis human papilloma virus	0	1 (<0.1)	1 (<0.1)
Cestode infection	0	1 (<0.1)	1 (<0.1)
Chest wall abscess	0	1 (<0.1)	1 (<0.1)
Cholangitis infective	0	1 (<0.1)	1 (<0.1)
Chronic hepatitis C	0	1 (<0.1)	1 (<0.1)
Clostridium difficile colitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Complicated appendicitis	0	1 (<0.1)	1 (<0.1)
Cytomegalovirus chorioretinitis	0	1 (<0.1)	1 (<0.1)
Cytomegalovirus hepatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Dermatophytosis	0	1 (<0.1)	1 (<0.1)
Dermatophytosis of nail	3 (<0.1)	1 (<0.1)	4 (<0.1)
Device related infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Diabetic gangrene	0	1 (<0.1)	1 (<0.1)
Diarrhoea infectious	0	1 (<0.1)	1 (<0.1)
Echinococciasis	0	1 (<0.1)	1 (<0.1)
Empyema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Encephalitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Endocarditis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Enteritis infectious	0	1 (<0.1)	1 (<0.1)
Epiglottitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Erythrasma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fallopian tube abscess	0	1 (<0.1)	1 (<0.1)
Genital herpes zoster	0	1 (<0.1)	1 (<0.1)
Giardiasis	0	1 (<0.1)	1 (<0.1)
Gonococcal infection	0	1 (<0.1)	1 (<0.1)
Groin abscess	0	1 (<0.1)	1 (<0.1)
H1N1 influenza	2 (<0.1)	1 (<0.1)	3 (<0.1)
HIV-associated neurocognitive disorder	0	1 (<0.1)	1 (<0.1)
Impetigo	1 (<0.1)	1 (<0.1)	2 (<0.1)
Infected skin ulcer	0	1 (<0.1)	1 (<0.1)
Lactobacillus infection	0	1 (<0.1)	1 (<0.1)
Laryngitis	0	1 (<0.1)	1 (<0.1)
Leptospirosis	0	1 (<0.1)	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Lower respiratory tract infection	0	1 (<0.1)	1 (<0.1)
Ludwig angina	0	1 (<0.1)	1 (<0.1)
Medical device site infection	0	1 (<0.1)	1 (<0.1)
Mumps	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mycobacterial infection	0	1 (<0.1)	1 (<0.1)
Nail infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasal herpes	0	1 (<0.1)	1 (<0.1)
Necrotising fasciitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Oesophageal candidiasis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ophthalmic herpes zoster	0	1 (<0.1)	1 (<0.1)
Orchitis	0	1 (<0.1)	1 (<0.1)
Orchitis mumps	0	1 (<0.1)	1 (<0.1)
Paronychia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Pelvic inflammatory disease	6 (<0.1)	1 (<0.1)	7 (<0.1)
Perichondritis	0	1 (<0.1)	1 (<0.1)
Perirectal abscess	0	1 (<0.1)	1 (<0.1)
Pertussis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pharyngeal abscess	0	1 (<0.1)	1 (<0.1)
Pneumocystis jirovecii pneumonia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pneumonia bacterial	4 (<0.1)	1 (<0.1)	5 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)	1 (<0.1)
Pneumonia respiratory syncytial viral	0	1 (<0.1)	1 (<0.1)
Post procedural cellulitis	0	1 (<0.1)	1 (<0.1)
Post procedural sepsis	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Prostate infection	0	1 (<0.1)	1 (<0.1)
Prostatic abscess	0	1 (<0.1)	1 (<0.1)
Pulpitis dental	0	1 (<0.1)	1 (<0.1)
Pustule	0	1 (<0.1)	1 (<0.1)
Respiratory syncytial virus infection	0	1 (<0.1)	1 (<0.1)
Respiratory tract infection	0	1 (<0.1)	1 (<0.1)
Sexually transmitted disease	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin bacterial infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin candida	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin infection	5 (<0.1)	1 (<0.1)	6 (<0.1)
Small intestine gangrene	0	1 (<0.1)	1 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Staphylococcal skin infection	0	1 (<0.1)	1 (<0.1)
Systemic viral infection	0	1 (<0.1)	1 (<0.1)
Taeniasis	0	1 (<0.1)	1 (<0.1)
Tinea cruris	5 (<0.1)	1 (<0.1)	6 (<0.1)
Trichomoniasis	0	1 (<0.1)	1 (<0.1)
Vaginal infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vestibular neuronitis	0	1 (<0.1)	1 (<0.1)
Viral hepatitis carrier	4 (<0.1)	1 (<0.1)	5 (<0.1)
Viral infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)	1 (<0.1)
Wound infection	0	1 (<0.1)	1 (<0.1)
Abscess neck	1 (<0.1)	0	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Arthritis infective	2 (<0.1)	0	2 (<0.1)
Aspergillus infection	1 (<0.1)	0	1 (<0.1)
Bacterial allergy	1 (<0.1)	0	1 (<0.1)
Balanitis candida	1 (<0.1)	0	1 (<0.1)
Breast abscess	1 (<0.1)	0	1 (<0.1)
Bronchiolitis	1 (<0.1)	0	1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0	1 (<0.1)
Campylobacter infection	2 (<0.1)	0	2 (<0.1)
Campylobacter sepsis	1 (<0.1)	0	1 (<0.1)
Cat scratch disease	1 (<0.1)	0	1 (<0.1)
Cellulitis orbital	1 (<0.1)	0	1 (<0.1)
Chronic active Epstein-Barr virus infection	1 (<0.1)	0	1 (<0.1)
Conjunctivitis chlamydial	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Cytomegalovirus infection	2 (<0.1)	0	2 (<0.1)
Encephalitis viral	1 (<0.1)	0	1 (<0.1)
Enterobacter sepsis	1 (<0.1)	0	1 (<0.1)
Extradural abscess	1 (<0.1)	0	1 (<0.1)
Focal epithelial hyperplasia	1 (<0.1)	0	1 (<0.1)
Fournier's gangrene	1 (<0.1)	0	1 (<0.1)
Gangrene	1 (<0.1)	0	1 (<0.1)
Gastroenteritis	1 (<0.1)	0	1 (<0.1)
Genital infection fungal	1 (<0.1)	0	1 (<0.1)
HIV peripheral neuropathy	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Haemophilus infection	1 (<0.1)	0	1 (<0.1)
Helicobacter gastritis	3 (<0.1)	0	3 (<0.1)
Herpes zoster reactivation	1 (<0.1)	0	1 (<0.1)
Infected bite	2 (<0.1)	0	2 (<0.1)
Infected cyst	1 (<0.1)	0	1 (<0.1)
Infection	1 (<0.1)	0	1 (<0.1)
Infectious pleural effusion	1 (<0.1)	0	1 (<0.1)
Joint abscess	1 (<0.1)	0	1 (<0.1)
Mediastinitis	1 (<0.1)	0	1 (<0.1)
Meningitis bacterial	3 (<0.1)	0	3 (<0.1)
Mycobacterium abscessus infection	2 (<0.1)	0	2 (<0.1)
Parasitic gastroenteritis	1 (<0.1)	0	1 (<0.1)
Penile abscess	1 (<0.1)	0	1 (<0.1)
Perihepatitis	1 (<0.1)	0	1 (<0.1)
Periorbital cellulitis	1 (<0.1)	0	1 (<0.1)
Plasmodium falciparum infection	1 (<0.1)	0	1 (<0.1)
Pneumocystis jirovecii infection	1 (<0.1)	0	1 (<0.1)
Pneumonia fungal	1 (<0.1)	0	1 (<0.1)
Pneumonia legionella	2 (<0.1)	0	2 (<0.1)
Pneumonia pneumococcal	1 (<0.1)	0	1 (<0.1)
Pneumonia streptococcal	1 (<0.1)	0	1 (<0.1)
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Post procedural pneumonia	1 (<0.1)	0	1 (<0.1)
Postoperative wound infection	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Proctitis herpes	1 (<0.1)	0	1 (<0.1)
Pyuria	1 (<0.1)	0	1 (<0.1)
Rectal abscess	1 (<0.1)	0	1 (<0.1)
Renal tuberculosis	1 (<0.1)	0	1 (<0.1)
Retinitis	1 (<0.1)	0	1 (<0.1)
Rubella	1 (<0.1)	0	1 (<0.1)
Septic shock	1 (<0.1)	0	1 (<0.1)
Sinusitis fungal	1 (<0.1)	0	1 (<0.1)
Spinal cord abscess	1 (<0.1)	0	1 (<0.1)
Staphylococcal osteomyelitis	1 (<0.1)	0	1 (<0.1)
Testicular abscess	1 (<0.1)	0	1 (<0.1)
Tetanus	1 (<0.1)	0	1 (<0.1)
Tonsillitis streptococcal	1 (<0.1)	0	1 (<0.1)
Toxoplasmosis	1 (<0.1)	0	1 (<0.1)
Tracheobronchitis	1 (<0.1)	0	1 (<0.1)
Trichiniasis	1 (<0.1)	0	1 (<0.1)
Trichosporon infection	1 (<0.1)	0	1 (<0.1)
Tubo-ovarian abscess	1 (<0.1)	0	1 (<0.1)
Urethritis	1 (<0.1)	0	1 (<0.1)
Uterine infection	2 (<0.1)	0	2 (<0.1)
Varicella zoster virus infection	2 (<0.1)	0	2 (<0.1)
West Nile viral infection	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1717 (11.3)	1826 (12.0)	3543 (11.7)
Uterine leiomyoma	370 (2.4)	394 (2.6)	764 (2.5)
Basal cell carcinoma	256 (1.7)	301 (2.0)	557 (1.8)
Prostate cancer	177 (1.2)	176 (1.2)	353 (1.2)
Breast cancer	169 (1.1)	160 (1.1)	329 (1.1)
Malignant melanoma	85 (0.6)	89 (0.6)	174 (0.6)
Squamous cell carcinoma	55 (0.4)	64 (0.4)	119 (0.4)
Benign neoplasm of thyroid gland	43 (0.3)	51 (0.3)	94 (0.3)
Skin cancer	59 (0.4)	51 (0.3)	110 (0.4)
Squamous cell carcinoma of skin	39 (0.3)	50 (0.3)	89 (0.3)
Lipoma	59 (0.4)	43 (0.3)	102 (0.3)
Thyroid cancer	37 (0.2)	35 (0.2)	72 (0.2)
Benign breast neoplasm	28 (0.2)	27 (0.2)	55 (0.2)
Cervix carcinoma	18 (0.1)	24 (0.2)	42 (0.1)
Colon cancer	28 (0.2)	23 (0.2)	51 (0.2)
Bladder cancer	13 (<0.1)	20 (0.1)	33 (0.1)
Melanocytic naevus	18 (0.1)	20 (0.1)	38 (0.1)
Lung neoplasm malignant	9 (<0.1)	19 (0.1)	28 (<0.1)
Non-Hodgkin's lymphoma	12 (<0.1)	17 (0.1)	29 (<0.1)
Ovarian cancer	11 (<0.1)	17 (0.1)	28 (<0.1)
Uterine cancer	19 (0.1)	15 (<0.1)	34 (0.1)
Benign uterine neoplasm	7 (<0.1)	14 (<0.1)	21 (<0.1)
Skin papilloma	8 (<0.1)	14 (<0.1)	22 (<0.1)
Testis cancer	13 (<0.1)	14 (<0.1)	27 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Seborrhoeic keratosis	20 (0.1)	13 (<0.1)	33 (0.1)
Colon adenoma	11 (<0.1)	12 (<0.1)	23 (<0.1)
Brain neoplasm benign	4 (<0.1)	11 (<0.1)	15 (<0.1)
Hodgkin's disease	7 (<0.1)	11 (<0.1)	18 (<0.1)
Renal cancer	18 (0.1)	11 (<0.1)	29 (<0.1)
Acrochordon	9 (<0.1)	10 (<0.1)	19 (<0.1)
Renal cell carcinoma	7 (<0.1)	10 (<0.1)	17 (<0.1)
Anogenital warts	3 (<0.1)	8 (<0.1)	11 (<0.1)
Benign neoplasm of skin	14 (<0.1)	8 (<0.1)	22 (<0.1)
Intraductal proliferative breast lesion	6 (<0.1)	8 (<0.1)	14 (<0.1)
Lymphoma	5 (<0.1)	8 (<0.1)	13 (<0.1)
Neuroma	6 (<0.1)	8 (<0.1)	14 (<0.1)
Papillary thyroid cancer	12 (<0.1)	8 (<0.1)	20 (<0.1)
Acoustic neuroma	4 (<0.1)	7 (<0.1)	11 (<0.1)
Benign ovarian tumour	7 (<0.1)	7 (<0.1)	14 (<0.1)
Endometrial cancer	11 (<0.1)	7 (<0.1)	18 (<0.1)
Leukaemia	2 (<0.1)	7 (<0.1)	9 (<0.1)
Meningioma	7 (<0.1)	6 (<0.1)	13 (<0.1)
Meningioma benign	2 (<0.1)	6 (<0.1)	8 (<0.1)
Pituitary tumour benign	12 (<0.1)	6 (<0.1)	18 (<0.1)
Prolactin-producing pituitary tumour	5 (<0.1)	6 (<0.1)	11 (<0.1)
Benign renal neoplasm	5 (<0.1)	5 (<0.1)	10 (<0.1)
Chronic lymphocytic leukaemia	4 (<0.1)	5 (<0.1)	9 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Gastric cancer	0	5 (<0.1)	5 (<0.1)
Haemangioma	2 (<0.1)	5 (<0.1)	7 (<0.1)
Hypergammaglobulinaemia benign monoclonal	2 (<0.1)	5 (<0.1)	7 (<0.1)
Invasive ductal breast carcinoma	0	5 (<0.1)	5 (<0.1)
Parathyroid tumour benign	2 (<0.1)	5 (<0.1)	7 (<0.1)
Schwannoma	1 (<0.1)	5 (<0.1)	6 (<0.1)
Tonsil cancer	3 (<0.1)	5 (<0.1)	8 (<0.1)
Benign lung neoplasm	4 (<0.1)	4 (<0.1)	8 (<0.1)
Cholesteatoma	5 (<0.1)	4 (<0.1)	9 (<0.1)
Fibroadenoma of breast	10 (<0.1)	4 (<0.1)	14 (<0.1)
Lipoma of breast	2 (<0.1)	4 (<0.1)	6 (<0.1)
Neoplasm skin	2 (<0.1)	4 (<0.1)	6 (<0.1)
Oesophageal carcinoma	2 (<0.1)	4 (<0.1)	6 (<0.1)
Anal cancer	0	3 (<0.1)	3 (<0.1)
B-cell lymphoma	4 (<0.1)	3 (<0.1)	7 (<0.1)
Basosquamous carcinoma	3 (<0.1)	3 (<0.1)	6 (<0.1)
Haemangioma of liver	2 (<0.1)	3 (<0.1)	5 (<0.1)
Juvenile melanoma benign	2 (<0.1)	3 (<0.1)	5 (<0.1)
Malignant melanoma in situ	6 (<0.1)	3 (<0.1)	9 (<0.1)
Osteoma	1 (<0.1)	3 (<0.1)	4 (<0.1)
Ovarian germ cell teratoma benign	1 (<0.1)	3 (<0.1)	4 (<0.1)
Pituitary tumour	1 (<0.1)	3 (<0.1)	4 (<0.1)
Renal neoplasm	3 (<0.1)	3 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Salivary gland neoplasm	1 (<0.1)	3 (<0.1)	4 (<0.1)
Seminoma	1 (<0.1)	3 (<0.1)	4 (<0.1)
Thyroid adenoma	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tongue neoplasm benign	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tongue neoplasm malignant stage unspecified	4 (<0.1)	3 (<0.1)	7 (<0.1)
Acute myeloid leukaemia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Adenocarcinoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Angiolipoma	2 (<0.1)	2 (<0.1)	4 (<0.1)
Benign abdominal neoplasm	0	2 (<0.1)	2 (<0.1)
Benign hepatic neoplasm	3 (<0.1)	2 (<0.1)	5 (<0.1)
Benign neoplasm of bladder	4 (<0.1)	2 (<0.1)	6 (<0.1)
Bone neoplasm	0	2 (<0.1)	2 (<0.1)
Brain neoplasm	0	2 (<0.1)	2 (<0.1)
Breast neoplasm	0	2 (<0.1)	2 (<0.1)
Cancer in remission	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cervix carcinoma stage 0	6 (<0.1)	2 (<0.1)	8 (<0.1)
Chronic myeloid leukaemia	0	2 (<0.1)	2 (<0.1)
Colorectal cancer	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cutaneous T-cell lymphoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dysplastic naevus	7 (<0.1)	2 (<0.1)	9 (<0.1)
Eye naevus	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gastrointestinal stromal tumour	1 (<0.1)	2 (<0.1)	3 (<0.1)
Large intestine benign neoplasm	1 (<0.1)	2 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Lip and/or oral cavity cancer	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lip squamous cell carcinoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Nasopharyngeal cancer	0	2 (<0.1)	2 (<0.1)
Pancreatic carcinoma	0	2 (<0.1)	2 (<0.1)
Phaeochromocytoma	0	2 (<0.1)	2 (<0.1)
Pleomorphic adenoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Prostate cancer stage I	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rectal cancer	4 (<0.1)	2 (<0.1)	6 (<0.1)
Salivary gland cancer	1 (<0.1)	2 (<0.1)	3 (<0.1)
Squamous cell carcinoma of the tongue	0	2 (<0.1)	2 (<0.1)
Testicular seminoma (pure)	0	2 (<0.1)	2 (<0.1)
Throat cancer	4 (<0.1)	2 (<0.1)	6 (<0.1)
Vulvovaginal warts	0	2 (<0.1)	2 (<0.1)
Adenocarcinoma of colon	0	1 (<0.1)	1 (<0.1)
Adenoid cystic carcinoma of salivary gland	0	1 (<0.1)	1 (<0.1)
Adenoma benign	4 (<0.1)	1 (<0.1)	5 (<0.1)
Adrenal adenoma	3 (<0.1)	1 (<0.1)	4 (<0.1)
Appendix cancer	0	1 (<0.1)	1 (<0.1)
Astrocytoma	0	1 (<0.1)	1 (<0.1)
Benign bone neoplasm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign cartilage neoplasm	0	1 (<0.1)	1 (<0.1)
Benign joint neoplasm	0	1 (<0.1)	1 (<0.1)
Benign neoplasm	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Benign neoplasm of cervix uteri	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of eye	0	1 (<0.1)	1 (<0.1)
Benign neoplasm of spinal cord	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of thymus	0	1 (<0.1)	1 (<0.1)
Benign salivary gland neoplasm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Benign soft tissue neoplasm	0	1 (<0.1)	1 (<0.1)
Biliary adenoma	0	1 (<0.1)	1 (<0.1)
Bladder papilloma	0	1 (<0.1)	1 (<0.1)
Bone cancer	0	1 (<0.1)	1 (<0.1)
Bone giant cell tumour	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bone giant cell tumour benign	0	1 (<0.1)	1 (<0.1)
Bowen's disease	0	1 (<0.1)	1 (<0.1)
Brain neoplasm malignant	0	1 (<0.1)	1 (<0.1)
Breast cancer in situ	0	1 (<0.1)	1 (<0.1)
Breast cancer stage I	6 (<0.1)	1 (<0.1)	7 (<0.1)
Breast cancer stage II	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast cancer stage III	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast fibroma	0	1 (<0.1)	1 (<0.1)
Burkitt's lymphoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
CNS germinoma	0	1 (<0.1)	1 (<0.1)
Carcinoid tumour pulmonary	1 (<0.1)	1 (<0.1)	2 (<0.1)
Carcinoma in situ	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac teratoma	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Cerebral haemangioma	0	1 (<0.1)	1 (<0.1)
Cervix carcinoma stage III	0	1 (<0.1)	1 (<0.1)
Cervix neoplasm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cervix warts	0	1 (<0.1)	1 (<0.1)
Colon cancer stage I	1 (<0.1)	1 (<0.1)	2 (<0.1)
Colon cancer stage II	0	1 (<0.1)	1 (<0.1)
Colon cancer stage III	0	1 (<0.1)	1 (<0.1)
Colon neoplasm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Craniopharyngioma	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Diaphragm neoplasm	0	1 (<0.1)	1 (<0.1)
Ear neoplasm malignant	0	1 (<0.1)	1 (<0.1)
Endometrial cancer stage II	0	1 (<0.1)	1 (<0.1)
Endometrial stromal sarcoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ewing's sarcoma	0	1 (<0.1)	1 (<0.1)
Eyelid haemangioma	0	1 (<0.1)	1 (<0.1)
Fallopian tube cancer	0	1 (<0.1)	1 (<0.1)
Follicular thyroid cancer	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gallbladder cancer	0	1 (<0.1)	1 (<0.1)
Ganglioglioma	0	1 (<0.1)	1 (<0.1)
Gastrointestinal carcinoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Glomus tumour	0	1 (<0.1)	1 (<0.1)
Granular cell tumour	0	1 (<0.1)	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Hepatic adenoma	0	1 (<0.1)	1 (<0.1)
Hepatobiliary neoplasm	0	1 (<0.1)	1 (<0.1)
Hodgkin's disease nodular sclerosis	0	1 (<0.1)	1 (<0.1)
Kaposi's sarcoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lacrimal gland neoplasm	0	1 (<0.1)	1 (<0.1)
Laryngeal squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)
Leiomyoma	3 (<0.1)	1 (<0.1)	4 (<0.1)
Lip neoplasm malignant stage unspecified	0	1 (<0.1)	1 (<0.1)
Lung adenocarcinoma	0	1 (<0.1)	1 (<0.1)
Lymphocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Malignant melanoma stage II	0	1 (<0.1)	1 (<0.1)
Malignant neoplasm of renal pelvis	0	1 (<0.1)	1 (<0.1)
Medullary thyroid cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meningioma malignant	0	1 (<0.1)	1 (<0.1)
Metastases to bone	0	1 (<0.1)	1 (<0.1)
Metastases to central nervous system	0	1 (<0.1)	1 (<0.1)
Metastatic malignant melanoma	0	1 (<0.1)	1 (<0.1)
Monoclonal gammopathy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Nasal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Nasal sinus cancer	0	1 (<0.1)	1 (<0.1)
Neoplasm malignant	0	1 (<0.1)	1 (<0.1)
Nephroblastoma	0	1 (<0.1)	1 (<0.1)
Neuroendocrine carcinoma of the skin	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Neuroendocrine tumour	0	1 (<0.1)	1 (<0.1)
Neurofibroma	0	1 (<0.1)	1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Non-small cell lung cancer stage IV	0	1 (<0.1)	1 (<0.1)
Oropharyngeal cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal squamous cell carcinoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteochondroma	6 (<0.1)	1 (<0.1)	7 (<0.1)
Osteosarcoma	0	1 (<0.1)	1 (<0.1)
Ovarian fibroma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ovarian germ cell teratoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ovarian neoplasm	2 (<0.1)	1 (<0.1)	3 (<0.1)
Paget's disease of nipple	0	1 (<0.1)	1 (<0.1)
Paraganglion neoplasm benign	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pearly penile papules	0	1 (<0.1)	1 (<0.1)
Plasma cell myeloma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Plasmacytoma	0	1 (<0.1)	1 (<0.1)
Polycythaemia vera	1 (<0.1)	1 (<0.1)	2 (<0.1)
Prostate cancer metastatic	0	1 (<0.1)	1 (<0.1)
Prostate cancer recurrent	0	1 (<0.1)	1 (<0.1)
Prostate cancer stage 0	0	1 (<0.1)	1 (<0.1)
Prostate cancer stage IV	0	1 (<0.1)	1 (<0.1)
Renal oncocytoma	0	1 (<0.1)	1 (<0.1)
Sarcoma	3 (<0.1)	1 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Small cell lung cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Small intestine carcinoma	0	1 (<0.1)	1 (<0.1)
Spindle cell sarcoma	0	1 (<0.1)	1 (<0.1)
Teratoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Teratoma benign	1 (<0.1)	1 (<0.1)	2 (<0.1)
Testicular germ cell cancer	0	1 (<0.1)	1 (<0.1)
Testicular yolk sac tumour	0	1 (<0.1)	1 (<0.1)
Thyroid cancer stage I	0	1 (<0.1)	1 (<0.1)
Thyroid cancer stage III	0	1 (<0.1)	1 (<0.1)
Thyroid neoplasm	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tonsillar neoplasm benign	0	1 (<0.1)	1 (<0.1)
Transitional cell carcinoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Triple negative breast cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tumour embolism	0	1 (<0.1)	1 (<0.1)
Uterine carcinoma in situ	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vulval cancer	0	1 (<0.1)	1 (<0.1)
Waldenstrom's macroglobulinaemia	0	1 (<0.1)	1 (<0.1)
Abdominal neoplasm	1 (<0.1)	0	1 (<0.1)
Acute leukaemia	1 (<0.1)	0	1 (<0.1)
Adenocarcinoma of the cervix	2 (<0.1)	0	2 (<0.1)
Adenoid cystic carcinoma	1 (<0.1)	0	1 (<0.1)
Adrenal gland cancer	1 (<0.1)	0	1 (<0.1)
Anal squamous cell carcinoma	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Appendix adenoma	1 (<0.1)	0	1 (<0.1)
Benign cardiac neoplasm	1 (<0.1)	0	1 (<0.1)
Benign ear neoplasm	2 (<0.1)	0	2 (<0.1)
Benign gastric neoplasm	1 (<0.1)	0	1 (<0.1)
Benign gastrointestinal neoplasm	2 (<0.1)	0	2 (<0.1)
Benign hydatidiform mole	1 (<0.1)	0	1 (<0.1)
Benign lymph node neoplasm	2 (<0.1)	0	2 (<0.1)
Benign neoplasm of choroid	1 (<0.1)	0	1 (<0.1)
Benign neoplasm of orbit	1 (<0.1)	0	1 (<0.1)
Benign pancreatic neoplasm	1 (<0.1)	0	1 (<0.1)
Benign respiratory tract neoplasm	1 (<0.1)	0	1 (<0.1)
Benign vascular neoplasm	1 (<0.1)	0	1 (<0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Carcinoid tumour	2 (<0.1)	0	2 (<0.1)
Carcinoid tumour of the small bowel	1 (<0.1)	0	1 (<0.1)
Castleman's disease	1 (<0.1)	0	1 (<0.1)
Cervix carcinoma stage I	1 (<0.1)	0	1 (<0.1)
Choriocarcinoma	1 (<0.1)	0	1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	0	1 (<0.1)
Desmoid tumour	1 (<0.1)	0	1 (<0.1)
Diffuse large B-cell lymphoma	1 (<0.1)	0	1 (<0.1)
Endometrial adenocarcinoma	1 (<0.1)	0	1 (<0.1)
Endometrial cancer stage I	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Extranodal marginal zone B-cell lymphoma (MALT type)	1 (<0.1)	0	1 (<0.1)
Eye haemangioma	1 (<0.1)	0	1 (<0.1)
Fibroma	1 (<0.1)	0	1 (<0.1)
Fibrosarcoma	1 (<0.1)	0	1 (<0.1)
Fibrous histiocytoma	4 (<0.1)	0	4 (<0.1)
Ganglioneuroma	1 (<0.1)	0	1 (<0.1)
Gastrointestinal lymphoma	1 (<0.1)	0	1 (<0.1)
Haemangioma of skin	4 (<0.1)	0	4 (<0.1)
Hepatic neoplasm	1 (<0.1)	0	1 (<0.1)
Hodgkin's disease stage IV	1 (<0.1)	0	1 (<0.1)
Intraductal papillary mucinous neoplasm	1 (<0.1)	0	1 (<0.1)
Invasive breast carcinoma	1 (<0.1)	0	1 (<0.1)
Joint neoplasm	1 (<0.1)	0	1 (<0.1)
Keratoacanthoma	2 (<0.1)	0	2 (<0.1)
Laryngeal cancer	2 (<0.1)	0	2 (<0.1)
Laryngeal papilloma	1 (<0.1)	0	1 (<0.1)
Leiomyosarcoma	1 (<0.1)	0	1 (<0.1)
Leiomyosarcoma recurrent	1 (<0.1)	0	1 (<0.1)
Lentigo maligna	1 (<0.1)	0	1 (<0.1)
Leukaemia in remission	1 (<0.1)	0	1 (<0.1)
Lip and/or oral cavity cancer stage 0	1 (<0.1)	0	1 (<0.1)
Lobular breast carcinoma in situ	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Lung carcinoma cell type unspecified stage I	1 (<0.1)	0	1 (<0.1)
Lymphatic system neoplasm	1 (<0.1)	0	1 (<0.1)
Lymphoplasmacytoid lymphoma/immunocytoma	1 (<0.1)	0	1 (<0.1)
Malignant melanoma stage I	1 (<0.1)	0	1 (<0.1)
Malignant melanoma stage III	1 (<0.1)	0	1 (<0.1)
Malignant neoplasm of eyelid	1 (<0.1)	0	1 (<0.1)
Malignant neoplasm of retina	1 (<0.1)	0	1 (<0.1)
Malignant neoplasm of thymus	1 (<0.1)	0	1 (<0.1)
Mucoepidermoid carcinoma	1 (<0.1)	0	1 (<0.1)
Mucoepidermoid carcinoma of salivary gland	1 (<0.1)	0	1 (<0.1)
Myxoid liposarcoma	1 (<0.1)	0	1 (<0.1)
Nervous system neoplasm benign	1 (<0.1)	0	1 (<0.1)
Neuroblastoma	1 (<0.1)	0	1 (<0.1)
Non-Hodgkin's lymphoma stage I	1 (<0.1)	0	1 (<0.1)
Oesophageal adenocarcinoma	1 (<0.1)	0	1 (<0.1)
Osteofibroma	1 (<0.1)	0	1 (<0.1)
Ovarian adenoma	1 (<0.1)	0	1 (<0.1)
Ovarian cancer stage I	1 (<0.1)	0	1 (<0.1)
Pancreatic neuroendocrine tumour	1 (<0.1)	0	1 (<0.1)
Papilloma	1 (<0.1)	0	1 (<0.1)
Paranasal sinus benign neoplasm	1 (<0.1)	0	1 (<0.1)
Parathyroid tumour	2 (<0.1)	0	2 (<0.1)
Penile cancer	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Penile wart	1 (<0.1)	0	1 (<0.1)
Phyllodes tumour	2 (<0.1)	0	2 (<0.1)
Renal hamartoma	1 (<0.1)	0	1 (<0.1)
Respiratory papilloma	1 (<0.1)	0	1 (<0.1)
Retinoblastoma	2 (<0.1)	0	2 (<0.1)
Small intestine adenocarcinoma	1 (<0.1)	0	1 (<0.1)
Squamous cell carcinoma of the cervix	1 (<0.1)	0	1 (<0.1)
Sweat gland tumour	1 (<0.1)	0	1 (<0.1)
T-cell lymphoma	1 (<0.1)	0	1 (<0.1)
Thyroid cancer metastatic	1 (<0.1)	0	1 (<0.1)
Uterine neoplasm	1 (<0.1)	0	1 (<0.1)
Vocal cord neoplasm	2 (<0.1)	0	2 (<0.1)
Blood and lymphatic system disorders	356 (2.3)	363 (2.4)	719 (2.4)
Anaemia	187 (1.2)	185 (1.2)	372 (1.2)
Iron deficiency anaemia	71 (0.5)	67 (0.4)	138 (0.5)
Lymphadenopathy	18 (0.1)	33 (0.2)	51 (0.2)
Increased tendency to bruise	30 (0.2)	19 (0.1)	49 (0.2)
Pernicious anaemia	5 (<0.1)	8 (<0.1)	13 (<0.1)
Thrombocytopenia	9 (<0.1)	7 (<0.1)	16 (<0.1)
Polycythaemia	5 (<0.1)	6 (<0.1)	11 (<0.1)
Antiphospholipid syndrome	2 (<0.1)	5 (<0.1)	7 (<0.1)
Immune thrombocytopenia	4 (<0.1)	5 (<0.1)	9 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Coagulopathy	1 (<0.1)	4 (<0.1)	5 (<0.1)
Hypercoagulation	6 (<0.1)	4 (<0.1)	10 (<0.1)
Eosinophilia	0	3 (<0.1)	3 (<0.1)
Leukopenia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Macrocytosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Microcytic anaemia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neutropenia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anaemia folate deficiency	0	1 (<0.1)	1 (<0.1)
Anaemia macrocytic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anaemia of chronic disease	0	1 (<0.1)	1 (<0.1)
Benign ethnic neutropenia	0	1 (<0.1)	1 (<0.1)
Bone marrow oedema	0	1 (<0.1)	1 (<0.1)
Coagulation factor deficiency	0	1 (<0.1)	1 (<0.1)
Cyclic neutropenia	0	1 (<0.1)	1 (<0.1)
Heparin-induced thrombocytopenia	0	1 (<0.1)	1 (<0.1)
Leukocytosis	0	1 (<0.1)	1 (<0.1)
Lymph node pain	0	1 (<0.1)	1 (<0.1)
Lymphatic disorder	0	1 (<0.1)	1 (<0.1)
Mast cell activation syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Normochromic normocytic anaemia	0	1 (<0.1)	1 (<0.1)
Platelet dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spherocytic anaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Splenomegaly	3 (<0.1)	1 (<0.1)	4 (<0.1)
Anaemia of pregnancy	1 (<0.1)	0	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Anaemia vitamin B12 deficiency	2 (<0.1)	0	2 (<0.1)
Aplastic anaemia	1 (<0.1)	0	1 (<0.1)
Deficiency anaemia	1 (<0.1)	0	1 (<0.1)
Disseminated intravascular coagulation	1 (<0.1)	0	1 (<0.1)
Hypochromic anaemia	1 (<0.1)	0	1 (<0.1)
Lymph node calcification	1 (<0.1)	0	1 (<0.1)
Lymphadenitis	3 (<0.1)	0	3 (<0.1)
Mastocytosis	2 (<0.1)	0	2 (<0.1)
Pseudolymphoma	1 (<0.1)	0	1 (<0.1)
Thrombocytosis	1 (<0.1)	0	1 (<0.1)
Thymus enlargement	1 (<0.1)	0	1 (<0.1)
Immune system disorders	5905 (38.9)	5893 (38.8)	11798 (38.9)
Seasonal allergy	4163 (27.5)	4196 (27.6)	8359 (27.5)
Drug hypersensitivity	1857 (12.2)	1881 (12.4)	3738 (12.3)
Food allergy	314 (2.1)	325 (2.1)	639 (2.1)
Hypersensitivity	277 (1.8)	277 (1.8)	554 (1.8)
Allergy to animal	164 (1.1)	138 (0.9)	302 (1.0)
Rubber sensitivity	109 (0.7)	117 (0.8)	226 (0.7)
Allergy to arthropod sting	58 (0.4)	62 (0.4)	120 (0.4)
Iodine allergy	53 (0.3)	49 (0.3)	102 (0.3)
Allergy to plants	34 (0.2)	41 (0.3)	75 (0.2)
Mycotic allergy	48 (0.3)	39 (0.3)	87 (0.3)
Dust allergy	49 (0.3)	38 (0.3)	87 (0.3)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Allergy to metals	18 (0.1)	27 (0.2)	45 (0.1)
Allergy to chemicals	25 (0.2)	25 (0.2)	50 (0.2)
Contrast media allergy	32 (0.2)	24 (0.2)	56 (0.2)
Anaphylactic reaction	27 (0.2)	23 (0.2)	50 (0.2)
Multiple allergies	25 (0.2)	19 (0.1)	44 (0.1)
Sarcoidosis	12 (<0.1)	17 (0.1)	29 (<0.1)
Allergy to vaccine	11 (<0.1)	14 (<0.1)	25 (<0.1)
Mite allergy	20 (0.1)	9 (<0.1)	29 (<0.1)
Perennial allergy	8 (<0.1)	9 (<0.1)	17 (<0.1)
Allergy to arthropod bite	8 (<0.1)	8 (<0.1)	16 (<0.1)
Milk allergy	14 (<0.1)	7 (<0.1)	21 (<0.1)
Perfume sensitivity	2 (<0.1)	3 (<0.1)	5 (<0.1)
Allergy to venom	5 (<0.1)	2 (<0.1)	7 (<0.1)
Immunodeficiency	0	2 (<0.1)	2 (<0.1)
Reaction to preservatives	2 (<0.1)	2 (<0.1)	4 (<0.1)
Smoke sensitivity	2 (<0.1)	2 (<0.1)	4 (<0.1)
Allergic reaction to excipient	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergy to silk	0	1 (<0.1)	1 (<0.1)
Caffeine allergy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cockroach allergy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Haemophagocytic lymphohistiocytosis	0	1 (<0.1)	1 (<0.1)
Oral allergy syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Reaction to azo-dyes	0	1 (<0.1)	1 (<0.1)
Reaction to food additive	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Allergy to surgical sutures	3 (<0.1)	0	3 (<0.1)
Allergy to synthetic fabric	1 (<0.1)	0	1 (<0.1)
Amyloidosis	1 (<0.1)	0	1 (<0.1)
Multiple chemical sensitivity	1 (<0.1)	0	1 (<0.1)
Reaction to colouring	1 (<0.1)	0	1 (<0.1)
Endocrine disorders	1756 (11.6)	1752 (11.5)	3508 (11.6)
Hypothyroidism	1459 (9.6)	1473 (9.7)	2932 (9.7)
Autoimmune thyroiditis	56 (0.4)	67 (0.4)	123 (0.4)
Hypogonadism	71 (0.5)	59 (0.4)	130 (0.4)
Hyperthyroidism	69 (0.5)	58 (0.4)	127 (0.4)
Goitre	42 (0.3)	41 (0.3)	83 (0.3)
Basedow's disease	29 (0.2)	25 (0.2)	54 (0.2)
Oestrogen deficiency	24 (0.2)	22 (0.1)	46 (0.2)
Thyroid mass	22 (0.1)	18 (0.1)	40 (0.1)
Androgen deficiency	21 (0.1)	14 (<0.1)	35 (0.1)
Hyperparathyroidism	9 (<0.1)	13 (<0.1)	22 (<0.1)
Thyroid cyst	5 (<0.1)	11 (<0.1)	16 (<0.1)
Thyroid disorder	9 (<0.1)	9 (<0.1)	18 (<0.1)
Hypogonadism male	7 (<0.1)	5 (<0.1)	12 (<0.1)
Testicular failure	6 (<0.1)	4 (<0.1)	10 (<0.1)
Hyperprolactinaemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hypoparathyroidism	4 (<0.1)	3 (<0.1)	7 (<0.1)
Parathyroid disorder	2 (<0.1)	3 (<0.1)	5 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders (Cont.)			
Thyroiditis subacute	1 (<0.1)	3 (<0.1)	4 (<0.1)
Addison's disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Adrenal insufficiency	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hyperaldosteronism	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hypoaldosteronism	0	2 (<0.1)	2 (<0.1)
Adrenal cyst	0	1 (<0.1)	1 (<0.1)
Anovulatory cycle	0	1 (<0.1)	1 (<0.1)
Hyperparathyroidism primary	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hyperplasia adrenal	0	1 (<0.1)	1 (<0.1)
Hypopituitarism	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypothalamo-pituitary disorder	0	1 (<0.1)	1 (<0.1)
Silent thyroiditis	0	1 (<0.1)	1 (<0.1)
Thyroiditis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Adrenal mass	3 (<0.1)	0	3 (<0.1)
Carcinoid syndrome	1 (<0.1)	0	1 (<0.1)
Cushing's syndrome	1 (<0.1)	0	1 (<0.1)
Diabetes insipidus	1 (<0.1)	0	1 (<0.1)
Growth hormone deficiency	2 (<0.1)	0	2 (<0.1)
Hypoprogesteronism	1 (<0.1)	0	1 (<0.1)
Parathyroid gland enlargement	1 (<0.1)	0	1 (<0.1)
Pituitary cyst	1 (<0.1)	0	1 (<0.1)
Secondary hypogonadism	1 (<0.1)	0	1 (<0.1)
Secondary hypothyroidism	1 (<0.1)	0	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders	5378 (35.5)	5341 (35.2)	10719 (35.3)
Hyperlipidaemia	1730 (11.4)	1659 (10.9)	3389 (11.2)
Hypercholesterolaemia	1500 (9.9)	1421 (9.4)	2921 (9.6)
Type 2 diabetes mellitus	1304 (8.6)	1279 (8.4)	2583 (8.5)
Obesity	1164 (7.7)	1150 (7.6)	2314 (7.6)
Vitamin D deficiency	429 (2.8)	434 (2.9)	863 (2.8)
Gout	267 (1.8)	271 (1.8)	538 (1.8)
Glucose tolerance impaired	210 (1.4)	188 (1.2)	398 (1.3)
Diabetes mellitus	138 (0.9)	137 (0.9)	275 (0.9)
Dyslipidaemia	132 (0.9)	106 (0.7)	238 (0.8)
Overweight	105 (0.7)	99 (0.7)	204 (0.7)
Type 1 diabetes mellitus	93 (0.6)	93 (0.6)	186 (0.6)
Lactose intolerance	60 (0.4)	67 (0.4)	127 (0.4)
Vitamin B12 deficiency	74 (0.5)	63 (0.4)	137 (0.5)
Hypertriglyceridaemia	64 (0.4)	56 (0.4)	120 (0.4)
Hypokalaemia	50 (0.3)	39 (0.3)	89 (0.3)
Fluid retention	23 (0.2)	29 (0.2)	52 (0.2)
Iron deficiency	39 (0.3)	27 (0.2)	66 (0.2)
Hyperglycaemia	19 (0.1)	18 (0.1)	37 (0.1)
Gluten sensitivity	28 (0.2)	16 (0.1)	44 (0.1)
Hypocholesterolaemia	9 (<0.1)	12 (<0.1)	21 (<0.1)
Insulin resistance	13 (<0.1)	10 (<0.1)	23 (<0.1)
Impaired fasting glucose	5 (<0.1)	9 (<0.1)	14 (<0.1)
Vitamin B complex deficiency	12 (<0.1)	8 (<0.1)	20 (<0.1)
Hypocalcaemia	5 (<0.1)	7 (<0.1)	12 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypoglycaemia	10 (<0.1)	6 (<0.1)	16 (<0.1)
Metabolic syndrome	13 (<0.1)	6 (<0.1)	19 (<0.1)
Food intolerance	3 (<0.1)	5 (<0.1)	8 (<0.1)
Haemochromatosis	10 (<0.1)	5 (<0.1)	15 (<0.1)
Hypovitaminosis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Dairy intolerance	8 (<0.1)	4 (<0.1)	12 (<0.1)
Hypercalcaemia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Folate deficiency	3 (<0.1)	3 (<0.1)	6 (<0.1)
Hyperinsulinaemia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hyperuricaemia	7 (<0.1)	3 (<0.1)	10 (<0.1)
Hypolipidaemia	0	3 (<0.1)	3 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Underweight	0	3 (<0.1)	3 (<0.1)
Dehydration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Hyperkalaemia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Hypo HDL cholesterolaemia	0	2 (<0.1)	2 (<0.1)
Hypomagnesaemia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Magnesium deficiency	2 (<0.1)	2 (<0.1)	4 (<0.1)
Postprandial hypoglycaemia	0	2 (<0.1)	2 (<0.1)
Abnormal loss of weight	0	1 (<0.1)	1 (<0.1)
Alcohol intolerance	0	1 (<0.1)	1 (<0.1)
Alkalosis	0	1 (<0.1)	1 (<0.1)
Calcium deficiency	5 (<0.1)	1 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Central obesity	2 (<0.1)	1 (<0.1)	3 (<0.1)
Copper deficiency	0	1 (<0.1)	1 (<0.1)
Hyperchloraemia	0	1 (<0.1)	1 (<0.1)
Hyperhomocysteinaemia	0	1 (<0.1)	1 (<0.1)
Hypotriglyceridaemia	0	1 (<0.1)	1 (<0.1)
Increased appetite	0	1 (<0.1)	1 (<0.1)
Insulin-requiring type 2 diabetes mellitus	0	1 (<0.1)	1 (<0.1)
Latent autoimmune diabetes in adults	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lipid metabolism disorder	0	1 (<0.1)	1 (<0.1)
Lipoedema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lipoprotein deficiency	0	1 (<0.1)	1 (<0.1)
Malnutrition	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mitochondrial cytopathy	0	1 (<0.1)	1 (<0.1)
Polydipsia	0	1 (<0.1)	1 (<0.1)
Vitamin B1 deficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vitamin B6 deficiency	0	1 (<0.1)	1 (<0.1)
Zinc deficiency	0	1 (<0.1)	1 (<0.1)
Body fat disorder	1 (<0.1)	0	1 (<0.1)
Calciphylaxis	1 (<0.1)	0	1 (<0.1)
Decreased appetite	2 (<0.1)	0	2 (<0.1)
Euglycaemic diabetic ketoacidosis	1 (<0.1)	0	1 (<0.1)
Hyperammonaemia	1 (<0.1)	0	1 (<0.1)
Hypernatraemia	1 (<0.1)	0	1 (<0.1)
Hyperphagia	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypoalbuminaemia	1 (<0.1)	0	1 (<0.1)
Hypophosphataemia	1 (<0.1)	0	1 (<0.1)
Insulin resistant diabetes	1 (<0.1)	0	1 (<0.1)
Ketoacidosis	2 (<0.1)	0	2 (<0.1)
Monogenic diabetes	1 (<0.1)	0	1 (<0.1)
Type 3 diabetes mellitus	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	4491 (29.6)	4538 (29.9)	9029 (29.8)
Depression	1977 (13.0)	1949 (12.8)	3926 (12.9)
Anxiety	1885 (12.4)	1930 (12.7)	3815 (12.6)
Insomnia	1312 (8.7)	1333 (8.8)	2645 (8.7)
Attention deficit hyperactivity disorder	553 (3.6)	597 (3.9)	1150 (3.8)
Bipolar disorder	156 (1.0)	169 (1.1)	325 (1.1)
Post-traumatic stress disorder	123 (0.8)	145 (1.0)	268 (0.9)
Generalised anxiety disorder	63 (0.4)	73 (0.5)	136 (0.4)
Major depression	54 (0.4)	42 (0.3)	96 (0.3)
Anxiety disorder	36 (0.2)	41 (0.3)	77 (0.3)
Obsessive-compulsive disorder	33 (0.2)	40 (0.3)	73 (0.2)
Sleep disorder	36 (0.2)	35 (0.2)	71 (0.2)
Panic attack	43 (0.3)	32 (0.2)	75 (0.2)
Alcoholism	16 (0.1)	31 (0.2)	47 (0.2)
Bipolar II disorder	21 (0.1)	31 (0.2)	52 (0.2)
Drug dependence	17 (0.1)	28 (0.2)	45 (0.1)
Libido decreased	24 (0.2)	27 (0.2)	51 (0.2)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Alcohol abuse	14 (<0.1)	22 (0.1)	36 (0.1)
Drug abuse	19 (0.1)	20 (0.1)	39 (0.1)
Nicotine dependence	15 (<0.1)	19 (0.1)	34 (0.1)
Schizophrenia	14 (<0.1)	19 (0.1)	33 (0.1)
Affective disorder	22 (0.1)	15 (<0.1)	37 (0.1)
Bipolar I disorder	13 (<0.1)	15 (<0.1)	28 (<0.1)
Perinatal depression	7 (<0.1)	12 (<0.1)	19 (<0.1)
Persistent depressive disorder	10 (<0.1)	12 (<0.1)	22 (<0.1)
Tobacco abuse	16 (0.1)	12 (<0.1)	28 (<0.1)
Autism spectrum disorder	14 (<0.1)	11 (<0.1)	25 (<0.1)
Adjustment disorder with depressed mood	12 (<0.1)	10 (<0.1)	22 (<0.1)
Panic disorder	13 (<0.1)	10 (<0.1)	23 (<0.1)
Drug use disorder	6 (<0.1)	9 (<0.1)	15 (<0.1)
Seasonal affective disorder	11 (<0.1)	9 (<0.1)	20 (<0.1)
Social anxiety disorder	2 (<0.1)	8 (<0.1)	10 (<0.1)
Mood swings	8 (<0.1)	7 (<0.1)	15 (<0.1)
Gender dysphoria	5 (<0.1)	6 (<0.1)	11 (<0.1)
Schizoaffective disorder	7 (<0.1)	6 (<0.1)	13 (<0.1)
Binge eating	7 (<0.1)	5 (<0.1)	12 (<0.1)
Alcohol use disorder	2 (<0.1)	4 (<0.1)	6 (<0.1)
Bruxism	5 (<0.1)	4 (<0.1)	9 (<0.1)
Dissociative identity disorder	0	4 (<0.1)	4 (<0.1)
Eating disorder	0	4 (<0.1)	4 (<0.1)
Mixed anxiety and depressive disorder	4 (<0.1)	4 (<0.1)	8 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Nightmare	3 (<0.1)	4 (<0.1)	7 (<0.1)
Psychotic disorder	1 (<0.1)	4 (<0.1)	5 (<0.1)
Suicide attempt	1 (<0.1)	4 (<0.1)	5 (<0.1)
Borderline personality disorder	6 (<0.1)	3 (<0.1)	9 (<0.1)
Dysphoria	0	3 (<0.1)	3 (<0.1)
Initial insomnia	4 (<0.1)	3 (<0.1)	7 (<0.1)
Sleep terror	3 (<0.1)	3 (<0.1)	6 (<0.1)
Substance abuse	7 (<0.1)	3 (<0.1)	10 (<0.1)
Anger	2 (<0.1)	2 (<0.1)	4 (<0.1)
Body dysmorphic disorder	0	2 (<0.1)	2 (<0.1)
Bulimia nervosa	3 (<0.1)	2 (<0.1)	5 (<0.1)
Depressed mood	2 (<0.1)	2 (<0.1)	4 (<0.1)
Menopausal depression	0	2 (<0.1)	2 (<0.1)
Premature ejaculation	0	2 (<0.1)	2 (<0.1)
Restlessness	2 (<0.1)	2 (<0.1)	4 (<0.1)
Schizoaffective disorder bipolar type	2 (<0.1)	2 (<0.1)	4 (<0.1)
Stress	3 (<0.1)	2 (<0.1)	5 (<0.1)
Substance use disorder	0	2 (<0.1)	2 (<0.1)
Tic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Trichotillomania	2 (<0.1)	2 (<0.1)	4 (<0.1)
Acrophobia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Acute stress disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Adjustment disorder	8 (<0.1)	1 (<0.1)	9 (<0.1)
Adjustment disorder with anxiety	3 (<0.1)	1 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Anorgasmia	0	1 (<0.1)	1 (<0.1)
Behaviour disorder	0	1 (<0.1)	1 (<0.1)
Claustrophobia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Cyclothymic disorder	0	1 (<0.1)	1 (<0.1)
Delusion	0	1 (<0.1)	1 (<0.1)
Delusion of parasitosis	0	1 (<0.1)	1 (<0.1)
Dermatillomania	0	1 (<0.1)	1 (<0.1)
Disruptive mood dysregulation disorder	0	1 (<0.1)	1 (<0.1)
Dysphemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Executive dysfunction	0	1 (<0.1)	1 (<0.1)
Hallucination, auditory	1 (<0.1)	1 (<0.1)	2 (<0.1)
Impulse-control disorder	0	1 (<0.1)	1 (<0.1)
Intentional self-injury	0	1 (<0.1)	1 (<0.1)
Intermittent explosive disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mania	1 (<0.1)	1 (<0.1)	2 (<0.1)
Middle insomnia	0	1 (<0.1)	1 (<0.1)
Paranoid personality disorder	0	1 (<0.1)	1 (<0.1)
Parasomnia	0	1 (<0.1)	1 (<0.1)
Personality disorder	0	1 (<0.1)	1 (<0.1)
Pseudodementia	0	1 (<0.1)	1 (<0.1)
Rapid eye movement sleep behaviour disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Selective eating disorder	0	1 (<0.1)	1 (<0.1)
Tobacco withdrawal symptoms	0	1 (<0.1)	1 (<0.1)
Anorexia nervosa	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Antisocial personality disorder	1 (<0.1)	0	1 (<0.1)
Breath holding	1 (<0.1)	0	1 (<0.1)
Conversion disorder	1 (<0.1)	0	1 (<0.1)
Emotional distress	1 (<0.1)	0	1 (<0.1)
Encopresis	1 (<0.1)	0	1 (<0.1)
Grief reaction	1 (<0.1)	0	1 (<0.1)
Hallucination	2 (<0.1)	0	2 (<0.1)
Impulsive behaviour	1 (<0.1)	0	1 (<0.1)
Irritability	1 (<0.1)	0	1 (<0.1)
Mental disorder	1 (<0.1)	0	1 (<0.1)
Nervousness	1 (<0.1)	0	1 (<0.1)
Paranoia	1 (<0.1)	0	1 (<0.1)
Psychiatric symptom	1 (<0.1)	0	1 (<0.1)
Psychogenic tremor	1 (<0.1)	0	1 (<0.1)
Somnambulism	1 (<0.1)	0	1 (<0.1)
Substance-induced mood disorder	1 (<0.1)	0	1 (<0.1)
Suicidal ideation	6 (<0.1)	0	6 (<0.1)
Tachyphrenia	1 (<0.1)	0	1 (<0.1)
Nervous system disorders	3090 (20.4)	3135 (20.6)	6225 (20.5)
Migraine	943 (6.2)	960 (6.3)	1903 (6.3)
Headache	887 (5.9)	862 (5.7)	1749 (5.8)
Carpal tunnel syndrome	176 (1.2)	175 (1.2)	351 (1.2)
Restless legs syndrome	160 (1.1)	162 (1.1)	322 (1.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Neuropathy peripheral	156 (1.0)	141 (0.9)	297 (1.0)
Sciatica	118 (0.8)	128 (0.8)	246 (0.8)
Tension headache	92 (0.6)	96 (0.6)	188 (0.6)
Diabetic neuropathy	97 (0.6)	89 (0.6)	186 (0.6)
Peripheral sensory neuropathy	84 (0.6)	80 (0.5)	164 (0.5)
Cerebrovascular accident	71 (0.5)	74 (0.5)	145 (0.5)
Transient ischaemic attack	55 (0.4)	63 (0.4)	118 (0.4)
Seizure	60 (0.4)	53 (0.3)	113 (0.4)
Tremor	25 (0.2)	44 (0.3)	69 (0.2)
Neuralgia	41 (0.3)	38 (0.3)	79 (0.3)
Essential tremor	40 (0.3)	37 (0.2)	77 (0.3)
Cervical radiculopathy	16 (0.1)	36 (0.2)	52 (0.2)
Sinus headache	39 (0.3)	34 (0.2)	73 (0.2)
Hypoaesthesia	32 (0.2)	33 (0.2)	65 (0.2)
Nerve compression	17 (0.1)	33 (0.2)	50 (0.2)
Facial paralysis	18 (0.1)	26 (0.2)	44 (0.1)
Migraine with aura	38 (0.3)	25 (0.2)	63 (0.2)
Amnesia	20 (0.1)	24 (0.2)	44 (0.1)
Narcolepsy	20 (0.1)	24 (0.2)	44 (0.1)
Dizziness	30 (0.2)	22 (0.1)	52 (0.2)
Syncope	29 (0.2)	22 (0.1)	51 (0.2)
Epilepsy	22 (0.1)	20 (0.1)	42 (0.1)
Radiculopathy	11 (<0.1)	20 (0.1)	31 (0.1)
Parkinson's disease	23 (0.2)	18 (0.1)	41 (0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Autonomic nervous system imbalance	10 (<0.1)	14 (<0.1)	24 (<0.1)
Anosmia	5 (<0.1)	12 (<0.1)	17 (<0.1)
Paraesthesia	17 (0.1)	12 (<0.1)	29 (<0.1)
Cluster headache	12 (<0.1)	11 (<0.1)	23 (<0.1)
Intracranial aneurysm	8 (<0.1)	11 (<0.1)	19 (<0.1)
Lumbar radiculopathy	12 (<0.1)	11 (<0.1)	23 (<0.1)
Trigeminal neuralgia	14 (<0.1)	11 (<0.1)	25 (<0.1)
Migraine without aura	15 (<0.1)	8 (<0.1)	23 (<0.1)
Multiple sclerosis	10 (<0.1)	8 (<0.1)	18 (<0.1)
Generalised tonic-clonic seizure	3 (<0.1)	7 (<0.1)	10 (<0.1)
Morton's neuralgia	11 (<0.1)	7 (<0.1)	18 (<0.1)
Post herpetic neuralgia	5 (<0.1)	7 (<0.1)	12 (<0.1)
Shift work disorder	5 (<0.1)	7 (<0.1)	12 (<0.1)
Carotid artery occlusion	4 (<0.1)	6 (<0.1)	10 (<0.1)
Carotid artery stenosis	9 (<0.1)	6 (<0.1)	15 (<0.1)
Hemiparesis	5 (<0.1)	6 (<0.1)	11 (<0.1)
Hypersomnia	5 (<0.1)	6 (<0.1)	11 (<0.1)
Idiopathic intracranial hypertension	3 (<0.1)	6 (<0.1)	9 (<0.1)
Peripheral motor neuropathy	6 (<0.1)	6 (<0.1)	12 (<0.1)
Peroneal nerve palsy	5 (<0.1)	6 (<0.1)	11 (<0.1)
Carotid arteriosclerosis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Carotid artery disease	6 (<0.1)	5 (<0.1)	11 (<0.1)
Dementia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)	7 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Petit mal epilepsy	4 (<0.1)	5 (<0.1)	9 (<0.1)
Presyncope	7 (<0.1)	5 (<0.1)	12 (<0.1)
Somnolence	6 (<0.1)	5 (<0.1)	11 (<0.1)
Ageusia	1 (<0.1)	4 (<0.1)	5 (<0.1)
Cerebral haemorrhage	3 (<0.1)	4 (<0.1)	7 (<0.1)
Cognitive disorder	8 (<0.1)	4 (<0.1)	12 (<0.1)
Cubital tunnel syndrome	8 (<0.1)	4 (<0.1)	12 (<0.1)
Dyskinesia	1 (<0.1)	4 (<0.1)	5 (<0.1)
Dystonia	5 (<0.1)	4 (<0.1)	9 (<0.1)
Ischaemic stroke	5 (<0.1)	4 (<0.1)	9 (<0.1)
Memory impairment	6 (<0.1)	4 (<0.1)	10 (<0.1)
Spinal cord compression	3 (<0.1)	4 (<0.1)	7 (<0.1)
Balance disorder	3 (<0.1)	3 (<0.1)	6 (<0.1)
Cerebral infarction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Complex regional pain syndrome	3 (<0.1)	3 (<0.1)	6 (<0.1)
Dementia Alzheimer's type	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hemiplegia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Hydrocephalus	2 (<0.1)	3 (<0.1)	5 (<0.1)
Intracranial pressure increased	4 (<0.1)	3 (<0.1)	7 (<0.1)
Myasthenia gravis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Nystagmus	3 (<0.1)	3 (<0.1)	6 (<0.1)
Peripheral sensorimotor neuropathy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Post-traumatic epilepsy	1 (<0.1)	3 (<0.1)	4 (<0.1)
Simple partial seizures	0	3 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Tarsal tunnel syndrome	2 (<0.1)	3 (<0.1)	5 (<0.1)
Thoracic outlet syndrome	6 (<0.1)	3 (<0.1)	9 (<0.1)
Aphasia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Cataplexy	0	2 (<0.1)	2 (<0.1)
Cerebrospinal fluid leakage	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cerebrovascular disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Circadian rhythm sleep disorder	0	2 (<0.1)	2 (<0.1)
Facial neuralgia	0	2 (<0.1)	2 (<0.1)
Haemorrhage intracranial	2 (<0.1)	2 (<0.1)	4 (<0.1)
Haemorrhagic stroke	0	2 (<0.1)	2 (<0.1)
Head titubation	0	2 (<0.1)	2 (<0.1)
Hyperreflexia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Intercostal neuralgia	0	2 (<0.1)	2 (<0.1)
Lumbosacral radiculopathy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mononeuropathy	0	2 (<0.1)	2 (<0.1)
Myoclonus	0	2 (<0.1)	2 (<0.1)
Neuralgic amyotrophy	0	2 (<0.1)	2 (<0.1)
Neuritis	0	2 (<0.1)	2 (<0.1)
Occipital neuralgia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Perineurial cyst	0	2 (<0.1)	2 (<0.1)
Periodic limb movement disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Pineal gland cyst	1 (<0.1)	2 (<0.1)	3 (<0.1)
Piriformis syndrome	2 (<0.1)	2 (<0.1)	4 (<0.1)
Transient global amnesia	2 (<0.1)	2 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Alcoholic seizure	0	1 (<0.1)	1 (<0.1)
Anaesthesia	0	1 (<0.1)	1 (<0.1)
Arachnoid cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Arachnoiditis	0	1 (<0.1)	1 (<0.1)
Aura	0	1 (<0.1)	1 (<0.1)
Axonal neuropathy	0	1 (<0.1)	1 (<0.1)
Brain injury	0	1 (<0.1)	1 (<0.1)
Brain oedema	0	1 (<0.1)	1 (<0.1)
Brain stem haemorrhage	0	1 (<0.1)	1 (<0.1)
Brown-Sequard syndrome	0	1 (<0.1)	1 (<0.1)
Carotid artery aneurysm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Carotid artery dissection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Carotid artery thrombosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cerebellar infarction	0	1 (<0.1)	1 (<0.1)
Cerebral atrophy	0	1 (<0.1)	1 (<0.1)
Cerebral cyst	0	1 (<0.1)	1 (<0.1)
Cerebrospinal fistula	0	1 (<0.1)	1 (<0.1)
Cervical cord compression	3 (<0.1)	1 (<0.1)	4 (<0.1)
Chronic paroxysmal hemicrania	0	1 (<0.1)	1 (<0.1)
Coma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cramp-fasciculation syndrome	0	1 (<0.1)	1 (<0.1)
Diabetic coma	0	1 (<0.1)	1 (<0.1)
Drug withdrawal headache	0	1 (<0.1)	1 (<0.1)
Dysgeusia	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Dyslexia	0	1 (<0.1)	1 (<0.1)
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Encephalopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Extrapyramidal disorder	0	1 (<0.1)	1 (<0.1)
Facial nerve disorder	0	1 (<0.1)	1 (<0.1)
Facial paresis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Facial spasm	3 (<0.1)	1 (<0.1)	4 (<0.1)
Febrile convulsion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Horner's syndrome	0	1 (<0.1)	1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
IIIrd nerve paralysis	1 (<0.1)	1 (<0.1)	2 (<0.1)
IVth nerve paralysis	0	1 (<0.1)	1 (<0.1)
Intention tremor	0	1 (<0.1)	1 (<0.1)
Irregular sleep phase	1 (<0.1)	1 (<0.1)	2 (<0.1)
Juvenile myoclonic epilepsy	0	1 (<0.1)	1 (<0.1)
Migrainous infarction	0	1 (<0.1)	1 (<0.1)
Mononeuritis	0	1 (<0.1)	1 (<0.1)
Motor dysfunction	0	1 (<0.1)	1 (<0.1)
Moyamoya disease	0	1 (<0.1)	1 (<0.1)
Multiple system atrophy	0	1 (<0.1)	1 (<0.1)
Muscle tension dysphonia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Optic neuritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pachymeningitis	0	1 (<0.1)	1 (<0.1)
Paralysis	3 (<0.1)	1 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Partial seizures	2 (<0.1)	1 (<0.1)	3 (<0.1)
Persistent postural-perceptual dizziness	0	1 (<0.1)	1 (<0.1)
Phantom limb syndrome	0	1 (<0.1)	1 (<0.1)
Phrenic nerve paralysis	0	1 (<0.1)	1 (<0.1)
Post polio syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Post-traumatic neuralgia	0	1 (<0.1)	1 (<0.1)
Primary cough headache	0	1 (<0.1)	1 (<0.1)
Primary progressive multiple sclerosis	0	1 (<0.1)	1 (<0.1)
Pronator teres syndrome	0	1 (<0.1)	1 (<0.1)
Radiculitis brachial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Resting tremor	0	1 (<0.1)	1 (<0.1)
Sensory loss	0	1 (<0.1)	1 (<0.1)
Sleep deficit	0	1 (<0.1)	1 (<0.1)
Small fibre neuropathy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Speech disorder	0	1 (<0.1)	1 (<0.1)
Subarachnoid haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Synkinesis	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Temporal lobe epilepsy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Transverse sinus thrombosis	0	1 (<0.1)	1 (<0.1)
Typical aura without headache	0	1 (<0.1)	1 (<0.1)
Ulnar tunnel syndrome	0	1 (<0.1)	1 (<0.1)
VIth nerve paralysis	0	1 (<0.1)	1 (<0.1)
Vocal cord paralysis	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Vocal cord paresis	0	1 (<0.1)	1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0	1 (<0.1)
Areflexia	1 (<0.1)	0	1 (<0.1)
Ataxia	1 (<0.1)	0	1 (<0.1)
Benign rolandic epilepsy	1 (<0.1)	0	1 (<0.1)
Cerebellar ataxia	1 (<0.1)	0	1 (<0.1)
Cerebellar stroke	1 (<0.1)	0	1 (<0.1)
Cerebral haematoma	1 (<0.1)	0	1 (<0.1)
Cerebral thrombosis	1 (<0.1)	0	1 (<0.1)
Cerebrovascular pseudoaneurysm	1 (<0.1)	0	1 (<0.1)
Cervical neuritis	1 (<0.1)	0	1 (<0.1)
Chorea	1 (<0.1)	0	1 (<0.1)
Delayed sleep phase	1 (<0.1)	0	1 (<0.1)
Diabetic autonomic neuropathy	1 (<0.1)	0	1 (<0.1)
Dizziness postural	2 (<0.1)	0	2 (<0.1)
Dysaesthesia	1 (<0.1)	0	1 (<0.1)
Dysarthria	1 (<0.1)	0	1 (<0.1)
Encephalitis haemorrhagic	1 (<0.1)	0	1 (<0.1)
Guillain-Barre syndrome	3 (<0.1)	0	3 (<0.1)
Hashimoto's encephalopathy	1 (<0.1)	0	1 (<0.1)
Hemiparaesthesia	1 (<0.1)	0	1 (<0.1)
Hepatic encephalopathy	1 (<0.1)	0	1 (<0.1)
Intensive care unit acquired weakness	1 (<0.1)	0	1 (<0.1)
Intraneural cyst	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Intraventricular haemorrhage	1 (<0.1)	0	1 (<0.1)
Lethargy	1 (<0.1)	0	1 (<0.1)
Loss of consciousness	1 (<0.1)	0	1 (<0.1)
Loss of proprioception	1 (<0.1)	0	1 (<0.1)
Lumbosacral plexopathy	1 (<0.1)	0	1 (<0.1)
Meralgia paraesthetica	1 (<0.1)	0	1 (<0.1)
Monoplegia	2 (<0.1)	0	2 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0	1 (<0.1)
Muscle spasticity	1 (<0.1)	0	1 (<0.1)
Myoclonic epilepsy	1 (<0.1)	0	1 (<0.1)
Nervous system disorder	1 (<0.1)	0	1 (<0.1)
Neurologic neglect syndrome	1 (<0.1)	0	1 (<0.1)
Neuromyopathy	1 (<0.1)	0	1 (<0.1)
Normal pressure hydrocephalus	1 (<0.1)	0	1 (<0.1)
Ophthalmoplegic migraine	1 (<0.1)	0	1 (<0.1)
Paraplegia	3 (<0.1)	0	3 (<0.1)
Parkinsonism	1 (<0.1)	0	1 (<0.1)
Poor quality sleep	3 (<0.1)	0	3 (<0.1)
Presenile dementia	1 (<0.1)	0	1 (<0.1)
Progressive multiple sclerosis	1 (<0.1)	0	1 (<0.1)
Pudendal canal syndrome	1 (<0.1)	0	1 (<0.1)
Retinal migraine	1 (<0.1)	0	1 (<0.1)
Sensory disturbance	1 (<0.1)	0	1 (<0.1)
Sensory processing disorder	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Spasmodic dysphonia	1 (<0.1)	0	1 (<0.1)
Taste disorder	1 (<0.1)	0	1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0	1 (<0.1)
Thunderclap headache	1 (<0.1)	0	1 (<0.1)
Vascular dementia	1 (<0.1)	0	1 (<0.1)
Vertebral artery dissection	3 (<0.1)	0	3 (<0.1)
Vestibular migraine	1 (<0.1)	0	1 (<0.1)
Vestibular nystagmus	1 (<0.1)	0	1 (<0.1)
Visual field defect	6 (<0.1)	0	6 (<0.1)
Eye disorders	2257 (14.9)	2308 (15.2)	4565 (15.0)
Myopia	695 (4.6)	697 (4.6)	1392 (4.6)
Cataract	549 (3.6)	529 (3.5)	1078 (3.6)
Hypermetropia	282 (1.9)	298 (2.0)	580 (1.9)
Presbyopia	252 (1.7)	278 (1.8)	530 (1.7)
Glaucoma	228 (1.5)	200 (1.3)	428 (1.4)
Dry eye	127 (0.8)	155 (1.0)	282 (0.9)
Astigmatism	105 (0.7)	105 (0.7)	210 (0.7)
Visual acuity reduced	106 (0.7)	101 (0.7)	207 (0.7)
Visual impairment	60 (0.4)	64 (0.4)	124 (0.4)
Macular degeneration	73 (0.5)	62 (0.4)	135 (0.4)
Retinal detachment	41 (0.3)	38 (0.3)	79 (0.3)
Strabismus	31 (0.2)	31 (0.2)	62 (0.2)
Retinal tear	12 (<0.1)	17 (0.1)	29 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Diabetic retinopathy	23 (0.2)	16 (0.1)	39 (0.1)
Amblyopia	10 (<0.1)	14 (<0.1)	24 (<0.1)
Blindness unilateral	12 (<0.1)	14 (<0.1)	26 (<0.1)
Eyelid ptosis	17 (0.1)	14 (<0.1)	31 (0.1)
Keratoconus	4 (<0.1)	14 (<0.1)	18 (<0.1)
Ocular hypertension	19 (0.1)	13 (<0.1)	32 (0.1)
Conjunctivitis allergic	6 (<0.1)	12 (<0.1)	18 (<0.1)
Vitreous detachment	8 (<0.1)	8 (<0.1)	16 (<0.1)
Diplopia	7 (<0.1)	7 (<0.1)	14 (<0.1)
Blepharitis	4 (<0.1)	6 (<0.1)	10 (<0.1)
Borderline glaucoma	7 (<0.1)	6 (<0.1)	13 (<0.1)
Retinopathy	4 (<0.1)	6 (<0.1)	10 (<0.1)
Uveitis	9 (<0.1)	6 (<0.1)	15 (<0.1)
Vision blurred	9 (<0.1)	6 (<0.1)	15 (<0.1)
Vitreous floaters	10 (<0.1)	6 (<0.1)	16 (<0.1)
Angle closure glaucoma	2 (<0.1)	5 (<0.1)	7 (<0.1)
Dacryostenosis acquired	3 (<0.1)	5 (<0.1)	8 (<0.1)
Dry age-related macular degeneration	3 (<0.1)	5 (<0.1)	8 (<0.1)
Macular oedema	5 (<0.1)	5 (<0.1)	10 (<0.1)
Pterygium	7 (<0.1)	5 (<0.1)	12 (<0.1)
Refraction disorder	1 (<0.1)	5 (<0.1)	6 (<0.1)
Age-related macular degeneration	3 (<0.1)	4 (<0.1)	7 (<0.1)
Eye pruritus	2 (<0.1)	4 (<0.1)	6 (<0.1)
Iridocyclitis	0	4 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Macular fibrosis	7 (<0.1)	4 (<0.1)	11 (<0.1)
Blepharospasm	3 (<0.1)	3 (<0.1)	6 (<0.1)
Chalazion	0	3 (<0.1)	3 (<0.1)
Conjunctival haemorrhage	0	3 (<0.1)	3 (<0.1)
Eczema eyelids	0	3 (<0.1)	3 (<0.1)
Eye haemorrhage	1 (<0.1)	3 (<0.1)	4 (<0.1)
Iritis	4 (<0.1)	3 (<0.1)	7 (<0.1)
Lacrimation increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Macular hole	5 (<0.1)	3 (<0.1)	8 (<0.1)
Normal tension glaucoma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Optic disc drusen	0	3 (<0.1)	3 (<0.1)
Optic ischaemic neuropathy	0	3 (<0.1)	3 (<0.1)
Posterior capsule opacification	1 (<0.1)	3 (<0.1)	4 (<0.1)
Retinal degeneration	1 (<0.1)	3 (<0.1)	4 (<0.1)
Blindness	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cataract nuclear	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chorioretinopathy	2 (<0.1)	2 (<0.1)	4 (<0.1)
Corneal disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Corneal opacity	1 (<0.1)	2 (<0.1)	3 (<0.1)
Endocrine ophthalmopathy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Eye disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Eye irritation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Meibomian gland dysfunction	0	2 (<0.1)	2 (<0.1)
Neovascular age-related macular degeneration	1 (<0.1)	2 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Ocular rosacea	2 (<0.1)	2 (<0.1)	4 (<0.1)
Open angle glaucoma	7 (<0.1)	2 (<0.1)	9 (<0.1)
Optic atrophy	0	2 (<0.1)	2 (<0.1)
Optic nerve disorder	0	2 (<0.1)	2 (<0.1)
Retinal drusen	2 (<0.1)	2 (<0.1)	4 (<0.1)
Retinal dystrophy	0	2 (<0.1)	2 (<0.1)
Retinal haemorrhage	0	2 (<0.1)	2 (<0.1)
Retinal oedema	1 (<0.1)	2 (<0.1)	3 (<0.1)
Retinal vein occlusion	4 (<0.1)	2 (<0.1)	6 (<0.1)
Scleritis	0	2 (<0.1)	2 (<0.1)
Ulcerative keratitis	0	2 (<0.1)	2 (<0.1)
Anisometropia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Aphakia	0	1 (<0.1)	1 (<0.1)
Arteriosclerotic retinopathy	0	1 (<0.1)	1 (<0.1)
Binocular eye movement disorder	0	1 (<0.1)	1 (<0.1)
Central vision loss	0	1 (<0.1)	1 (<0.1)
Choroidal neovascularisation	0	1 (<0.1)	1 (<0.1)
Conjunctival disorder	0	1 (<0.1)	1 (<0.1)
Corneal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Corneal perforation	0	1 (<0.1)	1 (<0.1)
Cortical visual impairment	0	1 (<0.1)	1 (<0.1)
Episcleritis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Extraocular muscle paresis	0	1 (<0.1)	1 (<0.1)
Eye allergy	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Eye inflammation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Eye swelling	0	1 (<0.1)	1 (<0.1)
Eyelid cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lacrimation decreased	0	1 (<0.1)	1 (<0.1)
Macular scar	0	1 (<0.1)	1 (<0.1)
Mydriasis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ocular discomfort	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ocular hyperaemia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ocular myasthenia	0	1 (<0.1)	1 (<0.1)
Ophthalmoplegia	0	1 (<0.1)	1 (<0.1)
Periorbital oedema	0	1 (<0.1)	1 (<0.1)
Photophobia	0	1 (<0.1)	1 (<0.1)
Pseudopapilloedema	0	1 (<0.1)	1 (<0.1)
Pupil fixed	0	1 (<0.1)	1 (<0.1)
Pupils unequal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Retinal artery occlusion	0	1 (<0.1)	1 (<0.1)
Retinal vascular disorder	0	1 (<0.1)	1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)	1 (<0.1)
Retinal vascular thrombosis	0	1 (<0.1)	1 (<0.1)
Retinopathy solar	0	1 (<0.1)	1 (<0.1)
Scintillating scotoma	0	1 (<0.1)	1 (<0.1)
Vitreous degeneration	0	1 (<0.1)	1 (<0.1)
Vitreous disorder	0	1 (<0.1)	1 (<0.1)
Vitreous haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Xerophthalmia	0	1 (<0.1)	1 (<0.1)
Antimetropia	1 (<0.1)	0	1 (<0.1)
Arcus lipoides	1 (<0.1)	0	1 (<0.1)
Cataract subcapsular	1 (<0.1)	0	1 (<0.1)
Conjunctival cyst	1 (<0.1)	0	1 (<0.1)
Conjunctival irritation	1 (<0.1)	0	1 (<0.1)
Corneal degeneration	1 (<0.1)	0	1 (<0.1)
Corneal neovascularisation	1 (<0.1)	0	1 (<0.1)
Corneal oedema	1 (<0.1)	0	1 (<0.1)
Corneal thinning	1 (<0.1)	0	1 (<0.1)
Dermatochalasis	3 (<0.1)	0	3 (<0.1)
Diabetic retinal oedema	1 (<0.1)	0	1 (<0.1)
Ectropion	2 (<0.1)	0	2 (<0.1)
Exfoliation glaucoma	1 (<0.1)	0	1 (<0.1)
Exophthalmos	1 (<0.1)	0	1 (<0.1)
Exposure keratitis	1 (<0.1)	0	1 (<0.1)
Eye movement disorder	1 (<0.1)	0	1 (<0.1)
Eye ulcer	1 (<0.1)	0	1 (<0.1)
Eyelid retraction	2 (<0.1)	0	2 (<0.1)
Keratitis	3 (<0.1)	0	3 (<0.1)
Keratitis interstitial	1 (<0.1)	0	1 (<0.1)
Lens disorder	1 (<0.1)	0	1 (<0.1)
Maculopathy	1 (<0.1)	0	1 (<0.1)
Meibomianitis	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Myopic chorioretinal degeneration	1 (<0.1)	0	1 (<0.1)
Optic nerve infarction	1 (<0.1)	0	1 (<0.1)
Papilloedema	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Photopsia	1 (<0.1)	0	1 (<0.1)
Pigment dispersion syndrome	2 (<0.1)	0	2 (<0.1)
Pigmentary glaucoma	1 (<0.1)	0	1 (<0.1)
Punctate keratitis	1 (<0.1)	0	1 (<0.1)
Pupillary disorder	1 (<0.1)	0	1 (<0.1)
Retinal disorder	2 (<0.1)	0	2 (<0.1)
Retinopathy of prematurity	3 (<0.1)	0	3 (<0.1)
Swelling of eyelid	1 (<0.1)	0	1 (<0.1)
Vitreoretinal traction syndrome	1 (<0.1)	0	1 (<0.1)
Vitreous adhesions	1 (<0.1)	0	1 (<0.1)
Ear and labyrinth disorders	658 (4.3)	648 (4.3)	1306 (4.3)
Tinnitus	207 (1.4)	167 (1.1)	374 (1.2)
Deafness bilateral	134 (0.9)	144 (0.9)	278 (0.9)
Vertigo	103 (0.7)	128 (0.8)	231 (0.8)
Deafness	102 (0.7)	86 (0.6)	188 (0.6)
Deafness unilateral	59 (0.4)	50 (0.3)	109 (0.4)
Hypoacusis	38 (0.3)	30 (0.2)	68 (0.2)
Meniere's disease	24 (0.2)	23 (0.2)	47 (0.2)
Vertigo positional	10 (<0.1)	15 (<0.1)	25 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Motion sickness	6 (<0.1)	14 (<0.1)	20 (<0.1)
Tympanic membrane perforation	14 (<0.1)	11 (<0.1)	25 (<0.1)
Deafness neurosensory	13 (<0.1)	9 (<0.1)	22 (<0.1)
Eustachian tube dysfunction	5 (<0.1)	9 (<0.1)	14 (<0.1)
Cerumen impaction	10 (<0.1)	5 (<0.1)	15 (<0.1)
Presbyacusis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Ear discomfort	2 (<0.1)	4 (<0.1)	6 (<0.1)
Excessive cerumen production	4 (<0.1)	4 (<0.1)	8 (<0.1)
Middle ear effusion	2 (<0.1)	4 (<0.1)	6 (<0.1)
Ear congestion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Ear pain	4 (<0.1)	2 (<0.1)	6 (<0.1)
Ear pruritus	1 (<0.1)	2 (<0.1)	3 (<0.1)
Otorrhoea	0	2 (<0.1)	2 (<0.1)
Otosclerosis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tympanic membrane scarring	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tympanosclerosis	0	2 (<0.1)	2 (<0.1)
Conductive deafness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ear disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Endolymphatic hydrops	0	1 (<0.1)	1 (<0.1)
Eustachian tube obstruction	0	1 (<0.1)	1 (<0.1)
Vestibular disorder	0	1 (<0.1)	1 (<0.1)
Auditory disorder	1 (<0.1)	0	1 (<0.1)
Deafness permanent	1 (<0.1)	0	1 (<0.1)
Ear deformity acquired	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Ear swelling	1 (<0.1)	0	1 (<0.1)
External ear disorder	1 (<0.1)	0	1 (<0.1)
Inner ear disorder	1 (<0.1)	0	1 (<0.1)
Cardiac disorders	1329 (8.8)	1298 (8.5)	2627 (8.7)
Atrial fibrillation	282 (1.9)	327 (2.2)	609 (2.0)
Coronary artery disease	344 (2.3)	322 (2.1)	666 (2.2)
Myocardial infarction	176 (1.2)	177 (1.2)	353 (1.2)
Bradycardia	83 (0.5)	64 (0.4)	147 (0.5)
Mitral valve prolapse	70 (0.5)	62 (0.4)	132 (0.4)
Supraventricular tachycardia	50 (0.3)	59 (0.4)	109 (0.4)
Arrhythmia	73 (0.5)	55 (0.4)	128 (0.4)
Tachycardia	43 (0.3)	55 (0.4)	98 (0.3)
Cardiac failure congestive	49 (0.3)	53 (0.3)	102 (0.3)
Angina pectoris	52 (0.3)	52 (0.3)	104 (0.3)
Ventricular extrasystoles	61 (0.4)	46 (0.3)	107 (0.4)
Palpitations	32 (0.2)	32 (0.2)	64 (0.2)
Cardiomyopathy	21 (0.1)	26 (0.2)	47 (0.2)
Arteriosclerosis coronary artery	22 (0.1)	16 (0.1)	38 (0.1)
Sinus tachycardia	15 (<0.1)	16 (0.1)	31 (0.1)
Cardiac failure	20 (0.1)	15 (<0.1)	35 (0.1)
Sinus bradycardia	19 (0.1)	14 (<0.1)	33 (0.1)
Bundle branch block right	11 (<0.1)	13 (<0.1)	24 (<0.1)
Mitral valve incompetence	24 (0.2)	12 (<0.1)	36 (0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Atrial flutter	16 (0.1)	11 (<0.1)	27 (<0.1)
Acute myocardial infarction	6 (<0.1)	9 (<0.1)	15 (<0.1)
Cardiovascular disorder	16 (0.1)	9 (<0.1)	25 (<0.1)
Bundle branch block left	13 (<0.1)	8 (<0.1)	21 (<0.1)
Supraventricular extrasystoles	16 (0.1)	8 (<0.1)	24 (<0.1)
Aortic valve stenosis	8 (<0.1)	7 (<0.1)	15 (<0.1)
Atrioventricular block	5 (<0.1)	7 (<0.1)	12 (<0.1)
Ventricular tachycardia	6 (<0.1)	7 (<0.1)	13 (<0.1)
Cardiac disorder	10 (<0.1)	6 (<0.1)	16 (<0.1)
Cardiomegaly	7 (<0.1)	6 (<0.1)	13 (<0.1)
Coronary artery occlusion	7 (<0.1)	6 (<0.1)	13 (<0.1)
Pericarditis	8 (<0.1)	6 (<0.1)	14 (<0.1)
Aortic valve disease	5 (<0.1)	5 (<0.1)	10 (<0.1)
Aortic valve incompetence	11 (<0.1)	5 (<0.1)	16 (<0.1)
Atrial tachycardia	7 (<0.1)	5 (<0.1)	12 (<0.1)
Atrioventricular block second degree	1 (<0.1)	5 (<0.1)	6 (<0.1)
Cardiac arrest	4 (<0.1)	5 (<0.1)	9 (<0.1)
Cardiac valve disease	4 (<0.1)	5 (<0.1)	9 (<0.1)
Congestive cardiomyopathy	2 (<0.1)	5 (<0.1)	7 (<0.1)
Myocardial ischaemia	3 (<0.1)	5 (<0.1)	8 (<0.1)
Postural orthostatic tachycardia syndrome	4 (<0.1)	5 (<0.1)	9 (<0.1)
Sinus node dysfunction	7 (<0.1)	5 (<0.1)	12 (<0.1)
Ventricular arrhythmia	2 (<0.1)	5 (<0.1)	7 (<0.1)
Pericardial effusion	0	4 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Stress cardiomyopathy	3 (<0.1)	4 (<0.1)	7 (<0.1)
Acute coronary syndrome	1 (<0.1)	3 (<0.1)	4 (<0.1)
Arteriospasm coronary	1 (<0.1)	3 (<0.1)	4 (<0.1)
Athletic heart syndrome	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cardiac failure chronic	3 (<0.1)	3 (<0.1)	6 (<0.1)
Heart valve incompetence	6 (<0.1)	3 (<0.1)	9 (<0.1)
Hypertensive heart disease	1 (<0.1)	3 (<0.1)	4 (<0.1)
Left ventricular failure	0	3 (<0.1)	3 (<0.1)
Microvascular coronary artery disease	0	3 (<0.1)	3 (<0.1)
Mitral valve stenosis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Tricuspid valve incompetence	4 (<0.1)	3 (<0.1)	7 (<0.1)
Wolff-Parkinson-White syndrome	5 (<0.1)	3 (<0.1)	8 (<0.1)
Bundle branch block	3 (<0.1)	2 (<0.1)	5 (<0.1)
Coronary artery dissection	0	2 (<0.1)	2 (<0.1)
Diastolic dysfunction	3 (<0.1)	2 (<0.1)	5 (<0.1)
Left ventricular enlargement	0	2 (<0.1)	2 (<0.1)
Left ventricular hypertrophy	6 (<0.1)	2 (<0.1)	8 (<0.1)
Mitral valve disease	4 (<0.1)	2 (<0.1)	6 (<0.1)
Rheumatic heart disease	0	2 (<0.1)	2 (<0.1)
Sinus arrhythmia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Tachyarrhythmia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Aortic valve disease mixed	0	1 (<0.1)	1 (<0.1)
Arrhythmia supraventricular	3 (<0.1)	1 (<0.1)	4 (<0.1)
Atrioventricular block complete	2 (<0.1)	1 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Atrioventricular block first degree	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bradyarrhythmia	0	1 (<0.1)	1 (<0.1)
Cardiac amyloidosis	0	1 (<0.1)	1 (<0.1)
Cardiac aneurysm	0	1 (<0.1)	1 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac septal hypertrophy	0	1 (<0.1)	1 (<0.1)
Chronic left ventricular failure	3 (<0.1)	1 (<0.1)	4 (<0.1)
Conduction disorder	0	1 (<0.1)	1 (<0.1)
Coronary artery thrombosis	0	1 (<0.1)	1 (<0.1)
Extrasystoles	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hypertensive cardiomyopathy	0	1 (<0.1)	1 (<0.1)
Ischaemic cardiomyopathy	3 (<0.1)	1 (<0.1)	4 (<0.1)
Left atrial dilatation	0	1 (<0.1)	1 (<0.1)
Left ventricular dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Long QT syndrome	0	1 (<0.1)	1 (<0.1)
Mitral valve calcification	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pericardial cyst	0	1 (<0.1)	1 (<0.1)
Pericardial fibrosis	0	1 (<0.1)	1 (<0.1)
Prinzmetal angina	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pulmonary valve incompetence	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pulmonary valve stenosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Silent myocardial infarction	0	1 (<0.1)	1 (<0.1)
Supravalvular aortic stenosis	0	1 (<0.1)	1 (<0.1)
Tachycardia paroxysmal	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Ventricular hypertrophy	0	1 (<0.1)	1 (<0.1)
Angina unstable	2 (<0.1)	0	2 (<0.1)
Bifascicular block	1 (<0.1)	0	1 (<0.1)
Cardiac tamponade	1 (<0.1)	0	1 (<0.1)
Chronotropic incompetence	1 (<0.1)	0	1 (<0.1)
Coronary artery embolism	1 (<0.1)	0	1 (<0.1)
Coronary artery stenosis	3 (<0.1)	0	3 (<0.1)
Myocardial calcification	1 (<0.1)	0	1 (<0.1)
Nonreassuring foetal heart rate pattern	1 (<0.1)	0	1 (<0.1)
Pericardial disease	1 (<0.1)	0	1 (<0.1)
Pleuropericarditis	1 (<0.1)	0	1 (<0.1)
Ventricular dysfunction	1 (<0.1)	0	1 (<0.1)
Ventricular dyssynchrony	1 (<0.1)	0	1 (<0.1)
Ventricular fibrillation	3 (<0.1)	0	3 (<0.1)
Vascular disorders	4861 (32.1)	4824 (31.8)	9685 (31.9)
Hypertension	4503 (29.7)	4449 (29.3)	8952 (29.5)
Hot flush	137 (0.9)	134 (0.9)	271 (0.9)
Deep vein thrombosis	78 (0.5)	68 (0.4)	146 (0.5)
Varicose vein	45 (0.3)	68 (0.4)	113 (0.4)
Raynaud's phenomenon	34 (0.2)	41 (0.3)	75 (0.2)
Aortic aneurysm	26 (0.2)	35 (0.2)	61 (0.2)
Essential hypertension	35 (0.2)	35 (0.2)	70 (0.2)
Peripheral vascular disorder	11 (<0.1)	33 (0.2)	44 (0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Arteriosclerosis	22 (0.1)	23 (0.2)	45 (0.1)
Lymphoedema	20 (0.1)	22 (0.1)	42 (0.1)
Peripheral venous disease	15 (<0.1)	21 (0.1)	36 (0.1)
White coat hypertension	17 (0.1)	21 (0.1)	38 (0.1)
Thrombosis	24 (0.2)	20 (0.1)	44 (0.1)
Aortic arteriosclerosis	12 (<0.1)	15 (<0.1)	27 (<0.1)
Peripheral arterial occlusive disease	14 (<0.1)	14 (<0.1)	28 (<0.1)
Aortic stenosis	19 (0.1)	13 (<0.1)	32 (0.1)
Hypotension	11 (<0.1)	13 (<0.1)	24 (<0.1)
Prehypertension	16 (0.1)	12 (<0.1)	28 (<0.1)
Aortic dilatation	5 (<0.1)	10 (<0.1)	15 (<0.1)
Arterial occlusive disease	3 (<0.1)	6 (<0.1)	9 (<0.1)
Orthostatic hypotension	6 (<0.1)	6 (<0.1)	12 (<0.1)
Intermittent claudication	0	4 (<0.1)	4 (<0.1)
Poor peripheral circulation	3 (<0.1)	4 (<0.1)	7 (<0.1)
Aneurysm	4 (<0.1)	3 (<0.1)	7 (<0.1)
Haemorrhage	6 (<0.1)	3 (<0.1)	9 (<0.1)
Aortic dissection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Malignant hypertension	2 (<0.1)	2 (<0.1)	4 (<0.1)
Orthostatic hypertension	0	2 (<0.1)	2 (<0.1)
Peripheral artery occlusion	0	2 (<0.1)	2 (<0.1)
Aneurysm ruptured	0	1 (<0.1)	1 (<0.1)
Angiopathy	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Arterial disorder	0	1 (<0.1)	1 (<0.1)
Arterial stenosis	0	1 (<0.1)	1 (<0.1)
Arteriovenous fistula	1 (<0.1)	1 (<0.1)	2 (<0.1)
Brachiocephalic artery stenosis	0	1 (<0.1)	1 (<0.1)
Embolism	1 (<0.1)	1 (<0.1)	2 (<0.1)
Embolism arterial	0	1 (<0.1)	1 (<0.1)
Granulomatosis with polyangiitis	0	1 (<0.1)	1 (<0.1)
Haematoma	7 (<0.1)	1 (<0.1)	8 (<0.1)
Kawasaki's disease	0	1 (<0.1)	1 (<0.1)
Labile hypertension	5 (<0.1)	1 (<0.1)	6 (<0.1)
May-Thurner syndrome	0	1 (<0.1)	1 (<0.1)
Microangiopathy	0	1 (<0.1)	1 (<0.1)
Phlebitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Secondary hypertension	1 (<0.1)	1 (<0.1)	2 (<0.1)
Subclavian artery stenosis	0	1 (<0.1)	1 (<0.1)
Subclavian vein occlusion	0	1 (<0.1)	1 (<0.1)
Systolic hypertension	1 (<0.1)	1 (<0.1)	2 (<0.1)
Temporal arteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thrombophlebitis	4 (<0.1)	1 (<0.1)	5 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vascular insufficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Venous thrombosis	0	1 (<0.1)	1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)	1 (<0.1)
Aortic aneurysm rupture	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Aortic occlusion	1 (<0.1)	0	1 (<0.1)
Aortic rupture	1 (<0.1)	0	1 (<0.1)
Arteritis	1 (<0.1)	0	1 (<0.1)
Behcet's syndrome	1 (<0.1)	0	1 (<0.1)
Bleeding varicose vein	1 (<0.1)	0	1 (<0.1)
Coeliac artery occlusion	1 (<0.1)	0	1 (<0.1)
Diastolic hypertension	1 (<0.1)	0	1 (<0.1)
Embolism venous	1 (<0.1)	0	1 (<0.1)
Flushing	1 (<0.1)	0	1 (<0.1)
Jugular vein thrombosis	1 (<0.1)	0	1 (<0.1)
Labile blood pressure	2 (<0.1)	0	2 (<0.1)
Neovascularisation	1 (<0.1)	0	1 (<0.1)
Pallor	1 (<0.1)	0	1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0	1 (<0.1)
Peripheral artery dissection	1 (<0.1)	0	1 (<0.1)
Peripheral artery stenosis	1 (<0.1)	0	1 (<0.1)
Peripheral coldness	1 (<0.1)	0	1 (<0.1)
Phlebitis superficial	1 (<0.1)	0	1 (<0.1)
Poor venous access	2 (<0.1)	0	2 (<0.1)
Spider vein	3 (<0.1)	0	3 (<0.1)
Steal syndrome	1 (<0.1)	0	1 (<0.1)
Vascular compression	1 (<0.1)	0	1 (<0.1)
Vascular shunt	1 (<0.1)	0	1 (<0.1)
Vein rupture	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders	2961 (19.5)	2960 (19.5)	5921 (19.5)
Asthma	1342 (8.9)	1327 (8.7)	2669 (8.8)
Sleep apnoea syndrome	583 (3.8)	634 (4.2)	1217 (4.0)
Rhinitis allergic	421 (2.8)	416 (2.7)	837 (2.8)
Chronic obstructive pulmonary disease	265 (1.7)	262 (1.7)	527 (1.7)
Nasal septum deviation	139 (0.9)	147 (1.0)	286 (0.9)
Asthma exercise induced	58 (0.4)	59 (0.4)	117 (0.4)
Cough	60 (0.4)	58 (0.4)	118 (0.4)
Pulmonary embolism	50 (0.3)	58 (0.4)	108 (0.4)
Rhinitis perennial	47 (0.3)	46 (0.3)	93 (0.3)
Sinus congestion	63 (0.4)	44 (0.3)	107 (0.4)
Nasal congestion	36 (0.2)	43 (0.3)	79 (0.3)
Emphysema	44 (0.3)	38 (0.3)	82 (0.3)
Dyspnoea	32 (0.2)	36 (0.2)	68 (0.2)
Epistaxis	19 (0.1)	29 (0.2)	48 (0.2)
Bronchitis chronic	42 (0.3)	28 (0.2)	70 (0.2)
Childhood asthma	25 (0.2)	23 (0.2)	48 (0.2)
Nasal polyps	28 (0.2)	23 (0.2)	51 (0.2)
Upper-airway cough syndrome	37 (0.2)	22 (0.1)	59 (0.2)
Bronchial hyperreactivity	30 (0.2)	18 (0.1)	48 (0.2)
Pneumothorax	18 (0.1)	14 (<0.1)	32 (0.1)
Pulmonary hypertension	15 (<0.1)	14 (<0.1)	29 (<0.1)
Rhinorrhoea	11 (<0.1)	14 (<0.1)	25 (<0.1)
Bronchospasm	5 (<0.1)	12 (<0.1)	17 (<0.1)
Bronchiectasis	9 (<0.1)	11 (<0.1)	20 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary mass	13 (<0.1)	11 (<0.1)	24 (<0.1)
Tonsillar hypertrophy	12 (<0.1)	10 (<0.1)	22 (<0.1)
Oropharyngeal pain	4 (<0.1)	8 (<0.1)	12 (<0.1)
Vasomotor rhinitis	7 (<0.1)	7 (<0.1)	14 (<0.1)
Wheezing	12 (<0.1)	7 (<0.1)	19 (<0.1)
Allergic cough	2 (<0.1)	6 (<0.1)	8 (<0.1)
Allergic sinusitis	2 (<0.1)	6 (<0.1)	8 (<0.1)
Dysphonia	6 (<0.1)	6 (<0.1)	12 (<0.1)
Dyspnoea exertional	3 (<0.1)	6 (<0.1)	9 (<0.1)
Adenoidal hypertrophy	3 (<0.1)	5 (<0.1)	8 (<0.1)
Idiopathic pulmonary fibrosis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Nasal obstruction	2 (<0.1)	5 (<0.1)	7 (<0.1)
Pulmonary fibrosis	6 (<0.1)	5 (<0.1)	11 (<0.1)
Sinus polyp	6 (<0.1)	5 (<0.1)	11 (<0.1)
Snoring	7 (<0.1)	5 (<0.1)	12 (<0.1)
Nasal turbinate hypertrophy	3 (<0.1)	4 (<0.1)	7 (<0.1)
Pleural effusion	2 (<0.1)	4 (<0.1)	6 (<0.1)
Respiratory tract congestion	2 (<0.1)	4 (<0.1)	6 (<0.1)
Diaphragmatic paralysis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Hypoxia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Interstitial lung disease	4 (<0.1)	3 (<0.1)	7 (<0.1)
Pleurisy	6 (<0.1)	3 (<0.1)	9 (<0.1)
Pulmonary arterial hypertension	0	3 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Reflux laryngitis	6 (<0.1)	3 (<0.1)	9 (<0.1)
Restrictive pulmonary disease	3 (<0.1)	3 (<0.1)	6 (<0.1)
Tonsillolith	2 (<0.1)	3 (<0.1)	5 (<0.1)
Vocal cord disorder	2 (<0.1)	3 (<0.1)	5 (<0.1)
Vocal cord thickening	1 (<0.1)	3 (<0.1)	4 (<0.1)
Asthma late onset	2 (<0.1)	2 (<0.1)	4 (<0.1)
Cough variant asthma	4 (<0.1)	2 (<0.1)	6 (<0.1)
Laryngospasm	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lung disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Nasal dryness	3 (<0.1)	2 (<0.1)	5 (<0.1)
Nasal septum perforation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Obstructive airways disorder	3 (<0.1)	2 (<0.1)	5 (<0.1)
Paranasal cyst	2 (<0.1)	2 (<0.1)	4 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pneumothorax spontaneous	6 (<0.1)	2 (<0.1)	8 (<0.1)
Pulmonary thrombosis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sinonasal obstruction	0	2 (<0.1)	2 (<0.1)
Sinus disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Throat irritation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tonsillar disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vocal cord atrophy	0	2 (<0.1)	2 (<0.1)
Acquired diaphragmatic eventration	0	1 (<0.1)	1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Acute respiratory failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergic bronchitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Aspirin-exacerbated respiratory disease	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cystic lung disease	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eosinophilic pneumonia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Haemothorax	0	1 (<0.1)	1 (<0.1)
Hiccups	1 (<0.1)	1 (<0.1)	2 (<0.1)
Laryngeal polyp	0	1 (<0.1)	1 (<0.1)
Lung cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meconium aspiration syndrome	0	1 (<0.1)	1 (<0.1)
Nasal septum disorder	0	1 (<0.1)	1 (<0.1)
Organising pneumonia	0	1 (<0.1)	1 (<0.1)
Oropharyngeal spasm	0	1 (<0.1)	1 (<0.1)
Pharyngeal cyst	0	1 (<0.1)	1 (<0.1)
Pharyngeal mass	0	1 (<0.1)	1 (<0.1)
Pharyngeal ulceration	0	1 (<0.1)	1 (<0.1)
Pleural adhesion	0	1 (<0.1)	1 (<0.1)
Pneumonitis	0	1 (<0.1)	1 (<0.1)
Productive cough	3 (<0.1)	1 (<0.1)	4 (<0.1)
Pulmonary granuloma	0	1 (<0.1)	1 (<0.1)
Pulmonary haemorrhage	0	1 (<0.1)	1 (<0.1)
Pulmonary microemboli	0	1 (<0.1)	1 (<0.1)
Pulmonary oedema	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary pain	0	1 (<0.1)	1 (<0.1)
Pulmonary sarcoidosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Respiratory disorder	0	1 (<0.1)	1 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stridor	0	1 (<0.1)	1 (<0.1)
Tachypnoea	0	1 (<0.1)	1 (<0.1)
Throat lesion	0	1 (<0.1)	1 (<0.1)
Tracheal stenosis	0	1 (<0.1)	1 (<0.1)
Tracheomalacia	0	1 (<0.1)	1 (<0.1)
Upper airway resistance syndrome	0	1 (<0.1)	1 (<0.1)
Velopharyngeal incompetence	0	1 (<0.1)	1 (<0.1)
Vocal cord dysfunction	4 (<0.1)	1 (<0.1)	5 (<0.1)
Vocal cord polyp	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergic respiratory disease	1 (<0.1)	0	1 (<0.1)
Aspiration	1 (<0.1)	0	1 (<0.1)
Asthma-chronic obstructive pulmonary disease overlap syndrome	3 (<0.1)	0	3 (<0.1)
Atelectasis	3 (<0.1)	0	3 (<0.1)
Hypopnoea	2 (<0.1)	0	2 (<0.1)
Laryngeal stenosis	1 (<0.1)	0	1 (<0.1)
Nasal cyst	1 (<0.1)	0	1 (<0.1)
Nasal disorder	1 (<0.1)	0	1 (<0.1)
Nasal mucosal disorder	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Paranasal sinus hypersecretion	1 (<0.1)	0	1 (<0.1)
Pharyngeal inflammation	1 (<0.1)	0	1 (<0.1)
Pharyngeal stenosis	1 (<0.1)	0	1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0	1 (<0.1)
Pulmonary toxicity	1 (<0.1)	0	1 (<0.1)
Reactive airways dysfunction syndrome	1 (<0.1)	0	1 (<0.1)
Sinus pain	2 (<0.1)	0	2 (<0.1)
Sneezing	1 (<0.1)	0	1 (<0.1)
Throat tightness	1 (<0.1)	0	1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Upper airway obstruction	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorders	3814 (25.2)	3980 (26.2)	7794 (25.7)
Gastrooesophageal reflux disease	2209 (14.6)	2326 (15.3)	4535 (14.9)
Dyspepsia	311 (2.1)	364 (2.4)	675 (2.2)
Irritable bowel syndrome	267 (1.8)	318 (2.1)	585 (1.9)
Constipation	271 (1.8)	258 (1.7)	529 (1.7)
Inguinal hernia	245 (1.6)	239 (1.6)	484 (1.6)
Haemorrhoids	151 (1.0)	150 (1.0)	301 (1.0)
Umbilical hernia	106 (0.7)	131 (0.9)	237 (0.8)
Tooth impacted	103 (0.7)	122 (0.8)	225 (0.7)
Hiatus hernia	123 (0.8)	107 (0.7)	230 (0.8)
Large intestine polyp	96 (0.6)	104 (0.7)	200 (0.7)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Diverticulum	92 (0.6)	71 (0.5)	163 (0.5)
Nausea	49 (0.3)	64 (0.4)	113 (0.4)
Diarrhoea	68 (0.4)	58 (0.4)	126 (0.4)
Abdominal hernia	63 (0.4)	49 (0.3)	112 (0.4)
Gastric ulcer	45 (0.3)	47 (0.3)	92 (0.3)
Gastritis	59 (0.4)	45 (0.3)	104 (0.3)
Barrett's oesophagus	36 (0.2)	42 (0.3)	78 (0.3)
Dental caries	36 (0.2)	40 (0.3)	76 (0.3)
Coeliac disease	31 (0.2)	29 (0.2)	60 (0.2)
Colitis ulcerative	35 (0.2)	29 (0.2)	64 (0.2)
Toothache	19 (0.1)	24 (0.2)	43 (0.1)
Crohn's disease	18 (0.1)	22 (0.1)	40 (0.1)
Peptic ulcer	13 (<0.1)	21 (0.1)	34 (0.1)
Abdominal pain	17 (0.1)	19 (0.1)	36 (0.1)
Colitis	14 (<0.1)	17 (0.1)	31 (0.1)
Dysphagia	19 (0.1)	16 (0.1)	35 (0.1)
Pancreatitis	17 (0.1)	15 (<0.1)	32 (0.1)
Colitis microscopic	8 (<0.1)	14 (<0.1)	22 (<0.1)
Dry mouth	10 (<0.1)	13 (<0.1)	23 (<0.1)
Flatulence	7 (<0.1)	13 (<0.1)	20 (<0.1)
Impaired gastric emptying	15 (<0.1)	12 (<0.1)	27 (<0.1)
Anal fissure	6 (<0.1)	11 (<0.1)	17 (<0.1)
Aphthous ulcer	9 (<0.1)	11 (<0.1)	20 (<0.1)
Oesophagitis	13 (<0.1)	11 (<0.1)	24 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastrointestinal haemorrhage	9 (<0.1)	10 (<0.1)	19 (<0.1)
Small intestinal obstruction	10 (<0.1)	10 (<0.1)	20 (<0.1)
Abdominal distension	2 (<0.1)	9 (<0.1)	11 (<0.1)
Intestinal obstruction	15 (<0.1)	9 (<0.1)	24 (<0.1)
Poor dental condition	4 (<0.1)	9 (<0.1)	13 (<0.1)
Abdominal pain upper	8 (<0.1)	8 (<0.1)	16 (<0.1)
Tooth loss	13 (<0.1)	8 (<0.1)	21 (<0.1)
Chronic gastritis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mouth ulceration	16 (0.1)	7 (<0.1)	23 (<0.1)
Oesophageal stenosis	6 (<0.1)	7 (<0.1)	13 (<0.1)
Abdominal adhesions	6 (<0.1)	6 (<0.1)	12 (<0.1)
Periodontal disease	7 (<0.1)	6 (<0.1)	13 (<0.1)
Tooth disorder	3 (<0.1)	6 (<0.1)	9 (<0.1)
Abdominal discomfort	9 (<0.1)	5 (<0.1)	14 (<0.1)
Abdominal pain lower	5 (<0.1)	5 (<0.1)	10 (<0.1)
Acquired oesophageal web	3 (<0.1)	5 (<0.1)	8 (<0.1)
Anal incontinence	1 (<0.1)	5 (<0.1)	6 (<0.1)
Diverticulum intestinal	10 (<0.1)	5 (<0.1)	15 (<0.1)
Eosinophilic oesophagitis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Haematochezia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Volvulus	6 (<0.1)	5 (<0.1)	11 (<0.1)
Duodenal ulcer	8 (<0.1)	4 (<0.1)	12 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	4 (<0.1)	5 (<0.1)
Gingival recession	4 (<0.1)	4 (<0.1)	8 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Pancreatic cyst	4 (<0.1)	4 (<0.1)	8 (<0.1)
Rectal prolapse	3 (<0.1)	4 (<0.1)	7 (<0.1)
Salivary gland cyst	3 (<0.1)	4 (<0.1)	7 (<0.1)
Anal fistula	10 (<0.1)	3 (<0.1)	13 (<0.1)
Anogenital dysplasia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Erosive oesophagitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Intestinal polyp	0	3 (<0.1)	3 (<0.1)
Large intestine perforation	4 (<0.1)	3 (<0.1)	7 (<0.1)
Malpositioned teeth	1 (<0.1)	3 (<0.1)	4 (<0.1)
Oesophageal spasm	7 (<0.1)	3 (<0.1)	10 (<0.1)
Short-bowel syndrome	0	3 (<0.1)	3 (<0.1)
Abdominal wall cyst	0	2 (<0.1)	2 (<0.1)
Burning mouth syndrome	2 (<0.1)	2 (<0.1)	4 (<0.1)
Duodenitis	0	2 (<0.1)	2 (<0.1)
Femoral hernia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Gastrointestinal ulcer haemorrhage	0	2 (<0.1)	2 (<0.1)
Inflammatory bowel disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Intestinal metaplasia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Malocclusion	3 (<0.1)	2 (<0.1)	5 (<0.1)
Oesophageal dilatation	5 (<0.1)	2 (<0.1)	7 (<0.1)
Oesophageal ulcer	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oral pain	4 (<0.1)	2 (<0.1)	6 (<0.1)
Pancreatitis acute	2 (<0.1)	2 (<0.1)	4 (<0.1)
Pancreatitis chronic	2 (<0.1)	2 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Portal hypertensive gastropathy	0	2 (<0.1)	2 (<0.1)
Proctitis ulcerative	0	2 (<0.1)	2 (<0.1)
Tongue discolouration	0	2 (<0.1)	2 (<0.1)
Varices oesophageal	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vomiting	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abdominal rigidity	0	1 (<0.1)	1 (<0.1)
Abdominal tenderness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Aerophagia	0	1 (<0.1)	1 (<0.1)
Anal polyp	0	1 (<0.1)	1 (<0.1)
Angular cheilitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anorectal stenosis	0	1 (<0.1)	1 (<0.1)
Ascites	0	1 (<0.1)	1 (<0.1)
Bile acid malabsorption	1 (<0.1)	1 (<0.1)	2 (<0.1)
Coeliac artery aneurysm	0	1 (<0.1)	1 (<0.1)
Dental cyst	0	1 (<0.1)	1 (<0.1)
Diabetic gastroparesis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Diverticulum oesophageal	0	1 (<0.1)	1 (<0.1)
Ectopic gastric mucosa	0	1 (<0.1)	1 (<0.1)
Enlarged uvula	0	1 (<0.1)	1 (<0.1)
Enterovesical fistula	0	1 (<0.1)	1 (<0.1)
Epigastric discomfort	0	1 (<0.1)	1 (<0.1)
Epiploic appendagitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eructation	0	1 (<0.1)	1 (<0.1)
Food poisoning	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gallstone ileus	0	1 (<0.1)	1 (<0.1)
Gastric fistula	0	1 (<0.1)	1 (<0.1)
Gastric haemorrhage	0	1 (<0.1)	1 (<0.1)
Gastric hypomotility	0	1 (<0.1)	1 (<0.1)
Gastric perforation	0	1 (<0.1)	1 (<0.1)
Gastric polyps	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastritis erosive	0	1 (<0.1)	1 (<0.1)
Gastrointestinal hypomotility	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal inflammation	0	1 (<0.1)	1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrointestinal necrosis	0	1 (<0.1)	1 (<0.1)
Gastrointestinal pain	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gastrointestinal ulcer	3 (<0.1)	1 (<0.1)	4 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Gingival cyst	0	1 (<0.1)	1 (<0.1)
Gingival swelling	0	1 (<0.1)	1 (<0.1)
Haemorrhoidal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Haemorrhoids thrombosed	0	1 (<0.1)	1 (<0.1)
Hyperaesthesia teeth	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hyperchlorhydria	2 (<0.1)	1 (<0.1)	3 (<0.1)
Incarcerated umbilical hernia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Internal hernia	0	1 (<0.1)	1 (<0.1)
Intestinal dilatation	0	1 (<0.1)	1 (<0.1)
Intestinal ischaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Intestinal mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intestinal perforation	3 (<0.1)	1 (<0.1)	4 (<0.1)
Intestinal strangulation	0	1 (<0.1)	1 (<0.1)
Intestinal ulcer	0	1 (<0.1)	1 (<0.1)
Intussusception	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestinal stenosis	0	1 (<0.1)	1 (<0.1)
Leukoplakia oral	0	1 (<0.1)	1 (<0.1)
Lip disorder	0	1 (<0.1)	1 (<0.1)
Lower gastrointestinal haemorrhage	0	1 (<0.1)	1 (<0.1)
Lumbar hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Malabsorption	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mesenteric artery aneurysm	0	1 (<0.1)	1 (<0.1)
Obstructive pancreatitis	0	1 (<0.1)	1 (<0.1)
Oesophageal haemorrhage	0	1 (<0.1)	1 (<0.1)
Oesophageal ulcer perforation	0	1 (<0.1)	1 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oral lichen planus	0	1 (<0.1)	1 (<0.1)
Pancreatic atrophy	0	1 (<0.1)	1 (<0.1)
Pancreatic mass	0	1 (<0.1)	1 (<0.1)
Parotid duct obstruction	0	1 (<0.1)	1 (<0.1)
Parotid gland enlargement	0	1 (<0.1)	1 (<0.1)
Pelvic floor dysfunction	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pharyngo-oesophageal diverticulum	1 (<0.1)	1 (<0.1)	2 (<0.1)
Precancerous lesion of digestive tract	3 (<0.1)	1 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Proctitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Rectal fissure	0	1 (<0.1)	1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rectal polyp	2 (<0.1)	1 (<0.1)	3 (<0.1)
Rectal spasm	0	1 (<0.1)	1 (<0.1)
Reflux gastritis	0	1 (<0.1)	1 (<0.1)
Salivary duct obstruction	0	1 (<0.1)	1 (<0.1)
Salivary gland enlargement	1 (<0.1)	1 (<0.1)	2 (<0.1)
Salivary gland mucocoele	0	1 (<0.1)	1 (<0.1)
Small intestinal haemorrhage	0	1 (<0.1)	1 (<0.1)
Spigelian hernia	0	1 (<0.1)	1 (<0.1)
Splenic artery aneurysm	1 (<0.1)	1 (<0.1)	2 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tongue cyst	0	1 (<0.1)	1 (<0.1)
Tongue oedema	0	1 (<0.1)	1 (<0.1)
Tongue ulceration	0	1 (<0.1)	1 (<0.1)
Tooth ankylosis	0	1 (<0.1)	1 (<0.1)
Abdominal fat apron	1 (<0.1)	0	1 (<0.1)
Abdominal migraine	2 (<0.1)	0	2 (<0.1)
Abdominal rebound tenderness	1 (<0.1)	0	1 (<0.1)
Anal pruritus	1 (<0.1)	0	1 (<0.1)
Anorectal disorder	1 (<0.1)	0	1 (<0.1)
Appendicitis noninfective	2 (<0.1)	0	2 (<0.1)
Bowel movement irregularity	4 (<0.1)	0	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Colon dysplasia	1 (<0.1)	0	1 (<0.1)
Cyclic vomiting syndrome	2 (<0.1)	0	2 (<0.1)
Dental plaque	1 (<0.1)	0	1 (<0.1)
Diaphragmatic hernia	2 (<0.1)	0	2 (<0.1)
Diastema	1 (<0.1)	0	1 (<0.1)
Diverticular perforation	1 (<0.1)	0	1 (<0.1)
Dumping syndrome	3 (<0.1)	0	3 (<0.1)
Duodenogastric reflux	1 (<0.1)	0	1 (<0.1)
Dysbiosis	1 (<0.1)	0	1 (<0.1)
Enteritis	1 (<0.1)	0	1 (<0.1)
Enterocele	1 (<0.1)	0	1 (<0.1)
Faeces discoloured	1 (<0.1)	0	1 (<0.1)
Gastric ulcer perforation	1 (<0.1)	0	1 (<0.1)
Gastritis hypertrophic	1 (<0.1)	0	1 (<0.1)
Gastroduodenal ulcer	1 (<0.1)	0	1 (<0.1)
Gastrointestinal disorder	3 (<0.1)	0	3 (<0.1)
Gastrointestinal toxicity	1 (<0.1)	0	1 (<0.1)
Gastrointestinal vascular malformation haemorrhagic	1 (<0.1)	0	1 (<0.1)
Gingival disorder	1 (<0.1)	0	1 (<0.1)
Haemoperitoneum	1 (<0.1)	0	1 (<0.1)
Hypoaesthesia oral	1 (<0.1)	0	1 (<0.1)
Infrequent bowel movements	1 (<0.1)	0	1 (<0.1)
Inguinal hernia perforation	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Intestinal cyst	1 (<0.1)	0	1 (<0.1)
Intestinal varices	1 (<0.1)	0	1 (<0.1)
Large intestinal obstruction	2 (<0.1)	0	2 (<0.1)
Lip swelling	1 (<0.1)	0	1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0	1 (<0.1)
Noninfective sialoadenitis	1 (<0.1)	0	1 (<0.1)
Oesophageal disorder	2 (<0.1)	0	2 (<0.1)
Oesophageal pain	1 (<0.1)	0	1 (<0.1)
Pancreatic failure	4 (<0.1)	0	4 (<0.1)
Peritoneal cyst	1 (<0.1)	0	1 (<0.1)
Peritoneal disorder	1 (<0.1)	0	1 (<0.1)
Regurgitation	1 (<0.1)	0	1 (<0.1)
Salivary gland calculus	5 (<0.1)	0	5 (<0.1)
Salivary hypersecretion	1 (<0.1)	0	1 (<0.1)
Small intestinal perforation	1 (<0.1)	0	1 (<0.1)
Supernumerary teeth	1 (<0.1)	0	1 (<0.1)
Terminal ileitis	1 (<0.1)	0	1 (<0.1)
Tongue movement disturbance	1 (<0.1)	0	1 (<0.1)
Upper gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Uvulitis	1 (<0.1)	0	1 (<0.1)
Hepatobiliary disorders	778 (5.1)	685 (4.5)	1463 (4.8)
Cholelithiasis	337 (2.2)	335 (2.2)	672 (2.2)
Cholecystitis	229 (1.5)	192 (1.3)	421 (1.4)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)			
Hepatic steatosis	83 (0.5)	59 (0.4)	142 (0.5)
Gallbladder disorder	41 (0.3)	31 (0.2)	72 (0.2)
Nonalcoholic fatty liver disease	17 (0.1)	20 (0.1)	37 (0.1)
Hepatic cirrhosis	8 (<0.1)	17 (0.1)	25 (<0.1)
Cholecystitis acute	14 (<0.1)	15 (<0.1)	29 (<0.1)
Non-alcoholic steatohepatitis	17 (0.1)	13 (<0.1)	30 (<0.1)
Gallbladder polyp	6 (<0.1)	6 (<0.1)	12 (<0.1)
Hepatic cyst	8 (<0.1)	6 (<0.1)	14 (<0.1)
Hepatitis	4 (<0.1)	6 (<0.1)	10 (<0.1)
Biliary colic	7 (<0.1)	3 (<0.1)	10 (<0.1)
Gallbladder hypofunction	4 (<0.1)	3 (<0.1)	7 (<0.1)
Hyperbilirubinaemia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Liver disorder	2 (<0.1)	2 (<0.1)	4 (<0.1)
Portal hypertension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Steatohepatitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Biliary cyst	0	1 (<0.1)	1 (<0.1)
Biliary dyskinesia	7 (<0.1)	1 (<0.1)	8 (<0.1)
Cholecystitis chronic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cholestasis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cirrhosis alcoholic	0	1 (<0.1)	1 (<0.1)
Drug-induced liver injury	0	1 (<0.1)	1 (<0.1)
Gallbladder hyperfunction	0	1 (<0.1)	1 (<0.1)
Gallbladder rupture	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)			
Granulomatous liver disease	0	1 (<0.1)	1 (<0.1)
Hepatic fibrosis	0	1 (<0.1)	1 (<0.1)
Hepatitis acute	0	1 (<0.1)	1 (<0.1)
Hepatomegaly	3 (<0.1)	1 (<0.1)	4 (<0.1)
Jaundice	0	1 (<0.1)	1 (<0.1)
Post cholecystectomy syndrome	0	1 (<0.1)	1 (<0.1)
Primary biliary cholangitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Alcoholic liver disease	1 (<0.1)	0	1 (<0.1)
Autoimmune hepatitis	1 (<0.1)	0	1 (<0.1)
Bile duct obstruction	2 (<0.1)	0	2 (<0.1)
Chronic hepatitis	1 (<0.1)	0	1 (<0.1)
Fatty liver alcoholic	1 (<0.1)	0	1 (<0.1)
Gallbladder obstruction	2 (<0.1)	0	2 (<0.1)
Hepatic lesion	2 (<0.1)	0	2 (<0.1)
Hepatic mass	1 (<0.1)	0	1 (<0.1)
Jaundice cholestatic	1 (<0.1)	0	1 (<0.1)
Perforation bile duct	1 (<0.1)	0	1 (<0.1)
Portal vein thrombosis	2 (<0.1)	0	2 (<0.1)
Sphincter of Oddi dysfunction	1 (<0.1)	0	1 (<0.1)
Skin and subcutaneous tissue disorders	1702 (11.2)	1708 (11.2)	3410 (11.2)
Eczema	351 (2.3)	325 (2.1)	676 (2.2)
Acne	278 (1.8)	267 (1.8)	545 (1.8)
Rosacea	171 (1.1)	153 (1.0)	324 (1.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Psoriasis	127 (0.8)	143 (0.9)	270 (0.9)
Alopecia	136 (0.9)	125 (0.8)	261 (0.9)
Actinic keratosis	73 (0.5)	83 (0.5)	156 (0.5)
Urticaria	88 (0.6)	83 (0.5)	171 (0.6)
Drug eruption	77 (0.5)	71 (0.5)	148 (0.5)
Dermatitis contact	84 (0.6)	68 (0.4)	152 (0.5)
Dermatitis	41 (0.3)	44 (0.3)	85 (0.3)
Dermatitis atopic	39 (0.3)	35 (0.2)	74 (0.2)
Dry skin	19 (0.1)	35 (0.2)	54 (0.2)
Seborrhoeic dermatitis	26 (0.2)	32 (0.2)	58 (0.2)
Vitiligo	31 (0.2)	31 (0.2)	62 (0.2)
Rash	40 (0.3)	30 (0.2)	70 (0.2)
Skin wrinkling	15 (<0.1)	24 (0.2)	39 (0.1)
Androgenetic alopecia	22 (0.1)	23 (0.2)	45 (0.1)
Dermal cyst	21 (0.1)	23 (0.2)	44 (0.1)
Pruritus	18 (0.1)	17 (0.1)	35 (0.1)
Hyperhidrosis	17 (0.1)	16 (0.1)	33 (0.1)
Acne cystic	9 (<0.1)	14 (<0.1)	23 (<0.1)
Pruritus allergic	10 (<0.1)	14 (<0.1)	24 (<0.1)
Hidradenitis	7 (<0.1)	13 (<0.1)	20 (<0.1)
Lichen sclerosus	10 (<0.1)	12 (<0.1)	22 (<0.1)
Ingrowing nail	2 (<0.1)	11 (<0.1)	13 (<0.1)
Precancerous skin lesion	5 (<0.1)	10 (<0.1)	15 (<0.1)
Skin lesion	10 (<0.1)	9 (<0.1)	19 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Keratosis pilaris	6 (<0.1)	8 (<0.1)	14 (<0.1)
Skin texture abnormal	3 (<0.1)	8 (<0.1)	11 (<0.1)
Hyperkeratosis	11 (<0.1)	7 (<0.1)	18 (<0.1)
Keloid scar	5 (<0.1)	6 (<0.1)	11 (<0.1)
Night sweats	3 (<0.1)	6 (<0.1)	9 (<0.1)
Chronic spontaneous urticaria	0	5 (<0.1)	5 (<0.1)
Cold urticaria	1 (<0.1)	5 (<0.1)	6 (<0.1)
Diabetic foot	2 (<0.1)	5 (<0.1)	7 (<0.1)
Lichen planus	7 (<0.1)	5 (<0.1)	12 (<0.1)
Skin ulcer	5 (<0.1)	5 (<0.1)	10 (<0.1)
Angioedema	2 (<0.1)	4 (<0.1)	6 (<0.1)
Dandruff	1 (<0.1)	4 (<0.1)	5 (<0.1)
Decubitus ulcer	0	4 (<0.1)	4 (<0.1)
Dermatitis allergic	11 (<0.1)	4 (<0.1)	15 (<0.1)
Dyshidrotic eczema	4 (<0.1)	4 (<0.1)	8 (<0.1)
Granuloma annulare	4 (<0.1)	4 (<0.1)	8 (<0.1)
Hair growth abnormal	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mechanical urticaria	10 (<0.1)	4 (<0.1)	14 (<0.1)
Neurodermatitis	0	4 (<0.1)	4 (<0.1)
Seborrhoea	3 (<0.1)	4 (<0.1)	7 (<0.1)
Urticaria chronic	1 (<0.1)	4 (<0.1)	5 (<0.1)
Blister	1 (<0.1)	3 (<0.1)	4 (<0.1)
Chloasma	2 (<0.1)	3 (<0.1)	5 (<0.1)
Ecchymosis	3 (<0.1)	3 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Eczema nummular	2 (<0.1)	3 (<0.1)	5 (<0.1)
Erythema	4 (<0.1)	3 (<0.1)	7 (<0.1)
Hirsutism	4 (<0.1)	3 (<0.1)	7 (<0.1)
Idiopathic urticaria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Ingrown hair	2 (<0.1)	3 (<0.1)	5 (<0.1)
Myxoid cyst	1 (<0.1)	3 (<0.1)	4 (<0.1)
Sensitive skin	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin discolouration	1 (<0.1)	3 (<0.1)	4 (<0.1)
Skin irritation	6 (<0.1)	3 (<0.1)	9 (<0.1)
Solar lentigo	1 (<0.1)	3 (<0.1)	4 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Urticaria cholinergic	0	3 (<0.1)	3 (<0.1)
Excessive skin	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hypertrichosis	0	2 (<0.1)	2 (<0.1)
Lipodystrophy acquired	2 (<0.1)	2 (<0.1)	4 (<0.1)
Miliaria	5 (<0.1)	2 (<0.1)	7 (<0.1)
Papule	0	2 (<0.1)	2 (<0.1)
Photodermatosis	0	2 (<0.1)	2 (<0.1)
Pityriasis	0	2 (<0.1)	2 (<0.1)
Purpura senile	4 (<0.1)	2 (<0.1)	6 (<0.1)
Rash erythematous	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rash macular	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rash papular	1 (<0.1)	2 (<0.1)	3 (<0.1)
Red man syndrome	0	2 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Skin exfoliation	0	2 (<0.1)	2 (<0.1)
Skin hyperpigmentation	0	2 (<0.1)	2 (<0.1)
Skin hypopigmentation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Skin mass	0	2 (<0.1)	2 (<0.1)
Stasis dermatitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Stevens-Johnson syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acanthosis	0	1 (<0.1)	1 (<0.1)
Acanthosis nigricans	0	1 (<0.1)	1 (<0.1)
Acute febrile neutrophilic dermatosis	0	1 (<0.1)	1 (<0.1)
Alopecia areata	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood blister	0	1 (<0.1)	1 (<0.1)
Brachioradial pruritus	0	1 (<0.1)	1 (<0.1)
Chronic actinic dermatitis	0	1 (<0.1)	1 (<0.1)
Confluent and reticulate papillomatosis	0	1 (<0.1)	1 (<0.1)
Ephelides	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hand dermatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Henoch-Schonlein purpura	0	1 (<0.1)	1 (<0.1)
Intertrigo	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lentigo	2 (<0.1)	1 (<0.1)	3 (<0.1)
Lichenoid keratosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lymphomatoid papulosis	0	1 (<0.1)	1 (<0.1)
Mid-dermal elastolysis	0	1 (<0.1)	1 (<0.1)
Milia	0	1 (<0.1)	1 (<0.1)
Nail discolouration	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Nail disorder	0	1 (<0.1)	1 (<0.1)
Pemphigoid	0	1 (<0.1)	1 (<0.1)
Pemphigus	0	1 (<0.1)	1 (<0.1)
Perioral dermatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Photosensitivity reaction	2 (<0.1)	1 (<0.1)	3 (<0.1)
Pigmentation disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pityriasis rosea	0	1 (<0.1)	1 (<0.1)
Pseudofolliculitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Scar pain	0	1 (<0.1)	1 (<0.1)
Sebaceous hyperplasia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin atrophy	0	1 (<0.1)	1 (<0.1)
Skin depigmentation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Telangiectasia	0	1 (<0.1)	1 (<0.1)
Adiposis dolorosa	1 (<0.1)	0	1 (<0.1)
Cafe au lait spots	1 (<0.1)	0	1 (<0.1)
Cutaneous lupus erythematosus	3 (<0.1)	0	3 (<0.1)
Dermatosis	1 (<0.1)	0	1 (<0.1)
Diabetic dermopathy	1 (<0.1)	0	1 (<0.1)
Diabetic ulcer	1 (<0.1)	0	1 (<0.1)
Eosinophilic cellulitis	1 (<0.1)	0	1 (<0.1)
Hypotrichosis	1 (<0.1)	0	1 (<0.1)
Idiopathic angioedema	1 (<0.1)	0	1 (<0.1)
Idiopathic guttate hypomelanosis	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Lichen planopilaris	2 (<0.1)	0	2 (<0.1)
Lichenification	1 (<0.1)	0	1 (<0.1)
Macule	2 (<0.1)	0	2 (<0.1)
Nail dystrophy	2 (<0.1)	0	2 (<0.1)
Nail hypertrophy	1 (<0.1)	0	1 (<0.1)
Onychoclasis	1 (<0.1)	0	1 (<0.1)
Onycholysis	3 (<0.1)	0	3 (<0.1)
Panniculitis	1 (<0.1)	0	1 (<0.1)
Parakeratosis	1 (<0.1)	0	1 (<0.1)
Petechiae	1 (<0.1)	0	1 (<0.1)
Rash follicular	1 (<0.1)	0	1 (<0.1)
Rash maculo-papular	1 (<0.1)	0	1 (<0.1)
Skin disorder	3 (<0.1)	0	3 (<0.1)
Skin fissures	1 (<0.1)	0	1 (<0.1)
Solar urticaria	1 (<0.1)	0	1 (<0.1)
Urticaria pressure	1 (<0.1)	0	1 (<0.1)
Urticaria vibratory	1 (<0.1)	0	1 (<0.1)
Xanthelasma	1 (<0.1)	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	4310 (28.4)	4300 (28.3)	8610 (28.4)
Osteoarthritis	1542 (10.2)	1563 (10.3)	3105 (10.2)
Back pain	862 (5.7)	902 (5.9)	1764 (5.8)
Arthralgia	453 (3.0)	456 (3.0)	909 (3.0)
Osteoporosis	256 (1.7)	293 (1.9)	549 (1.8)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Intervertebral disc protrusion	255 (1.7)	262 (1.7)	517 (1.7)
Osteopenia	221 (1.5)	236 (1.6)	457 (1.5)
Muscle spasms	196 (1.3)	180 (1.2)	376 (1.2)
Rotator cuff syndrome	189 (1.2)	179 (1.2)	368 (1.2)
Myalgia	219 (1.4)	172 (1.1)	391 (1.3)
Spinal osteoarthritis	157 (1.0)	157 (1.0)	314 (1.0)
Intervertebral disc degeneration	135 (0.9)	147 (1.0)	282 (0.9)
Arthritis	143 (0.9)	137 (0.9)	280 (0.9)
Fibromyalgia	123 (0.8)	136 (0.9)	259 (0.9)
Neck pain	138 (0.9)	135 (0.9)	273 (0.9)
Musculoskeletal pain	112 (0.7)	117 (0.8)	229 (0.8)
Pain in extremity	72 (0.5)	99 (0.7)	171 (0.6)
Foot deformity	69 (0.5)	83 (0.5)	152 (0.5)
Scoliosis	68 (0.4)	75 (0.5)	143 (0.5)
Tendonitis	77 (0.5)	63 (0.4)	140 (0.5)
Spinal stenosis	55 (0.4)	58 (0.4)	113 (0.4)
Plantar fasciitis	59 (0.4)	55 (0.4)	114 (0.4)
Bursitis	40 (0.3)	48 (0.3)	88 (0.3)
Exostosis	40 (0.3)	47 (0.3)	87 (0.3)
Rheumatoid arthritis	58 (0.4)	44 (0.3)	102 (0.3)
Temporomandibular joint syndrome	32 (0.2)	39 (0.3)	71 (0.2)
Synovial cyst	36 (0.2)	34 (0.2)	70 (0.2)
Trigger finger	31 (0.2)	34 (0.2)	65 (0.2)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Periarthritis	18 (0.1)	25 (0.2)	43 (0.1)
Cervical spinal stenosis	15 (<0.1)	23 (0.2)	38 (0.1)
Lumbar spinal stenosis	31 (0.2)	21 (0.1)	52 (0.2)
Intervertebral disc disorder	12 (<0.1)	18 (0.1)	30 (<0.1)
Spondylitis	17 (0.1)	17 (0.1)	34 (0.1)
Sjogren's syndrome	11 (<0.1)	16 (0.1)	27 (<0.1)
Polyarthritis	14 (<0.1)	15 (<0.1)	29 (<0.1)
Psoriatic arthropathy	9 (<0.1)	15 (<0.1)	24 (<0.1)
Spinal pain	10 (<0.1)	12 (<0.1)	22 (<0.1)
Spondylolisthesis	8 (<0.1)	12 (<0.1)	20 (<0.1)
Systemic lupus erythematosus	9 (<0.1)	12 (<0.1)	21 (<0.1)
Musculoskeletal stiffness	7 (<0.1)	10 (<0.1)	17 (<0.1)
Osteonecrosis	9 (<0.1)	10 (<0.1)	19 (<0.1)
Arthropathy	5 (<0.1)	9 (<0.1)	14 (<0.1)
Dupuytren's contracture	15 (<0.1)	9 (<0.1)	24 (<0.1)
Muscular weakness	8 (<0.1)	9 (<0.1)	17 (<0.1)
Tenosynovitis stenosans	9 (<0.1)	9 (<0.1)	18 (<0.1)
Joint swelling	8 (<0.1)	8 (<0.1)	16 (<0.1)
Muscle tightness	4 (<0.1)	7 (<0.1)	11 (<0.1)
Rheumatic fever	12 (<0.1)	7 (<0.1)	19 (<0.1)
Ankylosing spondylitis	7 (<0.1)	6 (<0.1)	13 (<0.1)
Joint stiffness	7 (<0.1)	6 (<0.1)	13 (<0.1)
Kyphosis	4 (<0.1)	6 (<0.1)	10 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Compartment syndrome	2 (<0.1)	5 (<0.1)	7 (<0.1)
Jaw disorder	1 (<0.1)	5 (<0.1)	6 (<0.1)
Joint effusion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Joint range of motion decreased	8 (<0.1)	5 (<0.1)	13 (<0.1)
Torticollis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Chondropathy	3 (<0.1)	4 (<0.1)	7 (<0.1)
Fistula	1 (<0.1)	4 (<0.1)	5 (<0.1)
Intervertebral disc compression	8 (<0.1)	4 (<0.1)	12 (<0.1)
Joint instability	2 (<0.1)	4 (<0.1)	6 (<0.1)
Pain in jaw	2 (<0.1)	4 (<0.1)	6 (<0.1)
Plantar fascial fibromatosis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Polymyalgia rheumatica	4 (<0.1)	4 (<0.1)	8 (<0.1)
Sacroiliitis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Tendon disorder	1 (<0.1)	4 (<0.1)	5 (<0.1)
Tendon pain	3 (<0.1)	4 (<0.1)	7 (<0.1)
Bone loss	3 (<0.1)	3 (<0.1)	6 (<0.1)
Connective tissue disorder	1 (<0.1)	3 (<0.1)	4 (<0.1)
Costochondritis	5 (<0.1)	3 (<0.1)	8 (<0.1)
Diastasis recti abdominis	5 (<0.1)	3 (<0.1)	8 (<0.1)
Femoroacetabular impingement	0	3 (<0.1)	3 (<0.1)
Retrognathia	0	3 (<0.1)	3 (<0.1)
Rhabdomyolysis	0	3 (<0.1)	3 (<0.1)
Tenosynovitis	6 (<0.1)	3 (<0.1)	9 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Vertebral foraminal stenosis	0	3 (<0.1)	3 (<0.1)
Back disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chondrocalcinosis pyrophosphate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Degenerative bone disease	0	2 (<0.1)	2 (<0.1)
Facet joint syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Jaw cyst	0	2 (<0.1)	2 (<0.1)
Joint contracture	0	2 (<0.1)	2 (<0.1)
Joint hyperextension	3 (<0.1)	2 (<0.1)	5 (<0.1)
Juvenile idiopathic arthritis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ligament laxity	1 (<0.1)	2 (<0.1)	3 (<0.1)
Limb deformity	0	2 (<0.1)	2 (<0.1)
Limb mass	1 (<0.1)	2 (<0.1)	3 (<0.1)
Muscle atrophy	4 (<0.1)	2 (<0.1)	6 (<0.1)
Muscle contracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Musculoskeletal discomfort	3 (<0.1)	2 (<0.1)	5 (<0.1)
Myopathy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Myositis	0	2 (<0.1)	2 (<0.1)
Neuropathic arthropathy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Osteochondrosis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Patellofemoral pain syndrome	6 (<0.1)	2 (<0.1)	8 (<0.1)
Perthes disease	0	2 (<0.1)	2 (<0.1)
Spinal disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Spinal synovial cyst	0	2 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Vertebral osteophyte	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acquired claw toe	0	1 (<0.1)	1 (<0.1)
Arthrofibrosis	0	1 (<0.1)	1 (<0.1)
Blount's disease	0	1 (<0.1)	1 (<0.1)
Bone cyst	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bone development abnormal	0	1 (<0.1)	1 (<0.1)
Bone disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bone pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cartilage atrophy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chest wall cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Chest wall haematoma	0	1 (<0.1)	1 (<0.1)
Extremity contracture	0	1 (<0.1)	1 (<0.1)
Floating patella	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gouty arthritis	0	1 (<0.1)	1 (<0.1)
Groin pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hip deformity	0	1 (<0.1)	1 (<0.1)
Inclusion body myositis	0	1 (<0.1)	1 (<0.1)
Intervertebral disc displacement	3 (<0.1)	1 (<0.1)	4 (<0.1)
Knee deformity	0	1 (<0.1)	1 (<0.1)
Kyphoscoliosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Limb asymmetry	0	1 (<0.1)	1 (<0.1)
Lordosis	0	1 (<0.1)	1 (<0.1)
Medial tibial stress syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Meniscal degeneration	0	1 (<0.1)	1 (<0.1)
Metatarsalgia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Morphoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Muscle disorder	0	1 (<0.1)	1 (<0.1)
Muscle fatigue	0	1 (<0.1)	1 (<0.1)
Musculoskeletal chest pain	3 (<0.1)	1 (<0.1)	4 (<0.1)
Musculoskeletal disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Myofascial pain syndrome	3 (<0.1)	1 (<0.1)	4 (<0.1)
Myositis ossificans	0	1 (<0.1)	1 (<0.1)
Osteitis	0	1 (<0.1)	1 (<0.1)
Osteochondritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Osteolysis	0	1 (<0.1)	1 (<0.1)
Osteosclerosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pathological fracture	0	1 (<0.1)	1 (<0.1)
Plica syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Scleroderma	3 (<0.1)	1 (<0.1)	4 (<0.1)
Slipping rib syndrome	0	1 (<0.1)	1 (<0.1)
Soft tissue mass	0	1 (<0.1)	1 (<0.1)
Soft tissue swelling	0	1 (<0.1)	1 (<0.1)
Somatic dysfunction	0	1 (<0.1)	1 (<0.1)
Spinal deformity	0	1 (<0.1)	1 (<0.1)
Spinal instability	0	1 (<0.1)	1 (<0.1)
Trismus	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Ulnocarpal abutment syndrome	0	1 (<0.1)	1 (<0.1)
Ankle deformity	1 (<0.1)	0	1 (<0.1)
Arthritis reactive	1 (<0.1)	0	1 (<0.1)
Bone deformity	1 (<0.1)	0	1 (<0.1)
Chest wall mass	1 (<0.1)	0	1 (<0.1)
Chondromalacia	3 (<0.1)	0	3 (<0.1)
Coccydynia	1 (<0.1)	0	1 (<0.1)
Diffuse idiopathic skeletal hyperostosis	1 (<0.1)	0	1 (<0.1)
Discoid meniscus	1 (<0.1)	0	1 (<0.1)
Dwarfism	1 (<0.1)	0	1 (<0.1)
Fasciitis	1 (<0.1)	0	1 (<0.1)
Flank pain	1 (<0.1)	0	1 (<0.1)
Fracture pain	1 (<0.1)	0	1 (<0.1)
Haemarthrosis	1 (<0.1)	0	1 (<0.1)
Hypermobility syndrome	3 (<0.1)	0	3 (<0.1)
Immunoglobulin G4 related disease	1 (<0.1)	0	1 (<0.1)
Intervertebral disc calcification	1 (<0.1)	0	1 (<0.1)
Joint lock	1 (<0.1)	0	1 (<0.1)
Joint noise	1 (<0.1)	0	1 (<0.1)
Ligament disorder	1 (<0.1)	0	1 (<0.1)
Ligament pain	1 (<0.1)	0	1 (<0.1)
Loose body in joint	1 (<0.1)	0	1 (<0.1)
Mixed connective tissue disease	1 (<0.1)	0	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Mueller-Weiss syndrome	1 (<0.1)	0	1 (<0.1)
Muscle hypertrophy	1 (<0.1)	0	1 (<0.1)
Neck mass	2 (<0.1)	0	2 (<0.1)
Nose deformity	1 (<0.1)	0	1 (<0.1)
Osteitis deformans	1 (<0.1)	0	1 (<0.1)
Osteoporosis postmenopausal	1 (<0.1)	0	1 (<0.1)
Posterior tibial tendon dysfunction	2 (<0.1)	0	2 (<0.1)
Prognathism	1 (<0.1)	0	1 (<0.1)
Scapular dyskinesis	1 (<0.1)	0	1 (<0.1)
Seronegative arthritis	1 (<0.1)	0	1 (<0.1)
Sinus tarsi syndrome	1 (<0.1)	0	1 (<0.1)
Sympathetic posterior cervical syndrome	1 (<0.1)	0	1 (<0.1)
Tendon laxity	1 (<0.1)	0	1 (<0.1)
Thoracic spinal stenosis	1 (<0.1)	0	1 (<0.1)
Renal and urinary disorders	916 (6.0)	886 (5.8)	1802 (5.9)
Nephrolithiasis	360 (2.4)	320 (2.1)	680 (2.2)
Hypertonic bladder	156 (1.0)	146 (1.0)	302 (1.0)
Urinary incontinence	82 (0.5)	104 (0.7)	186 (0.6)
Chronic kidney disease	82 (0.5)	79 (0.5)	161 (0.5)
Nocturia	39 (0.3)	35 (0.2)	74 (0.2)
Bladder prolapse	14 (<0.1)	24 (0.2)	38 (0.1)
Urinary retention	25 (0.2)	24 (0.2)	49 (0.2)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Pollakiuria	36 (0.2)	23 (0.2)	59 (0.2)
Stress urinary incontinence	19 (0.1)	21 (0.1)	40 (0.1)
Haematuria	23 (0.2)	15 (<0.1)	38 (0.1)
Renal failure	13 (<0.1)	15 (<0.1)	28 (<0.1)
Cystitis interstitial	9 (<0.1)	11 (<0.1)	20 (<0.1)
Dysuria	5 (<0.1)	11 (<0.1)	16 (<0.1)
Renal cyst	15 (<0.1)	10 (<0.1)	25 (<0.1)
Bladder spasm	2 (<0.1)	9 (<0.1)	11 (<0.1)
Micturition urgency	18 (0.1)	9 (<0.1)	27 (<0.1)
Nephropathy	11 (<0.1)	9 (<0.1)	20 (<0.1)
Renal impairment	9 (<0.1)	6 (<0.1)	15 (<0.1)
Proteinuria	4 (<0.1)	5 (<0.1)	9 (<0.1)
Acute kidney injury	5 (<0.1)	4 (<0.1)	9 (<0.1)
Incontinence	7 (<0.1)	4 (<0.1)	11 (<0.1)
Microalbuminuria	1 (<0.1)	4 (<0.1)	5 (<0.1)
Polyuria	3 (<0.1)	4 (<0.1)	7 (<0.1)
Urethral stenosis	10 (<0.1)	4 (<0.1)	14 (<0.1)
Urge incontinence	7 (<0.1)	4 (<0.1)	11 (<0.1)
IgA nephropathy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mixed incontinence	2 (<0.1)	3 (<0.1)	5 (<0.1)
Renal artery stenosis	0	3 (<0.1)	3 (<0.1)
Bladder dilatation	0	2 (<0.1)	2 (<0.1)
Bladder pain	0	2 (<0.1)	2 (<0.1)
Diabetic nephropathy	4 (<0.1)	2 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Glomerulonephritis	0	2 (<0.1)	2 (<0.1)
Nephropathy toxic	0	2 (<0.1)	2 (<0.1)
Renal atrophy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Renal injury	0	2 (<0.1)	2 (<0.1)
Single functional kidney	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ureteric stenosis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Urinary bladder polyp	0	2 (<0.1)	2 (<0.1)
Urinary hesitation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Urinary tract obstruction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vesicoureteric reflux	2 (<0.1)	2 (<0.1)	4 (<0.1)
Atonic urinary bladder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bladder hypertrophy	0	1 (<0.1)	1 (<0.1)
Bladder irritation	0	1 (<0.1)	1 (<0.1)
Bladder stenosis	0	1 (<0.1)	1 (<0.1)
Calculus bladder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Calyceal diverticulum	0	1 (<0.1)	1 (<0.1)
End stage renal disease	1 (<0.1)	1 (<0.1)	2 (<0.1)
Focal segmental glomerulosclerosis	0	1 (<0.1)	1 (<0.1)
Glomerulonephritis acute	0	1 (<0.1)	1 (<0.1)
Glomerulonephritis chronic	0	1 (<0.1)	1 (<0.1)
Glomerulonephritis minimal lesion	0	1 (<0.1)	1 (<0.1)
Glycosuria	0	1 (<0.1)	1 (<0.1)
Hydronephrosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypercalciuria	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Kidney fibrosis	0	1 (<0.1)	1 (<0.1)
Nephritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nephrotic syndrome	0	1 (<0.1)	1 (<0.1)
Pelvi-ureteric obstruction	0	1 (<0.1)	1 (<0.1)
Renal colic	0	1 (<0.1)	1 (<0.1)
Renal disorder	4 (<0.1)	1 (<0.1)	5 (<0.1)
Renal haematoma	0	1 (<0.1)	1 (<0.1)
Renal vein thrombosis	0	1 (<0.1)	1 (<0.1)
Ureteric obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urethral atrophy	0	1 (<0.1)	1 (<0.1)
Urethral dilatation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Urinary bladder rupture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Urine abnormality	0	1 (<0.1)	1 (<0.1)
Urine flow decreased	7 (<0.1)	1 (<0.1)	8 (<0.1)
Bladder cyst	1 (<0.1)	0	1 (<0.1)
Bladder diverticulum	1 (<0.1)	0	1 (<0.1)
Bladder neck obstruction	1 (<0.1)	0	1 (<0.1)
Bladder perforation	1 (<0.1)	0	1 (<0.1)
Calculus urinary	2 (<0.1)	0	2 (<0.1)
Glomerulonephritis membranous	2 (<0.1)	0	2 (<0.1)
Goodpasture's syndrome	1 (<0.1)	0	1 (<0.1)
Hypertensive nephropathy	1 (<0.1)	0	1 (<0.1)
Hypotonic urinary bladder	1 (<0.1)	0	1 (<0.1)
Lower urinary tract symptoms	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Micturition disorder	1 (<0.1)	0	1 (<0.1)
Nephrocalcinosis	2 (<0.1)	0	2 (<0.1)
Nephrosclerosis	1 (<0.1)	0	1 (<0.1)
Neurogenic bladder	3 (<0.1)	0	3 (<0.1)
Reflux nephropathy	1 (<0.1)	0	1 (<0.1)
Renal mass	1 (<0.1)	0	1 (<0.1)
Renal pain	2 (<0.1)	0	2 (<0.1)
Tubulointerstitial nephritis	1 (<0.1)	0	1 (<0.1)
Ureteral spasm	1 (<0.1)	0	1 (<0.1)
Ureterolithiasis	3 (<0.1)	0	3 (<0.1)
Urethral obstruction	1 (<0.1)	0	1 (<0.1)
Urinary tract discomfort	1 (<0.1)	0	1 (<0.1)
Urinary tract disorder	1 (<0.1)	0	1 (<0.1)
Vesical fistula	1 (<0.1)	0	1 (<0.1)
Pregnancy, puerperium and perinatal conditions	157 (1.0)	144 (0.9)	301 (1.0)
Gestational diabetes	35 (0.2)	38 (0.3)	73 (0.2)
Delivery	35 (0.2)	34 (0.2)	69 (0.2)
Ectopic pregnancy	23 (0.2)	26 (0.2)	49 (0.2)
Abortion spontaneous	22 (0.1)	16 (0.1)	38 (0.1)
Pregnancy	12 (<0.1)	8 (<0.1)	20 (<0.1)
Pre-eclampsia	7 (<0.1)	6 (<0.1)	13 (<0.1)
Placenta accreta	1 (<0.1)	3 (<0.1)	4 (<0.1)
Ruptured ectopic pregnancy	1 (<0.1)	3 (<0.1)	4 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions (Cont.)			
Abortion	4 (<0.1)	2 (<0.1)	6 (<0.1)
Breech presentation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Uterine atony	0	2 (<0.1)	2 (<0.1)
Breech delivery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Complication of pregnancy	0	1 (<0.1)	1 (<0.1)
Foetal death	1 (<0.1)	1 (<0.1)	2 (<0.1)
Foetal distress syndrome	0	1 (<0.1)	1 (<0.1)
HELLP syndrome	2 (<0.1)	1 (<0.1)	3 (<0.1)
Haemorrhage in pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Placenta praevia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Traumatic delivery	0	1 (<0.1)	1 (<0.1)
Umbilical cord around neck	0	1 (<0.1)	1 (<0.1)
Umbilical cord cyst	0	1 (<0.1)	1 (<0.1)
Birth trauma	1 (<0.1)	0	1 (<0.1)
Cervical incompetence	3 (<0.1)	0	3 (<0.1)
Foetal placental thrombosis	1 (<0.1)	0	1 (<0.1)
Gestational hypertension	1 (<0.1)	0	1 (<0.1)
Obstructed labour	2 (<0.1)	0	2 (<0.1)
Postpartum haemorrhage	1 (<0.1)	0	1 (<0.1)
Premature baby	2 (<0.1)	0	2 (<0.1)
Premature separation of placenta	3 (<0.1)	0	3 (<0.1)
Shoulder dystocia	1 (<0.1)	0	1 (<0.1)
Stillbirth	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions (Cont.)			
Uterine inversion	1 (<0.1)	0	1 (<0.1)
Reproductive system and breast disorders	2267 (15.0)	2192 (14.4)	4459 (14.7)
Benign prostatic hyperplasia	551 (3.6)	550 (3.6)	1101 (3.6)
Erectile dysfunction	424 (2.8)	379 (2.5)	803 (2.6)
Menorrhagia	239 (1.6)	203 (1.3)	442 (1.5)
Endometriosis	177 (1.2)	182 (1.2)	359 (1.2)
Ovarian cyst	143 (0.9)	140 (0.9)	283 (0.9)
Prostatomegaly	149 (1.0)	131 (0.9)	280 (0.9)
Dysmenorrhoea	125 (0.8)	114 (0.8)	239 (0.8)
Polycystic ovaries	101 (0.7)	98 (0.6)	199 (0.7)
Menopausal symptoms	44 (0.3)	49 (0.3)	93 (0.3)
Uterine prolapse	45 (0.3)	47 (0.3)	92 (0.3)
Menstruation irregular	34 (0.2)	40 (0.3)	74 (0.2)
Vulvovaginal dryness	31 (0.2)	39 (0.3)	70 (0.2)
Uterine haemorrhage	21 (0.1)	27 (0.2)	48 (0.2)
Cervical dysplasia	21 (0.1)	23 (0.2)	44 (0.1)
Uterine cyst	13 (<0.1)	22 (0.1)	35 (0.1)
Adenomyosis	19 (0.1)	19 (0.1)	38 (0.1)
Fibrocystic breast disease	17 (0.1)	18 (0.1)	35 (0.1)
Atrophic vulvovaginitis	22 (0.1)	16 (0.1)	38 (0.1)
Breast cyst	16 (0.1)	16 (0.1)	32 (0.1)
Dysfunctional uterine bleeding	18 (0.1)	16 (0.1)	34 (0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Uterine polyp	15 (<0.1)	14 (<0.1)	29 (<0.1)
Varicocele	8 (<0.1)	14 (<0.1)	22 (<0.1)
Amenorrhoea	11 (<0.1)	13 (<0.1)	24 (<0.1)
Prostatitis	22 (0.1)	13 (<0.1)	35 (0.1)
Peyronie's disease	3 (<0.1)	12 (<0.1)	15 (<0.1)
Vaginal haemorrhage	11 (<0.1)	12 (<0.1)	23 (<0.1)
Premenstrual syndrome	5 (<0.1)	11 (<0.1)	16 (<0.1)
Menometrorrhagia	4 (<0.1)	10 (<0.1)	14 (<0.1)
Premenstrual dysphoric disorder	9 (<0.1)	10 (<0.1)	19 (<0.1)
Prostatic disorder	16 (0.1)	10 (<0.1)	26 (<0.1)
Breast mass	5 (<0.1)	9 (<0.1)	14 (<0.1)
Postmenopausal haemorrhage	6 (<0.1)	9 (<0.1)	15 (<0.1)
Vaginal prolapse	1 (<0.1)	9 (<0.1)	10 (<0.1)
Cystocele	9 (<0.1)	8 (<0.1)	17 (<0.1)
Artificial menopause	9 (<0.1)	7 (<0.1)	16 (<0.1)
Endometrial hyperplasia	4 (<0.1)	7 (<0.1)	11 (<0.1)
Metrorrhagia	1 (<0.1)	7 (<0.1)	8 (<0.1)
Premature menopause	4 (<0.1)	7 (<0.1)	11 (<0.1)
Testicular torsion	11 (<0.1)	7 (<0.1)	18 (<0.1)
Breast enlargement	5 (<0.1)	6 (<0.1)	11 (<0.1)
Breast hyperplasia	2 (<0.1)	6 (<0.1)	8 (<0.1)
Testicular cyst	2 (<0.1)	6 (<0.1)	8 (<0.1)
Adnexal torsion	6 (<0.1)	5 (<0.1)	11 (<0.1)
Gynaecomastia	7 (<0.1)	5 (<0.1)	12 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Pelvic pain	4 (<0.1)	5 (<0.1)	9 (<0.1)
Rectocele	6 (<0.1)	5 (<0.1)	11 (<0.1)
Sexual dysfunction	5 (<0.1)	5 (<0.1)	10 (<0.1)
Dyspareunia	6 (<0.1)	4 (<0.1)	10 (<0.1)
Infertility	9 (<0.1)	4 (<0.1)	13 (<0.1)
Bartholin's cyst	1 (<0.1)	3 (<0.1)	4 (<0.1)
Breast calcifications	3 (<0.1)	3 (<0.1)	6 (<0.1)
Breast pain	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cervical polyp	3 (<0.1)	3 (<0.1)	6 (<0.1)
Menstrual disorder	3 (<0.1)	3 (<0.1)	6 (<0.1)
Oligomenorrhoea	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vulvovaginal pruritus	0	3 (<0.1)	3 (<0.1)
Fallopian tube cyst	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ovarian cyst ruptured	3 (<0.1)	2 (<0.1)	5 (<0.1)
Premenstrual pain	3 (<0.1)	2 (<0.1)	5 (<0.1)
Testicular swelling	0	2 (<0.1)	2 (<0.1)
Vulvovaginal pain	3 (<0.1)	2 (<0.1)	5 (<0.1)
Adnexa uteri mass	0	1 (<0.1)	1 (<0.1)
Asherman's syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Balanoposthitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Breast disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Breast hypoplasia	0	1 (<0.1)	1 (<0.1)
Calculus prostatic	0	1 (<0.1)	1 (<0.1)
Cervical cyst	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Endometrial atrophy	0	1 (<0.1)	1 (<0.1)
Endometrial disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fallopian tube disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fallopian tube obstruction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Female sexual dysfunction	0	1 (<0.1)	1 (<0.1)
Hydrocele female	0	1 (<0.1)	1 (<0.1)
Menopausal disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Menstrual discomfort	2 (<0.1)	1 (<0.1)	3 (<0.1)
Micromastia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ovarian cyst torsion	0	1 (<0.1)	1 (<0.1)
Pelvic adhesions	0	1 (<0.1)	1 (<0.1)
Pelvic prolapse	2 (<0.1)	1 (<0.1)	3 (<0.1)
Penis disorder	0	1 (<0.1)	1 (<0.1)
Priapism	0	1 (<0.1)	1 (<0.1)
Prostatic asymmetry	0	1 (<0.1)	1 (<0.1)
Prostatic obstruction	0	1 (<0.1)	1 (<0.1)
Pruritus genital	0	1 (<0.1)	1 (<0.1)
Uterine adhesions	0	1 (<0.1)	1 (<0.1)
Uterine fibrosis	0	1 (<0.1)	1 (<0.1)
Uterine mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Uterovaginal prolapse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vaginal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vulvovaginal discomfort	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Adnexa uteri pain	1 (<0.1)	0	1 (<0.1)
Bleeding anovulatory	1 (<0.1)	0	1 (<0.1)
Breast discharge	3 (<0.1)	0	3 (<0.1)
Breast haemorrhage	1 (<0.1)	0	1 (<0.1)
Cervix haemorrhage uterine	1 (<0.1)	0	1 (<0.1)
Colpocele	1 (<0.1)	0	1 (<0.1)
Ectropion of cervix	1 (<0.1)	0	1 (<0.1)
Endometrial dysplasia	2 (<0.1)	0	2 (<0.1)
Feminisation acquired	2 (<0.1)	0	2 (<0.1)
Infertility male	1 (<0.1)	0	1 (<0.1)
Mammary duct ectasia	1 (<0.1)	0	1 (<0.1)
Oligospermia	1 (<0.1)	0	1 (<0.1)
Ovarian failure	3 (<0.1)	0	3 (<0.1)
Ovarian fibrosis	1 (<0.1)	0	1 (<0.1)
Ovarian mass	2 (<0.1)	0	2 (<0.1)
Perineal fistula	1 (<0.1)	0	1 (<0.1)
Polymenorrhoea	1 (<0.1)	0	1 (<0.1)
Premenstrual headache	2 (<0.1)	0	2 (<0.1)
Prostatic haemorrhage	1 (<0.1)	0	1 (<0.1)
Prostatic hypoplasia	1 (<0.1)	0	1 (<0.1)
Prostatic mass	2 (<0.1)	0	2 (<0.1)
Prostatic pain	1 (<0.1)	0	1 (<0.1)
Prostatic polyp	1 (<0.1)	0	1 (<0.1)
Scrotal swelling	2 (<0.1)	0	2 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Spermatocele	1 (<0.1)	0	1 (<0.1)
Testicular disorder	1 (<0.1)	0	1 (<0.1)
Testicular mass	1 (<0.1)	0	1 (<0.1)
Testicular pain	1 (<0.1)	0	1 (<0.1)
Uterine disorder	1 (<0.1)	0	1 (<0.1)
Uterine enlargement	3 (<0.1)	0	3 (<0.1)
Uterine malposition	1 (<0.1)	0	1 (<0.1)
Vaginal hyperplasia	1 (<0.1)	0	1 (<0.1)
Vaginal lesion	1 (<0.1)	0	1 (<0.1)
Vulvar dysplasia	1 (<0.1)	0	1 (<0.1)
Congenital, familial and genetic disorders	350 (2.3)	372 (2.4)	722 (2.4)
Type V hyperlipidaemia	19 (0.1)	35 (0.2)	54 (0.2)
Gilbert's syndrome	14 (<0.1)	19 (0.1)	33 (0.1)
Factor V Leiden mutation	13 (<0.1)	18 (0.1)	31 (0.1)
Atrial septal defect	10 (<0.1)	17 (0.1)	27 (<0.1)
Type IIa hyperlipidaemia	13 (<0.1)	12 (<0.1)	25 (<0.1)
Bicuspid aortic valve	11 (<0.1)	10 (<0.1)	21 (<0.1)
Cryptorchism	2 (<0.1)	9 (<0.1)	11 (<0.1)
Thalassaemia minor	3 (<0.1)	8 (<0.1)	11 (<0.1)
Tourette's disorder	6 (<0.1)	8 (<0.1)	14 (<0.1)
Cerebral palsy	8 (<0.1)	7 (<0.1)	15 (<0.1)
Pyloric stenosis	9 (<0.1)	7 (<0.1)	16 (<0.1)
Renal aplasia	2 (<0.1)	7 (<0.1)	9 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Cleft palate	6 (<0.1)	6 (<0.1)	12 (<0.1)
Hereditary motor and sensory neuropathy	3 (<0.1)	6 (<0.1)	9 (<0.1)
Pectus excavatum	4 (<0.1)	6 (<0.1)	10 (<0.1)
Sickle cell trait	5 (<0.1)	6 (<0.1)	11 (<0.1)
Coarctation of the aorta	1 (<0.1)	5 (<0.1)	6 (<0.1)
Ehlers-Danlos syndrome	3 (<0.1)	5 (<0.1)	8 (<0.1)
Fallot's tetralogy	0	5 (<0.1)	5 (<0.1)
Familial tremor	3 (<0.1)	5 (<0.1)	8 (<0.1)
Glucose-6-phosphate dehydrogenase deficiency	1 (<0.1)	5 (<0.1)	6 (<0.1)
Talipes	3 (<0.1)	5 (<0.1)	8 (<0.1)
Thalassaemia	5 (<0.1)	5 (<0.1)	10 (<0.1)
Ventricular septal defect	7 (<0.1)	5 (<0.1)	12 (<0.1)
Arteriovenous malformation	3 (<0.1)	4 (<0.1)	7 (<0.1)
BRCA2 gene mutation	1 (<0.1)	4 (<0.1)	5 (<0.1)
Congenital jaw malformation	1 (<0.1)	4 (<0.1)	5 (<0.1)
Developmental hip dysplasia	6 (<0.1)	4 (<0.1)	10 (<0.1)
Duane's syndrome	0	4 (<0.1)	4 (<0.1)
Hydrocele	6 (<0.1)	4 (<0.1)	10 (<0.1)
Von Willebrand's disease	8 (<0.1)	4 (<0.1)	12 (<0.1)
Adrenogenital syndrome	0	3 (<0.1)	3 (<0.1)
Alpha-1 antitrypsin deficiency	4 (<0.1)	3 (<0.1)	7 (<0.1)
Congenital heart valve disorder	0	3 (<0.1)	3 (<0.1)
Corneal dystrophy	11 (<0.1)	3 (<0.1)	14 (<0.1)
Heart disease congenital	4 (<0.1)	3 (<0.1)	7 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Hypertrophic cardiomyopathy	4 (<0.1)	3 (<0.1)	7 (<0.1)
Thalassaemia alpha	2 (<0.1)	3 (<0.1)	5 (<0.1)
Thalassaemia beta	2 (<0.1)	3 (<0.1)	5 (<0.1)
Thyroglossal cyst	1 (<0.1)	3 (<0.1)	4 (<0.1)
Amniotic band syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Arnold-Chiari malformation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Benign familial haematuria	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cataract congenital	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cleft lip	2 (<0.1)	2 (<0.1)	4 (<0.1)
Congenital aortic stenosis	0	2 (<0.1)	2 (<0.1)
Congenital aortic valve incompetence	0	2 (<0.1)	2 (<0.1)
Congenital cystic kidney disease	8 (<0.1)	2 (<0.1)	10 (<0.1)
Congenital foot malformation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Congenital uterine anomaly	3 (<0.1)	2 (<0.1)	5 (<0.1)
Dextrocardia	0	2 (<0.1)	2 (<0.1)
Ear malformation	0	2 (<0.1)	2 (<0.1)
Fibrous dysplasia of bone	0	2 (<0.1)	2 (<0.1)
Limb malformation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Limb reduction defect	0	2 (<0.1)	2 (<0.1)
Muscular dystrophy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Phimosis	0	2 (<0.1)	2 (<0.1)
Porokeratosis	0	2 (<0.1)	2 (<0.1)
Preauricular cyst	1 (<0.1)	2 (<0.1)	3 (<0.1)
Retinitis pigmentosa	1 (<0.1)	2 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Accessory breast	0	1 (<0.1)	1 (<0.1)
Anal atresia	0	1 (<0.1)	1 (<0.1)
Asplenia	0	1 (<0.1)	1 (<0.1)
Asymptomatic gene carrier	0	1 (<0.1)	1 (<0.1)
Atrioventricular septal defect	0	1 (<0.1)	1 (<0.1)
BRCA1 gene mutation	3 (<0.1)	1 (<0.1)	4 (<0.1)
Benign familial pemphigus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiac septal defect	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cerebrovascular arteriovenous malformation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Colour blindness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Congenital amputation	0	1 (<0.1)	1 (<0.1)
Congenital anaemia	0	1 (<0.1)	1 (<0.1)
Congenital cystic lung	0	1 (<0.1)	1 (<0.1)
Congenital hiatus hernia	0	1 (<0.1)	1 (<0.1)
Congenital hydronephrosis	0	1 (<0.1)	1 (<0.1)
Congenital inguinal hernia	0	1 (<0.1)	1 (<0.1)
Congenital nephrogenic diabetes insipidus	0	1 (<0.1)	1 (<0.1)
Congenital pulmonary valve atresia	0	1 (<0.1)	1 (<0.1)
Congenital renal disorder	0	1 (<0.1)	1 (<0.1)
Congenital spinal stenosis	0	1 (<0.1)	1 (<0.1)
Congenital spondylolisthesis	0	1 (<0.1)	1 (<0.1)
Congenital torticollis	0	1 (<0.1)	1 (<0.1)
Congenital toxoplasmosis	0	1 (<0.1)	1 (<0.1)
Congenital tracheomalacia	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Congenital umbilical hernia	0	1 (<0.1)	1 (<0.1)
Cystic fibrosis lung	0	1 (<0.1)	1 (<0.1)
Dermoid cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Double heterozygous sickling disorders	0	1 (<0.1)	1 (<0.1)
Double ureter	0	1 (<0.1)	1 (<0.1)
Epidermolysis bullosa	0	1 (<0.1)	1 (<0.1)
Factor II deficiency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Factor V Leiden carrier	0	1 (<0.1)	1 (<0.1)
Factor V deficiency	3 (<0.1)	1 (<0.1)	4 (<0.1)
Factor VIII deficiency	0	1 (<0.1)	1 (<0.1)
Factor XIII deficiency	0	1 (<0.1)	1 (<0.1)
Familial hypocalciuric hypercalcaemia	0	1 (<0.1)	1 (<0.1)
Familial mediterranean fever	0	1 (<0.1)	1 (<0.1)
Gallbladder anomaly congenital	0	1 (<0.1)	1 (<0.1)
Gaucher's disease	0	1 (<0.1)	1 (<0.1)
Gene mutation	4 (<0.1)	1 (<0.1)	5 (<0.1)
Glycogen storage disease type I	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hereditary haemorrhagic telangiectasia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hereditary non-polyposis colorectal cancer syndrome	6 (<0.1)	1 (<0.1)	7 (<0.1)
Hypochondroplasia	0	1 (<0.1)	1 (<0.1)
Hypospadias	0	1 (<0.1)	1 (<0.1)
Ichthyosis	0	1 (<0.1)	1 (<0.1)
Infantile fibromatosis	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Kidney duplex	0	1 (<0.1)	1 (<0.1)
Kidney malformation	0	1 (<0.1)	1 (<0.1)
Liddle's syndrome	0	1 (<0.1)	1 (<0.1)
Malformation venous	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mayer-Rokitansky-Kuster-Hauser syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Methylenetetrahydrofolate reductase deficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Methylenetetrahydrofolate reductase gene mutation	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mitochondrial myopathy	0	1 (<0.1)	1 (<0.1)
Naevus flammeus	0	1 (<0.1)	1 (<0.1)
Neurofibromatosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Odontogenic cyst	0	1 (<0.1)	1 (<0.1)
Pancreas divisum	2 (<0.1)	1 (<0.1)	3 (<0.1)
Patent ductus arteriosus	5 (<0.1)	1 (<0.1)	6 (<0.1)
Pfeiffer syndrome	0	1 (<0.1)	1 (<0.1)
Phenylketonuria	0	1 (<0.1)	1 (<0.1)
Porphyria non-acute	0	1 (<0.1)	1 (<0.1)
Protein C deficiency	0	1 (<0.1)	1 (<0.1)
Pulmonary aplasia	0	1 (<0.1)	1 (<0.1)
Pulmonary artery stenosis congenital	0	1 (<0.1)	1 (<0.1)
Renal fusion anomaly	2 (<0.1)	1 (<0.1)	3 (<0.1)
Septate hymen	0	1 (<0.1)	1 (<0.1)
Sickle cell anaemia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Spina bifida	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spina bifida occulta	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Sturge-Weber syndrome	0	1 (<0.1)	1 (<0.1)
Syndactyly	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tracheobronchomegaly	0	1 (<0.1)	1 (<0.1)
Transposition of the great vessels	0	1 (<0.1)	1 (<0.1)
Trisomy 21	1 (<0.1)	1 (<0.1)	2 (<0.1)
Turner's syndrome	3 (<0.1)	1 (<0.1)	4 (<0.1)
Uterine hypoplasia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vitello-intestinal duct remnant	0	1 (<0.1)	1 (<0.1)
Accessory navicular syndrome	1 (<0.1)	0	1 (<0.1)
Androgen insensitivity syndrome	1 (<0.1)	0	1 (<0.1)
Anophthalmos	1 (<0.1)	0	1 (<0.1)
Birt-Hogg-Dube syndrome	1 (<0.1)	0	1 (<0.1)
Birth mark	2 (<0.1)	0	2 (<0.1)
Branchial cyst	1 (<0.1)	0	1 (<0.1)
Breast malformation	1 (<0.1)	0	1 (<0.1)
Bronchogenic cyst	1 (<0.1)	0	1 (<0.1)
Cerebral cavernous malformation	1 (<0.1)	0	1 (<0.1)
Coloboma	1 (<0.1)	0	1 (<0.1)
Combined immunodeficiency	1 (<0.1)	0	1 (<0.1)
Congenital anomaly	1 (<0.1)	0	1 (<0.1)
Congenital arterial malformation	1 (<0.1)	0	1 (<0.1)
Congenital bladder anomaly	1 (<0.1)	0	1 (<0.1)
Congenital diaphragmatic hernia	1 (<0.1)	0	1 (<0.1)
Congenital genitourinary abnormality	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Congenital hand malformation	2 (<0.1)	0	2 (<0.1)
Congenital joint malformation	1 (<0.1)	0	1 (<0.1)
Congenital knee deformity	3 (<0.1)	0	3 (<0.1)
Congenital musculoskeletal anomaly	1 (<0.1)	0	1 (<0.1)
Congenital myopathy	1 (<0.1)	0	1 (<0.1)
Congenital optic nerve anomaly	2 (<0.1)	0	2 (<0.1)
Congenital renal cyst	1 (<0.1)	0	1 (<0.1)
Congenital spinal fusion	1 (<0.1)	0	1 (<0.1)
Congenital urethral anomaly	1 (<0.1)	0	1 (<0.1)
Cystic fibrosis	2 (<0.1)	0	2 (<0.1)
Cytogenetic abnormality	1 (<0.1)	0	1 (<0.1)
Deafness congenital	2 (<0.1)	0	2 (<0.1)
Developmental glaucoma	1 (<0.1)	0	1 (<0.1)
Dolichocolon	1 (<0.1)	0	1 (<0.1)
Dopa-responsive dystonia	1 (<0.1)	0	1 (<0.1)
Ectopic kidney	1 (<0.1)	0	1 (<0.1)
Ectrodactyly	1 (<0.1)	0	1 (<0.1)
Faciodigitogenital dysplasia	1 (<0.1)	0	1 (<0.1)
Factor II mutation	3 (<0.1)	0	3 (<0.1)
Gastrointestinal malformation	1 (<0.1)	0	1 (<0.1)
Gorham's disease	1 (<0.1)	0	1 (<0.1)
Haemoglobin E trait	1 (<0.1)	0	1 (<0.1)
Hamartoma	1 (<0.1)	0	1 (<0.1)
Hereditary hypophosphataemic rickets	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Hereditary neuropathy with liability to pressure palsies	1 (<0.1)	0	1 (<0.1)
Hereditary spastic paraplegia	1 (<0.1)	0	1 (<0.1)
Hereditary spherocytosis	1 (<0.1)	0	1 (<0.1)
Homocystinaemia	1 (<0.1)	0	1 (<0.1)
Hypoplastic left heart syndrome	1 (<0.1)	0	1 (<0.1)
Iris coloboma	1 (<0.1)	0	1 (<0.1)
Johanson-Blizzard syndrome	1 (<0.1)	0	1 (<0.1)
Keratosis follicular	1 (<0.1)	0	1 (<0.1)
Klinefelter's syndrome	3 (<0.1)	0	3 (<0.1)
Meningomyelocele	1 (<0.1)	0	1 (<0.1)
Metachromatic leukodystrophy	1 (<0.1)	0	1 (<0.1)
Multiple endocrine neoplasia Type 1	1 (<0.1)	0	1 (<0.1)
Multiple epiphyseal dysplasia	1 (<0.1)	0	1 (<0.1)
Myocardial bridging	2 (<0.1)	0	2 (<0.1)
Myotonic dystrophy	2 (<0.1)	0	2 (<0.1)
Olfacto genital dysplasia	1 (<0.1)	0	1 (<0.1)
Optic nerve hypoplasia	1 (<0.1)	0	1 (<0.1)
Poland's syndrome	1 (<0.1)	0	1 (<0.1)
Polycystic liver disease	2 (<0.1)	0	2 (<0.1)
Polydactyly	1 (<0.1)	0	1 (<0.1)
Protein S deficiency	1 (<0.1)	0	1 (<0.1)
Sebaceous naevus	1 (<0.1)	0	1 (<0.1)
Sickle cell disease	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Spine malformation	2 (<0.1)	0	2 (<0.1)
Strabismus congenital	3 (<0.1)	0	3 (<0.1)
Uvula aplasia	1 (<0.1)	0	1 (<0.1)
Vaginal septum	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	547 (3.6)	566 (3.7)	1113 (3.7)
Pain	197 (1.3)	213 (1.4)	410 (1.4)
Oedema peripheral	150 (1.0)	133 (0.9)	283 (0.9)
Fatigue	50 (0.3)	56 (0.4)	106 (0.3)
Drug intolerance	30 (0.2)	31 (0.2)	61 (0.2)
Peripheral swelling	19 (0.1)	22 (0.1)	41 (0.1)
Cyst	25 (0.2)	16 (0.1)	41 (0.1)
Non-cardiac chest pain	6 (<0.1)	10 (<0.1)	16 (<0.1)
Chest pain	10 (<0.1)	9 (<0.1)	19 (<0.1)
Hernia	4 (<0.1)	9 (<0.1)	13 (<0.1)
Chronic fatigue syndrome	2 (<0.1)	8 (<0.1)	10 (<0.1)
Precancerous condition	5 (<0.1)	8 (<0.1)	13 (<0.1)
Ulcer	5 (<0.1)	8 (<0.1)	13 (<0.1)
Adverse drug reaction	7 (<0.1)	5 (<0.1)	12 (<0.1)
Dysplasia	1 (<0.1)	5 (<0.1)	6 (<0.1)
Generalised oedema	4 (<0.1)	5 (<0.1)	9 (<0.1)
Oedema	6 (<0.1)	5 (<0.1)	11 (<0.1)
Gait disturbance	7 (<0.1)	4 (<0.1)	11 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Chest discomfort	4 (<0.1)	3 (<0.1)	7 (<0.1)
Drug withdrawal syndrome	1 (<0.1)	3 (<0.1)	4 (<0.1)
Chills	1 (<0.1)	2 (<0.1)	3 (<0.1)
Granuloma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Inflammation	3 (<0.1)	2 (<0.1)	5 (<0.1)
Malaise	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mass	2 (<0.1)	2 (<0.1)	4 (<0.1)
Necrosis	0	2 (<0.1)	2 (<0.1)
Pelvic mass	0	2 (<0.1)	2 (<0.1)
Pyrexia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ulcer haemorrhage	0	2 (<0.1)	2 (<0.1)
Asthenia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cyst rupture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Disease susceptibility	0	1 (<0.1)	1 (<0.1)
Facial pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Feeling abnormal	0	1 (<0.1)	1 (<0.1)
Haemorrhagic cyst	0	1 (<0.1)	1 (<0.1)
Hyperthermia malignant	0	1 (<0.1)	1 (<0.1)
Hypertrophy	0	1 (<0.1)	1 (<0.1)
Ill-defined disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Implant site haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Inflammatory pain	0	1 (<0.1)	1 (<0.1)
Infusion site extravasation	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Nodule	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oedema due to cardiac disease	0	1 (<0.1)	1 (<0.1)
Procedural failure	0	1 (<0.1)	1 (<0.1)
Sensation of foreign body	2 (<0.1)	1 (<0.1)	3 (<0.1)
Soft tissue inflammation	0	1 (<0.1)	1 (<0.1)
Sudden cardiac death	0	1 (<0.1)	1 (<0.1)
Swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Atrophy	1 (<0.1)	0	1 (<0.1)
Calcinosis	1 (<0.1)	0	1 (<0.1)
Drug resistance	1 (<0.1)	0	1 (<0.1)
Face oedema	1 (<0.1)	0	1 (<0.1)
Gravitational oedema	4 (<0.1)	0	4 (<0.1)
Incarcerated hernia	1 (<0.1)	0	1 (<0.1)
Influenza like illness	1 (<0.1)	0	1 (<0.1)
Injection site eczema	1 (<0.1)	0	1 (<0.1)
Medical device site dermatitis	1 (<0.1)	0	1 (<0.1)
Perforated ulcer	1 (<0.1)	0	1 (<0.1)
Shoulder injury related to vaccine administration	1 (<0.1)	0	1 (<0.1)
Temperature intolerance	2 (<0.1)	0	2 (<0.1)
Vaccination site dermatitis	1 (<0.1)	0	1 (<0.1)
Vaccination site pain	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Xerosis	1 (<0.1)	0	1 (<0.1)
Investigations	1537 (10.1)	1525 (10.0)	3062 (10.1)
Blood cholesterol increased	618 (4.1)	614 (4.0)	1232 (4.1)
Blood testosterone decreased	176 (1.2)	168 (1.1)	344 (1.1)
Cardiac murmur	159 (1.0)	150 (1.0)	309 (1.0)
Arthroscopy	116 (0.8)	121 (0.8)	237 (0.8)
Colonoscopy	79 (0.5)	75 (0.5)	154 (0.5)
Blood triglycerides increased	69 (0.5)	71 (0.5)	140 (0.5)
Vitamin D decreased	35 (0.2)	41 (0.3)	76 (0.3)
Blood pressure increased	39 (0.3)	40 (0.3)	79 (0.3)
Biopsy breast	23 (0.2)	25 (0.2)	48 (0.2)
Endoscopy	14 (<0.1)	22 (0.1)	36 (0.1)
Heart rate irregular	40 (0.3)	21 (0.1)	61 (0.2)
Intraocular pressure increased	10 (<0.1)	19 (0.1)	29 (<0.1)
Smear cervix abnormal	22 (0.1)	18 (0.1)	40 (0.1)
Catheterisation cardiac	30 (0.2)	17 (0.1)	47 (0.2)
Laparoscopy	13 (<0.1)	16 (0.1)	29 (<0.1)
Prostatic specific antigen increased	13 (<0.1)	15 (<0.1)	28 (<0.1)
Blood oestrogen decreased	10 (<0.1)	14 (<0.1)	24 (<0.1)
Hormone level abnormal	12 (<0.1)	12 (<0.1)	24 (<0.1)
Hepatic enzyme increased	14 (<0.1)	10 (<0.1)	24 (<0.1)
Blood potassium decreased	7 (<0.1)	9 (<0.1)	16 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
HIV test positive	7 (<0.1)	8 (<0.1)	15 (<0.1)
Hysteroscopy	1 (<0.1)	8 (<0.1)	9 (<0.1)
Biopsy prostate	5 (<0.1)	7 (<0.1)	12 (<0.1)
Glycosylated haemoglobin increased	3 (<0.1)	6 (<0.1)	9 (<0.1)
Liver function test increased	4 (<0.1)	6 (<0.1)	10 (<0.1)
Mycobacterium tuberculosis complex test positive	3 (<0.1)	6 (<0.1)	9 (<0.1)
Oesophagogastroduodenoscopy	10 (<0.1)	6 (<0.1)	16 (<0.1)
Weight decreased	8 (<0.1)	6 (<0.1)	14 (<0.1)
Weight increased	4 (<0.1)	6 (<0.1)	10 (<0.1)
Antiphospholipid antibodies	0	5 (<0.1)	5 (<0.1)
Biopsy cervix	2 (<0.1)	5 (<0.1)	7 (<0.1)
Biopsy liver	1 (<0.1)	5 (<0.1)	6 (<0.1)
Blood iron decreased	4 (<0.1)	5 (<0.1)	9 (<0.1)
Blood uric acid increased	3 (<0.1)	5 (<0.1)	8 (<0.1)
Bone density decreased	5 (<0.1)	5 (<0.1)	10 (<0.1)
Cystoscopy	1 (<0.1)	5 (<0.1)	6 (<0.1)
Tuberculin test positive	8 (<0.1)	5 (<0.1)	13 (<0.1)
Angiogram	1 (<0.1)	4 (<0.1)	5 (<0.1)
Biopsy	2 (<0.1)	4 (<0.1)	6 (<0.1)
Blood bilirubin increased	3 (<0.1)	4 (<0.1)	7 (<0.1)
Colonoscopy normal	2 (<0.1)	4 (<0.1)	6 (<0.1)
Lipids increased	5 (<0.1)	4 (<0.1)	9 (<0.1)
Mammogram	4 (<0.1)	4 (<0.1)	8 (<0.1)
Progesterone decreased	3 (<0.1)	4 (<0.1)	7 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Smear cervix	2 (<0.1)	4 (<0.1)	6 (<0.1)
Aspiration pleural cavity	2 (<0.1)	3 (<0.1)	5 (<0.1)
Biopsy skin	3 (<0.1)	3 (<0.1)	6 (<0.1)
Blood calcium increased	1 (<0.1)	3 (<0.1)	4 (<0.1)
Blood magnesium decreased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Electrocardiogram abnormal	5 (<0.1)	3 (<0.1)	8 (<0.1)
Precancerous cells present	12 (<0.1)	3 (<0.1)	15 (<0.1)
White blood cell count decreased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Aortic bruit	2 (<0.1)	2 (<0.1)	4 (<0.1)
Biopsy kidney	2 (<0.1)	2 (<0.1)	4 (<0.1)
Body mass index increased	0	2 (<0.1)	2 (<0.1)
Bone densitometry	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cardiac stress test	1 (<0.1)	2 (<0.1)	3 (<0.1)
Carotid bruit	2 (<0.1)	2 (<0.1)	4 (<0.1)
Continuous glucose monitoring	1 (<0.1)	2 (<0.1)	3 (<0.1)
Endoscopy gastrointestinal	1 (<0.1)	2 (<0.1)	3 (<0.1)
Haemoglobin increased	0	2 (<0.1)	2 (<0.1)
Hepatitis C test negative	0	2 (<0.1)	2 (<0.1)
Intraocular pressure test	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oxygen saturation decreased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Serum ferritin decreased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tuberculin test	3 (<0.1)	2 (<0.1)	5 (<0.1)
Ureteroscopy	2 (<0.1)	2 (<0.1)	4 (<0.1)
Androgens increased	0	1 (<0.1)	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Anti-thyroid antibody positive	1 (<0.1)	1 (<0.1)	2 (<0.1)
Antiphospholipid antibodies positive	0	1 (<0.1)	1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Aspiration joint	1 (<0.1)	1 (<0.1)	2 (<0.1)
Autoantibody positive	0	1 (<0.1)	1 (<0.1)
Biopsy bone	1 (<0.1)	1 (<0.1)	2 (<0.1)
Biopsy ear	0	1 (<0.1)	1 (<0.1)
Biopsy lymph gland	3 (<0.1)	1 (<0.1)	4 (<0.1)
Biopsy prostate normal	0	1 (<0.1)	1 (<0.1)
Biopsy salivary gland	0	1 (<0.1)	1 (<0.1)
Biopsy thyroid gland	3 (<0.1)	1 (<0.1)	4 (<0.1)
Biopsy thyroid gland abnormal	0	1 (<0.1)	1 (<0.1)
Biopsy tongue	0	1 (<0.1)	1 (<0.1)
Biopsy uterus	0	1 (<0.1)	1 (<0.1)
Blood creatinine increased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Blood glucose abnormal	2 (<0.1)	1 (<0.1)	3 (<0.1)
Blood glucose decreased	0	1 (<0.1)	1 (<0.1)
Blood homocysteine increased	0	1 (<0.1)	1 (<0.1)
Blood immunoglobulin G decreased	0	1 (<0.1)	1 (<0.1)
Blood iron increased	0	1 (<0.1)	1 (<0.1)
Blood oestrogen increased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Blood phosphorus decreased	0	1 (<0.1)	1 (<0.1)
Blood pressure diastolic decreased	0	1 (<0.1)	1 (<0.1)
Blood prolactin increased	0	1 (<0.1)	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood testosterone increased	0	1 (<0.1)	1 (<0.1)
Blood thyroid stimulating hormone decreased	0	1 (<0.1)	1 (<0.1)
Blood triglycerides	0	1 (<0.1)	1 (<0.1)
Blood urine present	0	1 (<0.1)	1 (<0.1)
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Bone scan	0	1 (<0.1)	1 (<0.1)
Breath sounds abnormal	0	1 (<0.1)	1 (<0.1)
Cardiac murmur functional	0	1 (<0.1)	1 (<0.1)
Catheterisation cardiac normal	0	1 (<0.1)	1 (<0.1)
Coagulation factor VIII level increased	0	1 (<0.1)	1 (<0.1)
Colposcopy	4 (<0.1)	1 (<0.1)	5 (<0.1)
Computerised tomogram	0	1 (<0.1)	1 (<0.1)
Cortisol decreased	0	1 (<0.1)	1 (<0.1)
Diagnostic aspiration	0	1 (<0.1)	1 (<0.1)
Echocardiogram	0	1 (<0.1)	1 (<0.1)
Ejection fraction	0	1 (<0.1)	1 (<0.1)
Electrocardiogram	0	1 (<0.1)	1 (<0.1)
Electrocardiogram QT prolonged	1 (<0.1)	1 (<0.1)	2 (<0.1)
Electrocardiogram repolarisation abnormality	0	1 (<0.1)	1 (<0.1)
Endoscopic retrograde cholangiopancreatography	0	1 (<0.1)	1 (<0.1)
Endoscopy upper gastrointestinal tract	0	1 (<0.1)	1 (<0.1)
Endoscopy upper gastrointestinal tract normal	0	1 (<0.1)	1 (<0.1)
Epstein-Barr virus test positive	0	1 (<0.1)	1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Gastric pH decreased	0	1 (<0.1)	1 (<0.1)
Gene mutation identification test positive	0	1 (<0.1)	1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)	1 (<0.1)
Haematocrit	0	1 (<0.1)	1 (<0.1)
Haemoglobin decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Heart rate abnormal	0	1 (<0.1)	1 (<0.1)
Heart rate decreased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Heart rate increased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Hepatitis B core antibody	0	1 (<0.1)	1 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)	1 (<0.1)
High density lipoprotein decreased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Human papilloma virus test positive	2 (<0.1)	1 (<0.1)	3 (<0.1)
Interferon gamma release assay positive	0	1 (<0.1)	1 (<0.1)
Intraocular pressure test abnormal	0	1 (<0.1)	1 (<0.1)
Laryngoscopy	0	1 (<0.1)	1 (<0.1)
Lipoprotein (a) increased	0	1 (<0.1)	1 (<0.1)
Liver function test abnormal	0	1 (<0.1)	1 (<0.1)
Low density lipoprotein increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lumbar puncture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Myocardial strain	0	1 (<0.1)	1 (<0.1)
Nasoendoscopy	0	1 (<0.1)	1 (<0.1)
Occult blood positive	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oesophageal manometry	0	1 (<0.1)	1 (<0.1)
Pelvic laparoscopy	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Platelet count decreased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Platelet count increased	0	1 (<0.1)	1 (<0.1)
Prostate examination abnormal	0	1 (<0.1)	1 (<0.1)
Prostatic specific antigen	0	1 (<0.1)	1 (<0.1)
Pulmonary function test decreased	0	1 (<0.1)	1 (<0.1)
Pupillary light reflex tests abnormal	0	1 (<0.1)	1 (<0.1)
Red blood cell count decreased	0	1 (<0.1)	1 (<0.1)
Sinoscopy	0	1 (<0.1)	1 (<0.1)
Stool analysis normal	0	1 (<0.1)	1 (<0.1)
Thyroid hormones decreased	0	1 (<0.1)	1 (<0.1)
Transaminases increased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Urine calcium increased	0	1 (<0.1)	1 (<0.1)
Visual acuity tests	0	1 (<0.1)	1 (<0.1)
Vitamin B12 decreased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Weight abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
X-ray limb	0	1 (<0.1)	1 (<0.1)
Alpha-1 anti-trypsin abnormal	1 (<0.1)	0	1 (<0.1)
Angiocardiogram	1 (<0.1)	0	1 (<0.1)
Apolipoprotein	1 (<0.1)	0	1 (<0.1)
Aspiration breast	1 (<0.1)	0	1 (<0.1)
Bacterial test	1 (<0.1)	0	1 (<0.1)
Biopsy bone marrow	1 (<0.1)	0	1 (<0.1)
Biopsy brain	1 (<0.1)	0	1 (<0.1)
Biopsy breast normal	2 (<0.1)	0	2 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Biopsy endometrium	1 (<0.1)	0	1 (<0.1)
Biopsy larynx	1 (<0.1)	0	1 (<0.1)
Biopsy lung	2 (<0.1)	0	2 (<0.1)
Blood calcium decreased	1 (<0.1)	0	1 (<0.1)
Blood glucose increased	3 (<0.1)	0	3 (<0.1)
Blood insulin abnormal	1 (<0.1)	0	1 (<0.1)
Blood parathyroid hormone increased	1 (<0.1)	0	1 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	0	1 (<0.1)
Blood pressure systolic increased	3 (<0.1)	0	3 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0	1 (<0.1)
Breath sounds	1 (<0.1)	0	1 (<0.1)
CSF volume increased	1 (<0.1)	0	1 (<0.1)
Carbohydrate antigen 125	1 (<0.1)	0	1 (<0.1)
Cardiac stress test abnormal	1 (<0.1)	0	1 (<0.1)
Cardiac stress test normal	1 (<0.1)	0	1 (<0.1)
Cardiovascular function test abnormal	1 (<0.1)	0	1 (<0.1)
Chromopertubation	1 (<0.1)	0	1 (<0.1)
Ejection fraction decreased	1 (<0.1)	0	1 (<0.1)
Electrocardiogram J wave	1 (<0.1)	0	1 (<0.1)
Endoscopic ultrasound	1 (<0.1)	0	1 (<0.1)
False positive investigation result	1 (<0.1)	0	1 (<0.1)
Fungal test	1 (<0.1)	0	1 (<0.1)
HIV antibody positive	1 (<0.1)	0	1 (<0.1)
HLA-B*27 positive	1 (<0.1)	0	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Hepatitis B core antibody positive	1 (<0.1)	0	1 (<0.1)
Hepatitis C RNA negative	1 (<0.1)	0	1 (<0.1)
Hepatitis C virus test positive	1 (<0.1)	0	1 (<0.1)
Immunoglobulins	1 (<0.1)	0	1 (<0.1)
Intraocular pressure decreased	1 (<0.1)	0	1 (<0.1)
Investigation	1 (<0.1)	0	1 (<0.1)
Lymph node palpable	3 (<0.1)	0	3 (<0.1)
Mammogram abnormal	3 (<0.1)	0	3 (<0.1)
Mediastinoscopy	1 (<0.1)	0	1 (<0.1)
Mycobacterium tuberculosis complex test negative	1 (<0.1)	0	1 (<0.1)
Ophthalmological examination	1 (<0.1)	0	1 (<0.1)
Physical breast examination	1 (<0.1)	0	1 (<0.1)
Plasminogen activator inhibitor	1 (<0.1)	0	1 (<0.1)
Platelet aggregation abnormal	1 (<0.1)	0	1 (<0.1)
Progesterone receptor assay	1 (<0.1)	0	1 (<0.1)
Protein total decreased	1 (<0.1)	0	1 (<0.1)
Protein urine present	1 (<0.1)	0	1 (<0.1)
Radioisotope scan	1 (<0.1)	0	1 (<0.1)
SARS-CoV-2 test negative	2 (<0.1)	0	2 (<0.1)
SARS-CoV-2 test positive	1 (<0.1)	0	1 (<0.1)
Salivary scan	1 (<0.1)	0	1 (<0.1)
Serum ferritin increased	1 (<0.1)	0	1 (<0.1)
Staphylococcus test positive	1 (<0.1)	0	1 (<0.1)
Ultrasound scan	1 (<0.1)	0	1 (<0.1)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Vitamin B12	1 (<0.1)	0	1 (<0.1)
Vitamin D	1 (<0.1)	0	1 (<0.1)
Injury, poisoning and procedural complications	1543 (10.2)	1538 (10.1)	3081 (10.2)
Meniscus injury	204 (1.3)	213 (1.4)	417 (1.4)
Ligament rupture	139 (0.9)	141 (0.9)	280 (0.9)
Ankle fracture	113 (0.7)	101 (0.7)	214 (0.7)
Wrist fracture	91 (0.6)	80 (0.5)	171 (0.6)
Joint injury	58 (0.4)	76 (0.5)	134 (0.4)
Upper limb fracture	86 (0.6)	76 (0.5)	162 (0.5)
Hand fracture	53 (0.3)	71 (0.5)	124 (0.4)
Foot fracture	76 (0.5)	70 (0.5)	146 (0.5)
Tendon rupture	56 (0.4)	64 (0.4)	120 (0.4)
Limb injury	67 (0.4)	57 (0.4)	124 (0.4)
Cartilage injury	61 (0.4)	49 (0.3)	110 (0.4)
Lower limb fracture	43 (0.3)	42 (0.3)	85 (0.3)
Joint dislocation	47 (0.3)	40 (0.3)	87 (0.3)
Facial bones fracture	40 (0.3)	32 (0.2)	72 (0.2)
Clavicle fracture	38 (0.3)	31 (0.2)	69 (0.2)
Ligament sprain	33 (0.2)	31 (0.2)	64 (0.2)
Tibia fracture	21 (0.1)	31 (0.2)	52 (0.2)
Concussion	31 (0.2)	30 (0.2)	61 (0.2)
Road traffic accident	30 (0.2)	27 (0.2)	57 (0.2)
Femur fracture	25 (0.2)	23 (0.2)	48 (0.2)

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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Muscle strain	28 (0.2)	23 (0.2)	51 (0.2)
Craniocerebral injury	14 (<0.1)	20 (0.1)	34 (0.1)
Radius fracture	18 (0.1)	20 (0.1)	38 (0.1)
Tooth fracture	12 (<0.1)	18 (0.1)	30 (<0.1)
Skin laceration	16 (0.1)	17 (0.1)	33 (0.1)
Epicondylitis	24 (0.2)	16 (0.1)	40 (0.1)
Humerus fracture	10 (<0.1)	16 (0.1)	26 (<0.1)
Rib fracture	14 (<0.1)	16 (0.1)	30 (<0.1)
Cervical vertebral fracture	8 (<0.1)	15 (<0.1)	23 (<0.1)
Hip fracture	26 (0.2)	15 (<0.1)	41 (0.1)
Lumbar vertebral fracture	8 (<0.1)	15 (<0.1)	23 (<0.1)
Patella fracture	9 (<0.1)	15 (<0.1)	24 (<0.1)
Pelvic fracture	7 (<0.1)	15 (<0.1)	22 (<0.1)
Fibula fracture	9 (<0.1)	13 (<0.1)	22 (<0.1)
Tendon injury	10 (<0.1)	13 (<0.1)	23 (<0.1)
Back injury	8 (<0.1)	12 (<0.1)	20 (<0.1)
Head injury	14 (<0.1)	12 (<0.1)	26 (<0.1)
Muscle rupture	17 (0.1)	12 (<0.1)	29 (<0.1)
Spinal compression fracture	6 (<0.1)	12 (<0.1)	18 (<0.1)
Spinal fracture	12 (<0.1)	12 (<0.1)	24 (<0.1)
Gun shot wound	19 (0.1)	11 (<0.1)	30 (<0.1)
Scar	13 (<0.1)	11 (<0.1)	24 (<0.1)
Stress fracture	5 (<0.1)	11 (<0.1)	16 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Ligament injury	7 (<0.1)	10 (<0.1)	17 (<0.1)
Multiple fractures	13 (<0.1)	10 (<0.1)	23 (<0.1)
Skin abrasion	4 (<0.1)	10 (<0.1)	14 (<0.1)
Arthropod bite	2 (<0.1)	7 (<0.1)	9 (<0.1)
Fall	10 (<0.1)	7 (<0.1)	17 (<0.1)
Forearm fracture	4 (<0.1)	7 (<0.1)	11 (<0.1)
Jaw fracture	13 (<0.1)	7 (<0.1)	20 (<0.1)
Neck injury	5 (<0.1)	7 (<0.1)	12 (<0.1)
Nerve injury	22 (0.1)	7 (<0.1)	29 (<0.1)
Ulna fracture	11 (<0.1)	7 (<0.1)	18 (<0.1)
Contusion	6 (<0.1)	6 (<0.1)	12 (<0.1)
Post-traumatic pain	1 (<0.1)	6 (<0.1)	7 (<0.1)
Procedural pain	6 (<0.1)	6 (<0.1)	12 (<0.1)
Skull fracture	8 (<0.1)	6 (<0.1)	14 (<0.1)
Animal bite	4 (<0.1)	5 (<0.1)	9 (<0.1)
Fracture	1 (<0.1)	5 (<0.1)	6 (<0.1)
Incisional hernia	8 (<0.1)	5 (<0.1)	13 (<0.1)
Muscle injury	6 (<0.1)	5 (<0.1)	11 (<0.1)
Post procedural hypothyroidism	6 (<0.1)	5 (<0.1)	11 (<0.1)
Spinal cord injury	3 (<0.1)	5 (<0.1)	8 (<0.1)
Stab wound	5 (<0.1)	5 (<0.1)	10 (<0.1)
Thoracic vertebral fracture	4 (<0.1)	5 (<0.1)	9 (<0.1)
Wound	4 (<0.1)	5 (<0.1)	9 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Eye injury	7 (<0.1)	4 (<0.1)	11 (<0.1)
Fractured coccyx	3 (<0.1)	4 (<0.1)	7 (<0.1)
Intervertebral disc injury	0	4 (<0.1)	4 (<0.1)
Limb fracture	1 (<0.1)	4 (<0.1)	5 (<0.1)
Spinal column injury	10 (<0.1)	4 (<0.1)	14 (<0.1)
Subdural haematoma	3 (<0.1)	4 (<0.1)	7 (<0.1)
Arthropod sting	0	3 (<0.1)	3 (<0.1)
Asbestosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Compression fracture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Corneal abrasion	2 (<0.1)	3 (<0.1)	5 (<0.1)
Face injury	4 (<0.1)	3 (<0.1)	7 (<0.1)
Limb traumatic amputation	4 (<0.1)	3 (<0.1)	7 (<0.1)
Overdose	1 (<0.1)	3 (<0.1)	4 (<0.1)
Post concussion syndrome	1 (<0.1)	3 (<0.1)	4 (<0.1)
Sports injury	4 (<0.1)	3 (<0.1)	7 (<0.1)
Accident	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bone contusion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Burns first degree	0	2 (<0.1)	2 (<0.1)
Chest injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Foreign body	0	2 (<0.1)	2 (<0.1)
Limb crushing injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Musculoskeletal foreign body	0	2 (<0.1)	2 (<0.1)
Peripheral nerve injury	1 (<0.1)	2 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post-traumatic neck syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Procedural nausea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Scapula fracture	4 (<0.1)	2 (<0.1)	6 (<0.1)
Skeletal injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Soft tissue injury	2 (<0.1)	2 (<0.1)	4 (<0.1)
Sunburn	1 (<0.1)	2 (<0.1)	3 (<0.1)
Thermal burn	10 (<0.1)	2 (<0.1)	12 (<0.1)
Traumatic lung injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ulnar nerve injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Abdominal injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abdominal wall wound	0	1 (<0.1)	1 (<0.1)
Accident at work	1 (<0.1)	1 (<0.1)	2 (<0.1)
Acetabulum fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Aortic annulus rupture	0	1 (<0.1)	1 (<0.1)
Bladder injury	0	1 (<0.1)	1 (<0.1)
Burns third degree	0	1 (<0.1)	1 (<0.1)
Bursa injury	0	1 (<0.1)	1 (<0.1)
Chloracne	0	1 (<0.1)	1 (<0.1)
Craniofacial fracture	0	1 (<0.1)	1 (<0.1)
Deafness traumatic	0	1 (<0.1)	1 (<0.1)
Dental restoration failure	3 (<0.1)	1 (<0.1)	4 (<0.1)
Dislocation of vertebra	3 (<0.1)	1 (<0.1)	4 (<0.1)
Exposure to chemical pollution	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Exposure to communicable disease	6 (<0.1)	1 (<0.1)	7 (<0.1)
Exposure to toxic agent	5 (<0.1)	1 (<0.1)	6 (<0.1)
Eye contusion	0	1 (<0.1)	1 (<0.1)
Eyelid abrasion	0	1 (<0.1)	1 (<0.1)
Femoral nerve injury	0	1 (<0.1)	1 (<0.1)
Greenstick fracture	0	1 (<0.1)	1 (<0.1)
Heart injury	0	1 (<0.1)	1 (<0.1)
Heat stroke	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatic rupture	0	1 (<0.1)	1 (<0.1)
Hypobarism	0	1 (<0.1)	1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Immunisation anxiety related reaction	0	1 (<0.1)	1 (<0.1)
Impacted fracture	0	1 (<0.1)	1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)	1 (<0.1)
Injury	2 (<0.1)	1 (<0.1)	3 (<0.1)
Injury corneal	0	1 (<0.1)	1 (<0.1)
Joint capsule rupture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Kidney contusion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mallet finger	1 (<0.1)	1 (<0.1)	2 (<0.1)
Multiple injuries	0	1 (<0.1)	1 (<0.1)
Nail injury	0	1 (<0.1)	1 (<0.1)
Occupational exposure to noise	0	1 (<0.1)	1 (<0.1)
Open fracture	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Peroneal nerve injury	0	1 (<0.1)	1 (<0.1)
Post laminectomy syndrome	0	1 (<0.1)	1 (<0.1)
Post procedural diarrhoea	0	1 (<0.1)	1 (<0.1)
Post procedural haematuria	0	1 (<0.1)	1 (<0.1)
Post procedural pulmonary embolism	0	1 (<0.1)	1 (<0.1)
Procedural dizziness	0	1 (<0.1)	1 (<0.1)
Procedural vomiting	1 (<0.1)	1 (<0.1)	2 (<0.1)
Radiation injury	0	1 (<0.1)	1 (<0.1)
Radiation proctitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Skin injury	0	1 (<0.1)	1 (<0.1)
Spinal cord injury cervical	2 (<0.1)	1 (<0.1)	3 (<0.1)
Splenic injury	0	1 (<0.1)	1 (<0.1)
Splenic rupture	4 (<0.1)	1 (<0.1)	5 (<0.1)
Splinter	0	1 (<0.1)	1 (<0.1)
Testicular rupture	0	1 (<0.1)	1 (<0.1)
Torus fracture	0	1 (<0.1)	1 (<0.1)
Traumatic fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Traumatic haematoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ureteric injury	0	1 (<0.1)	1 (<0.1)
Uterine perforation	1 (<0.1)	1 (<0.1)	2 (<0.1)
VIIth nerve injury	0	1 (<0.1)	1 (<0.1)
Vascular pseudoaneurysm	0	1 (<0.1)	1 (<0.1)
Anal injury	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Arterial injury	1 (<0.1)	0	1 (<0.1)
Autonomic dysreflexia	1 (<0.1)	0	1 (<0.1)
Bite	1 (<0.1)	0	1 (<0.1)
Blindness traumatic	1 (<0.1)	0	1 (<0.1)
Brachial plexus injury	1 (<0.1)	0	1 (<0.1)
Brain contusion	2 (<0.1)	0	2 (<0.1)
Burns second degree	3 (<0.1)	0	3 (<0.1)
Cataract traumatic	1 (<0.1)	0	1 (<0.1)
Crush injury	1 (<0.1)	0	1 (<0.1)
Cuboid syndrome	1 (<0.1)	0	1 (<0.1)
Ear canal abrasion	1 (<0.1)	0	1 (<0.1)
Ear injury	1 (<0.1)	0	1 (<0.1)
Endotracheal intubation complication	1 (<0.1)	0	1 (<0.1)
Fallopian tube perforation	1 (<0.1)	0	1 (<0.1)
Fractured sacrum	2 (<0.1)	0	2 (<0.1)
Frostbite	1 (<0.1)	0	1 (<0.1)
Gastroenteritis radiation	1 (<0.1)	0	1 (<0.1)
Gastrointestinal injury	1 (<0.1)	0	1 (<0.1)
Haemolytic transfusion reaction	1 (<0.1)	0	1 (<0.1)
Injection related reaction	1 (<0.1)	0	1 (<0.1)
Injury to brachial plexus due to birth trauma	2 (<0.1)	0	2 (<0.1)
Kidney rupture	1 (<0.1)	0	1 (<0.1)
Lisfranc fracture	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Nasal injury	4 (<0.1)	0	4 (<0.1)
Nerve root injury cervical	1 (<0.1)	0	1 (<0.1)
Optic nerve injury	3 (<0.1)	0	3 (<0.1)
Pelvic organ injury	1 (<0.1)	0	1 (<0.1)
Petroleum distillate poisoning	1 (<0.1)	0	1 (<0.1)
Post procedural complication	2 (<0.1)	0	2 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0	1 (<0.1)
Post procedural swelling	1 (<0.1)	0	1 (<0.1)
Postoperative thrombosis	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Pulmonary contusion	1 (<0.1)	0	1 (<0.1)
Radiation skin injury	1 (<0.1)	0	1 (<0.1)
Restenosis	1 (<0.1)	0	1 (<0.1)
Sciatic nerve injury	1 (<0.1)	0	1 (<0.1)
Scrotal injury	1 (<0.1)	0	1 (<0.1)
Silicosis	1 (<0.1)	0	1 (<0.1)
Spleen procedural complication	1 (<0.1)	0	1 (<0.1)
Sternal fracture	2 (<0.1)	0	2 (<0.1)
Struck by lightning	1 (<0.1)	0	1 (<0.1)
Subdural haemorrhage	1 (<0.1)	0	1 (<0.1)
Tendon dislocation	1 (<0.1)	0	1 (<0.1)
Tooth injury	3 (<0.1)	0	3 (<0.1)
Toxicity to various agents	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Traumatic arthritis	3 (<0.1)	0	3 (<0.1)
Traumatic liver injury	1 (<0.1)	0	1 (<0.1)
Uterine rupture	1 (<0.1)	0	1 (<0.1)
Vaccination complication	1 (<0.1)	0	1 (<0.1)
Surgical and medical procedures	6550 (43.2)	6647 (43.8)	13197 (43.5)
Hysterectomy	1256 (8.3)	1309 (8.6)	2565 (8.5)
Female sterilisation	677 (4.5)	657 (4.3)	1334 (4.4)
Tonsillectomy	605 (4.0)	633 (4.2)	1238 (4.1)
Cholecystectomy	599 (4.0)	547 (3.6)	1146 (3.8)
Vasectomy	511 (3.4)	495 (3.3)	1006 (3.3)
Appendicectomy	462 (3.0)	479 (3.2)	941 (3.1)
Caesarean section	376 (2.5)	444 (2.9)	820 (2.7)
Botulinum toxin injection	305 (2.0)	398 (2.6)	703 (2.3)
Dermal filler injection	234 (1.5)	325 (2.1)	559 (1.8)
Knee arthroplasty	289 (1.9)	298 (2.0)	587 (1.9)
Cataract operation	284 (1.9)	271 (1.8)	555 (1.8)
Wisdom teeth removal	198 (1.3)	236 (1.6)	434 (1.4)
Inguinal hernia repair	189 (1.2)	200 (1.3)	389 (1.3)
Mammoplasty	193 (1.3)	190 (1.3)	383 (1.3)
Spinal fusion surgery	139 (0.9)	154 (1.0)	293 (1.0)
Hip arthroplasty	128 (0.8)	149 (1.0)	277 (0.9)
Rotator cuff repair	135 (0.9)	148 (1.0)	283 (0.9)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Keratomileusis	148 (1.0)	144 (0.9)	292 (1.0)
Thyroidectomy	122 (0.8)	142 (0.9)	264 (0.9)
Skin neoplasm excision	107 (0.7)	130 (0.9)	237 (0.8)
Ligament operation	111 (0.7)	121 (0.8)	232 (0.8)
Gastric bypass	115 (0.8)	118 (0.8)	233 (0.8)
Coronary arterial stent insertion	116 (0.8)	111 (0.7)	227 (0.7)
Meniscus operation	100 (0.7)	108 (0.7)	208 (0.7)
Knee operation	104 (0.7)	102 (0.7)	206 (0.7)
Carpal tunnel decompression	85 (0.6)	97 (0.6)	182 (0.6)
Fracture treatment	88 (0.6)	97 (0.6)	185 (0.6)
Nasal septal operation	81 (0.5)	93 (0.6)	174 (0.6)
Intervertebral disc operation	101 (0.7)	92 (0.6)	193 (0.6)
Adenoidectomy	72 (0.5)	86 (0.6)	158 (0.5)
Gastrectomy	85 (0.6)	86 (0.6)	171 (0.6)
Endometrial ablation	103 (0.7)	85 (0.6)	188 (0.6)
Shoulder operation	75 (0.5)	84 (0.6)	159 (0.5)
Tenoplasty	61 (0.4)	81 (0.5)	142 (0.5)
Spinal laminectomy	71 (0.5)	80 (0.5)	151 (0.5)
Mastectomy	54 (0.4)	78 (0.5)	132 (0.4)
Umbilical hernia repair	76 (0.5)	78 (0.5)	154 (0.5)
Cardiac ablation	68 (0.4)	73 (0.5)	141 (0.5)
Coronary artery bypass	97 (0.6)	73 (0.5)	170 (0.6)
Bunion operation	55 (0.4)	72 (0.5)	127 (0.4)
Prostatectomy	60 (0.4)	71 (0.5)	131 (0.4)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Spinal operation	85 (0.6)	71 (0.5)	156 (0.5)
Hernia repair	53 (0.3)	67 (0.4)	120 (0.4)
Abdominoplasty	66 (0.4)	65 (0.4)	131 (0.4)
Breast conserving surgery	80 (0.5)	65 (0.4)	145 (0.5)
Limb operation	43 (0.3)	58 (0.4)	101 (0.3)
Rhinoplasty	57 (0.4)	56 (0.4)	113 (0.4)
Oophorectomy bilateral	41 (0.3)	55 (0.4)	96 (0.3)
Sinus operation	53 (0.3)	54 (0.4)	107 (0.4)
Salpingectomy	48 (0.3)	53 (0.3)	101 (0.3)
Uterine dilation and curettage	55 (0.4)	51 (0.3)	106 (0.3)
Oophorectomy	73 (0.5)	48 (0.3)	121 (0.4)
Skin cosmetic procedure	57 (0.4)	47 (0.3)	104 (0.3)
Medical device implantation	38 (0.3)	46 (0.3)	84 (0.3)
Stent placement	27 (0.2)	46 (0.3)	73 (0.2)
Shoulder arthroplasty	33 (0.2)	44 (0.3)	77 (0.3)
Colectomy	40 (0.3)	42 (0.3)	82 (0.3)
Cyst removal	53 (0.3)	42 (0.3)	95 (0.3)
Micrographic skin surgery	33 (0.2)	42 (0.3)	75 (0.2)
Ankle operation	47 (0.3)	41 (0.3)	88 (0.3)
Cardiac pacemaker insertion	56 (0.4)	41 (0.3)	97 (0.3)
Cancer surgery	34 (0.2)	38 (0.3)	72 (0.2)
Open reduction of fracture	48 (0.3)	36 (0.2)	84 (0.3)
Renal stone removal	35 (0.2)	36 (0.2)	71 (0.2)
Urinary bladder suspension	32 (0.2)	35 (0.2)	67 (0.2)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Wrist surgery	41 (0.3)	35 (0.2)	76 (0.3)
Gastric banding	29 (0.2)	34 (0.2)	63 (0.2)
Foot operation	34 (0.2)	33 (0.2)	67 (0.2)
Myomectomy	33 (0.2)	33 (0.2)	66 (0.2)
Arthroscopic surgery	21 (0.1)	32 (0.2)	53 (0.2)
Dental implantation	23 (0.2)	32 (0.2)	55 (0.2)
Nephrectomy	27 (0.2)	32 (0.2)	59 (0.2)
Bone lesion excision	23 (0.2)	31 (0.2)	54 (0.2)
Haemorrhoid operation	45 (0.3)	31 (0.2)	76 (0.3)
Lipoma excision	38 (0.3)	29 (0.2)	67 (0.2)
Abdominal hernia repair	35 (0.2)	28 (0.2)	63 (0.2)
Bone operation	19 (0.1)	28 (0.2)	47 (0.2)
Intra-uterine contraceptive device insertion	29 (0.2)	27 (0.2)	56 (0.2)
Intraocular lens implant	32 (0.2)	27 (0.2)	59 (0.2)
Tooth extraction	26 (0.2)	27 (0.2)	53 (0.2)
Large intestinal polypectomy	20 (0.1)	26 (0.2)	46 (0.2)
Lithotripsy	38 (0.3)	26 (0.2)	64 (0.2)
Transurethral prostatectomy	28 (0.2)	26 (0.2)	54 (0.2)
Chondroplasty	16 (0.1)	24 (0.2)	40 (0.1)
Blepharoplasty	19 (0.1)	22 (0.1)	41 (0.1)
Liposuction	26 (0.2)	22 (0.1)	48 (0.2)
Meniscus removal	16 (0.1)	22 (0.1)	38 (0.1)
Hysterosalpingo-oophorectomy	16 (0.1)	21 (0.1)	37 (0.1)
Face lift	12 (<0.1)	20 (0.1)	32 (0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Synovial cyst removal	21 (0.1)	20 (0.1)	41 (0.1)
Tendon sheath incision	22 (0.1)	20 (0.1)	42 (0.1)
Ear tube insertion	17 (0.1)	19 (0.1)	36 (0.1)
Elbow operation	26 (0.2)	19 (0.1)	45 (0.1)
Hernia hiatus repair	24 (0.2)	19 (0.1)	43 (0.1)
Intrauterine contraception	22 (0.1)	19 (0.1)	41 (0.1)
Lymphadenectomy	22 (0.1)	19 (0.1)	41 (0.1)
Varicose vein operation	17 (0.1)	19 (0.1)	36 (0.1)
Metabolic surgery	16 (0.1)	18 (0.1)	34 (0.1)
Oesophagogastric fundoplasty	12 (<0.1)	18 (0.1)	30 (<0.1)
Adenotonsillectomy	11 (<0.1)	16 (0.1)	27 (<0.1)
Breast reconstruction	13 (<0.1)	16 (0.1)	29 (<0.1)
Eye operation	29 (0.2)	16 (0.1)	45 (0.1)
Hip surgery	14 (<0.1)	16 (0.1)	30 (<0.1)
Jaw operation	18 (0.1)	16 (0.1)	34 (0.1)
Leg amputation	7 (<0.1)	16 (0.1)	23 (<0.1)
Retinopexy	9 (<0.1)	16 (0.1)	25 (<0.1)
Ovarian cystectomy	31 (0.2)	15 (<0.1)	46 (0.2)
Radiotherapy	13 (<0.1)	15 (<0.1)	28 (<0.1)
Salpingo-oophorectomy bilateral	17 (0.1)	15 (<0.1)	32 (0.1)
Sinuplasty	18 (0.1)	15 (<0.1)	33 (0.1)
Strabismus correction	10 (<0.1)	15 (<0.1)	25 (<0.1)
Mole excision	11 (<0.1)	14 (<0.1)	25 (<0.1)
Polypectomy	11 (<0.1)	14 (<0.1)	25 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Skin graft	13 (<0.1)	14 (<0.1)	27 (<0.1)
Toe operation	13 (<0.1)	14 (<0.1)	27 (<0.1)
Tumour excision	13 (<0.1)	14 (<0.1)	27 (<0.1)
Varicocele repair	4 (<0.1)	14 (<0.1)	18 (<0.1)
Angioplasty	14 (<0.1)	13 (<0.1)	27 (<0.1)
Benign breast lump removal	13 (<0.1)	13 (<0.1)	26 (<0.1)
Implantable defibrillator insertion	13 (<0.1)	13 (<0.1)	26 (<0.1)
Intestinal resection	9 (<0.1)	13 (<0.1)	22 (<0.1)
Muscle operation	15 (<0.1)	13 (<0.1)	28 (<0.1)
Myringotomy	7 (<0.1)	13 (<0.1)	20 (<0.1)
Pilonidal sinus repair	14 (<0.1)	13 (<0.1)	27 (<0.1)
Vision correction operation	9 (<0.1)	13 (<0.1)	22 (<0.1)
Continuous positive airway pressure	17 (0.1)	12 (<0.1)	29 (<0.1)
Corneal transplant	11 (<0.1)	12 (<0.1)	23 (<0.1)
Loop electrosurgical excision procedure	6 (<0.1)	12 (<0.1)	18 (<0.1)
Osteotomy	11 (<0.1)	12 (<0.1)	23 (<0.1)
Permanent contraceptive tubal implant	5 (<0.1)	12 (<0.1)	17 (<0.1)
Sterilisation	5 (<0.1)	12 (<0.1)	17 (<0.1)
Ankle arthroplasty	6 (<0.1)	11 (<0.1)	17 (<0.1)
Craniotomy	11 (<0.1)	11 (<0.1)	22 (<0.1)
Heart valve replacement	5 (<0.1)	11 (<0.1)	16 (<0.1)
Nasal operation	14 (<0.1)	11 (<0.1)	25 (<0.1)
Neck surgery	17 (0.1)	11 (<0.1)	28 (<0.1)
Parathyroidectomy	13 (<0.1)	11 (<0.1)	24 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Retinal operation	13 (<0.1)	11 (<0.1)	24 (<0.1)
Atrial septal defect repair	6 (<0.1)	10 (<0.1)	16 (<0.1)
Coronary angioplasty	11 (<0.1)	10 (<0.1)	21 (<0.1)
Finger amputation	6 (<0.1)	10 (<0.1)	16 (<0.1)
Lung lobectomy	7 (<0.1)	10 (<0.1)	17 (<0.1)
Papilloma excision	2 (<0.1)	10 (<0.1)	12 (<0.1)
Plastic surgery to the face	6 (<0.1)	10 (<0.1)	16 (<0.1)
Radical prostatectomy	5 (<0.1)	10 (<0.1)	15 (<0.1)
Abscess drainage	14 (<0.1)	9 (<0.1)	23 (<0.1)
Benign tumour excision	16 (0.1)	9 (<0.1)	25 (<0.1)
Breast cyst excision	7 (<0.1)	9 (<0.1)	16 (<0.1)
Cryotherapy	5 (<0.1)	9 (<0.1)	14 (<0.1)
Endodontic procedure	11 (<0.1)	9 (<0.1)	20 (<0.1)
Eye laser surgery	11 (<0.1)	9 (<0.1)	20 (<0.1)
Hormone replacement therapy	11 (<0.1)	9 (<0.1)	20 (<0.1)
Internal fixation of fracture	4 (<0.1)	9 (<0.1)	13 (<0.1)
Medical device removal	9 (<0.1)	9 (<0.1)	18 (<0.1)
Neurectomy	9 (<0.1)	9 (<0.1)	18 (<0.1)
Orchidectomy	12 (<0.1)	9 (<0.1)	21 (<0.1)
Prostatic operation	16 (0.1)	9 (<0.1)	25 (<0.1)
Radiotherapy to prostate	5 (<0.1)	9 (<0.1)	14 (<0.1)
Tendon operation	8 (<0.1)	9 (<0.1)	17 (<0.1)
Turbinectomy	7 (<0.1)	9 (<0.1)	16 (<0.1)
Aortic valve replacement	28 (0.2)	8 (<0.1)	36 (0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Bladder repair	7 (<0.1)	8 (<0.1)	15 (<0.1)
Bone graft	4 (<0.1)	8 (<0.1)	12 (<0.1)
Chemotherapy	5 (<0.1)	8 (<0.1)	13 (<0.1)
Chest tube insertion	3 (<0.1)	8 (<0.1)	11 (<0.1)
Circumcision	7 (<0.1)	8 (<0.1)	15 (<0.1)
Gallbladder operation	2 (<0.1)	8 (<0.1)	10 (<0.1)
Hysterotomy	4 (<0.1)	8 (<0.1)	12 (<0.1)
Joint arthroplasty	12 (<0.1)	8 (<0.1)	20 (<0.1)
Joint debridement	8 (<0.1)	8 (<0.1)	16 (<0.1)
Nasal polypectomy	10 (<0.1)	8 (<0.1)	18 (<0.1)
Spinal nerve stimulator implantation	8 (<0.1)	8 (<0.1)	16 (<0.1)
Thoracotomy	7 (<0.1)	8 (<0.1)	15 (<0.1)
Tympanoplasty	11 (<0.1)	8 (<0.1)	19 (<0.1)
Uvulectomy	11 (<0.1)	8 (<0.1)	19 (<0.1)
Uvulopalatopharyngoplasty	6 (<0.1)	8 (<0.1)	14 (<0.1)
Cardiac operation	8 (<0.1)	7 (<0.1)	15 (<0.1)
Debridement	4 (<0.1)	7 (<0.1)	11 (<0.1)
Implantable cardiac monitor insertion	6 (<0.1)	7 (<0.1)	13 (<0.1)
Joint dislocation reduction	4 (<0.1)	7 (<0.1)	11 (<0.1)
Skin operation	3 (<0.1)	7 (<0.1)	10 (<0.1)
Toe amputation	7 (<0.1)	7 (<0.1)	14 (<0.1)
Vitrectomy	8 (<0.1)	7 (<0.1)	15 (<0.1)
Abdominal operation	6 (<0.1)	6 (<0.1)	12 (<0.1)
Anal fissure excision	1 (<0.1)	6 (<0.1)	7 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010401.sas 21JUN2021 11:14

Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Bladder operation	5 (<0.1)	6 (<0.1)	11 (<0.1)
Carotid endarterectomy	4 (<0.1)	6 (<0.1)	10 (<0.1)
Central venous catheterisation	2 (<0.1)	6 (<0.1)	8 (<0.1)
Dental operation	6 (<0.1)	6 (<0.1)	12 (<0.1)
Ear operation	4 (<0.1)	6 (<0.1)	10 (<0.1)
Finger repair operation	7 (<0.1)	6 (<0.1)	13 (<0.1)
Glaucoma surgery	2 (<0.1)	6 (<0.1)	8 (<0.1)
Hand repair operation	4 (<0.1)	6 (<0.1)	10 (<0.1)
Meningioma surgery	5 (<0.1)	6 (<0.1)	11 (<0.1)
Orchidopexy	1 (<0.1)	6 (<0.1)	7 (<0.1)
Parotidectomy	1 (<0.1)	6 (<0.1)	7 (<0.1)
Peripheral nerve operation	10 (<0.1)	6 (<0.1)	16 (<0.1)
Photorefractive keratectomy	10 (<0.1)	6 (<0.1)	16 (<0.1)
Prostate ablation	3 (<0.1)	6 (<0.1)	9 (<0.1)
Skin lesion removal	8 (<0.1)	6 (<0.1)	14 (<0.1)
Spinal decompression	3 (<0.1)	6 (<0.1)	9 (<0.1)
Testes exploration	4 (<0.1)	6 (<0.1)	10 (<0.1)
Testicular operation	7 (<0.1)	6 (<0.1)	13 (<0.1)
Tracheostomy	7 (<0.1)	6 (<0.1)	13 (<0.1)
Transfusion	11 (<0.1)	6 (<0.1)	17 (<0.1)
Transgender operation	3 (<0.1)	6 (<0.1)	9 (<0.1)
Arthrodesis	10 (<0.1)	5 (<0.1)	15 (<0.1)
Cardioversion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Cartilage operation	1 (<0.1)	5 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Colostomy	1 (<0.1)	5 (<0.1)	6 (<0.1)
Dacryocystorhinostomy	2 (<0.1)	5 (<0.1)	7 (<0.1)
Eye muscle operation	4 (<0.1)	5 (<0.1)	9 (<0.1)
Eyeglasses therapy	4 (<0.1)	5 (<0.1)	9 (<0.1)
Fascia release	5 (<0.1)	5 (<0.1)	10 (<0.1)
Gingival graft	1 (<0.1)	5 (<0.1)	6 (<0.1)
Hydrocele operation	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mitral valve replacement	7 (<0.1)	5 (<0.1)	12 (<0.1)
Pelvic floor repair	4 (<0.1)	5 (<0.1)	9 (<0.1)
Penile prosthesis insertion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Plastic surgery	5 (<0.1)	5 (<0.1)	10 (<0.1)
Rectocele repair	4 (<0.1)	5 (<0.1)	9 (<0.1)
Sebaceous cyst excision	3 (<0.1)	5 (<0.1)	8 (<0.1)
Small intestinal resection	4 (<0.1)	5 (<0.1)	9 (<0.1)
Splenectomy	6 (<0.1)	5 (<0.1)	11 (<0.1)
Tooth repair	2 (<0.1)	5 (<0.1)	7 (<0.1)
Uterine polypectomy	7 (<0.1)	5 (<0.1)	12 (<0.1)
Vascular graft	6 (<0.1)	5 (<0.1)	11 (<0.1)
Abdominal panniculectomy	0	4 (<0.1)	4 (<0.1)
Aortic aneurysm repair	4 (<0.1)	4 (<0.1)	8 (<0.1)
Arm amputation	1 (<0.1)	4 (<0.1)	5 (<0.1)
Axillary lymphadenectomy	6 (<0.1)	4 (<0.1)	10 (<0.1)
Bartholin's cyst removal	0	4 (<0.1)	4 (<0.1)
Breast prosthesis removal	4 (<0.1)	4 (<0.1)	8 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Cautery to nose	2 (<0.1)	4 (<0.1)	6 (<0.1)
Cleft palate repair	4 (<0.1)	4 (<0.1)	8 (<0.1)
Colon operation	7 (<0.1)	4 (<0.1)	11 (<0.1)
Contraception	9 (<0.1)	4 (<0.1)	13 (<0.1)
Corneal operation	0	4 (<0.1)	4 (<0.1)
Functional endoscopic sinus surgery	2 (<0.1)	4 (<0.1)	6 (<0.1)
High frequency ablation	4 (<0.1)	4 (<0.1)	8 (<0.1)
Ileostomy	4 (<0.1)	4 (<0.1)	8 (<0.1)
Incisional drainage	2 (<0.1)	4 (<0.1)	6 (<0.1)
Incisional hernia repair	3 (<0.1)	4 (<0.1)	7 (<0.1)
Influenza immunisation	7 (<0.1)	4 (<0.1)	11 (<0.1)
Intestinal operation	2 (<0.1)	4 (<0.1)	6 (<0.1)
Lipectomy	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mastoidectomy	5 (<0.1)	4 (<0.1)	9 (<0.1)
Mitral valve repair	12 (<0.1)	4 (<0.1)	16 (<0.1)
Peripheral nerve decompression	7 (<0.1)	4 (<0.1)	11 (<0.1)
Prophylaxis against HIV infection	4 (<0.1)	4 (<0.1)	8 (<0.1)
Pterygium operation	0	4 (<0.1)	4 (<0.1)
Pulmonary resection	2 (<0.1)	4 (<0.1)	6 (<0.1)
Radioactive iodine therapy	7 (<0.1)	4 (<0.1)	11 (<0.1)
Renal artery stent placement	0	4 (<0.1)	4 (<0.1)
Salpingo-oophorectomy unilateral	7 (<0.1)	4 (<0.1)	11 (<0.1)
Scar excision	3 (<0.1)	4 (<0.1)	7 (<0.1)
Sigmoidectomy	11 (<0.1)	4 (<0.1)	15 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Skin cyst excision	4 (<0.1)	4 (<0.1)	8 (<0.1)
Temporomandibular joint surgery	4 (<0.1)	4 (<0.1)	8 (<0.1)
Tendon transfer	1 (<0.1)	4 (<0.1)	5 (<0.1)
Tenotomy	2 (<0.1)	4 (<0.1)	6 (<0.1)
Thyroid therapy	0	4 (<0.1)	4 (<0.1)
Urethral operation	2 (<0.1)	4 (<0.1)	6 (<0.1)
Vena cava filter insertion	2 (<0.1)	4 (<0.1)	6 (<0.1)
Venous operation	1 (<0.1)	4 (<0.1)	5 (<0.1)
Adhesiolysis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Anticoagulant therapy	1 (<0.1)	3 (<0.1)	4 (<0.1)
Aorta coarctation repair	1 (<0.1)	3 (<0.1)	4 (<0.1)
Aortic bypass	0	3 (<0.1)	3 (<0.1)
Artificial urinary sphincter implant	0	3 (<0.1)	3 (<0.1)
Brain operation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Brain tumour operation	2 (<0.1)	3 (<0.1)	5 (<0.1)
CSF shunt operation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cardiac septal defect repair	0	3 (<0.1)	3 (<0.1)
Cervix cryotherapy	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cleft lip repair	2 (<0.1)	3 (<0.1)	5 (<0.1)
Closed fracture manipulation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Cochlea implant	2 (<0.1)	3 (<0.1)	5 (<0.1)
Colporrhaphy	0	3 (<0.1)	3 (<0.1)
Cranial nerve decompression	3 (<0.1)	3 (<0.1)	6 (<0.1)
Endometriosis ablation	6 (<0.1)	3 (<0.1)	9 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Endovenous ablation	2 (<0.1)	3 (<0.1)	5 (<0.1)
Explorative laparotomy	11 (<0.1)	3 (<0.1)	14 (<0.1)
Eye excision	7 (<0.1)	3 (<0.1)	10 (<0.1)
Eyelid operation	4 (<0.1)	3 (<0.1)	7 (<0.1)
Fallopian tube operation	2 (<0.1)	3 (<0.1)	5 (<0.1)
Fistula repair	3 (<0.1)	3 (<0.1)	6 (<0.1)
Fracture reduction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gastric banding reversal	4 (<0.1)	3 (<0.1)	7 (<0.1)
Gastric operation	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gastric ulcer surgery	2 (<0.1)	3 (<0.1)	5 (<0.1)
Gastroplasty	0	3 (<0.1)	3 (<0.1)
Haemangioma removal	2 (<0.1)	3 (<0.1)	5 (<0.1)
Intra-cerebral aneurysm operation	0	3 (<0.1)	3 (<0.1)
Joint injection	5 (<0.1)	3 (<0.1)	8 (<0.1)
Joint surgery	2 (<0.1)	3 (<0.1)	5 (<0.1)
Keratotomy	5 (<0.1)	3 (<0.1)	8 (<0.1)
Laparotomy	4 (<0.1)	3 (<0.1)	7 (<0.1)
Laser therapy	3 (<0.1)	3 (<0.1)	6 (<0.1)
Limb reconstructive surgery	4 (<0.1)	3 (<0.1)	7 (<0.1)
Liver operation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mass excision	5 (<0.1)	3 (<0.1)	8 (<0.1)
Maxillofacial operation	6 (<0.1)	3 (<0.1)	9 (<0.1)
Myopia correction	2 (<0.1)	3 (<0.1)	5 (<0.1)
Neck dissection	2 (<0.1)	3 (<0.1)	5 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Neuroprosthesis implantation	4 (<0.1)	3 (<0.1)	7 (<0.1)
Oesophageal dilation procedure	0	3 (<0.1)	3 (<0.1)
Oesophagectomy	1 (<0.1)	3 (<0.1)	4 (<0.1)
Penile operation	0	3 (<0.1)	3 (<0.1)
Peripheral artery bypass	1 (<0.1)	3 (<0.1)	4 (<0.1)
Phlebectomy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Radiotherapy to breast	2 (<0.1)	3 (<0.1)	5 (<0.1)
Renal surgery	4 (<0.1)	3 (<0.1)	7 (<0.1)
Sclerotherapy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Small intestine operation	3 (<0.1)	3 (<0.1)	6 (<0.1)
Splint application	2 (<0.1)	3 (<0.1)	5 (<0.1)
Stem cell transplant	1 (<0.1)	3 (<0.1)	4 (<0.1)
Talipes correction	1 (<0.1)	3 (<0.1)	4 (<0.1)
Tenodesis	0	3 (<0.1)	3 (<0.1)
Thyroglossal cyst excision	0	3 (<0.1)	3 (<0.1)
Thyroid nodule removal	5 (<0.1)	3 (<0.1)	8 (<0.1)
Trabeculectomy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Umbilicoplasty	0	3 (<0.1)	3 (<0.1)
Ureteral stent insertion	5 (<0.1)	3 (<0.1)	8 (<0.1)
Urethral repair	2 (<0.1)	3 (<0.1)	5 (<0.1)
Urinary control neurostimulator implantation	0	3 (<0.1)	3 (<0.1)
Vertebroplasty	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vocal cord nodule removal	1 (<0.1)	3 (<0.1)	4 (<0.1)
Vocal cord operation	2 (<0.1)	3 (<0.1)	5 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Weight control	0	3 (<0.1)	3 (<0.1)
Abdominal exploration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Amblyopia therapy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Anal fistula repair	3 (<0.1)	2 (<0.1)	5 (<0.1)
Aneurysm repair	4 (<0.1)	2 (<0.1)	6 (<0.1)
Anorectal operation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Aortic stent insertion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Aortic surgery	4 (<0.1)	2 (<0.1)	6 (<0.1)
Arterial stent insertion	5 (<0.1)	2 (<0.1)	7 (<0.1)
Artificial crown procedure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Atrial appendage closure	3 (<0.1)	2 (<0.1)	5 (<0.1)
Bladder neoplasm surgery	5 (<0.1)	2 (<0.1)	7 (<0.1)
Breast operation	5 (<0.1)	2 (<0.1)	7 (<0.1)
Bursa removal	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cardiac pacemaker replacement	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cardiovascular event prophylaxis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Carotid artery stent insertion	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cartilage graft	0	2 (<0.1)	2 (<0.1)
Catheter placement	1 (<0.1)	2 (<0.1)	3 (<0.1)
Cervical conisation	4 (<0.1)	2 (<0.1)	6 (<0.1)
Chondrectomy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Colostomy closure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Contraceptive implant	6 (<0.1)	2 (<0.1)	8 (<0.1)
Cyst drainage	1 (<0.1)	2 (<0.1)	3 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Cystocele repair	2 (<0.1)	2 (<0.1)	4 (<0.1)
Deep brain stimulation	0	2 (<0.1)	2 (<0.1)
Diverticulectomy	0	2 (<0.1)	2 (<0.1)
Drug delivery device implantation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Dupuytren's contracture operation	4 (<0.1)	2 (<0.1)	6 (<0.1)
Ear tube removal	0	2 (<0.1)	2 (<0.1)
Epidural injection	4 (<0.1)	2 (<0.1)	6 (<0.1)
External fixation of fracture	0	2 (<0.1)	2 (<0.1)
Fistulotomy	5 (<0.1)	2 (<0.1)	7 (<0.1)
Foraminotomy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gastric bypass reversal	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gastrointestinal tube insertion	0	2 (<0.1)	2 (<0.1)
Glaucoma drainage device placement	1 (<0.1)	2 (<0.1)	3 (<0.1)
Gluteoplasty	0	2 (<0.1)	2 (<0.1)
Hair transplant	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hearing aid therapy	0	2 (<0.1)	2 (<0.1)
Heart valve operation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hormone therapy	4 (<0.1)	2 (<0.1)	6 (<0.1)
Hypotensive anaesthesia procedure	0	2 (<0.1)	2 (<0.1)
In vitro fertilisation	4 (<0.1)	2 (<0.1)	6 (<0.1)
Joint resurfacing surgery	4 (<0.1)	2 (<0.1)	6 (<0.1)
Joint stabilisation	0	2 (<0.1)	2 (<0.1)
Lacrimal duct procedure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Lacrimal gland operation	0	2 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Large intestine operation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Lens extraction	4 (<0.1)	2 (<0.1)	6 (<0.1)
Lesion excision	3 (<0.1)	2 (<0.1)	5 (<0.1)
Limb reattachment surgery	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lip cosmetic procedure	7 (<0.1)	2 (<0.1)	9 (<0.1)
Modified radical mastectomy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Monovision presbyopia corrective procedure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Nail operation	0	2 (<0.1)	2 (<0.1)
Nephrostomy	0	2 (<0.1)	2 (<0.1)
Nerve graft	1 (<0.1)	2 (<0.1)	3 (<0.1)
Oesophageal variceal ligation	0	2 (<0.1)	2 (<0.1)
Oral surgery	4 (<0.1)	2 (<0.1)	6 (<0.1)
Orbit plastic repair	1 (<0.1)	2 (<0.1)	3 (<0.1)
Orthognathic surgery	5 (<0.1)	2 (<0.1)	7 (<0.1)
Ostectomy	3 (<0.1)	2 (<0.1)	5 (<0.1)
Otoplasty	1 (<0.1)	2 (<0.1)	3 (<0.1)
Ovarian operation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Paranasal sinus polypectomy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pelvic operation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Peripheral nerve transposition	1 (<0.1)	2 (<0.1)	3 (<0.1)
Physiotherapy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pituitary tumour removal	8 (<0.1)	2 (<0.1)	10 (<0.1)
Pneumonectomy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Precancerous lesion excision	4 (<0.1)	2 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Prostate cryoablation	0	2 (<0.1)	2 (<0.1)
Pulmonary valve replacement	0	2 (<0.1)	2 (<0.1)
Pyeloplasty	1 (<0.1)	2 (<0.1)	3 (<0.1)
Pyloromyotomy	4 (<0.1)	2 (<0.1)	6 (<0.1)
Radical hysterectomy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Radiotherapy to thyroid	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rectal fistula repair	1 (<0.1)	2 (<0.1)	3 (<0.1)
Salpingo-oophorectomy	3 (<0.1)	2 (<0.1)	5 (<0.1)
Scoliosis surgery	4 (<0.1)	2 (<0.1)	6 (<0.1)
Spleen operation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Stapedectomy	2 (<0.1)	2 (<0.1)	4 (<0.1)
Surgery	1 (<0.1)	2 (<0.1)	3 (<0.1)
Suture insertion	3 (<0.1)	2 (<0.1)	5 (<0.1)
Tarsal tunnel decompression	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tenolysis	7 (<0.1)	2 (<0.1)	9 (<0.1)
Testicular cyst excision	0	2 (<0.1)	2 (<0.1)
Therapeutic procedure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Thrombectomy	3 (<0.1)	2 (<0.1)	5 (<0.1)
Tongue operation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Transurethral bladder resection	4 (<0.1)	2 (<0.1)	6 (<0.1)
Ureteric repair	0	2 (<0.1)	2 (<0.1)
Uterine operation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Vascular stent insertion	0	2 (<0.1)	2 (<0.1)
Vasectomy reversal	4 (<0.1)	2 (<0.1)	6 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Ventricular septal defect repair	2 (<0.1)	2 (<0.1)	4 (<0.1)
Wound closure	5 (<0.1)	2 (<0.1)	7 (<0.1)
Wound treatment	2 (<0.1)	2 (<0.1)	4 (<0.1)
Abortion induced	2 (<0.1)	1 (<0.1)	3 (<0.1)
Acoustic neuroma removal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Adrenalectomy	3 (<0.1)	1 (<0.1)	4 (<0.1)
Amputation	0	1 (<0.1)	1 (<0.1)
Amygdalohippocampectomy	0	1 (<0.1)	1 (<0.1)
Anal sphincterotomy	5 (<0.1)	1 (<0.1)	6 (<0.1)
Anoplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Aortic valve repair	3 (<0.1)	1 (<0.1)	4 (<0.1)
Arterial aneurysm repair	1 (<0.1)	1 (<0.1)	2 (<0.1)
Artificial heart implant	1 (<0.1)	1 (<0.1)	2 (<0.1)
Baker's cyst excision	0	1 (<0.1)	1 (<0.1)
Bariatric gastric balloon insertion	0	1 (<0.1)	1 (<0.1)
Bilevel positive airway pressure	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bladder ablation	0	1 (<0.1)	1 (<0.1)
Bladder calculus removal	0	1 (<0.1)	1 (<0.1)
Bladder catheterisation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bladder polypectomy	0	1 (<0.1)	1 (<0.1)
Blepharectomy	0	1 (<0.1)	1 (<0.1)
Bone debridement	0	1 (<0.1)	1 (<0.1)
Bone marrow transplant	1 (<0.1)	1 (<0.1)	2 (<0.1)
Brachytherapy	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Brain stent insertion	0	1 (<0.1)	1 (<0.1)
Breast tumour excision	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bronchoplasty	0	1 (<0.1)	1 (<0.1)
Carotid artery bypass	0	1 (<0.1)	1 (<0.1)
Cast application	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cerumen removal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cheilectomy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Chemical peel of skin	0	1 (<0.1)	1 (<0.1)
Chest wall operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cholelithotomy	3 (<0.1)	1 (<0.1)	4 (<0.1)
Colectomy total	2 (<0.1)	1 (<0.1)	3 (<0.1)
Colorectostomy	0	1 (<0.1)	1 (<0.1)
Corneal implant	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cranial operation	0	1 (<0.1)	1 (<0.1)
Cranioplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Dialysis	0	1 (<0.1)	1 (<0.1)
Drug therapy	0	1 (<0.1)	1 (<0.1)
Duodenal operation	0	1 (<0.1)	1 (<0.1)
Ectopic pregnancy termination	2 (<0.1)	1 (<0.1)	3 (<0.1)
Electroconvulsive therapy	0	1 (<0.1)	1 (<0.1)
Electrodesiccation	4 (<0.1)	1 (<0.1)	5 (<0.1)
Electron radiation therapy	0	1 (<0.1)	1 (<0.1)
Endarterectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Enterorrhaphy	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Eustachian tube operation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Exploratory operation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Facetectomy	0	1 (<0.1)	1 (<0.1)
Facial lesion excision	0	1 (<0.1)	1 (<0.1)
Facial operation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Fasciotomy	5 (<0.1)	1 (<0.1)	6 (<0.1)
Femoral hernia repair	2 (<0.1)	1 (<0.1)	3 (<0.1)
Foot amputation	0	1 (<0.1)	1 (<0.1)
Gastrointestinal surgery	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gender reassignment therapy	0	1 (<0.1)	1 (<0.1)
Genital labial operation	0	1 (<0.1)	1 (<0.1)
Hand amputation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hepatolithectomy	0	1 (<0.1)	1 (<0.1)
High intensity focused ultrasound	0	1 (<0.1)	1 (<0.1)
Hymenectomy	0	1 (<0.1)	1 (<0.1)
Hysteropexy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hysterosalpingectomy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ileocaecal resection	0	1 (<0.1)	1 (<0.1)
Ileocolectomy	0	1 (<0.1)	1 (<0.1)
Immunomodulatory therapy	0	1 (<0.1)	1 (<0.1)
Implantable defibrillator removal	0	1 (<0.1)	1 (<0.1)
Incarcerated hernia repair	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intestinal adhesion lysis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intestinal anastomosis	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Intestinal polypectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Intra-uterine contraceptive device removal	2 (<0.1)	1 (<0.1)	3 (<0.1)
Intramedullary rod insertion	0	1 (<0.1)	1 (<0.1)
Intrathecal injection	0	1 (<0.1)	1 (<0.1)
Intravesical immunotherapy	0	1 (<0.1)	1 (<0.1)
Iridectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint fluid drainage	2 (<0.1)	1 (<0.1)	3 (<0.1)
Keratoplasty	2 (<0.1)	1 (<0.1)	3 (<0.1)
Laminaplasty	0	1 (<0.1)	1 (<0.1)
Laparoscopic surgery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Large intestinal obstruction reduction	0	1 (<0.1)	1 (<0.1)
Large intestine anastomosis	0	1 (<0.1)	1 (<0.1)
Laryngeal polypectomy	0	1 (<0.1)	1 (<0.1)
Laryngoplasty	0	1 (<0.1)	1 (<0.1)
Lip operation	0	1 (<0.1)	1 (<0.1)
Lower oesophageal sphincter magnetic augmentation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lung neoplasm surgery	0	1 (<0.1)	1 (<0.1)
Lymphoma operation	0	1 (<0.1)	1 (<0.1)
Matrixectomy	0	1 (<0.1)	1 (<0.1)
Middle ear operation	0	1 (<0.1)	1 (<0.1)
Muscle reattachment	4 (<0.1)	1 (<0.1)	5 (<0.1)
Neck lift	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neck plastic surgery	0	1 (<0.1)	1 (<0.1)
Nutritional supplementation	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Oesophageal operation	3 (<0.1)	1 (<0.1)	4 (<0.1)
Oocyte harvest	0	1 (<0.1)	1 (<0.1)
Oral cavity neoplasm surgery	0	1 (<0.1)	1 (<0.1)
Orchidotomy	0	1 (<0.1)	1 (<0.1)
Orthodontic procedure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Orthopaedic procedure	3 (<0.1)	1 (<0.1)	4 (<0.1)
Ovarian lesion excision	0	1 (<0.1)	1 (<0.1)
Pancreatectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pancreaticoduodenectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Parathyroid gland operation	0	1 (<0.1)	1 (<0.1)
Parotid cyst excision	0	1 (<0.1)	1 (<0.1)
Patella replacement	3 (<0.1)	1 (<0.1)	4 (<0.1)
Pericardial drainage	0	1 (<0.1)	1 (<0.1)
Pericardial excision	0	1 (<0.1)	1 (<0.1)
Periodontal operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral artery stent insertion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Peripheral revascularisation	0	1 (<0.1)	1 (<0.1)
Phaeochromocytoma excision	0	1 (<0.1)	1 (<0.1)
Pharyngeal operation	0	1 (<0.1)	1 (<0.1)
Platelet rich plasma therapy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pleurodesis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Posterior fossa decompression	0	1 (<0.1)	1 (<0.1)
Proctocolectomy	0	1 (<0.1)	1 (<0.1)
Product used for unknown indication	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Prophylaxis	0	1 (<0.1)	1 (<0.1)
Prostatic urethral lift procedure	3 (<0.1)	1 (<0.1)	4 (<0.1)
Psychosocial support	0	1 (<0.1)	1 (<0.1)
Ptosis repair	3 (<0.1)	1 (<0.1)	4 (<0.1)
Punctal plug insertion	0	1 (<0.1)	1 (<0.1)
Radiation therapy to ear, nose, or throat	0	1 (<0.1)	1 (<0.1)
Radical mastectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Radiotherapy to head and neck	0	1 (<0.1)	1 (<0.1)
Removal of foreign body	5 (<0.1)	1 (<0.1)	6 (<0.1)
Renal cyst excision	0	1 (<0.1)	1 (<0.1)
Renal tumour excision	3 (<0.1)	1 (<0.1)	4 (<0.1)
Retinal laser coagulation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Routine health maintenance	0	1 (<0.1)	1 (<0.1)
Roux loop conversion	0	1 (<0.1)	1 (<0.1)
Salivary gland resection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Salpingoplasty	0	1 (<0.1)	1 (<0.1)
Scleral buckling surgery	2 (<0.1)	1 (<0.1)	3 (<0.1)
Scleral operation	0	1 (<0.1)	1 (<0.1)
Scrotal operation	0	1 (<0.1)	1 (<0.1)
Sinus antrostomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Small intestinal obstruction reduction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Soft tissue flap operation	0	1 (<0.1)	1 (<0.1)
Spinal rod insertion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Sterilisation reversal	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Stomach lesion excision	0	1 (<0.1)	1 (<0.1)
Subdural haematoma evacuation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Surgical vascular shunt	1 (<0.1)	1 (<0.1)	2 (<0.1)
Systemic-pulmonary artery shunt	0	1 (<0.1)	1 (<0.1)
Tendon graft	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tendon sheath lesion excision	0	1 (<0.1)	1 (<0.1)
Tetanus immunisation	0	1 (<0.1)	1 (<0.1)
Tetralogy of Fallot repair	0	1 (<0.1)	1 (<0.1)
Therapeutic embolisation	3 (<0.1)	1 (<0.1)	4 (<0.1)
Therapeutic nerve ablation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Thoracic cavity drainage	0	1 (<0.1)	1 (<0.1)
Thoracic operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thoracoplasty	0	1 (<0.1)	1 (<0.1)
Thromboembolectomy	0	1 (<0.1)	1 (<0.1)
Thrombosis prophylaxis	0	1 (<0.1)	1 (<0.1)
Thymectomy	4 (<0.1)	1 (<0.1)	5 (<0.1)
Thyroid operation	5 (<0.1)	1 (<0.1)	6 (<0.1)
Transurethral incision of prostate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Trapeziectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Turbinoplasty	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ureteric calculus removal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ureteric operation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Urethrotomy	3 (<0.1)	1 (<0.1)	4 (<0.1)
Urostomy	1 (<0.1)	1 (<0.1)	2 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Uterine cystectomy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Uterine leiomyoma embolisation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Uterine prolapse repair	0	1 (<0.1)	1 (<0.1)
Uvuloplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vacuum extractor delivery	0	1 (<0.1)	1 (<0.1)
Vagal nerve stimulator implantation	0	1 (<0.1)	1 (<0.1)
Vaginal mesh removal surgery	0	1 (<0.1)	1 (<0.1)
Vaginal operation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vaginal prolapse repair	0	1 (<0.1)	1 (<0.1)
Vaginoplasty	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vagotomy	0	1 (<0.1)	1 (<0.1)
Vascular access placement	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vascular operation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vena cava filter removal	0	1 (<0.1)	1 (<0.1)
Venous stent insertion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ventriculo-peritoneal shunt	3 (<0.1)	1 (<0.1)	4 (<0.1)
Vesicoureteral reflux surgery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vulvectomy	0	1 (<0.1)	1 (<0.1)
Abdominal cavity drainage	1 (<0.1)	0	1 (<0.1)
Acrochordon excision	1 (<0.1)	0	1 (<0.1)
Adrenal gland operation	1 (<0.1)	0	1 (<0.1)
Amygdalotomy	1 (<0.1)	0	1 (<0.1)
Androgen therapy	1 (<0.1)	0	1 (<0.1)
Antiallergic therapy	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Apicectomy	1 (<0.1)	0	1 (<0.1)
Arterial bypass operation	2 (<0.1)	0	2 (<0.1)
Arterial repair	2 (<0.1)	0	2 (<0.1)
Arthrotomy	2 (<0.1)	0	2 (<0.1)
Assisted delivery	1 (<0.1)	0	1 (<0.1)
Atherectomy	1 (<0.1)	0	1 (<0.1)
Atherosclerosis prophylaxis	2 (<0.1)	0	2 (<0.1)
Autonomic nerve operation	1 (<0.1)	0	1 (<0.1)
Bile duct stent insertion	1 (<0.1)	0	1 (<0.1)
Biliary sphincterotomy	1 (<0.1)	0	1 (<0.1)
Biliary tract operation	1 (<0.1)	0	1 (<0.1)
Bone cyst excision	2 (<0.1)	0	2 (<0.1)
Bone marrow donation	1 (<0.1)	0	1 (<0.1)
Bone trimming	1 (<0.1)	0	1 (<0.1)
Brachytherapy to prostate	1 (<0.1)	0	1 (<0.1)
Breast capsulectomy	1 (<0.1)	0	1 (<0.1)
Burn debridement	1 (<0.1)	0	1 (<0.1)
Burn operation	1 (<0.1)	0	1 (<0.1)
Cardiac resynchronisation therapy	2 (<0.1)	0	2 (<0.1)
Central venous catheter removal	1 (<0.1)	0	1 (<0.1)
Cerebral endovascular aneurysm repair	1 (<0.1)	0	1 (<0.1)
Cervical polypectomy	1 (<0.1)	0	1 (<0.1)
Cervicectomy	4 (<0.1)	0	4 (<0.1)
Cervix cerclage procedure	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Cervix operation	1 (<0.1)	0	1 (<0.1)
Cholesteatoma removal	3 (<0.1)	0	3 (<0.1)
Congenital cardiovascular anomaly repair	1 (<0.1)	0	1 (<0.1)
Contact lens therapy	1 (<0.1)	0	1 (<0.1)
Decompressive craniectomy	1 (<0.1)	0	1 (<0.1)
Dental cleaning	1 (<0.1)	0	1 (<0.1)
Dental prosthesis placement	3 (<0.1)	0	3 (<0.1)
Ecchondroma surgery	1 (<0.1)	0	1 (<0.1)
Elective surgery	2 (<0.1)	0	2 (<0.1)
Electrocauterisation	1 (<0.1)	0	1 (<0.1)
Endocervical curettage	1 (<0.1)	0	1 (<0.1)
Endoscopic sleeve gastroplasty	1 (<0.1)	0	1 (<0.1)
Epididymal cyst removal	2 (<0.1)	0	2 (<0.1)
Eye prosthesis insertion	3 (<0.1)	0	3 (<0.1)
Forceps delivery	1 (<0.1)	0	1 (<0.1)
Gastrointestinal endoscopic therapy	2 (<0.1)	0	2 (<0.1)
Gastrooesophageal reflux prophylaxis	1 (<0.1)	0	1 (<0.1)
Gastrostomy	1 (<0.1)	0	1 (<0.1)
Haematoma evacuation	3 (<0.1)	0	3 (<0.1)
Hepatectomy	1 (<0.1)	0	1 (<0.1)
Hepatitis B immunisation	1 (<0.1)	0	1 (<0.1)
Hernia diaphragmatic repair	1 (<0.1)	0	1 (<0.1)
Hyoid bone suspension	1 (<0.1)	0	1 (<0.1)
Immune enhancement therapy	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Immune tolerance induction	2 (<0.1)	0	2 (<0.1)
Iridotomy	2 (<0.1)	0	2 (<0.1)
Jejunectomy	1 (<0.1)	0	1 (<0.1)
Keratectomy	1 (<0.1)	0	1 (<0.1)
Kidney ablation	1 (<0.1)	0	1 (<0.1)
Lip repair	2 (<0.1)	0	2 (<0.1)
Lipolysis procedure	1 (<0.1)	0	1 (<0.1)
Lumboperitoneal shunt	1 (<0.1)	0	1 (<0.1)
Lung cyst removal	1 (<0.1)	0	1 (<0.1)
Lung operation	2 (<0.1)	0	2 (<0.1)
Lymphoid tissue operation	1 (<0.1)	0	1 (<0.1)
Magnetic therapy	1 (<0.1)	0	1 (<0.1)
Mammary ductectomy	1 (<0.1)	0	1 (<0.1)
Metatarsal excision	1 (<0.1)	0	1 (<0.1)
Myoplasty	1 (<0.1)	0	1 (<0.1)
Nephroplasty	2 (<0.1)	0	2 (<0.1)
Nerve block	1 (<0.1)	0	1 (<0.1)
Nervous system disorder prophylaxis	1 (<0.1)	0	1 (<0.1)
Nervous system neoplasm surgery	2 (<0.1)	0	2 (<0.1)
Neurostimulator removal	1 (<0.1)	0	1 (<0.1)
Ophthalmologic treatment	1 (<0.1)	0	1 (<0.1)
Oral contraception	2 (<0.1)	0	2 (<0.1)
Ossiculoplasty	1 (<0.1)	0	1 (<0.1)
Ovarian neoplasm surgery	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Ovarian repair	1 (<0.1)	0	1 (<0.1)
Oxygen therapy	1 (<0.1)	0	1 (<0.1)
Palatoplasty	2 (<0.1)	0	2 (<0.1)
Pancreatic stent placement	1 (<0.1)	0	1 (<0.1)
Patent ductus arteriosus repair	2 (<0.1)	0	2 (<0.1)
Pelvic floor stimulation	1 (<0.1)	0	1 (<0.1)
Percutaneous coronary intervention	4 (<0.1)	0	4 (<0.1)
Peripheral artery angioplasty	1 (<0.1)	0	1 (<0.1)
Peripheral nerve neurostimulation	1 (<0.1)	0	1 (<0.1)
Photon radiation therapy to ear, nose, or throat	1 (<0.1)	0	1 (<0.1)
Pituitary gland operation	4 (<0.1)	0	4 (<0.1)
Platelet transfusion	1 (<0.1)	0	1 (<0.1)
Posterior lens capsulotomy	1 (<0.1)	0	1 (<0.1)
Prolapse repair	1 (<0.1)	0	1 (<0.1)
Pylorectomy	1 (<0.1)	0	1 (<0.1)
Radical cystectomy	1 (<0.1)	0	1 (<0.1)
Radiculotomy	2 (<0.1)	0	2 (<0.1)
Radiofrequency ablation of oesophagus	2 (<0.1)	0	2 (<0.1)
Rectal polypectomy	2 (<0.1)	0	2 (<0.1)
Reduction of increased intracranial pressure	1 (<0.1)	0	1 (<0.1)
Rehabilitation therapy	1 (<0.1)	0	1 (<0.1)
Renal disorder prophylaxis	1 (<0.1)	0	1 (<0.1)
Respiratory tract operation	2 (<0.1)	0	2 (<0.1)
Rheumatoid nodule removal	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Rib excision	2 (<0.1)	0	2 (<0.1)
Salivary gland calculus removal	1 (<0.1)	0	1 (<0.1)
Salivary gland operation	2 (<0.1)	0	2 (<0.1)
Septal myectomy	1 (<0.1)	0	1 (<0.1)
Skin ulcer excision	1 (<0.1)	0	1 (<0.1)
Skull fracture treatment	1 (<0.1)	0	1 (<0.1)
Sleep disorder therapy	2 (<0.1)	0	2 (<0.1)
Spermatic cord operation	1 (<0.1)	0	1 (<0.1)
Spinal cord operation	1 (<0.1)	0	1 (<0.1)
Spinal corpectomy	2 (<0.1)	0	2 (<0.1)
Spinal deformity correction	1 (<0.1)	0	1 (<0.1)
Spinal rod removal	1 (<0.1)	0	1 (<0.1)
Stem cell therapy	2 (<0.1)	0	2 (<0.1)
Steroid therapy	1 (<0.1)	0	1 (<0.1)
Surgical fixation of rib fracture	2 (<0.1)	0	2 (<0.1)
Sympathectomy	2 (<0.1)	0	2 (<0.1)
Thoracic outlet surgery	1 (<0.1)	0	1 (<0.1)
Thyroid adenoma removal	1 (<0.1)	0	1 (<0.1)
Thyroid cystectomy	1 (<0.1)	0	1 (<0.1)
Trabeculoplasty	1 (<0.1)	0	1 (<0.1)
Tracheal operation	1 (<0.1)	0	1 (<0.1)
Transcatheter aortic valve implantation	2 (<0.1)	0	2 (<0.1)
Transgender hormonal therapy	1 (<0.1)	0	1 (<0.1)
Tubulisation nerve repair	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Surgical and medical procedures (Cont.)			
Urethral dilation procedure	2 (<0.1)	0	2 (<0.1)
Urinary cystectomy	1 (<0.1)	0	1 (<0.1)
Urinary tract operation	1 (<0.1)	0	1 (<0.1)
Uterine dilation and evacuation	1 (<0.1)	0	1 (<0.1)
Vaginal cyst excision	1 (<0.1)	0	1 (<0.1)
Vascular cauterisation	1 (<0.1)	0	1 (<0.1)
Venous ligation	3 (<0.1)	0	3 (<0.1)
Vitamin supplementation	1 (<0.1)	0	1 (<0.1)
Vocal cord polypectomy	1 (<0.1)	0	1 (<0.1)
Volvulus repair	1 (<0.1)	0	1 (<0.1)
Social circumstances	3064 (20.2)	3234 (21.3)	6298 (20.8)
Postmenopause	2244 (14.8)	2370 (15.6)	4614 (15.2)
Menopause	456 (3.0)	479 (3.2)	935 (3.1)
Tobacco user	173 (1.1)	177 (1.2)	350 (1.2)
Alcohol use	153 (1.0)	160 (1.1)	313 (1.0)
Corrective lens user	125 (0.8)	138 (0.9)	263 (0.9)
Ex-tobacco user	80 (0.5)	76 (0.5)	156 (0.5)
Substance use	43 (0.3)	51 (0.3)	94 (0.3)
Blood donor	20 (0.1)	14 (<0.1)	34 (0.1)
Hearing aid user	10 (<0.1)	12 (<0.1)	22 (<0.1)
Organ donor	6 (<0.1)	11 (<0.1)	17 (<0.1)
Trans-sexualism	2 (<0.1)	9 (<0.1)	11 (<0.1)
Caffeine consumption	7 (<0.1)	8 (<0.1)	15 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Social circumstances (Cont.)			
Social alcohol drinker	9 (<0.1)	7 (<0.1)	16 (<0.1)
Denture wearer	5 (<0.1)	5 (<0.1)	10 (<0.1)
Electronic cigarette user	5 (<0.1)	4 (<0.1)	9 (<0.1)
Familial risk factor	3 (<0.1)	3 (<0.1)	6 (<0.1)
Eye prosthesis user	0	2 (<0.1)	2 (<0.1)
Dental prosthesis user	0	1 (<0.1)	1 (<0.1)
Drug abuser	0	1 (<0.1)	1 (<0.1)
Edentulous	0	1 (<0.1)	1 (<0.1)
Ex-drug abuser	1 (<0.1)	1 (<0.1)	2 (<0.1)
External ear prosthesis user	0	1 (<0.1)	1 (<0.1)
Non-tobacco user	4 (<0.1)	1 (<0.1)	5 (<0.1)
Oocyte donor	0	1 (<0.1)	1 (<0.1)
Sexual abuse	0	1 (<0.1)	1 (<0.1)
Tattoo	3 (<0.1)	1 (<0.1)	4 (<0.1)
Victim of sexual abuse	0	1 (<0.1)	1 (<0.1)
Alcoholic	1 (<0.1)	0	1 (<0.1)
Amputee	1 (<0.1)	0	1 (<0.1)
Breast prosthesis user	4 (<0.1)	0	4 (<0.1)
Cardiac assistance device user	2 (<0.1)	0	2 (<0.1)
Dependence on oxygen therapy	1 (<0.1)	0	1 (<0.1)
Disease risk factor	1 (<0.1)	0	1 (<0.1)
Homeless	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.1
Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Product issues	9 (<0.1)	1 (<0.1)	10 (<0.1)
Device dislocation	0	1 (<0.1)	1 (<0.1)
Device breakage	6 (<0.1)	0	6 (<0.1)
Device occlusion	2 (<0.1)	0	2 (<0.1)
Device physical property issue	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
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Table 14.1.4.4
Summary of Medical History — Autoimmune Disorder by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects with At Least One Autoimmune Disorder	1144 (7.5)	1152 (7.6)	2296 (7.6)
Psoriasis	127 (0.8)	143 (0.9)	270 (0.9)
Neuropathy peripheral	156 (1.0)	141 (0.9)	297 (1.0)
Alopecia	136 (0.9)	125 (0.8)	261 (0.9)
Type 1 diabetes mellitus	93 (0.6)	93 (0.6)	186 (0.6)
Peripheral sensory neuropathy	84 (0.6)	80 (0.5)	164 (0.5)
Drug eruption	77 (0.5)	71 (0.5)	148 (0.5)
Autoimmune thyroiditis	56 (0.4)	67 (0.4)	123 (0.4)
Rheumatoid arthritis	58 (0.4)	44 (0.3)	102 (0.3)
Raynaud's phenomenon	34 (0.2)	41 (0.3)	75 (0.2)
Neuralgia	41 (0.3)	38 (0.3)	79 (0.3)
Vitiligo	31 (0.2)	31 (0.2)	62 (0.2)
Coeliac disease	31 (0.2)	29 (0.2)	60 (0.2)
Colitis ulcerative	35 (0.2)	29 (0.2)	64 (0.2)
Cardiomyopathy	21 (0.1)	26 (0.2)	47 (0.2)
Facial paralysis	18 (0.1)	26 (0.2)	44 (0.1)
Basedow's disease	29 (0.2)	25 (0.2)	54 (0.2)
Narcolepsy	20 (0.1)	24 (0.2)	44 (0.1)
Androgenetic alopecia	22 (0.1)	23 (0.2)	45 (0.1)
Crohn's disease	18 (0.1)	22 (0.1)	40 (0.1)
Sarcoidosis	12 (<0.1)	17 (0.1)	29 (<0.1)
Sjogren's syndrome	11 (<0.1)	16 (0.1)	27 (<0.1)
Psoriatic arthropathy	9 (<0.1)	15 (<0.1)	24 (<0.1)
Systemic lupus erythematosus	9 (<0.1)	12 (<0.1)	21 (<0.1)
Multiple sclerosis	10 (<0.1)	8 (<0.1)	18 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.4
Summary of Medical History — Autoimmune Disorder by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Pernicious anaemia	5 (<0.1)	8 (<0.1)	13 (<0.1)
Ankylosing spondylitis	7 (<0.1)	6 (<0.1)	13 (<0.1)
Peripheral motor neuropathy	6 (<0.1)	6 (<0.1)	12 (<0.1)
Uveitis	9 (<0.1)	6 (<0.1)	15 (<0.1)
Antiphospholipid syndrome	2 (<0.1)	5 (<0.1)	7 (<0.1)
Hypergammaglobulinaemia benign monoclonal	2 (<0.1)	5 (<0.1)	7 (<0.1)
Idiopathic pulmonary fibrosis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Immune thrombocytopenia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Lichen planus	7 (<0.1)	5 (<0.1)	12 (<0.1)
Polymyalgia rheumatica	4 (<0.1)	4 (<0.1)	8 (<0.1)
Myasthenia gravis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Peripheral sensorimotor neuropathy	2 (<0.1)	3 (<0.1)	5 (<0.1)
Addison's disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Glomerulonephritis	0	2 (<0.1)	2 (<0.1)
Inflammatory bowel disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Juvenile idiopathic arthritis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Neuralgic amyotrophy	0	2 (<0.1)	2 (<0.1)
Neuritis	0	2 (<0.1)	2 (<0.1)
Proctitis ulcerative	0	2 (<0.1)	2 (<0.1)
Stevens-Johnson syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acute febrile neutrophilic dermatosis	0	1 (<0.1)	1 (<0.1)
Alopecia areata	2 (<0.1)	1 (<0.1)	3 (<0.1)
Axonal neuropathy	0	1 (<0.1)	1 (<0.1)
Benign familial pemphigus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Glomerulonephritis chronic	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.4
Summary of Medical History — Autoimmune Disorder by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Granulomatosis with polyangiitis	0	1 (<0.1)	1 (<0.1)
Henoch-Schonlein purpura	0	1 (<0.1)	1 (<0.1)
Kawasaki's disease	0	1 (<0.1)	1 (<0.1)
Monoclonal gammopathy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Morphoea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nephrotic syndrome	0	1 (<0.1)	1 (<0.1)
Optic neuritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oral lichen planus	0	1 (<0.1)	1 (<0.1)
Paralysis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Pemphigoid	0	1 (<0.1)	1 (<0.1)
Pemphigus	0	1 (<0.1)	1 (<0.1)
Primary biliary cholangitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Primary progressive multiple sclerosis	0	1 (<0.1)	1 (<0.1)
Pulmonary sarcoidosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Sensory loss	0	1 (<0.1)	1 (<0.1)
Small fibre neuropathy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Temporal arteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0	1 (<0.1)
Arteritis	1 (<0.1)	0	1 (<0.1)
Arthritis reactive	1 (<0.1)	0	1 (<0.1)
Autoimmune hepatitis	1 (<0.1)	0	1 (<0.1)
Behcet's syndrome	1 (<0.1)	0	1 (<0.1)
Cutaneous lupus erythematosus	3 (<0.1)	0	3 (<0.1)
Glomerulonephritis membranous	2 (<0.1)	0	2 (<0.1)
Goodpasture's syndrome	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.4
Summary of Medical History — Autoimmune Disorder by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Guillain-Barre syndrome	3 (<0.1)	0	3 (<0.1)
Hashimoto's encephalopathy	1 (<0.1)	0	1 (<0.1)
Loss of proprioception	1 (<0.1)	0	1 (<0.1)
Mixed connective tissue disease	1 (<0.1)	0	1 (<0.1)
Progressive multiple sclerosis	1 (<0.1)	0	1 (<0.1)
Sensory disturbance	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.4.5
Summary of Medical History — Angioedema [1] by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects with At Least One Angioedema Event	98 (0.6)	100 (0.7)	198 (0.7)
Urticaria	88 (0.6)	83 (0.5)	171 (0.6)
Angioedema	2 (<0.1)	4 (<0.1)	6 (<0.1)
Urticaria chronic	1 (<0.1)	4 (<0.1)	5 (<0.1)
Idiopathic urticaria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Urticaria cholinergic	0	3 (<0.1)	3 (<0.1)
Eye swelling	0	1 (<0.1)	1 (<0.1)
Gingival swelling	0	1 (<0.1)	1 (<0.1)
Periorbital oedema	0	1 (<0.1)	1 (<0.1)
Tongue oedema	0	1 (<0.1)	1 (<0.1)
Corneal oedema	1 (<0.1)	0	1 (<0.1)
Face oedema	1 (<0.1)	0	1 (<0.1)
Idiopathic angioedema	1 (<0.1)	0	1 (<0.1)
Lip swelling	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Swelling of eyelid	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
[1] Angioedema is identified through selected SMQ.
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Table 14.1.4.6
Summary of Medical History — Anaphylaxis [1] by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects with At Least One Anaphylaxis Event	27 (0.2)	23 (0.2)	50 (0.2)
Anaphylactic reaction	27 (0.2)	23 (0.2)	50 (0.2)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
[1] Anaphylaxis is identified through selected SMQ.
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Table 14.1.4.7
Summary of Medical History — Hypersensitivity [1] by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects with At Least One Hypersensitivity Event	3045 (20.1)	3064 (20.2)	6109 (20.1)
Drug hypersensitivity	1857 (12.2)	1881 (12.4)	3738 (12.3)
Rhinitis allergic	421 (2.8)	416 (2.7)	837 (2.8)
Eczema	351 (2.3)	325 (2.1)	676 (2.2)
Hypersensitivity	277 (1.8)	277 (1.8)	554 (1.8)
Urticaria	88 (0.6)	83 (0.5)	171 (0.6)
Drug eruption	77 (0.5)	71 (0.5)	148 (0.5)
Dermatitis contact	84 (0.6)	68 (0.4)	152 (0.5)
Iodine allergy	53 (0.3)	49 (0.3)	102 (0.3)
Dermatitis	41 (0.3)	44 (0.3)	85 (0.3)
Dermatitis atopic	39 (0.3)	35 (0.2)	74 (0.2)
Rash	40 (0.3)	30 (0.2)	70 (0.2)
Contrast media allergy	32 (0.2)	24 (0.2)	56 (0.2)
Anaphylactic reaction	27 (0.2)	23 (0.2)	50 (0.2)
Multiple allergies	25 (0.2)	19 (0.1)	44 (0.1)
Allergy to vaccine	11 (<0.1)	14 (<0.1)	25 (<0.1)
Pruritus allergic	10 (<0.1)	14 (<0.1)	24 (<0.1)
Bronchospasm	5 (<0.1)	12 (<0.1)	17 (<0.1)
Conjunctivitis allergic	6 (<0.1)	12 (<0.1)	18 (<0.1)
Allergic cough	2 (<0.1)	6 (<0.1)	8 (<0.1)
Allergic sinusitis	2 (<0.1)	6 (<0.1)	8 (<0.1)
Immune thrombocytopenia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Angioedema	2 (<0.1)	4 (<0.1)	6 (<0.1)
Dermatitis allergic	11 (<0.1)	4 (<0.1)	15 (<0.1)
Urticaria chronic	1 (<0.1)	4 (<0.1)	5 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.1.4.7
Summary of Medical History — Hypersensitivity [1] by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eczema nummular	2 (<0.1)	3 (<0.1)	5 (<0.1)
Idiopathic urticaria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Urticaria cholinergic	0	3 (<0.1)	3 (<0.1)
Laryngospasm	1 (<0.1)	2 (<0.1)	3 (<0.1)
Rash erythematous	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rash macular	1 (<0.1)	2 (<0.1)	3 (<0.1)
Reaction to preservatives	2 (<0.1)	2 (<0.1)	4 (<0.1)
Red man syndrome	0	2 (<0.1)	2 (<0.1)
Stevens-Johnson syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Allergic bronchitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Allergic reaction to excipient	1 (<0.1)	1 (<0.1)	2 (<0.1)
Aspirin-exacerbated respiratory disease	2 (<0.1)	1 (<0.1)	3 (<0.1)
Epidermolysis bullosa	0	1 (<0.1)	1 (<0.1)
Eye allergy	0	1 (<0.1)	1 (<0.1)
Eye swelling	0	1 (<0.1)	1 (<0.1)
Gingival swelling	0	1 (<0.1)	1 (<0.1)
Hand dermatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Henoch-Schonlein purpura	0	1 (<0.1)	1 (<0.1)
Heparin-induced thrombocytopenia	0	1 (<0.1)	1 (<0.1)
Oral allergy syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oropharyngeal spasm	0	1 (<0.1)	1 (<0.1)
Perioral dermatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Periorbital oedema	0	1 (<0.1)	1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)	2 (<0.1)
Reaction to azo-dyes	0	1 (<0.1)	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.1.4.7
Summary of Medical History — Hypersensitivity [1] by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reaction to food additive	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tongue oedema	0	1 (<0.1)	1 (<0.1)
Allergic respiratory disease	1 (<0.1)	0	1 (<0.1)
Allergy to surgical sutures	3 (<0.1)	0	3 (<0.1)
Antiallergic therapy	1 (<0.1)	0	1 (<0.1)
Corneal oedema	1 (<0.1)	0	1 (<0.1)
Face oedema	1 (<0.1)	0	1 (<0.1)
Immune tolerance induction	2 (<0.1)	0	2 (<0.1)
Injection related reaction	1 (<0.1)	0	1 (<0.1)
Injection site eczema	1 (<0.1)	0	1 (<0.1)
Lip swelling	1 (<0.1)	0	1 (<0.1)
Medical device site dermatitis	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Rash follicular	1 (<0.1)	0	1 (<0.1)
Rash maculo-papular	1 (<0.1)	0	1 (<0.1)
Reaction to colouring	1 (<0.1)	0	1 (<0.1)
Solar urticaria	1 (<0.1)	0	1 (<0.1)
Swelling of eyelid	1 (<0.1)	0	1 (<0.1)
Vaccination site dermatitis	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.1.4.8
Summary of Medical History — Dermal Fillers by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects with At Least One Dermal Fillers Event	15 (<0.1)	16 (0.1)	31 (0.1)
Allergy to vaccine	11 (<0.1)	14 (<0.1)	25 (<0.1)
Eye swelling	0	1 (<0.1)	1 (<0.1)
Periorbital oedema	0	1 (<0.1)	1 (<0.1)
Face oedema	1 (<0.1)	0	1 (<0.1)
Lip swelling	1 (<0.1)	0	1 (<0.1)
Periorbital swelling	1 (<0.1)	0	1 (<0.1)
Swelling of eyelid	1 (<0.1)	0	1 (<0.1)

Note: At each level of subject summarization, a subject is counted once if the subject reported one or more findings.
MedDRA version 23.0.
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Table 14.1.5.1.1
Summary of Concomitant Medication
Safety Set

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Any Concomitant Medications or Non-Study Vaccination Throughout the Study	7906 (52.1)	11012 (72.5)	18918 (62.3)
Any Concomitant Medications or Non-Study Vaccination Within 7 Days Post Injection	3845 (25.4)	9107 (60.0)	12952 (42.7)
Any Concomitant Medications or Non-Study Vaccination Within 14 Days Post Injection	4706 (31.0)	9530 (62.8)	14236 (46.9)
Any Concomitant Medications or Non-Study Vaccination Within 28 Days Post Injection	7846 (51.7)	10984 (72.3)	18830 (62.1)
Seasonal Influenza Vaccine Within 14 Days Post Injection	253 (1.7)	198 (1.3)	451 (1.5)
Seasonal Influenza Vaccine Within 28 Days Post Injection	3634 (24.0)	3364 (22.2)	6998 (23.1)
Antipyretic or Analgesic Medication Within 28 Days Post Injection	3517 (23.2)	8892 (58.6)	12409 (40.9)

Percentages are based on the number of safety subjects.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects with At Least One Concomitant Medication	13452 (88.7)	14149 (93.2)	27601 (91.0)
IBUPROFEN	2548 (16.8)	5074 (33.4)	7622 (25.1)
PARACETAMOL	1932 (12.7)	4867 (32.1)	6799 (22.4)
INFLUENZA VACCINE	3495 (23.1)	3255 (21.4)	6750 (22.2)
VITAMINS NOS	2554 (16.8)	2574 (17.0)	5128 (16.9)
ACETYLSALICYLIC ACID	1907 (12.6)	1945 (12.8)	3852 (12.7)
ATORVASTATIN	1893 (12.5)	1761 (11.6)	3654 (12.0)
LISINOPRIL	1358 (9.0)	1357 (8.9)	2715 (8.9)
OMEPRAZOLE	1094 (7.2)	1156 (7.6)	2250 (7.4)
VITAMIN D NOS	1145 (7.6)	1129 (7.4)	2274 (7.5)
METFORMIN	1107 (7.3)	1091 (7.2)	2198 (7.2)
LEVOTHYROXINE	977 (6.4)	1017 (6.7)	1994 (6.6)
COLECALCIFEROL	993 (6.5)	1013 (6.7)	2006 (6.6)
CETIRIZINE HYDROCHLORIDE	954 (6.3)	958 (6.3)	1912 (6.3)
AMLODIPINE	918 (6.1)	949 (6.3)	1867 (6.2)
SALBUTAMOL	860 (5.7)	851 (5.6)	1711 (5.6)
LOSARTAN	819 (5.4)	819 (5.4)	1638 (5.4)
LORATADINE	842 (5.6)	792 (5.2)	1634 (5.4)
FLUTICASONE PROPIONATE	731 (4.8)	757 (5.0)	1488 (4.9)
NAPROXEN SODIUM	416 (2.7)	727 (4.8)	1143 (3.8)
HYDROCHLOROTHIAZIDE	730 (4.8)	697 (4.6)	1427 (4.7)
ASCORBIC ACID	672 (4.4)	672 (4.4)	1344 (4.4)
FISH OIL	632 (4.2)	667 (4.4)	1299 (4.3)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
METOPROLOL	626 (4.1)	594 (3.9)	1220 (4.0)
GABAPENTIN	552 (3.6)	566 (3.7)	1118 (3.7)
SIMVASTATIN	560 (3.7)	556 (3.7)	1116 (3.7)
ROSUVASTATIN	490 (3.2)	519 (3.4)	1009 (3.3)
VITAMIN B12 NOS	498 (3.3)	516 (3.4)	1014 (3.3)
NAPROXEN	355 (2.3)	465 (3.1)	820 (2.7)
LEVOTHYROXINE SODIUM	468 (3.1)	461 (3.0)	929 (3.1)
CALCIUM	465 (3.1)	427 (2.8)	892 (2.9)
ESTRADIOL	376 (2.5)	423 (2.8)	799 (2.6)
TRAZODONE	348 (2.3)	402 (2.6)	750 (2.5)
MELATONIN	388 (2.6)	394 (2.6)	782 (2.6)
LEVONORGESTREL	442 (2.9)	385 (2.5)	827 (2.7)
DIPHENHYDRAMINE HYDROCHLORIDE	350 (2.3)	378 (2.5)	728 (2.4)
FAMOTIDINE	384 (2.5)	378 (2.5)	762 (2.5)
PANTOPRAZOLE	344 (2.3)	355 (2.3)	699 (2.3)
BUPROPION HYDROCHLORIDE	341 (2.2)	335 (2.2)	676 (2.2)
MELOXICAM	350 (2.3)	330 (2.2)	680 (2.2)
MAGNESIUM	342 (2.3)	317 (2.1)	659 (2.2)
BUPROPION	277 (1.8)	312 (2.1)	589 (1.9)
FEXOFENADINE HYDROCHLORIDE	335 (2.2)	310 (2.0)	645 (2.1)
CETIRIZINE	293 (1.9)	308 (2.0)	601 (2.0)
MONTELUKAST	288 (1.9)	301 (2.0)	589 (1.9)
BOTULINUM TOXIN TYPE A	225 (1.5)	298 (2.0)	523 (1.7)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
FINASTERIDE	282 (1.9)	298 (2.0)	580 (1.9)
ESCITALOPRAM OXALATE	277 (1.8)	295 (1.9)	572 (1.9)
SERTRALINE	303 (2.0)	291 (1.9)	594 (2.0)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	205 (1.4)	285 (1.9)	490 (1.6)
TAMSULOSIN	291 (1.9)	283 (1.9)	574 (1.9)
UBIDECARENONE	314 (2.1)	282 (1.9)	596 (2.0)
ALPRAZOLAM	276 (1.8)	281 (1.9)	557 (1.8)
PROBIOTICS NOS	279 (1.8)	269 (1.8)	548 (1.8)
ZINC	245 (1.6)	265 (1.7)	510 (1.7)
MONTELUKAST SODIUM	249 (1.6)	263 (1.7)	512 (1.7)
ROSUVASTATIN CALCIUM	264 (1.7)	261 (1.7)	525 (1.7)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	256 (1.7)	255 (1.7)	511 (1.7)
FLUTICASONE	252 (1.7)	253 (1.7)	505 (1.7)
PRAVASTATIN	272 (1.8)	251 (1.7)	523 (1.7)
BIOTIN	207 (1.4)	246 (1.6)	453 (1.5)
CARVEDILOL	232 (1.5)	243 (1.6)	475 (1.6)
SPIRONOLACTONE	233 (1.5)	238 (1.6)	471 (1.6)
VITAMIN B COMPLEX	237 (1.6)	237 (1.6)	474 (1.6)
ESCITALOPRAM	219 (1.4)	214 (1.4)	433 (1.4)
CURCUMA LONGA	204 (1.3)	213 (1.4)	417 (1.4)
TESTOSTERONE	242 (1.6)	210 (1.4)	452 (1.5)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
FLUOXETINE	172 (1.1)	209 (1.4)	381 (1.3)
SALBUTAMOL SULFATE	201 (1.3)	207 (1.4)	408 (1.3)
SUMATRIPTAN	201 (1.3)	197 (1.3)	398 (1.3)
ATENOLOL	182 (1.2)	196 (1.3)	378 (1.2)
CLONAZEPAM	190 (1.3)	196 (1.3)	386 (1.3)
IRON	193 (1.3)	196 (1.3)	389 (1.3)
TRAMADOL	182 (1.2)	196 (1.3)	378 (1.2)
ALLOPURINOL	198 (1.3)	186 (1.2)	384 (1.3)
CITALOPRAM	200 (1.3)	182 (1.2)	382 (1.3)
TADALAFIL	211 (1.4)	181 (1.2)	392 (1.3)
ZOLPIDEM TARTRATE	197 (1.3)	181 (1.2)	378 (1.2)
HYDROCHLOROTHIAZIDE;LISINOPRIL	170 (1.1)	180 (1.2)	350 (1.2)
SERTRALINE HYDROCHLORIDE	216 (1.4)	176 (1.2)	392 (1.3)
FUROSEMIDE	185 (1.2)	172 (1.1)	357 (1.2)
APIXABAN	155 (1.0)	169 (1.1)	324 (1.1)
LAMOTRIGINE	166 (1.1)	169 (1.1)	335 (1.1)
CELECOXIB	185 (1.2)	167 (1.1)	352 (1.2)
ESOMEPRAZOLE MAGNESIUM	130 (0.9)	166 (1.1)	296 (1.0)
PROGESTERONE	109 (0.7)	163 (1.1)	272 (0.9)
DICLOFENAC	166 (1.1)	162 (1.1)	328 (1.1)
SILDENAFIL	175 (1.2)	162 (1.1)	337 (1.1)
CALCIUM CARBONATE	148 (1.0)	159 (1.0)	307 (1.0)
TOPIRAMATE	133 (0.9)	158 (1.0)	291 (1.0)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
AMLODIPINE BESILATE	173 (1.1)	157 (1.0)	330 (1.1)
AMOXICILLIN	149 (1.0)	157 (1.0)	306 (1.0)
PROPRANOLOL	131 (0.9)	157 (1.0)	288 (0.9)
EZETIMIBE	154 (1.0)	155 (1.0)	309 (1.0)
FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE	149 (1.0)	155 (1.0)	304 (1.0)
DULOXETINE	166 (1.1)	154 (1.0)	320 (1.1)
BUDESONIDE;FORMOTEROL FUMARATE	179 (1.2)	152 (1.0)	331 (1.1)
HYDROCODONE BITARTRATE;PARACETAMOL	118 (0.8)	152 (1.0)	270 (0.9)
INSULIN GLARGINE	168 (1.1)	151 (1.0)	319 (1.1)
ONDANSETRON	110 (0.7)	148 (1.0)	258 (0.9)
CYCLOBENZAPRINE	136 (0.9)	147 (1.0)	283 (0.9)
TAMSULOSIN HYDROCHLORIDE	148 (1.0)	147 (1.0)	295 (1.0)
ZOLPIDEM	143 (0.9)	145 (1.0)	288 (0.9)
LORAZEPAM	127 (0.8)	144 (0.9)	271 (0.9)
VITAMIN E NOS	128 (0.8)	144 (0.9)	272 (0.9)
FENOFIBRATE	145 (1.0)	143 (0.9)	288 (0.9)
OMEGA-3 NOS	144 (0.9)	143 (0.9)	287 (0.9)
HYDROCORTISONE	126 (0.8)	141 (0.9)	267 (0.9)
VALACICLOVIR	145 (1.0)	137 (0.9)	282 (0.9)
FLUOXETINE HYDROCHLORIDE	133 (0.9)	134 (0.9)	267 (0.9)
GLIPIZIDE	136 (0.9)	133 (0.9)	269 (0.9)
PREDNISONE	110 (0.7)	132 (0.9)	242 (0.8)
VENLAFAXINE	131 (0.9)	131 (0.9)	262 (0.9)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BUSPIRONE	90 (0.6)	130 (0.9)	220 (0.7)
ETHINYLESTRADIOL;NORGESTIMATE	100 (0.7)	124 (0.8)	224 (0.7)
TRIAMCINOLONE ACETONIDE	125 (0.8)	124 (0.8)	249 (0.8)
LATANOPROST	128 (0.8)	123 (0.8)	251 (0.8)
LISDEXAMFETAMINE MESILATE	97 (0.6)	123 (0.8)	220 (0.7)
DULOXETINE HYDROCHLORIDE	104 (0.7)	122 (0.8)	226 (0.7)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	97 (0.6)	117 (0.8)	214 (0.7)
EMPAGLIFLOZIN	138 (0.9)	114 (0.8)	252 (0.8)
CHONDROITIN;GLUCOSAMINE	90 (0.6)	113 (0.7)	203 (0.7)
VALSARTAN	98 (0.6)	112 (0.7)	210 (0.7)
ALENDRONATE SODIUM	117 (0.8)	111 (0.7)	228 (0.8)
DOXYCYCLINE	105 (0.7)	110 (0.7)	215 (0.7)
DULAGLUTIDE	108 (0.7)	108 (0.7)	216 (0.7)
ETHINYLESTRADIOL;LEVONORGESTREL	98 (0.6)	107 (0.7)	205 (0.7)
GLUCOSAMINE	126 (0.8)	105 (0.7)	231 (0.8)
METFORMIN HYDROCHLORIDE	99 (0.7)	105 (0.7)	204 (0.7)
ACICLOVIR	99 (0.7)	104 (0.7)	203 (0.7)
HYALURONIC ACID	75 (0.5)	103 (0.7)	178 (0.6)
PREGABALIN	87 (0.6)	103 (0.7)	190 (0.6)
AMITRIPTYLINE	84 (0.6)	102 (0.7)	186 (0.6)
POTASSIUM	117 (0.8)	101 (0.7)	218 (0.7)
FOLIC ACID	106 (0.7)	100 (0.7)	206 (0.7)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
AZELASTINE	82 (0.5)	99 (0.7)	181 (0.6)
DOCUSATE SODIUM	101 (0.7)	99 (0.7)	200 (0.7)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	92 (0.6)	99 (0.7)	191 (0.6)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	89 (0.6)	99 (0.7)	188 (0.6)
TRIAMCINOLONE	73 (0.5)	99 (0.7)	172 (0.6)
GUAIFENESIN	94 (0.6)	98 (0.6)	192 (0.6)
GLIMEPIRIDE	105 (0.7)	97 (0.6)	202 (0.7)
INSULIN ASPART	95 (0.6)	96 (0.6)	191 (0.6)
POTASSIUM CHLORIDE	108 (0.7)	96 (0.6)	204 (0.7)
CEFALEXIN	90 (0.6)	95 (0.6)	185 (0.6)
HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM	98 (0.6)	95 (0.6)	193 (0.6)
METOPROLOL SUCCINATE	87 (0.6)	95 (0.6)	182 (0.6)
LEVOCETIRIZINE DIHYDROCHLORIDE	94 (0.6)	94 (0.6)	188 (0.6)
RIVAROXABAN	82 (0.5)	94 (0.6)	176 (0.6)
VENLAFAXINE HYDROCHLORIDE	118 (0.8)	94 (0.6)	212 (0.7)
HYDROXYZINE	83 (0.5)	93 (0.6)	176 (0.6)
SEMAGLUTIDE	115 (0.8)	93 (0.6)	208 (0.7)
LOSARTAN POTASSIUM	95 (0.6)	91 (0.6)	186 (0.6)
CLOPIDOGREL	74 (0.5)	89 (0.6)	163 (0.5)
ARIPIPRAZOLE	81 (0.5)	88 (0.6)	169 (0.6)
DIPHENHYDRAMINE	101 (0.7)	88 (0.6)	189 (0.6)
INSULIN LISPRO	112 (0.7)	87 (0.6)	199 (0.7)
METHOCARBAMOL	65 (0.4)	86 (0.6)	151 (0.5)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
FEXOFENADINE	87 (0.6)	85 (0.6)	172 (0.6)
VALACICLOVIR HYDROCHLORIDE	82 (0.5)	85 (0.6)	167 (0.6)
CITALOPRAM HYDROBROMIDE	74 (0.5)	84 (0.6)	158 (0.5)
OXYCODONE	75 (0.5)	84 (0.6)	159 (0.5)
PHENTERMINE	98 (0.6)	84 (0.6)	182 (0.6)
CHLORTALIDONE	85 (0.6)	83 (0.5)	168 (0.6)
DILTIAZEM	114 (0.8)	82 (0.5)	196 (0.6)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	47 (0.3)	81 (0.5)	128 (0.4)
AZITHROMYCIN	72 (0.5)	80 (0.5)	152 (0.5)
CLOPIDOGREL BISULFATE	56 (0.4)	80 (0.5)	136 (0.4)
LOVASTATIN	64 (0.4)	80 (0.5)	144 (0.5)
PSEUDOEPHEDRINE HYDROCHLORIDE	76 (0.5)	79 (0.5)	155 (0.5)
NITROFURANTOIN	69 (0.5)	78 (0.5)	147 (0.5)
CYCLOBENZAPRINE HYDROCHLORIDE	74 (0.5)	76 (0.5)	150 (0.5)
EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE	76 (0.5)	76 (0.5)	152 (0.5)
LANSOPRAZOLE	65 (0.4)	76 (0.5)	141 (0.5)
CALCIUM;VITAMIN D NOS	88 (0.6)	75 (0.5)	163 (0.5)
IRBESARTAN	64 (0.4)	75 (0.5)	139 (0.5)
ALLERGENS NOS	54 (0.4)	74 (0.5)	128 (0.4)
INTRAUTERINE CONTRACEPTIVE DEVICE	80 (0.5)	74 (0.5)	154 (0.5)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	61 (0.4)	74 (0.5)	135 (0.4)
FERROUS SULFATE	87 (0.6)	73 (0.5)	160 (0.5)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
OLMESARTAN	68 (0.4)	73 (0.5)	141 (0.5)
THYROID	72 (0.5)	72 (0.5)	144 (0.5)
TIZANIDINE	84 (0.6)	72 (0.5)	156 (0.5)
LIDOCAINE	50 (0.3)	71 (0.5)	121 (0.4)
CICLOSPORIN	58 (0.4)	69 (0.5)	127 (0.4)
ERGOCALCIFEROL	62 (0.4)	68 (0.4)	130 (0.4)
METRONIDAZOLE	73 (0.5)	68 (0.4)	141 (0.5)
EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE	66 (0.4)	67 (0.4)	133 (0.4)
SITAGLIPTIN	69 (0.5)	67 (0.4)	136 (0.4)
ETONOGESTREL	84 (0.6)	66 (0.4)	150 (0.5)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	53 (0.3)	66 (0.4)	119 (0.4)
BACLOFEN	81 (0.5)	64 (0.4)	145 (0.5)
BENAZEPRIL	76 (0.5)	64 (0.4)	140 (0.5)
ENALAPRIL	53 (0.3)	64 (0.4)	117 (0.4)
ETHINYLESTRADIOL;NORETHISTERONE ACETATE	53 (0.3)	64 (0.4)	117 (0.4)
OXYBUTYNIN	62 (0.4)	64 (0.4)	126 (0.4)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	49 (0.3)	63 (0.4)	112 (0.4)
LIRAGLUTIDE	74 (0.5)	63 (0.4)	137 (0.5)
NEBIVOLOL HYDROCHLORIDE	63 (0.4)	63 (0.4)	126 (0.4)
MOMETASONE FUROATE	45 (0.3)	62 (0.4)	107 (0.4)
QUETIAPINE FUMARATE	71 (0.5)	62 (0.4)	133 (0.4)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
WARFARIN	47 (0.3)	62 (0.4)	109 (0.4)
ESZOPICLONE	42 (0.3)	61 (0.4)	103 (0.3)
INFLUENZA VACCINE INACT SPLIT 4V	74 (0.5)	61 (0.4)	135 (0.4)
MIRTAZAPINE	64 (0.4)	61 (0.4)	125 (0.4)
ESTROGENS CONJUGATED	48 (0.3)	60 (0.4)	108 (0.4)
OTHER OPHTHALMOLOGICALS	68 (0.4)	60 (0.4)	128 (0.4)
SULFAMETHOXAZOLE;TRIMETHOPRIM	60 (0.4)	60 (0.4)	120 (0.4)
MACROGOL 3350	60 (0.4)	59 (0.4)	119 (0.4)
METOPROLOL TARTRATE	61 (0.4)	59 (0.4)	120 (0.4)
RIZATRIPTAN	39 (0.3)	59 (0.4)	98 (0.3)
BUSPIRONE HYDROCHLORIDE	50 (0.3)	58 (0.4)	108 (0.4)
MEDROXYPROGESTERONE ACETATE	49 (0.3)	58 (0.4)	107 (0.4)
PAROXETINE	70 (0.5)	58 (0.4)	128 (0.4)
VERAPAMIL	49 (0.3)	58 (0.4)	107 (0.4)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	48 (0.3)	57 (0.4)	105 (0.3)
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	69 (0.5)	57 (0.4)	126 (0.4)
METHYLPREDNISOLONE	62 (0.4)	57 (0.4)	119 (0.4)
TRETINOIN	54 (0.4)	57 (0.4)	111 (0.4)
CLINDAMYCIN	59 (0.4)	56 (0.4)	115 (0.4)
GLYCERYL TRINITRATE	39 (0.3)	56 (0.4)	95 (0.3)
MECLOZINE	26 (0.2)	56 (0.4)	82 (0.3)
NICOTINIC ACID	40 (0.3)	56 (0.4)	96 (0.3)
BUDESONIDE	41 (0.3)	55 (0.4)	96 (0.3)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PIOGLITAZONE	49 (0.3)	55 (0.4)	104 (0.3)
COLLAGEN	40 (0.3)	54 (0.4)	94 (0.3)
DENOSUMAB	51 (0.3)	54 (0.4)	105 (0.3)
TELMISARTAN	52 (0.3)	54 (0.4)	106 (0.3)
CANNABIDIOL	53 (0.3)	53 (0.3)	106 (0.3)
AMOXICILLIN;CLAVULANIC ACID	66 (0.4)	52 (0.3)	118 (0.4)
NORETHISTERONE	37 (0.2)	52 (0.3)	89 (0.3)
CIPROFLOXACIN	48 (0.3)	51 (0.3)	99 (0.3)
RAMIPRIL	84 (0.6)	51 (0.3)	135 (0.4)
ESOMEPRAZOLE	66 (0.4)	50 (0.3)	116 (0.4)
KRILL OIL	40 (0.3)	50 (0.3)	90 (0.3)
LOPERAMIDE HYDROCHLORIDE	49 (0.3)	50 (0.3)	99 (0.3)
MIRABEGRON	53 (0.3)	50 (0.3)	103 (0.3)
TESTOSTERONE CIPIONATE	49 (0.3)	50 (0.3)	99 (0.3)
INSULIN DEGLUDEC	49 (0.3)	49 (0.3)	98 (0.3)
CLONIDINE	44 (0.3)	48 (0.3)	92 (0.3)
TIOTROPIUM BROMIDE	67 (0.4)	48 (0.3)	115 (0.4)
AZELASTINE HYDROCHLORIDE	37 (0.2)	47 (0.3)	84 (0.3)
HYDROCHLOROTHIAZIDE;VALSARTAN	56 (0.4)	47 (0.3)	103 (0.3)
OLMESARTAN MEDOXOMIL	52 (0.3)	47 (0.3)	99 (0.3)
PSEUDOEPHEDRINE	49 (0.3)	47 (0.3)	96 (0.3)
DIAZEPAM	59 (0.4)	46 (0.3)	105 (0.3)
EICOSAPENTAENOIC ACID ETHYL ESTER	39 (0.3)	46 (0.3)	85 (0.3)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
HYDROCODONE	58 (0.4)	46 (0.3)	104 (0.3)
LEVOCETIRIZINE	49 (0.3)	46 (0.3)	95 (0.3)
LYSINE	40 (0.3)	46 (0.3)	86 (0.3)
TERAZOSIN	31 (0.2)	46 (0.3)	77 (0.3)
CALCIUM;COLECALCIFEROL	47 (0.3)	45 (0.3)	92 (0.3)
DROSPIRENONE;ETHINYLESTRADIOL	54 (0.4)	45 (0.3)	99 (0.3)
METHYLPHENIDATE HYDROCHLORIDE	37 (0.2)	45 (0.3)	82 (0.3)
NIFEDIPINE	58 (0.4)	45 (0.3)	103 (0.3)
EPINEPHRINE	43 (0.3)	44 (0.3)	87 (0.3)
ETHINYLESTRADIOL;ETONOGESTREL	55 (0.4)	44 (0.3)	99 (0.3)
DICLOFENAC SODIUM	50 (0.3)	43 (0.3)	93 (0.3)
FIBRE, DIETARY	34 (0.2)	43 (0.3)	77 (0.3)
LIOTHYRONINE	31 (0.2)	43 (0.3)	74 (0.2)
METHYLPHENIDATE	29 (0.2)	43 (0.3)	72 (0.2)
SODIUM CHLORIDE	42 (0.3)	43 (0.3)	85 (0.3)
ATORVASTATIN CALCIUM	55 (0.4)	42 (0.3)	97 (0.3)
CALCIUM CITRATE	36 (0.2)	42 (0.3)	78 (0.3)
DESOGESTREL;ETHINYLESTRADIOL	27 (0.2)	42 (0.3)	69 (0.2)
DEXLANSOPRAZOLE	34 (0.2)	42 (0.3)	76 (0.3)
LINACLOTIDE	45 (0.3)	42 (0.3)	87 (0.3)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	42 (0.3)	41 (0.3)	83 (0.3)
INSULIN DETEMIR	44 (0.3)	41 (0.3)	85 (0.3)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ROPINIROLE	44 (0.3)	41 (0.3)	85 (0.3)
BUTALBITAL;CAFFEINE;PARACETAMOL	39 (0.3)	40 (0.3)	79 (0.3)
SERENOA REPENS	32 (0.2)	40 (0.3)	72 (0.2)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE	46 (0.3)	39 (0.3)	85 (0.3)
KETOCONAZOLE	45 (0.3)	39 (0.3)	84 (0.3)
PLANTAGO OVATA	37 (0.2)	39 (0.3)	76 (0.3)
VITAMIN B NOS	47 (0.3)	39 (0.3)	86 (0.3)
VORTIOXETINE HYDROBROMIDE	35 (0.2)	39 (0.3)	74 (0.2)
ANASTROZOLE	44 (0.3)	38 (0.3)	82 (0.3)
GINKGO BILOBA	22 (0.1)	38 (0.3)	60 (0.2)
LEVETIRACETAM	30 (0.2)	38 (0.3)	68 (0.2)
TEMAZEPAM	46 (0.3)	38 (0.3)	84 (0.3)
TIMOLOL	30 (0.2)	38 (0.3)	68 (0.2)
XANTOFYL	31 (0.2)	38 (0.3)	69 (0.2)
BIMATOPROST	40 (0.3)	37 (0.2)	77 (0.3)
DICYCLOVERINE	39 (0.3)	37 (0.2)	76 (0.3)
LORATADINE;PSEUDOEPHEDRINE SULFATE	38 (0.3)	37 (0.2)	75 (0.2)
MAGNESIUM OXIDE	33 (0.2)	37 (0.2)	70 (0.2)
PNEUMOCOCCAL VACCINE	34 (0.2)	37 (0.2)	71 (0.2)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	33 (0.2)	36 (0.2)	69 (0.2)
PAROXETINE HYDROCHLORIDE	46 (0.3)	36 (0.2)	82 (0.3)
QUETIAPINE	33 (0.2)	36 (0.2)	69 (0.2)
VACCINIUM MACROCARPON	44 (0.3)	36 (0.2)	80 (0.3)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE	35 (0.2)	35 (0.2)	70 (0.2)
KETOROLAC	21 (0.1)	35 (0.2)	56 (0.2)
PRAMIPEXOLE	35 (0.2)	35 (0.2)	70 (0.2)
PRASTERONE	31 (0.2)	35 (0.2)	66 (0.2)
BECLOMETASONE DIPROPIONATE	37 (0.2)	34 (0.2)	71 (0.2)
EVOLOCUMAB	27 (0.2)	34 (0.2)	61 (0.2)
MONASCUS PURPUREUS	39 (0.3)	34 (0.2)	73 (0.2)
BISMUTH SUBSALICYLATE	46 (0.3)	33 (0.2)	79 (0.3)
FLUCONAZOLE	46 (0.3)	33 (0.2)	79 (0.3)
GEMFIBROZIL	40 (0.3)	33 (0.2)	73 (0.2)
IPRATROPIUM BROMIDE	30 (0.2)	33 (0.2)	63 (0.2)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN	35 (0.2)	33 (0.2)	68 (0.2)
MODAFINIL	20 (0.1)	33 (0.2)	53 (0.2)
CALCIUM CITRATE;COLECALCIFEROL	20 (0.1)	32 (0.2)	52 (0.2)
CLOBETASOL PROPIONATE	34 (0.2)	32 (0.2)	66 (0.2)
HYDROCODONE;PARACETAMOL	26 (0.2)	32 (0.2)	58 (0.2)
PREDNISOLONE	19 (0.1)	32 (0.2)	51 (0.2)
DIETARY SUPPLEMENT	23 (0.2)	31 (0.2)	54 (0.2)
FEXOFENADINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	22 (0.1)	31 (0.2)	53 (0.2)
MEDROXYPROGESTERONE	19 (0.1)	31 (0.2)	50 (0.2)
PRAZOSIN	27 (0.2)	31 (0.2)	58 (0.2)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
VALPROATE SEMISODIUM	40 (0.3)	31 (0.2)	71 (0.2)
ALFUZOSIN	32 (0.2)	30 (0.2)	62 (0.2)
DESVENLAFAXINE SUCCINATE	39 (0.3)	30 (0.2)	69 (0.2)
MINOCYCLINE	21 (0.1)	30 (0.2)	51 (0.2)
MINOXIDIL	32 (0.2)	30 (0.2)	62 (0.2)
PYRIDOXINE HYDROCHLORIDE	23 (0.2)	30 (0.2)	53 (0.2)
TERBINAFINE	41 (0.3)	30 (0.2)	71 (0.2)
VILAZODONE HYDROCHLORIDE	22 (0.1)	30 (0.2)	52 (0.2)
CANNABIS SATIVA	44 (0.3)	29 (0.2)	73 (0.2)
CLOBETASOL	43 (0.3)	29 (0.2)	72 (0.2)
DEXAMETHASONE	38 (0.3)	29 (0.2)	67 (0.2)
ERENUMAB	18 (0.1)	29 (0.2)	47 (0.2)
FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	33 (0.2)	29 (0.2)	62 (0.2)
HYDROCHLOROTHIAZIDE;LOSARTAN	31 (0.2)	29 (0.2)	60 (0.2)
KETOROLAC TROMETHAMINE	33 (0.2)	29 (0.2)	62 (0.2)
NORTRIPTYLINE	38 (0.3)	29 (0.2)	67 (0.2)
PROMETHAZINE	23 (0.2)	29 (0.2)	52 (0.2)
SENNOSIDE A+B	31 (0.2)	29 (0.2)	60 (0.2)
SIMETICONE	20 (0.1)	29 (0.2)	49 (0.2)
BETAMETHASONE	17 (0.1)	28 (0.2)	45 (0.1)
FLECAINIDE	31 (0.2)	28 (0.2)	59 (0.2)
LEVOTHYROXINE;LIOTHYRONINE	29 (0.2)	28 (0.2)	57 (0.2)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MESALAZINE	26 (0.2)	28 (0.2)	54 (0.2)
MUPIROCIN	22 (0.1)	28 (0.2)	50 (0.2)
OLOPATADINE HYDROCHLORIDE	15 (<0.1)	28 (0.2)	43 (0.1)
OXYBUTYNIN HYDROCHLORIDE	14 (<0.1)	28 (0.2)	42 (0.1)
OXYMETAZOLINE	28 (0.2)	28 (0.2)	56 (0.2)
THIOCTIC ACID	18 (0.1)	28 (0.2)	46 (0.2)
COLCHICINE	23 (0.2)	27 (0.2)	50 (0.2)
INDOMETACIN	31 (0.2)	27 (0.2)	58 (0.2)
INSULIN	28 (0.2)	27 (0.2)	55 (0.2)
LINUM USITATISSIMUM SEED OIL	20 (0.1)	27 (0.2)	47 (0.2)
RIZATRIPTAN BENZOATE	37 (0.2)	27 (0.2)	64 (0.2)
SILYBUM MARIANUM	31 (0.2)	27 (0.2)	58 (0.2)
SOTALOL	23 (0.2)	27 (0.2)	50 (0.2)
DOXAZOSIN	27 (0.2)	26 (0.2)	53 (0.2)
NICOTINAMIDE	15 (<0.1)	26 (0.2)	41 (0.1)
RISPERIDONE	21 (0.1)	26 (0.2)	47 (0.2)
VARICELLA ZOSTER VACCINE RGE (CHO)	20 (0.1)	26 (0.2)	46 (0.2)
CANAGLIFLOZIN	29 (0.2)	25 (0.2)	54 (0.2)
CINNAMOMUM VERUM	23 (0.2)	25 (0.2)	48 (0.2)
DESVENLAFAXINE	22 (0.1)	25 (0.2)	47 (0.2)
DUTASTERIDE	36 (0.2)	25 (0.2)	61 (0.2)
FLUOCINONIDE	25 (0.2)	25 (0.2)	50 (0.2)
FORMOTEROL FUMARATE;MOMETASONE FUROATE	20 (0.1)	25 (0.2)	45 (0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
HYDRALAZINE	50 (0.3)	25 (0.2)	75 (0.2)
POLYCARBOPHIL CALCIUM	27 (0.2)	25 (0.2)	52 (0.2)
RANITIDINE	28 (0.2)	25 (0.2)	53 (0.2)
SAMBUCUS NIGRA	27 (0.2)	25 (0.2)	52 (0.2)
SUCRALFATE	18 (0.1)	25 (0.2)	43 (0.1)
ALL OTHER NON-THERAPEUTIC PRODUCTS	21 (0.1)	24 (0.2)	45 (0.1)
CALCIUM CARBONATE;COLECALCIFEROL	26 (0.2)	24 (0.2)	50 (0.2)
CODEINE PHOSPHATE;PARACETAMOL	23 (0.2)	24 (0.2)	47 (0.2)
CYANOCOBALAMIN	34 (0.2)	24 (0.2)	58 (0.2)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN	33 (0.2)	24 (0.2)	57 (0.2)
HYDROXYZINE HYDROCHLORIDE	23 (0.2)	24 (0.2)	47 (0.2)
IBANDRONATE SODIUM	15 (<0.1)	24 (0.2)	39 (0.1)
ISOSORBIDE MONONITRATE	17 (0.1)	24 (0.2)	41 (0.1)
PRAVASTATIN SODIUM	24 (0.2)	24 (0.2)	48 (0.2)
VITAMIN A NOS	23 (0.2)	24 (0.2)	47 (0.2)
AMIODARONE	19 (0.1)	23 (0.2)	42 (0.1)
DOXEPIN	25 (0.2)	23 (0.2)	48 (0.2)
ESTRADIOL;NORETHISTERONE ACETATE	11 (<0.1)	23 (0.2)	34 (0.1)
INFLUENZA VACCINE INACT SPLIT 3V	29 (0.2)	23 (0.2)	52 (0.2)
MACROGOL 400;PROPYLENE GLYCOL	10 (<0.1)	23 (0.2)	33 (0.1)
MALUS SPP. VINEGAR EXTRACT	19 (0.1)	23 (0.2)	42 (0.1)
MORPHINE SULFATE	8 (<0.1)	23 (0.2)	31 (0.1)
OTHER DERMATOLOGICALS	24 (0.2)	23 (0.2)	47 (0.2)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
OXCARBAZEPINE	24 (0.2)	23 (0.2)	47 (0.2)
VARICELLA ZOSTER VACCINE	32 (0.2)	23 (0.2)	55 (0.2)
CEFTRIAXONE	17 (0.1)	22 (0.1)	39 (0.1)
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE HYDROCHLORIDE	14 (<0.1)	22 (0.1)	36 (0.1)
DILTIAZEM HYDROCHLORIDE	25 (0.2)	22 (0.1)	47 (0.2)
LEVOFLOXACIN	18 (0.1)	22 (0.1)	40 (0.1)
LIFITEGRAST	12 (<0.1)	22 (0.1)	34 (0.1)
LURASIDONE HYDROCHLORIDE	14 (<0.1)	22 (0.1)	36 (0.1)
MORPHINE	22 (0.1)	22 (0.1)	44 (0.1)
NALTREXONE	21 (0.1)	22 (0.1)	43 (0.1)
TIMOLOL MALEATE	15 (<0.1)	22 (0.1)	37 (0.1)
TRIAMTERENE	18 (0.1)	22 (0.1)	40 (0.1)
VARENICLINE TARTRATE	15 (<0.1)	22 (0.1)	37 (0.1)
ACETYLCYSTEINE	22 (0.1)	21 (0.1)	43 (0.1)
ALLIUM SATIVUM	23 (0.2)	21 (0.1)	44 (0.1)
ARMODAFINIL	7 (<0.1)	21 (0.1)	28 (<0.1)
BIFIDOBACTERIUM INFANTIS	24 (0.2)	21 (0.1)	45 (0.1)
BOTULINUM TOXIN TYPE A HAEMAGGLUTININ COMPLEX	16 (0.1)	21 (0.1)	37 (0.1)
MOMETASONE	15 (<0.1)	21 (0.1)	36 (0.1)
OLANZAPINE	15 (<0.1)	21 (0.1)	36 (0.1)
PITAVASTATIN CALCIUM	20 (0.1)	21 (0.1)	41 (0.1)
AMLODIPINE;BENAZEPRIL	11 (<0.1)	20 (0.1)	31 (0.1)
CANDESARTAN	17 (0.1)	20 (0.1)	37 (0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE	29 (0.2)	20 (0.1)	49 (0.2)
LITHIUM	17 (0.1)	20 (0.1)	37 (0.1)
TICAGRELOR	20 (0.1)	20 (0.1)	40 (0.1)
ASCORBIC ACID;CUPRIC OXIDE;DL-ALPHA TOCOPHERYL ACETATE;XANTOFYL;ZEAXANTHIN;ZINC OXIDE	11 (<0.1)	19 (0.1)	30 (<0.1)
BISACODYL	23 (0.2)	19 (0.1)	42 (0.1)
BRIMONIDINE	15 (<0.1)	19 (0.1)	34 (0.1)
BUPRENORPHINE HYDROCHLORIDE;NALOXONE HYDROCHLORIDE	17 (0.1)	19 (0.1)	36 (0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;IBUPROFEN	10 (<0.1)	19 (0.1)	29 (<0.1)
DOCUSATE	15 (<0.1)	19 (0.1)	34 (0.1)
ESTROGENS CONJUGATED;MEDROXYPROGESTERONE ACETATE	14 (<0.1)	19 (0.1)	33 (0.1)
FENTANYL	13 (<0.1)	19 (0.1)	32 (0.1)
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	16 (0.1)	19 (0.1)	35 (0.1)
IPRATROPIUM	17 (0.1)	19 (0.1)	36 (0.1)
METHADONE	11 (<0.1)	19 (0.1)	30 (<0.1)
PREDNISOLONE ACETATE	7 (<0.1)	19 (0.1)	26 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM;CYANOCOBALAMIN;FOLIC ACID;MAGNESIUM CARBONATE;MAGNESIUM HYDROXIDE;MANGANESE GLUCONATE;NICOTINIC ACID POTASSIUM BICARBONATE;POTASSIUM CARBONATE;POTASSIUM PHOSPHATE DIBASIC;PYRIDOXINE HYDROCHLORIDE;QUERCETIN;RIBOFLAVIN SODIUM PHOSPHATE;SODIUM BICARBONATE;SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE THIOCTIC ACID;ZINC ASCORBATE	15 (<0.1)	18 (0.1)	33 (0.1)
BISOPROLOL	23 (0.2)	18 (0.1)	41 (0.1)
CAFFEINE;PARACETAMOL	5 (<0.1)	18 (0.1)	23 (<0.1)
CALCIUM;MAGNESIUM;ZINC	29 (0.2)	18 (0.1)	47 (0.2)
CETIRIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	14 (<0.1)	18 (0.1)	32 (0.1)
DEXAMFETAMINE	18 (0.1)	18 (0.1)	36 (0.1)
INSULIN HUMAN;INSULIN HUMAN INJECTION, ISOPHANE	13 (<0.1)	18 (0.1)	31 (0.1)
LINUM USITATISSIMUM OIL	13 (<0.1)	18 (0.1)	31 (0.1)
METOCLOPRAMIDE	12 (<0.1)	18 (0.1)	30 (<0.1)
RALOXIFENE	9 (<0.1)	18 (0.1)	27 (<0.1)
TETANUS VACCINE	30 (0.2)	18 (0.1)	48 (0.2)
BENZONATATE	26 (0.2)	17 (0.1)	43 (0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CARMELLOSE SODIUM	11 (<0.1)	17 (0.1)	28 (<0.1)
CEFDINIR	20 (0.1)	17 (0.1)	37 (0.1)
ECHINACEA PURPUREA	11 (<0.1)	17 (0.1)	28 (<0.1)
EXENATIDE	17 (0.1)	17 (0.1)	34 (0.1)
FEBUXOSTAT	16 (0.1)	17 (0.1)	33 (0.1)
HYDROCHLOROTHIAZIDE;OLMESARTAN	20 (0.1)	17 (0.1)	37 (0.1)
HYOSCYAMINE	6 (<0.1)	17 (0.1)	23 (<0.1)
POTASSIUM CITRATE	28 (0.2)	17 (0.1)	45 (0.1)
PRIMIDONE	14 (<0.1)	17 (0.1)	31 (0.1)
QUINAPRIL	18 (0.1)	17 (0.1)	35 (0.1)
SELENIUM	15 (<0.1)	17 (0.1)	32 (0.1)
ACETYLSALICYLIC ACID;CAFFEINE	14 (<0.1)	16 (0.1)	30 (<0.1)
ATOMOXETINE HYDROCHLORIDE	11 (<0.1)	16 (0.1)	27 (<0.1)
CARISOPRODOL	11 (<0.1)	16 (0.1)	27 (<0.1)
CLOTRIMAZOLE	10 (<0.1)	16 (0.1)	26 (<0.1)
CORTICOSTEROID NOS	13 (<0.1)	16 (0.1)	29 (<0.1)
ETHINYLESTRADIOL;NORETHISTERONE	23 (0.2)	16 (0.1)	39 (0.1)
FLUTICASONE PROPIONATE;SALMETEROL	14 (<0.1)	16 (0.1)	30 (<0.1)
GLIBENCLAMIDE	18 (0.1)	16 (0.1)	34 (0.1)
HERBAL PREPARATION	21 (0.1)	16 (0.1)	37 (0.1)
NABUMETONE	19 (0.1)	16 (0.1)	35 (0.1)
PHENYLEPHRINE	16 (0.1)	16 (0.1)	32 (0.1)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	20 (0.1)	16 (0.1)	36 (0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PROPRANOLOL HYDROCHLORIDE	12 (<0.1)	16 (0.1)	28 (<0.1)
SACUBITRIL VALSARTAN SODIUM HYDRATE	15 (<0.1)	16 (0.1)	31 (0.1)
TAMOXIFEN	18 (0.1)	16 (0.1)	34 (0.1)
ZOLMITRIPTAN	16 (0.1)	16 (0.1)	32 (0.1)
AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE	15 (<0.1)	15 (<0.1)	30 (<0.1)
BISOPROLOL FUMARATE;HYDROCHLOROTHIAZIDE	8 (<0.1)	15 (<0.1)	23 (<0.1)
CARBIDOPA;LEVODOPA	23 (0.2)	15 (<0.1)	38 (0.1)
CREATINE	16 (0.1)	15 (<0.1)	31 (0.1)
CURCUMIN	16 (0.1)	15 (<0.1)	31 (0.1)
DICYCLOVERINE HYDROCHLORIDE	11 (<0.1)	15 (<0.1)	26 (<0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	24 (0.2)	15 (<0.1)	39 (0.1)
ERYTHROMYCIN	11 (<0.1)	15 (<0.1)	26 (<0.1)
ETHINYLESTRADIOL;NORGESTREL	20 (0.1)	15 (<0.1)	35 (0.1)
ISOSORBIDE	10 (<0.1)	15 (<0.1)	25 (<0.1)
LABETALOL	18 (0.1)	15 (<0.1)	33 (0.1)
LIOTHYRONINE SODIUM	14 (<0.1)	15 (<0.1)	29 (<0.1)
MINERALS NOS;VITAMINS NOS	9 (<0.1)	15 (<0.1)	24 (<0.1)
RANITIDINE HYDROCHLORIDE	11 (<0.1)	15 (<0.1)	26 (<0.1)
RESVERATROL	17 (0.1)	15 (<0.1)	32 (0.1)
RIBOFLAVIN	16 (0.1)	15 (<0.1)	31 (0.1)
TACROLIMUS	8 (<0.1)	15 (<0.1)	23 (<0.1)
TIZANIDINE HYDROCHLORIDE	22 (0.1)	15 (<0.1)	37 (0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
TRAMADOL HYDROCHLORIDE	18 (0.1)	15 (<0.1)	33 (0.1)
VITAMINS, OTHER COMBINATIONS	14 (<0.1)	15 (<0.1)	29 (<0.1)
CARBAMAZEPINE	17 (0.1)	14 (<0.1)	31 (0.1)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	17 (0.1)	14 (<0.1)	31 (0.1)
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL	11 (<0.1)	14 (<0.1)	25 (<0.1)
DEXTROMETHORPHAN;PARACETAMOL;PHENYLEPHRINE	5 (<0.1)	14 (<0.1)	19 (<0.1)
DIGOXIN	11 (<0.1)	14 (<0.1)	25 (<0.1)
EMPAGLIFLOZIN;METFORMIN HYDROCHLORIDE	13 (<0.1)	14 (<0.1)	27 (<0.1)
FLUTICASONE FUROATE	21 (0.1)	14 (<0.1)	35 (0.1)
HYDROXYCHLOROQUINE	15 (<0.1)	14 (<0.1)	29 (<0.1)
KETOTIFEN	12 (<0.1)	14 (<0.1)	26 (<0.1)
LACTOBACILLUS ACIDOPHILUS	13 (<0.1)	14 (<0.1)	27 (<0.1)
METAXALONE	14 (<0.1)	14 (<0.1)	28 (<0.1)
NICOTINE	20 (0.1)	14 (<0.1)	34 (0.1)
OFLOXACIN	11 (<0.1)	14 (<0.1)	25 (<0.1)
OLOPATADINE	17 (0.1)	14 (<0.1)	31 (0.1)
OMEGA-3 FATTY ACIDS	24 (0.2)	14 (<0.1)	38 (0.1)
QUERCETIN	19 (0.1)	14 (<0.1)	33 (0.1)
VITAMIN K NOS	26 (0.2)	14 (<0.1)	40 (0.1)
AMFETAMINE;DEXAMFETAMINE	17 (0.1)	13 (<0.1)	30 (<0.1)
ARGININE	12 (<0.1)	13 (<0.1)	25 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CAFFEINE	5 (<0.1)	13 (<0.1)	18 (<0.1)
CALCIUM;MAGNESIUM	12 (<0.1)	13 (<0.1)	25 (<0.1)
COLESTYRAMINE	15 (<0.1)	13 (<0.1)	28 (<0.1)
COUGH AND COLD PREPARATIONS	4 (<0.1)	13 (<0.1)	17 (<0.1)
DORZOLAMIDE	12 (<0.1)	13 (<0.1)	25 (<0.1)
EPLERENONE	8 (<0.1)	13 (<0.1)	21 (<0.1)
INFLUENZA VACCINE INACT SAG 3V	14 (<0.1)	13 (<0.1)	27 (<0.1)
IVERMECTIN	16 (0.1)	13 (<0.1)	29 (<0.1)
LEVOGLUTAMIDE	10 (<0.1)	13 (<0.1)	23 (<0.1)
MAGNESIUM CITRATE	13 (<0.1)	13 (<0.1)	26 (<0.1)
MAGNESIUM GLYCINATE	6 (<0.1)	13 (<0.1)	19 (<0.1)
METHYLCELLULOSE	11 (<0.1)	13 (<0.1)	24 (<0.1)
OXYCODONE HYDROCHLORIDE	14 (<0.1)	13 (<0.1)	27 (<0.1)
OXYCODONE;PARACETAMOL	12 (<0.1)	13 (<0.1)	25 (<0.1)
OXYGEN	22 (0.1)	13 (<0.1)	35 (0.1)
PHENYLEPHRINE HYDROCHLORIDE	21 (0.1)	13 (<0.1)	34 (0.1)
ROPINIROLE HYDROCHLORIDE	13 (<0.1)	13 (<0.1)	26 (<0.1)
VITAMIN B1 NOS	12 (<0.1)	13 (<0.1)	25 (<0.1)
WARFARIN SODIUM	22 (0.1)	13 (<0.1)	35 (0.1)
AMITRIPTYLINE HYDROCHLORIDE	10 (<0.1)	12 (<0.1)	22 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BORON;CALCIUM;CIMICIFUGA RACEMOSA EXTRACT;FOLIC ACID;GLYCINE MAX EXTRACT;MAGNOLIA OFFICINALIS;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SELENIUM;THIAMINE;TOCOPHEROL;VITAMIN B12 NOS	5 (<0.1)	12 (<0.1)	17 (<0.1)
BRIMONIDINE TARTRATE	18 (0.1)	12 (<0.1)	30 (<0.1)
BUMETANIDE	13 (<0.1)	12 (<0.1)	25 (<0.1)
CALCIPOTRIOL	2 (<0.1)	12 (<0.1)	14 (<0.1)
CODEINE;PARACETAMOL	9 (<0.1)	12 (<0.1)	21 (<0.1)
DOXYLAMINE SUCCINATE	14 (<0.1)	12 (<0.1)	26 (<0.1)
ETODOLAC	7 (<0.1)	12 (<0.1)	19 (<0.1)
FLUOROURACIL	15 (<0.1)	12 (<0.1)	27 (<0.1)
INDAPAMIDE	21 (0.1)	12 (<0.1)	33 (0.1)
ISOTRETINOIN	12 (<0.1)	12 (<0.1)	24 (<0.1)
LINAGLIPTIN	20 (0.1)	12 (<0.1)	32 (0.1)
LOPERAMIDE	16 (0.1)	12 (<0.1)	28 (<0.1)
LUBIPROSTONE	9 (<0.1)	12 (<0.1)	21 (<0.1)
MENTHOL	2 (<0.1)	12 (<0.1)	14 (<0.1)
NADOLOL	7 (<0.1)	12 (<0.1)	19 (<0.1)
NEBIVOLOL	4 (<0.1)	12 (<0.1)	16 (<0.1)
OMALIZUMAB	9 (<0.1)	12 (<0.1)	21 (<0.1)
OXYMETAZOLINE HYDROCHLORIDE	17 (0.1)	12 (<0.1)	29 (<0.1)
PIOGLITAZONE HYDROCHLORIDE	25 (0.2)	12 (<0.1)	37 (0.1)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
RABEPRAZOLE SODIUM	9 (<0.1)	12 (<0.1)	21 (<0.1)
RANOLAZINE	8 (<0.1)	12 (<0.1)	20 (<0.1)
SOLIFENACIN SUCCINATE	15 (<0.1)	12 (<0.1)	27 (<0.1)
TILACTASE	17 (0.1)	12 (<0.1)	29 (<0.1)
VANCOMYCIN	9 (<0.1)	12 (<0.1)	21 (<0.1)
BRIMONIDINE TARTRATE;TIMOLOL MALEATE	15 (<0.1)	11 (<0.1)	26 (<0.1)
BRINZOLAMIDE	10 (<0.1)	11 (<0.1)	21 (<0.1)
CHLORPHENAMINE MALEATE	11 (<0.1)	11 (<0.1)	22 (<0.1)
CIMICIFUGA RACEMOSA	8 (<0.1)	11 (<0.1)	19 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	11 (<0.1)	11 (<0.1)	22 (<0.1)
DORZOLAMIDE HYDROCHLORIDE;TIMOLOL MALEATE	17 (0.1)	11 (<0.1)	28 (<0.1)
DOXYCYCLINE HYCLATE	11 (<0.1)	11 (<0.1)	22 (<0.1)
ETHINYLESTRADIOL;NORELGESTROMIN	16 (0.1)	11 (<0.1)	27 (<0.1)
GALCANEZUMAB	14 (<0.1)	11 (<0.1)	25 (<0.1)
INSULIN HUMAN INJECTION, ISOPHANE	3 (<0.1)	11 (<0.1)	14 (<0.1)
LOTEPREDNOL ETABONATE	5 (<0.1)	11 (<0.1)	16 (<0.1)
MACROGOL	8 (<0.1)	11 (<0.1)	19 (<0.1)
OENOTHERA BIENNIS OIL	9 (<0.1)	11 (<0.1)	20 (<0.1)
OLODATEROL HYDROCHLORIDE;TIOTROPIUM BROMIDE MONOHYDRATE	2 (<0.1)	11 (<0.1)	13 (<0.1)
OXITRIPTAN	7 (<0.1)	11 (<0.1)	18 (<0.1)
PHYTOSTEROLS NOS	3 (<0.1)	11 (<0.1)	14 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PROPAFENONE	5 (<0.1)	11 (<0.1)	16 (<0.1)
PSYLLIUM HYDROPHILIC MUCILLOID	6 (<0.1)	11 (<0.1)	17 (<0.1)
RABEPRAZOLE	6 (<0.1)	11 (<0.1)	17 (<0.1)
TRAVOPROST	16 (0.1)	11 (<0.1)	27 (<0.1)
TRAZODONE HYDROCHLORIDE	11 (<0.1)	11 (<0.1)	22 (<0.1)
UBIQUINOL	8 (<0.1)	11 (<0.1)	19 (<0.1)
ZEAXANTHIN	9 (<0.1)	11 (<0.1)	20 (<0.1)
3,3'-DIINDOLYLMETHANE	5 (<0.1)	10 (<0.1)	15 (<0.1)
ALIROCUMAB	7 (<0.1)	10 (<0.1)	17 (<0.1)
ASCORBIC ACID;HERBAL NOS;LEVOGLUTAMIDE;LYSINE;MAGNESIUM;MANGANESE;RETINOL;RIBOFLAVIN;SELENIUM;TOCOPHEROL;ZINC	7 (<0.1)	10 (<0.1)	17 (<0.1)
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	4 (<0.1)	10 (<0.1)	14 (<0.1)
BREXPIPRAZOLE	5 (<0.1)	10 (<0.1)	15 (<0.1)
BUPRENORPHINE	5 (<0.1)	10 (<0.1)	15 (<0.1)
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	7 (<0.1)	10 (<0.1)	17 (<0.1)
CARIPRAZINE HYDROCHLORIDE	8 (<0.1)	10 (<0.1)	18 (<0.1)
CHONDROITIN	14 (<0.1)	10 (<0.1)	24 (<0.1)
CHROMIUM PICOLINATE	4 (<0.1)	10 (<0.1)	14 (<0.1)
CICLOPIROX	11 (<0.1)	10 (<0.1)	21 (<0.1)
CIMETIDINE	14 (<0.1)	10 (<0.1)	24 (<0.1)
COBICISTAT;ELVITEGRAVIR;EMTRICITABINE;TENOFOVIR ALAFENAMIDE	9 (<0.1)	10 (<0.1)	19 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
DEXTRIN	5 (<0.1)	10 (<0.1)	15 (<0.1)
DEXTROMETHORPHAN;GUAIFENESIN	4 (<0.1)	10 (<0.1)	14 (<0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	9 (<0.1)	10 (<0.1)	19 (<0.1)
GINSENG NOS	7 (<0.1)	10 (<0.1)	17 (<0.1)
HYDROCHLOROTHIAZIDE;TELMISARTAN	15 (<0.1)	10 (<0.1)	25 (<0.1)
HYDROMORPHONE	9 (<0.1)	10 (<0.1)	19 (<0.1)
HYPERICUM PERFORATUM	7 (<0.1)	10 (<0.1)	17 (<0.1)
NYSTATIN	12 (<0.1)	10 (<0.1)	22 (<0.1)
OMEGA-3-ACID ETHYL ESTER	23 (0.2)	10 (<0.1)	33 (0.1)
PHENAZOPYRIDINE HYDROCHLORIDE	9 (<0.1)	10 (<0.1)	19 (<0.1)
PLANTAGO OVATA FIBRE	7 (<0.1)	10 (<0.1)	17 (<0.1)
RALOXIFENE HYDROCHLORIDE	11 (<0.1)	10 (<0.1)	21 (<0.1)
SULFASALAZINE	6 (<0.1)	10 (<0.1)	16 (<0.1)
TORASEMIDE	10 (<0.1)	10 (<0.1)	20 (<0.1)
TRIAZOLAM	5 (<0.1)	10 (<0.1)	15 (<0.1)
ZOLEDRONIC ACID	8 (<0.1)	10 (<0.1)	18 (<0.1)
ALOGLIPTIN	10 (<0.1)	9 (<0.1)	19 (<0.1)
APOAEQUORIN	6 (<0.1)	9 (<0.1)	15 (<0.1)
ASCORBIC ACID;ZINC	9 (<0.1)	9 (<0.1)	18 (<0.1)
BETAMETHASONE DIPROPIONATE	8 (<0.1)	9 (<0.1)	17 (<0.1)
BISOPROLOL FUMARATE	5 (<0.1)	9 (<0.1)	14 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BUPIVACAINE	2 (<0.1)	9 (<0.1)	11 (<0.1)
CABERGOLINE	11 (<0.1)	9 (<0.1)	20 (<0.1)
CALCITRIOL	14 (<0.1)	9 (<0.1)	23 (<0.1)
CILOSTAZOL	7 (<0.1)	9 (<0.1)	16 (<0.1)
COLESEVELAM HYDROCHLORIDE	2 (<0.1)	9 (<0.1)	11 (<0.1)
DABIGATRAN ETEXILATE MESILATE	6 (<0.1)	9 (<0.1)	15 (<0.1)
DEXTROMETHORPHAN	3 (<0.1)	9 (<0.1)	12 (<0.1)
DOXAZOSIN MESILATE	9 (<0.1)	9 (<0.1)	18 (<0.1)
DROSPIRENONE;ETHINYLESTRADIOL BETADEX CLATHRATE	21 (0.1)	9 (<0.1)	30 (<0.1)
DUPILUMAB	4 (<0.1)	9 (<0.1)	13 (<0.1)
ELETRIPTAN	11 (<0.1)	9 (<0.1)	20 (<0.1)
ESTRADIOL;ESTRIOL	7 (<0.1)	9 (<0.1)	16 (<0.1)
FAMCICLOVIR	3 (<0.1)	9 (<0.1)	12 (<0.1)
FAMOTIDINE;IBUPROFEN	4 (<0.1)	9 (<0.1)	13 (<0.1)
FERROUS GLUCONATE	4 (<0.1)	9 (<0.1)	13 (<0.1)
FLUVOXAMINE	6 (<0.1)	9 (<0.1)	15 (<0.1)
GLYCOPYRRONIUM	5 (<0.1)	9 (<0.1)	14 (<0.1)
GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	11 (<0.1)	9 (<0.1)	20 (<0.1)
HORMONES	4 (<0.1)	9 (<0.1)	13 (<0.1)
HYDROCHLOROTHIAZIDE;IRBESARTAN	14 (<0.1)	9 (<0.1)	23 (<0.1)
LETROZOLE	9 (<0.1)	9 (<0.1)	18 (<0.1)
LISDEXAMFETAMINE	4 (<0.1)	9 (<0.1)	13 (<0.1)
METHYLPREDNISOLONE SODIUM SUCCINATE	8 (<0.1)	9 (<0.1)	17 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MOXIFLOXACIN	11 (<0.1)	9 (<0.1)	20 (<0.1)
MULTIVITAMINS, OTHER COMBINATIONS	2 (<0.1)	9 (<0.1)	11 (<0.1)
PENICILLIN NOS	11 (<0.1)	9 (<0.1)	20 (<0.1)
PENTOXIFYLLINE	2 (<0.1)	9 (<0.1)	11 (<0.1)
PHENYTOIN	3 (<0.1)	9 (<0.1)	12 (<0.1)
SOLIFENACIN	10 (<0.1)	9 (<0.1)	19 (<0.1)
SUMATRIPTAN SUCCINATE	10 (<0.1)	9 (<0.1)	19 (<0.1)
TOLTERODINE L-TARTRATE	8 (<0.1)	9 (<0.1)	17 (<0.1)
VORTIOXETINE	2 (<0.1)	9 (<0.1)	11 (<0.1)
ACETAZOLAMIDE	5 (<0.1)	8 (<0.1)	13 (<0.1)
ACETYLSALICYLIC ACID;CITRIC ACID;SODIUM BICARBONATE	3 (<0.1)	8 (<0.1)	11 (<0.1)
ADAPALENE	6 (<0.1)	8 (<0.1)	14 (<0.1)
AMFETAMINE	9 (<0.1)	8 (<0.1)	17 (<0.1)
AMMONIUM SUCCINATE;CALCIUM SUCCINATE;GLUTAMATE SODIUM;GLYCINE;MAGNESIUM SUCCINATE;TOCOPHERYL ACETATE;ZINC DIFUMARATE HYDRATE	5 (<0.1)	8 (<0.1)	13 (<0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM PANTOTHENATE;EQUISETUM ARVENSE;FERROUS FUMARATE;FOLIC ACID;MANGANESE AMINO ACID CHELATE;SILICON DIOXIDE;ZINC AMINO ACID CHELATE	7 (<0.1)	8 (<0.1)	15 (<0.1)
ATOMOXETINE	13 (<0.1)	8 (<0.1)	21 (<0.1)
BUPROPION HYDROCHLORIDE;NALTREXONE HYDROCHLORIDE	10 (<0.1)	8 (<0.1)	18 (<0.1)
CAMELLIA SINENSIS	8 (<0.1)	8 (<0.1)	16 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CHLORHEXIDINE GLUCONATE	7 (<0.1)	8 (<0.1)	15 (<0.1)
CHLORPHENAMINE	12 (<0.1)	8 (<0.1)	20 (<0.1)
DOCOSAHEXAENOIC ACID	3 (<0.1)	8 (<0.1)	11 (<0.1)
DOCOSANOL	9 (<0.1)	8 (<0.1)	17 (<0.1)
DONEPEZIL	14 (<0.1)	8 (<0.1)	22 (<0.1)
EMTRICITABINE;TENOFOVIR	5 (<0.1)	8 (<0.1)	13 (<0.1)
ENOXAPARIN SODIUM	5 (<0.1)	8 (<0.1)	13 (<0.1)
ESTROGENS ESTERIFIED;METHYLTESTOSTERONE	5 (<0.1)	8 (<0.1)	13 (<0.1)
HEPARIN	5 (<0.1)	8 (<0.1)	13 (<0.1)
HYDRALAZINE HYDROCHLORIDE	3 (<0.1)	8 (<0.1)	11 (<0.1)
IBUPROFEN;PARACETAMOL	4 (<0.1)	8 (<0.1)	12 (<0.1)
IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	7 (<0.1)	8 (<0.1)	15 (<0.1)
INSULIN HUMAN	16 (0.1)	8 (<0.1)	24 (<0.1)
IOHEXOL	4 (<0.1)	8 (<0.1)	12 (<0.1)
LATANOPROSTENE BUNOD	2 (<0.1)	8 (<0.1)	10 (<0.1)
LEUPRORELIN ACETATE	3 (<0.1)	8 (<0.1)	11 (<0.1)
LEVOSALBUTAMOL	12 (<0.1)	8 (<0.1)	20 (<0.1)
LINOLEIC ACID	3 (<0.1)	8 (<0.1)	11 (<0.1)
MAGNESIUM HYDROXIDE	4 (<0.1)	8 (<0.1)	12 (<0.1)
METHYLSULFONYLMETHANE	14 (<0.1)	8 (<0.1)	22 (<0.1)
MICONAZOLE NITRATE	5 (<0.1)	8 (<0.1)	13 (<0.1)
NARATRIPTAN	4 (<0.1)	8 (<0.1)	12 (<0.1)
PIMECROLIMUS	6 (<0.1)	8 (<0.1)	14 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
POLYPODIUM LEUCATOMOS EXTRACT	1 (<0.1)	8 (<0.1)	9 (<0.1)
PRAMIPEXOLE DIHYDROCHLORIDE	14 (<0.1)	8 (<0.1)	22 (<0.1)
SAMBUCUS NIGRA FRUIT	11 (<0.1)	8 (<0.1)	19 (<0.1)
SILICON DIOXIDE	2 (<0.1)	8 (<0.1)	10 (<0.1)
STEROIDS	3 (<0.1)	8 (<0.1)	11 (<0.1)
THIAMAZOLE	14 (<0.1)	8 (<0.1)	22 (<0.1)
TOLTERODINE	5 (<0.1)	8 (<0.1)	13 (<0.1)
UBROGEPANT	12 (<0.1)	8 (<0.1)	20 (<0.1)
UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE	21 (0.1)	8 (<0.1)	29 (<0.1)
WITHANIA SOMNIFERA	8 (<0.1)	8 (<0.1)	16 (<0.1)
XANTOFYL;ZEAXANTHIN	6 (<0.1)	8 (<0.1)	14 (<0.1)
ZALEPLON	9 (<0.1)	8 (<0.1)	17 (<0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	5 (<0.1)	7 (<0.1)	12 (<0.1)
AMMONIUM LACTATE	4 (<0.1)	7 (<0.1)	11 (<0.1)
ANTIBIOTICS	2 (<0.1)	7 (<0.1)	9 (<0.1)
AZELAIC ACID	10 (<0.1)	7 (<0.1)	17 (<0.1)
AZILSARTAN MEDOXOMIL;CHLORTALIDONE	9 (<0.1)	7 (<0.1)	16 (<0.1)
BEVACIZUMAB	6 (<0.1)	7 (<0.1)	13 (<0.1)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS GASSERI	3 (<0.1)	7 (<0.1)	10 (<0.1)
BUDESONIDE;FORMOTEROL	19 (0.1)	7 (<0.1)	26 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	4 (<0.1)	7 (<0.1)	11 (<0.1)
CHROMIUM	11 (<0.1)	7 (<0.1)	18 (<0.1)
COD-LIVER OIL	3 (<0.1)	7 (<0.1)	10 (<0.1)
CROMOGLICATE SODIUM	6 (<0.1)	7 (<0.1)	13 (<0.1)
DAPSONE	4 (<0.1)	7 (<0.1)	11 (<0.1)
DESOXIMETASONE	6 (<0.1)	7 (<0.1)	13 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE	8 (<0.1)	7 (<0.1)	15 (<0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;NAPROXEN SODIUM	2 (<0.1)	7 (<0.1)	9 (<0.1)
DIPHENHYDRAMINE;PARACETAMOL	5 (<0.1)	7 (<0.1)	12 (<0.1)
DROSPIRENONE	3 (<0.1)	7 (<0.1)	10 (<0.1)
ELETRIPTAN HYDROBROMIDE	15 (<0.1)	7 (<0.1)	22 (<0.1)
EMTRICITABINE;RILPIVIRINE HYDROCHLORIDE;TENOFOVIR ALAFENAMIDE FUMARATE	7 (<0.1)	7 (<0.1)	14 (<0.1)
EZETIMIBE;SIMVASTATIN	12 (<0.1)	7 (<0.1)	19 (<0.1)
FLUTICASONE;SALMETEROL	8 (<0.1)	7 (<0.1)	15 (<0.1)
GLUCOSAMINE HYDROCHLORIDE	7 (<0.1)	7 (<0.1)	14 (<0.1)
GLUCOSAMINE SULFATE	11 (<0.1)	7 (<0.1)	18 (<0.1)
HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	10 (<0.1)	7 (<0.1)	17 (<0.1)
HYDROMORPHONE HYDROCHLORIDE	10 (<0.1)	7 (<0.1)	17 (<0.1)
IPRATROPIUM;SALBUTAMOL	6 (<0.1)	7 (<0.1)	13 (<0.1)
KETOTIFEN FUMARATE	9 (<0.1)	7 (<0.1)	16 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
LINUM USITATISSIMUM SEED	9 (<0.1)	7 (<0.1)	16 (<0.1)
METHYLPREDNISOLONE ACETATE	13 (<0.1)	7 (<0.1)	20 (<0.1)
NORTRIPTYLINE HYDROCHLORIDE	4 (<0.1)	7 (<0.1)	11 (<0.1)
ORIGANUM MINUTIFLORUM OIL	0	7 (<0.1)	7 (<0.1)
POTASSIUM GLUCONATE	14 (<0.1)	7 (<0.1)	21 (<0.1)
PROCHLORPERAZINE	6 (<0.1)	7 (<0.1)	13 (<0.1)
PROPOFOL	7 (<0.1)	7 (<0.1)	14 (<0.1)
RETINOL	10 (<0.1)	7 (<0.1)	17 (<0.1)
SILDENAFIL CITRATE	16 (0.1)	7 (<0.1)	23 (<0.1)
SODIUM BICARBONATE	12 (<0.1)	7 (<0.1)	19 (<0.1)
TAPENTADOL HYDROCHLORIDE	5 (<0.1)	7 (<0.1)	12 (<0.1)
TAZAROTENE	6 (<0.1)	7 (<0.1)	13 (<0.1)
THEANINE	7 (<0.1)	7 (<0.1)	14 (<0.1)
ZIPRASIDONE	2 (<0.1)	7 (<0.1)	9 (<0.1)
ACETYLSALICYLIC ACID;CHLORPHENAMINE MALEATE;PHENYLEPHRINE BITARTRATE	1 (<0.1)	6 (<0.1)	7 (<0.1)
ADEMETIONINE	6 (<0.1)	6 (<0.1)	12 (<0.1)
AFLIBERCEPT	8 (<0.1)	6 (<0.1)	14 (<0.1)
ALL OTHER THERAPEUTIC PRODUCTS	12 (<0.1)	6 (<0.1)	18 (<0.1)
ALLIUM SATIVUM OIL	2 (<0.1)	6 (<0.1)	8 (<0.1)
ALOE VERA	3 (<0.1)	6 (<0.1)	9 (<0.1)
AMFETAMINE SULFATE	10 (<0.1)	6 (<0.1)	16 (<0.1)
ARTIFICIAL TEARS [UMBRELLA TERM]	2 (<0.1)	6 (<0.1)	8 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BECLOMETASONE	4 (<0.1)	6 (<0.1)	10 (<0.1)
BENZOYL PEROXIDE;CLINDAMYCIN PHOSPHATE	3 (<0.1)	6 (<0.1)	9 (<0.1)
BERBERINE	9 (<0.1)	6 (<0.1)	15 (<0.1)
BIOTIN;KERATIN	2 (<0.1)	6 (<0.1)	8 (<0.1)
BUTALBITAL	3 (<0.1)	6 (<0.1)	9 (<0.1)
CAFFEINE;MEPYRAMINE MALEATE;PARACETAMOL	7 (<0.1)	6 (<0.1)	13 (<0.1)
CALCIUM LEVOMEFOLATE	6 (<0.1)	6 (<0.1)	12 (<0.1)
CEFAZOLIN	6 (<0.1)	6 (<0.1)	12 (<0.1)
CHLORPHENAMINE MALEATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	5 (<0.1)	6 (<0.1)	11 (<0.1)
CHONDROITIN SULFATE	3 (<0.1)	6 (<0.1)	9 (<0.1)
CHORIONIC GONADOTROPHIN	11 (<0.1)	6 (<0.1)	17 (<0.1)
CICLESONIDE	14 (<0.1)	6 (<0.1)	20 (<0.1)
CLOMIFENE	4 (<0.1)	6 (<0.1)	10 (<0.1)
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE;METFORMIN HYDROCHLORIDE	5 (<0.1)	6 (<0.1)	11 (<0.1)
DESONIDE	7 (<0.1)	6 (<0.1)	13 (<0.1)
DEXAMETHASONE;TOBRAMYCIN	4 (<0.1)	6 (<0.1)	10 (<0.1)
DICLOFENAC POTASSIUM	4 (<0.1)	6 (<0.1)	10 (<0.1)
DIPHENHYDRAMINE CITRATE;IBUPROFEN	1 (<0.1)	6 (<0.1)	7 (<0.1)
DOFETILIDE	4 (<0.1)	6 (<0.1)	10 (<0.1)
DOLUTEGRAVIR SODIUM	12 (<0.1)	6 (<0.1)	18 (<0.1)
DORZOLAMIDE;TIMOLOL	11 (<0.1)	6 (<0.1)	17 (<0.1)

Percentages are based on the number of safety subjects.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
DOXYLAMINE	2 (<0.1)	6 (<0.1)	8 (<0.1)
EMTRICITABINE;TENOFOVIR ALAFENAMIDE	4 (<0.1)	6 (<0.1)	10 (<0.1)
ESTRADIOL;TESTOSTERONE	2 (<0.1)	6 (<0.1)	8 (<0.1)
ESTROGEN NOS;TESTOSTERONE	2 (<0.1)	6 (<0.1)	8 (<0.1)
FENOFIBRIC ACID	7 (<0.1)	6 (<0.1)	13 (<0.1)
FREMANEZUMAB	9 (<0.1)	6 (<0.1)	15 (<0.1)
GARCINIA GUMMI-GUTTA	1 (<0.1)	6 (<0.1)	7 (<0.1)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	6 (<0.1)	6 (<0.1)	12 (<0.1)
HEPATITIS B VACCINE	4 (<0.1)	6 (<0.1)	10 (<0.1)
IMMUNOTHERAPY	8 (<0.1)	6 (<0.1)	14 (<0.1)
INFLUENZA VACCINE INACT	12 (<0.1)	6 (<0.1)	18 (<0.1)
IRON;VITAMINS NOS	3 (<0.1)	6 (<0.1)	9 (<0.1)
LACTULOSE	5 (<0.1)	6 (<0.1)	11 (<0.1)
LEVOCARNITINE	5 (<0.1)	6 (<0.1)	11 (<0.1)
METAMIZOLE SODIUM	2 (<0.1)	6 (<0.1)	8 (<0.1)
METHOTREXATE	3 (<0.1)	6 (<0.1)	9 (<0.1)
MIDAZOLAM	0	6 (<0.1)	6 (<0.1)
NARATRIPTAN HYDROCHLORIDE	1 (<0.1)	6 (<0.1)	7 (<0.1)
NICOTINAMIDE RIBOSIDE	6 (<0.1)	6 (<0.1)	12 (<0.1)
NORGESTIMATE	0	6 (<0.1)	6 (<0.1)
OSPEMIFENE	3 (<0.1)	6 (<0.1)	9 (<0.1)
PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	5 (<0.1)	6 (<0.1)	11 (<0.1)
PHENTERMINE HYDROCHLORIDE	5 (<0.1)	6 (<0.1)	11 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PHENTERMINE HYDROCHLORIDE;TOPIRAMATE	2 (<0.1)	6 (<0.1)	8 (<0.1)
PRASUGREL	6 (<0.1)	6 (<0.1)	12 (<0.1)
PROPYLENE GLYCOL	0	6 (<0.1)	6 (<0.1)
PROTEIN	6 (<0.1)	6 (<0.1)	12 (<0.1)
RISEDRONATE SODIUM	10 (<0.1)	6 (<0.1)	16 (<0.1)
SITOSTEROL	7 (<0.1)	6 (<0.1)	13 (<0.1)
SODIUM FLUORIDE	4 (<0.1)	6 (<0.1)	10 (<0.1)
TAURINE	1 (<0.1)	6 (<0.1)	7 (<0.1)
TERBINAFINE HYDROCHLORIDE	5 (<0.1)	6 (<0.1)	11 (<0.1)
TERIPARATIDE	2 (<0.1)	6 (<0.1)	8 (<0.1)
TRYPTOPHAN, L-	1 (<0.1)	6 (<0.1)	7 (<0.1)
UMECLIDINIUM BROMIDE	7 (<0.1)	6 (<0.1)	13 (<0.1)
ZONISAMIDE	9 (<0.1)	6 (<0.1)	15 (<0.1)
ACEBUTOLOL	6 (<0.1)	5 (<0.1)	11 (<0.1)
ACETYLCARNITINE	6 (<0.1)	5 (<0.1)	11 (<0.1)
ACETYLSALICYLIC ACID;PARACETAMOL	5 (<0.1)	5 (<0.1)	10 (<0.1)
AMLODIPINE;HYDROCHLOROTHIAZIDE;VALSARTAN	2 (<0.1)	5 (<0.1)	7 (<0.1)
ANESTHETICS, GENERAL	1 (<0.1)	5 (<0.1)	6 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BACOPA MONNIERI;BIOTIN;BORON CITRATE;CALCIUM;CHOLINE BITARTRATE;CHROMIUM;COLECALCIFEROL;COPPER;DEANOL;DO COSAHEXAENOIC ACID;ELECTROLYTES NOS;FOLIC ACID;GAMMA-AMINOBUTYRIC ACID HUPERZIA SERRATA;INOSITOL;IODINE;IRON;LEVOGLUTAMIDE;MAGNESIU M;MANGANESE;MOLYBDENUM;N-ACETYLTYROSIN;NICOTINIC ACID;PANTOTHENIC ACID;PHOSPHATIDYL SERINE;PIDOLIC ACID;POTASSIUM;PYRIDOXINE HYDROCHLORIDE RIBOFLAVIN;SELENIUM;THIAMINE;TOCOPHERYL ACID SUCCINATE;TRACE ELEMENTS NOS;VACCINIUM MYRTILLUS;VANADYL SULFATE;VINPOCETINE;VITAMIN A NOS;VITAMIN B12 NOS;VITIS VINIFERA;ZINC	2 (<0.1)	5 (<0.1)	7 (<0.1)
ASCORBIC ACID;IRON	4 (<0.1)	5 (<0.1)	9 (<0.1)
ASTAXANTHIN	10 (<0.1)	5 (<0.1)	15 (<0.1)
ATENOLOL;CHLORTALIDONE	8 (<0.1)	5 (<0.1)	13 (<0.1)
AZILSARTAN KAMEDOXOMIL	7 (<0.1)	5 (<0.1)	12 (<0.1)
BACOPA MONNIERI HERB;CAMELLIA SINENSIS LEAF;CURCUMA LONGA RHIZOME;SILYBUM MARIANUM SEED;WITHANIA SOMNIFERA ROOT	2 (<0.1)	5 (<0.1)	7 (<0.1)
BAZEDOXIFENE;ESTROGENS CONJUGATED	1 (<0.1)	5 (<0.1)	6 (<0.1)
BENAZEPRIL;HYDROCHLOROTHIAZIDE	5 (<0.1)	5 (<0.1)	10 (<0.1)
BENZOCAINE	1 (<0.1)	5 (<0.1)	6 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BENZOYL PEROXIDE;CLINDAMYCIN	2 (<0.1)	5 (<0.1)	7 (<0.1)
BROMFENAC SODIUM	5 (<0.1)	5 (<0.1)	10 (<0.1)
CALCIUM CARBONATE;FAMOTIDINE;MAGNESIUM HYDROXIDE	1 (<0.1)	5 (<0.1)	6 (<0.1)
CAMPHOR;MENTHOL	1 (<0.1)	5 (<0.1)	6 (<0.1)
CARMELLOSE	3 (<0.1)	5 (<0.1)	8 (<0.1)
CHLORHEXIDINE	6 (<0.1)	5 (<0.1)	11 (<0.1)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	5 (<0.1)	6 (<0.1)
CHONDROITIN SULFATE;GLUCOSAMINE	2 (<0.1)	5 (<0.1)	7 (<0.1)
CLOMIFENE CITRATE	7 (<0.1)	5 (<0.1)	12 (<0.1)
COBICISTAT;DARUNAVIR ETHANOLATE	3 (<0.1)	5 (<0.1)	8 (<0.1)
COLESTIPOL	10 (<0.1)	5 (<0.1)	15 (<0.1)
COPPER	4 (<0.1)	5 (<0.1)	9 (<0.1)
CRISABOROLE	3 (<0.1)	5 (<0.1)	8 (<0.1)
DESLORATADINE	7 (<0.1)	5 (<0.1)	12 (<0.1)
DEXMETHYLPHENIDATE	1 (<0.1)	5 (<0.1)	6 (<0.1)
DIFLUPREDNATE	4 (<0.1)	5 (<0.1)	9 (<0.1)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID	9 (<0.1)	5 (<0.1)	14 (<0.1)
DRONEDARONE HYDROCHLORIDE	7 (<0.1)	5 (<0.1)	12 (<0.1)
ENALAPRIL MALEATE;HYDROCHLOROTHIAZIDE	1 (<0.1)	5 (<0.1)	6 (<0.1)
ENOXAPARIN	5 (<0.1)	5 (<0.1)	10 (<0.1)
ESTROGEN NOS;PROGESTERONE	7 (<0.1)	5 (<0.1)	12 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ETHINYLESTRADIOL	0	5 (<0.1)	5 (<0.1)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE	3 (<0.1)	5 (<0.1)	8 (<0.1)
FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	1 (<0.1)	5 (<0.1)	6 (<0.1)
GLUCOSE	4 (<0.1)	5 (<0.1)	9 (<0.1)
GLYCYRRHIZA GLABRA ROOT	2 (<0.1)	5 (<0.1)	7 (<0.1)
GUANFACINE	5 (<0.1)	5 (<0.1)	10 (<0.1)
HOMEOPATHIC PREPARATION	0	5 (<0.1)	5 (<0.1)
HYALURONATE SODIUM	7 (<0.1)	5 (<0.1)	12 (<0.1)
HYDROQUINONE	4 (<0.1)	5 (<0.1)	9 (<0.1)
HYOSCINE	3 (<0.1)	5 (<0.1)	8 (<0.1)
I.V. SOLUTIONS	3 (<0.1)	5 (<0.1)	8 (<0.1)
INFLUENZA VACCINE INACT SAG 4V	5 (<0.1)	5 (<0.1)	10 (<0.1)
IODINE	8 (<0.1)	5 (<0.1)	13 (<0.1)
LACOSAMIDE	0	5 (<0.1)	5 (<0.1)
LEVOMEFOLIC ACID	6 (<0.1)	5 (<0.1)	11 (<0.1)
LEVOSALBUTAMOL TARTRATE	2 (<0.1)	5 (<0.1)	7 (<0.1)
LITHIUM CARBONATE	11 (<0.1)	5 (<0.1)	16 (<0.1)
MECLOZINE HYDROCHLORIDE	0	5 (<0.1)	5 (<0.1)
MIDODRINE	0	5 (<0.1)	5 (<0.1)
MORINGA OLEIFERA	1 (<0.1)	5 (<0.1)	6 (<0.1)
OMEGA 9 FATTY ACIDS;OMEGA-3 FATTY ACIDS;OMEGA-6 FATTY ACIDS	2 (<0.1)	5 (<0.1)	7 (<0.1)
ORPHENADRINE	2 (<0.1)	5 (<0.1)	7 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
OTHER COMBINATIONS OF NUTRIENTS	2 (<0.1)	5 (<0.1)	7 (<0.1)
OTHER HYPNOTICS AND SEDATIVES	3 (<0.1)	5 (<0.1)	8 (<0.1)
PARACETAMOL;TRAMADOL HYDROCHLORIDE	4 (<0.1)	5 (<0.1)	9 (<0.1)
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	5 (<0.1)	5 (<0.1)	10 (<0.1)
PLECANATIDE	5 (<0.1)	5 (<0.1)	10 (<0.1)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	6 (<0.1)	5 (<0.1)	11 (<0.1)
PRASUGREL HYDROCHLORIDE	4 (<0.1)	5 (<0.1)	9 (<0.1)
PREDNISONE ACETATE	2 (<0.1)	5 (<0.1)	7 (<0.1)
RANIBIZUMAB	2 (<0.1)	5 (<0.1)	7 (<0.1)
REPAGLINIDE	5 (<0.1)	5 (<0.1)	10 (<0.1)
SACCHAROMYCES BOULARDII	2 (<0.1)	5 (<0.1)	7 (<0.1)
SULFAMETHOXAZOLE	7 (<0.1)	5 (<0.1)	12 (<0.1)
SUVOREXANT	6 (<0.1)	5 (<0.1)	11 (<0.1)
TROSPIUM	6 (<0.1)	5 (<0.1)	11 (<0.1)
VALERIANA OFFICINALIS ROOT	8 (<0.1)	5 (<0.1)	13 (<0.1)
ZINC PICOLINATE	2 (<0.1)	5 (<0.1)	7 (<0.1)
ZINGIBER OFFICINALE	8 (<0.1)	5 (<0.1)	13 (<0.1)
ABALOPARATIDE	2 (<0.1)	4 (<0.1)	6 (<0.1)
ACARBOSE	5 (<0.1)	4 (<0.1)	9 (<0.1)
ADAPALENE;BENZOYL PEROXIDE	3 (<0.1)	4 (<0.1)	7 (<0.1)
ALFUZOSIN HYDROCHLORIDE	11 (<0.1)	4 (<0.1)	15 (<0.1)
ALLERGENS, HOUSE DUST & MITE	1 (<0.1)	4 (<0.1)	5 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ALOE VERA EXTRACT;ALOE VERA LEAF POWDER;ANOGEISSUS LATIFOLIA GUM;ASTRAGALUS GUMMIFER GUM;GLUCOSAMINE HYDROCHLORIDE;LARIX DECIDUA GUM;ORYZA SATIVA STARCH	2 (<0.1)	4 (<0.1)	6 (<0.1)
AMYLASE;ASCORBIC ACID;CELLULASE;FOLIC ACID;LIPASE;PROTEASE NOS	2 (<0.1)	4 (<0.1)	6 (<0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CAPSICUM ANNUUM FRUIT;COLECALCIFEROL;COLLAGEN MARINE;CURCUMA LONGA;CYSTEINE HYDROCHLORIDE;EQUISETUM ARVENSE;FALLOPIA JAPONICA;HYALURONIC ACID;IODINE;KERATIN;LYSINE METHIONINE;PIPER NIGRUM;SELENIUM;SERENOA REPENS;TOCOTRIENOLS NOS;WITHANIA SOMNIFERA;ZINC	4 (<0.1)	4 (<0.1)	8 (<0.1)
ASCORBIC ACID;FERROUS FUMARATE	6 (<0.1)	4 (<0.1)	10 (<0.1)
ASCORBIC ACID;TOCOPHERYL ACETATE;XANTOFYL;ZEAXANTHIN;ZINC	0	4 (<0.1)	4 (<0.1)
BACITRACIN	1 (<0.1)	4 (<0.1)	5 (<0.1)
BENZOCAINE;MENTHOL	2 (<0.1)	4 (<0.1)	6 (<0.1)
BENZOYL PEROXIDE	8 (<0.1)	4 (<0.1)	12 (<0.1)
BETACAROTENE	7 (<0.1)	4 (<0.1)	11 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BREVIS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS CASEI;LACTOBACILLUS PARACASEI;LACTOBACILLUS PLANTARUM LACTOBACILLUS RHAMNOSUS;LACTOBACILLUS SALIVARIUS	1 (<0.1)	4 (<0.1)	5 (<0.1)
BORON;CHROMIUM;COPPER;GERMANIUM;IODINE;MANGANESE;MOLYBDENUM;SELENIUM;SILICON;SITOSTEROL;VANADIUM;VITAMIN D NOS;ZINC	1 (<0.1)	4 (<0.1)	5 (<0.1)
BOSWELLIA SERRATA	2 (<0.1)	4 (<0.1)	6 (<0.1)
BROMELAINS;QUERCETIN	1 (<0.1)	4 (<0.1)	5 (<0.1)
BUPRENORPHINE;NALOXONE	5 (<0.1)	4 (<0.1)	9 (<0.1)
CALCIUM CARBONATE;ERGOCALCIFEROL	4 (<0.1)	4 (<0.1)	8 (<0.1)
CALCIUM CARBONATE;VITAMIN D NOS	7 (<0.1)	4 (<0.1)	11 (<0.1)
CANAGLIFLOZIN;METFORMIN HYDROCHLORIDE	5 (<0.1)	4 (<0.1)	9 (<0.1)
CANDESARTAN CILEXETIL	2 (<0.1)	4 (<0.1)	6 (<0.1)
CAPSAICIN	2 (<0.1)	4 (<0.1)	6 (<0.1)
CAPTOPRIL	7 (<0.1)	4 (<0.1)	11 (<0.1)
CHLORPHENAMINE MALEATE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	4 (<0.1)	5 (<0.1)
CHOLINE FENOFIBRATE	3 (<0.1)	4 (<0.1)	7 (<0.1)
CHONDROITIN SULFATE;GLUCOSAMINE SULFATE;METHYLSULFONYLMETHANE	4 (<0.1)	4 (<0.1)	8 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CLINDAMYCIN PHOSPHATE	7 (<0.1)	4 (<0.1)	11 (<0.1)
CLOMIPRAMINE	1 (<0.1)	4 (<0.1)	5 (<0.1)
CLONIDINE HYDROCHLORIDE	5 (<0.1)	4 (<0.1)	9 (<0.1)
COBICISTAT;DARUNAVIR ETHANOLATE;EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE	2 (<0.1)	4 (<0.1)	6 (<0.1)
COCOS NUCIFERA OIL	2 (<0.1)	4 (<0.1)	6 (<0.1)
CROCUS SATIVUS	1 (<0.1)	4 (<0.1)	5 (<0.1)
DESMOPRESSIN	1 (<0.1)	4 (<0.1)	5 (<0.1)
DEXAMETHASONE;NEOMYCIN;POLYMYXIN B	3 (<0.1)	4 (<0.1)	7 (<0.1)
DEXMETHYLPHENIDATE HYDROCHLORIDE	3 (<0.1)	4 (<0.1)	7 (<0.1)
DIMENHYDRINATE	6 (<0.1)	4 (<0.1)	10 (<0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	2 (<0.1)	4 (<0.1)	6 (<0.1)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	2 (<0.1)	4 (<0.1)	6 (<0.1)
DOLUTEGRAVIR SODIUM;LAMIVUDINE	2 (<0.1)	4 (<0.1)	6 (<0.1)
DOLUTEGRAVIR SODIUM;RILPIVIRINE HYDROCHLORIDE	3 (<0.1)	4 (<0.1)	7 (<0.1)
DOXEPIN HYDROCHLORIDE	1 (<0.1)	4 (<0.1)	5 (<0.1)
DROSPIRENONE;ESTRADIOL	1 (<0.1)	4 (<0.1)	5 (<0.1)
EMPAGLIFLOZIN;LINAGLIPTIN	3 (<0.1)	4 (<0.1)	7 (<0.1)
ESTRADIOL VALERATE	2 (<0.1)	4 (<0.1)	6 (<0.1)
ESTROGEN NOS;PROGESTERONE;TESTOSTERONE	3 (<0.1)	4 (<0.1)	7 (<0.1)
ETHINYLESTRADIOL;ETYNODIOL DIACETATE	3 (<0.1)	4 (<0.1)	7 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
FELODIPINE	9 (<0.1)	4 (<0.1)	13 (<0.1)
FESOTERODINE FUMARATE	4 (<0.1)	4 (<0.1)	8 (<0.1)
FLUNISOLIDE	3 (<0.1)	4 (<0.1)	7 (<0.1)
FLUOCINOLONE ACETONIDE	6 (<0.1)	4 (<0.1)	10 (<0.1)
FLUTICASONE FUROATE;VILANTEROL	5 (<0.1)	4 (<0.1)	9 (<0.1)
FOSINOPRIL	2 (<0.1)	4 (<0.1)	6 (<0.1)
GLUCAGON	3 (<0.1)	4 (<0.1)	7 (<0.1)
HEPATITIS A VACCINE	2 (<0.1)	4 (<0.1)	6 (<0.1)
HYDROCORTISONE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	3 (<0.1)	4 (<0.1)	7 (<0.1)
HYOSCYAMINE SULFATE	4 (<0.1)	4 (<0.1)	8 (<0.1)
HYPROMELLOSE	0	4 (<0.1)	4 (<0.1)
IMIPRAMINE	2 (<0.1)	4 (<0.1)	6 (<0.1)
IMIQUIMOD	0	4 (<0.1)	4 (<0.1)
INFLUENZA VACCINES	5 (<0.1)	4 (<0.1)	9 (<0.1)
INSULIN GLARGINE;LIXISENATIDE	3 (<0.1)	4 (<0.1)	7 (<0.1)
KETAMINE	0	4 (<0.1)	4 (<0.1)
LACTOBACILLUS NOS	12 (<0.1)	4 (<0.1)	16 (<0.1)
LECITHIN	1 (<0.1)	4 (<0.1)	5 (<0.1)
LEVOMILNACIPRAN HYDROCHLORIDE	0	4 (<0.1)	4 (<0.1)
LEVOSALBUTAMOL HYDROCHLORIDE	11 (<0.1)	4 (<0.1)	15 (<0.1)
LIDOCAINE HYDROCHLORIDE	4 (<0.1)	4 (<0.1)	8 (<0.1)
LISINOPRIL DIHYDRATE	4 (<0.1)	4 (<0.1)	8 (<0.1)
LYCOPENE	7 (<0.1)	4 (<0.1)	11 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MAGNESIUM;ZINC	4 (<0.1)	4 (<0.1)	8 (<0.1)
MEMANTINE	8 (<0.1)	4 (<0.1)	12 (<0.1)
METFORMIN HYDROCHLORIDE;SAXAGLIPTIN HYDROCHLORIDE	0	4 (<0.1)	4 (<0.1)
METFORMIN;SITAGLIPTIN	0	4 (<0.1)	4 (<0.1)
NITRIC OXIDE	3 (<0.1)	4 (<0.1)	7 (<0.1)
NORETHISTERONE ACETATE	3 (<0.1)	4 (<0.1)	7 (<0.1)
ORAL CONTRACEPTIVE NOS	2 (<0.1)	4 (<0.1)	6 (<0.1)
ORLISTAT	2 (<0.1)	4 (<0.1)	6 (<0.1)
OTHER NUTRIENTS	3 (<0.1)	4 (<0.1)	7 (<0.1)
OTHER RESPIRATORY SYSTEM PRODUCTS	4 (<0.1)	4 (<0.1)	8 (<0.1)
OTHER VIRAL VACCINES	17 (0.1)	4 (<0.1)	21 (<0.1)
PHOSPHATIDYL SERINE	1 (<0.1)	4 (<0.1)	5 (<0.1)
PROBENECID	5 (<0.1)	4 (<0.1)	9 (<0.1)
PRUNUS CERASUS	5 (<0.1)	4 (<0.1)	9 (<0.1)
RHODIOLA ROSEA	3 (<0.1)	4 (<0.1)	7 (<0.1)
RIMEGEPANT	5 (<0.1)	4 (<0.1)	9 (<0.1)
RITONAVIR	2 (<0.1)	4 (<0.1)	6 (<0.1)
ROCURONIUM	3 (<0.1)	4 (<0.1)	7 (<0.1)
ROFLUMILAST	8 (<0.1)	4 (<0.1)	12 (<0.1)
ROTIGOTINE	2 (<0.1)	4 (<0.1)	6 (<0.1)
SALICYLIC ACID	7 (<0.1)	4 (<0.1)	11 (<0.1)
SOTALOL HYDROCHLORIDE	1 (<0.1)	4 (<0.1)	5 (<0.1)
SPIRULINA SPP.	3 (<0.1)	4 (<0.1)	7 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
SULFACETAMIDE SODIUM	1 (<0.1)	4 (<0.1)	5 (<0.1)
SULFACETAMIDE SODIUM;SULFUR	4 (<0.1)	4 (<0.1)	8 (<0.1)
SYMPATHOMIMETICS	5 (<0.1)	4 (<0.1)	9 (<0.1)
TENOFOVIR	2 (<0.1)	4 (<0.1)	6 (<0.1)
TESTOSTERONE ENANTHATE	3 (<0.1)	4 (<0.1)	7 (<0.1)
TESTOSTERONE UNDECANOATE	1 (<0.1)	4 (<0.1)	5 (<0.1)
TONICS	2 (<0.1)	4 (<0.1)	6 (<0.1)
TRANEXAMIC ACID	3 (<0.1)	4 (<0.1)	7 (<0.1)
TRIMETHOPRIM	2 (<0.1)	4 (<0.1)	6 (<0.1)
URSODEOXYCHOLIC ACID	4 (<0.1)	4 (<0.1)	8 (<0.1)
VILAZODONE	2 (<0.1)	4 (<0.1)	6 (<0.1)
VITIS VINIFERA SEED	5 (<0.1)	4 (<0.1)	9 (<0.1)
ZINC ACETATE;ZINC GLUCONATE	6 (<0.1)	4 (<0.1)	10 (<0.1)
ZINC SULFATE	5 (<0.1)	4 (<0.1)	9 (<0.1)
8-TETRAHYDROCANNABINOL	6 (<0.1)	3 (<0.1)	9 (<0.1)
ABACAVIR SULFATE;DOLUTEGRAVIR SODIUM;LAMIVUDINE	9 (<0.1)	3 (<0.1)	12 (<0.1)
ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE	1 (<0.1)	3 (<0.1)	4 (<0.1)
ALGELDRATE;SODIUM ALGINATE	2 (<0.1)	3 (<0.1)	5 (<0.1)
ALPHA-AMYLASE SWINE PANCREAS;CELLULASE;LIPASE;PROTEASE NOS	3 (<0.1)	3 (<0.1)	6 (<0.1)
ALPHA-D-GALACTOSIDASE	2 (<0.1)	3 (<0.1)	5 (<0.1)
ALPROSTADIL	3 (<0.1)	3 (<0.1)	6 (<0.1)
AMANTADINE	4 (<0.1)	3 (<0.1)	7 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
AMFEPRAMONE	3 (<0.1)	3 (<0.1)	6 (<0.1)
AMILORIDE	2 (<0.1)	3 (<0.1)	5 (<0.1)
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM	1 (<0.1)	3 (<0.1)	4 (<0.1)
AMLODIPINE BESILATE;HYDROCHLOROTHIAZIDE;OLMESARTAN MEDOXOMIL	3 (<0.1)	3 (<0.1)	6 (<0.1)
AMLODIPINE BESILATE;OLMESARTAN MEDOXOMIL	1 (<0.1)	3 (<0.1)	4 (<0.1)
AMLODIPINE;OLMESARTAN	7 (<0.1)	3 (<0.1)	10 (<0.1)
AMPICILLIN	6 (<0.1)	3 (<0.1)	9 (<0.1)
ANDROGRAPHIS PANICULATA;ECHINACEA PURPUREA ROOT;OLEA EUROPAEA LEAF	2 (<0.1)	3 (<0.1)	5 (<0.1)
ANILIDES	2 (<0.1)	3 (<0.1)	5 (<0.1)
ANTIHISTAMINES FOR SYSTEMIC USE	4 (<0.1)	3 (<0.1)	7 (<0.1)
ANTIOXIDANTS NOS	0	3 (<0.1)	3 (<0.1)
APOAEQUORIN;COLECALCIFEROL	3 (<0.1)	3 (<0.1)	6 (<0.1)
APREMILAST	2 (<0.1)	3 (<0.1)	5 (<0.1)
ARFORMOTEROL TARTRATE	1 (<0.1)	3 (<0.1)	4 (<0.1)
ASCOPHYLLUM NODOSUM;ASCORBIC ACID;BETACAROTENE;BORAGO OFFICINALIS;CAPSICUM ANNUUM;PETROSELINUM CRISPUM;PYRIDOXINE HYDROCHLORIDE;SERENOA REPENS;TOCOPHERYL ACETATE;ZEA MAYS STYLE;ZINC OXIDE	0	3 (<0.1)	3 (<0.1)
ASCORBIC ACID (VITAMIN C), COMBINATIONS	0	3 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BIOTIN;FOLIC ACID;NICOTINIC ACID;PANTOTHENIC ACID;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SODIUM;THIAMINE;VITAMIN B12 NOS	0	3 (<0.1)	3 (<0.1)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	4 (<0.1)	3 (<0.1)	7 (<0.1)
BACITRACIN ZINC;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	5 (<0.1)	3 (<0.1)	8 (<0.1)
BACITRACIN;NEOMYCIN;POLYMYXIN B	3 (<0.1)	3 (<0.1)	6 (<0.1)
BERBERIS VULGARIS ROOT;CAMELLIA SINENSIS LEAF EXTRACT;COPTIS CHINENSIS ROOT;CURCUMA LONGA RHIZOME;FALLOPIA JAPONICA ROOT WITH RHIZOME;ORIGANUM VULGARE LEAF;ROSMARINUS OFFICINALIS LEAF SCUTELLARIA BAICALENSIS ROOT;ZINGIBER OFFICINALE RHIZOME	3 (<0.1)	3 (<0.1)	6 (<0.1)
BETAHISTINE	1 (<0.1)	3 (<0.1)	4 (<0.1)
BETAMETHASONE;CLOTRIMAZOLE	2 (<0.1)	3 (<0.1)	5 (<0.1)
BICALUTAMIDE	2 (<0.1)	3 (<0.1)	5 (<0.1)
BIFIDOBACTERIUM BIFIDUM;LACTOBACILLUS ACIDOPHILUS	2 (<0.1)	3 (<0.1)	5 (<0.1)
BORON	0	3 (<0.1)	3 (<0.1)
BUNIUM PERSICUM OIL	1 (<0.1)	3 (<0.1)	4 (<0.1)
BUPIVACAINE HYDROCHLORIDE	2 (<0.1)	3 (<0.1)	5 (<0.1)
CAFFEINE;CODEINE PHOSPHATE;PARACETAMOL	0	3 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CAFFEINE;EPHEDRINE HYDROCHLORIDE;PARACETAMOL	2 (<0.1)	3 (<0.1)	5 (<0.1)
CALCIUM ACETATE	0	3 (<0.1)	3 (<0.1)
CALCIUM CARBONATE;COLECALCIFEROL;MAGNESIUM OXIDE;ZINC OXIDE	0	3 (<0.1)	3 (<0.1)
CALCIUM CARBONATE;MAGNESIUM HYDROXIDE	4 (<0.1)	3 (<0.1)	7 (<0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM	3 (<0.1)	3 (<0.1)	6 (<0.1)
CAROTENOIDS NOS	1 (<0.1)	3 (<0.1)	4 (<0.1)
CARTILAGE;HYALURONIC ACID	2 (<0.1)	3 (<0.1)	5 (<0.1)
CEFUROXIME	4 (<0.1)	3 (<0.1)	7 (<0.1)
CHLORELLA SPP.	3 (<0.1)	3 (<0.1)	6 (<0.1)
CHLORPHENAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE	0	3 (<0.1)	3 (<0.1)
CHONDROITIN SULFATE SODIUM	2 (<0.1)	3 (<0.1)	5 (<0.1)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE;MANGANESE ASCORBATE	0	3 (<0.1)	3 (<0.1)
CHONDROITIN;GLUCOSAMINE;METHYLSULFONYLMETHANE	2 (<0.1)	3 (<0.1)	5 (<0.1)
CIPROFLOXACIN HYDROCHLORIDE	3 (<0.1)	3 (<0.1)	6 (<0.1)
CIPROFLOXACIN HYDROCHLORIDE;DEXAMETHASONE	2 (<0.1)	3 (<0.1)	5 (<0.1)
CITRULLINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
COLESEVELAM	4 (<0.1)	3 (<0.1)	7 (<0.1)
DEXAMFETAMINE SULFATE	3 (<0.1)	3 (<0.1)	6 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE	1 (<0.1)	3 (<0.1)	4 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	3 (<0.1)	3 (<0.1)	6 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE	4 (<0.1)	3 (<0.1)	7 (<0.1)
DOCUSATE SODIUM;SENNOSIDE A+B	4 (<0.1)	3 (<0.1)	7 (<0.1)
EFAVIRENZ	0	3 (<0.1)	3 (<0.1)
ELUXADOLINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
EMTRICITABINE	4 (<0.1)	3 (<0.1)	7 (<0.1)
ENALAPRIL MALEATE	7 (<0.1)	3 (<0.1)	10 (<0.1)
ENZYME PREPARATIONS	2 (<0.1)	3 (<0.1)	5 (<0.1)
EPINEPHRINE;LIDOCAINE	1 (<0.1)	3 (<0.1)	4 (<0.1)
ESTRADIOL;PROGESTERONE	9 (<0.1)	3 (<0.1)	12 (<0.1)
FEXOFENADINE;PSEUDOEPHEDRINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
FEXOFENADINE;PSEUDOEPHEDRINE HYDROCHLORIDE	3 (<0.1)	3 (<0.1)	6 (<0.1)
FISH OIL;OMEGA-3 FATTY ACIDS	1 (<0.1)	3 (<0.1)	4 (<0.1)
FLUDROXYCORTIDE	1 (<0.1)	3 (<0.1)	4 (<0.1)
FLUOROMETHOLONE	1 (<0.1)	3 (<0.1)	4 (<0.1)
FLUTICASONE;VILANTEROL	2 (<0.1)	3 (<0.1)	5 (<0.1)
FROVATRIPTAN	2 (<0.1)	3 (<0.1)	5 (<0.1)
GLUTATHIONE	5 (<0.1)	3 (<0.1)	8 (<0.1)
GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
HYDROCHLOROTHIAZIDE;SPIRONOLACTONE	5 (<0.1)	3 (<0.1)	8 (<0.1)
HYLAN G-F 20	5 (<0.1)	3 (<0.1)	8 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
HYPOCHLOROUS ACID	0	3 (<0.1)	3 (<0.1)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	6 (<0.1)	3 (<0.1)	9 (<0.1)
INOSITOL	5 (<0.1)	3 (<0.1)	8 (<0.1)
INSULIN ASPART;INSULIN ASPART PROTAMINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
INTRAUTERINE CONTRACEPTIVES	2 (<0.1)	3 (<0.1)	5 (<0.1)
IOPAMIDOL	6 (<0.1)	3 (<0.1)	9 (<0.1)
ISOLEUCINE;LEUCINE;VALINE	1 (<0.1)	3 (<0.1)	4 (<0.1)
LATANOPROST;NETARSUDIL MESILATE	5 (<0.1)	3 (<0.1)	8 (<0.1)
LEPIDIUM MEYENII ROOT	2 (<0.1)	3 (<0.1)	5 (<0.1)
LORATADINE;PSEUDOEPHEDRINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
MAGNESIUM CITRATE;MAGNESIUM OXIDE;RIBOFLAVIN;TANACETUM PARTHENIUM	0	3 (<0.1)	3 (<0.1)
MAGNESIUM GLUCONATE	0	3 (<0.1)	3 (<0.1)
MAGNESIUM SULFATE	5 (<0.1)	3 (<0.1)	8 (<0.1)
MAGNESIUM;POTASSIUM	3 (<0.1)	3 (<0.1)	6 (<0.1)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	5 (<0.1)	3 (<0.1)	8 (<0.1)
MEDIUM-CHAIN TRIGLYCERIDES	1 (<0.1)	3 (<0.1)	4 (<0.1)
MEMANTINE HYDROCHLORIDE	6 (<0.1)	3 (<0.1)	9 (<0.1)
MENAQUINONE-7	4 (<0.1)	3 (<0.1)	7 (<0.1)
MENTHA X PIPERITA OIL	8 (<0.1)	3 (<0.1)	11 (<0.1)
METFORMIN HYDROCHLORIDE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	10 (<0.1)	3 (<0.1)	13 (<0.1)
METOLAZONE	5 (<0.1)	3 (<0.1)	8 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MINERAL OIL LIGHT;PARAFFIN, LIQUID	1 (<0.1)	3 (<0.1)	4 (<0.1)
MISOPROSTOL	1 (<0.1)	3 (<0.1)	4 (<0.1)
MULTIVITAMINS WITH MINERALS [UMBRELLA TERM]	2 (<0.1)	3 (<0.1)	5 (<0.1)
NALTREXONE HYDROCHLORIDE	0	3 (<0.1)	3 (<0.1)
NEFAZODONE	2 (<0.1)	3 (<0.1)	5 (<0.1)
NICOTINAMIDE RIBOSIDE;PTEROSTILBENE	2 (<0.1)	3 (<0.1)	5 (<0.1)
OLEA EUROPAEA LEAF	2 (<0.1)	3 (<0.1)	5 (<0.1)
ONDANSETRON HYDROCHLORIDE	6 (<0.1)	3 (<0.1)	9 (<0.1)
ORPHENADRINE CITRATE	1 (<0.1)	3 (<0.1)	4 (<0.1)
OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS	5 (<0.1)	3 (<0.1)	8 (<0.1)
OTHER ANTIOBESITY DRUGS	2 (<0.1)	3 (<0.1)	5 (<0.1)
OTHER EMOLLIENTS AND PROTECTIVES	3 (<0.1)	3 (<0.1)	6 (<0.1)
OTHER LIPID MODIFYING AGENTS	1 (<0.1)	3 (<0.1)	4 (<0.1)
OTHER PSYCHOSTIMULANTS AND NOOTROPICS	2 (<0.1)	3 (<0.1)	5 (<0.1)
PANCRELIPASE	3 (<0.1)	3 (<0.1)	6 (<0.1)
PHENAZOPYRIDINE	7 (<0.1)	3 (<0.1)	10 (<0.1)
PHENDIMETRAZINE	3 (<0.1)	3 (<0.1)	6 (<0.1)
PILOCARPINE	5 (<0.1)	3 (<0.1)	8 (<0.1)
PLANTAGO AFRA	4 (<0.1)	3 (<0.1)	7 (<0.1)
PLANTAGO OVATA HUSK	4 (<0.1)	3 (<0.1)	7 (<0.1)
PLANTAGO OVATA SEED HUSK	4 (<0.1)	3 (<0.1)	7 (<0.1)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	3 (<0.1)	3 (<0.1)	6 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
POLICOSANOL	1 (<0.1)	3 (<0.1)	4 (<0.1)
PROCHLORPERAZINE EDISYLATE	3 (<0.1)	3 (<0.1)	6 (<0.1)
PUNICA GRANATUM	0	3 (<0.1)	3 (<0.1)
QUINAPRIL HYDROCHLORIDE	4 (<0.1)	3 (<0.1)	7 (<0.1)
SALMON OIL	1 (<0.1)	3 (<0.1)	4 (<0.1)
SELEGILINE	2 (<0.1)	3 (<0.1)	5 (<0.1)
SILODOSIN	6 (<0.1)	3 (<0.1)	9 (<0.1)
SODIUM CHLORIDE;XYLITOL	1 (<0.1)	3 (<0.1)	4 (<0.1)
SULINDAC	3 (<0.1)	3 (<0.1)	6 (<0.1)
TAFLUPROST	3 (<0.1)	3 (<0.1)	6 (<0.1)
TERAZOSIN HYDROCHLORIDE	4 (<0.1)	3 (<0.1)	7 (<0.1)
TETANUS VACCINE TOXOID	1 (<0.1)	3 (<0.1)	4 (<0.1)
THEOPHYLLINE	3 (<0.1)	3 (<0.1)	6 (<0.1)
TIOTROPIUM	8 (<0.1)	3 (<0.1)	11 (<0.1)
TOBRAMYCIN	4 (<0.1)	3 (<0.1)	7 (<0.1)
TOLNAFTATE	4 (<0.1)	3 (<0.1)	7 (<0.1)
TRANDOLAPRIL	1 (<0.1)	3 (<0.1)	4 (<0.1)
TYROSINE	0	3 (<0.1)	3 (<0.1)
ULOBETASOL	2 (<0.1)	3 (<0.1)	5 (<0.1)
WITHANIA SOMNIFERA ROOT	2 (<0.1)	3 (<0.1)	5 (<0.1)
ZAFIRLUKAST	6 (<0.1)	3 (<0.1)	9 (<0.1)
ZINGIBER OFFICINALE ROOT	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
3,3'-DIINDOLYLMETHANE;PHOSPHATIDYL CHOLINE;TOCOPHERYL ACID SUCCINATE	0	2 (<0.1)	2 (<0.1)
AESCULUS HIPPOCASTANUM	3 (<0.1)	2 (<0.1)	5 (<0.1)
ALGAE NOS	2 (<0.1)	2 (<0.1)	4 (<0.1)
ALLERGENS EXTRACT NOS	0	2 (<0.1)	2 (<0.1)
ALLIUM SATIVUM BULB	0	2 (<0.1)	2 (<0.1)
ALLIUM SATIVUM BULB;ANDROGRAPHIS PANICULATA;ANGELICA SPP. ROOT;ASCORBIC ACID;ASTRAGALUS MONGHOLICUS ROOT;BETACAROTENE;BIOFLAVONOIDS NOS;CALCIUM;CINNAMOMUM SPP. BARK;COLECALCIFEROL;COPPER CITRATE ECHINACEA PURPUREA ROOT;ELEUTHEROCOCCUS SPP.;HYDRASTIS CANADENSIS ROOT;INULA HELENIUM ROOT;ISATIS SPP.;MARRUBIUM VULGARE;OLEA EUROPAEA LEAF;POLYGONATUM ODORATUM RHIZOME;PROPOLIS;PUERARIA LOBATA ROOT SAMBUCUS NIGRA FRUIT;SODIUM;SODIUM SELENITE;TABEBUIA IMPETIGINOSA BARK;VITIS VINIFERA SEED;ZINC ASCORBATE;ZINC CITRATE;ZINGIBER OFFICINALE RHIZOME	1 (<0.1)	2 (<0.1)	3 (<0.1)
ALLIUM SATIVUM EXTRACT	3 (<0.1)	2 (<0.1)	5 (<0.1)
ALLIUM SATIVUM;GANODERMA LUCIDUM;HERICIUM ERINACEUS;INONOTUS OBLIQUUS;LENTINUS EDODES	1 (<0.1)	2 (<0.1)	3 (<0.1)
ALMOTRIPTAN	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ALMOTRIPTAN MALATE	0	2 (<0.1)	2 (<0.1)
ALOE VERA EXTRACT	0	2 (<0.1)	2 (<0.1)
ALOGLIPTIN BENZOATE	2 (<0.1)	2 (<0.1)	4 (<0.1)
ALTHAEA OFFICINALIS ROOT;BERBERIS VULGARIS ROOT BARK;CALCIUM CARBONATE;CAPSICUM ANNUUM FRUIT;CHLORELLA VULGARIS;CHONDRUS CRISPUS LEAF;FOENICULUM VULGARE SEED;GLYCYRRHIZA GLABRA ROOT LACTOBACILLUS ACIDOPHILUS;PHYLLANTHUS EMBLICA;RHAMNUS PURSHIANA;RUBUS IDAEUS LEAF;TERMINALIA BELLIRICA FRUIT;TERMINALIA CHEBULA FRUIT;ULMUS RUBRA BARK;ZINGIBER OFFICINALE RHIZOME	1 (<0.1)	2 (<0.1)	3 (<0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM CARBONATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
AMANTADINE HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
AMILORIDE HYDROCHLORIDE;HYDROCHLOROTHIAZIDE	0	2 (<0.1)	2 (<0.1)
AMINO ACIDS NOS	8 (<0.1)	2 (<0.1)	10 (<0.1)
AMINOBENZOIC ACID;BIOTIN;CHOLINE BITARTRATE;FOLIC ACID;INOSITOL;LECITHIN;VITAMIN B NOS	0	2 (<0.1)	2 (<0.1)
AMLODIPINE BESILATE;VALSARTAN	5 (<0.1)	2 (<0.1)	7 (<0.1)
AMLODIPINE;VALSARTAN	5 (<0.1)	2 (<0.1)	7 (<0.1)
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	0	2 (<0.1)	2 (<0.1)
ANESTHETICS	2 (<0.1)	2 (<0.1)	4 (<0.1)
ANTACIDS	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ARNICA MONTANA	5 (<0.1)	2 (<0.1)	7 (<0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;BORIC ACID;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIC CHLORIDE;COLECALCIFEROL;COPPER SULFATE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;LYCOPENE;MAGNESIUM OXIDE MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PHYTOMENADIONE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SILICON DIOXIDE;SODIUM METAVANADATE;SODIUM MOLYBDATE;SODIUM SELENITE STANNOUS CHLORIDE;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE;XANTOFYL;ZINC OXIDE	0	2 (<0.1)	2 (<0.1)
ASCORBIC ACID;BIOFLAVONOIDS NOS	1 (<0.1)	2 (<0.1)	3 (<0.1)
ASCORBIC ACID;BIOTIN	0	2 (<0.1)	2 (<0.1)
ASCORBIC ACID;BOSWELLIA SERRATA RESIN;CHONDROITIN SULFATE;COLLAGEN;GLUCOSAMINE HYDROCHLORIDE;HYALURONIC ACID;MANGANESE SULFATE;METHYLSULFONYLMETHANE;SODIUM;SODIUM BORATE	0	2 (<0.1)	2 (<0.1)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
ASCORBIC ACID;COLLAGEN	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;CUPRIC OXIDE;CYANOCOBALAMIN;ERGOCALCIFEROL;FERROUS FUMARATE;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM FLUORIDE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE ZINC OXIDE	0	2 (<0.1)	2 (<0.1)
ASCORBIC ACID;FERROUS GLUCONATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
ASCORBIC ACID;VACCINIUM MACROCARPON	0	2 (<0.1)	2 (<0.1)
ASCORBIC ACID;VITAMIN B COMPLEX	2 (<0.1)	2 (<0.1)	4 (<0.1)
ASTRAGALUS MONGHOLICUS	0	2 (<0.1)	2 (<0.1)
ASTRAGALUS SPP.	0	2 (<0.1)	2 (<0.1)
AVANAFIL	0	2 (<0.1)	2 (<0.1)
AZELASTINE;FLUTICASONE	4 (<0.1)	2 (<0.1)	6 (<0.1)
AZILSARTAN	0	2 (<0.1)	2 (<0.1)
BENAZEPRIL HYDROCHLORIDE	6 (<0.1)	2 (<0.1)	8 (<0.1)
BENAZEPRIL HYDROCHLORIDE;HYDROCHLOROTHIAZIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
BENRALIZUMAB	5 (<0.1)	2 (<0.1)	7 (<0.1)
BENZALKONIUM CHLORIDE;SODIUM CHLORIDE	0	2 (<0.1)	2 (<0.1)
BENZATROPINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
BENZATROPINE MESILATE	2 (<0.1)	2 (<0.1)	4 (<0.1)
BETA VULGARIS	2 (<0.1)	2 (<0.1)	4 (<0.1)
BETAMETHASONE DIPROPIONATE;CLOTRIMAZOLE	4 (<0.1)	2 (<0.1)	6 (<0.1)
BETAXOLOL	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BICTEGRAVIR;EMTRICITABINE;TENOFOVIR	0	2 (<0.1)	2 (<0.1)
BIOFLAVONOIDS NOS	3 (<0.1)	2 (<0.1)	5 (<0.1)
BISOPROLOL;HYDROCHLOROTHIAZIDE	5 (<0.1)	2 (<0.1)	7 (<0.1)
BOSWELLIA SERRATA;COLECALCIFEROL;GLUCOSAMINE HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
BRIMONIDINE TARTRATE;BRINZOLAMIDE	4 (<0.1)	2 (<0.1)	6 (<0.1)
BROMPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
BUDESONIDE;FORMOTEROL FUMARATE DIHYDRATE	0	2 (<0.1)	2 (<0.1)
BUPRENORPHINE HYDROCHLORIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
BUPROPION HYDROBROMIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
BUPROPION;NALTREXONE	0	2 (<0.1)	2 (<0.1)
BUTALBITAL;PARACETAMOL	3 (<0.1)	2 (<0.1)	5 (<0.1)
CALAMINE	2 (<0.1)	2 (<0.1)	4 (<0.1)
CALAMINE;ZINC OXIDE	0	2 (<0.1)	2 (<0.1)
CALCIUM CARBONATE;CALCIUM PHOSPHATE DIBASIC;CUCURBITA PEPO SEED;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FOLIC ACID;LYCOPENE;MAGNESIUM OXIDE;PRUNUS AFRICANA BARK;PYRIDOXINE HYDROCHLORIDE SELENIUM AMINO ACID CHELATE;SERENOA REPENS FRUIT;ZINC GLYCINATE	0	2 (<0.1)	2 (<0.1)
CALCIUM CHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
CALCIUM CITRATE;MAGNESIUM CITRATE	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CALCIUM CITRATE;VITAMIN D NOS	4 (<0.1)	2 (<0.1)	6 (<0.1)
CALCIUM GLUCONATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CALCIUM GLYCEROPHOSPHATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CALCIUM LEVOMEFOLATE;DROSPIRENONE;ETHINYLESTRADIOL BETADEX CLATHRATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
CALCIUM LEVOMEFOLATE;MECOBALAMIN;PYRIDOXAL PHOSPHATE	0	2 (<0.1)	2 (<0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM;ZINC SULFATE	0	2 (<0.1)	2 (<0.1)
CALCIUM;MAGNESIUM;POTASSIUM	0	2 (<0.1)	2 (<0.1)
CALCIUM;MAGNESIUM;VITAMIN D NOS	1 (<0.1)	2 (<0.1)	3 (<0.1)
CALCIUM;MAGNESIUM;VITAMIN D NOS;ZINC	2 (<0.1)	2 (<0.1)	4 (<0.1)
CAMELLIA SINENSIS LEAF	0	2 (<0.1)	2 (<0.1)
CAMELLIA SINENSIS LEAF EXTRACT;CHROMIUM PICOLINATE;CINNAMOMUM VERUM BARK;COFFEA ARABICA SEED;PAULLINIA CUPANA SEED	0	2 (<0.1)	2 (<0.1)
CAMPHOR;EUCALYPTUS GLOBULUS OIL;MENTHOL	0	2 (<0.1)	2 (<0.1)
CANAGLIFLOZIN HEMIHYDRATE;METFORMIN HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CANDESARTAN;HYDROCHLOROTHIAZIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CANNABIDIOL;DRONABINOL	1 (<0.1)	2 (<0.1)	3 (<0.1)
CARBINOXAMINE MALEATE	0	2 (<0.1)	2 (<0.1)
CARIPRAZINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CEFAZOLIN SODIUM	1 (<0.1)	2 (<0.1)	3 (<0.1)
CEVIMELINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CEVIMELINE HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
CHLORPHENAMINE;PARACETAMOL;PHENYLEPHRINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CHLORPHENAMINE;PSEUDOEPHEDRINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CHLORPROMAZINE	0	2 (<0.1)	2 (<0.1)
CHONDROITIN SULFATE;GLUCOSAMINE;METHYLSULFONYLMETHANE	0	2 (<0.1)	2 (<0.1)
CHONDROITIN;COLECALCIFEROL;GLUCOSAMINE	0	2 (<0.1)	2 (<0.1)
CINNAMOMUM CASSIA BARK	0	2 (<0.1)	2 (<0.1)
CINNAMOMUM VERUM BARK	0	2 (<0.1)	2 (<0.1)
CIPROFLOXACIN;DEXAMETHASONE	0	2 (<0.1)	2 (<0.1)
CISAPRIDE	0	2 (<0.1)	2 (<0.1)
CLARITHROMYCIN	0	2 (<0.1)	2 (<0.1)
CLINDAMYCIN HYDROCHLORIDE	4 (<0.1)	2 (<0.1)	6 (<0.1)
CLINDAMYCIN;TRETINOIN	0	2 (<0.1)	2 (<0.1)
CLOZAPINE	2 (<0.1)	2 (<0.1)	4 (<0.1)
COAL TAR	4 (<0.1)	2 (<0.1)	6 (<0.1)
COLCHICINE;PROBENECID	0	2 (<0.1)	2 (<0.1)
COLECALCIFEROL;MENAQUINONE-7	5 (<0.1)	2 (<0.1)	7 (<0.1)
COLESTIPOL HYDROCHLORIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
COLFORSIN	2 (<0.1)	2 (<0.1)	4 (<0.1)
CRATAEGUS SPP. EXTRACT	0	2 (<0.1)	2 (<0.1)
CREATINE MONOHYDRATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
CURCUMA LONGA;ZINGIBER OFFICINALE	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
CYANOCOBALAMIN;ZINC	0	2 (<0.1)	2 (<0.1)
CYSTEINE	0	2 (<0.1)	2 (<0.1)
DARIFENACIN	2 (<0.1)	2 (<0.1)	4 (<0.1)
DARUNAVIR	2 (<0.1)	2 (<0.1)	4 (<0.1)
DESMOPRESSIN ACETATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
DEXTROMETHORPHAN;PARACETAMOL	0	2 (<0.1)	2 (<0.1)
DEXTROMETHORPHAN;PARACETAMOL;PSEUDOEPHEDRINE	0	2 (<0.1)	2 (<0.1)
DIENOGEST;ESTRADIOL VALERATE	5 (<0.1)	2 (<0.1)	7 (<0.1)
DIENOGEST;ETHINYLESTRADIOL	1 (<0.1)	2 (<0.1)	3 (<0.1)
DIPHENHYDRAMINE CITRATE;PARACETAMOL	3 (<0.1)	2 (<0.1)	5 (<0.1)
DIPHENHYDRAMINE;IBUPROFEN	3 (<0.1)	2 (<0.1)	5 (<0.1)
DIPHENOXYLATE	0	2 (<0.1)	2 (<0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	0	2 (<0.1)	2 (<0.1)
DOLUTEGRAVIR;RILPIVIRINE	0	2 (<0.1)	2 (<0.1)
DONEPEZIL HYDROCHLORIDE	8 (<0.1)	2 (<0.1)	10 (<0.1)
DUTASTERIDE;TAMSULOSIN HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
ECONAZOLE	4 (<0.1)	2 (<0.1)	6 (<0.1)
EFINACONAZOLE	2 (<0.1)	2 (<0.1)	4 (<0.1)
EFLORNITHINE HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
EICOSAPENTAENOIC ACID	3 (<0.1)	2 (<0.1)	5 (<0.1)
ENALAPRILAT	5 (<0.1)	2 (<0.1)	7 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ENTECAVIR	2 (<0.1)	2 (<0.1)	4 (<0.1)
EPTIFIBATIDE	0	2 (<0.1)	2 (<0.1)
ERTUGLIFLOZIN PIDOLATE	10 (<0.1)	2 (<0.1)	12 (<0.1)
ERTUGLIFLOZIN PIDOLATE;METFORMIN HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
ESTRADIOL;NORETHISTERONE	3 (<0.1)	2 (<0.1)	5 (<0.1)
EUCALYPTUS GLOBULUS OIL;GOSSYPIUM SPP. SEED OIL;MELALEUCA LEUCADENDRA OIL;MENTHA X PIPERITA OIL	1 (<0.1)	2 (<0.1)	3 (<0.1)
EXEMESTANE	5 (<0.1)	2 (<0.1)	7 (<0.1)
FENTANYL CITRATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
FERRIC CARBOXYMALTOSE	0	2 (<0.1)	2 (<0.1)
FERROUS BISGLYCINATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
FISH OIL;KRILL OIL	0	2 (<0.1)	2 (<0.1)
FLECAINIDE ACETATE	6 (<0.1)	2 (<0.1)	8 (<0.1)
FLUDROCORTISONE	1 (<0.1)	2 (<0.1)	3 (<0.1)
FLURBIPROFEN	0	2 (<0.1)	2 (<0.1)
FLUVASTATIN	3 (<0.1)	2 (<0.1)	5 (<0.1)
FORMOTEROL;MOMETASONE	1 (<0.1)	2 (<0.1)	3 (<0.1)
FRUCTOSE;GLUCOSE;PHOSPHORIC ACID	1 (<0.1)	2 (<0.1)	3 (<0.1)
GLIBENCLAMIDE;METFORMIN	3 (<0.1)	2 (<0.1)	5 (<0.1)
GLIBENCLAMIDE;METFORMIN HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
GLUCOSAMINE;METHYLSULFONYLMETHANE	6 (<0.1)	2 (<0.1)	8 (<0.1)
GLYCEROL	1 (<0.1)	2 (<0.1)	3 (<0.1)
GLYCOPYRRONIUM BROMIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
GOSERELIN	1 (<0.1)	2 (<0.1)	3 (<0.1)
GUANFACINE HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
HERBAL NOS;VITAMINS NOS	3 (<0.1)	2 (<0.1)	5 (<0.1)
HERBAL POLLEN NOS	0	2 (<0.1)	2 (<0.1)
HERICIUM ERINACEUS MYCELIUM	0	2 (<0.1)	2 (<0.1)
HOMEOPATHICS NOS	1 (<0.1)	2 (<0.1)	3 (<0.1)
HORMONES AND RELATED AGENTS	0	2 (<0.1)	2 (<0.1)
HPV VACCINE	0	2 (<0.1)	2 (<0.1)
HYDROCORTISONE ACETATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
HYDROCORTISONE ACETATE;PRAMOCAINE HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
HYDROCORTISONE BUTYRATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
HYDROCORTISONE;NEOMYCIN;POLYMYXIN B SULFATE	0	2 (<0.1)	2 (<0.1)
HYPNOTICS AND SEDATIVES	1 (<0.1)	2 (<0.1)	3 (<0.1)
IBUPROFEN;PHENYLEPHRINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
INDOLE-3-CARBINOL	1 (<0.1)	2 (<0.1)	3 (<0.1)
INFLUENZA A(H1N1)PDM09 VACCINE	0	2 (<0.1)	2 (<0.1)
INFLUENZA VACCINE LIVE REASSORT 3V	3 (<0.1)	2 (<0.1)	5 (<0.1)
IPAMORELIN	2 (<0.1)	2 (<0.1)	4 (<0.1)
ISOPROPANOL;PARAFFIN;SODIUM;STEARYL ALCOHOL	1 (<0.1)	2 (<0.1)	3 (<0.1)
LACTOBACILLUS RHAMNOSUS	3 (<0.1)	2 (<0.1)	5 (<0.1)
LAMIVUDINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
LEMBOREXANT	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
LEPIDIUM MEYENII	1 (<0.1)	2 (<0.1)	3 (<0.1)
LEVOCARNITINE TARTRATE	0	2 (<0.1)	2 (<0.1)
LEVOTHYROXINE SODIUM;LIOTHYRONINE SODIUM	1 (<0.1)	2 (<0.1)	3 (<0.1)
LIGHT LIQUID PARAFFIN;PARAFFIN, LIQUID;POLYSORBATE 80	1 (<0.1)	2 (<0.1)	3 (<0.1)
LINAGLIPTIN;METFORMIN HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
LOPERAMIDE HYDROCHLORIDE;SIMETICONE	0	2 (<0.1)	2 (<0.1)
LOTEPREDNOL	1 (<0.1)	2 (<0.1)	3 (<0.1)
MACITENTAN	0	2 (<0.1)	2 (<0.1)
MACROGOL;PROPYLENE GLYCOL;SIMETICONE;SORBIC ACID;SORBITOL;WHITE SOFT PARAFFIN	1 (<0.1)	2 (<0.1)	3 (<0.1)
MAGNESIUM CHELATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
MAGNESIUM SALICYLATE	0	2 (<0.1)	2 (<0.1)
MARAVIROC	0	2 (<0.1)	2 (<0.1)
MATRICARIA RECUTITA FLOWER;MELATONIN;MELISSA OFFICINALIS HERB;PASSIFLORA INCARNATA HERB;THEANINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
MEDICAGO SATIVA	2 (<0.1)	2 (<0.1)	4 (<0.1)
MELATONIN;THEANINE	0	2 (<0.1)	2 (<0.1)
MENINGOCOCCAL VACCINE	0	2 (<0.1)	2 (<0.1)
MENTHOL;METHYL SALICYLATE	4 (<0.1)	2 (<0.1)	6 (<0.1)
MEPYRAMINE MALEATE;PAMABROM;PARACETAMOL	2 (<0.1)	2 (<0.1)	4 (<0.1)
METFORMIN HYDROCHLORIDE;PIOGLITAZONE HYDROCHLORIDE	0	2 (<0.1)	2 (<0.1)
METFORMIN;SAXAGLIPTIN	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
METHENAMINE HIPPURATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
MILNACIPRAN HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
MINOCYCLINE HYDROCHLORIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
NALOXEGOL OXALATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
NALOXONE HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
NAPHAZOLINE HYDROCHLORIDE;PHENIRAMINE MALEATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
NAPHAZOLINE;PHENIRAMINE	0	2 (<0.1)	2 (<0.1)
NAPROXEN SODIUM;PSEUDOEPHEDRINE HYDROCHLORIDE	4 (<0.1)	2 (<0.1)	6 (<0.1)
NATEGLINIDE	4 (<0.1)	2 (<0.1)	6 (<0.1)
NEOMYCIN;POLYMYXIN	1 (<0.1)	2 (<0.1)	3 (<0.1)
NEOSTIGMINE	0	2 (<0.1)	2 (<0.1)
NETARSUDIL MESILATE	4 (<0.1)	2 (<0.1)	6 (<0.1)
NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
NSAIDS	2 (<0.1)	2 (<0.1)	4 (<0.1)
NUTRIENTS NOS	2 (<0.1)	2 (<0.1)	4 (<0.1)
OMEGA-3 FATTY ACIDS;XANTOFYL;ZEAXANTHIN	0	2 (<0.1)	2 (<0.1)
OMEGA-3 MARINE TRIGLYCERIDES	2 (<0.1)	2 (<0.1)	4 (<0.1)
ORAL REHYDRATION SALT FORMULATIONS	0	2 (<0.1)	2 (<0.1)
OTHER AGENTS FOR LOCAL ORAL TREATMENT	1 (<0.1)	2 (<0.1)	3 (<0.1)
OTHER ANTIALLERGICS	0	2 (<0.1)	2 (<0.1)
OTHER ANTIBIOTICS FOR TOPICAL USE	1 (<0.1)	2 (<0.1)	3 (<0.1)
OTHER ANTIHISTAMINES FOR SYSTEMIC USE	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	0	2 (<0.1)	2 (<0.1)
OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	1 (<0.1)	2 (<0.1)	3 (<0.1)
OXYMORPHONE	2 (<0.1)	2 (<0.1)	4 (<0.1)
PANCREATIN	6 (<0.1)	2 (<0.1)	8 (<0.1)
PARAFFIN, LIQUID	0	2 (<0.1)	2 (<0.1)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (<0.1)	2 (<0.1)	3 (<0.1)
PENTOSAN POLYSULFATE SODIUM	2 (<0.1)	2 (<0.1)	4 (<0.1)
PHENAZONE	1 (<0.1)	2 (<0.1)	3 (<0.1)
PHENOBARBITAL	3 (<0.1)	2 (<0.1)	5 (<0.1)
PHENOL	3 (<0.1)	2 (<0.1)	5 (<0.1)
PHENOXYMETHYLPENICILLIN POTASSIUM	3 (<0.1)	2 (<0.1)	5 (<0.1)
PIPERACILLIN;TAZOBACTAM	3 (<0.1)	2 (<0.1)	5 (<0.1)
PIROXICAM	4 (<0.1)	2 (<0.1)	6 (<0.1)
PLANTAGO PSYLLIUM	5 (<0.1)	2 (<0.1)	7 (<0.1)
POLIO VACCINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
POLYMYXIN	2 (<0.1)	2 (<0.1)	4 (<0.1)
POLYMYXIN B;TRIMETHOPRIM	0	2 (<0.1)	2 (<0.1)
POLYVINYL ALCOHOL	2 (<0.1)	2 (<0.1)	4 (<0.1)
POLYVINYL ALCOHOL;POVIDONE	2 (<0.1)	2 (<0.1)	4 (<0.1)
PREBIOTICS NOS	2 (<0.1)	2 (<0.1)	4 (<0.1)
PREBIOTICS NOS;PROBIOTICS NOS	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PROCAINE HYDROCHLORIDE	3 (<0.1)	2 (<0.1)	5 (<0.1)
PROGESTERONE;TESTOSTERONE	2 (<0.1)	2 (<0.1)	4 (<0.1)
PROMETHAZINE HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
PROTEIN SUPPLEMENTS	1 (<0.1)	2 (<0.1)	3 (<0.1)
PRUCALOPRIDE	0	2 (<0.1)	2 (<0.1)
PRUNUS AFRICANA	1 (<0.1)	2 (<0.1)	3 (<0.1)
PYRIDOSTIGMINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
PYRIDOXINE	2 (<0.1)	2 (<0.1)	4 (<0.1)
PYRIDOXINE HYDROCHLORIDE;VITAMIN B12 NOS	0	2 (<0.1)	2 (<0.1)
RASAGILINE	2 (<0.1)	2 (<0.1)	4 (<0.1)
RASAGILINE MESYLATE	2 (<0.1)	2 (<0.1)	4 (<0.1)
REVEFENACIN	0	2 (<0.1)	2 (<0.1)
RIFAMPICIN	0	2 (<0.1)	2 (<0.1)
RIFAXIMIN	5 (<0.1)	2 (<0.1)	7 (<0.1)
RIVASTIGMINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
ROMOSOZUMAB	0	2 (<0.1)	2 (<0.1)
SACCHARATED IRON OXIDE	0	2 (<0.1)	2 (<0.1)
SACUBITRIL;VALSARTAN	2 (<0.1)	2 (<0.1)	4 (<0.1)
SALMETEROL XINAFOATE	3 (<0.1)	2 (<0.1)	5 (<0.1)
SAXAGLIPTIN HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
SECUKINUMAB	1 (<0.1)	2 (<0.1)	3 (<0.1)
SERRAPEPTASE	1 (<0.1)	2 (<0.1)	3 (<0.1)
SODIUM BICARBONATE;SODIUM CHLORIDE	8 (<0.1)	2 (<0.1)	10 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
SODIUM CITRATE DIHYDRATE	0	2 (<0.1)	2 (<0.1)
SOLRIAMFETOL HYDROCHLORIDE	0	2 (<0.1)	2 (<0.1)
SOMATROPIN	1 (<0.1)	2 (<0.1)	3 (<0.1)
SULFACETAMIDE	4 (<0.1)	2 (<0.1)	6 (<0.1)
SULFADIAZINE SILVER	4 (<0.1)	2 (<0.1)	6 (<0.1)
SUXAMETHONIUM	0	2 (<0.1)	2 (<0.1)
TARAXACUM OFFICINALE ROOT	0	2 (<0.1)	2 (<0.1)
TAZAROTENE;ULOBETASOL PROPIONATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
TENOFOVIR DISOPROXIL FUMARATE	0	2 (<0.1)	2 (<0.1)
TETRACYCLINE	2 (<0.1)	2 (<0.1)	4 (<0.1)
THIAMINE	7 (<0.1)	2 (<0.1)	9 (<0.1)
THIAMINE HYDROCHLORIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
THYROID PREPARATIONS	2 (<0.1)	2 (<0.1)	4 (<0.1)
TRAMETES VERSICOLOR	2 (<0.1)	2 (<0.1)	4 (<0.1)
TRIGONELLA FOENUM-GRAECUM	2 (<0.1)	2 (<0.1)	4 (<0.1)
TROLAMINE SALICYLATE	0	2 (<0.1)	2 (<0.1)
TUBERCULIN PPD	1 (<0.1)	2 (<0.1)	3 (<0.1)
ULMUS RUBRA BARK	0	2 (<0.1)	2 (<0.1)
UMECLIDINIUM;VILANTEROL	1 (<0.1)	2 (<0.1)	3 (<0.1)
UNDECYLENIC ACID	0	2 (<0.1)	2 (<0.1)
UREA HYDROGEN PEROXIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
USTEKINUMAB	1 (<0.1)	2 (<0.1)	3 (<0.1)
VACCINIUM MYRTILLUS	0	2 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
VACCINIUM MYRTILLUS FRUIT	1 (<0.1)	2 (<0.1)	3 (<0.1)
VALERIANA OFFICINALIS	5 (<0.1)	2 (<0.1)	7 (<0.1)
VALPROIC ACID	0	2 (<0.1)	2 (<0.1)
VARDENAFIL	2 (<0.1)	2 (<0.1)	4 (<0.1)
VARDENAFIL HYDROCHLORIDE	5 (<0.1)	2 (<0.1)	7 (<0.1)
VARENICLINE	4 (<0.1)	2 (<0.1)	6 (<0.1)
VERAPAMIL HYDROCHLORIDE	2 (<0.1)	2 (<0.1)	4 (<0.1)
VITAMINS WITH MINERALS	1 (<0.1)	2 (<0.1)	3 (<0.1)
WHEY PROTEIN	5 (<0.1)	2 (<0.1)	7 (<0.1)
ZINC CITRATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
ZINC GLUCONATE	7 (<0.1)	2 (<0.1)	9 (<0.1)
ZINC OROTATE	1 (<0.1)	2 (<0.1)	3 (<0.1)
ZINC OXIDE	1 (<0.1)	2 (<0.1)	3 (<0.1)
(6S)-5-METHYLTETRAHYDROFOLATE GLUCOSAMINE;MECOBALAMIN;PYRIDOXAL PHOSPHATE;THIOCTIC ACID	0	1 (<0.1)	1 (<0.1)
3,3'-DIINDOLYLMETHANE;BRASSICA OLERACEA;CALCIUM GLUCARATE;CAMELLIA SINENSIS LEAF;CURCUMA LONGA ROOT;INDOLE-3-CARBINOL;ROSMARINUS OFFICINALIS LEAF;SILYBUM MARIANUM SEED;SOLANUM LYCOPERSICUM	0	1 (<0.1)	1 (<0.1)
3-OXOANDROSTEN (4) DERIVATIVES	0	1 (<0.1)	1 (<0.1)
4-(4-HYDROXYPHENYL)BUTAN-2-ONE	0	1 (<0.1)	1 (<0.1)
7-KETO-DEHYDROEPIANDROSTERONE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ABACAVIR	2 (<0.1)	1 (<0.1)	3 (<0.1)
ACEBUTOLOL HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
ACETIC ACID	1 (<0.1)	1 (<0.1)	2 (<0.1)
ACETYL-L-CARNITINE ARGINATE DIHYDROCHLORIDE;THIOCTIC ACID	0	1 (<0.1)	1 (<0.1)
ACETYLCARNITINE HYDROCHLORIDE;CAMELLIA SINENSIS LEAF;CORDYCEPS SINENSIS MYCELIUM;LITCHI CHINENSIS;PANAX QUINQUEFOLIUS ROOT;QUERCETIN;THIOCTIC ACID;UBIDECARENONE;WITHANIA SOMNIFERA ROOT	0	1 (<0.1)	1 (<0.1)
ACETYLCHOLINE	0	1 (<0.1)	1 (<0.1)
ACETYLCYSTEINE;ARGININE HYDROCHLORIDE;LEVOGLUTAMIDE;LYSINE HYDROCHLORIDE;PIDOLIC ACID;SCHIZONEPETA SPP.	0	1 (<0.1)	1 (<0.1)
ACETYLCYSTEINE;ASCORBIC ACID;BETACAROTENE;CHROMIUM;CITRUS AURANTIUM FRUIT;DL-SELENOMETHIONINE;GLUTATHIONE;QUERCETIN;RIB OFLAVIN;RUTOSIDE;TAURINE;TOCOPHERYL ACID SUCCINATE;VACCINIUM MYRTILLUS LEAF XANTOFYL;ZINC PICOLINATE	0	1 (<0.1)	1 (<0.1)
ACETYLCYSTEINE;LEVOMEFOLIC ACID;MECOBALAMIN	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ACETYLSALICYLIC ACID;ASCORBIC ACID;CAFFEINE	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;CAFFEINE;SALICYLAMIDE	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;CARISOPRODOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
ACETYLSALICYLIC ACID;CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PHENYLEPHRINE BITARTRATE	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;DIPHENHYDRAMINE CITRATE;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;DIPHENHYDRAMINE;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;OXYCODONE	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;OXYCODONE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
ACETYLSALICYLIC ACID;SITOSTEROLS	0	1 (<0.1)	1 (<0.1)
ACHILLEA MILLEFOLIUM;CAMELLIA SINENSIS;CORIANDRUM SATIVUM;ELYMUS REPENS;MELISSA OFFICINALIS	0	1 (<0.1)	1 (<0.1)
ACICLOVIR SODIUM	0	1 (<0.1)	1 (<0.1)
ACITRETIN	3 (<0.1)	1 (<0.1)	4 (<0.1)
ACONITUM NAPELLUS;CINCHONA OFFICINALIS;LEDUM PALUSTRE;MAGNESIUM PHOSPHATE;PSEUDOGNAPHALIUM OBTUSIFOLIUM;TOXICODENDRON PUBESCENS;VISCUM ALBUM	1 (<0.1)	1 (<0.1)	2 (<0.1)
ACRIVASTINE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ADALIMUMAB	1 (<0.1)	1 (<0.1)	2 (<0.1)
ADENOSINE	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ADRENAL CORTICAL EXTRACT;ADRENAL GLAND;CALCIUM PANTOTHENATE;CORDYCEPS SINENSIS MYCELIUM;ELEUTHEROCOCCUS SPP.;WITHANIA SOMNIFERA ROOT	0	1 (<0.1)	1 (<0.1)
AESCULUS HIPPOCASTANUM;CLEMATIS VITALBA;HELIANTHEMUM NUMMULARIUM;IMPATIENS GLANDULIFERA;ORNITHOGALUM UMBELLATUM;PRUNUS CERASIFERA	0	1 (<0.1)	1 (<0.1)
AFRAMOMUM MELEGUETA SEED	0	1 (<0.1)	1 (<0.1)
ALANINE;ARGININE HYDROCHLORIDE;ASPARTIC ACID;CYSTINE;GLUTAMIC ACID;GLYCINE;HISTIDINE HYDROCHLORIDE;ISOLEUCINE;LEUCINE;LYSINE HYDROCHLORIDE;PHENYLALANINE;PROLINE;SERINE;THREONINE;TYROSINE;VALINE	0	1 (<0.1)	1 (<0.1)
ALANINE;CUCURBITA PEPO SEED;GLUTAMIC ACID;GLYCINE;PANAX GINSENG;SERENOA REPENS FRUIT;SITOSTEROL;URTICA DIOICA LEAF;ZINC PICOLINATE	0	1 (<0.1)	1 (<0.1)
ALBUMIN HUMAN	2 (<0.1)	1 (<0.1)	3 (<0.1)
ALGELDRATE;MAGNESIUM HYDROXIDE	0	1 (<0.1)	1 (<0.1)
ALGINIC ACID;ALUMINIUM HYDROXIDE GEL, DRIED;MAGNESIUM TRISILICATE;SODIUM BICARBONATE	0	1 (<0.1)	1 (<0.1)
ALISKIREN FUMARATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ALLERGEN EXTRACTS	0	1 (<0.1)	1 (<0.1)
ALLERGENS	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ALLERGENS, MOULD & YEAST SPORE	0	1 (<0.1)	1 (<0.1)
ALLERGY MEDICATION	4 (<0.1)	1 (<0.1)	5 (<0.1)
ALLIUM SATIVUM BULB;APIUM GRAVEOLENS SEED;EQUISETUM ARVENSE HERB;URTICA DIOICA LEAF	0	1 (<0.1)	1 (<0.1)
ALLIUM SATIVUM POWDER;CRATAEGUS LAEVIGATA EXTRACT;HUMULUS LUPULUS EXTRACT;VISCUM ALBUM	0	1 (<0.1)	1 (<0.1)
ALLIUM SATIVUM;ALOE VERA LEAF;ARABINOGALACTAN;ASCORBIC ACID;ASTRAGALUS SPP. ROOT;BETACAROTENE;BIFIDOBACTERIUM NOS;CAPSICUM SPP.;CENTELLA ASIATICA;COMMIPHORA SPP. GUM RESIN;ECHINACEA PURPUREA ELEUTHEROCOCCUS SENTICOSUS ROOT;ERGOCALCIFEROL;FRUCTOOLIGOSACCHARIDES;FYTIC ACID;GANODERMA LUCIDUM MYCELIUM;GRIFOLA FRONDOSA MYCELIUM;HERBAL NOS;HERICIUM ERINACEUS;HYDRASTIS CANADENSIS ROOT;INULA SPP.LACTOBACILLUS NOS;LENTINUS EDODES;MAHONIA AQUIFOLIUM ROOT;MARRUBIUM VULGARE;OLEA EUROPAEA LEAF;RETINOL ACETATE;ROSMARINUS OFFICINALIS LEAF;SELENOMETHIONINE;THYMUS VULGARIS TRIGONELLA FOENUM-GRAECUM SEED;ZINC GLYCINATE	0	1 (<0.1)	1 (<0.1)
ALLIUM SATIVUM;CAPSICUM ANNUUM;CRATAEGUS SPP.;VACCINIUM MYRTILLUS;ZINGIBER OFFICINALE	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ALLOPURINOL SODIUM	1 (<0.1)	1 (<0.1)	2 (<0.1)
ALOE SPP.;AVENA SATIVA;VITAMIN E NOS	0	1 (<0.1)	1 (<0.1)
ALPHA GLUCOSIDASE INHIBITORS	0	1 (<0.1)	1 (<0.1)
ALPROSTADIL;PAPAVERINE;PHENTOLAMINE	3 (<0.1)	1 (<0.1)	4 (<0.1)
ALTEPLASE	0	1 (<0.1)	1 (<0.1)
ALTHAEA OFFICINALIS ROOT	0	1 (<0.1)	1 (<0.1)
ALUMINIUM CHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
AMBROXOL HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
AMFETAMINE ASPARTATE MONOHYDRATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	3 (<0.1)	1 (<0.1)	4 (<0.1)
AMILORIDE HYDROCHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
AMINO ACIDS NOS;AMINOBENZOIC ACID;ASCORBIC ACID;BETAINE;BIOFLAVONOIDS NOS;BIOTIN;CHOLINE;DEOXYRIBONUCLEIC ACID;EQUISETUM ARVENSE;FOLIC ACID;INOSITOL;LECITHIN;MACROCYSTIS PYRIFERA;MINERALS NOS NASTURTIUM OFFICINALE;NICOTINAMIDE;PANTOTHENIC ACID;PETROSELINUM CRISPUM;PROTEINS NOS;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBONUCLEIC ACID;ROSA CANINA;RUTOSIDE;VITAMIN B1 NOS;VITAMIN B12 NOS VITAMIN D NOS;VITAMIN E NOS;YEAST	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
AMINO ACIDS NOS;BETA VULGARIS;BETAINE;BIOFLAVONOIDS NOS;BROMELAINS;CAMELLIA SINENSIS;CAPSICUM ANNUUM;CHROMIUM;COMMIPHORA SPP. GUM RESIN;CRATAEGUS LAEVIGATA FRUIT;GINKGO BILOBA MALUS SPP. VINEGAR EXTRACT;MINERALS NOS;ORYZA SATIVA BRAN OIL;PHYTOSTEROLINS;SOYA ISOFLAVONES;UBIDECARENONE;VACCINIUM MYRTILLUS;VITAMINS NOS;VITIS VINIFERA	0	1 (<0.1)	1 (<0.1)
AMINO ACIDS NOS;CAROTENOIDS NOS;HERBAL NOS;HYALURONIC ACID;METHYLSULFONYLMETHANE;MINERALS NOS;VITAMINS NOS	2 (<0.1)	1 (<0.1)	3 (<0.1)
AMINO ACIDS NOS;ENZYMES NOS;MINERALS NOS	0	1 (<0.1)	1 (<0.1)
AMINO ACIDS NOS;MINERALS NOS	0	1 (<0.1)	1 (<0.1)
AMINOBENZOIC ACID	1 (<0.1)	1 (<0.1)	2 (<0.1)
AMINOBENZOIC ACID;ASCORBIC ACID;BIOTIN;CHOLINE BITARTRATE;FOLIC ACID;INOSITOL;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE;VITAMIN B12 NOS	1 (<0.1)	1 (<0.1)	2 (<0.1)
AMINOBENZOIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CHOLINE BITARTRATE;CYANOCOBALAMIN;FOLIC ACID;INOSITOL;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
AMIODARONE HYDROCHLORIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
AMLODIPINE BESILATE;HYDROCHLOROTHIAZIDE;VALSARTAN	2 (<0.1)	1 (<0.1)	3 (<0.1)
AMLODIPINE BESILATE;TELMISARTAN	0	1 (<0.1)	1 (<0.1)
AMLODIPINE MESILATE	0	1 (<0.1)	1 (<0.1)
AMLODIPINE;HYDROCHLOROTHIAZIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
AMLODIPINE;LOSARTAN	0	1 (<0.1)	1 (<0.1)
AMLODIPINE;TELMISARTAN	1 (<0.1)	1 (<0.1)	2 (<0.1)
AMOXICILLIN;CLAVULANATE POTASSIUM	3 (<0.1)	1 (<0.1)	4 (<0.1)
AMPICILLIN TRIHYDRATE	0	1 (<0.1)	1 (<0.1)
AMYLASE;BROMELAINS;CATALASE;CHYMOTRYPSIN;LIPASE;PANC REATIN;PAPAIN;SUPEROXIDE DISMUTASE;TRYPSIN	0	1 (<0.1)	1 (<0.1)
ANALGESICS	1 (<0.1)	1 (<0.1)	2 (<0.1)
ANDROGEN, PROGESTOGEN AND ESTROGEN IN COMBINATION	0	1 (<0.1)	1 (<0.1)
ANDROGENS AND ESTROGENS	1 (<0.1)	1 (<0.1)	2 (<0.1)
ANGELICA SINENSIS ROOT	0	1 (<0.1)	1 (<0.1)
ANGELICA SINENSIS ROOT;CIMICIFUGA RACEMOSA ROOT;DIOSCOREA SPP.;GLYCINE MAX	0	1 (<0.1)	1 (<0.1)
ANIMAL UNSPECIFIED;ASCORBIC ACID;HERBAL NOS;MINERALS NOS;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;VITAMIN E NOS	0	1 (<0.1)	1 (<0.1)
ANTIEMETICS AND ANTINAUSEANTS	0	1 (<0.1)	1 (<0.1)
ANTIFUNGALS FOR TOPICAL USE	0	1 (<0.1)	1 (<0.1)
ANTIHISTAMINES	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ANTIINFECTIVES	1 (<0.1)	1 (<0.1)	2 (<0.1)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS	0	1 (<0.1)	1 (<0.1)
ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS	2 (<0.1)	1 (<0.1)	3 (<0.1)
ARCTIUM LAPPA ROOT	0	1 (<0.1)	1 (<0.1)
ARCTOSTAPHYLOS UVA-URSI;CAFFEINE;CALCIUM CARBONATE;CALCIUM HYDROXIDE;CAMELLIA SINENSIS;CELLULOSE MICROCRYSTALLINE;COLECALCIFEROL;CYANOCOBALAMIN;EQUISETUM ARVENSE;FOLIC ACID;ILEX PARAGUARIENSIS LEAF PHOSPHATIDYL SERINE;PINUS PINASTER;PIPER NIGRUM;PYRIDOXINE HYDROCHLORIDE;RHODIOLA ROSEA ROOT;SALVIA SCLAREA;SITOSTEROL;SOYA ISOFLAVONES;TARAXACUM OFFICINALE LEAF;TARAXACUM OFFICINALE ROOT;THEANINE THEOBROMA CACAO SEED;VITEX AGNUS-CASTUS	0	1 (<0.1)	1 (<0.1)
ARGININE;BIOFLAVONOIDS NOS;GLUCOSAMINE HYDROCHLORIDE;MAHONIA AQUIFOLIUM;QUERCETIN;RETINOL PALMITATE;ZEA MAYS	0	1 (<0.1)	1 (<0.1)
ARGININE;CITRULLINE	0	1 (<0.1)	1 (<0.1)
ARGININE;ORNITHINE	0	1 (<0.1)	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ARNICA MONTANA;BENZOIC ACID;BRYONIA ALBA;MATRICARIA RECUTITA;POTASSIUM IODIDE;PULSATILLA PRATENSIS;RHODODENDRON CHRYSANTHUM;SOLANUM DULCAMARA;TOXICODENDRON PUBESCENS	0	1 (<0.1)	1 (<0.1)
ARNICA SPP.	0	1 (<0.1)	1 (<0.1)
AROMATASE INHIBITORS	0	1 (<0.1)	1 (<0.1)
ARTICAINE	0	1 (<0.1)	1 (<0.1)
ARTICAINE HYDROCHLORIDE;EPINEPHRINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;BETA VULGARIS;CATALASE;PANCRELIPASE;SUPEROXIDE DISMUTASE;TAURINE	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;BORON;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM PICOLINATE;COLECALCIFEROL;COPPER SULFATE;CYANOCOBALAMIN;FOLIC ACID;LYCOPENE;MAGNESIUM OXIDE MANGANESE SULFATE;NICKEL;NICOTINAMIDE;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SILICON DIOXIDE;SODIUM METAVANADATE;SODIUM MOLYBDATE SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;XANTOFYL;ZINC OXIDE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BETACAROTENE;BIOTIN;BORON;CALCIUM;CALCIUM PANTOTHENATE;CHLORIDE;CHROMIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;IRON;LYCOPENE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICKEL NICOTINAMIDE;PHOSPHORUS;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;SILICON DIOXIDE;THIAMINE;TIN;TOCOPHERYL ACETATE;VANADIUM;VITAMIN K NOS;ZINC	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATE;FOLIC ACID MAGNESIUM OXIDE;MANGANESE SULFATE;NICOTINAMIDE;PHYTOMENADIONE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SODIUM SELENATE;THIAMINE MONONITRATE;ZINC OXIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CHROMIC CHLORIDE;COLECALCIFEROL;CUPRIC OXIDE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FOLIC ACID;LYCOPENE;MAGNESIUM OXIDE MANGANESE SULFATE;NICOTINAMIDE;PHYTOMENADIONE;POTASSIUM CHLORIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SODIUM SELENATE;THIAMINE MONONITRATE;ZINC OXIDE	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;BETACAROTENE;COPPER;NICOTINAMIDE;SELENIUM;TOCOPHEROL;XANTOFYL;ZINC	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;BETACAROTENE;COPPER;TOCOPHERYL ACETATE;ZINC OXIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ASCORBIC ACID;BIOFLAVONOIDS NOS;BIOTIN;CALCIUM PANTOTHENATE;CHOLINE BITARTRATE;CYANOCOBALAMIN;FOLIC ACID;GLUTAMIC ACID;INOSITOL;METHYL HESPERIDIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	0	1 (<0.1)	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BIOFLAVONOIDS NOS;CALCIUM;MALPIGHIA GLABRA;ROSA CANINA FRUIT;RUTOSIDE	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE DIBASIC;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE;YEAST DRIED	2 (<0.1)	1 (<0.1)	3 (<0.1)
ASCORBIC ACID;BIOTIN;CALCIUM;COLECALCIFEROL;COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;IRON;NICOTINIC ACID;PANTOTHENIC ACID;PHYTOMENADIONE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM;THIAMINE TOCOPHERYL ACETATE;ZINC	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;BROMELAINS;CALCIUM PANTOTHENATE;CURCUMA LONGA RHIZOME;CYSTEINE;ENZYMES NOS;MAGNESIUM OXIDE;RUSCUS ACULEATUS RHIZOME;RUSCUS ACULEATUS ROOT	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;CALCIUM PHOSPHATE;LACTOBACILLUS NOS;VACCINIUM MACROCARPON	2 (<0.1)	1 (<0.1)	3 (<0.1)
ASCORBIC ACID;CHONDROITIN SULFATE SODIUM;COLLAGEN;GLUCOSAMINE SULFATE;MANGANESE	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;CHONDROITIN;GLUCOSAMINE	0	1 (<0.1)	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;COD-LIVER OIL;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;MAGNESIUM SULFATE;MUCIN;PYRIDOXAL PHOSPHATE;RETINOL PALMITATE;RIBES NIGRUM SEED OIL;TOCOPHEROL	2 (<0.1)	1 (<0.1)	3 (<0.1)
ASCORBIC ACID;COLECALCIFEROL	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;COLECALCIFEROL;COPPER GLUCONATE;CYANOCOBALAMIN;DURAPATITE;FOLIC ACID;GLUCOSAMINE HYDROCHLORIDE;MAGNESIUM OXIDE;MANGANESE SULFATE;PHYTOMENADIONE;SODIUM BORATE DECAHYDRATE ZINC AMINO ACID CHELATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;COLECALCIFEROL;CYANOCOBALAMIN;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;FOLIC ACID;IRON PENTACARBONYL;LEVOMEFOLIC ACID;MAGNESIUM OXIDE;NICOTINIC ACID;POTASSIUM IODIDE PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;COPPER GLUCONATE;FISH OIL;TOCOPHERYL ACETATE;XANTOFYL;ZEAXANTHIN;ZINC OXIDE	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;COPPER;VITAMIN E NOS;XANTOFYL;ZEAXANTHIN;ZINC	0	1 (<0.1)	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;CUPRIC OXIDE;TOCOPHERYL ACID SUCCINATE;XANTOFYL;ZEAXANTHIN;ZINC OXIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;FERROUS FUMARATE;IRON POLYSACCHARIDE COMPLEX;NICOTINAMIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ASCORBIC ACID;FOLIC ACID;VITAMIN B COMPLEX	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;PYRROLOQUINOLINE QUINONE;TOCOPHEROL	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;QUERCETIN	3 (<0.1)	1 (<0.1)	4 (<0.1)
ASCORBIC ACID;RETINOL;TOCOPHERYL ACETATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;ROSA CANINA	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;SAMBUCUS NIGRA;ZINC	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASCORBIC ACID;SODIUM ASCORBATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ASCORBIC ACID;VITAMIN B NOS	0	1 (<0.1)	1 (<0.1)
ASCORBIC ACID;VITAMINS NOS	0	1 (<0.1)	1 (<0.1)
ASENAPINE MALEATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ASPARAGINE	0	1 (<0.1)	1 (<0.1)
ASPARAGUS OFFICINALIS ROOT;CALCIUM CARBONATE;MAGNESIUM OXIDE;PETROSELINUM CRISPUM HERB;POTASSIUM CHLORIDE;SODIUM CHLORIDE;TARAXACUM OFFICINALE LEAF;ZEA MAYS	0	1 (<0.1)	1 (<0.1)
ASPARAGUS OFFICINALIS STEM;JUNIPERUS COMMUNIS FRUIT	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASPARTATE ZINC;MAGNESIUM ASPARTATE;PYRIDOXINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
ASTAXANTHIN;BORAGO OFFICINALIS SEED OIL;BOSWELLIA SPP. ESSENTIAL OIL;CARUM CARVI ESSENTIAL OIL;CITRUS SPP. OIL;COLECALCIFEROL;CUMINUM CYMINUM OIL;FISH OIL;LINUM USITATISSIMUM SEED OIL MATRICARIA RECUTITA ESSENTIAL OIL;MENTHA X PIPERITA ESSENTIAL OIL;PUNICA GRANATUM SEED OIL;SYZYGIUM AROMATICUM ESSENTIAL OIL;THYMUS SPP. ESSENTIAL OIL;TOCOPHEROL;TOCOPHEROLS MIXED VACCINIUM MACROCARPON SEED OIL;ZINGIBER OFFICINALE OIL	0	1 (<0.1)	1 (<0.1)
ASTRAGALUS MONGHOLICUS ROOT	0	1 (<0.1)	1 (<0.1)
ATAZANAVIR	0	1 (<0.1)	1 (<0.1)
ATORVASTATIN;FENOFIBRATE	0	1 (<0.1)	1 (<0.1)
ATROPINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ATROPINE SULFATE;DIPHENOXYLATE HYDROCHLORIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ATROPINE SULFATE;HYOSCINE HYDROBROMIDE;HYOSCYAMINE SULFATE;PHENOBARBITAL	0	1 (<0.1)	1 (<0.1)
ATROPINE;DIPHENOXYLATE	4 (<0.1)	1 (<0.1)	5 (<0.1)
AVENA SATIVA	2 (<0.1)	1 (<0.1)	3 (<0.1)
BACILLUS COAGULANS	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BACILLUS COAGULANS;BIFIDOBACTERIUM LACTIS;FRUCTOOLIGOSACCHARIDES;HERBAL NOS;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS REUTERI;MINERALS NOS;VITAMINS NOS	0	1 (<0.1)	1 (<0.1)
BACILLUS COAGULANS;INULIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
BACILLUS MESENTERICUS;CLOSTRIDIUM BUTYRICUM;ENTEROCOCCUS FAECALIS;FRUCTOOLIGOSACCHARIDES;LACTOBACILLUS ACIDOPHILUS	0	1 (<0.1)	1 (<0.1)
BACILLUS SUBTILIS;BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM LACTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BREVIS;LACTOBACILLUS CASEI;LACTOBACILLUS PARACASEILACTOBACILLUS PLANTARUM;LACTOBACILLUS RHAMNOSUS;LACTOBACILLUS SALIVARIUS	0	1 (<0.1)	1 (<0.1)
BALOXAVIR MARBOXIL	0	1 (<0.1)	1 (<0.1)
BALSALAZIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
BAMIPINE;PHENIRAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
BARIUM	0	1 (<0.1)	1 (<0.1)
BECLOMETASONE;LEVOSALBUTAMOL	0	1 (<0.1)	1 (<0.1)
BENZATHINE BENZYLPENICILLIN	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BENZODIAZEPINE DERIVATIVES	0	1 (<0.1)	1 (<0.1)
BENZOIC ACID	0	1 (<0.1)	1 (<0.1)
BENZYL ALCOHOL	0	1 (<0.1)	1 (<0.1)
BEPOTASTINE BESILATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
BESIFLOXACIN HYDROCHLORIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
BETA GLUCAN	0	1 (<0.1)	1 (<0.1)
BETA VULGARIS ROOT	0	1 (<0.1)	1 (<0.1)
BETA-HYDROXY-BETA-METHYLBUTYRATE	0	1 (<0.1)	1 (<0.1)
BETAINE	0	1 (<0.1)	1 (<0.1)
BETAMETHASONE DIPROPIONATE;CALCIPOTRIOL	2 (<0.1)	1 (<0.1)	3 (<0.1)
BETAMETHASONE DIPROPIONATE;CALCIPOTRIOL MONOHYDRATE	0	1 (<0.1)	1 (<0.1)
BETAMETHASONE;CALCIPOTRIOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
BETAXOLOL HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
BETHANECHOL	2 (<0.1)	1 (<0.1)	3 (<0.1)
BICTEGRAVIR	0	1 (<0.1)	1 (<0.1)
BICTEGRAVIR;EMTRICITABINE;TENOFOVIR ALAFENAMIDE	0	1 (<0.1)	1 (<0.1)
BIFIDOBACTERIUM BREVE;BIFIDOBACTERIUM INFANTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS BULGARICUS;LACTOBACILLUS PARACASEI;LACTOBACILLUS PLANTARUM;STREPTOCOCCUS THERMOPHILUS	2 (<0.1)	1 (<0.1)	3 (<0.1)
BIFIDOBACTERIUM INFANTIS;LACTOBACILLUS ACIDOPHILUS	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BIFIDOBACTERIUM LACTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS	0	1 (<0.1)	1 (<0.1)
BIFIDOBACTERIUM LACTIS;LACTOBACILLUS ACIDOPHILUS	0	1 (<0.1)	1 (<0.1)
BIOFLAVONOIDS NOS;VITAMINS NOS	3 (<0.1)	1 (<0.1)	4 (<0.1)
BIOTIN;CALCIUM PANTOTHENATE;CHOLINE BITARTRATE;CYANOCOBALAMIN;FOLIC ACID;INOSITOL;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
BIOTIN;CALCIUM PANTOTHENATE;CITRUS AURANTIUM;CITRUS LIMON;COPPER CITRATE;PYRIDOXINE HYDROCHLORIDE;ROSMARINUS OFFICINALIS LEAF;WITHANIA SOMNIFERA ROOT;ZINC ASCORBATE	0	1 (<0.1)	1 (<0.1)
BIOTIN;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;POTASSIUM;PROTEINS NOS;SODIUM;VITAMINS NOS	0	1 (<0.1)	1 (<0.1)
BIOTIN;COPPER SULFATE;CYSTEINE;EQUISETUM ARVENSE;MALUS DOMESTICA;METHIONINE;PANICUM MILIACEUM;PANTOTHENIC ACID;ZINC OXIDE	0	1 (<0.1)	1 (<0.1)
BIOTIN;PANTOTHENIC ACID;SILICON DIOXIDE;ZINC	0	1 (<0.1)	1 (<0.1)
BISMUTH	0	1 (<0.1)	1 (<0.1)
BORAGO OFFICINALIS OIL	0	1 (<0.1)	1 (<0.1)
BORAGO OFFICINALIS OIL;FISH OIL;LINUM USITATISSIMUM SEED OIL	2 (<0.1)	1 (<0.1)	3 (<0.1)
BORAGO OFFICINALIS OIL;FISH OIL;OLEA EUROPAEA OIL	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BORIC ACID	1 (<0.1)	1 (<0.1)	2 (<0.1)
BORIC ACID;HYDROXYQUINOLINE;SODIUM BORATE;SODIUM LAURYL SULFATE	0	1 (<0.1)	1 (<0.1)
BORIC ACID;POLOXAMINE;SODIUM BORATE;SODIUM CHLORIDE	0	1 (<0.1)	1 (<0.1)
BORON CITRATE;CALCIUM CARBONATE;CALCIUM CITRATE;COLECALCIFEROL;MAGNESIUM AMINO ACID CHELATE;MAGNESIUM CITRATE;MAGNESIUM OXIDE;VITAMIN K NOS	0	1 (<0.1)	1 (<0.1)
BORON GLYCINATE;CARTILAGE;HYALURONATE SODIUM;POTASSIUM CHLORIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
BORON GLYCINATE;CARTILAGE;HYALURONIC ACID	0	1 (<0.1)	1 (<0.1)
BOSWELLIA SACRA EXTRACT	0	1 (<0.1)	1 (<0.1)
BOSWELLIA SERRATA GUM;BROMELAINS;CURCUMA LONGA RHIZOME;CYAMOPSIS TETRAGONOLOBA GUM;CYANOCOBALAMIN;FOLIC ACID;HYALURONIC ACID;KERATIN;LACTOBACILLUS ACIDOPHILUS;MANGANESE SULFATE;PANAX GINSENG ROOT PANCREATIN;PAPAIN;PRUNUS CERASUS;PYRIDOXAL PHOSPHATE;SALIX ALBA;SERRAPEPTASE;ZINGIBER OFFICINALE RHIZOME	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BOSWELLIA SERRATA RESIN;BROMELAINS;CITROFLAVONOID;CURCUMA LONGA;DL-ALPHA TOCOPHEROL SUCCINATE;GLUTATHIONE;HARPAGOPHYTUM PROCUMBENS;PAPAIN;PROTEASE NOS;RUTOSIDE;YUCCA SCHIDIGERA ROOT ZINGIBER OFFICINALE RHIZOME	0	1 (<0.1)	1 (<0.1)
BOSWELLIA SERRATA;BROMELAINS;CALCIUM ASCORBATE;CALCIUM OROTATE;CHONDROITIN SULFATE;COPPER GLUCONATE;GLUCOSAMINE SULFATE;MANGANESE AMINO ACID CHELATE;ZINC AMINO ACID CHELATE	0	1 (<0.1)	1 (<0.1)
BOSWELLIA SERRATA;CURCUMA LONGA;DL-PHENYLALANINE;NATTOKINASE	2 (<0.1)	1 (<0.1)	3 (<0.1)
BRASSICA RAPA OIL;CUCURBITA PEPO OIL;LINUM USITATISSIMUM OIL;OENOTHERA BIENNIS OIL;RIBES NIGRUM OIL	0	1 (<0.1)	1 (<0.1)
BRIMONIDINE TARTRATE;TIMOLOL	0	1 (<0.1)	1 (<0.1)
BRIVARACETAM	2 (<0.1)	1 (<0.1)	3 (<0.1)
BROMAZEPAM	1 (<0.1)	1 (<0.1)	2 (<0.1)
BROMELAINS	1 (<0.1)	1 (<0.1)	2 (<0.1)
BROMFENAC	2 (<0.1)	1 (<0.1)	3 (<0.1)
BROMFENAC;GATIFLOXACIN;PREDNISOLONE ACETATE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BROMPHENIRAMINE MALEATE;PHENYLPROPANOLAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
BROMPHENIRAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
BUDESONIDE;FORMOTEROL FUMARATE;GLYCOPYRRONIUM BROMIDE	0	1 (<0.1)	1 (<0.1)
BUPIVACAINE HYDROCHLORIDE;METHYLPREDNISOLONE ACETATE	0	1 (<0.1)	1 (<0.1)
BUPIVACAINE;LIDOCAINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
BUPIVACAINE;METHYLPREDNISOLONE	0	1 (<0.1)	1 (<0.1)
BUTALBITAL;CAFFEINE;CODEINE PHOSPHATE;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
BUTORPHANOL TARTRATE	0	1 (<0.1)	1 (<0.1)
CABOTEGRAVIR	0	1 (<0.1)	1 (<0.1)
CAFFEINE;CAMELLIA SINENSIS LEAF EXTRACT;COLA NITIDA;ILEX PARAGUARIENSIS;NICOTINIC ACID;PANAX GINSENG ROOT;PAULLINIA CUPANA;PIPER NIGRUM;TURNERA DIFFUSA	0	1 (<0.1)	1 (<0.1)
CAFFEINE;CAMELLIA SINENSIS LEAF;CHROMIUM PICOLINATE;GARCINIA GUMMI-GUTTA FRUIT;POLIGLUSAM;SALIX ALBA BARK;TAURINE	0	1 (<0.1)	1 (<0.1)
CAFFEINE;MAGNESIUM SALICYLATE	0	1 (<0.1)	1 (<0.1)
CALAMINE;CAMPHOR;DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CALCIUM ASCORBATE	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CALCIUM CARBONATE;CINCHONA OFFICINALIS;COPPER;LYCOPODIUM SPP.;MAGNESIUM PHOSPHATE;MATRICARIA RECUTITA;POTASSIUM HYDROXIDE;SILICON;SULFUR;TOXICODENDRON PUBESCENS	0	1 (<0.1)	1 (<0.1)
CALCIUM CARBONATE;COLECALCIFEROL;CUPRIC OXIDE;MAGNESIUM OXIDE;MANGANESE SULFATE;SODIUM BORATE;ZINC OXIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
CALCIUM CARBONATE;RISEDRONATE SODIUM	0	1 (<0.1)	1 (<0.1)
CALCIUM CARBONATE;SODIUM FLUOROPHOSPHATE	0	1 (<0.1)	1 (<0.1)
CALCIUM CHLORIDE;PLACENTA EXTRACT	0	1 (<0.1)	1 (<0.1)
CALCIUM CITRATE;COLECALCIFEROL;SOYA ISOFLAVONES	0	1 (<0.1)	1 (<0.1)
CALCIUM CITRATE;MAGNESIUM	0	1 (<0.1)	1 (<0.1)
CALCIUM MEFOLINATE	0	1 (<0.1)	1 (<0.1)
CALCIUM MEFOLINATE;PYRIDOXINE HYDROCHLORIDE;VITAMIN B12 NOS	2 (<0.1)	1 (<0.1)	3 (<0.1)
CALCIUM PANTOTHENATE	0	1 (<0.1)	1 (<0.1)
CALCIUM PANTOTHENATE;COPPER SULFATE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM SULFATE;MANGANESE SULFATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SODIUM ASCORBATE THIAMINE MONONITRATE;ZINC SULFATE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CALCIUM PANTOTHENATE;GAMMA-AMINOBUTYRIC ACID;NICOTINIC ACID;PAPAVERINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CALCIUM PHOSPHATE;COLECALCIFEROL	0	1 (<0.1)	1 (<0.1)
CALCIUM PHOSPHATE;COLECALCIFEROL;PHOSPHORUS	0	1 (<0.1)	1 (<0.1)
CALCIUM PHOSPHATE;MAGNESIUM CARBONATE;POTASSIUM CHLORIDE	0	1 (<0.1)	1 (<0.1)
CALCIUM PHOSPHATE;MELATONIN;SODIUM CITRATE	0	1 (<0.1)	1 (<0.1)
CALCIUM SILICATE	0	1 (<0.1)	1 (<0.1)
CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS	0	1 (<0.1)	1 (<0.1)
CALCIUM;COLECALCIFEROL;GLUCOSAMINE	0	1 (<0.1)	1 (<0.1)
CALCIUM;GLUCOSAMINE	0	1 (<0.1)	1 (<0.1)
CALCIUM;MAGNESIUM;SODIUM	0	1 (<0.1)	1 (<0.1)
CALCIUM;MELATONIN;PYRIDOXINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CALCIUM;VITAMIN D NOS;VITAMIN K NOS	1 (<0.1)	1 (<0.1)	2 (<0.1)
CALCIUM;VITAMINS NOS	0	1 (<0.1)	1 (<0.1)
CAMPHOR;MENTHOL;METHYL SALICYLATE	0	1 (<0.1)	1 (<0.1)
CANDESARTAN CILEXETIL;HYDROCHLOROTHIAZIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CAPECITABINE	0	1 (<0.1)	1 (<0.1)
CAPSICUM SPP. TINCTURE	2 (<0.1)	1 (<0.1)	3 (<0.1)
CARBIDOPA	0	1 (<0.1)	1 (<0.1)
CARICA PAPAYA	2 (<0.1)	1 (<0.1)	3 (<0.1)
CARMELLOSE SODIUM;GLYCEROL;POLYSORBATE 80	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CARUM CARVI;MENTHA X PIPERITA	1 (<0.1)	1 (<0.1)	2 (<0.1)
CEFADROXIL	1 (<0.1)	1 (<0.1)	2 (<0.1)
CEFALEXIN HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CEFEPIME	2 (<0.1)	1 (<0.1)	3 (<0.1)
CEFIXIME	1 (<0.1)	1 (<0.1)	2 (<0.1)
CEFOTETAN	0	1 (<0.1)	1 (<0.1)
CEFRADINE	0	1 (<0.1)	1 (<0.1)
CEFUROXIME AXETIL	0	1 (<0.1)	1 (<0.1)
CERAMIDE;CHOLESTEROL;LINOLEIC ACID	0	1 (<0.1)	1 (<0.1)
CETIRIZINE;PSEUDOEPHEDRINE	4 (<0.1)	1 (<0.1)	5 (<0.1)
CETYL ALCOHOL;SODIUM LAURYL SULFATE	0	1 (<0.1)	1 (<0.1)
CETYL MYRISTOLEATE	0	1 (<0.1)	1 (<0.1)
CHARCOAL, ACTIVATED	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHEMOTHERAPEUTICS FOR TOPICAL USE	0	1 (<0.1)	1 (<0.1)
CHLORAMPHENICOL	0	1 (<0.1)	1 (<0.1)
CHLORCYCLIZINE HYDROCHLORIDE;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CHLORDIAZEPOXIDE	0	1 (<0.1)	1 (<0.1)
CHLORELLA SPP.;PLANTAGO OVATA SEED HUSK;SPIRULINA SPP.	0	1 (<0.1)	1 (<0.1)
CHLORELLA VULGARIS;HORDEUM VULGARE;SPIRULINA SPP.	0	1 (<0.1)	1 (<0.1)
CHLORELLA VULGARIS;SPIRULINA SPP.	0	1 (<0.1)	1 (<0.1)
CHLOROTHIAZIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE	0	1 (<0.1)	1 (<0.1)
CHLORPHENAMINE MALEATE;IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHLORPHENAMINE MALEATE;METHAPYRILENE FUMARATE;PHENYLPROPANOLAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CHLORPHENAMINE MALEATE;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
CHLORPHENAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHLORPHENAMINE;DEXTROMETHORPHAN;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
CHLORPHENAMINE;PHENYLEPHRINE	0	1 (<0.1)	1 (<0.1)
CHLORPHENIRAMINE POLISTIREX;HYDROCODONE POLISTIREX	0	1 (<0.1)	1 (<0.1)
CHLORZOXAZONE	2 (<0.1)	1 (<0.1)	3 (<0.1)
CHOLINE BITARTRATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHOLINE;SILICON	0	1 (<0.1)	1 (<0.1)
CHONDROITIN SULFATE SODIUM;GLUCOSAMINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHONDROITIN SULFATE;COLLAGEN;GLUCOSAMINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHONDROITIN SULFATE;COLLAGEN;HYALURONIC ACID	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE	4 (<0.1)	1 (<0.1)	5 (<0.1)
CHONDRUS CRISPUS	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CHROMIUM PICOLINATE;CINNAMOMUM SPP. BARK;CISSUS QUADRANGULARIS;CISSUS VERTICILLATA LEAF;COLECALCIFEROL;CYANOCOBALAMIN;GYMNEMA SYLVESTRE;LAGERSTROEMIA SPECIOSA;MORUS ALBA LEAF;OMEGA-3 FATTY ACIDS PHELLODENDRON SPP. BARK;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE;THIOCTIC ACID	0	1 (<0.1)	1 (<0.1)
CHROMIUM PICOLINATE;CINNAMOMUM VERUM BARK;COLECALCIFEROL	0	1 (<0.1)	1 (<0.1)
CHROMIUM PICOLINATE;EPHEDRA NOS;GARCINIA GUMMI-GUTTA;LEVOCARNITINE;PAULLINIA CUPANA;SALIX ALBA;SALIX PURPUREA	2 (<0.1)	1 (<0.1)	3 (<0.1)
CHROMIUM;DEXTRIN;MORUS SPP. LEAF;PHASEOLUS VULGARIS	1 (<0.1)	1 (<0.1)	2 (<0.1)
CHROMIUM;NICOTINIC ACID	0	1 (<0.1)	1 (<0.1)
CHROMIUM;POLIGLUSAM	0	1 (<0.1)	1 (<0.1)
CICLOPIROX OLAMINE	3 (<0.1)	1 (<0.1)	4 (<0.1)
CILNIDIPINE;TELMISARTAN	0	1 (<0.1)	1 (<0.1)
CIMICIFUGA RACEMOSA EXTRACT	0	1 (<0.1)	1 (<0.1)
CIMICIFUGA RACEMOSA ROOT	2 (<0.1)	1 (<0.1)	3 (<0.1)
CINCHOCAINE	0	1 (<0.1)	1 (<0.1)
CINCHONIDINE SULFATE;QUININE SULFATE	0	1 (<0.1)	1 (<0.1)
CINNAMOMUM VERUM OIL	1 (<0.1)	1 (<0.1)	2 (<0.1)
CIPROFLOXACIN;HYDROCORTISONE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CITICOLINE	2 (<0.1)	1 (<0.1)	3 (<0.1)
CITICOLINE SODIUM	1 (<0.1)	1 (<0.1)	2 (<0.1)
CITRIC ACID	0	1 (<0.1)	1 (<0.1)
CITRIC ACID;SODIUM BICARBONATE	0	1 (<0.1)	1 (<0.1)
CITRUS AURANTIUM	1 (<0.1)	1 (<0.1)	2 (<0.1)
CITRUS LIMON ESSENTIAL OIL	0	1 (<0.1)	1 (<0.1)
CITRUS LIMON ESSENTIAL OIL;LAVANDULA ANGUSTIFOLIA ESSENTIAL OIL;MENTHA X PIPERITA ESSENTIAL OIL	0	1 (<0.1)	1 (<0.1)
CLEMASTINE	0	1 (<0.1)	1 (<0.1)
CLIDINIUM	0	1 (<0.1)	1 (<0.1)
CLINDAMYCIN PHOSPHATE;TRETINOIN	2 (<0.1)	1 (<0.1)	3 (<0.1)
CLOCORTOLONE PIVALATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CLOFEDANOL HYDROCHLORIDE;MEPYRAMINE MALEATE	0	1 (<0.1)	1 (<0.1)
CLONIXIN	0	1 (<0.1)	1 (<0.1)
CLONIXIN LYSINATE;CYCLOBENZAPRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CLORAZEPATE DIPOTASSIUM	0	1 (<0.1)	1 (<0.1)
COBICISTAT;ELVITEGRAVIR;EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CODEINE PHOSPHATE;GUAIFENESIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
CODEINE PHOSPHATE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CODEINE;IBUPROFEN	0	1 (<0.1)	1 (<0.1)
CODEINE;PROMETHAZINE	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
COFFEA ARABICA	0	1 (<0.1)	1 (<0.1)
COLECALCIFEROL;COLLAGEN;FISH OIL	0	1 (<0.1)	1 (<0.1)
COLECALCIFEROL;DICALCIUM MALATE;DURAPATITE;GENISTEIN;MENAQUINONE-7;SODIUM PHOSPHATE DIBASIC;ZINC BIS GLYCINATE CHELATE	0	1 (<0.1)	1 (<0.1)
COLECALCIFEROL;FISH OIL	5 (<0.1)	1 (<0.1)	6 (<0.1)
COLECALCIFEROL;FISH OIL;TOCOPHEROL	0	1 (<0.1)	1 (<0.1)
COLECALCIFEROL;MENAQUINONE	3 (<0.1)	1 (<0.1)	4 (<0.1)
COLLAGEN BOVINE	0	1 (<0.1)	1 (<0.1)
COLLAGEN MARINE	0	1 (<0.1)	1 (<0.1)
COLLAGEN;HYALURONIC ACID	2 (<0.1)	1 (<0.1)	3 (<0.1)
COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	0	1 (<0.1)	1 (<0.1)
COLOSTRUM	2 (<0.1)	1 (<0.1)	3 (<0.1)
COMBINATIONS AND COMPLEXES OF ALUMINIUM, CALCIUM AND MAGNESIUM COMPOUNDS	0	1 (<0.1)	1 (<0.1)
COMMIPHORA MUKUL GUM	0	1 (<0.1)	1 (<0.1)
CONIUM MACULATUM;GRAPHITES;SULFUR	0	1 (<0.1)	1 (<0.1)
CONTRAST MEDIA	0	1 (<0.1)	1 (<0.1)
COPPER AMINO ACID CHELATE	0	1 (<0.1)	1 (<0.1)
COPPER;MANGANESE;ZINC	0	1 (<0.1)	1 (<0.1)
COPPER;ZINC	0	1 (<0.1)	1 (<0.1)
CORDYCEPS SINENSIS	1 (<0.1)	1 (<0.1)	2 (<0.1)
CORTICOSTEROIDS	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CORTISONE ACETATE	4 (<0.1)	1 (<0.1)	5 (<0.1)
CRATAEGUS LAEVIGATA	1 (<0.1)	1 (<0.1)	2 (<0.1)
CRATAEGUS LAEVIGATA FLOWER;CRATAEGUS LAEVIGATA LEAF	0	1 (<0.1)	1 (<0.1)
CREATININE	5 (<0.1)	1 (<0.1)	6 (<0.1)
CROFELEMER	0	1 (<0.1)	1 (<0.1)
CROMOGLICIC ACID	2 (<0.1)	1 (<0.1)	3 (<0.1)
CUCURBITA PEPO SEED OIL	0	1 (<0.1)	1 (<0.1)
CUCURBITA PEPO;GLYCINE MAX GERM;LYCOPENE;SELENOMETHIONINE;SERENOA REPENS;URTICA DIOICA;ZINC GLYCINATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CURCUMA LONGA ROOT	0	1 (<0.1)	1 (<0.1)
CURCUMA LONGA ROOT;PIPER NIGRUM FRUIT	0	1 (<0.1)	1 (<0.1)
CURCUMA LONGA;EPIMEDIUM SPP.;OMEGA-3 FATTY ACIDS;REYNOUTRIA JAPONICA	0	1 (<0.1)	1 (<0.1)
CURCUMA LONGA;LEVOMEFOLIC ACID;MECOBALAMIN	0	1 (<0.1)	1 (<0.1)
CYAMOPSIS TETRAGONOLOBA GUM	0	1 (<0.1)	1 (<0.1)
CYCLIZINE	2 (<0.1)	1 (<0.1)	3 (<0.1)
CYCLOPENTOLATE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
CYNARA CARDUNCULUS	0	1 (<0.1)	1 (<0.1)
CYNARA CARDUNCULUS LEAF;GANODERMA LUCIDUM;MONASCUS PURPUREUS;SILYBUM MARIANUM SEED;UBIDECARENONE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CYNARA CARDUNCULUS LEAF;HYDRASTIS CANADENSIS ROOT;SILYBUM MARIANUM SEED;TARAXACUM OFFICINALE ROOT;TRIFOLIUM PRATENSE	0	1 (<0.1)	1 (<0.1)
CYNARA CARDUNCULUS;MALUS SPP. VINEGAR EXTRACT;TARAXACUM OFFICINALE	1 (<0.1)	1 (<0.1)	2 (<0.1)
CYPROHEPTADINE	3 (<0.1)	1 (<0.1)	4 (<0.1)
CYPROTERONE ACETATE;ETHINYLESTRADIOL	3 (<0.1)	1 (<0.1)	4 (<0.1)
D-MANNOSE	8 (<0.1)	1 (<0.1)	9 (<0.1)
D-MANNOSE;VACCINIUM MACROCARPON	0	1 (<0.1)	1 (<0.1)
D-RIBOSE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DABIGATRAN	1 (<0.1)	1 (<0.1)	2 (<0.1)
DAPAGLIFLOZIN	6 (<0.1)	1 (<0.1)	7 (<0.1)
DARATUMUMAB	0	1 (<0.1)	1 (<0.1)
DARIFENACIN HYDROBROMIDE	0	1 (<0.1)	1 (<0.1)
DAROLUTAMIDE	0	1 (<0.1)	1 (<0.1)
DARUNAVIR ETHANOLATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DASATINIB	0	1 (<0.1)	1 (<0.1)
DASATINIB MONOHYDRATE	0	1 (<0.1)	1 (<0.1)
DEFLAZACORT	0	1 (<0.1)	1 (<0.1)
DEOXYCHOLIC ACID	2 (<0.1)	1 (<0.1)	3 (<0.1)
DESIPRAMINE	3 (<0.1)	1 (<0.1)	4 (<0.1)
DEXAMETHASONE SODIUM PHOSPHATE	0	1 (<0.1)	1 (<0.1)
DEXAMETHASONE;DIPHENHYDRAMINE;NYSTATIN;TETRACYCLINE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
DEXAMETHASONE;LIDOCAINE	0	1 (<0.1)	1 (<0.1)
DEXAMETHASONE;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DEXAMETHASONE;NEOMYCIN;POLYMYXIN B SULFATE	0	1 (<0.1)	1 (<0.1)
DEXAMETHASONE;TOBRAMYCIN SULFATE	0	1 (<0.1)	1 (<0.1)
DEXCHLORPHENIRAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PHENYLEPHRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DEXTRAN;HYPROMELLOSE	0	1 (<0.1)	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PHENYLEPHRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PHENYLPROPANOLAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLPROPANOLAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;PHENYLEPHRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;PHENYLPROPANOLAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
DEXTROMETHORPHAN POLISTIREX	1 (<0.1)	1 (<0.1)	2 (<0.1)
DEXTROMETHORPHAN;DIPHENHYDRAMINE;PARACETAMOL;PHENYLEPHRINE	0	1 (<0.1)	1 (<0.1)
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL;PHENYLEPHRINE	0	1 (<0.1)	1 (<0.1)
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL;PSEUDOEPHEDRINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DEXTROMETHORPHAN;GUAIFENESIN;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
DIACEREIN;GLUCOSAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DICHLORALPHENAZONE;ISOMETHEPTENE MUCATE;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
DICHLORALPHENAZONE;ISOMETHEPTENE;PARACETAMOL	2 (<0.1)	1 (<0.1)	3 (<0.1)
DICLOFENAC SODIUM;MISOPROSTOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
DICLOFENAC;MISOPROSTOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
DIHYDROERGOTAMINE MESILATE	0	1 (<0.1)	1 (<0.1)
DIMETHYL FUMARATE	0	1 (<0.1)	1 (<0.1)
DIMETICONE;MERADIMATE;OCTINOXATE;OCTISALATE;OXYBENZONE;TITANIUM DIOXIDE	0	1 (<0.1)	1 (<0.1)
DIOSMIN	3 (<0.1)	1 (<0.1)	4 (<0.1)
DIOSMIN;HESPERIDIN	3 (<0.1)	1 (<0.1)	4 (<0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;ZINC ACETATE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
DIPHENHYDRAMINE;PARACETAMOL;PHENYLEPHRINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DIPHENOXYLATE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	0	1 (<0.1)	1 (<0.1)
DIPHTHERIA VACCINE;TETANUS VACCINE	2 (<0.1)	1 (<0.1)	3 (<0.1)
DIPROPHYLLINE	0	1 (<0.1)	1 (<0.1)
DIPYRIDAMOLE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DISOPYRAMIDE	0	1 (<0.1)	1 (<0.1)
DISULFIRAM	1 (<0.1)	1 (<0.1)	2 (<0.1)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;OMEGA-3 FATTY ACIDS	1 (<0.1)	1 (<0.1)	2 (<0.1)
DOCUSATE SODIUM;SENNA ALEXANDRINA	2 (<0.1)	1 (<0.1)	3 (<0.1)
DOCUSATE;SENNA ALEXANDRINA	0	1 (<0.1)	1 (<0.1)
DOLUTEGRAVIR	5 (<0.1)	1 (<0.1)	6 (<0.1)
DOMPERIDONE	2 (<0.1)	1 (<0.1)	3 (<0.1)
DORAVIRINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DORNASE ALFA	0	1 (<0.1)	1 (<0.1)
DORZOLAMIDE HYDROCHLORIDE	6 (<0.1)	1 (<0.1)	7 (<0.1)
DORZOLAMIDE;TIMOLOL MALEATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
DOXYCYCLINE HYDROCHLORIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
DOXYCYCLINE MONOHYDRATE	4 (<0.1)	1 (<0.1)	5 (<0.1)
DOXYLAMINE;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
ECHINACEA ANGUSTIFOLIA ROOT;ECHINACEA PURPUREA ROOT;HYDRASTIS CANADENSIS ROOT	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ECONAZOLE NITRATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
EFAVIRENZ;EMTRICITABINE;TENOFOVIR DISOPROXIL FUMARATE	0	1 (<0.1)	1 (<0.1)
EGCG	1 (<0.1)	1 (<0.1)	2 (<0.1)
ELAGOLIX SODIUM	2 (<0.1)	1 (<0.1)	3 (<0.1)
ELECTROLYTES NOS	3 (<0.1)	1 (<0.1)	4 (<0.1)
ELECTROLYTES NOS;GLUCOSE	0	1 (<0.1)	1 (<0.1)
ELEUTHEROCOCCUS SENTICOSUS ROOT	1 (<0.1)	1 (<0.1)	2 (<0.1)
ELEXACAFTOR;IVACAFTOR;TEZACAFTOR	0	1 (<0.1)	1 (<0.1)
EMTRICITABINE;RILPIVIRINE;TENOFOVIR	0	1 (<0.1)	1 (<0.1)
ENALAPRIL;HYDROCHLOROTHIAZIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ENTACAPONE	0	1 (<0.1)	1 (<0.1)
ENZYMES	1 (<0.1)	1 (<0.1)	2 (<0.1)
ENZYMES NOS;FUNGI NOS;HERBAL NOS;MINERALS NOS;NUTRIENTS NOS;PROBIOTICS NOS;PROTEINS NOS;VITAMINS NOS	0	1 (<0.1)	1 (<0.1)
EPHEDRINE	0	1 (<0.1)	1 (<0.1)
EPHEDRINE HYDROCHLORIDE;GUAIFENESIN	0	1 (<0.1)	1 (<0.1)
EPINASTINE	0	1 (<0.1)	1 (<0.1)
EPINASTINE HYDROCHLORIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ERENUMAB AOOE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ERTUGLIFLOZIN PIDOLATE;SITAGLIPTIN PHOSPHATE MONOHYDRATE	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ERTUGLIFLOZIN;SITAGLIPTIN	0	1 (<0.1)	1 (<0.1)
ESLICARBAZEPINE ACETATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ESTAZOLAM	0	1 (<0.1)	1 (<0.1)
ESTRADIOL CIPIONATE;TESTOSTERONE CIPIONATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ESTRADIOL;LEVONORGESTREL	1 (<0.1)	1 (<0.1)	2 (<0.1)
ESTRADIOL;NORGESTIMATE	0	1 (<0.1)	1 (<0.1)
ESTROGEN NOS;MEDROXYPROGESTERONE ACETATE	0	1 (<0.1)	1 (<0.1)
ESTROGEN NOS;METHYLTESTOSTERONE	2 (<0.1)	1 (<0.1)	3 (<0.1)
ESTROGENS CONJUGATED;MEDROXYPROGESTERONE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ETHAMBUTOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
ETHINYLESTRADIOL;FERROUS BISGLYCINATE;LEVONORGESTREL	0	1 (<0.1)	1 (<0.1)
EUCALYPTUS GLOBULUS OIL;MENTHOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
EUTERPE OLERACEA	0	1 (<0.1)	1 (<0.1)
EUTERPE OLERACEA FRUIT	2 (<0.1)	1 (<0.1)	3 (<0.1)
FALLOPIA JAPONICA;VITIS VINIFERA	1 (<0.1)	1 (<0.1)	2 (<0.1)
FENBENDAZOLE	0	1 (<0.1)	1 (<0.1)
FERROUS FUMARATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
FERROUS FUMARATE;FOLIC ACID;VITAMIN B COMPLEX	0	1 (<0.1)	1 (<0.1)
FERUMOXYTOL	0	1 (<0.1)	1 (<0.1)
FESOTERODINE	0	1 (<0.1)	1 (<0.1)
FISH OIL;ROSMARINUS OFFICINALIS;TOCOPHEROL	1 (<0.1)	1 (<0.1)	2 (<0.1)
FISH OIL;UBIDECARENONE	0	1 (<0.1)	1 (<0.1)
FISH OIL;VITAMINS NOS	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
FLIBANSERIN	2 (<0.1)	1 (<0.1)	3 (<0.1)
FLUDROCORTISONE ACETATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
FLUORESCEIN	0	1 (<0.1)	1 (<0.1)
FLUVOXAMINE MALEATE	0	1 (<0.1)	1 (<0.1)
FOLIC ACID;IRON	2 (<0.1)	1 (<0.1)	3 (<0.1)
FOLIC ACID;MECOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIOCTIC ACID	0	1 (<0.1)	1 (<0.1)
FOLIC ACID;MINERALS NOS;VITAMINS NOS	2 (<0.1)	1 (<0.1)	3 (<0.1)
FOLIC ACID;PYRIDOXINE HYDROCHLORIDE;VITAMIN B12 NOS	0	1 (<0.1)	1 (<0.1)
FORMOTEROL	1 (<0.1)	1 (<0.1)	2 (<0.1)
FORMOTEROL FUMARATE	0	1 (<0.1)	1 (<0.1)
FOSFOMYCIN TROMETAMOL	0	1 (<0.1)	1 (<0.1)
FREMANEZUMAB VFRM	2 (<0.1)	1 (<0.1)	3 (<0.1)
FROVATRIPTAN SUCCINATE MONOHYDRATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
GADOBUTROL	0	1 (<0.1)	1 (<0.1)
GALCANEZUMAB GNLM	1 (<0.1)	1 (<0.1)	2 (<0.1)
GALPHIMIA GLAUCA FLOWERING TOP;LUFFA OPERCULATA FRUIT;SCHOENOCAULON OFFICINALE SEED	1 (<0.1)	1 (<0.1)	2 (<0.1)
GAMMA-AMINOBUTYRIC ACID	1 (<0.1)	1 (<0.1)	2 (<0.1)
GAMMA-AMINOBUTYRIC ACID;THEANINE	0	1 (<0.1)	1 (<0.1)
GANCICLOVIR	1 (<0.1)	1 (<0.1)	2 (<0.1)
GANODERMA LUCIDUM	0	1 (<0.1)	1 (<0.1)
GANODERMA LUCIDUM;GRIFOLA FRONDOSA;LENTINUS EDODES	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
GARCINIA KOLA	0	1 (<0.1)	1 (<0.1)
GATIFLOXACIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
GELATINE HYDROLYSATE;MAGNESIUM CARBONATE	0	1 (<0.1)	1 (<0.1)
GENISTEIN	0	1 (<0.1)	1 (<0.1)
GENTAMICIN	3 (<0.1)	1 (<0.1)	4 (<0.1)
GENTAMICIN SULFATE	0	1 (<0.1)	1 (<0.1)
GINKGO BILOBA EXTRACT;MELILOTUS OFFICINALIS;RUTOSIDE	0	1 (<0.1)	1 (<0.1)
GINKGO BILOBA LEAF	0	1 (<0.1)	1 (<0.1)
GINKGO BILOBA LEAF EXTRACT	1 (<0.1)	1 (<0.1)	2 (<0.1)
GLATIRAMER ACETATE	0	1 (<0.1)	1 (<0.1)
GLUCOSAMINE HYDROCHLORIDE;HYALURONIC ACID;METHYLSULFONYLMETHANE	0	1 (<0.1)	1 (<0.1)
GLUCOSAMINE;OMEGA-3 FATTY ACIDS	0	1 (<0.1)	1 (<0.1)
GLUCOSE;SODIUM CHLORIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
GLYCEROL;HYPROMELLOSE;MACROGOL 400;TETRYZOLINE HYDROCHLORIDE;ZINC SULFATE	0	1 (<0.1)	1 (<0.1)
GLYCEROL;NAPHAZOLINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
GLYCOPYRRONIUM TOSYLATE	0	1 (<0.1)	1 (<0.1)
GLYCYRRHIZA GLABRA	0	1 (<0.1)	1 (<0.1)
GRAMICIDIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	0	1 (<0.1)	1 (<0.1)
GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
GUAIFENESIN;PHENYLEPHRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
GYMNEMA SYLVESTRE	1 (<0.1)	1 (<0.1)	2 (<0.1)
GYMNEMA SYLVESTRE LEAF;LAGERSTROEMIA SPECIOSA LEAF;MORUS ALBA LEAF;THIOCTIC ACID	0	1 (<0.1)	1 (<0.1)
HALCINONIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
HALOPERIDOL	2 (<0.1)	1 (<0.1)	3 (<0.1)
HALOPERIDOL LACTATE	0	1 (<0.1)	1 (<0.1)
HAMAMELIS VIRGINIANA EXTRACT	0	1 (<0.1)	1 (<0.1)
HELIANTHUS ANNUUS SEED OIL;LINUM USITATISSIMUM SEED OIL;SESAMUM INDICUM SEED OIL	0	1 (<0.1)	1 (<0.1)
HERBAL EXTRACT NOS;HOMEOPATHICS NOS	0	1 (<0.1)	1 (<0.1)
HERBAL NOS;MINERALS NOS	1 (<0.1)	1 (<0.1)	2 (<0.1)
HERBAL POLLEN NOS;QUERCETIN	0	1 (<0.1)	1 (<0.1)
HERBAL REMEDIES WITH ESTROGEN-LIKE ACTIVITY	0	1 (<0.1)	1 (<0.1)
HIPPOPHAE RHAMNOIDES	0	1 (<0.1)	1 (<0.1)
HORDEUM VULGARE	0	1 (<0.1)	1 (<0.1)
HUPERZINE A	0	1 (<0.1)	1 (<0.1)
HYALURONATE SODIUM;MACROGOL 400;PROPYLENE GLYCOL	0	1 (<0.1)	1 (<0.1)
HYDRALAZINE HYDROCHLORIDE;HYDROCHLOROTHIAZIDE	0	1 (<0.1)	1 (<0.1)
HYDRASTIS CANADENSIS	0	1 (<0.1)	1 (<0.1)
HYDROCHLOROTHIAZIDE;LISINOPRIL DIHYDRATE	3 (<0.1)	1 (<0.1)	4 (<0.1)
HYDROCHLOROTHIAZIDE;METOPROLOL TARTRATE	0	1 (<0.1)	1 (<0.1)
HYDROCHLOROTHIAZIDE;NEBIVOLOL	0	1 (<0.1)	1 (<0.1)
HYDROCHLOROTHIAZIDE;QUINAPRIL	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
HYDROCORTISONE SODIUM SUCCINATE	0	1 (<0.1)	1 (<0.1)
HYDROCORTISONE;NEOMYCIN;POLYMYXIN B	3 (<0.1)	1 (<0.1)	4 (<0.1)
HYDROCORTISONE;PRAMOCAINE	0	1 (<0.1)	1 (<0.1)
HYDROQUININE	0	1 (<0.1)	1 (<0.1)
HYDROXOCOBALAMIN ACETATE	0	1 (<0.1)	1 (<0.1)
HYDROXYCHLOROQUINE SULFATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
HYDROXYPROGESTERONE	0	1 (<0.1)	1 (<0.1)
HYDROXYZINE EMBONATE	3 (<0.1)	1 (<0.1)	4 (<0.1)
HYOSCINE BUTYLBROMIDE;PARACETAMOL	0	1 (<0.1)	1 (<0.1)
HYOSCYAMINE SULFATE;METHENAMINE;METHYLTHIONINIUM CHLORIDE;SODIUM PHOSPHATE MONOBASIC	0	1 (<0.1)	1 (<0.1)
HYPROMELLOSE;NAPHAZOLINE HYDROCHLORIDE;POLYSORBATE 80;ZINC SULFATE	0	1 (<0.1)	1 (<0.1)
HYSSOPUS OFFICINALIS;MALVA SYLVESTRIS;MARRUBIUM VULGARE;MELISSA OFFICINALIS;MENTHA X PIPERITA;SALVIA OFFICINALIS;SAMBUCUS NIGRA;THYMUS SERPYLLUM;THYMUS VULGARIS;TILIA PLATYPHYLLOS	1 (<0.1)	1 (<0.1)	2 (<0.1)
IBANDRONIC ACID	2 (<0.1)	1 (<0.1)	3 (<0.1)
IBUPROFEN;PSEUDOEPHEDRINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
IMMUNOSTIMULANTS	0	1 (<0.1)	1 (<0.1)
INSULIN DEGLUDEC;LIRAGLUTIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
INSULIN GLULISINE	2 (<0.1)	1 (<0.1)	3 (<0.1)
INSULIN ISOPHANE BOVINE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
INSULIN LISPRO PROTAMINE SUSPENSION	0	1 (<0.1)	1 (<0.1)
INTERFERON BETA-1A	1 (<0.1)	1 (<0.1)	2 (<0.1)
INULIN;LACTOBACILLUS RHAMNOSUS	0	1 (<0.1)	1 (<0.1)
IOPROMIDE	0	1 (<0.1)	1 (<0.1)
IRON DEXTRAN	0	1 (<0.1)	1 (<0.1)
IRON IN OTHER COMBINATIONS	0	1 (<0.1)	1 (<0.1)
ISONIAZID	0	1 (<0.1)	1 (<0.1)
ISOSORBIDE DINITRATE	3 (<0.1)	1 (<0.1)	4 (<0.1)
ISOXSUPRINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
IVABRADINE HYDROCHLORIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
KERATIN	4 (<0.1)	1 (<0.1)	5 (<0.1)
KETOCONAZOLE;TRIAMCINOLONE	0	1 (<0.1)	1 (<0.1)
LACTITOL MONOHYDRATE;PLANTAGO OVATA HUSK	0	1 (<0.1)	1 (<0.1)
LACTOBACILLUS PLANTARUM	0	1 (<0.1)	1 (<0.1)
LAVANDULA ANGUSTIFOLIA;MATRICARIA RECUTITA;MELATONIN;MELISSA OFFICINALIS	0	1 (<0.1)	1 (<0.1)
LEVOBUNOLOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
LEVOBUNOLOL HYDROCHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
LEVODOPA	1 (<0.1)	1 (<0.1)	2 (<0.1)
LEVOMEFOLIC ACID;MECOBALAMIN	0	1 (<0.1)	1 (<0.1)
LEVOPROPYLHEXEDRINE	0	1 (<0.1)	1 (<0.1)
LIDOCAINE HYDROCHLORIDE;MENTHOL	0	1 (<0.1)	1 (<0.1)
LIDOCAINE;MENTHOL	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
LIDOCAINE;TRIAMCINOLONE	0	1 (<0.1)	1 (<0.1)
LINEZOLID	2 (<0.1)	1 (<0.1)	3 (<0.1)
LINOLENIC ACID	1 (<0.1)	1 (<0.1)	2 (<0.1)
LIPASE	0	1 (<0.1)	1 (<0.1)
LIXISENATIDE	0	1 (<0.1)	1 (<0.1)
LOPERAMIDE;SIMETICONE	1 (<0.1)	1 (<0.1)	2 (<0.1)
LOTEPREDNOL ETABONATE;TOBRAMYCIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
LOXOPROFEN	1 (<0.1)	1 (<0.1)	2 (<0.1)
LURASIDONE	0	1 (<0.1)	1 (<0.1)
LYCOPENE;PINUS SPP. BARK;PRUNUS AFRICANA BARK;SELENIUM AMINO ACID CHELATE;SERENOA REPENS FRUIT;SITOSTEROL;URTICA DIOICA LEAF;VITIS SPP.;ZINC	2 (<0.1)	1 (<0.1)	3 (<0.1)
MACROGOL 400	1 (<0.1)	1 (<0.1)	2 (<0.1)
MACROGOL;NAPHAZOLINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE;SODIUM SULFATE	0	1 (<0.1)	1 (<0.1)
MAGNESIUM ASPARTATE;MAGNESIUM CITRATE;MAGNESIUM OXIDE	0	1 (<0.1)	1 (<0.1)
MAGNESIUM ASPARTATE;MANGANESE AMINO ACID CHELATE;PYRIDOXINE HYDROCHLORIDE;ZINC AMINO ACID CHELATE	0	1 (<0.1)	1 (<0.1)
MAGNESIUM CARBONATE	0	1 (<0.1)	1 (<0.1)
MAGNESIUM CHLORIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MAGNESIUM MALATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MAGNESIUM SULFATE;POTASSIUM SULFATE;SODIUM SULFATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MAGNESIUM TAURATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MAGNESIUM;PYRIDOXINE HYDROCHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MAGNESIUM;SODIUM CHLORIDE	0	1 (<0.1)	1 (<0.1)
MAGNOLIA OFFICINALIS BARK;PHELLODENDRON AMURENSE BARK	1 (<0.1)	1 (<0.1)	2 (<0.1)
MAHONIA AQUIFOLIUM	0	1 (<0.1)	1 (<0.1)
MANGANESE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MANGANESE AMINO ACID CHELATE	0	1 (<0.1)	1 (<0.1)
MECOBALAMIN	3 (<0.1)	1 (<0.1)	4 (<0.1)
MEGESTROL	2 (<0.1)	1 (<0.1)	3 (<0.1)
MELALEUCA ALTERNIFOLIA OIL	1 (<0.1)	1 (<0.1)	2 (<0.1)
MENAQUINONE	5 (<0.1)	1 (<0.1)	6 (<0.1)
MENAQUINONE-7;MENATETRENONE;PHYTOMENADIONE;STEVIA REBAUDIANA LEAF	0	1 (<0.1)	1 (<0.1)
MEPOLIZUMAB	2 (<0.1)	1 (<0.1)	3 (<0.1)
MEQUITAZINE	0	1 (<0.1)	1 (<0.1)
MEROPENEM	0	1 (<0.1)	1 (<0.1)
MESO ZEAXANTHIN;XANTOFYL;ZEAXANTHIN	2 (<0.1)	1 (<0.1)	3 (<0.1)
METAMFETAMINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
METHADONE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
METHENAMINE	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MEXILETINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MICONAZOLE	4 (<0.1)	1 (<0.1)	5 (<0.1)
MIDAZOLAM HYDROCHLORIDE	4 (<0.1)	1 (<0.1)	5 (<0.1)
MILNACIPRAN	0	1 (<0.1)	1 (<0.1)
MINERAL SUPPLEMENTS	2 (<0.1)	1 (<0.1)	3 (<0.1)
MITRAGYNA SPECIOSA	0	1 (<0.1)	1 (<0.1)
MODIFIED CITRUSPECTIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
MONASCUS PURPUREUS;UBIDECARENONE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MORINDA CITRIFOLIA FRUIT	0	1 (<0.1)	1 (<0.1)
MOXIFLOXACIN HYDROCHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
MOXIFLOXACIN;NEPAFENAC;PREDNISOLONE	0	1 (<0.1)	1 (<0.1)
MUCUNA PRURIENS	1 (<0.1)	1 (<0.1)	2 (<0.1)
N,N-DIMETHYLGLYCINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
N-ACETYLGLUCOSAMINE	0	1 (<0.1)	1 (<0.1)
NALOXONE	0	1 (<0.1)	1 (<0.1)
NAPHAZOLINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
NAPROXEN SODIUM;SUMATRIPTAN	0	1 (<0.1)	1 (<0.1)
NAPROXEN SODIUM;SUMATRIPTAN SUCCINATE	0	1 (<0.1)	1 (<0.1)
NAPROXEN;SUMATRIPTAN	0	1 (<0.1)	1 (<0.1)
NASAL DECONGESTANTS FOR TOPICAL USE	0	1 (<0.1)	1 (<0.1)
NATALIZUMAB	0	1 (<0.1)	1 (<0.1)
NEOMYCIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
NEOMYCIN HYDROCHLORIDE;POLYMYXIN B SULFATE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
NEOMYCIN;POLYMYXIN B	0	1 (<0.1)	1 (<0.1)
NEOMYCIN;POLYMYXIN B SULFATE	0	1 (<0.1)	1 (<0.1)
NETARSUDIL	0	1 (<0.1)	1 (<0.1)
NICARDIPINE	2 (<0.1)	1 (<0.1)	3 (<0.1)
NIMESULIDE	0	1 (<0.1)	1 (<0.1)
NINTEDANIB ESILATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
NISOLDIPINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
NITAZOXANIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
NITRIC ACID	0	1 (<0.1)	1 (<0.1)
NITROGEN, LIQUID	1 (<0.1)	1 (<0.1)	2 (<0.1)
NIZATIDINE	0	1 (<0.1)	1 (<0.1)
NYSTATIN;TRIAMCINOLONE	4 (<0.1)	1 (<0.1)	5 (<0.1)
OCIMUM TENUIFLORUM	0	1 (<0.1)	1 (<0.1)
OCRILATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
OLODATEROL;TIOTROPIUM	2 (<0.1)	1 (<0.1)	3 (<0.1)
OMEGA 9 FATTY ACIDS	0	1 (<0.1)	1 (<0.1)
OMEGA-3 FATTY ACIDS;VITAMIN E NOS	0	1 (<0.1)	1 (<0.1)
OMEGA-6 FATTY ACIDS	0	1 (<0.1)	1 (<0.1)
OMEPRAZOLE MAGNESIUM	1 (<0.1)	1 (<0.1)	2 (<0.1)
OMEPRAZOLE SODIUM	0	1 (<0.1)	1 (<0.1)
OMEPRAZOLE;SODIUM BICARBONATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
OPIUM ALKALOIDS AND DERIVATIVES	0	1 (<0.1)	1 (<0.1)
OSELTAMIVIR PHOSPHATE	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
OTHER AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	0	1 (<0.1)	1 (<0.1)
OTHER ANALGESICS AND ANTIPYRETICS	0	1 (<0.1)	1 (<0.1)
OTHER ANTIFUNGALS FOR TOPICAL USE	0	1 (<0.1)	1 (<0.1)
OTHER ANTIMIGRAINE PREPARATIONS	0	1 (<0.1)	1 (<0.1)
OTHER BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS	2 (<0.1)	1 (<0.1)	3 (<0.1)
OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS	0	1 (<0.1)	1 (<0.1)
OTHER INTESTINAL ADSORBENTS	0	1 (<0.1)	1 (<0.1)
OTHER MINERAL PRODUCTS	0	1 (<0.1)	1 (<0.1)
OTHER NASAL PREPARATIONS	0	1 (<0.1)	1 (<0.1)
OTHER OTOLOGICALS	1 (<0.1)	1 (<0.1)	2 (<0.1)
OTHER PLAIN VITAMIN PREPARATIONS	0	1 (<0.1)	1 (<0.1)
OTHER UROLOGICALS	0	1 (<0.1)	1 (<0.1)
OTOLOGICALS	1 (<0.1)	1 (<0.1)	2 (<0.1)
OXAZEPAM	1 (<0.1)	1 (<0.1)	2 (<0.1)
OXAZOLAM	0	1 (<0.1)	1 (<0.1)
OXOGLURIC ACID	0	1 (<0.1)	1 (<0.1)
OXYBATE SODIUM	3 (<0.1)	1 (<0.1)	4 (<0.1)
P-PHENOLSULFONIC ACID;SULFURIC ACID	0	1 (<0.1)	1 (<0.1)
PACLITAXEL	0	1 (<0.1)	1 (<0.1)
PALIPERIDONE	0	1 (<0.1)	1 (<0.1)
PALIPERIDONE PALMITATE	4 (<0.1)	1 (<0.1)	5 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PAMABROM	0	1 (<0.1)	1 (<0.1)
PAMABROM;PARACETAMOL	1 (<0.1)	1 (<0.1)	2 (<0.1)
PAPAVERINE	0	1 (<0.1)	1 (<0.1)
PARACETAMOL;PYRIDOXINE HYDROCHLORIDE;VITAMIN B1 NOS;VITAMIN B12 NOS	0	1 (<0.1)	1 (<0.1)
PARACETAMOL;TRAMADOL	0	1 (<0.1)	1 (<0.1)
PARAFFIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
PASSIFLORA INCARNATA HERB	0	1 (<0.1)	1 (<0.1)
PAULLINIA CUPANA	1 (<0.1)	1 (<0.1)	2 (<0.1)
PECTIN	0	1 (<0.1)	1 (<0.1)
PEGVALIASE	0	1 (<0.1)	1 (<0.1)
PENICILLAMINE	0	1 (<0.1)	1 (<0.1)
PENTAZOCINE	0	1 (<0.1)	1 (<0.1)
PENTOSAN POLYSULFATE	0	1 (<0.1)	1 (<0.1)
PEPSIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
PEPTIDES NOS	0	1 (<0.1)	1 (<0.1)
PERINDOPRIL	2 (<0.1)	1 (<0.1)	3 (<0.1)
PERMETHRIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
PERTUSSIS VACCINE	0	1 (<0.1)	1 (<0.1)
PETASITES HYBRIDUS RHIZOME	0	1 (<0.1)	1 (<0.1)
PETROLATUM	0	1 (<0.1)	1 (<0.1)
PETROLATUM;WOOL FAT	0	1 (<0.1)	1 (<0.1)
PHASEOLUS VULGARIS	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PHENTERMINE;TOPIRAMATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
PHENYLEPHRINE HYDROCHLORIDE;THEOBROMA CACAO OIL	0	1 (<0.1)	1 (<0.1)
PILOCARPINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
PIRFENIDONE	3 (<0.1)	1 (<0.1)	4 (<0.1)
PITAVASTATIN	4 (<0.1)	1 (<0.1)	5 (<0.1)
PITOLISANT HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
PNEUMOCOCCAL VACCINE POLYSACCH	1 (<0.1)	1 (<0.1)	2 (<0.1)
POLY-L-LACTIC ACID	2 (<0.1)	1 (<0.1)	3 (<0.1)
POLYCARBOPHIL	0	1 (<0.1)	1 (<0.1)
POLYMYXIN B	3 (<0.1)	1 (<0.1)	4 (<0.1)
POLYMYXIN B SULFATE	0	1 (<0.1)	1 (<0.1)
POLYPODIUM LEUCATOMOS	2 (<0.1)	1 (<0.1)	3 (<0.1)
POMALIDOMIDE	0	1 (<0.1)	1 (<0.1)
POTASSIUM CARBONATE	0	1 (<0.1)	1 (<0.1)
POTASSIUM IODIDE	0	1 (<0.1)	1 (<0.1)
POTASSIUM MAGNESIUM ASPARTATE	0	1 (<0.1)	1 (<0.1)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (MONOHYDRATE)	1 (<0.1)	1 (<0.1)	2 (<0.1)
POVIDONE-IODINE	0	1 (<0.1)	1 (<0.1)
PRAMLINTIDE	0	1 (<0.1)	1 (<0.1)
PRAMOCAINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
PRAZOSIN HYDROCHLORIDE	7 (<0.1)	1 (<0.1)	8 (<0.1)
PREDNISOLONE SODIUM PHOSPHATE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PREGNENOLONE	2 (<0.1)	1 (<0.1)	3 (<0.1)
PROBIOTICS [UMBRELLA TERM]	0	1 (<0.1)	1 (<0.1)
PROCHLORPERAZINE MALEATE	0	1 (<0.1)	1 (<0.1)
PROPYLTHIOURACIL	0	1 (<0.1)	1 (<0.1)
PROTEASE NOS	0	1 (<0.1)	1 (<0.1)
PSEUDOEPHEDRINE SULFATE	0	1 (<0.1)	1 (<0.1)
PYRIDOSTIGMINE BROMIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
PYRIDOXINE;THIAMINE	0	1 (<0.1)	1 (<0.1)
PYRITHIONE ZINC	0	1 (<0.1)	1 (<0.1)
QUERCETIN DIHYDRATE	0	1 (<0.1)	1 (<0.1)
QUININE	1 (<0.1)	1 (<0.1)	2 (<0.1)
RABIES VACCINE INACT (HUMAN DIPLOID)	0	1 (<0.1)	1 (<0.1)
RAMELTEON	3 (<0.1)	1 (<0.1)	4 (<0.1)
RAUVOLFIA SERPENTINA	0	1 (<0.1)	1 (<0.1)
REMIFENTANIL	0	1 (<0.1)	1 (<0.1)
RHAMNUS PURSHIANA	0	1 (<0.1)	1 (<0.1)
RHEUM PALMATUM	0	1 (<0.1)	1 (<0.1)
RHODIOLA ROSEA ROOT	1 (<0.1)	1 (<0.1)	2 (<0.1)
RIBES NIGRUM	0	1 (<0.1)	1 (<0.1)
RIFABUTIN	1 (<0.1)	1 (<0.1)	2 (<0.1)
RILPIVIRINE HYDROCHLORIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
ROSIGLITAZONE	0	1 (<0.1)	1 (<0.1)
SACROSIDASE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
SALMETEROL	3 (<0.1)	1 (<0.1)	4 (<0.1)
SALSALATE	0	1 (<0.1)	1 (<0.1)
SALVIA HISPANICA	0	1 (<0.1)	1 (<0.1)
SELENOMETHIONINE (75 SE);XANTOFYL	0	1 (<0.1)	1 (<0.1)
SELEXIPAG	0	1 (<0.1)	1 (<0.1)
SENNA ALEXANDRINA	2 (<0.1)	1 (<0.1)	3 (<0.1)
SERINE	0	1 (<0.1)	1 (<0.1)
SERMORELIN ACETATE	0	1 (<0.1)	1 (<0.1)
SERTACONAZOLE NITRATE	0	1 (<0.1)	1 (<0.1)
SEVELAMER CARBONATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
SIBUTRAMINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
SILVER	3 (<0.1)	1 (<0.1)	4 (<0.1)
SILVER COLLOIDAL	0	1 (<0.1)	1 (<0.1)
SODIUM	1 (<0.1)	1 (<0.1)	2 (<0.1)
SODIUM ACEXAMATE	0	1 (<0.1)	1 (<0.1)
SODIUM LAURYL SULFATE	0	1 (<0.1)	1 (<0.1)
SODIUM NITRATE	0	1 (<0.1)	1 (<0.1)
SODIUM PHOSPHATE	0	1 (<0.1)	1 (<0.1)
SODIUM POLYSTYRENE SULFONATE	1 (<0.1)	1 (<0.1)	2 (<0.1)
SODIUM SELENATE	0	1 (<0.1)	1 (<0.1)
SODIUM SULFATE	0	1 (<0.1)	1 (<0.1)
SOLRIAMFETOL	0	1 (<0.1)	1 (<0.1)
STOMATOLOGICAL PREPARATIONS	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
STYPHNOLOBIUM JAPONICUM	0	1 (<0.1)	1 (<0.1)
SUGAMMADEX	2 (<0.1)	1 (<0.1)	3 (<0.1)
SULFADIMIDINE	1 (<0.1)	1 (<0.1)	2 (<0.1)
TAGETES SPP.	1 (<0.1)	1 (<0.1)	2 (<0.1)
TAPENTADOL	0	1 (<0.1)	1 (<0.1)
TARAXACUM OFFICINALE	1 (<0.1)	1 (<0.1)	2 (<0.1)
TAVABOROLE	1 (<0.1)	1 (<0.1)	2 (<0.1)
TENOFOVIR ALAFENAMIDE	1 (<0.1)	1 (<0.1)	2 (<0.1)
TERCONAZOLE	2 (<0.1)	1 (<0.1)	3 (<0.1)
TERMINALIA CHEBULA FRUIT	0	1 (<0.1)	1 (<0.1)
TESAMORELIN	0	1 (<0.1)	1 (<0.1)
TETRACAINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
TETRYZOLINE	0	1 (<0.1)	1 (<0.1)
THEOBROMA CACAO	1 (<0.1)	1 (<0.1)	2 (<0.1)
THROAT PREPARATIONS	0	1 (<0.1)	1 (<0.1)
THYMALFASIN	2 (<0.1)	1 (<0.1)	3 (<0.1)
THYROID HORMONES	0	1 (<0.1)	1 (<0.1)
TIBOLONE	1 (<0.1)	1 (<0.1)	2 (<0.1)
TIOCONAZOLE	0	1 (<0.1)	1 (<0.1)
TOCOPHEROLS MIXED;TOCOTRIENOLS NOS	0	1 (<0.1)	1 (<0.1)
TOCOTRIENOLS NOS	0	1 (<0.1)	1 (<0.1)
TOLVAPTAN	1 (<0.1)	1 (<0.1)	2 (<0.1)
TREPROSTINIL	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
TRETOQUINOL HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
TRIBULUS TERRESTRIS EXTRACT	0	1 (<0.1)	1 (<0.1)
TRICHLOROACETIC ACID	0	1 (<0.1)	1 (<0.1)
TROSPIUM CHLORIDE	2 (<0.1)	1 (<0.1)	3 (<0.1)
TURNERA DIFFUSA LEAF	1 (<0.1)	1 (<0.1)	2 (<0.1)
ULMUS RUBRA	0	1 (<0.1)	1 (<0.1)
ULOBETASOL PROPIONATE	2 (<0.1)	1 (<0.1)	3 (<0.1)
UMECLIDINIUM	1 (<0.1)	1 (<0.1)	2 (<0.1)
URTICA DIOICA	0	1 (<0.1)	1 (<0.1)
URTICA DIOICA LEAF	0	1 (<0.1)	1 (<0.1)
URTICA DIOICA ROOT	0	1 (<0.1)	1 (<0.1)
VACCINIUM MACROCARPON FRUIT	2 (<0.1)	1 (<0.1)	3 (<0.1)
VALERIANA OFFICINALIS ROOT;VALERIANA OFFICINALIS ROOT EXTRACT	0	1 (<0.1)	1 (<0.1)
VALGANCICLOVIR	0	1 (<0.1)	1 (<0.1)
VALPROATE SODIUM	3 (<0.1)	1 (<0.1)	4 (<0.1)
VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS	4 (<0.1)	1 (<0.1)	5 (<0.1)
VILANTEROL	1 (<0.1)	1 (<0.1)	2 (<0.1)
VITAMIN B-COMPLEX WITH MINERALS	1 (<0.1)	1 (<0.1)	2 (<0.1)
VITAMIN B-COMPLEX, PLAIN	0	1 (<0.1)	1 (<0.1)
VITAMINS NOS;XANTOFYL	0	1 (<0.1)	1 (<0.1)
VITEX AGNUS-CASTUS EXTRACT	0	1 (<0.1)	1 (<0.1)
VORICONAZOLE	0	1 (<0.1)	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
WATER PURIFIED	0	1 (<0.1)	1 (<0.1)
YOHIMBINE HYDROCHLORIDE	0	1 (<0.1)	1 (<0.1)
ZINGIBER OFFICINALE RHIZOME	1 (<0.1)	1 (<0.1)	2 (<0.1)
ZIPRASIDONE HYDROCHLORIDE	3 (<0.1)	1 (<0.1)	4 (<0.1)
ZOPICLONE	0	1 (<0.1)	1 (<0.1)
ABACAVIR SULFATE;LAMIVUDINE	1 (<0.1)	0	1 (<0.1)
ABATACEPT	1 (<0.1)	0	1 (<0.1)
ACACIA SENEGAL;ASCORBIC ACID;BETACAROTENE;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM SILICATE;CELLULOSE MICROCRYSTALLINE;COLECALCIFEROL;CROSCARMELLOSE SODIUM;CYANOCOBALAMIN;DEXTRIN DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATE;FOLIC ACID;GELATIN;GLUCOSE;HYPROMELLOSE;LECITHIN;MACROGOL ;MAGNESIUM OXIDE;MAGNESIUM STEARATE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE RIBOFLAVIN;SILICON DIOXIDE;STARCH;THIAMINE MONONITRATE;TITANIUM DIOXIDE;ZINC OXIDE	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ACETYLCARNITINE HYDROCHLORIDE;BACOPA MONNIERI LEAF;DEANOL BITARTRATE;GINKGO BILOBA LEAF;HUPERZINE A;HYPERICUM PERFORATUM FLOWER;LECITHIN;LEVOGLUTAMIDE;PHOSPHATIDYL SERINE;VINPOCETINE	1 (<0.1)	0	1 (<0.1)
ACETYLCARNITINE;ATRACTYLODES LANCEA RHIZOME;CURCUMA LONGA RHIZOME;CYANOCOBALAMIN;FOLIC ACID;PHELLODENDRON AMURENSE BARK;PHOSPHATIDYL CHOLINE;PYRIDOXINE HYDROCHLORIDE;SCUTELLARIA BAICALENSIS ROOT THIAMINE HYDROCHLORIDE;THIOCTIC ACID	1 (<0.1)	0	1 (<0.1)
ACETYLCARNITINE;CALCIUM PANTOTHENATE;CHOLINE BITARTRATE;GINKGO BILOBA;HUPERZINE A;IDEBENONE;MECOBALAMIN;PHOSPHATIDYL CHOLINE;PHOSPHATIDYL SERINE;PYRIDOXINE;TYROSINE;VITIS VINIFERA	1 (<0.1)	0	1 (<0.1)
ACETYLCYSTEINE;BORON CITRATE;INOSITOL;MINERALS NOS;NUTRIENTS NOS;SODIUM METASILICATE;THIOCTIC ACID;UBIDECARENONE;VANADYL SULFATE;VITAMINS NOS	1 (<0.1)	0	1 (<0.1)
ACETYLCYSTEINE;CALCIUM MEFOLINATE;MECOBALAMIN	1 (<0.1)	0	1 (<0.1)
ACETYLCYSTEINE;SELENOMETHIONINE;SODIUM MOLYBDATE	1 (<0.1)	0	1 (<0.1)
ACETYLSALICYLIC ACID;BUTALBITAL	1 (<0.1)	0	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE;CODEINE PHOSPHATE	1 (<0.1)	0	1 (<0.1)
ACETYLSALICYLIC ACID;CHLORPHENAMINE;PHENYLEPHRINE	1 (<0.1)	0	1 (<0.1)
ACETYLSALICYLIC ACID;DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PHENYLEPHRINE BITARTRATE	1 (<0.1)	0	1 (<0.1)
ACETYLSALICYLIC ACID;DIPYRIDAMOLE	1 (<0.1)	0	1 (<0.1)
ACETYLSALICYLIC ACID;OXYCODONE HYDROCHLORIDE;OXYCODONE TEREPHTHALATE	1 (<0.1)	0	1 (<0.1)
ACORUS CALAMUS;BACOPA MONNIERI;CELASTRUS PANICULATUS;CENTELLA ASIATICA;EVOLVULUS ALSINOIDES;FOENICULUM VULGARE;GLYCYRRHIZA GLABRA;MYRISTICA FRAGRANS;TERMINALIA ARJUNA;WITHANIA SOMNIFERA	1 (<0.1)	0	1 (<0.1)
ACRIVASTINE;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ADRAFINIL	1 (<0.1)	0	1 (<0.1)
ADRENAL GLAND;CALCIUM	1 (<0.1)	0	1 (<0.1)
AGARICUS BLAZEI;CORDYCEPS SINENSIS;GANODERMA SPP.;GRIFOLA FRONDOSA;LENTINUS EDODES;TRAMETES VERSICOLOR	1 (<0.1)	0	1 (<0.1)
AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE	1 (<0.1)	0	1 (<0.1)
AJUGA FORRESTII	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ALANINE	1 (<0.1)	0	1 (<0.1)
ALANINE;ASPARTIC ACID;BIOFLAVONOIDS NOS;BIOTIN;CHOLINE BITARTRATE;CYSTEINE HYDROCHLORIDE;EQUISETUM ARVENSE HERB;FOLIC ACID;FUCUS VESICULOSUS WHOLE PLANT;GLYCINE;HISTIDINE;INOSITOL;IODINE;ISOLEUCINE LECITHIN;LEUCINE;LYSINE HYDROCHLORIDE;MAGNESIUM OXIDE HEAVY;MANGANESE SULFATE MONOHYDRATE;MINERALS NOS;NASTURTIUM OFFICINALE;ORNITHINE;PETROSELINUM CRISPUM HERB;PHENYLALANINE;PROLINE;ROSA CANINA RUTOSIDE;SERINE;THREONINE;TYROSINE;VALINE;VITAMINS NOS;YEAST DRIED	2 (<0.1)	0	2 (<0.1)
ALCLOMETASONE DIPROPIONATE	1 (<0.1)	0	1 (<0.1)
ALENDRONIC ACID	1 (<0.1)	0	1 (<0.1)
ALGAE NOS;BIOFLAVONOIDS NOS;CHOLINE BITARTRATE;ENZYMES NOS;FIBRE, DIETARY;FUNGI NOS;HERBAL NOS;MINERALS NOS;RUTOSIDE;VITAMINS NOS;XANTOFYL	1 (<0.1)	0	1 (<0.1)
ALISKIREN	1 (<0.1)	0	1 (<0.1)
ALLIUM CEPA;SESAMUM INDICUM	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ALLIUM SATIVUM BULB POWDER;ARCTIUM LAPPA ROOT;ASCORBIC ACID;ASTRAGALUS MONGHOLICUS ROOT;BETA VULGARIS ROOT;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;INOSITOL;NICOTINIC ACID PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SCHISANDRA CHINENSIS FRUIT;SENNA ALEXANDRINA LEAF;SILYBUM MARIANUM;TAURINE;THIAMINE HYDROCHLORIDE;VACCINIUM MACROCARPON FRUIT JUICE;ZINC MONOMETHIONINE	1 (<0.1)	0	1 (<0.1)
ALOE SPP.;LINUM USITATISSIMUM SEED	2 (<0.1)	0	2 (<0.1)
ALOE VERA JUICE	1 (<0.1)	0	1 (<0.1)
ALOSETRON HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ALPHA-1-ANTITRYPSIN	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ALPHA-CAROTENE;BETACAROTENE;BIOTIN;BRASSICA CRETICA;BRASSICA OLERACEA;CALCIUM;CALCIUM ASCORBATE;CALCIUM PANTOTHENATE;CARUM CARVI SEED;CHROMIUM;CITRUS SPP.;COLECALCIFEROL;COPPER;DIMAGNESIUM MALATE FERROUS BISGLYCINATE;FOLIC ACID;MAGNESIUM ASCORBATE;MANGANESE;MECOBALAMIN;MENAQUINONE-7;MENTH A X PIPERITA LEAF;NICOTINIC ACID;PETROSELINUM CRISPUM LEAF;PHYTOMENADIONE;POTASSIUM IODIDE PTEROCARPUS MARSUPIUM;PUNICA GRANATUM FRUIT;PYRIDOXINE HYDROCHLORIDE;QUERCETIN;RESVERATROL;RETINOL PALMITATE;RIBOFLAVIN;RUTOSIDE;SELENIUM;SPINACIA OLERACEA LEAF;TARAXACUM OFFICINALE LEAF THIAMINE MONONITRATE;VITAMIN E NOS;VITIS VINIFERA SEED;ZINC BIS GLYCINATE CHELATE;ZINGIBER OFFICINALE ROOT	1 (<0.1)	0	1 (<0.1)
ALPRENOLOL	1 (<0.1)	0	1 (<0.1)
ALPROSTADIL;PAPAVERINE HYDROCHLORIDE;PHENTOLAMINE MESILATE	2 (<0.1)	0	2 (<0.1)
ALUM;CAMPHOR;MENTHOL;PHENOL;SALICYLIC ACID	1 (<0.1)	0	1 (<0.1)
ALUMINIUM HYDROXIDE;MAGNESIUM TRISILICATE	2 (<0.1)	0	2 (<0.1)
AMANTADINE;CHLORPHENAMINE;PARACETAMOL	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
AMBRISENTAN	1 (<0.1)	0	1 (<0.1)
AMFEPRAMONE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
AMFETAMINE ASPARTATE	1 (<0.1)	0	1 (<0.1)
AMIKACIN	1 (<0.1)	0	1 (<0.1)
AMIKACIN SULFATE	1 (<0.1)	0	1 (<0.1)
AMINO ACIDS AND DERIVATIVES	1 (<0.1)	0	1 (<0.1)
AMINOBENZOIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CHOLINE BITARTRATE;CYANOCOBALAMIN;FOLIC ACID;INOSITOL;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
AMINOPHYLLINE DIHYDRATE	1 (<0.1)	0	1 (<0.1)
AMLODIPINE BESILATE;BENAZEPRIL	1 (<0.1)	0	1 (<0.1)
AMLODIPINE;ATORVASTATIN	4 (<0.1)	0	4 (<0.1)
AMLODIPINE;HYDROCHLOROTHIAZIDE;OLMESARTAN	1 (<0.1)	0	1 (<0.1)
AMMONIUM CHLORIDE;DEXTROMETHORPHAN HYDROBROMIDE;SODIUM CITRATE	1 (<0.1)	0	1 (<0.1)
AMORPHOPHALLUS KONJAC	1 (<0.1)	0	1 (<0.1)
AMOXICILLIN TRIHYDRATE	1 (<0.1)	0	1 (<0.1)
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	1 (<0.1)	0	1 (<0.1)
AMPICILLIN;SULBACTAM	2 (<0.1)	0	2 (<0.1)
ANAGRELIDE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ANESTHETICS, LOCAL	2 (<0.1)	0	2 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ANIMAL UNSPECIFIED;FUNGI NOS;HERBAL NOS;RIBONUCLEIC ACID;THYMUS GLAND;VITAMINS NOS	1 (<0.1)	0	1 (<0.1)
ANNONA MURICATA	1 (<0.1)	0	1 (<0.1)
ANTI ALLERGIC AGENTS	2 (<0.1)	0	2 (<0.1)
ANTIDIARRHEAL MICROORGANISMS	1 (<0.1)	0	1 (<0.1)
ANTIFUNGALS	1 (<0.1)	0	1 (<0.1)
ANTIHISTAMINES FOR TOPICAL USE	2 (<0.1)	0	2 (<0.1)
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	1 (<0.1)	0	1 (<0.1)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS	1 (<0.1)	0	1 (<0.1)
ARFORMOTEROL	1 (<0.1)	0	1 (<0.1)
ARGININE HYDROCHLORIDE;CITRULLINE	1 (<0.1)	0	1 (<0.1)
ARGININE;CAPSICUM ANNUUM FRUIT;CITICOLINE;EPIMEDIUM SAGITTATUM;GINKGO BILOBA LEAF;LEPIDIUM MEYENII ROOT;LINUM USITATISSIMUM SEED OIL;N,N-DIMETHYLGLYCINE;NADH;PANAX GINSENG LEAF;PAUSINYSTALIA JOHIMBE PIPER NIGRUM FRUIT;TRIBULUS SPP.;TYROSINE;ZINGIBER OFFICINALE RHIZOME	1 (<0.1)	0	1 (<0.1)
ARIPIPRAZOLE LAUROXIL	1 (<0.1)	0	1 (<0.1)
ARNICA MONTANA TINCTURE	1 (<0.1)	0	1 (<0.1)
ARONIA MELANOCARPA	1 (<0.1)	0	1 (<0.1)
ARTICAINE HYDROCHLORIDE;EPINEPHRINE BITARTRATE	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM CARBONATE;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE;CHROMIUM PICOLINATE;COLECALCIFEROL;COPPER SULFATE;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FERROUS FUMARATEFOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICOTINAMIDE;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SODIUM MOLYBDATE;SODIUM SELENATE THIAMINE MONONITRATE;ZINC OXIDE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHLORINE;CHROMIUM; COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;IRON;MAGNESIUM;MANGANESE;MOLYBDENUM;NIC OTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;POTASSIUM PYRIDOXINE HYDROCHLORIDE;RETINOL ACETATE;RIBOFLAVIN;SELENIUM;THIAMINE HYDROCHLORIDE;TOCOPHEROL;VITAMIN D NOS;ZINC	1 (<0.1)	0	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BETACAROTENE;CALCIUM CARBONATE;COLECALCIFEROL;DOCOSAHEXAENOIC ACID;FERROUS FUMARATE;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE;TOCOPHERYL ACETATE VITAMIN B12 NOS;ZINC OXIDE	2 (<0.1)	0	2 (<0.1)
ASCORBIC ACID;BETACAROTENE;CHROMIUM PICOLINATE;LYCOPENE;MECOBALAMIN;PYRIDOXINE;RETINOL ACETATE;RIBOFLAVIN;THIAMINE;TOCOPHERYL ACETATE;VITAMIN B12 NOS;XANTOFYL;ZINC SULFATE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BETACAROTENE;COPPER;MANGANESE;SELENIUM;TOCOPHERYL ACETATE;ZINC	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BIOFLAVONOIDS NOS;HESPERIDIN;RUTOSIDE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BIOFLAVONOIDS NOS;MAGNESIUM HYDROXIDE;SODIUM BICARBONATE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BIOFLAVONOIDS NOS;ROSA CANINA	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;IRON POLYSACCHARIDE COMPLEX;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1 (<0.1)	0	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;DEXPANTHENOL;ERGOCALCIFEROL;FOLIC ACID;MENADIONE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;THIAMINE HYDROCHLORIDE;TOCOPHEROL	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BIOTIN;CYANOCOBALAMIN;FOLIC ACID;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;THIAMINE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BIOTIN;FOLIC ACID;MECOBALAMIN;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BOSWELLIA SERRATA;CHONDROITIN SULFATE SODIUM;COLECALCIFEROL;GLUCOSAMINE SULFATE POTASSIUM CHLORIDE;MANGANESE SULFATE;METHYLSULFONYLMETHANE;SODIUM BORATE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;BOSWELLIA SERRATA;CHONDROITIN SULFATE SODIUM;GLUCOSAMINE SULFATE;MANGANESE SULFATE;METHYLSULFONYLMETHANE;SODIUM BORATE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;CALCIUM	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;CALCIUM PANTOTHENATE;CALCIUM PHOSPHATE DIBASIC;CYANOCOBALAMIN;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	4 (<0.1)	0	4 (<0.1)
ASCORBIC ACID;CALCIUM;MAGNESIUM;VITAMIN D NOS;ZINC	1 (<0.1)	0	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;CALENDULA OFFICINALIS;HAEMATOCOCCUS PLUVIALIS;SODIUM SELENATE;TOCOPHERYL ACETATE;VACCINIUM MYRTILLUS;ZINC SULFATE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;CAMELLIA SINENSIS;CHROMIUM AMINO ACID CHELATE;CITRUS AURANTIUM PEEL;DEANOL;ILEX PARAGUARIENSIS;NICOTINIC ACID;PIPER NIGRUM;TYROSINE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;CHLOROPHYLL;FERROUS SUCCINATE;FOLIC ACID;LIVER EXTRACT;VITAMIN B12 NOS	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;CHROMIUM;COPPER;CYANOCOBALAMIN;FOLIC ACID;IODINE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICOTINIC ACID;PANTOTHENIC ACID;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;THIAMINE TOCOPHEROL;VITAMIN D NOS;ZINC	2 (<0.1)	0	2 (<0.1)
ASCORBIC ACID;COLECALCIFEROL;CYANOCOBALAMIN;DOCUSATE SODIUM;FOLIC ACID;MAGNESIUM;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;THIAMINE HYDROCHLORIDE;TOCOPHEROL;ZINC	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;CUPRIC OXIDE;OMEGA-3 FATTY ACIDS;TOCOPHERYL ACETATE;XANTOFYL;ZEAXANTHIN;ZINC	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;CYANOCOBALAMIN;DOCUSATE SODIUM;FOLIC ACID;IRON PENTACARBONYL	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;ECHINACEA PURPUREA;HYDRASTIS CANADENSIS	1 (<0.1)	0	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ASCORBIC ACID;FERROUS FUMARATE;FOLIC ACID;IRON POLYSACCHARIDE COMPLEX;NICOTINIC ACID	3 (<0.1)	0	3 (<0.1)
ASCORBIC ACID;GLUCOSAMINE SULFATE	2 (<0.1)	0	2 (<0.1)
ASCORBIC ACID;IRON;VITAMIN B12 NOS	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;NICOTINIC ACID;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;ROSA CANINA FRUIT	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;ROSA CANINA;SODIUM ASCORBATE	1 (<0.1)	0	1 (<0.1)
ASCORBIC ACID;VITAMIN D NOS	1 (<0.1)	0	1 (<0.1)
ASPARTAME;COLESTYRAMINE	1 (<0.1)	0	1 (<0.1)
ASTAXANTHIN;FISH OIL;HYALURONIC ACID	1 (<0.1)	0	1 (<0.1)
ASTRAGALUS PROPINQUUS	1 (<0.1)	0	1 (<0.1)
ASTRAGALUS SPP. ROOT;CALCIUM CARBONATE;CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ATENOLOL;HYDROCHLOROTHIAZIDE	1 (<0.1)	0	1 (<0.1)
ATOVAQUONE;PROGUANIL HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ATROPINE SULFATE;MORPHINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ATTAPULGITE	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
AVENA SATIVA SEED;OCIMUM TENUIFLORUM;RHODIOLA ROSEA ROOT;SCHISANDRA CHINENSIS FRUIT;WITHANIA SOMNIFERA ROOT	1 (<0.1)	0	1 (<0.1)
AVOBENZONE;OCTINOXATE	1 (<0.1)	0	1 (<0.1)
AZATHIOPRINE	1 (<0.1)	0	1 (<0.1)
AZELASTINE HYDROCHLORIDE;FLUTICASONE PROPIONATE;SODIUM CHLORIDE	1 (<0.1)	0	1 (<0.1)
AZTREONAM	1 (<0.1)	0	1 (<0.1)
BACILLUS COAGULANS;BIFIDOBACTERIUM LACTIS;BIFIDOBACTERIUM LONGUM;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS HELVETICUS;LACTOBACILLUS PLANTARUM;SACCHAROMYCES BOULARDII	1 (<0.1)	0	1 (<0.1)
BACILLUS COAGULANS;CALCIUM CARBONATE	1 (<0.1)	0	1 (<0.1)
BACITRACIN ZINC	1 (<0.1)	0	1 (<0.1)
BACITRACIN ZINC;NEOMYCIN SULFATE;POLYMYXIN B	1 (<0.1)	0	1 (<0.1)
BACITRACIN ZINC;NEOMYCIN SULFATE;POLYMYXIN B SULFATE;PRAMOCAINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
BACITRACIN ZINC;POLYMYXIN B SULFATE	1 (<0.1)	0	1 (<0.1)
BACOPA MONNIERI	1 (<0.1)	0	1 (<0.1)
BACOPA MONNIERI HERB;CALCIUM CARBONATE;CALCIUM PHOSPHATE;CAMELLIA SINENSIS LEAF;CURCUMA LONGA RHIZOME;SILYBUM MARIANUM SEED;WITHANIA SOMNIFERA ROOT	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BARIUM SULFATE	1 (<0.1)	0	1 (<0.1)
BAZEDOXIFENE ACETATE;ESTROGENS CONJUGATED	1 (<0.1)	0	1 (<0.1)
BEE POLLEN	2 (<0.1)	0	2 (<0.1)
BEE VENOM	2 (<0.1)	0	2 (<0.1)
BEMPEDOIC ACID	2 (<0.1)	0	2 (<0.1)
BENZOYL PEROXIDE;ERYTHROMYCIN	3 (<0.1)	0	3 (<0.1)
BENZYL ALCOHOL;CETYLPYRIDINIUM	1 (<0.1)	0	1 (<0.1)
BENZYLPENICILLIN	1 (<0.1)	0	1 (<0.1)
BETA-ALANINE	1 (<0.1)	0	1 (<0.1)
BETA-HYDROXYBUTYRIC ACID	1 (<0.1)	0	1 (<0.1)
BETACAROTENE;CALCIUM CARBONATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SODIUM ASCORBATE;THIAMINE HYDROCHLORIDE;TOCOPHERYL ACETATE	1 (<0.1)	0	1 (<0.1)
BETAMETHASONE VALERATE	1 (<0.1)	0	1 (<0.1)
BETAMETHASONE;INDOMETACIN;METHOCARBAMOL	1 (<0.1)	0	1 (<0.1)
BETAMETHASONE;LIDOCAINE	1 (<0.1)	0	1 (<0.1)
BIFIDOBACTERIUM ANIMALIS;LACTOBACILLUS ACIDOPHILUS	1 (<0.1)	0	1 (<0.1)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM BREVE;LACTOBACILLUS ACIDOPHILUS;LACTOBACILLUS CASEI;LACTOBACILLUS PLANTARUM;LACTOBACILLUS RHAMNOSUS;PEDIOCOCCUS ACIDILACTICI;STREPTOCOCCUS LACTIS	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BIFIDOBACTERIUM BIFIDUM;BIFIDOBACTERIUM LONGUM;INULIN;LACTOBACILLUS GASSERI	1 (<0.1)	0	1 (<0.1)
BIMATOPROST;BRIMONIDINE;TIMOLOL	1 (<0.1)	0	1 (<0.1)
BIOTIN;CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FOLIC ACID;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1 (<0.1)	0	1 (<0.1)
BIOTIN;CHOLINE BITARTRATE;CYANOCOBALAMIN;FOLIC ACID;INOSITOL;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
BISMUTH SUBCITRATE POTASSIUM;METRONIDAZOLE;TETRACYCLINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
BORAGO OFFICINALIS OIL;FISH OIL;LINUM USITATISSIMUM OIL	5 (<0.1)	0	5 (<0.1)
BORON;BOSWELLIA SERRATA GUM;BROMELAINS;CHONDROITIN SULFATE;GLUCOSAMINE SULFATE;GLYCINE MAX;HYALURONATE SODIUM;METHYLSULFONYLMETHANE;RUTOSIDE;TRYPSIN;UNCARIA TOMENTOSA BARK	1 (<0.1)	0	1 (<0.1)
BORON;CALCIUM;COLECALCIFEROL;COPPER;MAGNESIUM;ZINC	1 (<0.1)	0	1 (<0.1)
BOSWELLIA SACRA	1 (<0.1)	0	1 (<0.1)
BOSWELLIA SERRATA GUM RESIN	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
BOSWELLIA SERRATA;CHONDROITIN SULFATE;COLECALCIFEROL;GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	1 (<0.1)	0	1 (<0.1)
BOSWELLIA SERRATA;CURCUMA LONGA RHIZOME	1 (<0.1)	0	1 (<0.1)
BREMELANOTIDE ACETATE	1 (<0.1)	0	1 (<0.1)
BROMFENAC;GATIFLOXACIN;PREDNISOLONE	1 (<0.1)	0	1 (<0.1)
BROMHEXINE;SULFADIAZINE;TETROXOPRIM	1 (<0.1)	0	1 (<0.1)
BROMOCRIPTINE MESILATE	1 (<0.1)	0	1 (<0.1)
BULK-FORMING LAXATIVES	2 (<0.1)	0	2 (<0.1)
BUPIVACAINE HYDROCHLORIDE;EPINEPHRINE	1 (<0.1)	0	1 (<0.1)
BUTENAFINE HYDROCHLORIDE	2 (<0.1)	0	2 (<0.1)
BUTYRIC ACID	1 (<0.1)	0	1 (<0.1)
BUTYRIC ACID;CALCIUM PHOSPHATE;MAGNESIUM OXIDE	1 (<0.1)	0	1 (<0.1)
CAFFEINE;ERGOTAMINE	1 (<0.1)	0	1 (<0.1)
CAFFEINE;IBUPROFEN;PARACETAMOL	1 (<0.1)	0	1 (<0.1)
CAFFEINE;MEPYRAMINE;PARACETAMOL	1 (<0.1)	0	1 (<0.1)
CALCITONIN	3 (<0.1)	0	3 (<0.1)
CALCIUM AMINOACETATE;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;GAMOLENIC ACID;MAGNESIUM GLYCINATE;MOLYBDENUM AMINO ACID CHELATE;NICOTINIC ACID;PYRIDOXAL PHOSPHATE;TAURINE;TOCOPHERYL ACID SUCCINATE ZINC GLYCINATE	1 (<0.1)	0	1 (<0.1)
CALCIUM AMINOACETATE;MAGNESIUM GLYCINATE	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CALCIUM ASCORBATE;MAGNESIUM ASCORBATE;POTASSIUM ASCORBATE;VACCINIUM MYRTILLUS FRUIT;XANTOFYL;ZEAXANTHIN;ZINC ASCORBATE;ZINC CITRATE	1 (<0.1)	0	1 (<0.1)
CALCIUM CARBONATE;CALCIUM CITRATE;COLECALCIFEROL	1 (<0.1)	0	1 (<0.1)
CALCIUM CARBONATE;COLECALCIFEROL;COPPER SULFATE;MAGNESIUM CARBONATE;MAGNESIUM OXIDE;MANGANESE SULFATE;ZINC OXIDE	1 (<0.1)	0	1 (<0.1)
CALCIUM CARBONATE;COLECALCIFEROL;INULIN	1 (<0.1)	0	1 (<0.1)
CALCIUM CARBONATE;MAGNESIUM	1 (<0.1)	0	1 (<0.1)
CALCIUM CITRATE;COLECALCIFEROL;MAGNESIUM	1 (<0.1)	0	1 (<0.1)
CALCIUM FRUCTOBORATE;CHONDROITIN SULFATE;COLECALCIFEROL;GLUCOSAMINE HYDROCHLORIDE;HYALURONIC ACID;METHYLSULFONYLMETHANE	1 (<0.1)	0	1 (<0.1)
CALCIUM GLYCEROPHOSPHATE;CALCIUM PHOSPHATE;GLUTAMIC ACID;VITAMIN B NOS	1 (<0.1)	0	1 (<0.1)
CALCIUM PHOSPHATE;VITAMIN D NOS	1 (<0.1)	0	1 (<0.1)
CALCIUM;CHLORIDE;MAGNESIUM	1 (<0.1)	0	1 (<0.1)
CALCIUM;COLECALCIFEROL;COPPER;MANGANESE;ZINC	1 (<0.1)	0	1 (<0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM OXIDE;ZINC	1 (<0.1)	0	1 (<0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM;PHOSPHORUS	1 (<0.1)	0	1 (<0.1)
CALCIUM;COLECALCIFEROL;MAGNESIUM;ZINC	1 (<0.1)	0	1 (<0.1)
CALCIUM;DURAPATITE	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CALCIUM;MAGNESIUM;ZINC GLUCONATE	2 (<0.1)	0	2 (<0.1)
CALCIUM;VITAMIN B12 NOS	1 (<0.1)	0	1 (<0.1)
CALENDULA OFFICINALIS;GRINDELIA ROBUSTA;PLANTAGO MAJOR	1 (<0.1)	0	1 (<0.1)
CAMPHOR;EUCALYPTUS SPP. OIL;MENTHOL	1 (<0.1)	0	1 (<0.1)
CANNABINOL	1 (<0.1)	0	1 (<0.1)
CAPSAICIN;LIDOCAINE;MENTHOL;METHYL SALICYLATE	1 (<0.1)	0	1 (<0.1)
CARALLUMA ADSCENDENS VAR. FIMBRIATA	1 (<0.1)	0	1 (<0.1)
CARBIDOPA;ENTACAPONE;LEVODOPA	1 (<0.1)	0	1 (<0.1)
CARBOHYDRATES NOS;CHOLESTEROL;ENZYMES NOS;FATS NOS;HERBAL NOS;MINERALS NOS;NUTRIENTS NOS;PROBIOTICS NOS;PROTEINS NOS;VITAMINS NOS	1 (<0.1)	0	1 (<0.1)
CARBOHYDRATES NOS;ELECTROLYTES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 (<0.1)	0	1 (<0.1)
CARBOMER;GLYCEROL;PARAFFIN, LIQUID;POLYCARBOPHIL	1 (<0.1)	0	1 (<0.1)
CARISOPRODOL;NAPROXEN	1 (<0.1)	0	1 (<0.1)
CARNITINE	2 (<0.1)	0	2 (<0.1)
CARNOSINE	1 (<0.1)	0	1 (<0.1)
CARTEOLOL HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
CASEIN	1 (<0.1)	0	1 (<0.1)
CEFPODOXIME	2 (<0.1)	0	2 (<0.1)
CEFTAROLINE	1 (<0.1)	0	1 (<0.1)
CEFTRIAXONE SODIUM	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CENTELLA ASIATICA	1 (<0.1)	0	1 (<0.1)
CENTRALLY ACTING SYMPATHOMIMETICS	1 (<0.1)	0	1 (<0.1)
CEPHALOSPORIN NOS	2 (<0.1)	0	2 (<0.1)
CERTOLIZUMAB PEGOL	2 (<0.1)	0	2 (<0.1)
CETIRIZINE;MONTELUKAST	1 (<0.1)	0	1 (<0.1)
CHLORDIAZEPOXIDE;CLIDINIUM BROMIDE	1 (<0.1)	0	1 (<0.1)
CHLORMADINONE ACETATE;ETHINYLESTRADIOL	1 (<0.1)	0	1 (<0.1)
CHLOROPHYLL	1 (<0.1)	0	1 (<0.1)
CHLOROPHYLLIN COPPER COMPLEX SODIUM	1 (<0.1)	0	1 (<0.1)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL	2 (<0.1)	0	2 (<0.1)
CHLORPHENAMINE MALEATE;HYOSCINE METHONITRATE;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
CHLORPHENAMINE;HYDROCODONE	1 (<0.1)	0	1 (<0.1)
CHLORPHENAMINE;HYOSCINE	1 (<0.1)	0	1 (<0.1)
CHLORPHENAMINE;PARACETAMOL	1 (<0.1)	0	1 (<0.1)
CHOLESTEROL	1 (<0.1)	0	1 (<0.1)
CHOLINE	3 (<0.1)	0	3 (<0.1)
CHOLINE;INOSITOL;METHIONINE	1 (<0.1)	0	1 (<0.1)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE;HYALURONIC ACID;SODIUM	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	1 (<0.1)	0	1 (<0.1)
CHONDROITIN SULFATE;GLUCOSAMINE;HYALURONIC ACID	1 (<0.1)	0	1 (<0.1)
CHONDRUS CRISPUS EXTRACT	2 (<0.1)	0	2 (<0.1)
CHROMIUM NICOTINATE;NICOTINIC ACID	1 (<0.1)	0	1 (<0.1)
CICHORIUM INTYBUS ETHANOL EXTRACT	1 (<0.1)	0	1 (<0.1)
CINACALCET HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
CINNAMOMUM BURMANNI	1 (<0.1)	0	1 (<0.1)
CITRIC ACID;POTASSIUM BICARBONATE	1 (<0.1)	0	1 (<0.1)
CLOFEDANOL HYDROCHLORIDE;DEXBROMPHENIRAMINE MALEATE	1 (<0.1)	0	1 (<0.1)
CLOFEDANOL HYDROCHLORIDE;DEXCHLORPHENIRAMINE MALEATE;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
CLOMIPRAMINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
COBICISTAT	1 (<0.1)	0	1 (<0.1)
COBICISTAT;DARUNAVIR	1 (<0.1)	0	1 (<0.1)
COBICISTAT;ELVITEGRAVIR;EMTRICITABINE;TENOFOVIR	1 (<0.1)	0	1 (<0.1)
CODEINE	5 (<0.1)	0	5 (<0.1)
COFFEA ARABICA;PHOSPHATIDYL SERINE	1 (<0.1)	0	1 (<0.1)
COLECALCIFEROL;MAGNESIUM;ZINC	1 (<0.1)	0	1 (<0.1)
COLECALCIFEROL;MENADIONE	2 (<0.1)	0	2 (<0.1)
COLECALCIFEROL;OMEGA-3 TRIGLYCERIDES;XANTOFYL;ZEAXANTHIN	1 (<0.1)	0	1 (<0.1)
COLECALCIFEROL;ZINC	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS	1 (<0.1)	0	1 (<0.1)
CONTRACEPTIVES	1 (<0.1)	0	1 (<0.1)
CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION	1 (<0.1)	0	1 (<0.1)
CUCURBITA PEPO OIL;SERENOA REPENS;ZINC GLUCONATE	1 (<0.1)	0	1 (<0.1)
CUCURBITA PEPO SEED;GLYCINE MAX	1 (<0.1)	0	1 (<0.1)
CURCUMA LONGA RHIZOME	3 (<0.1)	0	3 (<0.1)
CURCUMA LONGA RHIZOME;PIPER NIGRUM FRUIT	1 (<0.1)	0	1 (<0.1)
CURCUMA LONGA;FISH OIL	1 (<0.1)	0	1 (<0.1)
CURCUMA LONGA;LECITHIN;VITAMIN E NOS	1 (<0.1)	0	1 (<0.1)
CURCUMIN;PIPERINE	1 (<0.1)	0	1 (<0.1)
CYANOCOBALAMIN;CYNARA CARDUNCULUS LEAF;GLUTATHIONE;HORDEUM VULGARE;LECITHIN;NICOTINAMIDE;PANTOTHENIC ACID;PYRIDOXINE;RIBOFLAVIN;SCHISANDRA SPP. FRUIT;SELENIUM AMINO ACID CHELATE;SILYBUM MARIANUM HERB SILYBUM MARIANUM SEED;TARAXACUM OFFICINALE ROOT;THIAMINE	1 (<0.1)	0	1 (<0.1)
CYANOCOBALAMIN;DEXPANTHENOL;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE	1 (<0.1)	0	1 (<0.1)
CYANOCOBALAMIN;FERROUS SULFATE;FOLIC ACID;SERINE	1 (<0.1)	0	1 (<0.1)
CYANOCOBALAMIN;METAMIZOLE SODIUM;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE MONONITRATE	1 (<0.1)	0	1 (<0.1)
CYCLOPENTOLATE	1 (<0.1)	0	1 (<0.1)
CYMBOPOGON CITRATUS	1 (<0.1)	0	1 (<0.1)
DABIGATRAN ETEXILATE	1 (<0.1)	0	1 (<0.1)
DANTROLENE	1 (<0.1)	0	1 (<0.1)
DEANOL	1 (<0.1)	0	1 (<0.1)
DEANOL BITARTRATE	2 (<0.1)	0	2 (<0.1)
DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE	1 (<0.1)	0	1 (<0.1)
DESLORATADINE;PSEUDOEPHEDRINE SULFATE	1 (<0.1)	0	1 (<0.1)
DEXCHLORPHENIRAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
DEXTRAN 70;GLYCEROL;HYPROMELLOSE	1 (<0.1)	0	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PHENYLEPHRINE	1 (<0.1)	0	1 (<0.1)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)

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Safety Set

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DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
DEXTROMETHORPHAN;DIPHENHYDRAMINE;GUAIFENESIN;PARACETAMOL;PHENYLEPHRINE	1 (<0.1)	0	1 (<0.1)
DIASTASE;PANCREATIN;PAPAIN;PEPSIN	1 (<0.1)	0	1 (<0.1)
DIAZEPAM;FENPROPOREX HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
DIAZEPAM;ISOPROPAMIDE IODIDE	1 (<0.1)	0	1 (<0.1)
DICLOFENAC EPOLAMINE	1 (<0.1)	0	1 (<0.1)
DICLOFENAC SODIUM;LINUM USITATISSIMUM;MENTHOL;METHYL SALICYLATE;THIOCOLCHICOSIDE	1 (<0.1)	0	1 (<0.1)
DICLOXACILLIN	4 (<0.1)	0	4 (<0.1)
DIENOGEST	1 (<0.1)	0	1 (<0.1)
DIFLUNISAL	1 (<0.1)	0	1 (<0.1)
DIMETICONE;PETROLATUM	1 (<0.1)	0	1 (<0.1)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
DIPHENHYDRAMINE;PARACETAMOL;PHENYLPROPANOLAMINE HYDROCHLORIDE	3 (<0.1)	0	3 (<0.1)
DISOPYRAMIDE PHOSPHATE	1 (<0.1)	0	1 (<0.1)
DL-ALPHA TOCOPHERYL ACETATE;RETINOL PALMITATE;XANTOFYL;ZEAXANTHIN;ZINC OXIDE	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;FISH OIL	1 (<0.1)	0	1 (<0.1)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;FISH OIL;OMEGA-3 FATTY ACIDS	1 (<0.1)	0	1 (<0.1)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;LINOLENIC ACID;OMEGA 9 FATTY ACIDS;OMEGA-6 FATTY ACIDS	1 (<0.1)	0	1 (<0.1)
DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID;TOCOPHERYL ACETATE	1 (<0.1)	0	1 (<0.1)
DOCOSAHEXAENOIC ACID;FISH OIL	1 (<0.1)	0	1 (<0.1)
DOCUSATE CALCIUM	2 (<0.1)	0	2 (<0.1)
DOCUSATE SODIUM;FERROUS FUMARATE	1 (<0.1)	0	1 (<0.1)
DOLUTEGRAVIR;LAMIVUDINE	1 (<0.1)	0	1 (<0.1)
DOXOFYLLINE	1 (<0.1)	0	1 (<0.1)
DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
DRONABINOL	2 (<0.1)	0	2 (<0.1)
DRONEDARONE	4 (<0.1)	0	4 (<0.1)
DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (<0.1)	0	1 (<0.1)
DURAPATITE	2 (<0.1)	0	2 (<0.1)
DUTASTERIDE;TAMSULOSIN	2 (<0.1)	0	2 (<0.1)
ECHINACEA ANGUSTIFOLIA;ECHINACEA PURPUREA;HYDRASTIS CANADENSIS HERB	1 (<0.1)	0	1 (<0.1)
ECHINACEA SPP.;VITAMINS NOS;ZINC AMINO ACID CHELATE	1 (<0.1)	0	1 (<0.1)
ELVITEGRAVIR	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
EMOLLIENTS AND PROTECTIVES	1 (<0.1)	0	1 (<0.1)
EMPAGLIFLOZIN;METFORMIN	1 (<0.1)	0	1 (<0.1)
EMTRICITABINE;TENOFOVIR DISOPROXIL	1 (<0.1)	0	1 (<0.1)
ENZYME AND ACID PREPARATIONS, COMBINATIONS	1 (<0.1)	0	1 (<0.1)
ENZYMES NOS	4 (<0.1)	0	4 (<0.1)
ENZYMES NOS;PROBIOTICS NOS	1 (<0.1)	0	1 (<0.1)
EPOETIN ZETA	1 (<0.1)	0	1 (<0.1)
ERGOTAMINE TARTRATE;HOMATROPINE METHYLBROMIDE;MEPROBAMATE	1 (<0.1)	0	1 (<0.1)
ESCHSCHOLZIA CALIFORNICA HERB	1 (<0.1)	0	1 (<0.1)
ESOMEPRAZOLE MAGNESIUM;NAPROXEN	2 (<0.1)	0	2 (<0.1)
ESTERIFIED OESTROGENS;METHYLTESTOSTERONE	2 (<0.1)	0	2 (<0.1)
ESTRADIOL ACETATE	1 (<0.1)	0	1 (<0.1)
ESTRADIOL CIPIONATE	1 (<0.1)	0	1 (<0.1)
ESTRADIOL;ESTRIOL;ESTRONE	1 (<0.1)	0	1 (<0.1)
ESTRIOL	6 (<0.1)	0	6 (<0.1)
ESTROGEN NOS	4 (<0.1)	0	4 (<0.1)
ESTROPIPATE	1 (<0.1)	0	1 (<0.1)
ETACRYNIC ACID	1 (<0.1)	0	1 (<0.1)
ETANERCEPT	2 (<0.1)	0	2 (<0.1)
ETHINYLESTRADIOL;GESTODENE	2 (<0.1)	0	2 (<0.1)
ETOMIDATE	1 (<0.1)	0	1 (<0.1)
EUCALYPTUS GLOBULUS OIL	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
EYE LUBRICANTS	1 (<0.1)	0	1 (<0.1)
FALLOPIA JAPONICA;VITIS VINIFERA SEED	1 (<0.1)	0	1 (<0.1)
FAMPRIDINE	1 (<0.1)	0	1 (<0.1)
FAT SOLUBLE VITAMINS NOS	1 (<0.1)	0	1 (<0.1)
FENTICLOR	1 (<0.1)	0	1 (<0.1)
FIMASARTAN	1 (<0.1)	0	1 (<0.1)
FINASTERIDE;MINOXIDIL	1 (<0.1)	0	1 (<0.1)
FINGOLIMOD HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
FISH OIL;GLYCINE MAX SEED OIL;LINUM USITATISSIMUM OIL;VITAMIN E NOS	1 (<0.1)	0	1 (<0.1)
FISH OIL;XANTOFYL;ZEAXANTHIN	1 (<0.1)	0	1 (<0.1)
FLUOCINOLONE ACETONIDE;HYDROQUINONE;TRETINOIN	1 (<0.1)	0	1 (<0.1)
FLUOCINOLONE ACETONIDE;NEOMYCIN SULFATE	1 (<0.1)	0	1 (<0.1)
FLUTICASONE;UMECLIDINIUM;VILANTEROL	2 (<0.1)	0	2 (<0.1)
FLUVASTATIN SODIUM	1 (<0.1)	0	1 (<0.1)
FOENICULUM VULGARE SEED;GLYCYRRHIZA GLABRA;MALVA SYLVESTRIS FLOWER;MEDICAGO SATIVA LEAF;PIMPINELLA ANISUM SEED;RHAMNUS FRANGULA BARK;RHEUM PALMATUM ROOT;SENNA ALEXANDRINA;VERONICASTRUM VIRGINICUM	1 (<0.1)	0	1 (<0.1)
FOLIC ACID AND DERIVATIVES	1 (<0.1)	0	1 (<0.1)
FOLIC ACID;VITAMIN B COMPLEX	1 (<0.1)	0	1 (<0.1)
FOLIC ACID;VITAMIN B12 NOS	2 (<0.1)	0	2 (<0.1)
FONDAPARINUX	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
FONDAPARINUX SODIUM	1 (<0.1)	0	1 (<0.1)
FORMOTEROL;GLYCOPYRRONIUM	1 (<0.1)	0	1 (<0.1)
FOSFOMYCIN	3 (<0.1)	0	3 (<0.1)
GABAPENTIN ENACARBIL	1 (<0.1)	0	1 (<0.1)
GAMMA ELEMENE	1 (<0.1)	0	1 (<0.1)
GELATIN	2 (<0.1)	0	2 (<0.1)
GELATINE HYDROLYSATE	3 (<0.1)	0	3 (<0.1)
GINKGO BILOBA;GINSENG NOS;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE;VITAMIN B12 NOS	1 (<0.1)	0	1 (<0.1)
GLIMEPIRIDE;METFORMIN	1 (<0.1)	0	1 (<0.1)
GLIPIZIDE;METFORMIN	1 (<0.1)	0	1 (<0.1)
GLIPIZIDE;METFORMIN HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
GLUCOMANNAN	1 (<0.1)	0	1 (<0.1)
GLUCONATE SODIUM;MAGNESIUM CHLORIDE HEXAHYDRATE;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	1 (<0.1)	0	1 (<0.1)
GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	2 (<0.1)	0	2 (<0.1)
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CITRATE ACID	1 (<0.1)	0	1 (<0.1)
GLUTATHIONE;PHOSPHATIDYL CHOLINE	2 (<0.1)	0	2 (<0.1)
GLYCERINE MONOLAURATE	1 (<0.1)	0	1 (<0.1)
GLYCEROL;HYPROMELLOSE;MACROGOL 400	1 (<0.1)	0	1 (<0.1)
GLYCEROL;PROPYLENE GLYCOL	1 (<0.1)	0	1 (<0.1)
GLYCOPYRRONIUM BROMIDE;INDACATEROL MALEATE	1 (<0.1)	0	1 (<0.1)

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Table 14.1.5.2.1
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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
GLYCYRRHIZA GLABRA ROOT;LACTOBACILLUS BREVIS;LACTOFERRIN;MATRICARIA RECUTITA FLOWER	1 (<0.1)	0	1 (<0.1)
GONADORELIN DIACETATE	1 (<0.1)	0	1 (<0.1)
GUAIFENESIN;PSEUDOEPHEDRINE	1 (<0.1)	0	1 (<0.1)
HEME IRON POLYPEPTIDE;IRON POLYSACCHARIDE COMPLEX	1 (<0.1)	0	1 (<0.1)
HEPATITIS A VACCINE INACT;HEPATITIS B VACCINE RHBSAG (YEAST)	2 (<0.1)	0	2 (<0.1)
HERBAL ANTIOBESITY PREPARATIONS	1 (<0.1)	0	1 (<0.1)
HERBAL DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY	1 (<0.1)	0	1 (<0.1)
HERBAL NOS;MINERALS NOS;VITAMINS NOS	4 (<0.1)	0	4 (<0.1)
HIBISCUS SPP.	2 (<0.1)	0	2 (<0.1)
HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE	1 (<0.1)	0	1 (<0.1)
HONEY	1 (<0.1)	0	1 (<0.1)
HOPANTENATE CALCIUM	1 (<0.1)	0	1 (<0.1)
HPV VACCINE VLP RL1 9V (YEAST)	1 (<0.1)	0	1 (<0.1)
HYALURONIDASE	1 (<0.1)	0	1 (<0.1)
HYDROCHLORIC ACID	1 (<0.1)	0	1 (<0.1)
HYDROCHLOROTHIAZIDE;IRBESARTAN HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
HYDROCHLOROTHIAZIDE;METOPROLOL	1 (<0.1)	0	1 (<0.1)
HYDROCODONE BITARTRATE;IBUPROFEN	1 (<0.1)	0	1 (<0.1)
HYDROCORTISONE ACETATE;LIDOCAINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
HYDROCORTISONE VALERATE	2 (<0.1)	0	2 (<0.1)
HYDROCORTISONE;NEOMYCIN SULFATE;POLYMYXIN B	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
HYDROXYCARBAMIDE	4 (<0.1)	0	4 (<0.1)
HYOSCYAMINE SULFATE;METHENAMINE;METHYLTHIONINIUM CHLORIDE;PHENYL SALICYLATE;SODIUM PHOSPHATE MONOBASIC	1 (<0.1)	0	1 (<0.1)
IBUPROFEN;METHOCARBAMOL	1 (<0.1)	0	1 (<0.1)
IMIPRAMINE HYDROCHLORIDE	5 (<0.1)	0	5 (<0.1)
IMMUNOGLOBULIN HUMAN NORMAL	1 (<0.1)	0	1 (<0.1)
IMMUNOGLOBULINS NOS	1 (<0.1)	0	1 (<0.1)
INSULIN HUMAN BIOSYNTHETIC	1 (<0.1)	0	1 (<0.1)
INSULIN LISPRO;INSULIN LISPRO PROTAMINE SUSPENSION	1 (<0.1)	0	1 (<0.1)
INULIN	1 (<0.1)	0	1 (<0.1)
IODINE;POTASSIUM IODIDE	1 (<0.1)	0	1 (<0.1)
IPRATROPIUM BROMIDE;SALBUTAMOL	3 (<0.1)	0	3 (<0.1)
IRON POLYSACCHARIDE COMPLEX	2 (<0.1)	0	2 (<0.1)
IRON;POTASSIUM	1 (<0.1)	0	1 (<0.1)
IRON;VITAMIN B NOS	1 (<0.1)	0	1 (<0.1)
IRVINGIA GABONENSIS	1 (<0.1)	0	1 (<0.1)
ISOPHANE INSULIN	1 (<0.1)	0	1 (<0.1)
ISOPROPANOL	1 (<0.1)	0	1 (<0.1)
ITRACONAZOLE	1 (<0.1)	0	1 (<0.1)
IVABRADINE	1 (<0.1)	0	1 (<0.1)
IVACAFTOR	1 (<0.1)	0	1 (<0.1)
LAMIVUDINE;ZIDOVUDINE	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
LANOLIN OIL	1 (<0.1)	0	1 (<0.1)
LANTHANUM CARBONATE	1 (<0.1)	0	1 (<0.1)
LASMIDITAN SUCCINATE	1 (<0.1)	0	1 (<0.1)
LATANOPROST;TIMOLOL	1 (<0.1)	0	1 (<0.1)
LATANOPROST;TIMOLOL MALEATE	1 (<0.1)	0	1 (<0.1)
LAVANDULA ANGUSTIFOLIA ESSENTIAL OIL	1 (<0.1)	0	1 (<0.1)
LEUCINE	1 (<0.1)	0	1 (<0.1)
LEVOFLOXACIN HEMIHYDRATE	1 (<0.1)	0	1 (<0.1)
LIDOCAINE HYDROCHLORIDE;METHYLPREDNISOLONE ACETATE	1 (<0.1)	0	1 (<0.1)
LIDOCAINE HYDROCHLORIDE;TRIAMCINOLONE ACETONIDE	1 (<0.1)	0	1 (<0.1)
LIDOCAINE;PRILOCAINE	1 (<0.1)	0	1 (<0.1)
LIDOCAINE;SODIUM BICARBONATE	1 (<0.1)	0	1 (<0.1)
LINUM USITATISSIMUM	1 (<0.1)	0	1 (<0.1)
LIVER THERAPY	1 (<0.1)	0	1 (<0.1)
LORATADINE;PSEUDOEPHEDRINE HYDROCHLORIDE	3 (<0.1)	0	3 (<0.1)
LUMATEPERONE TOSYLATE	1 (<0.1)	0	1 (<0.1)
LYCOPENE;SELENOMETHIONINE;SITOSTEROL;VACCINIUM MACROCARPON;ZINC AMINO ACID CHELATE	1 (<0.1)	0	1 (<0.1)
LYSINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
LYSOZYME CHLORIDE	1 (<0.1)	0	1 (<0.1)
MAGIC MOUTHWASH	1 (<0.1)	0	1 (<0.1)
MAGNESIUM AMINO ACID CHELATE	1 (<0.1)	0	1 (<0.1)
MAGNESIUM ASPARTATE;POTASSIUM ASPARTATE	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MAGNESIUM OXIDE;POTASSIUM CITRATE	1 (<0.1)	0	1 (<0.1)
MAGNESIUM OXIDE;PYRIDOXINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
MAGNESIUM STEARATE	1 (<0.1)	0	1 (<0.1)
MAGNESIUM;PYRIDOXINE;ZINC	1 (<0.1)	0	1 (<0.1)
MANNITOL	1 (<0.1)	0	1 (<0.1)
MECLOFENAMATE SODIUM	1 (<0.1)	0	1 (<0.1)
MEFENAMIC ACID	1 (<0.1)	0	1 (<0.1)
MEGLUMINE AMIDOTRIZOATE;SODIUM AMIDOTRIZOATE	1 (<0.1)	0	1 (<0.1)
MELATONIN;OXITRIPTAN	1 (<0.1)	0	1 (<0.1)
MELATONIN;PYRIDOXINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
MELISSA OFFICINALIS HERB	2 (<0.1)	0	2 (<0.1)
MELOXICAM;METHOCARBAMOL	2 (<0.1)	0	2 (<0.1)
MERCAPTOPURINE	1 (<0.1)	0	1 (<0.1)
MESTEROLONE	1 (<0.1)	0	1 (<0.1)
MESTRANOL;NORETHISTERONE	5 (<0.1)	0	5 (<0.1)
METAMIZOLE	1 (<0.1)	0	1 (<0.1)
METHYL SALICYLATE	1 (<0.1)	0	1 (<0.1)
METHYLDOPA	1 (<0.1)	0	1 (<0.1)
METHYLNALTREXONE	1 (<0.1)	0	1 (<0.1)
METOCLOPRAMIDE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
MILRINONE	1 (<0.1)	0	1 (<0.1)
MIMOSA PUDICA	1 (<0.1)	0	1 (<0.1)
MOEXIPRIL	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
MONASCUS PURPUREUS EXTRACT	1 (<0.1)	0	1 (<0.1)
MORINGA OLEIFERA LEAF	1 (<0.1)	0	1 (<0.1)
MUSCLE RELAXANTS	2 (<0.1)	0	2 (<0.1)
MYROXYLON BALSAMUM VAR. PEREIRAE;RICINUS COMMUNIS OIL	1 (<0.1)	0	1 (<0.1)
NASAL PREPARATIONS	2 (<0.1)	0	2 (<0.1)
NASTURTIUM OFFICINALE	1 (<0.1)	0	1 (<0.1)
NEFAZODONE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
NEOMYCIN SULFATE;POLYMYXIN B SULFATE;PRAMOCAINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
NEPAFENAC	3 (<0.1)	0	3 (<0.1)
NICARDIPINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
NICOTINE POLACRILEX	2 (<0.1)	0	2 (<0.1)
NITROFURANTOIN MONOHYDRATE	2 (<0.1)	0	2 (<0.1)
NOREPINEPHRINE	3 (<0.1)	0	3 (<0.1)
NORFLOXACIN	1 (<0.1)	0	1 (<0.1)
OCTANOIC ACID	1 (<0.1)	0	1 (<0.1)
OCTREOTIDE ACETATE	2 (<0.1)	0	2 (<0.1)
OLEA EUROPAEA OIL	2 (<0.1)	0	2 (<0.1)
OLEUROPEIN	1 (<0.1)	0	1 (<0.1)
OLODATEROL HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
ORNITHINE ASPARTATE;SELENIUM;SILYBUM MARIANUM;THIAMINE;THIOCTIC ACID	1 (<0.1)	0	1 (<0.1)

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Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
OSELTAMIVIR	1 (<0.1)	0	1 (<0.1)
OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	2 (<0.1)	0	2 (<0.1)
OTHER ANTIHYPERTENSIVES	1 (<0.1)	0	1 (<0.1)
OTHER COLD PREPARATIONS	1 (<0.1)	0	1 (<0.1)
OTHER MINERAL SUPPLEMENTS	1 (<0.1)	0	1 (<0.1)
OTHER NERVOUS SYSTEM DRUGS	1 (<0.1)	0	1 (<0.1)
OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	1 (<0.1)	0	1 (<0.1)
OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	2 (<0.1)	0	2 (<0.1)
OXAPROZIN	1 (<0.1)	0	1 (<0.1)
OXICONAZOLE NITRATE	1 (<0.1)	0	1 (<0.1)
PALMIDROL	1 (<0.1)	0	1 (<0.1)
PANAX GINSENG EXTRACT	1 (<0.1)	0	1 (<0.1)
PANTOTHENIC ACID	3 (<0.1)	0	3 (<0.1)
PAPAVER SOMNIFERUM TINCTURE	1 (<0.1)	0	1 (<0.1)
PARACETAMOL;PHENIRAMINE MALEATE;PHENYLEPHRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
PARICALCITOL	2 (<0.1)	0	2 (<0.1)
PATIROMER SORBITEX CALCIUM	1 (<0.1)	0	1 (<0.1)
PEARL	1 (<0.1)	0	1 (<0.1)
PERINDOPRIL ERBUMINE	1 (<0.1)	0	1 (<0.1)
PETHIDINE	1 (<0.1)	0	1 (<0.1)

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Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PETHIDINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
PETROSELINUM CRISPUM	1 (<0.1)	0	1 (<0.1)
PHENIRAMINE	1 (<0.1)	0	1 (<0.1)
PHENYLEPHRINE;PSEUDOEPHEDRINE	1 (<0.1)	0	1 (<0.1)
PHENYLPROPANOLAMINE HYDROCHLORIDE	2 (<0.1)	0	2 (<0.1)
PHOSPHATIDYL CHOLINE	1 (<0.1)	0	1 (<0.1)
PHYLLANTHUS EMBLICA;TERMINALIA BELLIRICA;TERMINALIA CHEBULA	1 (<0.1)	0	1 (<0.1)
PINDOLOL	2 (<0.1)	0	2 (<0.1)
PIPERACILLIN SODIUM	1 (<0.1)	0	1 (<0.1)
PIPERAZINE CITRATE	1 (<0.1)	0	1 (<0.1)
PISTACIA LENTISCUS LATEX	1 (<0.1)	0	1 (<0.1)
PLASMA	1 (<0.1)	0	1 (<0.1)
PLATINUM	1 (<0.1)	0	1 (<0.1)
PNEUMOCOCCAL VACCINE 13V	1 (<0.1)	0	1 (<0.1)
PNEUMOCOCCAL VACCINE POLYV	1 (<0.1)	0	1 (<0.1)
PODOPHYLLOTOXIN	1 (<0.1)	0	1 (<0.1)
POLYMYXIN B SULFATE;TRIMETHOPRIM	4 (<0.1)	0	4 (<0.1)
POLYSACCHARIDES NOS	1 (<0.1)	0	1 (<0.1)
POTASSIUM ACETATE	1 (<0.1)	0	1 (<0.1)
POTASSIUM GLUTAMATE	1 (<0.1)	0	1 (<0.1)
PRABOTULINUMTOXINA XVFS	2 (<0.1)	0	2 (<0.1)
PRAMOCAINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PROGESTOGENS AND ESTROGENS IN COMBINATION	1 (<0.1)	0	1 (<0.1)
PROPAFENONE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
PROPOLIS	2 (<0.1)	0	2 (<0.1)
PRUCALOPRIDE SUCCINATE	3 (<0.1)	0	3 (<0.1)
PRUNUS SEROTINA	1 (<0.1)	0	1 (<0.1)
PRUNUS SPP.;SENNA SPP. LEAF	1 (<0.1)	0	1 (<0.1)
PYCNOGENOL	4 (<0.1)	0	4 (<0.1)
PYRANTEL EMBONATE	1 (<0.1)	0	1 (<0.1)
PYRAZINAMIDE	1 (<0.1)	0	1 (<0.1)
QUINESTROL	1 (<0.1)	0	1 (<0.1)
RACECADOTRIL	1 (<0.1)	0	1 (<0.1)
RADIOTHERAPY	1 (<0.1)	0	1 (<0.1)
RALTEGRAVIR POTASSIUM	1 (<0.1)	0	1 (<0.1)
RED BLOOD CELLS, CONCENTRATED	2 (<0.1)	0	2 (<0.1)
REGADENOSON	1 (<0.1)	0	1 (<0.1)
RESPIRATORY SYSTEM	1 (<0.1)	0	1 (<0.1)
RHEUM RHAPONTICUM ROOT	1 (<0.1)	0	1 (<0.1)
RILUZOLE	1 (<0.1)	0	1 (<0.1)
RIMEGEPANT SULFATE	2 (<0.1)	0	2 (<0.1)
RIOCIGUAT	1 (<0.1)	0	1 (<0.1)
RISANKIZUMAB	2 (<0.1)	0	2 (<0.1)
RIVASTIGMINE HYDROGEN TARTRATE	2 (<0.1)	0	2 (<0.1)
ROPIVACAINE	4 (<0.1)	0	4 (<0.1)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
ROYAL JELLY	1 (<0.1)	0	1 (<0.1)
RUTOSIDE	2 (<0.1)	0	2 (<0.1)
SALICYLIC ACID AND DERIVATIVES	1 (<0.1)	0	1 (<0.1)
SALICYLIC ACID;UREA	1 (<0.1)	0	1 (<0.1)
SAMBUCUS NIGRA EXTRACT	1 (<0.1)	0	1 (<0.1)
SAMBUCUS NIGRA;ZINC GLUCONATE	1 (<0.1)	0	1 (<0.1)
SARECYCLINE	1 (<0.1)	0	1 (<0.1)
SARECYCLINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
SELENIUM SULFIDE	5 (<0.1)	0	5 (<0.1)
SENNA ALEXANDRINA EXTRACT	1 (<0.1)	0	1 (<0.1)
SERMORELIN	1 (<0.1)	0	1 (<0.1)
SILVER NITRATE	1 (<0.1)	0	1 (<0.1)
SIMVASTATIN;SITAGLIPTIN	1 (<0.1)	0	1 (<0.1)
SITOSTEROL;STIGMASTANOL	1 (<0.1)	0	1 (<0.1)
SODIUM BUTYRATE	1 (<0.1)	0	1 (<0.1)
SODIUM CALCIUM EDETATE	1 (<0.1)	0	1 (<0.1)
SODIUM CITRATE	1 (<0.1)	0	1 (<0.1)
SODIUM HYDROXIDE	1 (<0.1)	0	1 (<0.1)
SODIUM IODIDE (131 I)	1 (<0.1)	0	1 (<0.1)
SODIUM ZIRCONIUM CYCLOSILICATE	2 (<0.1)	0	2 (<0.1)
STRONTIUM	4 (<0.1)	0	4 (<0.1)
STRONTIUM CHLORIDE	1 (<0.1)	0	1 (<0.1)
SULFORAPHANE	1 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
SULFUR	1 (<0.1)	0	1 (<0.1)
TABEBUIA IMPETIGINOSA	1 (<0.1)	0	1 (<0.1)
TELITHROMYCIN	1 (<0.1)	0	1 (<0.1)
TENOFOVIR ALAFENAMIDE FUMARATE	2 (<0.1)	0	2 (<0.1)
TENOFOVIR DISOPROXIL	1 (<0.1)	0	1 (<0.1)
TERBUTALINE	1 (<0.1)	0	1 (<0.1)
TERIFLUNOMIDE	2 (<0.1)	0	2 (<0.1)
TESAMORELIN ACETATE	1 (<0.1)	0	1 (<0.1)
TESTOSTERONE ISOCAPROATE;TESTOSTERONE PHENYLPROPIONATE;TESTOSTERONE PROPIONATE	1 (<0.1)	0	1 (<0.1)
TESTOSTERONE PROPIONATE	1 (<0.1)	0	1 (<0.1)
TETRACYCLINE HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
TETRYZOLINE HYDROCHLORIDE	3 (<0.1)	0	3 (<0.1)
THYROGLOBULIN	1 (<0.1)	0	1 (<0.1)
TINIDAZOLE	1 (<0.1)	0	1 (<0.1)
TOCOPHEROL	1 (<0.1)	0	1 (<0.1)
TOCOPHEROL CALCIUM SUCCINATE	1 (<0.1)	0	1 (<0.1)
TOCOPHERYL ACETATE	1 (<0.1)	0	1 (<0.1)
TOFACITINIB CITRATE	1 (<0.1)	0	1 (<0.1)
TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN	1 (<0.1)	0	1 (<0.1)
TRENBOLONE	1 (<0.1)	0	1 (<0.1)
TRIBULUS TERRESTRIS	3 (<0.1)	0	3 (<0.1)
TRIFAROTENE	1 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.2.1
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
TRIHEXYPHENIDYL	2 (<0.1)	0	2 (<0.1)
TRIHEXYPHENIDYL HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
TRIMEBUTINE	1 (<0.1)	0	1 (<0.1)
TUBERCULIN	2 (<0.1)	0	2 (<0.1)
TUBERCULOSIS VACCINES	1 (<0.1)	0	1 (<0.1)
TYPHOID VACCINE	1 (<0.1)	0	1 (<0.1)
UBIDECARENONE;VITAMINS NOS	1 (<0.1)	0	1 (<0.1)
UNCARIA TOMENTOSA	1 (<0.1)	0	1 (<0.1)
UNSPECIFIED HERBAL	1 (<0.1)	0	1 (<0.1)
UREA	3 (<0.1)	0	3 (<0.1)
VANADYL SULFATE	1 (<0.1)	0	1 (<0.1)
VANCOMYCIN HYDROCHLORIDE	1 (<0.1)	0	1 (<0.1)
VASCULAR ENDOTHELIAL GROWTH FACTOR INHIBITORS	1 (<0.1)	0	1 (<0.1)
VASOPRESSIN	2 (<0.1)	0	2 (<0.1)
VEDOLIZUMAB	1 (<0.1)	0	1 (<0.1)
VERBASCUM SPP. EXTRACT	1 (<0.1)	0	1 (<0.1)
VITAMIN B-COMPLEX, OTHER COMBINATIONS	2 (<0.1)	0	2 (<0.1)
VITAMIN D AND ANALOGUES	1 (<0.1)	0	1 (<0.1)
VITAMIN D1	1 (<0.1)	0	1 (<0.1)
VITAMINS NOS;ZINC	2 (<0.1)	0	2 (<0.1)
VITIS VINIFERA EXTRACT	2 (<0.1)	0	2 (<0.1)
ZINC ACETATE	2 (<0.1)	0	2 (<0.1)

Percentages are based on the number of safety subjects.
Concomitant medication is defined as medication continued or newly received at or after the first injection through 28 days after the last injection.
WHODrug version Mar2020.
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Table 14.1.5.4.1
Summary of Concomitant Vaccine Use
Safety Set

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Any Concomitant Vaccine Use Throughout the Study	3705 (24.4)	3436 (22.6)	7141 (23.5)
Any Concomitant Vaccine Use Within 7 Days Post Injection	82 (0.5)	60 (0.4)	142 (0.5)
Any Concomitant Vaccine Use Within 14 Days Post Injection	283 (1.9)	226 (1.5)	509 (1.7)
Any Concomitant Vaccine Use Within 28 Days Post Injection	3683 (24.3)	3416 (22.5)	7099 (23.4)

Percentages are based on the number of safety subjects.
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Table 14.1.5.4.2
Summary of Concomitant Vaccine Use by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Who Used Concomitant Vaccine	3725 (24.6)	3451 (22.7)	7176 (23.6)
INFLUENZA VACCINE	3495 (23.1)	3255 (21.4)	6750 (22.2)
INFLUENZA VACCINE INACT SPLIT 4V	74 (0.5)	61 (0.4)	135 (0.4)
PNEUMOCOCCAL VACCINE	34 (0.2)	37 (0.2)	71 (0.2)
VARICELLA ZOSTER VACCINE RGE (CHO)	20 (0.1)	26 (0.2)	46 (0.2)
INFLUENZA VACCINE INACT SPLIT 3V	29 (0.2)	23 (0.2)	52 (0.2)
VARICELLA ZOSTER VACCINE	32 (0.2)	23 (0.2)	55 (0.2)
INFLUENZA VACCINE RHA 4V (BACULOVIRUS)	16 (0.1)	19 (0.1)	35 (0.1)
TETANUS VACCINE	30 (0.2)	18 (0.1)	48 (0.2)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	20 (0.1)	16 (0.1)	36 (0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	24 (0.2)	15 (<0.1)	39 (0.1)
INFLUENZA VACCINE INACT SAG 3V	14 (<0.1)	13 (<0.1)	27 (<0.1)
HEPATITIS B VACCINE	4 (<0.1)	6 (<0.1)	10 (<0.1)
INFLUENZA VACCINE INACT	12 (<0.1)	6 (<0.1)	18 (<0.1)
INFLUENZA VACCINE INACT SAG 4V	5 (<0.1)	5 (<0.1)	10 (<0.1)
PNEUMOCOCCAL VACCINE CONJ 13V (CRM197)	6 (<0.1)	5 (<0.1)	11 (<0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	2 (<0.1)	4 (<0.1)	6 (<0.1)
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	2 (<0.1)	4 (<0.1)	6 (<0.1)
HEPATITIS A VACCINE	2 (<0.1)	4 (<0.1)	6 (<0.1)
INFLUENZA VACCINES	5 (<0.1)	4 (<0.1)	9 (<0.1)
OTHER VIRAL VACCINES	17 (0.1)	4 (<0.1)	21 (<0.1)
INFLUENZA VACCINE RHA 3V (BACULOVIRUS)	6 (<0.1)	3 (<0.1)	9 (<0.1)
MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE	5 (<0.1)	3 (<0.1)	8 (<0.1)

Percentages are based on the number of safety subjects.
Preferred terms are sorted by descending frequency in mRNA-1273 column.
WHODrug version Mar2020.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1401050402.sas 21JUN2021 11:27

Table 14.1.5.4.2
Summary of Concomitant Vaccine Use by Preferred Term
Safety Set

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	3 (<0.1)	3 (<0.1)	6 (<0.1)
TETANUS VACCINE TOXOID	1 (<0.1)	3 (<0.1)	4 (<0.1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID	0	2 (<0.1)	2 (<0.1)
HPV VACCINE	0	2 (<0.1)	2 (<0.1)
INFLUENZA A(H1N1)PDM09 VACCINE	0	2 (<0.1)	2 (<0.1)
INFLUENZA VACCINE LIVE REASSORT 3V	3 (<0.1)	2 (<0.1)	5 (<0.1)
MENINGOCOCCAL VACCINE	0	2 (<0.1)	2 (<0.1)
POLIO VACCINE	1 (<0.1)	2 (<0.1)	3 (<0.1)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	0	1 (<0.1)	1 (<0.1)
DIPHTHERIA VACCINE;TETANUS VACCINE	2 (<0.1)	1 (<0.1)	3 (<0.1)
PERTUSSIS VACCINE	0	1 (<0.1)	1 (<0.1)
PNEUMOCOCCAL VACCINE POLYSACCH	1 (<0.1)	1 (<0.1)	2 (<0.1)
RABIES VACCINE INACT (HUMAN DIPLOID)	0	1 (<0.1)	1 (<0.1)
HEPATITIS A VACCINE INACT;HEPATITIS B VACCINE RHBSAG (YEAST)	2 (<0.1)	0	2 (<0.1)
HPV VACCINE VLP RL1 9V (YEAST)	1 (<0.1)	0	1 (<0.1)
PNEUMOCOCCAL VACCINE 13V	1 (<0.1)	0	1 (<0.1)
PNEUMOCOCCAL VACCINE POLYV	1 (<0.1)	0	1 (<0.1)
TUBERCULOSIS VACCINES	1 (<0.1)	0	1 (<0.1)
TYPHOID VACCINE	1 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety subjects.
Preferred terms are sorted by descending frequency in mRNA-1273 column.
WHODrug version Mar2020.
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Table 14.1.5.5.1
Summary of Medications for Pain/Fever after First Vaccination
First Injection Solicited Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Medication Taken for Pain or Fever	1523 (13.4)	2656 (23.3)	4179 (18.3)	477 (12.7)	673 (17.9)	1150 (15.3)	2000 (13.2)	3329 (22.0)	5329 (17.6)
Prevent Pain or Fever	257 (2.3)	396 (3.5)	653 (2.9)	124 (3.3)	162 (4.3)	286 (3.8)	381 (2.5)	558 (3.7)	939 (3.1)
Treat Pain or Fever	1385 (12.1)	2503 (21.9)	3888 (17.0)	414 (11.0)	595 (15.8)	1009 (13.4)	1799 (11.9)	3098 (20.4)	4897 (16.2)

Note: medications are collected on eDiary.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1401050501.sas 10JUN2021 10:41

Table 14.1.5.5.2
Summary of Medications for Pain/Fever after Second Vaccination
Second Injection Solicited Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Medication Taken for Pain or Fever	1254 (11.5)	6307 (57.3)	7561 (34.5)	331 (9.1)	1548 (41.9)	1879 (25.6)	1585 (10.9)	7855 (53.5)	9440 (32.3)
Prevent Pain or Fever	223 (2.0)	1137 (10.3)	1360 (6.2)	69 (1.9)	219 (5.9)	288 (3.9)	292 (2.0)	1356 (9.2)	1648 (5.6)
Treat Pain or Fever	1157 (10.6)	6126 (55.7)	7283 (33.2)	290 (7.9)	1495 (40.5)	1785 (24.3)	1447 (9.9)	7621 (51.9)	9068 (31.0)

Note: medications are collected on eDiary.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1401050502.sas 10JUN2021 10:41

Table 14.1.5.5.3
Summary of Medications for Pain/Fever after Any Vaccination
Solicited Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Medication Taken for Pain or Fever	2308 (20.2)	6894 (60.4)	9202 (40.3)	668 (17.8)	1752 (46.5)	2420 (32.2)	2976 (19.6)	8646 (57.0)	11622 (38.3)
Prevent Pain or Fever	437 (3.8)	1405 (12.3)	1842 (8.1)	166 (4.4)	336 (8.9)	502 (6.7)	603 (4.0)	1741 (11.5)	2344 (7.7)
Treat Pain or Fever	2131 (18.7)	6694 (58.7)	8825 (38.7)	594 (15.8)	1681 (44.6)	2275 (30.3)	2725 (18.0)	8375 (55.2)	11100 (36.6)

Note: medications are collected on eDiary.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1401050503.sas 21JUN2021 11:28

Table 14.1.5.5.4
Summary of Medications for Pain/Fever beyond 7 Days of First Vaccination
First Injection Solicited Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Medication Taken for Pain or Fever	135 (1.2)	116 (1.0)	251 (1.1)	65 (1.7)	63 (1.7)	128 (1.7)	200 (1.3)	179 (1.2)	379 (1.3)
Prevent Pain or Fever	43 (0.4)	31 (0.3)	74 (0.3)	27 (0.7)	28 (0.7)	55 (0.7)	70 (0.5)	59 (0.4)	129 (0.4)
Treat Pain or Fever	118 (1.0)	103 (0.9)	221 (1.0)	48 (1.3)	45 (1.2)	93 (1.2)	166 (1.1)	148 (1.0)	314 (1.0)

Note: medications are collected on eDiary.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1401050504.sas 21JUN2021 11:30

Table 14.1.5.5.5
Summary of Medications for Pain/Fever beyond 7 Days of Second Vaccination
Second Injection Solicited Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Medication Taken for Pain or Fever	103 (0.9)	118 (1.1)	221 (1.0)	34 (0.9)	47 (1.3)	81 (1.1)	137 (0.9)	165 (1.1)	302 (1.0)
Prevent Pain or Fever	33 (0.3)	27 (0.2)	60 (0.3)	14 (0.4)	18 (0.5)	32 (0.4)	47 (0.3)	45 (0.3)	92 (0.3)
Treat Pain or Fever	89 (0.8)	109 (1.0)	198 (0.9)	27 (0.7)	36 (1.0)	63 (0.9)	116 (0.8)	145 (1.0)	261 (0.9)

Note: medications are collected on eDiary.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1401050505.sas 21JUN2021 11:30

Table 14.1.5.5.6
Summary of Medications for Pain/Fever beyond 7 Days of Any Vaccination
Solicited Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Medication Taken for Pain or Fever	218 (1.9)	212 (1.9)	430 (1.9)	85 (2.3)	98 (2.6)	183 (2.4)	303 (2.0)	310 (2.0)	613 (2.0)
Prevent Pain or Fever	69 (0.6)	49 (0.4)	118 (0.5)	36 (1.0)	39 (1.0)	75 (1.0)	105 (0.7)	88 (0.6)	193 (0.6)
Treat Pain or Fever	191 (1.7)	195 (1.7)	386 (1.7)	66 (1.8)	74 (2.0)	140 (1.9)	257 (1.7)	269 (1.8)	526 (1.7)

Note: medications are collected on eDiary.
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Table 14.1.6.1
Summary of Study Duration
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Number of Subjects, n (%)			
Received First Injection	15166 (100)	15180 (100)	30346 (100)
Received Second Injection	14635 (96.5)	14727 (97.0)	29362 (96.8)
>= 49 Days Since First Injection	14996 (98.9)	15035 (99.0)	30031 (99.0)
>= 56 Days Since First Injection	14964 (98.7)	15019 (98.9)	29983 (98.8)
>= 2 Months Since First Injection	14933 (98.5)	14991 (98.8)	29924 (98.6)
< 28 Days Since Second Injection	36 (0.2)	24 (0.2)	60 (0.2)
>= 28 and < 56 Days Since Second Injection	120 (0.8)	51 (0.3)	171 (0.6)
>= 28 Days Since Second Injection	14599 (96.3)	14703 (96.9)	29302 (96.6)
>= 56 Days Since Second Injection	14479 (95.5)	14652 (96.5)	29131 (96.0)
>= 2 Months Since Second Injection	14442 (95.2)	14641 (96.4)	29083 (95.8)
>= 3 Months Since Second Injection	13931 (91.9)	14591 (96.1)	28522 (94.0)
>= 4 Months Since Second Injection	13267 (87.5)	14481 (95.4)	27748 (91.4)
>= 5 Months Since Second Injection	11639 (76.7)	12858 (84.7)	24497 (80.7)
>= 6 Months Since Second Injection	6782 (44.7)	7495 (49.4)	14277 (47.0)
Study Duration from Randomization (Days)			
Mean (SD)	198.4 (38.90)	206.1 (31.02)	202.2 (35.38)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 224.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in Full Analysis Set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.1
Summary of Study Duration
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Study Duration from First Injection (Days)			
Mean (SD)	198.4 (38.91)	206.0 (31.02)	202.2 (35.39)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 224.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	8239.2	8563.2	16802.4
Study Duration from Second Injection (Days) [2]			
Mean (SD)	165.4 (46.11)	173.7 (38.95)	169.5 (42.88)
Median	180.0	183.0	182.0
Q1, Q3	157.0, 193.0	166.0, 194.0	163.0, 194.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	14635	14727	29362
Mean (SD)	171.4 (34.28)	179.0 (24.65)	175.2 (30.09)
Median	180.0	184.0	183.0
Q1, Q3	161.0, 194.0	169.0, 196.0	165.0, 194.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in Full Analysis Set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14010601.sas 10JUN2021 12:30

Table 14.1.6.1
Summary of Study Duration
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)	Total (N=30346)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	14311	14533	28844
Mean (SD)	144.8 (25.45)	147.5 (25.65)	146.1 (25.59)
Median	146.0	148.0	148.0
Q1, Q3	128.0, 161.0	132.0, 163.0	131.0, 162.0
Min, Max	30, 237	44, 241	30, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	14311	14533	28844
Mean (SD)	59.0 (23.53)	63.2 (18.73)	61.1 (21.35)
Median	67.0	66.0	67.0
Q1, Q3	52.0, 75.0	55.0, 75.0	54.0, 75.0
Min, Max	1, 205	1, 179	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in Full Analysis Set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.1
Summary of Study Duration
Safety Set

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Number of Subjects, n (%)			
Received First Injection	15162 (100)	15184 (100)	30346 (100)
Received Second Injection	14631 (96.5)	14731 (97.0)	29362 (96.8)
>= 49 Days Since First Injection	14992 (98.9)	15039 (99.0)	30031 (99.0)
>= 56 Days Since First Injection	14960 (98.7)	15023 (98.9)	29983 (98.8)
>= 2 Months Since First Injection	14929 (98.5)	14995 (98.8)	29924 (98.6)
< 28 Days Since Second Injection	36 (0.2)	24 (0.2)	60 (0.2)
>= 28 and < 56 Days Since Second Injection	120 (0.8)	51 (0.3)	171 (0.6)
>= 28 Days Since Second Injection	14595 (96.3)	14707 (96.9)	29302 (96.6)
>= 56 Days Since Second Injection	14475 (95.5)	14656 (96.5)	29131 (96.0)
>= 2 Months Since Second Injection	14438 (95.2)	14645 (96.5)	29083 (95.8)
>= 3 Months Since Second Injection	13927 (91.9)	14595 (96.1)	28522 (94.0)
>= 4 Months Since Second Injection	13263 (87.5)	14485 (95.4)	27748 (91.4)
>= 5 Months Since Second Injection	11636 (76.7)	12861 (84.7)	24497 (80.7)
>= 6 Months Since Second Injection	6778 (44.7)	7499 (49.4)	14277 (47.0)
Study Duration from Randomization (Days)			
Mean (SD)	198.4 (38.90)	206.1 (31.02)	202.2 (35.38)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 224.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.1
Summary of Study Duration
Safety Set

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Study Duration from First Injection (Days)			
Mean (SD)	198.4 (38.91)	206.0 (31.02)	202.2 (35.39)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 224.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	8236.9	8565.5	16802.4
Study Duration from Second Injection (Days) [2]			
Mean (SD)	165.4 (46.12)	173.7 (38.95)	169.5 (42.88)
Median	180.0	183.0	182.0
Q1, Q3	157.0, 193.0	166.0, 194.0	163.0, 194.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	14631	14731	29362
Mean (SD)	171.4 (34.28)	179.0 (24.65)	175.2 (30.09)
Median	180.0	184.0	183.0
Q1, Q3	161.0, 194.0	169.0, 196.0	165.0, 194.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.1
Summary of Study Duration
Safety Set

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	14307	14537	28844
Mean (SD)	144.8 (25.46)	147.5 (25.64)	146.1 (25.59)
Median	146.0	148.0	148.0
Q1, Q3	128.0, 161.0	132.0, 163.0	131.0, 162.0
Min, Max	30, 237	44, 241	30, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	14307	14537	28844
Mean (SD)	58.9 (23.53)	63.2 (18.73)	61.1 (21.35)
Median	67.0	66.0	67.0
Q1, Q3	52.0, 75.0	55.0, 75.0	54.0, 75.0
Min, Max	1, 205	1, 179	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.2
Summary of Study Duration by Sex
Safety Set

Sex Group: Male

	Placebo (N=8056)	mRNA-1273 (N=7918)	Total (N=15974)
Number of Subjects, n (%)			
Received First Injection	8056 (100)	7918 (100)	15974 (100)
Received Second Injection	7755 (96.3)	7668 (96.8)	15423 (96.6)
>= 49 Days Since First Injection	7956 (98.8)	7824 (98.8)	15780 (98.8)
>= 56 Days Since First Injection	7935 (98.5)	7817 (98.7)	15752 (98.6)
>= 2 Months Since First Injection	7914 (98.2)	7801 (98.5)	15715 (98.4)
< 28 Days Since Second Injection	23 (0.3)	19 (0.2)	42 (0.3)
>= 28 and < 56 Days Since Second Injection	74 (0.9)	25 (0.3)	99 (0.6)
>= 28 Days Since Second Injection	7732 (96.0)	7649 (96.6)	15381 (96.3)
>= 56 Days Since Second Injection	7658 (95.1)	7624 (96.3)	15282 (95.7)
>= 2 Months Since Second Injection	7635 (94.8)	7617 (96.2)	15252 (95.5)
>= 3 Months Since Second Injection	7349 (91.2)	7586 (95.8)	14935 (93.5)
>= 4 Months Since Second Injection	7001 (86.9)	7519 (95.0)	14520 (90.9)
>= 5 Months Since Second Injection	6074 (75.4)	6607 (83.4)	12681 (79.4)
>= 6 Months Since Second Injection	3414 (42.4)	3736 (47.2)	7150 (44.8)
Study Duration from Randomization (Days)			
Mean (SD)	196.6 (39.98)	204.3 (32.54)	200.5 (36.68)
Median	208.0	212.0	211.0
Q1, Q3	185.0, 222.0	194.0, 225.0	191.0, 224.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.2
Summary of Study Duration by Sex
Safety Set

Sex Group: Male

	Placebo (N=8056)	mRNA-1273 (N=7918)	Total (N=15974)
Study Duration from First Injection (Days)			
Mean (SD)	196.6 (39.98)	204.3 (32.54)	200.4 (36.69)
Median	208.0	212.0	211.0
Q1, Q3	185.0, 222.0	194.0, 225.0	191.0, 224.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	4336.7	4429.7	8766.4
Study Duration from Second Injection (Days) [2]			
Mean (SD)	163.7 (47.07)	172.2 (39.83)	167.9 (43.84)
Median	179.0	183.0	180.0
Q1, Q3	155.0, 193.0	165.0, 194.0	159.0, 193.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	7755	7668	15423
Mean (SD)	170.0 (34.95)	177.8 (25.30)	173.9 (30.78)
Median	179.0	183.0	180.0
Q1, Q3	158.0, 193.0	166.0, 194.0	164.0, 194.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.2
Summary of Study Duration by Sex
Safety Set

Sex Group: Male

	Placebo (N=8056)	mRNA-1273 (N=7918)	Total (N=15974)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	7533	7530	15063
Mean (SD)	144.1 (25.56)	147.0 (25.93)	145.6 (25.79)
Median	146.0	148.0	147.0
Q1, Q3	128.0, 161.0	131.0, 162.0	129.0, 162.0
Min, Max	30, 237	44, 241	30, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	7533	7530	15063
Mean (SD)	58.5 (23.52)	62.5 (19.04)	60.5 (21.49)
Median	66.0	66.0	66.0
Q1, Q3	52.0, 74.0	54.0, 75.0	53.0, 75.0
Min, Max	1, 205	1, 165	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.2
Summary of Study Duration by Sex
Safety Set

Sex Group: Female

	Placebo (N=7106)	mRNA-1273 (N=7266)	Total (N=14372)
Number of Subjects, n (%)			
Received First Injection	7106 (100)	7266 (100)	14372 (100)
Received Second Injection	6876 (96.8)	7063 (97.2)	13939 (97.0)
>= 49 Days Since First Injection	7036 (99.0)	7215 (99.3)	14251 (99.2)
>= 56 Days Since First Injection	7025 (98.9)	7206 (99.2)	14231 (99.0)
>= 2 Months Since First Injection	7015 (98.7)	7194 (99.0)	14209 (98.9)
< 28 Days Since Second Injection	13 (0.2)	5 (<0.1)	18 (0.1)
>= 28 and < 56 Days Since Second Injection	46 (0.6)	26 (0.4)	72 (0.5)
>= 28 Days Since Second Injection	6863 (96.6)	7058 (97.1)	13921 (96.9)
>= 56 Days Since Second Injection	6817 (95.9)	7032 (96.8)	13849 (96.4)
>= 2 Months Since Second Injection	6803 (95.7)	7028 (96.7)	13831 (96.2)
>= 3 Months Since Second Injection	6578 (92.6)	7009 (96.5)	13587 (94.5)
>= 4 Months Since Second Injection	6262 (88.1)	6966 (95.9)	13228 (92.0)
>= 5 Months Since Second Injection	5562 (78.3)	6254 (86.1)	11816 (82.2)
>= 6 Months Since Second Injection	3364 (47.3)	3763 (51.8)	7127 (49.6)
Study Duration from Randomization (Days)			
Mean (SD)	200.5 (37.54)	207.9 (29.16)	204.2 (33.77)
Median	212.0	214.0	213.0
Q1, Q3	191.0, 225.0	198.0, 226.0	196.0, 226.0
Min, Max	8, 243	4, 243	4, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.2
Summary of Study Duration by Sex
Safety Set

Sex Group: Female

	Placebo (N=7106)	mRNA-1273 (N=7266)	Total (N=14372)
Study Duration from First Injection (Days)			
Mean (SD)	200.5 (37.55)	207.9 (29.16)	204.2 (33.78)
Median	212.0	214.0	213.0
Q1, Q3	191.0, 225.0	198.0, 226.0	196.0, 226.0
Min, Max	8, 243	4, 243	4, 243
Person-years from First Injection [1]	3900.2	4135.8	8036.0
Study Duration from Second Injection (Days) [2]			
Mean (SD)	167.3 (44.94)	175.3 (37.91)	171.4 (41.72)
Median	182.0	184.0	183.0
Q1, Q3	159.0, 194.0	169.0, 197.0	164.0, 196.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	6876	7063	13939
Mean (SD)	172.9 (33.45)	180.3 (23.86)	176.7 (29.23)
Median	183.0	185.0	184.0
Q1, Q3	163.0, 194.0	170.0, 197.0	166.0, 197.0
Min, Max	7, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.2
Summary of Study Duration by Sex
Safety Set

Sex Group: Female

	Placebo (N=7106)	mRNA-1273 (N=7266)	Total (N=14372)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	6774	7007	13781
Mean (SD)	145.5 (25.33)	147.9 (25.31)	146.8 (25.35)
Median	147.0	149.0	148.0
Q1, Q3	130.0, 162.0	133.0, 163.0	132.0, 162.0
Min, Max	47, 234	44, 239	44, 239
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	6774	7007	13781
Mean (SD)	59.5 (23.54)	63.9 (18.35)	61.7 (21.18)
Median	67.0	67.0	67.0
Q1, Q3	53.0, 75.0	57.0, 75.0	54.0, 75.0
Min, Max	1, 169	1, 179	1, 179

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.3
Summary of Study Duration by Age Group (<65, >=65)
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)
Number of Subjects, n (%)			
Received First Injection	11411 (100)	11415 (100)	22826 (100)
Received Second Injection	10964 (96.1)	11027 (96.6)	21991 (96.3)
>= 49 Days Since First Injection	11270 (98.8)	11286 (98.9)	22556 (98.8)
>= 56 Days Since First Injection	11241 (98.5)	11271 (98.7)	22512 (98.6)
>= 2 Months Since First Injection	11211 (98.2)	11245 (98.5)	22456 (98.4)
< 28 Days Since Second Injection	34 (0.3)	23 (0.2)	57 (0.2)
>= 28 and < 56 Days Since Second Injection	110 (1.0)	49 (0.4)	159 (0.7)
>= 28 Days Since Second Injection	10930 (95.8)	11004 (96.4)	21934 (96.1)
>= 56 Days Since Second Injection	10820 (94.8)	10955 (96.0)	21775 (95.4)
>= 2 Months Since Second Injection	10789 (94.5)	10948 (95.9)	21737 (95.2)
>= 3 Months Since Second Injection	10348 (90.7)	10907 (95.5)	21255 (93.1)
>= 4 Months Since Second Injection	9797 (85.9)	10818 (94.8)	20615 (90.3)
>= 5 Months Since Second Injection	8385 (73.5)	9398 (82.3)	17783 (77.9)
>= 6 Months Since Second Injection	4793 (42.0)	5396 (47.3)	10189 (44.6)
Study Duration from Randomization (Days)			
Mean (SD)	195.8 (40.61)	204.3 (32.81)	200.1 (37.15)
Median	207.0	212.0	211.0
Q1, Q3	183.0, 223.0	194.0, 225.0	190.0, 225.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.3
Summary of Study Duration by Age Group (<65, >=65)
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)
Study Duration from First Injection (Days)			
Mean (SD)	195.8 (40.62)	204.3 (32.81)	200.1 (37.16)
Median	207.0	212.0	211.0
Q1, Q3	183.0, 223.0	194.0, 225.0	190.0, 225.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	6118.4	6385.4	12503.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	162.3 (48.08)	171.6 (41.00)	166.9 (44.92)
Median	178.0	183.0	180.0
Q1, Q3	150.0, 193.0	164.0, 194.0	158.0, 194.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	10964	11027	21991
Mean (SD)	168.9 (35.89)	177.6 (25.85)	173.3 (31.56)
Median	179.0	183.0	180.0
Q1, Q3	156.0, 193.0	165.0, 194.0	162.0, 194.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.3
Summary of Study Duration by Age Group (<65, >=65)
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	10662	10822	21484
Mean (SD)	144.8 (26.80)	147.6 (26.94)	146.2 (26.90)
Median	147.0	149.0	148.0
Q1, Q3	127.0, 162.0	131.0, 164.0	129.0, 163.0
Min, Max	31, 237	44, 241	31, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	10662	10822	21484
Mean (SD)	56.8 (24.35)	62.0 (19.67)	59.4 (22.27)
Median	65.0	65.0	65.0
Q1, Q3	49.0, 74.0	53.0, 75.0	51.0, 74.0
Min, Max	1, 169	1, 165	1, 169

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.3
Summary of Study Duration by Age Group (<65, >=65)
Safety Set

Age Group: >=65 Years

	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)
Number of Subjects, n (%)			
Received First Injection	3751 (100)	3769 (100)	7520 (100)
Received Second Injection	3667 (97.8)	3704 (98.3)	7371 (98.0)
>= 49 Days Since First Injection	3722 (99.2)	3753 (99.6)	7475 (99.4)
>= 56 Days Since First Injection	3719 (99.1)	3752 (99.5)	7471 (99.3)
>= 2 Months Since First Injection	3718 (99.1)	3750 (99.5)	7468 (99.3)
< 28 Days Since Second Injection	2 (<0.1)	1 (<0.1)	3 (<0.1)
>= 28 and < 56 Days Since Second Injection	10 (0.3)	2 (<0.1)	12 (0.2)
>= 28 Days Since Second Injection	3665 (97.7)	3703 (98.2)	7368 (98.0)
>= 56 Days Since Second Injection	3655 (97.4)	3701 (98.2)	7356 (97.8)
>= 2 Months Since Second Injection	3649 (97.3)	3697 (98.1)	7346 (97.7)
>= 3 Months Since Second Injection	3579 (95.4)	3688 (97.9)	7267 (96.6)
>= 4 Months Since Second Injection	3466 (92.4)	3667 (97.3)	7133 (94.9)
>= 5 Months Since Second Injection	3251 (86.7)	3463 (91.9)	6714 (89.3)
>= 6 Months Since Second Injection	1985 (52.9)	2103 (55.8)	4088 (54.4)
Study Duration from Randomization (Days)			
Mean (SD)	206.3 (31.92)	211.3 (24.09)	208.8 (28.37)
Median	214.0	215.0	214.0
Q1, Q3	199.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	8, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.3
Summary of Study Duration by Age Group (<65, >=65)
Safety Set

Age Group: >=65 Years

	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)
Study Duration from First Injection (Days)			
Mean (SD)	206.3 (31.92)	211.3 (24.09)	208.8 (28.38)
Median	214.0	214.0	214.0
Q1, Q3	199.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	8, 243	7, 243	7, 243
Person-years from First Injection [1]	2118.5	2180.1	4298.6
Study Duration from Second Injection (Days) [2]			
Mean (SD)	174.7 (38.07)	180.1 (31.08)	177.4 (34.85)
Median	184.0	185.0	185.0
Q1, Q3	170.0, 196.0	173.0, 197.0	171.0, 197.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	3667	3704	7371
Mean (SD)	178.7 (27.70)	183.2 (20.10)	181.0 (24.28)
Median	185.0	186.0	185.0
Q1, Q3	171.0, 197.0	173.0, 197.0	172.0, 197.0
Min, Max	8, 218	22, 218	8, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.3
Summary of Study Duration by Age Group (<65, >=65)
Safety Set

Age Group: >=65 Years

	Placebo (N=3751)	mRNA-1273 (N=3769)	Total (N=7520)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	3645	3715	7360
Mean (SD)	144.6 (21.08)	147.2 (21.39)	145.9 (21.27)
Median	146.0	148.0	147.0
Q1, Q3	132.0, 158.0	134.0, 160.0	133.0, 159.0
Min, Max	30, 234	44, 224	30, 234
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	3645	3715	7360
Mean (SD)	65.4 (19.60)	66.6 (15.12)	66.0 (17.49)
Median	72.0	71.0	71.0
Q1, Q3	61.0, 78.0	60.0, 75.0	61.0, 78.0
Min, Max	1, 205	1, 179	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)
Number of Subjects, n (%)			
Received First Injection	11411 (100)	11415 (100)	22826 (100)
Received Second Injection	10964 (96.1)	11027 (96.6)	21991 (96.3)
>= 49 Days Since First Injection	11270 (98.8)	11286 (98.9)	22556 (98.8)
>= 56 Days Since First Injection	11241 (98.5)	11271 (98.7)	22512 (98.6)
>= 2 Months Since First Injection	11211 (98.2)	11245 (98.5)	22456 (98.4)
< 28 Days Since Second Injection	34 (0.3)	23 (0.2)	57 (0.2)
>= 28 and < 56 Days Since Second Injection	110 (1.0)	49 (0.4)	159 (0.7)
>= 28 Days Since Second Injection	10930 (95.8)	11004 (96.4)	21934 (96.1)
>= 56 Days Since Second Injection	10820 (94.8)	10955 (96.0)	21775 (95.4)
>= 2 Months Since Second Injection	10789 (94.5)	10948 (95.9)	21737 (95.2)
>= 3 Months Since Second Injection	10348 (90.7)	10907 (95.5)	21255 (93.1)
>= 4 Months Since Second Injection	9797 (85.9)	10818 (94.8)	20615 (90.3)
>= 5 Months Since Second Injection	8385 (73.5)	9398 (82.3)	17783 (77.9)
>= 6 Months Since Second Injection	4793 (42.0)	5396 (47.3)	10189 (44.6)
Study Duration from Randomization (Days)			
Mean (SD)	195.8 (40.61)	204.3 (32.81)	200.1 (37.15)
Median	207.0	212.0	211.0
Q1, Q3	183.0, 223.0	194.0, 225.0	190.0, 225.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)
Study Duration from First Injection (Days)			
Mean (SD)	195.8 (40.62)	204.3 (32.81)	200.1 (37.16)
Median	207.0	212.0	211.0
Q1, Q3	183.0, 223.0	194.0, 225.0	190.0, 225.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	6118.4	6385.4	12503.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	162.3 (48.08)	171.6 (41.00)	166.9 (44.92)
Median	178.0	183.0	180.0
Q1, Q3	150.0, 193.0	164.0, 194.0	158.0, 194.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	10964	11027	21991
Mean (SD)	168.9 (35.89)	177.6 (25.85)	173.3 (31.56)
Median	179.0	183.0	180.0
Q1, Q3	156.0, 193.0	165.0, 194.0	162.0, 194.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411)	mRNA-1273 (N=11415)	Total (N=22826)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	10662	10822	21484
Mean (SD)	144.8 (26.80)	147.6 (26.94)	146.2 (26.90)
Median	147.0	149.0	148.0
Q1, Q3	127.0, 162.0	131.0, 164.0	129.0, 163.0
Min, Max	31, 237	44, 241	31, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	10662	10822	21484
Mean (SD)	56.8 (24.35)	62.0 (19.67)	59.4 (22.27)
Median	65.0	65.0	65.0
Q1, Q3	49.0, 74.0	53.0, 75.0	51.0, 74.0
Min, Max	1, 169	1, 165	1, 169

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=65 and <75 Years

	Placebo (N=3010)	mRNA-1273 (N=3112)	Total (N=6122)
Number of Subjects, n (%)			
Received First Injection	3010 (100)	3112 (100)	6122 (100)
Received Second Injection	2946 (97.9)	3058 (98.3)	6004 (98.1)
>= 49 Days Since First Injection	2990 (99.3)	3101 (99.6)	6091 (99.5)
>= 56 Days Since First Injection	2987 (99.2)	3100 (99.6)	6087 (99.4)
>= 2 Months Since First Injection	2986 (99.2)	3098 (99.6)	6084 (99.4)
< 28 Days Since Second Injection	2 (<0.1)	1 (<0.1)	3 (<0.1)
>= 28 and < 56 Days Since Second Injection	10 (0.3)	0	10 (0.2)
>= 28 Days Since Second Injection	2944 (97.8)	3057 (98.2)	6001 (98.0)
>= 56 Days Since Second Injection	2934 (97.5)	3057 (98.2)	5991 (97.9)
>= 2 Months Since Second Injection	2928 (97.3)	3053 (98.1)	5981 (97.7)
>= 3 Months Since Second Injection	2864 (95.1)	3046 (97.9)	5910 (96.5)
>= 4 Months Since Second Injection	2774 (92.2)	3031 (97.4)	5805 (94.8)
>= 5 Months Since Second Injection	2600 (86.4)	2851 (91.6)	5451 (89.0)
>= 6 Months Since Second Injection	1591 (52.9)	1724 (55.4)	3315 (54.1)
Study Duration from Randomization (Days)			
Mean (SD)	206.0 (32.17)	211.3 (23.67)	208.7 (28.29)
Median	213.0	214.0	214.0
Q1, Q3	199.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	8, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=65 and <75 Years

	Placebo (N=3010)	mRNA-1273 (N=3112)	Total (N=6122)
Study Duration from First Injection (Days)			
Mean (SD)	206.0 (32.18)	211.2 (23.68)	208.7 (28.30)
Median	213.0	214.0	214.0
Q1, Q3	199.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	8, 243	7, 243	7, 243
Person-years from First Injection [1]	1697.9	1799.9	3497.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	174.6 (38.23)	179.9 (31.09)	177.3 (34.89)
Median	184.0	185.0	185.0
Q1, Q3	170.0, 197.0	173.0, 197.0	171.0, 197.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	2946	3058	6004
Mean (SD)	178.3 (28.58)	183.1 (20.04)	180.8 (24.72)
Median	185.0	186.0	185.0
Q1, Q3	171.0, 197.0	173.0, 197.0	172.0, 197.0
Min, Max	8, 218	22, 218	8, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=65 and <75 Years

	Placebo (N=3010)	mRNA-1273 (N=3112)	Total (N=6122)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	2925	3071	5996
Mean (SD)	144.8 (21.36)	147.1 (21.60)	146.0 (21.51)
Median	146.0	148.0	147.0
Q1, Q3	132.0, 159.0	134.0, 160.0	133.0, 160.0
Min, Max	55, 234	44, 224	44, 234
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	2925	3071	5996
Mean (SD)	64.8 (19.79)	66.5 (15.24)	65.7 (17.63)
Median	72.0	71.0	71.0
Q1, Q3	60.0, 78.0	60.0, 75.0	60.0, 78.0
Min, Max	1, 100	1, 179	1, 179

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=75 and <85 Years

	Placebo (N=692)	mRNA-1273 (N=616)	Total (N=1308)
Number of Subjects, n (%)			
Received First Injection	692 (100)	616 (100)	1308 (100)
Received Second Injection	674 (97.4)	608 (98.7)	1282 (98.0)
>= 49 Days Since First Injection	685 (99.0)	613 (99.5)	1298 (99.2)
>= 56 Days Since First Injection	685 (99.0)	613 (99.5)	1298 (99.2)
>= 2 Months Since First Injection	685 (99.0)	613 (99.5)	1298 (99.2)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	2 (0.3)	2 (0.2)
>= 28 Days Since Second Injection	674 (97.4)	608 (98.7)	1282 (98.0)
>= 56 Days Since Second Injection	674 (97.4)	606 (98.4)	1280 (97.9)
>= 2 Months Since Second Injection	674 (97.4)	606 (98.4)	1280 (97.9)
>= 3 Months Since Second Injection	668 (96.5)	604 (98.1)	1272 (97.2)
>= 4 Months Since Second Injection	649 (93.8)	600 (97.4)	1249 (95.5)
>= 5 Months Since Second Injection	612 (88.4)	577 (93.7)	1189 (90.9)
>= 6 Months Since Second Injection	366 (52.9)	359 (58.3)	725 (55.4)
Study Duration from Randomization (Days)			
Mean (SD)	207.7 (29.85)	212.1 (23.82)	209.8 (27.25)
Median	214.0	215.0	214.0
Q1, Q3	200.0, 225.0	204.0, 227.0	200.0, 226.0
Min, Max	13, 243	21, 243	13, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=75 and <85 Years

	Placebo (N=692)	mRNA-1273 (N=616)	Total (N=1308)
Study Duration from First Injection (Days)			
Mean (SD)	207.7 (29.85)	212.1 (23.82)	209.7 (27.26)
Median	214.0	215.0	214.0
Q1, Q3	200.0, 225.0	204.0, 227.0	200.0, 226.0
Min, Max	13, 243	21, 243	13, 243
Person-years from First Injection [1]	393.5	357.6	751.1
Study Duration from Second Injection (Days) [2]			
Mean (SD)	175.7 (36.93)	181.5 (28.93)	178.4 (33.52)
Median	184.0	186.0	185.0
Q1, Q3	170.0, 194.0	173.0, 198.0	171.0, 197.0
Min, Max	0, 215	0, 215	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	674	608	1282
Mean (SD)	180.3 (23.51)	183.9 (20.21)	182.0 (22.07)
Median	185.0	186.0	186.0
Q1, Q3	171.0, 194.0	176.0, 198.0	172.0, 197.0
Min, Max	65, 215	36, 215	36, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=75 and <85 Years

	Placebo (N=692)	mRNA-1273 (N=616)	Total (N=1308)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	673	606	1279
Mean (SD)	143.4 (19.92)	147.7 (20.35)	145.5 (20.23)
Median	145.0	148.5	147.0
Q1, Q3	132.0, 155.0	134.0, 160.0	133.0, 157.0
Min, Max	30, 218	77, 210	30, 218
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	673	606	1279
Mean (SD)	68.0 (18.16)	67.0 (14.52)	67.6 (16.54)
Median	73.0	71.0	72.0
Q1, Q3	65.0, 78.0	64.0, 75.0	64.0, 78.0
Min, Max	1, 205	1, 96	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=85 Years

	Placebo (N=49)	mRNA-1273 (N=41)	Total (N=90)
Number of Subjects, n (%)			
Received First Injection	49 (100)	41 (100)	90 (100)
Received Second Injection	47 (95.9)	38 (92.7)	85 (94.4)
>= 49 Days Since First Injection	47 (95.9)	39 (95.1)	86 (95.6)
>= 56 Days Since First Injection	47 (95.9)	39 (95.1)	86 (95.6)
>= 2 Months Since First Injection	47 (95.9)	39 (95.1)	86 (95.6)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	47 (95.9)	38 (92.7)	85 (94.4)
>= 56 Days Since Second Injection	47 (95.9)	38 (92.7)	85 (94.4)
>= 2 Months Since Second Injection	47 (95.9)	38 (92.7)	85 (94.4)
>= 3 Months Since Second Injection	47 (95.9)	38 (92.7)	85 (94.4)
>= 4 Months Since Second Injection	43 (87.8)	36 (87.8)	79 (87.8)
>= 5 Months Since Second Injection	39 (79.6)	35 (85.4)	74 (82.2)
>= 6 Months Since Second Injection	28 (57.1)	20 (48.8)	48 (53.3)
Study Duration from Randomization (Days)			
Mean (SD)	201.8 (42.66)	201.4 (47.55)	201.6 (44.70)
Median	215.0	212.0	214.5
Q1, Q3	193.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	38, 243	7, 240	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=85 Years

	Placebo (N=49)	mRNA-1273 (N=41)	Total (N=90)
Study Duration from First Injection (Days)			
Mean (SD)	201.8 (42.66)	201.4 (47.55)	201.6 (44.70)
Median	215.0	212.0	214.5
Q1, Q3	193.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	38, 243	7, 240	7, 243
Person-years from First Injection [1]	27.1	22.6	49.7
Study Duration from Second Injection (Days) [2]			
Mean (SD)	171.3 (44.44)	168.3 (52.59)	170.0 (48.07)
Median	185.0	180.0	185.0
Q1, Q3	165.0, 197.0	173.0, 194.0	165.0, 196.0
Min, Max	0, 215	0, 214	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	47	38	85
Mean (SD)	178.6 (27.02)	181.6 (22.62)	180.0 (25.05)
Median	185.0	185.5	185.0
Q1, Q3	173.0, 198.0	176.0, 196.0	176.0, 197.0
Min, Max	102, 215	116, 214	102, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.4
Summary of Study Duration by Age group (<65, >=65 and <75, >=75 and <85, >=85)
Safety Set

Age Group: >=85 Years

	Placebo (N=49)	mRNA-1273 (N=41)	Total (N=90)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	47	38	85
Mean (SD)	146.5 (19.80)	146.2 (20.10)	146.4 (19.82)
Median	145.0	148.0	147.0
Q1, Q3	137.0, 159.0	137.0, 157.0	137.0, 157.0
Min, Max	95, 189	82, 216	82, 216
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	47	38	85
Mean (SD)	63.2 (24.48)	67.5 (15.35)	65.1 (20.89)
Median	73.0	72.0	73.0
Q1, Q3	65.0, 78.0	65.0, 75.0	65.0, 75.0
Min, Max	1, 82	1, 82	1, 82

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: White

	Placebo (N=11998)	mRNA-1273 (N=12034)	Total (N=24032)
Number of Subjects, n (%)			
Received First Injection	11998 (100)	12034 (100)	24032 (100)
Received Second Injection	11615 (96.8)	11704 (97.3)	23319 (97.0)
>= 49 Days Since First Injection	11884 (99.0)	11930 (99.1)	23814 (99.1)
>= 56 Days Since First Injection	11858 (98.8)	11918 (99.0)	23776 (98.9)
>= 2 Months Since First Injection	11837 (98.7)	11903 (98.9)	23740 (98.8)
< 28 Days Since Second Injection	24 (0.2)	16 (0.1)	40 (0.2)
>= 28 and < 56 Days Since Second Injection	71 (0.6)	33 (0.3)	104 (0.4)
>= 28 Days Since Second Injection	11591 (96.6)	11688 (97.1)	23279 (96.9)
>= 56 Days Since Second Injection	11520 (96.0)	11655 (96.9)	23175 (96.4)
>= 2 Months Since Second Injection	11497 (95.8)	11645 (96.8)	23142 (96.3)
>= 3 Months Since Second Injection	11104 (92.5)	11607 (96.5)	22711 (94.5)
>= 4 Months Since Second Injection	10558 (88.0)	11533 (95.8)	22091 (91.9)
>= 5 Months Since Second Injection	9639 (80.3)	10686 (88.8)	20325 (84.6)
>= 6 Months Since Second Injection	5999 (50.0)	6657 (55.3)	12656 (52.7)
Study Duration from Randomization (Days)			
Mean (SD)	201.8 (37.82)	209.5 (29.43)	205.6 (34.10)
Median	213.0	215.0	214.0
Q1, Q3	196.0, 226.0	203.0, 227.0	199.0, 226.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: White

	Placebo (N=11998)	mRNA-1273 (N=12034)	Total (N=24032)
Study Duration from First Injection (Days)			
Mean (SD)	201.8 (37.83)	209.5 (29.43)	205.6 (34.10)
Median	213.0	215.0	214.0
Q1, Q3	196.0, 226.0	202.0, 227.0	199.0, 226.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	6627.4	6901.0	13528.4
Study Duration from Second Injection (Days) [2]			
Mean (SD)	168.9 (44.97)	177.2 (37.43)	173.1 (41.58)
Median	183.5	185.0	184.0
Q1, Q3	164.0, 196.0	171.0, 197.0	169.0, 197.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	11615	11704	23319
Mean (SD)	174.5 (33.43)	182.2 (23.01)	178.4 (28.94)
Median	184.0	186.0	185.0
Q1, Q3	166.0, 197.0	173.0, 198.0	170.0, 197.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: White

	Placebo (N=11998)	mRNA-1273 (N=12034)	Total (N=24032)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	11370	11585	22955
Mean (SD)	147.4 (24.06)	149.9 (24.28)	148.7 (24.20)
Median	148.0	151.0	149.0
Q1, Q3	133.0, 162.0	135.0, 164.0	134.0, 163.0
Min, Max	30, 237	44, 241	30, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	11370	11585	22955
Mean (SD)	59.4 (23.42)	63.8 (18.45)	61.6 (21.18)
Median	67.0	67.0	67.0
Q1, Q3	53.0, 75.0	57.0, 75.0	54.0, 75.0
Min, Max	1, 205	1, 179	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Black or African American

	Placebo (N=1531)	mRNA-1273 (N=1567)	Total (N=3098)
Number of Subjects, n (%)			
Received First Injection	1531 (100)	1567 (100)	3098 (100)
Received Second Injection	1441 (94.1)	1481 (94.5)	2922 (94.3)
>= 49 Days Since First Injection	1502 (98.1)	1540 (98.3)	3042 (98.2)
>= 56 Days Since First Injection	1497 (97.8)	1537 (98.1)	3034 (97.9)
>= 2 Months Since First Injection	1490 (97.3)	1528 (97.5)	3018 (97.4)
< 28 Days Since Second Injection	4 (0.3)	3 (0.2)	7 (0.2)
>= 28 and < 56 Days Since Second Injection	12 (0.8)	10 (0.6)	22 (0.7)
>= 28 Days Since Second Injection	1437 (93.9)	1478 (94.3)	2915 (94.1)
>= 56 Days Since Second Injection	1425 (93.1)	1468 (93.7)	2893 (93.4)
>= 2 Months Since Second Injection	1422 (92.9)	1468 (93.7)	2890 (93.3)
>= 3 Months Since Second Injection	1399 (91.4)	1463 (93.4)	2862 (92.4)
>= 4 Months Since Second Injection	1373 (89.7)	1445 (92.2)	2818 (91.0)
>= 5 Months Since Second Injection	1021 (66.7)	1056 (67.4)	2077 (67.0)
>= 6 Months Since Second Injection	427 (27.9)	405 (25.8)	832 (26.9)
Study Duration from Randomization (Days)			
Mean (SD)	189.9 (38.13)	191.2 (35.84)	190.6 (36.99)
Median	197.0	197.0	197.0
Q1, Q3	177.0, 214.0	178.0, 214.0	178.0, 214.0
Min, Max	11, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Black or African American

	Placebo (N=1531)	mRNA-1273 (N=1567)	Total (N=3098)
Study Duration from First Injection (Days)			
Mean (SD)	189.9 (38.13)	191.2 (35.83)	190.6 (36.99)
Median	197.0	197.0	197.0
Q1, Q3	177.0, 214.0	178.0, 214.0	178.0, 214.0
Min, Max	11, 243	7, 243	7, 243
Person-years from First Injection [1]	796.0	820.2	1616.2
Study Duration from Second Injection (Days) [2]			
Mean (SD)	155.3 (48.35)	157.0 (45.88)	156.2 (47.12)
Median	165.0	166.0	165.0
Q1, Q3	145.0, 185.0	145.0, 184.0	145.0, 184.0
Min, Max	0, 218	0, 215	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	1441	1481	2922
Mean (SD)	165.0 (29.71)	166.2 (26.67)	165.6 (28.22)
Median	169.0	169.0	169.0
Q1, Q3	150.0, 186.0	151.0, 185.0	150.0, 185.0
Min, Max	8, 218	1, 215	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Black or African American

	Placebo (N=1531)	mRNA-1273 (N=1567)	Total (N=3098)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	1404	1442	2846
Mean (SD)	136.8 (28.54)	139.4 (28.33)	138.2 (28.45)
Median	136.0	140.0	138.0
Q1, Q3	116.0, 155.0	120.0, 156.0	119.0, 156.0
Min, Max	68, 232	64, 239	64, 239
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	1404	1442	2846
Mean (SD)	60.0 (20.43)	58.7 (18.86)	59.3 (19.66)
Median	66.0	63.0	65.0
Q1, Q3	51.0, 74.0	50.0, 73.0	51.0, 74.0
Min, Max	1, 130	1, 102	1, 130

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Asian

	Placebo (N=739)	mRNA-1273 (N=656)	Total (N=1395)
Number of Subjects, n (%)			
Received First Injection	739 (100)	656 (100)	1395 (100)
Received Second Injection	719 (97.3)	641 (97.7)	1360 (97.5)
>= 49 Days Since First Injection	727 (98.4)	652 (99.4)	1379 (98.9)
>= 56 Days Since First Injection	726 (98.2)	651 (99.2)	1377 (98.7)
>= 2 Months Since First Injection	724 (98.0)	651 (99.2)	1375 (98.6)
< 28 Days Since Second Injection	3 (0.4)	1 (0.2)	4 (0.3)
>= 28 and < 56 Days Since Second Injection	25 (3.4)	3 (0.5)	28 (2.0)
>= 28 Days Since Second Injection	716 (96.9)	640 (97.6)	1356 (97.2)
>= 56 Days Since Second Injection	691 (93.5)	637 (97.1)	1328 (95.2)
>= 2 Months Since Second Injection	688 (93.1)	636 (97.0)	1324 (94.9)
>= 3 Months Since Second Injection	625 (84.6)	633 (96.5)	1258 (90.2)
>= 4 Months Since Second Injection	568 (76.9)	627 (95.6)	1195 (85.7)
>= 5 Months Since Second Injection	410 (55.5)	468 (71.3)	878 (62.9)
>= 6 Months Since Second Injection	154 (20.8)	196 (29.9)	350 (25.1)
Study Duration from Randomization (Days)			
Mean (SD)	177.6 (44.78)	196.3 (28.63)	186.4 (39.17)
Median	189.0	199.0	194.0
Q1, Q3	157.0, 211.0	180.0, 218.0	170.0, 214.0
Min, Max	8, 242	10, 242	8, 242

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Asian

	Placebo (N=739)	mRNA-1273 (N=656)	Total (N=1395)
Study Duration from First Injection (Days)			
Mean (SD)	177.5 (44.78)	196.3 (28.63)	186.4 (39.17)
Median	187.0	199.0	194.0
Q1, Q3	157.0, 211.0	180.0, 218.0	170.0, 214.0
Min, Max	8, 242	10, 242	8, 242
Person-years from First Injection [1]	359.2	352.6	711.9
Study Duration from Second Injection (Days) [2]			
Mean (SD)	145.7 (47.62)	164.1 (35.85)	154.3 (43.47)
Median	158.0	170.0	164.0
Q1, Q3	127.0, 180.0	150.0, 187.0	140.0, 184.0
Min, Max	0, 215	0, 215	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	719	641	1360
Mean (SD)	149.7 (41.51)	168.0 (25.87)	158.3 (36.17)
Median	159.0	171.0	165.0
Q1, Q3	129.0, 180.0	151.0, 187.0	142.0, 184.0
Min, Max	1, 215	21, 215	1, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Asian

	Placebo (N=739)	mRNA-1273 (N=656)	Total (N=1395)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	689	635	1324
Mean (SD)	132.5 (28.01)	135.7 (28.93)	134.0 (28.49)
Median	132.0	134.0	134.0
Q1, Q3	113.0, 153.0	116.0, 155.0	114.0, 154.0
Min, Max	61, 216	44, 236	44, 236
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	689	635	1324
Mean (SD)	50.3 (29.52)	63.3 (21.45)	56.5 (26.76)
Median	63.0	67.0	65.0
Q1, Q3	25.0, 74.0	54.0, 78.0	45.0, 75.0
Min, Max	1, 100	1, 165	1, 165

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: American Indian or Alaska Native

	Placebo (N=121)	mRNA-1273 (N=113)	Total (N=234)
Number of Subjects, n (%)			
Received First Injection	121 (100)	113 (100)	234 (100)
Received Second Injection	115 (95.0)	111 (98.2)	226 (96.6)
>= 49 Days Since First Injection	118 (97.5)	112 (99.1)	230 (98.3)
>= 56 Days Since First Injection	118 (97.5)	112 (99.1)	230 (98.3)
>= 2 Months Since First Injection	118 (97.5)	112 (99.1)	230 (98.3)
< 28 Days Since Second Injection	1 (0.8)	1 (0.9)	2 (0.9)
>= 28 and < 56 Days Since Second Injection	2 (1.7)	1 (0.9)	3 (1.3)
>= 28 Days Since Second Injection	114 (94.2)	110 (97.3)	224 (95.7)
>= 56 Days Since Second Injection	112 (92.6)	109 (96.5)	221 (94.4)
>= 2 Months Since Second Injection	110 (90.9)	109 (96.5)	219 (93.6)
>= 3 Months Since Second Injection	107 (88.4)	109 (96.5)	216 (92.3)
>= 4 Months Since Second Injection	103 (85.1)	105 (92.9)	208 (88.9)
>= 5 Months Since Second Injection	79 (65.3)	78 (69.0)	157 (67.1)
>= 6 Months Since Second Injection	32 (26.4)	32 (28.3)	64 (27.4)
Study Duration from Randomization (Days)			
Mean (SD)	186.2 (43.18)	195.7 (31.54)	190.8 (38.22)
Median	197.0	204.0	199.0
Q1, Q3	166.0, 214.0	177.0, 216.0	173.0, 215.0
Min, Max	13, 240	29, 243	13, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: American Indian or Alaska Native

	Placebo (N=121)	mRNA-1273 (N=113)	Total (N=234)
Study Duration from First Injection (Days)			
Mean (SD)	186.2 (43.18)	195.7 (31.54)	190.8 (38.22)
Median	197.0	204.0	199.0
Q1, Q3	166.0, 214.0	177.0, 216.0	173.0, 215.0
Min, Max	13, 240	29, 243	13, 243
Person-years from First Injection [1]	61.7	60.6	122.2
Study Duration from Second Injection (Days) [2]			
Mean (SD)	152.2 (50.62)	163.5 (38.24)	157.7 (45.33)
Median	165.0	173.0	168.5
Q1, Q3	137.0, 184.0	145.0, 185.0	142.0, 185.0
Min, Max	0, 213	0, 214	0, 214
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	115	111	226
Mean (SD)	160.1 (37.61)	166.5 (31.53)	163.3 (34.83)
Median	166.0	173.0	169.5
Q1, Q3	138.0, 186.0	148.0, 186.0	145.0, 186.0
Min, Max	7, 213	1, 214	1, 214

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: American Indian or Alaska Native

	Placebo (N=121)	mRNA-1273 (N=113)	Total (N=234)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	110	107	217
Mean (SD)	133.3 (29.08)	142.1 (29.18)	137.7 (29.39)
Median	135.5	142.0	139.0
Q1, Q3	113.0, 155.0	120.0, 162.0	116.0, 156.0
Min, Max	77, 220	76, 216	76, 220
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	110	107	217
Mean (SD)	58.3 (21.96)	57.7 (21.34)	58.0 (21.61)
Median	65.0	61.0	64.0
Q1, Q3	53.0, 73.0	46.0, 73.0	51.0, 73.0
Min, Max	1, 82	1, 99	1, 99

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

	Placebo (N=32)	mRNA-1273 (N=36)	Total (N=68)
Number of Subjects, n (%)			
Received First Injection	32 (100)	36 (100)	68 (100)
Received Second Injection	31 (96.9)	36 (100)	67 (98.5)
>= 49 Days Since First Injection	32 (100)	36 (100)	68 (100)
>= 56 Days Since First Injection	32 (100)	36 (100)	68 (100)
>= 2 Months Since First Injection	32 (100)	36 (100)	68 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	1 (3.1)	0	1 (1.5)
>= 28 Days Since Second Injection	31 (96.9)	36 (100)	67 (98.5)
>= 56 Days Since Second Injection	30 (93.8)	36 (100)	66 (97.1)
>= 2 Months Since Second Injection	29 (90.6)	36 (100)	65 (95.6)
>= 3 Months Since Second Injection	27 (84.4)	35 (97.2)	62 (91.2)
>= 4 Months Since Second Injection	24 (75.0)	35 (97.2)	59 (86.8)
>= 5 Months Since Second Injection	20 (62.5)	24 (66.7)	44 (64.7)
>= 6 Months Since Second Injection	9 (28.1)	16 (44.4)	25 (36.8)
Study Duration from Randomization (Days)			
Mean (SD)	180.4 (48.30)	200.3 (32.29)	190.9 (41.52)
Median	187.0	208.0	197.0
Q1, Q3	141.5, 217.0	173.0, 227.0	171.0, 221.5
Min, Max	70, 243	100, 243	70, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

	Placebo (N=32)	mRNA-1273 (N=36)	Total (N=68)
Study Duration from First Injection (Days)			
Mean (SD)	180.4 (48.30)	200.3 (32.29)	190.9 (41.52)
Median	187.0	208.0	197.0
Q1, Q3	141.5, 217.0	173.0, 227.0	171.0, 221.5
Min, Max	70, 243	100, 243	70, 243
Person-years from First Injection [1]	15.8	19.7	35.5
Study Duration from Second Injection (Days) [2]			
Mean (SD)	149.0 (54.76)	171.3 (32.00)	160.8 (45.25)
Median	160.5	174.5	168.5
Q1, Q3	114.0, 189.5	146.0, 197.5	143.0, 193.5
Min, Max	0, 218	70, 215	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	31	36	67
Mean (SD)	153.8 (48.32)	171.3 (32.00)	163.2 (41.00)
Median	161.0	174.5	169.0
Q1, Q3	131.0, 192.0	146.0, 197.5	144.0, 194.0
Min, Max	42, 218	70, 215	42, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

	Placebo (N=32)	mRNA-1273 (N=36)	Total (N=68)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	29	33	62
Mean (SD)	137.6 (34.66)	143.6 (30.45)	140.8 (32.36)
Median	135.0	149.0	144.5
Q1, Q3	114.0, 165.0	117.0, 155.0	114.0, 162.0
Min, Max	68, 210	95, 214	68, 214
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	29	33	62
Mean (SD)	47.6 (31.33)	63.2 (24.16)	55.9 (28.61)
Median	63.0	66.0	66.0
Q1, Q3	17.0, 72.0	54.0, 79.0	37.0, 75.0
Min, Max	1, 86	1, 99	1, 99

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Multiple

	Placebo (N=318)	mRNA-1273 (N=320)	Total (N=638)
Number of Subjects, n (%)			
Received First Injection	318 (100)	320 (100)	638 (100)
Received Second Injection	307 (96.5)	314 (98.1)	621 (97.3)
>= 49 Days Since First Injection	314 (98.7)	317 (99.1)	631 (98.9)
>= 56 Days Since First Injection	314 (98.7)	317 (99.1)	631 (98.9)
>= 2 Months Since First Injection	314 (98.7)	315 (98.4)	629 (98.6)
< 28 Days Since Second Injection	1 (0.3)	1 (0.3)	2 (0.3)
>= 28 and < 56 Days Since Second Injection	6 (1.9)	2 (0.6)	8 (1.3)
>= 28 Days Since Second Injection	306 (96.2)	313 (97.8)	619 (97.0)
>= 56 Days Since Second Injection	300 (94.3)	311 (97.2)	611 (95.8)
>= 2 Months Since Second Injection	298 (93.7)	311 (97.2)	609 (95.5)
>= 3 Months Since Second Injection	288 (90.6)	310 (96.9)	598 (93.7)
>= 4 Months Since Second Injection	277 (87.1)	308 (96.3)	585 (91.7)
>= 5 Months Since Second Injection	218 (68.6)	240 (75.0)	458 (71.8)
>= 6 Months Since Second Injection	84 (26.4)	89 (27.8)	173 (27.1)
Study Duration from Randomization (Days)			
Mean (SD)	188.8 (37.80)	196.2 (31.18)	192.5 (34.81)
Median	198.0	200.0	199.0
Q1, Q3	172.0, 214.0	183.0, 215.0	178.0, 214.0
Min, Max	28, 242	22, 243	22, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Multiple

	Placebo (N=318)	mRNA-1273 (N=320)	Total (N=638)
Study Duration from First Injection (Days)			
Mean (SD)	188.8 (37.80)	196.2 (31.18)	192.5 (34.81)
Median	198.0	200.0	199.0
Q1, Q3	172.0, 214.0	183.0, 215.0	178.0, 214.0
Min, Max	28, 242	22, 243	22, 243
Person-years from First Injection [1]	164.4	171.9	336.2
Study Duration from Second Injection (Days) [2]			
Mean (SD)	155.5 (45.46)	165.6 (34.59)	160.6 (40.66)
Median	169.0	171.0	170.0
Q1, Q3	142.0, 184.0	153.0, 185.0	149.0, 184.0
Min, Max	0, 214	0, 214	0, 214
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	307	314	621
Mean (SD)	161.1 (35.22)	168.8 (26.15)	165.0 (31.19)
Median	170.0	172.0	171.0
Q1, Q3	145.0, 185.0	155.0, 186.0	151.0, 185.0
Min, Max	10, 214	8, 214	8, 214

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Multiple

	Placebo (N=318)	mRNA-1273 (N=320)	Total (N=638)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	308	305	613
Mean (SD)	133.1 (25.48)	136.7 (25.26)	134.9 (25.41)
Median	133.0	137.0	134.0
Q1, Q3	116.0, 149.0	121.0, 153.0	119.0, 151.0
Min, Max	71, 211	58, 222	58, 222
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	308	305	613
Mean (SD)	59.5 (22.15)	64.2 (16.29)	61.9 (19.58)
Median	66.0	66.0	66.0
Q1, Q3	53.0, 74.0	56.0, 75.0	54.0, 74.0
Min, Max	1, 94	2, 102	1, 102

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Other/Not Reported/Unknown

	Placebo (N=423)	mRNA-1273 (N=458)	Total (N=881)
Number of Subjects, n (%)			
Received First Injection	423 (100)	458 (100)	881 (100)
Received Second Injection	403 (95.3)	444 (96.9)	847 (96.1)
>= 49 Days Since First Injection	415 (98.1)	452 (98.7)	867 (98.4)
>= 56 Days Since First Injection	415 (98.1)	452 (98.7)	867 (98.4)
>= 2 Months Since First Injection	414 (97.9)	450 (98.3)	864 (98.1)
< 28 Days Since Second Injection	3 (0.7)	2 (0.4)	5 (0.6)
>= 28 and < 56 Days Since Second Injection	3 (0.7)	2 (0.4)	5 (0.6)
>= 28 Days Since Second Injection	400 (94.6)	442 (96.5)	842 (95.6)
>= 56 Days Since Second Injection	397 (93.9)	440 (96.1)	837 (95.0)
>= 2 Months Since Second Injection	394 (93.1)	440 (96.1)	834 (94.7)
>= 3 Months Since Second Injection	377 (89.1)	438 (95.6)	815 (92.5)
>= 4 Months Since Second Injection	360 (85.1)	432 (94.3)	792 (89.9)
>= 5 Months Since Second Injection	249 (58.9)	309 (67.5)	558 (63.3)
>= 6 Months Since Second Injection	73 (17.3)	104 (22.7)	177 (20.1)
Study Duration from Randomization (Days)			
Mean (SD)	183.3 (37.98)	191.0 (32.59)	187.3 (35.47)
Median	191.0	193.0	192.0
Q1, Q3	170.0, 207.0	177.0, 212.0	173.0, 210.0
Min, Max	7, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Other/Not Reported/Unknown

	Placebo (N=423)	mRNA-1273 (N=458)	Total (N=881)
Study Duration from First Injection (Days)			
Mean (SD)	183.3 (37.97)	191.0 (32.58)	187.3 (35.46)
Median	191.0	193.0	192.0
Q1, Q3	170.0, 207.0	177.0, 212.0	173.0, 210.0
Min, Max	7, 243	1, 243	1, 243
Person-years from First Injection [1]	212.3	239.5	451.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	148.8 (46.29)	158.9 (38.56)	154.0 (42.72)
Median	159.0	163.0	162.0
Q1, Q3	137.0, 179.0	148.0, 180.0	143.0, 180.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	403	444	847
Mean (SD)	156.1 (33.07)	163.9 (26.66)	160.2 (30.11)
Median	162.0	164.0	163.0
Q1, Q3	143.0, 179.0	150.0, 183.0	145.0, 180.0
Min, Max	8, 218	8, 218	8, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.5
Summary of Study Duration by Race
Safety Set

Race Group: Other/Not Reported/Unknown

	Placebo (N=423)	mRNA-1273 (N=458)	Total (N=881)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	397	430	827
Mean (SD)	130.8 (26.49)	134.8 (29.09)	132.8 (27.93)
Median	128.0	133.0	130.0
Q1, Q3	113.0, 146.0	114.0, 153.0	114.0, 150.0
Min, Max	69, 221	74, 218	69, 221
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	397	430	827
Mean (SD)	58.7 (23.00)	61.2 (19.31)	60.0 (21.18)
Median	66.0	65.0	66.0
Q1, Q3	52.0, 74.0	52.0, 74.0	52.0, 74.0
Min, Max	1, 87	1, 101	1, 101

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.6
Summary of Study Duration by Ethnicity
Safety Set

Ethnicity Group: Hispanic or Latino

	Placebo (N=3108)	mRNA-1273 (N=3122)	Total (N=6230)
Number of Subjects, n (%)			
Received First Injection	3108 (100)	3122 (100)	6230 (100)
Received Second Injection	2921 (94.0)	2965 (95.0)	5886 (94.5)
>= 49 Days Since First Injection	3053 (98.2)	3071 (98.4)	6124 (98.3)
>= 56 Days Since First Injection	3045 (98.0)	3070 (98.3)	6115 (98.2)
>= 2 Months Since First Injection	3039 (97.8)	3059 (98.0)	6098 (97.9)
< 28 Days Since Second Injection	11 (0.4)	5 (0.2)	16 (0.3)
>= 28 and < 56 Days Since Second Injection	35 (1.1)	18 (0.6)	53 (0.9)
>= 28 Days Since Second Injection	2910 (93.6)	2960 (94.8)	5870 (94.2)
>= 56 Days Since Second Injection	2875 (92.5)	2942 (94.2)	5817 (93.4)
>= 2 Months Since Second Injection	2856 (91.9)	2940 (94.2)	5796 (93.0)
>= 3 Months Since Second Injection	2771 (89.2)	2928 (93.8)	5699 (91.5)
>= 4 Months Since Second Injection	2659 (85.6)	2907 (93.1)	5566 (89.3)
>= 5 Months Since Second Injection	1975 (63.5)	2178 (69.8)	4153 (66.7)
>= 6 Months Since Second Injection	877 (28.2)	996 (31.9)	1873 (30.1)
Study Duration from Randomization (Days)			
Mean (SD)	187.6 (39.83)	194.1 (34.79)	190.9 (37.53)
Median	197.0	199.0	198.0
Q1, Q3	171.0, 214.0	179.0, 217.0	176.0, 215.0
Min, Max	5, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.6
Summary of Study Duration by Ethnicity
Safety Set

Ethnicity Group: Hispanic or Latino

	Placebo (N=3108)	mRNA-1273 (N=3122)	Total (N=6230)
Study Duration from First Injection (Days)			
Mean (SD)	187.6 (39.84)	194.1 (34.79)	190.8 (37.53)
Median	197.0	199.0	198.0
Q1, Q3	171.0, 214.0	179.0, 217.0	176.0, 215.0
Min, Max	5, 243	1, 243	1, 243
Person-years from First Injection [1]	1596.1	1659.1	3255.2
Study Duration from Second Injection (Days) [2]			
Mean (SD)	152.0 (50.44)	159.9 (44.97)	156.0 (47.94)
Median	165.0	170.0	169.0
Q1, Q3	137.0, 185.0	148.0, 186.0	143.0, 186.0
Min, Max	0, 215	0, 215	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	2921	2965	5886
Mean (SD)	161.8 (33.64)	168.4 (26.51)	165.1 (30.44)
Median	169.0	171.0	170.0
Q1, Q3	144.0, 186.0	151.0, 187.0	149.0, 186.0
Min, Max	7, 215	6, 215	6, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.6
Summary of Study Duration by Ethnicity
Safety Set

Ethnicity Group: Hispanic or Latino

	Placebo (N=3108)	mRNA-1273 (N=3122)	Total (N=6230)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	2855	2880	5735
Mean (SD)	137.0 (27.65)	140.0 (29.07)	138.5 (28.40)
Median	138.0	141.0	140.0
Q1, Q3	119.0, 155.0	120.0, 157.0	120.0, 156.0
Min, Max	31, 228	58, 226	31, 228
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	2855	2880	5735
Mean (SD)	57.0 (23.35)	60.2 (19.66)	58.6 (21.63)
Median	65.0	64.0	64.0
Q1, Q3	50.0, 73.0	51.0, 74.0	51.0, 74.0
Min, Max	1, 129	1, 112	1, 129

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.6
Summary of Study Duration by Ethnicity
Safety Set

Ethnicity Group: Not Hispanic or Latino

	Placebo (N=11918)	mRNA-1273 (N=11920)	Total (N=23838)
Number of Subjects, n (%)			
Received First Injection	11918 (100)	11920 (100)	23838 (100)
Received Second Injection	11578 (97.1)	11628 (97.6)	23206 (97.3)
>= 49 Days Since First Injection	11806 (99.1)	11829 (99.2)	23635 (99.1)
>= 56 Days Since First Injection	11782 (98.9)	11814 (99.1)	23596 (99.0)
>= 2 Months Since First Injection	11757 (98.6)	11797 (99.0)	23554 (98.8)
< 28 Days Since Second Injection	24 (0.2)	19 (0.2)	43 (0.2)
>= 28 and < 56 Days Since Second Injection	85 (0.7)	33 (0.3)	118 (0.5)
>= 28 Days Since Second Injection	11554 (96.9)	11609 (97.4)	23163 (97.2)
>= 56 Days Since Second Injection	11469 (96.2)	11576 (97.1)	23045 (96.7)
>= 2 Months Since Second Injection	11451 (96.1)	11568 (97.0)	23019 (96.6)
>= 3 Months Since Second Injection	11031 (92.6)	11532 (96.7)	22563 (94.7)
>= 4 Months Since Second Injection	10487 (88.0)	11443 (96.0)	21930 (92.0)
>= 5 Months Since Second Injection	9559 (80.2)	10563 (88.6)	20122 (84.4)
>= 6 Months Since Second Injection	5839 (49.0)	6421 (53.9)	12260 (51.4)
Study Duration from Randomization (Days)			
Mean (SD)	201.3 (38.12)	209.2 (29.06)	205.2 (34.12)
Median	212.0	214.0	213.0
Q1, Q3	194.0, 226.0	200.0, 227.0	198.0, 226.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.6
Summary of Study Duration by Ethnicity
Safety Set

Ethnicity Group: Not Hispanic or Latino

	Placebo (N=11918)	mRNA-1273 (N=11920)	Total (N=23838)
Study Duration from First Injection (Days)			
Mean (SD)	201.3 (38.13)	209.2 (29.06)	205.2 (34.12)
Median	212.0	214.0	213.0
Q1, Q3	194.0, 226.0	200.0, 227.0	198.0, 226.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	6567.3	6826.0	13393.3
Study Duration from Second Injection (Days) [2]			
Mean (SD)	168.9 (44.27)	177.2 (36.36)	173.0 (40.73)
Median	183.0	185.0	184.0
Q1, Q3	163.0, 196.0	171.0, 197.0	169.0, 197.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	11578	11628	23206
Mean (SD)	173.8 (34.00)	181.7 (23.38)	177.8 (29.43)
Median	184.0	185.0	185.0
Q1, Q3	165.0, 197.0	172.0, 197.0	170.0, 197.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.6
Summary of Study Duration by Ethnicity
Safety Set

Ethnicity Group: Not Hispanic or Latino

	Placebo (N=11918)	mRNA-1273 (N=11920)	Total (N=23838)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	11325	11522	22847
Mean (SD)	146.7 (24.51)	149.3 (24.32)	148.0 (24.45)
Median	148.0	150.0	149.0
Q1, Q3	132.0, 162.0	135.0, 163.0	133.0, 163.0
Min, Max	30, 237	44, 241	30, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	11325	11522	22847
Mean (SD)	59.4 (23.56)	63.9 (18.40)	61.7 (21.24)
Median	67.0	67.0	67.0
Q1, Q3	53.0, 75.0	57.0, 75.0	54.0, 75.0
Min, Max	1, 205	1, 179	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=18 and <65 Years, Male

	Placebo (N=5955)	mRNA-1273 (N=5841)	Total (N=11796)
Number of Subjects, n (%)			
Received First Injection	5955 (100)	5841 (100)	11796 (100)
Received Second Injection	5701 (95.7)	5623 (96.3)	11324 (96.0)
>= 49 Days Since First Injection	5872 (98.6)	5757 (98.6)	11629 (98.6)
>= 56 Days Since First Injection	5853 (98.3)	5751 (98.5)	11604 (98.4)
>= 2 Months Since First Injection	5833 (98.0)	5737 (98.2)	11570 (98.1)
< 28 Days Since Second Injection	22 (0.4)	18 (0.3)	40 (0.3)
>= 28 and < 56 Days Since Second Injection	67 (1.1)	23 (0.4)	90 (0.8)
>= 28 Days Since Second Injection	5679 (95.4)	5605 (96.0)	11284 (95.7)
>= 56 Days Since Second Injection	5612 (94.2)	5582 (95.6)	11194 (94.9)
>= 2 Months Since Second Injection	5594 (93.9)	5578 (95.5)	11172 (94.7)
>= 3 Months Since Second Injection	5363 (90.1)	5555 (95.1)	10918 (92.6)
>= 4 Months Since Second Injection	5087 (85.4)	5504 (94.2)	10591 (89.8)
>= 5 Months Since Second Injection	4302 (72.2)	4709 (80.6)	9011 (76.4)
>= 6 Months Since Second Injection	2349 (39.4)	2598 (44.5)	4947 (41.9)
Study Duration from Randomization (Days)			
Mean (SD)	193.9 (41.54)	202.3 (34.39)	198.1 (38.39)
Median	206.0	211.0	208.0
Q1, Q3	180.0, 221.0	192.0, 224.0	186.0, 222.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=18 and <65 Years, Male

	Placebo (N=5955)	mRNA-1273 (N=5841)	Total (N=11796)
Study Duration from First Injection (Days)			
Mean (SD)	193.9 (41.54)	202.3 (34.39)	198.1 (38.39)
Median	206.0	211.0	208.0
Q1, Q3	180.0, 221.0	192.0, 224.0	186.0, 222.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	3161.4	3234.7	6396.2
Study Duration from Second Injection (Days) [2]			
Mean (SD)	160.4 (49.04)	169.5 (42.28)	164.9 (46.04)
Median	177.0	180.0	178.0
Q1, Q3	148.0, 192.0	162.0, 193.0	156.0, 193.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	5701	5623	11324
Mean (SD)	167.6 (36.26)	176.1 (26.45)	171.8 (32.05)
Median	178.0	180.0	179.0
Q1, Q3	155.0, 193.0	164.0, 194.0	159.0, 193.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=18 and <65 Years, Male

	Placebo (N=5955)	mRNA-1273 (N=5841)	Total (N=11796)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	5503	5494	10997
Mean (SD)	144.3 (26.93)	147.2 (27.38)	145.7 (27.19)
Median	146.0	148.0	147.0
Q1, Q3	127.0, 162.0	129.0, 164.0	128.0, 163.0
Min, Max	31, 237	44, 241	31, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	5503	5494	10997
Mean (SD)	56.2 (23.99)	61.0 (19.98)	58.6 (22.21)
Median	64.0	65.0	64.0
Q1, Q3	47.0, 73.0	52.0, 74.0	51.0, 74.0
Min, Max	1, 129	1, 165	1, 165

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=18 and <65 Years, Female

	Placebo (N=5456)	mRNA-1273 (N=5574)	Total (N=11030)
Number of Subjects, n (%)			
Received First Injection	5456 (100)	5574 (100)	11030 (100)
Received Second Injection	5263 (96.5)	5404 (97.0)	10667 (96.7)
>= 49 Days Since First Injection	5398 (98.9)	5529 (99.2)	10927 (99.1)
>= 56 Days Since First Injection	5388 (98.8)	5520 (99.0)	10908 (98.9)
>= 2 Months Since First Injection	5378 (98.6)	5508 (98.8)	10886 (98.7)
< 28 Days Since Second Injection	12 (0.2)	5 (<0.1)	17 (0.2)
>= 28 and < 56 Days Since Second Injection	43 (0.8)	26 (0.5)	69 (0.6)
>= 28 Days Since Second Injection	5251 (96.2)	5399 (96.9)	10650 (96.6)
>= 56 Days Since Second Injection	5208 (95.5)	5373 (96.4)	10581 (95.9)
>= 2 Months Since Second Injection	5195 (95.2)	5370 (96.3)	10565 (95.8)
>= 3 Months Since Second Injection	4985 (91.4)	5352 (96.0)	10337 (93.7)
>= 4 Months Since Second Injection	4710 (86.3)	5314 (95.3)	10024 (90.9)
>= 5 Months Since Second Injection	4083 (74.8)	4689 (84.1)	8772 (79.5)
>= 6 Months Since Second Injection	2444 (44.8)	2798 (50.2)	5242 (47.5)
Study Duration from Randomization (Days)			
Mean (SD)	198.0 (39.46)	206.5 (30.92)	202.3 (35.66)
Median	211.0	213.0	212.0
Q1, Q3	185.0, 225.0	197.0, 226.0	192.0, 226.0
Min, Max	11, 243	4, 243	4, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=18 and <65 Years, Female

	Placebo (N=5456)	mRNA-1273 (N=5574)	Total (N=11030)
Study Duration from First Injection (Days)			
Mean (SD)	198.0 (39.48)	206.5 (30.92)	202.3 (35.67)
Median	211.0	213.0	212.0
Q1, Q3	185.0, 225.0	197.0, 226.0	192.0, 226.0
Min, Max	9, 243	4, 243	4, 243
Person-years from First Injection [1]	2957.0	3150.7	6107.7
Study Duration from Second Injection (Days) [2]			
Mean (SD)	164.3 (46.92)	173.7 (39.51)	169.1 (43.58)
Median	180.0	184.0	183.0
Q1, Q3	152.0, 194.0	165.0, 197.0	162.0, 194.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	5263	5404	10667
Mean (SD)	170.4 (35.43)	179.1 (25.13)	174.8 (30.96)
Median	180.0	184.0	183.0
Q1, Q3	158.0, 194.0	169.0, 197.0	164.0, 196.0
Min, Max	7, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=18 and <65 Years, Female

	Placebo (N=5456)	mRNA-1273 (N=5574)	Total (N=11030)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	5159	5328	10487
Mean (SD)	145.5 (26.65)	148.0 (26.48)	146.8 (26.59)
Median	147.0	149.0	148.0
Q1, Q3	128.0, 162.0	132.0, 164.0	130.0, 163.0
Min, Max	47, 232	49, 239	47, 239
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	5159	5328	10487
Mean (SD)	57.4 (24.71)	63.1 (19.29)	60.3 (22.31)
Median	66.0	67.0	66.0
Q1, Q3	50.0, 75.0	54.0, 75.0	52.0, 75.0
Min, Max	1, 169	1, 148	1, 169

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=65 Years, Male

	Placebo (N=2101)	mRNA-1273 (N=2077)	Total (N=4178)
Number of Subjects, n (%)			
Received First Injection	2101 (100)	2077 (100)	4178 (100)
Received Second Injection	2054 (97.8)	2045 (98.5)	4099 (98.1)
>= 49 Days Since First Injection	2084 (99.2)	2067 (99.5)	4151 (99.4)
>= 56 Days Since First Injection	2082 (99.1)	2066 (99.5)	4148 (99.3)
>= 2 Months Since First Injection	2081 (99.0)	2064 (99.4)	4145 (99.2)
< 28 Days Since Second Injection	1 (<0.1)	1 (<0.1)	2 (<0.1)
>= 28 and < 56 Days Since Second Injection	7 (0.3)	2 (<0.1)	9 (0.2)
>= 28 Days Since Second Injection	2053 (97.7)	2044 (98.4)	4097 (98.1)
>= 56 Days Since Second Injection	2046 (97.4)	2042 (98.3)	4088 (97.8)
>= 2 Months Since Second Injection	2041 (97.1)	2039 (98.2)	4080 (97.7)
>= 3 Months Since Second Injection	1986 (94.5)	2031 (97.8)	4017 (96.1)
>= 4 Months Since Second Injection	1914 (91.1)	2015 (97.0)	3929 (94.0)
>= 5 Months Since Second Injection	1772 (84.3)	1898 (91.4)	3670 (87.8)
>= 6 Months Since Second Injection	1065 (50.7)	1138 (54.8)	2203 (52.7)
Study Duration from Randomization (Days)			
Mean (SD)	204.3 (34.03)	210.2 (25.80)	207.2 (30.36)
Median	213.0	214.0	214.0
Q1, Q3	198.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	13, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=65 Years, Male

	Placebo (N=2101)	mRNA-1273 (N=2077)	Total (N=4178)
Study Duration from First Injection (Days)			
Mean (SD)	204.3 (34.04)	210.1 (25.80)	207.2 (30.36)
Median	213.0	214.0	214.0
Q1, Q3	198.0, 226.0	204.0, 226.0	200.0, 226.0
Min, Max	13, 243	7, 243	7, 243
Person-years from First Injection [1]	1175.3	1195.0	2370.3
Study Duration from Second Injection (Days) [2]			
Mean (SD)	172.8 (39.56)	179.6 (30.76)	176.2 (35.61)
Median	184.0	185.0	184.0
Q1, Q3	169.0, 196.0	172.0, 197.0	171.0, 197.0
Min, Max	0, 218	0, 215	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	2054	2045	4099
Mean (SD)	176.8 (30.02)	182.4 (21.17)	179.6 (26.13)
Median	184.0	185.0	185.0
Q1, Q3	170.0, 197.0	173.0, 197.0	171.0, 197.0
Min, Max	8, 218	22, 215	8, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=65 Years, Male

	Placebo (N=2101)	mRNA-1273 (N=2077)	Total (N=4178)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	2030	2036	4066
Mean (SD)	143.6 (21.43)	146.7 (21.53)	145.1 (21.54)
Median	145.0	148.0	147.0
Q1, Q3	131.0, 157.0	134.0, 160.0	133.0, 159.0
Min, Max	30, 223	68, 224	30, 224
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	2030	2036	4066
Mean (SD)	64.7 (20.93)	66.5 (15.52)	65.6 (18.44)
Median	72.0	71.0	71.0
Q1, Q3	61.0, 78.0	60.0, 76.0	60.0, 78.0
Min, Max	1, 205	1, 148	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=65 Years, Female

	Placebo (N=1650)	mRNA-1273 (N=1692)	Total (N=3342)
Number of Subjects, n (%)			
Received First Injection	1650 (100)	1692 (100)	3342 (100)
Received Second Injection	1613 (97.8)	1659 (98.0)	3272 (97.9)
>= 49 Days Since First Injection	1638 (99.3)	1686 (99.6)	3324 (99.5)
>= 56 Days Since First Injection	1637 (99.2)	1686 (99.6)	3323 (99.4)
>= 2 Months Since First Injection	1637 (99.2)	1686 (99.6)	3323 (99.4)
< 28 Days Since Second Injection	1 (<0.1)	0	1 (<0.1)
>= 28 and < 56 Days Since Second Injection	3 (0.2)	0	3 (<0.1)
>= 28 Days Since Second Injection	1612 (97.7)	1659 (98.0)	3271 (97.9)
>= 56 Days Since Second Injection	1609 (97.5)	1659 (98.0)	3268 (97.8)
>= 2 Months Since Second Injection	1608 (97.5)	1658 (98.0)	3266 (97.7)
>= 3 Months Since Second Injection	1593 (96.5)	1657 (97.9)	3250 (97.2)
>= 4 Months Since Second Injection	1552 (94.1)	1652 (97.6)	3204 (95.9)
>= 5 Months Since Second Injection	1479 (89.6)	1565 (92.5)	3044 (91.1)
>= 6 Months Since Second Injection	920 (55.8)	965 (57.0)	1885 (56.4)
Study Duration from Randomization (Days)			
Mean (SD)	208.8 (28.81)	212.7 (21.74)	210.8 (25.55)
Median	214.0	215.0	215.0
Q1, Q3	204.0, 226.0	204.0, 227.0	204.0, 226.0
Min, Max	8, 243	17, 243	8, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=65 Years, Female

	Placebo (N=1650)	mRNA-1273 (N=1692)	Total (N=3342)
Study Duration from First Injection (Days)			
Mean (SD)	208.8 (28.82)	212.7 (21.74)	210.7 (25.55)
Median	214.0	215.0	215.0
Q1, Q3	204.0, 226.0	204.0, 227.0	204.0, 226.0
Min, Max	8, 243	17, 243	8, 243
Person-years from First Injection [1]	943.2	985.1	1928.3
Study Duration from Second Injection (Days) [2]			
Mean (SD)	177.1 (35.96)	180.7 (31.47)	178.9 (33.80)
Median	185.0	186.0	186.0
Q1, Q3	172.0, 197.0	173.0, 198.0	173.0, 197.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	1613	1659	3272
Mean (SD)	181.2 (24.21)	184.3 (18.63)	182.8 (21.62)
Median	186.0	186.0	186.0
Q1, Q3	173.0, 197.0	176.0, 198.0	175.0, 197.0
Min, Max	24, 215	58, 218	24, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.7
Summary of Study Duration by Age Group (<65, >=65) and Sex
Safety Set

Age and Sex Group: >=65 Years, Female

	Placebo (N=1650)	mRNA-1273 (N=1692)	Total (N=3342)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	1615	1679	3294
Mean (SD)	145.8 (20.58)	147.7 (21.20)	146.8 (20.91)
Median	146.0	148.0	147.0
Q1, Q3	134.0, 159.0	135.0, 161.0	134.0, 160.0
Min, Max	64, 234	44, 220	44, 234
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	1615	1679	3294
Mean (SD)	66.2 (17.76)	66.8 (14.63)	66.5 (16.24)
Median	72.0	71.0	71.0
Q1, Q3	61.0, 78.0	60.0, 75.0	61.0, 77.0
Min, Max	1, 89	1, 179	1, 179

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, At Risk

	Placebo (N=2322)	mRNA-1273 (N=2320)	Total (N=4642)
Number of Subjects, n (%)			
Received First Injection	2322 (100)	2320 (100)	4642 (100)
Received Second Injection	2238 (96.4)	2266 (97.7)	4504 (97.0)
>= 49 Days Since First Injection	2300 (99.1)	2298 (99.1)	4598 (99.1)
>= 56 Days Since First Injection	2297 (98.9)	2293 (98.8)	4590 (98.9)
>= 2 Months Since First Injection	2294 (98.8)	2288 (98.6)	4582 (98.7)
< 28 Days Since Second Injection	3 (0.1)	8 (0.3)	11 (0.2)
>= 28 and < 56 Days Since Second Injection	11 (0.5)	15 (0.6)	26 (0.6)
>= 28 Days Since Second Injection	2235 (96.3)	2258 (97.3)	4493 (96.8)
>= 56 Days Since Second Injection	2224 (95.8)	2243 (96.7)	4467 (96.2)
>= 2 Months Since Second Injection	2219 (95.6)	2243 (96.7)	4462 (96.1)
>= 3 Months Since Second Injection	2162 (93.1)	2236 (96.4)	4398 (94.7)
>= 4 Months Since Second Injection	2095 (90.2)	2219 (95.6)	4314 (92.9)
>= 5 Months Since Second Injection	1813 (78.1)	1961 (84.5)	3774 (81.3)
>= 6 Months Since Second Injection	1073 (46.2)	1167 (50.3)	2240 (48.3)
Study Duration from Randomization (Days)			
Mean (SD)	201.6 (36.34)	206.5 (31.87)	204.0 (34.26)
Median	211.0	213.0	212.0
Q1, Q3	190.0, 226.0	197.0, 227.0	193.0, 226.0
Min, Max	1, 243	4, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, At Risk

	Placebo (N=2322)	mRNA-1273 (N=2320)	Total (N=4642)
Study Duration from First Injection (Days)			
Mean (SD)	201.6 (36.34)	206.4 (31.88)	204.0 (34.26)
Median	211.0	213.0	212.0
Q1, Q3	190.0, 226.0	197.0, 227.0	193.0, 226.0
Min, Max	1, 243	4, 243	1, 243
Person-years from First Injection [1]	1281.5	1311.2	2592.7
Study Duration from Second Injection (Days) [2]			
Mean (SD)	168.1 (44.90)	174.6 (38.06)	171.4 (41.75)
Median	180.0	184.0	183.0
Q1, Q3	158.0, 196.0	166.0, 197.0	163.0, 197.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	2238	2266	4504
Mean (SD)	174.4 (31.48)	178.8 (27.18)	176.6 (29.47)
Median	183.0	184.0	183.0
Q1, Q3	162.0, 197.0	169.0, 197.0	165.0, 197.0
Min, Max	7, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, At Risk

	Placebo (N=2322)	mRNA-1273 (N=2320)	Total (N=4642)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	2210	2199	4409
Mean (SD)	147.1 (26.37)	149.1 (26.79)	148.1 (26.60)
Median	148.0	151.0	149.0
Q1, Q3	130.0, 164.0	133.0, 165.0	132.0, 165.0
Min, Max	31, 232	44, 240	31, 240
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	2210	2199	4409
Mean (SD)	59.2 (22.19)	62.3 (18.68)	60.8 (20.57)
Median	66.0	66.0	66.0
Q1, Q3	52.0, 74.0	53.0, 74.0	53.0, 74.0
Min, Max	1, 129	1, 165	1, 165

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Chronic Lung Disease

	Placebo (N=504)	mRNA-1273 (N=473)	Total (N=977)
Number of Subjects, n (%)			
Received First Injection	504 (100)	473 (100)	977 (100)
Received Second Injection	487 (96.6)	460 (97.3)	947 (96.9)
>= 49 Days Since First Injection	500 (99.2)	467 (98.7)	967 (99.0)
>= 56 Days Since First Injection	500 (99.2)	466 (98.5)	966 (98.9)
>= 2 Months Since First Injection	500 (99.2)	466 (98.5)	966 (98.9)
< 28 Days Since Second Injection	0	2 (0.4)	2 (0.2)
>= 28 and < 56 Days Since Second Injection	5 (1.0)	3 (0.6)	8 (0.8)
>= 28 Days Since Second Injection	487 (96.6)	458 (96.8)	945 (96.7)
>= 56 Days Since Second Injection	482 (95.6)	455 (96.2)	937 (95.9)
>= 2 Months Since Second Injection	482 (95.6)	455 (96.2)	937 (95.9)
>= 3 Months Since Second Injection	466 (92.5)	452 (95.6)	918 (94.0)
>= 4 Months Since Second Injection	450 (89.3)	450 (95.1)	900 (92.1)
>= 5 Months Since Second Injection	401 (79.6)	419 (88.6)	820 (83.9)
>= 6 Months Since Second Injection	271 (53.8)	273 (57.7)	544 (55.7)
Study Duration from Randomization (Days)			
Mean (SD)	204.9 (36.92)	209.6 (32.88)	207.2 (35.09)
Median	216.5	217.0	217.0
Q1, Q3	194.0, 229.0	204.0, 229.0	199.0, 229.0
Min, Max	14, 243	4, 243	4, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Chronic Lung Disease

	Placebo (N=504)	mRNA-1273 (N=473)	Total (N=977)
Study Duration from First Injection (Days)			
Mean (SD)	204.9 (36.92)	209.6 (32.88)	207.2 (35.08)
Median	216.5	217.0	217.0
Q1, Q3	194.0, 229.0	204.0, 228.0	199.0, 229.0
Min, Max	14, 243	4, 243	4, 243
Person-years from First Injection [1]	282.7	271.5	554.2
Study Duration from Second Injection (Days) [2]			
Mean (SD)	171.2 (45.80)	177.4 (40.00)	174.2 (43.18)
Median	185.5	186.0	186.0
Q1, Q3	163.0, 199.0	172.0, 199.0	169.0, 199.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	487	460	947
Mean (SD)	177.1 (33.32)	182.4 (26.99)	179.7 (30.51)
Median	186.0	187.0	187.0
Q1, Q3	165.0, 200.0	175.5, 199.5	171.0, 200.0
Min, Max	34, 218	12, 218	12, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Chronic Lung Disease

	Placebo (N=504)	mRNA-1273 (N=473)	Total (N=977)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	478	448	926
Mean (SD)	150.4 (25.99)	151.3 (26.26)	150.9 (26.11)
Median	152.0	152.0	152.0
Q1, Q3	136.0, 167.0	136.0, 167.0	136.0, 167.0
Min, Max	31, 232	44, 218	31, 232
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	478	448	926
Mean (SD)	59.3 (22.13)	64.1 (18.86)	61.6 (20.74)
Median	66.0	67.0	66.5
Q1, Q3	53.0, 74.0	57.0, 75.0	53.0, 75.0
Min, Max	1, 129	1, 165	1, 165

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Significant Cardiac Disease

	Placebo (N=292)	mRNA-1273 (N=321)	Total (N=613)
Number of Subjects, n (%)			
Received First Injection	292 (100)	321 (100)	613 (100)
Received Second Injection	286 (97.9)	313 (97.5)	599 (97.7)
>= 49 Days Since First Injection	291 (99.7)	318 (99.1)	609 (99.3)
>= 56 Days Since First Injection	291 (99.7)	317 (98.8)	608 (99.2)
>= 2 Months Since First Injection	291 (99.7)	316 (98.4)	607 (99.0)
< 28 Days Since Second Injection	0	1 (0.3)	1 (0.2)
>= 28 and < 56 Days Since Second Injection	0	4 (1.2)	4 (0.7)
>= 28 Days Since Second Injection	286 (97.9)	312 (97.2)	598 (97.6)
>= 56 Days Since Second Injection	286 (97.9)	308 (96.0)	594 (96.9)
>= 2 Months Since Second Injection	286 (97.9)	308 (96.0)	594 (96.9)
>= 3 Months Since Second Injection	281 (96.2)	308 (96.0)	589 (96.1)
>= 4 Months Since Second Injection	274 (93.8)	306 (95.3)	580 (94.6)
>= 5 Months Since Second Injection	248 (84.9)	276 (86.0)	524 (85.5)
>= 6 Months Since Second Injection	150 (51.4)	170 (53.0)	320 (52.2)
Study Duration from Randomization (Days)			
Mean (SD)	208.0 (28.65)	207.7 (33.01)	207.9 (30.99)
Median	214.0	214.0	214.0
Q1, Q3	197.0, 228.0	198.0, 228.0	198.0, 228.0
Min, Max	48, 243	10, 243	10, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Significant Cardiac Disease

	Placebo (N=292)	mRNA-1273 (N=321)	Total (N=613)
Study Duration from First Injection (Days)			
Mean (SD)	208.0 (28.65)	207.7 (33.01)	207.9 (30.99)
Median	214.0	214.0	214.0
Q1, Q3	197.0, 228.0	198.0, 228.0	198.0, 228.0
Min, Max	48, 243	10, 243	10, 243
Person-years from First Injection [1]	166.3	182.6	348.9
Study Duration from Second Injection (Days) [2]			
Mean (SD)	175.6 (36.73)	175.7 (39.65)	175.7 (38.26)
Median	184.5	185.0	185.0
Q1, Q3	165.0, 198.0	169.0, 198.0	166.0, 198.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	286	313	599
Mean (SD)	179.3 (26.74)	180.2 (28.30)	179.8 (27.55)
Median	185.0	185.0	185.0
Q1, Q3	166.0, 198.0	171.0, 199.0	169.0, 199.0
Min, Max	67, 215	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Significant Cardiac Disease

	Placebo (N=292)	mRNA-1273 (N=321)	Total (N=613)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	281	309	590
Mean (SD)	148.1 (24.58)	149.6 (26.84)	148.9 (25.78)
Median	150.0	153.0	151.0
Q1, Q3	133.0, 166.0	134.0, 167.0	133.0, 167.0
Min, Max	77, 224	60, 224	60, 224
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	281	309	590
Mean (SD)	62.5 (20.00)	62.7 (17.86)	62.6 (18.89)
Median	68.0	65.0	67.0
Q1, Q3	57.0, 75.0	54.0, 73.0	57.0, 75.0
Min, Max	1, 94	1, 102	1, 102

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Severe Obesity

	Placebo (N=905)	mRNA-1273 (N=896)	Total (N=1801)
Number of Subjects, n (%)			
Received First Injection	905 (100)	896 (100)	1801 (100)
Received Second Injection	873 (96.5)	873 (97.4)	1746 (96.9)
>= 49 Days Since First Injection	898 (99.2)	889 (99.2)	1787 (99.2)
>= 56 Days Since First Injection	896 (99.0)	886 (98.9)	1782 (98.9)
>= 2 Months Since First Injection	894 (98.8)	883 (98.5)	1777 (98.7)
< 28 Days Since Second Injection	3 (0.3)	2 (0.2)	5 (0.3)
>= 28 and < 56 Days Since Second Injection	3 (0.3)	4 (0.4)	7 (0.4)
>= 28 Days Since Second Injection	870 (96.1)	871 (97.2)	1741 (96.7)
>= 56 Days Since Second Injection	867 (95.8)	867 (96.8)	1734 (96.3)
>= 2 Months Since Second Injection	864 (95.5)	867 (96.8)	1731 (96.1)
>= 3 Months Since Second Injection	847 (93.6)	865 (96.5)	1712 (95.1)
>= 4 Months Since Second Injection	825 (91.2)	855 (95.4)	1680 (93.3)
>= 5 Months Since Second Injection	721 (79.7)	766 (85.5)	1487 (82.6)
>= 6 Months Since Second Injection	432 (47.7)	459 (51.2)	891 (49.5)
Study Duration from Randomization (Days)			
Mean (SD)	203.1 (34.98)	207.3 (31.05)	205.2 (33.15)
Median	212.0	214.0	213.0
Q1, Q3	191.0, 226.0	197.0, 227.0	194.0, 227.0
Min, Max	8, 243	4, 243	4, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Severe Obesity

	Placebo (N=905)	mRNA-1273 (N=896)	Total (N=1801)
Study Duration from First Injection (Days)			
Mean (SD)	203.1 (34.98)	207.3 (31.05)	205.2 (33.14)
Median	212.0	214.0	213.0
Q1, Q3	191.0, 226.0	197.0, 227.0	194.0, 227.0
Min, Max	8, 243	4, 243	4, 243
Person-years from First Injection [1]	503.1	508.5	1011.6
Study Duration from Second Injection (Days) [2]			
Mean (SD)	169.1 (44.55)	175.1 (38.13)	172.0 (41.58)
Median	183.0	184.0	183.0
Q1, Q3	159.0, 197.0	166.0, 197.0	164.0, 197.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	873	873	1746
Mean (SD)	175.3 (31.15)	179.7 (25.75)	177.5 (28.65)
Median	183.0	185.0	184.0
Q1, Q3	164.0, 197.0	169.0, 197.0	166.0, 197.0
Min, Max	7, 215	28, 218	7, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Severe Obesity

	Placebo (N=905)	mRNA-1273 (N=896)	Total (N=1801)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	863	844	1707
Mean (SD)	148.3 (26.45)	149.5 (25.99)	148.9 (26.22)
Median	149.0	152.0	150.0
Q1, Q3	132.0, 164.0	135.0, 165.0	133.0, 165.0
Min, Max	61, 221	68, 223	61, 223
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	863	844	1707
Mean (SD)	59.4 (21.61)	62.5 (18.45)	60.9 (20.17)
Median	66.0	66.0	66.0
Q1, Q3	51.0, 74.0	54.0, 75.0	53.0, 74.0
Min, Max	1, 100	1, 102	1, 102

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Diabetes

	Placebo (N=912)	mRNA-1273 (N=919)	Total (N=1831)
Number of Subjects, n (%)			
Received First Injection	912 (100)	919 (100)	1831 (100)
Received Second Injection	878 (96.3)	898 (97.7)	1776 (97.0)
>= 49 Days Since First Injection	900 (98.7)	910 (99.0)	1810 (98.9)
>= 56 Days Since First Injection	899 (98.6)	908 (98.8)	1807 (98.7)
>= 2 Months Since First Injection	898 (98.5)	906 (98.6)	1804 (98.5)
< 28 Days Since Second Injection	0	5 (0.5)	5 (0.3)
>= 28 and < 56 Days Since Second Injection	3 (0.3)	5 (0.5)	8 (0.4)
>= 28 Days Since Second Injection	878 (96.3)	893 (97.2)	1771 (96.7)
>= 56 Days Since Second Injection	875 (95.9)	888 (96.6)	1763 (96.3)
>= 2 Months Since Second Injection	873 (95.7)	888 (96.6)	1761 (96.2)
>= 3 Months Since Second Injection	850 (93.2)	885 (96.3)	1735 (94.8)
>= 4 Months Since Second Injection	825 (90.5)	881 (95.9)	1706 (93.2)
>= 5 Months Since Second Injection	716 (78.5)	760 (82.7)	1476 (80.6)
>= 6 Months Since Second Injection	423 (46.4)	433 (47.1)	856 (46.8)
Study Duration from Randomization (Days)			
Mean (SD)	200.6 (37.45)	204.9 (31.96)	202.8 (34.86)
Median	211.0	212.0	211.0
Q1, Q3	190.0, 226.0	194.0, 225.0	192.0, 225.0
Min, Max	1, 243	15, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Diabetes

	Placebo (N=912)	mRNA-1273 (N=919)	Total (N=1831)
Study Duration from First Injection (Days)			
Mean (SD)	200.6 (37.45)	204.9 (31.97)	202.8 (34.86)
Median	211.0	211.0	211.0
Q1, Q3	190.0, 226.0	194.0, 225.0	192.0, 225.0
Min, Max	1, 243	15, 243	1, 243
Person-years from First Injection [1]	500.9	515.6	1016.5
Study Duration from Second Injection (Days) [2]			
Mean (SD)	168.0 (44.41)	173.2 (38.26)	170.6 (41.51)
Median	180.0	183.0	182.0
Q1, Q3	159.0, 194.0	164.0, 196.0	162.0, 194.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	878	898	1776
Mean (SD)	174.5 (30.22)	177.2 (27.92)	175.9 (29.10)
Median	183.0	183.0	183.0
Q1, Q3	163.0, 194.0	166.0, 197.0	164.0, 196.0
Min, Max	29, 215	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Diabetes

	Placebo (N=912)	mRNA-1273 (N=919)	Total (N=1831)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	864	871	1735
Mean (SD)	146.8 (26.44)	148.6 (26.50)	147.7 (26.48)
Median	148.0	149.0	149.0
Q1, Q3	130.0, 163.0	133.0, 164.0	132.0, 164.0
Min, Max	73, 228	68, 240	68, 240
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	864	871	1735
Mean (SD)	59.0 (22.35)	61.5 (18.39)	60.3 (20.49)
Median	66.0	65.0	65.0
Q1, Q3	51.0, 74.0	53.0, 74.0	53.0, 74.0
Min, Max	1, 100	1, 102	1, 102

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Liver Disease

	Placebo (N=70)	mRNA-1273 (N=84)	Total (N=154)
Number of Subjects, n (%)			
Received First Injection	70 (100)	84 (100)	154 (100)
Received Second Injection	69 (98.6)	84 (100)	153 (99.4)
>= 49 Days Since First Injection	70 (100)	84 (100)	154 (100)
>= 56 Days Since First Injection	70 (100)	84 (100)	154 (100)
>= 2 Months Since First Injection	70 (100)	84 (100)	154 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	69 (98.6)	84 (100)	153 (99.4)
>= 56 Days Since Second Injection	69 (98.6)	84 (100)	153 (99.4)
>= 2 Months Since Second Injection	68 (97.1)	84 (100)	152 (98.7)
>= 3 Months Since Second Injection	67 (95.7)	84 (100)	151 (98.1)
>= 4 Months Since Second Injection	64 (91.4)	84 (100)	148 (96.1)
>= 5 Months Since Second Injection	56 (80.0)	70 (83.3)	126 (81.8)
>= 6 Months Since Second Injection	31 (44.3)	39 (46.4)	70 (45.5)
Study Duration from Randomization (Days)			
Mean (SD)	200.2 (31.34)	204.8 (22.18)	202.7 (26.75)
Median	207.5	210.0	209.0
Q1, Q3	189.0, 220.0	190.0, 221.5	190.0, 221.0
Min, Max	86, 242	155, 243	86, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Liver Disease

	Placebo (N=70)	mRNA-1273 (N=84)	Total (N=154)
Study Duration from First Injection (Days)			
Mean (SD)	200.2 (31.34)	204.8 (22.18)	202.7 (26.75)
Median	207.5	210.0	209.0
Q1, Q3	189.0, 220.0	190.0, 221.5	190.0, 221.0
Min, Max	86, 242	155, 243	86, 243
Person-years from First Injection [1]	38.4	47.1	85.5
Study Duration from Second Injection (Days) [2]			
Mean (SD)	168.7 (36.96)	175.6 (21.80)	172.5 (29.76)
Median	177.5	181.0	179.5
Q1, Q3	157.0, 191.0	162.0, 192.0	159.0, 192.0
Min, Max	0, 214	128, 214	0, 214
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	69	84	153
Mean (SD)	171.2 (31.01)	175.6 (21.80)	173.6 (26.35)
Median	178.0	181.0	180.0
Q1, Q3	158.0, 191.0	162.0, 192.0	161.0, 192.0
Min, Max	58, 214	128, 214	58, 214

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Liver Disease

	Placebo (N=70)	mRNA-1273 (N=84)	Total (N=154)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	68	78	146
Mean (SD)	145.3 (23.80)	143.1 (26.05)	144.1 (24.96)
Median	147.0	145.0	146.5
Q1, Q3	132.5, 161.5	126.0, 157.0	129.0, 160.0
Min, Max	84, 206	76, 210	76, 210
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	68	78	146
Mean (SD)	55.7 (24.64)	63.3 (22.17)	59.8 (23.59)
Median	63.5	67.0	65.0
Q1, Q3	51.5, 73.0	54.0, 77.0	53.0, 75.0
Min, Max	1, 87	1, 102	1, 102

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Human Immunodeficiency Virus Infection

	Placebo (N=75)	mRNA-1273 (N=77)	Total (N=152)
Number of Subjects, n (%)			
Received First Injection	75 (100)	77 (100)	152 (100)
Received Second Injection	70 (93.3)	74 (96.1)	144 (94.7)
>= 49 Days Since First Injection	75 (100)	76 (98.7)	151 (99.3)
>= 56 Days Since First Injection	75 (100)	76 (98.7)	151 (99.3)
>= 2 Months Since First Injection	75 (100)	75 (97.4)	150 (98.7)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	1 (1.3)	1 (1.3)	2 (1.3)
>= 28 Days Since Second Injection	70 (93.3)	74 (96.1)	144 (94.7)
>= 56 Days Since Second Injection	69 (92.0)	73 (94.8)	142 (93.4)
>= 2 Months Since Second Injection	69 (92.0)	73 (94.8)	142 (93.4)
>= 3 Months Since Second Injection	68 (90.7)	73 (94.8)	141 (92.8)
>= 4 Months Since Second Injection	66 (88.0)	72 (93.5)	138 (90.8)
>= 5 Months Since Second Injection	45 (60.0)	54 (70.1)	99 (65.1)
>= 6 Months Since Second Injection	5 (6.7)	8 (10.4)	13 (8.6)
Study Duration from Randomization (Days)			
Mean (SD)	184.7 (25.28)	189.1 (30.42)	186.9 (28.00)
Median	191.0	197.0	193.5
Q1, Q3	172.0, 204.0	181.0, 206.0	174.5, 205.0
Min, Max	82, 218	18, 228	18, 228

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Human Immunodeficiency Virus Infection

	Placebo (N=75)	mRNA-1273 (N=77)	Total (N=152)
Study Duration from First Injection (Days)			
Mean (SD)	184.7 (25.28)	189.1 (30.42)	186.9 (28.00)
Median	191.0	197.0	193.5
Q1, Q3	172.0, 204.0	181.0, 206.0	174.5, 205.0
Min, Max	82, 218	18, 228	18, 228
Person-years from First Injection [1]	37.9	39.9	77.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	146.1 (46.07)	155.8 (39.09)	151.0 (42.81)
Median	162.0	166.0	163.0
Q1, Q3	137.0, 172.0	150.0, 177.0	143.5, 176.0
Min, Max	0, 190	0, 200	0, 200
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	70	74	144
Mean (SD)	156.6 (24.85)	162.1 (23.53)	159.4 (24.25)
Median	162.0	167.0	165.0
Q1, Q3	145.0, 176.0	152.0, 178.0	146.5, 176.5
Min, Max	50, 190	32, 200	32, 200

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=18 and <65 Years, Human Immunodeficiency Virus Infection

	Placebo (N=75)	mRNA-1273 (N=77)	Total (N=152)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	73	74	147
Mean (SD)	126.0 (21.29)	134.3 (24.66)	130.2 (23.34)
Median	125.0	133.5	127.0
Q1, Q3	113.0, 139.0	120.0, 152.0	115.0, 148.0
Min, Max	81, 177	76, 196	76, 196
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	73	74	147
Mean (SD)	62.0 (18.28)	60.5 (18.86)	61.3 (18.53)
Median	67.0	60.0	65.0
Q1, Q3	57.0, 74.0	53.0, 75.0	53.0, 74.0
Min, Max	1, 80	1, 100	1, 100

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, At Risk

	Placebo (N=1135)	mRNA-1273 (N=1128)	Total (N=2263)
Number of Subjects, n (%)			
Received First Injection	1135 (100)	1128 (100)	2263 (100)
Received Second Injection	1097 (96.7)	1110 (98.4)	2207 (97.5)
>= 49 Days Since First Injection	1120 (98.7)	1123 (99.6)	2243 (99.1)
>= 56 Days Since First Injection	1117 (98.4)	1123 (99.6)	2240 (99.0)
>= 2 Months Since First Injection	1116 (98.3)	1123 (99.6)	2239 (98.9)
< 28 Days Since Second Injection	2 (0.2)	0	2 (<0.1)
>= 28 and < 56 Days Since Second Injection	5 (0.4)	1 (<0.1)	6 (0.3)
>= 28 Days Since Second Injection	1095 (96.5)	1110 (98.4)	2205 (97.4)
>= 56 Days Since Second Injection	1090 (96.0)	1109 (98.3)	2199 (97.2)
>= 2 Months Since Second Injection	1088 (95.9)	1108 (98.2)	2196 (97.0)
>= 3 Months Since Second Injection	1074 (94.6)	1106 (98.0)	2180 (96.3)
>= 4 Months Since Second Injection	1052 (92.7)	1095 (97.1)	2147 (94.9)
>= 5 Months Since Second Injection	979 (86.3)	1027 (91.0)	2006 (88.6)
>= 6 Months Since Second Injection	622 (54.8)	654 (58.0)	1276 (56.4)
Study Duration from Randomization (Days)			
Mean (SD)	206.9 (34.04)	211.7 (25.45)	209.3 (30.16)
Median	214.0	215.0	215.0
Q1, Q3	200.0, 227.0	205.0, 228.0	204.0, 227.0
Min, Max	16, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, At Risk

	Placebo (N=1135)	mRNA-1273 (N=1128)	Total (N=2263)
Study Duration from First Injection (Days)			
Mean (SD)	206.8 (34.04)	211.7 (25.46)	209.3 (30.16)
Median	214.0	215.0	215.0
Q1, Q3	200.0, 227.0	204.5, 228.0	204.0, 227.0
Min, Max	16, 243	7, 243	7, 243
Person-years from First Injection [1]	642.8	653.8	1296.6
Study Duration from Second Injection (Days) [2]			
Mean (SD)	174.2 (42.10)	180.9 (31.03)	177.5 (37.14)
Median	185.0	186.0	186.0
Q1, Q3	171.0, 198.0	173.0, 198.0	172.0, 198.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	1097	1110	2207
Mean (SD)	180.2 (27.30)	183.8 (20.95)	182.0 (24.37)
Median	186.0	186.0	186.0
Q1, Q3	172.0, 198.0	176.0, 198.0	173.0, 198.0
Min, Max	8, 215	36, 218	8, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, At Risk

	Placebo (N=1135)	mRNA-1273 (N=1128)	Total (N=2263)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	1090	1108	2198
Mean (SD)	145.5 (21.99)	148.7 (22.69)	147.1 (22.40)
Median	147.0	149.0	148.0
Q1, Q3	133.0, 160.0	135.0, 162.0	134.0, 161.0
Min, Max	30, 217	69, 224	30, 224
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	1090	1108	2198
Mean (SD)	66.4 (18.62)	65.9 (15.97)	66.2 (17.33)
Median	72.0	70.0	71.0
Q1, Q3	61.0, 78.0	60.0, 75.5	60.0, 78.0
Min, Max	1, 205	1, 148	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Chronic Lung Disease

	Placebo (N=245)	mRNA-1273 (N=239)	Total (N=484)
Number of Subjects, n (%)			
Received First Injection	245 (100)	239 (100)	484 (100)
Received Second Injection	234 (95.5)	233 (97.5)	467 (96.5)
>= 49 Days Since First Injection	241 (98.4)	236 (98.7)	477 (98.6)
>= 56 Days Since First Injection	241 (98.4)	236 (98.7)	477 (98.6)
>= 2 Months Since First Injection	241 (98.4)	236 (98.7)	477 (98.6)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	1 (0.4)	0	1 (0.2)
>= 28 Days Since Second Injection	234 (95.5)	233 (97.5)	467 (96.5)
>= 56 Days Since Second Injection	233 (95.1)	233 (97.5)	466 (96.3)
>= 2 Months Since Second Injection	233 (95.1)	233 (97.5)	466 (96.3)
>= 3 Months Since Second Injection	231 (94.3)	233 (97.5)	464 (95.9)
>= 4 Months Since Second Injection	228 (93.1)	231 (96.7)	459 (94.8)
>= 5 Months Since Second Injection	210 (85.7)	219 (91.6)	429 (88.6)
>= 6 Months Since Second Injection	141 (57.6)	153 (64.0)	294 (60.7)
Study Duration from Randomization (Days)			
Mean (SD)	207.6 (35.48)	213.3 (28.46)	210.4 (32.30)
Median	215.0	219.0	218.0
Q1, Q3	201.0, 227.0	206.0, 229.0	205.0, 228.0
Min, Max	16, 243	27, 243	16, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Chronic Lung Disease

	Placebo (N=245)	mRNA-1273 (N=239)	Total (N=484)
Study Duration from First Injection (Days)			
Mean (SD)	207.6 (35.51)	213.3 (28.46)	210.4 (32.32)
Median	215.0	219.0	218.0
Q1, Q3	201.0, 227.0	206.0, 229.0	205.0, 228.0
Min, Max	16, 243	27, 243	16, 243
Person-years from First Injection [1]	139.2	139.6	278.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	174.6 (44.95)	181.7 (35.18)	178.1 (40.54)
Median	185.0	190.0	187.0
Q1, Q3	171.0, 198.0	177.0, 200.0	173.0, 199.0
Min, Max	0, 215	0, 215	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	234	233	467
Mean (SD)	182.8 (24.70)	186.4 (19.85)	184.6 (22.46)
Median	186.0	190.0	187.0
Q1, Q3	176.0, 198.0	178.0, 200.0	177.0, 199.0
Min, Max	53, 215	95, 215	53, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Chronic Lung Disease

	Placebo (N=245)	mRNA-1273 (N=239)	Total (N=484)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	236	235	471
Mean (SD)	146.4 (21.62)	151.9 (20.78)	149.1 (21.36)
Median	147.5	151.0	150.0
Q1, Q3	136.0, 160.0	139.0, 163.0	137.0, 162.0
Min, Max	77, 215	79, 216	77, 216
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	236	235	471
Mean (SD)	66.7 (17.24)	65.0 (16.51)	65.9 (16.88)
Median	72.0	68.0	71.0
Q1, Q3	64.0, 78.0	59.0, 75.0	61.0, 77.0
Min, Max	1, 87	1, 100	1, 100

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Significant Cardiac Disease

	Placebo (N=450)	mRNA-1273 (N=441)	Total (N=891)
Number of Subjects, n (%)			
Received First Injection	450 (100)	441 (100)	891 (100)
Received Second Injection	433 (96.2)	435 (98.6)	868 (97.4)
>= 49 Days Since First Injection	445 (98.9)	440 (99.8)	885 (99.3)
>= 56 Days Since First Injection	443 (98.4)	440 (99.8)	883 (99.1)
>= 2 Months Since First Injection	442 (98.2)	440 (99.8)	882 (99.0)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	3 (0.7)	0	3 (0.3)
>= 28 Days Since Second Injection	433 (96.2)	435 (98.6)	868 (97.4)
>= 56 Days Since Second Injection	430 (95.6)	435 (98.6)	865 (97.1)
>= 2 Months Since Second Injection	430 (95.6)	434 (98.4)	864 (97.0)
>= 3 Months Since Second Injection	426 (94.7)	433 (98.2)	859 (96.4)
>= 4 Months Since Second Injection	418 (92.9)	427 (96.8)	845 (94.8)
>= 5 Months Since Second Injection	397 (88.2)	410 (93.0)	807 (90.6)
>= 6 Months Since Second Injection	246 (54.7)	258 (58.5)	504 (56.6)
Study Duration from Randomization (Days)			
Mean (SD)	208.4 (32.17)	212.4 (23.82)	210.4 (28.40)
Median	214.0	215.0	214.0
Q1, Q3	204.0, 227.0	205.0, 228.0	205.0, 227.0
Min, Max	29, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Significant Cardiac Disease

	Placebo (N=450)	mRNA-1273 (N=441)	Total (N=891)
Study Duration from First Injection (Days)			
Mean (SD)	208.4 (32.17)	212.4 (23.83)	210.4 (28.40)
Median	214.0	215.0	214.0
Q1, Q3	204.0, 227.0	205.0, 228.0	205.0, 227.0
Min, Max	29, 243	7, 243	7, 243
Person-years from First Injection [1]	256.8	256.4	513.2
Study Duration from Second Injection (Days) [2]			
Mean (SD)	174.6 (42.79)	181.6 (29.19)	178.1 (36.84)
Median	185.0	186.0	185.0
Q1, Q3	172.0, 198.0	175.0, 198.0	173.0, 198.0
Min, Max	0, 215	0, 215	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	433	435	868
Mean (SD)	181.5 (25.60)	184.1 (20.04)	182.8 (23.01)
Median	185.0	186.0	186.0
Q1, Q3	176.0, 198.0	176.0, 198.0	176.0, 198.0
Min, Max	29, 215	58, 215	29, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Significant Cardiac Disease

	Placebo (N=450)	mRNA-1273 (N=441)	Total (N=891)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	432	435	867
Mean (SD)	145.2 (21.23)	148.1 (21.31)	146.6 (21.31)
Median	145.0	149.0	147.0
Q1, Q3	133.0, 158.0	135.0, 161.0	134.0, 160.0
Min, Max	30, 215	74, 224	30, 224
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	432	435	867
Mean (SD)	68.1 (18.67)	66.6 (16.08)	67.3 (17.42)
Median	73.0	71.0	72.0
Q1, Q3	65.0, 79.0	60.0, 76.0	61.0, 78.0
Min, Max	1, 205	1, 148	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Severe Obesity

	Placebo (N=153)	mRNA-1273 (N=174)	Total (N=327)
Number of Subjects, n (%)			
Received First Injection	153 (100)	174 (100)	327 (100)
Received Second Injection	145 (94.8)	174 (100)	319 (97.6)
>= 49 Days Since First Injection	150 (98.0)	174 (100)	324 (99.1)
>= 56 Days Since First Injection	149 (97.4)	174 (100)	323 (98.8)
>= 2 Months Since First Injection	149 (97.4)	174 (100)	323 (98.8)
< 28 Days Since Second Injection	2 (1.3)	0	2 (0.6)
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	143 (93.5)	174 (100)	317 (96.9)
>= 56 Days Since Second Injection	143 (93.5)	174 (100)	317 (96.9)
>= 2 Months Since Second Injection	143 (93.5)	173 (99.4)	316 (96.6)
>= 3 Months Since Second Injection	143 (93.5)	173 (99.4)	316 (96.6)
>= 4 Months Since Second Injection	139 (90.8)	173 (99.4)	312 (95.4)
>= 5 Months Since Second Injection	134 (87.6)	161 (92.5)	295 (90.2)
>= 6 Months Since Second Injection	85 (55.6)	106 (60.9)	191 (58.4)
Study Duration from Randomization (Days)			
Mean (SD)	206.3 (32.83)	213.9 (22.10)	210.4 (27.86)
Median	214.0	218.5	215.0
Q1, Q3	200.0, 222.0	206.0, 228.0	205.0, 227.0
Min, Max	35, 240	89, 243	35, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Severe Obesity

	Placebo (N=153)	mRNA-1273 (N=174)	Total (N=327)
Study Duration from First Injection (Days)			
Mean (SD)	206.3 (32.83)	213.9 (22.10)	210.4 (27.86)
Median	214.0	218.5	215.0
Q1, Q3	200.0, 222.0	206.0, 228.0	205.0, 227.0
Min, Max	35, 240	89, 243	35, 243
Person-years from First Injection [1]	86.4	101.9	188.3
Study Duration from Second Injection (Days) [2]			
Mean (SD)	170.4 (48.40)	184.5 (22.06)	177.9 (37.41)
Median	186.0	187.0	186.0
Q1, Q3	170.0, 193.0	176.0, 199.0	175.0, 197.0
Min, Max	0, 212	58, 215	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	145	174	319
Mean (SD)	179.8 (27.75)	184.5 (22.06)	182.4 (24.87)
Median	186.0	187.0	186.0
Q1, Q3	176.0, 193.0	176.0, 199.0	176.0, 198.0
Min, Max	8, 212	58, 215	8, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Severe Obesity

	Placebo (N=153)	mRNA-1273 (N=174)	Total (N=327)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	147	172	319
Mean (SD)	147.2 (20.82)	149.6 (24.34)	148.5 (22.78)
Median	147.0	152.5	148.0
Q1, Q3	135.0, 160.0	136.0, 163.0	136.0, 162.0
Min, Max	69, 211	76, 209	69, 211
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	147	172	319
Mean (SD)	65.0 (16.77)	66.3 (13.50)	65.7 (15.09)
Median	68.0	70.0	68.0
Q1, Q3	59.0, 75.0	59.5, 76.0	59.0, 75.0
Min, Max	1, 89	12, 100	1, 100

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Diabetes

	Placebo (N=545)	mRNA-1273 (N=541)	Total (N=1086)
Number of Subjects, n (%)			
Received First Injection	545 (100)	541 (100)	1086 (100)
Received Second Injection	531 (97.4)	534 (98.7)	1065 (98.1)
>= 49 Days Since First Injection	539 (98.9)	541 (100)	1080 (99.4)
>= 56 Days Since First Injection	539 (98.9)	541 (100)	1080 (99.4)
>= 2 Months Since First Injection	538 (98.7)	541 (100)	1079 (99.4)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	2 (0.4)	1 (0.2)	3 (0.3)
>= 28 Days Since Second Injection	531 (97.4)	534 (98.7)	1065 (98.1)
>= 56 Days Since Second Injection	529 (97.1)	533 (98.5)	1062 (97.8)
>= 2 Months Since Second Injection	527 (96.7)	533 (98.5)	1060 (97.6)
>= 3 Months Since Second Injection	519 (95.2)	532 (98.3)	1051 (96.8)
>= 4 Months Since Second Injection	512 (93.9)	527 (97.4)	1039 (95.7)
>= 5 Months Since Second Injection	465 (85.3)	485 (89.6)	950 (87.5)
>= 6 Months Since Second Injection	300 (55.0)	312 (57.7)	612 (56.4)
Study Duration from Randomization (Days)			
Mean (SD)	206.8 (32.89)	211.4 (23.45)	209.1 (28.66)
Median	214.0	215.0	215.0
Q1, Q3	199.0, 227.0	204.0, 227.0	200.0, 227.0
Min, Max	17, 243	64, 243	17, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Diabetes

	Placebo (N=545)	mRNA-1273 (N=541)	Total (N=1086)
Study Duration from First Injection (Days)			
Mean (SD)	206.8 (32.89)	211.4 (23.45)	209.1 (28.66)
Median	214.0	215.0	215.0
Q1, Q3	199.0, 227.0	204.0, 227.0	200.0, 227.0
Min, Max	17, 243	64, 243	17, 243
Person-years from First Injection [1]	308.6	313.1	621.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	175.1 (39.18)	180.7 (29.94)	177.9 (34.98)
Median	185.0	186.0	185.0
Q1, Q3	170.0, 198.0	173.0, 198.0	172.0, 198.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	531	534	1065
Mean (SD)	179.7 (27.29)	183.0 (21.77)	181.4 (24.72)
Median	185.0	186.0	186.0
Q1, Q3	171.0, 198.0	176.0, 198.0	173.0, 198.0
Min, Max	29, 215	36, 218	29, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Diabetes

	Placebo (N=545)	mRNA-1273 (N=541)	Total (N=1086)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	526	529	1055
Mean (SD)	144.8 (22.63)	148.3 (22.91)	146.6 (22.83)
Median	147.0	149.0	148.0
Q1, Q3	132.0, 160.0	136.0, 161.0	134.0, 161.0
Min, Max	77, 217	69, 220	69, 220
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	526	529	1055
Mean (SD)	66.2 (17.91)	65.9 (15.57)	66.1 (16.77)
Median	72.0	70.0	71.0
Q1, Q3	61.0, 78.0	60.0, 76.0	60.0, 78.0
Min, Max	1, 95	1, 101	1, 101

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Liver Disease

	Placebo (N=26)	mRNA-1273 (N=20)	Total (N=46)
Number of Subjects, n (%)			
Received First Injection	26 (100)	20 (100)	46 (100)
Received Second Injection	25 (96.2)	18 (90.0)	43 (93.5)
>= 49 Days Since First Injection	26 (100)	19 (95.0)	45 (97.8)
>= 56 Days Since First Injection	26 (100)	19 (95.0)	45 (97.8)
>= 2 Months Since First Injection	26 (100)	19 (95.0)	45 (97.8)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	25 (96.2)	18 (90.0)	43 (93.5)
>= 56 Days Since Second Injection	25 (96.2)	18 (90.0)	43 (93.5)
>= 2 Months Since Second Injection	25 (96.2)	18 (90.0)	43 (93.5)
>= 3 Months Since Second Injection	25 (96.2)	18 (90.0)	43 (93.5)
>= 4 Months Since Second Injection	24 (92.3)	18 (90.0)	42 (91.3)
>= 5 Months Since Second Injection	24 (92.3)	17 (85.0)	41 (89.1)
>= 6 Months Since Second Injection	15 (57.7)	10 (50.0)	25 (54.3)
Study Duration from Randomization (Days)			
Mean (SD)	211.2 (23.63)	201.9 (47.74)	207.1 (35.98)
Median	213.5	211.5	213.5
Q1, Q3	206.0, 225.0	192.5, 229.0	199.0, 226.0
Min, Max	138, 241	22, 243	22, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Liver Disease

	Placebo (N=26)	mRNA-1273 (N=20)	Total (N=46)
Study Duration from First Injection (Days)			
Mean (SD)	211.2 (23.63)	201.9 (47.74)	207.1 (35.98)
Median	213.5	211.5	213.5
Q1, Q3	206.0, 225.0	192.5, 229.0	199.0, 226.0
Min, Max	138, 241	22, 243	22, 243
Person-years from First Injection [1]	15.0	11.1	26.1
Study Duration from Second Injection (Days) [2]			
Mean (SD)	178.1 (40.81)	165.9 (60.20)	172.8 (49.93)
Median	184.0	181.5	184.0
Q1, Q3	178.0, 197.0	163.5, 201.0	166.0, 198.0
Min, Max	0, 213	0, 214	0, 214
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	25	18	43
Mean (SD)	185.2 (18.97)	184.3 (21.28)	184.9 (19.73)
Median	184.0	188.5	184.0
Q1, Q3	178.0, 197.0	166.0, 204.0	173.0, 199.0
Min, Max	121, 213	145, 214	121, 214

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Liver Disease

	Placebo (N=26)	mRNA-1273 (N=20)	Total (N=46)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	25	18	43
Mean (SD)	150.2 (14.86)	157.0 (19.99)	153.0 (17.31)
Median	149.0	159.5	153.0
Q1, Q3	141.0, 159.0	149.0, 173.0	141.0, 163.0
Min, Max	121, 182	120, 193	120, 193
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	25	18	43
Mean (SD)	64.9 (16.99)	57.4 (20.45)	61.8 (18.66)
Median	67.0	66.0	67.0
Q1, Q3	64.0, 74.0	50.0, 71.0	54.0, 72.0
Min, Max	1, 82	8, 81	1, 82

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Human Immunodeficiency Virus Infection

	Placebo (N=16)	mRNA-1273 (N=17)	Total (N=33)
Number of Subjects, n (%)			
Received First Injection	16 (100)	17 (100)	33 (100)
Received Second Injection	16 (100)	16 (94.1)	32 (97.0)
>= 49 Days Since First Injection	16 (100)	17 (100)	33 (100)
>= 56 Days Since First Injection	16 (100)	17 (100)	33 (100)
>= 2 Months Since First Injection	16 (100)	17 (100)	33 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	16 (100)	16 (94.1)	32 (97.0)
>= 56 Days Since Second Injection	16 (100)	16 (94.1)	32 (97.0)
>= 2 Months Since Second Injection	16 (100)	16 (94.1)	32 (97.0)
>= 3 Months Since Second Injection	16 (100)	16 (94.1)	32 (97.0)
>= 4 Months Since Second Injection	15 (93.8)	16 (94.1)	31 (93.9)
>= 5 Months Since Second Injection	12 (75.0)	10 (58.8)	22 (66.7)
>= 6 Months Since Second Injection	2 (12.5)	1 (5.9)	3 (9.1)
Study Duration from Randomization (Days)			
Mean (SD)	193.4 (20.43)	193.1 (23.25)	193.3 (21.59)
Median	197.0	205.0	200.0
Q1, Q3	185.0, 207.0	169.0, 211.0	178.0, 210.0
Min, Max	143, 218	157, 220	143, 220

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Human Immunodeficiency Virus Infection

	Placebo (N=16)	mRNA-1273 (N=17)	Total (N=33)
Study Duration from First Injection (Days)			
Mean (SD)	193.4 (20.43)	193.1 (23.25)	193.3 (21.59)
Median	197.0	205.0	200.0
Q1, Q3	185.0, 207.0	169.0, 211.0	178.0, 210.0
Min, Max	143, 218	157, 220	143, 220
Person-years from First Injection [1]	8.5	9.0	17.5
Study Duration from Second Injection (Days) [2]			
Mean (SD)	163.6 (21.76)	154.0 (45.80)	158.6 (35.98)
Median	169.0	176.0	172.0
Q1, Q3	154.5, 180.0	137.0, 183.0	144.0, 180.0
Min, Max	113, 190	0, 190	0, 190
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	16	16	32
Mean (SD)	163.6 (21.76)	163.6 (23.62)	163.6 (22.34)
Median	169.0	177.0	172.5
Q1, Q3	154.5, 180.0	137.5, 183.0	144.5, 181.0
Min, Max	113, 190	127, 190	113, 190

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.8
Summary of Study Duration by Age Group (<65, >=65) and Risk for Severe COVID-19 at Screening
Safety Set

Age and Risk Group: >=65 Years, Human Immunodeficiency Virus Infection

	Placebo (N=16)	mRNA-1273 (N=17)	Total (N=33)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	16	16	32
Mean (SD)	134.5 (19.79)	126.9 (29.49)	130.7 (25.01)
Median	135.0	130.5	133.0
Q1, Q3	125.5, 138.5	107.5, 140.5	118.0, 139.0
Min, Max	91, 179	83, 195	83, 195
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	16	16	32
Mean (SD)	59.9 (25.42)	68.4 (14.97)	64.2 (20.96)
Median	69.0	73.0	71.0
Q1, Q3	51.5, 78.5	63.0, 79.5	60.0, 79.0
Min, Max	1, 80	26, 86	1, 86

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, At Least One Risk Factor

	Placebo (N=2322)	mRNA-1273 (N=2320)	Total (N=4642)
Number of Subjects, n (%)			
Received First Injection	2322 (100)	2320 (100)	4642 (100)
Received Second Injection	2238 (96.4)	2266 (97.7)	4504 (97.0)
>= 49 Days Since First Injection	2300 (99.1)	2298 (99.1)	4598 (99.1)
>= 56 Days Since First Injection	2297 (98.9)	2293 (98.8)	4590 (98.9)
>= 2 Months Since First Injection	2294 (98.8)	2288 (98.6)	4582 (98.7)
< 28 Days Since Second Injection	3 (0.1)	8 (0.3)	11 (0.2)
>= 28 and < 56 Days Since Second Injection	11 (0.5)	15 (0.6)	26 (0.6)
>= 28 Days Since Second Injection	2235 (96.3)	2258 (97.3)	4493 (96.8)
>= 56 Days Since Second Injection	2224 (95.8)	2243 (96.7)	4467 (96.2)
>= 2 Months Since Second Injection	2219 (95.6)	2243 (96.7)	4462 (96.1)
>= 3 Months Since Second Injection	2162 (93.1)	2236 (96.4)	4398 (94.7)
>= 4 Months Since Second Injection	2095 (90.2)	2219 (95.6)	4314 (92.9)
>= 5 Months Since Second Injection	1813 (78.1)	1961 (84.5)	3774 (81.3)
>= 6 Months Since Second Injection	1073 (46.2)	1167 (50.3)	2240 (48.3)
Study Duration from Randomization (Days)			
Mean (SD)	201.6 (36.34)	206.5 (31.87)	204.0 (34.26)
Median	211.0	213.0	212.0
Q1, Q3	190.0, 226.0	197.0, 227.0	193.0, 226.0
Min, Max	1, 243	4, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, At Least One Risk Factor

	Placebo (N=2322)	mRNA-1273 (N=2320)	Total (N=4642)
Study Duration from First Injection (Days)			
Mean (SD)	201.6 (36.34)	206.4 (31.88)	204.0 (34.26)
Median	211.0	213.0	212.0
Q1, Q3	190.0, 226.0	197.0, 227.0	193.0, 226.0
Min, Max	1, 243	4, 243	1, 243
Person-years from First Injection [1]	1281.5	1311.2	2592.7
Study Duration from Second Injection (Days) [2]			
Mean (SD)	168.1 (44.90)	174.6 (38.06)	171.4 (41.75)
Median	180.0	184.0	183.0
Q1, Q3	158.0, 196.0	166.0, 197.0	163.0, 197.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	2238	2266	4504
Mean (SD)	174.4 (31.48)	178.8 (27.18)	176.6 (29.47)
Median	183.0	184.0	183.0
Q1, Q3	162.0, 197.0	169.0, 197.0	165.0, 197.0
Min, Max	7, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, At Least One Risk Factor

	Placebo (N=2322)	mRNA-1273 (N=2320)	Total (N=4642)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	2210	2199	4409
Mean (SD)	147.1 (26.37)	149.1 (26.79)	148.1 (26.60)
Median	148.0	151.0	149.0
Q1, Q3	130.0, 164.0	133.0, 165.0	132.0, 165.0
Min, Max	31, 232	44, 240	31, 240
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	2210	2199	4409
Mean (SD)	59.2 (22.19)	62.3 (18.68)	60.8 (20.57)
Median	66.0	66.0	66.0
Q1, Q3	52.0, 74.0	53.0, 74.0	53.0, 74.0
Min, Max	1, 129	1, 165	1, 165

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, One Risk Factor

	Placebo (N=1937)	mRNA-1273 (N=1925)	Total (N=3862)
Number of Subjects, n (%)			
Received First Injection	1937 (100)	1925 (100)	3862 (100)
Received Second Injection	1864 (96.2)	1882 (97.8)	3746 (97.0)
>= 49 Days Since First Injection	1917 (99.0)	1907 (99.1)	3824 (99.0)
>= 56 Days Since First Injection	1914 (98.8)	1904 (98.9)	3818 (98.9)
>= 2 Months Since First Injection	1911 (98.7)	1901 (98.8)	3812 (98.7)
< 28 Days Since Second Injection	3 (0.2)	6 (0.3)	9 (0.2)
>= 28 and < 56 Days Since Second Injection	10 (0.5)	13 (0.7)	23 (0.6)
>= 28 Days Since Second Injection	1861 (96.1)	1876 (97.5)	3737 (96.8)
>= 56 Days Since Second Injection	1851 (95.6)	1863 (96.8)	3714 (96.2)
>= 2 Months Since Second Injection	1847 (95.4)	1863 (96.8)	3710 (96.1)
>= 3 Months Since Second Injection	1796 (92.7)	1857 (96.5)	3653 (94.6)
>= 4 Months Since Second Injection	1735 (89.6)	1842 (95.7)	3577 (92.6)
>= 5 Months Since Second Injection	1484 (76.6)	1624 (84.4)	3108 (80.5)
>= 6 Months Since Second Injection	865 (44.7)	984 (51.1)	1849 (47.9)
Study Duration from Randomization (Days)			
Mean (SD)	200.4 (37.32)	206.7 (31.74)	203.6 (34.79)
Median	211.0	213.0	212.0
Q1, Q3	187.0, 226.0	197.0, 227.0	192.0, 226.0
Min, Max	1, 243	7, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, One Risk Factor

	Placebo (N=1937)	mRNA-1273 (N=1925)	Total (N=3862)
Study Duration from First Injection (Days)			
Mean (SD)	200.4 (37.32)	206.7 (31.74)	203.6 (34.79)
Median	211.0	213.0	212.0
Q1, Q3	187.0, 226.0	197.0, 227.0	192.0, 226.0
Min, Max	1, 243	7, 243	1, 243
Person-years from First Injection [1]	1062.8	1089.5	2152.3
Study Duration from Second Injection (Days) [2]			
Mean (SD)	166.9 (45.72)	175.0 (37.79)	171.0 (42.14)
Median	180.0	184.0	183.0
Q1, Q3	157.0, 194.0	166.0, 197.0	162.0, 197.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	1864	1882	3746
Mean (SD)	173.5 (32.21)	179.0 (27.28)	176.2 (29.96)
Median	182.0	184.0	183.0
Q1, Q3	161.0, 197.0	169.0, 198.0	164.0, 197.0
Min, Max	7, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, One Risk Factor

	Placebo (N=1937)	mRNA-1273 (N=1925)	Total (N=3862)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	1842	1828	3670
Mean (SD)	146.6 (26.54)	149.5 (27.27)	148.0 (26.95)
Median	148.0	152.0	149.0
Q1, Q3	129.0, 164.0	133.0, 166.0	132.0, 165.0
Min, Max	31, 232	44, 240	31, 240
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	1842	1828	3670
Mean (SD)	58.8 (22.66)	62.2 (18.83)	60.5 (20.91)
Median	66.0	65.0	66.0
Q1, Q3	52.0, 74.0	53.0, 74.0	53.0, 74.0
Min, Max	1, 129	1, 165	1, 165

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Two Risk Factors

	Placebo (N=334)	mRNA-1273 (N=351)	Total (N=685)
Number of Subjects, n (%)			
Received First Injection	334 (100)	351 (100)	685 (100)
Received Second Injection	323 (96.7)	342 (97.4)	665 (97.1)
>= 49 Days Since First Injection	332 (99.4)	347 (98.9)	679 (99.1)
>= 56 Days Since First Injection	332 (99.4)	345 (98.3)	677 (98.8)
>= 2 Months Since First Injection	332 (99.4)	343 (97.7)	675 (98.5)
< 28 Days Since Second Injection	0	2 (0.6)	2 (0.3)
>= 28 and < 56 Days Since Second Injection	1 (0.3)	2 (0.6)	3 (0.4)
>= 28 Days Since Second Injection	323 (96.7)	340 (96.9)	663 (96.8)
>= 56 Days Since Second Injection	322 (96.4)	338 (96.3)	660 (96.4)
>= 2 Months Since Second Injection	321 (96.1)	338 (96.3)	659 (96.2)
>= 3 Months Since Second Injection	315 (94.3)	337 (96.0)	652 (95.2)
>= 4 Months Since Second Injection	311 (93.1)	335 (95.4)	646 (94.3)
>= 5 Months Since Second Injection	284 (85.0)	300 (85.5)	584 (85.3)
>= 6 Months Since Second Injection	177 (53.0)	158 (45.0)	335 (48.9)
Study Duration from Randomization (Days)			
Mean (SD)	207.3 (31.07)	204.2 (33.52)	205.7 (32.36)
Median	215.0	211.0	213.0
Q1, Q3	197.0, 228.0	197.0, 225.0	197.0, 226.0
Min, Max	29, 243	4, 243	4, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Two Risk Factors

	Placebo (N=334)	mRNA-1273 (N=351)	Total (N=685)
Study Duration from First Injection (Days)			
Mean (SD)	207.3 (31.07)	204.2 (33.51)	205.7 (32.36)
Median	215.0	211.0	213.0
Q1, Q3	197.0, 228.0	197.0, 225.0	197.0, 226.0
Min, Max	29, 243	4, 243	4, 243
Person-years from First Injection [1]	189.6	196.3	385.8
Study Duration from Second Injection (Days) [2]			
Mean (SD)	173.2 (41.85)	172.7 (38.78)	172.9 (40.28)
Median	185.0	180.0	183.0
Q1, Q3	164.0, 198.0	166.0, 194.0	165.0, 196.0
Min, Max	0, 214	0, 215	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	323	342	665
Mean (SD)	179.1 (27.42)	177.3 (27.12)	178.1 (27.26)
Median	185.0	180.0	184.0
Q1, Q3	169.0, 198.0	166.0, 194.0	168.0, 197.0
Min, Max	40, 214	1, 215	1, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Two Risk Factors

	Placebo (N=334)	mRNA-1273 (N=351)	Total (N=685)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	319	328	647
Mean (SD)	149.8 (25.25)	147.1 (24.02)	148.4 (24.65)
Median	151.0	148.0	149.0
Q1, Q3	137.0, 166.0	134.0, 162.0	135.0, 163.0
Min, Max	61, 224	68, 216	61, 224
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	319	328	647
Mean (SD)	61.2 (19.45)	63.1 (17.85)	62.2 (18.66)
Median	66.0	65.5	66.0
Q1, Q3	54.0, 74.0	54.5, 75.0	54.0, 74.0
Min, Max	1, 95	1, 102	1, 102

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Three Risk Factors

	Placebo (N=51)	mRNA-1273 (N=34)	Total (N=85)
Number of Subjects, n (%)			
Received First Injection	51 (100)	34 (100)	85 (100)
Received Second Injection	51 (100)	33 (97.1)	84 (98.8)
>= 49 Days Since First Injection	51 (100)	34 (100)	85 (100)
>= 56 Days Since First Injection	51 (100)	34 (100)	85 (100)
>= 2 Months Since First Injection	51 (100)	34 (100)	85 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	51 (100)	33 (97.1)	84 (98.8)
>= 56 Days Since Second Injection	51 (100)	33 (97.1)	84 (98.8)
>= 2 Months Since Second Injection	51 (100)	33 (97.1)	84 (98.8)
>= 3 Months Since Second Injection	51 (100)	33 (97.1)	84 (98.8)
>= 4 Months Since Second Injection	49 (96.1)	33 (97.1)	82 (96.5)
>= 5 Months Since Second Injection	45 (88.2)	28 (82.4)	73 (85.9)
>= 6 Months Since Second Injection	31 (60.8)	19 (55.9)	50 (58.8)
Study Duration from Randomization (Days)			
Mean (SD)	208.7 (25.00)	209.6 (23.09)	209.1 (24.12)
Median	214.0	218.5	216.0
Q1, Q3	198.0, 225.0	201.0, 225.0	199.0, 225.0
Min, Max	126, 241	156, 243	126, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Three Risk Factors

	Placebo (N=51)	mRNA-1273 (N=34)	Total (N=85)
Study Duration from First Injection (Days)			
Mean (SD)	208.7 (25.00)	209.6 (23.09)	209.1 (24.12)
Median	214.0	218.5	216.0
Q1, Q3	198.0, 225.0	201.0, 225.0	199.0, 225.0
Min, Max	126, 241	156, 243	126, 243
Person-years from First Injection [1]	29.1	19.5	48.7
Study Duration from Second Injection (Days) [2]			
Mean (SD)	179.6 (25.22)	174.3 (38.29)	177.5 (31.01)
Median	186.0	185.0	186.0
Q1, Q3	169.0, 196.0	169.0, 196.0	169.0, 196.0
Min, Max	100, 213	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	51	33	84
Mean (SD)	179.6 (25.22)	179.5 (23.11)	179.6 (24.27)
Median	186.0	185.0	186.0
Q1, Q3	169.0, 196.0	171.0, 196.0	169.5, 196.0
Min, Max	100, 213	127, 218	100, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Three Risk Factors

	Placebo (N=51)	mRNA-1273 (N=34)	Total (N=85)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	49	33	82
Mean (SD)	149.2 (26.32)	145.3 (26.88)	147.6 (26.45)
Median	154.0	148.0	151.0
Q1, Q3	136.0, 164.0	134.0, 160.0	136.0, 162.0
Min, Max	75, 206	83, 212	75, 212
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	49	33	82
Mean (SD)	61.7 (20.19)	64.5 (18.44)	62.9 (19.44)
Median	65.0	67.0	66.0
Q1, Q3	52.0, 78.0	61.0, 74.0	54.0, 78.0
Min, Max	1, 100	16, 93	1, 100

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Four Risk Factors

	Placebo (N=0)	mRNA-1273 (N=9)	Total (N=9)
Number of Subjects, n (%)			
Received First Injection	0	9 (100)	9 (100)
Received Second Injection	0	8 (88.9)	8 (88.9)
>= 49 Days Since First Injection	0	9 (100)	9 (100)
>= 56 Days Since First Injection	0	9 (100)	9 (100)
>= 2 Months Since First Injection	0	9 (100)	9 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	0	8 (88.9)	8 (88.9)
>= 56 Days Since Second Injection	0	8 (88.9)	8 (88.9)
>= 2 Months Since Second Injection	0	8 (88.9)	8 (88.9)
>= 3 Months Since Second Injection	0	8 (88.9)	8 (88.9)
>= 4 Months Since Second Injection	0	8 (88.9)	8 (88.9)
>= 5 Months Since Second Injection	0	8 (88.9)	8 (88.9)
>= 6 Months Since Second Injection	0	5 (55.6)	5 (55.6)
Study Duration from Randomization (Days)			
Mean (SD)		215.3 (20.46)	215.3 (20.46)
Median		214.0	214.0
Q1, Q3		203.0, 232.0	203.0, 232.0
Min, Max		184, 243	184, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Four Risk Factors

	Placebo (N=0)	mRNA-1273 (N=9)	Total (N=9)
Study Duration from First Injection (Days)			
Mean (SD)		215.3 (20.46)	215.3 (20.46)
Median		214.0	214.0
Q1, Q3		203.0, 232.0	203.0, 232.0
Min, Max		184, 243	184, 243
Person-years from First Injection [1]		5.3	5.3
Study Duration from Second Injection (Days) [2]			
Mean (SD)		169.7 (65.70)	169.7 (65.70)
Median		186.0	186.0
Q1, Q3		175.0, 202.0	175.0, 202.0
Min, Max		0, 214	0, 214
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	0	8	8
Mean (SD)		190.9 (17.53)	190.9 (17.53)
Median		193.0	193.0
Q1, Q3		175.5, 205.0	175.5, 205.0
Min, Max		166, 214	166, 214

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Four Risk Factors

	Placebo (N=0)	mRNA-1273 (N=9)	Total (N=9)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	0	9	9
Mean (SD)		157.8 (21.70)	157.8 (21.70)
Median		160.0	160.0
Q1, Q3		149.0, 170.0	149.0, 170.0
Min, Max		124, 192	124, 192
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	0	9	9
Mean (SD)		58.6 (20.89)	58.6 (20.89)
Median		67.0	67.0
Q1, Q3		53.0, 71.0	53.0, 71.0
Min, Max		23, 80	23, 80

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Five Risk Factors

	Placebo (N=0)	mRNA-1273 (N=1)	Total (N=1)
Number of Subjects, n (%)			
Received First Injection	0	1 (100)	1 (100)
Received Second Injection	0	1 (100)	1 (100)
>= 49 Days Since First Injection	0	1 (100)	1 (100)
>= 56 Days Since First Injection	0	1 (100)	1 (100)
>= 2 Months Since First Injection	0	1 (100)	1 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	0	1 (100)	1 (100)
>= 56 Days Since Second Injection	0	1 (100)	1 (100)
>= 2 Months Since Second Injection	0	1 (100)	1 (100)
>= 3 Months Since Second Injection	0	1 (100)	1 (100)
>= 4 Months Since Second Injection	0	1 (100)	1 (100)
>= 5 Months Since Second Injection	0	1 (100)	1 (100)
>= 6 Months Since Second Injection	0	1 (100)	1 (100)
Study Duration from Randomization (Days)			
Mean (SD)		237.0 (NA)	237.0 (NA)
Median		237.0	237.0
Q1, Q3		237.0, 237.0	237.0, 237.0
Min, Max		237, 237	237, 237

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Five Risk Factors

	Placebo (N=0)	mRNA-1273 (N=1)	Total (N=1)
Study Duration from First Injection (Days)			
Mean (SD)		237.0 (NA)	237.0 (NA)
Median		237.0	237.0
Q1, Q3		237.0, 237.0	237.0, 237.0
Min, Max		237, 237	237, 237
Person-years from First Injection [1]		0.6	0.6
Study Duration from Second Injection (Days) [2]			
Mean (SD)		208.0 (NA)	208.0 (NA)
Median		208.0	208.0
Q1, Q3		208.0, 208.0	208.0, 208.0
Min, Max		208, 208	208, 208
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	0	1	1
Mean (SD)		208.0 (NA)	208.0 (NA)
Median		208.0	208.0
Q1, Q3		208.0, 208.0	208.0, 208.0
Min, Max		208, 208	208, 208

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Five Risk Factors

	Placebo (N=0)	mRNA-1273 (N=1)	Total (N=1)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	0	1	1
Mean (SD)		165.0 (NA)	165.0 (NA)
Median		165.0	165.0
Q1, Q3		165.0, 165.0	165.0, 165.0
Min, Max		165, 165	165, 165
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	0	1	1
Mean (SD)		73.0 (NA)	73.0 (NA)
Median		73.0	73.0
Q1, Q3		73.0, 73.0	73.0, 73.0
Min, Max		73, 73	73, 73

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=18 and <65 Years, Six Risk Factors

	Placebo (N=0)	mRNA-1273 (N=0)	Total (N=0)

There are no observations for this section.

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, At Least One Risk Factor

	Placebo (N=1135)	mRNA-1273 (N=1128)	Total (N=2263)
Number of Subjects, n (%)			
Received First Injection	1135 (100)	1128 (100)	2263 (100)
Received Second Injection	1097 (96.7)	1110 (98.4)	2207 (97.5)
>= 49 Days Since First Injection	1120 (98.7)	1123 (99.6)	2243 (99.1)
>= 56 Days Since First Injection	1117 (98.4)	1123 (99.6)	2240 (99.0)
>= 2 Months Since First Injection	1116 (98.3)	1123 (99.6)	2239 (98.9)
< 28 Days Since Second Injection	2 (0.2)	0	2 (<0.1)
>= 28 and < 56 Days Since Second Injection	5 (0.4)	1 (<0.1)	6 (0.3)
>= 28 Days Since Second Injection	1095 (96.5)	1110 (98.4)	2205 (97.4)
>= 56 Days Since Second Injection	1090 (96.0)	1109 (98.3)	2199 (97.2)
>= 2 Months Since Second Injection	1088 (95.9)	1108 (98.2)	2196 (97.0)
>= 3 Months Since Second Injection	1074 (94.6)	1106 (98.0)	2180 (96.3)
>= 4 Months Since Second Injection	1052 (92.7)	1095 (97.1)	2147 (94.9)
>= 5 Months Since Second Injection	979 (86.3)	1027 (91.0)	2006 (88.6)
>= 6 Months Since Second Injection	622 (54.8)	654 (58.0)	1276 (56.4)
Study Duration from Randomization (Days)			
Mean (SD)	206.9 (34.04)	211.7 (25.45)	209.3 (30.16)
Median	214.0	215.0	215.0
Q1, Q3	200.0, 227.0	205.0, 228.0	204.0, 227.0
Min, Max	16, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, At Least One Risk Factor

	Placebo (N=1135)	mRNA-1273 (N=1128)	Total (N=2263)
Study Duration from First Injection (Days)			
Mean (SD)	206.8 (34.04)	211.7 (25.46)	209.3 (30.16)
Median	214.0	215.0	215.0
Q1, Q3	200.0, 227.0	204.5, 228.0	204.0, 227.0
Min, Max	16, 243	7, 243	7, 243
Person-years from First Injection [1]	642.8	653.8	1296.6
Study Duration from Second Injection (Days) [2]			
Mean (SD)	174.2 (42.10)	180.9 (31.03)	177.5 (37.14)
Median	185.0	186.0	186.0
Q1, Q3	171.0, 198.0	173.0, 198.0	172.0, 198.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	1097	1110	2207
Mean (SD)	180.2 (27.30)	183.8 (20.95)	182.0 (24.37)
Median	186.0	186.0	186.0
Q1, Q3	172.0, 198.0	176.0, 198.0	173.0, 198.0
Min, Max	8, 215	36, 218	8, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, At Least One Risk Factor

	Placebo (N=1135)	mRNA-1273 (N=1128)	Total (N=2263)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	1090	1108	2198
Mean (SD)	145.5 (21.99)	148.7 (22.69)	147.1 (22.40)
Median	147.0	149.0	148.0
Q1, Q3	133.0, 160.0	135.0, 162.0	134.0, 161.0
Min, Max	30, 217	69, 224	30, 224
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	1090	1108	2198
Mean (SD)	66.4 (18.62)	65.9 (15.97)	66.2 (17.33)
Median	72.0	70.0	71.0
Q1, Q3	61.0, 78.0	60.0, 75.5	60.0, 78.0
Min, Max	1, 205	1, 148	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, One Risk Factor

	Placebo (N=878)	mRNA-1273 (N=866)	Total (N=1744)
Number of Subjects, n (%)			
Received First Injection	878 (100)	866 (100)	1744 (100)
Received Second Injection	850 (96.8)	852 (98.4)	1702 (97.6)
>= 49 Days Since First Injection	866 (98.6)	861 (99.4)	1727 (99.0)
>= 56 Days Since First Injection	863 (98.3)	861 (99.4)	1724 (98.9)
>= 2 Months Since First Injection	863 (98.3)	861 (99.4)	1724 (98.9)
< 28 Days Since Second Injection	2 (0.2)	0	2 (0.1)
>= 28 and < 56 Days Since Second Injection	4 (0.5)	1 (0.1)	5 (0.3)
>= 28 Days Since Second Injection	848 (96.6)	852 (98.4)	1700 (97.5)
>= 56 Days Since Second Injection	844 (96.1)	851 (98.3)	1695 (97.2)
>= 2 Months Since Second Injection	842 (95.9)	851 (98.3)	1693 (97.1)
>= 3 Months Since Second Injection	828 (94.3)	849 (98.0)	1677 (96.2)
>= 4 Months Since Second Injection	808 (92.0)	840 (97.0)	1648 (94.5)
>= 5 Months Since Second Injection	752 (85.6)	792 (91.5)	1544 (88.5)
>= 6 Months Since Second Injection	479 (54.6)	495 (57.2)	974 (55.8)
Study Duration from Randomization (Days)			
Mean (SD)	206.1 (35.29)	211.4 (26.05)	208.7 (31.15)
Median	214.0	215.0	215.0
Q1, Q3	199.0, 227.0	204.0, 227.0	202.0, 227.0
Min, Max	16, 243	7, 243	7, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, One Risk Factor

	Placebo (N=878)	mRNA-1273 (N=866)	Total (N=1744)
Study Duration from First Injection (Days)			
Mean (SD)	206.1 (35.29)	211.4 (26.06)	208.7 (31.16)
Median	214.0	215.0	215.0
Q1, Q3	199.0, 227.0	204.0, 227.0	201.0, 227.0
Min, Max	16, 243	7, 243	7, 243
Person-years from First Injection [1]	495.4	501.3	996.7
Study Duration from Second Injection (Days) [2]			
Mean (SD)	173.8 (42.22)	180.8 (30.85)	177.2 (37.17)
Median	185.0	186.0	185.5
Q1, Q3	170.0, 198.0	173.0, 198.0	171.5, 198.0
Min, Max	0, 215	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	850	852	1702
Mean (SD)	179.5 (28.51)	183.7 (20.51)	181.6 (24.91)
Median	186.0	186.0	186.0
Q1, Q3	171.0, 198.0	176.0, 198.0	173.0, 198.0
Min, Max	8, 215	36, 218	8, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, One Risk Factor

	Placebo (N=878)	mRNA-1273 (N=866)	Total (N=1744)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	841	852	1693
Mean (SD)	145.3 (22.36)	148.6 (22.91)	146.9 (22.69)
Median	147.0	149.0	148.0
Q1, Q3	133.0, 160.0	135.0, 162.0	134.0, 161.0
Min, Max	30, 217	69, 224	30, 224
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	841	852	1693
Mean (SD)	66.1 (19.45)	65.8 (16.43)	66.0 (17.99)
Median	72.0	70.0	71.0
Q1, Q3	61.0, 78.0	60.0, 76.5	60.0, 78.0
Min, Max	1, 205	1, 148	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Two Risk Factors

	Placebo (N=219)	mRNA-1273 (N=223)	Total (N=442)
Number of Subjects, n (%)			
Received First Injection	219 (100)	223 (100)	442 (100)
Received Second Injection	212 (96.8)	219 (98.2)	431 (97.5)
>= 49 Days Since First Injection	216 (98.6)	223 (100)	439 (99.3)
>= 56 Days Since First Injection	216 (98.6)	223 (100)	439 (99.3)
>= 2 Months Since First Injection	215 (98.2)	223 (100)	438 (99.1)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	1 (0.5)	0	1 (0.2)
>= 28 Days Since Second Injection	212 (96.8)	219 (98.2)	431 (97.5)
>= 56 Days Since Second Injection	211 (96.3)	219 (98.2)	430 (97.3)
>= 2 Months Since Second Injection	211 (96.3)	218 (97.8)	429 (97.1)
>= 3 Months Since Second Injection	211 (96.3)	218 (97.8)	429 (97.1)
>= 4 Months Since Second Injection	209 (95.4)	216 (96.9)	425 (96.2)
>= 5 Months Since Second Injection	195 (89.0)	198 (88.8)	393 (88.9)
>= 6 Months Since Second Injection	119 (54.3)	135 (60.5)	254 (57.5)
Study Duration from Randomization (Days)			
Mean (SD)	209.4 (30.87)	212.3 (24.31)	210.8 (27.76)
Median	214.0	217.0	215.0
Q1, Q3	205.0, 227.0	205.0, 228.0	205.0, 228.0
Min, Max	29, 243	89, 242	29, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Two Risk Factors

	Placebo (N=219)	mRNA-1273 (N=223)	Total (N=442)
Study Duration from First Injection (Days)			
Mean (SD)	209.4 (30.87)	212.3 (24.31)	210.8 (27.76)
Median	214.0	217.0	215.0
Q1, Q3	205.0, 227.0	205.0, 228.0	205.0, 228.0
Min, Max	29, 243	89, 242	29, 243
Person-years from First Injection [1]	125.5	129.6	255.1
Study Duration from Second Injection (Days) [2]			
Mean (SD)	176.9 (39.59)	180.3 (33.57)	178.6 (36.68)
Median	184.0	186.0	185.5
Q1, Q3	176.0, 198.0	173.0, 200.0	175.0, 199.0
Min, Max	0, 215	0, 214	0, 215
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	212	219	431
Mean (SD)	182.7 (23.39)	183.6 (23.24)	183.2 (23.29)
Median	185.0	186.0	186.0
Q1, Q3	177.0, 198.0	176.0, 200.0	177.0, 199.0
Min, Max	29, 215	58, 214	29, 215

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Two Risk Factors

	Placebo (N=219)	mRNA-1273 (N=223)	Total (N=442)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	211	218	429
Mean (SD)	146.6 (20.77)	148.4 (22.44)	147.5 (21.63)
Median	148.0	151.0	149.0
Q1, Q3	135.0, 160.0	136.0, 163.0	136.0, 161.0
Min, Max	77, 205	77, 216	77, 216
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	211	218	429
Mean (SD)	67.4 (15.18)	66.5 (13.83)	67.0 (14.50)
Median	72.0	68.0	71.0
Q1, Q3	64.0, 78.0	59.0, 78.0	60.0, 78.0
Min, Max	1, 86	1, 95	1, 95

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Three Risk Factors

	Placebo (N=35)	mRNA-1273 (N=36)	Total (N=71)
Number of Subjects, n (%)			
Received First Injection	35 (100)	36 (100)	71 (100)
Received Second Injection	32 (91.4)	36 (100)	68 (95.8)
>= 49 Days Since First Injection	35 (100)	36 (100)	71 (100)
>= 56 Days Since First Injection	35 (100)	36 (100)	71 (100)
>= 2 Months Since First Injection	35 (100)	36 (100)	71 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	32 (91.4)	36 (100)	68 (95.8)
>= 56 Days Since Second Injection	32 (91.4)	36 (100)	68 (95.8)
>= 2 Months Since Second Injection	32 (91.4)	36 (100)	68 (95.8)
>= 3 Months Since Second Injection	32 (91.4)	36 (100)	68 (95.8)
>= 4 Months Since Second Injection	32 (91.4)	36 (100)	68 (95.8)
>= 5 Months Since Second Injection	30 (85.7)	34 (94.4)	64 (90.1)
>= 6 Months Since Second Injection	24 (68.6)	21 (58.3)	45 (63.4)
Study Duration from Randomization (Days)			
Mean (SD)	211.6 (17.21)	214.3 (17.87)	213.0 (17.47)
Median	214.0	215.5	214.0
Q1, Q3	206.0, 221.0	205.0, 229.0	205.0, 226.0
Min, Max	166, 235	167, 243	166, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Three Risk Factors

	Placebo (N=35)	mRNA-1273 (N=36)	Total (N=71)
Study Duration from First Injection (Days)			
Mean (SD)	211.6 (17.21)	214.3 (17.87)	213.0 (17.47)
Median	214.0	215.5	214.0
Q1, Q3	206.0, 221.0	205.0, 229.0	205.0, 226.0
Min, Max	166, 235	167, 243	166, 243
Person-years from First Injection [1]	20.3	21.1	41.4
Study Duration from Second Injection (Days) [2]			
Mean (SD)	169.3 (54.53)	185.4 (17.42)	177.5 (40.77)
Median	186.0	186.0	186.0
Q1, Q3	176.0, 191.0	177.0, 198.5	176.0, 194.0
Min, Max	0, 207	139, 214	0, 214
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	32	36	68
Mean (SD)	185.1 (15.13)	185.4 (17.42)	185.3 (16.26)
Median	186.0	186.0	186.0
Q1, Q3	181.5, 191.5	177.0, 198.5	178.0, 195.5
Min, Max	141, 207	139, 214	139, 214

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Three Risk Factors

	Placebo (N=35)	mRNA-1273 (N=36)	Total (N=71)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	35	35	70
Mean (SD)	144.3 (20.88)	152.8 (19.50)	148.5 (20.51)
Median	143.0	151.0	146.0
Q1, Q3	132.0, 152.0	137.0, 163.0	135.0, 159.0
Min, Max	98, 215	123, 212	98, 215
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	35	35	70
Mean (SD)	68.3 (17.35)	63.8 (16.75)	66.1 (17.08)
Median	73.0	68.0	71.0
Q1, Q3	65.0, 79.0	60.0, 73.0	64.0, 78.0
Min, Max	1, 82	14, 82	1, 82

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Four Risk Factors

	Placebo (N=2)	mRNA-1273 (N=3)	Total (N=5)
Number of Subjects, n (%)			
Received First Injection	2 (100)	3 (100)	5 (100)
Received Second Injection	2 (100)	3 (100)	5 (100)
>= 49 Days Since First Injection	2 (100)	3 (100)	5 (100)
>= 56 Days Since First Injection	2 (100)	3 (100)	5 (100)
>= 2 Months Since First Injection	2 (100)	3 (100)	5 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	2 (100)	3 (100)	5 (100)
>= 56 Days Since Second Injection	2 (100)	3 (100)	5 (100)
>= 2 Months Since Second Injection	2 (100)	3 (100)	5 (100)
>= 3 Months Since Second Injection	2 (100)	3 (100)	5 (100)
>= 4 Months Since Second Injection	2 (100)	3 (100)	5 (100)
>= 5 Months Since Second Injection	1 (50.0)	3 (100)	4 (80.0)
>= 6 Months Since Second Injection	0	3 (100)	3 (60.0)
Study Duration from Randomization (Days)			
Mean (SD)	193.0 (21.21)	220.7 (7.64)	209.6 (19.27)
Median	193.0	219.0	214.0
Q1, Q3	178.0, 208.0	214.0, 229.0	208.0, 219.0
Min, Max	178, 208	214, 229	178, 229

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Four Risk Factors

	Placebo (N=2)	mRNA-1273 (N=3)	Total (N=5)
Study Duration from First Injection (Days)			
Mean (SD)	193.0 (21.21)	220.7 (7.64)	209.6 (19.27)
Median	193.0	219.0	214.0
Q1, Q3	178.0, 208.0	214.0, 229.0	208.0, 219.0
Min, Max	178, 208	214, 229	178, 229
Person-years from First Injection [1]	1.1	1.8	2.9
Study Duration from Second Injection (Days) [2]			
Mean (SD)	166.5 (23.33)	191.0 (7.81)	181.2 (18.62)
Median	166.5	187.0	186.0
Q1, Q3	150.0, 183.0	186.0, 200.0	183.0, 187.0
Min, Max	150, 183	186, 200	150, 200
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	2	3	5
Mean (SD)	166.5 (23.33)	191.0 (7.81)	181.2 (18.62)
Median	166.5	187.0	186.0
Q1, Q3	150.0, 183.0	186.0, 200.0	183.0, 187.0
Min, Max	150, 183	186, 200	150, 200

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Four Risk Factors

	Placebo (N=2)	mRNA-1273 (N=3)	Total (N=5)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	2	3	5
Mean (SD)	135.0 (0.00)	149.3 (17.01)	143.6 (14.36)
Median	135.0	156.0	135.0
Q1, Q3	135.0, 135.0	130.0, 162.0	135.0, 156.0
Min, Max	135, 135	130, 162	130, 162
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	2	3	5
Mean (SD)	59.0 (21.21)	72.3 (24.58)	67.0 (21.63)
Median	59.0	64.0	64.0
Q1, Q3	44.0, 74.0	53.0, 100.0	53.0, 74.0
Min, Max	44, 74	53, 100	44, 100

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Five Risk Factors

	Placebo (N=0)	mRNA-1273 (N=0)	Total (N=0)

There are no observations for this section.

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Six Risk Factors

	Placebo (N=1)	mRNA-1273 (N=0)	Total (N=1)
Number of Subjects, n (%)			
Received First Injection	1 (100)	0	1 (100)
Received Second Injection	1 (100)	0	1 (100)
>= 49 Days Since First Injection	1 (100)	0	1 (100)
>= 56 Days Since First Injection	1 (100)	0	1 (100)
>= 2 Months Since First Injection	1 (100)	0	1 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	0	0	0
>= 28 Days Since Second Injection	1 (100)	0	1 (100)
>= 56 Days Since Second Injection	1 (100)	0	1 (100)
>= 2 Months Since Second Injection	1 (100)	0	1 (100)
>= 3 Months Since Second Injection	1 (100)	0	1 (100)
>= 4 Months Since Second Injection	1 (100)	0	1 (100)
>= 5 Months Since Second Injection	1 (100)	0	1 (100)
>= 6 Months Since Second Injection	0	0	0
Study Duration from Randomization (Days)			
Mean (SD)	187.0 (NA)		187.0 (NA)
Median	187.0		187.0
Q1, Q3	187.0, 187.0		187.0, 187.0
Min, Max	187, 187		187, 187

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Six Risk Factors

	Placebo (N=1)	mRNA-1273 (N=0)	Total (N=1)
Study Duration from First Injection (Days)			
Mean (SD)	187.0 (NA)		187.0 (NA)
Median	187.0		187.0
Q1, Q3	187.0, 187.0		187.0, 187.0
Min, Max	187, 187		187, 187
Person-years from First Injection [1]	0.5		0.5
Study Duration from Second Injection (Days) [2]			
Mean (SD)	159.0 (NA)		159.0 (NA)
Median	159.0		159.0
Q1, Q3	159.0, 159.0		159.0, 159.0
Min, Max	159, 159		159, 159
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	1	0	1
Mean (SD)	159.0 (NA)		159.0 (NA)
Median	159.0		159.0
Q1, Q3	159.0, 159.0		159.0, 159.0
Min, Max	159, 159		159, 159

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.2.9
Summary of Study Duration by Age (<65, >=65) and Number of Risk Factors for Severe COVID-19 at Screening
Safety Set

Age and Number of Risk Factors: >=65 Years, Six Risk Factors

	Placebo (N=1)	mRNA-1273 (N=0)	Total (N=1)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	1	0	1
Mean (SD)	121.0 (NA)		121.0 (NA)
Median	121.0		121.0
Q1, Q3	121.0, 121.0		121.0, 121.0
Min, Max	121, 121		121, 121
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	1	0	1
Mean (SD)	67.0 (NA)		67.0 (NA)
Median	67.0		67.0
Q1, Q3	67.0, 67.0		67.0, 67.0
Min, Max	67, 67		67, 67

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of safety subjects.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.3.1
Summary of Study Duration
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Number of Subjects, n (%)			
Received First Injection	14745 (100)	14746 (100)	29491 (100)
Received Second Injection	14320 (97.1)	14412 (97.7)	28732 (97.4)
>= 49 Days Since First Injection	14584 (98.9)	14617 (99.1)	29201 (99.0)
>= 56 Days Since First Injection	14552 (98.7)	14603 (99.0)	29155 (98.9)
>= 2 Months Since First Injection	14523 (98.5)	14577 (98.9)	29100 (98.7)
< 28 Days Since Second Injection	35 (0.2)	22 (0.1)	57 (0.2)
>= 28 and < 56 Days Since Second Injection	118 (0.8)	47 (0.3)	165 (0.6)
>= 28 Days Since Second Injection	14285 (96.9)	14390 (97.6)	28675 (97.2)
>= 56 Days Since Second Injection	14167 (96.1)	14343 (97.3)	28510 (96.7)
>= 2 Months Since Second Injection	14131 (95.8)	14333 (97.2)	28464 (96.5)
>= 3 Months Since Second Injection	13624 (92.4)	14283 (96.9)	27907 (94.6)
>= 4 Months Since Second Injection	12967 (87.9)	14176 (96.1)	27143 (92.0)
>= 5 Months Since Second Injection	11390 (77.2)	12617 (85.6)	24007 (81.4)
>= 6 Months Since Second Injection	6657 (45.1)	7361 (49.9)	14018 (47.5)
Study Duration from Randomization (Days)			
Mean (SD)	198.5 (38.84)	206.5 (30.33)	202.5 (35.07)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 225.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in mITT set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.3.1
Summary of Study Duration
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Study Duration from First Injection (Days)			
Mean (SD)	198.5 (38.85)	206.4 (30.33)	202.5 (35.07)
Median	210.0	213.0	212.0
Q1, Q3	189.0, 225.0	197.0, 226.0	193.0, 225.0
Min, Max	1, 243	1, 243	1, 243
Person-years from First Injection [1]	8013.0	8334.5	16347.5
Study Duration from Second Injection (Days) [2]			
Mean (SD)	166.4 (44.39)	175.1 (35.98)	170.8 (40.63)
Median	180.0	183.0	183.0
Q1, Q3	158.0, 193.0	166.0, 196.0	163.0, 194.0
Min, Max	0, 218	0, 218	0, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	14320	14412	28732
Mean (SD)	171.4 (34.38)	179.2 (24.44)	175.3 (30.07)
Median	180.0	184.0	183.0
Q1, Q3	162.0, 194.0	169.0, 196.0	165.0, 194.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in mITT set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.3.1
Summary of Study Duration
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	13937	14151	28088
Mean (SD)	144.7 (25.45)	147.5 (25.53)	146.1 (25.53)
Median	146.0	148.0	148.0
Q1, Q3	128.0, 161.0	133.0, 163.0	131.0, 162.0
Min, Max	30, 237	44, 241	30, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	13937	14151	28088
Mean (SD)	59.0 (23.58)	63.3 (18.66)	61.1 (21.35)
Median	67.0	67.0	67.0
Q1, Q3	53.0, 75.0	56.0, 75.0	54.0, 75.0
Min, Max	1, 205	1, 179	1, 205

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in mITT set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.3.2
Summary of Study Duration
mITT Set — Subjects Only Received One Injection

	Placebo (N=425)	mRNA-1273 (N=334)	Total (N=759)
Number of Subjects, n (%)			
Received First Injection	425 (100)	334 (100)	759 (100)
>= 49 Days Since First Injection	278 (65.4)	217 (65.0)	495 (65.2)
>= 56 Days Since First Injection	265 (62.4)	207 (62.0)	472 (62.2)
>= 2 Months Since First Injection	255 (60.0)	194 (58.1)	449 (59.2)
Study Duration from Randomization (Days)			
Mean (SD)	121.1 (80.60)	116.6 (82.33)	119.1 (81.34)
Median	126.0	98.5	114.0
Q1, Q3	36.0, 205.0	35.0, 205.0	36.0, 205.0
Min, Max	1, 241	1, 243	1, 243
Study Duration from First Injection (Days)			
Mean (SD)	121.1 (80.60)	116.6 (82.33)	119.1 (81.34)
Median	126.0	98.5	114.0
Q1, Q3	36.0, 205.0	35.0, 205.0	36.0, 205.0
Min, Max	1, 241	1, 243	1, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects who only received one injection in mITT set.
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Table 14.1.6.4
Summary of Study Duration
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Number of Subjects, n (%)			
Received First Injection	14164 (100)	14287 (100)	28451 (100)
Received Second Injection	14164 (100)	14287 (100)	28451 (100)
>= 49 Days Since First Injection	14150 (>99.9)	14275 (>99.9)	28425 (>99.9)
>= 56 Days Since First Injection	14131 (99.8)	14271 (99.9)	28402 (99.8)
>= 2 Months Since First Injection	14112 (99.6)	14258 (99.8)	28370 (99.7)
< 28 Days Since Second Injection	34 (0.2)	22 (0.2)	56 (0.2)
>= 28 and < 56 Days Since Second Injection	114 (0.8)	45 (0.3)	159 (0.6)
>= 28 Days Since Second Injection	14130 (99.8)	14265 (99.8)	28395 (99.8)
>= 56 Days Since Second Injection	14016 (99.0)	14220 (99.5)	28236 (99.2)
>= 2 Months Since Second Injection	13981 (98.7)	14210 (99.5)	28191 (99.1)
>= 3 Months Since Second Injection	13479 (95.2)	14161 (99.1)	27640 (97.1)
>= 4 Months Since Second Injection	12839 (90.6)	14058 (98.4)	26897 (94.5)
>= 5 Months Since Second Injection	11279 (79.6)	12513 (87.6)	23792 (83.6)
>= 6 Months Since Second Injection	6612 (46.7)	7327 (51.3)	13939 (49.0)
Study Duration from Randomization (Days)			
Mean (SD)	200.8 (34.28)	208.5 (24.32)	204.6 (29.95)
Median	211.0	213.0	212.0
Q1, Q3	191.0, 225.0	198.0, 226.0	194.0, 225.0
Min, Max	29, 243	29, 243	29, 243

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in Per-Protocol Set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.4
Summary of Study Duration
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Study Duration from First Injection (Days)			
Mean (SD)	200.8 (34.29)	208.5 (24.32)	204.6 (29.95)
Median	211.0	213.0	212.0
Q1, Q3	190.0, 225.0	198.0, 226.0	194.0, 225.0
Min, Max	29, 243	29, 243	29, 243
Person-years from First Injection [1]	7785.5	8154.5	15940.0
Study Duration from Second Injection (Days) [2]			
Mean (SD)	171.5 (34.31)	179.3 (24.37)	175.4 (29.99)
Median	180.0	184.0	183.0
Q1, Q3	162.0, 194.0	169.0, 197.0	165.0, 194.0
Min, Max	1, 218	1, 218	1, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	14164	14287	28451
Mean (SD)	171.5 (34.31)	179.3 (24.37)	175.4 (29.99)
Median	180.0	184.0	183.0
Q1, Q3	162.0, 194.0	169.0, 197.0	165.0, 194.0
Min, Max	1, 218	1, 218	1, 218

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in Per-Protocol Set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.4
Summary of Study Duration
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	13595	13897	27492
Mean (SD)	144.6 (25.40)	147.5 (25.48)	146.1 (25.48)
Median	146.0	148.0	148.0
Q1, Q3	128.0, 161.0	132.0, 163.0	131.0, 162.0
Min, Max	31, 237	44, 241	31, 241
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	13595	13897	27492
Mean (SD)	59.1 (23.48)	63.3 (18.61)	61.2 (21.27)
Median	67.0	67.0	67.0
Q1, Q3	53.0, 75.0	56.0, 75.0	54.0, 75.0
Min, Max	1, 169	1, 179	1, 179

1 month = 30.4375 days. PDV = Participant Decision Visit.
Percentages are based on the number of subjects in Per-Protocol Set.
[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.
[2] Study duration from second injection is 0 day for subjects who did not receive second injection.
[3] Only include subjects who had PDV/unblinding on/before data cutoff date.
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Table 14.1.6.4.2
Summary of Study Duration
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Number of Subjects, n (%)			
Received First Injection	744 (100)	55 (100)	799 (100)
Received Second Injection	744 (100)	55 (100)	799 (100)
>= 49 Days Since First Injection	744 (100)	55 (100)	799 (100)
>= 56 Days Since First Injection	744 (100)	55 (100)	799 (100)
>= 2 Months Since First Injection	744 (100)	55 (100)	799 (100)
< 28 Days Since Second Injection	0	0	0
>= 28 and < 56 Days Since Second Injection	2 (0.3)	0	2 (0.3)
>= 28 Days Since Second Injection	744 (100)	55 (100)	799 (100)
>= 56 Days Since Second Injection	742 (99.7)	55 (100)	797 (99.7)
>= 2 Months Since Second Injection	742 (99.7)	55 (100)	797 (99.7)
>= 3 Months Since Second Injection	731 (98.3)	55 (100)	786 (98.4)
>= 4 Months Since Second Injection	712 (95.7)	53 (96.4)	765 (95.7)
>= 5 Months Since Second Injection	627 (84.3)	45 (81.8)	672 (84.1)
>= 6 Months Since Second Injection	422 (56.7)	27 (49.1)	449 (56.2)
Study Duration from Randomization (Days)			
Mean (SD)	207.7 (27.66)	205.5 (26.62)	207.6 (27.58)
Median	214.0	211.0	214.0
Q1, Q3	197.0, 227.0	193.0, 227.0	197.0, 227.0
Min, Max	68, 243	134, 239	68, 243

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

1 month = 30.4375 days. PDV = Participant Decision Visit.

Percentages are based on the number of subjects in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.

[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.

[2] Study duration from second injection is 0 day for subjects who did not receive second injection.

[3] Only include subjects who had PDV/unblinding on/before data cutoff date.

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Table 14.1.6.4.2
Summary of Study Duration
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Study Duration from First Injection (Days)			
Mean (SD)	207.7 (27.66)	205.5 (26.62)	207.6 (27.58)
Median	214.0	211.0	214.0
Q1, Q3	197.0, 227.0	193.0, 227.0	197.0, 227.0
Min, Max	68, 243	134, 239	68, 243
Person-years from First Injection [1]	423.1	30.9	454.0
Study Duration from Second Injection (Days) [2]			
Mean (SD)	178.4 (27.85)	176.8 (26.32)	178.3 (27.73)
Median	185.0	180.0	185.0
Q1, Q3	167.0, 198.0	165.0, 197.0	166.0, 198.0
Min, Max	40, 218	105, 211	40, 218
Study Duration from Second Injection in Subjects Who Received Second Injection (Days)			
n	744	55	799
Mean (SD)	178.4 (27.85)	176.8 (26.32)	178.3 (27.73)
Median	185.0	180.0	185.0
Q1, Q3	167.0, 198.0	165.0, 197.0	166.0, 198.0
Min, Max	40, 218	105, 211	40, 218

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

1 month = 30.4375 days. PDV = Participant Decision Visit.

Percentages are based on the number of subjects in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.

[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.

[2] Study duration from second injection is 0 day for subjects who did not receive second injection.

[3] Only include subjects who had PDV/unblinding on/before data cutoff date.

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Table 14.1.6.4.2
Summary of Study Duration
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744)	mRNA-1273 (N=55)	Total (N=799)
Study Duration from Randomization to PDV/Unblinding (Days) [3]			
n	714	54	768
Mean (SD)	158.6 (26.38)	153.7 (31.00)	158.3 (26.74)
Median	159.0	156.5	159.0
Q1, Q3	141.0, 176.0	137.0, 167.0	141.0, 176.0
Min, Max	91, 237	76, 216	76, 237
Study Duration from PDV/Unblinding to Study Discontinuation/Data Cutoff Date (Days) [3]			
n	714	54	768
Mean (SD)	51.8 (21.11)	52.9 (21.10)	51.9 (21.10)
Median	53.0	58.0	53.0
Q1, Q3	37.0, 68.0	31.0, 71.0	37.0, 68.0
Min, Max	1, 101	2, 84	1, 101

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

1 month = 30.4375 days. PDV = Participant Decision Visit.

Percentages are based on the number of subjects in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.

[1] Person-years is defined as the total years from the first dose date to the earlier date of study discontinuation or data cutoff.

[2] Study duration from second injection is 0 day for subjects who did not receive second injection.

[3] Only include subjects who had PDV/unblinding on/before data cutoff date.

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Table 14.1.6.5.1
Summary of Timing of Second Injection
Safety Set

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Number of Subjects Received Second Injection, n (%)	14631 (96.5)	14731 (97.0)	29362 (96.8)
Number of Days after First Injection (Days)			
Mean (SD)	29.4 (3.35)	29.4 (3.27)	29.4 (3.31)
Median	28.0	28.0	28.0
Q1, Q3	28.0, 30.0	28.0, 30.0	28.0, 30.0
Min, Max	22, 84	22, 115	22, 115
Number of Days after First Injection			
<21	0	0	0
>=21 and <=42	14503 (95.7)	14625 (96.3)	29128 (96.0)
>=21 and <=27	1921 (12.7)	2078 (13.7)	3999 (13.2)
>=28 and <=34	11657 (76.9)	11619 (76.5)	23276 (76.7)
>=35 and <=42	925 (6.1)	928 (6.1)	1853 (6.1)
>42	128 (0.8)	106 (0.7)	234 (0.8)
>56	16 (0.1)	12 (<0.1)	28 (<0.1)

Percentages are based on the number of subjects in Safety Set.
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Table 14.1.6.5.2
Summary of Timing of Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Number of Subjects Received Second Injection, n (%)	14320 (97.1)	14412 (97.7)	28732 (97.4)
Number of Days after First Injection (Days)			
Mean (SD)	29.4 (3.29)	29.3 (3.25)	29.4 (3.27)
Median	28.0	28.0	28.0
Q1, Q3	28.0, 30.0	28.0, 30.0	28.0, 30.0
Min, Max	22, 84	22, 115	22, 115
Number of Days after First Injection			
<21	0	0	0
>=21 and <=42	14201 (96.3)	14310 (97.0)	28511 (96.7)
>=21 and <=27	1890 (12.8)	2033 (13.8)	3923 (13.3)
>=28 and <=34	11416 (77.4)	11378 (77.2)	22794 (77.3)
>=35 and <=42	895 (6.1)	899 (6.1)	1794 (6.1)
>42	119 (0.8)	102 (0.7)	221 (0.7)
>56	14 (<0.1)	11 (<0.1)	25 (<0.1)

Percentages are based on the number of subjects in mITT Set.
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Table 14.1.6.5.3
Summary of Timing of Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Number of Subjects Received Second Injection, n (%)	14164 (100)	14287 (100)	28451 (100)
Number of Days after First Injection (Days)			
Mean (SD)	29.2 (2.65)	29.2 (2.63)	29.2 (2.64)
Median	28.0	28.0	28.0
Q1, Q3	28.0, 30.0	28.0, 30.0	28.0, 30.0
Min, Max	22, 42	22, 42	22, 42
Number of Days after First Injection			
<21	0	0	0
>=21 and <=42	14164 (100)	14287 (100)	28451 (100)
>=21 and <=27	1890 (13.3)	2029 (14.2)	3919 (13.8)
>=28 and <=34	11380 (80.3)	11360 (79.5)	22740 (79.9)
>=35 and <=42	894 (6.3)	898 (6.3)	1792 (6.3)
>42	0	0	0
>56	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1401060503.sas 21JUN2021 11:45

Table 14.1.6.6.1
Summary of Timing of First Injection
Safety Set

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Number of Days after Randomization (Days)			
Mean (SD)	0.0 (0.27)	0.0 (0.37)	0.0 (0.32)
Median	0.0	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0
Min, Max	0, 24	0, 22	0, 24
Number of Days after Randomization			
On the Day of Randomization	15145 (99.9)	15162 (99.9)	30307 (99.9)
<=3	6 (<0.1)	8 (<0.1)	14 (<0.1)
>3 and <=7	8 (<0.1)	7 (<0.1)	15 (<0.1)
>7	3 (<0.1)	7 (<0.1)	10 (<0.1)
Number of Subjects with Adjudicated COVID-19* Cases [1]	755 (5.0)	57 (0.4)	812 (2.7)
Number of Days after Randomization [2]			
On the Day of Randomization	755 (100)	57 (100)	812 (100)
<=3	0	0	0
>3 and <=7	0	0	0
>7	0	0	0

Percentages are based on the number of subjects in Safety Set.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] COVID-19 cases based on adjudication committee assessments starting 14 days after second injection.
[2] Percentages are based on the number of subjects with adjudicated COVID-19 cases.
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Table 14.1.6.6.2
Summary of Timing of First Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)	Total (N=29491)
Number of Days after Randomization (Days)			
Mean (SD)	0.0 (0.27)	0.0 (0.37)	0.0 (0.32)
Median	0.0	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0
Min, Max	0, 24	0, 22	0, 24
Number of Days after Randomization			
On the Day of Randomization	14730 (99.9)	14724 (99.9)	29454 (99.9)
<=3	5 (<0.1)	8 (<0.1)	13 (<0.1)
>3 and <=7	7 (<0.1)	7 (<0.1)	14 (<0.1)
>7	3 (<0.1)	7 (<0.1)	10 (<0.1)
Number of Subjects with Adjudicated COVID-19* Cases [1]	751 (5.1)	58 (0.4)	809 (2.7)
Number of Days after Randomization [2]			
On the Day of Randomization	751 (100)	58 (100)	809 (100)
<=3	0	0	0
>3 and <=7	0	0	0
>7	0	0	0

Percentages are based on the number of subjects in mITT Set.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] COVID-19 cases based on adjudication committee assessments starting 14 days after second injection.
[2] Percentages are based on the number of subjects with adjudicated COVID-19 cases.
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Table 14.1.6.6.3
Summary of Timing of First Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)	Total (N=28451)
Number of Days after Randomization (Days)			
Mean (SD)	0.0 (0.27)	0.0 (0.38)	0.0 (0.33)
Median	0.0	0.0	0.0
Q1, Q3	0.0, 0.0	0.0, 0.0	0.0, 0.0
Min, Max	0, 24	0, 22	0, 24
Number of Days after Randomization			
On the Day of Randomization	14149 (99.9)	14265 (99.8)	28414 (99.9)
<=3	5 (<0.1)	8 (<0.1)	13 (<0.1)
>3 and <=7	7 (<0.1)	7 (<0.1)	14 (<0.1)
>7	3 (<0.1)	7 (<0.1)	10 (<0.1)
Number of Subjects with Adjudicated COVID-19* Cases [1]	744 (5.3)	55 (0.4)	799 (2.8)
Number of Days after Randomization [2]			
On the Day of Randomization	744 (100)	55 (100)	799 (100)
<=3	0	0	0
>3 and <=7	0	0	0
>7	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. [1] COVID-19 cases based on adjudication committee assessments starting 14 days after second injection.
[2] Percentages are based on the number of subjects with adjudicated COVID-19 cases.
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Figure 14.1.1.1 Discontinuation from Study by Month
Randomization Set

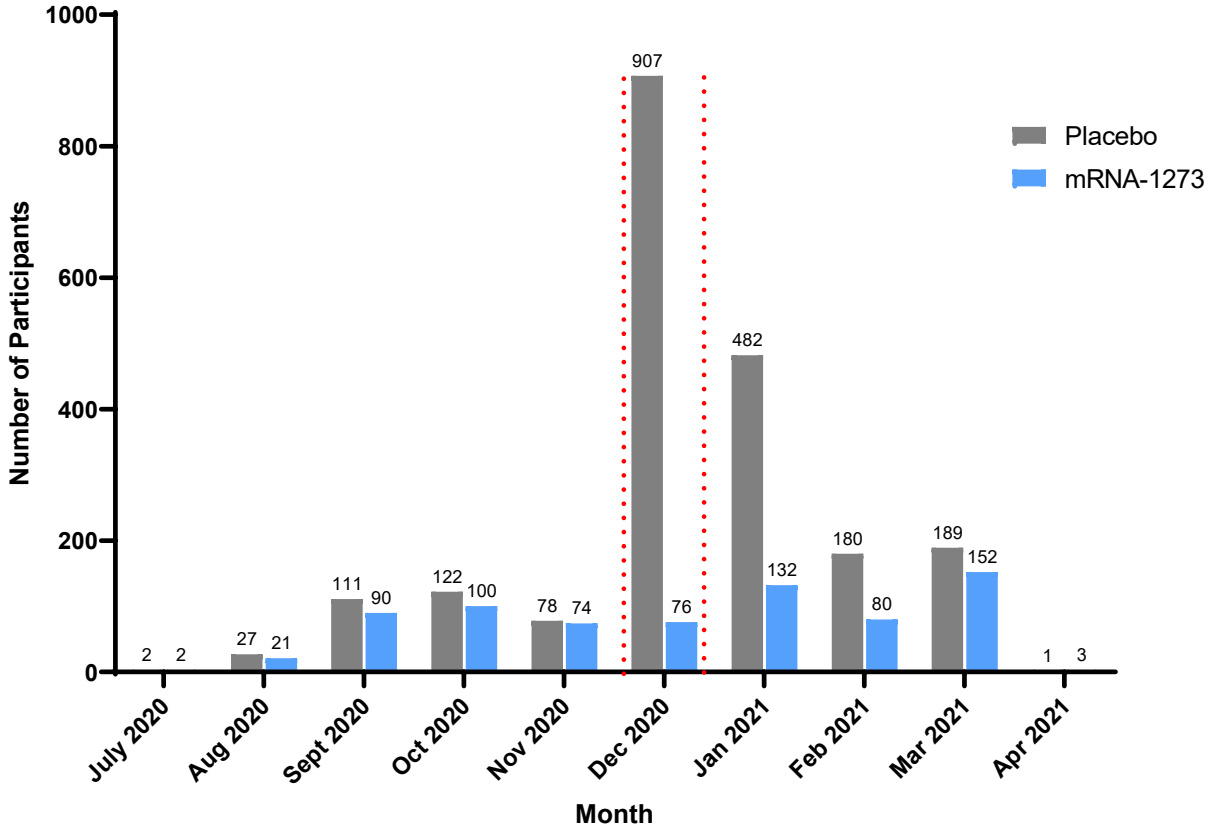

Table 14.2.2.1.1.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=13883)	mRNA-1273 (N=13934)
Number of Subjects with COVID-19, n (%)	90 (0.6)	5 (<0.1)
Number of Subjects Censored, n (%)	13793 (99.4)	13929 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.945 (0.865, 0.978)
p-value [2]		<.0001
Person-Years [3]	2697.5	2716.9
Incidence Rate per 1,000 Person-Years (95% CI) [4]	33.365 (26.829, 41.011)	1.840 (0.598, 4.295)
Vaccine Efficacy Based on Incidence Rate (95% CI) [5]		0.945 (0.866, 0.983)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.
[3] Person-years is defined as the total years from randomization date to the date of COVID-19 or last date of study participation, whichever is earlier.
[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[5] VE is defined as 1 – ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\EUA Nov 2020\TLF\t14020201010101.sas 13NOV2020 15:10

Table 14.2.2.1.1.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=14073)	mRNA-1273 (N=14134)
Number of Subjects with COVID-19, n (%)	185 (1.3)	11 (<0.1)
Number of Subjects Censored, n (%)	13888 (98.7)	14123 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.941 (0.893, 0.968)
p-value [2]		<.0001
Person-Years [3]	3273.7	3304.9
Incidence Rate per 1,000 Person-Years (95% CI) [4]	56.510 (48.660, 65.266)	3.328 (1.662, 5.955)
Vaccine Efficacy Based on Incidence Rate (95% CI) [5]		0.941 (0.892, 0.971)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.
[3] Person-years is defined as the total years from randomization date to the date of COVID-19, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[5] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.1.1.1.1.1.2
Summary of Primary and Secondary Efficacy Endpoint Analysis Results
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection		
Number of Events	744	55
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.910, 0.948)
p-value [2]		<.0001
COVID-19* Starting 14 Days After Second Injection		
Number of Events	751	55
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.911, 0.949)
Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection		
Number of Events	106	2
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.982 (0.928, 0.996)
Severe COVID-19* Starting 14 Days After Second Injection		
Number of Events	118	3
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.924, 0.992)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. For asymptomatic SARS-CoV-2 infection, VE and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.

[3] Including participant decision visit.

[4] n and N are based on the number of subjects in the Full Analysis Set.

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Table 14.2.1.1.1.1.1.2
Summary of Primary and Secondary Efficacy Endpoint Analysis Results
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After Second Injection [3]		
Number of Events	1339	280
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.820 (0.795, 0.842)
Secondary Definition of COVID-19* Starting 14 Days After Second Injection		
Number of Events	807	58
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.914, 0.949)
Death Caused by COVID-19 Starting 14 Days After Second Injection		
Number of Events	3	0
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. For asymptomatic SARS-CoV-2 infection, VE and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.

[3] Including participant decision visit.

[4] n and N are based on the number of subjects in the Full Analysis Set.

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Table 14.2.1.1.1.1.1.2
Summary of Primary and Secondary Efficacy Endpoint Analysis Results
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After First Injection		
Number of Events	769	56
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.933 (0.911, 0.949)
COVID-19* Starting 14 Days After First Injection		
Number of Events	782	58
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.931 (0.910, 0.947)
Asymptomatic SARS-CoV-2 Infection Starting 14 Days After Second Injection [3]		
Number of Events	498	214
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.630 (0.566, 0.685)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. For asymptomatic SARS-CoV-2 infection, VE and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.

[3] Including participant decision visit.

[4] n and N are based on the number of subjects in the Full Analysis Set.

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Table 14.2.1.1.1.1.1.2
Summary of Primary and Secondary Efficacy Endpoint Analysis Results
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection, n/N [4]		
Number of Events	754/15166	58/15180
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.928 (0.906, 0.945)
COVID-19* Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection, n/N [4]		
Number of Events	762/15166	58/15180
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.929 (0.907, 0.946)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. For asymptomatic SARS-CoV-2 infection, VE and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.

[3] Including participant decision visit.

[4] n and N are based on the number of subjects in the Full Analysis Set.

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Table 14.2.1.1.1.3.1
Concordance of COVID-19* Based on Adjudication Committee Assessments and COVID-19* Based on Symptoms Confirmed by RT-PCR Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164) n (%) Event*		mRNA-1273 (N=14287) n (%) Event*		Total (N=28451) n (%) Event*	
	Yes	No	Yes	No	Yes	No
Event* Based on Adjudication Committee Assessments						
Overall						
Yes	764 (5.4)	5 (<0.1)	55 (0.4)	1 (<0.1)	819 (2.9)	6 (<0.1)
No	18 (0.1)	13377 (94.4)	3 (<0.1)	14228 (99.6)	21 (<0.1)	27605 (97.0)
From Randomization up to 14 Days After First Injection						
Yes	0	0	0	0	0	0
No	0	14164 (100)	0	14287 (100)	0	28451 (100)
>=14 Days After First Injection up to Second Injection						
Yes	1 (<0.1)	0	0	0	1 (<0.1)	0
No	2 (<0.1)	14161 (>99.9)	0	14287 (100)	2 (<0.1)	28448 (>99.9)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020101010301.sas 10JUN2021 14:33

Table 14.2.1.1.1.3.1
Concordance of COVID-19* Based on Adjudication Committee Assessments and COVID-19* Based on Symptoms Confirmed by RT-PCR Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164) n (%) Event*		mRNA-1273 (N=14287) n (%) Event*		Total (N=28451) n (%) Event*	
	Yes	No	Yes	No	Yes	No
From Second Injection up to 14 Days After Second Injection						
Yes	24 (0.2)	0	1 (<0.1)	0	25 (<0.1)	0
No	4 (<0.1)	14136 (99.8)	2 (<0.1)	14284 (>99.9)	6 (<0.1)	28420 (99.9)
>=14 Days After Second Injection						
Yes	739 (5.2)	5 (<0.1)	54 (0.4)	1 (<0.1)	793 (2.8)	6 (<0.1)
No	12 (<0.1)	13408 (94.7)	1 (<0.1)	14231 (99.6)	13 (<0.1)	27639 (97.1)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
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Table 14.2.1.1.1.3.2
Concordance of COVID-19* Based on Adjudication Committee Assessments and COVID-19* Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745) n (%) Event*		mRNA-1273 (N=14746) n (%) Event*		Total (N=29491) n (%) Event*	
	Yes	No	Yes	No	Yes	No
Event* Based on Adjudication Committee Assessments						
Overall						
Yes	828 (5.6)	6 (<0.1)	68 (0.5)	1 (<0.1)	896 (3.0)	7 (<0.1)
No	20 (0.1)	13891 (94.2)	4 (<0.1)	14673 (99.5)	24 (<0.1)	28564 (96.9)
From Randomization up to 14 Days After First Injection						
Yes	11 (<0.1)	0	6 (<0.1)	0	17 (<0.1)	0
No	0	14734 (>99.9)	0	14740 (>99.9)	0	29474 (>99.9)
>=14 Days After First Injection up to Second Injection						
Yes	46 (0.3)	2 (<0.1)	4 (<0.1)	0	50 (0.2)	2 (<0.1)
No	4 (<0.1)	14693 (99.6)	1 (<0.1)	14741 (>99.9)	5 (<0.1)	29434 (99.8)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020101010302.sas 10JUN2021 14:34

Table 14.2.1.1.1.3.2
Concordance of COVID-19* Based on Adjudication Committee Assessments and COVID-19* Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745) n (%) Event*		mRNA-1273 (N=14746) n (%) Event*		Total (N=29491) n (%) Event*	
	Yes	No	Yes	No	Yes	No
From Second Injection up to 14 Days After Second Injection						
Yes	24 (0.2)	0	1 (<0.1)	0	25 (<0.1)	0
No	4 (<0.1)	14717 (99.8)	2 (<0.1)	14743 (>99.9)	6 (<0.1)	29460 (99.9)
>=14 Days After Second Injection						
Yes	746 (5.1)	5 (<0.1)	57 (0.4)	1 (<0.1)	803 (2.7)	6 (<0.1)
No	13 (<0.1)	13981 (94.8)	1 (<0.1)	14687 (99.6)	14 (<0.1)	28668 (97.2)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020101010302.sas 10JUN2021 14:34

Table 14.2.1.1.2.1.3.1
Summary of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	769 (5.4)	56 (0.4)
Number of Events		
From Randomization up to 14 Days After First Injection	0	0
>=14 up to 21 Days After First Injection	0	0
>=21 Days After First Injection up to Second Injection	1	0
From Second Injection up to 7 Days After Second Injection	11	1
>=7 up to 14 Days After Second Injection	13	0
>=14 up to 28 Days After Second Injection	49	4
>=28 up to 56 Days After Second Injection	178	15
>=56 up to 84 Days After Second Injection	228	12
>=84 up to 112 Days After Second Injection	206	16
>=112 Days After Second Injection	83	8

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

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Table 14.2.1.1.2.1.3.4
Summary of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	834 (5.7)	69 (0.5)
Number of Events		
From Randomization up to 14 Days After First Injection	11	6
>=14 up to 21 Days After First Injection	7	1
>=21 Days After First Injection up to Second Injection	41	3
From Second Injection up to 7 Days After Second Injection	11	1
>=7 up to 14 Days After Second Injection	13	0
>=14 up to 28 Days After Second Injection	49	4
>=28 up to 56 Days After Second Injection	181	16
>=56 up to 84 Days After Second Injection	230	13
>=84 up to 112 Days After Second Injection	207	17
>=112 Days After Second Injection	84	8

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

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Table 14.2.1.1.2.1.4.1
Summary of COVID-19* Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	782 (5.5)	58 (0.4)
Number of Events		
From Randomization up to 14 Days After First Injection	0	0
>=14 up to 21 Days After First Injection	0	0
>=21 Days After First Injection up to Second Injection	3	0
From Second Injection up to 7 Days After Second Injection	12	3
>=7 up to 14 Days After Second Injection	16	0
>=14 up to 28 Days After Second Injection	48	4
>=28 up to 56 Days After Second Injection	181	14
>=56 up to 84 Days After Second Injection	229	13
>=84 up to 112 Days After Second Injection	207	16
>=112 Days After Second Injection	86	8

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

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Table 14.2.1.1.2.1.4.4
Summary of COVID-19* Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	848 (5.8)	72 (0.5)
Number of Events		
From Randomization up to 14 Days After First Injection	11	6
>=14 up to 21 Days After First Injection	7	1
>=21 Days After First Injection up to Second Injection	43	4
From Second Injection up to 7 Days After Second Injection	12	3
>=7 up to 14 Days After Second Injection	16	0
>=14 up to 28 Days After Second Injection	48	4
>=28 up to 56 Days After Second Injection	185	15
>=56 up to 84 Days After Second Injection	231	14
>=84 up to 112 Days After Second Injection	208	17
>=112 Days After Second Injection	87	8

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

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Table 14.2.1.1.2.1.5.1
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
From Randomization		
Number of Subjects with COVID-19*	769	56
Incidence Rate per 1,000 Person-Years (95% CI) [1]	141.225 (131.418, 151.569)	9.773 (7.383, 12.691)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.931 (0.909, 0.948)
From >=14 Days After First Injection		
Number of Subjects with COVID-19*	769	56
Incidence Rate per 1,000 Person-Years (95% CI) [1]	141.225 (131.418, 151.569)	9.773 (7.383, 12.691)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.931 (0.909, 0.948)
From Second Injection		
Number of Subjects with COVID-19*	768	56
Incidence Rate per 1,000 Person-Years (95% CI) [1]	141.043 (131.243, 151.382)	9.773 (7.383, 12.691)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.931 (0.909, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

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Table 14.2.1.1.2.1.5.1
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
From >=14 Days After Second Injection		
Number of Subjects with COVID-19*	744	55
Incidence Rate per 1,000 Person-Years (95% CI) [1]	136.732 (127.082, 146.920)	9.600 (7.232, 12.496)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.930 (0.908, 0.948)
By Mutually Exclusive Time Periods		
From Randomization up to 14 Days After First Injection		
Number of Subjects with COVID-19*	0	0
Incidence Rate per 1,000 Person-Years (95% CI) [1]	0.000 (NE, 6.792)	0.000 (NE, 6.731)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		NE (NE, NE)
>=14 Days After First Injection up to Second Injection		
Number of Subjects with COVID-19*	1	0
Incidence Rate per 1,000 Person-Years (95% CI) [1]	0.882 (0.022, 4.912)	0.000 (NE, 3.228)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		1.000 (-37.716, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

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Table 14.2.1.1.2.1.5.1
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
From Second Injection up to 14 Days After Second Injection		
Number of Subjects with COVID-19*	24	1
Incidence Rate per 1,000 Person-Years (95% CI) [1]	14.317 (9.173, 21.302)	0.592 (0.015, 3.297)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.959 (0.747, 0.999)
>=14 up to 28 Days After Second Injection		
Number of Subjects with COVID-19*	49	4
Incidence Rate per 1,000 Person-Years (95% CI) [1]	22.145 (16.383, 29.277)	1.789 (0.487, 4.580)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.919 (0.780, 0.979)
>=28 up to 56 Days After Second Injection		
Number of Subjects with COVID-19*	178	15
Incidence Rate per 1,000 Person-Years (95% CI) [1]	54.503 (46.790, 63.124)	4.520 (2.530, 7.454)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.917 (0.859, 0.955)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

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Table 14.2.1.1.2.1.5.1
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
>=56 up to 84 Days After Second Injection		
Number of Subjects with COVID-19*	228	12
Incidence Rate per 1,000 Person-Years (95% CI) [1]	54.930 (48.030, 62.541)	2.791 (1.442, 4.875)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.949 (0.910, 0.974)
>=84 up to 112 Days After Second Injection		
Number of Subjects with COVID-19*	206	16
Incidence Rate per 1,000 Person-Years (95% CI) [1]	46.197 (40.103, 52.955)	3.328 (1.902, 5.404)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.928 (0.880, 0.960)
>=112 Days After Second Injection		
Number of Subjects with COVID-19*	83	8
Incidence Rate per 1,000 Person-Years (95% CI) [1]	26.004 (20.712, 32.236)	2.120 (0.915, 4.177)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.918 (0.832, 0.966)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

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Table 14.2.1.1.2.1.5.2
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
From Randomization		
Number of Subjects with COVID-19*	834	69
Incidence Rate per 1,000 Person-Years (95% CI) [1]	148.808 (138.879, 159.260)	11.768 (9.156, 14.893)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.921 (0.899, 0.939)
From >=14 Days After First Injection		
Number of Subjects with COVID-19*	823	63
Incidence Rate per 1,000 Person-Years (95% CI) [1]	146.861 (136.998, 157.247)	10.745 (8.257, 13.748)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.927 (0.905, 0.944)
From Second Injection		
Number of Subjects with COVID-19*	775	59
Incidence Rate per 1,000 Person-Years (95% CI) [1]	140.686 (130.954, 150.950)	10.202 (7.767, 13.160)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.927 (0.905, 0.945)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

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Table 14.2.1.1.2.1.5.2
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
From >=14 Days After Second Injection		
Number of Subjects with COVID-19*	751	58
Incidence Rate per 1,000 Person-Years (95% CI) [1]	136.424 (126.840, 146.540)	10.031 (7.617, 12.967)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.926 (0.904, 0.945)
By Mutually Exclusive Time Periods		
From Randomization up to 14 Days After First Injection		
Number of Subjects with COVID-19*	11	6
Incidence Rate per 1,000 Person-Years (95% CI) [1]	19.465 (9.717, 34.829)	10.613 (3.895, 23.101)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.455 (-0.608, 0.834)
>=14 Days After First Injection up to Second Injection		
Number of Subjects with COVID-19*	48	4
Incidence Rate per 1,000 Person-Years (95% CI) [1]	38.456 (28.354, 50.987)	3.230 (0.880, 8.270)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.916 (0.771, 0.978)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010102010502.sas 21JUN2021 07:47

Table 14.2.1.1.2.1.5.2
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
From Second Injection up to 14 Days After Second Injection		
Number of Subjects with COVID-19*	24	1
Incidence Rate per 1,000 Person-Years (95% CI) [1]	14.109 (9.040, 20.993)	0.585 (0.015, 3.257)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.959 (0.746, 0.999)
>=14 up to 28 Days After Second Injection		
Number of Subjects with COVID-19*	49	4
Incidence Rate per 1,000 Person-Years (95% CI) [1]	21.843 (16.160, 28.878)	1.769 (0.482, 4.529)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.919 (0.779, 0.979)
>=28 up to 56 Days After Second Injection		
Number of Subjects with COVID-19*	181	16
Incidence Rate per 1,000 Person-Years (95% CI) [1]	54.722 (47.040, 63.301)	4.771 (2.727, 7.748)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.913 (0.855, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

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Table 14.2.1.1.2.1.5.2
Incidence Rate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
>=56 up to 84 Days After Second Injection		
Number of Subjects with COVID-19*	230	13
Incidence Rate per 1,000 Person-Years (95% CI) [1]	54.754 (47.906, 62.306)	2.994 (1.594, 5.120)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.945 (0.905, 0.971)
>=84 up to 112 Days After Second Injection		
Number of Subjects with COVID-19*	207	17
Incidence Rate per 1,000 Person-Years (95% CI) [1]	45.898 (39.858, 52.595)	3.505 (2.042, 5.612)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.924 (0.875, 0.956)
>=112 Days After Second Injection		
Number of Subjects with COVID-19*	84	8
Incidence Rate per 1,000 Person-Years (95% CI) [1]	26.067 (20.792, 32.273)	2.105 (0.909, 4.147)
Vaccine Efficacy Based on Incidence Rate (95% CI) [2]		0.919 (0.834, 0.966)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Incidence rate for each time period is defined as the number of subjects with an event during the time period divided by the number of subjects at risk at the beginning of each time period and adjusted by person-years (total time at risk) in each treatment group. Person-years for each time period is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, the end of each time period, last date of study participation, or efficacy data cutoff date, whichever is the earliest. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[2] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years for the time period.

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Table 14.2.1.1.2.2.3.1
Summary of Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	107 (0.8)	2 (<0.1)
Number of Events		
From Randomization up to 14 Days After First Injection	0	0
>=14 up to 21 Days After First Injection	0	0
>=21 Days After First Injection up to Second Injection	0	0
From Second Injection up to 7 Days After Second Injection	0	0
>=7 up to 14 Days After Second Injection	1	0
>=14 up to 28 Days After Second Injection	7	0
>=28 up to 56 Days After Second Injection	25	0
>=56 up to 84 Days After Second Injection	33	2
>=84 up to 112 Days After Second Injection	28	0
>=112 Days After Second Injection	13	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
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Table 14.2.1.1.2.2.4.1
Summary of Severe COVID-19* Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	120 (0.8)	3 (<0.1)
Number of Events		
From Randomization up to 14 Days After First Injection	0	0
>=14 up to 21 Days After First Injection	0	0
>=21 Days After First Injection up to Second Injection	0	0
From Second Injection up to 7 Days After Second Injection	0	0
>=7 up to 14 Days After Second Injection	2	0
>=14 up to 28 Days After Second Injection	9	0
>=28 up to 56 Days After Second Injection	29	0
>=56 up to 84 Days After Second Injection	34	2
>=84 up to 112 Days After Second Injection	31	1
>=112 Days After Second Injection	15	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
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Table 14.2.1.1.2.3.1.2
Summary of SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Randomization Including Participant Decision Visit by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1434 (10.1)	313 (2.2)
Number of Events		
From Randomization up to 14 Days After First Injection	0	0
>=14 up to 21 Days After First Injection	1	0
>=21 Days After First Injection up to Second Injection	3	0
From Second Injection up to 7 Days After Second Injection	78	33
>=7 up to 14 Days After Second Injection	13	0
>=14 up to 28 Days After Second Injection	63	9
>=28 up to 56 Days After Second Injection	217	28
>=56 up to 84 Days After Second Injection	290	28
>=84 up to 112 Days After Second Injection	316	58
>=112 Days After Second Injection	453	157

Table 14.2.1.1.2.3.4.2
Summary of SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Randomization Including Participant Decision Visit by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1522 (10.3)	335 (2.3)
Number of Events		
From Randomization up to 14 Days After First Injection	11	6
>=14 up to 21 Days After First Injection	8	1
>=21 Days After First Injection up to Second Injection	59	8
From Second Injection up to 7 Days After Second Injection	79	34
>=7 up to 14 Days After Second Injection	13	0
>=14 up to 28 Days After Second Injection	63	9
>=28 up to 56 Days After Second Injection	221	29
>=56 up to 84 Days After Second Injection	292	29
>=84 up to 112 Days After Second Injection	318	61
>=112 Days After Second Injection	458	158

Table 14.2.1.1.2.4.2.1
Summary of Secondary Definition of COVID-19* Starting After Randomization by Time Period
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	839 (5.9)	62 (0.4)
Number of Events		
From Randomization up to 14 Days After First Injection	0	0
>=14 up to 21 Days After First Injection	1	0
>=21 Days After First Injection up to Second Injection	3	0
From Second Injection up to 7 Days After Second Injection	12	4
>=7 up to 14 Days After Second Injection	16	0
>=14 up to 28 Days After Second Injection	56	4
>=28 up to 56 Days After Second Injection	189	15
>=56 up to 84 Days After Second Injection	246	14
>=84 up to 112 Days After Second Injection	218	17
>=112 Days After Second Injection	98	8

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

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Table 14.2.1.1.2.4.2.4
Summary of Secondary Definition of COVID-19* Starting After Randomization by Time Period
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	909 (6.2)	77 (0.5)
Number of Events		
From Randomization up to 14 Days After First Injection	11	6
>=14 up to 21 Days After First Injection	8	1
>=21 Days After First Injection up to Second Injection	46	5
From Second Injection up to 7 Days After Second Injection	12	4
>=7 up to 14 Days After Second Injection	16	0
>=14 up to 28 Days After Second Injection	56	4
>=28 up to 56 Days After Second Injection	193	16
>=56 up to 84 Days After Second Injection	248	15
>=84 up to 112 Days After Second Injection	220	18
>=112 Days After Second Injection	99	8

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

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Table 14.2.1.1.2.5.1.1.2
Summary of Asymptomatic SARS-CoV-2 Infection Starting After Randomization Including Participant Decision Visit by Visit
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Asymptomatic SARS-CoV-2 Infection, n (%)	567 (4.0)	246 (1.7)
Number of Events		
At Day 29 [1]	69	32
By Both RT-PCR and Elecsys	8	3
By RT-PCR Only	35	12
By Elecsys Only	26	17
At Day 57 [1] (by Elecsys)	31	13
At Day 209 [1] (by Elecsys)	2	0
At Participant Decision Visit [2]	463	201
By Both RT-PCR and Elecsys	115	7
By RT-PCR Only	157	153
By Elecsys Only	191	41

RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition.
[1] Include cases that occurred in the blinded phase and not include cases that occurred in the open-label phase.
[2] Include cases that occurred at participant decision visit (PDV) before or on efficacy data cutoff date. If a subject has positive RT-PCR test or Elecsys anti-SARS-CoV-2 assay on the same date for both PDV and another scheduled visit, the subject is counted under PDV.
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Table 14.2.1.1.2.5.1.2.2
Summary of Asymptomatic SARS-CoV-2 Infection Starting After Randomization Including Participant Decision by Visit
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Asymptomatic SARS-CoV-2 Infection, n (%)	583 (4.0)	253 (1.7)
Number of Events		
At Day 29 [1]	75	33
By Both RT-PCR and Elecsys	12	3
By RT-PCR Only	36	13
By Elecsys Only	27	17
At Day 57 [1] (by Elecsys)	34	14
At Day 209 [1] (by Elecsys)	2	0
At Participant Decision Visit [2]	470	206
By Both RT-PCR and Elecsys	119	7
By RT-PCR Only	158	156
By Elecsys Only	193	43

RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition.
[1] Include cases that occurred in the blinded phase and not include cases that occurred in the open-label phase.
[2] Include cases that occurred at participant decision visit (PDV) before or on efficacy data cutoff date. If a subject has positive RT-PCR test or Elecsys anti-SARS-CoV-2 assay on the same date for both PDV and another scheduled visit, the subject is counted under PDV.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140201010205010202.sas 26JUL2021 21:19

Table 14.2.1.2.1
Summary of RT-PCR Test and Elecsys Anti-SARS-CoV-2 Assay Results at Baseline
Full Analysis Set

Baseline SARS-CoV-2 Status	Baseline RT-PCR Result [1]	Baseline Elecsys Result [1]	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Positive			337 (2.2)	347 (2.3)	684 (2.3)
	Positive	Positive	61 (0.4)	50 (0.3)	111 (0.4)
	Positive	Negative/Missing	34 (0.2)	38 (0.3)	72 (0.2)
	Negative/Missing	Positive	242 (1.6)	259 (1.7)	501 (1.7)
Negative	Negative	Negative	14745 (97.2)	14746 (97.1)	29491 (97.2)
Missing			84 (0.6)	87 (0.6)	171 (0.6)
	Negative	Missing	12 (<0.1)	9 (<0.1)	21 (<0.1)
	Missing	Negative	65 (0.4)	63 (0.4)	128 (0.4)
	Missing	Missing	7 (<0.1)	15 (<0.1)	22 (<0.1)

RT-PCR = reverse transcription polymerase chain reaction.
[1] Subjects with no RT-PCR result or no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010201.sas 10JUN2021 15:00

Table 14.2.1.2.1.2
Summary of RT-PCR Test and Elecsys Anti-SARS-CoV-2 Assay Results at Day 29
mITT Set

Baseline SARS-CoV-2 Status	RT-PCR Result at Day 29 [1]	Elecsys Result at Day 29 [1]	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Total (N=29491) n (%)
Negative	Positive	Positive	15 (0.1)	3 (<0.1)	18 (<0.1)
		Negative	39 (0.3)	14 (<0.1)	53 (0.2)
		Missing	1 (<0.1)	0	1 (<0.1)
	Negative	Positive	28 (0.2)	17 (0.1)	45 (0.2)
		Negative	14107 (95.7)	14229 (96.5)	28336 (96.1)
		Missing	98 (0.7)	116 (0.8)	214 (0.7)
	Missing	Positive	1 (<0.1)	0	1 (<0.1)
		Negative	102 (0.7)	85 (0.6)	187 (0.6)
		Missing	354 (2.4)	282 (1.9)	636 (2.2)

RT-PCR = reverse transcription polymerase chain reaction.
[1] Subjects with no RT-PCR result or no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140201020102.sas 10JUN2021 15:01

Table 14.2.1.2.2
Summary of RT-PCR Test Results for SARS-CoV-2 at Baseline
Full Analysis Set

	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Negative	14995 (98.9)	15013 (98.9)	30008 (98.9)
Positive	95 (0.6)	88 (0.6)	183 (0.6)
Missing [1]	76 (0.5)	79 (0.5)	155 (0.5)

RT-PCR = reverse transcription polymerase chain reaction.
[1] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010202.sas 21JUN2021 05:21

Table 14.2.1.2.3
Summary of Elecsys Anti-SARS-CoV-2 Assay Results at Baseline
Full Analysis Set

	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)	Total (N=30346) n (%)
Negative	14844 (97.9)	14847 (97.8)	29691 (97.8)
Positive	303 (2.0)	309 (2.0)	612 (2.0)
Missing [1]	19 (0.1)	24 (0.2)	43 (0.1)

[1] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010203.sas 21JUN2021 05:21

Table 14.2.1.3.1
Summary of RT-PCR Test Results for SARS-CoV-2
Per-Protocol Set

	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)
Baseline [1]		
Negative	14164 (100)	14287 (100)
Positive	0	0
Missing [2]	0	0
Day 29 [1]		
Negative	13988 (98.8)	14165 (99.1)
Positive	45 (0.3)	16 (0.1)
Missing [2]	131 (0.9)	106 (0.7)
RT-PCR Test Excluding Baseline and Day 29 [3]		
Negative	1516 (10.7)	1543 (10.8)
Positive	848 (6.0)	65 (0.5)
Prior to 14 Days After First Injection	0	0
14 Days After First Injection and Prior to Second Injection	4 (0.5)	0
Second Injection and Prior to 14 Days After Second Injection	27 (3.2)	0
14 Days After Second Injection and Beyond	817 (96.3)	65 (100)

RT-PCR = reverse transcription polymerase chain reaction.
[1] RT-PCR tests are scheduled at Day 1 (baseline) and Day 29 for all subjects in the study.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
[3] A subject may have multiple RT-PCR results, and will be counted under Positive if the subject had at least one positive result. A subject is counted in the time windows with the 1st occurrence of positive RT-PCR results excluding baseline and Day 29.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010301.sas 21JUN2021 07:57

Table 14.2.1.3.2
Summary of RT-PCR Test Results for SARS-CoV-2
mITT Set

	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)
Baseline [1]		
Negative	14745 (100)	14746 (100)
Positive	0	0
Missing [2]	0	0
Day 29 [1]		
Negative	14233 (96.5)	14362 (97.4)
Positive	55 (0.4)	17 (0.1)
Missing [2]	457 (3.1)	367 (2.5)
RT-PCR Test Excluding Baseline and Day 29 [3]		
Negative	1583 (10.7)	1606 (10.9)
Positive	918 (6.2)	80 (0.5)
Prior to 14 Days After First Injection	11 (1.2)	6 (7.5)
14 Days After First Injection and Prior to Second Injection	54 (5.9)	6 (7.5)
Second Injection and Prior to 14 Days After Second Injection	27 (2.9)	0
14 Days After Second Injection and Beyond	826 (90.0)	68 (85.0)

RT-PCR = reverse transcription polymerase chain reaction.
[1] RT-PCR tests are scheduled at Day 1 (baseline) and Day 29 for all subjects in the study.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
[3] A subject may have multiple RT-PCR results, and will be counted under Positive if the subject had at least one positive result. A subject is counted in the time windows with the 1st occurrence of positive RT-PCR results excluding baseline and Day 29.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010302.sas 21JUN2021 05:21

Table 14.2.1.3.3
Summary of RT-PCR Test Results for SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline [1]						
Negative	14745 (100)	14746 (100)	238 (70.6)	258 (74.4)	14995 (98.9)	15013 (98.9)
Positive	0	0	95 (28.2)	88 (25.4)	95 (0.6)	88 (0.6)
Missing [2]	0	0	4 (1.2)	1 (0.3)	76 (0.5)	79 (0.5)
Day 29 [1]						
Negative	14233 (96.5)	14362 (97.4)	279 (82.8)	278 (80.1)	14584 (96.2)	14716 (96.9)
Positive	55 (0.4)	17 (0.1)	29 (8.6)	30 (8.6)	84 (0.6)	47 (0.3)
Missing [2]	457 (3.1)	367 (2.5)	29 (8.6)	39 (11.2)	498 (3.3)	417 (2.7)

RT-PCR = reverse transcription polymerase chain reaction.
[1] RT-PCR tests are scheduled at Day 1 (baseline) and Day 29 for all subjects in the study.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
[3] A subject may have multiple RT-PCR results, and will be counted under Positive if the subject had at least one positive result. A subject is counted in the time windows with the 1st occurrence of positive RT-PCR results excluding baseline and Day 29.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010303.sas 21JUN2021 05:21

Table 14.2.1.3.3
Summary of RT-PCR Test Results for SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
RT-PCR Test Excluding Baseline and Day 29 [3]						
Negative	1583 (10.7)	1606 (10.9)	22 (6.5)	32 (9.2)	1616 (10.7)	1652 (10.9)
Positive	918 (6.2)	80 (0.5)	9 (2.7)	8 (2.3)	930 (6.1)	88 (0.6)
Prior to 14 Days After First Injection	11 (1.2)	6 (7.5)	7 (77.8)	8 (100)	18 (1.9)	14 (15.9)
14 Days After First Injection and Prior to Second Injection	54 (5.9)	6 (7.5)	0	0	54 (5.8)	6 (6.8)
Second Injection and Prior to 14 Days After Second Injection	27 (2.9)	0	0	0	27 (2.9)	0
14 Days After Second Injection and Beyond	826 (90.0)	68 (85.0)	2 (22.2)	0	831 (89.4)	68 (77.3)

RT-PCR = reverse transcription polymerase chain reaction.
[1] RT-PCR tests are scheduled at Day 1 (baseline) and Day 29 for all subjects in the study.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
[3] A subject may have multiple RT-PCR results, and will be counted under Positive if the subject had at least one positive result. A subject is counted in the time windows with the 1st occurrence of positive RT-PCR results excluding baseline and Day 29.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010303.sas 21JUN2021 05:21

Table 14.2.1.3.4
Summary of RT-PCR Test Results for SARS-CoV-2 at Scheduled Visits
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Baseline Post-baseline	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline RT-PCR Positive (N1)	0	0	95	88	95	88
RT-PCR Result at Day 29 [1]						
Positive	0	0	26 (27.4)	24 (27.3)	26 (27.4)	24 (27.3)
Negative	0	0	55 (57.9)	52 (59.1)	55 (57.9)	52 (59.1)
Missing [2]	0	0	14 (14.7)	12 (13.6)	14 (14.7)	12 (13.6)
Baseline RT-PCR Negative (N1)	14745	14746	238	258	14995	15013
RT-PCR Result at Day 29 [1]						
Positive	55 (0.4)	17 (0.1)	3 (1.3)	6 (2.3)	58 (0.4)	23 (0.2)
Negative	14233 (96.5)	14362 (97.4)	220 (92.4)	225 (87.2)	14464 (96.5)	14596 (97.2)
Missing [2]	457 (3.1)	367 (2.5)	15 (6.3)	27 (10.5)	473 (3.2)	394 (2.6)

RT-PCR = reverse transcription polymerase chain reaction.
[1] Percentages are based on N1.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010304.sas 10JUN2021 15:01

Table 14.2.1.3.4
Summary of RT-PCR Test Results for SARS-CoV-2 at Scheduled Visits
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Baseline Post-baseline	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline RT-PCR Missing (N1) [2]	0	0	4	1	76	79
RT-PCR Result at Day 29 [1]						
Positive	0	0	0	0	0	0
Negative	0	0	4 (100)	1 (100)	65 (85.5)	68 (86.1)
Missing [2]	0	0	0	0	11 (14.5)	11 (13.9)

RT-PCR = reverse transcription polymerase chain reaction.
[1] Percentages are based on N1.
[2] Subjects with no RT-PCR result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010304.sas 10JUN2021 15:01

Table 14.2.1.4.1
Summary of Elecsys Anti-SARS-CoV-2 Assay Results
Per-Protocol Set

	Placebo (N=14164) n (%)	mRNA-1273 (N=14287) n (%)
Baseline		
Negative	14164 (100)	14287 (100)
Positive	0	0
Missing [1]	0	0
Day 29		
Negative	14005 (98.9)	14130 (98.9)
Positive	34 (0.2)	20 (0.1)
Missing [1]	125 (0.9)	137 (1.0)
Day 57		
Negative	13602 (96.0)	13941 (97.6)
Positive	99 (0.7)	32 (0.2)
Missing [1]	463 (3.3)	314 (2.2)
Day 209		
Negative	17 (0.1)	22 (0.2)
Positive	10 (<0.1)	0
Missing [1]	14137 (99.8)	14265 (99.8)

[1] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010401.sas 21JUN2021 05:21

Table 14.2.1.4.2
Summary of Elecsys Anti-SARS-CoV-2 Assay Results
mITT Set

	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)
Baseline		
Negative	14745 (100)	14746 (100)
Positive	0	0
Missing [1]	0	0
Day 29		
Negative	14248 (96.6)	14328 (97.2)
Positive	44 (0.3)	20 (0.1)
Missing [1]	453 (3.1)	398 (2.7)
Day 57		
Negative	13869 (94.1)	14171 (96.1)
Positive	138 (0.9)	40 (0.3)
Missing [1]	738 (5.0)	535 (3.6)
Day 209		
Negative	19 (0.1)	23 (0.2)
Positive	11 (<0.1)	0
Missing [1]	14715 (99.8)	14723 (99.8)

[1] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010402.sas 21JUN2021 05:21

Table 14.2.1.4.3
Summary of Elecsys Anti-SARS-CoV-2 Assay Results
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline						
Negative	14745 (100)	14746 (100)	34 (10.1)	38 (11.0)	14844 (97.9)	14847 (97.8)
Positive	0	0	303 (89.9)	309 (89.0)	303 (2.0)	309 (2.0)
Missing [1]	0	0	0	0	19 (0.1)	24 (0.2)
Day 29						
Negative	14248 (96.6)	14328 (97.2)	21 (6.2)	19 (5.5)	14339 (94.5)	14427 (95.0)
Positive	44 (0.3)	20 (0.1)	290 (86.1)	292 (84.1)	334 (2.2)	313 (2.1)
Missing [1]	453 (3.1)	398 (2.7)	26 (7.7)	36 (10.4)	493 (3.3)	440 (2.9)
Day 57						
Negative	13869 (94.1)	14171 (96.1)	18 (5.3)	20 (5.8)	13960 (92.0)	14267 (94.0)
Positive	138 (0.9)	40 (0.3)	276 (81.9)	275 (79.3)	415 (2.7)	316 (2.1)
Missing [1]	738 (5.0)	535 (3.6)	43 (12.8)	52 (15.0)	791 (5.2)	597 (3.9)

[1] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010403.sas 21JUN2021 05:22

Table 14.2.1.4.3
Summary of Elecsys Anti-SARS-CoV-2 Assay Results
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Day 209						
Negative	19 (0.1)	23 (0.2)	1 (0.3)	1 (0.3)	20 (0.1)	25 (0.2)
Positive	11 (<0.1)	0	0	1 (0.3)	11 (<0.1)	1 (<0.1)
Missing [1]	14715 (99.8)	14723 (99.8)	336 (99.7)	345 (99.4)	15135 (99.8)	15154 (99.8)

[1] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010403.sas 21JUN2021 05:22

Table 14.2.1.4.4
Summary of Elecsys Anti-SARS-CoV-2 Assay Results at Scheduled Visits
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Baseline Post-baseline	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline Elecsys Positive (N1)	0	0	303	309	303	309
Elecsys Result at Day 29 [1]						
Positive	0	0	270 (89.1)	270 (87.4)	270 (89.1)	270 (87.4)
Negative	0	0	14 (4.6)	11 (3.6)	14 (4.6)	11 (3.6)
Missing [2]	0	0	19 (6.3)	28 (9.1)	19 (6.3)	28 (9.1)
Baseline Elecsys Negative (N1)	14745	14746	34	38	14844	14847
Elecsys Result at Day 29 [1]						
Positive	44 (0.3)	20 (0.1)	20 (58.8)	22 (57.9)	64 (0.4)	42 (0.3)
Negative	14248 (96.6)	14328 (97.2)	7 (20.6)	8 (21.1)	14316 (96.4)	14396 (97.0)
Missing [2]	453 (3.1)	398 (2.7)	7 (20.6)	8 (21.1)	464 (3.1)	409 (2.8)

[1] Percentages are based on N1.
[2] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010404.sas 24JUN2021 07:03

Table 14.2.1.4.4
Summary of Elecsys Anti-SARS-CoV-2 Assay Results at Scheduled Visits
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Baseline Post-baseline	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline Elecsys Missing (N1) [2]	0	0	0	0	19	24
Elecsys Result at Day 29 [1]						
Positive	0	0	0	0	0	1 (4.2)
Negative	0	0	0	0	9 (47.4)	20 (83.3)
Missing [2]	0	0	0	0	10 (52.6)	3 (12.5)
Baseline Elecsys Positive (N1)	0	0	303	309	303	309
Elecsys Result at Day 57 [1]						
Positive	0	0	255 (84.2)	253 (81.9)	255 (84.2)	253 (81.9)
Negative	0	0	11 (3.6)	10 (3.2)	11 (3.6)	10 (3.2)
Missing [2]	0	0	37 (12.2)	46 (14.9)	37 (12.2)	46 (14.9)

[1] Percentages are based on N1.
[2] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010404.sas 24JUN2021 07:03

Table 14.2.1.4.4
Summary of Elecsys Anti-SARS-CoV-2 Assay Results at Scheduled Visits
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Baseline Post-baseline	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline Elecsys Negative (N1)	14745	14746	34	38	14844	14847
Elecsys Result at Day 57 [1]						
Positive	138 (0.9)	40 (0.3)	21 (61.8)	22 (57.9)	159 (1.1)	62 (0.4)
Negative	13869 (94.1)	14171 (96.1)	7 (20.6)	10 (26.3)	13937 (93.9)	14237 (95.9)
Missing [2]	738 (5.0)	535 (3.6)	6 (17.6)	6 (15.8)	748 (5.0)	548 (3.7)
Baseline Elecsys Missing (N1) [2]	0	0	0	0	19	24
Elecsys Result at Day 57 [1]						
Positive	0	0	0	0	1 (5.3)	1 (4.2)
Negative	0	0	0	0	12 (63.2)	20 (83.3)
Missing [2]	0	0	0	0	6 (31.6)	3 (12.5)

[1] Percentages are based on N1.
[2] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010404.sas 24JUN2021 07:03

Table 14.2.1.4.4
Summary of Elecsys Anti-SARS-CoV-2 Assay Results at Scheduled Visits
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Baseline Post-baseline	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline Elecsys Positive (N1)	0	0	303	309	303	309
Elecsys Result at Day 209 [1]						
Positive	0	0	0	1 (0.3)	0	1 (0.3)
Negative	0	0	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)
Missing [2]	0	0	302 (99.7)	307 (99.4)	302 (99.7)	307 (99.4)
Baseline Elecsys Negative (N1)	14745	14746	34	38	14844	14847
Elecsys Result at Day 209 [1]						
Positive	11 (<0.1)	0	0	0	11 (<0.1)	0
Negative	19 (0.1)	23 (0.2)	0	0	19 (0.1)	24 (0.2)
Missing [2]	14715 (99.8)	14723 (99.8)	34 (100)	38 (100)	14814 (99.8)	14823 (99.8)

[1] Percentages are based on N1.
[2] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010404.sas 24JUN2021 07:03

Table 14.2.1.4.4
Summary of Elecsys Anti-SARS-CoV-2 Assay Results at Scheduled Visits
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Baseline Post-baseline	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Baseline Elecsys Missing (N1) [2]	0	0	0	0	19	24
Elecsys Result at Day 209 [1]						
Positive	0	0	0	0	0	0
Negative	0	0	0	0	0	0
Missing [2]	0	0	0	0	19 (100)	24 (100)

[1] Percentages are based on N1.
[2] Subjects with no Elecsys result include those who were tested but had no result and those who were not tested.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402010404.sas 24JUN2021 07:03

Table 14.2.1.5.4.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744) n (%)	mRNA-1273 (N=55) n (%)
Number of Subjects with Any Symptom [1]	744 (100)	55 (100)
Respiratory Symptom		
Clinical Evidence of Pneumonia	18 (2.4)	0
Cough	632 (84.9)	35 (63.6)
Difficulty Breathing	185 (24.9)	10 (18.2)
Radiographical Evidence of Pneumonia	16 (2.2)	0
Shortness of Breath	275 (37.0)	19 (34.5)
Systemic Symptom		
Body Aches	464 (62.4)	24 (43.6)
Chills	378 (50.8)	17 (30.9)
Diarrhea	282 (37.9)	16 (29.1)
Fatigue	620 (83.3)	39 (70.9)
Fever [2]	175 (23.5)	5 (9.1)
Headache	583 (78.4)	47 (85.5)
Muscle Aches (Myalgia)	409 (55.0)	23 (41.8)
Nasal Congestion	591 (79.4)	43 (78.2)
Nausea	272 (36.6)	15 (27.3)
New Loss of Smell	445 (59.8)	18 (32.7)
New Loss of Taste	416 (55.9)	14 (25.5)
Runny Nose (Rhinorrhea)	489 (65.7)	39 (70.9)
Sore Throat	386 (51.9)	34 (61.8)
Vomiting	79 (10.6)	3 (5.5)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140201050401.sas 10JUN2021 15:02

Table 14.2.1.5.4.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set - Subjects with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=744) n (%)	mRNA-1273 (N=55) n (%)
Number of Subjects with Any Severe Symptom [1]	112 (15.1)	3 (5.5)
Acute Renal Dysfunction	2 (0.3)	0
Acute Respiratory Distress Syndrome	2 (0.3)	0
ECMO	1 (0.1)	0
High-Flow Oxygen	6 (0.8)	1 (1.8)
Mechanical Ventilation	2 (0.3)	0
Non-Invasive Ventilation	2 (0.3)	0
Admission to An Intensive Care Unit due to SARS-CoV-2	4 (0.5)	0
Heart Rate >= 125 beats per minute	5 (0.7)	0
Hepatic Dysfunction	0	0
Neurologic Dysfunction	2 (0.3)	0
Oxygen Saturation <= 93% [3]	97 (13.0)	3 (5.5)
Oxygen Saturation of SpO2 <= 93% on Room Air at Sea Level	98 (13.2)	3 (5.5)
PaO2/FIO2 Ratio < 300 mmHg	1 (0.1)	0
Respiratory Failure	4 (0.5)	1 (1.8)
Respiratory Rate >= 30 per Minute	4 (0.5)	0
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	14 (1.9)	0
Vasopressors Required	0	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140201050401.sas 10JUN2021 15:02

Table 14.2.1.5.5.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set — Subjects with COVID-19* Starting 14 Days After Second Injection

	Placebo (N=751) n (%)	mRNA-1273 (N=55) n (%)
Number of Subjects with Any Symptom [1]	751 (100)	55 (100)
Respiratory Symptom		
Clinical Evidence of Pneumonia	19 (2.5)	0
Cough	640 (85.2)	35 (63.6)
Difficulty Breathing	186 (24.8)	10 (18.2)
Radiographical Evidence of Pneumonia	16 (2.1)	0
Shortness of Breath	277 (36.9)	19 (34.5)
Systemic Symptom		
Body Aches	468 (62.3)	24 (43.6)
Chills	383 (51.0)	17 (30.9)
Diarrhea	285 (37.9)	16 (29.1)
Fatigue	625 (83.2)	40 (72.7)
Fever [2]	175 (23.3)	5 (9.1)
Headache	587 (78.2)	48 (87.3)
Muscle Aches (Myalgia)	412 (54.9)	23 (41.8)
Nasal Congestion	595 (79.2)	44 (80.0)
Nausea	276 (36.8)	16 (29.1)
New Loss of Smell	447 (59.5)	18 (32.7)
New Loss of Taste	418 (55.7)	14 (25.5)
Runny Nose (Rhinorrhea)	492 (65.5)	39 (70.9)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140201050501.sas 21JUN2021 05:22

Table 14.2.1.5.5.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set — Subjects with COVID-19* Starting 14 Days After Second Injection

	Placebo (N=751) n (%)	mRNA-1273 (N=55) n (%)
Systemic Symptom (Cont.)		
Sore Throat	386 (51.4)	33 (60.0)
Vomiting	79 (10.5)	3 (5.5)
Number of Subjects with Any Severe Symptom [1]	114 (15.2)	3 (5.5)
Acute Renal Dysfunction	2 (0.3)	0
Acute Respiratory Distress Syndrome	2 (0.3)	0
ECMO	1 (0.1)	0
High-Flow Oxygen	7 (0.9)	1 (1.8)
Mechanical Ventilation	2 (0.3)	0
Non-Invasive Ventilation	2 (0.3)	0
Admission to An Intensive Care Unit due to SARS-CoV-2	4 (0.5)	0
Heart Rate >= 125 beats per minute	5 (0.7)	0
Hepatic Dysfunction	0	0
Neurologic Dysfunction	2 (0.3)	0
Oxygen Saturation <= 93% [3]	98 (13.0)	3 (5.5)
Oxygen Saturation of SpO2 <= 93% on Room Air at Sea Level	99 (13.2)	3 (5.5)
PaO2/FIO2 Ratio < 300 mmHg	1 (0.1)	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140201050501.sas 21JUN2021 05:22

Table 14.2.1.5.5.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set — Subjects with COVID-19* Starting 14 Days After Second Injection

	Placebo (N=751) n (%)	mRNA-1273 (N=55) n (%)
Respiratory Failure	5 (0.7)	1 (1.8)
Respiratory Rate >= 30 per Minute	4 (0.5)	0
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	14 (1.9)	0
Vasopressors Required	0	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140201050501.sas 21JUN2021 05:22

Table 14.2.1.5.6.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set — Subjects with Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=106) n (%)	mRNA-1273 (N=2) n (%)
Number of Subjects with Any Symptom [1]	106 (100)	2 (100)
Respiratory Symptom		
Clinical Evidence of Pneumonia	16 (15.1)	0
Cough	100 (94.3)	2 (100)
Difficulty Breathing	49 (46.2)	2 (100)
Radiographical Evidence of Pneumonia	14 (13.2)	0
Shortness of Breath	74 (69.8)	1 (50.0)
Systemic Symptom		
Body Aches	83 (78.3)	1 (50.0)
Chills	65 (61.3)	1 (50.0)
Diarrhea	55 (51.9)	2 (100)
Fatigue	96 (90.6)	1 (50.0)
Fever [2]	45 (42.5)	0
Headache	92 (86.8)	1 (50.0)
Muscle Aches (Myalgia)	76 (71.7)	1 (50.0)
Nasal Congestion	79 (74.5)	2 (100)
Nausea	49 (46.2)	2 (100)
New Loss of Smell	57 (53.8)	0
New Loss of Taste	58 (54.7)	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of severe COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
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Table 14.2.1.5.6.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set — Subjects with Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=106) n (%)	mRNA-1273 (N=2) n (%)
Systemic Symptom (Cont.)		
Runny Nose (Rhinorrhea)	72 (67.9)	2 (100)
Sore Throat	52 (49.1)	2 (100)
Vomiting	23 (21.7)	1 (50.0)
Number of Subjects with Any Severe Symptom [1]	103 (97.2)	2 (100)
Acute Renal Dysfunction	2 (1.9)	0
Acute Respiratory Distress Syndrome	2 (1.9)	0
ECMO	1 (0.9)	0
High-Flow Oxygen	6 (5.7)	1 (50.0)
Mechanical Ventilation	2 (1.9)	0
Non-Invasive Ventilation	2 (1.9)	0
Admission to An Intensive Care Unit due to SARS-CoV-2	5 (4.7)	0
Heart Rate >= 125 beats per minute	5 (4.7)	0
Hepatic Dysfunction	0	0
Neurologic Dysfunction	2 (1.9)	0
Oxygen Saturation <= 93% [3]	94 (88.7)	2 (100)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of severe COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
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Table 14.2.1.5.6.1
Summary of COVID-19 Symptoms and Severity Assessment
Per-Protocol Set — Subjects with Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

	Placebo (N=106) n (%)	mRNA-1273 (N=2) n (%)
Oxygen Saturation of SpO2 <= 93% on Room Air at Sea Level	94 (88.7)	2 (100)
PaO2/FIO2 Ratio < 300 mmHg	1 (0.9)	0
Respiratory Failure	5 (4.7)	1 (50.0)
Respiratory Rate >= 30 per Minute	3 (2.8)	0
Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg	9 (8.5)	0
Vasopressors Required	0	0

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
All symptoms reported are included, regardless of relationship with the positive RT-PCR test which is used to define the case of severe COVID-19.
[1] Subjects can be counted in more than one category.
[2] Derived based on temperature collected on case report form (CRF) symptom log page.
[3] Derived based on oxygen saturation collected on CRF symptom log page.
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Table 14.2.1.6.1
Summary of Test Results for Respiratory Pathogens Other than SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Pathogen Result	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Number of Subjects with Result for Any Respiratory Pathogens	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	250 (1.7)	253 (1.7)	3 (0.9)	8 (2.3)	253 (1.7)	261 (1.7)
Negative	1755 (11.9)	1123 (7.6)	25 (7.4)	23 (6.6)	1783 (11.8)	1151 (7.6)
Adenovirus	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	2 (<0.1)	1 (<0.1)	0	0	2 (<0.1)	1 (<0.1)
Negative	2003 (13.6)	1375 (9.3)	28 (8.3)	31 (8.9)	2034 (13.4)	1411 (9.3)
Bordetella pertussis	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	2 (<0.1)	0	0	0	2 (<0.1)
Negative	2005 (13.6)	1374 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1410 (9.3)
Chlamydophila pneumoniae	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)

Table 14.2.1.6.1
Summary of Test Results for Respiratory Pathogens Other than SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Pathogen Result	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Coronavirus 229E	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Coronavirus HKU1	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Negative	2004 (13.6)	1375 (9.3)	28 (8.3)	31 (8.9)	2035 (13.4)	1411 (9.3)
Coronavirus NL63	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	2 (<0.1)	3 (<0.1)	0	0	2 (<0.1)	3 (<0.1)
Negative	2003 (13.6)	1373 (9.3)	28 (8.3)	31 (8.9)	2034 (13.4)	1409 (9.3)
Coronavirus OC43	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	2 (<0.1)	0	0	0	2 (<0.1)
Negative	2005 (13.6)	1374 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1410 (9.3)

Table 14.2.1.6.1
Summary of Test Results for Respiratory Pathogens Other than SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Pathogen Result	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Human Rhinovirus/Enterovirus	2005 (13.6)	1375 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1411 (9.3)
Positive	245 (1.7)	243 (1.6)	3 (0.9)	8 (2.3)	248 (1.6)	251 (1.7)
Negative	1760 (11.9)	1132 (7.7)	25 (7.4)	23 (6.6)	1788 (11.8)	1160 (7.6)
Human metapneumovirus	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Influenza A	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Influenza A subtype H1	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)

Table 14.2.1.6.1
Summary of Test Results for Respiratory Pathogens Other than SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Pathogen Result	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Influenza A subtype H1/2009	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Influenza A subtype H3	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Influenza B	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Mycoplasma pneumoniae	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)

Table 14.2.1.6.1
Summary of Test Results for Respiratory Pathogens Other than SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Pathogen Result	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Parainfluenza Virus 1	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	1 (<0.1)	0	0	0	1 (<0.1)
Negative	2005 (13.6)	1375 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1411 (9.3)
Parainfluenza Virus 2	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Parainfluenza Virus 3	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Parainfluenza Virus 4	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)

Table 14.2.1.6.1
Summary of Test Results for Respiratory Pathogens Other than SARS-CoV-2
Full Analysis Set

	Baseline SARS-CoV-2 Negative		Baseline SARS-CoV-2 Positive		Overall	
Pathogen Result	Placebo (N=14745) n (%)	mRNA-1273 (N=14746) n (%)	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Placebo (N=15166) n (%)	mRNA-1273 (N=15180) n (%)
Respiratory Syncytial Virus	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)
Positive	0	0	0	0	0	0
Negative	2005 (13.6)	1376 (9.3)	28 (8.3)	31 (8.9)	2036 (13.4)	1412 (9.3)

Table 14.2.2.1.3.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	744 (5.3)	55 (0.4)
Number of Subjects Censored, n (%)	13420 (94.7)	14232 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.910, 0.948)
p-value [2]		<.0001
Person-Years [3]	5445.2	5729.9
Incidence Rate per 1,000 Person-Years (95% CI) [4]	136.633 (126.991, 146.814)	9.599 (7.231, 12.494)
Vaccine Efficacy Based on Incidence Rate (95% CI) [5]		0.930 (0.908, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] 1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE <= 0.3.

[3] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[4] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[5] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	751 (5.1)	58 (0.4)
Number of Subjects Censored, n (%)	13994 (94.9)	14688 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.928 (0.906, 0.945)
Person-Years [2]	5604.5	5863.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	133.999 (124.585, 143.935)	9.892 (7.511, 12.787)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.926 (0.904, 0.944)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.2.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	768 (5.4)	56 (0.4)
Number of Subjects Censored, n (%)	13396 (94.6)	14231 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.911, 0.948)
Person-Years [2]	5445.2	5729.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	141.041 (131.241, 151.379)	9.773 (7.383, 12.691)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.931 (0.909, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.2.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting After Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	775 (5.3)	59 (0.4)
Number of Subjects Censored, n (%)	13970 (94.7)	14687 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.929 (0.908, 0.946)
Person-Years [2]	5604.5	5863.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	138.281 (128.715, 148.369)	10.062 (7.660, 12.980)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.927 (0.905, 0.945)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.3.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After First Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	769 (5.4)	56 (0.4)
Number of Subjects Censored, n (%)	13395 (94.6)	14231 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.933 (0.911, 0.949)
Person-Years [2]	5445.2	5729.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	141.225 (131.418, 151.569)	9.773 (7.383, 12.691)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.931 (0.909, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.3.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After First Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	823 (5.6)	63 (0.4)
Number of Subjects Censored, n (%)	13922 (94.4)	14683 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.929 (0.908, 0.945)
Person-Years [2]	5604.5	5863.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	146.845 (136.983, 157.230)	10.744 (8.256, 13.747)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.927 (0.905, 0.944)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.3.3
Exploratory Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After First Injection
mITT Set — Subjects Only Received One Injection

	Placebo (N=425)	mRNA-1273 (N=334)
Number of Subjects with COVID-19*, n (%)	45 (10.6)	4 (1.2)
Number of Subjects Censored, n (%)	380 (89.4)	330 (98.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.893 (0.703, 0.962)
Person-Years [2]	95.5	80.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	471.128 (343.644, 630.407)	49.645 (13.527, 127.111)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.895 (0.711, 0.972)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.5.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	769 (5.4)	56 (0.4)
Number of Subjects Censored, n (%)	13395 (94.6)	14231 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.933 (0.911, 0.949)
Person-Years [2]	5445.2	5729.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	141.225 (131.418, 151.569)	9.773 (7.383, 12.691)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.931 (0.909, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.5.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	834 (5.7)	69 (0.5)
Number of Subjects Censored, n (%)	13911 (94.3)	14677 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.923 (0.901, 0.939)
Person-Years [2]	5604.5	5863.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	148.808 (138.879, 159.260)	11.768 (9.156, 14.893)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.921 (0.899, 0.939)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.5.3
Exploratory Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
mITT Set — Subjects Only Received One Injection

	Placebo (N=425)	mRNA-1273 (N=334)
Number of Subjects with COVID-19*, n (%)	56 (13.2)	10 (3.0)
Number of Subjects Censored, n (%)	369 (86.8)	324 (97.0)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.782 (0.573, 0.889)
Person-Years [2]	95.5	80.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	586.293 (442.879, 761.350)	124.112 (59.517, 228.247)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.788 (0.581, 0.904)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.1.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 Years)
Per-Protocol Set

Age Group: >=18 and <65 Years

	Placebo (N=10569)	mRNA-1273 (N=10661)
Number of Subjects with COVID-19*, n (%)	644 (6.1)	46 (0.4)
Number of Subjects Censored, n (%)	9925 (93.9)	10615 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.911, 0.951)
Person-Years [2]	4051.4	4282.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	158.958 (146.917, 171.723)	10.742 (7.864, 14.328)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.932 (0.909, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.1.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 Years)
Per-Protocol Set

Age Group: >=65 Years

	Placebo (N=3595)	mRNA-1273 (N=3626)
Number of Subjects with COVID-19*, n (%)	100 (2.8)	9 (0.2)
Number of Subjects Censored, n (%)	3495 (97.2)	3617 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.915 (0.832, 0.957)
Person-Years [2]	1393.8	1447.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	71.744 (58.374, 87.260)	6.217 (2.843, 11.802)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.913 (0.829, 0.961)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.1.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 Years)
mITT Set

Age Group: >=18 and <65 Years

	Placebo (N=11046)	mRNA-1273 (N=11037)
Number of Subjects with COVID-19*, n (%)	651 (5.9)	49 (0.4)
Number of Subjects Censored, n (%)	10395 (94.1)	10988 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.907, 0.948)
Person-Years [2]	4179.9	4388.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	155.746 (144.010, 168.183)	11.165 (8.260, 14.760)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.928 (0.904, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.1.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 Years)
mITT Set

Age Group: >=65 Years

	Placebo (N=3699)	mRNA-1273 (N=3709)
Number of Subjects with COVID-19*, n (%)	100 (2.7)	9 (0.2)
Number of Subjects Censored, n (%)	3599 (97.3)	3700 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.915 (0.832, 0.957)
Person-Years [2]	1424.6	1474.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	70.193 (57.112, 85.373)	6.103 (2.791, 11.586)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.913 (0.828, 0.961)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.2.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
Per-Protocol Set

Age Group: >=18 and <65 Years

	Placebo (N=10569)	mRNA-1273 (N=10661)
Number of Subjects with COVID-19*, n (%)	644 (6.1)	46 (0.4)
Number of Subjects Censored, n (%)	9925 (93.9)	10615 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.911, 0.951)
Person-Years [2]	4051.4	4282.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	158.958 (146.917, 171.723)	10.742 (7.864, 14.328)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.932 (0.909, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.2.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
Per-Protocol Set

Age Group: >=65 and <75 Years

	Placebo (N=2898)	mRNA-1273 (N=2990)
Number of Subjects with COVID-19*, n (%)	81 (2.8)	9 (0.3)
Number of Subjects Censored, n (%)	2817 (97.2)	2981 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.897 (0.796, 0.949)
Person-Years [2]	1125.3	1192.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	71.980 (57.163, 89.465)	7.546 (3.450, 14.324)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.895 (0.791, 0.954)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.2.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
Per-Protocol Set

Age Group: >=75 Years

	Placebo (N=697)	mRNA-1273 (N=636)
Number of Subjects with COVID-19*, n (%)	19 (2.7)	0
Number of Subjects Censored, n (%)	678 (97.3)	636 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	268.5	254.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	70.755 (42.599, 110.492)	0.000 (NE, 14.473)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.774, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.2.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
mITT Set

Age Group: >=18 and <65 Years

	Placebo (N=11046)	mRNA-1273 (N=11037)
Number of Subjects with COVID-19*, n (%)	651 (5.9)	49 (0.4)
Number of Subjects Censored, n (%)	10395 (94.1)	10988 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.907, 0.948)
Person-Years [2]	4179.9	4388.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	155.746 (144.010, 168.183)	11.165 (8.260, 14.760)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.928 (0.904, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.2.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
mITT Set

Age Group: >=65 and <75 Years

	Placebo (N=2974)	mRNA-1273 (N=3061)
Number of Subjects with COVID-19*, n (%)	81 (2.7)	9 (0.3)
Number of Subjects Censored, n (%)	2893 (97.3)	3052 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.897 (0.796, 0.948)
Person-Years [2]	1148.3	1216.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	70.538 (56.018, 87.673)	7.398 (3.383, 14.045)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.895 (0.791, 0.954)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.2.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
mITT Set

Age Group: >=75 Years

	Placebo (N=725)	mRNA-1273 (N=648)
Number of Subjects with COVID-19*, n (%)	19 (2.6)	0
Number of Subjects Censored, n (%)	706 (97.4)	648 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	276.3	258.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	68.757 (41.396, 107.373)	0.000 (NE, 14.290)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.771, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.3.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and Not at Risk

	Placebo (N=8428)	mRNA-1273 (N=8464)
Number of Subjects with COVID-19*, n (%)	501 (5.9)	35 (0.4)
Number of Subjects Censored, n (%)	7927 (94.1)	8429 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.935 (0.909, 0.954)
Person-Years [2]	3219.9	3391.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	155.593 (142.265, 169.833)	10.320 (7.188, 14.353)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.934 (0.907, 0.954)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.3.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and at Risk

	Placebo (N=2141)	mRNA-1273 (N=2197)
Number of Subjects with COVID-19*, n (%)	143 (6.7)	11 (0.5)
Number of Subjects Censored, n (%)	1998 (93.3)	2186 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.870, 0.962)
Person-Years [2]	831.4	891.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	171.991 (144.957, 202.603)	12.346 (6.163, 22.090)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.928 (0.868, 0.965)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.3.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=65 Years

	Placebo (N=3595)	mRNA-1273 (N=3626)
Number of Subjects with COVID-19*, n (%)	100 (2.8)	9 (0.2)
Number of Subjects Censored, n (%)	3495 (97.2)	3617 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.915 (0.832, 0.957)
Person-Years [2]	1393.8	1447.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	71.744 (58.374, 87.260)	6.217 (2.843, 11.802)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.913 (0.829, 0.961)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.3.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
mITT Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and Not at Risk

	Placebo (N=8810)	mRNA-1273 (N=8776)
Number of Subjects with COVID-19*, n (%)	505 (5.7)	37 (0.4)
Number of Subjects Censored, n (%)	8305 (94.3)	8739 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.905, 0.951)
Person-Years [2]	3322.3	3478.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	152.001 (139.031, 165.855)	10.637 (7.490, 14.662)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.902, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.3.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
mITT Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and at Risk

	Placebo (N=2236)	mRNA-1273 (N=2261)
Number of Subjects with COVID-19*, n (%)	146 (6.5)	12 (0.5)
Number of Subjects Censored, n (%)	2090 (93.5)	2249 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.924 (0.864, 0.958)
Person-Years [2]	857.5	910.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	170.254 (143.758, 200.218)	13.178 (6.809, 23.020)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.923 (0.861, 0.961)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.3.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
mITT Set

Age and Health Risk for Severe COVID-19: >=65 Years

	Placebo (N=3699)	mRNA-1273 (N=3709)
Number of Subjects with COVID-19*, n (%)	100 (2.7)	9 (0.2)
Number of Subjects Censored, n (%)	3599 (97.3)	3700 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.915 (0.832, 0.957)
Person-Years [2]	1424.6	1474.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	70.193 (57.112, 85.373)	6.103 (2.791, 11.586)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.913 (0.828, 0.961)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.4.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Sex
Per-Protocol Set

Sex: Male

	Placebo (N=7494)	mRNA-1273 (N=7439)
Number of Subjects with COVID-19*, n (%)	378 (5.0)	30 (0.4)
Number of Subjects Censored, n (%)	7116 (95.0)	7409 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.925 (0.891, 0.948)
Person-Years [2]	2871.1	2976.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	131.656 (118.716, 145.620)	10.081 (6.801, 14.391)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.923 (0.889, 0.949)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.4.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Sex
Per-Protocol Set

Sex: Female

	Placebo (N=6670)	mRNA-1273 (N=6848)
Number of Subjects with COVID-19*, n (%)	366 (5.5)	25 (0.4)
Number of Subjects Censored, n (%)	6304 (94.5)	6823 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.938 (0.907, 0.959)
Person-Years [2]	2574.1	2753.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	142.186 (127.990, 157.525)	9.078 (5.875, 13.401)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.936 (0.904, 0.959)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.4.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Sex
mITT Set

Sex: Male

	Placebo (N=7820)	mRNA-1273 (N=7678)
Number of Subjects with COVID-19*, n (%)	382 (4.9)	31 (0.4)
Number of Subjects Censored, n (%)	7438 (95.1)	7647 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.923 (0.889, 0.947)
Person-Years [2]	2956.5	3038.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	129.207 (116.573, 142.836)	10.202 (6.932, 14.481)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.921 (0.886, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.4.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Sex
mITT Set

Sex: Female

	Placebo (N=6925)	mRNA-1273 (N=7068)
Number of Subjects with COVID-19*, n (%)	369 (5.3)	27 (0.4)
Number of Subjects Censored, n (%)	6556 (94.7)	7041 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.902, 0.955)
Person-Years [2]	2648.0	2824.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	139.348 (125.491, 154.317)	9.558 (6.299, 13.906)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.931 (0.899, 0.955)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: White

	Placebo (N=11273)	mRNA-1273 (N=11391)
Number of Subjects with COVID-19*, n (%)	631 (5.6)	48 (0.4)
Number of Subjects Censored, n (%)	10642 (94.4)	11343 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.906, 0.947)
Person-Years [2]	4407.8	4640.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	143.155 (132.201, 154.773)	10.345 (7.627, 13.716)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.928 (0.903, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Black or African American

	Placebo (N=1352)	mRNA-1273 (N=1395)
Number of Subjects with COVID-19*, n (%)	41 (3.0)	4 (0.3)
Number of Subjects Censored, n (%)	1311 (97.0)	1391 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.911 (0.752, 0.968)
Person-Years [2]	497.3	532.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	82.452 (59.169, 111.856)	7.505 (2.045, 19.217)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.909 (0.749, 0.976)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Asian

	Placebo (N=700)	mRNA-1273 (N=628)
Number of Subjects with COVID-19*, n (%)	29 (4.1)	1 (0.2)
Number of Subjects Censored, n (%)	671 (95.9)	627 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.965 (0.742, 0.995)
Person-Years [2]	245.8	231.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	118.005 (79.030, 169.475)	4.312 (0.109, 24.023)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.963 (0.780, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: American Indian or Alaska Native

	Placebo (N=113)	mRNA-1273 (N=109)
Number of Subjects with COVID-19*, n (%)	5 (4.4)	0
Number of Subjects Censored, n (%)	108 (95.6)	109 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	40.9	41.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	122.198 (39.677, 285.170)	0.000 (NE, 87.965)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.065, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Native Hawaiian or Other Pacific Islander

	Placebo (N=31)	mRNA-1273 (N=36)
Number of Subjects with COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	31 (100)	36 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	11.6	14.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 317.027)	0.000 (NE, 262.849)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Multiple

	Placebo (N=304)	mRNA-1273 (N=300)
Number of Subjects with COVID-19*, n (%)	8 (2.6)	1 (0.3)
Number of Subjects Censored, n (%)	296 (97.4)	299 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.881 (0.046, 0.985)
Person-Years [2]	108.5	111.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	73.736 (31.834, 145.289)	8.960 (0.227, 49.923)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.878 (0.094, 0.997)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Other

	Placebo (N=274)	mRNA-1273 (N=282)
Number of Subjects with COVID-19*, n (%)	19 (6.9)	1 (0.4)
Number of Subjects Censored, n (%)	255 (93.1)	281 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.958 (0.686, 0.994)
Person-Years [2]	93.2	103.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	203.829 (122.718, 318.304)	9.677 (0.245, 53.914)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.953 (0.701, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Not Reported

	Placebo (N=65)	mRNA-1273 (N=90)
Number of Subjects with COVID-19*, n (%)	5 (7.7)	0
Number of Subjects Censored, n (%)	60 (92.3)	90 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	23.7	35.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	211.396 (68.640, 493.328)	0.000 (NE, 104.439)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.269, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Unknown

	Placebo (N=52)	mRNA-1273 (N=56)
Number of Subjects with COVID-19*, n (%)	6 (11.5)	0
Number of Subjects Censored, n (%)	46 (88.5)	56 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	16.5	18.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	364.097 (133.617, 792.486)	0.000 (NE, 196.266)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.255, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: White

	Placebo (N=11708)	mRNA-1273 (N=11738)
Number of Subjects with COVID-19*, n (%)	637 (5.4)	51 (0.4)
Number of Subjects Censored, n (%)	11071 (94.6)	11687 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.925 (0.901, 0.944)
Person-Years [2]	4532.3	4743.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	140.545 (129.841, 151.896)	10.751 (8.005, 14.135)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.924 (0.898, 0.944)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: Black or African American

	Placebo (N=1431)	mRNA-1273 (N=1463)
Number of Subjects with COVID-19*, n (%)	41 (2.9)	4 (0.3)
Number of Subjects Censored, n (%)	1390 (97.1)	1459 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.911 (0.751, 0.968)
Person-Years [2]	516.0	550.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	79.451 (57.015, 107.784)	7.273 (1.982, 18.621)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.908 (0.747, 0.976)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: Asian

	Placebo (N=730)	mRNA-1273 (N=645)
Number of Subjects with COVID-19*, n (%)	29 (4.0)	1 (0.2)
Number of Subjects Censored, n (%)	701 (96.0)	644 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.964 (0.739, 0.995)
Person-Years [2]	254.3	237.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	114.032 (76.369, 163.770)	4.216 (0.107, 23.492)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.963 (0.777, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: American Indian or Alaska Native

	Placebo (N=119)	mRNA-1273 (N=113)
Number of Subjects with COVID-19*, n (%)	5 (4.2)	0
Number of Subjects Censored, n (%)	114 (95.8)	113 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	42.8	43.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	116.955 (37.975, 272.934)	0.000 (NE, 84.474)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.068, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: Native Hawaiian or Other Pacific Islander

	Placebo (N=31)	mRNA-1273 (N=36)
Number of Subjects with COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	31 (100)	36 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	11.6	14.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 317.027)	0.000 (NE, 262.849)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: Multiple

	Placebo (N=316)	mRNA-1273 (N=310)
Number of Subjects with COVID-19*, n (%)	8 (2.5)	1 (0.3)
Number of Subjects Censored, n (%)	308 (97.5)	309 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.882 (0.055, 0.985)
Person-Years [2]	110.4	114.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	72.479 (31.291, 142.813)	8.731 (0.221, 48.646)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.880 (0.101, 0.997)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: Other

	Placebo (N=285)	mRNA-1273 (N=288)
Number of Subjects with COVID-19*, n (%)	20 (7.0)	1 (0.3)
Number of Subjects Censored, n (%)	265 (93.0)	287 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.960 (0.700, 0.995)
Person-Years [2]	95.4	104.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	209.721 (128.103, 323.897)	9.531 (0.241, 53.104)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.955 (0.716, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: Not Reported

	Placebo (N=70)	mRNA-1273 (N=92)
Number of Subjects with COVID-19*, n (%)	5 (7.1)	0
Number of Subjects Censored, n (%)	65 (92.9)	92 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	24.6	35.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	203.029 (65.923, 473.803)	0.000 (NE, 102.672)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.252, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.5.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
mITT Set

Race: Unknown

	Placebo (N=55)	mRNA-1273 (N=61)
Number of Subjects with COVID-19*, n (%)	6 (10.9)	0
Number of Subjects Censored, n (%)	49 (89.1)	61 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	17.1	19.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	351.258 (128.906, 764.541)	0.000 (NE, 190.252)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.252, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Hispanic or Latino

	Placebo (N=2787)	mRNA-1273 (N=2831)
Number of Subjects with COVID-19*, n (%)	177 (6.4)	10 (0.4)
Number of Subjects Censored, n (%)	2610 (93.6)	2821 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.948 (0.902, 0.973)
Person-Years [2]	1012.5	1086.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	174.817 (150.011, 202.554)	9.202 (4.413, 16.922)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.947 (0.901, 0.975)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Not Hispanic or Latino

	Placebo (N=11249)	mRNA-1273 (N=11322)
Number of Subjects with COVID-19*, n (%)	563 (5.0)	45 (0.4)
Number of Subjects Censored, n (%)	10686 (95.0)	11277 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.926 (0.900, 0.945)
Person-Years [2]	4384.2	4588.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	128.417 (118.027, 139.476)	9.807 (7.154, 13.123)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.924 (0.896, 0.945)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Not Reported

	Placebo (N=76)	mRNA-1273 (N=99)
Number of Subjects with COVID-19*, n (%)	2 (2.6)	0
Number of Subjects Censored, n (%)	74 (97.4)	99 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	30.0	41.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	66.725 (8.081, 241.032)	0.000 (NE, 88.718)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-2.838, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Unknown

	Placebo (N=52)	mRNA-1273 (N=35)
Number of Subjects with COVID-19*, n (%)	2 (3.8)	0
Number of Subjects Censored, n (%)	50 (96.2)	35 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	18.6	13.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	107.537 (13.023, 388.461)	0.000 (NE, 279.131)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-6.493, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
mITT Set

Ethnicity: Hispanic or Latino

	Placebo (N=2947)	mRNA-1273 (N=2957)
Number of Subjects with COVID-19*, n (%)	178 (6.0)	10 (0.3)
Number of Subjects Censored, n (%)	2769 (94.0)	2947 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.948 (0.902, 0.973)
Person-Years [2]	1052.9	1118.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	169.049 (145.126, 195.790)	8.941 (4.288, 16.443)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.947 (0.900, 0.975)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
mITT Set

Ethnicity: Not Hispanic or Latino

	Placebo (N=11665)	mRNA-1273 (N=11650)
Number of Subjects with COVID-19*, n (%)	569 (4.9)	48 (0.4)
Number of Subjects Censored, n (%)	11096 (95.1)	11602 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.921 (0.894, 0.941)
Person-Years [2]	4502.3	4689.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	126.379 (116.207, 137.203)	10.236 (7.547, 13.572)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.919 (0.891, 0.941)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
mITT Set

Ethnicity: Not Reported

	Placebo (N=80)	mRNA-1273 (N=102)
Number of Subjects with COVID-19*, n (%)	2 (2.5)	0
Number of Subjects Censored, n (%)	78 (97.5)	102 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	30.6	42.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	65.398 (7.920, 236.241)	0.000 (NE, 87.708)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-2.872, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.6.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
mITT Set

Ethnicity: Unknown

	Placebo (N=53)	mRNA-1273 (N=37)
Number of Subjects with COVID-19*, n (%)	2 (3.8)	0
Number of Subjects Censored, n (%)	51 (96.2)	37 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	18.7	13.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	107.080 (12.968, 386.810)	0.000 (NE, 269.311)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-6.260, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Yes

	Placebo (N=3212)	mRNA-1273 (N=3283)
Number of Subjects with COVID-19*, n (%)	177 (5.5)	16 (0.5)
Number of Subjects Censored, n (%)	3035 (94.5)	3267 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.917 (0.862, 0.950)
Person-Years [2]	1248.9	1328.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	141.721 (121.611, 164.207)	12.044 (6.884, 19.558)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.915 (0.858, 0.952)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: No

	Placebo (N=10952)	mRNA-1273 (N=11004)
Number of Subjects with COVID-19*, n (%)	567 (5.2)	39 (0.4)
Number of Subjects Censored, n (%)	10385 (94.8)	10965 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.936 (0.912, 0.954)
Person-Years [2]	4196.3	4401.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	135.119 (124.225, 146.713)	8.861 (6.301, 12.113)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.934 (0.909, 0.954)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: One Risk Factor

	Placebo (N=2610)	mRNA-1273 (N=2660)
Number of Subjects with COVID-19*, n (%)	143 (5.5)	14 (0.5)
Number of Subjects Censored, n (%)	2467 (94.5)	2646 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.911 (0.845, 0.948)
Person-Years [2]	1011.2	1077.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	141.420 (119.192, 166.591)	12.999 (7.107, 21.810)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.908 (0.841, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: At Least Two Risk Factors

	Placebo (N=602)	mRNA-1273 (N=623)
Number of Subjects with COVID-19*, n (%)	34 (5.6)	2 (0.3)
Number of Subjects Censored, n (%)	568 (94.4)	621 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.945 (0.771, 0.987)
Person-Years [2]	237.8	251.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	143.001 (99.032, 199.830)	7.953 (0.963, 28.728)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.944 (0.783, 0.994)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Chronic Lung Disease

	Placebo (N=692)	mRNA-1273 (N=675)
Number of Subjects with COVID-19*, n (%)	30 (4.3)	4 (0.6)
Number of Subjects Censored, n (%)	662 (95.7)	671 (99.4)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.872 (0.638, 0.955)
Person-Years [2]	274.8	277.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	109.173 (73.659, 155.852)	14.393 (3.922, 36.851)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.868 (0.626, 0.966)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Significant Cardiac Disease

	Placebo (N=696)	mRNA-1273 (N=726)
Number of Subjects with COVID-19*, n (%)	30 (4.3)	4 (0.6)
Number of Subjects Censored, n (%)	666 (95.7)	722 (99.4)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.880 (0.659, 0.958)
Person-Years [2]	272.7	292.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	110.007 (74.221, 157.042)	13.666 (3.723, 34.990)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.876 (0.647, 0.968)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Severe Obesity

	Placebo (N=980)	mRNA-1273 (N=1009)
Number of Subjects with COVID-19*, n (%)	75 (7.7)	7 (0.7)
Number of Subjects Censored, n (%)	905 (92.3)	1002 (99.3)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.914 (0.814, 0.960)
Person-Years [2]	380.8	411.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	196.938 (154.905, 246.864)	17.010 (6.839, 35.046)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.914 (0.813, 0.966)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Diabetes

	Placebo (N=1363)	mRNA-1273 (N=1402)
Number of Subjects with COVID-19*, n (%)	72 (5.3)	3 (0.2)
Number of Subjects Censored, n (%)	1291 (94.7)	1399 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.962 (0.879, 0.988)
Person-Years [2]	530.7	564.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	135.672 (106.155, 170.857)	5.313 (1.096, 15.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.961 (0.881, 0.992)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Liver Disease

	Placebo (N=90)	mRNA-1273 (N=100)
Number of Subjects with COVID-19*, n (%)	5 (5.6)	1 (1.0)
Number of Subjects Censored, n (%)	85 (94.4)	99 (99.0)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.810 (-0.648, 0.978)
Person-Years [2]	34.9	40.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	143.213 (46.501, 334.211)	24.677 (0.625, 137.494)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.828 (-0.540, 0.996)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Human Immunodeficiency Virus Infection

	Placebo (N=82)	mRNA-1273 (N=85)
Number of Subjects with COVID-19*, n (%)	4 (4.9)	0
Number of Subjects Censored, n (%)	78 (95.1)	85 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	27.5	30.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	145.445 (39.629, 372.398)	0.000 (NE, 121.428)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.371, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: Yes

	Placebo (N=3355)	mRNA-1273 (N=3375)
Number of Subjects with COVID-19*, n (%)	180 (5.4)	17 (0.5)
Number of Subjects Censored, n (%)	3175 (94.6)	3358 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.913 (0.856, 0.947)
Person-Years [2]	1289.2	1357.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	139.627 (119.973, 161.581)	12.524 (7.296, 20.052)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.910 (0.852, 0.949)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: No

	Placebo (N=11390)	mRNA-1273 (N=11371)
Number of Subjects with COVID-19*, n (%)	571 (5.0)	41 (0.4)
Number of Subjects Censored, n (%)	10819 (95.0)	11330 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.933 (0.908, 0.951)
Person-Years [2]	4315.4	4506.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	132.317 (121.685, 143.629)	9.099 (6.529, 12.344)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.931 (0.906, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: One Risk Factor

	Placebo (N=2728)	mRNA-1273 (N=2733)
Number of Subjects with COVID-19*, n (%)	146 (5.4)	15 (0.5)
Number of Subjects Censored, n (%)	2582 (94.6)	2718 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.906 (0.839, 0.945)
Person-Years [2]	1043.9	1100.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	139.862 (118.096, 164.477)	13.635 (7.631, 22.488)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.903 (0.834, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: At Least Two Risk Factors

	Placebo (N=627)	mRNA-1273 (N=642)
Number of Subjects with COVID-19*, n (%)	34 (5.4)	2 (0.3)
Number of Subjects Censored, n (%)	593 (94.6)	640 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.944 (0.769, 0.987)
Person-Years [2]	245.3	257.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	138.626 (96.002, 193.715)	7.775 (0.942, 28.084)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.944 (0.781, 0.993)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: Chronic Lung Disease

	Placebo (N=727)	mRNA-1273 (N=702)
Number of Subjects with COVID-19*, n (%)	32 (4.4)	4 (0.6)
Number of Subjects Censored, n (%)	695 (95.6)	698 (99.4)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.880 (0.660, 0.958)
Person-Years [2]	284.7	285.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	112.404 (76.884, 158.681)	14.009 (3.817, 35.869)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.875 (0.649, 0.968)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: Significant Cardiac Disease

	Placebo (N=722)	mRNA-1273 (N=745)
Number of Subjects with COVID-19*, n (%)	30 (4.2)	4 (0.5)
Number of Subjects Censored, n (%)	692 (95.8)	741 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.879 (0.657, 0.957)
Person-Years [2]	280.5	298.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	106.958 (72.164, 152.689)	13.390 (3.648, 34.284)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.875 (0.645, 0.968)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: Severe Obesity

	Placebo (N=1024)	mRNA-1273 (N=1041)
Number of Subjects with COVID-19*, n (%)	76 (7.4)	8 (0.8)
Number of Subjects Censored, n (%)	948 (92.6)	1033 (99.2)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.903 (0.799, 0.953)
Person-Years [2]	393.3	422.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	193.222 (152.237, 241.846)	18.959 (8.185, 37.357)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.902 (0.797, 0.959)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: Diabetes

	Placebo (N=1423)	mRNA-1273 (N=1431)
Number of Subjects with COVID-19*, n (%)	72 (5.1)	3 (0.2)
Number of Subjects Censored, n (%)	1351 (94.9)	1428 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.961 (0.877, 0.988)
Person-Years [2]	547.5	574.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	131.518 (102.905, 165.626)	5.223 (1.077, 15.263)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.960 (0.879, 0.992)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: Liver Disease

	Placebo (N=95)	mRNA-1273 (N=102)
Number of Subjects with COVID-19*, n (%)	5 (5.3)	1 (1.0)
Number of Subjects Censored, n (%)	90 (94.7)	101 (99.0)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.803 (-0.702, 0.977)
Person-Years [2]	36.6	40.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	136.583 (44.348, 318.739)	24.431 (0.619, 136.123)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.821 (-0.599, 0.996)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.7.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
mITT Set

Risk for Severe COVID-19 at Screening: Human Immunodeficiency Virus Infection

	Placebo (N=84)	mRNA-1273 (N=88)
Number of Subjects with COVID-19*, n (%)	4 (4.8)	0
Number of Subjects Censored, n (%)	80 (95.2)	88 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	28.1	31.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	142.107 (38.719, 363.850)	0.000 (NE, 118.304)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.367, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.8.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (Minority, Non-minority)
Per-Protocol Set

Race and Ethnicity Group: Minority

	Placebo (N=4156)	mRNA-1273 (N=4217)
Number of Subjects with COVID-19*, n (%)	220 (5.3)	14 (0.3)
Number of Subjects Censored, n (%)	3936 (94.7)	4203 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.941 (0.899, 0.966)
Person-Years [2]	1516.2	1616.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	145.104 (126.562, 165.598)	8.664 (4.736, 14.536)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.940 (0.898, 0.968)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.8.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (Minority, Non-minority)
Per-Protocol Set

Race and Ethnicity Group: Non-minority

	Placebo (N=9983)	mRNA-1273 (N=10045)
Number of Subjects with COVID-19*, n (%)	524 (5.2)	41 (0.4)
Number of Subjects Censored, n (%)	9459 (94.8)	10004 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.927 (0.900, 0.947)
Person-Years [2]	3920.1	4104.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	133.669 (122.468, 145.620)	9.990 (7.169, 13.553)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.925 (0.897, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.8.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (Minority, Non-minority)
Per-Protocol Set

Race and Ethnicity Group: Missing

	Placebo (N=25)	mRNA-1273 (N=25)
Number of Subjects with COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	25 (100)	25 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	8.9	9.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 412.542)	0.000 (NE, 373.748)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.8.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (Minority, Non-minority)
mITT Set

Race and Ethnicity Group: Minority

	Placebo (N=4388)	mRNA-1273 (N=4408)
Number of Subjects with COVID-19*, n (%)	221 (5.0)	14 (0.3)
Number of Subjects Censored, n (%)	4167 (95.0)	4394 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.941 (0.899, 0.966)
Person-Years [2]	1574.3	1665.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	140.378 (122.479, 160.156)	8.408 (4.597, 14.107)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.940 (0.897, 0.968)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.8.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (Minority, Non-minority)
mITT Set

Race and Ethnicity Group: Non-minority

	Placebo (N=10331)	mRNA-1273 (N=10312)
Number of Subjects with COVID-19*, n (%)	530 (5.1)	44 (0.4)
Number of Subjects Censored, n (%)	9801 (94.9)	10268 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.923 (0.895, 0.943)
Person-Years [2]	4021.2	4188.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	131.800 (120.817, 143.514)	10.505 (7.633, 14.102)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.920 (0.891, 0.943)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.8.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (Minority, Non-minority)
mITT Set

Race and Ethnicity Group: Missing

	Placebo (N=26)	mRNA-1273 (N=26)
Number of Subjects with COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	26 (100)	26 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	9.0	9.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 410.781)	0.000 (NE, 373.127)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Minority is defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.10.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
Per-Protocol Set

Race and Ethnicity Group: White

	Placebo (N=8998)	mRNA-1273 (N=9123)
Number of Subjects with COVID-19*, n (%)	488 (5.4)	39 (0.4)
Number of Subjects Censored, n (%)	8510 (94.6)	9084 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.926 (0.898, 0.947)
Person-Years [2]	3572.4	3761.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	136.603 (124.750, 149.278)	10.367 (7.372, 14.172)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.924 (0.895, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.10.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
Per-Protocol Set

Race and Ethnicity Group: Communities of Color

	Placebo (N=5141)	mRNA-1273 (N=5139)
Number of Subjects with COVID-19*, n (%)	256 (5.0)	16 (0.3)
Number of Subjects Censored, n (%)	4885 (95.0)	5123 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.942 (0.903, 0.965)
Person-Years [2]	1863.9	1958.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	137.348 (121.037, 155.244)	8.171 (4.670, 13.269)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.941 (0.902, 0.967)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.10.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
Per-Protocol Set

Race and Ethnicity Group: Missing

	Placebo (N=25)	mRNA-1273 (N=25)
Number of Subjects with COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	25 (100)	25 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	8.9	9.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 412.542)	0.000 (NE, 373.748)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.10.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
mITT Set

Race and Ethnicity Group: White

	Placebo (N=9303)	mRNA-1273 (N=9364)
Number of Subjects with COVID-19*, n (%)	494 (5.3)	42 (0.4)
Number of Subjects Censored, n (%)	8809 (94.7)	9322 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.921 (0.892, 0.942)
Person-Years [2]	3663.2	3838.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	134.854 (123.223, 147.287)	10.943 (7.887, 14.792)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.919 (0.889, 0.942)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.10.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
mITT Set

Race and Ethnicity Group: Communities of Color

	Placebo (N=5416)	mRNA-1273 (N=5356)
Number of Subjects with COVID-19*, n (%)	257 (4.7)	16 (0.3)
Number of Subjects Censored, n (%)	5159 (95.3)	5340 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.942 (0.903, 0.965)
Person-Years [2]	1932.3	2015.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	132.999 (117.234, 150.293)	7.938 (4.537, 12.891)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.940 (0.901, 0.966)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.10.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race and Ethnicity Group (White, Communities of Color)
mITT Set

Race and Ethnicity Group: Missing

	Placebo (N=26)	mRNA-1273 (N=26)
Number of Subjects with COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	26 (100)	26 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	9.0	9.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 410.781)	0.000 (NE, 373.127)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (>=18 and <65 Years and Not at Risk, >=18 and <65 Years and at Risk, >=65 Years and Not at Risk, >=65 Years and at Risk)

Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and Not at Risk

	Placebo (N=8428)	mRNA-1273 (N=8464)
Number of Subjects with COVID-19*, n (%)	501 (5.9)	35 (0.4)
Number of Subjects Censored, n (%)	7927 (94.1)	8429 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.935 (0.909, 0.954)
Person-Years [2]	3219.9	3391.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	155.593 (142.265, 169.833)	10.320 (7.188, 14.353)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.934 (0.907, 0.954)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (>=18 and <65 Years and Not at Risk, >=18 and <65 Years and at Risk, >=65 Years and Not at Risk, >=65 Years and at Risk)

Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and at Risk

	Placebo (N=2141)	mRNA-1273 (N=2197)
Number of Subjects with COVID-19*, n (%)	143 (6.7)	11 (0.5)
Number of Subjects Censored, n (%)	1998 (93.3)	2186 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.870, 0.962)
Person-Years [2]	831.4	891.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	171.991 (144.957, 202.603)	12.346 (6.163, 22.090)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.928 (0.868, 0.965)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (>=18 and <65 Years and Not at Risk, >=18 and <65 Years and at Risk, >=65 Years and Not at Risk, >=65 Years and at Risk)

Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=65 Years and Not at Risk

	Placebo (N=2524)	mRNA-1273 (N=2540)
Number of Subjects with COVID-19*, n (%)	66 (2.6)	4 (0.2)
Number of Subjects Censored, n (%)	2458 (97.4)	2536 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.943 (0.843, 0.979)
Person-Years [2]	976.4	1010.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	67.598 (52.281, 86.002)	3.960 (1.079, 10.140)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.941 (0.843, 0.984)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.11.1

Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19 (>=18 and <65 Years and Not at Risk, >=18 and <65 Years and at Risk, >=65 Years and Not at Risk, >=65 Years and at Risk)

Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=65 Years and at Risk

	Placebo (N=1071)	mRNA-1273 (N=1086)
Number of Subjects with COVID-19*, n (%)	34 (3.2)	5 (0.5)
Number of Subjects Censored, n (%)	1037 (96.8)	1081 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.864 (0.653, 0.947)
Person-Years [2]	417.5	437.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	81.439 (56.399, 113.802)	11.428 (3.711, 26.669)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.860 (0.639, 0.957)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.12.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Obesity
Per-Protocol Set

Obesity: Yes

	Placebo (N=5365)	mRNA-1273 (N=5460)
Number of Subjects with COVID-19*, n (%)	326 (6.1)	29 (0.5)
Number of Subjects Censored, n (%)	5039 (93.9)	5431 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.918 (0.881, 0.944)
Person-Years [2]	2083.2	2213.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	156.487 (139.959, 174.430)	13.102 (8.775, 18.817)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.916 (0.877, 0.945)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Obesity is defined as body mass index (BMI) >= 30 kg/m^2.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.12.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Obesity
Per-Protocol Set

Obesity: No

	Placebo (N=8719)	mRNA-1273 (N=8741)
Number of Subjects with COVID-19*, n (%)	415 (4.8)	26 (0.3)
Number of Subjects Censored, n (%)	8304 (95.2)	8715 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.942 (0.913, 0.961)
Person-Years [2]	3330.5	3482.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	124.605 (112.903, 137.190)	7.465 (4.877, 10.938)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.940 (0.911, 0.961)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Obesity is defined as body mass index (BMI) >= 30 kg/m^2.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.12.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Obesity
Per-Protocol Set

Obesity: Missing

	Placebo (N=80)	mRNA-1273 (N=86)
Number of Subjects with COVID-19*, n (%)	3 (3.8)	0
Number of Subjects Censored, n (%)	77 (96.3)	86 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	31.5	33.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	95.366 (19.667, 278.699)	0.000 (NE, 109.320)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-1.256, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Obesity is defined as body mass index (BMI) >= 30 kg/m^2.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Healthcare Workers

	Placebo (N=3621)	mRNA-1273 (N=3631)
Number of Subjects with COVID-19*, n (%)	209 (5.8)	13 (0.4)
Number of Subjects Censored, n (%)	3412 (94.2)	3618 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.944 (0.903, 0.968)
Person-Years [2]	1293.8	1376.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	161.537 (140.378, 184.985)	9.447 (5.030, 16.154)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.942 (0.898, 0.969)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Emergency Response

	Placebo (N=273)	mRNA-1273 (N=287)
Number of Subjects with COVID-19*, n (%)	25 (9.2)	2 (0.7)
Number of Subjects Censored, n (%)	248 (90.8)	285 (99.3)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.706, 0.984)
Person-Years [2]	100.0	114.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	249.986 (161.778, 369.029)	17.449 (2.113, 63.032)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.720, 0.992)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Retail or Restaurant Operations

	Placebo (N=875)	mRNA-1273 (N=870)
Number of Subjects with COVID-19*, n (%)	58 (6.6)	5 (0.6)
Number of Subjects Censored, n (%)	817 (93.4)	865 (99.4)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.920 (0.800, 0.968)
Person-Years [2]	350.0	365.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	165.693 (125.818, 214.196)	13.678 (4.441, 31.921)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.917 (0.796, 0.974)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Manufacturing and Production Operations

	Placebo (N=390)	mRNA-1273 (N=390)
Number of Subjects with COVID-19*, n (%)	21 (5.4)	2 (0.5)
Number of Subjects Censored, n (%)	369 (94.6)	388 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.909 (0.610, 0.979)
Person-Years [2]	159.9	166.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	131.360 (81.314, 200.798)	12.039 (1.458, 43.489)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.908 (0.625, 0.990)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Warehouse Shipping and Fulfillment Centers

	Placebo (N=158)	mRNA-1273 (N=174)
Number of Subjects with COVID-19*, n (%)	13 (8.2)	2 (1.1)
Number of Subjects Censored, n (%)	145 (91.8)	172 (98.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.861 (0.384, 0.969)
Person-Years [2]	63.4	72.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	204.949 (109.127, 350.468)	27.732 (3.359, 100.179)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.865 (0.402, 0.985)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Transportation and Delivery Services

	Placebo (N=428)	mRNA-1273 (N=428)
Number of Subjects with COVID-19*, n (%)	22 (5.1)	2 (0.5)
Number of Subjects Censored, n (%)	406 (94.9)	426 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.913 (0.628, 0.979)
Person-Years [2]	169.1	172.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	130.073 (81.516, 196.932)	11.613 (1.406, 41.952)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.911 (0.637, 0.990)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Border Protection and Military Personnel

	Placebo (N=66)	mRNA-1273 (N=64)
Number of Subjects with COVID-19*, n (%)	3 (4.5)	0
Number of Subjects Censored, n (%)	63 (95.5)	64 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	26.0	26.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	115.318 (23.781, 337.008)	0.000 (NE, 138.732)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-1.368, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Personal Care and In-Home Services

	Placebo (N=413)	mRNA-1273 (N=417)
Number of Subjects with COVID-19*, n (%)	29 (7.0)	2 (0.5)
Number of Subjects Censored, n (%)	384 (93.0)	415 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.935 (0.728, 0.985)
Person-Years [2]	163.4	171.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	177.463 (118.850, 254.867)	11.668 (1.413, 42.148)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.934 (0.740, 0.992)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Hospitality and Tourism Workers

	Placebo (N=200)	mRNA-1273 (N=214)
Number of Subjects with COVID-19*, n (%)	10 (5.0)	3 (1.4)
Number of Subjects Censored, n (%)	190 (95.0)	211 (98.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.741 (0.056, 0.929)
Person-Years [2]	80.4	87.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	124.315 (59.614, 228.620)	34.208 (7.055, 99.970)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.725 (-0.069, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Pastoral, Social or Public Health Workers

	Placebo (N=485)	mRNA-1273 (N=506)
Number of Subjects with COVID-19*, n (%)	36 (7.4)	1 (0.2)
Number of Subjects Censored, n (%)	449 (92.6)	505 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.822, 0.997)
Person-Years [2]	189.1	206.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	190.422 (133.369, 263.624)	4.851 (0.123, 27.027)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.975 (0.849, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Educators and Students

	Placebo (N=1478)	mRNA-1273 (N=1476)
Number of Subjects with COVID-19*, n (%)	77 (5.2)	7 (0.5)
Number of Subjects Censored, n (%)	1401 (94.8)	1469 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.913 (0.812, 0.960)
Person-Years [2]	574.7	596.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	133.977 (105.732, 167.448)	11.732 (4.717, 24.172)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.912 (0.811, 0.966)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: Other

	Placebo (N=4506)	mRNA-1273 (N=4586)
Number of Subjects with COVID-19*, n (%)	237 (5.3)	23 (0.5)
Number of Subjects Censored, n (%)	4269 (94.7)	4563 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.911 (0.863, 0.942)
Person-Years [2]	1752.4	1854.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	135.241 (118.570, 153.600)	12.399 (7.860, 18.605)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.908 (0.859, 0.943)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.13.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk
Per-Protocol Set

Occupational Risk: No Risk

	Placebo (N=2480)	mRNA-1273 (N=2541)
Number of Subjects with COVID-19*, n (%)	72 (2.9)	4 (0.2)
Number of Subjects Censored, n (%)	2408 (97.1)	2537 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.948 (0.858, 0.981)
Person-Years [2]	973.3	1025.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	73.973 (57.879, 93.157)	3.900 (1.063, 9.985)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.947 (0.859, 0.986)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.14.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk (Healthcare Workers, Other Essential Workers, No Risk)
Per-Protocol Set

Occupational Risk: Healthcare Workers

	Placebo (N=3621)	mRNA-1273 (N=3631)
Number of Subjects with COVID-19*, n (%)	209 (5.8)	13 (0.4)
Number of Subjects Censored, n (%)	3412 (94.2)	3618 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.944 (0.903, 0.968)
Person-Years [2]	1293.8	1376.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	161.537 (140.378, 184.985)	9.447 (5.030, 16.154)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.942 (0.898, 0.969)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.14.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk (Healthcare Workers, Other Essential Workers, No Risk)
Per-Protocol Set

Occupational Risk: Other Essential Workers

	Placebo (N=8063)	mRNA-1273 (N=8115)
Number of Subjects with COVID-19*, n (%)	463 (5.7)	38 (0.5)
Number of Subjects Censored, n (%)	7600 (94.3)	8077 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.923 (0.893, 0.945)
Person-Years [2]	3178.1	3328.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	145.685 (132.716, 159.580)	11.418 (8.080, 15.672)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.922 (0.891, 0.945)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.14.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Occupational Risk (Healthcare Workers, Other Essential Workers, No Risk)
Per-Protocol Set

Occupational Risk: No Risk

	Placebo (N=2480)	mRNA-1273 (N=2541)
Number of Subjects with COVID-19*, n (%)	72 (2.9)	4 (0.2)
Number of Subjects Censored, n (%)	2408 (97.1)	2537 (99.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.948 (0.858, 0.981)
Person-Years [2]	973.3	1025.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	73.973 (57.879, 93.157)	3.900 (1.063, 9.985)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.947 (0.859, 0.986)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=18 and <65 Years

	Placebo (N=10569)	mRNA-1273 (N=10661)
Number of Subjects with COVID-19*, n (%)	644 (6.1)	46 (0.4)
Number of Subjects Censored, n (%)	9925 (93.9)	10615 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.911, 0.951)
Person-Years [2]	4051.4	4282.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	158.958 (146.917, 171.723)	10.742 (7.864, 14.328)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.932 (0.909, 0.951)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=65 and <75 Years

	Placebo (N=2898)	mRNA-1273 (N=2990)
Number of Subjects with COVID-19*, n (%)	81 (2.8)	9 (0.3)
Number of Subjects Censored, n (%)	2817 (97.2)	2981 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.897 (0.796, 0.949)
Person-Years [2]	1125.3	1192.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	71.980 (57.163, 89.465)	7.546 (3.450, 14.324)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.895 (0.791, 0.954)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=75 and <85 Years

	Placebo (N=651)	mRNA-1273 (N=599)
Number of Subjects with COVID-19*, n (%)	15 (2.3)	0
Number of Subjects Censored, n (%)	636 (97.7)	599 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	251.0	240.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	59.767 (33.451, 98.576)	0.000 (NE, 15.355)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.709, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=85 Years

	Placebo (N=46)	mRNA-1273 (N=37)
Number of Subjects with COVID-19*, n (%)	4 (8.7)	0
Number of Subjects Censored, n (%)	42 (91.3)	37 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	17.6	14.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	227.818 (62.073, 583.306)	0.000 (NE, 251.891)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.816, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
mITT Set

Age Group: >=18 and <65 Years

	Placebo (N=11046)	mRNA-1273 (N=11037)
Number of Subjects with COVID-19*, n (%)	651 (5.9)	49 (0.4)
Number of Subjects Censored, n (%)	10395 (94.1)	10988 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.930 (0.907, 0.948)
Person-Years [2]	4179.9	4388.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	155.746 (144.010, 168.183)	11.165 (8.260, 14.760)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.928 (0.904, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
mITT Set

Age Group: >=65 and <75 Years

	Placebo (N=2974)	mRNA-1273 (N=3061)
Number of Subjects with COVID-19*, n (%)	81 (2.7)	9 (0.3)
Number of Subjects Censored, n (%)	2893 (97.3)	3052 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.897 (0.796, 0.948)
Person-Years [2]	1148.3	1216.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	70.538 (56.018, 87.673)	7.398 (3.383, 14.045)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.895 (0.791, 0.954)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
mITT Set

Age Group: >=75 and <85 Years

	Placebo (N=676)	mRNA-1273 (N=607)
Number of Subjects with COVID-19*, n (%)	15 (2.2)	0
Number of Subjects Censored, n (%)	661 (97.8)	607 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	258.1	242.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	58.119 (32.529, 95.859)	0.000 (NE, 15.208)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.703, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.6.15.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
mITT Set

Age Group: >=85 Years

	Placebo (N=49)	mRNA-1273 (N=41)
Number of Subjects with COVID-19*, n (%)	4 (8.2)	0
Number of Subjects Censored, n (%)	45 (91.8)	41 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	18.2	15.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	219.238 (59.735, 561.336)	0.000 (NE, 236.670)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.773, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.3.7.1
Kaplan-Meier Estimate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	769 (5.4)	56 (0.4)
Time to Onset (Days)		
Mean (SD)	101.6 (31.77)	102.4 (34.07)
Median	103.0	104.5
Min, Max	29, 203	30, 158
Number of Subjects Censored, n (%)	13395 (94.6)	14231 (99.6)
Cumulative Event Rate in % (95% CI) [1]		
14 Days After Randomization	0.000 (NE, NE)	0.000 (NE, NE)
28 Days After Randomization	0.014 (0.003, 0.051)	0.000 (NE, NE)
42 Days After Randomization	0.191 (0.129, 0.275)	0.014 (0.003, 0.051)
56 Days After Randomization	0.566 (0.452, 0.700)	0.042 (0.018, 0.090)
6 Months After Randomization	7.131 (6.583, 7.706)	0.508 (0.381, 0.668)
7 Months After Randomization	7.681 (6.792, 8.637)	0.508 (0.381, 0.668)
1 Year After Randomization	NE (NE, NE)	NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
6 months = 178 days (Month 6 visit), 7 months = 208 days (Month 7 visit), 1 year = 358 days (Month 12 visit).
[1] From the product-limit (Kaplan-Meier) method for censored data.
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Table 14.2.2.1.3.7.2
Kaplan-Meier Estimate of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	834 (5.7)	69 (0.5)
Time to Onset (Days)		
Mean (SD)	97.6 (35.80)	91.7 (43.68)
Median	99.5	98.0
Min, Max	7, 203	4, 158
Number of Subjects Censored, n (%)	13911 (94.3)	14677 (99.5)
Cumulative Event Rate in % (95% CI) [1]		
14 Days After Randomization	0.081 (0.045, 0.140)	0.041 (0.018, 0.087)
28 Days After Randomization	0.258 (0.186, 0.352)	0.054 (0.026, 0.105)
42 Days After Randomization	0.491 (0.388, 0.615)	0.075 (0.040, 0.132)
56 Days After Randomization	0.861 (0.721, 1.021)	0.102 (0.060, 0.166)
6 Months After Randomization	7.404 (6.860, 7.973)	0.599 (0.462, 0.766)
7 Months After Randomization	8.039 (7.158, 8.982)	0.599 (0.462, 0.766)
1 Year After Randomization	NE (NE, NE)	NE (NE, NE)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
6 months = 178 days (Month 6 visit), 7 months = 208 days (Month 7 visit), 1 year = 358 days (Month 12 visit).
[1] From the product-limit (Kaplan-Meier) method for censored data.
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Table 14.2.2.1.4.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	751 (5.3)	55 (0.4)
Number of Subjects Censored, n (%)	13413 (94.7)	14232 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.911, 0.949)
Person-Years [2]	5442.8	5729.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	137.982 (128.288, 148.213)	9.600 (7.232, 12.495)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.908, 0.948)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.4.3.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Starting 14 Days After First Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with COVID-19*, n (%)	782 (5.5)	58 (0.4)
Number of Subjects Censored, n (%)	13382 (94.5)	14229 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.931 (0.910, 0.947)
Person-Years [2]	5442.8	5729.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	143.677 (133.782, 154.110)	10.123 (7.687, 13.086)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.908, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.1.4.5.3
Exploratory Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Starting After Randomization
mITT Set — Subjects Only Received One Injection

	Placebo (N=425)	mRNA-1273 (N=334)
Number of Subjects with COVID-19*, n (%)	57 (13.4)	11 (3.3)
Number of Subjects Censored, n (%)	368 (86.6)	323 (96.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.766 (0.553, 0.878)
Person-Years [2]	95.2	80.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	598.908 (453.607, 775.955)	136.747 (68.263, 244.677)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.772 (0.560, 0.892)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	106 (0.7)	2 (<0.1)
Number of Subjects Censored, n (%)	14058 (99.3)	14285 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.982 (0.928, 0.996)
Person-Years [2]	5546.2	5737.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	19.112 (15.648, 23.116)	0.349 (0.042, 1.259)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.982 (0.932, 0.998)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Severe COVID-19*, n (%)	107 (0.7)	2 (<0.1)
Number of Subjects Censored, n (%)	14638 (99.3)	14744 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.982 (0.928, 0.996)
Person-Years [2]	5721.4	5874.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	18.702 (15.326, 22.599)	0.340 (0.041, 1.230)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.982 (0.933, 0.998)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	107 (0.8)	2 (<0.1)
Number of Subjects Censored, n (%)	14057 (99.2)	14285 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.982 (0.928, 0.996)
Person-Years [2]	5546.2	5737.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	19.293 (15.811, 23.313)	0.349 (0.042, 1.259)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.982 (0.933, 0.998)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.3
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments
Starting 14 Days After First Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	107 (0.8)	2 (<0.1)
Number of Subjects Censored, n (%)	14057 (99.2)	14285 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.982 (0.928, 0.996)
Person-Years [2]	5546.2	5737.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	19.293 (15.811, 23.313)	0.349 (0.042, 1.259)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.982 (0.933, 0.998)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.5.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	107 (0.8)	2 (<0.1)
Number of Subjects Censored, n (%)	14057 (99.2)	14285 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.982 (0.928, 0.996)
Person-Years [2]	5546.2	5737.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	19.293 (15.811, 23.313)	0.349 (0.042, 1.259)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.982 (0.933, 0.998)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.5.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Severe COVID-19*, n (%)	114 (0.8)	4 (<0.1)
Number of Subjects Censored, n (%)	14631 (99.2)	14742 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.966 (0.909, 0.988)
Person-Years [2]	5721.4	5874.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	19.925 (16.436, 23.936)	0.681 (0.186, 1.743)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.966 (0.910, 0.991)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 Years)
Per-Protocol Set

Age Group: >=18 and <65 Years

	Placebo (N=10569)	mRNA-1273 (N=10661)
Number of Subjects with Severe COVID-19*, n (%)	76 (0.7)	1 (<0.1)
Number of Subjects Censored, n (%)	10493 (99.3)	10660 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.987 (0.910, 0.998)
Person-Years [2]	4141.5	4288.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	18.351 (14.458, 22.969)	0.233 (0.006, 1.299)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.987 (0.927, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.1
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 Years)
Per-Protocol Set

Age Group: >=65 Years

	Placebo (N=3595)	mRNA-1273 (N=3626)
Number of Subjects with Severe COVID-19*, n (%)	30 (0.8)	1 (<0.1)
Number of Subjects Censored, n (%)	3565 (99.2)	3625 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.969 (0.771, 0.996)
Person-Years [2]	1404.6	1449.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.358 (14.410, 30.489)	0.690 (0.017, 3.845)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.968 (0.806, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
Per-Protocol Set

Age Group: >=18 and <65 Years

	Placebo (N=10569)	mRNA-1273 (N=10661)
Number of Subjects with Severe COVID-19*, n (%)	76 (0.7)	1 (<0.1)
Number of Subjects Censored, n (%)	10493 (99.3)	10660 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.987 (0.910, 0.998)
Person-Years [2]	4141.5	4288.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	18.351 (14.458, 22.969)	0.233 (0.006, 1.299)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.987 (0.927, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
Per-Protocol Set

Age Group: >=65 and <75 Years

	Placebo (N=2898)	mRNA-1273 (N=2990)
Number of Subjects with Severe COVID-19*, n (%)	23 (0.8)	1 (<0.1)
Number of Subjects Censored, n (%)	2875 (99.2)	2989 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.960 (0.705, 0.995)
Person-Years [2]	1134.0	1194.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	20.282 (12.857, 30.433)	0.837 (0.021, 4.666)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.959 (0.746, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.2
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 Years)
Per-Protocol Set

Age Group: >=75 Years

	Placebo (N=697)	mRNA-1273 (N=636)
Number of Subjects with Severe COVID-19*, n (%)	7 (1.0)	0
Number of Subjects Censored, n (%)	690 (99.0)	636 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	270.6	254.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	25.865 (10.399, 53.293)	0.000 (NE, 14.473)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.263, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.3
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and Not at Risk

	Placebo (N=8428)	mRNA-1273 (N=8464)
Number of Subjects with Severe COVID-19*, n (%)	46 (0.5)	1 (<0.1)
Number of Subjects Censored, n (%)	8382 (99.5)	8463 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.979 (0.849, 0.997)
Person-Years [2]	3292.2	3396.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	13.973 (10.230, 18.638)	0.294 (0.007, 1.640)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.979 (0.877, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.3
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=18 and <65 Years and at Risk

	Placebo (N=2141)	mRNA-1273 (N=2197)
Number of Subjects with Severe COVID-19*, n (%)	30 (1.4)	0
Number of Subjects Censored, n (%)	2111 (98.6)	2197 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	849.4	892.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	35.320 (23.830, 50.421)	0.000 (NE, 4.134)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.875, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.3
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age and Health Risk for Severe COVID-19
Per-Protocol Set

Age and Health Risk for Severe COVID-19: >=65 Years

	Placebo (N=3595)	mRNA-1273 (N=3626)
Number of Subjects with Severe COVID-19*, n (%)	30 (0.8)	1 (<0.1)
Number of Subjects Censored, n (%)	3565 (99.2)	3625 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.969 (0.771, 0.996)
Person-Years [2]	1404.6	1449.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.358 (14.410, 30.489)	0.690 (0.017, 3.845)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.968 (0.806, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.4
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Sex
Per-Protocol Set

Sex: Male

	Placebo (N=7494)	mRNA-1273 (N=7439)
Number of Subjects with Severe COVID-19*, n (%)	50 (0.7)	1 (<0.1)
Number of Subjects Censored, n (%)	7444 (99.3)	7438 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.981 (0.860, 0.997)
Person-Years [2]	2922.4	2980.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	17.109 (12.699, 22.557)	0.336 (0.008, 1.869)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.980 (0.886, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.4
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Sex
Per-Protocol Set

Sex: Female

	Placebo (N=6670)	mRNA-1273 (N=6848)
Number of Subjects with Severe COVID-19*, n (%)	56 (0.8)	1 (<0.1)
Number of Subjects Censored, n (%)	6614 (99.2)	6847 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.983 (0.880, 0.998)
Person-Years [2]	2623.8	2757.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.343 (16.122, 27.716)	0.363 (0.009, 2.021)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.983 (0.901, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: White

	Placebo (N=11273)	mRNA-1273 (N=11391)
Number of Subjects with Severe COVID-19*, n (%)	86 (0.8)	2 (<0.1)
Number of Subjects Censored, n (%)	11187 (99.2)	11389 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.978 (0.911, 0.995)
Person-Years [2]	4495.0	4647.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	19.132 (15.303, 23.628)	0.430 (0.052, 1.555)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.978 (0.916, 0.997)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Black or African American

	Placebo (N=1352)	mRNA-1273 (N=1395)
Number of Subjects with Severe COVID-19*, n (%)	6 (0.4)	0
Number of Subjects Censored, n (%)	1346 (99.6)	1395 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	503.4	533.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	11.919 (4.374, 25.943)	0.000 (NE, 6.917)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.198, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Asian

	Placebo (N=700)	mRNA-1273 (N=628)
Number of Subjects with Severe COVID-19*, n (%)	4 (0.6)	0
Number of Subjects Censored, n (%)	696 (99.4)	628 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	249.0	232.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	16.064 (4.377, 41.130)	0.000 (NE, 15.903)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.626, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: American Indian or Alaska Native

	Placebo (N=113)	mRNA-1273 (N=109)
Number of Subjects with Severe COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	113 (100)	109 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	41.6	41.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 88.695)	0.000 (NE, 87.965)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Native Hawaiian or Other Pacific Islander

	Placebo (N=31)	mRNA-1273 (N=36)
Number of Subjects with Severe COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	31 (100)	36 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	11.6	14.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 317.027)	0.000 (NE, 262.849)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Multiple

	Placebo (N=304)	mRNA-1273 (N=300)
Number of Subjects with Severe COVID-19*, n (%)	3 (1.0)	0
Number of Subjects Censored, n (%)	301 (99.0)	300 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	109.1	111.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	27.494 (5.670, 80.349)	0.000 (NE, 33.033)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-1.364, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Other

	Placebo (N=274)	mRNA-1273 (N=282)
Number of Subjects with Severe COVID-19*, n (%)	4 (1.5)	0
Number of Subjects Censored, n (%)	270 (98.5)	282 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	95.3	103.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	41.955 (11.431, 107.422)	0.000 (NE, 35.671)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-0.397, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Not Reported

	Placebo (N=65)	mRNA-1273 (N=90)
Number of Subjects with Severe COVID-19*, n (%)	2 (3.1)	0
Number of Subjects Censored, n (%)	63 (96.9)	90 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	24.1	35.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	82.945 (10.045, 299.627)	0.000 (NE, 104.439)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-2.635, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.5
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Race
Per-Protocol Set

Race: Unknown

	Placebo (N=52)	mRNA-1273 (N=56)
Number of Subjects with Severe COVID-19*, n (%)	1 (1.9)	0
Number of Subjects Censored, n (%)	51 (98.1)	56 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	17.0	18.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	58.883 (1.491, 328.074)	0.000 (NE, 196.266)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-34.239, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.6
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Hispanic or Latino

	Placebo (N=2787)	mRNA-1273 (N=2831)
Number of Subjects with Severe COVID-19*, n (%)	21 (0.8)	1 (<0.1)
Number of Subjects Censored, n (%)	2766 (99.2)	2830 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.955 (0.664, 0.994)
Person-Years [2]	1035.8	1088.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	20.274 (12.550, 30.991)	0.919 (0.023, 5.121)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.955 (0.718, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.6
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Not Hispanic or Latino

	Placebo (N=11249)	mRNA-1273 (N=11322)
Number of Subjects with Severe COVID-19*, n (%)	84 (0.7)	1 (<0.1)
Number of Subjects Censored, n (%)	11165 (99.3)	11321 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.989 (0.919, 0.998)
Person-Years [2]	4461.3	4595.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	18.829 (15.018, 23.311)	0.218 (0.006, 1.213)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.988 (0.934, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.6
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Not Reported

	Placebo (N=76)	mRNA-1273 (N=99)
Number of Subjects with Severe COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	76 (100)	99 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	30.2	41.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 122.088)	0.000 (NE, 88.718)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.6
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Ethnicity
Per-Protocol Set

Ethnicity: Unknown

	Placebo (N=52)	mRNA-1273 (N=35)
Number of Subjects with Severe COVID-19*, n (%)	1 (1.9)	0
Number of Subjects Censored, n (%)	51 (98.1)	35 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	18.8	13.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	53.066 (1.344, 295.662)	0.000 (NE, 279.131)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-54.612, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Yes

	Placebo (N=3212)	mRNA-1273 (N=3283)
Number of Subjects with Severe COVID-19*, n (%)	44 (1.4)	1 (<0.1)
Number of Subjects Censored, n (%)	3168 (98.6)	3282 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.979 (0.846, 0.997)
Person-Years [2]	1270.3	1330.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	34.638 (25.168, 46.500)	0.752 (0.019, 4.187)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.978 (0.873, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: No

	Placebo (N=10952)	mRNA-1273 (N=11004)
Number of Subjects with Severe COVID-19*, n (%)	62 (0.6)	1 (<0.1)
Number of Subjects Censored, n (%)	10890 (99.4)	11003 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.985 (0.889, 0.998)
Person-Years [2]	4275.9	4407.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	14.500 (11.117, 18.588)	0.227 (0.006, 1.264)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.984 (0.910, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: One Risk Factor

	Placebo (N=2610)	mRNA-1273 (N=2660)
Number of Subjects with Severe COVID-19*, n (%)	32 (1.2)	1 (<0.1)
Number of Subjects Censored, n (%)	2578 (98.8)	2659 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.971 (0.788, 0.996)
Person-Years [2]	1029.2	1078.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	31.091 (21.266, 43.891)	0.927 (0.023, 5.164)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.970 (0.822, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: At Least Two Risk Factors

	Placebo (N=602)	mRNA-1273 (N=623)
Number of Subjects with Severe COVID-19*, n (%)	12 (2.0)	0
Number of Subjects Censored, n (%)	590 (98.0)	623 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	241.0	251.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	49.785 (25.725, 86.964)	0.000 (NE, 14.651)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.655, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Chronic Lung Disease

	Placebo (N=692)	mRNA-1273 (N=675)
Number of Subjects with Severe COVID-19*, n (%)	9 (1.3)	1 (0.1)
Number of Subjects Censored, n (%)	683 (98.7)	674 (99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.896 (0.175, 0.987)
Person-Years [2]	278.6	278.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	32.304 (14.772, 61.324)	3.592 (0.091, 20.013)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.889 (0.198, 0.997)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 − ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Significant Cardiac Disease

	Placebo (N=696)	mRNA-1273 (N=726)
Number of Subjects with Severe COVID-19*, n (%)	9 (1.3)	0
Number of Subjects Censored, n (%)	687 (98.7)	726 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	275.6	293.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	32.651 (14.930, 61.981)	0.000 (NE, 12.581)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.524, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Severe Obesity

	Placebo (N=980)	mRNA-1273 (N=1009)
Number of Subjects with Severe COVID-19*, n (%)	15 (1.5)	0
Number of Subjects Censored, n (%)	965 (98.5)	1009 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	390.6	412.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	38.401 (21.493, 63.337)	0.000 (NE, 8.942)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.736, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Diabetes

	Placebo (N=1363)	mRNA-1273 (N=1402)
Number of Subjects with Severe COVID-19*, n (%)	22 (1.6)	0
Number of Subjects Censored, n (%)	1341 (98.4)	1402 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	537.9	565.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	40.897 (25.630, 61.919)	0.000 (NE, 6.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.826, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Liver Disease

	Placebo (N=90)	mRNA-1273 (N=100)
Number of Subjects with Severe COVID-19*, n (%)	1 (1.1)	0
Number of Subjects Censored, n (%)	89 (98.9)	100 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	35.6	40.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	28.075 (0.711, 156.421)	0.000 (NE, 90.977)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-33.260, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.7
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Risk for Severe COVID-19 at Screening
Per-Protocol Set

Risk for Severe COVID-19 at Screening: Human Immunodeficiency Virus Infection

	Placebo (N=82)	mRNA-1273 (N=85)
Number of Subjects with Severe COVID-19*, n (%)	1 (1.2)	0
Number of Subjects Censored, n (%)	81 (98.8)	85 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	28.0	30.4
Incidence Rate per 1,000 Person-Years (95% CI) [3]	35.652 (0.903, 198.638)	0.000 (NE, 121.428)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-35.009, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.8
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=18 and <65 Years

	Placebo (N=10569)	mRNA-1273 (N=10661)
Number of Subjects with Severe COVID-19*, n (%)	76 (0.7)	1 (<0.1)
Number of Subjects Censored, n (%)	10493 (99.3)	10660 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.987 (0.910, 0.998)
Person-Years [2]	4141.5	4288.9
Incidence Rate per 1,000 Person-Years (95% CI) [3]	18.351 (14.458, 22.969)	0.233 (0.006, 1.299)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.987 (0.927, 1.000)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.8
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=65 and <75 Years

	Placebo (N=2898)	mRNA-1273 (N=2990)
Number of Subjects with Severe COVID-19*, n (%)	23 (0.8)	1 (<0.1)
Number of Subjects Censored, n (%)	2875 (99.2)	2989 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.960 (0.705, 0.995)
Person-Years [2]	1134.0	1194.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	20.282 (12.857, 30.433)	0.837 (0.021, 4.666)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.959 (0.746, 0.999)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.8
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=75 and <85 Years

	Placebo (N=651)	mRNA-1273 (N=599)
Number of Subjects with Severe COVID-19*, n (%)	6 (0.9)	0
Number of Subjects Censored, n (%)	645 (99.1)	599 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	252.7	240.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	23.741 (8.713, 51.675)	0.000 (NE, 15.355)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (0.107, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.6.8
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection by Age Group (>=18 and <65 Years, >=65 and <75 Years, >=75 and <85 Years, >=85 Years)
Per-Protocol Set

Age Group: >=85 Years

	Placebo (N=46)	mRNA-1273 (N=37)
Number of Subjects with Severe COVID-19*, n (%)	1 (2.2)	0
Number of Subjects Censored, n (%)	45 (97.8)	37 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	17.9	14.6
Incidence Rate per 1,000 Person-Years (95% CI) [3]	55.849 (1.414, 311.169)	0.000 (NE, 251.891)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-46.684, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.3.7.1
Kaplan-Meier Estimate of Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	107 (0.8)	2 (<0.1)
Time to Onset (Days)		
Mean (SD)	104.7 (31.62)	98.5 (12.02)
Median	105.0	98.5
Min, Max	41, 176	90, 107
Number of Subjects Censored, n (%)	14057 (99.2)	14285(>99.9)
Cumulative Event Rate in % (95% CI) [1]		
14 Days After Randomization	0.000 (NE, NE)	0.000 (NE, NE)
28 Days After Randomization	0.000 (NE, NE)	0.000 (NE, NE)
42 Days After Randomization	0.007 (<0.001, 0.042)	0.000 (NE, NE)
56 Days After Randomization	0.050 (0.023, 0.100)	0.000 (NE, NE)
6 Months After Randomization	1.130 (0.876, 1.438)	0.015 (0.003, 0.053)
7 Months After Randomization	1.130 (0.876, 1.438)	0.015 (0.003, 0.053)
1 Year After Randomization	NE (NE, NE)	NE (NE, NE)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
6 months = 178 days (Month 6 visit), 7 months = 208 days (Month 7 visit), 1 year = 358 days (Month 12 visit).
[1] From the product-limit (Kaplan-Meier) method for censored data.
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Table 14.2.2.2.3.7.2
Kaplan-Meier Estimate of Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Severe COVID-19*, n (%)	114 (0.8)	4 (<0.1)
Time to Onset (Days)		
Mean (SD)	101.2 (34.36)	86.8 (45.11)
Median	102.0	98.5
Min, Max	21, 176	23, 127
Number of Subjects Censored, n (%)	14631 (99.2)	14742(>99.9)
Cumulative Event Rate in % (95% CI) [1]		
14 Days After Randomization	0.000 (NE, NE)	0.000 (NE, NE)
28 Days After Randomization	0.014 (0.003, 0.049)	0.007 (<0.001, 0.040)
42 Days After Randomization	0.041 (0.018, 0.088)	0.007 (<0.001, 0.040)
56 Days After Randomization	0.082 (0.046, 0.141)	0.007 (<0.001, 0.040)
6 Months After Randomization	1.145 (0.897, 1.444)	0.030 (0.010, 0.075)
7 Months After Randomization	1.145 (0.897, 1.444)	0.030 (0.010, 0.075)
1 Year After Randomization	NE (NE, NE)	NE (NE, NE)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
6 months = 178 days (Month 6 visit), 7 months = 208 days (Month 7 visit), 1 year = 358 days (Month 12 visit).
[1] From the product-limit (Kaplan-Meier) method for censored data.
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Table 14.2.2.2.4.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	118 (0.8)	3 (<0.1)
Number of Subjects Censored, n (%)	14046 (99.2)	14284 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.924, 0.992)
Person-Years [2]	5543.3	5737.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.287 (17.620, 25.492)	0.523 (0.108, 1.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.975 (0.926, 0.995)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting 14 Days After Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Severe COVID-19*, n (%)	119 (0.8)	3 (<0.1)
Number of Subjects Censored, n (%)	14626 (99.2)	14743 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.924, 0.992)
Person-Years [2]	5718.6	5874.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	20.809 (17.239, 24.901)	0.511 (0.105, 1.492)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.975 (0.927, 0.995)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.2.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	120 (0.8)	3 (<0.1)
Number of Subjects Censored, n (%)	14044 (99.2)	14284 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.925, 0.992)
Person-Years [2]	5543.3	5737.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.648 (17.948, 25.885)	0.523 (0.108, 1.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.976 (0.928, 0.995)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.2.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting After Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Severe COVID-19*, n (%)	121 (0.8)	3 (<0.1)
Number of Subjects Censored, n (%)	14624 (99.2)	14743 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.925, 0.992)
Person-Years [2]	5718.6	5874.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.159 (17.557, 25.282)	0.511 (0.105, 1.492)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.976 (0.928, 0.995)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.3.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting 14 Days After First Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	120 (0.8)	3 (<0.1)
Number of Subjects Censored, n (%)	14044 (99.2)	14284 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.925, 0.992)
Person-Years [2]	5543.3	5737.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.648 (17.948, 25.885)	0.523 (0.108, 1.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.976 (0.928, 0.995)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.3.2
Exploratory Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting 14 Days After First Injection
mITT Set — Subjects Only Received One Injection

	Placebo (N=425)	mRNA-1273 (N=334)
Number of Subjects with Severe COVID-19*, n (%)	6 (1.4)	1 (0.3)
Number of Subjects Censored, n (%)	419 (98.6)	333 (99.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.746 (-1.134, 0.970)
Person-Years [2]	110.3	83.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	54.413 (19.969, 118.435)	12.022 (0.304, 66.980)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.779 (-0.821, 0.995)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.5.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	120 (0.8)	3 (<0.1)
Number of Subjects Censored, n (%)	14044 (99.2)	14284 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.976 (0.925, 0.992)
Person-Years [2]	5543.3	5737.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	21.648 (17.948, 25.885)	0.523 (0.108, 1.528)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.976 (0.928, 0.995)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.5.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Severe COVID-19*, n (%)	127 (0.9)	5 (<0.1)
Number of Subjects Censored, n (%)	14618 (99.1)	14741 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.962 (0.908, 0.985)
Person-Years [2]	5718.6	5874.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	22.208 (18.514, 26.423)	0.851 (0.276, 1.986)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.962 (0.908, 0.988)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.5.3
Exploratory Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Starting After Randomization
mITT Set — Subjects Only Received One Injection

	Placebo (N=425)	mRNA-1273 (N=334)
Number of Subjects with Severe COVID-19*, n (%)	6 (1.4)	2 (0.6)
Number of Subjects Censored, n (%)	419 (98.6)	332 (99.4)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.506 (-1.477, 0.901)
Person-Years [2]	110.3	83.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	54.413 (19.969, 118.435)	24.043 (2.912, 86.852)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.558 (-1.471, 0.956)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of severe COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.2.4.7.1
Kaplan-Meier Estimate of Severe COVID-19* Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Severe COVID-19*, n (%)	120 (0.8)	3 (<0.1)
Time to Onset (Days)		
Mean (SD)	103.7 (32.04)	106.3 (17.01)
Median	104.0	107.0
Min, Max	39, 176	89, 123
Number of Subjects Censored, n (%)	14044 (99.2)	14284(>99.9)
Cumulative Event Rate in % (95% CI) [1]		
14 Days After Randomization	0.000 (NE, NE)	0.000 (NE, NE)
28 Days After Randomization	0.000 (NE, NE)	0.000 (NE, NE)
42 Days After Randomization	0.014 (0.003, 0.051)	0.000 (NE, NE)
56 Days After Randomization	0.071 (0.037, 0.128)	0.000 (NE, NE)
6 Months After Randomization	1.251 (0.987, 1.566)	0.023 (0.007, 0.067)
7 Months After Randomization	1.251 (0.987, 1.566)	0.023 (0.007, 0.067)
1 Year After Randomization	NE (NE, NE)	NE (NE, NE)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
6 months = 178 days (Month 6 visit), 7 months = 208 days (Month 7 visit), 1 year = 358 days (Month 12 visit).
[1] From the product-limit (Kaplan-Meier) method for censored data.
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Table 14.2.2.2.4.7.2
Kaplan-Meier Estimate of Severe COVID-19* Starting After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Severe COVID-19*, n (%)	127 (0.9)	5 (<0.1)
Time to Onset (Days)		
Mean (SD)	101.3 (33.88)	91.8 (46.53)
Median	102.0	107.0
Min, Max	21, 176	13, 127
Number of Subjects Censored, n (%)	14618 (99.1)	14741(>99.9)
Cumulative Event Rate in % (95% CI) [1]		
14 Days After Randomization	0.000 (NE, NE)	0.007 (<0.001, 0.040)
28 Days After Randomization	0.014 (0.003, 0.049)	0.007 (<0.001, 0.040)
42 Days After Randomization	0.041 (0.018, 0.088)	0.007 (<0.001, 0.040)
56 Days After Randomization	0.096 (0.056, 0.159)	0.007 (<0.001, 0.040)
6 Months After Randomization	1.263 (1.005, 1.569)	0.038 (0.015, 0.087)
7 Months After Randomization	1.263 (1.005, 1.569)	0.038 (0.015, 0.087)
1 Year After Randomization	NE (NE, NE)	NE (NE, NE)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
6 months = 178 days (Month 6 visit), 7 months = 208 days (Month 7 visit), 1 year = 358 days (Month 12 visit).
[1] From the product-limit (Kaplan-Meier) method for censored data.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020202040702.sas 21JUN2021 07:35

Table 14.2.2.3.1.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After Second Injection Including Participant Decision Visit
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1339 (9.5)	280 (2.0)
Number of Subjects Censored, n (%)	12825 (90.5)	14007 (98.0)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.820 (0.795, 0.842)
Person-Years [2]	5442.4	5755.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	246.032 (233.029, 259.572)	48.652 (43.120, 54.697)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.802 (0.775, 0.827)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.3.1.2.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After Second Injection Including Participant Decision Visit
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1352 (9.2)	286 (1.9)
Number of Subjects Censored, n (%)	13393 (90.8)	14460 (98.1)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.817 (0.792, 0.839)
Person-Years [2]	5598.9	5888.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	241.476 (228.774, 254.699)	48.566 (43.100, 54.534)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.799 (0.771, 0.824)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020203010202.sas 26JUL2021 03:43

Table 14.2.2.3.2.1.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Second Injection Including Participant Decision Visit
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1430 (10.1)	313 (2.2)
Number of Subjects Censored, n (%)	12734 (89.9)	13974 (97.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.810 (0.785, 0.832)
Person-Years [2]	5442.4	5755.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	262.752 (249.309, 276.732)	54.386 (48.527, 60.757)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.793 (0.766, 0.817)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020203020102.sas 26JUL2021 03:43

Table 14.2.2.3.2.2.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Second Injection Including Participant Decision Visit
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1444 (9.8)	320 (2.2)
Number of Subjects Censored, n (%)	13301 (90.2)	14426 (97.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.806 (0.781, 0.828)
Person-Years [2]	5598.9	5888.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	257.908 (244.776, 271.562)	54.340 (48.549, 60.632)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.789 (0.762, 0.814)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020203020202.sas 26JUL2021 03:43

Table 14.2.2.3.3.1.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After First Injection Including Participant Decision Visit
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1434 (10.1)	313 (2.2)
Number of Subjects Censored, n (%)	12730 (89.9)	13974 (97.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.810 (0.785, 0.832)
Person-Years [2]	5442.4	5755.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	263.487 (250.025, 277.486)	54.386 (48.527, 60.757)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.794 (0.767, 0.818)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020203030102.sas 26JUL2021 03:43

Table 14.2.2.3.3.2.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After First Injection Including Participant Decision Visit
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1511 (10.2)	329 (2.2)
Number of Subjects Censored, n (%)	13234 (89.8)	14417 (97.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.809 (0.785, 0.830)
Person-Years [2]	5598.9	5888.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	269.875 (256.437, 283.834)	55.868 (49.994, 62.243)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.793 (0.767, 0.817)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.3.5.1.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Randomization Including Participant Decision Visit
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1434 (10.1)	313 (2.2)
Number of Subjects Censored, n (%)	12730 (89.9)	13974 (97.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.810 (0.785, 0.832)
Person-Years [2]	5442.4	5755.2
Incidence Rate per 1,000 Person-Years (95% CI) [3]	263.487 (250.025, 277.486)	54.386 (48.527, 60.757)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.794 (0.767, 0.818)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.3.5.2.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Randomization Including Participant Decision Visit
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with SARS-CoV-2 Infection Regardless of Symptomatology and Severity, n (%)	1522 (10.3)	335 (2.3)
Number of Subjects Censored, n (%)	13223 (89.7)	14411 (97.7)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.807 (0.782, 0.828)
Person-Years [2]	5598.9	5888.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	271.839 (258.352, 285.848)	56.887 (50.958, 63.317)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.791 (0.764, 0.815)

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the date of SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.
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Table 14.2.2.4.2.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting 14 Days After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	807 (5.7)	58 (0.4)
Number of Subjects Censored, n (%)	13357 (94.3)	14229 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.934 (0.914, 0.949)
Person-Years [2]	5433.4	5728.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	148.525 (138.453, 159.136)	10.124 (7.688, 13.088)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.932 (0.911, 0.949)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.2.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting 14 Days After Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	816 (5.5)	61 (0.4)
Number of Subjects Censored, n (%)	13929 (94.5)	14685 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.931 (0.910, 0.947)
Person-Years [2]	5591.7	5862.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	145.930 (136.088, 156.296)	10.406 (7.960, 13.367)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.929 (0.907, 0.946)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.2.2.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting After Second Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	835 (5.9)	62 (0.4)
Number of Subjects Censored, n (%)	13329 (94.1)	14225 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.931 (0.911, 0.947)
Person-Years [2]	5433.4	5728.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	153.678 (143.430, 164.465)	10.823 (8.298, 13.874)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.909, 0.946)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.2.2.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting After Second Injection
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	844 (5.7)	65 (0.4)
Number of Subjects Censored, n (%)	13901 (94.3)	14681 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.929 (0.908, 0.945)
Person-Years [2]	5591.7	5862.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	150.938 (140.925, 161.474)	11.088 (8.558, 14.133)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.927 (0.905, 0.944)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.2.3
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting 14 Days After First Injection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	839 (5.9)	62 (0.4)
Number of Subjects Censored, n (%)	13325 (94.1)	14225 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.912, 0.947)
Person-Years [2]	5433.4	5728.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	154.414 (144.141, 165.226)	10.823 (8.298, 13.874)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.909, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.2.5.1
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	839 (5.9)	62 (0.4)
Number of Subjects Censored, n (%)	13325 (94.1)	14225 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.932 (0.912, 0.947)
Person-Years [2]	5433.4	5728.7
Incidence Rate per 1,000 Person-Years (95% CI) [3]	154.414 (144.141, 165.226)	10.823 (8.298, 13.874)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.930 (0.909, 0.947)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.2.5.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19* Starting After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	909 (6.2)	77 (0.5)
Number of Subjects Censored, n (%)	13836 (93.8)	14669 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.921 (0.900, 0.938)
Person-Years [2]	5591.7	5862.0
Incidence Rate per 1,000 Person-Years (95% CI) [3]	162.562 (152.165, 173.483)	13.135 (10.366, 16.417)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.919 (0.898, 0.937)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of secondary definition of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.4.2.6.1
Kaplan-Meier Estimate of Secondary Definition of COVID-19* Starting After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Secondary Definition of COVID-19*, n (%)	839 (5.9)	62 (0.4)
Time to Onset (Days)		
Mean (SD)	101.7 (32.64)	98.7 (36.26)
Median	103.0	103.5
Min, Max	19, 203	27, 158
Number of Subjects Censored, n (%)	13325 (94.1)	14225 (99.6)
Cumulative Event Rate in % (95% CI) [1]		
14 Days After Randomization	0.000 (NE, NE)	0.000 (NE, NE)
28 Days After Randomization	0.021 (0.006, 0.061)	0.014 (0.003, 0.051)
42 Days After Randomization	0.254 (0.182, 0.349)	0.035 (0.014, 0.080)
56 Days After Randomization	0.657 (0.535, 0.802)	0.070 (0.037, 0.127)
6 Months After Randomization	7.870 (7.280, 8.490)	0.550 (0.419, 0.713)
7 Months After Randomization	8.803 (7.736, 9.952)	0.550 (0.419, 0.713)
1 Year After Randomization	NE (NE, NE)	NE (NE, NE)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
6 months = 178 days (Month 6 visit), 7 months = 208 days (Month 7 visit), 1 year = 358 days (Month 12 visit).
[1] From the product-limit (Kaplan-Meier) method for censored data.
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Table 14.2.2.6.2.1.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting 14 Days After Second Injection Including Participant Decision Visit Using Competing Risk Method
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Asymptomatic SARS-CoV-2 Infection, n (%)	498 (3.5)	214 (1.5)
Number of Subjects with Competing Event, n (%)	863 (6.1)	62 (0.4)
Number of Subjects Censored, n (%)	12803 (90.4)	14011 (98.1)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.630 (0.566, 0.685)
Person-Years [2]	5442.1	5756.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	91.508 (83.646, 99.909)	37.178 (32.363, 42.507)

RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition. Disease cases (COVID-19 or second definition of COVID-19) are considered as competing events for asymptomatic SARS-CoV-2 infection.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.6.2.1.2.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting 14 Days After Second Injection Including Participant Decision Visit Using Competing Risk Method
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Asymptomatic SARS-CoV-2 Infection, n (%)	500 (3.4)	217 (1.5)
Number of Subjects with Competing Event, n (%)	935 (6.3)	77 (0.5)
Number of Subjects Censored, n (%)	13310 (90.3)	14452 (98.0)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.623 (0.557, 0.678)
Person-Years [2]	5598.5	5889.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	89.310 (81.652, 97.492)	36.843 (32.104, 42.085)

RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition. Disease cases (COVID-19 or second definition of COVID-19) are considered as competing events for asymptomatic SARS-CoV-2 infection.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.6.2.5.1.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting After Randomization Including Participant Decision Visit Using Competing Risk Method
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Asymptomatic SARS-CoV-2 Infection, n (%)	567 (4.0)	246 (1.7)
Number of Subjects with Competing Event, n (%)	863 (6.1)	62 (0.4)
Number of Subjects Censored, n (%)	12734 (89.9)	13979 (97.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.620 (0.558, 0.673)
Person-Years [2]	5442.1	5756.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	104.187 (95.786, 113.127)	42.737 (37.563, 48.425)

RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition. Disease cases (COVID-19 or second definition of COVID-19) are considered as competing events for asymptomatic SARS-CoV-2 infection.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.6.2.5.2.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Asymptomatic SARS-CoV-2 Infection Starting After Randomization Including Participant Decision Visit Using Competing Risk Method
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with Asymptomatic SARS-CoV-2 Infection, n (%)	583 (4.0)	253 (1.7)
Number of Subjects with Competing Event, n (%)	935 (6.3)	77 (0.5)
Number of Subjects Censored, n (%)	13227 (89.7)	14416 (97.8)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.616 (0.555, 0.669)
Person-Years [2]	5598.5	5889.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	104.135 (95.853, 112.942)	42.955 (37.825, 48.588)

RT-PCR test and Elecsys anti-SARS-CoV-2 assay results at post-baseline scheduled visits are considered in case definition. Disease cases (COVID-19 or second definition of COVID-19) are considered as competing events for asymptomatic SARS-CoV-2 infection.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

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Table 14.2.2.7.3.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)
Number of Subjects with COVID-19*, n (%)	754 (5.0)	58 (0.4)
Number of Subjects Censored, n (%)	14412 (95.0)	15122 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.928 (0.906, 0.945)
Person-Years [2]	5768.0	6027.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	130.721 (121.556, 140.394)	9.622 (7.306, 12.439)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.926 (0.904, 0.945)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.3.2
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting After Second Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)
Number of Subjects with COVID-19*, n (%)	778 (5.1)	59 (0.4)
Number of Subjects Censored, n (%)	14388 (94.9)	15121 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.929 (0.908, 0.946)
Person-Years [2]	5768.0	6027.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	134.882 (125.569, 144.702)	9.788 (7.451, 12.626)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.927 (0.905, 0.945)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.3.3
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After First Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)
Number of Subjects with COVID-19*, n (%)	826 (5.4)	64 (0.4)
Number of Subjects Censored, n (%)	14340 (94.6)	15116 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.927 (0.906, 0.944)
Person-Years [2]	5768.0	6027.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	143.204 (133.603, 153.312)	10.617 (8.177, 13.558)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.926 (0.904, 0.943)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.3.5
Sensitivity Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting After Randomization Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

	Placebo (N=15166)	mRNA-1273 (N=15180)
Number of Subjects with COVID-19*, n (%)	841 (5.5)	74 (0.5)
Number of Subjects Censored, n (%)	14325 (94.5)	15106 (99.5)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.917 (0.895, 0.935)
Person-Years [2]	5768.0	6027.8
Incidence Rate per 1,000 Person-Years (95% CI) [3]	145.804 (136.115, 156.001)	12.276 (9.640, 15.412)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.916 (0.893, 0.935)

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.3.6.10
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection by Baseline SARS-CoV-2 Status
Full Analysis Set

Baseline SARS-CoV-2 Status: Negative

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with COVID-19*, n (%)	751 (5.1)	58 (0.4)
Number of Subjects Censored, n (%)	13994 (94.9)	14688 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.928 (0.906, 0.945)
Person-Years [2]	5604.5	5863.5
Incidence Rate per 1,000 Person-Years (95% CI) [3]	133.999 (124.585, 143.935)	9.892 (7.511, 12.787)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		0.926 (0.904, 0.944)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.3.6.10
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection by Baseline SARS-CoV-2 Status
Full Analysis Set

Baseline SARS-CoV-2 Status: Positive

	Placebo (N=337)	mRNA-1273 (N=347)
Number of Subjects with COVID-19*, n (%)	0	0
Number of Subjects Censored, n (%)	337 (100)	347 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		NE (NE, NE)
Person-Years [2]	128.9	129.3
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.000 (NE, 28.623)	0.000 (NE, 28.539)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		NE (NE, NE)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.7.3.6.10
Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection by Baseline SARS-CoV-2 Status
Full Analysis Set

Baseline SARS-CoV-2 Status: Missing

	Placebo (N=84)	mRNA-1273 (N=87)
Number of Subjects with COVID-19*, n (%)	3 (3.6)	0
Number of Subjects Censored, n (%)	81 (96.4)	87 (100)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (NE, 1.000)
Person-Years [2]	34.6	35.1
Incidence Rate per 1,000 Person-Years (95% CI) [3]	86.723 (17.884, 253.443)	0.000 (NE, 105.189)
Vaccine Efficacy Based on Incidence Rate (95% CI) [4]		1.000 (-1.387, NE)

* With the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

[2] Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier.

[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.

[4] VE is defined as 1 - ratio of incidence rate (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

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Table 14.2.2.8.1.1
Analysis of Vaccine Efficacy of mRNA-1273 Against All-Cause Mortality After Randomization
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with All-Cause Mortality, n (%)	12 (<0.1)	12 (<0.1)
Number of Subjects Censored, n (%)	14152 (>99.9)	14275 (>99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.072 (-1.068, 0.583)

All-cause mortality includes death regardless of cause. Subjects without documented death are censored at the last date of study participation or efficacy data cutoff date, whichever is earlier.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140202080101.sas 10JUN2021 14:53

Table 14.2.2.8.1.2
Analysis of Vaccine Efficacy of mRNA-1273 Against All-Cause Mortality After Randomization
mITT Set

	Placebo (N=14745)	mRNA-1273 (N=14746)
Number of Subjects with All-Cause Mortality, n (%)	15 (0.1)	16 (0.1)
Number of Subjects Censored, n (%)	14730 (99.9)	14730 (99.9)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		-0.003 (-1.031, 0.504)

All-cause mortality includes death regardless of cause. Subjects without documented death are censored at the last date of study participation or efficacy data cutoff date, whichever is earlier.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140202080102.sas 10JUN2021 14:54

Table 14.2.3.1.1.1
Summary of Burden of Disease Score
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Each Level of BOD Score, n (%) [1]	14164	14287
0	13394 (94.6)	14230 (99.6)
1	741 (5.2)	55 (0.4)
2	28 (0.2)	2 (<0.1)
3	1 (<0.1)	0
BOD Score [2]		
Mean (SD)	0.1 (0.24)	0.0 (0.07)
Median	0.0	0.0
Min, Max	0, 3	0, 2

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without COVID-19 at randomization and have available post-baseline data. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140203010101.sas 24JUN2021 06:55

Table 14.2.3.1.1.1
Summary of Burden of Disease Score
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)
Number of Subjects with Each Level of BOD Score, n (%) [1]	8242	8271
0	7739 (93.9)	8236 (99.6)
1	496 (6.0)	35 (0.4)
2	7 (<0.1)	0
3	0	0
BOD Score [2]		
Mean (SD)	0.1 (0.24)	0.0 (0.06)
Median	0.0	0.0
Min, Max	0, 2	0, 1

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without COVID-19 at randomization and have available post-baseline data. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
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Table 14.2.3.1.1.1
Summary of Burden of Disease Score
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)
Number of Subjects with Each Level of BOD Score, n (%) [1]	2331	2395
0	2165 (92.9)	2383 (99.5)
1	157 (6.7)	12 (0.5)
2	8 (0.3)	0
3	1 (<0.1)	0
BOD Score [2]		
Mean (SD)	0.1 (0.28)	0.0 (0.07)
Median	0.0	0.0
Min, Max	0, 3	0, 1

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without COVID-19 at randomization and have available post-baseline data. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
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Table 14.2.3.1.1.1
Summary of Burden of Disease Score
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)
Number of Subjects with Each Level of BOD Score, n (%) [1]	3591	3621
0	3490 (97.2)	3611 (99.7)
1	88 (2.5)	8 (0.2)
2	13 (0.4)	2 (<0.1)
3	0	0
BOD Score [2]		
Mean (SD)	0.0 (0.19)	0.0 (0.07)
Median	0.0	0.0
Min, Max	0, 2	0, 2

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without COVID-19 at randomization and have available post-baseline data. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140203010101.sas 24JUN2021 06:55

Table 14.2.3.1.1.3
Vaccine Efficacy on Burden of Disease
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Mean of BOD Score	0.1	0.0
Treatment Comparison (mRNA-1273 vs. Placebo) [1]		
Ratio of the Mean BOD Score		0.068
95% CI		0.052, 0.090
1 - Ratio of the Mean BOD Score		0.932
95% CI		0.910, 0.948

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Vaccine efficacy is estimated using proportional means model including vaccination group as fixed effect and stratified with stratification factor at randomization.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140203010103.sas 10JUN2021 14:54

Table 14.2.3.1.2.1
Summary of Burden of Disease Score
Per-Protocol Set — Subjects with COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: Overall

	Placebo (N=770)	mRNA-1273 (N=57)
Number of Subjects with Each Level of BOD Score, n (%) [1]	770	57
1	741 (96.2)	55 (96.5)
2	28 (3.6)	2 (3.5)
3	1 (0.1)	0
BOD Score [2]		
Mean (SD)	1.0 (0.20)	1.0 (0.19)
Median	1.0	1.0
Min, Max	1, 3	1, 2

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with COVID-19 during the study. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140203010201.sas 22JUN2021 07:21

Table 14.2.3.1.2.1
Summary of Burden of Disease Score
Per-Protocol Set — Subjects with COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=503)	mRNA-1273 (N=35)
Number of Subjects with Each Level of BOD Score, n (%) [1]	503	35
1	496 (98.6)	35 (100)
2	7 (1.4)	0
3	0	0
BOD Score [2]		
Mean (SD)	1.0 (0.12)	1.0 (0.00)
Median	1.0	1.0
Min, Max	1, 2	1, 1

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with COVID-19 during the study. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
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Table 14.2.3.1.2.1
Summary of Burden of Disease Score
Per-Protocol Set — Subjects with COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=166)	mRNA-1273 (N=12)
Number of Subjects with Each Level of BOD Score, n (%) [1]	166	12
1	157 (94.6)	12 (100)
2	8 (4.8)	0
3	1 (0.6)	0
BOD Score [2]		
Mean (SD)	1.1 (0.26)	1.0 (0.00)
Median	1.0	1.0
Min, Max	1, 3	1, 1

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with COVID-19 during the study. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
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Table 14.2.3.1.2.1
Summary of Burden of Disease Score
Per-Protocol Set — Subjects with COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=65 Years

	Placebo (N=101)	mRNA-1273 (N=10)
Number of Subjects with Each Level of BOD Score, n (%) [1]	101	10
1	88 (87.1)	8 (80.0)
2	13 (12.9)	2 (20.0)
3	0	0
BOD Score [2]		
Mean (SD)	1.1 (0.34)	1.2 (0.42)
Median	1.0	1.0
Min, Max	1, 2	1, 2

BOD = Burden of Disease.
BOD is defined based on adjudicated COVID-19 cases. BOD Score: 0 = Without COVID-19, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with COVID-19 during the study. Percentages are based on number of subjects with BOD score.
[2] The maximum BOD score from randomization through study completion.
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Table 14.2.3.2.1.1
Summary of Burden of Infection Score
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)
Number of Subjects with Each Level of BOI Score, n (%) [1]	14164	14287
0	13295 (93.9)	14187 (99.3)
1/2	99 (0.7)	43 (0.3)
1	741 (5.2)	55 (0.4)
2	28 (0.2)	2 (<0.1)
3	1 (<0.1)	0
BOI Score [2]		
Mean (SD)	0.06 (0.243)	0.01 (0.072)
Median	0.00	0.00
Min, Max	0.0, 3.0	0.0, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at baseline and have available post-baseline data. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.1.1
Summary of Burden of Infection Score
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)
Number of Subjects with Each Level of BOI Score, n (%) [1]	8242	8271
0	7671 (93.1)	8212 (99.3)
1/2	68 (0.8)	24 (0.3)
1	496 (6.0)	35 (0.4)
2	7 (<0.1)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.07 (0.248)	0.01 (0.070)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at baseline and have available post-baseline data. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.1.1
Summary of Burden of Infection Score
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)
Number of Subjects with Each Level of BOI Score, n (%) [1]	2331	2395
0	2149 (92.2)	2370 (99.0)
1/2	16 (0.7)	13 (0.5)
1	157 (6.7)	12 (0.5)
2	8 (0.3)	0
3	1 (<0.1)	0
BOI Score [2]		
Mean (SD)	0.08 (0.284)	0.01 (0.079)
Median	0.00	0.00
Min, Max	0.0, 3.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at baseline and have available post-baseline data. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.1.1
Summary of Burden of Infection Score
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)
Number of Subjects with Each Level of BOI Score, n (%) [1]	3591	3621
0	3475 (96.8)	3605 (99.6)
1/2	15 (0.4)	6 (0.2)
1	88 (2.5)	8 (0.2)
2	13 (0.4)	2 (<0.1)
3	0	0
BOI Score [2]		
Mean (SD)	0.03 (0.197)	0.00 (0.069)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at baseline and have available post-baseline data. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	14164	14287
0	14116 (99.7)	14265 (99.8)
1/2	45 (0.3)	21 (0.1)
1	3 (<0.1)	1 (<0.1)
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.00 (0.032)	0.00 (0.021)
Median	0.00	0.00
Min, Max	0.0, 1.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	14116	14265
0	13991 (99.1)	14239 (99.8)
1/2	39 (0.3)	20 (0.1)
1	82 (0.6)	6 (<0.1)
2	4 (<0.1)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.01 (0.087)	0.00 (0.028)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: Overall

	Placebo (N=14164)	mRNA-1273 (N=14287)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	13991	14239
0	13295 (95.0)	14187 (99.6)
1/2	15 (0.1)	2 (<0.1)
1	656 (4.7)	48 (0.3)
2	24 (0.2)	2 (<0.1)
3	1 (<0.1)	0
BOI Score [2]		
Mean (SD)	0.05 (0.228)	0.00 (0.063)
Median	0.00	0.00
Min, Max	0.0, 3.0	0.0, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	8242	8271
0	8212 (99.6)	8262 (99.9)
1/2	27 (0.3)	9 (0.1)
1	3 (<0.1)	0
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.00 (0.034)	0.00 (0.016)
Median	0.00	0.00
Min, Max	0.0, 1.0	0.0, 0.5

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	8212	8262
0	8122 (98.9)	8243 (99.8)
1/2	32 (0.4)	14 (0.2)
1	56 (0.7)	5 (<0.1)
2	2 (<0.1)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.01 (0.093)	0.00 (0.032)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=8242)	mRNA-1273 (N=8271)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	8122	8243
0	7671 (94.4)	8212 (99.6)
1/2	9 (0.1)	1 (<0.1)
1	437 (5.4)	30 (0.4)
2	5 (<0.1)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.06 (0.231)	0.00 (0.060)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	2331	2395
0	2322 (99.6)	2386 (99.6)
1/2	9 (0.4)	9 (0.4)
1	0	0
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.00 (0.031)	0.00 (0.031)
Median	0.00	0.00
Min, Max	0.0, 0.5	0.0, 0.5

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	2322	2386
0	2301 (99.1)	2383 (99.9)
1/2	3 (0.1)	3 (0.1)
1	17 (0.7)	0
2	1 (<0.1)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.01 (0.096)	0.00 (0.018)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 0.5

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=2331)	mRNA-1273 (N=2395)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	2301	2383
0	2149 (93.4)	2370 (99.5)
1/2	4 (0.2)	1 (<0.1)
1	140 (6.1)	12 (0.5)
2	7 (0.3)	0
3	1 (<0.1)	0
BOI Score [2]		
Mean (SD)	0.07 (0.269)	0.01 (0.072)
Median	0.00	0.00
Min, Max	0.0, 3.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	3591	3621
0	3582 (99.7)	3617 (99.9)
1/2	9 (0.3)	3 (<0.1)
1	0	1 (<0.1)
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.00 (0.025)	0.00 (0.022)
Median	0.00	0.00
Min, Max	0.0, 0.5	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	3582	3617
0	3568 (99.6)	3613 (99.9)
1/2	4 (0.1)	3 (<0.1)
1	9 (0.3)	1 (<0.1)
2	1 (<0.1)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.00 (0.062)	0.00 (0.022)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set

Randomization Stratum: >=65 Years

	Placebo (N=3591)	mRNA-1273 (N=3621)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	3568	3613
0	3475 (97.4)	3605 (99.8)
1/2	2 (<0.1)	0
1	79 (2.2)	6 (0.2)
2	12 (0.3)	2 (<0.1)
3	0	0
BOI Score [2]		
Mean (SD)	0.03 (0.187)	0.00 (0.062)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are without SARS-CoV-2 infection at the beginning of each follow up period and have available data in each follow up period. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.1.3
Vaccine Efficacy on Burden of Infection
Per-Protocol Set

	Placebo (N=14164)	mRNA-1273 (N=14287)
Mean of BOI Score	0.06	0.01
Treatment Comparison (mRNA-1273 vs. Placebo) [1]		
Ratio of the Mean BOI Score		0.088
95% CI		0.070, 0.110
1 - Ratio of the Mean BOI Score		0.912
95% CI		0.890, 0.930

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Vaccine efficacy is estimated using proportional means model including vaccination group as fixed effect and stratified with stratification factor at randomization.
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Table 14.2.3.2.2.1
Summary of Burden of Infection Score
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: Overall

	Placebo (N=869)	mRNA-1273 (N=100)
Number of Subjects with Each Level of BOI Score, n (%) [1]	869	100
1/2	99 (11.4)	43 (43.0)
1	741 (85.3)	55 (55.0)
2	28 (3.2)	2 (2.0)
3	1 (0.1)	0
BOI Score [2]		
Mean (SD)	0.98 (0.255)	0.81 (0.301)
Median	1.00	1.00
Min, Max	0.5, 3.0	0.5, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection during the study. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.2.1
Summary of Burden of Infection Score
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=571)	mRNA-1273 (N=59)
Number of Subjects with Each Level of BOI Score, n (%) [1]	571	59
1/2	68 (11.9)	24 (40.7)
1	496 (86.9)	35 (59.3)
2	7 (1.2)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.95 (0.200)	0.80 (0.248)
Median	1.00	1.00
Min, Max	0.5, 2.0	0.5, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection during the study. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.2.1
Summary of Burden of Infection Score
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=182)	mRNA-1273 (N=25)
Number of Subjects with Each Level of BOI Score, n (%) [1]	182	25
1/2	16 (8.8)	13 (52.0)
1	157 (86.3)	12 (48.0)
2	8 (4.4)	0
3	1 (0.5)	0
BOI Score [2]		
Mean (SD)	1.01 (0.297)	0.74 (0.255)
Median	1.00	0.50
Min, Max	0.5, 3.0	0.5, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection during the study. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.2.1
Summary of Burden of Infection Score
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=65 Years

	Placebo (N=116)	mRNA-1273 (N=16)
Number of Subjects with Each Level of BOI Score, n (%) [1]	116	16
1/2	15 (12.9)	6 (37.5)
1	88 (75.9)	8 (50.0)
2	13 (11.2)	2 (12.5)
3	0	0
BOI Score [2]		
Mean (SD)	1.05 (0.379)	0.94 (0.479)
Median	1.00	1.00
Min, Max	0.5, 2.0	0.5, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection during the study. Percentages are based on number of subjects with BOI score.
[2] The maximum BOI score from randomization through study completion.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: Overall

	Placebo (N=869)	mRNA-1273 (N=100)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	869	100
0	821 (94.5)	78 (78.0)
1/2	45 (5.2)	21 (21.0)
1	3 (0.3)	1 (1.0)
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.03 (0.125)	0.12 (0.223)
Median	0.00	0.00
Min, Max	0.0, 1.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: Overall

	Placebo (N=869)	mRNA-1273 (N=100)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	821	78
0	696 (84.8)	52 (66.7)
1/2	39 (4.8)	20 (25.6)
1	82 (10.0)	6 (7.7)
2	4 (0.5)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.13 (0.337)	0.21 (0.317)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: Overall

	Placebo (N=869)	mRNA-1273 (N=100)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	696	52
0	0	0
1/2	15 (2.2)	2 (3.8)
1	656 (94.3)	48 (92.3)
2	24 (3.4)	2 (3.8)
3	1 (0.1)	0
BOI Score [2]		
Mean (SD)	1.03 (0.212)	1.02 (0.221)
Median	1.00	1.00
Min, Max	0.5, 3.0	0.5, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=571)	mRNA-1273 (N=59)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	571	59
0	541 (94.7)	50 (84.7)
1/2	27 (4.7)	9 (15.3)
1	3 (0.5)	0
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.03 (0.128)	0.08 (0.181)
Median	0.00	0.00
Min, Max	0.0, 1.0	0.0, 0.5

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=571)	mRNA-1273 (N=59)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	541	50
0	451 (83.4)	31 (62.0)
1/2	32 (5.9)	14 (28.0)
1	56 (10.4)	5 (10.0)
2	2 (0.4)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.14 (0.337)	0.24 (0.339)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and Not at Risk

	Placebo (N=571)	mRNA-1273 (N=59)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	451	31
0	0	0
1/2	9 (2.0)	1 (3.2)
1	437 (96.9)	30 (96.8)
2	5 (1.1)	0
3	0	0
BOI Score [2]		
Mean (SD)	1.00 (0.127)	0.98 (0.090)
Median	1.00	1.00
Min, Max	0.5, 2.0	0.5, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=182)	mRNA-1273 (N=25)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	182	25
0	173 (95.1)	16 (64.0)
1/2	9 (4.9)	9 (36.0)
1	0	0
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.02 (0.109)	0.18 (0.245)
Median	0.00	0.00
Min, Max	0.0, 0.5	0.0, 0.5

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=182)	mRNA-1273 (N=25)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	173	16
0	152 (87.9)	13 (81.3)
1/2	3 (1.7)	3 (18.8)
1	17 (9.8)	0
2	1 (0.6)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.12 (0.335)	0.09 (0.202)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 0.5

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=18 and <65 Years and at Risk

	Placebo (N=182)	mRNA-1273 (N=25)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	152	13
0	0	0
1/2	4 (2.6)	1 (7.7)
1	140 (92.1)	12 (92.3)
2	7 (4.6)	0
3	1 (0.7)	0
BOI Score [2]		
Mean (SD)	1.05 (0.278)	0.96 (0.139)
Median	1.00	1.00
Min, Max	0.5, 3.0	0.5, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=65 Years

	Placebo (N=116)	mRNA-1273 (N=16)
Baseline Through Month 1		
Number of Subjects with Each Level of BOI Score, n (%) [1]	116	16
0	107 (92.2)	12 (75.0)
1/2	9 (7.8)	3 (18.8)
1	0	1 (6.3)
2	0	0
3	0	0
BOI Score [2]		
Mean (SD)	0.04 (0.134)	0.16 (0.301)
Median	0.00	0.00
Min, Max	0.0, 0.5	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=65 Years

	Placebo (N=116)	mRNA-1273 (N=16)
After Month 1 Through Month 2		
Number of Subjects with Each Level of BOI Score, n (%) [1]	107	12
0	93 (86.9)	8 (66.7)
1/2	4 (3.7)	3 (25.0)
1	9 (8.4)	1 (8.3)
2	1 (0.9)	0
3	0	0
BOI Score [2]		
Mean (SD)	0.12 (0.342)	0.21 (0.334)
Median	0.00	0.00
Min, Max	0.0, 2.0	0.0, 1.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.2.2.2
Summary of Burden of Infection Score by Follow-up Period
Per-Protocol Set — Subjects with Asymptomatic Infection or COVID-19 Based on Adjudication Committee Assessments

Randomization Stratum: >=65 Years

	Placebo (N=116)	mRNA-1273 (N=16)
After Month 2 Through Month 7 [3]		
Number of Subjects with Each Level of BOI Score, n (%) [1]	93	8
0	0	0
1/2	2 (2.2)	0
1	79 (84.9)	6 (75.0)
2	12 (12.9)	2 (25.0)
3	0	0
BOI Score [2]		
Mean (SD)	1.12 (0.349)	1.25 (0.463)
Median	1.00	1.00
Min, Max	0.5, 2.0	1.0, 2.0

BOI = Burden of Infection.
BOI is defined based on asymptomatic infection and adjudicated COVID-19 cases. BOI score: 0 = No infection, 1/2 = Asymptomatic infection, 1 = COVID-19 without hospitalization, 2 = COVID-19 with hospitalization, 3 = Death.
[1] Number of subjects who are with SARS-CoV-2 infection at the beginning of each period or anytime during each period. Percentages are based on number of subjects with BOI score in the period.
[2] The maximum BOI score during the follow up period.
[3] Includes infection and COVID-19 cases occurred after month 2 through month 7 or participant decision visit or unblinding date whichever is earlier, with hospitalization and death are up to 28 days after COVID-19 onset date.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: Overall
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=770)	mRNA-1273 (N=57)
Total COVID-19 Symptoms Score [1]		
n	728	54
Mean (SD)	60.6 (66.62)	26.8 (27.36)
Median	38.0	21.0
Min, Max	0, 677	0, 130
Q1, Q3	20.0, 81.0	6.0, 33.0
Total COVID-19 Symptoms Score Between Min to < Q1 [2]		
n	165	23
Mean (SD)	9.6 (5.44)	6.8 (5.65)
Median	10.0	6.0
Min, Max	0, 18	0, 18
Q1, Q3	5.0, 15.0	2.0, 10.0
Total COVID-19 Symptoms Score Between Q1 to < Median [2]		
n	173	20
Mean (SD)	27.3 (5.09)	26.7 (5.34)
Median	28.0	28.5
Min, Max	19, 35	19, 35
Q1, Q3	23.0, 32.0	22.5, 31.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: Overall
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=770)	mRNA-1273 (N=57)
Total COVID-19 Symptoms Score Between Median to < Q3 [2]		
n	197	8
Mean (SD)	53.1 (12.95)	51.9 (9.48)
Median	51.0	52.0
Min, Max	36, 77	38, 63
Q1, Q3	41.0, 65.0	44.0, 61.0
Total COVID-19 Symptoms Score Between Q3 to Max [2]		
n	193	3
Mean (SD)	141.8 (81.69)	113.3 (23.86)
Median	117.0	124.0
Min, Max	78, 677	86, 130
Q1, Q3	92.0, 159.0	86.0, 130.0
Mean Daily COVID-19 Symptoms Score		
n	728	54
Mean (SD)	3.3 (2.86)	1.7 (1.48)
Median	2.6	1.4
Min, Max	0, 23	0, 7
Q1, Q3	1.4, 4.3	0.5, 2.5

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: Overall
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=770)	mRNA-1273 (N=57)
Number of Days with at Least One COVID-19 Symptom Score > 0		
Number of Subjects with at Least One COVID-19 Symptom Score > 0	717	52
Mean (SD)	13.1 (7.95)	7.8 (6.24)
Median	11.0	6.0
Min, Max	1, 29	1, 29
Q1, Q3	7.0, 18.0	4.0, 11.0
Number of Days with at Least one COVID-19 Symptom Score = 3		
Number of Subjects with Least one COVID-19 Symptom Score = 3	216	5
Mean (SD)	5.0 (5.65)	2.4 (2.61)
Median	3.0	1.0
Min, Max	1, 28	1, 7
Q1, Q3	1.0, 6.0	1.0, 2.0
Number of Days with at Least Two COVID-19 Symptoms Score >= 2		
Number of Subjects with at Least Two COVID-19 Symptoms Score >= 2	399	16
Mean (SD)	5.4 (5.71)	2.4 (1.75)
Median	3.0	2.0
Min, Max	1, 29	1, 8
Q1, Q3	1.0, 8.0	1.0, 3.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: Overall
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=770)	mRNA-1273 (N=57)
Number of Days with at Least One COVID-19 Symptom Score >= 2		
Number of Subjects with at Least One COVID-19 Symptom Score >= 2	510	26
Mean (SD)	6.7 (6.51)	3.8 (3.52)
Median	5.0	3.0
Min, Max	1, 29	1, 15
Q1, Q3	2.0, 9.0	1.0, 5.0
Highest Temperature (C)		
n	722	54
Mean (SD)	37.47 (2.339)	37.07 (0.397)
Median	37.20	37.10
Min, Max	36.2, 98.0	36.4, 39.1
Q1, Q3	37.00, 37.70	36.90, 37.20
Lowest Oxygen Saturation (%)		
n	718	54
Mean (SD)	95.7 (2.61)	96.9 (1.21)
Median	96.0	97.0
Min, Max	68, 100	93, 98
Q1, Q3	95.0, 97.0	96.0, 98.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and Not at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=503)	mRNA-1273 (N=35)
Total COVID-19 Symptoms Score [1]		
n	490	35
Mean (SD)	57.5 (60.07)	24.9 (25.11)
Median	37.0	19.0
Min, Max	0, 476	0, 130
Q1, Q3	20.0, 76.0	9.0, 33.0
Total COVID-19 Symptoms Score Between Min to < Q1 [2]		
n	116	16
Mean (SD)	9.3 (5.40)	7.7 (6.53)
Median	9.0	7.5
Min, Max	0, 18	0, 18
Q1, Q3	5.0, 14.0	1.0, 14.5
Total COVID-19 Symptoms Score Between Q1 to < Median [2]		
n	117	13
Mean (SD)	27.4 (5.26)	26.6 (5.81)
Median	28.0	29.0
Min, Max	19, 35	19, 35
Q1, Q3	23.0, 32.0	22.0, 32.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and Not at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=503)	mRNA-1273 (N=35)
Total COVID-19 Symptoms Score Between Median to < Q3 [2]		
n	138	5
Mean (SD)	53.3 (12.78)	54.6 (6.27)
Median	51.0	53.0
Min, Max	36, 77	47, 62
Q1, Q3	41.0, 64.0	51.0, 60.0
Total COVID-19 Symptoms Score Between Q3 to Max [2]		
n	119	1
Mean (SD)	138.7 (69.68)	130.0 (NA)
Median	117.0	130.0
Min, Max	78, 476	130, 130
Q1, Q3	94.0, 159.0	130.0, 130.0
Mean Daily COVID-19 Symptoms Score		
n	490	35
Mean (SD)	3.3 (2.72)	1.7 (1.36)
Median	2.6	1.4
Min, Max	0, 17	0, 5
Q1, Q3	1.4, 4.2	0.6, 2.1

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and Not at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=503)	mRNA-1273 (N=35)
Number of Days with at Least One COVID-19 Symptom Score > 0		
Number of Subjects with at Least One COVID-19 Symptom Score > 0	481	33
Mean (SD)	12.7 (7.99)	7.2 (5.77)
Median	11.0	6.0
Min, Max	1, 29	1, 29
Q1, Q3	6.0, 17.0	4.0, 10.0
Number of Days with at Least one COVID-19 Symptom Score = 3		
Number of Subjects with Least one COVID-19 Symptom Score = 3	142	2
Mean (SD)	5.1 (5.71)	1.0 (0.00)
Median	3.0	1.0
Min, Max	1, 28	1, 1
Q1, Q3	1.0, 6.0	1.0, 1.0
Number of Days with at Least Two COVID-19 Symptoms Score >= 2		
Number of Subjects with at Least Two COVID-19 Symptoms Score >= 2	263	9
Mean (SD)	5.3 (5.71)	2.1 (1.05)
Median	3.0	2.0
Min, Max	1, 27	1, 4
Q1, Q3	1.0, 7.0	1.0, 3.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and Not at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=503)	mRNA-1273 (N=35)
Number of Days with at Least One COVID-19 Symptom Score >= 2		
Number of Subjects with at Least One COVID-19 Symptom Score >= 2	346	17
Mean (SD)	6.4 (6.29)	2.8 (2.60)
Median	4.0	2.0
Min, Max	1, 29	1, 11
Q1, Q3	2.0, 8.0	1.0, 3.0
Highest Temperature (C)		
n	485	35
Mean (SD)	37.48 (2.816)	37.12 (0.437)
Median	37.20	37.10
Min, Max	36.2, 98.0	36.5, 39.1
Q1, Q3	37.00, 37.60	36.90, 37.20
Lowest Oxygen Saturation (%)		
n	483	35
Mean (SD)	96.1 (2.31)	97.0 (1.19)
Median	96.0	97.0
Min, Max	68, 99	93, 98
Q1, Q3	95.0, 97.0	96.0, 98.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=166)	mRNA-1273 (N=12)
Total COVID-19 Symptoms Score [1]		
n	153	12
Mean (SD)	74.6 (89.25)	34.5 (36.50)
Median	42.0	29.0
Min, Max	0, 677	2, 124
Q1, Q3	23.0, 94.0	6.0, 39.5
Total COVID-19 Symptoms Score Between Min to < Q1 [2]		
n	29	4
Mean (SD)	10.6 (4.86)	4.5 (1.91)
Median	12.0	5.0
Min, Max	0, 18	2, 6
Q1, Q3	8.0, 15.0	3.0, 6.0
Total COVID-19 Symptoms Score Between Q1 to < Median [2]		
n	33	4
Mean (SD)	26.5 (4.77)	26.8 (5.25)
Median	26.0	29.0
Min, Max	19, 35	19, 30
Q1, Q3	23.0, 30.0	23.5, 30.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=166)	mRNA-1273 (N=12)
Total COVID-19 Symptoms Score Between Median to < Q3 [2]		
n	38	2
Mean (SD)	51.8 (13.45)	39.5 (2.12)
Median	49.5	39.5
Min, Max	36, 75	38, 41
Q1, Q3	40.0, 65.0	38.0, 41.0
Total COVID-19 Symptoms Score Between Q3 to Max [2]		
n	53	2
Mean (SD)	155.9 (110.70)	105.0 (26.87)
Median	122.0	105.0
Min, Max	78, 677	86, 124
Q1, Q3	93.0, 166.0	86.0, 124.0
Mean Daily COVID-19 Symptoms Score		
n	153	12
Mean (SD)	3.8 (3.48)	2.1 (2.01)
Median	2.8	1.4
Min, Max	0, 23	0, 7
Q1, Q3	1.5, 4.8	0.4, 3.5

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=166)	mRNA-1273 (N=12)
Number of Days with at Least One COVID-19 Symptom Score > 0		
Number of Subjects with at Least One COVID-19 Symptom Score > 0	152	12
Mean (SD)	13.7 (7.59)	8.9 (6.76)
Median	13.0	7.0
Min, Max	1, 29	2, 27
Q1, Q3	8.0, 19.0	4.0, 11.5
Number of Days with at Least one COVID-19 Symptom Score = 3		
Number of Subjects with Least one COVID-19 Symptom Score = 3	52	2
Mean (SD)	5.5 (6.18)	4.5 (3.54)
Median	3.5	4.5
Min, Max	1, 27	2, 7
Q1, Q3	1.5, 6.0	2.0, 7.0
Number of Days with at Least Two COVID-19 Symptoms Score >= 2		
Number of Subjects with at Least Two COVID-19 Symptoms Score >= 2	95	6
Mean (SD)	6.3 (6.16)	2.8 (2.64)
Median	4.0	2.0
Min, Max	1, 29	1, 8
Q1, Q3	1.0, 9.0	1.0, 3.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=18 and <65 Years and at Risk
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=166)	mRNA-1273 (N=12)
Number of Days with at Least One COVID-19 Symptom Score >= 2		
Number of Subjects with at Least One COVID-19 Symptom Score >= 2	111	6
Mean (SD)	7.7 (7.06)	4.3 (3.08)
Median	6.0	3.5
Min, Max	1, 29	1, 10
Q1, Q3	2.0, 12.0	3.0, 5.0
Highest Temperature (C)		
n	153	12
Mean (SD)	37.47 (0.686)	36.98 (0.262)
Median	37.30	36.95
Min, Max	36.4, 39.7	36.6, 37.3
Q1, Q3	37.00, 37.70	36.80, 37.25
Lowest Oxygen Saturation (%)		
n	152	12
Mean (SD)	95.1 (3.32)	96.7 (1.37)
Median	96.0	97.0
Min, Max	68, 100	94, 98
Q1, Q3	94.0, 97.0	95.5, 98.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=65 Years
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=101)	mRNA-1273 (N=10)
Total COVID-19 Symptoms Score [1]		
n	85	7
Mean (SD)	53.6 (50.31)	22.9 (21.01)
Median	35.0	24.0
Min, Max	0, 296	4, 63
Q1, Q3	20.0, 72.0	4.0, 33.0
Total COVID-19 Symptoms Score Between Min to < Q1 [2]		
n	20	3
Mean (SD)	9.8 (6.46)	5.3 (2.31)
Median	9.5	4.0
Min, Max	0, 18	4, 8
Q1, Q3	3.5, 16.0	4.0, 8.0
Total COVID-19 Symptoms Score Between Q1 to < Median [2]		
n	23	3
Mean (SD)	28.0 (4.66)	27.0 (5.20)
Median	29.0	24.0
Min, Max	20, 35	24, 33
Q1, Q3	25.0, 31.0	24.0, 33.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=65 Years
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=101)	mRNA-1273 (N=10)
Total COVID-19 Symptoms Score Between Median to < Q3 [2]		
n	21	1
Mean (SD)	53.7 (13.67)	63.0 (NA)
Median	54.0	63.0
Min, Max	36, 72	63, 63
Q1, Q3	39.0, 66.0	63.0, 63.0
Total COVID-19 Symptoms Score Between Q3 to Max [2]		
n	21	0
Mean (SD)	123.3 (51.05)	
Median	109.0	
Min, Max	83, 296	
Q1, Q3	88.0, 133.0	
Mean Daily COVID-19 Symptoms Score		
n	85	7
Mean (SD)	2.9 (2.23)	1.4 (1.09)
Median	2.4	1.4
Min, Max	0, 13	0, 3
Q1, Q3	1.4, 3.9	0.3, 2.6

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402030301.sas 10JUN2021 16:58

Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=65 Years
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=101)	mRNA-1273 (N=10)
Number of Days with at Least One COVID-19 Symptom Score > 0		
Number of Subjects with at Least One COVID-19 Symptom Score > 0	84	7
Mean (SD)	13.8 (8.30)	8.9 (8.01)
Median	11.5	6.0
Min, Max	1, 28	1, 24
Q1, Q3	7.5, 21.0	3.0, 14.0
Number of Days with at Least one COVID-19 Symptom Score = 3		
Number of Subjects with Least one COVID-19 Symptom Score = 3	22	1
Mean (SD)	3.1 (3.28)	1.0 (NA)
Median	2.0	1.0
Min, Max	1, 13	1, 1
Q1, Q3	1.0, 3.0	1.0, 1.0
Number of Days with at Least Two COVID-19 Symptoms Score >= 2		
Number of Subjects with at Least Two COVID-19 Symptoms Score >= 2	41	1
Mean (SD)	4.3 (4.39)	2.0 (NA)
Median	3.0	2.0
Min, Max	1, 24	2, 2
Q1, Q3	1.0, 5.0	2.0, 2.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.1
Summary of COVID-19 Symptoms Score During Convalescence Period
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments
Randomization Stratum: >=65 Years
Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=101)	mRNA-1273 (N=10)
Number of Days with at Least One COVID-19 Symptom Score >= 2		
Number of Subjects with at Least One COVID-19 Symptom Score >= 2	53	3
Mean (SD)	6.8 (6.59)	8.3 (6.11)
Median	5.0	7.0
Min, Max	1, 26	3, 15
Q1, Q3	2.0, 9.0	3.0, 15.0
Highest Temperature (C)		
n	84	7
Mean (SD)	37.42 (0.627)	36.96 (0.369)
Median	37.30	36.90
Min, Max	36.2, 39.3	36.4, 37.6
Q1, Q3	36.95, 37.90	36.80, 37.10
Lowest Oxygen Saturation (%)		
n	83	7
Mean (SD)	94.6 (2.25)	96.6 (1.13)
Median	95.0	97.0
Min, Max	88, 98	95, 98
Q1, Q3	94.0, 96.0	95.0, 97.0

Min = Minimum; Max= Maximum; Q1 = First quartile; Q3 = Third quartile.
COVID-19 symptom scores are calculated based on scores of chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches (myalgia), body aches, headache, new loss of taste, new loss of smell, nasal congestion, runny nose (rhinorrhea), nausea, vomiting, diarrhea, and sore throat.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Total COVID-19 symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
[2] Category of quartiles (across the two treatment groups) based on total symptom scores.
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Table 14.2.3.3.2
Vaccine Efficacy on Duration and Severity of COVID-19 Symptoms
Per-Protocol Set - Subjects with COVID-19 Based on Adjudication Committee Assessments

Convalescence Period: Up to (<=28 Days) after COVID-19 Onset Date

	Placebo (N=770)	mRNA-1273 (N=57)
Mean of Total COVID-19 Symptoms Score	60.6	26.8
Treatment Comparison (mRNA-1273 vs. Placebo) [1]		
Ratio of the Mean Score		0.618
95% CI		0.457, 0.835
1 - Ratio of the Mean Score		0.382
95% CI		0.165, 0.543

[1] Vaccine Efficacy is estimated using proportional means model including vaccination group as fixed effect and stratified with stratification factor at randomization.
Symptom Score: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe.
Total symptom scores are calculated as the sum of recorded daily symptoms scores of all symptoms during the convalescence period.
Quartiles (across the two treatment groups) based on total symptom scores are used in proportional means model.
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Table 14.2.1.1.2.1.4.1
Summary of COVID-19* based on Adjudication Committee Assessments Starting After Randomization by Variant Groups
Per-Protocol Set

	Placbo (N=14164) n(%)	mRNA-1273 (N=14287) n(%)
Number of Subjects with COVID-19*, n (%)	769 (5.4)	56 (0.4)
Number of Events by Lineage, n (%)		
B.1	5 (<0.0)	
B.1.1	1 (<0.0)	
B.1.1.128	1 (<0.0)	
B.1.1.186	2 (<0.0)	
B.1.1.207	1 (<0.0)	
B.1.1.222	8 (0.1)	
B.1.1.316	1 (<0.0)	
B.1.1.337	1 (<0.0)	
B.1.1.432	1 (<0.0)	
B.1.1.434	1 (<0.0)	
B.1.1.519	2 (<0.0)	
B.1.2	394 (2.8)	13 (0.1)
B.1.232	1 (<0.0)	
B.1.234	6 (<0.0)	
B.1.240	1 (<0.0)	
B.1.243	23 (0.2)	1 (<0.0)
B.1.311	6 (<0.0)	
B.1.349	1 (<0.0)	
B.1.369	2 (<0.0)	
B.1.375	1 (<0.0)	
B.1.382	1 (<0.0)	
B.1.396	1 (<0.0)	
B.1.404	2 (<0.0)	

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Table 14.2.1.1.2.1.4.1
Summary of COVID-19* Summary of COVID-19* based on Adjudication Committee Assessments Starting After Randomization by Variant Groups
Per-Protocol Set – COVID-19 cases

	Placbo (N=14164) n(%)	mRNA-1273 (N=14287) n(%)
Number of Events by Lineage, n (%) (Cont.)		
B.1.427	6 (<0.0)	
B.1.429	9 (0.1)	3 (<0.0)
B.1.517	2 (<0.0)	
B.1.526.3	1 (<0.0)	
B.1.544	2 (<0.0)	
B.1.551	1 (<0.0)	
B.1.561	5 (<0.0)	
B.1.564	3 (<0.0)	
B.1.587	8 (0.1)	
B.1.595	2 (<0.0)	
B.1.596	13 (0.1)	
B.1.599	1 (<0.0)	
B.1.605	1 (<0.0)	
B.1.609	1 (<0.0)	
NONE	20 (0.1)	
P.1	1 (<0.0)	
P.2	2 (<0.0)	
R.1	3 (<0.0)	
WILD TYPE	1 (<0.0)	
By First Detected, n (%)		
Brazil	1 (<0.0)	
P.1	1 (<0.0)	
California	15 (0.1)	3 (<0.0)
B.1.427	6 (<0.0)	

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Table 14.2.1.1.2.1.4.1

Summary of COVID-19* Summary of COVID-19* based on Adjudication Committee Assessments Starting After Randomization by Variant Groups
Per-Protocol Set – COVID-19 cases

	Placbo (N=14164) n(%)	mRNA-1273 (N=14287) n(%)
By First Detected, n (%) (Cont.)		
B.1.429	9 (0.1)	3 (<0.0)
Variant of Concern		
B.1.427	6 (<0.0)	
B.1.429	9 (0.1)	3 (<0.0)
P.1	1 (<0.0)	
Variant of Interest		
P.2	2 (<0.0)	

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Table 14.2.1.1.2.1.4.2
Summary of COVID-19* based on Adjudication Committee Assessments Starting After Randomization by Variant Groups
mITT Set

	Placbo (N=14745) n(%)	mRNA-1273 (N=14746) n(%)
Number of Subjects with COVID-19*, n (%)	834 (5.7)	69 (0.5)
Number of Events by Lineage, n (%)		
B	1 (<0.0)	
B.1	7 (<0.0)	
B.1.1	1 (<0.0)	
B.1.1.128	1 (<0.0)	
B.1.1.186	3 (<0.0)	
B.1.1.207	1 (<0.0)	
B.1.1.222	9 (0.1)	
B.1.1.316	1 (<0.0)	
B.1.1.337	1 (<0.0)	
B.1.1.358	1 (<0.0)	
B.1.1.432	1 (<0.0)	
B.1.1.434	2 (<0.0)	
B.1.1.519	2 (<0.0)	
B.1.2	429 (2.9)	20 (0.1)
B.1.232	1 (<0.0)	
B.1.234	6 (<0.0)	
B.1.240	1 (<0.0)	
B.1.243	25 (0.2)	1 (<0.0)
B.1.311	7 (<0.0)	
B.1.349	1 (<0.0)	
B.1.369	2 (<0.0)	
B.1.375	1 (<0.0)	
B.1.382	1 (<0.0)	

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Table 14.2.1.1.2.1.4.2
Summary of COVID-19* Summary of COVID-19* based on Adjudication Committee Assessments Starting After Randomization by Variant Groups
mITT Set – COVID-19 cases

	Placbo (N=14745) n(%)	mRNA-1273 (N=14746) n(%)
Number of Events by Lineage, n (%) (Cont.)		
B.1.396	1 (<0.0)	
B.1.404	2 (<0.0)	
B.1.427	6 (<0.0)	
B.1.429	9 (0.1)	4 (<0.0)
B.1.517	2 (<0.0)	
B.1.526.3	1 (<0.0)	
B.1.544	2 (<0.0)	
B.1.551	1 (<0.0)	
B.1.561	5 (<0.0)	
B.1.564	3 (<0.0)	
B.1.587	8 (0.1)	
B.1.595	2 (<0.0)	
B.1.596	14 (0.1)	
B.1.599	1 (<0.0)	
B.1.605	1 (<0.0)	
B.1.609	1 (<0.0)	
NONE	21 (0.1)	1 (<0.0)
P.1	1 (<0.0)	
P.2	2 (<0.0)	
R.1	3 (<0.0)	
WILD TYPE	1 (<0.0)	
By First Detected, n (%)		
Brazil	1 (<0.0)	
P.1	1 (<0.0)	

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Table 14.2.1.1.2.1.4.2
Summary of COVID-19* Summary of COVID-19* based on Adjudication Committee Assessments Starting After Randomization by Variant Groups
mITT Set – COVID-19 cases

	Placbo (N=14745) n(%)	mRNA-1273 (N=14746) n(%)
By First Detected, n (%) (Cont.)		
California	15 (0.1)	4 (<0.0)
B.1.427	6 (<0.0)	
B.1.429	9 (0.1)	4 (<0.0)
Variant of Concern		
B.1.427	6 (<0.0)	
B.1.429	9 (0.1)	4 (<0.0)
P.1	1 (<0.0)	
Variant of Interest		
P.2	2 (<0.0)	

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Table 14.2.2.6.2.1.1
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* (first detected in California)
[based on Adjudication Committee Assessments Starting 14 Days After Second Injection] Using Competing Risk Method
Per-Protocol Set

	Placbo (N=14164) n(%)	mRNA-1273 (N=14287) n(%)
Number of Subjects with COVID-19 first detected in California , n (%)	15 (0.1)	3 (<0.0)
Number of Subjects with Competing Event, n (%)	729 (5.1)	52 (0.4)
Number of Subjects Censored, n (%)	13420 (94.7)	14232 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.812 (0.361, 0.945)
Person-Years [2]	5445.229	5729.927
Incidence Rate per 1,000 Person-Years (95% CI) [3]	2.755 (1.542, 4.543)	0.524 (0.108, 1.530)

*COVID-19 cases with Lineage other than B.1.427 or B.1.429 are considered as competing events
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
Source code: adhoc-t-ve-ca-sequence.sas adhoc-t-ve-ca-sequence.rtf Date/Time Generated: 07/01/2021 9:45

Table 14.2.2.6.2.1.2
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* (B.1.429)
[based on Adjudication Committee Assessments Starting 14 Days After Second Injection] Using Competing Risk Method
Per-Protocol Set

	Placbo (N=14164) n(%)	mRNA-1273 (N=14287) n(%)
Number of Subjects with COVID-19 first detected with B.1.429, n (%)	9 (0.1)	3 (<0.0)
Number of Subjects with Competing Event, n (%)	735 (5.2)	52 (0.4)
Number of Subjects Censored, n (%)	13420 (94.7)	14232 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.689 (-0.128, 0.914)
Person-Years [2]	5445.229	5729.927
Incidence Rate per 1,000 Person-Years (95% CI) [3]	1.653 (0.756, 3.138)	0.524 (0.108, 1.530)

*COVID-19 cases with Lineage other than B.1.429 are considered as competing events.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
Source code: adhoc-t-ve-b1429-sequence.sas adhoc-t-ve-b1429-sequence.rtf Date/Time Generated: 07/01/2021 9:45

Table 14.2.2.6.2.1.3
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* (Variant of Concern)
[based on Adjudication Committee Assessments Starting 14 Days After Second Injection] Using Competing Risk Method
Per-Protocol Set

	Placbo (N=14164) n(%)	mRNA-1273 (N=14287) n(%)
Number of Subjects with COVID-19 with Variant of Concern, n (%)	16 (0.1)	3 (<0.0)
Number of Subjects with Competing Event, n (%)	728 (5.1)	52 (0.4)
Number of Subjects Censored, n (%)	13420 (94.7)	14232 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		0.824 (0.404, 0.948)
Person-Years [2]	5445.229	5729.927
Incidence Rate per 1,000 Person-Years (95% CI) [3]	2.938 (1.680, 4.772)	0.524 (0.108, 1.530)

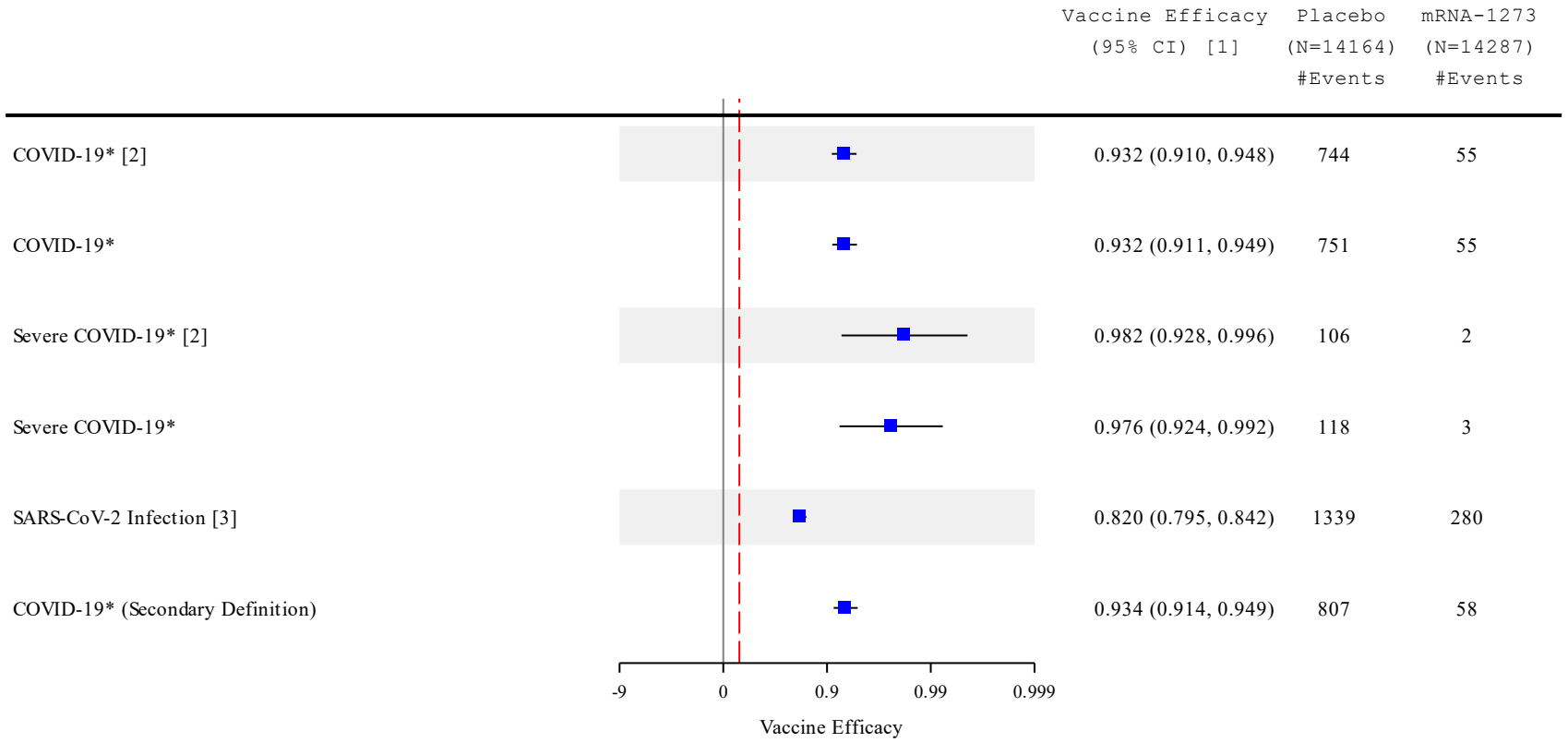
*COVID-19 cases with Lineage other than [variant of concern] are considered as competing events.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
Source code: adhoc-t-ve-vc-sequence.sas adhoc-t-ve-vc-sequence.rtf Date/Time Generated: 07/07/2021 10:50

Table 14.2.2.6.2.1.4
Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* (Variant of Interest)
[based on Adjudication Committee Assessments Starting 14 Days After Second Injection] Using Competing Risk Method
Per-Protocol Set

	Placbo (N=14164) n(%)	mRNA-1273 (N=14287) n(%)
Number of Subjects with COVID-19 with Variant of Interest, n (%)	2 (<0.0)	
Number of Subjects with Competing Event, n (%)	742 (5.2)	55 (0.4)
Number of Subjects Censored, n (%)	13420 (94.7)	14232 (99.6)
Vaccine Efficacy Based on Hazard Ratio (95% CI) [1]		1.000 (1.000, 1.000)
Person-Years [2]	5445.229	5729.927
Incidence Rate per 1,000 Person-Years (95% CI) [3]	0.367 (0.044, 1.327)	

*COVID-19 cases with Lineage other than [variant of interest] are considered as competing events.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.
[2] Person-years is defined as the total years from randomization date to the earliest of the date of symptomatic SARS-CoV-2 infection, the date of asymptomatic SARS-CoV-2 infection, last date of study participation, or efficacy data cutoff date, whichever is earlier.
[3] Incidence rate is defined as the number of subjects with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years.
Source code: adhoc-t-ve-vi-sequence.sas adhoc-t-ve-vi-sequence.rtf Date/Time Generated: 07/07/2021 10:50

Figure 14.2.1.1.1.2
Forest Plot of Primary and Secondary Efficacy Endpoint Results of Cases Starting 14 Days After Second Injection
Per-Protocol Set



Note: Footnotes are listed on the last page.
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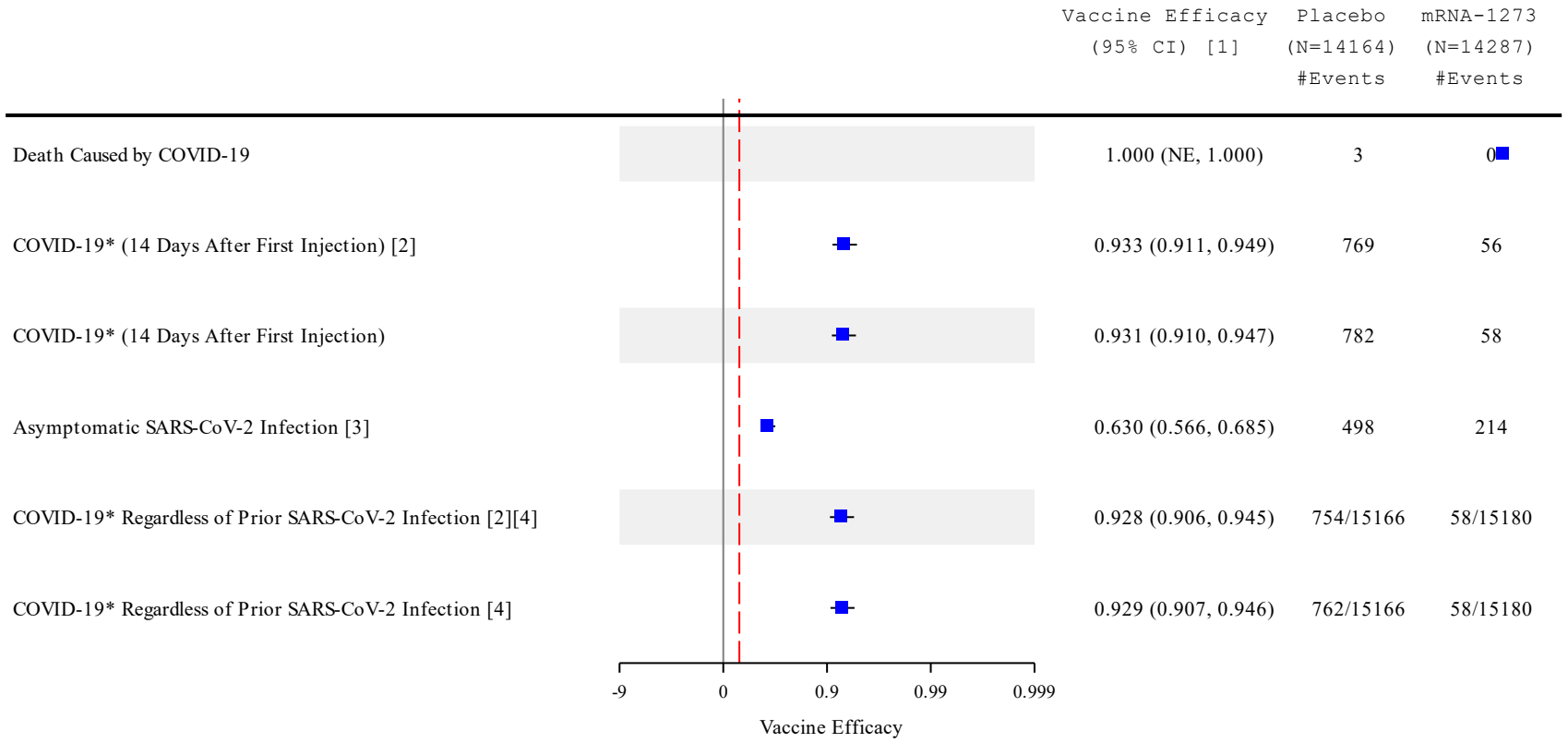
Figure 14.2.1.1.1.2
Forest Plot of Primary and Secondary Efficacy Endpoint Results of Cases Starting 14 Days After Second Injection
Per-Protocol Set



Note: Footnotes are listed on the last page.
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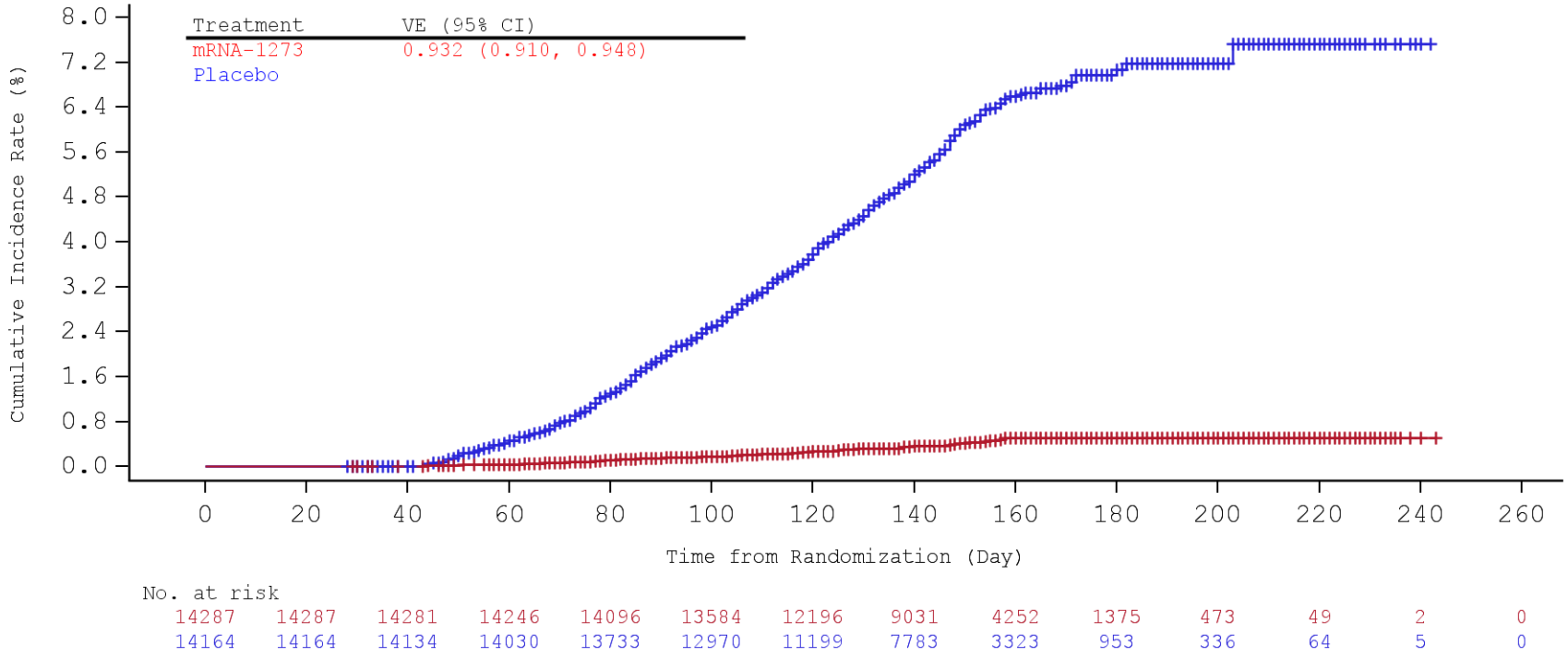
Figure 14.2.1.1.1.2
Forest Plot of Primary and Secondary Efficacy Endpoint Results of Cases Starting 14 Days After Second Injection
Per-Protocol Set

Source table: Table 14.2.1.1.1.1.1.2.
Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. For asymptomatic SARS-CoV-2 infection, VE and 95% CI are estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor.
[2] Based on Adjudication Committee assessments.
[3] Including participant decision visit.
[4] Based on the number of subjects in the Full Analysis Set.

Figure 14.2.2.1.3.1.1
Cumulative Incidence Curve of COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



Source table: Table 14.2.2.1.3.1.1.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
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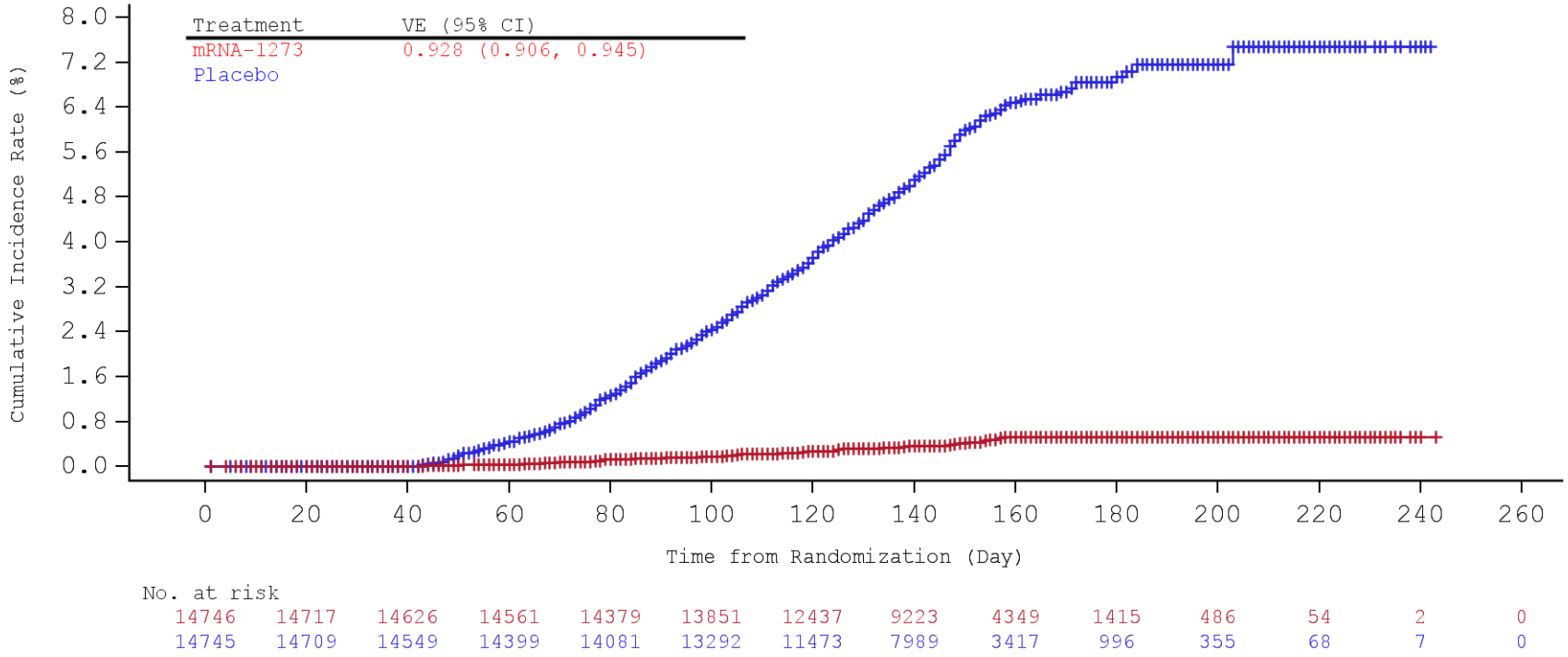
Figure 14.2.2.1.3.1.2
Cumulative Incidence Curve of COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
mITT Set



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* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
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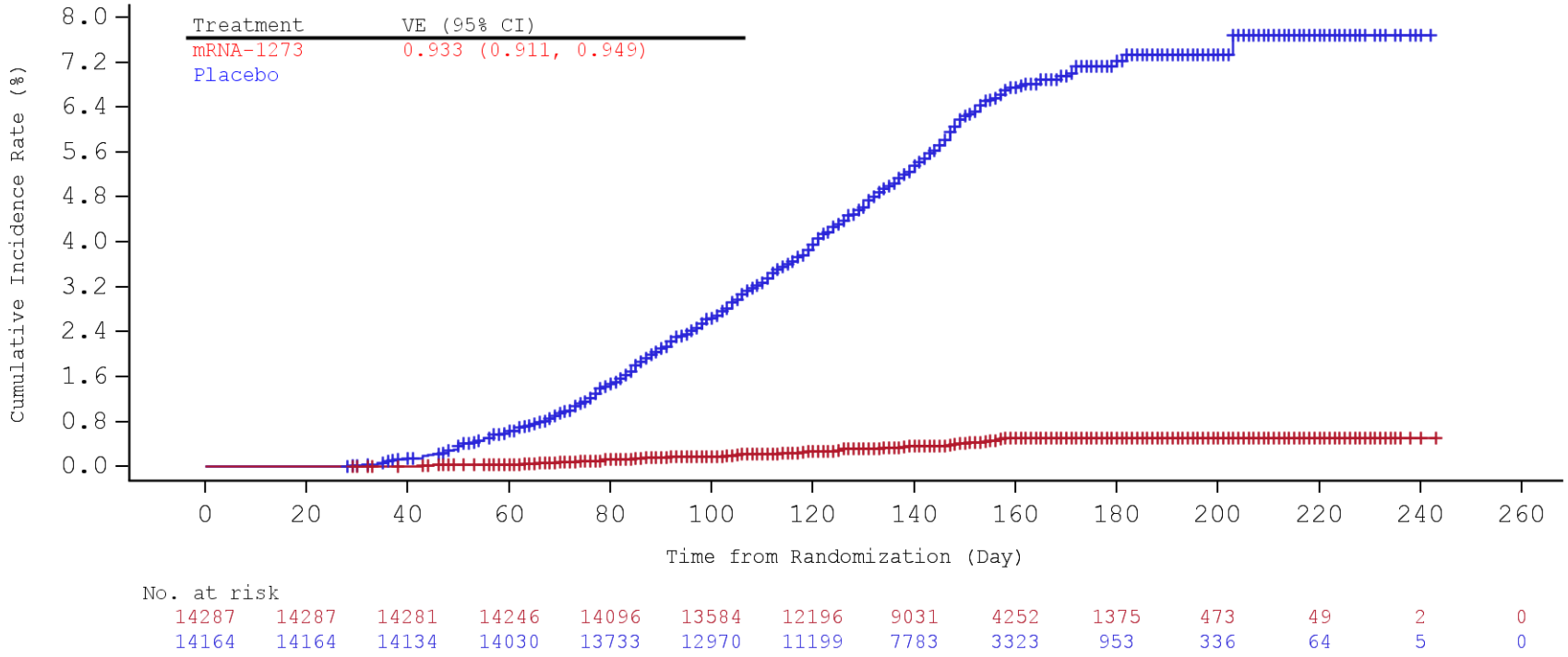
Figure 14.2.2.1.3.1.3
Cumulative Incidence Curve of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
Per-Protocol Set



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* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
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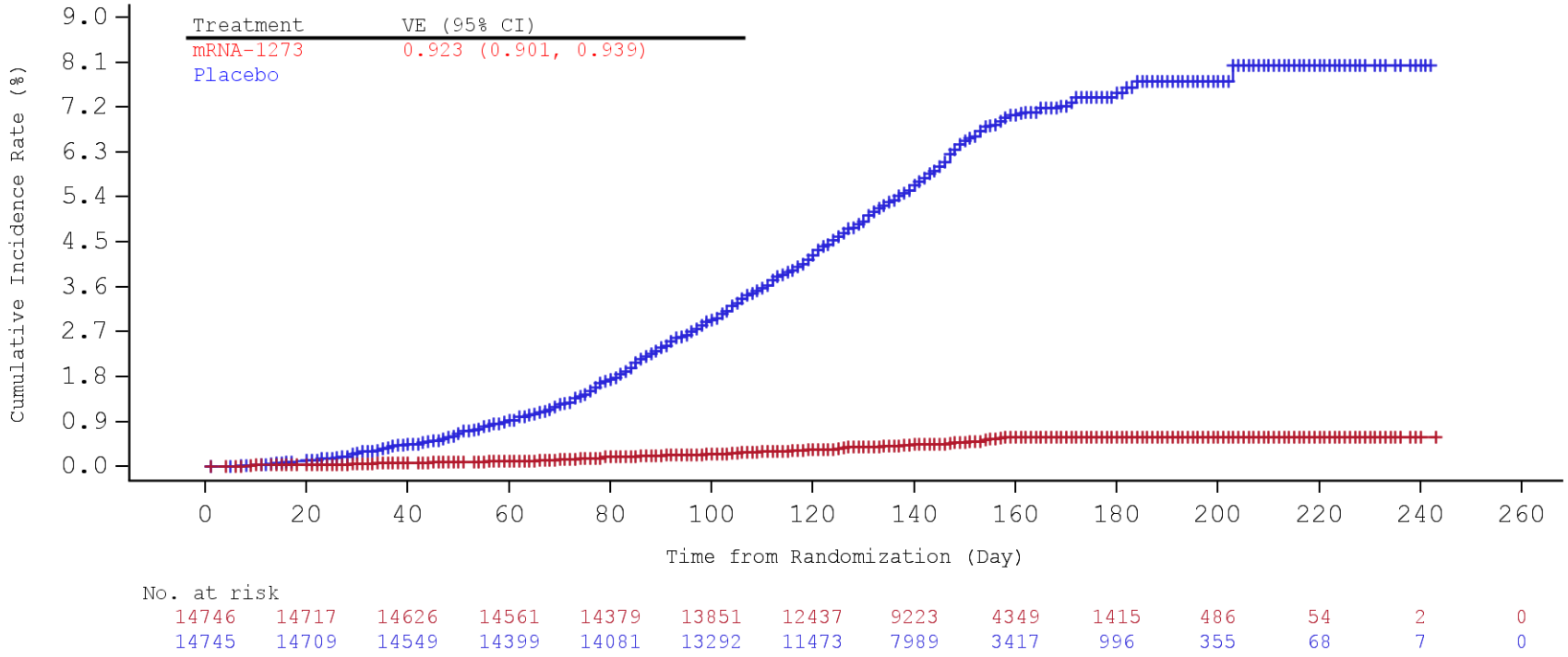
Figure 14.2.2.1.3.1.4
Cumulative Incidence Curve of COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
mITT Set



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* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020201030104.sas 10JUN2021 07:24

Figure 14.2.2.1.3.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments
Per-Protocol Set

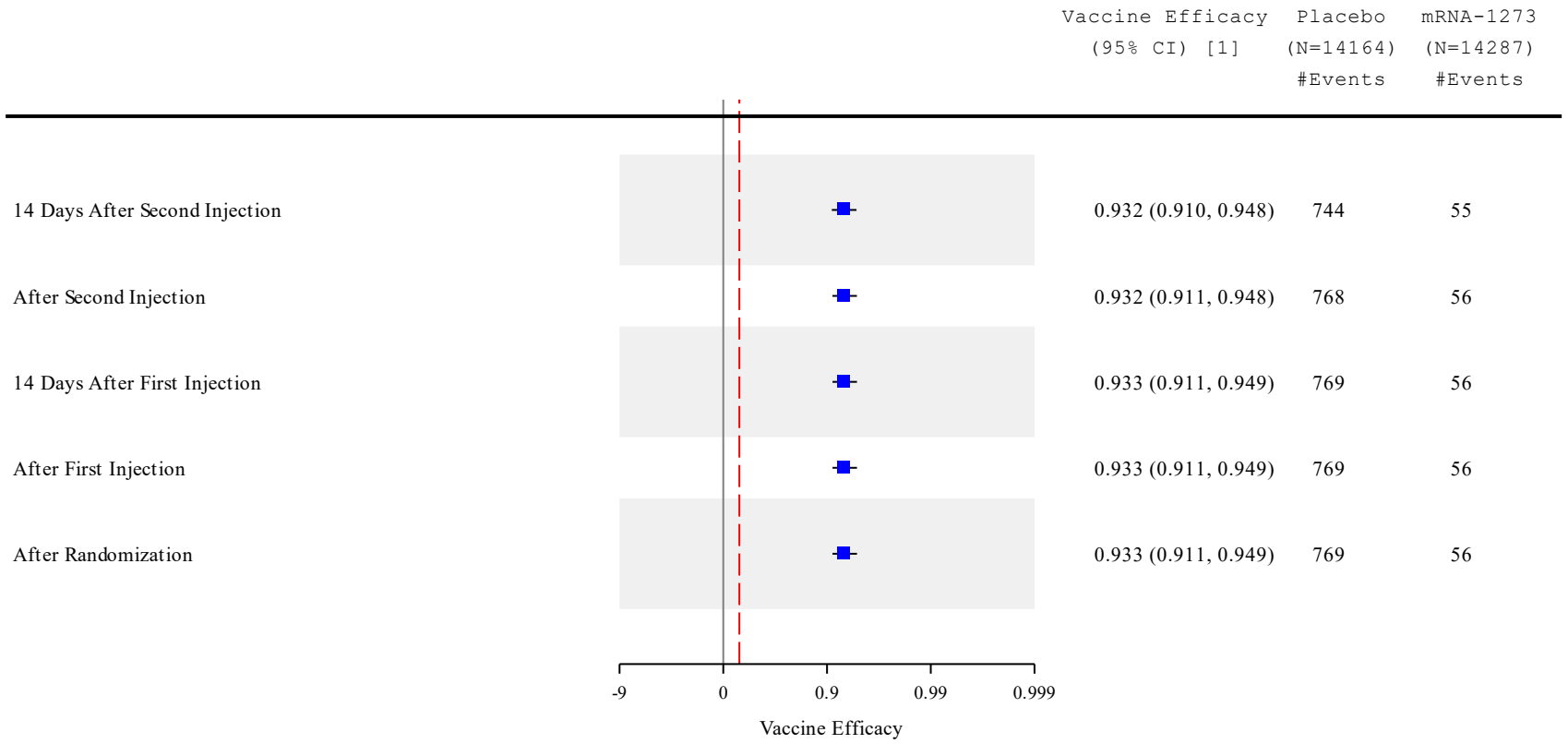

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Figure 14.2.2.1.3.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments
Per-Protocol Set

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Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Figure 14.2.2.1.3.2.3
Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

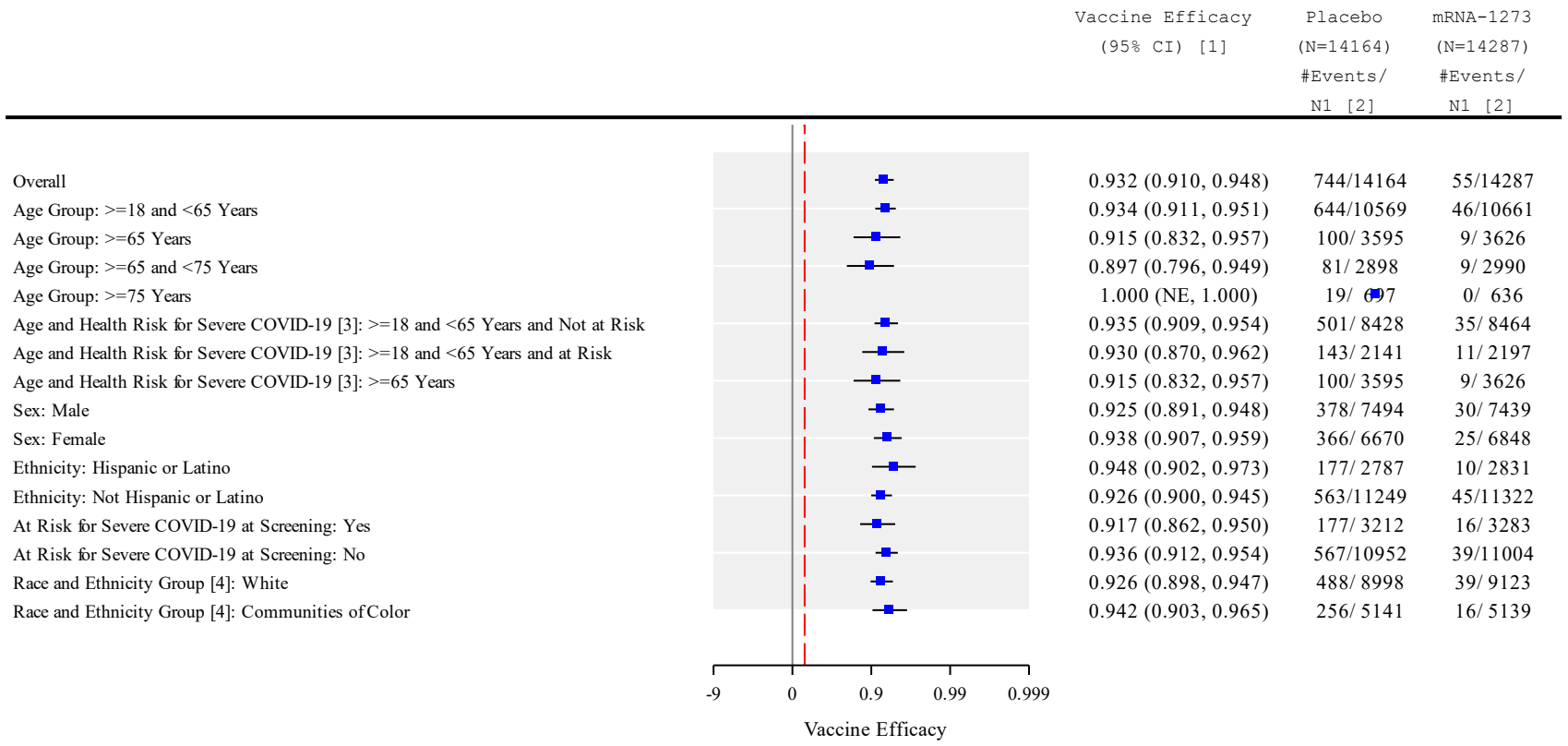

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Figure 14.2.2.1.3.2.3
Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

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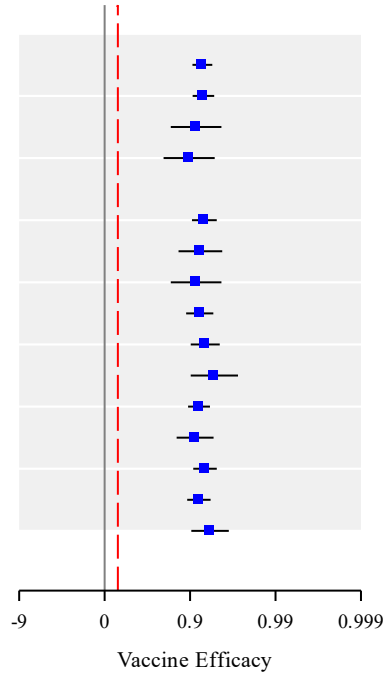
Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Based on the number of subjects in each subgroup.
[3] Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).
[4] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Figure 14.2.2.1.3.2.4
Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
mITT Set



	Vaccine Efficacy (95% CI) [1]	Placebo (N=14745) #Events/ N1 [2]	mRNA-1273 (N=14746) #Events/ N1 [2]
Overall	0.928 (0.906, 0.945)	751/14745	58/14746
Age Group: >=18 and <65 Years	0.930 (0.907, 0.948)	651/11046	49/11037
Age Group: >=65 Years	0.915 (0.832, 0.957)	100/ 3699	9/ 3709
Age Group: >=65 and <75 Years	0.897 (0.796, 0.948)	81/ 2974	9/ 3061
Age Group: >=75 Years	1.000 (NE, 1.000)	19/ 725	0/ 648
Age and Health Risk for Severe COVID-19 [3]: >=18 and <65 Years and Not at Risk	0.932 (0.905, 0.951)	505/ 8810	37/ 8776
Age and Health Risk for Severe COVID-19 [3]: >=18 and <65 Years and at Risk	0.924 (0.864, 0.958)	146/ 2236	12/ 2261
Age and Health Risk for Severe COVID-19 [3]: >=65 Years	0.915 (0.832, 0.957)	100/ 3699	9/ 3709
Sex: Male	0.923 (0.889, 0.947)	382/ 7820	31/ 7678
Sex: Female	0.934 (0.902, 0.955)	369/ 6925	27/ 7068
Ethnicity: Hispanic or Latino	0.948 (0.902, 0.973)	178/ 2947	10/ 2957
Ethnicity: Not Hispanic or Latino	0.921 (0.894, 0.941)	569/11665	48/11650
At Risk for Severe COVID-19 at Screening: Yes	0.913 (0.856, 0.947)	180/ 3355	17/ 3375
At Risk for Severe COVID-19 at Screening: No	0.933 (0.908, 0.951)	571/11390	41/11371
Race and Ethnicity Group [4]: White	0.921 (0.892, 0.942)	494/ 9303	42/ 9364
Race and Ethnicity Group [4]: Communities of Color	0.942 (0.903, 0.965)	257/ 5416	16/ 5356

Note: Footnotes are listed on the last page.
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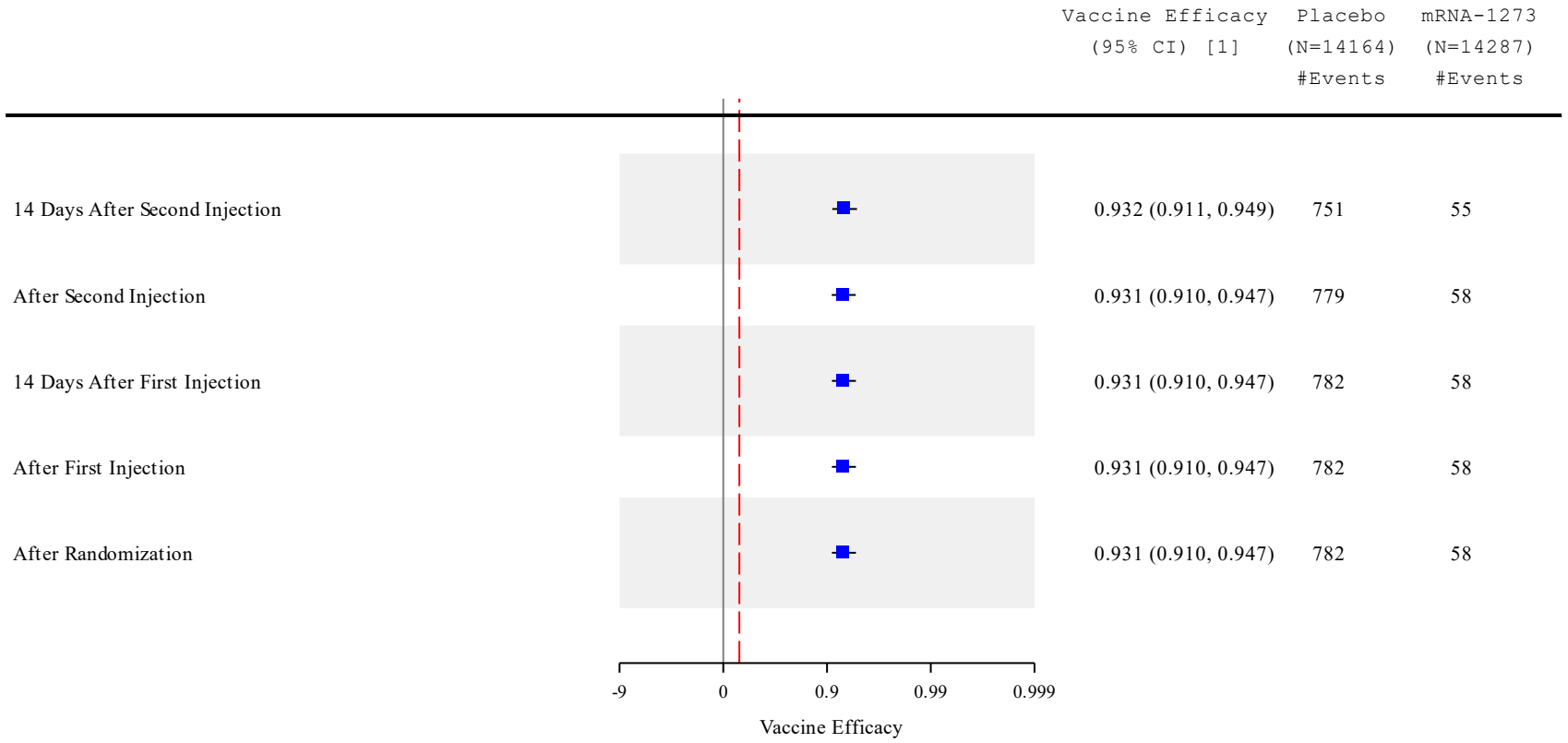
Figure 14.2.2.1.3.2.4
Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
mITT Set

Source table: Table 14.2.2.1.3.1.2, Table 14.2.2.1.3.6.1.2, Table 14.2.2.1.3.6.2.2, Table 14.2.2.1.3.6.3.2, Table 14.2.2.1.3.6.4.2, Table 14.2.2.1.3.6.6.2, Table 14.2.2.1.3.6.7.2, Table 14.2.2.1.3.6.10.2.
Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Based on the number of subjects in each subgroup.
[3] Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).
[4] White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing.

Figure 14.2.2.1.4.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19*
Per-Protocol Set



Note: Footnotes are listed on the last page.
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Figure 14.2.2.1.4.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19*
Per-Protocol Set

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Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Figure 14.2.2.1.4.2.2
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19*
mITT Set

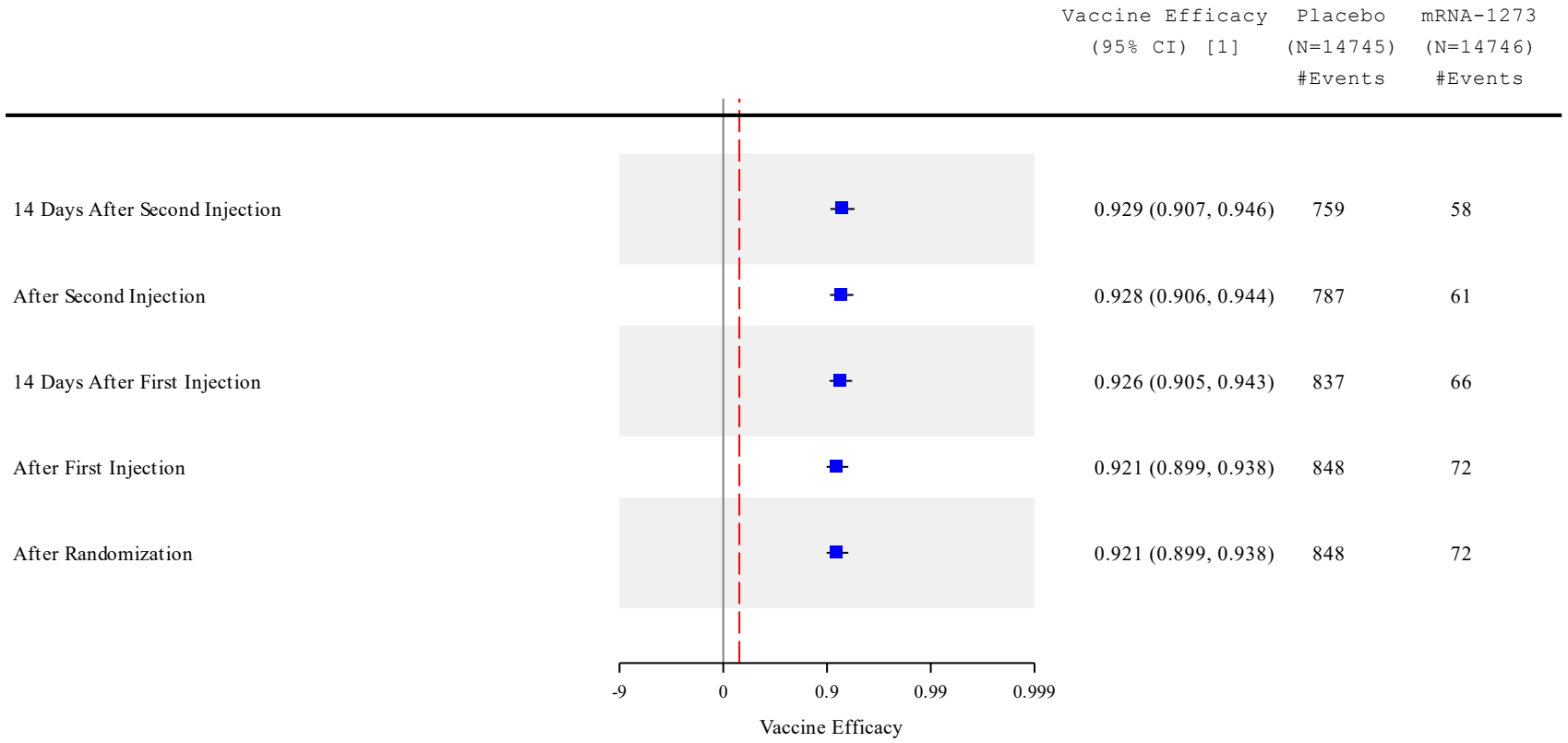

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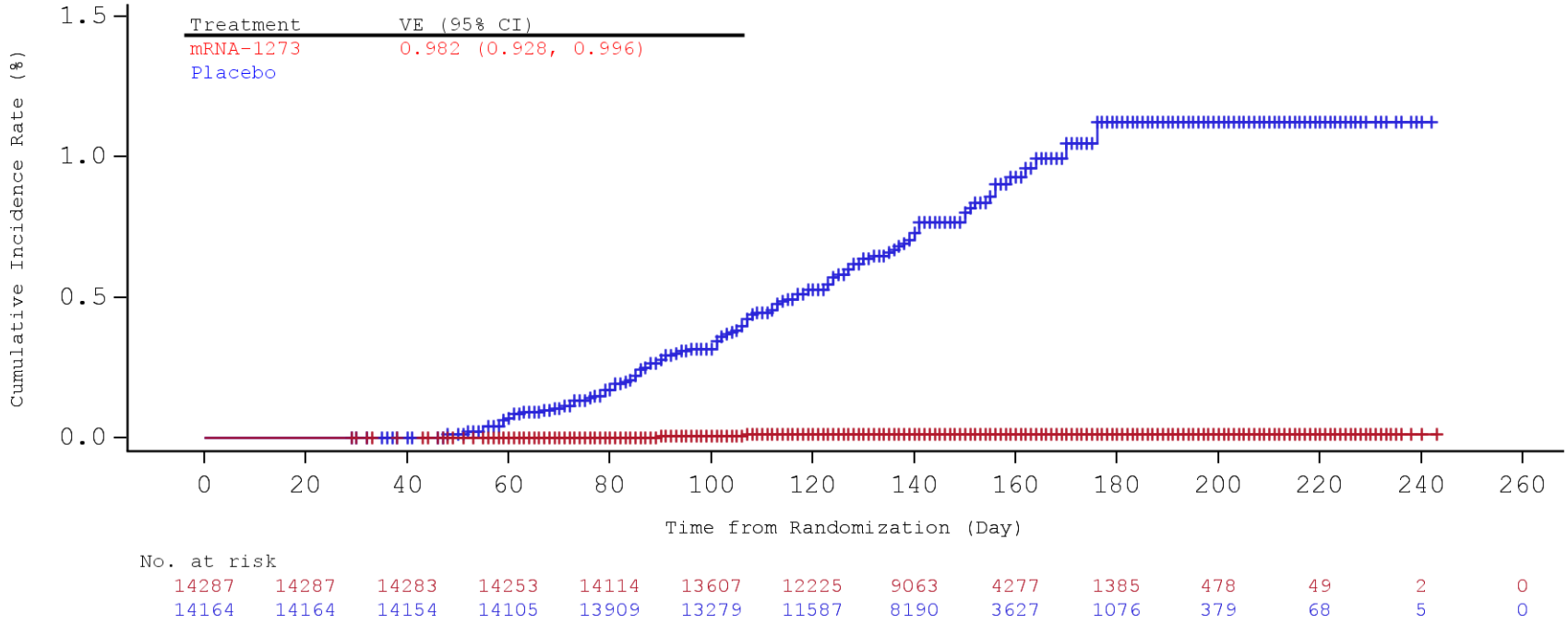
Figure 14.2.2.1.4.2.2
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19*
mITT Set

Source table: Table 14.2.2.1.4.1.2, Table 14.2.2.1.4.2.2, Table 14.2.2.1.4.3.2, Table 14.2.2.1.4.4.2, Table 14.2.2.1.4.5.2.
Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Figure 14.2.2.2.3.1.1
Cumulative Incidence Curve of Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



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* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
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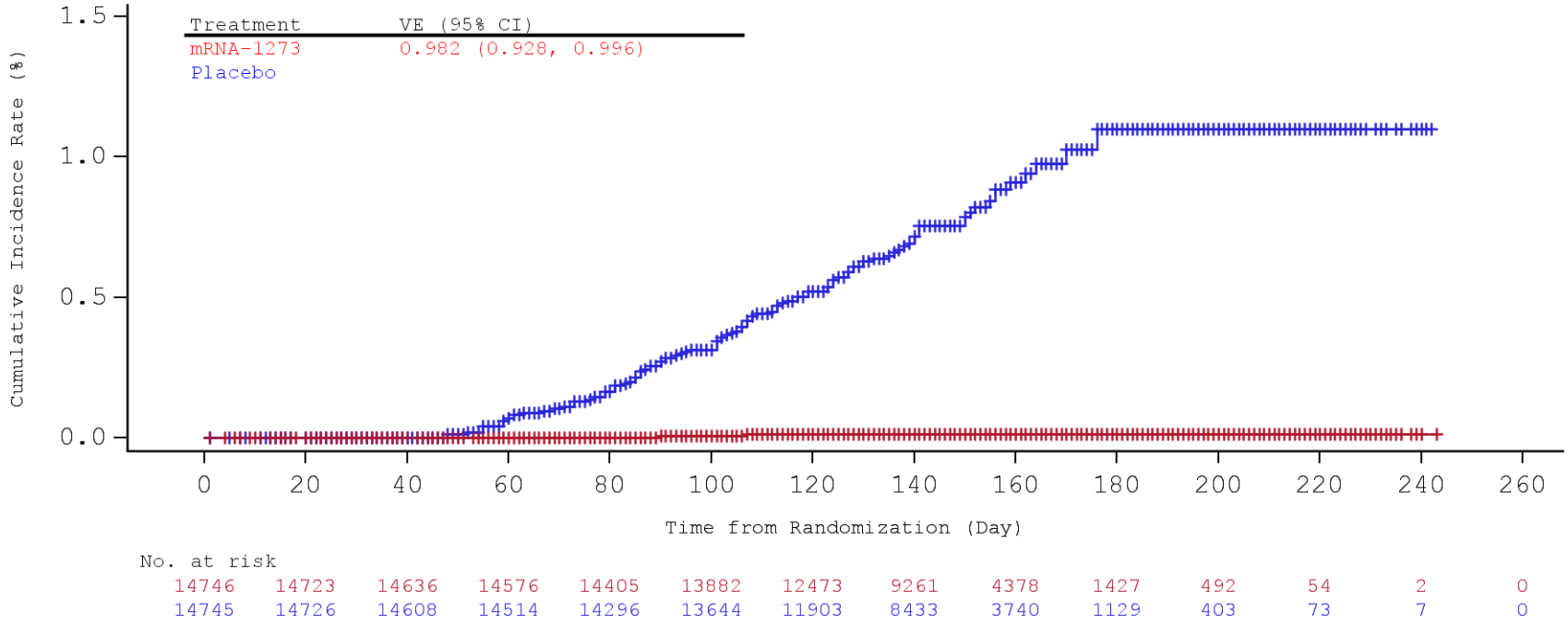
Figure 14.2.2.2.3.1.2
Cumulative Incidence Curve of Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
mITT Set



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* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
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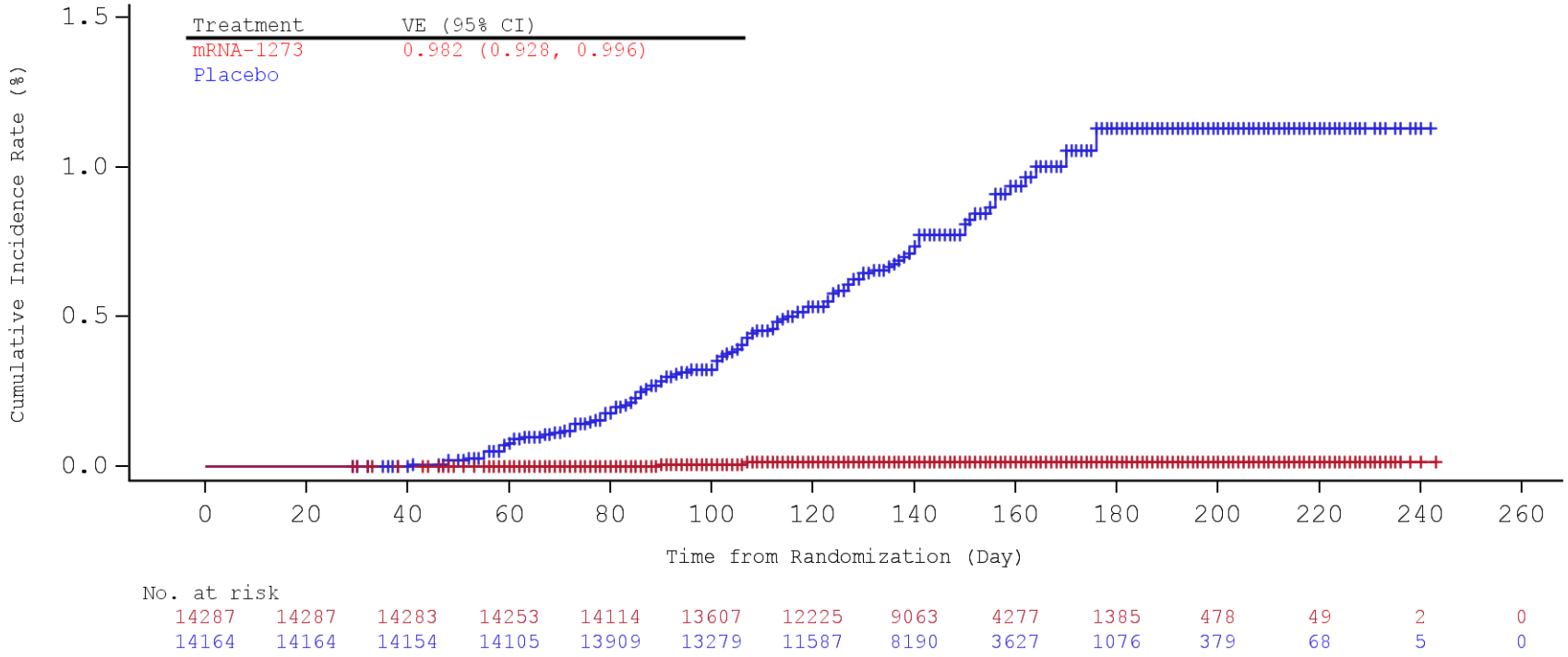
Figure 14.2.2.2.3.1.3
Cumulative Incidence Curve of Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
Per-Protocol Set



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Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
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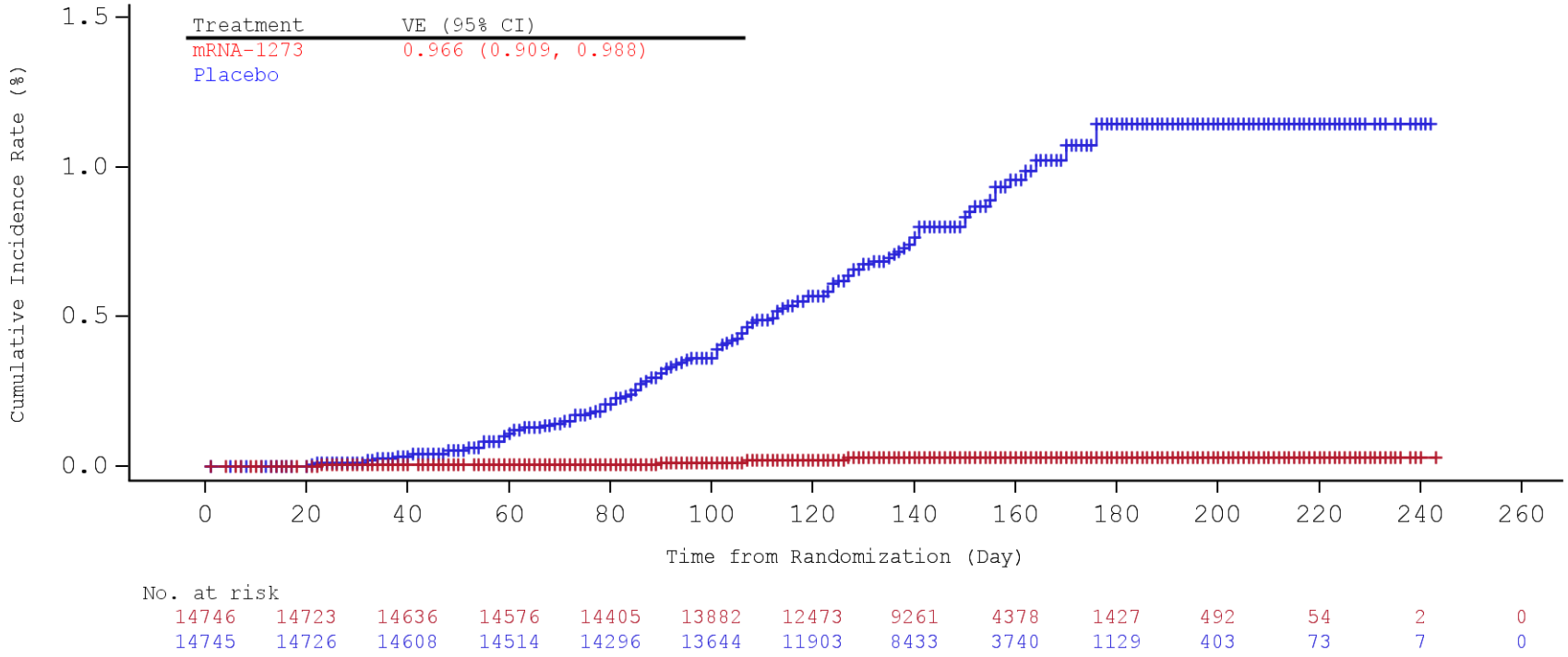
Figure 14.2.2.2.3.1.4
Cumulative Incidence Curve of Severe COVID-19* Based on Adjudication Committee Assessments Starting After Randomization
mITT Set



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* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
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Figure 14.2.2.2.3.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments
Per-Protocol Set

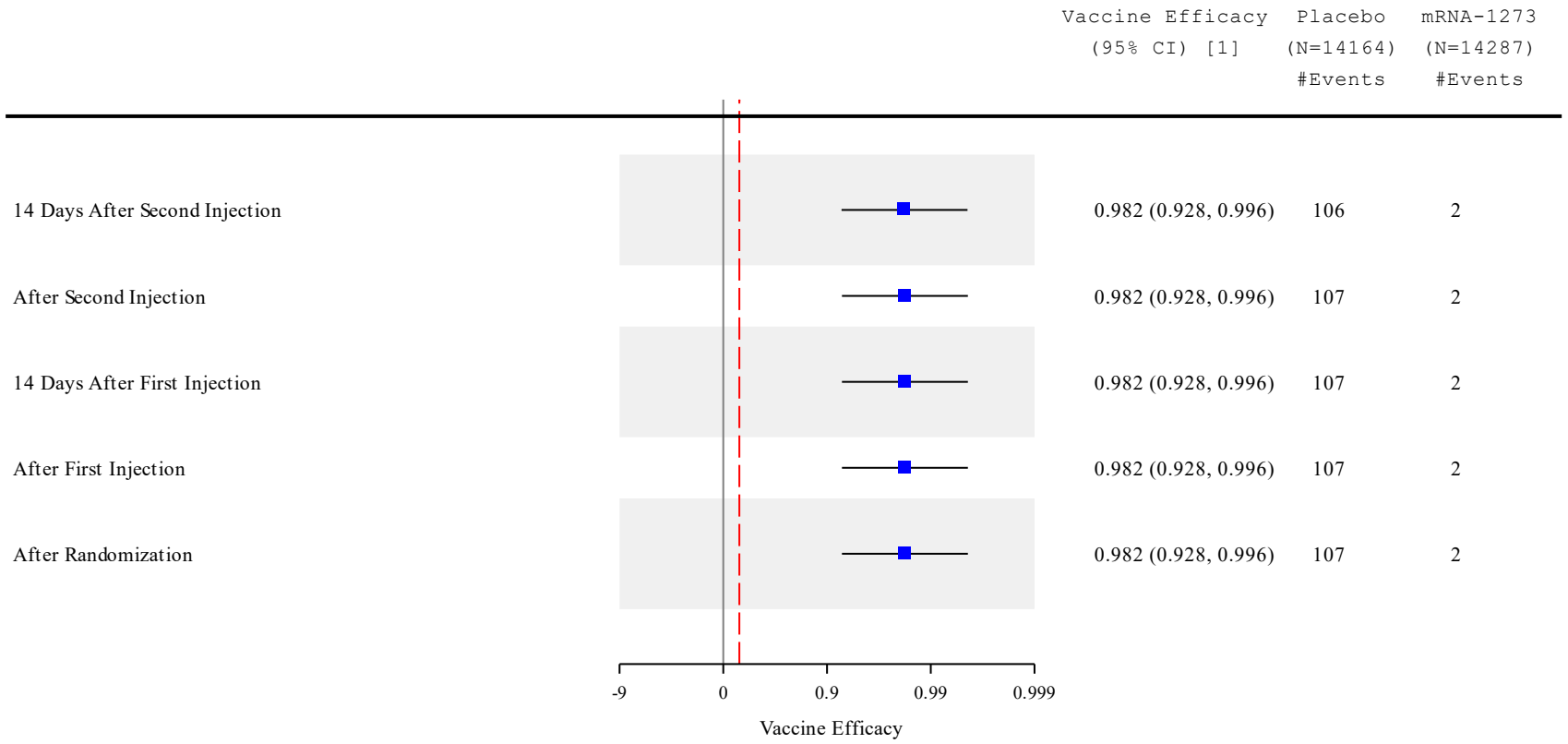

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Figure 14.2.2.2.3.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments
Per-Protocol Set

Source table: Table 14.2.2.2.3.1.1, Table 14.2.2.2.3.2, Table 14.2.2.2.3.3, Table 14.2.2.2.3.4, Table 14.2.2.2.3.5.1.
Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Figure 14.2.2.2.3.2.2
Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

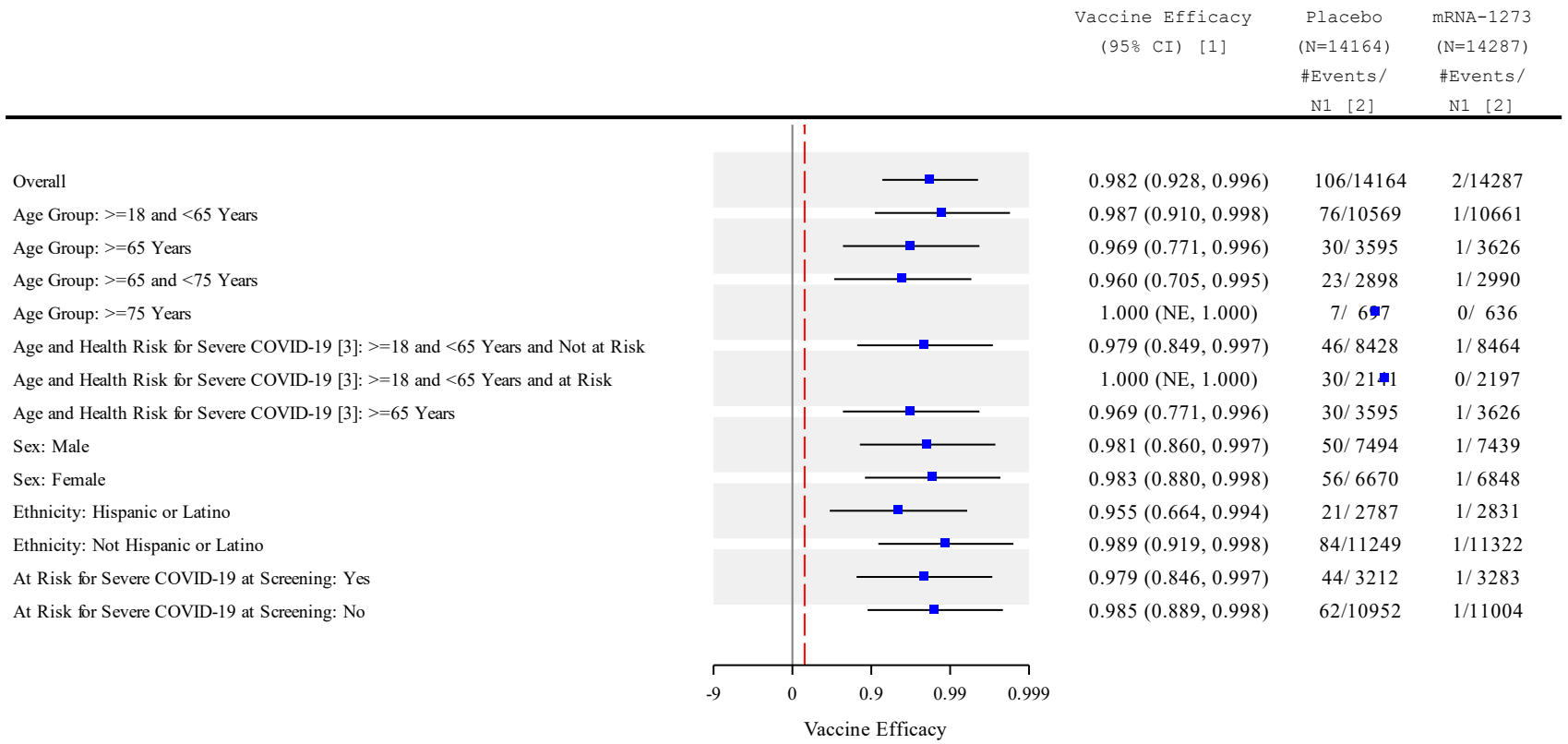

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Figure 14.2.2.2.3.2.2
Forest Plot of Subgroup Analysis of Vaccine Efficacy of mRNA-1273 to Prevent Severe COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set

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Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.
[2] Based on the number of subjects in each subgroup.
[3] Age and health risk for severe COVID-19 are derived from age and risk factor collected on case report form (CRF).

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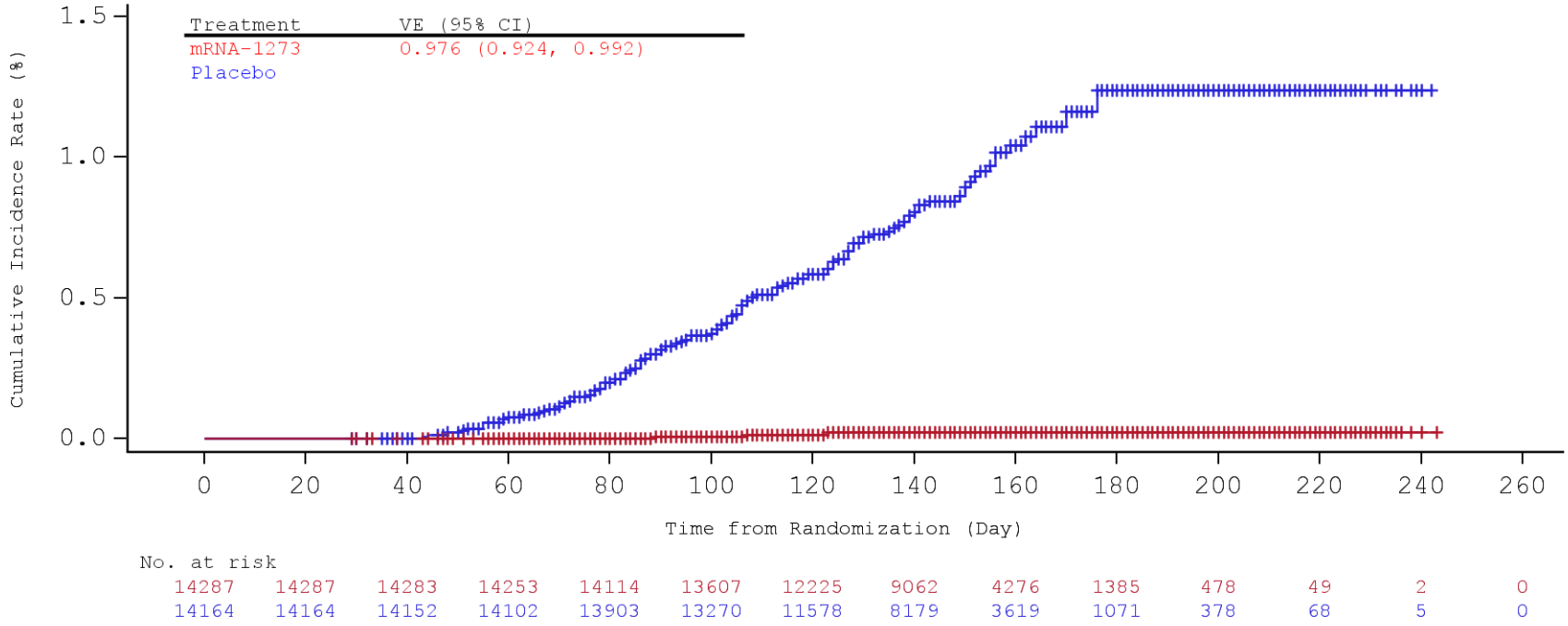
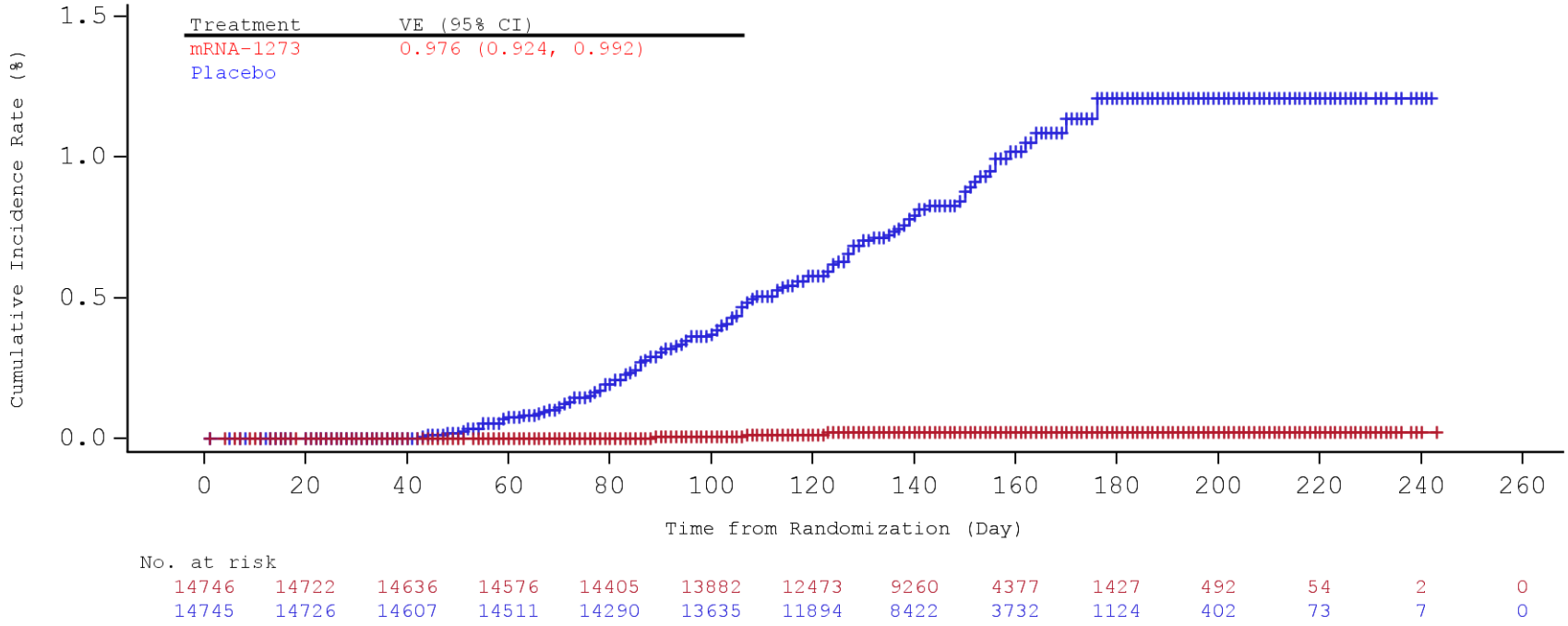
Figure 14.2.2.2.4.1.1
Cumulative Incidence Curve of Severe COVID-19* Starting 14 Days After Second Injection
Per-Protocol Set



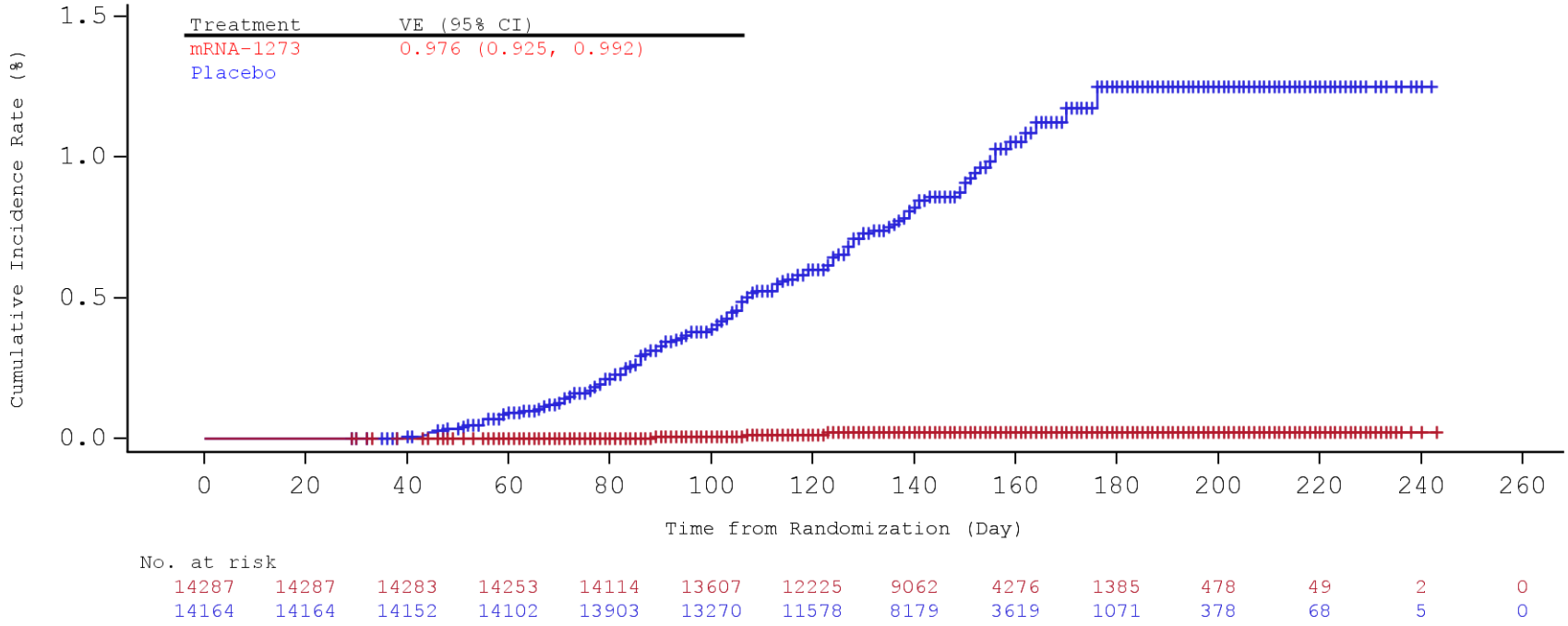
Source table: Table 14.2.2.2.4.1.1.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020202040101.sas 23JUN2021 06:30

Figure 14.2.2.2.4.1.2
Cumulative Incidence Curve of Severe COVID-19* Starting 14 Days After Second Injection
mITT Set



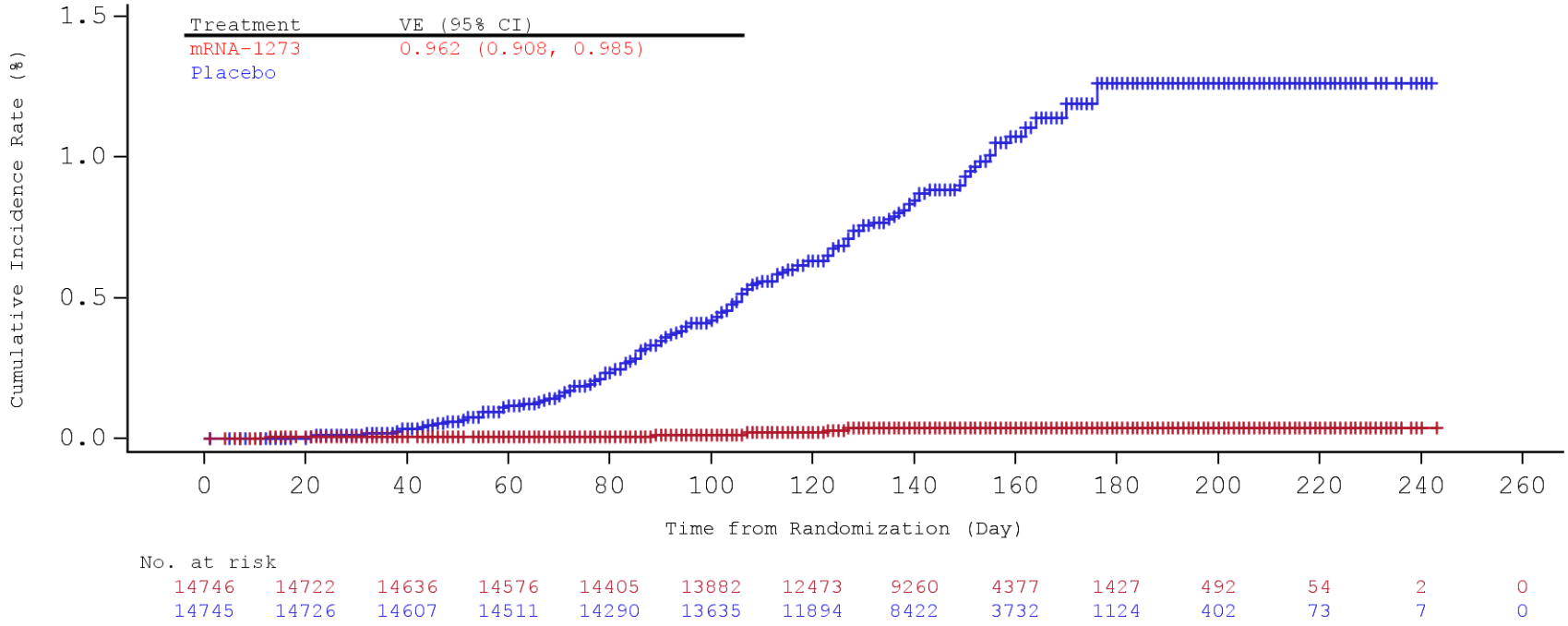
Source table: Table 14.2.2.2.4.1.2.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020202040102.sas 23JUN2021 06:30

Figure 14.2.2.2.4.1.3
Cumulative Incidence Curve of Severe COVID-19* Starting After Randomization
Per-Protocol Set



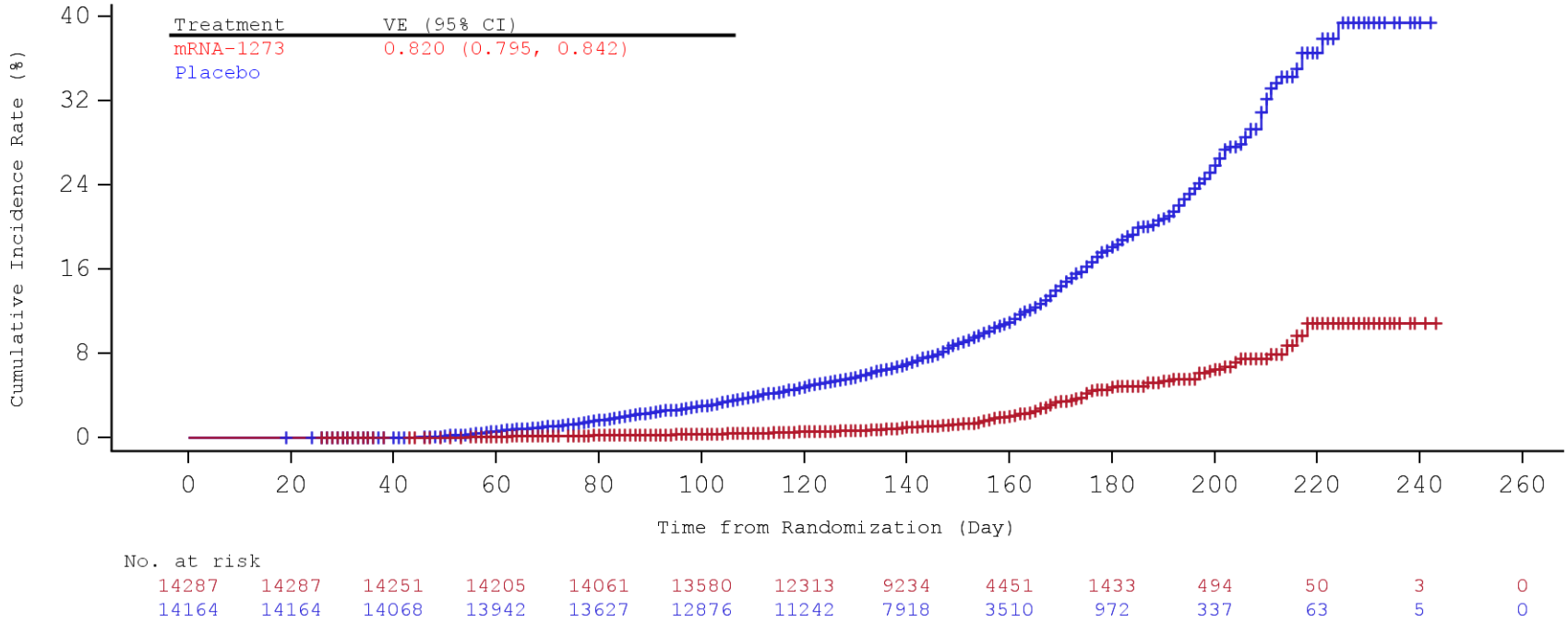
Source table: Table 14.2.2.2.4.5.1.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020202040103.sas 23JUN2021 06:31

Figure 14.2.2.2.4.1.4
Cumulative Incidence Curve of Severe COVID-19* Starting After Randomization
mITT Set



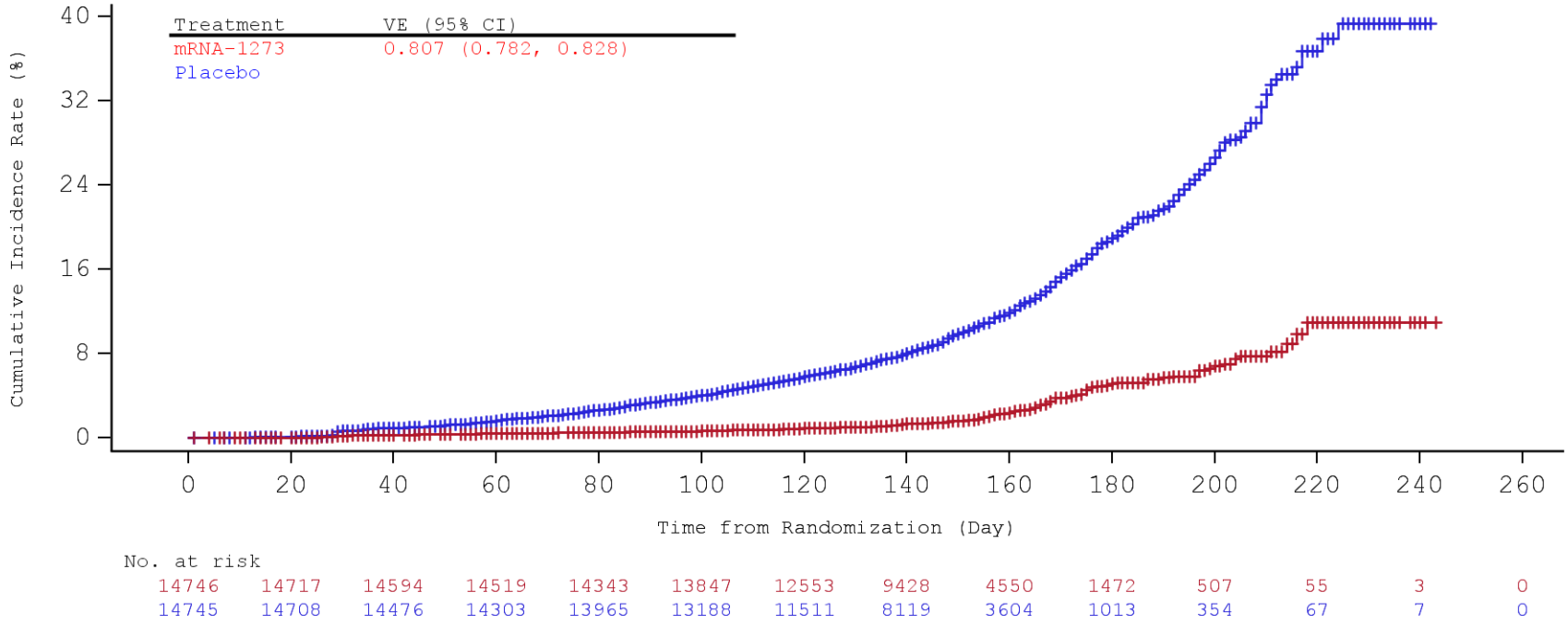
Source table: Table 14.2.2.2.4.5.2.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Severe COVID-19 case is defined based on COVID-19 case.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020202040104.sas 23JUN2021 06:31

Figure 14.2.2.3.1.1.2
Cumulative Incidence Curve of SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After Second Injection Including Participant Decision Visit
Per-Protocol Set



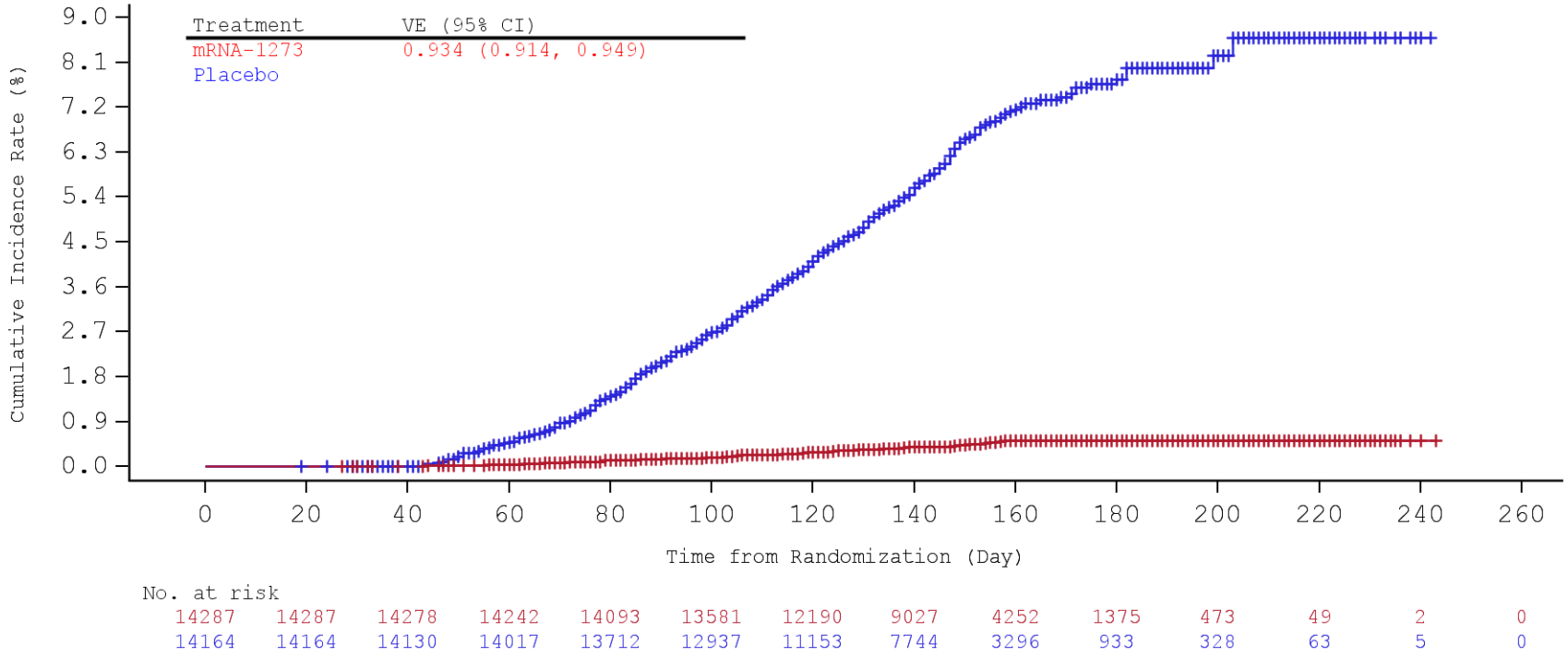
Source table: Table 14.2.2.3.1.1.2.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020203010102.sas 26JUL2021 03:25

Figure 14.2.2.3.1.4.2
Cumulative Incidence Curve of SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting After Randomization Including Participant Decision Visit
mITT Set



Source table: Table 14.2.2.3.5.2.2.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020203010402.sas 26JUL2021 03:25

Figure 14.2.2.4.2.1.1
Cumulative Incidence Curve of Secondary Definition of COVID-19* Starting 14 Days After Second Injection
Per-Protocol Set



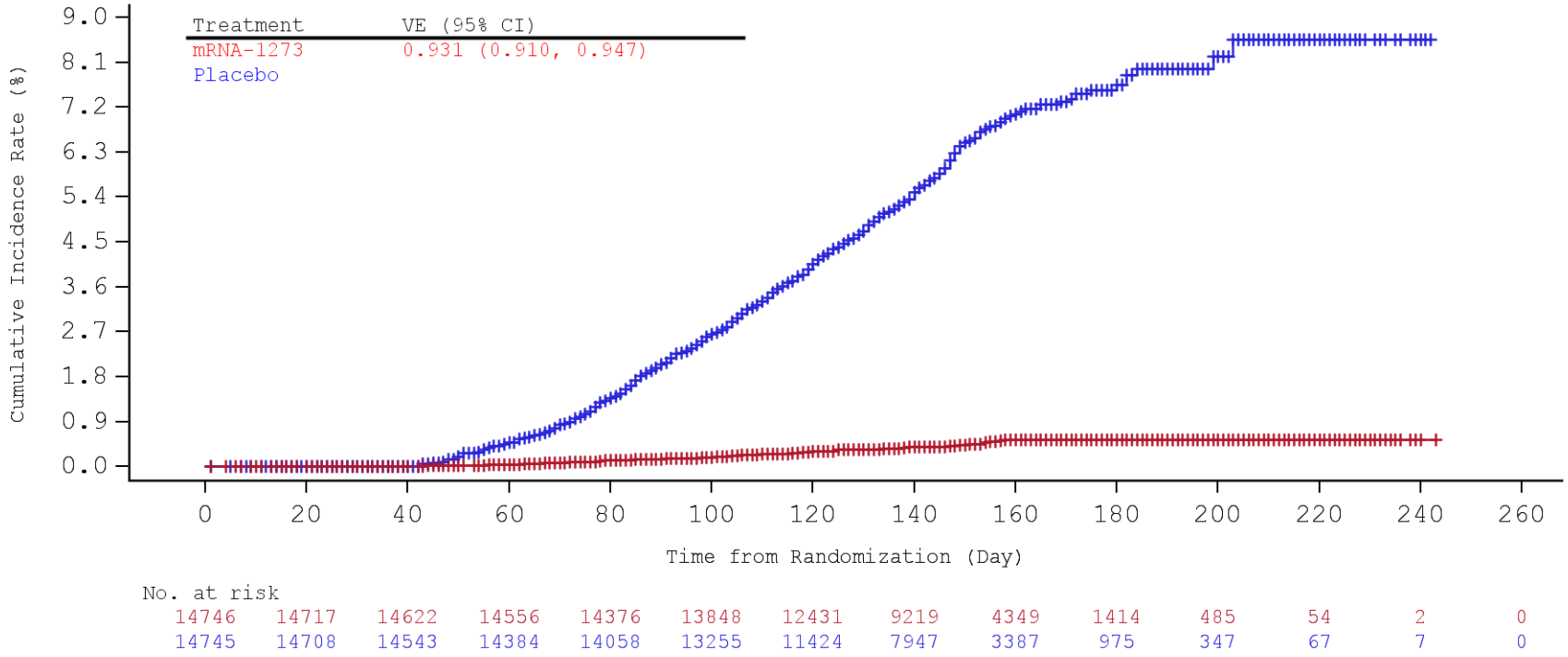
Source table: Table 14.2.2.4.2.1.1.

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

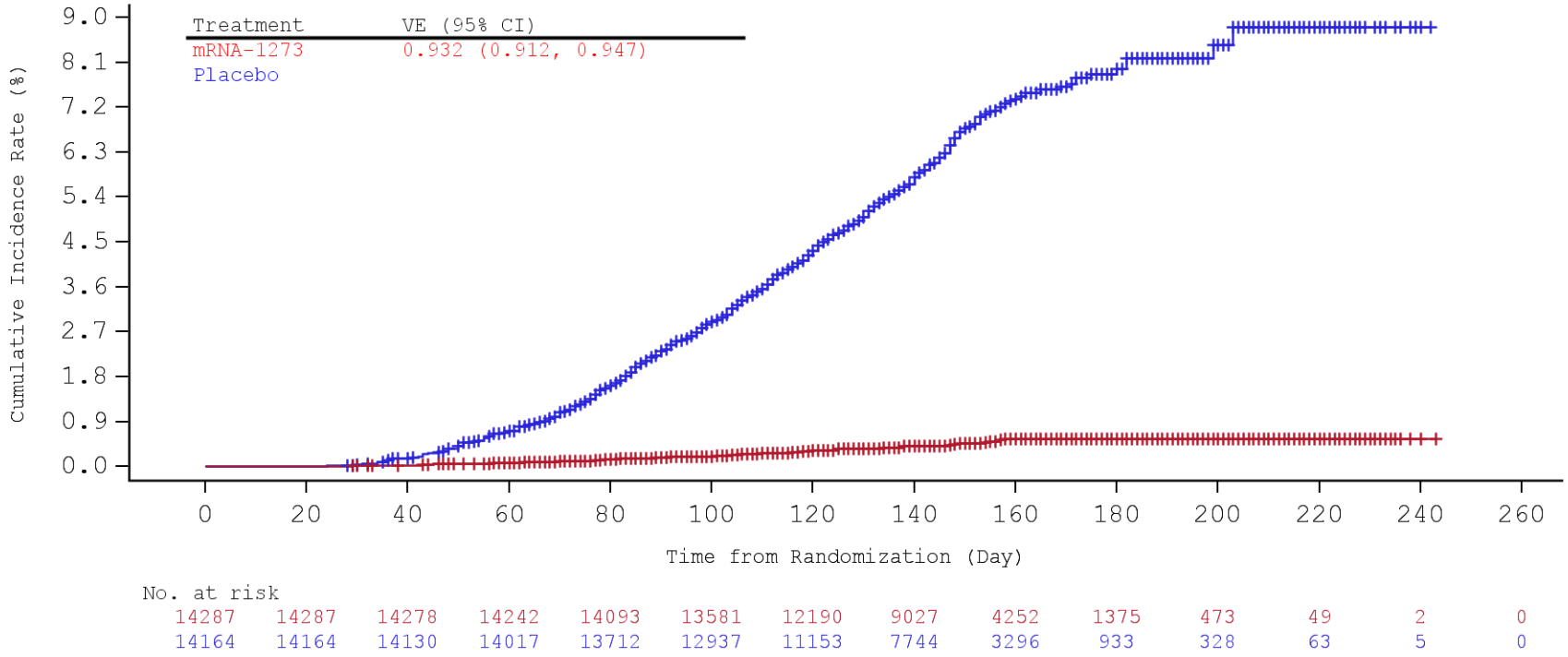
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020204020101.sas 10JUN2021 15:48

Figure 14.2.2.4.2.1.2
Cumulative Incidence Curve of Secondary Definition of COVID-19* Starting 14 Days After Second Injection
mITT Set



Source table: Table 14.2.2.4.2.1.2.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020204020102.sas 10JUN2021 15:49

Figure 14.2.2.4.2.1.3
Cumulative Incidence Curve of Secondary Definition of COVID-19* Starting After Randomization
Per-Protocol Set



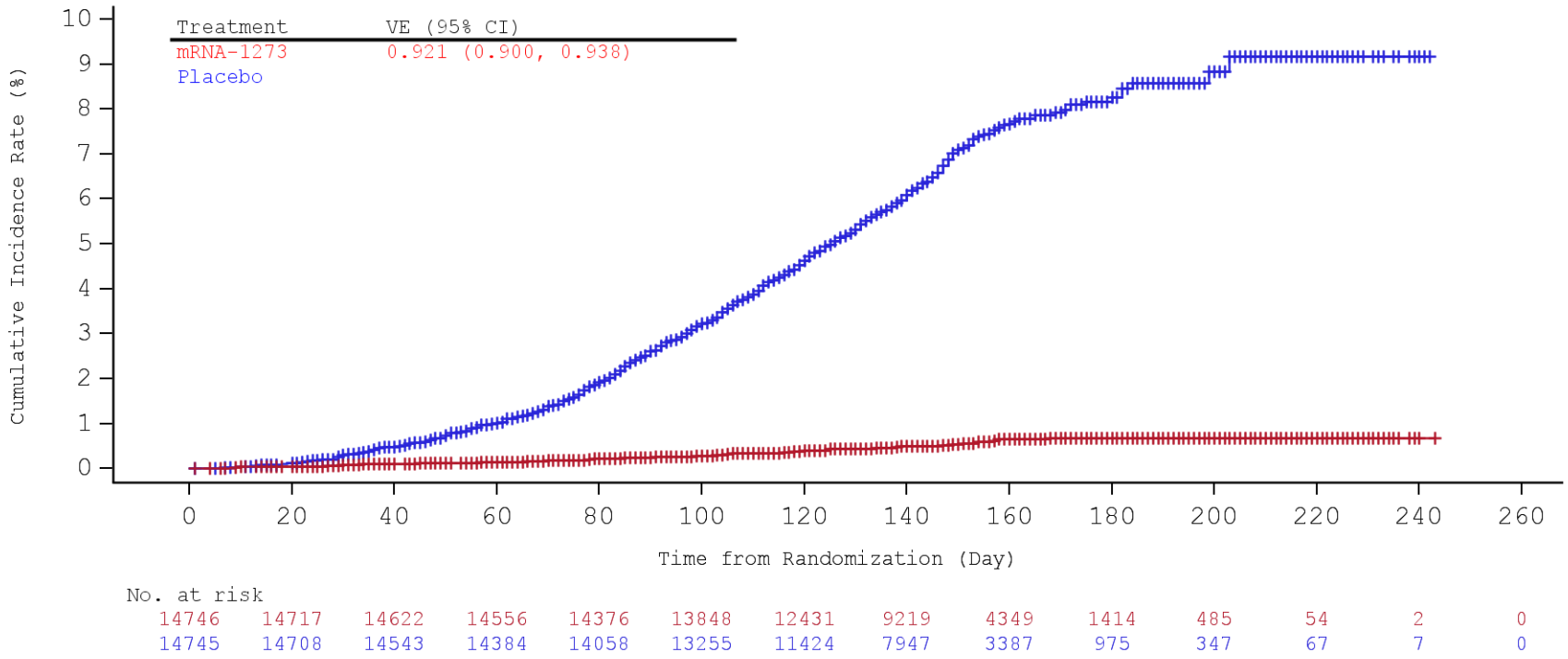
Source table: Table 14.2.2.4.2.5.1.

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

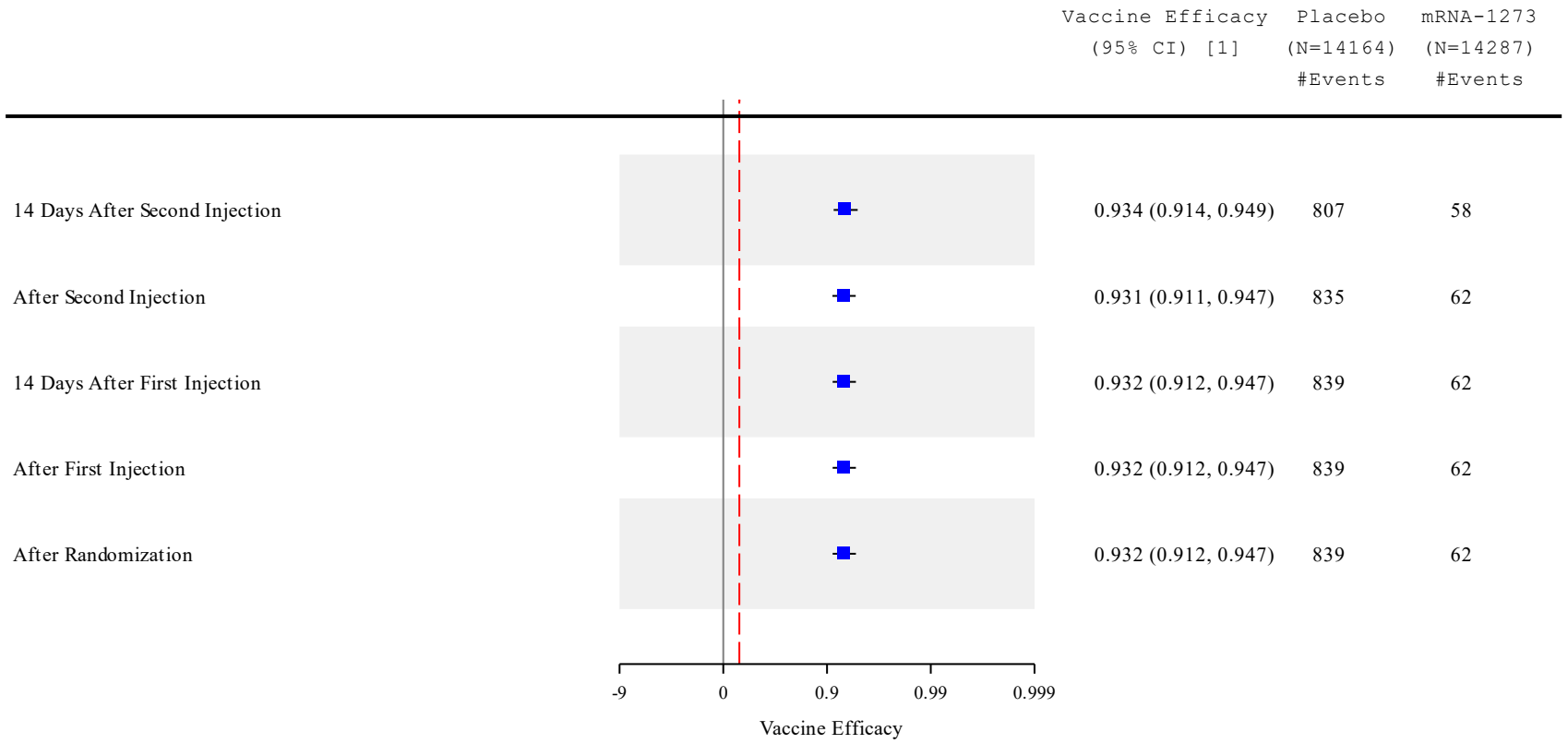
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020204020103.sas 10JUN2021 15:49

Figure 14.2.2.4.2.1.4
Cumulative Incidence Curve of Secondary Definition of COVID-19* Starting After Randomization
mITT Set



Source table: Table 14.2.2.4.2.5.2.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020204020104.sas 10JUN2021 15:49

Figure 14.2.2.4.2.2
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19*
Per-Protocol Set

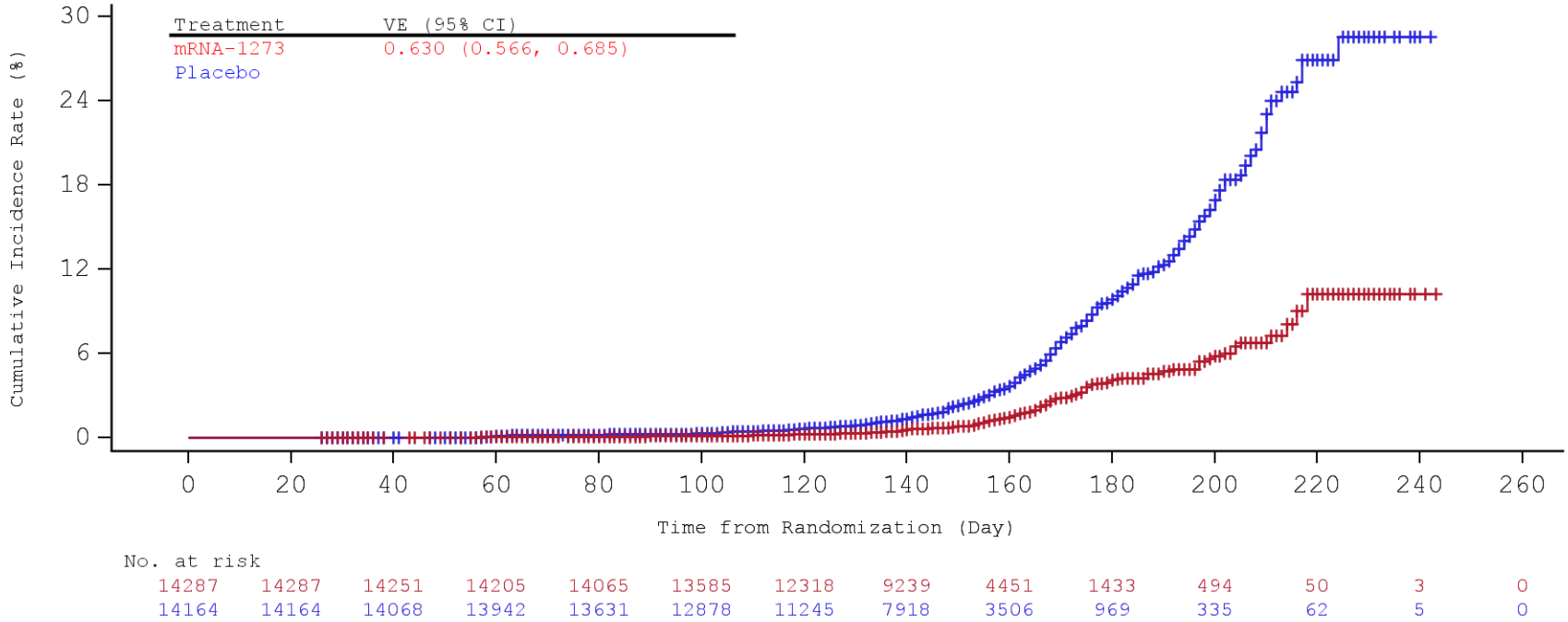


Note: Footnotes are listed on the last page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f140202040202.sas 10JUN2021 15:49

Figure 14.2.2.4.2.2
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent Secondary Definition of COVID-19*
Per-Protocol Set

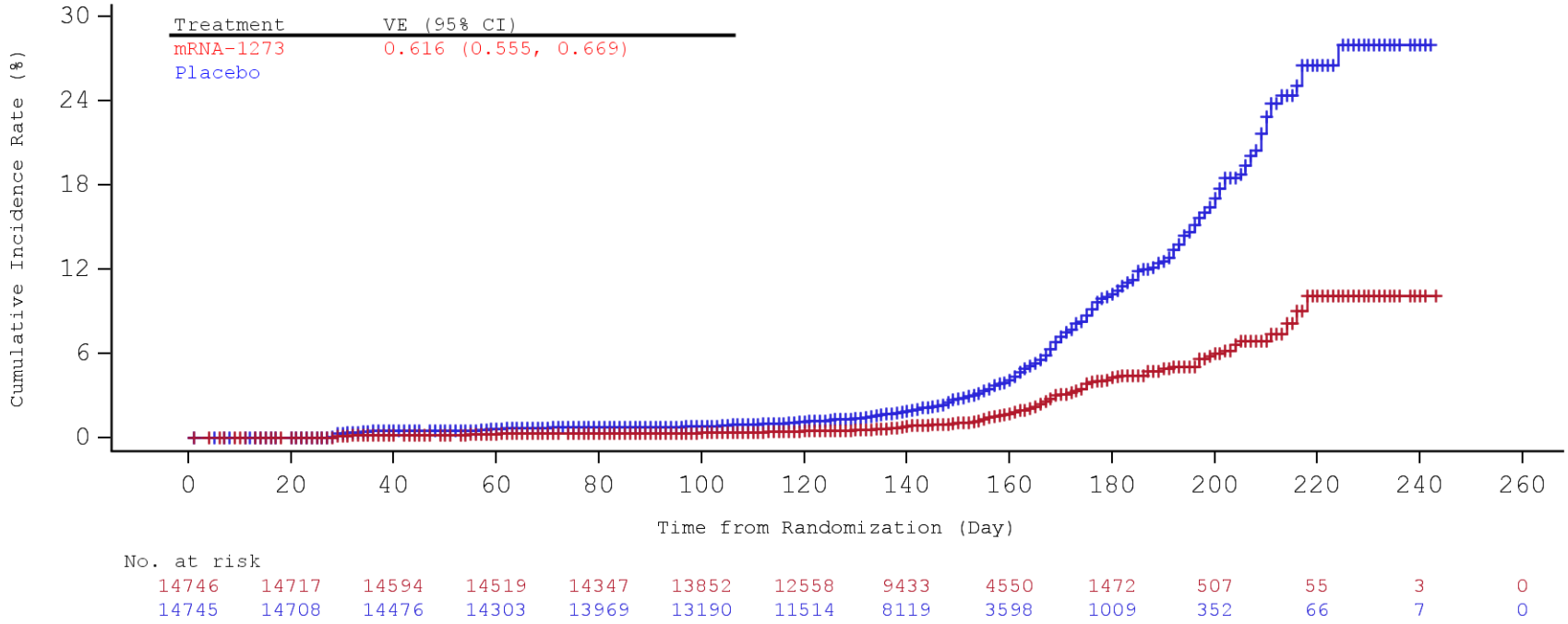
Source table: Table 14.2.2.4.2.1.1, Table 14.2.2.4.2.2.1, Table 14.2.2.4.2.3, Table 14.2.2.4.2.4, Table 14.2.2.4.2.5.1.
Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Figure 14.2.2.6.2.1.1.2
Cumulative Incidence Curve of Asymptomatic SARS-CoV-2 Infection Starting 14 Days After Second Injection Including Participant Decision Visit Using Competing Risk Method
Per-Protocol Set



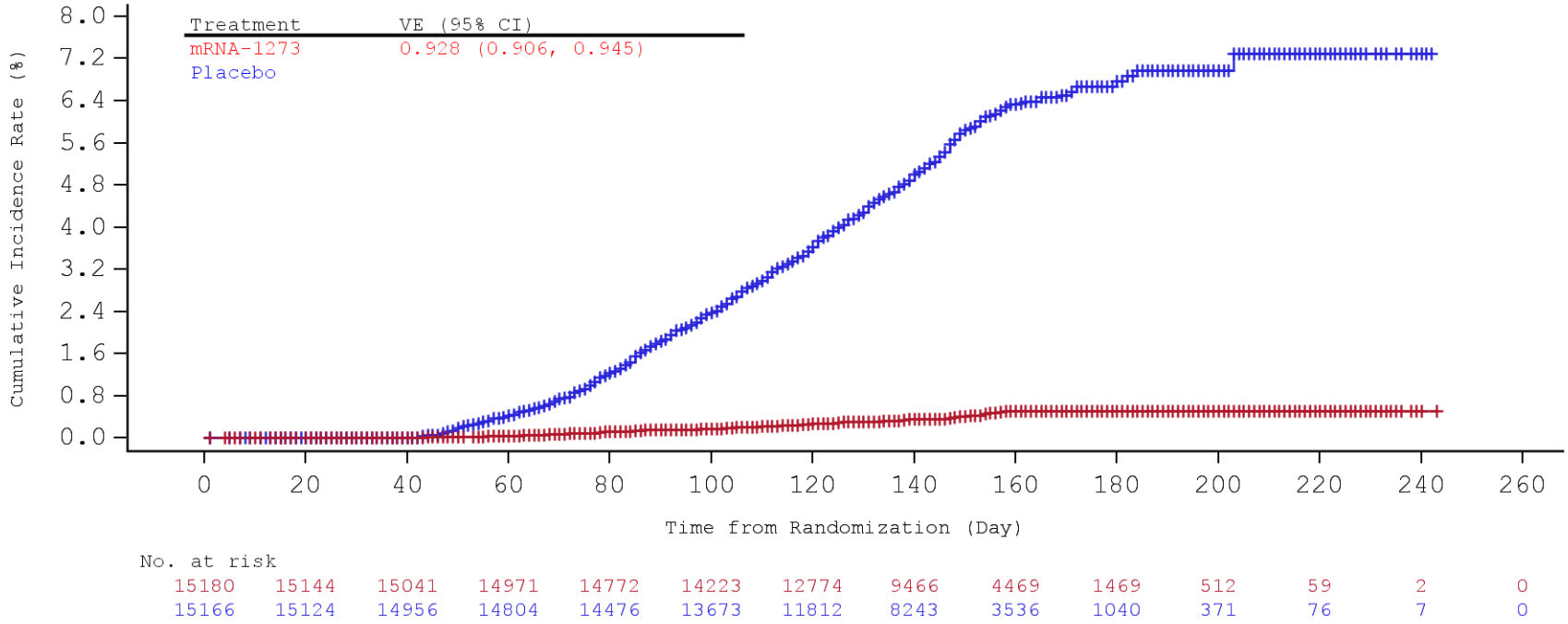
Source table: Table 14.2.2.6.2.1.1.2.
Cumulative incidence function is estimated using Aalen's method for asymptomatic SARS-CoV-2 infection (event of interest), with disease cases (COVID-19 or second definition of COVID-19) as competing events.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Fine and Gray subdistribution hazards model and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f1402020602010102.sas 26JUL2021 03:25

Figure 14.2.2.6.2.1.6.2
Cumulative Incidence Curve of Asymptomatic SARS-CoV-2 Infection Starting After Randomization Including Participant Decision Visit Using Competing Risk Method
mITT Set



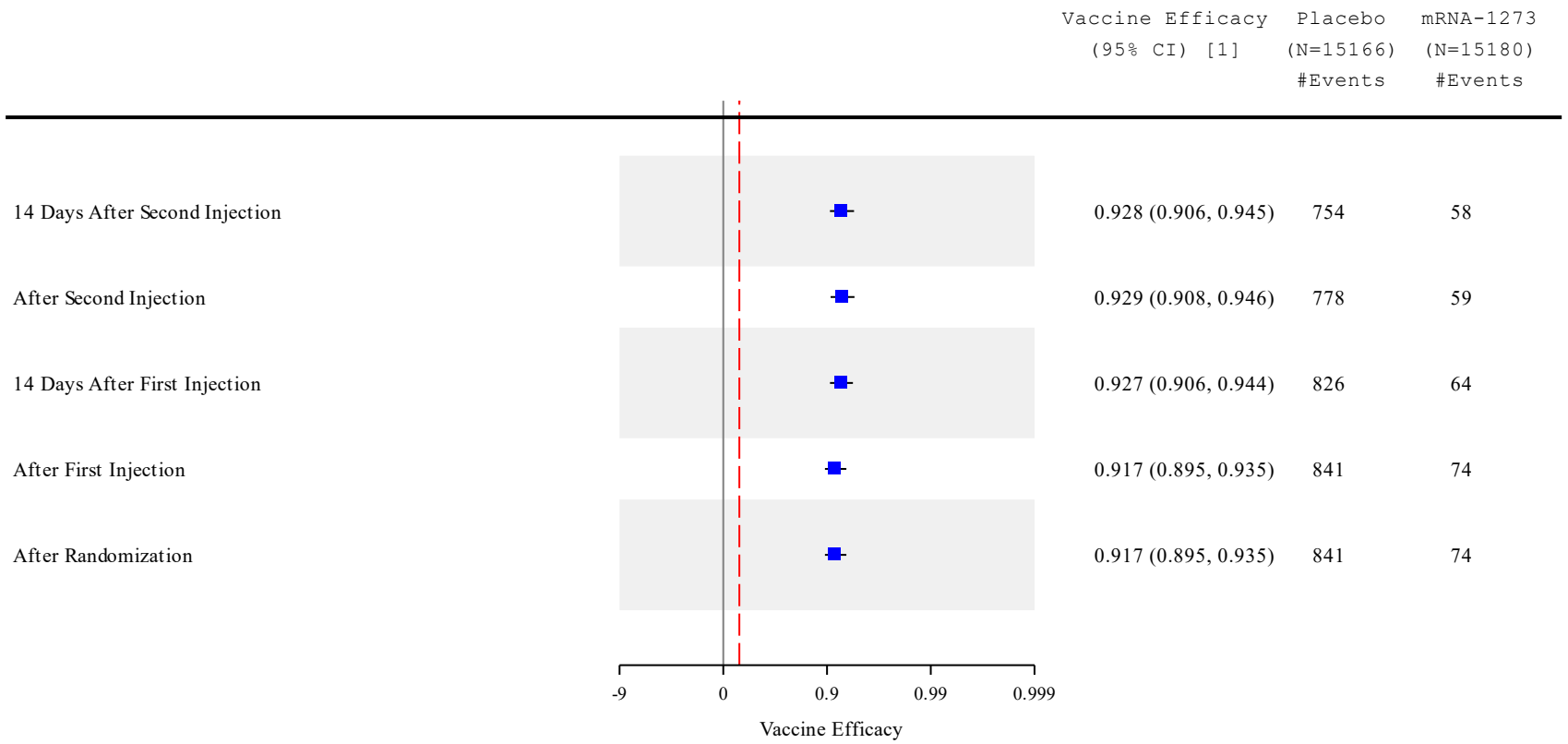
Source table: Table 14.2.2.6.2.5.2.2.
Cumulative incidence function is estimated using Aalen's method for asymptomatic SARS-CoV-2 infection (event of interest), with disease cases (COVID-19 or second definition of COVID-19) as competing events.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Fine and Gray subdistribution hazards model and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f1402020602010602.sas 26JUL2021 03:26

Figure 14.2.2.7.3.1.1
Cumulative Incidence Curve of COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set



Source table: Table 14.2.2.7.3.1.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020207030101.sas 23JUN2021 06:32

Figure 14.2.2.7.3.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set



Note: Footnotes are listed on the last page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020207030201.sas 23JUN2021 06:33

Figure 14.2.2.7.3.2.1
Forest Plot of Vaccine Efficacy of mRNA-1273 to Prevent COVID-19* Based on Adjudication Committee Assessments Regardless of Prior SARS-CoV-2 Infection
Full Analysis Set

Source table: Table 14.2.2.7.3.1, Table 14.2.2.7.3.2, Table 14.2.2.7.3.3, Table 14.2.2.7.3.4, Table 14.2.2.7.3.5.
Reference line indicates vaccine efficacy of 0.3.
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.
[1] Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Table 14.2.4.1.1.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline (Day 1)		
n [1]	139	1046
GM Level	114.514	114.842
95% CI [2]	(105.36, 124.46)	(110.82, 119.01)
Median	99.820	99.820
Min, Max	99.82, 4219.35	99.82, 686841.33
Day 29		
n [1]	139	1040
GM Level	117.183	35752.817
95% CI [2]	(105.96, 129.59)	(33375.81, 38299.12)
Median	99.820	38717.833
Min, Max	99.82, 12742.93	99.82, 1064384.47
N1	137	1033
GM Fold-Rise	1.02	309.51
95% CI [2]	(0.94, 1.12)	(287.70, 332.97)
Seroresponse [3]		
n (%) [4]	6 (4.4)	1024 (99.1)
95% CI [5]	(1.6, 9.3)	(98.4, 99.6)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	2 (1.5)	1024 (99.1)
95% CI [5]	(0.2, 5.2)	(98.4, 99.6)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	1022 (98.9)
95% CI [5]	(0.0, 4.0)	(98.1, 99.5)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	1022 (98.9)
95% CI [5]	(0.0, 4.0)	(98.1, 99.5)

Note: Footnotes are listed on last page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402040101010301.sas 01JUL2021 07:35

Table 14.2.4.1.1.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n [1]	141	1035
GM Level	125.014	316448.298
95% CI [2]	(106.43, 146.84)	(300071.44, 333718.95)
Median	99.820	347458.394
Min, Max	99.82, 415541.60	99.82, 2020355.24
N1	139	1027
GM Fold-Rise	1.10	2737.08
95% CI [2]	(0.94, 1.28)	(2571.78, 2913.01)
Seroresponse [3]		
n (%) [4]	6 (4.3)	1023 (99.6)
95% CI [5]	(1.6, 9.2)	(99.0, 99.9)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	3 (2.2)	1023 (99.6)
95% CI [5]	(0.4, 6.2)	(99.0, 99.9)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1022 (99.5)
95% CI [5]	(0.2, 5.1)	(98.9, 99.8)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1021 (99.4)
95% CI [5]	(0.2, 5.1)	(98.7, 99.8)

Note: Footnotes are listed on last page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402040101010301.sas 01JUL2021 07:35

Table 14.2.4.1.1.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Baseline (Day 1)		
n [1]	128	127
GM Level	7126.943	6988.940
95% CI [2]	(4898.91, 10368.28)	(4832.11, 10108.48)
Median	11824.822	9198.493
Min, Max	99.82, 3729897.61	99.82, 1373004.50
Day 29		
n [1]	127	130
GM Level	5672.206	410049.212
95% CI [2]	(3955.04, 8134.92)	(313904.05, 535642.52)
Median	8387.515	656888.423
Min, Max	99.82, 1279426.90	99.82, 6557162.89
N1	126	127
GM Fold-Rise	0.80	60.21
95% CI [2]	(0.71, 0.90)	(45.62, 79.47)
Seroresponse [3]		
n (%) [4]	3 (2.4)	124 (97.6)
95% CI [5]	(0.5, 6.8)	(93.3, 99.5)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	3 (2.4)	124 (97.6)
95% CI [5]	(0.5, 6.8)	(93.3, 99.5)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.6)	124 (97.6)
95% CI [5]	(0.2, 5.6)	(93.3, 99.5)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	2 (1.6)	123 (96.9)
95% CI [5]	(0.2, 5.6)	(92.1, 99.1)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.1.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n [1]	128	130
GM Level	5185.775	668685.136
95% CI [2]	(3609.31, 7450.81)	(570883.47, 783241.82)
Median	7845.081	755936.141
Min, Max	99.82, 1161989.31	435.65, 5834191.86
N1	127	127
GM Fold-Rise	0.73	95.78
95% CI [2]	(0.64, 0.83)	(68.47, 133.98)
Seroresponse [3]		
n (%) [4]	4 (3.1)	124 (97.6)
95% CI [5]	(0.9, 7.9)	(93.3, 99.5)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	4 (3.1)	124 (97.6)
95% CI [5]	(0.9, 7.9)	(93.3, 99.5)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	4 (3.1)	124 (97.6)
95% CI [5]	(0.9, 7.9)	(93.3, 99.5)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	3 (2.4)	124 (97.6)
95% CI [5]	(0.5, 6.7)	(93.3, 99.5)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.1.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

CI = confidence interval, GM = geometric mean, MSD = meso scale discovery.
N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
[1] Number of subjects with non-missing data at the corresponding timepoint.
[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.
[3] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 1.9-fold rise if baseline is equal to or above the LLOQ.
[4] Number of subjects meeting the criterion at the time point. Percentages are based on N1.
[5] 95% CI is calculated using the Clopper-Pearson method.
[6] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

Table 14.2.4.1.1.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Baseline (Day 1)				
n [1]	92	694	47	352
GM Level	117.105	118.350	109.606	108.228
95% CI [2]	(104.15, 131.68)	(112.66, 124.33)	(99.79, 120.39)	(103.82, 112.82)
Median	99.820	99.820	99.820	99.820
Min, Max	99.82, 4219.35	99.82, 686841.33	99.82, 465.25	99.82, 5077.32

Note: Footnotes are listed on last page.
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Table 14.2.4.1.1.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 29				
n [1]	93	689	46	351
GM Level	122.075	44534.329	107.883	23231.313
95% CI [2]	(105.50, 141.25)	(41259.11, 48069.54)	(99.80, 116.62)	(20460.52, 26377.33)
Median	99.820	47750.783	99.820	26867.256
Min, Max	99.82, 12742.93	99.82, 1064384.47	99.82, 350.81	99.82, 297563.42
N1	91	685	46	348
GM Fold-Rise	1.05	374.32	0.98	212.89
95% CI [2]	(0.93, 1.18)	(344.23, 407.03)	(0.89, 1.09)	(186.39, 243.16)
Seroresponse [3]				
n (%) [4]	4 (4.4)	680 (99.3)	2 (4.3)	344 (98.9)
95% CI [5]	(1.2, 10.9)	(98.3, 99.8)	(0.5, 14.8)	(97.1, 99.7)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	2 (2.2)	680 (99.3)	0	344 (98.9)
95% CI [5]	(0.3, 7.7)	(98.3, 99.8)	(0.0, 7.7)	(97.1, 99.7)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	679 (99.1)	0	343 (98.6)
95% CI [5]	(0.0, 6.0)	(98.1, 99.7)	(0.0, 7.7)	(96.7, 99.5)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	679 (99.1)	0	343 (98.6)
95% CI [5]	(0.0, 6.0)	(98.1, 99.7)	(0.0, 7.7)	(96.7, 99.5)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.1.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 57				
n [1]	94	687	47	348
GM Level	123.515	342705.171	128.068	270372.346
95% CI [2]	(101.23, 150.70)	(321384.23, 365440.57)	(96.41, 170.12)	(246469.00, 296593.91)
Median	99.820	367731.291	99.820	309277.361
Min, Max	99.82, 415541.60	99.82, 2020355.24	99.82, 53916.65	758.31, 1420483.52
N1	92	682	47	345
GM Fold-Rise	1.06	2875.38	1.17	2482.96
95% CI [2]	(0.87, 1.29)	(2658.16, 3110.35)	(0.89, 1.54)	(2244.18, 2747.15)
Seroresponse [3]				
n (%) [4]	3 (3.3)	678 (99.4)	3 (6.4)	345 (100)
95% CI [5]	(0.7, 9.2)	(98.5, 99.8)	(1.3, 17.5)	(98.9, 100.0)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	2 (2.2)	678 (99.4)	1 (2.1)	345 (100)
95% CI [5]	(0.3, 7.6)	(98.5, 99.8)	(0.1, 11.3)	(98.9, 100.0)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	677 (99.3)	1 (2.1)	345 (100)
95% CI [5]	(0.0, 5.9)	(98.3, 99.8)	(0.1, 11.3)	(98.9, 100.0)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	677 (99.3)	1 (2.1)	344 (99.7)
95% CI [5]	(0.0, 5.9)	(98.3, 99.8)	(0.1, 11.3)	(98.4, 100.0)

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Table 14.2.4.1.1.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Baseline (Day 1)				
n [1]	109	104	19	23
GM Level	7208.447	7280.557	6676.865	5809.455
95% CI [2]	(4921.69, 10557.70)	(4977.81, 10648.57)	(1684.21, 26469.74)	(1798.02, 18770.55)
Median	11809.022	8627.384	17604.328	16337.432
Min, Max	99.82, 3729897.61	99.82, 1373004.50	99.82, 266305.31	99.82, 171363.87

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Table 14.2.4.1.1.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 29				
n [1]	109	107	18	23
GM Level	5761.640	460938.044	5159.526	237944.115
95% CI [2]	(3990.28, 8319.34)	(358978.97, 591856.06)	(1327.15, 20058.61)	(87695.66, 645612.37)
Median	7546.690	657850.666	17910.997	634798.316
Min, Max	99.82, 1279426.90	2174.94, 6557162.89	99.82, 151698.01	99.82, 2826194.17
N1	108	104	18	23
GM Fold-Rise	0.80	65.57	0.79	40.96
95% CI [2]	(0.69, 0.92)	(49.35, 87.12)	(0.69, 0.92)	(17.05, 98.42)
Seroresponse [3]				
n (%) [4]	3 (2.8)	102 (98.1)	0	22 (95.7)
95% CI [5]	(0.6, 7.9)	(93.2, 99.8)	(0.0, 18.5)	(78.1, 99.9)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	3 (2.8)	102 (98.1)	0	22 (95.7)
95% CI [5]	(0.6, 7.9)	(93.2, 99.8)	(0.0, 18.5)	(78.1, 99.9)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	2 (1.9)	102 (98.1)	0	22 (95.7)
95% CI [5]	(0.2, 6.5)	(93.2, 99.8)	(0.0, 18.5)	(78.1, 99.9)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	2 (1.9)	102 (98.1)	0	21 (91.3)
95% CI [5]	(0.2, 6.5)	(93.2, 99.8)	(0.0, 18.5)	(72.0, 98.9)

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Table 14.2.4.1.1.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 57				
n [1]	109	107	19	23
GM Level	5145.374	659633.449	5423.756	712455.733
95% CI [2]	(3564.96, 7426.42)	(548965.86, 792610.83)	(1402.38, 20976.61)	(534717.32, 949273.86)
Median	7170.788	735693.871	13672.267	851325.768
Min, Max	99.82, 1161989.31	435.65, 5834191.86	99.82, 766406.96	123554.67, 2016745.98
N1	108	104	19	23
GM Fold-Rise	0.71	90.68	0.81	122.64
95% CI [2]	(0.61, 0.83)	(63.33, 129.85)	(0.60, 1.10)	(47.13, 319.15)
Seroresponse [3]				
n (%) [4]	3 (2.8)	101 (97.1)	1 (5.3)	23 (100)
95% CI [5]	(0.6, 7.9)	(91.8, 99.4)	(0.1, 26.0)	(85.2, 100.0)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	3 (2.8)	101 (97.1)	1 (5.3)	23 (100)
95% CI [5]	(0.6, 7.9)	(91.8, 99.4)	(0.1, 26.0)	(85.2, 100.0)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	3 (2.8)	101 (97.1)	1 (5.3)	23 (100)
95% CI [5]	(0.6, 7.9)	(91.8, 99.4)	(0.1, 26.0)	(85.2, 100.0)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	2 (1.9)	101 (97.1)	1 (5.3)	23 (100)
95% CI [5]	(0.2, 6.5)	(91.8, 99.4)	(0.1, 26.0)	(85.2, 100.0)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.1.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

CI = confidence interval, GM = geometric mean, MSD = meso scale discovery.
N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
[1] Number of subjects with non-missing data at the corresponding timepoint.
[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.
[3] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 1.9-fold rise if baseline is equal to or above the LLOQ.
[4] Number of subjects meeting the criterion at the time point. Percentages are based on N1.
[5] 95% CI is calculated using the Clopper-Pearson method.
[6] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

Table 14.2.4.1.1.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 29		
n	139	1040
N1	137	1033
GLSM	120.458	35916.422
95% CI	101.105, 143.515	33687.886, 38292.381
mRNA-1273 vs. Placebo		
Ratio of GLSM		298.17
95% CI		247.44, 359.29

CI = confidence interval, GLSM = geometric least squares mean, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.1.1.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n	141	1035
N1	139	1027
GLSM	125.176	317589.692
95% CI	108.322, 144.653	301116.470, 334964.118
mRNA-1273 vs. Placebo		
Ratio of GLSM		2537.14
95% CI		2174.81, 2959.83

CI = confidence interval, GLSM = geometric least squares mean, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402040101020301.sas 10JUN2021 21:54

Table 14.2.4.1.1.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 29		
n	127	130
N1	126	127
GLSM	5695.468	436329.369
95% CI	4670.151, 6945.889	356631.734, 533837.289
mRNA-1273 vs. Placebo		
Ratio of GLSM		76.61
95% CI		58.96, 99.54

CI = confidence interval, GLSM = geometric least squares mean, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402040101020301.sas 10JUN2021 21:54

Table 14.2.4.1.1.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n	128	130
N1	127	127
GLSM	5193.123	694064.723
95% CI	4220.385, 6390.062	561820.936, 857436.610
mRNA-1273 vs. Placebo		
Ratio of GLSM		133.65
95% CI		101.39, 176.17

CI = confidence interval, GLSM = geometric least squares mean, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.1.1.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Statistics	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline		
n	139	1046
GLSM	114.582	114.900
95% CI	(104.103, 126.115)	(110.952, 118.989)
GMR (mRNA-1273 vs. Placebo)		1.00
95% CI		(0.91, 1.11)
Day 29		
n	139	1040
N1	137	1033
GLSM	117.046	35839.432
95% CI	(98.433, 139.179)	(33640.039, 38182.622)
GMR (mRNA-1273 vs. Placebo)		306.20
95% CI		(254.64, 368.20)

CI = confidence interval, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402040101030301.sas 10JUN2021 21:54

Table 14.2.4.1.1.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Statistics	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n	141	1035
N1	139	1027
GLSM	125.257	317175.817
95% CI	(108.414, 144.718)	(300707.786, 334545.707)
GMR (mRNA-1273 vs. Placebo)		2532.19
95% CI		(2170.93, 2953.57)

CI = confidence interval, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1402040101030301.sas 10JUN2021 21:54

Table 14.2.4.1.1.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Statistics	Placebo (N=130)	mRNA-1273 (N=130)
Baseline		
n	128	127
GLSM	6563.559	7321.983
95% CI	(4477.413, 9621.697)	(4940.691, 10851.001)
GMR (mRNA-1273 vs. Placebo)		1.12
95% CI		(0.68, 1.84)
Day 29		
n	127	130
N1	126	127
GLSM	5419.106	412936.413
95% CI	(4432.133, 6625.864)	(336730.225, 506388.997)
GMR (mRNA-1273 vs. Placebo)		76.20
95% CI		(58.76, 98.82)

CI = confidence interval, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
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Table 14.2.4.1.1.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Timepoint Statistics	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n	128	130
N1	127	127
GLSM	5603.195	748422.664
95% CI	(4546.743, 6905.117)	(604242.849, 927005.566)
GMR (mRNA-1273 vs. Placebo)		133.57
95% CI		(101.78, 175.30)

CI = confidence interval, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
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Table 14.2.4.1.2.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline (Day 1)		
n [1]	141	1052
GM Level	0.67	0.71
95% CI [2]	(0.60, 0.75)	(0.68, 0.75)
Median	0.50	0.50
Min, Max	0.5, 63.2	0.5, 1333.4
Day 29		
n [1]	141	1055
GM Level	0.70	106.97
95% CI [2]	(0.61, 0.81)	(100.64, 113.69)
Median	0.50	121.30
Min, Max	0.5, 74.8	0.5, 2052.0
N1	140	1052
GM Fold-Rise	1.05	149.48
95% CI [2]	(0.94, 1.17)	(139.36, 160.34)
Seroresponse [3]		
n (%) [4]	8 (5.7)	1042 (99.0)
95% CI [5]	(2.5, 10.9)	(98.3, 99.5)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1041 (99.0)
95% CI [5]	(0.2, 5.1)	(98.1, 99.5)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1039 (98.8)
95% CI [5]	(0.2, 5.1)	(97.9, 99.3)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1038 (98.7)
95% CI [5]	(0.2, 5.1)	(97.8, 99.3)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.2.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n [1]	141	1053
GM Level	0.71	694.75
95% CI [2]	(0.61, 0.84)	(664.75, 726.10)
Median	0.50	758.10
Min, Max	0.5, 1103.4	0.5, 2052.0
N1	140	1050
GM Fold-Rise	1.06	970.86
95% CI [2]	(0.92, 1.23)	(914.22, 1031.00)
Seroresponse [3]		
n (%) [4]	10 (7.1)	1046 (99.6)
95% CI [5]	(3.5, 12.7)	(99.0, 99.9)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	3 (2.1)	1046 (99.6)
95% CI [5]	(0.4, 6.1)	(99.0, 99.9)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1046 (99.6)
95% CI [5]	(0.2, 5.1)	(99.0, 99.9)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1046 (99.6)
95% CI [5]	(0.2, 5.1)	(99.0, 99.9)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.2.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Baseline (Day 1)		
n [1]	129	130
GM Level	24.08	23.76
95% CI [2]	(17.35, 33.40)	(17.08, 33.06)
Median	38.10	27.15
Min, Max	0.5, 2052.0	0.5, 2052.0
Day 29		
n [1]	129	130
GM Level	18.76	772.15
95% CI [2]	(13.66, 25.77)	(628.74, 948.27)
Median	25.40	1182.80
Min, Max	0.5, 2052.0	0.5, 2052.0
N1	128	130
GM Fold-Rise	0.81	32.49
95% CI [2]	(0.74, 0.88)	(25.33, 41.68)
Seroresponse [3]		
n (%) [4]	3 (2.3)	125 (96.2)
95% CI [5]	(0.5, 6.7)	(91.3, 98.7)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	2 (1.6)	127 (97.7)
95% CI [5]	(0.2, 5.5)	(93.4, 99.5)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.6)	127 (97.7)
95% CI [5]	(0.2, 5.5)	(93.4, 99.5)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	126 (96.9)
95% CI [5]	(0.0, 4.3)	(92.3, 99.2)

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Table 14.2.4.1.2.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n [1]	130	130
GM Level	16.09	1097.47
95% CI [2]	(11.77, 21.99)	(950.57, 1267.08)
Median	22.10	1188.60
Min, Max	0.5, 1424.9	0.5, 2052.0
N1	129	130
GM Fold-Rise	0.69	46.18
95% CI [2]	(0.62, 0.76)	(33.53, 63.62)
Seroresponse [3]		
n (%) [4]	1 (0.8)	124 (95.4)
95% CI [5]	(0.0, 4.2)	(90.2, 98.3)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	3 (2.3)	127 (97.7)
95% CI [5]	(0.5, 6.6)	(93.4, 99.5)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	127 (97.7)
95% CI [5]	(0.0, 4.2)	(93.4, 99.5)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	0	126 (96.9)
95% CI [5]	(0.0, 2.8)	(92.3, 99.2)

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Table 14.2.4.1.2.1.3.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GM = geometric mean.
N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
[1] Number of subjects with non-missing data at the corresponding timepoint.
[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.
[3] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise if baseline is equal to or above the LLOQ.
[4] Number of subjects meeting the criterion at the time point. Percentages are based on N1.
[5] 95% CI is calculated using the Clopper-Pearson method.
[6] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

Table 14.2.4.1.2.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Baseline (Day 1)				
n [1]	93	700	48	352
GM Level	0.68	0.74	0.65	0.67
95% CI [2]	(0.60, 0.78)	(0.70, 0.78)	(0.51, 0.81)	(0.63, 0.71)
Median	0.50	0.50	0.50	0.50
Min, Max	0.5, 22.3	0.5, 1333.4	0.5, 63.2	0.5, 9.2

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Table 14.2.4.1.2.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 29				
n [1]	94	700	47	355
GM Level	0.68	127.94	0.75	75.16
95% CI [2]	(0.59, 0.80)	(119.47, 137.00)	(0.55, 1.02)	(67.16, 84.12)
Median	0.50	136.05	0.50	84.60
Min, Max	0.5, 47.2	0.5, 2052.0	0.5, 74.8	0.5, 746.6
N1	93	700	47	352
GM Fold-Rise	1.00	173.51	1.15	111.14
95% CI [2]	(0.89, 1.13)	(159.39, 188.89)	(0.92, 1.45)	(98.71, 125.13)
Seroresponse [3]				
n (%) [4]	4 (4.3)	692 (98.9)	4 (8.5)	350 (99.4)
95% CI [5]	(1.2, 10.6)	(97.8, 99.5)	(2.4, 20.4)	(98.0, 99.9)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	693 (99.0)	1 (2.1)	348 (98.9)
95% CI [5]	(0.0, 5.8)	(98.0, 99.6)	(0.1, 11.3)	(97.1, 99.7)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	692 (98.9)	1 (2.1)	347 (98.6)
95% CI [5]	(0.0, 5.8)	(97.8, 99.5)	(0.1, 11.3)	(96.7, 99.5)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	691 (98.7)	1 (2.1)	347 (98.6)
95% CI [5]	(0.0, 5.8)	(97.6, 99.4)	(0.1, 11.3)	(96.7, 99.5)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.2.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 57				
n [1]	93	698	48	355
GM Level	0.69	740.62	0.76	612.68
95% CI [2]	(0.57, 0.84)	(702.10, 781.25)	(0.55, 1.03)	(567.34, 661.63)
Median	0.50	799.85	0.50	649.50
Min, Max	0.5, 1103.4	0.5, 2052.0	0.5, 108.8	4.0, 2052.0
N1	92	698	48	352
GM Fold-Rise	1.01	1003.33	1.17	909.53
95% CI [2]	(0.84, 1.22)	(928.62, 1084.06)	(0.91, 1.49)	(828.87, 998.04)
Seroresponse [3]				
n (%) [4]	4 (4.3)	694 (99.4)	6 (12.5)	352 (100)
95% CI [5]	(1.2, 10.8)	(98.5, 99.8)	(4.7, 25.2)	(99.0, 100.0)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	2 (2.2)	694 (99.4)	1 (2.1)	352 (100)
95% CI [5]	(0.3, 7.6)	(98.5, 99.8)	(0.1, 11.1)	(99.0, 100.0)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	694 (99.4)	1 (2.1)	352 (100)
95% CI [5]	(0.0, 5.9)	(98.5, 99.8)	(0.1, 11.1)	(99.0, 100.0)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	694 (99.4)	1 (2.1)	352 (100)
95% CI [5]	(0.0, 5.9)	(98.5, 99.8)	(0.1, 11.1)	(99.0, 100.0)

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Table 14.2.4.1.2.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Baseline (Day 1)				
n [1]	109	107	20	23
GM Level	24.83	24.32	20.35	21.35
95% CI [2]	(17.84, 34.57)	(17.30, 34.18)	(6.17, 67.08)	(7.38, 61.72)
Median	37.40	27.10	45.90	49.40
Min, Max	0.5, 2052.0	0.5, 2052.0	0.5, 401.8	0.5, 471.4

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Table 14.2.4.1.2.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 29				
n [1]	110	107	19	23
GM Level	19.36	845.77	15.65	505.48
95% CI [2]	(14.02, 26.74)	(708.70, 1009.36)	(4.86, 50.43)	(215.39, 1186.26)
Median	25.30	1153.90	35.10	1242.40
Min, Max	0.5, 2052.0	31.0, 2052.0	0.5, 296.3	0.5, 2052.0
N1	109	107	19	23
GM Fold-Rise	0.81	34.78	0.81	23.68
95% CI [2]	(0.73, 0.90)	(27.22, 44.44)	(0.70, 0.93)	(9.91, 56.60)
Seroresponse [3]				
n (%) [4]	3 (2.8)	104 (97.2)	0	21 (91.3)
95% CI [5]	(0.6, 7.8)	(92.0, 99.4)	(0.0, 17.6)	(72.0, 98.9)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	2 (1.8)	105 (98.1)	0	22 (95.7)
95% CI [5]	(0.2, 6.5)	(93.4, 99.8)	(0.0, 17.6)	(78.1, 99.9)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	2 (1.8)	105 (98.1)	0	22 (95.7)
95% CI [5]	(0.2, 6.5)	(93.4, 99.8)	(0.0, 17.6)	(78.1, 99.9)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	1 (0.9)	104 (97.2)	0	22 (95.7)
95% CI [5]	(0.0, 5.0)	(92.0, 99.4)	(0.0, 17.6)	(78.1, 99.9)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.2.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 57				
n [1]	110	107	20	23
GM Level	16.17	1056.72	15.63	1308.70
95% CI [2]	(11.80, 22.17)	(893.38, 1249.93)	(4.96, 49.30)	(1039.32, 1647.91)
Median	21.75	1161.10	30.15	1590.10
Min, Max	0.5, 1424.9	0.5, 2052.0	0.5, 1313.9	314.9, 2052.0
N1	109	107	20	23
GM Fold-Rise	0.67	43.46	0.77	61.31
95% CI [2]	(0.60, 0.76)	(30.84, 61.24)	(0.60, 0.98)	(24.65, 152.48)
Seroresponse [3]				
n (%) [4]	1 (0.9)	102 (95.3)	0	22 (95.7)
95% CI [5]	(0.0, 5.0)	(89.4, 98.5)	(0.0, 16.8)	(78.1, 99.9)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	2 (1.8)	104 (97.2)	1 (5.0)	23 (100)
95% CI [5]	(0.2, 6.5)	(92.0, 99.4)	(0.1, 24.9)	(85.2, 100.0)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	0	104 (97.2)	1 (5.0)	23 (100)
95% CI [5]	(0.0, 3.3)	(92.0, 99.4)	(0.1, 24.9)	(85.2, 100.0)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	0	103 (96.3)	0	23 (100)
95% CI [5]	(0.0, 3.3)	(90.7, 99.0)	(0.0, 16.8)	(85.2, 100.0)

Note: Footnotes are listed on last page.
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Table 14.2.4.1.2.1.4.1
Summary of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GM = geometric mean.
N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
[1] Number of subjects with non-missing data at the corresponding timepoint.
[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.
[3] Seroresponse at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise if baseline is equal to or above the LLOQ.
[4] Number of subjects meeting the criterion at the time point. Percentages are based on N1.
[5] 95% CI is calculated using the Clopper-Pearson method.
[6] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher level ratio in participants with baseline antibody level equal to or above the LLOQ.

Table 14.2.4.1.2.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 29		
n	141	1055
N1	140	1052
GLSM	0.703	107.195
95% CI	0.599, 0.826	101.090, 113.669
mRNA-1273 vs. Placebo		
Ratio of GLSM		152.39
95% CI		128.49, 180.73

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.1.2.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n	141	1053
N1	140	1050
GLSM	0.715	696.879
95% CI	0.631, 0.810	665.710, 729.508
mRNA-1273 vs. Placebo		
Ratio of GLSM		974.98
95% CI		853.55, 1113.69

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.1.2.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 29		
n	129	130
N1	128	130
GLSM	18.886	778.912
95% CI	16.037, 22.242	659.431, 920.042
mRNA-1273 vs. Placebo		
Ratio of GLSM		41.24
95% CI		33.26, 51.14

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.1.2.2.3.1
MMRM Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n	130	130
N1	129	130
GLSM	16.122	1107.081
95% CI	13.352, 19.466	914.144, 1340.737
mRNA-1273 vs. Placebo		
Ratio of GLSM		68.67
95% CI		53.31, 88.45

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed binding antibody levels at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.1.2.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Statistics	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline		
n	141	1052
GLSM	0.672	0.716
95% CI	(0.599, 0.755)	(0.686, 0.747)
GMR (mRNA-1273 vs. Placebo)		1.06
95% CI		(0.94, 1.20)
Day 29		
n	141	1055
N1	140	1052
GLSM	0.703	107.194
95% CI	(0.599, 0.824)	(101.128, 113.625)
GMR (mRNA-1273 vs. Placebo)		152.50
95% CI		(128.71, 180.69)

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
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Table 14.2.4.1.2.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Statistics	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n	141	1053
N1	140	1050
GLSM	0.716	696.399
95% CI	(0.632, 0.811)	(665.263, 728.992)
GMR (mRNA-1273 vs. Placebo)		972.69
95% CI		(851.50, 1111.12)

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
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Table 14.2.4.1.2.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Statistics	Placebo (N=130)	mRNA-1273 (N=130)
Baseline		
n	129	130
GLSM	22.985	25.528
95% CI	(16.354, 32.305)	(18.003, 36.200)
GMR (mRNA-1273 vs. Placebo)		1.11
95% CI		(0.71, 1.73)
Day 29		
n	129	130
N1	128	130
GLSM	18.172	751.585
95% CI	(15.414, 21.424)	(635.591, 888.747)
GMR (mRNA-1273 vs. Placebo)		41.36
95% CI		(33.39, 51.22)

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
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Table 14.2.4.1.2.3.3.1
ANCOVA Analysis of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Statistics	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n	130	130
N1	129	130
GLSM	17.263	1184.524
95% CI	(14.274, 20.878)	(974.548, 1439.743)
GMR (mRNA-1273 vs. Placebo)		68.62
95% CI		(53.52, 87.97)

CI = confidence interval, ELISA = enzyme-linked immunosorbent assay, GLSM = geometric least squares mean, GMR = geometric mean ratio, MSD = meso scale discovery.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline (Day 1)		
n [1]	142	1052
GM Titer	9.250	9.624
95% CI [2]	(NE, NE)	(9.35, 9.90)
Median	9.250	9.250
Min, Max	9.25, 9.25	9.25, 18997.56
Day 29		
n [1]	142	1055
GM Titer	9.515	54.866
95% CI [2]	(9.00, 10.06)	(50.98, 59.04)
Median	9.250	55.527
Min, Max	9.25, 512.90	9.25, 26386.22
N1	142	1052
GM Fold-Rise	1.03	5.69
95% CI [2]	(0.97, 1.09)	(5.29, 6.12)
Seroresponse [3]		
n (%) [4]	1 (0.7)	856 (81.4)
95% CI [5]	(0.0, 3.9)	(78.9, 83.7)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	652 (62.0)
95% CI [5]	(0.0, 3.9)	(59.0, 64.9)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	521 (49.5)
95% CI [5]	(0.0, 3.9)	(46.5, 52.6)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	437 (41.5)
95% CI [5]	(0.0, 3.9)	(38.5, 44.6)

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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n [1]	142	1053
GM Titer	9.903	1081.124
95% CI [2]	(8.99, 10.90)	(1019.80, 1146.14)
Median	9.250	1060.676
Min, Max	9.25, 2616.89	9.25, 63402.68
N1	142	1050
GM Fold-Rise	1.07	112.30
95% CI [2]	(0.97, 1.18)	(105.42, 119.62)
Seroresponse [3]		
n (%) [4]	2 (1.4)	1038 (98.9)
95% CI [5]	(0.2, 5.0)	(98.0, 99.4)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1036 (98.7)
95% CI [5]	(0.2, 5.0)	(97.8, 99.3)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1034 (98.5)
95% CI [5]	(0.2, 5.0)	(97.5, 99.1)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1033 (98.4)
95% CI [5]	(0.2, 5.0)	(97.4, 99.1)

Note: Footnotes are listed on last page.
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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline (Day 1)		
n [1]	142	1052
GM Titer	7.150	7.332
95% CI [2]	(NE, NE)	(7.18, 7.49)
Median	7.150	7.150
Min, Max	7.15, 7.15	7.15, 4341.61
Day 29		
n [1]	142	1055
GM Titer	7.279	19.684
95% CI [2]	(7.03, 7.54)	(18.55, 20.89)
Median	7.150	18.282
Min, Max	7.15, 90.31	7.15, 5105.99
N1	142	1052
GM Fold-Rise	1.02	2.68
95% CI [2]	(0.98, 1.05)	(2.53, 2.84)
Seroresponse [3]		
n (%) [4]	1 (0.7)	663 (63.0)
95% CI [5]	(0.0, 3.9)	(60.0, 65.9)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	324 (30.8)
95% CI [5]	(0.0, 3.9)	(28.0, 33.7)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	235 (22.3)
95% CI [5]	(0.0, 3.9)	(19.9, 25.0)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	1 (0.7)	182 (17.3)
95% CI [5]	(0.0, 3.9)	(15.1, 19.7)

Note: Footnotes are listed on last page.
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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n [1]	142	1053
GM Titer	7.522	334.867
95% CI [2]	(7.00, 8.09)	(317.84, 352.81)
Median	7.150	365.886
Min, Max	7.15, 583.06	7.15, 6798.73
N1	142	1050
GM Fold-Rise	1.05	45.62
95% CI [2]	(0.98, 1.13)	(43.21, 48.17)
Seroresponse [3]		
n (%) [4]	2 (1.4)	1038 (98.9)
95% CI [5]	(0.2, 5.0)	(98.0, 99.4)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1035 (98.6)
95% CI [5]	(0.2, 5.0)	(97.7, 99.2)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1029 (98.0)
95% CI [5]	(0.2, 5.0)	(97.0, 98.8)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	2 (1.4)	1023 (97.4)
95% CI [5]	(0.2, 5.0)	(96.3, 98.3)

Note: Footnotes are listed on last page.
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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Baseline (Day 1)		
n [1]	129	130
GM Titer	82.519	68.117
95% CI [2]	(59.40, 114.64)	(49.88, 93.02)
Median	68.199	67.343
Min, Max	9.25, 135391.03	9.25, 258320.14
Day 29		
n [1]	129	130
GM Titer	52.728	1478.910
95% CI [2]	(39.45, 70.48)	(1069.60, 2044.86)
Median	45.877	2485.351
Min, Max	9.25, 48317.06	9.25, 68671.79
N1	128	130
GM Fold-Rise	0.64	21.71
95% CI [2]	(0.56, 0.73)	(16.08, 29.32)
Seroresponse [3]		
n (%) [4]	1 (0.8)	114 (87.7)
95% CI [5]	(0.0, 4.3)	(80.8, 92.8)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	3 (2.3)	115 (88.5)
95% CI [5]	(0.5, 6.7)	(81.7, 93.4)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	108 (83.1)
95% CI [5]	(0.0, 4.3)	(75.5, 89.1)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	0	102 (78.5)
95% CI [5]	(0.0, 2.8)	(70.4, 85.2)

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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n [1]	130	130
GM Titer	47.708	3145.904
95% CI [2]	(35.41, 64.28)	(2539.80, 3896.66)
Median	37.961	3337.000
Min, Max	9.25, 49231.00	9.25, 54959.75
N1	129	130
GM Fold-Rise	0.59	46.18
95% CI [2]	(0.50, 0.69)	(34.10, 62.55)
Seroresponse [3]		
n (%) [4]	2 (1.6)	123 (94.6)
95% CI [5]	(0.2, 5.5)	(89.2, 97.8)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	4 (3.1)	124 (95.4)
95% CI [5]	(0.9, 7.7)	(90.2, 98.3)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	2 (1.6)	123 (94.6)
95% CI [5]	(0.2, 5.5)	(89.2, 97.8)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	123 (94.6)
95% CI [5]	(0.0, 4.2)	(89.2, 97.8)

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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Baseline (Day 1)		
n [1]	129	130
GM Titer	29.580	24.996
95% CI [2]	(22.39, 39.09)	(19.12, 32.68)
Median	21.162	18.572
Min, Max	7.15, 42704.93	7.15, 60964.89
Day 29		
n [1]	129	130
GM Titer	20.994	518.388
95% CI [2]	(16.42, 26.84)	(380.39, 706.44)
Median	15.843	776.746
Min, Max	7.15, 12132.57	7.15, 16637.72
N1	128	130
GM Fold-Rise	0.71	20.74
95% CI [2]	(0.64, 0.79)	(15.30, 28.10)
Seroresponse [3]		
n (%) [4]	4 (3.1)	117 (90.0)
95% CI [5]	(0.9, 7.8)	(83.5, 94.6)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	111 (85.4)
95% CI [5]	(0.0, 4.3)	(78.1, 91.0)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	108 (83.1)
95% CI [5]	(0.0, 4.3)	(75.5, 89.1)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	0	99 (76.2)
95% CI [5]	(0.0, 2.8)	(67.9, 83.2)

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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n [1]	130	130
GM Titer	19.228	1099.847
95% CI [2]	(15.03, 24.60)	(903.83, 1338.37)
Median	14.911	1367.157
Min, Max	7.15, 8168.14	7.15, 19222.41
N1	129	130
GM Fold-Rise	0.66	44.00
95% CI [2]	(0.57, 0.75)	(33.99, 56.97)
Seroresponse [3]		
n (%) [4]	3 (2.3)	125 (96.2)
95% CI [5]	(0.5, 6.6)	(91.3, 98.7)
>= 2-fold Increase from Baseline [6]		
n (%) [4]	2 (1.6)	125 (96.2)
95% CI [5]	(0.2, 5.5)	(91.3, 98.7)
>= 3-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	125 (96.2)
95% CI [5]	(0.0, 4.2)	(91.3, 98.7)
>= 4-fold Increase from Baseline [6]		
n (%) [4]	1 (0.8)	124 (95.4)
95% CI [5]	(0.0, 4.2)	(90.2, 98.3)

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Table 14.2.4.2.1.3.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

CI = confidence interval, GM = geometric mean.
N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
[1] Number of subjects with non-missing data at the corresponding timepoint.
[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.
[3] Seroresponse to pseudovirus neutralizing antibody ID50 titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 3.3-fold rise if baseline is equal to or above the LLOQ. Seroresponse to pseudovirus neutralizing antibody ID80 titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 2.3-fold rise if baseline is equal to or above the LLOQ.
[4] Number of subjects meeting the criterion at the time point. Percentages are based on N1.
[5] 95% CI is calculated using the Clopper-Pearson method.
[6] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody titer below LLOQ, or a z-times or higher titer ratio in participants with baseline antibody titer equal to or above the LLOQ.

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Baseline (Day 1)				
n [1]	94	699	48	353
GM Titer	9.250	9.767	9.250	9.348
95% CI [2]	(NE, NE)	(9.37, 10.18)	(NE, NE)	(9.16, 9.54)
Median	9.250	9.250	9.250	9.250
Min, Max	9.25, 9.25	9.25, 18997.56	9.25, 9.25	9.25, 385.04

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 29				
n [1]	94	700	48	355
GM Titer	9.250	66.828	10.057	37.188
95% CI [2]	(NE, NE)	(61.14, 73.04)	(8.50, 11.90)	(32.97, 41.94)
Median	9.250	69.063	9.250	33.600
Min, Max	9.25, 9.25	9.25, 26386.22	9.25, 512.90	9.25, 1087.16
N1	94	699	48	353
GM Fold-Rise	1.00	6.84	1.09	3.95
95% CI [2]	(NE, NE)	(6.26, 7.47)	(0.92, 1.29)	(3.50, 4.46)
Seroresponse [3]				
n (%) [4]	0	605 (86.6)	1 (2.1)	251 (71.1)
95% CI [5]	(0.0, 3.8)	(83.8, 89.0)	(0.1, 11.1)	(66.1, 75.8)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	0	492 (70.4)	1 (2.1)	160 (45.3)
95% CI [5]	(0.0, 3.8)	(66.8, 73.8)	(0.1, 11.1)	(40.0, 50.7)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	0	390 (55.8)	1 (2.1)	131 (37.1)
95% CI [5]	(0.0, 3.8)	(52.0, 59.5)	(0.1, 11.1)	(32.1, 42.4)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	0	330 (47.2)	1 (2.1)	107 (30.3)
95% CI [5]	(0.0, 3.8)	(43.5, 51.0)	(0.1, 11.1)	(25.6, 35.4)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 57				
n [1]	94	698	48	355
GM Titer	9.823	1206.589	10.063	871.203
95% CI [2]	(8.72, 11.07)	(1125.71, 1293.28)	(8.49, 11.92)	(785.48, 966.29)
Median	9.250	1163.740	9.250	829.568
Min, Max	9.25, 2616.89	9.25, 63402.68	9.25, 526.79	9.25, 11494.25
N1	94	697	48	353
GM Fold-Rise	1.06	123.56	1.09	92.98
95% CI [2]	(0.94, 1.20)	(114.34, 133.53)	(0.92, 1.29)	(83.57, 103.45)
Seroresponse [3]				
n (%) [4]	1 (1.1)	687 (98.6)	1 (2.1)	351 (99.4)
95% CI [5]	(0.0, 5.8)	(97.4, 99.3)	(0.1, 11.1)	(98.0, 99.9)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	687 (98.6)	1 (2.1)	349 (98.9)
95% CI [5]	(0.0, 5.8)	(97.4, 99.3)	(0.1, 11.1)	(97.1, 99.7)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	686 (98.4)	1 (2.1)	348 (98.6)
95% CI [5]	(0.0, 5.8)	(97.2, 99.2)	(0.1, 11.1)	(96.7, 99.5)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	686 (98.4)	1 (2.1)	347 (98.3)
95% CI [5]	(0.0, 5.8)	(97.2, 99.2)	(0.1, 11.1)	(96.3, 99.4)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Baseline (Day 1)				
n [1]	94	699	48	353
GM Titer	7.150	7.400	7.150	7.199
95% CI [2]	(NE, NE)	(7.18, 7.63)	(NE, NE)	(7.10, 7.30)
Median	7.150	7.150	7.150	7.150
Min, Max	7.15, 7.15	7.15, 4341.61	7.15, 7.15	7.15, 78.00

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 29				
n [1]	94	700	48	355
GM Titer	7.150	23.065	7.538	14.401
95% CI [2]	(NE, NE)	(21.40, 24.85)	(6.78, 8.38)	(13.16, 15.76)
Median	7.150	20.713	7.150	7.150
Min, Max	7.15, 7.15	7.15, 5105.99	7.15, 90.31	7.15, 319.10
N1	94	699	48	353
GM Fold-Rise	1.00	3.12	1.05	1.99
95% CI [2]	(NE, NE)	(2.90, 3.35)	(0.95, 1.17)	(1.82, 2.18)
Seroresponse [3]				
n (%) [4]	0	497 (71.1)	1 (2.1)	166 (47.0)
95% CI [5]	(0.0, 3.8)	(67.6, 74.4)	(0.1, 11.1)	(41.7, 52.4)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	0	257 (36.8)	1 (2.1)	67 (19.0)
95% CI [5]	(0.0, 3.8)	(33.2, 40.5)	(0.1, 11.1)	(15.0, 23.5)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	0	187 (26.8)	1 (2.1)	48 (13.6)
95% CI [5]	(0.0, 3.8)	(23.5, 30.2)	(0.1, 11.1)	(10.2, 17.6)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	0	142 (20.3)	1 (2.1)	40 (11.3)
95% CI [5]	(0.0, 3.8)	(17.4, 23.5)	(0.1, 11.1)	(8.2, 15.1)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=94)	mRNA-1273 (N=700)	Placebo (N=48)	mRNA-1273 (N=355)
Day 57				
n [1]	94	698	48	355
GM Titer	7.493	373.287	7.579	270.474
95% CI [2]	(6.83, 8.22)	(351.16, 396.80)	(6.74, 8.52)	(246.15, 297.20)
Median	7.150	387.675	7.150	306.371
Min, Max	7.15, 583.06	7.15, 6798.73	7.15, 117.11	7.15, 2863.73
N1	94	697	48	353
GM Fold-Rise	1.05	50.45	1.06	37.40
95% CI [2]	(0.95, 1.15)	(47.28, 53.84)	(0.94, 1.19)	(33.99, 41.15)
Seroresponse [3]				
n (%) [4]	1 (1.1)	689 (98.9)	1 (2.1)	349 (98.9)
95% CI [5]	(0.0, 5.8)	(97.8, 99.5)	(0.1, 11.1)	(97.1, 99.7)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	690 (99.0)	1 (2.1)	345 (97.7)
95% CI [5]	(0.0, 5.8)	(97.9, 99.6)	(0.1, 11.1)	(95.6, 99.0)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	687 (98.6)	1 (2.1)	342 (96.9)
95% CI [5]	(0.0, 5.8)	(97.4, 99.3)	(0.1, 11.1)	(94.5, 98.4)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	1 (1.1)	683 (98.0)	1 (2.1)	340 (96.3)
95% CI [5]	(0.0, 5.8)	(96.7, 98.9)	(0.1, 11.1)	(93.8, 98.0)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Baseline (Day 1)				
n [1]	110	107	19	23
GM Titer	83.804	69.563	75.461	61.774
95% CI [2]	(58.48, 120.09)	(49.20, 98.36)	(31.17, 182.69)	(28.63, 133.27)
Median	67.612	66.753	93.412	70.090
Min, Max	9.25, 135391.03	9.25, 258320.14	9.25, 1348.36	9.25, 1108.98

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 29				
n [1]	110	107	19	23
GM Titer	53.238	1722.766	49.868	727.067
95% CI [2]	(38.66, 73.31)	(1235.17, 2402.85)	(23.78, 104.59)	(269.07, 1964.65)
Median	43.814	2602.959	68.673	2081.484
Min, Max	9.25, 48317.06	9.25, 68671.79	9.25, 629.82	9.25, 11895.95
N1	110	107	18	23
GM Fold-Rise	0.64	24.77	0.69	11.77
95% CI [2]	(0.55, 0.73)	(17.93, 34.21)	(0.48, 0.98)	(5.28, 26.23)
Seroresponse [3]				
n (%) [4]	1 (0.9)	96 (89.7)	0	18 (78.3)
95% CI [5]	(0.0, 5.0)	(82.3, 94.8)	(0.0, 18.5)	(56.3, 92.5)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	2 (1.8)	97 (90.7)	1 (5.6)	18 (78.3)
95% CI [5]	(0.2, 6.4)	(83.5, 95.4)	(0.1, 27.3)	(56.3, 92.5)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (0.9)	94 (87.9)	0	14 (60.9)
95% CI [5]	(0.0, 5.0)	(80.1, 93.4)	(0.0, 18.5)	(38.5, 80.3)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	0	88 (82.2)	0	14 (60.9)
95% CI [5]	(0.0, 3.3)	(73.7, 89.0)	(0.0, 18.5)	(38.5, 80.3)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 57				
n [1]	110	107	20	23
GM Titer	47.158	3108.874	50.846	3324.057
95% CI [2]	(34.37, 64.71)	(2432.91, 3972.65)	(20.03, 129.08)	(2142.62, 5156.94)
Median	39.899	3317.995	29.833	3359.011
Min, Max	9.25, 49231.00	9.25, 54959.75	9.25, 32343.08	276.41, 22307.78
N1	110	107	19	23
GM Fold-Rise	0.56	44.69	0.74	53.81
95% CI [2]	(0.48, 0.66)	(31.70, 63.00)	(0.40, 1.35)	(27.42, 105.62)
Seroresponse [3]				
n (%) [4]	1 (0.9)	101 (94.4)	1 (5.3)	22 (95.7)
95% CI [5]	(0.0, 5.0)	(88.2, 97.9)	(0.1, 26.0)	(78.1, 99.9)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	3 (2.7)	101 (94.4)	1 (5.3)	23 (100)
95% CI [5]	(0.6, 7.8)	(88.2, 97.9)	(0.1, 26.0)	(85.2, 100.0)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	1 (0.9)	101 (94.4)	1 (5.3)	22 (95.7)
95% CI [5]	(0.0, 5.0)	(88.2, 97.9)	(0.1, 26.0)	(78.1, 99.9)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	0	101 (94.4)	1 (5.3)	22 (95.7)
95% CI [5]	(0.0, 3.3)	(88.2, 97.9)	(0.1, 26.0)	(78.1, 99.9)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Baseline (Day 1)				
n [1]	110	107	19	23
GM Titer	29.175	24.754	32.036	26.152
95% CI [2]	(21.41, 39.75)	(18.27, 33.54)	(16.33, 62.83)	(14.44, 47.35)
Median	20.189	17.341	24.358	19.802
Min, Max	7.15, 42704.93	7.15, 60964.89	7.15, 363.63	7.15, 285.67

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 29				
n [1]	110	107	19	23
GM Titer	20.672	607.318	22.956	248.180
95% CI [2]	(15.74, 27.15)	(443.66, 831.34)	(12.69, 41.53)	(94.05, 654.89)
Median	15.839	861.455	18.862	660.308
Min, Max	7.15, 12132.57	7.15, 16637.72	7.15, 219.21	7.15, 3812.03
N1	110	107	18	23
GM Fold-Rise	0.71	24.53	0.73	9.49
95% CI [2]	(0.63, 0.80)	(17.70, 34.01)	(0.54, 1.00)	(4.37, 20.61)
Seroresponse [3]				
n (%) [4]	3 (2.7)	99 (92.5)	1 (5.6)	18 (78.3)
95% CI [5]	(0.6, 7.8)	(85.8, 96.7)	(0.1, 27.3)	(56.3, 92.5)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	0	94 (87.9)	1 (5.6)	17 (73.9)
95% CI [5]	(0.0, 3.3)	(80.1, 93.4)	(0.1, 27.3)	(51.6, 89.8)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	0	93 (86.9)	1 (5.6)	15 (65.2)
95% CI [5]	(0.0, 3.3)	(79.0, 92.7)	(0.1, 27.3)	(42.7, 83.6)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	0	85 (79.4)	0	14 (60.9)
95% CI [5]	(0.0, 3.3)	(70.5, 86.6)	(0.0, 18.5)	(38.5, 80.3)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

	>=18 and <65 Years		>=65 Years	
Timepoint Data Category Statistic	Placebo (N=110)	mRNA-1273 (N=107)	Placebo (N=20)	mRNA-1273 (N=23)
Day 57				
n [1]	110	107	20	23
GM Titer	18.774	1097.788	21.932	1109.478
95% CI [2]	(14.50, 24.31)	(878.34, 1372.06)	(9.82, 49.01)	(723.29, 1701.87)
Median	15.076	1301.842	7.150	1539.763
Min, Max	7.15, 8168.14	7.15, 19222.41	7.15, 7142.49	93.78, 4498.33
N1	110	107	19	23
GM Fold-Rise	0.64	44.35	0.73	42.42
95% CI [2]	(0.56, 0.74)	(32.98, 59.63)	(0.43, 1.23)	(25.01, 71.97)
Seroresponse [3]				
n (%) [4]	2 (1.8)	102 (95.3)	1 (5.3)	23 (100)
95% CI [5]	(0.2, 6.4)	(89.4, 98.5)	(0.1, 26.0)	(85.2, 100.0)
>= 2-fold Increase from Baseline [6]				
n (%) [4]	1 (0.9)	102 (95.3)	1 (5.3)	23 (100)
95% CI [5]	(0.0, 5.0)	(89.4, 98.5)	(0.1, 26.0)	(85.2, 100.0)
>= 3-fold Increase from Baseline [6]				
n (%) [4]	0	102 (95.3)	1 (5.3)	23 (100)
95% CI [5]	(0.0, 3.3)	(89.4, 98.5)	(0.1, 26.0)	(85.2, 100.0)
>= 4-fold Increase from Baseline [6]				
n (%) [4]	0	102 (95.3)	1 (5.3)	22 (95.7)
95% CI [5]	(0.0, 3.3)	(89.4, 98.5)	(0.1, 26.0)	(78.1, 99.9)

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Table 14.2.4.2.1.4.1
Summary of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

CI = confidence interval, GM = geometric mean.
N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
[1] Number of subjects with non-missing data at the corresponding timepoint.
[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.
[3] Seroresponse to pseudovirus neutralizing antibody ID50 titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 3.3-fold rise if baseline is equal to or above the LLOQ. Seroresponse to pseudovirus neutralizing antibody ID80 titer at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 2.3-fold rise if baseline is equal to or above the LLOQ.
[4] Number of subjects meeting the criterion at the time point. Percentages are based on N1.
[5] 95% CI is calculated using the Clopper-Pearson method.
[6] >= z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody titer below LLOQ, or a z-times or higher titer ratio in participants with baseline antibody titer equal to or above the LLOQ.

Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 29		
n	142	1055
N1	142	1052
GLSM	9.540	55.027
95% CI	7.937, 11.467	51.434, 58.870
mRNA-1273 vs. Placebo		
Ratio of GLSM		5.77
95% CI		4.74, 7.02

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n	142	1053
N1	142	1050
GLSM	9.929	1085.081
95% CI	8.542, 11.540	1026.777, 1146.695
mRNA-1273 vs. Placebo		
Ratio of GLSM		109.29
95% CI		93.11, 128.27

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 29		
n	142	1055
N1	142	1052
GLSM	7.299	19.740
95% CI	6.288, 8.472	18.689, 20.850
mRNA-1273 vs. Placebo		
Ratio of GLSM		2.70
95% CI		2.31, 3.17

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=142)	mRNA-1273 (N=1055)
Day 57		
n	142	1053
N1	142	1050
GLSM	7.542	336.074
95% CI	6.602, 8.616	320.042, 352.908
mRNA-1273 vs. Placebo		
Ratio of GLSM		44.56
95% CI		38.67, 51.35

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 29		
n	129	130
N1	128	130
GLSM	49.371	1585.571
95% CI	39.394, 61.874	1262.638, 1991.098
mRNA-1273 vs. Placebo		
Ratio of GLSM		32.12
95% CI		23.77, 43.38

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n	130	130
N1	129	130
GLSM	44.895	3372.792
95% CI	36.445, 55.304	2728.799, 4168.765
mRNA-1273 vs. Placebo		
Ratio of GLSM		75.13
95% CI		57.01, 98.99

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 29		
n	129	130
N1	128	130
GLSM	19.654	547.420
95% CI	15.734, 24.550	437.539, 684.894
mRNA-1273 vs. Placebo		
Ratio of GLSM		27.85
95% CI		20.66, 37.55

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.2.3.1
MMRM Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Data Category Statistic	Placebo (N=130)	mRNA-1273 (N=130)
Day 57		
n	130	130
N1	129	130
GLSM	18.106	1161.443
95% CI	15.124, 21.676	966.938, 1395.073
mRNA-1273 vs. Placebo		
Ratio of GLSM		64.15
95% CI		50.68, 81.19

CI = confidence interval, GLSM = geometric least squares mean.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The GLSM, ratio of GLSM, and corresponding 95% confidence intervals (CI) are estimated using a restricted maximum likelihood-based linear mixed effects model, including all available log-transformed neutralizing antibody titers at each post-baseline visit as the dependent variable, treatment group, visit, and interaction of treatment group and visit as fixed effects, and randomization stratification factor, minority/non-minority, baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive), and subject as random effects, then back transformed to the original scale for presentation. An unstructured covariance structure is used to model the within-subject errors and the Kenward-Roger method is used to approximate the denominator degrees of freedom.
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Table 14.2.4.2.3.3.1
ANCOVA Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Statistics	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline		
n	142	1052
GLSM	9.253	9.626
95% CI	(8.600, 9.955)	(9.371, 9.888)
GMR (mRNA-1273 vs. Placebo)		1.04
95% CI		(0.96, 1.12)
Day 29		
n	142	1055
N1	142	1052
GLSM	9.544	55.048
95% CI	(7.943, 11.469)	(51.460, 58.887)
GMR (mRNA-1273 vs. Placebo)		5.77
95% CI		(4.74, 7.01)
Day 57		
n	142	1053
N1	142	1050
GLSM	9.927	1084.518
95% CI	(8.541, 11.537)	(1026.249, 1146.095)
GMR (mRNA-1273 vs. Placebo)		109.25
95% CI		(93.08, 128.23)

Note: Footnotes are listed on last page.
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Table 14.2.4.2.3.3.1
ANCOVA Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Statistics	Placebo (N=142)	mRNA-1273 (N=1055)
Baseline		
n	142	1052
GLSM	7.151	7.332
95% CI	(6.781, 7.541)	(7.191, 7.477)
GMR (mRNA-1273 vs. Placebo)		1.03
95% CI		(0.97, 1.09)
Day 29		
n	142	1055
N1	142	1052
GLSM	7.299	19.741
95% CI	(6.289, 8.472)	(18.691, 20.851)
GMR (mRNA-1273 vs. Placebo)		2.70
95% CI		(2.31, 3.17)
Day 57		
n	142	1053
N1	142	1050
GLSM	7.542	335.914
95% CI	(6.602, 8.615)	(319.888, 352.743)
GMR (mRNA-1273 vs. Placebo)		44.54
95% CI		(38.65, 51.32)

Note: Footnotes are listed on last page.
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Table 14.2.4.2.3.3.1
ANCOVA Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Timepoint Statistics	Placebo (N=130)	mRNA-1273 (N=130)
Baseline		
n	129	130
GLSM	80.390	71.725
95% CI	(57.145, 113.089)	(50.613, 101.642)
GMR (mRNA-1273 vs. Placebo)		0.89
95% CI		(0.57, 1.39)
Day 29		
n	129	130
N1	128	130
GLSM	44.705	1457.213
95% CI	(35.502, 56.295)	(1153.667, 1840.625)
GMR (mRNA-1273 vs. Placebo)		32.60
95% CI		(24.20, 43.90)
Day 57		
n	130	130
N1	129	130
GLSM	48.178	3589.349
95% CI	(39.022, 59.482)	(2894.244, 4451.396)
GMR (mRNA-1273 vs. Placebo)		74.50
95% CI		(56.65, 97.97)

Note: Footnotes are listed on last page.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14020402030301.sas 10JUN2021 21:55

Table 14.2.4.2.3.3.1
ANCOVA Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Timepoint Statistics	Placebo (N=130)	mRNA-1273 (N=130)
Baseline		
n	129	130
GLSM	29.901	26.687
95% CI	(22.301, 40.092)	(19.778, 36.008)
GMR (mRNA-1273 vs. Placebo)		0.89
95% CI		(0.61, 1.31)
Day 29		
n	129	130
N1	128	130
GLSM	17.640	499.208
95% CI	(14.021, 22.193)	(395.636, 629.894)
GMR (mRNA-1273 vs. Placebo)		28.30
95% CI		(21.04, 38.07)
Day 57		
n	130	130
N1	129	130
GLSM	18.873	1203.779
95% CI	(15.748, 22.618)	(1000.718, 1448.044)
GMR (mRNA-1273 vs. Placebo)		63.78
95% CI		(50.42, 80.69)

Note: Footnotes are listed on last page.
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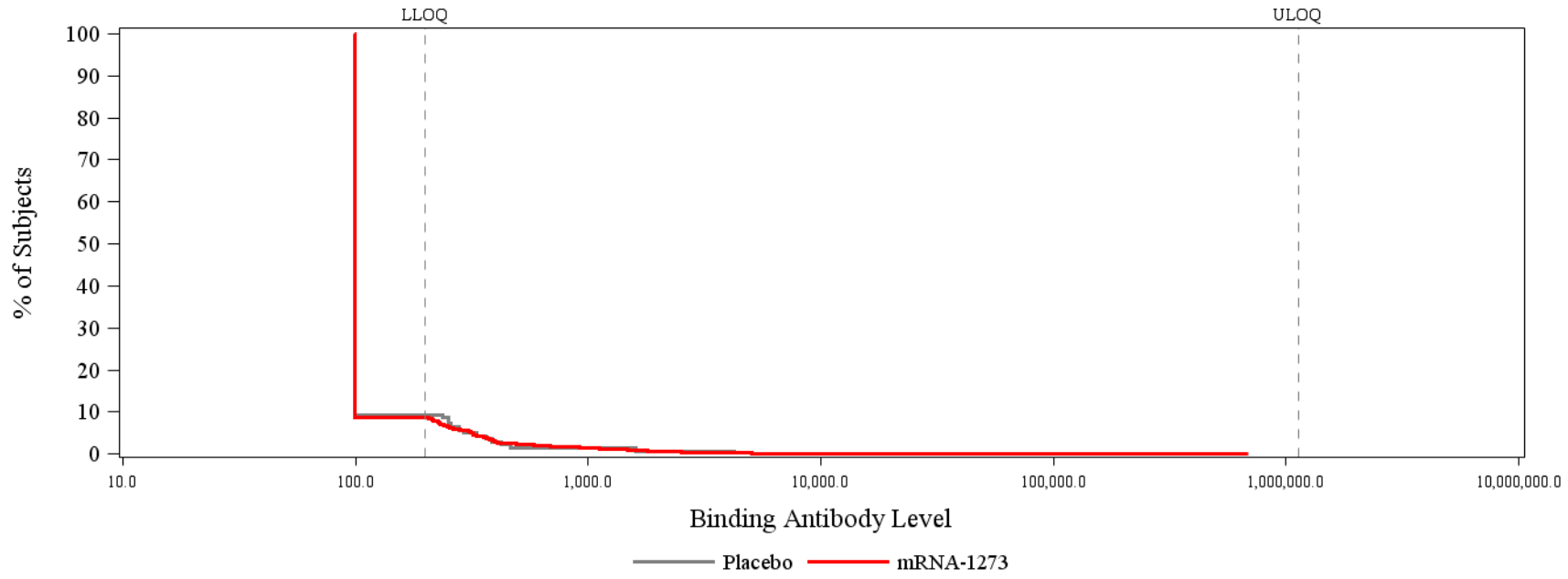
Table 14.2.4.2.3.3.1
ANCOVA Analysis of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

CI = confidence interval, GLSM = geometric least squares mean, GMR = geometric mean ratio.
n = Number of subjects with non-missing data at the corresponding timepoint. N1 = Number of subjects with non-missing data at baseline and the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
The log-transformed antibody titers are analyzed using an analysis of covariance (ANCOVA) model with the treatment group as fixed effect and adjusted with randomization stratification factor, minority/non-minority, and baseline log-transformed value (only for subjects with baseline SARS-CoV-2 positive at post-baseline timepoint). The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.

Figure 14.2.4.1.1.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Baseline (Day 1)



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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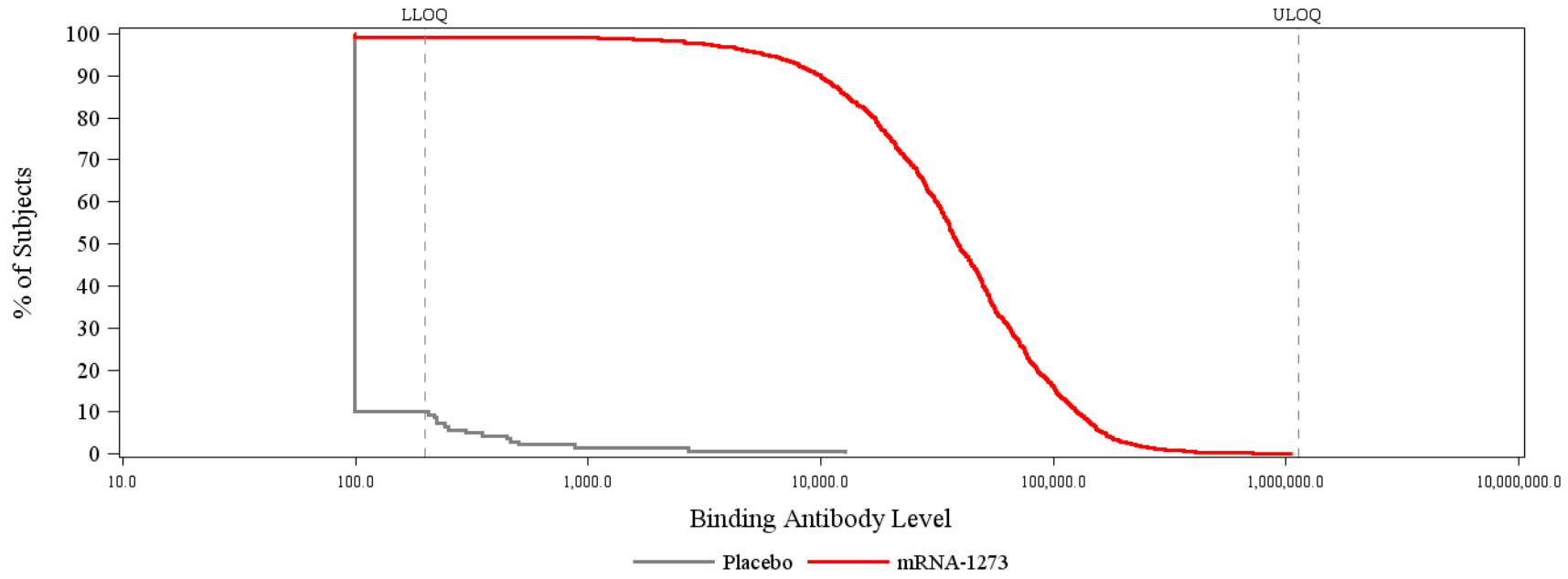
Figure 14.2.4.1.1.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 29



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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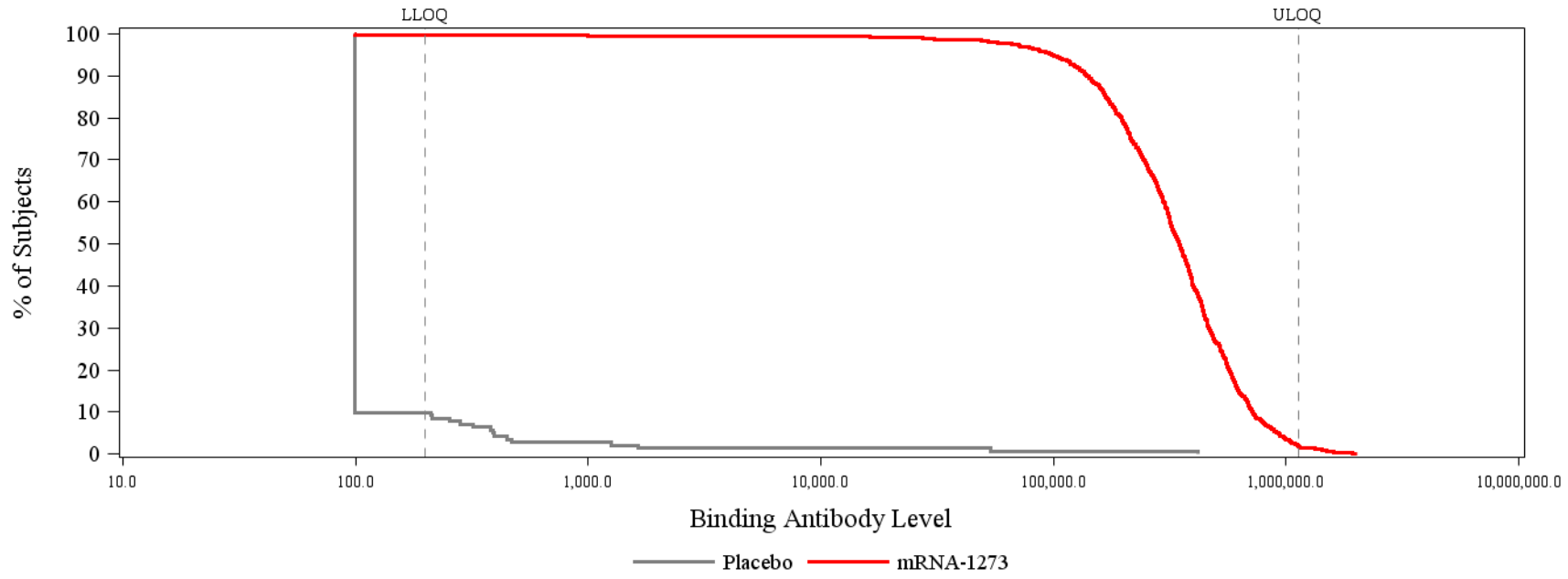
Figure 14.2.4.1.1.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 57



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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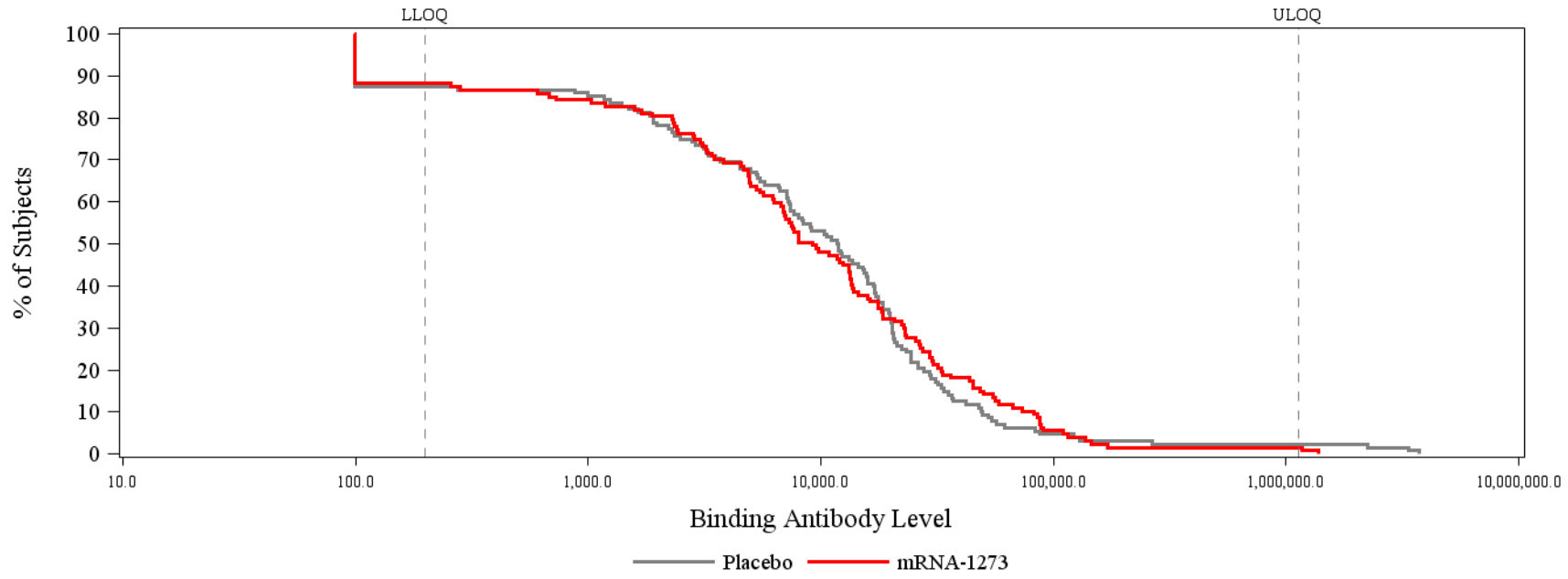
Figure 14.2.4.1.1.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Baseline (Day 1)



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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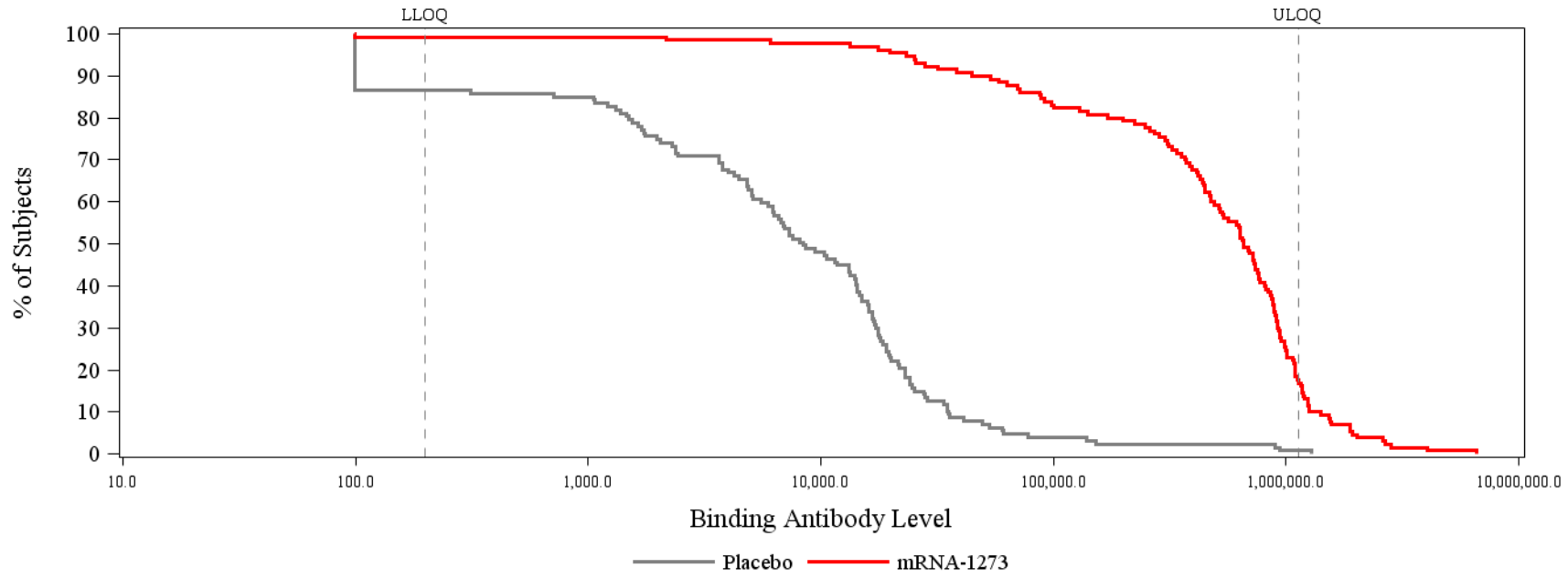
Figure 14.2.4.1.1.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 29



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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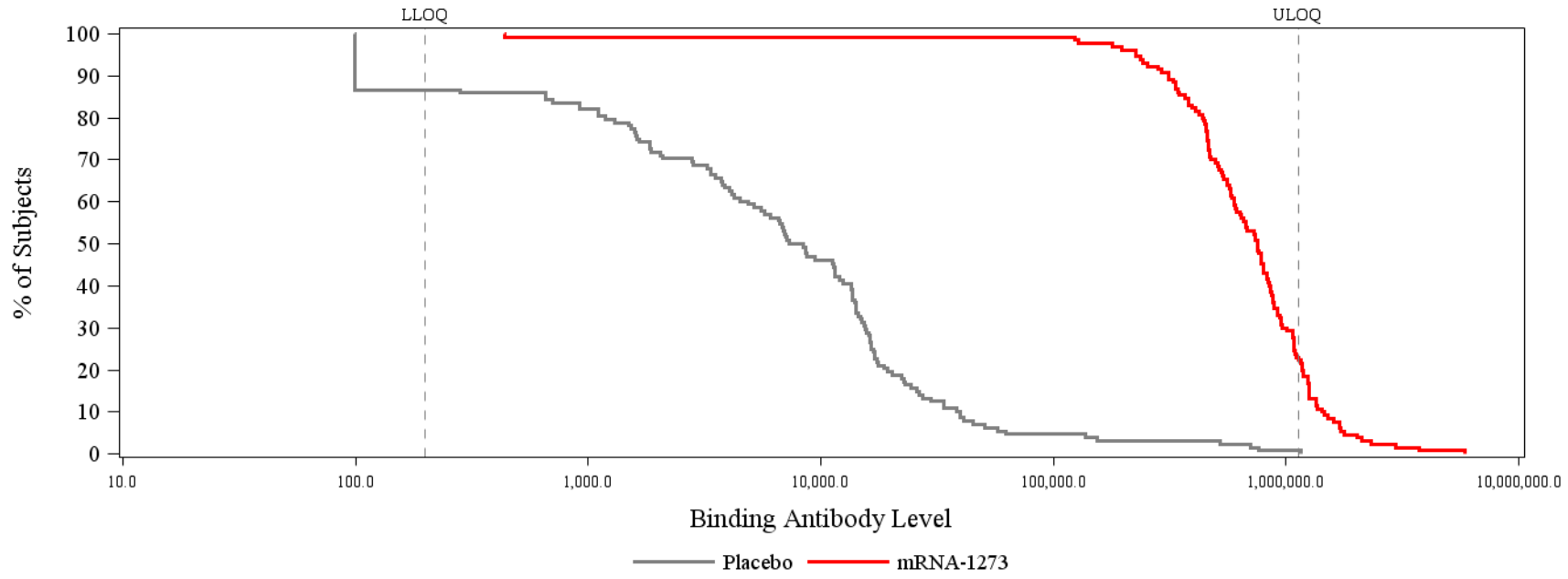
Figure 14.2.4.1.1.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 57



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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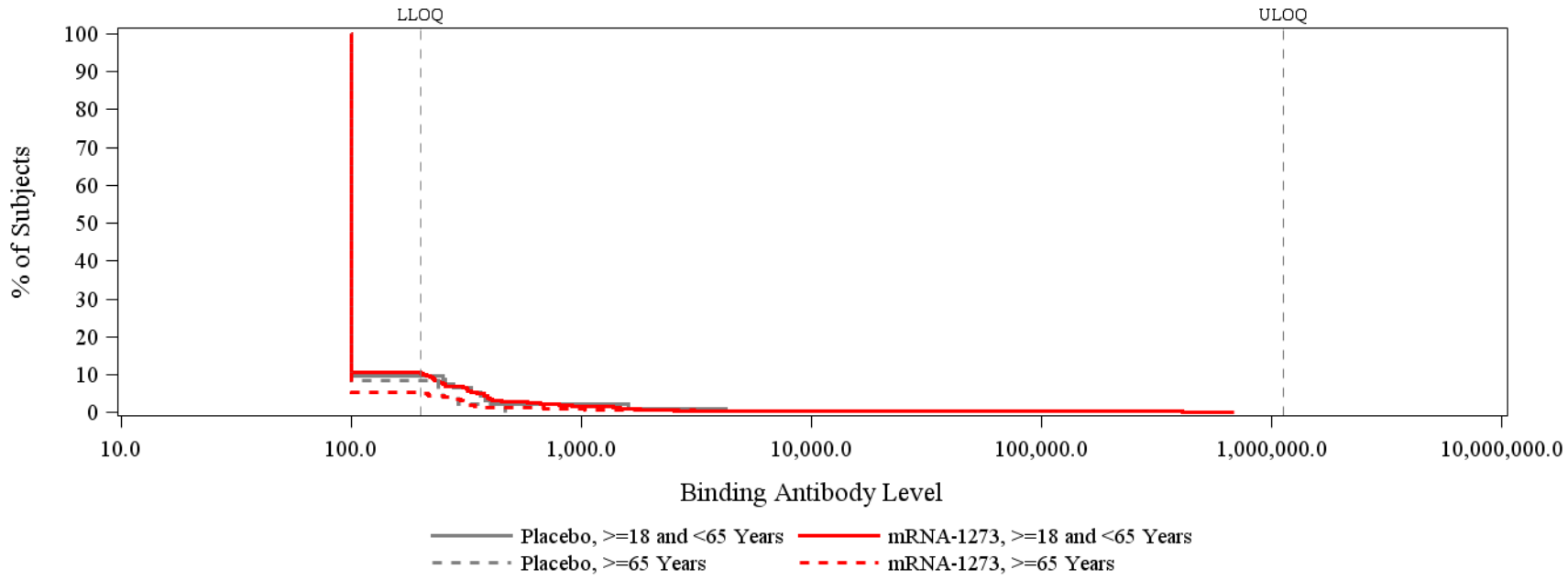
Figure 14.2.4.1.1.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Baseline (Day 1)



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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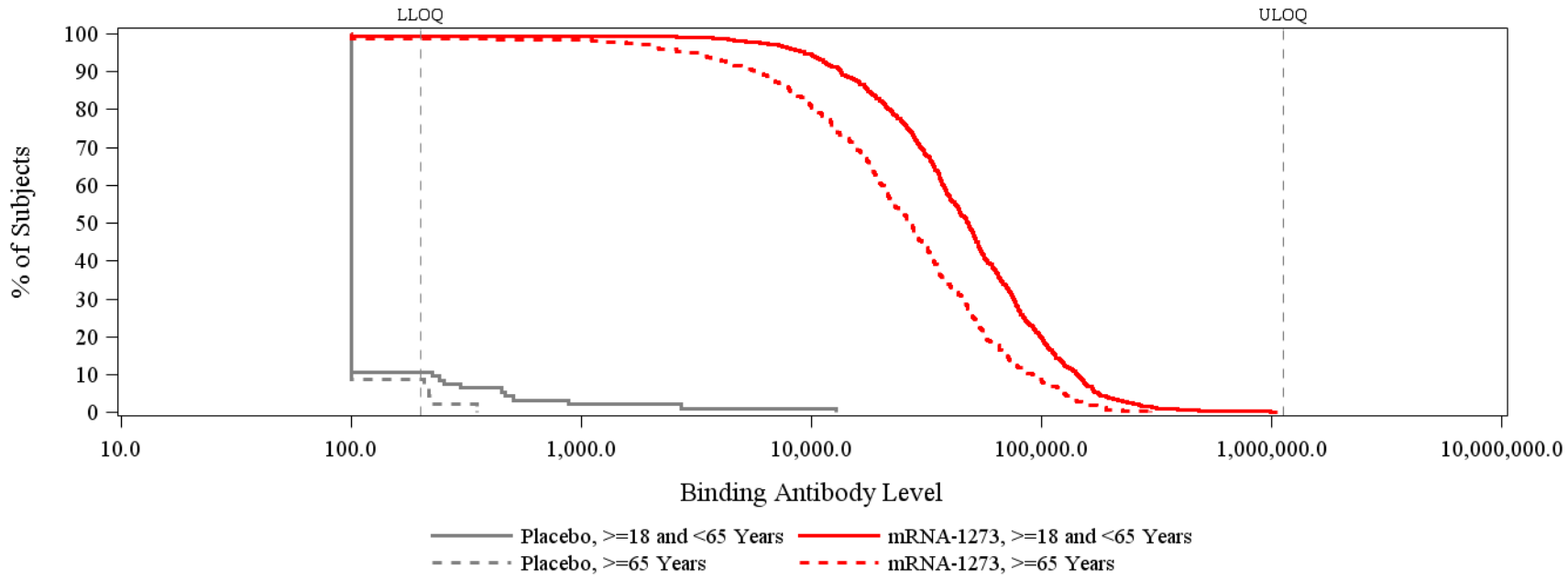
Figure 14.2.4.1.1.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 29



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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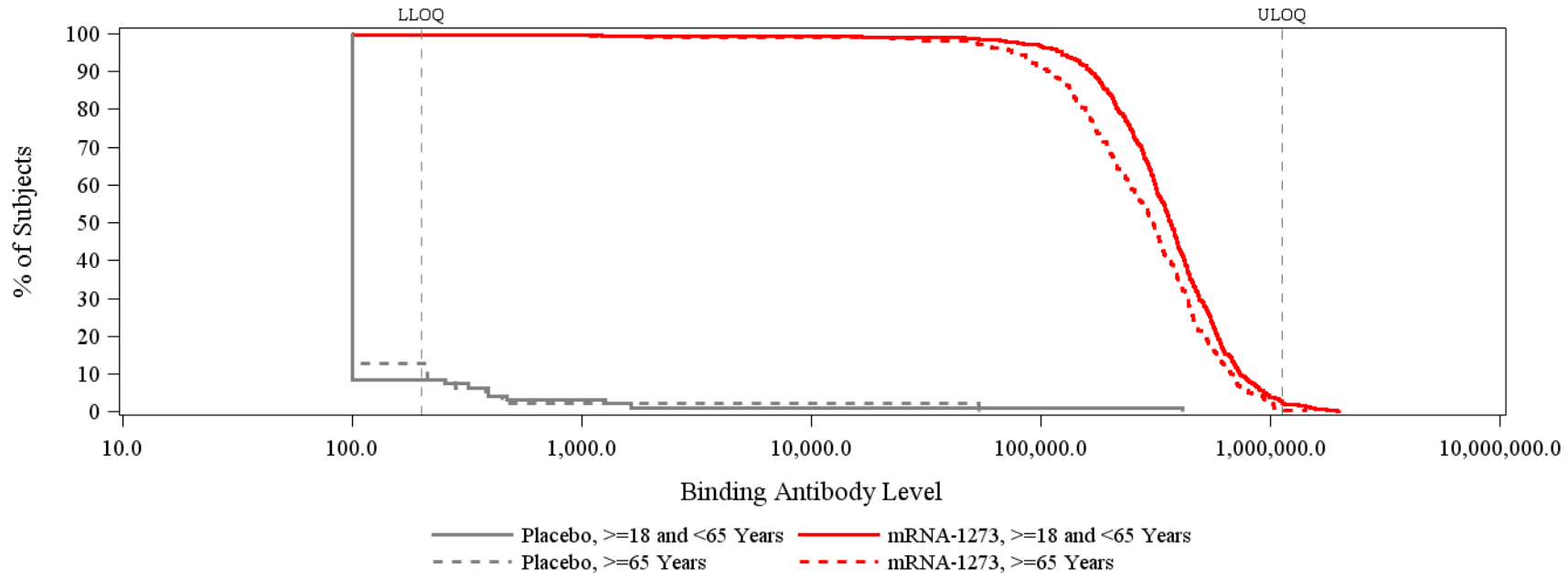
Figure 14.2.4.1.1.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 57



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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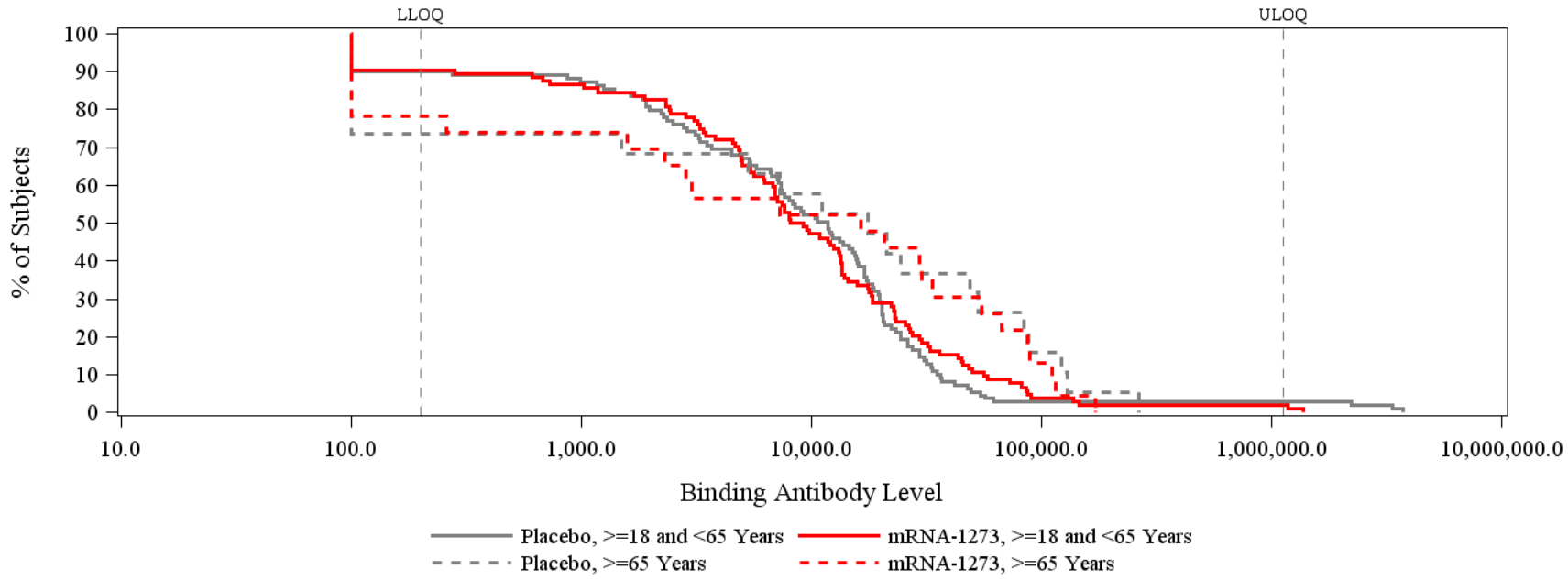
Figure 14.2.4.1.1.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Baseline (Day 1)



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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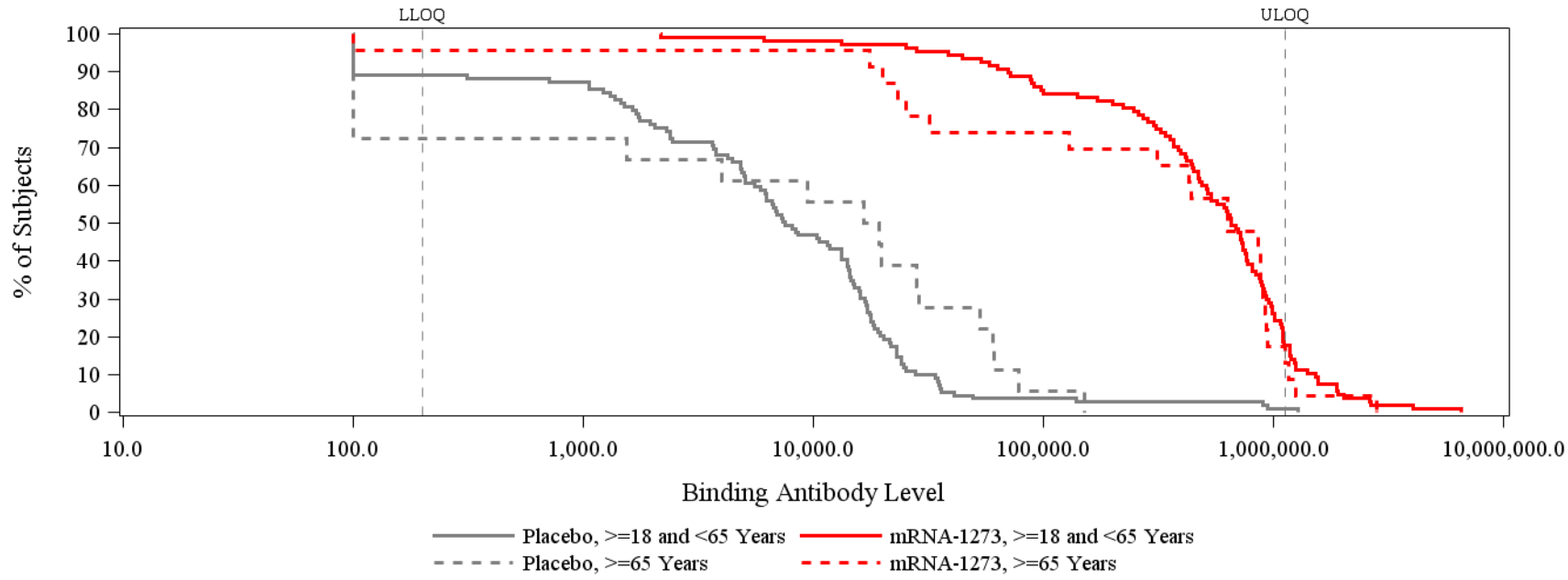
Figure 14.2.4.1.1.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 29



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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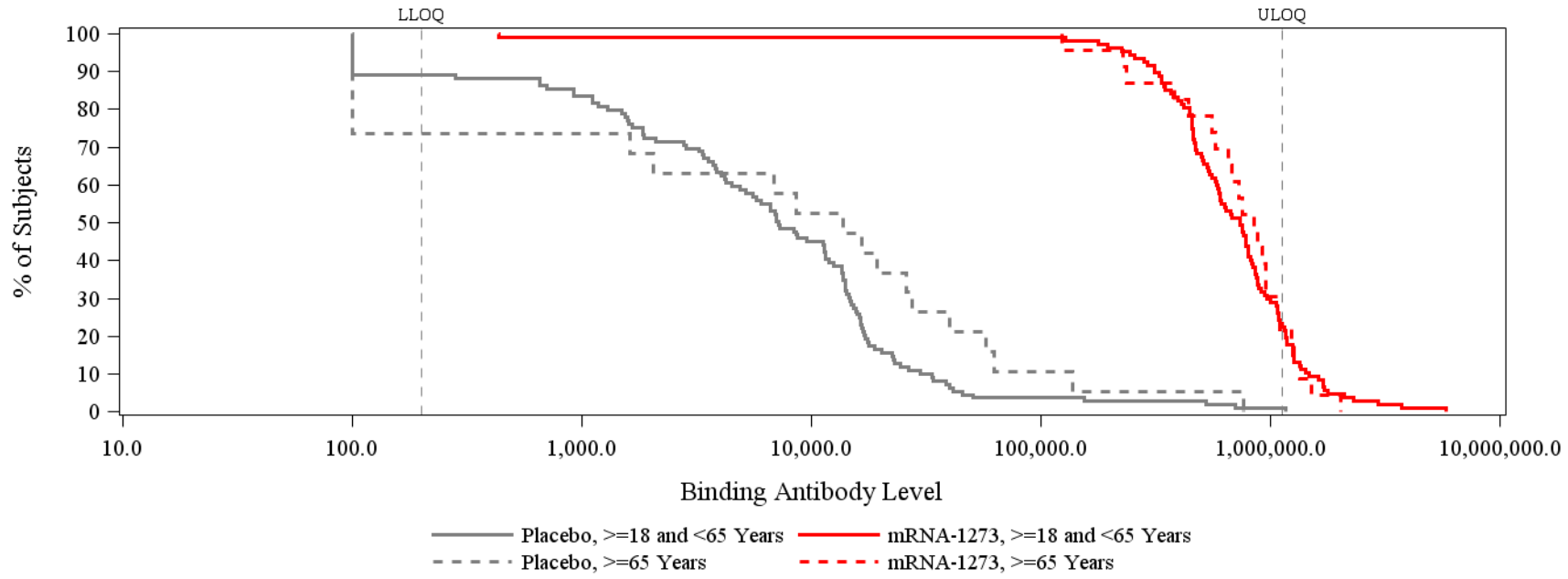
Figure 14.2.4.1.1.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)

Day 57



MSD = meso scale discovery.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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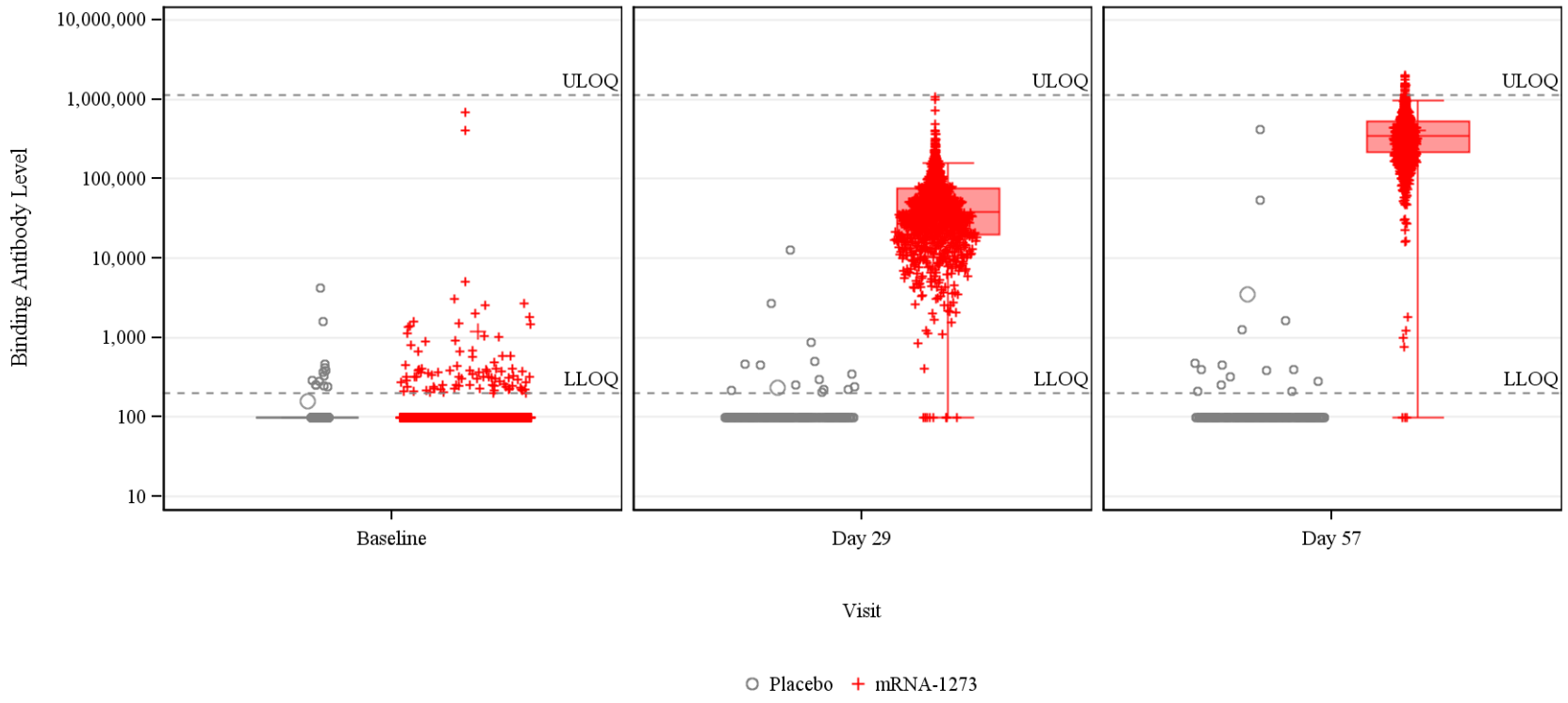
Figure 14.2.4.1.1.4.3.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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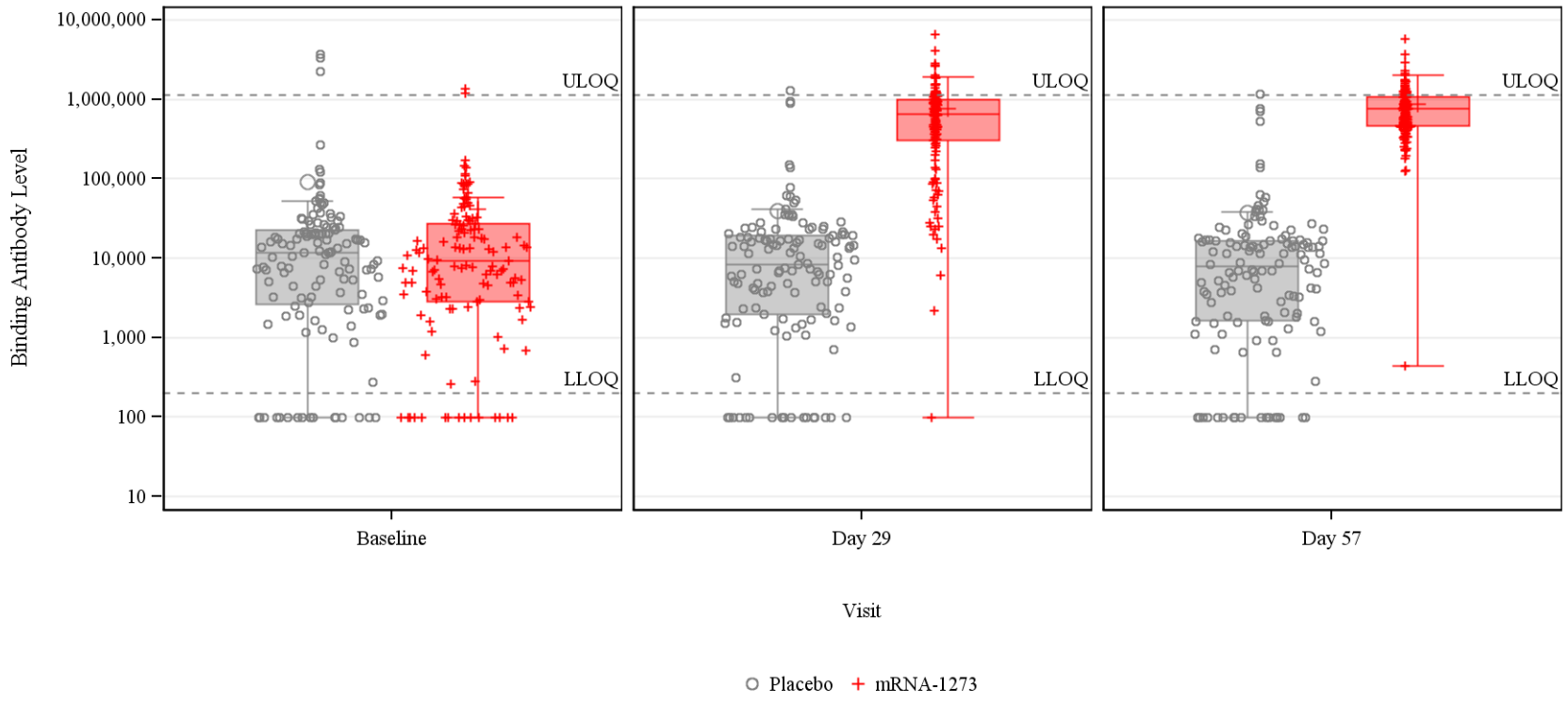
Figure 14.2.4.1.1.4.3.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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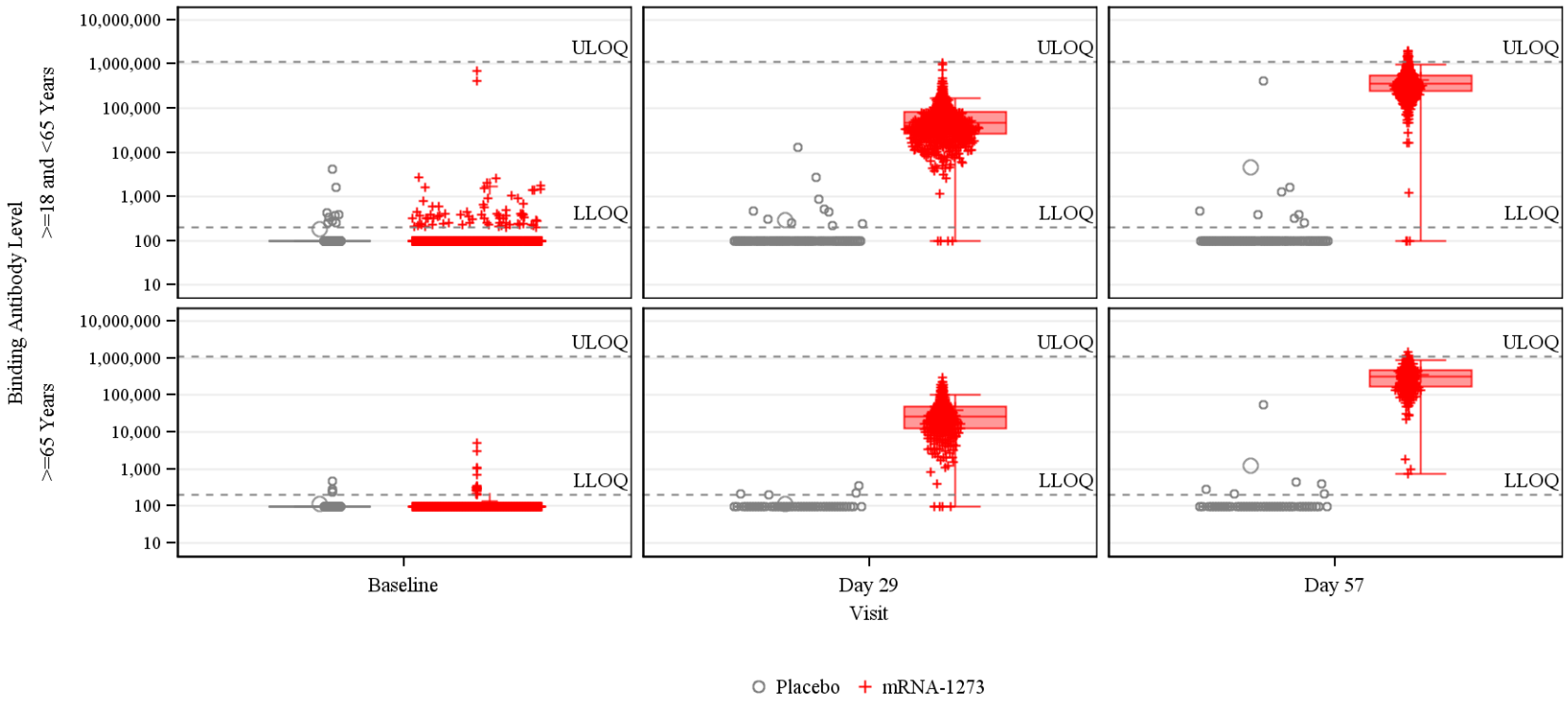
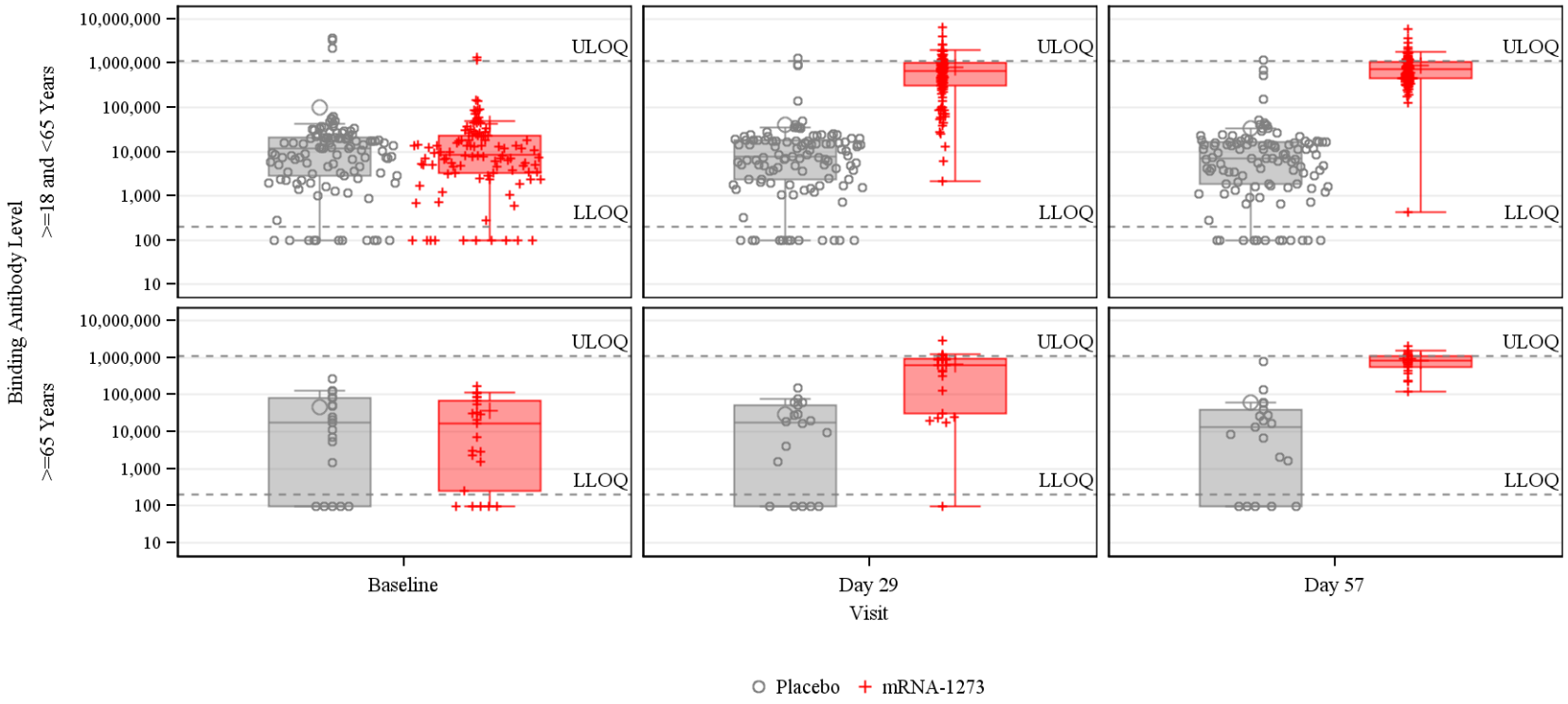
Figure 14.2.4.1.1.4.4.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f1402040101040401.sas 10JUN2021 16:28

Figure 14.2.4.1.1.4.4.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: SARSCOV2S2P IgG Antibody (AU/mL) by MSD MULTIPLEX (LLOQ: 199.64, ULOQ: 1128438.87)



MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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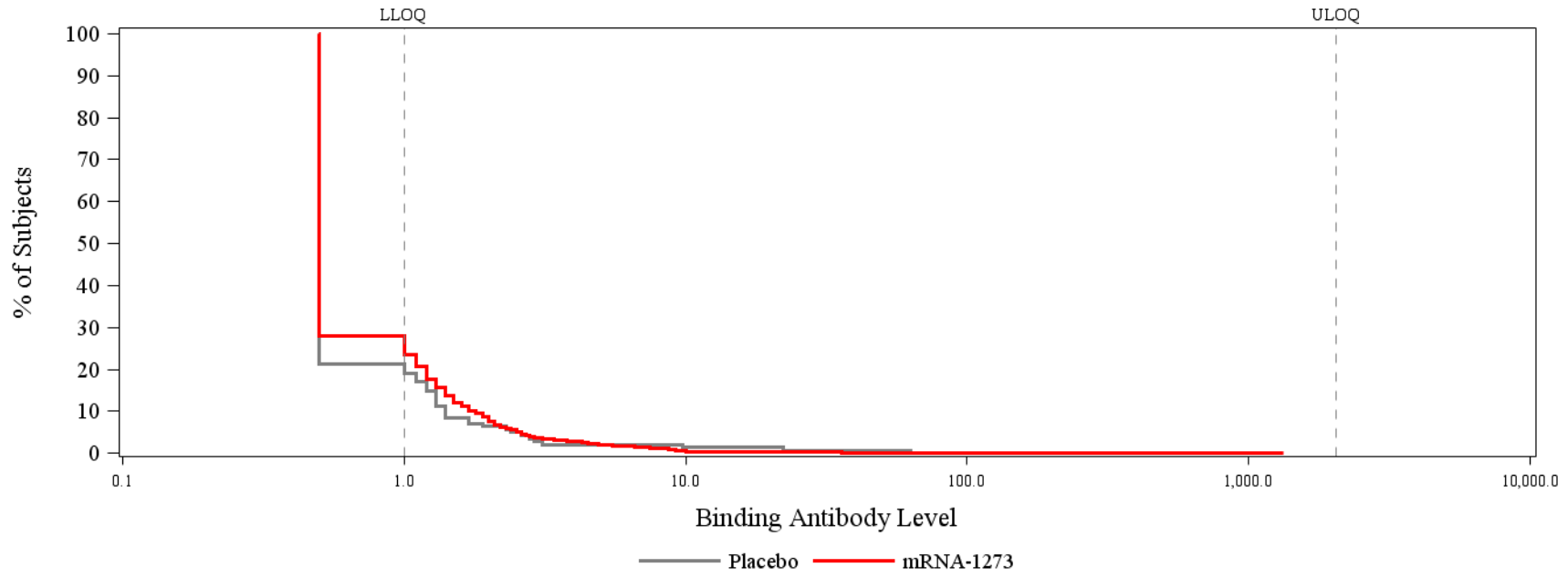
Figure 14.2.4.1.2.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Baseline (Day 1)



ELISA = enzyme-linked immunosorbent assay.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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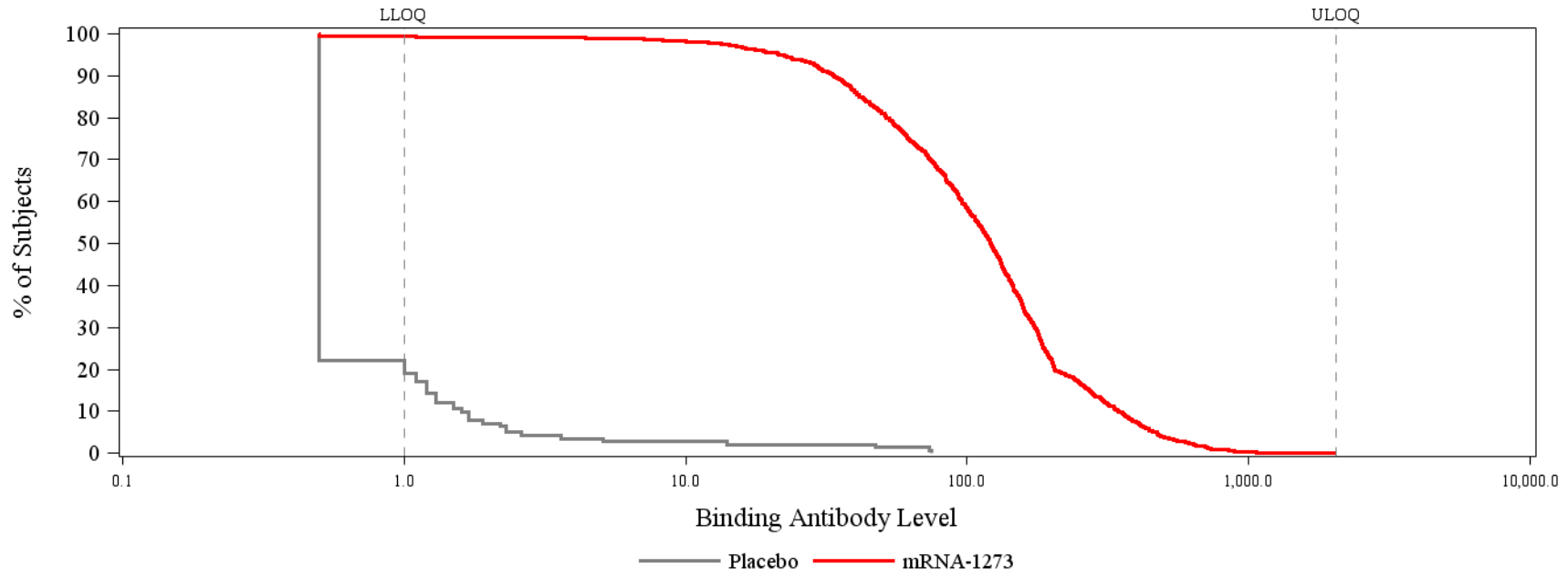
Figure 14.2.4.1.2.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 29



ELISA = enzyme-linked immunosorbent assay.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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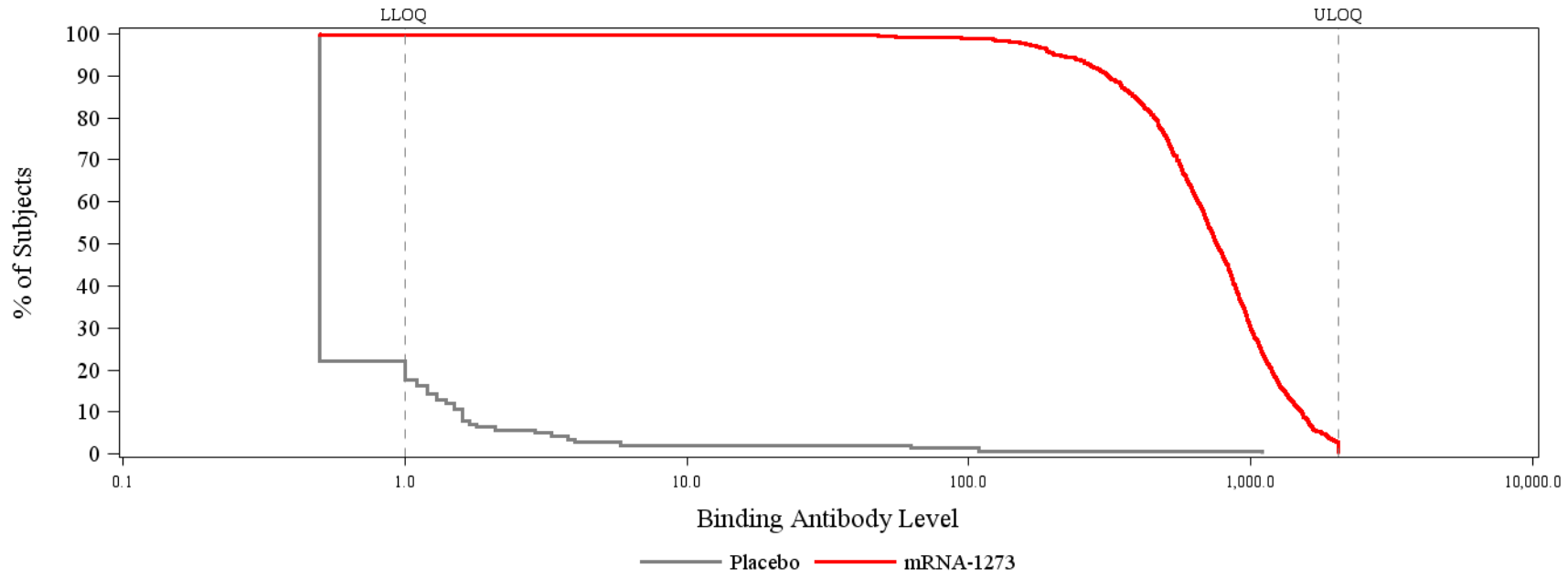
Figure 14.2.4.1.2.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 57



ELISA = enzyme-linked immunosorbent assay.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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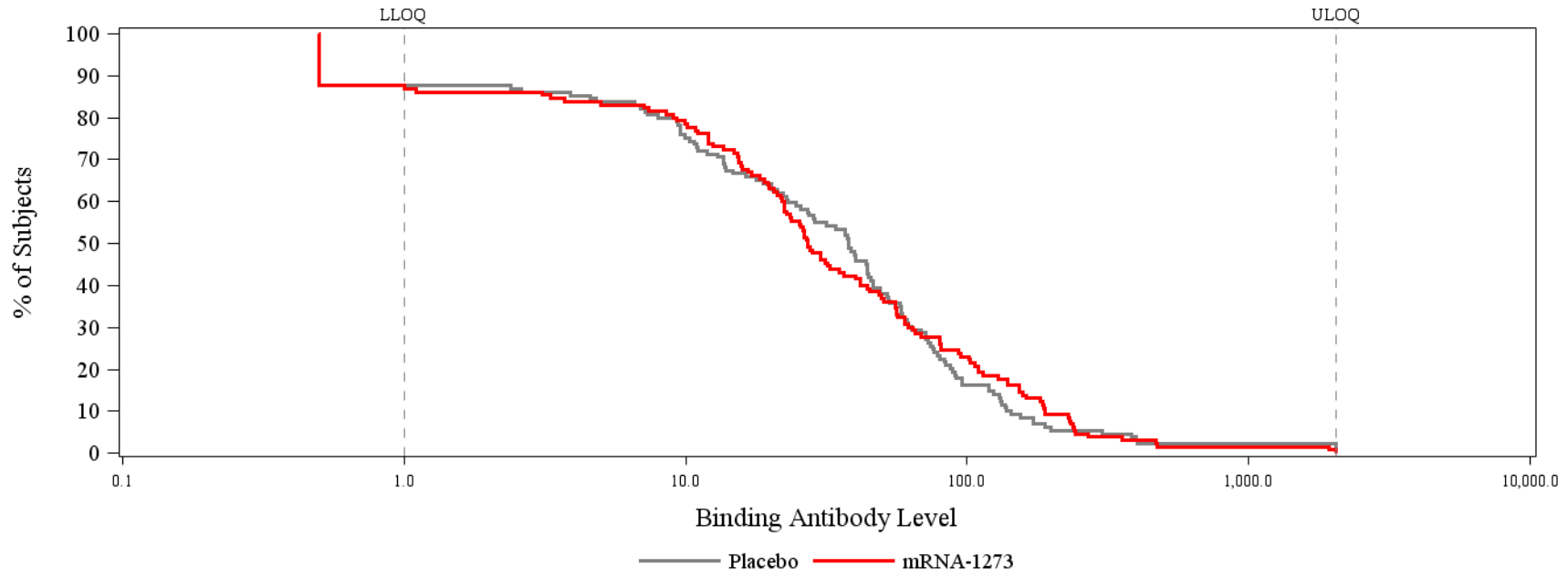
Figure 14.2.4.1.2.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Baseline (Day 1)



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Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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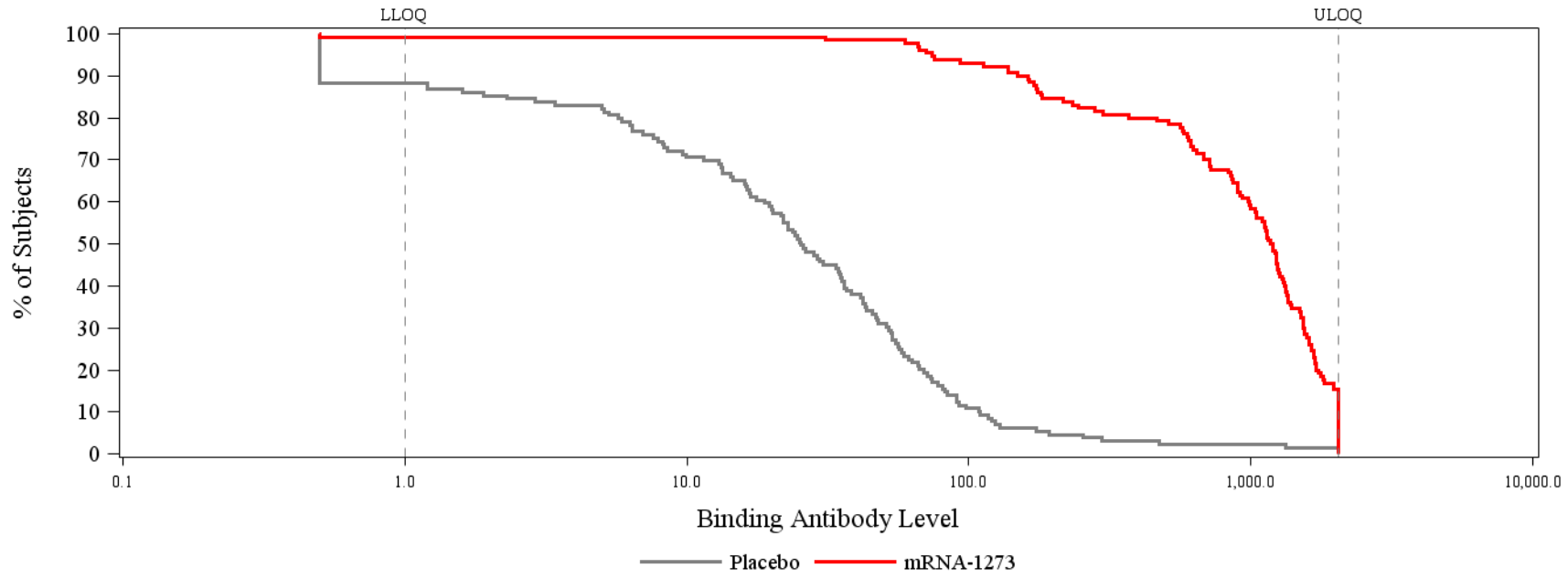
Figure 14.2.4.1.2.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 29



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Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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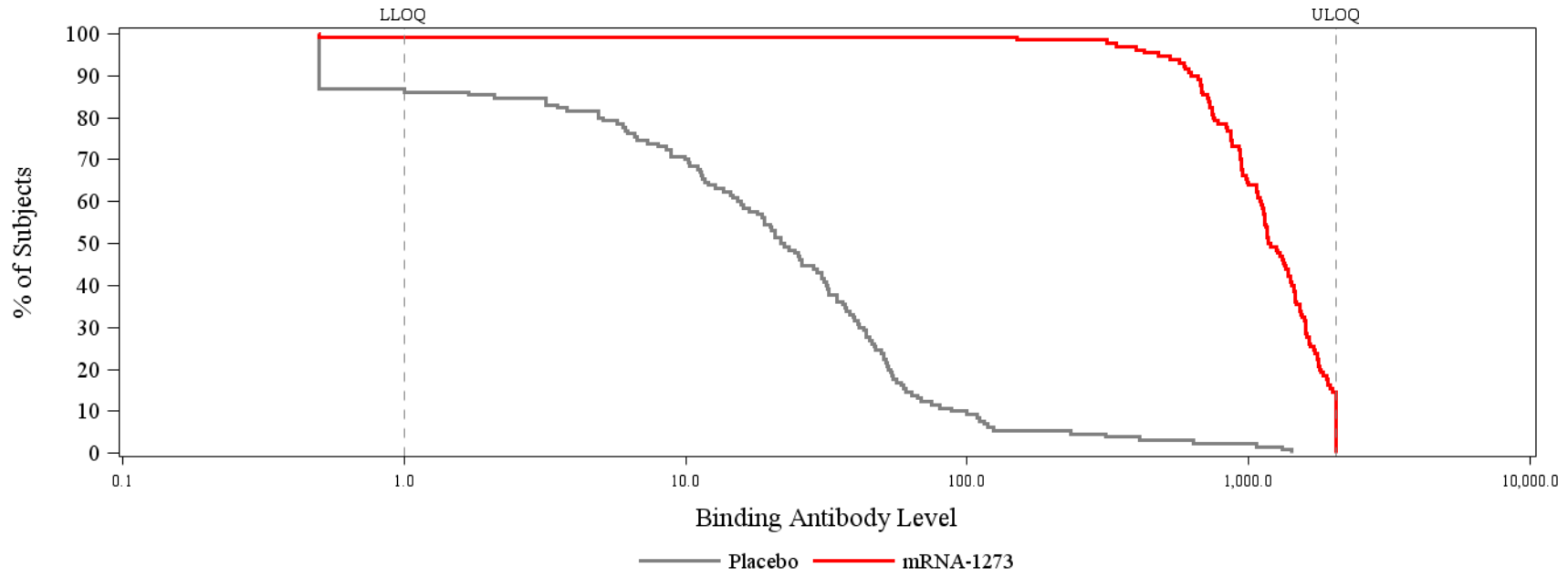
Figure 14.2.4.1.2.3.3.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 57



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Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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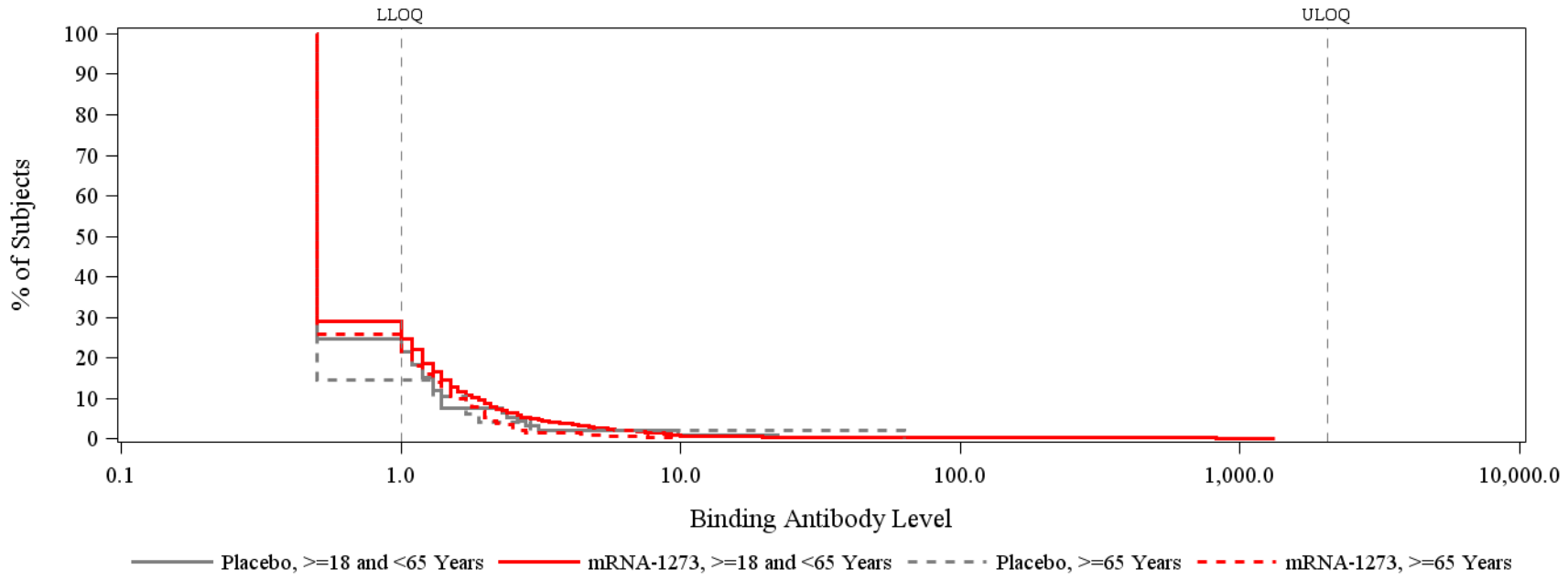
Figure 14.2.4.1.2.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Baseline (Day 1)



ELISA = enzyme-linked immunosorbent assay.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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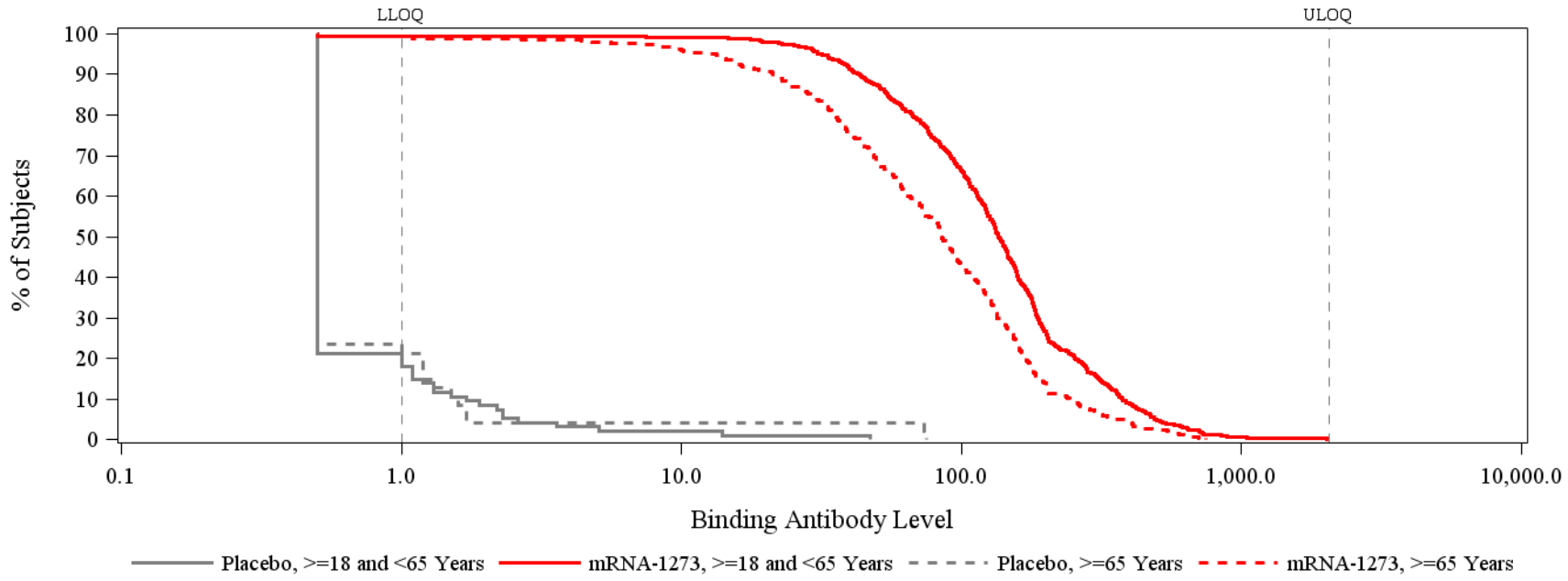
Figure 14.2.4.1.2.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 29



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Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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Figure 14.2.4.1.2.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 57

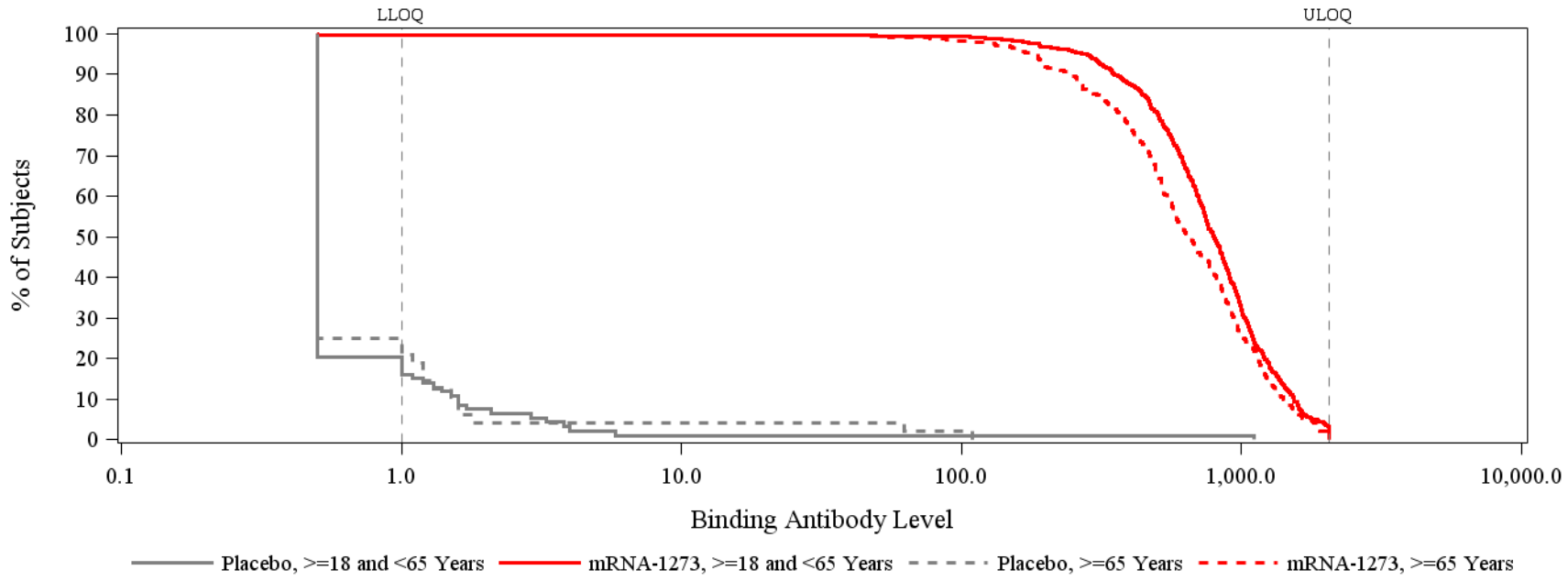

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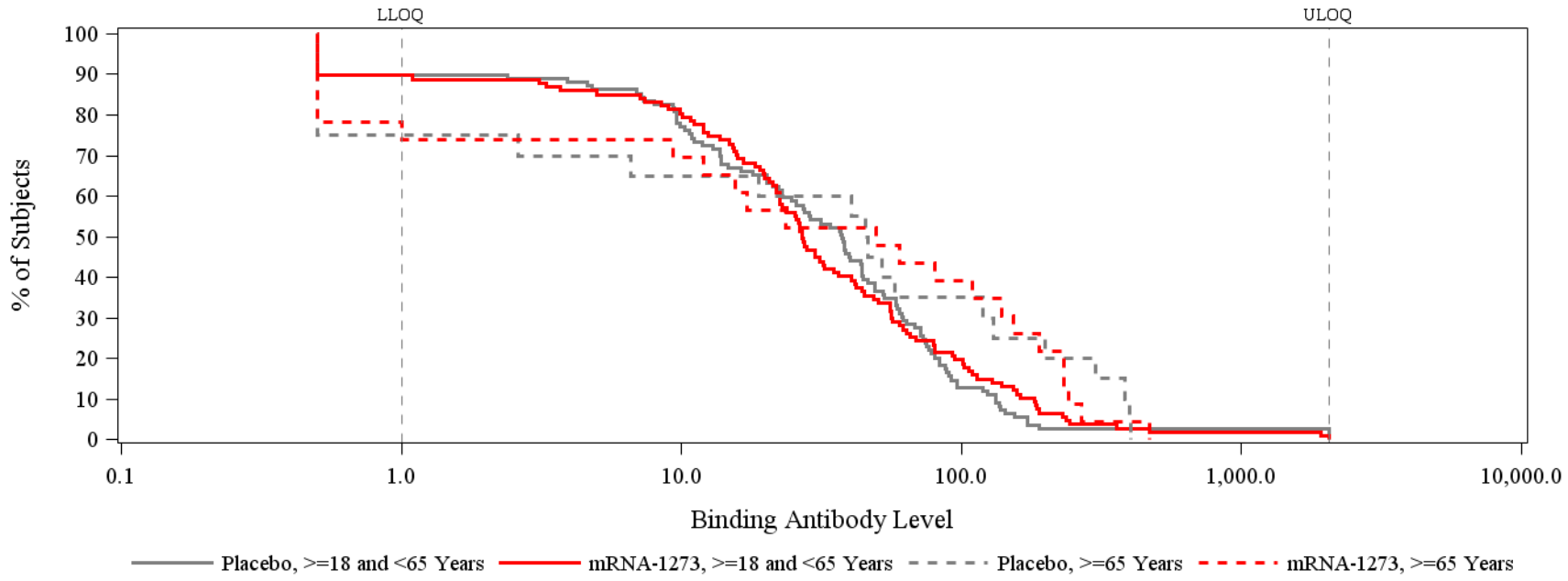
Figure 14.2.4.1.2.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Baseline (Day 1)



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Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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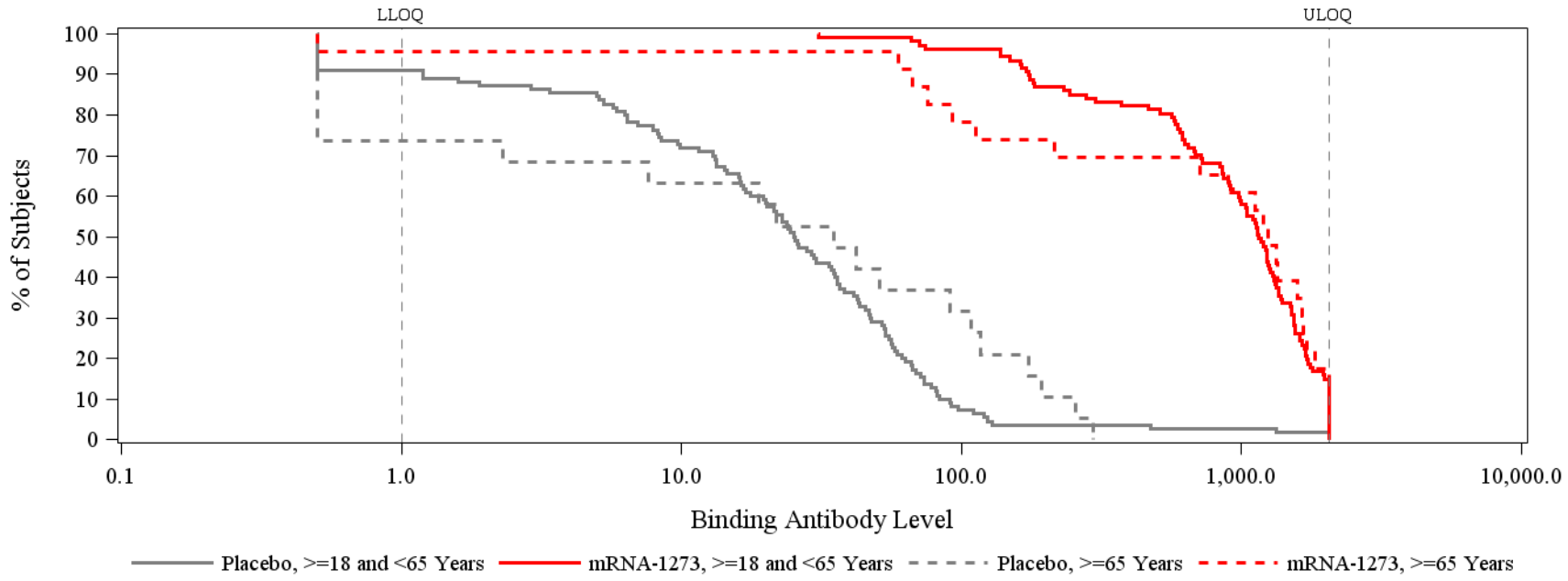
Figure 14.2.4.1.2.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 29



ELISA = enzyme-linked immunosorbent assay.
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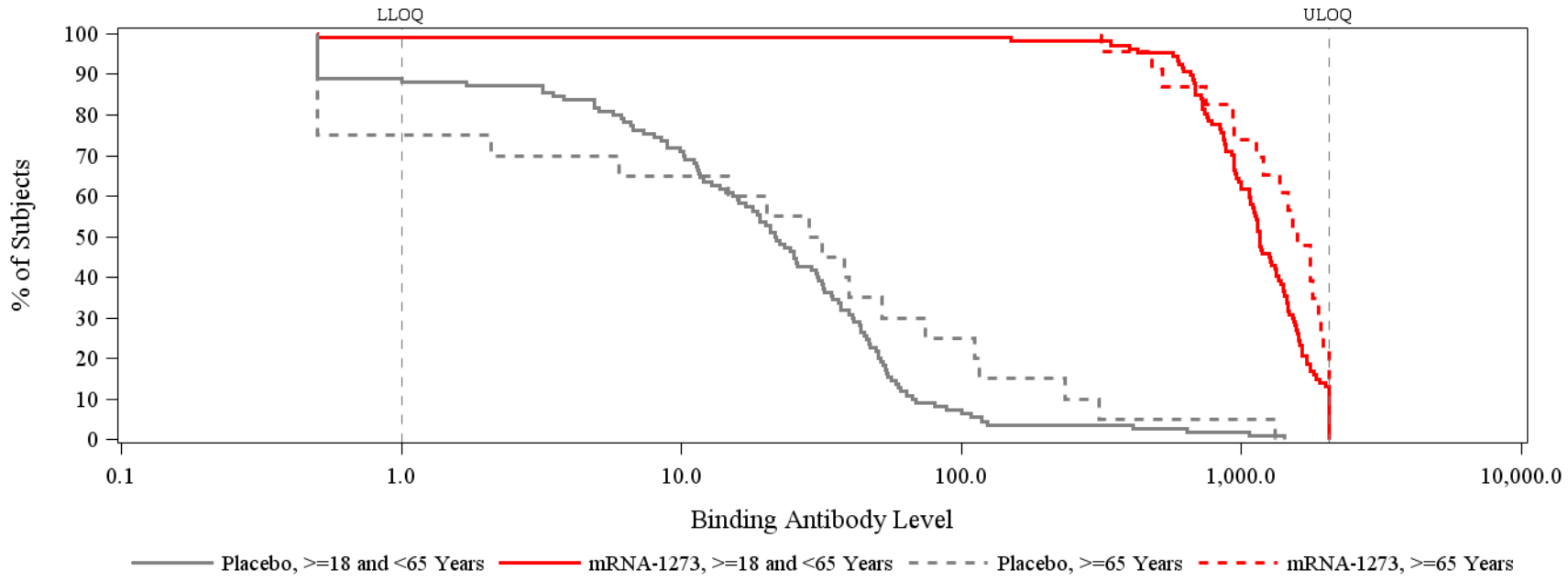
Figure 14.2.4.1.2.3.4.1
Reverse Cumulative Distribution Function of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Day 57



ELISA = enzyme-linked immunosorbent assay.
Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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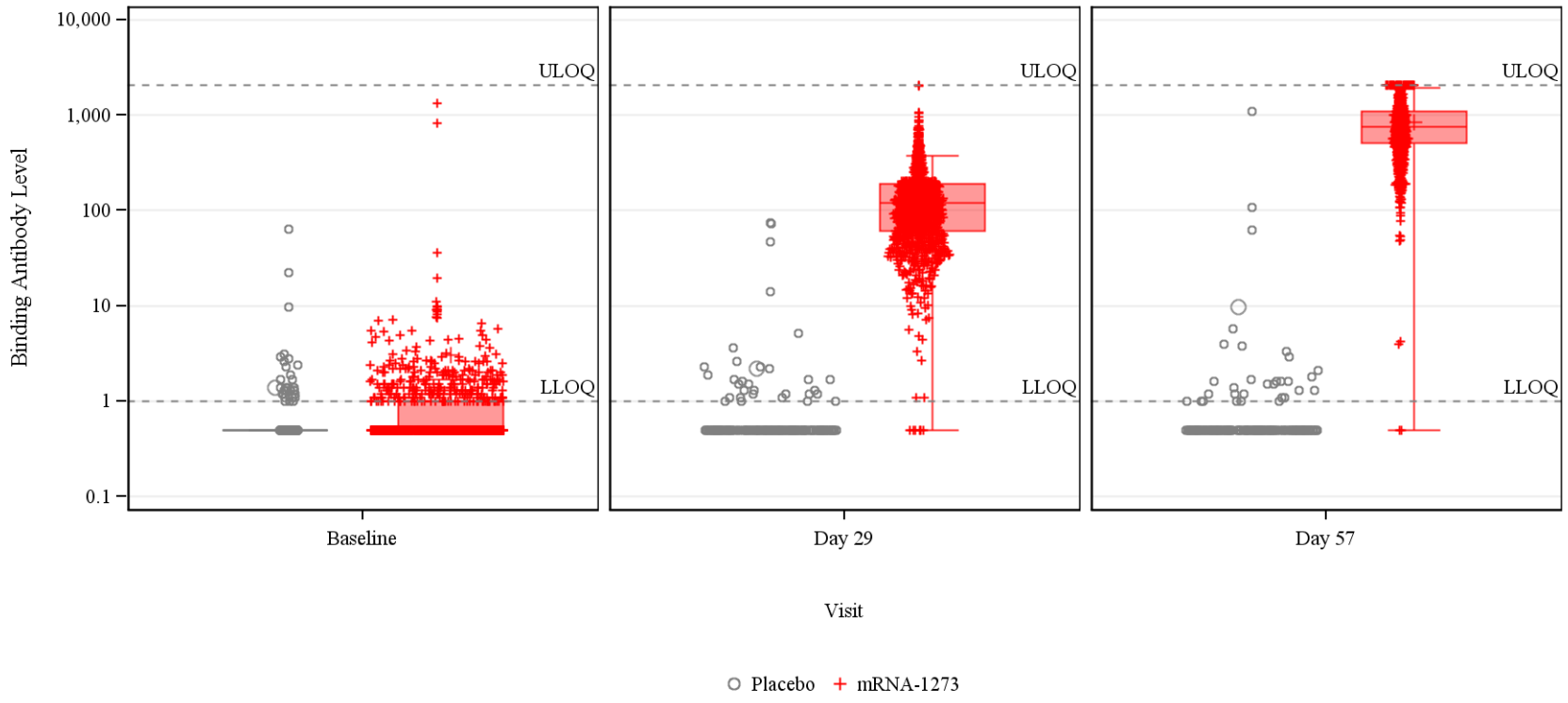
Figure 14.2.4.1.2.4.3.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



ELISA = enzyme-linked immunosorbent assay.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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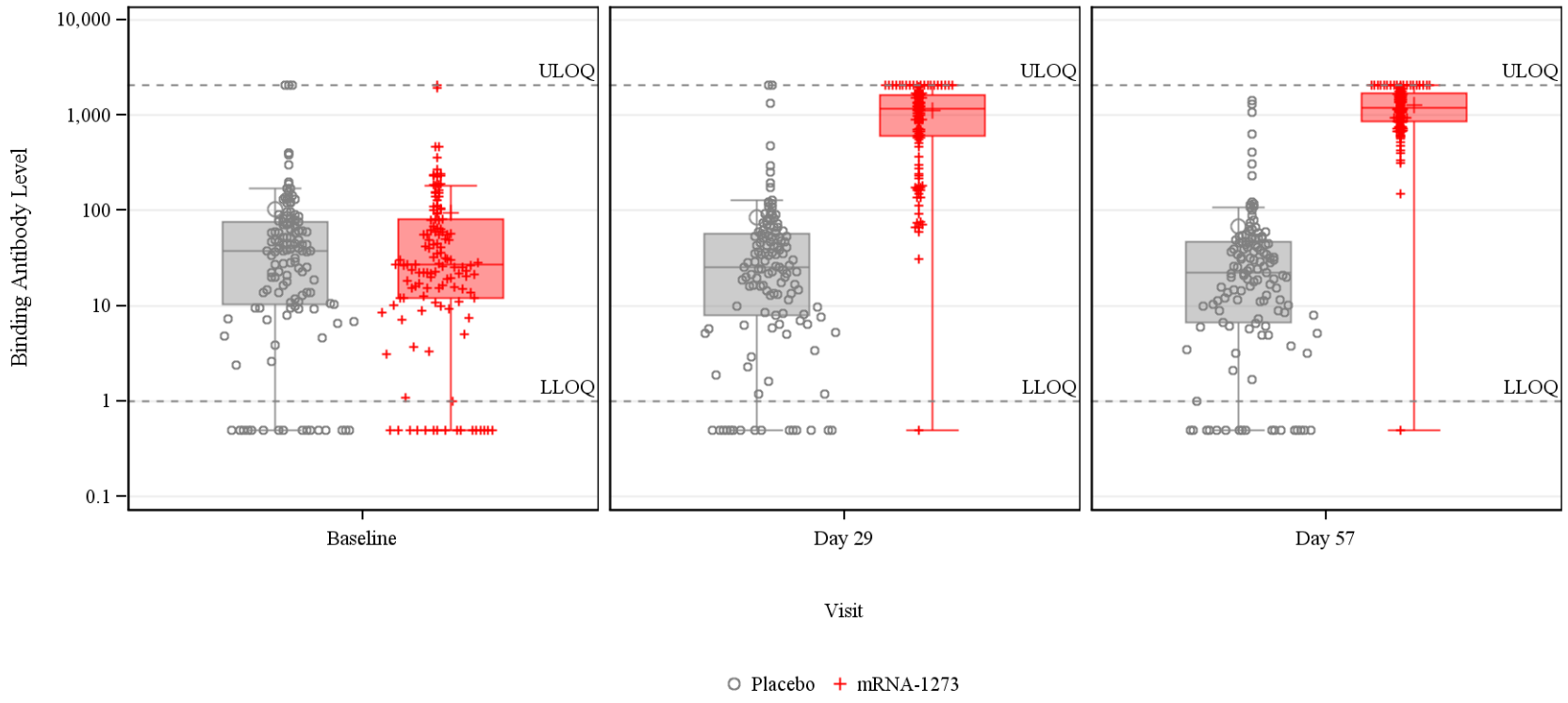
Figure 14.2.4.1.2.4.3.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



ELISA = enzyme-linked immunosorbent assay.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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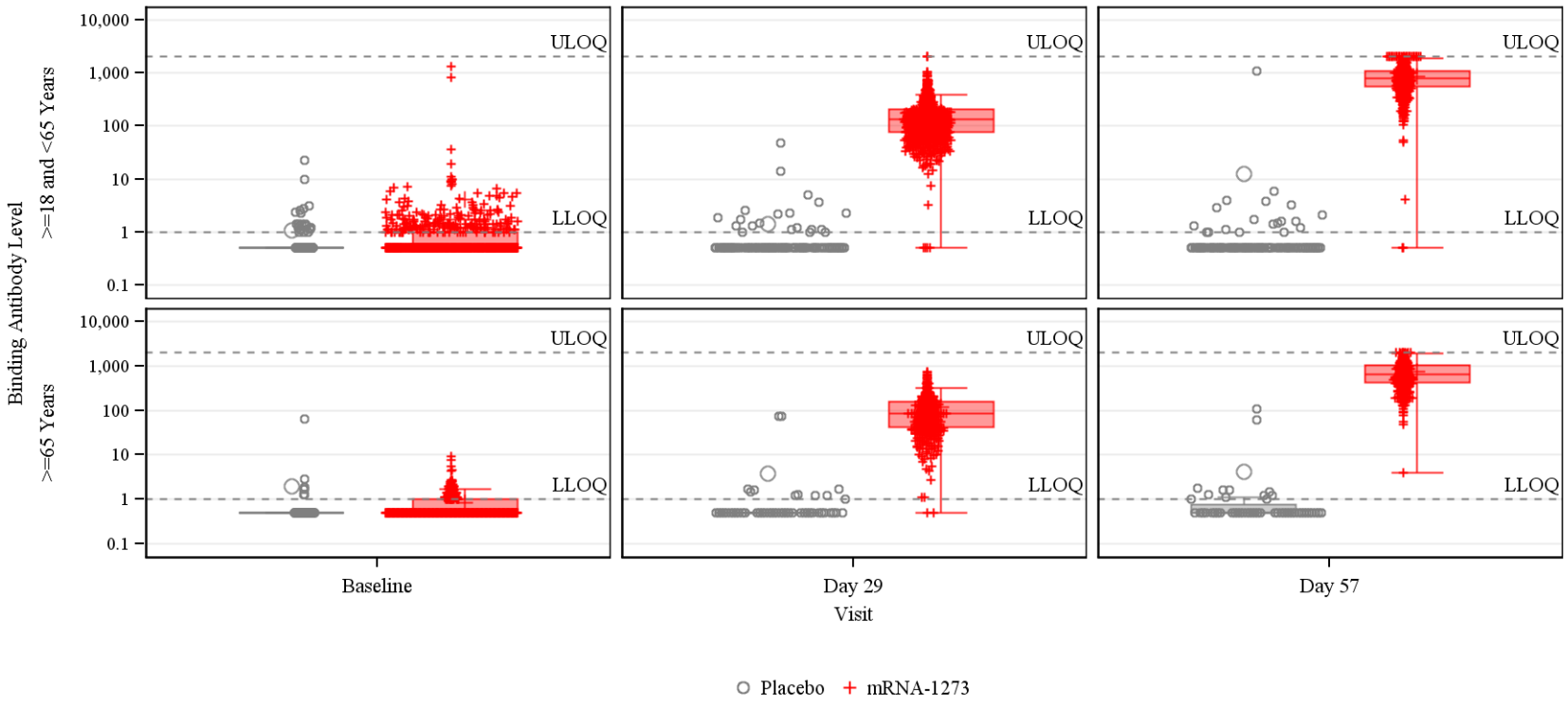
Figure 14.2.4.1.2.4.4.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



ELISA = enzyme-linked immunosorbent assay.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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Figure 14.2.4.1.2.4.4.1
Box Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

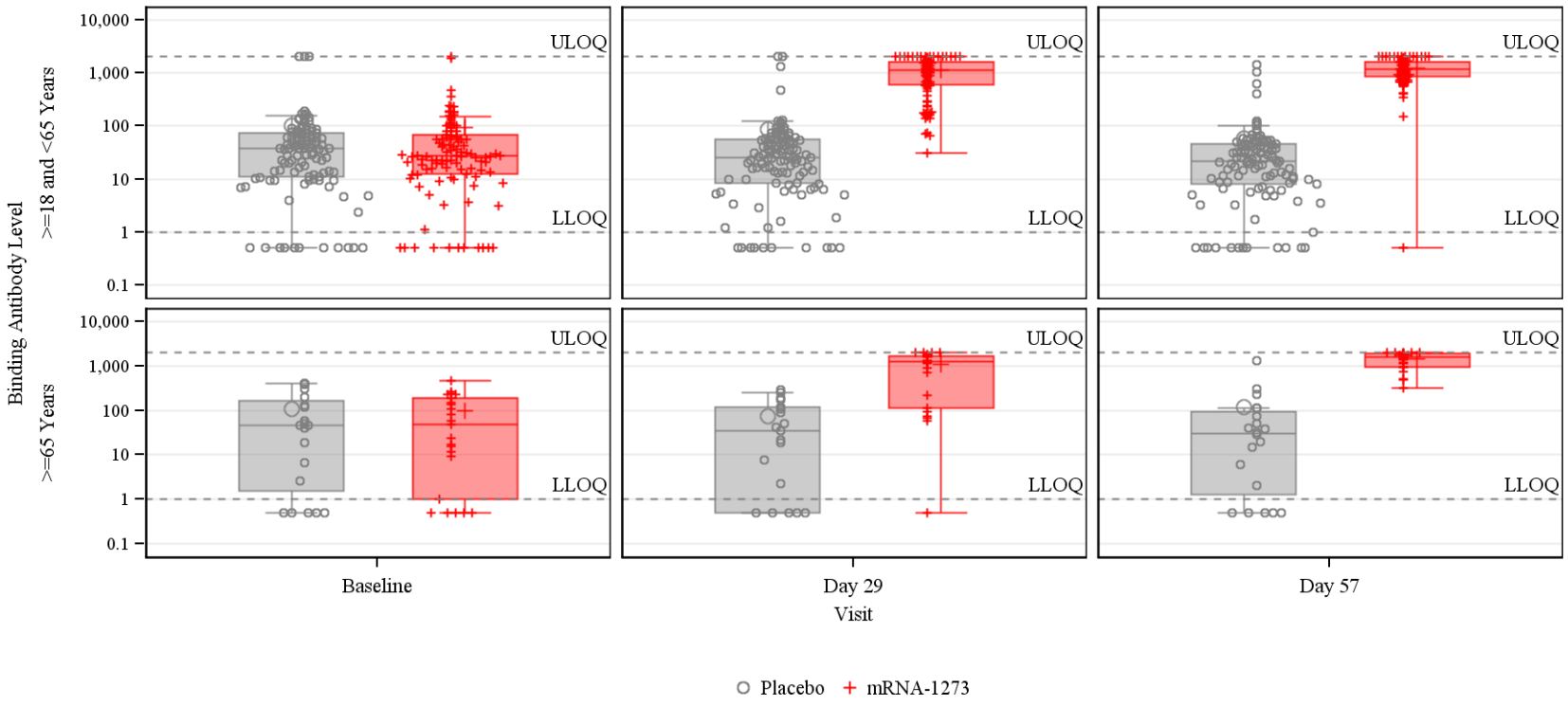

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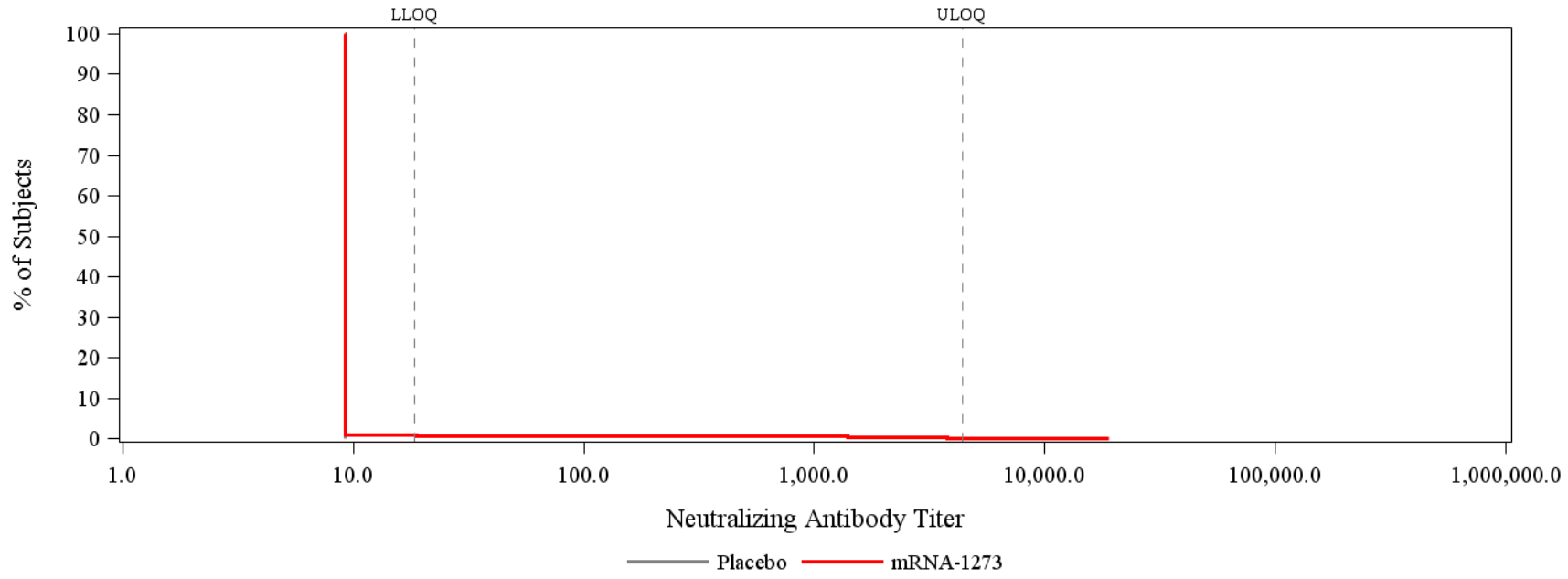
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Baseline (Day 1)



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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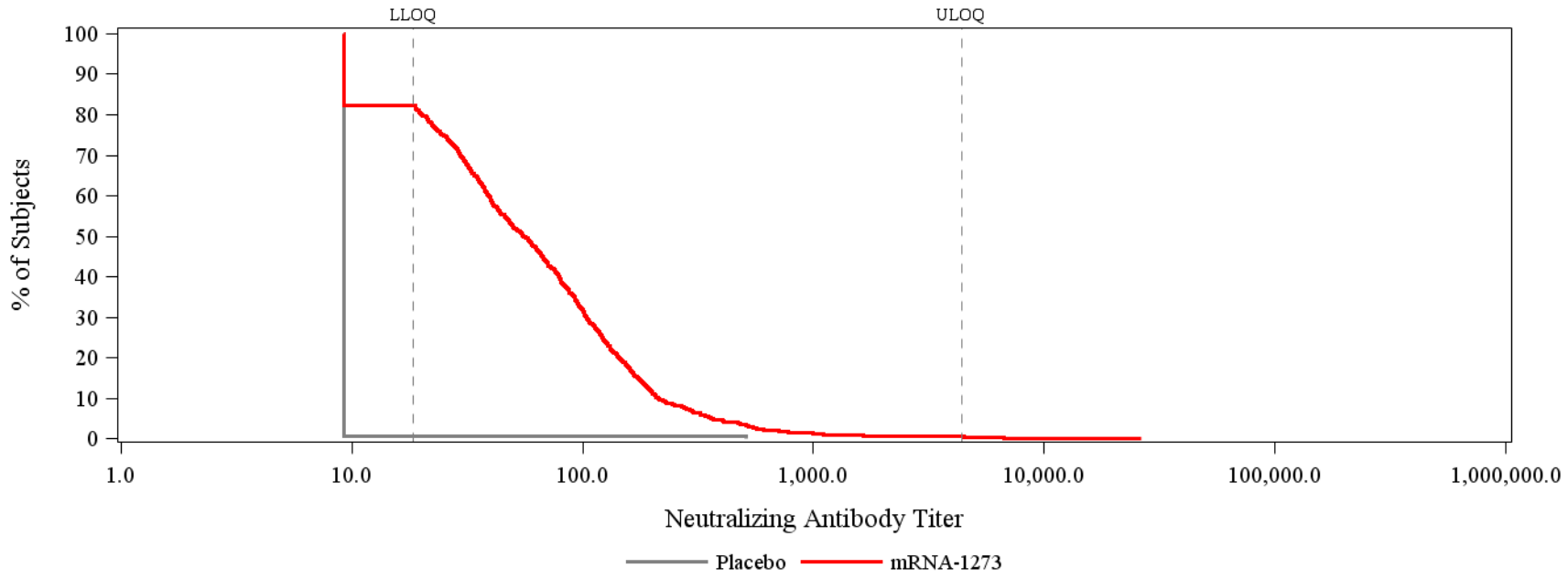
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 29



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 57

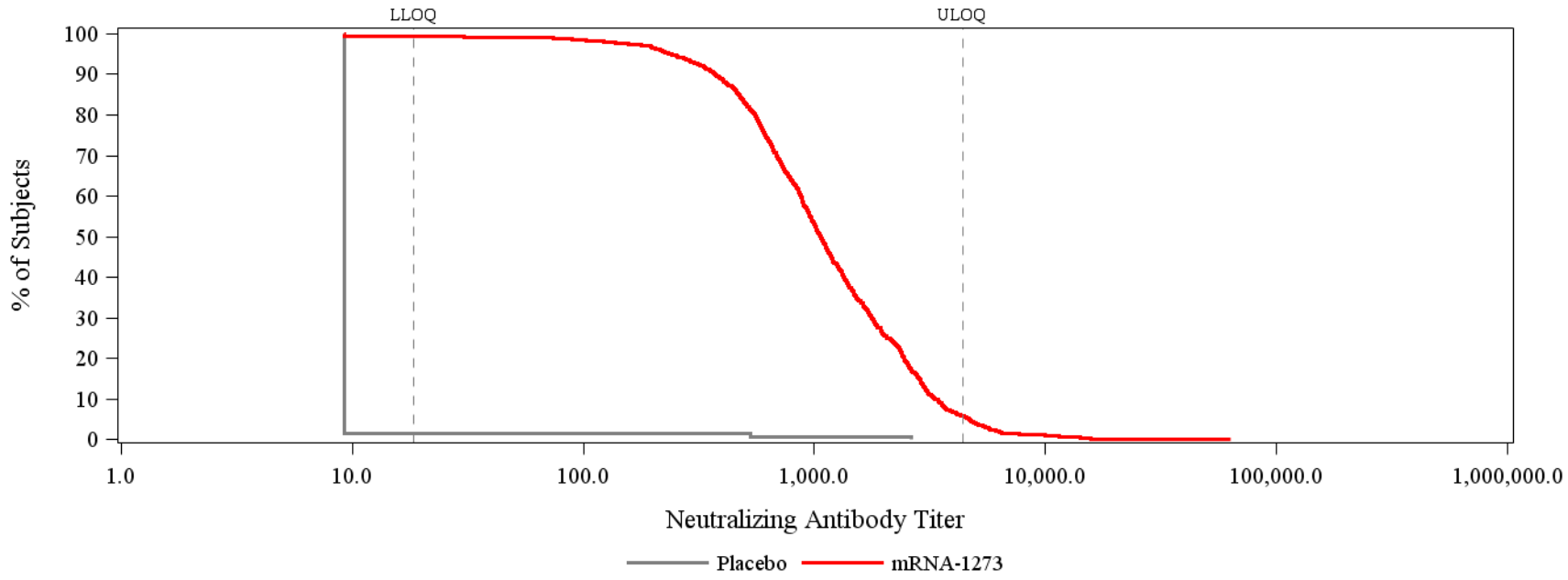

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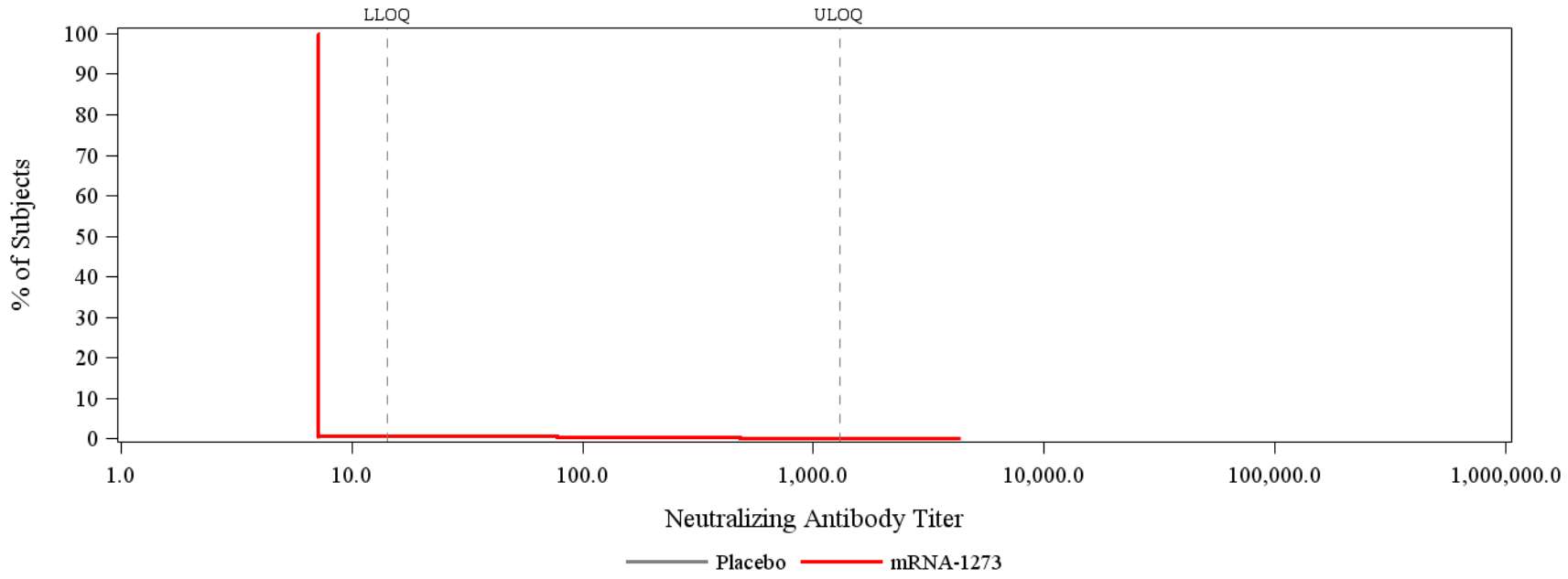
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Baseline (Day 1)



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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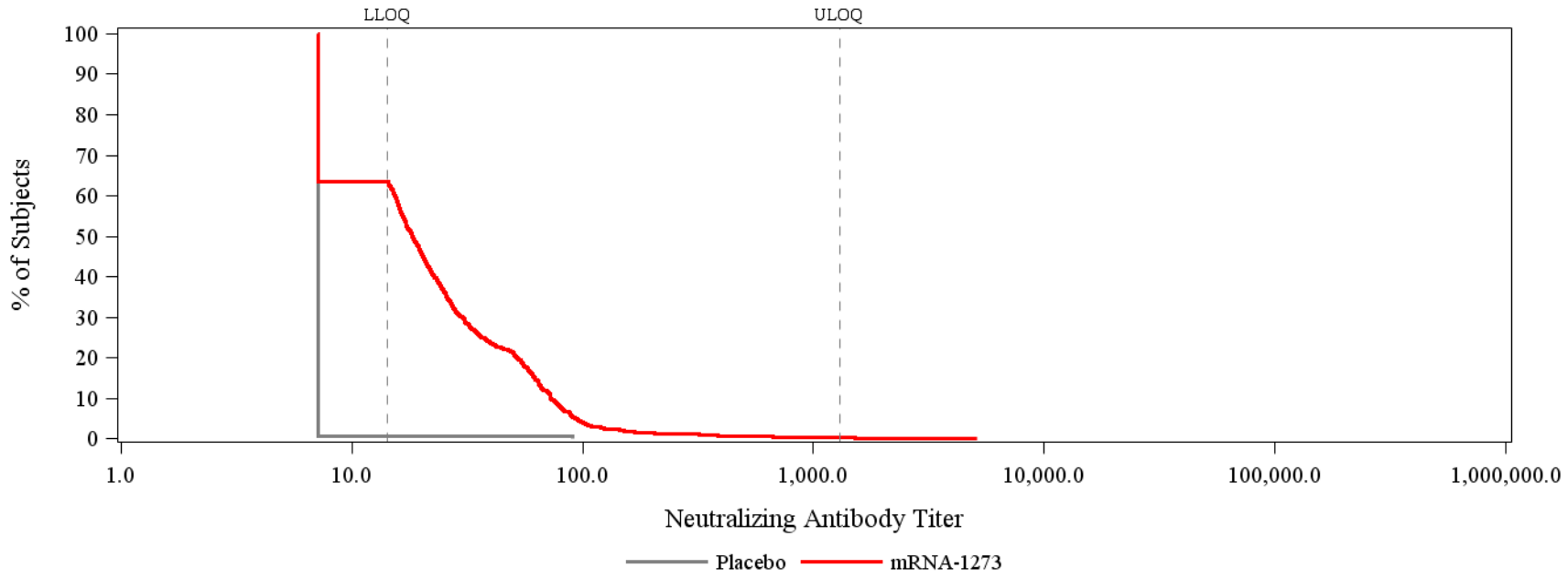
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 29



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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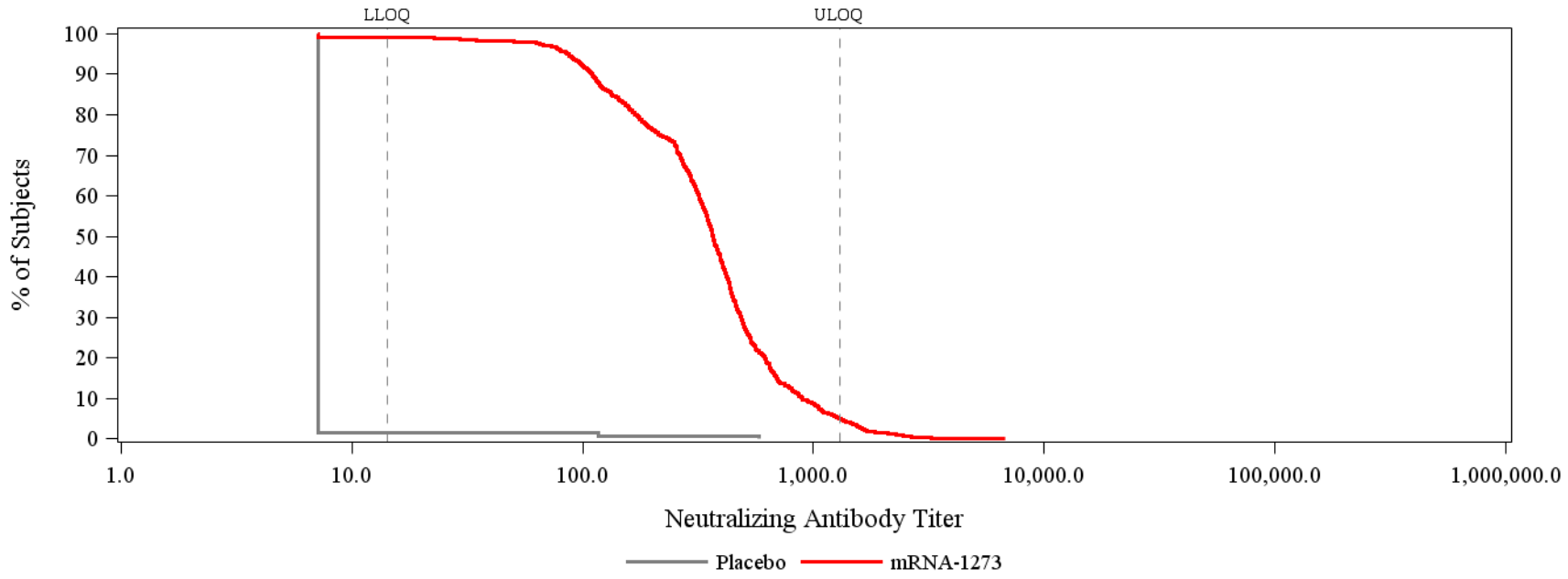
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 57



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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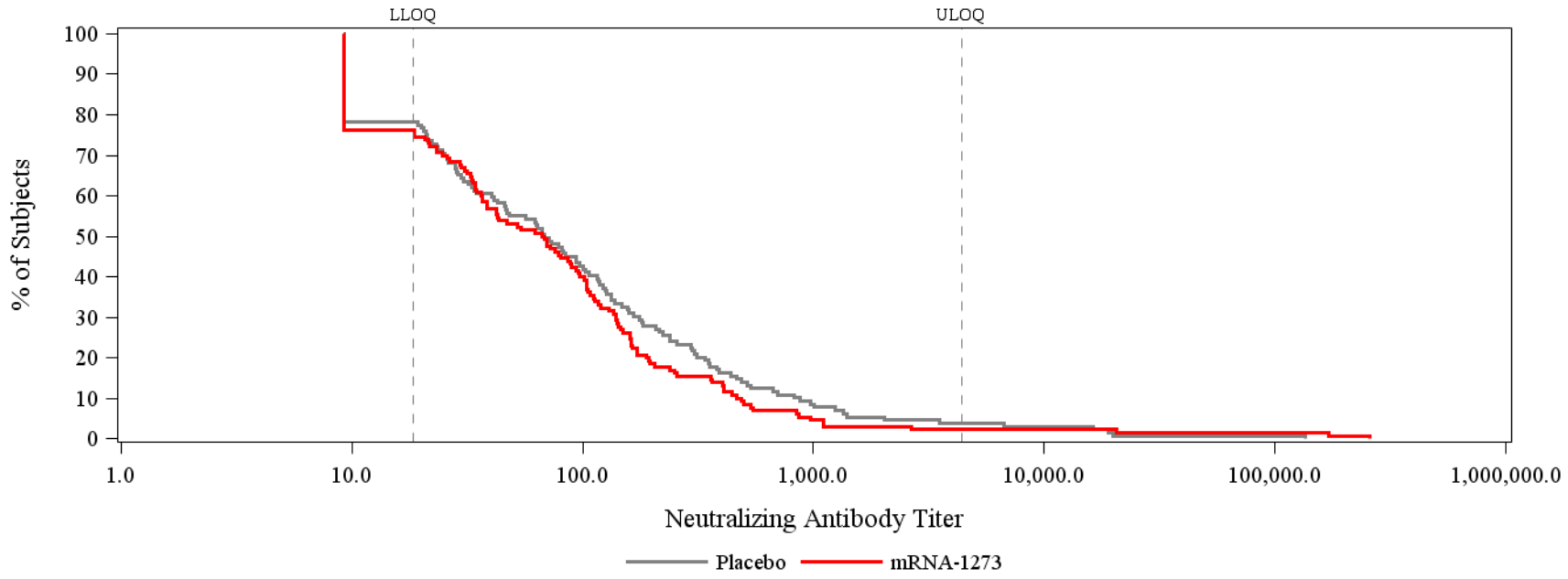
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Baseline (Day 1)



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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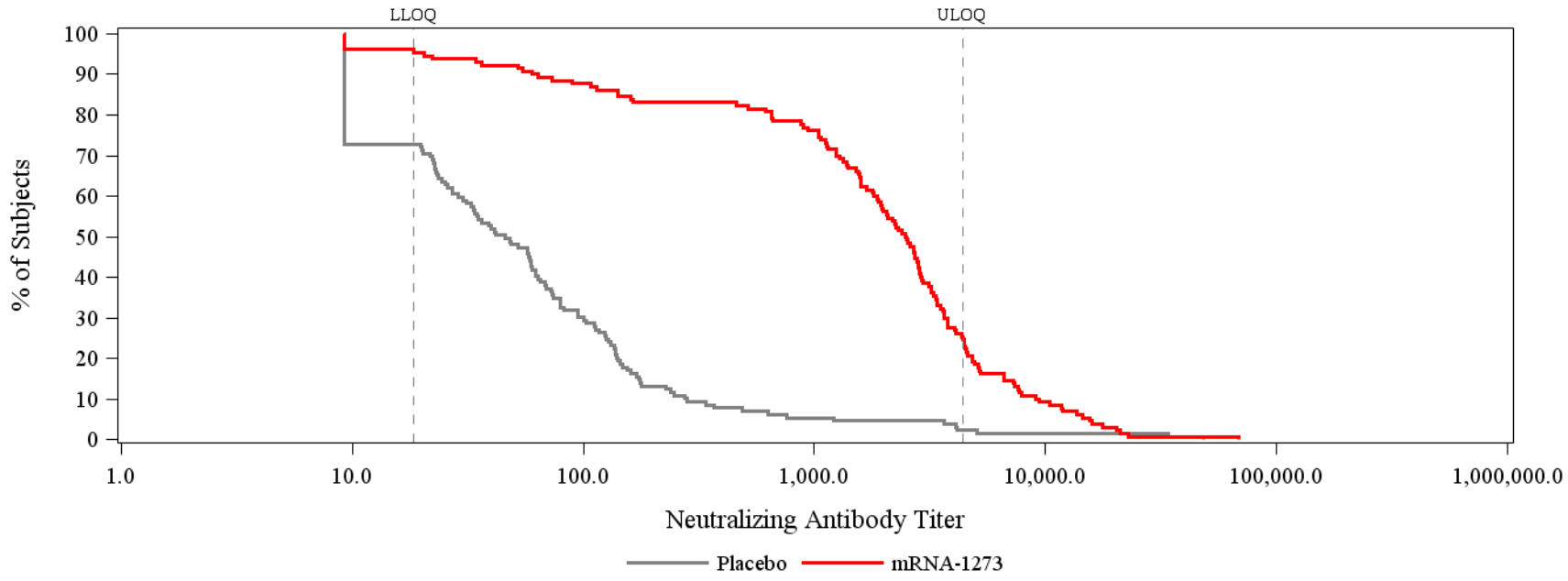
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 29



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 57

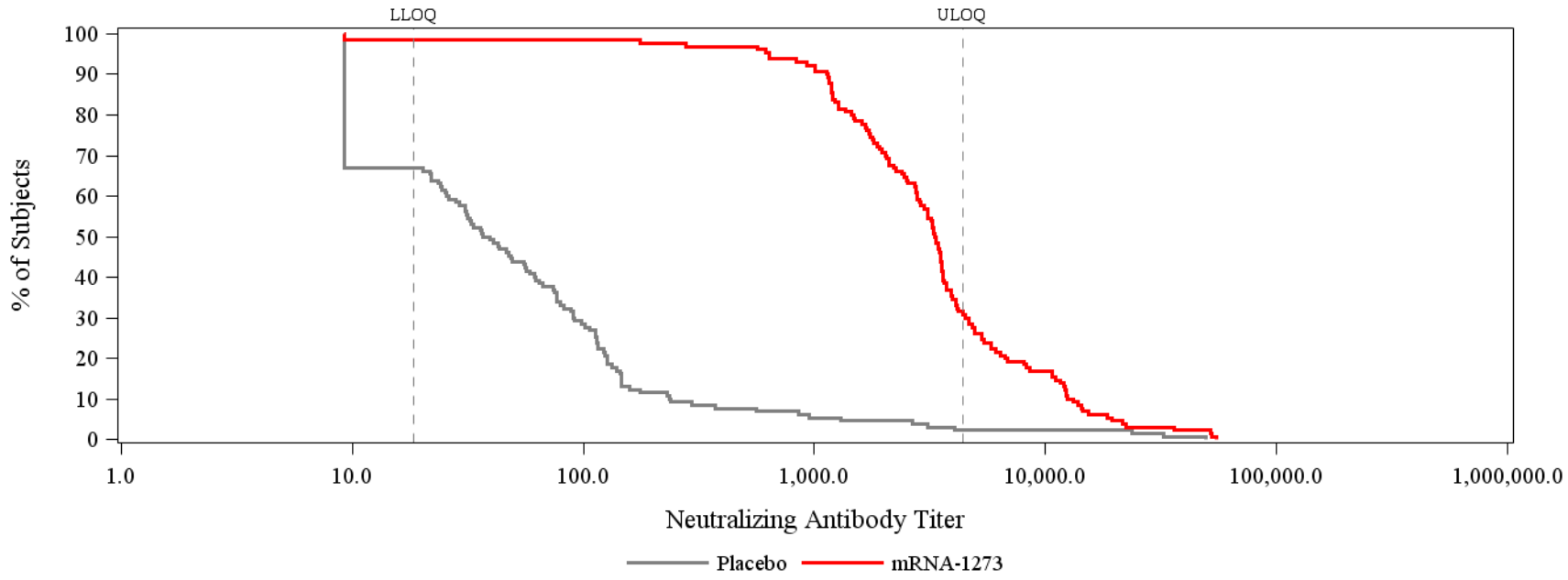

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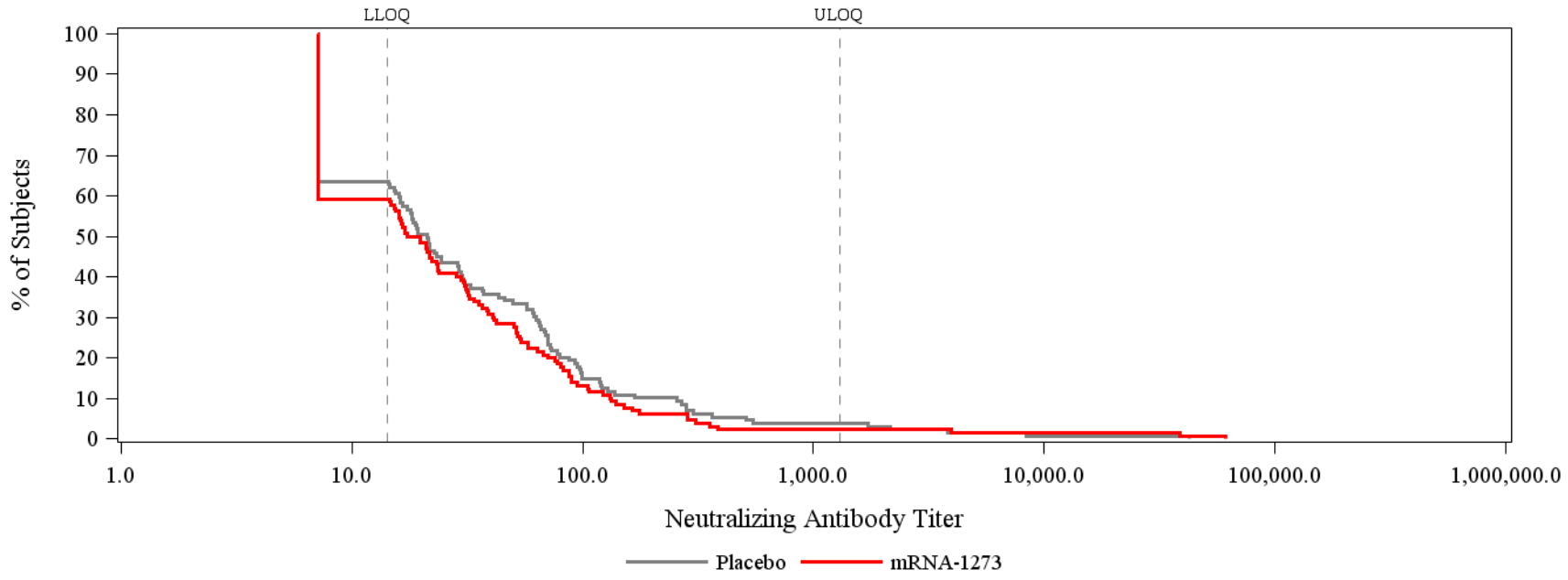
Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Baseline (Day 1)



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 29

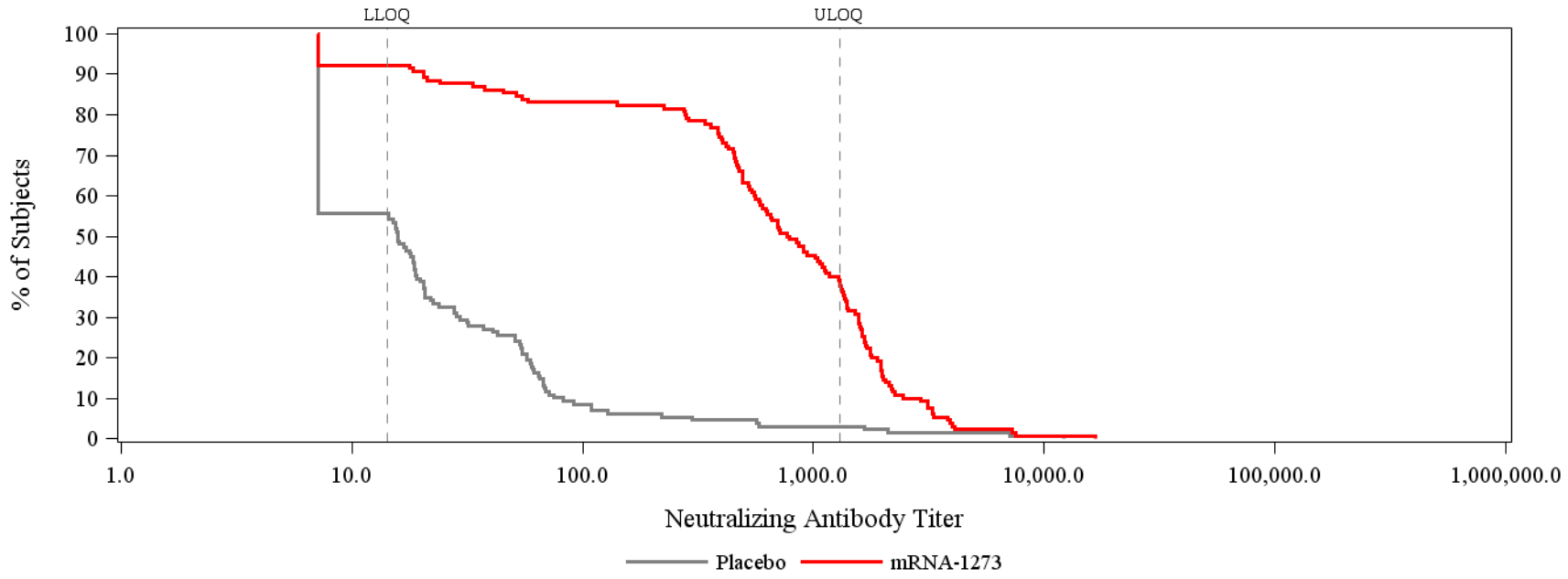

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Figure 14.2.4.2.3.3.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 57

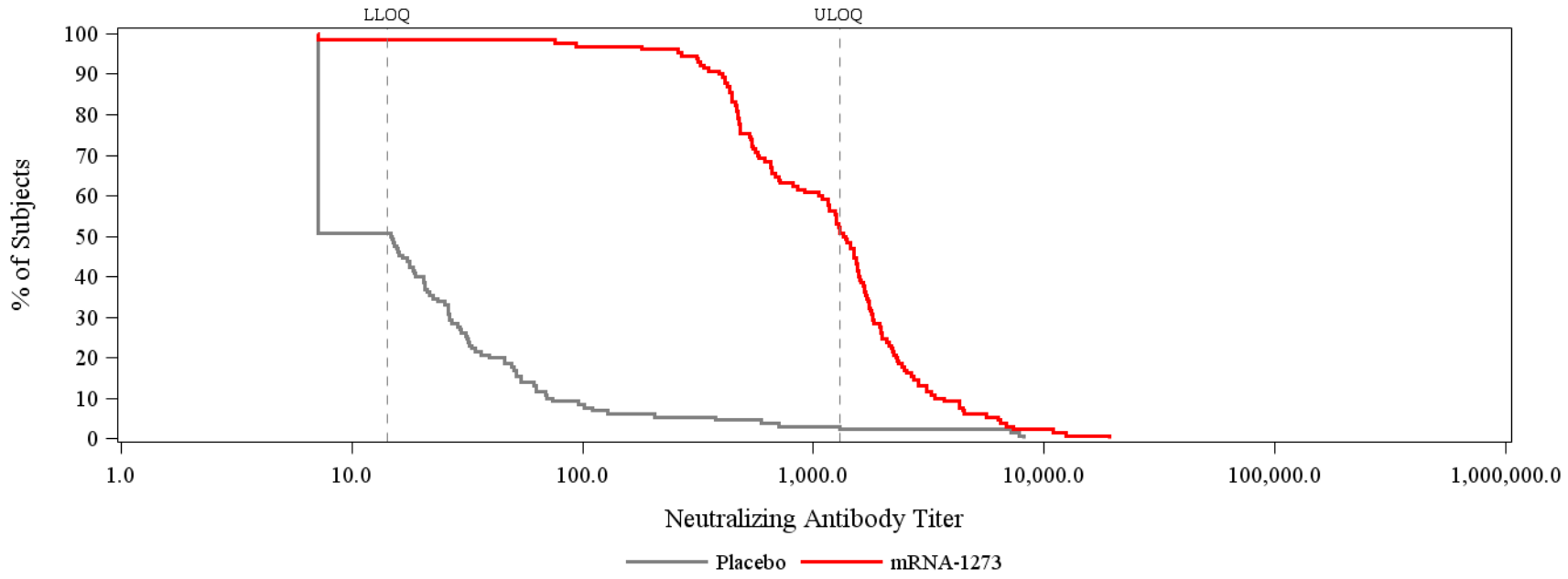

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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Baseline (Day 1)

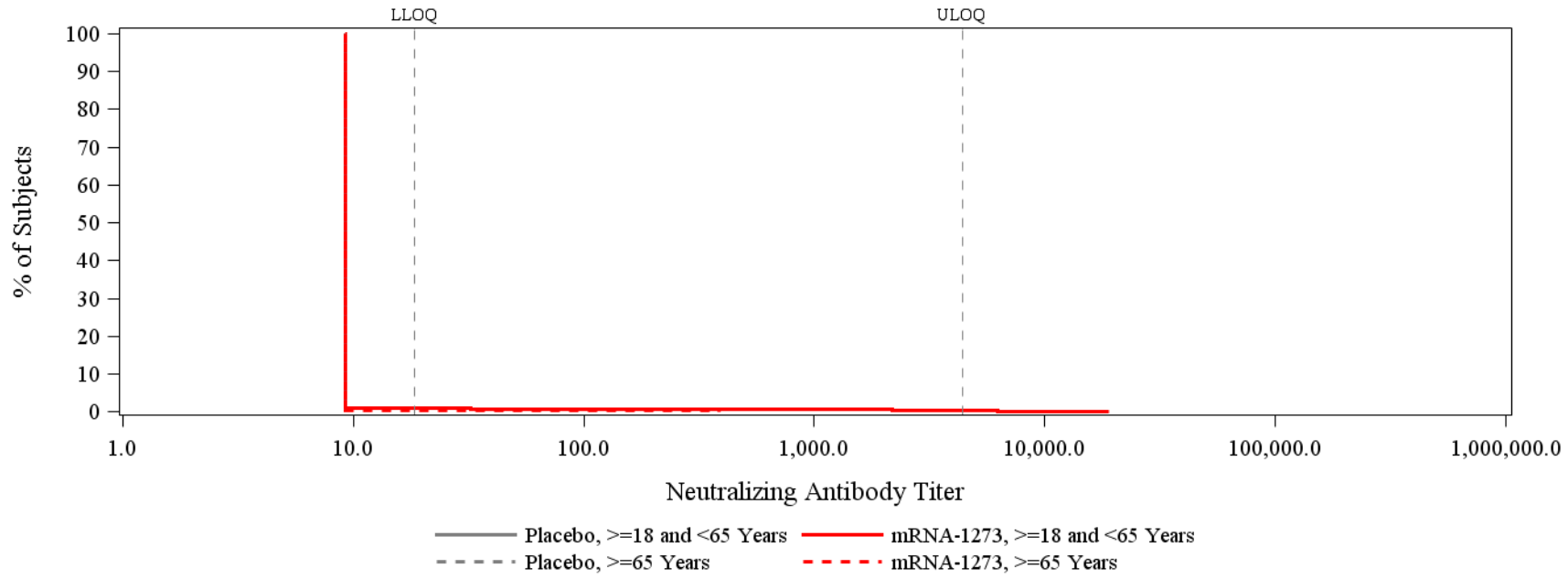

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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 29

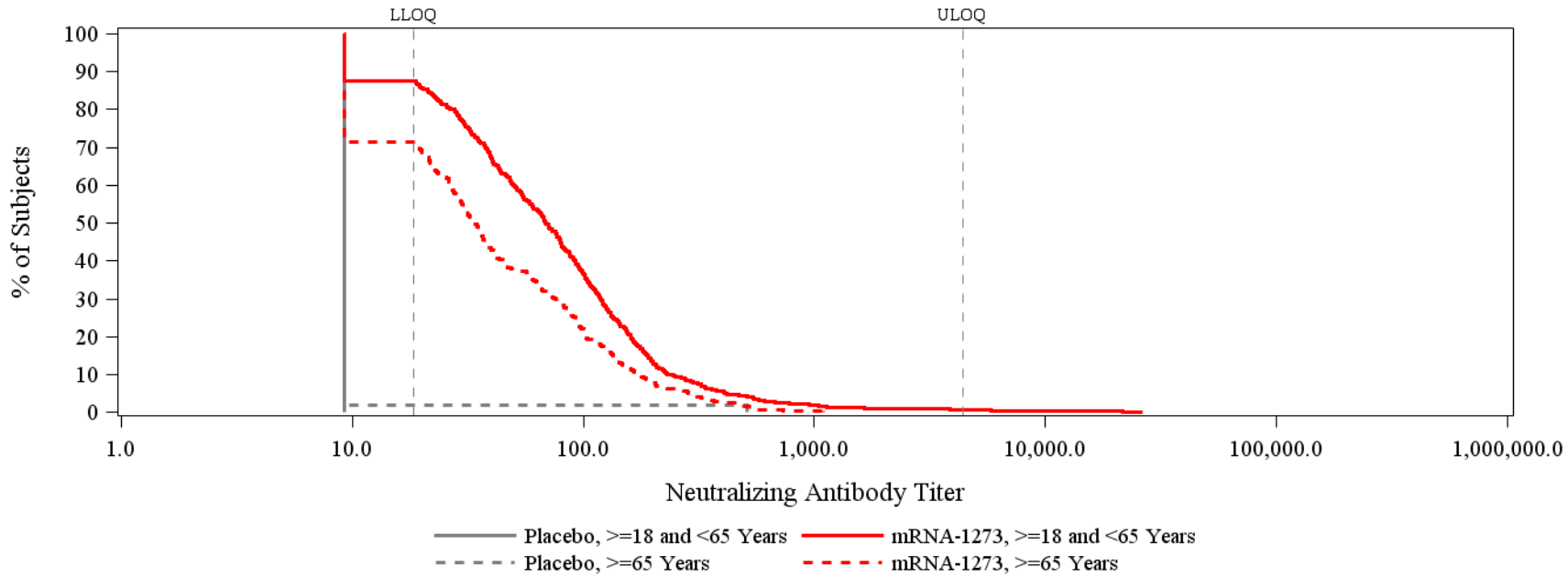

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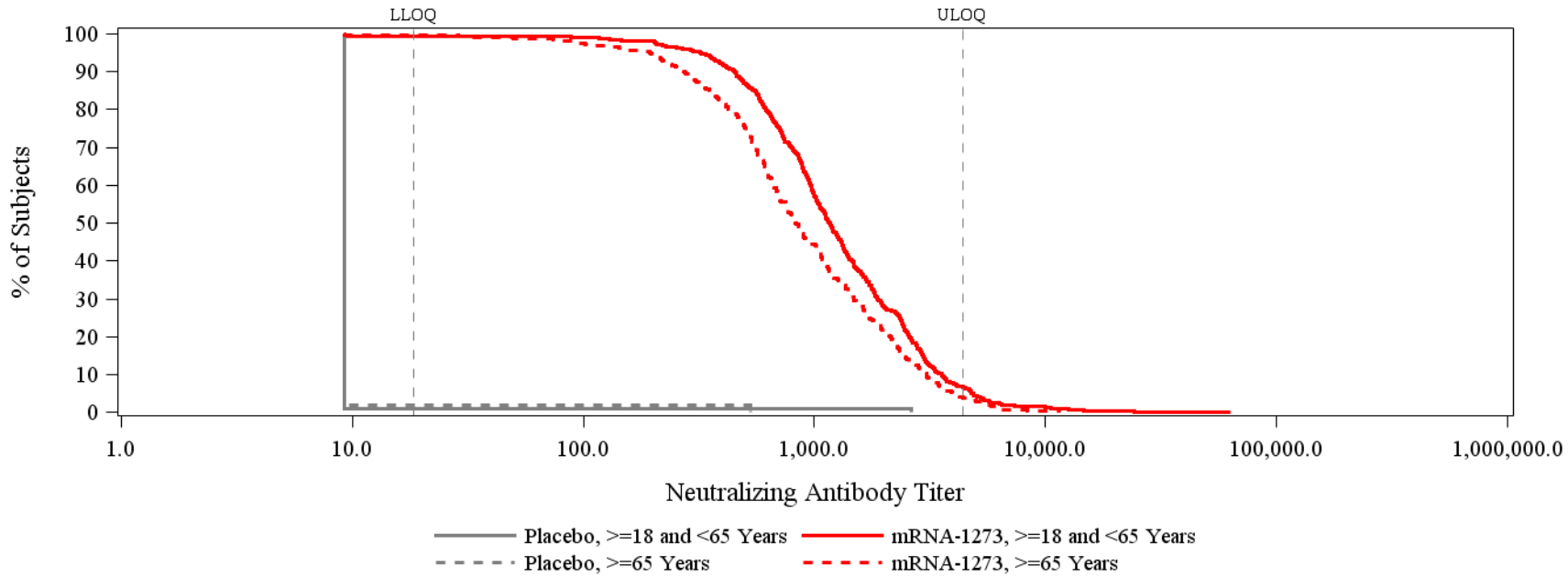
Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 57



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Baseline (Day 1)

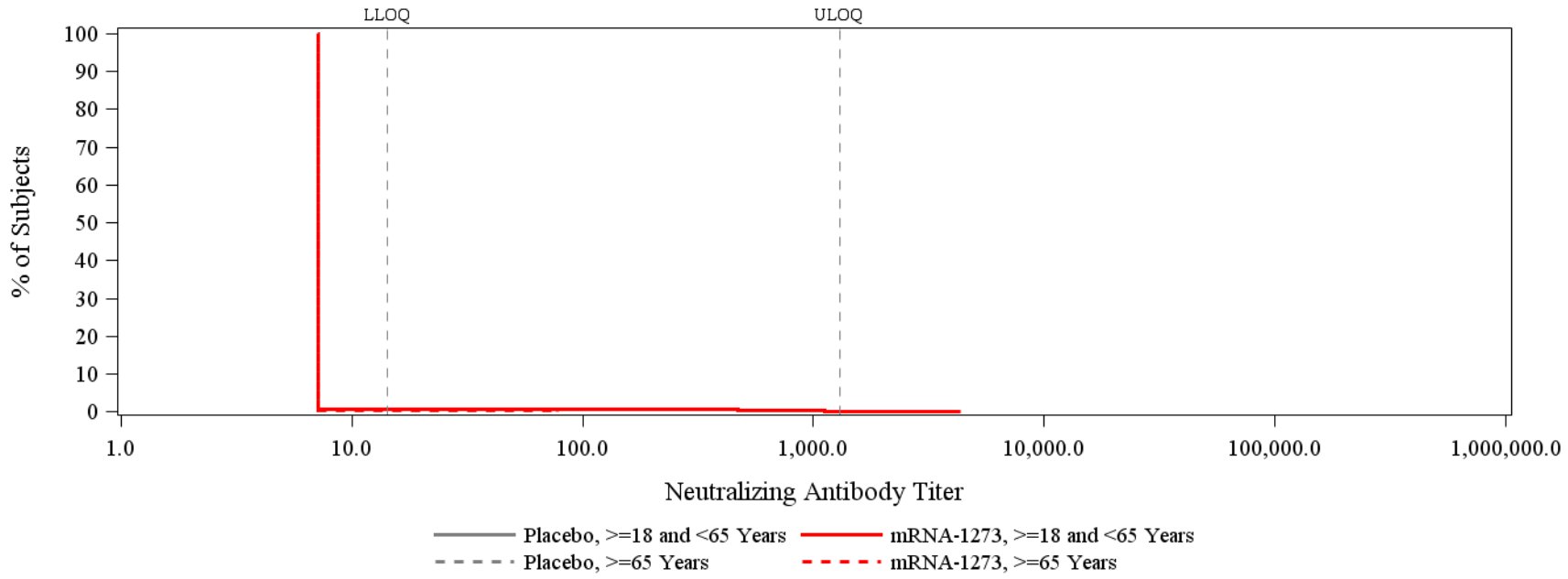

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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 29

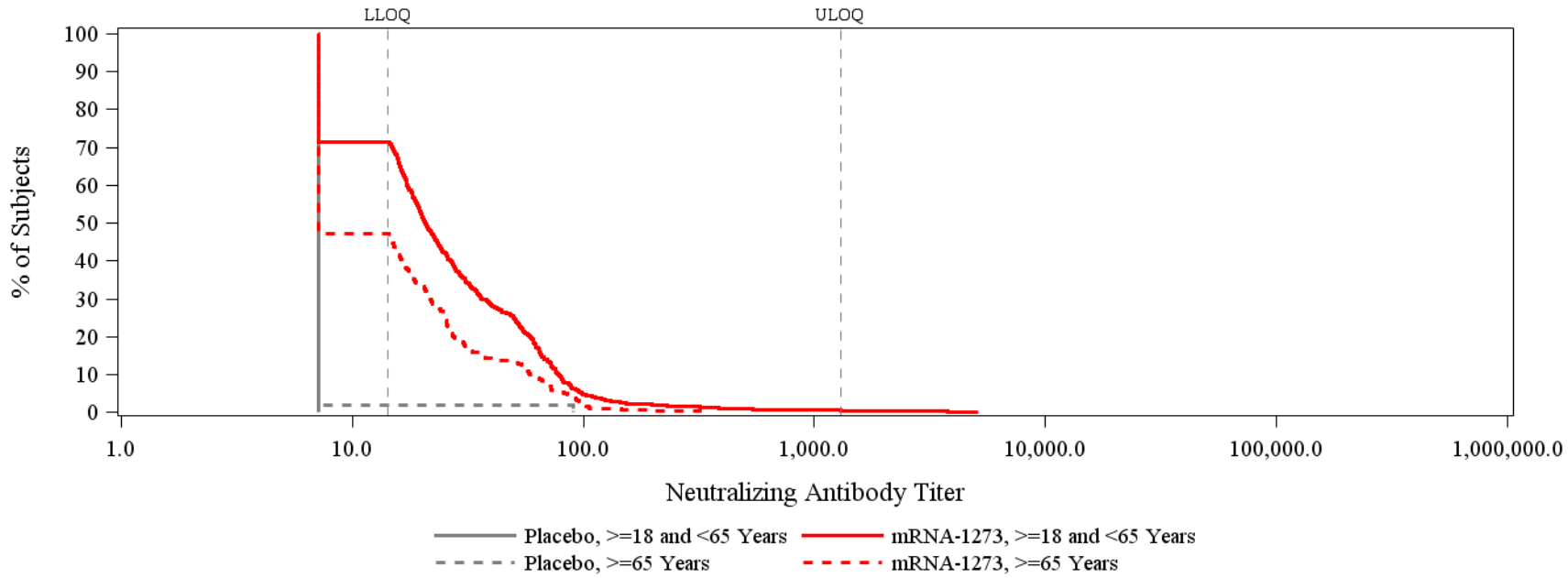

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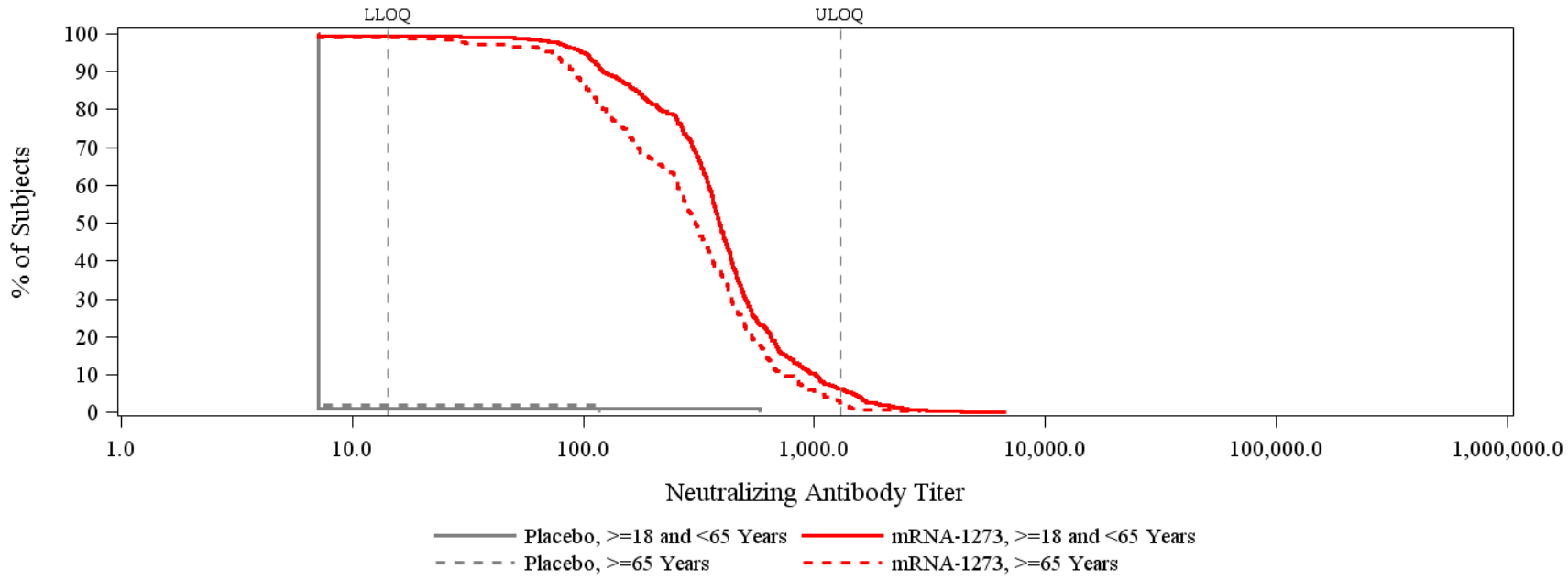
Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 57



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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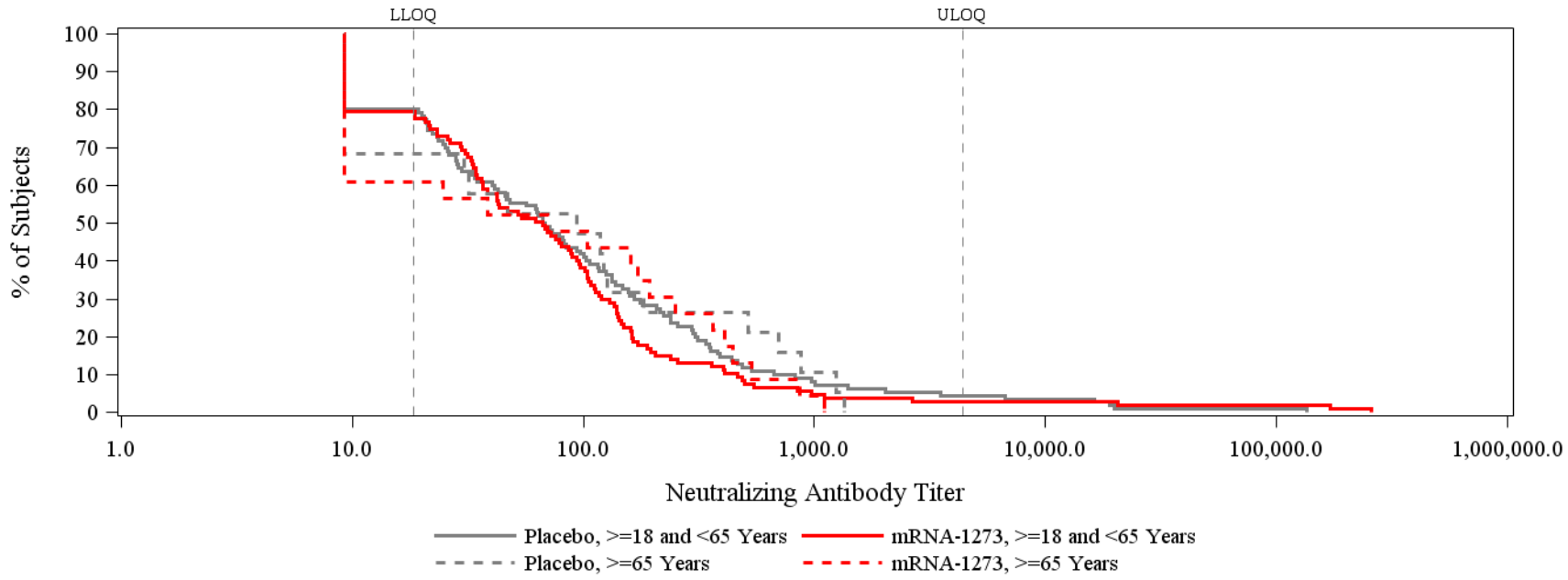
Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Baseline (Day 1)



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 29

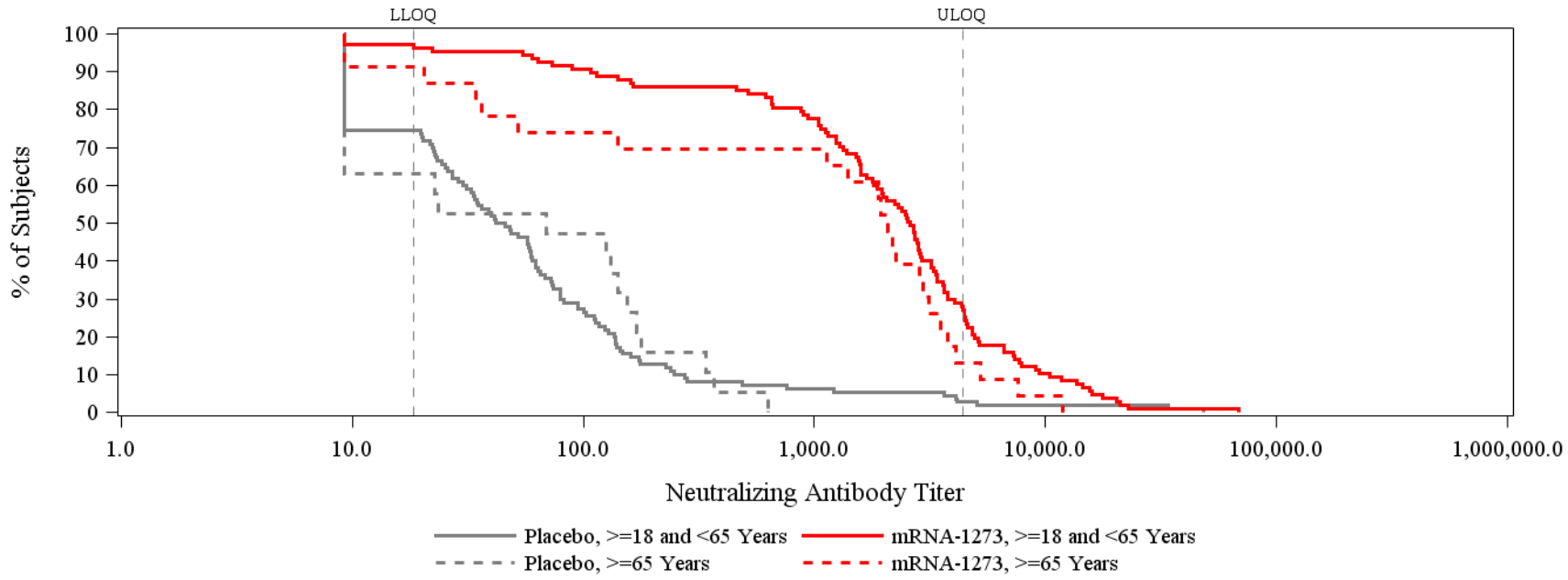

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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

Day 57

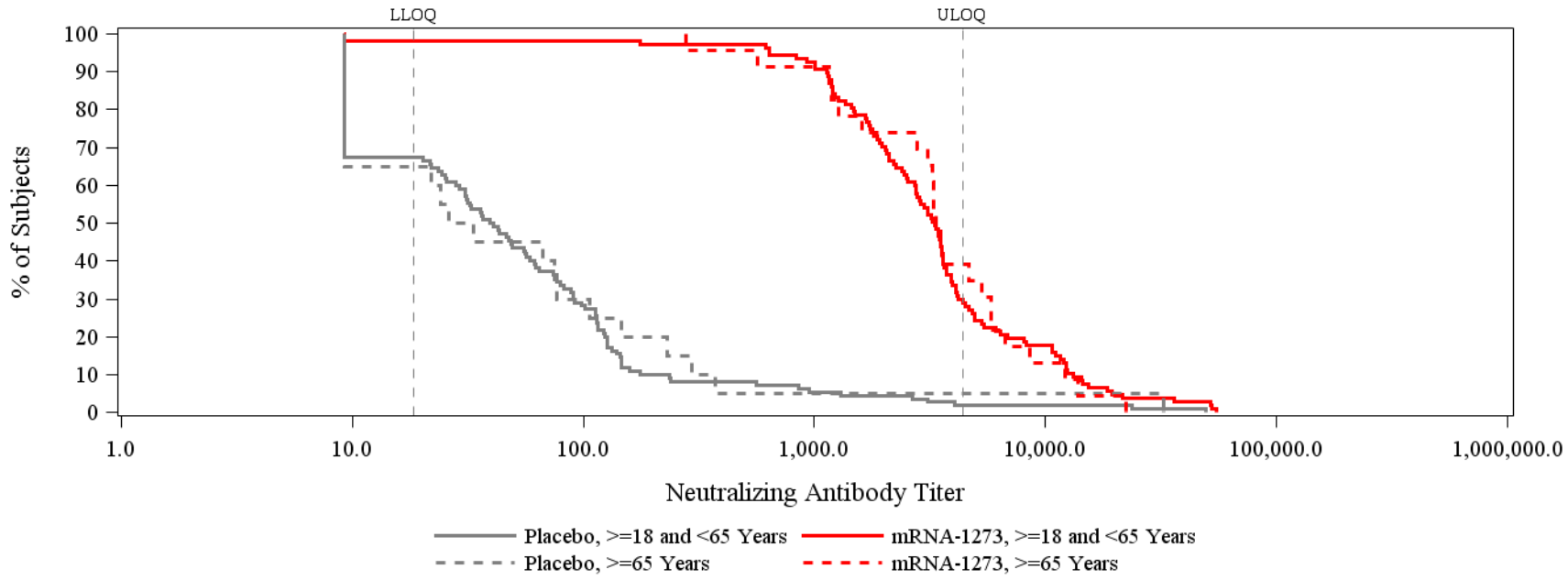

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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Baseline (Day 1)

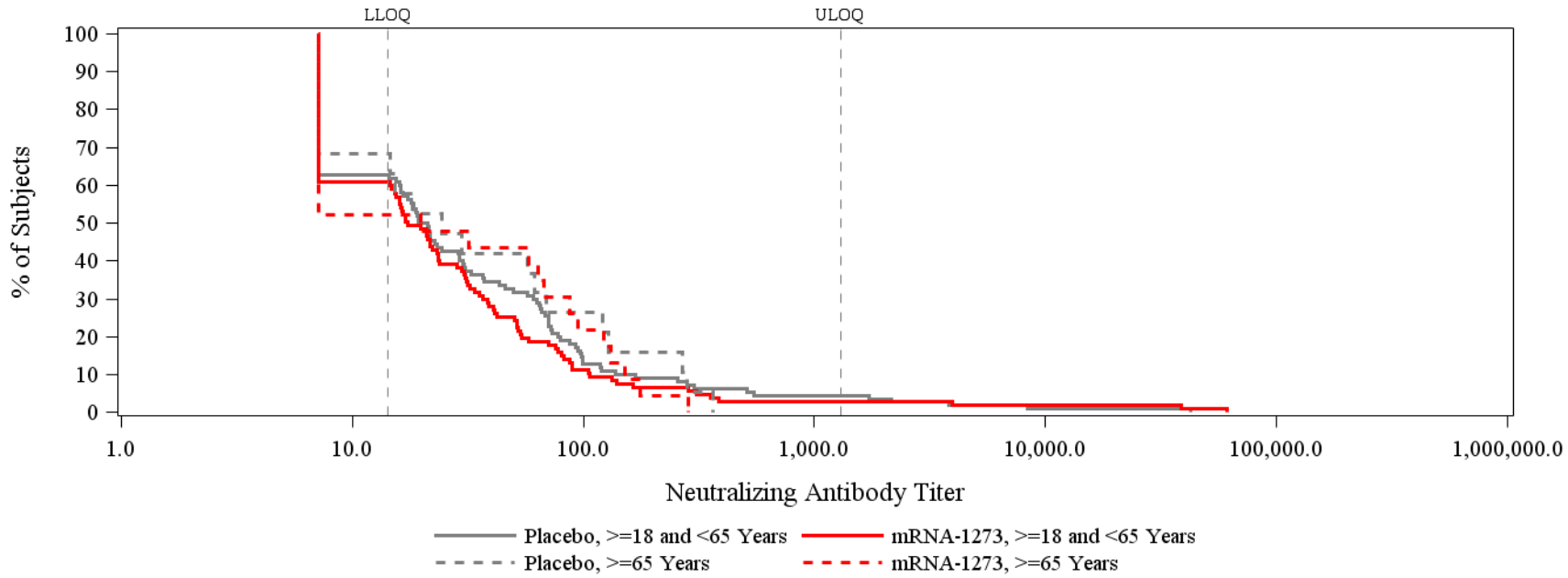

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Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 29

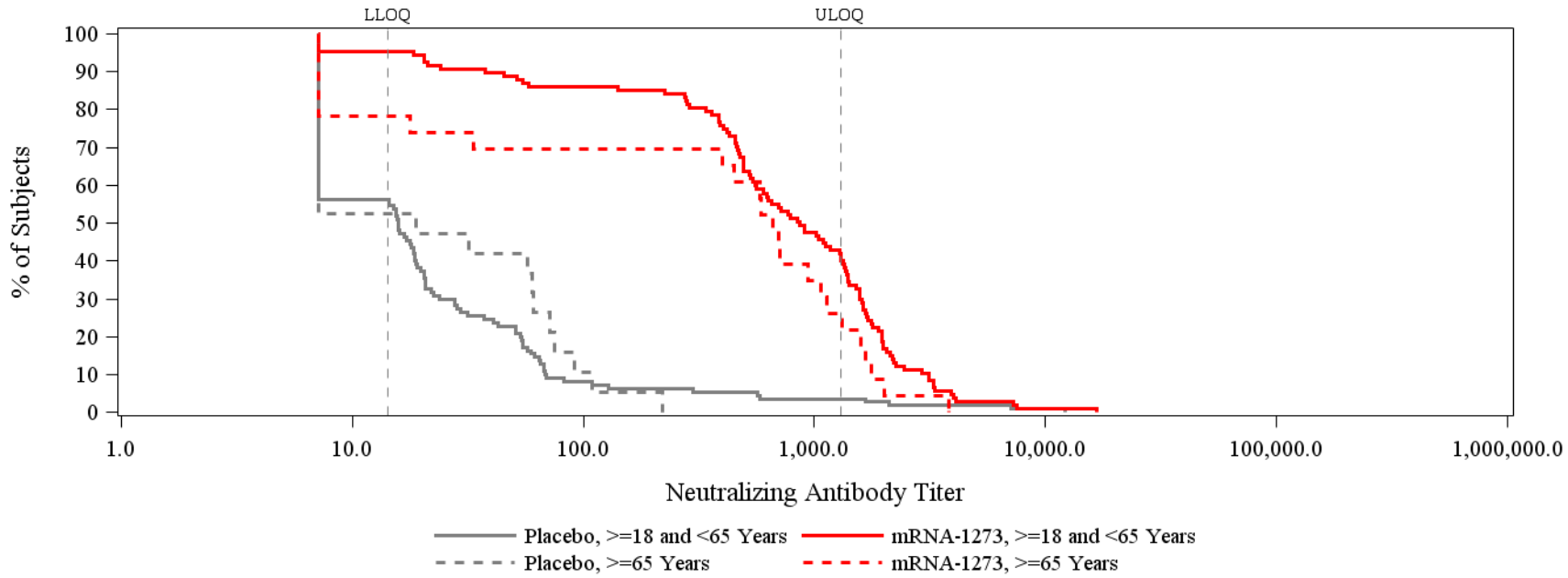

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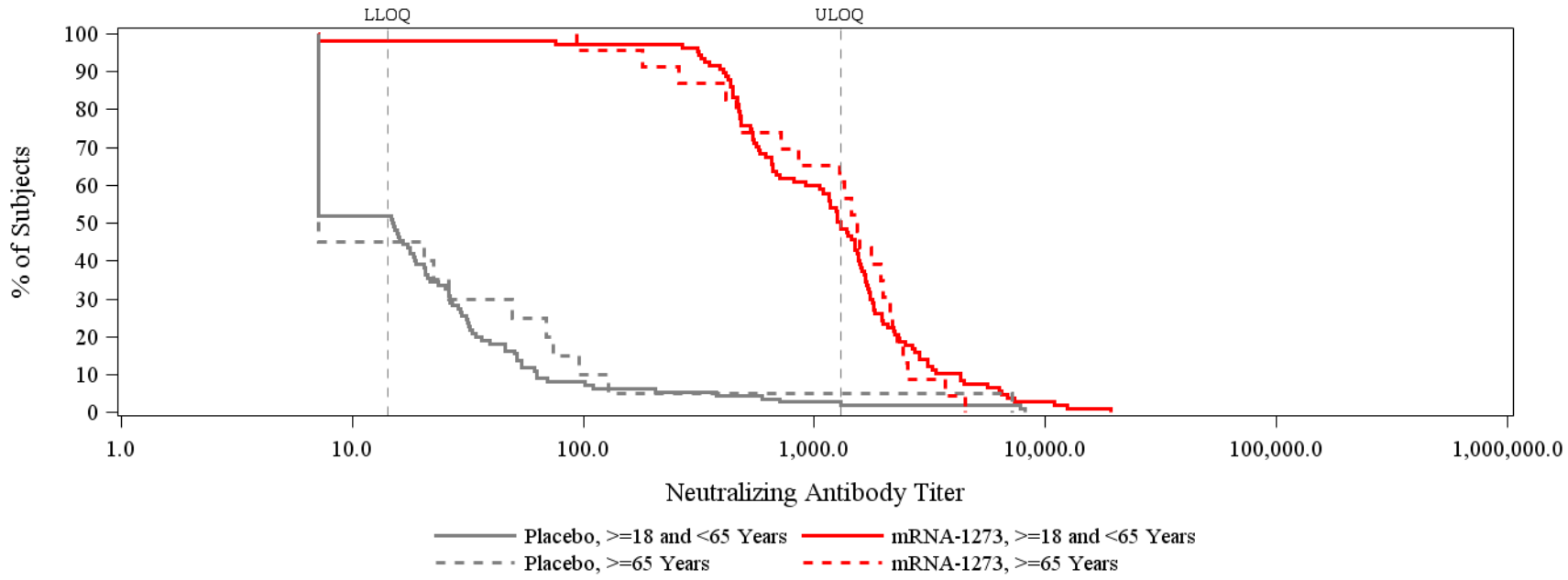
Figure 14.2.4.2.3.4.1
Reverse Cumulative Distribution Function of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity

Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

Day 57



Percentages are based on the number of subjects with non-missing data at the corresponding timepoint.
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Figure 14.2.4.2.4.3.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)

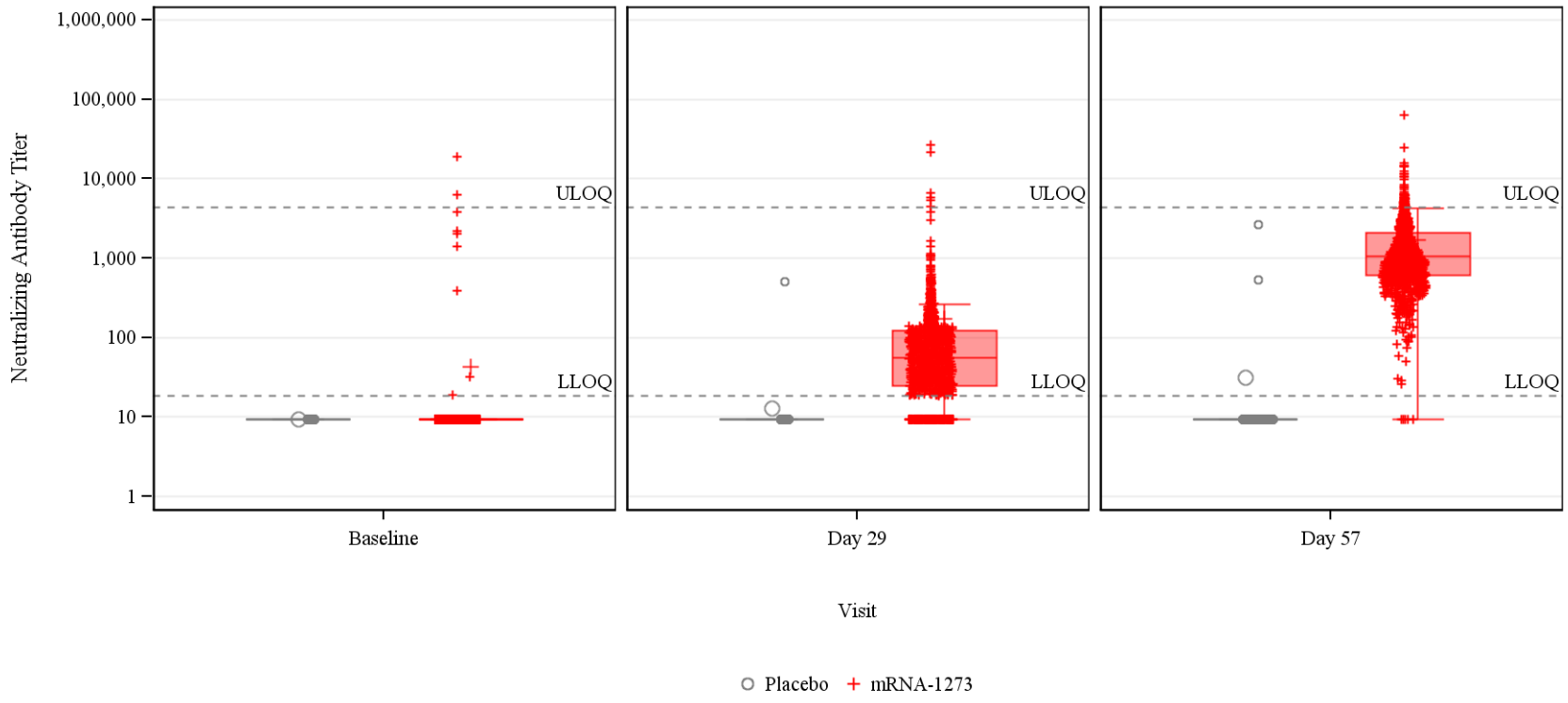

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Figure 14.2.4.2.4.3.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)

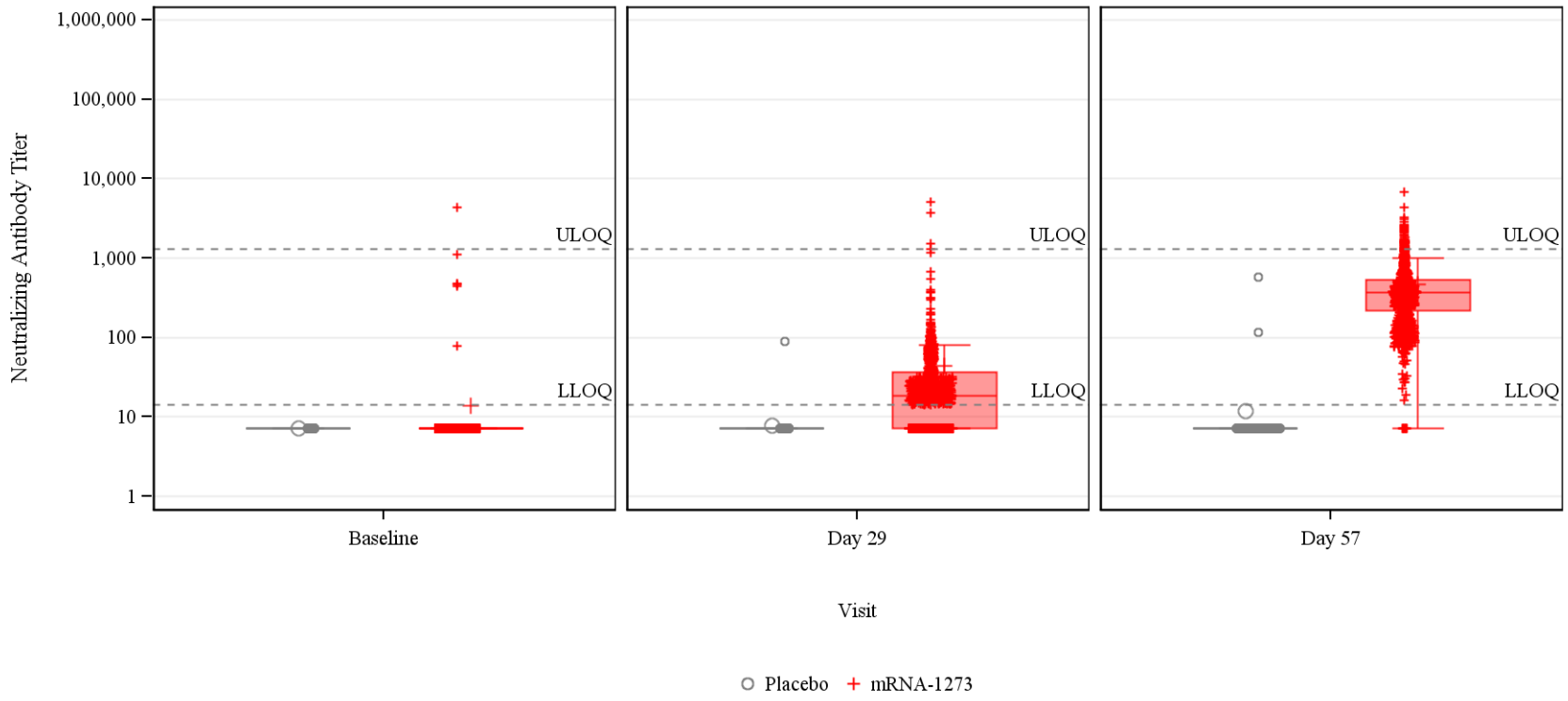

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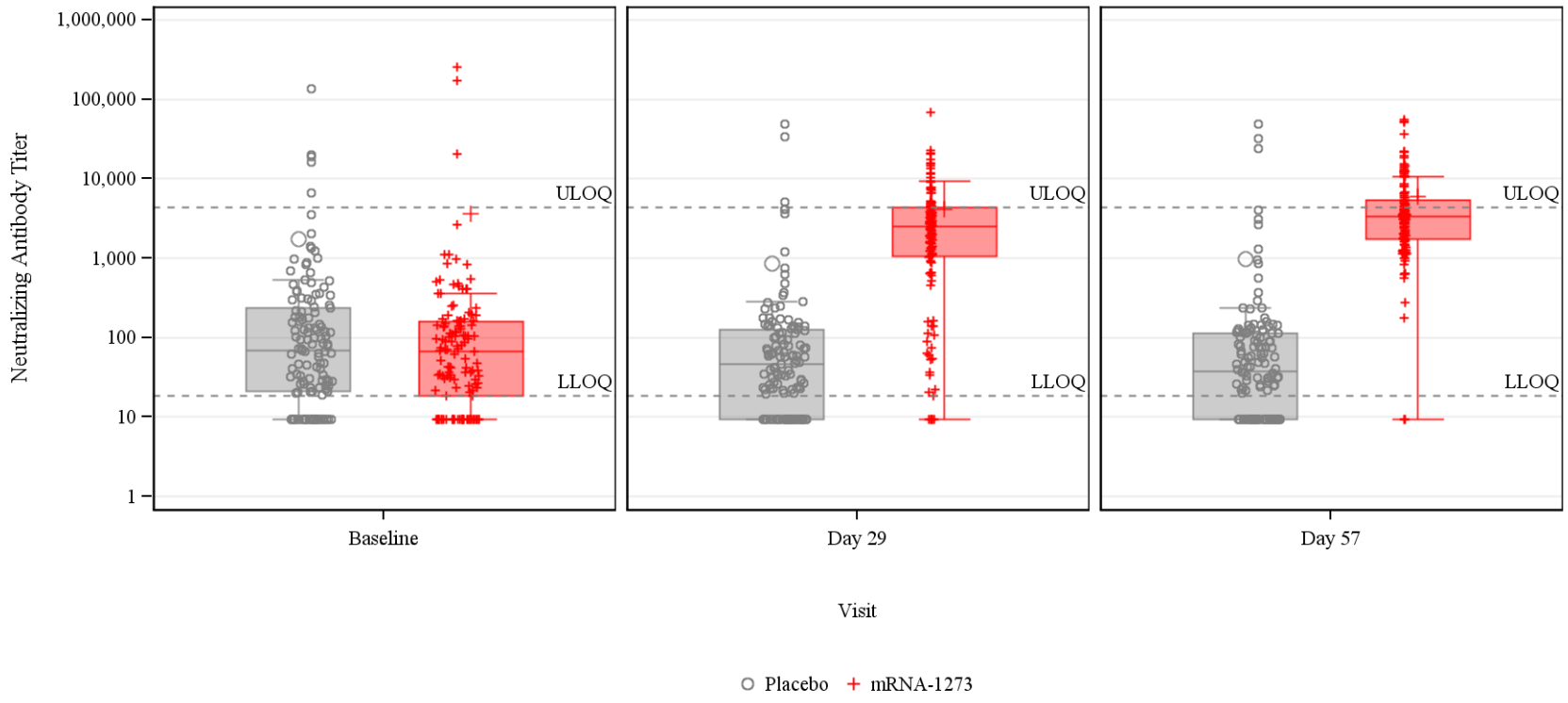
Figure 14.2.4.2.4.3.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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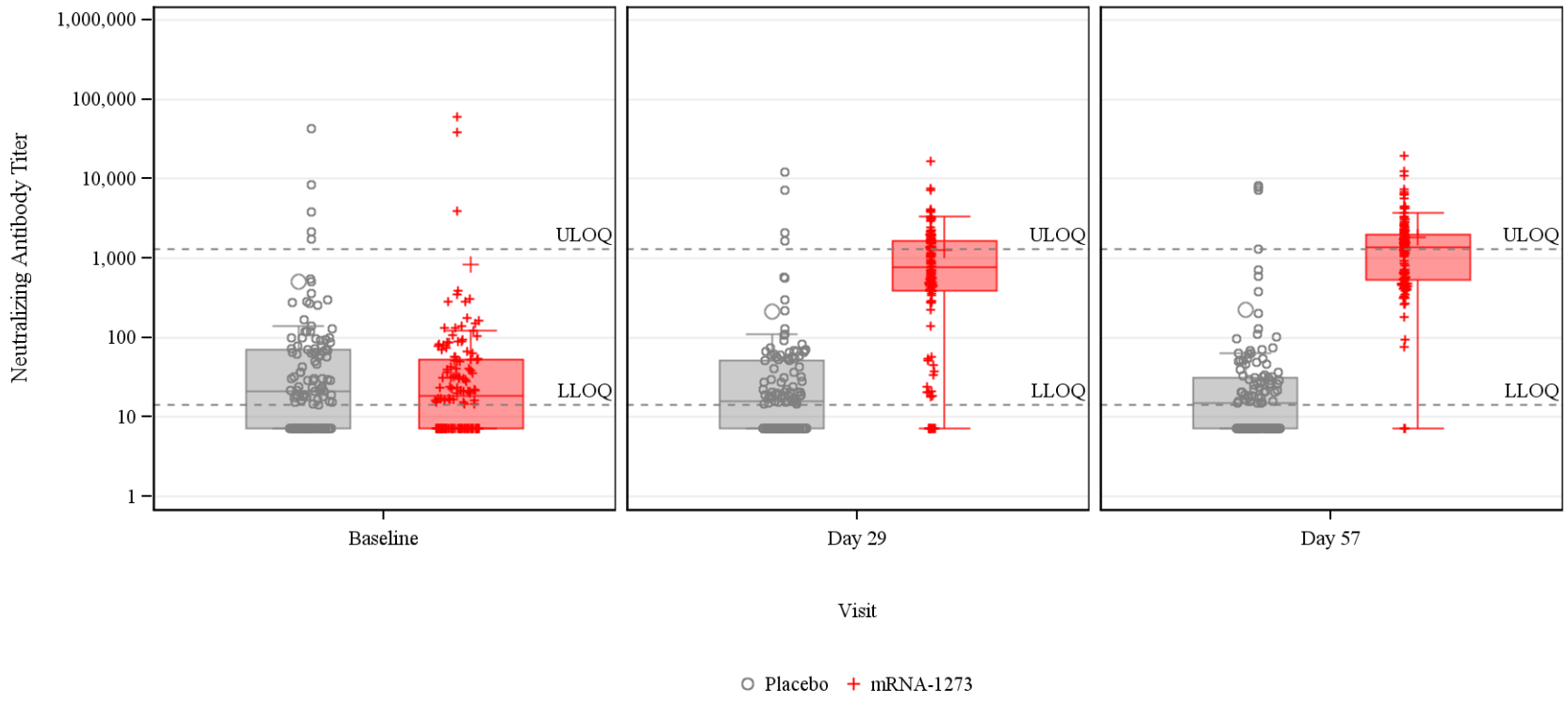
Figure 14.2.4.2.4.3.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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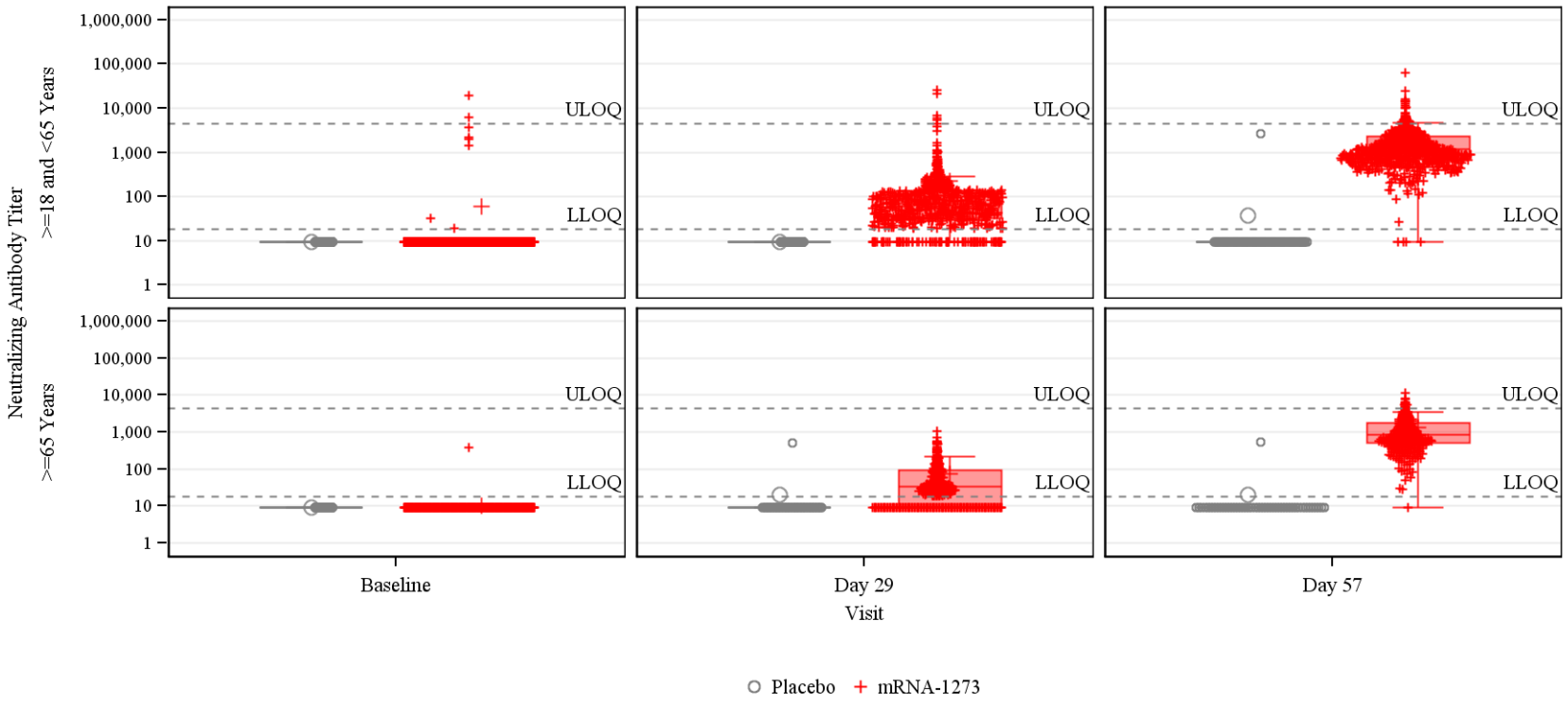
Figure 14.2.4.2.4.4.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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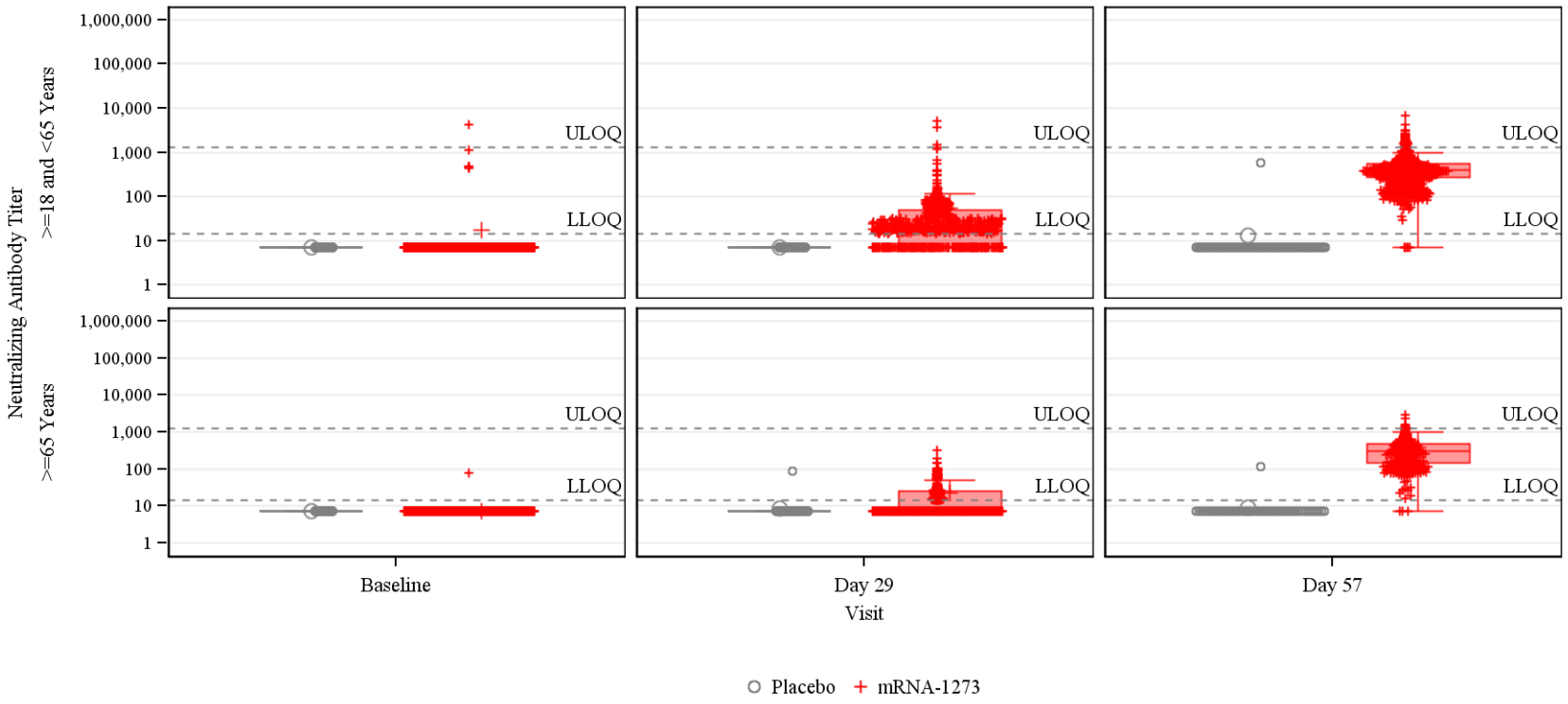
Figure 14.2.4.2.4.4.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Negative
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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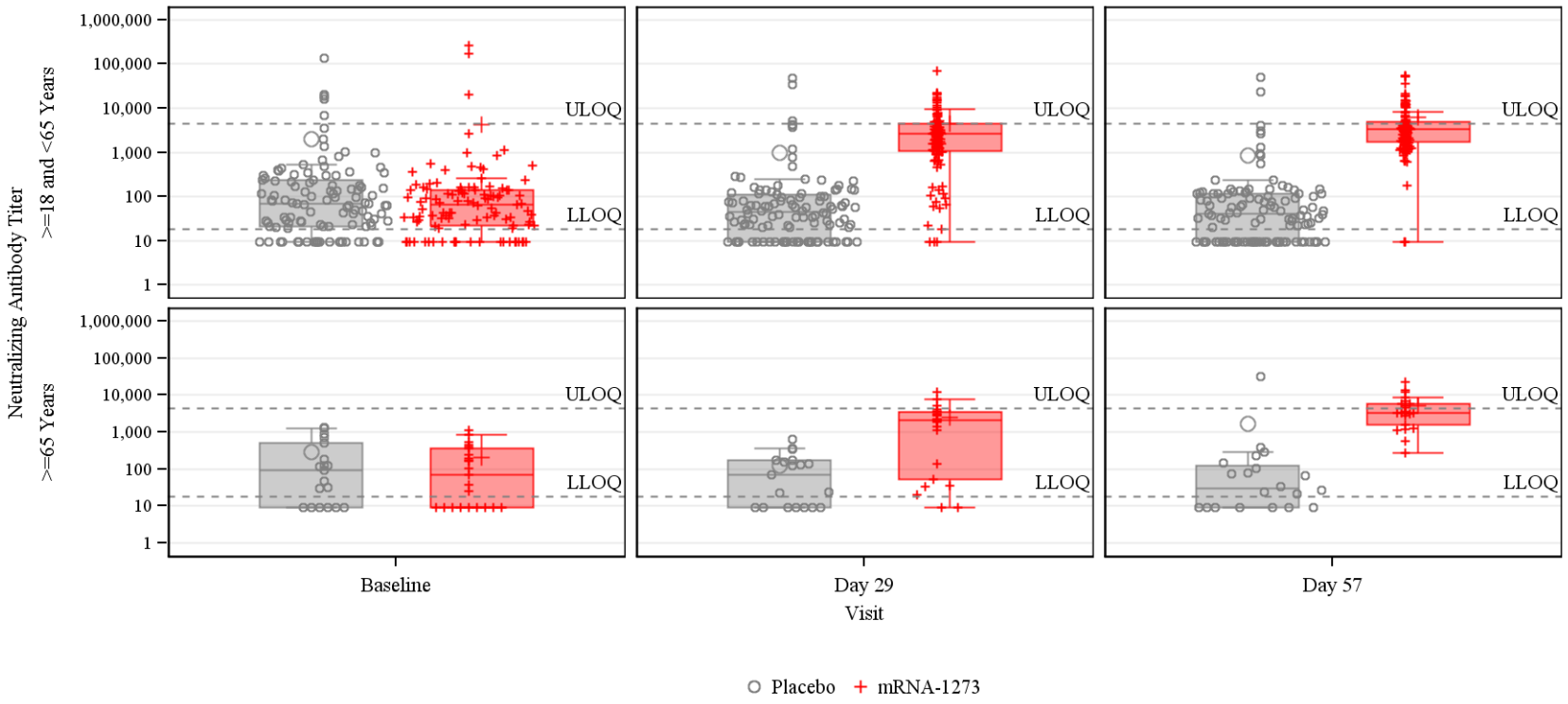
Figure 14.2.4.2.4.4.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID50 Titers (LLOQ: 18.5, ULOQ: 4404)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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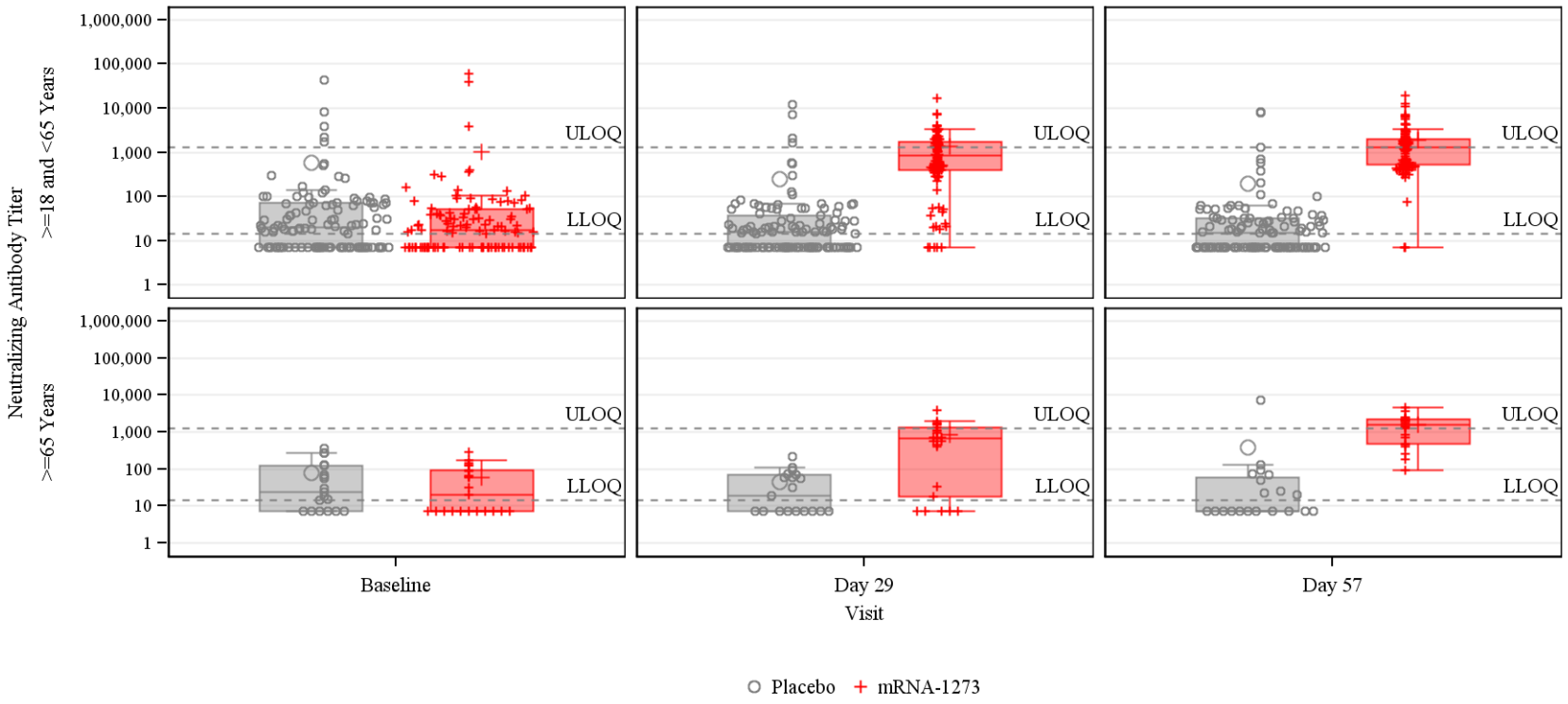
Figure 14.2.4.2.4.4.1
Box Plot of Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity
Baseline SARS-CoV-2 Status: Positive
Antibody: Pseudovirus Neutralizing Antibody ID80 Titers (LLOQ: 14.3, ULOQ: 1295)



Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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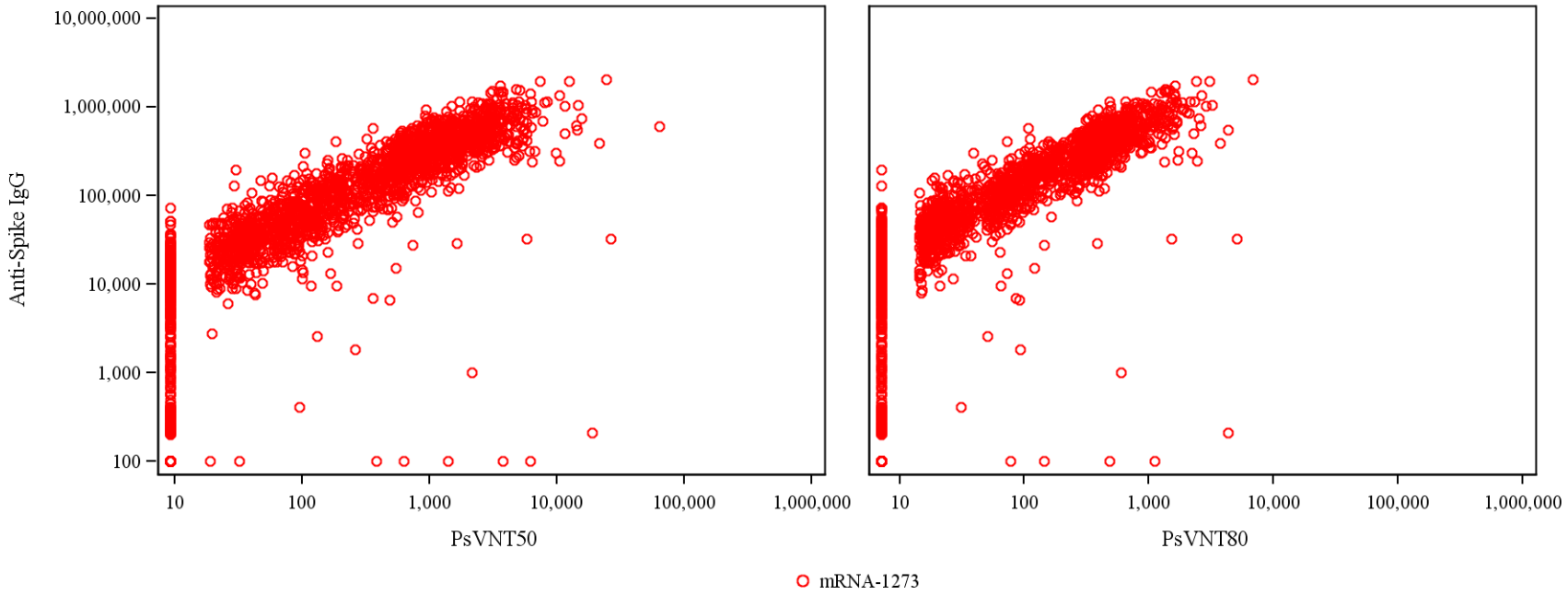
Figure 14.2.4.3.1.3.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity — mRNA-1273 Group
Baseline SARS-CoV-2 Status: Negative



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, MSD = meso scale discovery, PsVNT50 = pseudovirus neutralizing antibody ID50 titers, PsVNT80 = pseudovirus neutralizing antibody ID80 titers.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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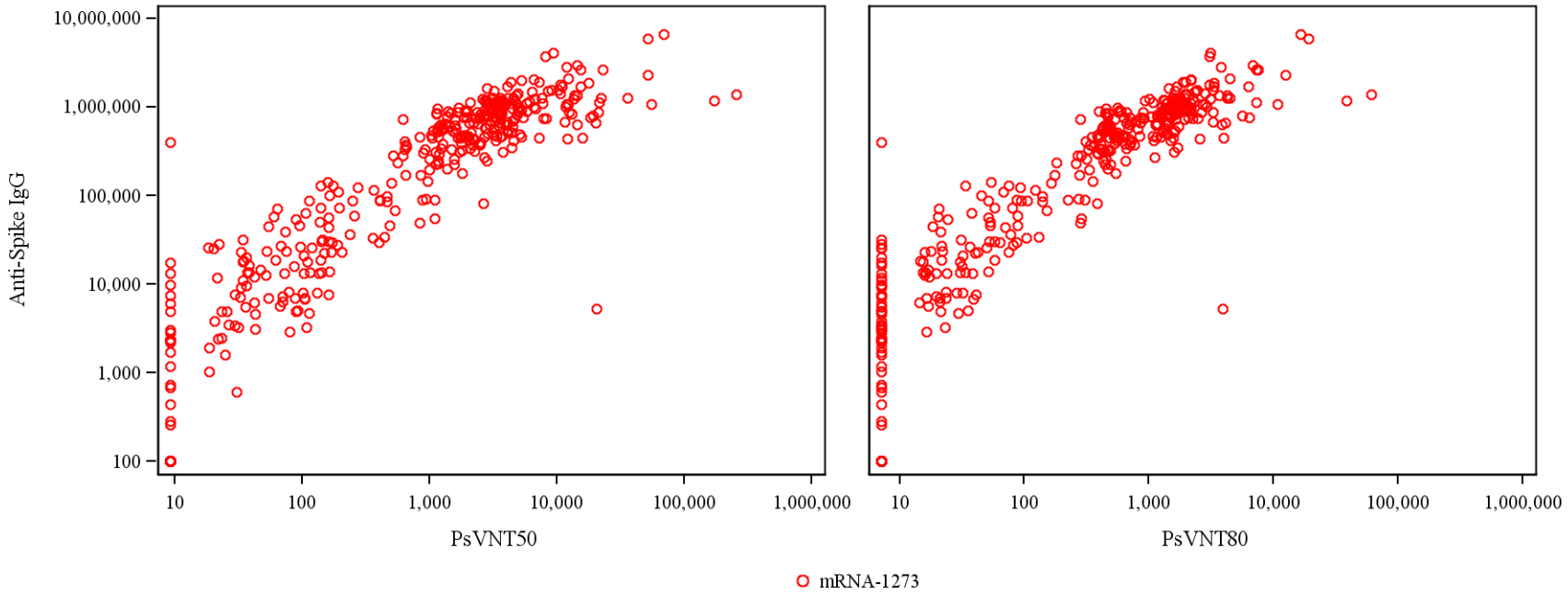
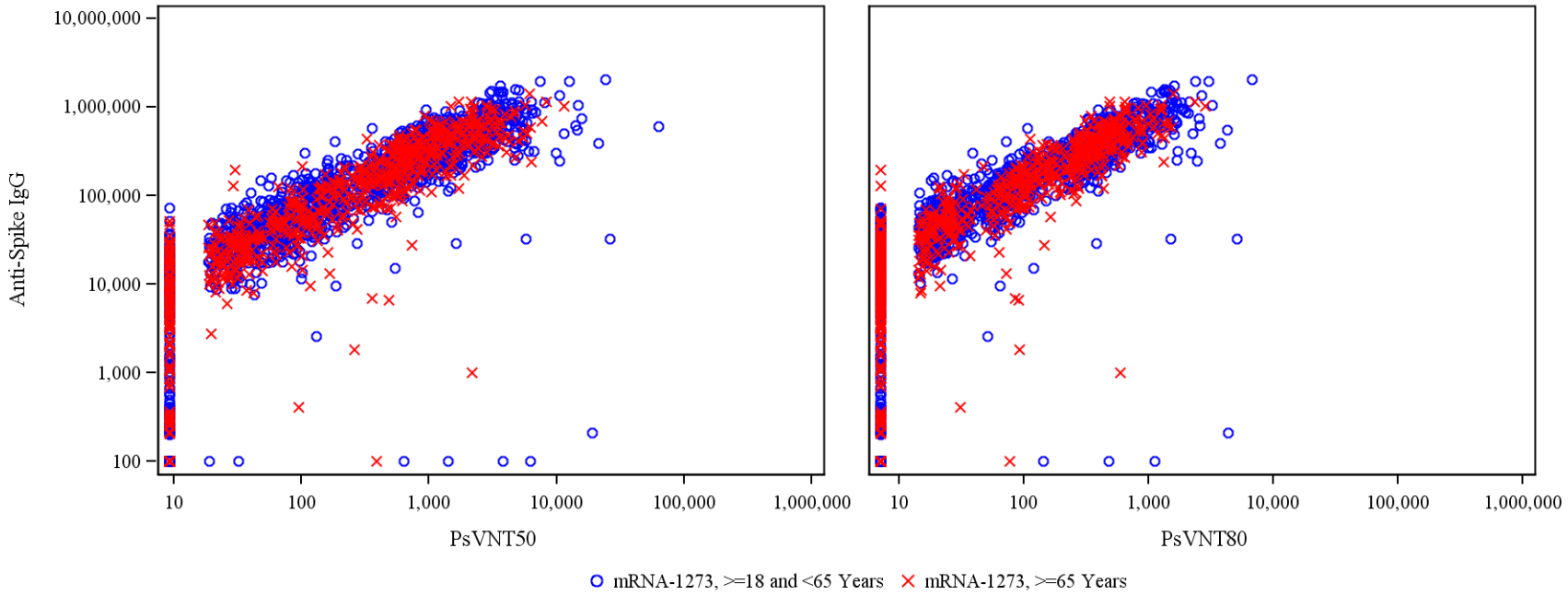
Figure 14.2.4.3.1.3.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity — mRNA-1273 Group
Baseline SARS-CoV-2 Status: Positive



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, MSD = meso scale discovery, PsVNT50 = pseudovirus neutralizing antibody ID50 titers, PsVNT80 = pseudovirus neutralizing antibody ID80 titers.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\f14020403010301.sas 25JUN2021 15:37

Figure 14.2.4.3.1.4.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity – mRNA-1273 Group
Baseline SARS-CoV-2 Status: Negative



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, MSD = meso scale discovery, PsVNT50 = pseudovirus neutralizing antibody ID50 titers, PsVNT80 = pseudovirus neutralizing antibody ID80 titers.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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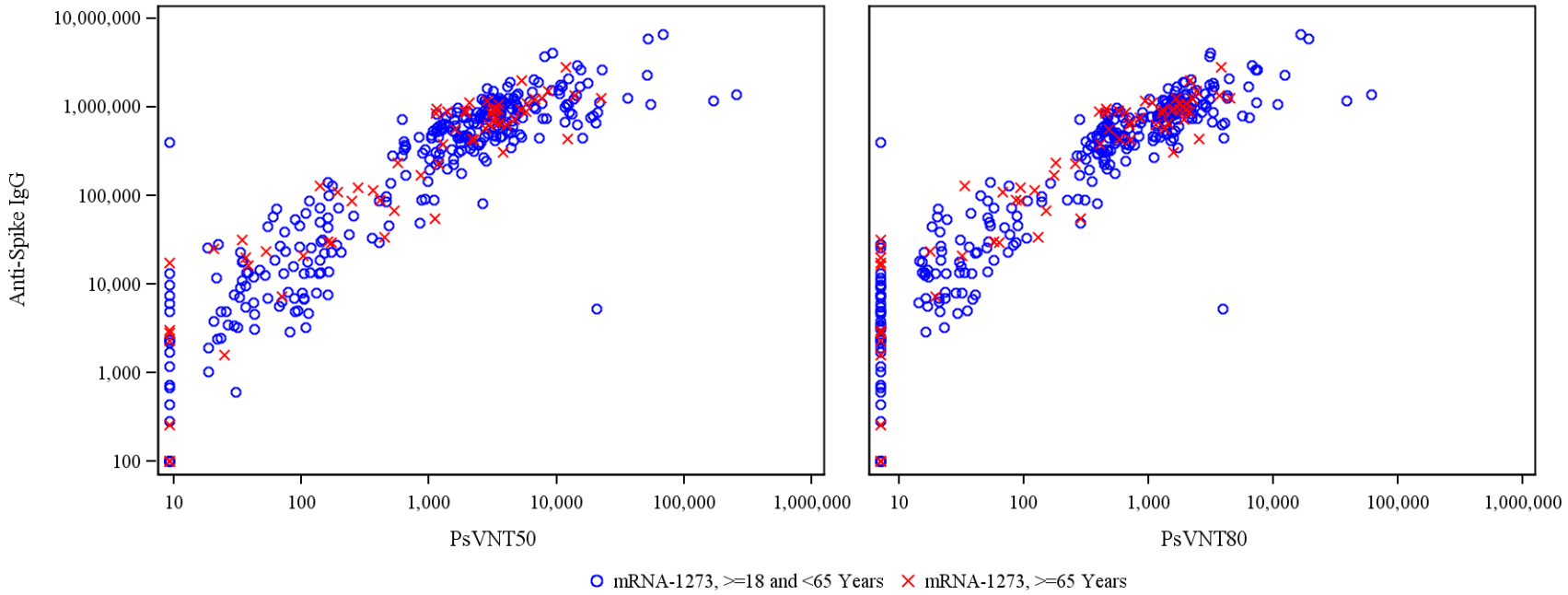
Figure 14.2.4.3.1.4.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity — mRNA-1273 Group
Baseline SARS-CoV-2 Status: Positive



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, MSD = meso scale discovery, PsVNT50 = pseudovirus neutralizing antibody ID50 titers, PsVNT80 = pseudovirus neutralizing antibody ID80 titers.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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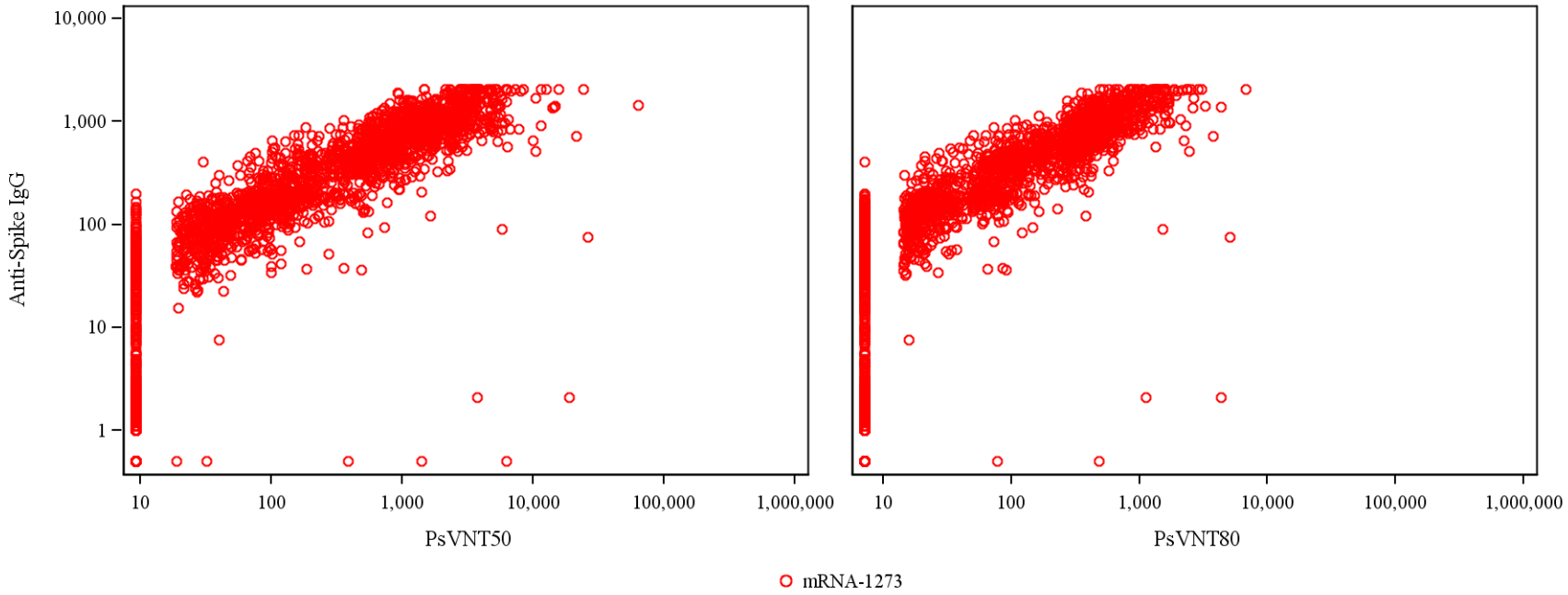
Figure 14.2.4.3.2.3.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA and Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity — mRNA-1273 Group
Baseline SARS-CoV-2 Status: Negative



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, ELISA = enzyme-linked immunosorbent assay, PsVNT50 = pseudovirus neutralizing antibody ID50 titers, PsVNT80 = pseudovirus neutralizing antibody ID80 titers.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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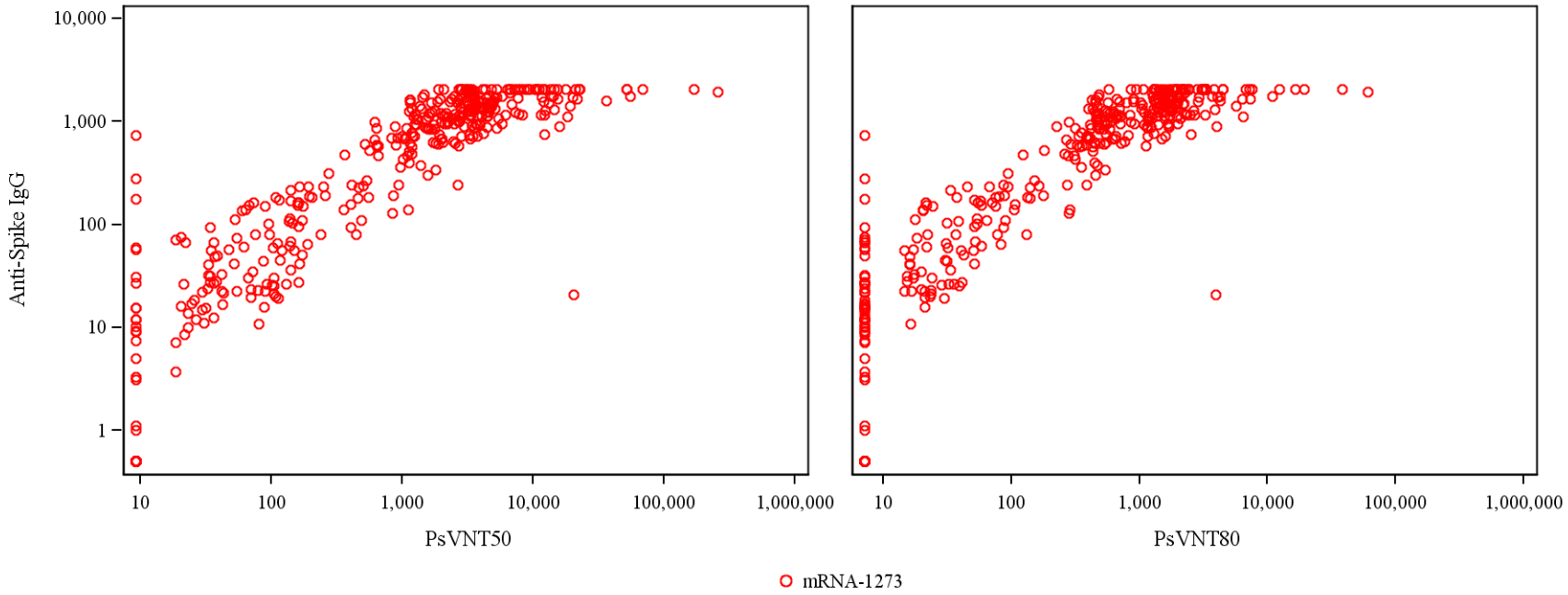
Figure 14.2.4.3.2.3.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA and Pseudovirus Neutralizing Antibody ID50 and ID80 Titers by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity — mRNA-1273 Group
Baseline SARS-CoV-2 Status: Positive



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, ELISA = enzyme-linked immunosorbent assay, PsVNT50 = pseudovirus neutralizing antibody ID50 titers, PsVNT80 = pseudovirus neutralizing antibody ID80 titers.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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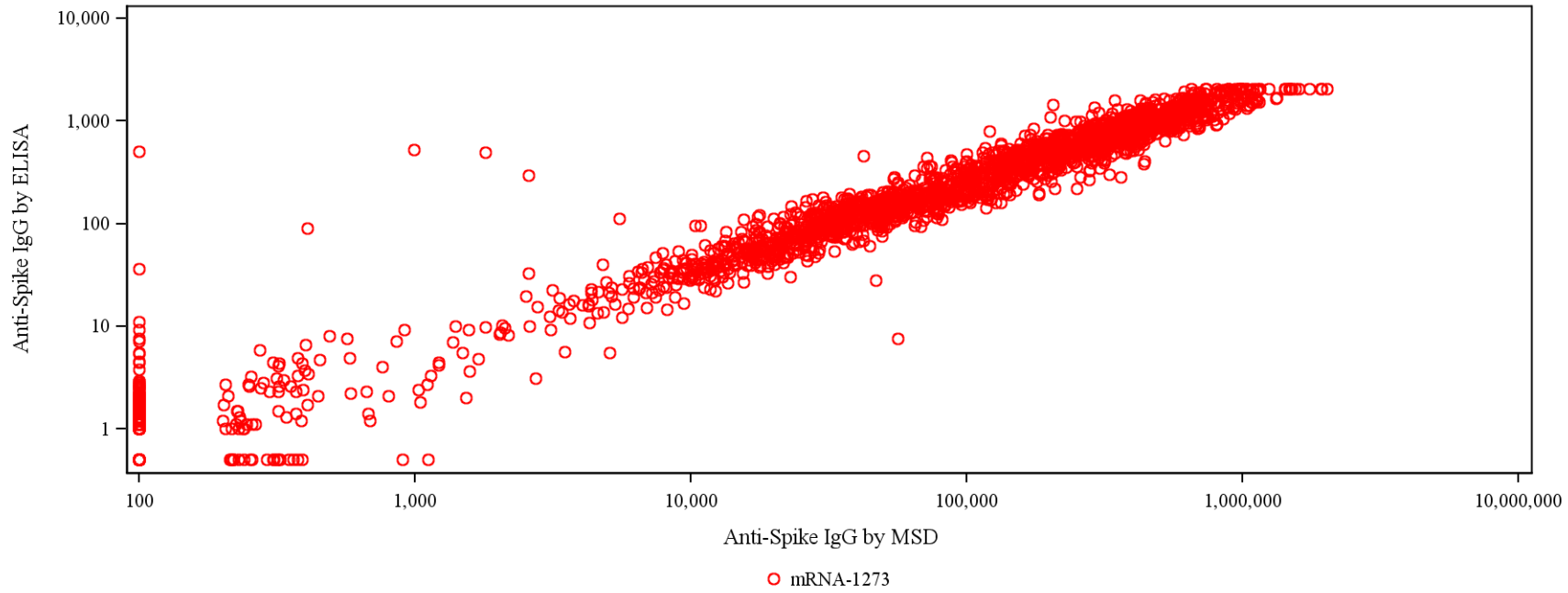
Figure 14.2.4.3.3.3.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity — mRNA-1273 Group
Baseline SARS-CoV-2 Status: Negative



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, ELISA = enzyme-linked immunosorbent assay, MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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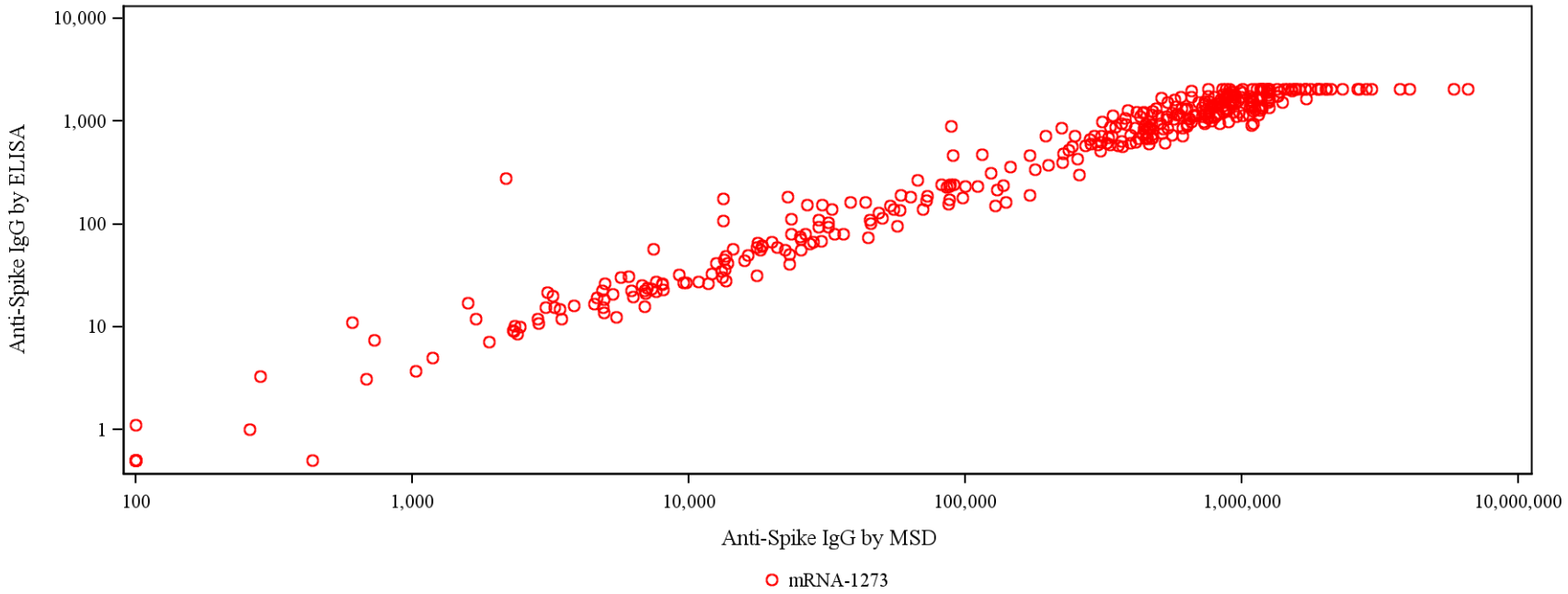
Figure 14.2.4.3.3.3.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status
Per-Protocol Random Subcohort for Immunogenicity — mRNA-1273 Group
Baseline SARS-CoV-2 Status: Positive



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, ELISA = enzyme-linked immunosorbent assay, MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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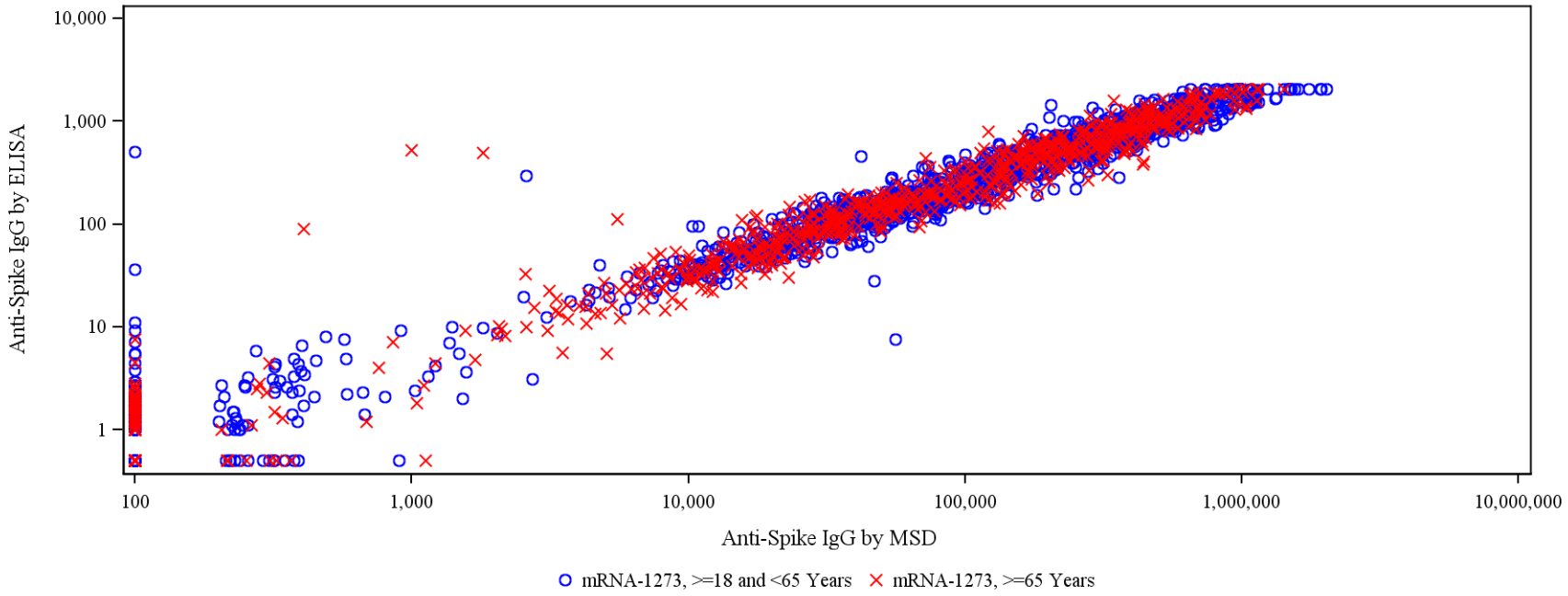
Figure 14.2.4.3.3.4.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity – mRNA-1273 Group
Baseline SARS-CoV-2 Status: Negative



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, ELISA = enzyme-linked immunosorbent assay, MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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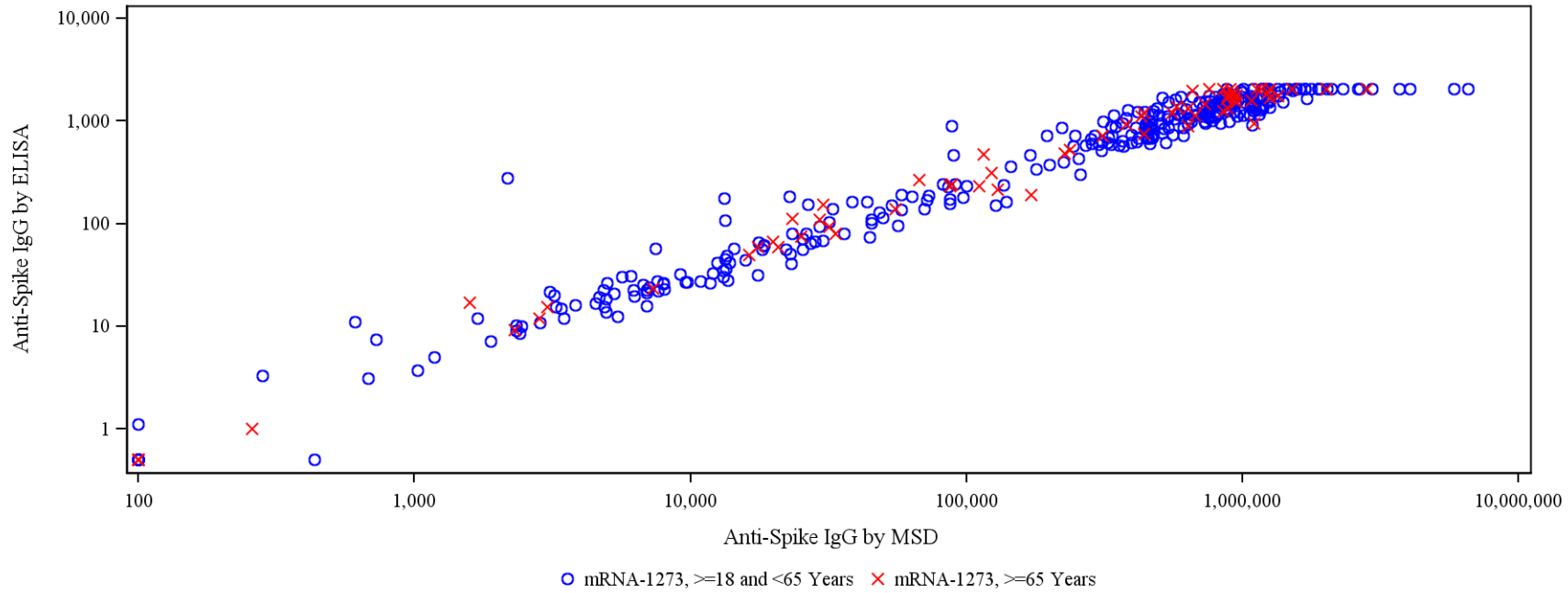
Figure 14.2.4.3.3.4.1
Scatter Plot of Binding Antibody Specific to SARS-CoV-2 Spike Protein by MSD and Binding Antibody Specific to SARS-CoV-2 Spike Protein by ELISA by Baseline SARS-CoV-2 Status and Age Group
Per-Protocol Random Subcohort for Immunogenicity – mRNA-1273 Group
Baseline SARS-CoV-2 Status: Positive



Anti-Spike IgG = binding antibody (IgG) specific to SARS-CoV-2 Spike, ELISA = enzyme-linked immunosorbent assay, MSD = meso scale discovery.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.
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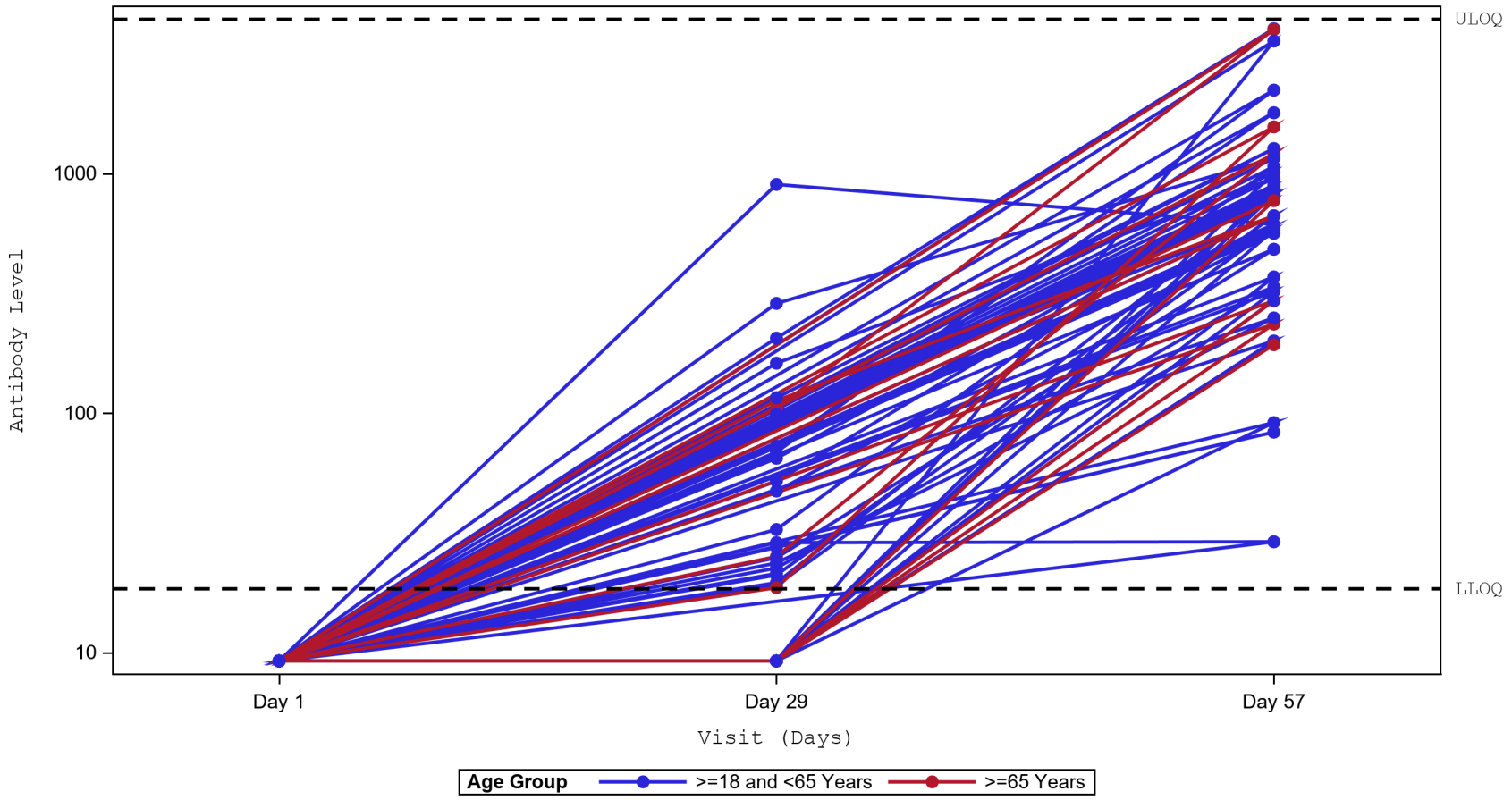
Figure 16.2.2.1.3.1.1.1
Plot of Pseudovirus Neutralizing Antibody ID50 in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



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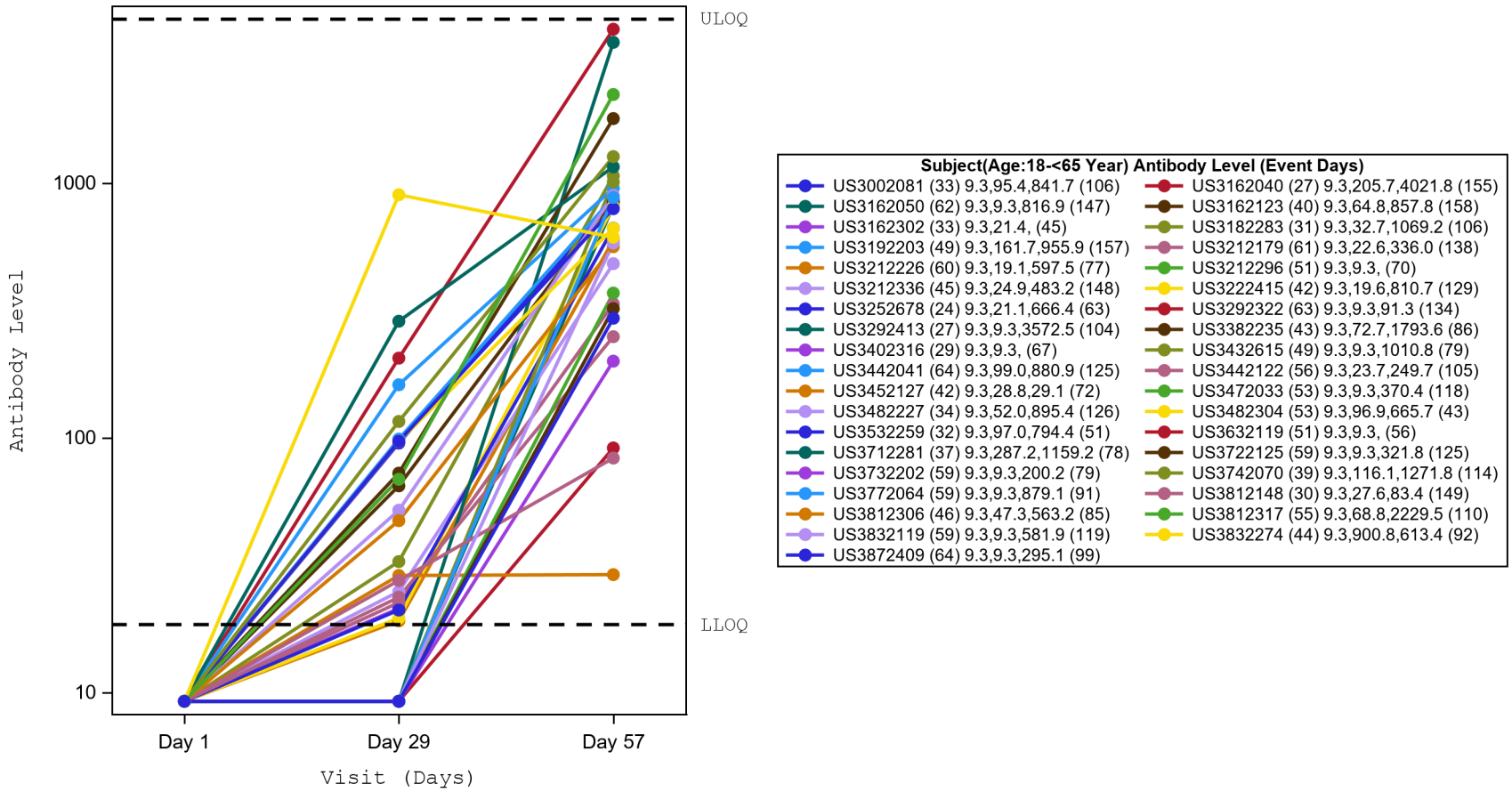
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening, becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373726

Figure 16.2.2.1.3.1.1.1

Plot of Pseudovirus Neutralizing Antibody ID50 in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

Per-Protocol Set



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COVID-19 cases with corresponding immunogenicity data available

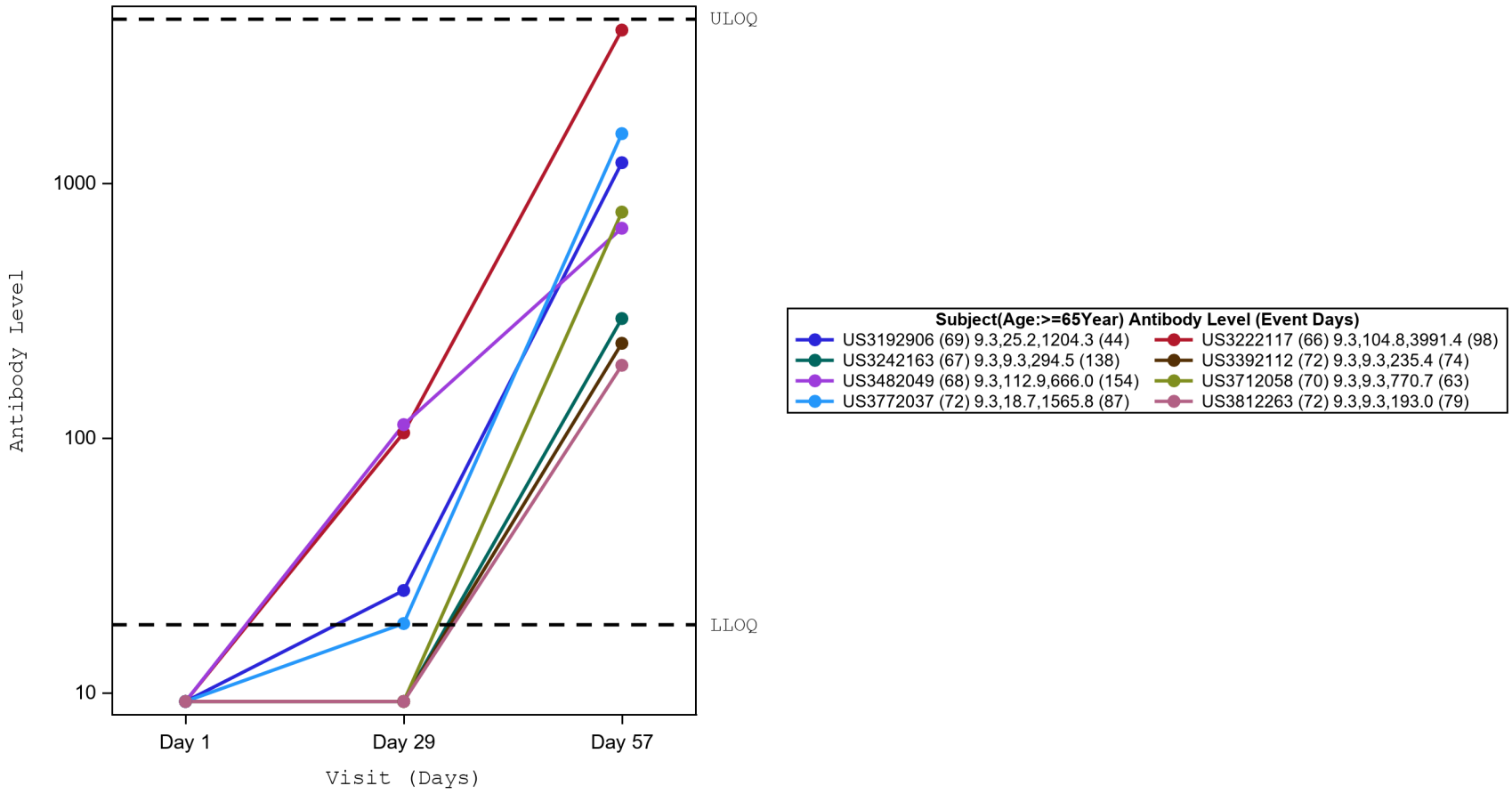
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening visit becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373727

Figure 16.2.2.1.3.1.1.1

Plot of Pseudovirus Neutralizing Antibody ID50 in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

Per-Protocol Set



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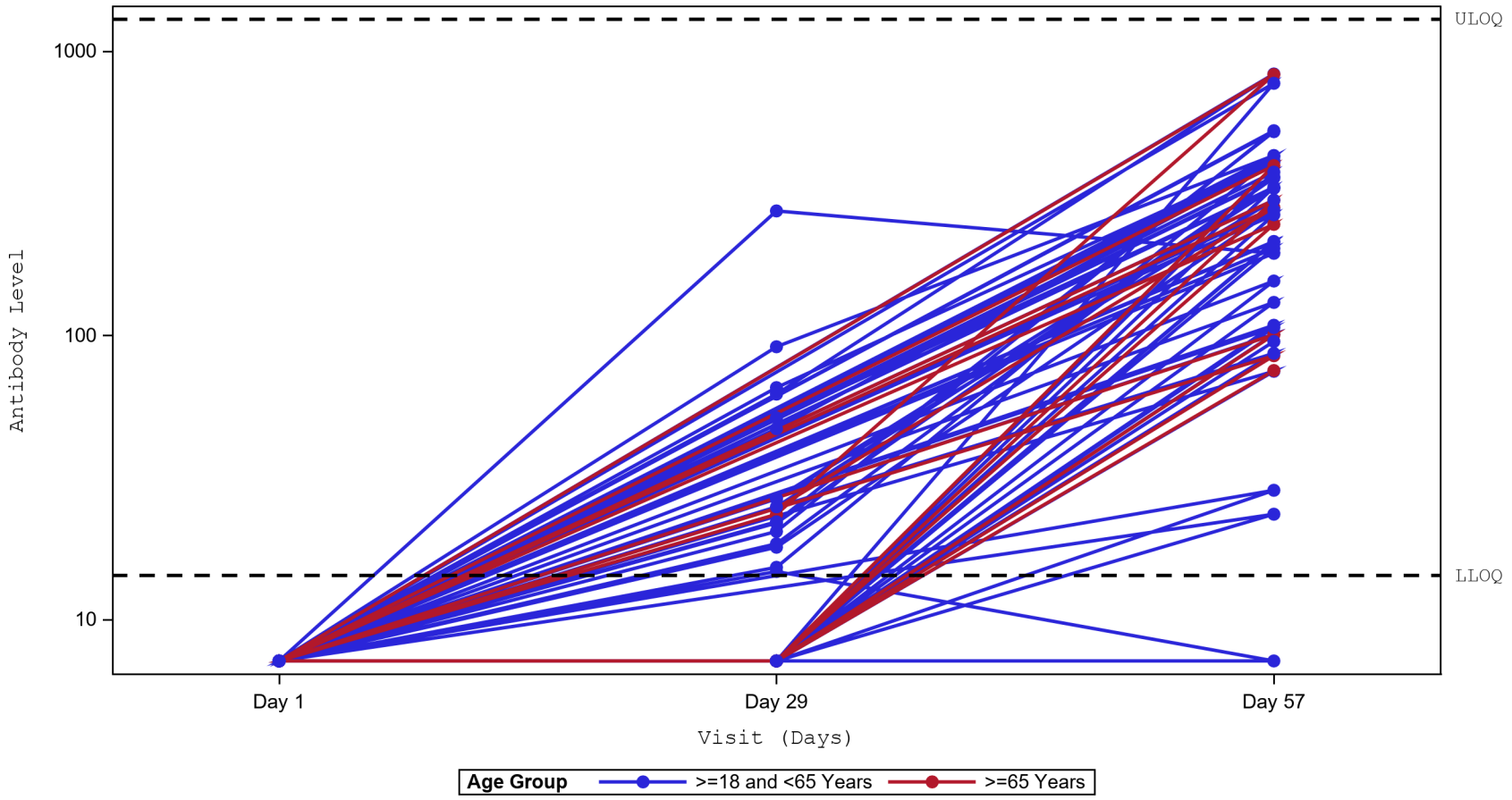
COVID-19 cases with corresponding immunogenicity data available

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening visit becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373728

Figure 16.2.2.1.3.1.1.2
Plot of Pseudovirus Neutralizing Antibody ID80 in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



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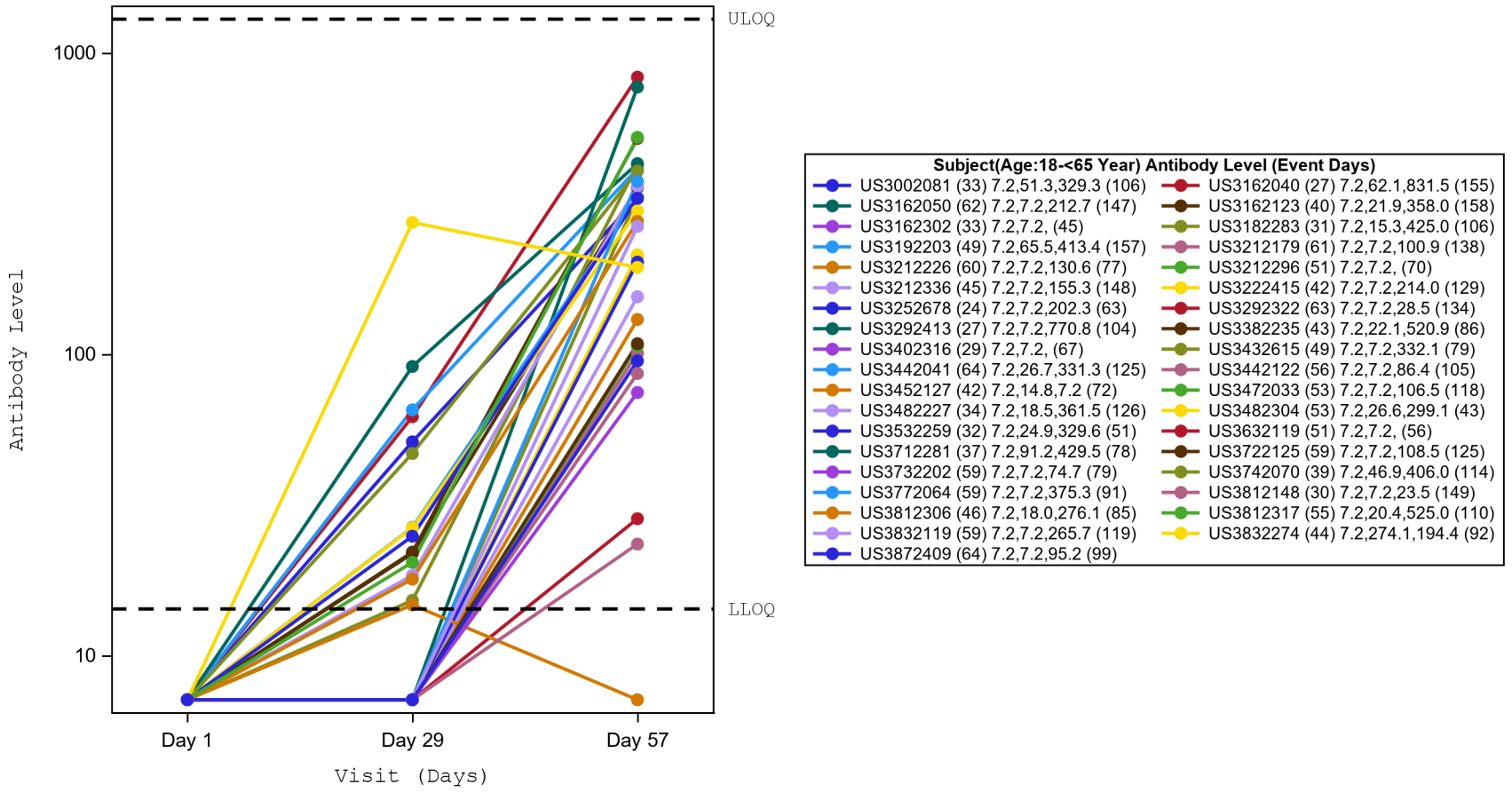
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373729

Figure 16.2.2.1.3.1.1.2
Plot of Pseudovirus Neutralizing Antibody ID80 in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



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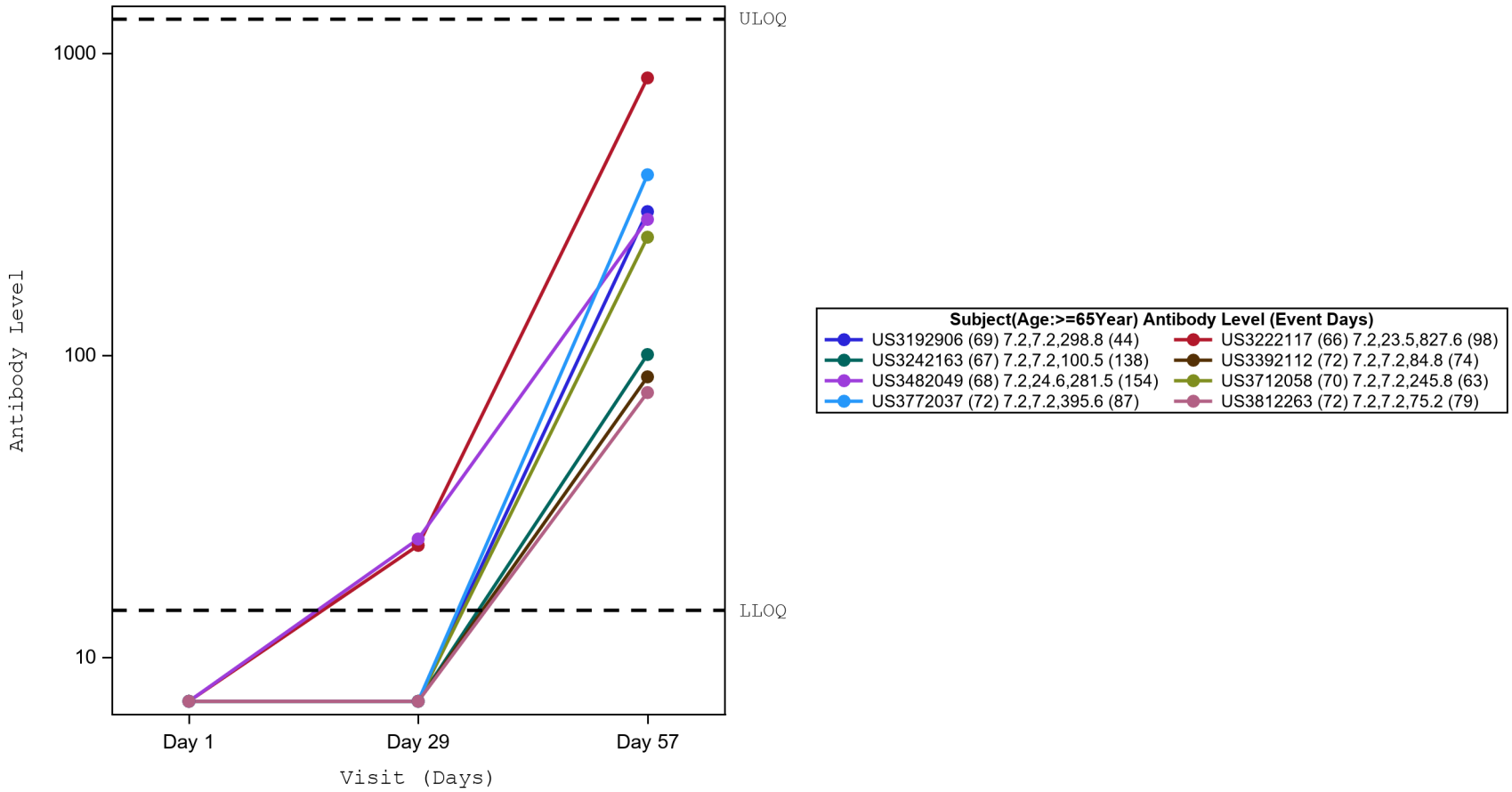
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening visit without becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373730

Figure 16.2.2.1.3.1.1.2
Plot of Pseudovirus Neutralizing Antibody ID80 in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



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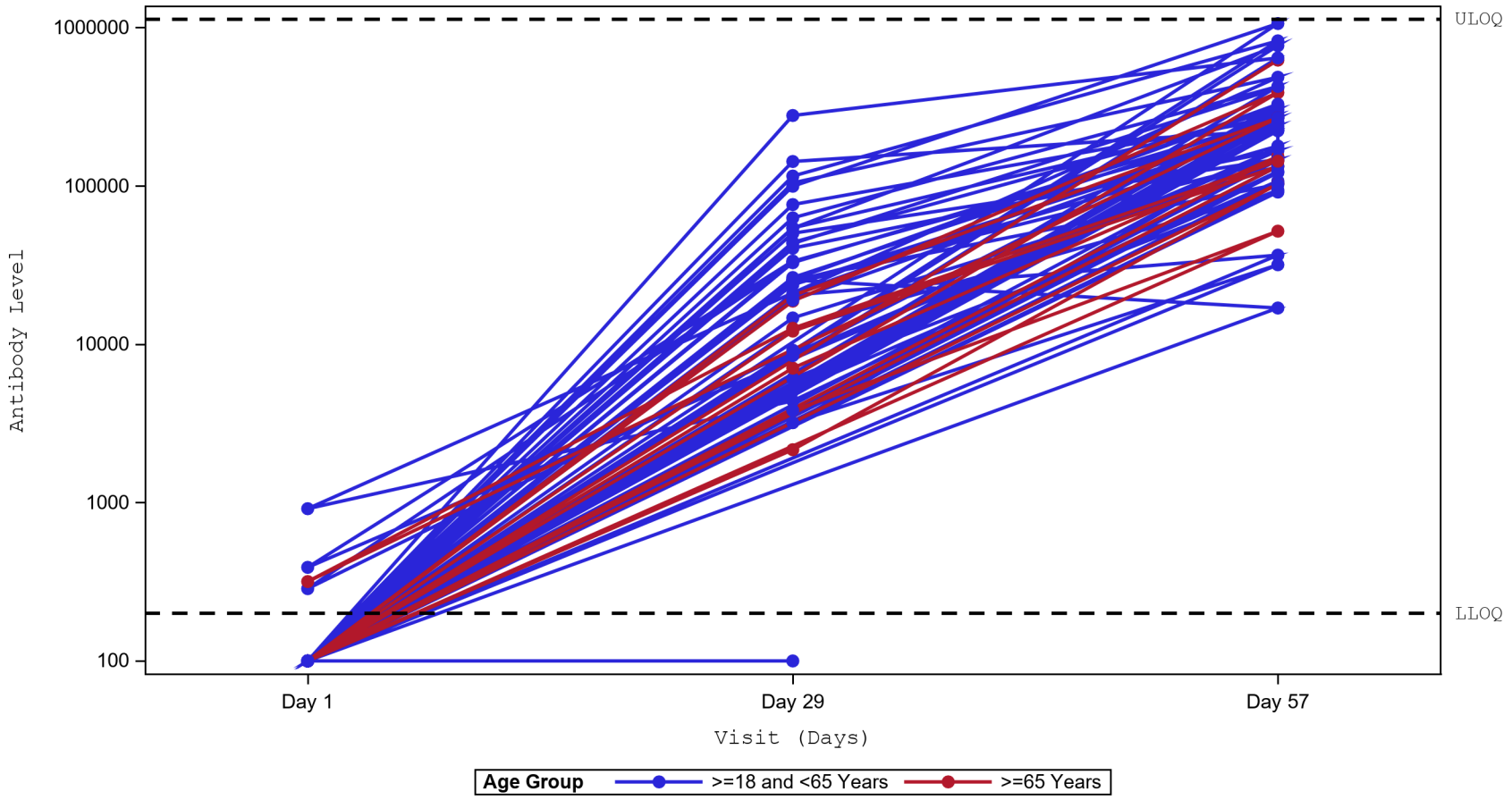
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening before becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-337731

Figure 16.2.2.1.3.1.1.3

Plot of anti-Spike by MSD in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection

Per-Protocol Set



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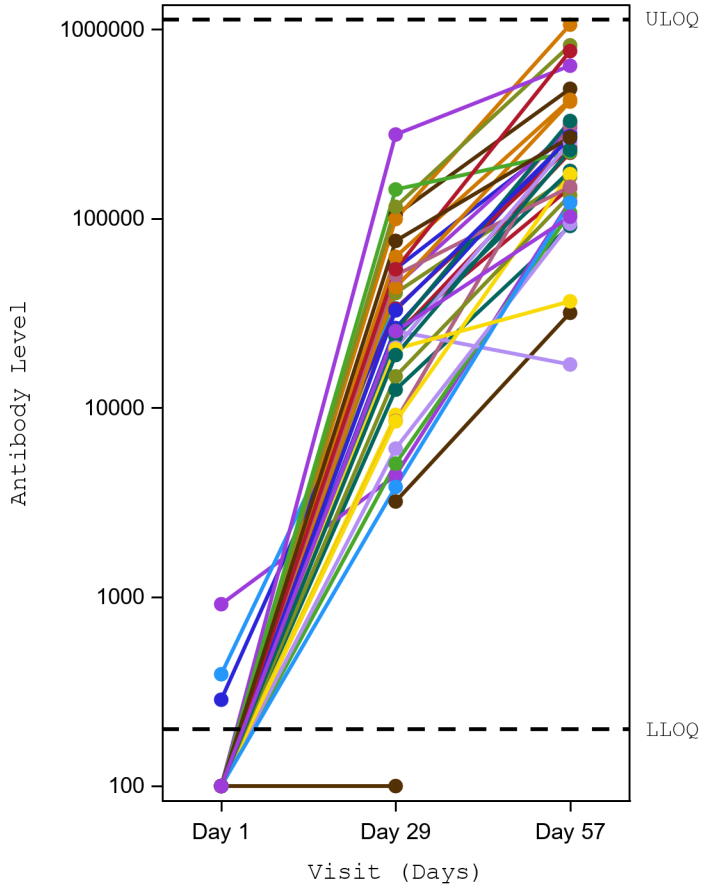
COVID-19 cases with corresponding immunogenicity data available

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

Figure 16.2.2.1.3.1.1.3
Plot of anti-Spike by MSD in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



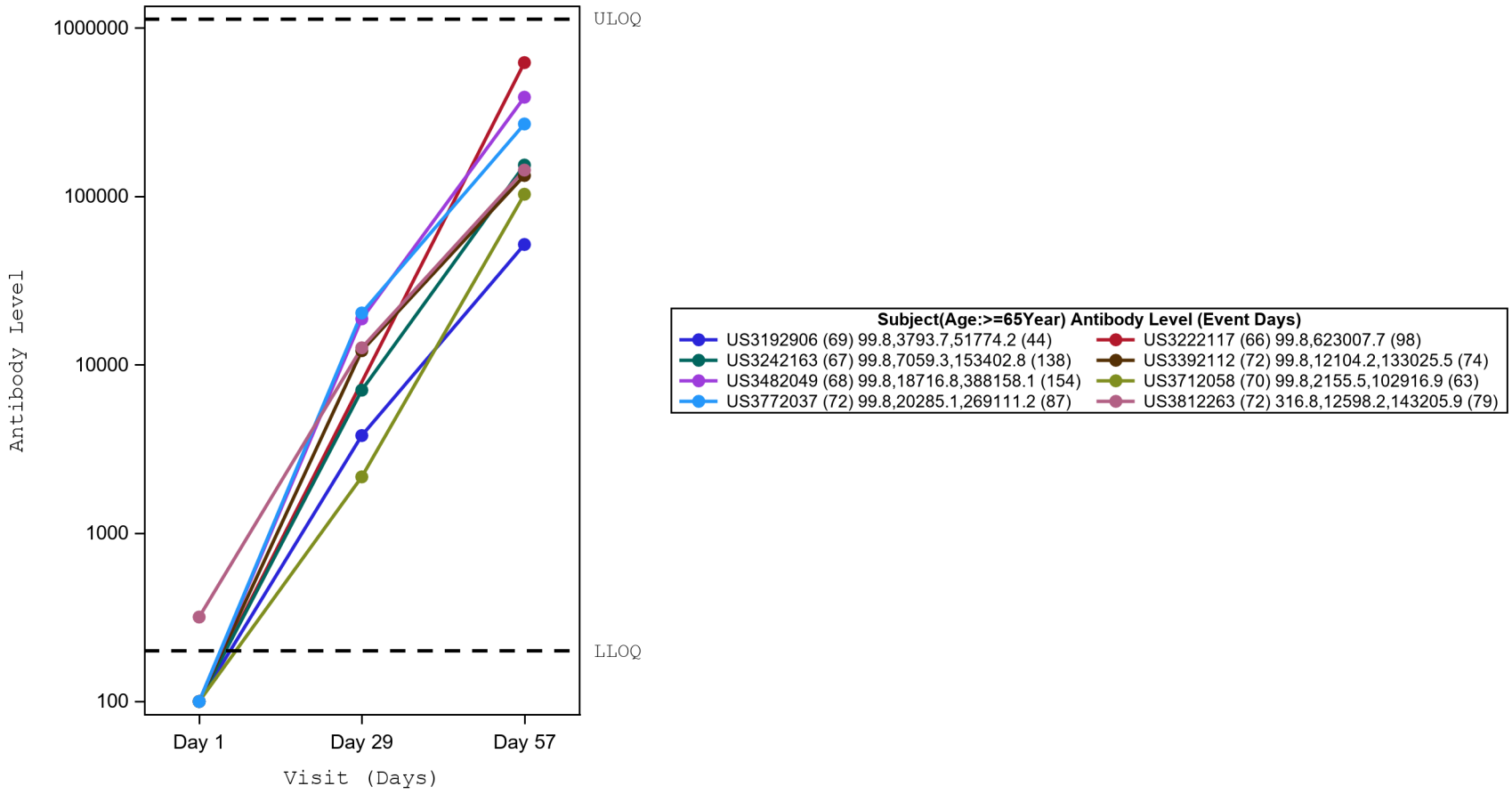
Subject(Age:18-<65 Year) Antibody Level (Event Days)

US3002081 (33) 99.8,54268.0,280847.4 (106)	US3002132 (42) 99.8,25009.6,145547.0 (140)
US3042072 (27) 99.8,12452.9,91439.6 (118)	US3162040 (27) 99.8,104455.9,485799.7 (155)
US3162050 (62) 914.0,4387.1,123443.6 (147)	US3162123 (40) 99.8,40417.3,166669.5 (158)
US3162302 (33) 389.5,33527.9, (45)	US3182283 (31) 99.8,25780.9,320462.0 (106)
US3192203 (49) 99.8,99497.1,1060630.5 (157)	US3212179 (61) 99.8,5062.2,107344.4 (138)
US3212226 (60) 99.8,6078.2,94084.4 (77)	US3212296 (51) 99.8,9167.8, (70)
US3212336 (45) 285.7,32747.0, (148)	US3222415 (42) 99.8,23869.9,222894.8 (129)
US3252678 (24) 99.8,23796.7,178710.1 (63)	US3292322 (63) 3191.6,31761.5 (134)
US3292413 (27) 99.8,43997.0,302894.1 (104)	US3382235 (43) 99.8,115356.6,824553.6 (86)
US3402316 (29) 99.8,19389.4, (67)	US3432615 (49) 99.8,8519.2,313323.9 (79)
US3442041 (64) 99.8,43233.3,415766.4 (125)	US3442122 (56) 104675.4 (105)
US3452127 (42) 99.8,25456.5,16928.4 (72)	US3472033 (53) 99.8,8471.2,171968.5 (118)
US3482227 (34) 99.8,26375.1,272400.1 (126)	US3482304 (53) 99.8,33371.9,238684.7 (43)
US3532259 (32) 99.8,25547.2,328336.9 (51)	US3632119 (51) 99.8,99.8, (56)
US3712281 (37) 99.8,278367.2,643520.6 (78)	US3722125 (59) 99.8,14651.9,132857.1 (125)
US3732202 (59) 99.8,3812.9,121346.6 (79)	US3732399 (32) 99.8,50205.0,147298.4 (66)
US3742070 (39) 99.8,62812.8,425029.9 (114)	US3742357 (53) 99.8,142619.7,224886.2 (103)
US3772064 (59) 99.8,20791.0,253593.1 (91)	US3812148 (30) 99.8,20438.3,36530.3 (149)
US3812306 (46) 99.8,32769.5,267129.3 (85)	US3812317 (55) 99.8,53972.2,768951.8 (110)
US3832119 (59) 99.8,18980.7,230750.4 (119)	US3832274 (44) 99.8,76220.7,269067.4 (92)
US3872409 (64) 99.8,25400.5,102368.5 (99)	

Program Name: [...]\p301\ia_bla\source\others\adhoc-f-covid-immune-by-assay.sas Creation Date and Time: 07JUL2021 11:04
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening visit becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

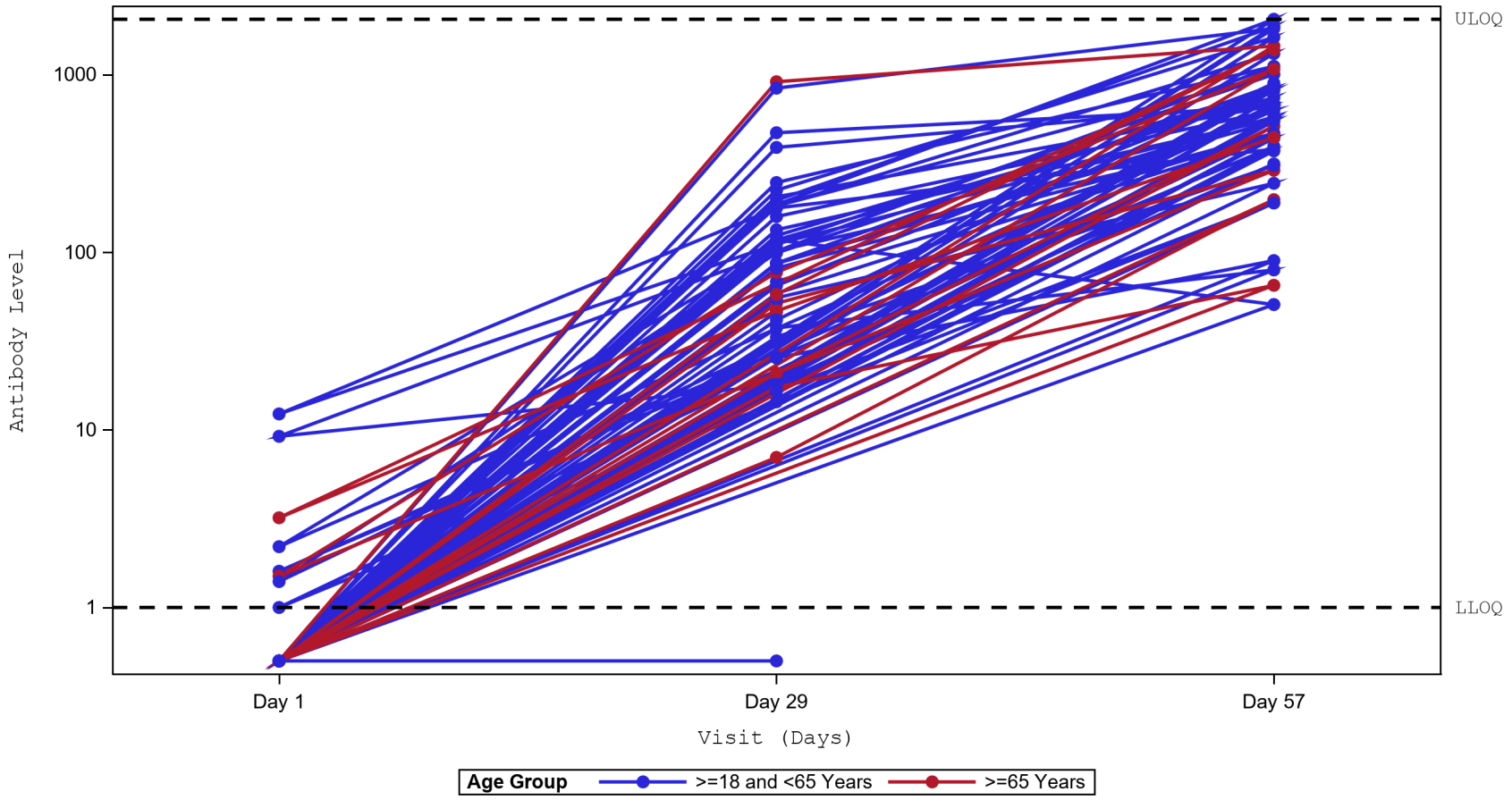
Figure 16.2.2.1.3.1.1.3

Plot of anti-Spike by MSD in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



Program Name: [...]\p301\ia_bla\source\others\adhoc-f-covid-immune-by-assay.sas Creation Date and Time: 07JUL2021 11:04
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

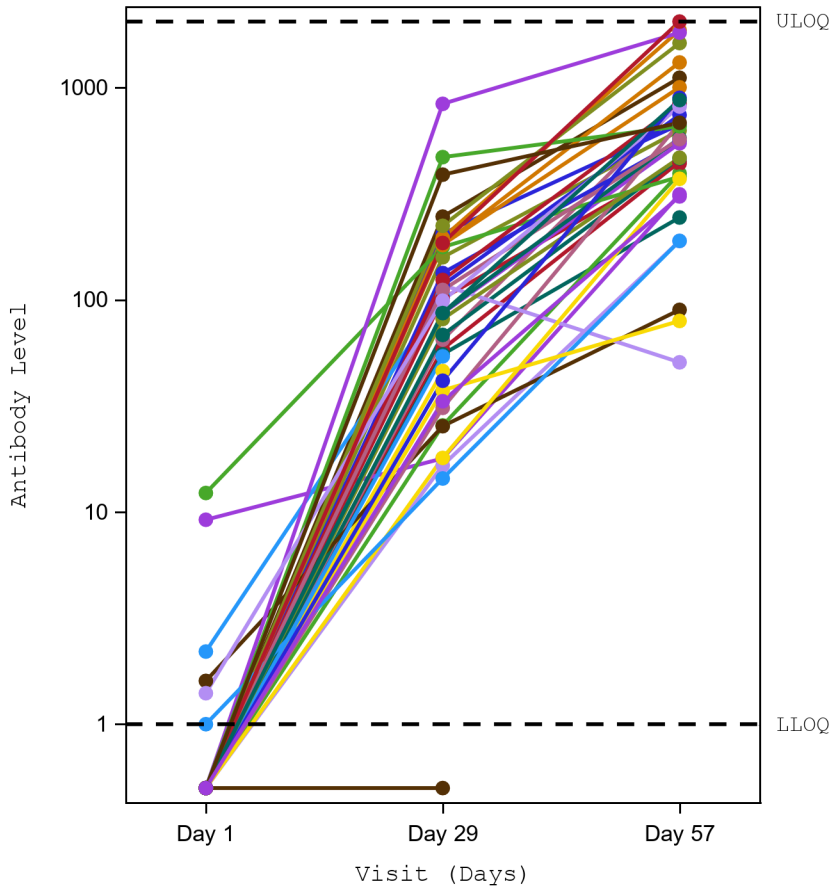
Figure 16.2.2.1.3.1.1.4
Plot of anti-Spike ELISA in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



Program Name: [...]\p301\ia_bla\source\others\adhoc-f-covid-immune-by-assay.sas Creation Date and Time: 07JUL2021 11:04
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening visit becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373735

Figure 16.2.2.1.3.1.1.4
Plot of anti-Spike ELISA in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



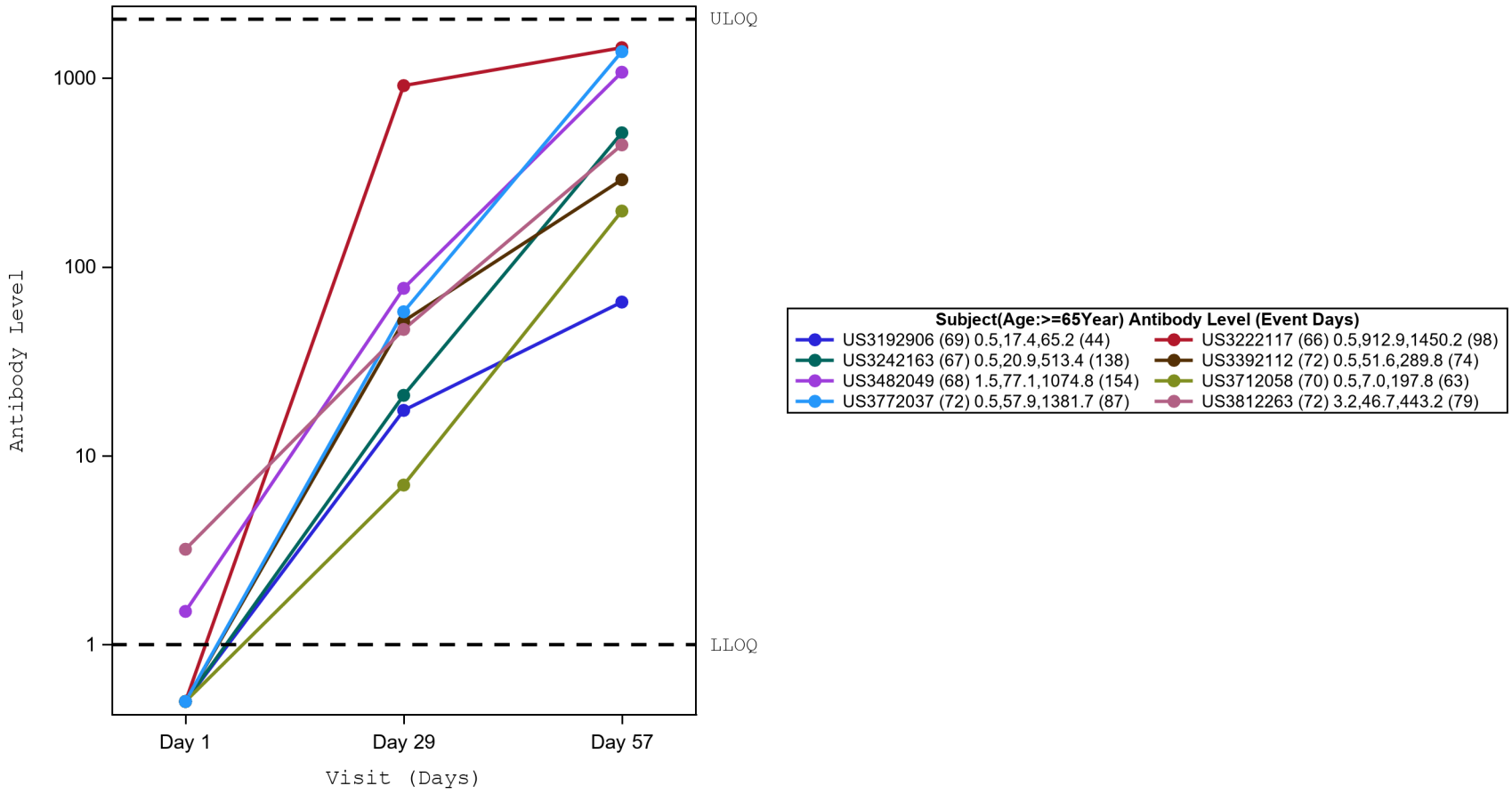
Subject(Age:18-<65 Year) Antibody Level (Event Days)

US3002081 (33) 0.5,205.2,671.8 (106)
US3002132 (42) 0.5,58.7,447.9 (140)
US3042072 (27) 0.5,55.4,244.6 (118)
US3162040 (27) 0.5,247.0,1115.2 (155)
US3162050 (62) 9.2,17.9,314.6 (147)
US3162123 (40) 0.5,158.9,629.2 (158)
US3162302 (33) 2.2,105.2, (45)
US3182283 (31) 0.5,65.0,838.1 (106)
US3192203 (49) 0.5,196.4,1867.9 (157)
US3212179 (61) 0.5,25.6,394.8 (138)
US3212226 (60) 0.5,16.6,189.6 (77)
US3212296 (51) 0.5,46.2, (70)
US3212336 (45) 0.5,133.9,561.2 (148)
US3222415 (42) 0.5,101.8,439.4 (129)
US3252678 (24) 0.5,68.4,465.8 (63)
US3292322 (63) 1.6,25.4,89.8 (134)
US3292413 (27) 0.5,86.5,547.6 (104)
US3382235 (43) 0.5,223.6,1625.1 (86)
US3402316 (29) 0.5,54.2, (67)
US3432615 (49) 0.5,31.0,681.3 (79)
US3442041 (64) 0.5,182.4,1005.2 (125)
US3442122 (56) 12.3,177.5,381.2 (105)
US3452127 (42) 0.5,117.6,50.8 (72)
US3472033 (53) 0.5,18.0,372.4 (118)
US3482227 (34) 0.5,117.4,744.4 (126)
US3482304 (53) 0.5,124.2,838.8 (43)
US3532259 (32) 0.5,87.1,579.1 (51)
US3632119 (51) 0.5,0.5, (56)
US3712281 (37) 0.5,840.1,1820.4 (78)
US3722125 (59) 0.5,81.3,468.1 (125)
US3732202 (59) 1.0,14.4,189.8 (79)
US3732399 (32) 0.5,111.5,572.9 (66)
US3742070 (39) 0.5,181.3,1316.6 (114)
US3742357 (53) 0.5,471.2,658.8 (103)
US3772064 (59) 1.4,99.2,816.0 (91)
US3812148 (30) 0.5,37.5,79.6 (149)
US3812306 (46) 0.5,41.6,896.8 (85)
US3812317 (55) 0.5,185.5,2052.0 (110)
US3832119 (59) 0.5,86.7,875.4 (119)
US3832274 (44) 0.5,389.5,684.4 (92)
US3872409 (64) 0.5,33.3,307.6 (99)

Program Name: [...]\p301\ia_bla\source\others\adhoc-f-covid-immune-by-assay.sas Creation Date and Time: 07JUL2021 11:04
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening before becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373736

Figure 16.2.2.1.3.1.1.4
Plot of anti-Spike ELISA in Participants on mRNA-1273 with COVID-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection
Per-Protocol Set



Program Name: [...]\p301\ia_bla\source\others\adhoc-f-covid-immune-by-assay.sas Creation Date and Time: 07JUL2021 11:04
COVID-19 cases with corresponding immunogenicity data available
* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a subject had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at screening before becoming a COVID-19 case, the subject is censored at the date with positive RT-PCR or Elecsys.

FDA-CBER-2022-1614-3373737

Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Adverse Reactions - N1	15151	15166	30317
Any Solicited Adverse Reactions	7285 (48.1)	13317 (87.8)	20602 (68.0)
95% CI	47.3, 48.9	87.3, 88.3	67.4, 68.5
Grade 1	5134 (33.9)	9329 (61.5)	14463 (47.7)
Grade 2	1782 (11.8)	3134 (20.7)	4916 (16.2)
Grade 3	363 (2.4)	849 (5.6)	1212 (4.0)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 3 or Above	369 (2.4)	854 (5.6)	1223 (4.0)
Solicited Local Adverse Reactions - N1	15147	15162	30309
Any Solicited Local Adverse Reactions	3009 (19.9)	12765 (84.2)	15774 (52.0)
95% CI	19.2, 20.5	83.6, 84.8	51.5, 52.6
Grade 1	2842 (18.8)	10725 (70.7)	13567 (44.8)
Grade 2	89 (0.6)	1511 (10.0)	1600 (5.3)
Grade 3	78 (0.5)	529 (3.5)	607 (2.0)
Grade 4	0	0	0
Grade 3 or Above	78 (0.5)	529 (3.5)	607 (2.0)
Pain - N1	15147	15162	30309
Any	2665 (17.6)	12688 (83.7)	15353 (50.7)
Grade 1	2551 (16.8)	10985 (72.5)	13536 (44.7)
Grade 2	59 (0.4)	1287 (8.5)	1346 (4.4)
Grade 3	55 (0.4)	416 (2.7)	471 (1.6)
Grade 4	0	0	0
Grade 3 or Above	55 (0.4)	416 (2.7)	471 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010101.sas 10JUN2021 07:58

Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Erythema (Redness) - N1	15147	15162	30309
Any	77 (0.5)	445 (2.9)	522 (1.7)
Grade 1	57 (0.4)	281 (1.9)	338 (1.1)
Grade 2	7 (<0.1)	122 (0.8)	129 (0.4)
Grade 3	13 (<0.1)	42 (0.3)	55 (0.2)
Grade 4	0	0	0
Grade 3 or Above	13 (<0.1)	42 (0.3)	55 (0.2)
Swelling (Hardness) - N1	15147	15162	30309
Any	65 (0.4)	935 (6.2)	1000 (3.3)
Grade 1	50 (0.3)	608 (4.0)	658 (2.2)
Grade 2	9 (<0.1)	245 (1.6)	254 (0.8)
Grade 3	6 (<0.1)	82 (0.5)	88 (0.3)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	82 (0.5)	88 (0.3)
Axillary Swelling or Tenderness - N1	15147	15162	30309
Any	722 (4.8)	1553 (10.2)	2275 (7.5)
Grade 1	668 (4.4)	1394 (9.2)	2062 (6.8)
Grade 2	27 (0.2)	110 (0.7)	137 (0.5)
Grade 3	27 (0.2)	49 (0.3)	76 (0.3)
Grade 4	0	0	0
Grade 3 or Above	27 (0.2)	49 (0.3)	76 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010101.sas 10JUN2021 07:58

Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Systemic Adverse Reactions - N1	15151	15166	30317
Any Solicited Systemic Adverse Reactions	6397 (42.2)	8316 (54.8)	14713 (48.5)
95% CI	41.4, 43.0	54.0, 55.6	48.0, 49.1
Grade 1	4334 (28.6)	5358 (35.3)	9692 (32.0)
Grade 2	1746 (11.5)	2504 (16.5)	4250 (14.0)
Grade 3	311 (2.1)	449 (3.0)	760 (2.5)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 3 or Above	317 (2.1)	454 (3.0)	771 (2.5)
Fever - N1	15149	15163	30312
Any	44 (0.3)	112 (0.7)	156 (0.5)
Grade 1	28 (0.2)	73 (0.5)	101 (0.3)
Grade 2	8 (<0.1)	24 (0.2)	32 (0.1)
Grade 3	2 (<0.1)	11 (<0.1)	13 (<0.1)
Grade 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Grade 3 or Above	8 (<0.1)	15 (<0.1)	23 (<0.1)
Headache - N1	15146	15162	30308
Any	4026 (26.6)	4950 (32.6)	8976 (29.6)
Grade 1	3297 (21.8)	3947 (26.0)	7244 (23.9)
Grade 2	532 (3.5)	730 (4.8)	1262 (4.2)
Grade 3	197 (1.3)	273 (1.8)	470 (1.6)
Grade 4	0	0	0
Grade 3 or Above	197 (1.3)	273 (1.8)	470 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010101.sas 10JUN2021 07:58

Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Fatigue - N1	15146	15162	30308
Any	4133 (27.3)	5636 (37.2)	9769 (32.2)
Grade 1	2705 (17.9)	3585 (23.6)	6290 (20.8)
Grade 2	1323 (8.7)	1899 (12.5)	3222 (10.6)
Grade 3	105 (0.7)	151 (1.0)	256 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	105 (0.7)	152 (1.0)	257 (0.8)
Myalgia - N1	15146	15162	30308
Any	2069 (13.7)	3442 (22.7)	5511 (18.2)
Grade 1	1560 (10.3)	2442 (16.1)	4002 (13.2)
Grade 2	462 (3.1)	909 (6.0)	1371 (4.5)
Grade 3	47 (0.3)	91 (0.6)	138 (0.5)
Grade 4	0	0	0
Grade 3 or Above	47 (0.3)	91 (0.6)	138 (0.5)
Arthralgia - N1	15146	15162	30308
Any	1784 (11.8)	2510 (16.6)	4294 (14.2)
Grade 1	1333 (8.8)	1842 (12.1)	3175 (10.5)
Grade 2	413 (2.7)	607 (4.0)	1020 (3.4)
Grade 3	38 (0.3)	60 (0.4)	98 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	38 (0.3)	61 (0.4)	99 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010101.sas 10JUN2021 07:58

Table 14.3.1.1.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Nausea/Vomiting - N1	15146	15162	30308
Any	1075 (7.1)	1262 (8.3)	2337 (7.7)
Grade 1	887 (5.9)	1047 (6.9)	1934 (6.4)
Grade 2	175 (1.2)	205 (1.4)	380 (1.3)
Grade 3	13 (<0.1)	10 (<0.1)	23 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	13 (<0.1)	10 (<0.1)	23 (<0.1)
Chills - N1	15146	15162	30308
Any	878 (5.8)	1251 (8.3)	2129 (7.0)
Grade 1	706 (4.7)	938 (6.2)	1644 (5.4)
Grade 2	158 (1.0)	289 (1.9)	447 (1.5)
Grade 3	14 (<0.1)	24 (0.2)	38 (0.1)
Grade 4	0	0	0
Grade 3 or Above	14 (<0.1)	24 (0.2)	38 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010101.sas 10JUN2021 07:58

Table 14.3.1.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Adverse Reactions - N1	14578	14691	29269
Any Solicited Adverse Reactions	6255 (42.9)	13556 (92.3)	19811 (67.7)
95% CI	42.1, 43.7	91.8, 92.7	67.1, 68.2
Grade 1	4346 (29.8)	4847 (33.0)	9193 (31.4)
Grade 2	1558 (10.7)	5800 (39.5)	7358 (25.1)
Grade 3	348 (2.4)	2895 (19.7)	3243 (11.1)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or Above	351 (2.4)	2909 (19.8)	3260 (11.1)
Solicited Local Adverse Reactions - N1	14577	14688	29265
Any Solicited Local Adverse Reactions	2757 (18.9)	13029 (88.7)	15786 (53.9)
95% CI	18.3, 19.6	88.2, 89.2	53.4, 54.5
Grade 1	2594 (17.8)	8789 (59.8)	11383 (38.9)
Grade 2	88 (0.6)	3217 (21.9)	3305 (11.3)
Grade 3	75 (0.5)	1023 (7.0)	1098 (3.8)
Grade 4	0	0	0
Grade 3 or Above	75 (0.5)	1023 (7.0)	1098 (3.8)
Pain - N1	14577	14688	29265
Any	2486 (17.1)	12964 (88.3)	15450 (52.8)
Grade 1	2384 (16.4)	9508 (64.7)	11892 (40.6)
Grade 2	61 (0.4)	2850 (19.4)	2911 (9.9)
Grade 3	41 (0.3)	606 (4.1)	647 (2.2)
Grade 4	0	0	0
Grade 3 or Above	41 (0.3)	606 (4.1)	647 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=14578) n	Placebo (N=14578) (%)	mRNA-1273 (N=14691) n	mRNA-1273 (N=14691) (%)	Total (N=29269) n	Total (N=29269) (%)
Erythema (Redness) - N1	14577		14687		29264	
Any	68	(0.5)	1274	(8.7)	1342	(4.6)
Grade 1	48	(0.3)	456	(3.1)	504	(1.7)
Grade 2	5	(<0.1)	531	(3.6)	536	(1.8)
Grade 3	15	(0.1)	287	(2.0)	302	(1.0)
Grade 4	0		0		0	
Grade 3 or Above	15	(0.1)	287	(2.0)	302	(1.0)
Swelling (Hardness) - N1	14577		14687		29264	
Any	60	(0.4)	1807	(12.3)	1867	(6.4)
Grade 1	38	(0.3)	900	(6.1)	938	(3.2)
Grade 2	10	(<0.1)	652	(4.4)	662	(2.3)
Grade 3	12	(<0.1)	255	(1.7)	267	(0.9)
Grade 4	0		0		0	
Grade 3 or Above	12	(<0.1)	255	(1.7)	267	(0.9)
Axillary Swelling or Tenderness - N1	14577		14687		29264	
Any	571	(3.9)	2092	(14.2)	2663	(9.1)
Grade 1	523	(3.6)	1735	(11.8)	2258	(7.7)
Grade 2	28	(0.2)	289	(2.0)	317	(1.1)
Grade 3	20	(0.1)	68	(0.5)	88	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	20	(0.1)	68	(0.5)	88	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Systemic Adverse Reactions - N1	14577	14690	29267
Any Solicited Systemic Adverse Reactions	5343 (36.7)	11678 (79.5)	17021 (58.2)
95% CI	35.9, 37.4	78.8, 80.1	57.6, 58.7
Grade 1	3519 (24.1)	3717 (25.3)	7236 (24.7)
Grade 2	1535 (10.5)	5611 (38.2)	7146 (24.4)
Grade 3	286 (2.0)	2336 (15.9)	2622 (9.0)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or Above	289 (2.0)	2350 (16.0)	2639 (9.0)
Fever - N1	14573	14682	29255
Any	43 (0.3)	2276 (15.5)	2319 (7.9)
Grade 1	33 (0.2)	1363 (9.3)	1396 (4.8)
Grade 2	5 (<0.1)	697 (4.7)	702 (2.4)
Grade 3	2 (<0.1)	203 (1.4)	205 (0.7)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)
Grade 3 or Above	5 (<0.1)	216 (1.5)	221 (0.8)
Headache - N1	14575	14687	29262
Any	3427 (23.5)	8637 (58.8)	12064 (41.2)
Grade 1	2740 (18.8)	4815 (32.8)	7555 (25.8)
Grade 2	522 (3.6)	3156 (21.5)	3678 (12.6)
Grade 3	165 (1.1)	666 (4.5)	831 (2.8)
Grade 4	0	0	0
Grade 3 or Above	165 (1.1)	666 (4.5)	831 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Fatigue - N1	14575	14687	29262
Any	3418 (23.5)	9607 (65.4)	13025 (44.5)
Grade 1	2181 (15.0)	3431 (23.4)	5612 (19.2)
Grade 2	1129 (7.7)	4743 (32.3)	5872 (20.1)
Grade 3	108 (0.7)	1433 (9.8)	1541 (5.3)
Grade 4	0	0	0
Grade 3 or Above	108 (0.7)	1433 (9.8)	1541 (5.3)
Myalgia - N1	14575	14687	29262
Any	1824 (12.5)	8529 (58.1)	10353 (35.4)
Grade 1	1307 (9.0)	3242 (22.1)	4549 (15.5)
Grade 2	465 (3.2)	3966 (27.0)	4431 (15.1)
Grade 3	52 (0.4)	1321 (9.0)	1373 (4.7)
Grade 4	0	0	0
Grade 3 or Above	52 (0.4)	1321 (9.0)	1373 (4.7)
Arthralgia - N1	14575	14687	29262
Any	1579 (10.8)	6303 (42.9)	7882 (26.9)
Grade 1	1143 (7.8)	2809 (19.1)	3952 (13.5)
Grade 2	392 (2.7)	2719 (18.5)	3111 (10.6)
Grade 3	44 (0.3)	775 (5.3)	819 (2.8)
Grade 4	0	0	0
Grade 3 or Above	44 (0.3)	775 (5.3)	819 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Nausea/Vomiting - N1	14575	14687	29262
Any	941 (6.5)	2794 (19.0)	3735 (12.8)
Grade 1	761 (5.2)	2094 (14.3)	2855 (9.8)
Grade 2	169 (1.2)	678 (4.6)	847 (2.9)
Grade 3	11 (<0.1)	21 (0.1)	32 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	11 (<0.1)	22 (0.1)	33 (0.1)
Chills - N1	14575	14687	29262
Any	813 (5.6)	6500 (44.3)	7313 (25.0)
Grade 1	629 (4.3)	2907 (19.8)	3536 (12.1)
Grade 2	167 (1.1)	3402 (23.2)	3569 (12.2)
Grade 3	17 (0.1)	191 (1.3)	208 (0.7)
Grade 4	0	0	0
Grade 3 or Above	17 (0.1)	191 (1.3)	208 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Solicited Adverse Reactions - N1	15159	15179	30338
Any Solicited Adverse Reactions	9113 (60.1)	14402 (94.9)	23515 (77.5)
95% CI	59.3, 60.9	94.5, 95.2	77.0, 78.0
Grade 1	5804 (38.3)	4798 (31.6)	10602 (34.9)
Grade 2	2630 (17.3)	6181 (40.7)	8811 (29.0)
Grade 3	670 (4.4)	3404 (22.4)	4074 (13.4)
Grade 4	9 (<0.1)	19 (0.1)	28 (<0.1)
Grade 3 or Above	679 (4.5)	3423 (22.6)	4102 (13.5)
Solicited Local Adverse Reactions - N1	15158	15179	30337
Any Solicited Local Adverse Reactions	4468 (29.5)	14032 (92.4)	18500 (61.0)
95% CI	28.8, 30.2	92.0, 92.9	60.4, 61.5
Grade 1	4157 (27.4)	9003 (59.3)	13160 (43.4)
Grade 2	163 (1.1)	3609 (23.8)	3772 (12.4)
Grade 3	148 (1.0)	1420 (9.4)	1568 (5.2)
Grade 4	0	0	0
Grade 3 or Above	148 (1.0)	1420 (9.4)	1568 (5.2)
Pain - N1	15158	15179	30337
Any	4046 (26.7)	13969 (92.0)	18015 (59.4)
Grade 1	3842 (25.3)	9825 (64.7)	13667 (45.1)
Grade 2	111 (0.7)	3221 (21.2)	3332 (11.0)
Grade 3	93 (0.6)	923 (6.1)	1016 (3.3)
Grade 4	0	0	0
Grade 3 or Above	93 (0.6)	923 (6.1)	1016 (3.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Erythema (Redness) - N1	15158	15178	30336
Any	137 (0.9)	1549 (10.2)	1686 (5.6)
Grade 1	98 (0.6)	632 (4.2)	730 (2.4)
Grade 2	12 (<0.1)	593 (3.9)	605 (2.0)
Grade 3	27 (0.2)	324 (2.1)	351 (1.2)
Grade 4	0	0	0
Grade 3 or Above	27 (0.2)	324 (2.1)	351 (1.2)
Swelling (Hardness) - N1	15158	15178	30336
Any	116 (0.8)	2249 (14.8)	2365 (7.8)
Grade 1	81 (0.5)	1151 (7.6)	1232 (4.1)
Grade 2	18 (0.1)	771 (5.1)	789 (2.6)
Grade 3	17 (0.1)	327 (2.2)	344 (1.1)
Grade 4	0	0	0
Grade 3 or Above	17 (0.1)	327 (2.2)	344 (1.1)
Axillary Swelling or Tenderness - N1	15158	15178	30336
Any	1101 (7.3)	3013 (19.9)	4114 (13.6)
Grade 1	1004 (6.6)	2532 (16.7)	3536 (11.7)
Grade 2	51 (0.3)	370 (2.4)	421 (1.4)
Grade 3	46 (0.3)	111 (0.7)	157 (0.5)
Grade 4	0	0	0
Grade 3 or Above	46 (0.3)	111 (0.7)	157 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Solicited Systemic Adverse Reactions - N1	15159	15178	30337
Any Solicited Systemic Adverse Reactions	8117 (53.5)	12779 (84.2)	20896 (68.9)
95% CI	52.7, 54.3	83.6, 84.8	68.4, 69.4
Grade 1	4946 (32.6)	4040 (26.6)	8986 (29.6)
Grade 2	2600 (17.2)	6099 (40.2)	8699 (28.7)
Grade 3	562 (3.7)	2621 (17.3)	3183 (10.5)
Grade 4	9 (<0.1)	19 (0.1)	28 (<0.1)
Grade 3 or Above	571 (3.8)	2640 (17.4)	3211 (10.6)
Fever - N1	15158	15177	30335
Any	86 (0.6)	2350 (15.5)	2436 (8.0)
Grade 1	60 (0.4)	1408 (9.3)	1468 (4.8)
Grade 2	13 (<0.1)	712 (4.7)	725 (2.4)
Grade 3	4 (<0.1)	213 (1.4)	217 (0.7)
Grade 4	9 (<0.1)	17 (0.1)	26 (<0.1)
Grade 3 or Above	13 (<0.1)	230 (1.5)	243 (0.8)
Headache - N1	15158	15178	30336
Any	5613 (37.0)	9844 (64.9)	15457 (51.0)
Grade 1	4355 (28.7)	5579 (36.8)	9934 (32.7)
Grade 2	914 (6.0)	3390 (22.3)	4304 (14.2)
Grade 3	344 (2.3)	875 (5.8)	1219 (4.0)
Grade 4	0	0	0
Grade 3 or Above	344 (2.3)	875 (5.8)	1219 (4.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Fatigue - N1	15158	15178	30336
Any	5549 (36.6)	10640 (70.1)	16189 (53.4)
Grade 1	3343 (22.1)	3802 (25.0)	7145 (23.6)
Grade 2	2004 (13.2)	5303 (34.9)	7307 (24.1)
Grade 3	202 (1.3)	1534 (10.1)	1736 (5.7)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	202 (1.3)	1535 (10.1)	1737 (5.7)
Myalgia - N1	15158	15178	30336
Any	3118 (20.6)	9348 (61.6)	12466 (41.1)
Grade 1	2195 (14.5)	3686 (24.3)	5881 (19.4)
Grade 2	825 (5.4)	4277 (28.2)	5102 (16.8)
Grade 3	98 (0.6)	1385 (9.1)	1483 (4.9)
Grade 4	0	0	0
Grade 3 or Above	98 (0.6)	1385 (9.1)	1483 (4.9)
Arthralgia - N1	15158	15178	30336
Any	2672 (17.6)	7055 (46.5)	9727 (32.1)
Grade 1	1873 (12.4)	3248 (21.4)	5121 (16.9)
Grade 2	718 (4.7)	2990 (19.7)	3708 (12.2)
Grade 3	81 (0.5)	816 (5.4)	897 (3.0)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	81 (0.5)	817 (5.4)	898 (3.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Nausea/Vomiting - N1	15158	15178	30336
Any	1723 (11.4)	3493 (23.0)	5216 (17.2)
Grade 1	1380 (9.1)	2622 (17.3)	4002 (13.2)
Grade 2	319 (2.1)	840 (5.5)	1159 (3.8)
Grade 3	24 (0.2)	30 (0.2)	54 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	24 (0.2)	31 (0.2)	55 (0.2)
Chills - N1	15158	15178	30336
Any	1473 (9.7)	6907 (45.5)	8380 (27.6)
Grade 1	1132 (7.5)	3144 (20.7)	4276 (14.1)
Grade 2	310 (2.0)	3552 (23.4)	3862 (12.7)
Grade 3	31 (0.2)	211 (1.4)	242 (0.8)
Grade 4	0	0	0
Grade 3 or Above	31 (0.2)	211 (1.4)	242 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.8.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with HIV by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Solicited Adverse Reactions - N1	91	94	185
Any Solicited Adverse Reactions	48 (52.7)	85 (90.4)	133 (71.9)
95% CI	42.0, 63.3	82.6, 95.5	64.8, 78.2
Grade 1	23 (25.3)	39 (41.5)	62 (33.5)
Grade 2	23 (25.3)	30 (31.9)	53 (28.6)
Grade 3	2 (2.2)	16 (17.0)	18 (9.7)
Grade 4	0	0	0
Grade 3 or Above	2 (2.2)	16 (17.0)	18 (9.7)
Solicited Local Adverse Reactions - N1	91	94	185
Any Solicited Local Adverse Reactions	22 (24.2)	79 (84.0)	101 (54.6)
95% CI	15.8, 34.3	75.0, 90.8	47.1, 61.9
Grade 1	21 (23.1)	62 (66.0)	83 (44.9)
Grade 2	1 (1.1)	10 (10.6)	11 (5.9)
Grade 3	0	7 (7.4)	7 (3.8)
Grade 4	0	0	0
Grade 3 or Above	0	7 (7.4)	7 (3.8)
Pain - N1	91	94	185
Any	19 (20.9)	79 (84.0)	98 (53.0)
Grade 1	18 (19.8)	67 (71.3)	85 (45.9)
Grade 2	1 (1.1)	9 (9.6)	10 (5.4)
Grade 3	0	3 (3.2)	3 (1.6)
Grade 4	0	0	0
Grade 3 or Above	0	3 (3.2)	3 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.8.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with HIV by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Erythema (Redness) - N1	91	94	185
Any	1 (1.1)	5 (5.3)	6 (3.2)
Grade 1	1 (1.1)	2 (2.1)	3 (1.6)
Grade 2	0	0	0
Grade 3	0	3 (3.2)	3 (1.6)
Grade 4	0	0	0
Grade 3 or Above	0	3 (3.2)	3 (1.6)
Swelling (Hardness) - N1	91	94	185
Any	3 (3.3)	11 (11.7)	14 (7.6)
Grade 1	3 (3.3)	7 (7.4)	10 (5.4)
Grade 2	0	2 (2.1)	2 (1.1)
Grade 3	0	2 (2.1)	2 (1.1)
Grade 4	0	0	0
Grade 3 or Above	0	2 (2.1)	2 (1.1)
Axillary Swelling or Tenderness - N1	91	94	185
Any	4 (4.4)	14 (14.9)	18 (9.7)
Grade 1	4 (4.4)	12 (12.8)	16 (8.6)
Grade 2	0	1 (1.1)	1 (0.5)
Grade 3	0	1 (1.1)	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.1)	1 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.8.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with HIV by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Solicited Systemic Adverse Reactions - N1	91	94	185
Any Solicited Systemic Adverse Reactions	44 (48.4)	70 (74.5)	114 (61.6)
95% CI	37.7, 59.1	64.4, 82.9	54.2, 68.7
Grade 1	19 (20.9)	28 (29.8)	47 (25.4)
Grade 2	23 (25.3)	31 (33.0)	54 (29.2)
Grade 3	2 (2.2)	11 (11.7)	13 (7.0)
Grade 4	0	0	0
Grade 3 or Above	2 (2.2)	11 (11.7)	13 (7.0)
Fever - N1	91	94	185
Any	2 (2.2)	11 (11.7)	13 (7.0)
Grade 1	2 (2.2)	5 (5.3)	7 (3.8)
Grade 2	0	5 (5.3)	5 (2.7)
Grade 3	0	1 (1.1)	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.1)	1 (0.5)
Headache - N1	91	94	185
Any	32 (35.2)	51 (54.3)	83 (44.9)
Grade 1	24 (26.4)	33 (35.1)	57 (30.8)
Grade 2	7 (7.7)	12 (12.8)	19 (10.3)
Grade 3	1 (1.1)	6 (6.4)	7 (3.8)
Grade 4	0	0	0
Grade 3 or Above	1 (1.1)	6 (6.4)	7 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.8.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with HIV by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Fatigue - N1	91	94	185
Any	34 (37.4)	55 (58.5)	89 (48.1)
Grade 1	16 (17.6)	25 (26.6)	41 (22.2)
Grade 2	17 (18.7)	24 (25.5)	41 (22.2)
Grade 3	1 (1.1)	6 (6.4)	7 (3.8)
Grade 4	0	0	0
Grade 3 or Above	1 (1.1)	6 (6.4)	7 (3.8)
Myalgia - N1	91	94	185
Any	23 (25.3)	46 (48.9)	69 (37.3)
Grade 1	14 (15.4)	21 (22.3)	35 (18.9)
Grade 2	9 (9.9)	19 (20.2)	28 (15.1)
Grade 3	0	6 (6.4)	6 (3.2)
Grade 4	0	0	0
Grade 3 or Above	0	6 (6.4)	6 (3.2)
Arthralgia - N1	91	94	185
Any	19 (20.9)	34 (36.2)	53 (28.6)
Grade 1	9 (9.9)	22 (23.4)	31 (16.8)
Grade 2	10 (11.0)	11 (11.7)	21 (11.4)
Grade 3	0	1 (1.1)	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.1)	1 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.8.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with HIV by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Nausea/Vomiting - N1	91	94	185
Any	10 (11.0)	22 (23.4)	32 (17.3)
Grade 1	9 (9.9)	17 (18.1)	26 (14.1)
Grade 2	1 (1.1)	5 (5.3)	6 (3.2)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	91	94	185
Any	11 (12.1)	35 (37.2)	46 (24.9)
Grade 1	6 (6.6)	24 (25.5)	30 (16.2)
Grade 2	5 (5.5)	11 (11.7)	16 (8.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.9.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=1144) n (%)	mRNA-1273 (N=1150) n (%)	Total (N=2294) n (%)
Solicited Adverse Reactions - N1	1144	1150	2294
Any Solicited Adverse Reactions	739 (64.6)	1097 (95.4)	1836 (80.0)
95% CI	61.7, 67.4	94.0, 96.5	78.3, 81.7
Grade 1	433 (37.8)	347 (30.2)	780 (34.0)
Grade 2	244 (21.3)	469 (40.8)	713 (31.1)
Grade 3	62 (5.4)	280 (24.3)	342 (14.9)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	62 (5.4)	281 (24.4)	343 (15.0)
Solicited Local Adverse Reactions - N1	1144	1150	2294
Any Solicited Local Adverse Reactions	372 (32.5)	1072 (93.2)	1444 (62.9)
95% CI	29.8, 35.3	91.6, 94.6	60.9, 64.9
Grade 1	338 (29.5)	669 (58.2)	1007 (43.9)
Grade 2	21 (1.8)	295 (25.7)	316 (13.8)
Grade 3	13 (1.1)	108 (9.4)	121 (5.3)
Grade 4	0	0	0
Grade 3 or Above	13 (1.1)	108 (9.4)	121 (5.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.9.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=1144) n (%)	mRNA-1273 (N=1150) n (%)	Total (N=2294) n (%)
Pain - N1	1144	1150	2294
Any	326 (28.5)	1065 (92.6)	1391 (60.6)
Grade 1	301 (26.3)	726 (63.1)	1027 (44.8)
Grade 2	15 (1.3)	267 (23.2)	282 (12.3)
Grade 3	10 (0.9)	72 (6.3)	82 (3.6)
Grade 4	0	0	0
Grade 3 or Above	10 (0.9)	72 (6.3)	82 (3.6)
Erythema (Redness) - N1	1144	1150	2294
Any	14 (1.2)	114 (9.9)	128 (5.6)
Grade 1	9 (0.8)	49 (4.3)	58 (2.5)
Grade 2	2 (0.2)	46 (4.0)	48 (2.1)
Grade 3	3 (0.3)	19 (1.7)	22 (1.0)
Grade 4	0	0	0
Grade 3 or Above	3 (0.3)	19 (1.7)	22 (1.0)
Swelling (Hardness) - N1	1144	1150	2294
Any	13 (1.1)	174 (15.1)	187 (8.2)
Grade 1	11 (1.0)	81 (7.0)	92 (4.0)
Grade 2	1 (<0.1)	68 (5.9)	69 (3.0)
Grade 3	1 (<0.1)	25 (2.2)	26 (1.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	25 (2.2)	26 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.9.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=1144) n (%)	mRNA-1273 (N=1150) n (%)	Total (N=2294) n (%)
Axillary Swelling or Tenderness - N1	1144	1150	2294
Any	103 (9.0)	236 (20.5)	339 (14.8)
Grade 1	96 (8.4)	198 (17.2)	294 (12.8)
Grade 2	6 (0.5)	29 (2.5)	35 (1.5)
Grade 3	1 (<0.1)	9 (0.8)	10 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	9 (0.8)	10 (0.4)
Solicited Systemic Adverse Reactions - N1	1144	1150	2294
Any Solicited Systemic Adverse Reactions	655 (57.3)	989 (86.0)	1644 (71.7)
95% CI	54.3, 60.1	83.9, 88.0	69.8, 73.5
Grade 1	368 (32.2)	293 (25.5)	661 (28.8)
Grade 2	235 (20.5)	469 (40.8)	704 (30.7)
Grade 3	52 (4.5)	226 (19.7)	278 (12.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	52 (4.5)	227 (19.7)	279 (12.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.9.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=1144) n (%)	mRNA-1273 (N=1150) n (%)	Total (N=2294) n (%)
Fever - N1	1144	1150	2294
Any	2 (0.2)	175 (15.2)	177 (7.7)
Grade 1	2 (0.2)	106 (9.2)	108 (4.7)
Grade 2	0	58 (5.0)	58 (2.5)
Grade 3	0	11 (1.0)	11 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	11 (1.0)	11 (0.5)
Headache - N1	1144	1150	2294
Any	429 (37.5)	764 (66.4)	1193 (52.0)
Grade 1	332 (29.0)	438 (38.1)	770 (33.6)
Grade 2	72 (6.3)	253 (22.0)	325 (14.2)
Grade 3	25 (2.2)	73 (6.3)	98 (4.3)
Grade 4	0	0	0
Grade 3 or Above	25 (2.2)	73 (6.3)	98 (4.3)
Fatigue - N1	1144	1150	2294
Any	454 (39.7)	837 (72.8)	1291 (56.3)
Grade 1	248 (21.7)	272 (23.7)	520 (22.7)
Grade 2	184 (16.1)	425 (37.0)	609 (26.5)
Grade 3	22 (1.9)	140 (12.2)	162 (7.1)
Grade 4	0	0	0
Grade 3 or Above	22 (1.9)	140 (12.2)	162 (7.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.9.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=1144) n (%)	mRNA-1273 (N=1150) n (%)	Total (N=2294) n (%)
Myalgia - N1	1144	1150	2294
Any	274 (24.0)	739 (64.3)	1013 (44.2)
Grade 1	188 (16.4)	279 (24.3)	467 (20.4)
Grade 2	78 (6.8)	327 (28.4)	405 (17.7)
Grade 3	8 (0.7)	133 (11.6)	141 (6.1)
Grade 4	0	0	0
Grade 3 or Above	8 (0.7)	133 (11.6)	141 (6.1)
Arthralgia - N1	1144	1150	2294
Any	246 (21.5)	567 (49.3)	813 (35.4)
Grade 1	162 (14.2)	258 (22.4)	420 (18.3)
Grade 2	76 (6.6)	232 (20.2)	308 (13.4)
Grade 3	8 (0.7)	77 (6.7)	85 (3.7)
Grade 4	0	0	0
Grade 3 or Above	8 (0.7)	77 (6.7)	85 (3.7)
Nausea/Vomiting - N1	1144	1150	2294
Any	150 (13.1)	284 (24.7)	434 (18.9)
Grade 1	118 (10.3)	199 (17.3)	317 (13.8)
Grade 2	32 (2.8)	83 (7.2)	115 (5.0)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	0	2 (0.2)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.9.3
Summary of Solicited Adverse Reactions Within 7 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=1144) n (%)	mRNA-1273 (N=1150) n (%)	Total (N=2294) n (%)
Chills - N1	1144	1150	2294
Any	125 (10.9)	525 (45.7)	650 (28.3)
Grade 1	97 (8.5)	237 (20.6)	334 (14.6)
Grade 2	28 (2.4)	273 (23.7)	301 (13.1)
Grade 3	0	15 (1.3)	15 (0.7)
Grade 4	0	0	0
Grade 3 or Above	0	15 (1.3)	15 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8050) n (%)	mRNA-1273 (N=7906) n (%)	Total (N=15956) n (%)
Solicited Adverse Reactions - N1	8050	7906	15956
Any Solicited Adverse Reactions	3625 (45.0)	6761 (85.5)	10386 (65.1)
95% CI	43.9, 46.1	84.7, 86.3	64.3, 65.8
Grade 1	2654 (33.0)	5060 (64.0)	7714 (48.3)
Grade 2	822 (10.2)	1354 (17.1)	2176 (13.6)
Grade 3	145 (1.8)	346 (4.4)	491 (3.1)
Grade 4	4 (<0.1)	1 (<0.1)	5 (<0.1)
Grade 3 or Above	149 (1.9)	347 (4.4)	496 (3.1)
Solicited Local Adverse Reactions - N1	8047	7905	15952
Any Solicited Local Adverse Reactions	1481 (18.4)	6446 (81.5)	7927 (49.7)
95% CI	17.6, 19.3	80.7, 82.4	48.9, 50.5
Grade 1	1391 (17.3)	5623 (71.1)	7014 (44.0)
Grade 2	49 (0.6)	601 (7.6)	650 (4.1)
Grade 3	41 (0.5)	222 (2.8)	263 (1.6)
Grade 4	0	0	0
Grade 3 or Above	41 (0.5)	222 (2.8)	263 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8050) n (%)	mRNA-1273 (N=7906) n (%)	Total (N=15956) n (%)
Pain - N1	8047	7905	15952
Any	1288 (16.0)	6408 (81.1)	7696 (48.2)
Grade 1	1228 (15.3)	5747 (72.7)	6975 (43.7)
Grade 2	33 (0.4)	498 (6.3)	531 (3.3)
Grade 3	27 (0.3)	163 (2.1)	190 (1.2)
Grade 4	0	0	0
Grade 3 or Above	27 (0.3)	163 (2.1)	190 (1.2)
Erythema (Redness) - N1	8047	7905	15952
Any	50 (0.6)	167 (2.1)	217 (1.4)
Grade 1	37 (0.5)	106 (1.3)	143 (0.9)
Grade 2	3 (<0.1)	38 (0.5)	41 (0.3)
Grade 3	10 (0.1)	23 (0.3)	33 (0.2)
Grade 4	0	0	0
Grade 3 or Above	10 (0.1)	23 (0.3)	33 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8050) n (%)	mRNA-1273 (N=7906) n (%)	Total (N=15956) n (%)
Swelling (Hardness) - N1	8047	7905	15952
Any	41 (0.5)	423 (5.4)	464 (2.9)
Grade 1	30 (0.4)	275 (3.5)	305 (1.9)
Grade 2	6 (<0.1)	106 (1.3)	112 (0.7)
Grade 3	5 (<0.1)	42 (0.5)	47 (0.3)
Grade 4	0	0	0
Grade 3 or Above	5 (<0.1)	42 (0.5)	47 (0.3)
Axillary Swelling or Tenderness - N1	8047	7905	15952
Any	384 (4.8)	726 (9.2)	1110 (7.0)
Grade 1	361 (4.5)	675 (8.5)	1036 (6.5)
Grade 2	12 (0.1)	34 (0.4)	46 (0.3)
Grade 3	11 (0.1)	17 (0.2)	28 (0.2)
Grade 4	0	0	0
Grade 3 or Above	11 (0.1)	17 (0.2)	28 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8050) n (%)	mRNA-1273 (N=7906) n (%)	Total (N=15956) n (%)
Solicited Systemic Adverse Reactions - N1	8050	7906	15956
Any Solicited Systemic Adverse Reactions	3153 (39.2)	4010 (50.7)	7163 (44.9)
95% CI	38.1, 40.2	49.6, 51.8	44.1, 45.7
Grade 1	2237 (27.8)	2743 (34.7)	4980 (31.2)
Grade 2	798 (9.9)	1093 (13.8)	1891 (11.9)
Grade 3	114 (1.4)	173 (2.2)	287 (1.8)
Grade 4	4 (<0.1)	1 (<0.1)	5 (<0.1)
Grade 3 or Above	118 (1.5)	174 (2.2)	292 (1.8)
Fever - N1	8049	7904	15953
Any	15 (0.2)	50 (0.6)	65 (0.4)
Grade 1	7 (<0.1)	33 (0.4)	40 (0.3)
Grade 2	2 (<0.1)	10 (0.1)	12 (<0.1)
Grade 3	2 (<0.1)	6 (<0.1)	8 (<0.1)
Grade 4	4 (<0.1)	1 (<0.1)	5 (<0.1)
Grade 3 or Above	6 (<0.1)	7 (<0.1)	13 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category / Grade	Placebo (N=8050) n (%)	mRNA-1273 (N=7906) n (%)	Total (N=15956) n (%)
Headache - N1	8046	7905	15951
Any	1844 (22.9)	2215 (28.0)	4059 (25.4)
Grade 1	1595 (19.8)	1863 (23.6)	3458 (21.7)
Grade 2	188 (2.3)	259 (3.3)	447 (2.8)
Grade 3	61 (0.8)	93 (1.2)	154 (1.0)
Grade 4	0	0	0
Grade 3 or Above	61 (0.8)	93 (1.2)	154 (1.0)
Fatigue - N1	8046	7905	15951
Any	2041 (25.4)	2667 (33.7)	4708 (29.5)
Grade 1	1396 (17.4)	1786 (22.6)	3182 (19.9)
Grade 2	602 (7.5)	812 (10.3)	1414 (8.9)
Grade 3	43 (0.5)	69 (0.9)	112 (0.7)
Grade 4	0	0	0
Grade 3 or Above	43 (0.5)	69 (0.9)	112 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8050) n (%)	mRNA-1273 (N=7906) n (%)	Total (N=15956) n (%)
Myalgia - N1	8046	7905	15951
Any	1067 (13.3)	1760 (22.3)	2827 (17.7)
Grade 1	831 (10.3)	1288 (16.3)	2119 (13.3)
Grade 2	216 (2.7)	434 (5.5)	650 (4.1)
Grade 3	20 (0.2)	38 (0.5)	58 (0.4)
Grade 4	0	0	0
Grade 3 or Above	20 (0.2)	38 (0.5)	58 (0.4)
Arthralgia - N1	8046	7905	15951
Any	935 (11.6)	1305 (16.5)	2240 (14.0)
Grade 1	723 (9.0)	987 (12.5)	1710 (10.7)
Grade 2	195 (2.4)	295 (3.7)	490 (3.1)
Grade 3	17 (0.2)	23 (0.3)	40 (0.3)
Grade 4	0	0	0
Grade 3 or Above	17 (0.2)	23 (0.3)	40 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8050) n (%)	mRNA-1273 (N=7906) n (%)	Total (N=15956) n (%)
Nausea/Vomiting - N1	8046	7905	15951
Any	456 (5.7)	504 (6.4)	960 (6.0)
Grade 1	375 (4.7)	427 (5.4)	802 (5.0)
Grade 2	74 (0.9)	73 (0.9)	147 (0.9)
Grade 3	7 (<0.1)	4 (<0.1)	11 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	7 (<0.1)	4 (<0.1)	11 (<0.1)
Chills - N1	8046	7905	15951
Any	431 (5.4)	625 (7.9)	1056 (6.6)
Grade 1	353 (4.4)	475 (6.0)	828 (5.2)
Grade 2	72 (0.9)	141 (1.8)	213 (1.3)
Grade 3	6 (<0.1)	9 (0.1)	15 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	9 (0.1)	15 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7101) n (%)	mRNA-1273 (N=7260) n (%)	Total (N=14361) n (%)
Solicited Adverse Reactions - N1	7101	7260	14361
Any Solicited Adverse Reactions	3660 (51.5)	6556 (90.3)	10216 (71.1)
95% CI	50.4, 52.7	89.6, 91.0	70.4, 71.9
Grade 1	2480 (34.9)	4269 (58.8)	6749 (47.0)
Grade 2	960 (13.5)	1780 (24.5)	2740 (19.1)
Grade 3	218 (3.1)	503 (6.9)	721 (5.0)
Grade 4	2 (<0.1)	4 (<0.1)	6 (<0.1)
Grade 3 or Above	220 (3.1)	507 (7.0)	727 (5.1)
Solicited Local Adverse Reactions - N1	7100	7257	14357
Any Solicited Local Adverse Reactions	1528 (21.5)	6319 (87.1)	7847 (54.7)
95% CI	20.6, 22.5	86.3, 87.8	53.8, 55.5
Grade 1	1451 (20.4)	5102 (70.3)	6553 (45.6)
Grade 2	40 (0.6)	910 (12.5)	950 (6.6)
Grade 3	37 (0.5)	307 (4.2)	344 (2.4)
Grade 4	0	0	0
Grade 3 or Above	37 (0.5)	307 (4.2)	344 (2.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7101) n (%)	mRNA-1273 (N=7260) n (%)	Total (N=14361) n (%)
Pain - N1	7100	7257	14357
Any	1377 (19.4)	6280 (86.5)	7657 (53.3)
Grade 1	1323 (18.6)	5238 (72.2)	6561 (45.7)
Grade 2	26 (0.4)	789 (10.9)	815 (5.7)
Grade 3	28 (0.4)	253 (3.5)	281 (2.0)
Grade 4	0	0	0
Grade 3 or Above	28 (0.4)	253 (3.5)	281 (2.0)
Erythema (Redness) - N1	7100	7257	14357
Any	27 (0.4)	278 (3.8)	305 (2.1)
Grade 1	20 (0.3)	175 (2.4)	195 (1.4)
Grade 2	4 (<0.1)	84 (1.2)	88 (0.6)
Grade 3	3 (<0.1)	19 (0.3)	22 (0.2)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	19 (0.3)	22 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7101) n (%)	mRNA-1273 (N=7260) n (%)	Total (N=14361) n (%)
Swelling (Hardness) - N1	7100	7257	14357
Any	24 (0.3)	512 (7.1)	536 (3.7)
Grade 1	20 (0.3)	333 (4.6)	353 (2.5)
Grade 2	3 (<0.1)	139 (1.9)	142 (1.0)
Grade 3	1 (<0.1)	40 (0.6)	41 (0.3)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	40 (0.6)	41 (0.3)
Axillary Swelling or Tenderness - N1	7100	7257	14357
Any	338 (4.8)	827 (11.4)	1165 (8.1)
Grade 1	307 (4.3)	719 (9.9)	1026 (7.1)
Grade 2	15 (0.2)	76 (1.0)	91 (0.6)
Grade 3	16 (0.2)	32 (0.4)	48 (0.3)
Grade 4	0	0	0
Grade 3 or Above	16 (0.2)	32 (0.4)	48 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7101) n (%)	mRNA-1273 (N=7260) n (%)	Total (N=14361) n (%)
Solicited Systemic Adverse Reactions - N1	7101	7260	14361
Any Solicited Systemic Adverse Reactions	3244 (45.7)	4306 (59.3)	7550 (52.6)
95% CI	44.5, 46.9	58.2, 60.4	51.8, 53.4
Grade 1	2097 (29.5)	2615 (36.0)	4712 (32.8)
Grade 2	948 (13.4)	1411 (19.4)	2359 (16.4)
Grade 3	197 (2.8)	276 (3.8)	473 (3.3)
Grade 4	2 (<0.1)	4 (<0.1)	6 (<0.1)
Grade 3 or Above	199 (2.8)	280 (3.9)	479 (3.3)
Fever - N1	7100	7259	14359
Any	29 (0.4)	62 (0.9)	91 (0.6)
Grade 1	21 (0.3)	40 (0.6)	61 (0.4)
Grade 2	6 (<0.1)	14 (0.2)	20 (0.1)
Grade 3	0	5 (<0.1)	5 (<0.1)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	2 (<0.1)	8 (0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7101) n (%)	mRNA-1273 (N=7260) n (%)	Total (N=14361) n (%)
Headache - N1	7100	7257	14357
Any	2182 (30.7)	2735 (37.7)	4917 (34.2)
Grade 1	1702 (24.0)	2084 (28.7)	3786 (26.4)
Grade 2	344 (4.8)	471 (6.5)	815 (5.7)
Grade 3	136 (1.9)	180 (2.5)	316 (2.2)
Grade 4	0	0	0
Grade 3 or Above	136 (1.9)	180 (2.5)	316 (2.2)
Fatigue - N1	7100	7257	14357
Any	2092 (29.5)	2969 (40.9)	5061 (35.3)
Grade 1	1309 (18.4)	1799 (24.8)	3108 (21.6)
Grade 2	721 (10.2)	1087 (15.0)	1808 (12.6)
Grade 3	62 (0.9)	82 (1.1)	144 (1.0)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	62 (0.9)	83 (1.1)	145 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category / Grade	Placebo (N=7101) n (%)	mRNA-1273 (N=7260) n (%)	Total (N=14361) n (%)
Myalgia - N1	7100	7257	14357
Any	1002 (14.1)	1682 (23.2)	2684 (18.7)
Grade 1	729 (10.3)	1154 (15.9)	1883 (13.1)
Grade 2	246 (3.5)	475 (6.5)	721 (5.0)
Grade 3	27 (0.4)	53 (0.7)	80 (0.6)
Grade 4	0	0	0
Grade 3 or Above	27 (0.4)	53 (0.7)	80 (0.6)
Arthralgia - N1	7100	7257	14357
Any	849 (12.0)	1205 (16.6)	2054 (14.3)
Grade 1	610 (8.6)	855 (11.8)	1465 (10.2)
Grade 2	218 (3.1)	312 (4.3)	530 (3.7)
Grade 3	21 (0.3)	37 (0.5)	58 (0.4)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	21 (0.3)	38 (0.5)	59 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Sex and Grade
First Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category / Grade	Placebo (N=7101) n (%)	mRNA-1273 (N=7260) n (%)	Total (N=14361) n (%)
Nausea/Vomiting - N1	7100	7257	14357
Any	619 (8.7)	758 (10.4)	1377 (9.6)
Grade 1	512 (7.2)	620 (8.5)	1132 (7.9)
Grade 2	101 (1.4)	132 (1.8)	233 (1.6)
Grade 3	6 (<0.1)	6 (<0.1)	12 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	6 (<0.1)	12 (<0.1)
Chills - N1	7100	7257	14357
Any	447 (6.3)	626 (8.6)	1073 (7.5)
Grade 1	353 (5.0)	463 (6.4)	816 (5.7)
Grade 2	86 (1.2)	148 (2.0)	234 (1.6)
Grade 3	8 (0.1)	15 (0.2)	23 (0.2)
Grade 4	0	0	0
Grade 3 or Above	8 (0.1)	15 (0.2)	23 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=7731) n (%)	mRNA-1273 (N=7646) n (%)	Total (N=15377) n (%)
Solicited Adverse Reactions - N1	7731	7646	15377
Any Solicited Adverse Reactions	2963 (38.3)	6921 (90.5)	9884 (64.3)
95% CI	37.2, 39.4	89.8, 91.2	63.5, 65.0
Grade 1	2140 (27.7)	2945 (38.5)	5085 (33.1)
Grade 2	683 (8.8)	2846 (37.2)	3529 (22.9)
Grade 3	138 (1.8)	1126 (14.7)	1264 (8.2)
Grade 4	2 (<0.1)	4 (<0.1)	6 (<0.1)
Grade 3 or Above	140 (1.8)	1130 (14.8)	1270 (8.3)
Solicited Local Adverse Reactions - N1	7731	7646	15377
Any Solicited Local Adverse Reactions	1320 (17.1)	6606 (86.4)	7926 (51.5)
95% CI	16.2, 17.9	85.6, 87.2	50.8, 52.3
Grade 1	1239 (16.0)	4982 (65.2)	6221 (40.5)
Grade 2	40 (0.5)	1249 (16.3)	1289 (8.4)
Grade 3	41 (0.5)	375 (4.9)	416 (2.7)
Grade 4	0	0	0
Grade 3 or Above	41 (0.5)	375 (4.9)	416 (2.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=7731) n (%)	mRNA-1273 (N=7646) n (%)	Total (N=15377) n (%)
Pain - N1	7731	7646	15377
Any	1178 (15.2)	6571 (85.9)	7749 (50.4)
Grade 1	1126 (14.6)	5280 (69.1)	6406 (41.7)
Grade 2	28 (0.4)	1074 (14.0)	1102 (7.2)
Grade 3	24 (0.3)	217 (2.8)	241 (1.6)
Grade 4	0	0	0
Grade 3 or Above	24 (0.3)	217 (2.8)	241 (1.6)
Erythema (Redness) - N1	7731	7645	15376
Any	38 (0.5)	436 (5.7)	474 (3.1)
Grade 1	30 (0.4)	181 (2.4)	211 (1.4)
Grade 2	3 (<0.1)	148 (1.9)	151 (1.0)
Grade 3	5 (<0.1)	107 (1.4)	112 (0.7)
Grade 4	0	0	0
Grade 3 or Above	5 (<0.1)	107 (1.4)	112 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=7731) n	(%)	mRNA-1273 (N=7646) n	(%)	Total (N=15377) n	(%)
Swelling (Hardness) - N1	7731		7645		15376	
Any	30	(0.4)	735	(9.6)	765	(5.0)
Grade 1	21	(0.3)	415	(5.4)	436	(2.8)
Grade 2	3	(<0.1)	235	(3.1)	238	(1.5)
Grade 3	6	(<0.1)	85	(1.1)	91	(0.6)
Grade 4	0		0		0	
Grade 3 or Above	6	(<0.1)	85	(1.1)	91	(0.6)
Axillary Swelling or Tenderness - N1	7731		7645		15376	
Any	290	(3.8)	890	(11.6)	1180	(7.7)
Grade 1	266	(3.4)	777	(10.2)	1043	(6.8)
Grade 2	13	(0.2)	92	(1.2)	105	(0.7)
Grade 3	11	(0.1)	21	(0.3)	32	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	11	(0.1)	21	(0.3)	32	(0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=7731) n (%)	mRNA-1273 (N=7646) n (%)	Total (N=15377) n (%)
Solicited Systemic Adverse Reactions - N1	7730	7645	15375
Any Solicited Systemic Adverse Reactions	2482 (32.1)	5804 (75.9)	8286 (53.9)
95% CI	31.1, 33.2	74.9, 76.9	53.1, 54.7
Grade 1	1706 (22.1)	2146 (28.1)	3852 (25.1)
Grade 2	669 (8.7)	2752 (36.0)	3421 (22.3)
Grade 3	105 (1.4)	902 (11.8)	1007 (6.5)
Grade 4	2 (<0.1)	4 (<0.1)	6 (<0.1)
Grade 3 or Above	107 (1.4)	906 (11.9)	1013 (6.6)
Fever - N1	7728	7639	15367
Any	22 (0.3)	1000 (13.1)	1022 (6.7)
Grade 1	15 (0.2)	609 (8.0)	624 (4.1)
Grade 2	4 (<0.1)	294 (3.8)	298 (1.9)
Grade 3	1 (<0.1)	93 (1.2)	94 (0.6)
Grade 4	2 (<0.1)	4 (<0.1)	6 (<0.1)
Grade 3 or Above	3 (<0.1)	97 (1.3)	100 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=7731) n (%)	mRNA-1273 (N=7646) n (%)	Total (N=15377) n (%)
Headache - N1	7729	7645	15374
Any	1494 (19.3)	4043 (52.9)	5537 (36.0)
Grade 1	1243 (16.1)	2535 (33.2)	3778 (24.6)
Grade 2	201 (2.6)	1286 (16.8)	1487 (9.7)
Grade 3	50 (0.6)	222 (2.9)	272 (1.8)
Grade 4	0	0	0
Grade 3 or Above	50 (0.6)	222 (2.9)	272 (1.8)
Fatigue - N1	7729	7645	15374
Any	1620 (21.0)	4700 (61.5)	6320 (41.1)
Grade 1	1076 (13.9)	1876 (24.5)	2952 (19.2)
Grade 2	494 (6.4)	2260 (29.6)	2754 (17.9)
Grade 3	50 (0.6)	564 (7.4)	614 (4.0)
Grade 4	0	0	0
Grade 3 or Above	50 (0.6)	564 (7.4)	614 (4.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=7731) n (%)	mRNA-1273 (N=7646) n (%)	Total (N=15377) n (%)
Myalgia - N1	7729	7645	15374
Any	883 (11.4)	4226 (55.3)	5109 (33.2)
Grade 1	646 (8.4)	1847 (24.2)	2493 (16.2)
Grade 2	213 (2.8)	1894 (24.8)	2107 (13.7)
Grade 3	24 (0.3)	485 (6.3)	509 (3.3)
Grade 4	0	0	0
Grade 3 or Above	24 (0.3)	485 (6.3)	509 (3.3)
Arthralgia - N1	7729	7645	15374
Any	757 (9.8)	3126 (40.9)	3883 (25.3)
Grade 1	562 (7.3)	1591 (20.8)	2153 (14.0)
Grade 2	177 (2.3)	1274 (16.7)	1451 (9.4)
Grade 3	18 (0.2)	261 (3.4)	279 (1.8)
Grade 4	0	0	0
Grade 3 or Above	18 (0.2)	261 (3.4)	279 (1.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=7731) n (%)	mRNA-1273 (N=7646) n (%)	Total (N=15377) n (%)
Nausea/Vomiting - N1	7729	7645	15374
Any	390 (5.0)	1032 (13.5)	1422 (9.2)
Grade 1	315 (4.1)	817 (10.7)	1132 (7.4)
Grade 2	69 (0.9)	210 (2.7)	279 (1.8)
Grade 3	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	5 (<0.1)	11 (<0.1)
Chills - N1	7729	7645	15374
Any	369 (4.8)	3173 (41.5)	3542 (23.0)
Grade 1	294 (3.8)	1568 (20.5)	1862 (12.1)
Grade 2	68 (0.9)	1522 (19.9)	1590 (10.3)
Grade 3	7 (<0.1)	83 (1.1)	90 (0.6)
Grade 4	0	0	0
Grade 3 or Above	7 (<0.1)	83 (1.1)	90 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=6847) n (%)	mRNA-1273 (N=7045) n (%)	Total (N=13892) n (%)
Solicited Adverse Reactions - N1	6847	7045	13892
Any Solicited Adverse Reactions	3292 (48.1)	6635 (94.2)	9927 (71.5)
95% CI	46.9, 49.3	93.6, 94.7	70.7, 72.2
Grade 1	2206 (32.2)	1902 (27.0)	4108 (29.6)
Grade 2	875 (12.8)	2954 (41.9)	3829 (27.6)
Grade 3	210 (3.1)	1769 (25.1)	1979 (14.2)
Grade 4	1 (<0.1)	10 (0.1)	11 (<0.1)
Grade 3 or Above	211 (3.1)	1779 (25.3)	1990 (14.3)
Solicited Local Adverse Reactions - N1	6846	7042	13888
Any Solicited Local Adverse Reactions	1437 (21.0)	6423 (91.2)	7860 (56.6)
95% CI	20.0, 22.0	90.5, 91.9	55.8, 57.4
Grade 1	1355 (19.8)	3807 (54.1)	5162 (37.2)
Grade 2	48 (0.7)	1968 (27.9)	2016 (14.5)
Grade 3	34 (0.5)	648 (9.2)	682 (4.9)
Grade 4	0	0	0
Grade 3 or Above	34 (0.5)	648 (9.2)	682 (4.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category / Grade	Placebo (N=6847) n (%)	mRNA-1273 (N=7045) n (%)	Total (N=13892) n (%)
Pain - N1	6846	7042	13888
Any	1308 (19.1)	6393 (90.8)	7701 (55.5)
Grade 1	1258 (18.4)	4228 (60.0)	5486 (39.5)
Grade 2	33 (0.5)	1776 (25.2)	1809 (13.0)
Grade 3	17 (0.2)	389 (5.5)	406 (2.9)
Grade 4	0	0	0
Grade 3 or Above	17 (0.2)	389 (5.5)	406 (2.9)
Erythema (Redness) - N1	6846	7042	13888
Any	30 (0.4)	838 (11.9)	868 (6.3)
Grade 1	18 (0.3)	275 (3.9)	293 (2.1)
Grade 2	2 (<0.1)	383 (5.4)	385 (2.8)
Grade 3	10 (0.1)	180 (2.6)	190 (1.4)
Grade 4	0	0	0
Grade 3 or Above	10 (0.1)	180 (2.6)	190 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=6847) n (%)	mRNA-1273 (N=7045) n (%)	Total (N=13892) n (%)
Swelling (Hardness) - N1	6846	7042	13888
Any	30 (0.4)	1072 (15.2)	1102 (7.9)
Grade 1	17 (0.2)	485 (6.9)	502 (3.6)
Grade 2	7 (0.1)	417 (5.9)	424 (3.1)
Grade 3	6 (<0.1)	170 (2.4)	176 (1.3)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	170 (2.4)	176 (1.3)
Axillary Swelling or Tenderness - N1	6846	7042	13888
Any	281 (4.1)	1202 (17.1)	1483 (10.7)
Grade 1	257 (3.8)	958 (13.6)	1215 (8.7)
Grade 2	15 (0.2)	197 (2.8)	212 (1.5)
Grade 3	9 (0.1)	47 (0.7)	56 (0.4)
Grade 4	0	0	0
Grade 3 or Above	9 (0.1)	47 (0.7)	56 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=6847) n (%)	mRNA-1273 (N=7045) n (%)	Total (N=13892) n (%)
Solicited Systemic Adverse Reactions - N1	6847	7045	13892
Any Solicited Systemic Adverse Reactions	2861 (41.8)	5874 (83.4)	8735 (62.9)
95% CI	40.6, 43.0	82.5, 84.2	62.1, 63.7
Grade 1	1813 (26.5)	1571 (22.3)	3384 (24.4)
Grade 2	866 (12.6)	2859 (40.6)	3725 (26.8)
Grade 3	181 (2.6)	1434 (20.4)	1615 (11.6)
Grade 4	1 (<0.1)	10 (0.1)	11 (<0.1)
Grade 3 or Above	182 (2.7)	1444 (20.5)	1626 (11.7)
Fever - N1	6845	7043	13888
Any	21 (0.3)	1276 (18.1)	1297 (9.3)
Grade 1	18 (0.3)	754 (10.7)	772 (5.6)
Grade 2	1 (<0.1)	403 (5.7)	404 (2.9)
Grade 3	1 (<0.1)	110 (1.6)	111 (0.8)
Grade 4	1 (<0.1)	9 (0.1)	10 (<0.1)
Grade 3 or Above	2 (<0.1)	119 (1.7)	121 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=6847) n (%)	mRNA-1273 (N=7045) n (%)	Total (N=13892) n (%)
Headache - N1	6846	7042	13888
Any	1933 (28.2)	4594 (65.2)	6527 (47.0)
Grade 1	1497 (21.9)	2280 (32.4)	3777 (27.2)
Grade 2	321 (4.7)	1870 (26.6)	2191 (15.8)
Grade 3	115 (1.7)	444 (6.3)	559 (4.0)
Grade 4	0	0	0
Grade 3 or Above	115 (1.7)	444 (6.3)	559 (4.0)
Fatigue - N1	6846	7042	13888
Any	1798 (26.3)	4907 (69.7)	6705 (48.3)
Grade 1	1105 (16.1)	1555 (22.1)	2660 (19.2)
Grade 2	635 (9.3)	2483 (35.3)	3118 (22.5)
Grade 3	58 (0.8)	869 (12.3)	927 (6.7)
Grade 4	0	0	0
Grade 3 or Above	58 (0.8)	869 (12.3)	927 (6.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=6847) n (%)	mRNA-1273 (N=7045) n (%)	Total (N=13892) n (%)
Myalgia - N1	6846	7042	13888
Any	941 (13.7)	4303 (61.1)	5244 (37.8)
Grade 1	661 (9.7)	1395 (19.8)	2056 (14.8)
Grade 2	252 (3.7)	2072 (29.4)	2324 (16.7)
Grade 3	28 (0.4)	836 (11.9)	864 (6.2)
Grade 4	0	0	0
Grade 3 or Above	28 (0.4)	836 (11.9)	864 (6.2)
Arthralgia - N1	6846	7042	13888
Any	822 (12.0)	3177 (45.1)	3999 (28.8)
Grade 1	581 (8.5)	1218 (17.3)	1799 (13.0)
Grade 2	215 (3.1)	1445 (20.5)	1660 (12.0)
Grade 3	26 (0.4)	514 (7.3)	540 (3.9)
Grade 4	0	0	0
Grade 3 or Above	26 (0.4)	514 (7.3)	540 (3.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Sex and Grade
Second Injection Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=6847) n (%)	mRNA-1273 (N=7045) n (%)	Total (N=13892) n (%)
Nausea/Vomiting - N1	6846	7042	13888
Any	551 (8.0)	1762 (25.0)	2313 (16.7)
Grade 1	446 (6.5)	1277 (18.1)	1723 (12.4)
Grade 2	100 (1.5)	468 (6.6)	568 (4.1)
Grade 3	5 (<0.1)	16 (0.2)	21 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	5 (<0.1)	17 (0.2)	22 (0.2)
Chills - N1	6846	7042	13888
Any	444 (6.5)	3327 (47.2)	3771 (27.2)
Grade 1	335 (4.9)	1339 (19.0)	1674 (12.1)
Grade 2	99 (1.4)	1880 (26.7)	1979 (14.2)
Grade 3	10 (0.1)	108 (1.5)	118 (0.8)
Grade 4	0	0	0
Grade 3 or Above	10 (0.1)	108 (1.5)	118 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8055) n (%)	mRNA-1273 (N=7914) n (%)	Total (N=15969) n (%)
Solicited Adverse Reactions - N1	8055	7914	15969
Any Solicited Adverse Reactions	4526 (56.2)	7399 (93.5)	11925 (74.7)
95% CI	55.1, 57.3	92.9, 94.0	74.0, 75.3
Grade 1	3034 (37.7)	2956 (37.4)	5990 (37.5)
Grade 2	1216 (15.1)	3077 (38.9)	4293 (26.9)
Grade 3	270 (3.4)	1361 (17.2)	1631 (10.2)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 3 or Above	276 (3.4)	1366 (17.3)	1642 (10.3)
Solicited Local Adverse Reactions - N1	8054	7914	15968
Any Solicited Local Adverse Reactions	2189 (27.2)	7166 (90.5)	9355 (58.6)
95% CI	26.2, 28.2	89.9, 91.2	57.8, 59.4
Grade 1	2027 (25.2)	5164 (65.3)	7191 (45.0)
Grade 2	83 (1.0)	1453 (18.4)	1536 (9.6)
Grade 3	79 (1.0)	549 (6.9)	628 (3.9)
Grade 4	0	0	0
Grade 3 or Above	79 (1.0)	549 (6.9)	628 (3.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8055) n (%)	mRNA-1273 (N=7914) n (%)	Total (N=15969) n (%)
Pain - N1	8054	7914	15968
Any	1951 (24.2)	7129 (90.1)	9080 (56.9)
Grade 1	1844 (22.9)	5530 (69.9)	7374 (46.2)
Grade 2	57 (0.7)	1256 (15.9)	1313 (8.2)
Grade 3	50 (0.6)	343 (4.3)	393 (2.5)
Grade 4	0	0	0
Grade 3 or Above	50 (0.6)	343 (4.3)	393 (2.5)
Erythema (Redness) - N1	8054	7913	15967
Any	85 (1.1)	549 (6.9)	634 (4.0)
Grade 1	65 (0.8)	252 (3.2)	317 (2.0)
Grade 2	6 (<0.1)	170 (2.1)	176 (1.1)
Grade 3	14 (0.2)	127 (1.6)	141 (0.9)
Grade 4	0	0	0
Grade 3 or Above	14 (0.2)	127 (1.6)	141 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8055) n (%)	mRNA-1273 (N=7914) n (%)	Total (N=15969) n (%)
Swelling (Hardness) - N1	8054	7913	15967
Any	64 (0.8)	938 (11.9)	1002 (6.3)
Grade 1	45 (0.6)	527 (6.7)	572 (3.6)
Grade 2	9 (0.1)	291 (3.7)	300 (1.9)
Grade 3	10 (0.1)	120 (1.5)	130 (0.8)
Grade 4	0	0	0
Grade 3 or Above	10 (0.1)	120 (1.5)	130 (0.8)
Axillary Swelling or Tenderness - N1	8054	7913	15967
Any	570 (7.1)	1339 (16.9)	1909 (12.0)
Grade 1	525 (6.5)	1180 (14.9)	1705 (10.7)
Grade 2	23 (0.3)	122 (1.5)	145 (0.9)
Grade 3	22 (0.3)	37 (0.5)	59 (0.4)
Grade 4	0	0	0
Grade 3 or Above	22 (0.3)	37 (0.5)	59 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8055) n (%)	mRNA-1273 (N=7914) n (%)	Total (N=15969) n (%)
Solicited Systemic Adverse Reactions - N1	8055	7913	15968
Any Solicited Systemic Adverse Reactions	3973 (49.3)	6427 (81.2)	10400 (65.1)
95% CI	48.2, 50.4	80.3, 82.1	64.4, 65.9
Grade 1	2563 (31.8)	2389 (30.2)	4952 (31.0)
Grade 2	1193 (14.8)	3012 (38.1)	4205 (26.3)
Grade 3	211 (2.6)	1021 (12.9)	1232 (7.7)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 3 or Above	217 (2.7)	1026 (13.0)	1243 (7.8)
Fever - N1	8055	7912	15967
Any	37 (0.5)	1036 (13.1)	1073 (6.7)
Grade 1	22 (0.3)	632 (8.0)	654 (4.1)
Grade 2	6 (<0.1)	300 (3.8)	306 (1.9)
Grade 3	3 (<0.1)	99 (1.3)	102 (0.6)
Grade 4	6 (<0.1)	5 (<0.1)	11 (<0.1)
Grade 3 or Above	9 (0.1)	104 (1.3)	113 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8055) n (%)	mRNA-1273 (N=7914) n (%)	Total (N=15969) n (%)
Headache - N1	8054	7913	15967
Any	2558 (31.8)	4657 (58.9)	7215 (45.2)
Grade 1	2098 (26.0)	2981 (37.7)	5079 (31.8)
Grade 2	351 (4.4)	1381 (17.5)	1732 (10.8)
Grade 3	109 (1.4)	295 (3.7)	404 (2.5)
Grade 4	0	0	0
Grade 3 or Above	109 (1.4)	295 (3.7)	404 (2.5)
Fatigue - N1	8054	7913	15967
Any	2720 (33.8)	5227 (66.1)	7947 (49.8)
Grade 1	1725 (21.4)	2099 (26.5)	3824 (23.9)
Grade 2	908 (11.3)	2515 (31.8)	3423 (21.4)
Grade 3	87 (1.1)	613 (7.7)	700 (4.4)
Grade 4	0	0	0
Grade 3 or Above	87 (1.1)	613 (7.7)	700 (4.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8055) n (%)	mRNA-1273 (N=7914) n (%)	Total (N=15969) n (%)
Myalgia - N1	8054	7913	15967
Any	1577 (19.6)	4664 (58.9)	6241 (39.1)
Grade 1	1150 (14.3)	2097 (26.5)	3247 (20.3)
Grade 2	384 (4.8)	2055 (26.0)	2439 (15.3)
Grade 3	43 (0.5)	512 (6.5)	555 (3.5)
Grade 4	0	0	0
Grade 3 or Above	43 (0.5)	512 (6.5)	555 (3.5)
Arthralgia - N1	8054	7913	15967
Any	1341 (16.7)	3534 (44.7)	4875 (30.5)
Grade 1	974 (12.1)	1837 (23.2)	2811 (17.6)
Grade 2	333 (4.1)	1418 (17.9)	1751 (11.0)
Grade 3	34 (0.4)	279 (3.5)	313 (2.0)
Grade 4	0	0	0
Grade 3 or Above	34 (0.4)	279 (3.5)	313 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Male

Solicited Adverse Reaction Category Grade	Placebo (N=8055) n (%)	mRNA-1273 (N=7914) n (%)	Total (N=15969) n (%)
Nausea/Vomiting - N1	8054	7913	15967
Any	727 (9.0)	1338 (16.9)	2065 (12.9)
Grade 1	585 (7.3)	1058 (13.4)	1643 (10.3)
Grade 2	129 (1.6)	271 (3.4)	400 (2.5)
Grade 3	13 (0.2)	9 (0.1)	22 (0.1)
Grade 4	0	0	0
Grade 3 or Above	13 (0.2)	9 (0.1)	22 (0.1)
Chills - N1	8054	7913	15967
Any	699 (8.7)	3376 (42.7)	4075 (25.5)
Grade 1	551 (6.8)	1685 (21.3)	2236 (14.0)
Grade 2	135 (1.7)	1599 (20.2)	1734 (10.9)
Grade 3	13 (0.2)	92 (1.2)	105 (0.7)
Grade 4	0	0	0
Grade 3 or Above	13 (0.2)	92 (1.2)	105 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7104) n (%)	mRNA-1273 (N=7265) n (%)	Total (N=14369) n (%)
Solicited Adverse Reactions - N1	7104	7265	14369
Any Solicited Adverse Reactions	4587 (64.6)	7003 (96.4)	11590 (80.7)
95% CI	63.4, 65.7	95.9, 96.8	80.0, 81.3
Grade 1	2770 (39.0)	1842 (25.4)	4612 (32.1)
Grade 2	1414 (19.9)	3104 (42.7)	4518 (31.4)
Grade 3	400 (5.6)	2043 (28.1)	2443 (17.0)
Grade 4	3 (<0.1)	14 (0.2)	17 (0.1)
Grade 3 or Above	403 (5.7)	2057 (28.3)	2460 (17.1)
Solicited Local Adverse Reactions - N1	7104	7265	14369
Any Solicited Local Adverse Reactions	2279 (32.1)	6866 (94.5)	9145 (63.6)
95% CI	31.0, 33.2	94.0, 95.0	62.9, 64.4
Grade 1	2130 (30.0)	3839 (52.8)	5969 (41.5)
Grade 2	80 (1.1)	2156 (29.7)	2236 (15.6)
Grade 3	69 (1.0)	871 (12.0)	940 (6.5)
Grade 4	0	0	0
Grade 3 or Above	69 (1.0)	871 (12.0)	940 (6.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7104) n (%)	mRNA-1273 (N=7265) n (%)	Total (N=14369) n (%)
Pain - N1	7104	7265	14369
Any	2095 (29.5)	6840 (94.2)	8935 (62.2)
Grade 1	1998 (28.1)	4295 (59.1)	6293 (43.8)
Grade 2	54 (0.8)	1965 (27.0)	2019 (14.1)
Grade 3	43 (0.6)	580 (8.0)	623 (4.3)
Grade 4	0	0	0
Grade 3 or Above	43 (0.6)	580 (8.0)	623 (4.3)
Erythema (Redness) - N1	7104	7265	14369
Any	52 (0.7)	1000 (13.8)	1052 (7.3)
Grade 1	33 (0.5)	380 (5.2)	413 (2.9)
Grade 2	6 (<0.1)	423 (5.8)	429 (3.0)
Grade 3	13 (0.2)	197 (2.7)	210 (1.5)
Grade 4	0	0	0
Grade 3 or Above	13 (0.2)	197 (2.7)	210 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category / Grade	Placebo (N=7104) n (%)	mRNA-1273 (N=7265) n (%)	Total (N=14369) n (%)
Swelling (Hardness) - N1	7104	7265	14369
Any	52 (0.7)	1311 (18.0)	1363 (9.5)
Grade 1	36 (0.5)	624 (8.6)	660 (4.6)
Grade 2	9 (0.1)	480 (6.6)	489 (3.4)
Grade 3	7 (<0.1)	207 (2.8)	214 (1.5)
Grade 4	0	0	0
Grade 3 or Above	7 (<0.1)	207 (2.8)	214 (1.5)
Axillary Swelling or Tenderness - N1	7104	7265	14369
Any	531 (7.5)	1674 (23.0)	2205 (15.3)
Grade 1	479 (6.7)	1352 (18.6)	1831 (12.7)
Grade 2	28 (0.4)	248 (3.4)	276 (1.9)
Grade 3	24 (0.3)	74 (1.0)	98 (0.7)
Grade 4	0	0	0
Grade 3 or Above	24 (0.3)	74 (1.0)	98 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7104) n (%)	mRNA-1273 (N=7265) n (%)	Total (N=14369) n (%)
Solicited Systemic Adverse Reactions - N1	7104	7265	14369
Any Solicited Systemic Adverse Reactions	4144 (58.3)	6352 (87.4)	10496 (73.0)
95% CI	57.2, 59.5	86.6, 88.2	72.3, 73.8
Grade 1	2383 (33.5)	1651 (22.7)	4034 (28.1)
Grade 2	1407 (19.8)	3087 (42.5)	4494 (31.3)
Grade 3	351 (4.9)	1600 (22.0)	1951 (13.6)
Grade 4	3 (<0.1)	14 (0.2)	17 (0.1)
Grade 3 or Above	354 (5.0)	1614 (22.2)	1968 (13.7)
Fever - N1	7103	7265	14368
Any	49 (0.7)	1314 (18.1)	1363 (9.5)
Grade 1	38 (0.5)	776 (10.7)	814 (5.7)
Grade 2	7 (<0.1)	412 (5.7)	419 (2.9)
Grade 3	1 (<0.1)	114 (1.6)	115 (0.8)
Grade 4	3 (<0.1)	12 (0.2)	15 (0.1)
Grade 3 or Above	4 (<0.1)	126 (1.7)	130 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7104) n (%)	mRNA-1273 (N=7265) n (%)	Total (N=14369) n (%)
Headache - N1	7104	7265	14369
Any	3055 (43.0)	5187 (71.4)	8242 (57.4)
Grade 1	2257 (31.8)	2598 (35.8)	4855 (33.8)
Grade 2	563 (7.9)	2009 (27.7)	2572 (17.9)
Grade 3	235 (3.3)	580 (8.0)	815 (5.7)
Grade 4	0	0	0
Grade 3 or Above	235 (3.3)	580 (8.0)	815 (5.7)
Fatigue - N1	7104	7265	14369
Any	2829 (39.8)	5413 (74.5)	8242 (57.4)
Grade 1	1618 (22.8)	1703 (23.4)	3321 (23.1)
Grade 2	1096 (15.4)	2788 (38.4)	3884 (27.0)
Grade 3	115 (1.6)	921 (12.7)	1036 (7.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	115 (1.6)	922 (12.7)	1037 (7.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7104) n (%)	mRNA-1273 (N=7265) n (%)	Total (N=14369) n (%)
Myalgia - N1	7104	7265	14369
Any	1541 (21.7)	4684 (64.5)	6225 (43.3)
Grade 1	1045 (14.7)	1589 (21.9)	2634 (18.3)
Grade 2	441 (6.2)	2222 (30.6)	2663 (18.5)
Grade 3	55 (0.8)	873 (12.0)	928 (6.5)
Grade 4	0	0	0
Grade 3 or Above	55 (0.8)	873 (12.0)	928 (6.5)
Arthralgia - N1	7104	7265	14369
Any	1331 (18.7)	3521 (48.5)	4852 (33.8)
Grade 1	899 (12.7)	1411 (19.4)	2310 (16.1)
Grade 2	385 (5.4)	1572 (21.6)	1957 (13.6)
Grade 3	47 (0.7)	537 (7.4)	584 (4.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	47 (0.7)	538 (7.4)	585 (4.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.7.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Sex and Grade
Solicited Safety Set

Sex Group: Female

Solicited Adverse Reaction Category Grade	Placebo (N=7104) n (%)	mRNA-1273 (N=7265) n (%)	Total (N=14369) n (%)
Nausea/Vomiting - N1	7104	7265	14369
Any	996 (14.0)	2155 (29.7)	3151 (21.9)
Grade 1	795 (11.2)	1564 (21.5)	2359 (16.4)
Grade 2	190 (2.7)	569 (7.8)	759 (5.3)
Grade 3	11 (0.2)	21 (0.3)	32 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	11 (0.2)	22 (0.3)	33 (0.2)
Chills - N1	7104	7265	14369
Any	774 (10.9)	3531 (48.6)	4305 (30.0)
Grade 1	581 (8.2)	1459 (20.1)	2040 (14.2)
Grade 2	175 (2.5)	1953 (26.9)	2128 (14.8)
Grade 3	18 (0.3)	119 (1.6)	137 (1.0)
Grade 4	0	0	0
Grade 3 or Above	18 (0.3)	119 (1.6)	137 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11996) n (%)	mRNA-1273 (N=12030) n (%)	Total (N=24026) n (%)
Solicited Adverse Reactions - N1	11996	12030	24026
Any Solicited Adverse Reactions	7300 (60.9)	11537 (95.9)	18837 (78.4)
95% CI	60.0, 61.7	95.5, 96.2	77.9, 78.9
Grade 1	4692 (39.1)	3832 (31.9)	8524 (35.5)
Grade 2	2071 (17.3)	4962 (41.2)	7033 (29.3)
Grade 3	531 (4.4)	2728 (22.7)	3259 (13.6)
Grade 4	6 (<0.1)	15 (0.1)	21 (<0.1)
Grade 3 or Above	537 (4.5)	2743 (22.8)	3280 (13.7)
Solicited Local Adverse Reactions - N1	11995	12030	24025
Any Solicited Local Adverse Reactions	3583 (29.9)	11281 (93.8)	14864 (61.9)
95% CI	29.1, 30.7	93.3, 94.2	61.3, 62.5
Grade 1	3351 (27.9)	7267 (60.4)	10618 (44.2)
Grade 2	119 (1.0)	2887 (24.0)	3006 (12.5)
Grade 3	113 (0.9)	1127 (9.4)	1240 (5.2)
Grade 4	0	0	0
Grade 3 or Above	113 (0.9)	1127 (9.4)	1240 (5.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11996) n (%)	mRNA-1273 (N=12030) n (%)	Total (N=24026) n (%)
Pain - N1	11995	12030	24025
Any	3241 (27.0)	11239 (93.4)	14480 (60.3)
Grade 1	3093 (25.8)	7951 (66.1)	11044 (46.0)
Grade 2	80 (0.7)	2570 (21.4)	2650 (11.0)
Grade 3	68 (0.6)	718 (6.0)	786 (3.3)
Grade 4	0	0	0
Grade 3 or Above	68 (0.6)	718 (6.0)	786 (3.3)
Erythema (Redness) - N1	11995	12029	24024
Any	103 (0.9)	1286 (10.7)	1389 (5.8)
Grade 1	74 (0.6)	517 (4.3)	591 (2.5)
Grade 2	10 (<0.1)	504 (4.2)	514 (2.1)
Grade 3	19 (0.2)	265 (2.2)	284 (1.2)
Grade 4	0	0	0
Grade 3 or Above	19 (0.2)	265 (2.2)	284 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11996) n (%)	mRNA-1273 (N=12030) n (%)	Total (N=24026) n (%)
Swelling (Hardness) - N1	11995	12029	24024
Any	93 (0.8)	1794 (14.9)	1887 (7.9)
Grade 1	65 (0.5)	907 (7.5)	972 (4.0)
Grade 2	14 (0.1)	620 (5.2)	634 (2.6)
Grade 3	14 (0.1)	267 (2.2)	281 (1.2)
Grade 4	0	0	0
Grade 3 or Above	14 (0.1)	267 (2.2)	281 (1.2)
Axillary Swelling or Tenderness - N1	11995	12029	24024
Any	857 (7.1)	2331 (19.4)	3188 (13.3)
Grade 1	785 (6.5)	1966 (16.3)	2751 (11.5)
Grade 2	35 (0.3)	282 (2.3)	317 (1.3)
Grade 3	37 (0.3)	83 (0.7)	120 (0.5)
Grade 4	0	0	0
Grade 3 or Above	37 (0.3)	83 (0.7)	120 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11996) n (%)	mRNA-1273 (N=12030) n (%)	Total (N=24026) n (%)
Solicited Systemic Adverse Reactions - N1	11996	12029	24025
Any Solicited Systemic Adverse Reactions	6499 (54.2)	10227 (85.0)	16726 (69.6)
95% CI	53.3, 55.1	84.4, 85.7	69.0, 70.2
Grade 1	4002 (33.4)	3243 (27.0)	7245 (30.2)
Grade 2	2047 (17.1)	4867 (40.5)	6914 (28.8)
Grade 3	444 (3.7)	2102 (17.5)	2546 (10.6)
Grade 4	6 (<0.1)	15 (0.1)	21 (<0.1)
Grade 3 or Above	450 (3.8)	2117 (17.6)	2567 (10.7)
Fever - N1	11995	12028	24023
Any	69 (0.6)	1855 (15.4)	1924 (8.0)
Grade 1	48 (0.4)	1143 (9.5)	1191 (5.0)
Grade 2	12 (0.1)	546 (4.5)	558 (2.3)
Grade 3	3 (<0.1)	153 (1.3)	156 (0.6)
Grade 4	6 (<0.1)	13 (0.1)	19 (<0.1)
Grade 3 or Above	9 (<0.1)	166 (1.4)	175 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11996) n (%)	mRNA-1273 (N=12030) n (%)	Total (N=24026) n (%)
Headache - N1	11995	12029	24024
Any	4529 (37.8)	7925 (65.9)	12454 (51.8)
Grade 1	3531 (29.4)	4474 (37.2)	8005 (33.3)
Grade 2	728 (6.1)	2765 (23.0)	3493 (14.5)
Grade 3	270 (2.3)	686 (5.7)	956 (4.0)
Grade 4	0	0	0
Grade 3 or Above	270 (2.3)	686 (5.7)	956 (4.0)
Fatigue - N1	11995	12029	24024
Any	4450 (37.1)	8574 (71.3)	13024 (54.2)
Grade 1	2712 (22.6)	3075 (25.6)	5787 (24.1)
Grade 2	1578 (13.2)	4257 (35.4)	5835 (24.3)
Grade 3	160 (1.3)	1241 (10.3)	1401 (5.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	160 (1.3)	1242 (10.3)	1402 (5.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11996) n (%)	mRNA-1273 (N=12030) n (%)	Total (N=24026) n (%)
Myalgia - N1	11995	12029	24024
Any	2422 (20.2)	7454 (62.0)	9876 (41.1)
Grade 1	1731 (14.4)	2946 (24.5)	4677 (19.5)
Grade 2	617 (5.1)	3379 (28.1)	3996 (16.6)
Grade 3	74 (0.6)	1129 (9.4)	1203 (5.0)
Grade 4	0	0	0
Grade 3 or Above	74 (0.6)	1129 (9.4)	1203 (5.0)
Arthralgia - N1	11995	12029	24024
Any	2068 (17.2)	5656 (47.0)	7724 (32.2)
Grade 1	1479 (12.3)	2598 (21.6)	4077 (17.0)
Grade 2	532 (4.4)	2391 (19.9)	2923 (12.2)
Grade 3	57 (0.5)	666 (5.5)	723 (3.0)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	57 (0.5)	667 (5.5)	724 (3.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11996) n (%)	mRNA-1273 (N=12030) n (%)	Total (N=24026) n (%)
Nausea/Vomiting - N1	11995	12029	24024
Any	1335 (11.1)	2808 (23.3)	4143 (17.2)
Grade 1	1071 (8.9)	2122 (17.6)	3193 (13.3)
Grade 2	245 (2.0)	661 (5.5)	906 (3.8)
Grade 3	19 (0.2)	24 (0.2)	43 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	19 (0.2)	25 (0.2)	44 (0.2)
Chills - N1	11995	12029	24024
Any	1138 (9.5)	5477 (45.5)	6615 (27.5)
Grade 1	885 (7.4)	2490 (20.7)	3375 (14.0)
Grade 2	229 (1.9)	2835 (23.6)	3064 (12.8)
Grade 3	24 (0.2)	152 (1.3)	176 (0.7)
Grade 4	0	0	0
Grade 3 or Above	24 (0.2)	152 (1.3)	176 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1530) n (%)	mRNA-1273 (N=1566) n (%)	Total (N=3096) n (%)
Solicited Adverse Reactions - N1	1530	1566	3096
Any Solicited Adverse Reactions	818 (53.5)	1330 (84.9)	2148 (69.4)
95% CI	50.9, 56.0	83.1, 86.7	67.7, 71.0
Grade 1	482 (31.5)	560 (35.8)	1042 (33.7)
Grade 2	257 (16.8)	532 (34.0)	789 (25.5)
Grade 3	76 (5.0)	235 (15.0)	311 (10.0)
Grade 4	3 (0.2)	3 (0.2)	6 (0.2)
Grade 3 or Above	79 (5.2)	238 (15.2)	317 (10.2)
Solicited Local Adverse Reactions - N1	1530	1566	3096
Any Solicited Local Adverse Reactions	369 (24.1)	1245 (79.5)	1614 (52.1)
95% CI	22.0, 26.3	77.4, 81.5	50.4, 53.9
Grade 1	322 (21.0)	871 (55.6)	1193 (38.5)
Grade 2	24 (1.6)	265 (16.9)	289 (9.3)
Grade 3	23 (1.5)	109 (7.0)	132 (4.3)
Grade 4	0	0	0
Grade 3 or Above	23 (1.5)	109 (7.0)	132 (4.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1530) n (%)	mRNA-1273 (N=1566) n (%)	Total (N=3096) n (%)
Pain - N1	1530	1566	3096
Any	333 (21.8)	1226 (78.3)	1559 (50.4)
Grade 1	297 (19.4)	916 (58.5)	1213 (39.2)
Grade 2	20 (1.3)	236 (15.1)	256 (8.3)
Grade 3	16 (1.0)	74 (4.7)	90 (2.9)
Grade 4	0	0	0
Grade 3 or Above	16 (1.0)	74 (4.7)	90 (2.9)
Erythema (Redness) - N1	1530	1566	3096
Any	15 (1.0)	70 (4.5)	85 (2.7)
Grade 1	8 (0.5)	27 (1.7)	35 (1.1)
Grade 2	1 (<0.1)	19 (1.2)	20 (0.6)
Grade 3	6 (0.4)	24 (1.5)	30 (1.0)
Grade 4	0	0	0
Grade 3 or Above	6 (0.4)	24 (1.5)	30 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1530) n (%)	mRNA-1273 (N=1566) n (%)	Total (N=3096) n (%)
Swelling (Hardness) - N1	1530	1566	3096
Any	7 (0.5)	140 (8.9)	147 (4.7)
Grade 1	5 (0.3)	65 (4.2)	70 (2.3)
Grade 2	1 (<0.1)	50 (3.2)	51 (1.6)
Grade 3	1 (<0.1)	25 (1.6)	26 (0.8)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	25 (1.6)	26 (0.8)
Axillary Swelling or Tenderness - N1	1530	1566	3096
Any	110 (7.2)	286 (18.3)	396 (12.8)
Grade 1	95 (6.2)	240 (15.3)	335 (10.8)
Grade 2	9 (0.6)	33 (2.1)	42 (1.4)
Grade 3	6 (0.4)	13 (0.8)	19 (0.6)
Grade 4	0	0	0
Grade 3 or Above	6 (0.4)	13 (0.8)	19 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1530) n (%)	mRNA-1273 (N=1566) n (%)	Total (N=3096) n (%)
Solicited Systemic Adverse Reactions - N1	1530	1566	3096
Any Solicited Systemic Adverse Reactions	729 (47.6)	1133 (72.3)	1862 (60.1)
95% CI	45.1, 50.2	70.1, 74.6	58.4, 61.9
Grade 1	406 (26.5)	433 (27.7)	839 (27.1)
Grade 2	258 (16.9)	528 (33.7)	786 (25.4)
Grade 3	62 (4.1)	169 (10.8)	231 (7.5)
Grade 4	3 (0.2)	3 (0.2)	6 (0.2)
Grade 3 or Above	65 (4.2)	172 (11.0)	237 (7.7)
Fever - N1	1530	1566	3096
Any	14 (0.9)	167 (10.7)	181 (5.8)
Grade 1	9 (0.6)	93 (5.9)	102 (3.3)
Grade 2	1 (<0.1)	50 (3.2)	51 (1.6)
Grade 3	1 (<0.1)	21 (1.3)	22 (0.7)
Grade 4	3 (0.2)	3 (0.2)	6 (0.2)
Grade 3 or Above	4 (0.3)	24 (1.5)	28 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1530) n (%)	mRNA-1273 (N=1566) n (%)	Total (N=3096) n (%)
Headache - N1	1530	1566	3096
Any	484 (31.6)	771 (49.2)	1255 (40.5)
Grade 1	358 (23.4)	486 (31.0)	844 (27.3)
Grade 2	87 (5.7)	215 (13.7)	302 (9.8)
Grade 3	39 (2.5)	70 (4.5)	109 (3.5)
Grade 4	0	0	0
Grade 3 or Above	39 (2.5)	70 (4.5)	109 (3.5)
Fatigue - N1	1530	1566	3096
Any	469 (30.7)	838 (53.5)	1307 (42.2)
Grade 1	249 (16.3)	357 (22.8)	606 (19.6)
Grade 2	197 (12.9)	399 (25.5)	596 (19.3)
Grade 3	23 (1.5)	82 (5.2)	105 (3.4)
Grade 4	0	0	0
Grade 3 or Above	23 (1.5)	82 (5.2)	105 (3.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1530) n (%)	mRNA-1273 (N=1566) n (%)	Total (N=3096) n (%)
Myalgia - N1	1530	1566	3096
Any	315 (20.6)	768 (49.0)	1083 (35.0)
Grade 1	194 (12.7)	353 (22.5)	547 (17.7)
Grade 2	107 (7.0)	335 (21.4)	442 (14.3)
Grade 3	14 (0.9)	80 (5.1)	94 (3.0)
Grade 4	0	0	0
Grade 3 or Above	14 (0.9)	80 (5.1)	94 (3.0)
Arthralgia - N1	1530	1566	3096
Any	288 (18.8)	561 (35.8)	849 (27.4)
Grade 1	170 (11.1)	271 (17.3)	441 (14.2)
Grade 2	102 (6.7)	237 (15.1)	339 (10.9)
Grade 3	16 (1.0)	53 (3.4)	69 (2.2)
Grade 4	0	0	0
Grade 3 or Above	16 (1.0)	53 (3.4)	69 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1530) n (%)	mRNA-1273 (N=1566) n (%)	Total (N=3096) n (%)
Nausea/Vomiting - N1	1530	1566	3096
Any	183 (12.0)	267 (17.0)	450 (14.5)
Grade 1	135 (8.8)	202 (12.9)	337 (10.9)
Grade 2	45 (2.9)	60 (3.8)	105 (3.4)
Grade 3	3 (0.2)	5 (0.3)	8 (0.3)
Grade 4	0	0	0
Grade 3 or Above	3 (0.2)	5 (0.3)	8 (0.3)
Chills - N1	1530	1566	3096
Any	160 (10.5)	548 (35.0)	708 (22.9)
Grade 1	110 (7.2)	295 (18.8)	405 (13.1)
Grade 2	46 (3.0)	228 (14.6)	274 (8.9)
Grade 3	4 (0.3)	25 (1.6)	29 (0.9)
Grade 4	0	0	0
Grade 3 or Above	4 (0.3)	25 (1.6)	29 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Solicited Adverse Reactions - N1	739	656	1395
Any Solicited Adverse Reactions	420 (56.8)	644 (98.2)	1064 (76.3)
95% CI	53.2, 60.4	96.8, 99.1	74.0, 78.5
Grade 1	292 (39.5)	147 (22.4)	439 (31.5)
Grade 2	106 (14.3)	298 (45.4)	404 (29.0)
Grade 3	22 (3.0)	199 (30.3)	221 (15.8)
Grade 4	0	0	0
Grade 3 or Above	22 (3.0)	199 (30.3)	221 (15.8)
Solicited Local Adverse Reactions - N1	739	656	1395
Any Solicited Local Adverse Reactions	217 (29.4)	630 (96.0)	847 (60.7)
95% CI	26.1, 32.8	94.2, 97.4	58.1, 63.3
Grade 1	206 (27.9)	348 (53.0)	554 (39.7)
Grade 2	7 (0.9)	193 (29.4)	200 (14.3)
Grade 3	4 (0.5)	89 (13.6)	93 (6.7)
Grade 4	0	0	0
Grade 3 or Above	4 (0.5)	89 (13.6)	93 (6.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Pain - N1	739	656	1395
Any	206 (27.9)	630 (96.0)	836 (59.9)
Grade 1	198 (26.8)	394 (60.1)	592 (42.4)
Grade 2	5 (0.7)	168 (25.6)	173 (12.4)
Grade 3	3 (0.4)	68 (10.4)	71 (5.1)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	68 (10.4)	71 (5.1)
Erythema (Redness) - N1	739	656	1395
Any	3 (0.4)	84 (12.8)	87 (6.2)
Grade 1	2 (0.3)	41 (6.3)	43 (3.1)
Grade 2	0	29 (4.4)	29 (2.1)
Grade 3	1 (0.1)	14 (2.1)	15 (1.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	14 (2.1)	15 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Swelling (Hardness) - N1	739	656	1395
Any	4 (0.5)	139 (21.2)	143 (10.3)
Grade 1	3 (0.4)	83 (12.7)	86 (6.2)
Grade 2	0	44 (6.7)	44 (3.2)
Grade 3	1 (0.1)	12 (1.8)	13 (0.9)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	12 (1.8)	13 (0.9)
Axillary Swelling or Tenderness - N1	739	656	1395
Any	48 (6.5)	131 (20.0)	179 (12.8)
Grade 1	46 (6.2)	106 (16.2)	152 (10.9)
Grade 2	2 (0.3)	18 (2.7)	20 (1.4)
Grade 3	0	7 (1.1)	7 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	7 (1.1)	7 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Solicited Systemic Adverse Reactions - N1	739	656	1395
Any Solicited Systemic Adverse Reactions	368 (49.8)	603 (91.9)	971 (69.6)
95% CI	46.1, 53.5	89.6, 93.9	67.1, 72.0
Grade 1	244 (33.0)	136 (20.7)	380 (27.2)
Grade 2	105 (14.2)	319 (48.6)	424 (30.4)
Grade 3	19 (2.6)	148 (22.6)	167 (12.0)
Grade 4	0	0	0
Grade 3 or Above	19 (2.6)	148 (22.6)	167 (12.0)
Fever - N1	739	656	1395
Any	2 (0.3)	163 (24.8)	165 (11.8)
Grade 1	2 (0.3)	86 (13.1)	88 (6.3)
Grade 2	0	58 (8.8)	58 (4.2)
Grade 3	0	19 (2.9)	19 (1.4)
Grade 4	0	0	0
Grade 3 or Above	0	19 (2.9)	19 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Headache - N1	739	656	1395
Any	228 (30.9)	483 (73.6)	711 (51.0)
Grade 1	180 (24.4)	262 (39.9)	442 (31.7)
Grade 2	37 (5.0)	167 (25.5)	204 (14.6)
Grade 3	11 (1.5)	54 (8.2)	65 (4.7)
Grade 4	0	0	0
Grade 3 or Above	11 (1.5)	54 (8.2)	65 (4.7)
Fatigue - N1	739	656	1395
Any	252 (34.1)	539 (82.2)	791 (56.7)
Grade 1	165 (22.3)	157 (23.9)	322 (23.1)
Grade 2	81 (11.0)	289 (44.1)	370 (26.5)
Grade 3	6 (0.8)	93 (14.2)	99 (7.1)
Grade 4	0	0	0
Grade 3 or Above	6 (0.8)	93 (14.2)	99 (7.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Myalgia - N1	739	656	1395
Any	152 (20.6)	489 (74.5)	641 (45.9)
Grade 1	117 (15.8)	153 (23.3)	270 (19.4)
Grade 2	33 (4.5)	260 (39.6)	293 (21.0)
Grade 3	2 (0.3)	76 (11.6)	78 (5.6)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	76 (11.6)	78 (5.6)
Arthralgia - N1	739	656	1395
Any	105 (14.2)	348 (53.0)	453 (32.5)
Grade 1	83 (11.2)	156 (23.8)	239 (17.1)
Grade 2	20 (2.7)	155 (23.6)	175 (12.5)
Grade 3	2 (0.3)	37 (5.6)	39 (2.8)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	37 (5.6)	39 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Nausea/Vomiting - N1	739	656	1395
Any	73 (9.9)	169 (25.8)	242 (17.3)
Grade 1	62 (8.4)	125 (19.1)	187 (13.4)
Grade 2	10 (1.4)	43 (6.6)	53 (3.8)
Grade 3	1 (0.1)	1 (0.2)	2 (0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	1 (0.2)	2 (0.1)
Chills - N1	739	656	1395
Any	69 (9.3)	412 (62.8)	481 (34.5)
Grade 1	51 (6.9)	151 (23.0)	202 (14.5)
Grade 2	17 (2.3)	242 (36.9)	259 (18.6)
Grade 3	1 (0.1)	19 (2.9)	20 (1.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	19 (2.9)	20 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Solicited Adverse Reactions - N1	121	113	234
Any Solicited Adverse Reactions	71 (58.7)	109 (96.5)	180 (76.9)
95% CI	49.4, 67.6	91.2, 99.0	71.0, 82.2
Grade 1	41 (33.9)	36 (31.9)	77 (32.9)
Grade 2	25 (20.7)	49 (43.4)	74 (31.6)
Grade 3	5 (4.1)	24 (21.2)	29 (12.4)
Grade 4	0	0	0
Grade 3 or Above	5 (4.1)	24 (21.2)	29 (12.4)
Solicited Local Adverse Reactions - N1	121	113	234
Any Solicited Local Adverse Reactions	34 (28.1)	107 (94.7)	141 (60.3)
95% CI	20.3, 37.0	88.8, 98.0	53.7, 66.6
Grade 1	31 (25.6)	70 (61.9)	101 (43.2)
Grade 2	1 (0.8)	28 (24.8)	29 (12.4)
Grade 3	2 (1.7)	9 (8.0)	11 (4.7)
Grade 4	0	0	0
Grade 3 or Above	2 (1.7)	9 (8.0)	11 (4.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Pain - N1	121	113	234
Any	30 (24.8)	107 (94.7)	137 (58.5)
Grade 1	29 (24.0)	76 (67.3)	105 (44.9)
Grade 2	0	24 (21.2)	24 (10.3)
Grade 3	1 (0.8)	7 (6.2)	8 (3.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	7 (6.2)	8 (3.4)
Erythema (Redness) - N1	121	113	234
Any	3 (2.5)	12 (10.6)	15 (6.4)
Grade 1	1 (0.8)	8 (7.1)	9 (3.8)
Grade 2	1 (0.8)	4 (3.5)	5 (2.1)
Grade 3	1 (0.8)	0	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	0	1 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Swelling (Hardness) - N1	121	113	234
Any	0	18 (15.9)	18 (7.7)
Grade 1	0	8 (7.1)	8 (3.4)
Grade 2	0	8 (7.1)	8 (3.4)
Grade 3	0	2 (1.8)	2 (0.9)
Grade 4	0	0	0
Grade 3 or Above	0	2 (1.8)	2 (0.9)
Axillary Swelling or Tenderness - N1	121	113	234
Any	9 (7.4)	26 (23.0)	35 (15.0)
Grade 1	8 (6.6)	22 (19.5)	30 (12.8)
Grade 2	0	4 (3.5)	4 (1.7)
Grade 3	1 (0.8)	0	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	0	1 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Solicited Systemic Adverse Reactions - N1	121	113	234
Any Solicited Systemic Adverse Reactions	65 (53.7)	103 (91.2)	168 (71.8)
95% CI	44.4, 62.8	84.3, 95.7	65.6, 77.5
Grade 1	37 (30.6)	34 (30.1)	71 (30.3)
Grade 2	24 (19.8)	47 (41.6)	71 (30.3)
Grade 3	4 (3.3)	22 (19.5)	26 (11.1)
Grade 4	0	0	0
Grade 3 or Above	4 (3.3)	22 (19.5)	26 (11.1)
Fever - N1	121	113	234
Any	1 (0.8)	18 (15.9)	19 (8.1)
Grade 1	1 (0.8)	14 (12.4)	15 (6.4)
Grade 2	0	3 (2.7)	3 (1.3)
Grade 3	0	1 (0.9)	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.9)	1 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Headache - N1	121	113	234
Any	49 (40.5)	84 (74.3)	133 (56.8)
Grade 1	38 (31.4)	57 (50.4)	95 (40.6)
Grade 2	8 (6.6)	19 (16.8)	27 (11.5)
Grade 3	3 (2.5)	8 (7.1)	11 (4.7)
Grade 4	0	0	0
Grade 3 or Above	3 (2.5)	8 (7.1)	11 (4.7)
Fatigue - N1	121	113	234
Any	46 (38.0)	86 (76.1)	132 (56.4)
Grade 1	29 (24.0)	28 (24.8)	57 (24.4)
Grade 2	16 (13.2)	47 (41.6)	63 (26.9)
Grade 3	1 (0.8)	11 (9.7)	12 (5.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	11 (9.7)	12 (5.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Myalgia - N1	121	113	234
Any	25 (20.7)	71 (62.8)	96 (41.0)
Grade 1	19 (15.7)	25 (22.1)	44 (18.8)
Grade 2	5 (4.1)	34 (30.1)	39 (16.7)
Grade 3	1 (0.8)	12 (10.6)	13 (5.6)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	12 (10.6)	13 (5.6)
Arthralgia - N1	121	113	234
Any	30 (24.8)	64 (56.6)	94 (40.2)
Grade 1	20 (16.5)	29 (25.7)	49 (20.9)
Grade 2	9 (7.4)	27 (23.9)	36 (15.4)
Grade 3	1 (0.8)	8 (7.1)	9 (3.8)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	8 (7.1)	9 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Nausea/Vomiting - N1	121	113	234
Any	17 (14.0)	32 (28.3)	49 (20.9)
Grade 1	17 (14.0)	23 (20.4)	40 (17.1)
Grade 2	0	9 (8.0)	9 (3.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	121	113	234
Any	10 (8.3)	48 (42.5)	58 (24.8)
Grade 1	9 (7.4)	20 (17.7)	29 (12.4)
Grade 2	0	26 (23.0)	26 (11.1)
Grade 3	1 (0.8)	2 (1.8)	3 (1.3)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	2 (1.8)	3 (1.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Solicited Adverse Reactions - N1	32	36	68
Any Solicited Adverse Reactions	22 (68.8)	34 (94.4)	56 (82.4)
95% CI	50.0, 83.9	81.3, 99.3	71.2, 90.5
Grade 1	12 (37.5)	9 (25.0)	21 (30.9)
Grade 2	8 (25.0)	18 (50.0)	26 (38.2)
Grade 3	2 (6.3)	7 (19.4)	9 (13.2)
Grade 4	0	0	0
Grade 3 or Above	2 (6.3)	7 (19.4)	9 (13.2)
Solicited Local Adverse Reactions - N1	32	36	68
Any Solicited Local Adverse Reactions	9 (28.1)	34 (94.4)	43 (63.2)
95% CI	13.7, 46.7	81.3, 99.3	50.7, 74.6
Grade 1	7 (21.9)	22 (61.1)	29 (42.6)
Grade 2	0	8 (22.2)	8 (11.8)
Grade 3	2 (6.3)	4 (11.1)	6 (8.8)
Grade 4	0	0	0
Grade 3 or Above	2 (6.3)	4 (11.1)	6 (8.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Pain - N1	32	36	68
Any	9 (28.1)	34 (94.4)	43 (63.2)
Grade 1	7 (21.9)	24 (66.7)	31 (45.6)
Grade 2	0	8 (22.2)	8 (11.8)
Grade 3	2 (6.3)	2 (5.6)	4 (5.9)
Grade 4	0	0	0
Grade 3 or Above	2 (6.3)	2 (5.6)	4 (5.9)
Erythema (Redness) - N1	32	36	68
Any	0	2 (5.6)	2 (2.9)
Grade 1	0	0	0
Grade 2	0	1 (2.8)	1 (1.5)
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Swelling (Hardness) - N1	32	36	68
Any	0	5 (13.9)	5 (7.4)
Grade 1	0	3 (8.3)	3 (4.4)
Grade 2	0	1 (2.8)	1 (1.5)
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)
Axillary Swelling or Tenderness - N1	32	36	68
Any	2 (6.3)	8 (22.2)	10 (14.7)
Grade 1	1 (3.1)	7 (19.4)	8 (11.8)
Grade 2	0	0	0
Grade 3	1 (3.1)	1 (2.8)	2 (2.9)
Grade 4	0	0	0
Grade 3 or Above	1 (3.1)	1 (2.8)	2 (2.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Solicited Systemic Adverse Reactions - N1	32	36	68
Any Solicited Systemic Adverse Reactions	21 (65.6)	31 (86.1)	52 (76.5)
95% CI	46.8, 81.4	70.5, 95.3	64.6, 85.9
Grade 1	13 (40.6)	10 (27.8)	23 (33.8)
Grade 2	8 (25.0)	17 (47.2)	25 (36.8)
Grade 3	0	4 (11.1)	4 (5.9)
Grade 4	0	0	0
Grade 3 or Above	0	4 (11.1)	4 (5.9)
Fever - N1	32	36	68
Any	0	6 (16.7)	6 (8.8)
Grade 1	0	5 (13.9)	5 (7.4)
Grade 2	0	0	0
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Headache - N1	32	36	68
Any	11 (34.4)	20 (55.6)	31 (45.6)
Grade 1	10 (31.3)	9 (25.0)	19 (27.9)
Grade 2	1 (3.1)	9 (25.0)	10 (14.7)
Grade 3	0	2 (5.6)	2 (2.9)
Grade 4	0	0	0
Grade 3 or Above	0	2 (5.6)	2 (2.9)
Fatigue - N1	32	36	68
Any	15 (46.9)	25 (69.4)	40 (58.8)
Grade 1	7 (21.9)	8 (22.2)	15 (22.1)
Grade 2	8 (25.0)	14 (38.9)	22 (32.4)
Grade 3	0	3 (8.3)	3 (4.4)
Grade 4	0	0	0
Grade 3 or Above	0	3 (8.3)	3 (4.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Myalgia - N1	32	36	68
Any	9 (28.1)	23 (63.9)	32 (47.1)
Grade 1	8 (25.0)	11 (30.6)	19 (27.9)
Grade 2	1 (3.1)	10 (27.8)	11 (16.2)
Grade 3	0	2 (5.6)	2 (2.9)
Grade 4	0	0	0
Grade 3 or Above	0	2 (5.6)	2 (2.9)
Arthralgia - N1	32	36	68
Any	6 (18.8)	17 (47.2)	23 (33.8)
Grade 1	5 (15.6)	8 (22.2)	13 (19.1)
Grade 2	1 (3.1)	7 (19.4)	8 (11.8)
Grade 3	0	2 (5.6)	2 (2.9)
Grade 4	0	0	0
Grade 3 or Above	0	2 (5.6)	2 (2.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Nausea/Vomiting - N1	32	36	68
Any	4 (12.5)	5 (13.9)	9 (13.2)
Grade 1	3 (9.4)	2 (5.6)	5 (7.4)
Grade 2	1 (3.1)	3 (8.3)	4 (5.9)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	32	36	68
Any	3 (9.4)	18 (50.0)	21 (30.9)
Grade 1	2 (6.3)	6 (16.7)	8 (11.8)
Grade 2	1 (3.1)	12 (33.3)	13 (19.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Solicited Adverse Reactions - N1	318	320	638
Any Solicited Adverse Reactions	204 (64.2)	312 (97.5)	516 (80.9)
95% CI	58.6, 69.4	95.1, 98.9	77.6, 83.9
Grade 1	116 (36.5)	80 (25.0)	196 (30.7)
Grade 2	72 (22.6)	140 (43.8)	212 (33.2)
Grade 3	16 (5.0)	91 (28.4)	107 (16.8)
Grade 4	0	1 (0.3)	1 (0.2)
Grade 3 or Above	16 (5.0)	92 (28.8)	108 (16.9)
Solicited Local Adverse Reactions - N1	318	320	638
Any Solicited Local Adverse Reactions	118 (37.1)	308 (96.3)	426 (66.8)
95% CI	31.8, 42.7	93.5, 98.0	63.0, 70.4
Grade 1	110 (34.6)	174 (54.4)	284 (44.5)
Grade 2	7 (2.2)	100 (31.3)	107 (16.8)
Grade 3	1 (0.3)	34 (10.6)	35 (5.5)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	34 (10.6)	35 (5.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Pain - N1	318	320	638
Any	106 (33.3)	306 (95.6)	412 (64.6)
Grade 1	102 (32.1)	191 (59.7)	293 (45.9)
Grade 2	3 (0.9)	91 (28.4)	94 (14.7)
Grade 3	1 (0.3)	24 (7.5)	25 (3.9)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	24 (7.5)	25 (3.9)
Erythema (Redness) - N1	318	320	638
Any	6 (1.9)	43 (13.4)	49 (7.7)
Grade 1	6 (1.9)	19 (5.9)	25 (3.9)
Grade 2	0	15 (4.7)	15 (2.4)
Grade 3	0	9 (2.8)	9 (1.4)
Grade 4	0	0	0
Grade 3 or Above	0	9 (2.8)	9 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Swelling (Hardness) - N1	318	320	638
Any	8 (2.5)	68 (21.3)	76 (11.9)
Grade 1	6 (1.9)	39 (12.2)	45 (7.1)
Grade 2	2 (0.6)	21 (6.6)	23 (3.6)
Grade 3	0	8 (2.5)	8 (1.3)
Grade 4	0	0	0
Grade 3 or Above	0	8 (2.5)	8 (1.3)
Axillary Swelling or Tenderness - N1	318	320	638
Any	31 (9.7)	85 (26.6)	116 (18.2)
Grade 1	28 (8.8)	67 (20.9)	95 (14.9)
Grade 2	3 (0.9)	16 (5.0)	19 (3.0)
Grade 3	0	2 (0.6)	2 (0.3)
Grade 4	0	0	0
Grade 3 or Above	0	2 (0.6)	2 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Solicited Systemic Adverse Reactions - N1	318	320	638
Any Solicited Systemic Adverse Reactions	187 (58.8)	285 (89.1)	472 (74.0)
95% CI	53.2, 64.3	85.1, 92.3	70.4, 77.3
Grade 1	102 (32.1)	70 (21.9)	172 (27.0)
Grade 2	69 (21.7)	138 (43.1)	207 (32.4)
Grade 3	16 (5.0)	76 (23.8)	92 (14.4)
Grade 4	0	1 (0.3)	1 (0.2)
Grade 3 or Above	16 (5.0)	77 (24.1)	93 (14.6)
Fever - N1	318	320	638
Any	0	54 (16.9)	54 (8.5)
Grade 1	0	27 (8.4)	27 (4.2)
Grade 2	0	21 (6.6)	21 (3.3)
Grade 3	0	5 (1.6)	5 (0.8)
Grade 4	0	1 (0.3)	1 (0.2)
Grade 3 or Above	0	6 (1.9)	6 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Headache - N1	318	320	638
Any	132 (41.5)	240 (75.0)	372 (58.3)
Grade 1	102 (32.1)	130 (40.6)	232 (36.4)
Grade 2	23 (7.2)	87 (27.2)	110 (17.2)
Grade 3	7 (2.2)	23 (7.2)	30 (4.7)
Grade 4	0	0	0
Grade 3 or Above	7 (2.2)	23 (7.2)	30 (4.7)
Fatigue - N1	318	320	638
Any	140 (44.0)	252 (78.8)	392 (61.4)
Grade 1	74 (23.3)	65 (20.3)	139 (21.8)
Grade 2	59 (18.6)	142 (44.4)	201 (31.5)
Grade 3	7 (2.2)	45 (14.1)	52 (8.2)
Grade 4	0	0	0
Grade 3 or Above	7 (2.2)	45 (14.1)	52 (8.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Myalgia - N1	318	320	638
Any	80 (25.2)	222 (69.4)	302 (47.3)
Grade 1	49 (15.4)	78 (24.4)	127 (19.9)
Grade 2	27 (8.5)	109 (34.1)	136 (21.3)
Grade 3	4 (1.3)	35 (10.9)	39 (6.1)
Grade 4	0	0	0
Grade 3 or Above	4 (1.3)	35 (10.9)	39 (6.1)
Arthralgia - N1	318	320	638
Any	70 (22.0)	158 (49.4)	228 (35.7)
Grade 1	47 (14.8)	61 (19.1)	108 (16.9)
Grade 2	20 (6.3)	73 (22.8)	93 (14.6)
Grade 3	3 (0.9)	24 (7.5)	27 (4.2)
Grade 4	0	0	0
Grade 3 or Above	3 (0.9)	24 (7.5)	27 (4.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Nausea/Vomiting - N1	318	320	638
Any	51 (16.0)	91 (28.4)	142 (22.3)
Grade 1	41 (12.9)	63 (19.7)	104 (16.3)
Grade 2	9 (2.8)	28 (8.8)	37 (5.8)
Grade 3	1 (0.3)	0	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	0	1 (0.2)
Chills - N1	318	320	638
Any	40 (12.6)	179 (55.9)	219 (34.3)
Grade 1	31 (9.7)	89 (27.8)	120 (18.8)
Grade 2	8 (2.5)	84 (26.3)	92 (14.4)
Grade 3	1 (0.3)	6 (1.9)	7 (1.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	6 (1.9)	7 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Solicited Adverse Reactions - N1	423	458	881
Any Solicited Adverse Reactions	278 (65.7)	436 (95.2)	714 (81.0)
95% CI	61.0, 70.2	92.8, 97.0	78.3, 83.6
Grade 1	169 (40.0)	134 (29.3)	303 (34.4)
Grade 2	91 (21.5)	182 (39.7)	273 (31.0)
Grade 3	18 (4.3)	120 (26.2)	138 (15.7)
Grade 4	0	0	0
Grade 3 or Above	18 (4.3)	120 (26.2)	138 (15.7)
Solicited Local Adverse Reactions - N1	423	458	881
Any Solicited Local Adverse Reactions	138 (32.6)	427 (93.2)	565 (64.1)
95% CI	28.2, 37.3	90.5, 95.4	60.9, 67.3
Grade 1	130 (30.7)	251 (54.8)	381 (43.2)
Grade 2	5 (1.2)	128 (27.9)	133 (15.1)
Grade 3	3 (0.7)	48 (10.5)	51 (5.8)
Grade 4	0	0	0
Grade 3 or Above	3 (0.7)	48 (10.5)	51 (5.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Pain - N1	423	458	881
Any	121 (28.6)	427 (93.2)	548 (62.2)
Grade 1	116 (27.4)	273 (59.6)	389 (44.2)
Grade 2	3 (0.7)	124 (27.1)	127 (14.4)
Grade 3	2 (0.5)	30 (6.6)	32 (3.6)
Grade 4	0	0	0
Grade 3 or Above	2 (0.5)	30 (6.6)	32 (3.6)
Erythema (Redness) - N1	423	458	881
Any	7 (1.7)	52 (11.4)	59 (6.7)
Grade 1	7 (1.7)	20 (4.4)	27 (3.1)
Grade 2	0	21 (4.6)	21 (2.4)
Grade 3	0	11 (2.4)	11 (1.2)
Grade 4	0	0	0
Grade 3 or Above	0	11 (2.4)	11 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Swelling (Hardness) - N1	423	458	881
Any	4 (0.9)	85 (18.6)	89 (10.1)
Grade 1	2 (0.5)	46 (10.0)	48 (5.4)
Grade 2	1 (0.2)	27 (5.9)	28 (3.2)
Grade 3	1 (0.2)	12 (2.6)	13 (1.5)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	12 (2.6)	13 (1.5)
Axillary Swelling or Tenderness - N1	423	458	881
Any	44 (10.4)	146 (31.9)	190 (21.6)
Grade 1	41 (9.7)	124 (27.1)	165 (18.7)
Grade 2	2 (0.5)	17 (3.7)	19 (2.2)
Grade 3	1 (0.2)	5 (1.1)	6 (0.7)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	5 (1.1)	6 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Solicited Systemic Adverse Reactions - N1	423	458	881
Any Solicited Systemic Adverse Reactions	248 (58.6)	397 (86.7)	645 (73.2)
95% CI	53.8, 63.4	83.2, 89.7	70.2, 76.1
Grade 1	142 (33.6)	114 (24.9)	256 (29.1)
Grade 2	89 (21.0)	183 (40.0)	272 (30.9)
Grade 3	17 (4.0)	100 (21.8)	117 (13.3)
Grade 4	0	0	0
Grade 3 or Above	17 (4.0)	100 (21.8)	117 (13.3)
Fever - N1	423	458	881
Any	0	87 (19.0)	87 (9.9)
Grade 1	0	40 (8.7)	40 (4.5)
Grade 2	0	34 (7.4)	34 (3.9)
Grade 3	0	13 (2.8)	13 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	13 (2.8)	13 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Headache - N1	423	458	881
Any	180 (42.6)	321 (70.1)	501 (56.9)
Grade 1	136 (32.2)	161 (35.2)	297 (33.7)
Grade 2	30 (7.1)	128 (27.9)	158 (17.9)
Grade 3	14 (3.3)	32 (7.0)	46 (5.2)
Grade 4	0	0	0
Grade 3 or Above	14 (3.3)	32 (7.0)	46 (5.2)
Fatigue - N1	423	458	881
Any	177 (41.8)	326 (71.2)	503 (57.1)
Grade 1	107 (25.3)	112 (24.5)	219 (24.9)
Grade 2	65 (15.4)	155 (33.8)	220 (25.0)
Grade 3	5 (1.2)	59 (12.9)	64 (7.3)
Grade 4	0	0	0
Grade 3 or Above	5 (1.2)	59 (12.9)	64 (7.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Myalgia - N1	423	458	881
Any	115 (27.2)	321 (70.1)	436 (49.5)
Grade 1	77 (18.2)	120 (26.2)	197 (22.4)
Grade 2	35 (8.3)	150 (32.8)	185 (21.0)
Grade 3	3 (0.7)	51 (11.1)	54 (6.1)
Grade 4	0	0	0
Grade 3 or Above	3 (0.7)	51 (11.1)	54 (6.1)
Arthralgia - N1	423	458	881
Any	105 (24.8)	251 (54.8)	356 (40.4)
Grade 1	69 (16.3)	125 (27.3)	194 (22.0)
Grade 2	34 (8.0)	100 (21.8)	134 (15.2)
Grade 3	2 (0.5)	26 (5.7)	28 (3.2)
Grade 4	0	0	0
Grade 3 or Above	2 (0.5)	26 (5.7)	28 (3.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Race and Grade
Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Nausea/Vomiting - N1	423	458	881
Any	60 (14.2)	121 (26.4)	181 (20.5)
Grade 1	51 (12.1)	85 (18.6)	136 (15.4)
Grade 2	9 (2.1)	36 (7.9)	45 (5.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	423	458	881
Any	53 (12.5)	225 (49.1)	278 (31.6)
Grade 1	44 (10.4)	93 (20.3)	137 (15.6)
Grade 2	9 (2.1)	125 (27.3)	134 (15.2)
Grade 3	0	7 (1.5)	7 (0.8)
Grade 4	0	0	0
Grade 3 or Above	0	7 (1.5)	7 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3107) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6229) n (%)
Solicited Adverse Reactions - N1	3107	3122	6229
Any Solicited Adverse Reactions	1808 (58.2)	2888 (92.5)	4696 (75.4)
95% CI	56.4, 59.9	91.5, 93.4	74.3, 76.5
Grade 1	1121 (36.1)	965 (30.9)	2086 (33.5)
Grade 2	562 (18.1)	1207 (38.7)	1769 (28.4)
Grade 3	121 (3.9)	709 (22.7)	830 (13.3)
Grade 4	4 (0.1)	7 (0.2)	11 (0.2)
Grade 3 or Above	125 (4.0)	716 (22.9)	841 (13.5)
Solicited Local Adverse Reactions - N1	3107	3122	6229
Any Solicited Local Adverse Reactions	924 (29.7)	2813 (90.1)	3737 (60.0)
95% CI	28.1, 31.4	89.0, 91.1	58.8, 61.2
Grade 1	841 (27.1)	1762 (56.4)	2603 (41.8)
Grade 2	49 (1.6)	766 (24.5)	815 (13.1)
Grade 3	34 (1.1)	285 (9.1)	319 (5.1)
Grade 4	0	0	0
Grade 3 or Above	34 (1.1)	285 (9.1)	319 (5.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3107) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6229) n (%)
Pain - N1	3107	3122	6229
Any	811 (26.1)	2796 (89.6)	3607 (57.9)
Grade 1	751 (24.2)	1913 (61.3)	2664 (42.8)
Grade 2	38 (1.2)	694 (22.2)	732 (11.8)
Grade 3	22 (0.7)	189 (6.1)	211 (3.4)
Grade 4	0	0	0
Grade 3 or Above	22 (0.7)	189 (6.1)	211 (3.4)
Erythema (Redness) - N1	3107	3121	6228
Any	29 (0.9)	296 (9.5)	325 (5.2)
Grade 1	20 (0.6)	127 (4.1)	147 (2.4)
Grade 2	1 (<0.1)	109 (3.5)	110 (1.8)
Grade 3	8 (0.3)	60 (1.9)	68 (1.1)
Grade 4	0	0	0
Grade 3 or Above	8 (0.3)	60 (1.9)	68 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3107) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6229) n (%)
Swelling (Hardness) - N1	3107	3121	6228
Any	24 (0.8)	453 (14.5)	477 (7.7)
Grade 1	17 (0.5)	224 (7.2)	241 (3.9)
Grade 2	4 (0.1)	157 (5.0)	161 (2.6)
Grade 3	3 (<0.1)	72 (2.3)	75 (1.2)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	72 (2.3)	75 (1.2)
Axillary Swelling or Tenderness - N1	3107	3121	6228
Any	278 (8.9)	763 (24.4)	1041 (16.7)
Grade 1	246 (7.9)	616 (19.7)	862 (13.8)
Grade 2	19 (0.6)	115 (3.7)	134 (2.2)
Grade 3	13 (0.4)	32 (1.0)	45 (0.7)
Grade 4	0	0	0
Grade 3 or Above	13 (0.4)	32 (1.0)	45 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010503.sas 21JUN2021 15:06

Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3107) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6229) n (%)
Solicited Systemic Adverse Reactions - N1	3107	3121	6228
Any Solicited Systemic Adverse Reactions	1648 (53.0)	2589 (83.0)	4237 (68.0)
95% CI	51.3, 54.8	81.6, 84.3	66.9, 69.2
Grade 1	990 (31.9)	833 (26.7)	1823 (29.3)
Grade 2	554 (17.8)	1177 (37.7)	1731 (27.8)
Grade 3	100 (3.2)	572 (18.3)	672 (10.8)
Grade 4	4 (0.1)	7 (0.2)	11 (0.2)
Grade 3 or Above	104 (3.3)	579 (18.6)	683 (11.0)
Fever - N1	3106	3120	6226
Any	26 (0.8)	506 (16.2)	532 (8.5)
Grade 1	18 (0.6)	295 (9.5)	313 (5.0)
Grade 2	3 (<0.1)	157 (5.0)	160 (2.6)
Grade 3	1 (<0.1)	48 (1.5)	49 (0.8)
Grade 4	4 (0.1)	6 (0.2)	10 (0.2)
Grade 3 or Above	5 (0.2)	54 (1.7)	59 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3107) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6229) n (%)
Headache - N1	3107	3121	6228
Any	1157 (37.2)	2054 (65.8)	3211 (51.6)
Grade 1	878 (28.3)	1142 (36.6)	2020 (32.4)
Grade 2	220 (7.1)	737 (23.6)	957 (15.4)
Grade 3	59 (1.9)	175 (5.6)	234 (3.8)
Grade 4	0	0	0
Grade 3 or Above	59 (1.9)	175 (5.6)	234 (3.8)
Fatigue - N1	3107	3121	6228
Any	1120 (36.0)	2082 (66.7)	3202 (51.4)
Grade 1	676 (21.8)	769 (24.6)	1445 (23.2)
Grade 2	409 (13.2)	998 (32.0)	1407 (22.6)
Grade 3	35 (1.1)	314 (10.1)	349 (5.6)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	35 (1.1)	315 (10.1)	350 (5.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3107) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6229) n (%)
Myalgia - N1	3107	3121	6228
Any	738 (23.8)	2015 (64.6)	2753 (44.2)
Grade 1	519 (16.7)	780 (25.0)	1299 (20.9)
Grade 2	192 (6.2)	908 (29.1)	1100 (17.7)
Grade 3	27 (0.9)	327 (10.5)	354 (5.7)
Grade 4	0	0	0
Grade 3 or Above	27 (0.9)	327 (10.5)	354 (5.7)
Arthralgia - N1	3107	3121	6228
Any	632 (20.3)	1554 (49.8)	2186 (35.1)
Grade 1	444 (14.3)	712 (22.8)	1156 (18.6)
Grade 2	167 (5.4)	640 (20.5)	807 (13.0)
Grade 3	21 (0.7)	201 (6.4)	222 (3.6)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	21 (0.7)	202 (6.5)	223 (3.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3107) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6229) n (%)
Nausea/Vomiting - N1	3107	3121	6228
Any	397 (12.8)	747 (23.9)	1144 (18.4)
Grade 1	319 (10.3)	571 (18.3)	890 (14.3)
Grade 2	72 (2.3)	168 (5.4)	240 (3.9)
Grade 3	6 (0.2)	8 (0.3)	14 (0.2)
Grade 4	0	0	0
Grade 3 or Above	6 (0.2)	8 (0.3)	14 (0.2)
Chills - N1	3107	3121	6228
Any	372 (12.0)	1508 (48.3)	1880 (30.2)
Grade 1	287 (9.2)	706 (22.6)	993 (15.9)
Grade 2	73 (2.3)	750 (24.0)	823 (13.2)
Grade 3	12 (0.4)	52 (1.7)	64 (1.0)
Grade 4	0	0	0
Grade 3 or Above	12 (0.4)	52 (1.7)	64 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11916) n (%)	mRNA-1273 (N=11915) n (%)	Total (N=23831) n (%)
Solicited Adverse Reactions - N1	11916	11915	23831
Any Solicited Adverse Reactions	7217 (60.6)	11378 (95.5)	18595 (78.0)
95% CI	59.7, 61.4	95.1, 95.9	77.5, 78.6
Grade 1	4626 (38.8)	3783 (31.7)	8409 (35.3)
Grade 2	2041 (17.1)	4913 (41.2)	6954 (29.2)
Grade 3	545 (4.6)	2670 (22.4)	3215 (13.5)
Grade 4	5 (<0.1)	12 (0.1)	17 (<0.1)
Grade 3 or Above	550 (4.6)	2682 (22.5)	3232 (13.6)
Solicited Local Adverse Reactions - N1	11915	11915	23830
Any Solicited Local Adverse Reactions	3501 (29.4)	11089 (93.1)	14590 (61.2)
95% CI	28.6, 30.2	92.6, 93.5	60.6, 61.8
Grade 1	3275 (27.5)	7152 (60.0)	10427 (43.8)
Grade 2	113 (0.9)	2813 (23.6)	2926 (12.3)
Grade 3	113 (0.9)	1124 (9.4)	1237 (5.2)
Grade 4	0	0	0
Grade 3 or Above	113 (0.9)	1124 (9.4)	1237 (5.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11916) n (%)	mRNA-1273 (N=11915) n (%)	Total (N=23831) n (%)
Pain - N1	11915	11915	23830
Any	3197 (26.8)	11043 (92.7)	14240 (59.8)
Grade 1	3054 (25.6)	7817 (65.6)	10871 (45.6)
Grade 2	72 (0.6)	2498 (21.0)	2570 (10.8)
Grade 3	71 (0.6)	728 (6.1)	799 (3.4)
Grade 4	0	0	0
Grade 3 or Above	71 (0.6)	728 (6.1)	799 (3.4)
Erythema (Redness) - N1	11915	11915	23830
Any	108 (0.9)	1242 (10.4)	1350 (5.7)
Grade 1	78 (0.7)	499 (4.2)	577 (2.4)
Grade 2	11 (<0.1)	482 (4.0)	493 (2.1)
Grade 3	19 (0.2)	261 (2.2)	280 (1.2)
Grade 4	0	0	0
Grade 3 or Above	19 (0.2)	261 (2.2)	280 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11916) n (%)	mRNA-1273 (N=11915) n (%)	Total (N=23831) n (%)
Swelling (Hardness) - N1	11915	11915	23830
Any	91 (0.8)	1780 (14.9)	1871 (7.9)
Grade 1	64 (0.5)	919 (7.7)	983 (4.1)
Grade 2	14 (0.1)	609 (5.1)	623 (2.6)
Grade 3	13 (0.1)	252 (2.1)	265 (1.1)
Grade 4	0	0	0
Grade 3 or Above	13 (0.1)	252 (2.1)	265 (1.1)
Axillary Swelling or Tenderness - N1	11915	11915	23830
Any	815 (6.8)	2221 (18.6)	3036 (12.7)
Grade 1	750 (6.3)	1887 (15.8)	2637 (11.1)
Grade 2	32 (0.3)	255 (2.1)	287 (1.2)
Grade 3	33 (0.3)	79 (0.7)	112 (0.5)
Grade 4	0	0	0
Grade 3 or Above	33 (0.3)	79 (0.7)	112 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11916) n (%)	mRNA-1273 (N=11915) n (%)	Total (N=23831) n (%)
Solicited Systemic Adverse Reactions - N1	11916	11915	23831
Any Solicited Systemic Adverse Reactions	6393 (53.7)	10069 (84.5)	16462 (69.1)
95% CI	52.8, 54.5	83.8, 85.2	68.5, 69.7
Grade 1	3910 (32.8)	3167 (26.6)	7077 (29.7)
Grade 2	2019 (16.9)	4858 (40.8)	6877 (28.9)
Grade 3	459 (3.9)	2032 (17.1)	2491 (10.5)
Grade 4	5 (<0.1)	12 (0.1)	17 (<0.1)
Grade 3 or Above	464 (3.9)	2044 (17.2)	2508 (10.5)
Fever - N1	11916	11915	23831
Any	60 (0.5)	1826 (15.3)	1886 (7.9)
Grade 1	42 (0.4)	1105 (9.3)	1147 (4.8)
Grade 2	10 (<0.1)	546 (4.6)	556 (2.3)
Grade 3	3 (<0.1)	164 (1.4)	167 (0.7)
Grade 4	5 (<0.1)	11 (<0.1)	16 (<0.1)
Grade 3 or Above	8 (<0.1)	175 (1.5)	183 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11916) n (%)	mRNA-1273 (N=11915) n (%)	Total (N=23831) n (%)
Headache - N1	11915	11915	23830
Any	4408 (37.0)	7702 (64.6)	12110 (50.8)
Grade 1	3434 (28.8)	4387 (36.8)	7821 (32.8)
Grade 2	690 (5.8)	2622 (22.0)	3312 (13.9)
Grade 3	284 (2.4)	693 (5.8)	977 (4.1)
Grade 4	0	0	0
Grade 3 or Above	284 (2.4)	693 (5.8)	977 (4.1)
Fatigue - N1	11915	11915	23830
Any	4371 (36.7)	8462 (71.0)	12833 (53.9)
Grade 1	2629 (22.1)	2999 (25.2)	5628 (23.6)
Grade 2	1577 (13.2)	4257 (35.7)	5834 (24.5)
Grade 3	165 (1.4)	1206 (10.1)	1371 (5.8)
Grade 4	0	0	0
Grade 3 or Above	165 (1.4)	1206 (10.1)	1371 (5.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11916) n (%)	mRNA-1273 (N=11915) n (%)	Total (N=23831) n (%)
Myalgia - N1	11915	11915	23830
Any	2352 (19.7)	7244 (60.8)	9596 (40.3)
Grade 1	1658 (13.9)	2869 (24.1)	4527 (19.0)
Grade 2	624 (5.2)	3329 (27.9)	3953 (16.6)
Grade 3	70 (0.6)	1046 (8.8)	1116 (4.7)
Grade 4	0	0	0
Grade 3 or Above	70 (0.6)	1046 (8.8)	1116 (4.7)
Arthralgia - N1	11915	11915	23830
Any	2012 (16.9)	5431 (45.6)	7443 (31.2)
Grade 1	1409 (11.8)	2502 (21.0)	3911 (16.4)
Grade 2	543 (4.6)	2320 (19.5)	2863 (12.0)
Grade 3	60 (0.5)	609 (5.1)	669 (2.8)
Grade 4	0	0	0
Grade 3 or Above	60 (0.5)	609 (5.1)	669 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Ethnicity and Grade
Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11916) n (%)	mRNA-1273 (N=11915) n (%)	Total (N=23831) n (%)
Nausea/Vomiting - N1	11915	11915	23830
Any	1312 (11.0)	2717 (22.8)	4029 (16.9)
Grade 1	1050 (8.8)	2027 (17.0)	3077 (12.9)
Grade 2	244 (2.0)	667 (5.6)	911 (3.8)
Grade 3	18 (0.2)	22 (0.2)	40 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	18 (0.2)	23 (0.2)	41 (0.2)
Chills - N1	11915	11915	23830
Any	1091 (9.2)	5331 (44.7)	6422 (26.9)
Grade 1	838 (7.0)	2397 (20.1)	3235 (13.6)
Grade 2	234 (2.0)	2776 (23.3)	3010 (12.6)
Grade 3	19 (0.2)	158 (1.3)	177 (0.7)
Grade 4	0	0	0
Grade 3 or Above	19 (0.2)	158 (1.3)	177 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3456) n (%)	mRNA-1273 (N=3445) n (%)	Total (N=6901) n (%)
Solicited Adverse Reactions - N1	3456	3445	6901
Any Solicited Adverse Reactions	2092 (60.5)	3219 (93.4)	5311 (77.0)
95% CI	58.9, 62.2	92.6, 94.2	75.9, 77.9
Grade 1	1276 (36.9)	1278 (37.1)	2554 (37.0)
Grade 2	648 (18.8)	1251 (36.3)	1899 (27.5)
Grade 3	166 (4.8)	686 (19.9)	852 (12.3)
Grade 4	2 (<0.1)	4 (0.1)	6 (<0.1)
Grade 3 or Above	168 (4.9)	690 (20.0)	858 (12.4)
Solicited Local Adverse Reactions - N1	3456	3445	6901
Any Solicited Local Adverse Reactions	1014 (29.3)	3100 (90.0)	4114 (59.6)
95% CI	27.8, 30.9	88.9, 91.0	58.4, 60.8
Grade 1	920 (26.6)	2114 (61.4)	3034 (44.0)
Grade 2	44 (1.3)	691 (20.1)	735 (10.7)
Grade 3	50 (1.4)	295 (8.6)	345 (5.0)
Grade 4	0	0	0
Grade 3 or Above	50 (1.4)	295 (8.6)	345 (5.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3456) n (%)	mRNA-1273 (N=3445) n (%)	Total (N=6901) n (%)
Pain - N1	3456	3445	6901
Any	908 (26.3)	3081 (89.4)	3989 (57.8)
Grade 1	838 (24.2)	2299 (66.7)	3137 (45.5)
Grade 2	34 (1.0)	592 (17.2)	626 (9.1)
Grade 3	36 (1.0)	190 (5.5)	226 (3.3)
Grade 4	0	0	0
Grade 3 or Above	36 (1.0)	190 (5.5)	226 (3.3)
Erythema (Redness) - N1	3456	3444	6900
Any	35 (1.0)	344 (10.0)	379 (5.5)
Grade 1	24 (0.7)	142 (4.1)	166 (2.4)
Grade 2	3 (<0.1)	133 (3.9)	136 (2.0)
Grade 3	8 (0.2)	69 (2.0)	77 (1.1)
Grade 4	0	0	0
Grade 3 or Above	8 (0.2)	69 (2.0)	77 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3456) n (%)	mRNA-1273 (N=3445) n (%)	Total (N=6901) n (%)
Swelling (Hardness) - N1	3456	3444	6900
Any	37 (1.1)	522 (15.2)	559 (8.1)
Grade 1	25 (0.7)	268 (7.8)	293 (4.2)
Grade 2	8 (0.2)	182 (5.3)	190 (2.8)
Grade 3	4 (0.1)	72 (2.1)	76 (1.1)
Grade 4	0	0	0
Grade 3 or Above	4 (0.1)	72 (2.1)	76 (1.1)
Axillary Swelling or Tenderness - N1	3456	3444	6900
Any	281 (8.1)	648 (18.8)	929 (13.5)
Grade 1	257 (7.4)	540 (15.7)	797 (11.6)
Grade 2	12 (0.3)	71 (2.1)	83 (1.2)
Grade 3	12 (0.3)	37 (1.1)	49 (0.7)
Grade 4	0	0	0
Grade 3 or Above	12 (0.3)	37 (1.1)	49 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3456) n (%)	mRNA-1273 (N=3445) n (%)	Total (N=6901) n (%)
Solicited Systemic Adverse Reactions - N1	3456	3444	6900
Any Solicited Systemic Adverse Reactions	1880 (54.4)	2740 (79.6)	4620 (67.0)
95% CI	52.7, 56.1	78.2, 80.9	65.8, 68.1
Grade 1	1107 (32.0)	988 (28.7)	2095 (30.4)
Grade 2	641 (18.5)	1222 (35.5)	1863 (27.0)
Grade 3	130 (3.8)	526 (15.3)	656 (9.5)
Grade 4	2 (<0.1)	4 (0.1)	6 (<0.1)
Grade 3 or Above	132 (3.8)	530 (15.4)	662 (9.6)
Fever - N1	3456	3443	6899
Any	17 (0.5)	409 (11.9)	426 (6.2)
Grade 1	13 (0.4)	240 (7.0)	253 (3.7)
Grade 2	2 (<0.1)	119 (3.5)	121 (1.8)
Grade 3	0	46 (1.3)	46 (0.7)
Grade 4	2 (<0.1)	4 (0.1)	6 (<0.1)
Grade 3 or Above	2 (<0.1)	50 (1.5)	52 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3456) n (%)	mRNA-1273 (N=3445) n (%)	Total (N=6901) n (%)
Headache - N1	3456	3444	6900
Any	1238 (35.8)	2028 (58.9)	3266 (47.3)
Grade 1	951 (27.5)	1225 (35.6)	2176 (31.5)
Grade 2	209 (6.0)	601 (17.5)	810 (11.7)
Grade 3	78 (2.3)	202 (5.9)	280 (4.1)
Grade 4	0	0	0
Grade 3 or Above	78 (2.3)	202 (5.9)	280 (4.1)
Fatigue - N1	3456	3444	6900
Any	1296 (37.5)	2212 (64.2)	3508 (50.8)
Grade 1	751 (21.7)	842 (24.4)	1593 (23.1)
Grade 2	494 (14.3)	1065 (30.9)	1559 (22.6)
Grade 3	51 (1.5)	305 (8.9)	356 (5.2)
Grade 4	0	0	0
Grade 3 or Above	51 (1.5)	305 (8.9)	356 (5.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3456) n (%)	mRNA-1273 (N=3445) n (%)	Total (N=6901) n (%)
Myalgia - N1	3456	3444	6900
Any	823 (23.8)	1899 (55.1)	2722 (39.4)
Grade 1	567 (16.4)	830 (24.1)	1397 (20.2)
Grade 2	236 (6.8)	831 (24.1)	1067 (15.5)
Grade 3	20 (0.6)	238 (6.9)	258 (3.7)
Grade 4	0	0	0
Grade 3 or Above	20 (0.6)	238 (6.9)	258 (3.7)
Arthralgia - N1	3456	3444	6900
Any	733 (21.2)	1486 (43.1)	2219 (32.2)
Grade 1	495 (14.3)	720 (20.9)	1215 (17.6)
Grade 2	219 (6.3)	606 (17.6)	825 (12.0)
Grade 3	19 (0.5)	160 (4.6)	179 (2.6)
Grade 4	0	0	0
Grade 3 or Above	19 (0.5)	160 (4.6)	179 (2.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3456) n (%)	mRNA-1273 (N=3445) n (%)	Total (N=6901) n (%)
Nausea/Vomiting - N1	3456	3444	6900
Any	477 (13.8)	734 (21.3)	1211 (17.6)
Grade 1	386 (11.2)	546 (15.9)	932 (13.5)
Grade 2	88 (2.5)	175 (5.1)	263 (3.8)
Grade 3	3 (<0.1)	13 (0.4)	16 (0.2)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	13 (0.4)	16 (0.2)
Chills - N1	3456	3444	6900
Any	355 (10.3)	1270 (36.9)	1625 (23.6)
Grade 1	278 (8.0)	608 (17.7)	886 (12.8)
Grade 2	72 (2.1)	618 (17.9)	690 (10.0)
Grade 3	5 (0.1)	44 (1.3)	49 (0.7)
Grade 4	0	0	0
Grade 3 or Above	5 (0.1)	44 (1.3)	49 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Solicited Adverse Reactions - N1	11703	11734	23437
Any Solicited Adverse Reactions	7021 (60.0)	11183 (95.3)	18204 (77.7)
95% CI	59.1, 60.9	94.9, 95.7	77.1, 78.2
Grade 1	4528 (38.7)	3520 (30.0)	8048 (34.3)
Grade 2	1982 (16.9)	4930 (42.0)	6912 (29.5)
Grade 3	504 (4.3)	2718 (23.2)	3222 (13.7)
Grade 4	7 (<0.1)	15 (0.1)	22 (<0.1)
Grade 3 or Above	511 (4.4)	2733 (23.3)	3244 (13.8)
Solicited Local Adverse Reactions - N1	11702	11734	23436
Any Solicited Local Adverse Reactions	3454 (29.5)	10932 (93.2)	14386 (61.4)
95% CI	28.7, 30.4	92.7, 93.6	60.8, 62.0
Grade 1	3237 (27.7)	6889 (58.7)	10126 (43.2)
Grade 2	119 (1.0)	2918 (24.9)	3037 (13.0)
Grade 3	98 (0.8)	1125 (9.6)	1223 (5.2)
Grade 4	0	0	0
Grade 3 or Above	98 (0.8)	1125 (9.6)	1223 (5.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category / Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Pain - N1	11702	11734	23436
Any	3138 (26.8)	10888 (92.8)	14026 (59.8)
Grade 1	3004 (25.7)	7526 (64.1)	10530 (44.9)
Grade 2	77 (0.7)	2629 (22.4)	2706 (11.5)
Grade 3	57 (0.5)	733 (6.2)	790 (3.4)
Grade 4	0	0	0
Grade 3 or Above	57 (0.5)	733 (6.2)	790 (3.4)
Erythema (Redness) - N1	11702	11734	23436
Any	102 (0.9)	1205 (10.3)	1307 (5.6)
Grade 1	74 (0.6)	490 (4.2)	564 (2.4)
Grade 2	9 (<0.1)	460 (3.9)	469 (2.0)
Grade 3	19 (0.2)	255 (2.2)	274 (1.2)
Grade 4	0	0	0
Grade 3 or Above	19 (0.2)	255 (2.2)	274 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Swelling (Hardness) - N1	11702	11734	23436
Any	79 (0.7)	1727 (14.7)	1806 (7.7)
Grade 1	56 (0.5)	883 (7.5)	939 (4.0)
Grade 2	10 (<0.1)	589 (5.0)	599 (2.6)
Grade 3	13 (0.1)	255 (2.2)	268 (1.1)
Grade 4	0	0	0
Grade 3 or Above	13 (0.1)	255 (2.2)	268 (1.1)
Axillary Swelling or Tenderness - N1	11702	11734	23436
Any	820 (7.0)	2365 (20.2)	3185 (13.6)
Grade 1	747 (6.4)	1992 (17.0)	2739 (11.7)
Grade 2	39 (0.3)	299 (2.5)	338 (1.4)
Grade 3	34 (0.3)	74 (0.6)	108 (0.5)
Grade 4	0	0	0
Grade 3 or Above	34 (0.3)	74 (0.6)	108 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Solicited Systemic Adverse Reactions - N1	11703	11734	23437
Any Solicited Systemic Adverse Reactions	6237 (53.3)	10039 (85.6)	16276 (69.4)
95% CI	52.4, 54.2	84.9, 86.2	68.9, 70.0
Grade 1	3839 (32.8)	3052 (26.0)	6891 (29.4)
Grade 2	1959 (16.7)	4877 (41.6)	6836 (29.2)
Grade 3	432 (3.7)	2095 (17.9)	2527 (10.8)
Grade 4	7 (<0.1)	15 (0.1)	22 (<0.1)
Grade 3 or Above	439 (3.8)	2110 (18.0)	2549 (10.9)
Fever - N1	11702	11734	23436
Any	69 (0.6)	1941 (16.5)	2010 (8.6)
Grade 1	47 (0.4)	1168 (10.0)	1215 (5.2)
Grade 2	11 (<0.1)	593 (5.1)	604 (2.6)
Grade 3	4 (<0.1)	167 (1.4)	171 (0.7)
Grade 4	7 (<0.1)	13 (0.1)	20 (<0.1)
Grade 3 or Above	11 (<0.1)	180 (1.5)	191 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Headache - N1	11702	11734	23436
Any	4375 (37.4)	7816 (66.6)	12191 (52.0)
Grade 1	3404 (29.1)	4354 (37.1)	7758 (33.1)
Grade 2	705 (6.0)	2789 (23.8)	3494 (14.9)
Grade 3	266 (2.3)	673 (5.7)	939 (4.0)
Grade 4	0	0	0
Grade 3 or Above	266 (2.3)	673 (5.7)	939 (4.0)
Fatigue - N1	11702	11734	23436
Any	4253 (36.3)	8428 (71.8)	12681 (54.1)
Grade 1	2592 (22.2)	2960 (25.2)	5552 (23.7)
Grade 2	1510 (12.9)	4238 (36.1)	5748 (24.5)
Grade 3	151 (1.3)	1229 (10.5)	1380 (5.9)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	151 (1.3)	1230 (10.5)	1381 (5.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Myalgia - N1	11702	11734	23436
Any	2295 (19.6)	7449 (63.5)	9744 (41.6)
Grade 1	1628 (13.9)	2856 (24.3)	4484 (19.1)
Grade 2	589 (5.0)	3446 (29.4)	4035 (17.2)
Grade 3	78 (0.7)	1147 (9.8)	1225 (5.2)
Grade 4	0	0	0
Grade 3 or Above	78 (0.7)	1147 (9.8)	1225 (5.2)
Arthralgia - N1	11702	11734	23436
Any	1939 (16.6)	5569 (47.5)	7508 (32.0)
Grade 1	1378 (11.8)	2528 (21.5)	3906 (16.7)
Grade 2	499 (4.3)	2384 (20.3)	2883 (12.3)
Grade 3	62 (0.5)	656 (5.6)	718 (3.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	62 (0.5)	657 (5.6)	719 (3.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category / Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Nausea/Vomiting - N1	11702	11734	23436
Any	1246 (10.6)	2759 (23.5)	4005 (17.1)
Grade 1	994 (8.5)	2076 (17.7)	3070 (13.1)
Grade 2	231 (2.0)	665 (5.7)	896 (3.8)
Grade 3	21 (0.2)	17 (0.1)	38 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	21 (0.2)	18 (0.2)	39 (0.2)
Chills - N1	11702	11734	23436
Any	1118 (9.6)	5637 (48.0)	6755 (28.8)
Grade 1	854 (7.3)	2536 (21.6)	3390 (14.5)
Grade 2	238 (2.0)	2934 (25.0)	3172 (13.5)
Grade 3	26 (0.2)	167 (1.4)	193 (0.8)
Grade 4	0	0	0
Grade 3 or Above	26 (0.2)	167 (1.4)	193 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Chronic Lung Disease

Solicited Adverse Reaction Category Grade	Placebo (N=748) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1460) n (%)
Solicited Adverse Reactions - N1	748	712	1460
Any Solicited Adverse Reactions	495 (66.2)	671 (94.2)	1166 (79.9)
95% CI	62.7, 69.6	92.3, 95.8	77.7, 81.9
Grade 1	290 (38.8)	213 (29.9)	503 (34.5)
Grade 2	159 (21.3)	272 (38.2)	431 (29.5)
Grade 3	44 (5.9)	185 (26.0)	229 (15.7)
Grade 4	2 (0.3)	1 (0.1)	3 (0.2)
Grade 3 or Above	46 (6.1)	186 (26.1)	232 (15.9)
Solicited Local Adverse Reactions - N1	748	712	1460
Any Solicited Local Adverse Reactions	244 (32.6)	651 (91.4)	895 (61.3)
95% CI	29.3, 36.1	89.1, 93.4	58.7, 63.8
Grade 1	226 (30.2)	402 (56.5)	628 (43.0)
Grade 2	5 (0.7)	168 (23.6)	173 (11.8)
Grade 3	13 (1.7)	81 (11.4)	94 (6.4)
Grade 4	0	0	0
Grade 3 or Above	13 (1.7)	81 (11.4)	94 (6.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Chronic Lung Disease

Solicited Adverse Reaction Category Grade	Placebo (N=748) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1460) n (%)
Pain - N1	748	712	1460
Any	214 (28.6)	646 (90.7)	860 (58.9)
Grade 1	202 (27.0)	440 (61.8)	642 (44.0)
Grade 2	5 (0.7)	154 (21.6)	159 (10.9)
Grade 3	7 (0.9)	52 (7.3)	59 (4.0)
Grade 4	0	0	0
Grade 3 or Above	7 (0.9)	52 (7.3)	59 (4.0)
Erythema (Redness) - N1	748	712	1460
Any	7 (0.9)	71 (10.0)	78 (5.3)
Grade 1	3 (0.4)	22 (3.1)	25 (1.7)
Grade 2	1 (0.1)	33 (4.6)	34 (2.3)
Grade 3	3 (0.4)	16 (2.2)	19 (1.3)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	16 (2.2)	19 (1.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Chronic Lung Disease

Solicited Adverse Reaction Category Grade	Placebo (N=748) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1460) n (%)
Swelling (Hardness) - N1	748	712	1460
Any	8 (1.1)	120 (16.9)	128 (8.8)
Grade 1	4 (0.5)	54 (7.6)	58 (4.0)
Grade 2	1 (0.1)	45 (6.3)	46 (3.2)
Grade 3	3 (0.4)	21 (2.9)	24 (1.6)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	21 (2.9)	24 (1.6)
Axillary Swelling or Tenderness - N1	748	712	1460
Any	61 (8.2)	172 (24.2)	233 (16.0)
Grade 1	55 (7.4)	138 (19.4)	193 (13.2)
Grade 2	3 (0.4)	17 (2.4)	20 (1.4)
Grade 3	3 (0.4)	17 (2.4)	20 (1.4)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	17 (2.4)	20 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Chronic Lung Disease

Solicited Adverse Reaction Category Grade	Placebo (N=748) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1460) n (%)
Solicited Systemic Adverse Reactions - N1	748	712	1460
Any Solicited Systemic Adverse Reactions	442 (59.1)	597 (83.8)	1039 (71.2)
95% CI	55.5, 62.6	80.9, 86.5	68.8, 73.5
Grade 1	245 (32.8)	182 (25.6)	427 (29.2)
Grade 2	160 (21.4)	269 (37.8)	429 (29.4)
Grade 3	35 (4.7)	145 (20.4)	180 (12.3)
Grade 4	2 (0.3)	1 (0.1)	3 (0.2)
Grade 3 or Above	37 (4.9)	146 (20.5)	183 (12.5)
Fever - N1	748	712	1460
Any	6 (0.8)	84 (11.8)	90 (6.2)
Grade 1	3 (0.4)	48 (6.7)	51 (3.5)
Grade 2	1 (0.1)	26 (3.7)	27 (1.8)
Grade 3	0	9 (1.3)	9 (0.6)
Grade 4	2 (0.3)	1 (0.1)	3 (0.2)
Grade 3 or Above	2 (0.3)	10 (1.4)	12 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Chronic Lung Disease

Solicited Adverse Reaction Category Grade	Placebo (N=748) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1460) n (%)
Headache - N1	748	712	1460
Any	290 (38.8)	474 (66.6)	764 (52.3)
Grade 1	212 (28.3)	260 (36.5)	472 (32.3)
Grade 2	56 (7.5)	153 (21.5)	209 (14.3)
Grade 3	22 (2.9)	61 (8.6)	83 (5.7)
Grade 4	0	0	0
Grade 3 or Above	22 (2.9)	61 (8.6)	83 (5.7)
Fatigue - N1	748	712	1460
Any	307 (41.0)	489 (68.7)	796 (54.5)
Grade 1	166 (22.2)	162 (22.8)	328 (22.5)
Grade 2	125 (16.7)	242 (34.0)	367 (25.1)
Grade 3	16 (2.1)	85 (11.9)	101 (6.9)
Grade 4	0	0	0
Grade 3 or Above	16 (2.1)	85 (11.9)	101 (6.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Chronic Lung Disease

Solicited Adverse Reaction Category Grade	Placebo (N=748) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1460) n (%)
Myalgia - N1	748	712	1460
Any	195 (26.1)	432 (60.7)	627 (42.9)
Grade 1	123 (16.4)	162 (22.8)	285 (19.5)
Grade 2	67 (9.0)	192 (27.0)	259 (17.7)
Grade 3	5 (0.7)	78 (11.0)	83 (5.7)
Grade 4	0	0	0
Grade 3 or Above	5 (0.7)	78 (11.0)	83 (5.7)
Arthralgia - N1	748	712	1460
Any	162 (21.7)	334 (46.9)	496 (34.0)
Grade 1	103 (13.8)	128 (18.0)	231 (15.8)
Grade 2	53 (7.1)	160 (22.5)	213 (14.6)
Grade 3	6 (0.8)	46 (6.5)	52 (3.6)
Grade 4	0	0	0
Grade 3 or Above	6 (0.8)	46 (6.5)	52 (3.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Chronic Lung Disease

Solicited Adverse Reaction Category Grade	Placebo (N=748) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1460) n (%)
Nausea/Vomiting - N1	748	712	1460
Any	100 (13.4)	187 (26.3)	287 (19.7)
Grade 1	74 (9.9)	128 (18.0)	202 (13.8)
Grade 2	25 (3.3)	54 (7.6)	79 (5.4)
Grade 3	1 (0.1)	5 (0.7)	6 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	5 (0.7)	6 (0.4)
Chills - N1	748	712	1460
Any	103 (13.8)	299 (42.0)	402 (27.5)
Grade 1	75 (10.0)	122 (17.1)	197 (13.5)
Grade 2	27 (3.6)	157 (22.1)	184 (12.6)
Grade 3	1 (0.1)	20 (2.8)	21 (1.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	20 (2.8)	21 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Significant Cardiac Disease

Solicited Adverse Reaction Category Grade	Placebo (N=742) n (%)	mRNA-1273 (N=761) n (%)	Total (N=1503) n (%)
Solicited Adverse Reactions - N1	742	761	1503
Any Solicited Adverse Reactions	424 (57.1)	711 (93.4)	1135 (75.5)
95% CI	53.5, 60.7	91.4, 95.1	73.3, 77.7
Grade 1	287 (38.7)	293 (38.5)	580 (38.6)
Grade 2	105 (14.2)	281 (36.9)	386 (25.7)
Grade 3	32 (4.3)	137 (18.0)	169 (11.2)
Grade 4	0	0	0
Grade 3 or Above	32 (4.3)	137 (18.0)	169 (11.2)
Solicited Local Adverse Reactions - N1	742	761	1503
Any Solicited Local Adverse Reactions	187 (25.2)	675 (88.7)	862 (57.4)
95% CI	22.1, 28.5	86.2, 90.9	54.8, 59.9
Grade 1	170 (22.9)	478 (62.8)	648 (43.1)
Grade 2	8 (1.1)	137 (18.0)	145 (9.6)
Grade 3	9 (1.2)	60 (7.9)	69 (4.6)
Grade 4	0	0	0
Grade 3 or Above	9 (1.2)	60 (7.9)	69 (4.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Significant Cardiac Disease

Solicited Adverse Reaction Category Grade	Placebo (N=742) n (%)	mRNA-1273 (N=761) n (%)	Total (N=1503) n (%)
Pain - N1	742	761	1503
Any	169 (22.8)	670 (88.0)	839 (55.8)
Grade 1	157 (21.2)	524 (68.9)	681 (45.3)
Grade 2	4 (0.5)	107 (14.1)	111 (7.4)
Grade 3	8 (1.1)	39 (5.1)	47 (3.1)
Grade 4	0	0	0
Grade 3 or Above	8 (1.1)	39 (5.1)	47 (3.1)
Erythema (Redness) - N1	742	761	1503
Any	11 (1.5)	59 (7.8)	70 (4.7)
Grade 1	8 (1.1)	23 (3.0)	31 (2.1)
Grade 2	3 (0.4)	26 (3.4)	29 (1.9)
Grade 3	0	10 (1.3)	10 (0.7)
Grade 4	0	0	0
Grade 3 or Above	0	10 (1.3)	10 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Significant Cardiac Disease

Solicited Adverse Reaction Category Grade	Placebo (N=742) n (%)	mRNA-1273 (N=761) n (%)	Total (N=1503) n (%)
Swelling (Hardness) - N1	742	761	1503
Any	8 (1.1)	104 (13.7)	112 (7.5)
Grade 1	6 (0.8)	54 (7.1)	60 (4.0)
Grade 2	1 (0.1)	33 (4.3)	34 (2.3)
Grade 3	1 (0.1)	17 (2.2)	18 (1.2)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	17 (2.2)	18 (1.2)
Axillary Swelling or Tenderness - N1	742	761	1503
Any	44 (5.9)	120 (15.8)	164 (10.9)
Grade 1	42 (5.7)	106 (13.9)	148 (9.8)
Grade 2	1 (0.1)	6 (0.8)	7 (0.5)
Grade 3	1 (0.1)	8 (1.1)	9 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	8 (1.1)	9 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Significant Cardiac Disease

Solicited Adverse Reaction Category Grade	Placebo (N=742) n (%)	mRNA-1273 (N=761) n (%)	Total (N=1503) n (%)
Solicited Systemic Adverse Reactions - N1	742	761	1503
Any Solicited Systemic Adverse Reactions	371 (50.0)	603 (79.2)	974 (64.8)
95% CI	46.3, 53.7	76.2, 82.1	62.3, 67.2
Grade 1	245 (33.0)	230 (30.2)	475 (31.6)
Grade 2	102 (13.7)	269 (35.3)	371 (24.7)
Grade 3	24 (3.2)	104 (13.7)	128 (8.5)
Grade 4	0	0	0
Grade 3 or Above	24 (3.2)	104 (13.7)	128 (8.5)
Fever - N1	742	760	1502
Any	2 (0.3)	80 (10.5)	82 (5.5)
Grade 1	2 (0.3)	49 (6.4)	51 (3.4)
Grade 2	0	25 (3.3)	25 (1.7)
Grade 3	0	6 (0.8)	6 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	6 (0.8)	6 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Significant Cardiac Disease

Solicited Adverse Reaction Category Grade	Placebo (N=742) n (%)	mRNA-1273 (N=761) n (%)	Total (N=1503) n (%)
Headache - N1	742	761	1503
Any	223 (30.1)	409 (53.7)	632 (42.0)
Grade 1	187 (25.2)	262 (34.4)	449 (29.9)
Grade 2	24 (3.2)	116 (15.2)	140 (9.3)
Grade 3	12 (1.6)	31 (4.1)	43 (2.9)
Grade 4	0	0	0
Grade 3 or Above	12 (1.6)	31 (4.1)	43 (2.9)
Fatigue - N1	742	761	1503
Any	255 (34.4)	492 (64.7)	747 (49.7)
Grade 1	167 (22.5)	199 (26.1)	366 (24.4)
Grade 2	78 (10.5)	227 (29.8)	305 (20.3)
Grade 3	10 (1.3)	66 (8.7)	76 (5.1)
Grade 4	0	0	0
Grade 3 or Above	10 (1.3)	66 (8.7)	76 (5.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Significant Cardiac Disease

Solicited Adverse Reaction Category Grade	Placebo (N=742) n (%)	mRNA-1273 (N=761) n (%)	Total (N=1503) n (%)
Myalgia - N1	742	761	1503
Any	151 (20.4)	417 (54.8)	568 (37.8)
Grade 1	113 (15.2)	189 (24.8)	302 (20.1)
Grade 2	35 (4.7)	182 (23.9)	217 (14.4)
Grade 3	3 (0.4)	46 (6.0)	49 (3.3)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	46 (6.0)	49 (3.3)
Arthralgia - N1	742	761	1503
Any	145 (19.5)	323 (42.4)	468 (31.1)
Grade 1	102 (13.7)	169 (22.2)	271 (18.0)
Grade 2	40 (5.4)	124 (16.3)	164 (10.9)
Grade 3	3 (0.4)	30 (3.9)	33 (2.2)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	30 (3.9)	33 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Significant Cardiac Disease

Solicited Adverse Reaction Category Grade	Placebo (N=742) n (%)	mRNA-1273 (N=761) n (%)	Total (N=1503) n (%)
Nausea/Vomiting - N1	742	761	1503
Any	77 (10.4)	127 (16.7)	204 (13.6)
Grade 1	62 (8.4)	85 (11.2)	147 (9.8)
Grade 2	13 (1.8)	37 (4.9)	50 (3.3)
Grade 3	2 (0.3)	5 (0.7)	7 (0.5)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	5 (0.7)	7 (0.5)
Chills - N1	742	761	1503
Any	70 (9.4)	275 (36.1)	345 (23.0)
Grade 1	53 (7.1)	123 (16.2)	176 (11.7)
Grade 2	16 (2.2)	143 (18.8)	159 (10.6)
Grade 3	1 (0.1)	9 (1.2)	10 (0.7)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	9 (1.2)	10 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Severe Obesity

Solicited Adverse Reaction Category Grade	Placebo (N=1057) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2127) n (%)
Solicited Adverse Reactions - N1	1057	1070	2127
Any Solicited Adverse Reactions	673 (63.7)	994 (92.9)	1667 (78.4)
95% CI	60.7, 66.6	91.2, 94.4	76.6, 80.1
Grade 1	384 (36.3)	381 (35.6)	765 (36.0)
Grade 2	230 (21.8)	392 (36.6)	622 (29.2)
Grade 3	58 (5.5)	221 (20.7)	279 (13.1)
Grade 4	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	59 (5.6)	221 (20.7)	280 (13.2)
Solicited Local Adverse Reactions - N1	1057	1070	2127
Any Solicited Local Adverse Reactions	331 (31.3)	956 (89.3)	1287 (60.5)
95% CI	28.5, 34.2	87.3, 91.1	58.4, 62.6
Grade 1	302 (28.6)	627 (58.6)	929 (43.7)
Grade 2	17 (1.6)	238 (22.2)	255 (12.0)
Grade 3	12 (1.1)	91 (8.5)	103 (4.8)
Grade 4	0	0	0
Grade 3 or Above	12 (1.1)	91 (8.5)	103 (4.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Severe Obesity

Solicited Adverse Reaction Category Grade	Placebo (N=1057) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2127) n (%)
Pain - N1	1057	1070	2127
Any	305 (28.9)	953 (89.1)	1258 (59.1)
Grade 1	282 (26.7)	692 (64.7)	974 (45.8)
Grade 2	15 (1.4)	206 (19.3)	221 (10.4)
Grade 3	8 (0.8)	55 (5.1)	63 (3.0)
Grade 4	0	0	0
Grade 3 or Above	8 (0.8)	55 (5.1)	63 (3.0)
Erythema (Redness) - N1	1057	1070	2127
Any	8 (0.8)	149 (13.9)	157 (7.4)
Grade 1	5 (0.5)	63 (5.9)	68 (3.2)
Grade 2	0	59 (5.5)	59 (2.8)
Grade 3	3 (0.3)	27 (2.5)	30 (1.4)
Grade 4	0	0	0
Grade 3 or Above	3 (0.3)	27 (2.5)	30 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Severe Obesity

Solicited Adverse Reaction Category Grade	Placebo (N=1057) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2127) n (%)
Swelling (Hardness) - N1	1057	1070	2127
Any	15 (1.4)	185 (17.3)	200 (9.4)
Grade 1	11 (1.0)	90 (8.4)	101 (4.7)
Grade 2	3 (0.3)	74 (6.9)	77 (3.6)
Grade 3	1 (<0.1)	21 (2.0)	22 (1.0)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	21 (2.0)	22 (1.0)
Axillary Swelling or Tenderness - N1	1057	1070	2127
Any	91 (8.6)	212 (19.8)	303 (14.2)
Grade 1	84 (7.9)	171 (16.0)	255 (12.0)
Grade 2	6 (0.6)	34 (3.2)	40 (1.9)
Grade 3	1 (<0.1)	7 (0.7)	8 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	7 (0.7)	8 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Severe Obesity

Solicited Adverse Reaction Category Grade	Placebo (N=1057) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2127) n (%)
Solicited Systemic Adverse Reactions - N1	1057	1070	2127
Any Solicited Systemic Adverse Reactions	626 (59.2)	862 (80.6)	1488 (70.0)
95% CI	56.2, 62.2	78.1, 82.9	68.0, 71.9
Grade 1	345 (32.6)	306 (28.6)	651 (30.6)
Grade 2	232 (21.9)	382 (35.7)	614 (28.9)
Grade 3	48 (4.5)	174 (16.3)	222 (10.4)
Grade 4	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	49 (4.6)	174 (16.3)	223 (10.5)
Fever - N1	1057	1070	2127
Any	8 (0.8)	132 (12.3)	140 (6.6)
Grade 1	6 (0.6)	70 (6.5)	76 (3.6)
Grade 2	1 (<0.1)	40 (3.7)	41 (1.9)
Grade 3	0	22 (2.1)	22 (1.0)
Grade 4	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	1 (<0.1)	22 (2.1)	23 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Severe Obesity

Solicited Adverse Reaction Category Grade	Placebo (N=1057) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2127) n (%)
Headache - N1	1057	1070	2127
Any	444 (42.0)	663 (62.0)	1107 (52.0)
Grade 1	328 (31.0)	394 (36.8)	722 (33.9)
Grade 2	89 (8.4)	209 (19.5)	298 (14.0)
Grade 3	27 (2.6)	60 (5.6)	87 (4.1)
Grade 4	0	0	0
Grade 3 or Above	27 (2.6)	60 (5.6)	87 (4.1)
Fatigue - N1	1057	1070	2127
Any	430 (40.7)	692 (64.7)	1122 (52.8)
Grade 1	229 (21.7)	256 (23.9)	485 (22.8)
Grade 2	180 (17.0)	339 (31.7)	519 (24.4)
Grade 3	21 (2.0)	97 (9.1)	118 (5.5)
Grade 4	0	0	0
Grade 3 or Above	21 (2.0)	97 (9.1)	118 (5.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Severe Obesity

Solicited Adverse Reaction Category Grade	Placebo (N=1057) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2127) n (%)
Myalgia - N1	1057	1070	2127
Any	270 (25.5)	586 (54.8)	856 (40.2)
Grade 1	179 (16.9)	249 (23.3)	428 (20.1)
Grade 2	79 (7.5)	260 (24.3)	339 (15.9)
Grade 3	12 (1.1)	77 (7.2)	89 (4.2)
Grade 4	0	0	0
Grade 3 or Above	12 (1.1)	77 (7.2)	89 (4.2)
Arthralgia - N1	1057	1070	2127
Any	257 (24.3)	473 (44.2)	730 (34.3)
Grade 1	170 (16.1)	211 (19.7)	381 (17.9)
Grade 2	77 (7.3)	210 (19.6)	287 (13.5)
Grade 3	10 (0.9)	52 (4.9)	62 (2.9)
Grade 4	0	0	0
Grade 3 or Above	10 (0.9)	52 (4.9)	62 (2.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Severe Obesity

Solicited Adverse Reaction Category Grade	Placebo (N=1057) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2127) n (%)
Nausea/Vomiting - N1	1057	1070	2127
Any	177 (16.7)	253 (23.6)	430 (20.2)
Grade 1	140 (13.2)	200 (18.7)	340 (16.0)
Grade 2	37 (3.5)	50 (4.7)	87 (4.1)
Grade 3	0	3 (0.3)	3 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	3 (0.3)	3 (0.1)
Chills - N1	1057	1070	2127
Any	120 (11.4)	385 (36.0)	505 (23.7)
Grade 1	96 (9.1)	192 (17.9)	288 (13.5)
Grade 2	23 (2.2)	181 (16.9)	204 (9.6)
Grade 3	1 (<0.1)	12 (1.1)	13 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	12 (1.1)	13 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Diabetes

Solicited Adverse Reaction Category Grade	Placebo (N=1457) n (%)	mRNA-1273 (N=1458) n (%)	Total (N=2915) n (%)
Solicited Adverse Reactions - N1	1457	1458	2915
Any Solicited Adverse Reactions	819 (56.2)	1345 (92.2)	2164 (74.2)
95% CI	53.6, 58.8	90.8, 93.6	72.6, 75.8
Grade 1	518 (35.6)	611 (41.9)	1129 (38.7)
Grade 2	240 (16.5)	488 (33.5)	728 (25.0)
Grade 3	61 (4.2)	244 (16.7)	305 (10.5)
Grade 4	0	2 (0.1)	2 (<0.1)
Grade 3 or Above	61 (4.2)	246 (16.9)	307 (10.5)
Solicited Local Adverse Reactions - N1	1457	1458	2915
Any Solicited Local Adverse Reactions	404 (27.7)	1304 (89.4)	1708 (58.6)
95% CI	25.4, 30.1	87.7, 91.0	56.8, 60.4
Grade 1	358 (24.6)	939 (64.4)	1297 (44.5)
Grade 2	20 (1.4)	259 (17.8)	279 (9.6)
Grade 3	26 (1.8)	106 (7.3)	132 (4.5)
Grade 4	0	0	0
Grade 3 or Above	26 (1.8)	106 (7.3)	132 (4.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Diabetes

Solicited Adverse Reaction Category Grade	Placebo (N=1457) n (%)	mRNA-1273 (N=1458) n (%)	Total (N=2915) n (%)
Pain - N1	1457	1458	2915
Any	358 (24.6)	1293 (88.7)	1651 (56.6)
Grade 1	324 (22.2)	1003 (68.8)	1327 (45.5)
Grade 2	15 (1.0)	214 (14.7)	229 (7.9)
Grade 3	19 (1.3)	76 (5.2)	95 (3.3)
Grade 4	0	0	0
Grade 3 or Above	19 (1.3)	76 (5.2)	95 (3.3)
Erythema (Redness) - N1	1457	1457	2914
Any	14 (1.0)	108 (7.4)	122 (4.2)
Grade 1	9 (0.6)	42 (2.9)	51 (1.8)
Grade 2	0	43 (3.0)	43 (1.5)
Grade 3	5 (0.3)	23 (1.6)	28 (1.0)
Grade 4	0	0	0
Grade 3 or Above	5 (0.3)	23 (1.6)	28 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Diabetes

Solicited Adverse Reaction Category Grade	Placebo (N=1457) n (%)	mRNA-1273 (N=1458) n (%)	Total (N=2915) n (%)
Swelling (Hardness) - N1	1457	1457	2914
Any	13 (0.9)	176 (12.1)	189 (6.5)
Grade 1	8 (0.5)	100 (6.9)	108 (3.7)
Grade 2	4 (0.3)	59 (4.0)	63 (2.2)
Grade 3	1 (<0.1)	17 (1.2)	18 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	17 (1.2)	18 (0.6)
Axillary Swelling or Tenderness - N1	1457	1457	2914
Any	120 (8.2)	251 (17.2)	371 (12.7)
Grade 1	110 (7.5)	212 (14.6)	322 (11.1)
Grade 2	3 (0.2)	24 (1.6)	27 (0.9)
Grade 3	7 (0.5)	15 (1.0)	22 (0.8)
Grade 4	0	0	0
Grade 3 or Above	7 (0.5)	15 (1.0)	22 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Diabetes

Solicited Adverse Reaction Category Grade	Placebo (N=1457) n (%)	mRNA-1273 (N=1458) n (%)	Total (N=2915) n (%)
Solicited Systemic Adverse Reactions - N1	1457	1457	2914
Any Solicited Systemic Adverse Reactions	726 (49.8)	1094 (75.1)	1820 (62.5)
95% CI	47.2, 52.4	72.8, 77.3	60.7, 64.2
Grade 1	450 (30.9)	438 (30.1)	888 (30.5)
Grade 2	232 (15.9)	469 (32.2)	701 (24.1)
Grade 3	44 (3.0)	185 (12.7)	229 (7.9)
Grade 4	0	2 (0.1)	2 (<0.1)
Grade 3 or Above	44 (3.0)	187 (12.8)	231 (7.9)
Fever - N1	1457	1457	2914
Any	6 (0.4)	148 (10.2)	154 (5.3)
Grade 1	6 (0.4)	86 (5.9)	92 (3.2)
Grade 2	0	47 (3.2)	47 (1.6)
Grade 3	0	13 (0.9)	13 (0.4)
Grade 4	0	2 (0.1)	2 (<0.1)
Grade 3 or Above	0	15 (1.0)	15 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Diabetes

Solicited Adverse Reaction Category Grade	Placebo (N=1457) n (%)	mRNA-1273 (N=1458) n (%)	Total (N=2915) n (%)
Headache - N1	1457	1457	2914
Any	461 (31.6)	777 (53.3)	1238 (42.5)
Grade 1	369 (25.3)	495 (34.0)	864 (29.6)
Grade 2	63 (4.3)	205 (14.1)	268 (9.2)
Grade 3	29 (2.0)	77 (5.3)	106 (3.6)
Grade 4	0	0	0
Grade 3 or Above	29 (2.0)	77 (5.3)	106 (3.6)
Fatigue - N1	1457	1457	2914
Any	481 (33.0)	871 (59.8)	1352 (46.4)
Grade 1	289 (19.8)	373 (25.6)	662 (22.7)
Grade 2	179 (12.3)	393 (27.0)	572 (19.6)
Grade 3	13 (0.9)	105 (7.2)	118 (4.0)
Grade 4	0	0	0
Grade 3 or Above	13 (0.9)	105 (7.2)	118 (4.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Diabetes

Solicited Adverse Reaction Category Grade	Placebo (N=1457) n (%)	mRNA-1273 (N=1458) n (%)	Total (N=2915) n (%)
Myalgia - N1	1457	1457	2914
Any	341 (23.4)	748 (51.3)	1089 (37.4)
Grade 1	246 (16.9)	373 (25.6)	619 (21.2)
Grade 2	90 (6.2)	308 (21.1)	398 (13.7)
Grade 3	5 (0.3)	67 (4.6)	72 (2.5)
Grade 4	0	0	0
Grade 3 or Above	5 (0.3)	67 (4.6)	72 (2.5)
Arthralgia - N1	1457	1457	2914
Any	291 (20.0)	589 (40.4)	880 (30.2)
Grade 1	205 (14.1)	332 (22.8)	537 (18.4)
Grade 2	81 (5.6)	211 (14.5)	292 (10.0)
Grade 3	5 (0.3)	46 (3.2)	51 (1.8)
Grade 4	0	0	0
Grade 3 or Above	5 (0.3)	46 (3.2)	51 (1.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Diabetes

Solicited Adverse Reaction Category Grade	Placebo (N=1457) n (%)	mRNA-1273 (N=1458) n (%)	Total (N=2915) n (%)
Nausea/Vomiting - N1	1457	1457	2914
Any	184 (12.6)	275 (18.9)	459 (15.8)
Grade 1	156 (10.7)	208 (14.3)	364 (12.5)
Grade 2	27 (1.9)	59 (4.0)	86 (3.0)
Grade 3	1 (<0.1)	8 (0.5)	9 (0.3)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	8 (0.5)	9 (0.3)
Chills - N1	1457	1457	2914
Any	117 (8.0)	464 (31.8)	581 (19.9)
Grade 1	97 (6.7)	239 (16.4)	336 (11.5)
Grade 2	16 (1.1)	211 (14.5)	227 (7.8)
Grade 3	4 (0.3)	14 (1.0)	18 (0.6)
Grade 4	0	0	0
Grade 3 or Above	4 (0.3)	14 (1.0)	18 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Liver Disease

Solicited Adverse Reaction Category Grade	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Solicited Adverse Reactions - N1	96	104	200
Any Solicited Adverse Reactions	68 (70.8)	99 (95.2)	167 (83.5)
95% CI	60.7, 79.7	89.1, 98.4	77.6, 88.4
Grade 1	44 (45.8)	40 (38.5)	84 (42.0)
Grade 2	16 (16.7)	42 (40.4)	58 (29.0)
Grade 3	8 (8.3)	16 (15.4)	24 (12.0)
Grade 4	0	1 (1.0)	1 (0.5)
Grade 3 or Above	8 (8.3)	17 (16.3)	25 (12.5)
Solicited Local Adverse Reactions - N1	96	104	200
Any Solicited Local Adverse Reactions	41 (42.7)	96 (92.3)	137 (68.5)
95% CI	32.7, 53.2	85.4, 96.6	61.6, 74.9
Grade 1	39 (40.6)	74 (71.2)	113 (56.5)
Grade 2	0	15 (14.4)	15 (7.5)
Grade 3	2 (2.1)	7 (6.7)	9 (4.5)
Grade 4	0	0	0
Grade 3 or Above	2 (2.1)	7 (6.7)	9 (4.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Liver Disease

Solicited Adverse Reaction Category Grade	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Pain - N1	96	104	200
Any	37 (38.5)	96 (92.3)	133 (66.5)
Grade 1	36 (37.5)	77 (74.0)	113 (56.5)
Grade 2	0	16 (15.4)	16 (8.0)
Grade 3	1 (1.0)	3 (2.9)	4 (2.0)
Grade 4	0	0	0
Grade 3 or Above	1 (1.0)	3 (2.9)	4 (2.0)
Erythema (Redness) - N1	96	104	200
Any	2 (2.1)	6 (5.8)	8 (4.0)
Grade 1	2 (2.1)	3 (2.9)	5 (2.5)
Grade 2	0	3 (2.9)	3 (1.5)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Liver Disease

Solicited Adverse Reaction Category Grade	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Swelling (Hardness) - N1	96	104	200
Any	1 (1.0)	16 (15.4)	17 (8.5)
Grade 1	0	8 (7.7)	8 (4.0)
Grade 2	0	4 (3.8)	4 (2.0)
Grade 3	1 (1.0)	4 (3.8)	5 (2.5)
Grade 4	0	0	0
Grade 3 or Above	1 (1.0)	4 (3.8)	5 (2.5)
Axillary Swelling or Tenderness - N1	96	104	200
Any	9 (9.4)	18 (17.3)	27 (13.5)
Grade 1	9 (9.4)	14 (13.5)	23 (11.5)
Grade 2	0	4 (3.8)	4 (2.0)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Liver Disease

Solicited Adverse Reaction Category Grade	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Solicited Systemic Adverse Reactions - N1	96	104	200
Any Solicited Systemic Adverse Reactions	58 (60.4)	87 (83.7)	145 (72.5)
95% CI	49.9, 70.3	75.1, 90.2	65.8, 78.6
Grade 1	36 (37.5)	28 (26.9)	64 (32.0)
Grade 2	16 (16.7)	48 (46.2)	64 (32.0)
Grade 3	6 (6.3)	10 (9.6)	16 (8.0)
Grade 4	0	1 (1.0)	1 (0.5)
Grade 3 or Above	6 (6.3)	11 (10.6)	17 (8.5)
Fever - N1	96	104	200
Any	0	16 (15.4)	16 (8.0)
Grade 1	0	8 (7.7)	8 (4.0)
Grade 2	0	6 (5.8)	6 (3.0)
Grade 3	0	1 (1.0)	1 (0.5)
Grade 4	0	1 (1.0)	1 (0.5)
Grade 3 or Above	0	2 (1.9)	2 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Liver Disease

Solicited Adverse Reaction Category Grade	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Headache - N1	96	104	200
Any	39 (40.6)	64 (61.5)	103 (51.5)
Grade 1	25 (26.0)	39 (37.5)	64 (32.0)
Grade 2	12 (12.5)	22 (21.2)	34 (17.0)
Grade 3	2 (2.1)	3 (2.9)	5 (2.5)
Grade 4	0	0	0
Grade 3 or Above	2 (2.1)	3 (2.9)	5 (2.5)
Fatigue - N1	96	104	200
Any	39 (40.6)	70 (67.3)	109 (54.5)
Grade 1	26 (27.1)	24 (23.1)	50 (25.0)
Grade 2	10 (10.4)	39 (37.5)	49 (24.5)
Grade 3	3 (3.1)	7 (6.7)	10 (5.0)
Grade 4	0	0	0
Grade 3 or Above	3 (3.1)	7 (6.7)	10 (5.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Liver Disease

Solicited Adverse Reaction Category Grade	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Myalgia - N1	96	104	200
Any	27 (28.1)	60 (57.7)	87 (43.5)
Grade 1	22 (22.9)	25 (24.0)	47 (23.5)
Grade 2	4 (4.2)	30 (28.8)	34 (17.0)
Grade 3	1 (1.0)	5 (4.8)	6 (3.0)
Grade 4	0	0	0
Grade 3 or Above	1 (1.0)	5 (4.8)	6 (3.0)
Arthralgia - N1	96	104	200
Any	29 (30.2)	54 (51.9)	83 (41.5)
Grade 1	20 (20.8)	23 (22.1)	43 (21.5)
Grade 2	7 (7.3)	26 (25.0)	33 (16.5)
Grade 3	2 (2.1)	5 (4.8)	7 (3.5)
Grade 4	0	0	0
Grade 3 or Above	2 (2.1)	5 (4.8)	7 (3.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Liver Disease

Solicited Adverse Reaction Category Grade	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Nausea/Vomiting - N1	96	104	200
Any	18 (18.8)	23 (22.1)	41 (20.5)
Grade 1	15 (15.6)	18 (17.3)	33 (16.5)
Grade 2	2 (2.1)	5 (4.8)	7 (3.5)
Grade 3	1 (1.0)	0	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	1 (1.0)	0	1 (0.5)
Chills - N1	96	104	200
Any	15 (15.6)	42 (40.4)	57 (28.5)
Grade 1	12 (12.5)	19 (18.3)	31 (15.5)
Grade 2	2 (2.1)	23 (22.1)	25 (12.5)
Grade 3	1 (1.0)	0	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	1 (1.0)	0	1 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Human Immunodeficiency Virus Infection

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Solicited Adverse Reactions - N1	91	94	185
Any Solicited Adverse Reactions	48 (52.7)	85 (90.4)	133 (71.9)
95% CI	42.0, 63.3	82.6, 95.5	64.8, 78.2
Grade 1	23 (25.3)	39 (41.5)	62 (33.5)
Grade 2	23 (25.3)	30 (31.9)	53 (28.6)
Grade 3	2 (2.2)	16 (17.0)	18 (9.7)
Grade 4	0	0	0
Grade 3 or Above	2 (2.2)	16 (17.0)	18 (9.7)
Solicited Local Adverse Reactions - N1	91	94	185
Any Solicited Local Adverse Reactions	22 (24.2)	79 (84.0)	101 (54.6)
95% CI	15.8, 34.3	75.0, 90.8	47.1, 61.9
Grade 1	21 (23.1)	62 (66.0)	83 (44.9)
Grade 2	1 (1.1)	10 (10.6)	11 (5.9)
Grade 3	0	7 (7.4)	7 (3.8)
Grade 4	0	0	0
Grade 3 or Above	0	7 (7.4)	7 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Human Immunodeficiency Virus Infection

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Pain - N1	91	94	185
Any	19 (20.9)	79 (84.0)	98 (53.0)
Grade 1	18 (19.8)	67 (71.3)	85 (45.9)
Grade 2	1 (1.1)	9 (9.6)	10 (5.4)
Grade 3	0	3 (3.2)	3 (1.6)
Grade 4	0	0	0
Grade 3 or Above	0	3 (3.2)	3 (1.6)
Erythema (Redness) - N1	91	94	185
Any	1 (1.1)	5 (5.3)	6 (3.2)
Grade 1	1 (1.1)	2 (2.1)	3 (1.6)
Grade 2	0	0	0
Grade 3	0	3 (3.2)	3 (1.6)
Grade 4	0	0	0
Grade 3 or Above	0	3 (3.2)	3 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Human Immunodeficiency Virus Infection

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Swelling (Hardness) - N1	91	94	185
Any	3 (3.3)	11 (11.7)	14 (7.6)
Grade 1	3 (3.3)	7 (7.4)	10 (5.4)
Grade 2	0	2 (2.1)	2 (1.1)
Grade 3	0	2 (2.1)	2 (1.1)
Grade 4	0	0	0
Grade 3 or Above	0	2 (2.1)	2 (1.1)
Axillary Swelling or Tenderness - N1	91	94	185
Any	4 (4.4)	14 (14.9)	18 (9.7)
Grade 1	4 (4.4)	12 (12.8)	16 (8.6)
Grade 2	0	1 (1.1)	1 (0.5)
Grade 3	0	1 (1.1)	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.1)	1 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Human Immunodeficiency Virus Infection

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Solicited Systemic Adverse Reactions - N1	91	94	185
Any Solicited Systemic Adverse Reactions	44 (48.4)	70 (74.5)	114 (61.6)
95% CI	37.7, 59.1	64.4, 82.9	54.2, 68.7
Grade 1	19 (20.9)	28 (29.8)	47 (25.4)
Grade 2	23 (25.3)	31 (33.0)	54 (29.2)
Grade 3	2 (2.2)	11 (11.7)	13 (7.0)
Grade 4	0	0	0
Grade 3 or Above	2 (2.2)	11 (11.7)	13 (7.0)
Fever - N1	91	94	185
Any	2 (2.2)	11 (11.7)	13 (7.0)
Grade 1	2 (2.2)	5 (5.3)	7 (3.8)
Grade 2	0	5 (5.3)	5 (2.7)
Grade 3	0	1 (1.1)	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.1)	1 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Human Immunodeficiency Virus Infection

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Headache - N1	91	94	185
Any	32 (35.2)	51 (54.3)	83 (44.9)
Grade 1	24 (26.4)	33 (35.1)	57 (30.8)
Grade 2	7 (7.7)	12 (12.8)	19 (10.3)
Grade 3	1 (1.1)	6 (6.4)	7 (3.8)
Grade 4	0	0	0
Grade 3 or Above	1 (1.1)	6 (6.4)	7 (3.8)
Fatigue - N1	91	94	185
Any	34 (37.4)	55 (58.5)	89 (48.1)
Grade 1	16 (17.6)	25 (26.6)	41 (22.2)
Grade 2	17 (18.7)	24 (25.5)	41 (22.2)
Grade 3	1 (1.1)	6 (6.4)	7 (3.8)
Grade 4	0	0	0
Grade 3 or Above	1 (1.1)	6 (6.4)	7 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Human Immunodeficiency Virus Infection

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Myalgia - N1	91	94	185
Any	23 (25.3)	46 (48.9)	69 (37.3)
Grade 1	14 (15.4)	21 (22.3)	35 (18.9)
Grade 2	9 (9.9)	19 (20.2)	28 (15.1)
Grade 3	0	6 (6.4)	6 (3.2)
Grade 4	0	0	0
Grade 3 or Above	0	6 (6.4)	6 (3.2)
Arthralgia - N1	91	94	185
Any	19 (20.9)	34 (36.2)	53 (28.6)
Grade 1	9 (9.9)	22 (23.4)	31 (16.8)
Grade 2	10 (11.0)	11 (11.7)	21 (11.4)
Grade 3	0	1 (1.1)	1 (0.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.1)	1 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Individual Risk Factor for Severe COVID-19 at Screening and Grade
Solicited Safety Set

Risk Group: Human Immunodeficiency Virus Infection

Solicited Adverse Reaction Category Grade	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Nausea/Vomiting - N1	91	94	185
Any	10 (11.0)	22 (23.4)	32 (17.3)
Grade 1	9 (9.9)	17 (18.1)	26 (14.1)
Grade 2	1 (1.1)	5 (5.3)	6 (3.2)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	91	94	185
Any	11 (12.1)	35 (37.2)	46 (24.9)
Grade 1	6 (6.6)	24 (25.5)	30 (16.2)
Grade 2	5 (5.5)	11 (11.7)	16 (8.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: Not at Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Solicited Adverse Reactions - N1	11703	11734	23437
Any Solicited Adverse Reactions	7021 (60.0)	11183 (95.3)	18204 (77.7)
95% CI	59.1, 60.9	94.9, 95.7	77.1, 78.2
Grade 1	4528 (38.7)	3520 (30.0)	8048 (34.3)
Grade 2	1982 (16.9)	4930 (42.0)	6912 (29.5)
Grade 3	504 (4.3)	2718 (23.2)	3222 (13.7)
Grade 4	7 (<0.1)	15 (0.1)	22 (<0.1)
Grade 3 or Above	511 (4.4)	2733 (23.3)	3244 (13.8)
Solicited Local Adverse Reactions - N1	11702	11734	23436
Any Solicited Local Adverse Reactions	3454 (29.5)	10932 (93.2)	14386 (61.4)
95% CI	28.7, 30.4	92.7, 93.6	60.8, 62.0
Grade 1	3237 (27.7)	6889 (58.7)	10126 (43.2)
Grade 2	119 (1.0)	2918 (24.9)	3037 (13.0)
Grade 3	98 (0.8)	1125 (9.6)	1223 (5.2)
Grade 4	0	0	0
Grade 3 or Above	98 (0.8)	1125 (9.6)	1223 (5.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: Not at Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Pain - N1	11702	11734	23436
Any	3138 (26.8)	10888 (92.8)	14026 (59.8)
Grade 1	3004 (25.7)	7526 (64.1)	10530 (44.9)
Grade 2	77 (0.7)	2629 (22.4)	2706 (11.5)
Grade 3	57 (0.5)	733 (6.2)	790 (3.4)
Grade 4	0	0	0
Grade 3 or Above	57 (0.5)	733 (6.2)	790 (3.4)
Erythema (Redness) - N1	11702	11734	23436
Any	102 (0.9)	1205 (10.3)	1307 (5.6)
Grade 1	74 (0.6)	490 (4.2)	564 (2.4)
Grade 2	9 (<0.1)	460 (3.9)	469 (2.0)
Grade 3	19 (0.2)	255 (2.2)	274 (1.2)
Grade 4	0	0	0
Grade 3 or Above	19 (0.2)	255 (2.2)	274 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: Not at Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Swelling (Hardness) - N1	11702	11734	23436
Any	79 (0.7)	1727 (14.7)	1806 (7.7)
Grade 1	56 (0.5)	883 (7.5)	939 (4.0)
Grade 2	10 (<0.1)	589 (5.0)	599 (2.6)
Grade 3	13 (0.1)	255 (2.2)	268 (1.1)
Grade 4	0	0	0
Grade 3 or Above	13 (0.1)	255 (2.2)	268 (1.1)
Axillary Swelling or Tenderness - N1	11702	11734	23436
Any	820 (7.0)	2365 (20.2)	3185 (13.6)
Grade 1	747 (6.4)	1992 (17.0)	2739 (11.7)
Grade 2	39 (0.3)	299 (2.5)	338 (1.4)
Grade 3	34 (0.3)	74 (0.6)	108 (0.5)
Grade 4	0	0	0
Grade 3 or Above	34 (0.3)	74 (0.6)	108 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: Not at Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Solicited Systemic Adverse Reactions - N1	11703	11734	23437
Any Solicited Systemic Adverse Reactions	6237 (53.3)	10039 (85.6)	16276 (69.4)
95% CI	52.4, 54.2	84.9, 86.2	68.9, 70.0
Grade 1	3839 (32.8)	3052 (26.0)	6891 (29.4)
Grade 2	1959 (16.7)	4877 (41.6)	6836 (29.2)
Grade 3	432 (3.7)	2095 (17.9)	2527 (10.8)
Grade 4	7 (<0.1)	15 (0.1)	22 (<0.1)
Grade 3 or Above	439 (3.8)	2110 (18.0)	2549 (10.9)
Fever - N1	11702	11734	23436
Any	69 (0.6)	1941 (16.5)	2010 (8.6)
Grade 1	47 (0.4)	1168 (10.0)	1215 (5.2)
Grade 2	11 (<0.1)	593 (5.1)	604 (2.6)
Grade 3	4 (<0.1)	167 (1.4)	171 (0.7)
Grade 4	7 (<0.1)	13 (0.1)	20 (<0.1)
Grade 3 or Above	11 (<0.1)	180 (1.5)	191 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: Not at Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Headache - N1	11702	11734	23436
Any	4375 (37.4)	7816 (66.6)	12191 (52.0)
Grade 1	3404 (29.1)	4354 (37.1)	7758 (33.1)
Grade 2	705 (6.0)	2789 (23.8)	3494 (14.9)
Grade 3	266 (2.3)	673 (5.7)	939 (4.0)
Grade 4	0	0	0
Grade 3 or Above	266 (2.3)	673 (5.7)	939 (4.0)
Fatigue - N1	11702	11734	23436
Any	4253 (36.3)	8428 (71.8)	12681 (54.1)
Grade 1	2592 (22.2)	2960 (25.2)	5552 (23.7)
Grade 2	1510 (12.9)	4238 (36.1)	5748 (24.5)
Grade 3	151 (1.3)	1229 (10.5)	1380 (5.9)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	151 (1.3)	1230 (10.5)	1381 (5.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: Not at Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Myalgia - N1	11702	11734	23436
Any	2295 (19.6)	7449 (63.5)	9744 (41.6)
Grade 1	1628 (13.9)	2856 (24.3)	4484 (19.1)
Grade 2	589 (5.0)	3446 (29.4)	4035 (17.2)
Grade 3	78 (0.7)	1147 (9.8)	1225 (5.2)
Grade 4	0	0	0
Grade 3 or Above	78 (0.7)	1147 (9.8)	1225 (5.2)
Arthralgia - N1	11702	11734	23436
Any	1939 (16.6)	5569 (47.5)	7508 (32.0)
Grade 1	1378 (11.8)	2528 (21.5)	3906 (16.7)
Grade 2	499 (4.3)	2384 (20.3)	2883 (12.3)
Grade 3	62 (0.5)	656 (5.6)	718 (3.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	62 (0.5)	657 (5.6)	719 (3.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: Not at Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11703) n (%)	mRNA-1273 (N=11734) n (%)	Total (N=23437) n (%)
Nausea/Vomiting - N1	11702	11734	23436
Any	1246 (10.6)	2759 (23.5)	4005 (17.1)
Grade 1	994 (8.5)	2076 (17.7)	3070 (13.1)
Grade 2	231 (2.0)	665 (5.7)	896 (3.8)
Grade 3	21 (0.2)	17 (0.1)	38 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	21 (0.2)	18 (0.2)	39 (0.2)
Chills - N1	11702	11734	23436
Any	1118 (9.6)	5637 (48.0)	6755 (28.8)
Grade 1	854 (7.3)	2536 (21.6)	3390 (14.5)
Grade 2	238 (2.0)	2934 (25.0)	3172 (13.5)
Grade 3	26 (0.2)	167 (1.4)	193 (0.8)
Grade 4	0	0	0
Grade 3 or Above	26 (0.2)	167 (1.4)	193 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 1 Risk Factor

Solicited Adverse Reaction Category Grade	Placebo (N=2815) n (%)	mRNA-1273 (N=2788) n (%)	Total (N=5603) n (%)
Solicited Adverse Reactions - N1	2815	2788	5603
Any Solicited Adverse Reactions	1704 (60.5)	2618 (93.9)	4322 (77.1)
95% CI	58.7, 62.3	92.9, 94.8	76.0, 78.2
Grade 1	1034 (36.7)	1015 (36.4)	2049 (36.6)
Grade 2	537 (19.1)	1024 (36.7)	1561 (27.9)
Grade 3	132 (4.7)	575 (20.6)	707 (12.6)
Grade 4	1 (<0.1)	4 (0.1)	5 (<0.1)
Grade 3 or Above	133 (4.7)	579 (20.8)	712 (12.7)
Solicited Local Adverse Reactions - N1	2815	2788	5603
Any Solicited Local Adverse Reactions	818 (29.1)	2522 (90.5)	3340 (59.6)
95% CI	27.4, 30.8	89.3, 91.5	58.3, 60.9
Grade 1	742 (26.4)	1704 (61.1)	2446 (43.7)
Grade 2	37 (1.3)	570 (20.4)	607 (10.8)
Grade 3	39 (1.4)	248 (8.9)	287 (5.1)
Grade 4	0	0	0
Grade 3 or Above	39 (1.4)	248 (8.9)	287 (5.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 1 Risk Factor

Solicited Adverse Reaction Category Grade	Placebo (N=2815) n (%)	mRNA-1273 (N=2788) n (%)	Total (N=5603) n (%)
Pain - N1	2815	2788	5603
Any	733 (26.0)	2508 (90.0)	3241 (57.8)
Grade 1	675 (24.0)	1858 (66.6)	2533 (45.2)
Grade 2	28 (1.0)	492 (17.6)	520 (9.3)
Grade 3	30 (1.1)	158 (5.7)	188 (3.4)
Grade 4	0	0	0
Grade 3 or Above	30 (1.1)	158 (5.7)	188 (3.4)
Erythema (Redness) - N1	2815	2787	5602
Any	27 (1.0)	295 (10.6)	322 (5.7)
Grade 1	20 (0.7)	130 (4.7)	150 (2.7)
Grade 2	2 (<0.1)	105 (3.8)	107 (1.9)
Grade 3	5 (0.2)	60 (2.2)	65 (1.2)
Grade 4	0	0	0
Grade 3 or Above	5 (0.2)	60 (2.2)	65 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 1 Risk Factor

Solicited Adverse Reaction Category Grade	Placebo (N=2815) n (%)	mRNA-1273 (N=2788) n (%)	Total (N=5603) n (%)
Swelling (Hardness) - N1	2815	2787	5602
Any	27 (1.0)	444 (15.9)	471 (8.4)
Grade 1	19 (0.7)	228 (8.2)	247 (4.4)
Grade 2	7 (0.2)	151 (5.4)	158 (2.8)
Grade 3	1 (<0.1)	65 (2.3)	66 (1.2)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	65 (2.3)	66 (1.2)
Axillary Swelling or Tenderness - N1	2815	2787	5602
Any	236 (8.4)	527 (18.9)	763 (13.6)
Grade 1	213 (7.6)	441 (15.8)	654 (11.7)
Grade 2	11 (0.4)	57 (2.0)	68 (1.2)
Grade 3	12 (0.4)	29 (1.0)	41 (0.7)
Grade 4	0	0	0
Grade 3 or Above	12 (0.4)	29 (1.0)	41 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 1 Risk Factor

Solicited Adverse Reaction Category Grade	Placebo (N=2815) n (%)	mRNA-1273 (N=2788) n (%)	Total (N=5603) n (%)
Solicited Systemic Adverse Reactions - N1	2815	2787	5602
Any Solicited Systemic Adverse Reactions	1536 (54.6)	2237 (80.3)	3773 (67.4)
95% CI	52.7, 56.4	78.7, 81.7	66.1, 68.6
Grade 1	899 (31.9)	790 (28.3)	1689 (30.1)
Grade 2	531 (18.9)	1003 (36.0)	1534 (27.4)
Grade 3	105 (3.7)	440 (15.8)	545 (9.7)
Grade 4	1 (<0.1)	4 (0.1)	5 (<0.1)
Grade 3 or Above	106 (3.8)	444 (15.9)	550 (9.8)
Fever - N1	2815	2786	5601
Any	10 (0.4)	353 (12.7)	363 (6.5)
Grade 1	7 (0.2)	217 (7.8)	224 (4.0)
Grade 2	2 (<0.1)	92 (3.3)	94 (1.7)
Grade 3	0	40 (1.4)	40 (0.7)
Grade 4	1 (<0.1)	4 (0.1)	5 (<0.1)
Grade 3 or Above	1 (<0.1)	44 (1.6)	45 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 1 Risk Factor

Solicited Adverse Reaction Category Grade	Placebo (N=2815) n (%)	mRNA-1273 (N=2788) n (%)	Total (N=5603) n (%)
Headache - N1	2815	2787	5602
Any	1018 (36.2)	1669 (59.9)	2687 (48.0)
Grade 1	782 (27.8)	997 (35.8)	1779 (31.8)
Grade 2	172 (6.1)	500 (17.9)	672 (12.0)
Grade 3	64 (2.3)	172 (6.2)	236 (4.2)
Grade 4	0	0	0
Grade 3 or Above	64 (2.3)	172 (6.2)	236 (4.2)
Fatigue - N1	2815	2787	5602
Any	1072 (38.1)	1808 (64.9)	2880 (51.4)
Grade 1	624 (22.2)	664 (23.8)	1288 (23.0)
Grade 2	408 (14.5)	890 (31.9)	1298 (23.2)
Grade 3	40 (1.4)	254 (9.1)	294 (5.2)
Grade 4	0	0	0
Grade 3 or Above	40 (1.4)	254 (9.1)	294 (5.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 1 Risk Factor

Solicited Adverse Reaction Category Grade	Placebo (N=2815) n (%)	mRNA-1273 (N=2788) n (%)	Total (N=5603) n (%)
Myalgia - N1	2815	2787	5602
Any	658 (23.4)	1555 (55.8)	2213 (39.5)
Grade 1	451 (16.0)	665 (23.9)	1116 (19.9)
Grade 2	192 (6.8)	686 (24.6)	878 (15.7)
Grade 3	15 (0.5)	204 (7.3)	219 (3.9)
Grade 4	0	0	0
Grade 3 or Above	15 (0.5)	204 (7.3)	219 (3.9)
Arthralgia - N1	2815	2787	5602
Any	581 (20.6)	1207 (43.3)	1788 (31.9)
Grade 1	393 (14.0)	577 (20.7)	970 (17.3)
Grade 2	174 (6.2)	486 (17.4)	660 (11.8)
Grade 3	14 (0.5)	144 (5.2)	158 (2.8)
Grade 4	0	0	0
Grade 3 or Above	14 (0.5)	144 (5.2)	158 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 1 Risk Factor

Solicited Adverse Reaction Category Grade	Placebo (N=2815) n (%)	mRNA-1273 (N=2788) n (%)	Total (N=5603) n (%)
Nausea/Vomiting - N1	2815	2787	5602
Any	398 (14.1)	604 (21.7)	1002 (17.9)
Grade 1	322 (11.4)	452 (16.2)	774 (13.8)
Grade 2	74 (2.6)	144 (5.2)	218 (3.9)
Grade 3	2 (<0.1)	8 (0.3)	10 (0.2)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	8 (0.3)	10 (0.2)
Chills - N1	2815	2787	5602
Any	284 (10.1)	1067 (38.3)	1351 (24.1)
Grade 1	224 (8.0)	505 (18.1)	729 (13.0)
Grade 2	57 (2.0)	527 (18.9)	584 (10.4)
Grade 3	3 (0.1)	35 (1.3)	38 (0.7)
Grade 4	0	0	0
Grade 3 or Above	3 (0.1)	35 (1.3)	38 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 2 or More Risk Factors

Solicited Adverse Reaction Category Grade	Placebo (N=641) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1298) n (%)
Solicited Adverse Reactions - N1	641	657	1298
Any Solicited Adverse Reactions	388 (60.5)	601 (91.5)	989 (76.2)
95% CI	56.6, 64.3	89.1, 93.5	73.8, 78.5
Grade 1	242 (37.8)	263 (40.0)	505 (38.9)
Grade 2	111 (17.3)	227 (34.6)	338 (26.0)
Grade 3	34 (5.3)	111 (16.9)	145 (11.2)
Grade 4	1 (0.2)	0	1 (<0.1)
Grade 3 or Above	35 (5.5)	111 (16.9)	146 (11.2)
Solicited Local Adverse Reactions - N1	641	657	1298
Any Solicited Local Adverse Reactions	196 (30.6)	578 (88.0)	774 (59.6)
95% CI	27.0, 34.3	85.2, 90.4	56.9, 62.3
Grade 1	178 (27.8)	410 (62.4)	588 (45.3)
Grade 2	7 (1.1)	121 (18.4)	128 (9.9)
Grade 3	11 (1.7)	47 (7.2)	58 (4.5)
Grade 4	0	0	0
Grade 3 or Above	11 (1.7)	47 (7.2)	58 (4.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 2 or More Risk Factors

Solicited Adverse Reaction Category Grade	Placebo (N=641) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1298) n (%)
Pain - N1	641	657	1298
Any	175 (27.3)	573 (87.2)	748 (57.6)
Grade 1	163 (25.4)	441 (67.1)	604 (46.5)
Grade 2	6 (0.9)	100 (15.2)	106 (8.2)
Grade 3	6 (0.9)	32 (4.9)	38 (2.9)
Grade 4	0	0	0
Grade 3 or Above	6 (0.9)	32 (4.9)	38 (2.9)
Erythema (Redness) - N1	641	657	1298
Any	8 (1.2)	49 (7.5)	57 (4.4)
Grade 1	4 (0.6)	12 (1.8)	16 (1.2)
Grade 2	1 (0.2)	28 (4.3)	29 (2.2)
Grade 3	3 (0.5)	9 (1.4)	12 (0.9)
Grade 4	0	0	0
Grade 3 or Above	3 (0.5)	9 (1.4)	12 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 2 or More Risk Factors

Solicited Adverse Reaction Category Grade	Placebo (N=641) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1298) n (%)
Swelling (Hardness) - N1	641	657	1298
Any	10 (1.6)	78 (11.9)	88 (6.8)
Grade 1	6 (0.9)	40 (6.1)	46 (3.5)
Grade 2	1 (0.2)	31 (4.7)	32 (2.5)
Grade 3	3 (0.5)	7 (1.1)	10 (0.8)
Grade 4	0	0	0
Grade 3 or Above	3 (0.5)	7 (1.1)	10 (0.8)
Axillary Swelling or Tenderness - N1	641	657	1298
Any	45 (7.0)	121 (18.4)	166 (12.8)
Grade 1	44 (6.9)	99 (15.1)	143 (11.0)
Grade 2	1 (0.2)	14 (2.1)	15 (1.2)
Grade 3	0	8 (1.2)	8 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	8 (1.2)	8 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 2 or More Risk Factors

Solicited Adverse Reaction Category Grade	Placebo (N=641) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1298) n (%)
Solicited Systemic Adverse Reactions - N1	641	657	1298
Any Solicited Systemic Adverse Reactions	344 (53.7)	503 (76.6)	847 (65.3)
95% CI	49.7, 57.6	73.1, 79.8	62.6, 67.8
Grade 1	208 (32.4)	198 (30.1)	406 (31.3)
Grade 2	110 (17.2)	219 (33.3)	329 (25.3)
Grade 3	25 (3.9)	86 (13.1)	111 (8.6)
Grade 4	1 (0.2)	0	1 (<0.1)
Grade 3 or Above	26 (4.1)	86 (13.1)	112 (8.6)
Fever - N1	641	657	1298
Any	7 (1.1)	56 (8.5)	63 (4.9)
Grade 1	6 (0.9)	23 (3.5)	29 (2.2)
Grade 2	0	27 (4.1)	27 (2.1)
Grade 3	0	6 (0.9)	6 (0.5)
Grade 4	1 (0.2)	0	1 (<0.1)
Grade 3 or Above	1 (0.2)	6 (0.9)	7 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 2 or More Risk Factors

Solicited Adverse Reaction Category Grade	Placebo (N=641) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1298) n (%)
Headache - N1	641	657	1298
Any	220 (34.3)	359 (54.6)	579 (44.6)
Grade 1	169 (26.4)	228 (34.7)	397 (30.6)
Grade 2	37 (5.8)	101 (15.4)	138 (10.6)
Grade 3	14 (2.2)	30 (4.6)	44 (3.4)
Grade 4	0	0	0
Grade 3 or Above	14 (2.2)	30 (4.6)	44 (3.4)
Fatigue - N1	641	657	1298
Any	224 (34.9)	404 (61.5)	628 (48.4)
Grade 1	127 (19.8)	178 (27.1)	305 (23.5)
Grade 2	86 (13.4)	175 (26.6)	261 (20.1)
Grade 3	11 (1.7)	51 (7.8)	62 (4.8)
Grade 4	0	0	0
Grade 3 or Above	11 (1.7)	51 (7.8)	62 (4.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 2 or More Risk Factors

Solicited Adverse Reaction Category Grade	Placebo (N=641) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1298) n (%)
Myalgia - N1	641	657	1298
Any	165 (25.7)	344 (52.4)	509 (39.2)
Grade 1	116 (18.1)	165 (25.1)	281 (21.6)
Grade 2	44 (6.9)	145 (22.1)	189 (14.6)
Grade 3	5 (0.8)	34 (5.2)	39 (3.0)
Grade 4	0	0	0
Grade 3 or Above	5 (0.8)	34 (5.2)	39 (3.0)
Arthralgia - N1	641	657	1298
Any	152 (23.7)	279 (42.5)	431 (33.2)
Grade 1	102 (15.9)	143 (21.8)	245 (18.9)
Grade 2	45 (7.0)	120 (18.3)	165 (12.7)
Grade 3	5 (0.8)	16 (2.4)	21 (1.6)
Grade 4	0	0	0
Grade 3 or Above	5 (0.8)	16 (2.4)	21 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.4.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Screening and Grade
Solicited Safety Set

Risk Group: with 2 or More Risk Factors

Solicited Adverse Reaction Category Grade	Placebo (N=641) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1298) n (%)
Nausea/Vomiting - N1	641	657	1298
Any	79 (12.3)	130 (19.8)	209 (16.1)
Grade 1	64 (10.0)	94 (14.3)	158 (12.2)
Grade 2	14 (2.2)	31 (4.7)	45 (3.5)
Grade 3	1 (0.2)	5 (0.8)	6 (0.5)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	5 (0.8)	6 (0.5)
Chills - N1	641	657	1298
Any	71 (11.1)	203 (30.9)	274 (21.1)
Grade 1	54 (8.4)	103 (15.7)	157 (12.1)
Grade 2	15 (2.3)	91 (13.9)	106 (8.2)
Grade 3	2 (0.3)	9 (1.4)	11 (0.8)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	9 (1.4)	11 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Solicited Adverse Reactions - N1	11402	11406	22808
Any Solicited Adverse Reactions	5737 (50.3)	10262 (90.0)	15999 (70.1)
95% CI	49.4, 51.2	89.4, 90.5	69.5, 70.7
Grade 1	3993 (35.0)	6951 (60.9)	10944 (48.0)
Grade 2	1466 (12.9)	2601 (22.8)	4067 (17.8)
Grade 3	274 (2.4)	705 (6.2)	979 (4.3)
Grade 4	4 (<0.1)	5 (<0.1)	9 (<0.1)
Grade 3 or Above	278 (2.4)	710 (6.2)	988 (4.3)
Solicited Local Adverse Reactions - N1	11400	11402	22802
Any Solicited Local Adverse Reactions	2436 (21.4)	9961 (87.4)	12397 (54.4)
95% CI	20.6, 22.1	86.7, 88.0	53.7, 55.0
Grade 1	2334 (20.5)	8151 (71.5)	10485 (46.0)
Grade 2	63 (0.6)	1358 (11.9)	1421 (6.2)
Grade 3	39 (0.3)	452 (4.0)	491 (2.2)
Grade 4	0	0	0
Grade 3 or Above	39 (0.3)	452 (4.0)	491 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Pain - N1	11400	11402	22802
Any	2183 (19.1)	9908 (86.9)	12091 (53.0)
Grade 1	2116 (18.6)	8360 (73.3)	10476 (45.9)
Grade 2	44 (0.4)	1182 (10.4)	1226 (5.4)
Grade 3	23 (0.2)	366 (3.2)	389 (1.7)
Grade 4	0	0	0
Grade 3 or Above	23 (0.2)	366 (3.2)	389 (1.7)
Erythema (Redness) - N1	11400	11402	22802
Any	54 (0.5)	354 (3.1)	408 (1.8)
Grade 1	39 (0.3)	222 (1.9)	261 (1.1)
Grade 2	4 (<0.1)	98 (0.9)	102 (0.4)
Grade 3	11 (<0.1)	34 (0.3)	45 (0.2)
Grade 4	0	0	0
Grade 3 or Above	11 (<0.1)	34 (0.3)	45 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Swelling (Hardness) - N1	11400	11402	22802
Any	42 (0.4)	766 (6.7)	808 (3.5)
Grade 1	35 (0.3)	499 (4.4)	534 (2.3)
Grade 2	4 (<0.1)	205 (1.8)	209 (0.9)
Grade 3	3 (<0.1)	62 (0.5)	65 (0.3)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	62 (0.5)	65 (0.3)
Axillary Swelling or Tenderness - N1	11400	11402	22802
Any	567 (5.0)	1322 (11.6)	1889 (8.3)
Grade 1	534 (4.7)	1180 (10.3)	1714 (7.5)
Grade 2	20 (0.2)	105 (0.9)	125 (0.5)
Grade 3	13 (0.1)	37 (0.3)	50 (0.2)
Grade 4	0	0	0
Grade 3 or Above	13 (0.1)	37 (0.3)	50 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Solicited Systemic Adverse Reactions - N1	11402	11406	22808
Any Solicited Systemic Adverse Reactions	5063 (44.4)	6499 (57.0)	11562 (50.7)
95% CI	43.5, 45.3	56.1, 57.9	50.0, 51.3
Grade 1	3367 (29.5)	4079 (35.8)	7446 (32.6)
Grade 2	1442 (12.6)	2050 (18.0)	3492 (15.3)
Grade 3	250 (2.2)	365 (3.2)	615 (2.7)
Grade 4	4 (<0.1)	5 (<0.1)	9 (<0.1)
Grade 3 or Above	254 (2.2)	370 (3.2)	624 (2.7)
Fever - N1	11400	11404	22804
Any	37 (0.3)	102 (0.9)	139 (0.6)
Grade 1	25 (0.2)	66 (0.6)	91 (0.4)
Grade 2	7 (<0.1)	22 (0.2)	29 (0.1)
Grade 3	1 (<0.1)	10 (<0.1)	11 (<0.1)
Grade 4	4 (<0.1)	4 (<0.1)	8 (<0.1)
Grade 3 or Above	5 (<0.1)	14 (0.1)	19 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Headache - N1	11400	11402	22802
Any	3303 (29.0)	4028 (35.3)	7331 (32.2)
Grade 1	2668 (23.4)	3168 (27.8)	5836 (25.6)
Grade 2	472 (4.1)	640 (5.6)	1112 (4.9)
Grade 3	163 (1.4)	220 (1.9)	383 (1.7)
Grade 4	0	0	0
Grade 3 or Above	163 (1.4)	220 (1.9)	383 (1.7)
Fatigue - N1	11400	11402	22802
Any	3281 (28.8)	4385 (38.5)	7666 (33.6)
Grade 1	2100 (18.4)	2732 (24.0)	4832 (21.2)
Grade 2	1098 (9.6)	1531 (13.4)	2629 (11.5)
Grade 3	83 (0.7)	121 (1.1)	204 (0.9)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	83 (0.7)	122 (1.1)	205 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Myalgia - N1	11400	11402	22802
Any	1625 (14.3)	2700 (23.7)	4325 (19.0)
Grade 1	1200 (10.5)	1874 (16.4)	3074 (13.5)
Grade 2	387 (3.4)	752 (6.6)	1139 (5.0)
Grade 3	38 (0.3)	74 (0.6)	112 (0.5)
Grade 4	0	0	0
Grade 3 or Above	38 (0.3)	74 (0.6)	112 (0.5)
Arthralgia - N1	11400	11402	22802
Any	1327 (11.6)	1892 (16.6)	3219 (14.1)
Grade 1	966 (8.5)	1368 (12.0)	2334 (10.2)
Grade 2	331 (2.9)	476 (4.2)	807 (3.5)
Grade 3	30 (0.3)	47 (0.4)	77 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	30 (0.3)	48 (0.4)	78 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Nausea/Vomiting - N1	11400	11402	22802
Any	908 (8.0)	1068 (9.4)	1976 (8.7)
Grade 1	749 (6.6)	889 (7.8)	1638 (7.2)
Grade 2	151 (1.3)	173 (1.5)	324 (1.4)
Grade 3	8 (<0.1)	6 (<0.1)	14 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	6 (<0.1)	14 (<0.1)
Chills - N1	11400	11402	22802
Any	730 (6.4)	1050 (9.2)	1780 (7.8)
Grade 1	584 (5.1)	780 (6.8)	1364 (6.0)
Grade 2	138 (1.2)	253 (2.2)	391 (1.7)
Grade 3	8 (<0.1)	17 (0.1)	25 (0.1)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	17 (0.1)	25 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Solicited Adverse Reactions - N1	3749	3760	7509
Any Solicited Adverse Reactions	1548 (41.3)	3055 (81.3)	4603 (61.3)
95% CI	39.7, 42.9	80.0, 82.5	60.2, 62.4
Grade 1	1141 (30.4)	2378 (63.2)	3519 (46.9)
Grade 2	316 (8.4)	533 (14.2)	849 (11.3)
Grade 3	89 (2.4)	144 (3.8)	233 (3.1)
Grade 4	2 (<0.1)	0	2 (<0.1)
Grade 3 or Above	91 (2.4)	144 (3.8)	235 (3.1)
Solicited Local Adverse Reactions - N1	3747	3760	7507
Any Solicited Local Adverse Reactions	573 (15.3)	2804 (74.6)	3377 (45.0)
95% CI	14.2, 16.5	73.2, 76.0	43.9, 46.1
Grade 1	508 (13.6)	2574 (68.5)	3082 (41.1)
Grade 2	26 (0.7)	153 (4.1)	179 (2.4)
Grade 3	39 (1.0)	77 (2.0)	116 (1.5)
Grade 4	0	0	0
Grade 3 or Above	39 (1.0)	77 (2.0)	116 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Pain - N1	3747	3760	7507
Any	482 (12.9)	2780 (73.9)	3262 (43.5)
Grade 1	435 (11.6)	2625 (69.8)	3060 (40.8)
Grade 2	15 (0.4)	105 (2.8)	120 (1.6)
Grade 3	32 (0.9)	50 (1.3)	82 (1.1)
Grade 4	0	0	0
Grade 3 or Above	32 (0.9)	50 (1.3)	82 (1.1)
Erythema (Redness) - N1	3747	3760	7507
Any	23 (0.6)	91 (2.4)	114 (1.5)
Grade 1	18 (0.5)	59 (1.6)	77 (1.0)
Grade 2	3 (<0.1)	24 (0.6)	27 (0.4)
Grade 3	2 (<0.1)	8 (0.2)	10 (0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	8 (0.2)	10 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Swelling (Hardness) - N1	3747	3760	7507
Any	23 (0.6)	169 (4.5)	192 (2.6)
Grade 1	15 (0.4)	109 (2.9)	124 (1.7)
Grade 2	5 (0.1)	40 (1.1)	45 (0.6)
Grade 3	3 (<0.1)	20 (0.5)	23 (0.3)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	20 (0.5)	23 (0.3)
Axillary Swelling or Tenderness - N1	3747	3760	7507
Any	155 (4.1)	231 (6.1)	386 (5.1)
Grade 1	134 (3.6)	214 (5.7)	348 (4.6)
Grade 2	7 (0.2)	5 (0.1)	12 (0.2)
Grade 3	14 (0.4)	12 (0.3)	26 (0.3)
Grade 4	0	0	0
Grade 3 or Above	14 (0.4)	12 (0.3)	26 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Solicited Systemic Adverse Reactions - N1	3749	3760	7509
Any Solicited Systemic Adverse Reactions	1334 (35.6)	1817 (48.3)	3151 (42.0)
95% CI	34.0, 37.1	46.7, 49.9	40.8, 43.1
Grade 1	967 (25.8)	1279 (34.0)	2246 (29.9)
Grade 2	304 (8.1)	454 (12.1)	758 (10.1)
Grade 3	61 (1.6)	84 (2.2)	145 (1.9)
Grade 4	2 (<0.1)	0	2 (<0.1)
Grade 3 or Above	63 (1.7)	84 (2.2)	147 (2.0)
Fever - N1	3749	3759	7508
Any	7 (0.2)	10 (0.3)	17 (0.2)
Grade 1	3 (<0.1)	7 (0.2)	10 (0.1)
Grade 2	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	2 (<0.1)	0	2 (<0.1)
Grade 3 or Above	3 (<0.1)	1 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Headache - N1	3746	3760	7506
Any	723 (19.3)	922 (24.5)	1645 (21.9)
Grade 1	629 (16.8)	779 (20.7)	1408 (18.8)
Grade 2	60 (1.6)	90 (2.4)	150 (2.0)
Grade 3	34 (0.9)	53 (1.4)	87 (1.2)
Grade 4	0	0	0
Grade 3 or Above	34 (0.9)	53 (1.4)	87 (1.2)
Fatigue - N1	3746	3760	7506
Any	852 (22.7)	1251 (33.3)	2103 (28.0)
Grade 1	605 (16.2)	853 (22.7)	1458 (19.4)
Grade 2	225 (6.0)	368 (9.8)	593 (7.9)
Grade 3	22 (0.6)	30 (0.8)	52 (0.7)
Grade 4	0	0	0
Grade 3 or Above	22 (0.6)	30 (0.8)	52 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Myalgia - N1	3746	3760	7506
Any	444 (11.9)	742 (19.7)	1186 (15.8)
Grade 1	360 (9.6)	568 (15.1)	928 (12.4)
Grade 2	75 (2.0)	157 (4.2)	232 (3.1)
Grade 3	9 (0.2)	17 (0.5)	26 (0.3)
Grade 4	0	0	0
Grade 3 or Above	9 (0.2)	17 (0.5)	26 (0.3)
Arthralgia - N1	3746	3760	7506
Any	457 (12.2)	618 (16.4)	1075 (14.3)
Grade 1	367 (9.8)	474 (12.6)	841 (11.2)
Grade 2	82 (2.2)	131 (3.5)	213 (2.8)
Grade 3	8 (0.2)	13 (0.3)	21 (0.3)
Grade 4	0	0	0
Grade 3 or Above	8 (0.2)	13 (0.3)	21 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Nausea/Vomiting - N1	3746	3760	7506
Any	167 (4.5)	194 (5.2)	361 (4.8)
Grade 1	138 (3.7)	158 (4.2)	296 (3.9)
Grade 2	24 (0.6)	32 (0.9)	56 (0.7)
Grade 3	5 (0.1)	4 (0.1)	9 (0.1)
Grade 4	0	0	0
Grade 3 or Above	5 (0.1)	4 (0.1)	9 (0.1)
Chills - N1	3746	3760	7506
Any	148 (4.0)	201 (5.3)	349 (4.6)
Grade 1	122 (3.3)	158 (4.2)	280 (3.7)
Grade 2	20 (0.5)	36 (1.0)	56 (0.7)
Grade 3	6 (0.2)	7 (0.2)	13 (0.2)
Grade 4	0	0	0
Grade 3 or Above	6 (0.2)	7 (0.2)	13 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Adverse Reactions - N1	11408	11413	22821
Any Solicited Adverse Reactions	7088 (62.1)	10889 (95.4)	17977 (78.8)
95% CI	61.2, 63.0	95.0, 95.8	78.2, 79.3
Grade 1	4452 (39.0)	3250 (28.5)	7702 (33.7)
Grade 2	2130 (18.7)	4853 (42.5)	6983 (30.6)
Grade 3	500 (4.4)	2769 (24.3)	3269 (14.3)
Grade 4	6 (<0.1)	17 (0.1)	23 (0.1)
Grade 3 or Above	506 (4.4)	2786 (24.4)	3292 (14.4)
Solicited Local Adverse Reactions - N1	11407	11413	22820
Any Solicited Local Adverse Reactions	3590 (31.5)	10680 (93.6)	14270 (62.5)
95% CI	30.6, 32.3	93.1, 94.0	61.9, 63.2
Grade 1	3386 (29.7)	6490 (56.9)	9876 (43.3)
Grade 2	124 (1.1)	3057 (26.8)	3181 (13.9)
Grade 3	80 (0.7)	1133 (9.9)	1213 (5.3)
Grade 4	0	0	0
Grade 3 or Above	80 (0.7)	1133 (9.9)	1213 (5.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Pain - N1	11407	11413	22820
Any	3283 (28.8)	10643 (93.3)	13926 (61.0)
Grade 1	3156 (27.7)	7082 (62.1)	10238 (44.9)
Grade 2	84 (0.7)	2783 (24.4)	2867 (12.6)
Grade 3	43 (0.4)	778 (6.8)	821 (3.6)
Grade 4	0	0	0
Grade 3 or Above	43 (0.4)	778 (6.8)	821 (3.6)
Erythema (Redness) - N1	11407	11412	22819
Any	100 (0.9)	1202 (10.5)	1302 (5.7)
Grade 1	69 (0.6)	491 (4.3)	560 (2.5)
Grade 2	9 (<0.1)	472 (4.1)	481 (2.1)
Grade 3	22 (0.2)	239 (2.1)	261 (1.1)
Grade 4	0	0	0
Grade 3 or Above	22 (0.2)	239 (2.1)	261 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Swelling (Hardness) - N1	11407	11412	22819
Any	82 (0.7)	1761 (15.4)	1843 (8.1)
Grade 1	62 (0.5)	910 (8.0)	972 (4.3)
Grade 2	13 (0.1)	613 (5.4)	626 (2.7)
Grade 3	7 (<0.1)	238 (2.1)	245 (1.1)
Grade 4	0	0	0
Grade 3 or Above	7 (<0.1)	238 (2.1)	245 (1.1)
Axillary Swelling or Tenderness - N1	11407	11412	22819
Any	878 (7.7)	2536 (22.2)	3414 (15.0)
Grade 1	810 (7.1)	2117 (18.6)	2927 (12.8)
Grade 2	43 (0.4)	338 (3.0)	381 (1.7)
Grade 3	25 (0.2)	81 (0.7)	106 (0.5)
Grade 4	0	0	0
Grade 3 or Above	25 (0.2)	81 (0.7)	106 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Systemic Adverse Reactions - N1	11408	11412	22820
Any Solicited Systemic Adverse Reactions	6351 (55.7)	9825 (86.1)	16176 (70.9)
95% CI	54.8, 56.6	85.4, 86.7	70.3, 71.5
Grade 1	3792 (33.2)	2837 (24.9)	6629 (29.0)
Grade 2	2108 (18.5)	4803 (42.1)	6911 (30.3)
Grade 3	445 (3.9)	2168 (19.0)	2613 (11.5)
Grade 4	6 (<0.1)	17 (0.1)	23 (0.1)
Grade 3 or Above	451 (4.0)	2185 (19.1)	2636 (11.6)
Fever - N1	11407	11411	22818
Any	74 (0.6)	1977 (17.3)	2051 (9.0)
Grade 1	54 (0.5)	1153 (10.1)	1207 (5.3)
Grade 2	11 (<0.1)	613 (5.4)	624 (2.7)
Grade 3	3 (<0.1)	195 (1.7)	198 (0.9)
Grade 4	6 (<0.1)	16 (0.1)	22 (<0.1)
Grade 3 or Above	9 (<0.1)	211 (1.8)	220 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Headache - N1	11407	11412	22819
Any	4534 (39.7)	7835 (68.7)	12369 (54.2)
Grade 1	3447 (30.2)	4215 (36.9)	7662 (33.6)
Grade 2	808 (7.1)	2893 (25.4)	3701 (16.2)
Grade 3	279 (2.4)	727 (6.4)	1006 (4.4)
Grade 4	0	0	0
Grade 3 or Above	279 (2.4)	727 (6.4)	1006 (4.4)
Fatigue - N1	11407	11412	22819
Any	4346 (38.1)	8200 (71.9)	12546 (55.0)
Grade 1	2555 (22.4)	2776 (24.3)	5331 (23.4)
Grade 2	1630 (14.3)	4166 (36.5)	5796 (25.4)
Grade 3	161 (1.4)	1257 (11.0)	1418 (6.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	161 (1.4)	1258 (11.0)	1419 (6.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Myalgia - N1	11407	11412	22819
Any	2433 (21.3)	7397 (64.8)	9830 (43.1)
Grade 1	1674 (14.7)	2728 (23.9)	4402 (19.3)
Grade 2	680 (6.0)	3503 (30.7)	4183 (18.3)
Grade 3	79 (0.7)	1166 (10.2)	1245 (5.5)
Grade 4	0	0	0
Grade 3 or Above	79 (0.7)	1166 (10.2)	1245 (5.5)
Arthralgia - N1	11407	11412	22819
Any	2001 (17.5)	5541 (48.6)	7542 (33.1)
Grade 1	1375 (12.1)	2414 (21.2)	3789 (16.6)
Grade 2	560 (4.9)	2444 (21.4)	3004 (13.2)
Grade 3	66 (0.6)	682 (6.0)	748 (3.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	66 (0.6)	683 (6.0)	749 (3.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Nausea/Vomiting - N1	11407	11412	22819
Any	1448 (12.7)	2929 (25.7)	4377 (19.2)
Grade 1	1155 (10.1)	2187 (19.2)	3342 (14.6)
Grade 2	277 (2.4)	725 (6.4)	1002 (4.4)
Grade 3	16 (0.1)	17 (0.1)	33 (0.1)
Grade 4	0	0	0
Grade 3 or Above	16 (0.1)	17 (0.1)	33 (0.1)
Chills - N1	11407	11412	22819
Any	1207 (10.6)	5676 (49.7)	6883 (30.2)
Grade 1	917 (8.0)	2494 (21.9)	3411 (14.9)
Grade 2	267 (2.3)	3003 (26.3)	3270 (14.3)
Grade 3	23 (0.2)	179 (1.6)	202 (0.9)
Grade 4	0	0	0
Grade 3 or Above	23 (0.2)	179 (1.6)	202 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=65 and <75 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3010) n (%)	mRNA-1273 (N=3109) n (%)	Total (N=6119) n (%)
Solicited Adverse Reactions - N1	3010	3109	6119
Any Solicited Adverse Reactions	1633 (54.3)	2917 (93.8)	4550 (74.4)
95% CI	52.5, 56.0	92.9, 94.6	73.2, 75.4
Grade 1	1116 (37.1)	1279 (41.1)	2395 (39.1)
Grade 2	392 (13.0)	1116 (35.9)	1508 (24.6)
Grade 3	122 (4.1)	520 (16.7)	642 (10.5)
Grade 4	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 3 or Above	125 (4.2)	522 (16.8)	647 (10.6)
Solicited Local Adverse Reactions - N1	3010	3109	6119
Any Solicited Local Adverse Reactions	708 (23.5)	2797 (90.0)	3505 (57.3)
95% CI	22.0, 25.1	88.9, 91.0	56.0, 58.5
Grade 1	640 (21.3)	2089 (67.2)	2729 (44.6)
Grade 2	30 (1.0)	475 (15.3)	505 (8.3)
Grade 3	38 (1.3)	233 (7.5)	271 (4.4)
Grade 4	0	0	0
Grade 3 or Above	38 (1.3)	233 (7.5)	271 (4.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=65 and <75 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3010) n (%)	mRNA-1273 (N=3109) n (%)	Total (N=6119) n (%)
Pain - N1	3010	3109	6119
Any	613 (20.4)	2780 (89.4)	3393 (55.5)
Grade 1	568 (18.9)	2287 (73.6)	2855 (46.7)
Grade 2	21 (0.7)	374 (12.0)	395 (6.5)
Grade 3	24 (0.8)	119 (3.8)	143 (2.3)
Grade 4	0	0	0
Grade 3 or Above	24 (0.8)	119 (3.8)	143 (2.3)
Erythema (Redness) - N1	3010	3109	6119
Any	30 (1.0)	290 (9.3)	320 (5.2)
Grade 1	25 (0.8)	117 (3.8)	142 (2.3)
Grade 2	1 (<0.1)	103 (3.3)	104 (1.7)
Grade 3	4 (0.1)	70 (2.3)	74 (1.2)
Grade 4	0	0	0
Grade 3 or Above	4 (0.1)	70 (2.3)	74 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=65 and <75 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3010) n (%)	mRNA-1273 (N=3109) n (%)	Total (N=6119) n (%)
Swelling (Hardness) - N1	3010	3109	6119
Any	29 (1.0)	408 (13.1)	437 (7.1)
Grade 1	15 (0.5)	202 (6.5)	217 (3.5)
Grade 2	4 (0.1)	136 (4.4)	140 (2.3)
Grade 3	10 (0.3)	70 (2.3)	80 (1.3)
Grade 4	0	0	0
Grade 3 or Above	10 (0.3)	70 (2.3)	80 (1.3)
Axillary Swelling or Tenderness - N1	3010	3109	6119
Any	155 (5.1)	397 (12.8)	552 (9.0)
Grade 1	144 (4.8)	345 (11.1)	489 (8.0)
Grade 2	5 (0.2)	29 (0.9)	34 (0.6)
Grade 3	6 (0.2)	23 (0.7)	29 (0.5)
Grade 4	0	0	0
Grade 3 or Above	6 (0.2)	23 (0.7)	29 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=65 and <75 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3010) n (%)	mRNA-1273 (N=3109) n (%)	Total (N=6119) n (%)
Solicited Systemic Adverse Reactions - N1	3010	3109	6119
Any Solicited Systemic Adverse Reactions	1420 (47.2)	2451 (78.8)	3871 (63.3)
95% CI	45.4, 49.0	77.4, 80.3	62.0, 64.5
Grade 1	944 (31.4)	993 (31.9)	1937 (31.7)
Grade 2	385 (12.8)	1081 (34.8)	1466 (24.0)
Grade 3	88 (2.9)	375 (12.1)	463 (7.6)
Grade 4	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 3 or Above	91 (3.0)	377 (12.1)	468 (7.6)
Fever - N1	3010	3109	6119
Any	12 (0.4)	323 (10.4)	335 (5.5)
Grade 1	6 (0.2)	219 (7.0)	225 (3.7)
Grade 2	2 (<0.1)	88 (2.8)	90 (1.5)
Grade 3	1 (<0.1)	15 (0.5)	16 (0.3)
Grade 4	3 (<0.1)	1 (<0.1)	4 (<0.1)
Grade 3 or Above	4 (0.1)	16 (0.5)	20 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=65 and <75 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3010) n (%)	mRNA-1273 (N=3109) n (%)	Total (N=6119) n (%)
Headache - N1	3010	3109	6119
Any	885 (29.4)	1718 (55.3)	2603 (42.5)
Grade 1	754 (25.0)	1159 (37.3)	1913 (31.3)
Grade 2	86 (2.9)	426 (13.7)	512 (8.4)
Grade 3	45 (1.5)	133 (4.3)	178 (2.9)
Grade 4	0	0	0
Grade 3 or Above	45 (1.5)	133 (4.3)	178 (2.9)
Fatigue - N1	3010	3109	6119
Any	947 (31.5)	2021 (65.0)	2968 (48.5)
Grade 1	622 (20.7)	850 (27.3)	1472 (24.1)
Grade 2	290 (9.6)	943 (30.3)	1233 (20.2)
Grade 3	35 (1.2)	228 (7.3)	263 (4.3)
Grade 4	0	0	0
Grade 3 or Above	35 (1.2)	228 (7.3)	263 (4.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=65 and <75 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3010) n (%)	mRNA-1273 (N=3109) n (%)	Total (N=6119) n (%)
Myalgia - N1	3010	3109	6119
Any	539 (17.9)	1629 (52.4)	2168 (35.4)
Grade 1	407 (13.5)	794 (25.5)	1201 (19.6)
Grade 2	119 (4.0)	658 (21.2)	777 (12.7)
Grade 3	13 (0.4)	177 (5.7)	190 (3.1)
Grade 4	0	0	0
Grade 3 or Above	13 (0.4)	177 (5.7)	190 (3.1)
Arthralgia - N1	3010	3109	6119
Any	533 (17.7)	1255 (40.4)	1788 (29.2)
Grade 1	392 (13.0)	695 (22.4)	1087 (17.8)
Grade 2	127 (4.2)	457 (14.7)	584 (9.5)
Grade 3	14 (0.5)	103 (3.3)	117 (1.9)
Grade 4	0	0	0
Grade 3 or Above	14 (0.5)	103 (3.3)	117 (1.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=65 and <75 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3010) n (%)	mRNA-1273 (N=3109) n (%)	Total (N=6119) n (%)
Nausea/Vomiting - N1	3010	3109	6119
Any	214 (7.1)	468 (15.1)	682 (11.1)
Grade 1	175 (5.8)	362 (11.6)	537 (8.8)
Grade 2	34 (1.1)	97 (3.1)	131 (2.1)
Grade 3	5 (0.2)	8 (0.3)	13 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	5 (0.2)	9 (0.3)	14 (0.2)
Chills - N1	3010	3109	6119
Any	210 (7.0)	1028 (33.1)	1238 (20.2)
Grade 1	167 (5.5)	544 (17.5)	711 (11.6)
Grade 2	38 (1.3)	460 (14.8)	498 (8.1)
Grade 3	5 (0.2)	24 (0.8)	29 (0.5)
Grade 4	0	0	0
Grade 3 or Above	5 (0.2)	24 (0.8)	29 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=75 and <85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Solicited Adverse Reactions - N1	692	616	1308
Any Solicited Adverse Reactions	359 (51.9)	564 (91.6)	923 (70.6)
95% CI	48.1, 55.7	89.1, 93.6	68.0, 73.0
Grade 1	220 (31.8)	257 (41.7)	477 (36.5)
Grade 2	96 (13.9)	200 (32.5)	296 (22.6)
Grade 3	43 (6.2)	107 (17.4)	150 (11.5)
Grade 4	0	0	0
Grade 3 or Above	43 (6.2)	107 (17.4)	150 (11.5)
Solicited Local Adverse Reactions - N1	692	616	1308
Any Solicited Local Adverse Reactions	155 (22.4)	526 (85.4)	681 (52.1)
95% CI	19.3, 25.7	82.3, 88.1	49.3, 54.8
Grade 1	123 (17.8)	401 (65.1)	524 (40.1)
Grade 2	7 (1.0)	75 (12.2)	82 (6.3)
Grade 3	25 (3.6)	50 (8.1)	75 (5.7)
Grade 4	0	0	0
Grade 3 or Above	25 (3.6)	50 (8.1)	75 (5.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=75 and <85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Pain - N1	692	616	1308
Any	137 (19.8)	518 (84.1)	655 (50.1)
Grade 1	110 (15.9)	431 (70.0)	541 (41.4)
Grade 2	6 (0.9)	64 (10.4)	70 (5.4)
Grade 3	21 (3.0)	23 (3.7)	44 (3.4)
Grade 4	0	0	0
Grade 3 or Above	21 (3.0)	23 (3.7)	44 (3.4)
Erythema (Redness) - N1	692	616	1308
Any	7 (1.0)	53 (8.6)	60 (4.6)
Grade 1	4 (0.6)	22 (3.6)	26 (2.0)
Grade 2	2 (0.3)	17 (2.8)	19 (1.5)
Grade 3	1 (0.1)	14 (2.3)	15 (1.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	14 (2.3)	15 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=75 and <85 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Swelling (Hardness) - N1	692	616	1308
Any	4 (0.6)	74 (12.0)	78 (6.0)
Grade 1	4 (0.6)	35 (5.7)	39 (3.0)
Grade 2	0	20 (3.2)	20 (1.5)
Grade 3	0	19 (3.1)	19 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	19 (3.1)	19 (1.5)
Axillary Swelling or Tenderness - N1	692	616	1308
Any	58 (8.4)	73 (11.9)	131 (10.0)
Grade 1	41 (5.9)	65 (10.6)	106 (8.1)
Grade 2	2 (0.3)	2 (0.3)	4 (0.3)
Grade 3	15 (2.2)	6 (1.0)	21 (1.6)
Grade 4	0	0	0
Grade 3 or Above	15 (2.2)	6 (1.0)	21 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=75 and <85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Solicited Systemic Adverse Reactions - N1	692	616	1308
Any Solicited Systemic Adverse Reactions	315 (45.5)	475 (77.1)	790 (60.4)
95% CI	41.8, 49.3	73.6, 80.4	57.7, 63.1
Grade 1	191 (27.6)	200 (32.5)	391 (29.9)
Grade 2	95 (13.7)	203 (33.0)	298 (22.8)
Grade 3	29 (4.2)	72 (11.7)	101 (7.7)
Grade 4	0	0	0
Grade 3 or Above	29 (4.2)	72 (11.7)	101 (7.7)
Fever - N1	692	616	1308
Any	0	48 (7.8)	48 (3.7)
Grade 1	0	34 (5.5)	34 (2.6)
Grade 2	0	11 (1.8)	11 (0.8)
Grade 3	0	3 (0.5)	3 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	3 (0.5)	3 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=75 and <85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Headache - N1	692	616	1308
Any	179 (25.9)	276 (44.8)	455 (34.8)
Grade 1	141 (20.4)	194 (31.5)	335 (25.6)
Grade 2	18 (2.6)	70 (11.4)	88 (6.7)
Grade 3	20 (2.9)	12 (1.9)	32 (2.4)
Grade 4	0	0	0
Grade 3 or Above	20 (2.9)	12 (1.9)	32 (2.4)
Fatigue - N1	692	616	1308
Any	233 (33.7)	397 (64.4)	630 (48.2)
Grade 1	149 (21.5)	166 (26.9)	315 (24.1)
Grade 2	78 (11.3)	186 (30.2)	264 (20.2)
Grade 3	6 (0.9)	45 (7.3)	51 (3.9)
Grade 4	0	0	0
Grade 3 or Above	6 (0.9)	45 (7.3)	51 (3.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=75 and <85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Myalgia - N1	692	616	1308
Any	131 (18.9)	308 (50.0)	439 (33.6)
Grade 1	104 (15.0)	156 (25.3)	260 (19.9)
Grade 2	21 (3.0)	113 (18.3)	134 (10.2)
Grade 3	6 (0.9)	39 (6.3)	45 (3.4)
Grade 4	0	0	0
Grade 3 or Above	6 (0.9)	39 (6.3)	45 (3.4)
Arthralgia - N1	692	616	1308
Any	123 (17.8)	245 (39.8)	368 (28.1)
Grade 1	95 (13.7)	134 (21.8)	229 (17.5)
Grade 2	27 (3.9)	83 (13.5)	110 (8.4)
Grade 3	1 (0.1)	28 (4.5)	29 (2.2)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	28 (4.5)	29 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=75 and <85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Nausea/Vomiting - N1	692	616	1308
Any	57 (8.2)	89 (14.4)	146 (11.2)
Grade 1	46 (6.6)	69 (11.2)	115 (8.8)
Grade 2	8 (1.2)	17 (2.8)	25 (1.9)
Grade 3	3 (0.4)	3 (0.5)	6 (0.5)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	3 (0.5)	6 (0.5)
Chills - N1	692	616	1308
Any	52 (7.5)	195 (31.7)	247 (18.9)
Grade 1	44 (6.4)	104 (16.9)	148 (11.3)
Grade 2	5 (0.7)	85 (13.8)	90 (6.9)
Grade 3	3 (0.4)	6 (1.0)	9 (0.7)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	6 (1.0)	9 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Solicited Adverse Reactions - N1	49	41	90
Any Solicited Adverse Reactions	33 (67.3)	32 (78.0)	65 (72.2)
95% CI	52.5, 80.1	62.4, 89.4	61.8, 81.1
Grade 1	16 (32.7)	12 (29.3)	28 (31.1)
Grade 2	12 (24.5)	12 (29.3)	24 (26.7)
Grade 3	5 (10.2)	8 (19.5)	13 (14.4)
Grade 4	0	0	0
Grade 3 or Above	5 (10.2)	8 (19.5)	13 (14.4)
Solicited Local Adverse Reactions - N1	49	41	90
Any Solicited Local Adverse Reactions	15 (30.6)	29 (70.7)	44 (48.9)
95% CI	18.3, 45.4	54.5, 83.9	38.2, 59.7
Grade 1	8 (16.3)	23 (56.1)	31 (34.4)
Grade 2	2 (4.1)	2 (4.9)	4 (4.4)
Grade 3	5 (10.2)	4 (9.8)	9 (10.0)
Grade 4	0	0	0
Grade 3 or Above	5 (10.2)	4 (9.8)	9 (10.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Pain - N1	49	41	90
Any	13 (26.5)	28 (68.3)	41 (45.6)
Grade 1	8 (16.3)	25 (61.0)	33 (36.7)
Grade 2	0	0	0
Grade 3	5 (10.2)	3 (7.3)	8 (8.9)
Grade 4	0	0	0
Grade 3 or Above	5 (10.2)	3 (7.3)	8 (8.9)
Erythema (Redness) - N1	49	41	90
Any	0	4 (9.8)	4 (4.4)
Grade 1	0	2 (4.9)	2 (2.2)
Grade 2	0	1 (2.4)	1 (1.1)
Grade 3	0	1 (2.4)	1 (1.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.4)	1 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=85 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Swelling (Hardness) - N1	49	41	90
Any	1 (2.0)	6 (14.6)	7 (7.8)
Grade 1	0	4 (9.8)	4 (4.4)
Grade 2	1 (2.0)	2 (4.9)	3 (3.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	49	41	90
Any	10 (20.4)	7 (17.1)	17 (18.9)
Grade 1	9 (18.4)	5 (12.2)	14 (15.6)
Grade 2	1 (2.0)	1 (2.4)	2 (2.2)
Grade 3	0	1 (2.4)	1 (1.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.4)	1 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Solicited Systemic Adverse Reactions - N1	49	41	90
Any Solicited Systemic Adverse Reactions	31 (63.3)	28 (68.3)	59 (65.6)
95% CI	48.3, 76.6	51.9, 81.9	54.8, 75.3
Grade 1	19 (38.8)	10 (24.4)	29 (32.2)
Grade 2	12 (24.5)	12 (29.3)	24 (26.7)
Grade 3	0	6 (14.6)	6 (6.7)
Grade 4	0	0	0
Grade 3 or Above	0	6 (14.6)	6 (6.7)
Fever - N1	49	41	90
Any	0	2 (4.9)	2 (2.2)
Grade 1	0	2 (4.9)	2 (2.2)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Headache - N1	49	41	90
Any	15 (30.6)	15 (36.6)	30 (33.3)
Grade 1	13 (26.5)	11 (26.8)	24 (26.7)
Grade 2	2 (4.1)	1 (2.4)	3 (3.3)
Grade 3	0	3 (7.3)	3 (3.3)
Grade 4	0	0	0
Grade 3 or Above	0	3 (7.3)	3 (3.3)
Fatigue - N1	49	41	90
Any	23 (46.9)	22 (53.7)	45 (50.0)
Grade 1	17 (34.7)	10 (24.4)	27 (30.0)
Grade 2	6 (12.2)	8 (19.5)	14 (15.6)
Grade 3	0	4 (9.8)	4 (4.4)
Grade 4	0	0	0
Grade 3 or Above	0	4 (9.8)	4 (4.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=85 Years

Solicited Adverse Reaction Category Grade	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Myalgia - N1	49	41	90
Any	15 (30.6)	14 (34.1)	29 (32.2)
Grade 1	10 (20.4)	8 (19.5)	18 (20.0)
Grade 2	5 (10.2)	3 (7.3)	8 (8.9)
Grade 3	0	3 (7.3)	3 (3.3)
Grade 4	0	0	0
Grade 3 or Above	0	3 (7.3)	3 (3.3)
Arthralgia - N1	49	41	90
Any	15 (30.6)	14 (34.1)	29 (32.2)
Grade 1	11 (22.4)	5 (12.2)	16 (17.8)
Grade 2	4 (8.2)	6 (14.6)	10 (11.1)
Grade 3	0	3 (7.3)	3 (3.3)
Grade 4	0	0	0
Grade 3 or Above	0	3 (7.3)	3 (3.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group (<65, >=65 and <75, >=75 and <85, >=85) and Grade
Solicited Safety Set

Age Group: >=85 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Nausea/Vomiting - N1	49	41	90
Any	4 (8.2)	7 (17.1)	11 (12.2)
Grade 1	4 (8.2)	4 (9.8)	8 (8.9)
Grade 2	0	1 (2.4)	1 (1.1)
Grade 3	0	2 (4.9)	2 (2.2)
Grade 4	0	0	0
Grade 3 or Above	0	2 (4.9)	2 (2.2)
Chills - N1	49	41	90
Any	4 (8.2)	8 (19.5)	12 (13.3)
Grade 1	4 (8.2)	2 (4.9)	6 (6.7)
Grade 2	0	4 (9.8)	4 (4.4)
Grade 3	0	2 (4.9)	2 (2.2)
Grade 4	0	0	0
Grade 3 or Above	0	2 (4.9)	2 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Solicited Adverse Reactions - N1	10929	11000	21929
Any Solicited Adverse Reactions	4921 (45.0)	10252 (93.2)	15173 (69.2)
95% CI	44.1, 46.0	92.7, 93.7	68.6, 69.8
Grade 1	3392 (31.0)	3290 (29.9)	6682 (30.5)
Grade 2	1266 (11.6)	4592 (41.7)	5858 (26.7)
Grade 3	261 (2.4)	2358 (21.4)	2619 (11.9)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Grade 3 or Above	263 (2.4)	2370 (21.5)	2633 (12.0)
Solicited Local Adverse Reactions - N1	10928	10999	21927
Any Solicited Local Adverse Reactions	2262 (20.7)	9936 (90.3)	12198 (55.6)
95% CI	19.9, 21.5	89.8, 90.9	55.0, 56.3
Grade 1	2145 (19.6)	6424 (58.4)	8569 (39.1)
Grade 2	73 (0.7)	2709 (24.6)	2782 (12.7)
Grade 3	44 (0.4)	803 (7.3)	847 (3.9)
Grade 4	0	0	0
Grade 3 or Above	44 (0.4)	803 (7.3)	847 (3.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Pain - N1	10928	10999	21927
Any	2048 (18.7)	9893 (89.9)	11941 (54.5)
Grade 1	1978 (18.1)	6933 (63.0)	8911 (40.6)
Grade 2	48 (0.4)	2454 (22.3)	2502 (11.4)
Grade 3	22 (0.2)	506 (4.6)	528 (2.4)
Grade 4	0	0	0
Grade 3 or Above	22 (0.2)	506 (4.6)	528 (2.4)
Erythema (Redness) - N1	10928	10998	21926
Any	53 (0.5)	989 (9.0)	1042 (4.8)
Grade 1	36 (0.3)	358 (3.3)	394 (1.8)
Grade 2	5 (<0.1)	421 (3.8)	426 (1.9)
Grade 3	12 (0.1)	210 (1.9)	222 (1.0)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	210 (1.9)	222 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Swelling (Hardness) - N1	10928	10998	21926
Any	46 (0.4)	1399 (12.7)	1445 (6.6)
Grade 1	32 (0.3)	706 (6.4)	738 (3.4)
Grade 2	9 (<0.1)	510 (4.6)	519 (2.4)
Grade 3	5 (<0.1)	183 (1.7)	188 (0.9)
Grade 4	0	0	0
Grade 3 or Above	5 (<0.1)	183 (1.7)	188 (0.9)
Axillary Swelling or Tenderness - N1	10928	10998	21926
Any	474 (4.3)	1777 (16.2)	2251 (10.3)
Grade 1	435 (4.0)	1468 (13.3)	1903 (8.7)
Grade 2	27 (0.2)	262 (2.4)	289 (1.3)
Grade 3	12 (0.1)	47 (0.4)	59 (0.3)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	47 (0.4)	59 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Solicited Systemic Adverse Reactions - N1	10928	10999	21927
Any Solicited Systemic Adverse Reactions	4208 (38.5)	9023 (82.0)	13231 (60.3)
95% CI	37.6, 39.4	81.3, 82.7	59.7, 61.0
Grade 1	2731 (25.0)	2615 (23.8)	5346 (24.4)
Grade 2	1248 (11.4)	4458 (40.5)	5706 (26.0)
Grade 3	227 (2.1)	1938 (17.6)	2165 (9.9)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Grade 3 or Above	229 (2.1)	1950 (17.7)	2179 (9.9)
Fever - N1	10925	10993	21918
Any	38 (0.3)	1909 (17.4)	1947 (8.9)
Grade 1	30 (0.3)	1112 (10.1)	1142 (5.2)
Grade 2	4 (<0.1)	600 (5.5)	604 (2.8)
Grade 3	2 (<0.1)	185 (1.7)	187 (0.9)
Grade 4	2 (<0.1)	12 (0.1)	14 (<0.1)
Grade 3 or Above	4 (<0.1)	197 (1.8)	201 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Headache - N1	10926	10998	21924
Any	2775 (25.4)	6929 (63.0)	9704 (44.3)
Grade 1	2182 (20.0)	3669 (33.4)	5851 (26.7)
Grade 2	461 (4.2)	2701 (24.6)	3162 (14.4)
Grade 3	132 (1.2)	559 (5.1)	691 (3.2)
Grade 4	0	0	0
Grade 3 or Above	132 (1.2)	559 (5.1)	691 (3.2)
Fatigue - N1	10926	10998	21924
Any	2701 (24.7)	7453 (67.8)	10154 (46.3)
Grade 1	1701 (15.6)	2527 (23.0)	4228 (19.3)
Grade 2	912 (8.3)	3748 (34.1)	4660 (21.3)
Grade 3	88 (0.8)	1178 (10.7)	1266 (5.8)
Grade 4	0	0	0
Grade 3 or Above	88 (0.8)	1178 (10.7)	1266 (5.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Myalgia - N1	10926	10998	21924
Any	1425 (13.0)	6789 (61.7)	8214 (37.5)
Grade 1	1002 (9.2)	2415 (22.0)	3417 (15.6)
Grade 2	381 (3.5)	3258 (29.6)	3639 (16.6)
Grade 3	42 (0.4)	1116 (10.1)	1158 (5.3)
Grade 4	0	0	0
Grade 3 or Above	42 (0.4)	1116 (10.1)	1158 (5.3)
Arthralgia - N1	10926	10998	21924
Any	1180 (10.8)	5010 (45.6)	6190 (28.2)
Grade 1	841 (7.7)	2111 (19.2)	2952 (13.5)
Grade 2	302 (2.8)	2249 (20.4)	2551 (11.6)
Grade 3	37 (0.3)	650 (5.9)	687 (3.1)
Grade 4	0	0	0
Grade 3 or Above	37 (0.3)	650 (5.9)	687 (3.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Nausea/Vomiting - N1	10926	10998	21924
Any	807 (7.4)	2355 (21.4)	3162 (14.4)
Grade 1	651 (6.0)	1755 (16.0)	2406 (11.0)
Grade 2	148 (1.4)	589 (5.4)	737 (3.4)
Grade 3	8 (<0.1)	11 (0.1)	19 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	11 (0.1)	19 (<0.1)
Chills - N1	10926	10998	21924
Any	662 (6.1)	5357 (48.7)	6019 (27.5)
Grade 1	505 (4.6)	2316 (21.1)	2821 (12.9)
Grade 2	142 (1.3)	2877 (26.2)	3019 (13.8)
Grade 3	15 (0.1)	164 (1.5)	179 (0.8)
Grade 4	0	0	0
Grade 3 or Above	15 (0.1)	164 (1.5)	179 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Solicited Adverse Reactions - N1	3649	3691	7340
Any Solicited Adverse Reactions	1334 (36.6)	3304 (89.5)	4638 (63.2)
95% CI	35.0, 38.1	88.5, 90.5	62.1, 64.3
Grade 1	954 (26.1)	1557 (42.2)	2511 (34.2)
Grade 2	292 (8.0)	1208 (32.7)	1500 (20.4)
Grade 3	87 (2.4)	537 (14.5)	624 (8.5)
Grade 4	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3 or Above	88 (2.4)	539 (14.6)	627 (8.5)
Solicited Local Adverse Reactions - N1	3649	3689	7338
Any Solicited Local Adverse Reactions	495 (13.6)	3093 (83.8)	3588 (48.9)
95% CI	12.5, 14.7	82.6, 85.0	47.7, 50.0
Grade 1	449 (12.3)	2365 (64.1)	2814 (38.3)
Grade 2	15 (0.4)	508 (13.8)	523 (7.1)
Grade 3	31 (0.8)	220 (6.0)	251 (3.4)
Grade 4	0	0	0
Grade 3 or Above	31 (0.8)	220 (6.0)	251 (3.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Pain - N1	3649	3689	7338
Any	438 (12.0)	3071 (83.2)	3509 (47.8)
Grade 1	406 (11.1)	2575 (69.8)	2981 (40.6)
Grade 2	13 (0.4)	396 (10.7)	409 (5.6)
Grade 3	19 (0.5)	100 (2.7)	119 (1.6)
Grade 4	0	0	0
Grade 3 or Above	19 (0.5)	100 (2.7)	119 (1.6)
Erythema (Redness) - N1	3649	3689	7338
Any	15 (0.4)	285 (7.7)	300 (4.1)
Grade 1	12 (0.3)	98 (2.7)	110 (1.5)
Grade 2	0	110 (3.0)	110 (1.5)
Grade 3	3 (<0.1)	77 (2.1)	80 (1.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	77 (2.1)	80 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Swelling (Hardness) - N1	3649	3689	7338
Any	14 (0.4)	408 (11.1)	422 (5.8)
Grade 1	6 (0.2)	194 (5.3)	200 (2.7)
Grade 2	1 (<0.1)	142 (3.8)	143 (1.9)
Grade 3	7 (0.2)	72 (2.0)	79 (1.1)
Grade 4	0	0	0
Grade 3 or Above	7 (0.2)	72 (2.0)	79 (1.1)
Axillary Swelling or Tenderness - N1	3649	3689	7338
Any	97 (2.7)	315 (8.5)	412 (5.6)
Grade 1	88 (2.4)	267 (7.2)	355 (4.8)
Grade 2	1 (<0.1)	27 (0.7)	28 (0.4)
Grade 3	8 (0.2)	21 (0.6)	29 (0.4)
Grade 4	0	0	0
Grade 3 or Above	8 (0.2)	21 (0.6)	29 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Solicited Systemic Adverse Reactions - N1	3649	3691	7340
Any Solicited Systemic Adverse Reactions	1135 (31.1)	2655 (71.9)	3790 (51.6)
95% CI	29.6, 32.6	70.5, 73.4	50.5, 52.8
Grade 1	788 (21.6)	1102 (29.9)	1890 (25.7)
Grade 2	287 (7.9)	1153 (31.2)	1440 (19.6)
Grade 3	59 (1.6)	398 (10.8)	457 (6.2)
Grade 4	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 3 or Above	60 (1.6)	400 (10.8)	460 (6.3)
Fever - N1	3648	3689	7337
Any	5 (0.1)	367 (9.9)	372 (5.1)
Grade 1	3 (<0.1)	251 (6.8)	254 (3.5)
Grade 2	1 (<0.1)	97 (2.6)	98 (1.3)
Grade 3	0	18 (0.5)	18 (0.2)
Grade 4	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 3 or Above	1 (<0.1)	19 (0.5)	20 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Headache - N1	3649	3689	7338
Any	652 (17.9)	1708 (46.3)	2360 (32.2)
Grade 1	558 (15.3)	1146 (31.1)	1704 (23.2)
Grade 2	61 (1.7)	455 (12.3)	516 (7.0)
Grade 3	33 (0.9)	107 (2.9)	140 (1.9)
Grade 4	0	0	0
Grade 3 or Above	33 (0.9)	107 (2.9)	140 (1.9)
Fatigue - N1	3649	3689	7338
Any	717 (19.6)	2154 (58.4)	2871 (39.1)
Grade 1	480 (13.2)	904 (24.5)	1384 (18.9)
Grade 2	217 (5.9)	995 (27.0)	1212 (16.5)
Grade 3	20 (0.5)	255 (6.9)	275 (3.7)
Grade 4	0	0	0
Grade 3 or Above	20 (0.5)	255 (6.9)	275 (3.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Myalgia - N1	3649	3689	7338
Any	399 (10.9)	1740 (47.2)	2139 (29.1)
Grade 1	305 (8.4)	827 (22.4)	1132 (15.4)
Grade 2	84 (2.3)	708 (19.2)	792 (10.8)
Grade 3	10 (0.3)	205 (5.6)	215 (2.9)
Grade 4	0	0	0
Grade 3 or Above	10 (0.3)	205 (5.6)	215 (2.9)
Arthralgia - N1	3649	3689	7338
Any	399 (10.9)	1293 (35.1)	1692 (23.1)
Grade 1	302 (8.3)	698 (18.9)	1000 (13.6)
Grade 2	90 (2.5)	470 (12.7)	560 (7.6)
Grade 3	7 (0.2)	125 (3.4)	132 (1.8)
Grade 4	0	0	0
Grade 3 or Above	7 (0.2)	125 (3.4)	132 (1.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Nausea/Vomiting - N1	3649	3689	7338
Any	134 (3.7)	439 (11.9)	573 (7.8)
Grade 1	110 (3.0)	339 (9.2)	449 (6.1)
Grade 2	21 (0.6)	89 (2.4)	110 (1.5)
Grade 3	3 (<0.1)	10 (0.3)	13 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	3 (<0.1)	11 (0.3)	14 (0.2)
Chills - N1	3649	3689	7338
Any	151 (4.1)	1143 (31.0)	1294 (17.6)
Grade 1	124 (3.4)	591 (16.0)	715 (9.7)
Grade 2	25 (0.7)	525 (14.2)	550 (7.5)
Grade 3	2 (<0.1)	27 (0.7)	29 (0.4)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	27 (0.7)	29 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Adverse Reactions - N1	11408	11413	22821
Any Solicited Adverse Reactions	7088 (62.1)	10889 (95.4)	17977 (78.8)
95% CI	61.2, 63.0	95.0, 95.8	78.2, 79.3
Grade 1	4452 (39.0)	3250 (28.5)	7702 (33.7)
Grade 2	2130 (18.7)	4853 (42.5)	6983 (30.6)
Grade 3	500 (4.4)	2769 (24.3)	3269 (14.3)
Grade 4	6 (<0.1)	17 (0.1)	23 (0.1)
Grade 3 or Above	506 (4.4)	2786 (24.4)	3292 (14.4)
Solicited Local Adverse Reactions - N1	11407	11413	22820
Any Solicited Local Adverse Reactions	3590 (31.5)	10680 (93.6)	14270 (62.5)
95% CI	30.6, 32.3	93.1, 94.0	61.9, 63.2
Grade 1	3386 (29.7)	6490 (56.9)	9876 (43.3)
Grade 2	124 (1.1)	3057 (26.8)	3181 (13.9)
Grade 3	80 (0.7)	1133 (9.9)	1213 (5.3)
Grade 4	0	0	0
Grade 3 or Above	80 (0.7)	1133 (9.9)	1213 (5.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Pain - N1	11407	11413	22820
Any	3283 (28.8)	10643 (93.3)	13926 (61.0)
Grade 1	3156 (27.7)	7082 (62.1)	10238 (44.9)
Grade 2	84 (0.7)	2783 (24.4)	2867 (12.6)
Grade 3	43 (0.4)	778 (6.8)	821 (3.6)
Grade 4	0	0	0
Grade 3 or Above	43 (0.4)	778 (6.8)	821 (3.6)
Erythema (Redness) - N1	11407	11412	22819
Any	100 (0.9)	1202 (10.5)	1302 (5.7)
Grade 1	69 (0.6)	491 (4.3)	560 (2.5)
Grade 2	9 (<0.1)	472 (4.1)	481 (2.1)
Grade 3	22 (0.2)	239 (2.1)	261 (1.1)
Grade 4	0	0	0
Grade 3 or Above	22 (0.2)	239 (2.1)	261 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Swelling (Hardness) - N1	11407	11412	22819
Any	82 (0.7)	1761 (15.4)	1843 (8.1)
Grade 1	62 (0.5)	910 (8.0)	972 (4.3)
Grade 2	13 (0.1)	613 (5.4)	626 (2.7)
Grade 3	7 (<0.1)	238 (2.1)	245 (1.1)
Grade 4	0	0	0
Grade 3 or Above	7 (<0.1)	238 (2.1)	245 (1.1)
Axillary Swelling or Tenderness - N1	11407	11412	22819
Any	878 (7.7)	2536 (22.2)	3414 (15.0)
Grade 1	810 (7.1)	2117 (18.6)	2927 (12.8)
Grade 2	43 (0.4)	338 (3.0)	381 (1.7)
Grade 3	25 (0.2)	81 (0.7)	106 (0.5)
Grade 4	0	0	0
Grade 3 or Above	25 (0.2)	81 (0.7)	106 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Systemic Adverse Reactions - N1	11408	11412	22820
Any Solicited Systemic Adverse Reactions	6351 (55.7)	9825 (86.1)	16176 (70.9)
95% CI	54.8, 56.6	85.4, 86.7	70.3, 71.5
Grade 1	3792 (33.2)	2837 (24.9)	6629 (29.0)
Grade 2	2108 (18.5)	4803 (42.1)	6911 (30.3)
Grade 3	445 (3.9)	2168 (19.0)	2613 (11.5)
Grade 4	6 (<0.1)	17 (0.1)	23 (0.1)
Grade 3 or Above	451 (4.0)	2185 (19.1)	2636 (11.6)
Fever - N1	11407	11411	22818
Any	74 (0.6)	1977 (17.3)	2051 (9.0)
Grade 1	54 (0.5)	1153 (10.1)	1207 (5.3)
Grade 2	11 (<0.1)	613 (5.4)	624 (2.7)
Grade 3	3 (<0.1)	195 (1.7)	198 (0.9)
Grade 4	6 (<0.1)	16 (0.1)	22 (<0.1)
Grade 3 or Above	9 (<0.1)	211 (1.8)	220 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Headache - N1	11407	11412	22819
Any	4534 (39.7)	7835 (68.7)	12369 (54.2)
Grade 1	3447 (30.2)	4215 (36.9)	7662 (33.6)
Grade 2	808 (7.1)	2893 (25.4)	3701 (16.2)
Grade 3	279 (2.4)	727 (6.4)	1006 (4.4)
Grade 4	0	0	0
Grade 3 or Above	279 (2.4)	727 (6.4)	1006 (4.4)
Fatigue - N1	11407	11412	22819
Any	4346 (38.1)	8200 (71.9)	12546 (55.0)
Grade 1	2555 (22.4)	2776 (24.3)	5331 (23.4)
Grade 2	1630 (14.3)	4166 (36.5)	5796 (25.4)
Grade 3	161 (1.4)	1257 (11.0)	1418 (6.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	161 (1.4)	1258 (11.0)	1419 (6.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Myalgia - N1	11407	11412	22819
Any	2433 (21.3)	7397 (64.8)	9830 (43.1)
Grade 1	1674 (14.7)	2728 (23.9)	4402 (19.3)
Grade 2	680 (6.0)	3503 (30.7)	4183 (18.3)
Grade 3	79 (0.7)	1166 (10.2)	1245 (5.5)
Grade 4	0	0	0
Grade 3 or Above	79 (0.7)	1166 (10.2)	1245 (5.5)
Arthralgia - N1	11407	11412	22819
Any	2001 (17.5)	5541 (48.6)	7542 (33.1)
Grade 1	1375 (12.1)	2414 (21.2)	3789 (16.6)
Grade 2	560 (4.9)	2444 (21.4)	3004 (13.2)
Grade 3	66 (0.6)	682 (6.0)	748 (3.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	66 (0.6)	683 (6.0)	749 (3.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Nausea/Vomiting - N1	11407	11412	22819
Any	1448 (12.7)	2929 (25.7)	4377 (19.2)
Grade 1	1155 (10.1)	2187 (19.2)	3342 (14.6)
Grade 2	277 (2.4)	725 (6.4)	1002 (4.4)
Grade 3	16 (0.1)	17 (0.1)	33 (0.1)
Grade 4	0	0	0
Grade 3 or Above	16 (0.1)	17 (0.1)	33 (0.1)
Chills - N1	11407	11412	22819
Any	1207 (10.6)	5676 (49.7)	6883 (30.2)
Grade 1	917 (8.0)	2494 (21.9)	3411 (14.9)
Grade 2	267 (2.3)	3003 (26.3)	3270 (14.3)
Grade 3	23 (0.2)	179 (1.6)	202 (0.9)
Grade 4	0	0	0
Grade 3 or Above	23 (0.2)	179 (1.6)	202 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Solicited Adverse Reactions - N1	3751	3766	7517
Any Solicited Adverse Reactions	2025 (54.0)	3513 (93.3)	5538 (73.7)
95% CI	52.4, 55.6	92.4, 94.1	72.7, 74.7
Grade 1	1352 (36.0)	1548 (41.1)	2900 (38.6)
Grade 2	500 (13.3)	1328 (35.3)	1828 (24.3)
Grade 3	170 (4.5)	635 (16.9)	805 (10.7)
Grade 4	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 3 or Above	173 (4.6)	637 (16.9)	810 (10.8)
Solicited Local Adverse Reactions - N1	3751	3766	7517
Any Solicited Local Adverse Reactions	878 (23.4)	3352 (89.0)	4230 (56.3)
95% CI	22.1, 24.8	88.0, 90.0	55.1, 57.4
Grade 1	771 (20.6)	2513 (66.7)	3284 (43.7)
Grade 2	39 (1.0)	552 (14.7)	591 (7.9)
Grade 3	68 (1.8)	287 (7.6)	355 (4.7)
Grade 4	0	0	0
Grade 3 or Above	68 (1.8)	287 (7.6)	355 (4.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Pain - N1	3751	3766	7517
Any	763 (20.3)	3326 (88.3)	4089 (54.4)
Grade 1	686 (18.3)	2743 (72.8)	3429 (45.6)
Grade 2	27 (0.7)	438 (11.6)	465 (6.2)
Grade 3	50 (1.3)	145 (3.9)	195 (2.6)
Grade 4	0	0	0
Grade 3 or Above	50 (1.3)	145 (3.9)	195 (2.6)
Erythema (Redness) - N1	3751	3766	7517
Any	37 (1.0)	347 (9.2)	384 (5.1)
Grade 1	29 (0.8)	141 (3.7)	170 (2.3)
Grade 2	3 (<0.1)	121 (3.2)	124 (1.6)
Grade 3	5 (0.1)	85 (2.3)	90 (1.2)
Grade 4	0	0	0
Grade 3 or Above	5 (0.1)	85 (2.3)	90 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Swelling (Hardness) - N1	3751	3766	7517
Any	34 (0.9)	488 (13.0)	522 (6.9)
Grade 1	19 (0.5)	241 (6.4)	260 (3.5)
Grade 2	5 (0.1)	158 (4.2)	163 (2.2)
Grade 3	10 (0.3)	89 (2.4)	99 (1.3)
Grade 4	0	0	0
Grade 3 or Above	10 (0.3)	89 (2.4)	99 (1.3)
Axillary Swelling or Tenderness - N1	3751	3766	7517
Any	223 (5.9)	477 (12.7)	700 (9.3)
Grade 1	194 (5.2)	415 (11.0)	609 (8.1)
Grade 2	8 (0.2)	32 (0.8)	40 (0.5)
Grade 3	21 (0.6)	30 (0.8)	51 (0.7)
Grade 4	0	0	0
Grade 3 or Above	21 (0.6)	30 (0.8)	51 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Solicited Systemic Adverse Reactions - N1	3751	3766	7517
Any Solicited Systemic Adverse Reactions	1766 (47.1)	2954 (78.4)	4720 (62.8)
95% CI	45.5, 48.7	77.1, 79.7	61.7, 63.9
Grade 1	1154 (30.8)	1203 (31.9)	2357 (31.4)
Grade 2	492 (13.1)	1296 (34.4)	1788 (23.8)
Grade 3	117 (3.1)	453 (12.0)	570 (7.6)
Grade 4	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 3 or Above	120 (3.2)	455 (12.1)	575 (7.6)
Fever - N1	3751	3766	7517
Any	12 (0.3)	373 (9.9)	385 (5.1)
Grade 1	6 (0.2)	255 (6.8)	261 (3.5)
Grade 2	2 (<0.1)	99 (2.6)	101 (1.3)
Grade 3	1 (<0.1)	18 (0.5)	19 (0.3)
Grade 4	3 (<0.1)	1 (<0.1)	4 (<0.1)
Grade 3 or Above	4 (0.1)	19 (0.5)	23 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Headache - N1	3751	3766	7517
Any	1079 (28.8)	2009 (53.3)	3088 (41.1)
Grade 1	908 (24.2)	1364 (36.2)	2272 (30.2)
Grade 2	106 (2.8)	497 (13.2)	603 (8.0)
Grade 3	65 (1.7)	148 (3.9)	213 (2.8)
Grade 4	0	0	0
Grade 3 or Above	65 (1.7)	148 (3.9)	213 (2.8)
Fatigue - N1	3751	3766	7517
Any	1203 (32.1)	2440 (64.8)	3643 (48.5)
Grade 1	788 (21.0)	1026 (27.2)	1814 (24.1)
Grade 2	374 (10.0)	1137 (30.2)	1511 (20.1)
Grade 3	41 (1.1)	277 (7.4)	318 (4.2)
Grade 4	0	0	0
Grade 3 or Above	41 (1.1)	277 (7.4)	318 (4.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Myalgia - N1	3751	3766	7517
Any	685 (18.3)	1951 (51.8)	2636 (35.1)
Grade 1	521 (13.9)	958 (25.4)	1479 (19.7)
Grade 2	145 (3.9)	774 (20.6)	919 (12.2)
Grade 3	19 (0.5)	219 (5.8)	238 (3.2)
Grade 4	0	0	0
Grade 3 or Above	19 (0.5)	219 (5.8)	238 (3.2)
Arthralgia - N1	3751	3766	7517
Any	671 (17.9)	1514 (40.2)	2185 (29.1)
Grade 1	498 (13.3)	834 (22.1)	1332 (17.7)
Grade 2	158 (4.2)	546 (14.5)	704 (9.4)
Grade 3	15 (0.4)	134 (3.6)	149 (2.0)
Grade 4	0	0	0
Grade 3 or Above	15 (0.4)	134 (3.6)	149 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Nausea/Vomiting - N1	3751	3766	7517
Any	275 (7.3)	564 (15.0)	839 (11.2)
Grade 1	225 (6.0)	435 (11.6)	660 (8.8)
Grade 2	42 (1.1)	115 (3.1)	157 (2.1)
Grade 3	8 (0.2)	13 (0.3)	21 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	8 (0.2)	14 (0.4)	22 (0.3)
Chills - N1	3751	3766	7517
Any	266 (7.1)	1231 (32.7)	1497 (19.9)
Grade 1	215 (5.7)	650 (17.3)	865 (11.5)
Grade 2	43 (1.1)	549 (14.6)	592 (7.9)
Grade 3	8 (0.2)	32 (0.8)	40 (0.5)
Grade 4	0	0	0
Grade 3 or Above	8 (0.2)	32 (0.8)	40 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030101020103.sas 21JUN2021 15:00

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Solicited Adverse Reactions - N1	14730	14733	29463
Any Solicited Adverse Reactions	7105 (48.2)	12976 (88.1)	20081 (68.2)
95% CI	47.4, 49.0	87.5, 88.6	67.6, 68.7
Grade 1	5015 (34.0)	9136 (62.0)	14151 (48.0)
Grade 2	1736 (11.8)	3022 (20.5)	4758 (16.1)
Grade 3	349 (2.4)	814 (5.5)	1163 (3.9)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)
Grade 3 or Above	354 (2.4)	818 (5.6)	1172 (4.0)
Solicited Local Adverse Reactions - N1	14726	14729	29455
Any Solicited Local Adverse Reactions	2934 (19.9)	12442 (84.5)	15376 (52.2)
95% CI	19.3, 20.6	83.9, 85.1	51.6, 52.8
Grade 1	2771 (18.8)	10481 (71.2)	13252 (45.0)
Grade 2	88 (0.6)	1449 (9.8)	1537 (5.2)
Grade 3	75 (0.5)	512 (3.5)	587 (2.0)
Grade 4	0	0	0
Grade 3 or Above	75 (0.5)	512 (3.5)	587 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Pain - N1	14726	14729	29455
Any	2596 (17.6)	12369 (84.0)	14965 (50.8)
Grade 1	2484 (16.9)	10735 (72.9)	13219 (44.9)
Grade 2	58 (0.4)	1232 (8.4)	1290 (4.4)
Grade 3	54 (0.4)	402 (2.7)	456 (1.5)
Grade 4	0	0	0
Grade 3 or Above	54 (0.4)	402 (2.7)	456 (1.5)
Erythema (Redness) - N1	14726	14729	29455
Any	74 (0.5)	429 (2.9)	503 (1.7)
Grade 1	56 (0.4)	272 (1.8)	328 (1.1)
Grade 2	7 (<0.1)	117 (0.8)	124 (0.4)
Grade 3	11 (<0.1)	40 (0.3)	51 (0.2)
Grade 4	0	0	0
Grade 3 or Above	11 (<0.1)	40 (0.3)	51 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010301.sas 10JUN2021 10:48

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n	Placebo (N=14730) (%)	mRNA-1273 (N=14733) n	mRNA-1273 (N=14733) (%)	Total (N=29463) n	Total (N=29463) (%)
Swelling (Hardness) - N1	14726		14729		29455	
Any	63	(0.4)	910	(6.2)	973	(3.3)
Grade 1	48	(0.3)	593	(4.0)	641	(2.2)
Grade 2	9	(<0.1)	236	(1.6)	245	(0.8)
Grade 3	6	(<0.1)	81	(0.5)	87	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	6	(<0.1)	81	(0.5)	87	(0.3)
Axillary Swelling or Tenderness - N1	14726		14729		29455	
Any	701	(4.8)	1487	(10.1)	2188	(7.4)
Grade 1	648	(4.4)	1344	(9.1)	1992	(6.8)
Grade 2	27	(0.2)	98	(0.7)	125	(0.4)
Grade 3	26	(0.2)	45	(0.3)	71	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	26	(0.2)	45	(0.3)	71	(0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010301.sas 10JUN2021 10:48

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Solicited Systemic Adverse Reactions - N1	14730	14733	29463
Any Solicited Systemic Adverse Reactions	6239 (42.4)	8053 (54.7)	14292 (48.5)
95% CI	41.6, 43.2	53.9, 55.5	47.9, 49.1
Grade 1	4234 (28.7)	5214 (35.4)	9448 (32.1)
Grade 2	1701 (11.5)	2412 (16.4)	4113 (14.0)
Grade 3	299 (2.0)	423 (2.9)	722 (2.5)
Grade 4	5 (<0.1)	4 (<0.1)	9 (<0.1)
Grade 3 or Above	304 (2.1)	427 (2.9)	731 (2.5)
Fever - N1	14729	14731	29460
Any	38 (0.3)	78 (0.5)	116 (0.4)
Grade 1	25 (0.2)	52 (0.4)	77 (0.3)
Grade 2	6 (<0.1)	14 (<0.1)	20 (<0.1)
Grade 3	2 (<0.1)	9 (<0.1)	11 (<0.1)
Grade 4	5 (<0.1)	3 (<0.1)	8 (<0.1)
Grade 3 or Above	7 (<0.1)	12 (<0.1)	19 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Headache - N1	14725	14729	29454
Any	3917 (26.6)	4787 (32.5)	8704 (29.6)
Grade 1	3214 (21.8)	3833 (26.0)	7047 (23.9)
Grade 2	514 (3.5)	695 (4.7)	1209 (4.1)
Grade 3	189 (1.3)	259 (1.8)	448 (1.5)
Grade 4	0	0	0
Grade 3 or Above	189 (1.3)	259 (1.8)	448 (1.5)
Fatigue - N1	14725	14729	29454
Any	4038 (27.4)	5466 (37.1)	9504 (32.3)
Grade 1	2646 (18.0)	3490 (23.7)	6136 (20.8)
Grade 2	1292 (8.8)	1834 (12.5)	3126 (10.6)
Grade 3	100 (0.7)	141 (1.0)	241 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	100 (0.7)	142 (1.0)	242 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Myalgia - N1	14725	14729	29454
Any	2011 (13.7)	3295 (22.4)	5306 (18.0)
Grade 1	1524 (10.3)	2355 (16.0)	3879 (13.2)
Grade 2	443 (3.0)	857 (5.8)	1300 (4.4)
Grade 3	44 (0.3)	83 (0.6)	127 (0.4)
Grade 4	0	0	0
Grade 3 or Above	44 (0.3)	83 (0.6)	127 (0.4)
Arthralgia - N1	14725	14729	29454
Any	1735 (11.8)	2406 (16.3)	4141 (14.1)
Grade 1	1305 (8.9)	1776 (12.1)	3081 (10.5)
Grade 2	395 (2.7)	574 (3.9)	969 (3.3)
Grade 3	35 (0.2)	55 (0.4)	90 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	35 (0.2)	56 (0.4)	91 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Nausea/Vomiting - N1	14725	14729	29454
Any	1044 (7.1)	1210 (8.2)	2254 (7.7)
Grade 1	866 (5.9)	1009 (6.9)	1875 (6.4)
Grade 2	165 (1.1)	191 (1.3)	356 (1.2)
Grade 3	13 (<0.1)	10 (<0.1)	23 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	13 (<0.1)	10 (<0.1)	23 (<0.1)
Chills - N1	14725	14729	29454
Any	846 (5.7)	1162 (7.9)	2008 (6.8)
Grade 1	684 (4.6)	891 (6.0)	1575 (5.3)
Grade 2	149 (1.0)	250 (1.7)	399 (1.4)
Grade 3	13 (<0.1)	21 (0.1)	34 (0.1)
Grade 4	0	0	0
Grade 3 or Above	13 (<0.1)	21 (0.1)	34 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010301.sas 10JUN2021 10:48

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Solicited Adverse Reactions - N1	337	346	683
Any Solicited Adverse Reactions	138 (40.9)	265 (76.6)	403 (59.0)
95% CI	35.7, 46.4	71.8, 81.0	55.2, 62.7
Grade 1	83 (24.6)	137 (39.6)	220 (32.2)
Grade 2	41 (12.2)	98 (28.3)	139 (20.4)
Grade 3	13 (3.9)	29 (8.4)	42 (6.1)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or Above	14 (4.2)	30 (8.7)	44 (6.4)
Solicited Local Adverse Reactions - N1	337	346	683
Any Solicited Local Adverse Reactions	60 (17.8)	250 (72.3)	310 (45.4)
95% CI	13.9, 22.3	67.2, 76.9	41.6, 49.2
Grade 1	56 (16.6)	180 (52.0)	236 (34.6)
Grade 2	1 (0.3)	56 (16.2)	57 (8.3)
Grade 3	3 (0.9)	14 (4.0)	17 (2.5)
Grade 4	0	0	0
Grade 3 or Above	3 (0.9)	14 (4.0)	17 (2.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Pain - N1	337	346	683
Any	56 (16.6)	247 (71.4)	303 (44.4)
Grade 1	54 (16.0)	184 (53.2)	238 (34.8)
Grade 2	1 (0.3)	52 (15.0)	53 (7.8)
Grade 3	1 (0.3)	11 (3.2)	12 (1.8)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	11 (3.2)	12 (1.8)
Erythema (Redness) - N1	337	346	683
Any	3 (0.9)	10 (2.9)	13 (1.9)
Grade 1	1 (0.3)	6 (1.7)	7 (1.0)
Grade 2	0	2 (0.6)	2 (0.3)
Grade 3	2 (0.6)	2 (0.6)	4 (0.6)
Grade 4	0	0	0
Grade 3 or Above	2 (0.6)	2 (0.6)	4 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010301.sas 10JUN2021 10:48

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Swelling (Hardness) - N1	337	346	683
Any	2 (0.6)	19 (5.5)	21 (3.1)
Grade 1	2 (0.6)	10 (2.9)	12 (1.8)
Grade 2	0	8 (2.3)	8 (1.2)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.1)
Axillary Swelling or Tenderness - N1	337	346	683
Any	18 (5.3)	56 (16.2)	74 (10.8)
Grade 1	17 (5.0)	40 (11.6)	57 (8.3)
Grade 2	0	12 (3.5)	12 (1.8)
Grade 3	1 (0.3)	4 (1.2)	5 (0.7)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	4 (1.2)	5 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010301.sas 10JUN2021 10:48

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Solicited Systemic Adverse Reactions - N1	337	346	683
Any Solicited Systemic Adverse Reactions	122 (36.2)	214 (61.8)	336 (49.2)
95% CI	31.1, 41.6	56.5, 67.0	45.4, 53.0
Grade 1	70 (20.8)	108 (31.2)	178 (26.1)
Grade 2	40 (11.9)	82 (23.7)	122 (17.9)
Grade 3	11 (3.3)	23 (6.6)	34 (5.0)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or Above	12 (3.6)	24 (6.9)	36 (5.3)
Fever - N1	336	346	682
Any	6 (1.8)	33 (9.5)	39 (5.7)
Grade 1	3 (0.9)	20 (5.8)	23 (3.4)
Grade 2	2 (0.6)	10 (2.9)	12 (1.8)
Grade 3	0	2 (0.6)	2 (0.3)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or Above	1 (0.3)	3 (0.9)	4 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Headache - N1	337	346	683
Any	83 (24.6)	134 (38.7)	217 (31.8)
Grade 1	60 (17.8)	89 (25.7)	149 (21.8)
Grade 2	16 (4.7)	33 (9.5)	49 (7.2)
Grade 3	7 (2.1)	12 (3.5)	19 (2.8)
Grade 4	0	0	0
Grade 3 or Above	7 (2.1)	12 (3.5)	19 (2.8)
Fatigue - N1	337	346	683
Any	72 (21.4)	138 (39.9)	210 (30.7)
Grade 1	40 (11.9)	71 (20.5)	111 (16.3)
Grade 2	28 (8.3)	57 (16.5)	85 (12.4)
Grade 3	4 (1.2)	10 (2.9)	14 (2.0)
Grade 4	0	0	0
Grade 3 or Above	4 (1.2)	10 (2.9)	14 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010301.sas 10JUN2021 10:48

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Myalgia - N1	337	346	683
Any	47 (13.9)	128 (37.0)	175 (25.6)
Grade 1	27 (8.0)	71 (20.5)	98 (14.3)
Grade 2	18 (5.3)	50 (14.5)	68 (10.0)
Grade 3	2 (0.6)	7 (2.0)	9 (1.3)
Grade 4	0	0	0
Grade 3 or Above	2 (0.6)	7 (2.0)	9 (1.3)
Arthralgia - N1	337	346	683
Any	40 (11.9)	88 (25.4)	128 (18.7)
Grade 1	21 (6.2)	54 (15.6)	75 (11.0)
Grade 2	17 (5.0)	29 (8.4)	46 (6.7)
Grade 3	2 (0.6)	5 (1.4)	7 (1.0)
Grade 4	0	0	0
Grade 3 or Above	2 (0.6)	5 (1.4)	7 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010301.sas 10JUN2021 10:48

Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Nausea/Vomiting - N1	337	346	683
Any	25 (7.4)	43 (12.4)	68 (10.0)
Grade 1	17 (5.0)	30 (8.7)	47 (6.9)
Grade 2	8 (2.4)	13 (3.8)	21 (3.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	337	346	683
Any	27 (8.0)	81 (23.4)	108 (15.8)
Grade 1	17 (5.0)	43 (12.4)	60 (8.8)
Grade 2	9 (2.7)	35 (10.1)	44 (6.4)
Grade 3	1 (0.3)	3 (0.9)	4 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	3 (0.9)	4 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Adverse Reactions - N1	84	87	171
Any Solicited Adverse Reactions	42 (50.0)	76 (87.4)	118 (69.0)
95% CI	38.9, 61.1	78.5, 93.5	61.5, 75.8
Grade 1	36 (42.9)	56 (64.4)	92 (53.8)
Grade 2	5 (6.0)	14 (16.1)	19 (11.1)
Grade 3	1 (1.2)	6 (6.9)	7 (4.1)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	6 (6.9)	7 (4.1)
Solicited Local Adverse Reactions - N1	84	87	171
Any Solicited Local Adverse Reactions	15 (17.9)	73 (83.9)	88 (51.5)
95% CI	10.4, 27.7	74.5, 90.9	43.7, 59.2
Grade 1	15 (17.9)	64 (73.6)	79 (46.2)
Grade 2	0	6 (6.9)	6 (3.5)
Grade 3	0	3 (3.4)	3 (1.8)
Grade 4	0	0	0
Grade 3 or Above	0	3 (3.4)	3 (1.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Pain - N1	84	87	171
Any	13 (15.5)	72 (82.8)	85 (49.7)
Grade 1	13 (15.5)	66 (75.9)	79 (46.2)
Grade 2	0	3 (3.4)	3 (1.8)
Grade 3	0	3 (3.4)	3 (1.8)
Grade 4	0	0	0
Grade 3 or Above	0	3 (3.4)	3 (1.8)
Erythema (Redness) - N1	84	87	171
Any	0	6 (6.9)	6 (3.5)
Grade 1	0	3 (3.4)	3 (1.8)
Grade 2	0	3 (3.4)	3 (1.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Swelling (Hardness) - N1	84	87	171
Any	0	6 (6.9)	6 (3.5)
Grade 1	0	5 (5.7)	5 (2.9)
Grade 2	0	1 (1.1)	1 (0.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	84	87	171
Any	3 (3.6)	10 (11.5)	13 (7.6)
Grade 1	3 (3.6)	10 (11.5)	13 (7.6)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Systemic Adverse Reactions - N1	84	87	171
Any Solicited Systemic Adverse Reactions	36 (42.9)	49 (56.3)	85 (49.7)
95% CI	32.1, 54.1	45.3, 66.9	42.0, 57.4
Grade 1	30 (35.7)	36 (41.4)	66 (38.6)
Grade 2	5 (6.0)	10 (11.5)	15 (8.8)
Grade 3	1 (1.2)	3 (3.4)	4 (2.3)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	3 (3.4)	4 (2.3)
Fever - N1	84	86	170
Any	0	1 (1.2)	1 (0.6)
Grade 1	0	1 (1.2)	1 (0.6)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Headache - N1	84	87	171
Any	26 (31.0)	29 (33.3)	55 (32.2)
Grade 1	23 (27.4)	25 (28.7)	48 (28.1)
Grade 2	2 (2.4)	2 (2.3)	4 (2.3)
Grade 3	1 (1.2)	2 (2.3)	3 (1.8)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	2 (2.3)	3 (1.8)
Fatigue - N1	84	87	171
Any	23 (27.4)	32 (36.8)	55 (32.2)
Grade 1	19 (22.6)	24 (27.6)	43 (25.1)
Grade 2	3 (3.6)	8 (9.2)	11 (6.4)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Myalgia - N1	84	87	171
Any	11 (13.1)	19 (21.8)	30 (17.5)
Grade 1	9 (10.7)	16 (18.4)	25 (14.6)
Grade 2	1 (1.2)	2 (2.3)	3 (1.8)
Grade 3	1 (1.2)	1 (1.1)	2 (1.2)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	1 (1.1)	2 (1.2)
Arthralgia - N1	84	87	171
Any	9 (10.7)	16 (18.4)	25 (14.6)
Grade 1	7 (8.3)	12 (13.8)	19 (11.1)
Grade 2	1 (1.2)	4 (4.6)	5 (2.9)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Nausea/Vomiting - N1	84	87	171
Any	6 (7.1)	9 (10.3)	15 (8.8)
Grade 1	4 (4.8)	8 (9.2)	12 (7.0)
Grade 2	2 (2.4)	1 (1.1)	3 (1.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	84	87	171
Any	5 (6.0)	8 (9.2)	13 (7.6)
Grade 1	5 (6.0)	4 (4.6)	9 (5.3)
Grade 2	0	4 (4.6)	4 (2.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Solicited Adverse Reactions - N1	14267	14378	28645
Any Solicited Adverse Reactions	6141 (43.0)	13294 (92.5)	19435 (67.8)
95% CI	42.2, 43.9	92.0, 92.9	67.3, 68.4
Grade 1	4269 (29.9)	4739 (33.0)	9008 (31.4)
Grade 2	1524 (10.7)	5692 (39.6)	7216 (25.2)
Grade 3	345 (2.4)	2849 (19.8)	3194 (11.2)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or Above	348 (2.4)	2863 (19.9)	3211 (11.2)
Solicited Local Adverse Reactions - N1	14267	14375	28642
Any Solicited Local Adverse Reactions	2699 (18.9)	12783 (88.9)	15482 (54.1)
95% CI	18.3, 19.6	88.4, 89.4	53.5, 54.6
Grade 1	2543 (17.8)	8620 (60.0)	11163 (39.0)
Grade 2	83 (0.6)	3160 (22.0)	3243 (11.3)
Grade 3	73 (0.5)	1003 (7.0)	1076 (3.8)
Grade 4	0	0	0
Grade 3 or Above	73 (0.5)	1003 (7.0)	1076 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Pain - N1	14267	14375	28642
Any	2435 (17.1)	12722 (88.5)	15157 (52.9)
Grade 1	2337 (16.4)	9330 (64.9)	11667 (40.7)
Grade 2	58 (0.4)	2797 (19.5)	2855 (10.0)
Grade 3	40 (0.3)	595 (4.1)	635 (2.2)
Grade 4	0	0	0
Grade 3 or Above	40 (0.3)	595 (4.1)	635 (2.2)
Erythema (Redness) - N1	14267	14374	28641
Any	66 (0.5)	1259 (8.8)	1325 (4.6)
Grade 1	47 (0.3)	452 (3.1)	499 (1.7)
Grade 2	5 (<0.1)	527 (3.7)	532 (1.9)
Grade 3	14 (<0.1)	280 (1.9)	294 (1.0)
Grade 4	0	0	0
Grade 3 or Above	14 (<0.1)	280 (1.9)	294 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n	Placebo (N=14267) (%)	mRNA-1273 (N=14378) n	mRNA-1273 (N=14378) (%)	Total (N=28645) n	Total (N=28645) (%)
Swelling (Hardness) - N1	14267		14374		28641	
Any	59	(0.4)	1783	(12.4)	1842	(6.4)
Grade 1	38	(0.3)	890	(6.2)	928	(3.2)
Grade 2	9	(<0.1)	642	(4.5)	651	(2.3)
Grade 3	12	(<0.1)	251	(1.7)	263	(0.9)
Grade 4	0		0		0	
Grade 3 or Above	12	(<0.1)	251	(1.7)	263	(0.9)
Axillary Swelling or Tenderness - N1	14267		14374		28641	
Any	557	(3.9)	2047	(14.2)	2604	(9.1)
Grade 1	512	(3.6)	1704	(11.9)	2216	(7.7)
Grade 2	25	(0.2)	277	(1.9)	302	(1.1)
Grade 3	20	(0.1)	66	(0.5)	86	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	20	(0.1)	66	(0.5)	86	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Solicited Systemic Adverse Reactions - N1	14266	14377	28643
Any Solicited Systemic Adverse Reactions	5241 (36.7)	11459 (79.7)	16700 (58.3)
95% CI	35.9, 37.5	79.0, 80.4	57.7, 58.9
Grade 1	3453 (24.2)	3642 (25.3)	7095 (24.8)
Grade 2	1500 (10.5)	5498 (38.2)	6998 (24.4)
Grade 3	285 (2.0)	2305 (16.0)	2590 (9.0)
Grade 4	3 (<0.1)	14 (<0.1)	17 (<0.1)
Grade 3 or Above	288 (2.0)	2319 (16.1)	2607 (9.1)
Fever - N1	14263	14370	28633
Any	42 (0.3)	2235 (15.6)	2277 (8.0)
Grade 1	32 (0.2)	1340 (9.3)	1372 (4.8)
Grade 2	5 (<0.1)	682 (4.7)	687 (2.4)
Grade 3	2 (<0.1)	200 (1.4)	202 (0.7)
Grade 4	3 (<0.1)	13 (<0.1)	16 (<0.1)
Grade 3 or Above	5 (<0.1)	213 (1.5)	218 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Headache - N1	14265	14374	28639
Any	3363 (23.6)	8488 (59.1)	11851 (41.4)
Grade 1	2688 (18.8)	4725 (32.9)	7413 (25.9)
Grade 2	510 (3.6)	3105 (21.6)	3615 (12.6)
Grade 3	165 (1.2)	658 (4.6)	823 (2.9)
Grade 4	0	0	0
Grade 3 or Above	165 (1.2)	658 (4.6)	823 (2.9)
Fatigue - N1	14265	14374	28639
Any	3344 (23.4)	9446 (65.7)	12790 (44.7)
Grade 1	2134 (15.0)	3375 (23.5)	5509 (19.2)
Grade 2	1103 (7.7)	4655 (32.4)	5758 (20.1)
Grade 3	107 (0.8)	1416 (9.9)	1523 (5.3)
Grade 4	0	0	0
Grade 3 or Above	107 (0.8)	1416 (9.9)	1523 (5.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Myalgia - N1	14265	14374	28639
Any	1775 (12.4)	8357 (58.1)	10132 (35.4)
Grade 1	1271 (8.9)	3166 (22.0)	4437 (15.5)
Grade 2	452 (3.2)	3886 (27.0)	4338 (15.1)
Grade 3	52 (0.4)	1305 (9.1)	1357 (4.7)
Grade 4	0	0	0
Grade 3 or Above	52 (0.4)	1305 (9.1)	1357 (4.7)
Arthralgia - N1	14265	14374	28639
Any	1543 (10.8)	6181 (43.0)	7724 (27.0)
Grade 1	1115 (7.8)	2758 (19.2)	3873 (13.5)
Grade 2	384 (2.7)	2655 (18.5)	3039 (10.6)
Grade 3	44 (0.3)	768 (5.3)	812 (2.8)
Grade 4	0	0	0
Grade 3 or Above	44 (0.3)	768 (5.3)	812 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Nausea/Vomiting - N1	14265	14374	28639
Any	922 (6.5)	2741 (19.1)	3663 (12.8)
Grade 1	747 (5.2)	2052 (14.3)	2799 (9.8)
Grade 2	164 (1.1)	668 (4.6)	832 (2.9)
Grade 3	11 (<0.1)	20 (0.1)	31 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	11 (<0.1)	21 (0.1)	32 (0.1)
Chills - N1	14265	14374	28639
Any	790 (5.5)	6384 (44.4)	7174 (25.0)
Grade 1	610 (4.3)	2854 (19.9)	3464 (12.1)
Grade 2	163 (1.1)	3340 (23.2)	3503 (12.2)
Grade 3	17 (0.1)	190 (1.3)	207 (0.7)
Grade 4	0	0	0
Grade 3 or Above	17 (0.1)	190 (1.3)	207 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Solicited Adverse Reactions - N1	233	232	465
Any Solicited Adverse Reactions	82 (35.2)	187 (80.6)	269 (57.8)
95% CI	29.1, 41.7	74.9, 85.5	53.2, 62.4
Grade 1	52 (22.3)	90 (38.8)	142 (30.5)
Grade 2	27 (11.6)	68 (29.3)	95 (20.4)
Grade 3	3 (1.3)	29 (12.5)	32 (6.9)
Grade 4	0	0	0
Grade 3 or Above	3 (1.3)	29 (12.5)	32 (6.9)
Solicited Local Adverse Reactions - N1	232	232	464
Any Solicited Local Adverse Reactions	42 (18.1)	172 (74.1)	214 (46.1)
95% CI	13.4, 23.7	68.0, 79.6	41.5, 50.8
Grade 1	35 (15.1)	125 (53.9)	160 (34.5)
Grade 2	5 (2.2)	36 (15.5)	41 (8.8)
Grade 3	2 (0.9)	11 (4.7)	13 (2.8)
Grade 4	0	0	0
Grade 3 or Above	2 (0.9)	11 (4.7)	13 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Pain - N1	232	232	464
Any	36 (15.5)	169 (72.8)	205 (44.2)
Grade 1	32 (13.8)	126 (54.3)	158 (34.1)
Grade 2	3 (1.3)	36 (15.5)	39 (8.4)
Grade 3	1 (0.4)	7 (3.0)	8 (1.7)
Grade 4	0	0	0
Grade 3 or Above	1 (0.4)	7 (3.0)	8 (1.7)
Erythema (Redness) - N1	232	232	464
Any	1 (0.4)	9 (3.9)	10 (2.2)
Grade 1	0	2 (0.9)	2 (0.4)
Grade 2	0	4 (1.7)	4 (0.9)
Grade 3	1 (0.4)	3 (1.3)	4 (0.9)
Grade 4	0	0	0
Grade 3 or Above	1 (0.4)	3 (1.3)	4 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=233) n	Placebo (N=233) (%)	mRNA-1273 (N=232) n	mRNA-1273 (N=232) (%)	Total (N=465) n	Total (N=465) (%)
Swelling (Hardness) - N1	232		232		464	
Any	1	(0.4)	11	(4.7)	12	(2.6)
Grade 1	0		4	(1.7)	4	(0.9)
Grade 2	1	(0.4)	5	(2.2)	6	(1.3)
Grade 3	0		2	(0.9)	2	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	0		2	(0.9)	2	(0.4)
Axillary Swelling or Tenderness - N1	232		232		464	
Any	11	(4.7)	32	(13.8)	43	(9.3)
Grade 1	8	(3.4)	22	(9.5)	30	(6.5)
Grade 2	3	(1.3)	8	(3.4)	11	(2.4)
Grade 3	0		2	(0.9)	2	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	0		2	(0.9)	2	(0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Solicited Systemic Adverse Reactions - N1	233	232	465
Any Solicited Systemic Adverse Reactions	73 (31.3)	152 (65.5)	225 (48.4)
95% CI	25.4, 37.7	59.0, 71.6	43.8, 53.0
Grade 1	44 (18.9)	61 (26.3)	105 (22.6)
Grade 2	28 (12.0)	70 (30.2)	98 (21.1)
Grade 3	1 (0.4)	21 (9.1)	22 (4.7)
Grade 4	0	0	0
Grade 3 or Above	1 (0.4)	21 (9.1)	22 (4.7)
Fever - N1	232	232	464
Any	1 (0.4)	31 (13.4)	32 (6.9)
Grade 1	1 (0.4)	20 (8.6)	21 (4.5)
Grade 2	0	9 (3.9)	9 (1.9)
Grade 3	0	2 (0.9)	2 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	2 (0.9)	2 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Headache - N1	232	232	464
Any	43 (18.5)	98 (42.2)	141 (30.4)
Grade 1	35 (15.1)	61 (26.3)	96 (20.7)
Grade 2	8 (3.4)	31 (13.4)	39 (8.4)
Grade 3	0	6 (2.6)	6 (1.3)
Grade 4	0	0	0
Grade 3 or Above	0	6 (2.6)	6 (1.3)
Fatigue - N1	232	232	464
Any	54 (23.3)	106 (45.7)	160 (34.5)
Grade 1	31 (13.4)	42 (18.1)	73 (15.7)
Grade 2	22 (9.5)	52 (22.4)	74 (15.9)
Grade 3	1 (0.4)	12 (5.2)	13 (2.8)
Grade 4	0	0	0
Grade 3 or Above	1 (0.4)	12 (5.2)	13 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Myalgia - N1	232	232	464
Any	34 (14.7)	117 (50.4)	151 (32.5)
Grade 1	22 (9.5)	60 (25.9)	82 (17.7)
Grade 2	12 (5.2)	46 (19.8)	58 (12.5)
Grade 3	0	11 (4.7)	11 (2.4)
Grade 4	0	0	0
Grade 3 or Above	0	11 (4.7)	11 (2.4)
Arthralgia - N1	232	232	464
Any	26 (11.2)	77 (33.2)	103 (22.2)
Grade 1	19 (8.2)	37 (15.9)	56 (12.1)
Grade 2	7 (3.0)	36 (15.5)	43 (9.3)
Grade 3	0	4 (1.7)	4 (0.9)
Grade 4	0	0	0
Grade 3 or Above	0	4 (1.7)	4 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Nausea/Vomiting - N1	232	232	464
Any	13 (5.6)	33 (14.2)	46 (9.9)
Grade 1	10 (4.3)	25 (10.8)	35 (7.5)
Grade 2	3 (1.3)	7 (3.0)	10 (2.2)
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.4)	1 (0.2)
Chills - N1	232	232	464
Any	19 (8.2)	80 (34.5)	99 (21.3)
Grade 1	16 (6.9)	40 (17.2)	56 (12.1)
Grade 2	3 (1.3)	40 (17.2)	43 (9.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Solicited Adverse Reactions - N1	78	81	159
Any Solicited Adverse Reactions	32 (41.0)	75 (92.6)	107 (67.3)
95% CI	30.0, 52.7	84.6, 97.2	59.4, 74.5
Grade 1	25 (32.1)	18 (22.2)	43 (27.0)
Grade 2	7 (9.0)	40 (49.4)	47 (29.6)
Grade 3	0	17 (21.0)	17 (10.7)
Grade 4	0	0	0
Grade 3 or Above	0	17 (21.0)	17 (10.7)
Solicited Local Adverse Reactions - N1	78	81	159
Any Solicited Local Adverse Reactions	16 (20.5)	74 (91.4)	90 (56.6)
95% CI	12.2, 31.2	83.0, 96.5	48.5, 64.4
Grade 1	16 (20.5)	44 (54.3)	60 (37.7)
Grade 2	0	21 (25.9)	21 (13.2)
Grade 3	0	9 (11.1)	9 (5.7)
Grade 4	0	0	0
Grade 3 or Above	0	9 (11.1)	9 (5.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Pain - N1	78	81	159
Any	15 (19.2)	73 (90.1)	88 (55.3)
Grade 1	15 (19.2)	52 (64.2)	67 (42.1)
Grade 2	0	17 (21.0)	17 (10.7)
Grade 3	0	4 (4.9)	4 (2.5)
Grade 4	0	0	0
Grade 3 or Above	0	4 (4.9)	4 (2.5)
Erythema (Redness) - N1	78	81	159
Any	1 (1.3)	6 (7.4)	7 (4.4)
Grade 1	1 (1.3)	2 (2.5)	3 (1.9)
Grade 2	0	0	0
Grade 3	0	4 (4.9)	4 (2.5)
Grade 4	0	0	0
Grade 3 or Above	0	4 (4.9)	4 (2.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Swelling (Hardness) - N1	78	81	159
Any	0	13 (16.0)	13 (8.2)
Grade 1	0	6 (7.4)	6 (3.8)
Grade 2	0	5 (6.2)	5 (3.1)
Grade 3	0	2 (2.5)	2 (1.3)
Grade 4	0	0	0
Grade 3 or Above	0	2 (2.5)	2 (1.3)
Axillary Swelling or Tenderness - N1	78	81	159
Any	3 (3.8)	13 (16.0)	16 (10.1)
Grade 1	3 (3.8)	9 (11.1)	12 (7.5)
Grade 2	0	4 (4.9)	4 (2.5)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Solicited Systemic Adverse Reactions - N1	78	81	159
Any Solicited Systemic Adverse Reactions	29 (37.2)	67 (82.7)	96 (60.4)
95% CI	26.5, 48.9	72.7, 90.2	52.3, 68.0
Grade 1	22 (28.2)	14 (17.3)	36 (22.6)
Grade 2	7 (9.0)	43 (53.1)	50 (31.4)
Grade 3	0	10 (12.3)	10 (6.3)
Grade 4	0	0	0
Grade 3 or Above	0	10 (12.3)	10 (6.3)
Fever - N1	78	80	158
Any	0	10 (12.5)	10 (6.3)
Grade 1	0	3 (3.8)	3 (1.9)
Grade 2	0	6 (7.5)	6 (3.8)
Grade 3	0	1 (1.3)	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.3)	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Headache - N1	78	81	159
Any	21 (26.9)	51 (63.0)	72 (45.3)
Grade 1	17 (21.8)	29 (35.8)	46 (28.9)
Grade 2	4 (5.1)	20 (24.7)	24 (15.1)
Grade 3	0	2 (2.5)	2 (1.3)
Grade 4	0	0	0
Grade 3 or Above	0	2 (2.5)	2 (1.3)
Fatigue - N1	78	81	159
Any	20 (25.6)	55 (67.9)	75 (47.2)
Grade 1	16 (20.5)	14 (17.3)	30 (18.9)
Grade 2	4 (5.1)	36 (44.4)	40 (25.2)
Grade 3	0	5 (6.2)	5 (3.1)
Grade 4	0	0	0
Grade 3 or Above	0	5 (6.2)	5 (3.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Myalgia - N1	78	81	159
Any	15 (19.2)	55 (67.9)	70 (44.0)
Grade 1	14 (17.9)	16 (19.8)	30 (18.9)
Grade 2	1 (1.3)	34 (42.0)	35 (22.0)
Grade 3	0	5 (6.2)	5 (3.1)
Grade 4	0	0	0
Grade 3 or Above	0	5 (6.2)	5 (3.1)
Arthralgia - N1	78	81	159
Any	10 (12.8)	45 (55.6)	55 (34.6)
Grade 1	9 (11.5)	14 (17.3)	23 (14.5)
Grade 2	1 (1.3)	28 (34.6)	29 (18.2)
Grade 3	0	3 (3.7)	3 (1.9)
Grade 4	0	0	0
Grade 3 or Above	0	3 (3.7)	3 (1.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Nausea/Vomiting - N1	78	81	159
Any	6 (7.7)	20 (24.7)	26 (16.4)
Grade 1	4 (5.1)	17 (21.0)	21 (13.2)
Grade 2	2 (2.6)	3 (3.7)	5 (3.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	78	81	159
Any	4 (5.1)	36 (44.4)	40 (25.2)
Grade 1	3 (3.8)	13 (16.0)	16 (10.1)
Grade 2	1 (1.3)	22 (27.2)	23 (14.5)
Grade 3	0	1 (1.2)	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.2)	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Solicited Adverse Reactions - N1	14738	14745	29483
Any Solicited Adverse Reactions	8907 (60.4)	14034 (95.2)	22941 (77.8)
95% CI	59.6, 61.2	94.8, 95.5	77.3, 78.3
Grade 1	5680 (38.5)	4653 (31.6)	10333 (35.0)
Grade 2	2566 (17.4)	6030 (40.9)	8596 (29.2)
Grade 3	653 (4.4)	3333 (22.6)	3986 (13.5)
Grade 4	8 (<0.1)	18 (0.1)	26 (<0.1)
Grade 3 or Above	661 (4.5)	3351 (22.7)	4012 (13.6)
Solicited Local Adverse Reactions - N1	14737	14745	29482
Any Solicited Local Adverse Reactions	4366 (29.6)	13676 (92.8)	18042 (61.2)
95% CI	28.9, 30.4	92.3, 93.2	60.6, 61.8
Grade 1	4066 (27.6)	8775 (59.5)	12841 (43.6)
Grade 2	157 (1.1)	3516 (23.8)	3673 (12.5)
Grade 3	143 (1.0)	1385 (9.4)	1528 (5.2)
Grade 4	0	0	0
Grade 3 or Above	143 (1.0)	1385 (9.4)	1528 (5.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Pain - N1	14737	14745	29482
Any	3953 (26.8)	13618 (92.4)	17571 (59.6)
Grade 1	3755 (25.5)	9585 (65.0)	13340 (45.2)
Grade 2	107 (0.7)	3133 (21.2)	3240 (11.0)
Grade 3	91 (0.6)	900 (6.1)	991 (3.4)
Grade 4	0	0	0
Grade 3 or Above	91 (0.6)	900 (6.1)	991 (3.4)
Erythema (Redness) - N1	14737	14744	29481
Any	132 (0.9)	1520 (10.3)	1652 (5.6)
Grade 1	96 (0.7)	620 (4.2)	716 (2.4)
Grade 2	12 (<0.1)	585 (4.0)	597 (2.0)
Grade 3	24 (0.2)	315 (2.1)	339 (1.1)
Grade 4	0	0	0
Grade 3 or Above	24 (0.2)	315 (2.1)	339 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Swelling (Hardness) - N1	14737	14744	29481
Any	113 (0.8)	2207 (15.0)	2320 (7.9)
Grade 1	79 (0.5)	1129 (7.7)	1208 (4.1)
Grade 2	17 (0.1)	756 (5.1)	773 (2.6)
Grade 3	17 (0.1)	322 (2.2)	339 (1.1)
Grade 4	0	0	0
Grade 3 or Above	17 (0.1)	322 (2.2)	339 (1.1)
Axillary Swelling or Tenderness - N1	14737	14744	29481
Any	1074 (7.3)	2920 (19.8)	3994 (13.5)
Grade 1	981 (6.7)	2465 (16.7)	3446 (11.7)
Grade 2	48 (0.3)	350 (2.4)	398 (1.4)
Grade 3	45 (0.3)	105 (0.7)	150 (0.5)
Grade 4	0	0	0
Grade 3 or Above	45 (0.3)	105 (0.7)	150 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Solicited Systemic Adverse Reactions - N1	14738	14744	29482
Any Solicited Systemic Adverse Reactions	7931 (53.8)	12465 (84.5)	20396 (69.2)
95% CI	53.0, 54.6	83.9, 85.1	68.7, 69.7
Grade 1	4839 (32.8)	3926 (26.6)	8765 (29.7)
Grade 2	2535 (17.2)	5949 (40.3)	8484 (28.8)
Grade 3	549 (3.7)	2572 (17.4)	3121 (10.6)
Grade 4	8 (<0.1)	18 (0.1)	26 (<0.1)
Grade 3 or Above	557 (3.8)	2590 (17.6)	3147 (10.7)
Fever - N1	14738	14744	29482
Any	79 (0.5)	2285 (15.5)	2364 (8.0)
Grade 1	56 (0.4)	1371 (9.3)	1427 (4.8)
Grade 2	11 (<0.1)	690 (4.7)	701 (2.4)
Grade 3	4 (<0.1)	208 (1.4)	212 (0.7)
Grade 4	8 (<0.1)	16 (0.1)	24 (<0.1)
Grade 3 or Above	12 (<0.1)	224 (1.5)	236 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Headache - N1	14737	14744	29481
Any	5480 (37.2)	9620 (65.2)	15100 (51.2)
Grade 1	4257 (28.9)	5445 (36.9)	9702 (32.9)
Grade 2	887 (6.0)	3320 (22.5)	4207 (14.3)
Grade 3	336 (2.3)	855 (5.8)	1191 (4.0)
Grade 4	0	0	0
Grade 3 or Above	336 (2.3)	855 (5.8)	1191 (4.0)
Fatigue - N1	14737	14744	29481
Any	5421 (36.8)	10409 (70.6)	15830 (53.7)
Grade 1	3268 (22.2)	3717 (25.2)	6985 (23.7)
Grade 2	1957 (13.3)	5181 (35.1)	7138 (24.2)
Grade 3	196 (1.3)	1510 (10.2)	1706 (5.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	196 (1.3)	1511 (10.2)	1707 (5.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Myalgia - N1	14737	14744	29481
Any	3032 (20.6)	9111 (61.8)	12143 (41.2)
Grade 1	2141 (14.5)	3581 (24.3)	5722 (19.4)
Grade 2	796 (5.4)	4166 (28.3)	4962 (16.8)
Grade 3	95 (0.6)	1364 (9.3)	1459 (4.9)
Grade 4	0	0	0
Grade 3 or Above	95 (0.6)	1364 (9.3)	1459 (4.9)
Arthralgia - N1	14737	14744	29481
Any	2602 (17.7)	6879 (46.7)	9481 (32.2)
Grade 1	1829 (12.4)	3167 (21.5)	4996 (16.9)
Grade 2	695 (4.7)	2905 (19.7)	3600 (12.2)
Grade 3	78 (0.5)	806 (5.5)	884 (3.0)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	78 (0.5)	807 (5.5)	885 (3.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Nausea/Vomiting - N1	14737	14744	29481
Any	1680 (11.4)	3402 (23.1)	5082 (17.2)
Grade 1	1352 (9.2)	2553 (17.3)	3905 (13.2)
Grade 2	304 (2.1)	819 (5.6)	1123 (3.8)
Grade 3	24 (0.2)	29 (0.2)	53 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	24 (0.2)	30 (0.2)	54 (0.2)
Chills - N1	14737	14744	29481
Any	1426 (9.7)	6744 (45.7)	8170 (27.7)
Grade 1	1099 (7.5)	3068 (20.8)	4167 (14.1)
Grade 2	297 (2.0)	3469 (23.5)	3766 (12.8)
Grade 3	30 (0.2)	207 (1.4)	237 (0.8)
Grade 4	0	0	0
Grade 3 or Above	30 (0.2)	207 (1.4)	237 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Solicited Adverse Reactions - N1	337	347	684
Any Solicited Adverse Reactions	156 (46.3)	285 (82.1)	441 (64.5)
95% CI	40.9, 51.8	77.7, 86.0	60.8, 68.1
Grade 1	85 (25.2)	122 (35.2)	207 (30.3)
Grade 2	54 (16.0)	113 (32.6)	167 (24.4)
Grade 3	16 (4.7)	49 (14.1)	65 (9.5)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or Above	17 (5.0)	50 (14.4)	67 (9.8)
Solicited Local Adverse Reactions - N1	337	347	684
Any Solicited Local Adverse Reactions	77 (22.8)	274 (79.0)	351 (51.3)
95% CI	18.5, 27.7	74.3, 83.1	47.5, 55.1
Grade 1	66 (19.6)	181 (52.2)	247 (36.1)
Grade 2	6 (1.8)	70 (20.2)	76 (11.1)
Grade 3	5 (1.5)	23 (6.6)	28 (4.1)
Grade 4	0	0	0
Grade 3 or Above	5 (1.5)	23 (6.6)	28 (4.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Pain - N1	337	347	684
Any	70 (20.8)	271 (78.1)	341 (49.9)
Grade 1	64 (19.0)	185 (53.3)	249 (36.4)
Grade 2	4 (1.2)	70 (20.2)	74 (10.8)
Grade 3	2 (0.6)	16 (4.6)	18 (2.6)
Grade 4	0	0	0
Grade 3 or Above	2 (0.6)	16 (4.6)	18 (2.6)
Erythema (Redness) - N1	337	347	684
Any	4 (1.2)	18 (5.2)	22 (3.2)
Grade 1	1 (0.3)	7 (2.0)	8 (1.2)
Grade 2	0	6 (1.7)	6 (0.9)
Grade 3	3 (0.9)	5 (1.4)	8 (1.2)
Grade 4	0	0	0
Grade 3 or Above	3 (0.9)	5 (1.4)	8 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Swelling (Hardness) - N1	337	347	684
Any	3 (0.9)	26 (7.5)	29 (4.2)
Grade 1	2 (0.6)	13 (3.7)	15 (2.2)
Grade 2	1 (0.3)	10 (2.9)	11 (1.6)
Grade 3	0	3 (0.9)	3 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	3 (0.9)	3 (0.4)
Axillary Swelling or Tenderness - N1	337	347	684
Any	22 (6.5)	74 (21.3)	96 (14.0)
Grade 1	18 (5.3)	52 (15.0)	70 (10.2)
Grade 2	3 (0.9)	16 (4.6)	19 (2.8)
Grade 3	1 (0.3)	6 (1.7)	7 (1.0)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	6 (1.7)	7 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Solicited Systemic Adverse Reactions - N1	337	347	684
Any Solicited Systemic Adverse Reactions	141 (41.8)	244 (70.3)	385 (56.3)
95% CI	36.5, 47.3	65.2, 75.1	52.5, 60.0
Grade 1	73 (21.7)	97 (28.0)	170 (24.9)
Grade 2	55 (16.3)	109 (31.4)	164 (24.0)
Grade 3	12 (3.6)	37 (10.7)	49 (7.2)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or Above	13 (3.9)	38 (11.0)	51 (7.5)
Fever - N1	336	347	683
Any	7 (2.1)	55 (15.9)	62 (9.1)
Grade 1	4 (1.2)	34 (9.8)	38 (5.6)
Grade 2	2 (0.6)	16 (4.6)	18 (2.6)
Grade 3	0	4 (1.2)	4 (0.6)
Grade 4	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3 or Above	1 (0.3)	5 (1.4)	6 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Headache - N1	337	347	684
Any	98 (29.1)	168 (48.4)	266 (38.9)
Grade 1	69 (20.5)	103 (29.7)	172 (25.1)
Grade 2	22 (6.5)	49 (14.1)	71 (10.4)
Grade 3	7 (2.1)	16 (4.6)	23 (3.4)
Grade 4	0	0	0
Grade 3 or Above	7 (2.1)	16 (4.6)	23 (3.4)
Fatigue - N1	337	347	684
Any	96 (28.5)	172 (49.6)	268 (39.2)
Grade 1	50 (14.8)	69 (19.9)	119 (17.4)
Grade 2	41 (12.2)	84 (24.2)	125 (18.3)
Grade 3	5 (1.5)	19 (5.5)	24 (3.5)
Grade 4	0	0	0
Grade 3 or Above	5 (1.5)	19 (5.5)	24 (3.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Myalgia - N1	337	347	684
Any	66 (19.6)	180 (51.9)	246 (36.0)
Grade 1	37 (11.0)	88 (25.4)	125 (18.3)
Grade 2	27 (8.0)	76 (21.9)	103 (15.1)
Grade 3	2 (0.6)	16 (4.6)	18 (2.6)
Grade 4	0	0	0
Grade 3 or Above	2 (0.6)	16 (4.6)	18 (2.6)
Arthralgia - N1	337	347	684
Any	55 (16.3)	128 (36.9)	183 (26.8)
Grade 1	32 (9.5)	65 (18.7)	97 (14.2)
Grade 2	21 (6.2)	56 (16.1)	77 (11.3)
Grade 3	2 (0.6)	7 (2.0)	9 (1.3)
Grade 4	0	0	0
Grade 3 or Above	2 (0.6)	7 (2.0)	9 (1.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Nausea/Vomiting - N1	337	347	684
Any	35 (10.4)	65 (18.7)	100 (14.6)
Grade 1	24 (7.1)	47 (13.5)	71 (10.4)
Grade 2	11 (3.3)	17 (4.9)	28 (4.1)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.1)
Chills - N1	337	347	684
Any	40 (11.9)	126 (36.3)	166 (24.3)
Grade 1	27 (8.0)	63 (18.2)	90 (13.2)
Grade 2	12 (3.6)	60 (17.3)	72 (10.5)
Grade 3	1 (0.3)	3 (0.9)	4 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	3 (0.9)	4 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Adverse Reactions - N1	84	87	171
Any Solicited Adverse Reactions	50 (59.5)	83 (95.4)	133 (77.8)
95% CI	48.3, 70.1	88.6, 98.7	70.8, 83.8
Grade 1	39 (46.4)	23 (26.4)	62 (36.3)
Grade 2	10 (11.9)	38 (43.7)	48 (28.1)
Grade 3	1 (1.2)	22 (25.3)	23 (13.5)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	22 (25.3)	23 (13.5)
Solicited Local Adverse Reactions - N1	84	87	171
Any Solicited Local Adverse Reactions	25 (29.8)	82 (94.3)	107 (62.6)
95% CI	20.3, 40.7	87.1, 98.1	54.9, 69.8
Grade 1	25 (29.8)	47 (54.0)	72 (42.1)
Grade 2	0	23 (26.4)	23 (13.5)
Grade 3	0	12 (13.8)	12 (7.0)
Grade 4	0	0	0
Grade 3 or Above	0	12 (13.8)	12 (7.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Pain - N1	84	87	171
Any	23 (27.4)	80 (92.0)	103 (60.2)
Grade 1	23 (27.4)	55 (63.2)	78 (45.6)
Grade 2	0	18 (20.7)	18 (10.5)
Grade 3	0	7 (8.0)	7 (4.1)
Grade 4	0	0	0
Grade 3 or Above	0	7 (8.0)	7 (4.1)
Erythema (Redness) - N1	84	87	171
Any	1 (1.2)	11 (12.6)	12 (7.0)
Grade 1	1 (1.2)	5 (5.7)	6 (3.5)
Grade 2	0	2 (2.3)	2 (1.2)
Grade 3	0	4 (4.6)	4 (2.3)
Grade 4	0	0	0
Grade 3 or Above	0	4 (4.6)	4 (2.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Swelling (Hardness) - N1	84	87	171
Any	0	16 (18.4)	16 (9.4)
Grade 1	0	9 (10.3)	9 (5.3)
Grade 2	0	5 (5.7)	5 (2.9)
Grade 3	0	2 (2.3)	2 (1.2)
Grade 4	0	0	0
Grade 3 or Above	0	2 (2.3)	2 (1.2)
Axillary Swelling or Tenderness - N1	84	87	171
Any	5 (6.0)	19 (21.8)	24 (14.0)
Grade 1	5 (6.0)	15 (17.2)	20 (11.7)
Grade 2	0	4 (4.6)	4 (2.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Systemic Adverse Reactions - N1	84	87	171
Any Solicited Systemic Adverse Reactions	45 (53.6)	70 (80.5)	115 (67.3)
95% CI	42.4, 64.5	70.6, 88.2	59.7, 74.2
Grade 1	34 (40.5)	17 (19.5)	51 (29.8)
Grade 2	10 (11.9)	41 (47.1)	51 (29.8)
Grade 3	1 (1.2)	12 (13.8)	13 (7.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	12 (13.8)	13 (7.6)
Fever - N1	84	86	170
Any	0	10 (11.6)	10 (5.9)
Grade 1	0	3 (3.5)	3 (1.8)
Grade 2	0	6 (7.0)	6 (3.5)
Grade 3	0	1 (1.2)	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.2)	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Headache - N1	84	87	171
Any	35 (41.7)	56 (64.4)	91 (53.2)
Grade 1	29 (34.5)	31 (35.6)	60 (35.1)
Grade 2	5 (6.0)	21 (24.1)	26 (15.2)
Grade 3	1 (1.2)	4 (4.6)	5 (2.9)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	4 (4.6)	5 (2.9)
Fatigue - N1	84	87	171
Any	32 (38.1)	59 (67.8)	91 (53.2)
Grade 1	25 (29.8)	16 (18.4)	41 (24.0)
Grade 2	6 (7.1)	38 (43.7)	44 (25.7)
Grade 3	1 (1.2)	5 (5.7)	6 (3.5)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	5 (5.7)	6 (3.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Myalgia - N1	84	87	171
Any	20 (23.8)	57 (65.5)	77 (45.0)
Grade 1	17 (20.2)	17 (19.5)	34 (19.9)
Grade 2	2 (2.4)	35 (40.2)	37 (21.6)
Grade 3	1 (1.2)	5 (5.7)	6 (3.5)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	5 (5.7)	6 (3.5)
Arthralgia - N1	84	87	171
Any	15 (17.9)	48 (55.2)	63 (36.8)
Grade 1	12 (14.3)	16 (18.4)	28 (16.4)
Grade 2	2 (2.4)	29 (33.3)	31 (18.1)
Grade 3	1 (1.2)	3 (3.4)	4 (2.3)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	3 (3.4)	4 (2.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Nausea/Vomiting - N1	84	87	171
Any	8 (9.5)	26 (29.9)	34 (19.9)
Grade 1	4 (4.8)	22 (25.3)	26 (15.2)
Grade 2	4 (4.8)	4 (4.6)	8 (4.7)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	84	87	171
Any	7 (8.3)	37 (42.5)	44 (25.7)
Grade 1	6 (7.1)	13 (14.9)	19 (11.1)
Grade 2	1 (1.2)	23 (26.4)	24 (14.0)
Grade 3	0	1 (1.1)	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.1)	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11993) n (%)	mRNA-1273 (N=12020) n (%)	Total (N=24013) n (%)
Solicited Adverse Reactions - N1	11993	12020	24013
Any Solicited Adverse Reactions	5827 (48.6)	10662 (88.7)	16489 (68.7)
95% CI	47.7, 49.5	88.1, 89.3	68.1, 69.3
Grade 1	4150 (34.6)	7546 (62.8)	11696 (48.7)
Grade 2	1383 (11.5)	2469 (20.5)	3852 (16.0)
Grade 3	290 (2.4)	643 (5.3)	933 (3.9)
Grade 4	4 (<0.1)	4 (<0.1)	8 (<0.1)
Grade 3 or Above	294 (2.5)	647 (5.4)	941 (3.9)
Solicited Local Adverse Reactions - N1	11991	12018	24009
Any Solicited Local Adverse Reactions	2410 (20.1)	10247 (85.3)	12657 (52.7)
95% CI	19.4, 20.8	84.6, 85.9	52.1, 53.4
Grade 1	2285 (19.1)	8664 (72.1)	10949 (45.6)
Grade 2	63 (0.5)	1193 (9.9)	1256 (5.2)
Grade 3	62 (0.5)	390 (3.2)	452 (1.9)
Grade 4	0	0	0
Grade 3 or Above	62 (0.5)	390 (3.2)	452 (1.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11993) n (%)	mRNA-1273 (N=12020) n (%)	Total (N=24013) n (%)
Pain - N1	11991	12018	24009
Any	2132 (17.8)	10194 (84.8)	12326 (51.3)
Grade 1	2050 (17.1)	8867 (73.8)	10917 (45.5)
Grade 2	39 (0.3)	1018 (8.5)	1057 (4.4)
Grade 3	43 (0.4)	309 (2.6)	352 (1.5)
Grade 4	0	0	0
Grade 3 or Above	43 (0.4)	309 (2.6)	352 (1.5)
Erythema (Redness) - N1	11991	12018	24009
Any	59 (0.5)	363 (3.0)	422 (1.8)
Grade 1	43 (0.4)	233 (1.9)	276 (1.1)
Grade 2	6 (<0.1)	100 (0.8)	106 (0.4)
Grade 3	10 (<0.1)	30 (0.2)	40 (0.2)
Grade 4	0	0	0
Grade 3 or Above	10 (<0.1)	30 (0.2)	40 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11993) n (%)	mRNA-1273 (N=12020) n (%)	Total (N=24013) n (%)
Swelling (Hardness) - N1	11991	12018	24009
Any	52 (0.4)	710 (5.9)	762 (3.2)
Grade 1	41 (0.3)	465 (3.9)	506 (2.1)
Grade 2	6 (<0.1)	184 (1.5)	190 (0.8)
Grade 3	5 (<0.1)	61 (0.5)	66 (0.3)
Grade 4	0	0	0
Grade 3 or Above	5 (<0.1)	61 (0.5)	66 (0.3)
Axillary Swelling or Tenderness - N1	11991	12018	24009
Any	553 (4.6)	1161 (9.7)	1714 (7.1)
Grade 1	514 (4.3)	1050 (8.7)	1564 (6.5)
Grade 2	19 (0.2)	78 (0.6)	97 (0.4)
Grade 3	20 (0.2)	33 (0.3)	53 (0.2)
Grade 4	0	0	0
Grade 3 or Above	20 (0.2)	33 (0.3)	53 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11993) n (%)	mRNA-1273 (N=12020) n (%)	Total (N=24013) n (%)
Solicited Systemic Adverse Reactions - N1	11993	12020	24013
Any Solicited Systemic Adverse Reactions	5117 (42.7)	6567 (54.6)	11684 (48.7)
95% CI	41.8, 43.6	53.7, 55.5	48.0, 49.3
Grade 1	3509 (29.3)	4279 (35.6)	7788 (32.4)
Grade 2	1358 (11.3)	1946 (16.2)	3304 (13.8)
Grade 3	246 (2.1)	338 (2.8)	584 (2.4)
Grade 4	4 (<0.1)	4 (<0.1)	8 (<0.1)
Grade 3 or Above	250 (2.1)	342 (2.8)	592 (2.5)
Fever - N1	11991	12017	24008
Any	34 (0.3)	78 (0.6)	112 (0.5)
Grade 1	22 (0.2)	45 (0.4)	67 (0.3)
Grade 2	7 (<0.1)	19 (0.2)	26 (0.1)
Grade 3	1 (<0.1)	11 (<0.1)	12 (<0.1)
Grade 4	4 (<0.1)	3 (<0.1)	7 (<0.1)
Grade 3 or Above	5 (<0.1)	14 (0.1)	19 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11993) n (%)	mRNA-1273 (N=12020) n (%)	Total (N=24013) n (%)
Headache - N1	11991	12018	24009
Any	3246 (27.1)	3953 (32.9)	7199 (30.0)
Grade 1	2674 (22.3)	3162 (26.3)	5836 (24.3)
Grade 2	421 (3.5)	588 (4.9)	1009 (4.2)
Grade 3	151 (1.3)	203 (1.7)	354 (1.5)
Grade 4	0	0	0
Grade 3 or Above	151 (1.3)	203 (1.7)	354 (1.5)
Fatigue - N1	11991	12018	24009
Any	3302 (27.5)	4462 (37.1)	7764 (32.3)
Grade 1	2181 (18.2)	2849 (23.7)	5030 (21.0)
Grade 2	1035 (8.6)	1499 (12.5)	2534 (10.6)
Grade 3	86 (0.7)	113 (0.9)	199 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	86 (0.7)	114 (0.9)	200 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11993) n (%)	mRNA-1273 (N=12020) n (%)	Total (N=24013) n (%)
Myalgia - N1	11991	12018	24009
Any	1593 (13.3)	2602 (21.7)	4195 (17.5)
Grade 1	1227 (10.2)	1890 (15.7)	3117 (13.0)
Grade 2	328 (2.7)	647 (5.4)	975 (4.1)
Grade 3	38 (0.3)	65 (0.5)	103 (0.4)
Grade 4	0	0	0
Grade 3 or Above	38 (0.3)	65 (0.5)	103 (0.4)
Arthralgia - N1	11991	12018	24009
Any	1377 (11.5)	1935 (16.1)	3312 (13.8)
Grade 1	1051 (8.8)	1451 (12.1)	2502 (10.4)
Grade 2	298 (2.5)	440 (3.7)	738 (3.1)
Grade 3	28 (0.2)	43 (0.4)	71 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	28 (0.2)	44 (0.4)	72 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11993) n (%)	mRNA-1273 (N=12020) n (%)	Total (N=24013) n (%)
Nausea/Vomiting - N1	11991	12018	24009
Any	832 (6.9)	982 (8.2)	1814 (7.6)
Grade 1	689 (5.7)	820 (6.8)	1509 (6.3)
Grade 2	133 (1.1)	156 (1.3)	289 (1.2)
Grade 3	10 (<0.1)	6 (<0.1)	16 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	10 (<0.1)	6 (<0.1)	16 (<0.1)
Chills - N1	11991	12018	24009
Any	662 (5.5)	916 (7.6)	1578 (6.6)
Grade 1	534 (4.5)	700 (5.8)	1234 (5.1)
Grade 2	116 (1.0)	203 (1.7)	319 (1.3)
Grade 3	12 (0.1)	13 (0.1)	25 (0.1)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	13 (0.1)	25 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1527) n (%)	mRNA-1273 (N=1564) n (%)	Total (N=3091) n (%)
Solicited Adverse Reactions - N1	1527	1564	3091
Any Solicited Adverse Reactions	653 (42.8)	1202 (76.9)	1855 (60.0)
95% CI	40.3, 45.3	74.7, 78.9	58.3, 61.7
Grade 1	421 (27.6)	848 (54.2)	1269 (41.1)
Grade 2	192 (12.6)	272 (17.4)	464 (15.0)
Grade 3	38 (2.5)	81 (5.2)	119 (3.8)
Grade 4	2 (0.1)	1 (<0.1)	3 (<0.1)
Grade 3 or Above	40 (2.6)	82 (5.2)	122 (3.9)
Solicited Local Adverse Reactions - N1	1526	1564	3090
Any Solicited Local Adverse Reactions	249 (16.3)	1107 (70.8)	1356 (43.9)
95% CI	14.5, 18.3	68.5, 73.0	42.1, 45.7
Grade 1	225 (14.7)	943 (60.3)	1168 (37.8)
Grade 2	15 (1.0)	112 (7.2)	127 (4.1)
Grade 3	9 (0.6)	52 (3.3)	61 (2.0)
Grade 4	0	0	0
Grade 3 or Above	9 (0.6)	52 (3.3)	61 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1527) n (%)	mRNA-1273 (N=1564) n (%)	Total (N=3091) n (%)
Pain - N1	1526	1564	3090
Any	219 (14.4)	1087 (69.5)	1306 (42.3)
Grade 1	200 (13.1)	958 (61.3)	1158 (37.5)
Grade 2	13 (0.9)	93 (5.9)	106 (3.4)
Grade 3	6 (0.4)	36 (2.3)	42 (1.4)
Grade 4	0	0	0
Grade 3 or Above	6 (0.4)	36 (2.3)	42 (1.4)
Erythema (Redness) - N1	1526	1564	3090
Any	9 (0.6)	28 (1.8)	37 (1.2)
Grade 1	6 (0.4)	12 (0.8)	18 (0.6)
Grade 2	1 (<0.1)	5 (0.3)	6 (0.2)
Grade 3	2 (0.1)	11 (0.7)	13 (0.4)
Grade 4	0	0	0
Grade 3 or Above	2 (0.1)	11 (0.7)	13 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1527) n (%)	mRNA-1273 (N=1564) n (%)	Total (N=3091) n (%)
Swelling (Hardness) - N1	1526	1564	3090
Any	4 (0.3)	73 (4.7)	77 (2.5)
Grade 1	3 (0.2)	41 (2.6)	44 (1.4)
Grade 2	0	22 (1.4)	22 (0.7)
Grade 3	1 (<0.1)	10 (0.6)	11 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	10 (0.6)	11 (0.4)
Axillary Swelling or Tenderness - N1	1526	1564	3090
Any	76 (5.0)	161 (10.3)	237 (7.7)
Grade 1	67 (4.4)	139 (8.9)	206 (6.7)
Grade 2	5 (0.3)	14 (0.9)	19 (0.6)
Grade 3	4 (0.3)	8 (0.5)	12 (0.4)
Grade 4	0	0	0
Grade 3 or Above	4 (0.3)	8 (0.5)	12 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1527) n (%)	mRNA-1273 (N=1564) n (%)	Total (N=3091) n (%)
Solicited Systemic Adverse Reactions - N1	1527	1564	3091
Any Solicited Systemic Adverse Reactions	574 (37.6)	785 (50.2)	1359 (44.0)
95% CI	35.2, 40.1	47.7, 52.7	42.2, 45.7
Grade 1	352 (23.1)	505 (32.3)	857 (27.7)
Grade 2	186 (12.2)	234 (15.0)	420 (13.6)
Grade 3	34 (2.2)	45 (2.9)	79 (2.6)
Grade 4	2 (0.1)	1 (<0.1)	3 (<0.1)
Grade 3 or Above	36 (2.4)	46 (2.9)	82 (2.7)
Fever - N1	1527	1564	3091
Any	9 (0.6)	17 (1.1)	26 (0.8)
Grade 1	5 (0.3)	13 (0.8)	18 (0.6)
Grade 2	1 (<0.1)	3 (0.2)	4 (0.1)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	2 (0.1)	1 (<0.1)	3 (<0.1)
Grade 3 or Above	3 (0.2)	1 (<0.1)	4 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1527) n (%)	mRNA-1273 (N=1564) n (%)	Total (N=3091) n (%)
Headache - N1	1526	1564	3090
Any	352 (23.1)	400 (25.6)	752 (24.3)
Grade 1	271 (17.8)	325 (20.8)	596 (19.3)
Grade 2	56 (3.7)	46 (2.9)	102 (3.3)
Grade 3	25 (1.6)	29 (1.9)	54 (1.7)
Grade 4	0	0	0
Grade 3 or Above	25 (1.6)	29 (1.9)	54 (1.7)
Fatigue - N1	1526	1564	3090
Any	353 (23.1)	472 (30.2)	825 (26.7)
Grade 1	213 (14.0)	312 (19.9)	525 (17.0)
Grade 2	129 (8.5)	150 (9.6)	279 (9.0)
Grade 3	11 (0.7)	10 (0.6)	21 (0.7)
Grade 4	0	0	0
Grade 3 or Above	11 (0.7)	10 (0.6)	21 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1527) n (%)	mRNA-1273 (N=1564) n (%)	Total (N=3091) n (%)
Myalgia - N1	1526	1564	3090
Any	209 (13.7)	365 (23.3)	574 (18.6)
Grade 1	138 (9.0)	235 (15.0)	373 (12.1)
Grade 2	68 (4.5)	116 (7.4)	184 (6.0)
Grade 3	3 (0.2)	14 (0.9)	17 (0.6)
Grade 4	0	0	0
Grade 3 or Above	3 (0.2)	14 (0.9)	17 (0.6)
Arthralgia - N1	1526	1564	3090
Any	191 (12.5)	274 (17.5)	465 (15.0)
Grade 1	116 (7.6)	183 (11.7)	299 (9.7)
Grade 2	69 (4.5)	82 (5.2)	151 (4.9)
Grade 3	6 (0.4)	9 (0.6)	15 (0.5)
Grade 4	0	0	0
Grade 3 or Above	6 (0.4)	9 (0.6)	15 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1527) n (%)	mRNA-1273 (N=1564) n (%)	Total (N=3091) n (%)
Nausea/Vomiting - N1	1526	1564	3090
Any	113 (7.4)	120 (7.7)	233 (7.5)
Grade 1	85 (5.6)	96 (6.1)	181 (5.9)
Grade 2	27 (1.8)	21 (1.3)	48 (1.6)
Grade 3	1 (<0.1)	3 (0.2)	4 (0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	3 (0.2)	4 (0.1)
Chills - N1	1526	1564	3090
Any	102 (6.7)	140 (9.0)	242 (7.8)
Grade 1	78 (5.1)	104 (6.6)	182 (5.9)
Grade 2	23 (1.5)	30 (1.9)	53 (1.7)
Grade 3	1 (<0.1)	6 (0.4)	7 (0.2)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	6 (0.4)	7 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=737) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1393) n (%)
Solicited Adverse Reactions - N1	737	656	1393
Any Solicited Adverse Reactions	334 (45.3)	605 (92.2)	939 (67.4)
95% CI	41.7, 49.0	89.9, 94.2	64.9, 69.9
Grade 1	251 (34.1)	398 (60.7)	649 (46.6)
Grade 2	74 (10.0)	151 (23.0)	225 (16.2)
Grade 3	9 (1.2)	56 (8.5)	65 (4.7)
Grade 4	0	0	0
Grade 3 or Above	9 (1.2)	56 (8.5)	65 (4.7)
Solicited Local Adverse Reactions - N1	736	655	1391
Any Solicited Local Adverse Reactions	154 (20.9)	590 (90.1)	744 (53.5)
95% CI	18.0, 24.0	87.5, 92.3	50.8, 56.1
Grade 1	149 (20.2)	453 (69.2)	602 (43.3)
Grade 2	4 (0.5)	95 (14.5)	99 (7.1)
Grade 3	1 (0.1)	42 (6.4)	43 (3.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	42 (6.4)	43 (3.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=737) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1393) n (%)
Pain - N1	736	655	1391
Any	143 (19.4)	590 (90.1)	733 (52.7)
Grade 1	139 (18.9)	478 (73.0)	617 (44.4)
Grade 2	3 (0.4)	78 (11.9)	81 (5.8)
Grade 3	1 (0.1)	34 (5.2)	35 (2.5)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	34 (5.2)	35 (2.5)
Erythema (Redness) - N1	736	655	1391
Any	1 (0.1)	18 (2.7)	19 (1.4)
Grade 1	1 (0.1)	11 (1.7)	12 (0.9)
Grade 2	0	7 (1.1)	7 (0.5)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=737) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1393) n (%)
Swelling (Hardness) - N1	736	655	1391
Any	1 (0.1)	76 (11.6)	77 (5.5)
Grade 1	1 (0.1)	50 (7.6)	51 (3.7)
Grade 2	0	20 (3.1)	20 (1.4)
Grade 3	0	6 (0.9)	6 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	6 (0.9)	6 (0.4)
Axillary Swelling or Tenderness - N1	736	655	1391
Any	31 (4.2)	82 (12.5)	113 (8.1)
Grade 1	30 (4.1)	69 (10.5)	99 (7.1)
Grade 2	1 (0.1)	9 (1.4)	10 (0.7)
Grade 3	0	4 (0.6)	4 (0.3)
Grade 4	0	0	0
Grade 3 or Above	0	4 (0.6)	4 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=737) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1393) n (%)
Solicited Systemic Adverse Reactions - N1	737	656	1393
Any Solicited Systemic Adverse Reactions	283 (38.4)	392 (59.8)	675 (48.5)
95% CI	34.9, 42.0	55.9, 63.5	45.8, 51.1
Grade 1	202 (27.4)	244 (37.2)	446 (32.0)
Grade 2	73 (9.9)	125 (19.1)	198 (14.2)
Grade 3	8 (1.1)	23 (3.5)	31 (2.2)
Grade 4	0	0	0
Grade 3 or Above	8 (1.1)	23 (3.5)	31 (2.2)
Fever - N1	737	656	1393
Any	0	8 (1.2)	8 (0.6)
Grade 1	0	8 (1.2)	8 (0.6)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=737) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1393) n (%)
Headache - N1	736	655	1391
Any	154 (20.9)	230 (35.1)	384 (27.6)
Grade 1	130 (17.7)	180 (27.5)	310 (22.3)
Grade 2	19 (2.6)	34 (5.2)	53 (3.8)
Grade 3	5 (0.7)	16 (2.4)	21 (1.5)
Grade 4	0	0	0
Grade 3 or Above	5 (0.7)	16 (2.4)	21 (1.5)
Fatigue - N1	736	655	1391
Any	190 (25.8)	299 (45.6)	489 (35.2)
Grade 1	131 (17.8)	185 (28.2)	316 (22.7)
Grade 2	57 (7.7)	102 (15.6)	159 (11.4)
Grade 3	2 (0.3)	12 (1.8)	14 (1.0)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	12 (1.8)	14 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=737) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1393) n (%)
Myalgia - N1	736	655	1391
Any	102 (13.9)	200 (30.5)	302 (21.7)
Grade 1	82 (11.1)	129 (19.7)	211 (15.2)
Grade 2	20 (2.7)	65 (9.9)	85 (6.1)
Grade 3	0	6 (0.9)	6 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	6 (0.9)	6 (0.4)
Arthralgia - N1	736	655	1391
Any	70 (9.5)	120 (18.3)	190 (13.7)
Grade 1	60 (8.2)	82 (12.5)	142 (10.2)
Grade 2	10 (1.4)	36 (5.5)	46 (3.3)
Grade 3	0	2 (0.3)	2 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	2 (0.3)	2 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=737) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1393) n (%)
Nausea/Vomiting - N1	736	655	1391
Any	50 (6.8)	53 (8.1)	103 (7.4)
Grade 1	44 (6.0)	43 (6.6)	87 (6.3)
Grade 2	5 (0.7)	9 (1.4)	14 (1.0)
Grade 3	1 (0.1)	1 (0.2)	2 (0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	1 (0.2)	2 (0.1)
Chills - N1	736	655	1391
Any	40 (5.4)	98 (15.0)	138 (9.9)
Grade 1	33 (4.5)	72 (11.0)	105 (7.5)
Grade 2	7 (1.0)	24 (3.7)	31 (2.2)
Grade 3	0	2 (0.3)	2 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	2 (0.3)	2 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Solicited Adverse Reactions - N1	121	113	234
Any Solicited Adverse Reactions	53 (43.8)	105 (92.9)	158 (67.5)
95% CI	34.8, 53.1	86.5, 96.9	61.1, 73.5
Grade 1	39 (32.2)	68 (60.2)	107 (45.7)
Grade 2	10 (8.3)	27 (23.9)	37 (15.8)
Grade 3	4 (3.3)	10 (8.8)	14 (6.0)
Grade 4	0	0	0
Grade 3 or Above	4 (3.3)	10 (8.8)	14 (6.0)
Solicited Local Adverse Reactions - N1	121	113	234
Any Solicited Local Adverse Reactions	20 (16.5)	99 (87.6)	119 (50.9)
95% CI	10.4, 24.4	80.1, 93.1	44.3, 57.4
Grade 1	18 (14.9)	81 (71.7)	99 (42.3)
Grade 2	0	11 (9.7)	11 (4.7)
Grade 3	2 (1.7)	7 (6.2)	9 (3.8)
Grade 4	0	0	0
Grade 3 or Above	2 (1.7)	7 (6.2)	9 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Pain - N1	121	113	234
Any	18 (14.9)	99 (87.6)	117 (50.0)
Grade 1	17 (14.0)	82 (72.6)	99 (42.3)
Grade 2	0	11 (9.7)	11 (4.7)
Grade 3	1 (0.8)	6 (5.3)	7 (3.0)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	6 (5.3)	7 (3.0)
Erythema (Redness) - N1	121	113	234
Any	1 (0.8)	5 (4.4)	6 (2.6)
Grade 1	0	4 (3.5)	4 (1.7)
Grade 2	0	1 (0.9)	1 (0.4)
Grade 3	1 (0.8)	0	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	0	1 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Swelling (Hardness) - N1	121	113	234
Any	0	11 (9.7)	11 (4.7)
Grade 1	0	8 (7.1)	8 (3.4)
Grade 2	0	2 (1.8)	2 (0.9)
Grade 3	0	1 (0.9)	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.9)	1 (0.4)
Axillary Swelling or Tenderness - N1	121	113	234
Any	7 (5.8)	12 (10.6)	19 (8.1)
Grade 1	6 (5.0)	12 (10.6)	18 (7.7)
Grade 2	0	0	0
Grade 3	1 (0.8)	0	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.8)	0	1 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Solicited Systemic Adverse Reactions - N1	121	113	234
Any Solicited Systemic Adverse Reactions	48 (39.7)	75 (66.4)	123 (52.6)
95% CI	30.9, 49.0	56.9, 75.0	46.0, 59.1
Grade 1	35 (28.9)	46 (40.7)	81 (34.6)
Grade 2	10 (8.3)	23 (20.4)	33 (14.1)
Grade 3	3 (2.5)	6 (5.3)	9 (3.8)
Grade 4	0	0	0
Grade 3 or Above	3 (2.5)	6 (5.3)	9 (3.8)
Fever - N1	121	113	234
Any	1 (0.8)	0	1 (0.4)
Grade 1	1 (0.8)	0	1 (0.4)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Headache - N1	121	113	234
Any	36 (29.8)	44 (38.9)	80 (34.2)
Grade 1	29 (24.0)	34 (30.1)	63 (26.9)
Grade 2	4 (3.3)	7 (6.2)	11 (4.7)
Grade 3	3 (2.5)	3 (2.7)	6 (2.6)
Grade 4	0	0	0
Grade 3 or Above	3 (2.5)	3 (2.7)	6 (2.6)
Fatigue - N1	121	113	234
Any	33 (27.3)	52 (46.0)	85 (36.3)
Grade 1	25 (20.7)	29 (25.7)	54 (23.1)
Grade 2	8 (6.6)	21 (18.6)	29 (12.4)
Grade 3	0	2 (1.8)	2 (0.9)
Grade 4	0	0	0
Grade 3 or Above	0	2 (1.8)	2 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Myalgia - N1	121	113	234
Any	14 (11.6)	33 (29.2)	47 (20.1)
Grade 1	13 (10.7)	26 (23.0)	39 (16.7)
Grade 2	1 (0.8)	5 (4.4)	6 (2.6)
Grade 3	0	2 (1.8)	2 (0.9)
Grade 4	0	0	0
Grade 3 or Above	0	2 (1.8)	2 (0.9)
Arthralgia - N1	121	113	234
Any	15 (12.4)	24 (21.2)	39 (16.7)
Grade 1	12 (9.9)	15 (13.3)	27 (11.5)
Grade 2	3 (2.5)	8 (7.1)	11 (4.7)
Grade 3	0	1 (0.9)	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.9)	1 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Nausea/Vomiting - N1	121	113	234
Any	9 (7.4)	12 (10.6)	21 (9.0)
Grade 1	9 (7.4)	11 (9.7)	20 (8.5)
Grade 2	0	1 (0.9)	1 (0.4)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	121	113	234
Any	5 (4.1)	5 (4.4)	10 (4.3)
Grade 1	5 (4.1)	3 (2.7)	8 (3.4)
Grade 2	0	2 (1.8)	2 (0.9)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Solicited Adverse Reactions - N1	32	36	68
Any Solicited Adverse Reactions	16 (50.0)	32 (88.9)	48 (70.6)
95% CI	31.9, 68.1	73.9, 96.9	58.3, 81.0
Grade 1	9 (28.1)	26 (72.2)	35 (51.5)
Grade 2	5 (15.6)	5 (13.9)	10 (14.7)
Grade 3	2 (6.3)	1 (2.8)	3 (4.4)
Grade 4	0	0	0
Grade 3 or Above	2 (6.3)	1 (2.8)	3 (4.4)
Solicited Local Adverse Reactions - N1	32	36	68
Any Solicited Local Adverse Reactions	7 (21.9)	32 (88.9)	39 (57.4)
95% CI	9.3, 40.0	73.9, 96.9	44.8, 69.3
Grade 1	5 (15.6)	27 (75.0)	32 (47.1)
Grade 2	0	4 (11.1)	4 (5.9)
Grade 3	2 (6.3)	1 (2.8)	3 (4.4)
Grade 4	0	0	0
Grade 3 or Above	2 (6.3)	1 (2.8)	3 (4.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Pain - N1	32	36	68
Any	6 (18.8)	32 (88.9)	38 (55.9)
Grade 1	4 (12.5)	28 (77.8)	32 (47.1)
Grade 2	0	3 (8.3)	3 (4.4)
Grade 3	2 (6.3)	1 (2.8)	3 (4.4)
Grade 4	0	0	0
Grade 3 or Above	2 (6.3)	1 (2.8)	3 (4.4)
Erythema (Redness) - N1	32	36	68
Any	0	1 (2.8)	1 (1.5)
Grade 1	0	0	0
Grade 2	0	1 (2.8)	1 (1.5)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Swelling (Hardness) - N1	32	36	68
Any	0	2 (5.6)	2 (2.9)
Grade 1	0	1 (2.8)	1 (1.5)
Grade 2	0	1 (2.8)	1 (1.5)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	32	36	68
Any	2 (6.3)	6 (16.7)	8 (11.8)
Grade 1	1 (3.1)	5 (13.9)	6 (8.8)
Grade 2	0	0	0
Grade 3	1 (3.1)	1 (2.8)	2 (2.9)
Grade 4	0	0	0
Grade 3 or Above	1 (3.1)	1 (2.8)	2 (2.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Solicited Systemic Adverse Reactions - N1	32	36	68
Any Solicited Systemic Adverse Reactions	16 (50.0)	15 (41.7)	31 (45.6)
95% CI	31.9, 68.1	25.5, 59.2	33.5, 58.1
Grade 1	11 (34.4)	12 (33.3)	23 (33.8)
Grade 2	5 (15.6)	2 (5.6)	7 (10.3)
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)
Fever - N1	32	36	68
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Headache - N1	32	36	68
Any	8 (25.0)	9 (25.0)	17 (25.0)
Grade 1	7 (21.9)	8 (22.2)	15 (22.1)
Grade 2	1 (3.1)	0	1 (1.5)
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)
Fatigue - N1	32	36	68
Any	11 (34.4)	8 (22.2)	19 (27.9)
Grade 1	6 (18.8)	5 (13.9)	11 (16.2)
Grade 2	5 (15.6)	2 (5.6)	7 (10.3)
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Myalgia - N1	32	36	68
Any	6 (18.8)	7 (19.4)	13 (19.1)
Grade 1	5 (15.6)	6 (16.7)	11 (16.2)
Grade 2	1 (3.1)	1 (2.8)	2 (2.9)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Arthralgia - N1	32	36	68
Any	5 (15.6)	3 (8.3)	8 (11.8)
Grade 1	5 (15.6)	2 (5.6)	7 (10.3)
Grade 2	0	1 (2.8)	1 (1.5)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Nausea/Vomiting - N1	32	36	68
Any	3 (9.4)	3 (8.3)	6 (8.8)
Grade 1	3 (9.4)	3 (8.3)	6 (8.8)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	32	36	68
Any	3 (9.4)	2 (5.6)	5 (7.4)
Grade 1	2 (6.3)	1 (2.8)	3 (4.4)
Grade 2	1 (3.1)	1 (2.8)	2 (2.9)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Solicited Adverse Reactions - N1	318	320	638
Any Solicited Adverse Reactions	167 (52.5)	303 (94.7)	470 (73.7)
95% CI	46.9, 58.1	91.6, 96.9	70.1, 77.0
Grade 1	105 (33.0)	178 (55.6)	283 (44.4)
Grade 2	55 (17.3)	98 (30.6)	153 (24.0)
Grade 3	7 (2.2)	27 (8.4)	34 (5.3)
Grade 4	0	0	0
Grade 3 or Above	7 (2.2)	27 (8.4)	34 (5.3)
Solicited Local Adverse Reactions - N1	318	319	637
Any Solicited Local Adverse Reactions	69 (21.7)	298 (93.4)	367 (57.6)
95% CI	17.3, 26.6	90.1, 95.9	53.7, 61.5
Grade 1	64 (20.1)	234 (73.4)	298 (46.8)
Grade 2	4 (1.3)	48 (15.0)	52 (8.2)
Grade 3	1 (0.3)	16 (5.0)	17 (2.7)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	16 (5.0)	17 (2.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Pain - N1	318	319	637
Any	59 (18.6)	297 (93.1)	356 (55.9)
Grade 1	56 (17.6)	243 (76.2)	299 (46.9)
Grade 2	2 (0.6)	40 (12.5)	42 (6.6)
Grade 3	1 (0.3)	14 (4.4)	15 (2.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	14 (4.4)	15 (2.4)
Erythema (Redness) - N1	318	319	637
Any	4 (1.3)	13 (4.1)	17 (2.7)
Grade 1	4 (1.3)	11 (3.4)	15 (2.4)
Grade 2	0	2 (0.6)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Swelling (Hardness) - N1	318	319	637
Any	5 (1.6)	26 (8.2)	31 (4.9)
Grade 1	3 (0.9)	17 (5.3)	20 (3.1)
Grade 2	2 (0.6)	7 (2.2)	9 (1.4)
Grade 3	0	2 (0.6)	2 (0.3)
Grade 4	0	0	0
Grade 3 or Above	0	2 (0.6)	2 (0.3)
Axillary Swelling or Tenderness - N1	318	319	637
Any	21 (6.6)	50 (15.7)	71 (11.1)
Grade 1	20 (6.3)	44 (13.8)	64 (10.0)
Grade 2	1 (0.3)	5 (1.6)	6 (0.9)
Grade 3	0	1 (0.3)	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Solicited Systemic Adverse Reactions - N1	318	320	638
Any Solicited Systemic Adverse Reactions	153 (48.1)	205 (64.1)	358 (56.1)
95% CI	42.5, 53.8	58.5, 69.3	52.2, 60.0
Grade 1	93 (29.2)	107 (33.4)	200 (31.3)
Grade 2	53 (16.7)	82 (25.6)	135 (21.2)
Grade 3	7 (2.2)	16 (5.0)	23 (3.6)
Grade 4	0	0	0
Grade 3 or Above	7 (2.2)	16 (5.0)	23 (3.6)
Fever - N1	318	320	638
Any	0	2 (0.6)	2 (0.3)
Grade 1	0	2 (0.6)	2 (0.3)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Headache - N1	318	319	637
Any	91 (28.6)	142 (44.5)	233 (36.6)
Grade 1	75 (23.6)	103 (32.3)	178 (27.9)
Grade 2	15 (4.7)	29 (9.1)	44 (6.9)
Grade 3	1 (0.3)	10 (3.1)	11 (1.7)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	10 (3.1)	11 (1.7)
Fatigue - N1	318	319	637
Any	111 (34.9)	154 (48.3)	265 (41.6)
Grade 1	64 (20.1)	82 (25.7)	146 (22.9)
Grade 2	43 (13.5)	66 (20.7)	109 (17.1)
Grade 3	4 (1.3)	6 (1.9)	10 (1.6)
Grade 4	0	0	0
Grade 3 or Above	4 (1.3)	6 (1.9)	10 (1.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010401.sas 21JUN2021 15:02

Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Myalgia - N1	318	319	637
Any	65 (20.4)	103 (32.3)	168 (26.4)
Grade 1	42 (13.2)	68 (21.3)	110 (17.3)
Grade 2	20 (6.3)	34 (10.7)	54 (8.5)
Grade 3	3 (0.9)	1 (0.3)	4 (0.6)
Grade 4	0	0	0
Grade 3 or Above	3 (0.9)	1 (0.3)	4 (0.6)
Arthralgia - N1	318	319	637
Any	55 (17.3)	69 (21.6)	124 (19.5)
Grade 1	39 (12.3)	45 (14.1)	84 (13.2)
Grade 2	13 (4.1)	21 (6.6)	34 (5.3)
Grade 3	3 (0.9)	3 (0.9)	6 (0.9)
Grade 4	0	0	0
Grade 3 or Above	3 (0.9)	3 (0.9)	6 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010401.sas 21JUN2021 15:02

Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Nausea/Vomiting - N1	318	319	637
Any	31 (9.7)	38 (11.9)	69 (10.8)
Grade 1	26 (8.2)	30 (9.4)	56 (8.8)
Grade 2	4 (1.3)	8 (2.5)	12 (1.9)
Grade 3	1 (0.3)	0	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	0	1 (0.2)
Chills - N1	318	319	637
Any	28 (8.8)	39 (12.2)	67 (10.5)
Grade 1	21 (6.6)	28 (8.8)	49 (7.7)
Grade 2	6 (1.9)	11 (3.4)	17 (2.7)
Grade 3	1 (0.3)	0	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	0	1 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010401.sas 21JUN2021 15:02

Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=457) n (%)	Total (N=880) n (%)
Solicited Adverse Reactions - N1	423	457	880
Any Solicited Adverse Reactions	235 (55.6)	408 (89.3)	643 (73.1)
95% CI	50.7, 60.4	86.1, 92.0	70.0, 76.0
Grade 1	159 (37.6)	265 (58.0)	424 (48.2)
Grade 2	63 (14.9)	112 (24.5)	175 (19.9)
Grade 3	13 (3.1)	31 (6.8)	44 (5.0)
Grade 4	0	0	0
Grade 3 or Above	13 (3.1)	31 (6.8)	44 (5.0)
Solicited Local Adverse Reactions - N1	423	457	880
Any Solicited Local Adverse Reactions	100 (23.6)	392 (85.8)	492 (55.9)
95% CI	19.7, 28.0	82.2, 88.8	52.6, 59.2
Grade 1	96 (22.7)	323 (70.7)	419 (47.6)
Grade 2	3 (0.7)	48 (10.5)	51 (5.8)
Grade 3	1 (0.2)	21 (4.6)	22 (2.5)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	21 (4.6)	22 (2.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=457) n (%)	Total (N=880) n (%)
Pain - N1	423	457	880
Any	88 (20.8)	389 (85.1)	477 (54.2)
Grade 1	85 (20.1)	329 (72.0)	414 (47.0)
Grade 2	2 (0.5)	44 (9.6)	46 (5.2)
Grade 3	1 (0.2)	16 (3.5)	17 (1.9)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	16 (3.5)	17 (1.9)
Erythema (Redness) - N1	423	457	880
Any	3 (0.7)	17 (3.7)	20 (2.3)
Grade 1	3 (0.7)	10 (2.2)	13 (1.5)
Grade 2	0	6 (1.3)	6 (0.7)
Grade 3	0	1 (0.2)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.2)	1 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=457) n (%)	Total (N=880) n (%)
Swelling (Hardness) - N1	423	457	880
Any	3 (0.7)	37 (8.1)	40 (4.5)
Grade 1	2 (0.5)	26 (5.7)	28 (3.2)
Grade 2	1 (0.2)	9 (2.0)	10 (1.1)
Grade 3	0	2 (0.4)	2 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	2 (0.4)	2 (0.2)
Axillary Swelling or Tenderness - N1	423	457	880
Any	32 (7.6)	81 (17.7)	113 (12.8)
Grade 1	30 (7.1)	75 (16.4)	105 (11.9)
Grade 2	1 (0.2)	4 (0.9)	5 (0.6)
Grade 3	1 (0.2)	2 (0.4)	3 (0.3)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	2 (0.4)	3 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=457) n (%)	Total (N=880) n (%)
Solicited Systemic Adverse Reactions - N1	423	457	880
Any Solicited Systemic Adverse Reactions	206 (48.7)	277 (60.6)	483 (54.9)
95% CI	43.8, 53.6	56.0, 65.1	51.5, 58.2
Grade 1	132 (31.2)	165 (36.1)	297 (33.8)
Grade 2	61 (14.4)	92 (20.1)	153 (17.4)
Grade 3	13 (3.1)	20 (4.4)	33 (3.8)
Grade 4	0	0	0
Grade 3 or Above	13 (3.1)	20 (4.4)	33 (3.8)
Fever - N1	423	457	880
Any	0	7 (1.5)	7 (0.8)
Grade 1	0	5 (1.1)	5 (0.6)
Grade 2	0	2 (0.4)	2 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=457) n (%)	Total (N=880) n (%)
Headache - N1	422	457	879
Any	139 (32.9)	172 (37.6)	311 (35.4)
Grade 1	111 (26.3)	135 (29.5)	246 (28.0)
Grade 2	16 (3.8)	26 (5.7)	42 (4.8)
Grade 3	12 (2.8)	11 (2.4)	23 (2.6)
Grade 4	0	0	0
Grade 3 or Above	12 (2.8)	11 (2.4)	23 (2.6)
Fatigue - N1	422	457	879
Any	133 (31.5)	189 (41.4)	322 (36.6)
Grade 1	85 (20.1)	123 (26.9)	208 (23.7)
Grade 2	46 (10.9)	59 (12.9)	105 (11.9)
Grade 3	2 (0.5)	7 (1.5)	9 (1.0)
Grade 4	0	0	0
Grade 3 or Above	2 (0.5)	7 (1.5)	9 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=457) n (%)	Total (N=880) n (%)
Myalgia - N1	422	457	879
Any	80 (19.0)	132 (28.9)	212 (24.1)
Grade 1	53 (12.6)	88 (19.3)	141 (16.0)
Grade 2	24 (5.7)	41 (9.0)	65 (7.4)
Grade 3	3 (0.7)	3 (0.7)	6 (0.7)
Grade 4	0	0	0
Grade 3 or Above	3 (0.7)	3 (0.7)	6 (0.7)
Arthralgia - N1	422	457	879
Any	71 (16.8)	85 (18.6)	156 (17.7)
Grade 1	50 (11.8)	64 (14.0)	114 (13.0)
Grade 2	20 (4.7)	19 (4.2)	39 (4.4)
Grade 3	1 (0.2)	2 (0.4)	3 (0.3)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	2 (0.4)	3 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Race and Grade
First Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=423) n (%)	mRNA-1273 (N=457) n (%)	Total (N=880) n (%)
Nausea/Vomiting - N1	422	457	879
Any	37 (8.8)	54 (11.8)	91 (10.4)
Grade 1	31 (7.3)	44 (9.6)	75 (8.5)
Grade 2	6 (1.4)	10 (2.2)	16 (1.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	422	457	879
Any	38 (9.0)	51 (11.2)	89 (10.1)
Grade 1	33 (7.8)	30 (6.6)	63 (7.2)
Grade 2	5 (1.2)	18 (3.9)	23 (2.6)
Grade 3	0	3 (0.7)	3 (0.3)
Grade 4	0	0	0
Grade 3 or Above	0	3 (0.7)	3 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11572) n (%)	mRNA-1273 (N=11677) n (%)	Total (N=23249) n (%)
Solicited Adverse Reactions - N1	11572	11677	23249
Any Solicited Adverse Reactions	5034 (43.5)	10914 (93.5)	15948 (68.6)
95% CI	42.6, 44.4	93.0, 93.9	68.0, 69.2
Grade 1	3523 (30.4)	3881 (33.2)	7404 (31.8)
Grade 2	1236 (10.7)	4683 (40.1)	5919 (25.5)
Grade 3	273 (2.4)	2339 (20.0)	2612 (11.2)
Grade 4	2 (<0.1)	11 (<0.1)	13 (<0.1)
Grade 3 or Above	275 (2.4)	2350 (20.1)	2625 (11.3)
Solicited Local Adverse Reactions - N1	11571	11674	23245
Any Solicited Local Adverse Reactions	2215 (19.1)	10510 (90.0)	12725 (54.7)
95% CI	18.4, 19.9	89.5, 90.6	54.1, 55.4
Grade 1	2097 (18.1)	7099 (60.8)	9196 (39.6)
Grade 2	64 (0.6)	2581 (22.1)	2645 (11.4)
Grade 3	54 (0.5)	830 (7.1)	884 (3.8)
Grade 4	0	0	0
Grade 3 or Above	54 (0.5)	830 (7.1)	884 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301010402.sas 21JUN2021 15:03

Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11572) n (%)	mRNA-1273 (N=11677) n (%)	Total (N=23249) n (%)
Pain - N1	11571	11674	23245
Any	1998 (17.3)	10462 (89.6)	12460 (53.6)
Grade 1	1926 (16.6)	7713 (66.1)	9639 (41.5)
Grade 2	45 (0.4)	2272 (19.5)	2317 (10.0)
Grade 3	27 (0.2)	477 (4.1)	504 (2.2)
Grade 4	0	0	0
Grade 3 or Above	27 (0.2)	477 (4.1)	504 (2.2)
Erythema (Redness) - N1	11571	11673	23244
Any	50 (0.4)	1069 (9.2)	1119 (4.8)
Grade 1	37 (0.3)	378 (3.2)	415 (1.8)
Grade 2	4 (<0.1)	451 (3.9)	455 (2.0)
Grade 3	9 (<0.1)	240 (2.1)	249 (1.1)
Grade 4	0	0	0
Grade 3 or Above	9 (<0.1)	240 (2.1)	249 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11572) n (%)	mRNA-1273 (N=11677) n (%)	Total (N=23249) n (%)
Swelling (Hardness) - N1	11571	11673	23244
Any	46 (0.4)	1461 (12.5)	1507 (6.5)
Grade 1	28 (0.2)	714 (6.1)	742 (3.2)
Grade 2	9 (<0.1)	533 (4.6)	542 (2.3)
Grade 3	9 (<0.1)	214 (1.8)	223 (1.0)
Grade 4	0	0	0
Grade 3 or Above	9 (<0.1)	214 (1.8)	223 (1.0)
Axillary Swelling or Tenderness - N1	11571	11673	23244
Any	454 (3.9)	1633 (14.0)	2087 (9.0)
Grade 1	418 (3.6)	1354 (11.6)	1772 (7.6)
Grade 2	18 (0.2)	224 (1.9)	242 (1.0)
Grade 3	18 (0.2)	55 (0.5)	73 (0.3)
Grade 4	0	0	0
Grade 3 or Above	18 (0.2)	55 (0.5)	73 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11572) n (%)	mRNA-1273 (N=11677) n (%)	Total (N=23249) n (%)
Solicited Systemic Adverse Reactions - N1	11572	11676	23248
Any Solicited Systemic Adverse Reactions	4307 (37.2)	9404 (80.5)	13711 (59.0)
95% CI	36.3, 38.1	79.8, 81.3	58.3, 59.6
Grade 1	2860 (24.7)	3002 (25.7)	5862 (25.2)
Grade 2	1218 (10.5)	4507 (38.6)	5725 (24.6)
Grade 3	227 (2.0)	1884 (16.1)	2111 (9.1)
Grade 4	2 (<0.1)	11 (<0.1)	13 (<0.1)
Grade 3 or Above	229 (2.0)	1895 (16.2)	2124 (9.1)
Fever - N1	11570	11671	23241
Any	36 (0.3)	1802 (15.4)	1838 (7.9)
Grade 1	27 (0.2)	1114 (9.5)	1141 (4.9)
Grade 2	5 (<0.1)	535 (4.6)	540 (2.3)
Grade 3	2 (<0.1)	143 (1.2)	145 (0.6)
Grade 4	2 (<0.1)	10 (<0.1)	12 (<0.1)
Grade 3 or Above	4 (<0.1)	153 (1.3)	157 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11572) n (%)	mRNA-1273 (N=11677) n (%)	Total (N=23249) n (%)
Headache - N1	11571	11673	23244
Any	2806 (24.3)	6982 (59.8)	9788 (42.1)
Grade 1	2256 (19.5)	3898 (33.4)	6154 (26.5)
Grade 2	417 (3.6)	2556 (21.9)	2973 (12.8)
Grade 3	133 (1.1)	528 (4.5)	661 (2.8)
Grade 4	0	0	0
Grade 3 or Above	133 (1.1)	528 (4.5)	661 (2.8)
Fatigue - N1	11571	11673	23244
Any	2741 (23.7)	7768 (66.5)	10509 (45.2)
Grade 1	1759 (15.2)	2778 (23.8)	4537 (19.5)
Grade 2	899 (7.8)	3826 (32.8)	4725 (20.3)
Grade 3	83 (0.7)	1164 (10.0)	1247 (5.4)
Grade 4	0	0	0
Grade 3 or Above	83 (0.7)	1164 (10.0)	1247 (5.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11572) n (%)	mRNA-1273 (N=11677) n (%)	Total (N=23249) n (%)
Myalgia - N1	11571	11673	23244
Any	1416 (12.2)	6861 (58.8)	8277 (35.6)
Grade 1	1020 (8.8)	2614 (22.4)	3634 (15.6)
Grade 2	359 (3.1)	3163 (27.1)	3522 (15.2)
Grade 3	37 (0.3)	1084 (9.3)	1121 (4.8)
Grade 4	0	0	0
Grade 3 or Above	37 (0.3)	1084 (9.3)	1121 (4.8)
Arthralgia - N1	11571	11673	23244
Any	1228 (10.6)	5087 (43.6)	6315 (27.2)
Grade 1	895 (7.7)	2251 (19.3)	3146 (13.5)
Grade 2	303 (2.6)	2200 (18.8)	2503 (10.8)
Grade 3	30 (0.3)	636 (5.4)	666 (2.9)
Grade 4	0	0	0
Grade 3 or Above	30 (0.3)	636 (5.4)	666 (2.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: White

Solicited Adverse Reaction Category Grade	Placebo (N=11572) n (%)	mRNA-1273 (N=11677) n (%)	Total (N=23249) n (%)
Nausea/Vomiting - N1	11571	11673	23244
Any	737 (6.4)	2266 (19.4)	3003 (12.9)
Grade 1	595 (5.1)	1711 (14.7)	2306 (9.9)
Grade 2	133 (1.1)	535 (4.6)	668 (2.9)
Grade 3	9 (<0.1)	19 (0.2)	28 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	9 (<0.1)	20 (0.2)	29 (0.1)
Chills - N1	11571	11673	23244
Any	636 (5.5)	5182 (44.4)	5818 (25.0)
Grade 1	499 (4.3)	2315 (19.8)	2814 (12.1)
Grade 2	125 (1.1)	2727 (23.4)	2852 (12.3)
Grade 3	12 (0.1)	140 (1.2)	152 (0.7)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	140 (1.2)	152 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1432) n (%)	mRNA-1273 (N=1470) n (%)	Total (N=2902) n (%)
Solicited Adverse Reactions - N1	1432	1470	2902
Any Solicited Adverse Reactions	532 (37.2)	1168 (79.5)	1700 (58.6)
95% CI	34.6, 39.7	77.3, 81.5	56.8, 60.4
Grade 1	351 (24.5)	542 (36.9)	893 (30.8)
Grade 2	138 (9.6)	443 (30.1)	581 (20.0)
Grade 3	42 (2.9)	181 (12.3)	223 (7.7)
Grade 4	1 (<0.1)	2 (0.1)	3 (0.1)
Grade 3 or Above	43 (3.0)	183 (12.4)	226 (7.8)
Solicited Local Adverse Reactions - N1	1432	1470	2902
Any Solicited Local Adverse Reactions	215 (15.0)	1094 (74.4)	1309 (45.1)
95% CI	13.2, 17.0	72.1, 76.6	43.3, 46.9
Grade 1	187 (13.1)	805 (54.8)	992 (34.2)
Grade 2	12 (0.8)	219 (14.9)	231 (8.0)
Grade 3	16 (1.1)	70 (4.8)	86 (3.0)
Grade 4	0	0	0
Grade 3 or Above	16 (1.1)	70 (4.8)	86 (3.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1432) n (%)	mRNA-1273 (N=1470) n (%)	Total (N=2902) n (%)
Pain - N1	1432	1470	2902
Any	195 (13.6)	1079 (73.4)	1274 (43.9)
Grade 1	175 (12.2)	833 (56.7)	1008 (34.7)
Grade 2	9 (0.6)	197 (13.4)	206 (7.1)
Grade 3	11 (0.8)	49 (3.3)	60 (2.1)
Grade 4	0	0	0
Grade 3 or Above	11 (0.8)	49 (3.3)	60 (2.1)
Erythema (Redness) - N1	1432	1470	2902
Any	8 (0.6)	47 (3.2)	55 (1.9)
Grade 1	3 (0.2)	17 (1.2)	20 (0.7)
Grade 2	0	17 (1.2)	17 (0.6)
Grade 3	5 (0.3)	13 (0.9)	18 (0.6)
Grade 4	0	0	0
Grade 3 or Above	5 (0.3)	13 (0.9)	18 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1432) n (%)	mRNA-1273 (N=1470) n (%)	Total (N=2902) n (%)
Swelling (Hardness) - N1	1432	1470	2902
Any	5 (0.3)	97 (6.6)	102 (3.5)
Grade 1	3 (0.2)	46 (3.1)	49 (1.7)
Grade 2	1 (<0.1)	36 (2.4)	37 (1.3)
Grade 3	1 (<0.1)	15 (1.0)	16 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	15 (1.0)	16 (0.6)
Axillary Swelling or Tenderness - N1	1432	1470	2902
Any	52 (3.6)	173 (11.8)	225 (7.8)
Grade 1	45 (3.1)	147 (10.0)	192 (6.6)
Grade 2	5 (0.3)	21 (1.4)	26 (0.9)
Grade 3	2 (0.1)	5 (0.3)	7 (0.2)
Grade 4	0	0	0
Grade 3 or Above	2 (0.1)	5 (0.3)	7 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1432) n (%)	mRNA-1273 (N=1470) n (%)	Total (N=2902) n (%)
Solicited Systemic Adverse Reactions - N1	1432	1470	2902
Any Solicited Systemic Adverse Reactions	459 (32.1)	938 (63.8)	1397 (48.1)
95% CI	29.6, 34.5	61.3, 66.3	46.3, 50.0
Grade 1	290 (20.3)	365 (24.8)	655 (22.6)
Grade 2	137 (9.6)	433 (29.5)	570 (19.6)
Grade 3	31 (2.2)	138 (9.4)	169 (5.8)
Grade 4	1 (<0.1)	2 (0.1)	3 (0.1)
Grade 3 or Above	32 (2.2)	140 (9.5)	172 (5.9)
Fever - N1	1431	1470	2901
Any	5 (0.3)	155 (10.5)	160 (5.5)
Grade 1	4 (0.3)	84 (5.7)	88 (3.0)
Grade 2	0	48 (3.3)	48 (1.7)
Grade 3	0	21 (1.4)	21 (0.7)
Grade 4	1 (<0.1)	2 (0.1)	3 (0.1)
Grade 3 or Above	1 (<0.1)	23 (1.6)	24 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1432) n (%)	mRNA-1273 (N=1470) n (%)	Total (N=2902) n (%)
Headache - N1	1431	1470	2901
Any	260 (18.2)	610 (41.5)	870 (30.0)
Grade 1	202 (14.1)	364 (24.8)	566 (19.5)
Grade 2	43 (3.0)	198 (13.5)	241 (8.3)
Grade 3	15 (1.0)	48 (3.3)	63 (2.2)
Grade 4	0	0	0
Grade 3 or Above	15 (1.0)	48 (3.3)	63 (2.2)
Fatigue - N1	1431	1470	2901
Any	282 (19.7)	707 (48.1)	989 (34.1)
Grade 1	165 (11.5)	300 (20.4)	465 (16.0)
Grade 2	103 (7.2)	334 (22.7)	437 (15.1)
Grade 3	14 (1.0)	73 (5.0)	87 (3.0)
Grade 4	0	0	0
Grade 3 or Above	14 (1.0)	73 (5.0)	87 (3.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1432) n (%)	mRNA-1273 (N=1470) n (%)	Total (N=2902) n (%)
Myalgia - N1	1431	1470	2901
Any	184 (12.9)	618 (42.0)	802 (27.6)
Grade 1	121 (8.5)	272 (18.5)	393 (13.5)
Grade 2	52 (3.6)	277 (18.8)	329 (11.3)
Grade 3	11 (0.8)	69 (4.7)	80 (2.8)
Grade 4	0	0	0
Grade 3 or Above	11 (0.8)	69 (4.7)	80 (2.8)
Arthralgia - N1	1431	1470	2901
Any	160 (11.2)	447 (30.4)	607 (20.9)
Grade 1	111 (7.8)	213 (14.5)	324 (11.2)
Grade 2	39 (2.7)	186 (12.7)	225 (7.8)
Grade 3	10 (0.7)	48 (3.3)	58 (2.0)
Grade 4	0	0	0
Grade 3 or Above	10 (0.7)	48 (3.3)	58 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Black or African American

Solicited Adverse Reaction Category Grade	Placebo (N=1432) n (%)	mRNA-1273 (N=1470) n (%)	Total (N=2902) n (%)
Nausea/Vomiting - N1	1431	1470	2901
Any	96 (6.7)	191 (13.0)	287 (9.9)
Grade 1	74 (5.2)	145 (9.9)	219 (7.5)
Grade 2	20 (1.4)	44 (3.0)	64 (2.2)
Grade 3	2 (0.1)	2 (0.1)	4 (0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (0.1)	2 (0.1)	4 (0.1)
Chills - N1	1431	1470	2901
Any	82 (5.7)	479 (32.6)	561 (19.3)
Grade 1	54 (3.8)	249 (16.9)	303 (10.4)
Grade 2	25 (1.7)	209 (14.2)	234 (8.1)
Grade 3	3 (0.2)	21 (1.4)	24 (0.8)
Grade 4	0	0	0
Grade 3 or Above	3 (0.2)	21 (1.4)	24 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=718) n (%)	mRNA-1273 (N=641) n (%)	Total (N=1359) n (%)
Solicited Adverse Reactions - N1	718	641	1359
Any Solicited Adverse Reactions	291 (40.5)	620 (96.7)	911 (67.0)
95% CI	36.9, 44.2	95.0, 98.0	64.5, 69.5
Grade 1	214 (29.8)	149 (23.2)	363 (26.7)
Grade 2	62 (8.6)	303 (47.3)	365 (26.9)
Grade 3	15 (2.1)	168 (26.2)	183 (13.5)
Grade 4	0	0	0
Grade 3 or Above	15 (2.1)	168 (26.2)	183 (13.5)
Solicited Local Adverse Reactions - N1	718	641	1359
Any Solicited Local Adverse Reactions	141 (19.6)	599 (93.4)	740 (54.5)
95% CI	16.8, 22.7	91.2, 95.2	51.8, 57.1
Grade 1	134 (18.7)	363 (56.6)	497 (36.6)
Grade 2	4 (0.6)	176 (27.5)	180 (13.2)
Grade 3	3 (0.4)	60 (9.4)	63 (4.6)
Grade 4	0	0	0
Grade 3 or Above	3 (0.4)	60 (9.4)	63 (4.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=718) n (%)	mRNA-1273 (N=641) n (%)	Total (N=1359) n (%)
Pain - N1	718	641	1359
Any	131 (18.2)	599 (93.4)	730 (53.7)
Grade 1	126 (17.5)	400 (62.4)	526 (38.7)
Grade 2	3 (0.4)	155 (24.2)	158 (11.6)
Grade 3	2 (0.3)	44 (6.9)	46 (3.4)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	44 (6.9)	46 (3.4)
Erythema (Redness) - N1	718	641	1359
Any	2 (0.3)	72 (11.2)	74 (5.4)
Grade 1	1 (0.1)	32 (5.0)	33 (2.4)
Grade 2	0	26 (4.1)	26 (1.9)
Grade 3	1 (0.1)	14 (2.2)	15 (1.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	14 (2.2)	15 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=718) n (%)	mRNA-1273 (N=641) n (%)	Total (N=1359) n (%)
Swelling (Hardness) - N1	718	641	1359
Any	3 (0.4)	108 (16.8)	111 (8.2)
Grade 1	2 (0.3)	65 (10.1)	67 (4.9)
Grade 2	0	36 (5.6)	36 (2.6)
Grade 3	1 (0.1)	7 (1.1)	8 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	7 (1.1)	8 (0.6)
Axillary Swelling or Tenderness - N1	718	641	1359
Any	26 (3.6)	95 (14.8)	121 (8.9)
Grade 1	25 (3.5)	82 (12.8)	107 (7.9)
Grade 2	1 (0.1)	10 (1.6)	11 (0.8)
Grade 3	0	3 (0.5)	3 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	3 (0.5)	3 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=718) n (%)	mRNA-1273 (N=641) n (%)	Total (N=1359) n (%)
Solicited Systemic Adverse Reactions - N1	717	641	1358
Any Solicited Systemic Adverse Reactions	236 (32.9)	574 (89.5)	810 (59.6)
95% CI	29.5, 36.5	86.9, 91.8	57.0, 62.3
Grade 1	164 (22.9)	133 (20.7)	297 (21.9)
Grade 2	60 (8.4)	305 (47.6)	365 (26.9)
Grade 3	12 (1.7)	136 (21.2)	148 (10.9)
Grade 4	0	0	0
Grade 3 or Above	12 (1.7)	136 (21.2)	148 (10.9)
Fever - N1	716	641	1357
Any	2 (0.3)	161 (25.1)	163 (12.0)
Grade 1	2 (0.3)	84 (13.1)	86 (6.3)
Grade 2	0	58 (9.0)	58 (4.3)
Grade 3	0	19 (3.0)	19 (1.4)
Grade 4	0	0	0
Grade 3 or Above	0	19 (3.0)	19 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=718) n (%)	mRNA-1273 (N=641) n (%)	Total (N=1359) n (%)
Headache - N1	717	641	1358
Any	137 (19.1)	440 (68.6)	577 (42.5)
Grade 1	109 (15.2)	235 (36.7)	344 (25.3)
Grade 2	21 (2.9)	164 (25.6)	185 (13.6)
Grade 3	7 (1.0)	41 (6.4)	48 (3.5)
Grade 4	0	0	0
Grade 3 or Above	7 (1.0)	41 (6.4)	48 (3.5)
Fatigue - N1	717	641	1358
Any	157 (21.9)	503 (78.5)	660 (48.6)
Grade 1	111 (15.5)	148 (23.1)	259 (19.1)
Grade 2	42 (5.9)	268 (41.8)	310 (22.8)
Grade 3	4 (0.6)	87 (13.6)	91 (6.7)
Grade 4	0	0	0
Grade 3 or Above	4 (0.6)	87 (13.6)	91 (6.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=718) n (%)	mRNA-1273 (N=641) n (%)	Total (N=1359) n (%)
Myalgia - N1	717	641	1358
Any	90 (12.6)	461 (71.9)	551 (40.6)
Grade 1	68 (9.5)	143 (22.3)	211 (15.5)
Grade 2	20 (2.8)	247 (38.5)	267 (19.7)
Grade 3	2 (0.3)	71 (11.1)	73 (5.4)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	71 (11.1)	73 (5.4)
Arthralgia - N1	717	641	1358
Any	56 (7.8)	325 (50.7)	381 (28.1)
Grade 1	42 (5.9)	140 (21.8)	182 (13.4)
Grade 2	12 (1.7)	150 (23.4)	162 (11.9)
Grade 3	2 (0.3)	35 (5.5)	37 (2.7)
Grade 4	0	0	0
Grade 3 or Above	2 (0.3)	35 (5.5)	37 (2.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Asian

Solicited Adverse Reaction Category Grade	Placebo (N=718) n (%)	mRNA-1273 (N=641) n (%)	Total (N=1359) n (%)
Nausea/Vomiting - N1	717	641	1358
Any	33 (4.6)	142 (22.2)	175 (12.9)
Grade 1	28 (3.9)	105 (16.4)	133 (9.8)
Grade 2	5 (0.7)	37 (5.8)	42 (3.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	717	641	1358
Any	42 (5.9)	392 (61.2)	434 (32.0)
Grade 1	30 (4.2)	144 (22.5)	174 (12.8)
Grade 2	11 (1.5)	231 (36.0)	242 (17.8)
Grade 3	1 (0.1)	17 (2.7)	18 (1.3)
Grade 4	0	0	0
Grade 3 or Above	1 (0.1)	17 (2.7)	18 (1.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=115) n (%)	mRNA-1273 (N=110) n (%)	Total (N=225) n (%)
Solicited Adverse Reactions - N1	115	110	225
Any Solicited Adverse Reactions	49 (42.6)	105 (95.5)	154 (68.4)
95% CI	33.4, 52.2	89.7, 98.5	61.9, 74.5
Grade 1	29 (25.2)	40 (36.4)	69 (30.7)
Grade 2	19 (16.5)	46 (41.8)	65 (28.9)
Grade 3	1 (0.9)	19 (17.3)	20 (8.9)
Grade 4	0	0	0
Grade 3 or Above	1 (0.9)	19 (17.3)	20 (8.9)
Solicited Local Adverse Reactions - N1	115	110	225
Any Solicited Local Adverse Reactions	22 (19.1)	101 (91.8)	123 (54.7)
95% CI	12.4, 27.5	85.0, 96.2	47.9, 61.3
Grade 1	21 (18.3)	71 (64.5)	92 (40.9)
Grade 2	1 (0.9)	27 (24.5)	28 (12.4)
Grade 3	0	3 (2.7)	3 (1.3)
Grade 4	0	0	0
Grade 3 or Above	0	3 (2.7)	3 (1.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=115) n (%)	mRNA-1273 (N=110) n (%)	Total (N=225) n (%)
Pain - N1	115	110	225
Any	19 (16.5)	101 (91.8)	120 (53.3)
Grade 1	19 (16.5)	76 (69.1)	95 (42.2)
Grade 2	0	23 (20.9)	23 (10.2)
Grade 3	0	2 (1.8)	2 (0.9)
Grade 4	0	0	0
Grade 3 or Above	0	2 (1.8)	2 (0.9)
Erythema (Redness) - N1	115	110	225
Any	2 (1.7)	9 (8.2)	11 (4.9)
Grade 1	1 (0.9)	5 (4.5)	6 (2.7)
Grade 2	1 (0.9)	4 (3.6)	5 (2.2)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=115) n (%)	mRNA-1273 (N=110) n (%)	Total (N=225) n (%)
Swelling (Hardness) - N1	115	110	225
Any	0	12 (10.9)	12 (5.3)
Grade 1	0	3 (2.7)	3 (1.3)
Grade 2	0	8 (7.3)	8 (3.6)
Grade 3	0	1 (0.9)	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.9)	1 (0.4)
Axillary Swelling or Tenderness - N1	115	110	225
Any	3 (2.6)	18 (16.4)	21 (9.3)
Grade 1	3 (2.6)	14 (12.7)	17 (7.6)
Grade 2	0	4 (3.6)	4 (1.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=115) n (%)	mRNA-1273 (N=110) n (%)	Total (N=225) n (%)
Solicited Systemic Adverse Reactions - N1	115	110	225
Any Solicited Systemic Adverse Reactions	44 (38.3)	90 (81.8)	134 (59.6)
95% CI	29.4, 47.8	73.3, 88.5	52.8, 66.0
Grade 1	25 (21.7)	30 (27.3)	55 (24.4)
Grade 2	18 (15.7)	42 (38.2)	60 (26.7)
Grade 3	1 (0.9)	18 (16.4)	19 (8.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.9)	18 (16.4)	19 (8.4)
Fever - N1	115	110	225
Any	0	18 (16.4)	18 (8.0)
Grade 1	0	14 (12.7)	14 (6.2)
Grade 2	0	3 (2.7)	3 (1.3)
Grade 3	0	1 (0.9)	1 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.9)	1 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=115) n (%)	mRNA-1273 (N=110) n (%)	Total (N=225) n (%)
Headache - N1	115	110	225
Any	26 (22.6)	71 (64.5)	97 (43.1)
Grade 1	21 (18.3)	45 (40.9)	66 (29.3)
Grade 2	5 (4.3)	20 (18.2)	25 (11.1)
Grade 3	0	6 (5.5)	6 (2.7)
Grade 4	0	0	0
Grade 3 or Above	0	6 (5.5)	6 (2.7)
Fatigue - N1	115	110	225
Any	28 (24.3)	78 (70.9)	106 (47.1)
Grade 1	17 (14.8)	28 (25.5)	45 (20.0)
Grade 2	10 (8.7)	41 (37.3)	51 (22.7)
Grade 3	1 (0.9)	9 (8.2)	10 (4.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.9)	9 (8.2)	10 (4.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=115) n (%)	mRNA-1273 (N=110) n (%)	Total (N=225) n (%)
Myalgia - N1	115	110	225
Any	17 (14.8)	62 (56.4)	79 (35.1)
Grade 1	12 (10.4)	20 (18.2)	32 (14.2)
Grade 2	4 (3.5)	32 (29.1)	36 (16.0)
Grade 3	1 (0.9)	10 (9.1)	11 (4.9)
Grade 4	0	0	0
Grade 3 or Above	1 (0.9)	10 (9.1)	11 (4.9)
Arthralgia - N1	115	110	225
Any	21 (18.3)	55 (50.0)	76 (33.8)
Grade 1	13 (11.3)	26 (23.6)	39 (17.3)
Grade 2	7 (6.1)	22 (20.0)	29 (12.9)
Grade 3	1 (0.9)	7 (6.4)	8 (3.6)
Grade 4	0	0	0
Grade 3 or Above	1 (0.9)	7 (6.4)	8 (3.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: American Indian or Alaska Native

Solicited Adverse Reaction Category Grade	Placebo (N=115) n (%)	mRNA-1273 (N=110) n (%)	Total (N=225) n (%)
Nausea/Vomiting - N1	115	110	225
Any	10 (8.7)	25 (22.7)	35 (15.6)
Grade 1	10 (8.7)	17 (15.5)	27 (12.0)
Grade 2	0	8 (7.3)	8 (3.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	115	110	225
Any	7 (6.1)	46 (41.8)	53 (23.6)
Grade 1	6 (5.2)	19 (17.3)	25 (11.1)
Grade 2	0	25 (22.7)	25 (11.1)
Grade 3	1 (0.9)	2 (1.8)	3 (1.3)
Grade 4	0	0	0
Grade 3 or Above	1 (0.9)	2 (1.8)	3 (1.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=31) n (%)	mRNA-1273 (N=36) n (%)	Total (N=67) n (%)
Solicited Adverse Reactions - N1	31	36	67
Any Solicited Adverse Reactions	18 (58.1)	34 (94.4)	52 (77.6)
95% CI	39.1, 75.5	81.3, 99.3	65.8, 86.9
Grade 1	13 (41.9)	11 (30.6)	24 (35.8)
Grade 2	5 (16.1)	16 (44.4)	21 (31.3)
Grade 3	0	7 (19.4)	7 (10.4)
Grade 4	0	0	0
Grade 3 or Above	0	7 (19.4)	7 (10.4)
Solicited Local Adverse Reactions - N1	31	36	67
Any Solicited Local Adverse Reactions	5 (16.1)	33 (91.7)	38 (56.7)
95% CI	5.5, 33.7	77.5, 98.2	44.0, 68.8
Grade 1	5 (16.1)	22 (61.1)	27 (40.3)
Grade 2	0	7 (19.4)	7 (10.4)
Grade 3	0	4 (11.1)	4 (6.0)
Grade 4	0	0	0
Grade 3 or Above	0	4 (11.1)	4 (6.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=31) n (%)	mRNA-1273 (N=36) n (%)	Total (N=67) n (%)
Pain - N1	31	36	67
Any	5 (16.1)	33 (91.7)	38 (56.7)
Grade 1	5 (16.1)	24 (66.7)	29 (43.3)
Grade 2	0	7 (19.4)	7 (10.4)
Grade 3	0	2 (5.6)	2 (3.0)
Grade 4	0	0	0
Grade 3 or Above	0	2 (5.6)	2 (3.0)
Erythema (Redness) - N1	31	36	67
Any	0	2 (5.6)	2 (3.0)
Grade 1	0	0	0
Grade 2	0	1 (2.8)	1 (1.5)
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=31) n (%)	mRNA-1273 (N=36) n (%)	Total (N=67) n (%)
Swelling (Hardness) - N1	31	36	67
Any	0	4 (11.1)	4 (6.0)
Grade 1	0	2 (5.6)	2 (3.0)
Grade 2	0	1 (2.8)	1 (1.5)
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)
Axillary Swelling or Tenderness - N1	31	36	67
Any	0	6 (16.7)	6 (9.0)
Grade 1	0	5 (13.9)	5 (7.5)
Grade 2	0	0	0
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=31) n (%)	mRNA-1273 (N=36) n (%)	Total (N=67) n (%)
Solicited Systemic Adverse Reactions - N1	31	36	67
Any Solicited Systemic Adverse Reactions	16 (51.6)	30 (83.3)	46 (68.7)
95% CI	33.1, 69.8	67.2, 93.6	56.2, 79.4
Grade 1	11 (35.5)	10 (27.8)	21 (31.3)
Grade 2	5 (16.1)	16 (44.4)	21 (31.3)
Grade 3	0	4 (11.1)	4 (6.0)
Grade 4	0	0	0
Grade 3 or Above	0	4 (11.1)	4 (6.0)
Fever - N1	31	36	67
Any	0	6 (16.7)	6 (9.0)
Grade 1	0	5 (13.9)	5 (7.5)
Grade 2	0	0	0
Grade 3	0	1 (2.8)	1 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	1 (2.8)	1 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=31) n (%)	mRNA-1273 (N=36) n (%)	Total (N=67) n (%)
Headache - N1	31	36	67
Any	7 (22.6)	19 (52.8)	26 (38.8)
Grade 1	6 (19.4)	8 (22.2)	14 (20.9)
Grade 2	1 (3.2)	9 (25.0)	10 (14.9)
Grade 3	0	2 (5.6)	2 (3.0)
Grade 4	0	0	0
Grade 3 or Above	0	2 (5.6)	2 (3.0)
Fatigue - N1	31	36	67
Any	12 (38.7)	23 (63.9)	35 (52.2)
Grade 1	7 (22.6)	8 (22.2)	15 (22.4)
Grade 2	5 (16.1)	12 (33.3)	17 (25.4)
Grade 3	0	3 (8.3)	3 (4.5)
Grade 4	0	0	0
Grade 3 or Above	0	3 (8.3)	3 (4.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=31) n (%)	mRNA-1273 (N=36) n (%)	Total (N=67) n (%)
Myalgia - N1	31	36	67
Any	7 (22.6)	23 (63.9)	30 (44.8)
Grade 1	7 (22.6)	11 (30.6)	18 (26.9)
Grade 2	0	10 (27.8)	10 (14.9)
Grade 3	0	2 (5.6)	2 (3.0)
Grade 4	0	0	0
Grade 3 or Above	0	2 (5.6)	2 (3.0)
Arthralgia - N1	31	36	67
Any	5 (16.1)	17 (47.2)	22 (32.8)
Grade 1	4 (12.9)	8 (22.2)	12 (17.9)
Grade 2	1 (3.2)	7 (19.4)	8 (11.9)
Grade 3	0	2 (5.6)	2 (3.0)
Grade 4	0	0	0
Grade 3 or Above	0	2 (5.6)	2 (3.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

Solicited Adverse Reaction Category Grade	Placebo (N=31) n (%)	mRNA-1273 (N=36) n (%)	Total (N=67) n (%)
Nausea/Vomiting - N1	31	36	67
Any	2 (6.5)	4 (11.1)	6 (9.0)
Grade 1	1 (3.2)	1 (2.8)	2 (3.0)
Grade 2	1 (3.2)	3 (8.3)	4 (6.0)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	31	36	67
Any	0	18 (50.0)	18 (26.9)
Grade 1	0	6 (16.7)	6 (9.0)
Grade 2	0	12 (33.3)	12 (17.9)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=307) n (%)	mRNA-1273 (N=314) n (%)	Total (N=621) n (%)
Solicited Adverse Reactions - N1	307	314	621
Any Solicited Adverse Reactions	150 (48.9)	303 (96.5)	453 (72.9)
95% CI	43.1, 54.6	93.8, 98.2	69.3, 76.4
Grade 1	95 (30.9)	93 (29.6)	188 (30.3)
Grade 2	45 (14.7)	133 (42.4)	178 (28.7)
Grade 3	10 (3.3)	76 (24.2)	86 (13.8)
Grade 4	0	1 (0.3)	1 (0.2)
Grade 3 or Above	10 (3.3)	77 (24.5)	87 (14.0)
Solicited Local Adverse Reactions - N1	307	314	621
Any Solicited Local Adverse Reactions	81 (26.4)	296 (94.3)	377 (60.7)
95% CI	21.5, 31.7	91.1, 96.6	56.7, 64.6
Grade 1	77 (25.1)	184 (58.6)	261 (42.0)
Grade 2	4 (1.3)	88 (28.0)	92 (14.8)
Grade 3	0	24 (7.6)	24 (3.9)
Grade 4	0	0	0
Grade 3 or Above	0	24 (7.6)	24 (3.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=307) n (%)	mRNA-1273 (N=314) n (%)	Total (N=621) n (%)
Pain - N1	307	314	621
Any	72 (23.5)	294 (93.6)	366 (58.9)
Grade 1	70 (22.8)	197 (62.7)	267 (43.0)
Grade 2	2 (0.7)	83 (26.4)	85 (13.7)
Grade 3	0	14 (4.5)	14 (2.3)
Grade 4	0	0	0
Grade 3 or Above	0	14 (4.5)	14 (2.3)
Erythema (Redness) - N1	307	314	621
Any	2 (0.7)	34 (10.8)	36 (5.8)
Grade 1	2 (0.7)	11 (3.5)	13 (2.1)
Grade 2	0	14 (4.5)	14 (2.3)
Grade 3	0	9 (2.9)	9 (1.4)
Grade 4	0	0	0
Grade 3 or Above	0	9 (2.9)	9 (1.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=307) n (%)	mRNA-1273 (N=314) n (%)	Total (N=621) n (%)
Swelling (Hardness) - N1	307	314	621
Any	4 (1.3)	57 (18.2)	61 (9.8)
Grade 1	4 (1.3)	33 (10.5)	37 (6.0)
Grade 2	0	17 (5.4)	17 (2.7)
Grade 3	0	7 (2.2)	7 (1.1)
Grade 4	0	0	0
Grade 3 or Above	0	7 (2.2)	7 (1.1)
Axillary Swelling or Tenderness - N1	307	314	621
Any	17 (5.5)	64 (20.4)	81 (13.0)
Grade 1	14 (4.6)	49 (15.6)	63 (10.1)
Grade 2	3 (1.0)	14 (4.5)	17 (2.7)
Grade 3	0	1 (0.3)	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=307) n (%)	mRNA-1273 (N=314) n (%)	Total (N=621) n (%)
Solicited Systemic Adverse Reactions - N1	307	314	621
Any Solicited Systemic Adverse Reactions	122 (39.7)	271 (86.3)	393 (63.3)
95% CI	34.2, 45.5	82.0, 89.9	59.4, 67.1
Grade 1	68 (22.1)	74 (23.6)	142 (22.9)
Grade 2	44 (14.3)	131 (41.7)	175 (28.2)
Grade 3	10 (3.3)	65 (20.7)	75 (12.1)
Grade 4	0	1 (0.3)	1 (0.2)
Grade 3 or Above	10 (3.3)	66 (21.0)	76 (12.2)
Fever - N1	307	312	619
Any	0	53 (17.0)	53 (8.6)
Grade 1	0	26 (8.3)	26 (4.2)
Grade 2	0	21 (6.7)	21 (3.4)
Grade 3	0	5 (1.6)	5 (0.8)
Grade 4	0	1 (0.3)	1 (0.2)
Grade 3 or Above	0	6 (1.9)	6 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=307) n (%)	mRNA-1273 (N=314) n (%)	Total (N=621) n (%)
Headache - N1	307	314	621
Any	84 (27.4)	217 (69.1)	301 (48.5)
Grade 1	63 (20.5)	118 (37.6)	181 (29.1)
Grade 2	14 (4.6)	82 (26.1)	96 (15.5)
Grade 3	7 (2.3)	17 (5.4)	24 (3.9)
Grade 4	0	0	0
Grade 3 or Above	7 (2.3)	17 (5.4)	24 (3.9)
Fatigue - N1	307	314	621
Any	89 (29.0)	230 (73.2)	319 (51.4)
Grade 1	50 (16.3)	67 (21.3)	117 (18.8)
Grade 2	36 (11.7)	122 (38.9)	158 (25.4)
Grade 3	3 (1.0)	41 (13.1)	44 (7.1)
Grade 4	0	0	0
Grade 3 or Above	3 (1.0)	41 (13.1)	44 (7.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=307) n (%)	mRNA-1273 (N=314) n (%)	Total (N=621) n (%)
Myalgia - N1	307	314	621
Any	38 (12.4)	202 (64.3)	240 (38.6)
Grade 1	25 (8.1)	68 (21.7)	93 (15.0)
Grade 2	12 (3.9)	99 (31.5)	111 (17.9)
Grade 3	1 (0.3)	35 (11.1)	36 (5.8)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	35 (11.1)	36 (5.8)
Arthralgia - N1	307	314	621
Any	39 (12.7)	144 (45.9)	183 (29.5)
Grade 1	27 (8.8)	58 (18.5)	85 (13.7)
Grade 2	12 (3.9)	64 (20.4)	76 (12.2)
Grade 3	0	22 (7.0)	22 (3.5)
Grade 4	0	0	0
Grade 3 or Above	0	22 (7.0)	22 (3.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Multiple

Solicited Adverse Reaction Category Grade	Placebo (N=307) n (%)	mRNA-1273 (N=314) n (%)	Total (N=621) n (%)
Nausea/Vomiting - N1	307	314	621
Any	29 (9.4)	73 (23.2)	102 (16.4)
Grade 1	23 (7.5)	50 (15.9)	73 (11.8)
Grade 2	6 (2.0)	23 (7.3)	29 (4.7)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	307	314	621
Any	19 (6.2)	171 (54.5)	190 (30.6)
Grade 1	17 (5.5)	86 (27.4)	103 (16.6)
Grade 2	2 (0.7)	79 (25.2)	81 (13.0)
Grade 3	0	6 (1.9)	6 (1.0)
Grade 4	0	0	0
Grade 3 or Above	0	6 (1.9)	6 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=403) n (%)	mRNA-1273 (N=443) n (%)	Total (N=846) n (%)
Solicited Adverse Reactions - N1	403	443	846
Any Solicited Adverse Reactions	181 (44.9)	412 (93.0)	593 (70.1)
95% CI	40.0, 49.9	90.2, 95.2	66.9, 73.2
Grade 1	121 (30.0)	131 (29.6)	252 (29.8)
Grade 2	53 (13.2)	176 (39.7)	229 (27.1)
Grade 3	7 (1.7)	105 (23.7)	112 (13.2)
Grade 4	0	0	0
Grade 3 or Above	7 (1.7)	105 (23.7)	112 (13.2)
Solicited Local Adverse Reactions - N1	403	443	846
Any Solicited Local Adverse Reactions	78 (19.4)	396 (89.4)	474 (56.0)
95% CI	15.6, 23.6	86.1, 92.1	52.6, 59.4
Grade 1	73 (18.1)	245 (55.3)	318 (37.6)
Grade 2	3 (0.7)	119 (26.9)	122 (14.4)
Grade 3	2 (0.5)	32 (7.2)	34 (4.0)
Grade 4	0	0	0
Grade 3 or Above	2 (0.5)	32 (7.2)	34 (4.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=403) n (%)	mRNA-1273 (N=443) n (%)	Total (N=846) n (%)
Pain - N1	403	443	846
Any	66 (16.4)	396 (89.4)	462 (54.6)
Grade 1	63 (15.6)	265 (59.8)	328 (38.8)
Grade 2	2 (0.5)	113 (25.5)	115 (13.6)
Grade 3	1 (0.2)	18 (4.1)	19 (2.2)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	18 (4.1)	19 (2.2)
Erythema (Redness) - N1	403	443	846
Any	4 (1.0)	41 (9.3)	45 (5.3)
Grade 1	4 (1.0)	13 (2.9)	17 (2.0)
Grade 2	0	18 (4.1)	18 (2.1)
Grade 3	0	10 (2.3)	10 (1.2)
Grade 4	0	0	0
Grade 3 or Above	0	10 (2.3)	10 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category / Grade	Placebo (N=403) n (%)	mRNA-1273 (N=443) n (%)	Total (N=846) n (%)
Swelling (Hardness) - N1	403	443	846
Any	2 (0.5)	68 (15.3)	70 (8.3)
Grade 1	1 (0.2)	37 (8.4)	38 (4.5)
Grade 2	0	21 (4.7)	21 (2.5)
Grade 3	1 (0.2)	10 (2.3)	11 (1.3)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	10 (2.3)	11 (1.3)
Axillary Swelling or Tenderness - N1	403	443	846
Any	19 (4.7)	103 (23.3)	122 (14.4)
Grade 1	18 (4.5)	84 (19.0)	102 (12.1)
Grade 2	1 (0.2)	16 (3.6)	17 (2.0)
Grade 3	0	3 (0.7)	3 (0.4)
Grade 4	0	0	0
Grade 3 or Above	0	3 (0.7)	3 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=403) n (%)	mRNA-1273 (N=443) n (%)	Total (N=846) n (%)
Solicited Systemic Adverse Reactions - N1	403	443	846
Any Solicited Systemic Adverse Reactions	159 (39.5)	371 (83.7)	530 (62.6)
95% CI	34.7, 44.4	80.0, 87.1	59.3, 65.9
Grade 1	101 (25.1)	103 (23.3)	204 (24.1)
Grade 2	53 (13.2)	177 (40.0)	230 (27.2)
Grade 3	5 (1.2)	91 (20.5)	96 (11.3)
Grade 4	0	0	0
Grade 3 or Above	5 (1.2)	91 (20.5)	96 (11.3)
Fever - N1	403	442	845
Any	0	81 (18.3)	81 (9.6)
Grade 1	0	36 (8.1)	36 (4.3)
Grade 2	0	32 (7.2)	32 (3.8)
Grade 3	0	13 (2.9)	13 (1.5)
Grade 4	0	0	0
Grade 3 or Above	0	13 (2.9)	13 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=403) n (%)	mRNA-1273 (N=443) n (%)	Total (N=846) n (%)
Headache - N1	403	443	846
Any	107 (26.6)	298 (67.3)	405 (47.9)
Grade 1	83 (20.6)	147 (33.2)	230 (27.2)
Grade 2	21 (5.2)	127 (28.7)	148 (17.5)
Grade 3	3 (0.7)	24 (5.4)	27 (3.2)
Grade 4	0	0	0
Grade 3 or Above	3 (0.7)	24 (5.4)	27 (3.2)
Fatigue - N1	403	443	846
Any	109 (27.0)	298 (67.3)	407 (48.1)
Grade 1	72 (17.9)	102 (23.0)	174 (20.6)
Grade 2	34 (8.4)	140 (31.6)	174 (20.6)
Grade 3	3 (0.7)	56 (12.6)	59 (7.0)
Grade 4	0	0	0
Grade 3 or Above	3 (0.7)	56 (12.6)	59 (7.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=403) n (%)	mRNA-1273 (N=443) n (%)	Total (N=846) n (%)
Myalgia - N1	403	443	846
Any	72 (17.9)	302 (68.2)	374 (44.2)
Grade 1	54 (13.4)	114 (25.7)	168 (19.9)
Grade 2	18 (4.5)	138 (31.2)	156 (18.4)
Grade 3	0	50 (11.3)	50 (5.9)
Grade 4	0	0	0
Grade 3 or Above	0	50 (11.3)	50 (5.9)
Arthralgia - N1	403	443	846
Any	70 (17.4)	228 (51.5)	298 (35.2)
Grade 1	51 (12.7)	113 (25.5)	164 (19.4)
Grade 2	18 (4.5)	90 (20.3)	108 (12.8)
Grade 3	1 (0.2)	25 (5.6)	26 (3.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.2)	25 (5.6)	26 (3.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.4.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Race and Grade
Second Injection Solicited Safety Set

Race Group: Other/Not Reported/Unknown

Solicited Adverse Reaction Category Grade	Placebo (N=403) n (%)	mRNA-1273 (N=443) n (%)	Total (N=846) n (%)
Nausea/Vomiting - N1	403	443	846
Any	34 (8.4)	93 (21.0)	127 (15.0)
Grade 1	30 (7.4)	65 (14.7)	95 (11.2)
Grade 2	4 (1.0)	28 (6.3)	32 (3.8)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	403	443	846
Any	27 (6.7)	212 (47.9)	239 (28.3)
Grade 1	23 (5.7)	88 (19.9)	111 (13.1)
Grade 2	4 (1.0)	119 (26.9)	123 (14.5)
Grade 3	0	5 (1.1)	5 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	5 (1.1)	5 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Solicited Adverse Reactions - N1	3106	3119	6225
Any Solicited Adverse Reactions	1476 (47.5)	2673 (85.7)	4149 (66.7)
95% CI	45.8, 49.3	84.4, 86.9	65.5, 67.8
Grade 1	1026 (33.0)	1811 (58.1)	2837 (45.6)
Grade 2	375 (12.1)	660 (21.2)	1035 (16.6)
Grade 3	73 (2.4)	199 (6.4)	272 (4.4)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	75 (2.4)	202 (6.5)	277 (4.4)
Solicited Local Adverse Reactions - N1	3106	3119	6225
Any Solicited Local Adverse Reactions	626 (20.2)	2574 (82.5)	3200 (51.4)
95% CI	18.8, 21.6	81.1, 83.8	50.2, 52.7
Grade 1	580 (18.7)	2130 (68.3)	2710 (43.5)
Grade 2	26 (0.8)	328 (10.5)	354 (5.7)
Grade 3	20 (0.6)	116 (3.7)	136 (2.2)
Grade 4	0	0	0
Grade 3 or Above	20 (0.6)	116 (3.7)	136 (2.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Pain - N1	3106	3119	6225
Any	546 (17.6)	2551 (81.8)	3097 (49.8)
Grade 1	511 (16.5)	2175 (69.7)	2686 (43.1)
Grade 2	21 (0.7)	285 (9.1)	306 (4.9)
Grade 3	14 (0.5)	91 (2.9)	105 (1.7)
Grade 4	0	0	0
Grade 3 or Above	14 (0.5)	91 (2.9)	105 (1.7)
Erythema (Redness) - N1	3106	3119	6225
Any	17 (0.5)	97 (3.1)	114 (1.8)
Grade 1	12 (0.4)	63 (2.0)	75 (1.2)
Grade 2	0	23 (0.7)	23 (0.4)
Grade 3	5 (0.2)	11 (0.4)	16 (0.3)
Grade 4	0	0	0
Grade 3 or Above	5 (0.2)	11 (0.4)	16 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Swelling (Hardness) - N1	3106	3119	6225
Any	10 (0.3)	196 (6.3)	206 (3.3)
Grade 1	7 (0.2)	121 (3.9)	128 (2.1)
Grade 2	1 (<0.1)	57 (1.8)	58 (0.9)
Grade 3	2 (<0.1)	18 (0.6)	20 (0.3)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	18 (0.6)	20 (0.3)
Axillary Swelling or Tenderness - N1	3106	3119	6225
Any	176 (5.7)	421 (13.5)	597 (9.6)
Grade 1	161 (5.2)	365 (11.7)	526 (8.4)
Grade 2	8 (0.3)	38 (1.2)	46 (0.7)
Grade 3	7 (0.2)	18 (0.6)	25 (0.4)
Grade 4	0	0	0
Grade 3 or Above	7 (0.2)	18 (0.6)	25 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Solicited Systemic Adverse Reactions - N1	3106	3119	6225
Any Solicited Systemic Adverse Reactions	1327 (42.7)	1727 (55.4)	3054 (49.1)
95% CI	41.0, 44.5	53.6, 57.1	47.8, 50.3
Grade 1	897 (28.9)	1081 (34.7)	1978 (31.8)
Grade 2	366 (11.8)	522 (16.7)	888 (14.3)
Grade 3	62 (2.0)	121 (3.9)	183 (2.9)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	64 (2.1)	124 (4.0)	188 (3.0)
Fever - N1	3105	3118	6223
Any	11 (0.4)	39 (1.3)	50 (0.8)
Grade 1	8 (0.3)	22 (0.7)	30 (0.5)
Grade 2	1 (<0.1)	8 (0.3)	9 (0.1)
Grade 3	0	7 (0.2)	7 (0.1)
Grade 4	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 3 or Above	2 (<0.1)	9 (0.3)	11 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Headache - N1	3106	3119	6225
Any	865 (27.8)	1031 (33.1)	1896 (30.5)
Grade 1	688 (22.2)	805 (25.8)	1493 (24.0)
Grade 2	137 (4.4)	156 (5.0)	293 (4.7)
Grade 3	40 (1.3)	70 (2.2)	110 (1.8)
Grade 4	0	0	0
Grade 3 or Above	40 (1.3)	70 (2.2)	110 (1.8)
Fatigue - N1	3106	3119	6225
Any	828 (26.7)	1154 (37.0)	1982 (31.8)
Grade 1	554 (17.8)	728 (23.3)	1282 (20.6)
Grade 2	260 (8.4)	386 (12.4)	646 (10.4)
Grade 3	14 (0.5)	39 (1.3)	53 (0.9)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	14 (0.5)	40 (1.3)	54 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Myalgia - N1	3106	3119	6225
Any	504 (16.2)	825 (26.5)	1329 (21.3)
Grade 1	380 (12.2)	570 (18.3)	950 (15.3)
Grade 2	108 (3.5)	226 (7.2)	334 (5.4)
Grade 3	16 (0.5)	29 (0.9)	45 (0.7)
Grade 4	0	0	0
Grade 3 or Above	16 (0.5)	29 (0.9)	45 (0.7)
Arthralgia - N1	3106	3119	6225
Any	409 (13.2)	585 (18.8)	994 (16.0)
Grade 1	305 (9.8)	440 (14.1)	745 (12.0)
Grade 2	93 (3.0)	128 (4.1)	221 (3.6)
Grade 3	11 (0.4)	16 (0.5)	27 (0.4)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	11 (0.4)	17 (0.5)	28 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=3106) n (%)	mRNA-1273 (N=3119) n (%)	Total (N=6225) n (%)
Nausea/Vomiting - N1	3106	3119	6225
Any	257 (8.3)	305 (9.8)	562 (9.0)
Grade 1	209 (6.7)	258 (8.3)	467 (7.5)
Grade 2	46 (1.5)	42 (1.3)	88 (1.4)
Grade 3	2 (<0.1)	5 (0.2)	7 (0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	5 (0.2)	7 (0.1)
Chills - N1	3106	3119	6225
Any	229 (7.4)	342 (11.0)	571 (9.2)
Grade 1	182 (5.9)	250 (8.0)	432 (6.9)
Grade 2	41 (1.3)	78 (2.5)	119 (1.9)
Grade 3	6 (0.2)	14 (0.4)	20 (0.3)
Grade 4	0	0	0
Grade 3 or Above	6 (0.2)	14 (0.4)	20 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Solicited Adverse Reactions - N1	11909	11905	23814
Any Solicited Adverse Reactions	5737 (48.2)	10515 (88.3)	16252 (68.2)
95% CI	47.3, 49.1	87.7, 88.9	67.7, 68.8
Grade 1	4057 (34.1)	7425 (62.4)	11482 (48.2)
Grade 2	1387 (11.6)	2442 (20.5)	3829 (16.1)
Grade 3	289 (2.4)	646 (5.4)	935 (3.9)
Grade 4	4 (<0.1)	2 (<0.1)	6 (<0.1)
Grade 3 or Above	293 (2.5)	648 (5.4)	941 (4.0)
Solicited Local Adverse Reactions - N1	11905	11901	23806
Any Solicited Local Adverse Reactions	2354 (19.8)	10071 (84.6)	12425 (52.2)
95% CI	19.1, 20.5	84.0, 85.3	51.6, 52.8
Grade 1	2233 (18.8)	8486 (71.3)	10719 (45.0)
Grade 2	63 (0.5)	1173 (9.9)	1236 (5.2)
Grade 3	58 (0.5)	412 (3.5)	470 (2.0)
Grade 4	0	0	0
Grade 3 or Above	58 (0.5)	412 (3.5)	470 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Pain - N1	11905	11901	23806
Any	2093 (17.6)	10018 (84.2)	12111 (50.9)
Grade 1	2014 (16.9)	8701 (73.1)	10715 (45.0)
Grade 2	38 (0.3)	993 (8.3)	1031 (4.3)
Grade 3	41 (0.3)	324 (2.7)	365 (1.5)
Grade 4	0	0	0
Grade 3 or Above	41 (0.3)	324 (2.7)	365 (1.5)
Erythema (Redness) - N1	11905	11901	23806
Any	60 (0.5)	346 (2.9)	406 (1.7)
Grade 1	45 (0.4)	216 (1.8)	261 (1.1)
Grade 2	7 (<0.1)	99 (0.8)	106 (0.4)
Grade 3	8 (<0.1)	31 (0.3)	39 (0.2)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	31 (0.3)	39 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Swelling (Hardness) - N1	11905	11901	23806
Any	55 (0.5)	732 (6.2)	787 (3.3)
Grade 1	43 (0.4)	482 (4.1)	525 (2.2)
Grade 2	8 (<0.1)	186 (1.6)	194 (0.8)
Grade 3	4 (<0.1)	64 (0.5)	68 (0.3)
Grade 4	0	0	0
Grade 3 or Above	4 (<0.1)	64 (0.5)	68 (0.3)
Axillary Swelling or Tenderness - N1	11905	11901	23806
Any	542 (4.6)	1118 (9.4)	1660 (7.0)
Grade 1	503 (4.2)	1015 (8.5)	1518 (6.4)
Grade 2	19 (0.2)	72 (0.6)	91 (0.4)
Grade 3	20 (0.2)	31 (0.3)	51 (0.2)
Grade 4	0	0	0
Grade 3 or Above	20 (0.2)	31 (0.3)	51 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Solicited Systemic Adverse Reactions - N1	11909	11905	23814
Any Solicited Systemic Adverse Reactions	5009 (42.1)	6502 (54.6)	11511 (48.3)
95% CI	41.2, 43.0	53.7, 55.5	47.7, 49.0
Grade 1	3397 (28.5)	4219 (35.4)	7616 (32.0)
Grade 2	1360 (11.4)	1956 (16.4)	3316 (13.9)
Grade 3	248 (2.1)	325 (2.7)	573 (2.4)
Grade 4	4 (<0.1)	2 (<0.1)	6 (<0.1)
Grade 3 or Above	252 (2.1)	327 (2.7)	579 (2.4)
Fever - N1	11908	11903	23811
Any	33 (0.3)	73 (0.6)	106 (0.4)
Grade 1	20 (0.2)	51 (0.4)	71 (0.3)
Grade 2	7 (<0.1)	16 (0.1)	23 (<0.1)
Grade 3	2 (<0.1)	4 (<0.1)	6 (<0.1)
Grade 4	4 (<0.1)	2 (<0.1)	6 (<0.1)
Grade 3 or Above	6 (<0.1)	6 (<0.1)	12 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Headache - N1	11905	11901	23806
Any	3122 (26.2)	3870 (32.5)	6992 (29.4)
Grade 1	2574 (21.6)	3102 (26.1)	5676 (23.8)
Grade 2	392 (3.3)	566 (4.8)	958 (4.0)
Grade 3	156 (1.3)	202 (1.7)	358 (1.5)
Grade 4	0	0	0
Grade 3 or Above	156 (1.3)	202 (1.7)	358 (1.5)
Fatigue - N1	11905	11901	23806
Any	3261 (27.4)	4429 (37.2)	7690 (32.3)
Grade 1	2121 (17.8)	2824 (23.7)	4945 (20.8)
Grade 2	1049 (8.8)	1494 (12.6)	2543 (10.7)
Grade 3	91 (0.8)	111 (0.9)	202 (0.8)
Grade 4	0	0	0
Grade 3 or Above	91 (0.8)	111 (0.9)	202 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Myalgia - N1	11905	11901	23806
Any	1549 (13.0)	2587 (21.7)	4136 (17.4)
Grade 1	1171 (9.8)	1854 (15.6)	3025 (12.7)
Grade 2	347 (2.9)	673 (5.7)	1020 (4.3)
Grade 3	31 (0.3)	60 (0.5)	91 (0.4)
Grade 4	0	0	0
Grade 3 or Above	31 (0.3)	60 (0.5)	91 (0.4)
Arthralgia - N1	11905	11901	23806
Any	1354 (11.4)	1899 (16.0)	3253 (13.7)
Grade 1	1011 (8.5)	1381 (11.6)	2392 (10.0)
Grade 2	316 (2.7)	476 (4.0)	792 (3.3)
Grade 3	27 (0.2)	42 (0.4)	69 (0.3)
Grade 4	0	0	0
Grade 3 or Above	27 (0.2)	42 (0.4)	69 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Ethnicity and Grade
First Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11909) n (%)	mRNA-1273 (N=11905) n (%)	Total (N=23814) n (%)
Nausea/Vomiting - N1	11905	11901	23806
Any	809 (6.8)	946 (7.9)	1755 (7.4)
Grade 1	670 (5.6)	780 (6.6)	1450 (6.1)
Grade 2	128 (1.1)	161 (1.4)	289 (1.2)
Grade 3	11 (<0.1)	5 (<0.1)	16 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	11 (<0.1)	5 (<0.1)	16 (<0.1)
Chills - N1	11905	11901	23806
Any	645 (5.4)	893 (7.5)	1538 (6.5)
Grade 1	521 (4.4)	673 (5.7)	1194 (5.0)
Grade 2	116 (1.0)	210 (1.8)	326 (1.4)
Grade 3	8 (<0.1)	10 (<0.1)	18 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	10 (<0.1)	18 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=2905) n (%)	mRNA-1273 (N=2958) n (%)	Total (N=5863) n (%)
Solicited Adverse Reactions - N1	2905	2958	5863
Any Solicited Adverse Reactions	1247 (42.9)	2667 (90.2)	3914 (66.8)
95% CI	41.1, 44.7	89.0, 91.2	65.5, 68.0
Grade 1	849 (29.2)	940 (31.8)	1789 (30.5)
Grade 2	341 (11.7)	1131 (38.2)	1472 (25.1)
Grade 3	55 (1.9)	592 (20.0)	647 (11.0)
Grade 4	2 (<0.1)	4 (0.1)	6 (0.1)
Grade 3 or Above	57 (2.0)	596 (20.1)	653 (11.1)
Solicited Local Adverse Reactions - N1	2904	2957	5861
Any Solicited Local Adverse Reactions	571 (19.7)	2557 (86.5)	3128 (53.4)
95% CI	18.2, 21.2	85.2, 87.7	52.1, 54.7
Grade 1	527 (18.1)	1666 (56.3)	2193 (37.4)
Grade 2	29 (1.0)	689 (23.3)	718 (12.3)
Grade 3	15 (0.5)	202 (6.8)	217 (3.7)
Grade 4	0	0	0
Grade 3 or Above	15 (0.5)	202 (6.8)	217 (3.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=2905) n (%)	mRNA-1273 (N=2958) n (%)	Total (N=5863) n (%)
Pain - N1	2904	2957	5861
Any	500 (17.2)	2542 (86.0)	3042 (51.9)
Grade 1	471 (16.2)	1808 (61.1)	2279 (38.9)
Grade 2	20 (0.7)	610 (20.6)	630 (10.7)
Grade 3	9 (0.3)	124 (4.2)	133 (2.3)
Grade 4	0	0	0
Grade 3 or Above	9 (0.3)	124 (4.2)	133 (2.3)
Erythema (Redness) - N1	2904	2956	5860
Any	13 (0.4)	232 (7.8)	245 (4.2)
Grade 1	9 (0.3)	84 (2.8)	93 (1.6)
Grade 2	1 (<0.1)	98 (3.3)	99 (1.7)
Grade 3	3 (0.1)	50 (1.7)	53 (0.9)
Grade 4	0	0	0
Grade 3 or Above	3 (0.1)	50 (1.7)	53 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=2905) n (%)	mRNA-1273 (N=2958) n (%)	Total (N=5863) n (%)
Swelling (Hardness) - N1	2904	2956	5860
Any	16 (0.6)	357 (12.1)	373 (6.4)
Grade 1	12 (0.4)	168 (5.7)	180 (3.1)
Grade 2	3 (0.1)	134 (4.5)	137 (2.3)
Grade 3	1 (<0.1)	55 (1.9)	56 (1.0)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	55 (1.9)	56 (1.0)
Axillary Swelling or Tenderness - N1	2904	2956	5860
Any	145 (5.0)	513 (17.4)	658 (11.2)
Grade 1	125 (4.3)	409 (13.8)	534 (9.1)
Grade 2	14 (0.5)	87 (2.9)	101 (1.7)
Grade 3	6 (0.2)	17 (0.6)	23 (0.4)
Grade 4	0	0	0
Grade 3 or Above	6 (0.2)	17 (0.6)	23 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=2905) n (%)	mRNA-1273 (N=2958) n (%)	Total (N=5863) n (%)
Solicited Systemic Adverse Reactions - N1	2905	2957	5862
Any Solicited Systemic Adverse Reactions	1086 (37.4)	2351 (79.5)	3437 (58.6)
95% CI	35.6, 39.2	78.0, 80.9	57.4, 59.9
Grade 1	706 (24.3)	765 (25.9)	1471 (25.1)
Grade 2	333 (11.5)	1092 (36.9)	1425 (24.3)
Grade 3	45 (1.5)	490 (16.6)	535 (9.1)
Grade 4	2 (<0.1)	4 (0.1)	6 (0.1)
Grade 3 or Above	47 (1.6)	494 (16.7)	541 (9.2)
Fever - N1	2904	2953	5857
Any	16 (0.6)	477 (16.2)	493 (8.4)
Grade 1	11 (0.4)	279 (9.4)	290 (5.0)
Grade 2	2 (<0.1)	152 (5.1)	154 (2.6)
Grade 3	1 (<0.1)	42 (1.4)	43 (0.7)
Grade 4	2 (<0.1)	4 (0.1)	6 (0.1)
Grade 3 or Above	3 (0.1)	46 (1.6)	49 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=2905) n (%)	mRNA-1273 (N=2958) n (%)	Total (N=5863) n (%)
Headache - N1	2904	2956	5860
Any	703 (24.2)	1804 (61.0)	2507 (42.8)
Grade 1	565 (19.5)	995 (33.7)	1560 (26.6)
Grade 2	116 (4.0)	690 (23.3)	806 (13.8)
Grade 3	22 (0.8)	119 (4.0)	141 (2.4)
Grade 4	0	0	0
Grade 3 or Above	22 (0.8)	119 (4.0)	141 (2.4)
Fatigue - N1	2904	2956	5860
Any	709 (24.4)	1858 (62.9)	2567 (43.8)
Grade 1	445 (15.3)	685 (23.2)	1130 (19.3)
Grade 2	240 (8.3)	887 (30.0)	1127 (19.2)
Grade 3	24 (0.8)	286 (9.7)	310 (5.3)
Grade 4	0	0	0
Grade 3 or Above	24 (0.8)	286 (9.7)	310 (5.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=2905) n (%)	mRNA-1273 (N=2958) n (%)	Total (N=5863) n (%)
Myalgia - N1	2904	2956	5860
Any	439 (15.1)	1820 (61.6)	2259 (38.5)
Grade 1	315 (10.8)	683 (23.1)	998 (17.0)
Grade 2	113 (3.9)	831 (28.1)	944 (16.1)
Grade 3	11 (0.4)	306 (10.4)	317 (5.4)
Grade 4	0	0	0
Grade 3 or Above	11 (0.4)	306 (10.4)	317 (5.4)
Arthralgia - N1	2904	2956	5860
Any	395 (13.6)	1378 (46.6)	1773 (30.3)
Grade 1	287 (9.9)	596 (20.2)	883 (15.1)
Grade 2	98 (3.4)	592 (20.0)	690 (11.8)
Grade 3	10 (0.3)	190 (6.4)	200 (3.4)
Grade 4	0	0	0
Grade 3 or Above	10 (0.3)	190 (6.4)	200 (3.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=2905) n (%)	mRNA-1273 (N=2958) n (%)	Total (N=5863) n (%)
Nausea/Vomiting - N1	2904	2956	5860
Any	214 (7.4)	583 (19.7)	797 (13.6)
Grade 1	175 (6.0)	443 (15.0)	618 (10.5)
Grade 2	35 (1.2)	136 (4.6)	171 (2.9)
Grade 3	4 (0.1)	4 (0.1)	8 (0.1)
Grade 4	0	0	0
Grade 3 or Above	4 (0.1)	4 (0.1)	8 (0.1)
Chills - N1	2904	2956	5860
Any	202 (7.0)	1387 (46.9)	1589 (27.1)
Grade 1	158 (5.4)	635 (21.5)	793 (13.5)
Grade 2	38 (1.3)	712 (24.1)	750 (12.8)
Grade 3	6 (0.2)	40 (1.4)	46 (0.8)
Grade 4	0	0	0
Grade 3 or Above	6 (0.2)	40 (1.4)	46 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11541) n (%)	mRNA-1273 (N=11596) n (%)	Total (N=23137) n (%)
Solicited Adverse Reactions - N1	11541	11596	23137
Any Solicited Adverse Reactions	4953 (42.9)	10760 (92.8)	15713 (67.9)
95% CI	42.0, 43.8	92.3, 93.3	67.3, 68.5
Grade 1	3457 (30.0)	3857 (33.3)	7314 (31.6)
Grade 2	1205 (10.4)	4613 (39.8)	5818 (25.1)
Grade 3	290 (2.5)	2280 (19.7)	2570 (11.1)
Grade 4	1 (<0.1)	10 (<0.1)	11 (<0.1)
Grade 3 or Above	291 (2.5)	2290 (19.7)	2581 (11.2)
Solicited Local Adverse Reactions - N1	11541	11594	23135
Any Solicited Local Adverse Reactions	2161 (18.7)	10351 (89.3)	12512 (54.1)
95% CI	18.0, 19.4	88.7, 89.8	53.4, 54.7
Grade 1	2044 (17.7)	7039 (60.7)	9083 (39.3)
Grade 2	58 (0.5)	2501 (21.6)	2559 (11.1)
Grade 3	59 (0.5)	811 (7.0)	870 (3.8)
Grade 4	0	0	0
Grade 3 or Above	59 (0.5)	811 (7.0)	870 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11541) n (%)	mRNA-1273 (N=11596) n (%)	Total (N=23137) n (%)
Pain - N1	11541	11594	23135
Any	1965 (17.0)	10301 (88.8)	12266 (53.0)
Grade 1	1893 (16.4)	7610 (65.6)	9503 (41.1)
Grade 2	40 (0.3)	2214 (19.1)	2254 (9.7)
Grade 3	32 (0.3)	477 (4.1)	509 (2.2)
Grade 4	0	0	0
Grade 3 or Above	32 (0.3)	477 (4.1)	509 (2.2)
Erythema (Redness) - N1	11541	11594	23135
Any	55 (0.5)	1032 (8.9)	1087 (4.7)
Grade 1	39 (0.3)	367 (3.2)	406 (1.8)
Grade 2	4 (<0.1)	431 (3.7)	435 (1.9)
Grade 3	12 (0.1)	234 (2.0)	246 (1.1)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	234 (2.0)	246 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category / Grade	Placebo (N=11541) n (%)	mRNA-1273 (N=11596) n (%)	Total (N=23137) n (%)
Swelling (Hardness) - N1	11541	11594	23135
Any	43 (0.4)	1436 (12.4)	1479 (6.4)
Grade 1	26 (0.2)	724 (6.2)	750 (3.2)
Grade 2	7 (<0.1)	515 (4.4)	522 (2.3)
Grade 3	10 (<0.1)	197 (1.7)	207 (0.9)
Grade 4	0	0	0
Grade 3 or Above	10 (<0.1)	197 (1.7)	207 (0.9)
Axillary Swelling or Tenderness - N1	11541	11594	23135
Any	421 (3.6)	1557 (13.4)	1978 (8.5)
Grade 1	393 (3.4)	1304 (11.2)	1697 (7.3)
Grade 2	14 (0.1)	202 (1.7)	216 (0.9)
Grade 3	14 (0.1)	51 (0.4)	65 (0.3)
Grade 4	0	0	0
Grade 3 or Above	14 (0.1)	51 (0.4)	65 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11541) n (%)	mRNA-1273 (N=11596) n (%)	Total (N=23137) n (%)
Solicited Systemic Adverse Reactions - N1	11540	11596	23136
Any Solicited Systemic Adverse Reactions	4209 (36.5)	9219 (79.5)	13428 (58.0)
95% CI	35.6, 37.4	78.8, 80.2	57.4, 58.7
Grade 1	2779 (24.1)	2917 (25.2)	5696 (24.6)
Grade 2	1190 (10.3)	4462 (38.5)	5652 (24.4)
Grade 3	239 (2.1)	1830 (15.8)	2069 (8.9)
Grade 4	1 (<0.1)	10 (<0.1)	11 (<0.1)
Grade 3 or Above	240 (2.1)	1840 (15.9)	2080 (9.0)
Fever - N1	11537	11592	23129
Any	27 (0.2)	1781 (15.4)	1808 (7.8)
Grade 1	22 (0.2)	1076 (9.3)	1098 (4.7)
Grade 2	3 (<0.1)	536 (4.6)	539 (2.3)
Grade 3	1 (<0.1)	160 (1.4)	161 (0.7)
Grade 4	1 (<0.1)	9 (<0.1)	10 (<0.1)
Grade 3 or Above	2 (<0.1)	169 (1.5)	171 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11541) n (%)	mRNA-1273 (N=11596) n (%)	Total (N=23137) n (%)
Headache - N1	11539	11594	23133
Any	2701 (23.4)	6756 (58.3)	9457 (40.9)
Grade 1	2153 (18.7)	3778 (32.6)	5931 (25.6)
Grade 2	405 (3.5)	2438 (21.0)	2843 (12.3)
Grade 3	143 (1.2)	540 (4.7)	683 (3.0)
Grade 4	0	0	0
Grade 3 or Above	143 (1.2)	540 (4.7)	683 (3.0)
Fatigue - N1	11539	11594	23133
Any	2675 (23.2)	7662 (66.1)	10337 (44.7)
Grade 1	1713 (14.8)	2711 (23.4)	4424 (19.1)
Grade 2	880 (7.6)	3817 (32.9)	4697 (20.3)
Grade 3	82 (0.7)	1134 (9.8)	1216 (5.3)
Grade 4	0	0	0
Grade 3 or Above	82 (0.7)	1134 (9.8)	1216 (5.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11541) n (%)	mRNA-1273 (N=11596) n (%)	Total (N=23137) n (%)
Myalgia - N1	11539	11594	23133
Any	1368 (11.9)	6627 (57.2)	7995 (34.6)
Grade 1	979 (8.5)	2523 (21.8)	3502 (15.1)
Grade 2	349 (3.0)	3100 (26.7)	3449 (14.9)
Grade 3	40 (0.3)	1004 (8.7)	1044 (4.5)
Grade 4	0	0	0
Grade 3 or Above	40 (0.3)	1004 (8.7)	1044 (4.5)
Arthralgia - N1	11539	11594	23133
Any	1168 (10.1)	4862 (41.9)	6030 (26.1)
Grade 1	844 (7.3)	2183 (18.8)	3027 (13.1)
Grade 2	290 (2.5)	2099 (18.1)	2389 (10.3)
Grade 3	34 (0.3)	580 (5.0)	614 (2.7)
Grade 4	0	0	0
Grade 3 or Above	34 (0.3)	580 (5.0)	614 (2.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.5.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Ethnicity and Grade
Second Injection Solicited Safety Set

Ethnicity Group: Not Hispanic or Latino

Solicited Adverse Reaction Category Grade	Placebo (N=11541) n (%)	mRNA-1273 (N=11596) n (%)	Total (N=23137) n (%)
Nausea/Vomiting - N1	11539	11594	23133
Any	719 (6.2)	2189 (18.9)	2908 (12.6)
Grade 1	580 (5.0)	1633 (14.1)	2213 (9.6)
Grade 2	132 (1.1)	538 (4.6)	670 (2.9)
Grade 3	7 (<0.1)	17 (0.1)	24 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	7 (<0.1)	18 (0.2)	25 (0.1)
Chills - N1	11539	11594	23133
Any	604 (5.2)	5050 (43.6)	5654 (24.4)
Grade 1	466 (4.0)	2236 (19.3)	2702 (11.7)
Grade 2	127 (1.1)	2664 (23.0)	2791 (12.1)
Grade 3	11 (<0.1)	150 (1.3)	161 (0.7)
Grade 4	0	0	0
Grade 3 or Above	11 (<0.1)	150 (1.3)	161 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3454) n (%)	mRNA-1273 (N=3439) n (%)	Total (N=6893) n (%)
Solicited Adverse Reactions - N1	3454	3439	6893
Any Solicited Adverse Reactions	1659 (48.0)	2925 (85.1)	4584 (66.5)
95% CI	46.4, 49.7	83.8, 86.2	65.4, 67.6
Grade 1	1110 (32.1)	2060 (59.9)	3170 (46.0)
Grade 2	455 (13.2)	674 (19.6)	1129 (16.4)
Grade 3	94 (2.7)	190 (5.5)	284 (4.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	94 (2.7)	191 (5.6)	285 (4.1)
Solicited Local Adverse Reactions - N1	3452	3438	6890
Any Solicited Local Adverse Reactions	700 (20.3)	2723 (79.2)	3423 (49.7)
95% CI	18.9, 21.7	77.8, 80.5	48.5, 50.9
Grade 1	647 (18.7)	2349 (68.3)	2996 (43.5)
Grade 2	27 (0.8)	268 (7.8)	295 (4.3)
Grade 3	26 (0.8)	106 (3.1)	132 (1.9)
Grade 4	0	0	0
Grade 3 or Above	26 (0.8)	106 (3.1)	132 (1.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3454) n (%)	mRNA-1273 (N=3439) n (%)	Total (N=6893) n (%)
Pain - N1	3452	3438	6890
Any	613 (17.8)	2709 (78.8)	3322 (48.2)
Grade 1	576 (16.7)	2408 (70.0)	2984 (43.3)
Grade 2	17 (0.5)	218 (6.3)	235 (3.4)
Grade 3	20 (0.6)	83 (2.4)	103 (1.5)
Grade 4	0	0	0
Grade 3 or Above	20 (0.6)	83 (2.4)	103 (1.5)
Erythema (Redness) - N1	3452	3438	6890
Any	21 (0.6)	104 (3.0)	125 (1.8)
Grade 1	16 (0.5)	70 (2.0)	86 (1.2)
Grade 2	2 (<0.1)	28 (0.8)	30 (0.4)
Grade 3	3 (<0.1)	6 (0.2)	9 (0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	6 (0.2)	9 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3454) n (%)	mRNA-1273 (N=3439) n (%)	Total (N=6893) n (%)
Swelling (Hardness) - N1	3452	3438	6890
Any	21 (0.6)	196 (5.7)	217 (3.1)
Grade 1	15 (0.4)	130 (3.8)	145 (2.1)
Grade 2	5 (0.1)	51 (1.5)	56 (0.8)
Grade 3	1 (<0.1)	15 (0.4)	16 (0.2)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	15 (0.4)	16 (0.2)
Axillary Swelling or Tenderness - N1	3452	3438	6890
Any	188 (5.4)	337 (9.8)	525 (7.6)
Grade 1	172 (5.0)	304 (8.8)	476 (6.9)
Grade 2	9 (0.3)	16 (0.5)	25 (0.4)
Grade 3	7 (0.2)	17 (0.5)	24 (0.3)
Grade 4	0	0	0
Grade 3 or Above	7 (0.2)	17 (0.5)	24 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3454) n (%)	mRNA-1273 (N=3439) n (%)	Total (N=6893) n (%)
Solicited Systemic Adverse Reactions - N1	3454	3439	6893
Any Solicited Systemic Adverse Reactions	1470 (42.6)	1900 (55.2)	3370 (48.9)
95% CI	40.9, 44.2	53.6, 56.9	47.7, 50.1
Grade 1	952 (27.6)	1210 (35.2)	2162 (31.4)
Grade 2	441 (12.8)	571 (16.6)	1012 (14.7)
Grade 3	77 (2.2)	118 (3.4)	195 (2.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	77 (2.2)	119 (3.5)	196 (2.8)
Fever - N1	3454	3438	6892
Any	7 (0.2)	23 (0.7)	30 (0.4)
Grade 1	6 (0.2)	13 (0.4)	19 (0.3)
Grade 2	1 (<0.1)	7 (0.2)	8 (0.1)
Grade 3	0	2 (<0.1)	2 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	0	3 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category / Grade	Placebo (N=3454) n (%)	mRNA-1273 (N=3439) n (%)	Total (N=6893) n (%)
Headache - N1	3452	3438	6890
Any	890 (25.8)	1090 (31.7)	1980 (28.7)
Grade 1	718 (20.8)	860 (25.0)	1578 (22.9)
Grade 2	124 (3.6)	154 (4.5)	278 (4.0)
Grade 3	48 (1.4)	76 (2.2)	124 (1.8)
Grade 4	0	0	0
Grade 3 or Above	48 (1.4)	76 (2.2)	124 (1.8)
Fatigue - N1	3452	3438	6890
Any	960 (27.8)	1294 (37.6)	2254 (32.7)
Grade 1	597 (17.3)	821 (23.9)	1418 (20.6)
Grade 2	335 (9.7)	431 (12.5)	766 (11.1)
Grade 3	28 (0.8)	42 (1.2)	70 (1.0)
Grade 4	0	0	0
Grade 3 or Above	28 (0.8)	42 (1.2)	70 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category / Grade	Placebo (N=3454) n (%)	mRNA-1273 (N=3439) n (%)	Total (N=6893) n (%)
Myalgia - N1	3452	3438	6890
Any	554 (16.0)	815 (23.7)	1369 (19.9)
Grade 1	411 (11.9)	575 (16.7)	986 (14.3)
Grade 2	133 (3.9)	215 (6.3)	348 (5.1)
Grade 3	10 (0.3)	25 (0.7)	35 (0.5)
Grade 4	0	0	0
Grade 3 or Above	10 (0.3)	25 (0.7)	35 (0.5)
Arthralgia - N1	3452	3438	6890
Any	514 (14.9)	635 (18.5)	1149 (16.7)
Grade 1	366 (10.6)	439 (12.8)	805 (11.7)
Grade 2	139 (4.0)	177 (5.1)	316 (4.6)
Grade 3	9 (0.3)	19 (0.6)	28 (0.4)
Grade 4	0	0	0
Grade 3 or Above	9 (0.3)	19 (0.6)	28 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3454) n (%)	mRNA-1273 (N=3439) n (%)	Total (N=6893) n (%)
Nausea/Vomiting - N1	3452	3438	6890
Any	289 (8.4)	312 (9.1)	601 (8.7)
Grade 1	244 (7.1)	251 (7.3)	495 (7.2)
Grade 2	44 (1.3)	56 (1.6)	100 (1.5)
Grade 3	1 (<0.1)	5 (0.1)	6 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	5 (0.1)	6 (<0.1)
Chills - N1	3452	3438	6890
Any	222 (6.4)	276 (8.0)	498 (7.2)
Grade 1	184 (5.3)	203 (5.9)	387 (5.6)
Grade 2	36 (1.0)	64 (1.9)	100 (1.5)
Grade 3	2 (<0.1)	9 (0.3)	11 (0.2)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	9 (0.3)	11 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11697) n (%)	mRNA-1273 (N=11727) n (%)	Total (N=23424) n (%)
Solicited Adverse Reactions - N1	11697	11727	23424
Any Solicited Adverse Reactions	5626 (48.1)	10392 (88.6)	16018 (68.4)
95% CI	47.2, 49.0	88.0, 89.2	67.8, 69.0
Grade 1	4024 (34.4)	7269 (62.0)	11293 (48.2)
Grade 2	1327 (11.3)	2460 (21.0)	3787 (16.2)
Grade 3	269 (2.3)	659 (5.6)	928 (4.0)
Grade 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Grade 3 or Above	275 (2.4)	663 (5.7)	938 (4.0)
Solicited Local Adverse Reactions - N1	11695	11724	23419
Any Solicited Local Adverse Reactions	2309 (19.7)	10042 (85.7)	12351 (52.7)
95% CI	19.0, 20.5	85.0, 86.3	52.1, 53.4
Grade 1	2195 (18.8)	8376 (71.4)	10571 (45.1)
Grade 2	62 (0.5)	1243 (10.6)	1305 (5.6)
Grade 3	52 (0.4)	423 (3.6)	475 (2.0)
Grade 4	0	0	0
Grade 3 or Above	52 (0.4)	423 (3.6)	475 (2.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11697) n (%)	mRNA-1273 (N=11727) n (%)	Total (N=23424) n (%)
Pain - N1	11695	11724	23419
Any	2052 (17.5)	9979 (85.1)	12031 (51.4)
Grade 1	1975 (16.9)	8577 (73.2)	10552 (45.1)
Grade 2	42 (0.4)	1069 (9.1)	1111 (4.7)
Grade 3	35 (0.3)	333 (2.8)	368 (1.6)
Grade 4	0	0	0
Grade 3 or Above	35 (0.3)	333 (2.8)	368 (1.6)
Erythema (Redness) - N1	11695	11724	23419
Any	56 (0.5)	341 (2.9)	397 (1.7)
Grade 1	41 (0.4)	211 (1.8)	252 (1.1)
Grade 2	5 (<0.1)	94 (0.8)	99 (0.4)
Grade 3	10 (<0.1)	36 (0.3)	46 (0.2)
Grade 4	0	0	0
Grade 3 or Above	10 (<0.1)	36 (0.3)	46 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11697) n (%)	mRNA-1273 (N=11727) n (%)	Total (N=23424) n (%)
Swelling (Hardness) - N1	11695	11724	23419
Any	44 (0.4)	739 (6.3)	783 (3.3)
Grade 1	35 (0.3)	478 (4.1)	513 (2.2)
Grade 2	4 (<0.1)	194 (1.7)	198 (0.8)
Grade 3	5 (<0.1)	67 (0.6)	72 (0.3)
Grade 4	0	0	0
Grade 3 or Above	5 (<0.1)	67 (0.6)	72 (0.3)
Axillary Swelling or Tenderness - N1	11695	11724	23419
Any	534 (4.6)	1216 (10.4)	1750 (7.5)
Grade 1	496 (4.2)	1090 (9.3)	1586 (6.8)
Grade 2	18 (0.2)	94 (0.8)	112 (0.5)
Grade 3	20 (0.2)	32 (0.3)	52 (0.2)
Grade 4	0	0	0
Grade 3 or Above	20 (0.2)	32 (0.3)	52 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11697) n (%)	mRNA-1273 (N=11727) n (%)	Total (N=23424) n (%)
Solicited Systemic Adverse Reactions - N1	11697	11727	23424
Any Solicited Systemic Adverse Reactions	4927 (42.1)	6416 (54.7)	11343 (48.4)
95% CI	41.2, 43.0	53.8, 55.6	47.8, 49.1
Grade 1	3382 (28.9)	4148 (35.4)	7530 (32.1)
Grade 2	1305 (11.2)	1933 (16.5)	3238 (13.8)
Grade 3	234 (2.0)	331 (2.8)	565 (2.4)
Grade 4	6 (<0.1)	4 (<0.1)	10 (<0.1)
Grade 3 or Above	240 (2.1)	335 (2.9)	575 (2.5)
Fever - N1	11695	11725	23420
Any	37 (0.3)	89 (0.8)	126 (0.5)
Grade 1	22 (0.2)	60 (0.5)	82 (0.4)
Grade 2	7 (<0.1)	17 (0.1)	24 (0.1)
Grade 3	2 (<0.1)	9 (<0.1)	11 (<0.1)
Grade 4	6 (<0.1)	3 (<0.1)	9 (<0.1)
Grade 3 or Above	8 (<0.1)	12 (0.1)	20 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11697) n (%)	mRNA-1273 (N=11727) n (%)	Total (N=23424) n (%)
Headache - N1	11694	11724	23418
Any	3136 (26.8)	3860 (32.9)	6996 (29.9)
Grade 1	2579 (22.1)	3087 (26.3)	5666 (24.2)
Grade 2	408 (3.5)	576 (4.9)	984 (4.2)
Grade 3	149 (1.3)	197 (1.7)	346 (1.5)
Grade 4	0	0	0
Grade 3 or Above	149 (1.3)	197 (1.7)	346 (1.5)
Fatigue - N1	11694	11724	23418
Any	3173 (27.1)	4342 (37.0)	7515 (32.1)
Grade 1	2108 (18.0)	2764 (23.6)	4872 (20.8)
Grade 2	988 (8.4)	1468 (12.5)	2456 (10.5)
Grade 3	77 (0.7)	109 (0.9)	186 (0.8)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	77 (0.7)	110 (0.9)	187 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11697) n (%)	mRNA-1273 (N=11727) n (%)	Total (N=23424) n (%)
Myalgia - N1	11694	11724	23418
Any	1515 (13.0)	2627 (22.4)	4142 (17.7)
Grade 1	1149 (9.8)	1867 (15.9)	3016 (12.9)
Grade 2	329 (2.8)	694 (5.9)	1023 (4.4)
Grade 3	37 (0.3)	66 (0.6)	103 (0.4)
Grade 4	0	0	0
Grade 3 or Above	37 (0.3)	66 (0.6)	103 (0.4)
Arthralgia - N1	11694	11724	23418
Any	1270 (10.9)	1875 (16.0)	3145 (13.4)
Grade 1	967 (8.3)	1403 (12.0)	2370 (10.1)
Grade 2	274 (2.3)	430 (3.7)	704 (3.0)
Grade 3	29 (0.2)	41 (0.3)	70 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	29 (0.2)	42 (0.4)	71 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Risk for Severe COVID-19 at Screening and Grade
First Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category / Grade	Placebo (N=11697) n (%)	mRNA-1273 (N=11727) n (%)	Total (N=23424) n (%)
Nausea/Vomiting - N1	11694	11724	23418
Any	786 (6.7)	950 (8.1)	1736 (7.4)
Grade 1	643 (5.5)	796 (6.8)	1439 (6.1)
Grade 2	131 (1.1)	149 (1.3)	280 (1.2)
Grade 3	12 (0.1)	5 (<0.1)	17 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	5 (<0.1)	17 (<0.1)
Chills - N1	11694	11724	23418
Any	656 (5.6)	975 (8.3)	1631 (7.0)
Grade 1	522 (4.5)	735 (6.3)	1257 (5.4)
Grade 2	122 (1.0)	225 (1.9)	347 (1.5)
Grade 3	12 (0.1)	15 (0.1)	27 (0.1)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	15 (0.1)	27 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3323) n (%)	mRNA-1273 (N=3362) n (%)	Total (N=6685) n (%)
Solicited Adverse Reactions - N1	3323	3362	6685
Any Solicited Adverse Reactions	1462 (44.0)	3001 (89.3)	4463 (66.8)
95% CI	42.3, 45.7	88.2, 90.3	65.6, 67.9
Grade 1	996 (30.0)	1305 (38.8)	2301 (34.4)
Grade 2	378 (11.4)	1127 (33.5)	1505 (22.5)
Grade 3	86 (2.6)	566 (16.8)	652 (9.8)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	88 (2.6)	569 (16.9)	657 (9.8)
Solicited Local Adverse Reactions - N1	3323	3360	6683
Any Solicited Local Adverse Reactions	622 (18.7)	2852 (84.9)	3474 (52.0)
95% CI	17.4, 20.1	83.6, 86.1	50.8, 53.2
Grade 1	577 (17.4)	2016 (60.0)	2593 (38.8)
Grade 2	20 (0.6)	618 (18.4)	638 (9.5)
Grade 3	25 (0.8)	218 (6.5)	243 (3.6)
Grade 4	0	0	0
Grade 3 or Above	25 (0.8)	218 (6.5)	243 (3.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category / Grade	Placebo (N=3323) n (%)	mRNA-1273 (N=3362) n (%)	Total (N=6685) n (%)
Pain - N1	3323	3360	6683
Any	552 (16.6)	2833 (84.3)	3385 (50.7)
Grade 1	518 (15.6)	2179 (64.9)	2697 (40.4)
Grade 2	18 (0.5)	528 (15.7)	546 (8.2)
Grade 3	16 (0.5)	126 (3.8)	142 (2.1)
Grade 4	0	0	0
Grade 3 or Above	16 (0.5)	126 (3.8)	142 (2.1)
Erythema (Redness) - N1	3323	3359	6682
Any	15 (0.5)	285 (8.5)	300 (4.5)
Grade 1	9 (0.3)	101 (3.0)	110 (1.6)
Grade 2	1 (<0.1)	119 (3.5)	120 (1.8)
Grade 3	5 (0.2)	65 (1.9)	70 (1.0)
Grade 4	0	0	0
Grade 3 or Above	5 (0.2)	65 (1.9)	70 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3323) n (%)	mRNA-1273 (N=3362) n (%)	Total (N=6685) n (%)
Swelling (Hardness) - N1	3323	3359	6682
Any	19 (0.6)	431 (12.8)	450 (6.7)
Grade 1	13 (0.4)	213 (6.3)	226 (3.4)
Grade 2	3 (<0.1)	159 (4.7)	162 (2.4)
Grade 3	3 (<0.1)	59 (1.8)	62 (0.9)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	59 (1.8)	62 (0.9)
Axillary Swelling or Tenderness - N1	3323	3359	6682
Any	149 (4.5)	448 (13.3)	597 (8.9)
Grade 1	139 (4.2)	364 (10.8)	503 (7.5)
Grade 2	5 (0.2)	61 (1.8)	66 (1.0)
Grade 3	5 (0.2)	23 (0.7)	28 (0.4)
Grade 4	0	0	0
Grade 3 or Above	5 (0.2)	23 (0.7)	28 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3323) n (%)	mRNA-1273 (N=3362) n (%)	Total (N=6685) n (%)
Solicited Systemic Adverse Reactions - N1	3323	3361	6684
Any Solicited Systemic Adverse Reactions	1262 (38.0)	2416 (71.9)	3678 (55.0)
95% CI	36.3, 39.7	70.3, 73.4	53.8, 56.2
Grade 1	818 (24.6)	900 (26.8)	1718 (25.7)
Grade 2	378 (11.4)	1064 (31.7)	1442 (21.6)
Grade 3	64 (1.9)	449 (13.4)	513 (7.7)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	66 (2.0)	452 (13.4)	518 (7.7)
Fever - N1	3323	3360	6683
Any	10 (0.3)	390 (11.6)	400 (6.0)
Grade 1	7 (0.2)	228 (6.8)	235 (3.5)
Grade 2	1 (<0.1)	115 (3.4)	116 (1.7)
Grade 3	0	44 (1.3)	44 (0.7)
Grade 4	2 (<0.1)	3 (<0.1)	5 (<0.1)
Grade 3 or Above	2 (<0.1)	47 (1.4)	49 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3323) n (%)	mRNA-1273 (N=3362) n (%)	Total (N=6685) n (%)
Headache - N1	3322	3359	6681
Any	769 (23.1)	1697 (50.5)	2466 (36.9)
Grade 1	609 (18.3)	1006 (29.9)	1615 (24.2)
Grade 2	126 (3.8)	548 (16.3)	674 (10.1)
Grade 3	34 (1.0)	143 (4.3)	177 (2.6)
Grade 4	0	0	0
Grade 3 or Above	34 (1.0)	143 (4.3)	177 (2.6)
Fatigue - N1	3322	3359	6681
Any	809 (24.4)	1914 (57.0)	2723 (40.8)
Grade 1	501 (15.1)	728 (21.7)	1229 (18.4)
Grade 2	280 (8.4)	912 (27.2)	1192 (17.8)
Grade 3	28 (0.8)	274 (8.2)	302 (4.5)
Grade 4	0	0	0
Grade 3 or Above	28 (0.8)	274 (8.2)	302 (4.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3323) n (%)	mRNA-1273 (N=3362) n (%)	Total (N=6685) n (%)
Myalgia - N1	3322	3359	6681
Any	482 (14.5)	1670 (49.7)	2152 (32.2)
Grade 1	344 (10.4)	707 (21.0)	1051 (15.7)
Grade 2	127 (3.8)	743 (22.1)	870 (13.0)
Grade 3	11 (0.3)	220 (6.5)	231 (3.5)
Grade 4	0	0	0
Grade 3 or Above	11 (0.3)	220 (6.5)	231 (3.5)
Arthralgia - N1	3322	3359	6681
Any	424 (12.8)	1271 (37.8)	1695 (25.4)
Grade 1	310 (9.3)	613 (18.2)	923 (13.8)
Grade 2	103 (3.1)	511 (15.2)	614 (9.2)
Grade 3	11 (0.3)	147 (4.4)	158 (2.4)
Grade 4	0	0	0
Grade 3 or Above	11 (0.3)	147 (4.4)	158 (2.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=3323) n (%)	mRNA-1273 (N=3362) n (%)	Total (N=6685) n (%)
Nausea/Vomiting - N1	3322	3359	6681
Any	269 (8.1)	547 (16.3)	816 (12.2)
Grade 1	219 (6.6)	409 (12.2)	628 (9.4)
Grade 2	48 (1.4)	129 (3.8)	177 (2.6)
Grade 3	2 (<0.1)	9 (0.3)	11 (0.2)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	9 (0.3)	11 (0.2)
Chills - N1	3322	3359	6681
Any	191 (5.7)	1160 (34.5)	1351 (20.2)
Grade 1	150 (4.5)	547 (16.3)	697 (10.4)
Grade 2	38 (1.1)	577 (17.2)	615 (9.2)
Grade 3	3 (<0.1)	36 (1.1)	39 (0.6)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	36 (1.1)	39 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11255) n (%)	mRNA-1273 (N=11329) n (%)	Total (N=22584) n (%)
Solicited Adverse Reactions - N1	11255	11329	22584
Any Solicited Adverse Reactions	4793 (42.6)	10555 (93.2)	15348 (68.0)
95% CI	41.7, 43.5	92.7, 93.6	67.3, 68.6
Grade 1	3350 (29.8)	3542 (31.3)	6892 (30.5)
Grade 2	1180 (10.5)	4673 (41.2)	5853 (25.9)
Grade 3	262 (2.3)	2329 (20.6)	2591 (11.5)
Grade 4	1 (<0.1)	11 (<0.1)	12 (<0.1)
Grade 3 or Above	263 (2.3)	2340 (20.7)	2603 (11.5)
Solicited Local Adverse Reactions - N1	11254	11328	22582
Any Solicited Local Adverse Reactions	2135 (19.0)	10177 (89.8)	12312 (54.5)
95% CI	18.3, 19.7	89.3, 90.4	53.9, 55.2
Grade 1	2017 (17.9)	6773 (59.8)	8790 (38.9)
Grade 2	68 (0.6)	2599 (22.9)	2667 (11.8)
Grade 3	50 (0.4)	805 (7.1)	855 (3.8)
Grade 4	0	0	0
Grade 3 or Above	50 (0.4)	805 (7.1)	855 (3.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11255) n (%)	mRNA-1273 (N=11329) n (%)	Total (N=22584) n (%)
Pain - N1	11254	11328	22582
Any	1934 (17.2)	10131 (89.4)	12065 (53.4)
Grade 1	1866 (16.6)	7329 (64.7)	9195 (40.7)
Grade 2	43 (0.4)	2322 (20.5)	2365 (10.5)
Grade 3	25 (0.2)	480 (4.2)	505 (2.2)
Grade 4	0	0	0
Grade 3 or Above	25 (0.2)	480 (4.2)	505 (2.2)
Erythema (Redness) - N1	11254	11328	22582
Any	53 (0.5)	989 (8.7)	1042 (4.6)
Grade 1	39 (0.3)	355 (3.1)	394 (1.7)
Grade 2	4 (<0.1)	412 (3.6)	416 (1.8)
Grade 3	10 (<0.1)	222 (2.0)	232 (1.0)
Grade 4	0	0	0
Grade 3 or Above	10 (<0.1)	222 (2.0)	232 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11255) n (%)	mRNA-1273 (N=11329) n (%)	Total (N=22584) n (%)
Swelling (Hardness) - N1	11254	11328	22582
Any	41 (0.4)	1376 (12.1)	1417 (6.3)
Grade 1	25 (0.2)	687 (6.1)	712 (3.2)
Grade 2	7 (<0.1)	493 (4.4)	500 (2.2)
Grade 3	9 (<0.1)	196 (1.7)	205 (0.9)
Grade 4	0	0	0
Grade 3 or Above	9 (<0.1)	196 (1.7)	205 (0.9)
Axillary Swelling or Tenderness - N1	11254	11328	22582
Any	422 (3.7)	1644 (14.5)	2066 (9.1)
Grade 1	384 (3.4)	1371 (12.1)	1755 (7.8)
Grade 2	23 (0.2)	228 (2.0)	251 (1.1)
Grade 3	15 (0.1)	45 (0.4)	60 (0.3)
Grade 4	0	0	0
Grade 3 or Above	15 (0.1)	45 (0.4)	60 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11255) n (%)	mRNA-1273 (N=11329) n (%)	Total (N=22584) n (%)
Solicited Systemic Adverse Reactions - N1	11254	11329	22583
Any Solicited Systemic Adverse Reactions	4081 (36.3)	9262 (81.8)	13343 (59.1)
95% CI	35.4, 37.2	81.0, 82.5	58.4, 59.7
Grade 1	2701 (24.0)	2817 (24.9)	5518 (24.4)
Grade 2	1157 (10.3)	4547 (40.1)	5704 (25.3)
Grade 3	222 (2.0)	1887 (16.7)	2109 (9.3)
Grade 4	1 (<0.1)	11 (<0.1)	12 (<0.1)
Grade 3 or Above	223 (2.0)	1898 (16.8)	2121 (9.4)
Fever - N1	11250	11322	22572
Any	33 (0.3)	1886 (16.7)	1919 (8.5)
Grade 1	26 (0.2)	1135 (10.0)	1161 (5.1)
Grade 2	4 (<0.1)	582 (5.1)	586 (2.6)
Grade 3	2 (<0.1)	159 (1.4)	161 (0.7)
Grade 4	1 (<0.1)	10 (<0.1)	11 (<0.1)
Grade 3 or Above	3 (<0.1)	169 (1.5)	172 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11255) n (%)	mRNA-1273 (N=11329) n (%)	Total (N=22584) n (%)
Headache - N1	11253	11328	22581
Any	2658 (23.6)	6940 (61.3)	9598 (42.5)
Grade 1	2131 (18.9)	3809 (33.6)	5940 (26.3)
Grade 2	396 (3.5)	2608 (23.0)	3004 (13.3)
Grade 3	131 (1.2)	523 (4.6)	654 (2.9)
Grade 4	0	0	0
Grade 3 or Above	131 (1.2)	523 (4.6)	654 (2.9)
Fatigue - N1	11253	11328	22581
Any	2609 (23.2)	7693 (67.9)	10302 (45.6)
Grade 1	1680 (14.9)	2703 (23.9)	4383 (19.4)
Grade 2	849 (7.5)	3831 (33.8)	4680 (20.7)
Grade 3	80 (0.7)	1159 (10.2)	1239 (5.5)
Grade 4	0	0	0
Grade 3 or Above	80 (0.7)	1159 (10.2)	1239 (5.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11255) n (%)	mRNA-1273 (N=11329) n (%)	Total (N=22584) n (%)
Myalgia - N1	11253	11328	22581
Any	1342 (11.9)	6859 (60.5)	8201 (36.3)
Grade 1	963 (8.6)	2535 (22.4)	3498 (15.5)
Grade 2	338 (3.0)	3223 (28.5)	3561 (15.8)
Grade 3	41 (0.4)	1101 (9.7)	1142 (5.1)
Grade 4	0	0	0
Grade 3 or Above	41 (0.4)	1101 (9.7)	1142 (5.1)
Arthralgia - N1	11253	11328	22581
Any	1155 (10.3)	5032 (44.4)	6187 (27.4)
Grade 1	833 (7.4)	2196 (19.4)	3029 (13.4)
Grade 2	289 (2.6)	2208 (19.5)	2497 (11.1)
Grade 3	33 (0.3)	628 (5.5)	661 (2.9)
Grade 4	0	0	0
Grade 3 or Above	33 (0.3)	628 (5.5)	661 (2.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Risk for Severe COVID-19 at Screening and Grade
Second Injection Solicited Safety Set

Risk Group: Not At Risk

Solicited Adverse Reaction Category Grade	Placebo (N=11255) n (%)	mRNA-1273 (N=11329) n (%)	Total (N=22584) n (%)
Nausea/Vomiting - N1	11253	11328	22581
Any	672 (6.0)	2247 (19.8)	2919 (12.9)
Grade 1	542 (4.8)	1685 (14.9)	2227 (9.9)
Grade 2	121 (1.1)	549 (4.8)	670 (3.0)
Grade 3	9 (<0.1)	12 (0.1)	21 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)
Grade 3 or Above	9 (<0.1)	13 (0.1)	22 (<0.1)
Chills - N1	11253	11328	22581
Any	622 (5.5)	5340 (47.1)	5962 (26.4)
Grade 1	479 (4.3)	2360 (20.8)	2839 (12.6)
Grade 2	129 (1.1)	2825 (24.9)	2954 (13.1)
Grade 3	14 (0.1)	155 (1.4)	169 (0.7)
Grade 4	0	0	0
Grade 3 or Above	14 (0.1)	155 (1.4)	169 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	14767	14047	14728	14691	14583	14544	14537	14530
Any Solicited Adverse Reactions	1596 (10.8)	3101 (22.1)	3422 (23.2)	2868 (19.5)	2419 (16.6)	2237 (15.4)	2125 (14.6)	1883 (13.0)
95% CI	10.3, 11.3	21.4, 22.8	22.6, 23.9	18.9, 20.2	16.0, 17.2	14.8, 16.0	14.0, 15.2	12.4, 13.5
Grade 1	1515 (10.3)	2576 (18.3)	2691 (18.3)	2238 (15.2)	1858 (12.7)	1718 (11.8)	1623 (11.2)	1426 (9.8)
Grade 2	49 (0.3)	467 (3.3)	638 (4.3)	547 (3.7)	486 (3.3)	448 (3.1)	447 (3.1)	401 (2.8)
Grade 3	31 (0.2)	58 (0.4)	92 (0.6)	81 (0.6)	74 (0.5)	70 (0.5)	55 (0.4)	55 (0.4)
Grade 4	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	32 (0.2)	58 (0.4)	93 (0.6)	83 (0.6)	75 (0.5)	71 (0.5)	55 (0.4)	56 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	14689	13932	14664	14640	14520	14487	14494	14485
Any Solicited Local Adverse Reactions	1139 (7.8)	1184 (8.5)	1089 (7.4)	730 (5.0)	495 (3.4)	423 (2.9)	361 (2.5)	262 (1.8)
95% CI	7.3, 8.2	8.0, 9.0	7.0, 7.9	4.6, 5.4	3.1, 3.7	2.7, 3.2	2.2, 2.8	1.6, 2.0
Grade 1	1108 (7.5)	1152 (8.3)	1041 (7.1)	686 (4.7)	466 (3.2)	400 (2.8)	337 (2.3)	236 (1.6)
Grade 2	8 (<0.1)	17 (0.1)	31 (0.2)	33 (0.2)	21 (0.1)	18 (0.1)	16 (0.1)	22 (0.2)
Grade 3	23 (0.2)	15 (0.1)	17 (0.1)	11 (<0.1)	8 (<0.1)	5 (<0.1)	8 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	23 (0.2)	15 (0.1)	17 (0.1)	11 (<0.1)	8 (<0.1)	5 (<0.1)	8 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	14689	13931	14662	14640	14517	14487	14494	14484
Any	1100 (7.5)	1077 (7.7)	926 (6.3)	556 (3.8)	329 (2.3)	270 (1.9)	221 (1.5)	141 (1.0)
Grade 1	1073 (7.3)	1055 (7.6)	894 (6.1)	528 (3.6)	310 (2.1)	259 (1.8)	206 (1.4)	125 (0.9)
Grade 2	7 (<0.1)	11 (<0.1)	21 (0.1)	22 (0.2)	13 (<0.1)	10 (<0.1)	11 (<0.1)	14 (<0.1)
Grade 3	20 (0.1)	11 (<0.1)	11 (<0.1)	6 (<0.1)	6 (<0.1)	1 (<0.1)	4 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	20 (0.1)	11 (<0.1)	11 (<0.1)	6 (<0.1)	6 (<0.1)	1 (<0.1)	4 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	14689	13930	14663	14640	14517	14487	14494	14483
Any	2 (<0.1)	29 (0.2)	32 (0.2)	31 (0.2)	24 (0.2)	23 (0.2)	24 (0.2)	24 (0.2)
Grade 1	1 (<0.1)	24 (0.2)	26 (0.2)	24 (0.2)	22 (0.2)	21 (0.1)	21 (0.1)	22 (0.2)
Grade 2	0	2 (<0.1)	4 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3	1 (<0.1)	3 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	14689	13929	14662	14640	14518	14487	14494	14484
Any	9 (<0.1)	29 (0.2)	41 (0.3)	33 (0.2)	29 (0.2)	27 (0.2)	26 (0.2)	31 (0.2)
Grade 1	7 (<0.1)	25 (0.2)	34 (0.2)	29 (0.2)	24 (0.2)	22 (0.2)	23 (0.2)	27 (0.2)
Grade 2	1 (<0.1)	4 (<0.1)	4 (<0.1)	3 (<0.1)	5 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)
Grade 3	1 (<0.1)	0	3 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	0	3 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	14689	13929	14663	14640	14517	14487	14494	14483
Any	97 (0.7)	160 (1.1)	222 (1.5)	219 (1.5)	170 (1.2)	153 (1.1)	143 (1.0)	115 (0.8)
Grade 1	88 (0.6)	154 (1.1)	209 (1.4)	208 (1.4)	163 (1.1)	146 (1.0)	135 (0.9)	106 (0.7)
Grade 2	2 (<0.1)	3 (<0.1)	6 (<0.1)	7 (<0.1)	4 (<0.1)	5 (<0.1)	4 (<0.1)	7 (<0.1)
Grade 3	7 (<0.1)	3 (<0.1)	7 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	4 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	7 (<0.1)	3 (<0.1)	7 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	4 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	14762	14036	14724	14687	14581	14539	14536	14527
Any Solicited Systemic Adverse Reactions	683 (4.6)	2497 (17.8)	2938 (20.0)	2501 (17.0)	2172 (14.9)	2017 (13.9)	1930 (13.3)	1728 (11.9)
95% CI	4.3, 5.0	17.2, 18.4	19.3, 20.6	16.4, 17.6	14.3, 15.5	13.3, 14.4	12.7, 13.8	11.4, 12.4
Grade 1	625 (4.2)	1994 (14.2)	2235 (15.2)	1900 (12.9)	1629 (11.2)	1516 (10.4)	1444 (9.9)	1289 (8.9)
Grade 2	43 (0.3)	456 (3.2)	624 (4.2)	526 (3.6)	473 (3.2)	435 (3.0)	437 (3.0)	387 (2.7)
Grade 3	14 (<0.1)	47 (0.3)	78 (0.5)	73 (0.5)	69 (0.5)	65 (0.4)	49 (0.3)	51 (0.4)
Grade 4	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	15 (0.1)	47 (0.3)	79 (0.5)	75 (0.5)	70 (0.5)	66 (0.5)	49 (0.3)	52 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	14739	13867	14562	14509	14365	14298	14283	14269
Any	3 (<0.1)	5 (<0.1)	8 (<0.1)	10 (<0.1)	8 (<0.1)	11 (<0.1)	8 (<0.1)	6 (<0.1)
Grade 1	2 (<0.1)	3 (<0.1)	5 (<0.1)	5 (<0.1)	5 (<0.1)	7 (<0.1)	6 (<0.1)	4 (<0.1)
Grade 2	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	0
Grade 3	0	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)
Grade 4	1 (<0.1)	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	14617	13901	14646	14620	14512	14476	14475	14473
Any	364 (2.5)	1184 (8.5)	1445 (9.9)	1183 (8.1)	1018 (7.0)	931 (6.4)	910 (6.3)	833 (5.8)
Grade 1	345 (2.4)	1084 (7.8)	1260 (8.6)	987 (6.8)	834 (5.7)	755 (5.2)	736 (5.1)	668 (4.6)
Grade 2	7 (<0.1)	78 (0.6)	140 (1.0)	147 (1.0)	144 (1.0)	136 (0.9)	148 (1.0)	136 (0.9)
Grade 3	12 (<0.1)	22 (0.2)	45 (0.3)	49 (0.3)	40 (0.3)	40 (0.3)	26 (0.2)	29 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	12 (<0.1)	22 (0.2)	45 (0.3)	49 (0.3)	40 (0.3)	40 (0.3)	26 (0.2)	29 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	14617	13915	14647	14621	14516	14480	14482	14476
Any	236 (1.6)	1574 (11.3)	1825 (12.5)	1496 (10.2)	1237 (8.5)	1158 (8.0)	1075 (7.4)	922 (6.4)
Grade 1	215 (1.5)	1186 (8.5)	1322 (9.0)	1108 (7.6)	919 (6.3)	855 (5.9)	797 (5.5)	674 (4.7)
Grade 2	18 (0.1)	367 (2.6)	473 (3.2)	368 (2.5)	298 (2.1)	286 (2.0)	260 (1.8)	232 (1.6)
Grade 3	3 (<0.1)	21 (0.2)	30 (0.2)	20 (0.1)	20 (0.1)	17 (0.1)	18 (0.1)	16 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	21 (0.2)	30 (0.2)	20 (0.1)	20 (0.1)	17 (0.1)	18 (0.1)	16 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	14617	13906	14644	14618	14513	14470	14478	14473
Any	123 (0.8)	538 (3.9)	833 (5.7)	692 (4.7)	642 (4.4)	583 (4.0)	528 (3.6)	474 (3.3)
Grade 1	112 (0.8)	462 (3.3)	682 (4.7)	563 (3.9)	505 (3.5)	452 (3.1)	410 (2.8)	356 (2.5)
Grade 2	9 (<0.1)	69 (0.5)	145 (1.0)	121 (0.8)	127 (0.9)	122 (0.8)	109 (0.8)	107 (0.7)
Grade 3	2 (<0.1)	7 (<0.1)	6 (<0.1)	8 (<0.1)	10 (<0.1)	9 (<0.1)	9 (<0.1)	11 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	7 (<0.1)	6 (<0.1)	8 (<0.1)	10 (<0.1)	9 (<0.1)	9 (<0.1)	11 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	14617	13904	14645	14620	14513	14472	14479	14473
Any	99	391	710	669	633	583	560	504
	(0.7)	(2.8)	(4.8)	(4.6)	(4.4)	(4.0)	(3.9)	(3.5)
Grade 1	91	328	594	550	504	456	433	388
	(0.6)	(2.4)	(4.1)	(3.8)	(3.5)	(3.2)	(3.0)	(2.7)
Grade 2	7	57	112	110	117	116	118	107
	(<0.1)	(0.4)	(0.8)	(0.8)	(0.8)	(0.8)	(0.8)	(0.7)
Grade 3	1	6	4	9	12	11	9	9
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1	6	4	9	12	11	9	9
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	14617	13898	14645	14618	14508	14467	14473	14468
Any	49	202	314	291	230	224	221	202
	(0.3)	(1.5)	(2.1)	(2.0)	(1.6)	(1.5)	(1.5)	(1.4)
Grade 1	44	183	271	252	190	180	177	171
	(0.3)	(1.3)	(1.9)	(1.7)	(1.3)	(1.2)	(1.2)	(1.2)
Grade 2	4	17	41	38	38	41	42	31
	(<0.1)	(0.1)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)	(0.2)
Grade 3	1	2	2	1	2	3	2	0
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1	2	2	1	2	3	2	0
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: Placebo (N=15151)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	14617	13899	14644	14616	14509	14469	14473	14468
Any	86 (0.6)	219 (1.6)	251 (1.7)	206 (1.4)	169 (1.2)	164 (1.1)	143 (1.0)	132 (0.9)
Grade 1	80 (0.5)	191 (1.4)	200 (1.4)	171 (1.2)	135 (0.9)	137 (0.9)	115 (0.8)	108 (0.7)
Grade 2	4 (<0.1)	26 (0.2)	50 (0.3)	33 (0.2)	30 (0.2)	26 (0.2)	27 (0.2)	23 (0.2)
Grade 3	2 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	14777	14173	14801	14730	14640	14564	14549	14516
Any Solicited Adverse Reactions	1572 (10.6)	8113 (57.2)	12155 (82.1)	8600 (58.4)	4314 (29.5)	2690 (18.5)	2347 (16.1)	2094 (14.4)
95% CI	10.1, 11.1	56.4, 58.1	81.5, 82.7	57.6, 59.2	28.7, 30.2	17.8, 19.1	15.5, 16.7	13.9, 15.0
Grade 1	1493 (10.1)	7066 (49.9)	9681 (65.4)	7259 (49.3)	3626 (24.8)	2131 (14.6)	1845 (12.7)	1592 (11.0)
Grade 2	45 (0.3)	871 (6.1)	2005 (13.5)	1141 (7.7)	598 (4.1)	477 (3.3)	413 (2.8)	433 (3.0)
Grade 3	34 (0.2)	174 (1.2)	467 (3.2)	198 (1.3)	89 (0.6)	81 (0.6)	87 (0.6)	69 (0.5)
Grade 4	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	0
Grade 3 or Above	34 (0.2)	176 (1.2)	469 (3.2)	200 (1.4)	90 (0.6)	82 (0.6)	89 (0.6)	69 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	14692	14050	14734	14683	14593	14524	14509	14476
Any Solicited Local Adverse Reactions	1129 (7.7)	7283 (51.8)	11781 (80.0)	7650 (52.1)	2840 (19.5)	1028 (7.1)	625 (4.3)	583 (4.0)
95% CI	7.3, 8.1	51.0, 52.7	79.3, 80.6	51.3, 52.9	18.8, 20.1	6.7, 7.5	4.0, 4.7	3.7, 4.4
Grade 1	1095 (7.5)	6829 (48.6)	10249 (69.6)	7006 (47.7)	2670 (18.3)	946 (6.5)	555 (3.8)	515 (3.6)
Grade 2	12 (<0.1)	329 (2.3)	1194 (8.1)	534 (3.6)	140 (1.0)	57 (0.4)	47 (0.3)	52 (0.4)
Grade 3	22 (0.1)	125 (0.9)	338 (2.3)	110 (0.7)	30 (0.2)	25 (0.2)	23 (0.2)	16 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	22 (0.1)	125 (0.9)	338 (2.3)	110 (0.7)	30 (0.2)	25 (0.2)	23 (0.2)	16 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	14692	14049	14733	14683	14592	14523	14507	14474
Any	1088 (7.4)	7206 (51.3)	11709 (79.5)	7512 (51.2)	2627 (18.0)	803 (5.5)	354 (2.4)	228 (1.6)
Grade 1	1062 (7.2)	6814 (48.5)	10394 (70.5)	7055 (48.0)	2545 (17.4)	762 (5.2)	322 (2.2)	198 (1.4)
Grade 2	5 (<0.1)	287 (2.0)	1041 (7.1)	387 (2.6)	65 (0.4)	32 (0.2)	24 (0.2)	23 (0.2)
Grade 3	21 (0.1)	105 (0.7)	274 (1.9)	70 (0.5)	17 (0.1)	9 (<0.1)	8 (<0.1)	7 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	21 (0.1)	105 (0.7)	274 (1.9)	70 (0.5)	17 (0.1)	9 (<0.1)	8 (<0.1)	7 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	14692	14042	14732	14677	14590	14517	14504	14470
Any	10 (<0.1)	67 (0.5)	267 (1.8)	295 (2.0)	153 (1.0)	83 (0.6)	51 (0.4)	43 (0.3)
Grade 1	6 (<0.1)	50 (0.4)	199 (1.4)	197 (1.3)	104 (0.7)	62 (0.4)	39 (0.3)	37 (0.3)
Grade 2	4 (<0.1)	11 (<0.1)	50 (0.3)	82 (0.6)	45 (0.3)	15 (0.1)	8 (<0.1)	5 (<0.1)
Grade 3	0	6 (<0.1)	18 (0.1)	16 (0.1)	4 (<0.1)	6 (<0.1)	4 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	6 (<0.1)	18 (0.1)	16 (0.1)	4 (<0.1)	6 (<0.1)	4 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	14692	14041	14733	14677	14591	14518	14505	14470
Any	13 (<0.1)	214 (1.5)	732 (5.0)	480 (3.3)	210 (1.4)	81 (0.6)	56 (0.4)	47 (0.3)
Grade 1	11 (<0.1)	157 (1.1)	496 (3.4)	336 (2.3)	165 (1.1)	67 (0.5)	47 (0.3)	40 (0.3)
Grade 2	2 (<0.1)	44 (0.3)	183 (1.2)	114 (0.8)	37 (0.3)	7 (<0.1)	4 (<0.1)	5 (<0.1)
Grade 3	0	13 (<0.1)	53 (0.4)	30 (0.2)	8 (<0.1)	7 (<0.1)	5 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	13 (<0.1)	53 (0.4)	30 (0.2)	8 (<0.1)	7 (<0.1)	5 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	14692	14041	14732	14677	14590	14517	14505	14472
Any	97 (0.7)	373 (2.7)	637 (4.3)	471 (3.2)	283 (1.9)	227 (1.6)	256 (1.8)	350 (2.4)
Grade 1	85 (0.6)	348 (2.5)	577 (3.9)	431 (2.9)	268 (1.8)	208 (1.4)	234 (1.6)	317 (2.2)
Grade 2	4 (<0.1)	18 (0.1)	46 (0.3)	30 (0.2)	13 (<0.1)	10 (<0.1)	12 (<0.1)	25 (0.2)
Grade 3	8 (<0.1)	7 (<0.1)	14 (<0.1)	10 (<0.1)	2 (<0.1)	9 (<0.1)	10 (<0.1)	8 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	8 (<0.1)	7 (<0.1)	14 (<0.1)	10 (<0.1)	2 (<0.1)	9 (<0.1)	10 (<0.1)	8 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	14776	14162	14794	14727	14635	14557	14543	14510
Any Solicited Systemic Adverse Reactions	648 (4.4)	3446 (24.3)	5185 (35.0)	3686 (25.0)	2474 (16.9)	2060 (14.2)	1968 (13.5)	1738 (12.0)
95% CI	4.1, 4.7	23.6, 25.0	34.3, 35.8	24.3, 25.7	16.3, 17.5	13.6, 14.7	13.0, 14.1	11.5, 12.5
Grade 1	596 (4.0)	2716 (19.2)	3678 (24.9)	2770 (18.8)	1912 (13.1)	1562 (10.7)	1513 (10.4)	1278 (8.8)
Grade 2	35 (0.2)	662 (4.7)	1321 (8.9)	806 (5.5)	497 (3.4)	437 (3.0)	386 (2.7)	404 (2.8)
Grade 3	17 (0.1)	66 (0.5)	184 (1.2)	108 (0.7)	64 (0.4)	60 (0.4)	67 (0.5)	56 (0.4)
Grade 4	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	0
Grade 3 or Above	17 (0.1)	68 (0.5)	186 (1.3)	110 (0.7)	65 (0.4)	61 (0.4)	69 (0.5)	56 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	14744	13998	14658	14533	14411	14296	14252	14187
Any	2 (<0.1)	14 (0.1)	59 (0.4)	32 (0.2)	8 (<0.1)	11 (<0.1)	7 (<0.1)	5 (<0.1)
Grade 1	2 (<0.1)	10 (<0.1)	37 (0.3)	24 (0.2)	5 (<0.1)	8 (<0.1)	4 (<0.1)	3 (<0.1)
Grade 2	0	2 (<0.1)	15 (0.1)	4 (<0.1)	3 (<0.1)	3 (<0.1)	0	0
Grade 3	0	1 (<0.1)	6 (<0.1)	3 (<0.1)	0	0	2 (<0.1)	2 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	0
Grade 3 or Above	0	2 (<0.1)	7 (<0.1)	4 (<0.1)	0	0	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	14613	14006	14707	14656	14570	14509	14491	14455
Any	360 (2.5)	1577 (11.3)	2321 (15.8)	1605 (11.0)	1058 (7.3)	931 (6.4)	922 (6.4)	851 (5.9)
Grade 1	340 (2.3)	1432 (10.2)	1903 (12.9)	1318 (9.0)	862 (5.9)	763 (5.3)	755 (5.2)	686 (4.7)
Grade 2	8 (<0.1)	106 (0.8)	309 (2.1)	234 (1.6)	164 (1.1)	140 (1.0)	133 (0.9)	137 (0.9)
Grade 3	12 (<0.1)	39 (0.3)	109 (0.7)	53 (0.4)	32 (0.2)	28 (0.2)	34 (0.2)	28 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	12 (<0.1)	39 (0.3)	109 (0.7)	53 (0.4)	32 (0.2)	28 (0.2)	34 (0.2)	28 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	14613	14007	14708	14661	14570	14511	14491	14461
Any	248 (1.7)	2125 (15.2)	3359 (22.8)	2354 (16.1)	1518 (10.4)	1226 (8.4)	1134 (7.8)	963 (6.7)
Grade 1	232 (1.6)	1625 (11.6)	2332 (15.9)	1764 (12.0)	1168 (8.0)	925 (6.4)	872 (6.0)	679 (4.7)
Grade 2	12 (<0.1)	476 (3.4)	974 (6.6)	544 (3.7)	320 (2.2)	276 (1.9)	236 (1.6)	258 (1.8)
Grade 3	4 (<0.1)	23 (0.2)	52 (0.4)	45 (0.3)	29 (0.2)	24 (0.2)	25 (0.2)	26 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0
Grade 3 or Above	4 (<0.1)	24 (0.2)	53 (0.4)	46 (0.3)	30 (0.2)	25 (0.2)	26 (0.2)	26 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	14613	14004	14707	14656	14570	14508	14490	14452
Any	130	1000	2058	1315	746	591	516	440
	(0.9)	(7.1)	(14.0)	(9.0)	(5.1)	(4.1)	(3.6)	(3.0)
Grade 1	119	800	1527	1012	615	478	417	324
	(0.8)	(5.7)	(10.4)	(6.9)	(4.2)	(3.3)	(2.9)	(2.2)
Grade 2	6	190	496	272	116	96	86	100
	(<0.1)	(1.4)	(3.4)	(1.9)	(0.8)	(0.7)	(0.6)	(0.7)
Grade 3	5	10	35	31	15	17	13	16
	(<0.1)	(<0.1)	(0.2)	(0.2)	(0.1)	(0.1)	(<0.1)	(0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	5	10	35	31	15	17	13	16
	(<0.1)	(<0.1)	(0.2)	(0.2)	(0.1)	(0.1)	(<0.1)	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	14613	14004	14706	14658	14569	14507	14489	14450
Any	106 (0.7)	651 (4.6)	1320 (9.0)	1023 (7.0)	683 (4.7)	559 (3.9)	518 (3.6)	458 (3.2)
Grade 1	93 (0.6)	529 (3.8)	1022 (6.9)	806 (5.5)	567 (3.9)	458 (3.2)	425 (2.9)	348 (2.4)
Grade 2	10 (<0.1)	116 (0.8)	274 (1.9)	193 (1.3)	107 (0.7)	87 (0.6)	81 (0.6)	96 (0.7)
Grade 3	3 (<0.1)	5 (<0.1)	23 (0.2)	23 (0.2)	8 (<0.1)	14 (<0.1)	12 (<0.1)	14 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	0
Grade 3 or Above	3 (<0.1)	6 (<0.1)	24 (0.2)	24 (0.2)	9 (<0.1)	14 (<0.1)	12 (<0.1)	14 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	14613	13997	14704	14651	14566	14503	14486	14447
Any	41 (0.3)	240 (1.7)	480 (3.3)	384 (2.6)	256 (1.8)	209 (1.4)	210 (1.4)	168 (1.2)
Grade 1	38 (0.3)	223 (1.6)	414 (2.8)	329 (2.2)	216 (1.5)	177 (1.2)	183 (1.3)	142 (1.0)
Grade 2	0	16 (0.1)	64 (0.4)	53 (0.4)	38 (0.3)	31 (0.2)	25 (0.2)	23 (0.2)
Grade 3	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=15166)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	14613	13997	14704	14651	14566	14503	14484	14446
Any	73 (0.5)	303 (2.2)	564 (3.8)	380 (2.6)	163 (1.1)	141 (1.0)	102 (0.7)	92 (0.6)
Grade 1	66 (0.5)	258 (1.8)	434 (3.0)	273 (1.9)	133 (0.9)	110 (0.8)	79 (0.5)	66 (0.5)
Grade 2	5 (<0.1)	43 (0.3)	121 (0.8)	99 (0.7)	25 (0.2)	29 (0.2)	19 (0.1)	22 (0.2)
Grade 3	2 (<0.1)	2 (<0.1)	9 (<0.1)	8 (<0.1)	5 (<0.1)	2 (<0.1)	4 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	2 (<0.1)	9 (<0.1)	8 (<0.1)	5 (<0.1)	2 (<0.1)	4 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	14072	13546	13920	13853	13741	13621	13715	13717
Any Solicited Adverse Reactions	1567 (11.1)	2848 (21.0)	2967 (21.3)	2501 (18.1)	2184 (15.9)	1871 (13.7)	1801 (13.1)	1568 (11.4)
95% CI	10.6, 11.7	20.3, 21.7	20.6, 22.0	17.4, 18.7	15.3, 16.5	13.2, 14.3	12.6, 13.7	10.9, 12.0
Grade 1	1490 (10.6)	2343 (17.3)	2293 (16.5)	1943 (14.0)	1647 (12.0)	1436 (10.5)	1351 (9.9)	1154 (8.4)
Grade 2	41 (0.3)	441 (3.3)	595 (4.3)	487 (3.5)	481 (3.5)	377 (2.8)	385 (2.8)	358 (2.6)
Grade 3	36 (0.3)	64 (0.5)	78 (0.6)	70 (0.5)	55 (0.4)	57 (0.4)	65 (0.5)	56 (0.4)
Grade 4	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	36 (0.3)	64 (0.5)	79 (0.6)	71 (0.5)	56 (0.4)	58 (0.4)	65 (0.5)	56 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	14027	13503	13894	13831	13718	13584	13688	13689
Any Solicited Local Adverse Reactions	1198 (8.5)	1276 (9.4)	1007 (7.2)	684 (4.9)	502 (3.7)	376 (2.8)	299 (2.2)	226 (1.7)
95% CI	8.1, 9.0	9.0, 10.0	6.8, 7.7	4.6, 5.3	3.4, 4.0	2.5, 3.1	1.9, 2.4	1.4, 1.9
Grade 1	1166 (8.3)	1230 (9.1)	959 (6.9)	649 (4.7)	464 (3.4)	346 (2.5)	267 (2.0)	199 (1.5)
Grade 2	9 (<0.1)	28 (0.2)	34 (0.2)	24 (0.2)	24 (0.2)	19 (0.1)	21 (0.2)	16 (0.1)
Grade 3	23 (0.2)	18 (0.1)	14 (0.1)	11 (<0.1)	14 (0.1)	11 (<0.1)	11 (<0.1)	11 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	23 (0.2)	18 (0.1)	14 (0.1)	11 (<0.1)	14 (0.1)	11 (<0.1)	11 (<0.1)	11 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	14027	13502	13893	13831	13717	13584	13687	13687
Any	1166 (8.3)	1181 (8.7)	840 (6.0)	542 (3.9)	356 (2.6)	242 (1.8)	178 (1.3)	127 (0.9)
Grade 1	1142 (8.1)	1150 (8.5)	812 (5.8)	522 (3.8)	335 (2.4)	224 (1.6)	159 (1.2)	110 (0.8)
Grade 2	7 (<0.1)	22 (0.2)	22 (0.2)	15 (0.1)	17 (0.1)	13 (<0.1)	13 (<0.1)	11 (<0.1)
Grade 3	17 (0.1)	9 (<0.1)	6 (<0.1)	5 (<0.1)	4 (<0.1)	5 (<0.1)	6 (<0.1)	6 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	17 (0.1)	9 (<0.1)	6 (<0.1)	5 (<0.1)	4 (<0.1)	5 (<0.1)	6 (<0.1)	6 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	14027	13502	13894	13828	13716	13582	13686	13687
Any	8 (<0.1)	31 (0.2)	25 (0.2)	26 (0.2)	23 (0.2)	24 (0.2)	23 (0.2)	19 (0.1)
Grade 1	5 (<0.1)	23 (0.2)	19 (0.1)	20 (0.1)	17 (0.1)	17 (0.1)	18 (0.1)	15 (0.1)
Grade 2	0	4 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)
Grade 3	3 (<0.1)	4 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	4 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	4 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	4 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	14027	13503	13893	13828	13715	13582	13686	13687
Any	12 (<0.1)	28 (0.2)	28 (0.2)	24 (0.2)	21 (0.2)	24 (0.2)	23 (0.2)	22 (0.2)
Grade 1	8 (<0.1)	23 (0.2)	17 (0.1)	19 (0.1)	15 (0.1)	19 (0.1)	18 (0.1)	18 (0.1)
Grade 2	2 (<0.1)	2 (<0.1)	6 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 3	2 (<0.1)	3 (<0.1)	5 (<0.1)	2 (<0.1)	4 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	3 (<0.1)	5 (<0.1)	2 (<0.1)	4 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	14027	13503	13893	13828	13715	13581	13685	13686
Any	63 (0.4)	168 (1.2)	232 (1.7)	194 (1.4)	171 (1.2)	144 (1.1)	129 (0.9)	91 (0.7)
Grade 1	57 (0.4)	158 (1.2)	223 (1.6)	183 (1.3)	159 (1.2)	136 (1.0)	121 (0.9)	87 (0.6)
Grade 2	0	5 (<0.1)	6 (<0.1)	9 (<0.1)	7 (<0.1)	5 (<0.1)	6 (<0.1)	2 (<0.1)
Grade 3	6 (<0.1)	5 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (<0.1)	5 (<0.1)	3 (<0.1)	2 (<0.1)	5 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	14069	13546	13920	13850	13740	13620	13712	13714
Any Solicited Systemic Adverse Reactions	547 (3.9)	2162 (16.0)	2525 (18.1)	2184 (15.8)	1950 (14.2)	1692 (12.4)	1662 (12.1)	1456 (10.6)
95% CI	3.6, 4.2	15.3, 16.6	17.5, 18.8	15.2, 16.4	13.6, 14.8	11.9, 13.0	11.6, 12.7	10.1, 11.1
Grade 1	495 (3.5)	1687 (12.5)	1884 (13.5)	1646 (11.9)	1433 (10.4)	1274 (9.4)	1226 (8.9)	1058 (7.7)
Grade 2	34 (0.2)	427 (3.2)	575 (4.1)	478 (3.5)	473 (3.4)	368 (2.7)	380 (2.8)	353 (2.6)
Grade 3	18 (0.1)	48 (0.4)	65 (0.5)	59 (0.4)	43 (0.3)	49 (0.4)	56 (0.4)	45 (0.3)
Grade 4	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	18 (0.1)	48 (0.4)	66 (0.5)	60 (0.4)	44 (0.3)	50 (0.4)	56 (0.4)	45 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	14036	13379	13759	13627	13501	13363	13437	13432
Any	1 (<0.1)	5 (<0.1)	7 (<0.1)	9 (<0.1)	6 (<0.1)	7 (<0.1)	9 (<0.1)	7 (<0.1)
Grade 1	1 (<0.1)	4 (<0.1)	4 (<0.1)	7 (<0.1)	4 (<0.1)	5 (<0.1)	7 (<0.1)	5 (<0.1)
Grade 2	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
Grade 3	0	0	0	0	0	0	2 (<0.1)	0
Grade 4	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	13990	13484	13879	13819	13702	13576	13672	13680
Any	265 (1.9)	1086 (8.1)	1280 (9.2)	1128 (8.2)	964 (7.0)	800 (5.9)	812 (5.9)	721 (5.3)
Grade 1	246 (1.8)	969 (7.2)	1101 (7.9)	938 (6.8)	799 (5.8)	639 (4.7)	639 (4.7)	571 (4.2)
Grade 2	5 (<0.1)	92 (0.7)	150 (1.1)	160 (1.2)	144 (1.1)	133 (1.0)	147 (1.1)	126 (0.9)
Grade 3	14 (0.1)	25 (0.2)	29 (0.2)	30 (0.2)	21 (0.2)	28 (0.2)	26 (0.2)	24 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	14 (0.1)	25 (0.2)	29 (0.2)	30 (0.2)	21 (0.2)	28 (0.2)	26 (0.2)	24 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	13990	13484	13881	13822	13706	13580	13677	13683
Any	217	1323	1607	1331	1156	994	950	761
	(1.6)	(9.8)	(11.6)	(9.6)	(8.4)	(7.3)	(6.9)	(5.6)
Grade 1	192	985	1153	990	826	742	696	524
	(1.4)	(7.3)	(8.3)	(7.2)	(6.0)	(5.5)	(5.1)	(3.8)
Grade 2	21	319	426	316	310	231	230	221
	(0.2)	(2.4)	(3.1)	(2.3)	(2.3)	(1.7)	(1.7)	(1.6)
Grade 3	4	19	28	25	20	21	24	16
	(<0.1)	(0.1)	(0.2)	(0.2)	(0.1)	(0.2)	(0.2)	(0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4	19	28	25	20	21	24	16
	(<0.1)	(0.1)	(0.2)	(0.2)	(0.1)	(0.2)	(0.2)	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	13990	13486	13877	13820	13701	13578	13678	13680
Any	112 (0.8)	526 (3.9)	771 (5.6)	711 (5.1)	624 (4.6)	534 (3.9)	527 (3.9)	431 (3.2)
Grade 1	101 (0.7)	424 (3.1)	601 (4.3)	550 (4.0)	479 (3.5)	427 (3.1)	389 (2.8)	312 (2.3)
Grade 2	10 (<0.1)	94 (0.7)	161 (1.2)	147 (1.1)	125 (0.9)	99 (0.7)	120 (0.9)	110 (0.8)
Grade 3	1 (<0.1)	8 (<0.1)	9 (<0.1)	14 (0.1)	20 (0.1)	8 (<0.1)	18 (0.1)	9 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	8 (<0.1)	9 (<0.1)	14 (0.1)	20 (0.1)	8 (<0.1)	18 (0.1)	9 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	13990	13482	13876	13820	13702	13578	13672	13680
Any	117 (0.8)	448 (3.3)	660 (4.8)	619 (4.5)	600 (4.4)	507 (3.7)	541 (4.0)	455 (3.3)
Grade 1	107 (0.8)	365 (2.7)	512 (3.7)	489 (3.5)	473 (3.5)	404 (3.0)	411 (3.0)	335 (2.4)
Grade 2	7 (<0.1)	74 (0.5)	139 (1.0)	117 (0.8)	114 (0.8)	96 (0.7)	118 (0.9)	112 (0.8)
Grade 3	3 (<0.1)	9 (<0.1)	9 (<0.1)	13 (<0.1)	13 (<0.1)	7 (<0.1)	12 (<0.1)	8 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	9 (<0.1)	9 (<0.1)	13 (<0.1)	13 (<0.1)	7 (<0.1)	12 (<0.1)	8 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	13990	13475	13875	13816	13697	13570	13667	13675
Any	44 (0.3)	240 (1.8)	305 (2.2)	247 (1.8)	212 (1.5)	189 (1.4)	192 (1.4)	155 (1.1)
Grade 1	39 (0.3)	213 (1.6)	254 (1.8)	203 (1.5)	174 (1.3)	155 (1.1)	151 (1.1)	129 (0.9)
Grade 2	4 (<0.1)	25 (0.2)	49 (0.4)	43 (0.3)	35 (0.3)	33 (0.2)	38 (0.3)	25 (0.2)
Grade 3	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: Placebo (N=14578)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	13990	13477	13875	13817	13700	13569	13669	13676
Any	59 (0.4)	233 (1.7)	278 (2.0)	201 (1.5)	182 (1.3)	152 (1.1)	164 (1.2)	129 (0.9)
Grade 1	55 (0.4)	199 (1.5)	224 (1.6)	156 (1.1)	145 (1.1)	116 (0.9)	125 (0.9)	102 (0.7)
Grade 2	3 (<0.1)	31 (0.2)	52 (0.4)	44 (0.3)	33 (0.2)	35 (0.3)	33 (0.2)	25 (0.2)
Grade 3	1 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)	6 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)	6 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	14177	14033	14351	14147	13990	13822	13839	13853
Any Solicited Adverse Reactions	1460 (10.3)	9604 (68.4)	12897 (89.9)	10002 (70.7)	6352 (45.4)	3934 (28.5)	2765 (20.0)	2059 (14.9)
95% CI	9.8, 10.8	67.7, 69.2	89.4, 90.4	69.9, 71.4	44.6, 46.2	27.7, 29.2	19.3, 20.7	14.3, 15.5
Grade 1	1388 (9.8)	7449 (53.1)	5163 (36.0)	6960 (49.2)	4872 (34.8)	3000 (21.7)	2061 (14.9)	1510 (10.9)
Grade 2	41 (0.3)	1703 (12.1)	5445 (37.9)	2431 (17.2)	1183 (8.5)	731 (5.3)	586 (4.2)	455 (3.3)
Grade 3	31 (0.2)	446 (3.2)	2282 (15.9)	609 (4.3)	296 (2.1)	201 (1.5)	117 (0.8)	93 (0.7)
Grade 4	0	6 (<0.1)	7 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	31 (0.2)	452 (3.2)	2289 (16.0)	611 (4.3)	297 (2.1)	203 (1.5)	118 (0.9)	94 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	14104	13990	14326	14125	13949	13782	13804	13820
Any Solicited Local Adverse Reactions	1111 (7.9)	8991 (64.3)	12210 (85.2)	8992 (63.7)	5112 (36.6)	2429 (17.6)	1227 (8.9)	672 (4.9)
95% CI	7.4, 8.3	63.5, 65.1	84.6, 85.8	62.9, 64.5	35.8, 37.5	17.0, 18.3	8.4, 9.4	4.5, 5.2
Grade 1	1084 (7.7)	7917 (56.6)	8783 (61.3)	7470 (52.9)	4386 (31.4)	2068 (15.0)	1051 (7.6)	564 (4.1)
Grade 2	9 (<0.1)	840 (6.0)	2865 (20.0)	1205 (8.5)	518 (3.7)	250 (1.8)	119 (0.9)	78 (0.6)
Grade 3	18 (0.1)	234 (1.7)	562 (3.9)	317 (2.2)	208 (1.5)	111 (0.8)	57 (0.4)	30 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	18 (0.1)	234 (1.7)	562 (3.9)	317 (2.2)	208 (1.5)	111 (0.8)	57 (0.4)	30 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	14104	13987	14325	14125	13949	13779	13802	13816
Any	1070 (7.6)	8912 (63.7)	12150 (84.8)	8797 (62.3)	4744 (34.0)	2035 (14.8)	909 (6.6)	421 (3.0)
Grade 1	1050 (7.4)	8019 (57.3)	9178 (64.1)	7939 (56.2)	4519 (32.4)	1954 (14.2)	865 (6.3)	386 (2.8)
Grade 2	5 (<0.1)	707 (5.1)	2563 (17.9)	766 (5.4)	201 (1.4)	69 (0.5)	34 (0.2)	30 (0.2)
Grade 3	15 (0.1)	186 (1.3)	409 (2.9)	92 (0.7)	24 (0.2)	12 (<0.1)	10 (<0.1)	5 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	15 (0.1)	186 (1.3)	409 (2.9)	92 (0.7)	24 (0.2)	12 (<0.1)	10 (<0.1)	5 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	14104	13984	14323	14123	13944	13771	13799	13809
Any	4 (<0.1)	152 (1.1)	619 (4.3)	952 (6.7)	677 (4.9)	376 (2.7)	195 (1.4)	126 (0.9)
Grade 1	3 (<0.1)	106 (0.8)	318 (2.2)	347 (2.5)	246 (1.8)	155 (1.1)	91 (0.7)	63 (0.5)
Grade 2	1 (<0.1)	33 (0.2)	242 (1.7)	442 (3.1)	289 (2.1)	143 (1.0)	71 (0.5)	45 (0.3)
Grade 3	0	13 (<0.1)	59 (0.4)	163 (1.2)	142 (1.0)	78 (0.6)	33 (0.2)	18 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	13 (<0.1)	59 (0.4)	163 (1.2)	142 (1.0)	78 (0.6)	33 (0.2)	18 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	14104	13985	14324	14123	13944	13772	13797	13809
Any	17	534	1315	1111	675	369	178	111
	(0.1)	(3.8)	(9.2)	(7.9)	(4.8)	(2.7)	(1.3)	(0.8)
Grade 1	16	345	738	612	376	226	119	81
	(0.1)	(2.5)	(5.2)	(4.3)	(2.7)	(1.6)	(0.9)	(0.6)
Grade 2	1	152	453	376	209	107	45	23
	(<0.1)	(1.1)	(3.2)	(2.7)	(1.5)	(0.8)	(0.3)	(0.2)
Grade 3	0	37	124	123	90	36	14	7
		(0.3)	(0.9)	(0.9)	(0.6)	(0.3)	(0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	37	124	123	90	36	14	7
		(0.3)	(0.9)	(0.9)	(0.6)	(0.3)	(0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	14104	13983	14323	14123	13944	13770	13796	13807
Any	76 (0.5)	535 (3.8)	1211 (8.5)	1022 (7.2)	764 (5.5)	456 (3.3)	295 (2.1)	190 (1.4)
Grade 1	67 (0.5)	480 (3.4)	1002 (7.0)	889 (6.3)	710 (5.1)	427 (3.1)	280 (2.0)	177 (1.3)
Grade 2	2 (<0.1)	40 (0.3)	183 (1.3)	114 (0.8)	44 (0.3)	25 (0.2)	10 (<0.1)	9 (<0.1)
Grade 3	7 (<0.1)	15 (0.1)	26 (0.2)	19 (0.1)	10 (<0.1)	4 (<0.1)	5 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	7 (<0.1)	15 (0.1)	26 (0.2)	19 (0.1)	10 (<0.1)	4 (<0.1)	5 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	14177	14027	14348	14147	13986	13817	13835	13841
Any Solicited Systemic Adverse Reactions	520 (3.7)	4760 (33.9)	10592 (73.8)	6150 (43.5)	3531 (25.2)	2559 (18.5)	2067 (14.9)	1673 (12.1)
95% CI	3.4, 4.0	33.2, 34.7	73.1, 74.5	42.7, 44.3	24.5, 26.0	17.9, 19.2	14.4, 15.5	11.5, 12.6
Grade 1	467 (3.3)	3156 (22.5)	3514 (24.5)	3868 (27.3)	2574 (18.4)	1889 (13.7)	1496 (10.8)	1198 (8.7)
Grade 2	35 (0.2)	1324 (9.4)	5089 (35.5)	1943 (13.7)	853 (6.1)	572 (4.1)	505 (3.7)	408 (2.9)
Grade 3	18 (0.1)	274 (2.0)	1982 (13.8)	337 (2.4)	103 (0.7)	96 (0.7)	65 (0.5)	66 (0.5)
Grade 4	0	6 (<0.1)	7 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	18 (0.1)	280 (2.0)	1989 (13.9)	339 (2.4)	104 (0.7)	98 (0.7)	66 (0.5)	67 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	14151	13871	14224	13971	13706	13466	13455	13448
Any	2 (<0.1)	229 (1.7)	1954 (13.7)	297 (2.1)	19 (0.1)	13 (<0.1)	10 (<0.1)	5 (<0.1)
Grade 1	2 (<0.1)	152 (1.1)	1181 (8.3)	180 (1.3)	8 (<0.1)	6 (<0.1)	7 (<0.1)	4 (<0.1)
Grade 2	0	59 (0.4)	591 (4.2)	92 (0.7)	8 (<0.1)	4 (<0.1)	3 (<0.1)	1 (<0.1)
Grade 3	0	13 (<0.1)	176 (1.2)	24 (0.2)	3 (<0.1)	2 (<0.1)	0	0
Grade 4	0	5 (<0.1)	6 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	0
Grade 3 or Above	0	18 (0.1)	182 (1.3)	25 (0.2)	3 (<0.1)	3 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	14060	13970	14307	14110	13944	13767	13796	13804
Any	265 (1.9)	2403 (17.2)	7261 (50.8)	3314 (23.5)	1800 (12.9)	1359 (9.9)	1151 (8.3)	906 (6.6)
Grade 1	245 (1.7)	1936 (13.9)	4074 (28.5)	2403 (17.0)	1401 (10.0)	1057 (7.7)	882 (6.4)	688 (5.0)
Grade 2	6 (<0.1)	372 (2.7)	2701 (18.9)	808 (5.7)	351 (2.5)	248 (1.8)	238 (1.7)	184 (1.3)
Grade 3	14 (<0.1)	95 (0.7)	486 (3.4)	103 (0.7)	48 (0.3)	54 (0.4)	31 (0.2)	34 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	14 (<0.1)	95 (0.7)	486 (3.4)	103 (0.7)	48 (0.3)	54 (0.4)	31 (0.2)	34 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	14060	13978	14307	14110	13946	13773	13800	13811
Any	231	3171	8554	4378	2219	1569	1195	923
	(1.6)	(22.7)	(59.8)	(31.0)	(15.9)	(11.4)	(8.7)	(6.7)
Grade 1	212	2102	3129	2811	1609	1190	877	674
	(1.5)	(15.0)	(21.9)	(19.9)	(11.5)	(8.6)	(6.4)	(4.9)
Grade 2	15	931	4176	1377	566	345	287	223
	(0.1)	(6.7)	(29.2)	(9.8)	(4.1)	(2.5)	(2.1)	(1.6)
Grade 3	4	138	1249	190	44	34	31	26
	(<0.1)	(1.0)	(8.7)	(1.3)	(0.3)	(0.2)	(0.2)	(0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4	138	1249	190	44	34	31	26
	(<0.1)	(1.0)	(8.7)	(1.3)	(0.3)	(0.2)	(0.2)	(0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	14060	13974	14307	14110	13938	13765	13791	13802
Any	102 (0.7)	2127 (15.2)	7690 (53.7)	3413 (24.2)	1340 (9.6)	778 (5.7)	552 (4.0)	434 (3.1)
Grade 1	91 (0.6)	1327 (9.5)	2956 (20.7)	2326 (16.5)	1023 (7.3)	614 (4.5)	415 (3.0)	311 (2.3)
Grade 2	7 (<0.1)	672 (4.8)	3574 (25.0)	938 (6.6)	291 (2.1)	143 (1.0)	126 (0.9)	113 (0.8)
Grade 3	4 (<0.1)	128 (0.9)	1160 (8.1)	149 (1.1)	26 (0.2)	21 (0.2)	11 (<0.1)	10 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	128 (0.9)	1160 (8.1)	149 (1.1)	26 (0.2)	21 (0.2)	11 (<0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	14060	13974	14308	14109	13938	13767	13792	13801
Any	119 (0.8)	1464 (10.5)	5504 (38.5)	2506 (17.8)	1146 (8.2)	737 (5.4)	548 (4.0)	467 (3.4)
Grade 1	100 (0.7)	973 (7.0)	2447 (17.1)	1736 (12.3)	899 (6.4)	587 (4.3)	420 (3.0)	350 (2.5)
Grade 2	14 (<0.1)	416 (3.0)	2403 (16.8)	664 (4.7)	229 (1.6)	139 (1.0)	119 (0.9)	109 (0.8)
Grade 3	5 (<0.1)	75 (0.5)	654 (4.6)	106 (0.8)	18 (0.1)	11 (<0.1)	9 (<0.1)	8 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	5 (<0.1)	75 (0.5)	654 (4.6)	106 (0.8)	18 (0.1)	11 (<0.1)	9 (<0.1)	8 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	14060	13966	14305	14108	13935	13758	13784	13796
Any	38	530	2085	762	400	254	219	161
	(0.3)	(3.8)	(14.6)	(5.4)	(2.9)	(1.8)	(1.6)	(1.2)
Grade 1	29	439	1595	628	331	188	173	118
	(0.2)	(3.1)	(11.1)	(4.5)	(2.4)	(1.4)	(1.3)	(0.9)
Grade 2	5	84	483	128	66	62	44	36
	(<0.1)	(0.6)	(3.4)	(0.9)	(0.5)	(0.5)	(0.3)	(0.3)
Grade 3	4	6	6	5	2	3	1	6
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 4	0	1	1	1	1	1	1	1
		(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 3 or Above	4	7	7	6	3	4	2	7
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Treatment Group: mRNA-1273 (N=14691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	14060	13966	14305	14108	13936	13758	13786	13797
Any	47 (0.3)	1136 (8.1)	5729 (40.0)	1424 (10.1)	376 (2.7)	195 (1.4)	159 (1.2)	133 (1.0)
Grade 1	41 (0.3)	740 (5.3)	2567 (17.9)	940 (6.7)	290 (2.1)	149 (1.1)	118 (0.9)	103 (0.7)
Grade 2	2 (<0.1)	376 (2.7)	3008 (21.0)	459 (3.3)	80 (0.6)	43 (0.3)	39 (0.3)	27 (0.2)
Grade 3	4 (<0.1)	20 (0.1)	154 (1.1)	25 (0.2)	6 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	20 (0.1)	154 (1.1)	25 (0.2)	6 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	15095	14862	15040	15010	14979	14957	14976	14967
Any Solicited Adverse Reactions	2695 (17.9)	4689 (31.6)	4971 (33.1)	4270 (28.4)	3722 (24.8)	3360 (22.5)	3219 (21.5)	2896 (19.3)
95% CI	17.2, 18.5	30.8, 32.3	32.3, 33.8	27.7, 29.2	24.2, 25.5	21.8, 23.1	20.8, 22.2	18.7, 20.0
Grade 1	2543 (16.8)	3769 (25.4)	3713 (24.7)	3199 (21.3)	2721 (18.2)	2485 (16.6)	2343 (15.6)	2094 (14.0)
Grade 2	84 (0.6)	800 (5.4)	1090 (7.2)	920 (6.1)	872 (5.8)	749 (5.0)	759 (5.1)	694 (4.6)
Grade 3	67 (0.4)	120 (0.8)	166 (1.1)	148 (1.0)	127 (0.8)	124 (0.8)	117 (0.8)	107 (0.7)
Grade 4	1 (<0.1)	0	2 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)	0	1 (<0.1)
Grade 3 or Above	68 (0.5)	120 (0.8)	168 (1.1)	151 (1.0)	129 (0.9)	126 (0.8)	117 (0.8)	108 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	15081	14823	15020	14996	14956	14935	14962	14949
Any Solicited Local Adverse Reactions	2026 (13.4)	2103 (14.2)	1769 (11.8)	1219 (8.1)	873 (5.8)	724 (4.8)	602 (4.0)	446 (3.0)
95% CI	12.9, 14.0	13.6, 14.8	11.3, 12.3	7.7, 8.6	5.5, 6.2	4.5, 5.2	3.7, 4.4	2.7, 3.3
Grade 1	1965 (13.0)	2026 (13.7)	1678 (11.2)	1144 (7.6)	809 (5.4)	673 (4.5)	549 (3.7)	397 (2.7)
Grade 2	15 (<0.1)	44 (0.3)	61 (0.4)	54 (0.4)	42 (0.3)	35 (0.2)	35 (0.2)	35 (0.2)
Grade 3	46 (0.3)	33 (0.2)	30 (0.2)	21 (0.1)	22 (0.1)	16 (0.1)	18 (0.1)	14 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	46 (0.3)	33 (0.2)	30 (0.2)	21 (0.1)	22 (0.1)	16 (0.1)	18 (0.1)	14 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	15081	14823	15019	14996	14956	14935	14962	14948
Any	1963 (13.0)	1933 (13.0)	1512 (10.1)	958 (6.4)	602 (4.0)	472 (3.2)	372 (2.5)	252 (1.7)
Grade 1	1914 (12.7)	1881 (12.7)	1454 (9.7)	912 (6.1)	563 (3.8)	444 (3.0)	340 (2.3)	221 (1.5)
Grade 2	12 (<0.1)	32 (0.2)	41 (0.3)	35 (0.2)	29 (0.2)	22 (0.1)	23 (0.2)	23 (0.2)
Grade 3	37 (0.2)	20 (0.1)	17 (0.1)	11 (<0.1)	10 (<0.1)	6 (<0.1)	9 (<0.1)	8 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	37 (0.2)	20 (0.1)	17 (0.1)	11 (<0.1)	10 (<0.1)	6 (<0.1)	9 (<0.1)	8 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	15081	14822	15019	14996	14956	14935	14962	14948
Any	10 (<0.1)	57 (0.4)	54 (0.4)	53 (0.4)	45 (0.3)	45 (0.3)	45 (0.3)	40 (0.3)
Grade 1	6 (<0.1)	44 (0.3)	43 (0.3)	41 (0.3)	37 (0.2)	36 (0.2)	37 (0.2)	35 (0.2)
Grade 2	0	6 (<0.1)	7 (<0.1)	6 (<0.1)	4 (<0.1)	4 (<0.1)	4 (<0.1)	3 (<0.1)
Grade 3	4 (<0.1)	7 (<0.1)	4 (<0.1)	6 (<0.1)	4 (<0.1)	5 (<0.1)	4 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	7 (<0.1)	4 (<0.1)	6 (<0.1)	4 (<0.1)	5 (<0.1)	4 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	15081	14822	15019	14996	14956	14935	14962	14949
Any	21	55	64	51	46	48	46	49
	(0.1)	(0.4)	(0.4)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
Grade 1	15	46	48	43	35	38	38	42
	(<0.1)	(0.3)	(0.3)	(0.3)	(0.2)	(0.3)	(0.3)	(0.3)
Grade 2	3	6	9	6	7	6	5	5
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 3	3	3	7	2	4	4	3	2
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3	3	7	2	4	4	3	2
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	15081	14822	15020	14996	14956	14935	14962	14948
Any	155 (1.0)	299 (2.0)	397 (2.6)	364 (2.4)	302 (2.0)	264 (1.8)	245 (1.6)	183 (1.2)
Grade 1	140 (0.9)	283 (1.9)	377 (2.5)	343 (2.3)	284 (1.9)	250 (1.7)	230 (1.5)	171 (1.1)
Grade 2	2 (<0.1)	8 (<0.1)	10 (<0.1)	15 (0.1)	10 (<0.1)	9 (<0.1)	9 (<0.1)	8 (<0.1)
Grade 3	13 (<0.1)	8 (<0.1)	10 (<0.1)	6 (<0.1)	8 (<0.1)	5 (<0.1)	6 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	13 (<0.1)	8 (<0.1)	10 (<0.1)	6 (<0.1)	8 (<0.1)	5 (<0.1)	6 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	15093	14859	15039	15010	14979	14955	14976	14966
Any Solicited Systemic Adverse Reactions	1112 (7.4)	3771 (25.4)	4332 (28.8)	3795 (25.3)	3362 (22.4)	3049 (20.4)	2957 (19.7)	2691 (18.0)
95% CI	7.0, 7.8	24.7, 26.1	28.1, 29.5	24.6, 26.0	21.8, 23.1	19.7, 21.0	19.1, 20.4	17.4, 18.6
Grade 1	1007 (6.7)	2899 (19.5)	3125 (20.8)	2768 (18.4)	2396 (16.0)	2206 (14.8)	2107 (14.1)	1917 (12.8)
Grade 2	72 (0.5)	779 (5.2)	1065 (7.1)	894 (6.0)	854 (5.7)	730 (4.9)	748 (5.0)	680 (4.5)
Grade 3	32 (0.2)	93 (0.6)	140 (0.9)	130 (0.9)	110 (0.7)	111 (0.7)	102 (0.7)	93 (0.6)
Grade 4	1 (<0.1)	0	2 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)	0	1 (<0.1)
Grade 3 or Above	33 (0.2)	93 (0.6)	142 (0.9)	133 (0.9)	112 (0.7)	113 (0.8)	102 (0.7)	94 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	15082	14784	14977	14927	14874	14831	14854	14842
Any	4 (<0.1)	9 (<0.1)	15 (0.1)	19 (0.1)	14 (<0.1)	18 (0.1)	17 (0.1)	13 (<0.1)
Grade 1	3 (<0.1)	6 (<0.1)	9 (<0.1)	12 (<0.1)	9 (<0.1)	12 (<0.1)	13 (<0.1)	9 (<0.1)
Grade 2	0	3 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 3	0	0	0	1 (<0.1)	1 (<0.1)	0	3 (<0.1)	1 (<0.1)
Grade 4	1 (<0.1)	0	2 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)	0	1 (<0.1)
Grade 3 or Above	1 (<0.1)	0	2 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	15064	14807	15010	14987	14953	14929	14954	14942
Any	588	1985	2366	2031	1760	1543	1541	1407
	(3.9)	(13.4)	(15.8)	(13.6)	(11.8)	(10.3)	(10.3)	(9.4)
Grade 1	551	1779	2016	1665	1428	1221	1211	1106
	(3.7)	(12.0)	(13.4)	(11.1)	(9.5)	(8.2)	(8.1)	(7.4)
Grade 2	11	159	277	288	272	255	279	250
	(<0.1)	(1.1)	(1.8)	(1.9)	(1.8)	(1.7)	(1.9)	(1.7)
Grade 3	26	47	73	78	60	67	51	51
	(0.2)	(0.3)	(0.5)	(0.5)	(0.4)	(0.4)	(0.3)	(0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	26	47	73	78	60	67	51	51
	(0.2)	(0.3)	(0.5)	(0.5)	(0.4)	(0.4)	(0.3)	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	15064	14810	15012	14986	14951	14931	14957	14944
Any	420	2397	2818	2377	2012	1818	1724	1463
	(2.8)	(16.2)	(18.8)	(15.9)	(13.5)	(12.2)	(11.5)	(9.8)
Grade 1	377	1745	1954	1716	1407	1302	1224	1010
	(2.5)	(11.8)	(13.0)	(11.5)	(9.4)	(8.7)	(8.2)	(6.8)
Grade 2	36	614	808	616	566	479	459	422
	(0.2)	(4.1)	(5.4)	(4.1)	(3.8)	(3.2)	(3.1)	(2.8)
Grade 3	7	38	56	45	39	37	41	31
	(<0.1)	(0.3)	(0.4)	(0.3)	(0.3)	(0.2)	(0.3)	(0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	7	38	56	45	39	37	41	31
	(<0.1)	(0.3)	(0.4)	(0.3)	(0.3)	(0.2)	(0.3)	(0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	15064	14813	15009	14986	14952	14928	14955	14944
Any	224 (1.5)	940 (6.3)	1387 (9.2)	1218 (8.1)	1103 (7.4)	968 (6.5)	920 (6.2)	809 (5.4)
Grade 1	203 (1.3)	769 (5.2)	1088 (7.2)	947 (6.3)	833 (5.6)	742 (5.0)	674 (4.5)	582 (3.9)
Grade 2	18 (0.1)	156 (1.1)	284 (1.9)	249 (1.7)	240 (1.6)	209 (1.4)	219 (1.5)	208 (1.4)
Grade 3	3 (<0.1)	15 (0.1)	15 (<0.1)	22 (0.1)	30 (0.2)	17 (0.1)	27 (0.2)	19 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	15 (0.1)	15 (<0.1)	22 (0.1)	30 (0.2)	17 (0.1)	27 (0.2)	19 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	15064	14808	15010	14986	14952	14930	14955	14946
Any	210 (1.4)	746 (5.0)	1175 (7.8)	1103 (7.4)	1051 (7.0)	919 (6.2)	956 (6.4)	831 (5.6)
Grade 1	192 (1.3)	601 (4.1)	928 (6.2)	870 (5.8)	810 (5.4)	703 (4.7)	709 (4.7)	605 (4.0)
Grade 2	14 (<0.1)	130 (0.9)	234 (1.6)	211 (1.4)	216 (1.4)	198 (1.3)	226 (1.5)	209 (1.4)
Grade 3	4 (<0.1)	15 (0.1)	13 (<0.1)	22 (0.1)	25 (0.2)	18 (0.1)	21 (0.1)	17 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	15 (0.1)	13 (<0.1)	22 (0.1)	25 (0.2)	18 (0.1)	21 (0.1)	17 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	15064	14804	15009	14986	14951	14926	14954	14941
Any	89 (0.6)	404 (2.7)	570 (3.8)	495 (3.3)	410 (2.7)	378 (2.5)	384 (2.6)	337 (2.3)
Grade 1	80 (0.5)	359 (2.4)	480 (3.2)	416 (2.8)	334 (2.2)	304 (2.0)	302 (2.0)	283 (1.9)
Grade 2	7 (<0.1)	41 (0.3)	86 (0.6)	77 (0.5)	71 (0.5)	70 (0.5)	77 (0.5)	53 (0.4)
Grade 3	2 (<0.1)	4 (<0.1)	4 (<0.1)	2 (<0.1)	5 (<0.1)	4 (<0.1)	5 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	4 (<0.1)	4 (<0.1)	2 (<0.1)	5 (<0.1)	4 (<0.1)	5 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: Placebo (N=15159)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	15064	14805	15010	14986	14952	14927	14954	14942
Any	139	412	488	378	328	297	291	244
	(0.9)	(2.8)	(3.3)	(2.5)	(2.2)	(2.0)	(1.9)	(1.6)
Grade 1	129	352	386	301	257	235	225	193
	(0.9)	(2.4)	(2.6)	(2.0)	(1.7)	(1.6)	(1.5)	(1.3)
Grade 2	7	55	99	74	63	60	59	48
	(<0.1)	(0.4)	(0.7)	(0.5)	(0.4)	(0.4)	(0.4)	(0.3)
Grade 3	3	5	3	3	8	2	7	3
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3	5	3	3	8	2	7	3
	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	15119	14952	15100	15070	15016	15005	14996	14998
Any Solicited Adverse Reactions	2627 (17.4)	11340 (75.8)	13940 (92.3)	11706 (77.7)	7842 (52.2)	5282 (35.2)	4150 (27.7)	3459 (23.1)
95% CI	16.8, 18.0	75.1, 76.5	91.9, 92.7	77.0, 78.3	51.4, 53.0	34.4, 36.0	27.0, 28.4	22.4, 23.7
Grade 1	2482 (16.4)	8546 (57.2)	5611 (37.2)	7910 (52.5)	5872 (39.1)	3911 (26.1)	3031 (20.2)	2484 (16.6)
Grade 2	82 (0.5)	2196 (14.7)	5723 (37.9)	3022 (20.1)	1599 (10.6)	1093 (7.3)	919 (6.1)	814 (5.4)
Grade 3	63 (0.4)	590 (3.9)	2597 (17.2)	770 (5.1)	369 (2.5)	275 (1.8)	197 (1.3)	160 (1.1)
Grade 4	0	8 (<0.1)	9 (<0.1)	4 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)
Grade 3 or Above	63 (0.4)	598 (4.0)	2606 (17.3)	774 (5.1)	371 (2.5)	278 (1.9)	200 (1.3)	161 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	15100	14914	15078	15048	14995	14982	14983	14978
Any Solicited Local Adverse Reactions	1989 (13.2)	10659 (71.5)	13544 (89.8)	10764 (71.5)	6132 (40.9)	2955 (19.7)	1627 (10.9)	1122 (7.5)
95% CI	12.6, 13.7	70.7, 72.2	89.3, 90.3	70.8, 72.3	40.1, 41.7	19.1, 20.4	10.4, 11.4	7.1, 7.9
Grade 1	1929 (12.8)	9290 (62.3)	9441 (62.6)	8832 (58.7)	5286 (35.3)	2532 (16.9)	1390 (9.3)	954 (6.4)
Grade 2	21 (0.1)	1032 (6.9)	3255 (21.6)	1526 (10.1)	615 (4.1)	291 (1.9)	160 (1.1)	124 (0.8)
Grade 3	39 (0.3)	337 (2.3)	848 (5.6)	406 (2.7)	231 (1.5)	132 (0.9)	77 (0.5)	44 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	39 (0.3)	337 (2.3)	848 (5.6)	406 (2.7)	231 (1.5)	132 (0.9)	77 (0.5)	44 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	15100	14913	15078	15048	14994	14981	14982	14975
Any	1915 (12.7)	10578 (70.9)	13488 (89.5)	10593 (70.4)	5749 (38.3)	2452 (16.4)	1129 (7.5)	594 (4.0)
Grade 1	1870 (12.4)	9422 (63.2)	9927 (65.8)	9419 (62.6)	5454 (36.4)	2335 (15.6)	1055 (7.0)	532 (3.6)
Grade 2	10 (<0.1)	884 (5.9)	2920 (19.4)	1024 (6.8)	254 (1.7)	98 (0.7)	57 (0.4)	51 (0.3)
Grade 3	35 (0.2)	272 (1.8)	641 (4.3)	150 (1.0)	41 (0.3)	19 (0.1)	17 (0.1)	11 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	35 (0.2)	272 (1.8)	641 (4.3)	150 (1.0)	41 (0.3)	19 (0.1)	17 (0.1)	11 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	15100	14911	15076	15046	14992	14979	14980	14971
Any	14	207	808	1138	781	442	238	163
	(<0.1)	(1.4)	(5.4)	(7.6)	(5.2)	(3.0)	(1.6)	(1.1)
Grade 1	9	148	459	469	319	206	125	96
	(<0.1)	(1.0)	(3.0)	(3.1)	(2.1)	(1.4)	(0.8)	(0.6)
Grade 2	5	40	272	491	317	152	76	48
	(<0.1)	(0.3)	(1.8)	(3.3)	(2.1)	(1.0)	(0.5)	(0.3)
Grade 3	0	19	77	178	145	84	37	19
		(0.1)	(0.5)	(1.2)	(1.0)	(0.6)	(0.2)	(0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	19	77	178	145	84	37	19
		(0.1)	(0.5)	(1.2)	(1.0)	(0.6)	(0.2)	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	15100	14911	15076	15046	14993	14978	14981	14970
Any	30	674	1709	1373	807	434	223	150
	(0.2)	(4.5)	(11.3)	(9.1)	(5.4)	(2.9)	(1.5)	(1.0)
Grade 1	27	447	976	778	475	282	157	114
	(0.2)	(3.0)	(6.5)	(5.2)	(3.2)	(1.9)	(1.0)	(0.8)
Grade 2	3	178	561	448	237	111	48	28
	(<0.1)	(1.2)	(3.7)	(3.0)	(1.6)	(0.7)	(0.3)	(0.2)
Grade 3	0	49	172	147	95	41	18	8
		(0.3)	(1.1)	(1.0)	(0.6)	(0.3)	(0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	49	172	147	95	41	18	8
		(0.3)	(1.1)	(1.0)	(0.6)	(0.3)	(0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	15100	14910	15076	15046	14992	14978	14980	14972
Any	169 (1.1)	845 (5.7)	1627 (10.8)	1325 (8.8)	942 (6.3)	613 (4.1)	491 (3.3)	486 (3.2)
Grade 1	148 (1.0)	768 (5.2)	1367 (9.1)	1157 (7.7)	877 (5.8)	569 (3.8)	455 (3.0)	441 (2.9)
Grade 2	6 (<0.1)	56 (0.4)	221 (1.5)	139 (0.9)	53 (0.4)	32 (0.2)	22 (0.1)	33 (0.2)
Grade 3	15 (<0.1)	21 (0.1)	39 (0.3)	29 (0.2)	12 (<0.1)	12 (<0.1)	14 (<0.1)	12 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	15 (<0.1)	21 (0.1)	39 (0.3)	29 (0.2)	12 (<0.1)	12 (<0.1)	14 (<0.1)	12 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	15119	14947	15099	15069	15014	15003	14994	14989
Any Solicited Systemic Adverse Reactions	1058 (7.0)	6269 (41.9)	11458 (75.9)	7488 (49.7)	4804 (32.0)	3816 (25.4)	3337 (22.3)	2886 (19.3)
95% CI	6.6, 7.4	41.1, 42.7	75.2, 76.6	48.9, 50.5	31.3, 32.7	24.7, 26.1	21.6, 22.9	18.6, 19.9
Grade 1	958 (6.3)	4160 (27.8)	3962 (26.2)	4654 (30.9)	3419 (22.8)	2741 (18.3)	2386 (15.9)	2020 (13.5)
Grade 2	66 (0.4)	1767 (11.8)	5376 (35.6)	2404 (16.0)	1223 (8.1)	920 (6.1)	820 (5.5)	744 (5.0)
Grade 3	34 (0.2)	334 (2.2)	2111 (14.0)	426 (2.8)	160 (1.1)	152 (1.0)	128 (0.9)	121 (0.8)
Grade 4	0	8 (<0.1)	9 (<0.1)	4 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)
Grade 3 or Above	34 (0.2)	342 (2.3)	2120 (14.0)	430 (2.9)	162 (1.1)	155 (1.0)	131 (0.9)	122 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	15109	14896	15049	14989	14909	14854	14835	14812
Any	4 (<0.1)	241 (1.6)	1998 (13.3)	325 (2.2)	27 (0.2)	24 (0.2)	16 (0.1)	10 (<0.1)
Grade 1	4 (<0.1)	160 (1.1)	1208 (8.0)	201 (1.3)	13 (<0.1)	14 (<0.1)	10 (<0.1)	7 (<0.1)
Grade 2	0	61 (0.4)	601 (4.0)	95 (0.6)	11 (<0.1)	7 (<0.1)	3 (<0.1)	1 (<0.1)
Grade 3	0	14 (<0.1)	182 (1.2)	27 (0.2)	3 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	6 (<0.1)	7 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	0
Grade 3 or Above	0	20 (0.1)	189 (1.3)	29 (0.2)	3 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	15086	14897	15070	15044	14985	14978	14979	14963
Any	583 (3.9)	3364 (22.6)	7949 (52.7)	4179 (27.8)	2505 (16.7)	2019 (13.5)	1834 (12.2)	1584 (10.6)
Grade 1	543 (3.6)	2778 (18.6)	4564 (30.3)	3057 (20.3)	1948 (13.0)	1578 (10.5)	1418 (9.5)	1218 (8.1)
Grade 2	14 (<0.1)	455 (3.1)	2809 (18.6)	974 (6.5)	480 (3.2)	361 (2.4)	352 (2.3)	305 (2.0)
Grade 3	26 (0.2)	131 (0.9)	576 (3.8)	148 (1.0)	77 (0.5)	80 (0.5)	64 (0.4)	61 (0.4)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	26 (0.2)	131 (0.9)	576 (3.8)	148 (1.0)	77 (0.5)	80 (0.5)	64 (0.4)	61 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	15086	14901	15071	15045	14984	14979	14977	14963
Any	441 (2.9)	4271 (28.7)	9261 (61.4)	5398 (35.9)	3094 (20.6)	2376 (15.9)	1988 (13.3)	1646 (11.0)
Grade 1	407 (2.7)	2840 (19.1)	3492 (23.2)	3434 (22.8)	2202 (14.7)	1738 (11.6)	1445 (9.6)	1147 (7.7)
Grade 2	26 (0.2)	1272 (8.5)	4486 (29.8)	1733 (11.5)	819 (5.5)	580 (3.9)	487 (3.3)	448 (3.0)
Grade 3	8 (<0.1)	158 (1.1)	1282 (8.5)	230 (1.5)	72 (0.5)	57 (0.4)	55 (0.4)	51 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0
Grade 3 or Above	8 (<0.1)	159 (1.1)	1283 (8.5)	231 (1.5)	73 (0.5)	58 (0.4)	56 (0.4)	51 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	15086	14898	15072	15044	14984	14975	14975	14958
Any	214 (1.4)	2732 (18.3)	8215 (54.5)	4042 (26.9)	1809 (12.1)	1193 (8.0)	946 (6.3)	784 (5.2)
Grade 1	192 (1.3)	1778 (11.9)	3287 (21.8)	2740 (18.2)	1389 (9.3)	935 (6.2)	724 (4.8)	558 (3.7)
Grade 2	13 (<0.1)	817 (5.5)	3743 (24.8)	1125 (7.5)	379 (2.5)	222 (1.5)	199 (1.3)	201 (1.3)
Grade 3	9 (<0.1)	137 (0.9)	1185 (7.9)	177 (1.2)	41 (0.3)	36 (0.2)	23 (0.2)	25 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	9 (<0.1)	137 (0.9)	1185 (7.9)	177 (1.2)	41 (0.3)	36 (0.2)	23 (0.2)	25 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	15086	14898	15071	15045	14983	14977	14976	14957
Any	210 (1.4)	1863 (12.5)	5916 (39.3)	3026 (20.1)	1577 (10.5)	1108 (7.4)	917 (6.1)	798 (5.3)
Grade 1	181 (1.2)	1274 (8.6)	2726 (18.1)	2096 (13.9)	1233 (8.2)	877 (5.9)	712 (4.8)	586 (3.9)
Grade 2	22 (0.1)	508 (3.4)	2516 (16.7)	801 (5.3)	318 (2.1)	208 (1.4)	187 (1.2)	191 (1.3)
Grade 3	7 (<0.1)	80 (0.5)	673 (4.5)	128 (0.9)	25 (0.2)	23 (0.2)	18 (0.1)	21 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	0
Grade 3 or Above	7 (<0.1)	81 (0.5)	674 (4.5)	129 (0.9)	26 (0.2)	23 (0.2)	18 (0.1)	21 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	15086	14897	15070	15043	14983	14974	14975	14956
Any	77 (0.5)	724 (4.9)	2371 (15.7)	1054 (7.0)	612 (4.1)	427 (2.9)	399 (2.7)	312 (2.1)
Grade 1	65 (0.4)	616 (4.1)	1828 (12.1)	872 (5.8)	504 (3.4)	333 (2.2)	328 (2.2)	244 (1.6)
Grade 2	5 (<0.1)	100 (0.7)	534 (3.5)	174 (1.2)	103 (0.7)	90 (0.6)	67 (0.4)	58 (0.4)
Grade 3	7 (<0.1)	7 (<0.1)	8 (<0.1)	7 (<0.1)	4 (<0.1)	3 (<0.1)	3 (<0.1)	9 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	7 (<0.1)	8 (<0.1)	9 (<0.1)	8 (<0.1)	5 (<0.1)	4 (<0.1)	4 (<0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Treatment Group: mRNA-1273 (N=15179)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	15086	14897	15070	15043	14983	14975	14975	14958
Any	117	1349	5925	1690	503	306	246	216
	(0.8)	(9.1)	(39.3)	(11.2)	(3.4)	(2.0)	(1.6)	(1.4)
Grade 1	104	912	2691	1115	392	237	186	163
	(0.7)	(6.1)	(17.9)	(7.4)	(2.6)	(1.6)	(1.2)	(1.1)
Grade 2	7	415	3071	542	100	65	55	47
	(<0.1)	(2.8)	(20.4)	(3.6)	(0.7)	(0.4)	(0.4)	(0.3)
Grade 3	6	22	163	33	11	4	5	6
	(<0.1)	(0.1)	(1.1)	(0.2)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6	22	163	33	11	4	5	6
	(<0.1)	(0.1)	(1.1)	(0.2)	(<0.1)	(<0.1)	(<0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	11145	10636	11072	11038	10924	10914	10898	10908
Any Solicited Adverse Reactions	1341 (12.0)	2541 (23.9)	2728 (24.6)	2275 (20.6)	1899 (17.4)	1774 (16.3)	1644 (15.1)	1459 (13.4)
95% CI	11.4, 12.7	23.1, 24.7	23.8, 25.5	19.9, 21.4	16.7, 18.1	15.6, 17.0	14.4, 15.8	12.7, 14.0
Grade 1	1288 (11.6)	2105 (19.8)	2139 (19.3)	1743 (15.8)	1433 (13.1)	1343 (12.3)	1243 (11.4)	1085 (9.9)
Grade 2	39 (0.3)	394 (3.7)	522 (4.7)	462 (4.2)	403 (3.7)	370 (3.4)	357 (3.3)	335 (3.1)
Grade 3	14 (0.1)	42 (0.4)	66 (0.6)	68 (0.6)	62 (0.6)	60 (0.5)	44 (0.4)	39 (0.4)
Grade 4	0	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	14 (0.1)	42 (0.4)	67 (0.6)	70 (0.6)	63 (0.6)	61 (0.6)	44 (0.4)	39 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	11089	10577	11043	11015	10899	10886	10875	10880
Any Solicited Local Adverse Reactions	977 (8.8)	1004 (9.5)	871 (7.9)	576 (5.2)	369 (3.4)	320 (2.9)	272 (2.5)	189 (1.7)
95% CI	8.3, 9.4	8.9, 10.1	7.4, 8.4	4.8, 5.7	3.1, 3.7	2.6, 3.3	2.2, 2.8	1.5, 2.0
Grade 1	964 (8.7)	982 (9.3)	841 (7.6)	544 (4.9)	352 (3.2)	305 (2.8)	257 (2.4)	170 (1.6)
Grade 2	4 (<0.1)	12 (0.1)	25 (0.2)	23 (0.2)	13 (0.1)	12 (0.1)	10 (<0.1)	18 (0.2)
Grade 3	9 (<0.1)	10 (<0.1)	5 (<0.1)	9 (<0.1)	4 (<0.1)	3 (<0.1)	5 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	9 (<0.1)	10 (<0.1)	5 (<0.1)	9 (<0.1)	4 (<0.1)	3 (<0.1)	5 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	11089	10577	11042	11015	10897	10886	10875	10879
Any	945 (8.5)	921 (8.7)	756 (6.8)	447 (4.1)	251 (2.3)	207 (1.9)	168 (1.5)	97 (0.9)
Grade 1	934 (8.4)	908 (8.6)	735 (6.7)	427 (3.9)	240 (2.2)	200 (1.8)	159 (1.5)	85 (0.8)
Grade 2	4 (<0.1)	7 (<0.1)	17 (0.2)	16 (0.1)	9 (<0.1)	6 (<0.1)	8 (<0.1)	12 (0.1)
Grade 3	7 (<0.1)	6 (<0.1)	4 (<0.1)	4 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	7 (<0.1)	6 (<0.1)	4 (<0.1)	4 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	11089	10575	11042	11015	10898	10886	10875	10878
Any	2 (<0.1)	23 (0.2)	18 (0.2)	17 (0.2)	14 (0.1)	9 (<0.1)	14 (0.1)	14 (0.1)
Grade 1	1 (<0.1)	19 (0.2)	14 (0.1)	12 (0.1)	13 (0.1)	9 (<0.1)	12 (0.1)	13 (0.1)
Grade 2	0	1 (<0.1)	3 (<0.1)	1 (<0.1)	0	0	0	0
Grade 3	1 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	11089	10575	11042	11015	10898	10886	10875	10879
Any	8 (<0.1)	20 (0.2)	22 (0.2)	18 (0.2)	15 (0.1)	16 (0.1)	15 (0.1)	19 (0.2)
Grade 1	6 (<0.1)	16 (0.2)	19 (0.2)	15 (0.1)	13 (0.1)	13 (0.1)	13 (0.1)	16 (0.1)
Grade 2	1 (<0.1)	4 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 3	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	11089	10575	11043	11015	10898	10886	10875	10878
Any	74 (0.7)	135 (1.3)	176 (1.6)	182 (1.7)	135 (1.2)	129 (1.2)	115 (1.1)	92 (0.8)
Grade 1	69 (0.6)	131 (1.2)	171 (1.5)	172 (1.6)	130 (1.2)	122 (1.1)	110 (1.0)	86 (0.8)
Grade 2	0	2 (<0.1)	5 (<0.1)	6 (<0.1)	4 (<0.1)	5 (<0.1)	3 (<0.1)	6 (<0.1)
Grade 3	5 (<0.1)	2 (<0.1)	0	4 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	5 (<0.1)	2 (<0.1)	0	4 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	11142	10629	11069	11036	10923	10909	10897	10905
Any Solicited Systemic Adverse Reactions	561 (5.0)	2045 (19.2)	2358 (21.3)	1997 (18.1)	1725 (15.8)	1609 (14.7)	1502 (13.8)	1352 (12.4)
95% CI	4.6, 5.5	18.5, 20.0	20.5, 22.1	17.4, 18.8	15.1, 16.5	14.1, 15.4	13.1, 14.4	11.8, 13.0
Grade 1	517 (4.6)	1625 (15.3)	1783 (16.1)	1483 (13.4)	1267 (11.6)	1188 (10.9)	1111 (10.2)	991 (9.1)
Grade 2	36 (0.3)	386 (3.6)	512 (4.6)	450 (4.1)	397 (3.6)	363 (3.3)	351 (3.2)	323 (3.0)
Grade 3	8 (<0.1)	34 (0.3)	62 (0.6)	62 (0.6)	60 (0.5)	57 (0.5)	40 (0.4)	38 (0.3)
Grade 4	0	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	8 (<0.1)	34 (0.3)	63 (0.6)	64 (0.6)	61 (0.6)	58 (0.5)	40 (0.4)	38 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	11122	10501	10942	10897	10741	10708	10685	10701
Any	2 (<0.1)	2 (<0.1)	8 (<0.1)	8 (<0.1)	8 (<0.1)	10 (<0.1)	7 (<0.1)	4 (<0.1)
Grade 1	2 (<0.1)	1 (<0.1)	5 (<0.1)	3 (<0.1)	5 (<0.1)	7 (<0.1)	6 (<0.1)	4 (<0.1)
Grade 2	0	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	0	0
Grade 3	0	0	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0
Grade 4	0	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	0	0	1 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	11041	10563	11039	11007	10891	10883	10868	10877
Any	297 (2.7)	988 (9.4)	1201 (10.9)	988 (9.0)	843 (7.7)	774 (7.1)	759 (7.0)	685 (6.3)
Grade 1	284 (2.6)	899 (8.5)	1041 (9.4)	814 (7.4)	682 (6.3)	624 (5.7)	610 (5.6)	543 (5.0)
Grade 2	5 (<0.1)	70 (0.7)	122 (1.1)	132 (1.2)	126 (1.2)	115 (1.1)	129 (1.2)	122 (1.1)
Grade 3	8 (<0.1)	19 (0.2)	38 (0.3)	42 (0.4)	35 (0.3)	35 (0.3)	20 (0.2)	20 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	8 (<0.1)	19 (0.2)	38 (0.3)	42 (0.4)	35 (0.3)	35 (0.3)	20 (0.2)	20 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	11041	10572	11039	11007	10894	10884	10875	10880
Any	197 (1.8)	1285 (12.2)	1452 (13.2)	1202 (10.9)	965 (8.9)	921 (8.5)	828 (7.6)	727 (6.7)
Grade 1	180 (1.6)	959 (9.1)	1042 (9.4)	870 (7.9)	700 (6.4)	662 (6.1)	601 (5.5)	521 (4.8)
Grade 2	16 (0.1)	314 (3.0)	388 (3.5)	315 (2.9)	247 (2.3)	245 (2.3)	213 (2.0)	194 (1.8)
Grade 3	1 (<0.1)	12 (0.1)	22 (0.2)	17 (0.2)	18 (0.2)	14 (0.1)	14 (0.1)	12 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	12 (0.1)	22 (0.2)	17 (0.2)	18 (0.2)	14 (0.1)	14 (0.1)	12 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	11041	10567	11037	11005	10891	10877	10871	10876
Any	102 (0.9)	433 (4.1)	663 (6.0)	531 (4.8)	504 (4.6)	444 (4.1)	400 (3.7)	345 (3.2)
Grade 1	93 (0.8)	371 (3.5)	530 (4.8)	422 (3.8)	385 (3.5)	339 (3.1)	310 (2.9)	253 (2.3)
Grade 2	8 (<0.1)	58 (0.5)	128 (1.2)	102 (0.9)	110 (1.0)	96 (0.9)	82 (0.8)	82 (0.8)
Grade 3	1 (<0.1)	4 (<0.1)	5 (<0.1)	7 (<0.1)	9 (<0.1)	9 (<0.1)	8 (<0.1)	10 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	4 (<0.1)	5 (<0.1)	7 (<0.1)	9 (<0.1)	9 (<0.1)	8 (<0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	11041	10565	11038	11005	10891	10878	10871	10876
Any	76 (0.7)	305 (2.9)	531 (4.8)	500 (4.5)	465 (4.3)	416 (3.8)	402 (3.7)	340 (3.1)
Grade 1	70 (0.6)	255 (2.4)	436 (3.9)	397 (3.6)	358 (3.3)	317 (2.9)	308 (2.8)	250 (2.3)
Grade 2	5 (<0.1)	46 (0.4)	91 (0.8)	96 (0.9)	97 (0.9)	88 (0.8)	87 (0.8)	83 (0.8)
Grade 3	1 (<0.1)	4 (<0.1)	4 (<0.1)	7 (<0.1)	10 (<0.1)	11 (0.1)	7 (<0.1)	7 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	4 (<0.1)	4 (<0.1)	7 (<0.1)	10 (<0.1)	11 (0.1)	7 (<0.1)	7 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	11041	10562	11038	11006	10889	10876	10867	10873
Any	44 (0.4)	179 (1.7)	262 (2.4)	246 (2.2)	205 (1.9)	193 (1.8)	181 (1.7)	169 (1.6)
Grade 1	39 (0.4)	165 (1.6)	227 (2.1)	212 (1.9)	170 (1.6)	151 (1.4)	147 (1.4)	139 (1.3)
Grade 2	4 (<0.1)	14 (0.1)	34 (0.3)	33 (0.3)	33 (0.3)	40 (0.4)	33 (0.3)	30 (0.3)
Grade 3	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11402)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	11041	10563	11037	11004	10890	10877	10867	10873
Any	74 (0.7)	183 (1.7)	207 (1.9)	175 (1.6)	145 (1.3)	143 (1.3)	120 (1.1)	111 (1.0)
Grade 1	70 (0.6)	161 (1.5)	161 (1.5)	145 (1.3)	115 (1.1)	120 (1.1)	96 (0.9)	89 (0.8)
Grade 2	3 (<0.1)	22 (0.2)	45 (0.4)	29 (0.3)	27 (0.2)	22 (0.2)	24 (0.2)	21 (0.2)
Grade 3	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	0	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	11131	10734	11123	11065	10987	10929	10909	10907
Any Solicited Adverse Reactions	1332 (12.0)	6704 (62.5)	9486 (85.3)	6761 (61.1)	3391 (30.9)	2089 (19.1)	1833 (16.8)	1659 (15.2)
95% CI	11.4, 12.6	61.5, 63.4	84.6, 85.9	60.2, 62.0	30.0, 31.7	18.4, 19.9	16.1, 17.5	14.5, 15.9
Grade 1	1282 (11.5)	5796 (54.0)	7342 (66.0)	5658 (51.1)	2836 (25.8)	1634 (15.0)	1435 (13.2)	1256 (11.5)
Grade 2	33 (0.3)	754 (7.0)	1732 (15.6)	941 (8.5)	482 (4.4)	390 (3.6)	331 (3.0)	346 (3.2)
Grade 3	17 (0.2)	152 (1.4)	410 (3.7)	160 (1.4)	72 (0.7)	64 (0.6)	65 (0.6)	57 (0.5)
Grade 4	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	0
Grade 3 or Above	17 (0.2)	154 (1.4)	412 (3.7)	162 (1.5)	73 (0.7)	65 (0.6)	67 (0.6)	57 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category / Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	11075	10675	11091	11043	10961	10907	10885	10877
Any Solicited Local Adverse Reactions	974 (8.8)	6163 (57.7)	9254 (83.4)	6069 (55.0)	2276 (20.8)	824 (7.6)	508 (4.7)	502 (4.6)
95% CI	8.3, 9.3	56.8, 58.7	82.7, 84.1	54.0, 55.9	20.0, 21.5	7.1, 8.1	4.3, 5.1	4.2, 5.0
Grade 1	955 (8.6)	5738 (53.8)	7858 (70.9)	5518 (50.0)	2133 (19.5)	754 (6.9)	452 (4.2)	445 (4.1)
Grade 2	9 (<0.1)	312 (2.9)	1094 (9.9)	461 (4.2)	117 (1.1)	49 (0.4)	41 (0.4)	46 (0.4)
Grade 3	10 (<0.1)	113 (1.1)	302 (2.7)	90 (0.8)	26 (0.2)	21 (0.2)	15 (0.1)	11 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	10 (<0.1)	113 (1.1)	302 (2.7)	90 (0.8)	26 (0.2)	21 (0.2)	15 (0.1)	11 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	11075	10675	11091	11043	10960	10906	10884	10875
Any	939 (8.5)	6105 (57.2)	9201 (83.0)	5972 (54.1)	2108 (19.2)	637 (5.8)	275 (2.5)	181 (1.7)
Grade 1	926 (8.4)	5734 (53.7)	7975 (71.9)	5565 (50.4)	2038 (18.6)	603 (5.5)	251 (2.3)	156 (1.4)
Grade 2	3 (<0.1)	274 (2.6)	971 (8.8)	346 (3.1)	55 (0.5)	28 (0.3)	21 (0.2)	21 (0.2)
Grade 3	10 (<0.1)	97 (0.9)	255 (2.3)	61 (0.6)	15 (0.1)	6 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	10 (<0.1)	97 (0.9)	255 (2.3)	61 (0.6)	15 (0.1)	6 (<0.1)	3 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	11075	10668	11090	11037	10958	10901	10881	10871
Any	8 (<0.1)	52 (0.5)	218 (2.0)	231 (2.1)	118 (1.1)	64 (0.6)	36 (0.3)	32 (0.3)
Grade 1	5 (<0.1)	39 (0.4)	165 (1.5)	152 (1.4)	79 (0.7)	47 (0.4)	30 (0.3)	29 (0.3)
Grade 2	3 (<0.1)	7 (<0.1)	39 (0.4)	65 (0.6)	36 (0.3)	11 (0.1)	5 (<0.1)	2 (<0.1)
Grade 3	0	6 (<0.1)	14 (0.1)	14 (0.1)	3 (<0.1)	6 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	6 (<0.1)	14 (0.1)	14 (0.1)	3 (<0.1)	6 (<0.1)	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	11075	10668	11090	11037	10959	10902	10882	10871
Any	10 (<0.1)	188 (1.8)	608 (5.5)	383 (3.5)	171 (1.6)	65 (0.6)	47 (0.4)	38 (0.3)
Grade 1	8 (<0.1)	135 (1.3)	412 (3.7)	269 (2.4)	134 (1.2)	54 (0.5)	38 (0.3)	32 (0.3)
Grade 2	2 (<0.1)	43 (0.4)	157 (1.4)	94 (0.9)	30 (0.3)	5 (<0.1)	4 (<0.1)	5 (<0.1)
Grade 3	0	10 (<0.1)	39 (0.4)	20 (0.2)	7 (<0.1)	6 (<0.1)	5 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	10 (<0.1)	39 (0.4)	20 (0.2)	7 (<0.1)	6 (<0.1)	5 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	11075	10668	11090	11037	10958	10901	10881	10873
Any	71 (0.6)	314 (2.9)	542 (4.9)	405 (3.7)	245 (2.2)	196 (1.8)	228 (2.1)	325 (3.0)
Grade 1	64 (0.6)	291 (2.7)	485 (4.4)	369 (3.3)	231 (2.1)	179 (1.6)	208 (1.9)	295 (2.7)
Grade 2	3 (<0.1)	17 (0.2)	45 (0.4)	29 (0.3)	13 (0.1)	10 (<0.1)	12 (0.1)	24 (0.2)
Grade 3	4 (<0.1)	6 (<0.1)	12 (0.1)	7 (<0.1)	1 (<0.1)	7 (<0.1)	8 (<0.1)	6 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	6 (<0.1)	12 (0.1)	7 (<0.1)	1 (<0.1)	7 (<0.1)	8 (<0.1)	6 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	11131	10729	11121	11062	10985	10923	10906	10901
Any Solicited Systemic Adverse Reactions	528 (4.7)	2767 (25.8)	4106 (36.9)	2894 (26.2)	1921 (17.5)	1589 (14.5)	1526 (14.0)	1344 (12.3)
95% CI	4.4, 5.2	25.0, 26.6	36.0, 37.8	25.3, 27.0	16.8, 18.2	13.9, 15.2	13.3, 14.7	11.7, 13.0
Grade 1	494 (4.4)	2156 (20.1)	2835 (25.5)	2150 (19.4)	1473 (13.4)	1187 (10.9)	1166 (10.7)	976 (9.0)
Grade 2	25 (0.2)	554 (5.2)	1111 (10.0)	655 (5.9)	397 (3.6)	356 (3.3)	306 (2.8)	321 (2.9)
Grade 3	9 (<0.1)	55 (0.5)	158 (1.4)	87 (0.8)	50 (0.5)	45 (0.4)	52 (0.5)	47 (0.4)
Grade 4	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	0
Grade 3 or Above	9 (<0.1)	57 (0.5)	160 (1.4)	89 (0.8)	51 (0.5)	46 (0.4)	54 (0.5)	47 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	11109	10606	11004	10898	10791	10694	10658	10631
Any	2 (<0.1)	11 (0.1)	58 (0.5)	31 (0.3)	8 (<0.1)	8 (<0.1)	5 (<0.1)	4 (<0.1)
Grade 1	2 (<0.1)	7 (<0.1)	36 (0.3)	23 (0.2)	5 (<0.1)	7 (<0.1)	3 (<0.1)	3 (<0.1)
Grade 2	0	2 (<0.1)	15 (0.1)	4 (<0.1)	3 (<0.1)	1 (<0.1)	0	0
Grade 3	0	1 (<0.1)	6 (<0.1)	3 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	0
Grade 3 or Above	0	2 (<0.1)	7 (<0.1)	4 (<0.1)	0	0	2 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	11028	10652	11082	11028	10950	10897	10883	10864
Any	294 (2.7)	1286 (12.1)	1903 (17.2)	1325 (12.0)	873 (8.0)	759 (7.0)	763 (7.0)	698 (6.4)
Grade 1	284 (2.6)	1163 (10.9)	1532 (13.8)	1076 (9.8)	706 (6.4)	620 (5.7)	622 (5.7)	559 (5.1)
Grade 2	4 (<0.1)	92 (0.9)	278 (2.5)	205 (1.9)	143 (1.3)	121 (1.1)	114 (1.0)	116 (1.1)
Grade 3	6 (<0.1)	31 (0.3)	93 (0.8)	44 (0.4)	24 (0.2)	18 (0.2)	27 (0.2)	23 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (<0.1)	31 (0.3)	93 (0.8)	44 (0.4)	24 (0.2)	18 (0.2)	27 (0.2)	23 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	11028	10650	11083	11031	10950	10899	10882	10870
Any	206 (1.9)	1705 (16.0)	2659 (24.0)	1834 (16.6)	1158 (10.6)	939 (8.6)	856 (7.9)	731 (6.7)
Grade 1	195 (1.8)	1289 (12.1)	1801 (16.3)	1364 (12.4)	881 (8.0)	693 (6.4)	656 (6.0)	510 (4.7)
Grade 2	9 (<0.1)	395 (3.7)	814 (7.3)	435 (3.9)	254 (2.3)	227 (2.1)	182 (1.7)	201 (1.8)
Grade 3	2 (<0.1)	20 (0.2)	43 (0.4)	34 (0.3)	22 (0.2)	18 (0.2)	17 (0.2)	20 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0
Grade 3 or Above	2 (<0.1)	21 (0.2)	44 (0.4)	35 (0.3)	23 (0.2)	19 (0.2)	18 (0.2)	20 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	11028	10648	11082	11028	10950	10896	10882	10862
Any	104 (0.9)	798 (7.5)	1669 (15.1)	1017 (9.2)	538 (4.9)	437 (4.0)	359 (3.3)	315 (2.9)
Grade 1	95 (0.9)	629 (5.9)	1213 (10.9)	770 (7.0)	443 (4.0)	355 (3.3)	283 (2.6)	227 (2.1)
Grade 2	6 (<0.1)	159 (1.5)	428 (3.9)	222 (2.0)	84 (0.8)	67 (0.6)	66 (0.6)	77 (0.7)
Grade 3	3 (<0.1)	10 (<0.1)	28 (0.3)	25 (0.2)	11 (0.1)	15 (0.1)	10 (<0.1)	11 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	10 (<0.1)	28 (0.3)	25 (0.2)	11 (0.1)	15 (0.1)	10 (<0.1)	11 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	11028	10648	11081	11029	10949	10895	10881	10860
Any	77 (0.7)	498 (4.7)	1037 (9.4)	774 (7.0)	474 (4.3)	384 (3.5)	347 (3.2)	311 (2.9)
Grade 1	66 (0.6)	399 (3.7)	789 (7.1)	605 (5.5)	391 (3.6)	310 (2.8)	282 (2.6)	228 (2.1)
Grade 2	8 (<0.1)	93 (0.9)	227 (2.0)	150 (1.4)	76 (0.7)	61 (0.6)	56 (0.5)	73 (0.7)
Grade 3	3 (<0.1)	5 (<0.1)	20 (0.2)	18 (0.2)	6 (<0.1)	13 (0.1)	9 (<0.1)	10 (<0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	0
Grade 3 or Above	3 (<0.1)	6 (<0.1)	21 (0.2)	19 (0.2)	7 (<0.1)	13 (0.1)	9 (<0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	11028	10645	11079	11023	10946	10891	10878	10857
Any	33 (0.3)	217 (2.0)	418 (3.8)	321 (2.9)	220 (2.0)	176 (1.6)	172 (1.6)	134 (1.2)
Grade 1	31 (0.3)	200 (1.9)	358 (3.2)	277 (2.5)	185 (1.7)	151 (1.4)	155 (1.4)	117 (1.1)
Grade 2	0	16 (0.2)	59 (0.5)	43 (0.4)	34 (0.3)	25 (0.2)	17 (0.2)	16 (0.1)
Grade 3	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11406)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	11028	10645	11079	11023	10946	10891	10877	10856
Any	63 (0.6)	253 (2.4)	491 (4.4)	318 (2.9)	134 (1.2)	116 (1.1)	82 (0.8)	74 (0.7)
Grade 1	57 (0.5)	210 (2.0)	371 (3.3)	227 (2.1)	110 (1.0)	93 (0.9)	62 (0.6)	52 (0.5)
Grade 2	4 (<0.1)	41 (0.4)	114 (1.0)	85 (0.8)	22 (0.2)	22 (0.2)	18 (0.2)	20 (0.2)
Grade 3	2 (<0.1)	2 (<0.1)	6 (<0.1)	6 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	2 (<0.1)	6 (<0.1)	6 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	3622	3411	3656	3653	3659	3630	3639	3622
Any Solicited Adverse Reactions	255 (7.0)	560 (16.4)	694 (19.0)	593 (16.2)	520 (14.2)	463 (12.8)	481 (13.2)	424 (11.7)
95% CI	6.2, 7.9	15.2, 17.7	17.7, 20.3	15.1, 17.5	13.1, 15.4	11.7, 13.9	12.1, 14.4	10.7, 12.8
Grade 1	227 (6.3)	471 (13.8)	552 (15.1)	495 (13.6)	425 (11.6)	375 (10.3)	380 (10.4)	341 (9.4)
Grade 2	10 (0.3)	73 (2.1)	116 (3.2)	85 (2.3)	83 (2.3)	78 (2.1)	90 (2.5)	66 (1.8)
Grade 3	17 (0.5)	16 (0.5)	26 (0.7)	13 (0.4)	12 (0.3)	10 (0.3)	11 (0.3)	16 (0.4)
Grade 4	1 (<0.1)	0	0	0	0	0	0	1 (<0.1)
Grade 3 or Above	18 (0.5)	16 (0.5)	26 (0.7)	13 (0.4)	12 (0.3)	10 (0.3)	11 (0.3)	17 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	3600	3355	3621	3625	3621	3601	3619	3605
Any Solicited Local Adverse Reactions	162 (4.5)	180 (5.4)	218 (6.0)	154 (4.2)	126 (3.5)	103 (2.9)	89 (2.5)	73 (2.0)
95% CI	3.8, 5.2	4.6, 6.2	5.3, 6.8	3.6, 5.0	2.9, 4.1	2.3, 3.5	2.0, 3.0	1.6, 2.5
Grade 1	144 (4.0)	170 (5.1)	200 (5.5)	142 (3.9)	114 (3.1)	95 (2.6)	80 (2.2)	66 (1.8)
Grade 2	4 (0.1)	5 (0.1)	6 (0.2)	10 (0.3)	8 (0.2)	6 (0.2)	6 (0.2)	4 (0.1)
Grade 3	14 (0.4)	5 (0.1)	12 (0.3)	2 (<0.1)	4 (0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	14 (0.4)	5 (0.1)	12 (0.3)	2 (<0.1)	4 (0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	3600	3354	3620	3625	3620	3601	3619	3605
Any	155 (4.3)	156 (4.7)	170 (4.7)	109 (3.0)	78 (2.2)	63 (1.7)	53 (1.5)	44 (1.2)
Grade 1	139 (3.9)	147 (4.4)	159 (4.4)	101 (2.8)	70 (1.9)	59 (1.6)	47 (1.3)	40 (1.1)
Grade 2	3 (<0.1)	4 (0.1)	4 (0.1)	6 (0.2)	4 (0.1)	4 (0.1)	3 (<0.1)	2 (<0.1)
Grade 3	13 (0.4)	5 (0.1)	7 (0.2)	2 (<0.1)	4 (0.1)	0	3 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	13 (0.4)	5 (0.1)	7 (0.2)	2 (<0.1)	4 (0.1)	0	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	3600	3355	3621	3625	3619	3601	3619	3605
Any	0	6 (0.2)	14 (0.4)	14 (0.4)	10 (0.3)	14 (0.4)	10 (0.3)	10 (0.3)
Grade 1	0	5 (0.1)	12 (0.3)	12 (0.3)	9 (0.2)	12 (0.3)	9 (0.2)	9 (0.2)
Grade 2	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3	0	0	1 (<0.1)	0	0	1 (<0.1)	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	0	1 (<0.1)	0	0	1 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	3600	3354	3620	3625	3620	3601	3619	3605
Any	1 (<0.1)	9 (0.3)	19 (0.5)	15 (0.4)	14 (0.4)	11 (0.3)	11 (0.3)	12 (0.3)
Grade 1	1 (<0.1)	9 (0.3)	15 (0.4)	14 (0.4)	11 (0.3)	9 (0.2)	10 (0.3)	11 (0.3)
Grade 2	0	0	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3	0	0	2 (<0.1)	0	0	1 (<0.1)	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	0	2 (<0.1)	0	0	1 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	3600	3354	3620	3625	3619	3601	3619	3605
Any	23 (0.6)	25 (0.7)	46 (1.3)	37 (1.0)	35 (1.0)	24 (0.7)	28 (0.8)	23 (0.6)
Grade 1	19 (0.5)	23 (0.7)	38 (1.0)	36 (1.0)	33 (0.9)	24 (0.7)	25 (0.7)	20 (0.6)
Grade 2	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Grade 3	2 (<0.1)	1 (<0.1)	7 (0.2)	0	2 (<0.1)	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	1 (<0.1)	7 (0.2)	0	2 (<0.1)	0	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	3620	3407	3655	3651	3658	3630	3639	3622
Any Solicited Systemic Adverse Reactions	122 (3.4)	452 (13.3)	580 (15.9)	504 (13.8)	447 (12.2)	408 (11.2)	428 (11.8)	376 (10.4)
95% CI	2.8, 4.0	12.1, 14.5	14.7, 17.1	12.7, 15.0	11.2, 13.3	10.2, 12.3	10.7, 12.9	9.4, 11.4
Grade 1	108 (3.0)	369 (10.8)	452 (12.4)	417 (11.4)	362 (9.9)	328 (9.0)	333 (9.2)	298 (8.2)
Grade 2	7 (0.2)	70 (2.1)	112 (3.1)	76 (2.1)	76 (2.1)	72 (2.0)	86 (2.4)	64 (1.8)
Grade 3	6 (0.2)	13 (0.4)	16 (0.4)	11 (0.3)	9 (0.2)	8 (0.2)	9 (0.2)	13 (0.4)
Grade 4	1 (<0.1)	0	0	0	0	0	0	1 (<0.1)
Grade 3 or Above	7 (0.2)	13 (0.4)	16 (0.4)	11 (0.3)	9 (0.2)	8 (0.2)	9 (0.2)	14 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	3617	3366	3620	3612	3624	3590	3598	3568
Any	1 (<0.1)	3 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 1	0	2 (<0.1)	0	2 (<0.1)	0	0	0	0
Grade 2	0	1 (<0.1)	0	0	0	1 (<0.1)	1 (<0.1)	0
Grade 3	0	0	0	0	0	0	0	1 (<0.1)
Grade 4	1 (<0.1)	0	0	0	0	0	0	1 (<0.1)
Grade 3 or Above	1 (<0.1)	0	0	0	0	0	0	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	3576	3338	3607	3613	3621	3593	3607	3596
Any	67 (1.9)	196 (5.9)	244 (6.8)	195 (5.4)	175 (4.8)	157 (4.4)	151 (4.2)	148 (4.1)
Grade 1	61 (1.7)	185 (5.5)	219 (6.1)	173 (4.8)	152 (4.2)	131 (3.6)	126 (3.5)	125 (3.5)
Grade 2	2 (<0.1)	8 (0.2)	18 (0.5)	15 (0.4)	18 (0.5)	21 (0.6)	19 (0.5)	14 (0.4)
Grade 3	4 (0.1)	3 (<0.1)	7 (0.2)	7 (0.2)	5 (0.1)	5 (0.1)	6 (0.2)	9 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (0.1)	3 (<0.1)	7 (0.2)	7 (0.2)	5 (0.1)	5 (0.1)	6 (0.2)	9 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	3576	3343	3608	3614	3622	3596	3607	3596
Any	39 (1.1)	289 (8.6)	373 (10.3)	294 (8.1)	272 (7.5)	237 (6.6)	247 (6.8)	195 (5.4)
Grade 1	35 (1.0)	227 (6.8)	280 (7.8)	238 (6.6)	219 (6.0)	193 (5.4)	196 (5.4)	153 (4.3)
Grade 2	2 (<0.1)	53 (1.6)	85 (2.4)	53 (1.5)	51 (1.4)	41 (1.1)	47 (1.3)	38 (1.1)
Grade 3	2 (<0.1)	9 (0.3)	8 (0.2)	3 (<0.1)	2 (<0.1)	3 (<0.1)	4 (0.1)	4 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	9 (0.3)	8 (0.2)	3 (<0.1)	2 (<0.1)	3 (<0.1)	4 (0.1)	4 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	3576	3339	3607	3613	3622	3593	3607	3597
Any	21 (0.6)	105 (3.1)	170 (4.7)	161 (4.5)	138 (3.8)	139 (3.9)	128 (3.5)	129 (3.6)
Grade 1	19 (0.5)	91 (2.7)	152 (4.2)	141 (3.9)	120 (3.3)	113 (3.1)	100 (2.8)	103 (2.9)
Grade 2	1 (<0.1)	11 (0.3)	17 (0.5)	19 (0.5)	17 (0.5)	26 (0.7)	27 (0.7)	25 (0.7)
Grade 3	1 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	3576	3339	3607	3615	3622	3594	3608	3597
Any	23 (0.6)	86 (2.6)	179 (5.0)	169 (4.7)	168 (4.6)	167 (4.6)	158 (4.4)	164 (4.6)
Grade 1	21 (0.6)	73 (2.2)	158 (4.4)	153 (4.2)	146 (4.0)	139 (3.9)	125 (3.5)	138 (3.8)
Grade 2	2 (<0.1)	11 (0.3)	21 (0.6)	14 (0.4)	20 (0.6)	28 (0.8)	31 (0.9)	24 (0.7)
Grade 3	0	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	0	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	3576	3336	3607	3612	3619	3591	3606	3595
Any	5 (0.1)	23 (0.7)	52 (1.4)	45 (1.2)	25 (0.7)	31 (0.9)	40 (1.1)	33 (0.9)
Grade 1	5 (0.1)	18 (0.5)	44 (1.2)	40 (1.1)	20 (0.6)	29 (0.8)	30 (0.8)	32 (0.9)
Grade 2	0	3 (<0.1)	7 (0.2)	5 (0.1)	5 (0.1)	1 (<0.1)	9 (0.2)	1 (<0.1)
Grade 3	0	2 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	2 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3749)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	3576	3336	3607	3612	3619	3592	3606	3595
Any	12 (0.3)	36 (1.1)	44 (1.2)	31 (0.9)	24 (0.7)	21 (0.6)	23 (0.6)	21 (0.6)
Grade 1	10 (0.3)	30 (0.9)	39 (1.1)	26 (0.7)	20 (0.6)	17 (0.5)	19 (0.5)	19 (0.5)
Grade 2	1 (<0.1)	4 (0.1)	5 (0.1)	4 (0.1)	3 (<0.1)	4 (0.1)	3 (<0.1)	2 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	3646	3439	3678	3665	3653	3635	3640	3609
Any Solicited Adverse Reactions	240 (6.6)	1409 (41.0)	2669 (72.6)	1839 (50.2)	923 (25.3)	601 (16.5)	514 (14.1)	435 (12.1)
95% CI	5.8, 7.4	39.3, 42.6	71.1, 74.0	48.5, 51.8	23.9, 26.7	15.3, 17.8	13.0, 15.3	11.0, 13.2
Grade 1	211 (5.8)	1270 (36.9)	2339 (63.6)	1601 (43.7)	790 (21.6)	497 (13.7)	410 (11.3)	336 (9.3)
Grade 2	12 (0.3)	117 (3.4)	273 (7.4)	200 (5.5)	116 (3.2)	87 (2.4)	82 (2.3)	87 (2.4)
Grade 3	17 (0.5)	22 (0.6)	57 (1.5)	38 (1.0)	17 (0.5)	17 (0.5)	22 (0.6)	12 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	17 (0.5)	22 (0.6)	57 (1.5)	38 (1.0)	17 (0.5)	17 (0.5)	22 (0.6)	12 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	3617	3375	3643	3640	3632	3617	3624	3599
Any Solicited Local Adverse Reactions	155 (4.3)	1120 (33.2)	2527 (69.4)	1581 (43.4)	564 (15.5)	204 (5.6)	117 (3.2)	81 (2.3)
95% CI	3.6, 5.0	31.6, 34.8	67.8, 70.9	41.8, 45.1	14.4, 16.7	4.9, 6.4	2.7, 3.9	1.8, 2.8
Grade 1	140 (3.9)	1091 (32.3)	2391 (65.6)	1488 (40.9)	537 (14.8)	192 (5.3)	103 (2.8)	70 (1.9)
Grade 2	3 (<0.1)	17 (0.5)	100 (2.7)	73 (2.0)	23 (0.6)	8 (0.2)	6 (0.2)	6 (0.2)
Grade 3	12 (0.3)	12 (0.4)	36 (1.0)	20 (0.5)	4 (0.1)	4 (0.1)	8 (0.2)	5 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	12 (0.3)	12 (0.4)	36 (1.0)	20 (0.5)	4 (0.1)	4 (0.1)	8 (0.2)	5 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	3617	3374	3642	3640	3632	3617	3623	3599
Any	149 (4.1)	1101 (32.6)	2508 (68.9)	1540 (42.3)	519 (14.3)	166 (4.6)	79 (2.2)	47 (1.3)
Grade 1	136 (3.8)	1080 (32.0)	2419 (66.4)	1490 (40.9)	507 (14.0)	159 (4.4)	71 (2.0)	42 (1.2)
Grade 2	2 (<0.1)	13 (0.4)	70 (1.9)	41 (1.1)	10 (0.3)	4 (0.1)	3 (<0.1)	2 (<0.1)
Grade 3	11 (0.3)	8 (0.2)	19 (0.5)	9 (0.2)	2 (<0.1)	3 (<0.1)	5 (0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	11 (0.3)	8 (0.2)	19 (0.5)	9 (0.2)	2 (<0.1)	3 (<0.1)	5 (0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	3617	3374	3642	3640	3632	3616	3623	3599
Any	2 (<0.1)	15 (0.4)	49 (1.3)	64 (1.8)	35 (1.0)	19 (0.5)	15 (0.4)	11 (0.3)
Grade 1	1 (<0.1)	11 (0.3)	34 (0.9)	45 (1.2)	25 (0.7)	15 (0.4)	9 (0.2)	8 (0.2)
Grade 2	1 (<0.1)	4 (0.1)	11 (0.3)	17 (0.5)	9 (0.2)	4 (0.1)	3 (<0.1)	3 (<0.1)
Grade 3	0	0	4 (0.1)	2 (<0.1)	1 (<0.1)	0	3 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	0	4 (0.1)	2 (<0.1)	1 (<0.1)	0	3 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	3617	3373	3643	3640	3632	3616	3623	3599
Any	3 (<0.1)	26 (0.8)	124 (3.4)	97 (2.7)	39 (1.1)	16 (0.4)	9 (0.2)	9 (0.3)
Grade 1	3 (<0.1)	22 (0.7)	84 (2.3)	67 (1.8)	31 (0.9)	13 (0.4)	9 (0.2)	8 (0.2)
Grade 2	0	1 (<0.1)	26 (0.7)	20 (0.5)	7 (0.2)	2 (<0.1)	0	0
Grade 3	0	3 (<0.1)	14 (0.4)	10 (0.3)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	3 (<0.1)	14 (0.4)	10 (0.3)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	3617	3373	3642	3640	3632	3616	3624	3599
Any	26 (0.7)	59 (1.7)	95 (2.6)	66 (1.8)	38 (1.0)	31 (0.9)	28 (0.8)	25 (0.7)
Grade 1	21 (0.6)	57 (1.7)	92 (2.5)	62 (1.7)	37 (1.0)	29 (0.8)	26 (0.7)	22 (0.6)
Grade 2	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	0	1 (<0.1)
Grade 3	4 (0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category / Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	3645	3433	3673	3665	3650	3634	3637	3609
Any Solicited Systemic Adverse Reactions	120 (3.3)	679 (19.8)	1079 (29.4)	792 (21.6)	553 (15.2)	471 (13.0)	442 (12.2)	394 (10.9)
95% CI	2.7, 3.9	18.5, 21.2	27.9, 30.9	20.3, 23.0	14.0, 16.4	11.9, 14.1	11.1, 13.3	9.9, 12.0
Grade 1	102 (2.8)	560 (16.3)	843 (23.0)	620 (16.9)	439 (12.0)	375 (10.3)	347 (9.5)	302 (8.4)
Grade 2	10 (0.3)	108 (3.1)	210 (5.7)	151 (4.1)	100 (2.7)	81 (2.2)	80 (2.2)	83 (2.3)
Grade 3	8 (0.2)	11 (0.3)	26 (0.7)	21 (0.6)	14 (0.4)	15 (0.4)	15 (0.4)	9 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	8 (0.2)	11 (0.3)	26 (0.7)	21 (0.6)	14 (0.4)	15 (0.4)	15 (0.4)	9 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	3635	3392	3654	3635	3620	3602	3594	3556
Any	0	3 (<0.1)	1 (<0.1)	1 (<0.1)	0	3 (<0.1)	2 (<0.1)	1 (<0.1)
Grade 1	0	3 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0
Grade 2	0	0	0	0	0	2 (<0.1)	0	0
Grade 3	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	0	0	0	0	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	3585	3354	3625	3628	3620	3612	3608	3591
Any	66 (1.8)	291 (8.7)	418 (11.5)	280 (7.7)	185 (5.1)	172 (4.8)	159 (4.4)	153 (4.3)
Grade 1	56 (1.6)	269 (8.0)	371 (10.2)	242 (6.7)	156 (4.3)	143 (4.0)	133 (3.7)	127 (3.5)
Grade 2	4 (0.1)	14 (0.4)	31 (0.9)	29 (0.8)	21 (0.6)	19 (0.5)	19 (0.5)	21 (0.6)
Grade 3	6 (0.2)	8 (0.2)	16 (0.4)	9 (0.2)	8 (0.2)	10 (0.3)	7 (0.2)	5 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (0.2)	8 (0.2)	16 (0.4)	9 (0.2)	8 (0.2)	10 (0.3)	7 (0.2)	5 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	3585	3357	3625	3630	3620	3612	3609	3591
Any	42 (1.2)	420 (12.5)	700 (19.3)	520 (14.3)	360 (9.9)	287 (7.9)	278 (7.7)	232 (6.5)
Grade 1	37 (1.0)	336 (10.0)	531 (14.6)	400 (11.0)	287 (7.9)	232 (6.4)	216 (6.0)	169 (4.7)
Grade 2	3 (<0.1)	81 (2.4)	160 (4.4)	109 (3.0)	66 (1.8)	49 (1.4)	54 (1.5)	57 (1.6)
Grade 3	2 (<0.1)	3 (<0.1)	9 (0.2)	11 (0.3)	7 (0.2)	6 (0.2)	8 (0.2)	6 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	3 (<0.1)	9 (0.2)	11 (0.3)	7 (0.2)	6 (0.2)	8 (0.2)	6 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	3585	3356	3625	3628	3620	3612	3608	3590
Any	26 (0.7)	202 (6.0)	389 (10.7)	298 (8.2)	208 (5.7)	154 (4.3)	157 (4.4)	125 (3.5)
Grade 1	24 (0.7)	171 (5.1)	314 (8.7)	242 (6.7)	172 (4.8)	123 (3.4)	134 (3.7)	97 (2.7)
Grade 2	0	31 (0.9)	68 (1.9)	50 (1.4)	32 (0.9)	29 (0.8)	20 (0.6)	23 (0.6)
Grade 3	2 (<0.1)	0	7 (0.2)	6 (0.2)	4 (0.1)	2 (<0.1)	3 (<0.1)	5 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	0	7 (0.2)	6 (0.2)	4 (0.1)	2 (<0.1)	3 (<0.1)	5 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	3585	3356	3625	3629	3620	3612	3608	3590
Any	29 (0.8)	153 (4.6)	283 (7.8)	249 (6.9)	209 (5.8)	175 (4.8)	171 (4.7)	147 (4.1)
Grade 1	27 (0.8)	130 (3.9)	233 (6.4)	201 (5.5)	176 (4.9)	148 (4.1)	143 (4.0)	120 (3.3)
Grade 2	2 (<0.1)	23 (0.7)	47 (1.3)	43 (1.2)	31 (0.9)	26 (0.7)	25 (0.7)	23 (0.6)
Grade 3	0	0	3 (<0.1)	5 (0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	4 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	0	3 (<0.1)	5 (0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)	4 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	3585	3352	3625	3628	3620	3612	3608	3590
Any	8 (0.2)	23 (0.7)	62 (1.7)	63 (1.7)	36 (1.0)	33 (0.9)	38 (1.1)	34 (0.9)
Grade 1	7 (0.2)	23 (0.7)	56 (1.5)	52 (1.4)	31 (0.9)	26 (0.7)	28 (0.8)	25 (0.7)
Grade 2	0	0	5 (0.1)	10 (0.3)	4 (0.1)	6 (0.2)	8 (0.2)	7 (0.2)
Grade 3	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group, Grade and Day of Reporting
First Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3760)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	3585	3352	3625	3628	3620	3612	3607	3590
Any	10 (0.3)	50 (1.5)	73 (2.0)	62 (1.7)	29 (0.8)	25 (0.7)	20 (0.6)	18 (0.5)
Grade 1	9 (0.3)	48 (1.4)	63 (1.7)	46 (1.3)	23 (0.6)	17 (0.5)	17 (0.5)	14 (0.4)
Grade 2	1 (<0.1)	2 (<0.1)	7 (0.2)	14 (0.4)	3 (<0.1)	7 (0.2)	1 (<0.1)	2 (<0.1)
Grade 3	0	0	3 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	0	3 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	10594	10154	10406	10348	10239	10154	10242	10230
Any Solicited Adverse Reactions	1325 (12.5)	2301 (22.7)	2332 (22.4)	1973 (19.1)	1709 (16.7)	1481 (14.6)	1408 (13.7)	1226 (12.0)
95% CI	11.9, 13.2	21.8, 23.5	21.6, 23.2	18.3, 19.8	16.0, 17.4	13.9, 15.3	13.1, 14.4	11.4, 12.6
Grade 1	1277 (12.1)	1890 (18.6)	1781 (17.1)	1510 (14.6)	1265 (12.4)	1131 (11.1)	1035 (10.1)	889 (8.7)
Grade 2	35 (0.3)	361 (3.6)	487 (4.7)	403 (3.9)	400 (3.9)	298 (2.9)	315 (3.1)	291 (2.8)
Grade 3	13 (0.1)	50 (0.5)	64 (0.6)	59 (0.6)	43 (0.4)	52 (0.5)	58 (0.6)	46 (0.4)
Grade 4	0	0	0	1 (<0.1)	1 (<0.1)	0	0	0
Grade 3 or Above	13 (0.1)	50 (0.5)	64 (0.6)	60 (0.6)	44 (0.4)	52 (0.5)	58 (0.6)	46 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	10566	10122	10388	10336	10226	10131	10227	10210
Any Solicited Local Adverse Reactions	1061 (10.0)	1075 (10.6)	806 (7.8)	547 (5.3)	394 (3.9)	317 (3.1)	239 (2.3)	180 (1.8)
95% CI	9.5, 10.6	10.0, 11.2	7.3, 8.3	4.9, 5.7	3.5, 4.2	2.8, 3.5	2.1, 2.6	1.5, 2.0
Grade 1	1044 (9.9)	1038 (10.3)	767 (7.4)	517 (5.0)	363 (3.5)	292 (2.9)	211 (2.1)	157 (1.5)
Grade 2	7 (<0.1)	26 (0.3)	29 (0.3)	21 (0.2)	20 (0.2)	15 (0.1)	18 (0.2)	14 (0.1)
Grade 3	10 (<0.1)	11 (0.1)	10 (<0.1)	9 (<0.1)	11 (0.1)	10 (<0.1)	10 (<0.1)	9 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	10 (<0.1)	11 (0.1)	10 (<0.1)	9 (<0.1)	11 (0.1)	10 (<0.1)	10 (<0.1)	9 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	10566	10121	10387	10336	10225	10131	10226	10208
Any	1037 (9.8)	998 (9.9)	677 (6.5)	435 (4.2)	275 (2.7)	204 (2.0)	142 (1.4)	101 (1.0)
Grade 1	1025 (9.7)	973 (9.6)	653 (6.3)	418 (4.0)	258 (2.5)	190 (1.9)	127 (1.2)	88 (0.9)
Grade 2	5 (<0.1)	20 (0.2)	19 (0.2)	12 (0.1)	14 (0.1)	9 (<0.1)	10 (<0.1)	9 (<0.1)
Grade 3	7 (<0.1)	5 (<0.1)	5 (<0.1)	5 (<0.1)	3 (<0.1)	5 (<0.1)	5 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	7 (<0.1)	5 (<0.1)	5 (<0.1)	5 (<0.1)	3 (<0.1)	5 (<0.1)	5 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	10566	10121	10388	10333	10224	10130	10225	10208
Any	7 (<0.1)	23 (0.2)	21 (0.2)	20 (0.2)	20 (0.2)	20 (0.2)	18 (0.2)	15 (0.1)
Grade 1	4 (<0.1)	16 (0.2)	15 (0.1)	15 (0.1)	14 (0.1)	14 (0.1)	13 (0.1)	11 (0.1)
Grade 2	0	4 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)
Grade 3	3 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	10566	10122	10387	10333	10223	10130	10225	10208
Any	9 (<0.1)	21 (0.2)	20 (0.2)	19 (0.2)	16 (0.2)	21 (0.2)	20 (0.2)	19 (0.2)
Grade 1	6 (<0.1)	18 (0.2)	13 (0.1)	15 (0.1)	12 (0.1)	16 (0.2)	15 (0.1)	15 (0.1)
Grade 2	2 (<0.1)	2 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 3	1 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	10566	10122	10387	10333	10223	10129	10224	10207
Any	49 (0.5)	143 (1.4)	190 (1.8)	158 (1.5)	141 (1.4)	123 (1.2)	103 (1.0)	74 (0.7)
Grade 1	48 (0.5)	134 (1.3)	182 (1.8)	147 (1.4)	131 (1.3)	115 (1.1)	95 (0.9)	70 (0.7)
Grade 2	0	5 (<0.1)	6 (<0.1)	9 (<0.1)	6 (<0.1)	5 (<0.1)	6 (<0.1)	2 (<0.1)
Grade 3	1 (<0.1)	4 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	4 (<0.1)	2 (<0.1)	2 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	10592	10154	10406	10345	10238	10154	10240	10227
Any Solicited Systemic Adverse Reactions	421 (4.0)	1733 (17.1)	1989 (19.1)	1732 (16.7)	1535 (15.0)	1330 (13.1)	1296 (12.7)	1135 (11.1)
95% CI	3.6, 4.4	16.3, 17.8	18.4, 19.9	16.0, 17.5	14.3, 15.7	12.4, 13.8	12.0, 13.3	10.5, 11.7
Grade 1	386 (3.6)	1343 (13.2)	1462 (14.0)	1284 (12.4)	1109 (10.8)	994 (9.8)	935 (9.1)	811 (7.9)
Grade 2	30 (0.3)	349 (3.4)	472 (4.5)	397 (3.8)	391 (3.8)	291 (2.9)	311 (3.0)	287 (2.8)
Grade 3	5 (<0.1)	41 (0.4)	55 (0.5)	50 (0.5)	34 (0.3)	45 (0.4)	50 (0.5)	37 (0.4)
Grade 4	0	0	0	1 (<0.1)	1 (<0.1)	0	0	0
Grade 3 or Above	5 (<0.1)	41 (0.4)	55 (0.5)	51 (0.5)	35 (0.3)	45 (0.4)	50 (0.5)	37 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301020202.sas 21JUN2021 16:53

Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	10571	10021	10272	10160	10035	9942	10012	9993
Any	1 (<0.1)	5 (<0.1)	5 (<0.1)	8 (<0.1)	5 (<0.1)	5 (<0.1)	8 (<0.1)	7 (<0.1)
Grade 1	1 (<0.1)	4 (<0.1)	4 (<0.1)	6 (<0.1)	4 (<0.1)	4 (<0.1)	6 (<0.1)	5 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)
Grade 3	0	0	0	0	0	0	2 (<0.1)	0
Grade 4	0	0	0	1 (<0.1)	1 (<0.1)	0	0	0
Grade 3 or Above	0	0	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	10540	10112	10387	10328	10219	10127	10221	10206
Any	208 (2.0)	916 (9.1)	1031 (9.9)	934 (9.0)	810 (7.9)	659 (6.5)	665 (6.5)	595 (5.8)
Grade 1	200 (1.9)	818 (8.1)	870 (8.4)	764 (7.4)	661 (6.5)	519 (5.1)	517 (5.1)	468 (4.6)
Grade 2	4 (<0.1)	77 (0.8)	135 (1.3)	145 (1.4)	130 (1.3)	115 (1.1)	124 (1.2)	108 (1.1)
Grade 3	4 (<0.1)	21 (0.2)	26 (0.3)	25 (0.2)	19 (0.2)	25 (0.2)	24 (0.2)	19 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	21 (0.2)	26 (0.3)	25 (0.2)	19 (0.2)	25 (0.2)	24 (0.2)	19 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	10540	10113	10387	10330	10220	10132	10223	10207
Any	168 (1.6)	1056 (10.4)	1276 (12.3)	1063 (10.3)	895 (8.8)	777 (7.7)	734 (7.2)	578 (5.7)
Grade 1	149 (1.4)	778 (7.7)	907 (8.7)	780 (7.6)	627 (6.1)	574 (5.7)	519 (5.1)	386 (3.8)
Grade 2	19 (0.2)	260 (2.6)	345 (3.3)	261 (2.5)	253 (2.5)	183 (1.8)	193 (1.9)	179 (1.8)
Grade 3	0	18 (0.2)	24 (0.2)	22 (0.2)	15 (0.1)	20 (0.2)	22 (0.2)	13 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	18 (0.2)	24 (0.2)	22 (0.2)	15 (0.1)	20 (0.2)	22 (0.2)	13 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	10540	10113	10385	10329	10217	10130	10224	10206
Any	79 (0.7)	431 (4.3)	594 (5.7)	557 (5.4)	483 (4.7)	404 (4.0)	407 (4.0)	341 (3.3)
Grade 1	71 (0.7)	344 (3.4)	451 (4.3)	423 (4.1)	362 (3.5)	319 (3.1)	291 (2.8)	244 (2.4)
Grade 2	8 (<0.1)	80 (0.8)	136 (1.3)	122 (1.2)	105 (1.0)	77 (0.8)	99 (1.0)	88 (0.9)
Grade 3	0	7 (<0.1)	7 (<0.1)	12 (0.1)	16 (0.2)	8 (<0.1)	17 (0.2)	9 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	7 (<0.1)	7 (<0.1)	12 (0.1)	16 (0.2)	8 (<0.1)	17 (0.2)	9 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	10540	10110	10384	10328	10218	10128	10219	10205
Any	75 (0.7)	344 (3.4)	481 (4.6)	464 (4.5)	441 (4.3)	371 (3.7)	397 (3.9)	331 (3.2)
Grade 1	70 (0.7)	274 (2.7)	362 (3.5)	357 (3.5)	336 (3.3)	292 (2.9)	294 (2.9)	238 (2.3)
Grade 2	5 (<0.1)	61 (0.6)	112 (1.1)	94 (0.9)	94 (0.9)	72 (0.7)	91 (0.9)	85 (0.8)
Grade 3	0	9 (<0.1)	7 (<0.1)	13 (0.1)	11 (0.1)	7 (<0.1)	12 (0.1)	8 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	9 (<0.1)	7 (<0.1)	13 (0.1)	11 (0.1)	7 (<0.1)	12 (0.1)	8 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	10540	10105	10383	10325	10214	10123	10216	10201
Any	35 (0.3)	215 (2.1)	267 (2.6)	215 (2.1)	187 (1.8)	169 (1.7)	167 (1.6)	130 (1.3)
Grade 1	32 (0.3)	188 (1.9)	218 (2.1)	177 (1.7)	157 (1.5)	141 (1.4)	132 (1.3)	106 (1.0)
Grade 2	3 (<0.1)	25 (0.2)	47 (0.5)	38 (0.4)	27 (0.3)	27 (0.3)	33 (0.3)	23 (0.2)
Grade 3	0	2 (<0.1)	2 (<0.1)	0	3 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	2 (<0.1)	2 (<0.1)	0	3 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=10929)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	10540	10107	10383	10326	10217	10122	10217	10202
Any	47 (0.4)	197 (1.9)	226 (2.2)	168 (1.6)	154 (1.5)	126 (1.2)	131 (1.3)	106 (1.0)
Grade 1	44 (0.4)	167 (1.7)	180 (1.7)	129 (1.2)	121 (1.2)	92 (0.9)	96 (0.9)	82 (0.8)
Grade 2	2 (<0.1)	28 (0.3)	44 (0.4)	38 (0.4)	29 (0.3)	33 (0.3)	30 (0.3)	22 (0.2)
Grade 3	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)	5 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	4 (<0.1)	1 (<0.1)	5 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	10660	10526	10732	10563	10421	10289	10287	10322
Any Solicited Adverse Reactions	1222 (11.5)	7661 (72.8)	9786 (91.2)	7731 (73.2)	4902 (47.0)	3011 (29.3)	2073 (20.2)	1536 (14.9)
95% CI	10.9, 12.1	71.9, 73.6	90.6, 91.7	72.3, 74.0	46.1, 48.0	28.4, 30.2	19.4, 20.9	14.2, 15.6
Grade 1	1170 (11.0)	5811 (55.2)	3547 (33.1)	5269 (49.9)	3724 (35.7)	2279 (22.1)	1531 (14.9)	1117 (10.8)
Grade 2	38 (0.4)	1466 (13.9)	4353 (40.6)	1975 (18.7)	949 (9.1)	576 (5.6)	454 (4.4)	352 (3.4)
Grade 3	14 (0.1)	380 (3.6)	1880 (17.5)	486 (4.6)	229 (2.2)	155 (1.5)	88 (0.9)	67 (0.6)
Grade 4	0	4 (<0.1)	6 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	0
Grade 3 or Above	14 (0.1)	384 (3.6)	1886 (17.6)	487 (4.6)	229 (2.2)	156 (1.5)	88 (0.9)	67 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	10630	10500	10715	10550	10388	10260	10259	10299
Any Solicited Local Adverse Reactions	949 (8.9)	7263 (69.2)	9345 (87.2)	7008 (66.4)	3941 (37.9)	1826 (17.8)	889 (8.7)	486 (4.7)
95% CI	8.4, 9.5	68.3, 70.1	86.6, 87.8	65.5, 67.3	37.0, 38.9	17.1, 18.6	8.1, 9.2	4.3, 5.1
Grade 1	933 (8.8)	6303 (60.0)	6469 (60.4)	5771 (54.7)	3372 (32.5)	1558 (15.2)	766 (7.5)	412 (4.0)
Grade 2	9 (<0.1)	759 (7.2)	2435 (22.7)	998 (9.5)	413 (4.0)	188 (1.8)	85 (0.8)	54 (0.5)
Grade 3	7 (<0.1)	201 (1.9)	441 (4.1)	239 (2.3)	156 (1.5)	80 (0.8)	38 (0.4)	20 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	7 (<0.1)	201 (1.9)	441 (4.1)	239 (2.3)	156 (1.5)	80 (0.8)	38 (0.4)	20 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	10630	10499	10714	10550	10388	10258	10257	10297
Any	916 (8.6)	7211 (68.7)	9299 (86.8)	6860 (65.0)	3661 (35.2)	1520 (14.8)	651 (6.3)	301 (2.9)
Grade 1	905 (8.5)	6402 (61.0)	6747 (63.0)	6109 (57.9)	3466 (33.4)	1453 (14.2)	620 (6.0)	275 (2.7)
Grade 2	5 (<0.1)	647 (6.2)	2213 (20.7)	670 (6.4)	174 (1.7)	57 (0.6)	24 (0.2)	23 (0.2)
Grade 3	6 (<0.1)	162 (1.5)	339 (3.2)	81 (0.8)	21 (0.2)	10 (<0.1)	7 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (<0.1)	162 (1.5)	339 (3.2)	81 (0.8)	21 (0.2)	10 (<0.1)	7 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	10630	10495	10712	10549	10384	10251	10256	10291
Any	3	116	474	742	506	269	122	73
	(<0.1)	(1.1)	(4.4)	(7.0)	(4.9)	(2.6)	(1.2)	(0.7)
Grade 1	2	80	243	281	178	108	51	35
	(<0.1)	(0.8)	(2.3)	(2.7)	(1.7)	(1.1)	(0.5)	(0.3)
Grade 2	1	28	197	342	221	106	49	26
	(<0.1)	(0.3)	(1.8)	(3.2)	(2.1)	(1.0)	(0.5)	(0.3)
Grade 3	0	8	34	119	107	55	22	12
		(<0.1)	(0.3)	(1.1)	(1.0)	(0.5)	(0.2)	(0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	8	34	119	107	55	22	12
		(<0.1)	(0.3)	(1.1)	(1.0)	(0.5)	(0.2)	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	10630	10496	10713	10549	10384	10253	10254	10291
Any	13	432	1019	855	501	268	125	77
	(0.1)	(4.1)	(9.5)	(8.1)	(4.8)	(2.6)	(1.2)	(0.7)
Grade 1	12	271	583	474	281	169	86	56
	(0.1)	(2.6)	(5.4)	(4.5)	(2.7)	(1.6)	(0.8)	(0.5)
Grade 2	1	129	352	296	156	72	29	16
	(<0.1)	(1.2)	(3.3)	(2.8)	(1.5)	(0.7)	(0.3)	(0.2)
Grade 3	0	32	84	85	64	27	10	5
		(0.3)	(0.8)	(0.8)	(0.6)	(0.3)	(<0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	32	84	85	64	27	10	5
		(0.3)	(0.8)	(0.8)	(0.6)	(0.3)	(<0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	10630	10495	10712	10549	10384	10251	10254	10290
Any	61 (0.6)	470 (4.5)	1029 (9.6)	909 (8.6)	683 (6.6)	410 (4.0)	262 (2.6)	167 (1.6)
Grade 1	57 (0.5)	422 (4.0)	850 (7.9)	787 (7.5)	632 (6.1)	384 (3.7)	249 (2.4)	156 (1.5)
Grade 2	2 (<0.1)	38 (0.4)	159 (1.5)	107 (1.0)	43 (0.4)	23 (0.2)	9 (<0.1)	8 (<0.1)
Grade 3	2 (<0.1)	10 (<0.1)	20 (0.2)	15 (0.1)	8 (<0.1)	3 (<0.1)	4 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	10 (<0.1)	20 (0.2)	15 (0.1)	8 (<0.1)	3 (<0.1)	4 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	10660	10523	10729	10563	10418	10284	10285	10314
Any Solicited Systemic Adverse Reactions	418 (3.9)	3835 (36.4)	8215 (76.6)	4925 (46.6)	2797 (26.8)	2009 (19.5)	1588 (15.4)	1271 (12.3)
95% CI	3.6, 4.3	35.5, 37.4	75.8, 77.4	45.7, 47.6	26.0, 27.7	18.8, 20.3	14.7, 16.2	11.7, 13.0
Grade 1	377 (3.5)	2474 (23.5)	2490 (23.2)	3041 (28.8)	2011 (19.3)	1461 (14.2)	1136 (11.0)	900 (8.7)
Grade 2	32 (0.3)	1129 (10.7)	4065 (37.9)	1596 (15.1)	700 (6.7)	467 (4.5)	398 (3.9)	322 (3.1)
Grade 3	9 (<0.1)	228 (2.2)	1654 (15.4)	287 (2.7)	86 (0.8)	80 (0.8)	54 (0.5)	49 (0.5)
Grade 4	0	4 (<0.1)	6 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	0
Grade 3 or Above	9 (<0.1)	232 (2.2)	1660 (15.5)	288 (2.7)	86 (0.8)	81 (0.8)	54 (0.5)	49 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	10640	10395	10621	10415	10174	9965	9957	9983
Any	1 (<0.1)	200 (1.9)	1629 (15.3)	266 (2.6)	17 (0.2)	13 (0.1)	9 (<0.1)	5 (<0.1)
Grade 1	1 (<0.1)	133 (1.3)	953 (9.0)	160 (1.5)	7 (<0.1)	6 (<0.1)	7 (<0.1)	4 (<0.1)
Grade 2	0	51 (0.5)	510 (4.8)	83 (0.8)	7 (<0.1)	4 (<0.1)	2 (<0.1)	1 (<0.1)
Grade 3	0	12 (0.1)	160 (1.5)	22 (0.2)	3 (<0.1)	2 (<0.1)	0	0
Grade 4	0	4 (<0.1)	6 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	0
Grade 3 or Above	0	16 (0.2)	166 (1.6)	23 (0.2)	3 (<0.1)	3 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	10602	10493	10708	10539	10390	10255	10260	10292
Any	220	1984	5852	2782	1523	1159	940	755
	(2.1)	(18.9)	(54.7)	(26.4)	(14.7)	(11.3)	(9.2)	(7.3)
Grade 1	208	1583	3139	1973	1165	890	708	566
	(2.0)	(15.1)	(29.3)	(18.7)	(11.2)	(8.7)	(6.9)	(5.5)
Grade 2	6	323	2300	720	313	221	205	161
	(<0.1)	(3.1)	(21.5)	(6.8)	(3.0)	(2.2)	(2.0)	(1.6)
Grade 3	6	78	413	89	45	48	27	28
	(<0.1)	(0.7)	(3.9)	(0.8)	(0.4)	(0.5)	(0.3)	(0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6	78	413	89	45	48	27	28
	(<0.1)	(0.7)	(3.9)	(0.8)	(0.4)	(0.5)	(0.3)	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	10602	10499	10707	10539	10390	10258	10264	10299
Any	191 (1.8)	2589 (24.7)	6646 (62.1)	3512 (33.3)	1704 (16.4)	1188 (11.6)	899 (8.8)	681 (6.6)
Grade 1	176 (1.7)	1681 (16.0)	2302 (21.5)	2244 (21.3)	1228 (11.8)	895 (8.7)	660 (6.4)	496 (4.8)
Grade 2	15 (0.1)	796 (7.6)	3310 (30.9)	1109 (10.5)	442 (4.3)	265 (2.6)	215 (2.1)	166 (1.6)
Grade 3	0	112 (1.1)	1034 (9.7)	159 (1.5)	34 (0.3)	28 (0.3)	24 (0.2)	19 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	112 (1.1)	1034 (9.7)	159 (1.5)	34 (0.3)	28 (0.3)	24 (0.2)	19 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	10602	10496	10707	10540	10383	10251	10255	10291
Any	73 (0.7)	1739 (16.6)	6144 (57.4)	2825 (26.8)	1058 (10.2)	584 (5.7)	418 (4.1)	327 (3.2)
Grade 1	67 (0.6)	1054 (10.0)	2211 (20.7)	1892 (18.0)	798 (7.7)	453 (4.4)	312 (3.0)	234 (2.3)
Grade 2	5 (<0.1)	578 (5.5)	2948 (27.5)	808 (7.7)	238 (2.3)	117 (1.1)	97 (0.9)	86 (0.8)
Grade 3	1 (<0.1)	107 (1.0)	985 (9.2)	125 (1.2)	22 (0.2)	14 (0.1)	9 (<0.1)	7 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	107 (1.0)	985 (9.2)	125 (1.2)	22 (0.2)	14 (0.1)	9 (<0.1)	7 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	10602	10496	10707	10539	10383	10253	10255	10289
Any	81 (0.8)	1162 (11.1)	4415 (41.2)	2046 (19.4)	880 (8.5)	537 (5.2)	395 (3.9)	328 (3.2)
Grade 1	68 (0.6)	747 (7.1)	1867 (17.4)	1382 (13.1)	679 (6.5)	421 (4.1)	300 (2.9)	249 (2.4)
Grade 2	11 (0.1)	353 (3.4)	1999 (18.7)	574 (5.4)	187 (1.8)	110 (1.1)	88 (0.9)	76 (0.7)
Grade 3	2 (<0.1)	62 (0.6)	549 (5.1)	90 (0.9)	14 (0.1)	6 (<0.1)	7 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	62 (0.6)	549 (5.1)	90 (0.9)	14 (0.1)	6 (<0.1)	7 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	10602	10492	10706	10538	10381	10246	10250	10286
Any	27	453	1769	661	343	224	181	136
	(0.3)	(4.3)	(16.5)	(6.3)	(3.3)	(2.2)	(1.8)	(1.3)
Grade 1	22	375	1347	549	287	167	144	103
	(0.2)	(3.6)	(12.6)	(5.2)	(2.8)	(1.6)	(1.4)	(1.0)
Grade 2	5	74	417	109	54	55	36	31
	(<0.1)	(0.7)	(3.9)	(1.0)	(0.5)	(0.5)	(0.4)	(0.3)
Grade 3	0	4	5	3	2	2	1	2
		(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	4	5	3	2	2	1	2
		(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11000)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	10602	10492	10706	10538	10382	10246	10252	10286
Any	34 (0.3)	966 (9.2)	4747 (44.3)	1221 (11.6)	315 (3.0)	164 (1.6)	133 (1.3)	105 (1.0)
Grade 1	32 (0.3)	629 (6.0)	2062 (19.3)	802 (7.6)	244 (2.4)	127 (1.2)	100 (1.0)	82 (0.8)
Grade 2	2 (<0.1)	322 (3.1)	2547 (23.8)	396 (3.8)	67 (0.6)	36 (0.4)	32 (0.3)	21 (0.2)
Grade 3	0	15 (0.1)	138 (1.3)	23 (0.2)	4 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	15 (0.1)	138 (1.3)	23 (0.2)	4 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	3478	3392	3514	3505	3502	3467	3473	3487
Any Solicited Adverse Reactions	242 (7.0)	547 (16.1)	635 (18.1)	528 (15.1)	475 (13.6)	390 (11.2)	393 (11.3)	342 (9.8)
95% CI	6.1, 7.9	14.9, 17.4	16.8, 19.4	13.9, 16.3	12.4, 14.7	10.2, 12.3	10.3, 12.4	8.8, 10.8
Grade 1	213 (6.1)	453 (13.4)	512 (14.6)	433 (12.4)	382 (10.9)	305 (8.8)	316 (9.1)	265 (7.6)
Grade 2	6 (0.2)	80 (2.4)	108 (3.1)	84 (2.4)	81 (2.3)	79 (2.3)	70 (2.0)	67 (1.9)
Grade 3	23 (0.7)	14 (0.4)	14 (0.4)	11 (0.3)	12 (0.3)	5 (0.1)	7 (0.2)	10 (0.3)
Grade 4	0	0	1 (<0.1)	0	0	1 (<0.1)	0	0
Grade 3 or Above	23 (0.7)	14 (0.4)	15 (0.4)	11 (0.3)	12 (0.3)	6 (0.2)	7 (0.2)	10 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	3461	3381	3506	3495	3492	3453	3461	3479
Any Solicited Local Adverse Reactions	137 (4.0)	201 (5.9)	201 (5.7)	137 (3.9)	108 (3.1)	59 (1.7)	60 (1.7)	46 (1.3)
95% CI	3.3, 4.7	5.2, 6.8	5.0, 6.6	3.3, 4.6	2.5, 3.7	1.3, 2.2	1.3, 2.2	1.0, 1.8
Grade 1	122 (3.5)	192 (5.7)	192 (5.5)	132 (3.8)	101 (2.9)	54 (1.6)	56 (1.6)	42 (1.2)
Grade 2	2 (<0.1)	2 (<0.1)	5 (0.1)	3 (<0.1)	4 (0.1)	4 (0.1)	3 (<0.1)	2 (<0.1)
Grade 3	13 (0.4)	7 (0.2)	4 (0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	13 (0.4)	7 (0.2)	4 (0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	3461	3381	3506	3495	3492	3453	3461	3479
Any	129 (3.7)	183 (5.4)	163 (4.6)	107 (3.1)	81 (2.3)	38 (1.1)	36 (1.0)	26 (0.7)
Grade 1	117 (3.4)	177 (5.2)	159 (4.5)	104 (3.0)	77 (2.2)	34 (1.0)	32 (0.9)	22 (0.6)
Grade 2	2 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	4 (0.1)	3 (<0.1)	2 (<0.1)
Grade 3	10 (0.3)	4 (0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	10 (0.3)	4 (0.1)	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	3461	3381	3506	3495	3492	3452	3461	3479
Any	1 (<0.1)	8 (0.2)	4 (0.1)	6 (0.2)	3 (<0.1)	4 (0.1)	5 (0.1)	4 (0.1)
Grade 1	1 (<0.1)	7 (0.2)	4 (0.1)	5 (0.1)	3 (<0.1)	3 (<0.1)	5 (0.1)	4 (0.1)
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	3461	3381	3506	3495	3492	3452	3461	3479
Any	3 (<0.1)	7 (0.2)	8 (0.2)	5 (0.1)	5 (0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)
Grade 1	2 (<0.1)	5 (0.1)	4 (0.1)	4 (0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)
Grade 2	0	0	2 (<0.1)	0	0	0	0	0
Grade 3	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	3461	3381	3506	3495	3492	3452	3461	3479
Any	14 (0.4)	25 (0.7)	42 (1.2)	36 (1.0)	30 (0.9)	21 (0.6)	26 (0.8)	17 (0.5)
Grade 1	9 (0.3)	24 (0.7)	41 (1.2)	36 (1.0)	28 (0.8)	21 (0.6)	26 (0.8)	17 (0.5)
Grade 2	0	0	0	0	1 (<0.1)	0	0	0
Grade 3	5 (0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	5 (0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	3477	3392	3514	3505	3502	3466	3472	3487
Any Solicited Systemic Adverse Reactions	126 (3.6)	429 (12.6)	536 (15.3)	452 (12.9)	415 (11.9)	362 (10.4)	366 (10.5)	321 (9.2)
95% CI	3.0, 4.3	11.5, 13.8	14.1, 16.5	11.8, 14.1	10.8, 13.0	9.4, 11.5	9.5, 11.6	8.3, 10.2
Grade 1	109 (3.1)	344 (10.1)	422 (12.0)	362 (10.3)	324 (9.3)	280 (8.1)	291 (8.4)	247 (7.1)
Grade 2	4 (0.1)	78 (2.3)	103 (2.9)	81 (2.3)	82 (2.3)	77 (2.2)	69 (2.0)	66 (1.9)
Grade 3	13 (0.4)	7 (0.2)	10 (0.3)	9 (0.3)	9 (0.3)	4 (0.1)	6 (0.2)	8 (0.2)
Grade 4	0	0	1 (<0.1)	0	0	1 (<0.1)	0	0
Grade 3 or Above	13 (0.4)	7 (0.2)	11 (0.3)	9 (0.3)	9 (0.3)	5 (0.1)	6 (0.2)	8 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	3465	3358	3487	3467	3466	3421	3425	3439
Any	0	0	2 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	0
Grade 1	0	0	0	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0
Grade 2	0	0	1 (<0.1)	0	1 (<0.1)	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	1 (<0.1)	0	0	1 (<0.1)	0	0
Grade 3 or Above	0	0	1 (<0.1)	0	0	1 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	3450	3372	3492	3491	3483	3449	3451	3474
Any	57 (1.7)	170 (5.0)	249 (7.1)	194 (5.6)	154 (4.4)	141 (4.1)	147 (4.3)	126 (3.6)
Grade 1	46 (1.3)	151 (4.5)	231 (6.6)	174 (5.0)	138 (4.0)	120 (3.5)	122 (3.5)	103 (3.0)
Grade 2	1 (<0.1)	15 (0.4)	15 (0.4)	15 (0.4)	14 (0.4)	18 (0.5)	23 (0.7)	18 (0.5)
Grade 3	10 (0.3)	4 (0.1)	3 (<0.1)	5 (0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	5 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	10 (0.3)	4 (0.1)	3 (<0.1)	5 (0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	5 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	3450	3371	3494	3492	3486	3448	3454	3476
Any	49 (1.4)	267 (7.9)	331 (9.5)	268 (7.7)	261 (7.5)	217 (6.3)	216 (6.3)	183 (5.3)
Grade 1	43 (1.2)	207 (6.1)	246 (7.0)	210 (6.0)	199 (5.7)	168 (4.9)	177 (5.1)	138 (4.0)
Grade 2	2 (<0.1)	59 (1.8)	81 (2.3)	55 (1.6)	57 (1.6)	48 (1.4)	37 (1.1)	42 (1.2)
Grade 3	4 (0.1)	1 (<0.1)	4 (0.1)	3 (<0.1)	5 (0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (0.1)	1 (<0.1)	4 (0.1)	3 (<0.1)	5 (0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	3450	3373	3492	3491	3484	3448	3454	3474
Any	33 (1.0)	95 (2.8)	177 (5.1)	154 (4.4)	141 (4.0)	130 (3.8)	120 (3.5)	90 (2.6)
Grade 1	30 (0.9)	80 (2.4)	150 (4.3)	127 (3.6)	117 (3.4)	108 (3.1)	98 (2.8)	68 (2.0)
Grade 2	2 (<0.1)	14 (0.4)	25 (0.7)	25 (0.7)	20 (0.6)	22 (0.6)	21 (0.6)	22 (0.6)
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	4 (0.1)	0	1 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	4 (0.1)	0	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	3450	3372	3492	3492	3484	3450	3453	3475
Any	42 (1.2)	104 (3.1)	179 (5.1)	155 (4.4)	159 (4.6)	136 (3.9)	144 (4.2)	124 (3.6)
Grade 1	37 (1.1)	91 (2.7)	150 (4.3)	132 (3.8)	137 (3.9)	112 (3.2)	117 (3.4)	97 (2.8)
Grade 2	2 (<0.1)	13 (0.4)	27 (0.8)	23 (0.7)	20 (0.6)	24 (0.7)	27 (0.8)	27 (0.8)
Grade 3	3 (<0.1)	0	2 (<0.1)	0	2 (<0.1)	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	0	2 (<0.1)	0	2 (<0.1)	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	3450	3370	3492	3491	3483	3447	3451	3474
Any	9 (0.3)	25 (0.7)	38 (1.1)	32 (0.9)	25 (0.7)	20 (0.6)	25 (0.7)	25 (0.7)
Grade 1	7 (0.2)	25 (0.7)	36 (1.0)	26 (0.7)	17 (0.5)	14 (0.4)	19 (0.6)	23 (0.7)
Grade 2	1 (<0.1)	0	2 (<0.1)	5 (0.1)	8 (0.2)	6 (0.2)	5 (0.1)	2 (<0.1)
Grade 3	1 (<0.1)	0	0	1 (<0.1)	0	0	1 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	0	0	1 (<0.1)	0	0	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3649)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	3450	3370	3492	3491	3483	3447	3452	3474
Any	12 (0.3)	36 (1.1)	52 (1.5)	33 (0.9)	28 (0.8)	26 (0.8)	33 (1.0)	23 (0.7)
Grade 1	11 (0.3)	32 (0.9)	44 (1.3)	27 (0.8)	24 (0.7)	24 (0.7)	29 (0.8)	20 (0.6)
Grade 2	1 (<0.1)	3 (<0.1)	8 (0.2)	6 (0.2)	4 (0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)
Grade 3	0	1 (<0.1)	0	0	0	0	1 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	1 (<0.1)	0	0	0	0	1 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	3517	3507	3619	3584	3569	3533	3552	3531
Any Solicited Adverse Reactions	238 (6.8)	1943 (55.4)	3111 (86.0)	2271 (63.4)	1450 (40.6)	923 (26.1)	692 (19.5)	523 (14.8)
95% CI	6.0, 7.6	53.7, 57.1	84.8, 87.1	61.8, 64.9	39.0, 42.3	24.7, 27.6	18.2, 20.8	13.7, 16.0
Grade 1	218 (6.2)	1638 (46.7)	1616 (44.7)	1691 (47.2)	1148 (32.2)	721 (20.4)	530 (14.9)	393 (11.1)
Grade 2	3 (<0.1)	237 (6.8)	1092 (30.2)	456 (12.7)	234 (6.6)	155 (4.4)	132 (3.7)	103 (2.9)
Grade 3	17 (0.5)	66 (1.9)	402 (11.1)	123 (3.4)	67 (1.9)	46 (1.3)	29 (0.8)	26 (0.7)
Grade 4	0	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	17 (0.5)	68 (1.9)	403 (11.1)	124 (3.5)	68 (1.9)	47 (1.3)	30 (0.8)	27 (0.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	3474	3490	3611	3575	3561	3522	3545	3521
Any Solicited Local Adverse Reactions	162 (4.7)	1728 (49.5)	2865 (79.3)	1984 (55.5)	1171 (32.9)	603 (17.1)	338 (9.5)	186 (5.3)
95% CI	4.0, 5.4	47.8, 51.2	78.0, 80.7	53.8, 57.1	31.3, 34.5	15.9, 18.4	8.6, 10.5	4.6, 6.1
Grade 1	151 (4.3)	1614 (46.2)	2314 (64.1)	1699 (47.5)	1014 (28.5)	510 (14.5)	285 (8.0)	152 (4.3)
Grade 2	0	81 (2.3)	430 (11.9)	207 (5.8)	105 (2.9)	62 (1.8)	34 (1.0)	24 (0.7)
Grade 3	11 (0.3)	33 (0.9)	121 (3.4)	78 (2.2)	52 (1.5)	31 (0.9)	19 (0.5)	10 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	11 (0.3)	33 (0.9)	121 (3.4)	78 (2.2)	52 (1.5)	31 (0.9)	19 (0.5)	10 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	3474	3488	3611	3575	3561	3521	3545	3519
Any	154 (4.4)	1701 (48.8)	2851 (79.0)	1937 (54.2)	1083 (30.4)	515 (14.6)	258 (7.3)	120 (3.4)
Grade 1	145 (4.2)	1617 (46.4)	2431 (67.3)	1830 (51.2)	1053 (29.6)	501 (14.2)	245 (6.9)	111 (3.2)
Grade 2	0	60 (1.7)	350 (9.7)	96 (2.7)	27 (0.8)	12 (0.3)	10 (0.3)	7 (0.2)
Grade 3	9 (0.3)	24 (0.7)	70 (1.9)	11 (0.3)	3 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	9 (0.3)	24 (0.7)	70 (1.9)	11 (0.3)	3 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	3474	3489	3611	3574	3560	3520	3543	3518
Any	1 (<0.1)	36 (1.0)	145 (4.0)	210 (5.9)	171 (4.8)	107 (3.0)	73 (2.1)	53 (1.5)
Grade 1	1 (<0.1)	26 (0.7)	75 (2.1)	66 (1.8)	68 (1.9)	47 (1.3)	40 (1.1)	28 (0.8)
Grade 2	0	5 (0.1)	45 (1.2)	100 (2.8)	68 (1.9)	37 (1.1)	22 (0.6)	19 (0.5)
Grade 3	0	5 (0.1)	25 (0.7)	44 (1.2)	35 (1.0)	23 (0.7)	11 (0.3)	6 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	5 (0.1)	25 (0.7)	44 (1.2)	35 (1.0)	23 (0.7)	11 (0.3)	6 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	3474	3489	3611	3574	3560	3519	3543	3518
Any	4 (0.1)	102 (2.9)	296 (8.2)	256 (7.2)	174 (4.9)	101 (2.9)	53 (1.5)	34 (1.0)
Grade 1	4 (0.1)	74 (2.1)	155 (4.3)	138 (3.9)	95 (2.7)	57 (1.6)	33 (0.9)	25 (0.7)
Grade 2	0	23 (0.7)	101 (2.8)	80 (2.2)	53 (1.5)	35 (1.0)	16 (0.5)	7 (0.2)
Grade 3	0	5 (0.1)	40 (1.1)	38 (1.1)	26 (0.7)	9 (0.3)	4 (0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	5 (0.1)	40 (1.1)	38 (1.1)	26 (0.7)	9 (0.3)	4 (0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	3474	3488	3611	3574	3560	3519	3542	3517
Any	15 (0.4)	65 (1.9)	182 (5.0)	113 (3.2)	81 (2.3)	46 (1.3)	33 (0.9)	23 (0.7)
Grade 1	10 (0.3)	58 (1.7)	152 (4.2)	102 (2.9)	78 (2.2)	43 (1.2)	31 (0.9)	21 (0.6)
Grade 2	0	2 (<0.1)	24 (0.7)	7 (0.2)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3	5 (0.1)	5 (0.1)	6 (0.2)	4 (0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	5 (0.1)	5 (0.1)	6 (0.2)	4 (0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	3517	3504	3619	3584	3568	3533	3550	3527
Any Solicited Systemic Adverse Reactions	102 (2.9)	925 (26.4)	2377 (65.7)	1225 (34.2)	734 (20.6)	550 (15.6)	479 (13.5)	402 (11.4)
95% CI	2.4, 3.5	24.9, 27.9	64.1, 67.2	32.6, 35.8	19.3, 21.9	14.4, 16.8	12.4, 14.7	10.4, 12.5
Grade 1	90 (2.6)	682 (19.5)	1024 (28.3)	827 (23.1)	563 (15.8)	428 (12.1)	360 (10.1)	298 (8.4)
Grade 2	3 (<0.1)	195 (5.6)	1024 (28.3)	347 (9.7)	153 (4.3)	105 (3.0)	107 (3.0)	86 (2.4)
Grade 3	9 (0.3)	46 (1.3)	328 (9.1)	50 (1.4)	17 (0.5)	16 (0.5)	11 (0.3)	17 (0.5)
Grade 4	0	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	9 (0.3)	48 (1.4)	329 (9.1)	51 (1.4)	18 (0.5)	17 (0.5)	12 (0.3)	18 (0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	3511	3476	3603	3556	3532	3501	3498	3465
Any	1 (<0.1)	29 (0.8)	325 (9.0)	31 (0.9)	2 (<0.1)	0	1 (<0.1)	0
Grade 1	1 (<0.1)	19 (0.5)	228 (6.3)	20 (0.6)	1 (<0.1)	0	0	0
Grade 2	0	8 (0.2)	81 (2.2)	9 (0.3)	1 (<0.1)	0	1 (<0.1)	0
Grade 3	0	1 (<0.1)	16 (0.4)	2 (<0.1)	0	0	0	0
Grade 4	0	1 (<0.1)	0	0	0	0	0	0
Grade 3 or Above	0	2 (<0.1)	16 (0.4)	2 (<0.1)	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	3458	3477	3599	3571	3554	3512	3536	3512
Any	45 (1.3)	419 (12.1)	1409 (39.1)	532 (14.9)	277 (7.8)	200 (5.7)	211 (6.0)	151 (4.3)
Grade 1	37 (1.1)	353 (10.2)	935 (26.0)	430 (12.0)	236 (6.6)	167 (4.8)	174 (4.9)	122 (3.5)
Grade 2	0	49 (1.4)	401 (11.1)	88 (2.5)	38 (1.1)	27 (0.8)	33 (0.9)	23 (0.7)
Grade 3	8 (0.2)	17 (0.5)	73 (2.0)	14 (0.4)	3 (<0.1)	6 (0.2)	4 (0.1)	6 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	8 (0.2)	17 (0.5)	73 (2.0)	14 (0.4)	3 (<0.1)	6 (0.2)	4 (0.1)	6 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	3458	3479	3600	3571	3556	3515	3536	3512
Any	40 (1.2)	582 (16.7)	1908 (53.0)	866 (24.3)	515 (14.5)	381 (10.8)	296 (8.4)	242 (6.9)
Grade 1	36 (1.0)	421 (12.1)	827 (23.0)	567 (15.9)	381 (10.7)	295 (8.4)	217 (6.1)	178 (5.1)
Grade 2	0	135 (3.9)	866 (24.1)	268 (7.5)	124 (3.5)	80 (2.3)	72 (2.0)	57 (1.6)
Grade 3	4 (0.1)	26 (0.7)	215 (6.0)	31 (0.9)	10 (0.3)	6 (0.2)	7 (0.2)	7 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (0.1)	26 (0.7)	215 (6.0)	31 (0.9)	10 (0.3)	6 (0.2)	7 (0.2)	7 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	3458	3478	3600	3570	3555	3514	3536	3511
Any	29 (0.8)	388 (11.2)	1546 (42.9)	588 (16.5)	282 (7.9)	194 (5.5)	134 (3.8)	107 (3.0)
Grade 1	24 (0.7)	273 (7.8)	745 (20.7)	434 (12.2)	225 (6.3)	161 (4.6)	103 (2.9)	77 (2.2)
Grade 2	2 (<0.1)	94 (2.7)	626 (17.4)	130 (3.6)	53 (1.5)	26 (0.7)	29 (0.8)	27 (0.8)
Grade 3	3 (<0.1)	21 (0.6)	175 (4.9)	24 (0.7)	4 (0.1)	7 (0.2)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	21 (0.6)	175 (4.9)	24 (0.7)	4 (0.1)	7 (0.2)	2 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	3458	3478	3601	3570	3555	3514	3537	3512
Any	38 (1.1)	302 (8.7)	1089 (30.2)	460 (12.9)	266 (7.5)	200 (5.7)	153 (4.3)	139 (4.0)
Grade 1	32 (0.9)	226 (6.5)	580 (16.1)	354 (9.9)	220 (6.2)	166 (4.7)	120 (3.4)	101 (2.9)
Grade 2	3 (<0.1)	63 (1.8)	404 (11.2)	90 (2.5)	42 (1.2)	29 (0.8)	31 (0.9)	33 (0.9)
Grade 3	3 (<0.1)	13 (0.4)	105 (2.9)	16 (0.4)	4 (0.1)	5 (0.1)	2 (<0.1)	5 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	13 (0.4)	105 (2.9)	16 (0.4)	4 (0.1)	5 (0.1)	2 (<0.1)	5 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	3458	3474	3599	3570	3554	3512	3534	3510
Any	11 (0.3)	77 (2.2)	316 (8.8)	101 (2.8)	57 (1.6)	30 (0.9)	38 (1.1)	25 (0.7)
Grade 1	7 (0.2)	64 (1.8)	248 (6.9)	79 (2.2)	44 (1.2)	21 (0.6)	29 (0.8)	15 (0.4)
Grade 2	0	10 (0.3)	66 (1.8)	19 (0.5)	12 (0.3)	7 (0.2)	8 (0.2)	5 (0.1)
Grade 3	4 (0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	0	4 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	4 (0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	5 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group, Grade and Day of Reporting
Second Injection Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3691)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	3458	3474	3599	3570	3554	3512	3534	3511
Any	13 (0.4)	170 (4.9)	982 (27.3)	203 (5.7)	61 (1.7)	31 (0.9)	26 (0.7)	28 (0.8)
Grade 1	9 (0.3)	111 (3.2)	505 (14.0)	138 (3.9)	46 (1.3)	22 (0.6)	18 (0.5)	21 (0.6)
Grade 2	0	54 (1.6)	461 (12.8)	63 (1.8)	13 (0.4)	7 (0.2)	7 (0.2)	6 (0.2)
Grade 3	4 (0.1)	5 (0.1)	16 (0.4)	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (0.1)	5 (0.1)	16 (0.4)	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	11368	11199	11304	11286	11250	11237	11255	11250
Any Solicited Adverse Reactions	2238 (19.7)	3796 (33.9)	3912 (34.6)	3354 (29.7)	2917 (25.9)	2673 (23.8)	2499 (22.2)	2251 (20.0)
95% CI	19.0, 20.4	33.0, 34.8	33.7, 35.5	28.9, 30.6	25.1, 26.7	23.0, 24.6	21.4, 23.0	19.3, 20.8
Grade 1	2141 (18.8)	3045 (27.2)	2895 (25.6)	2460 (21.8)	2095 (18.6)	1961 (17.5)	1790 (15.9)	1597 (14.2)
Grade 2	70 (0.6)	661 (5.9)	889 (7.9)	767 (6.8)	717 (6.4)	602 (5.4)	610 (5.4)	572 (5.1)
Grade 3	27 (0.2)	90 (0.8)	127 (1.1)	124 (1.1)	103 (0.9)	109 (1.0)	99 (0.9)	82 (0.7)
Grade 4	0	0	1 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	27 (0.2)	90 (0.8)	128 (1.1)	127 (1.1)	105 (0.9)	110 (1.0)	99 (0.9)	82 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	11357	11174	11292	11279	11241	11227	11248	11242
Any Solicited Local Adverse Reactions	1749 (15.4)	1766 (15.8)	1406 (12.5)	958 (8.5)	667 (5.9)	579 (5.2)	463 (4.1)	335 (3.0)
95% CI	14.7, 16.1	15.1, 16.5	11.8, 13.1	8.0, 9.0	5.5, 6.4	4.8, 5.6	3.8, 4.5	2.7, 3.3
Grade 1	1720 (15.1)	1708 (15.3)	1341 (11.9)	900 (8.0)	622 (5.5)	541 (4.8)	423 (3.8)	297 (2.6)
Grade 2	10 (<0.1)	37 (0.3)	51 (0.5)	41 (0.4)	30 (0.3)	25 (0.2)	26 (0.2)	29 (0.3)
Grade 3	19 (0.2)	21 (0.2)	14 (0.1)	17 (0.2)	15 (0.1)	13 (0.1)	14 (0.1)	9 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	19 (0.2)	21 (0.2)	14 (0.1)	17 (0.2)	15 (0.1)	13 (0.1)	14 (0.1)	9 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	11357	11174	11291	11279	11241	11227	11248	11241
Any	1700 (15.0)	1633 (14.6)	1224 (10.8)	765 (6.8)	463 (4.1)	381 (3.4)	288 (2.6)	185 (1.6)
Grade 1	1678 (14.8)	1596 (14.3)	1181 (10.5)	730 (6.5)	436 (3.9)	361 (3.2)	266 (2.4)	162 (1.4)
Grade 2	8 (<0.1)	26 (0.2)	34 (0.3)	26 (0.2)	22 (0.2)	14 (0.1)	17 (0.2)	19 (0.2)
Grade 3	14 (0.1)	11 (<0.1)	9 (<0.1)	9 (<0.1)	5 (<0.1)	6 (<0.1)	5 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	14 (0.1)	11 (<0.1)	9 (<0.1)	9 (<0.1)	5 (<0.1)	6 (<0.1)	5 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	11357	11173	11291	11279	11241	11227	11248	11241
Any	9 (<0.1)	44 (0.4)	37 (0.3)	34 (0.3)	33 (0.3)	28 (0.2)	31 (0.3)	27 (0.2)
Grade 1	5 (<0.1)	33 (0.3)	28 (0.2)	25 (0.2)	26 (0.2)	22 (0.2)	24 (0.2)	23 (0.2)
Grade 2	0	5 (<0.1)	6 (<0.1)	4 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)
Grade 3	4 (<0.1)	6 (<0.1)	3 (<0.1)	5 (<0.1)	4 (<0.1)	3 (<0.1)	4 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	6 (<0.1)	3 (<0.1)	5 (<0.1)	4 (<0.1)	3 (<0.1)	4 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	11357	11173	11291	11279	11241	11227	11248	11242
Any	17 (0.1)	40 (0.4)	40 (0.4)	32 (0.3)	28 (0.2)	35 (0.3)	33 (0.3)	35 (0.3)
Grade 1	12 (0.1)	33 (0.3)	31 (0.3)	26 (0.2)	22 (0.2)	27 (0.2)	26 (0.2)	29 (0.3)
Grade 2	3 (<0.1)	6 (<0.1)	6 (<0.1)	5 (<0.1)	4 (<0.1)	5 (<0.1)	4 (<0.1)	4 (<0.1)
Grade 3	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	11357	11173	11292	11279	11241	11227	11248	11241
Any	120 (1.1)	253 (2.3)	315 (2.8)	297 (2.6)	242 (2.2)	224 (2.0)	193 (1.7)	147 (1.3)
Grade 1	114 (1.0)	240 (2.1)	304 (2.7)	277 (2.5)	228 (2.0)	210 (1.9)	181 (1.6)	138 (1.2)
Grade 2	0	7 (<0.1)	9 (<0.1)	14 (0.1)	9 (<0.1)	9 (<0.1)	8 (<0.1)	7 (<0.1)
Grade 3	6 (<0.1)	6 (<0.1)	2 (<0.1)	6 (<0.1)	5 (<0.1)	5 (<0.1)	4 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (<0.1)	6 (<0.1)	2 (<0.1)	6 (<0.1)	5 (<0.1)	5 (<0.1)	4 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	11366	11198	11303	11286	11250	11235	11255	11249
Any Solicited Systemic Adverse Reactions	875 (7.7)	3053 (27.3)	3434 (30.4)	3007 (26.6)	2661 (23.7)	2426 (21.6)	2301 (20.4)	2102 (18.7)
95% CI	7.2, 8.2	26.4, 28.1	29.5, 31.2	25.8, 27.5	22.9, 24.4	20.8, 22.4	19.7, 21.2	18.0, 19.4
Grade 1	800 (7.0)	2336 (20.9)	2447 (21.6)	2142 (19.0)	1862 (16.6)	1735 (15.4)	1611 (14.3)	1468 (13.1)
Grade 2	62 (0.5)	644 (5.8)	871 (7.7)	752 (6.7)	705 (6.3)	591 (5.3)	603 (5.4)	561 (5.0)
Grade 3	13 (0.1)	73 (0.7)	115 (1.0)	110 (1.0)	92 (0.8)	99 (0.9)	87 (0.8)	73 (0.6)
Grade 4	0	0	1 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	13 (0.1)	73 (0.7)	116 (1.0)	113 (1.0)	94 (0.8)	100 (0.9)	87 (0.8)	73 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301020203.sas 21JUN2021 16:53

Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	11356	11137	11259	11218	11162	11132	11151	11143
Any	3 (<0.1)	6 (<0.1)	13 (0.1)	16 (0.1)	13 (0.1)	15 (0.1)	15 (0.1)	11 (<0.1)
Grade 1	3 (<0.1)	4 (<0.1)	9 (<0.1)	9 (<0.1)	9 (<0.1)	11 (<0.1)	12 (0.1)	9 (<0.1)
Grade 2	0	2 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)	3 (<0.1)	0	2 (<0.1)
Grade 3	0	0	0	1 (<0.1)	1 (<0.1)	0	3 (<0.1)	0
Grade 4	0	0	1 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	0	0
Grade 3 or Above	0	0	1 (<0.1)	4 (<0.1)	3 (<0.1)	1 (<0.1)	3 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	11344	11166	11288	11277	11238	11224	11246	11240
Any	465 (4.1)	1657 (14.8)	1939 (17.2)	1682 (14.9)	1461 (13.0)	1274 (11.4)	1271 (11.3)	1157 (10.3)
Grade 1	445 (3.9)	1480 (13.3)	1632 (14.5)	1357 (12.0)	1167 (10.4)	997 (8.9)	990 (8.8)	900 (8.0)
Grade 2	8 (<0.1)	137 (1.2)	244 (2.2)	259 (2.3)	241 (2.1)	218 (1.9)	238 (2.1)	219 (1.9)
Grade 3	12 (0.1)	40 (0.4)	63 (0.6)	66 (0.6)	53 (0.5)	59 (0.5)	43 (0.4)	38 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	12 (0.1)	40 (0.4)	63 (0.6)	66 (0.6)	53 (0.5)	59 (0.5)	43 (0.4)	38 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	11344	11170	11289	11276	11237	11224	11249	11242
Any	334 (2.9)	1939 (17.4)	2236 (19.8)	1901 (16.9)	1569 (14.0)	1447 (12.9)	1334 (11.9)	1140 (10.1)
Grade 1	300 (2.6)	1399 (12.5)	1533 (13.6)	1343 (11.9)	1075 (9.6)	1021 (9.1)	921 (8.2)	769 (6.8)
Grade 2	33 (0.3)	512 (4.6)	658 (5.8)	519 (4.6)	462 (4.1)	393 (3.5)	378 (3.4)	347 (3.1)
Grade 3	1 (<0.1)	28 (0.3)	45 (0.4)	39 (0.3)	32 (0.3)	33 (0.3)	35 (0.3)	24 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	28 (0.3)	45 (0.4)	39 (0.3)	32 (0.3)	33 (0.3)	35 (0.3)	24 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	11344	11171	11287	11276	11237	11223	11247	11242
Any	171 (1.5)	762 (6.8)	1095 (9.7)	948 (8.4)	868 (7.7)	743 (6.6)	714 (6.3)	622 (5.5)
Grade 1	155 (1.4)	620 (5.6)	838 (7.4)	721 (6.4)	640 (5.7)	564 (5.0)	517 (4.6)	440 (3.9)
Grade 2	15 (0.1)	131 (1.2)	245 (2.2)	208 (1.8)	203 (1.8)	162 (1.4)	172 (1.5)	164 (1.5)
Grade 3	1 (<0.1)	11 (<0.1)	12 (0.1)	19 (0.2)	25 (0.2)	17 (0.2)	25 (0.2)	18 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	11 (<0.1)	12 (0.1)	19 (0.2)	25 (0.2)	17 (0.2)	25 (0.2)	18 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	11344	11167	11288	11276	11237	11224	11247	11243
Any	148 (1.3)	576 (5.2)	867 (7.7)	825 (7.3)	776 (6.9)	668 (6.0)	700 (6.2)	583 (5.2)
Grade 1	137 (1.2)	457 (4.1)	670 (5.9)	630 (5.6)	576 (5.1)	502 (4.5)	511 (4.5)	407 (3.6)
Grade 2	10 (<0.1)	106 (0.9)	186 (1.6)	175 (1.6)	179 (1.6)	148 (1.3)	170 (1.5)	161 (1.4)
Grade 3	1 (<0.1)	13 (0.1)	11 (<0.1)	20 (0.2)	21 (0.2)	18 (0.2)	19 (0.2)	15 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	13 (0.1)	11 (<0.1)	20 (0.2)	21 (0.2)	18 (0.2)	19 (0.2)	15 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	11344	11164	11287	11276	11237	11222	11246	11239
Any	76 (0.7)	361 (3.2)	485 (4.3)	423 (3.8)	362 (3.2)	329 (2.9)	322 (2.9)	280 (2.5)
Grade 1	69 (0.6)	321 (2.9)	405 (3.6)	354 (3.1)	299 (2.7)	263 (2.3)	256 (2.3)	229 (2.0)
Grade 2	6 (<0.1)	38 (0.3)	77 (0.7)	68 (0.6)	58 (0.5)	63 (0.6)	63 (0.6)	50 (0.4)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	5 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	5 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: Placebo (N=11408)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	11344	11165	11288	11276	11238	11222	11246	11240
Any	115 (1.0)	343 (3.1)	398 (3.5)	319 (2.8)	277 (2.5)	253 (2.3)	239 (2.1)	205 (1.8)
Grade 1	108 (1.0)	293 (2.6)	309 (2.7)	252 (2.2)	214 (1.9)	196 (1.7)	181 (1.6)	159 (1.4)
Grade 2	5 (<0.1)	48 (0.4)	86 (0.8)	65 (0.6)	56 (0.5)	55 (0.5)	53 (0.5)	43 (0.4)
Grade 3	2 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	7 (<0.1)	2 (<0.1)	5 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	7 (<0.1)	2 (<0.1)	5 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	11368	11248	11349	11322	11280	11268	11262	11261
Any Solicited Adverse Reactions	2193 (19.3)	8966 (79.7)	10590 (93.3)	9019 (79.7)	6053 (53.7)	4048 (35.9)	3156 (28.0)	2669 (23.7)
95% CI	18.6, 20.0	79.0, 80.5	92.8, 93.8	78.9, 80.4	52.7, 54.6	35.0, 36.8	27.2, 28.9	22.9, 24.5
Grade 1	2095 (18.4)	6580 (58.5)	3864 (34.0)	5946 (52.5)	4484 (39.8)	2961 (26.3)	2280 (20.2)	1904 (16.9)
Grade 2	68 (0.6)	1875 (16.7)	4570 (40.3)	2455 (21.7)	1281 (11.4)	871 (7.7)	726 (6.4)	642 (5.7)
Grade 3	30 (0.3)	505 (4.5)	2148 (18.9)	615 (5.4)	287 (2.5)	214 (1.9)	148 (1.3)	123 (1.1)
Grade 4	0	6 (<0.1)	8 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	0
Grade 3 or Above	30 (0.3)	511 (4.5)	2156 (19.0)	618 (5.5)	288 (2.6)	216 (1.9)	150 (1.3)	123 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	11358	11222	11332	11309	11266	11253	11252	11246
Any Solicited Local Adverse Reactions	1695 (14.9)	8560 (76.3)	10354 (91.4)	8368 (74.0)	4765 (42.3)	2247 (20.0)	1210 (10.8)	880 (7.8)
95% CI	14.3, 15.6	75.5, 77.1	90.8, 91.9	73.2, 74.8	41.4, 43.2	19.2, 20.7	10.2, 11.3	7.3, 8.3
Grade 1	1660 (14.6)	7328 (65.3)	6879 (60.7)	6784 (60.0)	4094 (36.3)	1923 (17.1)	1036 (9.2)	753 (6.7)
Grade 2	18 (0.2)	940 (8.4)	2782 (24.5)	1273 (11.3)	495 (4.4)	225 (2.0)	123 (1.1)	97 (0.9)
Grade 3	17 (0.1)	292 (2.6)	693 (6.1)	311 (2.8)	176 (1.6)	99 (0.9)	51 (0.5)	30 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	17 (0.1)	292 (2.6)	693 (6.1)	311 (2.8)	176 (1.6)	99 (0.9)	51 (0.5)	30 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	11358	11222	11332	11309	11265	11253	11251	11244
Any	1635 (14.4)	8512 (75.9)	10314 (91.0)	8246 (72.9)	4476 (39.7)	1851 (16.4)	817 (7.3)	441 (3.9)
Grade 1	1611 (14.2)	7458 (66.5)	7230 (63.8)	7218 (63.8)	4222 (37.5)	1753 (15.6)	762 (6.8)	391 (3.5)
Grade 2	8 (<0.1)	814 (7.3)	2532 (22.3)	897 (7.9)	218 (1.9)	82 (0.7)	45 (0.4)	43 (0.4)
Grade 3	16 (0.1)	240 (2.1)	552 (4.9)	131 (1.2)	36 (0.3)	16 (0.1)	10 (<0.1)	7 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	16 (0.1)	240 (2.1)	552 (4.9)	131 (1.2)	36 (0.3)	16 (0.1)	10 (<0.1)	7 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	11358	11220	11330	11307	11263	11250	11249	11240
Any	11	158	627	884	587	321	152	101
	(<0.1)	(1.4)	(5.5)	(7.8)	(5.2)	(2.9)	(1.4)	(0.9)
Grade 1	7	112	356	369	234	146	76	60
	(<0.1)	(1.0)	(3.1)	(3.3)	(2.1)	(1.3)	(0.7)	(0.5)
Grade 2	4	32	223	383	244	114	53	28
	(<0.1)	(0.3)	(2.0)	(3.4)	(2.2)	(1.0)	(0.5)	(0.2)
Grade 3	0	14	48	132	109	61	23	13
		(0.1)	(0.4)	(1.2)	(1.0)	(0.5)	(0.2)	(0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	14	48	132	109	61	23	13
		(0.1)	(0.4)	(1.2)	(1.0)	(0.5)	(0.2)	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	11358	11220	11330	11307	11264	11250	11250	11240
Any	23	553	1353	1057	609	322	163	109
	(0.2)	(4.9)	(11.9)	(9.3)	(5.4)	(2.9)	(1.4)	(1.0)
Grade 1	20	357	783	600	360	216	117	83
	(0.2)	(3.2)	(6.9)	(5.3)	(3.2)	(1.9)	(1.0)	(0.7)
Grade 2	3	155	450	356	181	75	32	21
	(<0.1)	(1.4)	(4.0)	(3.1)	(1.6)	(0.7)	(0.3)	(0.2)
Grade 3	0	41	120	101	68	31	14	5
		(0.4)	(1.1)	(0.9)	(0.6)	(0.3)	(0.1)	(<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	41	120	101	68	31	14	5
		(0.4)	(1.1)	(0.9)	(0.6)	(0.3)	(0.1)	(<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	11358	11220	11330	11307	11263	11250	11249	11242
Any	128 (1.1)	726 (6.5)	1377 (12.2)	1163 (10.3)	831 (7.4)	542 (4.8)	435 (3.9)	443 (3.9)
Grade 1	117 (1.0)	658 (5.9)	1150 (10.2)	1010 (8.9)	770 (6.8)	502 (4.5)	403 (3.6)	403 (3.6)
Grade 2	5 (<0.1)	53 (0.5)	196 (1.7)	131 (1.2)	52 (0.5)	30 (0.3)	21 (0.2)	31 (0.3)
Grade 3	6 (<0.1)	15 (0.1)	31 (0.3)	22 (0.2)	9 (<0.1)	10 (<0.1)	11 (<0.1)	9 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (<0.1)	15 (0.1)	31 (0.3)	22 (0.2)	9 (<0.1)	10 (<0.1)	11 (<0.1)	9 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	11368	11245	11348	11321	11278	11266	11260	11254
Any Solicited Systemic Adverse Reactions	854 (7.5)	4999 (44.5)	8880 (78.3)	5930 (52.4)	3759 (33.3)	2967 (26.3)	2569 (22.8)	2222 (19.7)
95% CI	7.0, 8.0	43.5, 45.4	77.5, 79.0	51.5, 53.3	32.5, 34.2	25.5, 27.2	22.0, 23.6	19.0, 20.5
Grade 1	783 (6.9)	3227 (28.7)	2818 (24.8)	3603 (31.8)	2636 (23.4)	2094 (18.6)	1811 (16.1)	1535 (13.6)
Grade 2	54 (0.5)	1487 (13.2)	4292 (37.8)	1967 (17.4)	992 (8.8)	749 (6.6)	652 (5.8)	591 (5.3)
Grade 3	17 (0.1)	279 (2.5)	1762 (15.5)	357 (3.2)	130 (1.2)	122 (1.1)	104 (0.9)	96 (0.9)
Grade 4	0	6 (<0.1)	8 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	2 (<0.1)	0
Grade 3 or Above	17 (0.1)	285 (2.5)	1770 (15.6)	360 (3.2)	131 (1.2)	124 (1.1)	106 (0.9)	96 (0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	11362	11203	11302	11254	11181	11126	11121	11107
Any	3 (<0.1)	209 (1.9)	1673 (14.8)	294 (2.6)	25 (0.2)	21 (0.2)	13 (0.1)	9 (<0.1)
Grade 1	3 (<0.1)	138 (1.2)	980 (8.7)	181 (1.6)	12 (0.1)	13 (0.1)	9 (<0.1)	7 (<0.1)
Grade 2	0	53 (0.5)	520 (4.6)	86 (0.8)	10 (<0.1)	5 (<0.1)	2 (<0.1)	1 (<0.1)
Grade 3	0	13 (0.1)	166 (1.5)	25 (0.2)	3 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 4	0	5 (<0.1)	7 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	0
Grade 3 or Above	0	18 (0.2)	173 (1.5)	27 (0.2)	3 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	11350	11217	11332	11307	11262	11250	11253	11239
Any	477	2746	6395	3478	2090	1693	1504	1311
	(4.2)	(24.5)	(56.4)	(30.8)	(18.6)	(15.0)	(13.4)	(11.7)
Grade 1	455	2246	3514	2489	1598	1312	1148	997
	(4.0)	(20.0)	(31.0)	(22.0)	(14.2)	(11.7)	(10.2)	(8.9)
Grade 2	10	393	2390	863	425	316	302	263
	(<0.1)	(3.5)	(21.1)	(7.6)	(3.8)	(2.8)	(2.7)	(2.3)
Grade 3	12	107	491	126	67	65	54	51
	(0.1)	(1.0)	(4.3)	(1.1)	(0.6)	(0.6)	(0.5)	(0.5)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	12	107	491	126	67	65	54	51
	(0.1)	(1.0)	(4.3)	(1.1)	(0.6)	(0.6)	(0.5)	(0.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	11350	11219	11333	11308	11261	11251	11252	11239
Any	363 (3.2)	3422 (30.5)	7180 (63.4)	4266 (37.7)	2345 (20.8)	1798 (16.0)	1498 (13.3)	1232 (11.0)
Grade 1	338 (3.0)	2221 (19.8)	2556 (22.6)	2679 (23.7)	1645 (14.6)	1289 (11.5)	1081 (9.6)	850 (7.6)
Grade 2	23 (0.2)	1070 (9.5)	3564 (31.4)	1397 (12.4)	644 (5.7)	462 (4.1)	375 (3.3)	343 (3.1)
Grade 3	2 (<0.1)	130 (1.2)	1059 (9.3)	189 (1.7)	55 (0.5)	46 (0.4)	41 (0.4)	39 (0.3)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0
Grade 3 or Above	2 (<0.1)	131 (1.2)	1060 (9.4)	190 (1.7)	56 (0.5)	47 (0.4)	42 (0.4)	39 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	11350	11218	11334	11307	11261	11247	11250	11235
Any	164 (1.4)	2217 (19.8)	6560 (57.9)	3296 (29.2)	1387 (12.3)	889 (7.9)	693 (6.2)	579 (5.2)
Grade 1	149 (1.3)	1401 (12.5)	2459 (21.7)	2190 (19.4)	1055 (9.4)	691 (6.1)	519 (4.6)	407 (3.6)
Grade 2	11 (<0.1)	700 (6.2)	3098 (27.3)	959 (8.5)	299 (2.7)	170 (1.5)	155 (1.4)	154 (1.4)
Grade 3	4 (<0.1)	116 (1.0)	1003 (8.8)	147 (1.3)	33 (0.3)	28 (0.2)	19 (0.2)	18 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (<0.1)	116 (1.0)	1003 (8.8)	147 (1.3)	33 (0.3)	28 (0.2)	19 (0.2)	18 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	11350	11217	11333	11308	11260	11249	11251	11234
Any	149 (1.3)	1468 (13.1)	4719 (41.6)	2409 (21.3)	1166 (10.4)	784 (7.0)	643 (5.7)	551 (4.9)
Grade 1	127 (1.1)	975 (8.7)	2063 (18.2)	1622 (14.3)	897 (8.0)	609 (5.4)	492 (4.4)	398 (3.5)
Grade 2	18 (0.2)	425 (3.8)	2090 (18.4)	679 (6.0)	249 (2.2)	158 (1.4)	137 (1.2)	140 (1.2)
Grade 3	4 (<0.1)	67 (0.6)	565 (5.0)	107 (0.9)	19 (0.2)	17 (0.2)	14 (0.1)	13 (0.1)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	0
Grade 3 or Above	4 (<0.1)	68 (0.6)	566 (5.0)	108 (1.0)	20 (0.2)	17 (0.2)	14 (0.1)	13 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	11350	11217	11332	11306	11260	11246	11250	11233
Any	58 (0.5)	630 (5.6)	2013 (17.8)	900 (8.0)	525 (4.7)	366 (3.3)	324 (2.9)	254 (2.3)
Grade 1	51 (0.4)	535 (4.8)	1541 (13.6)	749 (6.6)	435 (3.9)	286 (2.5)	272 (2.4)	205 (1.8)
Grade 2	5 (<0.1)	90 (0.8)	466 (4.1)	147 (1.3)	87 (0.8)	78 (0.7)	51 (0.5)	46 (0.4)
Grade 3	2 (<0.1)	5 (<0.1)	6 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	5 (<0.1)	6 (<0.1)	4 (<0.1)	3 (<0.1)	2 (<0.1)	1 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=18 and <65 Years; Treatment Group: mRNA-1273 (N=11413)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	11350	11217	11332	11306	11260	11247	11250	11234
Any	94 (0.8)	1143 (10.2)	4912 (43.3)	1446 (12.8)	416 (3.7)	256 (2.3)	204 (1.8)	173 (1.5)
Grade 1	86 (0.8)	767 (6.8)	2161 (19.1)	951 (8.4)	326 (2.9)	203 (1.8)	154 (1.4)	130 (1.2)
Grade 2	6 (<0.1)	359 (3.2)	2607 (23.0)	466 (4.1)	84 (0.7)	51 (0.5)	47 (0.4)	39 (0.3)
Grade 3	2 (<0.1)	17 (0.2)	144 (1.3)	29 (0.3)	6 (<0.1)	2 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	17 (0.2)	144 (1.3)	29 (0.3)	6 (<0.1)	2 (<0.1)	3 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	3727	3663	3736	3724	3729	3720	3721	3717
Any Solicited Adverse Reactions	457 (12.3)	893 (24.4)	1059 (28.3)	916 (24.6)	805 (21.6)	687 (18.5)	720 (19.3)	645 (17.4)
95% CI	11.2, 13.4	23.0, 25.8	26.9, 29.8	23.2, 26.0	20.3, 22.9	17.2, 19.8	18.1, 20.7	16.1, 18.6
Grade 1	402 (10.8)	724 (19.8)	818 (21.9)	739 (19.8)	626 (16.8)	524 (14.1)	553 (14.9)	497 (13.4)
Grade 2	14 (0.4)	139 (3.8)	201 (5.4)	153 (4.1)	155 (4.2)	147 (4.0)	149 (4.0)	122 (3.3)
Grade 3	40 (1.1)	30 (0.8)	39 (1.0)	24 (0.6)	24 (0.6)	15 (0.4)	18 (0.5)	25 (0.7)
Grade 4	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	41 (1.1)	30 (0.8)	40 (1.1)	24 (0.6)	24 (0.6)	16 (0.4)	18 (0.5)	26 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	3724	3649	3728	3717	3715	3708	3714	3707
Any Solicited Local Adverse Reactions	277 (7.4)	337 (9.2)	363 (9.7)	261 (7.0)	206 (5.5)	145 (3.9)	139 (3.7)	111 (3.0)
95% CI	6.6, 8.3	8.3, 10.2	8.8, 10.7	6.2, 7.9	4.8, 6.3	3.3, 4.6	3.2, 4.4	2.5, 3.6
Grade 1	245 (6.6)	318 (8.7)	337 (9.0)	244 (6.6)	187 (5.0)	132 (3.6)	126 (3.4)	100 (2.7)
Grade 2	5 (0.1)	7 (0.2)	10 (0.3)	13 (0.3)	12 (0.3)	10 (0.3)	9 (0.2)	6 (0.2)
Grade 3	27 (0.7)	12 (0.3)	16 (0.4)	4 (0.1)	7 (0.2)	3 (<0.1)	4 (0.1)	5 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	27 (0.7)	12 (0.3)	16 (0.4)	4 (0.1)	7 (0.2)	3 (<0.1)	4 (0.1)	5 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	3724	3649	3728	3717	3715	3708	3714	3707
Any	263 (7.1)	300 (8.2)	288 (7.7)	193 (5.2)	139 (3.7)	91 (2.5)	84 (2.3)	67 (1.8)
Grade 1	236 (6.3)	285 (7.8)	273 (7.3)	182 (4.9)	127 (3.4)	83 (2.2)	74 (2.0)	59 (1.6)
Grade 2	4 (0.1)	6 (0.2)	7 (0.2)	9 (0.2)	7 (0.2)	8 (0.2)	6 (0.2)	4 (0.1)
Grade 3	23 (0.6)	9 (0.2)	8 (0.2)	2 (<0.1)	5 (0.1)	0	4 (0.1)	4 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	23 (0.6)	9 (0.2)	8 (0.2)	2 (<0.1)	5 (0.1)	0	4 (0.1)	4 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	3724	3649	3728	3717	3715	3708	3714	3707
Any	1 (<0.1)	13 (0.4)	17 (0.5)	19 (0.5)	12 (0.3)	17 (0.5)	14 (0.4)	13 (0.4)
Grade 1	1 (<0.1)	11 (0.3)	15 (0.4)	16 (0.4)	11 (0.3)	14 (0.4)	13 (0.4)	12 (0.3)
Grade 2	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	3724	3649	3728	3717	3715	3708	3714	3707
Any	4 (0.1)	15 (0.4)	24 (0.6)	19 (0.5)	18 (0.5)	13 (0.4)	13 (0.4)	14 (0.4)
Grade 1	3 (<0.1)	13 (0.4)	17 (0.5)	17 (0.5)	13 (0.3)	11 (0.3)	12 (0.3)	13 (0.4)
Grade 2	0	0	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	4 (0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	4 (0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	3724	3649	3728	3717	3715	3708	3714	3707
Any	35 (0.9)	46 (1.3)	82 (2.2)	67 (1.8)	60 (1.6)	40 (1.1)	52 (1.4)	36 (1.0)
Grade 1	26 (0.7)	43 (1.2)	73 (2.0)	66 (1.8)	56 (1.5)	40 (1.1)	49 (1.3)	33 (0.9)
Grade 2	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)
Grade 3	7 (0.2)	2 (<0.1)	8 (0.2)	0	3 (<0.1)	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	7 (0.2)	2 (<0.1)	8 (0.2)	0	3 (<0.1)	0	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	3727	3661	3736	3724	3729	3720	3721	3717
Any Solicited Systemic Adverse Reactions	237 (6.4)	718 (19.6)	898 (24.0)	788 (21.2)	701 (18.8)	623 (16.7)	656 (17.6)	589 (15.8)
95% CI	5.6, 7.2	18.3, 20.9	22.7, 25.4	19.9, 22.5	17.6, 20.1	15.6, 18.0	16.4, 18.9	14.7, 17.1
Grade 1	207 (5.6)	563 (15.4)	678 (18.1)	626 (16.8)	534 (14.3)	471 (12.7)	496 (13.3)	449 (12.1)
Grade 2	10 (0.3)	135 (3.7)	194 (5.2)	142 (3.8)	149 (4.0)	139 (3.7)	145 (3.9)	119 (3.2)
Grade 3	19 (0.5)	20 (0.5)	25 (0.7)	20 (0.5)	18 (0.5)	12 (0.3)	15 (0.4)	20 (0.5)
Grade 4	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	20 (0.5)	20 (0.5)	26 (0.7)	20 (0.5)	18 (0.5)	13 (0.3)	15 (0.4)	21 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	3726	3647	3718	3709	3712	3699	3703	3699
Any	1 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	3 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 1	0	2 (<0.1)	0	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	0
Grade 2	0	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0
Grade 3	0	0	0	0	0	0	0	1 (<0.1)
Grade 4	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	0	1 (<0.1)
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)	0	0	1 (<0.1)	0	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	3720	3641	3722	3710	3715	3705	3708	3702
Any	123 (3.3)	328 (9.0)	427 (11.5)	349 (9.4)	299 (8.0)	269 (7.3)	270 (7.3)	250 (6.8)
Grade 1	106 (2.8)	299 (8.2)	384 (10.3)	308 (8.3)	261 (7.0)	224 (6.0)	221 (6.0)	206 (5.6)
Grade 2	3 (<0.1)	22 (0.6)	33 (0.9)	29 (0.8)	31 (0.8)	37 (1.0)	41 (1.1)	31 (0.8)
Grade 3	14 (0.4)	7 (0.2)	10 (0.3)	12 (0.3)	7 (0.2)	8 (0.2)	8 (0.2)	13 (0.4)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	14 (0.4)	7 (0.2)	10 (0.3)	12 (0.3)	7 (0.2)	8 (0.2)	8 (0.2)	13 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	3720	3640	3723	3710	3714	3707	3708	3702
Any	86 (2.3)	458 (12.6)	582 (15.6)	476 (12.8)	443 (11.9)	371 (10.0)	390 (10.5)	323 (8.7)
Grade 1	77 (2.1)	346 (9.5)	421 (11.3)	373 (10.1)	332 (8.9)	281 (7.6)	303 (8.2)	241 (6.5)
Grade 2	3 (<0.1)	102 (2.8)	150 (4.0)	97 (2.6)	104 (2.8)	86 (2.3)	81 (2.2)	75 (2.0)
Grade 3	6 (0.2)	10 (0.3)	11 (0.3)	6 (0.2)	7 (0.2)	4 (0.1)	6 (0.2)	7 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (0.2)	10 (0.3)	11 (0.3)	6 (0.2)	7 (0.2)	4 (0.1)	6 (0.2)	7 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	3720	3642	3722	3710	3715	3705	3708	3702
Any	53 (1.4)	178 (4.9)	292 (7.8)	270 (7.3)	235 (6.3)	225 (6.1)	206 (5.6)	187 (5.1)
Grade 1	48 (1.3)	149 (4.1)	250 (6.7)	226 (6.1)	193 (5.2)	178 (4.8)	157 (4.2)	142 (3.8)
Grade 2	3 (<0.1)	25 (0.7)	39 (1.0)	41 (1.1)	37 (1.0)	47 (1.3)	47 (1.3)	44 (1.2)
Grade 3	2 (<0.1)	4 (0.1)	3 (<0.1)	3 (<0.1)	5 (0.1)	0	2 (<0.1)	1 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	2 (<0.1)	4 (0.1)	3 (<0.1)	3 (<0.1)	5 (0.1)	0	2 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	3720	3641	3722	3710	3715	3706	3708	3703
Any	62 (1.7)	170 (4.7)	308 (8.3)	278 (7.5)	275 (7.4)	251 (6.8)	256 (6.9)	248 (6.7)
Grade 1	55 (1.5)	144 (4.0)	258 (6.9)	240 (6.5)	234 (6.3)	201 (5.4)	198 (5.3)	198 (5.3)
Grade 2	4 (0.1)	24 (0.7)	48 (1.3)	36 (1.0)	37 (1.0)	50 (1.3)	56 (1.5)	48 (1.3)
Grade 3	3 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	4 (0.1)	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	4 (0.1)	0	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	3720	3640	3722	3710	3714	3704	3708	3702
Any	13	43	85	72	48	49	62	57
	(0.3)	(1.2)	(2.3)	(1.9)	(1.3)	(1.3)	(1.7)	(1.5)
Grade 1	11	38	75	62	35	41	46	54
	(0.3)	(1.0)	(2.0)	(1.7)	(0.9)	(1.1)	(1.2)	(1.5)
Grade 2	1	3	9	9	13	7	14	3
	(<0.1)	(<0.1)	(0.2)	(0.2)	(0.4)	(0.2)	(0.4)	(<0.1)
Grade 3	1	2	1	1	0	1	2	0
	(<0.1)	(<0.1)	(<0.1)	(<0.1)		(<0.1)	(<0.1)	
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1	2	1	1	0	1	2	0
	(<0.1)	(<0.1)	(<0.1)	(<0.1)		(<0.1)	(<0.1)	

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: Placebo (N=3751)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	3720	3640	3722	3710	3714	3705	3708	3702
Any	24 (0.6)	69 (1.9)	90 (2.4)	59 (1.6)	51 (1.4)	44 (1.2)	52 (1.4)	39 (1.1)
Grade 1	21 (0.6)	59 (1.6)	77 (2.1)	49 (1.3)	43 (1.2)	39 (1.1)	44 (1.2)	34 (0.9)
Grade 2	2 (<0.1)	7 (0.2)	13 (0.3)	9 (0.2)	7 (0.2)	5 (0.1)	6 (0.2)	5 (0.1)
Grade 3	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	0	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	3751	3704	3751	3748	3736	3737	3734	3737
Any Solicited Adverse Reactions	434 (11.6)	2374 (64.1)	3350 (89.3)	2687 (71.7)	1789 (47.9)	1234 (33.0)	994 (26.6)	790 (21.1)
95% CI	10.6, 12.6	62.5, 65.6	88.3, 90.3	70.2, 73.1	46.3, 49.5	31.5, 34.6	25.2, 28.1	19.8, 22.5
Grade 1	387 (10.3)	1966 (53.1)	1747 (46.6)	1964 (52.4)	1388 (37.2)	950 (25.4)	751 (20.1)	580 (15.5)
Grade 2	14 (0.4)	321 (8.7)	1153 (30.7)	567 (15.1)	318 (8.5)	222 (5.9)	193 (5.2)	172 (4.6)
Grade 3	33 (0.9)	85 (2.3)	449 (12.0)	155 (4.1)	82 (2.2)	61 (1.6)	49 (1.3)	37 (1.0)
Grade 4	0	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	33 (0.9)	87 (2.3)	450 (12.0)	156 (4.2)	83 (2.2)	62 (1.7)	50 (1.3)	38 (1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Local Adverse Reactions - N1	3742	3692	3746	3739	3729	3729	3731	3732
Any Solicited Local Adverse Reactions	294 (7.9)	2099 (56.9)	3190 (85.2)	2396 (64.1)	1367 (36.7)	708 (19.0)	417 (11.2)	242 (6.5)
95% CI	7.0, 8.8	55.2, 58.5	84.0, 86.3	62.5, 65.6	35.1, 38.2	17.7, 20.3	10.2, 12.2	5.7, 7.3
Grade 1	269 (7.2)	1962 (53.1)	2562 (68.4)	2048 (54.8)	1192 (32.0)	609 (16.3)	354 (9.5)	201 (5.4)
Grade 2	3 (<0.1)	92 (2.5)	473 (12.6)	253 (6.8)	120 (3.2)	66 (1.8)	37 (1.0)	27 (0.7)
Grade 3	22 (0.6)	45 (1.2)	155 (4.1)	95 (2.5)	55 (1.5)	33 (0.9)	26 (0.7)	14 (0.4)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	22 (0.6)	45 (1.2)	155 (4.1)	95 (2.5)	55 (1.5)	33 (0.9)	26 (0.7)	14 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	3742	3691	3746	3739	3729	3728	3731	3731
Any	280 (7.5)	2066 (56.0)	3174 (84.7)	2347 (62.8)	1273 (34.1)	601 (16.1)	312 (8.4)	153 (4.1)
Grade 1	259 (6.9)	1964 (53.2)	2697 (72.0)	2201 (58.9)	1232 (33.0)	582 (15.6)	293 (7.9)	141 (3.8)
Grade 2	2 (<0.1)	70 (1.9)	388 (10.4)	127 (3.4)	36 (1.0)	16 (0.4)	12 (0.3)	8 (0.2)
Grade 3	19 (0.5)	32 (0.9)	89 (2.4)	19 (0.5)	5 (0.1)	3 (<0.1)	7 (0.2)	4 (0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	19 (0.5)	32 (0.9)	89 (2.4)	19 (0.5)	5 (0.1)	3 (<0.1)	7 (0.2)	4 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Erythema (Redness) - N1	3742	3691	3746	3739	3729	3729	3731	3731
Any	3 (<0.1)	49 (1.3)	181 (4.8)	254 (6.8)	194 (5.2)	121 (3.2)	86 (2.3)	62 (1.7)
Grade 1	2 (<0.1)	36 (1.0)	103 (2.7)	100 (2.7)	85 (2.3)	60 (1.6)	49 (1.3)	36 (1.0)
Grade 2	1 (<0.1)	8 (0.2)	49 (1.3)	108 (2.9)	73 (2.0)	38 (1.0)	23 (0.6)	20 (0.5)
Grade 3	0	5 (0.1)	29 (0.8)	46 (1.2)	36 (1.0)	23 (0.6)	14 (0.4)	6 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	5 (0.1)	29 (0.8)	46 (1.2)	36 (1.0)	23 (0.6)	14 (0.4)	6 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Swelling (Hardness) - N1	3742	3691	3746	3739	3729	3728	3731	3730
Any	7 (0.2)	121 (3.3)	356 (9.5)	316 (8.5)	198 (5.3)	112 (3.0)	60 (1.6)	41 (1.1)
Grade 1	7 (0.2)	90 (2.4)	193 (5.2)	178 (4.8)	115 (3.1)	66 (1.8)	40 (1.1)	31 (0.8)
Grade 2	0	23 (0.6)	111 (3.0)	92 (2.5)	56 (1.5)	36 (1.0)	16 (0.4)	7 (0.2)
Grade 3	0	8 (0.2)	52 (1.4)	46 (1.2)	27 (0.7)	10 (0.3)	4 (0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	0	8 (0.2)	52 (1.4)	46 (1.2)	27 (0.7)	10 (0.3)	4 (0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Axillary Swelling or Tenderness - N1	3742	3690	3746	3739	3729	3728	3731	3730
Any	41 (1.1)	119 (3.2)	250 (6.7)	162 (4.3)	111 (3.0)	71 (1.9)	56 (1.5)	43 (1.2)
Grade 1	31 (0.8)	110 (3.0)	217 (5.8)	147 (3.9)	107 (2.9)	67 (1.8)	52 (1.4)	38 (1.0)
Grade 2	1 (<0.1)	3 (<0.1)	25 (0.7)	8 (0.2)	1 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 3	9 (0.2)	6 (0.2)	8 (0.2)	7 (0.2)	3 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	9 (0.2)	6 (0.2)	8 (0.2)	7 (0.2)	3 (<0.1)	2 (<0.1)	3 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Systemic Adverse Reactions - N1	3751	3702	3751	3748	3736	3737	3734	3735
Any Solicited Systemic Adverse Reactions	204 (5.4)	1270 (34.3)	2578 (68.7)	1558 (41.6)	1045 (28.0)	849 (22.7)	768 (20.6)	664 (17.8)
95% CI	4.7, 6.2	32.8, 35.9	67.2, 70.2	40.0, 43.2	26.5, 29.4	21.4, 24.1	19.3, 21.9	16.6, 19.0
Grade 1	175 (4.7)	933 (25.2)	1144 (30.5)	1051 (28.0)	783 (21.0)	647 (17.3)	575 (15.4)	485 (13.0)
Grade 2	12 (0.3)	280 (7.6)	1084 (28.9)	437 (11.7)	231 (6.2)	171 (4.6)	168 (4.5)	153 (4.1)
Grade 3	17 (0.5)	55 (1.5)	349 (9.3)	69 (1.8)	30 (0.8)	30 (0.8)	24 (0.6)	25 (0.7)
Grade 4	0	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	17 (0.5)	57 (1.5)	350 (9.3)	70 (1.9)	31 (0.8)	31 (0.8)	25 (0.7)	26 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fever - N1	3747	3693	3747	3735	3728	3728	3714	3705
Any	1 (<0.1)	32 (0.9)	325 (8.7)	31 (0.8)	2 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)
Grade 1	1 (<0.1)	22 (0.6)	228 (6.1)	20 (0.5)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0
Grade 2	0	8 (0.2)	81 (2.2)	9 (0.2)	1 (<0.1)	2 (<0.1)	1 (<0.1)	0
Grade 3	0	1 (<0.1)	16 (0.4)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)
Grade 4	0	1 (<0.1)	0	0	0	0	0	0
Grade 3 or Above	0	2 (<0.1)	16 (0.4)	2 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Headache - N1	3736	3680	3738	3737	3723	3728	3726	3724
Any	106 (2.8)	618 (16.8)	1554 (41.6)	701 (18.8)	415 (11.1)	326 (8.7)	330 (8.9)	273 (7.3)
Grade 1	88 (2.4)	532 (14.5)	1050 (28.1)	568 (15.2)	350 (9.4)	266 (7.1)	270 (7.2)	221 (5.9)
Grade 2	4 (0.1)	62 (1.7)	419 (11.2)	111 (3.0)	55 (1.5)	45 (1.2)	50 (1.3)	42 (1.1)
Grade 3	14 (0.4)	24 (0.7)	85 (2.3)	22 (0.6)	10 (0.3)	15 (0.4)	10 (0.3)	10 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	14 (0.4)	24 (0.7)	85 (2.3)	22 (0.6)	10 (0.3)	15 (0.4)	10 (0.3)	10 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Fatigue - N1	3736	3682	3738	3737	3723	3728	3725	3724
Any	78 (2.1)	849 (23.1)	2081 (55.7)	1132 (30.3)	749 (20.1)	578 (15.5)	490 (13.2)	414 (11.1)
Grade 1	69 (1.8)	619 (16.8)	936 (25.0)	755 (20.2)	557 (15.0)	449 (12.0)	364 (9.8)	297 (8.0)
Grade 2	3 (<0.1)	202 (5.5)	922 (24.7)	336 (9.0)	175 (4.7)	118 (3.2)	112 (3.0)	105 (2.8)
Grade 3	6 (0.2)	28 (0.8)	223 (6.0)	41 (1.1)	17 (0.5)	11 (0.3)	14 (0.4)	12 (0.3)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	6 (0.2)	28 (0.8)	223 (6.0)	41 (1.1)	17 (0.5)	11 (0.3)	14 (0.4)	12 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	3736	3680	3738	3737	3723	3728	3725	3723
Any	50 (1.3)	515 (14.0)	1655 (44.3)	746 (20.0)	422 (11.3)	304 (8.2)	253 (6.8)	205 (5.5)
Grade 1	43 (1.2)	377 (10.2)	828 (22.2)	550 (14.7)	334 (9.0)	244 (6.5)	205 (5.5)	151 (4.1)
Grade 2	2 (<0.1)	117 (3.2)	645 (17.3)	166 (4.4)	80 (2.1)	52 (1.4)	44 (1.2)	47 (1.3)
Grade 3	5 (0.1)	21 (0.6)	182 (4.9)	30 (0.8)	8 (0.2)	8 (0.2)	4 (0.1)	7 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	5 (0.1)	21 (0.6)	182 (4.9)	30 (0.8)	8 (0.2)	8 (0.2)	4 (0.1)	7 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Arthralgia - N1	3736	3681	3738	3737	3723	3728	3725	3723
Any	61 (1.6)	395 (10.7)	1197 (32.0)	617 (16.5)	411 (11.0)	324 (8.7)	274 (7.4)	247 (6.6)
Grade 1	54 (1.4)	299 (8.1)	663 (17.7)	474 (12.7)	336 (9.0)	268 (7.2)	220 (5.9)	188 (5.0)
Grade 2	4 (0.1)	83 (2.3)	426 (11.4)	122 (3.3)	69 (1.9)	50 (1.3)	50 (1.3)	51 (1.4)
Grade 3	3 (<0.1)	13 (0.4)	108 (2.9)	21 (0.6)	6 (0.2)	6 (0.2)	4 (0.1)	8 (0.2)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	3 (<0.1)	13 (0.4)	108 (2.9)	21 (0.6)	6 (0.2)	6 (0.2)	4 (0.1)	8 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301020203.sas 21JUN2021 16:53

Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Nausea/Vomiting - N1	3736	3680	3738	3737	3723	3728	3725	3723
Any	19 (0.5)	94 (2.6)	358 (9.6)	154 (4.1)	87 (2.3)	61 (1.6)	75 (2.0)	58 (1.6)
Grade 1	14 (0.4)	81 (2.2)	287 (7.7)	123 (3.3)	69 (1.9)	47 (1.3)	56 (1.5)	39 (1.0)
Grade 2	0	10 (0.3)	68 (1.8)	27 (0.7)	16 (0.4)	12 (0.3)	16 (0.4)	12 (0.3)
Grade 3	5 (0.1)	2 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	6 (0.2)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 3 or Above	5 (0.1)	3 (<0.1)	3 (<0.1)	4 (0.1)	2 (<0.1)	2 (<0.1)	3 (<0.1)	7 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301020203.sas 21JUN2021 16:53

Table 14.3.1.2.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group, Grade and Day of Reporting
Solicited Safety Set

Age Group: >=65 Years; Treatment Group: mRNA-1273 (N=3766)

Solicited Adverse Reaction Category Grade	Day 1 30 Min After Vaccination n (%)	Day 1 At Home n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	3736	3680	3738	3737	3723	3728	3725	3724
Any	23 (0.6)	206 (5.6)	1013 (27.1)	244 (6.5)	87 (2.3)	50 (1.3)	42 (1.1)	43 (1.2)
Grade 1	18 (0.5)	145 (3.9)	530 (14.2)	164 (4.4)	66 (1.8)	34 (0.9)	32 (0.9)	33 (0.9)
Grade 2	1 (<0.1)	56 (1.5)	464 (12.4)	76 (2.0)	16 (0.4)	14 (0.4)	8 (0.2)	8 (0.2)
Grade 3	4 (0.1)	5 (0.1)	19 (0.5)	4 (0.1)	5 (0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0	0	0	0	0	0
Grade 3 or Above	4 (0.1)	5 (0.1)	19 (0.5)	4 (0.1)	5 (0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301020203.sas 21JUN2021 16:53

Table 14.3.1.3.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Adverse Reactions - N1	15151	15166	30317
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1596 (10.5)	1572 (10.4)	3168 (10.4)
Day 1, after Vaccination (at Home)	2248 (14.8)	6860 (45.2)	9108 (30.0)
Day 2	1544 (10.2)	4407 (29.1)	5951 (19.6)
Day 3	743 (4.9)	283 (1.9)	1026 (3.4)
Day 4	411 (2.7)	72 (0.5)	483 (1.6)
Day 5	321 (2.1)	40 (0.3)	361 (1.2)
Day 6	249 (1.6)	48 (0.3)	297 (1.0)
Day 7	173 (1.1)	35 (0.2)	208 (0.7)
Solicited Local Adverse Reactions - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1139 (7.5)	1129 (7.4)	2268 (7.5)
Day 1, after Vaccination (at Home)	792 (5.2)	6413 (42.3)	7205 (23.8)
Day 2	574 (3.8)	4885 (32.2)	5459 (18.0)
Day 3	213 (1.4)	253 (1.7)	466 (1.5)
Day 4	115 (0.8)	44 (0.3)	159 (0.5)
Day 5	85 (0.6)	12 (<0.1)	97 (0.3)
Day 6	60 (0.4)	13 (<0.1)	73 (0.2)
Day 7	31 (0.2)	16 (0.1)	47 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030101.sas 21JUN2021 17:04

Table 14.3.1.3.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Pain - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1100 (7.3)	1088 (7.2)	2188 (7.2)
Day 1, after Vaccination (at Home)	713 (4.7)	6366 (42.0)	7079 (23.4)
Day 2	486 (3.2)	4915 (32.4)	5401 (17.8)
Day 3	161 (1.1)	259 (1.7)	420 (1.4)
Day 4	83 (0.5)	38 (0.3)	121 (0.4)
Day 5	56 (0.4)	8 (<0.1)	64 (0.2)
Day 6	40 (0.3)	6 (<0.1)	46 (0.2)
Day 7	26 (0.2)	8 (<0.1)	34 (0.1)
Erythema (Redness) - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	10 (<0.1)	12 (<0.1)
Day 1, after Vaccination (at Home)	29 (0.2)	64 (0.4)	93 (0.3)
Day 2	17 (0.1)	222 (1.5)	239 (0.8)
Day 3	11 (<0.1)	114 (0.8)	125 (0.4)
Day 4	4 (<0.1)	18 (0.1)	22 (<0.1)
Day 5	5 (<0.1)	5 (<0.1)	10 (<0.1)
Day 6	6 (<0.1)	5 (<0.1)	11 (<0.1)
Day 7	3 (<0.1)	7 (<0.1)	10 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030101.sas 21JUN2021 17:04

Table 14.3.1.3.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Swelling (Hardness) - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	23 (0.2)	205 (1.4)	228 (0.8)
Day 2	18 (0.1)	580 (3.8)	598 (2.0)
Day 3	4 (<0.1)	107 (0.7)	111 (0.4)
Day 4	1 (<0.1)	24 (0.2)	25 (<0.1)
Day 5	4 (<0.1)	1 (<0.1)	5 (<0.1)
Day 6	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 7	5 (<0.1)	2 (<0.1)	7 (<0.1)
Axillary Swelling or Tenderness - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	97 (0.6)	97 (0.6)	194 (0.6)
Day 1, after Vaccination (at Home)	148 (1.0)	354 (2.3)	502 (1.7)
Day 2	164 (1.1)	488 (3.2)	652 (2.2)
Day 3	103 (0.7)	230 (1.5)	333 (1.1)
Day 4	65 (0.4)	100 (0.7)	165 (0.5)
Day 5	60 (0.4)	60 (0.4)	120 (0.4)
Day 6	52 (0.3)	91 (0.6)	143 (0.5)
Day 7	33 (0.2)	133 (0.9)	166 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030101.sas 21JUN2021 17:04

Table 14.3.1.3.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Systemic Adverse Reactions - N1	15151	15166	30317
Day 1, 30 Minutes after Vaccination (at Study Clinic)	683 (4.5)	648 (4.3)	1331 (4.4)
Day 1, after Vaccination (at Home)	2110 (13.9)	3032 (20.0)	5142 (17.0)
Day 2	1549 (10.2)	2797 (18.4)	4346 (14.3)
Day 3	784 (5.2)	866 (5.7)	1650 (5.4)
Day 4	444 (2.9)	330 (2.2)	774 (2.6)
Day 5	355 (2.3)	246 (1.6)	601 (2.0)
Day 6	274 (1.8)	241 (1.6)	515 (1.7)
Day 7	198 (1.3)	156 (1.0)	354 (1.2)
Fever - N1	15149	15163	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	14 (<0.1)	19 (<0.1)
Day 2	6 (<0.1)	55 (0.4)	61 (0.2)
Day 3	7 (<0.1)	25 (0.2)	32 (0.1)
Day 4	7 (<0.1)	5 (<0.1)	12 (<0.1)
Day 5	8 (<0.1)	6 (<0.1)	14 (<0.1)
Day 6	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 7	4 (<0.1)	1 (<0.1)	5 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030101.sas 21JUN2021 17:04

Table 14.3.1.3.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Headache - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	364 (2.4)	360 (2.4)	724 (2.4)
Day 1, after Vaccination (at Home)	1016 (6.7)	1412 (9.3)	2428 (8.0)
Day 2	942 (6.2)	1510 (10.0)	2452 (8.1)
Day 3	554 (3.7)	691 (4.6)	1245 (4.1)
Day 4	362 (2.4)	294 (1.9)	656 (2.2)
Day 5	314 (2.1)	249 (1.6)	563 (1.9)
Day 6	279 (1.8)	255 (1.7)	534 (1.8)
Day 7	195 (1.3)	179 (1.2)	374 (1.2)
Fatigue - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	236 (1.6)	248 (1.6)	484 (1.6)
Day 1, after Vaccination (at Home)	1451 (9.6)	1974 (13.0)	3425 (11.3)
Day 2	1053 (7.0)	2066 (13.6)	3119 (10.3)
Day 3	517 (3.4)	673 (4.4)	1190 (3.9)
Day 4	296 (2.0)	248 (1.6)	544 (1.8)
Day 5	251 (1.7)	160 (1.1)	411 (1.4)
Day 6	198 (1.3)	167 (1.1)	365 (1.2)
Day 7	131 (0.9)	100 (0.7)	231 (0.8)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030101.sas 21JUN2021 17:04

Table 14.3.1.3.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Onset Day	Placebo (N=15151) n	(%)	mRNA-1273 (N=15166) n	(%)	Total (N=30317) n	(%)
Myalgia - N1	15146		15162		30308	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	123	(0.8)	130	(0.9)	253	(0.8)
Day 1, after Vaccination (at Home)	495	(3.3)	940	(6.2)	1435	(4.7)
Day 2	555	(3.7)	1456	(9.6)	2011	(6.6)
Day 3	292	(1.9)	479	(3.2)	771	(2.5)
Day 4	228	(1.5)	163	(1.1)	391	(1.3)
Day 5	156	(1.0)	106	(0.7)	262	(0.9)
Day 6	121	(0.8)	103	(0.7)	224	(0.7)
Day 7	99	(0.7)	65	(0.4)	164	(0.5)
Arthralgia - N1	15146		15162		30308	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	99	(0.7)	106	(0.7)	205	(0.7)
Day 1, after Vaccination (at Home)	351	(2.3)	594	(3.9)	945	(3.1)
Day 2	490	(3.2)	919	(6.1)	1409	(4.6)
Day 3	290	(1.9)	424	(2.8)	714	(2.4)
Day 4	196	(1.3)	180	(1.2)	376	(1.2)
Day 5	146	(1.0)	109	(0.7)	255	(0.8)
Day 6	130	(0.9)	102	(0.7)	232	(0.8)
Day 7	82	(0.5)	76	(0.5)	158	(0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030101.sas 21JUN2021 17:04

Table 14.3.1.3.1.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Nausea/Vomiting - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	49 (0.3)	41 (0.3)	90 (0.3)
Day 1, after Vaccination (at Home)	184 (1.2)	222 (1.5)	406 (1.3)
Day 2	245 (1.6)	398 (2.6)	643 (2.1)
Day 3	167 (1.1)	243 (1.6)	410 (1.4)
Day 4	122 (0.8)	126 (0.8)	248 (0.8)
Day 5	111 (0.7)	85 (0.6)	196 (0.6)
Day 6	118 (0.8)	84 (0.6)	202 (0.7)
Day 7	79 (0.5)	63 (0.4)	142 (0.5)
Chills - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	86 (0.6)	73 (0.5)	159 (0.5)
Day 1, after Vaccination (at Home)	200 (1.3)	280 (1.8)	480 (1.6)
Day 2	194 (1.3)	462 (3.0)	656 (2.2)
Day 3	131 (0.9)	240 (1.6)	371 (1.2)
Day 4	86 (0.6)	72 (0.5)	158 (0.5)
Day 5	75 (0.5)	57 (0.4)	132 (0.4)
Day 6	63 (0.4)	37 (0.2)	100 (0.3)
Day 7	43 (0.3)	30 (0.2)	73 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030101.sas 21JUN2021 17:04

Table 14.3.1.3.4.1
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category / Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Local Adverse Reactions			
Pain - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	26 (0.2)	66 (0.4)	92 (0.3)
Day 1, after Vaccination (at Home)	11 (<0.1)	260 (1.7)	271 (0.9)
Day 2	8 (<0.1)	85 (0.6)	93 (0.3)
Day 3	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 4	4 (<0.1)	2 (<0.1)	6 (<0.1)
Day 5	0	0	0
Day 6	1 (<0.1)	0	1 (<0.1)
Day 7	2 (<0.1)	1 (<0.1)	3 (<0.1)
Erythema (Redness) - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	0	1 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	6 (<0.1)	9 (<0.1)
Day 2	2 (<0.1)	20 (0.1)	22 (<0.1)
Day 3	3 (<0.1)	9 (<0.1)	12 (<0.1)
Day 4	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 5	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 6	2 (<0.1)	3 (<0.1)	5 (<0.1)
Day 7	0	1 (<0.1)	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030401.sas 23JUN2021 08:11

Table 14.3.1.3.4.1
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Swelling (Hardness) - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	0	1 (<0.1)
Day 1, after Vaccination (at Home)	1 (<0.1)	22 (0.1)	23 (<0.1)
Day 2	3 (<0.1)	49 (0.3)	52 (0.2)
Day 3	0	7 (<0.1)	7 (<0.1)
Day 4	0	2 (<0.1)	2 (<0.1)
Day 5	1 (<0.1)	0	1 (<0.1)
Day 6	0	1 (<0.1)	1 (<0.1)
Day 7	0	1 (<0.1)	1 (<0.1)
Axillary Swelling or Tenderness - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	9 (<0.1)	17 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	7 (<0.1)	10 (<0.1)
Day 2	6 (<0.1)	16 (0.1)	22 (<0.1)
Day 3	2 (<0.1)	6 (<0.1)	8 (<0.1)
Day 4	2 (<0.1)	0	2 (<0.1)
Day 5	1 (<0.1)	5 (<0.1)	6 (<0.1)
Day 6	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030401.sas 23JUN2021 08:11

Table 14.3.1.3.4.1
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Systemic Adverse Reactions			
Fever - N1	15149	15163	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (<0.1)	1 (<0.1)
Day 2	0	5 (<0.1)	5 (<0.1)
Day 3	0	3 (<0.1)	3 (<0.1)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	1 (<0.1)	0	1 (<0.1)
Day 6	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 7	0	0	0
Headache - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	27 (0.2)	27 (0.2)	54 (0.2)
Day 1, after Vaccination (at Home)	43 (0.3)	87 (0.6)	130 (0.4)
Day 2	48 (0.3)	91 (0.6)	139 (0.5)
Day 3	28 (0.2)	31 (0.2)	59 (0.2)
Day 4	22 (0.1)	11 (<0.1)	33 (0.1)
Day 5	13 (<0.1)	9 (<0.1)	22 (<0.1)
Day 6	10 (<0.1)	12 (<0.1)	22 (<0.1)
Day 7	6 (<0.1)	5 (<0.1)	11 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030401.sas 23JUN2021 08:11

Table 14.3.1.3.4.1
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Fatigue - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (<0.1)	8 (<0.1)	19 (<0.1)
Day 1, after Vaccination (at Home)	45 (0.3)	65 (0.4)	110 (0.4)
Day 2	22 (0.1)	50 (0.3)	72 (0.2)
Day 3	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 4	8 (<0.1)	6 (<0.1)	14 (<0.1)
Day 5	4 (<0.1)	6 (<0.1)	10 (<0.1)
Day 6	6 (<0.1)	1 (<0.1)	7 (<0.1)
Day 7	0	2 (<0.1)	2 (<0.1)
Myalgia - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	9 (<0.1)	12 (<0.1)
Day 1, after Vaccination (at Home)	13 (<0.1)	27 (0.2)	40 (0.1)
Day 2	12 (<0.1)	30 (0.2)	42 (0.1)
Day 3	1 (<0.1)	13 (<0.1)	14 (<0.1)
Day 4	5 (<0.1)	4 (<0.1)	9 (<0.1)
Day 5	7 (<0.1)	6 (<0.1)	13 (<0.1)
Day 6	3 (<0.1)	1 (<0.1)	4 (<0.1)
Day 7	3 (<0.1)	1 (<0.1)	4 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030401.sas 23JUN2021 08:11

Table 14.3.1.3.4.1
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Arthralgia - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	7 (<0.1)	9 (<0.1)
Day 1, after Vaccination (at Home)	13 (<0.1)	16 (0.1)	29 (<0.1)
Day 2	8 (<0.1)	19 (0.1)	27 (<0.1)
Day 3	6 (<0.1)	9 (<0.1)	15 (<0.1)
Day 4	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 5	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 6	3 (<0.1)	1 (<0.1)	4 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)
Nausea/Vomiting - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	0	3 (<0.1)
Day 2	4 (<0.1)	3 (<0.1)	7 (<0.1)
Day 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 4	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 5	2 (<0.1)	1 (<0.1)	3 (<0.1)
Day 6	1 (<0.1)	0	1 (<0.1)
Day 7	0	1 (<0.1)	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030401.sas 23JUN2021 08:11

Table 14.3.1.3.4.1
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Chills - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	3 (<0.1)	5 (<0.1)
Day 1, after Vaccination (at Home)	2 (<0.1)	4 (<0.1)	6 (<0.1)
Day 2	3 (<0.1)	9 (<0.1)	12 (<0.1)
Day 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 4	5 (<0.1)	2 (<0.1)	7 (<0.1)
Day 5	0	0	0
Day 6	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 7	0	2 (<0.1)	2 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030401.sas 23JUN2021 08:11

Table 14.3.1.3.5.1
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Local Adverse Reactions			
Pain - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Erythema (Redness) - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030501.sas 23JUN2021 08:11

Table 14.3.1.3.5.1
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Swelling (Hardness) - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	15147	15162	30309
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030501.sas 23JUN2021 08:11

Table 14.3.1.3.5.1
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Systemic Adverse Reactions			
Fever - N1	15149	15163	30312
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	0	1 (<0.1)
Day 1, after Vaccination (at Home)	0	1 (<0.1)	1 (<0.1)
Day 2	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 3	2 (<0.1)	1 (<0.1)	3 (<0.1)
Day 4	1 (<0.1)	0	1 (<0.1)
Day 5	0	0	0
Day 6	0	1 (<0.1)	1 (<0.1)
Day 7	1 (<0.1)	0	1 (<0.1)
Headache - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030501.sas 23JUN2021 08:11

Table 14.3.1.3.5.1
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Fatigue - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (<0.1)	1 (<0.1)
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Myalgia - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030501.sas 23JUN2021 08:11

Table 14.3.1.3.5.1
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Arthralgia - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (<0.1)	1 (<0.1)
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Nausea/Vomiting - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030501.sas 23JUN2021 08:11

Table 14.3.1.3.5.1
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Chills - N1	15146	15162	30308
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030501.sas 23JUN2021 08:11

Table 14.3.1.3.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Adverse Reactions - N1	14578	14691	29269
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1567 (10.7)	1460 (9.9)	3027 (10.3)
Day 1, after Vaccination (at Home)	1957 (13.4)	8331 (56.7)	10288 (35.1)
Day 2	1177 (8.1)	3560 (24.2)	4737 (16.2)
Day 3	573 (3.9)	139 (0.9)	712 (2.4)
Day 4	351 (2.4)	29 (0.2)	380 (1.3)
Day 5	275 (1.9)	13 (<0.1)	288 (1.0)
Day 6	211 (1.4)	14 (<0.1)	225 (0.8)
Day 7	144 (1.0)	10 (<0.1)	154 (0.5)
Solicited Local Adverse Reactions - N1	14577	14688	29265
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1198 (8.2)	1111 (7.6)	2309 (7.9)
Day 1, after Vaccination (at Home)	773 (5.3)	8043 (54.8)	8816 (30.1)
Day 2	404 (2.8)	3672 (25.0)	4076 (13.9)
Day 3	182 (1.2)	156 (1.1)	338 (1.2)
Day 4	85 (0.6)	25 (0.2)	110 (0.4)
Day 5	56 (0.4)	9 (<0.1)	65 (0.2)
Day 6	33 (0.2)	8 (<0.1)	41 (0.1)
Day 7	26 (0.2)	5 (<0.1)	31 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030102.sas 21JUN2021 17:04

Table 14.3.1.3.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Pain - N1	14577	14688	29265
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1166 (8.0)	1070 (7.3)	2236 (7.6)
Day 1, after Vaccination (at Home)	711 (4.9)	7999 (54.5)	8710 (29.8)
Day 2	326 (2.2)	3704 (25.2)	4030 (13.8)
Day 3	146 (1.0)	155 (1.1)	301 (1.0)
Day 4	60 (0.4)	22 (0.1)	82 (0.3)
Day 5	39 (0.3)	5 (<0.1)	44 (0.2)
Day 6	24 (0.2)	6 (<0.1)	30 (0.1)
Day 7	14 (<0.1)	3 (<0.1)	17 (<0.1)
Erythema (Redness) - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	4 (<0.1)	12 (<0.1)
Day 1, after Vaccination (at Home)	28 (0.2)	149 (1.0)	177 (0.6)
Day 2	10 (<0.1)	494 (3.4)	504 (1.7)
Day 3	9 (<0.1)	495 (3.4)	504 (1.7)
Day 4	5 (<0.1)	109 (0.7)	114 (0.4)
Day 5	4 (<0.1)	15 (0.1)	19 (<0.1)
Day 6	3 (<0.1)	4 (<0.1)	7 (<0.1)
Day 7	1 (<0.1)	4 (<0.1)	5 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030102.sas 21JUN2021 17:04

Table 14.3.1.3.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Swelling (Hardness) - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (<0.1)	17 (0.1)	29 (<0.1)
Day 1, after Vaccination (at Home)	20 (0.1)	524 (3.6)	544 (1.9)
Day 2	13 (<0.1)	896 (6.1)	909 (3.1)
Day 3	7 (<0.1)	291 (2.0)	298 (1.0)
Day 4	3 (<0.1)	64 (0.4)	67 (0.2)
Day 5	4 (<0.1)	11 (<0.1)	15 (<0.1)
Day 6	0	2 (<0.1)	2 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)
Axillary Swelling or Tenderness - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	63 (0.4)	76 (0.5)	139 (0.5)
Day 1, after Vaccination (at Home)	146 (1.0)	498 (3.4)	644 (2.2)
Day 2	153 (1.0)	889 (6.1)	1042 (3.6)
Day 3	86 (0.6)	398 (2.7)	484 (1.7)
Day 4	49 (0.3)	153 (1.0)	202 (0.7)
Day 5	39 (0.3)	39 (0.3)	78 (0.3)
Day 6	20 (0.1)	23 (0.2)	43 (0.1)
Day 7	15 (0.1)	16 (0.1)	31 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030102.sas 21JUN2021 17:04

Table 14.3.1.3.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Systemic Adverse Reactions - N1	14577	14690	29267
Day 1, 30 Minutes after Vaccination (at Study Clinic)	547 (3.8)	520 (3.5)	1067 (3.6)
Day 1, after Vaccination (at Home)	1825 (12.5)	4344 (29.6)	6169 (21.1)
Day 2	1234 (8.5)	6221 (42.3)	7455 (25.5)
Day 3	618 (4.2)	369 (2.5)	987 (3.4)
Day 4	395 (2.7)	97 (0.7)	492 (1.7)
Day 5	312 (2.1)	44 (0.3)	356 (1.2)
Day 6	244 (1.7)	58 (0.4)	302 (1.0)
Day 7	168 (1.2)	25 (0.2)	193 (0.7)
Fever - N1	14573	14682	29255
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	229 (1.6)	234 (0.8)
Day 2	7 (<0.1)	1871 (12.7)	1878 (6.4)
Day 3	8 (<0.1)	162 (1.1)	170 (0.6)
Day 4	3 (<0.1)	4 (<0.1)	7 (<0.1)
Day 5	5 (<0.1)	4 (<0.1)	9 (<0.1)
Day 6	8 (<0.1)	2 (<0.1)	10 (<0.1)
Day 7	6 (<0.1)	2 (<0.1)	8 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030102.sas 21JUN2021 17:04

Table 14.3.1.3.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Headache - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	265 (1.8)	265 (1.8)	530 (1.8)
Day 1, after Vaccination (at Home)	942 (6.5)	2219 (15.1)	3161 (10.8)
Day 2	772 (5.3)	5271 (35.9)	6043 (20.7)
Day 3	489 (3.4)	442 (3.0)	931 (3.2)
Day 4	326 (2.2)	163 (1.1)	489 (1.7)
Day 5	239 (1.6)	111 (0.8)	350 (1.2)
Day 6	229 (1.6)	111 (0.8)	340 (1.2)
Day 7	165 (1.1)	55 (0.4)	220 (0.8)
Fatigue - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	217 (1.5)	231 (1.6)	448 (1.5)
Day 1, after Vaccination (at Home)	1196 (8.2)	2991 (20.4)	4187 (14.3)
Day 2	863 (5.9)	5765 (39.3)	6628 (22.7)
Day 3	413 (2.8)	418 (2.8)	831 (2.8)
Day 4	251 (1.7)	80 (0.5)	331 (1.1)
Day 5	214 (1.5)	53 (0.4)	267 (0.9)
Day 6	176 (1.2)	44 (0.3)	220 (0.8)
Day 7	88 (0.6)	25 (0.2)	113 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030102.sas 21JUN2021 17:04

Table 14.3.1.3.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Myalgia - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	112 (0.8)	102 (0.7)	214 (0.7)
Day 1, after Vaccination (at Home)	464 (3.2)	2050 (14.0)	2514 (8.6)
Day 2	490 (3.4)	5879 (40.0)	6369 (21.8)
Day 3	262 (1.8)	348 (2.4)	610 (2.1)
Day 4	178 (1.2)	67 (0.5)	245 (0.8)
Day 5	119 (0.8)	32 (0.2)	151 (0.5)
Day 6	126 (0.9)	32 (0.2)	158 (0.5)
Day 7	73 (0.5)	19 (0.1)	92 (0.3)
Arthralgia - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	117 (0.8)	119 (0.8)	236 (0.8)
Day 1, after Vaccination (at Home)	385 (2.6)	1383 (9.4)	1768 (6.0)
Day 2	388 (2.7)	4283 (29.2)	4671 (16.0)
Day 3	230 (1.6)	337 (2.3)	567 (1.9)
Day 4	175 (1.2)	82 (0.6)	257 (0.9)
Day 5	99 (0.7)	42 (0.3)	141 (0.5)
Day 6	121 (0.8)	39 (0.3)	160 (0.5)
Day 7	64 (0.4)	18 (0.1)	82 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030102.sas 21JUN2021 17:04

Table 14.3.1.3.1.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Nausea/Vomiting - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	44 (0.3)	38 (0.3)	82 (0.3)
Day 1, after Vaccination (at Home)	214 (1.5)	511 (3.5)	725 (2.5)
Day 2	222 (1.5)	1756 (12.0)	1978 (6.8)
Day 3	141 (1.0)	264 (1.8)	405 (1.4)
Day 4	100 (0.7)	95 (0.6)	195 (0.7)
Day 5	76 (0.5)	50 (0.3)	126 (0.4)
Day 6	82 (0.6)	49 (0.3)	131 (0.4)
Day 7	62 (0.4)	31 (0.2)	93 (0.3)
Chills - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	59 (0.4)	47 (0.3)	106 (0.4)
Day 1, after Vaccination (at Home)	213 (1.5)	1114 (7.6)	1327 (4.5)
Day 2	193 (1.3)	4871 (33.2)	5064 (17.3)
Day 3	104 (0.7)	364 (2.5)	468 (1.6)
Day 4	75 (0.5)	46 (0.3)	121 (0.4)
Day 5	63 (0.4)	16 (0.1)	79 (0.3)
Day 6	69 (0.5)	23 (0.2)	92 (0.3)
Day 7	37 (0.3)	19 (0.1)	56 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030102.sas 21JUN2021 17:04

Table 14.3.1.3.4.2
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Local Adverse Reactions			
Pain - N1	14577	14688	29265
Day 1, 30 Minutes after Vaccination (at Study Clinic)	19 (0.1)	83 (0.6)	102 (0.3)
Day 1, after Vaccination (at Home)	12 (<0.1)	417 (2.8)	429 (1.5)
Day 2	4 (<0.1)	99 (0.7)	103 (0.4)
Day 3	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 4	0	2 (<0.1)	2 (<0.1)
Day 5	1 (<0.1)	0	1 (<0.1)
Day 6	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)
Erythema (Redness) - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	0	3 (<0.1)
Day 1, after Vaccination (at Home)	4 (<0.1)	38 (0.3)	42 (0.1)
Day 2	1 (<0.1)	110 (0.7)	111 (0.4)
Day 3	3 (<0.1)	106 (0.7)	109 (0.4)
Day 4	1 (<0.1)	26 (0.2)	27 (<0.1)
Day 5	1 (<0.1)	5 (<0.1)	6 (<0.1)
Day 6	1 (<0.1)	0	1 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030402.sas 23JUN2021 08:11

Table 14.3.1.3.4.2
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Swelling (Hardness) - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 1, after Vaccination (at Home)	2 (<0.1)	75 (0.5)	77 (0.3)
Day 2	3 (<0.1)	117 (0.8)	120 (0.4)
Day 3	2 (<0.1)	49 (0.3)	51 (0.2)
Day 4	2 (<0.1)	11 (<0.1)	13 (<0.1)
Day 5	0	1 (<0.1)	1 (<0.1)
Day 6	0	0	0
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	6 (<0.1)	11 (<0.1)	17 (<0.1)
Day 1, after Vaccination (at Home)	7 (<0.1)	28 (0.2)	35 (0.1)
Day 2	1 (<0.1)	14 (<0.1)	15 (<0.1)
Day 3	2 (<0.1)	10 (<0.1)	12 (<0.1)
Day 4	2 (<0.1)	2 (<0.1)	4 (<0.1)
Day 5	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 6	0	1 (<0.1)	1 (<0.1)
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030402.sas 23JUN2021 08:11

Table 14.3.1.3.4.2
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Systemic Adverse Reactions			
Fever - N1	14573	14682	29255
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	28 (0.2)	28 (<0.1)
Day 2	0	164 (1.1)	164 (0.6)
Day 3	0	10 (<0.1)	10 (<0.1)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	1 (<0.1)	0	1 (<0.1)
Day 6	1 (<0.1)	0	1 (<0.1)
Day 7	0	0	0
Headache - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	18 (0.1)	47 (0.3)	65 (0.2)
Day 1, after Vaccination (at Home)	46 (0.3)	225 (1.5)	271 (0.9)
Day 2	31 (0.2)	362 (2.5)	393 (1.3)
Day 3	23 (0.2)	17 (0.1)	40 (0.1)
Day 4	16 (0.1)	4 (<0.1)	20 (<0.1)
Day 5	13 (<0.1)	7 (<0.1)	20 (<0.1)
Day 6	10 (<0.1)	2 (<0.1)	12 (<0.1)
Day 7	8 (<0.1)	2 (<0.1)	10 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030402.sas 23JUN2021 08:11

Table 14.3.1.3.4.2
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Fatigue - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (<0.1)	55 (0.4)	65 (0.2)
Day 1, after Vaccination (at Home)	42 (0.3)	619 (4.2)	661 (2.3)
Day 2	25 (0.2)	742 (5.1)	767 (2.6)
Day 3	16 (0.1)	13 (<0.1)	29 (<0.1)
Day 4	8 (<0.1)	2 (<0.1)	10 (<0.1)
Day 5	5 (<0.1)	2 (<0.1)	7 (<0.1)
Day 6	2 (<0.1)	0	2 (<0.1)
Day 7	0	0	0
Myalgia - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	22 (0.1)	25 (<0.1)
Day 1, after Vaccination (at Home)	18 (0.1)	467 (3.2)	485 (1.7)
Day 2	8 (<0.1)	813 (5.5)	821 (2.8)
Day 3	9 (<0.1)	14 (<0.1)	23 (<0.1)
Day 4	9 (<0.1)	1 (<0.1)	10 (<0.1)
Day 5	3 (<0.1)	2 (<0.1)	5 (<0.1)
Day 6	2 (<0.1)	2 (<0.1)	4 (<0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030402.sas 23JUN2021 08:11

Table 14.3.1.3.4.2
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Arthralgia - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	6 (<0.1)	19 (0.1)	25 (<0.1)
Day 1, after Vaccination (at Home)	17 (0.1)	260 (1.8)	277 (0.9)
Day 2	4 (<0.1)	474 (3.2)	478 (1.6)
Day 3	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 4	4 (<0.1)	3 (<0.1)	7 (<0.1)
Day 5	0	4 (<0.1)	4 (<0.1)
Day 6	3 (<0.1)	1 (<0.1)	4 (<0.1)
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nausea/Vomiting - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	4 (<0.1)	5 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	7 (<0.1)	10 (<0.1)
Day 2	2 (<0.1)	4 (<0.1)	6 (<0.1)
Day 3	2 (<0.1)	2 (<0.1)	4 (<0.1)
Day 4	1 (<0.1)	0	1 (<0.1)
Day 5	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 6	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 7	0	1 (<0.1)	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030402.sas 23JUN2021 08:11

Table 14.3.1.3.4.2
Summary of Subjects with Grade 3 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Chills - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	6 (<0.1)	8 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	59 (0.4)	62 (0.2)
Day 2	2 (<0.1)	121 (0.8)	123 (0.4)
Day 3	2 (<0.1)	5 (<0.1)	7 (<0.1)
Day 4	2 (<0.1)	0	2 (<0.1)
Day 5	1 (<0.1)	0	1 (<0.1)
Day 6	4 (<0.1)	0	4 (<0.1)
Day 7	1 (<0.1)	0	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030402.sas 23JUN2021 08:11

Table 14.3.1.3.5.2
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Local Adverse Reactions			
Pain - N1	14577	14688	29265
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Erythema (Redness) - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030502.sas 23JUN2021 08:11

Table 14.3.1.3.5.2
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Swelling (Hardness) - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	14577	14687	29264
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030502.sas 23JUN2021 08:11

Table 14.3.1.3.5.2
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Systemic Adverse Reactions			
Fever - N1	14573	14682	29255
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	6 (<0.1)	6 (<0.1)
Day 2	1 (<0.1)	6 (<0.1)	7 (<0.1)
Day 3	2 (<0.1)	1 (<0.1)	3 (<0.1)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Headache - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030502.sas 23JUN2021 08:11

Table 14.3.1.3.5.2
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Fatigue - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Myalgia - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030502.sas 23JUN2021 08:11

Table 14.3.1.3.5.2
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Arthralgia - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Nausea/Vomiting - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (<0.1)	1 (<0.1)
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030502.sas 23JUN2021 08:11

Table 14.3.1.3.5.2
Summary of Subjects with Grade 4 Solicited Adverse Reactions Within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Chills - N1	14575	14687	29262
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030502.sas 23JUN2021 08:11

Table 14.3.1.3.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Solicited Adverse Reactions - N1	15159	15179	30338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2695 (17.8)	2627 (17.3)	5322 (17.5)
Day 1, after Vaccination (at Home)	2933 (19.3)	8957 (59.0)	11890 (39.2)
Day 2	1637 (10.8)	2644 (17.4)	4281 (14.1)
Day 3	744 (4.9)	103 (0.7)	847 (2.8)
Day 4	423 (2.8)	17 (0.1)	440 (1.5)
Day 5	307 (2.0)	23 (0.2)	330 (1.1)
Day 6	213 (1.4)	13 (<0.1)	226 (0.7)
Day 7	161 (1.1)	18 (0.1)	179 (0.6)
Solicited Local Adverse Reactions - N1	15158	15179	30337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2026 (13.4)	1989 (13.1)	4015 (13.2)
Day 1, after Vaccination (at Home)	1180 (7.8)	8885 (58.5)	10065 (33.2)
Day 2	663 (4.4)	2999 (19.8)	3662 (12.1)
Day 3	265 (1.7)	115 (0.8)	380 (1.3)
Day 4	138 (0.9)	15 (<0.1)	153 (0.5)
Day 5	93 (0.6)	10 (<0.1)	103 (0.3)
Day 6	65 (0.4)	9 (<0.1)	74 (0.2)
Day 7	38 (0.3)	10 (<0.1)	48 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030103.sas 21JUN2021 17:04

Table 14.3.1.3.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Pain - N1	15158	15179	30337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1963 (13.0)	1915 (12.6)	3878 (12.8)
Day 1, after Vaccination (at Home)	1078 (7.1)	8873 (58.5)	9951 (32.8)
Day 2	560 (3.7)	3041 (20.0)	3601 (11.9)
Day 3	205 (1.4)	111 (0.7)	316 (1.0)
Day 4	99 (0.7)	11 (<0.1)	110 (0.4)
Day 5	69 (0.5)	4 (<0.1)	73 (0.2)
Day 6	46 (0.3)	7 (<0.1)	53 (0.2)
Day 7	26 (0.2)	7 (<0.1)	33 (0.1)
Erythema (Redness) - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (<0.1)	14 (<0.1)	24 (<0.1)
Day 1, after Vaccination (at Home)	54 (0.4)	201 (1.3)	255 (0.8)
Day 2	26 (0.2)	640 (4.2)	666 (2.2)
Day 3	18 (0.1)	543 (3.6)	561 (1.8)
Day 4	9 (<0.1)	116 (0.8)	125 (0.4)
Day 5	9 (<0.1)	17 (0.1)	26 (<0.1)
Day 6	8 (<0.1)	9 (<0.1)	17 (<0.1)
Day 7	3 (<0.1)	9 (<0.1)	12 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030103.sas 21JUN2021 17:04

Table 14.3.1.3.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Swelling (Hardness) - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	21 (0.1)	30 (0.2)	51 (0.2)
Day 1, after Vaccination (at Home)	41 (0.3)	654 (4.3)	695 (2.3)
Day 2	28 (0.2)	1165 (7.7)	1193 (3.9)
Day 3	8 (<0.1)	313 (2.1)	321 (1.1)
Day 4	4 (<0.1)	68 (0.4)	72 (0.2)
Day 5	8 (<0.1)	11 (<0.1)	19 (<0.1)
Day 6	1 (<0.1)	4 (<0.1)	5 (<0.1)
Day 7	5 (<0.1)	4 (<0.1)	9 (<0.1)
Axillary Swelling or Tenderness - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	155 (1.0)	169 (1.1)	324 (1.1)
Day 1, after Vaccination (at Home)	258 (1.7)	785 (5.2)	1043 (3.4)
Day 2	265 (1.7)	1135 (7.5)	1400 (4.6)
Day 3	150 (1.0)	497 (3.3)	647 (2.1)
Day 4	92 (0.6)	197 (1.3)	289 (1.0)
Day 5	82 (0.5)	67 (0.4)	149 (0.5)
Day 6	60 (0.4)	72 (0.5)	132 (0.4)
Day 7	39 (0.3)	91 (0.6)	130 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030103.sas 21JUN2021 17:04

Table 14.3.1.3.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Solicited Systemic Adverse Reactions - N1	15159	15178	30337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1112 (7.3)	1058 (7.0)	2170 (7.2)
Day 1, after Vaccination (at Home)	3032 (20.0)	5428 (35.8)	8460 (27.9)
Day 2	1824 (12.0)	5579 (36.8)	7403 (24.4)
Day 3	849 (5.6)	401 (2.6)	1250 (4.1)
Day 4	468 (3.1)	122 (0.8)	590 (1.9)
Day 5	364 (2.4)	83 (0.5)	447 (1.5)
Day 6	267 (1.8)	66 (0.4)	333 (1.1)
Day 7	201 (1.3)	42 (0.3)	243 (0.8)
Fever - N1	15158	15177	30335
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 1, after Vaccination (at Home)	9 (<0.1)	241 (1.6)	250 (0.8)
Day 2	13 (<0.1)	1906 (12.6)	1919 (6.3)
Day 3	15 (<0.1)	174 (1.1)	189 (0.6)
Day 4	10 (<0.1)	8 (<0.1)	18 (<0.1)
Day 5	13 (<0.1)	10 (<0.1)	23 (<0.1)
Day 6	12 (<0.1)	4 (<0.1)	16 (<0.1)
Day 7	10 (<0.1)	3 (<0.1)	13 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030103.sas 21JUN2021 17:04

Table 14.3.1.3.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Headache - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	588 (3.9)	583 (3.8)	1171 (3.9)
Day 1, after Vaccination (at Home)	1651 (10.9)	2986 (19.7)	4637 (15.3)
Day 2	1320 (8.7)	5112 (33.7)	6432 (21.2)
Day 3	742 (4.9)	527 (3.5)	1269 (4.2)
Day 4	440 (2.9)	226 (1.5)	666 (2.2)
Day 5	346 (2.3)	157 (1.0)	503 (1.7)
Day 6	294 (1.9)	160 (1.1)	454 (1.5)
Day 7	232 (1.5)	93 (0.6)	325 (1.1)
Fatigue - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	420 (2.8)	441 (2.9)	861 (2.8)
Day 1, after Vaccination (at Home)	2138 (14.1)	3933 (25.9)	6071 (20.0)
Day 2	1352 (8.9)	5474 (36.1)	6826 (22.5)
Day 3	634 (4.2)	462 (3.0)	1096 (3.6)
Day 4	350 (2.3)	117 (0.8)	467 (1.5)
Day 5	281 (1.9)	82 (0.5)	363 (1.2)
Day 6	244 (1.6)	83 (0.5)	327 (1.1)
Day 7	130 (0.9)	48 (0.3)	178 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030103.sas 21JUN2021 17:04

Table 14.3.1.3.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Myalgia - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	224 (1.5)	214 (1.4)	438 (1.4)
Day 1, after Vaccination (at Home)	825 (5.4)	2587 (17.0)	3412 (11.2)
Day 2	831 (5.5)	5874 (38.7)	6705 (22.1)
Day 3	430 (2.8)	420 (2.8)	850 (2.8)
Day 4	308 (2.0)	101 (0.7)	409 (1.3)
Day 5	187 (1.2)	56 (0.4)	243 (0.8)
Day 6	183 (1.2)	61 (0.4)	244 (0.8)
Day 7	130 (0.9)	35 (0.2)	165 (0.5)
Arthralgia - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	210 (1.4)	210 (1.4)	420 (1.4)
Day 1, after Vaccination (at Home)	632 (4.2)	1721 (11.3)	2353 (7.8)
Day 2	715 (4.7)	4350 (28.7)	5065 (16.7)
Day 3	393 (2.6)	451 (3.0)	844 (2.8)
Day 4	269 (1.8)	138 (0.9)	407 (1.3)
Day 5	171 (1.1)	72 (0.5)	243 (0.8)
Day 6	181 (1.2)	69 (0.5)	250 (0.8)
Day 7	101 (0.7)	44 (0.3)	145 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030103.sas 21JUN2021 17:04

Table 14.3.1.3.1.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Nausea/Vomiting - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	89 (0.6)	77 (0.5)	166 (0.5)
Day 1, after Vaccination (at Home)	359 (2.4)	685 (4.5)	1044 (3.4)
Day 2	409 (2.7)	1929 (12.7)	2338 (7.7)
Day 3	255 (1.7)	379 (2.5)	634 (2.1)
Day 4	189 (1.2)	170 (1.1)	359 (1.2)
Day 5	151 (1.0)	92 (0.6)	243 (0.8)
Day 6	157 (1.0)	93 (0.6)	250 (0.8)
Day 7	114 (0.8)	68 (0.4)	182 (0.6)
Chills - N1	15158	15178	30336
Day 1, 30 Minutes after Vaccination (at Study Clinic)	139 (0.9)	117 (0.8)	256 (0.8)
Day 1, after Vaccination (at Home)	371 (2.4)	1298 (8.6)	1669 (5.5)
Day 2	338 (2.2)	4879 (32.1)	5217 (17.2)
Day 3	201 (1.3)	430 (2.8)	631 (2.1)
Day 4	129 (0.9)	69 (0.5)	198 (0.7)
Day 5	117 (0.8)	40 (0.3)	157 (0.5)
Day 6	110 (0.7)	44 (0.3)	154 (0.5)
Day 7	68 (0.4)	30 (0.2)	98 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030103.sas 21JUN2021 17:04

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Solicited Adverse Reactions - N1	11402	11406	22808
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1341 (11.8)	1332 (11.7)	2673 (11.7)
Day 1, after Vaccination (at Home)	1786 (15.7)	5594 (49.0)	7380 (32.4)
Day 2	1173 (10.3)	3051 (26.7)	4224 (18.5)
Day 3	570 (5.0)	168 (1.5)	738 (3.2)
Day 4	304 (2.7)	38 (0.3)	342 (1.5)
Day 5	252 (2.2)	28 (0.2)	280 (1.2)
Day 6	179 (1.6)	30 (0.3)	209 (0.9)
Day 7	132 (1.2)	21 (0.2)	153 (0.7)
Solicited Local Adverse Reactions - N1	11400	11402	22802
Day 1, 30 Minutes after Vaccination (at Study Clinic)	977 (8.6)	974 (8.5)	1951 (8.6)
Day 1, after Vaccination (at Home)	646 (5.7)	5379 (47.2)	6025 (26.4)
Day 2	434 (3.8)	3387 (29.7)	3821 (16.8)
Day 3	161 (1.4)	158 (1.4)	319 (1.4)
Day 4	85 (0.7)	31 (0.3)	116 (0.5)
Day 5	67 (0.6)	10 (<0.1)	77 (0.3)
Day 6	44 (0.4)	10 (<0.1)	54 (0.2)
Day 7	22 (0.2)	12 (0.1)	34 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Pain - N1	11400	11402	22802
Day 1, 30 Minutes after Vaccination (at Study Clinic)	945 (8.3)	939 (8.2)	1884 (8.3)
Day 1, after Vaccination (at Home)	589 (5.2)	5346 (46.9)	5935 (26.0)
Day 2	374 (3.3)	3416 (30.0)	3790 (16.6)
Day 3	128 (1.1)	165 (1.4)	293 (1.3)
Day 4	59 (0.5)	25 (0.2)	84 (0.4)
Day 5	41 (0.4)	7 (<0.1)	48 (0.2)
Day 6	29 (0.3)	4 (<0.1)	33 (0.1)
Day 7	18 (0.2)	6 (<0.1)	24 (0.1)
Erythema (Redness) - N1	11400	11402	22802
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	8 (<0.1)	10 (<0.1)
Day 1, after Vaccination (at Home)	23 (0.2)	50 (0.4)	73 (0.3)
Day 2	8 (<0.1)	182 (1.6)	190 (0.8)
Day 3	7 (<0.1)	86 (0.8)	93 (0.4)
Day 4	4 (<0.1)	15 (0.1)	19 (<0.1)
Day 5	1 (<0.1)	5 (<0.1)	6 (<0.1)
Day 6	6 (<0.1)	2 (<0.1)	8 (<0.1)
Day 7	3 (<0.1)	6 (<0.1)	9 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Swelling (Hardness) - N1	11400	11402	22802
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (<0.1)	10 (<0.1)	18 (<0.1)
Day 1, after Vaccination (at Home)	15 (0.1)	182 (1.6)	197 (0.9)
Day 2	8 (<0.1)	475 (4.2)	483 (2.1)
Day 3	2 (<0.1)	77 (0.7)	79 (0.3)
Day 4	0	17 (0.1)	17 (<0.1)
Day 5	4 (<0.1)	1 (<0.1)	5 (<0.1)
Day 6	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 7	4 (<0.1)	1 (<0.1)	5 (<0.1)
Axillary Swelling or Tenderness - N1	11400	11402	22802
Day 1, 30 Minutes after Vaccination (at Study Clinic)	74 (0.6)	71 (0.6)	145 (0.6)
Day 1, after Vaccination (at Home)	124 (1.1)	299 (2.6)	423 (1.9)
Day 2	124 (1.1)	415 (3.6)	539 (2.4)
Day 3	78 (0.7)	195 (1.7)	273 (1.2)
Day 4	50 (0.4)	84 (0.7)	134 (0.6)
Day 5	54 (0.5)	50 (0.4)	104 (0.5)
Day 6	38 (0.3)	82 (0.7)	120 (0.5)
Day 7	25 (0.2)	126 (1.1)	151 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Solicited Systemic Adverse Reactions - N1	11402	11406	22808
Day 1, 30 Minutes after Vaccination (at Study Clinic)	561 (4.9)	528 (4.6)	1089 (4.8)
Day 1, after Vaccination (at Home)	1711 (15.0)	2411 (21.1)	4122 (18.1)
Day 2	1212 (10.6)	2167 (19.0)	3379 (14.8)
Day 3	605 (5.3)	650 (5.7)	1255 (5.5)
Day 4	337 (3.0)	241 (2.1)	578 (2.5)
Day 5	282 (2.5)	196 (1.7)	478 (2.1)
Day 6	202 (1.8)	184 (1.6)	386 (1.7)
Day 7	153 (1.3)	122 (1.1)	275 (1.2)
Fever - N1	11400	11404	22804
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	2 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	2 (<0.1)	11 (<0.1)	13 (<0.1)
Day 2	6 (<0.1)	54 (0.5)	60 (0.3)
Day 3	6 (<0.1)	24 (0.2)	30 (0.1)
Day 4	7 (<0.1)	5 (<0.1)	12 (<0.1)
Day 5	7 (<0.1)	3 (<0.1)	10 (<0.1)
Day 6	4 (<0.1)	2 (<0.1)	6 (<0.1)
Day 7	3 (<0.1)	1 (<0.1)	4 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Headache - N1	11400	11402	22802
Day 1, 30 Minutes after Vaccination (at Study Clinic)	297 (2.6)	294 (2.6)	591 (2.6)
Day 1, after Vaccination (at Home)	842 (7.4)	1140 (10.0)	1982 (8.7)
Day 2	778 (6.8)	1235 (10.8)	2013 (8.8)
Day 3	446 (3.9)	557 (4.9)	1003 (4.4)
Day 4	299 (2.6)	242 (2.1)	541 (2.4)
Day 5	249 (2.2)	205 (1.8)	454 (2.0)
Day 6	230 (2.0)	212 (1.9)	442 (1.9)
Day 7	162 (1.4)	143 (1.3)	305 (1.3)
Fatigue - N1	11400	11402	22802
Day 1, 30 Minutes after Vaccination (at Study Clinic)	197 (1.7)	206 (1.8)	403 (1.8)
Day 1, after Vaccination (at Home)	1175 (10.3)	1571 (13.8)	2746 (12.0)
Day 2	831 (7.3)	1601 (14.0)	2432 (10.7)
Day 3	414 (3.6)	508 (4.5)	922 (4.0)
Day 4	219 (1.9)	176 (1.5)	395 (1.7)
Day 5	204 (1.8)	124 (1.1)	328 (1.4)
Day 6	141 (1.2)	119 (1.0)	260 (1.1)
Day 7	100 (0.9)	80 (0.7)	180 (0.8)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=11402) n	(%)	mRNA-1273 (N=11406) n	(%)	Total (N=22808) n	(%)
Myalgia - N1	11400		11402		22802	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	102	(0.9)	104	(0.9)	206	(0.9)
Day 1, after Vaccination (at Home)	396	(3.5)	748	(6.6)	1144	(5.0)
Day 2	438	(3.8)	1192	(10.5)	1630	(7.1)
Day 3	216	(1.9)	353	(3.1)	569	(2.5)
Day 4	180	(1.6)	108	(0.9)	288	(1.3)
Day 5	123	(1.1)	83	(0.7)	206	(0.9)
Day 6	95	(0.8)	62	(0.5)	157	(0.7)
Day 7	75	(0.7)	50	(0.4)	125	(0.5)
Arthralgia - N1	11400		11402		22802	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	76	(0.7)	77	(0.7)	153	(0.7)
Day 1, after Vaccination (at Home)	276	(2.4)	458	(4.0)	734	(3.2)
Day 2	362	(3.2)	733	(6.4)	1095	(4.8)
Day 3	213	(1.9)	317	(2.8)	530	(2.3)
Day 4	144	(1.3)	114	(1.0)	258	(1.1)
Day 5	102	(0.9)	71	(0.6)	173	(0.8)
Day 6	94	(0.8)	65	(0.6)	159	(0.7)
Day 7	60	(0.5)	57	(0.5)	117	(0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=11402) n	(%)	mRNA-1273 (N=11406) n	(%)	Total (N=22808) n	(%)
Nausea/Vomiting - N1	11400		11402		22802	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	44	(0.4)	33	(0.3)	77	(0.3)
Day 1, after Vaccination (at Home)	162	(1.4)	201	(1.8)	363	(1.6)
Day 2	201	(1.8)	341	(3.0)	542	(2.4)
Day 3	139	(1.2)	201	(1.8)	340	(1.5)
Day 4	107	(0.9)	108	(0.9)	215	(0.9)
Day 5	97	(0.9)	66	(0.6)	163	(0.7)
Day 6	93	(0.8)	67	(0.6)	160	(0.7)
Day 7	65	(0.6)	51	(0.4)	116	(0.5)
Chills - N1	11400		11402		22802	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	74	(0.6)	63	(0.6)	137	(0.6)
Day 1, after Vaccination (at Home)	166	(1.5)	232	(2.0)	398	(1.7)
Day 2	157	(1.4)	405	(3.6)	562	(2.5)
Day 3	108	(0.9)	197	(1.7)	305	(1.3)
Day 4	70	(0.6)	54	(0.5)	124	(0.5)
Day 5	66	(0.6)	44	(0.4)	110	(0.5)
Day 6	50	(0.4)	31	(0.3)	81	(0.4)
Day 7	39	(0.3)	24	(0.2)	63	(0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Solicited Adverse Reactions - N1	3749	3760	7509
Day 1, 30 Minutes after Vaccination (at Study Clinic)	255 (6.8)	240 (6.4)	495 (6.6)
Day 1, after Vaccination (at Home)	462 (12.3)	1266 (33.7)	1728 (23.0)
Day 2	371 (9.9)	1356 (36.1)	1727 (23.0)
Day 3	173 (4.6)	115 (3.1)	288 (3.8)
Day 4	107 (2.9)	34 (0.9)	141 (1.9)
Day 5	69 (1.8)	12 (0.3)	81 (1.1)
Day 6	70 (1.9)	18 (0.5)	88 (1.2)
Day 7	41 (1.1)	14 (0.4)	55 (0.7)
Solicited Local Adverse Reactions - N1	3747	3760	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	162 (4.3)	155 (4.1)	317 (4.2)
Day 1, after Vaccination (at Home)	146 (3.9)	1034 (27.5)	1180 (15.7)
Day 2	140 (3.7)	1498 (39.8)	1638 (21.8)
Day 3	52 (1.4)	95 (2.5)	147 (2.0)
Day 4	30 (0.8)	13 (0.3)	43 (0.6)
Day 5	18 (0.5)	2 (<0.1)	20 (0.3)
Day 6	16 (0.4)	3 (<0.1)	19 (0.3)
Day 7	9 (0.2)	4 (0.1)	13 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Pain - N1	3747	3760	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	155 (4.1)	149 (4.0)	304 (4.0)
Day 1, after Vaccination (at Home)	124 (3.3)	1020 (27.1)	1144 (15.2)
Day 2	112 (3.0)	1499 (39.9)	1611 (21.5)
Day 3	33 (0.9)	94 (2.5)	127 (1.7)
Day 4	24 (0.6)	13 (0.3)	37 (0.5)
Day 5	15 (0.4)	1 (<0.1)	16 (0.2)
Day 6	11 (0.3)	2 (<0.1)	13 (0.2)
Day 7	8 (0.2)	2 (<0.1)	10 (0.1)
Erythema (Redness) - N1	3747	3760	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	6 (0.2)	14 (0.4)	20 (0.3)
Day 2	9 (0.2)	40 (1.1)	49 (0.7)
Day 3	4 (0.1)	28 (0.7)	32 (0.4)
Day 4	0	3 (<0.1)	3 (<0.1)
Day 5	4 (0.1)	0	4 (<0.1)
Day 6	0	3 (<0.1)	3 (<0.1)
Day 7	0	1 (<0.1)	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Swelling (Hardness) - N1	3747	3760	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	8 (0.2)	23 (0.6)	31 (0.4)
Day 2	10 (0.3)	105 (2.8)	115 (1.5)
Day 3	2 (<0.1)	30 (0.8)	32 (0.4)
Day 4	1 (<0.1)	7 (0.2)	8 (0.1)
Day 5	0	0	0
Day 6	0	0	0
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)
Axillary Swelling or Tenderness - N1	3747	3760	7507
Day 1, 30 Minutes after Vaccination (at Study Clinic)	23 (0.6)	26 (0.7)	49 (0.7)
Day 1, after Vaccination (at Home)	24 (0.6)	55 (1.5)	79 (1.1)
Day 2	40 (1.1)	73 (1.9)	113 (1.5)
Day 3	25 (0.7)	35 (0.9)	60 (0.8)
Day 4	15 (0.4)	16 (0.4)	31 (0.4)
Day 5	6 (0.2)	10 (0.3)	16 (0.2)
Day 6	14 (0.4)	9 (0.2)	23 (0.3)
Day 7	8 (0.2)	7 (0.2)	15 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Solicited Systemic Adverse Reactions - N1	3749	3760	7509
Day 1, 30 Minutes after Vaccination (at Study Clinic)	122 (3.3)	120 (3.2)	242 (3.2)
Day 1, after Vaccination (at Home)	399 (10.6)	621 (16.5)	1020 (13.6)
Day 2	337 (9.0)	630 (16.8)	967 (12.9)
Day 3	179 (4.8)	216 (5.7)	395 (5.3)
Day 4	107 (2.9)	89 (2.4)	196 (2.6)
Day 5	73 (1.9)	50 (1.3)	123 (1.6)
Day 6	72 (1.9)	57 (1.5)	129 (1.7)
Day 7	45 (1.2)	34 (0.9)	79 (1.1)
Fever - N1	3749	3759	7508
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	0	1 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 2	0	1 (<0.1)	1 (<0.1)
Day 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 4	0	0	0
Day 5	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 6	0	2 (<0.1)	2 (<0.1)
Day 7	1 (<0.1)	0	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Headache - N1	3746	3760	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	67 (1.8)	66 (1.8)	133 (1.8)
Day 1, after Vaccination (at Home)	174 (4.6)	272 (7.2)	446 (5.9)
Day 2	164 (4.4)	275 (7.3)	439 (5.8)
Day 3	108 (2.9)	134 (3.6)	242 (3.2)
Day 4	63 (1.7)	52 (1.4)	115 (1.5)
Day 5	65 (1.7)	44 (1.2)	109 (1.5)
Day 6	49 (1.3)	43 (1.1)	92 (1.2)
Day 7	33 (0.9)	36 (1.0)	69 (0.9)
Fatigue - N1	3746	3760	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	39 (1.0)	42 (1.1)	81 (1.1)
Day 1, after Vaccination (at Home)	276 (7.4)	403 (10.7)	679 (9.0)
Day 2	222 (5.9)	465 (12.4)	687 (9.2)
Day 3	103 (2.7)	165 (4.4)	268 (3.6)
Day 4	77 (2.1)	72 (1.9)	149 (2.0)
Day 5	47 (1.3)	36 (1.0)	83 (1.1)
Day 6	57 (1.5)	48 (1.3)	105 (1.4)
Day 7	31 (0.8)	20 (0.5)	51 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3749) n	(%)	mRNA-1273 (N=3760) n	(%)	Total (N=7509) n	(%)
Myalgia - N1	3746		3760		7506	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	21	(0.6)	26	(0.7)	47	(0.6)
Day 1, after Vaccination (at Home)	99	(2.6)	192	(5.1)	291	(3.9)
Day 2	117	(3.1)	264	(7.0)	381	(5.1)
Day 3	76	(2.0)	126	(3.4)	202	(2.7)
Day 4	48	(1.3)	55	(1.5)	103	(1.4)
Day 5	33	(0.9)	23	(0.6)	56	(0.7)
Day 6	26	(0.7)	41	(1.1)	67	(0.9)
Day 7	24	(0.6)	15	(0.4)	39	(0.5)
Arthralgia - N1	3746		3760		7506	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	23	(0.6)	29	(0.8)	52	(0.7)
Day 1, after Vaccination (at Home)	75	(2.0)	136	(3.6)	211	(2.8)
Day 2	128	(3.4)	186	(4.9)	314	(4.2)
Day 3	77	(2.1)	107	(2.8)	184	(2.5)
Day 4	52	(1.4)	66	(1.8)	118	(1.6)
Day 5	44	(1.2)	38	(1.0)	82	(1.1)
Day 6	36	(1.0)	37	(1.0)	73	(1.0)
Day 7	22	(0.6)	19	(0.5)	41	(0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Age Group and Onset Day
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Nausea/Vomiting - N1	3746	3760	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (0.1)	8 (0.2)	13 (0.2)
Day 1, after Vaccination (at Home)	22 (0.6)	21 (0.6)	43 (0.6)
Day 2	44 (1.2)	57 (1.5)	101 (1.3)
Day 3	28 (0.7)	42 (1.1)	70 (0.9)
Day 4	15 (0.4)	18 (0.5)	33 (0.4)
Day 5	14 (0.4)	19 (0.5)	33 (0.4)
Day 6	25 (0.7)	17 (0.5)	42 (0.6)
Day 7	14 (0.4)	12 (0.3)	26 (0.3)
Chills - N1	3746	3760	7506
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (0.3)	10 (0.3)	22 (0.3)
Day 1, after Vaccination (at Home)	34 (0.9)	48 (1.3)	82 (1.1)
Day 2	37 (1.0)	57 (1.5)	94 (1.3)
Day 3	23 (0.6)	43 (1.1)	66 (0.9)
Day 4	16 (0.4)	18 (0.5)	34 (0.5)
Day 5	9 (0.2)	13 (0.3)	22 (0.3)
Day 6	13 (0.3)	6 (0.2)	19 (0.3)
Day 7	4 (0.1)	6 (0.2)	10 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030201.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Solicited Adverse Reactions - N1	10929	11000	21929
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1325 (12.1)	1222 (11.1)	2547 (11.6)
Day 1, after Vaccination (at Home)	1524 (13.9)	6568 (59.7)	8092 (36.9)
Day 2	887 (8.1)	2332 (21.2)	3219 (14.7)
Day 3	446 (4.1)	89 (0.8)	535 (2.4)
Day 4	261 (2.4)	17 (0.2)	278 (1.3)
Day 5	212 (1.9)	7 (<0.1)	219 (1.0)
Day 6	158 (1.4)	9 (<0.1)	167 (0.8)
Day 7	108 (1.0)	8 (<0.1)	116 (0.5)
Solicited Local Adverse Reactions - N1	10928	10999	21927
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1061 (9.7)	949 (8.6)	2010 (9.2)
Day 1, after Vaccination (at Home)	613 (5.6)	6430 (58.5)	7043 (32.1)
Day 2	293 (2.7)	2427 (22.1)	2720 (12.4)
Day 3	140 (1.3)	103 (0.9)	243 (1.1)
Day 4	59 (0.5)	16 (0.1)	75 (0.3)
Day 5	49 (0.4)	3 (<0.1)	52 (0.2)
Day 6	23 (0.2)	4 (<0.1)	27 (0.1)
Day 7	24 (0.2)	4 (<0.1)	28 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Pain - N1	10928	10999	21927
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1037 (9.5)	916 (8.3)	1953 (8.9)
Day 1, after Vaccination (at Home)	563 (5.2)	6406 (58.2)	6969 (31.8)
Day 2	235 (2.2)	2447 (22.2)	2682 (12.2)
Day 3	113 (1.0)	102 (0.9)	215 (1.0)
Day 4	35 (0.3)	14 (0.1)	49 (0.2)
Day 5	35 (0.3)	2 (<0.1)	37 (0.2)
Day 6	18 (0.2)	4 (<0.1)	22 (0.1)
Day 7	12 (0.1)	2 (<0.1)	14 (<0.1)
Erythema (Redness) - N1	10928	10998	21926
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (<0.1)	3 (<0.1)	10 (<0.1)
Day 1, after Vaccination (at Home)	21 (0.2)	114 (1.0)	135 (0.6)
Day 2	9 (<0.1)	379 (3.4)	388 (1.8)
Day 3	6 (<0.1)	397 (3.6)	403 (1.8)
Day 4	5 (<0.1)	83 (0.8)	88 (0.4)
Day 5	3 (<0.1)	9 (<0.1)	12 (<0.1)
Day 6	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Swelling (Hardness) - N1	10928	10998	21926
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (0.1)	22 (0.1)
Day 1, after Vaccination (at Home)	15 (0.1)	425 (3.9)	440 (2.0)
Day 2	10 (<0.1)	674 (6.1)	684 (3.1)
Day 3	6 (<0.1)	229 (2.1)	235 (1.1)
Day 4	1 (<0.1)	48 (0.4)	49 (0.2)
Day 5	4 (<0.1)	7 (<0.1)	11 (<0.1)
Day 6	0	1 (<0.1)	1 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)
Axillary Swelling or Tenderness - N1	10928	10998	21926
Day 1, 30 Minutes after Vaccination (at Study Clinic)	49 (0.4)	61 (0.6)	110 (0.5)
Day 1, after Vaccination (at Home)	126 (1.2)	436 (4.0)	562 (2.6)
Day 2	122 (1.1)	740 (6.7)	862 (3.9)
Day 3	70 (0.6)	346 (3.1)	416 (1.9)
Day 4	46 (0.4)	129 (1.2)	175 (0.8)
Day 5	31 (0.3)	32 (0.3)	63 (0.3)
Day 6	16 (0.1)	18 (0.2)	34 (0.2)
Day 7	14 (0.1)	15 (0.1)	29 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Solicited Systemic Adverse Reactions - N1	10928	10999	21927
Day 1, 30 Minutes after Vaccination (at Study Clinic)	421 (3.9)	418 (3.8)	839 (3.8)
Day 1, after Vaccination (at Home)	1462 (13.4)	3483 (31.7)	4945 (22.6)
Day 2	965 (8.8)	4688 (42.6)	5653 (25.8)
Day 3	494 (4.5)	271 (2.5)	765 (3.5)
Day 4	304 (2.8)	71 (0.6)	375 (1.7)
Day 5	245 (2.2)	32 (0.3)	277 (1.3)
Day 6	187 (1.7)	42 (0.4)	229 (1.0)
Day 7	130 (1.2)	18 (0.2)	148 (0.7)
Fever - N1	10925	10993	21918
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	200 (1.8)	205 (0.9)
Day 2	5 (<0.1)	1556 (14.2)	1561 (7.1)
Day 3	7 (<0.1)	142 (1.3)	149 (0.7)
Day 4	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 5	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 6	7 (<0.1)	1 (<0.1)	8 (<0.1)
Day 7	6 (<0.1)	2 (<0.1)	8 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Headache - N1	10926	10998	21924
Day 1, 30 Minutes after Vaccination (at Study Clinic)	208 (1.9)	220 (2.0)	428 (2.0)
Day 1, after Vaccination (at Home)	791 (7.2)	1819 (16.5)	2610 (11.9)
Day 2	600 (5.5)	4179 (38.0)	4779 (21.8)
Day 3	399 (3.7)	355 (3.2)	754 (3.4)
Day 4	270 (2.5)	135 (1.2)	405 (1.8)
Day 5	194 (1.8)	90 (0.8)	284 (1.3)
Day 6	183 (1.7)	83 (0.8)	266 (1.2)
Day 7	130 (1.2)	48 (0.4)	178 (0.8)
Fatigue - N1	10926	10998	21924
Day 1, 30 Minutes after Vaccination (at Study Clinic)	168 (1.5)	191 (1.7)	359 (1.6)
Day 1, after Vaccination (at Home)	957 (8.8)	2434 (22.1)	3391 (15.5)
Day 2	680 (6.2)	4362 (39.7)	5042 (23.0)
Day 3	333 (3.0)	321 (2.9)	654 (3.0)
Day 4	186 (1.7)	57 (0.5)	243 (1.1)
Day 5	177 (1.6)	40 (0.4)	217 (1.0)
Day 6	138 (1.3)	34 (0.3)	172 (0.8)
Day 7	62 (0.6)	14 (0.1)	76 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
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Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Myalgia - N1	10926	10998	21924
Day 1, 30 Minutes after Vaccination (at Study Clinic)	79 (0.7)	73 (0.7)	152 (0.7)
Day 1, after Vaccination (at Home)	385 (3.5)	1681 (15.3)	2066 (9.4)
Day 2	362 (3.3)	4655 (42.3)	5017 (22.9)
Day 3	204 (1.9)	275 (2.5)	479 (2.2)
Day 4	146 (1.3)	50 (0.5)	196 (0.9)
Day 5	90 (0.8)	21 (0.2)	111 (0.5)
Day 6	99 (0.9)	20 (0.2)	119 (0.5)
Day 7	60 (0.5)	14 (0.1)	74 (0.3)
Arthralgia - N1	10926	10998	21924
Day 1, 30 Minutes after Vaccination (at Study Clinic)	75 (0.7)	81 (0.7)	156 (0.7)
Day 1, after Vaccination (at Home)	304 (2.8)	1105 (10.0)	1409 (6.4)
Day 2	277 (2.5)	3429 (31.2)	3706 (16.9)
Day 3	176 (1.6)	270 (2.5)	446 (2.0)
Day 4	133 (1.2)	56 (0.5)	189 (0.9)
Day 5	77 (0.7)	27 (0.2)	104 (0.5)
Day 6	91 (0.8)	29 (0.3)	120 (0.5)
Day 7	47 (0.4)	13 (0.1)	60 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Nausea/Vomiting - N1	10926	10998	21924
Day 1, 30 Minutes after Vaccination (at Study Clinic)	35 (0.3)	27 (0.2)	62 (0.3)
Day 1, after Vaccination (at Home)	192 (1.8)	436 (4.0)	628 (2.9)
Day 2	189 (1.7)	1480 (13.5)	1669 (7.6)
Day 3	121 (1.1)	223 (2.0)	344 (1.6)
Day 4	85 (0.8)	81 (0.7)	166 (0.8)
Day 5	68 (0.6)	44 (0.4)	112 (0.5)
Day 6	70 (0.6)	38 (0.3)	108 (0.5)
Day 7	47 (0.4)	26 (0.2)	73 (0.3)
Chills - N1	10926	10998	21924
Day 1, 30 Minutes after Vaccination (at Study Clinic)	47 (0.4)	34 (0.3)	81 (0.4)
Day 1, after Vaccination (at Home)	182 (1.7)	949 (8.6)	1131 (5.2)
Day 2	149 (1.4)	4005 (36.4)	4154 (18.9)
Day 3	85 (0.8)	287 (2.6)	372 (1.7)
Day 4	62 (0.6)	33 (0.3)	95 (0.4)
Day 5	50 (0.5)	15 (0.1)	65 (0.3)
Day 6	54 (0.5)	20 (0.2)	74 (0.3)
Day 7	33 (0.3)	14 (0.1)	47 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Solicited Adverse Reactions - N1	3649	3691	7340
Day 1, 30 Minutes after Vaccination (at Study Clinic)	242 (6.6)	238 (6.4)	480 (6.5)
Day 1, after Vaccination (at Home)	433 (11.9)	1763 (47.8)	2196 (29.9)
Day 2	290 (7.9)	1228 (33.3)	1518 (20.7)
Day 3	127 (3.5)	50 (1.4)	177 (2.4)
Day 4	90 (2.5)	12 (0.3)	102 (1.4)
Day 5	63 (1.7)	6 (0.2)	69 (0.9)
Day 6	53 (1.5)	5 (0.1)	58 (0.8)
Day 7	36 (1.0)	2 (<0.1)	38 (0.5)
Solicited Local Adverse Reactions - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	137 (3.8)	162 (4.4)	299 (4.1)
Day 1, after Vaccination (at Home)	160 (4.4)	1613 (43.7)	1773 (24.2)
Day 2	111 (3.0)	1245 (33.7)	1356 (18.5)
Day 3	42 (1.2)	53 (1.4)	95 (1.3)
Day 4	26 (0.7)	9 (0.2)	35 (0.5)
Day 5	7 (0.2)	6 (0.2)	13 (0.2)
Day 6	10 (0.3)	4 (0.1)	14 (0.2)
Day 7	2 (<0.1)	1 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Pain - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	129 (3.5)	154 (4.2)	283 (3.9)
Day 1, after Vaccination (at Home)	148 (4.1)	1593 (43.2)	1741 (23.7)
Day 2	91 (2.5)	1257 (34.1)	1348 (18.4)
Day 3	33 (0.9)	53 (1.4)	86 (1.2)
Day 4	25 (0.7)	8 (0.2)	33 (0.4)
Day 5	4 (0.1)	3 (<0.1)	7 (<0.1)
Day 6	6 (0.2)	2 (<0.1)	8 (0.1)
Day 7	2 (<0.1)	1 (<0.1)	3 (<0.1)
Erythema (Redness) - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	7 (0.2)	35 (0.9)	42 (0.6)
Day 2	1 (<0.1)	115 (3.1)	116 (1.6)
Day 3	3 (<0.1)	98 (2.7)	101 (1.4)
Day 4	0	26 (0.7)	26 (0.4)
Day 5	1 (<0.1)	6 (0.2)	7 (<0.1)
Day 6	2 (<0.1)	2 (<0.1)	4 (<0.1)
Day 7	0	2 (<0.1)	2 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Swelling (Hardness) - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	4 (0.1)	7 (<0.1)
Day 1, after Vaccination (at Home)	5 (0.1)	99 (2.7)	104 (1.4)
Day 2	3 (<0.1)	222 (6.0)	225 (3.1)
Day 3	1 (<0.1)	62 (1.7)	63 (0.9)
Day 4	2 (<0.1)	16 (0.4)	18 (0.2)
Day 5	0	4 (0.1)	4 (<0.1)
Day 6	0	1 (<0.1)	1 (<0.1)
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	14 (0.4)	15 (0.4)	29 (0.4)
Day 1, after Vaccination (at Home)	20 (0.5)	62 (1.7)	82 (1.1)
Day 2	31 (0.8)	149 (4.0)	180 (2.5)
Day 3	16 (0.4)	52 (1.4)	68 (0.9)
Day 4	3 (<0.1)	24 (0.7)	27 (0.4)
Day 5	8 (0.2)	7 (0.2)	15 (0.2)
Day 6	4 (0.1)	5 (0.1)	9 (0.1)
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Solicited Systemic Adverse Reactions - N1	3649	3691	7340
Day 1, 30 Minutes after Vaccination (at Study Clinic)	126 (3.5)	102 (2.8)	228 (3.1)
Day 1, after Vaccination (at Home)	363 (9.9)	861 (23.3)	1224 (16.7)
Day 2	269 (7.4)	1533 (41.5)	1802 (24.6)
Day 3	124 (3.4)	98 (2.7)	222 (3.0)
Day 4	91 (2.5)	26 (0.7)	117 (1.6)
Day 5	67 (1.8)	12 (0.3)	79 (1.1)
Day 6	57 (1.6)	16 (0.4)	73 (1.0)
Day 7	38 (1.0)	7 (0.2)	45 (0.6)
Fever - N1	3648	3689	7337
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (<0.1)	1 (<0.1)
Day 1, after Vaccination (at Home)	0	29 (0.8)	29 (0.4)
Day 2	2 (<0.1)	315 (8.5)	317 (4.3)
Day 3	1 (<0.1)	20 (0.5)	21 (0.3)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	1 (<0.1)	0	1 (<0.1)
Day 6	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Headache - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	57 (1.6)	45 (1.2)	102 (1.4)
Day 1, after Vaccination (at Home)	151 (4.1)	400 (10.8)	551 (7.5)
Day 2	172 (4.7)	1092 (29.6)	1264 (17.2)
Day 3	90 (2.5)	87 (2.4)	177 (2.4)
Day 4	56 (1.5)	28 (0.8)	84 (1.1)
Day 5	45 (1.2)	21 (0.6)	66 (0.9)
Day 6	46 (1.3)	28 (0.8)	74 (1.0)
Day 7	35 (1.0)	7 (0.2)	42 (0.6)
Fatigue - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	49 (1.3)	40 (1.1)	89 (1.2)
Day 1, after Vaccination (at Home)	239 (6.5)	557 (15.1)	796 (10.8)
Day 2	183 (5.0)	1403 (38.0)	1586 (21.6)
Day 3	80 (2.2)	97 (2.6)	177 (2.4)
Day 4	65 (1.8)	23 (0.6)	88 (1.2)
Day 5	37 (1.0)	13 (0.4)	50 (0.7)
Day 6	38 (1.0)	10 (0.3)	48 (0.7)
Day 7	26 (0.7)	11 (0.3)	37 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Myalgia - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	33 (0.9)	29 (0.8)	62 (0.8)
Day 1, after Vaccination (at Home)	79 (2.2)	369 (10.0)	448 (6.1)
Day 2	128 (3.5)	1224 (33.2)	1352 (18.4)
Day 3	58 (1.6)	73 (2.0)	131 (1.8)
Day 4	32 (0.9)	17 (0.5)	49 (0.7)
Day 5	29 (0.8)	11 (0.3)	40 (0.5)
Day 6	27 (0.7)	12 (0.3)	39 (0.5)
Day 7	13 (0.4)	5 (0.1)	18 (0.2)
Arthralgia - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	42 (1.2)	38 (1.0)	80 (1.1)
Day 1, after Vaccination (at Home)	81 (2.2)	278 (7.5)	359 (4.9)
Day 2	111 (3.0)	854 (23.1)	965 (13.2)
Day 3	54 (1.5)	67 (1.8)	121 (1.6)
Day 4	42 (1.2)	26 (0.7)	68 (0.9)
Day 5	22 (0.6)	15 (0.4)	37 (0.5)
Day 6	30 (0.8)	10 (0.3)	40 (0.5)
Day 7	17 (0.5)	5 (0.1)	22 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Age Group and Onset Day
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Nausea/Vomiting - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (0.2)	11 (0.3)	20 (0.3)
Day 1, after Vaccination (at Home)	22 (0.6)	75 (2.0)	97 (1.3)
Day 2	33 (0.9)	276 (7.5)	309 (4.2)
Day 3	20 (0.5)	41 (1.1)	61 (0.8)
Day 4	15 (0.4)	14 (0.4)	29 (0.4)
Day 5	8 (0.2)	6 (0.2)	14 (0.2)
Day 6	12 (0.3)	11 (0.3)	23 (0.3)
Day 7	15 (0.4)	5 (0.1)	20 (0.3)
Chills - N1	3649	3689	7338
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (0.3)	13 (0.4)	25 (0.3)
Day 1, after Vaccination (at Home)	31 (0.8)	165 (4.5)	196 (2.7)
Day 2	44 (1.2)	866 (23.5)	910 (12.4)
Day 3	19 (0.5)	77 (2.1)	96 (1.3)
Day 4	13 (0.4)	13 (0.4)	26 (0.4)
Day 5	13 (0.4)	1 (<0.1)	14 (0.2)
Day 6	15 (0.4)	3 (<0.1)	18 (0.2)
Day 7	4 (0.1)	5 (0.1)	9 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030202.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Adverse Reactions - N1	11408	11413	22821
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2238 (19.6)	2193 (19.2)	4431 (19.4)
Day 1, after Vaccination (at Home)	2271 (19.9)	6936 (60.8)	9207 (40.3)
Day 2	1196 (10.5)	1659 (14.5)	2855 (12.5)
Day 3	555 (4.9)	59 (0.5)	614 (2.7)
Day 4	311 (2.7)	7 (<0.1)	318 (1.4)
Day 5	232 (2.0)	14 (0.1)	246 (1.1)
Day 6	156 (1.4)	8 (<0.1)	164 (0.7)
Day 7	129 (1.1)	13 (0.1)	142 (0.6)
Solicited Local Adverse Reactions - N1	11407	11413	22820
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1749 (15.3)	1695 (14.9)	3444 (15.1)
Day 1, after Vaccination (at Home)	931 (8.2)	7010 (61.4)	7941 (34.8)
Day 2	468 (4.1)	1877 (16.4)	2345 (10.3)
Day 3	197 (1.7)	70 (0.6)	267 (1.2)
Day 4	99 (0.9)	12 (0.1)	111 (0.5)
Day 5	72 (0.6)	4 (<0.1)	76 (0.3)
Day 6	45 (0.4)	4 (<0.1)	49 (0.2)
Day 7	29 (0.3)	8 (<0.1)	37 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Pain - N1	11407	11413	22820
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1700 (14.9)	1635 (14.3)	3335 (14.6)
Day 1, after Vaccination (at Home)	855 (7.5)	7018 (61.5)	7873 (34.5)
Day 2	402 (3.5)	1903 (16.7)	2305 (10.1)
Day 3	158 (1.4)	65 (0.6)	223 (1.0)
Day 4	64 (0.6)	10 (<0.1)	74 (0.3)
Day 5	52 (0.5)	2 (<0.1)	54 (0.2)
Day 6	33 (0.3)	4 (<0.1)	37 (0.2)
Day 7	19 (0.2)	6 (<0.1)	25 (0.1)
Erythema (Redness) - N1	11407	11412	22819
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	11 (<0.1)	20 (<0.1)
Day 1, after Vaccination (at Home)	42 (0.4)	154 (1.3)	196 (0.9)
Day 2	16 (0.1)	498 (4.4)	514 (2.3)
Day 3	11 (<0.1)	428 (3.8)	439 (1.9)
Day 4	9 (<0.1)	90 (0.8)	99 (0.4)
Day 5	4 (<0.1)	11 (<0.1)	15 (<0.1)
Day 6	6 (<0.1)	4 (<0.1)	10 (<0.1)
Day 7	3 (<0.1)	6 (<0.1)	9 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Swelling (Hardness) - N1	11407	11412	22819
Day 1, 30 Minutes after Vaccination (at Study Clinic)	17 (0.1)	23 (0.2)	40 (0.2)
Day 1, after Vaccination (at Home)	29 (0.3)	539 (4.7)	568 (2.5)
Day 2	17 (0.1)	903 (7.9)	920 (4.0)
Day 3	5 (<0.1)	236 (2.1)	241 (1.1)
Day 4	1 (<0.1)	47 (0.4)	48 (0.2)
Day 5	8 (<0.1)	7 (<0.1)	15 (<0.1)
Day 6	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 7	4 (<0.1)	3 (<0.1)	7 (<0.1)
Axillary Swelling or Tenderness - N1	11407	11412	22819
Day 1, 30 Minutes after Vaccination (at Study Clinic)	120 (1.1)	128 (1.1)	248 (1.1)
Day 1, after Vaccination (at Home)	218 (1.9)	674 (5.9)	892 (3.9)
Day 2	200 (1.8)	944 (8.3)	1144 (5.0)
Day 3	119 (1.0)	424 (3.7)	543 (2.4)
Day 4	76 (0.7)	163 (1.4)	239 (1.0)
Day 5	71 (0.6)	56 (0.5)	127 (0.6)
Day 6	43 (0.4)	62 (0.5)	105 (0.5)
Day 7	31 (0.3)	85 (0.7)	116 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Systemic Adverse Reactions - N1	11408	11412	22820
Day 1, 30 Minutes after Vaccination (at Study Clinic)	875 (7.7)	854 (7.5)	1729 (7.6)
Day 1, after Vaccination (at Home)	2445 (21.4)	4287 (37.6)	6732 (29.5)
Day 2	1396 (12.2)	4178 (36.6)	5574 (24.4)
Day 3	646 (5.7)	275 (2.4)	921 (4.0)
Day 4	342 (3.0)	93 (0.8)	435 (1.9)
Day 5	286 (2.5)	60 (0.5)	346 (1.5)
Day 6	203 (1.8)	47 (0.4)	250 (1.1)
Day 7	158 (1.4)	31 (0.3)	189 (0.8)
Fever - N1	11407	11411	22818
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 1, after Vaccination (at Home)	6 (<0.1)	209 (1.8)	215 (0.9)
Day 2	11 (<0.1)	1591 (13.9)	1602 (7.0)
Day 3	13 (0.1)	154 (1.3)	167 (0.7)
Day 4	10 (<0.1)	7 (<0.1)	17 (<0.1)
Day 5	11 (<0.1)	7 (<0.1)	18 (<0.1)
Day 6	11 (<0.1)	3 (<0.1)	14 (<0.1)
Day 7	9 (<0.1)	3 (<0.1)	12 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Headache - N1	11407	11412	22819
Day 1, 30 Minutes after Vaccination (at Study Clinic)	465 (4.1)	477 (4.2)	942 (4.1)
Day 1, after Vaccination (at Home)	1372 (12.0)	2414 (21.2)	3786 (16.6)
Day 2	1057 (9.3)	4036 (35.4)	5093 (22.3)
Day 3	592 (5.2)	399 (3.5)	991 (4.3)
Day 4	352 (3.1)	189 (1.7)	541 (2.4)
Day 5	269 (2.4)	124 (1.1)	393 (1.7)
Day 6	239 (2.1)	127 (1.1)	366 (1.6)
Day 7	188 (1.6)	69 (0.6)	257 (1.1)
Fatigue - N1	11407	11412	22819
Day 1, 30 Minutes after Vaccination (at Study Clinic)	334 (2.9)	363 (3.2)	697 (3.1)
Day 1, after Vaccination (at Home)	1721 (15.1)	3129 (27.4)	4850 (21.3)
Day 2	1044 (9.2)	4126 (36.2)	5170 (22.7)
Day 3	500 (4.4)	348 (3.0)	848 (3.7)
Day 4	249 (2.2)	80 (0.7)	329 (1.4)
Day 5	226 (2.0)	59 (0.5)	285 (1.2)
Day 6	179 (1.6)	59 (0.5)	238 (1.0)
Day 7	93 (0.8)	36 (0.3)	129 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
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Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Myalgia - N1	11407	11412	22819
Day 1, 30 Minutes after Vaccination (at Study Clinic)	171 (1.5)	164 (1.4)	335 (1.5)
Day 1, after Vaccination (at Home)	671 (5.9)	2100 (18.4)	2771 (12.1)
Day 2	635 (5.6)	4648 (40.7)	5283 (23.2)
Day 3	321 (2.8)	315 (2.8)	636 (2.8)
Day 4	248 (2.2)	68 (0.6)	316 (1.4)
Day 5	144 (1.3)	38 (0.3)	182 (0.8)
Day 6	141 (1.2)	36 (0.3)	177 (0.8)
Day 7	102 (0.9)	28 (0.2)	130 (0.6)
Arthralgia - N1	11407	11412	22819
Day 1, 30 Minutes after Vaccination (at Study Clinic)	148 (1.3)	149 (1.3)	297 (1.3)
Day 1, after Vaccination (at Home)	497 (4.4)	1364 (12.0)	1861 (8.2)
Day 2	521 (4.6)	3469 (30.4)	3990 (17.5)
Day 3	288 (2.5)	342 (3.0)	630 (2.8)
Day 4	205 (1.8)	87 (0.8)	292 (1.3)
Day 5	126 (1.1)	47 (0.4)	173 (0.8)
Day 6	137 (1.2)	52 (0.5)	189 (0.8)
Day 7	79 (0.7)	31 (0.3)	110 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=11408) n	(%)	mRNA-1273 (N=11413) n	(%)	Total (N=22821) n	(%)
Nausea/Vomiting - N1	11407		11412		22819	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	76	(0.7)	58	(0.5)	134	(0.6)
Day 1, after Vaccination (at Home)	319	(2.8)	595	(5.2)	914	(4.0)
Day 2	338	(3.0)	1620	(14.2)	1958	(8.6)
Day 3	212	(1.9)	311	(2.7)	523	(2.3)
Day 4	160	(1.4)	146	(1.3)	306	(1.3)
Day 5	131	(1.1)	73	(0.6)	204	(0.9)
Day 6	124	(1.1)	69	(0.6)	193	(0.8)
Day 7	88	(0.8)	57	(0.5)	145	(0.6)
Chills - N1	11407		11412		22819	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	115	(1.0)	94	(0.8)	209	(0.9)
Day 1, after Vaccination (at Home)	309	(2.7)	1101	(9.6)	1410	(6.2)
Day 2	267	(2.3)	4008	(35.1)	4275	(18.7)
Day 3	165	(1.4)	332	(2.9)	497	(2.2)
Day 4	107	(0.9)	46	(0.4)	153	(0.7)
Day 5	98	(0.9)	35	(0.3)	133	(0.6)
Day 6	85	(0.7)	37	(0.3)	122	(0.5)
Day 7	61	(0.5)	23	(0.2)	84	(0.4)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Solicited Adverse Reactions - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	457 (12.2)	434 (11.5)	891 (11.9)
Day 1, after Vaccination (at Home)	662 (17.6)	2021 (53.7)	2683 (35.7)
Day 2	441 (11.8)	985 (26.2)	1426 (19.0)
Day 3	189 (5.0)	44 (1.2)	233 (3.1)
Day 4	112 (3.0)	10 (0.3)	122 (1.6)
Day 5	75 (2.0)	9 (0.2)	84 (1.1)
Day 6	57 (1.5)	5 (0.1)	62 (0.8)
Day 7	32 (0.9)	5 (0.1)	37 (0.5)
Solicited Local Adverse Reactions - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	277 (7.4)	294 (7.8)	571 (7.6)
Day 1, after Vaccination (at Home)	249 (6.6)	1875 (49.8)	2124 (28.3)
Day 2	195 (5.2)	1122 (29.8)	1317 (17.5)
Day 3	68 (1.8)	45 (1.2)	113 (1.5)
Day 4	39 (1.0)	3 (<0.1)	42 (0.6)
Day 5	21 (0.6)	6 (0.2)	27 (0.4)
Day 6	20 (0.5)	5 (0.1)	25 (0.3)
Day 7	9 (0.2)	2 (<0.1)	11 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Pain - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	263 (7.0)	280 (7.4)	543 (7.2)
Day 1, after Vaccination (at Home)	223 (5.9)	1855 (49.3)	2078 (27.6)
Day 2	158 (4.2)	1138 (30.2)	1296 (17.2)
Day 3	47 (1.3)	46 (1.2)	93 (1.2)
Day 4	35 (0.9)	1 (<0.1)	36 (0.5)
Day 5	17 (0.5)	2 (<0.1)	19 (0.3)
Day 6	13 (0.3)	3 (<0.1)	16 (0.2)
Day 7	7 (0.2)	1 (<0.1)	8 (0.1)
Erythema (Redness) - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	12 (0.3)	47 (1.2)	59 (0.8)
Day 2	10 (0.3)	142 (3.8)	152 (2.0)
Day 3	7 (0.2)	115 (3.1)	122 (1.6)
Day 4	0	26 (0.7)	26 (0.3)
Day 5	5 (0.1)	6 (0.2)	11 (0.1)
Day 6	2 (<0.1)	5 (0.1)	7 (<0.1)
Day 7	0	3 (<0.1)	3 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Swelling (Hardness) - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (0.1)	7 (0.2)	11 (0.1)
Day 1, after Vaccination (at Home)	12 (0.3)	115 (3.1)	127 (1.7)
Day 2	11 (0.3)	262 (7.0)	273 (3.6)
Day 3	3 (<0.1)	77 (2.0)	80 (1.1)
Day 4	3 (<0.1)	21 (0.6)	24 (0.3)
Day 5	0	4 (0.1)	4 (<0.1)
Day 6	0	1 (<0.1)	1 (<0.1)
Day 7	1 (<0.1)	1 (<0.1)	2 (<0.1)
Axillary Swelling or Tenderness - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	35 (0.9)	41 (1.1)	76 (1.0)
Day 1, after Vaccination (at Home)	40 (1.1)	111 (2.9)	151 (2.0)
Day 2	65 (1.7)	191 (5.1)	256 (3.4)
Day 3	31 (0.8)	73 (1.9)	104 (1.4)
Day 4	16 (0.4)	34 (0.9)	50 (0.7)
Day 5	11 (0.3)	11 (0.3)	22 (0.3)
Day 6	17 (0.5)	10 (0.3)	27 (0.4)
Day 7	8 (0.2)	6 (0.2)	14 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Solicited Systemic Adverse Reactions - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	237 (6.3)	204 (5.4)	441 (5.9)
Day 1, after Vaccination (at Home)	587 (15.6)	1141 (30.3)	1728 (23.0)
Day 2	428 (11.4)	1401 (37.2)	1829 (24.3)
Day 3	203 (5.4)	126 (3.3)	329 (4.4)
Day 4	126 (3.4)	29 (0.8)	155 (2.1)
Day 5	78 (2.1)	23 (0.6)	101 (1.3)
Day 6	64 (1.7)	19 (0.5)	83 (1.1)
Day 7	43 (1.1)	11 (0.3)	54 (0.7)
Fever - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	3 (<0.1)	32 (0.8)	35 (0.5)
Day 2	2 (<0.1)	315 (8.4)	317 (4.2)
Day 3	2 (<0.1)	20 (0.5)	22 (0.3)
Day 4	0	1 (<0.1)	1 (<0.1)
Day 5	2 (<0.1)	3 (<0.1)	5 (<0.1)
Day 6	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 7	1 (<0.1)	0	1 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Onset Day	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Headache - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	123 (3.3)	106 (2.8)	229 (3.0)
Day 1, after Vaccination (at Home)	279 (7.4)	572 (15.2)	851 (11.3)
Day 2	263 (7.0)	1076 (28.6)	1339 (17.8)
Day 3	150 (4.0)	128 (3.4)	278 (3.7)
Day 4	88 (2.3)	37 (1.0)	125 (1.7)
Day 5	77 (2.1)	33 (0.9)	110 (1.5)
Day 6	55 (1.5)	33 (0.9)	88 (1.2)
Day 7	44 (1.2)	24 (0.6)	68 (0.9)
Fatigue - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	86 (2.3)	78 (2.1)	164 (2.2)
Day 1, after Vaccination (at Home)	417 (11.1)	804 (21.3)	1221 (16.2)
Day 2	308 (8.2)	1348 (35.8)	1656 (22.0)
Day 3	134 (3.6)	114 (3.0)	248 (3.3)
Day 4	101 (2.7)	37 (1.0)	138 (1.8)
Day 5	55 (1.5)	23 (0.6)	78 (1.0)
Day 6	65 (1.7)	24 (0.6)	89 (1.2)
Day 7	37 (1.0)	12 (0.3)	49 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Myalgia - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	53 (1.4)	50 (1.3)	103 (1.4)
Day 1, after Vaccination (at Home)	154 (4.1)	487 (12.9)	641 (8.5)
Day 2	196 (5.2)	1226 (32.6)	1422 (18.9)
Day 3	109 (2.9)	105 (2.8)	214 (2.8)
Day 4	60 (1.6)	33 (0.9)	93 (1.2)
Day 5	43 (1.1)	18 (0.5)	61 (0.8)
Day 6	42 (1.1)	25 (0.7)	67 (0.9)
Day 7	28 (0.7)	7 (0.2)	35 (0.5)
Arthralgia - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	62 (1.7)	61 (1.6)	123 (1.6)
Day 1, after Vaccination (at Home)	135 (3.6)	357 (9.5)	492 (6.5)
Day 2	194 (5.2)	881 (23.4)	1075 (14.3)
Day 3	105 (2.8)	109 (2.9)	214 (2.8)
Day 4	64 (1.7)	51 (1.4)	115 (1.5)
Day 5	45 (1.2)	25 (0.7)	70 (0.9)
Day 6	44 (1.2)	17 (0.5)	61 (0.8)
Day 7	22 (0.6)	13 (0.3)	35 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.2.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Age Group and Onset Day
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Onset Day	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Nausea/Vomiting - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	13 (0.3)	19 (0.5)	32 (0.4)
Day 1, after Vaccination (at Home)	40 (1.1)	90 (2.4)	130 (1.7)
Day 2	71 (1.9)	309 (8.2)	380 (5.1)
Day 3	43 (1.1)	68 (1.8)	111 (1.5)
Day 4	29 (0.8)	24 (0.6)	53 (0.7)
Day 5	20 (0.5)	19 (0.5)	39 (0.5)
Day 6	33 (0.9)	24 (0.6)	57 (0.8)
Day 7	26 (0.7)	11 (0.3)	37 (0.5)
Chills - N1	3751	3766	7517
Day 1, 30 Minutes after Vaccination (at Study Clinic)	24 (0.6)	23 (0.6)	47 (0.6)
Day 1, after Vaccination (at Home)	62 (1.7)	197 (5.2)	259 (3.4)
Day 2	71 (1.9)	871 (23.1)	942 (12.5)
Day 3	36 (1.0)	98 (2.6)	134 (1.8)
Day 4	22 (0.6)	23 (0.6)	45 (0.6)
Day 5	19 (0.5)	5 (0.1)	24 (0.3)
Day 6	25 (0.7)	7 (0.2)	32 (0.4)
Day 7	7 (0.2)	7 (0.2)	14 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030203.sas 21JUN2021 17:05

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Solicited Adverse Reactions - N1	14730	14733	29463
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1558 (10.6)	1538 (10.4)	3096 (10.5)
Day 1, after Vaccination (at Home)	2201 (14.9)	6697 (45.5)	8898 (30.2)
Day 2	1503 (10.2)	4280 (29.1)	5783 (19.6)
Day 3	726 (4.9)	270 (1.8)	996 (3.4)
Day 4	396 (2.7)	70 (0.5)	466 (1.6)
Day 5	314 (2.1)	39 (0.3)	353 (1.2)
Day 6	244 (1.7)	48 (0.3)	292 (1.0)
Day 7	163 (1.1)	34 (0.2)	197 (0.7)
Solicited Local Adverse Reactions - N1	14726	14729	29455
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1111 (7.5)	1107 (7.5)	2218 (7.5)
Day 1, after Vaccination (at Home)	775 (5.3)	6270 (42.6)	7045 (23.9)
Day 2	561 (3.8)	4745 (32.2)	5306 (18.0)
Day 3	207 (1.4)	240 (1.6)	447 (1.5)
Day 4	111 (0.8)	42 (0.3)	153 (0.5)
Day 5	82 (0.6)	11 (<0.1)	93 (0.3)
Day 6	59 (0.4)	12 (<0.1)	71 (0.2)
Day 7	28 (0.2)	15 (0.1)	43 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Pain - N1	14726	14729	29455
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1072 (7.3)	1067 (7.2)	2139 (7.3)
Day 1, after Vaccination (at Home)	697 (4.7)	6223 (42.2)	6920 (23.5)
Day 2	473 (3.2)	4779 (32.4)	5252 (17.8)
Day 3	158 (1.1)	244 (1.7)	402 (1.4)
Day 4	80 (0.5)	36 (0.2)	116 (0.4)
Day 5	53 (0.4)	8 (<0.1)	61 (0.2)
Day 6	40 (0.3)	5 (<0.1)	45 (0.2)
Day 7	23 (0.2)	7 (<0.1)	30 (0.1)
Erythema (Redness) - N1	14726	14729	29455
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (<0.1)	9 (<0.1)	11 (<0.1)
Day 1, after Vaccination (at Home)	29 (0.2)	62 (0.4)	91 (0.3)
Day 2	16 (0.1)	215 (1.5)	231 (0.8)
Day 3	10 (<0.1)	111 (0.8)	121 (0.4)
Day 4	3 (<0.1)	16 (0.1)	19 (<0.1)
Day 5	5 (<0.1)	5 (<0.1)	10 (<0.1)
Day 6	6 (<0.1)	4 (<0.1)	10 (<0.1)
Day 7	3 (<0.1)	7 (<0.1)	10 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Swelling (Hardness) - N1	14726	14729	29455
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	22 (0.1)	198 (1.3)	220 (0.7)
Day 2	17 (0.1)	566 (3.8)	583 (2.0)
Day 3	4 (<0.1)	105 (0.7)	109 (0.4)
Day 4	1 (<0.1)	23 (0.2)	24 (<0.1)
Day 5	4 (<0.1)	1 (<0.1)	5 (<0.1)
Day 6	1 (<0.1)	2 (<0.1)	3 (<0.1)
Day 7	5 (<0.1)	2 (<0.1)	7 (<0.1)
Axillary Swelling or Tenderness - N1	14726	14729	29455
Day 1, 30 Minutes after Vaccination (at Study Clinic)	96 (0.7)	95 (0.6)	191 (0.6)
Day 1, after Vaccination (at Home)	146 (1.0)	344 (2.3)	490 (1.7)
Day 2	163 (1.1)	459 (3.1)	622 (2.1)
Day 3	98 (0.7)	215 (1.5)	313 (1.1)
Day 4	64 (0.4)	95 (0.6)	159 (0.5)
Day 5	56 (0.4)	58 (0.4)	114 (0.4)
Day 6	47 (0.3)	90 (0.6)	137 (0.5)
Day 7	31 (0.2)	131 (0.9)	162 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Solicited Systemic Adverse Reactions - N1	14730	14733	29463
Day 1, 30 Minutes after Vaccination (at Study Clinic)	669 (4.5)	631 (4.3)	1300 (4.4)
Day 1, after Vaccination (at Home)	2067 (14.0)	2949 (20.0)	5016 (17.0)
Day 2	1509 (10.2)	2670 (18.1)	4179 (14.2)
Day 3	762 (5.2)	847 (5.7)	1609 (5.5)
Day 4	426 (2.9)	321 (2.2)	747 (2.5)
Day 5	350 (2.4)	244 (1.7)	594 (2.0)
Day 6	269 (1.8)	236 (1.6)	505 (1.7)
Day 7	187 (1.3)	155 (1.1)	342 (1.2)
Fever - N1	14729	14731	29460
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (<0.1)	1 (<0.1)	4 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	13 (<0.1)	18 (<0.1)
Day 2	5 (<0.1)	28 (0.2)	33 (0.1)
Day 3	4 (<0.1)	23 (0.2)	27 (<0.1)
Day 4	7 (<0.1)	3 (<0.1)	10 (<0.1)
Day 5	6 (<0.1)	5 (<0.1)	11 (<0.1)
Day 6	4 (<0.1)	4 (<0.1)	8 (<0.1)
Day 7	4 (<0.1)	1 (<0.1)	5 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14730) n	Placebo (N=14730) (%)	mRNA-1273 (N=14733) n	mRNA-1273 (N=14733) (%)	Total (N=29463) n	Total (N=29463) (%)
Headache - N1	14725		14729		29454	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	355	(2.4)	354	(2.4)	709	(2.4)
Day 1, after Vaccination (at Home)	998	(6.8)	1371	(9.3)	2369	(8.0)
Day 2	915	(6.2)	1436	(9.7)	2351	(8.0)
Day 3	538	(3.7)	675	(4.6)	1213	(4.1)
Day 4	347	(2.4)	282	(1.9)	629	(2.1)
Day 5	307	(2.1)	242	(1.6)	549	(1.9)
Day 6	271	(1.8)	250	(1.7)	521	(1.8)
Day 7	186	(1.3)	177	(1.2)	363	(1.2)
Fatigue - N1	14725		14729		29454	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	232	(1.6)	240	(1.6)	472	(1.6)
Day 1, after Vaccination (at Home)	1424	(9.7)	1930	(13.1)	3354	(11.4)
Day 2	1032	(7.0)	1977	(13.4)	3009	(10.2)
Day 3	502	(3.4)	658	(4.5)	1160	(3.9)
Day 4	284	(1.9)	245	(1.7)	529	(1.8)
Day 5	246	(1.7)	157	(1.1)	403	(1.4)
Day 6	192	(1.3)	161	(1.1)	353	(1.2)
Day 7	126	(0.9)	98	(0.7)	224	(0.8)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14730) n	(%)	mRNA-1273 (N=14733) n	(%)	Total (N=29463) n	(%)
Myalgia - N1	14725		14729		29454	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	121	(0.8)	128	(0.9)	249	(0.8)
Day 1, after Vaccination (at Home)	487	(3.3)	900	(6.1)	1387	(4.7)
Day 2	535	(3.6)	1374	(9.3)	1909	(6.5)
Day 3	283	(1.9)	467	(3.2)	750	(2.5)
Day 4	221	(1.5)	159	(1.1)	380	(1.3)
Day 5	150	(1.0)	102	(0.7)	252	(0.9)
Day 6	120	(0.8)	102	(0.7)	222	(0.8)
Day 7	94	(0.6)	63	(0.4)	157	(0.5)
Arthralgia - N1	14725		14729		29454	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	98	(0.7)	103	(0.7)	201	(0.7)
Day 1, after Vaccination (at Home)	345	(2.3)	571	(3.9)	916	(3.1)
Day 2	478	(3.2)	866	(5.9)	1344	(4.6)
Day 3	278	(1.9)	411	(2.8)	689	(2.3)
Day 4	188	(1.3)	175	(1.2)	363	(1.2)
Day 5	145	(1.0)	104	(0.7)	249	(0.8)
Day 6	128	(0.9)	102	(0.7)	230	(0.8)
Day 7	75	(0.5)	74	(0.5)	149	(0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14730) n	Placebo (N=14730) (%)	mRNA-1273 (N=14733) n	mRNA-1273 (N=14733) (%)	Total (N=29463) n	Total (N=29463) (%)
Nausea/Vomiting - N1	14725		14729		29454	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	49	(0.3)	40	(0.3)	89	(0.3)
Day 1, after Vaccination (at Home)	180	(1.2)	219	(1.5)	399	(1.4)
Day 2	238	(1.6)	373	(2.5)	611	(2.1)
Day 3	164	(1.1)	233	(1.6)	397	(1.3)
Day 4	120	(0.8)	122	(0.8)	242	(0.8)
Day 5	106	(0.7)	82	(0.6)	188	(0.6)
Day 6	114	(0.8)	81	(0.5)	195	(0.7)
Day 7	73	(0.5)	60	(0.4)	133	(0.5)
Chills - N1	14725		14729		29454	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	85	(0.6)	71	(0.5)	156	(0.5)
Day 1, after Vaccination (at Home)	195	(1.3)	267	(1.8)	462	(1.6)
Day 2	187	(1.3)	404	(2.7)	591	(2.0)
Day 3	125	(0.8)	230	(1.6)	355	(1.2)
Day 4	80	(0.5)	71	(0.5)	151	(0.5)
Day 5	73	(0.5)	55	(0.4)	128	(0.4)
Day 6	62	(0.4)	36	(0.2)	98	(0.3)
Day 7	39	(0.3)	28	(0.2)	67	(0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Solicited Adverse Reactions - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	27 (8.0)	27 (7.8)	54 (7.9)
Day 1, after Vaccination (at Home)	40 (11.9)	123 (35.5)	163 (23.9)
Day 2	30 (8.9)	102 (29.5)	132 (19.3)
Day 3	14 (4.2)	9 (2.6)	23 (3.4)
Day 4	11 (3.3)	2 (0.6)	13 (1.9)
Day 5	5 (1.5)	1 (0.3)	6 (0.9)
Day 6	3 (0.9)	0	3 (0.4)
Day 7	8 (2.4)	1 (0.3)	9 (1.3)
Solicited Local Adverse Reactions - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	19 (5.6)	15 (4.3)	34 (5.0)
Day 1, after Vaccination (at Home)	16 (4.7)	108 (31.2)	124 (18.2)
Day 2	10 (3.0)	113 (32.7)	123 (18.0)
Day 3	5 (1.5)	11 (3.2)	16 (2.3)
Day 4	4 (1.2)	1 (0.3)	5 (0.7)
Day 5	3 (0.9)	1 (0.3)	4 (0.6)
Day 6	0	0	0
Day 7	3 (0.9)	1 (0.3)	4 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Pain - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	19 (5.6)	15 (4.3)	34 (5.0)
Day 1, after Vaccination (at Home)	15 (4.5)	108 (31.2)	123 (18.0)
Day 2	10 (3.0)	109 (31.5)	119 (17.4)
Day 3	3 (0.9)	13 (3.8)	16 (2.3)
Day 4	3 (0.9)	1 (0.3)	4 (0.6)
Day 5	3 (0.9)	0	3 (0.4)
Day 6	0	0	0
Day 7	3 (0.9)	1 (0.3)	4 (0.6)
Erythema (Redness) - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	2 (0.6)	2 (0.3)
Day 2	1 (0.3)	3 (0.9)	4 (0.6)
Day 3	1 (0.3)	2 (0.6)	3 (0.4)
Day 4	1 (0.3)	2 (0.6)	3 (0.4)
Day 5	0	0	0
Day 6	0	1 (0.3)	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n	Placebo (N=337) (%)	mRNA-1273 (N=346) n	mRNA-1273 (N=346) (%)	Total (N=683) n	Total (N=683) (%)
Swelling (Hardness) - N1	337		346		683	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0		0		0	
Day 1, after Vaccination (at Home)	1	(0.3)	4	(1.2)	5	(0.7)
Day 2	1	(0.3)	12	(3.5)	13	(1.9)
Day 3	0		1	(0.3)	1	(0.1)
Day 4	0		1	(0.3)	1	(0.1)
Day 5	0		0		0	
Day 6	0		1	(0.3)	1	(0.1)
Day 7	0		0		0	
Axillary Swelling or Tenderness - N1	337		346		683	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0		2	(0.6)	2	(0.3)
Day 1, after Vaccination (at Home)	2	(0.6)	7	(2.0)	9	(1.3)
Day 2	1	(0.3)	24	(6.9)	25	(3.7)
Day 3	4	(1.2)	15	(4.3)	19	(2.8)
Day 4	1	(0.3)	4	(1.2)	5	(0.7)
Day 5	4	(1.2)	2	(0.6)	6	(0.9)
Day 6	4	(1.2)	0		4	(0.6)
Day 7	2	(0.6)	2	(0.6)	4	(0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Solicited Systemic Adverse Reactions - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (3.0)	17 (4.9)	27 (4.0)
Day 1, after Vaccination (at Home)	35 (10.4)	62 (17.9)	97 (14.2)
Day 2	30 (8.9)	112 (32.4)	142 (20.8)
Day 3	19 (5.6)	13 (3.8)	32 (4.7)
Day 4	13 (3.9)	5 (1.4)	18 (2.6)
Day 5	3 (0.9)	2 (0.6)	5 (0.7)
Day 6	3 (0.9)	2 (0.6)	5 (0.7)
Day 7	9 (2.7)	1 (0.3)	10 (1.5)
Fever - N1	336	346	682
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.3)	1 (0.1)
Day 1, after Vaccination (at Home)	0	0	0
Day 2	1 (0.3)	27 (7.8)	28 (4.1)
Day 3	3 (0.9)	2 (0.6)	5 (0.7)
Day 4	0	2 (0.6)	2 (0.3)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Headache - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (1.5)	6 (1.7)	11 (1.6)
Day 1, after Vaccination (at Home)	14 (4.2)	33 (9.5)	47 (6.9)
Day 2	23 (6.8)	65 (18.8)	88 (12.9)
Day 3	13 (3.9)	12 (3.5)	25 (3.7)
Day 4	10 (3.0)	9 (2.6)	19 (2.8)
Day 5	6 (1.8)	7 (2.0)	13 (1.9)
Day 6	5 (1.5)	2 (0.6)	7 (1.0)
Day 7	7 (2.1)	0	7 (1.0)
Fatigue - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (0.9)	8 (2.3)	11 (1.6)
Day 1, after Vaccination (at Home)	22 (6.5)	34 (9.8)	56 (8.2)
Day 2	15 (4.5)	76 (22.0)	91 (13.3)
Day 3	14 (4.2)	10 (2.9)	24 (3.5)
Day 4	8 (2.4)	2 (0.6)	10 (1.5)
Day 5	3 (0.9)	3 (0.9)	6 (0.9)
Day 6	3 (0.9)	3 (0.9)	6 (0.9)
Day 7	4 (1.2)	2 (0.6)	6 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Myalgia - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	2 (0.6)	3 (0.4)
Day 1, after Vaccination (at Home)	5 (1.5)	29 (8.4)	34 (5.0)
Day 2	16 (4.7)	79 (22.8)	95 (13.9)
Day 3	8 (2.4)	11 (3.2)	19 (2.8)
Day 4	7 (2.1)	2 (0.6)	9 (1.3)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	1 (0.3)	1 (0.3)	2 (0.3)
Day 7	5 (1.5)	2 (0.6)	7 (1.0)
Arthralgia - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	3 (0.9)	4 (0.6)
Day 1, after Vaccination (at Home)	4 (1.2)	20 (5.8)	24 (3.5)
Day 2	11 (3.3)	46 (13.3)	57 (8.3)
Day 3	10 (3.0)	11 (3.2)	21 (3.1)
Day 4	6 (1.8)	3 (0.9)	9 (1.3)
Day 5	1 (0.3)	3 (0.9)	4 (0.6)
Day 6	1 (0.3)	0	1 (0.1)
Day 7	6 (1.8)	2 (0.6)	8 (1.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Nausea/Vomiting - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.3)	1 (0.1)
Day 1, after Vaccination (at Home)	4 (1.2)	3 (0.9)	7 (1.0)
Day 2	4 (1.2)	23 (6.6)	27 (4.0)
Day 3	3 (0.9)	8 (2.3)	11 (1.6)
Day 4	2 (0.6)	4 (1.2)	6 (0.9)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	3 (0.9)	0	3 (0.4)
Day 7	5 (1.5)	2 (0.6)	7 (1.0)
Chills - N1	337	346	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	2 (0.6)	3 (0.4)
Day 1, after Vaccination (at Home)	5 (1.5)	12 (3.5)	17 (2.5)
Day 2	7 (2.1)	54 (15.6)	61 (8.9)
Day 3	6 (1.8)	8 (2.3)	14 (2.0)
Day 4	4 (1.2)	1 (0.3)	5 (0.7)
Day 5	1 (0.3)	2 (0.6)	3 (0.4)
Day 6	0	0	0
Day 7	3 (0.9)	2 (0.6)	5 (0.7)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Adverse Reactions - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (13.1)	7 (8.0)	18 (10.5)
Day 1, after Vaccination (at Home)	7 (8.3)	40 (46.0)	47 (27.5)
Day 2	11 (13.1)	25 (28.7)	36 (21.1)
Day 3	3 (3.6)	4 (4.6)	7 (4.1)
Day 4	4 (4.8)	0	4 (2.3)
Day 5	2 (2.4)	0	2 (1.2)
Day 6	2 (2.4)	0	2 (1.2)
Day 7	2 (2.4)	0	2 (1.2)
Solicited Local Adverse Reactions - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (10.7)	7 (8.0)	16 (9.4)
Day 1, after Vaccination (at Home)	1 (1.2)	35 (40.2)	36 (21.1)
Day 2	3 (3.6)	27 (31.0)	30 (17.5)
Day 3	1 (1.2)	2 (2.3)	3 (1.8)
Day 4	0	1 (1.1)	1 (0.6)
Day 5	0	0	0
Day 6	1 (1.2)	1 (1.1)	2 (1.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Pain - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (10.7)	6 (6.9)	15 (8.8)
Day 1, after Vaccination (at Home)	1 (1.2)	35 (40.2)	36 (21.1)
Day 2	3 (3.6)	27 (31.0)	30 (17.5)
Day 3	0	2 (2.3)	2 (1.2)
Day 4	0	1 (1.1)	1 (0.6)
Day 5	0	0	0
Day 6	0	1 (1.1)	1 (0.6)
Day 7	0	0	0
Erythema (Redness) - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (1.1)	1 (0.6)
Day 1, after Vaccination (at Home)	0	0	0
Day 2	0	4 (4.6)	4 (2.3)
Day 3	0	1 (1.1)	1 (0.6)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Swelling (Hardness) - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	3 (3.4)	3 (1.8)
Day 2	0	2 (2.3)	2 (1.2)
Day 3	0	1 (1.1)	1 (0.6)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.2)	0	1 (0.6)
Day 1, after Vaccination (at Home)	0	3 (3.4)	3 (1.8)
Day 2	0	5 (5.7)	5 (2.9)
Day 3	1 (1.2)	0	1 (0.6)
Day 4	0	1 (1.1)	1 (0.6)
Day 5	0	0	0
Day 6	1 (1.2)	1 (1.1)	2 (1.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Systemic Adverse Reactions - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (4.8)	0	4 (2.3)
Day 1, after Vaccination (at Home)	8 (9.5)	21 (24.1)	29 (17.0)
Day 2	10 (11.9)	15 (17.2)	25 (14.6)
Day 3	3 (3.6)	6 (6.9)	9 (5.3)
Day 4	5 (6.0)	4 (4.6)	9 (5.3)
Day 5	2 (2.4)	0	2 (1.2)
Day 6	2 (2.4)	3 (3.4)	5 (2.9)
Day 7	2 (2.4)	0	2 (1.2)
Fever - N1	84	86	170
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (1.2)	1 (0.6)
Day 2	0	0	0
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Headache - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (4.8)	0	4 (2.3)
Day 1, after Vaccination (at Home)	4 (4.8)	8 (9.2)	12 (7.0)
Day 2	4 (4.8)	9 (10.3)	13 (7.6)
Day 3	3 (3.6)	4 (4.6)	7 (4.1)
Day 4	5 (6.0)	3 (3.4)	8 (4.7)
Day 5	1 (1.2)	0	1 (0.6)
Day 6	3 (3.6)	3 (3.4)	6 (3.5)
Day 7	2 (2.4)	2 (2.3)	4 (2.3)
Fatigue - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.2)	0	1 (0.6)
Day 1, after Vaccination (at Home)	5 (6.0)	10 (11.5)	15 (8.8)
Day 2	6 (7.1)	13 (14.9)	19 (11.1)
Day 3	1 (1.2)	5 (5.7)	6 (3.5)
Day 4	4 (4.8)	1 (1.1)	5 (2.9)
Day 5	2 (2.4)	0	2 (1.2)
Day 6	3 (3.6)	3 (3.4)	6 (3.5)
Day 7	1 (1.2)	0	1 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Myalgia - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.2)	0	1 (0.6)
Day 1, after Vaccination (at Home)	3 (3.6)	11 (12.6)	14 (8.2)
Day 2	4 (4.8)	3 (3.4)	7 (4.1)
Day 3	1 (1.2)	1 (1.1)	2 (1.2)
Day 4	0	2 (2.3)	2 (1.2)
Day 5	2 (2.4)	2 (2.3)	4 (2.3)
Day 6	0	0	0
Day 7	0	0	0
Arthralgia - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	2 (2.4)	3 (3.4)	5 (2.9)
Day 2	1 (1.2)	7 (8.0)	8 (4.7)
Day 3	2 (2.4)	2 (2.3)	4 (2.3)
Day 4	2 (2.4)	2 (2.3)	4 (2.3)
Day 5	0	2 (2.3)	2 (1.2)
Day 6	1 (1.2)	0	1 (0.6)
Day 7	1 (1.2)	0	1 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.1
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After First Injection by Baseline SARS-CoV-2 Status and Onset Day
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Nausea/Vomiting - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	0	0
Day 2	3 (3.6)	2 (2.3)	5 (2.9)
Day 3	0	2 (2.3)	2 (1.2)
Day 4	0	0	0
Day 5	1 (1.2)	1 (1.1)	2 (1.2)
Day 6	1 (1.2)	3 (3.4)	4 (2.3)
Day 7	1 (1.2)	1 (1.1)	2 (1.2)
Chills - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (1.1)	1 (0.6)
Day 2	0	4 (4.6)	4 (2.3)
Day 3	0	2 (2.3)	2 (1.2)
Day 4	2 (2.4)	0	2 (1.2)
Day 5	1 (1.2)	0	1 (0.6)
Day 6	1 (1.2)	1 (1.1)	2 (1.2)
Day 7	1 (1.2)	0	1 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030301.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Solicited Adverse Reactions - N1	14267	14378	28645
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1535 (10.8)	1435 (10.0)	2970 (10.4)
Day 1, after Vaccination (at Home)	1922 (13.5)	8175 (56.9)	10097 (35.2)
Day 2	1154 (8.1)	3484 (24.2)	4638 (16.2)
Day 3	563 (3.9)	137 (1.0)	700 (2.4)
Day 4	346 (2.4)	28 (0.2)	374 (1.3)
Day 5	271 (1.9)	12 (<0.1)	283 (1.0)
Day 6	207 (1.5)	14 (<0.1)	221 (0.8)
Day 7	143 (1.0)	9 (<0.1)	152 (0.5)
Solicited Local Adverse Reactions - N1	14267	14375	28642
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1175 (8.2)	1095 (7.6)	2270 (7.9)
Day 1, after Vaccination (at Home)	754 (5.3)	7890 (54.9)	8644 (30.2)
Day 2	395 (2.8)	3601 (25.1)	3996 (14.0)
Day 3	178 (1.2)	153 (1.1)	331 (1.2)
Day 4	84 (0.6)	23 (0.2)	107 (0.4)
Day 5	55 (0.4)	9 (<0.1)	64 (0.2)
Day 6	32 (0.2)	8 (<0.1)	40 (0.1)
Day 7	26 (0.2)	4 (<0.1)	30 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Pain - N1	14267	14375	28642
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1143 (8.0)	1054 (7.3)	2197 (7.7)
Day 1, after Vaccination (at Home)	693 (4.9)	7847 (54.6)	8540 (29.8)
Day 2	320 (2.2)	3635 (25.3)	3955 (13.8)
Day 3	144 (1.0)	152 (1.1)	296 (1.0)
Day 4	59 (0.4)	21 (0.1)	80 (0.3)
Day 5	38 (0.3)	5 (<0.1)	43 (0.2)
Day 6	24 (0.2)	6 (<0.1)	30 (0.1)
Day 7	14 (<0.1)	2 (<0.1)	16 (<0.1)
Erythema (Redness) - N1	14267	14374	28641
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (<0.1)	4 (<0.1)	11 (<0.1)
Day 1, after Vaccination (at Home)	28 (0.2)	147 (1.0)	175 (0.6)
Day 2	10 (<0.1)	487 (3.4)	497 (1.7)
Day 3	8 (<0.1)	493 (3.4)	501 (1.7)
Day 4	5 (<0.1)	105 (0.7)	110 (0.4)
Day 5	4 (<0.1)	15 (0.1)	19 (<0.1)
Day 6	3 (<0.1)	4 (<0.1)	7 (<0.1)
Day 7	1 (<0.1)	4 (<0.1)	5 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Swelling (Hardness) - N1	14267	14374	28641
Day 1, 30 Minutes after Vaccination (at Study Clinic)	12 (<0.1)	17 (0.1)	29 (0.1)
Day 1, after Vaccination (at Home)	20 (0.1)	515 (3.6)	535 (1.9)
Day 2	13 (<0.1)	886 (6.2)	899 (3.1)
Day 3	7 (<0.1)	288 (2.0)	295 (1.0)
Day 4	3 (<0.1)	63 (0.4)	66 (0.2)
Day 5	3 (<0.1)	10 (<0.1)	13 (<0.1)
Day 6	0	2 (<0.1)	2 (<0.1)
Day 7	1 (<0.1)	2 (<0.1)	3 (<0.1)
Axillary Swelling or Tenderness - N1	14267	14374	28641
Day 1, 30 Minutes after Vaccination (at Study Clinic)	62 (0.4)	76 (0.5)	138 (0.5)
Day 1, after Vaccination (at Home)	144 (1.0)	486 (3.4)	630 (2.2)
Day 2	147 (1.0)	867 (6.0)	1014 (3.5)
Day 3	84 (0.6)	392 (2.7)	476 (1.7)
Day 4	49 (0.3)	148 (1.0)	197 (0.7)
Day 5	38 (0.3)	39 (0.3)	77 (0.3)
Day 6	18 (0.1)	23 (0.2)	41 (0.1)
Day 7	15 (0.1)	16 (0.1)	31 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Solicited Systemic Adverse Reactions - N1	14266	14377	28643
Day 1, 30 Minutes after Vaccination (at Study Clinic)	531 (3.7)	510 (3.5)	1041 (3.6)
Day 1, after Vaccination (at Home)	1791 (12.6)	4250 (29.6)	6041 (21.1)
Day 2	1208 (8.5)	6114 (42.5)	7322 (25.6)
Day 3	607 (4.3)	367 (2.6)	974 (3.4)
Day 4	390 (2.7)	95 (0.7)	485 (1.7)
Day 5	308 (2.2)	42 (0.3)	350 (1.2)
Day 6	240 (1.7)	56 (0.4)	296 (1.0)
Day 7	166 (1.2)	25 (0.2)	191 (0.7)
Fever - N1	14263	14370	28633
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (<0.1)	1 (<0.1)	2 (<0.1)
Day 1, after Vaccination (at Home)	5 (<0.1)	223 (1.6)	228 (0.8)
Day 2	7 (<0.1)	1840 (12.8)	1847 (6.5)
Day 3	8 (<0.1)	160 (1.1)	168 (0.6)
Day 4	3 (<0.1)	3 (<0.1)	6 (<0.1)
Day 5	5 (<0.1)	4 (<0.1)	9 (<0.1)
Day 6	7 (<0.1)	2 (<0.1)	9 (<0.1)
Day 7	6 (<0.1)	2 (<0.1)	8 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Headache - N1	14265	14374	28639
Day 1, 30 Minutes after Vaccination (at Study Clinic)	258 (1.8)	262 (1.8)	520 (1.8)
Day 1, after Vaccination (at Home)	920 (6.4)	2174 (15.1)	3094 (10.8)
Day 2	760 (5.3)	5181 (36.0)	5941 (20.7)
Day 3	478 (3.4)	439 (3.1)	917 (3.2)
Day 4	323 (2.3)	161 (1.1)	484 (1.7)
Day 5	236 (1.7)	108 (0.8)	344 (1.2)
Day 6	225 (1.6)	108 (0.8)	333 (1.2)
Day 7	163 (1.1)	55 (0.4)	218 (0.8)
Fatigue - N1	14265	14374	28639
Day 1, 30 Minutes after Vaccination (at Study Clinic)	211 (1.5)	225 (1.6)	436 (1.5)
Day 1, after Vaccination (at Home)	1171 (8.2)	2936 (20.4)	4107 (14.3)
Day 2	848 (5.9)	5668 (39.4)	6516 (22.8)
Day 3	403 (2.8)	415 (2.9)	818 (2.9)
Day 4	243 (1.7)	80 (0.6)	323 (1.1)
Day 5	207 (1.5)	53 (0.4)	260 (0.9)
Day 6	173 (1.2)	44 (0.3)	217 (0.8)
Day 7	88 (0.6)	25 (0.2)	113 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14267) n	Placebo (N=14267) (%)	mRNA-1273 (N=14378) n	mRNA-1273 (N=14378) (%)	Total (N=28645) n	Total (N=28645) (%)
Myalgia - N1	14265		14374		28639	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	109	(0.8)	100	(0.7)	209	(0.7)
Day 1, after Vaccination (at Home)	455	(3.2)	2001	(13.9)	2456	(8.6)
Day 2	478	(3.4)	5767	(40.1)	6245	(21.8)
Day 3	254	(1.8)	343	(2.4)	597	(2.1)
Day 4	171	(1.2)	65	(0.5)	236	(0.8)
Day 5	114	(0.8)	32	(0.2)	146	(0.5)
Day 6	124	(0.9)	30	(0.2)	154	(0.5)
Day 7	70	(0.5)	19	(0.1)	89	(0.3)
Arthralgia - N1	14265		14374		28639	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	115	(0.8)	116	(0.8)	231	(0.8)
Day 1, after Vaccination (at Home)	376	(2.6)	1345	(9.4)	1721	(6.0)
Day 2	378	(2.6)	4212	(29.3)	4590	(16.0)
Day 3	223	(1.6)	332	(2.3)	555	(1.9)
Day 4	171	(1.2)	80	(0.6)	251	(0.9)
Day 5	98	(0.7)	42	(0.3)	140	(0.5)
Day 6	120	(0.8)	36	(0.3)	156	(0.5)
Day 7	62	(0.4)	18	(0.1)	80	(0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14267) n	Placebo (N=14267) (%)	mRNA-1273 (N=14378) n	mRNA-1273 (N=14378) (%)	Total (N=28645) n	Total (N=28645) (%)
Nausea/Vomiting - N1	14265		14374		28639	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	44	(0.3)	38	(0.3)	82	(0.3)
Day 1, after Vaccination (at Home)	212	(1.5)	496	(3.5)	708	(2.5)
Day 2	217	(1.5)	1725	(12.0)	1942	(6.8)
Day 3	136	(1.0)	259	(1.8)	395	(1.4)
Day 4	96	(0.7)	94	(0.7)	190	(0.7)
Day 5	76	(0.5)	50	(0.3)	126	(0.4)
Day 6	80	(0.6)	48	(0.3)	128	(0.4)
Day 7	61	(0.4)	31	(0.2)	92	(0.3)
Chills - N1	14265		14374		28639	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	57	(0.4)	47	(0.3)	104	(0.4)
Day 1, after Vaccination (at Home)	210	(1.5)	1087	(7.6)	1297	(4.5)
Day 2	189	(1.3)	4788	(33.3)	4977	(17.4)
Day 3	101	(0.7)	360	(2.5)	461	(1.6)
Day 4	70	(0.5)	45	(0.3)	115	(0.4)
Day 5	61	(0.4)	16	(0.1)	77	(0.3)
Day 6	68	(0.5)	22	(0.2)	90	(0.3)
Day 7	34	(0.2)	19	(0.1)	53	(0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Solicited Adverse Reactions - N1	233	232	465
Day 1, 30 Minutes after Vaccination (at Study Clinic)	22 (9.4)	15 (6.5)	37 (8.0)
Day 1, after Vaccination (at Home)	29 (12.4)	109 (47.0)	138 (29.7)
Day 2	14 (6.0)	58 (25.0)	72 (15.5)
Day 3	5 (2.1)	2 (0.9)	7 (1.5)
Day 4	4 (1.7)	1 (0.4)	5 (1.1)
Day 5	3 (1.3)	1 (0.4)	4 (0.9)
Day 6	4 (1.7)	0	4 (0.9)
Day 7	1 (0.4)	1 (0.4)	2 (0.4)
Solicited Local Adverse Reactions - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	15 (6.5)	9 (3.9)	24 (5.2)
Day 1, after Vaccination (at Home)	16 (6.9)	104 (44.8)	120 (25.9)
Day 2	7 (3.0)	53 (22.8)	60 (12.9)
Day 3	1 (0.4)	3 (1.3)	4 (0.9)
Day 4	1 (0.4)	2 (0.9)	3 (0.6)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	1 (0.4)	0	1 (0.2)
Day 7	0	1 (0.4)	1 (0.2)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Onset Day	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Pain - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	15 (6.5)	9 (3.9)	24 (5.2)
Day 1, after Vaccination (at Home)	15 (6.5)	103 (44.4)	118 (25.4)
Day 2	4 (1.7)	53 (22.8)	57 (12.3)
Day 3	0	2 (0.9)	2 (0.4)
Day 4	1 (0.4)	1 (0.4)	2 (0.4)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	0	0	0
Day 7	0	1 (0.4)	1 (0.2)
Erythema (Redness) - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	1 (0.4)	1 (0.2)
Day 2	0	3 (1.3)	3 (0.6)
Day 3	1 (0.4)	2 (0.9)	3 (0.6)
Day 4	0	3 (1.3)	3 (0.6)
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Swelling (Hardness) - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	4 (1.7)	4 (0.9)
Day 2	0	3 (1.3)	3 (0.6)
Day 3	0	2 (0.9)	2 (0.4)
Day 4	0	1 (0.4)	1 (0.2)
Day 5	1 (0.4)	1 (0.4)	2 (0.4)
Day 6	0	0	0
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	2 (0.9)	10 (4.3)	12 (2.6)
Day 2	5 (2.2)	14 (6.0)	19 (4.1)
Day 3	1 (0.4)	3 (1.3)	4 (0.9)
Day 4	0	5 (2.2)	5 (1.1)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	2 (0.9)	0	2 (0.4)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Solicited Systemic Adverse Reactions - N1	233	232	465
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (4.7)	7 (3.0)	18 (3.9)
Day 1, after Vaccination (at Home)	26 (11.2)	66 (28.4)	92 (19.8)
Day 2	16 (6.9)	71 (30.6)	87 (18.7)
Day 3	7 (3.0)	2 (0.9)	9 (1.9)
Day 4	4 (1.7)	2 (0.9)	6 (1.3)
Day 5	3 (1.3)	2 (0.9)	5 (1.1)
Day 6	4 (1.7)	2 (0.9)	6 (1.3)
Day 7	2 (0.9)	0	2 (0.4)
Fever - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.4)	1 (0.2)
Day 1, after Vaccination (at Home)	0	4 (1.7)	4 (0.9)
Day 2	0	23 (9.9)	23 (5.0)
Day 3	0	2 (0.9)	2 (0.4)
Day 4	0	1 (0.4)	1 (0.2)
Day 5	0	0	0
Day 6	1 (0.4)	0	1 (0.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Headache - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	6 (2.6)	2 (0.9)	8 (1.7)
Day 1, after Vaccination (at Home)	14 (6.0)	33 (14.2)	47 (10.1)
Day 2	9 (3.9)	54 (23.3)	63 (13.6)
Day 3	5 (2.2)	2 (0.9)	7 (1.5)
Day 4	2 (0.9)	2 (0.9)	4 (0.9)
Day 5	2 (0.9)	2 (0.9)	4 (0.9)
Day 6	4 (1.7)	3 (1.3)	7 (1.5)
Day 7	1 (0.4)	0	1 (0.2)
Fatigue - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (2.2)	4 (1.7)	9 (1.9)
Day 1, after Vaccination (at Home)	19 (8.2)	36 (15.5)	55 (11.9)
Day 2	9 (3.9)	63 (27.2)	72 (15.5)
Day 3	8 (3.4)	3 (1.3)	11 (2.4)
Day 4	6 (2.6)	0	6 (1.3)
Day 5	5 (2.2)	0	5 (1.1)
Day 6	2 (0.9)	0	2 (0.4)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Myalgia - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (0.9)	2 (0.4)
Day 1, after Vaccination (at Home)	8 (3.4)	34 (14.7)	42 (9.1)
Day 2	8 (3.4)	74 (31.9)	82 (17.7)
Day 3	4 (1.7)	3 (1.3)	7 (1.5)
Day 4	7 (3.0)	2 (0.9)	9 (1.9)
Day 5	2 (0.9)	0	2 (0.4)
Day 6	2 (0.9)	2 (0.9)	4 (0.9)
Day 7	3 (1.3)	0	3 (0.6)
Arthralgia - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.4)	3 (1.3)	4 (0.9)
Day 1, after Vaccination (at Home)	9 (3.9)	22 (9.5)	31 (6.7)
Day 2	5 (2.2)	44 (19.0)	49 (10.6)
Day 3	3 (1.3)	5 (2.2)	8 (1.7)
Day 4	4 (1.7)	1 (0.4)	5 (1.1)
Day 5	1 (0.4)	0	1 (0.2)
Day 6	1 (0.4)	2 (0.9)	3 (0.6)
Day 7	2 (0.9)	0	2 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Nausea/Vomiting - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	12 (5.2)	12 (2.6)
Day 2	2 (0.9)	16 (6.9)	18 (3.9)
Day 3	5 (2.2)	3 (1.3)	8 (1.7)
Day 4	4 (1.7)	1 (0.4)	5 (1.1)
Day 5	0	0	0
Day 6	1 (0.4)	1 (0.4)	2 (0.4)
Day 7	1 (0.4)	0	1 (0.2)
Chills - N1	232	232	464
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.9)	0	2 (0.4)
Day 1, after Vaccination (at Home)	3 (1.3)	20 (8.6)	23 (5.0)
Day 2	2 (0.9)	55 (23.7)	57 (12.3)
Day 3	3 (1.3)	3 (1.3)	6 (1.3)
Day 4	3 (1.3)	1 (0.4)	4 (0.9)
Day 5	2 (0.9)	0	2 (0.4)
Day 6	1 (0.4)	1 (0.4)	2 (0.4)
Day 7	3 (1.3)	0	3 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Solicited Adverse Reactions - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	10 (12.8)	10 (12.3)	20 (12.6)
Day 1, after Vaccination (at Home)	6 (7.7)	47 (58.0)	53 (33.3)
Day 2	9 (11.5)	18 (22.2)	27 (17.0)
Day 3	5 (6.4)	0	5 (3.1)
Day 4	1 (1.3)	0	1 (0.6)
Day 5	1 (1.3)	0	1 (0.6)
Day 6	0	0	0
Day 7	0	0	0
Solicited Local Adverse Reactions - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (10.3)	7 (8.6)	15 (9.4)
Day 1, after Vaccination (at Home)	3 (3.8)	49 (60.5)	52 (32.7)
Day 2	2 (2.6)	18 (22.2)	20 (12.6)
Day 3	3 (3.8)	0	3 (1.9)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Pain - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (10.3)	7 (8.6)	15 (9.4)
Day 1, after Vaccination (at Home)	3 (3.8)	49 (60.5)	52 (32.7)
Day 2	2 (2.6)	16 (19.8)	18 (11.3)
Day 3	2 (2.6)	1 (1.2)	3 (1.9)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Erythema (Redness) - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.3)	0	1 (0.6)
Day 1, after Vaccination (at Home)	0	1 (1.2)	1 (0.6)
Day 2	0	4 (4.9)	4 (2.5)
Day 3	0	0	0
Day 4	0	1 (1.2)	1 (0.6)
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Swelling (Hardness) - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	5 (6.2)	5 (3.1)
Day 2	0	7 (8.6)	7 (4.4)
Day 3	0	1 (1.2)	1 (0.6)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.3)	0	1 (0.6)
Day 1, after Vaccination (at Home)	0	2 (2.5)	2 (1.3)
Day 2	1 (1.3)	8 (9.9)	9 (5.7)
Day 3	1 (1.3)	3 (3.7)	4 (2.5)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Solicited Systemic Adverse Reactions - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (6.4)	3 (3.7)	8 (5.0)
Day 1, after Vaccination (at Home)	8 (10.3)	28 (34.6)	36 (22.6)
Day 2	10 (12.8)	36 (44.4)	46 (28.9)
Day 3	4 (5.1)	0	4 (2.5)
Day 4	1 (1.3)	0	1 (0.6)
Day 5	1 (1.3)	0	1 (0.6)
Day 6	0	0	0
Day 7	0	0	0
Fever - N1	78	80	158
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	2 (2.5)	2 (1.3)
Day 2	0	8 (10.0)	8 (5.1)
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Headache - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.3)	1 (1.2)	2 (1.3)
Day 1, after Vaccination (at Home)	8 (10.3)	12 (14.8)	20 (12.6)
Day 2	3 (3.8)	36 (44.4)	39 (24.5)
Day 3	6 (7.7)	1 (1.2)	7 (4.4)
Day 4	1 (1.3)	0	1 (0.6)
Day 5	1 (1.3)	1 (1.2)	2 (1.3)
Day 6	0	0	0
Day 7	1 (1.3)	0	1 (0.6)
Fatigue - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.3)	2 (2.5)	3 (1.9)
Day 1, after Vaccination (at Home)	6 (7.7)	19 (23.5)	25 (15.7)
Day 2	6 (7.7)	34 (42.0)	40 (25.2)
Day 3	2 (2.6)	0	2 (1.3)
Day 4	2 (2.6)	0	2 (1.3)
Day 5	2 (2.6)	0	2 (1.3)
Day 6	1 (1.3)	0	1 (0.6)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Myalgia - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (3.8)	0	3 (1.9)
Day 1, after Vaccination (at Home)	1 (1.3)	15 (18.5)	16 (10.1)
Day 2	4 (5.1)	38 (46.9)	42 (26.4)
Day 3	4 (5.1)	2 (2.5)	6 (3.8)
Day 4	0	0	0
Day 5	3 (3.8)	0	3 (1.9)
Day 6	0	0	0
Day 7	0	0	0
Arthralgia - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.3)	0	1 (0.6)
Day 1, after Vaccination (at Home)	0	16 (19.8)	16 (10.1)
Day 2	5 (6.4)	27 (33.3)	32 (20.1)
Day 3	4 (5.1)	0	4 (2.5)
Day 4	0	1 (1.2)	1 (0.6)
Day 5	0	0	0
Day 6	0	1 (1.2)	1 (0.6)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.2
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Onset Day
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Nausea/Vomiting - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	2 (2.6)	3 (3.7)	5 (3.1)
Day 2	3 (3.8)	15 (18.5)	18 (11.3)
Day 3	0	2 (2.5)	2 (1.3)
Day 4	0	0	0
Day 5	0	0	0
Day 6	1 (1.3)	0	1 (0.6)
Day 7	0	0	0
Chills - N1	78	81	159
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	7 (8.6)	7 (4.4)
Day 2	2 (2.6)	28 (34.6)	30 (18.9)
Day 3	0	1 (1.2)	1 (0.6)
Day 4	2 (2.6)	0	2 (1.3)
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030302.sas 21JUN2021 17:06

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Solicited Adverse Reactions - N1	14738	14745	29483
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2638 (17.9)	2570 (17.4)	5208 (17.7)
Day 1, after Vaccination (at Home)	2874 (19.5)	8744 (59.3)	11618 (39.4)
Day 2	1594 (10.8)	2554 (17.3)	4148 (14.1)
Day 3	728 (4.9)	98 (0.7)	826 (2.8)
Day 4	411 (2.8)	16 (0.1)	427 (1.4)
Day 5	303 (2.1)	23 (0.2)	326 (1.1)
Day 6	209 (1.4)	13 (<0.1)	222 (0.8)
Day 7	150 (1.0)	16 (0.1)	166 (0.6)
Solicited Local Adverse Reactions - N1	14737	14745	29482
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1983 (13.5)	1951 (13.2)	3934 (13.3)
Day 1, after Vaccination (at Home)	1152 (7.8)	8676 (58.8)	9828 (33.3)
Day 2	646 (4.4)	2903 (19.7)	3549 (12.0)
Day 3	260 (1.8)	108 (0.7)	368 (1.2)
Day 4	135 (0.9)	12 (<0.1)	147 (0.5)
Day 5	91 (0.6)	9 (<0.1)	100 (0.3)
Day 6	63 (0.4)	9 (<0.1)	72 (0.2)
Day 7	36 (0.2)	8 (<0.1)	44 (0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Pain - N1	14737	14745	29482
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1920 (13.0)	1878 (12.7)	3798 (12.9)
Day 1, after Vaccination (at Home)	1052 (7.1)	8663 (58.8)	9715 (33.0)
Day 2	545 (3.7)	2947 (20.0)	3492 (11.8)
Day 3	203 (1.4)	105 (0.7)	308 (1.0)
Day 4	97 (0.7)	9 (<0.1)	106 (0.4)
Day 5	66 (0.4)	4 (<0.1)	70 (0.2)
Day 6	46 (0.3)	7 (<0.1)	53 (0.2)
Day 7	24 (0.2)	5 (<0.1)	29 (<0.1)
Erythema (Redness) - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	9 (<0.1)	13 (<0.1)	22 (<0.1)
Day 1, after Vaccination (at Home)	54 (0.4)	197 (1.3)	251 (0.9)
Day 2	25 (0.2)	628 (4.3)	653 (2.2)
Day 3	16 (0.1)	538 (3.6)	554 (1.9)
Day 4	8 (<0.1)	110 (0.7)	118 (0.4)
Day 5	9 (<0.1)	17 (0.1)	26 (<0.1)
Day 6	8 (<0.1)	8 (<0.1)	16 (<0.1)
Day 7	3 (<0.1)	9 (<0.1)	12 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Swelling (Hardness) - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	21 (0.1)	30 (0.2)	51 (0.2)
Day 1, after Vaccination (at Home)	40 (0.3)	640 (4.3)	680 (2.3)
Day 2	27 (0.2)	1144 (7.8)	1171 (4.0)
Day 3	8 (<0.1)	310 (2.1)	318 (1.1)
Day 4	4 (<0.1)	66 (0.4)	70 (0.2)
Day 5	7 (<0.1)	10 (<0.1)	17 (<0.1)
Day 6	1 (<0.1)	3 (<0.1)	4 (<0.1)
Day 7	5 (<0.1)	4 (<0.1)	9 (<0.1)
Axillary Swelling or Tenderness - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	153 (1.0)	167 (1.1)	320 (1.1)
Day 1, after Vaccination (at Home)	254 (1.7)	764 (5.2)	1018 (3.5)
Day 2	259 (1.8)	1093 (7.4)	1352 (4.6)
Day 3	145 (1.0)	482 (3.3)	627 (2.1)
Day 4	92 (0.6)	188 (1.3)	280 (0.9)
Day 5	78 (0.5)	65 (0.4)	143 (0.5)
Day 6	56 (0.4)	71 (0.5)	127 (0.4)
Day 7	37 (0.3)	90 (0.6)	127 (0.4)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Solicited Systemic Adverse Reactions - N1	14738	14744	29482
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1084 (7.4)	1032 (7.0)	2116 (7.2)
Day 1, after Vaccination (at Home)	2973 (20.2)	5290 (35.9)	8263 (28.0)
Day 2	1779 (12.1)	5444 (36.9)	7223 (24.5)
Day 3	830 (5.6)	394 (2.7)	1224 (4.2)
Day 4	453 (3.1)	117 (0.8)	570 (1.9)
Day 5	361 (2.4)	82 (0.6)	443 (1.5)
Day 6	262 (1.8)	64 (0.4)	326 (1.1)
Day 7	189 (1.3)	42 (0.3)	231 (0.8)
Fever - N1	14738	14744	29482
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (<0.1)	2 (<0.1)	6 (<0.1)
Day 1, after Vaccination (at Home)	9 (<0.1)	234 (1.6)	243 (0.8)
Day 2	12 (<0.1)	1858 (12.6)	1870 (6.3)
Day 3	12 (<0.1)	170 (1.2)	182 (0.6)
Day 4	10 (<0.1)	5 (<0.1)	15 (<0.1)
Day 5	11 (<0.1)	9 (<0.1)	20 (<0.1)
Day 6	11 (<0.1)	4 (<0.1)	15 (<0.1)
Day 7	10 (<0.1)	3 (<0.1)	13 (<0.1)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Headache - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	572 (3.9)	574 (3.9)	1146 (3.9)
Day 1, after Vaccination (at Home)	1618 (11.0)	2911 (19.7)	4529 (15.4)
Day 2	1291 (8.8)	5001 (33.9)	6292 (21.3)
Day 3	725 (4.9)	519 (3.5)	1244 (4.2)
Day 4	428 (2.9)	217 (1.5)	645 (2.2)
Day 5	338 (2.3)	152 (1.0)	490 (1.7)
Day 6	287 (1.9)	153 (1.0)	440 (1.5)
Day 7	221 (1.5)	93 (0.6)	314 (1.1)
Fatigue - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	411 (2.8)	427 (2.9)	838 (2.8)
Day 1, after Vaccination (at Home)	2097 (14.2)	3849 (26.1)	5946 (20.2)
Day 2	1323 (9.0)	5358 (36.3)	6681 (22.7)
Day 3	614 (4.2)	453 (3.1)	1067 (3.6)
Day 4	338 (2.3)	115 (0.8)	453 (1.5)
Day 5	273 (1.9)	80 (0.5)	353 (1.2)
Day 6	240 (1.6)	81 (0.5)	321 (1.1)
Day 7	125 (0.8)	46 (0.3)	171 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Onset Day	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Myalgia - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	219 (1.5)	210 (1.4)	429 (1.5)
Day 1, after Vaccination (at Home)	808 (5.5)	2510 (17.0)	3318 (11.3)
Day 2	807 (5.5)	5738 (38.9)	6545 (22.2)
Day 3	418 (2.8)	408 (2.8)	826 (2.8)
Day 4	296 (2.0)	99 (0.7)	395 (1.3)
Day 5	180 (1.2)	54 (0.4)	234 (0.8)
Day 6	180 (1.2)	59 (0.4)	239 (0.8)
Day 7	124 (0.8)	33 (0.2)	157 (0.5)
Arthralgia - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	207 (1.4)	204 (1.4)	411 (1.4)
Day 1, after Vaccination (at Home)	618 (4.2)	1664 (11.3)	2282 (7.7)
Day 2	695 (4.7)	4259 (28.9)	4954 (16.8)
Day 3	380 (2.6)	439 (3.0)	819 (2.8)
Day 4	261 (1.8)	133 (0.9)	394 (1.3)
Day 5	170 (1.2)	70 (0.5)	240 (0.8)
Day 6	179 (1.2)	67 (0.5)	246 (0.8)
Day 7	92 (0.6)	43 (0.3)	135 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Onset Day	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Nausea/Vomiting - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	89 (0.6)	76 (0.5)	165 (0.6)
Day 1, after Vaccination (at Home)	353 (2.4)	667 (4.5)	1020 (3.5)
Day 2	398 (2.7)	1882 (12.8)	2280 (7.7)
Day 3	248 (1.7)	367 (2.5)	615 (2.1)
Day 4	185 (1.3)	166 (1.1)	351 (1.2)
Day 5	147 (1.0)	90 (0.6)	237 (0.8)
Day 6	152 (1.0)	89 (0.6)	241 (0.8)
Day 7	108 (0.7)	65 (0.4)	173 (0.6)
Chills - N1	14737	14744	29481
Day 1, 30 Minutes after Vaccination (at Study Clinic)	136 (0.9)	115 (0.8)	251 (0.9)
Day 1, after Vaccination (at Home)	363 (2.5)	1260 (8.5)	1623 (5.5)
Day 2	327 (2.2)	4770 (32.4)	5097 (17.3)
Day 3	194 (1.3)	420 (2.8)	614 (2.1)
Day 4	122 (0.8)	68 (0.5)	190 (0.6)
Day 5	114 (0.8)	39 (0.3)	153 (0.5)
Day 6	108 (0.7)	43 (0.3)	151 (0.5)
Day 7	62 (0.4)	29 (0.2)	91 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Solicited Adverse Reactions - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	42 (12.5)	41 (11.8)	83 (12.1)
Day 1, after Vaccination (at Home)	49 (14.5)	159 (45.8)	208 (30.4)
Day 2	27 (8.0)	77 (22.2)	104 (15.2)
Day 3	14 (4.2)	5 (1.4)	19 (2.8)
Day 4	10 (3.0)	1 (0.3)	11 (1.6)
Day 5	3 (0.9)	0	3 (0.4)
Day 6	2 (0.6)	0	2 (0.3)
Day 7	9 (2.7)	2 (0.6)	11 (1.6)
Solicited Local Adverse Reactions - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	30 (8.9)	24 (6.9)	54 (7.9)
Day 1, after Vaccination (at Home)	24 (7.1)	154 (44.4)	178 (26.0)
Day 2	12 (3.6)	83 (23.9)	95 (13.9)
Day 3	3 (0.9)	7 (2.0)	10 (1.5)
Day 4	3 (0.9)	3 (0.9)	6 (0.9)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	1 (0.3)	0	1 (0.1)
Day 7	2 (0.6)	2 (0.6)	4 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Pain - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	30 (8.9)	24 (6.9)	54 (7.9)
Day 1, after Vaccination (at Home)	22 (6.5)	154 (44.4)	176 (25.7)
Day 2	10 (3.0)	83 (23.9)	93 (13.6)
Day 3	1 (0.3)	6 (1.7)	7 (1.0)
Day 4	2 (0.6)	2 (0.6)	4 (0.6)
Day 5	3 (0.9)	0	3 (0.4)
Day 6	0	0	0
Day 7	2 (0.6)	2 (0.6)	4 (0.6)
Erythema (Redness) - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	3 (0.9)	3 (0.4)
Day 2	1 (0.3)	5 (1.4)	6 (0.9)
Day 3	2 (0.6)	4 (1.2)	6 (0.9)
Day 4	1 (0.3)	5 (1.4)	6 (0.9)
Day 5	0	0	0
Day 6	0	1 (0.3)	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n	(%)	mRNA-1273 (N=347) n	(%)	Total (N=684) n	(%)
Swelling (Hardness) - N1	337		347		684	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0		0		0	
Day 1, after Vaccination (at Home)	1	(0.3)	7	(2.0)	8	(1.2)
Day 2	1	(0.3)	13	(3.7)	14	(2.0)
Day 3	0		2	(0.6)	2	(0.3)
Day 4	0		2	(0.6)	2	(0.3)
Day 5	1	(0.3)	1	(0.3)	2	(0.3)
Day 6	0		1	(0.3)	1	(0.1)
Day 7	0		0		0	
Axillary Swelling or Tenderness - N1	337		347		684	
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0		2	(0.6)	2	(0.3)
Day 1, after Vaccination (at Home)	4	(1.2)	16	(4.6)	20	(2.9)
Day 2	5	(1.5)	31	(8.9)	36	(5.3)
Day 3	4	(1.2)	13	(3.7)	17	(2.5)
Day 4	0		9	(2.6)	9	(1.3)
Day 5	4	(1.2)	2	(0.6)	6	(0.9)
Day 6	3	(0.9)	0		3	(0.4)
Day 7	2	(0.6)	1	(0.3)	3	(0.4)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Solicited Systemic Adverse Reactions - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	20 (5.9)	23 (6.6)	43 (6.3)
Day 1, after Vaccination (at Home)	47 (13.9)	101 (29.1)	148 (21.6)
Day 2	30 (8.9)	105 (30.3)	135 (19.7)
Day 3	17 (5.0)	7 (2.0)	24 (3.5)
Day 4	12 (3.6)	5 (1.4)	17 (2.5)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	3 (0.9)	2 (0.6)	5 (0.7)
Day 7	10 (3.0)	0	10 (1.5)
Fever - N1	336	347	683
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	2 (0.6)	2 (0.3)
Day 1, after Vaccination (at Home)	0	4 (1.2)	4 (0.6)
Day 2	1 (0.3)	41 (11.8)	42 (6.1)
Day 3	3 (0.9)	4 (1.2)	7 (1.0)
Day 4	0	3 (0.9)	3 (0.4)
Day 5	2 (0.6)	1 (0.3)	3 (0.4)
Day 6	1 (0.3)	0	1 (0.1)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Headache - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	11 (3.3)	8 (2.3)	19 (2.8)
Day 1, after Vaccination (at Home)	24 (7.1)	57 (16.4)	81 (11.8)
Day 2	24 (7.1)	80 (23.1)	104 (15.2)
Day 3	12 (3.6)	6 (1.7)	18 (2.6)
Day 4	8 (2.4)	8 (2.3)	16 (2.3)
Day 5	6 (1.8)	4 (1.2)	10 (1.5)
Day 6	5 (1.5)	5 (1.4)	10 (1.5)
Day 7	8 (2.4)	0	8 (1.2)
Fatigue - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	7 (2.1)	12 (3.5)	19 (2.8)
Day 1, after Vaccination (at Home)	32 (9.5)	58 (16.7)	90 (13.2)
Day 2	19 (5.6)	87 (25.1)	106 (15.5)
Day 3	18 (5.3)	9 (2.6)	27 (3.9)
Day 4	9 (2.7)	1 (0.3)	10 (1.5)
Day 5	5 (1.5)	2 (0.6)	7 (1.0)
Day 6	2 (0.6)	1 (0.3)	3 (0.4)
Day 7	4 (1.2)	2 (0.6)	6 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Myalgia - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (0.3)	4 (1.2)	5 (0.7)
Day 1, after Vaccination (at Home)	13 (3.9)	58 (16.7)	71 (10.4)
Day 2	19 (5.6)	101 (29.1)	120 (17.5)
Day 3	8 (2.4)	10 (2.9)	18 (2.6)
Day 4	12 (3.6)	2 (0.6)	14 (2.0)
Day 5	4 (1.2)	1 (0.3)	5 (0.7)
Day 6	3 (0.9)	2 (0.6)	5 (0.7)
Day 7	6 (1.8)	2 (0.6)	8 (1.2)
Arthralgia - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (0.6)	6 (1.7)	8 (1.2)
Day 1, after Vaccination (at Home)	12 (3.6)	40 (11.5)	52 (7.6)
Day 2	14 (4.2)	64 (18.4)	78 (11.4)
Day 3	9 (2.7)	12 (3.5)	21 (3.1)
Day 4	7 (2.1)	2 (0.6)	9 (1.3)
Day 5	1 (0.3)	2 (0.6)	3 (0.4)
Day 6	2 (0.6)	1 (0.3)	3 (0.4)
Day 7	8 (2.4)	1 (0.3)	9 (1.3)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Onset Day	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Nausea/Vomiting - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	1 (0.3)	1 (0.1)
Day 1, after Vaccination (at Home)	4 (1.2)	15 (4.3)	19 (2.8)
Day 2	6 (1.8)	31 (8.9)	37 (5.4)
Day 3	7 (2.1)	9 (2.6)	16 (2.3)
Day 4	4 (1.2)	4 (1.2)	8 (1.2)
Day 5	4 (1.2)	2 (0.6)	6 (0.9)
Day 6	4 (1.2)	1 (0.3)	5 (0.7)
Day 7	6 (1.8)	2 (0.6)	8 (1.2)
Chills - N1	337	347	684
Day 1, 30 Minutes after Vaccination (at Study Clinic)	3 (0.9)	2 (0.6)	5 (0.7)
Day 1, after Vaccination (at Home)	8 (2.4)	30 (8.6)	38 (5.6)
Day 2	9 (2.7)	81 (23.3)	90 (13.2)
Day 3	7 (2.1)	9 (2.6)	16 (2.3)
Day 4	4 (1.2)	1 (0.3)	5 (0.7)
Day 5	3 (0.9)	1 (0.3)	4 (0.6)
Day 6	1 (0.3)	1 (0.3)	2 (0.3)
Day 7	5 (1.5)	1 (0.3)	6 (0.9)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Adverse Reactions - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	15 (17.9)	16 (18.4)	31 (18.1)
Day 1, after Vaccination (at Home)	10 (11.9)	54 (62.1)	64 (37.4)
Day 2	16 (19.0)	13 (14.9)	29 (17.0)
Day 3	2 (2.4)	0	2 (1.2)
Day 4	2 (2.4)	0	2 (1.2)
Day 5	1 (1.2)	0	1 (0.6)
Day 6	2 (2.4)	0	2 (1.2)
Day 7	2 (2.4)	0	2 (1.2)
Solicited Local Adverse Reactions - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	13 (15.5)	14 (16.1)	27 (15.8)
Day 1, after Vaccination (at Home)	4 (4.8)	55 (63.2)	59 (34.5)
Day 2	5 (6.0)	13 (14.9)	18 (10.5)
Day 3	2 (2.4)	0	2 (1.2)
Day 4	0	0	0
Day 5	0	0	0
Day 6	1 (1.2)	0	1 (0.6)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Pain - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	13 (15.5)	13 (14.9)	26 (15.2)
Day 1, after Vaccination (at Home)	4 (4.8)	56 (64.4)	60 (35.1)
Day 2	5 (6.0)	11 (12.6)	16 (9.4)
Day 3	1 (1.2)	0	1 (0.6)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Erythema (Redness) - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.2)	1 (1.1)	2 (1.2)
Day 1, after Vaccination (at Home)	0	1 (1.1)	1 (0.6)
Day 2	0	7 (8.0)	7 (4.1)
Day 3	0	1 (1.1)	1 (0.6)
Day 4	0	1 (1.1)	1 (0.6)
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Swelling (Hardness) - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	7 (8.0)	7 (4.1)
Day 2	0	8 (9.2)	8 (4.7)
Day 3	0	1 (1.1)	1 (0.6)
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0
Axillary Swelling or Tenderness - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (2.4)	0	2 (1.2)
Day 1, after Vaccination (at Home)	0	5 (5.7)	5 (2.9)
Day 2	1 (1.2)	11 (12.6)	12 (7.0)
Day 3	1 (1.2)	2 (2.3)	3 (1.8)
Day 4	0	0	0
Day 5	0	0	0
Day 6	1 (1.2)	1 (1.1)	2 (1.2)
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Systemic Adverse Reactions - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	8 (9.5)	3 (3.4)	11 (6.4)
Day 1, after Vaccination (at Home)	12 (14.3)	37 (42.5)	49 (28.7)
Day 2	15 (17.9)	30 (34.5)	45 (26.3)
Day 3	2 (2.4)	0	2 (1.2)
Day 4	3 (3.6)	0	3 (1.8)
Day 5	1 (1.2)	0	1 (0.6)
Day 6	2 (2.4)	0	2 (1.2)
Day 7	2 (2.4)	0	2 (1.2)
Fever - N1	84	86	170
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	3 (3.5)	3 (1.8)
Day 2	0	7 (8.1)	7 (4.1)
Day 3	0	0	0
Day 4	0	0	0
Day 5	0	0	0
Day 6	0	0	0
Day 7	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Headache - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	5 (6.0)	1 (1.1)	6 (3.5)
Day 1, after Vaccination (at Home)	9 (10.7)	18 (20.7)	27 (15.8)
Day 2	5 (6.0)	31 (35.6)	36 (21.1)
Day 3	5 (6.0)	2 (2.3)	7 (4.1)
Day 4	4 (4.8)	1 (1.1)	5 (2.9)
Day 5	2 (2.4)	1 (1.1)	3 (1.8)
Day 6	2 (2.4)	2 (2.3)	4 (2.3)
Day 7	3 (3.6)	0	3 (1.8)
Fatigue - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	2 (2.4)	2 (2.3)	4 (2.3)
Day 1, after Vaccination (at Home)	9 (10.7)	26 (29.9)	35 (20.5)
Day 2	10 (11.9)	29 (33.3)	39 (22.8)
Day 3	2 (2.4)	0	2 (1.2)
Day 4	3 (3.6)	1 (1.1)	4 (2.3)
Day 5	3 (3.6)	0	3 (1.8)
Day 6	2 (2.4)	1 (1.1)	3 (1.8)
Day 7	1 (1.2)	0	1 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Myalgia - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	4 (4.8)	0	4 (2.3)
Day 1, after Vaccination (at Home)	4 (4.8)	19 (21.8)	23 (13.5)
Day 2	5 (6.0)	35 (40.2)	40 (23.4)
Day 3	4 (4.8)	2 (2.3)	6 (3.5)
Day 4	0	0	0
Day 5	3 (3.6)	1 (1.1)	4 (2.3)
Day 6	0	0	0
Day 7	0	0	0
Arthralgia - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	1 (1.2)	0	1 (0.6)
Day 1, after Vaccination (at Home)	2 (2.4)	17 (19.5)	19 (11.1)
Day 2	6 (7.1)	27 (31.0)	33 (19.3)
Day 3	4 (4.8)	0	4 (2.3)
Day 4	1 (1.2)	3 (3.4)	4 (2.3)
Day 5	0	0	0
Day 6	0	1 (1.1)	1 (0.6)
Day 7	1 (1.2)	0	1 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.3.3.3
Summary of Subjects with Solicited Adverse Reactions Within 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Onset Day
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Onset Day	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Nausea/Vomiting - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	2 (2.4)	3 (3.4)	5 (2.9)
Day 2	5 (6.0)	16 (18.4)	21 (12.3)
Day 3	0	3 (3.4)	3 (1.8)
Day 4	0	0	0
Day 5	0	0	0
Day 6	1 (1.2)	3 (3.4)	4 (2.3)
Day 7	0	1 (1.1)	1 (0.6)
Chills - N1	84	87	171
Day 1, 30 Minutes after Vaccination (at Study Clinic)	0	0	0
Day 1, after Vaccination (at Home)	0	8 (9.2)	8 (4.7)
Day 2	2 (2.4)	28 (32.2)	30 (17.5)
Day 3	0	1 (1.1)	1 (0.6)
Day 4	3 (3.6)	0	3 (1.8)
Day 5	0	0	0
Day 6	1 (1.2)	0	1 (0.6)
Day 7	1 (1.2)	0	1 (0.6)

N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301030303.sas 21JUN2021 17:07

Table 14.3.1.4.1.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Solicited Adverse Reactions			
n	7285	13317	20602
Mean (SD)	3.3 (5.35)	3.5 (4.18)	3.4 (4.63)
Median	2.0	3.0	3.0
Min, Max	1, 189	1, 193	1, 193
Solicited Local Adverse Reactions			
n	3009	12765	15774
Mean (SD)	2.0 (2.88)	2.7 (2.22)	2.5 (2.37)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 71	1, 71
Pain			
n	2665	12688	15353
Mean (SD)	1.7 (2.25)	2.5 (1.61)	2.3 (1.76)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 69	1, 69
Erythema (Redness)			
n	77	445	522
Mean (SD)	4.2 (6.17)	2.8 (4.00)	3.0 (4.41)
Median	1.0	2.0	2.0
Min, Max	1, 28	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040101.sas 10JUN2021 10:50

Table 14.3.1.4.1.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Swelling (Hardness)			
n	65	935	1000
Mean (SD)	6.8 (8.75)	2.2 (2.67)	2.5 (3.59)
Median	2.0	1.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary Swelling or Tenderness			
n	722	1553	2275
Mean (SD)	2.1 (2.86)	2.3 (3.31)	2.3 (3.18)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 69	1, 69
Solicited Systemic Adverse Reactions			
n	6397	8316	14713
Mean (SD)	3.3 (5.47)	3.1 (4.81)	3.2 (5.11)
Median	2.0	2.0	2.0
Min, Max	1, 188	1, 193	1, 193
Fever			
n	44	112	156
Mean (SD)	1.4 (0.62)	1.3 (0.96)	1.3 (0.88)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 8	1, 8

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040101.sas 10JUN2021 10:50

Table 14.3.1.4.1.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Headache			
n	4026	4950	8976
Mean (SD)	2.2 (2.76)	2.1 (2.36)	2.2 (2.55)
Median	1.0	1.0	1.0
Min, Max	1, 85	1, 46	1, 85
Fatigue			
n	4133	5636	9769
Mean (SD)	2.9 (4.39)	2.8 (3.90)	2.8 (4.12)
Median	2.0	2.0	2.0
Min, Max	1, 131	1, 92	1, 131
Myalgia			
n	2069	3442	5511
Mean (SD)	2.8 (3.93)	2.4 (3.58)	2.5 (3.72)
Median	1.0	1.0	1.0
Min, Max	1, 53	1, 74	1, 74
Arthralgia			
n	1784	2510	4294
Mean (SD)	3.5 (7.47)	2.9 (6.71)	3.1 (7.04)
Median	2.0	1.0	1.0
Min, Max	1, 188	1, 193	1, 193

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040101.sas 10JUN2021 10:50

Table 14.3.1.4.1.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Nausea/Vomiting			
n	1075	1262	2337
Mean (SD)	1.8 (2.10)	1.7 (1.65)	1.7 (1.87)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 24	1, 35
Chills			
n	878	1251	2129
Mean (SD)	1.7 (1.87)	1.5 (1.67)	1.6 (1.76)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 28	1, 35

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040101.sas 10JUN2021 10:50

Table 14.3.1.4.4.1
Summary of Number of Days of Grade 3 or Above Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Solicited Local Adverse Reactions			
Pain			
n	55	416	471
Mean (SD)	1.8 (1.38)	3.2 (2.23)	3.0 (2.19)
Median	1.0	3.0	3.0
Min, Max	1, 8	1, 34	1, 34
Erythema (Redness)			
n	13	42	55
Mean (SD)	1.6 (2.22)	2.6 (5.26)	2.4 (4.72)
Median	1.0	1.0	1.0
Min, Max	1, 9	1, 35	1, 35
Swelling (Hardness)			
n	6	82	88
Mean (SD)	3.7 (4.18)	2.2 (1.39)	2.3 (1.72)
Median	1.0	2.0	2.0
Min, Max	1, 10	1, 8	1, 10
Axillary Swelling or Tenderness			
n	27	49	76
Mean (SD)	1.5 (0.85)	2.8 (4.42)	2.4 (3.63)
Median	1.0	1.0	1.0
Min, Max	1, 4	1, 29	1, 29

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.4.1
Summary of Number of Days of Grade 3 or Above Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Solicited Systemic Adverse Reactions			
Fever			
n	8	15	23
Mean (SD)	1.6 (0.74)	1.6 (1.59)	1.6 (1.34)
Median	1.5	1.0	1.0
Min, Max	1, 3	1, 7	1, 7
Headache			
n	197	273	470
Mean (SD)	3.1 (3.55)	3.1 (4.12)	3.1 (3.89)
Median	2.0	2.0	2.0
Min, Max	1, 27	1, 41	1, 41
Fatigue			
n	105	152	257
Mean (SD)	6.4 (13.30)	6.1 (8.82)	6.2 (10.86)
Median	4.0	4.0	4.0
Min, Max	1, 131	1, 82	1, 131
Myalgia			
n	47	91	138
Mean (SD)	5.8 (6.23)	5.1 (6.61)	5.3 (6.47)
Median	3.0	3.0	3.0
Min, Max	1, 25	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040401.sas 10JUN2021 10:50

Table 14.3.1.4.4.1
Summary of Number of Days of Grade 3 or Above Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Arthralgia			
n	38	61	99
Mean (SD)	5.9 (6.01)	5.3 (6.23)	5.5 (6.12)
Median	3.0	3.0	3.0
Min, Max	1, 25	1, 32	1, 32
Nausea/Vomiting			
n	13	10	23
Mean (SD)	1.6 (1.19)	2.3 (2.31)	1.9 (1.76)
Median	1.0	1.0	1.0
Min, Max	1, 5	1, 7	1, 7
Chills			
n	14	24	38
Mean (SD)	1.8 (1.12)	3.7 (5.68)	3.0 (4.63)
Median	1.5	2.0	2.0
Min, Max	1, 5	1, 28	1, 28

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040401.sas 10JUN2021 10:50

Table 14.3.1.4.5.1
Summary of Number of Days of Grade 4 Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Solicited Local Adverse Reactions			
Pain			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Erythema (Redness)			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Swelling (Hardness)			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Axillary Swelling or Tenderness			
n	0	0	0
Mean (SD)			
Median			
Min, Max			

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.5.1
Summary of Number of Days of Grade 4 Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Solicited Systemic Adverse Reactions			
Fever			
n	6	4	10
Mean (SD)	1.5 (0.55)	1.0 (0.00)	1.3 (0.48)
Median	1.5	1.0	1.0
Min, Max	1, 2	1, 1	1, 2
Headache			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Fatigue			
n	0	1	1
Mean (SD)		6.0 (NA)	6.0 (NA)
Median		6.0	6.0
Min, Max		6, 6	6, 6
Myalgia			
n	0	0	0
Mean (SD)			
Median			
Min, Max			

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040501.sas 10JUN2021 10:51

Table 14.3.1.4.5.1
Summary of Number of Days of Grade 4 Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15151)	mRNA-1273 (N=15166)	Total (N=30317)
Arthralgia			
n	0	1	1
Mean (SD)		4.0 (NA)	4.0 (NA)
Median		4.0	4.0
Min, Max		4, 4	4, 4
Nausea/Vomiting			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Chills			
n	0	0	0
Mean (SD)			
Median			
Min, Max			

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040501.sas 10JUN2021 10:51

Table 14.3.1.4.1.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Solicited Adverse Reactions			
n	6255	13556	19811
Mean (SD)	3.7 (8.69)	4.2 (7.76)	4.0 (8.07)
Median	2.0	3.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited Local Adverse Reactions			
n	2757	13029	15786
Mean (SD)	2.2 (6.40)	3.2 (3.28)	3.0 (4.02)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 154	1, 212
Pain			
n	2486	12964	15450
Mean (SD)	1.9 (4.89)	3.0 (2.47)	2.8 (3.02)
Median	1.0	3.0	3.0
Min, Max	1, 159	1, 154	1, 159
Erythema (Redness)			
n	68	1274	1342
Mean (SD)	3.8 (5.28)	2.7 (2.69)	2.7 (2.88)
Median	1.0	2.0	2.0
Min, Max	1, 29	1, 39	1, 39

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040102.sas 10JUN2021 10:50

Table 14.3.1.4.1.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Swelling (Hardness)			
n	60	1807	1867
Mean (SD)	4.2 (5.30)	2.5 (2.06)	2.5 (2.26)
Median	1.0	2.0	2.0
Min, Max	1, 31	1, 31	1, 31
Axillary Swelling or Tenderness			
n	571	2092	2663
Mean (SD)	3.0 (11.51)	2.5 (5.19)	2.6 (7.04)
Median	1.0	2.0	2.0
Min, Max	1, 212	1, 151	1, 212
Solicited Systemic Adverse Reactions			
n	5343	11678	17021
Mean (SD)	3.7 (8.73)	3.4 (7.91)	3.5 (8.18)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	43	2276	2319
Mean (SD)	1.4 (1.56)	1.1 (0.41)	1.1 (0.46)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 9	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040102.sas 10JUN2021 10:50

Table 14.3.1.4.1.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Headache			
n	3427	8637	12064
Mean (SD)	2.4 (5.00)	2.4 (4.80)	2.4 (4.86)
Median	1.0	2.0	2.0
Min, Max	1, 169	1, 196	1, 196
Fatigue			
n	3418	9607	13025
Mean (SD)	3.3 (8.27)	2.8 (6.49)	2.9 (7.01)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	1824	8529	10353
Mean (SD)	3.7 (9.82)	2.2 (4.22)	2.4 (5.65)
Median	2.0	1.0	2.0
Min, Max	1, 169	1, 170	1, 170
Arthralgia			
n	1579	6303	7882
Mean (SD)	4.1 (10.02)	2.3 (4.73)	2.7 (6.20)
Median	2.0	1.0	1.0
Min, Max	1, 169	1, 185	1, 185

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.1.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Nausea/Vomiting			
n	941	2794	3735
Mean (SD)	2.0 (5.79)	1.7 (3.69)	1.8 (4.31)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 176	1, 176
Chills			
n	813	6500	7313
Mean (SD)	2.2 (7.43)	1.5 (2.27)	1.6 (3.28)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 158	1, 169

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.4.2
Summary of Number of Days of Grade 3 Above Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Solicited Local Adverse Reactions			
Pain			
n	41	606	647
Mean (SD)	4.8 (15.33)	3.8 (2.16)	3.9 (4.36)
Median	1.0	3.0	3.0
Min, Max	1, 99	1, 25	1, 99
Erythema (Redness)			
n	15	287	302
Mean (SD)	1.7 (1.53)	3.5 (3.53)	3.4 (3.48)
Median	1.0	3.0	3.0
Min, Max	1, 7	1, 39	1, 39
Swelling (Hardness)			
n	12	255	267
Mean (SD)	2.3 (2.01)	3.2 (2.26)	3.1 (2.25)
Median	1.0	3.0	3.0
Min, Max	1, 7	1, 16	1, 16
Axillary Swelling or Tenderness			
n	20	68	88
Mean (SD)	2.3 (2.34)	4.8 (10.90)	4.3 (9.69)
Median	1.0	2.0	2.0
Min, Max	1, 10	1, 66	1, 66

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040402.sas 10JUN2021 12:18

Table 14.3.1.4.4.2
Summary of Number of Days of Grade 3 Above Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Solicited Systemic Adverse Reactions			
Fever			
n	5	216	221
Mean (SD)	3.6 (4.22)	1.4 (0.71)	1.4 (0.96)
Median	2.0	1.0	1.0
Min, Max	1, 11	1, 5	1, 11
Headache			
n	165	666	831
Mean (SD)	3.5 (8.27)	3.3 (6.57)	3.4 (6.94)
Median	2.0	2.0	2.0
Min, Max	1, 102	1, 158	1, 158
Fatigue			
n	108	1433	1541
Mean (SD)	6.2 (5.94)	4.2 (10.05)	4.3 (9.83)
Median	4.0	3.0	3.0
Min, Max	1, 32	1, 198	1, 198
Myalgia			
n	52	1321	1373
Mean (SD)	8.3 (10.31)	3.0 (5.65)	3.2 (5.97)
Median	4.5	2.0	2.0
Min, Max	1, 52	1, 151	1, 151

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040402.sas 10JUN2021 12:18

Table 14.3.1.4.4.2
Summary of Number of Days of Grade 3 Above Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Arthralgia			
n	44	775	819
Mean (SD)	6.2 (5.89)	3.5 (7.82)	3.6 (7.75)
Median	4.0	2.0	2.0
Min, Max	1, 23	1, 185	1, 185
Nausea/Vomiting			
n	11	22	33
Mean (SD)	2.5 (1.37)	4.3 (3.91)	3.7 (3.37)
Median	3.0	3.0	3.0
Min, Max	1, 4	1, 12	1, 12
Chills			
n	17	191	208
Mean (SD)	2.8 (2.73)	2.3 (2.76)	2.4 (2.75)
Median	2.0	2.0	2.0
Min, Max	1, 10	1, 29	1, 29

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040402.sas 10JUN2021 12:18

Table 14.3.1.4.5.2
Summary of Number of Days of Grade 4 Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Solicited Local Adverse Reactions			
Pain			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Erythema (Redness)			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Swelling (Hardness)			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Axillary Swelling or Tenderness			
n	0	0	0
Mean (SD)			
Median			
Min, Max			

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040502.sas 10JUN2021 10:51

Table 14.3.1.4.5.2
Summary of Number of Days of Grade 4 Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Solicited Systemic Adverse Reactions			
Fever			
n	3	13	16
Mean (SD)	2.0 (1.00)	1.4 (0.51)	1.5 (0.63)
Median	2.0	1.0	1.0
Min, Max	1, 3	1, 2	1, 3
Headache			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Fatigue			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Myalgia			
n	0	0	0
Mean (SD)			
Median			
Min, Max			

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040502.sas 10JUN2021 10:51

Table 14.3.1.4.5.2
Summary of Number of Days of Grade 4 Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=14578)	mRNA-1273 (N=14691)	Total (N=29269)
Arthralgia			
n	0	0	0
Mean (SD)			
Median			
Min, Max			
Nausea/Vomiting			
n	0	1	1
Mean (SD)		7.0 (NA)	7.0 (NA)
Median		7.0	7.0
Min, Max		7, 7	7, 7
Chills			
n	0	0	0
Mean (SD)			
Median			
Min, Max			

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.1.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15159)	mRNA-1273 (N=15179)	Total (N=30338)
Solicited Adverse Reactions			
n	9113	14402	23515
Mean (SD)	4.0 (8.33)	4.8 (8.10)	4.5 (8.20)
Median	2.0	4.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited Local Adverse Reactions			
n	4468	14032	18500
Mean (SD)	2.3 (5.44)	3.5 (3.52)	3.2 (4.10)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 154	1, 212
Pain			
n	4046	13969	18015
Mean (SD)	1.9 (4.14)	3.2 (2.61)	2.9 (3.07)
Median	1.0	3.0	3.0
Min, Max	1, 159	1, 154	1, 159
Erythema (Redness)			
n	137	1549	1686
Mean (SD)	4.0 (5.87)	2.8 (3.18)	2.9 (3.49)
Median	1.0	2.0	2.0
Min, Max	1, 29	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.1.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15159)	mRNA-1273 (N=15179)	Total (N=30338)
Swelling (Hardness)			
n	116	2249	2365
Mean (SD)	5.6 (7.54)	2.5 (2.39)	2.7 (2.94)
Median	2.0	2.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary Swelling or Tenderness			
n	1101	3013	4114
Mean (SD)	2.6 (8.50)	2.5 (4.68)	2.5 (5.94)
Median	1.0	1.0	1.0
Min, Max	1, 212	1, 151	1, 212
Solicited Systemic Adverse Reactions			
n	8117	12779	20896
Mean (SD)	3.9 (8.28)	3.8 (8.16)	3.8 (8.21)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	86	2350	2436
Mean (SD)	1.4 (1.18)	1.1 (0.45)	1.1 (0.50)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 9	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.1.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15159)	mRNA-1273 (N=15179)	Total (N=30338)
Headache			
n	5613	9844	15457
Mean (SD)	2.5 (4.31)	2.5 (4.70)	2.5 (4.56)
Median	2.0	2.0	2.0
Min, Max	1, 169	1, 196	1, 196
Fatigue			
n	5549	10640	16189
Mean (SD)	3.4 (7.32)	3.1 (6.62)	3.2 (6.87)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	3118	9348	12466
Mean (SD)	3.3 (7.92)	2.3 (4.47)	2.6 (5.55)
Median	2.0	2.0	2.0
Min, Max	1, 169	1, 170	1, 170
Arthralgia			
n	2672	7055	9727
Mean (SD)	4.0 (9.60)	2.6 (5.54)	3.0 (6.92)
Median	2.0	1.0	2.0
Min, Max	1, 188	1, 193	1, 193

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.1.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Placebo (N=15159)	mRNA-1273 (N=15179)	Total (N=30338)
Nausea/Vomiting			
n	1723	3493	5216
Mean (SD)	1.9 (4.49)	1.8 (3.41)	1.8 (3.80)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 176	1, 176
Chills			
n	1473	6907	8380
Mean (SD)	2.0 (5.62)	1.5 (2.27)	1.6 (3.13)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 158	1, 169

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11402)	mRNA-1273 (N=11406)	Total (N=22808)
Solicited Adverse Reactions			
n	5737	10262	15999
Mean (SD)	3.2 (4.10)	3.6 (3.87)	3.4 (3.96)
Median	2.0	3.0	3.0
Min, Max	1, 101	1, 193	1, 193
Solicited Local Adverse Reactions			
n	2436	9961	12397
Mean (SD)	1.9 (2.47)	2.7 (2.27)	2.6 (2.33)
Median	1.0	2.0	2.0
Min, Max	1, 35	1, 71	1, 71
Pain			
n	2183	9908	12091
Mean (SD)	1.7 (1.91)	2.5 (1.60)	2.4 (1.70)
Median	1.0	2.0	2.0
Min, Max	1, 35	1, 69	1, 69
Erythema (Redness)			
n	54	354	408
Mean (SD)	3.4 (5.74)	2.7 (3.66)	2.8 (4.00)
Median	1.0	2.0	2.0
Min, Max	1, 28	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11402)	mRNA-1273 (N=11406)	Total (N=22808)
Swelling (Hardness)			
n	42	766	808
Mean (SD)	5.4 (7.77)	2.2 (2.77)	2.4 (3.29)
Median	2.0	2.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary Swelling or Tenderness			
n	567	1322	1889
Mean (SD)	2.2 (3.03)	2.4 (3.41)	2.4 (3.30)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 69	1, 69
Solicited Systemic Adverse Reactions			
n	5063	6499	11562
Mean (SD)	3.2 (4.18)	3.0 (4.35)	3.1 (4.27)
Median	2.0	2.0	2.0
Min, Max	1, 101	1, 193	1, 193
Fever			
n	37	102	139
Mean (SD)	1.4 (0.60)	1.3 (1.00)	1.3 (0.91)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 8	1, 8

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11402)	mRNA-1273 (N=11406)	Total (N=22808)
Headache			
n	3303	4028	7331
Mean (SD)	2.2 (2.79)	2.1 (2.33)	2.2 (2.55)
Median	1.0	1.0	1.0
Min, Max	1, 85	1, 46	1, 85
Fatigue			
n	3281	4385	7666
Mean (SD)	2.8 (3.54)	2.7 (3.54)	2.7 (3.54)
Median	2.0	2.0	2.0
Min, Max	1, 50	1, 56	1, 56
Myalgia			
n	1625	2700	4325
Mean (SD)	2.6 (3.49)	2.3 (3.25)	2.4 (3.35)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 49	1, 49
Arthralgia			
n	1327	1892	3219
Mean (SD)	3.2 (5.18)	2.7 (5.88)	2.9 (5.61)
Median	2.0	1.0	1.0
Min, Max	1, 101	1, 193	1, 193

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11402)	mRNA-1273 (N=11406)	Total (N=22808)
Nausea/Vomiting			
n	908	1068	1976
Mean (SD)	1.8 (2.18)	1.7 (1.69)	1.8 (1.93)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 24	1, 35
Chills			
n	730	1050	1780
Mean (SD)	1.7 (1.96)	1.6 (1.68)	1.6 (1.80)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 28	1, 35

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Statistic	Placebo (N=3749)	mRNA-1273 (N=3760)	Total (N=7509)
Solicited Adverse Reactions			
n	1548	3055	4603
Mean (SD)	3.8 (8.48)	3.3 (5.06)	3.5 (6.42)
Median	2.0	2.0	2.0
Min, Max	1, 189	1, 169	1, 189
Solicited Local Adverse Reactions			
n	573	2804	3377
Mean (SD)	2.4 (4.16)	2.3 (2.02)	2.3 (2.51)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 41	1, 51
Pain			
n	482	2780	3262
Mean (SD)	1.9 (3.39)	2.2 (1.60)	2.2 (1.97)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 41	1, 51
Erythema (Redness)			
n	23	91	114
Mean (SD)	5.9 (6.90)	3.2 (5.11)	3.7 (5.59)
Median	1.0	2.0	2.0
Min, Max	1, 27	1, 35	1, 35

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3749)	mRNA-1273 (N=3760)	Total (N=7509)
Swelling (Hardness)			
n	23	169	192
Mean (SD)	9.4 (9.97)	2.0 (2.14)	2.9 (4.61)
Median	4.0	1.0	2.0
Min, Max	1, 29	1, 21	1, 29
Axillary Swelling or Tenderness			
n	155	231	386
Mean (SD)	1.8 (2.08)	1.9 (2.63)	1.8 (2.42)
Median	1.0	1.0	1.0
Min, Max	1, 16	1, 24	1, 24
Solicited Systemic Adverse Reactions			
n	1334	1817	3151
Mean (SD)	3.7 (8.79)	3.2 (6.18)	3.4 (7.40)
Median	2.0	2.0	2.0
Min, Max	1, 188	1, 169	1, 188
Fever			
n	7	10	17
Mean (SD)	1.4 (0.79)	1.1 (0.32)	1.2 (0.56)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 2	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3749)	mRNA-1273 (N=3760)	Total (N=7509)
Headache			
n	723	922	1645
Mean (SD)	2.1 (2.63)	2.1 (2.48)	2.1 (2.54)
Median	1.0	1.0	1.0
Min, Max	1, 30	1, 41	1, 41
Fatigue			
n	852	1251	2103
Mean (SD)	3.3 (6.71)	2.9 (4.98)	3.1 (5.75)
Median	2.0	2.0	2.0
Min, Max	1, 131	1, 92	1, 131
Myalgia			
n	444	742	1186
Mean (SD)	3.3 (5.20)	2.6 (4.57)	2.9 (4.82)
Median	1.0	1.0	1.0
Min, Max	1, 53	1, 74	1, 74
Arthralgia			
n	457	618	1075
Mean (SD)	4.3 (11.79)	3.5 (8.76)	3.8 (10.16)
Median	2.0	1.0	1.0
Min, Max	1, 188	1, 169	1, 188

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Age Group
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3749)	mRNA-1273 (N=3760)	Total (N=7509)
Nausea/Vomiting			
n	167	194	361
Mean (SD)	1.6 (1.56)	1.6 (1.41)	1.6 (1.48)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 11	1, 11
Chills			
n	148	201	349
Mean (SD)	1.5 (1.33)	1.5 (1.61)	1.5 (1.49)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 17	1, 17

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Statistic	Placebo (N=10929)	mRNA-1273 (N=11000)	Total (N=21929)
Solicited Adverse Reactions			
n	4921	10252	15173
Mean (SD)	3.6 (8.90)	4.3 (7.74)	4.1 (8.14)
Median	2.0	3.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited Local Adverse Reactions			
n	2262	9936	12198
Mean (SD)	2.3 (6.97)	3.3 (3.29)	3.1 (4.24)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 154	1, 212
Pain			
n	2048	9893	11941
Mean (SD)	2.0 (5.34)	3.0 (2.25)	2.9 (3.04)
Median	1.0	3.0	3.0
Min, Max	1, 159	1, 154	1, 159
Erythema (Redness)			
n	53	989	1042
Mean (SD)	3.7 (4.82)	2.5 (2.24)	2.6 (2.45)
Median	2.0	2.0	2.0
Min, Max	1, 29	1, 24	1, 29

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=10929)	mRNA-1273 (N=11000)	Total (N=21929)
Swelling (Hardness)			
n	46	1399	1445
Mean (SD)	4.0 (4.01)	2.5 (2.08)	2.5 (2.18)
Median	1.0	2.0	2.0
Min, Max	1, 17	1, 31	1, 31
Axillary Swelling or Tenderness			
n	474	1777	2251
Mean (SD)	3.2 (12.60)	2.7 (5.59)	2.8 (7.62)
Median	1.0	2.0	2.0
Min, Max	1, 212	1, 151	1, 212
Solicited Systemic Adverse Reactions			
n	4208	9023	13231
Mean (SD)	3.6 (8.82)	3.4 (7.83)	3.5 (8.15)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	38	1909	1947
Mean (SD)	1.4 (1.65)	1.1 (0.43)	1.1 (0.48)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 9	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=10929)	mRNA-1273 (N=11000)	Total (N=21929)
Headache			
n	2775	6929	9704
Mean (SD)	2.5 (5.09)	2.5 (4.73)	2.5 (4.83)
Median	1.0	2.0	2.0
Min, Max	1, 169	1, 176	1, 176
Fatigue			
n	2701	7453	10154
Mean (SD)	3.3 (8.55)	2.7 (6.37)	2.9 (7.02)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	1425	6789	8214
Mean (SD)	3.5 (9.25)	2.1 (4.01)	2.4 (5.33)
Median	2.0	2.0	2.0
Min, Max	1, 169	1, 170	1, 170
Arthralgia			
n	1180	5010	6190
Mean (SD)	3.8 (9.18)	2.3 (4.43)	2.6 (5.68)
Median	2.0	1.0	1.0
Min, Max	1, 169	1, 185	1, 185

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=10929)	mRNA-1273 (N=11000)	Total (N=21929)
Nausea/Vomiting			
n	807	2355	3162
Mean (SD)	2.1 (6.22)	1.8 (3.93)	1.8 (4.63)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 176	1, 176
Chills			
n	662	5357	6019
Mean (SD)	2.3 (8.14)	1.5 (1.15)	1.6 (2.92)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 29	1, 169

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Statistic	Placebo (N=3649)	mRNA-1273 (N=3691)	Total (N=7340)
Solicited Adverse Reactions			
n	1334	3304	4638
Mean (SD)	3.8 (7.89)	4.0 (7.82)	4.0 (7.84)
Median	2.0	3.0	3.0
Min, Max	1, 146	1, 196	1, 196
Solicited Local Adverse Reactions			
n	495	3093	3588
Mean (SD)	2.0 (2.49)	3.0 (3.27)	2.9 (3.19)
Median	1.0	3.0	2.0
Min, Max	1, 31	1, 147	1, 147
Pain			
n	438	3071	3509
Mean (SD)	1.7 (1.46)	2.9 (3.06)	2.7 (2.93)
Median	1.0	3.0	2.0
Min, Max	1, 13	1, 147	1, 147
Erythema (Redness)			
n	15	285	300
Mean (SD)	4.2 (6.85)	3.3 (3.80)	3.3 (3.99)
Median	1.0	2.0	2.0
Min, Max	1, 26	1, 39	1, 39

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3649)	mRNA-1273 (N=3691)	Total (N=7340)
Swelling (Hardness)			
n	14	408	422
Mean (SD)	4.9 (8.45)	2.6 (1.99)	2.7 (2.49)
Median	1.0	2.0	2.0
Min, Max	1, 31	1, 12	1, 31
Axillary Swelling or Tenderness			
n	97	315	412
Mean (SD)	2.3 (2.02)	1.8 (1.38)	1.9 (1.57)
Median	1.0	1.0	1.0
Min, Max	1, 14	1, 9	1, 14
Solicited Systemic Adverse Reactions			
n	1135	2655	3790
Mean (SD)	3.9 (8.42)	3.3 (8.19)	3.5 (8.26)
Median	2.0	2.0	2.0
Min, Max	1, 146	1, 196	1, 196
Fever			
n	5	367	372
Mean (SD)	1.4 (0.55)	1.1 (0.26)	1.1 (0.27)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Statistic	Placebo (N=3649)	mRNA-1273 (N=3691)	Total (N=7340)
Headache			
n	652	1708	2360
Mean (SD)	2.4 (4.58)	2.1 (5.10)	2.2 (4.96)
Median	1.0	1.0	1.0
Min, Max	1, 89	1, 196	1, 196
Fatigue			
n	717	2154	2871
Mean (SD)	3.4 (7.12)	2.8 (6.92)	2.9 (6.97)
Median	2.0	2.0	2.0
Min, Max	1, 146	1, 172	1, 172
Myalgia			
n	399	1740	2139
Mean (SD)	4.4 (11.61)	2.2 (4.94)	2.6 (6.76)
Median	2.0	1.0	1.0
Min, Max	1, 146	1, 162	1, 162
Arthralgia			
n	399	1293	1692
Mean (SD)	5.0 (12.15)	2.6 (5.74)	3.1 (7.81)
Median	2.0	1.0	1.0
Min, Max	1, 146	1, 162	1, 162

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Age Group
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3649)	mRNA-1273 (N=3691)	Total (N=7340)
Nausea/Vomiting			
n	134	439	573
Mean (SD)	1.6 (1.50)	1.6 (1.86)	1.6 (1.78)
Median	1.0	1.0	1.0
Min, Max	1, 10	1, 29	1, 29
Chills			
n	151	1143	1294
Mean (SD)	1.9 (2.52)	1.5 (4.80)	1.5 (4.60)
Median	1.0	1.0	1.0
Min, Max	1, 27	1, 158	1, 158

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Statistic	Placebo (N=11408)	mRNA-1273 (N=11413)	Total (N=22821)
Solicited Adverse Reactions			
n	7088	10889	17977
Mean (SD)	3.9 (7.98)	4.8 (8.07)	4.5 (8.05)
Median	2.0	4.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited Local Adverse Reactions			
n	3590	10680	14270
Mean (SD)	2.2 (5.78)	3.5 (3.53)	3.2 (4.25)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 154	1, 212
Pain			
n	3283	10643	13926
Mean (SD)	1.9 (4.39)	3.2 (2.42)	2.9 (3.05)
Median	1.0	3.0	3.0
Min, Max	1, 159	1, 154	1, 159
Erythema (Redness)			
n	100	1202	1302
Mean (SD)	3.6 (5.40)	2.6 (2.78)	2.7 (3.07)
Median	1.0	2.0	2.0
Min, Max	1, 29	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040203.sas 21JUN2021 17:06

Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11408)	mRNA-1273 (N=11413)	Total (N=22821)
Swelling (Hardness)			
n	82	1761	1843
Mean (SD)	4.6 (6.24)	2.5 (2.46)	2.6 (2.77)
Median	1.0	2.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary Swelling or Tenderness			
n	878	2536	3414
Mean (SD)	2.7 (9.45)	2.6 (5.01)	2.6 (6.45)
Median	1.0	2.0	1.0
Min, Max	1, 212	1, 151	1, 212
Solicited Systemic Adverse Reactions			
n	6351	9825	16176
Mean (SD)	3.8 (7.79)	3.8 (8.08)	3.8 (7.97)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	74	1977	2051
Mean (SD)	1.4 (1.25)	1.1 (0.48)	1.1 (0.53)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 9	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=11408)	mRNA-1273 (N=11413)	Total (N=22821)
Headache			
n	4534	7835	12369
Mean (SD)	2.5 (4.37)	2.6 (4.64)	2.6 (4.54)
Median	2.0	2.0	2.0
Min, Max	1, 169	1, 176	1, 176
Fatigue			
n	4346	8200	12546
Mean (SD)	3.3 (7.24)	3.0 (6.44)	3.1 (6.73)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	2433	7397	9830
Mean (SD)	3.2 (7.46)	2.3 (4.21)	2.5 (5.22)
Median	2.0	2.0	2.0
Min, Max	1, 169	1, 170	1, 170
Arthralgia			
n	2001	5541	7542
Mean (SD)	3.7 (8.01)	2.5 (5.28)	2.8 (6.15)
Median	2.0	1.0	2.0
Min, Max	1, 169	1, 193	1, 193

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Statistic	Placebo (N=11408)	mRNA-1273 (N=11413)	Total (N=22821)
Nausea/Vomiting			
n	1448	2929	4377
Mean (SD)	2.0 (4.85)	1.8 (3.64)	1.8 (4.08)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 176	1, 176
Chills			
n	1207	5676	6883
Mean (SD)	2.0 (6.13)	1.5 (1.24)	1.6 (2.81)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 29	1, 169

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3751)	mRNA-1273 (N=3766)	Total (N=7517)
Solicited Adverse Reactions			
n	2025	3513	5538
Mean (SD)	4.2 (9.44)	4.6 (8.20)	4.4 (8.68)
Median	2.0	3.0	3.0
Min, Max	1, 189	1, 196	1, 196
Solicited Local Adverse Reactions			
n	878	3352	4230
Mean (SD)	2.3 (3.74)	3.2 (3.47)	3.0 (3.54)
Median	1.0	3.0	2.0
Min, Max	1, 51	1, 147	1, 147
Pain			
n	763	3326	4089
Mean (SD)	1.9 (2.85)	3.0 (3.13)	2.8 (3.11)
Median	1.0	3.0	2.0
Min, Max	1, 51	1, 147	1, 147
Erythema (Redness)			
n	37	347	384
Mean (SD)	5.2 (6.93)	3.3 (4.25)	3.5 (4.60)
Median	1.0	2.0	2.0
Min, Max	1, 27	1, 39	1, 39

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3751)	mRNA-1273 (N=3766)	Total (N=7517)
Swelling (Hardness)			
n	34	488	522
Mean (SD)	7.9 (9.75)	2.5 (2.11)	2.9 (3.45)
Median	2.0	2.0	2.0
Min, Max	1, 31	1, 21	1, 31
Axillary Swelling or Tenderness			
n	223	477	700
Mean (SD)	2.0 (2.05)	1.8 (2.09)	1.9 (2.08)
Median	1.0	1.0	1.0
Min, Max	1, 16	1, 24	1, 24
Solicited Systemic Adverse Reactions			
n	1766	2954	4720
Mean (SD)	4.2 (9.84)	3.7 (8.42)	3.9 (8.98)
Median	2.0	2.0	2.0
Min, Max	1, 188	1, 196	1, 196
Fever			
n	12	373	385
Mean (SD)	1.4 (0.67)	1.1 (0.26)	1.1 (0.29)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3751)	mRNA-1273 (N=3766)	Total (N=7517)
Headache			
n	1079	2009	3088
Mean (SD)	2.4 (4.05)	2.2 (4.92)	2.3 (4.64)
Median	1.0	1.0	1.0
Min, Max	1, 89	1, 196	1, 196
Fatigue			
n	1203	2440	3643
Mean (SD)	3.5 (7.61)	3.2 (7.20)	3.3 (7.34)
Median	2.0	2.0	2.0
Min, Max	1, 146	1, 172	1, 172
Myalgia			
n	685	1951	2636
Mean (SD)	3.8 (9.37)	2.4 (5.33)	2.8 (6.65)
Median	1.0	1.0	1.0
Min, Max	1, 146	1, 162	1, 162
Arthralgia			
n	671	1514	2185
Mean (SD)	5.0 (13.20)	2.9 (6.37)	3.5 (9.08)
Median	2.0	1.0	1.0
Min, Max	1, 188	1, 169	1, 188

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040203.sas 21JUN2021 17:06

Table 14.3.1.4.2.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Age Group
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Statistic	Placebo (N=3751)	mRNA-1273 (N=3766)	Total (N=7517)
Nausea/Vomiting			
n	275	564	839
Mean (SD)	1.6 (1.54)	1.6 (1.82)	1.6 (1.73)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 29	1, 29
Chills			
n	266	1231	1497
Mean (SD)	1.7 (2.09)	1.5 (4.67)	1.6 (4.32)
Median	1.0	1.0	1.0
Min, Max	1, 27	1, 158	1, 158

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040203.sas 21JUN2021 17:06

Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Statistic	Placebo (N=14730)	mRNA-1273 (N=14733)	Total (N=29463)
Solicited Adverse Reactions			
n	7105	12976	20081
Mean (SD)	3.3 (5.34)	3.5 (4.20)	3.4 (4.64)
Median	2.0	3.0	3.0
Min, Max	1, 189	1, 193	1, 193
Solicited Local Adverse Reactions			
n	2934	12442	15376
Mean (SD)	2.0 (2.90)	2.7 (2.24)	2.5 (2.39)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 71	1, 71
Pain			
n	2596	12369	14965
Mean (SD)	1.7 (2.27)	2.5 (1.62)	2.3 (1.77)
Median	1.0	2.0	2.0
Min, Max	1, 51	1, 69	1, 69
Erythema (Redness)			
n	74	429	503
Mean (SD)	4.3 (6.26)	2.8 (4.06)	3.0 (4.48)
Median	1.0	2.0	2.0
Min, Max	1, 28	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040301.sas 21JUN2021 17:06

Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Statistic	Placebo (N=14730)	mRNA-1273 (N=14733)	Total (N=29463)
Swelling (Hardness)			
n	63	910	973
Mean (SD)	7.0 (8.83)	2.2 (2.66)	2.5 (3.61)
Median	3.0	2.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary Swelling or Tenderness			
n	701	1487	2188
Mean (SD)	2.1 (2.88)	2.4 (3.37)	2.3 (3.22)
Median	1.0	1.0	1.0
Min, Max	1, 33	1, 69	1, 69
Solicited Systemic Adverse Reactions			
n	6239	8053	14292
Mean (SD)	3.3 (5.47)	3.1 (4.84)	3.2 (5.12)
Median	2.0	2.0	2.0
Min, Max	1, 188	1, 193	1, 193
Fever			
n	38	78	116
Mean (SD)	1.4 (0.65)	1.3 (1.13)	1.4 (0.99)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 8	1, 8

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14730)	mRNA-1273 (N=14733)	Total (N=29463)
Headache			
n	3917	4787	8704
Mean (SD)	2.2 (2.78)	2.1 (2.34)	2.2 (2.54)
Median	1.0	1.0	1.0
Min, Max	1, 85	1, 46	1, 85
Fatigue			
n	4038	5466	9504
Mean (SD)	2.9 (4.36)	2.8 (3.92)	2.8 (4.11)
Median	2.0	2.0	2.0
Min, Max	1, 131	1, 92	1, 131
Myalgia			
n	2011	3295	5306
Mean (SD)	2.7 (3.86)	2.4 (3.60)	2.5 (3.70)
Median	1.0	1.0	1.0
Min, Max	1, 53	1, 74	1, 74
Arthralgia			
n	1735	2406	4141
Mean (SD)	3.4 (7.47)	2.9 (6.84)	3.1 (7.11)
Median	2.0	1.0	1.0
Min, Max	1, 188	1, 193	1, 193

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14730)	mRNA-1273 (N=14733)	Total (N=29463)
Nausea/Vomiting			
n	1044	1210	2254
Mean (SD)	1.8 (2.12)	1.7 (1.64)	1.7 (1.88)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 24	1, 35
Chills			
n	846	1162	2008
Mean (SD)	1.7 (1.89)	1.5 (1.69)	1.6 (1.78)
Median	1.0	1.0	1.0
Min, Max	1, 35	1, 28	1, 35

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Statistic	Placebo (N=337)	mRNA-1273 (N=346)	Total (N=683)
Solicited Adverse Reactions			
n	138	265	403
Mean (SD)	3.6 (4.20)	3.6 (3.75)	3.6 (3.91)
Median	2.0	3.0	3.0
Min, Max	1, 32	1, 33	1, 33
Solicited Local Adverse Reactions			
n	60	250	310
Mean (SD)	1.9 (1.56)	2.6 (1.59)	2.4 (1.60)
Median	1.0	2.0	2.0
Min, Max	1, 10	1, 16	1, 16
Pain			
n	56	247	303
Mean (SD)	1.6 (1.32)	2.4 (1.23)	2.2 (1.28)
Median	1.0	2.0	2.0
Min, Max	1, 9	1, 7	1, 9
Erythema (Redness)			
n	3	10	13
Mean (SD)	1.0 (0.00)	2.4 (2.12)	2.1 (1.93)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 7	1, 7

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=337)	mRNA-1273 (N=346)	Total (N=683)
Swelling (Hardness)			
n	2	19	21
Mean (SD)	1.5 (0.71)	2.4 (3.24)	2.3 (3.09)
Median	1.5	1.0	1.0
Min, Max	1, 2	1, 15	1, 15
Axillary Swelling or Tenderness			
n	18	56	74
Mean (SD)	2.3 (2.24)	1.9 (1.29)	2.0 (1.57)
Median	1.5	1.0	1.0
Min, Max	1, 10	1, 6	1, 10
Solicited Systemic Adverse Reactions			
n	122	214	336
Mean (SD)	3.6 (4.38)	3.1 (4.10)	3.3 (4.21)
Median	2.0	2.0	2.0
Min, Max	1, 32	1, 33	1, 33
Fever			
n	6	33	39
Mean (SD)	1.3 (0.52)	1.2 (0.36)	1.2 (0.39)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 2	1, 2

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Statistic	Placebo (N=337)	mRNA-1273 (N=346)	Total (N=683)
Headache			
n	83	134	217
Mean (SD)	2.3 (2.38)	2.6 (3.06)	2.5 (2.82)
Median	1.0	1.0	1.0
Min, Max	1, 15	1, 21	1, 21
Fatigue			
n	72	138	210
Mean (SD)	3.4 (3.46)	2.6 (3.66)	2.9 (3.60)
Median	2.0	2.0	2.0
Min, Max	1, 15	1, 30	1, 30
Myalgia			
n	47	128	175
Mean (SD)	3.6 (4.07)	2.2 (3.19)	2.6 (3.49)
Median	2.0	1.0	2.0
Min, Max	1, 18	1, 33	1, 33
Arthralgia			
n	40	88	128
Mean (SD)	4.1 (6.19)	1.9 (1.63)	2.5 (3.82)
Median	2.0	1.0	1.0
Min, Max	1, 32	1, 11	1, 32

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=337)	mRNA-1273 (N=346)	Total (N=683)
Nausea/Vomiting			
n	25	43	68
Mean (SD)	1.7 (1.38)	1.8 (1.91)	1.7 (1.72)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 13	1, 13
Chills			
n	27	81	108
Mean (SD)	2.0 (1.34)	1.6 (1.39)	1.7 (1.38)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 10	1, 10

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Solicited Adverse Reactions			
n	42	76	118
Mean (SD)	4.4 (8.33)	3.3 (1.78)	3.6 (5.16)
Median	2.0	3.0	2.0
Min, Max	1, 41	1, 8	1, 41
Solicited Local Adverse Reactions			
n	15	73	88
Mean (SD)	1.3 (0.72)	2.5 (1.11)	2.3 (1.14)
Median	1.0	2.0	2.0
Min, Max	1, 3	1, 5	1, 5
Pain			
n	13	72	85
Mean (SD)	1.2 (0.60)	2.4 (1.04)	2.2 (1.07)
Median	1.0	2.0	2.0
Min, Max	1, 3	1, 5	1, 5
Erythema (Redness)			
n	0	6	6
Mean (SD)		2.5 (1.05)	2.5 (1.05)
Median		2.5	2.5
Min, Max		1, 4	1, 4

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Swelling (Hardness)			
n	0	6	6
Mean (SD)		1.7 (1.03)	1.7 (1.03)
Median		1.0	1.0
Min, Max		1, 3	1, 3
Axillary Swelling or Tenderness			
n	3	10	13
Mean (SD)	1.7 (1.15)	1.7 (0.82)	1.7 (0.85)
Median	1.0	1.5	1.0
Min, Max	1, 3	1, 3	1, 3
Solicited Systemic Adverse Reactions			
n	36	49	85
Mean (SD)	4.7 (8.87)	2.7 (2.04)	3.5 (6.01)
Median	2.0	2.0	2.0
Min, Max	1, 41	1, 8	1, 41
Fever			
n	0	1	1
Mean (SD)		1.0 (NA)	1.0 (NA)
Median		1.0	1.0
Min, Max		1, 1	1, 1

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Headache			
n	26	29	55
Mean (SD)	2.3 (2.09)	1.6 (0.78)	1.9 (1.57)
Median	1.5	1.0	1.0
Min, Max	1, 9	1, 4	1, 9
Fatigue			
n	23	32	55
Mean (SD)	4.3 (9.22)	2.6 (2.15)	3.3 (6.16)
Median	1.0	2.0	2.0
Min, Max	1, 41	1, 8	1, 41
Myalgia			
n	11	19	30
Mean (SD)	6.0 (10.27)	2.2 (1.61)	3.6 (6.44)
Median	2.0	2.0	2.0
Min, Max	1, 30	1, 7	1, 30
Arthralgia			
n	9	16	25
Mean (SD)	7.0 (11.84)	2.0 (1.26)	3.8 (7.33)
Median	1.0	1.5	1.0
Min, Max	1, 32	1, 5	1, 32

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection by Baseline SARS-CoV-2 Status
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Nausea/Vomiting			
n	6	9	15
Mean (SD)	1.2 (0.41)	1.6 (0.88)	1.4 (0.74)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 3
Chills			
n	5	8	13
Mean (SD)	1.4 (0.55)	1.1 (0.35)	1.2 (0.44)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 2	1, 2

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Statistic	Placebo (N=14267)	mRNA-1273 (N=14378)	Total (N=28645)
Solicited Adverse Reactions			
n	6141	13294	19435
Mean (SD)	3.6 (8.55)	4.2 (7.70)	4.0 (7.98)
Median	2.0	3.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited Local Adverse Reactions			
n	2699	12783	15482
Mean (SD)	2.2 (6.46)	3.2 (3.02)	3.0 (3.87)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 151	1, 212
Pain			
n	2435	12722	15157
Mean (SD)	1.9 (4.93)	3.0 (2.08)	2.8 (2.77)
Median	1.0	3.0	3.0
Min, Max	1, 159	1, 147	1, 159
Erythema (Redness)			
n	66	1259	1325
Mean (SD)	3.9 (5.34)	2.7 (2.67)	2.7 (2.87)
Median	1.0	2.0	2.0
Min, Max	1, 29	1, 39	1, 39

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14267)	mRNA-1273 (N=14378)	Total (N=28645)
Swelling (Hardness)			
n	59	1783	1842
Mean (SD)	4.3 (5.33)	2.5 (2.04)	2.5 (2.24)
Median	1.0	2.0	2.0
Min, Max	1, 31	1, 31	1, 31
Axillary Swelling or Tenderness			
n	557	2047	2604
Mean (SD)	3.0 (11.64)	2.5 (5.24)	2.6 (7.11)
Median	1.0	2.0	2.0
Min, Max	1, 212	1, 151	1, 212
Solicited Systemic Adverse Reactions			
n	5241	11459	16700
Mean (SD)	3.7 (8.55)	3.4 (7.95)	3.5 (8.15)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	42	2235	2277
Mean (SD)	1.4 (1.58)	1.1 (0.41)	1.1 (0.46)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 9	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14267)	mRNA-1273 (N=14378)	Total (N=28645)
Headache			
n	3363	8488	11851
Mean (SD)	2.4 (5.03)	2.4 (4.82)	2.4 (4.88)
Median	1.0	2.0	2.0
Min, Max	1, 169	1, 196	1, 196
Fatigue			
n	3344	9446	12790
Mean (SD)	3.3 (8.34)	2.8 (6.54)	2.9 (7.06)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	1775	8357	10132
Mean (SD)	3.6 (9.26)	2.2 (4.20)	2.4 (5.47)
Median	2.0	1.0	2.0
Min, Max	1, 169	1, 170	1, 170
Arthralgia			
n	1543	6181	7724
Mean (SD)	4.1 (10.09)	2.3 (4.72)	2.7 (6.22)
Median	2.0	1.0	1.0
Min, Max	1, 169	1, 185	1, 185

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14267)	mRNA-1273 (N=14378)	Total (N=28645)
Nausea/Vomiting			
n	922	2741	3663
Mean (SD)	2.0 (5.85)	1.7 (3.72)	1.8 (4.35)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 176	1, 176
Chills			
n	790	6384	7174
Mean (SD)	2.2 (7.52)	1.5 (2.29)	1.6 (3.31)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 158	1, 169

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Statistic	Placebo (N=233)	mRNA-1273 (N=232)	Total (N=465)
Solicited Adverse Reactions			
n	82	187	269
Mean (SD)	5.7 (17.02)	4.2 (12.17)	4.7 (13.82)
Median	2.0	3.0	3.0
Min, Max	1, 153	1, 154	1, 154
Solicited Local Adverse Reactions			
n	42	172	214
Mean (SD)	2.5 (2.96)	3.5 (11.75)	3.3 (10.61)
Median	1.0	2.0	2.0
Min, Max	1, 18	1, 154	1, 154
Pain			
n	36	169	205
Mean (SD)	1.6 (0.99)	3.5 (11.85)	3.2 (10.78)
Median	1.0	2.0	2.0
Min, Max	1, 5	1, 154	1, 154
Erythema (Redness)			
n	1	9	10
Mean (SD)	2.0 (NA)	4.6 (5.22)	4.3 (4.99)
Median	2.0	3.0	3.0
Min, Max	2, 2	1, 18	1, 18

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Statistic	Placebo (N=233)	mRNA-1273 (N=232)	Total (N=465)
Swelling (Hardness)			
n	1	11	12
Mean (SD)	1.0 (NA)	3.7 (4.84)	3.5 (4.68)
Median	1.0	3.0	2.5
Min, Max	1, 1	1, 18	1, 18
Axillary Swelling or Tenderness			
n	11	32	43
Mean (SD)	4.6 (4.54)	2.3 (1.70)	2.9 (2.86)
Median	4.0	1.5	2.0
Min, Max	1, 17	1, 7	1, 17
Solicited Systemic Adverse Reactions			
n	73	152	225
Mean (SD)	6.0 (18.01)	3.1 (5.73)	4.0 (11.33)
Median	2.0	2.0	2.0
Min, Max	1, 153	1, 63	1, 153
Fever			
n	1	31	32
Mean (SD)	1.0 (NA)	1.0 (0.18)	1.0 (0.18)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 2

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=233)	mRNA-1273 (N=232)	Total (N=465)
Headache			
n	43	98	141
Mean (SD)	2.9 (3.05)	2.8 (4.57)	2.8 (4.16)
Median	2.0	1.5	2.0
Min, Max	1, 15	1, 33	1, 33
Fatigue			
n	54	106	160
Mean (SD)	3.4 (4.36)	2.3 (1.98)	2.7 (3.03)
Median	2.0	2.0	2.0
Min, Max	1, 25	1, 13	1, 25
Myalgia			
n	34	117	151
Mean (SD)	8.0 (26.14)	2.4 (5.86)	3.7 (13.50)
Median	2.0	1.0	2.0
Min, Max	1, 153	1, 63	1, 153
Arthralgia			
n	26	77	103
Mean (SD)	4.8 (5.51)	2.7 (6.06)	3.2 (5.97)
Median	2.0	2.0	2.0
Min, Max	1, 24	1, 53	1, 53

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=233)	mRNA-1273 (N=232)	Total (N=465)
Nausea/Vomiting			
n	13	33	46
Mean (SD)	1.5 (0.78)	1.8 (1.20)	1.7 (1.10)
Median	1.0	1.0	1.0
Min, Max	1, 3	1, 6	1, 6
Chills			
n	19	80	99
Mean (SD)	2.6 (3.11)	1.6 (0.94)	1.8 (1.62)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 5	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Statistic	Placebo (N=78)	mRNA-1273 (N=81)	Total (N=159)
Solicited Adverse Reactions			
n	32	75	107
Mean (SD)	3.4 (4.56)	3.7 (2.52)	3.6 (3.24)
Median	2.0	3.0	3.0
Min, Max	1, 25	1, 17	1, 25
Solicited Local Adverse Reactions			
n	16	74	90
Mean (SD)	1.9 (1.54)	3.1 (1.75)	2.8 (1.77)
Median	1.0	3.0	2.0
Min, Max	1, 7	1, 11	1, 11
Pain			
n	15	73	88
Mean (SD)	1.9 (1.55)	3.0 (1.72)	2.8 (1.74)
Median	1.0	3.0	2.0
Min, Max	1, 7	1, 11	1, 11
Erythema (Redness)			
n	1	6	7
Mean (SD)	1.0 (NA)	2.5 (1.05)	2.3 (1.11)
Median	1.0	2.5	2.0
Min, Max	1, 1	1, 4	1, 4

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=78)	mRNA-1273 (N=81)	Total (N=159)
Swelling (Hardness)			
n	0	13	13
Mean (SD)		2.5 (1.61)	2.5 (1.61)
Median		2.0	2.0
Min, Max		1, 7	1, 7
Axillary Swelling or Tenderness			
n	3	13	16
Mean (SD)	1.3 (0.58)	2.8 (1.69)	2.5 (1.63)
Median	1.0	2.0	2.0
Min, Max	1, 2	1, 6	1, 6
Solicited Systemic Adverse Reactions			
n	29	67	96
Mean (SD)	3.6 (4.78)	2.9 (2.69)	3.1 (3.44)
Median	2.0	2.0	2.0
Min, Max	1, 25	1, 17	1, 25
Fever			
n	0	10	10
Mean (SD)		1.1 (0.32)	1.1 (0.32)
Median		1.0	1.0
Min, Max		1, 2	1, 2

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=78)	mRNA-1273 (N=81)	Total (N=159)
Headache			
n	21	51	72
Mean (SD)	2.4 (1.66)	2.1 (1.58)	2.2 (1.59)
Median	2.0	2.0	2.0
Min, Max	1, 6	1, 10	1, 10
Fatigue			
n	20	55	75
Mean (SD)	2.9 (2.66)	2.6 (2.41)	2.7 (2.46)
Median	1.5	2.0	2.0
Min, Max	1, 9	1, 17	1, 17
Myalgia			
n	15	55	70
Mean (SD)	3.2 (6.11)	2.0 (1.74)	2.3 (3.19)
Median	1.0	1.0	1.0
Min, Max	1, 25	1, 9	1, 25
Arthralgia			
n	10	45	55
Mean (SD)	4.0 (7.41)	2.1 (1.66)	2.4 (3.46)
Median	2.0	1.0	2.0
Min, Max	1, 25	1, 8	1, 25

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection by Baseline SARS-CoV-2 Status
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=78)	mRNA-1273 (N=81)	Total (N=159)
Nausea/Vomiting			
n	6	20	26
Mean (SD)	1.5 (0.55)	1.5 (0.61)	1.5 (0.58)
Median	1.5	1.0	1.0
Min, Max	1, 2	1, 3	1, 3
Chills			
n	4	36	40
Mean (SD)	1.0 (0.00)	1.3 (0.61)	1.3 (0.59)
Median	1.0	1.0	1.0
Min, Max	1, 1	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Statistic	Placebo (N=14738)	mRNA-1273 (N=14745)	Total (N=29483)
Solicited Adverse Reactions			
n	8907	14034	22941
Mean (SD)	3.9 (8.23)	4.8 (8.08)	4.5 (8.15)
Median	2.0	4.0	3.0
Min, Max	1, 212	1, 198	1, 212
Solicited Local Adverse Reactions			
n	4366	13676	18042
Mean (SD)	2.3 (5.50)	3.5 (3.31)	3.2 (3.98)
Median	1.0	3.0	3.0
Min, Max	1, 212	1, 151	1, 212
Pain			
n	3953	13618	17571
Mean (SD)	1.9 (4.19)	3.2 (2.28)	2.9 (2.87)
Median	1.0	3.0	3.0
Min, Max	1, 159	1, 147	1, 159
Erythema (Redness)			
n	132	1520	1652
Mean (SD)	4.1 (5.95)	2.8 (3.18)	2.9 (3.50)
Median	1.0	2.0	2.0
Min, Max	1, 29	1, 41	1, 41

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Statistic	Placebo (N=14738)	mRNA-1273 (N=14745)	Total (N=29483)
Swelling (Hardness)			
n	113	2207	2320
Mean (SD)	5.7 (7.61)	2.5 (2.36)	2.7 (2.93)
Median	2.0	2.0	2.0
Min, Max	1, 33	1, 36	1, 36
Axillary Swelling or Tenderness			
n	1074	2920	3994
Mean (SD)	2.5 (8.58)	2.5 (4.74)	2.5 (6.02)
Median	1.0	1.0	1.0
Min, Max	1, 212	1, 151	1, 212
Solicited Systemic Adverse Reactions			
n	7931	12465	20396
Mean (SD)	3.9 (8.16)	3.8 (8.22)	3.8 (8.20)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Fever			
n	79	2285	2364
Mean (SD)	1.4 (1.23)	1.1 (0.46)	1.1 (0.50)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 9	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14738)	mRNA-1273 (N=14745)	Total (N=29483)
Headache			
n	5480	9620	15100
Mean (SD)	2.5 (4.34)	2.5 (4.73)	2.5 (4.59)
Median	2.0	2.0	2.0
Min, Max	1, 169	1, 196	1, 196
Fatigue			
n	5421	10409	15830
Mean (SD)	3.4 (7.36)	3.1 (6.68)	3.2 (6.92)
Median	2.0	2.0	2.0
Min, Max	1, 204	1, 198	1, 204
Myalgia			
n	3032	9111	12143
Mean (SD)	3.3 (7.50)	2.3 (4.46)	2.6 (5.40)
Median	2.0	2.0	2.0
Min, Max	1, 169	1, 170	1, 170
Arthralgia			
n	2602	6879	9481
Mean (SD)	4.0 (9.66)	2.6 (5.57)	3.0 (6.96)
Median	2.0	1.0	2.0
Min, Max	1, 188	1, 193	1, 193

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Statistic	Placebo (N=14738)	mRNA-1273 (N=14745)	Total (N=29483)
Nausea/Vomiting			
n	1680	3402	5082
Mean (SD)	1.9 (4.54)	1.8 (3.45)	1.8 (3.84)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 176	1, 176
Chills			
n	1426	6744	8170
Mean (SD)	2.0 (5.70)	1.5 (2.29)	1.6 (3.17)
Median	1.0	1.0	1.0
Min, Max	1, 169	1, 158	1, 169

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Statistic	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)
Solicited Adverse Reactions			
n	156	285	441
Mean (SD)	5.1 (12.80)	4.6 (10.30)	4.8 (11.24)
Median	2.0	3.0	3.0
Min, Max	1, 153	1, 154	1, 154
Solicited Local Adverse Reactions			
n	77	274	351
Mean (SD)	2.3 (2.48)	3.4 (9.37)	3.2 (8.37)
Median	1.0	3.0	2.0
Min, Max	1, 18	1, 154	1, 154
Pain			
n	70	271	341
Mean (SD)	1.7 (1.30)	3.3 (9.38)	2.9 (8.40)
Median	1.0	3.0	2.0
Min, Max	1, 9	1, 154	1, 154
Erythema (Redness)			
n	4	18	22
Mean (SD)	1.3 (0.50)	3.6 (4.02)	3.1 (3.73)
Median	1.0	3.0	2.0
Min, Max	1, 2	1, 18	1, 18

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Statistic	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)
Swelling (Hardness)			
n	3	26	29
Mean (SD)	1.3 (0.58)	3.0 (4.14)	2.9 (3.95)
Median	1.0	1.5	1.0
Min, Max	1, 2	1, 18	1, 18
Axillary Swelling or Tenderness			
n	22	74	96
Mean (SD)	3.5 (3.83)	2.0 (1.49)	2.4 (2.30)
Median	2.0	1.0	1.0
Min, Max	1, 17	1, 7	1, 17
Solicited Systemic Adverse Reactions			
n	141	244	385
Mean (SD)	5.2 (13.44)	3.6 (5.63)	4.2 (9.31)
Median	2.0	2.0	2.0
Min, Max	1, 153	1, 63	1, 153
Fever			
n	7	55	62
Mean (SD)	1.3 (0.49)	1.1 (0.31)	1.1 (0.34)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 2	1, 2

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Statistic	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)
Headache			
n	98	168	266
Mean (SD)	2.7 (2.88)	2.9 (4.00)	2.8 (3.63)
Median	2.0	2.0	2.0
Min, Max	1, 15	1, 33	1, 33
Fatigue			
n	96	172	268
Mean (SD)	3.8 (4.23)	2.8 (3.43)	3.2 (3.76)
Median	2.0	2.0	2.0
Min, Max	1, 25	1, 30	1, 30
Myalgia			
n	66	180	246
Mean (SD)	6.0 (18.94)	2.6 (5.38)	3.5 (10.89)
Median	2.0	2.0	2.0
Min, Max	1, 153	1, 63	1, 153
Arthralgia			
n	55	128	183
Mean (SD)	4.5 (6.17)	2.5 (4.85)	3.1 (5.34)
Median	2.0	2.0	2.0
Min, Max	1, 32	1, 53	1, 53

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Statistic	Placebo (N=337)	mRNA-1273 (N=347)	Total (N=684)
Nausea/Vomiting			
n	35	65	100
Mean (SD)	1.7 (1.24)	1.7 (1.64)	1.7 (1.51)
Median	1.0	1.0	1.0
Min, Max	1, 6	1, 13	1, 13
Chills			
n	40	126	166
Mean (SD)	2.4 (2.35)	1.7 (1.29)	1.9 (1.63)
Median	1.0	1.0	1.0
Min, Max	1, 11	1, 10	1, 11

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
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Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Solicited Adverse Reactions			
n	50	83	133
Mean (SD)	4.3 (7.73)	4.0 (2.47)	4.1 (5.10)
Median	2.0	4.0	3.0
Min, Max	1, 41	1, 17	1, 41
Solicited Local Adverse Reactions			
n	25	82	107
Mean (SD)	1.7 (1.34)	3.2 (1.64)	2.9 (1.69)
Median	1.0	3.0	2.0
Min, Max	1, 7	1, 11	1, 11
Pain			
n	23	80	103
Mean (SD)	1.7 (1.34)	3.1 (1.60)	2.8 (1.66)
Median	1.0	3.0	2.0
Min, Max	1, 7	1, 11	1, 11
Erythema (Redness)			
n	1	11	12
Mean (SD)	1.0 (NA)	2.5 (1.04)	2.4 (1.08)
Median	1.0	3.0	2.5
Min, Max	1, 1	1, 4	1, 4

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040303.sas 21JUN2021 17:07

Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Swelling (Hardness)			
n	0	16	16
Mean (SD)		2.3 (1.57)	2.3 (1.57)
Median		2.0	2.0
Min, Max		1, 7	1, 7
Axillary Swelling or Tenderness			
n	5	19	24
Mean (SD)	1.6 (0.89)	2.5 (1.54)	2.3 (1.46)
Median	1.0	2.0	2.0
Min, Max	1, 3	1, 6	1, 6
Solicited Systemic Adverse Reactions			
n	45	70	115
Mean (SD)	4.5 (8.04)	3.3 (2.69)	3.8 (5.45)
Median	2.0	3.0	2.0
Min, Max	1, 41	1, 17	1, 41
Fever			
n	0	10	10
Mean (SD)		1.1 (0.32)	1.1 (0.32)
Median		1.0	1.0
Min, Max		1, 2	1, 2

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040303.sas 21JUN2021 17:07

Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Headache			
n	35	56	91
Mean (SD)	2.4 (2.02)	2.2 (1.51)	2.3 (1.72)
Median	2.0	2.0	2.0
Min, Max	1, 9	1, 10	1, 10
Fatigue			
n	32	59	91
Mean (SD)	4.0 (7.95)	2.9 (2.51)	3.3 (5.11)
Median	1.0	2.0	2.0
Min, Max	1, 41	1, 17	1, 41
Myalgia			
n	20	57	77
Mean (SD)	4.1 (7.81)	2.1 (1.76)	2.6 (4.27)
Median	1.0	1.0	1.0
Min, Max	1, 30	1, 9	1, 30
Arthralgia			
n	15	48	63
Mean (SD)	4.9 (9.34)	2.2 (1.67)	2.8 (4.82)
Median	1.0	2.0	2.0
Min, Max	1, 32	1, 8	1, 32

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040303.sas 21JUN2021 17:07

Table 14.3.1.4.3.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection by Baseline SARS-CoV-2 Status
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Statistic	Placebo (N=84)	mRNA-1273 (N=87)	Total (N=171)
Nausea/Vomiting			
n	8	26	34
Mean (SD)	1.5 (0.53)	1.5 (0.65)	1.5 (0.62)
Median	1.5	1.0	1.0
Min, Max	1, 2	1, 3	1, 3
Chills			
n	7	37	44
Mean (SD)	1.3 (0.49)	1.3 (0.62)	1.3 (0.59)
Median	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days higher with solicited events after either the first or the second injection is summarized.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301040303.sas 21JUN2021 17:07

Table 14.3.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Adverse Reactions - N1	15151	15166	30317
Any Solicited Adverse Reactions	927 (6.1)	1122 (7.4)	2049 (6.8)
95% CI	5.7, 6.5	7.0, 7.8	6.5, 7.0
Grade 1	406 (2.7)	507 (3.3)	913 (3.0)
Grade 2	427 (2.8)	503 (3.3)	930 (3.1)
Grade 3	94 (0.6)	112 (0.7)	206 (0.7)
Grade 4	0	0	0
Grade 3 or Above	94 (0.6)	112 (0.7)	206 (0.7)
Solicited Local Adverse Reactions - N1	15147	15162	30309
Any Solicited Local Adverse Reactions	133 (0.9)	361 (2.4)	494 (1.6)
95% CI	0.7, 1.0	2.1, 2.6	1.5, 1.8
Grade 1	100 (0.7)	251 (1.7)	351 (1.2)
Grade 2	29 (0.2)	88 (0.6)	117 (0.4)
Grade 3	4 (<0.1)	22 (0.1)	26 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	4 (<0.1)	22 (0.1)	26 (<0.1)
Pain - N1	15147	15162	30309
Any	57 (0.4)	101 (0.7)	158 (0.5)
Grade 1	42 (0.3)	50 (0.3)	92 (0.3)
Grade 2	13 (<0.1)	41 (0.3)	54 (0.2)
Grade 3	2 (<0.1)	10 (<0.1)	12 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	10 (<0.1)	12 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Erythema (Redness) - N1	15147	15162	30309
Any	20 (0.1)	35 (0.2)	55 (0.2)
Grade 1	19 (0.1)	22 (0.1)	41 (0.1)
Grade 2	0	10 (<0.1)	10 (<0.1)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	4 (<0.1)
Swelling (Hardness) - N1	15147	15162	30309
Any	22 (0.1)	33 (0.2)	55 (0.2)
Grade 1	16 (0.1)	22 (0.1)	38 (0.1)
Grade 2	4 (<0.1)	9 (<0.1)	13 (<0.1)
Grade 3	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	2 (<0.1)	4 (<0.1)
Axillary Swelling or Tenderness - N1	15147	15162	30309
Any	57 (0.4)	234 (1.5)	291 (1.0)
Grade 1	43 (0.3)	181 (1.2)	224 (0.7)
Grade 2	14 (<0.1)	43 (0.3)	57 (0.2)
Grade 3	0	10 (<0.1)	10 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	10 (<0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Solicited Systemic Adverse Reactions - N1	15151	15166	30317
Any Solicited Systemic Adverse Reactions	841 (5.6)	861 (5.7)	1702 (5.6)
95% CI	5.2, 5.9	5.3, 6.1	5.4, 5.9
Grade 1	341 (2.3)	315 (2.1)	656 (2.2)
Grade 2	409 (2.7)	449 (3.0)	858 (2.8)
Grade 3	91 (0.6)	97 (0.6)	188 (0.6)
Grade 4	0	0	0
Grade 3 or Above	91 (0.6)	97 (0.6)	188 (0.6)
Fever - N1	15149	15163	30312
Any	3 (<0.1)	4 (<0.1)	7 (<0.1)
Grade 1	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)
Headache - N1	15146	15162	30308
Any	303 (2.0)	336 (2.2)	639 (2.1)
Grade 1	148 (1.0)	174 (1.1)	322 (1.1)
Grade 2	113 (0.7)	125 (0.8)	238 (0.8)
Grade 3	42 (0.3)	37 (0.2)	79 (0.3)
Grade 4	0	0	0
Grade 3 or Above	42 (0.3)	37 (0.2)	79 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n	(%)	mRNA-1273 (N=15166) n	(%)	Total (N=30317) n	(%)
Fatigue - N1	15146		15162		30308	
Any	462	(3.1)	511	(3.4)	973	(3.2)
Grade 1	151	(1.0)	139	(0.9)	290	(1.0)
Grade 2	265	(1.7)	319	(2.1)	584	(1.9)
Grade 3	46	(0.3)	53	(0.3)	99	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	46	(0.3)	53	(0.3)	99	(0.3)
Myalgia - N1	15146		15162		30308	
Any	243	(1.6)	223	(1.5)	466	(1.5)
Grade 1	95	(0.6)	78	(0.5)	173	(0.6)
Grade 2	125	(0.8)	113	(0.7)	238	(0.8)
Grade 3	23	(0.2)	32	(0.2)	55	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	23	(0.2)	32	(0.2)	55	(0.2)
Arthralgia - N1	15146		15162		30308	
Any	278	(1.8)	244	(1.6)	522	(1.7)
Grade 1	128	(0.8)	99	(0.7)	227	(0.7)
Grade 2	131	(0.9)	120	(0.8)	251	(0.8)
Grade 3	19	(0.1)	25	(0.2)	44	(0.1)
Grade 4	0		0		0	
Grade 3 or Above	19	(0.1)	25	(0.2)	44	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Total (N=30317) n (%)
Nausea/Vomiting - N1	15146	15162	30308
Any	65 (0.4)	61 (0.4)	126 (0.4)
Grade 1	40 (0.3)	31 (0.2)	71 (0.2)
Grade 2	24 (0.2)	28 (0.2)	52 (0.2)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chills - N1	15146	15162	30308
Any	45 (0.3)	32 (0.2)	77 (0.3)
Grade 1	26 (0.2)	10 (<0.1)	36 (0.1)
Grade 2	18 (0.1)	17 (0.1)	35 (0.1)
Grade 3	1 (<0.1)	5 (<0.1)	6 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	5 (<0.1)	6 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Solicited Adverse Reactions - N1	14578	14691	29269
Any Solicited Adverse Reactions	790 (5.4)	1024 (7.0)	1814 (6.2)
95% CI	5.1, 5.8	6.6, 7.4	5.9, 6.5
Grade 1	323 (2.2)	221 (1.5)	544 (1.9)
Grade 2	368 (2.5)	518 (3.5)	886 (3.0)
Grade 3	99 (0.7)	285 (1.9)	384 (1.3)
Grade 4	0	0	0
Grade 3 or Above	99 (0.7)	285 (1.9)	384 (1.3)
Solicited Local Adverse Reactions - N1	14577	14688	29265
Any Solicited Local Adverse Reactions	124 (0.9)	315 (2.1)	439 (1.5)
95% CI	0.7, 1.0	1.9, 2.4	1.4, 1.6
Grade 1	97 (0.7)	117 (0.8)	214 (0.7)
Grade 2	17 (0.1)	131 (0.9)	148 (0.5)
Grade 3	10 (<0.1)	67 (0.5)	77 (0.3)
Grade 4	0	0	0
Grade 3 or Above	10 (<0.1)	67 (0.5)	77 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Pain - N1	14577	14688	29265
Any	58 (0.4)	158 (1.1)	216 (0.7)
Grade 1	40 (0.3)	50 (0.3)	90 (0.3)
Grade 2	12 (<0.1)	81 (0.6)	93 (0.3)
Grade 3	6 (<0.1)	27 (0.2)	33 (0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	27 (0.2)	33 (0.1)
Erythema (Redness) - N1	14577	14687	29264
Any	13 (<0.1)	71 (0.5)	84 (0.3)
Grade 1	11 (<0.1)	20 (0.1)	31 (0.1)
Grade 2	2 (<0.1)	25 (0.2)	27 (<0.1)
Grade 3	0	26 (0.2)	26 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	26 (0.2)	26 (<0.1)
Swelling (Hardness) - N1	14577	14687	29264
Any	16 (0.1)	70 (0.5)	86 (0.3)
Grade 1	14 (<0.1)	27 (0.2)	41 (0.1)
Grade 2	1 (<0.1)	28 (0.2)	29 (<0.1)
Grade 3	1 (<0.1)	15 (0.1)	16 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	15 (0.1)	16 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Axillary Swelling or Tenderness - N1	14577	14687	29264
Any	51 (0.3)	96 (0.7)	147 (0.5)
Grade 1	44 (0.3)	61 (0.4)	105 (0.4)
Grade 2	4 (<0.1)	27 (0.2)	31 (0.1)
Grade 3	3 (<0.1)	8 (<0.1)	11 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	8 (<0.1)	11 (<0.1)
Solicited Systemic Adverse Reactions - N1	14577	14690	29267
Any Solicited Systemic Adverse Reactions	717 (4.9)	838 (5.7)	1555 (5.3)
95% CI	4.6, 5.3	5.3, 6.1	5.1, 5.6
Grade 1	264 (1.8)	148 (1.0)	412 (1.4)
Grade 2	363 (2.5)	459 (3.1)	822 (2.8)
Grade 3	90 (0.6)	231 (1.6)	321 (1.1)
Grade 4	0	0	0
Grade 3 or Above	90 (0.6)	231 (1.6)	321 (1.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Fever - N1	14573	14682	29255
Any	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 1	0	1 (<0.1)	1 (<0.1)
Grade 2	0	0	0
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	1 (<0.1)	2 (<0.1)
Headache - N1	14575	14687	29262
Any	304 (2.1)	388 (2.6)	692 (2.4)
Grade 1	145 (1.0)	98 (0.7)	243 (0.8)
Grade 2	125 (0.9)	232 (1.6)	357 (1.2)
Grade 3	34 (0.2)	58 (0.4)	92 (0.3)
Grade 4	0	0	0
Grade 3 or Above	34 (0.2)	58 (0.4)	92 (0.3)
Fatigue - N1	14575	14687	29262
Any	397 (2.7)	487 (3.3)	884 (3.0)
Grade 1	107 (0.7)	65 (0.4)	172 (0.6)
Grade 2	238 (1.6)	269 (1.8)	507 (1.7)
Grade 3	52 (0.4)	153 (1.0)	205 (0.7)
Grade 4	0	0	0
Grade 3 or Above	52 (0.4)	153 (1.0)	205 (0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Myalgia - N1	14575	14687	29262
Any	231 (1.6)	240 (1.6)	471 (1.6)
Grade 1	82 (0.6)	41 (0.3)	123 (0.4)
Grade 2	120 (0.8)	136 (0.9)	256 (0.9)
Grade 3	29 (0.2)	63 (0.4)	92 (0.3)
Grade 4	0	0	0
Grade 3 or Above	29 (0.2)	63 (0.4)	92 (0.3)
Arthralgia - N1	14575	14687	29262
Any	264 (1.8)	270 (1.8)	534 (1.8)
Grade 1	102 (0.7)	59 (0.4)	161 (0.6)
Grade 2	139 (1.0)	157 (1.1)	296 (1.0)
Grade 3	23 (0.2)	54 (0.4)	77 (0.3)
Grade 4	0	0	0
Grade 3 or Above	23 (0.2)	54 (0.4)	77 (0.3)
Nausea/Vomiting - N1	14575	14687	29262
Any	48 (0.3)	59 (0.4)	107 (0.4)
Grade 1	19 (0.1)	11 (<0.1)	30 (0.1)
Grade 2	28 (0.2)	43 (0.3)	71 (0.2)
Grade 3	1 (<0.1)	5 (<0.1)	6 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	5 (<0.1)	6 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category / Grade	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)	Total (N=29269) n (%)
Chills - N1	14575	14687	29262
Any	50 (0.3)	53 (0.4)	103 (0.4)
Grade 1	23 (0.2)	11 (<0.1)	34 (0.1)
Grade 2	21 (0.1)	34 (0.2)	55 (0.2)
Grade 3	6 (<0.1)	8 (<0.1)	14 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	8 (<0.1)	14 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Solicited Adverse Reactions - N1	15159	15179	30338
Any Solicited Adverse Reactions	1470 (9.7)	1859 (12.2)	3329 (11.0)
95% CI	9.2, 10.2	11.7, 12.8	10.6, 11.3
Grade 1	603 (4.0)	599 (3.9)	1202 (4.0)
Grade 2	684 (4.5)	881 (5.8)	1565 (5.2)
Grade 3	183 (1.2)	379 (2.5)	562 (1.9)
Grade 4	0	0	0
Grade 3 or Above	183 (1.2)	379 (2.5)	562 (1.9)
Solicited Local Adverse Reactions - N1	15158	15179	30337
Any Solicited Local Adverse Reactions	237 (1.6)	618 (4.1)	855 (2.8)
95% CI	1.4, 1.8	3.8, 4.4	2.6, 3.0
Grade 1	180 (1.2)	330 (2.2)	510 (1.7)
Grade 2	43 (0.3)	200 (1.3)	243 (0.8)
Grade 3	14 (<0.1)	88 (0.6)	102 (0.3)
Grade 4	0	0	0
Grade 3 or Above	14 (<0.1)	88 (0.6)	102 (0.3)
Pain - N1	15158	15179	30337
Any	108 (0.7)	239 (1.6)	347 (1.1)
Grade 1	77 (0.5)	89 (0.6)	166 (0.5)
Grade 2	23 (0.2)	114 (0.8)	137 (0.5)
Grade 3	8 (<0.1)	36 (0.2)	44 (0.1)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	36 (0.2)	44 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Erythema (Redness) - N1	15158	15178	30336
Any	32 (0.2)	101 (0.7)	133 (0.4)
Grade 1	29 (0.2)	41 (0.3)	70 (0.2)
Grade 2	2 (<0.1)	31 (0.2)	33 (0.1)
Grade 3	1 (<0.1)	29 (0.2)	30 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	29 (0.2)	30 (<0.1)
Swelling (Hardness) - N1	15158	15178	30336
Any	35 (0.2)	99 (0.7)	134 (0.4)
Grade 1	27 (0.2)	46 (0.3)	73 (0.2)
Grade 2	5 (<0.1)	36 (0.2)	41 (0.1)
Grade 3	3 (<0.1)	17 (0.1)	20 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	17 (0.1)	20 (<0.1)
Axillary Swelling or Tenderness - N1	15158	15178	30336
Any	97 (0.6)	303 (2.0)	400 (1.3)
Grade 1	77 (0.5)	222 (1.5)	299 (1.0)
Grade 2	17 (0.1)	63 (0.4)	80 (0.3)
Grade 3	3 (<0.1)	18 (0.1)	21 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	18 (0.1)	21 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Solicited Systemic Adverse Reactions - N1	15159	15178	30337
Any Solicited Systemic Adverse Reactions	1333 (8.8)	1483 (9.8)	2816 (9.3)
95% CI	8.3, 9.3	9.3, 10.3	9.0, 9.6
Grade 1	496 (3.3)	387 (2.5)	883 (2.9)
Grade 2	666 (4.4)	783 (5.2)	1449 (4.8)
Grade 3	171 (1.1)	313 (2.1)	484 (1.6)
Grade 4	0	0	0
Grade 3 or Above	171 (1.1)	313 (2.1)	484 (1.6)
Fever - N1	15158	15177	30335
Any	4 (<0.1)	6 (<0.1)	10 (<0.1)
Grade 1	3 (<0.1)	3 (<0.1)	6 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)
Headache - N1	15158	15178	30336
Any	559 (3.7)	663 (4.4)	1222 (4.0)
Grade 1	265 (1.7)	236 (1.6)	501 (1.7)
Grade 2	221 (1.5)	332 (2.2)	553 (1.8)
Grade 3	73 (0.5)	95 (0.6)	168 (0.6)
Grade 4	0	0	0
Grade 3 or Above	73 (0.5)	95 (0.6)	168 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n	(%)	mRNA-1273 (N=15179) n	(%)	Total (N=30338) n	(%)
Fatigue - N1	15158		15178		30336	
Any	750	(4.9)	883	(5.8)	1633	(5.4)
Grade 1	220	(1.5)	171	(1.1)	391	(1.3)
Grade 2	437	(2.9)	514	(3.4)	951	(3.1)
Grade 3	93	(0.6)	198	(1.3)	291	(1.0)
Grade 4	0		0		0	
Grade 3 or Above	93	(0.6)	198	(1.3)	291	(1.0)
Myalgia - N1	15158		15178		30336	
Any	422	(2.8)	419	(2.8)	841	(2.8)
Grade 1	148	(1.0)	99	(0.7)	247	(0.8)
Grade 2	223	(1.5)	230	(1.5)	453	(1.5)
Grade 3	51	(0.3)	90	(0.6)	141	(0.5)
Grade 4	0		0		0	
Grade 3 or Above	51	(0.3)	90	(0.6)	141	(0.5)
Arthralgia - N1	15158		15178		30336	
Any	475	(3.1)	448	(3.0)	923	(3.0)
Grade 1	189	(1.2)	123	(0.8)	312	(1.0)
Grade 2	245	(1.6)	254	(1.7)	499	(1.6)
Grade 3	41	(0.3)	71	(0.5)	112	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	41	(0.3)	71	(0.5)	112	(0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.1.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Placebo (N=15159) n (%)	mRNA-1273 (N=15179) n (%)	Total (N=30338) n (%)
Nausea/Vomiting - N1	15158	15178	30336
Any	104 (0.7)	113 (0.7)	217 (0.7)
Grade 1	54 (0.4)	38 (0.3)	92 (0.3)
Grade 2	48 (0.3)	68 (0.4)	116 (0.4)
Grade 3	2 (<0.1)	7 (<0.1)	9 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	7 (<0.1)	9 (<0.1)
Chills - N1	15158	15178	30336
Any	89 (0.6)	81 (0.5)	170 (0.6)
Grade 1	46 (0.3)	20 (0.1)	66 (0.2)
Grade 2	36 (0.2)	50 (0.3)	86 (0.3)
Grade 3	7 (<0.1)	11 (<0.1)	18 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	7 (<0.1)	11 (<0.1)	18 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Solicited Adverse Reactions - N1	11402	11406	22808
Any Solicited Adverse Reactions	707 (6.2)	892 (7.8)	1599 (7.0)
95% CI	5.8, 6.7	7.3, 8.3	6.7, 7.3
Grade 1	294 (2.6)	403 (3.5)	697 (3.1)
Grade 2	335 (2.9)	399 (3.5)	734 (3.2)
Grade 3	78 (0.7)	90 (0.8)	168 (0.7)
Grade 4	0	0	0
Grade 3 or Above	78 (0.7)	90 (0.8)	168 (0.7)
Solicited Local Adverse Reactions - N1	11400	11402	22802
Any Solicited Local Adverse Reactions	98 (0.9)	325 (2.9)	423 (1.9)
95% CI	0.7, 1.0	2.6, 3.2	1.7, 2.0
Grade 1	76 (0.7)	228 (2.0)	304 (1.3)
Grade 2	19 (0.2)	78 (0.7)	97 (0.4)
Grade 3	3 (<0.1)	19 (0.2)	22 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	19 (0.2)	22 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Pain - N1	11400	11402	22802
Any	45 (0.4)	89 (0.8)	134 (0.6)
Grade 1	34 (0.3)	45 (0.4)	79 (0.3)
Grade 2	9 (<0.1)	35 (0.3)	44 (0.2)
Grade 3	2 (<0.1)	9 (<0.1)	11 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	9 (<0.1)	11 (<0.1)
Erythema (Redness) - N1	11400	11402	22802
Any	11 (<0.1)	25 (0.2)	36 (0.2)
Grade 1	10 (<0.1)	16 (0.1)	26 (0.1)
Grade 2	0	7 (<0.1)	7 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Swelling (Hardness) - N1	11400	11402	22802
Any	11 (<0.1)	28 (0.2)	39 (0.2)
Grade 1	8 (<0.1)	18 (0.2)	26 (0.1)
Grade 2	2 (<0.1)	8 (<0.1)	10 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)
Axillary Swelling or Tenderness - N1	11400	11402	22802
Any	49 (0.4)	223 (2.0)	272 (1.2)
Grade 1	39 (0.3)	172 (1.5)	211 (0.9)
Grade 2	10 (<0.1)	42 (0.4)	52 (0.2)
Grade 3	0	9 (<0.1)	9 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	9 (<0.1)	9 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Solicited Systemic Adverse Reactions - N1	11402	11406	22808
Any Solicited Systemic Adverse Reactions	650 (5.7)	657 (5.8)	1307 (5.7)
95% CI	5.3, 6.1	5.3, 6.2	5.4, 6.0
Grade 1	248 (2.2)	230 (2.0)	478 (2.1)
Grade 2	326 (2.9)	351 (3.1)	677 (3.0)
Grade 3	76 (0.7)	76 (0.7)	152 (0.7)
Grade 4	0	0	0
Grade 3 or Above	76 (0.7)	76 (0.7)	152 (0.7)
Fever - N1	11400	11404	22804
Any	3 (<0.1)	4 (<0.1)	7 (<0.1)
Grade 1	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11402) n	(%)	mRNA-1273 (N=11406) n	(%)	Total (N=22808) n	(%)
Headache - N1	11400		11402		22802	
Any	247	(2.2)	280	(2.5)	527	(2.3)
Grade 1	114	(1.0)	141	(1.2)	255	(1.1)
Grade 2	96	(0.8)	112	(1.0)	208	(0.9)
Grade 3	37	(0.3)	27	(0.2)	64	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	37	(0.3)	27	(0.2)	64	(0.3)
Fatigue - N1	11400		11402		22802	
Any	358	(3.1)	380	(3.3)	738	(3.2)
Grade 1	107	(0.9)	96	(0.8)	203	(0.9)
Grade 2	216	(1.9)	244	(2.1)	460	(2.0)
Grade 3	35	(0.3)	40	(0.4)	75	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	35	(0.3)	40	(0.4)	75	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n	(%)	mRNA-1273 (N=11406) n	(%)	Total (N=22808) n	(%)
Myalgia - N1	11400		11402		22802	
Any	172	(1.5)	161	(1.4)	333	(1.5)
Grade 1	61	(0.5)	50	(0.4)	111	(0.5)
Grade 2	91	(0.8)	85	(0.7)	176	(0.8)
Grade 3	20	(0.2)	26	(0.2)	46	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	20	(0.2)	26	(0.2)	46	(0.2)
Arthralgia - N1	11400		11402		22802	
Any	189	(1.7)	163	(1.4)	352	(1.5)
Grade 1	78	(0.7)	65	(0.6)	143	(0.6)
Grade 2	97	(0.9)	80	(0.7)	177	(0.8)
Grade 3	14	(0.1)	18	(0.2)	32	(0.1)
Grade 4	0		0		0	
Grade 3 or Above	14	(0.1)	18	(0.2)	32	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11402) n (%)	mRNA-1273 (N=11406) n (%)	Total (N=22808) n (%)
Nausea/Vomiting - N1	11400	11402	22802
Any	55 (0.5)	51 (0.4)	106 (0.5)
Grade 1	32 (0.3)	27 (0.2)	59 (0.3)
Grade 2	22 (0.2)	24 (0.2)	46 (0.2)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)
Chills - N1	11400	11402	22802
Any	38 (0.3)	27 (0.2)	65 (0.3)
Grade 1	21 (0.2)	7 (<0.1)	28 (0.1)
Grade 2	16 (0.1)	17 (0.1)	33 (0.1)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Solicited Adverse Reactions - N1	3749	3760	7509
Any Solicited Adverse Reactions	220 (5.9)	230 (6.1)	450 (6.0)
95% CI	5.1, 6.7	5.4, 6.9	5.5, 6.6
Grade 1	112 (3.0)	104 (2.8)	216 (2.9)
Grade 2	92 (2.5)	104 (2.8)	196 (2.6)
Grade 3	16 (0.4)	22 (0.6)	38 (0.5)
Grade 4	0	0	0
Grade 3 or Above	16 (0.4)	22 (0.6)	38 (0.5)
Solicited Local Adverse Reactions - N1	3747	3760	7507
Any Solicited Local Adverse Reactions	35 (0.9)	36 (1.0)	71 (0.9)
95% CI	0.7, 1.3	0.7, 1.3	0.7, 1.2
Grade 1	24 (0.6)	23 (0.6)	47 (0.6)
Grade 2	10 (0.3)	10 (0.3)	20 (0.3)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Pain - N1	3747	3760	7507
Any	12 (0.3)	12 (0.3)	24 (0.3)
Grade 1	8 (0.2)	5 (0.1)	13 (0.2)
Grade 2	4 (0.1)	6 (0.2)	10 (0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)
Erythema (Redness) - N1	3747	3760	7507
Any	9 (0.2)	10 (0.3)	19 (0.3)
Grade 1	9 (0.2)	6 (0.2)	15 (0.2)
Grade 2	0	3 (<0.1)	3 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Swelling (Hardness) - N1	3747	3760	7507
Any	11 (0.3)	5 (0.1)	16 (0.2)
Grade 1	8 (0.2)	4 (0.1)	12 (0.2)
Grade 2	2 (<0.1)	1 (<0.1)	3 (<0.1)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)
Axillary Swelling or Tenderness - N1	3747	3760	7507
Any	8 (0.2)	11 (0.3)	19 (0.3)
Grade 1	4 (0.1)	9 (0.2)	13 (0.2)
Grade 2	4 (0.1)	1 (<0.1)	5 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Solicited Systemic Adverse Reactions - N1	3749	3760	7509
Any Solicited Systemic Adverse Reactions	191 (5.1)	204 (5.4)	395 (5.3)
95% CI	4.4, 5.8	4.7, 6.2	4.8, 5.8
Grade 1	93 (2.5)	85 (2.3)	178 (2.4)
Grade 2	83 (2.2)	98 (2.6)	181 (2.4)
Grade 3	15 (0.4)	21 (0.6)	36 (0.5)
Grade 4	0	0	0
Grade 3 or Above	15 (0.4)	21 (0.6)	36 (0.5)
Fever - N1	3749	3759	7508
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Headache - N1	3746	3760	7506
Any	56 (1.5)	56 (1.5)	112 (1.5)
Grade 1	34 (0.9)	33 (0.9)	67 (0.9)
Grade 2	17 (0.5)	13 (0.3)	30 (0.4)
Grade 3	5 (0.1)	10 (0.3)	15 (0.2)
Grade 4	0	0	0
Grade 3 or Above	5 (0.1)	10 (0.3)	15 (0.2)
Fatigue - N1	3746	3760	7506
Any	104 (2.8)	131 (3.5)	235 (3.1)
Grade 1	44 (1.2)	43 (1.1)	87 (1.2)
Grade 2	49 (1.3)	75 (2.0)	124 (1.7)
Grade 3	11 (0.3)	13 (0.3)	24 (0.3)
Grade 4	0	0	0
Grade 3 or Above	11 (0.3)	13 (0.3)	24 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Myalgia - N1	3746	3760	7506
Any	71 (1.9)	62 (1.6)	133 (1.8)
Grade 1	34 (0.9)	28 (0.7)	62 (0.8)
Grade 2	34 (0.9)	28 (0.7)	62 (0.8)
Grade 3	3 (<0.1)	6 (0.2)	9 (0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	6 (0.2)	9 (0.1)
Arthralgia - N1	3746	3760	7506
Any	89 (2.4)	81 (2.2)	170 (2.3)
Grade 1	50 (1.3)	34 (0.9)	84 (1.1)
Grade 2	34 (0.9)	40 (1.1)	74 (1.0)
Grade 3	5 (0.1)	7 (0.2)	12 (0.2)
Grade 4	0	0	0
Grade 3 or Above	5 (0.1)	7 (0.2)	12 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Age Group and Grade
First Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3749) n (%)	mRNA-1273 (N=3760) n (%)	Total (N=7509) n (%)
Nausea/Vomiting - N1	3746	3760	7506
Any	10 (0.3)	10 (0.3)	20 (0.3)
Grade 1	8 (0.2)	4 (0.1)	12 (0.2)
Grade 2	2 (<0.1)	4 (0.1)	6 (<0.1)
Grade 3	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	2 (<0.1)	2 (<0.1)
Chills - N1	3746	3760	7506
Any	7 (0.2)	5 (0.1)	12 (0.2)
Grade 1	5 (0.1)	3 (<0.1)	8 (0.1)
Grade 2	2 (<0.1)	0	2 (<0.1)
Grade 3	0	2 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	2 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Solicited Adverse Reactions - N1	10929	11000	21929
Any Solicited Adverse Reactions	606 (5.5)	777 (7.1)	1383 (6.3)
95% CI	5.1, 6.0	6.6, 7.6	6.0, 6.6
Grade 1	238 (2.2)	157 (1.4)	395 (1.8)
Grade 2	286 (2.6)	396 (3.6)	682 (3.1)
Grade 3	82 (0.8)	224 (2.0)	306 (1.4)
Grade 4	0	0	0
Grade 3 or Above	82 (0.8)	224 (2.0)	306 (1.4)
Solicited Local Adverse Reactions - N1	10928	10999	21927
Any Solicited Local Adverse Reactions	102 (0.9)	234 (2.1)	336 (1.5)
95% CI	0.8, 1.1	1.9, 2.4	1.4, 1.7
Grade 1	79 (0.7)	86 (0.8)	165 (0.8)
Grade 2	14 (0.1)	96 (0.9)	110 (0.5)
Grade 3	9 (<0.1)	52 (0.5)	61 (0.3)
Grade 4	0	0	0
Grade 3 or Above	9 (<0.1)	52 (0.5)	61 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Pain - N1	10928	10999	21927
Any	46 (0.4)	115 (1.0)	161 (0.7)
Grade 1	32 (0.3)	33 (0.3)	65 (0.3)
Grade 2	8 (<0.1)	59 (0.5)	67 (0.3)
Grade 3	6 (<0.1)	23 (0.2)	29 (0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	23 (0.2)	29 (0.1)
Erythema (Redness) - N1	10928	10998	21926
Any	10 (<0.1)	40 (0.4)	50 (0.2)
Grade 1	8 (<0.1)	9 (<0.1)	17 (<0.1)
Grade 2	2 (<0.1)	13 (0.1)	15 (<0.1)
Grade 3	0	18 (0.2)	18 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	18 (0.2)	18 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Swelling (Hardness) - N1	10928	10998	21926
Any	13 (0.1)	48 (0.4)	61 (0.3)
Grade 1	11 (0.1)	18 (0.2)	29 (0.1)
Grade 2	1 (<0.1)	19 (0.2)	20 (<0.1)
Grade 3	1 (<0.1)	11 (0.1)	12 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	11 (0.1)	12 (<0.1)
Axillary Swelling or Tenderness - N1	10928	10998	21926
Any	46 (0.4)	89 (0.8)	135 (0.6)
Grade 1	40 (0.4)	56 (0.5)	96 (0.4)
Grade 2	4 (<0.1)	25 (0.2)	29 (0.1)
Grade 3	2 (<0.1)	8 (<0.1)	10 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	8 (<0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Solicited Systemic Adverse Reactions - N1	10928	10999	21927
Any Solicited Systemic Adverse Reactions	545 (5.0)	644 (5.9)	1189 (5.4)
95% CI	4.6, 5.4	5.4, 6.3	5.1, 5.7
Grade 1	189 (1.7)	105 (1.0)	294 (1.3)
Grade 2	282 (2.6)	356 (3.2)	638 (2.9)
Grade 3	74 (0.7)	183 (1.7)	257 (1.2)
Grade 4	0	0	0
Grade 3 or Above	74 (0.7)	183 (1.7)	257 (1.2)
Fever - N1	10925	10993	21918
Any	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 1	0	1 (<0.1)	1 (<0.1)
Grade 2	0	0	0
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	1 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=10929) n	(%)	mRNA-1273 (N=11000) n	(%)	Total (N=21929) n	(%)
Headache - N1	10926		10998		21924	
Any	248	(2.3)	331	(3.0)	579	(2.6)
Grade 1	113	(1.0)	76	(0.7)	189	(0.9)
Grade 2	103	(0.9)	201	(1.8)	304	(1.4)
Grade 3	32	(0.3)	54	(0.5)	86	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	32	(0.3)	54	(0.5)	86	(0.4)
Fatigue - N1	10926		10998		21924	
Any	304	(2.8)	375	(3.4)	679	(3.1)
Grade 1	78	(0.7)	46	(0.4)	124	(0.6)
Grade 2	184	(1.7)	212	(1.9)	396	(1.8)
Grade 3	42	(0.4)	117	(1.1)	159	(0.7)
Grade 4	0		0		0	
Grade 3 or Above	42	(0.4)	117	(1.1)	159	(0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=10929) n	(%)	mRNA-1273 (N=11000) n	(%)	Total (N=21929) n	(%)
Myalgia - N1	10926		10998		21924	
Any	178	(1.6)	179	(1.6)	357	(1.6)
Grade 1	57	(0.5)	27	(0.2)	84	(0.4)
Grade 2	96	(0.9)	103	(0.9)	199	(0.9)
Grade 3	25	(0.2)	49	(0.4)	74	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	25	(0.2)	49	(0.4)	74	(0.3)
Arthralgia - N1	10926		10998		21924	
Any	188	(1.7)	196	(1.8)	384	(1.8)
Grade 1	66	(0.6)	40	(0.4)	106	(0.5)
Grade 2	103	(0.9)	118	(1.1)	221	(1.0)
Grade 3	19	(0.2)	38	(0.3)	57	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	19	(0.2)	38	(0.3)	57	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=10929) n (%)	mRNA-1273 (N=11000) n (%)	Total (N=21929) n (%)
Nausea/Vomiting - N1	10926	10998	21924
Any	42 (0.4)	52 (0.5)	94 (0.4)
Grade 1	18 (0.2)	10 (<0.1)	28 (0.1)
Grade 2	23 (0.2)	40 (0.4)	63 (0.3)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chills - N1	10926	10998	21924
Any	38 (0.3)	43 (0.4)	81 (0.4)
Grade 1	16 (0.1)	10 (<0.1)	26 (0.1)
Grade 2	16 (0.1)	26 (0.2)	42 (0.2)
Grade 3	6 (<0.1)	7 (<0.1)	13 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	7 (<0.1)	13 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Solicited Adverse Reactions - N1	3649	3691	7340
Any Solicited Adverse Reactions	184 (5.0)	247 (6.7)	431 (5.9)
95% CI	4.4, 5.8	5.9, 7.5	5.3, 6.4
Grade 1	85 (2.3)	64 (1.7)	149 (2.0)
Grade 2	82 (2.2)	122 (3.3)	204 (2.8)
Grade 3	17 (0.5)	61 (1.7)	78 (1.1)
Grade 4	0	0	0
Grade 3 or Above	17 (0.5)	61 (1.7)	78 (1.1)
Solicited Local Adverse Reactions - N1	3649	3689	7338
Any Solicited Local Adverse Reactions	22 (0.6)	81 (2.2)	103 (1.4)
95% CI	0.4, 0.9	1.7, 2.7	1.1, 1.7
Grade 1	18 (0.5)	31 (0.8)	49 (0.7)
Grade 2	3 (<0.1)	35 (0.9)	38 (0.5)
Grade 3	1 (<0.1)	15 (0.4)	16 (0.2)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	15 (0.4)	16 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Pain - N1	3649	3689	7338
Any	12 (0.3)	43 (1.2)	55 (0.7)
Grade 1	8 (0.2)	17 (0.5)	25 (0.3)
Grade 2	4 (0.1)	22 (0.6)	26 (0.4)
Grade 3	0	4 (0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	4 (0.1)	4 (<0.1)
Erythema (Redness) - N1	3649	3689	7338
Any	3 (<0.1)	31 (0.8)	34 (0.5)
Grade 1	3 (<0.1)	11 (0.3)	14 (0.2)
Grade 2	0	12 (0.3)	12 (0.2)
Grade 3	0	8 (0.2)	8 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	8 (0.2)	8 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Swelling (Hardness) - N1	3649	3689	7338
Any	3 (<0.1)	22 (0.6)	25 (0.3)
Grade 1	3 (<0.1)	9 (0.2)	12 (0.2)
Grade 2	0	9 (0.2)	9 (0.1)
Grade 3	0	4 (0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	4 (0.1)	4 (<0.1)
Axillary Swelling or Tenderness - N1	3649	3689	7338
Any	5 (0.1)	7 (0.2)	12 (0.2)
Grade 1	4 (0.1)	5 (0.1)	9 (0.1)
Grade 2	0	2 (<0.1)	2 (<0.1)
Grade 3	1 (<0.1)	0	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	0	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Solicited Systemic Adverse Reactions - N1	3649	3691	7340
Any Solicited Systemic Adverse Reactions	172 (4.7)	194 (5.3)	366 (5.0)
95% CI	4.0, 5.5	4.6, 6.0	4.5, 5.5
Grade 1	75 (2.1)	43 (1.2)	118 (1.6)
Grade 2	81 (2.2)	103 (2.8)	184 (2.5)
Grade 3	16 (0.4)	48 (1.3)	64 (0.9)
Grade 4	0	0	0
Grade 3 or Above	16 (0.4)	48 (1.3)	64 (0.9)
Fever - N1	3648	3689	7337
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Headache - N1	3649	3689	7338
Any	56 (1.5)	57 (1.5)	113 (1.5)
Grade 1	32 (0.9)	22 (0.6)	54 (0.7)
Grade 2	22 (0.6)	31 (0.8)	53 (0.7)
Grade 3	2 (<0.1)	4 (0.1)	6 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	4 (0.1)	6 (<0.1)
Fatigue - N1	3649	3689	7338
Any	93 (2.5)	112 (3.0)	205 (2.8)
Grade 1	29 (0.8)	19 (0.5)	48 (0.7)
Grade 2	54 (1.5)	57 (1.5)	111 (1.5)
Grade 3	10 (0.3)	36 (1.0)	46 (0.6)
Grade 4	0	0	0
Grade 3 or Above	10 (0.3)	36 (1.0)	46 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n	(%)	mRNA-1273 (N=3691) n	(%)	Total (N=7340) n	(%)
Myalgia - N1	3649		3689		7338	
Any	53	(1.5)	61	(1.7)	114	(1.6)
Grade 1	25	(0.7)	14	(0.4)	39	(0.5)
Grade 2	24	(0.7)	33	(0.9)	57	(0.8)
Grade 3	4	(0.1)	14	(0.4)	18	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	4	(0.1)	14	(0.4)	18	(0.2)
Arthralgia - N1	3649		3689		7338	
Any	76	(2.1)	74	(2.0)	150	(2.0)
Grade 1	36	(1.0)	19	(0.5)	55	(0.7)
Grade 2	36	(1.0)	39	(1.1)	75	(1.0)
Grade 3	4	(0.1)	16	(0.4)	20	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	4	(0.1)	16	(0.4)	20	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Age Group and Grade
Second Injection Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3649) n (%)	mRNA-1273 (N=3691) n (%)	Total (N=7340) n (%)
Nausea/Vomiting - N1	3649	3689	7338
Any	6 (0.2)	7 (0.2)	13 (0.2)
Grade 1	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 2	5 (0.1)	3 (<0.1)	8 (0.1)
Grade 3	0	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	3 (<0.1)	3 (<0.1)
Chills - N1	3649	3689	7338
Any	12 (0.3)	10 (0.3)	22 (0.3)
Grade 1	7 (0.2)	1 (<0.1)	8 (0.1)
Grade 2	5 (0.1)	8 (0.2)	13 (0.2)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Adverse Reactions - N1	11408	11413	22821
Any Solicited Adverse Reactions	1133 (9.9)	1438 (12.6)	2571 (11.3)
95% CI	9.4, 10.5	12.0, 13.2	10.9, 11.7
Grade 1	440 (3.9)	455 (4.0)	895 (3.9)
Grade 2	542 (4.8)	685 (6.0)	1227 (5.4)
Grade 3	151 (1.3)	298 (2.6)	449 (2.0)
Grade 4	0	0	0
Grade 3 or Above	151 (1.3)	298 (2.6)	449 (2.0)
Solicited Local Adverse Reactions - N1	11407	11413	22820
Any Solicited Local Adverse Reactions	184 (1.6)	509 (4.5)	693 (3.0)
95% CI	1.4, 1.9	4.1, 4.9	2.8, 3.3
Grade 1	142 (1.2)	280 (2.5)	422 (1.8)
Grade 2	30 (0.3)	159 (1.4)	189 (0.8)
Grade 3	12 (0.1)	70 (0.6)	82 (0.4)
Grade 4	0	0	0
Grade 3 or Above	12 (0.1)	70 (0.6)	82 (0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Pain - N1	11407	11413	22820
Any	85 (0.7)	188 (1.6)	273 (1.2)
Grade 1	62 (0.5)	69 (0.6)	131 (0.6)
Grade 2	15 (0.1)	88 (0.8)	103 (0.5)
Grade 3	8 (<0.1)	31 (0.3)	39 (0.2)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	31 (0.3)	39 (0.2)
Erythema (Redness) - N1	11407	11412	22819
Any	20 (0.2)	62 (0.5)	82 (0.4)
Grade 1	17 (0.1)	24 (0.2)	41 (0.2)
Grade 2	2 (<0.1)	18 (0.2)	20 (<0.1)
Grade 3	1 (<0.1)	20 (0.2)	21 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	20 (0.2)	21 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Swelling (Hardness) - N1	11407	11412	22819
Any	22 (0.2)	74 (0.6)	96 (0.4)
Grade 1	17 (0.1)	34 (0.3)	51 (0.2)
Grade 2	3 (<0.1)	27 (0.2)	30 (0.1)
Grade 3	2 (<0.1)	13 (0.1)	15 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	13 (0.1)	15 (<0.1)
Axillary Swelling or Tenderness - N1	11407	11412	22819
Any	86 (0.8)	286 (2.5)	372 (1.6)
Grade 1	71 (0.6)	209 (1.8)	280 (1.2)
Grade 2	13 (0.1)	60 (0.5)	73 (0.3)
Grade 3	2 (<0.1)	17 (0.1)	19 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	17 (0.1)	19 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Solicited Systemic Adverse Reactions - N1	11408	11412	22820
Any Solicited Systemic Adverse Reactions	1033 (9.1)	1132 (9.9)	2165 (9.5)
95% CI	8.5, 9.6	9.4, 10.5	9.1, 9.9
Grade 1	358 (3.1)	277 (2.4)	635 (2.8)
Grade 2	534 (4.7)	609 (5.3)	1143 (5.0)
Grade 3	141 (1.2)	246 (2.2)	387 (1.7)
Grade 4	0	0	0
Grade 3 or Above	141 (1.2)	246 (2.2)	387 (1.7)
Fever - N1	11407	11411	22818
Any	4 (<0.1)	6 (<0.1)	10 (<0.1)
Grade 1	3 (<0.1)	3 (<0.1)	6 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n	(%)	mRNA-1273 (N=11413) n	(%)	Total (N=22821) n	(%)
Headache - N1	11407		11412		22819	
Any	457	(4.0)	557	(4.9)	1014	(4.4)
Grade 1	206	(1.8)	187	(1.6)	393	(1.7)
Grade 2	185	(1.6)	289	(2.5)	474	(2.1)
Grade 3	66	(0.6)	81	(0.7)	147	(0.6)
Grade 4	0		0		0	
Grade 3 or Above	66	(0.6)	81	(0.7)	147	(0.6)
Fatigue - N1	11407		11412		22819	
Any	585	(5.1)	665	(5.8)	1250	(5.5)
Grade 1	159	(1.4)	118	(1.0)	277	(1.2)
Grade 2	354	(3.1)	398	(3.5)	752	(3.3)
Grade 3	72	(0.6)	149	(1.3)	221	(1.0)
Grade 4	0		0		0	
Grade 3 or Above	72	(0.6)	149	(1.3)	221	(1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n	(%)	mRNA-1273 (N=11413) n	(%)	Total (N=22821) n	(%)
Myalgia - N1	11407		11412		22819	
Any	318	(2.8)	309	(2.7)	627	(2.7)
Grade 1	102	(0.9)	65	(0.6)	167	(0.7)
Grade 2	172	(1.5)	174	(1.5)	346	(1.5)
Grade 3	44	(0.4)	70	(0.6)	114	(0.5)
Grade 4	0		0		0	
Grade 3 or Above	44	(0.4)	70	(0.6)	114	(0.5)
Arthralgia - N1	11407		11412		22819	
Any	333	(2.9)	310	(2.7)	643	(2.8)
Grade 1	117	(1.0)	78	(0.7)	195	(0.9)
Grade 2	183	(1.6)	183	(1.6)	366	(1.6)
Grade 3	33	(0.3)	49	(0.4)	82	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	33	(0.3)	49	(0.4)	82	(0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=18 and <65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=11408) n (%)	mRNA-1273 (N=11413) n (%)	Total (N=22821) n (%)
Nausea/Vomiting - N1	11407	11412	22819
Any	89 (0.8)	96 (0.8)	185 (0.8)
Grade 1	46 (0.4)	33 (0.3)	79 (0.3)
Grade 2	41 (0.4)	61 (0.5)	102 (0.4)
Grade 3	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	2 (<0.1)	4 (<0.1)
Chills - N1	11407	11412	22819
Any	72 (0.6)	66 (0.6)	138 (0.6)
Grade 1	35 (0.3)	16 (0.1)	51 (0.2)
Grade 2	30 (0.3)	42 (0.4)	72 (0.3)
Grade 3	7 (<0.1)	8 (<0.1)	15 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	7 (<0.1)	8 (<0.1)	15 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Solicited Adverse Reactions - N1	3751	3766	7517
Any Solicited Adverse Reactions	337 (9.0)	421 (11.2)	758 (10.1)
95% CI	8.1, 9.9	10.2, 12.2	9.4, 10.8
Grade 1	163 (4.3)	144 (3.8)	307 (4.1)
Grade 2	142 (3.8)	196 (5.2)	338 (4.5)
Grade 3	32 (0.9)	81 (2.2)	113 (1.5)
Grade 4	0	0	0
Grade 3 or Above	32 (0.9)	81 (2.2)	113 (1.5)
Solicited Local Adverse Reactions - N1	3751	3766	7517
Any Solicited Local Adverse Reactions	53 (1.4)	109 (2.9)	162 (2.2)
95% CI	1.1, 1.8	2.4, 3.5	1.8, 2.5
Grade 1	38 (1.0)	50 (1.3)	88 (1.2)
Grade 2	13 (0.3)	41 (1.1)	54 (0.7)
Grade 3	2 (<0.1)	18 (0.5)	20 (0.3)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	18 (0.5)	20 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Pain - N1	3751	3766	7517
Any	23 (0.6)	51 (1.4)	74 (1.0)
Grade 1	15 (0.4)	20 (0.5)	35 (0.5)
Grade 2	8 (0.2)	26 (0.7)	34 (0.5)
Grade 3	0	5 (0.1)	5 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	5 (0.1)	5 (<0.1)
Erythema (Redness) - N1	3751	3766	7517
Any	12 (0.3)	39 (1.0)	51 (0.7)
Grade 1	12 (0.3)	17 (0.5)	29 (0.4)
Grade 2	0	13 (0.3)	13 (0.2)
Grade 3	0	9 (0.2)	9 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	9 (0.2)	9 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Swelling (Hardness) - N1	3751	3766	7517
Any	13 (0.3)	25 (0.7)	38 (0.5)
Grade 1	10 (0.3)	12 (0.3)	22 (0.3)
Grade 2	2 (<0.1)	9 (0.2)	11 (0.1)
Grade 3	1 (<0.1)	4 (0.1)	5 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	4 (0.1)	5 (<0.1)
Axillary Swelling or Tenderness - N1	3751	3766	7517
Any	11 (0.3)	17 (0.5)	28 (0.4)
Grade 1	6 (0.2)	13 (0.3)	19 (0.3)
Grade 2	4 (0.1)	3 (<0.1)	7 (<0.1)
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	1 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Solicited Systemic Adverse Reactions - N1	3751	3766	7517
Any Solicited Systemic Adverse Reactions	300 (8.0)	351 (9.3)	651 (8.7)
95% CI	7.1, 8.9	8.4, 10.3	8.0, 9.3
Grade 1	138 (3.7)	110 (2.9)	248 (3.3)
Grade 2	132 (3.5)	174 (4.6)	306 (4.1)
Grade 3	30 (0.8)	67 (1.8)	97 (1.3)
Grade 4	0	0	0
Grade 3 or Above	30 (0.8)	67 (1.8)	97 (1.3)
Fever - N1	3751	3766	7517
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3751) n	(%)	mRNA-1273 (N=3766) n	(%)	Total (N=7517) n	(%)
Headache - N1	3751		3766		7517	
Any	102	(2.7)	106	(2.8)	208	(2.8)
Grade 1	59	(1.6)	49	(1.3)	108	(1.4)
Grade 2	36	(1.0)	43	(1.1)	79	(1.1)
Grade 3	7	(0.2)	14	(0.4)	21	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	7	(0.2)	14	(0.4)	21	(0.3)
Fatigue - N1	3751		3766		7517	
Any	165	(4.4)	218	(5.8)	383	(5.1)
Grade 1	61	(1.6)	53	(1.4)	114	(1.5)
Grade 2	83	(2.2)	116	(3.1)	199	(2.6)
Grade 3	21	(0.6)	49	(1.3)	70	(0.9)
Grade 4	0		0		0	
Grade 3 or Above	21	(0.6)	49	(1.3)	70	(0.9)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3751) n	(%)	mRNA-1273 (N=3766) n	(%)	Total (N=7517) n	(%)
Myalgia - N1	3751		3766		7517	
Any	104	(2.8)	110	(2.9)	214	(2.8)
Grade 1	46	(1.2)	34	(0.9)	80	(1.1)
Grade 2	51	(1.4)	56	(1.5)	107	(1.4)
Grade 3	7	(0.2)	20	(0.5)	27	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	7	(0.2)	20	(0.5)	27	(0.4)
Arthralgia - N1	3751		3766		7517	
Any	142	(3.8)	138	(3.7)	280	(3.7)
Grade 1	72	(1.9)	45	(1.2)	117	(1.6)
Grade 2	62	(1.7)	71	(1.9)	133	(1.8)
Grade 3	8	(0.2)	22	(0.6)	30	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	8	(0.2)	22	(0.6)	30	(0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.2.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Age Group and Grade
Solicited Safety Set

Age Group: >=65 Years

Solicited Adverse Reaction Category / Grade	Placebo (N=3751) n (%)	mRNA-1273 (N=3766) n (%)	Total (N=7517) n (%)
Nausea/Vomiting - N1	3751	3766	7517
Any	15 (0.4)	17 (0.5)	32 (0.4)
Grade 1	8 (0.2)	5 (0.1)	13 (0.2)
Grade 2	7 (0.2)	7 (0.2)	14 (0.2)
Grade 3	0	5 (0.1)	5 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	5 (0.1)	5 (<0.1)
Chills - N1	3751	3766	7517
Any	17 (0.5)	15 (0.4)	32 (0.4)
Grade 1	11 (0.3)	4 (0.1)	15 (0.2)
Grade 2	6 (0.2)	8 (0.2)	14 (0.2)
Grade 3	0	3 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	3 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Solicited Adverse Reactions - N1	14730	14733	29463
Any Solicited Adverse Reactions	896 (6.1)	1094 (7.4)	1990 (6.8)
95% CI	5.7, 6.5	7.0, 7.9	6.5, 7.0
Grade 1	396 (2.7)	499 (3.4)	895 (3.0)
Grade 2	413 (2.8)	487 (3.3)	900 (3.1)
Grade 3	87 (0.6)	108 (0.7)	195 (0.7)
Grade 4	0	0	0
Grade 3 or Above	87 (0.6)	108 (0.7)	195 (0.7)
Solicited Local Adverse Reactions - N1	14726	14729	29455
Any Solicited Local Adverse Reactions	128 (0.9)	356 (2.4)	484 (1.6)
95% CI	0.7, 1.0	2.2, 2.7	1.5, 1.8
Grade 1	95 (0.6)	247 (1.7)	342 (1.2)
Grade 2	29 (0.2)	88 (0.6)	117 (0.4)
Grade 3	4 (<0.1)	21 (0.1)	25 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	4 (<0.1)	21 (0.1)	25 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Pain - N1	14726	14729	29455
Any	56 (0.4)	100 (0.7)	156 (0.5)
Grade 1	41 (0.3)	50 (0.3)	91 (0.3)
Grade 2	13 (<0.1)	41 (0.3)	54 (0.2)
Grade 3	2 (<0.1)	9 (<0.1)	11 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	9 (<0.1)	11 (<0.1)
Erythema (Redness) - N1	14726	14729	29455
Any	20 (0.1)	34 (0.2)	54 (0.2)
Grade 1	19 (0.1)	21 (0.1)	40 (0.1)
Grade 2	0	10 (<0.1)	10 (<0.1)
Grade 3	1 (<0.1)	3 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	3 (<0.1)	4 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Swelling (Hardness) - N1	14726	14729	29455
Any	22 (0.1)	32 (0.2)	54 (0.2)
Grade 1	16 (0.1)	21 (0.1)	37 (0.1)
Grade 2	4 (<0.1)	9 (<0.1)	13 (<0.1)
Grade 3	2 (<0.1)	2 (<0.1)	4 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	2 (<0.1)	4 (<0.1)
Axillary Swelling or Tenderness - N1	14726	14729	29455
Any	52 (0.4)	231 (1.6)	283 (1.0)
Grade 1	38 (0.3)	179 (1.2)	217 (0.7)
Grade 2	14 (<0.1)	42 (0.3)	56 (0.2)
Grade 3	0	10 (<0.1)	10 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	10 (<0.1)	10 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Solicited Systemic Adverse Reactions - N1	14730	14733	29463
Any Solicited Systemic Adverse Reactions	814 (5.5)	837 (5.7)	1651 (5.6)
95% CI	5.2, 5.9	5.3, 6.1	5.3, 5.9
Grade 1	335 (2.3)	311 (2.1)	646 (2.2)
Grade 2	395 (2.7)	433 (2.9)	828 (2.8)
Grade 3	84 (0.6)	93 (0.6)	177 (0.6)
Grade 4	0	0	0
Grade 3 or Above	84 (0.6)	93 (0.6)	177 (0.6)
Fever - N1	14729	14731	29460
Any	3 (<0.1)	3 (<0.1)	6 (<0.1)
Grade 1	3 (<0.1)	1 (<0.1)	4 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	0	1 (<0.1)	1 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (<0.1)	1 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301060301.sas 21JUN2021 17:12

Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n	(%)	mRNA-1273 (N=14733) n	(%)	Total (N=29463) n	(%)
Headache - N1	14725		14729		29454	
Any	290	(2.0)	324	(2.2)	614	(2.1)
Grade 1	145	(1.0)	171	(1.2)	316	(1.1)
Grade 2	107	(0.7)	119	(0.8)	226	(0.8)
Grade 3	38	(0.3)	34	(0.2)	72	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	38	(0.3)	34	(0.2)	72	(0.2)
Fatigue - N1	14725		14729		29454	
Any	444	(3.0)	496	(3.4)	940	(3.2)
Grade 1	145	(1.0)	136	(0.9)	281	(1.0)
Grade 2	256	(1.7)	308	(2.1)	564	(1.9)
Grade 3	43	(0.3)	52	(0.4)	95	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	43	(0.3)	52	(0.4)	95	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14730) n	(%)	mRNA-1273 (N=14733) n	(%)	Total (N=29463) n	(%)
Myalgia - N1	14725		14729		29454	
Any	230	(1.6)	216	(1.5)	446	(1.5)
Grade 1	93	(0.6)	76	(0.5)	169	(0.6)
Grade 2	116	(0.8)	108	(0.7)	224	(0.8)
Grade 3	21	(0.1)	32	(0.2)	53	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	21	(0.1)	32	(0.2)	53	(0.2)
Arthralgia - N1	14725		14729		29454	
Any	268	(1.8)	240	(1.6)	508	(1.7)
Grade 1	127	(0.9)	99	(0.7)	226	(0.8)
Grade 2	124	(0.8)	116	(0.8)	240	(0.8)
Grade 3	17	(0.1)	25	(0.2)	42	(0.1)
Grade 4	0		0		0	
Grade 3 or Above	17	(0.1)	25	(0.2)	42	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14730) n (%)	mRNA-1273 (N=14733) n (%)	Total (N=29463) n (%)
Nausea/Vomiting - N1	14725	14729	29454
Any	64 (0.4)	59 (0.4)	123 (0.4)
Grade 1	40 (0.3)	30 (0.2)	70 (0.2)
Grade 2	23 (0.2)	27 (0.2)	50 (0.2)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)
Chills - N1	14725	14729	29454
Any	42 (0.3)	31 (0.2)	73 (0.2)
Grade 1	24 (0.2)	10 (<0.1)	34 (0.1)
Grade 2	18 (0.1)	16 (0.1)	34 (0.1)
Grade 3	0	5 (<0.1)	5 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	5 (<0.1)	5 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Solicited Adverse Reactions - N1	337	346	683
Any Solicited Adverse Reactions	25 (7.4)	20 (5.8)	45 (6.6)
95% CI	4.9, 10.8	3.6, 8.8	4.8, 8.7
Grade 1	7 (2.1)	6 (1.7)	13 (1.9)
Grade 2	12 (3.6)	10 (2.9)	22 (3.2)
Grade 3	6 (1.8)	4 (1.2)	10 (1.5)
Grade 4	0	0	0
Grade 3 or Above	6 (1.8)	4 (1.2)	10 (1.5)
Solicited Local Adverse Reactions - N1	337	346	683
Any Solicited Local Adverse Reactions	4 (1.2)	4 (1.2)	8 (1.2)
95% CI	0.3, 3.0	0.3, 2.9	0.5, 2.3
Grade 1	4 (1.2)	3 (0.9)	7 (1.0)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Pain - N1	337	346	683
Any	1 (0.3)	1 (0.3)	2 (0.3)
Grade 1	1 (0.3)	0	1 (0.1)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.1)
Erythema (Redness) - N1	337	346	683
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Swelling (Hardness) - N1	337	346	683
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	337	346	683
Any	4 (1.2)	2 (0.6)	6 (0.9)
Grade 1	4 (1.2)	1 (0.3)	5 (0.7)
Grade 2	0	1 (0.3)	1 (0.1)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301060301.sas 21JUN2021 17:12

Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Solicited Systemic Adverse Reactions - N1	337	346	683
Any Solicited Systemic Adverse Reactions	22 (6.5)	17 (4.9)	39 (5.7)
95% CI	4.1, 9.7	2.9, 7.8	4.1, 7.7
Grade 1	4 (1.2)	3 (0.9)	7 (1.0)
Grade 2	12 (3.6)	10 (2.9)	22 (3.2)
Grade 3	6 (1.8)	4 (1.2)	10 (1.5)
Grade 4	0	0	0
Grade 3 or Above	6 (1.8)	4 (1.2)	10 (1.5)
Fever - N1	336	346	682
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301060301.sas 21JUN2021 17:12

Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n	(%)	mRNA-1273 (N=346) n	(%)	Total (N=683) n	(%)
Headache - N1	337		346		683	
Any	10	(3.0)	12	(3.5)	22	(3.2)
Grade 1	2	(0.6)	3	(0.9)	5	(0.7)
Grade 2	5	(1.5)	6	(1.7)	11	(1.6)
Grade 3	3	(0.9)	3	(0.9)	6	(0.9)
Grade 4	0		0		0	
Grade 3 or Above	3	(0.9)	3	(0.9)	6	(0.9)
Fatigue - N1	337		346		683	
Any	14	(4.2)	9	(2.6)	23	(3.4)
Grade 1	3	(0.9)	2	(0.6)	5	(0.7)
Grade 2	9	(2.7)	6	(1.7)	15	(2.2)
Grade 3	2	(0.6)	1	(0.3)	3	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	2	(0.6)	1	(0.3)	3	(0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Myalgia - N1	337	346	683
Any	11 (3.3)	6 (1.7)	17 (2.5)
Grade 1	2 (0.6)	2 (0.6)	4 (0.6)
Grade 2	8 (2.4)	4 (1.2)	12 (1.8)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	0	1 (0.1)
Arthralgia - N1	337	346	683
Any	8 (2.4)	3 (0.9)	11 (1.6)
Grade 1	1 (0.3)	0	1 (0.1)
Grade 2	6 (1.8)	3 (0.9)	9 (1.3)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	0	1 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=346) n (%)	Total (N=683) n (%)
Nausea/Vomiting - N1	337	346	683
Any	1 (0.3)	1 (0.3)	2 (0.3)
Grade 1	0	0	0
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	337	346	683
Any	3 (0.9)	1 (0.3)	4 (0.6)
Grade 1	2 (0.6)	0	2 (0.3)
Grade 2	0	1 (0.3)	1 (0.1)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	0	1 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Adverse Reactions - N1	84	87	171
Any Solicited Adverse Reactions	6 (7.1)	8 (9.2)	14 (8.2)
95% CI	2.7, 14.9	4.1, 17.3	4.5, 13.4
Grade 1	3 (3.6)	2 (2.3)	5 (2.9)
Grade 2	2 (2.4)	6 (6.9)	8 (4.7)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)
Solicited Local Adverse Reactions - N1	84	87	171
Any Solicited Local Adverse Reactions	1 (1.2)	1 (1.1)	2 (1.2)
95% CI	0.0, 6.5	0.0, 6.2	0.1, 4.2
Grade 1	1 (1.2)	1 (1.1)	2 (1.2)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Pain - N1	84	87	171
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Erythema (Redness) - N1	84	87	171
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Swelling (Hardness) - N1	84	87	171
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	84	87	171
Any	1 (1.2)	1 (1.1)	2 (1.2)
Grade 1	1 (1.2)	1 (1.1)	2 (1.2)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Systemic Adverse Reactions - N1	84	87	171
Any Solicited Systemic Adverse Reactions	5 (6.0)	7 (8.0)	12 (7.0)
95% CI	2.0, 13.3	3.3, 15.9	3.7, 11.9
Grade 1	2 (2.4)	1 (1.1)	3 (1.8)
Grade 2	2 (2.4)	6 (6.9)	8 (4.7)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)
Fever - N1	84	86	170
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Headache - N1	84	87	171
Any	3 (3.6)	0	3 (1.8)
Grade 1	1 (1.2)	0	1 (0.6)
Grade 2	1 (1.2)	0	1 (0.6)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)
Fatigue - N1	84	87	171
Any	4 (4.8)	6 (6.9)	10 (5.8)
Grade 1	3 (3.6)	1 (1.1)	4 (2.3)
Grade 2	0	5 (5.7)	5 (2.9)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Myalgia - N1	84	87	171
Any	2 (2.4)	1 (1.1)	3 (1.8)
Grade 1	0	0	0
Grade 2	1 (1.2)	1 (1.1)	2 (1.2)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)
Arthralgia - N1	84	87	171
Any	2 (2.4)	1 (1.1)	3 (1.8)
Grade 1	0	0	0
Grade 2	1 (1.2)	1 (1.1)	2 (1.2)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.1
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After First Injection by Baseline SARS-CoV-2 Status and Grade
First Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Nausea/Vomiting - N1	84	87	171
Any	0	1 (1.1)	1 (0.6)
Grade 1	0	1 (1.1)	1 (0.6)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	84	87	171
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Solicited Adverse Reactions - N1	14267	14378	28645
Any Solicited Adverse Reactions	769 (5.4)	1011 (7.0)	1780 (6.2)
95% CI	5.0, 5.8	6.6, 7.5	5.9, 6.5
Grade 1	313 (2.2)	220 (1.5)	533 (1.9)
Grade 2	358 (2.5)	508 (3.5)	866 (3.0)
Grade 3	98 (0.7)	283 (2.0)	381 (1.3)
Grade 4	0	0	0
Grade 3 or Above	98 (0.7)	283 (2.0)	381 (1.3)
Solicited Local Adverse Reactions - N1	14267	14375	28642
Any Solicited Local Adverse Reactions	119 (0.8)	311 (2.2)	430 (1.5)
95% CI	0.7, 1.0	1.9, 2.4	1.4, 1.6
Grade 1	93 (0.7)	116 (0.8)	209 (0.7)
Grade 2	16 (0.1)	129 (0.9)	145 (0.5)
Grade 3	10 (<0.1)	66 (0.5)	76 (0.3)
Grade 4	0	0	0
Grade 3 or Above	10 (<0.1)	66 (0.5)	76 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Pain - N1	14267	14375	28642
Any	57 (0.4)	154 (1.1)	211 (0.7)
Grade 1	39 (0.3)	49 (0.3)	88 (0.3)
Grade 2	12 (<0.1)	79 (0.5)	91 (0.3)
Grade 3	6 (<0.1)	26 (0.2)	32 (0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	26 (0.2)	32 (0.1)
Erythema (Redness) - N1	14267	14374	28641
Any	13 (<0.1)	70 (0.5)	83 (0.3)
Grade 1	11 (<0.1)	20 (0.1)	31 (0.1)
Grade 2	2 (<0.1)	25 (0.2)	27 (<0.1)
Grade 3	0	25 (0.2)	25 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	0	25 (0.2)	25 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Swelling (Hardness) - N1	14267	14374	28641
Any	16 (0.1)	68 (0.5)	84 (0.3)
Grade 1	14 (<0.1)	25 (0.2)	39 (0.1)
Grade 2	1 (<0.1)	28 (0.2)	29 (0.1)
Grade 3	1 (<0.1)	15 (0.1)	16 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	15 (0.1)	16 (<0.1)
Axillary Swelling or Tenderness - N1	14267	14374	28641
Any	47 (0.3)	95 (0.7)	142 (0.5)
Grade 1	41 (0.3)	60 (0.4)	101 (0.4)
Grade 2	3 (<0.1)	27 (0.2)	30 (0.1)
Grade 3	3 (<0.1)	8 (<0.1)	11 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	8 (<0.1)	11 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Solicited Systemic Adverse Reactions - N1	14266	14377	28643
Any Solicited Systemic Adverse Reactions	698 (4.9)	826 (5.7)	1524 (5.3)
95% CI	4.5, 5.3	5.4, 6.1	5.1, 5.6
Grade 1	256 (1.8)	147 (1.0)	403 (1.4)
Grade 2	353 (2.5)	449 (3.1)	802 (2.8)
Grade 3	89 (0.6)	230 (1.6)	319 (1.1)
Grade 4	0	0	0
Grade 3 or Above	89 (0.6)	230 (1.6)	319 (1.1)
Fever - N1	14263	14370	28633
Any	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 1	0	1 (<0.1)	1 (<0.1)
Grade 2	0	0	0
Grade 3	1 (<0.1)	1 (<0.1)	2 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	1 (<0.1)	2 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n	(%)	mRNA-1273 (N=14378) n	(%)	Total (N=28645) n	(%)
Headache - N1	14265		14374		28639	
Any	296	(2.1)	381	(2.7)	677	(2.4)
Grade 1	141	(1.0)	96	(0.7)	237	(0.8)
Grade 2	121	(0.8)	227	(1.6)	348	(1.2)
Grade 3	34	(0.2)	58	(0.4)	92	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	34	(0.2)	58	(0.4)	92	(0.3)
Fatigue - N1	14265		14374		28639	
Any	386	(2.7)	481	(3.3)	867	(3.0)
Grade 1	103	(0.7)	65	(0.5)	168	(0.6)
Grade 2	232	(1.6)	264	(1.8)	496	(1.7)
Grade 3	51	(0.4)	152	(1.1)	203	(0.7)
Grade 4	0		0		0	
Grade 3 or Above	51	(0.4)	152	(1.1)	203	(0.7)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14267) n	(%)	mRNA-1273 (N=14378) n	(%)	Total (N=28645) n	(%)
Myalgia - N1	14265		14374		28639	
Any	224	(1.6)	235	(1.6)	459	(1.6)
Grade 1	80	(0.6)	41	(0.3)	121	(0.4)
Grade 2	115	(0.8)	131	(0.9)	246	(0.9)
Grade 3	29	(0.2)	63	(0.4)	92	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	29	(0.2)	63	(0.4)	92	(0.3)
Arthralgia - N1	14265		14374		28639	
Any	255	(1.8)	266	(1.9)	521	(1.8)
Grade 1	96	(0.7)	59	(0.4)	155	(0.5)
Grade 2	136	(1.0)	153	(1.1)	289	(1.0)
Grade 3	23	(0.2)	54	(0.4)	77	(0.3)
Grade 4	0		0		0	
Grade 3 or Above	23	(0.2)	54	(0.4)	77	(0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14267) n (%)	mRNA-1273 (N=14378) n (%)	Total (N=28645) n (%)
Nausea/Vomiting - N1	14265	14374	28639
Any	48 (0.3)	59 (0.4)	107 (0.4)
Grade 1	19 (0.1)	11 (<0.1)	30 (0.1)
Grade 2	28 (0.2)	43 (0.3)	71 (0.2)
Grade 3	1 (<0.1)	5 (<0.1)	6 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	5 (<0.1)	6 (<0.1)
Chills - N1	14265	14374	28639
Any	47 (0.3)	53 (0.4)	100 (0.3)
Grade 1	21 (0.1)	11 (<0.1)	32 (0.1)
Grade 2	20 (0.1)	34 (0.2)	54 (0.2)
Grade 3	6 (<0.1)	8 (<0.1)	14 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	8 (<0.1)	14 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Solicited Adverse Reactions - N1	233	232	465
Any Solicited Adverse Reactions	17 (7.3)	9 (3.9)	26 (5.6)
95% CI	4.3, 11.4	1.8, 7.2	3.7, 8.1
Grade 1	8 (3.4)	1 (0.4)	9 (1.9)
Grade 2	8 (3.4)	7 (3.0)	15 (3.2)
Grade 3	1 (0.4)	1 (0.4)	2 (0.4)
Grade 4	0	0	0
Grade 3 or Above	1 (0.4)	1 (0.4)	2 (0.4)
Solicited Local Adverse Reactions - N1	232	232	464
Any Solicited Local Adverse Reactions	4 (1.7)	3 (1.3)	7 (1.5)
95% CI	0.5, 4.4	0.3, 3.7	0.6, 3.1
Grade 1	3 (1.3)	1 (0.4)	4 (0.9)
Grade 2	1 (0.4)	1 (0.4)	2 (0.4)
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.4)	1 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Pain - N1	232	232	464
Any	0	3 (1.3)	3 (0.6)
Grade 1	0	1 (0.4)	1 (0.2)
Grade 2	0	1 (0.4)	1 (0.2)
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.4)	1 (0.2)
Erythema (Redness) - N1	232	232	464
Any	0	1 (0.4)	1 (0.2)
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	1 (0.4)	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.4)	1 (0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Swelling (Hardness) - N1	232	232	464
Any	0	2 (0.9)	2 (0.4)
Grade 1	0	2 (0.9)	2 (0.4)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	232	232	464
Any	4 (1.7)	1 (0.4)	5 (1.1)
Grade 1	3 (1.3)	1 (0.4)	4 (0.9)
Grade 2	1 (0.4)	0	1 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Solicited Systemic Adverse Reactions - N1	233	232	465
Any Solicited Systemic Adverse Reactions	15 (6.4)	8 (3.4)	23 (4.9)
95% CI	3.6, 10.4	1.5, 6.7	3.2, 7.3
Grade 1	6 (2.6)	1 (0.4)	7 (1.5)
Grade 2	8 (3.4)	7 (3.0)	15 (3.2)
Grade 3	1 (0.4)	0	1 (0.2)
Grade 4	0	0	0
Grade 3 or Above	1 (0.4)	0	1 (0.2)
Fever - N1	232	232	464
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=233) n	Placebo (N=233) (%)	mRNA-1273 (N=232) n	mRNA-1273 (N=232) (%)	Total (N=465) n	Total (N=465) (%)
Headache - N1	232		232		464	
Any	5	(2.2)	6	(2.6)	11	(2.4)
Grade 1	2	(0.9)	2	(0.9)	4	(0.9)
Grade 2	3	(1.3)	4	(1.7)	7	(1.5)
Grade 3	0		0		0	
Grade 4	0		0		0	
Grade 3 or Above	0		0		0	
Fatigue - N1	232		232		464	
Any	8	(3.4)	4	(1.7)	12	(2.6)
Grade 1	2	(0.9)	0		2	(0.4)
Grade 2	5	(2.2)	4	(1.7)	9	(1.9)
Grade 3	1	(0.4)	0		1	(0.2)
Grade 4	0		0		0	
Grade 3 or Above	1	(0.4)	0		1	(0.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=233) n	(%)	mRNA-1273 (N=232) n	(%)	Total (N=465) n	(%)
Myalgia - N1	232		232		464	
Any	6	(2.6)	3	(1.3)	9	(1.9)
Grade 1	2	(0.9)	0		2	(0.4)
Grade 2	4	(1.7)	3	(1.3)	7	(1.5)
Grade 3	0		0		0	
Grade 4	0		0		0	
Grade 3 or Above	0		0		0	
Arthralgia - N1	232		232		464	
Any	8	(3.4)	3	(1.3)	11	(2.4)
Grade 1	5	(2.2)	0		5	(1.1)
Grade 2	3	(1.3)	3	(1.3)	6	(1.3)
Grade 3	0		0		0	
Grade 4	0		0		0	
Grade 3 or Above	0		0		0	

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=233) n (%)	mRNA-1273 (N=232) n (%)	Total (N=465) n (%)
Nausea/Vomiting - N1	232	232	464
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	232	232	464
Any	3 (1.3)	0	3 (0.6)
Grade 1	2 (0.9)	0	2 (0.4)
Grade 2	1 (0.4)	0	1 (0.2)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Solicited Adverse Reactions - N1	78	81	159
Any Solicited Adverse Reactions	4 (5.1)	4 (4.9)	8 (5.0)
95% CI	1.4, 12.6	1.4, 12.2	2.2, 9.7
Grade 1	2 (2.6)	0	2 (1.3)
Grade 2	2 (2.6)	3 (3.7)	5 (3.1)
Grade 3	0	1 (1.2)	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.2)	1 (0.6)
Solicited Local Adverse Reactions - N1	78	81	159
Any Solicited Local Adverse Reactions	1 (1.3)	1 (1.2)	2 (1.3)
95% CI	0.0, 6.9	0.0, 6.7	0.2, 4.5
Grade 1	1 (1.3)	0	1 (0.6)
Grade 2	0	1 (1.2)	1 (0.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Pain - N1	78	81	159
Any	1 (1.3)	1 (1.2)	2 (1.3)
Grade 1	1 (1.3)	0	1 (0.6)
Grade 2	0	1 (1.2)	1 (0.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Erythema (Redness) - N1	78	81	159
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Swelling (Hardness) - N1	78	81	159
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	78	81	159
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Solicited Systemic Adverse Reactions - N1	78	81	159
Any Solicited Systemic Adverse Reactions	4 (5.1)	4 (4.9)	8 (5.0)
95% CI	1.4, 12.6	1.4, 12.2	2.2, 9.7
Grade 1	2 (2.6)	0	2 (1.3)
Grade 2	2 (2.6)	3 (3.7)	5 (3.1)
Grade 3	0	1 (1.2)	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.2)	1 (0.6)
Fever - N1	78	80	158
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Headache - N1	78	81	159
Any	3 (3.8)	1 (1.2)	4 (2.5)
Grade 1	2 (2.6)	0	2 (1.3)
Grade 2	1 (1.3)	1 (1.2)	2 (1.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Fatigue - N1	78	81	159
Any	3 (3.8)	2 (2.5)	5 (3.1)
Grade 1	2 (2.6)	0	2 (1.3)
Grade 2	1 (1.3)	1 (1.2)	2 (1.3)
Grade 3	0	1 (1.2)	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	0	1 (1.2)	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category / Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Myalgia - N1	78	81	159
Any	1 (1.3)	2 (2.5)	3 (1.9)
Grade 1	0	0	0
Grade 2	1 (1.3)	2 (2.5)	3 (1.9)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Arthralgia - N1	78	81	159
Any	1 (1.3)	1 (1.2)	2 (1.3)
Grade 1	1 (1.3)	0	1 (0.6)
Grade 2	0	1 (1.2)	1 (0.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.2
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Second Injection by Baseline SARS-CoV-2 Status and Grade
Second Injection Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=78) n (%)	mRNA-1273 (N=81) n (%)	Total (N=159) n (%)
Nausea/Vomiting - N1	78	81	159
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	78	81	159
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Solicited Adverse Reactions - N1	14738	14745	29483
Any Solicited Adverse Reactions	1425 (9.7)	1823 (12.4)	3248 (11.0)
95% CI	9.2, 10.2	11.8, 12.9	10.7, 11.4
Grade 1	587 (4.0)	590 (4.0)	1177 (4.0)
Grade 2	663 (4.5)	859 (5.8)	1522 (5.2)
Grade 3	175 (1.2)	374 (2.5)	549 (1.9)
Grade 4	0	0	0
Grade 3 or Above	175 (1.2)	374 (2.5)	549 (1.9)
Solicited Local Adverse Reactions - N1	14737	14745	29482
Any Solicited Local Adverse Reactions	229 (1.6)	610 (4.1)	839 (2.8)
95% CI	1.4, 1.8	3.8, 4.5	2.7, 3.0
Grade 1	173 (1.2)	325 (2.2)	498 (1.7)
Grade 2	42 (0.3)	198 (1.3)	240 (0.8)
Grade 3	14 (<0.1)	87 (0.6)	101 (0.3)
Grade 4	0	0	0
Grade 3 or Above	14 (<0.1)	87 (0.6)	101 (0.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Pain - N1	14737	14745	29482
Any	106 (0.7)	235 (1.6)	341 (1.2)
Grade 1	75 (0.5)	88 (0.6)	163 (0.6)
Grade 2	23 (0.2)	112 (0.8)	135 (0.5)
Grade 3	8 (<0.1)	35 (0.2)	43 (0.1)
Grade 4	0	0	0
Grade 3 or Above	8 (<0.1)	35 (0.2)	43 (0.1)
Erythema (Redness) - N1	14737	14744	29481
Any	32 (0.2)	99 (0.7)	131 (0.4)
Grade 1	29 (0.2)	40 (0.3)	69 (0.2)
Grade 2	2 (<0.1)	31 (0.2)	33 (0.1)
Grade 3	1 (<0.1)	28 (0.2)	29 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	28 (0.2)	29 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Swelling (Hardness) - N1	14737	14744	29481
Any	35 (0.2)	96 (0.7)	131 (0.4)
Grade 1	27 (0.2)	43 (0.3)	70 (0.2)
Grade 2	5 (<0.1)	36 (0.2)	41 (0.1)
Grade 3	3 (<0.1)	17 (0.1)	20 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	17 (0.1)	20 (<0.1)
Axillary Swelling or Tenderness - N1	14737	14744	29481
Any	90 (0.6)	299 (2.0)	389 (1.3)
Grade 1	71 (0.5)	219 (1.5)	290 (1.0)
Grade 2	16 (0.1)	62 (0.4)	78 (0.3)
Grade 3	3 (<0.1)	18 (0.1)	21 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	3 (<0.1)	18 (0.1)	21 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Solicited Systemic Adverse Reactions - N1	14738	14744	29482
Any Solicited Systemic Adverse Reactions	1292 (8.8)	1452 (9.8)	2744 (9.3)
95% CI	8.3, 9.2	9.4, 10.3	9.0, 9.6
Grade 1	484 (3.3)	382 (2.6)	866 (2.9)
Grade 2	645 (4.4)	762 (5.2)	1407 (4.8)
Grade 3	163 (1.1)	308 (2.1)	471 (1.6)
Grade 4	0	0	0
Grade 3 or Above	163 (1.1)	308 (2.1)	471 (1.6)
Fever - N1	14738	14744	29482
Any	4 (<0.1)	5 (<0.1)	9 (<0.1)
Grade 1	3 (<0.1)	2 (<0.1)	5 (<0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)
Grade 3	1 (<0.1)	2 (<0.1)	3 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (<0.1)	2 (<0.1)	3 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n	(%)	mRNA-1273 (N=14745) n	(%)	Total (N=29483) n	(%)
Headache - N1	14737		14744		29481	
Any	540	(3.7)	647	(4.4)	1187	(4.0)
Grade 1	260	(1.8)	232	(1.6)	492	(1.7)
Grade 2	211	(1.4)	323	(2.2)	534	(1.8)
Grade 3	69	(0.5)	92	(0.6)	161	(0.5)
Grade 4	0		0		0	
Grade 3 or Above	69	(0.5)	92	(0.6)	161	(0.5)
Fatigue - N1	14737		14744		29481	
Any	724	(4.9)	864	(5.9)	1588	(5.4)
Grade 1	212	(1.4)	168	(1.1)	380	(1.3)
Grade 2	423	(2.9)	500	(3.4)	923	(3.1)
Grade 3	89	(0.6)	196	(1.3)	285	(1.0)
Grade 4	0		0		0	
Grade 3 or Above	89	(0.6)	196	(1.3)	285	(1.0)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n	(%)	mRNA-1273 (N=14745) n	(%)	Total (N=29483) n	(%)
Myalgia - N1	14737		14744		29481	
Any	404	(2.7)	407	(2.8)	811	(2.8)
Grade 1	144	(1.0)	97	(0.7)	241	(0.8)
Grade 2	211	(1.4)	220	(1.5)	431	(1.5)
Grade 3	49	(0.3)	90	(0.6)	139	(0.5)
Grade 4	0		0		0	
Grade 3 or Above	49	(0.3)	90	(0.6)	139	(0.5)
Arthralgia - N1	14737		14744		29481	
Any	458	(3.1)	440	(3.0)	898	(3.0)
Grade 1	183	(1.2)	123	(0.8)	306	(1.0)
Grade 2	236	(1.6)	246	(1.7)	482	(1.6)
Grade 3	39	(0.3)	71	(0.5)	110	(0.4)
Grade 4	0		0		0	
Grade 3 or Above	39	(0.3)	71	(0.5)	110	(0.4)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Negative

Solicited Adverse Reaction Category / Grade	Placebo (N=14738) n (%)	mRNA-1273 (N=14745) n (%)	Total (N=29483) n (%)
Nausea/Vomiting - N1	14737	14744	29481
Any	103 (0.7)	111 (0.8)	214 (0.7)
Grade 1	54 (0.4)	37 (0.3)	91 (0.3)
Grade 2	47 (0.3)	67 (0.5)	114 (0.4)
Grade 3	2 (<0.1)	7 (<0.1)	9 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	2 (<0.1)	7 (<0.1)	9 (<0.1)
Chills - N1	14737	14744	29481
Any	83 (0.6)	80 (0.5)	163 (0.6)
Grade 1	42 (0.3)	20 (0.1)	62 (0.2)
Grade 2	35 (0.2)	49 (0.3)	84 (0.3)
Grade 3	6 (<0.1)	11 (<0.1)	17 (<0.1)
Grade 4	0	0	0
Grade 3 or Above	6 (<0.1)	11 (<0.1)	17 (<0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Solicited Adverse Reactions - N1	337	347	684
Any Solicited Adverse Reactions	37 (11.0)	26 (7.5)	63 (9.2)
95% CI	7.8, 14.8	5.0, 10.8	7.2, 11.6
Grade 1	12 (3.6)	7 (2.0)	19 (2.8)
Grade 2	18 (5.3)	15 (4.3)	33 (4.8)
Grade 3	7 (2.1)	4 (1.2)	11 (1.6)
Grade 4	0	0	0
Grade 3 or Above	7 (2.1)	4 (1.2)	11 (1.6)
Solicited Local Adverse Reactions - N1	337	347	684
Any Solicited Local Adverse Reactions	6 (1.8)	6 (1.7)	12 (1.8)
95% CI	0.7, 3.8	0.6, 3.7	0.9, 3.0
Grade 1	5 (1.5)	4 (1.2)	9 (1.3)
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Pain - N1	337	347	684
Any	1 (0.3)	3 (0.9)	4 (0.6)
Grade 1	1 (0.3)	1 (0.3)	2 (0.3)
Grade 2	0	1 (0.3)	1 (0.1)
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.1)
Erythema (Redness) - N1	337	347	684
Any	0	2 (0.6)	2 (0.3)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	1 (0.3)	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	0	1 (0.3)	1 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301060303.sas 21JUN2021 17:14

Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Swelling (Hardness) - N1	337	347	684
Any	0	3 (0.9)	3 (0.4)
Grade 1	0	3 (0.9)	3 (0.4)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	337	347	684
Any	6 (1.8)	3 (0.9)	9 (1.3)
Grade 1	5 (1.5)	2 (0.6)	7 (1.0)
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301060303.sas 21JUN2021 17:14

Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Solicited Systemic Adverse Reactions - N1	337	347	684
Any Solicited Systemic Adverse Reactions	34 (10.1)	22 (6.3)	56 (8.2)
95% CI	7.1, 13.8	4.0, 9.4	6.2, 10.5
Grade 1	9 (2.7)	4 (1.2)	13 (1.9)
Grade 2	18 (5.3)	14 (4.0)	32 (4.7)
Grade 3	7 (2.1)	4 (1.2)	11 (1.6)
Grade 4	0	0	0
Grade 3 or Above	7 (2.1)	4 (1.2)	11 (1.6)
Fever - N1	336	347	683
Any	0	1 (0.3)	1 (0.1)
Grade 1	0	1 (0.3)	1 (0.1)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=337) n	(%)	mRNA-1273 (N=347) n	(%)	Total (N=684) n	(%)
Headache - N1	337		347		684	
Any	14	(4.2)	15	(4.3)	29	(4.2)
Grade 1	3	(0.9)	4	(1.2)	7	(1.0)
Grade 2	8	(2.4)	8	(2.3)	16	(2.3)
Grade 3	3	(0.9)	3	(0.9)	6	(0.9)
Grade 4	0		0		0	
Grade 3 or Above	3	(0.9)	3	(0.9)	6	(0.9)
Fatigue - N1	337		347		684	
Any	20	(5.9)	12	(3.5)	32	(4.7)
Grade 1	4	(1.2)	2	(0.6)	6	(0.9)
Grade 2	13	(3.9)	9	(2.6)	22	(3.2)
Grade 3	3	(0.9)	1	(0.3)	4	(0.6)
Grade 4	0		0		0	
Grade 3 or Above	3	(0.9)	1	(0.3)	4	(0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category / Grade	Placebo (N=337) n	(%)	mRNA-1273 (N=347) n	(%)	Total (N=684) n	(%)
Myalgia - N1	337		347		684	
Any	16	(4.7)	9	(2.6)	25	(3.7)
Grade 1	4	(1.2)	2	(0.6)	6	(0.9)
Grade 2	11	(3.3)	7	(2.0)	18	(2.6)
Grade 3	1	(0.3)	0		1	(0.1)
Grade 4	0		0		0	
Grade 3 or Above	1	(0.3)	0		1	(0.1)
Arthralgia - N1	337		347		684	
Any	15	(4.5)	6	(1.7)	21	(3.1)
Grade 1	6	(1.8)	0		6	(0.9)
Grade 2	8	(2.4)	6	(1.7)	14	(2.0)
Grade 3	1	(0.3)	0		1	(0.1)
Grade 4	0		0		0	
Grade 3 or Above	1	(0.3)	0		1	(0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Positive

Solicited Adverse Reaction Category Grade	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Nausea/Vomiting - N1	337	347	684
Any	1 (0.3)	1 (0.3)	2 (0.3)
Grade 1	0	0	0
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	337	347	684
Any	6 (1.8)	1 (0.3)	7 (1.0)
Grade 1	4 (1.2)	0	4 (0.6)
Grade 2	1 (0.3)	1 (0.3)	2 (0.3)
Grade 3	1 (0.3)	0	1 (0.1)
Grade 4	0	0	0
Grade 3 or Above	1 (0.3)	0	1 (0.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Adverse Reactions - N1	84	87	171
Any Solicited Adverse Reactions	8 (9.5)	10 (11.5)	18 (10.5)
95% CI	4.2, 17.9	5.7, 20.1	6.4, 16.1
Grade 1	4 (4.8)	2 (2.3)	6 (3.5)
Grade 2	3 (3.6)	7 (8.0)	10 (5.8)
Grade 3	1 (1.2)	1 (1.1)	2 (1.2)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	1 (1.1)	2 (1.2)
Solicited Local Adverse Reactions - N1	84	87	171
Any Solicited Local Adverse Reactions	2 (2.4)	2 (2.3)	4 (2.3)
95% CI	0.3, 8.3	0.3, 8.1	0.6, 5.9
Grade 1	2 (2.4)	1 (1.1)	3 (1.8)
Grade 2	0	1 (1.1)	1 (0.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Pain - N1	84	87	171
Any	1 (1.2)	1 (1.1)	2 (1.2)
Grade 1	1 (1.2)	0	1 (0.6)
Grade 2	0	1 (1.1)	1 (0.6)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Erythema (Redness) - N1	84	87	171
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Swelling (Hardness) - N1	84	87	171
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Axillary Swelling or Tenderness - N1	84	87	171
Any	1 (1.2)	1 (1.1)	2 (1.2)
Grade 1	1 (1.2)	1 (1.1)	2 (1.2)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Solicited Systemic Adverse Reactions - N1	84	87	171
Any Solicited Systemic Adverse Reactions	7 (8.3)	9 (10.3)	16 (9.4)
95% CI	3.4, 16.4	4.8, 18.7	5.4, 14.7
Grade 1	3 (3.6)	1 (1.1)	4 (2.3)
Grade 2	3 (3.6)	7 (8.0)	10 (5.8)
Grade 3	1 (1.2)	1 (1.1)	2 (1.2)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	1 (1.1)	2 (1.2)
Fever - N1	84	86	170
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Headache - N1	84	87	171
Any	5 (6.0)	1 (1.1)	6 (3.5)
Grade 1	2 (2.4)	0	2 (1.2)
Grade 2	2 (2.4)	1 (1.1)	3 (1.8)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)
Fatigue - N1	84	87	171
Any	6 (7.1)	7 (8.0)	13 (7.6)
Grade 1	4 (4.8)	1 (1.1)	5 (2.9)
Grade 2	1 (1.2)	5 (5.7)	6 (3.5)
Grade 3	1 (1.2)	1 (1.1)	2 (1.2)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	1 (1.1)	2 (1.2)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Myalgia - N1	84	87	171
Any	2 (2.4)	3 (3.4)	5 (2.9)
Grade 1	0	0	0
Grade 2	1 (1.2)	3 (3.4)	4 (2.3)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)
Arthralgia - N1	84	87	171
Any	2 (2.4)	2 (2.3)	4 (2.3)
Grade 1	0	0	0
Grade 2	1 (1.2)	2 (2.3)	3 (1.8)
Grade 3	1 (1.2)	0	1 (0.6)
Grade 4	0	0	0
Grade 3 or Above	1 (1.2)	0	1 (0.6)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.6.3.3
Summary of Subjects with Solicited Adverse Reactions Persisting Beyond 7 Days After Any Injection by Baseline SARS-CoV-2 Status and Grade
Solicited Safety Set

Baseline SARS-CoV-2 Status: Missing

Solicited Adverse Reaction Category Grade	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Nausea/Vomiting - N1	84	87	171
Any	0	1 (1.1)	1 (0.6)
Grade 1	0	1 (1.1)	1 (0.6)
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0
Chills - N1	84	87	171
Any	0	0	0
Grade 1	0	0	0
Grade 2	0	0	0
Grade 3	0	0	0
Grade 4	0	0	0
Grade 3 or Above	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event. Any = Grade 1 or higher.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.
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Table 14.3.1.7.1.1
Summary of Unsolicited TEAE up to 28 Days After Any Injection
Safety Set

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	4338 (28.6)	4752 (31.3)	9090 (30.0)
Serious	104 (0.7)	98 (0.6)	202 (0.7)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-Attended	1940 (12.8)	1819 (12.0)	3759 (12.4)
Leading to Discontinuation from Study Vaccine	92 (0.6)	61 (0.4)	153 (0.5)
Leading to Discontinuation from Participation in the Study	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	233 (1.5)	258 (1.7)	491 (1.6)
Unsolicited TEAEs Related to Study Vaccination			
All	1236 (8.2)	2067 (13.6)	3303 (10.9)
Serious	3 (<0.1)	8 (<0.1)	11 (<0.1)
Fatal	0	0	0
Medically-Attended	95 (0.6)	198 (1.3)	293 (1.0)
Leading to Discontinuation from Study Vaccine	14 (<0.1)	20 (0.1)	34 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	31 (0.2)	83 (0.5)	114 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.8.1
Summary of Unsolicited TEAE up to 28 Days After Any Injection in Subjects with HIV
Safety Set

	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	38 (41.8)	35 (37.2)	73 (39.5)
Serious	1 (1.1)	1 (1.1)	2 (1.1)
Fatal	0	0	0
Medically-Attended	14 (15.4)	12 (12.8)	26 (14.1)
Leading to Discontinuation from Study Vaccine	1 (1.1)	0	1 (0.5)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	4 (4.4)	2 (2.1)	6 (3.2)
Unsolicited TEAEs Related to Study Vaccination			
All	10 (11.0)	11 (11.7)	21 (11.4)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	1 (1.1)	2 (2.1)	3 (1.6)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	1 (1.1)	1 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.9.1
Summary of Unsolicited TEAE up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Total (N=2296) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	380 (33.2)	423 (36.7)	803 (35.0)
Serious	22 (1.9)	10 (0.9)	32 (1.4)
Fatal	0	0	0
Medically-Attended	192 (16.8)	175 (15.2)	367 (16.0)
Leading to Discontinuation from Study Vaccine	8 (0.7)	10 (0.9)	18 (0.8)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	30 (2.6)	17 (1.5)	47 (2.0)
Unsolicited TEAEs Related to Study Vaccination			
All	106 (9.3)	193 (16.8)	299 (13.0)
Serious	2 (0.2)	1 (<0.1)	3 (0.1)
Fatal	0	0	0
Medically-Attended	9 (0.8)	19 (1.6)	28 (1.2)
Leading to Discontinuation from Study Vaccine	2 (0.2)	4 (0.3)	6 (0.3)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	5 (0.4)	8 (0.7)	13 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.7.1
Summary of Unsolicited TEAE up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Total (N=15974) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	2092 (26.0)	2173 (27.4)	4265 (26.7)
Serious	49 (0.6)	51 (0.6)	100 (0.6)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-Attended	895 (11.1)	820 (10.4)	1715 (10.7)
Leading to Discontinuation from Study Vaccine	45 (0.6)	29 (0.4)	74 (0.5)
Leading to Discontinuation from Participation in the Study	3 (<0.1)	5 (<0.1)	8 (<0.1)
Severe	103 (1.3)	125 (1.6)	228 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	567 (7.0)	843 (10.6)	1410 (8.8)
Serious	2 (<0.1)	2 (<0.1)	4 (<0.1)
Fatal	0	0	0
Medically-Attended	44 (0.5)	78 (1.0)	122 (0.8)
Leading to Discontinuation from Study Vaccine	6 (<0.1)	6 (<0.1)	12 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	13 (0.2)	34 (0.4)	47 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.7.1
Summary of Unsolicited TEAE up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Total (N=14372) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	2246 (31.6)	2579 (35.5)	4825 (33.6)
Serious	55 (0.8)	47 (0.6)	102 (0.7)
Fatal	0	0	0
Medically-Attended	1045 (14.7)	999 (13.7)	2044 (14.2)
Leading to Discontinuation from Study Vaccine	47 (0.7)	32 (0.4)	79 (0.5)
Leading to Discontinuation from Participation in the Study	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	130 (1.8)	133 (1.8)	263 (1.8)
Unsolicited TEAEs Related to Study Vaccination			
All	669 (9.4)	1224 (16.8)	1893 (13.2)
Serious	1 (<0.1)	6 (<0.1)	7 (<0.1)
Fatal	0	0	0
Medically-Attended	51 (0.7)	120 (1.7)	171 (1.2)
Leading to Discontinuation from Study Vaccine	8 (0.1)	14 (0.2)	22 (0.2)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	18 (0.3)	49 (0.7)	67 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.4.1
Summary of Unsolicited TEAE by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Total (N=24032) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3326 (27.7)	3674 (30.5)	7000 (29.1)
Serious	80 (0.7)	75 (0.6)	155 (0.6)
Fatal	0	2 (<0.1)	2 (<0.1)
Medically-Attended	1548 (12.9)	1446 (12.0)	2994 (12.5)
Leading to Discontinuation from Study Vaccine	70 (0.6)	43 (0.4)	113 (0.5)
Leading to Discontinuation from Participation in the Study	4 (<0.1)	6 (<0.1)	10 (<0.1)
Severe	172 (1.4)	194 (1.6)	366 (1.5)
Unsolicited TEAEs Related to Study Vaccination			
All	957 (8.0)	1585 (13.2)	2542 (10.6)
Serious	1 (<0.1)	5 (<0.1)	6 (<0.1)
Fatal	0	0	0
Medically-Attended	72 (0.6)	147 (1.2)	219 (0.9)
Leading to Discontinuation from Study Vaccine	12 (0.1)	15 (0.1)	27 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	26 (0.2)	68 (0.6)	94 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.4.1
Summary of Unsolicited TEAE by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Total (N=3098) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	465 (30.4)	484 (30.9)	949 (30.6)
Serious	15 (1.0)	12 (0.8)	27 (0.9)
Fatal	0	0	0
Medically-Attended	184 (12.0)	174 (11.1)	358 (11.6)
Leading to Discontinuation from Study Vaccine	10 (0.7)	10 (0.6)	20 (0.6)
Leading to Discontinuation from Participation in the Study	0	2 (0.1)	2 (<0.1)
Severe	33 (2.2)	34 (2.2)	67 (2.2)
Unsolicited TEAEs Related to Study Vaccination			
All	132 (8.6)	196 (12.5)	328 (10.6)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	14 (0.9)	15 (1.0)	29 (0.9)
Leading to Discontinuation from Study Vaccine	0	2 (0.1)	2 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	4 (0.3)	6 (0.4)	10 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.4.1
Summary of Unsolicited TEAE by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Total (N=1395) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	188 (25.4)	218 (33.2)	406 (29.1)
Serious	1 (0.1)	3 (0.5)	4 (0.3)
Fatal	0	0	0
Medically-Attended	65 (8.8)	74 (11.3)	139 (10.0)
Leading to Discontinuation from Study Vaccine	1 (0.1)	4 (0.6)	5 (0.4)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	5 (0.7)	11 (1.7)	16 (1.1)
Unsolicited TEAEs Related to Study Vaccination			
All	39 (5.3)	112 (17.1)	151 (10.8)
Serious	0	3 (0.5)	3 (0.2)
Fatal	0	0	0
Medically-Attended	1 (0.1)	14 (2.1)	15 (1.1)
Leading to Discontinuation from Study Vaccine	0	3 (0.5)	3 (0.2)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	4 (0.6)	4 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.4.1
Summary of Unsolicited TEAE by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Total (N=234) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	39 (32.2)	47 (41.6)	86 (36.8)
Serious	1 (0.8)	0	1 (0.4)
Fatal	1 (0.8)	0	1 (0.4)
Medically-Attended	21 (17.4)	21 (18.6)	42 (17.9)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	1 (0.8)	0	1 (0.4)
Severe	1 (0.8)	2 (1.8)	3 (1.3)
Unsolicited TEAEs Related to Study Vaccination			
All	11 (9.1)	16 (14.2)	27 (11.5)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	1 (0.9)	1 (0.4)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.4.1
Summary of Unsolicited TEAE by Race up to 28 Days After Any Injection
Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Total (N=68) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	9 (28.1)	8 (22.2)	17 (25.0)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (15.6)	2 (5.6)	7 (10.3)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (3.1)	0	1 (1.5)
Unsolicited TEAEs Related to Study Vaccination			
All	2 (6.3)	3 (8.3)	5 (7.4)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	0	0
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.4.1
Summary of Unsolicited TEAE by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Total (N=638) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	129 (40.6)	132 (41.3)	261 (40.9)
Serious	3 (0.9)	4 (1.3)	7 (1.1)
Fatal	0	0	0
Medically-Attended	53 (16.7)	51 (15.9)	104 (16.3)
Leading to Discontinuation from Study Vaccine	4 (1.3)	1 (0.3)	5 (0.8)
Leading to Discontinuation from Participation in the Study	0	1 (0.3)	1 (0.2)
Severe	8 (2.5)	7 (2.2)	15 (2.4)
Unsolicited TEAEs Related to Study Vaccination			
All	43 (13.5)	65 (20.3)	108 (16.9)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	4 (1.3)	12 (3.8)	16 (2.5)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	1 (0.3)	1 (0.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.4.1
Summary of Unsolicited TEAE by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Total (N=881) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	182 (43.0)	189 (41.3)	371 (42.1)
Serious	4 (0.9)	4 (0.9)	8 (0.9)
Fatal	1 (0.2)	0	1 (0.1)
Medically-Attended	64 (15.1)	51 (11.1)	115 (13.1)
Leading to Discontinuation from Study Vaccine	7 (1.7)	3 (0.7)	10 (1.1)
Leading to Discontinuation from Participation in the Study	1 (0.2)	0	1 (0.1)
Severe	13 (3.1)	10 (2.2)	23 (2.6)
Unsolicited TEAEs Related to Study Vaccination			
All	52 (12.3)	90 (19.7)	142 (16.1)
Serious	2 (0.5)	0	2 (0.2)
Fatal	0	0	0
Medically-Attended	4 (0.9)	9 (2.0)	13 (1.5)
Leading to Discontinuation from Study Vaccine	2 (0.5)	0	2 (0.2)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.2)	4 (0.9)	5 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.5.1
Summary of Unsolicited TEAE by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Total (N=6230) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	1005 (32.3)	1029 (33.0)	2034 (32.6)
Serious	17 (0.5)	12 (0.4)	29 (0.5)
Fatal	0	0	0
Medically-Attended	417 (13.4)	364 (11.7)	781 (12.5)
Leading to Discontinuation from Study Vaccine	22 (0.7)	16 (0.5)	38 (0.6)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	48 (1.5)	37 (1.2)	85 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	305 (9.8)	450 (14.4)	755 (12.1)
Serious	2 (<0.1)	0	2 (<0.1)
Fatal	0	0	0
Medically-Attended	29 (0.9)	43 (1.4)	72 (1.2)
Leading to Discontinuation from Study Vaccine	3 (<0.1)	4 (0.1)	7 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	4 (0.1)	11 (0.4)	15 (0.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.5.1
Summary of Unsolicited TEAE by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Total (N=23838) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3295 (27.6)	3679 (30.9)	6974 (29.3)
Serious	85 (0.7)	86 (0.7)	171 (0.7)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-Attended	1506 (12.6)	1439 (12.1)	2945 (12.4)
Leading to Discontinuation from Study Vaccine	69 (0.6)	44 (0.4)	113 (0.5)
Leading to Discontinuation from Participation in the Study	6 (<0.1)	8 (<0.1)	14 (<0.1)
Severe	181 (1.5)	220 (1.8)	401 (1.7)
Unsolicited TEAEs Related to Study Vaccination			
All	924 (7.8)	1598 (13.4)	2522 (10.6)
Serious	1 (<0.1)	8 (<0.1)	9 (<0.1)
Fatal	0	0	0
Medically-Attended	66 (0.6)	154 (1.3)	220 (0.9)
Leading to Discontinuation from Study Vaccine	11 (<0.1)	16 (0.1)	27 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	27 (0.2)	72 (0.6)	99 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.6.2.1
Summary of Unsolicited TEAE by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Total (N=6905) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	1073 (31.0)	1188 (34.5)	2261 (32.7)
Serious	49 (1.4)	36 (1.0)	85 (1.2)
Fatal	0	0	0
Medically-Attended	516 (14.9)	494 (14.3)	1010 (14.6)
Leading to Discontinuation from Study Vaccine	27 (0.8)	14 (0.4)	41 (0.6)
Leading to Discontinuation from Participation in the Study	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	85 (2.5)	59 (1.7)	144 (2.1)
Unsolicited TEAEs Related to Study Vaccination			
All	327 (9.5)	522 (15.1)	849 (12.3)
Serious	2 (<0.1)	2 (<0.1)	4 (<0.1)
Fatal	0	0	0
Medically-Attended	21 (0.6)	61 (1.8)	82 (1.2)
Leading to Discontinuation from Study Vaccine	3 (<0.1)	5 (0.1)	8 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	14 (0.4)	19 (0.6)	33 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.6.2.1
Summary of Unsolicited TEAE by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Total (N=23441) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3265 (27.9)	3564 (30.4)	6829 (29.1)
Serious	55 (0.5)	62 (0.5)	117 (0.5)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-Attended	1424 (12.2)	1325 (11.3)	2749 (11.7)
Leading to Discontinuation from Study Vaccine	65 (0.6)	47 (0.4)	112 (0.5)
Leading to Discontinuation from Participation in the Study	4 (<0.1)	8 (<0.1)	12 (<0.1)
Severe	148 (1.3)	199 (1.7)	347 (1.5)
Unsolicited TEAEs Related to Study Vaccination			
All	909 (7.8)	1545 (13.2)	2454 (10.5)
Serious	1 (<0.1)	6 (<0.1)	7 (<0.1)
Fatal	0	0	0
Medically-Attended	74 (0.6)	137 (1.2)	211 (0.9)
Leading to Discontinuation from Study Vaccine	11 (<0.1)	15 (0.1)	26 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	17 (0.1)	64 (0.5)	81 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.6.3.1
Summary of Unsolicited TEAE by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Total (N=1461) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	232 (31.0)	261 (36.7)	493 (33.7)
Serious	14 (1.9)	10 (1.4)	24 (1.6)
Fatal	0	0	0
Medically-Attended	120 (16.0)	115 (16.2)	235 (16.1)
Leading to Discontinuation from Study Vaccine	4 (0.5)	4 (0.6)	8 (0.5)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	26 (3.5)	15 (2.1)	41 (2.8)
Unsolicited TEAEs Related to Study Vaccination			
All	78 (10.4)	128 (18.0)	206 (14.1)
Serious	1 (0.1)	1 (0.1)	2 (0.1)
Fatal	0	0	0
Medically-Attended	7 (0.9)	13 (1.8)	20 (1.4)
Leading to Discontinuation from Study Vaccine	1 (0.1)	2 (0.3)	3 (0.2)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	5 (0.7)	3 (0.4)	8 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107060301.sas 21JUN2021 14:28

Table 14.3.1.7.6.3.1
Summary of Unsolicited TEAE by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Total (N=1504) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	209 (28.2)	255 (33.5)	464 (30.9)
Serious	12 (1.6)	8 (1.0)	20 (1.3)
Fatal	0	0	0
Medically-Attended	95 (12.8)	106 (13.9)	201 (13.4)
Leading to Discontinuation from Study Vaccine	6 (0.8)	4 (0.5)	10 (0.7)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	17 (2.3)	17 (2.2)	34 (2.3)
Unsolicited TEAEs Related to Study Vaccination			
All	73 (9.8)	101 (13.3)	174 (11.6)
Serious	1 (0.1)	0	1 (<0.1)
Fatal	0	0	0
Medically-Attended	4 (0.5)	9 (1.2)	13 (0.9)
Leading to Discontinuation from Study Vaccine	1 (0.1)	0	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	5 (0.7)	7 (0.9)	12 (0.8)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107060301.sas 21JUN2021 14:28

Table 14.3.1.7.6.3.1
Summary of Unsolicited TEAE by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Total (N=2128) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	327 (30.9)	378 (35.3)	705 (33.1)
Serious	18 (1.7)	7 (0.7)	25 (1.2)
Fatal	0	0	0
Medically-Attended	172 (16.3)	156 (14.6)	328 (15.4)
Leading to Discontinuation from Study Vaccine	14 (1.3)	4 (0.4)	18 (0.8)
Leading to Discontinuation from Participation in the Study	1 (<0.1)	0	1 (<0.1)
Severe	31 (2.9)	11 (1.0)	42 (2.0)
Unsolicited TEAEs Related to Study Vaccination			
All	98 (9.3)	180 (16.8)	278 (13.1)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (0.5)	16 (1.5)	21 (1.0)
Leading to Discontinuation from Study Vaccine	1 (<0.1)	2 (0.2)	3 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	6 (0.6)	5 (0.5)	11 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107060301.sas 21JUN2021 14:28

Table 14.3.1.7.6.3.1
Summary of Unsolicited TEAE by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Total (N=2917) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	453 (31.1)	479 (32.8)	932 (32.0)
Serious	20 (1.4)	19 (1.3)	39 (1.3)
Fatal	0	0	0
Medically-Attended	211 (14.5)	205 (14.0)	416 (14.3)
Leading to Discontinuation from Study Vaccine	8 (0.5)	5 (0.3)	13 (0.4)
Leading to Discontinuation from Participation in the Study	1 (<0.1)	0	1 (<0.1)
Severe	28 (1.9)	19 (1.3)	47 (1.6)
Unsolicited TEAEs Related to Study Vaccination			
All	120 (8.2)	182 (12.5)	302 (10.4)
Serious	0	1 (<0.1)	1 (<0.1)
Fatal	0	0	0
Medically-Attended	3 (0.2)	29 (2.0)	32 (1.1)
Leading to Discontinuation from Study Vaccine	0	1 (<0.1)	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	3 (0.2)	4 (0.3)	7 (0.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107060301.sas 21JUN2021 14:28

Table 14.3.1.7.6.3.1
Summary of Unsolicited TEAE by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Total (N=200) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	42 (43.8)	37 (35.6)	79 (39.5)
Serious	1 (1.0)	2 (1.9)	3 (1.5)
Fatal	0	0	0
Medically-Attended	24 (25.0)	17 (16.3)	41 (20.5)
Leading to Discontinuation from Study Vaccine	1 (1.0)	1 (1.0)	2 (1.0)
Leading to Discontinuation from Participation in the Study	0	1 (1.0)	1 (0.5)
Severe	2 (2.1)	2 (1.9)	4 (2.0)
Unsolicited TEAEs Related to Study Vaccination			
All	15 (15.6)	16 (15.4)	31 (15.5)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	2 (2.1)	3 (2.9)	5 (2.5)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	1 (1.0)	1 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.6.3.1
Summary of Unsolicited TEAE by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Total (N=185) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	38 (41.8)	35 (37.2)	73 (39.5)
Serious	1 (1.1)	1 (1.1)	2 (1.1)
Fatal	0	0	0
Medically-Attended	14 (15.4)	12 (12.8)	26 (14.1)
Leading to Discontinuation from Study Vaccine	1 (1.1)	0	1 (0.5)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	4 (4.4)	2 (2.1)	6 (3.2)
Unsolicited TEAEs Related to Study Vaccination			
All	10 (11.0)	11 (11.7)	21 (11.4)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	1 (1.1)	2 (2.1)	3 (1.6)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	1 (1.1)	1 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.6.4.1
Summary of Unsolicited TEAE by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baselineine up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Total (N=23441) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3265 (27.9)	3564 (30.4)	6829 (29.1)
Serious	55 (0.5)	62 (0.5)	117 (0.5)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-Attended	1424 (12.2)	1325 (11.3)	2749 (11.7)
Leading to Discontinuation from Study Vaccine	65 (0.6)	47 (0.4)	112 (0.5)
Leading to Discontinuation from Participation in the Study	4 (<0.1)	8 (<0.1)	12 (<0.1)
Severe	148 (1.3)	199 (1.7)	347 (1.5)
Unsolicited TEAEs Related to Study Vaccination			
All	909 (7.8)	1545 (13.2)	2454 (10.5)
Serious	1 (<0.1)	6 (<0.1)	7 (<0.1)
Fatal	0	0	0
Medically-Attended	74 (0.6)	137 (1.2)	211 (0.9)
Leading to Discontinuation from Study Vaccine	11 (<0.1)	15 (0.1)	26 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	17 (0.1)	64 (0.5)	81 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.6.4.1
Summary of Unsolicited TEAE by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baselineine up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Total (N=5606) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	871 (30.9)	968 (34.7)	1839 (32.8)
Serious	35 (1.2)	25 (0.9)	60 (1.1)
Fatal	0	0	0
Medically-Attended	412 (14.6)	395 (14.2)	807 (14.4)
Leading to Discontinuation from Study Vaccine	20 (0.7)	12 (0.4)	32 (0.6)
Leading to Discontinuation from Participation in the Study	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	66 (2.3)	52 (1.9)	118 (2.1)
Unsolicited TEAEs Related to Study Vaccination			
All	268 (9.5)	442 (15.8)	710 (12.7)
Serious	2 (<0.1)	2 (<0.1)	4 (<0.1)
Fatal	0	0	0
Medically-Attended	20 (0.7)	50 (1.8)	70 (1.2)
Leading to Discontinuation from Study Vaccine	3 (0.1)	5 (0.2)	8 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	11 (0.4)	17 (0.6)	28 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.6.4.1
Summary of Unsolicited TEAE by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baselineine up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Total (N=1299) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	202 (31.5)	220 (33.5)	422 (32.5)
Serious	14 (2.2)	11 (1.7)	25 (1.9)
Fatal	0	0	0
Medically-Attended	104 (16.2)	99 (15.1)	203 (15.6)
Leading to Discontinuation from Study Vaccine	7 (1.1)	2 (0.3)	9 (0.7)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	19 (3.0)	7 (1.1)	26 (2.0)
Unsolicited TEAEs Related to Study Vaccination			
All	59 (9.2)	80 (12.2)	139 (10.7)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	1 (0.2)	11 (1.7)	12 (0.9)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	3 (0.5)	2 (0.3)	5 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.2.2.1
Summary of Unsolicited TEAE by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3275 (28.7)	3515 (30.8)	6790 (29.7)
Serious	54 (0.5)	59 (0.5)	113 (0.5)
Fatal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Medically-Attended	1419 (12.4)	1311 (11.5)	2730 (12.0)
Leading to Discontinuation from Study Vaccine	70 (0.6)	49 (0.4)	119 (0.5)
Leading to Discontinuation from Participation in the Study	3 (<0.1)	7 (<0.1)	10 (<0.1)
Severe	152 (1.3)	177 (1.6)	329 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	945 (8.3)	1580 (13.8)	2525 (11.1)
Serious	2 (<0.1)	6 (<0.1)	8 (<0.1)
Fatal	0	0	0
Medically-Attended	78 (0.7)	161 (1.4)	239 (1.0)
Leading to Discontinuation from Study Vaccine	8 (<0.1)	17 (0.1)	25 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	20 (0.2)	59 (0.5)	79 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107020201.sas 21JUN2021 14:26

Table 14.3.1.7.2.2.1
Summary of Unsolicited TEAE by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Total (N=6122) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	846 (28.1)	1019 (32.7)	1865 (30.5)
Serious	34 (1.1)	29 (0.9)	63 (1.0)
Fatal	0	0	0
Medically-Attended	421 (14.0)	416 (13.4)	837 (13.7)
Leading to Discontinuation from Study Vaccine	16 (0.5)	12 (0.4)	28 (0.5)
Leading to Discontinuation from Participation in the Study	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	58 (1.9)	60 (1.9)	118 (1.9)
Unsolicited TEAEs Related to Study Vaccination			
All	228 (7.6)	396 (12.7)	624 (10.2)
Serious	0	2 (<0.1)	2 (<0.1)
Fatal	0	0	0
Medically-Attended	8 (0.3)	30 (1.0)	38 (0.6)
Leading to Discontinuation from Study Vaccine	5 (0.2)	3 (<0.1)	8 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	5 (0.2)	19 (0.6)	24 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.2.2.1
Summary of Unsolicited TEAE by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Total (N=1308) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	201 (29.0)	203 (33.0)	404 (30.9)
Serious	13 (1.9)	10 (1.6)	23 (1.8)
Fatal	1 (0.1)	1 (0.2)	2 (0.2)
Medically-Attended	93 (13.4)	86 (14.0)	179 (13.7)
Leading to Discontinuation from Study Vaccine	5 (0.7)	0	5 (0.4)
Leading to Discontinuation from Participation in the Study	1 (0.1)	1 (0.2)	2 (0.2)
Severe	20 (2.9)	19 (3.1)	39 (3.0)
Unsolicited TEAEs Related to Study Vaccination			
All	57 (8.2)	85 (13.8)	142 (10.9)
Serious	1 (0.1)	0	1 (<0.1)
Fatal	0	0	0
Medically-Attended	6 (0.9)	7 (1.1)	13 (1.0)
Leading to Discontinuation from Study Vaccine	1 (0.1)	0	1 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	5 (0.7)	5 (0.8)	10 (0.8)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107020201.sas 21JUN2021 14:26

Table 14.3.1.7.2.2.1
Summary of Unsolicited TEAE by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=85 Years

	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Total (N=90) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	16 (32.7)	15 (36.6)	31 (34.4)
Serious	3 (6.1)	0	3 (3.3)
Fatal	0	0	0
Medically-Attended	7 (14.3)	6 (14.6)	13 (14.4)
Leading to Discontinuation from Study Vaccine	1 (2.0)	0	1 (1.1)
Leading to Discontinuation from Participation in the Study	1 (2.0)	0	1 (1.1)
Severe	3 (6.1)	2 (4.9)	5 (5.6)
Unsolicited TEAEs Related to Study Vaccination			
All	6 (12.2)	6 (14.6)	12 (13.3)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	3 (6.1)	0	3 (3.3)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (2.0)	0	1 (1.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107020201.sas 21JUN2021 14:26

Table 14.3.1.7.1.3
Summary of Unsolicited TEAE in Overall Stage
Safety Set

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	6513 (43.0)	6310 (41.6)	12823 (42.3)
Serious	292 (1.9)	268 (1.8)	560 (1.8)
Fatal	16 (0.1)	17 (0.1)	33 (0.1)
Medically-Attended	4131 (27.2)	3468 (22.8)	7599 (25.0)
Leading to Discontinuation from Study Vaccine	109 (0.7)	74 (0.5)	183 (0.6)
Leading to Discontinuation from Participation in the Study	23 (0.2)	26 (0.2)	49 (0.2)
Severe	486 (3.2)	461 (3.0)	947 (3.1)
Unsolicited TEAEs Related to Study Vaccination			
All	1288 (8.5)	2107 (13.9)	3395 (11.2)
Serious	4 (<0.1)	12 (<0.1)	16 (<0.1)
Fatal	0	0	0
Medically-Attended	109 (0.7)	213 (1.4)	322 (1.1)
Leading to Discontinuation from Study Vaccine	15 (<0.1)	20 (0.1)	35 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	34 (0.2)	88 (0.6)	122 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.2.1.1
Summary of Unsolicited TEAE by Age Group up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	3275 (28.7)	3515 (30.8)	6790 (29.7)
Serious	54 (0.5)	59 (0.5)	113 (0.5)
Fatal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Medically-Attended	1419 (12.4)	1311 (11.5)	2730 (12.0)
Leading to Discontinuation from Study Vaccine	70 (0.6)	49 (0.4)	119 (0.5)
Leading to Discontinuation from Participation in the Study	3 (<0.1)	7 (<0.1)	10 (<0.1)
Severe	152 (1.3)	177 (1.6)	329 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	945 (8.3)	1580 (13.8)	2525 (11.1)
Serious	2 (<0.1)	6 (<0.1)	8 (<0.1)
Fatal	0	0	0
Medically-Attended	78 (0.7)	161 (1.4)	239 (1.0)
Leading to Discontinuation from Study Vaccine	8 (<0.1)	17 (0.1)	25 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	20 (0.2)	59 (0.5)	79 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107020101.sas 10JUN2021 12:49

Table 14.3.1.7.2.1.1
Summary of Unsolicited TEAE by Age Group up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	1063 (28.3)	1237 (32.8)	2300 (30.6)
Serious	50 (1.3)	39 (1.0)	89 (1.2)
Fatal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Medically-Attended	521 (13.9)	508 (13.5)	1029 (13.7)
Leading to Discontinuation from Study Vaccine	22 (0.6)	12 (0.3)	34 (0.5)
Leading to Discontinuation from Participation in the Study	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	81 (2.2)	81 (2.1)	162 (2.2)
Unsolicited TEAEs Related to Study Vaccination			
All	291 (7.8)	487 (12.9)	778 (10.3)
Serious	1 (<0.1)	2 (<0.1)	3 (<0.1)
Fatal	0	0	0
Medically-Attended	17 (0.5)	37 (1.0)	54 (0.7)
Leading to Discontinuation from Study Vaccine	6 (0.2)	3 (<0.1)	9 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	11 (0.3)	24 (0.6)	35 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
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Table 14.3.1.7.2.1.3
Summary of Unsolicited TEAE by Age Group in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	4909 (43.0)	4639 (40.6)	9548 (41.8)
Serious	168 (1.5)	150 (1.3)	318 (1.4)
Fatal	10 (<0.1)	8 (<0.1)	18 (<0.1)
Medically-Attended	3089 (27.1)	2457 (21.5)	5546 (24.3)
Leading to Discontinuation from Study Vaccine	82 (0.7)	59 (0.5)	141 (0.6)
Leading to Discontinuation from Participation in the Study	15 (0.1)	15 (0.1)	30 (0.1)
Severe	319 (2.8)	304 (2.7)	623 (2.7)
Unsolicited TEAEs Related to Study Vaccination			
All	986 (8.6)	1610 (14.1)	2596 (11.4)
Serious	2 (<0.1)	9 (<0.1)	11 (<0.1)
Fatal	0	0	0
Medically-Attended	89 (0.8)	172 (1.5)	261 (1.1)
Leading to Discontinuation from Study Vaccine	8 (<0.1)	17 (0.1)	25 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	23 (0.2)	62 (0.5)	85 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107020103.sas 10JUN2021 12:49

Table 14.3.1.7.2.1.3
Summary of Unsolicited TEAE by Age Group in Overall Stage
Safety Set

Age Group: >=65 Years

	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	1604 (42.8)	1671 (44.3)	3275 (43.6)
Serious	124 (3.3)	118 (3.1)	242 (3.2)
Fatal	6 (0.2)	9 (0.2)	15 (0.2)
Medically-Attended	1042 (27.8)	1011 (26.8)	2053 (27.3)
Leading to Discontinuation from Study Vaccine	27 (0.7)	15 (0.4)	42 (0.6)
Leading to Discontinuation from Participation in the Study	8 (0.2)	11 (0.3)	19 (0.3)
Severe	167 (4.5)	157 (4.2)	324 (4.3)
Unsolicited TEAEs Related to Study Vaccination			
All	302 (8.1)	497 (13.2)	799 (10.6)
Serious	2 (<0.1)	3 (<0.1)	5 (<0.1)
Fatal	0	0	0
Medically-Attended	20 (0.5)	41 (1.1)	61 (0.8)
Leading to Discontinuation from Study Vaccine	7 (0.2)	3 (<0.1)	10 (0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	11 (0.3)	26 (0.7)	37 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030107020103.sas 10JUN2021 12:49

Table 14.3.1.7.3.1
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Total (N=29491) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	4233 (28.7)	4652 (31.5)	8885 (30.1)
Serious	101 (0.7)	96 (0.7)	197 (0.7)
Fatal	2 (<0.1)	2 (<0.1)	4 (<0.1)
Medically-Attended	1902 (12.9)	1782 (12.1)	3684 (12.5)
Leading to Discontinuation from Study Vaccine	84 (0.6)	54 (0.4)	138 (0.5)
Leading to Discontinuation from Participation in the Study	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	225 (1.5)	256 (1.7)	481 (1.6)
Unsolicited TEAEs Related to Study Vaccination			
All	1201 (8.1)	2032 (13.8)	3233 (11.0)
Serious	3 (<0.1)	8 (<0.1)	11 (<0.1)
Fatal	0	0	0
Medically-Attended	90 (0.6)	197 (1.3)	287 (1.0)
Leading to Discontinuation from Study Vaccine	14 (<0.1)	20 (0.1)	34 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	30 (0.2)	83 (0.6)	113 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301070301.sas 10JUN2021 12:49

Table 14.3.1.7.3.1
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	92 (27.3)	77 (22.2)	169 (24.7)
Serious	3 (0.9)	1 (0.3)	4 (0.6)
Fatal	0	0	0
Medically-Attended	35 (10.4)	25 (7.2)	60 (8.8)
Leading to Discontinuation from Study Vaccine	8 (2.4)	6 (1.7)	14 (2.0)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	7 (2.1)	1 (0.3)	8 (1.2)
Unsolicited TEAEs Related to Study Vaccination			
All	30 (8.9)	30 (8.6)	60 (8.8)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (1.5)	1 (0.3)	6 (0.9)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.3)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301070301.sas 10JUN2021 12:49

Table 14.3.1.7.3.1
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	13 (15.5)	23 (26.4)	36 (21.1)
Serious	0	1 (1.1)	1 (0.6)
Fatal	0	0	0
Medically-Attended	3 (3.6)	12 (13.8)	15 (8.8)
Leading to Discontinuation from Study Vaccine	0	1 (1.1)	1 (0.6)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (1.2)	1 (1.1)	2 (1.2)
Unsolicited TEAEs Related to Study Vaccination			
All	5 (6.0)	5 (5.7)	10 (5.8)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	0	0
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301070301.sas 10JUN2021 12:49

Table 14.3.1.7.3.3
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Total (N=29491) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	6359 (43.1)	6175 (41.9)	12534 (42.5)
Serious	285 (1.9)	266 (1.8)	551 (1.9)
Fatal	16 (0.1)	17 (0.1)	33 (0.1)
Medically-Attended	4054 (27.5)	3397 (23.0)	7451 (25.3)
Leading to Discontinuation from Study Vaccine	101 (0.7)	67 (0.5)	168 (0.6)
Leading to Discontinuation from Participation in the Study	23 (0.2)	26 (0.2)	49 (0.2)
Severe	472 (3.2)	457 (3.1)	929 (3.2)
Unsolicited TEAEs Related to Study Vaccination			
All	1253 (8.5)	2072 (14.0)	3325 (11.3)
Serious	4 (<0.1)	12 (<0.1)	16 (<0.1)
Fatal	0	0	0
Medically-Attended	104 (0.7)	212 (1.4)	316 (1.1)
Leading to Discontinuation from Study Vaccine	15 (0.1)	20 (0.1)	35 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	33 (0.2)	88 (0.6)	121 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301070303.sas 21JUN2021 14:26

Table 14.3.1.7.3.3
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Total (N=684) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	131 (38.9)	105 (30.3)	236 (34.5)
Serious	7 (2.1)	1 (0.3)	8 (1.2)
Fatal	0	0	0
Medically-Attended	65 (19.3)	51 (14.7)	116 (17.0)
Leading to Discontinuation from Study Vaccine	8 (2.4)	6 (1.7)	14 (2.0)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	12 (3.6)	3 (0.9)	15 (2.2)
Unsolicited TEAEs Related to Study Vaccination			
All	30 (8.9)	30 (8.6)	60 (8.8)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (1.5)	1 (0.3)	6 (0.9)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (0.3)	0	1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301070303.sas 21JUN2021 14:26

Table 14.3.1.7.3.3
Summary of Unsolicited TEAE by Baseline SARS-CoV-2 Status in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Missing

	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Total (N=171) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	23 (27.4)	30 (34.5)	53 (31.0)
Serious	0	1 (1.1)	1 (0.6)
Fatal	0	0	0
Medically-Attended	12 (14.3)	20 (23.0)	32 (18.7)
Leading to Discontinuation from Study Vaccine	0	1 (1.1)	1 (0.6)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	2 (2.4)	1 (1.1)	3 (1.8)
Unsolicited TEAEs Related to Study Vaccination			
All	5 (6.0)	5 (5.7)	10 (5.8)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	0	0	0
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301070303.sas 21JUN2021 14:26

Table 14.3.1.23.1.1
Summary of Unsolicited Non-Serious TEAE up to 28 Days After Any Injection
Safety Set

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	4294 (28.3)	4716 (31.1)	9010 (29.7)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	1884 (12.4)	1766 (11.6)	3650 (12.0)
Leading to Discontinuation from Study Vaccine	77 (0.5)	48 (0.3)	125 (0.4)
Leading to Discontinuation from Participation in the Study	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	186 (1.2)	225 (1.5)	411 (1.4)
Unsolicited TEAEs Related to Study Vaccination			
All	1234 (8.1)	2062 (13.6)	3296 (10.9)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	92 (0.6)	193 (1.3)	285 (0.9)
Leading to Discontinuation from Study Vaccine	13 (<0.1)	19 (0.1)	32 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	30 (0.2)	82 (0.5)	112 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301230101.sas 21JUN2021 14:59

Table 14.3.1.23.1.3
Summary of Unsolicited Non-Serious TEAE in Overall Stage
Safety Set

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	6429 (42.4)	6230 (41.0)	12659 (41.7)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	4018 (26.5)	3356 (22.1)	7374 (24.3)
Leading to Discontinuation from Study Vaccine	91 (0.6)	58 (0.4)	149 (0.5)
Leading to Discontinuation from Participation in the Study	5 (<0.1)	4 (<0.1)	9 (<0.1)
Severe	368 (2.4)	365 (2.4)	733 (2.4)
Unsolicited TEAEs Related to Study Vaccination			
All	1286 (8.5)	2101 (13.8)	3387 (11.2)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	106 (0.7)	207 (1.4)	313 (1.0)
Leading to Discontinuation from Study Vaccine	13 (<0.1)	19 (0.1)	32 (0.1)
Leading to Discontinuation from Participation in the Study	0	1 (<0.1)	1 (<0.1)
Severe	33 (0.2)	85 (0.6)	118 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301230103.sas 21JUN2021 14:59

Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4338 (28.6)	4752 (31.3)		9090 (30.0)
Number of Unsolicited Adverse Events	8599	9541		18140
Infections and infestations	952 (6.3)	783 (5.2)		1735 (5.7)
Urinary tract infection	112 (0.7)	94 (0.6)	0.84 (0.64, 1.10)	206 (0.7)
Upper respiratory tract infection	118 (0.8)	82 (0.5)	0.69 (0.52, 0.92)	200 (0.7)
Sinusitis	46 (0.3)	61 (0.4)	1.32 (0.91, 1.94)	107 (0.4)
Viral infection	52 (0.3)	41 (0.3)	0.79 (0.52, 1.18)	93 (0.3)
Rhinovirus infection	30 (0.2)	36 (0.2)	1.20 (0.74, 1.94)	66 (0.2)
Suspected COVID-19	35 (0.2)	34 (0.2)	0.97 (0.61, 1.55)	69 (0.2)
Tooth infection	18 (0.1)	26 (0.2)	1.44 (0.80, 2.61)	44 (0.1)
Tooth abscess	26 (0.2)	23 (0.2)	0.88 (0.51, 1.54)	49 (0.2)
COVID-19	156 (1.0)	22 (0.1)	0.14 (0.09, 0.22)	178 (0.6)
Herpes zoster	15 (<0.1)	22 (0.1)	1.46 (0.77, 2.79)	37 (0.1)
Gastroenteritis	17 (0.1)	19 (0.1)	1.12 (0.59, 2.12)	36 (0.1)
Pharyngitis	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Ear infection	10 (<0.1)	18 (0.1)	1.80 (0.85, 3.82)	28 (<0.1)
Conjunctivitis	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Pharyngitis streptococcal	21 (0.1)	13 (<0.1)	0.62 (0.31, 1.22)	34 (0.1)
Cellulitis	17 (0.1)	12 (<0.1)	0.70 (0.34, 1.45)	29 (<0.1)
Hordeolum	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Oral herpes	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080101.sas 10JUN2021 07:58

Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Viral upper respiratory tract infection	14 (<0.1)	11 (<0.1)	0.78 (0.36, 1.69)	25 (<0.1)
Diverticulitis	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Fungal infection	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Gingivitis	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Herpes simplex	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Otitis media	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Bronchitis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Localised infection	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Onychomycosis	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Folliculitis	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Otitis externa	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Paronychia	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Acute sinusitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Bacterial vaginosis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vulvovaginal mycotic infection	14 (<0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Abscess limb	1 (<0.1)	5 (<0.1)		6 (<0.1)
Asymptomatic COVID-19	3 (<0.1)	5 (<0.1)		8 (<0.1)
Nasopharyngitis	12 (<0.1)	5 (<0.1)	0.42 (0.15, 1.13)	17 (<0.1)
Pneumonia	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Subcutaneous abscess	2 (<0.1)	5 (<0.1)		7 (<0.1)
Enterovirus infection	2 (<0.1)	4 (<0.1)		6 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080101.sas 10JUN2021 07:58

Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Laryngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Skin infection	4 (<0.1)	4 (<0.1)		8 (<0.1)
Staphylococcal infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Clostridium difficile infection	0	3 (<0.1)		3 (<0.1)
Cystitis	11 (<0.1)	3 (<0.1)	0.27 (0.08, 0.91)	14 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	10 (<0.1)	3 (<0.1)	0.30 (0.09, 1.01)	13 (<0.1)
Helicobacter infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis media acute	2 (<0.1)	2 (<0.1)		4 (<0.1)
Respiratory tract infection viral	5 (<0.1)	2 (<0.1)		7 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea pedis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Tonsillitis	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080101.sas 10JUN2021 07:58

Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Candida infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080101.sas 10JUN2021 07:58

Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rhinitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Tinea cruris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Wound infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	2 (<0.1)	0		2 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Sinusitis bacterial	2 (<0.1)	0		2 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	56 (0.4)	62 (0.4)		118 (0.4)
Basal cell carcinoma	16 (0.1)	10 (<0.1)	0.62 (0.29, 1.35)	26 (<0.1)
Benign neoplasm of skin	2 (<0.1)	4 (<0.1)		6 (<0.1)
Squamous cell carcinoma	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Uterine leiomyoma	1 (<0.1)	4 (<0.1)		5 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lipoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)		5 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	148 (1.0)	292 (1.9)		440 (1.4)
Lymphadenopathy	127 (0.8)	264 (1.7)	2.08 (1.68, 2.56)	391 (1.3)
Anaemia	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Lymph node pain	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)				
Lymphadenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Iron deficiency anaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	66 (0.4)	47 (0.3)		113 (0.4)
Seasonal allergy	47 (0.3)	33 (0.2)	0.70 (0.45, 1.09)	80 (0.3)
Hypersensitivity	6 (<0.1)	6 (<0.1)		12 (<0.1)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	5 (<0.1)	1 (<0.1)		6 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	0		2 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Endocrine disorders	17 (0.1)	12 (<0.1)		29 (<0.1)
Hypothyroidism	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	113 (0.7)	128 (0.8)		241 (0.8)
Hyperlipidaemia	21 (0.1)	23 (0.2)	1.09 (0.61, 1.96)	44 (0.1)
Type 2 diabetes mellitus	11 (<0.1)	21 (0.1)	1.91 (0.93, 3.89)	32 (0.1)
Hypercholesterolaemia	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Vitamin D deficiency	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Decreased appetite	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Dehydration	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Gout	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Diabetes mellitus	5 (<0.1)	6 (<0.1)		11 (<0.1)
Glucose tolerance impaired	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Hyperglycaemia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Abnormal loss of weight	0	2 (<0.1)		2 (<0.1)
Hypoglycaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypocalcaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)

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Metabolism and nutrition disorders (Cont.)				
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	116 (0.8)	159 (1.0)		275 (0.9)
Anxiety	38 (0.3)	52 (0.3)	1.37 (0.90, 2.07)	90 (0.3)
Depression	29 (0.2)	35 (0.2)	1.21 (0.74, 1.96)	64 (0.2)
Insomnia	24 (0.2)	32 (0.2)	1.33 (0.79, 2.25)	56 (0.2)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)
Panic attack	3 (<0.1)	4 (<0.1)		7 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)		4 (<0.1)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress	1 (<0.1)	2 (<0.1)		3 (<0.1)
Suicidal ideation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	3 (<0.1)	0		3 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders	881 (5.8)	1008 (6.6)		1889 (6.2)
Headache	687 (4.5)	744 (4.9)	1.08 (0.98, 1.20)	1431 (4.7)
Dizziness	56 (0.4)	74 (0.5)	1.32 (0.93, 1.86)	130 (0.4)
Paraesthesia	27 (0.2)	34 (0.2)	1.26 (0.76, 2.07)	61 (0.2)
Sinus headache	6 (<0.1)	20 (0.1)	3.33 (1.38, 8.05)	26 (<0.1)
Ageusia	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Migraine	24 (0.2)	15 (<0.1)	0.62 (0.33, 1.18)	39 (0.1)
Hypoaesthesia	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Dysgeusia	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Syncope	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Sciatica	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Anosmia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Cervical radiculopathy	1 (<0.1)	8 (<0.1)	7.99 (1.30, 49.20)	9 (<0.1)
Tension headache	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Hyperaesthesia	0	6 (<0.1)		6 (<0.1)
Presyncope	14 (<0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Carpal tunnel syndrome	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Memory impairment	0	4 (<0.1)		4 (<0.1)
Burning sensation	0	3 (<0.1)		3 (<0.1)
Cerebrovascular accident	0	3 (<0.1)		3 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Nerve compression	3 (<0.1)	3 (<0.1)		6 (<0.1)
Peripheral sensory neuropathy	0	3 (<0.1)		3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	3 (<0.1)		5 (<0.1)
Amnesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neuropathy peripheral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Parosmia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Post-traumatic headache	1 (<0.1)	2 (<0.1)		3 (<0.1)
Somnolence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	3 (<0.1)	0		3 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	67 (0.4)	70 (0.5)		137 (0.5)
Eye irritation	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Eye pruritus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Vision blurred	3 (<0.1)	6 (<0.1)		9 (<0.1)
Dry eye	6 (<0.1)	4 (<0.1)		10 (<0.1)
Eye pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Eye inflammation	0	3 (<0.1)		3 (<0.1)
Glaucoma	4 (<0.1)	3 (<0.1)		7 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Retinal detachment	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blepharitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular hyperaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vitreous floaters	2 (<0.1)	2 (<0.1)		4 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cataract	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Visual impairment	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Ear and labyrinth disorders	83 (0.5)	81 (0.5)		164 (0.5)
Vertigo	18 (0.1)	23 (0.2)	1.28 (0.70, 2.34)	41 (0.1)
Ear pain	18 (0.1)	17 (0.1)	0.94 (0.49, 1.81)	35 (0.1)
Tinnitus	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Vertigo positional	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Cerumen impaction	2 (<0.1)	4 (<0.1)		6 (<0.1)
Ear discomfort	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ear canal erythema	4 (<0.1)	2 (<0.1)		6 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ear congestion	4 (<0.1)	1 (<0.1)		5 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tympanic membrane perforation	6 (<0.1)	1 (<0.1)		7 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	3 (<0.1)	0		3 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	75 (0.5)	79 (0.5)		154 (0.5)
Tachycardia	9 (<0.1)	15 (<0.1)	1.66 (0.74, 3.72)	24 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Bradycardia	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Atrial fibrillation	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Palpitations	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Angina pectoris	4 (<0.1)	5 (<0.1)		9 (<0.1)
Arrhythmia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Cardiac failure congestive	4 (<0.1)	4 (<0.1)		8 (<0.1)
Coronary artery disease	4 (<0.1)	3 (<0.1)		7 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Sinus tachycardia	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Atrial flutter	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)		4 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	204 (1.3)	198 (1.3)		402 (1.3)
Hypertension	161 (1.1)	153 (1.0)	0.95 (0.76, 1.18)	314 (1.0)
Hot flush	8 (<0.1)	15 (<0.1)	1.87 (0.81, 4.31)	23 (<0.1)
Flushing	5 (<0.1)	6 (<0.1)		11 (<0.1)
Haematoma	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hypertensive urgency	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hypotension	4 (<0.1)	4 (<0.1)		8 (<0.1)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Orthostatic hypotension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders (Cont.)				
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	667 (4.4)	603 (4.0)		1270 (4.2)
Cough	165 (1.1)	177 (1.2)	1.07 (0.87, 1.32)	342 (1.1)
Oropharyngeal pain	232 (1.5)	158 (1.0)	0.68 (0.56, 0.83)	390 (1.3)
Nasal congestion	165 (1.1)	155 (1.0)	0.94 (0.75, 1.17)	320 (1.1)
Rhinorrhoea	145 (1.0)	130 (0.9)	0.90 (0.71, 1.13)	275 (0.9)
Dyspnoea	41 (0.3)	43 (0.3)	1.05 (0.69, 1.60)	84 (0.3)
Tachypnoea	32 (0.2)	33 (0.2)	1.03 (0.64, 1.67)	65 (0.2)
Respiratory tract congestion	7 (<0.1)	18 (0.1)	2.57 (1.10, 5.99)	25 (<0.1)
Asthma	17 (0.1)	16 (0.1)	0.94 (0.48, 1.84)	33 (0.1)
Epistaxis	11 (<0.1)	16 (0.1)	1.45 (0.69, 3.07)	27 (<0.1)
Sinus congestion	26 (0.2)	16 (0.1)	0.61 (0.33, 1.13)	42 (0.1)
Throat irritation	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Rhinitis allergic	15 (<0.1)	12 (<0.1)	0.80 (0.38, 1.68)	27 (<0.1)
Upper-airway cough syndrome	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Sneezing	14 (<0.1)	11 (<0.1)	0.78 (0.36, 1.69)	25 (<0.1)
Chronic obstructive pulmonary disease	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Dysphonia	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pharyngeal erythema	3 (<0.1)	5 (<0.1)		8 (<0.1)
Sinus pain	4 (<0.1)	5 (<0.1)		9 (<0.1)
Dry throat	3 (<0.1)	4 (<0.1)		7 (<0.1)
Dyspnoea exertional	1 (<0.1)	4 (<0.1)		5 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)		7 (<0.1)
Productive cough	6 (<0.1)	4 (<0.1)		10 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Pleural effusion	4 (<0.1)	3 (<0.1)		7 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)
Wheezing	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acute respiratory failure	3 (<0.1)	2 (<0.1)		5 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory failure	0	2 (<0.1)		2 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	4 (<0.1)	1 (<0.1)		5 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	567 (3.7)	599 (3.9)		1166 (3.8)
Diarrhoea	199 (1.3)	204 (1.3)	1.02 (0.84, 1.24)	403 (1.3)
Nausea	164 (1.1)	162 (1.1)	0.99 (0.80, 1.22)	326 (1.1)
Vomiting	53 (0.3)	62 (0.4)	1.17 (0.81, 1.68)	115 (0.4)
Gastrooesophageal reflux disease	29 (0.2)	41 (0.3)	1.41 (0.88, 2.26)	70 (0.2)
Toothache	28 (0.2)	35 (0.2)	1.25 (0.76, 2.04)	63 (0.2)
Abdominal pain	20 (0.1)	26 (0.2)	1.30 (0.73, 2.31)	46 (0.2)
Constipation	21 (0.1)	16 (0.1)	0.76 (0.40, 1.44)	37 (0.1)
Dental caries	11 (<0.1)	15 (<0.1)	1.36 (0.64, 2.91)	26 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal pain upper	20 (0.1)	14 (<0.1)	0.70 (0.36, 1.37)	34 (0.1)
Dyspepsia	16 (0.1)	14 (<0.1)	0.87 (0.43, 1.76)	30 (<0.1)
Food poisoning	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Abdominal pain lower	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Abdominal discomfort	13 (<0.1)	6 (<0.1)	0.46 (0.18, 1.17)	19 (<0.1)
Colitis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Gastric ulcer	2 (<0.1)	5 (<0.1)		7 (<0.1)
Haemorrhoids	4 (<0.1)	5 (<0.1)		9 (<0.1)
Inguinal hernia	4 (<0.1)	5 (<0.1)		9 (<0.1)
Abdominal distension	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hiatus hernia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Flatulence	2 (<0.1)	3 (<0.1)		5 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)		4 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Large intestine polyp	5 (<0.1)	3 (<0.1)		8 (<0.1)
Paraesthesia oral	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tooth impacted	2 (<0.1)	3 (<0.1)		5 (<0.1)
Umbilical hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Dysphagia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastritis	5 (<0.1)	2 (<0.1)		7 (<0.1)
Gastrointestinal disorder	0	2 (<0.1)		2 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)		4 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)
Proctalgia	0	2 (<0.1)		2 (<0.1)
Rectal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small intestinal obstruction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0		2 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	5 (<0.1)	0		5 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	5 (<0.1)	13 (<0.1)		18 (<0.1)
Cholelithiasis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Hepatic steatosis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)				
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	235 (1.5)	295 (1.9)		530 (1.7)
Urticaria	33 (0.2)	44 (0.3)	1.33 (0.85, 2.08)	77 (0.3)
Rash	31 (0.2)	35 (0.2)	1.13 (0.70, 1.82)	66 (0.2)
Pruritus	23 (0.2)	25 (0.2)	1.09 (0.62, 1.90)	48 (0.2)
Dermatitis contact	31 (0.2)	24 (0.2)	0.77 (0.46, 1.31)	55 (0.2)
Erythema	5 (<0.1)	15 (<0.1)	3.00 (1.13, 7.93)	20 (<0.1)
Hyperhidrosis	11 (<0.1)	13 (<0.1)	1.18 (0.54, 2.58)	24 (<0.1)
Eczema	3 (<0.1)	10 (<0.1)	3.33 (0.99, 11.21)	13 (<0.1)
Night sweats	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Acne	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Dermatitis	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Rash maculo-papular	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Rash papular	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Alopecia	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Rash macular	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Actinic keratosis	2 (<0.1)	6 (<0.1)		8 (<0.1)
Dermatitis atopic	6 (<0.1)	5 (<0.1)		11 (<0.1)
Ecchymosis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Psoriasis	1 (<0.1)	5 (<0.1)		6 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash pruritic	6 (<0.1)	5 (<0.1)		11 (<0.1)
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)
Rosacea	2 (<0.1)	4 (<0.1)		6 (<0.1)
Blister	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dry skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hidradenitis	0	3 (<0.1)		3 (<0.1)
Macule	0	3 (<0.1)		3 (<0.1)
Pain of skin	0	3 (<0.1)		3 (<0.1)
Rash erythematous	3 (<0.1)	3 (<0.1)		6 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Angioedema	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hand dermatitis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Papule	2 (<0.1)	1 (<0.1)		3 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	4 (<0.1)	0		4 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	1017 (6.7)	1007 (6.6)		2024 (6.7)
Arthralgia	389 (2.6)	391 (2.6)	1.00 (0.87, 1.15)	780 (2.6)
Myalgia	388 (2.6)	387 (2.5)	1.00 (0.87, 1.14)	775 (2.6)
Back pain	130 (0.9)	106 (0.7)	0.81 (0.63, 1.05)	236 (0.8)
Pain in extremity	77 (0.5)	67 (0.4)	0.87 (0.63, 1.20)	144 (0.5)
Musculoskeletal pain	38 (0.3)	49 (0.3)	1.29 (0.85, 1.96)	87 (0.3)
Neck pain	38 (0.3)	46 (0.3)	1.21 (0.79, 1.85)	84 (0.3)
Muscle spasms	29 (0.2)	35 (0.2)	1.21 (0.74, 1.96)	64 (0.2)
Osteoarthritis	28 (0.2)	23 (0.2)	0.82 (0.48, 1.41)	51 (0.2)
Musculoskeletal chest pain	14 (<0.1)	15 (<0.1)	1.07 (0.52, 2.18)	29 (<0.1)
Tendonitis	13 (<0.1)	15 (<0.1)	1.15 (0.56, 2.38)	28 (<0.1)
Bursitis	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Musculoskeletal stiffness	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Rotator cuff syndrome	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Arthritis	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Intervertebral disc protrusion	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Trigger finger	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Groin pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Joint swelling	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Muscle tightness	1 (<0.1)	6 (<0.1)		7 (<0.1)
Muscular weakness	2 (<0.1)	6 (<0.1)		8 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Limb discomfort	2 (<0.1)	5 (<0.1)		7 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Costochondritis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Fibromyalgia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Osteoporosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pain in jaw	6 (<0.1)	4 (<0.1)		10 (<0.1)
Spinal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Spinal stenosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Flank pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Muscle twitching	3 (<0.1)	3 (<0.1)		6 (<0.1)
Neck mass	0	3 (<0.1)		3 (<0.1)
Spinal osteoarthritis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Axillary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Temporomandibular joint syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	4 (<0.1)	1 (<0.1)		5 (<0.1)
Joint stiffness	3 (<0.1)	1 (<0.1)		4 (<0.1)
Limb mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	3 (<0.1)	0		3 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	2 (<0.1)	0		2 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	46 (0.3)	50 (0.3)		96 (0.3)
Nephrolithiasis	21 (0.1)	14 (<0.1)	0.67 (0.34, 1.29)	35 (0.1)
Dysuria	1 (<0.1)	5 (<0.1)		6 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Haematuria	6 (<0.1)	3 (<0.1)		9 (<0.1)
Pollakiuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Polyuria	0	3 (<0.1)		3 (<0.1)
Acute kidney injury	4 (<0.1)	2 (<0.1)		6 (<0.1)
Chronic kidney disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertonic bladder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nocturia	0	2 (<0.1)		2 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary incontinence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary retention	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chromaturia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	2 (<0.1)	0		2 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	59 (0.4)	61 (0.4)		120 (0.4)
Benign prostatic hyperplasia	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Dysmenorrhoea	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Erectile dysfunction	3 (<0.1)	5 (<0.1)		8 (<0.1)
Pelvic pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Prostatitis	6 (<0.1)	3 (<0.1)		9 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Menopausal symptoms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1065 (7.0)	1606 (10.6)		2671 (8.8)
Fatigue	666 (4.4)	752 (5.0)	1.13 (1.02, 1.25)	1418 (4.7)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site pain	118 (0.8)	258 (1.7)	2.18 (1.76, 2.71)	376 (1.2)
Injection site erythema	39 (0.3)	157 (1.0)	4.02 (2.84, 5.69)	196 (0.6)
Chills	111 (0.7)	131 (0.9)	1.18 (0.92, 1.51)	242 (0.8)
Pyrexia	62 (0.4)	118 (0.8)	1.90 (1.40, 2.58)	180 (0.6)
Injection site swelling	29 (0.2)	115 (0.8)	3.96 (2.64, 5.93)	144 (0.5)
Injection site pruritus	13 (<0.1)	88 (0.6)	6.76 (3.81, 12.00)	101 (0.3)
Pain	66 (0.4)	72 (0.5)	1.09 (0.78, 1.52)	138 (0.5)
Injection site lymphadenopathy	15 (<0.1)	66 (0.4)	4.39 (2.53, 7.64)	81 (0.3)
Injection site induration	18 (0.1)	53 (0.3)	2.94 (1.73, 4.99)	71 (0.2)
Injection site macule	4 (<0.1)	45 (0.3)	11.23 (4.21, 30.01)	49 (0.2)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.94 (6.58, 218.91)	39 (0.1)
Axillary pain	14 (<0.1)	26 (0.2)	1.85 (0.98, 3.51)	40 (0.1)
Injection site rash	1 (<0.1)	24 (0.2)	23.97 (4.11, 139.71)	25 (<0.1)
Injection site bruising	21 (0.1)	18 (0.1)	0.86 (0.46, 1.59)	39 (0.1)
Malaise	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	12.98 (2.18, 77.49)	14 (<0.1)
Chest discomfort	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Chest pain	5 (<0.1)	10 (<0.1)	2.00 (0.71, 5.58)	15 (<0.1)
Peripheral swelling	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Non-cardiac chest pain	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Reactogenicity event	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Feeling hot	3 (<0.1)	6 (<0.1)		9 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haemorrhage	5 (<0.1)	6 (<0.1)		11 (<0.1)
Injection site paraesthesia	3 (<0.1)	6 (<0.1)		9 (<0.1)
Oedema peripheral	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Feeling abnormal	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Vaccination site pain	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site reaction	0	3 (<0.1)		3 (<0.1)
Swelling face	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Hangover	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Asthenia	5 (<0.1)	1 (<0.1)		6 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)

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General disorders and administration site conditions (Cont.)				
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Xerosis	1 (<0.1)	0		1 (<0.1)
Investigations	80 (0.5)	107 (0.7)		187 (0.6)
Blood pressure increased	27 (0.2)	25 (0.2)	0.92 (0.54, 1.58)	52 (0.2)
Blood pressure systolic increased	9 (<0.1)	15 (<0.1)	1.66 (0.74, 3.72)	24 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	10 (<0.1)	4.99 (1.23, 20.26)	12 (<0.1)
Body temperature increased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood cholesterol increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Heart rate increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hepatic enzyme increased	4 (<0.1)	4 (<0.1)		8 (<0.1)
Transaminases increased	0	4 (<0.1)		4 (<0.1)
Blood glucose increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood triglycerides increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Weight decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Investigations (Cont.)				
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	2 (<0.1)	0		2 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	397 (2.6)	331 (2.2)		728 (2.4)
Muscle strain	35 (0.2)	39 (0.3)	1.11 (0.71, 1.75)	74 (0.2)
Ligament sprain	29 (0.2)	30 (0.2)	1.03 (0.62, 1.71)	59 (0.2)
Arthropod bite	31 (0.2)	24 (0.2)	0.77 (0.46, 1.31)	55 (0.2)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin laceration	32 (0.2)	23 (0.2)	0.72 (0.42, 1.22)	55 (0.2)
Fall	27 (0.2)	21 (0.1)	0.78 (0.44, 1.36)	48 (0.2)
Contusion	29 (0.2)	20 (0.1)	0.69 (0.39, 1.21)	49 (0.2)
Procedural pain	31 (0.2)	18 (0.1)	0.58 (0.33, 1.03)	49 (0.2)
Tooth fracture	17 (0.1)	17 (0.1)	1.00 (0.52, 1.93)	34 (0.1)
Road traffic accident	7 (<0.1)	13 (<0.1)	1.85 (0.76, 4.51)	20 (<0.1)
Foot fracture	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Limb injury	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Skin abrasion	22 (0.1)	11 (<0.1)	0.50 (0.25, 1.01)	33 (0.1)
Arthropod sting	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (<0.1)
Joint injury	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Animal bite	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Meniscus injury	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Post-traumatic pain	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Concussion	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hand fracture	3 (<0.1)	5 (<0.1)		8 (<0.1)
Rib fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Head injury	1 (<0.1)	4 (<0.1)		5 (<0.1)
Wrist fracture	4 (<0.1)	4 (<0.1)		8 (<0.1)
Bone contusion	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Epicondylitis	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tendon rupture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Thermal burn	3 (<0.1)	3 (<0.1)		6 (<0.1)
Upper limb fracture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Ankle fracture	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Back injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	2 (<0.1)	1 (<0.1)		3 (<0.1)
Wound	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	2 (<0.1)	0		2 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Lip injury	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	5 (<0.1)		8 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with HIV
Safety Set

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	38 (41.8)	35 (37.2)		73 (39.5)
Number of Unsolicited Adverse Events	110	76		186
Infections and infestations	6 (6.6)	6 (6.4)		12 (6.5)
Gingivitis	0	1 (1.1)		1 (0.5)
Herpes simplex	0	1 (1.1)		1 (0.5)
Nail infection	0	1 (1.1)		1 (0.5)
Suspected COVID-19	0	1 (1.1)		1 (0.5)
Tooth infection	0	1 (1.1)		1 (0.5)
Upper respiratory tract infection	1 (1.1)	1 (1.1)		2 (1.1)
COVID-19	2 (2.2)	0		2 (1.1)
Cellulitis	1 (1.1)	0		1 (0.5)
Cystitis	1 (1.1)	0		1 (0.5)
Otitis externa	1 (1.1)	0		1 (0.5)
Sepsis	1 (1.1)	0		1 (0.5)
Viral infection	1 (1.1)	0		1 (0.5)
Viral upper respiratory tract infection	1 (1.1)	0		1 (0.5)
Immune system disorders	2 (2.2)	0		2 (1.1)
Seasonal allergy	2 (2.2)	0		2 (1.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with HIV
Safety Set

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Metabolism and nutrition disorders	3 (3.3)	3 (3.2)		6 (3.2)
Abnormal loss of weight	0	1 (1.1)		1 (0.5)
Hyperlipidaemia	0	1 (1.1)		1 (0.5)
Hypoferritinaemia	0	1 (1.1)		1 (0.5)
Dyslipidaemia	1 (1.1)	0		1 (0.5)
Electrolyte imbalance	1 (1.1)	0		1 (0.5)
Hypercholesterolaemia	1 (1.1)	0		1 (0.5)
Hypocalcaemia	1 (1.1)	0		1 (0.5)
Hypoglycaemia	1 (1.1)	0		1 (0.5)
Hypokalaemia	1 (1.1)	0		1 (0.5)
Hypomagnesaemia	1 (1.1)	0		1 (0.5)
Psychiatric disorders	4 (4.4)	3 (3.2)		7 (3.8)
Anxiety	1 (1.1)	1 (1.1)		2 (1.1)
Insomnia	0	1 (1.1)		1 (0.5)
Nightmare	0	1 (1.1)		1 (0.5)
Agitation	1 (1.1)	0		1 (0.5)
Depression	1 (1.1)	0		1 (0.5)
Mental status changes	1 (1.1)	0		1 (0.5)
Schizophrenia	1 (1.1)	0		1 (0.5)
Nervous system disorders	11 (12.1)	7 (7.4)		18 (9.7)
Headache	8 (8.8)	5 (5.3)	0.61 (0.21, 1.70)	13 (7.0)
Ageusia	1 (1.1)	1 (1.1)		2 (1.1)
Dizziness	1 (1.1)	1 (1.1)		2 (1.1)

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Table 14.3.1.8.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with HIV
Safety Set

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Nervous system disorders (Cont.)				
Anosmia	1 (1.1)	0		1 (0.5)
Encephalopathy	1 (1.1)	0		1 (0.5)
Lethargy	1 (1.1)	0		1 (0.5)
Paraesthesia	1 (1.1)	0		1 (0.5)
Eye disorders	2 (2.2)	1 (1.1)		3 (1.6)
Eye pain	0	1 (1.1)		1 (0.5)
Eye pruritus	2 (2.2)	0		2 (1.1)
Lacrimation increased	1 (1.1)	0		1 (0.5)
Ear and labyrinth disorders	1 (1.1)	0		1 (0.5)
Tinnitus	1 (1.1)	0		1 (0.5)
Cardiac disorders	0	2 (2.1)		2 (1.1)
Bradycardia	0	1 (1.1)		1 (0.5)
Sinus tachycardia	0	1 (1.1)		1 (0.5)
Vascular disorders	5 (5.5)	1 (1.1)		6 (3.2)
Hot flush	0	1 (1.1)		1 (0.5)
Deep vein thrombosis	1 (1.1)	0		1 (0.5)
Hypertension	2 (2.2)	0		2 (1.1)
Hypotension	1 (1.1)	0		1 (0.5)
Orthostatic hypotension	1 (1.1)	0		1 (0.5)

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Table 14.3.1.8.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with HIV
Safety Set

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Respiratory, thoracic and mediastinal disorders	8 (8.8)	10 (10.6)		18 (9.7)
Cough	0	2 (2.1)		2 (1.1)
Nasal congestion	0	2 (2.1)		2 (1.1)
Rhinorrhoea	0	2 (2.1)		2 (1.1)
Asthma	0	1 (1.1)		1 (0.5)
Dry throat	0	1 (1.1)		1 (0.5)
Dysphonia	0	1 (1.1)		1 (0.5)
Dyspnoea	1 (1.1)	1 (1.1)		2 (1.1)
Rhinitis allergic	1 (1.1)	1 (1.1)		2 (1.1)
Sinus congestion	0	1 (1.1)		1 (0.5)
Sneezing	0	1 (1.1)		1 (0.5)
Tachypnoea	0	1 (1.1)		1 (0.5)
Atelectasis	1 (1.1)	0		1 (0.5)
Oropharyngeal pain	4 (4.4)	0		4 (2.2)
Tonsillar inflammation	1 (1.1)	0		1 (0.5)
Wheezing	1 (1.1)	0		1 (0.5)
Gastrointestinal disorders	7 (7.7)	7 (7.4)		14 (7.6)
Nausea	0	3 (3.2)		3 (1.6)
Diarrhoea	5 (5.5)	2 (2.1)		7 (3.8)
Colitis	0	1 (1.1)		1 (0.5)
Dry mouth	0	1 (1.1)		1 (0.5)
Hiatus hernia	0	1 (1.1)		1 (0.5)
Pancreatitis	0	1 (1.1)		1 (0.5)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with HIV
Safety Set

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Gastrointestinal disorders (Cont.)				
Dyspepsia	1 (1.1)	0		1 (0.5)
Dysphagia	1 (1.1)	0		1 (0.5)
Skin and subcutaneous tissue disorders	2 (2.2)	5 (5.3)		7 (3.8)
Acne	1 (1.1)	1 (1.1)		2 (1.1)
Hyperhidrosis	0	1 (1.1)		1 (0.5)
Pruritus	0	1 (1.1)		1 (0.5)
Rash pruritic	0	1 (1.1)		1 (0.5)
Urticaria	0	1 (1.1)		1 (0.5)
Blister	1 (1.1)	0		1 (0.5)
Musculoskeletal and connective tissue disorders	9 (9.9)	3 (3.2)		12 (6.5)
Arthralgia	3 (3.3)	2 (2.1)		5 (2.7)
Myalgia	3 (3.3)	2 (2.1)		5 (2.7)
Pain in extremity	2 (2.2)	1 (1.1)		3 (1.6)
Groin pain	1 (1.1)	0		1 (0.5)
Musculoskeletal pain	1 (1.1)	0		1 (0.5)
Osteoarthritis	1 (1.1)	0		1 (0.5)
Osteonecrosis	1 (1.1)	0		1 (0.5)
General disorders and administration site conditions	15 (16.5)	11 (11.7)		26 (14.1)
Fatigue	10 (11.0)	7 (7.4)	0.68 (0.28, 1.65)	17 (9.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080801.sas 10JUN2021 12:56

Table 14.3.1.8.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with HIV
Safety Set

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
General disorders and administration site conditions (Cont.)				
Chest pain	0	1 (1.1)		1 (0.5)
Chills	4 (4.4)	1 (1.1)		5 (2.7)
Injection site swelling	2 (2.2)	1 (1.1)		3 (1.6)
Pain	0	1 (1.1)		1 (0.5)
Chest discomfort	1 (1.1)	0		1 (0.5)
Injection site pruritus	1 (1.1)	0		1 (0.5)
Peripheral swelling	1 (1.1)	0		1 (0.5)
Pyrexia	1 (1.1)	0		1 (0.5)
Investigations	1 (1.1)	0		1 (0.5)
Blood pressure systolic increased	1 (1.1)	0		1 (0.5)
Injury, poisoning and procedural complications	2 (2.2)	1 (1.1)		3 (1.6)
Arthropod bite	0	1 (1.1)		1 (0.5)
Arthropod sting	1 (1.1)	0		1 (0.5)
Concussion	1 (1.1)	0		1 (0.5)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	380 (33.2)	423 (36.7)		803 (35.0)
Number of Unsolicited Adverse Events	749	930		1679
Infections and infestations	100 (8.7)	80 (6.9)		180 (7.8)
Urinary tract infection	17 (1.5)	12 (1.0)	0.70 (0.34, 1.44)	29 (1.3)
Upper respiratory tract infection	10 (0.9)	8 (0.7)	0.79 (0.32, 1.95)	18 (0.8)
Viral infection	7 (0.6)	6 (0.5)	0.85 (0.30, 2.41)	13 (0.6)
Sinusitis	5 (0.4)	5 (0.4)		10 (0.4)
Pharyngitis	2 (0.2)	4 (0.3)		6 (0.3)
Gastroenteritis	0	3 (0.3)		3 (0.1)
Herpes simplex	1 (<0.1)	3 (0.3)		4 (0.2)
Localised infection	1 (<0.1)	3 (0.3)		4 (0.2)
Furuncle	0	2 (0.2)		2 (<0.1)
Herpes zoster	1 (<0.1)	2 (0.2)		3 (0.1)
Otitis media	1 (<0.1)	2 (0.2)		3 (0.1)
Respiratory tract infection	1 (<0.1)	2 (0.2)		3 (0.1)
Suspected COVID-19	4 (0.3)	2 (0.2)		6 (0.3)
Tooth abscess	3 (0.3)	2 (0.2)		5 (0.2)
Vulvovaginal candidiasis	0	2 (0.2)		2 (<0.1)
Appendicitis	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Infections and infestations (Cont.)				
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chlamydial infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diverticulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Genital herpes	0	1 (<0.1)		1 (<0.1)
Hordeolum	0	1 (<0.1)		1 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)
Oral herpes	0	1 (<0.1)		1 (<0.1)
Otitis externa	0	1 (<0.1)		1 (<0.1)
Paronychia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia	2 (0.2)	1 (<0.1)		3 (0.1)
Rhinitis	0	1 (<0.1)		1 (<0.1)
Rhinovirus infection	2 (0.2)	1 (<0.1)		3 (0.1)
Sepsis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Staphylococcal infection	0	1 (<0.1)		1 (<0.1)
Staphylococcal skin infection	0	1 (<0.1)		1 (<0.1)
Tooth infection	5 (0.4)	1 (<0.1)		6 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Infections and infestations (Cont.)				
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginal mycotic infection	3 (0.3)	1 (<0.1)		4 (0.2)
Bacterial vaginosis	2 (0.2)	0		2 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
COVID-19	8 (0.7)	0		8 (0.3)
Candida infection	1 (<0.1)	0		1 (<0.1)
Cellulitis	5 (0.4)	0		5 (0.2)
Folliculitis	2 (0.2)	0		2 (<0.1)
Fungal infection	1 (<0.1)	0		1 (<0.1)
Gastroenteritis viral	2 (0.2)	0		2 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Oral candidiasis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	3 (0.3)	0		3 (0.1)
Respiratory tract infection viral	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Viral upper respiratory tract infection	2 (0.2)	0		2 (<0.1)
Wound infection	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (0.8)	7 (0.6)		16 (0.7)
Basal cell carcinoma	1 (<0.1)	2 (0.2)		3 (0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign breast neoplasm	1 (<0.1)	0		1 (<0.1)
Benign neoplasm of skin	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Lipoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer	1 (<0.1)	0		1 (<0.1)
Skin cancer	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	13 (1.1)	21 (1.8)		34 (1.5)
Lymphadenopathy	11 (1.0)	16 (1.4)	1.44 (0.69, 3.05)	27 (1.2)
Lymph node pain	0	2 (0.2)		2 (<0.1)
Anaemia	2 (0.2)	1 (<0.1)		3 (0.1)
Leukocytosis	0	1 (<0.1)		1 (<0.1)
Lymphadenitis	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Immune system disorders	6 (0.5)	7 (0.6)		13 (0.6)
Seasonal allergy	4 (0.3)	5 (0.4)		9 (0.4)
Hypersensitivity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Allergy to arthropod bite	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	2 (0.2)	0		2 (<0.1)
Hypogonadism	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	10 (0.9)	9 (0.8)		19 (0.8)
Hyperlipidaemia	0	3 (0.3)		3 (0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Decreased appetite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gout	0	1 (<0.1)		1 (<0.1)
Hypercholesterolaemia	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	0	1 (<0.1)		1 (<0.1)
Hypertriglyceridaemia	0	1 (<0.1)		1 (<0.1)
Type 2 diabetes mellitus	3 (0.3)	1 (<0.1)		4 (0.2)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Glucose tolerance impaired	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Metabolism and nutrition disorders (Cont.)				
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Vitamin D deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	14 (1.2)	14 (1.2)		28 (1.2)
Anxiety	4 (0.3)	6 (0.5)		10 (0.4)
Depression	3 (0.3)	2 (0.2)		5 (0.2)
Insomnia	2 (0.2)	2 (0.2)		4 (0.2)
Abnormal dreams	1 (<0.1)	1 (<0.1)		2 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Stress	0	1 (<0.1)		1 (<0.1)
Attention deficit hyperactivity disorder	3 (0.3)	0		3 (0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	77 (6.7)	89 (7.7)		166 (7.2)
Headache	55 (4.8)	61 (5.3)	1.10 (0.77, 1.57)	116 (5.1)
Dizziness	5 (0.4)	8 (0.7)	1.59 (0.55, 4.60)	13 (0.6)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Nervous system disorders (Cont.)				
Paraesthesia	5 (0.4)	4 (0.3)		9 (0.4)
Dysgeusia	0	3 (0.3)		3 (0.1)
Hypoaesthesia	2 (0.2)	2 (0.2)		4 (0.2)
Migraine	1 (<0.1)	2 (0.2)		3 (0.1)
Peripheral sensory neuropathy	0	2 (0.2)		2 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Disturbance in attention	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Presyncope	2 (0.2)	1 (<0.1)		3 (0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Sinus headache	0	1 (<0.1)		1 (<0.1)
Somnolence	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ageusia	1 (<0.1)	0		1 (<0.1)
Carpal tunnel syndrome	2 (0.2)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Neuralgia	2 (0.2)	0		2 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Nervous system disorders (Cont.)				
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)
Sciatica	1 (<0.1)	0		1 (<0.1)
Syncope	3 (0.3)	0		3 (0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Tension headache	2 (0.2)	0		2 (<0.1)
Eye disorders	12 (1.0)	8 (0.7)		20 (0.9)
Blepharitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Conjunctival haemorrhage	0	1 (<0.1)		1 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Eye swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Vision blurred	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Conjunctivitis allergic	2 (0.2)	0		2 (<0.1)
Dry eye	2 (0.2)	0		2 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eye pain	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Ear and labyrinth disorders	10 (0.9)	5 (0.4)		15 (0.7)
Ear pain	1 (<0.1)	2 (0.2)		3 (0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Tinnitus	0	1 (<0.1)		1 (<0.1)
Vertigo	2 (0.2)	1 (<0.1)		3 (0.1)
Cerumen impaction	1 (<0.1)	0		1 (<0.1)
Ear canal erythema	1 (<0.1)	0		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Ear pruritus	2 (0.2)	0		2 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	10 (0.9)	7 (0.6)		17 (0.7)
Bradycardia	1 (<0.1)	2 (0.2)		3 (0.1)
Palpitations	0	2 (0.2)		2 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinus tachycardia	0	1 (<0.1)		1 (<0.1)
Tachycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	4 (0.3)	0		4 (0.2)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Cardiac failure	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Cardiac disorders (Cont.)				
Myocardial infarction	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Vascular disorders	11 (1.0)	18 (1.6)		29 (1.3)
Hypertension	11 (1.0)	14 (1.2)	1.26 (0.59, 2.72)	25 (1.1)
Flushing	0	2 (0.2)		2 (<0.1)
Hot flush	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	50 (4.4)	53 (4.6)		103 (4.5)
Cough	10 (0.9)	17 (1.5)	1.69 (0.79, 3.61)	27 (1.2)
Nasal congestion	9 (0.8)	16 (1.4)	1.77 (0.80, 3.90)	25 (1.1)
Oropharyngeal pain	13 (1.1)	14 (1.2)	1.07 (0.51, 2.23)	27 (1.2)
Rhinorrhoea	12 (1.0)	11 (1.0)	0.91 (0.41, 2.01)	23 (1.0)
Dysphonia	0	3 (0.3)		3 (0.1)
Dyspnoea	2 (0.2)	3 (0.3)		5 (0.2)
Asthma	4 (0.3)	2 (0.2)		6 (0.3)
Chronic obstructive pulmonary disease	1 (<0.1)	2 (0.2)		3 (0.1)
Respiratory tract congestion	1 (<0.1)	2 (0.2)		3 (0.1)
Allergic sinusitis	0	1 (<0.1)		1 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dry throat	0	1 (<0.1)		1 (<0.1)
Rhinitis allergic	0	1 (<0.1)		1 (<0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)		1 (<0.1)
Sneezing	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Upper-airway cough syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Pleural effusion	2 (0.2)	0		2 (<0.1)
Pleuritic pain	2 (0.2)	0		2 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pulmonary embolism	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Sinus congestion	2 (0.2)	0		2 (<0.1)
Tachypnoea	2 (0.2)	0		2 (<0.1)
Throat irritation	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	49 (4.3)	66 (5.7)		115 (5.0)
Diarrhoea	19 (1.7)	28 (2.4)	1.46 (0.83, 2.59)	47 (2.0)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Gastrointestinal disorders (Cont.)				
Nausea	7 (0.6)	15 (1.3)	2.13 (0.90, 5.06)	22 (1.0)
Vomiting	5 (0.4)	7 (0.6)	1.39 (0.47, 4.14)	12 (0.5)
Toothache	3 (0.3)	5 (0.4)		8 (0.3)
Abdominal pain lower	0	3 (0.3)		3 (0.1)
Abdominal pain upper	2 (0.2)	2 (0.2)		4 (0.2)
Constipation	1 (<0.1)	2 (0.2)		3 (0.1)
Gastrooesophageal reflux disease	4 (0.3)	2 (0.2)		6 (0.3)
Abdominal pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chapped lips	0	1 (<0.1)		1 (<0.1)
Dental caries	3 (0.3)	1 (<0.1)		4 (0.2)
Diverticulum intestinal	0	1 (<0.1)		1 (<0.1)
Dry mouth	0	1 (<0.1)		1 (<0.1)
Dyspepsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysphagia	0	1 (<0.1)		1 (<0.1)
Food poisoning	0	1 (<0.1)		1 (<0.1)
Haematochezia	0	1 (<0.1)		1 (<0.1)
Hiatus hernia	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Irritable bowel syndrome	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	1 (<0.1)	1 (<0.1)		2 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Gastrointestinal disorders (Cont.)				
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	1 (<0.1)	0		1 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Haemorrhoids	1 (<0.1)	0		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Oral pain	1 (<0.1)	0		1 (<0.1)
Paraesthesia oral	1 (<0.1)	0		1 (<0.1)
Salivary hypersecretion	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	3 (0.3)		3 (0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Skin and subcutaneous tissue disorders	18 (1.6)	31 (2.7)		49 (2.1)
Psoriasis	0	5 (0.4)		5 (0.2)
Hyperhidrosis	0	3 (0.3)		3 (0.1)
Urticaria	1 (<0.1)	3 (0.3)		4 (0.2)
Dermatitis contact	2 (0.2)	2 (0.2)		4 (0.2)
Rash macular	1 (<0.1)	2 (0.2)		3 (0.1)
Rash maculo-papular	0	2 (0.2)		2 (<0.1)
Rash pruritic	0	2 (0.2)		2 (<0.1)
Acne	0	1 (<0.1)		1 (<0.1)
Actinic keratosis	0	1 (<0.1)		1 (<0.1)
Alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis atopic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry skin	0	1 (<0.1)		1 (<0.1)
Erythema	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Rash erythematous	0	1 (<0.1)		1 (<0.1)
Rosacea	0	1 (<0.1)		1 (<0.1)
Skin mass	0	1 (<0.1)		1 (<0.1)
Skin ulcer	0	1 (<0.1)		1 (<0.1)
Angioedema	2 (0.2)	0		2 (<0.1)
Ecchymosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Intertrigo	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	1 (<0.1)	0		1 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Pruritus	1 (<0.1)	0		1 (<0.1)
Rash	2 (0.2)	0		2 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	90 (7.9)	105 (9.1)		195 (8.5)
Arthralgia	41 (3.6)	47 (4.1)	1.14 (0.76, 1.71)	88 (3.8)
Myalgia	29 (2.5)	38 (3.3)	1.30 (0.81, 2.09)	67 (2.9)
Back pain	10 (0.9)	8 (0.7)	0.79 (0.32, 1.95)	18 (0.8)
Musculoskeletal pain	4 (0.3)	8 (0.7)	1.99 (0.64, 6.19)	12 (0.5)
Pain in extremity	7 (0.6)	8 (0.7)	1.13 (0.43, 3.00)	15 (0.7)
Neck pain	0	7 (0.6)		7 (0.3)
Muscle spasms	6 (0.5)	5 (0.4)		11 (0.5)
Osteoarthritis	1 (<0.1)	4 (0.3)		5 (0.2)
Intervertebral disc protrusion	0	3 (0.3)		3 (0.1)
Rotator cuff syndrome	3 (0.3)	3 (0.3)		6 (0.3)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Muscle fatigue	0	2 (0.2)		2 (<0.1)
Tendonitis	0	2 (0.2)		2 (<0.1)
Axillary mass	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	2 (0.2)	1 (<0.1)		3 (0.1)
Flank pain	0	1 (<0.1)		1 (<0.1)
Joint range of motion decreased	0	1 (<0.1)		1 (<0.1)
Limb discomfort	0	1 (<0.1)		1 (<0.1)
Musculoskeletal stiffness	2 (0.2)	1 (<0.1)		3 (0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	0	1 (<0.1)		1 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Bursitis	1 (<0.1)	0		1 (<0.1)
Exostosis	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Plantar fasciitis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	1 (<0.1)	0		1 (<0.1)
Trigger finger	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Renal and urinary disorders	4 (0.3)	4 (0.3)		8 (0.3)
Nephrolithiasis	3 (0.3)	3 (0.3)		6 (0.3)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urinary retention	0	1 (<0.1)		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	6 (0.5)	7 (0.6)		13 (0.6)
Dysmenorrhoea	0	2 (0.2)		2 (<0.1)
Erectile dysfunction	1 (<0.1)	2 (0.2)		3 (0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Menopausal symptoms	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	88 (7.7)	145 (12.6)		233 (10.1)
Fatigue	50 (4.4)	76 (6.6)	1.51 (1.07, 2.13)	126 (5.5)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
General disorders and administration site conditions (Cont.)				
Injection site erythema	5 (0.4)	17 (1.5)	3.38 (1.30, 8.80)	22 (1.0)
Injection site pain	9 (0.8)	17 (1.5)	1.88 (0.86, 4.11)	26 (1.1)
Pyrexia	8 (0.7)	14 (1.2)	1.74 (0.75, 4.03)	22 (1.0)
Injection site pruritus	1 (<0.1)	12 (1.0)	11.92 (1.99, 71.41)	13 (0.6)
Injection site swelling	4 (0.3)	9 (0.8)	2.23 (0.73, 6.83)	13 (0.6)
Injection site lymphadenopathy	3 (0.3)	6 (0.5)		9 (0.4)
Injection site macule	0	6 (0.5)		6 (0.3)
Pain	5 (0.4)	6 (0.5)		11 (0.5)
Chills	5 (0.4)	5 (0.4)		10 (0.4)
Injection site induration	2 (0.2)	4 (0.3)		6 (0.3)
Injection site papule	0	3 (0.3)		3 (0.1)
Injection site urticaria	0	3 (0.3)		3 (0.1)
Axillary pain	1 (<0.1)	2 (0.2)		3 (0.1)
Injection site bruising	1 (<0.1)	2 (0.2)		3 (0.1)
Injection site hypoaesthesia	1 (<0.1)	2 (0.2)		3 (0.1)
Chest discomfort	0	1 (<0.1)		1 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hangover	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site paraesthesia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
General disorders and administration site conditions (Cont.)				
Injection site rash	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Malaise	2 (0.2)	1 (<0.1)		3 (0.1)
Peripheral swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site erythema	0	1 (<0.1)		1 (<0.1)
Vaccination site pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Feeling abnormal	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Injection site discolouration	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Non-cardiac chest pain	2 (0.2)	0		2 (<0.1)
Oedema peripheral	1 (<0.1)	0		1 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	1 (<0.1)	0		1 (<0.1)
Investigations	2 (0.2)	10 (0.9)		12 (0.5)
Blood pressure increased	0	2 (0.2)		2 (<0.1)
Transaminases increased	0	2 (0.2)		2 (<0.1)
Blood cholesterol increased	0	1 (<0.1)		1 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Investigations (Cont.)				
Blood pressure systolic increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	34 (3.0)	36 (3.1)		70 (3.0)
Ligament sprain	2 (0.2)	6 (0.5)		8 (0.3)
Muscle strain	0	4 (0.3)		4 (0.2)
Arthropod bite	2 (0.2)	3 (0.3)		5 (0.2)
Fall	2 (0.2)	3 (0.3)		5 (0.2)
Foot fracture	1 (<0.1)	2 (0.2)		3 (0.1)
Head injury	0	2 (0.2)		2 (<0.1)
Heat exhaustion	0	2 (0.2)		2 (<0.1)
Limb injury	1 (<0.1)	2 (0.2)		3 (0.1)
Skin abrasion	2 (0.2)	2 (0.2)		4 (0.2)
Skin laceration	1 (<0.1)	2 (0.2)		3 (0.1)
Ankle fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	0	1 (<0.1)		1 (<0.1)
Cervical vertebral fracture	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080901.sas 10JUN2021 12:57

Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Injury, poisoning and procedural complications (Cont.)				
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Concussion	0	1 (<0.1)		1 (<0.1)
Contusion	4 (0.3)	1 (<0.1)		5 (0.2)
Face injury	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Hand fracture	0	1 (<0.1)		1 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle rupture	0	1 (<0.1)		1 (<0.1)
Post-traumatic pain	0	1 (<0.1)		1 (<0.1)
Procedural pain	3 (0.3)	1 (<0.1)		4 (0.2)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress fracture	0	1 (<0.1)		1 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	0	1 (<0.1)		1 (<0.1)
Tendon rupture	2 (0.2)	1 (<0.1)		3 (0.1)
Arthropod sting	1 (<0.1)	0		1 (<0.1)
Back injury	1 (<0.1)	0		1 (<0.1)
Bone contusion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080901.sas 10JUN2021 12:57

Table 14.3.1.8.9.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection in Subjects with Autoimmune Disorder at Baseline
Safety Set

System Organ Class Preferred Term	Placebo (N=1144) n (%)	mRNA-1273 (N=1152) n (%)	Rate Ratio (95% CI)	Total (N=2296) n (%)
Injury, poisoning and procedural complications (Cont.)				
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Radius fracture	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Tooth fracture	2 (0.2)	0		2 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080901.sas 10JUN2021 12:57

Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2092 (26.0)	2173 (27.4)		4265 (26.7)
Number of Unsolicited Adverse Events	4023	4133		8156
Infections and infestations	396 (4.9)	308 (3.9)		704 (4.4)
Upper respiratory tract infection	54 (0.7)	36 (0.5)	0.68 (0.45, 1.03)	90 (0.6)
Rhinovirus infection	16 (0.2)	19 (0.2)	1.21 (0.63, 2.32)	35 (0.2)
Viral infection	25 (0.3)	19 (0.2)	0.77 (0.43, 1.39)	44 (0.3)
Sinusitis	19 (0.2)	17 (0.2)	0.91 (0.48, 1.73)	36 (0.2)
COVID-19	93 (1.2)	14 (0.2)	0.15 (0.09, 0.27)	107 (0.7)
Suspected COVID-19	14 (0.2)	13 (0.2)	0.94 (0.45, 1.98)	27 (0.2)
Ear infection	3 (<0.1)	11 (0.1)	3.73 (1.12, 12.42)	14 (<0.1)
Tooth abscess	10 (0.1)	10 (0.1)	1.02 (0.43, 2.38)	20 (0.1)
Pharyngitis	8 (<0.1)	9 (0.1)	1.14 (0.46, 2.87)	17 (0.1)
Tooth infection	13 (0.2)	9 (0.1)	0.70 (0.31, 1.61)	22 (0.1)
Urinary tract infection	10 (0.1)	9 (0.1)	0.92 (0.38, 2.19)	19 (0.1)
Herpes zoster	7 (<0.1)	8 (0.1)	1.16 (0.44, 3.08)	15 (<0.1)
Cellulitis	4 (<0.1)	7 (<0.1)	1.78 (0.56, 5.69)	11 (<0.1)
Conjunctivitis	4 (<0.1)	7 (<0.1)	1.78 (0.56, 5.69)	11 (<0.1)
Gastroenteritis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Hordeolum	4 (<0.1)	6 (<0.1)		10 (<0.1)
Localised infection	6 (<0.1)	6 (<0.1)		12 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Infections and infestations (Cont.)				
Herpes simplex	0	5 (<0.1)		5 (<0.1)
Oral herpes	4 (<0.1)	5 (<0.1)		9 (<0.1)
Paronychia	4 (<0.1)	5 (<0.1)		9 (<0.1)
Pharyngitis streptococcal	9 (0.1)	5 (<0.1)	0.57 (0.20, 1.61)	14 (<0.1)
Viral upper respiratory tract infection	5 (<0.1)	5 (<0.1)		10 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	4 (<0.1)		6 (<0.1)
Folliculitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Onychomycosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Staphylococcal skin infection	0	4 (<0.1)		4 (<0.1)
Bronchitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gingivitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Otitis externa	6 (<0.1)	3 (<0.1)		9 (<0.1)
Skin infection	0	3 (<0.1)		3 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abscess limb	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Diverticulitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Helicobacter infection	3 (<0.1)	2 (<0.1)		5 (<0.1)
Nasopharyngitis	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.23)	9 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Infections and infestations (Cont.)				
Otitis media	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pneumonia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Subcutaneous abscess	1 (<0.1)	2 (<0.1)		3 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Appendicitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Chlamydial infection	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	0	1 (<0.1)		1 (<0.1)
Fungal skin infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Furuncle	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Gastroenteritis viral	5 (<0.1)	1 (<0.1)		6 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Gonorrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)
Infected bite	0	1 (<0.1)		1 (<0.1)
Kidney infection	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Infections and infestations (Cont.)				
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lyme disease	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Oral candidiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Sepsis	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	0	1 (<0.1)		1 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	0	1 (<0.1)		1 (<0.1)
Tinea cruris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Infections and infestations (Cont.)				
Wound infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Acute sinusitis	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Body tinea	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0		2 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Cystitis	1 (<0.1)	0		1 (<0.1)
Enterovirus infection	1 (<0.1)	0		1 (<0.1)
Eye infection	1 (<0.1)	0		1 (<0.1)
Fungal infection	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Laryngitis	1 (<0.1)	0		1 (<0.1)
Mastoiditis	1 (<0.1)	0		1 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Otitis media acute	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Infections and infestations (Cont.)				
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	4 (<0.1)	0		4 (<0.1)
Rhinitis	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea pedis	2 (<0.1)	0		2 (<0.1)
Tonsillitis	4 (<0.1)	0		4 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	32 (0.4)	29 (0.4)		61 (0.4)
Basal cell carcinoma	12 (0.1)	4 (<0.1)	0.34 (0.12, 1.00)	16 (0.1)
Benign neoplasm of skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Malignant melanoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Skin cancer	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Melanocytic naevus	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	1 (<0.1)	1 (<0.1)		2 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	5 (<0.1)	0		5 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	83 (1.0)	103 (1.3)		186 (1.2)
Lymphadenopathy	73 (0.9)	93 (1.2)	1.30 (0.96, 1.76)	166 (1.0)
Lymph node pain	7 (<0.1)	5 (<0.1)	0.73 (0.24, 2.17)	12 (<0.1)
Anaemia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	0		1 (<0.1)
Lymphadenitis	1 (<0.1)	0		1 (<0.1)
Immune system disorders	27 (0.3)	20 (0.3)		47 (0.3)
Seasonal allergy	18 (0.2)	13 (0.2)	0.73 (0.37, 1.48)	31 (0.2)
Hypersensitivity	4 (<0.1)	2 (<0.1)		6 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Immune system disorders (Cont.)				
Food allergy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hypothyroidism	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	58 (0.7)	69 (0.9)		127 (0.8)
Hyperlipidaemia	12 (0.1)	12 (0.2)	1.02 (0.47, 2.22)	24 (0.2)
Type 2 diabetes mellitus	8 (<0.1)	12 (0.2)	1.53 (0.64, 3.63)	20 (0.1)
Dehydration	1 (<0.1)	7 (<0.1)	7.12 (1.14, 44.37)	8 (<0.1)
Gout	7 (<0.1)	7 (<0.1)	1.02 (0.37, 2.78)	14 (<0.1)
Diabetes mellitus	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hypercholesterolaemia	7 (<0.1)	5 (<0.1)	0.73 (0.24, 2.17)	12 (<0.1)
Vitamin D deficiency	6 (<0.1)	4 (<0.1)		10 (<0.1)
Decreased appetite	4 (<0.1)	3 (<0.1)		7 (<0.1)
Glucose tolerance impaired	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Metabolism and nutrition disorders (Cont.)				
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyponatraemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Vitamin B12 deficiency	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Psychiatric disorders	52 (0.6)	68 (0.9)		120 (0.8)
Anxiety	17 (0.2)	20 (0.3)	1.20 (0.63, 2.26)	37 (0.2)
Insomnia	15 (0.2)	18 (0.2)	1.22 (0.62, 2.39)	33 (0.2)
Depression	10 (0.1)	9 (0.1)	0.92 (0.38, 2.19)	19 (0.1)
Abnormal dreams	1 (<0.1)	2 (<0.1)		3 (<0.1)
Attention deficit hyperactivity disorder	5 (<0.1)	2 (<0.1)		7 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Psychiatric disorders (Cont.)				
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nightmare	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sleep disorder	0	2 (<0.1)		2 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Panic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Psychiatric disorders (Cont.)				
Bipolar disorder	3 (<0.1)	0		3 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0		1 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Substance abuse	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	377 (4.7)	430 (5.4)		807 (5.1)
Headache	289 (3.6)	299 (3.8)	1.05 (0.90, 1.23)	588 (3.7)
Dizziness	26 (0.3)	39 (0.5)	1.53 (0.93, 2.49)	65 (0.4)
Paraesthesia	11 (0.1)	10 (0.1)	0.92 (0.40, 2.12)	21 (0.1)
Sinus headache	2 (<0.1)	10 (0.1)	5.09 (1.25, 20.64)	12 (<0.1)
Ageusia	5 (<0.1)	8 (0.1)	1.63 (0.56, 4.73)	13 (<0.1)
Sciatica	6 (<0.1)	8 (0.1)	1.36 (0.49, 3.74)	14 (<0.1)
Anosmia	5 (<0.1)	7 (<0.1)	1.42 (0.48, 4.25)	12 (<0.1)
Dysgeusia	3 (<0.1)	6 (<0.1)		9 (<0.1)
Hypoaesthesia	4 (<0.1)	6 (<0.1)		10 (<0.1)
Syncope	8 (<0.1)	6 (<0.1)	0.76 (0.28, 2.10)	14 (<0.1)
Presyncope	7 (<0.1)	5 (<0.1)	0.73 (0.24, 2.17)	12 (<0.1)
Cervical radiculopathy	1 (<0.1)	4 (<0.1)		5 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Nervous system disorders (Cont.)				
Hyperaesthesia	0	4 (<0.1)		4 (<0.1)
Tension headache	4 (<0.1)	4 (<0.1)		8 (<0.1)
Migraine	4 (<0.1)	3 (<0.1)		7 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)
Disturbance in attention	0	2 (<0.1)		2 (<0.1)
Memory impairment	0	2 (<0.1)		2 (<0.1)
Nerve compression	3 (<0.1)	2 (<0.1)		5 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Post-traumatic headache	0	2 (<0.1)		2 (<0.1)
Taste disorder	0	2 (<0.1)		2 (<0.1)
Transient ischaemic attack	1 (<0.1)	2 (<0.1)		3 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Carpal tunnel syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Nervous system disorders (Cont.)				
Lethargy	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Somnolence	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Tremor	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Balance disorder	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	3 (<0.1)	0		3 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Nervous system disorders (Cont.)				
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Facial paralysis	1 (<0.1)	0		1 (<0.1)
Hypogeusia	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	22 (0.3)	31 (0.4)		53 (0.3)
Vision blurred	2 (<0.1)	5 (<0.1)		7 (<0.1)
Eye pain	0	3 (<0.1)		3 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Eye irritation	0	2 (<0.1)		2 (<0.1)
Eye pruritus	5 (<0.1)	2 (<0.1)		7 (<0.1)
Ocular hyperaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blepharitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cataract	1 (<0.1)	1 (<0.1)		2 (<0.1)
Conjunctival haemorrhage	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Eye disorders (Cont.)				
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Dry eye	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye inflammation	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Glaucoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Lacrimation increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Photophobia	0	1 (<0.1)		1 (<0.1)
Scleritis	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	1 (<0.1)	1 (<0.1)		2 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Ear and labyrinth disorders	38 (0.5)	45 (0.6)		83 (0.5)
Vertigo	7 (<0.1)	13 (0.2)	1.89 (0.78, 4.60)	20 (0.1)
Ear pain	8 (<0.1)	7 (<0.1)	0.89 (0.34, 2.36)	15 (<0.1)
Tinnitus	9 (0.1)	7 (<0.1)	0.79 (0.31, 2.05)	16 (0.1)
Cerumen impaction	1 (<0.1)	4 (<0.1)		5 (<0.1)
Vertigo positional	0	4 (<0.1)		4 (<0.1)
Ear discomfort	4 (<0.1)	2 (<0.1)		6 (<0.1)
Deafness neurosensory	0	1 (<0.1)		1 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear canal erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ear congestion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eustachian tube dysfunction	0	1 (<0.1)		1 (<0.1)
Meniere's disease	0	1 (<0.1)		1 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Otorrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tympanic membrane perforation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	44 (0.5)	46 (0.6)		90 (0.6)
Bradycardia	12 (0.1)	9 (0.1)	0.76 (0.33, 1.77)	21 (0.1)
Atrial fibrillation	9 (0.1)	8 (0.1)	0.90 (0.36, 2.27)	17 (0.1)
Tachycardia	5 (<0.1)	8 (0.1)	1.63 (0.56, 4.73)	13 (<0.1)
Palpitations	2 (<0.1)	5 (<0.1)		7 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Cardiac disorders (Cont.)				
Angina pectoris	1 (<0.1)	4 (<0.1)		5 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Arrhythmia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Atrial flutter	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure congestive	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ventricular extrasystoles	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	1 (<0.1)	0		1 (<0.1)
Vascular disorders	115 (1.4)	104 (1.3)		219 (1.4)
Hypertension	96 (1.2)	83 (1.0)	0.88 (0.66, 1.18)	179 (1.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Vascular disorders (Cont.)				
Hot flush	1 (<0.1)	5 (<0.1)		6 (<0.1)
Haematoma	1 (<0.1)	4 (<0.1)		5 (<0.1)
Flushing	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypertensive urgency	2 (<0.1)	2 (<0.1)		4 (<0.1)
Systolic hypertension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Orthostatic hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	3 (<0.1)	0		3 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	3 (<0.1)	0		3 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	346 (4.3)	291 (3.7)		637 (4.0)
Nasal congestion	79 (1.0)	77 (1.0)	0.99 (0.73, 1.35)	156 (1.0)
Cough	90 (1.1)	72 (0.9)	0.81 (0.60, 1.11)	162 (1.0)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Oropharyngeal pain	110 (1.4)	66 (0.8)	0.61 (0.45, 0.83)	176 (1.1)
Rhinorrhoea	74 (0.9)	54 (0.7)	0.74 (0.52, 1.05)	128 (0.8)
Dyspnoea	23 (0.3)	17 (0.2)	0.75 (0.41, 1.39)	40 (0.3)
Tachypnoea	20 (0.2)	16 (0.2)	0.81 (0.43, 1.55)	36 (0.2)
Epistaxis	5 (<0.1)	12 (0.2)	2.44 (0.90, 6.64)	17 (0.1)
Sinus congestion	14 (0.2)	12 (0.2)	0.87 (0.41, 1.85)	26 (0.2)
Respiratory tract congestion	4 (<0.1)	11 (0.1)	2.80 (0.94, 8.32)	15 (<0.1)
Throat irritation	5 (<0.1)	9 (0.1)	1.83 (0.64, 5.21)	14 (<0.1)
Asthma	4 (<0.1)	8 (0.1)	2.03 (0.65, 6.35)	12 (<0.1)
Sneezing	8 (<0.1)	7 (<0.1)	0.89 (0.34, 2.36)	15 (<0.1)
Chronic obstructive pulmonary disease	7 (<0.1)	5 (<0.1)	0.73 (0.24, 2.17)	12 (<0.1)
Rhinitis allergic	6 (<0.1)	5 (<0.1)		11 (<0.1)
Upper-airway cough syndrome	5 (<0.1)	5 (<0.1)		10 (<0.1)
Sinus pain	0	4 (<0.1)		4 (<0.1)
Dyspnoea exertional	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pharyngeal erythema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Productive cough	4 (<0.1)	3 (<0.1)		7 (<0.1)
Wheezing	1 (<0.1)	3 (<0.1)		4 (<0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Dry throat	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dysphonia	6 (<0.1)	2 (<0.1)		8 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pulmonary embolism	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory failure	0	2 (<0.1)		2 (<0.1)
Acute respiratory failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Increased viscosity of upper respiratory secretion	0	1 (<0.1)		1 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Oropharyngeal discomfort	0	1 (<0.1)		1 (<0.1)
Pleurisy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	2 (<0.1)	1 (<0.1)		3 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Painful respiration	1 (<0.1)	0		1 (<0.1)
Paranasal sinus discomfort	2 (<0.1)	0		2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pleuritic pain	2 (<0.1)	0		2 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	255 (3.2)	267 (3.4)		522 (3.3)
Diarrhoea	99 (1.2)	87 (1.1)	0.89 (0.67, 1.19)	186 (1.2)
Nausea	54 (0.7)	69 (0.9)	1.30 (0.91, 1.85)	123 (0.8)
Vomiting	18 (0.2)	26 (0.3)	1.47 (0.81, 2.66)	44 (0.3)
Toothache	12 (0.1)	21 (0.3)	1.78 (0.89, 3.57)	33 (0.2)
Gastrooesophageal reflux disease	13 (0.2)	20 (0.3)	1.57 (0.79, 3.10)	33 (0.2)
Dental caries	5 (<0.1)	9 (0.1)	1.83 (0.64, 5.21)	14 (<0.1)
Dyspepsia	9 (0.1)	8 (0.1)	0.90 (0.36, 2.27)	17 (0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal pain upper	10 (0.1)	7 (<0.1)	0.71 (0.28, 1.81)	17 (0.1)
Abdominal pain	8 (<0.1)	6 (<0.1)	0.76 (0.28, 2.10)	14 (<0.1)
Constipation	13 (0.2)	6 (<0.1)	0.47 (0.18, 1.19)	19 (0.1)
Abdominal pain lower	3 (<0.1)	4 (<0.1)		7 (<0.1)
Food poisoning	6 (<0.1)	4 (<0.1)		10 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)		6 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abdominal discomfort	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.23)	9 (<0.1)
Aphthous ulcer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Diverticulum intestinal	0	2 (<0.1)		2 (<0.1)
Flatulence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gastric ulcer	0	2 (<0.1)		2 (<0.1)
Haematochezia	0	2 (<0.1)		2 (<0.1)
Hiatus hernia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Inguinal hernia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tooth impacted	2 (<0.1)	2 (<0.1)		4 (<0.1)
Umbilical hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal distension	0	1 (<0.1)		1 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Gastrointestinal disorders (Cont.)				
Dry mouth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Enteritis	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lip swelling	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	3 (<0.1)	1 (<0.1)		4 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Gastrointestinal disorders (Cont.)				
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Stomatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tongue discolouration	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival pain	1 (<0.1)	0		1 (<0.1)
Loose tooth	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral disorder	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Hepatobiliary disorders	2 (<0.1)	6 (<0.1)		8 (<0.1)
Cholelithiasis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hepatic steatosis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	108 (1.3)	130 (1.6)		238 (1.5)
Urticaria	10 (0.1)	19 (0.2)	1.93 (0.92, 4.08)	29 (0.2)
Dermatitis contact	15 (0.2)	14 (0.2)	0.95 (0.47, 1.94)	29 (0.2)
Rash	17 (0.2)	14 (0.2)	0.84 (0.42, 1.68)	31 (0.2)
Hyperhidrosis	5 (<0.1)	10 (0.1)	2.03 (0.73, 5.68)	15 (<0.1)
Pruritus	14 (0.2)	10 (0.1)	0.73 (0.33, 1.60)	24 (0.2)
Night sweats	5 (<0.1)	8 (0.1)	1.63 (0.56, 4.73)	13 (<0.1)
Erythema	5 (<0.1)	5 (<0.1)		10 (<0.1)
Eczema	1 (<0.1)	4 (<0.1)		5 (<0.1)
Acne	3 (<0.1)	3 (<0.1)		6 (<0.1)
Actinic keratosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermatitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Psoriasis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rash erythematous	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rash macular	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rash maculo-papular	0	3 (<0.1)		3 (<0.1)
Rash pruritic	4 (<0.1)	3 (<0.1)		7 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Alopecia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blister	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hand dermatitis	0	2 (<0.1)		2 (<0.1)
Hidradenitis	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Rash papular	0	2 (<0.1)		2 (<0.1)
Acne cystic	0	1 (<0.1)		1 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	0	1 (<0.1)		1 (<0.1)
Dermal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ecchymosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Rosacea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Skin burning sensation	0	1 (<0.1)		1 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin ulcer	0	1 (<0.1)		1 (<0.1)
Urticaria papular	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)
Dermatitis atopic	2 (<0.1)	0		2 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ingrowing nail	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Papule	2 (<0.1)	0		2 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin lesion	3 (<0.1)	0		3 (<0.1)
Skin mass	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	492 (6.1)	488 (6.2)		980 (6.1)
Arthralgia	190 (2.4)	193 (2.4)	1.03 (0.85, 1.26)	383 (2.4)
Myalgia	182 (2.3)	183 (2.3)	1.02 (0.84, 1.25)	365 (2.3)
Back pain	77 (1.0)	44 (0.6)	0.58 (0.40, 0.84)	121 (0.8)
Musculoskeletal pain	22 (0.3)	30 (0.4)	1.39 (0.81, 2.39)	52 (0.3)
Pain in extremity	41 (0.5)	30 (0.4)	0.74 (0.47, 1.19)	71 (0.4)
Neck pain	21 (0.3)	23 (0.3)	1.11 (0.62, 2.00)	44 (0.3)
Osteoarthritis	7 (<0.1)	13 (0.2)	1.89 (0.78, 4.60)	20 (0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Muscle spasms	14 (0.2)	12 (0.2)	0.87 (0.41, 1.85)	26 (0.2)
Musculoskeletal chest pain	8 (<0.1)	8 (0.1)	1.02 (0.40, 2.62)	16 (0.1)
Musculoskeletal stiffness	8 (<0.1)	8 (0.1)	1.02 (0.40, 2.62)	16 (0.1)
Bursitis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Rotator cuff syndrome	6 (<0.1)	6 (<0.1)		12 (<0.1)
Tendonitis	7 (<0.1)	6 (<0.1)	0.87 (0.31, 2.47)	13 (<0.1)
Arthritis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	5 (<0.1)		9 (<0.1)
Joint swelling	4 (<0.1)	5 (<0.1)		9 (<0.1)
Muscle tightness	0	5 (<0.1)		5 (<0.1)
Muscular weakness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Trigger finger	1 (<0.1)	5 (<0.1)		6 (<0.1)
Limb discomfort	2 (<0.1)	4 (<0.1)		6 (<0.1)
Groin pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Neck mass	0	3 (<0.1)		3 (<0.1)
Costochondritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Flank pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pain in jaw	3 (<0.1)	2 (<0.1)		5 (<0.1)
Spinal osteoarthritis	0	2 (<0.1)		2 (<0.1)
Axillary mass	0	1 (<0.1)		1 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Exostosis	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	3 (<0.1)	1 (<0.1)		4 (<0.1)
Joint range of motion decreased	0	1 (<0.1)		1 (<0.1)
Joint stiffness	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle fatigue	0	1 (<0.1)		1 (<0.1)
Muscle twitching	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteoporosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal pain	0	1 (<0.1)		1 (<0.1)
Spinal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	0	1 (<0.1)		1 (<0.1)
Torticollis	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Plantar fasciitis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	35 (0.4)	38 (0.5)		73 (0.5)
Nephrolithiasis	17 (0.2)	12 (0.2)	0.72 (0.35, 1.48)	29 (0.2)
Dysuria	0	3 (<0.1)		3 (<0.1)
Haematuria	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acute kidney injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Chronic kidney disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nocturia	0	2 (<0.1)		2 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Polyuria	0	2 (<0.1)		2 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Renal and urinary disorders (Cont.)				
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hypertonic bladder	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Urinary retention	3 (<0.1)	1 (<0.1)		4 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urinary incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	21 (0.3)	22 (0.3)		43 (0.3)
Benign prostatic hyperplasia	8 (<0.1)	5 (<0.1)	0.64 (0.22, 1.85)	13 (<0.1)
Erectile dysfunction	3 (<0.1)	5 (<0.1)		8 (<0.1)
Prostatitis	6 (<0.1)	3 (<0.1)		9 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Reproductive system and breast disorders (Cont.)				
Breast swelling	0	1 (<0.1)		1 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
General disorders and administration site conditions	491 (6.1)	655 (8.3)		1146 (7.2)
Fatigue	297 (3.7)	319 (4.0)	1.09 (0.94, 1.28)	616 (3.9)
Injection site pain	49 (0.6)	101 (1.3)	2.10 (1.50, 2.94)	150 (0.9)
Chills	55 (0.7)	59 (0.7)	1.09 (0.76, 1.57)	114 (0.7)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
General disorders and administration site conditions (Cont.)				
Pyrexia	38 (0.5)	53 (0.7)	1.42 (0.94, 2.14)	91 (0.6)
Injection site erythema	27 (0.3)	48 (0.6)	1.81 (1.13, 2.88)	75 (0.5)
Pain	27 (0.3)	37 (0.5)	1.39 (0.85, 2.28)	64 (0.4)
Injection site lymphadenopathy	8 (<0.1)	28 (0.4)	3.56 (1.66, 7.66)	36 (0.2)
Injection site swelling	17 (0.2)	28 (0.4)	1.68 (0.93, 3.03)	45 (0.3)
Injection site macule	3 (<0.1)	15 (0.2)	5.09 (1.58, 16.41)	18 (0.1)
Axillary pain	11 (0.1)	13 (0.2)	1.20 (0.55, 2.63)	24 (0.2)
Injection site induration	8 (<0.1)	12 (0.2)	1.53 (0.64, 3.63)	20 (0.1)
Injection site pruritus	4 (<0.1)	11 (0.1)	2.80 (0.94, 8.32)	15 (<0.1)
Malaise	0	8 (0.1)		8 (<0.1)
Chest pain	3 (<0.1)	7 (<0.1)	2.37 (0.67, 8.42)	10 (<0.1)
Chest discomfort	8 (<0.1)	6 (<0.1)	0.76 (0.28, 2.10)	14 (<0.1)
Injection site rash	0	6 (<0.1)		6 (<0.1)
Injection site bruising	6 (<0.1)	5 (<0.1)		11 (<0.1)
Injection site haematoma	1 (<0.1)	5 (<0.1)		6 (<0.1)
Injection site paraesthesia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Non-cardiac chest pain	6 (<0.1)	5 (<0.1)		11 (<0.1)
Peripheral swelling	7 (<0.1)	5 (<0.1)	0.73 (0.24, 2.17)	12 (<0.1)
Feeling hot	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site joint pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site mass	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
General disorders and administration site conditions (Cont.)				
Injection site urticaria	0	3 (<0.1)		3 (<0.1)
Vaccination site pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hangover	0	2 (<0.1)		2 (<0.1)
Injection site haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Precancerous condition	0	2 (<0.1)		2 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Asthenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site irritation	0	1 (<0.1)		1 (<0.1)
Injection site papule	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Reactogenicity event	1 (<0.1)	1 (<0.1)		2 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
General disorders and administration site conditions (Cont.)				
Tenderness	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site swelling	0	1 (<0.1)		1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Cyst	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Facial pain	2 (<0.1)	0		2 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discolouration	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Oedema peripheral	5 (<0.1)	0		5 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling face	2 (<0.1)	0		2 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
General disorders and administration site conditions (Cont.)				
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	1 (<0.1)	0		1 (<0.1)
Investigations	39 (0.5)	58 (0.7)		97 (0.6)
Blood pressure increased	16 (0.2)	16 (0.2)	1.02 (0.52, 2.01)	32 (0.2)
Blood pressure systolic increased	3 (<0.1)	8 (0.1)	2.71 (0.78, 9.42)	11 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	6 (<0.1)		7 (<0.1)
Heart rate increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Blood cholesterol increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Blood glucose increased	0	2 (<0.1)		2 (<0.1)
Blood testosterone decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hepatic enzyme increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Transaminases increased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood triglycerides increased	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Investigations (Cont.)				
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Body temperature increased	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	0	1 (<0.1)		1 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Weight decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Heart rate irregular	2 (<0.1)	0		2 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Investigations (Cont.)				
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	182 (2.3)	166 (2.1)		348 (2.2)
Muscle strain	17 (0.2)	19 (0.2)	1.14 (0.60, 2.16)	36 (0.2)
Arthropod bite	12 (0.1)	12 (0.2)	1.02 (0.47, 2.22)	24 (0.2)
Skin laceration	18 (0.2)	12 (0.2)	0.68 (0.33, 1.39)	30 (0.2)
Ligament sprain	12 (0.1)	11 (0.1)	0.93 (0.42, 2.07)	23 (0.1)
Contusion	15 (0.2)	10 (0.1)	0.68 (0.31, 1.48)	25 (0.2)
Procedural pain	5 (<0.1)	9 (0.1)	1.83 (0.64, 5.21)	14 (<0.1)
Fall	10 (0.1)	8 (0.1)	0.81 (0.33, 2.00)	18 (0.1)
Tooth fracture	7 (<0.1)	8 (0.1)	1.16 (0.44, 3.08)	15 (<0.1)
Limb injury	3 (<0.1)	7 (<0.1)	2.37 (0.67, 8.42)	10 (<0.1)
Road traffic accident	5 (<0.1)	7 (<0.1)	1.42 (0.48, 4.25)	12 (<0.1)
Arthropod sting	8 (<0.1)	6 (<0.1)	0.76 (0.28, 2.10)	14 (<0.1)
Skin abrasion	14 (0.2)	5 (<0.1)	0.36 (0.14, 0.97)	19 (0.1)
Animal bite	6 (<0.1)	4 (<0.1)		10 (<0.1)
Foot fracture	3 (<0.1)	4 (<0.1)		7 (<0.1)
Meniscus injury	4 (<0.1)	4 (<0.1)		8 (<0.1)
Rib fracture	2 (<0.1)	4 (<0.1)		6 (<0.1)
Concussion	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hand fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post-traumatic pain	4 (<0.1)	3 (<0.1)		7 (<0.1)
Upper limb fracture	0	3 (<0.1)		3 (<0.1)
Cartilage injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Epicondylitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Joint injury	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Bone contusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ligament injury	0	1 (<0.1)		1 (<0.1)
Ligament rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Muscle rupture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural swelling	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Sunburn	0	1 (<0.1)		1 (<0.1)
Tibia fracture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wound	2 (<0.1)	1 (<0.1)		3 (<0.1)
Animal scratch	1 (<0.1)	0		1 (<0.1)
Ankle fracture	3 (<0.1)	0		3 (<0.1)
Back injury	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Injury, poisoning and procedural complications (Cont.)				
Burns second degree	2 (<0.1)	0		2 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Corneal abrasion	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Head injury	1 (<0.1)	0		1 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	1 (<0.1)	0		1 (<0.1)
Lip injury	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Male

System Organ Class Preferred Term	Placebo (N=8056) n (%)	mRNA-1273 (N=7918) n (%)	Rate Ratio (95% CI)	Total (N=15974) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Stress fracture	3 (<0.1)	0		3 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Thermal burn	1 (<0.1)	0		1 (<0.1)
Tooth injury	3 (<0.1)	0		3 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	1 (<0.1)		4 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Device breakage	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2246 (31.6)	2579 (35.5)		4825 (33.6)
Number of Unsolicited Adverse Events	4576	5408		9984
Infections and infestations	556 (7.8)	475 (6.5)		1031 (7.2)
Urinary tract infection	102 (1.4)	85 (1.2)	0.81 (0.61, 1.08)	187 (1.3)
Upper respiratory tract infection	64 (0.9)	46 (0.6)	0.70 (0.48, 1.02)	110 (0.8)
Sinusitis	27 (0.4)	44 (0.6)	1.59 (0.99, 2.56)	71 (0.5)
Viral infection	27 (0.4)	22 (0.3)	0.80 (0.46, 1.39)	49 (0.3)
Suspected COVID-19	21 (0.3)	21 (0.3)	0.98 (0.54, 1.77)	42 (0.3)
Rhinovirus infection	14 (0.2)	17 (0.2)	1.19 (0.59, 2.37)	31 (0.2)
Tooth infection	5 (<0.1)	17 (0.2)	3.33 (1.27, 8.68)	22 (0.2)
Herpes zoster	8 (0.1)	14 (0.2)	1.71 (0.74, 3.98)	22 (0.2)
Gastroenteritis	11 (0.2)	13 (0.2)	1.16 (0.53, 2.53)	24 (0.2)
Tooth abscess	16 (0.2)	13 (0.2)	0.79 (0.39, 1.63)	29 (0.2)
Pharyngitis	13 (0.2)	10 (0.1)	0.75 (0.34, 1.68)	23 (0.2)
Fungal infection	10 (0.1)	9 (0.1)	0.88 (0.37, 2.11)	19 (0.1)
COVID-19	63 (0.9)	8 (0.1)	0.12 (0.06, 0.25)	71 (0.5)
Pharyngitis streptococcal	12 (0.2)	8 (0.1)	0.65 (0.27, 1.55)	20 (0.1)
Diverticulitis	7 (<0.1)	7 (<0.1)	0.98 (0.36, 2.67)	14 (<0.1)
Ear infection	7 (<0.1)	7 (<0.1)	0.98 (0.36, 2.67)	14 (<0.1)
Oral herpes	5 (<0.1)	7 (<0.1)	1.37 (0.46, 4.08)	12 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Infections and infestations (Cont.)				
Otitis media	6 (<0.1)	7 (<0.1)	1.14 (0.40, 3.24)	13 (<0.1)
Acute sinusitis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Bacterial vaginosis	7 (<0.1)	6 (<0.1)	0.84 (0.30, 2.38)	13 (<0.1)
Conjunctivitis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Gingivitis	1 (<0.1)	6 (<0.1)		7 (<0.1)
Hordeolum	8 (0.1)	6 (<0.1)	0.73 (0.27, 2.02)	14 (<0.1)
Viral upper respiratory tract infection	9 (0.1)	6 (<0.1)	0.65 (0.24, 1.76)	15 (0.1)
Vulvovaginal candidiasis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vulvovaginal mycotic infection	14 (0.2)	6 (<0.1)	0.42 (0.17, 1.05)	20 (0.1)
Bronchitis	8 (0.1)	5 (<0.1)	0.61 (0.21, 1.77)	13 (<0.1)
Cellulitis	13 (0.2)	5 (<0.1)	0.38 (0.14, 1.01)	18 (0.1)
Enterovirus infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Herpes simplex	5 (<0.1)	4 (<0.1)		9 (<0.1)
Laryngitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Onychomycosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Otitis externa	5 (<0.1)	4 (<0.1)		9 (<0.1)
Respiratory tract infection	4 (<0.1)	4 (<0.1)		8 (<0.1)
Abscess limb	0	3 (<0.1)		3 (<0.1)
Cystitis	10 (0.1)	3 (<0.1)	0.29 (0.09, 0.99)	13 (<0.1)
Folliculitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Infections and infestations (Cont.)				
Lyme disease	0	3 (<0.1)		3 (<0.1)
Nasopharyngitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Pneumonia	6 (<0.1)	3 (<0.1)		9 (<0.1)
Subcutaneous abscess	1 (<0.1)	3 (<0.1)		4 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Furuncle	0	2 (<0.1)		2 (<0.1)
Gastroenteritis viral	5 (<0.1)	2 (<0.1)		7 (<0.1)
Impetigo	0	2 (<0.1)		2 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Localised infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis media acute	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paronychia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory tract infection viral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea pedis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tonsillitis	7 (<0.1)	2 (<0.1)	0.28 (0.07, 1.18)	9 (<0.1)
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Body tinea	0	1 (<0.1)		1 (<0.1)
Candida infection	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Infections and infestations (Cont.)				
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chlamydial infection	0	1 (<0.1)		1 (<0.1)
Eye infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gonorrhoea	0	1 (<0.1)		1 (<0.1)
Helicobacter infection	0	1 (<0.1)		1 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral candidiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rhinitis	4 (<0.1)	1 (<0.1)		5 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Infections and infestations (Cont.)				
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Skin infection	4 (<0.1)	1 (<0.1)		5 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Staphylococcal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Appendicitis	2 (<0.1)	0		2 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)
Chronic sinusitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Fungal skin infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Infections and infestations (Cont.)				
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Genital herpes simplex	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Infected bite	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Mastoiditis	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Sepsis	2 (<0.1)	0		2 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Sialoadenitis	2 (<0.1)	0		2 (<0.1)
Sinusitis bacterial	2 (<0.1)	0		2 (<0.1)
Staphylococcal skin infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Wound infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.3)	33 (0.5)		57 (0.4)
Basal cell carcinoma	4 (<0.1)	6 (<0.1)		10 (<0.1)
Squamous cell carcinoma	3 (<0.1)	4 (<0.1)		7 (<0.1)
Uterine leiomyoma	1 (<0.1)	4 (<0.1)		5 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lipoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Melanocytic naevus	0	2 (<0.1)		2 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of skin	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin cancer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Haemangioma of liver	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma of skin	3 (<0.1)	0		3 (<0.1)
Blood and lymphatic system disorders	65 (0.9)	189 (2.6)		254 (1.8)
Lymphadenopathy	54 (0.8)	171 (2.4)	3.10 (2.29, 4.19)	225 (1.6)
Anaemia	3 (<0.1)	7 (<0.1)	2.28 (0.64, 8.09)	10 (<0.1)
Lymph node pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Lymphadenitis	0	3 (<0.1)		3 (<0.1)
Iron deficiency anaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Immune system disorders	39 (0.5)	27 (0.4)		66 (0.5)
Seasonal allergy	29 (0.4)	20 (0.3)	0.67 (0.38, 1.18)	49 (0.3)
Hypersensitivity	2 (<0.1)	4 (<0.1)		6 (<0.1)
Food allergy	0	2 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Drug hypersensitivity	3 (<0.1)	0		3 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	13 (0.2)	9 (0.1)		22 (0.2)
Hypothyroidism	8 (0.1)	7 (<0.1)	0.86 (0.32, 2.27)	15 (0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Metabolism and nutrition disorders	55 (0.8)	59 (0.8)		114 (0.8)
Hyperlipidaemia	9 (0.1)	11 (0.2)	1.20 (0.51, 2.81)	20 (0.1)
Type 2 diabetes mellitus	3 (<0.1)	9 (0.1)	2.93 (0.86, 10.02)	12 (<0.1)
Decreased appetite	5 (<0.1)	8 (0.1)	1.56 (0.54, 4.54)	13 (<0.1)
Vitamin D deficiency	8 (0.1)	8 (0.1)	0.98 (0.38, 2.51)	16 (0.1)
Hypercholesterolaemia	6 (<0.1)	7 (<0.1)	1.14 (0.40, 3.24)	13 (<0.1)
Dehydration	5 (<0.1)	3 (<0.1)		8 (<0.1)
Glucose tolerance impaired	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyponatraemia	0	2 (<0.1)		2 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertriglyceridaemia	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypokalaemia	3 (<0.1)	0		3 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Iron deficiency	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Polydipsia	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	64 (0.9)	91 (1.3)		155 (1.1)
Anxiety	21 (0.3)	32 (0.4)	1.49 (0.87, 2.56)	53 (0.4)
Depression	19 (0.3)	26 (0.4)	1.34 (0.75, 2.40)	45 (0.3)
Insomnia	9 (0.1)	14 (0.2)	1.52 (0.67, 3.43)	23 (0.2)
Abnormal dreams	1 (<0.1)	3 (<0.1)		4 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	3 (<0.1)		4 (<0.1)
Attention deficit hyperactivity disorder	4 (<0.1)	3 (<0.1)		7 (<0.1)
Bipolar disorder	2 (<0.1)	3 (<0.1)		5 (<0.1)
Panic attack	2 (<0.1)	3 (<0.1)		5 (<0.1)
Sleep disorder	0	3 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Psychiatric disorders (Cont.)				
Post-traumatic stress disorder	0	2 (<0.1)		2 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Stress	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	3 (<0.1)	0		3 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Mental status changes	3 (<0.1)	0		3 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	504 (7.1)	578 (8.0)		1082 (7.5)
Headache	398 (5.6)	445 (6.1)	1.09 (0.96, 1.25)	843 (5.9)
Dizziness	30 (0.4)	35 (0.5)	1.14 (0.70, 1.85)	65 (0.5)
Paraesthesia	16 (0.2)	24 (0.3)	1.47 (0.79, 2.73)	40 (0.3)
Migraine	20 (0.3)	12 (0.2)	0.59 (0.29, 1.18)	32 (0.2)
Sinus headache	4 (<0.1)	10 (0.1)	2.44 (0.81, 7.36)	14 (<0.1)
Ageusia	5 (<0.1)	7 (<0.1)	1.37 (0.46, 4.08)	12 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Nervous system disorders (Cont.)				
Hypoaesthesia	5 (<0.1)	7 (<0.1)	1.37 (0.46, 4.08)	12 (<0.1)
Dysgeusia	5 (<0.1)	6 (<0.1)		11 (<0.1)
Syncope	6 (<0.1)	6 (<0.1)		12 (<0.1)
Cervical radiculopathy	0	4 (<0.1)		4 (<0.1)
Tension headache	2 (<0.1)	4 (<0.1)		6 (<0.1)
Carpal tunnel syndrome	6 (<0.1)	3 (<0.1)		9 (<0.1)
Disturbance in attention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Sciatica	3 (<0.1)	3 (<0.1)		6 (<0.1)
Anosmia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Facial paralysis	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia	0	2 (<0.1)		2 (<0.1)
Memory impairment	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Neuralgia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Seizure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Amnesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Nervous system disorders (Cont.)				
Burning sensation	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Nerve compression	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Parosmia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Presyncope	7 (<0.1)	1 (<0.1)	0.14 (0.02, 0.87)	8 (<0.1)
Somnolence	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Nervous system disorders (Cont.)				
Taste disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	1 (<0.1)	0		1 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Lethargy	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Post-traumatic headache	1 (<0.1)	0		1 (<0.1)
Restless legs syndrome	2 (<0.1)	0		2 (<0.1)
Transient ischaemic attack	1 (<0.1)	0		1 (<0.1)
Tremor	2 (<0.1)	0		2 (<0.1)
Eye disorders	45 (0.6)	39 (0.5)		84 (0.6)
Eye irritation	1 (<0.1)	5 (<0.1)		6 (<0.1)
Eye pruritus	3 (<0.1)	5 (<0.1)		8 (<0.1)
Dry eye	5 (<0.1)	3 (<0.1)		8 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Eye inflammation	0	2 (<0.1)		2 (<0.1)
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Eye disorders (Cont.)				
Glaucoma	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vitreous floaters	2 (<0.1)	2 (<0.1)		4 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blepharitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eye pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lacrimation increased	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Photophobia	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Scleritis	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vision blurred	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cataract	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Eye disorders (Cont.)				
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	2 (<0.1)	0		2 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	45 (0.6)	36 (0.5)		81 (0.6)
Ear pain	10 (0.1)	10 (0.1)	0.98 (0.42, 2.29)	20 (0.1)
Vertigo	11 (0.2)	10 (0.1)	0.89 (0.39, 2.04)	21 (0.1)
Tinnitus	5 (<0.1)	5 (<0.1)		10 (<0.1)
Vertigo positional	1 (<0.1)	3 (<0.1)		4 (<0.1)
Ear discomfort	4 (<0.1)	2 (<0.1)		6 (<0.1)
Deafness neurosensory	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Ear and labyrinth disorders (Cont.)				
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear canal erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Meniere's disease	0	1 (<0.1)		1 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Otorrhoea	0	1 (<0.1)		1 (<0.1)
Cerumen impaction	1 (<0.1)	0		1 (<0.1)
Ear congestion	2 (<0.1)	0		2 (<0.1)
Ear pruritus	3 (<0.1)	0		3 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	3 (<0.1)	0		3 (<0.1)
Cardiac disorders	31 (0.4)	33 (0.5)		64 (0.4)
Tachycardia	4 (<0.1)	7 (<0.1)	1.71 (0.54, 5.47)	11 (<0.1)
Atrial fibrillation	3 (<0.1)	4 (<0.1)		7 (<0.1)
Bradycardia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Palpitations	5 (<0.1)	4 (<0.1)		9 (<0.1)
Cardiac failure congestive	2 (<0.1)	3 (<0.1)		5 (<0.1)
Sinus tachycardia	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Cardiac disorders (Cont.)				
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arrhythmia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Coronary artery disease	2 (<0.1)	2 (<0.1)		4 (<0.1)
Angina pectoris	3 (<0.1)	1 (<0.1)		4 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Cardiac failure	0	1 (<0.1)		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiac flutter	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	89 (1.3)	94 (1.3)		183 (1.3)
Hypertension	65 (0.9)	70 (1.0)	1.05 (0.75, 1.47)	135 (0.9)
Hot flush	7 (<0.1)	10 (0.1)	1.40 (0.55, 3.55)	17 (0.1)
Flushing	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hypotension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertensive urgency	0	2 (<0.1)		2 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Vascular disorders (Cont.)				
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Systolic hypertension	2 (<0.1)	1 (<0.1)		3 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Haematoma	2 (<0.1)	0		2 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	321 (4.5)	312 (4.3)		633 (4.4)
Cough	75 (1.1)	105 (1.4)	1.37 (1.02, 1.84)	180 (1.3)
Oropharyngeal pain	122 (1.7)	92 (1.3)	0.74 (0.56, 0.96)	214 (1.5)
Nasal congestion	86 (1.2)	78 (1.1)	0.89 (0.65, 1.20)	164 (1.1)
Rhinorrhoea	71 (1.0)	76 (1.0)	1.05 (0.76, 1.44)	147 (1.0)
Dyspnoea	18 (0.3)	26 (0.4)	1.41 (0.78, 2.55)	44 (0.3)
Tachypnoea	12 (0.2)	17 (0.2)	1.39 (0.67, 2.85)	29 (0.2)
Asthma	13 (0.2)	8 (0.1)	0.60 (0.26, 1.41)	21 (0.1)
Respiratory tract congestion	3 (<0.1)	7 (<0.1)	2.28 (0.64, 8.09)	10 (<0.1)
Rhinitis allergic	9 (0.1)	7 (<0.1)	0.76 (0.29, 1.97)	16 (0.1)
Throat irritation	11 (0.2)	7 (<0.1)	0.62 (0.25, 1.55)	18 (0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Upper-airway cough syndrome	7 (<0.1)	7 (<0.1)	0.98 (0.36, 2.67)	14 (<0.1)
Epistaxis	6 (<0.1)	4 (<0.1)		10 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	4 (<0.1)		5 (<0.1)
Sinus congestion	12 (0.2)	4 (<0.1)	0.33 (0.11, 0.96)	16 (0.1)
Sneezing	6 (<0.1)	4 (<0.1)		10 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Dysphonia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chronic obstructive pulmonary disease	4 (<0.1)	2 (<0.1)		6 (<0.1)
Dry throat	2 (<0.1)	2 (<0.1)		4 (<0.1)
Paranasal sinus hypersecretion	0	2 (<0.1)		2 (<0.1)
Pharyngeal erythema	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleural effusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pleurisy	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Productive cough	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary embolism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Sinus pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Painful respiration	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Tonsillolith	2 (<0.1)	0		2 (<0.1)
Wheezing	3 (<0.1)	0		3 (<0.1)
Gastrointestinal disorders	312 (4.4)	332 (4.6)		644 (4.5)
Diarrhoea	100 (1.4)	117 (1.6)	1.14 (0.88, 1.49)	217 (1.5)
Nausea	110 (1.5)	93 (1.3)	0.83 (0.63, 1.09)	203 (1.4)
Vomiting	35 (0.5)	36 (0.5)	1.01 (0.63, 1.59)	71 (0.5)
Gastrooesophageal reflux disease	16 (0.2)	21 (0.3)	1.28 (0.68, 2.43)	37 (0.3)
Abdominal pain	12 (0.2)	20 (0.3)	1.63 (0.81, 3.28)	32 (0.2)
Toothache	16 (0.2)	14 (0.2)	0.86 (0.42, 1.73)	30 (0.2)
Constipation	8 (0.1)	10 (0.1)	1.22 (0.50, 3.00)	18 (0.1)
Abdominal pain upper	10 (0.1)	7 (<0.1)	0.68 (0.27, 1.74)	17 (0.1)
Food poisoning	1 (<0.1)	7 (<0.1)	6.85 (1.10, 42.65)	8 (<0.1)
Dental caries	6 (<0.1)	6 (<0.1)		12 (<0.1)
Dyspepsia	7 (<0.1)	6 (<0.1)	0.84 (0.30, 2.38)	13 (<0.1)
Abdominal discomfort	6 (<0.1)	4 (<0.1)		10 (<0.1)
Abdominal pain lower	5 (<0.1)	4 (<0.1)		9 (<0.1)
Abdominal distension	2 (<0.1)	3 (<0.1)		5 (<0.1)
Gastric ulcer	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Gastrointestinal disorders (Cont.)				
Inguinal hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Colitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hiatus hernia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Large intestine polyp	3 (<0.1)	2 (<0.1)		5 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)
Paraesthesia oral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Aphthous ulcer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry mouth	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dysphagia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Flatulence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Gastrointestinal disorders (Cont.)				
Gingival pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Haematochezia	0	1 (<0.1)		1 (<0.1)
Haemorrhoids	2 (<0.1)	1 (<0.1)		3 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Loose tooth	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral disorder	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stomatitis	0	1 (<0.1)		1 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discolouration	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Tooth impacted	0	1 (<0.1)		1 (<0.1)
Umbilical hernia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Gastrointestinal disorders (Cont.)				
Diverticulum	1 (<0.1)	0		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	0		1 (<0.1)
Enteritis	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral pain	3 (<0.1)	0		3 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	3 (<0.1)	7 (<0.1)		10 (<0.1)
Cholelithiasis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Skin and subcutaneous tissue disorders	127 (1.8)	165 (2.3)		292 (2.0)
Urticaria	23 (0.3)	25 (0.3)	1.06 (0.61, 1.86)	48 (0.3)
Rash	14 (0.2)	21 (0.3)	1.47 (0.76, 2.85)	35 (0.2)
Pruritus	9 (0.1)	15 (0.2)	1.63 (0.73, 3.64)	24 (0.2)
Dermatitis contact	16 (0.2)	10 (0.1)	0.61 (0.28, 1.32)	26 (0.2)
Erythema	0	10 (0.1)		10 (<0.1)
Acne	4 (<0.1)	6 (<0.1)		10 (<0.1)
Eczema	2 (<0.1)	6 (<0.1)		8 (<0.1)
Rash papular	4 (<0.1)	6 (<0.1)		10 (<0.1)
Alopecia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Dermatitis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Dermatitis atopic	4 (<0.1)	5 (<0.1)		9 (<0.1)
Rash maculo-papular	2 (<0.1)	5 (<0.1)		7 (<0.1)
Ecchymosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Rash macular	0	4 (<0.1)		4 (<0.1)
Actinic keratosis	0	3 (<0.1)		3 (<0.1)
Hyperhidrosis	6 (<0.1)	3 (<0.1)		9 (<0.1)
Pain of skin	0	3 (<0.1)		3 (<0.1)
Rosacea	1 (<0.1)	3 (<0.1)		4 (<0.1)
Angioedema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dry skin	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Night sweats	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Rash pruritic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Skin burning sensation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urticaria papular	4 (<0.1)	2 (<0.1)		6 (<0.1)
Acne cystic	0	1 (<0.1)		1 (<0.1)
Blister	0	1 (<0.1)		1 (<0.1)
Dermatitis allergic	3 (<0.1)	1 (<0.1)		4 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Macule	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Papule	0	1 (<0.1)		1 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin mass	0	1 (<0.1)		1 (<0.1)
Skin ulcer	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	0		1 (<0.1)
Dermal cyst	3 (<0.1)	0		3 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash erythematous	2 (<0.1)	0		2 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Musculoskeletal and connective tissue disorders	525 (7.4)	519 (7.1)		1044 (7.3)
Myalgia	206 (2.9)	204 (2.8)	0.97 (0.80, 1.17)	410 (2.9)
Arthralgia	199 (2.8)	198 (2.7)	0.97 (0.80, 1.18)	397 (2.8)
Back pain	53 (0.7)	62 (0.9)	1.14 (0.80, 1.65)	115 (0.8)
Pain in extremity	36 (0.5)	37 (0.5)	1.01 (0.64, 1.58)	73 (0.5)
Muscle spasms	15 (0.2)	23 (0.3)	1.50 (0.79, 2.84)	38 (0.3)
Neck pain	17 (0.2)	23 (0.3)	1.32 (0.71, 2.45)	40 (0.3)
Musculoskeletal pain	16 (0.2)	19 (0.3)	1.16 (0.60, 2.23)	35 (0.2)
Osteoarthritis	21 (0.3)	10 (0.1)	0.47 (0.22, 0.97)	31 (0.2)
Tendonitis	6 (<0.1)	9 (0.1)	1.47 (0.54, 3.95)	15 (0.1)
Musculoskeletal chest pain	6 (<0.1)	7 (<0.1)	1.14 (0.40, 3.24)	13 (<0.1)
Bursitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Rotator cuff syndrome	6 (<0.1)	5 (<0.1)		11 (<0.1)
Arthritis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Fibromyalgia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Joint range of motion decreased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Musculoskeletal stiffness	6 (<0.1)	4 (<0.1)		10 (<0.1)
Bone pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Groin pain	0	3 (<0.1)		3 (<0.1)
Osteoporosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Spinal pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Spinal stenosis	0	3 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Costochondritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Muscle twitching	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pain in jaw	3 (<0.1)	2 (<0.1)		5 (<0.1)
Plantar fasciitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Trigger finger	2 (<0.1)	2 (<0.1)		4 (<0.1)
Axillary mass	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Flank pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Joint swelling	5 (<0.1)	1 (<0.1)		6 (<0.1)
Limb discomfort	0	1 (<0.1)		1 (<0.1)
Limb mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle fatigue	0	1 (<0.1)		1 (<0.1)
Muscle tightness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Exostosis	2 (<0.1)	0		2 (<0.1)
Foot deformity	3 (<0.1)	0		3 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Periarthritis	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	0		2 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Synovial cyst	2 (<0.1)	0		2 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Tenosynovitis	1 (<0.1)	0		1 (<0.1)
Torticollis	2 (<0.1)	0		2 (<0.1)
Renal and urinary disorders	11 (0.2)	12 (0.2)		23 (0.2)
Dysuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nephrolithiasis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Hypertonic bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pollakiuria	0	1 (<0.1)		1 (<0.1)
Polyuria	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Urinary retention	0	1 (<0.1)		1 (<0.1)
Acute kidney injury	2 (<0.1)	0		2 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Haematuria	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Renal and urinary disorders (Cont.)				
Renal colic	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	38 (0.5)	39 (0.5)		77 (0.5)
Dysmenorrhoea	7 (<0.1)	5 (<0.1)	0.70 (0.23, 2.08)	12 (<0.1)
Pelvic pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Menopausal symptoms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Reproductive system and breast disorders (Cont.)				
Menstruation irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Congenital, familial and genetic disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	574 (8.1)	951 (13.1)		1525 (10.6)
Fatigue	369 (5.2)	433 (6.0)	1.15 (1.00, 1.31)	802 (5.6)
Injection site pain	69 (1.0)	157 (2.2)	2.23 (1.68, 2.95)	226 (1.6)
Injection site erythema	12 (0.2)	109 (1.5)	8.88 (4.94, 15.98)	121 (0.8)
Injection site swelling	12 (0.2)	87 (1.2)	7.09 (3.92, 12.84)	99 (0.7)
Injection site pruritus	9 (0.1)	77 (1.1)	8.37 (4.25, 16.46)	86 (0.6)
Chills	56 (0.8)	72 (1.0)	1.26 (0.89, 1.78)	128 (0.9)
Pyrexia	24 (0.3)	65 (0.9)	2.65 (1.67, 4.21)	89 (0.6)
Injection site induration	10 (0.1)	41 (0.6)	4.01 (2.04, 7.90)	51 (0.4)
Injection site lymphadenopathy	7 (<0.1)	38 (0.5)	5.31 (2.42, 11.64)	45 (0.3)
Injection site urticaria	1 (<0.1)	35 (0.5)	34.23 (5.93, 197.77)	36 (0.3)
Pain	39 (0.5)	35 (0.5)	0.88 (0.56, 1.38)	74 (0.5)
Injection site macule	1 (<0.1)	30 (0.4)	29.34 (5.06, 170.07)	31 (0.2)
Injection site rash	1 (<0.1)	18 (0.2)	17.60 (2.99, 103.59)	19 (0.1)
Axillary pain	3 (<0.1)	13 (0.2)	4.24 (1.30, 13.86)	16 (0.1)
Injection site bruising	15 (0.2)	13 (0.2)	0.85 (0.41, 1.75)	28 (0.2)
Injection site papule	0	12 (0.2)		12 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
General disorders and administration site conditions (Cont.)				
Malaise	10 (0.1)	7 (<0.1)	0.68 (0.27, 1.74)	17 (0.1)
Chest discomfort	6 (<0.1)	6 (<0.1)		12 (<0.1)
Injection site warmth	1 (<0.1)	6 (<0.1)		7 (<0.1)
Oedema peripheral	2 (<0.1)	6 (<0.1)		8 (<0.1)
Reactogenicity event	1 (<0.1)	6 (<0.1)		7 (<0.1)
Peripheral swelling	4 (<0.1)	5 (<0.1)		9 (<0.1)
Vaccination site swelling	0	5 (<0.1)		5 (<0.1)
Injection site haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Chest pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Feeling abnormal	1 (<0.1)	3 (<0.1)		4 (<0.1)
Feeling hot	2 (<0.1)	3 (<0.1)		5 (<0.1)
Swelling face	1 (<0.1)	3 (<0.1)		4 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site hypoaesthesia	0	2 (<0.1)		2 (<0.1)
Injection site irritation	0	2 (<0.1)		2 (<0.1)
Injection site joint pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Non-cardiac chest pain	4 (<0.1)	2 (<0.1)		6 (<0.1)
Tenderness	0	2 (<0.1)		2 (<0.1)
Vaccination site pain	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
General disorders and administration site conditions (Cont.)				
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site haematoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site mass	0	1 (<0.1)		1 (<0.1)
Injection site paraesthesia	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Asthenia	4 (<0.1)	0		4 (<0.1)
Crying	1 (<0.1)	0		1 (<0.1)
Hangover	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
General disorders and administration site conditions (Cont.)				
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Precancerous condition	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	1 (<0.1)	0		1 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)
Investigations	41 (0.6)	49 (0.7)		90 (0.6)
Blood pressure increased	11 (0.2)	9 (0.1)	0.80 (0.34, 1.88)	20 (0.1)
Blood pressure systolic increased	6 (<0.1)	7 (<0.1)	1.14 (0.40, 3.24)	13 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	4 (<0.1)		5 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Investigations (Cont.)				
Body temperature increased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Blood cholesterol increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood triglycerides increased	0	2 (<0.1)		2 (<0.1)
Hepatic enzyme increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Transaminases increased	0	2 (<0.1)		2 (<0.1)
Blood glucose increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood testosterone decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Investigations (Cont.)				
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Weight decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	215 (3.0)	165 (2.3)		380 (2.6)
Muscle strain	18 (0.3)	20 (0.3)	1.09 (0.58, 2.03)	38 (0.3)
Ligament sprain	17 (0.2)	19 (0.3)	1.09 (0.57, 2.08)	36 (0.3)
Fall	17 (0.2)	13 (0.2)	0.75 (0.37, 1.52)	30 (0.2)
Arthropod bite	19 (0.3)	12 (0.2)	0.62 (0.30, 1.25)	31 (0.2)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin laceration	14 (0.2)	11 (0.2)	0.77 (0.36, 1.66)	25 (0.2)
Contusion	14 (0.2)	10 (0.1)	0.70 (0.32, 1.54)	24 (0.2)
Procedural pain	26 (0.4)	9 (0.1)	0.34 (0.16, 0.71)	35 (0.2)
Tooth fracture	10 (0.1)	9 (0.1)	0.88 (0.37, 2.11)	19 (0.1)
Foot fracture	10 (0.1)	8 (0.1)	0.78 (0.32, 1.92)	18 (0.1)
Road traffic accident	2 (<0.1)	6 (<0.1)		8 (<0.1)
Skin abrasion	8 (0.1)	6 (<0.1)	0.73 (0.27, 2.02)	14 (<0.1)
Joint injury	3 (<0.1)	5 (<0.1)		8 (<0.1)
Limb injury	5 (<0.1)	5 (<0.1)		10 (<0.1)
Arthropod sting	9 (0.1)	4 (<0.1)	0.43 (0.14, 1.33)	13 (<0.1)
Head injury	0	4 (<0.1)		4 (<0.1)
Facial bones fracture	0	3 (<0.1)		3 (<0.1)
Post-traumatic pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tendon rupture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Thermal burn	2 (<0.1)	3 (<0.1)		5 (<0.1)
Animal bite	5 (<0.1)	2 (<0.1)		7 (<0.1)
Ankle fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bone contusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Concussion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hand fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Injury, poisoning and procedural complications (Cont.)				
Meniscus injury	5 (<0.1)	2 (<0.1)		7 (<0.1)
Wrist fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Back injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns second degree	0	1 (<0.1)		1 (<0.1)
Cartilage injury	0	1 (<0.1)		1 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Epicondylitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Ligament injury	0	1 (<0.1)		1 (<0.1)
Ligament rupture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Rib fracture	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Injury, poisoning and procedural complications (Cont.)				
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tooth injury	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Burns first degree	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Post procedural swelling	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.7.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection by Sex
Safety Set

Sex Group: Female

System Organ Class Preferred Term	Placebo (N=7106) n (%)	mRNA-1273 (N=7266) n (%)	Rate Ratio (95% CI)	Total (N=14372) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Sunburn	3 (<0.1)	0		3 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Upper limb fracture	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	0	4 (<0.1)		4 (<0.1)
Device breakage	0	2 (<0.1)		2 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3326 (27.7)	3674 (30.5)		7000 (29.1)
Number of Unsolicited Adverse Events	6392	7122		13514
Infections and infestations	728 (6.1)	609 (5.1)		1337 (5.6)
Urinary tract infection	89 (0.7)	74 (0.6)	0.83 (0.61, 1.13)	163 (0.7)
Sinusitis	37 (0.3)	54 (0.4)	1.46 (0.96, 2.20)	91 (0.4)
Upper respiratory tract infection	85 (0.7)	54 (0.4)	0.63 (0.45, 0.89)	139 (0.6)
Rhinovirus infection	26 (0.2)	31 (0.3)	1.19 (0.71, 1.99)	57 (0.2)
Suspected COVID-19	26 (0.2)	29 (0.2)	1.11 (0.66, 1.88)	55 (0.2)
Viral infection	36 (0.3)	25 (0.2)	0.69 (0.42, 1.15)	61 (0.3)
Tooth abscess	23 (0.2)	20 (0.2)	0.87 (0.48, 1.56)	43 (0.2)
COVID-19	112 (0.9)	18 (0.1)	0.16 (0.10, 0.26)	130 (0.5)
Herpes zoster	12 (0.1)	18 (0.1)	1.50 (0.73, 3.06)	30 (0.1)
Tooth infection	13 (0.1)	16 (0.1)	1.23 (0.60, 2.51)	29 (0.1)
Gastroenteritis	11 (<0.1)	15 (0.1)	1.36 (0.64, 2.91)	26 (0.1)
Pharyngitis	15 (0.1)	15 (0.1)	1.00 (0.49, 2.01)	30 (0.1)
Conjunctivitis	5 (<0.1)	12 (<0.1)	2.39 (0.88, 6.51)	17 (<0.1)
Hordeolum	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.86)	20 (<0.1)
Cellulitis	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (0.1)
Ear infection	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Pharyngitis streptococcal	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Infections and infestations (Cont.)				
Oral herpes	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Diverticulitis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.56)	16 (<0.1)
Localised infection	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.63)	13 (<0.1)
Bronchitis	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.31)	15 (<0.1)
Herpes simplex	4 (<0.1)	7 (<0.1)	1.74 (0.55, 5.58)	11 (<0.1)
Onychomycosis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.25)	10 (<0.1)
Viral upper respiratory tract infection	12 (0.1)	7 (<0.1)	0.58 (0.24, 1.43)	19 (<0.1)
Folliculitis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Fungal infection	6 (<0.1)	6 (<0.1)		12 (<0.1)
Gingivitis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Otitis media	6 (<0.1)	6 (<0.1)		12 (<0.1)
Acute sinusitis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Nasopharyngitis	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Paronychia	4 (<0.1)	5 (<0.1)		9 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Enterovirus infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Laryngitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Otitis externa	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.55)	12 (<0.1)
Skin infection	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Infections and infestations (Cont.)				
Staphylococcal infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Vulvovaginal mycotic infection	11 (<0.1)	4 (<0.1)	0.36 (0.12, 1.08)	15 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)		4 (<0.1)
Asymptomatic COVID-19	0	3 (<0.1)		3 (<0.1)
Bacterial vaginosis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Clostridium difficile infection	0	3 (<0.1)		3 (<0.1)
Cystitis	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.13)	12 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.13)	12 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Pneumonia	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Subcutaneous abscess	2 (<0.1)	3 (<0.1)		5 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Impetigo	0	2 (<0.1)		2 (<0.1)
Kidney infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media acute	2 (<0.1)	2 (<0.1)		4 (<0.1)
Respiratory tract infection viral	4 (<0.1)	2 (<0.1)		6 (<0.1)
Tinea pedis	4 (<0.1)	2 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Infections and infestations (Cont.)				
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Candida infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Epididymitis	0	1 (<0.1)		1 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Gonorrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Helicobacter infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Infections and infestations (Cont.)				
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rhinitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea cruris	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Infections and infestations (Cont.)				
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral pharyngitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wound infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Infections and infestations (Cont.)				
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Tonsillitis	7 (<0.1)	0		7 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	52 (0.4)	53 (0.4)		105 (0.4)
Basal cell carcinoma	16 (0.1)	9 (<0.1)	0.56 (0.25, 1.24)	25 (0.1)
Squamous cell carcinoma	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.55)	12 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Uterine leiomyoma	0	3 (<0.1)		3 (<0.1)
Benign neoplasm of skin	2 (<0.1)	2 (<0.1)		4 (<0.1)
Lipoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign breast neoplasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)		5 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Haemangioma of liver	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)

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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	106 (0.9)	223 (1.9)		329 (1.4)
Lymphadenopathy	93 (0.8)	199 (1.7)	2.13 (1.67, 2.72)	292 (1.2)
Lymph node pain	4 (<0.1)	8 (<0.1)	1.99 (0.64, 6.22)	12 (<0.1)
Anaemia	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.16)	12 (<0.1)
Lymphadenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Iron deficiency anaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	49 (0.4)	35 (0.3)		84 (0.3)
Seasonal allergy	35 (0.3)	25 (0.2)	0.71 (0.43, 1.18)	60 (0.2)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypersensitivity	6 (<0.1)	3 (<0.1)		9 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Immune system disorders (Cont.)				
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	4 (<0.1)	1 (<0.1)		5 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to arthropod bite	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	16 (0.1)	9 (<0.1)		25 (0.1)
Hypothyroidism	10 (<0.1)	8 (<0.1)	0.80 (0.32, 1.96)	18 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	84 (0.7)	104 (0.9)		188 (0.8)
Hyperlipidaemia	13 (0.1)	21 (0.2)	1.61 (0.82, 3.17)	34 (0.1)
Type 2 diabetes mellitus	10 (<0.1)	17 (0.1)	1.69 (0.79, 3.63)	27 (0.1)
Decreased appetite	5 (<0.1)	10 (<0.1)	1.99 (0.71, 5.57)	15 (<0.1)

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Table 14.3.1.8.4.1
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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypercholesterolaemia	11 (<0.1)	10 (<0.1)	0.91 (0.39, 2.08)	21 (<0.1)
Dehydration	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Vitamin D deficiency	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.22)	17 (<0.1)
Diabetes mellitus	3 (<0.1)	6 (<0.1)		9 (<0.1)
Gout	6 (<0.1)	4 (<0.1)		10 (<0.1)
Hyperglycaemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Glucose tolerance impaired	6 (<0.1)	2 (<0.1)		8 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypocalcaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypoglycaemia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hypokalaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Metabolism and nutrition disorders (Cont.)				
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	2 (<0.1)	0		2 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Iron deficiency	2 (<0.1)	0		2 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	87 (0.7)	124 (1.0)		211 (0.9)
Anxiety	30 (0.3)	44 (0.4)	1.46 (0.92, 2.31)	74 (0.3)
Depression	24 (0.2)	29 (0.2)	1.20 (0.71, 2.05)	53 (0.2)
Insomnia	14 (0.1)	20 (0.2)	1.42 (0.73, 2.78)	34 (0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)
Attention deficit hyperactivity disorder	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Abnormal dreams	2 (<0.1)	3 (<0.1)		5 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Psychiatric disorders (Cont.)				
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Nightmare	0	3 (<0.1)		3 (<0.1)
Panic attack	1 (<0.1)	3 (<0.1)		4 (<0.1)
Major depression	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Libido decreased	0	1 (<0.1)		1 (<0.1)
Post-traumatic stress disorder	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	3 (<0.1)	0		3 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Psychiatric disorders (Cont.)				
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	3 (<0.1)	0		3 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Substance abuse	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	666 (5.6)	730 (6.1)		1396 (5.8)
Headache	521 (4.3)	548 (4.6)	1.05 (0.93, 1.18)	1069 (4.4)
Dizziness	42 (0.4)	52 (0.4)	1.23 (0.82, 1.85)	94 (0.4)
Paraesthesia	10 (<0.1)	26 (0.2)	2.59 (1.27, 5.29)	36 (0.1)
Sinus headache	4 (<0.1)	16 (0.1)	3.99 (1.40, 11.36)	20 (<0.1)
Migraine	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (0.1)
Dysgeusia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.63)	13 (<0.1)
Sciatica	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.16)	12 (<0.1)
Syncope	14 (0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Anosmia	5 (<0.1)	6 (<0.1)		11 (<0.1)
Cervical radiculopathy	0	6 (<0.1)		6 (<0.1)
Hypoaesthesia	5 (<0.1)	6 (<0.1)		11 (<0.1)
Tension headache	4 (<0.1)	6 (<0.1)		10 (<0.1)
Ageusia	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Disturbance in attention	2 (<0.1)	4 (<0.1)		6 (<0.1)
Presyncope	11 (<0.1)	4 (<0.1)	0.36 (0.12, 1.08)	15 (<0.1)
Carpal tunnel syndrome	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Nervous system disorders (Cont.)				
Hyperaesthesia	0	3 (<0.1)		3 (<0.1)
Memory impairment	0	3 (<0.1)		3 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Amnesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neuropathy peripheral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Parosmia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Taste disorder	2 (<0.1)	2 (<0.1)		4 (<0.1)
Transient ischaemic attack	0	2 (<0.1)		2 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)

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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Nervous system disorders (Cont.)				
Dyslexia	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Nerve compression	3 (<0.1)	1 (<0.1)		4 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Nervous system disorders (Cont.)				
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	2 (<0.1)	0		2 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Facial paralysis	1 (<0.1)	0		1 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Lethargy	1 (<0.1)	0		1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	0		2 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Tremor	2 (<0.1)	0		2 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	54 (0.5)	50 (0.4)		104 (0.4)
Eye pruritus	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.16)	12 (<0.1)
Eye irritation	0	6 (<0.1)		6 (<0.1)
Dry eye	4 (<0.1)	3 (<0.1)		7 (<0.1)
Retinal detachment	1 (<0.1)	3 (<0.1)		4 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Eye disorders (Cont.)				
Blepharitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Eye inflammation	0	2 (<0.1)		2 (<0.1)
Eye pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)
Glaucoma	4 (<0.1)	2 (<0.1)		6 (<0.1)
Lacrimation increased	0	2 (<0.1)		2 (<0.1)
Ocular hyperaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vision blurred	2 (<0.1)	2 (<0.1)		4 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cataract	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)

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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Eye disorders (Cont.)				
Scleritis	0	1 (<0.1)		1 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	2 (<0.1)	1 (<0.1)		3 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)

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Safety Set

Race Group: White

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Eye disorders (Cont.)				
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	59 (0.5)	61 (0.5)		120 (0.5)
Vertigo	16 (0.1)	19 (0.2)	1.18 (0.62, 2.27)	35 (0.1)
Ear pain	12 (0.1)	12 (<0.1)	1.00 (0.46, 2.17)	24 (<0.1)
Tinnitus	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Vertigo positional	0	7 (<0.1)		7 (<0.1)
Cerumen impaction	2 (<0.1)	4 (<0.1)		6 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear congestion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Ear discomfort	6 (<0.1)	1 (<0.1)		7 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)

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Safety Set

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Ear and labyrinth disorders (Cont.)				
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	0		4 (<0.1)
Cardiac disorders	58 (0.5)	58 (0.5)		116 (0.5)
Atrial fibrillation	9 (<0.1)	12 (<0.1)	1.33 (0.57, 3.08)	21 (<0.1)
Bradycardia	10 (<0.1)	8 (<0.1)	0.80 (0.32, 1.96)	18 (<0.1)
Tachycardia	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Palpitations	6 (<0.1)	6 (<0.1)		12 (<0.1)
Angina pectoris	3 (<0.1)	4 (<0.1)		7 (<0.1)
Arrhythmia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Coronary artery disease	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiac failure congestive	4 (<0.1)	2 (<0.1)		6 (<0.1)
Sinus tachycardia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Cardiac failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	0	1 (<0.1)		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Cardiac disorders (Cont.)				
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myocardial infarction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)		4 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	151 (1.3)	149 (1.2)		300 (1.2)
Hypertension	118 (1.0)	115 (1.0)	0.97 (0.75, 1.25)	233 (1.0)
Hot flush	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.31)	19 (<0.1)
Flushing	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hypotension	4 (<0.1)	4 (<0.1)		8 (<0.1)
Haematoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertensive urgency	2 (<0.1)	2 (<0.1)		4 (<0.1)
Systolic hypertension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	3 (<0.1)	1 (<0.1)		4 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Vascular disorders (Cont.)				
Orthostatic hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	2 (<0.1)	0		2 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	459 (3.8)	429 (3.6)		888 (3.7)
Cough	114 (1.0)	127 (1.1)	1.11 (0.86, 1.43)	241 (1.0)
Oropharyngeal pain	169 (1.4)	122 (1.0)	0.72 (0.57, 0.91)	291 (1.2)
Nasal congestion	124 (1.0)	112 (0.9)	0.90 (0.70, 1.16)	236 (1.0)
Rhinorrhoea	89 (0.7)	89 (0.7)	1.00 (0.74, 1.33)	178 (0.7)
Dyspnoea	27 (0.2)	30 (0.2)	1.11 (0.66, 1.85)	57 (0.2)
Tachypnoea	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Respiratory tract congestion	5 (<0.1)	15 (0.1)	2.99 (1.13, 7.91)	20 (<0.1)
Asthma	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Sinus congestion	19 (0.2)	12 (<0.1)	0.63 (0.31, 1.28)	31 (0.1)
Upper-airway cough syndrome	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.31)	19 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Epistaxis	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.81)	17 (<0.1)
Rhinitis allergic	13 (0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Sneezing	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Throat irritation	11 (<0.1)	7 (<0.1)	0.63 (0.25, 1.58)	18 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Dysphonia	6 (<0.1)	4 (<0.1)		10 (<0.1)
Sinus pain	4 (<0.1)	4 (<0.1)		8 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Pharyngeal erythema	1 (<0.1)	3 (<0.1)		4 (<0.1)
Productive cough	6 (<0.1)	3 (<0.1)		9 (<0.1)
Pulmonary embolism	1 (<0.1)	3 (<0.1)		4 (<0.1)
Acute respiratory failure	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Dyspnoea exertional	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	2 (<0.1)		5 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sleep apnoea syndrome	0	2 (<0.1)		2 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atelectasis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dry throat	2 (<0.1)	1 (<0.1)		3 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleural effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Pleuritic pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Wheezing	3 (<0.1)	1 (<0.1)		4 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)

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Safety Set

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	439 (3.7)	447 (3.7)		886 (3.7)
Diarrhoea	160 (1.3)	157 (1.3)	0.98 (0.79, 1.22)	317 (1.3)
Nausea	120 (1.0)	113 (0.9)	0.94 (0.73, 1.21)	233 (1.0)
Vomiting	40 (0.3)	44 (0.4)	1.10 (0.72, 1.68)	84 (0.3)
Toothache	23 (0.2)	28 (0.2)	1.21 (0.70, 2.09)	51 (0.2)

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Safety Set

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Gastrointestinal disorders (Cont.)				
Gastrooesophageal reflux disease	21 (0.2)	26 (0.2)	1.23 (0.70, 2.18)	47 (0.2)
Abdominal pain	17 (0.1)	13 (0.1)	0.76 (0.38, 1.55)	30 (0.1)
Abdominal pain upper	15 (0.1)	12 (<0.1)	0.80 (0.38, 1.67)	27 (0.1)
Constipation	17 (0.1)	12 (<0.1)	0.70 (0.34, 1.45)	29 (0.1)
Dyspepsia	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.52)	21 (<0.1)
Dental caries	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.06)	18 (<0.1)
Food poisoning	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Abdominal discomfort	9 (<0.1)	5 (<0.1)	0.55 (0.19, 1.57)	14 (<0.1)
Abdominal pain lower	6 (<0.1)	4 (<0.1)		10 (<0.1)
Colitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hiatus hernia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Inguinal hernia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Aphthous ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastric ulcer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hyperaesthesia teeth	0	3 (<0.1)		3 (<0.1)
Irritable bowel syndrome	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dysphagia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastrointestinal disorder	0	2 (<0.1)		2 (<0.1)
Haemorrhoids	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Gastrointestinal disorders (Cont.)				
Large intestine polyp	5 (<0.1)	2 (<0.1)		7 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)
Paraesthesia oral	4 (<0.1)	2 (<0.1)		6 (<0.1)
Rectal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Chapped lips	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Dry mouth	2 (<0.1)	1 (<0.1)		3 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Flatulence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Haematochezia	0	1 (<0.1)		1 (<0.1)

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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Gastrointestinal disorders (Cont.)				
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small intestinal obstruction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discolouration	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Tooth impacted	1 (<0.1)	1 (<0.1)		2 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)

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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Gastrointestinal disorders (Cont.)				
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Enteritis	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Glossitis	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral pain	5 (<0.1)	0		5 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Tongue discomfort	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	4 (<0.1)	11 (<0.1)		15 (<0.1)
Cholelithiasis	3 (<0.1)	6 (<0.1)		9 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Hepatobiliary disorders (Cont.)				
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	179 (1.5)	233 (1.9)		412 (1.7)
Urticaria	20 (0.2)	38 (0.3)	1.89 (1.11, 3.23)	58 (0.2)
Rash	21 (0.2)	28 (0.2)	1.33 (0.76, 2.32)	49 (0.2)
Dermatitis contact	30 (0.3)	20 (0.2)	0.66 (0.38, 1.16)	50 (0.2)
Pruritus	13 (0.1)	18 (0.1)	1.38 (0.69, 2.78)	31 (0.1)
Erythema	5 (<0.1)	14 (0.1)	2.79 (1.05, 7.45)	19 (<0.1)
Hyperhidrosis	6 (<0.1)	9 (<0.1)	1.50 (0.55, 4.03)	15 (<0.1)
Dermatitis	4 (<0.1)	8 (<0.1)	1.99 (0.64, 6.22)	12 (<0.1)
Eczema	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.59)	10 (<0.1)
Night sweats	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Acne	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.16)	12 (<0.1)
Actinic keratosis	2 (<0.1)	6 (<0.1)		8 (<0.1)
Rash maculo-papular	2 (<0.1)	6 (<0.1)		8 (<0.1)
Rash papular	0	6 (<0.1)		6 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash macular	2 (<0.1)	5 (<0.1)		7 (<0.1)
Alopecia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Dermatitis atopic	5 (<0.1)	4 (<0.1)		9 (<0.1)
Ecchymosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Psoriasis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Rash pruritic	4 (<0.1)	4 (<0.1)		8 (<0.1)
Rosacea	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pityriasis rosea	0	3 (<0.1)		3 (<0.1)
Rash erythematous	0	3 (<0.1)		3 (<0.1)
Angioedema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blister	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Acne cystic	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dry skin	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Papule	1 (<0.1)	1 (<0.1)		2 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Skin burning sensation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Urticaria papular	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)

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Safety Set

Race Group: White

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Skin and subcutaneous tissue disorders (Cont.)				
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	4 (<0.1)	0		4 (<0.1)
Skin mass	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	746 (6.2)	759 (6.3)		1505 (6.3)
Arthralgia	286 (2.4)	290 (2.4)	1.01 (0.86, 1.19)	576 (2.4)
Myalgia	285 (2.4)	280 (2.3)	0.98 (0.83, 1.15)	565 (2.4)
Back pain	89 (0.7)	77 (0.6)	0.86 (0.64, 1.17)	166 (0.7)
Pain in extremity	45 (0.4)	50 (0.4)	1.11 (0.74, 1.65)	95 (0.4)
Musculoskeletal pain	30 (0.3)	37 (0.3)	1.23 (0.76, 1.98)	67 (0.3)
Neck pain	25 (0.2)	34 (0.3)	1.36 (0.81, 2.26)	59 (0.2)
Muscle spasms	20 (0.2)	26 (0.2)	1.30 (0.73, 2.30)	46 (0.2)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Osteoarthritis	24 (0.2)	17 (0.1)	0.71 (0.38, 1.30)	41 (0.2)
Tendonitis	10 (<0.1)	15 (0.1)	1.50 (0.69, 3.26)	25 (0.1)
Musculoskeletal chest pain	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Bursitis	5 (<0.1)	12 (<0.1)	2.39 (0.88, 6.51)	17 (<0.1)
Rotator cuff syndrome	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Musculoskeletal stiffness	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Arthritis	4 (<0.1)	7 (<0.1)	1.74 (0.55, 5.58)	11 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	7 (<0.1)	1.74 (0.55, 5.58)	11 (<0.1)
Trigger finger	3 (<0.1)	6 (<0.1)		9 (<0.1)
Costochondritis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Joint range of motion decreased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Joint swelling	4 (<0.1)	4 (<0.1)		8 (<0.1)
Muscle tightness	1 (<0.1)	4 (<0.1)		5 (<0.1)
Muscular weakness	1 (<0.1)	4 (<0.1)		5 (<0.1)
Osteoporosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pain in jaw	5 (<0.1)	4 (<0.1)		9 (<0.1)
Spinal pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Spinal stenosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Fibromyalgia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Groin pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Limb discomfort	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Neck mass	0	3 (<0.1)		3 (<0.1)
Axillary mass	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Flank pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Plantar fasciitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spinal osteoarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	4 (<0.1)	1 (<0.1)		5 (<0.1)
Joint stiffness	3 (<0.1)	1 (<0.1)		4 (<0.1)
Limb mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle twitching	2 (<0.1)	1 (<0.1)		3 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	2 (<0.1)	0		2 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Periarthritis	2 (<0.1)	0		2 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Scoliosis	2 (<0.1)	0		2 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Tenosynovitis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Renal and urinary disorders	38 (0.3)	39 (0.3)		77 (0.3)
Nephrolithiasis	18 (0.2)	13 (0.1)	0.72 (0.36, 1.45)	31 (0.1)
Dysuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Haematuria	4 (<0.1)	3 (<0.1)		7 (<0.1)
Chronic kidney disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertonic bladder	0	2 (<0.1)		2 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary incontinence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary retention	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute kidney injury	4 (<0.1)	1 (<0.1)		5 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Renal and urinary disorders (Cont.)				
Urinary hesitation	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	2 (<0.1)	0		2 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	41 (0.3)	50 (0.4)		91 (0.4)
Benign prostatic hyperplasia	6 (<0.1)	5 (<0.1)		11 (<0.1)
Dysmenorrhoea	3 (<0.1)	5 (<0.1)		8 (<0.1)
Erectile dysfunction	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pelvic pain	0	4 (<0.1)		4 (<0.1)
Breast cyst	0	2 (<0.1)		2 (<0.1)
Menopausal symptoms	0	2 (<0.1)		2 (<0.1)
Menorrhagia	0	2 (<0.1)		2 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	0	2 (<0.1)		2 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Reproductive system and breast disorders (Cont.)				
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Reproductive system and breast disorders (Cont.)				
Dysfunctional uterine bleeding	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
General disorders and administration site conditions	807 (6.7)	1216 (10.1)		2023 (8.4)
Fatigue	514 (4.3)	575 (4.8)	1.12 (0.99, 1.25)	1089 (4.5)
Injection site pain	86 (0.7)	188 (1.6)	2.18 (1.69, 2.81)	274 (1.1)
Injection site erythema	27 (0.2)	128 (1.1)	4.73 (3.13, 7.13)	155 (0.6)
Chills	77 (0.6)	88 (0.7)	1.14 (0.84, 1.54)	165 (0.7)
Pyrexia	49 (0.4)	87 (0.7)	1.77 (1.25, 2.51)	136 (0.6)
Injection site swelling	19 (0.2)	85 (0.7)	4.46 (2.73, 7.29)	104 (0.4)
Injection site pruritus	10 (<0.1)	69 (0.6)	6.88 (3.59, 13.19)	79 (0.3)
Injection site lymphadenopathy	8 (<0.1)	46 (0.4)	5.73 (2.75, 11.94)	54 (0.2)
Pain	45 (0.4)	46 (0.4)	1.02 (0.68, 1.53)	91 (0.4)
Injection site induration	15 (0.1)	40 (0.3)	2.66 (1.48, 4.77)	55 (0.2)
Injection site macule	3 (<0.1)	40 (0.3)	13.29 (4.36, 40.52)	43 (0.2)
Injection site urticaria	1 (<0.1)	31 (0.3)	30.91 (5.34, 179.03)	32 (0.1)
Injection site rash	1 (<0.1)	18 (0.1)	17.95 (3.05, 105.61)	19 (<0.1)
Injection site bruising	17 (0.1)	17 (0.1)	1.00 (0.52, 1.93)	34 (0.1)
Axillary pain	8 (<0.1)	15 (0.1)	1.87 (0.81, 4.30)	23 (<0.1)
Injection site papule	1 (<0.1)	12 (<0.1)	11.96 (2.00, 71.72)	13 (<0.1)
Malaise	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.31)	19 (<0.1)
Chest discomfort	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.81)	17 (<0.1)
Chest pain	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.25)	10 (<0.1)
Injection site paraesthesia	2 (<0.1)	6 (<0.1)		8 (<0.1)
Oedema peripheral	6 (<0.1)	6 (<0.1)		12 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
General disorders and administration site conditions (Cont.)				
Injection site haematoma	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site haemorrhage	5 (<0.1)	5 (<0.1)		10 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)		6 (<0.1)
Reactogenicity event	0	5 (<0.1)		5 (<0.1)
Vaccination site swelling	0	5 (<0.1)		5 (<0.1)
Non-cardiac chest pain	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Peripheral swelling	9 (<0.1)	4 (<0.1)	0.44 (0.14, 1.36)	13 (<0.1)
Feeling abnormal	2 (<0.1)	3 (<0.1)		5 (<0.1)
Feeling hot	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site joint pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site reaction	0	3 (<0.1)		3 (<0.1)
Swelling face	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Vaccination site pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site irritation	0	2 (<0.1)		2 (<0.1)
Injection site mass	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenderness	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
General disorders and administration site conditions (Cont.)				
Asthenia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Hangover	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	0	1 (<0.1)		1 (<0.1)
Vessel puncture site bruise	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
General disorders and administration site conditions (Cont.)				
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Influenza like illness	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	1 (<0.1)	0		1 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Investigations	60 (0.5)	82 (0.7)		142 (0.6)
Blood pressure increased	19 (0.2)	18 (0.1)	0.94 (0.50, 1.78)	37 (0.2)
Blood pressure systolic increased	8 (<0.1)	14 (0.1)	1.74 (0.75, 4.05)	22 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	7 (<0.1)	6.98 (1.12, 43.48)	8 (<0.1)
Body temperature increased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood cholesterol increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hepatic enzyme increased	4 (<0.1)	4 (<0.1)		8 (<0.1)
Blood triglycerides increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Heart rate increased	0	3 (<0.1)		3 (<0.1)
Transaminases increased	0	3 (<0.1)		3 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Weight decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Investigations (Cont.)				
Heart rate irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Prostatic specific antigen increased	0	1 (<0.1)		1 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Investigations (Cont.)				
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	320 (2.7)	264 (2.2)		584 (2.4)
Muscle strain	26 (0.2)	33 (0.3)	1.27 (0.76, 2.10)	59 (0.2)
Ligament sprain	20 (0.2)	23 (0.2)	1.15 (0.64, 2.07)	43 (0.2)
Arthropod bite	24 (0.2)	22 (0.2)	0.91 (0.52, 1.62)	46 (0.2)
Contusion	23 (0.2)	17 (0.1)	0.74 (0.40, 1.37)	40 (0.2)
Fall	21 (0.2)	17 (0.1)	0.81 (0.43, 1.51)	38 (0.2)
Skin laceration	29 (0.2)	17 (0.1)	0.58 (0.32, 1.05)	46 (0.2)
Tooth fracture	14 (0.1)	15 (0.1)	1.07 (0.52, 2.18)	29 (0.1)
Procedural pain	24 (0.2)	13 (0.1)	0.54 (0.28, 1.05)	37 (0.2)
Foot fracture	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Limb injury	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.06)	18 (<0.1)
Arthropod sting	14 (0.1)	9 (<0.1)	0.64 (0.28, 1.45)	23 (<0.1)
Road traffic accident	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Animal bite	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.58)	16 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Injury, poisoning and procedural complications (Cont.)				
Joint injury	4 (<0.1)	6 (<0.1)		10 (<0.1)
Skin abrasion	17 (0.1)	6 (<0.1)	0.35 (0.14, 0.87)	23 (<0.1)
Meniscus injury	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Rib fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Hand fracture	2 (<0.1)	4 (<0.1)		6 (<0.1)
Wrist fracture	4 (<0.1)	4 (<0.1)		8 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Head injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Post-traumatic pain	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Upper limb fracture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Ankle fracture	4 (<0.1)	2 (<0.1)		6 (<0.1)
Bone contusion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Concussion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Epicondylitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tendon rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Injury, poisoning and procedural complications (Cont.)				
Thermal burn	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stress fracture	4 (<0.1)	1 (<0.1)		5 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tendon injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound	2 (<0.1)	1 (<0.1)		3 (<0.1)
Back injury	2 (<0.1)	0		2 (<0.1)
Burns second degree	2 (<0.1)	0		2 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Corneal abrasion	3 (<0.1)	0		3 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Injury, poisoning and procedural complications (Cont.)				
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Hip fracture	2 (<0.1)	0		2 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: White

System Organ Class Preferred Term	Placebo (N=11998) n (%)	mRNA-1273 (N=12034) n (%)	Rate Ratio (95% CI)	Total (N=24032) n (%)
Injury, poisoning and procedural complications (Cont.)				
Radius fracture	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)		7 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	465 (30.4)	484 (30.9)		949 (30.6)
Number of Unsolicited Adverse Events	992	1038		2030
Infections and infestations	91 (5.9)	77 (4.9)		168 (5.4)
Upper respiratory tract infection	10 (0.7)	15 (1.0)	1.47 (0.67, 3.19)	25 (0.8)
Urinary tract infection	5 (0.3)	9 (0.6)	1.76 (0.62, 4.99)	14 (0.5)
Viral infection	2 (0.1)	5 (0.3)		7 (0.2)
Tooth infection	3 (0.2)	4 (0.3)		7 (0.2)
COVID-19	24 (1.6)	3 (0.2)	0.12 (0.04, 0.38)	27 (0.9)
Gastroenteritis	4 (0.3)	3 (0.2)		7 (0.2)
Sinusitis	3 (0.2)	3 (0.2)		6 (0.2)
Ear infection	1 (<0.1)	2 (0.1)		3 (<0.1)
Gingivitis	1 (<0.1)	2 (0.1)		3 (<0.1)
Helicobacter infection	1 (<0.1)	2 (0.1)		3 (<0.1)
Otitis media	0	2 (0.1)		2 (<0.1)
Subcutaneous abscess	0	2 (0.1)		2 (<0.1)
Tonsillitis	2 (0.1)	2 (0.1)		4 (0.1)
Tooth abscess	2 (0.1)	2 (0.1)		4 (0.1)
Viral upper respiratory tract infection	1 (<0.1)	2 (0.1)		3 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Infections and infestations (Cont.)				
Abscess limb	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Acute sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diverticulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Epididymitis	0	1 (<0.1)		1 (<0.1)
Fungal infection	0	1 (<0.1)		1 (<0.1)
Gonorrhoea	0	1 (<0.1)		1 (<0.1)
Herpes simplex	0	1 (<0.1)		1 (<0.1)
Herpes zoster	2 (0.1)	1 (<0.1)		3 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)
Kidney infection	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Onychomycosis	0	1 (<0.1)		1 (<0.1)
Oral herpes	0	1 (<0.1)		1 (<0.1)
Paronychia	0	1 (<0.1)		1 (<0.1)
Pharyngitis	2 (0.1)	1 (<0.1)		3 (<0.1)
Pharyngitis streptococcal	3 (0.2)	1 (<0.1)		4 (0.1)
Pneumonia	3 (0.2)	1 (<0.1)		4 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Infections and infestations (Cont.)				
Rhinovirus infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suspected COVID-19	2 (0.1)	1 (<0.1)		3 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Vulvovaginal mycotic infection	0	1 (<0.1)		1 (<0.1)
Bacterial vaginosis	3 (0.2)	0		3 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Conjunctivitis	4 (0.3)	0		4 (0.1)
Folliculitis	1 (<0.1)	0		1 (<0.1)
Gastroenteritis viral	1 (<0.1)	0		1 (<0.1)
Genital herpes	2 (0.1)	0		2 (<0.1)
Hordeolum	2 (0.1)	0		2 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Localised infection	2 (0.1)	0		2 (<0.1)
Nasopharyngitis	1 (<0.1)	0		1 (<0.1)
Otitis externa	3 (0.2)	0		3 (<0.1)
Postoperative wound infection	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Infections and infestations (Cont.)				
Vulvovaginal candidiasis	2 (0.1)	0		2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.1)	6 (0.4)		8 (0.3)
Benign neoplasm of skin	0	2 (0.1)		2 (<0.1)
Benign breast neoplasm	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	19 (1.2)	27 (1.7)		46 (1.5)
Lymphadenopathy	16 (1.0)	26 (1.7)	1.59 (0.86, 2.92)	42 (1.4)
Anaemia	0	1 (<0.1)		1 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Lymph node pain	2 (0.1)	0		2 (<0.1)
Immune system disorders	7 (0.5)	5 (0.3)		12 (0.4)
Seasonal allergy	6 (0.4)	3 (0.2)		9 (0.3)
Allergy to arthropod bite	0	1 (<0.1)		1 (<0.1)
Hypersensitivity	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Immune system disorders (Cont.)				
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	2 (0.1)		2 (<0.1)
Hypothyroidism	0	1 (<0.1)		1 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	10 (0.7)	12 (0.8)		22 (0.7)
Glucose tolerance impaired	0	3 (0.2)		3 (<0.1)
Type 2 diabetes mellitus	0	2 (0.1)		2 (<0.1)
Vitamin D deficiency	1 (<0.1)	2 (0.1)		3 (<0.1)
Decreased appetite	2 (0.1)	1 (<0.1)		3 (<0.1)
Dehydration	0	1 (<0.1)		1 (<0.1)
Gout	0	1 (<0.1)		1 (<0.1)
Hypercholesterolaemia	2 (0.1)	1 (<0.1)		3 (<0.1)
Hyperlipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoglycaemia	0	1 (<0.1)		1 (<0.1)
Iron deficiency	0	1 (<0.1)		1 (<0.1)
Abnormal weight gain	1 (<0.1)	0		1 (<0.1)
Diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Psychiatric disorders	17 (1.1)	17 (1.1)		34 (1.1)
Insomnia	6 (0.4)	6 (0.4)		12 (0.4)
Anxiety	3 (0.2)	5 (0.3)		8 (0.3)
Depression	3 (0.2)	2 (0.1)		5 (0.2)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Attention deficit hyperactivity disorder	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0		1 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	91 (5.9)	114 (7.3)		205 (6.6)
Headache	74 (4.8)	76 (4.9)	1.00 (0.74, 1.37)	150 (4.8)
Dizziness	4 (0.3)	10 (0.6)	2.44 (0.81, 7.35)	14 (0.5)
Ageusia	1 (<0.1)	7 (0.4)	6.84 (1.10, 42.59)	8 (0.3)
Paraesthesia	5 (0.3)	4 (0.3)		9 (0.3)
Hypoaesthesia	1 (<0.1)	3 (0.2)		4 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Nervous system disorders (Cont.)				
Migraine	4 (0.3)	3 (0.2)		7 (0.2)
Nerve compression	0	2 (0.1)		2 (<0.1)
Sciatica	3 (0.2)	2 (0.1)		5 (0.2)
Syncope	0	2 (0.1)		2 (<0.1)
Anosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Burning sensation	0	1 (<0.1)		1 (<0.1)
Carpal tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Dysgeusia	3 (0.2)	1 (<0.1)		4 (0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Sinus headache	2 (0.1)	1 (<0.1)		3 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Taste disorder	0	1 (<0.1)		1 (<0.1)
Tension headache	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Nervous system disorders (Cont.)				
Presyncope	1 (<0.1)	0		1 (<0.1)
Somnolence	1 (<0.1)	0		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	0		1 (<0.1)
Eye disorders	7 (0.5)	9 (0.6)		16 (0.5)
Blepharospasm	0	2 (0.1)		2 (<0.1)
Vision blurred	1 (<0.1)	2 (0.1)		3 (<0.1)
Dry eye	0	1 (<0.1)		1 (<0.1)
Eye pain	0	1 (<0.1)		1 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Photophobia	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	0	1 (<0.1)		1 (<0.1)
Blepharitis	1 (<0.1)	0		1 (<0.1)
Eye irritation	1 (<0.1)	0		1 (<0.1)
Eye pruritus	1 (<0.1)	0		1 (<0.1)
Lacrimation increased	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Ear and labyrinth disorders	10 (0.7)	6 (0.4)		16 (0.5)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear canal erythema	2 (0.1)	1 (<0.1)		3 (<0.1)
Ear discomfort	0	1 (<0.1)		1 (<0.1)
Ear pain	2 (0.1)	1 (<0.1)		3 (<0.1)
Tinnitus	4 (0.3)	1 (<0.1)		5 (0.2)
Vertigo	0	1 (<0.1)		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	8 (0.5)	13 (0.8)		21 (0.7)
Tachycardia	1 (<0.1)	4 (0.3)		5 (0.2)
Bradycardia	2 (0.1)	3 (0.2)		5 (0.2)
Myocardial infarction	0	2 (0.1)		2 (<0.1)
Palpitations	0	2 (0.1)		2 (<0.1)
Acute left ventricular failure	0	1 (<0.1)		1 (<0.1)
Angina pectoris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac failure congestive	0	1 (<0.1)		1 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	2 (0.1)	0		2 (<0.1)
Cardiac failure	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Vascular disorders	28 (1.8)	30 (1.9)		58 (1.9)
Hypertension	22 (1.4)	25 (1.6)	1.11 (0.63, 1.95)	47 (1.5)
Hot flush	0	2 (0.1)		2 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Hypertensive urgency	0	1 (<0.1)		1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Flushing	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	1 (<0.1)	0		1 (<0.1)
Systolic hypertension	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	90 (5.9)	76 (4.9)		166 (5.4)
Cough	20 (1.3)	25 (1.6)	1.22 (0.69, 2.17)	45 (1.5)
Nasal congestion	19 (1.2)	19 (1.2)	0.98 (0.52, 1.82)	38 (1.2)
Rhinorrhoea	22 (1.4)	17 (1.1)	0.75 (0.41, 1.40)	39 (1.3)
Oropharyngeal pain	29 (1.9)	10 (0.6)	0.34 (0.17, 0.68)	39 (1.3)
Tachypnoea	11 (0.7)	7 (0.4)	0.62 (0.25, 1.55)	18 (0.6)
Dyspnoea	4 (0.3)	6 (0.4)		10 (0.3)
Asthma	5 (0.3)	2 (0.1)		7 (0.2)
Dry throat	0	2 (0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Epistaxis	0	2 (0.1)		2 (<0.1)
Paranasal sinus discomfort	0	2 (0.1)		2 (<0.1)
Sneezing	2 (0.1)	2 (0.1)		4 (0.1)
Wheezing	1 (<0.1)	2 (0.1)		3 (<0.1)
Chronic obstructive pulmonary disease	3 (0.2)	1 (<0.1)		4 (0.1)
Dysphonia	0	1 (<0.1)		1 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Paranasal sinus hypersecretion	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	0	1 (<0.1)		1 (<0.1)
Pleural effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Sinus congestion	3 (0.2)	1 (<0.1)		4 (0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Throat irritation	3 (0.2)	1 (<0.1)		4 (0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Painful respiration	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pulmonary embolism	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis allergic	1 (<0.1)	0		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	0		1 (<0.1)
Upper-airway cough syndrome	4 (0.3)	0		4 (0.1)
Gastrointestinal disorders	49 (3.2)	60 (3.8)		109 (3.5)
Nausea	20 (1.3)	25 (1.6)	1.22 (0.69, 2.17)	45 (1.5)
Diarrhoea	17 (1.1)	17 (1.1)	0.98 (0.51, 1.88)	34 (1.1)
Vomiting	4 (0.3)	9 (0.6)	2.20 (0.72, 6.72)	13 (0.4)
Abdominal pain	1 (<0.1)	5 (0.3)		6 (0.2)
Abdominal pain lower	2 (0.1)	2 (0.1)		4 (0.1)
Dental caries	1 (<0.1)	2 (0.1)		3 (<0.1)
Gastrooesophageal reflux disease	2 (0.1)	2 (0.1)		4 (0.1)
Haemorrhoids	0	2 (0.1)		2 (<0.1)
Toothache	1 (<0.1)	2 (0.1)		3 (<0.1)
Abdominal discomfort	2 (0.1)	1 (<0.1)		3 (<0.1)
Abdominal pain upper	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Constipation	2 (0.1)	1 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Gastrointestinal disorders (Cont.)				
Dry mouth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dyspepsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Enteritis	0	1 (<0.1)		1 (<0.1)
Flatulence	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	0	1 (<0.1)		1 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Tooth impacted	1 (<0.1)	1 (<0.1)		2 (<0.1)
Umbilical hernia	0	1 (<0.1)		1 (<0.1)
Colitis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Inguinal hernia	1 (<0.1)	0		1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	28 (1.8)	27 (1.7)		55 (1.8)
Dermatitis contact	0	3 (0.2)		3 (<0.1)
Acne	1 (<0.1)	2 (0.1)		3 (<0.1)
Alopecia	0	2 (0.1)		2 (<0.1)
Dry skin	0	2 (0.1)		2 (<0.1)
Hidradenitis	0	2 (0.1)		2 (<0.1)
Hyperhidrosis	2 (0.1)	2 (0.1)		4 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Night sweats	1 (<0.1)	2 (0.1)		3 (<0.1)
Pruritus	3 (0.2)	2 (0.1)		5 (0.2)
Rash macular	1 (<0.1)	2 (0.1)		3 (<0.1)
Dermatitis atopic	0	1 (<0.1)		1 (<0.1)
Eczema	0	1 (<0.1)		1 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Pain of skin	0	1 (<0.1)		1 (<0.1)
Rash	2 (0.1)	1 (<0.1)		3 (<0.1)
Rash papular	4 (0.3)	1 (<0.1)		5 (0.2)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin mass	0	1 (<0.1)		1 (<0.1)
Urticaria	8 (0.5)	1 (<0.1)	0.12 (0.02, 0.75)	9 (0.3)
Urticaria papular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Blister	1 (<0.1)	0		1 (<0.1)
Dermatitis	1 (<0.1)	0		1 (<0.1)
Papule	1 (<0.1)	0		1 (<0.1)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash pruritic	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Musculoskeletal and connective tissue disorders	134 (8.8)	109 (7.0)		243 (7.8)
Myalgia	48 (3.1)	49 (3.1)	1.00 (0.68, 1.47)	97 (3.1)
Arthralgia	52 (3.4)	45 (2.9)	0.85 (0.57, 1.25)	97 (3.1)
Back pain	21 (1.4)	12 (0.8)	0.56 (0.28, 1.11)	33 (1.1)
Pain in extremity	13 (0.8)	8 (0.5)	0.60 (0.26, 1.41)	21 (0.7)
Muscle spasms	7 (0.5)	6 (0.4)	0.84 (0.30, 2.37)	13 (0.4)
Neck pain	8 (0.5)	6 (0.4)	0.73 (0.27, 2.02)	14 (0.5)
Musculoskeletal pain	2 (0.1)	5 (0.3)		7 (0.2)
Osteoarthritis	2 (0.1)	4 (0.3)		6 (0.2)
Musculoskeletal stiffness	4 (0.3)	3 (0.2)		7 (0.2)
Groin pain	1 (<0.1)	2 (0.1)		3 (<0.1)
Musculoskeletal chest pain	3 (0.2)	2 (0.1)		5 (0.2)
Rotator cuff syndrome	0	2 (0.1)		2 (<0.1)
Arthritis	0	1 (<0.1)		1 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flank pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint swelling	4 (0.3)	1 (<0.1)		5 (0.2)
Muscle twitching	0	1 (<0.1)		1 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Periarthritis	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Axillary mass	1 (<0.1)	0		1 (<0.1)
Bursitis	2 (0.1)	0		2 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Limb discomfort	1 (<0.1)	0		1 (<0.1)
Limb mass	1 (<0.1)	0		1 (<0.1)
Muscular weakness	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Pain in jaw	1 (<0.1)	0		1 (<0.1)
Plantar fasciitis	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Tendonitis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	6 (0.4)	5 (0.3)		11 (0.4)
Polyuria	0	3 (0.2)		3 (<0.1)
Dysuria	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Haematuria	2 (0.1)	0		2 (<0.1)
Hypertonic bladder	1 (<0.1)	0		1 (<0.1)
Nephrolithiasis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Reproductive system and breast disorders	10 (0.7)	6 (0.4)		16 (0.5)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Dysfunctional uterine bleeding	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	0		1 (<0.1)
Breast pain	2 (0.1)	0		2 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)
Menopausal symptoms	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	1 (<0.1)	0		1 (<0.1)
Prostatitis	1 (<0.1)	0		1 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
Vaginal haemorrhage	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	0	2 (0.1)		2 (<0.1)
Arnold-Chiari malformation	0	2 (0.1)		2 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
General disorders and administration site conditions	127 (8.3)	162 (10.3)		289 (9.3)
Fatigue	69 (4.5)	75 (4.8)	1.06 (0.77, 1.46)	144 (4.6)
Injection site pain	18 (1.2)	30 (1.9)	1.63 (0.92, 2.89)	48 (1.5)
Chills	24 (1.6)	22 (1.4)	0.90 (0.51, 1.58)	46 (1.5)
Injection site swelling	1 (<0.1)	12 (0.8)	11.72 (1.96, 70.26)	13 (0.4)
Pyrexia	6 (0.4)	11 (0.7)	1.79 (0.69, 4.66)	17 (0.5)
Injection site pruritus	2 (0.1)	9 (0.6)	4.40 (1.07, 18.03)	11 (0.4)
Injection site erythema	5 (0.3)	8 (0.5)	1.56 (0.54, 4.53)	13 (0.4)
Pain	13 (0.8)	8 (0.5)	0.60 (0.26, 1.41)	21 (0.7)
Injection site lymphadenopathy	3 (0.2)	5 (0.3)		8 (0.3)
Axillary pain	3 (0.2)	3 (0.2)		6 (0.2)
Injection site induration	0	3 (0.2)		3 (<0.1)
Injection site urticaria	0	3 (0.2)		3 (<0.1)
Peripheral swelling	1 (<0.1)	3 (0.2)		4 (0.1)
Non-cardiac chest pain	2 (0.1)	2 (0.1)		4 (0.1)
Chest discomfort	3 (0.2)	1 (<0.1)		4 (0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)
Feeling hot	0	1 (<0.1)		1 (<0.1)
Injection site haematoma	0	1 (<0.1)		1 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site irritation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
General disorders and administration site conditions (Cont.)				
Injection site joint pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site macule	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Reactogenicity event	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Tenderness	0	1 (<0.1)		1 (<0.1)
Vaccination site pain	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Facial pain	2 (0.1)	0		2 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Influenza like illness	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	1 (<0.1)	0		1 (<0.1)
Malaise	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Investigations	9 (0.6)	11 (0.7)		20 (0.6)
Blood pressure increased	5 (0.3)	4 (0.3)		9 (0.3)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Prostatic specific antigen increased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic increased	1 (<0.1)	0		1 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	28 (1.8)	34 (2.2)		62 (2.0)
Muscle strain	4 (0.3)	5 (0.3)		9 (0.3)
Ligament sprain	3 (0.2)	4 (0.3)		7 (0.2)
Procedural pain	2 (0.1)	3 (0.2)		5 (0.2)
Road traffic accident	1 (<0.1)	3 (0.2)		4 (0.1)
Skin abrasion	0	3 (0.2)		3 (<0.1)
Skin laceration	3 (0.2)	3 (0.2)		6 (0.2)
Contusion	2 (0.1)	2 (0.1)		4 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Injury, poisoning and procedural complications (Cont.)				
Arthropod bite	3 (0.2)	1 (<0.1)		4 (0.1)
Arthropod sting	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Fall	2 (0.1)	1 (<0.1)		3 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	0	1 (<0.1)		1 (<0.1)
Meniscus injury	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Tendon injury	0	1 (<0.1)		1 (<0.1)
Tendon rupture	0	1 (<0.1)		1 (<0.1)
Tooth fracture	0	1 (<0.1)		1 (<0.1)
Concussion	1 (<0.1)	0		1 (<0.1)
Epicondylitis	2 (0.1)	0		2 (<0.1)
Foot fracture	2 (0.1)	0		2 (<0.1)
Hand fracture	1 (<0.1)	0		1 (<0.1)
Joint injury	2 (0.1)	0		2 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Black or African American

System Organ Class Preferred Term	Placebo (N=1531) n (%)	mRNA-1273 (N=1567) n (%)	Rate Ratio (95% CI)	Total (N=3098) n (%)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	188 (25.4)	218 (33.2)		406 (29.1)
Number of Unsolicited Adverse Events	352	452		804
Infections and infestations	39 (5.3)	35 (5.3)		74 (5.3)
Upper respiratory tract infection	6 (0.8)	5 (0.8)		11 (0.8)
Urinary tract infection	6 (0.8)	3 (0.5)		9 (0.6)
Viral infection	1 (0.1)	3 (0.5)		4 (0.3)
Bacterial vaginosis	0	2 (0.3)		2 (0.1)
Ear infection	0	2 (0.3)		2 (0.1)
Otitis externa	0	2 (0.3)		2 (0.1)
Sinusitis	2 (0.3)	2 (0.3)		4 (0.3)
Tooth infection	1 (0.1)	2 (0.3)		3 (0.2)
Viral upper respiratory tract infection	0	2 (0.3)		2 (0.1)
Abdominal abscess	0	1 (0.2)		1 (<0.1)
Abscess limb	0	1 (0.2)		1 (<0.1)
Cellulitis	0	1 (0.2)		1 (<0.1)
Folliculitis	0	1 (0.2)		1 (<0.1)
Herpes simplex	0	1 (0.2)		1 (<0.1)
Herpes zoster	1 (0.1)	1 (0.2)		2 (0.1)
Oral herpes	0	1 (0.2)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Infections and infestations (Cont.)				
Pharyngitis	2 (0.3)	1 (0.2)		3 (0.2)
Pharyngitis streptococcal	0	1 (0.2)		1 (<0.1)
Rhinovirus infection	0	1 (0.2)		1 (<0.1)
Suspected COVID-19	1 (0.1)	1 (0.2)		2 (0.1)
Tooth abscess	0	1 (0.2)		1 (<0.1)
Viral pharyngitis	0	1 (0.2)		1 (<0.1)
Vulvovaginal candidiasis	0	1 (0.2)		1 (<0.1)
Vulvovaginal mycotic infection	2 (0.3)	1 (0.2)		3 (0.2)
Asymptomatic COVID-19	1 (0.1)	0		1 (<0.1)
COVID-19	6 (0.8)	0		6 (0.4)
Fungal infection	3 (0.4)	0		3 (0.2)
Gastroenteritis	2 (0.3)	0		2 (0.1)
Hordeolum	1 (0.1)	0		1 (<0.1)
Laryngitis	1 (0.1)	0		1 (<0.1)
Nasopharyngitis	1 (0.1)	0		1 (<0.1)
Root canal infection	1 (0.1)	0		1 (<0.1)
Skin candida	1 (0.1)	0		1 (<0.1)
Tonsillitis	1 (0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.1)	1 (0.2)		2 (0.1)
Meningioma benign	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Breast cancer	1 (0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	6 (0.8)	15 (2.3)		21 (1.5)
Lymphadenopathy	4 (0.5)	14 (2.1)	3.94 (1.37, 11.35)	18 (1.3)
Lymph node pain	0	1 (0.2)		1 (<0.1)
Anaemia	1 (0.1)	0		1 (<0.1)
Iron deficiency anaemia	1 (0.1)	0		1 (<0.1)
Immune system disorders	1 (0.1)	4 (0.6)		5 (0.4)
Hypersensitivity	0	2 (0.3)		2 (0.1)
Seasonal allergy	0	2 (0.3)		2 (0.1)
Anaphylactic reaction	1 (0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (0.2)		1 (<0.1)
Hypothyroidism	0	1 (0.2)		1 (<0.1)
Metabolism and nutrition disorders	5 (0.7)	4 (0.6)		9 (0.6)
Dehydration	0	1 (0.2)		1 (<0.1)
Gout	1 (0.1)	1 (0.2)		2 (0.1)
Hyperlipidaemia	2 (0.3)	1 (0.2)		3 (0.2)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Metabolism and nutrition disorders (Cont.)				
Vitamin D deficiency	1 (0.1)	1 (0.2)		2 (0.1)
Glucose tolerance impaired	1 (0.1)	0		1 (<0.1)
Hypokalaemia	1 (0.1)	0		1 (<0.1)
Psychiatric disorders	3 (0.4)	8 (1.2)		11 (0.8)
Insomnia	1 (0.1)	4 (0.6)		5 (0.4)
Anxiety	2 (0.3)	2 (0.3)		4 (0.3)
Depression	1 (0.1)	2 (0.3)		3 (0.2)
Abnormal dreams	0	1 (0.2)		1 (<0.1)
Nervous system disorders	37 (5.0)	52 (7.9)		89 (6.4)
Headache	26 (3.5)	36 (5.5)	1.56 (0.96, 2.54)	62 (4.4)
Dizziness	1 (0.1)	4 (0.6)		5 (0.4)
Paraesthesia	1 (0.1)	2 (0.3)		3 (0.2)
Ageusia	0	1 (0.2)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (0.2)		1 (<0.1)
Cervical radiculopathy	0	1 (0.2)		1 (<0.1)
Disturbance in attention	0	1 (0.2)		1 (<0.1)
Dizziness postural	0	1 (0.2)		1 (<0.1)
Dysgeusia	0	1 (0.2)		1 (<0.1)
Facial paralysis	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Nervous system disorders (Cont.)				
Hypoaesthesia	1 (0.1)	1 (0.2)		2 (0.1)
Lumbar radiculopathy	1 (0.1)	1 (0.2)		2 (0.1)
Presyncope	2 (0.3)	1 (0.2)		3 (0.2)
Syncope	0	1 (0.2)		1 (<0.1)
Anosmia	1 (0.1)	0		1 (<0.1)
Dysaesthesia	1 (0.1)	0		1 (<0.1)
Dyskinesia	1 (0.1)	0		1 (<0.1)
Hypogeusia	1 (0.1)	0		1 (<0.1)
Tension headache	1 (0.1)	0		1 (<0.1)
Transient ischaemic attack	1 (0.1)	0		1 (<0.1)
Eye disorders	2 (0.3)	2 (0.3)		4 (0.3)
Photophobia	0	1 (0.2)		1 (<0.1)
Swelling of eyelid	0	1 (0.2)		1 (<0.1)
Dry eye	1 (0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (0.1)	0		1 (<0.1)
Periorbital swelling	1 (0.1)	0		1 (<0.1)
Ear and labyrinth disorders	5 (0.7)	3 (0.5)		8 (0.6)
Tinnitus	2 (0.3)	2 (0.3)		4 (0.3)
Vertigo	0	1 (0.2)		1 (<0.1)
Ear discomfort	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Ear and labyrinth disorders (Cont.)				
Ear pain	1 (0.1)	0		1 (<0.1)
Middle ear effusion	1 (0.1)	0		1 (<0.1)
Cardiac disorders	1 (0.1)	4 (0.6)		5 (0.4)
Bradycardia	1 (0.1)	2 (0.3)		3 (0.2)
Tachycardia	0	2 (0.3)		2 (0.1)
Vascular disorders	7 (0.9)	9 (1.4)		16 (1.1)
Hypertension	6 (0.8)	8 (1.2)	1.50 (0.55, 4.13)	14 (1.0)
Hot flush	0	1 (0.2)		1 (<0.1)
Vasodilatation	1 (0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	39 (5.3)	25 (3.8)		64 (4.6)
Cough	11 (1.5)	8 (1.2)	0.82 (0.34, 1.97)	19 (1.4)
Nasal congestion	5 (0.7)	4 (0.6)		9 (0.6)
Oropharyngeal pain	15 (2.0)	4 (0.6)	0.30 (0.11, 0.86)	19 (1.4)
Throat irritation	2 (0.3)	4 (0.6)		6 (0.4)
Rhinorrhoea	9 (1.2)	3 (0.5)	0.38 (0.11, 1.28)	12 (0.9)
Dyspnoea	3 (0.4)	2 (0.3)		5 (0.4)
Asthma	2 (0.3)	1 (0.2)		3 (0.2)
Dry throat	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Epistaxis	2 (0.3)	1 (0.2)		3 (0.2)
Rhinitis allergic	0	1 (0.2)		1 (<0.1)
Sneezing	1 (0.1)	1 (0.2)		2 (0.1)
Tachypnoea	2 (0.3)	1 (0.2)		3 (0.2)
Upper-airway cough syndrome	0	1 (0.2)		1 (<0.1)
Oropharyngeal discomfort	1 (0.1)	0		1 (<0.1)
Pleuritic pain	1 (0.1)	0		1 (<0.1)
Sinus congestion	3 (0.4)	0		3 (0.2)
Gastrointestinal disorders	23 (3.1)	37 (5.6)		60 (4.3)
Diarrhoea	5 (0.7)	12 (1.8)	2.70 (1.00, 7.33)	17 (1.2)
Nausea	4 (0.5)	11 (1.7)	3.10 (1.05, 9.18)	15 (1.1)
Abdominal pain	0	5 (0.8)		5 (0.4)
Vomiting	1 (0.1)	5 (0.8)		6 (0.4)
Gastrooesophageal reflux disease	3 (0.4)	3 (0.5)		6 (0.4)
Toothache	2 (0.3)	3 (0.5)		5 (0.4)
Constipation	0	2 (0.3)		2 (0.1)
Dental caries	0	2 (0.3)		2 (0.1)
Abdominal pain lower	0	1 (0.2)		1 (<0.1)
Abdominal pain upper	2 (0.3)	1 (0.2)		3 (0.2)
Chapped lips	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Gastrointestinal disorders (Cont.)				
Food poisoning	0	1 (0.2)		1 (<0.1)
Glossitis	0	1 (0.2)		1 (<0.1)
Haemorrhoids	1 (0.1)	1 (0.2)		2 (0.1)
Tongue discomfort	0	1 (0.2)		1 (<0.1)
Abdominal discomfort	2 (0.3)	0		2 (0.1)
Dyspepsia	1 (0.1)	0		1 (<0.1)
Flatulence	1 (0.1)	0		1 (<0.1)
Gastritis	1 (0.1)	0		1 (<0.1)
Hiatus hernia	1 (0.1)	0		1 (<0.1)
Mouth ulceration	1 (0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (0.1)	0		1 (<0.1)
Cholelithiasis	1 (0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	5 (0.7)	12 (1.8)		17 (1.2)
Rash	1 (0.1)	3 (0.5)		4 (0.3)
Urticaria	2 (0.3)	3 (0.5)		5 (0.4)
Pruritus	1 (0.1)	2 (0.3)		3 (0.2)
Alopecia areata	0	1 (0.2)		1 (<0.1)
Blister	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ecchymosis	0	1 (0.2)		1 (<0.1)
Macule	0	1 (0.2)		1 (<0.1)
Rash pruritic	1 (0.1)	1 (0.2)		2 (0.1)
Rash erythematous	1 (0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	42 (5.7)	42 (6.4)		84 (6.0)
Myalgia	16 (2.2)	18 (2.7)	1.27 (0.66, 2.44)	34 (2.4)
Arthralgia	18 (2.4)	17 (2.6)	1.06 (0.56, 2.02)	35 (2.5)
Back pain	5 (0.7)	7 (1.1)	1.58 (0.53, 4.69)	12 (0.9)
Muscle spasms	0	2 (0.3)		2 (0.1)
Musculoskeletal pain	0	2 (0.3)		2 (0.1)
Neck pain	1 (0.1)	2 (0.3)		3 (0.2)
Joint swelling	0	1 (0.2)		1 (<0.1)
Muscular weakness	0	1 (0.2)		1 (<0.1)
Pain in extremity	8 (1.1)	1 (0.2)	0.14 (0.02, 0.86)	9 (0.6)
Rheumatoid arthritis	0	1 (0.2)		1 (<0.1)
Tenosynovitis	0	1 (0.2)		1 (<0.1)
Trigger finger	0	1 (0.2)		1 (<0.1)
Costochondritis	1 (0.1)	0		1 (<0.1)
Musculoskeletal stiffness	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Osteopenia	1 (0.1)	0		1 (<0.1)
Spinal pain	1 (0.1)	0		1 (<0.1)
Tendonitis	1 (0.1)	0		1 (<0.1)
Renal and urinary disorders	0	1 (0.2)		1 (<0.1)
Acute kidney injury	0	1 (0.2)		1 (<0.1)
Reproductive system and breast disorders	4 (0.5)	0		4 (0.3)
Breast cyst	1 (0.1)	0		1 (<0.1)
Dysmenorrhoea	2 (0.3)	0		2 (0.1)
Erectile dysfunction	1 (0.1)	0		1 (<0.1)
Prostatitis	1 (0.1)	0		1 (<0.1)
General disorders and administration site conditions	47 (6.4)	88 (13.4)		135 (9.7)
Fatigue	28 (3.8)	39 (5.9)	1.57 (0.98, 2.51)	67 (4.8)
Injection site pain	7 (0.9)	13 (2.0)	2.09 (0.86, 5.07)	20 (1.4)
Chills	2 (0.3)	9 (1.4)	5.07 (1.24, 20.77)	11 (0.8)
Injection site swelling	2 (0.3)	9 (1.4)	5.07 (1.24, 20.77)	11 (0.8)
Injection site erythema	1 (0.1)	8 (1.2)	9.01 (1.47, 55.47)	9 (0.6)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
General disorders and administration site conditions (Cont.)				
Injection site pruritus	0	7 (1.1)		7 (0.5)
Pyrexia	4 (0.5)	7 (1.1)	1.97 (0.62, 6.28)	11 (0.8)
Pain	1 (0.1)	6 (0.9)		7 (0.5)
Injection site lymphadenopathy	1 (0.1)	5 (0.8)		6 (0.4)
Axillary pain	3 (0.4)	4 (0.6)		7 (0.5)
Injection site induration	1 (0.1)	3 (0.5)		4 (0.3)
Feeling abnormal	1 (0.1)	2 (0.3)		3 (0.2)
Injection site mass	0	2 (0.3)		2 (0.1)
Injection site rash	0	2 (0.3)		2 (0.1)
Injection site urticaria	0	2 (0.3)		2 (0.1)
Chest pain	0	1 (0.2)		1 (<0.1)
Hangover	0	1 (0.2)		1 (<0.1)
Injection site macule	1 (0.1)	1 (0.2)		2 (0.1)
Injection site warmth	0	1 (0.2)		1 (<0.1)
Peripheral swelling	0	1 (0.2)		1 (<0.1)
Vaccination site pain	0	1 (0.2)		1 (<0.1)
Facial pain	1 (0.1)	0		1 (<0.1)
Influenza like illness	1 (0.1)	0		1 (<0.1)
Injection site bruising	2 (0.3)	0		2 (0.1)
Oedema peripheral	1 (0.1)	0		1 (<0.1)
Reactogenicity event	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
General disorders and administration site conditions (Cont.)				
Swelling face	1 (0.1)	0		1 (<0.1)
Investigations	2 (0.3)	7 (1.1)		9 (0.6)
Aspartate aminotransferase increased	0	1 (0.2)		1 (<0.1)
Blood pressure diastolic increased	0	1 (0.2)		1 (<0.1)
Blood pressure increased	1 (0.1)	1 (0.2)		2 (0.1)
Blood pressure systolic increased	0	1 (0.2)		1 (<0.1)
Blood uric acid increased	0	1 (0.2)		1 (<0.1)
Fibrin D dimer increased	0	1 (0.2)		1 (<0.1)
Transaminases increased	0	1 (0.2)		1 (<0.1)
White blood cell count decreased	0	1 (0.2)		1 (<0.1)
Alanine aminotransferase increased	1 (0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	15 (2.0)	7 (1.1)		22 (1.6)
Ligament sprain	3 (0.4)	2 (0.3)		5 (0.4)
Bone contusion	0	1 (0.2)		1 (<0.1)
Concussion	0	1 (0.2)		1 (<0.1)
Fibula fracture	0	1 (0.2)		1 (<0.1)
Muscle strain	2 (0.3)	1 (0.2)		3 (0.2)
Vaccination complication	1 (0.1)	1 (0.2)		2 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Asian

System Organ Class Preferred Term	Placebo (N=739) n (%)	mRNA-1273 (N=656) n (%)	Rate Ratio (95% CI)	Total (N=1395) n (%)
Injury, poisoning and procedural complications (Cont.)				
Animal bite	1 (0.1)	0		1 (<0.1)
Arthropod bite	1 (0.1)	0		1 (<0.1)
Arthropod sting	1 (0.1)	0		1 (<0.1)
Back injury	1 (0.1)	0		1 (<0.1)
Fall	2 (0.3)	0		2 (0.1)
Procedural haemorrhage	1 (0.1)	0		1 (<0.1)
Procedural pain	2 (0.3)	0		2 (0.1)
Skin abrasion	1 (0.1)	0		1 (<0.1)
Thermal burn	1 (0.1)	0		1 (<0.1)
Tooth fracture	1 (0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

System Organ Class Preferred Term	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Rate Ratio (95% CI)	Total (N=234) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	39 (32.2)	47 (41.6)		86 (36.8)
Number of Unsolicited Adverse Events	115	92		207
Infections and infestations	9 (7.4)	12 (10.6)		21 (9.0)
Suspected COVID-19	1 (0.8)	2 (1.8)		3 (1.3)
Tooth infection	0	2 (1.8)		2 (0.9)
Upper respiratory tract infection	1 (0.8)	2 (1.8)		3 (1.3)
Viral infection	0	2 (1.8)		2 (0.9)
Herpes zoster	0	1 (0.9)		1 (0.4)
Pharyngitis streptococcal	0	1 (0.9)		1 (0.4)
Rhinovirus infection	0	1 (0.9)		1 (0.4)
Soft tissue infection	0	1 (0.9)		1 (0.4)
COVID-19	1 (0.8)	0		1 (0.4)
Pharyngitis	1 (0.8)	0		1 (0.4)
Sinusitis	2 (1.7)	0		2 (0.9)
Urinary tract infection	3 (2.5)	0		3 (1.3)
Blood and lymphatic system disorders	3 (2.5)	3 (2.7)		6 (2.6)
Lymphadenopathy	2 (1.7)	3 (2.7)		5 (2.1)
Lymph node pain	1 (0.8)	0		1 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

System Organ Class Preferred Term	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Rate Ratio (95% CI)	Total (N=234) n (%)
Immune system disorders	3 (2.5)	1 (0.9)		4 (1.7)
Seasonal allergy	2 (1.7)	1 (0.9)		3 (1.3)
Anaphylactic reaction	1 (0.8)	0		1 (0.4)
Metabolism and nutrition disorders	5 (4.1)	2 (1.8)		7 (3.0)
Hypercholesterolaemia	0	1 (0.9)		1 (0.4)
Type 2 diabetes mellitus	1 (0.8)	1 (0.9)		2 (0.9)
Decreased appetite	1 (0.8)	0		1 (0.4)
Folate deficiency	1 (0.8)	0		1 (0.4)
Hyperglycaemia	1 (0.8)	0		1 (0.4)
Hyperlipidaemia	1 (0.8)	0		1 (0.4)
Psychiatric disorders	1 (0.8)	1 (0.9)		2 (0.9)
Depression	0	1 (0.9)		1 (0.4)
Insomnia	1 (0.8)	0		1 (0.4)
Nervous system disorders	11 (9.1)	8 (7.1)		19 (8.1)
Headache	9 (7.4)	6 (5.3)	0.71 (0.27, 1.87)	15 (6.4)
Cervical radiculopathy	0	1 (0.9)		1 (0.4)
Sinus headache	0	1 (0.9)		1 (0.4)
Ageusia	1 (0.8)	0		1 (0.4)
Anosmia	1 (0.8)	0		1 (0.4)
Balance disorder	1 (0.8)	0		1 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

System Organ Class Preferred Term	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Rate Ratio (95% CI)	Total (N=234) n (%)
Nervous system disorders (Cont.)				
Paraesthesia	1 (0.8)	0		1 (0.4)
Ear and labyrinth disorders	0	1 (0.9)		1 (0.4)
Ear discomfort	0	1 (0.9)		1 (0.4)
Cardiac disorders	2 (1.7)	0		2 (0.9)
Atrial fibrillation	1 (0.8)	0		1 (0.4)
Tachycardia	1 (0.8)	0		1 (0.4)
Vascular disorders	2 (1.7)	1 (0.9)		3 (1.3)
Hypertension	2 (1.7)	1 (0.9)		3 (1.3)
Respiratory, thoracic and mediastinal disorders	14 (11.6)	9 (8.0)		23 (9.8)
Rhinorrhoea	6 (5.0)	4 (3.5)		10 (4.3)
Nasal congestion	3 (2.5)	3 (2.7)		6 (2.6)
Oropharyngeal pain	2 (1.7)	3 (2.7)		5 (2.1)
Cough	4 (3.3)	2 (1.8)		6 (2.6)
Chronic obstructive pulmonary disease	0	1 (0.9)		1 (0.4)
Asthma	2 (1.7)	0		2 (0.9)
Dyspnoea	3 (2.5)	0		3 (1.3)
Tachypnoea	1 (0.8)	0		1 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

System Organ Class Preferred Term	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Rate Ratio (95% CI)	Total (N=234) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Tonsillolith	1 (0.8)	0		1 (0.4)
Gastrointestinal disorders	7 (5.8)	7 (6.2)		14 (6.0)
Diarrhoea	3 (2.5)	4 (3.5)		7 (3.0)
Gastrooesophageal reflux disease	1 (0.8)	1 (0.9)		2 (0.9)
Nausea	3 (2.5)	1 (0.9)		4 (1.7)
Toothache	0	1 (0.9)		1 (0.4)
Abdominal pain upper	1 (0.8)	0		1 (0.4)
Constipation	1 (0.8)	0		1 (0.4)
Gastric perforation	1 (0.8)	0		1 (0.4)
Hepatobiliary disorders	0	1 (0.9)		1 (0.4)
Cholelithiasis	0	1 (0.9)		1 (0.4)
Skin and subcutaneous tissue disorders	3 (2.5)	1 (0.9)		4 (1.7)
Rash maculo-papular	0	1 (0.9)		1 (0.4)
Acne	1 (0.8)	0		1 (0.4)
Dermatitis contact	1 (0.8)	0		1 (0.4)
Hyperhidrosis	1 (0.8)	0		1 (0.4)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

System Organ Class Preferred Term	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Rate Ratio (95% CI)	Total (N=234) n (%)
Musculoskeletal and connective tissue disorders	10 (8.3)	12 (10.6)		22 (9.4)
Arthralgia	4 (3.3)	6 (5.3)		10 (4.3)
Myalgia	5 (4.1)	4 (3.5)		9 (3.8)
Back pain	0	1 (0.9)		1 (0.4)
Musculoskeletal pain	1 (0.8)	1 (0.9)		2 (0.9)
Spinal osteoarthritis	0	1 (0.9)		1 (0.4)
Temporomandibular joint syndrome	0	1 (0.9)		1 (0.4)
Neck pain	1 (0.8)	0		1 (0.4)
Osteoarthritis	1 (0.8)	0		1 (0.4)
Pain in extremity	1 (0.8)	0		1 (0.4)
Renal and urinary disorders	2 (1.7)	0		2 (0.9)
Nephrolithiasis	2 (1.7)	0		2 (0.9)
Reproductive system and breast disorders	1 (0.8)	0		1 (0.4)
Pelvic pain	1 (0.8)	0		1 (0.4)
General disorders and administration site conditions	10 (8.3)	13 (11.5)		23 (9.8)
Fatigue	6 (5.0)	9 (8.0)	1.61 (0.61, 4.23)	15 (6.4)
Injection site pain	0	3 (2.7)		3 (1.3)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

System Organ Class Preferred Term	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Rate Ratio (95% CI)	Total (N=234) n (%)
General disorders and administration site conditions (Cont.)				
Chest discomfort	1 (0.8)	1 (0.9)		2 (0.9)
Exercise tolerance decreased	0	1 (0.9)		1 (0.4)
Injection site erythema	1 (0.8)	1 (0.9)		2 (0.9)
Injection site macule	0	1 (0.9)		1 (0.4)
Pyrexia	1 (0.8)	1 (0.9)		2 (0.9)
Reactogenicity event	0	1 (0.9)		1 (0.4)
Chills	3 (2.5)	0		3 (1.3)
Injection site pruritus	1 (0.8)	0		1 (0.4)
Pain	2 (1.7)	0		2 (0.9)
Sluggishness	1 (0.8)	0		1 (0.4)
Investigations	2 (1.7)	1 (0.9)		3 (1.3)
Blood testosterone decreased	0	1 (0.9)		1 (0.4)
Heart rate increased	1 (0.8)	0		1 (0.4)
Vitamin B12 decreased	1 (0.8)	0		1 (0.4)
Vitamin D decreased	1 (0.8)	0		1 (0.4)
Injury, poisoning and procedural complications	2 (1.7)	4 (3.5)		6 (2.6)
Contusion	0	1 (0.9)		1 (0.4)
Fall	0	1 (0.9)		1 (0.4)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: American Indian or Alaska Native

System Organ Class Preferred Term	Placebo (N=121) n (%)	mRNA-1273 (N=113) n (%)	Rate Ratio (95% CI)	Total (N=234) n (%)
Injury, poisoning and procedural complications (Cont.)				
Limb injury	0	1 (0.9)		1 (0.4)
Post-traumatic pain	0	1 (0.9)		1 (0.4)
Procedural pain	0	1 (0.9)		1 (0.4)
Arthropod bite	1 (0.8)	0		1 (0.4)
Muscle strain	1 (0.8)	0		1 (0.4)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

System Organ Class Preferred Term	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Rate Ratio (95% CI)	Total (N=68) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	9 (28.1)	8 (22.2)		17 (25.0)
Number of Unsolicited Adverse Events	17	12		29
Infections and infestations	2 (6.3)	0		2 (2.9)
Rhinovirus infection	1 (3.1)	0		1 (1.5)
Viral infection	1 (3.1)	0		1 (1.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (2.8)		1 (1.5)
Basal cell carcinoma	0	1 (2.8)		1 (1.5)
Blood and lymphatic system disorders	0	4 (11.1)		4 (5.9)
Lymphadenopathy	0	4 (11.1)		4 (5.9)
Immune system disorders	0	1 (2.8)		1 (1.5)
Seasonal allergy	0	1 (2.8)		1 (1.5)
Nervous system disorders	3 (9.4)	1 (2.8)		4 (5.9)
Headache	1 (3.1)	1 (2.8)		2 (2.9)
Dizziness	1 (3.1)	0		1 (1.5)
Hypoaesthesia	1 (3.1)	0		1 (1.5)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

System Organ Class Preferred Term	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Rate Ratio (95% CI)	Total (N=68) n (%)
Eye disorders	0	1 (2.8)		1 (1.5)
Conjunctival haemorrhage	0	1 (2.8)		1 (1.5)
Vascular disorders	2 (6.3)	0		2 (2.9)
Hypertension	1 (3.1)	0		1 (1.5)
White coat hypertension	1 (3.1)	0		1 (1.5)
Respiratory, thoracic and mediastinal disorders	1 (3.1)	0		1 (1.5)
Nasal congestion	1 (3.1)	0		1 (1.5)
Musculoskeletal and connective tissue disorders	3 (9.4)	0		3 (4.4)
Arthralgia	2 (6.3)	0		2 (2.9)
Back pain	1 (3.1)	0		1 (1.5)
Myalgia	2 (6.3)	0		2 (2.9)
Neck pain	1 (3.1)	0		1 (1.5)
Pain in extremity	1 (3.1)	0		1 (1.5)
General disorders and administration site conditions	0	2 (5.6)		2 (2.9)
Fatigue	0	2 (5.6)		2 (2.9)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Native Hawaiian or Other Pacific Islander

System Organ Class Preferred Term	Placebo (N=32) n (%)	mRNA-1273 (N=36) n (%)	Rate Ratio (95% CI)	Total (N=68) n (%)
Injury, poisoning and procedural complications	1 (3.1)	1 (2.8)		2 (2.9)
Ligament sprain	0	1 (2.8)		1 (1.5)
Muscle strain	1 (3.1)	0		1 (1.5)
Product issues	0	1 (2.8)		1 (1.5)
Device breakage	0	1 (2.8)		1 (1.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	129 (40.6)	132 (41.3)		261 (40.9)
Number of Unsolicited Adverse Events	263	338		601
Infections and infestations	34 (10.7)	20 (6.3)		54 (8.5)
Urinary tract infection	4 (1.3)	5 (1.6)		9 (1.4)
Pharyngitis	0	2 (0.6)		2 (0.3)
Upper respiratory tract infection	4 (1.3)	2 (0.6)		6 (0.9)
Bacterial vaginosis	0	1 (0.3)		1 (0.2)
Conjunctivitis	0	1 (0.3)		1 (0.2)
Ear infection	0	1 (0.3)		1 (0.2)
Gastroenteritis	0	1 (0.3)		1 (0.2)
Herpes zoster	0	1 (0.3)		1 (0.2)
Hordeolum	0	1 (0.3)		1 (0.2)
Laryngitis viral	0	1 (0.3)		1 (0.2)
Paronychia	0	1 (0.3)		1 (0.2)
Pneumonia	0	1 (0.3)		1 (0.2)
Rhinovirus infection	2 (0.6)	1 (0.3)		3 (0.5)
Sinusitis	0	1 (0.3)		1 (0.2)
Tooth infection	1 (0.3)	1 (0.3)		2 (0.3)
Viral infection	3 (0.9)	1 (0.3)		4 (0.6)
COVID-19	4 (1.3)	0		4 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Infections and infestations (Cont.)				
Cystitis	1 (0.3)	0		1 (0.2)
Diverticulitis	1 (0.3)	0		1 (0.2)
Fungal infection	1 (0.3)	0		1 (0.2)
Genital herpes simplex	1 (0.3)	0		1 (0.2)
Herpes ophthalmic	1 (0.3)	0		1 (0.2)
Herpes simplex	1 (0.3)	0		1 (0.2)
Latent tuberculosis	1 (0.3)	0		1 (0.2)
Localised infection	1 (0.3)	0		1 (0.2)
Nasopharyngitis	2 (0.6)	0		2 (0.3)
Oral herpes	1 (0.3)	0		1 (0.2)
Rhinitis	1 (0.3)	0		1 (0.2)
Skin infection	1 (0.3)	0		1 (0.2)
Suspected COVID-19	3 (0.9)	0		3 (0.5)
Tonsillitis	1 (0.3)	0		1 (0.2)
Tooth abscess	1 (0.3)	0		1 (0.2)
Viral upper respiratory tract infection	1 (0.3)	0		1 (0.2)
Vulvovaginal mycotic infection	1 (0.3)	0		1 (0.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.3)	1 (0.3)		2 (0.3)
Colorectal cancer	0	1 (0.3)		1 (0.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Pelvic neoplasm	0	1 (0.3)		1 (0.2)
Lung adenocarcinoma	1 (0.3)	0		1 (0.2)
Blood and lymphatic system disorders	7 (2.2)	9 (2.8)		16 (2.5)
Lymphadenopathy	5 (1.6)	8 (2.5)	1.59 (0.55, 4.58)	13 (2.0)
Anaemia	0	1 (0.3)		1 (0.2)
Lymph node pain	2 (0.6)	0		2 (0.3)
Immune system disorders	5 (1.6)	0		5 (0.8)
Allergy to metals	1 (0.3)	0		1 (0.2)
Drug hypersensitivity	1 (0.3)	0		1 (0.2)
Seasonal allergy	3 (0.9)	0		3 (0.5)
Metabolism and nutrition disorders	3 (0.9)	2 (0.6)		5 (0.8)
Abnormal loss of weight	0	1 (0.3)		1 (0.2)
Gout	0	1 (0.3)		1 (0.2)
Diabetes mellitus	1 (0.3)	0		1 (0.2)
Vitamin D deficiency	2 (0.6)	0		2 (0.3)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Psychiatric disorders	4 (1.3)	0		4 (0.6)
Anxiety	1 (0.3)	0		1 (0.2)
Attention deficit hyperactivity disorder	1 (0.3)	0		1 (0.2)
Depression	1 (0.3)	0		1 (0.2)
Panic attack	1 (0.3)	0		1 (0.2)
Schizoaffective disorder	1 (0.3)	0		1 (0.2)
Nervous system disorders	24 (7.5)	49 (15.3)		73 (11.4)
Headache	19 (6.0)	36 (11.3)	1.88 (1.11, 3.20)	55 (8.6)
Dizziness	2 (0.6)	2 (0.6)		4 (0.6)
Hypoaesthesia	0	2 (0.6)		2 (0.3)
Paraesthesia	2 (0.6)	2 (0.6)		4 (0.6)
Sinus headache	0	2 (0.6)		2 (0.3)
Ageusia	0	1 (0.3)		1 (0.2)
Anosmia	0	1 (0.3)		1 (0.2)
Hyperaesthesia	0	1 (0.3)		1 (0.2)
Migraine	0	1 (0.3)		1 (0.2)
Presyncope	0	1 (0.3)		1 (0.2)
Sciatica	1 (0.3)	1 (0.3)		2 (0.3)
Syncope	0	1 (0.3)		1 (0.2)
Toxic encephalopathy	0	1 (0.3)		1 (0.2)
Tremor	0	1 (0.3)		1 (0.2)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Nervous system disorders (Cont.)				
Vestibular migraine	0	1 (0.3)		1 (0.2)
Hypogeusia	1 (0.3)	0		1 (0.2)
Hyposmia	1 (0.3)	0		1 (0.2)
Eye disorders	2 (0.6)	3 (0.9)		5 (0.8)
Eye irritation	0	1 (0.3)		1 (0.2)
Eye pain	0	1 (0.3)		1 (0.2)
Scleritis	0	1 (0.3)		1 (0.2)
Dry eye	1 (0.3)	0		1 (0.2)
Eyelid ptosis	1 (0.3)	0		1 (0.2)
Ear and labyrinth disorders	3 (0.9)	5 (1.6)		8 (1.3)
Ear pain	1 (0.3)	2 (0.6)		3 (0.5)
Vertigo	1 (0.3)	2 (0.6)		3 (0.5)
Ear canal erythema	0	1 (0.3)		1 (0.2)
Tympanic membrane perforation	1 (0.3)	0		1 (0.2)
Cardiac disorders	3 (0.9)	2 (0.6)		5 (0.8)
Cardiac failure congestive	0	1 (0.3)		1 (0.2)
Palpitations	1 (0.3)	1 (0.3)		2 (0.3)
Atrial tachycardia	1 (0.3)	0		1 (0.2)
Bradycardia	1 (0.3)	0		1 (0.2)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Vascular disorders	3 (0.9)	2 (0.6)		5 (0.8)
Hot flush	0	1 (0.3)		1 (0.2)
Systolic hypertension	0	1 (0.3)		1 (0.2)
Hypertension	3 (0.9)	0		3 (0.5)
Respiratory, thoracic and mediastinal disorders	24 (7.5)	27 (8.4)		51 (8.0)
Cough	4 (1.3)	9 (2.8)	2.24 (0.74, 6.80)	13 (2.0)
Nasal congestion	4 (1.3)	8 (2.5)	1.99 (0.64, 6.16)	12 (1.9)
Oropharyngeal pain	7 (2.2)	8 (2.5)	1.14 (0.43, 2.98)	15 (2.4)
Rhinorrhoea	7 (2.2)	8 (2.5)	1.14 (0.43, 2.98)	15 (2.4)
Dyspnoea	1 (0.3)	4 (1.3)		5 (0.8)
Epistaxis	0	2 (0.6)		2 (0.3)
Rhinitis allergic	1 (0.3)	2 (0.6)		3 (0.5)
Sinus congestion	0	2 (0.6)		2 (0.3)
Throat irritation	0	2 (0.6)		2 (0.3)
Atelectasis	0	1 (0.3)		1 (0.2)
Nasal pruritus	0	1 (0.3)		1 (0.2)
Pharyngeal erythema	0	1 (0.3)		1 (0.2)
Respiratory tract congestion	0	1 (0.3)		1 (0.2)
Tachypnoea	1 (0.3)	1 (0.3)		2 (0.3)
Dry throat	1 (0.3)	0		1 (0.2)
Dysphonia	1 (0.3)	0		1 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary embolism	1 (0.3)	0		1 (0.2)
Gastrointestinal disorders	15 (4.7)	16 (5.0)		31 (4.9)
Diarrhoea	4 (1.3)	5 (1.6)		9 (1.4)
Gastrooesophageal reflux disease	1 (0.3)	3 (0.9)		4 (0.6)
Vomiting	3 (0.9)	3 (0.9)		6 (0.9)
Nausea	7 (2.2)	2 (0.6)	0.28 (0.07, 1.19)	9 (1.4)
Abdominal distension	0	1 (0.3)		1 (0.2)
Abdominal pain lower	0	1 (0.3)		1 (0.2)
Faeces soft	0	1 (0.3)		1 (0.2)
Flatulence	0	1 (0.3)		1 (0.2)
Gastric ulcer	0	1 (0.3)		1 (0.2)
Haematochezia	0	1 (0.3)		1 (0.2)
Inguinal hernia	0	1 (0.3)		1 (0.2)
Large intestine polyp	0	1 (0.3)		1 (0.2)
Tooth impacted	0	1 (0.3)		1 (0.2)
Umbilical hernia	0	1 (0.3)		1 (0.2)
Aphthous ulcer	1 (0.3)	0		1 (0.2)
Dental caries	1 (0.3)	0		1 (0.2)
Gastrointestinal motility disorder	1 (0.3)	0		1 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Hepatobiliary disorders	0	1 (0.3)		1 (0.2)
Hepatic steatosis	0	1 (0.3)		1 (0.2)
Skin and subcutaneous tissue disorders	6 (1.9)	12 (3.8)		18 (2.8)
Pruritus	2 (0.6)	2 (0.6)		4 (0.6)
Rash	1 (0.3)	2 (0.6)		3 (0.5)
Acne cystic	0	1 (0.3)		1 (0.2)
Eczema	1 (0.3)	1 (0.3)		2 (0.3)
Erythema	0	1 (0.3)		1 (0.2)
Hyperhidrosis	0	1 (0.3)		1 (0.2)
Psoriasis	0	1 (0.3)		1 (0.2)
Rash maculo-papular	0	1 (0.3)		1 (0.2)
Skin burning sensation	0	1 (0.3)		1 (0.2)
Urticaria	1 (0.3)	1 (0.3)		2 (0.3)
Urticaria papular	0	1 (0.3)		1 (0.2)
Rash erythematous	1 (0.3)	0		1 (0.2)
Musculoskeletal and connective tissue disorders	33 (10.4)	35 (10.9)		68 (10.7)
Arthralgia	8 (2.5)	12 (3.8)	1.49 (0.63, 3.51)	20 (3.1)
Myalgia	13 (4.1)	12 (3.8)	0.92 (0.43, 1.95)	25 (3.9)
Pain in extremity	2 (0.6)	3 (0.9)		5 (0.8)
Limb discomfort	0	2 (0.6)		2 (0.3)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Musculoskeletal pain	1 (0.3)	2 (0.6)		3 (0.5)
Neck pain	0	2 (0.6)		2 (0.3)
Arthritis	0	1 (0.3)		1 (0.2)
Back pain	8 (2.5)	1 (0.3)	0.12 (0.02, 0.76)	9 (1.4)
Groin pain	0	1 (0.3)		1 (0.2)
Muscle spasms	2 (0.6)	1 (0.3)		3 (0.5)
Muscle tightness	0	1 (0.3)		1 (0.2)
Muscle twitching	1 (0.3)	1 (0.3)		2 (0.3)
Muscular weakness	0	1 (0.3)		1 (0.2)
Osteoarthritis	0	1 (0.3)		1 (0.2)
Cervical spinal stenosis	1 (0.3)	0		1 (0.2)
Musculoskeletal chest pain	1 (0.3)	0		1 (0.2)
Musculoskeletal discomfort	1 (0.3)	0		1 (0.2)
Musculoskeletal stiffness	1 (0.3)	0		1 (0.2)
Tendonitis	1 (0.3)	0		1 (0.2)
Renal and urinary disorders	0	2 (0.6)		2 (0.3)
Bladder pain	0	1 (0.3)		1 (0.2)
Nephrolithiasis	0	1 (0.3)		1 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Reproductive system and breast disorders	1 (0.3)	1 (0.3)		2 (0.3)
Erectile dysfunction	0	1 (0.3)		1 (0.2)
Haematospermia	1 (0.3)	0		1 (0.2)
General disorders and administration site conditions	30 (9.4)	51 (15.9)		81 (12.7)
Fatigue	22 (6.9)	28 (8.8)	1.26 (0.74, 2.15)	50 (7.8)
Injection site pain	3 (0.9)	12 (3.8)	3.98 (1.22, 13.04)	15 (2.4)
Pain	0	5 (1.6)		5 (0.8)
Pyrexia	1 (0.3)	5 (1.6)		6 (0.9)
Chills	3 (0.9)	3 (0.9)		6 (0.9)
Injection site induration	1 (0.3)	3 (0.9)		4 (0.6)
Injection site lymphadenopathy	1 (0.3)	3 (0.9)		4 (0.6)
Injection site erythema	2 (0.6)	2 (0.6)		4 (0.6)
Injection site rash	0	2 (0.6)		2 (0.3)
Injection site swelling	6 (1.9)	2 (0.6)		8 (1.3)
Malaise	1 (0.3)	2 (0.6)		3 (0.5)
Chest discomfort	0	1 (0.3)		1 (0.2)
Injection site bruising	1 (0.3)	1 (0.3)		2 (0.3)
Injection site haemorrhage	0	1 (0.3)		1 (0.2)
Injection site hypoaesthesia	0	1 (0.3)		1 (0.2)
Injection site macule	0	1 (0.3)		1 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
General disorders and administration site conditions (Cont.)				
Non-cardiac chest pain	0	1 (0.3)		1 (0.2)
Peripheral swelling	0	1 (0.3)		1 (0.2)
Vaccination site swelling	0	1 (0.3)		1 (0.2)
Chest pain	1 (0.3)	0		1 (0.2)
Vaccination site pain	1 (0.3)	0		1 (0.2)
Investigations	1 (0.3)	1 (0.3)		2 (0.3)
Blood glucose increased	0	1 (0.3)		1 (0.2)
Blood potassium decreased	1 (0.3)	0		1 (0.2)
Injury, poisoning and procedural complications	10 (3.1)	9 (2.8)		19 (3.0)
Skin laceration	0	2 (0.6)		2 (0.3)
Arthropod bite	0	1 (0.3)		1 (0.2)
Clavicle fracture	0	1 (0.3)		1 (0.2)
Concussion	0	1 (0.3)		1 (0.2)
Epicondylitis	0	1 (0.3)		1 (0.2)
Fall	2 (0.6)	1 (0.3)		3 (0.5)
Joint injury	0	1 (0.3)		1 (0.2)
Skin abrasion	3 (0.9)	1 (0.3)		4 (0.6)
Anaemia postoperative	1 (0.3)	0		1 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Multiple

System Organ Class Preferred Term	Placebo (N=318) n (%)	mRNA-1273 (N=320) n (%)	Rate Ratio (95% CI)	Total (N=638) n (%)
Injury, poisoning and procedural complications (Cont.)				
Contusion	2 (0.6)	0		2 (0.3)
Ligament sprain	2 (0.6)	0		2 (0.3)
Lip injury	1 (0.3)	0		1 (0.2)
Radius fracture	1 (0.3)	0		1 (0.2)
Tooth fracture	1 (0.3)	0		1 (0.2)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	182 (43.0)	189 (41.3)		371 (42.1)
Number of Unsolicited Adverse Events	468	487		955
Infections and infestations	49 (11.6)	30 (6.6)		79 (9.0)
Viral infection	9 (2.1)	5 (1.1)	0.51 (0.18, 1.45)	14 (1.6)
Upper respiratory tract infection	12 (2.8)	4 (0.9)	0.31 (0.11, 0.90)	16 (1.8)
Ear infection	0	3 (0.7)		3 (0.3)
Urinary tract infection	5 (1.2)	3 (0.7)		8 (0.9)
Fungal infection	1 (0.2)	2 (0.4)		3 (0.3)
Asymptomatic COVID-19	1 (0.2)	1 (0.2)		2 (0.2)
COVID-19	9 (2.1)	1 (0.2)	0.10 (0.02, 0.62)	10 (1.1)
Cellulitis	0	1 (0.2)		1 (0.1)
Gastroenteritis bacterial	0	1 (0.2)		1 (0.1)
Gingivitis	0	1 (0.2)		1 (0.1)
Liver abscess	0	1 (0.2)		1 (0.1)
Oral herpes	1 (0.2)	1 (0.2)		2 (0.2)
Osteomyelitis	0	1 (0.2)		1 (0.1)
Otitis externa	0	1 (0.2)		1 (0.1)
Otitis media	1 (0.2)	1 (0.2)		2 (0.2)
Pneumonia mycoplasmal	0	1 (0.2)		1 (0.1)
Rhinovirus infection	0	1 (0.2)		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Infections and infestations (Cont.)				
Sinusitis	2 (0.5)	1 (0.2)		3 (0.3)
Suspected COVID-19	2 (0.5)	1 (0.2)		3 (0.3)
Tooth infection	0	1 (0.2)		1 (0.1)
Tuberculosis	0	1 (0.2)		1 (0.1)
Cystitis	1 (0.2)	0		1 (0.1)
Epididymitis	1 (0.2)	0		1 (0.1)
Helicobacter infection	1 (0.2)	0		1 (0.1)
Ophthalmic herpes zoster	1 (0.2)	0		1 (0.1)
Oral candidiasis	1 (0.2)	0		1 (0.1)
Paronychia	1 (0.2)	0		1 (0.1)
Pharyngitis	1 (0.2)	0		1 (0.1)
Pharyngitis streptococcal	1 (0.2)	0		1 (0.1)
Varicella zoster virus infection	1 (0.2)	0		1 (0.1)
Blood and lymphatic system disorders	7 (1.7)	11 (2.4)		18 (2.0)
Lymphadenopathy	7 (1.7)	10 (2.2)	1.32 (0.52, 3.33)	17 (1.9)
Anaemia	0	1 (0.2)		1 (0.1)
Immune system disorders	1 (0.2)	1 (0.2)		2 (0.2)
Seasonal allergy	1 (0.2)	1 (0.2)		2 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Endocrine disorders	1 (0.2)	0		1 (0.1)
Hyperparathyroidism primary	1 (0.2)	0		1 (0.1)
Metabolism and nutrition disorders	6 (1.4)	4 (0.9)		10 (1.1)
Glucose tolerance impaired	0	1 (0.2)		1 (0.1)
Hypoferritinaemia	0	1 (0.2)		1 (0.1)
Type 2 diabetes mellitus	0	1 (0.2)		1 (0.1)
Vitamin D deficiency	1 (0.2)	1 (0.2)		2 (0.2)
Decreased appetite	1 (0.2)	0		1 (0.1)
Dyslipidaemia	1 (0.2)	0		1 (0.1)
Hyperlipidaemia	4 (0.9)	0		4 (0.5)
Psychiatric disorders	4 (0.9)	9 (2.0)		13 (1.5)
Insomnia	2 (0.5)	2 (0.4)		4 (0.5)
Abnormal dreams	0	1 (0.2)		1 (0.1)
Anxiety	2 (0.5)	1 (0.2)		3 (0.3)
Attention deficit hyperactivity disorder	0	1 (0.2)		1 (0.1)
Bruxism	0	1 (0.2)		1 (0.1)
Claustrophobia	0	1 (0.2)		1 (0.1)
Depression	0	1 (0.2)		1 (0.1)
Libido decreased	0	1 (0.2)		1 (0.1)
Panic attack	1 (0.2)	1 (0.2)		2 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Psychiatric disorders (Cont.)				
Premature ejaculation	0	1 (0.2)		1 (0.1)
Nightmare	1 (0.2)	0		1 (0.1)
Nervous system disorders	49 (11.6)	54 (11.8)		103 (11.7)
Headache	37 (8.7)	41 (9.0)	1.02 (0.67, 1.56)	78 (8.9)
Dizziness	6 (1.4)	6 (1.3)		12 (1.4)
Ageusia	1 (0.2)	2 (0.4)		3 (0.3)
Dysgeusia	0	2 (0.4)		2 (0.2)
Hyperaesthesia	0	2 (0.4)		2 (0.2)
Anosmia	1 (0.2)	1 (0.2)		2 (0.2)
Facial paralysis	0	1 (0.2)		1 (0.1)
Hypoaesthesia	1 (0.2)	1 (0.2)		2 (0.2)
Memory impairment	0	1 (0.2)		1 (0.1)
Migraine	3 (0.7)	1 (0.2)		4 (0.5)
Sciatica	0	1 (0.2)		1 (0.1)
Syncope	0	1 (0.2)		1 (0.1)
Tension headache	1 (0.2)	1 (0.2)		2 (0.2)
Paraesthesia	8 (1.9)	0		8 (0.9)
Restless legs syndrome	1 (0.2)	0		1 (0.1)
Eye disorders	2 (0.5)	5 (1.1)		7 (0.8)
Vision blurred	0	2 (0.4)		2 (0.2)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Eye disorders (Cont.)				
Conjunctival haemorrhage	0	1 (0.2)		1 (0.1)
Eye inflammation	0	1 (0.2)		1 (0.1)
Swelling of eyelid	0	1 (0.2)		1 (0.1)
Eye pruritus	2 (0.5)	0		2 (0.2)
Ear and labyrinth disorders	6 (1.4)	5 (1.1)		11 (1.2)
Ear pain	2 (0.5)	2 (0.4)		4 (0.5)
Ear discomfort	1 (0.2)	1 (0.2)		2 (0.2)
Tinnitus	1 (0.2)	1 (0.2)		2 (0.2)
Tympanic membrane perforation	0	1 (0.2)		1 (0.1)
Ear canal erythema	2 (0.5)	0		2 (0.2)
Ear pruritus	1 (0.2)	0		1 (0.1)
Vertigo	1 (0.2)	0		1 (0.1)
Vertigo positional	1 (0.2)	0		1 (0.1)
Cardiac disorders	3 (0.7)	2 (0.4)		5 (0.6)
Sinus tachycardia	0	1 (0.2)		1 (0.1)
Tachycardia	0	1 (0.2)		1 (0.1)
Bradycardia	2 (0.5)	0		2 (0.2)
Cardio-respiratory arrest	1 (0.2)	0		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Vascular disorders	11 (2.6)	7 (1.5)		18 (2.0)
Hypertension	9 (2.1)	4 (0.9)	0.41 (0.13, 1.25)	13 (1.5)
Deep vein thrombosis	1 (0.2)	1 (0.2)		2 (0.2)
Flushing	0	1 (0.2)		1 (0.1)
Hypertensive urgency	0	1 (0.2)		1 (0.1)
Aortic stenosis	1 (0.2)	0		1 (0.1)
Respiratory, thoracic and mediastinal disorders	40 (9.5)	37 (8.1)		77 (8.7)
Oropharyngeal pain	10 (2.4)	11 (2.4)	1.02 (0.45, 2.31)	21 (2.4)
Nasal congestion	9 (2.1)	9 (2.0)	0.92 (0.38, 2.24)	18 (2.0)
Rhinorrhoea	12 (2.8)	9 (2.0)	0.69 (0.30, 1.59)	21 (2.4)
Tachypnoea	1 (0.2)	7 (1.5)	6.47 (1.04, 40.24)	8 (0.9)
Cough	12 (2.8)	6 (1.3)	0.46 (0.18, 1.18)	18 (2.0)
Epistaxis	1 (0.2)	2 (0.4)		3 (0.3)
Respiratory tract congestion	2 (0.5)	2 (0.4)		4 (0.5)
Throat irritation	0	2 (0.4)		2 (0.2)
Allergic cough	0	1 (0.2)		1 (0.1)
Asthma	0	1 (0.2)		1 (0.1)
Dyspnoea	3 (0.7)	1 (0.2)		4 (0.5)
Dyspnoea exertional	0	1 (0.2)		1 (0.1)
Pleural effusion	0	1 (0.2)		1 (0.1)
Productive cough	0	1 (0.2)		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory failure	0	1 (0.2)		1 (0.1)
Sinus congestion	1 (0.2)	1 (0.2)		2 (0.2)
Dysphonia	1 (0.2)	0		1 (0.1)
Painful respiration	1 (0.2)	0		1 (0.1)
Pharyngeal erythema	2 (0.5)	0		2 (0.2)
Pleuritic pain	2 (0.5)	0		2 (0.2)
Sneezing	4 (0.9)	0		4 (0.5)
Gastrointestinal disorders	34 (8.0)	32 (7.0)		66 (7.5)
Nausea	10 (2.4)	10 (2.2)	0.92 (0.40, 2.14)	20 (2.3)
Diarrhoea	10 (2.4)	9 (2.0)	0.83 (0.35, 1.97)	19 (2.2)
Gastrooesophageal reflux disease	1 (0.2)	6 (1.3)		7 (0.8)
Abdominal pain	2 (0.5)	3 (0.7)		5 (0.6)
Dyspepsia	4 (0.9)	2 (0.4)		6 (0.7)
Abdominal distension	1 (0.2)	1 (0.2)		2 (0.2)
Colitis	0	1 (0.2)		1 (0.1)
Constipation	1 (0.2)	1 (0.2)		2 (0.2)
Dental caries	1 (0.2)	1 (0.2)		2 (0.2)
Gastric ulcer	0	1 (0.2)		1 (0.1)
Gastritis	0	1 (0.2)		1 (0.1)
Haematochezia	0	1 (0.2)		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Gastrointestinal disorders (Cont.)				
Mouth ulceration	0	1 (0.2)		1 (0.1)
Oesophageal ulcer	0	1 (0.2)		1 (0.1)
Proctalgia	0	1 (0.2)		1 (0.1)
Tongue discolouration	0	1 (0.2)		1 (0.1)
Toothache	2 (0.5)	1 (0.2)		3 (0.3)
Vomiting	5 (1.2)	1 (0.2)		6 (0.7)
Abdominal pain upper	1 (0.2)	0		1 (0.1)
Aphthous ulcer	1 (0.2)	0		1 (0.1)
Dental necrosis	1 (0.2)	0		1 (0.1)
Food poisoning	1 (0.2)	0		1 (0.1)
Hyperaesthesia teeth	1 (0.2)	0		1 (0.1)
Skin and subcutaneous tissue disorders	14 (3.3)	10 (2.2)		24 (2.7)
Alopecia	0	1 (0.2)		1 (0.1)
Chronic spontaneous urticaria	0	1 (0.2)		1 (0.1)
Dermatitis contact	0	1 (0.2)		1 (0.1)
Hyperhidrosis	2 (0.5)	1 (0.2)		3 (0.3)
Pityriasis rosea	0	1 (0.2)		1 (0.1)
Pruritus	4 (0.9)	1 (0.2)		5 (0.6)
Rash	6 (1.4)	1 (0.2)		7 (0.8)
Rash papular	0	1 (0.2)		1 (0.1)
Skin burning sensation	0	1 (0.2)		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Urticaria	2 (0.5)	1 (0.2)		3 (0.3)
Dermatitis atopic	1 (0.2)	0		1 (0.1)
Night sweats	1 (0.2)	0		1 (0.1)
Musculoskeletal and connective tissue disorders	49 (11.6)	50 (10.9)		99 (11.2)
Myalgia	19 (4.5)	24 (5.2)	1.17 (0.65, 2.08)	43 (4.9)
Arthralgia	19 (4.5)	21 (4.6)	1.02 (0.56, 1.86)	40 (4.5)
Back pain	6 (1.4)	8 (1.7)	1.23 (0.45, 3.38)	14 (1.6)
Pain in extremity	7 (1.7)	5 (1.1)	0.66 (0.22, 1.95)	12 (1.4)
Musculoskeletal pain	4 (0.9)	2 (0.4)		6 (0.7)
Neck pain	2 (0.5)	2 (0.4)		4 (0.5)
Bone pain	0	1 (0.2)		1 (0.1)
Bone swelling	0	1 (0.2)		1 (0.1)
Joint range of motion decreased	0	1 (0.2)		1 (0.1)
Muscle tightness	0	1 (0.2)		1 (0.1)
Musculoskeletal stiffness	1 (0.2)	1 (0.2)		2 (0.2)
Osteoarthritis	1 (0.2)	1 (0.2)		2 (0.2)
Palindromic rheumatism	0	1 (0.2)		1 (0.1)
Undifferentiated connective tissue disease	0	1 (0.2)		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Costochondritis	1 (0.2)	0		1 (0.1)
Fibromyalgia	1 (0.2)	0		1 (0.1)
Joint swelling	1 (0.2)	0		1 (0.1)
Musculoskeletal chest pain	1 (0.2)	0		1 (0.1)
Rotator cuff syndrome	1 (0.2)	0		1 (0.1)
Spinal osteoarthritis	1 (0.2)	0		1 (0.1)
Synovitis	1 (0.2)	0		1 (0.1)
Renal and urinary disorders	0	3 (0.7)		3 (0.3)
Dysuria	0	1 (0.2)		1 (0.1)
Nocturia	0	1 (0.2)		1 (0.1)
Pollakiuria	0	1 (0.2)		1 (0.1)
Reproductive system and breast disorders	2 (0.5)	4 (0.9)		6 (0.7)
Prostatitis	0	2 (0.4)		2 (0.2)
Menorrhagia	0	1 (0.2)		1 (0.1)
Vulvovaginal pain	0	1 (0.2)		1 (0.1)
Benign prostatic hyperplasia	1 (0.2)	0		1 (0.1)
Dysmenorrhoea	1 (0.2)	0		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
General disorders and administration site conditions	44 (10.4)	74 (16.2)		118 (13.4)
Fatigue	27 (6.4)	24 (5.2)	0.82 (0.48, 1.39)	51 (5.8)
Injection site pain	4 (0.9)	12 (2.6)	2.77 (0.95, 8.11)	16 (1.8)
Injection site erythema	3 (0.7)	10 (2.2)	3.08 (0.92, 10.33)	13 (1.5)
Chills	2 (0.5)	9 (2.0)	4.16 (1.02, 17.01)	11 (1.2)
Injection site lymphadenopathy	2 (0.5)	7 (1.5)	3.23 (0.77, 13.65)	9 (1.0)
Injection site swelling	1 (0.2)	7 (1.5)	6.47 (1.04, 40.24)	8 (0.9)
Pain	5 (1.2)	7 (1.5)	1.29 (0.44, 3.83)	12 (1.4)
Pyrexia	1 (0.2)	7 (1.5)	6.47 (1.04, 40.24)	8 (0.9)
Axillary pain	0	4 (0.9)		4 (0.5)
Injection site induration	1 (0.2)	4 (0.9)		5 (0.6)
Injection site pruritus	0	3 (0.7)		3 (0.3)
Feeling hot	2 (0.5)	2 (0.4)		4 (0.5)
Injection site rash	0	2 (0.4)		2 (0.2)
Injection site urticaria	0	2 (0.4)		2 (0.2)
Malaise	0	2 (0.4)		2 (0.2)
Chest pain	0	1 (0.2)		1 (0.1)
Facial pain	1 (0.2)	1 (0.2)		2 (0.2)
Injection site joint pain	0	1 (0.2)		1 (0.1)
Injection site macule	0	1 (0.2)		1 (0.1)
Injection site papule	0	1 (0.2)		1 (0.1)
Injection site warmth	0	1 (0.2)		1 (0.1)

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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
General disorders and administration site conditions (Cont.)				
Peripheral swelling	1 (0.2)	1 (0.2)		2 (0.2)
Secretion discharge	0	1 (0.2)		1 (0.1)
Sensation of foreign body	0	1 (0.2)		1 (0.1)
Chest discomfort	2 (0.5)	0		2 (0.2)
Injection site bruising	1 (0.2)	0		1 (0.1)
Injection site paraesthesia	1 (0.2)	0		1 (0.1)
Non-cardiac chest pain	1 (0.2)	0		1 (0.1)
Swelling face	1 (0.2)	0		1 (0.1)
Vaccination site nodule	1 (0.2)	0		1 (0.1)
Vaccination site pain	1 (0.2)	0		1 (0.1)
Vessel puncture site bruise	1 (0.2)	0		1 (0.1)
Investigations	6 (1.4)	5 (1.1)		11 (1.2)
Blood pressure increased	2 (0.5)	2 (0.4)		4 (0.5)
Blood glucose increased	0	1 (0.2)		1 (0.1)
Blood pressure diastolic increased	1 (0.2)	1 (0.2)		2 (0.2)
Heart rate increased	1 (0.2)	1 (0.2)		2 (0.2)
Blood calcium increased	1 (0.2)	0		1 (0.1)
Blood pressure diastolic decreased	1 (0.2)	0		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Injury, poisoning and procedural complications	21 (5.0)	12 (2.6)		33 (3.7)
Post-traumatic pain	0	2 (0.4)		2 (0.2)
Road traffic accident	0	2 (0.4)		2 (0.2)
Back injury	0	1 (0.2)		1 (0.1)
Concussion	0	1 (0.2)		1 (0.1)
Fall	0	1 (0.2)		1 (0.1)
Hand fracture	0	1 (0.2)		1 (0.1)
Hypobarism	0	1 (0.2)		1 (0.1)
Limb injury	0	1 (0.2)		1 (0.1)
Procedural pain	3 (0.7)	1 (0.2)		4 (0.5)
Skin abrasion	1 (0.2)	1 (0.2)		2 (0.2)
Skin laceration	0	1 (0.2)		1 (0.1)
Thermal burn	1 (0.2)	1 (0.2)		2 (0.2)
Tooth fracture	1 (0.2)	1 (0.2)		2 (0.2)
Arthropod bite	2 (0.5)	0		2 (0.2)
Arthropod sting	1 (0.2)	0		1 (0.1)
Contusion	2 (0.5)	0		2 (0.2)
Exposure to toxic agent	1 (0.2)	0		1 (0.1)
Foot fracture	1 (0.2)	0		1 (0.1)
Immunisation anxiety related reaction	1 (0.2)	0		1 (0.1)
Ligament sprain	1 (0.2)	0		1 (0.1)
Meniscus injury	1 (0.2)	0		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.4.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Race up to 28 Days After Any Injection
Safety Set

Race Group: Other/Not Reported/Unknown

System Organ Class Preferred Term	Placebo (N=423) n (%)	mRNA-1273 (N=458) n (%)	Rate Ratio (95% CI)	Total (N=881) n (%)
Injury, poisoning and procedural complications (Cont.)				
Muscle strain	1 (0.2)	0		1 (0.1)
Procedural complication	1 (0.2)	0		1 (0.1)
Procedural haemorrhage	1 (0.2)	0		1 (0.1)
Radius fracture	1 (0.2)	0		1 (0.1)
Respiratory fume inhalation disorder	1 (0.2)	0		1 (0.1)
Stress fracture	1 (0.2)	0		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1005 (32.3)	1029 (33.0)		2034 (32.6)
Number of Unsolicited Adverse Events	2197	2197		4394
Infections and infestations	232 (7.5)	189 (6.1)		421 (6.8)
Urinary tract infection	19 (0.6)	24 (0.8)	1.26 (0.70, 2.27)	43 (0.7)
Upper respiratory tract infection	35 (1.1)	19 (0.6)	0.54 (0.31, 0.94)	54 (0.9)
Viral infection	19 (0.6)	16 (0.5)	0.84 (0.44, 1.61)	35 (0.6)
COVID-19	41 (1.3)	11 (0.4)	0.27 (0.14, 0.51)	52 (0.8)
Rhinovirus infection	10 (0.3)	11 (0.4)	1.10 (0.48, 2.51)	21 (0.3)
Suspected COVID-19	8 (0.3)	9 (0.3)	1.12 (0.45, 2.81)	17 (0.3)
Pharyngitis	4 (0.1)	8 (0.3)	1.99 (0.64, 6.21)	12 (0.2)
Sinusitis	11 (0.4)	8 (0.3)	0.72 (0.30, 1.75)	19 (0.3)
Herpes zoster	3 (<0.1)	7 (0.2)	2.32 (0.66, 8.24)	10 (0.2)
Conjunctivitis	1 (<0.1)	5 (0.2)		6 (<0.1)
Ear infection	1 (<0.1)	5 (0.2)		6 (<0.1)
Tooth abscess	0	5 (0.2)		5 (<0.1)
Tooth infection	4 (0.1)	5 (0.2)		9 (0.1)
Fungal infection	2 (<0.1)	4 (0.1)		6 (<0.1)
Folliculitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Gastroenteritis	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.2)
Hordeolum	4 (0.1)	3 (<0.1)		7 (0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Infections and infestations (Cont.)				
Onychomycosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Oral herpes	4 (0.1)	3 (<0.1)		7 (0.1)
Otitis media	2 (<0.1)	3 (<0.1)		5 (<0.1)
Pharyngitis streptococcal	4 (0.1)	3 (<0.1)		7 (0.1)
Viral upper respiratory tract infection	6 (0.2)	3 (<0.1)		9 (0.1)
Bacterial vaginosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bronchitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Diverticulitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Enterovirus infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gingivitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Herpes simplex	1 (<0.1)	2 (<0.1)		3 (<0.1)
Staphylococcal skin infection	0	2 (<0.1)		2 (<0.1)
Abscess limb	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic COVID-19	0	1 (<0.1)		1 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Body tinea	0	1 (<0.1)		1 (<0.1)
Cellulitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	0	1 (<0.1)		1 (<0.1)
Fungal skin infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Furuncle	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Infections and infestations (Cont.)				
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Genital herpes	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Helicobacter infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis externa	2 (<0.1)	1 (<0.1)		3 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory tract infection viral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rhinitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Viral rhinitis	0	1 (<0.1)		1 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Infections and infestations (Cont.)				
Appendicitis	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)
Candida infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Cystitis	3 (<0.1)	0		3 (<0.1)
Epididymitis	1 (<0.1)	0		1 (<0.1)
Eye infection	1 (<0.1)	0		1 (<0.1)
Gastroenteritis viral	2 (<0.1)	0		2 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Laryngitis	1 (<0.1)	0		1 (<0.1)
Localised infection	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Nasopharyngitis	3 (<0.1)	0		3 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oral candidiasis	1 (<0.1)	0		1 (<0.1)
Otitis media acute	1 (<0.1)	0		1 (<0.1)
Paronychia	3 (<0.1)	0		3 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Infections and infestations (Cont.)				
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Skin infection	1 (<0.1)	0		1 (<0.1)
Subcutaneous abscess	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Tonsillitis	4 (0.1)	0		4 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Viral pharyngitis	1 (<0.1)	0		1 (<0.1)
Vulvovaginal mycotic infection	4 (0.1)	0		4 (<0.1)
Wound infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	8 (0.3)		9 (0.1)
Benign neoplasm of skin	0	2 (<0.1)		2 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Basal cell carcinoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Prostate cancer	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	0	1 (<0.1)		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	41 (1.3)	65 (2.1)		106 (1.7)
Lymphadenopathy	38 (1.2)	61 (2.0)	1.60 (1.07, 2.38)	99 (1.6)
Lymph node pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Anaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lymphadenitis	0	1 (<0.1)		1 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	19 (0.6)	12 (0.4)		31 (0.5)
Seasonal allergy	12 (0.4)	6 (0.2)	0.50 (0.19, 1.28)	18 (0.3)
Hypersensitivity	3 (<0.1)	3 (<0.1)		6 (<0.1)
Food allergy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Drug hypersensitivity	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Endocrine disorders	1 (<0.1)	0		1 (<0.1)
Hypogonadism	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	32 (1.0)	30 (1.0)		62 (1.0)
Hyperlipidaemia	6 (0.2)	5 (0.2)		11 (0.2)
Diabetes mellitus	1 (<0.1)	4 (0.1)		5 (<0.1)
Glucose tolerance impaired	3 (<0.1)	3 (<0.1)		6 (<0.1)
Type 2 diabetes mellitus	3 (<0.1)	3 (<0.1)		6 (<0.1)
Vitamin D deficiency	6 (0.2)	3 (<0.1)		9 (0.1)
Decreased appetite	4 (0.1)	2 (<0.1)		6 (<0.1)
Gout	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dehydration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Hypercholesterolaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hyponatraemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dyslipidaemia	2 (<0.1)	0		2 (<0.1)
Electrolyte imbalance	1 (<0.1)	0		1 (<0.1)
Hyperglycaemia	1 (<0.1)	0		1 (<0.1)
Hypocalcaemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypoglycaemia	2 (<0.1)	0		2 (<0.1)
Hypokalaemia	2 (<0.1)	0		2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Iron deficiency	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	26 (0.8)	30 (1.0)		56 (0.9)
Anxiety	10 (0.3)	9 (0.3)	0.90 (0.37, 2.14)	19 (0.3)
Depression	10 (0.3)	9 (0.3)	0.90 (0.37, 2.14)	19 (0.3)
Insomnia	6 (0.2)	7 (0.2)	1.16 (0.41, 3.29)	13 (0.2)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Panic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abnormal dreams	0	1 (<0.1)		1 (<0.1)
Adjustment disorder with depressed mood	0	1 (<0.1)		1 (<0.1)
Bipolar disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Nightmare	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Psychiatric disorders (Cont.)				
Suicidal ideation	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	254 (8.2)	246 (7.9)		500 (8.0)
Headache	195 (6.3)	185 (5.9)	0.94 (0.78, 1.15)	380 (6.1)
Dizziness	21 (0.7)	20 (0.6)	0.95 (0.52, 1.73)	41 (0.7)
Hypoaesthesia	2 (<0.1)	6 (0.2)		8 (0.1)
Dysgeusia	2 (<0.1)	5 (0.2)		7 (0.1)
Migraine	7 (0.2)	5 (0.2)	0.71 (0.24, 2.12)	12 (0.2)
Paraesthesia	11 (0.4)	5 (0.2)	0.45 (0.16, 1.24)	16 (0.3)
Presyncope	3 (<0.1)	4 (0.1)		7 (0.1)
Sciatica	3 (<0.1)	4 (0.1)		7 (0.1)
Tension headache	2 (<0.1)	4 (0.1)		6 (<0.1)
Ageusia	6 (0.2)	3 (<0.1)		9 (0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Sinus headache	2 (<0.1)	3 (<0.1)		5 (<0.1)
Anosmia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia	0	2 (<0.1)		2 (<0.1)
Memory impairment	0	2 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Syncope	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Nervous system disorders (Cont.)				
Disturbance in attention	1 (<0.1)	1 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Amnesia	1 (<0.1)	0		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Cervical radiculopathy	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Lethargy	1 (<0.1)	0		1 (<0.1)
Parosmia	3 (<0.1)	0		3 (<0.1)
Seizure	1 (<0.1)	0		1 (<0.1)
Eye disorders	10 (0.3)	14 (0.4)		24 (0.4)
Conjunctival haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye irritation	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Eye disorders (Cont.)				
Scleritis	0	2 (<0.1)		2 (<0.1)
Vision blurred	0	2 (<0.1)		2 (<0.1)
Dry eye	0	1 (<0.1)		1 (<0.1)
Eye inflammation	0	1 (<0.1)		1 (<0.1)
Eye pain	0	1 (<0.1)		1 (<0.1)
Retinal detachment	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Eye pruritus	4 (0.1)	0		4 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)
Vitreous floaters	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	20 (0.6)	18 (0.6)		38 (0.6)
Ear pain	5 (0.2)	6 (0.2)		11 (0.2)
Vertigo	4 (0.1)	4 (0.1)		8 (0.1)
Ear discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tinnitus	3 (<0.1)	2 (<0.1)		5 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Otorrhoea	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Ear and labyrinth disorders (Cont.)				
Tympanic membrane perforation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vertigo positional	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear canal erythema	2 (<0.1)	0		2 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	1 (<0.1)	0		1 (<0.1)
Middle ear effusion	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	16 (0.5)	11 (0.4)		27 (0.4)
Tachycardia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Bradycardia	5 (0.2)	2 (<0.1)		7 (0.1)
Palpitations	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angina pectoris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial fibrillation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Sinus tachycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiac failure congestive	2 (<0.1)	0		2 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Vascular disorders	39 (1.3)	41 (1.3)		80 (1.3)
Hypertension	31 (1.0)	29 (0.9)	0.93 (0.57, 1.53)	60 (1.0)
Hot flush	0	4 (0.1)		4 (<0.1)
Flushing	0	2 (<0.1)		2 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Haematoma	2 (<0.1)	1 (<0.1)		3 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Systolic hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	184 (5.9)	154 (4.9)		338 (5.4)
Cough	41 (1.3)	44 (1.4)	1.07 (0.70, 1.63)	85 (1.4)
Oropharyngeal pain	64 (2.1)	44 (1.4)	0.68 (0.47, 1.00)	108 (1.7)
Nasal congestion	47 (1.5)	38 (1.2)	0.80 (0.53, 1.23)	85 (1.4)
Rhinorrhoea	43 (1.4)	30 (1.0)	0.69 (0.44, 1.10)	73 (1.2)
Tachypnoea	5 (0.2)	10 (0.3)	1.99 (0.71, 5.56)	15 (0.2)
Dyspnoea	13 (0.4)	7 (0.2)	0.54 (0.22, 1.30)	20 (0.3)
Respiratory tract congestion	3 (<0.1)	7 (0.2)	2.32 (0.66, 8.24)	10 (0.2)
Rhinitis allergic	5 (0.2)	6 (0.2)		11 (0.2)
Sinus congestion	7 (0.2)	5 (0.2)	0.71 (0.24, 2.12)	12 (0.2)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Epistaxis	3 (<0.1)	4 (0.1)		7 (0.1)
Upper-airway cough syndrome	2 (<0.1)	4 (0.1)		6 (<0.1)
Dyspnoea exertional	1 (<0.1)	3 (<0.1)		4 (<0.1)
Productive cough	2 (<0.1)	3 (<0.1)		5 (<0.1)
Sneezing	6 (0.2)	3 (<0.1)		9 (0.1)
Throat irritation	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.2)
Asthma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Atelectasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry throat	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Tonsillolith	2 (<0.1)	1 (<0.1)		3 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	2 (<0.1)	0		2 (<0.1)
Dysphonia	3 (<0.1)	0		3 (<0.1)
Painful respiration	1 (<0.1)	0		1 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	2 (<0.1)	0		2 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Wheezing	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	153 (4.9)	143 (4.6)		296 (4.8)
Diarrhoea	55 (1.8)	56 (1.8)	1.01 (0.70, 1.46)	111 (1.8)
Nausea	43 (1.4)	38 (1.2)	0.88 (0.57, 1.35)	81 (1.3)
Gastrooesophageal reflux disease	4 (0.1)	10 (0.3)	2.49 (0.83, 7.49)	14 (0.2)
Vomiting	20 (0.6)	9 (0.3)	0.45 (0.21, 0.96)	29 (0.5)
Abdominal pain	6 (0.2)	8 (0.3)	1.33 (0.48, 3.66)	14 (0.2)
Toothache	10 (0.3)	8 (0.3)	0.80 (0.32, 1.95)	18 (0.3)
Dyspepsia	9 (0.3)	7 (0.2)	0.77 (0.30, 2.00)	16 (0.3)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal distension	1 (<0.1)	3 (<0.1)		4 (<0.1)
Constipation	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.2)
Abdominal pain lower	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal pain upper	8 (0.3)	2 (<0.1)	0.25 (0.06, 1.03)	10 (0.2)
Aphthous ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Colitis	0	2 (<0.1)		2 (<0.1)
Gastritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Haematochezia	0	2 (<0.1)		2 (<0.1)
Proctalgia	0	2 (<0.1)		2 (<0.1)
Tooth impacted	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dental caries	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dysphagia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Flatulence	0	1 (<0.1)		1 (<0.1)
Food poisoning	5 (0.2)	1 (<0.1)		6 (<0.1)
Gastric ulcer	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	0	1 (<0.1)		1 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Gastrointestinal disorders (Cont.)				
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Tongue discolouration	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	4 (0.1)	0		4 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Dry mouth	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Haemorrhoids	2 (<0.1)	0		2 (<0.1)
Hiatus hernia	1 (<0.1)	0		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	0		1 (<0.1)
Loose tooth	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	4 (0.1)		5 (<0.1)
Cholelithiasis	1 (<0.1)	4 (0.1)		5 (<0.1)
Skin and subcutaneous tissue disorders	51 (1.6)	70 (2.2)		121 (1.9)
Urticaria	8 (0.3)	14 (0.4)	1.74 (0.75, 4.04)	22 (0.4)
Pruritus	7 (0.2)	11 (0.4)	1.56 (0.63, 3.90)	18 (0.3)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash	9 (0.3)	9 (0.3)	1.00 (0.41, 2.43)	18 (0.3)
Dermatitis contact	2 (<0.1)	5 (0.2)		7 (0.1)
Eczema	0	5 (0.2)		5 (<0.1)
Hyperhidrosis	5 (0.2)	5 (0.2)		10 (0.2)
Erythema	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin burning sensation	0	3 (<0.1)		3 (<0.1)
Ecchymosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Rash maculo-papular	0	2 (<0.1)		2 (<0.1)
Acne	3 (<0.1)	1 (<0.1)		4 (<0.1)
Acne cystic	0	1 (<0.1)		1 (<0.1)
Blister	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Lichen planus	0	1 (<0.1)		1 (<0.1)
Macule	0	1 (<0.1)		1 (<0.1)
Night sweats	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pain of skin	0	1 (<0.1)		1 (<0.1)
Psoriasis	0	1 (<0.1)		1 (<0.1)
Rash papular	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin ulcer	0	1 (<0.1)		1 (<0.1)
Urticaria papular	0	1 (<0.1)		1 (<0.1)
Alopecia	2 (<0.1)	0		2 (<0.1)
Dermatitis	1 (<0.1)	0		1 (<0.1)
Dermatitis atopic	3 (<0.1)	0		3 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Papule	1 (<0.1)	0		1 (<0.1)
Petechiae	1 (<0.1)	0		1 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash pruritic	3 (<0.1)	0		3 (<0.1)
Rosacea	1 (<0.1)	0		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	254 (8.2)	227 (7.3)		481 (7.7)
Myalgia	99 (3.2)	94 (3.0)	0.95 (0.72, 1.25)	193 (3.1)
Arthralgia	102 (3.3)	86 (2.8)	0.84 (0.63, 1.11)	188 (3.0)
Back pain	28 (0.9)	26 (0.8)	0.92 (0.55, 1.56)	54 (0.9)
Pain in extremity	22 (0.7)	22 (0.7)	1.00 (0.56, 1.78)	44 (0.7)
Musculoskeletal pain	15 (0.5)	10 (0.3)	0.66 (0.30, 1.45)	25 (0.4)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Neck pain	13 (0.4)	10 (0.3)	0.77 (0.34, 1.71)	23 (0.4)
Muscle spasms	5 (0.2)	9 (0.3)	1.79 (0.63, 5.09)	14 (0.2)
Tendonitis	0	5 (0.2)		5 (<0.1)
Osteoarthritis	5 (0.2)	4 (0.1)		9 (0.1)
Arthritis	0	3 (<0.1)		3 (<0.1)
Bursitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Flank pain	0	2 (<0.1)		2 (<0.1)
Groin pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Intervertebral disc protrusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Limb discomfort	0	2 (<0.1)		2 (<0.1)
Muscle tightness	0	2 (<0.1)		2 (<0.1)
Muscular weakness	0	2 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	5 (0.2)	2 (<0.1)		7 (0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Costochondritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibromyalgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Muscle fatigue	0	1 (<0.1)		1 (<0.1)
Muscle twitching	0	1 (<0.1)		1 (<0.1)
Osteoporosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in jaw	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal pain	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Torticollis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Trigger finger	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Axillary mass	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	0		2 (<0.1)
Joint range of motion decreased	1 (<0.1)	0		1 (<0.1)
Joint swelling	2 (<0.1)	0		2 (<0.1)
Musculoskeletal stiffness	3 (<0.1)	0		3 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rotator cuff syndrome	4 (0.1)	0		4 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	1 (<0.1)	0		1 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	11 (0.4)	12 (0.4)		23 (0.4)
Dysuria	0	3 (<0.1)		3 (<0.1)
Nephrolithiasis	8 (0.3)	3 (<0.1)	0.37 (0.11, 1.30)	11 (0.2)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertonic bladder	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Pollakiuria	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	0	1 (<0.1)		1 (<0.1)
Chronic kidney disease	1 (<0.1)	0		1 (<0.1)
Haematuria	2 (<0.1)	0		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal cyst	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Reproductive system and breast disorders	13 (0.4)	8 (0.3)		21 (0.3)
Prostatitis	0	2 (<0.1)		2 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Erectile dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Benign prostatic hyperplasia	2 (<0.1)	0		2 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Dysmenorrhoea	2 (<0.1)	0		2 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Menstruation irregular	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Vaginal haemorrhage	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Hydrocele	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
General disorders and administration site conditions	246 (7.9)	360 (11.5)		606 (9.7)
Fatigue	163 (5.2)	169 (5.4)	1.03 (0.84, 1.27)	332 (5.3)
Injection site pain	27 (0.9)	53 (1.7)	1.95 (1.24, 3.09)	80 (1.3)
Chills	26 (0.8)	32 (1.0)	1.23 (0.74, 2.04)	58 (0.9)
Injection site erythema	4 (0.1)	31 (1.0)	7.72 (2.84, 20.94)	35 (0.6)
Pyrexia	10 (0.3)	26 (0.8)	2.59 (1.27, 5.28)	36 (0.6)
Injection site pruritus	3 (<0.1)	24 (0.8)	7.96 (2.56, 24.83)	27 (0.4)
Injection site lymphadenopathy	6 (0.2)	23 (0.7)	3.82 (1.60, 9.11)	29 (0.5)
Injection site swelling	5 (0.2)	21 (0.7)	4.18 (1.64, 10.70)	26 (0.4)
Injection site induration	2 (<0.1)	17 (0.5)	8.46 (2.18, 32.90)	19 (0.3)
Injection site macule	0	16 (0.5)		16 (0.3)
Pain	23 (0.7)	16 (0.5)	0.69 (0.37, 1.29)	39 (0.6)
Injection site urticaria	1 (<0.1)	8 (0.3)	7.96 (1.29, 49.05)	9 (0.1)
Injection site bruising	5 (0.2)	7 (0.2)	1.39 (0.47, 4.15)	12 (0.2)
Axillary pain	6 (0.2)	5 (0.2)		11 (0.2)
Injection site papule	0	5 (0.2)		5 (<0.1)
Injection site rash	0	5 (0.2)		5 (<0.1)
Malaise	3 (<0.1)	5 (0.2)		8 (0.1)
Feeling hot	2 (<0.1)	4 (0.1)		6 (<0.1)
Chest discomfort	5 (0.2)	3 (<0.1)		8 (0.1)
Peripheral swelling	1 (<0.1)	3 (<0.1)		4 (<0.1)
Vaccination site pain	0	3 (<0.1)		3 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
General disorders and administration site conditions (Cont.)				
Injection site paraesthesia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Non-cardiac chest pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Reactogenicity event	0	2 (<0.1)		2 (<0.1)
Chest pain	0	1 (<0.1)		1 (<0.1)
Cyst	0	1 (<0.1)		1 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)
Facial pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	0	1 (<0.1)		1 (<0.1)
Injection site haematoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site haemorrhage	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site mass	0	1 (<0.1)		1 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Tenderness	0	1 (<0.1)		1 (<0.1)
Vaccination site erythema	0	1 (<0.1)		1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Crying	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
General disorders and administration site conditions (Cont.)				
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site warmth	1 (<0.1)	0		1 (<0.1)
Oedema peripheral	1 (<0.1)	0		1 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)
Investigations	20 (0.6)	22 (0.7)		42 (0.7)
Blood pressure increased	9 (0.3)	6 (0.2)	0.66 (0.25, 1.79)	15 (0.2)
Blood pressure systolic increased	1 (<0.1)	4 (0.1)		5 (<0.1)
Blood cholesterol increased	0	3 (<0.1)		3 (<0.1)
Heart rate increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic abnormal	0	1 (<0.1)		1 (<0.1)
Blood testosterone decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Weight decreased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Investigations (Cont.)				
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	82 (2.6)	53 (1.7)		135 (2.2)
Contusion	9 (0.3)	4 (0.1)	0.44 (0.14, 1.35)	13 (0.2)
Limb injury	0	4 (0.1)		4 (<0.1)
Skin laceration	9 (0.3)	4 (0.1)	0.44 (0.14, 1.35)	13 (0.2)
Joint injury	0	3 (<0.1)		3 (<0.1)
Ligament sprain	6 (0.2)	3 (<0.1)		9 (0.1)
Muscle strain	6 (0.2)	3 (<0.1)		9 (0.1)
Procedural pain	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.2)
Animal bite	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arthropod bite	8 (0.3)	2 (<0.1)	0.25 (0.06, 1.03)	10 (0.2)
Concussion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Fall	6 (0.2)	2 (<0.1)		8 (0.1)
Foot fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post-traumatic pain	4 (0.1)	2 (<0.1)		6 (<0.1)
Road traffic accident	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin abrasion	4 (0.1)	2 (<0.1)		6 (<0.1)
Thermal burn	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arthropod sting	2 (<0.1)	1 (<0.1)		3 (<0.1)
Back injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Hand fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Ligament injury	0	1 (<0.1)		1 (<0.1)
Ligament rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural swelling	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ankle fracture	2 (<0.1)	0		2 (<0.1)
Bone contusion	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=3108) n (%)	mRNA-1273 (N=3122) n (%)	Rate Ratio (95% CI)	Total (N=6230) n (%)
Injury, poisoning and procedural complications (Cont.)				
Burns first degree	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	1 (<0.1)	0		1 (<0.1)
Meniscus injury	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Stress fracture	2 (<0.1)	0		2 (<0.1)
Tooth injury	2 (<0.1)	0		2 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Wrist fracture	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3295 (27.6)	3679 (30.9)		6974 (29.3)
Number of Unsolicited Adverse Events	6323	7232		13555
Infections and infestations	711 (6.0)	587 (4.9)		1298 (5.4)
Urinary tract infection	92 (0.8)	70 (0.6)	0.76 (0.56, 1.04)	162 (0.7)
Upper respiratory tract infection	81 (0.7)	62 (0.5)	0.77 (0.55, 1.06)	143 (0.6)
Sinusitis	35 (0.3)	53 (0.4)	1.51 (0.99, 2.31)	88 (0.4)
Viral infection	33 (0.3)	25 (0.2)	0.76 (0.45, 1.27)	58 (0.2)
Rhinovirus infection	19 (0.2)	24 (0.2)	1.26 (0.70, 2.28)	43 (0.2)
Suspected COVID-19	27 (0.2)	24 (0.2)	0.89 (0.52, 1.53)	51 (0.2)
Tooth infection	14 (0.1)	20 (0.2)	1.43 (0.73, 2.79)	34 (0.1)
Tooth abscess	26 (0.2)	17 (0.1)	0.65 (0.36, 1.19)	43 (0.2)
Gastroenteritis	10 (<0.1)	16 (0.1)	1.60 (0.74, 3.46)	26 (0.1)
Herpes zoster	12 (0.1)	15 (0.1)	1.25 (0.60, 2.62)	27 (0.1)
Ear infection	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.30)	22 (<0.1)
COVID-19	113 (0.9)	11 (<0.1)	0.10 (0.05, 0.18)	124 (0.5)
Cellulitis	14 (0.1)	11 (<0.1)	0.79 (0.36, 1.70)	25 (0.1)
Pharyngitis	16 (0.1)	11 (<0.1)	0.69 (0.32, 1.45)	27 (0.1)
Pharyngitis streptococcal	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (0.1)
Hordeolum	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Oral herpes	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Infections and infestations (Cont.)				
Conjunctivitis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Localised infection	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Viral upper respiratory tract infection	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Diverticulitis	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Herpes simplex	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Paronychia	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Acute sinusitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Bronchitis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Gingivitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Otitis externa	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Otitis media	5 (<0.1)	6 (<0.1)		11 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vulvovaginal mycotic infection	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Fungal infection	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Nasopharyngitis	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Onychomycosis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Pneumonia	11 (<0.1)	5 (<0.1)	0.45 (0.17, 1.25)	16 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	4 (<0.1)		6 (<0.1)
Bacterial vaginosis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Folliculitis	5 (<0.1)	4 (<0.1)		9 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Infections and infestations (Cont.)				
Laryngitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Skin infection	3 (<0.1)	4 (<0.1)		7 (<0.1)
Staphylococcal infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Subcutaneous abscess	1 (<0.1)	4 (<0.1)		5 (<0.1)
Abscess limb	0	3 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	3 (<0.1)		3 (<0.1)
Cystitis	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Gastroenteritis viral	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Enterovirus infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Epididymitis	0	2 (<0.1)		2 (<0.1)
Furuncle	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Helicobacter infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media acute	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Infections and infestations (Cont.)				
Soft tissue infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Staphylococcal skin infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea pedis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tonsillitis	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Viral pharyngitis	0	2 (<0.1)		2 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Candida infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Eye infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Infections and infestations (Cont.)				
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection viral	4 (<0.1)	1 (<0.1)		5 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Tinea cruris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral rhinitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Wound infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Infections and infestations (Cont.)				
Body tinea	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0		2 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Fungal skin infection	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Genital herpes	2 (<0.1)	0		2 (<0.1)
Genital herpes simplex	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Infections and infestations (Cont.)				
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Postoperative wound infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Rhinitis	2 (<0.1)	0		2 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	2 (<0.1)	0		2 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	54 (0.5)	53 (0.4)		107 (0.4)
Basal cell carcinoma	16 (0.1)	9 (<0.1)	0.56 (0.25, 1.25)	25 (0.1)
Squamous cell carcinoma	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Uterine leiomyoma	0	3 (<0.1)		3 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Benign neoplasm of skin	2 (<0.1)	2 (<0.1)		4 (<0.1)
Lipoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)		5 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)		5 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Blood and lymphatic system disorders	105 (0.9)	225 (1.9)		330 (1.4)
Lymphadenopathy	88 (0.7)	202 (1.7)	2.30 (1.79, 2.94)	290 (1.2)
Anaemia	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Lymph node pain	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Iron deficiency anaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lymphadenitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	47 (0.4)	35 (0.3)		82 (0.3)
Seasonal allergy	35 (0.3)	27 (0.2)	0.77 (0.47, 1.27)	62 (0.3)
Hypersensitivity	3 (<0.1)	3 (<0.1)		6 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	4 (<0.1)	1 (<0.1)		5 (<0.1)
Food allergy	0	1 (<0.1)		1 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Immune system disorders (Cont.)				
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	16 (0.1)	12 (0.1)		28 (0.1)
Hypothyroidism	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypogonadism	0	1 (<0.1)		1 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	81 (0.7)	96 (0.8)		177 (0.7)
Hyperlipidaemia	15 (0.1)	18 (0.2)	1.20 (0.61, 2.35)	33 (0.1)
Type 2 diabetes mellitus	8 (<0.1)	17 (0.1)	2.12 (0.94, 4.81)	25 (0.1)
Hypercholesterolaemia	12 (0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Decreased appetite	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)
Dehydration	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)
Vitamin D deficiency	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Gout	6 (<0.1)	5 (<0.1)		11 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Metabolism and nutrition disorders (Cont.)				
Glucose tolerance impaired	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hyperglycaemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abnormal loss of weight	0	2 (<0.1)		2 (<0.1)
Diabetes mellitus	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hypertriglyceridaemia	0	2 (<0.1)		2 (<0.1)
Hypoglycaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hyponatraemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Electrolyte imbalance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypokalaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Metabolism and nutrition disorders (Cont.)				
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Obesity	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	88 (0.7)	129 (1.1)		217 (0.9)
Anxiety	28 (0.2)	43 (0.4)	1.54 (0.96, 2.46)	71 (0.3)
Depression	19 (0.2)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.2)
Insomnia	18 (0.2)	25 (0.2)	1.39 (0.76, 2.52)	43 (0.2)
Attention deficit hyperactivity disorder	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)
Abnormal dreams	2 (<0.1)	4 (<0.1)		6 (<0.1)
Nightmare	0	3 (<0.1)		3 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bipolar disorder	2 (<0.1)	2 (<0.1)		4 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Panic attack	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Psychiatric disorders (Cont.)				
Suicidal ideation	0	2 (<0.1)		2 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Nervous system disorders	620 (5.2)	752 (6.3)		1372 (5.8)
Headache	488 (4.1)	552 (4.6)	1.13 (1.00, 1.27)	1040 (4.4)
Dizziness	35 (0.3)	54 (0.5)	1.54 (1.01, 2.35)	89 (0.4)
Paraesthesia	16 (0.1)	28 (0.2)	1.75 (0.96, 3.20)	44 (0.2)
Sinus headache	4 (<0.1)	17 (0.1)	4.25 (1.50, 12.04)	21 (<0.1)
Ageusia	4 (<0.1)	11 (<0.1)	2.75 (0.93, 8.17)	15 (<0.1)
Migraine	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (0.1)
Syncope	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Cervical radiculopathy	0	8 (<0.1)		8 (<0.1)
Dysgeusia	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Hypoaesthesia	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Sciatica	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Anosmia	6 (<0.1)	6 (<0.1)		12 (<0.1)
Disturbance in attention	1 (<0.1)	4 (<0.1)		5 (<0.1)
Hyperaesthesia	0	4 (<0.1)		4 (<0.1)
Tension headache	4 (<0.1)	4 (<0.1)		8 (<0.1)
Burning sensation	0	3 (<0.1)		3 (<0.1)
Cerebrovascular accident	0	3 (<0.1)		3 (<0.1)
Nerve compression	3 (<0.1)	3 (<0.1)		6 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Amnesia	0	2 (<0.1)		2 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	2 (<0.1)		6 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Nervous system disorders (Cont.)				
Memory impairment	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Parosmia	0	2 (<0.1)		2 (<0.1)
Post-traumatic headache	1 (<0.1)	2 (<0.1)		3 (<0.1)
Presyncope	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)
Seizure	0	2 (<0.1)		2 (<0.1)
Taste disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Nervous system disorders (Cont.)				
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Somnolence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Nervous system disorders (Cont.)				
Dysaesthesia	2 (<0.1)	0		2 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Eye disorders	56 (0.5)	55 (0.5)		111 (0.5)
Eye pruritus	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Eye irritation	1 (<0.1)	5 (<0.1)		6 (<0.1)
Dry eye	6 (<0.1)	3 (<0.1)		9 (<0.1)
Eye pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Glaucoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Vision blurred	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blepharitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Eye inflammation	0	2 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Eye disorders (Cont.)				
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular hyperaemia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Retinal detachment	2 (<0.1)	2 (<0.1)		4 (<0.1)
Vitreous floaters	1 (<0.1)	2 (<0.1)		3 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cataract	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Eye disorders (Cont.)				
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Ear and labyrinth disorders	63 (0.5)	62 (0.5)		125 (0.5)
Vertigo	14 (0.1)	19 (0.2)	1.36 (0.69, 2.67)	33 (0.1)
Ear pain	13 (0.1)	11 (<0.1)	0.85 (0.39, 1.85)	24 (0.1)
Tinnitus	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Vertigo positional	0	6 (<0.1)		6 (<0.1)
Cerumen impaction	2 (<0.1)	4 (<0.1)		6 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ear canal erythema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ear discomfort	6 (<0.1)	2 (<0.1)		8 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Ear congestion	4 (<0.1)	1 (<0.1)		5 (<0.1)
Middle ear effusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Otorrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	0		4 (<0.1)
Cardiac disorders	58 (0.5)	68 (0.6)		126 (0.5)
Tachycardia	7 (<0.1)	12 (0.1)	1.71 (0.70, 4.22)	19 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Cardiac disorders (Cont.)				
Atrial fibrillation	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.53)	21 (<0.1)
Bradycardia	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.53)	21 (<0.1)
Palpitations	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Angina pectoris	3 (<0.1)	4 (<0.1)		7 (<0.1)
Arrhythmia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cardiac failure congestive	2 (<0.1)	4 (<0.1)		6 (<0.1)
Coronary artery disease	4 (<0.1)	3 (<0.1)		7 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus tachycardia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Atrial flutter	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cardiac flutter	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Cardiac disorders (Cont.)				
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	160 (1.3)	154 (1.3)		314 (1.3)
Hypertension	125 (1.0)	123 (1.0)	0.98 (0.77, 1.26)	248 (1.0)
Hot flush	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Flushing	5 (<0.1)	4 (<0.1)		9 (<0.1)
Haematoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Systolic hypertension	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Orthostatic hypotension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	2 (<0.1)	0		2 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Vascular disorders (Cont.)				
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	478 (4.0)	438 (3.7)		916 (3.8)
Cough	124 (1.0)	129 (1.1)	1.04 (0.81, 1.33)	253 (1.1)
Nasal congestion	116 (1.0)	114 (1.0)	0.98 (0.76, 1.27)	230 (1.0)
Oropharyngeal pain	166 (1.4)	110 (0.9)	0.66 (0.52, 0.84)	276 (1.2)
Rhinorrhoea	100 (0.8)	96 (0.8)	0.96 (0.73, 1.27)	196 (0.8)
Dyspnoea	28 (0.2)	35 (0.3)	1.25 (0.76, 2.04)	63 (0.3)
Tachypnoea	27 (0.2)	21 (0.2)	0.78 (0.44, 1.36)	48 (0.2)
Asthma	16 (0.1)	14 (0.1)	0.87 (0.43, 1.77)	30 (0.1)
Throat irritation	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Epistaxis	8 (<0.1)	12 (0.1)	1.50 (0.63, 3.57)	20 (<0.1)
Sinus congestion	19 (0.2)	11 (<0.1)	0.58 (0.28, 1.20)	30 (0.1)
Respiratory tract congestion	3 (<0.1)	10 (<0.1)	3.33 (0.99, 11.22)	13 (<0.1)
Sneezing	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Upper-airway cough syndrome	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Chronic obstructive pulmonary disease	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinitis allergic	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Dysphonia	5 (<0.1)	5 (<0.1)		10 (<0.1)
Pharyngeal erythema	1 (<0.1)	4 (<0.1)		5 (<0.1)
Dry throat	1 (<0.1)	3 (<0.1)		4 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	3 (<0.1)		6 (<0.1)
Sinus pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Wheezing	3 (<0.1)	3 (<0.1)		6 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bronchiectasis	0	2 (<0.1)		2 (<0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Paranasal sinus hypersecretion	0	2 (<0.1)		2 (<0.1)
Pleural effusion	4 (<0.1)	2 (<0.1)		6 (<0.1)
Pleurisy	0	2 (<0.1)		2 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)		5 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Productive cough	4 (<0.1)	1 (<0.1)		5 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	0		1 (<0.1)
Painful respiration	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Tonsillolith	2 (<0.1)	0		2 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	408 (3.4)	448 (3.8)		856 (3.6)
Diarrhoea	141 (1.2)	144 (1.2)	1.02 (0.81, 1.29)	285 (1.2)
Nausea	120 (1.0)	120 (1.0)	1.00 (0.78, 1.29)	240 (1.0)
Vomiting	33 (0.3)	51 (0.4)	1.55 (1.00, 2.38)	84 (0.4)
Gastrooesophageal reflux disease	24 (0.2)	31 (0.3)	1.29 (0.76, 2.19)	55 (0.2)
Toothache	18 (0.2)	27 (0.2)	1.50 (0.83, 2.70)	45 (0.2)
Abdominal pain	14 (0.1)	18 (0.2)	1.29 (0.65, 2.55)	32 (0.1)
Dental caries	9 (<0.1)	14 (0.1)	1.56 (0.69, 3.51)	23 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Gastrointestinal disorders (Cont.)				
Constipation	14 (0.1)	13 (0.1)	0.93 (0.44, 1.94)	27 (0.1)
Abdominal pain upper	12 (0.1)	12 (0.1)	1.00 (0.46, 2.18)	24 (0.1)
Food poisoning	2 (<0.1)	10 (<0.1)	5.00 (1.23, 20.29)	12 (<0.1)
Dyspepsia	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Abdominal discomfort	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Abdominal pain lower	6 (<0.1)	6 (<0.1)		12 (<0.1)
Haemorrhoids	2 (<0.1)	5 (<0.1)		7 (<0.1)
Gastric ulcer	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hiatus hernia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Inguinal hernia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Colitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Umbilical hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dry mouth	2 (<0.1)	2 (<0.1)		4 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastrointestinal disorder	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	2 (<0.1)		2 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Large intestine polyp	5 (<0.1)	2 (<0.1)		7 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Gastrointestinal disorders (Cont.)				
Lip swelling	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)
Paraesthesia oral	4 (<0.1)	2 (<0.1)		6 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Abdominal distension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Aphthous ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Haematochezia	0	1 (<0.1)		1 (<0.1)
Impaired gastric emptying	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Gastrointestinal disorders (Cont.)				
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small intestinal obstruction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discolouration	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Tooth impacted	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Gastrointestinal disorders (Cont.)				
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastritis	4 (<0.1)	0		4 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gingival pain	3 (<0.1)	0		3 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	5 (<0.1)	0		5 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	4 (<0.1)	9 (<0.1)		13 (<0.1)
Cholelithiasis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Hepatic steatosis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Hepatobiliary disorders (Cont.)				
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	182 (1.5)	223 (1.9)		405 (1.7)
Urticaria	25 (0.2)	29 (0.2)	1.16 (0.68, 1.97)	54 (0.2)
Rash	22 (0.2)	25 (0.2)	1.14 (0.65, 2.00)	47 (0.2)
Dermatitis contact	29 (0.2)	19 (0.2)	0.66 (0.37, 1.16)	48 (0.2)
Pruritus	16 (0.1)	14 (0.1)	0.87 (0.43, 1.77)	30 (0.1)
Erythema	4 (<0.1)	12 (0.1)	3.00 (1.02, 8.82)	16 (<0.1)
Night sweats	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)
Acne	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Dermatitis	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Hyperhidrosis	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Alopecia	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Rash macular	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Rash papular	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Actinic keratosis	2 (<0.1)	6 (<0.1)		8 (<0.1)
Rash maculo-papular	2 (<0.1)	6 (<0.1)		8 (<0.1)
Dermatitis atopic	3 (<0.1)	5 (<0.1)		8 (<0.1)
Eczema	3 (<0.1)	5 (<0.1)		8 (<0.1)
Rash pruritic	3 (<0.1)	5 (<0.1)		8 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Psoriasis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Rosacea	1 (<0.1)	4 (<0.1)		5 (<0.1)
Dry skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Ecchymosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rash erythematous	3 (<0.1)	3 (<0.1)		6 (<0.1)
Angioedema	3 (<0.1)	2 (<0.1)		5 (<0.1)
Blister	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hidradenitis	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Urticaria papular	5 (<0.1)	2 (<0.1)		7 (<0.1)
Acne cystic	0	1 (<0.1)		1 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermal cyst	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Lichen planus	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Papule	1 (<0.1)	1 (<0.1)		2 (<0.1)
Petechiae	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin ulcer	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Scab	1 (<0.1)	0		1 (<0.1)
Skin burning sensation	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	3 (<0.1)	0		3 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	755 (6.3)	770 (6.5)		1525 (6.4)
Arthralgia	284 (2.4)	301 (2.5)	1.06 (0.90, 1.24)	585 (2.5)
Myalgia	284 (2.4)	284 (2.4)	1.00 (0.85, 1.18)	568 (2.4)
Back pain	100 (0.8)	80 (0.7)	0.80 (0.60, 1.07)	180 (0.8)
Pain in extremity	55 (0.5)	45 (0.4)	0.82 (0.55, 1.21)	100 (0.4)
Musculoskeletal pain	23 (0.2)	39 (0.3)	1.70 (1.02, 2.82)	62 (0.3)
Neck pain	25 (0.2)	36 (0.3)	1.44 (0.87, 2.38)	61 (0.3)
Muscle spasms	24 (0.2)	26 (0.2)	1.08 (0.63, 1.87)	50 (0.2)
Osteoarthritis	23 (0.2)	19 (0.2)	0.83 (0.45, 1.50)	42 (0.2)
Musculoskeletal chest pain	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Musculoskeletal stiffness	11 (<0.1)	12 (0.1)	1.09 (0.49, 2.42)	23 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rotator cuff syndrome	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.32)	19 (<0.1)
Tendonitis	13 (0.1)	10 (<0.1)	0.77 (0.34, 1.72)	23 (<0.1)
Bursitis	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Arthritis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Joint swelling	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Trigger finger	3 (<0.1)	6 (<0.1)		9 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	5 (<0.1)		8 (<0.1)
Joint range of motion decreased	0	5 (<0.1)		5 (<0.1)
Groin pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Muscle tightness	1 (<0.1)	4 (<0.1)		5 (<0.1)
Muscular weakness	2 (<0.1)	4 (<0.1)		6 (<0.1)
Spinal stenosis	0	4 (<0.1)		4 (<0.1)
Bone pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Costochondritis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Fibromyalgia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Limb discomfort	2 (<0.1)	3 (<0.1)		5 (<0.1)
Osteoporosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Pain in jaw	4 (<0.1)	3 (<0.1)		7 (<0.1)
Spinal pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Axillary mass	2 (<0.1)	2 (<0.1)		4 (<0.1)
Muscle twitching	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Plantar fasciitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Spinal osteoarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Flank pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Joint stiffness	3 (<0.1)	1 (<0.1)		4 (<0.1)
Limb mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle fatigue	0	1 (<0.1)		1 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Temporomandibular joint syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	3 (<0.1)	0		3 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Torticollis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	34 (0.3)	37 (0.3)		71 (0.3)
Nephrolithiasis	13 (0.1)	11 (<0.1)	0.85 (0.39, 1.85)	24 (0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Renal and urinary disorders (Cont.)				
Haematuria	4 (<0.1)	3 (<0.1)		7 (<0.1)
Chronic kidney disease	0	2 (<0.1)		2 (<0.1)
Dysuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Polyuria	0	2 (<0.1)		2 (<0.1)
Urinary incontinence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary retention	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute kidney injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chromaturia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Hypertonic bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Renal cyst	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Renal and urinary disorders (Cont.)				
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	45 (0.4)	52 (0.4)		97 (0.4)
Benign prostatic hyperplasia	6 (<0.1)	5 (<0.1)		11 (<0.1)
Dysmenorrhoea	5 (<0.1)	5 (<0.1)		10 (<0.1)
Erectile dysfunction	1 (<0.1)	4 (<0.1)		5 (<0.1)
Pelvic pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Menopausal symptoms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Menorrhagia	0	2 (<0.1)		2 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	0	2 (<0.1)		2 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Reproductive system and breast disorders (Cont.)				
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatitis	6 (<0.1)	1 (<0.1)		7 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Reproductive system and breast disorders (Cont.)				
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	809 (6.8)	1227 (10.3)		2036 (8.5)
Fatigue	500 (4.2)	573 (4.8)	1.15 (1.02, 1.29)	1073 (4.5)
Injection site pain	88 (0.7)	203 (1.7)	2.31 (1.80, 2.96)	291 (1.2)
Injection site erythema	35 (0.3)	126 (1.1)	3.60 (2.48, 5.22)	161 (0.7)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
General disorders and administration site conditions (Cont.)				
Chills	84 (0.7)	96 (0.8)	1.14 (0.85, 1.53)	180 (0.8)
Injection site swelling	24 (0.2)	94 (0.8)	3.92 (2.51, 6.10)	118 (0.5)
Pyrexia	51 (0.4)	90 (0.8)	1.76 (1.25, 2.48)	141 (0.6)
Injection site pruritus	10 (<0.1)	64 (0.5)	6.40 (3.33, 12.31)	74 (0.3)
Pain	43 (0.4)	54 (0.5)	1.26 (0.84, 1.87)	97 (0.4)
Injection site lymphadenopathy	8 (<0.1)	41 (0.3)	5.12 (2.44, 10.74)	49 (0.2)
Injection site induration	16 (0.1)	36 (0.3)	2.25 (1.26, 4.02)	52 (0.2)
Injection site macule	4 (<0.1)	29 (0.2)	7.25 (2.66, 19.76)	33 (0.1)
Injection site urticaria	0	29 (0.2)		29 (0.1)
Axillary pain	8 (<0.1)	21 (0.2)	2.62 (1.19, 5.80)	29 (0.1)
Injection site rash	1 (<0.1)	18 (0.2)	18.00 (3.06, 105.91)	19 (<0.1)
Injection site bruising	16 (0.1)	11 (<0.1)	0.69 (0.32, 1.45)	27 (0.1)
Malaise	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.63)	17 (<0.1)
Chest discomfort	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Chest pain	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)
Injection site papule	1 (<0.1)	8 (<0.1)	8.00 (1.30, 49.26)	9 (<0.1)
Injection site warmth	0	7 (<0.1)		7 (<0.1)
Peripheral swelling	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Oedema peripheral	6 (<0.1)	6 (<0.1)		12 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Feeling abnormal	3 (<0.1)	5 (<0.1)		8 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
General disorders and administration site conditions (Cont.)				
Injection site haematoma	1 (<0.1)	5 (<0.1)		6 (<0.1)
Injection site haemorrhage	5 (<0.1)	5 (<0.1)		10 (<0.1)
Non-cardiac chest pain	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Reactogenicity event	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site joint pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site paraesthesia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site mass	1 (<0.1)	3 (<0.1)		4 (<0.1)
Swelling face	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hangover	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenderness	0	2 (<0.1)		2 (<0.1)
Vaccination site erythema	0	2 (<0.1)		2 (<0.1)
Vaccination site pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Asthenia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
General disorders and administration site conditions (Cont.)				
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Facial pain	4 (<0.1)	0		4 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
General disorders and administration site conditions (Cont.)				
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discolouration	2 (<0.1)	0		2 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
General disorders and administration site conditions (Cont.)				
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)
Investigations	60 (0.5)	85 (0.7)		145 (0.6)
Blood pressure increased	18 (0.2)	19 (0.2)	1.06 (0.56, 1.99)	37 (0.2)
Blood pressure systolic increased	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.32)	19 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	9 (<0.1)	9.00 (1.47, 54.93)	10 (<0.1)
Body temperature increased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Hepatic enzyme increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Transaminases increased	0	4 (<0.1)		4 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Blood glucose increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood testosterone decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood triglycerides increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Heart rate increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood cholesterol increased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Investigations (Cont.)				
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Weight decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Investigations (Cont.)				
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	313 (2.6)	272 (2.3)		585 (2.5)
Muscle strain	29 (0.2)	35 (0.3)	1.21 (0.74, 1.96)	64 (0.3)
Ligament sprain	23 (0.2)	25 (0.2)	1.09 (0.62, 1.90)	48 (0.2)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Injury, poisoning and procedural complications (Cont.)				
Arthropod bite	23 (0.2)	22 (0.2)	0.96 (0.54, 1.70)	45 (0.2)
Fall	21 (0.2)	19 (0.2)	0.90 (0.49, 1.67)	40 (0.2)
Skin laceration	22 (0.2)	19 (0.2)	0.86 (0.47, 1.58)	41 (0.2)
Contusion	20 (0.2)	16 (0.1)	0.80 (0.42, 1.53)	36 (0.2)
Tooth fracture	15 (0.1)	16 (0.1)	1.07 (0.53, 2.13)	31 (0.1)
Procedural pain	24 (0.2)	15 (0.1)	0.62 (0.33, 1.18)	39 (0.2)
Road traffic accident	5 (<0.1)	11 (<0.1)	2.20 (0.80, 6.06)	16 (<0.1)
Foot fracture	12 (0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Arthropod sting	15 (0.1)	9 (<0.1)	0.60 (0.27, 1.34)	24 (0.1)
Skin abrasion	18 (0.2)	9 (<0.1)	0.50 (0.23, 1.09)	27 (0.1)
Limb injury	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Meniscus injury	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Rib fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Animal bite	9 (<0.1)	4 (<0.1)	0.44 (0.15, 1.36)	13 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Joint injury	6 (<0.1)	4 (<0.1)		10 (<0.1)
Post-traumatic pain	3 (<0.1)	4 (<0.1)		7 (<0.1)
Wrist fracture	3 (<0.1)	4 (<0.1)		7 (<0.1)
Bone contusion	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hand fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Injury, poisoning and procedural complications (Cont.)				
Head injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Tendon rupture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Upper limb fracture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Ankle fracture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Concussion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Epicondylitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Muscle rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Injury, poisoning and procedural complications (Cont.)				
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ligament injury	0	1 (<0.1)		1 (<0.1)
Ligament rupture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thermal burn	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tooth injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wound	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Back injury	2 (<0.1)	0		2 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Lip injury	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Injury, poisoning and procedural complications (Cont.)				
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Post procedural swelling	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.5.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Ethnicity up to 28 Days After Any Injection
Safety Set

Ethnicity Group: Not Hispanic or Latino

System Organ Class Preferred Term	Placebo (N=11918) n (%)	mRNA-1273 (N=11920) n (%)	Rate Ratio (95% CI)	Total (N=23838) n (%)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	5 (<0.1)		8 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1073 (31.0)	1188 (34.5)		2261 (32.7)
Number of Unsolicited Adverse Events	2369	2493		4862
Infections and infestations	221 (6.4)	190 (5.5)		411 (6.0)
Urinary tract infection	19 (0.5)	31 (0.9)	1.64 (0.93, 2.87)	50 (0.7)
Upper respiratory tract infection	26 (0.8)	15 (0.4)	0.58 (0.31, 1.08)	41 (0.6)
Sinusitis	12 (0.3)	14 (0.4)	1.17 (0.55, 2.48)	26 (0.4)
Suspected COVID-19	9 (0.3)	11 (0.3)	1.23 (0.52, 2.88)	20 (0.3)
Herpes zoster	7 (0.2)	7 (0.2)	1.00 (0.37, 2.74)	14 (0.2)
Rhinovirus infection	4 (0.1)	6 (0.2)		10 (0.1)
Tooth abscess	8 (0.2)	6 (0.2)	0.75 (0.27, 2.07)	14 (0.2)
Tooth infection	6 (0.2)	6 (0.2)		12 (0.2)
COVID-19	35 (1.0)	5 (0.1)	0.14 (0.06, 0.35)	40 (0.6)
Ear infection	5 (0.1)	5 (0.1)		10 (0.1)
Localised infection	3 (<0.1)	5 (0.1)		8 (0.1)
Pharyngitis	3 (<0.1)	5 (0.1)		8 (0.1)
Viral infection	9 (0.3)	5 (0.1)	0.56 (0.20, 1.58)	14 (0.2)
Cellulitis	5 (0.1)	4 (0.1)		9 (0.1)
Conjunctivitis	0	4 (0.1)		4 (<0.1)
Gastroenteritis	6 (0.2)	4 (0.1)		10 (0.1)
Gingivitis	0	4 (0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Infections and infestations (Cont.)				
Otitis externa	2 (<0.1)	4 (0.1)		6 (<0.1)
Diverticulitis	5 (0.1)	3 (<0.1)		8 (0.1)
Kidney infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Otitis media	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pharyngitis streptococcal	5 (0.1)	3 (<0.1)		8 (0.1)
Abscess limb	0	2 (<0.1)		2 (<0.1)
Acute sinusitis	0	2 (<0.1)		2 (<0.1)
Bronchitis	5 (0.1)	2 (<0.1)		7 (0.1)
Helicobacter infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Herpes simplex	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hordeolum	0	2 (<0.1)		2 (<0.1)
Laryngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory tract infection viral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Viral upper respiratory tract infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Vulvovaginal candidiasis	0	2 (<0.1)		2 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacterial vaginosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Candida infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Infections and infestations (Cont.)				
Coronavirus infection	0	1 (<0.1)		1 (<0.1)
Cystitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Folliculitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fungal infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Nasopharyngitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral candidiasis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oral herpes	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	0	1 (<0.1)		1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Soft tissue infection	0	1 (<0.1)		1 (<0.1)
Staphylococcal skin infection	0	1 (<0.1)		1 (<0.1)
Subcutaneous abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Infections and infestations (Cont.)				
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral rhinitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginal mycotic infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)
Chronic sinusitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Enterovirus infection	1 (<0.1)	0		1 (<0.1)
Epididymitis	1 (<0.1)	0		1 (<0.1)
Eye infection	1 (<0.1)	0		1 (<0.1)
Fungal skin infection	1 (<0.1)	0		1 (<0.1)
Gastroenteritis viral	3 (<0.1)	0		3 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Infections and infestations (Cont.)				
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Onychomycosis	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Paronychia	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia	8 (0.2)	0		8 (0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Postoperative wound infection	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin infection	3 (<0.1)	0		3 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea cruris	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	22 (0.6)	14 (0.4)		36 (0.5)
Basal cell carcinoma	6 (0.2)	2 (<0.1)		8 (0.1)
Skin cancer	0	2 (<0.1)		2 (<0.1)
Benign breast neoplasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of skin	1 (<0.1)	1 (<0.1)		2 (<0.1)

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up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	2 (<0.1)	0		2 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	0		2 (<0.1)
Blood and lymphatic system disorders	33 (1.0)	70 (2.0)		103 (1.5)
Lymphadenopathy	26 (0.8)	64 (1.9)	2.47 (1.57, 3.87)	90 (1.3)

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Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Blood and lymphatic system disorders (Cont.)				
Anaemia	5 (0.1)	4 (0.1)		9 (0.1)
Lymph node pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	16 (0.5)	10 (0.3)		26 (0.4)
Seasonal allergy	13 (0.4)	7 (0.2)	0.54 (0.22, 1.31)	20 (0.3)
Hypersensitivity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	4 (0.1)	2 (<0.1)		6 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypothyroidism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	49 (1.4)	50 (1.5)		99 (1.4)
Type 2 diabetes mellitus	6 (0.2)	15 (0.4)	2.51 (1.01, 6.25)	21 (0.3)

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Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Metabolism and nutrition disorders (Cont.)				
Hyperlipidaemia	5 (0.1)	6 (0.2)		11 (0.2)
Dehydration	1 (<0.1)	5 (0.1)		6 (<0.1)
Diabetes mellitus	5 (0.1)	4 (0.1)		9 (0.1)
Vitamin D deficiency	3 (<0.1)	4 (0.1)		7 (0.1)
Hypercholesterolaemia	5 (0.1)	3 (<0.1)		8 (0.1)
Abnormal loss of weight	0	2 (<0.1)		2 (<0.1)
Glucose tolerance impaired	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gout	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Decreased appetite	4 (0.1)	1 (<0.1)		5 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Vitamin B12 deficiency	0	1 (<0.1)		1 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Electrolyte imbalance	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Metabolism and nutrition disorders (Cont.)				
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypocalcaemia	2 (<0.1)	0		2 (<0.1)
Hypokalaemia	2 (<0.1)	0		2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Iron deficiency	1 (<0.1)	0		1 (<0.1)
Obesity	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	23 (0.7)	29 (0.8)		52 (0.8)
Anxiety	8 (0.2)	12 (0.3)	1.50 (0.63, 3.58)	20 (0.3)
Insomnia	4 (0.1)	6 (0.2)		10 (0.1)
Depression	7 (0.2)	4 (0.1)	0.57 (0.18, 1.83)	11 (0.2)
Attention deficit hyperactivity disorder	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Post-traumatic stress disorder	0	1 (<0.1)		1 (<0.1)
Stress	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Psychiatric disorders (Cont.)				
Agitation	1 (<0.1)	0		1 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	225 (6.5)	233 (6.8)		458 (6.6)
Headache	174 (5.0)	184 (5.3)	1.06 (0.87, 1.30)	358 (5.2)
Dizziness	14 (0.4)	16 (0.5)	1.15 (0.57, 2.31)	30 (0.4)
Paraesthesia	3 (<0.1)	6 (0.2)		9 (0.1)
Ageusia	2 (<0.1)	5 (0.1)		7 (0.1)
Migraine	5 (0.1)	4 (0.1)		9 (0.1)
Hypoaesthesia	4 (0.1)	3 (<0.1)		7 (0.1)
Sinus headache	4 (0.1)	3 (<0.1)		7 (0.1)
Anosmia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Carpal tunnel syndrome	3 (<0.1)	2 (<0.1)		5 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Mental impairment	0	2 (<0.1)		2 (<0.1)
Sciatica	2 (<0.1)	2 (<0.1)		4 (<0.1)
Burning sensation	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)		1 (<0.1)
Dysgeusia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)

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Nervous system disorders (Cont.)				
Hyposmia	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Nerve compression	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neuralgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Syncope	2 (<0.1)	1 (<0.1)		3 (<0.1)
Taste disorder	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Amnesia	1 (<0.1)	0		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Balance disorder	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	2 (<0.1)	0		2 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Facial paralysis	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)

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Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Nervous system disorders (Cont.)				
Lumbar radiculopathy	1 (<0.1)	0		1 (<0.1)
Parosmia	1 (<0.1)	0		1 (<0.1)
Presyncope	3 (<0.1)	0		3 (<0.1)
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)
Somnolence	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tension headache	2 (<0.1)	0		2 (<0.1)
Tremor	1 (<0.1)	0		1 (<0.1)
Eye disorders	14 (0.4)	15 (0.4)		29 (0.4)
Eye pruritus	3 (<0.1)	2 (<0.1)		5 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling of eyelid	0	2 (<0.1)		2 (<0.1)
Blepharitis	0	1 (<0.1)		1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye inflammation	0	1 (<0.1)		1 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Eye pain	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vision blurred	0	1 (<0.1)		1 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Eye disorders (Cont.)				
Blindness	1 (<0.1)	0		1 (<0.1)
Cataract	1 (<0.1)	0		1 (<0.1)
Lacrimation increased	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	3 (<0.1)	0		3 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)
Vitreous floaters	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	17 (0.5)	17 (0.5)		34 (0.5)
Vertigo	4 (0.1)	9 (0.3)	2.26 (0.74, 6.90)	13 (0.2)
Ear pain	4 (0.1)	4 (0.1)		8 (0.1)
Tinnitus	4 (0.1)	2 (<0.1)		6 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear canal erythema	1 (<0.1)	0		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	23 (0.7)	28 (0.8)		51 (0.7)
Atrial fibrillation	5 (0.1)	5 (0.1)		10 (0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Cardiac disorders (Cont.)				
Tachycardia	4 (0.1)	4 (0.1)		8 (0.1)
Myocardial infarction	0	3 (<0.1)		3 (<0.1)
Sinus tachycardia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Angina pectoris	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bradycardia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)		4 (<0.1)
Palpitations	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute myocardial infarction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arrhythmia	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Vascular disorders	57 (1.6)	49 (1.4)		106 (1.5)
Hypertension	45 (1.3)	39 (1.1)	0.87 (0.57, 1.33)	84 (1.2)
Hot flush	0	3 (<0.1)		3 (<0.1)
Flushing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Hypertensive urgency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	3 (<0.1)	0		3 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Orthostatic hypotension	1 (<0.1)	0		1 (<0.1)
Systolic hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	181 (5.2)	161 (4.7)		342 (5.0)
Cough	46 (1.3)	55 (1.6)	1.20 (0.81, 1.76)	101 (1.5)
Nasal congestion	47 (1.4)	40 (1.2)	0.85 (0.56, 1.29)	87 (1.3)
Rhinorrhoea	36 (1.0)	36 (1.0)	1.00 (0.64, 1.58)	72 (1.0)
Oropharyngeal pain	49 (1.4)	28 (0.8)	0.57 (0.36, 0.91)	77 (1.1)
Dyspnoea	11 (0.3)	18 (0.5)	1.64 (0.79, 3.41)	29 (0.4)
Asthma	11 (0.3)	10 (0.3)	0.91 (0.40, 2.09)	21 (0.3)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Chronic obstructive pulmonary disease	10 (0.3)	6 (0.2)	0.60 (0.23, 1.59)	16 (0.2)
Respiratory tract congestion	2 (<0.1)	6 (0.2)		8 (0.1)
Tachypnoea	6 (0.2)	5 (0.1)		11 (0.2)
Upper-airway cough syndrome	1 (<0.1)	4 (0.1)		5 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Rhinitis allergic	8 (0.2)	3 (<0.1)	0.38 (0.11, 1.30)	11 (0.2)
Sinus congestion	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.52)	10 (0.1)
Sneezing	4 (0.1)	3 (<0.1)		7 (0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Dysphonia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dyspnoea exertional	1 (<0.1)	2 (<0.1)		3 (<0.1)
Epistaxis	4 (0.1)	2 (<0.1)		6 (<0.1)
Productive cough	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Throat irritation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute respiratory failure	0	1 (<0.1)		1 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Atelectasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry throat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Paranasal sinus hypersecretion	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	0	1 (<0.1)		1 (<0.1)
Pleural effusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Respiratory disorder	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	2 (<0.1)	0		2 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Tonsillolith	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Wheezing	2 (<0.1)	0		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Gastrointestinal disorders	140 (4.0)	168 (4.9)		308 (4.5)
Diarrhoea	58 (1.7)	53 (1.5)	0.92 (0.63, 1.32)	111 (1.6)
Nausea	38 (1.1)	48 (1.4)	1.27 (0.83, 1.93)	86 (1.2)
Vomiting	10 (0.3)	17 (0.5)	1.70 (0.80, 3.65)	27 (0.4)
Gastrooesophageal reflux disease	8 (0.2)	11 (0.3)	1.38 (0.57, 3.33)	19 (0.3)
Toothache	6 (0.2)	8 (0.2)	1.34 (0.49, 3.68)	14 (0.2)
Constipation	5 (0.1)	5 (0.1)		10 (0.1)
Abdominal pain	6 (0.2)	4 (0.1)		10 (0.1)
Colitis	1 (<0.1)	4 (0.1)		5 (<0.1)
Dental caries	2 (<0.1)	4 (0.1)		6 (<0.1)
Abdominal distension	0	3 (<0.1)		3 (<0.1)
Abdominal pain upper	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abdominal pain lower	0	2 (<0.1)		2 (<0.1)
Dry mouth	1 (<0.1)	2 (<0.1)		3 (<0.1)
Food poisoning	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastric ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Haemorrhoids	0	2 (<0.1)		2 (<0.1)
Hiatus hernia	0	2 (<0.1)		2 (<0.1)
Inguinal hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Large intestine polyp	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Gastrointestinal disorders (Cont.)				
Diverticulum intestinal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysphagia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Flatulence	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	0	1 (<0.1)		1 (<0.1)
Irritable bowel syndrome	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	0	1 (<0.1)		1 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tooth impacted	0	1 (<0.1)		1 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)

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Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Gastrointestinal disorders (Cont.)				
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Dyspepsia	2 (<0.1)	0		2 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	0		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	0		1 (<0.1)
Loose tooth	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	3 (<0.1)	0		3 (<0.1)
Paraesthesia oral	1 (<0.1)	0		1 (<0.1)
Salivary hypersecretion	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)
Stomatitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	3 (<0.1)	6 (0.2)		9 (0.1)
Cholelithiasis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Skin and subcutaneous tissue disorders	55 (1.6)	60 (1.7)		115 (1.7)
Urticaria	8 (0.2)	7 (0.2)	0.88 (0.33, 2.32)	15 (0.2)
Dermatitis contact	6 (0.2)	6 (0.2)		12 (0.2)
Pruritus	6 (0.2)	5 (0.1)		11 (0.2)
Rash	7 (0.2)	5 (0.1)	0.72 (0.24, 2.13)	12 (0.2)
Ecchymosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyperhidrosis	4 (0.1)	3 (<0.1)		7 (0.1)
Psoriasis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rash maculo-papular	0	3 (<0.1)		3 (<0.1)
Eczema	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Rash macular	0	2 (<0.1)		2 (<0.1)
Rash papular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rash pruritic	0	2 (<0.1)		2 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Acne	2 (<0.1)	1 (<0.1)		3 (<0.1)
Alopecia	0	1 (<0.1)		1 (<0.1)
Blister	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dermatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dermatitis atopic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erythema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Papule	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash erythematous	0	1 (<0.1)		1 (<0.1)
Rosacea	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Actinic keratosis	1 (<0.1)	0		1 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermal cyst	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Night sweats	2 (<0.1)	0		2 (<0.1)
Perioral dermatitis	1 (<0.1)	0		1 (<0.1)
Petechiae	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Skin mass	1 (<0.1)	0		1 (<0.1)
Urticaria papular	2 (<0.1)	0		2 (<0.1)
Musculoskeletal and connective tissue disorders	293 (8.5)	274 (7.9)		567 (8.2)
Myalgia	115 (3.3)	118 (3.4)	1.03 (0.80, 1.32)	233 (3.4)

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Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Arthralgia	129 (3.7)	116 (3.4)	0.90 (0.71, 1.15)	245 (3.5)
Back pain	27 (0.8)	24 (0.7)	0.89 (0.52, 1.53)	51 (0.7)
Pain in extremity	16 (0.5)	23 (0.7)	1.44 (0.77, 2.70)	39 (0.6)
Musculoskeletal pain	16 (0.5)	13 (0.4)	0.81 (0.40, 1.67)	29 (0.4)
Neck pain	9 (0.3)	12 (0.3)	1.34 (0.58, 3.09)	21 (0.3)
Muscle spasms	8 (0.2)	8 (0.2)	1.00 (0.39, 2.58)	16 (0.2)
Osteoarthritis	12 (0.3)	7 (0.2)	0.58 (0.24, 1.44)	19 (0.3)
Bursitis	1 (<0.1)	5 (0.1)		6 (<0.1)
Fibromyalgia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rotator cuff syndrome	5 (0.1)	3 (<0.1)		8 (0.1)
Spinal stenosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Tendonitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Arthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Costochondritis	0	2 (<0.1)		2 (<0.1)
Intervertebral disc protrusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Musculoskeletal chest pain	7 (0.2)	2 (<0.1)	0.29 (0.07, 1.21)	9 (0.1)
Pain in jaw	2 (<0.1)	2 (<0.1)		4 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)
Trigger finger	2 (<0.1)	2 (<0.1)		4 (<0.1)
Axillary mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Groin pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint range of motion decreased	0	1 (<0.1)		1 (<0.1)
Joint swelling	3 (<0.1)	1 (<0.1)		4 (<0.1)
Muscle tightness	0	1 (<0.1)		1 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal stiffness	4 (0.1)	1 (<0.1)		5 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteoporosis	0	1 (<0.1)		1 (<0.1)
Periarthritis	0	1 (<0.1)		1 (<0.1)
Plantar fasciitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rheumatoid arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal osteoarthritis	0	1 (<0.1)		1 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Exostosis	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	3 (<0.1)	0		3 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Limb discomfort	1 (<0.1)	0		1 (<0.1)
Limb mass	2 (<0.1)	0		2 (<0.1)
Muscle twitching	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	15 (0.4)	18 (0.5)		33 (0.5)
Nephrolithiasis	7 (0.2)	8 (0.2)	1.15 (0.43, 3.04)	15 (0.2)
Dysuria	0	2 (<0.1)		2 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute kidney injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic kidney disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertonic bladder	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Pollakiuria	0	1 (<0.1)		1 (<0.1)
Haematuria	1 (<0.1)	0		1 (<0.1)
Renal cyst	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Renal and urinary disorders (Cont.)				
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urinary retention	2 (<0.1)	0		2 (<0.1)
Reproductive system and breast disorders	9 (0.3)	13 (0.4)		22 (0.3)
Benign prostatic hyperplasia	0	2 (<0.1)		2 (<0.1)
Dysmenorrhoea	2 (<0.1)	2 (<0.1)		4 (<0.1)
Erectile dysfunction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic pain	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)		1 (<0.1)
Prostatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	0		2 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	0	1 (<0.1)		1 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
General disorders and administration site conditions	298 (8.6)	435 (12.6)		733 (10.6)
Fatigue	188 (5.4)	230 (6.7)	1.23 (1.02, 1.48)	418 (6.1)
Injection site pain	32 (0.9)	67 (1.9)	2.10 (1.39, 3.18)	99 (1.4)
Injection site erythema	17 (0.5)	47 (1.4)	2.77 (1.61, 4.79)	64 (0.9)
Chills	34 (1.0)	42 (1.2)	1.24 (0.79, 1.93)	76 (1.1)
Pyrexia	16 (0.5)	32 (0.9)	2.01 (1.11, 3.62)	48 (0.7)
Injection site swelling	10 (0.3)	31 (0.9)	3.11 (1.55, 6.24)	41 (0.6)
Injection site pruritus	4 (0.1)	18 (0.5)	4.51 (1.60, 12.71)	22 (0.3)
Pain	20 (0.6)	18 (0.5)	0.90 (0.48, 1.69)	38 (0.6)
Injection site induration	6 (0.2)	14 (0.4)	2.34 (0.93, 5.88)	20 (0.3)
Injection site urticaria	0	10 (0.3)		10 (0.1)
Axillary pain	1 (<0.1)	8 (0.2)	8.02 (1.30, 49.40)	9 (0.1)
Injection site macule	0	8 (0.2)		8 (0.1)
Injection site lymphadenopathy	4 (0.1)	6 (0.2)		10 (0.1)
Injection site bruising	3 (<0.1)	5 (0.1)		8 (0.1)
Chest discomfort	7 (0.2)	4 (0.1)	0.57 (0.18, 1.83)	11 (0.2)
Chest pain	1 (<0.1)	4 (0.1)		5 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Injection site haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site hypoaesthesia	0	2 (<0.1)		2 (<0.1)
Injection site mass	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site papule	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
General disorders and administration site conditions (Cont.)				
Injection site scab	0	2 (<0.1)		2 (<0.1)
Non-cardiac chest pain	6 (0.2)	2 (<0.1)		8 (0.1)
Peripheral swelling	5 (0.1)	2 (<0.1)		7 (0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Cyst	0	1 (<0.1)		1 (<0.1)
Feeling hot	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Oedema peripheral	4 (0.1)	1 (<0.1)		5 (<0.1)
Precancerous condition	0	1 (<0.1)		1 (<0.1)
Reactogenicity event	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vaccination site swelling	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
General disorders and administration site conditions (Cont.)				
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site discomfort	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site paraesthesia	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)
Investigations	23 (0.7)	26 (0.8)		49 (0.7)
Blood pressure increased	5 (0.1)	6 (0.2)		11 (0.2)
Blood pressure systolic increased	3 (<0.1)	5 (0.1)		8 (0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood triglycerides increased	0	2 (<0.1)		2 (<0.1)
Blood cholesterol increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Investigations (Cont.)				
Body temperature increased	0	1 (<0.1)		1 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)		2 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Heart rate increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Weight decreased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Injury, poisoning and procedural complications	119 (3.4)	85 (2.5)		204 (3.0)
Ligament sprain	8 (0.2)	9 (0.3)	1.13 (0.45, 2.83)	17 (0.2)
Muscle strain	14 (0.4)	9 (0.3)	0.64 (0.29, 1.45)	23 (0.3)
Procedural pain	6 (0.2)	7 (0.2)	1.17 (0.41, 3.32)	13 (0.2)
Fall	12 (0.3)	6 (0.2)	0.50 (0.20, 1.29)	18 (0.3)
Arthropod bite	14 (0.4)	5 (0.1)	0.36 (0.13, 0.95)	19 (0.3)
Contusion	7 (0.2)	5 (0.1)	0.72 (0.24, 2.13)	12 (0.2)
Road traffic accident	2 (<0.1)	5 (0.1)		7 (0.1)
Foot fracture	7 (0.2)	4 (0.1)	0.57 (0.18, 1.83)	11 (0.2)
Limb injury	1 (<0.1)	4 (0.1)		5 (<0.1)
Skin laceration	9 (0.3)	4 (0.1)	0.45 (0.15, 1.36)	13 (0.2)
Tooth fracture	8 (0.2)	4 (0.1)	0.50 (0.16, 1.56)	12 (0.2)
Joint injury	4 (0.1)	3 (<0.1)		7 (0.1)
Tendon rupture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Arthropod sting	3 (<0.1)	2 (<0.1)		5 (<0.1)
Concussion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Post-traumatic pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Animal bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Back injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Injury, poisoning and procedural complications (Cont.)				
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hand fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Heat exhaustion	0	1 (<0.1)		1 (<0.1)
Hip fracture	0	1 (<0.1)		1 (<0.1)
Ligament rupture	0	1 (<0.1)		1 (<0.1)
Rib fracture	0	1 (<0.1)		1 (<0.1)
Skin abrasion	8 (0.2)	1 (<0.1)	0.13 (0.02, 0.77)	9 (0.1)
Sunburn	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thermal burn	0	1 (<0.1)		1 (<0.1)
Tooth injury	0	1 (<0.1)		1 (<0.1)
Wrist fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Bone contusion	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Corneal abrasion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: At Risk

System Organ Class Preferred Term	Placebo (N=3457) n (%)	mRNA-1273 (N=3448) n (%)	Rate Ratio (95% CI)	Total (N=6905) n (%)
Injury, poisoning and procedural complications (Cont.)				
Lip injury	1 (<0.1)	0		1 (<0.1)
Lower limb fracture	1 (<0.1)	0		1 (<0.1)
Muscle rupture	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	2 (<0.1)	0		2 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3265 (27.9)	3564 (30.4)		6829 (29.1)
Number of Unsolicited Adverse Events	6230	7048		13278
Infections and infestations	731 (6.2)	593 (5.1)		1324 (5.6)
Upper respiratory tract infection	92 (0.8)	67 (0.6)	0.73 (0.53, 0.99)	159 (0.7)
Urinary tract infection	93 (0.8)	63 (0.5)	0.68 (0.49, 0.93)	156 (0.7)
Sinusitis	34 (0.3)	47 (0.4)	1.38 (0.89, 2.13)	81 (0.3)
Viral infection	43 (0.4)	36 (0.3)	0.83 (0.54, 1.29)	79 (0.3)
Rhinovirus infection	26 (0.2)	30 (0.3)	1.15 (0.69, 1.93)	56 (0.2)
Suspected COVID-19	26 (0.2)	23 (0.2)	0.88 (0.51, 1.53)	49 (0.2)
Tooth infection	12 (0.1)	20 (0.2)	1.66 (0.82, 3.35)	32 (0.1)
COVID-19	121 (1.0)	17 (0.1)	0.14 (0.08, 0.23)	138 (0.6)
Tooth abscess	18 (0.2)	17 (0.1)	0.94 (0.49, 1.81)	35 (0.1)
Gastroenteritis	11 (<0.1)	15 (0.1)	1.36 (0.64, 2.91)	26 (0.1)
Herpes zoster	8 (<0.1)	15 (0.1)	1.87 (0.81, 4.30)	23 (<0.1)
Pharyngitis	18 (0.2)	14 (0.1)	0.78 (0.39, 1.54)	32 (0.1)
Ear infection	5 (<0.1)	13 (0.1)	2.59 (0.96, 6.98)	18 (<0.1)
Oral herpes	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.31)	19 (<0.1)
Hordeolum	12 (0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Pharyngitis streptococcal	16 (0.1)	10 (<0.1)	0.62 (0.29, 1.35)	26 (0.1)
Conjunctivitis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Viral upper respiratory tract infection	12 (0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Cellulitis	12 (0.1)	8 (<0.1)	0.66 (0.28, 1.58)	20 (<0.1)
Fungal infection	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.22)	17 (<0.1)
Onychomycosis	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.60)	10 (<0.1)
Herpes simplex	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Paronychia	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Bronchitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Diverticulitis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Folliculitis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Otitis media	6 (<0.1)	6 (<0.1)		12 (<0.1)
Bacterial vaginosis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Gingivitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Pneumonia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Vulvovaginal mycotic infection	12 (0.1)	5 (<0.1)	0.42 (0.15, 1.13)	17 (<0.1)
Acute sinusitis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	4 (<0.1)		6 (<0.1)
Enterovirus infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Nasopharyngitis	11 (<0.1)	4 (<0.1)	0.36 (0.12, 1.08)	15 (<0.1)
Skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Staphylococcal infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Subcutaneous abscess	1 (<0.1)	4 (<0.1)		5 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)		4 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Localised infection	5 (<0.1)	3 (<0.1)		8 (<0.1)
Otitis externa	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.13)	12 (<0.1)
Staphylococcal skin infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Cystitis	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Epididymitis	0	2 (<0.1)		2 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Laryngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea pedis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tonsillitis	10 (<0.1)	2 (<0.1)	0.20 (0.05, 0.81)	12 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Coronavirus infection	0	1 (<0.1)		1 (<0.1)
Eye infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fungal skin infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)
Helicobacter infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral candidiasis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rhinitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea cruris	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Viral rhinitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0		2 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Genital herpes	2 (<0.1)	0		2 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	4 (<0.1)	0		4 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Wound infection	3 (<0.1)	0		3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	34 (0.3)	48 (0.4)		82 (0.3)
Basal cell carcinoma	10 (<0.1)	8 (<0.1)	0.80 (0.32, 1.96)	18 (<0.1)
Squamous cell carcinoma	6 (<0.1)	4 (<0.1)		10 (<0.1)
Benign neoplasm of skin	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Prostate cancer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Uterine leiomyoma	0	3 (<0.1)		3 (<0.1)
Malignant melanoma	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign breast neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin cancer	3 (<0.1)	1 (<0.1)		4 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	1 (<0.1)		3 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	115 (1.0)	222 (1.9)		337 (1.4)
Lymphadenopathy	101 (0.9)	200 (1.7)	1.97 (1.56, 2.50)	301 (1.3)

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MedDRA version 23.0.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Blood and lymphatic system disorders (Cont.)				
Lymph node pain	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Anaemia	1 (<0.1)	6 (<0.1)		7 (<0.1)
Lymphadenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Iron deficiency anaemia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	50 (0.4)	37 (0.3)		87 (0.4)
Seasonal allergy	34 (0.3)	26 (0.2)	0.76 (0.46, 1.26)	60 (0.3)
Hypersensitivity	5 (<0.1)	5 (<0.1)		10 (<0.1)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	5 (<0.1)	1 (<0.1)		6 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Endocrine disorders	13 (0.1)	10 (<0.1)		23 (<0.1)
Hypothyroidism	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.81)	17 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	64 (0.5)	78 (0.7)		142 (0.6)
Hyperlipidaemia	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Decreased appetite	5 (<0.1)	10 (<0.1)	1.99 (0.71, 5.57)	15 (<0.1)
Hypercholesterolaemia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.81)	17 (<0.1)
Vitamin D deficiency	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Type 2 diabetes mellitus	5 (<0.1)	6 (<0.1)		11 (<0.1)
Dehydration	5 (<0.1)	5 (<0.1)		10 (<0.1)
Gout	5 (<0.1)	5 (<0.1)		10 (<0.1)
Glucose tolerance impaired	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Diabetes mellitus	0	2 (<0.1)		2 (<0.1)
Hyperglycaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrolyte imbalance	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Metabolism and nutrition disorders (Cont.)				
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abnormal weight gain	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Polydipsia	1 (<0.1)	0		1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	93 (0.8)	130 (1.1)		223 (1.0)
Anxiety	30 (0.3)	40 (0.3)	1.33 (0.83, 2.12)	70 (0.3)
Depression	22 (0.2)	31 (0.3)	1.41 (0.82, 2.41)	53 (0.2)
Insomnia	20 (0.2)	26 (0.2)	1.30 (0.73, 2.30)	46 (0.2)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Psychiatric disorders (Cont.)				
Attention deficit hyperactivity disorder	6 (<0.1)	4 (<0.1)		10 (<0.1)
Panic attack	3 (<0.1)	4 (<0.1)		7 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nightmare	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Psychiatric disorders (Cont.)				
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	656 (5.6)	775 (6.6)		1431 (6.1)
Headache	513 (4.4)	560 (4.8)	1.09 (0.97, 1.22)	1073 (4.6)
Dizziness	42 (0.4)	58 (0.5)	1.38 (0.93, 2.04)	100 (0.4)
Paraesthesia	24 (0.2)	28 (0.2)	1.16 (0.68, 1.99)	52 (0.2)
Sinus headache	2 (<0.1)	17 (0.1)	8.48 (2.18, 32.97)	19 (<0.1)
Dysgeusia	5 (<0.1)	11 (<0.1)	2.19 (0.80, 6.04)	16 (<0.1)
Migraine	19 (0.2)	11 (<0.1)	0.58 (0.28, 1.19)	30 (0.1)
Syncope	12 (0.1)	11 (<0.1)	0.91 (0.41, 2.03)	23 (<0.1)
Ageusia	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.06)	18 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Hypoaesthesia	5 (<0.1)	10 (<0.1)	1.99 (0.71, 5.57)	15 (<0.1)
Sciatica	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Cervical radiculopathy	1 (<0.1)	8 (<0.1)	7.98 (1.30, 49.14)	9 (<0.1)
Tension headache	4 (<0.1)	8 (<0.1)	1.99 (0.64, 6.22)	12 (<0.1)
Anosmia	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.72)	14 (<0.1)
Presyncope	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Hyperaesthesia	0	5 (<0.1)		5 (<0.1)
Memory impairment	0	4 (<0.1)		4 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Amnesia	0	2 (<0.1)		2 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Facial paralysis	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Nerve compression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Parosmia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Mental impairment	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neuropathy peripheral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)

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Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Post-traumatic headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tremor	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	53 (0.5)	55 (0.5)		108 (0.5)
Eye irritation	1 (<0.1)	6 (<0.1)		7 (<0.1)
Eye pruritus	5 (<0.1)	5 (<0.1)		10 (<0.1)
Vision blurred	3 (<0.1)	5 (<0.1)		8 (<0.1)
Dry eye	6 (<0.1)	4 (<0.1)		10 (<0.1)
Eye pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Glaucoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye inflammation	0	2 (<0.1)		2 (<0.1)
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	0	2 (<0.1)		2 (<0.1)
Ocular hyperaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Vitreous floaters	1 (<0.1)	2 (<0.1)		3 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blepharitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Eye disorders (Cont.)				
Cataract	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Eye disorders (Cont.)				
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	66 (0.6)	64 (0.5)		130 (0.6)
Vertigo	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Ear pain	14 (0.1)	13 (0.1)	0.93 (0.44, 1.94)	27 (0.1)
Tinnitus	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.33)	20 (<0.1)
Vertigo positional	1 (<0.1)	7 (<0.1)	6.98 (1.12, 43.49)	8 (<0.1)
Ear discomfort	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Cerumen impaction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Ear and labyrinth disorders (Cont.)				
Ear canal erythema	3 (<0.1)	2 (<0.1)		5 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear congestion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tympanic membrane perforation	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	3 (<0.1)	0		3 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	52 (0.4)	51 (0.4)		103 (0.4)
Bradycardia	13 (0.1)	11 (<0.1)	0.84 (0.39, 1.85)	24 (0.1)
Tachycardia	5 (<0.1)	11 (<0.1)	2.19 (0.80, 6.04)	16 (<0.1)
Atrial fibrillation	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.72)	14 (<0.1)
Palpitations	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Angina pectoris	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arrhythmia	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Cardiac disorders (Cont.)				
Cardiac failure congestive	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronary artery disease	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute myocardial infarction	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Cardiac failure	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)		4 (<0.1)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	0		1 (<0.1)
Myocardial infarction	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	3 (<0.1)	0		3 (<0.1)
Vascular disorders	147 (1.3)	149 (1.3)		296 (1.3)
Hypertension	116 (1.0)	114 (1.0)	0.98 (0.76, 1.27)	230 (1.0)
Hot flush	8 (<0.1)	12 (0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Flushing	4 (<0.1)	4 (<0.1)		8 (<0.1)
Haematoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertensive urgency	0	3 (<0.1)		3 (<0.1)
Hypotension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Systolic hypertension	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Vascular disorders (Cont.)				
Orthostatic hypotension	0	2 (<0.1)		2 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	486 (4.2)	442 (3.8)		928 (4.0)
Oropharyngeal pain	183 (1.6)	130 (1.1)	0.71 (0.57, 0.89)	313 (1.3)
Cough	119 (1.0)	122 (1.0)	1.02 (0.80, 1.31)	241 (1.0)
Nasal congestion	118 (1.0)	115 (1.0)	0.97 (0.75, 1.25)	233 (1.0)
Rhinorrhoea	109 (0.9)	94 (0.8)	0.86 (0.65, 1.13)	203 (0.9)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Tachypnoea	26 (0.2)	28 (0.2)	1.07 (0.63, 1.82)	54 (0.2)
Dyspnoea	30 (0.3)	25 (0.2)	0.83 (0.49, 1.40)	55 (0.2)
Epistaxis	7 (<0.1)	14 (0.1)	1.99 (0.83, 4.80)	21 (<0.1)
Throat irritation	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Sinus congestion	19 (0.2)	13 (0.1)	0.68 (0.34, 1.36)	32 (0.1)
Respiratory tract congestion	5 (<0.1)	12 (0.1)	2.39 (0.88, 6.51)	17 (<0.1)
Rhinitis allergic	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Sneezing	10 (<0.1)	8 (<0.1)	0.80 (0.32, 1.96)	18 (<0.1)
Upper-airway cough syndrome	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Asthma	6 (<0.1)	6 (<0.1)		12 (<0.1)
Pharyngeal erythema	3 (<0.1)	4 (<0.1)		7 (<0.1)
Dry throat	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dysphonia	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	3 (<0.1)		6 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)
Sinus pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Wheezing	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dyspnoea exertional	0	2 (<0.1)		2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Productive cough	5 (<0.1)	2 (<0.1)		7 (<0.1)
Acute respiratory failure	3 (<0.1)	1 (<0.1)		4 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory disorder	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	427 (3.6)	431 (3.7)		858 (3.7)
Diarrhoea	141 (1.2)	151 (1.3)	1.07 (0.85, 1.34)	292 (1.2)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Nausea	126 (1.1)	114 (1.0)	0.90 (0.70, 1.16)	240 (1.0)
Vomiting	43 (0.4)	45 (0.4)	1.04 (0.69, 1.58)	88 (0.4)
Gastrooesophageal reflux disease	21 (0.2)	30 (0.3)	1.42 (0.82, 2.47)	51 (0.2)
Toothache	22 (0.2)	27 (0.2)	1.22 (0.70, 2.13)	49 (0.2)
Abdominal pain	14 (0.1)	22 (0.2)	1.57 (0.81, 3.03)	36 (0.2)
Dyspepsia	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Abdominal pain upper	18 (0.2)	11 (<0.1)	0.61 (0.29, 1.27)	29 (0.1)
Constipation	16 (0.1)	11 (<0.1)	0.69 (0.32, 1.45)	27 (0.1)
Dental caries	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.86)	20 (<0.1)
Food poisoning	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.10)	14 (<0.1)
Abdominal pain lower	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Abdominal discomfort	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Gastric ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Haemorrhoids	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hyperaesthesia teeth	0	3 (<0.1)		3 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Paraesthesia oral	3 (<0.1)	3 (<0.1)		6 (<0.1)
Umbilical hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Hiatus hernia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Irritable bowel syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Stomatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Tooth impacted	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal distension	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Colitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Gastritis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	4 (<0.1)	1 (<0.1)		5 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Loose tooth	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Diverticulum	1 (<0.1)	0		1 (<0.1)
Dry mouth	2 (<0.1)	0		2 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	2 (<0.1)	7 (<0.1)		9 (<0.1)
Cholelithiasis	1 (<0.1)	5 (<0.1)		6 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Hepatobiliary disorders (Cont.)				
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	180 (1.5)	235 (2.0)		415 (1.8)
Urticaria	25 (0.2)	37 (0.3)	1.48 (0.89, 2.44)	62 (0.3)
Rash	24 (0.2)	30 (0.3)	1.25 (0.73, 2.12)	54 (0.2)
Pruritus	17 (0.1)	20 (0.2)	1.17 (0.62, 2.21)	37 (0.2)
Dermatitis contact	25 (0.2)	18 (0.2)	0.72 (0.40, 1.30)	43 (0.2)
Erythema	4 (<0.1)	14 (0.1)	3.49 (1.21, 10.08)	18 (<0.1)
Hyperhidrosis	7 (<0.1)	10 (<0.1)	1.42 (0.56, 3.62)	17 (<0.1)
Night sweats	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Acne	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.63)	13 (<0.1)
Eczema	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.23)	11 (<0.1)
Dermatitis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.25)	10 (<0.1)
Actinic keratosis	1 (<0.1)	6 (<0.1)		7 (<0.1)
Alopecia	4 (<0.1)	6 (<0.1)		10 (<0.1)
Rash papular	3 (<0.1)	6 (<0.1)		9 (<0.1)
Rash macular	3 (<0.1)	5 (<0.1)		8 (<0.1)
Rash maculo-papular	2 (<0.1)	5 (<0.1)		7 (<0.1)
Dermatitis atopic	5 (<0.1)	4 (<0.1)		9 (<0.1)
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dry skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Rash pruritic	6 (<0.1)	3 (<0.1)		9 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	3 (<0.1)	3 (<0.1)		6 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Angioedema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blister	0	2 (<0.1)		2 (<0.1)
Ecchymosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hidradenitis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Rash erythematous	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Macule	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Pain of skin	0	1 (<0.1)		1 (<0.1)
Petechiae	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin mass	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Papule	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	2 (<0.1)	0		2 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	3 (<0.1)	0		3 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	724 (6.2)	733 (6.2)		1457 (6.2)
Arthralgia	260 (2.2)	275 (2.3)	1.05 (0.89, 1.25)	535 (2.3)
Myalgia	273 (2.3)	269 (2.3)	0.98 (0.83, 1.16)	542 (2.3)
Back pain	103 (0.9)	82 (0.7)	0.79 (0.60, 1.06)	185 (0.8)
Pain in extremity	61 (0.5)	44 (0.4)	0.72 (0.49, 1.06)	105 (0.4)
Musculoskeletal pain	22 (0.2)	36 (0.3)	1.63 (0.97, 2.76)	58 (0.2)
Neck pain	29 (0.2)	34 (0.3)	1.17 (0.72, 1.91)	63 (0.3)
Muscle spasms	21 (0.2)	27 (0.2)	1.28 (0.73, 2.25)	48 (0.2)
Osteoarthritis	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Musculoskeletal chest pain	7 (<0.1)	13 (0.1)	1.85 (0.76, 4.51)	20 (<0.1)
Tendonitis	11 (<0.1)	12 (0.1)	1.09 (0.49, 2.41)	23 (<0.1)
Musculoskeletal stiffness	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.52)	21 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rotator cuff syndrome	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Arthritis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.25)	10 (<0.1)
Bursitis	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Groin pain	1 (<0.1)	5 (<0.1)		6 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	5 (<0.1)		8 (<0.1)
Joint swelling	6 (<0.1)	5 (<0.1)		11 (<0.1)
Limb discomfort	1 (<0.1)	5 (<0.1)		6 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Muscular weakness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Trigger finger	1 (<0.1)	5 (<0.1)		6 (<0.1)
Joint range of motion decreased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Bone pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Flank pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Muscle twitching	2 (<0.1)	3 (<0.1)		5 (<0.1)
Osteoporosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Costochondritis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Pain in jaw	4 (<0.1)	2 (<0.1)		6 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spinal osteoarthritis	3 (<0.1)	2 (<0.1)		5 (<0.1)

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up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spinal pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Axillary mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Exostosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibromyalgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint stiffness	3 (<0.1)	1 (<0.1)		4 (<0.1)
Limb mass	0	1 (<0.1)		1 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Plantar fasciitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal stenosis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)

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up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	3 (<0.1)	0		3 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Periarthritis	2 (<0.1)	0		2 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	31 (0.3)	32 (0.3)		63 (0.3)
Nephrolithiasis	14 (0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Dysuria	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030108060101.sas 21JUN2021 14:29

Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Renal and urinary disorders (Cont.)				
Haematuria	5 (<0.1)	3 (<0.1)		8 (<0.1)
Polyuria	0	3 (<0.1)		3 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary retention	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chronic kidney disease	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Hypertonic bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Renal cyst	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Renal and urinary disorders (Cont.)				
Chromaturia	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	2 (<0.1)	0		2 (<0.1)
Urinary incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	50 (0.4)	48 (0.4)		98 (0.4)
Benign prostatic hyperplasia	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Dysmenorrhoea	5 (<0.1)	3 (<0.1)		8 (<0.1)
Erectile dysfunction	2 (<0.1)	3 (<0.1)		5 (<0.1)
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Pelvic pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Prostatitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Reproductive system and breast disorders (Cont.)				
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Reproductive system and breast disorders (Cont.)				
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Menstruation irregular	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline
up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions	767 (6.6)	1171 (10.0)		1938 (8.3)
Fatigue	478 (4.1)	522 (4.4)	1.09 (0.96, 1.23)	1000 (4.3)
Injection site pain	86 (0.7)	191 (1.6)	2.22 (1.72, 2.85)	277 (1.2)
Injection site erythema	22 (0.2)	110 (0.9)	4.99 (3.17, 7.85)	132 (0.6)
Chills	77 (0.7)	89 (0.8)	1.15 (0.85, 1.56)	166 (0.7)
Pyrexia	46 (0.4)	86 (0.7)	1.86 (1.31, 2.66)	132 (0.6)
Injection site swelling	19 (0.2)	84 (0.7)	4.41 (2.70, 7.21)	103 (0.4)
Injection site pruritus	9 (<0.1)	70 (0.6)	7.76 (3.93, 15.32)	79 (0.3)
Injection site lymphadenopathy	11 (<0.1)	60 (0.5)	5.44 (2.89, 10.23)	71 (0.3)
Pain	46 (0.4)	54 (0.5)	1.17 (0.79, 1.73)	100 (0.4)
Injection site induration	12 (0.1)	39 (0.3)	3.24 (1.72, 6.12)	51 (0.2)
Injection site macule	4 (<0.1)	37 (0.3)	9.23 (3.43, 24.84)	41 (0.2)
Injection site urticaria	1 (<0.1)	28 (0.2)	27.93 (4.81, 162.14)	29 (0.1)
Injection site rash	1 (<0.1)	23 (0.2)	22.94 (3.93, 133.89)	24 (0.1)
Axillary pain	13 (0.1)	18 (0.2)	1.38 (0.69, 2.78)	31 (0.1)
Malaise	10 (<0.1)	14 (0.1)	1.40 (0.63, 3.08)	24 (0.1)
Injection site bruising	18 (0.2)	13 (0.1)	0.72 (0.36, 1.45)	31 (0.1)
Injection site papule	0	11 (<0.1)		11 (<0.1)
Chest discomfort	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Peripheral swelling	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	6.98 (1.12, 43.49)	8 (<0.1)
Chest pain	4 (<0.1)	6 (<0.1)		10 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions (Cont.)				
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site paraesthesia	2 (<0.1)	6 (<0.1)		8 (<0.1)
Reactogenicity event	1 (<0.1)	6 (<0.1)		7 (<0.1)
Feeling abnormal	3 (<0.1)	5 (<0.1)		8 (<0.1)
Feeling hot	3 (<0.1)	5 (<0.1)		8 (<0.1)
Non-cardiac chest pain	4 (<0.1)	5 (<0.1)		9 (<0.1)
Oedema peripheral	3 (<0.1)	5 (<0.1)		8 (<0.1)
Vaccination site pain	3 (<0.1)	5 (<0.1)		8 (<0.1)
Vaccination site swelling	0	5 (<0.1)		5 (<0.1)
Injection site haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Injection site joint pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Swelling face	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Hangover	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site mass	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Asthenia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions (Cont.)				
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Precancerous condition	1 (<0.1)	1 (<0.1)		2 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions (Cont.)				
Crying	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discomfort	1 (<0.1)	0		1 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Investigations	57 (0.5)	81 (0.7)		138 (0.6)
Blood pressure increased	22 (0.2)	19 (0.2)	0.86 (0.47, 1.58)	41 (0.2)
Blood pressure systolic increased	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.60)	10 (<0.1)
Body temperature increased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Blood cholesterol increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Heart rate increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hepatic enzyme increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Transaminases increased	0	3 (<0.1)		3 (<0.1)
Blood glucose increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Weight decreased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood triglycerides increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	1 (<0.1)	1 (<0.1)		2 (<0.1)

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up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Investigations (Cont.)				
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood potassium decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Investigations (Cont.)				
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Cardiac murmur	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	278 (2.4)	246 (2.1)		524 (2.2)
Muscle strain	21 (0.2)	30 (0.3)	1.42 (0.82, 2.47)	51 (0.2)
Ligament sprain	21 (0.2)	21 (0.2)	1.00 (0.55, 1.81)	42 (0.2)
Arthropod bite	17 (0.1)	19 (0.2)	1.11 (0.59, 2.12)	36 (0.2)
Skin laceration	23 (0.2)	19 (0.2)	0.82 (0.45, 1.50)	42 (0.2)
Contusion	22 (0.2)	15 (0.1)	0.68 (0.36, 1.30)	37 (0.2)
Fall	15 (0.1)	15 (0.1)	1.00 (0.49, 2.01)	30 (0.1)
Tooth fracture	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Procedural pain	25 (0.2)	11 (<0.1)	0.44 (0.22, 0.88)	36 (0.2)
Skin abrasion	14 (0.1)	10 (<0.1)	0.71 (0.32, 1.57)	24 (0.1)
Arthropod sting	14 (0.1)	8 (<0.1)	0.57 (0.25, 1.32)	22 (<0.1)
Foot fracture	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Limb injury	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Road traffic accident	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.63)	13 (<0.1)
Meniscus injury	9 (<0.1)	6 (<0.1)	0.66 (0.25, 1.79)	15 (<0.1)
Animal bite	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.39)	15 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Hand fracture	2 (<0.1)	4 (<0.1)		6 (<0.1)
Joint injury	2 (<0.1)	4 (<0.1)		6 (<0.1)
Post-traumatic pain	4 (<0.1)	4 (<0.1)		8 (<0.1)
Rib fracture	2 (<0.1)	4 (<0.1)		6 (<0.1)
Bone contusion	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Concussion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Head injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Upper limb fracture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Wrist fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Ankle fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Epicondylitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Thermal burn	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Corneal abrasion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Heat exhaustion	0	1 (<0.1)		1 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ligament rupture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Lower limb fracture	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	2 (<0.1)	1 (<0.1)		3 (<0.1)
Wound	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Animal scratch	1 (<0.1)	0		1 (<0.1)
Back injury	2 (<0.1)	0		2 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Eye injury	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Hip fracture	2 (<0.1)	0		2 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sunburn	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.6.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk for Severe COVID (Y/N) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not At Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Tendon rupture	1 (<0.1)	0		1 (<0.1)
Tooth injury	3 (<0.1)	0		3 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Product issues	1 (<0.1)	5 (<0.1)		6 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	232 (31.0)	261 (36.7)		493 (33.7)
Number of Unsolicited Adverse Events	605	578		1183
Infections and infestations	55 (7.3)	38 (5.3)		93 (6.4)
Upper respiratory tract infection	9 (1.2)	4 (0.6)	0.47 (0.15, 1.42)	13 (0.9)
Localised infection	0	3 (0.4)		3 (0.2)
Suspected COVID-19	2 (0.3)	3 (0.4)		5 (0.3)
Diverticulitis	2 (0.3)	2 (0.3)		4 (0.3)
Kidney infection	1 (0.1)	2 (0.3)		3 (0.2)
Pharyngitis	0	2 (0.3)		2 (0.1)
Sinusitis	6 (0.8)	2 (0.3)		8 (0.5)
Urinary tract infection	3 (0.4)	2 (0.3)		5 (0.3)
Abscess limb	0	1 (0.1)		1 (<0.1)
Acute sinusitis	0	1 (0.1)		1 (<0.1)
COVID-19	9 (1.2)	1 (0.1)	0.12 (0.02, 0.71)	10 (0.7)
Candida infection	0	1 (0.1)		1 (<0.1)
Cellulitis	1 (0.1)	1 (0.1)		2 (0.1)
Clostridium difficile infection	0	1 (0.1)		1 (<0.1)
Cystitis	1 (0.1)	1 (0.1)		2 (0.1)
Folliculitis	0	1 (0.1)		1 (<0.1)
Gastroenteritis	0	1 (0.1)		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Infections and infestations (Cont.)				
Herpes zoster	2 (0.3)	1 (0.1)		3 (0.2)
Hordeolum	0	1 (0.1)		1 (<0.1)
Oral candidiasis	1 (0.1)	1 (0.1)		2 (0.1)
Otitis externa	0	1 (0.1)		1 (<0.1)
Otitis media acute	0	1 (0.1)		1 (<0.1)
Respiratory tract infection viral	0	1 (0.1)		1 (<0.1)
Rhinovirus infection	1 (0.1)	1 (0.1)		2 (0.1)
Tooth abscess	4 (0.5)	1 (0.1)		5 (0.3)
Vaginal infection	0	1 (0.1)		1 (<0.1)
Viral infection	2 (0.3)	1 (0.1)		3 (0.2)
Vulvovaginal mycotic infection	0	1 (0.1)		1 (<0.1)
Breast abscess	2 (0.3)	0		2 (0.1)
Bronchitis	2 (0.3)	0		2 (0.1)
Bullous impetigo	1 (0.1)	0		1 (<0.1)
Chronic sinusitis	1 (0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (0.1)	0		1 (<0.1)
Denture stomatitis	1 (0.1)	0		1 (<0.1)
Ear infection	2 (0.3)	0		2 (0.1)
Enterovirus infection	1 (0.1)	0		1 (<0.1)
Epididymitis	1 (0.1)	0		1 (<0.1)
Gastroenteritis viral	1 (0.1)	0		1 (<0.1)
Nasopharyngitis	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Infections and infestations (Cont.)				
Pneumonia	3 (0.4)	0		3 (0.2)
Pneumonia viral	1 (0.1)	0		1 (<0.1)
Sepsis	1 (0.1)	0		1 (<0.1)
Skin infection	1 (0.1)	0		1 (<0.1)
Tooth infection	1 (0.1)	0		1 (<0.1)
Viral upper respiratory tract infection	1 (0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (0.4)	0		3 (0.2)
Bladder neoplasm	1 (0.1)	0		1 (<0.1)
Breast cancer stage I	1 (0.1)	0		1 (<0.1)
Renal hamartoma	1 (0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	6 (0.8)	16 (2.2)		22 (1.5)
Lymphadenopathy	4 (0.5)	16 (2.2)	4.21 (1.48, 11.95)	20 (1.4)
Iron deficiency anaemia	1 (0.1)	0		1 (<0.1)
Lymph node pain	1 (0.1)	0		1 (<0.1)
Immune system disorders	4 (0.5)	2 (0.3)		6 (0.4)
Sarcoidosis	0	1 (0.1)		1 (<0.1)
Seasonal allergy	2 (0.3)	1 (0.1)		3 (0.2)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Immune system disorders (Cont.)				
Anaphylactic reaction	1 (0.1)	0		1 (<0.1)
Milk allergy	1 (0.1)	0		1 (<0.1)
Smoke sensitivity	1 (0.1)	0		1 (<0.1)
Endocrine disorders	3 (0.4)	0		3 (0.2)
Androgen deficiency	1 (0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (0.1)	0		1 (<0.1)
Hypothyroidism	1 (0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	6 (0.8)	6 (0.8)		12 (0.8)
Dehydration	0	2 (0.3)		2 (0.1)
Abnormal weight gain	0	1 (0.1)		1 (<0.1)
Gout	0	1 (0.1)		1 (<0.1)
Type 2 diabetes mellitus	0	1 (0.1)		1 (<0.1)
Vitamin D deficiency	0	1 (0.1)		1 (<0.1)
Decreased appetite	1 (0.1)	0		1 (<0.1)
Diabetes mellitus	1 (0.1)	0		1 (<0.1)
Electrolyte imbalance	1 (0.1)	0		1 (<0.1)
Folate deficiency	1 (0.1)	0		1 (<0.1)
Hypercholesterolaemia	1 (0.1)	0		1 (<0.1)
Hyperglycaemia	1 (0.1)	0		1 (<0.1)
Hypocalcaemia	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypoglycaemia	1 (0.1)	0		1 (<0.1)
Hypokalaemia	1 (0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (0.1)	0		1 (<0.1)
Psychiatric disorders	5 (0.7)	6 (0.8)		11 (0.8)
Insomnia	0	3 (0.4)		3 (0.2)
Anxiety	0	2 (0.3)		2 (0.1)
Depression	2 (0.3)	1 (0.1)		3 (0.2)
Agitation	1 (0.1)	0		1 (<0.1)
Attention deficit hyperactivity disorder	1 (0.1)	0		1 (<0.1)
Mental status changes	2 (0.3)	0		2 (0.1)
Nervous system disorders	63 (8.4)	54 (7.6)		117 (8.0)
Headache	51 (6.8)	48 (6.7)	0.99 (0.68, 1.45)	99 (6.8)
Dizziness	2 (0.3)	2 (0.3)		4 (0.3)
Migraine	2 (0.3)	2 (0.3)		4 (0.3)
Ageusia	1 (0.1)	1 (0.1)		2 (0.1)
Hypoaesthesia	2 (0.3)	1 (0.1)		3 (0.2)
Idiopathic intracranial hypertension	0	1 (0.1)		1 (<0.1)
Paraesthesia	1 (0.1)	1 (0.1)		2 (0.1)

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Table 14.3.1.8.6.2.1
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Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Nervous system disorders (Cont.)				
Piriformis syndrome	0	1 (0.1)		1 (<0.1)
Sciatica	1 (0.1)	1 (0.1)		2 (0.1)
Anosmia	1 (0.1)	0		1 (<0.1)
Encephalopathy	1 (0.1)	0		1 (<0.1)
Facial paralysis	1 (0.1)	0		1 (<0.1)
Lethargy	1 (0.1)	0		1 (<0.1)
Presyncope	1 (0.1)	0		1 (<0.1)
Sinus headache	3 (0.4)	0		3 (0.2)
Tension headache	1 (0.1)	0		1 (<0.1)
Transient ischaemic attack	1 (0.1)	0		1 (<0.1)
Tremor	1 (0.1)	0		1 (<0.1)
Eye disorders	4 (0.5)	6 (0.8)		10 (0.7)
Conjunctivitis allergic	0	1 (0.1)		1 (<0.1)
Eye irritation	0	1 (0.1)		1 (<0.1)
Eye pruritus	0	1 (0.1)		1 (<0.1)
Swelling of eyelid	0	1 (0.1)		1 (<0.1)
Vision blurred	0	1 (0.1)		1 (<0.1)
Xerophthalmia	0	1 (0.1)		1 (<0.1)
Cataract	1 (0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (0.1)	0		1 (<0.1)
Visual impairment	1 (0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Eye disorders (Cont.)				
Vitreous floaters	1 (0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (0.3)	4 (0.6)		6 (0.4)
Vertigo	2 (0.3)	3 (0.4)		5 (0.3)
Tinnitus	0	1 (0.1)		1 (<0.1)
Cardiac disorders	5 (0.7)	5 (0.7)		10 (0.7)
Cardiac failure congestive	1 (0.1)	2 (0.3)		3 (0.2)
Acute myocardial infarction	0	1 (0.1)		1 (<0.1)
Angina pectoris	0	1 (0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (0.1)		1 (<0.1)
Coronary artery disease	0	1 (0.1)		1 (<0.1)
Palpitations	1 (0.1)	0		1 (<0.1)
Sinus tachycardia	1 (0.1)	0		1 (<0.1)
Tachycardia	2 (0.3)	0		2 (0.1)
Vascular disorders	10 (1.3)	17 (2.4)		27 (1.8)
Hypertension	7 (0.9)	15 (2.1)	2.25 (0.95, 5.35)	22 (1.5)
Flushing	0	2 (0.3)		2 (0.1)
Aortic stenosis	1 (0.1)	0		1 (<0.1)
Hypertensive emergency	1 (0.1)	0		1 (<0.1)
Hypotension	1 (0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Respiratory, thoracic and mediastinal disorders	56 (7.5)	40 (5.6)		96 (6.6)
Cough	13 (1.7)	10 (1.4)	0.81 (0.36, 1.79)	23 (1.6)
Chronic obstructive pulmonary disease	9 (1.2)	6 (0.8)	0.70 (0.26, 1.88)	15 (1.0)
Asthma	8 (1.1)	5 (0.7)	0.66 (0.23, 1.90)	13 (0.9)
Rhinorrhoea	13 (1.7)	5 (0.7)	0.40 (0.15, 1.08)	18 (1.2)
Dyspnoea	6 (0.8)	4 (0.6)		10 (0.7)
Nasal congestion	17 (2.3)	4 (0.6)	0.25 (0.09, 0.70)	21 (1.4)
Oropharyngeal pain	12 (1.6)	3 (0.4)	0.26 (0.08, 0.86)	15 (1.0)
Bronchiectasis	0	2 (0.3)		2 (0.1)
Acute respiratory failure	0	1 (0.1)		1 (<0.1)
Atelectasis	1 (0.1)	1 (0.1)		2 (0.1)
Dysphonia	0	1 (0.1)		1 (<0.1)
Dyspnoea exertional	0	1 (0.1)		1 (<0.1)
Emphysema	1 (0.1)	1 (0.1)		2 (0.1)
Productive cough	1 (0.1)	1 (0.1)		2 (0.1)
Respiratory disorder	0	1 (0.1)		1 (<0.1)
Respiratory tract congestion	0	1 (0.1)		1 (<0.1)
Sinus pain	1 (0.1)	1 (0.1)		2 (0.1)
Sleep apnoea syndrome	0	1 (0.1)		1 (<0.1)
Sneezing	2 (0.3)	1 (0.1)		3 (0.2)
Throat irritation	1 (0.1)	1 (0.1)		2 (0.1)
Epistaxis	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Hypoxia	1 (0.1)	0		1 (<0.1)
Laryngeal oedema	1 (0.1)	0		1 (<0.1)
Pleurisy	1 (0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (0.1)	0		1 (<0.1)
Rhinitis allergic	3 (0.4)	0		3 (0.2)
Tonsillolith	1 (0.1)	0		1 (<0.1)
Wheezing	1 (0.1)	0		1 (<0.1)
Gastrointestinal disorders	32 (4.3)	44 (6.2)		76 (5.2)
Nausea	10 (1.3)	17 (2.4)	1.79 (0.84, 3.81)	27 (1.8)
Diarrhoea	13 (1.7)	10 (1.4)	0.81 (0.36, 1.79)	23 (1.6)
Vomiting	4 (0.5)	6 (0.8)		10 (0.7)
Gastrooesophageal reflux disease	1 (0.1)	3 (0.4)		4 (0.3)
Abdominal pain upper	0	2 (0.3)		2 (0.1)
Constipation	1 (0.1)	2 (0.3)		3 (0.2)
Toothache	1 (0.1)	2 (0.3)		3 (0.2)
Abdominal distension	0	1 (0.1)		1 (<0.1)
Abdominal pain lower	0	1 (0.1)		1 (<0.1)
Colitis	0	1 (0.1)		1 (<0.1)
Dysphagia	1 (0.1)	1 (0.1)		2 (0.1)
Faeces soft	0	1 (0.1)		1 (<0.1)

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Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Gastrointestinal disorders (Cont.)				
Food poisoning	0	1 (0.1)		1 (<0.1)
Gastric ulcer	1 (0.1)	1 (0.1)		2 (0.1)
Gastrointestinal disorder	0	1 (0.1)		1 (<0.1)
Gastrointestinal haemorrhage	0	1 (0.1)		1 (<0.1)
Irritable bowel syndrome	0	1 (0.1)		1 (<0.1)
Large intestine polyp	0	1 (0.1)		1 (<0.1)
Oesophagitis	0	1 (0.1)		1 (<0.1)
Submaxillary gland enlargement	0	1 (0.1)		1 (<0.1)
Abdominal pain	4 (0.5)	0		4 (0.3)
Dental caries	1 (0.1)	0		1 (<0.1)
Hyperaesthesia teeth	1 (0.1)	0		1 (<0.1)
Impaired gastric emptying	1 (0.1)	0		1 (<0.1)
Oral cavity fistula	1 (0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	2 (0.3)		2 (0.1)
Biliary colic	0	1 (0.1)		1 (<0.1)
Cholecystitis	0	1 (0.1)		1 (<0.1)
Cholecystitis acute	0	1 (0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	11 (1.5)	10 (1.4)		21 (1.4)
Urticaria	2 (0.3)	3 (0.4)		5 (0.3)
Psoriasis	0	2 (0.3)		2 (0.1)

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Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dermatitis contact	1 (0.1)	1 (0.1)		2 (0.1)
Pruritus	1 (0.1)	1 (0.1)		2 (0.1)
Rash	3 (0.4)	1 (0.1)		4 (0.3)
Rash maculo-papular	0	1 (0.1)		1 (<0.1)
Rash papular	0	1 (0.1)		1 (<0.1)
Blister	1 (0.1)	0		1 (<0.1)
Dermal cyst	1 (0.1)	0		1 (<0.1)
Scab	1 (0.1)	0		1 (<0.1)
Urticaria papular	1 (0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	72 (9.6)	64 (9.0)		136 (9.3)
Arthralgia	30 (4.0)	30 (4.2)	1.05 (0.64, 1.72)	60 (4.1)
Myalgia	31 (4.1)	30 (4.2)	1.02 (0.63, 1.66)	61 (4.2)
Pain in extremity	6 (0.8)	6 (0.8)		12 (0.8)
Back pain	7 (0.9)	4 (0.6)	0.60 (0.19, 1.91)	11 (0.8)
Bursitis	0	3 (0.4)		3 (0.2)
Osteoarthritis	2 (0.3)	3 (0.4)		5 (0.3)
Fibromyalgia	0	2 (0.3)		2 (0.1)
Neck pain	2 (0.3)	2 (0.3)		4 (0.3)
Costochondritis	0	1 (0.1)		1 (<0.1)

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Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Degenerative bone disease	0	1 (0.1)		1 (<0.1)
Musculoskeletal pain	2 (0.3)	1 (0.1)		3 (0.2)
Rheumatoid arthritis	0	1 (0.1)		1 (<0.1)
Rotator cuff syndrome	1 (0.1)	1 (0.1)		2 (0.1)
Spinal stenosis	0	1 (0.1)		1 (<0.1)
Tendonitis	1 (0.1)	1 (0.1)		2 (0.1)
Arthritis	1 (0.1)	0		1 (<0.1)
Axillary mass	1 (0.1)	0		1 (<0.1)
Intervertebral disc degeneration	1 (0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (0.1)	0		1 (<0.1)
Joint swelling	1 (0.1)	0		1 (<0.1)
Limb mass	2 (0.3)	0		2 (0.1)
Muscle twitching	1 (0.1)	0		1 (<0.1)
Musculoskeletal chest pain	3 (0.4)	0		3 (0.2)
Osteonecrosis	1 (0.1)	0		1 (<0.1)
Pain in jaw	1 (0.1)	0		1 (<0.1)
Scoliosis	1 (0.1)	0		1 (<0.1)
Renal and urinary disorders	4 (0.5)	3 (0.4)		7 (0.5)
Nephrolithiasis	1 (0.1)	2 (0.3)		3 (0.2)
Pollakiuria	0	1 (0.1)		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Renal and urinary disorders (Cont.)				
Acute kidney injury	2 (0.3)	0		2 (0.1)
Renal cyst	1 (0.1)	0		1 (<0.1)
Renal impairment	1 (0.1)	0		1 (<0.1)
Urinary incontinence	1 (0.1)	0		1 (<0.1)
Reproductive system and breast disorders	2 (0.3)	6 (0.8)		8 (0.5)
Benign prostatic hyperplasia	0	1 (0.1)		1 (<0.1)
Menstruation irregular	1 (0.1)	1 (0.1)		2 (0.1)
Pelvic pain	0	1 (0.1)		1 (<0.1)
Perineal rash	0	1 (0.1)		1 (<0.1)
Postmenopausal haemorrhage	0	1 (0.1)		1 (<0.1)
Vaginal discharge	0	1 (0.1)		1 (<0.1)
Dysmenorrhoea	1 (0.1)	0		1 (<0.1)
General disorders and administration site conditions	72 (9.6)	107 (15.0)		179 (12.3)
Fatigue	55 (7.3)	60 (8.4)	1.15 (0.81, 1.63)	115 (7.9)
Injection site pain	5 (0.7)	17 (2.4)	3.58 (1.38, 9.31)	22 (1.5)
Injection site erythema	3 (0.4)	13 (1.8)	4.56 (1.40, 14.87)	16 (1.1)
Chills	16 (2.1)	10 (1.4)	0.66 (0.31, 1.41)	26 (1.8)
Pyrexia	4 (0.5)	7 (1.0)	1.84 (0.58, 5.87)	11 (0.8)

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Risk Group: Chronic Lung Disease

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General disorders and administration site conditions (Cont.)				
Injection site swelling	1 (0.1)	5 (0.7)		6 (0.4)
Injection site induration	1 (0.1)	4 (0.6)		5 (0.3)
Axillary pain	0	2 (0.3)		2 (0.1)
Injection site bruising	1 (0.1)	2 (0.3)		3 (0.2)
Injection site lymphadenopathy	1 (0.1)	2 (0.3)		3 (0.2)
Injection site macule	0	2 (0.3)		2 (0.1)
Injection site pruritus	0	2 (0.3)		2 (0.1)
Injection site scab	0	2 (0.3)		2 (0.1)
Pain	8 (1.1)	2 (0.3)	0.26 (0.06, 1.09)	10 (0.7)
Chest discomfort	0	1 (0.1)		1 (<0.1)
Chest pain	0	1 (0.1)		1 (<0.1)
Exercise tolerance decreased	0	1 (0.1)		1 (<0.1)
Feeling hot	0	1 (0.1)		1 (<0.1)
Injection site haemorrhage	1 (0.1)	1 (0.1)		2 (0.1)
Injection site reaction	0	1 (0.1)		1 (<0.1)
Non-cardiac chest pain	1 (0.1)	1 (0.1)		2 (0.1)
Peripheral swelling	1 (0.1)	1 (0.1)		2 (0.1)
Vaccination site swelling	0	1 (0.1)		1 (<0.1)
Pelvic mass	1 (0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Investigations	4 (0.5)	9 (1.3)		13 (0.9)
Blood pressure systolic increased	0	3 (0.4)		3 (0.2)
Blood pressure increased	1 (0.1)	2 (0.3)		3 (0.2)
Blood parathyroid hormone increased	0	1 (0.1)		1 (<0.1)
Blood pressure diastolic increased	0	1 (0.1)		1 (<0.1)
Heart rate increased	0	1 (0.1)		1 (<0.1)
Neutrophil count increased	0	1 (0.1)		1 (<0.1)
Blood prolactin increased	1 (0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (0.1)	0		1 (<0.1)
Cardiac murmur	1 (0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	16 (2.1)	17 (2.4)		33 (2.3)
Ligament sprain	0	4 (0.6)		4 (0.3)
Muscle strain	1 (0.1)	3 (0.4)		4 (0.3)
Contusion	0	2 (0.3)		2 (0.1)
Arthropod bite	2 (0.3)	1 (0.1)		3 (0.2)
Hip fracture	0	1 (0.1)		1 (<0.1)
Limb injury	1 (0.1)	1 (0.1)		2 (0.1)
Rib fracture	0	1 (0.1)		1 (<0.1)
Skin laceration	1 (0.1)	1 (0.1)		2 (0.1)
Tendon rupture	0	1 (0.1)		1 (<0.1)
Tooth fracture	1 (0.1)	1 (0.1)		2 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Chronic Lung Disease

System Organ Class Preferred Term	Placebo (N=749) n (%)	mRNA-1273 (N=712) n (%)	Rate Ratio (95% CI)	Total (N=1461) n (%)
Injury, poisoning and procedural complications (Cont.)				
Wrist fracture	0	1 (0.1)		1 (<0.1)
Animal bite	1 (0.1)	0		1 (<0.1)
Concussion	1 (0.1)	0		1 (<0.1)
Fall	4 (0.5)	0		4 (0.3)
Foot fracture	2 (0.3)	0		2 (0.1)
Lower limb fracture	1 (0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (0.1)	0		1 (<0.1)
Pulmonary contusion	1 (0.1)	0		1 (<0.1)
Road traffic accident	1 (0.1)	0		1 (<0.1)
Skin abrasion	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	209 (28.2)	255 (33.5)		464 (30.9)
Number of Unsolicited Adverse Events	416	473		889
Infections and infestations	34 (4.6)	38 (5.0)		72 (4.8)
Urinary tract infection	3 (0.4)	7 (0.9)	2.27 (0.64, 8.04)	10 (0.7)
Upper respiratory tract infection	1 (0.1)	4 (0.5)		5 (0.3)
COVID-19	4 (0.5)	3 (0.4)		7 (0.5)
Conjunctivitis	0	2 (0.3)		2 (0.1)
Ear infection	0	2 (0.3)		2 (0.1)
Herpes zoster	3 (0.4)	2 (0.3)		5 (0.3)
Tooth abscess	1 (0.1)	2 (0.3)		3 (0.2)
Tooth infection	1 (0.1)	2 (0.3)		3 (0.2)
Asymptomatic COVID-19	0	1 (0.1)		1 (<0.1)
Coronavirus infection	0	1 (0.1)		1 (<0.1)
Fungal infection	0	1 (0.1)		1 (<0.1)
Gingivitis	0	1 (0.1)		1 (<0.1)
Herpes simplex	0	1 (0.1)		1 (<0.1)
Hordeolum	0	1 (0.1)		1 (<0.1)
Localised infection	0	1 (0.1)		1 (<0.1)
Otitis media acute	0	1 (0.1)		1 (<0.1)
Parainfluenzae virus infection	0	1 (0.1)		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Infections and infestations (Cont.)				
Pharyngitis	0	1 (0.1)		1 (<0.1)
Rhinovirus infection	1 (0.1)	1 (0.1)		2 (0.1)
Sinusitis	4 (0.5)	1 (0.1)		5 (0.3)
Suspected COVID-19	0	1 (0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (0.1)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (0.1)		1 (<0.1)
Blastocystis infection	1 (0.1)	0		1 (<0.1)
Cystitis	1 (0.1)	0		1 (<0.1)
Diverticulitis	1 (0.1)	0		1 (<0.1)
Fungal skin infection	1 (0.1)	0		1 (<0.1)
Gingival abscess	1 (0.1)	0		1 (<0.1)
Helicobacter infection	1 (0.1)	0		1 (<0.1)
Oral viral infection	1 (0.1)	0		1 (<0.1)
Otitis externa	1 (0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (0.1)	0		1 (<0.1)
Pneumonia	2 (0.3)	0		2 (0.1)
Postoperative wound infection	1 (0.1)	0		1 (<0.1)
Respiratory tract infection viral	1 (0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (0.1)	0		1 (<0.1)
Tinea pedis	1 (0.1)	0		1 (<0.1)
Viral infection	2 (0.3)	0		2 (0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (0.8)	2 (0.3)		8 (0.5)
Chronic myelomonocytic leukaemia	0	1 (0.1)		1 (<0.1)
Skin cancer	0	1 (0.1)		1 (<0.1)
Basal cell carcinoma	1 (0.1)	0		1 (<0.1)
Benign neoplasm of skin	1 (0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (0.1)	0		1 (<0.1)
Prostate cancer	1 (0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	3 (0.4)	8 (1.0)		11 (0.7)
Lymphadenopathy	3 (0.4)	8 (1.0)	2.60 (0.75, 9.00)	11 (0.7)
Immune system disorders	3 (0.4)	2 (0.3)		5 (0.3)
Seasonal allergy	2 (0.3)	1 (0.1)		3 (0.2)
Type IV hypersensitivity reaction	0	1 (0.1)		1 (<0.1)
Smoke sensitivity	1 (0.1)	0		1 (<0.1)
Endocrine disorders	1 (0.1)	0		1 (<0.1)
Hypothyroidism	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Metabolism and nutrition disorders	7 (0.9)	10 (1.3)		17 (1.1)
Diabetes mellitus	1 (0.1)	2 (0.3)		3 (0.2)
Dehydration	0	1 (0.1)		1 (<0.1)
Gout	0	1 (0.1)		1 (<0.1)
Hypercholesterolaemia	0	1 (0.1)		1 (<0.1)
Hyperlipidaemia	1 (0.1)	1 (0.1)		2 (0.1)
Hypoglycaemia	0	1 (0.1)		1 (<0.1)
Magnesium deficiency	0	1 (0.1)		1 (<0.1)
Type 2 diabetes mellitus	1 (0.1)	1 (0.1)		2 (0.1)
Vitamin B12 deficiency	0	1 (0.1)		1 (<0.1)
Decreased appetite	3 (0.4)	0		3 (0.2)
Hypocalcaemia	1 (0.1)	0		1 (<0.1)
Psychiatric disorders	2 (0.3)	3 (0.4)		5 (0.3)
Anxiety	1 (0.1)	1 (0.1)		2 (0.1)
Hallucination	0	1 (0.1)		1 (<0.1)
Insomnia	0	1 (0.1)		1 (<0.1)
Depression	1 (0.1)	0		1 (<0.1)
Nervous system disorders	38 (5.1)	50 (6.6)		88 (5.9)
Headache	25 (3.4)	38 (5.0)	1.48 (0.91, 2.42)	63 (4.2)
Dizziness	5 (0.7)	2 (0.3)		7 (0.5)
Mental impairment	0	2 (0.3)		2 (0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Nervous system disorders (Cont.)				
Anosmia	1 (0.1)	1 (0.1)		2 (0.1)
Hypoaesthesia	1 (0.1)	1 (0.1)		2 (0.1)
Idiopathic intracranial hypertension	0	1 (0.1)		1 (<0.1)
Movement disorder	0	1 (0.1)		1 (<0.1)
Nerve compression	0	1 (0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (0.1)		1 (<0.1)
Paraesthesia	0	1 (0.1)		1 (<0.1)
Peripheral sensory neuropathy	0	1 (0.1)		1 (<0.1)
Piriformis syndrome	0	1 (0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (0.1)		1 (<0.1)
Ageusia	1 (0.1)	0		1 (<0.1)
Amnesia	1 (0.1)	0		1 (<0.1)
Dysaesthesia	1 (0.1)	0		1 (<0.1)
Ischaemic stroke	1 (0.1)	0		1 (<0.1)
Lumbar radiculopathy	1 (0.1)	0		1 (<0.1)
Neuralgia	1 (0.1)	0		1 (<0.1)
Presyncope	1 (0.1)	0		1 (<0.1)
Sciatica	1 (0.1)	0		1 (<0.1)
Sinus headache	1 (0.1)	0		1 (<0.1)
Speech disorder	1 (0.1)	0		1 (<0.1)
Syncope	2 (0.3)	0		2 (0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Eye disorders	1 (0.1)	1 (0.1)		2 (0.1)
Eye inflammation	0	1 (0.1)		1 (<0.1)
Blindness	1 (0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (0.3)	8 (1.0)		10 (0.7)
Vertigo	1 (0.1)	4 (0.5)		5 (0.3)
Ear pain	0	2 (0.3)		2 (0.1)
Cerumen impaction	0	1 (0.1)		1 (<0.1)
Tinnitus	0	1 (0.1)		1 (<0.1)
Ear discomfort	1 (0.1)	0		1 (<0.1)
Cardiac disorders	9 (1.2)	15 (2.0)		24 (1.6)
Atrial fibrillation	2 (0.3)	5 (0.7)		7 (0.5)
Myocardial infarction	0	3 (0.4)		3 (0.2)
Bradycardia	2 (0.3)	2 (0.3)		4 (0.3)
Acute coronary syndrome	0	1 (0.1)		1 (<0.1)
Acute left ventricular failure	0	1 (0.1)		1 (<0.1)
Angina pectoris	1 (0.1)	1 (0.1)		2 (0.1)
Arrhythmia	0	1 (0.1)		1 (<0.1)
Atrial flutter	1 (0.1)	1 (0.1)		2 (0.1)
Cardiac failure congestive	0	1 (0.1)		1 (<0.1)
Cardiomyopathy	0	1 (0.1)		1 (<0.1)
Tachycardia	1 (0.1)	1 (0.1)		2 (0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Cardiac disorders (Cont.)				
Cardiac failure	2 (0.3)	0		2 (0.1)
Coronary artery disease	1 (0.1)	0		1 (<0.1)
Vascular disorders	12 (1.6)	9 (1.2)		21 (1.4)
Hypertension	11 (1.5)	6 (0.8)	0.53 (0.20, 1.38)	17 (1.1)
Haematoma	0	1 (0.1)		1 (<0.1)
Hypertensive urgency	0	1 (0.1)		1 (<0.1)
Peripheral coldness	0	1 (0.1)		1 (<0.1)
Deep vein thrombosis	1 (0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	30 (4.0)	27 (3.5)		57 (3.8)
Rhinorrhoea	7 (0.9)	9 (1.2)	1.25 (0.49, 3.23)	16 (1.1)
Nasal congestion	6 (0.8)	8 (1.0)	1.30 (0.47, 3.57)	14 (0.9)
Cough	5 (0.7)	5 (0.7)		10 (0.7)
Oropharyngeal pain	9 (1.2)	3 (0.4)	0.32 (0.10, 1.10)	12 (0.8)
Tachypnoea	2 (0.3)	3 (0.4)		5 (0.3)
Asthma	0	2 (0.3)		2 (0.1)
Dyspnoea	2 (0.3)	2 (0.3)		4 (0.3)
Bronchospasm	0	1 (0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (0.1)	1 (0.1)		2 (0.1)
Epistaxis	2 (0.3)	1 (0.1)		3 (0.2)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory tract congestion	1 (0.1)	1 (0.1)		2 (0.1)
Sinus pain	0	1 (0.1)		1 (<0.1)
Sleep apnoea syndrome	0	1 (0.1)		1 (<0.1)
Dysphonia	1 (0.1)	0		1 (<0.1)
Dyspnoea exertional	1 (0.1)	0		1 (<0.1)
Pleural effusion	1 (0.1)	0		1 (<0.1)
Pleuritic pain	1 (0.1)	0		1 (<0.1)
Productive cough	1 (0.1)	0		1 (<0.1)
Rhinitis allergic	3 (0.4)	0		3 (0.2)
Sinus congestion	2 (0.3)	0		2 (0.1)
Gastrointestinal disorders	25 (3.4)	31 (4.1)		56 (3.7)
Diarrhoea	10 (1.3)	11 (1.4)	1.07 (0.47, 2.45)	21 (1.4)
Nausea	6 (0.8)	10 (1.3)	1.62 (0.62, 4.28)	16 (1.1)
Vomiting	1 (0.1)	2 (0.3)		3 (0.2)
Abdominal discomfort	0	1 (0.1)		1 (<0.1)
Abdominal pain upper	0	1 (0.1)		1 (<0.1)
Gastrointestinal haemorrhage	0	1 (0.1)		1 (<0.1)
Gastrooesophageal reflux disease	2 (0.3)	1 (0.1)		3 (0.2)
Haemorrhoids	0	1 (0.1)		1 (<0.1)
Inguinal hernia	1 (0.1)	1 (0.1)		2 (0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Gastrointestinal disorders (Cont.)				
Large intestine polyp	0	1 (0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (0.1)		1 (<0.1)
Swollen tongue	0	1 (0.1)		1 (<0.1)
Constipation	2 (0.3)	0		2 (0.1)
Dental caries	1 (0.1)	0		1 (<0.1)
Dyspepsia	1 (0.1)	0		1 (<0.1)
Oral pain	1 (0.1)	0		1 (<0.1)
Salivary hypersecretion	1 (0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (0.1)	0		1 (<0.1)
Stomatitis	1 (0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (0.1)	1 (0.1)		2 (0.1)
Nonalcoholic fatty liver disease	0	1 (0.1)		1 (<0.1)
Cholelithiasis	1 (0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	13 (1.8)	11 (1.4)		24 (1.6)
Rash	1 (0.1)	3 (0.4)		4 (0.3)
Dermatitis contact	3 (0.4)	2 (0.3)		5 (0.3)
Dermatitis	1 (0.1)	1 (0.1)		2 (0.1)
Hyperhidrosis	2 (0.3)	1 (0.1)		3 (0.2)
Papule	0	1 (0.1)		1 (<0.1)
Pruritus	1 (0.1)	1 (0.1)		2 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030108060201.sas 21JUN2021 14:30

Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Psoriasis	0	1 (0.1)		1 (<0.1)
Rash macular	0	1 (0.1)		1 (<0.1)
Rash pruritic	0	1 (0.1)		1 (<0.1)
Blister	1 (0.1)	0		1 (<0.1)
Ecchymosis	1 (0.1)	0		1 (<0.1)
Skin mass	1 (0.1)	0		1 (<0.1)
Urticaria	1 (0.1)	0		1 (<0.1)
Urticaria papular	1 (0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	53 (7.1)	66 (8.7)		119 (7.9)
Arthralgia	23 (3.1)	28 (3.7)	1.19 (0.69, 2.03)	51 (3.4)
Myalgia	17 (2.3)	22 (2.9)	1.26 (0.68, 2.33)	39 (2.6)
Pain in extremity	4 (0.5)	8 (1.0)	1.95 (0.63, 6.06)	12 (0.8)
Musculoskeletal pain	4 (0.5)	4 (0.5)		8 (0.5)
Neck pain	3 (0.4)	4 (0.5)		7 (0.5)
Back pain	6 (0.8)	3 (0.4)		9 (0.6)
Osteoarthritis	2 (0.3)	2 (0.3)		4 (0.3)
Arthritis	0	1 (0.1)		1 (<0.1)
Bursitis	0	1 (0.1)		1 (<0.1)
Costochondritis	0	1 (0.1)		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Groin pain	0	1 (0.1)		1 (<0.1)
Intervertebral disc protrusion	0	1 (0.1)		1 (<0.1)
Joint swelling	0	1 (0.1)		1 (<0.1)
Muscle spasms	1 (0.1)	1 (0.1)		2 (0.1)
Plantar fasciitis	0	1 (0.1)		1 (<0.1)
Rotator cuff syndrome	1 (0.1)	1 (0.1)		2 (0.1)
Spinal pain	0	1 (0.1)		1 (<0.1)
Spinal stenosis	0	1 (0.1)		1 (<0.1)
Spondylitis	0	1 (0.1)		1 (<0.1)
Spondylolysis	0	1 (0.1)		1 (<0.1)
Trigger finger	0	1 (0.1)		1 (<0.1)
Cervical spinal stenosis	1 (0.1)	0		1 (<0.1)
Musculoskeletal chest pain	2 (0.3)	0		2 (0.1)
Musculoskeletal stiffness	1 (0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (0.1)	0		1 (<0.1)
Renal and urinary disorders	1 (0.1)	4 (0.5)		5 (0.3)
Nephrolithiasis	1 (0.1)	2 (0.3)		3 (0.2)
Nocturia	0	1 (0.1)		1 (<0.1)
Pollakiuria	0	1 (0.1)		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Reproductive system and breast disorders	0	3 (0.4)		3 (0.2)
Benign prostatic hyperplasia	0	1 (0.1)		1 (<0.1)
Erectile dysfunction	0	1 (0.1)		1 (<0.1)
Prostatitis	0	1 (0.1)		1 (<0.1)
General disorders and administration site conditions	63 (8.5)	82 (10.8)		145 (9.6)
Fatigue	38 (5.1)	47 (6.2)	1.20 (0.80, 1.82)	85 (5.7)
Injection site erythema	7 (0.9)	11 (1.4)	1.53 (0.62, 3.81)	18 (1.2)
Injection site pain	3 (0.4)	11 (1.4)	3.57 (1.08, 11.86)	14 (0.9)
Chills	7 (0.9)	8 (1.0)	1.11 (0.42, 2.94)	15 (1.0)
Pyrexia	4 (0.5)	8 (1.0)	1.95 (0.63, 6.06)	12 (0.8)
Pain	4 (0.5)	6 (0.8)		10 (0.7)
Injection site swelling	0	5 (0.7)		5 (0.3)
Chest pain	0	2 (0.3)		2 (0.1)
Injection site pruritus	1 (0.1)	2 (0.3)		3 (0.2)
Exercise tolerance decreased	0	1 (0.1)		1 (<0.1)
Injection site hypoaesthesia	0	1 (0.1)		1 (<0.1)
Injection site lymphadenopathy	0	1 (0.1)		1 (<0.1)
Injection site mass	1 (0.1)	1 (0.1)		2 (0.1)
Injection site scab	0	1 (0.1)		1 (<0.1)
Peripheral swelling	1 (0.1)	1 (0.1)		2 (0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
General disorders and administration site conditions (Cont.)				
Precancerous condition	0	1 (0.1)		1 (<0.1)
Asthenia	1 (0.1)	0		1 (<0.1)
Chest discomfort	2 (0.3)	0		2 (0.1)
Impaired healing	1 (0.1)	0		1 (<0.1)
Injection site induration	1 (0.1)	0		1 (<0.1)
Injection site oedema	1 (0.1)	0		1 (<0.1)
Oedema peripheral	4 (0.5)	0		4 (0.3)
Polyp	1 (0.1)	0		1 (<0.1)
Reactogenicity event	1 (0.1)	0		1 (<0.1)
Investigations	5 (0.7)	2 (0.3)		7 (0.5)
Blood pressure systolic increased	0	1 (0.1)		1 (<0.1)
Transaminases increased	0	1 (0.1)		1 (<0.1)
C-reactive protein increased	1 (0.1)	0		1 (<0.1)
Heart rate increased	1 (0.1)	0		1 (<0.1)
Heart rate irregular	1 (0.1)	0		1 (<0.1)
Hepatic enzyme increased	2 (0.3)	0		2 (0.1)
Serum ferritin increased	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Injury, poisoning and procedural complications	24 (3.2)	22 (2.9)		46 (3.1)
Procedural pain	2 (0.3)	5 (0.7)		7 (0.5)
Arthropod bite	2 (0.3)	2 (0.3)		4 (0.3)
Fall	4 (0.5)	2 (0.3)		6 (0.4)
Muscle strain	1 (0.1)	2 (0.3)		3 (0.2)
Skin laceration	2 (0.3)	2 (0.3)		4 (0.3)
Tooth fracture	1 (0.1)	2 (0.3)		3 (0.2)
Arthropod sting	1 (0.1)	1 (0.1)		2 (0.1)
Contusion	1 (0.1)	1 (0.1)		2 (0.1)
Hand fracture	0	1 (0.1)		1 (<0.1)
Joint injury	1 (0.1)	1 (0.1)		2 (0.1)
Ligament sprain	3 (0.4)	1 (0.1)		4 (0.3)
Limb injury	0	1 (0.1)		1 (<0.1)
Post-traumatic pain	1 (0.1)	1 (0.1)		2 (0.1)
Road traffic accident	0	1 (0.1)		1 (<0.1)
Tooth injury	0	1 (0.1)		1 (<0.1)
Ankle fracture	1 (0.1)	0		1 (<0.1)
Buttock injury	1 (0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	1 (0.1)	0		1 (<0.1)
Foot fracture	1 (0.1)	0		1 (<0.1)
Lip injury	1 (0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Significant Cardiac Disease

System Organ Class Preferred Term	Placebo (N=742) n (%)	mRNA-1273 (N=762) n (%)	Rate Ratio (95% CI)	Total (N=1504) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (0.1)	0		1 (<0.1)
Skin abrasion	1 (0.1)	0		1 (<0.1)
Wrist fracture	1 (0.1)	0		1 (<0.1)
Product issues	1 (0.1)	0		1 (<0.1)
Lead dislodgement	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	327 (30.9)	378 (35.3)		705 (33.1)
Number of Unsolicited Adverse Events	747	847		1594
Infections and infestations	79 (7.5)	74 (6.9)		153 (7.2)
Urinary tract infection	8 (0.8)	10 (0.9)	1.24 (0.50, 3.03)	18 (0.8)
Sinusitis	2 (0.2)	5 (0.5)		7 (0.3)
Suspected COVID-19	6 (0.6)	5 (0.5)		11 (0.5)
Upper respiratory tract infection	6 (0.6)	4 (0.4)		10 (0.5)
Viral infection	4 (0.4)	4 (0.4)		8 (0.4)
Cellulitis	2 (0.2)	3 (0.3)		5 (0.2)
Ear infection	1 (<0.1)	3 (0.3)		4 (0.2)
Localised infection	1 (<0.1)	3 (0.3)		4 (0.2)
Pharyngitis streptococcal	3 (0.3)	3 (0.3)		6 (0.3)
Rhinovirus infection	0	3 (0.3)		3 (0.1)
Abscess limb	0	2 (0.2)		2 (<0.1)
Bronchitis	2 (0.2)	2 (0.2)		4 (0.2)
COVID-19	16 (1.5)	2 (0.2)	0.12 (0.03, 0.48)	18 (0.8)
Conjunctivitis	0	2 (0.2)		2 (<0.1)
Gastroenteritis	3 (0.3)	2 (0.2)		5 (0.2)
Otitis externa	0	2 (0.2)		2 (<0.1)
Pharyngitis	1 (<0.1)	2 (0.2)		3 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Infections and infestations (Cont.)				
Tooth abscess	4 (0.4)	2 (0.2)		6 (0.3)
Tooth infection	3 (0.3)	2 (0.2)		5 (0.2)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Acute sinusitis	0	1 (<0.1)		1 (<0.1)
Bacterial vaginosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diverticulitis	3 (0.3)	1 (<0.1)		4 (0.2)
Gingivitis	0	1 (<0.1)		1 (<0.1)
Helicobacter infection	0	1 (<0.1)		1 (<0.1)
Herpes zoster	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Oral herpes	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis media	0	1 (<0.1)		1 (<0.1)
Otitis media acute	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	0	1 (<0.1)		1 (<0.1)
Staphylococcal skin infection	0	1 (<0.1)		1 (<0.1)
Subcutaneous abscess	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Infections and infestations (Cont.)				
Viral rhinitis	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (0.2)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Folliculitis	1 (<0.1)	0		1 (<0.1)
Gastroenteritis viral	3 (0.3)	0		3 (0.1)
Herpes simplex	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Laryngitis	1 (<0.1)	0		1 (<0.1)
Onychomycosis	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin infection	1 (<0.1)	0		1 (<0.1)
Tinea cruris	1 (<0.1)	0		1 (<0.1)
Vulvovaginal mycotic infection	2 (0.2)	0		2 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.7)	4 (0.4)		11 (0.5)
Basal cell carcinoma	2 (0.2)	1 (<0.1)		3 (0.1)
Benign breast neoplasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	11 (1.0)	26 (2.4)		37 (1.7)
Lymphadenopathy	9 (0.9)	24 (2.2)	2.64 (1.25, 5.55)	33 (1.6)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	5 (0.5)	5 (0.5)		10 (0.5)
Seasonal allergy	4 (0.4)	4 (0.4)		8 (0.4)
Hypersensitivity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Metabolism and nutrition disorders	21 (2.0)	13 (1.2)		34 (1.6)
Type 2 diabetes mellitus	4 (0.4)	6 (0.6)		10 (0.5)
Vitamin D deficiency	1 (<0.1)	2 (0.2)		3 (0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Metabolism and nutrition disorders (Cont.)				
Dehydration	0	1 (<0.1)		1 (<0.1)
Glucose tolerance impaired	2 (0.2)	1 (<0.1)		3 (0.1)
Hypercholesterolaemia	2 (0.2)	1 (<0.1)		3 (0.1)
Hyperlipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Decreased appetite	2 (0.2)	0		2 (<0.1)
Diabetes mellitus	2 (0.2)	0		2 (<0.1)
Dyslipidaemia	2 (0.2)	0		2 (<0.1)
Gout	2 (0.2)	0		2 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Obesity	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	9 (0.9)	14 (1.3)		23 (1.1)
Anxiety	4 (0.4)	6 (0.6)		10 (0.5)
Depression	1 (<0.1)	3 (0.3)		4 (0.2)
Attention deficit hyperactivity disorder	2 (0.2)	1 (<0.1)		3 (0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Insomnia	3 (0.3)	1 (<0.1)		4 (0.2)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Psychiatric disorders (Cont.)				
Post-traumatic stress disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	73 (6.9)	74 (6.9)		147 (6.9)
Headache	59 (5.6)	62 (5.8)	1.04 (0.74, 1.47)	121 (5.7)
Dizziness	2 (0.2)	5 (0.5)		7 (0.3)
Hypoaesthesia	1 (<0.1)	2 (0.2)		3 (0.1)
Sciatica	1 (<0.1)	2 (0.2)		3 (0.1)
Ageusia	0	1 (<0.1)		1 (<0.1)
Anosmia	0	1 (<0.1)		1 (<0.1)
Dysgeusia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	0	1 (<0.1)		1 (<0.1)
Migraine	2 (0.2)	1 (<0.1)		3 (0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinus headache	2 (0.2)	1 (<0.1)		3 (0.1)
Syncope	0	1 (<0.1)		1 (<0.1)
Taste disorder	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Carpal tunnel syndrome	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Nervous system disorders (Cont.)				
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Parosmia	1 (<0.1)	0		1 (<0.1)
Somnolence	1 (<0.1)	0		1 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	0		1 (<0.1)
Eye disorders	5 (0.5)	2 (0.2)		7 (0.3)
Conjunctival haemorrhage	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0		1 (<0.1)
Eye pruritus	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	2 (0.2)	0		2 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	3 (0.3)	3 (0.3)		6 (0.3)
Vertigo	0	2 (0.2)		2 (<0.1)
Ear pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear canal erythema	1 (<0.1)	0		1 (<0.1)
Tinnitus	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	5 (0.5)	4 (0.4)		9 (0.4)
Palpitations	0	2 (0.2)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Cardiac disorders (Cont.)				
Tachycardia	0	2 (0.2)		2 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Angina pectoris	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	1 (<0.1)	0		1 (<0.1)
Cardiac failure congestive	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	20 (1.9)	16 (1.5)		36 (1.7)
Hypertension	15 (1.4)	15 (1.4)	0.99 (0.49, 1.98)	30 (1.4)
Hot flush	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Flushing	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	1 (<0.1)	0		1 (<0.1)
Hypertensive urgency	1 (<0.1)	0		1 (<0.1)
Systolic hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	50 (4.7)	50 (4.7)		100 (4.7)
Cough	19 (1.8)	21 (2.0)	1.09 (0.60, 2.00)	40 (1.9)
Oropharyngeal pain	13 (1.2)	13 (1.2)	0.99 (0.47, 2.09)	26 (1.2)

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Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinorrhoea	10 (0.9)	13 (1.2)	1.29 (0.58, 2.86)	23 (1.1)
Nasal congestion	17 (1.6)	10 (0.9)	0.58 (0.27, 1.24)	27 (1.3)
Dyspnoea	1 (<0.1)	8 (0.7)	7.91 (1.29, 48.70)	9 (0.4)
Asthma	4 (0.4)	4 (0.4)		8 (0.4)
Tachypnoea	2 (0.2)	3 (0.3)		5 (0.2)
Productive cough	0	2 (0.2)		2 (<0.1)
Respiratory tract congestion	0	2 (0.2)		2 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Epistaxis	0	1 (<0.1)		1 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Rhinitis allergic	0	1 (<0.1)		1 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)		1 (<0.1)
Throat irritation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Upper-airway cough syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic obstructive pulmonary disease	2 (0.2)	0		2 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Pleural effusion	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Sneezing	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Wheezing	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	45 (4.3)	52 (4.9)		97 (4.6)
Diarrhoea	14 (1.3)	24 (2.2)	1.70 (0.89, 3.22)	38 (1.8)
Nausea	13 (1.2)	15 (1.4)	1.14 (0.55, 2.35)	28 (1.3)
Gastrooesophageal reflux disease	3 (0.3)	5 (0.5)		8 (0.4)
Vomiting	3 (0.3)	4 (0.4)		7 (0.3)
Toothache	5 (0.5)	3 (0.3)		8 (0.4)
Abdominal pain	1 (<0.1)	2 (0.2)		3 (0.1)
Abdominal distension	0	1 (<0.1)		1 (<0.1)
Abdominal pain upper	1 (<0.1)	1 (<0.1)		2 (<0.1)
Constipation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dental caries	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry mouth	0	1 (<0.1)		1 (<0.1)
Gastric ulcer	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Tooth impacted	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	2 (0.2)	0		2 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Severe Obesity

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Gastrointestinal disorders (Cont.)				
Dysphagia	1 (<0.1)	0		1 (<0.1)
Food poisoning	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholelithiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin and subcutaneous tissue disorders	9 (0.9)	16 (1.5)		25 (1.2)
Ecchymosis	0	3 (0.3)		3 (0.1)
Rash	1 (<0.1)	2 (0.2)		3 (0.1)
Blister	0	1 (<0.1)		1 (<0.1)
Dermatitis atopic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eczema	0	1 (<0.1)		1 (<0.1)
Erythema	0	1 (<0.1)		1 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Hyperhidrosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash maculo-papular	0	1 (<0.1)		1 (<0.1)
Skin ulcer	0	1 (<0.1)		1 (<0.1)
Urticaria	3 (0.3)	1 (<0.1)		4 (0.2)
Angioedema	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Severe Obesity

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Skin and subcutaneous tissue disorders (Cont.)				
Night sweats	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	87 (8.2)	91 (8.5)		178 (8.4)
Myalgia	33 (3.1)	39 (3.6)	1.17 (0.74, 1.84)	72 (3.4)
Arthralgia	45 (4.3)	38 (3.6)	0.83 (0.55, 1.27)	83 (3.9)
Back pain	7 (0.7)	9 (0.8)	1.27 (0.49, 3.28)	16 (0.8)
Pain in extremity	5 (0.5)	9 (0.8)	1.78 (0.63, 5.05)	14 (0.7)
Musculoskeletal pain	4 (0.4)	7 (0.7)	1.73 (0.54, 5.52)	11 (0.5)
Muscle spasms	4 (0.4)	6 (0.6)		10 (0.5)
Neck pain	4 (0.4)	4 (0.4)		8 (0.4)
Osteoarthritis	3 (0.3)	4 (0.4)		7 (0.3)
Arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Axillary mass	0	1 (<0.1)		1 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Bursitis	0	1 (<0.1)		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	2 (0.2)	1 (<0.1)		3 (0.1)
Musculoskeletal stiffness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Musculoskeletal and connective tissue disorders (Cont.)				
Osteitis	0	1 (<0.1)		1 (<0.1)
Pain in jaw	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal osteoarthritis	0	1 (<0.1)		1 (<0.1)
Spinal stenosis	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Exostosis	1 (<0.1)	0		1 (<0.1)
Fibromyalgia	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	2 (0.2)	0		2 (<0.1)
Joint swelling	1 (<0.1)	0		1 (<0.1)
Plantar fasciitis	2 (0.2)	0		2 (<0.1)
Renal and urinary disorders	7 (0.7)	4 (0.4)		11 (0.5)
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysuria	0	1 (<0.1)		1 (<0.1)
Nephrolithiasis	2 (0.2)	1 (<0.1)		3 (0.1)
Urinary incontinence	0	1 (<0.1)		1 (<0.1)
Acute kidney injury	2 (0.2)	0		2 (<0.1)
Chronic kidney disease	1 (<0.1)	0		1 (<0.1)
Renal cyst	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Renal and urinary disorders (Cont.)				
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	6 (0.6)	5 (0.5)		11 (0.5)
Dysmenorrhoea	1 (<0.1)	2 (0.2)		3 (0.1)
Erectile dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (0.2)	0		2 (<0.1)
Prostatitis	1 (<0.1)	0		1 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	97 (9.2)	147 (13.7)		244 (11.5)
Fatigue	59 (5.6)	79 (7.4)	1.32 (0.96, 1.83)	138 (6.5)
Injection site pain	11 (1.0)	22 (2.1)	1.98 (0.98, 4.00)	33 (1.6)
Injection site swelling	5 (0.5)	20 (1.9)	3.96 (1.54, 10.15)	25 (1.2)
Injection site erythema	3 (0.3)	16 (1.5)	5.27 (1.65, 16.90)	19 (0.9)
Chills	10 (0.9)	12 (1.1)	1.19 (0.53, 2.67)	22 (1.0)
Pyrexia	6 (0.6)	10 (0.9)	1.65 (0.62, 4.35)	16 (0.8)
Injection site pruritus	2 (0.2)	9 (0.8)	4.45 (1.09, 18.24)	11 (0.5)
Injection site induration	3 (0.3)	7 (0.7)	2.31 (0.65, 8.17)	10 (0.5)

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Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
General disorders and administration site conditions (Cont.)				
Injection site urticaria	0	5 (0.5)		5 (0.2)
Pain	4 (0.4)	5 (0.5)		9 (0.4)
Injection site lymphadenopathy	2 (0.2)	3 (0.3)		5 (0.2)
Injection site macule	0	3 (0.3)		3 (0.1)
Axillary pain	0	2 (0.2)		2 (<0.1)
Chest discomfort	4 (0.4)	2 (0.2)		6 (0.3)
Injection site bruising	1 (<0.1)	2 (0.2)		3 (0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Cyst	0	1 (<0.1)		1 (<0.1)
Feeling hot	0	1 (<0.1)		1 (<0.1)
Injection site haemorrhage	0	1 (<0.1)		1 (<0.1)
Injection site papule	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	2 (0.2)	1 (<0.1)		3 (0.1)
Peripheral swelling	2 (0.2)	1 (<0.1)		3 (0.1)
Chest pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (0.2)	0		2 (<0.1)
Injection site discomfort	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
General disorders and administration site conditions (Cont.)				
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Investigations	8 (0.8)	10 (0.9)		18 (0.8)
Blood pressure increased	3 (0.3)	2 (0.2)		5 (0.2)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	2 (0.2)	1 (<0.1)		3 (0.1)
Blood triglycerides increased	0	1 (<0.1)		1 (<0.1)
Body temperature increased	0	1 (<0.1)		1 (<0.1)
Cardiac murmur	0	1 (<0.1)		1 (<0.1)
Heart rate increased	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	2 (0.2)	0		2 (<0.1)
Glycosylated haemoglobin increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	37 (3.5)	29 (2.7)		66 (3.1)
Fall	3 (0.3)	3 (0.3)		6 (0.3)
Foot fracture	4 (0.4)	3 (0.3)		7 (0.3)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural pain	2 (0.2)	3 (0.3)		5 (0.2)
Road traffic accident	0	3 (0.3)		3 (0.1)
Contusion	1 (<0.1)	2 (0.2)		3 (0.1)
Joint injury	2 (0.2)	2 (0.2)		4 (0.2)
Ligament sprain	2 (0.2)	2 (0.2)		4 (0.2)
Muscle strain	5 (0.5)	2 (0.2)		7 (0.3)
Skin laceration	4 (0.4)	2 (0.2)		6 (0.3)
Tendon rupture	1 (<0.1)	2 (0.2)		3 (0.1)
Tooth fracture	1 (<0.1)	2 (0.2)		3 (0.1)
Animal bite	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Concussion	2 (0.2)	1 (<0.1)		3 (0.1)
Exposure to SARS-CoV-2	0	1 (<0.1)		1 (<0.1)
Post-traumatic pain	0	1 (<0.1)		1 (<0.1)
Thermal burn	0	1 (<0.1)		1 (<0.1)
Arthropod bite	6 (0.6)	0		6 (0.3)
Corneal abrasion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Hand fracture	1 (<0.1)	0		1 (<0.1)
Muscle rupture	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Severe Obesity

System Organ Class Preferred Term	Placebo (N=1058) n (%)	mRNA-1273 (N=1070) n (%)	Rate Ratio (95% CI)	Total (N=2128) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin abrasion	2 (0.2)	0		2 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Sunburn	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	453 (31.1)	479 (32.8)		932 (32.0)
Number of Unsolicited Adverse Events	925	971		1896
Infections and infestations	81 (5.6)	75 (5.1)		156 (5.3)
Urinary tract infection	11 (0.8)	18 (1.2)	1.63 (0.79, 3.39)	29 (1.0)
Sinusitis	3 (0.2)	7 (0.5)	2.33 (0.66, 8.25)	10 (0.3)
Upper respiratory tract infection	11 (0.8)	6 (0.4)	0.54 (0.21, 1.41)	17 (0.6)
Herpes zoster	2 (0.1)	3 (0.2)		5 (0.2)
Pharyngitis	3 (0.2)	3 (0.2)		6 (0.2)
Suspected COVID-19	1 (<0.1)	3 (0.2)		4 (0.1)
COVID-19	9 (0.6)	2 (0.1)	0.22 (0.05, 0.91)	11 (0.4)
Gastroenteritis	5 (0.3)	2 (0.1)		7 (0.2)
Helicobacter infection	0	2 (0.1)		2 (<0.1)
Herpes simplex	0	2 (0.1)		2 (<0.1)
Laryngitis	0	2 (0.1)		2 (<0.1)
Localised infection	2 (0.1)	2 (0.1)		4 (0.1)
Otitis externa	0	2 (0.1)		2 (<0.1)
Otitis media	1 (<0.1)	2 (0.1)		3 (0.1)
Tooth infection	1 (<0.1)	2 (0.1)		3 (0.1)
Viral infection	3 (0.2)	2 (0.1)		5 (0.2)
Vulvovaginal candidiasis	0	2 (0.1)		2 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Infections and infestations (Cont.)				
Abscess limb	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	0	1 (<0.1)		1 (<0.1)
Bronchitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cellulitis	3 (0.2)	1 (<0.1)		4 (0.1)
Conjunctivitis bacterial	0	1 (<0.1)		1 (<0.1)
Coronavirus infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	0	1 (<0.1)		1 (<0.1)
Gingivitis	0	1 (<0.1)		1 (<0.1)
Kidney infection	0	1 (<0.1)		1 (<0.1)
Nasopharyngitis	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection viral	0	1 (<0.1)		1 (<0.1)
Rhinovirus infection	2 (0.1)	1 (<0.1)		3 (0.1)
Tooth abscess	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Breast abscess	1 (<0.1)	0		1 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Infections and infestations (Cont.)				
Candida infection	2 (0.1)	0		2 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Ear infection	2 (0.1)	0		2 (<0.1)
Eye infection	1 (<0.1)	0		1 (<0.1)
Folliculitis	1 (<0.1)	0		1 (<0.1)
Fungal infection	2 (0.1)	0		2 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Oral candidiasis	1 (<0.1)	0		1 (<0.1)
Oral herpes	1 (<0.1)	0		1 (<0.1)
Paronychia	1 (<0.1)	0		1 (<0.1)
Pneumonia	3 (0.2)	0		3 (0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Postoperative wound infection	1 (<0.1)	0		1 (<0.1)
Skin infection	2 (0.1)	0		2 (<0.1)
Subcutaneous abscess	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Vulvovaginal mycotic infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (0.5)	8 (0.5)		16 (0.5)
Basal cell carcinoma	3 (0.2)	1 (<0.1)		4 (0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign neoplasm of skin	0	1 (<0.1)		1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Skin cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma of skin	2 (0.1)	0		2 (<0.1)
Blood and lymphatic system disorders	13 (0.9)	27 (1.8)		40 (1.4)
Lymphadenopathy	10 (0.7)	23 (1.6)	2.30 (1.11, 4.73)	33 (1.1)
Anaemia	3 (0.2)	3 (0.2)		6 (0.2)
Lymph node pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Immune system disorders	6 (0.4)	5 (0.3)		11 (0.4)
Seasonal allergy	5 (0.3)	5 (0.3)		10 (0.3)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Endocrine disorders	0	2 (0.1)		2 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypothyroidism	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	26 (1.8)	29 (2.0)		55 (1.9)
Type 2 diabetes mellitus	5 (0.3)	11 (0.8)	2.20 (0.80, 6.04)	16 (0.5)
Hyperlipidaemia	3 (0.2)	4 (0.3)		7 (0.2)
Diabetes mellitus	5 (0.3)	3 (0.2)		8 (0.3)
Dehydration	1 (<0.1)	2 (0.1)		3 (0.1)
Hypercholesterolaemia	1 (<0.1)	2 (0.1)		3 (0.1)
Vitamin D deficiency	2 (0.1)	2 (0.1)		4 (0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Decreased appetite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoglycaemia	2 (0.1)	1 (<0.1)		3 (0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Iron deficiency	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Psychiatric disorders	7 (0.5)	13 (0.9)		20 (0.7)
Anxiety	3 (0.2)	5 (0.3)		8 (0.3)
Insomnia	1 (<0.1)	3 (0.2)		4 (0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Depression	4 (0.3)	1 (<0.1)		5 (0.2)
Hallucination	0	1 (<0.1)		1 (<0.1)
Stress	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	81 (5.6)	91 (6.2)		172 (5.9)
Headache	61 (4.2)	66 (4.5)	1.08 (0.77, 1.52)	127 (4.4)
Dizziness	7 (0.5)	8 (0.5)	1.14 (0.43, 3.02)	15 (0.5)
Paraesthesia	0	3 (0.2)		3 (0.1)
Ageusia	1 (<0.1)	2 (0.1)		3 (0.1)
Carpal tunnel syndrome	2 (0.1)	2 (0.1)		4 (0.1)
Sinus headache	0	2 (0.1)		2 (<0.1)
Anosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burning sensation	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Nervous system disorders (Cont.)				
Migraine	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neuralgia	2 (0.1)	1 (<0.1)		3 (0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Syncope	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Balance disorder	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Presyncope	2 (0.1)	0		2 (<0.1)
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)
Sciatica	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)
Eye disorders	6 (0.4)	5 (0.3)		11 (0.4)
Blepharitis	0	1 (<0.1)		1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Eye disorders (Cont.)				
Eye pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal detachment	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Cataract	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	11 (0.8)	9 (0.6)		20 (0.7)
Ear pain	3 (0.2)	4 (0.3)		7 (0.2)
Vertigo	2 (0.1)	3 (0.2)		5 (0.2)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear canal erythema	1 (<0.1)	0		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Tinnitus	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	11 (0.8)	6 (0.4)		17 (0.6)
Sinus tachycardia	0	2 (0.1)		2 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Cardiac disorders (Cont.)				
Tachycardia	2 (0.1)	2 (0.1)		4 (0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Angina pectoris	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	3 (0.2)	0		3 (0.1)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Bradycardia	1 (<0.1)	0		1 (<0.1)
Coronary artery disease	1 (<0.1)	0		1 (<0.1)
Palpitations	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	20 (1.4)	16 (1.1)		36 (1.2)
Hypertension	18 (1.2)	13 (0.9)	0.72 (0.36, 1.44)	31 (1.1)
Hot flush	0	1 (<0.1)		1 (<0.1)
Hypotension	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Hypertensive urgency	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Respiratory, thoracic and mediastinal disorders	72 (4.9)	59 (4.0)		131 (4.5)
Cough	19 (1.3)	27 (1.8)	1.42 (0.80, 2.52)	46 (1.6)
Nasal congestion	21 (1.4)	21 (1.4)	1.00 (0.55, 1.80)	42 (1.4)
Rhinorrhoea	15 (1.0)	16 (1.1)	1.06 (0.54, 2.12)	31 (1.1)
Oropharyngeal pain	19 (1.3)	14 (1.0)	0.74 (0.37, 1.44)	33 (1.1)
Dyspnoea	3 (0.2)	4 (0.3)		7 (0.2)
Respiratory tract congestion	0	2 (0.1)		2 (<0.1)
Rhinitis allergic	1 (<0.1)	2 (0.1)		3 (0.1)
Sinus congestion	4 (0.3)	2 (0.1)		6 (0.2)
Upper-airway cough syndrome	0	2 (0.1)		2 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Asthma	2 (0.1)	1 (<0.1)		3 (0.1)
Epistaxis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Paranasal sinus hypersecretion	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	0	1 (<0.1)		1 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Productive cough	0	1 (<0.1)		1 (<0.1)
Respiratory disorder	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Tachypnoea	3 (0.2)	1 (<0.1)		4 (0.1)
Chronic obstructive pulmonary disease	2 (0.1)	0		2 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Sneezing	2 (0.1)	0		2 (<0.1)
Wheezing	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	52 (3.6)	71 (4.9)		123 (4.2)
Nausea	15 (1.0)	23 (1.6)	1.53 (0.81, 2.89)	38 (1.3)
Diarrhoea	27 (1.9)	21 (1.4)	0.78 (0.44, 1.36)	48 (1.6)
Vomiting	2 (0.1)	10 (0.7)	4.99 (1.23, 20.23)	12 (0.4)
Gastrooesophageal reflux disease	3 (0.2)	4 (0.3)		7 (0.2)
Dental caries	0	3 (0.2)		3 (0.1)
Toothache	2 (0.1)	3 (0.2)		5 (0.2)
Abdominal distension	0	2 (0.1)		2 (<0.1)
Abdominal pain	1 (<0.1)	2 (0.1)		3 (0.1)
Colitis	1 (<0.1)	2 (0.1)		3 (0.1)
Constipation	0	2 (0.1)		2 (<0.1)
Hiatus hernia	0	2 (0.1)		2 (<0.1)
Abdominal pain lower	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Gastrointestinal disorders (Cont.)				
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flatulence	0	1 (<0.1)		1 (<0.1)
Food poisoning	1 (<0.1)	1 (<0.1)		2 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastric ulcer	0	1 (<0.1)		1 (<0.1)
Gastritis	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	1 (<0.1)	0		1 (<0.1)
Abdominal pain upper	1 (<0.1)	0		1 (<0.1)
Dry mouth	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Loose tooth	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	3 (0.2)	0		3 (0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Hepatobiliary disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholelithiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	25 (1.7)	24 (1.6)		49 (1.7)
Dermatitis contact	3 (0.2)	3 (0.2)		6 (0.2)
Urticaria	2 (0.1)	3 (0.2)		5 (0.2)
Macule	0	2 (0.1)		2 (<0.1)
Pain of skin	0	2 (0.1)		2 (<0.1)
Rash	4 (0.3)	2 (0.1)		6 (0.2)
Acne	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia	0	1 (<0.1)		1 (<0.1)
Dermatitis atopic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eczema	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Pruritus	3 (0.2)	1 (<0.1)		4 (0.1)
Rash erythematous	0	1 (<0.1)		1 (<0.1)
Rash maculo-papular	0	1 (<0.1)		1 (<0.1)
Rash papular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rosacea	0	1 (<0.1)		1 (<0.1)
Skin ulcer	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Actinic keratosis	1 (<0.1)	0		1 (<0.1)
Dermatitis	1 (<0.1)	0		1 (<0.1)
Hyperhidrosis	2 (0.1)	0		2 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Night sweats	1 (<0.1)	0		1 (<0.1)
Papule	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	1 (<0.1)	0		1 (<0.1)
Petechiae	1 (<0.1)	0		1 (<0.1)
Psoriasis	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	129 (8.9)	110 (7.5)		239 (8.2)
Myalgia	50 (3.4)	52 (3.6)	1.04 (0.71, 1.52)	102 (3.5)
Arthralgia	57 (3.9)	42 (2.9)	0.74 (0.50, 1.09)	99 (3.4)
Back pain	11 (0.8)	11 (0.8)	1.00 (0.44, 2.24)	22 (0.8)
Pain in extremity	5 (0.3)	10 (0.7)	2.00 (0.72, 5.57)	15 (0.5)
Neck pain	3 (0.2)	6 (0.4)		9 (0.3)
Musculoskeletal pain	8 (0.5)	4 (0.3)	0.50 (0.16, 1.55)	12 (0.4)
Osteoarthritis	6 (0.4)	3 (0.2)		9 (0.3)
Muscle spasms	3 (0.2)	2 (0.1)		5 (0.2)

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Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in jaw	1 (<0.1)	2 (0.1)		3 (0.1)
Spinal stenosis	1 (<0.1)	2 (0.1)		3 (0.1)
Tendonitis	1 (<0.1)	2 (0.1)		3 (0.1)
Trigger finger	2 (0.1)	2 (0.1)		4 (0.1)
Bursitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	0	1 (<0.1)		1 (<0.1)
Joint range of motion decreased	0	1 (<0.1)		1 (<0.1)
Muscle tightness	0	1 (<0.1)		1 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	3 (0.2)	1 (<0.1)		4 (0.1)
Musculoskeletal stiffness	2 (0.1)	1 (<0.1)		3 (0.1)
Osteoporosis	0	1 (<0.1)		1 (<0.1)
Periarthritis	0	1 (<0.1)		1 (<0.1)
Rotator cuff syndrome	3 (0.2)	1 (<0.1)		4 (0.1)
Spinal pain	0	1 (<0.1)		1 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Axillary mass	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Groin pain	1 (<0.1)	0		1 (<0.1)
Joint swelling	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Limb discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	8 (0.5)	10 (0.7)		18 (0.6)
Nephrolithiasis	5 (0.3)	4 (0.3)		9 (0.3)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic kidney disease	0	1 (<0.1)		1 (<0.1)
Dysuria	0	1 (<0.1)		1 (<0.1)
Hypertonic bladder	0	1 (<0.1)		1 (<0.1)
Pollakiuria	0	1 (<0.1)		1 (<0.1)
Urinary incontinence	0	1 (<0.1)		1 (<0.1)
Haematuria	1 (<0.1)	0		1 (<0.1)
Renal cyst	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urinary retention	2 (0.1)	0		2 (<0.1)

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Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Reproductive system and breast disorders	1 (<0.1)	2 (0.1)		3 (0.1)
Erectile dysfunction	0	1 (<0.1)		1 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)		1 (<0.1)
Prostatitis	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	0	1 (<0.1)		1 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	103 (7.1)	155 (10.6)		258 (8.8)
Fatigue	56 (3.8)	80 (5.5)	1.43 (1.02, 1.99)	136 (4.7)
Injection site pain	15 (1.0)	27 (1.8)	1.80 (0.97, 3.33)	42 (1.4)
Chills	8 (0.5)	17 (1.2)	2.12 (0.94, 4.79)	25 (0.9)
Injection site erythema	5 (0.3)	12 (0.8)	2.40 (0.88, 6.51)	17 (0.6)
Pyrexia	5 (0.3)	11 (0.8)	2.20 (0.80, 6.04)	16 (0.5)
Injection site pruritus	1 (<0.1)	6 (0.4)		7 (0.2)
Pain	12 (0.8)	6 (0.4)	0.50 (0.19, 1.28)	18 (0.6)
Injection site swelling	5 (0.3)	5 (0.3)		10 (0.3)
Injection site urticaria	0	5 (0.3)		5 (0.2)
Axillary pain	1 (<0.1)	4 (0.3)		5 (0.2)
Injection site macule	0	4 (0.3)		4 (0.1)

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Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
General disorders and administration site conditions (Cont.)				
Injection site induration	3 (0.2)	3 (0.2)		6 (0.2)
Injection site lymphadenopathy	1 (<0.1)	3 (0.2)		4 (0.1)
Chest pain	0	2 (0.1)		2 (<0.1)
Injection site bruising	1 (<0.1)	2 (0.1)		3 (0.1)
Chest discomfort	3 (0.2)	1 (<0.1)		4 (0.1)
Cyst	0	1 (<0.1)		1 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site mass	0	1 (<0.1)		1 (<0.1)
Injection site papule	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	2 (0.1)	1 (<0.1)		3 (0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Precancerous condition	0	1 (<0.1)		1 (<0.1)
Reactogenicity event	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (0.1)	0		2 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
General disorders and administration site conditions (Cont.)				
Injection site discomfort	1 (<0.1)	0		1 (<0.1)
Injection site haemorrhage	1 (<0.1)	0		1 (<0.1)
Injection site paraesthesia	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Peripheral swelling	1 (<0.1)	0		1 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)
Investigations	8 (0.5)	9 (0.6)		17 (0.6)
Blood pressure increased	1 (<0.1)	2 (0.1)		3 (0.1)
Blood cholesterol increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	2 (0.1)	1 (<0.1)		3 (0.1)
Blood triglycerides increased	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	1 (<0.1)	0		1 (<0.1)
Heart rate increased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Investigations (Cont.)				
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Weight decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	65 (4.5)	31 (2.1)		96 (3.3)
Ligament sprain	4 (0.3)	3 (0.2)		7 (0.2)
Arthropod bite	7 (0.5)	2 (0.1)	0.29 (0.07, 1.20)	9 (0.3)
Concussion	0	2 (0.1)		2 (<0.1)
Contusion	4 (0.3)	2 (0.1)		6 (0.2)
Fall	8 (0.5)	2 (0.1)	0.25 (0.06, 1.04)	10 (0.3)
Limb injury	0	2 (0.1)		2 (<0.1)
Muscle strain	9 (0.6)	2 (0.1)	0.22 (0.05, 0.91)	11 (0.4)
Procedural pain	2 (0.1)	2 (0.1)		4 (0.1)
Road traffic accident	1 (<0.1)	2 (0.1)		3 (0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Arthropod sting	2 (0.1)	1 (<0.1)		3 (0.1)
Back injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Foot fracture	3 (0.2)	1 (<0.1)		4 (0.1)
Heat exhaustion	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Injury, poisoning and procedural complications (Cont.)				
Joint injury	3 (0.2)	1 (<0.1)		4 (0.1)
Ligament rupture	0	1 (<0.1)		1 (<0.1)
Rib fracture	0	1 (<0.1)		1 (<0.1)
Skin abrasion	5 (0.3)	1 (<0.1)		6 (0.2)
Sunburn	0	1 (<0.1)		1 (<0.1)
Tendon rupture	0	1 (<0.1)		1 (<0.1)
Thermal burn	0	1 (<0.1)		1 (<0.1)
Tooth fracture	6 (0.4)	1 (<0.1)		7 (0.2)
Tooth injury	0	1 (<0.1)		1 (<0.1)
Bone contusion	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Corneal abrasion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Lower limb fracture	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	3 (0.2)	0		3 (0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Diabetes

System Organ Class Preferred Term	Placebo (N=1457) n (%)	mRNA-1273 (N=1460) n (%)	Rate Ratio (95% CI)	Total (N=2917) n (%)
Injury, poisoning and procedural complications (Cont.)				
Scar	1 (<0.1)	0		1 (<0.1)
Skin laceration	4 (0.3)	0		4 (0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

System Organ Class Preferred Term	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Rate Ratio (95% CI)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	42 (43.8)	37 (35.6)		79 (39.5)
Number of Unsolicited Adverse Events	109	88		197
Infections and infestations	9 (9.4)	5 (4.8)		14 (7.0)
Abscess limb	0	1 (1.0)		1 (0.5)
Otitis media	0	1 (1.0)		1 (0.5)
Pneumonia mycoplasmal	0	1 (1.0)		1 (0.5)
Sepsis	0	1 (1.0)		1 (0.5)
Sinusitis	0	1 (1.0)		1 (0.5)
Tooth infection	1 (1.0)	1 (1.0)		2 (1.0)
COVID-19	2 (2.1)	0		2 (1.0)
Candida infection	1 (1.0)	0		1 (0.5)
Herpes zoster	2 (2.1)	0		2 (1.0)
Oral herpes	1 (1.0)	0		1 (0.5)
Suspected COVID-19	1 (1.0)	0		1 (0.5)
Upper respiratory tract infection	1 (1.0)	0		1 (0.5)
Urinary tract infection	1 (1.0)	0		1 (0.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.0)		1 (0.5)
Benign hepatic neoplasm	0	1 (1.0)		1 (0.5)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

System Organ Class Preferred Term	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Rate Ratio (95% CI)	Total (N=200) n (%)
Blood and lymphatic system disorders	3 (3.1)	4 (3.8)		7 (3.5)
Lymphadenopathy	2 (2.1)	4 (3.8)		6 (3.0)
Anaemia	1 (1.0)	0		1 (0.5)
Immune system disorders	0	3 (2.9)		3 (1.5)
Seasonal allergy	0	2 (1.9)		2 (1.0)
Sarcoidosis	0	1 (1.0)		1 (0.5)
Metabolism and nutrition disorders	1 (1.0)	3 (2.9)		4 (2.0)
Abnormal loss of weight	0	1 (1.0)		1 (0.5)
Decreased appetite	0	1 (1.0)		1 (0.5)
Glucose tolerance impaired	0	1 (1.0)		1 (0.5)
Hyperlipidaemia	0	1 (1.0)		1 (0.5)
Gout	1 (1.0)	0		1 (0.5)
Nervous system disorders	13 (13.5)	9 (8.7)		22 (11.0)
Headache	8 (8.3)	9 (8.7)	1.04 (0.43, 2.52)	17 (8.5)
Dizziness	1 (1.0)	0		1 (0.5)
Dysgeusia	2 (2.1)	0		2 (1.0)
Dyskinesia	1 (1.0)	0		1 (0.5)
Sciatica	1 (1.0)	0		1 (0.5)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

System Organ Class Preferred Term	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Rate Ratio (95% CI)	Total (N=200) n (%)
Eye disorders	2 (2.1)	1 (1.0)		3 (1.5)
Retinal detachment	0	1 (1.0)		1 (0.5)
Eye pruritus	1 (1.0)	0		1 (0.5)
Ocular hyperaemia	1 (1.0)	0		1 (0.5)
Periorbital swelling	1 (1.0)	0		1 (0.5)
Ear and labyrinth disorders	2 (2.1)	0		2 (1.0)
Tinnitus	2 (2.1)	0		2 (1.0)
Cardiac disorders	1 (1.0)	0		1 (0.5)
Tachycardia	1 (1.0)	0		1 (0.5)
Vascular disorders	2 (2.1)	0		2 (1.0)
Hypertension	2 (2.1)	0		2 (1.0)
Respiratory, thoracic and mediastinal disorders	8 (8.3)	7 (6.7)		15 (7.5)
Bronchospasm	0	1 (1.0)		1 (0.5)
Cough	1 (1.0)	1 (1.0)		2 (1.0)
Dyspnoea	0	1 (1.0)		1 (0.5)
Dyspnoea exertional	0	1 (1.0)		1 (0.5)
Nasal congestion	0	1 (1.0)		1 (0.5)
Oropharyngeal pain	2 (2.1)	1 (1.0)		3 (1.5)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

System Organ Class Preferred Term	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Rate Ratio (95% CI)	Total (N=200) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pleural effusion	0	1 (1.0)		1 (0.5)
Respiratory failure	0	1 (1.0)		1 (0.5)
Respiratory tract congestion	1 (1.0)	1 (1.0)		2 (1.0)
Rhinorrhoea	2 (2.1)	1 (1.0)		3 (1.5)
Sneezing	0	1 (1.0)		1 (0.5)
Upper-airway cough syndrome	0	1 (1.0)		1 (0.5)
Asthma	1 (1.0)	0		1 (0.5)
Dry throat	1 (1.0)	0		1 (0.5)
Pleuritic pain	1 (1.0)	0		1 (0.5)
Sinus congestion	1 (1.0)	0		1 (0.5)
Gastrointestinal disorders	7 (7.3)	7 (6.7)		14 (7.0)
Abdominal pain upper	0	1 (1.0)		1 (0.5)
Anal fissure	0	1 (1.0)		1 (0.5)
Colitis	0	1 (1.0)		1 (0.5)
Diarrhoea	4 (4.2)	1 (1.0)		5 (2.5)
Dysphagia	0	1 (1.0)		1 (0.5)
Frequent bowel movements	0	1 (1.0)		1 (0.5)
Gastrooesophageal reflux disease	1 (1.0)	1 (1.0)		2 (1.0)
Haemorrhoids	0	1 (1.0)		1 (0.5)
Nausea	0	1 (1.0)		1 (0.5)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

System Organ Class Preferred Term	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Rate Ratio (95% CI)	Total (N=200) n (%)
Gastrointestinal disorders (Cont.)				
Pancreatitis acute	0	1 (1.0)		1 (0.5)
Proctitis	0	1 (1.0)		1 (0.5)
Constipation	1 (1.0)	0		1 (0.5)
Noninfective gingivitis	1 (1.0)	0		1 (0.5)
Oral mucosal erythema	1 (1.0)	0		1 (0.5)
Paraesthesia oral	1 (1.0)	0		1 (0.5)
Hepatobiliary disorders	0	1 (1.0)		1 (0.5)
Bile duct stone	0	1 (1.0)		1 (0.5)
Skin and subcutaneous tissue disorders	4 (4.2)	3 (2.9)		7 (3.5)
Acne	0	1 (1.0)		1 (0.5)
Rash maculo-papular	0	1 (1.0)		1 (0.5)
Urticaria	1 (1.0)	1 (1.0)		2 (1.0)
Erythema	1 (1.0)	0		1 (0.5)
Pruritus	3 (3.1)	0		3 (1.5)
Musculoskeletal and connective tissue disorders	10 (10.4)	10 (9.6)		20 (10.0)
Arthralgia	5 (5.2)	5 (4.8)		10 (5.0)
Myalgia	4 (4.2)	5 (4.8)		9 (4.5)
Pain in extremity	0	4 (3.8)		4 (2.0)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

System Organ Class Preferred Term	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Rate Ratio (95% CI)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Back pain	1 (1.0)	1 (1.0)		2 (1.0)
Neck pain	0	1 (1.0)		1 (0.5)
Osteoarthritis	0	1 (1.0)		1 (0.5)
Intervertebral disc protrusion	1 (1.0)	0		1 (0.5)
Muscle spasms	1 (1.0)	0		1 (0.5)
Musculoskeletal pain	1 (1.0)	0		1 (0.5)
Renal and urinary disorders	1 (1.0)	0		1 (0.5)
Nephrolithiasis	1 (1.0)	0		1 (0.5)
General disorders and administration site conditions	17 (17.7)	8 (7.7)		25 (12.5)
Fatigue	9 (9.4)	7 (6.7)	0.72 (0.29, 1.80)	16 (8.0)
Chills	1 (1.0)	1 (1.0)		2 (1.0)
Injection site pain	2 (2.1)	1 (1.0)		3 (1.5)
Injection site pruritus	0	1 (1.0)		1 (0.5)
Chest discomfort	2 (2.1)	0		2 (1.0)
Facial pain	1 (1.0)	0		1 (0.5)
Injection site erythema	2 (2.1)	0		2 (1.0)
Non-cardiac chest pain	1 (1.0)	0		1 (0.5)
Pain	1 (1.0)	0		1 (0.5)

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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Liver Disease

System Organ Class Preferred Term	Placebo (N=96) n (%)	mRNA-1273 (N=104) n (%)	Rate Ratio (95% CI)	Total (N=200) n (%)
General disorders and administration site conditions (Cont.)				
Peripheral swelling	1 (1.0)	0		1 (0.5)
Swelling face	1 (1.0)	0		1 (0.5)
Investigations	1 (1.0)	0		1 (0.5)
Vitamin B12 decreased	1 (1.0)	0		1 (0.5)
Vitamin D decreased	1 (1.0)	0		1 (0.5)
Injury, poisoning and procedural complications	4 (4.2)	2 (1.9)		6 (3.0)
Head injury	0	1 (1.0)		1 (0.5)
Procedural pain	0	1 (1.0)		1 (0.5)
Contusion	1 (1.0)	0		1 (0.5)
Muscle strain	1 (1.0)	0		1 (0.5)
Patella fracture	1 (1.0)	0		1 (0.5)
Sunburn	1 (1.0)	0		1 (0.5)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	38 (41.8)	35 (37.2)		73 (39.5)
Number of Unsolicited Adverse Events	110	76		186
Infections and infestations	6 (6.6)	6 (6.4)		12 (6.5)
Gingivitis	0	1 (1.1)		1 (0.5)
Herpes simplex	0	1 (1.1)		1 (0.5)
Nail infection	0	1 (1.1)		1 (0.5)
Suspected COVID-19	0	1 (1.1)		1 (0.5)
Tooth infection	0	1 (1.1)		1 (0.5)
Upper respiratory tract infection	1 (1.1)	1 (1.1)		2 (1.1)
COVID-19	2 (2.2)	0		2 (1.1)
Cellulitis	1 (1.1)	0		1 (0.5)
Cystitis	1 (1.1)	0		1 (0.5)
Otitis externa	1 (1.1)	0		1 (0.5)
Sepsis	1 (1.1)	0		1 (0.5)
Viral infection	1 (1.1)	0		1 (0.5)
Viral upper respiratory tract infection	1 (1.1)	0		1 (0.5)
Immune system disorders	2 (2.2)	0		2 (1.1)
Seasonal allergy	2 (2.2)	0		2 (1.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Metabolism and nutrition disorders	3 (3.3)	3 (3.2)		6 (3.2)
Abnormal loss of weight	0	1 (1.1)		1 (0.5)
Hyperlipidaemia	0	1 (1.1)		1 (0.5)
Hypoferritinaemia	0	1 (1.1)		1 (0.5)
Dyslipidaemia	1 (1.1)	0		1 (0.5)
Electrolyte imbalance	1 (1.1)	0		1 (0.5)
Hypercholesterolaemia	1 (1.1)	0		1 (0.5)
Hypocalcaemia	1 (1.1)	0		1 (0.5)
Hypoglycaemia	1 (1.1)	0		1 (0.5)
Hypokalaemia	1 (1.1)	0		1 (0.5)
Hypomagnesaemia	1 (1.1)	0		1 (0.5)
Psychiatric disorders	4 (4.4)	3 (3.2)		7 (3.8)
Anxiety	1 (1.1)	1 (1.1)		2 (1.1)
Insomnia	0	1 (1.1)		1 (0.5)
Nightmare	0	1 (1.1)		1 (0.5)
Agitation	1 (1.1)	0		1 (0.5)
Depression	1 (1.1)	0		1 (0.5)
Mental status changes	1 (1.1)	0		1 (0.5)
Schizophrenia	1 (1.1)	0		1 (0.5)
Nervous system disorders	11 (12.1)	7 (7.4)		18 (9.7)
Headache	8 (8.8)	5 (5.3)	0.61 (0.21, 1.70)	13 (7.0)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Nervous system disorders (Cont.)				
Ageusia	1 (1.1)	1 (1.1)		2 (1.1)
Dizziness	1 (1.1)	1 (1.1)		2 (1.1)
Anosmia	1 (1.1)	0		1 (0.5)
Encephalopathy	1 (1.1)	0		1 (0.5)
Lethargy	1 (1.1)	0		1 (0.5)
Paraesthesia	1 (1.1)	0		1 (0.5)
Eye disorders	2 (2.2)	1 (1.1)		3 (1.6)
Eye pain	0	1 (1.1)		1 (0.5)
Eye pruritus	2 (2.2)	0		2 (1.1)
Lacrimation increased	1 (1.1)	0		1 (0.5)
Ear and labyrinth disorders	1 (1.1)	0		1 (0.5)
Tinnitus	1 (1.1)	0		1 (0.5)
Cardiac disorders	0	2 (2.1)		2 (1.1)
Bradycardia	0	1 (1.1)		1 (0.5)
Sinus tachycardia	0	1 (1.1)		1 (0.5)
Vascular disorders	5 (5.5)	1 (1.1)		6 (3.2)
Hot flush	0	1 (1.1)		1 (0.5)
Deep vein thrombosis	1 (1.1)	0		1 (0.5)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Vascular disorders (Cont.)				
Hypertension	2 (2.2)	0		2 (1.1)
Hypotension	1 (1.1)	0		1 (0.5)
Orthostatic hypotension	1 (1.1)	0		1 (0.5)
Respiratory, thoracic and mediastinal disorders	8 (8.8)	10 (10.6)		18 (9.7)
Cough	0	2 (2.1)		2 (1.1)
Nasal congestion	0	2 (2.1)		2 (1.1)
Rhinorrhoea	0	2 (2.1)		2 (1.1)
Asthma	0	1 (1.1)		1 (0.5)
Dry throat	0	1 (1.1)		1 (0.5)
Dysphonia	0	1 (1.1)		1 (0.5)
Dyspnoea	1 (1.1)	1 (1.1)		2 (1.1)
Rhinitis allergic	1 (1.1)	1 (1.1)		2 (1.1)
Sinus congestion	0	1 (1.1)		1 (0.5)
Sneezing	0	1 (1.1)		1 (0.5)
Tachypnoea	0	1 (1.1)		1 (0.5)
Atelectasis	1 (1.1)	0		1 (0.5)
Oropharyngeal pain	4 (4.4)	0		4 (2.2)
Tonsillar inflammation	1 (1.1)	0		1 (0.5)
Wheezing	1 (1.1)	0		1 (0.5)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Gastrointestinal disorders	7 (7.7)	7 (7.4)		14 (7.6)
Nausea	0	3 (3.2)		3 (1.6)
Diarrhoea	5 (5.5)	2 (2.1)		7 (3.8)
Colitis	0	1 (1.1)		1 (0.5)
Dry mouth	0	1 (1.1)		1 (0.5)
Hiatus hernia	0	1 (1.1)		1 (0.5)
Pancreatitis	0	1 (1.1)		1 (0.5)
Dyspepsia	1 (1.1)	0		1 (0.5)
Dysphagia	1 (1.1)	0		1 (0.5)
Skin and subcutaneous tissue disorders	2 (2.2)	5 (5.3)		7 (3.8)
Acne	1 (1.1)	1 (1.1)		2 (1.1)
Hyperhidrosis	0	1 (1.1)		1 (0.5)
Pruritus	0	1 (1.1)		1 (0.5)
Rash pruritic	0	1 (1.1)		1 (0.5)
Urticaria	0	1 (1.1)		1 (0.5)
Blister	1 (1.1)	0		1 (0.5)
Musculoskeletal and connective tissue disorders	9 (9.9)	3 (3.2)		12 (6.5)
Arthralgia	3 (3.3)	2 (2.1)		5 (2.7)
Myalgia	3 (3.3)	2 (2.1)		5 (2.7)
Pain in extremity	2 (2.2)	1 (1.1)		3 (1.6)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Groin pain	1 (1.1)	0		1 (0.5)
Musculoskeletal pain	1 (1.1)	0		1 (0.5)
Osteoarthritis	1 (1.1)	0		1 (0.5)
Osteonecrosis	1 (1.1)	0		1 (0.5)
General disorders and administration site conditions	15 (16.5)	11 (11.7)		26 (14.1)
Fatigue	10 (11.0)	7 (7.4)	0.68 (0.28, 1.65)	17 (9.2)
Chest pain	0	1 (1.1)		1 (0.5)
Chills	4 (4.4)	1 (1.1)		5 (2.7)
Injection site swelling	2 (2.2)	1 (1.1)		3 (1.6)
Pain	0	1 (1.1)		1 (0.5)
Chest discomfort	1 (1.1)	0		1 (0.5)
Injection site pruritus	1 (1.1)	0		1 (0.5)
Peripheral swelling	1 (1.1)	0		1 (0.5)
Pyrexia	1 (1.1)	0		1 (0.5)
Investigations	1 (1.1)	0		1 (0.5)
Blood pressure systolic increased	1 (1.1)	0		1 (0.5)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Individual Risk Factor for Severe COVID at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Human Immunodeficiency Virus Infection

System Organ Class Preferred Term	Placebo (N=91) n (%)	mRNA-1273 (N=94) n (%)	Rate Ratio (95% CI)	Total (N=185) n (%)
Injury, poisoning and procedural complications	2 (2.2)	1 (1.1)		3 (1.6)
Arthropod bite	0	1 (1.1)		1 (0.5)
Arthropod sting	1 (1.1)	0		1 (0.5)
Concussion	1 (1.1)	0		1 (0.5)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3265 (27.9)	3564 (30.4)		6829 (29.1)
Number of Unsolicited Adverse Events	6230	7048		13278
Infections and infestations	731 (6.2)	593 (5.1)		1324 (5.6)
Upper respiratory tract infection	92 (0.8)	67 (0.6)	0.73 (0.53, 0.99)	159 (0.7)
Urinary tract infection	93 (0.8)	63 (0.5)	0.68 (0.49, 0.93)	156 (0.7)
Sinusitis	34 (0.3)	47 (0.4)	1.38 (0.89, 2.13)	81 (0.3)
Viral infection	43 (0.4)	36 (0.3)	0.83 (0.54, 1.29)	79 (0.3)
Rhinovirus infection	26 (0.2)	30 (0.3)	1.15 (0.69, 1.93)	56 (0.2)
Suspected COVID-19	26 (0.2)	23 (0.2)	0.88 (0.51, 1.53)	49 (0.2)
Tooth infection	12 (0.1)	20 (0.2)	1.66 (0.82, 3.35)	32 (0.1)
COVID-19	121 (1.0)	17 (0.1)	0.14 (0.08, 0.23)	138 (0.6)
Tooth abscess	18 (0.2)	17 (0.1)	0.94 (0.49, 1.81)	35 (0.1)
Gastroenteritis	11 (<0.1)	15 (0.1)	1.36 (0.64, 2.91)	26 (0.1)
Herpes zoster	8 (<0.1)	15 (0.1)	1.87 (0.81, 4.30)	23 (<0.1)
Pharyngitis	18 (0.2)	14 (0.1)	0.78 (0.39, 1.54)	32 (0.1)
Ear infection	5 (<0.1)	13 (0.1)	2.59 (0.96, 6.98)	18 (<0.1)
Oral herpes	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.31)	19 (<0.1)
Hordeolum	12 (0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Pharyngitis streptococcal	16 (0.1)	10 (<0.1)	0.62 (0.29, 1.35)	26 (0.1)
Conjunctivitis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Viral upper respiratory tract infection	12 (0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Cellulitis	12 (0.1)	8 (<0.1)	0.66 (0.28, 1.58)	20 (<0.1)
Fungal infection	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.22)	17 (<0.1)
Onychomycosis	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.60)	10 (<0.1)
Herpes simplex	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Paronychia	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Bronchitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Diverticulitis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Folliculitis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Otitis media	6 (<0.1)	6 (<0.1)		12 (<0.1)
Bacterial vaginosis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Gingivitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Pneumonia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Vulvovaginal mycotic infection	12 (0.1)	5 (<0.1)	0.42 (0.15, 1.13)	17 (<0.1)
Acute sinusitis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Asymptomatic COVID-19	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Enterovirus infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Nasopharyngitis	11 (<0.1)	4 (<0.1)	0.36 (0.12, 1.08)	15 (<0.1)
Skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Staphylococcal infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Subcutaneous abscess	1 (<0.1)	4 (<0.1)		5 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Abscess limb	1 (<0.1)	3 (<0.1)		4 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Localised infection	5 (<0.1)	3 (<0.1)		8 (<0.1)
Otitis externa	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.13)	12 (<0.1)
Staphylococcal skin infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Cystitis	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Epididymitis	0	2 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Laryngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea pedis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tonsillitis	10 (<0.1)	2 (<0.1)	0.20 (0.05, 0.81)	12 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Coronavirus infection	0	1 (<0.1)		1 (<0.1)
Eye infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fungal skin infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Helicobacter infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral candidiasis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rhinitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea cruris	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Viral rhinitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0		2 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Genital herpes	2 (<0.1)	0		2 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	4 (<0.1)	0		4 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Infections and infestations (Cont.)				
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Wound infection	3 (<0.1)	0		3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	34 (0.3)	48 (0.4)		82 (0.3)
Basal cell carcinoma	10 (<0.1)	8 (<0.1)	0.80 (0.32, 1.96)	18 (<0.1)
Squamous cell carcinoma	6 (<0.1)	4 (<0.1)		10 (<0.1)
Benign neoplasm of skin	1 (<0.1)	3 (<0.1)		4 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Prostate cancer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Uterine leiomyoma	0	3 (<0.1)		3 (<0.1)
Malignant melanoma	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign breast neoplasm	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Skin cancer	3 (<0.1)	1 (<0.1)		4 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	1 (<0.1)		3 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	115 (1.0)	222 (1.9)		337 (1.4)
Lymphadenopathy	101 (0.9)	200 (1.7)	1.97 (1.56, 2.50)	301 (1.3)
Lymph node pain	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Anaemia	1 (<0.1)	6 (<0.1)		7 (<0.1)
Lymphadenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Blood and lymphatic system disorders (Cont.)				
Iron deficiency anaemia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	50 (0.4)	37 (0.3)		87 (0.4)
Seasonal allergy	34 (0.3)	26 (0.2)	0.76 (0.46, 1.26)	60 (0.3)
Hypersensitivity	5 (<0.1)	5 (<0.1)		10 (<0.1)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	5 (<0.1)	1 (<0.1)		6 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Endocrine disorders	13 (0.1)	10 (<0.1)		23 (<0.1)
Hypothyroidism	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.81)	17 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	64 (0.5)	78 (0.7)		142 (0.6)
Hyperlipidaemia	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Decreased appetite	5 (<0.1)	10 (<0.1)	1.99 (0.71, 5.57)	15 (<0.1)
Hypercholesterolaemia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.81)	17 (<0.1)
Vitamin D deficiency	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Type 2 diabetes mellitus	5 (<0.1)	6 (<0.1)		11 (<0.1)
Dehydration	5 (<0.1)	5 (<0.1)		10 (<0.1)
Gout	5 (<0.1)	5 (<0.1)		10 (<0.1)
Glucose tolerance impaired	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Diabetes mellitus	0	2 (<0.1)		2 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Metabolism and nutrition disorders (Cont.)				
Hyperglycaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrolyte imbalance	0	1 (<0.1)		1 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abnormal weight gain	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Polydipsia	1 (<0.1)	0		1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	93 (0.8)	130 (1.1)		223 (1.0)
Anxiety	30 (0.3)	40 (0.3)	1.33 (0.83, 2.12)	70 (0.3)
Depression	22 (0.2)	31 (0.3)	1.41 (0.82, 2.41)	53 (0.2)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Psychiatric disorders (Cont.)				
Insomnia	20 (0.2)	26 (0.2)	1.30 (0.73, 2.30)	46 (0.2)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)
Attention deficit hyperactivity disorder	6 (<0.1)	4 (<0.1)		10 (<0.1)
Panic attack	3 (<0.1)	4 (<0.1)		7 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nightmare	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Psychiatric disorders (Cont.)				
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	656 (5.6)	775 (6.6)		1431 (6.1)
Headache	513 (4.4)	560 (4.8)	1.09 (0.97, 1.22)	1073 (4.6)

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MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Dizziness	42 (0.4)	58 (0.5)	1.38 (0.93, 2.04)	100 (0.4)
Paraesthesia	24 (0.2)	28 (0.2)	1.16 (0.68, 1.99)	52 (0.2)
Sinus headache	2 (<0.1)	17 (0.1)	8.48 (2.18, 32.97)	19 (<0.1)
Dysgeusia	5 (<0.1)	11 (<0.1)	2.19 (0.80, 6.04)	16 (<0.1)
Migraine	19 (0.2)	11 (<0.1)	0.58 (0.28, 1.19)	30 (0.1)
Syncope	12 (0.1)	11 (<0.1)	0.91 (0.41, 2.03)	23 (<0.1)
Ageusia	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.06)	18 (<0.1)
Hypoaesthesia	5 (<0.1)	10 (<0.1)	1.99 (0.71, 5.57)	15 (<0.1)
Sciatica	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Cervical radiculopathy	1 (<0.1)	8 (<0.1)	7.98 (1.30, 49.14)	9 (<0.1)
Tension headache	4 (<0.1)	8 (<0.1)	1.99 (0.64, 6.22)	12 (<0.1)
Anosmia	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.72)	14 (<0.1)
Presyncope	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Hyperaesthesia	0	5 (<0.1)		5 (<0.1)
Memory impairment	0	4 (<0.1)		4 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Amnesia	0	2 (<0.1)		2 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Carpal tunnel syndrome	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Facial paralysis	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Nerve compression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Parosmia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Dyslexia	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Mental impairment	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neuropathy peripheral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Nervous system disorders (Cont.)				
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tremor	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	53 (0.5)	55 (0.5)		108 (0.5)
Eye irritation	1 (<0.1)	6 (<0.1)		7 (<0.1)
Eye pruritus	5 (<0.1)	5 (<0.1)		10 (<0.1)
Vision blurred	3 (<0.1)	5 (<0.1)		8 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Eye disorders (Cont.)				
Dry eye	6 (<0.1)	4 (<0.1)		10 (<0.1)
Eye pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Glaucoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye inflammation	0	2 (<0.1)		2 (<0.1)
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	0	2 (<0.1)		2 (<0.1)
Ocular hyperaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Vitreous floaters	1 (<0.1)	2 (<0.1)		3 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blepharitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cataract	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Eye disorders (Cont.)				
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Eye disorders (Cont.)				
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	66 (0.6)	64 (0.5)		130 (0.6)
Vertigo	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Ear pain	14 (0.1)	13 (0.1)	0.93 (0.44, 1.94)	27 (0.1)
Tinnitus	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.33)	20 (<0.1)
Vertigo positional	1 (<0.1)	7 (<0.1)	6.98 (1.12, 43.49)	8 (<0.1)
Ear discomfort	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Cerumen impaction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear canal erythema	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Ear and labyrinth disorders (Cont.)				
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear congestion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tympanic membrane perforation	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	3 (<0.1)	0		3 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	52 (0.4)	51 (0.4)		103 (0.4)
Bradycardia	13 (0.1)	11 (<0.1)	0.84 (0.39, 1.85)	24 (0.1)
Tachycardia	5 (<0.1)	11 (<0.1)	2.19 (0.80, 6.04)	16 (<0.1)
Atrial fibrillation	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.72)	14 (<0.1)
Palpitations	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Angina pectoris	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Cardiac disorders (Cont.)				
Arrhythmia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronary artery disease	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute myocardial infarction	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Cardiac failure	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)		4 (<0.1)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	0		1 (<0.1)
Myocardial infarction	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	3 (<0.1)	0		3 (<0.1)
Vascular disorders	147 (1.3)	149 (1.3)		296 (1.3)
Hypertension	116 (1.0)	114 (1.0)	0.98 (0.76, 1.27)	230 (1.0)
Hot flush	8 (<0.1)	12 (0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Flushing	4 (<0.1)	4 (<0.1)		8 (<0.1)
Haematoma	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Vascular disorders (Cont.)				
Hypertensive urgency	0	3 (<0.1)		3 (<0.1)
Hypotension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Systolic hypertension	2 (<0.1)	3 (<0.1)		5 (<0.1)
Orthostatic hypotension	0	2 (<0.1)		2 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Respiratory, thoracic and mediastinal disorders	486 (4.2)	442 (3.8)		928 (4.0)
Oropharyngeal pain	183 (1.6)	130 (1.1)	0.71 (0.57, 0.89)	313 (1.3)
Cough	119 (1.0)	122 (1.0)	1.02 (0.80, 1.31)	241 (1.0)
Nasal congestion	118 (1.0)	115 (1.0)	0.97 (0.75, 1.25)	233 (1.0)
Rhinorrhoea	109 (0.9)	94 (0.8)	0.86 (0.65, 1.13)	203 (0.9)
Tachypnoea	26 (0.2)	28 (0.2)	1.07 (0.63, 1.82)	54 (0.2)
Dyspnoea	30 (0.3)	25 (0.2)	0.83 (0.49, 1.40)	55 (0.2)
Epistaxis	7 (<0.1)	14 (0.1)	1.99 (0.83, 4.80)	21 (<0.1)
Throat irritation	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Sinus congestion	19 (0.2)	13 (0.1)	0.68 (0.34, 1.36)	32 (0.1)
Respiratory tract congestion	5 (<0.1)	12 (0.1)	2.39 (0.88, 6.51)	17 (<0.1)
Rhinitis allergic	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Sneezing	10 (<0.1)	8 (<0.1)	0.80 (0.32, 1.96)	18 (<0.1)
Upper-airway cough syndrome	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Asthma	6 (<0.1)	6 (<0.1)		12 (<0.1)
Pharyngeal erythema	3 (<0.1)	4 (<0.1)		7 (<0.1)
Dry throat	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dysphonia	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	3 (<0.1)		6 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Sinus pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Wheezing	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dyspnoea exertional	0	2 (<0.1)		2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	0	2 (<0.1)		2 (<0.1)
Productive cough	5 (<0.1)	2 (<0.1)		7 (<0.1)
Acute respiratory failure	3 (<0.1)	1 (<0.1)		4 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	427 (3.6)	431 (3.7)		858 (3.7)
Diarrhoea	141 (1.2)	151 (1.3)	1.07 (0.85, 1.34)	292 (1.2)
Nausea	126 (1.1)	114 (1.0)	0.90 (0.70, 1.16)	240 (1.0)
Vomiting	43 (0.4)	45 (0.4)	1.04 (0.69, 1.58)	88 (0.4)
Gastrooesophageal reflux disease	21 (0.2)	30 (0.3)	1.42 (0.82, 2.47)	51 (0.2)
Toothache	22 (0.2)	27 (0.2)	1.22 (0.70, 2.13)	49 (0.2)
Abdominal pain	14 (0.1)	22 (0.2)	1.57 (0.81, 3.03)	36 (0.2)
Dyspepsia	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Abdominal pain upper	18 (0.2)	11 (<0.1)	0.61 (0.29, 1.27)	29 (0.1)
Constipation	16 (0.1)	11 (<0.1)	0.69 (0.32, 1.45)	27 (0.1)
Dental caries	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.86)	20 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Food poisoning	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.10)	14 (<0.1)
Abdominal pain lower	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Abdominal discomfort	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Gastric ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Haemorrhoids	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hyperaesthesia teeth	0	3 (<0.1)		3 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Paraesthesia oral	3 (<0.1)	3 (<0.1)		6 (<0.1)
Umbilical hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hiatus hernia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Irritable bowel syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Stomatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Tooth impacted	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal distension	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Colitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Gastritis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	4 (<0.1)	1 (<0.1)		5 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Loose tooth	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Dry mouth	2 (<0.1)	0		2 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Gastrointestinal disorders (Cont.)				
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	2 (<0.1)	7 (<0.1)		9 (<0.1)
Cholelithiasis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Hepatobiliary disorders (Cont.)				
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	180 (1.5)	235 (2.0)		415 (1.8)
Urticaria	25 (0.2)	37 (0.3)	1.48 (0.89, 2.44)	62 (0.3)
Rash	24 (0.2)	30 (0.3)	1.25 (0.73, 2.12)	54 (0.2)
Pruritus	17 (0.1)	20 (0.2)	1.17 (0.62, 2.21)	37 (0.2)
Dermatitis contact	25 (0.2)	18 (0.2)	0.72 (0.40, 1.30)	43 (0.2)
Erythema	4 (<0.1)	14 (0.1)	3.49 (1.21, 10.08)	18 (<0.1)
Hyperhidrosis	7 (<0.1)	10 (<0.1)	1.42 (0.56, 3.62)	17 (<0.1)
Night sweats	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Acne	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.63)	13 (<0.1)
Eczema	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.23)	11 (<0.1)
Dermatitis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.25)	10 (<0.1)
Actinic keratosis	1 (<0.1)	6 (<0.1)		7 (<0.1)
Alopecia	4 (<0.1)	6 (<0.1)		10 (<0.1)
Rash papular	3 (<0.1)	6 (<0.1)		9 (<0.1)
Rash macular	3 (<0.1)	5 (<0.1)		8 (<0.1)
Rash maculo-papular	2 (<0.1)	5 (<0.1)		7 (<0.1)
Dermatitis atopic	5 (<0.1)	4 (<0.1)		9 (<0.1)

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030108060301.sas 21JUN2021 14:30

Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)
Dry skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Rash pruritic	6 (<0.1)	3 (<0.1)		9 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	3 (<0.1)	3 (<0.1)		6 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Angioedema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blister	0	2 (<0.1)		2 (<0.1)
Ecchymosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hidradenitis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Rash erythematous	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Macule	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Pain of skin	0	1 (<0.1)		1 (<0.1)
Petechiae	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin mass	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Papule	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	2 (<0.1)	0		2 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	3 (<0.1)	0		3 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	724 (6.2)	733 (6.2)		1457 (6.2)
Arthralgia	260 (2.2)	275 (2.3)	1.05 (0.89, 1.25)	535 (2.3)
Myalgia	273 (2.3)	269 (2.3)	0.98 (0.83, 1.16)	542 (2.3)
Back pain	103 (0.9)	82 (0.7)	0.79 (0.60, 1.06)	185 (0.8)
Pain in extremity	61 (0.5)	44 (0.4)	0.72 (0.49, 1.06)	105 (0.4)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Musculoskeletal pain	22 (0.2)	36 (0.3)	1.63 (0.97, 2.76)	58 (0.2)
Neck pain	29 (0.2)	34 (0.3)	1.17 (0.72, 1.91)	63 (0.3)
Muscle spasms	21 (0.2)	27 (0.2)	1.28 (0.73, 2.25)	48 (0.2)
Osteoarthritis	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Musculoskeletal chest pain	7 (<0.1)	13 (0.1)	1.85 (0.76, 4.51)	20 (<0.1)
Tendonitis	11 (<0.1)	12 (0.1)	1.09 (0.49, 2.41)	23 (<0.1)
Musculoskeletal stiffness	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.52)	21 (<0.1)
Rotator cuff syndrome	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Arthritis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.25)	10 (<0.1)
Bursitis	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Groin pain	1 (<0.1)	5 (<0.1)		6 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	5 (<0.1)		8 (<0.1)
Joint swelling	6 (<0.1)	5 (<0.1)		11 (<0.1)
Limb discomfort	1 (<0.1)	5 (<0.1)		6 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Muscular weakness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Trigger finger	1 (<0.1)	5 (<0.1)		6 (<0.1)
Joint range of motion decreased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Bone pain	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Flank pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Muscle twitching	2 (<0.1)	3 (<0.1)		5 (<0.1)
Osteoporosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Costochondritis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Pain in jaw	4 (<0.1)	2 (<0.1)		6 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spinal osteoarthritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Spinal pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Axillary mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Exostosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibromyalgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Joint stiffness	3 (<0.1)	1 (<0.1)		4 (<0.1)
Limb mass	0	1 (<0.1)		1 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Plantar fasciitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal stenosis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	3 (<0.1)	0		3 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Periarthritis	2 (<0.1)	0		2 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	31 (0.3)	32 (0.3)		63 (0.3)
Nephrolithiasis	14 (0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Dysuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Haematuria	5 (<0.1)	3 (<0.1)		8 (<0.1)
Polyuria	0	3 (<0.1)		3 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary retention	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Renal and urinary disorders (Cont.)				
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chronic kidney disease	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Hypertonic bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Renal cyst	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	2 (<0.1)	0		2 (<0.1)
Urinary incontinence	1 (<0.1)	0		1 (<0.1)

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Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Reproductive system and breast disorders	50 (0.4)	48 (0.4)		98 (0.4)
Benign prostatic hyperplasia	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Dysmenorrhoea	5 (<0.1)	3 (<0.1)		8 (<0.1)
Erectile dysfunction	2 (<0.1)	3 (<0.1)		5 (<0.1)
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Pelvic pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Prostatitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Reproductive system and breast disorders (Cont.)				
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Reproductive system and breast disorders (Cont.)				
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Menstruation irregular	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions	767 (6.6)	1171 (10.0)		1938 (8.3)
Fatigue	478 (4.1)	522 (4.4)	1.09 (0.96, 1.23)	1000 (4.3)
Injection site pain	86 (0.7)	191 (1.6)	2.22 (1.72, 2.85)	277 (1.2)
Injection site erythema	22 (0.2)	110 (0.9)	4.99 (3.17, 7.85)	132 (0.6)
Chills	77 (0.7)	89 (0.8)	1.15 (0.85, 1.56)	166 (0.7)
Pyrexia	46 (0.4)	86 (0.7)	1.86 (1.31, 2.66)	132 (0.6)
Injection site swelling	19 (0.2)	84 (0.7)	4.41 (2.70, 7.21)	103 (0.4)
Injection site pruritus	9 (<0.1)	70 (0.6)	7.76 (3.93, 15.32)	79 (0.3)
Injection site lymphadenopathy	11 (<0.1)	60 (0.5)	5.44 (2.89, 10.23)	71 (0.3)
Pain	46 (0.4)	54 (0.5)	1.17 (0.79, 1.73)	100 (0.4)
Injection site induration	12 (0.1)	39 (0.3)	3.24 (1.72, 6.12)	51 (0.2)
Injection site macule	4 (<0.1)	37 (0.3)	9.23 (3.43, 24.84)	41 (0.2)
Injection site urticaria	1 (<0.1)	28 (0.2)	27.93 (4.81, 162.14)	29 (0.1)
Injection site rash	1 (<0.1)	23 (0.2)	22.94 (3.93, 133.89)	24 (0.1)
Axillary pain	13 (0.1)	18 (0.2)	1.38 (0.69, 2.78)	31 (0.1)
Malaise	10 (<0.1)	14 (0.1)	1.40 (0.63, 3.08)	24 (0.1)
Injection site bruising	18 (0.2)	13 (0.1)	0.72 (0.36, 1.45)	31 (0.1)
Injection site papule	0	11 (<0.1)		11 (<0.1)
Chest discomfort	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Peripheral swelling	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions (Cont.)				
Injection site warmth	1 (<0.1)	7 (<0.1)	6.98 (1.12, 43.49)	8 (<0.1)
Chest pain	4 (<0.1)	6 (<0.1)		10 (<0.1)
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site paraesthesia	2 (<0.1)	6 (<0.1)		8 (<0.1)
Reactogenicity event	1 (<0.1)	6 (<0.1)		7 (<0.1)
Feeling abnormal	3 (<0.1)	5 (<0.1)		8 (<0.1)
Feeling hot	3 (<0.1)	5 (<0.1)		8 (<0.1)
Non-cardiac chest pain	4 (<0.1)	5 (<0.1)		9 (<0.1)
Oedema peripheral	3 (<0.1)	5 (<0.1)		8 (<0.1)
Vaccination site pain	3 (<0.1)	5 (<0.1)		8 (<0.1)
Vaccination site swelling	0	5 (<0.1)		5 (<0.1)
Injection site haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Injection site joint pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Swelling face	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Hangover	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site mass	0	2 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions (Cont.)				
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Asthenia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Precancerous condition	1 (<0.1)	1 (<0.1)		2 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions (Cont.)				
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Crying	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discomfort	1 (<0.1)	0		1 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
General disorders and administration site conditions (Cont.)				
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)
Investigations	57 (0.5)	81 (0.7)		138 (0.6)
Blood pressure increased	22 (0.2)	19 (0.2)	0.86 (0.47, 1.58)	41 (0.2)
Blood pressure systolic increased	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.60)	10 (<0.1)
Body temperature increased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Blood cholesterol increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Heart rate increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hepatic enzyme increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Transaminases increased	0	3 (<0.1)		3 (<0.1)
Blood glucose increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Investigations (Cont.)				
Weight decreased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood triglycerides increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Investigations (Cont.)				
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood potassium decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Cardiac murmur	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications	278 (2.4)	246 (2.1)		524 (2.2)
Muscle strain	21 (0.2)	30 (0.3)	1.42 (0.82, 2.47)	51 (0.2)
Ligament sprain	21 (0.2)	21 (0.2)	1.00 (0.55, 1.81)	42 (0.2)
Arthropod bite	17 (0.1)	19 (0.2)	1.11 (0.59, 2.12)	36 (0.2)
Skin laceration	23 (0.2)	19 (0.2)	0.82 (0.45, 1.50)	42 (0.2)
Contusion	22 (0.2)	15 (0.1)	0.68 (0.36, 1.30)	37 (0.2)
Fall	15 (0.1)	15 (0.1)	1.00 (0.49, 2.01)	30 (0.1)
Tooth fracture	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Procedural pain	25 (0.2)	11 (<0.1)	0.44 (0.22, 0.88)	36 (0.2)
Skin abrasion	14 (0.1)	10 (<0.1)	0.71 (0.32, 1.57)	24 (0.1)
Arthropod sting	14 (0.1)	8 (<0.1)	0.57 (0.25, 1.32)	22 (<0.1)
Foot fracture	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Limb injury	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.02)	15 (<0.1)
Road traffic accident	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.63)	13 (<0.1)
Meniscus injury	9 (<0.1)	6 (<0.1)	0.66 (0.25, 1.79)	15 (<0.1)
Animal bite	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.39)	15 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Hand fracture	2 (<0.1)	4 (<0.1)		6 (<0.1)
Joint injury	2 (<0.1)	4 (<0.1)		6 (<0.1)
Post-traumatic pain	4 (<0.1)	4 (<0.1)		8 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Rib fracture	2 (<0.1)	4 (<0.1)		6 (<0.1)
Bone contusion	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Concussion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Head injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Upper limb fracture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Wrist fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Ankle fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Epicondylitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Thermal burn	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030108060301.sas 21JUN2021 14:30

Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Corneal abrasion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Heat exhaustion	0	1 (<0.1)		1 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ligament rupture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Lower limb fracture	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	2 (<0.1)	1 (<0.1)		3 (<0.1)
Wound	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Animal scratch	1 (<0.1)	0		1 (<0.1)
Back injury	2 (<0.1)	0		2 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Hip fracture	2 (<0.1)	0		2 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: Not at Risk

System Organ Class Preferred Term	Placebo (N=11705) n (%)	mRNA-1273 (N=11736) n (%)	Rate Ratio (95% CI)	Total (N=23441) n (%)
Injury, poisoning and procedural complications (Cont.)				
Sunburn	2 (<0.1)	0		2 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Tendon rupture	1 (<0.1)	0		1 (<0.1)
Tooth injury	3 (<0.1)	0		3 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Product issues	1 (<0.1)	5 (<0.1)		6 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	871 (30.9)	968 (34.7)		1839 (32.8)
Number of Unsolicited Adverse Events	1889	2035		3924
Infections and infestations	180 (6.4)	152 (5.4)		332 (5.9)
Urinary tract infection	12 (0.4)	25 (0.9)	2.10 (1.07, 4.12)	37 (0.7)
Sinusitis	9 (0.3)	12 (0.4)	1.34 (0.58, 3.11)	21 (0.4)
Upper respiratory tract infection	23 (0.8)	11 (0.4)	0.48 (0.24, 0.97)	34 (0.6)
Suspected COVID-19	8 (0.3)	9 (0.3)	1.13 (0.45, 2.84)	17 (0.3)
Herpes zoster	5 (0.2)	7 (0.3)	1.41 (0.47, 4.21)	12 (0.2)
Rhinovirus infection	4 (0.1)	6 (0.2)		10 (0.2)
Tooth abscess	7 (0.2)	6 (0.2)	0.86 (0.31, 2.45)	13 (0.2)
Ear infection	5 (0.2)	5 (0.2)		10 (0.2)
COVID-19	28 (1.0)	4 (0.1)	0.14 (0.05, 0.39)	32 (0.6)
Conjunctivitis	0	4 (0.1)		4 (<0.1)
Gingivitis	0	4 (0.1)		4 (<0.1)
Tooth infection	5 (0.2)	4 (0.1)		9 (0.2)
Cellulitis	3 (0.1)	3 (0.1)		6 (0.1)
Diverticulitis	4 (0.1)	3 (0.1)		7 (0.1)
Gastroenteritis	4 (0.1)	3 (0.1)		7 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Infections and infestations (Cont.)				
Kidney infection	1 (<0.1)	3 (0.1)		4 (<0.1)
Localised infection	3 (0.1)	3 (0.1)		6 (0.1)
Otitis externa	2 (<0.1)	3 (0.1)		5 (<0.1)
Pharyngitis	2 (<0.1)	3 (0.1)		5 (<0.1)
Viral infection	6 (0.2)	3 (0.1)		9 (0.2)
Acute sinusitis	0	2 (<0.1)		2 (<0.1)
Hordeolum	0	2 (<0.1)		2 (<0.1)
Laryngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pharyngitis streptococcal	5 (0.2)	2 (<0.1)		7 (0.1)
Respiratory tract infection viral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vulvovaginal candidiasis	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Bacterial vaginosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchitis	5 (0.2)	1 (<0.1)		6 (0.1)
Candida infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Cystitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Folliculitis	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Infections and infestations (Cont.)				
Fungal infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes	0	1 (<0.1)		1 (<0.1)
Helicobacter infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Nasopharyngitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral candidiasis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oral herpes	0	1 (<0.1)		1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Sepsis	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	0	1 (<0.1)		1 (<0.1)
Staphylococcal skin infection	0	1 (<0.1)		1 (<0.1)
Subcutaneous abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral rhinitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Infections and infestations (Cont.)				
Viral upper respiratory tract infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vulvovaginal mycotic infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)
Chronic sinusitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Enterovirus infection	1 (<0.1)	0		1 (<0.1)
Epididymitis	1 (<0.1)	0		1 (<0.1)
Eye infection	1 (<0.1)	0		1 (<0.1)
Fungal skin infection	1 (<0.1)	0		1 (<0.1)
Gastroenteritis viral	2 (<0.1)	0		2 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Herpes simplex	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Infections and infestations (Cont.)				
Influenza	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Onychomycosis	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Paronychia	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia	7 (0.2)	0		7 (0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin infection	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea cruris	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21 (0.7)	13 (0.5)		34 (0.6)
Basal cell carcinoma	6 (0.2)	2 (<0.1)		8 (0.1)
Skin cancer	0	2 (<0.1)		2 (<0.1)
Benign breast neoplasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign neoplasm of skin	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Lipoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	2 (<0.1)	0		2 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Blood and lymphatic system disorders	30 (1.1)	61 (2.2)		91 (1.6)
Lymphadenopathy	24 (0.9)	55 (2.0)	2.31 (1.44, 3.71)	79 (1.4)
Anaemia	5 (0.2)	4 (0.1)		9 (0.2)
Lymph node pain	3 (0.1)	2 (<0.1)		5 (<0.1)
Immune system disorders	14 (0.5)	6 (0.2)		20 (0.4)
Seasonal allergy	12 (0.4)	4 (0.1)	0.34 (0.11, 0.99)	16 (0.3)
Hypersensitivity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	4 (0.1)	2 (<0.1)		6 (0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypothyroidism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	37 (1.3)	36 (1.3)		73 (1.3)
Type 2 diabetes mellitus	2 (<0.1)	11 (0.4)	5.55 (1.38, 22.30)	13 (0.2)
Dehydration	1 (<0.1)	4 (0.1)		5 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Metabolism and nutrition disorders (Cont.)				
Hyperlipidaemia	5 (0.2)	4 (0.1)		9 (0.2)
Diabetes mellitus	2 (<0.1)	3 (0.1)		5 (<0.1)
Vitamin D deficiency	3 (0.1)	3 (0.1)		6 (0.1)
Glucose tolerance impaired	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypercholesterolaemia	5 (0.2)	2 (<0.1)		7 (0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperglycaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Vitamin B12 deficiency	0	1 (<0.1)		1 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Decreased appetite	2 (<0.1)	0		2 (<0.1)
Dyslipidaemia	2 (<0.1)	0		2 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypocalcaemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypoglycaemia	2 (<0.1)	0		2 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Iron deficiency	1 (<0.1)	0		1 (<0.1)
Obesity	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	19 (0.7)	21 (0.8)		40 (0.7)
Anxiety	7 (0.2)	10 (0.4)	1.44 (0.57, 3.65)	17 (0.3)
Depression	5 (0.2)	3 (0.1)		8 (0.1)
Insomnia	4 (0.1)	3 (0.1)		7 (0.1)
Attention deficit hyperactivity disorder	3 (0.1)	1 (<0.1)		4 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Post-traumatic stress disorder	0	1 (<0.1)		1 (<0.1)
Stress	0	1 (<0.1)		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Nervous system disorders	178 (6.3)	188 (6.7)		366 (6.5)
Headache	141 (5.0)	146 (5.2)	1.04 (0.83, 1.31)	287 (5.1)
Dizziness	10 (0.4)	14 (0.5)	1.41 (0.64, 3.11)	24 (0.4)
Paraesthesia	3 (0.1)	6 (0.2)		9 (0.2)
Ageusia	1 (<0.1)	5 (0.2)		6 (0.1)
Migraine	5 (0.2)	4 (0.1)		9 (0.2)
Sinus headache	3 (0.1)	3 (0.1)		6 (0.1)
Carpal tunnel syndrome	3 (0.1)	2 (<0.1)		5 (<0.1)
Hypoaesthesia	4 (0.1)	2 (<0.1)		6 (0.1)
Mental impairment	0	2 (<0.1)		2 (<0.1)
Anosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burning sensation	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Diabetic neuropathy	0	1 (<0.1)		1 (<0.1)
Dysgeusia	3 (0.1)	1 (<0.1)		4 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Nerve compression	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Nervous system disorders (Cont.)				
Neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Sciatica	0	1 (<0.1)		1 (<0.1)
Taste disorder	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)		1 (<0.1)
Amnesia	1 (<0.1)	0		1 (<0.1)
Balance disorder	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	2 (<0.1)	0		2 (<0.1)
Facial paralysis	1 (<0.1)	0		1 (<0.1)
Lumbar radiculopathy	1 (<0.1)	0		1 (<0.1)
Parosmia	1 (<0.1)	0		1 (<0.1)
Presyncope	2 (<0.1)	0		2 (<0.1)
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)
Somnolence	1 (<0.1)	0		1 (<0.1)
Syncope	2 (<0.1)	0		2 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)
Tremor	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Eye disorders	9 (0.3)	14 (0.5)		23 (0.4)
Eye pruritus	2 (<0.1)	2 (<0.1)		4 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling of eyelid	0	2 (<0.1)		2 (<0.1)
Blepharitis	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye inflammation	0	1 (<0.1)		1 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Eye pain	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vision blurred	0	1 (<0.1)		1 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0		1 (<0.1)
Lacrimation increased	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)
Vitreous floaters	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	13 (0.5)	11 (0.4)		24 (0.4)
Vertigo	3 (0.1)	7 (0.3)	2.35 (0.66, 8.34)	10 (0.2)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Ear and labyrinth disorders (Cont.)				
Tinnitus	3 (0.1)	2 (<0.1)		5 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear pain	4 (0.1)	1 (<0.1)		5 (<0.1)
Cerumen impaction	1 (<0.1)	0		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	16 (0.6)	24 (0.9)		40 (0.7)
Atrial fibrillation	4 (0.1)	5 (0.2)		9 (0.2)
Sinus tachycardia	1 (<0.1)	3 (0.1)		4 (<0.1)
Tachycardia	2 (<0.1)	3 (0.1)		5 (<0.1)
Angina pectoris	0	2 (<0.1)		2 (<0.1)
Myocardial infarction	0	2 (<0.1)		2 (<0.1)
Palpitations	0	2 (<0.1)		2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute myocardial infarction	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arrhythmia	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Cardiac disorders (Cont.)				
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Bradycardia	3 (0.1)	1 (<0.1)		4 (<0.1)
Cardiac failure congestive	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Vascular disorders	46 (1.6)	41 (1.5)		87 (1.6)
Hypertension	36 (1.3)	31 (1.1)	0.87 (0.54, 1.39)	67 (1.2)
Hot flush	0	3 (0.1)		3 (<0.1)
Flushing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Hypertensive urgency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypotension	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Vascular disorders (Cont.)				
Deep vein thrombosis	2 (<0.1)	0		2 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Orthostatic hypotension	1 (<0.1)	0		1 (<0.1)
Systolic hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	144 (5.1)	133 (4.8)		277 (4.9)
Cough	37 (1.3)	44 (1.6)	1.20 (0.78, 1.85)	81 (1.4)
Nasal congestion	36 (1.3)	34 (1.2)	0.95 (0.60, 1.51)	70 (1.2)
Rhinorrhoea	27 (1.0)	27 (1.0)	1.01 (0.60, 1.70)	54 (1.0)
Oropharyngeal pain	41 (1.5)	23 (0.8)	0.57 (0.34, 0.94)	64 (1.1)
Dyspnoea	9 (0.3)	16 (0.6)	1.79 (0.81, 3.97)	25 (0.4)
Asthma	8 (0.3)	8 (0.3)	1.01 (0.39, 2.59)	16 (0.3)
Chronic obstructive pulmonary disease	6 (0.2)	5 (0.2)		11 (0.2)
Respiratory tract congestion	2 (<0.1)	5 (0.2)		7 (0.1)
Upper-airway cough syndrome	1 (<0.1)	4 (0.1)		5 (<0.1)
Bronchiectasis	0	3 (0.1)		3 (<0.1)
Sinus congestion	7 (0.2)	3 (0.1)	0.43 (0.12, 1.53)	10 (0.2)
Sneezing	3 (0.1)	3 (0.1)		6 (0.1)
Tachypnoea	5 (0.2)	3 (0.1)		8 (0.1)

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Table 14.3.1.8.6.3.1
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Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Dysphonia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dyspnoea exertional	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rhinitis allergic	8 (0.3)	2 (<0.1)	0.25 (0.06, 1.05)	10 (0.2)
Throat irritation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute respiratory failure	0	1 (<0.1)		1 (<0.1)
Allergic cough	0	1 (<0.1)		1 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Dry throat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Epistaxis	4 (0.1)	1 (<0.1)		5 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Paranasal sinus hypersecretion	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	0	1 (<0.1)		1 (<0.1)
Sinus pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)

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Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Pleural effusion	2 (<0.1)	0		2 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Tonsillolith	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	116 (4.1)	131 (4.7)		247 (4.4)
Diarrhoea	47 (1.7)	39 (1.4)	0.84 (0.55, 1.27)	86 (1.5)
Nausea	33 (1.2)	32 (1.1)	0.98 (0.61, 1.58)	65 (1.2)
Vomiting	10 (0.4)	13 (0.5)	1.31 (0.59, 2.92)	23 (0.4)
Gastrooesophageal reflux disease	6 (0.2)	9 (0.3)	1.51 (0.56, 4.07)	15 (0.3)
Toothache	4 (0.1)	8 (0.3)	2.02 (0.65, 6.29)	12 (0.2)
Constipation	5 (0.2)	5 (0.2)		10 (0.2)
Abdominal pain	6 (0.2)	4 (0.1)		10 (0.2)
Dental caries	1 (<0.1)	4 (0.1)		5 (<0.1)
Colitis	1 (<0.1)	3 (0.1)		4 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal distension	0	2 (<0.1)		2 (<0.1)
Abdominal pain lower	0	2 (<0.1)		2 (<0.1)
Abdominal pain upper	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dry mouth	1 (<0.1)	2 (<0.1)		3 (<0.1)
Food poisoning	2 (<0.1)	2 (<0.1)		4 (<0.1)
Haemorrhoids	0	2 (<0.1)		2 (<0.1)
Inguinal hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anal fissure	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Flatulence	0	1 (<0.1)		1 (<0.1)
Gastric ulcer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Hiatus hernia	0	1 (<0.1)		1 (<0.1)
Irritable bowel syndrome	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Gastrointestinal disorders (Cont.)				
Mouth ulceration	0	1 (<0.1)		1 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tooth impacted	0	1 (<0.1)		1 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Dyspepsia	2 (<0.1)	0		2 (<0.1)
Dysphagia	2 (<0.1)	0		2 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	0		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	0		1 (<0.1)
Large intestine polyp	1 (<0.1)	0		1 (<0.1)
Loose tooth	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Paraesthesia oral	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Gastrointestinal disorders (Cont.)				
Salivary hypersecretion	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)
Stomatitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	3 (0.1)	6 (0.2)		9 (0.2)
Cholelithiasis	3 (0.1)	2 (<0.1)		5 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	46 (1.6)	53 (1.9)		99 (1.8)
Dermatitis contact	5 (0.2)	6 (0.2)		11 (0.2)
Pruritus	4 (0.1)	5 (0.2)		9 (0.2)
Urticaria	7 (0.2)	5 (0.2)	0.72 (0.24, 2.15)	12 (0.2)
Ecchymosis	1 (<0.1)	3 (0.1)		4 (<0.1)
Hyperhidrosis	3 (0.1)	3 (0.1)		6 (0.1)
Psoriasis	1 (<0.1)	3 (0.1)		4 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash	5 (0.2)	3 (0.1)		8 (0.1)
Eczema	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Rash macular	0	2 (<0.1)		2 (<0.1)
Rash maculo-papular	0	2 (<0.1)		2 (<0.1)
Rash papular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rash pruritic	0	2 (<0.1)		2 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Alopecia	0	1 (<0.1)		1 (<0.1)
Blister	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Erythema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Papule	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash erythematous	0	1 (<0.1)		1 (<0.1)
Rosacea	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin warm	0	1 (<0.1)		1 (<0.1)
Acne	2 (<0.1)	0		2 (<0.1)
Actinic keratosis	1 (<0.1)	0		1 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermal cyst	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Night sweats	2 (<0.1)	0		2 (<0.1)
Perioral dermatitis	1 (<0.1)	0		1 (<0.1)
Petechiae	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Skin mass	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	234 (8.3)	218 (7.8)		452 (8.1)
Arthralgia	97 (3.4)	93 (3.3)	0.97 (0.73, 1.28)	190 (3.4)
Myalgia	93 (3.3)	93 (3.3)	1.01 (0.76, 1.34)	186 (3.3)
Back pain	24 (0.9)	20 (0.7)	0.84 (0.47, 1.51)	44 (0.8)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in extremity	11 (0.4)	13 (0.5)	1.19 (0.55, 2.60)	24 (0.4)
Musculoskeletal pain	12 (0.4)	10 (0.4)	0.84 (0.37, 1.90)	22 (0.4)
Neck pain	6 (0.2)	8 (0.3)	1.34 (0.49, 3.71)	14 (0.2)
Muscle spasms	7 (0.2)	7 (0.3)	1.01 (0.37, 2.75)	14 (0.2)
Bursitis	1 (<0.1)	4 (0.1)		5 (<0.1)
Osteoarthritis	10 (0.4)	4 (0.1)	0.40 (0.13, 1.21)	14 (0.2)
Fibromyalgia	1 (<0.1)	3 (0.1)		4 (<0.1)
Rotator cuff syndrome	5 (0.2)	3 (0.1)		8 (0.1)
Tendonitis	2 (<0.1)	3 (0.1)		5 (<0.1)
Arthritis	0	2 (<0.1)		2 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Musculoskeletal chest pain	5 (0.2)	2 (<0.1)		7 (0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Axillary mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Groin pain	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Joint range of motion decreased	0	1 (<0.1)		1 (<0.1)
Joint swelling	3 (0.1)	1 (<0.1)		4 (<0.1)
Muscle tightness	0	1 (<0.1)		1 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteoporosis	0	1 (<0.1)		1 (<0.1)
Pain in jaw	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periarthritis	0	1 (<0.1)		1 (<0.1)
Plantar fasciitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rheumatoid arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal osteoarthritis	0	1 (<0.1)		1 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Trigger finger	2 (<0.1)	1 (<0.1)		3 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Exostosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Intervertebral disc degeneration	3 (0.1)	0		3 (<0.1)
Limb discomfort	1 (<0.1)	0		1 (<0.1)
Limb mass	2 (<0.1)	0		2 (<0.1)
Muscle twitching	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Musculoskeletal stiffness	4 (0.1)	0		4 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	11 (0.4)	16 (0.6)		27 (0.5)
Nephrolithiasis	5 (0.2)	7 (0.3)	1.41 (0.47, 4.21)	12 (0.2)
Dysuria	0	2 (<0.1)		2 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute kidney injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic kidney disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertonic bladder	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
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Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Renal and urinary disorders (Cont.)				
Haematuria	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	9 (0.3)	10 (0.4)		19 (0.3)
Benign prostatic hyperplasia	0	2 (<0.1)		2 (<0.1)
Dysmenorrhoea	2 (<0.1)	2 (<0.1)		4 (<0.1)
Erectile dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic pain	0	1 (<0.1)		1 (<0.1)
Prostatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	0		2 (<0.1)
Uterine spasm	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	0	1 (<0.1)		1 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)

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Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
General disorders and administration site conditions	237 (8.4)	369 (13.2)		606 (10.8)
Fatigue	155 (5.5)	186 (6.7)	1.21 (0.98, 1.49)	341 (6.1)
Injection site pain	28 (1.0)	57 (2.0)	2.05 (1.32, 3.21)	85 (1.5)
Injection site erythema	14 (0.5)	43 (1.5)	3.10 (1.71, 5.60)	57 (1.0)
Chills	24 (0.9)	35 (1.3)	1.47 (0.88, 2.45)	59 (1.1)
Injection site swelling	7 (0.2)	28 (1.0)	4.03 (1.80, 9.02)	35 (0.6)
Pyrexia	12 (0.4)	28 (1.0)	2.35 (1.21, 4.56)	40 (0.7)
Injection site pruritus	3 (0.1)	16 (0.6)	5.38 (1.68, 17.25)	19 (0.3)
Pain	13 (0.5)	16 (0.6)	1.24 (0.61, 2.54)	29 (0.5)
Injection site induration	4 (0.1)	14 (0.5)	3.53 (1.22, 10.19)	18 (0.3)
Injection site urticaria	0	10 (0.4)		10 (0.2)
Axillary pain	1 (<0.1)	8 (0.3)	8.07 (1.31, 49.69)	9 (0.2)
Injection site macule	0	7 (0.3)		7 (0.1)
Chest discomfort	2 (<0.1)	4 (0.1)		6 (0.1)
Injection site bruising	3 (0.1)	4 (0.1)		7 (0.1)
Injection site lymphadenopathy	4 (0.1)	3 (0.1)		7 (0.1)
Chest pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Injection site haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site hypoaesthesia	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
General disorders and administration site conditions (Cont.)				
Injection site mass	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site papule	1 (<0.1)	2 (<0.1)		3 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	6 (0.2)	1 (<0.1)		7 (0.1)
Oedema peripheral	4 (0.1)	1 (<0.1)		5 (<0.1)
Peripheral swelling	3 (0.1)	1 (<0.1)		4 (<0.1)
Reactogenicity event	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vaccination site swelling	0	1 (<0.1)		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
General disorders and administration site conditions (Cont.)				
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site paraesthesia	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Investigations	19 (0.7)	23 (0.8)		42 (0.7)
Blood pressure increased	5 (0.2)	6 (0.2)		11 (0.2)
Blood pressure systolic increased	1 (<0.1)	4 (0.1)		5 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood triglycerides increased	0	2 (<0.1)		2 (<0.1)
Blood cholesterol increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	0	1 (<0.1)		1 (<0.1)
Body temperature increased	0	1 (<0.1)		1 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)		2 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Investigations (Cont.)				
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Weight decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	94 (3.3)	70 (2.5)		164 (2.9)
Muscle strain	12 (0.4)	9 (0.3)	0.76 (0.33, 1.75)	21 (0.4)
Ligament sprain	7 (0.2)	8 (0.3)	1.15 (0.44, 3.05)	15 (0.3)
Fall	8 (0.3)	5 (0.2)	0.63 (0.22, 1.83)	13 (0.2)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Injury, poisoning and procedural complications (Cont.)				
Arthropod bite	11 (0.4)	4 (0.1)	0.37 (0.12, 1.09)	15 (0.3)
Foot fracture	4 (0.1)	4 (0.1)		8 (0.1)
Limb injury	1 (<0.1)	4 (0.1)		5 (<0.1)
Procedural pain	6 (0.2)	4 (0.1)		10 (0.2)
Road traffic accident	2 (<0.1)	4 (0.1)		6 (0.1)
Contusion	7 (0.2)	3 (0.1)	0.43 (0.12, 1.53)	10 (0.2)
Skin laceration	7 (0.2)	3 (0.1)	0.43 (0.12, 1.53)	10 (0.2)
Tooth fracture	7 (0.2)	3 (0.1)	0.43 (0.12, 1.53)	10 (0.2)
Arthropod sting	2 (<0.1)	2 (<0.1)		4 (<0.1)
Joint injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Animal bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Back injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Concussion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Injury, poisoning and procedural complications (Cont.)				
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hand fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Heat exhaustion	0	1 (<0.1)		1 (<0.1)
Hip fracture	0	1 (<0.1)		1 (<0.1)
Ligament rupture	0	1 (<0.1)		1 (<0.1)
Skin abrasion	7 (0.2)	1 (<0.1)	0.14 (0.02, 0.90)	8 (0.1)
Sunburn	0	1 (<0.1)		1 (<0.1)
Wrist fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Bone contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Lip injury	1 (<0.1)	0		1 (<0.1)
Muscle rupture	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 1 Risk Factor

System Organ Class Preferred Term	Placebo (N=2815) n (%)	mRNA-1273 (N=2791) n (%)	Rate Ratio (95% CI)	Total (N=5606) n (%)
Injury, poisoning and procedural complications (Cont.)				
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	2 (<0.1)	0		2 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	202 (31.5)	220 (33.5)		422 (32.5)
Number of Unsolicited Adverse Events	480	458		938
Infections and infestations	41 (6.4)	38 (5.8)		79 (6.1)
Urinary tract infection	7 (1.1)	6 (0.9)	0.84 (0.30, 2.36)	13 (1.0)
Upper respiratory tract infection	3 (0.5)	4 (0.6)		7 (0.5)
Herpes simplex	0	2 (0.3)		2 (0.2)
Localised infection	0	2 (0.3)		2 (0.2)
Pharyngitis	1 (0.2)	2 (0.3)		3 (0.2)
Sinusitis	3 (0.5)	2 (0.3)		5 (0.4)
Suspected COVID-19	1 (0.2)	2 (0.3)		3 (0.2)
Tooth infection	1 (0.2)	2 (0.3)		3 (0.2)
Viral infection	3 (0.5)	2 (0.3)		5 (0.4)
Abscess limb	0	1 (0.2)		1 (<0.1)
Asymptomatic COVID-19	0	1 (0.2)		1 (<0.1)
Bronchitis	0	1 (0.2)		1 (<0.1)
COVID-19	7 (1.1)	1 (0.2)	0.14 (0.02, 0.87)	8 (0.6)
Cellulitis	2 (0.3)	1 (0.2)		3 (0.2)
Conjunctivitis bacterial	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Infections and infestations (Cont.)				
Coronavirus infection	0	1 (0.2)		1 (<0.1)
Gastroenteritis	2 (0.3)	1 (0.2)		3 (0.2)
Helicobacter infection	0	1 (0.2)		1 (<0.1)
Osteomyelitis	0	1 (0.2)		1 (<0.1)
Otitis externa	0	1 (0.2)		1 (<0.1)
Otitis media	0	1 (0.2)		1 (<0.1)
Otitis media acute	0	1 (0.2)		1 (<0.1)
Pharyngitis streptococcal	0	1 (0.2)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (0.2)		1 (<0.1)
Trichomoniasis	0	1 (0.2)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (0.2)		1 (<0.1)
Breast abscess	2 (0.3)	0		2 (0.2)
Breast cellulitis	1 (0.2)	0		1 (<0.1)
Candida infection	1 (0.2)	0		1 (<0.1)
Cystitis	1 (0.2)	0		1 (<0.1)
Diverticulitis	1 (0.2)	0		1 (<0.1)
Gastroenteritis viral	1 (0.2)	0		1 (<0.1)
Herpes virus infection	1 (0.2)	0		1 (<0.1)
Herpes zoster	2 (0.3)	0		2 (0.2)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Infections and infestations (Cont.)				
Oral herpes	1 (0.2)	0		1 (<0.1)
Pneumonia	1 (0.2)	0		1 (<0.1)
Pneumonia viral	1 (0.2)	0		1 (<0.1)
Postoperative wound infection	1 (0.2)	0		1 (<0.1)
Sepsis	1 (0.2)	0		1 (<0.1)
Skin infection	1 (0.2)	0		1 (<0.1)
Tooth abscess	1 (0.2)	0		1 (<0.1)
Vulvovaginal mycotic infection	1 (0.2)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.2)	1 (0.2)		2 (0.2)
Thyroid cancer metastatic	0	1 (0.2)		1 (<0.1)
Breast cancer stage I	1 (0.2)	0		1 (<0.1)
Blood and lymphatic system disorders	3 (0.5)	9 (1.4)		12 (0.9)
Lymphadenopathy	2 (0.3)	9 (1.4)	4.40 (1.08, 18.01)	11 (0.8)
Iron deficiency anaemia	1 (0.2)	0		1 (<0.1)
Immune system disorders	2 (0.3)	4 (0.6)		6 (0.5)
Seasonal allergy	1 (0.2)	3 (0.5)		4 (0.3)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Immune system disorders (Cont.)				
Sarcoidosis	0	1 (0.2)		1 (<0.1)
Smoke sensitivity	1 (0.2)	0		1 (<0.1)
Metabolism and nutrition disorders	12 (1.9)	14 (2.1)		26 (2.0)
Type 2 diabetes mellitus	4 (0.6)	4 (0.6)		8 (0.6)
Hyperlipidaemia	0	2 (0.3)		2 (0.2)
Abnormal loss of weight	0	1 (0.2)		1 (<0.1)
Decreased appetite	2 (0.3)	1 (0.2)		3 (0.2)
Dehydration	0	1 (0.2)		1 (<0.1)
Diabetes mellitus	3 (0.5)	1 (0.2)		4 (0.3)
Gout	1 (0.2)	1 (0.2)		2 (0.2)
Hypercholesterolaemia	0	1 (0.2)		1 (<0.1)
Hypoglycaemia	1 (0.2)	1 (0.2)		2 (0.2)
Magnesium deficiency	0	1 (0.2)		1 (<0.1)
Vitamin D deficiency	0	1 (0.2)		1 (<0.1)
Dyslipidaemia	1 (0.2)	0		1 (<0.1)
Electrolyte imbalance	1 (0.2)	0		1 (<0.1)
Hypocalcaemia	1 (0.2)	0		1 (<0.1)
Hypokalaemia	1 (0.2)	0		1 (<0.1)
Hypomagnesaemia	1 (0.2)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Psychiatric disorders	4 (0.6)	8 (1.2)		12 (0.9)
Insomnia	0	3 (0.5)		3 (0.2)
Anxiety	1 (0.2)	2 (0.3)		3 (0.2)
Depression	2 (0.3)	1 (0.2)		3 (0.2)
Hallucination	0	1 (0.2)		1 (<0.1)
Suicidal ideation	0	1 (0.2)		1 (<0.1)
Agitation	1 (0.2)	0		1 (<0.1)
Mental status changes	1 (0.2)	0		1 (<0.1)
Nervous system disorders	47 (7.3)	45 (6.8)		92 (7.1)
Headache	33 (5.1)	38 (5.8)	1.13 (0.72, 1.76)	71 (5.5)
Dizziness	4 (0.6)	2 (0.3)		6 (0.5)
Anosmia	1 (0.2)	1 (0.2)		2 (0.2)
Hypoaesthesia	0	1 (0.2)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (0.2)		1 (<0.1)
Neuropathy peripheral	0	1 (0.2)		1 (<0.1)
Peripheral sensory neuropathy	0	1 (0.2)		1 (<0.1)
Piriformis syndrome	0	1 (0.2)		1 (<0.1)
Sciatica	2 (0.3)	1 (0.2)		3 (0.2)
Syncope	0	1 (0.2)		1 (<0.1)
Ageusia	1 (0.2)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Nervous system disorders (Cont.)				
Aphasia	1 (0.2)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (0.2)	0		1 (<0.1)
Dyskinesia	1 (0.2)	0		1 (<0.1)
Encephalopathy	1 (0.2)	0		1 (<0.1)
Ischaemic stroke	1 (0.2)	0		1 (<0.1)
Lethargy	1 (0.2)	0		1 (<0.1)
Neuralgia	1 (0.2)	0		1 (<0.1)
Presyncope	1 (0.2)	0		1 (<0.1)
Sinus headache	1 (0.2)	0		1 (<0.1)
Speech disorder	1 (0.2)	0		1 (<0.1)
Tension headache	1 (0.2)	0		1 (<0.1)
Transient ischaemic attack	1 (0.2)	0		1 (<0.1)
Eye disorders	5 (0.8)	1 (0.2)		6 (0.5)
Conjunctival haemorrhage	0	1 (0.2)		1 (<0.1)
Blindness	1 (0.2)	0		1 (<0.1)
Cataract	1 (0.2)	0		1 (<0.1)
Eye pruritus	1 (0.2)	0		1 (<0.1)
Ocular hyperaemia	2 (0.3)	0		2 (0.2)
Periorbital swelling	1 (0.2)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Ear and labyrinth disorders	4 (0.6)	6 (0.9)		10 (0.8)
Ear pain	0	3 (0.5)		3 (0.2)
Vertigo	1 (0.2)	2 (0.3)		3 (0.2)
Cerumen impaction	0	1 (0.2)		1 (<0.1)
Ear canal erythema	1 (0.2)	0		1 (<0.1)
Ear discomfort	1 (0.2)	0		1 (<0.1)
Tinnitus	1 (0.2)	0		1 (<0.1)
Cardiac disorders	7 (1.1)	4 (0.6)		11 (0.8)
Bradycardia	0	1 (0.2)		1 (<0.1)
Cardiac failure congestive	0	1 (0.2)		1 (<0.1)
Myocardial infarction	0	1 (0.2)		1 (<0.1)
Tachycardia	2 (0.3)	1 (0.2)		3 (0.2)
Acute myocardial infarction	1 (0.2)	0		1 (<0.1)
Angina pectoris	1 (0.2)	0		1 (<0.1)
Atrial fibrillation	1 (0.2)	0		1 (<0.1)
Atrial flutter	1 (0.2)	0		1 (<0.1)
Coronary artery disease	1 (0.2)	0		1 (<0.1)
Palpitations	1 (0.2)	0		1 (<0.1)
Ventricular fibrillation	1 (0.2)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Vascular disorders	11 (1.7)	8 (1.2)		19 (1.5)
Hypertension	9 (1.4)	8 (1.2)	0.87 (0.35, 2.17)	17 (1.3)
Deep vein thrombosis	1 (0.2)	0		1 (<0.1)
Hypotension	1 (0.2)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	37 (5.8)	28 (4.3)		65 (5.0)
Cough	9 (1.4)	11 (1.7)	1.19 (0.51, 2.79)	20 (1.5)
Rhinorrhoea	9 (1.4)	9 (1.4)	0.98 (0.40, 2.38)	18 (1.4)
Nasal congestion	11 (1.7)	6 (0.9)	0.53 (0.21, 1.38)	17 (1.3)
Oropharyngeal pain	8 (1.2)	5 (0.8)	0.61 (0.21, 1.77)	13 (1.0)
Asthma	3 (0.5)	2 (0.3)		5 (0.4)
Dyspnoea	2 (0.3)	2 (0.3)		4 (0.3)
Productive cough	1 (0.2)	2 (0.3)		3 (0.2)
Tachypnoea	1 (0.2)	2 (0.3)		3 (0.2)
Chronic obstructive pulmonary disease	4 (0.6)	1 (0.2)		5 (0.4)
Epistaxis	0	1 (0.2)		1 (<0.1)
Pleural effusion	0	1 (0.2)		1 (<0.1)
Respiratory disorder	0	1 (0.2)		1 (<0.1)
Respiratory failure	0	1 (0.2)		1 (<0.1)
Respiratory tract congestion	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinitis allergic	0	1 (0.2)		1 (<0.1)
Sinus pain	0	1 (0.2)		1 (<0.1)
Sleep apnoea syndrome	0	1 (0.2)		1 (<0.1)
Atelectasis	1 (0.2)	0		1 (<0.1)
Pleuritic pain	1 (0.2)	0		1 (<0.1)
Pulmonary mass	1 (0.2)	0		1 (<0.1)
Sneezing	1 (0.2)	0		1 (<0.1)
Tonsillar inflammation	1 (0.2)	0		1 (<0.1)
Wheezing	2 (0.3)	0		2 (0.2)
Gastrointestinal disorders	24 (3.7)	37 (5.6)		61 (4.7)
Nausea	5 (0.8)	16 (2.4)	3.13 (1.20, 8.19)	21 (1.6)
Diarrhoea	11 (1.7)	14 (2.1)	1.24 (0.58, 2.67)	25 (1.9)
Vomiting	0	4 (0.6)		4 (0.3)
Gastrooesophageal reflux disease	2 (0.3)	2 (0.3)		4 (0.3)
Large intestine polyp	0	2 (0.3)		2 (0.2)
Abdominal distension	0	1 (0.2)		1 (<0.1)
Abdominal pain upper	0	1 (0.2)		1 (<0.1)
Colitis	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Gastrointestinal disorders (Cont.)				
Dysphagia	1 (0.2)	1 (0.2)		2 (0.2)
Frequent bowel movements	0	1 (0.2)		1 (<0.1)
Gastric ulcer	0	1 (0.2)		1 (<0.1)
Gastrointestinal haemorrhage	0	1 (0.2)		1 (<0.1)
Hiatus hernia	0	1 (0.2)		1 (<0.1)
Proctalgia	0	1 (0.2)		1 (<0.1)
Abdominal discomfort	1 (0.2)	0		1 (<0.1)
Dental caries	1 (0.2)	0		1 (<0.1)
Diverticulum intestinal	1 (0.2)	0		1 (<0.1)
Noninfective gingivitis	1 (0.2)	0		1 (<0.1)
Oral mucosal erythema	1 (0.2)	0		1 (<0.1)
Oral pain	1 (0.2)	0		1 (<0.1)
Toothache	2 (0.3)	0		2 (0.2)
Skin and subcutaneous tissue disorders	9 (1.4)	7 (1.1)		16 (1.2)
Rash	2 (0.3)	2 (0.3)		4 (0.3)
Urticaria	1 (0.2)	2 (0.3)		3 (0.2)
Acne	0	1 (0.2)		1 (<0.1)
Dermatitis atopic	1 (0.2)	1 (0.2)		2 (0.2)
Rash maculo-papular	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Blister	1 (0.2)	0		1 (<0.1)
Dermatitis contact	1 (0.2)	0		1 (<0.1)
Hyperhidrosis	1 (0.2)	0		1 (<0.1)
Pruritus	2 (0.3)	0		2 (0.2)
Urticaria papular	1 (0.2)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	59 (9.2)	56 (8.5)		115 (8.9)
Myalgia	22 (3.4)	25 (3.8)	1.11 (0.64, 1.94)	47 (3.6)
Arthralgia	32 (5.0)	23 (3.5)	0.70 (0.42, 1.18)	55 (4.2)
Pain in extremity	5 (0.8)	10 (1.5)	1.95 (0.70, 5.44)	15 (1.2)
Back pain	3 (0.5)	4 (0.6)		7 (0.5)
Neck pain	3 (0.5)	4 (0.6)		7 (0.5)
Musculoskeletal pain	4 (0.6)	3 (0.5)		7 (0.5)
Osteoarthritis	2 (0.3)	3 (0.5)		5 (0.4)
Bursitis	0	1 (0.2)		1 (<0.1)
Costochondritis	0	1 (0.2)		1 (<0.1)
Muscle spasms	1 (0.2)	1 (0.2)		2 (0.2)
Musculoskeletal stiffness	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in jaw	1 (0.2)	1 (0.2)		2 (0.2)
Spinal stenosis	0	1 (0.2)		1 (<0.1)
Trigger finger	0	1 (0.2)		1 (<0.1)
Arthritis	1 (0.2)	0		1 (<0.1)
Groin pain	1 (0.2)	0		1 (<0.1)
Intervertebral disc protrusion	1 (0.2)	0		1 (<0.1)
Musculoskeletal chest pain	2 (0.3)	0		2 (0.2)
Osteonecrosis	1 (0.2)	0		1 (<0.1)
Renal and urinary disorders	4 (0.6)	2 (0.3)		6 (0.5)
Nephrolithiasis	2 (0.3)	1 (0.2)		3 (0.2)
Pollakiuria	0	1 (0.2)		1 (<0.1)
Acute kidney injury	1 (0.2)	0		1 (<0.1)
Renal cyst	1 (0.2)	0		1 (<0.1)
Renal impairment	1 (0.2)	0		1 (<0.1)
Urinary retention	1 (0.2)	0		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Reproductive system and breast disorders	0	3 (0.5)		3 (0.2)
Erectile dysfunction	0	1 (0.2)		1 (<0.1)
Perineal rash	0	1 (0.2)		1 (<0.1)
Postmenopausal haemorrhage	0	1 (0.2)		1 (<0.1)
General disorders and administration site conditions	61 (9.5)	66 (10.0)		127 (9.8)
Fatigue	33 (5.1)	44 (6.7)	1.30 (0.84, 2.01)	77 (5.9)
Injection site pain	4 (0.6)	10 (1.5)	2.44 (0.82, 7.34)	14 (1.1)
Chills	10 (1.6)	7 (1.1)	0.68 (0.27, 1.73)	17 (1.3)
Injection site erythema	3 (0.5)	4 (0.6)		7 (0.5)
Pyrexia	4 (0.6)	4 (0.6)		8 (0.6)
Injection site lymphadenopathy	0	3 (0.5)		3 (0.2)
Injection site swelling	3 (0.5)	3 (0.5)		6 (0.5)
Chest pain	0	2 (0.3)		2 (0.2)
Injection site pruritus	1 (0.2)	2 (0.3)		3 (0.2)
Pain	7 (1.1)	2 (0.3)	0.28 (0.07, 1.18)	9 (0.7)
Cyst	0	1 (0.2)		1 (<0.1)
Feeling hot	0	1 (0.2)		1 (<0.1)
Injection site bruising	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
General disorders and administration site conditions (Cont.)				
Injection site macule	0	1 (0.2)		1 (<0.1)
Injection site scab	0	1 (0.2)		1 (<0.1)
Non-cardiac chest pain	0	1 (0.2)		1 (<0.1)
Peripheral swelling	2 (0.3)	1 (0.2)		3 (0.2)
Precancerous condition	0	1 (0.2)		1 (<0.1)
Asthenia	1 (0.2)	0		1 (<0.1)
Chest discomfort	5 (0.8)	0		5 (0.4)
Facial pain	1 (0.2)	0		1 (<0.1)
Gait disturbance	1 (0.2)	0		1 (<0.1)
Incarcerated hernia	1 (0.2)	0		1 (<0.1)
Injection site discomfort	1 (0.2)	0		1 (<0.1)
Injection site induration	2 (0.3)	0		2 (0.2)
Injection site scar	1 (0.2)	0		1 (<0.1)
Polyp	1 (0.2)	0		1 (<0.1)
Reactogenicity event	1 (0.2)	0		1 (<0.1)
Swelling face	1 (0.2)	0		1 (<0.1)
Investigations	4 (0.6)	3 (0.5)		7 (0.5)
Blood parathyroid hormone increased	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Investigations (Cont.)				
Blood pressure systolic increased	2 (0.3)	1 (0.2)		3 (0.2)
Heart rate increased	1 (0.2)	1 (0.2)		2 (0.2)
Blood iron decreased	1 (0.2)	0		1 (<0.1)
Injury, poisoning and procedural complications	25 (3.9)	15 (2.3)		40 (3.1)
Procedural pain	0	3 (0.5)		3 (0.2)
Contusion	0	2 (0.3)		2 (0.2)
Arthropod bite	3 (0.5)	1 (0.2)		4 (0.3)
Concussion	1 (0.2)	1 (0.2)		2 (0.2)
Fall	4 (0.6)	1 (0.2)		5 (0.4)
Joint injury	2 (0.3)	1 (0.2)		3 (0.2)
Ligament sprain	1 (0.2)	1 (0.2)		2 (0.2)
Rib fracture	0	1 (0.2)		1 (<0.1)
Road traffic accident	0	1 (0.2)		1 (<0.1)
Skin laceration	2 (0.3)	1 (0.2)		3 (0.2)
Tendon rupture	0	1 (0.2)		1 (<0.1)
Thermal burn	0	1 (0.2)		1 (<0.1)
Tooth fracture	1 (0.2)	1 (0.2)		2 (0.2)
Tooth injury	0	1 (0.2)		1 (<0.1)

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Table 14.3.1.8.6.3.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Risk Factor for Severe COVID (No, with 1 Risk Factor, with 2 or More Risk Factors) at Baseline up to 28 Days After Any Injection
Safety Set

Risk Group: with 2 or More Risk Factors

System Organ Class Preferred Term	Placebo (N=642) n (%)	mRNA-1273 (N=657) n (%)	Rate Ratio (95% CI)	Total (N=1299) n (%)
Injury, poisoning and procedural complications (Cont.)				
Arthropod sting	1 (0.2)	0		1 (<0.1)
Buttock injury	1 (0.2)	0		1 (<0.1)
Corneal abrasion	1 (0.2)	0		1 (<0.1)
Femur fracture	1 (0.2)	0		1 (<0.1)
Fibula fracture	1 (0.2)	0		1 (<0.1)
Foot fracture	3 (0.5)	0		3 (0.2)
Lower limb fracture	1 (0.2)	0		1 (<0.1)
Muscle strain	2 (0.3)	0		2 (0.2)
Post procedural haematoma	1 (0.2)	0		1 (<0.1)
Post-traumatic pain	1 (0.2)	0		1 (<0.1)
Skin abrasion	1 (0.2)	0		1 (<0.1)
Sunburn	1 (0.2)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3275 (28.7)	3515 (30.8)		6790 (29.7)
Number of Unsolicited Adverse Events	6564	7126		13690
Infections and infestations	763 (6.7)	617 (5.4)		1380 (6.0)
Upper respiratory tract infection	108 (0.9)	71 (0.6)	0.66 (0.49, 0.88)	179 (0.8)
Urinary tract infection	73 (0.6)	67 (0.6)	0.92 (0.66, 1.28)	140 (0.6)
Sinusitis	38 (0.3)	49 (0.4)	1.29 (0.85, 1.96)	87 (0.4)
Viral infection	46 (0.4)	37 (0.3)	0.80 (0.52, 1.23)	83 (0.4)
Rhinovirus infection	28 (0.2)	30 (0.3)	1.07 (0.64, 1.78)	58 (0.3)
Suspected COVID-19	28 (0.2)	29 (0.3)	1.04 (0.62, 1.73)	57 (0.2)
Tooth infection	15 (0.1)	20 (0.2)	1.33 (0.69, 2.57)	35 (0.2)
COVID-19	139 (1.2)	17 (0.1)	0.12 (0.07, 0.20)	156 (0.7)
Pharyngitis	20 (0.2)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.2)
Tooth abscess	15 (0.1)	16 (0.1)	1.07 (0.53, 2.13)	31 (0.1)
Ear infection	9 (<0.1)	15 (0.1)	1.67 (0.75, 3.72)	24 (0.1)
Gastroenteritis	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Herpes zoster	11 (<0.1)	14 (0.1)	1.27 (0.59, 2.75)	25 (0.1)
Pharyngitis streptococcal	18 (0.2)	13 (0.1)	0.72 (0.36, 1.45)	31 (0.1)
Conjunctivitis	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.63)	17 (<0.1)
Viral upper respiratory tract infection	13 (0.1)	10 (<0.1)	0.77 (0.34, 1.72)	23 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Bronchitis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Cellulitis	12 (0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Hordeolum	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Oral herpes	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Otitis media	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Fungal infection	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Bacterial vaginosis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Folliculitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Herpes simplex	4 (<0.1)	6 (<0.1)		10 (<0.1)
Vulvovaginal mycotic infection	13 (0.1)	6 (<0.1)	0.46 (0.18, 1.17)	19 (<0.1)
Acute sinusitis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Asymptomatic COVID-19	3 (<0.1)	5 (<0.1)		8 (<0.1)
Diverticulitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Localised infection	5 (<0.1)	5 (<0.1)		10 (<0.1)
Nasopharyngitis	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.40)	15 (<0.1)
Otitis externa	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Paronychia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Vulvovaginal candidiasis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Abscess limb	1 (<0.1)	4 (<0.1)		5 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Onychomycosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Respiratory tract infection	3 (<0.1)	4 (<0.1)		7 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	10 (<0.1)	3 (<0.1)	0.30 (0.09, 1.01)	13 (<0.1)
Gingivitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	0	3 (<0.1)		3 (<0.1)
Skin infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Subcutaneous abscess	2 (<0.1)	3 (<0.1)		5 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Enterovirus infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Impetigo	0	2 (<0.1)		2 (<0.1)
Oral candidiasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pneumonia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Soft tissue infection	0	2 (<0.1)		2 (<0.1)
Tonsillitis	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	0	1 (<0.1)		1 (<0.1)
Candida infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Chronic sinusitis	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystitis	9 (<0.1)	1 (<0.1)	0.11 (0.02, 0.68)	10 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection viral	4 (<0.1)	1 (<0.1)		5 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Staphylococcal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea cruris	0	1 (<0.1)		1 (<0.1)
Tinea pedis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Appendicitis	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	2 (<0.1)	0		2 (<0.1)
Laryngitis	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Latent tuberculosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Rhinitis	4 (<0.1)	0		4 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Sialoadenitis	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	22 (0.2)	33 (0.3)		55 (0.2)
Uterine leiomyoma	1 (<0.1)	4 (<0.1)		5 (<0.1)
Basal cell carcinoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Benign neoplasm of skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Squamous cell carcinoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	2 (<0.1)	1 (<0.1)		3 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Prostate cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Lipoma	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Skin cancer	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	0		2 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	132 (1.2)	261 (2.3)		393 (1.7)
Lymphadenopathy	114 (1.0)	238 (2.1)	2.09 (1.67, 2.60)	352 (1.5)
Lymph node pain	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Blood and lymphatic system disorders (Cont.)				
Anaemia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Iron deficiency anaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Lymphadenitis	0	2 (<0.1)		2 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	0		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	55 (0.5)	33 (0.3)		88 (0.4)
Seasonal allergy	38 (0.3)	24 (0.2)	0.63 (0.38, 1.05)	62 (0.3)
Hypersensitivity	6 (<0.1)	4 (<0.1)		10 (<0.1)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	0		2 (<0.1)
Drug hypersensitivity	4 (<0.1)	0		4 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Endocrine disorders	11 (<0.1)	10 (<0.1)		21 (<0.1)
Hypothyroidism	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	87 (0.8)	77 (0.7)		164 (0.7)
Type 2 diabetes mellitus	8 (<0.1)	13 (0.1)	1.62 (0.69, 3.82)	21 (<0.1)
Hyperlipidaemia	16 (0.1)	12 (0.1)	0.75 (0.36, 1.56)	28 (0.1)
Decreased appetite	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Vitamin D deficiency	14 (0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Dehydration	4 (<0.1)	6 (<0.1)		10 (<0.1)
Glucose tolerance impaired	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Diabetes mellitus	2 (<0.1)	4 (<0.1)		6 (<0.1)
Gout	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypercholesterolaemia	12 (0.1)	3 (<0.1)	0.25 (0.08, 0.82)	15 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abnormal loss of weight	0	2 (<0.1)		2 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypokalaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyponatraemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Iron deficiency	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders	98 (0.9)	128 (1.1)		226 (1.0)
Anxiety	31 (0.3)	41 (0.4)	1.32 (0.83, 2.10)	72 (0.3)
Depression	26 (0.2)	30 (0.3)	1.15 (0.69, 1.94)	56 (0.2)
Insomnia	19 (0.2)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.2)
Abnormal dreams	1 (<0.1)	5 (<0.1)		6 (<0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Panic attack	3 (<0.1)	4 (<0.1)		7 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	3 (<0.1)		4 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Sleep disorder	0	3 (<0.1)		3 (<0.1)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	3 (<0.1)	0		3 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Nightmare	1 (<0.1)	0		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	707 (6.2)	805 (7.1)		1512 (6.6)
Headache	568 (5.0)	605 (5.3)	1.06 (0.95, 1.19)	1173 (5.1)
Dizziness	39 (0.3)	52 (0.5)	1.33 (0.88, 2.01)	91 (0.4)
Paraesthesia	24 (0.2)	27 (0.2)	1.12 (0.65, 1.93)	51 (0.2)
Ageusia	9 (<0.1)	14 (0.1)	1.56 (0.69, 3.51)	23 (0.1)
Migraine	21 (0.2)	14 (0.1)	0.67 (0.34, 1.29)	35 (0.2)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Sinus headache	4 (<0.1)	12 (0.1)	3.00 (1.02, 8.82)	16 (<0.1)
Dysgeusia	5 (<0.1)	11 (<0.1)	2.20 (0.80, 6.06)	16 (<0.1)
Hypoaesthesia	6 (<0.1)	10 (<0.1)	1.67 (0.63, 4.41)	16 (<0.1)
Syncope	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Anosmia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Sciatica	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Tension headache	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Presyncope	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Cervical radiculopathy	1 (<0.1)	5 (<0.1)		6 (<0.1)
Hyperaesthesia	0	4 (<0.1)		4 (<0.1)
Burning sensation	0	3 (<0.1)		3 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	3 (<0.1)		7 (<0.1)
Disturbance in attention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Memory impairment	0	3 (<0.1)		3 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Nerve compression	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Neuropathy peripheral	0	2 (<0.1)		2 (<0.1)
Seizure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Somnolence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Taste disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Facial paralysis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuralgia	0	1 (<0.1)		1 (<0.1)
Parosmia	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	2 (<0.1)	0		2 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Eye disorders	37 (0.3)	47 (0.4)		84 (0.4)
Eye pruritus	6 (<0.1)	5 (<0.1)		11 (<0.1)
Vision blurred	2 (<0.1)	5 (<0.1)		7 (<0.1)
Eye irritation	1 (<0.1)	4 (<0.1)		5 (<0.1)
Conjunctival haemorrhage	0	3 (<0.1)		3 (<0.1)
Blepharitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Dry eye	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular hyperaemia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye inflammation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Eye pain	0	1 (<0.1)		1 (<0.1)
Eye swelling	3 (<0.1)	1 (<0.1)		4 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Glaucoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Cataract	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	59 (0.5)	56 (0.5)		115 (0.5)
Ear pain	15 (0.1)	14 (0.1)	0.93 (0.46, 1.90)	29 (0.1)
Vertigo	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Tinnitus	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Ear discomfort	5 (<0.1)	4 (<0.1)		9 (<0.1)
Vertigo positional	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cerumen impaction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear canal erythema	4 (<0.1)	2 (<0.1)		6 (<0.1)
Otorrhoea	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear congestion	3 (<0.1)	0		3 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)
Middle ear effusion	3 (<0.1)	0		3 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Ear and labyrinth disorders (Cont.)				
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	44 (0.4)	44 (0.4)		88 (0.4)
Tachycardia	7 (<0.1)	13 (0.1)	1.86 (0.76, 4.52)	20 (<0.1)
Bradycardia	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Palpitations	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Atrial fibrillation	3 (<0.1)	3 (<0.1)		6 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Angina pectoris	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiac failure congestive	3 (<0.1)	2 (<0.1)		5 (<0.1)
Sinus tachycardia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Cardiac failure	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	2 (<0.1)	0		2 (<0.1)
Vascular disorders	130 (1.1)	128 (1.1)		258 (1.1)
Hypertension	105 (0.9)	103 (0.9)	0.98 (0.75, 1.28)	208 (0.9)
Hot flush	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Flushing	4 (<0.1)	4 (<0.1)		8 (<0.1)
Haematoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Systolic hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders (Cont.)				
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	538 (4.7)	478 (4.2)		1016 (4.5)
Cough	143 (1.3)	145 (1.3)	1.01 (0.81, 1.27)	288 (1.3)
Oropharyngeal pain	195 (1.7)	134 (1.2)	0.69 (0.55, 0.85)	329 (1.4)
Nasal congestion	135 (1.2)	128 (1.1)	0.95 (0.75, 1.20)	263 (1.2)
Rhinorrhoea	113 (1.0)	97 (0.8)	0.86 (0.66, 1.12)	210 (0.9)
Dyspnoea	34 (0.3)	35 (0.3)	1.03 (0.65, 1.64)	69 (0.3)
Tachypnoea	29 (0.3)	30 (0.3)	1.03 (0.62, 1.71)	59 (0.3)
Respiratory tract congestion	6 (<0.1)	15 (0.1)	2.50 (1.00, 6.24)	21 (<0.1)
Sinus congestion	22 (0.2)	15 (0.1)	0.68 (0.36, 1.30)	37 (0.2)
Throat irritation	13 (0.1)	14 (0.1)	1.08 (0.51, 2.25)	27 (0.1)
Epistaxis	6 (<0.1)	12 (0.1)	2.00 (0.78, 5.14)	18 (<0.1)
Asthma	15 (0.1)	10 (<0.1)	0.67 (0.31, 1.45)	25 (0.1)
Rhinitis allergic	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Upper-airway cough syndrome	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.76)	19 (<0.1)
Sneezing	12 (0.1)	6 (<0.1)	0.50 (0.19, 1.28)	18 (<0.1)
Chronic obstructive pulmonary disease	6 (<0.1)	5 (<0.1)		11 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)		7 (<0.1)
Productive cough	4 (<0.1)	4 (<0.1)		8 (<0.1)
Sinus pain	3 (<0.1)	4 (<0.1)		7 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dry throat	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dyspnoea exertional	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pharyngeal erythema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchiectasis	0	2 (<0.1)		2 (<0.1)
Dysphonia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wheezing	2 (<0.1)	2 (<0.1)		4 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchospasm	0	1 (<0.1)		1 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	4 (<0.1)	1 (<0.1)		5 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory disorder	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	420 (3.7)	444 (3.9)		864 (3.8)
Diarrhoea	139 (1.2)	159 (1.4)	1.14 (0.91, 1.43)	298 (1.3)
Nausea	132 (1.2)	120 (1.1)	0.91 (0.71, 1.16)	252 (1.1)
Vomiting	45 (0.4)	44 (0.4)	0.98 (0.65, 1.48)	89 (0.4)
Gastrooesophageal reflux disease	21 (0.2)	28 (0.2)	1.33 (0.76, 2.33)	49 (0.2)
Toothache	22 (0.2)	25 (0.2)	1.14 (0.65, 2.00)	47 (0.2)
Abdominal pain	18 (0.2)	22 (0.2)	1.22 (0.66, 2.25)	40 (0.2)
Constipation	13 (0.1)	12 (0.1)	0.92 (0.43, 1.98)	25 (0.1)
Dental caries	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Dyspepsia	13 (0.1)	10 (<0.1)	0.77 (0.34, 1.72)	23 (0.1)
Food poisoning	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.59)	15 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal pain upper	16 (0.1)	8 (<0.1)	0.50 (0.22, 1.14)	24 (0.1)
Abdominal pain lower	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Abdominal discomfort	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Abdominal distension	2 (<0.1)	4 (<0.1)		6 (<0.1)
Gastric ulcer	2 (<0.1)	4 (<0.1)		6 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)		6 (<0.1)
Aphthous ulcer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Colitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Hiatus hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tooth impacted	2 (<0.1)	3 (<0.1)		5 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastritis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastrointestinal disorder	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	2 (<0.1)		3 (<0.1)
Inguinal hernia	0	2 (<0.1)		2 (<0.1)
Large intestine polyp	1 (<0.1)	2 (<0.1)		3 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Proctalgia	0	2 (<0.1)		2 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Umbilical hernia	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry mouth	2 (<0.1)	1 (<0.1)		3 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival pain	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0		2 (<0.1)
Oral disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	3 (<0.1)	0		3 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	5 (<0.1)	8 (<0.1)		13 (<0.1)
Cholelithiasis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	182 (1.6)	212 (1.9)		394 (1.7)
Urticaria	26 (0.2)	33 (0.3)	1.27 (0.76, 2.11)	59 (0.3)
Rash	27 (0.2)	26 (0.2)	0.96 (0.57, 1.64)	53 (0.2)
Pruritus	15 (0.1)	18 (0.2)	1.20 (0.61, 2.35)	33 (0.1)
Dermatitis contact	20 (0.2)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.2)
Hyperhidrosis	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Eczema	3 (<0.1)	10 (<0.1)	3.33 (0.99, 11.22)	13 (<0.1)
Acne	7 (<0.1)	9 (<0.1)	1.29 (0.50, 3.33)	16 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Night sweats	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Alopecia	4 (<0.1)	6 (<0.1)		10 (<0.1)
Dermatitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Rash maculo-papular	2 (<0.1)	6 (<0.1)		8 (<0.1)
Rash papular	4 (<0.1)	6 (<0.1)		10 (<0.1)
Ecchymosis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Erythema	3 (<0.1)	5 (<0.1)		8 (<0.1)
Psoriasis	0	4 (<0.1)		4 (<0.1)
Blister	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hidradenitis	0	3 (<0.1)		3 (<0.1)
Pain of skin	0	3 (<0.1)		3 (<0.1)
Pityriasis rosea	0	3 (<0.1)		3 (<0.1)
Rash erythematous	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rash pruritic	6 (<0.1)	3 (<0.1)		9 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Angioedema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dermatitis atopic	6 (<0.1)	2 (<0.1)		8 (<0.1)
Hand dermatitis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Macule	0	2 (<0.1)		2 (<0.1)
Rash macular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Actinic keratosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	0	1 (<0.1)		1 (<0.1)
Dermal cyst	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dry skin	2 (<0.1)	1 (<0.1)		3 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Papule	2 (<0.1)	1 (<0.1)		3 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ingrowing nail	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	3 (<0.1)	0		3 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	742 (6.5)	715 (6.3)		1457 (6.4)
Myalgia	304 (2.7)	288 (2.5)	0.95 (0.81, 1.11)	592 (2.6)
Arthralgia	283 (2.5)	270 (2.4)	0.95 (0.81, 1.12)	553 (2.4)
Back pain	93 (0.8)	79 (0.7)	0.85 (0.63, 1.14)	172 (0.8)
Pain in extremity	55 (0.5)	46 (0.4)	0.84 (0.57, 1.23)	101 (0.4)
Neck pain	28 (0.2)	35 (0.3)	1.25 (0.76, 2.04)	63 (0.3)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Musculoskeletal pain	28 (0.2)	34 (0.3)	1.21 (0.74, 1.99)	62 (0.3)
Muscle spasms	20 (0.2)	26 (0.2)	1.30 (0.73, 2.31)	46 (0.2)
Musculoskeletal chest pain	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Osteoarthritis	12 (0.1)	12 (0.1)	1.00 (0.46, 2.18)	24 (0.1)
Tendonitis	6 (<0.1)	10 (<0.1)	1.67 (0.63, 4.41)	16 (<0.1)
Rotator cuff syndrome	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Groin pain	1 (<0.1)	6 (<0.1)		7 (<0.1)
Musculoskeletal stiffness	12 (0.1)	6 (<0.1)	0.50 (0.19, 1.28)	18 (<0.1)
Bursitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Arthritis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Joint range of motion decreased	0	4 (<0.1)		4 (<0.1)
Limb discomfort	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pain in jaw	4 (<0.1)	4 (<0.1)		8 (<0.1)
Spinal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Costochondritis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Joint swelling	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.14)	12 (<0.1)
Trigger finger	1 (<0.1)	3 (<0.1)		4 (<0.1)
Axillary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Fibromyalgia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Muscular weakness	2 (<0.1)	2 (<0.1)		4 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Polyarthritis	0	2 (<0.1)		2 (<0.1)
Spinal osteoarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Flank pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Limb mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle twitching	3 (<0.1)	1 (<0.1)		4 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteoporosis	0	1 (<0.1)		1 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Joint stiffness	2 (<0.1)	0		2 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	2 (<0.1)	0		2 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	25 (0.2)	26 (0.2)		51 (0.2)
Nephrolithiasis	14 (0.1)	8 (<0.1)	0.57 (0.25, 1.33)	22 (<0.1)
Dysuria	1 (<0.1)	4 (<0.1)		5 (<0.1)
Acute kidney injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertonic bladder	0	2 (<0.1)		2 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Haematuria	5 (<0.1)	1 (<0.1)		6 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Polyuria	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary incontinence	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Renal and urinary disorders (Cont.)				
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Chronic kidney disease	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	51 (0.4)	45 (0.4)		96 (0.4)
Dysmenorrhoea	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Pelvic pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Erectile dysfunction	2 (<0.1)	3 (<0.1)		5 (<0.1)
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Prostatitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	6 (<0.1)	1 (<0.1)		7 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Haematospermia	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	813 (7.1)	1200 (10.5)		2013 (8.8)
Fatigue	526 (4.6)	557 (4.9)	1.06 (0.94, 1.19)	1083 (4.7)
Injection site pain	88 (0.8)	196 (1.7)	2.23 (1.73, 2.86)	284 (1.2)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Chills	85 (0.7)	103 (0.9)	1.21 (0.91, 1.61)	188 (0.8)
Injection site erythema	23 (0.2)	101 (0.9)	4.39 (2.80, 6.87)	124 (0.5)
Pyrexia	47 (0.4)	88 (0.8)	1.87 (1.32, 2.66)	135 (0.6)
Injection site swelling	19 (0.2)	84 (0.7)	4.42 (2.70, 7.23)	103 (0.5)
Injection site pruritus	11 (<0.1)	63 (0.6)	5.73 (3.05, 10.75)	74 (0.3)
Injection site lymphadenopathy	14 (0.1)	58 (0.5)	4.14 (2.33, 7.36)	72 (0.3)
Pain	52 (0.5)	58 (0.5)	1.11 (0.77, 1.62)	110 (0.5)
Injection site induration	11 (<0.1)	43 (0.4)	3.91 (2.04, 7.49)	54 (0.2)
Injection site macule	3 (<0.1)	31 (0.3)	10.33 (3.36, 31.81)	34 (0.1)
Injection site urticaria	0	27 (0.2)		27 (0.1)
Axillary pain	13 (0.1)	23 (0.2)	1.77 (0.91, 3.45)	36 (0.2)
Injection site rash	1 (<0.1)	18 (0.2)	17.99 (3.06, 105.89)	19 (<0.1)
Injection site bruising	12 (0.1)	15 (0.1)	1.25 (0.60, 2.62)	27 (0.1)
Malaise	5 (<0.1)	13 (0.1)	2.60 (0.97, 7.00)	18 (<0.1)
Injection site papule	1 (<0.1)	12 (0.1)	12.00 (2.00, 71.91)	13 (<0.1)
Chest discomfort	12 (0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Chest pain	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Non-cardiac chest pain	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Peripheral swelling	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Reactogenicity event	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.59)	8 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Feeling hot	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site paraesthesia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)		6 (<0.1)
Feeling abnormal	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site haemorrhage	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site joint pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site haematoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site hypoaesthesia	0	3 (<0.1)		3 (<0.1)
Injection site mass	0	3 (<0.1)		3 (<0.1)
Oedema peripheral	3 (<0.1)	3 (<0.1)		6 (<0.1)
Swelling face	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Vaccination site pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Injection site irritation	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Hangover	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Asthenia	4 (<0.1)	0		4 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discolouration	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Precancerous condition	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations	62 (0.5)	72 (0.6)		134 (0.6)
Blood pressure increased	21 (0.2)	18 (0.2)	0.86 (0.46, 1.59)	39 (0.2)
Blood pressure systolic increased	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.59)	15 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	8 (<0.1)	4.00 (0.96, 16.63)	10 (<0.1)
Body temperature increased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Hepatic enzyme increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Heart rate increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Transaminases increased	0	3 (<0.1)		3 (<0.1)
Blood cholesterol increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood glucose increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood triglycerides increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Weight decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Cardiac murmur	2 (<0.1)	0		2 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	2 (<0.1)	0		2 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	280 (2.5)	223 (2.0)		503 (2.2)
Muscle strain	28 (0.2)	29 (0.3)	1.04 (0.62, 1.73)	57 (0.2)
Ligament sprain	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Arthropod bite	25 (0.2)	15 (0.1)	0.60 (0.32, 1.13)	40 (0.2)
Skin laceration	25 (0.2)	15 (0.1)	0.60 (0.32, 1.13)	40 (0.2)
Tooth fracture	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Arthropod sting	7 (<0.1)	9 (<0.1)	1.29 (0.50, 3.33)	16 (<0.1)
Foot fracture	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Procedural pain	20 (0.2)	9 (<0.1)	0.45 (0.21, 0.97)	29 (0.1)
Contusion	22 (0.2)	8 (<0.1)	0.36 (0.17, 0.80)	30 (0.1)
Fall	16 (0.1)	8 (<0.1)	0.50 (0.22, 1.14)	24 (0.1)
Road traffic accident	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Skin abrasion	15 (0.1)	8 (<0.1)	0.53 (0.23, 1.23)	23 (0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Limb injury	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Joint injury	5 (<0.1)	6 (<0.1)		11 (<0.1)
Animal bite	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Meniscus injury	6 (<0.1)	5 (<0.1)		11 (<0.1)
Concussion	3 (<0.1)	4 (<0.1)		7 (<0.1)
Post-traumatic pain	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hand fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Ankle fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Epicondylitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Facial bones fracture	0	2 (<0.1)		2 (<0.1)
Head injury	0	2 (<0.1)		2 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tendon injury	0	2 (<0.1)		2 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Thermal burn	3 (<0.1)	2 (<0.1)		5 (<0.1)
Upper limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Back injury	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Bone contusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Exposure to SARS-CoV-2	0	1 (<0.1)		1 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)		1 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Muscle rupture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rib fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Sunburn	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Burns first degree	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	2 (<0.1)	0		2 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Vaccination complication	2 (<0.1)	0		2 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	0	4 (<0.1)		4 (<0.1)
Device breakage	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	846 (28.1)	1019 (32.7)		1865 (30.5)
Number of Unsolicited Adverse Events	1589	1998		3587
Infections and infestations	161 (5.3)	139 (4.5)		300 (4.9)
Urinary tract infection	35 (1.2)	23 (0.7)	0.64 (0.38, 1.07)	58 (0.9)
Sinusitis	5 (0.2)	11 (0.4)	2.13 (0.77, 5.86)	16 (0.3)
Upper respiratory tract infection	7 (0.2)	10 (0.3)	1.38 (0.54, 3.50)	17 (0.3)
Herpes zoster	3 (<0.1)	6 (0.2)		9 (0.1)
Tooth infection	3 (<0.1)	6 (0.2)		9 (0.1)
COVID-19	15 (0.5)	5 (0.2)	0.32 (0.12, 0.85)	20 (0.3)
Gastroenteritis	1 (<0.1)	5 (0.2)		6 (<0.1)
Gingivitis	2 (<0.1)	5 (0.2)		7 (0.1)
Rhinovirus infection	2 (<0.1)	5 (0.2)		7 (0.1)
Tooth abscess	10 (0.3)	5 (0.2)	0.48 (0.17, 1.35)	15 (0.2)
Cellulitis	2 (<0.1)	4 (0.1)		6 (<0.1)
Diverticulitis	4 (0.1)	4 (0.1)		8 (0.1)
Oral herpes	1 (<0.1)	4 (0.1)		5 (<0.1)
Suspected COVID-19	6 (0.2)	4 (0.1)		10 (0.2)
Conjunctivitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hordeolum	1 (<0.1)	3 (<0.1)		4 (<0.1)
Laryngitis	0	3 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Infections and infestations (Cont.)				
Localised infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Viral infection	6 (0.2)	3 (<0.1)		9 (0.1)
Ear infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Enterovirus infection	0	2 (<0.1)		2 (<0.1)
Herpes simplex	1 (<0.1)	2 (<0.1)		3 (<0.1)
Onychomycosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis externa	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pneumonia	4 (0.1)	2 (<0.1)		6 (<0.1)
Subcutaneous abscess	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Acute sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Chronic sinusitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Cystitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Folliculitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Infections and infestations (Cont.)				
Joint abscess	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	0	1 (<0.1)		1 (<0.1)
Paronychia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rhinitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sialoadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Skin infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea pedis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Body tinea	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Infections and infestations (Cont.)				
Candida infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Fungal skin infection	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Genital herpes simplex	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Helicobacter infection	1 (<0.1)	0		1 (<0.1)
Kidney infection	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Nasopharyngitis	2 (<0.1)	0		2 (<0.1)
Oral candidiasis	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	0		2 (<0.1)
Postoperative wound infection	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Soft tissue infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea cruris	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Infections and infestations (Cont.)				
Vulvovaginal mycotic infection	1 (<0.1)	0		1 (<0.1)
Wound infection	2 (<0.1)	0		2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	26 (0.9)	23 (0.7)		49 (0.8)
Basal cell carcinoma	8 (0.3)	5 (0.2)	0.60 (0.21, 1.75)	13 (0.2)
Lipoma	0	2 (<0.1)		2 (<0.1)
Malignant melanoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)		5 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of skin	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma	7 (0.2)	1 (<0.1)	0.14 (0.02, 0.86)	8 (0.1)
Squamous cell carcinoma of skin	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Skin cancer	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	12 (0.4)	22 (0.7)		34 (0.6)
Lymphadenopathy	9 (0.3)	19 (0.6)	2.04 (0.94, 4.42)	28 (0.5)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Lymphadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	1 (<0.1)	0		1 (<0.1)
Immune system disorders	7 (0.2)	11 (0.4)		18 (0.3)
Seasonal allergy	6 (0.2)	8 (0.3)	1.29 (0.47, 3.55)	14 (0.2)
Hypersensitivity	0	2 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Allergy to chemicals	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Endocrine disorders	6 (0.2)	2 (<0.1)		8 (0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypothyroidism	4 (0.1)	1 (<0.1)		5 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	20 (0.7)	46 (1.5)		66 (1.1)
Hypercholesterolaemia	1 (<0.1)	9 (0.3)	8.71 (1.43, 53.13)	10 (0.2)
Hyperlipidaemia	5 (0.2)	9 (0.3)	1.74 (0.61, 4.95)	14 (0.2)
Type 2 diabetes mellitus	2 (<0.1)	6 (0.2)		8 (0.1)
Dehydration	2 (<0.1)	4 (0.1)		6 (<0.1)
Vitamin D deficiency	0	4 (0.1)		4 (<0.1)
Decreased appetite	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyponatraemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetes mellitus	3 (<0.1)	2 (<0.1)		5 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Glucose tolerance impaired	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperglycaemia	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Metabolism and nutrition disorders (Cont.)				
Vitamin B12 deficiency	0	1 (<0.1)		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypocalcaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	14 (0.5)	25 (0.8)		39 (0.6)
Anxiety	6 (0.2)	10 (0.3)	1.61 (0.61, 4.26)	16 (0.3)
Depression	3 (<0.1)	4 (0.1)		7 (0.1)
Insomnia	3 (<0.1)	4 (0.1)		7 (0.1)
Nightmare	0	2 (<0.1)		2 (<0.1)
Sleep disorder	0	2 (<0.1)		2 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Abnormal dreams	1 (<0.1)	0		1 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Nervous system disorders	140 (4.7)	173 (5.6)		313 (5.1)
Headache	93 (3.1)	121 (3.9)	1.26 (0.97, 1.64)	214 (3.5)
Dizziness	16 (0.5)	17 (0.5)	1.03 (0.53, 2.01)	33 (0.5)
Sinus headache	2 (<0.1)	8 (0.3)	3.87 (0.93, 16.09)	10 (0.2)
Paraesthesia	3 (<0.1)	5 (0.2)		8 (0.1)
Sciatica	4 (0.1)	3 (<0.1)		7 (0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Cervical radiculopathy	0	2 (<0.1)		2 (<0.1)
Disturbance in attention	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia	0	2 (<0.1)		2 (<0.1)
Hypoaesthesia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Syncope	4 (0.1)	2 (<0.1)		6 (<0.1)
Ageusia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Amnesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dysgeusia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Nervous system disorders (Cont.)				
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Parosmia	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tension headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tremor	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anosmia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Lumbar radiculopathy	1 (<0.1)	0		1 (<0.1)
Migraine	2 (<0.1)	0		2 (<0.1)
Nerve compression	2 (<0.1)	0		2 (<0.1)
Neuralgia	2 (<0.1)	0		2 (<0.1)
Neuropathy peripheral	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Presyncope	3 (<0.1)	0		3 (<0.1)
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Eye disorders	23 (0.8)	21 (0.7)		44 (0.7)
Eye irritation	0	3 (<0.1)		3 (<0.1)
Eye pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dry eye	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye inflammation	0	2 (<0.1)		2 (<0.1)
Eye pruritus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Glaucoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Eye swelling	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Vision blurred	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blepharitis	2 (<0.1)	0		2 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	0		2 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Eye disorders (Cont.)				
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	17 (0.6)	20 (0.6)		37 (0.6)
Vertigo	4 (0.1)	7 (0.2)	1.69 (0.53, 5.41)	11 (0.2)
Vertigo positional	0	3 (<0.1)		3 (<0.1)
Ear pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Tinnitus	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear congestion	0	1 (<0.1)		1 (<0.1)
Middle ear effusion	0	1 (<0.1)		1 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Ear discomfort	3 (<0.1)	0		3 (<0.1)
Ear pruritus	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Cardiac disorders	21 (0.7)	27 (0.9)		48 (0.8)
Atrial fibrillation	7 (0.2)	8 (0.3)	1.11 (0.42, 2.93)	15 (0.2)
Arrhythmia	1 (<0.1)	4 (0.1)		5 (<0.1)
Palpitations	0	3 (<0.1)		3 (<0.1)
Angina pectoris	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bradycardia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cardiac failure congestive	0	2 (<0.1)		2 (<0.1)
Tachycardia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute myocardial infarction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinus tachycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Cardiac failure	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	54 (1.8)	56 (1.8)		110 (1.8)
Hypertension	43 (1.4)	41 (1.3)	0.92 (0.60, 1.41)	84 (1.4)
Hot flush	3 (<0.1)	6 (0.2)		9 (0.1)
Flushing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertensive urgency	0	2 (<0.1)		2 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Vascular disorders (Cont.)				
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Hypotension	0	1 (<0.1)		1 (<0.1)
Systolic hypertension	2 (<0.1)	1 (<0.1)		3 (<0.1)
Aortic aneurysm	2 (<0.1)	0		2 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	103 (3.4)	102 (3.3)		205 (3.3)
Rhinorrhoea	27 (0.9)	30 (1.0)	1.07 (0.64, 1.79)	57 (0.9)
Cough	19 (0.6)	28 (0.9)	1.43 (0.80, 2.53)	47 (0.8)
Nasal congestion	24 (0.8)	21 (0.7)	0.85 (0.48, 1.50)	45 (0.7)
Oropharyngeal pain	32 (1.1)	21 (0.7)	0.63 (0.37, 1.09)	53 (0.9)
Dyspnoea	3 (<0.1)	6 (0.2)		9 (0.1)
Sneezing	2 (<0.1)	4 (0.1)		6 (<0.1)
Epistaxis	5 (0.2)	3 (<0.1)		8 (0.1)
Rhinitis allergic	4 (0.1)	3 (<0.1)		7 (0.1)
Tachypnoea	3 (<0.1)	3 (<0.1)		6 (<0.1)
Upper-airway cough syndrome	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dysphonia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pharyngeal erythema	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory tract congestion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Throat irritation	3 (<0.1)	2 (<0.1)		5 (<0.1)
Asthma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Bronchospasm	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dry throat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Respiratory disorder	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sinus congestion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Sinus pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	0		1 (<0.1)

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030108020201.sas 21JUN2021 14:29

Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Productive cough	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Wheezing	2 (<0.1)	0		2 (<0.1)
Gastrointestinal disorders	110 (3.7)	132 (4.2)		242 (4.0)
Diarrhoea	43 (1.4)	42 (1.3)	0.94 (0.62, 1.44)	85 (1.4)
Nausea	24 (0.8)	35 (1.1)	1.41 (0.85, 2.35)	59 (1.0)
Vomiting	5 (0.2)	13 (0.4)	2.51 (0.94, 6.77)	18 (0.3)
Gastrooesophageal reflux disease	5 (0.2)	11 (0.4)	2.13 (0.77, 5.86)	16 (0.3)
Toothache	5 (0.2)	8 (0.3)	1.55 (0.53, 4.49)	13 (0.2)
Abdominal pain upper	3 (<0.1)	5 (0.2)		8 (0.1)
Dental caries	2 (<0.1)	5 (0.2)		7 (0.1)
Abdominal pain	2 (<0.1)	4 (0.1)		6 (<0.1)
Constipation	6 (0.2)	3 (<0.1)		9 (0.1)
Dyspepsia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Inguinal hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Colitis	0	2 (<0.1)		2 (<0.1)
Abdominal pain lower	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Gastrointestinal disorders (Cont.)				
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	0	1 (<0.1)		1 (<0.1)
Dry mouth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysphagia	0	1 (<0.1)		1 (<0.1)
Flatulence	0	1 (<0.1)		1 (<0.1)
Food poisoning	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	0	1 (<0.1)		1 (<0.1)
Gingival pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Haemorrhoids	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hiatus hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	3 (<0.1)	1 (<0.1)		4 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	0	1 (<0.1)		1 (<0.1)
Oral disorder	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Gastrointestinal disorders (Cont.)				
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal discomfort	3 (<0.1)	0		3 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)		3 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	39 (1.3)	73 (2.3)		112 (1.8)
Rash	3 (<0.1)	9 (0.3)	2.90 (0.85, 9.90)	12 (0.2)
Urticaria	5 (0.2)	9 (0.3)	1.74 (0.61, 4.95)	14 (0.2)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Erythema	1 (<0.1)	7 (0.2)	6.77 (1.09, 42.17)	8 (0.1)
Dermatitis contact	11 (0.4)	6 (0.2)	0.53 (0.20, 1.37)	17 (0.3)
Pruritus	3 (<0.1)	6 (0.2)		9 (0.1)
Actinic keratosis	1 (<0.1)	5 (0.2)		6 (<0.1)
Rash macular	2 (<0.1)	5 (0.2)		7 (0.1)
Dermatitis atopic	0	3 (<0.1)		3 (<0.1)
Night sweats	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dry skin	0	2 (<0.1)		2 (<0.1)
Hyperhidrosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Rash maculo-papular	0	2 (<0.1)		2 (<0.1)
Rash pruritic	0	2 (<0.1)		2 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Macule	0	1 (<0.1)		1 (<0.1)
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Psoriasis	0	1 (<0.1)		1 (<0.1)
Rash papular	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin mass	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Cold sweat	1 (<0.1)	0		1 (<0.1)
Dermal cyst	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	220 (7.3)	239 (7.7)		459 (7.5)
Arthralgia	87 (2.9)	89 (2.9)	0.99 (0.74, 1.32)	176 (2.9)
Myalgia	63 (2.1)	82 (2.6)	1.26 (0.91, 1.74)	145 (2.4)
Pain in extremity	19 (0.6)	17 (0.5)	0.87 (0.46, 1.64)	36 (0.6)
Back pain	34 (1.1)	16 (0.5)	0.46 (0.25, 0.82)	50 (0.8)
Musculoskeletal pain	7 (0.2)	15 (0.5)	2.07 (0.87, 4.94)	22 (0.4)
Osteoarthritis	11 (0.4)	11 (0.4)	0.97 (0.43, 2.18)	22 (0.4)
Neck pain	8 (0.3)	10 (0.3)	1.21 (0.49, 2.97)	18 (0.3)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Muscle spasms	9 (0.3)	9 (0.3)	0.97 (0.40, 2.36)	18 (0.3)
Bursitis	0	7 (0.2)		7 (0.1)
Arthritis	1 (<0.1)	5 (0.2)		6 (<0.1)
Musculoskeletal stiffness	2 (<0.1)	5 (0.2)		7 (0.1)
Tendonitis	7 (0.2)	4 (0.1)	0.55 (0.17, 1.76)	11 (0.2)
Trigger finger	2 (<0.1)	4 (0.1)		6 (<0.1)
Joint swelling	0	3 (<0.1)		3 (<0.1)
Muscular weakness	0	3 (<0.1)		3 (<0.1)
Osteoporosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Rotator cuff syndrome	5 (0.2)	3 (<0.1)		8 (0.1)
Fibromyalgia	0	2 (<0.1)		2 (<0.1)
Flank pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Joint range of motion decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint stiffness	0	1 (<0.1)		1 (<0.1)
Limb discomfort	0	1 (<0.1)		1 (<0.1)
Muscle tightness	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Muscle twitching	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foot deformity	2 (<0.1)	0		2 (<0.1)
Groin pain	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	0		1 (<0.1)
Limb mass	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Osteopenia	1 (<0.1)	0		1 (<0.1)
Pain in jaw	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	17 (0.6)	19 (0.6)		36 (0.6)
Nephrolithiasis	6 (0.2)	5 (0.2)		11 (0.2)
Pollakiuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Polyuria	0	2 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Renal and urinary disorders (Cont.)				
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Chronic kidney disease	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Dysuria	0	1 (<0.1)		1 (<0.1)
Haematuria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary hesitation	0	1 (<0.1)		1 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute kidney injury	2 (<0.1)	0		2 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Hypertonic bladder	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urinary retention	2 (<0.1)	0		2 (<0.1)
Reproductive system and breast disorders	6 (0.2)	13 (0.4)		19 (0.3)
Benign prostatic hyperplasia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Erectile dysfunction	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Reproductive system and breast disorders (Cont.)				
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Breast cyst	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Prostatitis	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	191 (6.3)	335 (10.8)		526 (8.6)
Fatigue	106 (3.5)	161 (5.2)	1.47 (1.16, 1.87)	267 (4.4)
Injection site pain	25 (0.8)	50 (1.6)	1.93 (1.21, 3.11)	75 (1.2)
Injection site erythema	14 (0.5)	47 (1.5)	3.25 (1.81, 5.84)	61 (1.0)
Pyrexia	13 (0.4)	28 (0.9)	2.08 (1.09, 3.97)	41 (0.7)
Chills	20 (0.7)	25 (0.8)	1.21 (0.68, 2.15)	45 (0.7)
Injection site pruritus	2 (<0.1)	23 (0.7)	11.12 (2.91, 42.55)	25 (0.4)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
General disorders and administration site conditions (Cont.)				
Injection site swelling	8 (0.3)	23 (0.7)	2.78 (1.27, 6.08)	31 (0.5)
Pain	13 (0.4)	11 (0.4)	0.82 (0.37, 1.79)	24 (0.4)
Injection site induration	6 (0.2)	10 (0.3)	1.61 (0.61, 4.26)	16 (0.3)
Injection site macule	0	10 (0.3)		10 (0.2)
Injection site lymphadenopathy	1 (<0.1)	8 (0.3)	7.74 (1.26, 47.65)	9 (0.1)
Injection site urticaria	0	7 (0.2)		7 (0.1)
Injection site rash	0	5 (0.2)		5 (<0.1)
Axillary pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site haematoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Peripheral swelling	3 (<0.1)	3 (<0.1)		6 (<0.1)
Injection site bruising	6 (0.2)	2 (<0.1)		8 (0.1)
Injection site haemorrhage	0	2 (<0.1)		2 (<0.1)
Oedema peripheral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Precancerous condition	0	2 (<0.1)		2 (<0.1)
Vaccination site pain	0	2 (<0.1)		2 (<0.1)
Chest discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cyst	0	1 (<0.1)		1 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)
Feeling abnormal	0	1 (<0.1)		1 (<0.1)
Feeling hot	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
General disorders and administration site conditions (Cont.)				
Hangover	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site irritation	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site papule	0	1 (<0.1)		1 (<0.1)
Injection site paraesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)
Malaise	5 (0.2)	1 (<0.1)		6 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Non-cardiac chest pain	3 (<0.1)	0		3 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
General disorders and administration site conditions (Cont.)				
Vessel puncture site bruise	1 (<0.1)	0		1 (<0.1)
Investigations	15 (0.5)	30 (1.0)		45 (0.7)
Blood pressure increased	6 (0.2)	6 (0.2)		12 (0.2)
Blood pressure systolic increased	4 (0.1)	3 (<0.1)		7 (0.1)
Blood cholesterol increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood testosterone decreased	0	1 (<0.1)		1 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
Body temperature increased	0	1 (<0.1)		1 (<0.1)
Cardiac murmur	0	1 (<0.1)		1 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Heart rate increased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Investigations (Cont.)				
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	0	1 (<0.1)		1 (<0.1)
Weight decreased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	97 (3.2)	85 (2.7)		182 (3.0)
Fall	8 (0.3)	11 (0.4)	1.33 (0.55, 3.21)	19 (0.3)
Contusion	7 (0.2)	10 (0.3)	1.38 (0.54, 3.50)	17 (0.3)
Procedural pain	8 (0.3)	9 (0.3)	1.09 (0.43, 2.73)	17 (0.3)
Muscle strain	7 (0.2)	7 (0.2)	0.97 (0.35, 2.64)	14 (0.2)
Skin laceration	6 (0.2)	6 (0.2)		12 (0.2)
Arthropod bite	4 (0.1)	5 (0.2)		9 (0.1)
Ligament sprain	3 (<0.1)	5 (0.2)		8 (0.1)
Road traffic accident	2 (<0.1)	5 (0.2)		7 (0.1)
Tooth fracture	6 (0.2)	5 (0.2)		11 (0.2)
Limb injury	3 (<0.1)	3 (<0.1)		6 (<0.1)
Skin abrasion	5 (0.2)	3 (<0.1)		8 (0.1)
Bone contusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Foot fracture	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Injury, poisoning and procedural complications (Cont.)				
Head injury	0	2 (<0.1)		2 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Rib fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Animal bite	2 (<0.1)	1 (<0.1)		3 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthropod sting	9 (0.3)	1 (<0.1)	0.11 (0.02, 0.66)	10 (0.2)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Cervical vertebral fracture	0	1 (<0.1)		1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Hand fracture	0	1 (<0.1)		1 (<0.1)
Hip fracture	0	1 (<0.1)		1 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Muscle rupture	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Post-traumatic pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Scratch	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Injury, poisoning and procedural complications (Cont.)				
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thermal burn	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Vaccination complication	0	1 (<0.1)		1 (<0.1)
Wrist fracture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Joint dislocation	2 (<0.1)	0		2 (<0.1)
Ligament rupture	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Sunburn	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=65 and <75 Years

System Organ Class Preferred Term	Placebo (N=3010) n (%)	mRNA-1273 (N=3112) n (%)	Rate Ratio (95% CI)	Total (N=6122) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tendon injury	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Product issues	2 (<0.1)	1 (<0.1)		3 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	201 (29.0)	203 (33.0)		404 (30.9)
Number of Unsolicited Adverse Events	416	395		811
Infections and infestations	26 (3.8)	24 (3.9)		50 (3.8)
Urinary tract infection	3 (0.4)	3 (0.5)		6 (0.5)
Onychomycosis	0	2 (0.3)		2 (0.2)
Tooth abscess	1 (0.1)	2 (0.3)		3 (0.2)
Cystitis	0	1 (0.2)		1 (<0.1)
Ear infection	0	1 (0.2)		1 (<0.1)
Fungal infection	0	1 (0.2)		1 (<0.1)
Herpes simplex	0	1 (0.2)		1 (<0.1)
Herpes zoster	1 (0.1)	1 (0.2)		2 (0.2)
Hordeolum	1 (0.1)	1 (0.2)		2 (0.2)
Infected dermal cyst	0	1 (0.2)		1 (<0.1)
Laryngitis	0	1 (0.2)		1 (<0.1)
Otitis media	0	1 (0.2)		1 (<0.1)
Otitis media acute	0	1 (0.2)		1 (<0.1)
Paronychia	0	1 (0.2)		1 (<0.1)
Pneumonia	2 (0.3)	1 (0.2)		3 (0.2)
Respiratory tract infection viral	0	1 (0.2)		1 (<0.1)
Rhinovirus infection	0	1 (0.2)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Infections and infestations (Cont.)				
Sinusitis	3 (0.4)	1 (0.2)		4 (0.3)
Suspected COVID-19	1 (0.1)	1 (0.2)		2 (0.2)
Upper respiratory tract infection	3 (0.4)	1 (0.2)		4 (0.3)
Viral infection	0	1 (0.2)		1 (<0.1)
COVID-19	2 (0.3)	0		2 (0.2)
Cellulitis	3 (0.4)	0		3 (0.2)
Gastroenteritis	2 (0.3)	0		2 (0.2)
Localised infection	1 (0.1)	0		1 (<0.1)
Otitis externa	1 (0.1)	0		1 (<0.1)
Periodontitis	1 (0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (0.1)	0		1 (<0.1)
Pulpitis dental	1 (0.1)	0		1 (<0.1)
Tinea pedis	1 (0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (1.2)	6 (1.0)		14 (1.1)
Skin cancer	1 (0.1)	3 (0.5)		4 (0.3)
Basal cell carcinoma	4 (0.6)	2 (0.3)		6 (0.5)
Benign neoplasm of thyroid gland	0	1 (0.2)		1 (<0.1)
Lipoma	1 (0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (0.1)	0		1 (<0.1)
Renal hamartoma	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Blood and lymphatic system disorders	3 (0.4)	9 (1.5)		12 (0.9)
Lymphadenopathy	3 (0.4)	7 (1.1)	2.62 (0.74, 9.27)	10 (0.8)
Anaemia	0	1 (0.2)		1 (<0.1)
Leukocytosis	0	1 (0.2)		1 (<0.1)
Immune system disorders	4 (0.6)	3 (0.5)		7 (0.5)
Drug hypersensitivity	1 (0.1)	1 (0.2)		2 (0.2)
Seasonal allergy	3 (0.4)	1 (0.2)		4 (0.3)
Type IV hypersensitivity reaction	0	1 (0.2)		1 (<0.1)
Metabolism and nutrition disorders	6 (0.9)	5 (0.8)		11 (0.8)
Gout	1 (0.1)	2 (0.3)		3 (0.2)
Hyperlipidaemia	0	2 (0.3)		2 (0.2)
Type 2 diabetes mellitus	1 (0.1)	2 (0.3)		3 (0.2)
Vitamin D deficiency	0	1 (0.2)		1 (<0.1)
Decreased appetite	1 (0.1)	0		1 (<0.1)
Hyperglycaemia	1 (0.1)	0		1 (<0.1)
Hyperkalaemia	1 (0.1)	0		1 (<0.1)
Hypoglycaemia	1 (0.1)	0		1 (<0.1)
Psychiatric disorders	3 (0.4)	6 (1.0)		9 (0.7)
Insomnia	1 (0.1)	2 (0.3)		3 (0.2)
Anxiety	1 (0.1)	1 (0.2)		2 (0.2)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Psychiatric disorders (Cont.)				
Depressed mood	0	1 (0.2)		1 (<0.1)
Depression	0	1 (0.2)		1 (<0.1)
Hallucination	0	1 (0.2)		1 (<0.1)
Nightmare	0	1 (0.2)		1 (<0.1)
Confusional state	1 (0.1)	0		1 (<0.1)
Nervous system disorders	32 (4.6)	30 (4.9)		62 (4.7)
Headache	25 (3.6)	18 (2.9)	0.81 (0.45, 1.46)	43 (3.3)
Dizziness	1 (0.1)	5 (0.8)		6 (0.5)
Paraesthesia	0	2 (0.3)		2 (0.2)
Cervical radiculopathy	0	1 (0.2)		1 (<0.1)
Hypoaesthesia	1 (0.1)	1 (0.2)		2 (0.2)
Hyposmia	0	1 (0.2)		1 (<0.1)
Migraine	1 (0.1)	1 (0.2)		2 (0.2)
Neuralgia	0	1 (0.2)		1 (<0.1)
Post herpetic neuralgia	0	1 (0.2)		1 (<0.1)
Toxic encephalopathy	0	1 (0.2)		1 (<0.1)
Transient ischaemic attack	0	1 (0.2)		1 (<0.1)
Balance disorder	1 (0.1)	0		1 (<0.1)
Carpal tunnel syndrome	1 (0.1)	0		1 (<0.1)
Ischaemic stroke	1 (0.1)	0		1 (<0.1)
Presyncope	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Nervous system disorders (Cont.)				
Speech disorder	1 (0.1)	0		1 (<0.1)
Tremor	1 (0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (0.1)	0		1 (<0.1)
Eye disorders	7 (1.0)	2 (0.3)		9 (0.7)
Accommodation disorder	0	1 (0.2)		1 (<0.1)
Cataract	1 (0.1)	1 (0.2)		2 (0.2)
Conjunctivitis allergic	1 (0.1)	0		1 (<0.1)
Dry eye	2 (0.3)	0		2 (0.2)
Eye discharge	1 (0.1)	0		1 (<0.1)
Eye pruritus	1 (0.1)	0		1 (<0.1)
Glaucoma	1 (0.1)	0		1 (<0.1)
Ear and labyrinth disorders	6 (0.9)	5 (0.8)		11 (0.8)
Vertigo	3 (0.4)	3 (0.5)		6 (0.5)
Ear pain	1 (0.1)	1 (0.2)		2 (0.2)
Tinnitus	0	1 (0.2)		1 (<0.1)
Ear congestion	1 (0.1)	0		1 (<0.1)
Excessive cerumen production	1 (0.1)	0		1 (<0.1)
Cardiac disorders	9 (1.3)	8 (1.3)		17 (1.3)
Coronary artery disease	1 (0.1)	2 (0.3)		3 (0.2)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Cardiac disorders (Cont.)				
Acute coronary syndrome	0	1 (0.2)		1 (<0.1)
Acute myocardial infarction	0	1 (0.2)		1 (<0.1)
Angina pectoris	0	1 (0.2)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (0.2)		1 (<0.1)
Atrial fibrillation	2 (0.3)	1 (0.2)		3 (0.2)
Cardio-respiratory arrest	0	1 (0.2)		1 (<0.1)
Palpitations	0	1 (0.2)		1 (<0.1)
Ventricular extrasystoles	1 (0.1)	1 (0.2)		2 (0.2)
Atrial flutter	1 (0.1)	0		1 (<0.1)
Bradycardia	2 (0.3)	0		2 (0.2)
Cardiac failure	1 (0.1)	0		1 (<0.1)
Cardiac failure congestive	1 (0.1)	0		1 (<0.1)
Vascular disorders	19 (2.7)	13 (2.1)		32 (2.4)
Hypertension	12 (1.7)	8 (1.3)	0.75 (0.32, 1.77)	20 (1.5)
Aortic aneurysm	1 (0.1)	1 (0.2)		2 (0.2)
Hot flush	1 (0.1)	1 (0.2)		2 (0.2)
Hypotension	2 (0.3)	1 (0.2)		3 (0.2)
Orthostatic hypotension	1 (0.1)	1 (0.2)		2 (0.2)
Peripheral vascular disorder	0	1 (0.2)		1 (<0.1)
Systolic hypertension	0	1 (0.2)		1 (<0.1)
Fibromuscular dysplasia	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Vascular disorders (Cont.)				
Hypertensive urgency	1 (0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	26 (3.8)	22 (3.6)		48 (3.7)
Nasal congestion	6 (0.9)	6 (1.0)		12 (0.9)
Asthma	1 (0.1)	5 (0.8)		6 (0.5)
Cough	3 (0.4)	4 (0.6)		7 (0.5)
Oropharyngeal pain	5 (0.7)	3 (0.5)		8 (0.6)
Dyspnoea	4 (0.6)	2 (0.3)		6 (0.5)
Rhinorrhoea	5 (0.7)	2 (0.3)		7 (0.5)
Chronic obstructive pulmonary disease	2 (0.3)	1 (0.2)		3 (0.2)
Dysphonia	1 (0.1)	1 (0.2)		2 (0.2)
Emphysema	0	1 (0.2)		1 (<0.1)
Epistaxis	0	1 (0.2)		1 (<0.1)
Respiratory tract congestion	0	1 (0.2)		1 (<0.1)
Sleep apnoea syndrome	0	1 (0.2)		1 (<0.1)
Sneezing	0	1 (0.2)		1 (<0.1)
Upper-airway cough syndrome	0	1 (0.2)		1 (<0.1)
Wheezing	0	1 (0.2)		1 (<0.1)
Pleural effusion	2 (0.3)	0		2 (0.2)
Productive cough	1 (0.1)	0		1 (<0.1)
Rhinitis allergic	2 (0.3)	0		2 (0.2)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Sinus congestion	1 (0.1)	0		1 (<0.1)
Gastrointestinal disorders	32 (4.6)	21 (3.4)		53 (4.1)
Nausea	8 (1.2)	7 (1.1)	0.98 (0.37, 2.59)	15 (1.1)
Vomiting	2 (0.3)	5 (0.8)		7 (0.5)
Diarrhoea	14 (2.0)	3 (0.5)	0.24 (0.07, 0.78)	17 (1.3)
Toothache	1 (0.1)	2 (0.3)		3 (0.2)
Abdominal discomfort	2 (0.3)	1 (0.2)		3 (0.2)
Abdominal pain upper	1 (0.1)	1 (0.2)		2 (0.2)
Constipation	1 (0.1)	1 (0.2)		2 (0.2)
Dyspepsia	0	1 (0.2)		1 (<0.1)
Gastric ulcer	0	1 (0.2)		1 (<0.1)
Gastrooesophageal reflux disease	2 (0.3)	1 (0.2)		3 (0.2)
Paraesthesia oral	0	1 (0.2)		1 (<0.1)
Dental caries	1 (0.1)	0		1 (<0.1)
Dysphagia	1 (0.1)	0		1 (<0.1)
Food poisoning	2 (0.3)	0		2 (0.2)
Gastric perforation	1 (0.1)	0		1 (<0.1)
Gastritis	1 (0.1)	0		1 (<0.1)
Inguinal hernia	1 (0.1)	0		1 (<0.1)
Large intestine polyp	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Gastrointestinal disorders (Cont.)				
Lip swelling	1 (0.1)	0		1 (<0.1)
Oral discomfort	1 (0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	2 (0.3)		2 (0.2)
Biliary colic	0	1 (0.2)		1 (<0.1)
Cholecystitis acute	0	1 (0.2)		1 (<0.1)
Hepatic steatosis	0	1 (0.2)		1 (<0.1)
Skin and subcutaneous tissue disorders	13 (1.9)	10 (1.6)		23 (1.8)
Erythema	1 (0.1)	3 (0.5)		4 (0.3)
Urticaria	2 (0.3)	2 (0.3)		4 (0.3)
Alopecia	0	1 (0.2)		1 (<0.1)
Dermatitis	0	1 (0.2)		1 (<0.1)
Dermatitis contact	0	1 (0.2)		1 (<0.1)
Pruritus	5 (0.7)	1 (0.2)		6 (0.5)
Rash papular	0	1 (0.2)		1 (<0.1)
Dermatitis bullous	1 (0.1)	0		1 (<0.1)
Ecchymosis	1 (0.1)	0		1 (<0.1)
Psoriasis	1 (0.1)	0		1 (<0.1)
Rash	1 (0.1)	0		1 (<0.1)
Skin mass	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Musculoskeletal and connective tissue disorders	51 (7.4)	51 (8.3)		102 (7.8)
Arthralgia	17 (2.5)	30 (4.9)	1.98 (1.11, 3.53)	47 (3.6)
Myalgia	19 (2.7)	16 (2.6)	0.95 (0.50, 1.80)	35 (2.7)
Back pain	3 (0.4)	11 (1.8)	4.12 (1.24, 13.68)	14 (1.1)
Pain in extremity	3 (0.4)	4 (0.6)		7 (0.5)
Spinal stenosis	0	2 (0.3)		2 (0.2)
Costochondritis	0	1 (0.2)		1 (<0.1)
Muscle twitching	0	1 (0.2)		1 (<0.1)
Muscular weakness	0	1 (0.2)		1 (<0.1)
Musculoskeletal stiffness	0	1 (0.2)		1 (<0.1)
Neck pain	2 (0.3)	1 (0.2)		3 (0.2)
Spondylitis	0	1 (0.2)		1 (<0.1)
Tendon disorder	0	1 (0.2)		1 (<0.1)
Tendonitis	0	1 (0.2)		1 (<0.1)
Bursitis	3 (0.4)	0		3 (0.2)
Cervical spinal stenosis	1 (0.1)	0		1 (<0.1)
Intervertebral disc degeneration	1 (0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (0.1)	0		1 (<0.1)
Joint stiffness	1 (0.1)	0		1 (<0.1)
Musculoskeletal chest pain	1 (0.1)	0		1 (<0.1)
Musculoskeletal pain	3 (0.4)	0		3 (0.2)
Osteoarthritis	5 (0.7)	0		5 (0.4)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in jaw	1 (0.1)	0		1 (<0.1)
Polyarthritis	1 (0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (0.1)	0		1 (<0.1)
Scoliosis	1 (0.1)	0		1 (<0.1)
Renal and urinary disorders	4 (0.6)	5 (0.8)		9 (0.7)
Urinary retention	0	2 (0.3)		2 (0.2)
Chronic kidney disease	0	1 (0.2)		1 (<0.1)
Haematuria	0	1 (0.2)		1 (<0.1)
Nephrolithiasis	1 (0.1)	1 (0.2)		2 (0.2)
Acute kidney injury	1 (0.1)	0		1 (<0.1)
Renal colic	1 (0.1)	0		1 (<0.1)
Urinary incontinence	1 (0.1)	0		1 (<0.1)
Reproductive system and breast disorders	2 (0.3)	3 (0.5)		5 (0.4)
Benign prostatic hyperplasia	1 (0.1)	2 (0.3)		3 (0.2)
Balanoposthitis	0	1 (0.2)		1 (<0.1)
Prostatitis	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
General disorders and administration site conditions	58 (8.4)	64 (10.4)		122 (9.3)
Fatigue	32 (4.6)	30 (4.9)	1.05 (0.65, 1.70)	62 (4.7)
Injection site pain	4 (0.6)	11 (1.8)	3.09 (1.04, 9.15)	15 (1.1)
Injection site erythema	1 (0.1)	9 (1.5)	10.11 (1.66, 61.67)	10 (0.8)
Injection site swelling	2 (0.3)	8 (1.3)	4.49 (1.08, 18.66)	10 (0.8)
Injection site macule	1 (0.1)	4 (0.6)		5 (0.4)
Injection site urticaria	1 (0.1)	4 (0.6)		5 (0.4)
Chills	6 (0.9)	3 (0.5)		9 (0.7)
Pain	1 (0.1)	3 (0.5)		4 (0.3)
Injection site pruritus	0	2 (0.3)		2 (0.2)
Pyrexia	2 (0.3)	2 (0.3)		4 (0.3)
Chest discomfort	0	1 (0.2)		1 (<0.1)
Injection site rash	0	1 (0.2)		1 (<0.1)
Injection site warmth	0	1 (0.2)		1 (<0.1)
Malaise	0	1 (0.2)		1 (<0.1)
Oedema peripheral	3 (0.4)	1 (0.2)		4 (0.3)
Asthenia	1 (0.1)	0		1 (<0.1)
Feeling abnormal	1 (0.1)	0		1 (<0.1)
Impaired healing	1 (0.1)	0		1 (<0.1)
Injection site bruising	3 (0.4)	0		3 (0.2)
Injection site haemorrhage	3 (0.4)	0		3 (0.2)
Injection site induration	1 (0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
General disorders and administration site conditions (Cont.)				
Injection site oedema	1 (0.1)	0		1 (<0.1)
Pelvic mass	1 (0.1)	0		1 (<0.1)
Peripheral swelling	1 (0.1)	0		1 (<0.1)
Reactogenicity event	1 (0.1)	0		1 (<0.1)
Investigations	3 (0.4)	4 (0.6)		7 (0.5)
Blood creatinine increased	0	1 (0.2)		1 (<0.1)
Blood pressure increased	0	1 (0.2)		1 (<0.1)
Blood pressure systolic increased	0	1 (0.2)		1 (<0.1)
C-reactive protein increased	1 (0.1)	1 (0.2)		2 (0.2)
Blood glucose increased	1 (0.1)	0		1 (<0.1)
Serum ferritin increased	1 (0.1)	0		1 (<0.1)
Weight decreased	1 (0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	18 (2.6)	21 (3.4)		39 (3.0)
Arthropod bite	1 (0.1)	4 (0.6)		5 (0.4)
Muscle strain	0	3 (0.5)		3 (0.2)
Contusion	0	2 (0.3)		2 (0.2)
Fall	2 (0.3)	2 (0.3)		4 (0.3)
Skin laceration	1 (0.1)	2 (0.3)		3 (0.2)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tooth fracture	2 (0.3)	2 (0.3)		4 (0.3)
Cervical vertebral fracture	0	1 (0.2)		1 (<0.1)
Facial bones fracture	0	1 (0.2)		1 (<0.1)
Femoral neck fracture	0	1 (0.2)		1 (<0.1)
Fibula fracture	0	1 (0.2)		1 (<0.1)
Foot fracture	0	1 (0.2)		1 (<0.1)
Hand fracture	0	1 (0.2)		1 (<0.1)
Ligament sprain	1 (0.1)	1 (0.2)		2 (0.2)
Limb injury	1 (0.1)	1 (0.2)		2 (0.2)
Post-traumatic pain	1 (0.1)	1 (0.2)		2 (0.2)
Rib fracture	0	1 (0.2)		1 (<0.1)
Subdural haematoma	0	1 (0.2)		1 (<0.1)
Upper limb fracture	0	1 (0.2)		1 (<0.1)
Animal bite	1 (0.1)	0		1 (<0.1)
Arthropod sting	1 (0.1)	0		1 (<0.1)
Foreign body	1 (0.1)	0		1 (<0.1)
Foreign body in ear	1 (0.1)	0		1 (<0.1)
Head injury	1 (0.1)	0		1 (<0.1)
Lip injury	1 (0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (0.1)	0		1 (<0.1)
Procedural pain	3 (0.4)	0		3 (0.2)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=75 and <85 Years

System Organ Class Preferred Term	Placebo (N=692) n (%)	mRNA-1273 (N=616) n (%)	Rate Ratio (95% CI)	Total (N=1308) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin abrasion	2 (0.3)	0		2 (0.2)
Product issues	1 (0.1)	0		1 (<0.1)
Lead dislodgement	1 (0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=85 Years

System Organ Class Preferred Term	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Rate Ratio (95% CI)	Total (N=90) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	16 (32.7)	15 (36.6)		31 (34.4)
Number of Unsolicited Adverse Events	30	22		52
Infections and infestations	2 (4.1)	3 (7.3)		5 (5.6)
Gingivitis	0	1 (2.4)		1 (1.1)
Herpes zoster	0	1 (2.4)		1 (1.1)
Urinary tract infection	1 (2.0)	1 (2.4)		2 (2.2)
Hordeolum	1 (2.0)	0		1 (1.1)
Blood and lymphatic system disorders	1 (2.0)	0		1 (1.1)
Lymphadenopathy	1 (2.0)	0		1 (1.1)
Psychiatric disorders	1 (2.0)	0		1 (1.1)
Insomnia	1 (2.0)	0		1 (1.1)
Nervous system disorders	2 (4.1)	0		2 (2.2)
Headache	1 (2.0)	0		1 (1.1)
Neuralgia	1 (2.0)	0		1 (1.1)
Ear and labyrinth disorders	1 (2.0)	0		1 (1.1)
Vertigo	1 (2.0)	0		1 (1.1)

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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=85 Years

System Organ Class Preferred Term	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Rate Ratio (95% CI)	Total (N=90) n (%)
Cardiac disorders	1 (2.0)	0		1 (1.1)
Coronary artery disease	1 (2.0)	0		1 (1.1)
Vascular disorders	1 (2.0)	1 (2.4)		2 (2.2)
Hypertension	1 (2.0)	1 (2.4)		2 (2.2)
Respiratory, thoracic and mediastinal disorders	0	1 (2.4)		1 (1.1)
Rhinorrhoea	0	1 (2.4)		1 (1.1)
Gastrointestinal disorders	5 (10.2)	2 (4.9)		7 (7.8)
Gastrooesophageal reflux disease	1 (2.0)	1 (2.4)		2 (2.2)
Hypoaesthesia oral	0	1 (2.4)		1 (1.1)
Constipation	1 (2.0)	0		1 (1.1)
Diarrhoea	3 (6.1)	0		3 (3.3)
Duodenal ulcer haemorrhage	1 (2.0)	0		1 (1.1)
Vomiting	1 (2.0)	0		1 (1.1)
Skin and subcutaneous tissue disorders	1 (2.0)	0		1 (1.1)
Dermatitis	1 (2.0)	0		1 (1.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=85 Years

System Organ Class Preferred Term	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Rate Ratio (95% CI)	Total (N=90) n (%)
Musculoskeletal and connective tissue disorders	4 (8.2)	2 (4.9)		6 (6.7)
Arthralgia	2 (4.1)	2 (4.9)		4 (4.4)
Myalgia	2 (4.1)	1 (2.4)		3 (3.3)
Spinal osteoarthritis	1 (2.0)	0		1 (1.1)
General disorders and administration site conditions	3 (6.1)	7 (17.1)		10 (11.1)
Fatigue	2 (4.1)	4 (9.8)		6 (6.7)
Asthenia	0	1 (2.4)		1 (1.1)
Injection site bruising	0	1 (2.4)		1 (1.1)
Injection site pain	1 (2.0)	1 (2.4)		2 (2.2)
Injection site erythema	1 (2.0)	0		1 (1.1)
Investigations	0	1 (2.4)		1 (1.1)
Blood pressure systolic increased	0	1 (2.4)		1 (1.1)
Injury, poisoning and procedural complications	2 (4.1)	2 (4.9)		4 (4.4)
Limb injury	0	1 (2.4)		1 (1.1)
Rib fracture	0	1 (2.4)		1 (1.1)
Wrist fracture	0	1 (2.4)		1 (1.1)
Arthropod bite	1 (2.0)	0		1 (1.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.2.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term by Age Groups (<65, >=65 and <75, >=75 and <85, >=85) up to 28 Days After Any Injection
Safety Set

Age Group: >=85 Years

System Organ Class Preferred Term	Placebo (N=49) n (%)	mRNA-1273 (N=41) n (%)	Rate Ratio (95% CI)	Total (N=90) n (%)
Injury, poisoning and procedural complications (Cont.)				
Fall	1 (2.0)	0		1 (1.1)
Hip fracture	1 (2.0)	0		1 (1.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6513 (43.0)	6310 (41.6)		12823 (42.3)
Number of Unsolicited Adverse Events	15229	14869		30098
Infections and infestations	2533 (16.7)	1717 (11.3)		4250 (14.0)
Upper respiratory tract infection	314 (2.1)	262 (1.7)	0.83 (0.71, 0.98)	576 (1.9)
Urinary tract infection	205 (1.4)	171 (1.1)	0.83 (0.68, 1.02)	376 (1.2)
Viral infection	159 (1.0)	164 (1.1)	1.03 (0.83, 1.28)	323 (1.1)
Sinusitis	120 (0.8)	133 (0.9)	1.11 (0.87, 1.41)	253 (0.8)
Suspected COVID-19	124 (0.8)	132 (0.9)	1.06 (0.83, 1.36)	256 (0.8)
COVID-19	979 (6.5)	86 (0.6)	0.09 (0.07, 0.11)	1065 (3.5)
Rhinovirus infection	75 (0.5)	84 (0.6)	1.12 (0.82, 1.52)	159 (0.5)
Herpes zoster	23 (0.2)	50 (0.3)	2.17 (1.33, 3.54)	73 (0.2)
Viral upper respiratory tract infection	41 (0.3)	41 (0.3)	1.00 (0.65, 1.53)	82 (0.3)
Tooth infection	36 (0.2)	36 (0.2)	1.00 (0.63, 1.58)	72 (0.2)
Tooth abscess	46 (0.3)	34 (0.2)	0.74 (0.48, 1.15)	80 (0.3)
Pharyngitis	32 (0.2)	32 (0.2)	1.00 (0.61, 1.62)	64 (0.2)
Gastroenteritis	41 (0.3)	31 (0.2)	0.76 (0.48, 1.20)	72 (0.2)
Ear infection	25 (0.2)	30 (0.2)	1.20 (0.71, 2.02)	55 (0.2)
Cellulitis	36 (0.2)	28 (0.2)	0.78 (0.48, 1.27)	64 (0.2)
Pharyngitis streptococcal	39 (0.3)	26 (0.2)	0.67 (0.41, 1.09)	65 (0.2)
Bronchitis	33 (0.2)	25 (0.2)	0.76 (0.45, 1.26)	58 (0.2)
Hordeolum	27 (0.2)	23 (0.2)	0.85 (0.49, 1.47)	50 (0.2)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Otitis media	20 (0.1)	21 (0.1)	1.05 (0.57, 1.92)	41 (0.1)
Conjunctivitis	24 (0.2)	20 (0.1)	0.83 (0.46, 1.49)	44 (0.1)
Asymptomatic COVID-19	16 (0.1)	19 (0.1)	1.19 (0.62, 2.28)	35 (0.1)
Pneumonia	34 (0.2)	19 (0.1)	0.56 (0.32, 0.97)	53 (0.2)
Diverticulitis	21 (0.1)	18 (0.1)	0.86 (0.46, 1.59)	39 (0.1)
Nasopharyngitis	29 (0.2)	18 (0.1)	0.62 (0.35, 1.11)	47 (0.2)
Oral herpes	18 (0.1)	18 (0.1)	1.00 (0.53, 1.90)	36 (0.1)
Respiratory tract infection	13 (<0.1)	15 (<0.1)	1.15 (0.56, 2.38)	28 (<0.1)
Acute sinusitis	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Fungal infection	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Bacterial vaginosis	11 (<0.1)	12 (<0.1)	1.09 (0.49, 2.42)	23 (<0.1)
Gingivitis	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Herpes simplex	5 (<0.1)	12 (<0.1)	2.40 (0.88, 6.52)	17 (<0.1)
Localised infection	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Onychomycosis	6 (<0.1)	12 (<0.1)	2.00 (0.78, 5.13)	18 (<0.1)
Otitis externa	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Enterovirus infection	4 (<0.1)	11 (<0.1)	2.75 (0.92, 8.16)	15 (<0.1)
Vulvovaginal mycotic infection	21 (0.1)	10 (<0.1)	0.48 (0.23, 0.99)	31 (0.1)
Folliculitis	16 (0.1)	9 (<0.1)	0.56 (0.25, 1.24)	25 (<0.1)
Paronychia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Skin infection	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Vulvovaginal candidiasis	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Abscess limb	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Gastroenteritis viral	17 (0.1)	8 (<0.1)	0.47 (0.21, 1.06)	25 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Cystitis	18 (0.1)	7 (<0.1)	0.39 (0.17, 0.91)	25 (<0.1)
Furuncle	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Laryngitis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Subcutaneous abscess	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Clostridium difficile infection	1 (<0.1)	6 (<0.1)		7 (<0.1)
Lyme disease	0	6 (<0.1)		6 (<0.1)
Oral candidiasis	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Pyelonephritis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Sepsis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Staphylococcal infection	3 (<0.1)	6 (<0.1)		9 (<0.1)
Staphylococcal skin infection	1 (<0.1)	6 (<0.1)		7 (<0.1)
Appendicitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Helicobacter infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Kidney infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Postoperative wound infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Chlamydial infection	0	4 (<0.1)		4 (<0.1)
Eye infection	6 (<0.1)	4 (<0.1)		10 (<0.1)
Gonorrhoea	2 (<0.1)	4 (<0.1)		6 (<0.1)
Impetigo	1 (<0.1)	4 (<0.1)		5 (<0.1)
Periodontitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Respiratory tract infection viral	12 (<0.1)	4 (<0.1)	0.33 (0.11, 0.98)	16 (<0.1)
Rhinitis	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Sinusitis bacterial	4 (<0.1)	4 (<0.1)		8 (<0.1)
Viral pharyngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Abdominal abscess	0	3 (<0.1)		3 (<0.1)
Abscess jaw	0	3 (<0.1)		3 (<0.1)
Chronic sinusitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Coronavirus infection	0	3 (<0.1)		3 (<0.1)
Epididymitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Tonsillitis	14 (<0.1)	3 (<0.1)	0.21 (0.07, 0.69)	17 (<0.1)
Wound infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Candida infection	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cat scratch disease	0	2 (<0.1)		2 (<0.1)
Conjunctivitis bacterial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Fungal skin infection	5 (<0.1)	2 (<0.1)		7 (<0.1)
Gastrointestinal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Infected bite	2 (<0.1)	2 (<0.1)		4 (<0.1)
Infected cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nail infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media acute	5 (<0.1)	2 (<0.1)		7 (<0.1)
Peritonitis	0	2 (<0.1)		2 (<0.1)
Pertussis	0	2 (<0.1)		2 (<0.1)
Post procedural infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Pulpitis dental	2 (<0.1)	2 (<0.1)		4 (<0.1)
Septic shock	3 (<0.1)	2 (<0.1)		5 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Tinea cruris	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tinea pedis	5 (<0.1)	2 (<0.1)		7 (<0.1)
Tuberculosis	0	2 (<0.1)		2 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urinary tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urosepsis	0	2 (<0.1)		2 (<0.1)
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Viral sinusitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic bacteriuria	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atypical mycobacterial infection	0	1 (<0.1)		1 (<0.1)
Atypical pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Body tinea	3 (<0.1)	1 (<0.1)		4 (<0.1)
Breast abscess	2 (<0.1)	1 (<0.1)		3 (<0.1)
Breast cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiolitis	0	1 (<0.1)		1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Colonic abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Dacryocystitis	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)
Genital infection fungal	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Gingival abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Groin abscess	0	1 (<0.1)		1 (<0.1)
Helminthic infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza	6 (<0.1)	1 (<0.1)		7 (<0.1)
Injection site infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Labyrinthitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Papilloma viral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Perineal abscess	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pyoderma	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin candida	4 (<0.1)	1 (<0.1)		5 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Streptococcal infection	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Tinea versicolour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Vulvitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)		1 (<0.1)
Abscess	2 (<0.1)	0		2 (<0.1)
Abscess neck	1 (<0.1)	0		1 (<0.1)
Adenovirus infection	1 (<0.1)	0		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Balanitis candida	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Bronchitis bacterial	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	16 (0.1)	0		16 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cervicitis	2 (<0.1)	0		2 (<0.1)
Cholecystitis infective	2 (<0.1)	0		2 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	2 (<0.1)	0		2 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Ear infection fungal	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
HIV infection	2 (<0.1)	0		2 (<0.1)
Hepatitis C	1 (<0.1)	0		1 (<0.1)
Herpangina	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Infection	1 (<0.1)	0		1 (<0.1)
Klebsiella bacteraemia	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	3 (<0.1)	0		3 (<0.1)
Mastoiditis	3 (<0.1)	0		3 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Nasal vestibulitis	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Perineal cellulitis	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Perirectal abscess	2 (<0.1)	0		2 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	2 (<0.1)	0		2 (<0.1)
Proteus infection	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	3 (<0.1)	0		3 (<0.1)
Tinea barbae	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Vaginal abscess	1 (<0.1)	0		1 (<0.1)
Vaginitis chlamydial	2 (<0.1)	0		2 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Vestibular neuronitis	1 (<0.1)	0		1 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	124 (0.8)	138 (0.9)		262 (0.9)
Basal cell carcinoma	28 (0.2)	24 (0.2)	0.86 (0.50, 1.47)	52 (0.2)
Prostate cancer	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Uterine leiomyoma	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Benign neoplasm of skin	2 (<0.1)	6 (<0.1)		8 (<0.1)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Skin cancer	4 (<0.1)	6 (<0.1)		10 (<0.1)
Squamous cell carcinoma	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Malignant melanoma	5 (<0.1)	5 (<0.1)		10 (<0.1)
Squamous cell carcinoma of skin	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Benign breast neoplasm	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of thyroid gland	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lipoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Malignant melanoma in situ	1 (<0.1)	3 (<0.1)		4 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin papilloma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Benign hepatic neoplasm	0	2 (<0.1)		2 (<0.1)
Breast cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Invasive ductal breast carcinoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Plasma cell myeloma	0	2 (<0.1)		2 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Adrenal adenoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign ovarian tumour	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign salivary gland neoplasm	0	1 (<0.1)		1 (<0.1)
Brain neoplasm	0	1 (<0.1)		1 (<0.1)
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Breast cancer in situ	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Fibrous histiocytoma	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Intraductal papilloma of breast	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to bone	1 (<0.1)	1 (<0.1)		2 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Nasal cavity cancer	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)		1 (<0.1)
Prostate cancer stage I	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal neoplasm	0	1 (<0.1)		1 (<0.1)
Seborrhoeic keratosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Benign bone neoplasm	1 (<0.1)	0		1 (<0.1)
Benign neoplasm of eyelid	1 (<0.1)	0		1 (<0.1)
Bladder cancer	1 (<0.1)	0		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Breast neoplasm	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Enchondromatosis	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	3 (<0.1)	0		3 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	200 (1.3)	342 (2.3)		542 (1.8)
Lymphadenopathy	156 (1.0)	287 (1.9)	1.84 (1.51, 2.23)	443 (1.5)
Anaemia	17 (0.1)	21 (0.1)	1.23 (0.66, 2.31)	38 (0.1)
Lymph node pain	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Iron deficiency anaemia	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Lymphadenitis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Thrombocytopenia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Leukocytosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)
Normocytic anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eosinophilia	0	1 (<0.1)		1 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Nucleated red cells	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)				
Splenic calcification	1 (<0.1)	0		1 (<0.1)
Immune system disorders	99 (0.7)	90 (0.6)		189 (0.6)
Seasonal allergy	72 (0.5)	59 (0.4)	0.82 (0.58, 1.15)	131 (0.4)
Drug hypersensitivity	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Food allergy	2 (<0.1)	4 (<0.1)		6 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Mycotic allergy	0	2 (<0.1)		2 (<0.1)
Allergy to animal	0	1 (<0.1)		1 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	2 (<0.1)	0		2 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	40 (0.3)	38 (0.3)		78 (0.3)
Hypothyroidism	19 (0.1)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.1)
Thyroid mass	1 (<0.1)	4 (<0.1)		5 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Endocrine disorders (Cont.)				
Goitre	6 (<0.1)	2 (<0.1)		8 (<0.1)
Hyperparathyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperthyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Basedow's disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypogonadism	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Thyroiditis	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	2 (<0.1)	0		2 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroiditis subacute	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	288 (1.9)	264 (1.7)		552 (1.8)
Type 2 diabetes mellitus	33 (0.2)	44 (0.3)	1.33 (0.85, 2.08)	77 (0.3)
Hyperlipidaemia	52 (0.3)	42 (0.3)	0.81 (0.54, 1.21)	94 (0.3)
Vitamin D deficiency	40 (0.3)	30 (0.2)	0.75 (0.47, 1.20)	70 (0.2)
Hypercholesterolaemia	39 (0.3)	29 (0.2)	0.74 (0.46, 1.19)	68 (0.2)
Decreased appetite	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Dehydration	15 (<0.1)	15 (<0.1)	1.00 (0.50, 2.01)	30 (<0.1)
Diabetes mellitus	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Gout	17 (0.1)	13 (<0.1)	0.76 (0.38, 1.55)	30 (<0.1)
Glucose tolerance impaired	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Hyponatraemia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypokalaemia	17 (0.1)	7 (<0.1)	0.41 (0.18, 0.97)	24 (<0.1)
Hyperglycaemia	6 (<0.1)	5 (<0.1)		11 (<0.1)
Hypertriglyceridaemia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Hypoglycaemia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Vitamin B12 deficiency	4 (<0.1)	4 (<0.1)		8 (<0.1)
Abnormal loss of weight	4 (<0.1)	3 (<0.1)		7 (<0.1)
Diabetes mellitus inadequate control	3 (<0.1)	3 (<0.1)		6 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperkalaemia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Iron deficiency	6 (<0.1)	3 (<0.1)		9 (<0.1)
Obesity	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypocalcaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Insulin resistance	0	2 (<0.1)		2 (<0.1)
Malnutrition	0	2 (<0.1)		2 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dairy intolerance	0	1 (<0.1)		1 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)		4 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Food intolerance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypercalcaemia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypomagnesaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Hypophosphataemia	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin K deficiency	0	1 (<0.1)		1 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Fluid overload	1 (<0.1)	0		1 (<0.1)
Fluid retention	1 (<0.1)	0		1 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypermagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	266 (1.8)	319 (2.1)		585 (1.9)
Anxiety	87 (0.6)	108 (0.7)	1.24 (0.94, 1.64)	195 (0.6)
Depression	85 (0.6)	96 (0.6)	1.13 (0.84, 1.51)	181 (0.6)
Insomnia	54 (0.4)	60 (0.4)	1.11 (0.77, 1.60)	114 (0.4)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Attention deficit hyperactivity disorder	24 (0.2)	20 (0.1)	0.83 (0.46, 1.49)	44 (0.1)
Bipolar disorder	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Sleep disorder	1 (<0.1)	5 (<0.1)		6 (<0.1)
Panic attack	6 (<0.1)	4 (<0.1)		10 (<0.1)
Post-traumatic stress disorder	2 (<0.1)	4 (<0.1)		6 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Libido decreased	0	3 (<0.1)		3 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)		4 (<0.1)
Suicidal ideation	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alcohol withdrawal syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bipolar II disorder	0	2 (<0.1)		2 (<0.1)
Generalised anxiety disorder	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Major depression	4 (<0.1)	2 (<0.1)		6 (<0.1)
Stress	2 (<0.1)	2 (<0.1)		4 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Confusional state	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Dysphemia	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental fatigue	2 (<0.1)	1 (<0.1)		3 (<0.1)
Mental status changes	4 (<0.1)	1 (<0.1)		5 (<0.1)
Obsessive-compulsive personality disorder	0	1 (<0.1)		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Psychotic disorder	0	1 (<0.1)		1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Social anxiety disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Terminal insomnia	0	1 (<0.1)		1 (<0.1)
Agitation	2 (<0.1)	0		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Delirium	1 (<0.1)	0		1 (<0.1)
Depression suicidal	2 (<0.1)	0		2 (<0.1)
Disorientation	1 (<0.1)	0		1 (<0.1)
Dissociative disorder	1 (<0.1)	0		1 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Mixed anxiety and depressive disorder	1 (<0.1)	0		1 (<0.1)
Nicotine dependence	1 (<0.1)	0		1 (<0.1)
Schizophrenia	2 (<0.1)	0		2 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	1240 (8.2)	1311 (8.6)		2551 (8.4)
Headache	886 (5.8)	907 (6.0)	1.02 (0.93, 1.12)	1793 (5.9)
Dizziness	88 (0.6)	97 (0.6)	1.10 (0.83, 1.47)	185 (0.6)
Paraesthesia	31 (0.2)	43 (0.3)	1.39 (0.88, 2.19)	74 (0.2)
Migraine	42 (0.3)	32 (0.2)	0.76 (0.48, 1.20)	74 (0.2)
Syncope	40 (0.3)	25 (0.2)	0.62 (0.38, 1.02)	65 (0.2)
Sciatica	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Ageusia	30 (0.2)	23 (0.2)	0.77 (0.45, 1.31)	53 (0.2)
Sinus headache	12 (<0.1)	21 (0.1)	1.75 (0.87, 3.50)	33 (0.1)
Anosmia	25 (0.2)	19 (0.1)	0.76 (0.42, 1.37)	44 (0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Cervical radiculopathy	2 (<0.1)	17 (0.1)	8.49 (2.18, 33.01)	19 (<0.1)
Hypoaesthesia	14 (<0.1)	17 (0.1)	1.21 (0.61, 2.42)	31 (0.1)
Presyncope	16 (0.1)	15 (<0.1)	0.94 (0.47, 1.87)	31 (0.1)
Dysgeusia	8 (<0.1)	13 (<0.1)	1.62 (0.69, 3.81)	21 (<0.1)
Nerve compression	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Carpal tunnel syndrome	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Tension headache	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Facial paralysis	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Cerebrovascular accident	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Burning sensation	1 (<0.1)	6 (<0.1)		7 (<0.1)
Hyperaesthesia	0	6 (<0.1)		6 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Lumbar radiculopathy	5 (<0.1)	5 (<0.1)		10 (<0.1)
Memory impairment	1 (<0.1)	5 (<0.1)		6 (<0.1)
Seizure	6 (<0.1)	5 (<0.1)		11 (<0.1)
Parosmia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	4 (<0.1)		7 (<0.1)
Subarachnoid haemorrhage	0	4 (<0.1)		4 (<0.1)
Taste disorder	2 (<0.1)	4 (<0.1)		6 (<0.1)
Amnesia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Lethargy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Migraine with aura	3 (<0.1)	3 (<0.1)		6 (<0.1)
Neuralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Neuropathy peripheral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Somnolence	3 (<0.1)	3 (<0.1)		6 (<0.1)
Transient ischaemic attack	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tremor	5 (<0.1)	3 (<0.1)		8 (<0.1)
Carotid artery stenosis	0	2 (<0.1)		2 (<0.1)
Cubital tunnel syndrome	0	2 (<0.1)		2 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Dizziness postural	0	2 (<0.1)		2 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Morton's neuralgia	0	2 (<0.1)		2 (<0.1)
Optic neuritis	0	2 (<0.1)		2 (<0.1)
Piriformis syndrome	0	2 (<0.1)		2 (<0.1)
Post herpetic neuralgia	0	2 (<0.1)		2 (<0.1)
Post-traumatic headache	2 (<0.1)	2 (<0.1)		4 (<0.1)
Restless legs syndrome	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Aphasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Central nervous system lesion	0	1 (<0.1)		1 (<0.1)
Cerebral atrophy	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Complex regional pain syndrome	0	1 (<0.1)		1 (<0.1)
Dementia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Depressed level of consciousness	0	1 (<0.1)		1 (<0.1)
Diabetic mononeuropathy	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Essential tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Hypersomnia	0	1 (<0.1)		1 (<0.1)
Hyposmia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Loss of consciousness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle contractions involuntary	2 (<0.1)	1 (<0.1)		3 (<0.1)
New daily persistent headache	0	1 (<0.1)		1 (<0.1)
Occipital neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Poor quality sleep	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Trigeminal neuralgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	2 (<0.1)	0		2 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Cerebral cyst	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	3 (<0.1)	0		3 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	3 (<0.1)	0		3 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Hypogeusia	4 (<0.1)	0		4 (<0.1)
Intention tremor	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0		1 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Myoclonus	1 (<0.1)	0		1 (<0.1)
Perineurial cyst	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Radicular pain	1 (<0.1)	0		1 (<0.1)
Right hemisphere deficit syndrome	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Speech disorder	2 (<0.1)	0		2 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0		1 (<0.1)
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
VIth nerve paralysis	1 (<0.1)	0		1 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)
Vocal cord paralysis	1 (<0.1)	0		1 (<0.1)
Eye disorders	124 (0.8)	139 (0.9)		263 (0.9)
Cataract	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Eye pruritus	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Dry eye	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Eye irritation	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Glaucoma	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Retinal detachment	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Vision blurred	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Eye pain	4 (<0.1)	6 (<0.1)		10 (<0.1)
Blepharitis	4 (<0.1)	5 (<0.1)		9 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Conjunctival haemorrhage	3 (<0.1)	5 (<0.1)		8 (<0.1)
Chalazion	1 (<0.1)	4 (<0.1)		5 (<0.1)
Swelling of eyelid	1 (<0.1)	4 (<0.1)		5 (<0.1)
Visual impairment	3 (<0.1)	4 (<0.1)		7 (<0.1)
Eye inflammation	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lacrimation increased	4 (<0.1)	3 (<0.1)		7 (<0.1)
Uveitis	0	3 (<0.1)		3 (<0.1)
Vitreous floaters	4 (<0.1)	3 (<0.1)		7 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Eye haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye swelling	5 (<0.1)	2 (<0.1)		7 (<0.1)
Macular degeneration	1 (<0.1)	2 (<0.1)		3 (<0.1)
Macular hole	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular discomfort	0	2 (<0.1)		2 (<0.1)
Ocular hyperaemia	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Photophobia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Diabetic retinopathy	0	1 (<0.1)		1 (<0.1)
Diplopia	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye disorder	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Foreign body sensation in eyes	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Keratitis	0	1 (<0.1)		1 (<0.1)
Lenticular opacities	0	1 (<0.1)		1 (<0.1)
Macular fibrosis	0	1 (<0.1)		1 (<0.1)
Macular oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Orbital haematoma	0	1 (<0.1)		1 (<0.1)
Papilloedema	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Presbyopia	0	1 (<0.1)		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Retinopathy hypertensive	0	1 (<0.1)		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eye ulcer	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	3 (<0.1)	0		3 (<0.1)
Nictitating spasm	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	3 (<0.1)	0		3 (<0.1)
Photopsia	2 (<0.1)	0		2 (<0.1)
Retinal infarction	1 (<0.1)	0		1 (<0.1)
Retinal oedema	1 (<0.1)	0		1 (<0.1)
Retinal tear	2 (<0.1)	0		2 (<0.1)
Strabismus	2 (<0.1)	0		2 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	4 (<0.1)	0		4 (<0.1)
Ear and labyrinth disorders	149 (1.0)	134 (0.9)		283 (0.9)
Vertigo	34 (0.2)	46 (0.3)	1.35 (0.87, 2.10)	80 (0.3)
Ear pain	35 (0.2)	29 (0.2)	0.83 (0.51, 1.35)	64 (0.2)
Tinnitus	22 (0.1)	20 (0.1)	0.91 (0.50, 1.65)	42 (0.1)
Vertigo positional	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Ear discomfort	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Meniere's disease	2 (<0.1)	6 (<0.1)		8 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)				
Cerumen impaction	5 (<0.1)	4 (<0.1)		9 (<0.1)
Deafness unilateral	2 (<0.1)	3 (<0.1)		5 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear canal erythema	6 (<0.1)	2 (<0.1)		8 (<0.1)
Ear congestion	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Eustachian tube dysfunction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tympanic membrane perforation	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Ear pruritus	6 (<0.1)	1 (<0.1)		7 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Diplacusis	1 (<0.1)	0		1 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	2 (<0.1)	0		2 (<0.1)
External ear pain	1 (<0.1)	0		1 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	167 (1.1)	165 (1.1)		332 (1.1)
Atrial fibrillation	28 (0.2)	25 (0.2)	0.89 (0.52, 1.52)	53 (0.2)
Palpitations	13 (<0.1)	22 (0.1)	1.69 (0.86, 3.31)	35 (0.1)
Tachycardia	23 (0.2)	21 (0.1)	0.91 (0.51, 1.63)	44 (0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Bradycardia	23 (0.2)	15 (<0.1)	0.65 (0.34, 1.23)	38 (0.1)
Angina pectoris	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Coronary artery disease	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Ventricular extrasystoles	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Sinus tachycardia	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Cardiac failure congestive	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Arrhythmia	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Acute myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Cardiac failure	4 (<0.1)	4 (<0.1)		8 (<0.1)
Supraventricular tachycardia	0	4 (<0.1)		4 (<0.1)
Acute coronary syndrome	0	3 (<0.1)		3 (<0.1)
Atrial flutter	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acute left ventricular failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiomyopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ventricular tachycardia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial enlargement	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiovascular symptom	0	1 (<0.1)		1 (<0.1)
Left ventricular hypertrophy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinus bradycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial tachycardia	2 (<0.1)	0		2 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac disorder	1 (<0.1)	0		1 (<0.1)
Cardiac steatosis	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	2 (<0.1)	0		2 (<0.1)
Diastolic dysfunction	1 (<0.1)	0		1 (<0.1)
Extrasystoles	1 (<0.1)	0		1 (<0.1)
Left atrial enlargement	1 (<0.1)	0		1 (<0.1)
Mitral valve incompetence	2 (<0.1)	0		2 (<0.1)
Mitral valve thickening	1 (<0.1)	0		1 (<0.1)
Myocardial ischaemia	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Postural orthostatic tachycardia syndrome	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Sinus arrest	1 (<0.1)	0		1 (<0.1)
Tricuspid valve incompetence	2 (<0.1)	0		2 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	405 (2.7)	347 (2.3)		752 (2.5)
Hypertension	332 (2.2)	262 (1.7)	0.79 (0.67, 0.92)	594 (2.0)
Hot flush	11 (<0.1)	17 (0.1)	1.54 (0.74, 3.24)	28 (<0.1)
Haematoma	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Deep vein thrombosis	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Flushing	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Hypotension	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Orthostatic hypotension	1 (<0.1)	6 (<0.1)		7 (<0.1)
Hypertensive urgency	2 (<0.1)	5 (<0.1)		7 (<0.1)
Arteriosclerosis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Aortic dilatation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Labile hypertension	0	2 (<0.1)		2 (<0.1)
Prehypertension	0	2 (<0.1)		2 (<0.1)
Raynaud's phenomenon	1 (<0.1)	2 (<0.1)		3 (<0.1)
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders (Cont.)				
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Diastolic hypotension	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive emergency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pallor	0	1 (<0.1)		1 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral coldness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Phlebitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	2 (<0.1)	0		2 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	2 (<0.1)	0		2 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Lymphoedema	1 (<0.1)	0		1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral venous disease	1 (<0.1)	0		1 (<0.1)
Secondary hypertension	1 (<0.1)	0		1 (<0.1)
Vascular calcification	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders (Cont.)				
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	2 (<0.1)	0		2 (<0.1)
Respiratory, thoracic and mediastinal disorders	1094 (7.2)	970 (6.4)		2064 (6.8)
Cough	307 (2.0)	310 (2.0)	1.01 (0.86, 1.18)	617 (2.0)
Oropharyngeal pain	381 (2.5)	304 (2.0)	0.80 (0.69, 0.92)	685 (2.3)
Nasal congestion	291 (1.9)	270 (1.8)	0.93 (0.79, 1.09)	561 (1.8)
Rhinorrhoea	258 (1.7)	246 (1.6)	0.95 (0.80, 1.13)	504 (1.7)
Dyspnoea	86 (0.6)	92 (0.6)	1.07 (0.80, 1.43)	178 (0.6)
Tachypnoea	43 (0.3)	39 (0.3)	0.91 (0.59, 1.39)	82 (0.3)
Sinus congestion	48 (0.3)	33 (0.2)	0.69 (0.44, 1.06)	81 (0.3)
Asthma	39 (0.3)	32 (0.2)	0.82 (0.52, 1.30)	71 (0.2)
Respiratory tract congestion	19 (0.1)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.1)
Upper-airway cough syndrome	22 (0.1)	23 (0.2)	1.04 (0.59, 1.86)	45 (0.1)
Epistaxis	17 (0.1)	22 (0.1)	1.29 (0.69, 2.41)	39 (0.1)
Sneezing	22 (0.1)	22 (0.1)	1.00 (0.56, 1.79)	44 (0.1)
Rhinitis allergic	26 (0.2)	21 (0.1)	0.81 (0.46, 1.42)	47 (0.2)
Throat irritation	20 (0.1)	18 (0.1)	0.90 (0.48, 1.68)	38 (0.1)
Chronic obstructive pulmonary disease	24 (0.2)	14 (<0.1)	0.58 (0.30, 1.11)	38 (0.1)
Sinus pain	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Acute respiratory failure	14 (<0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Paranasal sinus discomfort	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Pharyngeal erythema	6 (<0.1)	6 (<0.1)		12 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pleural effusion	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Respiratory disorder	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Dry throat	5 (<0.1)	5 (<0.1)		10 (<0.1)
Dysphonia	14 (<0.1)	5 (<0.1)	0.36 (0.13, 0.95)	19 (<0.1)
Dyspnoea exertional	5 (<0.1)	5 (<0.1)		10 (<0.1)
Productive cough	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Sleep apnoea syndrome	6 (<0.1)	5 (<0.1)		11 (<0.1)
Wheezing	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Bronchiectasis	0	4 (<0.1)		4 (<0.1)
Atelectasis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bronchospasm	1 (<0.1)	3 (<0.1)		4 (<0.1)
Emphysema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypoxia	6 (<0.1)	3 (<0.1)		9 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Allergic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nasal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Paranasal sinus hypersecretion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Choking sensation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lung infiltration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nasal dryness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal mucosal disorder	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	8 (<0.1)	1 (<0.1)	0.12 (0.02, 0.77)	9 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary congestion	0	1 (<0.1)		1 (<0.1)
Pulmonary hypertension	0	1 (<0.1)		1 (<0.1)
Pulmonary oedema	0	1 (<0.1)		1 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Rhonchi	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	6 (<0.1)	1 (<0.1)		7 (<0.1)
Vasomotor rhinitis	0	1 (<0.1)		1 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Vocal cord thickening	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Bronchial hyperreactivity	1 (<0.1)	0		1 (<0.1)
Haemoptysis	4 (<0.1)	0		4 (<0.1)
Laryngeal stenosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Lung cyst	1 (<0.1)	0		1 (<0.1)
Lung opacity	2 (<0.1)	0		2 (<0.1)
Nasal turbinate hypertrophy	1 (<0.1)	0		1 (<0.1)
Nasal ulcer	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary granuloma	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Rales	2 (<0.1)	0		2 (<0.1)
Reflux laryngitis	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	4 (<0.1)	0		4 (<0.1)
Rhinalgia	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	2 (<0.1)	0		2 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	3 (<0.1)	0		3 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	2 (<0.1)	0		2 (<0.1)
Gastrointestinal disorders	884 (5.8)	904 (6.0)		1788 (5.9)
Diarrhoea	280 (1.8)	282 (1.9)	1.01 (0.85, 1.18)	562 (1.9)
Nausea	242 (1.6)	243 (1.6)	1.00 (0.84, 1.20)	485 (1.6)
Vomiting	84 (0.6)	91 (0.6)	1.08 (0.81, 1.45)	175 (0.6)
Gastrooesophageal reflux disease	59 (0.4)	83 (0.5)	1.40 (1.01, 1.96)	142 (0.5)
Abdominal pain	40 (0.3)	46 (0.3)	1.15 (0.75, 1.75)	86 (0.3)
Toothache	49 (0.3)	45 (0.3)	0.92 (0.61, 1.37)	94 (0.3)
Constipation	39 (0.3)	27 (0.2)	0.69 (0.43, 1.12)	66 (0.2)
Abdominal pain upper	32 (0.2)	26 (0.2)	0.81 (0.49, 1.35)	58 (0.2)
Dental caries	31 (0.2)	25 (0.2)	0.81 (0.48, 1.36)	56 (0.2)
Dyspepsia	24 (0.2)	23 (0.2)	0.96 (0.54, 1.68)	47 (0.2)
Food poisoning	15 (<0.1)	13 (<0.1)	0.87 (0.42, 1.79)	28 (<0.1)
Abdominal pain lower	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Inguinal hernia	6 (<0.1)	12 (<0.1)	2.00 (0.78, 5.13)	18 (<0.1)
Hiatus hernia	6 (<0.1)	11 (<0.1)	1.83 (0.70, 4.77)	17 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal discomfort	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (<0.1)
Large intestine polyp	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Colitis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Gastritis	15 (<0.1)	8 (<0.1)	0.53 (0.23, 1.23)	23 (<0.1)
Haemorrhoids	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Irritable bowel syndrome	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Gastric ulcer	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Umbilical hernia	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Abdominal distension	2 (<0.1)	6 (<0.1)		8 (<0.1)
Flatulence	3 (<0.1)	6 (<0.1)		9 (<0.1)
Lip swelling	2 (<0.1)	6 (<0.1)		8 (<0.1)
Tooth impacted	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Diverticulum intestinal	1 (<0.1)	5 (<0.1)		6 (<0.1)
Gastrointestinal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Haematochezia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Oesophagitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Rectal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Small intestinal obstruction	4 (<0.1)	4 (<0.1)		8 (<0.1)
Aphthous ulcer	6 (<0.1)	3 (<0.1)		9 (<0.1)
Barrett's oesophagus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diverticulum	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dysphagia	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Faeces soft	0	3 (<0.1)		3 (<0.1)
Gastrointestinal pain	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Gingival pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypoaesthesia oral	0	3 (<0.1)		3 (<0.1)
Pancreatitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Paraesthesia oral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Periodontal disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Stomatitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Dry mouth	5 (<0.1)	2 (<0.1)		7 (<0.1)
Duodenal ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Faeces discoloured	0	2 (<0.1)		2 (<0.1)
Frequent bowel movements	0	2 (<0.1)		2 (<0.1)
Gastrointestinal disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gingival bleeding	0	2 (<0.1)		2 (<0.1)
Intestinal obstruction	0	2 (<0.1)		2 (<0.1)
Melaena	0	2 (<0.1)		2 (<0.1)
Mouth ulceration	4 (<0.1)	2 (<0.1)		6 (<0.1)
Oesophageal spasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oesophageal ulcer	0	2 (<0.1)		2 (<0.1)
Peptic ulcer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Proctalgia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swollen tongue	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anorectal disorder	0	1 (<0.1)		1 (<0.1)
Chronic gastritis	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Duodenitis	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Faecaloma	0	1 (<0.1)		1 (<0.1)
Gingival disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Intussusception	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Noninfective gingivitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral mucosal blistering	0	1 (<0.1)		1 (<0.1)
Oral mucosal eruption	0	1 (<0.1)		1 (<0.1)
Oral pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Pancreatic cyst	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Poor dental condition	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal fissure	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Saliva altered	1 (<0.1)	1 (<0.1)		2 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue ulceration	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Abdominal rigidity	2 (<0.1)	0		2 (<0.1)
Abdominal tenderness	1 (<0.1)	0		1 (<0.1)
Abdominal wall cyst	1 (<0.1)	0		1 (<0.1)
Anal fistula	1 (<0.1)	0		1 (<0.1)
Anorectal discomfort	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Ascites	2 (<0.1)	0		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Colitis microscopic	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Eosinophilic oesophagitis	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	2 (<0.1)	0		2 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival recession	1 (<0.1)	0		1 (<0.1)
Glossodynia	2 (<0.1)	0		2 (<0.1)
Hypertrophy of tongue papillae	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Lip blister	1 (<0.1)	0		1 (<0.1)
Mouth haemorrhage	1 (<0.1)	0		1 (<0.1)
Obstructive pancreatitis	1 (<0.1)	0		1 (<0.1)
Odynophagia	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Palatal disorder	1 (<0.1)	0		1 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Terminal ileitis	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Tongue dry	1 (<0.1)	0		1 (<0.1)
Tooth disorder	3 (<0.1)	0		3 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Upper gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Uvulitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	21 (0.1)	31 (0.2)		52 (0.2)
Cholelithiasis	9 (<0.1)	15 (<0.1)	1.66 (0.74, 3.72)	24 (<0.1)
Cholecystitis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Hepatic steatosis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Bile duct stone	0	2 (<0.1)		2 (<0.1)
Biliary colic	0	2 (<0.1)		2 (<0.1)
Biliary dyskinesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholecystitis acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Jaundice	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)				
Hepatic haematoma	1 (<0.1)	0		1 (<0.1)
Hyperbilirubinaemia	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	374 (2.5)	394 (2.6)		768 (2.5)
Urticaria	46 (0.3)	55 (0.4)	1.19 (0.81, 1.76)	101 (0.3)
Rash	47 (0.3)	44 (0.3)	0.93 (0.62, 1.41)	91 (0.3)
Dermatitis contact	41 (0.3)	34 (0.2)	0.83 (0.53, 1.30)	75 (0.2)
Pruritus	29 (0.2)	28 (0.2)	0.96 (0.58, 1.61)	57 (0.2)
Eczema	11 (<0.1)	18 (0.1)	1.63 (0.78, 3.40)	29 (<0.1)
Erythema	8 (<0.1)	17 (0.1)	2.12 (0.94, 4.80)	25 (<0.1)
Hyperhidrosis	12 (<0.1)	16 (0.1)	1.33 (0.64, 2.77)	28 (<0.1)
Acne	19 (0.1)	15 (<0.1)	0.79 (0.41, 1.53)	34 (0.1)
Night sweats	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Dermatitis	14 (<0.1)	10 (<0.1)	0.71 (0.32, 1.57)	24 (<0.1)
Actinic keratosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Rash maculo-papular	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Rash papular	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Alopecia	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Rash macular	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Ecchymosis	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Psoriasis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Rosacea	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Dermatitis atopic	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Rash pruritic	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dry skin	4 (<0.1)	5 (<0.1)		9 (<0.1)
Ingrowing nail	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)
Skin lesion	6 (<0.1)	4 (<0.1)		10 (<0.1)
Angioedema	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blister	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dermal cyst	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Dermatitis allergic	5 (<0.1)	3 (<0.1)		8 (<0.1)
Eczema nummular	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hidradenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Macule	1 (<0.1)	3 (<0.1)		4 (<0.1)
Neurodermatitis	0	3 (<0.1)		3 (<0.1)
Pain of skin	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rash erythematous	4 (<0.1)	3 (<0.1)		7 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Diabetic foot	0	2 (<0.1)		2 (<0.1)
Hand dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Papule	2 (<0.1)	2 (<0.1)		4 (<0.1)
Precancerous skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash vesicular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood blister	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Decubitus ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Onychoclasis	0	1 (<0.1)		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin hypopigmentation	0	1 (<0.1)		1 (<0.1)
Skin mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitiligo	0	1 (<0.1)		1 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Hyperkeratosis	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	4 (<0.1)	0		4 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Miliaria	1 (<0.1)	0		1 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin discolouration	2 (<0.1)	0		2 (<0.1)
Skin fissures	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin wrinkling	1 (<0.1)	0		1 (<0.1)
Stasis dermatitis	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders	1342 (8.9)	1315 (8.7)		2657 (8.8)
Arthralgia	436 (2.9)	443 (2.9)	1.01 (0.89, 1.16)	879 (2.9)
Myalgia	451 (3.0)	434 (2.9)	0.96 (0.84, 1.09)	885 (2.9)
Back pain	185 (1.2)	163 (1.1)	0.88 (0.71, 1.08)	348 (1.1)
Pain in extremity	101 (0.7)	84 (0.6)	0.83 (0.62, 1.11)	185 (0.6)
Musculoskeletal pain	53 (0.3)	67 (0.4)	1.26 (0.88, 1.81)	120 (0.4)
Neck pain	54 (0.4)	62 (0.4)	1.15 (0.80, 1.65)	116 (0.4)
Osteoarthritis	75 (0.5)	61 (0.4)	0.81 (0.58, 1.14)	136 (0.4)
Muscle spasms	44 (0.3)	43 (0.3)	0.98 (0.64, 1.48)	87 (0.3)
Rotator cuff syndrome	26 (0.2)	25 (0.2)	0.96 (0.56, 1.65)	51 (0.2)
Tendonitis	24 (0.2)	21 (0.1)	0.87 (0.49, 1.56)	45 (0.1)
Bursitis	13 (<0.1)	20 (0.1)	1.54 (0.77, 3.05)	33 (0.1)
Musculoskeletal chest pain	26 (0.2)	18 (0.1)	0.69 (0.38, 1.25)	44 (0.1)
Intervertebral disc protrusion	13 (<0.1)	17 (0.1)	1.31 (0.64, 2.65)	30 (<0.1)
Musculoskeletal stiffness	16 (0.1)	15 (<0.1)	0.94 (0.47, 1.87)	31 (0.1)
Arthritis	12 (<0.1)	14 (<0.1)	1.16 (0.55, 2.47)	26 (<0.1)
Joint swelling	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Muscular weakness	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Osteopenia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Osteoporosis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Trigger finger	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Groin pain	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Periarthritis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Flank pain	6 (<0.1)	6 (<0.1)		12 (<0.1)
Muscle tightness	2 (<0.1)	6 (<0.1)		8 (<0.1)
Pain in jaw	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Costochondritis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Limb discomfort	2 (<0.1)	5 (<0.1)		7 (<0.1)
Plantar fasciitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Spinal pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	5 (<0.1)		7 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Fibromyalgia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Intervertebral disc degeneration	6 (<0.1)	4 (<0.1)		10 (<0.1)
Muscle twitching	3 (<0.1)	4 (<0.1)		7 (<0.1)
Spinal stenosis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Limb mass	2 (<0.1)	3 (<0.1)		5 (<0.1)
Muscle fatigue	0	3 (<0.1)		3 (<0.1)
Neck mass	0	3 (<0.1)		3 (<0.1)
Spondylolisthesis	0	3 (<0.1)		3 (<0.1)
Synovial cyst	6 (<0.1)	3 (<0.1)		9 (<0.1)
Axillary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cervical spinal stenosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Exostosis	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Foot deformity	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Joint stiffness	3 (<0.1)	2 (<0.1)		5 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rheumatoid arthritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Spondylitis	0	2 (<0.1)		2 (<0.1)
Tenosynovitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Compartment syndrome	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)		1 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)		1 (<0.1)
Joint noise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ligament pain	0	1 (<0.1)		1 (<0.1)
Ligamentum flavum hypertrophy	0	1 (<0.1)		1 (<0.1)
Medial tibial stress syndrome	0	1 (<0.1)		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteonecrosis	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal synovial cyst	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis stenosans	2 (<0.1)	1 (<0.1)		3 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)		1 (<0.1)
Fasciitis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Joint effusion	1 (<0.1)	0		1 (<0.1)
Kyphosis	1 (<0.1)	0		1 (<0.1)
Lumbar spinal stenosis	2 (<0.1)	0		2 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Scoliosis	3 (<0.1)	0		3 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Synovitis	2 (<0.1)	0		2 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Renal and urinary disorders	99 (0.7)	100 (0.7)		199 (0.7)
Nephrolithiasis	34 (0.2)	29 (0.2)	0.85 (0.52, 1.39)	63 (0.2)
Dysuria	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Acute kidney injury	13 (<0.1)	7 (<0.1)	0.54 (0.22, 1.31)	20 (<0.1)
Chronic kidney disease	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Haematuria	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Urinary retention	4 (<0.1)	6 (<0.1)		10 (<0.1)
Hypertonic bladder	3 (<0.1)	5 (<0.1)		8 (<0.1)
Pollakiuria	6 (<0.1)	5 (<0.1)		11 (<0.1)
Polyuria	0	5 (<0.1)		5 (<0.1)
Nocturia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Urinary incontinence	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hydronephrosis	0	3 (<0.1)		3 (<0.1)
Bladder pain	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Renal cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Urinary hesitation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder spasm	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calculus bladder	0	1 (<0.1)		1 (<0.1)
Chromaturia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cystitis interstitial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetic nephropathy	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Micturition urgency	3 (<0.1)	1 (<0.1)		4 (<0.1)
Renal disorder	0	1 (<0.1)		1 (<0.1)
Renal failure	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Renal tubular necrosis	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal colic	2 (<0.1)	0		2 (<0.1)
Renal impairment	2 (<0.1)	0		2 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions	3 (<0.1)	3 (<0.1)		6 (<0.1)
Abortion spontaneous	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)		1 (<0.1)
Morning sickness	0	1 (<0.1)		1 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	132 (0.9)	115 (0.8)		247 (0.8)
Benign prostatic hyperplasia	22 (0.1)	11 (<0.1)	0.50 (0.25, 1.01)	33 (0.1)
Erectile dysfunction	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Ovarian cyst	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Pelvic pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Prostatitis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Breast cyst	4 (<0.1)	5 (<0.1)		9 (<0.1)
Dysmenorrhoea	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.39)	15 (<0.1)
Menorrhagia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Prostatomegaly	6 (<0.1)	5 (<0.1)		11 (<0.1)
Menopausal symptoms	2 (<0.1)	4 (<0.1)		6 (<0.1)
Vaginal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Postmenopausal haemorrhage	3 (<0.1)	3 (<0.1)		6 (<0.1)
Uterine polyp	3 (<0.1)	3 (<0.1)		6 (<0.1)
Breast hyperplasia	0	2 (<0.1)		2 (<0.1)
Breast mass	5 (<0.1)	2 (<0.1)		7 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Breast pain	5 (<0.1)	2 (<0.1)		7 (<0.1)
Breast ulceration	0	2 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Rectocele	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexa uteri pain	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Artificial menopause	0	1 (<0.1)		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast enlargement	0	1 (<0.1)		1 (<0.1)
Breast fibrosis	0	1 (<0.1)		1 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Breast tenderness	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical polyp	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystocele	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Endometriosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibrocystic breast disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Polymenorrhoea	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatic cyst	0	1 (<0.1)		1 (<0.1)
Testicular pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaginal cyst	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vaginal prolapse	0	1 (<0.1)		1 (<0.1)
Vulva cyst	0	1 (<0.1)		1 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	3 (<0.1)	0		3 (<0.1)
Dyspareunia	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Haematospermia	2 (<0.1)	0		2 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Ovarian mass	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Pelvic floor muscle weakness	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
Peyronie's disease	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	3 (<0.1)	0		3 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Pruritus genital	1 (<0.1)	0		1 (<0.1)
Testicular swelling	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	2 (<0.1)	0		2 (<0.1)
Vulvovaginal dryness	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	5 (<0.1)	8 (<0.1)		13 (<0.1)
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Developmental hip dysplasia	0	1 (<0.1)		1 (<0.1)
Gilbert's syndrome	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)				
Preauricular cyst	0	1 (<0.1)		1 (<0.1)
Type IIa hyperlipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Von Willebrand's disease	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1330 (8.8)	1836 (12.1)		3166 (10.4)
Fatigue	799 (5.3)	882 (5.8)	1.10 (1.00, 1.21)	1681 (5.5)
Injection site pain	141 (0.9)	269 (1.8)	1.91 (1.56, 2.33)	410 (1.4)
Chills	162 (1.1)	175 (1.2)	1.08 (0.87, 1.33)	337 (1.1)
Pyrexia	120 (0.8)	168 (1.1)	1.40 (1.11, 1.76)	288 (0.9)
Injection site erythema	40 (0.3)	158 (1.0)	3.94 (2.80, 5.57)	198 (0.7)
Pain	135 (0.9)	133 (0.9)	0.98 (0.78, 1.25)	268 (0.9)
Injection site swelling	31 (0.2)	119 (0.8)	3.83 (2.59, 5.67)	150 (0.5)
Injection site pruritus	13 (<0.1)	88 (0.6)	6.76 (3.81, 12.00)	101 (0.3)
Injection site lymphadenopathy	17 (0.1)	69 (0.5)	4.05 (2.40, 6.85)	86 (0.3)
Injection site induration	18 (0.1)	53 (0.3)	2.94 (1.73, 4.99)	71 (0.2)
Injection site macule	4 (<0.1)	45 (0.3)	11.23 (4.21, 30.01)	49 (0.2)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.94 (6.58, 218.91)	39 (0.1)
Axillary pain	15 (<0.1)	27 (0.2)	1.80 (0.97, 3.34)	42 (0.1)
Injection site rash	1 (<0.1)	25 (0.2)	24.96 (4.29, 145.37)	26 (<0.1)
Chest discomfort	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site bruising	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Malaise	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
Peripheral swelling	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
Chest pain	11 (<0.1)	15 (<0.1)	1.36 (0.64, 2.91)	26 (<0.1)
Non-cardiac chest pain	16 (0.1)	15 (<0.1)	0.94 (0.47, 1.87)	31 (0.1)
Oedema peripheral	17 (0.1)	14 (<0.1)	0.82 (0.41, 1.64)	31 (0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	12.98 (2.18, 77.49)	14 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Reactogenicity event	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Asthenia	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Feeling hot	3 (<0.1)	6 (<0.1)		9 (<0.1)
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haemorrhage	5 (<0.1)	6 (<0.1)		11 (<0.1)
Injection site paraesthesia	3 (<0.1)	6 (<0.1)		9 (<0.1)
Swelling face	4 (<0.1)	6 (<0.1)		10 (<0.1)
Vaccination site swelling	1 (<0.1)	6 (<0.1)		7 (<0.1)
Feeling abnormal	6 (<0.1)	5 (<0.1)		11 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Vaccination site pain	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Influenza like illness	6 (<0.1)	4 (<0.1)		10 (<0.1)
Injection site mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cyst	6 (<0.1)	3 (<0.1)		9 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site reaction	0	3 (<0.1)		3 (<0.1)
Injury associated with device	0	3 (<0.1)		3 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Adverse drug reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Hangover	1 (<0.1)	2 (<0.1)		3 (<0.1)
Inflammation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	2 (<0.1)		3 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Dysplasia	0	1 (<0.1)		1 (<0.1)
Early satiety	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	6 (<0.1)	1 (<0.1)		7 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Granuloma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Medical device site pain	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Xerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Capsular contracture associated with breast implant	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Drug intolerance	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	4 (<0.1)	0		4 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	2 (<0.1)	0		2 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations	166 (1.1)	172 (1.1)		338 (1.1)
Blood pressure increased	53 (0.3)	41 (0.3)	0.77 (0.52, 1.16)	94 (0.3)
Blood pressure systolic increased	21 (0.1)	21 (0.1)	1.00 (0.55, 1.81)	42 (0.1)
Blood pressure diastolic increased	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Blood cholesterol increased	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Hepatic enzyme increased	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Body temperature increased	2 (<0.1)	5 (<0.1)		7 (<0.1)
Heart rate increased	3 (<0.1)	5 (<0.1)		8 (<0.1)
Prostatic specific antigen increased	2 (<0.1)	5 (<0.1)		7 (<0.1)
Blood glucose increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Transaminases increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Weight decreased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood triglycerides increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
C-reactive protein increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cardiac murmur	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Blood creatine increased	0	2 (<0.1)		2 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Blood parathyroid hormone increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood potassium decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrocardiogram QT prolonged	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	6 (<0.1)	2 (<0.1)		8 (<0.1)
Hepatic enzyme abnormal	0	2 (<0.1)		2 (<0.1)
Human rhinovirus test positive	1 (<0.1)	2 (<0.1)		3 (<0.1)
White blood cell count increased	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Antinuclear antibody positive	0	1 (<0.1)		1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood uric acid increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood urine present	1 (<0.1)	1 (<0.1)		2 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)		1 (<0.1)
Glycosylated haemoglobin increased	5 (<0.1)	1 (<0.1)		6 (<0.1)
Haemoglobin decreased	0	1 (<0.1)		1 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Liver function test increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Respiratory rate increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stool analysis abnormal	0	1 (<0.1)		1 (<0.1)
Streptococcus test negative	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Troponin increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Vitamin B12 decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitamin D decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Weight increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	2 (<0.1)	0		2 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Haematocrit increased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Liver function test abnormal	1 (<0.1)	0		1 (<0.1)
Pregnancy test positive	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Renal function test abnormal	1 (<0.1)	0		1 (<0.1)
SARS-CoV-2 test positive	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Total lung capacity decreased	1 (<0.1)	0		1 (<0.1)
Viral test positive	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	651 (4.3)	571 (3.8)		1222 (4.0)
Muscle strain	51 (0.3)	53 (0.3)	1.04 (0.71, 1.52)	104 (0.3)
Ligament sprain	50 (0.3)	49 (0.3)	0.98 (0.66, 1.45)	99 (0.3)
Fall	48 (0.3)	46 (0.3)	0.96 (0.64, 1.43)	94 (0.3)
Skin laceration	53 (0.3)	37 (0.2)	0.70 (0.46, 1.06)	90 (0.3)
Tooth fracture	36 (0.2)	32 (0.2)	0.89 (0.55, 1.42)	68 (0.2)
Contusion	36 (0.2)	30 (0.2)	0.83 (0.52, 1.34)	66 (0.2)
Procedural pain	56 (0.4)	30 (0.2)	0.53 (0.34, 0.83)	86 (0.3)
Arthropod bite	37 (0.2)	29 (0.2)	0.78 (0.48, 1.27)	66 (0.2)
Foot fracture	23 (0.2)	23 (0.2)	1.00 (0.56, 1.77)	46 (0.2)
Limb injury	17 (0.1)	20 (0.1)	1.17 (0.62, 2.22)	37 (0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Animal bite	18 (0.1)	18 (0.1)	1.00 (0.53, 1.90)	36 (0.1)
Meniscus injury	21 (0.1)	18 (0.1)	0.86 (0.46, 1.59)	39 (0.1)
Road traffic accident	14 (<0.1)	16 (0.1)	1.14 (0.57, 2.30)	30 (<0.1)
Joint injury	9 (<0.1)	15 (<0.1)	1.66 (0.74, 3.72)	24 (<0.1)
Skin abrasion	31 (0.2)	15 (<0.1)	0.48 (0.26, 0.89)	46 (0.2)
Rib fracture	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Arthropod sting	18 (0.1)	10 (<0.1)	0.55 (0.26, 1.18)	28 (<0.1)
Concussion	5 (<0.1)	10 (<0.1)	2.00 (0.71, 5.58)	15 (<0.1)
Post-traumatic pain	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Head injury	2 (<0.1)	9 (<0.1)	4.49 (1.10, 18.44)	11 (<0.1)
Facial bones fracture	1 (<0.1)	8 (<0.1)	7.99 (1.30, 49.20)	9 (<0.1)
Thermal burn	3 (<0.1)	6 (<0.1)		9 (<0.1)
Ankle fracture	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.39)	15 (<0.1)
Bone contusion	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Clavicle fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Corneal abrasion	6 (<0.1)	5 (<0.1)		11 (<0.1)
Epicondylitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Hand fracture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Humerus fracture	3 (<0.1)	5 (<0.1)		8 (<0.1)
Joint dislocation	4 (<0.1)	5 (<0.1)		9 (<0.1)
Ligament rupture	5 (<0.1)	5 (<0.1)		10 (<0.1)
Muscle rupture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Stress fracture	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Upper limb fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Back injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Cartilage injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Dental restoration failure	3 (<0.1)	4 (<0.1)		7 (<0.1)
Wrist fracture	6 (<0.1)	4 (<0.1)		10 (<0.1)
Alcohol poisoning	0	3 (<0.1)		3 (<0.1)
Craniocerebral injury	0	3 (<0.1)		3 (<0.1)
Hip fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Inappropriate schedule of product administration	4 (<0.1)	3 (<0.1)		7 (<0.1)
Subdural haematoma	0	3 (<0.1)		3 (<0.1)
Tendon injury	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tendon rupture	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.14)	12 (<0.1)
Cervical vertebral fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Exposure to SARS-CoV-2	3 (<0.1)	2 (<0.1)		5 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Hypobarism	0	2 (<0.1)		2 (<0.1)
Ligament injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Lip injury	4 (<0.1)	2 (<0.1)		6 (<0.1)
Lower limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post procedural haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Procedural nausea	4 (<0.1)	2 (<0.1)		6 (<0.1)
Skin wound	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Spinal compression fracture	0	2 (<0.1)		2 (<0.1)
Vaccination complication	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wound	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	3 (<0.1)	1 (<0.1)		4 (<0.1)
Carbon monoxide poisoning	0	1 (<0.1)		1 (<0.1)
Chemical burn	0	1 (<0.1)		1 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Chillblains	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)		1 (<0.1)
Dural tear	0	1 (<0.1)		1 (<0.1)
Eyelid injury	0	1 (<0.1)		1 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)		1 (<0.1)
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Fractured sacrum	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Graft complication	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injury	0	1 (<0.1)		1 (<0.1)
Limb traumatic amputation	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Multiple fractures	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Neck injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural fever	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural haematoma	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Procedural site reaction	0	1 (<0.1)		1 (<0.1)
Product administration interrupted	1 (<0.1)	1 (<0.1)		2 (<0.1)
Radius fracture	6 (<0.1)	1 (<0.1)		7 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scar	1 (<0.1)	1 (<0.1)		2 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal column injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splinter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sports injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Superficial injury of eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Traumatic haemorrhage	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eye injury	2 (<0.1)	0		2 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	3 (<0.1)	0		3 (<0.1)
Foreign body in ear	2 (<0.1)	0		2 (<0.1)
Fractured coccyx	1 (<0.1)	0		1 (<0.1)
Gingival injury	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Keratorhexis	1 (<0.1)	0		1 (<0.1)
Mallet finger	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Multiple injuries	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Musculoskeletal foreign body	1 (<0.1)	0		1 (<0.1)
Nail injury	2 (<0.1)	0		2 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural constipation	2 (<0.1)	0		2 (<0.1)
Post procedural contusion	1 (<0.1)	0		1 (<0.1)
Post procedural hypothyroidism	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	2 (<0.1)	0		2 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural vomiting	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	2 (<0.1)	0		2 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	2 (<0.1)	0		2 (<0.1)
Uterine perforation	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	3 (<0.1)	2 (<0.1)		5 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Postmenopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Product issues	3 (<0.1)	5 (<0.1)		8 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3275 (28.7)	3515 (30.8)		6790 (29.7)
Number of Unsolicited Adverse Events	6564	7126		13690
Infections and infestations	763 (6.7)	617 (5.4)		1380 (6.0)
Upper respiratory tract infection	108 (0.9)	71 (0.6)	0.66 (0.49, 0.88)	179 (0.8)
Urinary tract infection	73 (0.6)	67 (0.6)	0.92 (0.66, 1.28)	140 (0.6)
Sinusitis	38 (0.3)	49 (0.4)	1.29 (0.85, 1.96)	87 (0.4)
Viral infection	46 (0.4)	37 (0.3)	0.80 (0.52, 1.23)	83 (0.4)
Rhinovirus infection	28 (0.2)	30 (0.3)	1.07 (0.64, 1.78)	58 (0.3)
Suspected COVID-19	28 (0.2)	29 (0.3)	1.04 (0.62, 1.73)	57 (0.2)
Tooth infection	15 (0.1)	20 (0.2)	1.33 (0.69, 2.57)	35 (0.2)
COVID-19	139 (1.2)	17 (0.1)	0.12 (0.07, 0.20)	156 (0.7)
Pharyngitis	20 (0.2)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.2)
Tooth abscess	15 (0.1)	16 (0.1)	1.07 (0.53, 2.13)	31 (0.1)
Ear infection	9 (<0.1)	15 (0.1)	1.67 (0.75, 3.72)	24 (0.1)
Gastroenteritis	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Herpes zoster	11 (<0.1)	14 (0.1)	1.27 (0.59, 2.75)	25 (0.1)
Pharyngitis streptococcal	18 (0.2)	13 (0.1)	0.72 (0.36, 1.45)	31 (0.1)
Conjunctivitis	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.63)	17 (<0.1)
Viral upper respiratory tract infection	13 (0.1)	10 (<0.1)	0.77 (0.34, 1.72)	23 (0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Bronchitis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Cellulitis	12 (0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Hordeolum	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Oral herpes	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Otitis media	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Fungal infection	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Bacterial vaginosis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Folliculitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Herpes simplex	4 (<0.1)	6 (<0.1)		10 (<0.1)
Vulvovaginal mycotic infection	13 (0.1)	6 (<0.1)	0.46 (0.18, 1.17)	19 (<0.1)
Acute sinusitis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Asymptomatic COVID-19	3 (<0.1)	5 (<0.1)		8 (<0.1)
Diverticulitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Localised infection	5 (<0.1)	5 (<0.1)		10 (<0.1)
Nasopharyngitis	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.40)	15 (<0.1)
Otitis externa	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Paronychia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Vulvovaginal candidiasis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Abscess limb	1 (<0.1)	4 (<0.1)		5 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Onychomycosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Respiratory tract infection	3 (<0.1)	4 (<0.1)		7 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	10 (<0.1)	3 (<0.1)	0.30 (0.09, 1.01)	13 (<0.1)
Gingivitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	0	3 (<0.1)		3 (<0.1)
Skin infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Subcutaneous abscess	2 (<0.1)	3 (<0.1)		5 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Enterovirus infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Impetigo	0	2 (<0.1)		2 (<0.1)
Oral candidiasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pneumonia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Soft tissue infection	0	2 (<0.1)		2 (<0.1)
Tonsillitis	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	0	1 (<0.1)		1 (<0.1)
Candida infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Chronic sinusitis	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystitis	9 (<0.1)	1 (<0.1)	0.11 (0.02, 0.68)	10 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection viral	4 (<0.1)	1 (<0.1)		5 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Staphylococcal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea cruris	0	1 (<0.1)		1 (<0.1)
Tinea pedis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Appendicitis	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	2 (<0.1)	0		2 (<0.1)
Laryngitis	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Latent tuberculosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Rhinitis	4 (<0.1)	0		4 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Sialoadenitis	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	22 (0.2)	33 (0.3)		55 (0.2)
Uterine leiomyoma	1 (<0.1)	4 (<0.1)		5 (<0.1)
Basal cell carcinoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Benign neoplasm of skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Squamous cell carcinoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	2 (<0.1)	1 (<0.1)		3 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Prostate cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Lipoma	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Skin cancer	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	0		2 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	132 (1.2)	261 (2.3)		393 (1.7)
Lymphadenopathy	114 (1.0)	238 (2.1)	2.09 (1.67, 2.60)	352 (1.5)
Lymph node pain	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Blood and lymphatic system disorders (Cont.)				
Anaemia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Iron deficiency anaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Lymphadenitis	0	2 (<0.1)		2 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	0		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	55 (0.5)	33 (0.3)		88 (0.4)
Seasonal allergy	38 (0.3)	24 (0.2)	0.63 (0.38, 1.05)	62 (0.3)
Hypersensitivity	6 (<0.1)	4 (<0.1)		10 (<0.1)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	0		2 (<0.1)
Drug hypersensitivity	4 (<0.1)	0		4 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Endocrine disorders	11 (<0.1)	10 (<0.1)		21 (<0.1)
Hypothyroidism	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	87 (0.8)	77 (0.7)		164 (0.7)
Type 2 diabetes mellitus	8 (<0.1)	13 (0.1)	1.62 (0.69, 3.82)	21 (<0.1)
Hyperlipidaemia	16 (0.1)	12 (0.1)	0.75 (0.36, 1.56)	28 (0.1)
Decreased appetite	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Vitamin D deficiency	14 (0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Dehydration	4 (<0.1)	6 (<0.1)		10 (<0.1)
Glucose tolerance impaired	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Diabetes mellitus	2 (<0.1)	4 (<0.1)		6 (<0.1)
Gout	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypercholesterolaemia	12 (0.1)	3 (<0.1)	0.25 (0.08, 0.82)	15 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abnormal loss of weight	0	2 (<0.1)		2 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypokalaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyponatraemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Iron deficiency	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders	98 (0.9)	128 (1.1)		226 (1.0)
Anxiety	31 (0.3)	41 (0.4)	1.32 (0.83, 2.10)	72 (0.3)
Depression	26 (0.2)	30 (0.3)	1.15 (0.69, 1.94)	56 (0.2)
Insomnia	19 (0.2)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.2)
Abnormal dreams	1 (<0.1)	5 (<0.1)		6 (<0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Panic attack	3 (<0.1)	4 (<0.1)		7 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	3 (<0.1)		4 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Sleep disorder	0	3 (<0.1)		3 (<0.1)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	3 (<0.1)	0		3 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Nightmare	1 (<0.1)	0		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	707 (6.2)	805 (7.1)		1512 (6.6)
Headache	568 (5.0)	605 (5.3)	1.06 (0.95, 1.19)	1173 (5.1)
Dizziness	39 (0.3)	52 (0.5)	1.33 (0.88, 2.01)	91 (0.4)
Paraesthesia	24 (0.2)	27 (0.2)	1.12 (0.65, 1.93)	51 (0.2)
Ageusia	9 (<0.1)	14 (0.1)	1.56 (0.69, 3.51)	23 (0.1)
Migraine	21 (0.2)	14 (0.1)	0.67 (0.34, 1.29)	35 (0.2)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Sinus headache	4 (<0.1)	12 (0.1)	3.00 (1.02, 8.82)	16 (<0.1)
Dysgeusia	5 (<0.1)	11 (<0.1)	2.20 (0.80, 6.06)	16 (<0.1)
Hypoaesthesia	6 (<0.1)	10 (<0.1)	1.67 (0.63, 4.41)	16 (<0.1)
Syncope	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Anosmia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Sciatica	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Tension headache	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Presyncope	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Cervical radiculopathy	1 (<0.1)	5 (<0.1)		6 (<0.1)
Hyperaesthesia	0	4 (<0.1)		4 (<0.1)
Burning sensation	0	3 (<0.1)		3 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	3 (<0.1)		7 (<0.1)
Disturbance in attention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Memory impairment	0	3 (<0.1)		3 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Nerve compression	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Neuropathy peripheral	0	2 (<0.1)		2 (<0.1)
Seizure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Somnolence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Taste disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Facial paralysis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuralgia	0	1 (<0.1)		1 (<0.1)
Parosmia	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	2 (<0.1)	0		2 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Eye disorders	37 (0.3)	47 (0.4)		84 (0.4)
Eye pruritus	6 (<0.1)	5 (<0.1)		11 (<0.1)
Vision blurred	2 (<0.1)	5 (<0.1)		7 (<0.1)
Eye irritation	1 (<0.1)	4 (<0.1)		5 (<0.1)
Conjunctival haemorrhage	0	3 (<0.1)		3 (<0.1)
Blepharitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Dry eye	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular hyperaemia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye inflammation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Eye pain	0	1 (<0.1)		1 (<0.1)
Eye swelling	3 (<0.1)	1 (<0.1)		4 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Glaucoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Cataract	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	59 (0.5)	56 (0.5)		115 (0.5)
Ear pain	15 (0.1)	14 (0.1)	0.93 (0.46, 1.90)	29 (0.1)
Vertigo	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Tinnitus	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Ear discomfort	5 (<0.1)	4 (<0.1)		9 (<0.1)
Vertigo positional	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cerumen impaction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear canal erythema	4 (<0.1)	2 (<0.1)		6 (<0.1)
Otorrhoea	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear congestion	3 (<0.1)	0		3 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)
Middle ear effusion	3 (<0.1)	0		3 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Ear and labyrinth disorders (Cont.)				
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	44 (0.4)	44 (0.4)		88 (0.4)
Tachycardia	7 (<0.1)	13 (0.1)	1.86 (0.76, 4.52)	20 (<0.1)
Bradycardia	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Palpitations	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Atrial fibrillation	3 (<0.1)	3 (<0.1)		6 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Angina pectoris	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiac failure congestive	3 (<0.1)	2 (<0.1)		5 (<0.1)
Sinus tachycardia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Cardiac failure	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	2 (<0.1)	0		2 (<0.1)
Vascular disorders	130 (1.1)	128 (1.1)		258 (1.1)
Hypertension	105 (0.9)	103 (0.9)	0.98 (0.75, 1.28)	208 (0.9)
Hot flush	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Flushing	4 (<0.1)	4 (<0.1)		8 (<0.1)
Haematoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Systolic hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders (Cont.)				
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	538 (4.7)	478 (4.2)		1016 (4.5)
Cough	143 (1.3)	145 (1.3)	1.01 (0.81, 1.27)	288 (1.3)
Oropharyngeal pain	195 (1.7)	134 (1.2)	0.69 (0.55, 0.85)	329 (1.4)
Nasal congestion	135 (1.2)	128 (1.1)	0.95 (0.75, 1.20)	263 (1.2)
Rhinorrhoea	113 (1.0)	97 (0.8)	0.86 (0.66, 1.12)	210 (0.9)
Dyspnoea	34 (0.3)	35 (0.3)	1.03 (0.65, 1.64)	69 (0.3)
Tachypnoea	29 (0.3)	30 (0.3)	1.03 (0.62, 1.71)	59 (0.3)
Respiratory tract congestion	6 (<0.1)	15 (0.1)	2.50 (1.00, 6.24)	21 (<0.1)
Sinus congestion	22 (0.2)	15 (0.1)	0.68 (0.36, 1.30)	37 (0.2)
Throat irritation	13 (0.1)	14 (0.1)	1.08 (0.51, 2.25)	27 (0.1)
Epistaxis	6 (<0.1)	12 (0.1)	2.00 (0.78, 5.14)	18 (<0.1)
Asthma	15 (0.1)	10 (<0.1)	0.67 (0.31, 1.45)	25 (0.1)
Rhinitis allergic	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Upper-airway cough syndrome	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.76)	19 (<0.1)
Sneezing	12 (0.1)	6 (<0.1)	0.50 (0.19, 1.28)	18 (<0.1)
Chronic obstructive pulmonary disease	6 (<0.1)	5 (<0.1)		11 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)		7 (<0.1)
Productive cough	4 (<0.1)	4 (<0.1)		8 (<0.1)
Sinus pain	3 (<0.1)	4 (<0.1)		7 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dry throat	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dyspnoea exertional	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pharyngeal erythema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchiectasis	0	2 (<0.1)		2 (<0.1)
Dysphonia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wheezing	2 (<0.1)	2 (<0.1)		4 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchospasm	0	1 (<0.1)		1 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	4 (<0.1)	1 (<0.1)		5 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory disorder	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	420 (3.7)	444 (3.9)		864 (3.8)
Diarrhoea	139 (1.2)	159 (1.4)	1.14 (0.91, 1.43)	298 (1.3)
Nausea	132 (1.2)	120 (1.1)	0.91 (0.71, 1.16)	252 (1.1)
Vomiting	45 (0.4)	44 (0.4)	0.98 (0.65, 1.48)	89 (0.4)
Gastrooesophageal reflux disease	21 (0.2)	28 (0.2)	1.33 (0.76, 2.33)	49 (0.2)
Toothache	22 (0.2)	25 (0.2)	1.14 (0.65, 2.00)	47 (0.2)
Abdominal pain	18 (0.2)	22 (0.2)	1.22 (0.66, 2.25)	40 (0.2)
Constipation	13 (0.1)	12 (0.1)	0.92 (0.43, 1.98)	25 (0.1)
Dental caries	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Dyspepsia	13 (0.1)	10 (<0.1)	0.77 (0.34, 1.72)	23 (0.1)
Food poisoning	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.59)	15 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal pain upper	16 (0.1)	8 (<0.1)	0.50 (0.22, 1.14)	24 (0.1)
Abdominal pain lower	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Abdominal discomfort	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Abdominal distension	2 (<0.1)	4 (<0.1)		6 (<0.1)
Gastric ulcer	2 (<0.1)	4 (<0.1)		6 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)		6 (<0.1)
Aphthous ulcer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Colitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Hiatus hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tooth impacted	2 (<0.1)	3 (<0.1)		5 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastritis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastrointestinal disorder	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	2 (<0.1)		3 (<0.1)
Inguinal hernia	0	2 (<0.1)		2 (<0.1)
Large intestine polyp	1 (<0.1)	2 (<0.1)		3 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Proctalgia	0	2 (<0.1)		2 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Umbilical hernia	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dry mouth	2 (<0.1)	1 (<0.1)		3 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Peptic ulcer	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival pain	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0		2 (<0.1)
Oral disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	3 (<0.1)	0		3 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	5 (<0.1)	8 (<0.1)		13 (<0.1)
Cholelithiasis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	182 (1.6)	212 (1.9)		394 (1.7)
Urticaria	26 (0.2)	33 (0.3)	1.27 (0.76, 2.11)	59 (0.3)
Rash	27 (0.2)	26 (0.2)	0.96 (0.57, 1.64)	53 (0.2)
Pruritus	15 (0.1)	18 (0.2)	1.20 (0.61, 2.35)	33 (0.1)
Dermatitis contact	20 (0.2)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.2)
Hyperhidrosis	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Eczema	3 (<0.1)	10 (<0.1)	3.33 (0.99, 11.22)	13 (<0.1)
Acne	7 (<0.1)	9 (<0.1)	1.29 (0.50, 3.33)	16 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Night sweats	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Alopecia	4 (<0.1)	6 (<0.1)		10 (<0.1)
Dermatitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Rash maculo-papular	2 (<0.1)	6 (<0.1)		8 (<0.1)
Rash papular	4 (<0.1)	6 (<0.1)		10 (<0.1)
Ecchymosis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Erythema	3 (<0.1)	5 (<0.1)		8 (<0.1)
Psoriasis	0	4 (<0.1)		4 (<0.1)
Blister	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hidradenitis	0	3 (<0.1)		3 (<0.1)
Pain of skin	0	3 (<0.1)		3 (<0.1)
Pityriasis rosea	0	3 (<0.1)		3 (<0.1)
Rash erythematous	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rash pruritic	6 (<0.1)	3 (<0.1)		9 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Angioedema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dermatitis atopic	6 (<0.1)	2 (<0.1)		8 (<0.1)
Hand dermatitis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Macule	0	2 (<0.1)		2 (<0.1)
Rash macular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Actinic keratosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	0	1 (<0.1)		1 (<0.1)
Dermal cyst	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dry skin	2 (<0.1)	1 (<0.1)		3 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Papule	2 (<0.1)	1 (<0.1)		3 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ingrowing nail	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	3 (<0.1)	0		3 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	742 (6.5)	715 (6.3)		1457 (6.4)
Myalgia	304 (2.7)	288 (2.5)	0.95 (0.81, 1.11)	592 (2.6)
Arthralgia	283 (2.5)	270 (2.4)	0.95 (0.81, 1.12)	553 (2.4)
Back pain	93 (0.8)	79 (0.7)	0.85 (0.63, 1.14)	172 (0.8)
Pain in extremity	55 (0.5)	46 (0.4)	0.84 (0.57, 1.23)	101 (0.4)
Neck pain	28 (0.2)	35 (0.3)	1.25 (0.76, 2.04)	63 (0.3)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Musculoskeletal pain	28 (0.2)	34 (0.3)	1.21 (0.74, 1.99)	62 (0.3)
Muscle spasms	20 (0.2)	26 (0.2)	1.30 (0.73, 2.31)	46 (0.2)
Musculoskeletal chest pain	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Osteoarthritis	12 (0.1)	12 (0.1)	1.00 (0.46, 2.18)	24 (0.1)
Tendonitis	6 (<0.1)	10 (<0.1)	1.67 (0.63, 4.41)	16 (<0.1)
Rotator cuff syndrome	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Groin pain	1 (<0.1)	6 (<0.1)		7 (<0.1)
Musculoskeletal stiffness	12 (0.1)	6 (<0.1)	0.50 (0.19, 1.28)	18 (<0.1)
Bursitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Arthritis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Joint range of motion decreased	0	4 (<0.1)		4 (<0.1)
Limb discomfort	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pain in jaw	4 (<0.1)	4 (<0.1)		8 (<0.1)
Spinal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Costochondritis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Joint swelling	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.14)	12 (<0.1)
Trigger finger	1 (<0.1)	3 (<0.1)		4 (<0.1)
Axillary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Fibromyalgia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Muscular weakness	2 (<0.1)	2 (<0.1)		4 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Polyarthritis	0	2 (<0.1)		2 (<0.1)
Spinal osteoarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Flank pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Limb mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle twitching	3 (<0.1)	1 (<0.1)		4 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteoporosis	0	1 (<0.1)		1 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Joint stiffness	2 (<0.1)	0		2 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	2 (<0.1)	0		2 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	25 (0.2)	26 (0.2)		51 (0.2)
Nephrolithiasis	14 (0.1)	8 (<0.1)	0.57 (0.25, 1.33)	22 (<0.1)
Dysuria	1 (<0.1)	4 (<0.1)		5 (<0.1)
Acute kidney injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertonic bladder	0	2 (<0.1)		2 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Haematuria	5 (<0.1)	1 (<0.1)		6 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Polyuria	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary incontinence	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Renal and urinary disorders (Cont.)				
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Chronic kidney disease	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	51 (0.4)	45 (0.4)		96 (0.4)
Dysmenorrhoea	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Pelvic pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Erectile dysfunction	2 (<0.1)	3 (<0.1)		5 (<0.1)
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Prostatitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	6 (<0.1)	1 (<0.1)		7 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Haematospermia	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	813 (7.1)	1200 (10.5)		2013 (8.8)
Fatigue	526 (4.6)	557 (4.9)	1.06 (0.94, 1.19)	1083 (4.7)
Injection site pain	88 (0.8)	196 (1.7)	2.23 (1.73, 2.86)	284 (1.2)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Chills	85 (0.7)	103 (0.9)	1.21 (0.91, 1.61)	188 (0.8)
Injection site erythema	23 (0.2)	101 (0.9)	4.39 (2.80, 6.87)	124 (0.5)
Pyrexia	47 (0.4)	88 (0.8)	1.87 (1.32, 2.66)	135 (0.6)
Injection site swelling	19 (0.2)	84 (0.7)	4.42 (2.70, 7.23)	103 (0.5)
Injection site pruritus	11 (<0.1)	63 (0.6)	5.73 (3.05, 10.75)	74 (0.3)
Injection site lymphadenopathy	14 (0.1)	58 (0.5)	4.14 (2.33, 7.36)	72 (0.3)
Pain	52 (0.5)	58 (0.5)	1.11 (0.77, 1.62)	110 (0.5)
Injection site induration	11 (<0.1)	43 (0.4)	3.91 (2.04, 7.49)	54 (0.2)
Injection site macule	3 (<0.1)	31 (0.3)	10.33 (3.36, 31.81)	34 (0.1)
Injection site urticaria	0	27 (0.2)		27 (0.1)
Axillary pain	13 (0.1)	23 (0.2)	1.77 (0.91, 3.45)	36 (0.2)
Injection site rash	1 (<0.1)	18 (0.2)	17.99 (3.06, 105.89)	19 (<0.1)
Injection site bruising	12 (0.1)	15 (0.1)	1.25 (0.60, 2.62)	27 (0.1)
Malaise	5 (<0.1)	13 (0.1)	2.60 (0.97, 7.00)	18 (<0.1)
Injection site papule	1 (<0.1)	12 (0.1)	12.00 (2.00, 71.91)	13 (<0.1)
Chest discomfort	12 (0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Chest pain	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Non-cardiac chest pain	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Peripheral swelling	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Reactogenicity event	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.59)	8 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Feeling hot	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site paraesthesia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)		6 (<0.1)
Feeling abnormal	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site haemorrhage	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site joint pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site haematoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site hypoaesthesia	0	3 (<0.1)		3 (<0.1)
Injection site mass	0	3 (<0.1)		3 (<0.1)
Oedema peripheral	3 (<0.1)	3 (<0.1)		6 (<0.1)
Swelling face	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Vaccination site pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Injection site irritation	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Hangover	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Asthenia	4 (<0.1)	0		4 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discolouration	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Precancerous condition	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations	62 (0.5)	72 (0.6)		134 (0.6)
Blood pressure increased	21 (0.2)	18 (0.2)	0.86 (0.46, 1.59)	39 (0.2)
Blood pressure systolic increased	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.59)	15 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	8 (<0.1)	4.00 (0.96, 16.63)	10 (<0.1)
Body temperature increased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Hepatic enzyme increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Heart rate increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Transaminases increased	0	3 (<0.1)		3 (<0.1)
Blood cholesterol increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood glucose increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood triglycerides increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Weight decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Cardiac murmur	2 (<0.1)	0		2 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	2 (<0.1)	0		2 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	280 (2.5)	223 (2.0)		503 (2.2)
Muscle strain	28 (0.2)	29 (0.3)	1.04 (0.62, 1.73)	57 (0.2)
Ligament sprain	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Arthropod bite	25 (0.2)	15 (0.1)	0.60 (0.32, 1.13)	40 (0.2)
Skin laceration	25 (0.2)	15 (0.1)	0.60 (0.32, 1.13)	40 (0.2)
Tooth fracture	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Arthropod sting	7 (<0.1)	9 (<0.1)	1.29 (0.50, 3.33)	16 (<0.1)
Foot fracture	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Procedural pain	20 (0.2)	9 (<0.1)	0.45 (0.21, 0.97)	29 (0.1)
Contusion	22 (0.2)	8 (<0.1)	0.36 (0.17, 0.80)	30 (0.1)
Fall	16 (0.1)	8 (<0.1)	0.50 (0.22, 1.14)	24 (0.1)
Road traffic accident	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Skin abrasion	15 (0.1)	8 (<0.1)	0.53 (0.23, 1.23)	23 (0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Limb injury	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Joint injury	5 (<0.1)	6 (<0.1)		11 (<0.1)
Animal bite	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Meniscus injury	6 (<0.1)	5 (<0.1)		11 (<0.1)
Concussion	3 (<0.1)	4 (<0.1)		7 (<0.1)
Post-traumatic pain	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hand fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Ankle fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Epicondylitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Facial bones fracture	0	2 (<0.1)		2 (<0.1)
Head injury	0	2 (<0.1)		2 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tendon injury	0	2 (<0.1)		2 (<0.1)
Tendon rupture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Thermal burn	3 (<0.1)	2 (<0.1)		5 (<0.1)
Upper limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Back injury	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Bone contusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Exposure to SARS-CoV-2	0	1 (<0.1)		1 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)		1 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Muscle rupture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rib fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Sunburn	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Burns first degree	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	2 (<0.1)	0		2 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Vaccination complication	2 (<0.1)	0		2 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	0	4 (<0.1)		4 (<0.1)
Device breakage	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1063 (28.3)	1237 (32.8)		2300 (30.6)
Number of Unsolicited Adverse Events	2035	2415		4450
Infections and infestations	189 (5.0)	166 (4.4)		355 (4.7)
Urinary tract infection	39 (1.0)	27 (0.7)	0.69 (0.42, 1.12)	66 (0.9)
Sinusitis	8 (0.2)	12 (0.3)	1.49 (0.63, 3.55)	20 (0.3)
Upper respiratory tract infection	10 (0.3)	11 (0.3)	1.09 (0.48, 2.51)	21 (0.3)
Herpes zoster	4 (0.1)	8 (0.2)	1.99 (0.64, 6.21)	12 (0.2)
Tooth abscess	11 (0.3)	7 (0.2)	0.63 (0.25, 1.58)	18 (0.2)
Gingivitis	2 (<0.1)	6 (0.2)		8 (0.1)
Rhinovirus infection	2 (<0.1)	6 (0.2)		8 (0.1)
Tooth infection	3 (<0.1)	6 (0.2)		9 (0.1)
COVID-19	17 (0.5)	5 (0.1)	0.29 (0.11, 0.76)	22 (0.3)
Gastroenteritis	3 (<0.1)	5 (0.1)		8 (0.1)
Suspected COVID-19	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)
Cellulitis	5 (0.1)	4 (0.1)		9 (0.1)
Diverticulitis	4 (0.1)	4 (0.1)		8 (0.1)
Hordeolum	3 (<0.1)	4 (0.1)		7 (<0.1)
Laryngitis	0	4 (0.1)		4 (<0.1)
Onychomycosis	1 (<0.1)	4 (0.1)		5 (<0.1)
Oral herpes	1 (<0.1)	4 (0.1)		5 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Viral infection	6 (0.2)	4 (0.1)		10 (0.1)
Conjunctivitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Ear infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Herpes simplex	1 (<0.1)	3 (<0.1)		4 (<0.1)
Localised infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Pneumonia	6 (0.2)	3 (<0.1)		9 (0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cystitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Enterovirus infection	0	2 (<0.1)		2 (<0.1)
Fungal infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis externa	3 (<0.1)	2 (<0.1)		5 (<0.1)
Paronychia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subcutaneous abscess	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Acute sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Chronic sinusitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Folliculitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	0	1 (<0.1)		1 (<0.1)
Otitis media	0	1 (<0.1)		1 (<0.1)
Otitis media acute	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory tract infection viral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rhinitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sialoadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Skin infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea pedis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Vulvovaginal candidiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Body tinea	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
Candida infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Fungal skin infection	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Genital herpes simplex	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Helicobacter infection	1 (<0.1)	0		1 (<0.1)
Kidney infection	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Nasopharyngitis	2 (<0.1)	0		2 (<0.1)
Oral candidiasis	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Periodontitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	3 (<0.1)	0		3 (<0.1)
Postoperative wound infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Soft tissue infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea cruris	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)
Vulvovaginal mycotic infection	1 (<0.1)	0		1 (<0.1)
Wound infection	2 (<0.1)	0		2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	34 (0.9)	29 (0.8)		63 (0.8)
Basal cell carcinoma	12 (0.3)	7 (0.2)	0.58 (0.24, 1.43)	19 (0.3)
Skin cancer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Malignant melanoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)		5 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of skin	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma	7 (0.2)	1 (<0.1)	0.14 (0.02, 0.89)	8 (0.1)
Squamous cell carcinoma of skin	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	16 (0.4)	31 (0.8)		47 (0.6)
Lymphadenopathy	13 (0.3)	26 (0.7)	1.99 (1.04, 3.82)	39 (0.5)
Anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Blood and lymphatic system disorders (Cont.)				
Lymphadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	1 (<0.1)	0		1 (<0.1)
Immune system disorders	11 (0.3)	14 (0.4)		25 (0.3)
Seasonal allergy	9 (0.2)	9 (0.2)	1.00 (0.41, 2.43)	18 (0.2)
Hypersensitivity	0	2 (<0.1)		2 (<0.1)
Drug hypersensitivity	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to chemicals	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	6 (0.2)	2 (<0.1)		8 (0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypothyroidism	4 (0.1)	1 (<0.1)		5 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	26 (0.7)	51 (1.4)		77 (1.0)
Hyperlipidaemia	5 (0.1)	11 (0.3)	2.19 (0.80, 6.03)	16 (0.2)
Hypercholesterolaemia	1 (<0.1)	9 (0.2)	8.96 (1.47, 54.67)	10 (0.1)
Type 2 diabetes mellitus	3 (<0.1)	8 (0.2)	2.65 (0.76, 9.21)	11 (0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)				
Vitamin D deficiency	0	5 (0.1)		5 (<0.1)
Dehydration	2 (<0.1)	4 (0.1)		6 (<0.1)
Decreased appetite	2 (<0.1)	3 (<0.1)		5 (<0.1)
Gout	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hyponatraemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetes mellitus	3 (<0.1)	2 (<0.1)		5 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Glucose tolerance impaired	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoglycaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	0	1 (<0.1)		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypocalcaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	18 (0.5)	31 (0.8)		49 (0.7)
Anxiety	7 (0.2)	11 (0.3)	1.56 (0.63, 3.90)	18 (0.2)
Insomnia	5 (0.1)	6 (0.2)		11 (0.1)
Depression	3 (<0.1)	5 (0.1)		8 (0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Psychiatric disorders (Cont.)				
Nightmare	0	3 (<0.1)		3 (<0.1)
Sleep disorder	0	2 (<0.1)		2 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Abnormal dreams	1 (<0.1)	0		1 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	174 (4.6)	203 (5.4)		377 (5.0)
Headache	119 (3.2)	139 (3.7)	1.16 (0.91, 1.48)	258 (3.4)
Dizziness	17 (0.5)	22 (0.6)	1.29 (0.69, 2.40)	39 (0.5)
Sinus headache	2 (<0.1)	8 (0.2)	3.98 (0.96, 16.56)	10 (0.1)
Paraesthesia	3 (<0.1)	7 (0.2)	2.32 (0.66, 8.23)	10 (0.1)
Cervical radiculopathy	0	3 (<0.1)		3 (<0.1)
Hypoaesthesia	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Sciatica	4 (0.1)	3 (<0.1)		7 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Disturbance in attention	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia	0	2 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Syncope	4 (0.1)	2 (<0.1)		6 (<0.1)
Ageusia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Amnesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Carpal tunnel syndrome	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dysgeusia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)
Migraine	3 (<0.1)	1 (<0.1)		4 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Neuralgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Parosmia	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tension headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)		1 (<0.1)
Tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anosmia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Lumbar radiculopathy	1 (<0.1)	0		1 (<0.1)
Nerve compression	2 (<0.1)	0		2 (<0.1)
Neuropathy peripheral	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Presyncope	4 (0.1)	0		4 (<0.1)
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Eye disorders	30 (0.8)	23 (0.6)		53 (0.7)
Eye irritation	0	3 (<0.1)		3 (<0.1)
Eye pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dry eye	3 (<0.1)	2 (<0.1)		5 (<0.1)
Eye inflammation	0	2 (<0.1)		2 (<0.1)
Eye pruritus	2 (<0.1)	2 (<0.1)		4 (<0.1)
Glaucoma	3 (<0.1)	2 (<0.1)		5 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Cataract	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Eye swelling	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Vision blurred	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blepharitis	2 (<0.1)	0		2 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	0		2 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Eye disorders (Cont.)				
Eye discharge	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual impairment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	24 (0.6)	25 (0.7)		49 (0.7)
Vertigo	8 (0.2)	10 (0.3)	1.24 (0.51, 3.05)	18 (0.2)
Ear pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tinnitus	3 (<0.1)	3 (<0.1)		6 (<0.1)
Vertigo positional	0	3 (<0.1)		3 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear congestion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	0	1 (<0.1)		1 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Ear and labyrinth disorders (Cont.)				
Ear discomfort	3 (<0.1)	0		3 (<0.1)
Ear pruritus	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	31 (0.8)	35 (0.9)		66 (0.9)
Atrial fibrillation	9 (0.2)	9 (0.2)	1.00 (0.41, 2.43)	18 (0.2)
Arrhythmia	1 (<0.1)	4 (0.1)		5 (<0.1)
Palpitations	0	4 (0.1)		4 (<0.1)
Angina pectoris	3 (<0.1)	3 (<0.1)		6 (<0.1)
Coronary artery disease	4 (0.1)	3 (<0.1)		7 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bradycardia	5 (0.1)	2 (<0.1)		7 (<0.1)
Cardiac failure congestive	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tachycardia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Cardio-respiratory arrest	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Sinus tachycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders (Cont.)				
Ventricular extrasystoles	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	2 (<0.1)	0		2 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	74 (2.0)	70 (1.9)		144 (1.9)
Hypertension	56 (1.5)	50 (1.3)	0.89 (0.61, 1.29)	106 (1.4)
Hot flush	4 (0.1)	7 (0.2)	1.74 (0.55, 5.56)	11 (0.1)
Flushing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Systolic hypertension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aortic aneurysm	3 (<0.1)	1 (<0.1)		4 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Orthostatic hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders	129 (3.4)	125 (3.3)		254 (3.4)
Rhinorrhoea	32 (0.9)	33 (0.9)	1.03 (0.64, 1.66)	65 (0.9)
Cough	22 (0.6)	32 (0.8)	1.45 (0.85, 2.47)	54 (0.7)
Nasal congestion	30 (0.8)	27 (0.7)	0.90 (0.54, 1.50)	57 (0.8)
Oropharyngeal pain	37 (1.0)	24 (0.6)	0.65 (0.39, 1.07)	61 (0.8)
Dyspnoea	7 (0.2)	8 (0.2)	1.14 (0.43, 3.01)	15 (0.2)
Asthma	2 (<0.1)	6 (0.2)		8 (0.1)
Sneezing	2 (<0.1)	5 (0.1)		7 (<0.1)
Epistaxis	5 (0.1)	4 (0.1)		9 (0.1)
Upper-airway cough syndrome	1 (<0.1)	4 (0.1)		5 (<0.1)
Dysphonia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Respiratory tract congestion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rhinitis allergic	6 (0.2)	3 (<0.1)		9 (0.1)
Tachypnoea	3 (<0.1)	3 (<0.1)		6 (<0.1)
Chronic obstructive pulmonary disease	5 (0.1)	2 (<0.1)		7 (<0.1)
Pharyngeal erythema	1 (<0.1)	2 (<0.1)		3 (<0.1)
Throat irritation	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Bronchospasm	0	1 (<0.1)		1 (<0.1)
Dry throat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleural effusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Respiratory disorder	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sinus congestion	4 (0.1)	1 (<0.1)		5 (<0.1)
Sinus pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sleep apnoea syndrome	0	1 (<0.1)		1 (<0.1)
Wheezing	2 (<0.1)	1 (<0.1)		3 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Productive cough	2 (<0.1)	0		2 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	147 (3.9)	155 (4.1)		302 (4.0)
Diarrhoea	60 (1.6)	45 (1.2)	0.75 (0.51, 1.09)	105 (1.4)
Nausea	32 (0.9)	42 (1.1)	1.31 (0.83, 2.06)	74 (1.0)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Vomiting	8 (0.2)	18 (0.5)	2.24 (1.00, 5.03)	26 (0.3)
Gastrooesophageal reflux disease	8 (0.2)	13 (0.3)	1.62 (0.69, 3.80)	21 (0.3)
Toothache	6 (0.2)	10 (0.3)	1.66 (0.63, 4.39)	16 (0.2)
Abdominal pain upper	4 (0.1)	6 (0.2)		10 (0.1)
Dental caries	3 (<0.1)	5 (0.1)		8 (0.1)
Abdominal pain	2 (<0.1)	4 (0.1)		6 (<0.1)
Constipation	8 (0.2)	4 (0.1)	0.50 (0.16, 1.55)	12 (0.2)
Dyspepsia	3 (<0.1)	4 (0.1)		7 (<0.1)
Inguinal hernia	4 (0.1)	3 (<0.1)		7 (<0.1)
Colitis	0	2 (<0.1)		2 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Paraesthesia oral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal discomfort	5 (0.1)	1 (<0.1)		6 (<0.1)
Abdominal pain lower	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diverticulum intestinal	0	1 (<0.1)		1 (<0.1)
Dry mouth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysphagia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flatulence	0	1 (<0.1)		1 (<0.1)
Food poisoning	2 (<0.1)	1 (<0.1)		3 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastric ulcer	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Gastrointestinal haemorrhage	0	1 (<0.1)		1 (<0.1)
Gingival pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Haemorrhoids	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hiatus hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	4 (0.1)	1 (<0.1)		5 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral disorder	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	5 (0.1)		5 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	53 (1.4)	83 (2.2)		136 (1.8)
Urticaria	7 (0.2)	11 (0.3)	1.56 (0.63, 3.90)	18 (0.2)
Erythema	2 (<0.1)	10 (0.3)	4.98 (1.23, 20.19)	12 (0.2)
Rash	4 (0.1)	9 (0.2)	2.24 (0.73, 6.85)	13 (0.2)
Dermatitis contact	11 (0.3)	7 (0.2)	0.63 (0.25, 1.58)	18 (0.2)
Pruritus	8 (0.2)	7 (0.2)	0.87 (0.33, 2.31)	15 (0.2)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Actinic keratosis	1 (<0.1)	5 (0.1)		6 (<0.1)
Rash macular	2 (<0.1)	5 (0.1)		7 (<0.1)
Dermatitis atopic	0	3 (<0.1)		3 (<0.1)
Night sweats	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dry skin	0	2 (<0.1)		2 (<0.1)
Hyperhidrosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Rash maculo-papular	0	2 (<0.1)		2 (<0.1)
Rash papular	0	2 (<0.1)		2 (<0.1)
Rash pruritic	0	2 (<0.1)		2 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alopecia	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Macule	0	1 (<0.1)		1 (<0.1)
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Psoriasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Angioedema	1 (<0.1)	0		1 (<0.1)
Cold sweat	1 (<0.1)	0		1 (<0.1)
Dermal cyst	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ecchymosis	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	275 (7.3)	292 (7.7)		567 (7.5)
Arthralgia	106 (2.8)	121 (3.2)	1.14 (0.88, 1.47)	227 (3.0)
Myalgia	84 (2.2)	99 (2.6)	1.17 (0.88, 1.56)	183 (2.4)
Back pain	37 (1.0)	27 (0.7)	0.73 (0.45, 1.18)	64 (0.9)
Pain in extremity	22 (0.6)	21 (0.6)	0.95 (0.53, 1.71)	43 (0.6)
Musculoskeletal pain	10 (0.3)	15 (0.4)	1.49 (0.69, 3.25)	25 (0.3)
Neck pain	10 (0.3)	11 (0.3)	1.09 (0.48, 2.51)	21 (0.3)
Osteoarthritis	16 (0.4)	11 (0.3)	0.68 (0.32, 1.45)	27 (0.4)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Muscle spasms	9 (0.2)	9 (0.2)	1.00 (0.41, 2.43)	18 (0.2)
Bursitis	3 (<0.1)	7 (0.2)	2.32 (0.66, 8.23)	10 (0.1)
Musculoskeletal stiffness	2 (<0.1)	6 (0.2)		8 (0.1)
Arthritis	1 (<0.1)	5 (0.1)		6 (<0.1)
Tendonitis	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)
Muscular weakness	0	4 (0.1)		4 (<0.1)
Spinal stenosis	0	4 (0.1)		4 (<0.1)
Trigger finger	2 (<0.1)	4 (0.1)		6 (<0.1)
Joint swelling	0	3 (<0.1)		3 (<0.1)
Osteoporosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Rotator cuff syndrome	5 (0.1)	3 (<0.1)		8 (0.1)
Fibromyalgia	0	2 (<0.1)		2 (<0.1)
Flank pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Muscle twitching	0	2 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	4 (0.1)	2 (<0.1)		6 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Joint range of motion decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint stiffness	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Limb discomfort	0	1 (<0.1)		1 (<0.1)
Muscle tightness	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Foot deformity	2 (<0.1)	0		2 (<0.1)
Groin pain	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	0		2 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Limb mass	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Osteopenia	1 (<0.1)	0		1 (<0.1)
Pain in jaw	2 (<0.1)	0		2 (<0.1)
Polyarthritis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	21 (0.6)	24 (0.6)		45 (0.6)
Nephrolithiasis	7 (0.2)	6 (0.2)	0.85 (0.30, 2.42)	13 (0.2)
Pollakiuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chronic kidney disease	0	2 (<0.1)		2 (<0.1)
Haematuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Polyuria	0	2 (<0.1)		2 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Dysuria	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary hesitation	0	1 (<0.1)		1 (<0.1)
Urinary incontinence	2 (<0.1)	1 (<0.1)		3 (<0.1)
Acute kidney injury	3 (<0.1)	0		3 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)				
Hypertonic bladder	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	8 (0.2)	16 (0.4)		24 (0.3)
Benign prostatic hyperplasia	2 (<0.1)	4 (0.1)		6 (<0.1)
Erectile dysfunction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast cyst	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)				
Prostatitis	2 (<0.1)	0		2 (<0.1)
General disorders and administration site conditions	252 (6.7)	406 (10.8)		658 (8.8)
Fatigue	140 (3.7)	195 (5.2)	1.39 (1.12, 1.71)	335 (4.5)
Injection site pain	30 (0.8)	62 (1.6)	2.06 (1.34, 3.16)	92 (1.2)
Injection site erythema	16 (0.4)	56 (1.5)	3.48 (2.02, 6.02)	72 (1.0)
Injection site swelling	10 (0.3)	31 (0.8)	3.09 (1.54, 6.20)	41 (0.5)
Pyrexia	15 (0.4)	30 (0.8)	1.99 (1.08, 3.66)	45 (0.6)
Chills	26 (0.7)	28 (0.7)	1.07 (0.63, 1.81)	54 (0.7)
Injection site pruritus	2 (<0.1)	25 (0.7)	12.44 (3.27, 47.41)	27 (0.4)
Injection site macule	1 (<0.1)	14 (0.4)	13.93 (2.34, 82.86)	15 (0.2)
Pain	14 (0.4)	14 (0.4)	1.00 (0.48, 2.05)	28 (0.4)
Injection site urticaria	1 (<0.1)	11 (0.3)	10.95 (1.82, 65.95)	12 (0.2)
Injection site induration	7 (0.2)	10 (0.3)	1.42 (0.56, 3.61)	17 (0.2)
Injection site lymphadenopathy	1 (<0.1)	8 (0.2)	7.96 (1.29, 49.03)	9 (0.1)
Injection site rash	0	6 (0.2)		6 (<0.1)
Axillary pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site bruising	9 (0.2)	3 (<0.1)	0.33 (0.10, 1.13)	12 (0.2)
Injection site haematoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Oedema peripheral	4 (0.1)	3 (<0.1)		7 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Peripheral swelling	4 (0.1)	3 (<0.1)		7 (<0.1)
Chest discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site haemorrhage	3 (<0.1)	2 (<0.1)		5 (<0.1)
Injection site warmth	0	2 (<0.1)		2 (<0.1)
Malaise	5 (0.1)	2 (<0.1)		7 (<0.1)
Precancerous condition	0	2 (<0.1)		2 (<0.1)
Vaccination site pain	0	2 (<0.1)		2 (<0.1)
Asthenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cyst	0	1 (<0.1)		1 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)
Feeling abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Feeling hot	0	1 (<0.1)		1 (<0.1)
Hangover	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site irritation	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site papule	0	1 (<0.1)		1 (<0.1)
Injection site paraesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Non-cardiac chest pain	3 (<0.1)	0		3 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Reactogenicity event	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	0		1 (<0.1)
Investigations	18 (0.5)	35 (0.9)		53 (0.7)
Blood pressure increased	6 (0.2)	7 (0.2)	1.16 (0.41, 3.29)	13 (0.2)
Blood pressure systolic increased	4 (0.1)	5 (0.1)		9 (0.1)
Blood cholesterol increased	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations (Cont.)				
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood testosterone decreased	0	1 (<0.1)		1 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
Body temperature increased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac murmur	0	1 (<0.1)		1 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Heart rate increased	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	0	1 (<0.1)		1 (<0.1)
Weight decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations (Cont.)				
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	117 (3.1)	108 (2.9)		225 (3.0)
Fall	11 (0.3)	13 (0.3)	1.18 (0.54, 2.57)	24 (0.3)
Contusion	7 (0.2)	12 (0.3)	1.71 (0.69, 4.20)	19 (0.3)
Muscle strain	7 (0.2)	10 (0.3)	1.42 (0.56, 3.61)	17 (0.2)
Arthropod bite	6 (0.2)	9 (0.2)	1.49 (0.55, 4.02)	15 (0.2)
Procedural pain	11 (0.3)	9 (0.2)	0.81 (0.35, 1.91)	20 (0.3)
Skin laceration	7 (0.2)	8 (0.2)	1.14 (0.43, 3.01)	15 (0.2)
Tooth fracture	8 (0.2)	7 (0.2)	0.87 (0.33, 2.31)	15 (0.2)
Ligament sprain	4 (0.1)	6 (0.2)		10 (0.1)
Limb injury	4 (0.1)	5 (0.1)		9 (0.1)
Road traffic accident	2 (<0.1)	5 (0.1)		7 (<0.1)
Rib fracture	1 (<0.1)	4 (0.1)		5 (<0.1)
Foot fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin abrasion	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.1)
Bone contusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Facial bones fracture	0	2 (<0.1)		2 (<0.1)
Hand fracture	0	2 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Head injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Post-traumatic pain	4 (0.1)	2 (<0.1)		6 (<0.1)
Wrist fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Animal bite	3 (<0.1)	1 (<0.1)		4 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthropod sting	10 (0.3)	1 (<0.1)	0.10 (0.02, 0.60)	11 (0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Muscle rupture	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Scratch	0	1 (<0.1)		1 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thermal burn	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	0	1 (<0.1)		1 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Joint dislocation	2 (<0.1)	0		2 (<0.1)
Ligament rupture	1 (<0.1)	0		1 (<0.1)
Lip injury	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.1
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Sunburn	1 (<0.1)	0		1 (<0.1)
Tendon injury	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	1 (<0.1)		4 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4909 (43.0)	4639 (40.6)		9548 (41.8)
Number of Unsolicited Adverse Events	11550	11026		22576
Infections and infestations	2056 (18.0)	1333 (11.7)		3389 (14.8)
Upper respiratory tract infection	279 (2.4)	217 (1.9)	0.78 (0.65, 0.93)	496 (2.2)
Viral infection	138 (1.2)	137 (1.2)	0.99 (0.79, 1.25)	275 (1.2)
Urinary tract infection	137 (1.2)	116 (1.0)	0.85 (0.66, 1.08)	253 (1.1)
Suspected COVID-19	101 (0.9)	113 (1.0)	1.12 (0.86, 1.46)	214 (0.9)
Sinusitis	93 (0.8)	102 (0.9)	1.10 (0.83, 1.45)	195 (0.9)
Rhinovirus infection	65 (0.6)	73 (0.6)	1.12 (0.81, 1.56)	138 (0.6)
COVID-19	844 (7.4)	68 (0.6)	0.08 (0.06, 0.10)	912 (4.0)
Viral upper respiratory tract infection	38 (0.3)	36 (0.3)	0.95 (0.60, 1.49)	74 (0.3)
Herpes zoster	18 (0.2)	31 (0.3)	1.72 (0.97, 3.05)	49 (0.2)
Pharyngitis	31 (0.3)	28 (0.2)	0.90 (0.54, 1.50)	59 (0.3)
Tooth infection	24 (0.2)	27 (0.2)	1.12 (0.65, 1.93)	51 (0.2)
Ear infection	19 (0.2)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.2)
Pharyngitis streptococcal	35 (0.3)	26 (0.2)	0.74 (0.45, 1.23)	61 (0.3)
Tooth abscess	28 (0.2)	25 (0.2)	0.89 (0.52, 1.52)	53 (0.2)
Gastroenteritis	36 (0.3)	24 (0.2)	0.67 (0.40, 1.11)	60 (0.3)
Bronchitis	32 (0.3)	21 (0.2)	0.66 (0.38, 1.13)	53 (0.2)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Otitis media	19 (0.2)	19 (0.2)	1.00 (0.53, 1.87)	38 (0.2)
Asymptomatic COVID-19	15 (0.1)	18 (0.2)	1.20 (0.61, 2.35)	33 (0.1)
Cellulitis	27 (0.2)	17 (0.1)	0.63 (0.35, 1.14)	44 (0.2)
Conjunctivitis	20 (0.2)	15 (0.1)	0.75 (0.39, 1.45)	35 (0.2)
Hordeolum	19 (0.2)	15 (0.1)	0.79 (0.41, 1.53)	34 (0.1)
Nasopharyngitis	22 (0.2)	15 (0.1)	0.68 (0.36, 1.30)	37 (0.2)
Oral herpes	16 (0.1)	13 (0.1)	0.81 (0.40, 1.66)	29 (0.1)
Respiratory tract infection	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Bacterial vaginosis	11 (<0.1)	12 (0.1)	1.09 (0.49, 2.42)	23 (0.1)
Pneumonia	25 (0.2)	12 (0.1)	0.48 (0.24, 0.94)	37 (0.2)
Acute sinusitis	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Diverticulitis	12 (0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Fungal infection	14 (0.1)	10 (<0.1)	0.71 (0.32, 1.57)	24 (0.1)
Otitis externa	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Folliculitis	12 (0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Gastroenteritis viral	17 (0.1)	8 (<0.1)	0.47 (0.21, 1.06)	25 (0.1)
Herpes simplex	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Skin infection	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Vulvovaginal candidiasis	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Vulvovaginal mycotic infection	19 (0.2)	8 (<0.1)	0.42 (0.19, 0.94)	27 (0.1)
Abscess limb	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Enterovirus infection	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Furuncle	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Localised infection	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Gingivitis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Lyme disease	0	6 (<0.1)		6 (<0.1)
Onychomycosis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Paronychia	3 (<0.1)	6 (<0.1)		9 (<0.1)
Helicobacter infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Kidney infection	2 (<0.1)	5 (<0.1)		7 (<0.1)
Pyelonephritis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Subcutaneous abscess	2 (<0.1)	5 (<0.1)		7 (<0.1)
Chlamydial infection	0	4 (<0.1)		4 (<0.1)
Cystitis	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Gonorrhoea	2 (<0.1)	4 (<0.1)		6 (<0.1)
Oral candidiasis	6 (<0.1)	4 (<0.1)		10 (<0.1)
Sepsis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Clostridium difficile infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Impetigo	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Laryngitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rhinitis	6 (<0.1)	3 (<0.1)		9 (<0.1)
Sinusitis bacterial	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Staphylococcal infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tonsillitis	14 (0.1)	3 (<0.1)	0.21 (0.07, 0.70)	17 (<0.1)
Viral pharyngitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Wound infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abscess jaw	0	2 (<0.1)		2 (<0.1)
Appendicitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Candida infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cat scratch disease	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye infection	5 (<0.1)	2 (<0.1)		7 (<0.1)
Fungal skin infection	3 (<0.1)	2 (<0.1)		5 (<0.1)
Infected bite	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nail infection	0	2 (<0.1)		2 (<0.1)
Periodontitis	0	2 (<0.1)		2 (<0.1)
Pertussis	0	2 (<0.1)		2 (<0.1)
Postoperative wound infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulpitis dental	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory tract infection viral	10 (<0.1)	2 (<0.1)	0.20 (0.05, 0.81)	12 (<0.1)
Soft tissue infection	0	2 (<0.1)		2 (<0.1)
Tinea cruris	0	2 (<0.1)		2 (<0.1)
Tuberculosis	0	2 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Upper respiratory tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urinary tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Viral rhinitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	0	1 (<0.1)		1 (<0.1)
Bacterial infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast abscess	2 (<0.1)	1 (<0.1)		3 (<0.1)
Breast cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiolitis	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Chronic sinusitis	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	4 (<0.1)	1 (<0.1)		5 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Dacryocystitis	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Gingival abscess	0	1 (<0.1)		1 (<0.1)
Groin abscess	0	1 (<0.1)		1 (<0.1)
Helminthic infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza	6 (<0.1)	1 (<0.1)		7 (<0.1)
Labyrinthitis	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	5 (<0.1)	1 (<0.1)		6 (<0.1)
Papilloma viral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Perineal abscess	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Pyoderma	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Septic shock	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Skin candida	4 (<0.1)	1 (<0.1)		5 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Streptococcal infection	0	1 (<0.1)		1 (<0.1)
Tinea pedis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tinea versicolour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Viral sinusitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vulvitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Abscess	2 (<0.1)	0		2 (<0.1)
Abscess neck	1 (<0.1)	0		1 (<0.1)
Adenovirus infection	1 (<0.1)	0		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Asymptomatic bacteriuria	2 (<0.1)	0		2 (<0.1)
Atypical pneumonia	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bronchitis bacterial	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	9 (<0.1)	0		9 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cervicitis	2 (<0.1)	0		2 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	2 (<0.1)	0		2 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
HIV infection	2 (<0.1)	0		2 (<0.1)
Hepatitis C	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Infected dermal cyst	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Infection	1 (<0.1)	0		1 (<0.1)
Injection site infection	1 (<0.1)	0		1 (<0.1)
Latent tuberculosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	3 (<0.1)	0		3 (<0.1)
Mastoiditis	3 (<0.1)	0		3 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Perineal cellulitis	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	2 (<0.1)	0		2 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sialoadenitis	1 (<0.1)	0		1 (<0.1)
Sinusitis fungal	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Syphilis	3 (<0.1)	0		3 (<0.1)
Tinea barbae	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Tinea infection	2 (<0.1)	0		2 (<0.1)
Vaginal abscess	1 (<0.1)	0		1 (<0.1)
Vaginitis chlamydial	2 (<0.1)	0		2 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Vestibular neuronitis	1 (<0.1)	0		1 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	60 (0.5)	78 (0.7)		138 (0.6)
Basal cell carcinoma	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Uterine leiomyoma	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Squamous cell carcinoma	2 (<0.1)	5 (<0.1)		7 (<0.1)
Benign neoplasm of skin	2 (<0.1)	4 (<0.1)		6 (<0.1)
Prostate cancer	1 (<0.1)	4 (<0.1)		5 (<0.1)
Benign breast neoplasm	3 (<0.1)	3 (<0.1)		6 (<0.1)
Malignant melanoma in situ	1 (<0.1)	3 (<0.1)		4 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin papilloma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of thyroid gland	2 (<0.1)	2 (<0.1)		4 (<0.1)
Breast cancer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Adrenal adenoma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast cancer in situ	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Fibrous histiocytoma	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Intraductal papilloma of breast	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	4 (<0.1)	1 (<0.1)		5 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Prostate cancer stage I	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	0	1 (<0.1)		1 (<0.1)
Renal neoplasm	0	1 (<0.1)		1 (<0.1)
Skin cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Squamous cell carcinoma of skin	5 (<0.1)	1 (<0.1)		6 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign bone neoplasm	1 (<0.1)	0		1 (<0.1)
Benign neoplasm of eyelid	1 (<0.1)	0		1 (<0.1)
Breast neoplasm	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Enchondromatosis	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	2 (<0.1)	0		2 (<0.1)
Lipoma	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	173 (1.5)	299 (2.6)		472 (2.1)
Lymphadenopathy	140 (1.2)	254 (2.2)	1.81 (1.48, 2.22)	394 (1.7)
Anaemia	11 (<0.1)	16 (0.1)	1.45 (0.69, 3.08)	27 (0.1)
Lymph node pain	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Iron deficiency anaemia	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.76)	19 (<0.1)
Lymphadenitis	0	4 (<0.1)		4 (<0.1)
Thrombocytopenia	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Blood and lymphatic system disorders (Cont.)				
Leukopenia	0	2 (<0.1)		2 (<0.1)
Normocytic anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eosinophilia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	0	1 (<0.1)		1 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Nucleated red cells	1 (<0.1)	0		1 (<0.1)
Immune system disorders	77 (0.7)	65 (0.6)		142 (0.6)
Seasonal allergy	56 (0.5)	44 (0.4)	0.79 (0.53, 1.16)	100 (0.4)
Drug hypersensitivity	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Hypersensitivity	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Food allergy	2 (<0.1)	4 (<0.1)		6 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Mycotic allergy	0	2 (<0.1)		2 (<0.1)
Allergy to animal	0	1 (<0.1)		1 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Immune system disorders (Cont.)				
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	31 (0.3)	21 (0.2)		52 (0.2)
Hypothyroidism	15 (0.1)	16 (0.1)	1.07 (0.53, 2.13)	31 (0.1)
Hyperthyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Thyroid mass	0	2 (<0.1)		2 (<0.1)
Hyperparathyroidism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypogonadism	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Autoimmune thyroiditis	2 (<0.1)	0		2 (<0.1)
Basedow's disease	1 (<0.1)	0		1 (<0.1)
Goitre	4 (<0.1)	0		4 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroiditis subacute	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	200 (1.8)	174 (1.5)		374 (1.6)
Type 2 diabetes mellitus	25 (0.2)	32 (0.3)	1.28 (0.76, 2.15)	57 (0.2)
Hyperlipidaemia	35 (0.3)	25 (0.2)	0.71 (0.43, 1.19)	60 (0.3)
Vitamin D deficiency	32 (0.3)	24 (0.2)	0.75 (0.44, 1.26)	56 (0.2)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypercholesterolaemia	30 (0.3)	17 (0.1)	0.57 (0.32, 1.02)	47 (0.2)
Decreased appetite	11 (<0.1)	13 (0.1)	1.18 (0.54, 2.58)	24 (0.1)
Dehydration	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Diabetes mellitus	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Glucose tolerance impaired	12 (0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Gout	9 (<0.1)	4 (<0.1)	0.44 (0.15, 1.36)	13 (<0.1)
Hyperglycaemia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypertriglyceridaemia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hypokalaemia	13 (0.1)	4 (<0.1)	0.31 (0.11, 0.90)	17 (<0.1)
Hyponatraemia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Abnormal loss of weight	2 (<0.1)	3 (<0.1)		5 (<0.1)
Diabetes mellitus inadequate control	3 (<0.1)	2 (<0.1)		5 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hypoglycaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Iron deficiency	5 (<0.1)	2 (<0.1)		7 (<0.1)
Obesity	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vitamin B12 deficiency	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dairy intolerance	0	1 (<0.1)		1 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Food intolerance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypercalcaemia	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypophosphataemia	0	1 (<0.1)		1 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	4 (<0.1)	0		4 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	2 (<0.1)	0		2 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders	231 (2.0)	265 (2.3)		496 (2.2)
Anxiety	75 (0.7)	89 (0.8)	1.19 (0.87, 1.61)	164 (0.7)
Depression	79 (0.7)	86 (0.8)	1.09 (0.80, 1.47)	165 (0.7)
Insomnia	41 (0.4)	48 (0.4)	1.17 (0.77, 1.77)	89 (0.4)
Attention deficit hyperactivity disorder	24 (0.2)	19 (0.2)	0.79 (0.44, 1.43)	43 (0.2)
Bipolar disorder	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Abnormal dreams	1 (<0.1)	5 (<0.1)		6 (<0.1)
Panic attack	6 (<0.1)	4 (<0.1)		10 (<0.1)
Post-traumatic stress disorder	2 (<0.1)	4 (<0.1)		6 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	3 (<0.1)		4 (<0.1)
Libido decreased	0	3 (<0.1)		3 (<0.1)
Sleep disorder	1 (<0.1)	3 (<0.1)		4 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bipolar II disorder	0	2 (<0.1)		2 (<0.1)
Generalised anxiety disorder	6 (<0.1)	2 (<0.1)		8 (<0.1)
Major depression	4 (<0.1)	2 (<0.1)		6 (<0.1)
Stress	2 (<0.1)	2 (<0.1)		4 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Dysphemia	0	1 (<0.1)		1 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Obsessive-compulsive personality disorder	0	1 (<0.1)		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Psychotic disorder	0	1 (<0.1)		1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Social anxiety disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Agitation	2 (<0.1)	0		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Confusional state	1 (<0.1)	0		1 (<0.1)
Delirium	1 (<0.1)	0		1 (<0.1)
Depression suicidal	2 (<0.1)	0		2 (<0.1)
Disorientation	1 (<0.1)	0		1 (<0.1)
Dissociative disorder	1 (<0.1)	0		1 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Mental fatigue	2 (<0.1)	0		2 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Mixed anxiety and depressive disorder	1 (<0.1)	0		1 (<0.1)
Nicotine dependence	1 (<0.1)	0		1 (<0.1)
Nightmare	1 (<0.1)	0		1 (<0.1)
Schizophrenia	2 (<0.1)	0		2 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	984 (8.6)	1046 (9.2)		2030 (8.9)
Headache	734 (6.4)	745 (6.5)	1.01 (0.92, 1.12)	1479 (6.5)
Dizziness	58 (0.5)	71 (0.6)	1.22 (0.87, 1.73)	129 (0.6)
Paraesthesia	27 (0.2)	34 (0.3)	1.26 (0.76, 2.07)	61 (0.3)
Migraine	38 (0.3)	29 (0.3)	0.76 (0.47, 1.23)	67 (0.3)
Ageusia	22 (0.2)	22 (0.2)	1.00 (0.56, 1.79)	44 (0.2)
Syncope	28 (0.2)	20 (0.2)	0.71 (0.41, 1.26)	48 (0.2)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Anosmia	21 (0.2)	18 (0.2)	0.86 (0.46, 1.59)	39 (0.2)
Sciatica	14 (0.1)	16 (0.1)	1.14 (0.57, 2.31)	30 (0.1)
Presyncope	12 (0.1)	15 (0.1)	1.25 (0.60, 2.62)	27 (0.1)
Hypoaesthesia	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Dysgeusia	5 (<0.1)	12 (0.1)	2.40 (0.88, 6.53)	17 (<0.1)
Sinus headache	7 (<0.1)	12 (0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Cervical radiculopathy	2 (<0.1)	10 (<0.1)	5.00 (1.23, 20.28)	12 (<0.1)
Nerve compression	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Carpal tunnel syndrome	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Tension headache	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Burning sensation	1 (<0.1)	6 (<0.1)		7 (<0.1)
Facial paralysis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Cerebrovascular accident	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hyperaesthesia	0	4 (<0.1)		4 (<0.1)
Memory impairment	1 (<0.1)	4 (<0.1)		5 (<0.1)
Seizure	6 (<0.1)	4 (<0.1)		10 (<0.1)
Disturbance in attention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Lethargy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Somnolence	3 (<0.1)	3 (<0.1)		6 (<0.1)
Taste disorder	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Lumbar radiculopathy	3 (<0.1)	2 (<0.1)		5 (<0.1)
Migraine with aura	3 (<0.1)	2 (<0.1)		5 (<0.1)
Morton's neuralgia	0	2 (<0.1)		2 (<0.1)
Neuropathy peripheral	3 (<0.1)	2 (<0.1)		5 (<0.1)
Parosmia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Restless legs syndrome	6 (<0.1)	2 (<0.1)		8 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Central nervous system lesion	0	1 (<0.1)		1 (<0.1)
Cerebral atrophy	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Complex regional pain syndrome	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Depressed level of consciousness	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Diabetic mononeuropathy	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Head discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Hypersomnia	0	1 (<0.1)		1 (<0.1)
Loss of consciousness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle contractions involuntary	2 (<0.1)	1 (<0.1)		3 (<0.1)
Neuralgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Occipital neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	4 (<0.1)	1 (<0.1)		5 (<0.1)
Tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trigeminal neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Arachnoid cyst	2 (<0.1)	0		2 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Cerebral cyst	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	2 (<0.1)	0		2 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	3 (<0.1)	0		3 (<0.1)
Essential tremor	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Hypogeusia	4 (<0.1)	0		4 (<0.1)
Hyposmia	4 (<0.1)	0		4 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0		1 (<0.1)
Myoclonus	1 (<0.1)	0		1 (<0.1)
Perineurial cyst	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Poor quality sleep	1 (<0.1)	0		1 (<0.1)
Radicular pain	1 (<0.1)	0		1 (<0.1)
Right hemisphere deficit syndrome	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0		1 (<0.1)
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
VIth nerve paralysis	1 (<0.1)	0		1 (<0.1)
Vocal cord paralysis	1 (<0.1)	0		1 (<0.1)
Eye disorders	64 (0.6)	77 (0.7)		141 (0.6)
Eye pruritus	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Vision blurred	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Retinal detachment	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blepharitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Cataract	2 (<0.1)	4 (<0.1)		6 (<0.1)
Conjunctival haemorrhage	0	4 (<0.1)		4 (<0.1)
Dry eye	5 (<0.1)	4 (<0.1)		9 (<0.1)
Eye irritation	3 (<0.1)	4 (<0.1)		7 (<0.1)
Swelling of eyelid	1 (<0.1)	3 (<0.1)		4 (<0.1)
Visual impairment	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Eye haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ocular discomfort	0	2 (<0.1)		2 (<0.1)
Ocular hyperaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Photophobia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Uveitis	0	2 (<0.1)		2 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetic retinopathy	0	1 (<0.1)		1 (<0.1)
Diplopia	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye disorder	0	1 (<0.1)		1 (<0.1)
Eye inflammation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eye swelling	4 (<0.1)	1 (<0.1)		5 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Glaucoma	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Iris disorder	0	1 (<0.1)		1 (<0.1)
Macular oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Orbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	0	1 (<0.1)		1 (<0.1)
Presbyopia	0	1 (<0.1)		1 (<0.1)
Ulcerative keratitis	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	2 (<0.1)	1 (<0.1)		3 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Eye ulcer	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Nictitating spasm	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Retinal oedema	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Vitreous detachment	4 (<0.1)	0		4 (<0.1)
Ear and labyrinth disorders	105 (0.9)	92 (0.8)		197 (0.9)
Vertigo	22 (0.2)	27 (0.2)	1.23 (0.70, 2.14)	49 (0.2)
Ear pain	25 (0.2)	22 (0.2)	0.88 (0.50, 1.55)	47 (0.2)
Tinnitus	18 (0.2)	16 (0.1)	0.89 (0.46, 1.72)	34 (0.1)
Ear discomfort	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Vertigo positional	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cerumen impaction	4 (<0.1)	3 (<0.1)		7 (<0.1)
Meniere's disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear canal erythema	5 (<0.1)	2 (<0.1)		7 (<0.1)
Otorrhoea	0	2 (<0.1)		2 (<0.1)
Tympanic membrane perforation	6 (<0.1)	2 (<0.1)		8 (<0.1)
Deafness unilateral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ear congestion	6 (<0.1)	1 (<0.1)		7 (<0.1)
Ear pruritus	4 (<0.1)	1 (<0.1)		5 (<0.1)
Eustachian tube dysfunction	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Diplacusis	1 (<0.1)	0		1 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Ear and labyrinth disorders (Cont.)				
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
External ear pain	1 (<0.1)	0		1 (<0.1)
Middle ear effusion	3 (<0.1)	0		3 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	95 (0.8)	83 (0.7)		178 (0.8)
Tachycardia	21 (0.2)	18 (0.2)	0.86 (0.46, 1.59)	39 (0.2)
Palpitations	11 (<0.1)	16 (0.1)	1.45 (0.69, 3.08)	27 (0.1)
Bradycardia	15 (0.1)	11 (<0.1)	0.73 (0.34, 1.57)	26 (0.1)
Atrial fibrillation	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Angina pectoris	6 (<0.1)	5 (<0.1)		11 (<0.1)
Myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Ventricular extrasystoles	4 (<0.1)	4 (<0.1)		8 (<0.1)
Coronary artery disease	0	3 (<0.1)		3 (<0.1)
Sinus tachycardia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acute left ventricular failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute myocardial infarction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Atrial flutter	0	2 (<0.1)		2 (<0.1)
Cardiac failure	0	2 (<0.1)		2 (<0.1)
Cardiac failure congestive	4 (<0.1)	2 (<0.1)		6 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arrhythmia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Cardiac failure acute	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular tachycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arteriosclerosis coronary artery	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiac disorder	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Diastolic dysfunction	1 (<0.1)	0		1 (<0.1)
Extrasystoles	1 (<0.1)	0		1 (<0.1)
Mitral valve thickening	1 (<0.1)	0		1 (<0.1)
Myocardial ischaemia	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Postural orthostatic tachycardia syndrome	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Sinus arrest	1 (<0.1)	0		1 (<0.1)
Sinus bradycardia	1 (<0.1)	0		1 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	263 (2.3)	218 (1.9)		481 (2.1)
Hypertension	215 (1.9)	173 (1.5)	0.80 (0.66, 0.98)	388 (1.7)
Hot flush	6 (<0.1)	10 (<0.1)	1.67 (0.63, 4.41)	16 (<0.1)
Flushing	4 (<0.1)	5 (<0.1)		9 (<0.1)
Haematoma	5 (<0.1)	5 (<0.1)		10 (<0.1)
Deep vein thrombosis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Orthostatic hypotension	0	4 (<0.1)		4 (<0.1)
Hypotension	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prehypertension	0	2 (<0.1)		2 (<0.1)
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Diastolic hypotension	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Labile hypertension	0	1 (<0.1)		1 (<0.1)
Pallor	0	1 (<0.1)		1 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders (Cont.)				
Peripheral coldness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Raynaud's phenomenon	1 (<0.1)	1 (<0.1)		2 (<0.1)
Systolic hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Arteriosclerosis	2 (<0.1)	0		2 (<0.1)
Diastolic hypertension	2 (<0.1)	0		2 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Lymphoedema	1 (<0.1)	0		1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)
Peripheral venous disease	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Secondary hypertension	1 (<0.1)	0		1 (<0.1)
White coat hypertension	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders	859 (7.5)	753 (6.6)		1612 (7.1)
Oropharyngeal pain	319 (2.8)	258 (2.3)	0.81 (0.69, 0.95)	577 (2.5)
Cough	250 (2.2)	251 (2.2)	1.00 (0.84, 1.19)	501 (2.2)
Nasal congestion	241 (2.1)	223 (2.0)	0.92 (0.77, 1.11)	464 (2.0)
Rhinorrhoea	201 (1.8)	185 (1.6)	0.92 (0.76, 1.12)	386 (1.7)
Dyspnoea	63 (0.6)	76 (0.7)	1.21 (0.87, 1.68)	139 (0.6)
Tachypnoea	37 (0.3)	36 (0.3)	0.97 (0.62, 1.53)	73 (0.3)
Sinus congestion	39 (0.3)	29 (0.3)	0.74 (0.46, 1.20)	68 (0.3)
Asthma	32 (0.3)	21 (0.2)	0.66 (0.38, 1.13)	53 (0.2)
Respiratory tract congestion	14 (0.1)	21 (0.2)	1.50 (0.77, 2.91)	35 (0.2)
Epistaxis	9 (<0.1)	17 (0.1)	1.89 (0.86, 4.15)	26 (0.1)
Throat irritation	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Rhinitis allergic	18 (0.2)	15 (0.1)	0.83 (0.43, 1.63)	33 (0.1)
Upper-airway cough syndrome	19 (0.2)	15 (0.1)	0.79 (0.41, 1.53)	34 (0.1)
Sneezing	18 (0.2)	12 (0.1)	0.67 (0.33, 1.36)	30 (0.1)
Chronic obstructive pulmonary disease	13 (0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Sinus pain	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Paranasal sinus discomfort	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Dry throat	4 (<0.1)	4 (<0.1)		8 (<0.1)
Productive cough	5 (<0.1)	4 (<0.1)		9 (<0.1)
Pulmonary embolism	5 (<0.1)	4 (<0.1)		9 (<0.1)
Wheezing	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Acute respiratory failure	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Dyspnoea exertional	3 (<0.1)	3 (<0.1)		6 (<0.1)
Pharyngeal erythema	4 (<0.1)	3 (<0.1)		7 (<0.1)
Pleural effusion	3 (<0.1)	3 (<0.1)		6 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Allergic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dysphonia	12 (0.1)	2 (<0.1)	0.17 (0.04, 0.66)	14 (<0.1)
Hypoxia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory disorder	5 (<0.1)	2 (<0.1)		7 (<0.1)
Sleep apnoea syndrome	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bronchospasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Choking sensation	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal dryness	0	1 (<0.1)		1 (<0.1)
Nasal mucosal disorder	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	7 (<0.1)	1 (<0.1)	0.14 (0.02, 0.89)	8 (<0.1)
Pulmonary congestion	0	1 (<0.1)		1 (<0.1)
Pulmonary oedema	0	1 (<0.1)		1 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	6 (<0.1)	1 (<0.1)		7 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Vocal cord thickening	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Bronchial hyperreactivity	1 (<0.1)	0		1 (<0.1)
Haemoptysis	3 (<0.1)	0		3 (<0.1)
Laryngeal stenosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Lung cyst	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Lung infiltration	2 (<0.1)	0		2 (<0.1)
Lung opacity	2 (<0.1)	0		2 (<0.1)
Nasal septum deviation	2 (<0.1)	0		2 (<0.1)
Nasal turbinate hypertrophy	1 (<0.1)	0		1 (<0.1)
Nasal ulcer	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pneumothorax	2 (<0.1)	0		2 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary granuloma	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	2 (<0.1)	0		2 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	3 (<0.1)	0		3 (<0.1)
Rhinalgia	2 (<0.1)	0		2 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	2 (<0.1)	0		2 (<0.1)
Gastrointestinal disorders	649 (5.7)	661 (5.8)		1310 (5.7)
Diarrhoea	200 (1.8)	218 (1.9)	1.09 (0.90, 1.32)	418 (1.8)
Nausea	192 (1.7)	188 (1.6)	0.98 (0.80, 1.19)	380 (1.7)
Vomiting	67 (0.6)	67 (0.6)	1.00 (0.71, 1.40)	134 (0.6)
Gastrooesophageal reflux disease	44 (0.4)	57 (0.5)	1.30 (0.88, 1.91)	101 (0.4)
Abdominal pain	34 (0.3)	35 (0.3)	1.03 (0.65, 1.64)	69 (0.3)
Toothache	40 (0.4)	32 (0.3)	0.80 (0.50, 1.27)	72 (0.3)
Constipation	24 (0.2)	19 (0.2)	0.79 (0.44, 1.43)	43 (0.2)
Dyspepsia	21 (0.2)	18 (0.2)	0.86 (0.46, 1.59)	39 (0.2)
Abdominal pain upper	26 (0.2)	17 (0.1)	0.65 (0.36, 1.19)	43 (0.2)
Dental caries	21 (0.2)	17 (0.1)	0.81 (0.43, 1.52)	38 (0.2)
Abdominal pain lower	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Food poisoning	12 (0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Abdominal discomfort	12 (0.1)	9 (<0.1)	0.75 (0.32, 1.74)	21 (<0.1)
Hiatus hernia	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.26)	11 (<0.1)
Irritable bowel syndrome	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Large intestine polyp	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Abdominal distension	2 (<0.1)	6 (<0.1)		8 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Gastritis	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Haemorrhoids	3 (<0.1)	6 (<0.1)		9 (<0.1)
Tooth impacted	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Gastric ulcer	6 (<0.1)	5 (<0.1)		11 (<0.1)
Lip swelling	1 (<0.1)	5 (<0.1)		6 (<0.1)
Haematochezia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Umbilical hernia	0	4 (<0.1)		4 (<0.1)
Aphthous ulcer	5 (<0.1)	3 (<0.1)		8 (<0.1)
Colitis	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Flatulence	3 (<0.1)	3 (<0.1)		6 (<0.1)
Inguinal hernia	0	3 (<0.1)		3 (<0.1)
Rectal haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Diverticulum	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Faeces soft	0	2 (<0.1)		2 (<0.1)
Gastrointestinal disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gastrointestinal pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gingival bleeding	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	2 (<0.1)		3 (<0.1)
Mouth ulceration	4 (<0.1)	2 (<0.1)		6 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Oesophageal ulcer	0	2 (<0.1)		2 (<0.1)
Oesophagitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pancreatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Peptic ulcer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Periodontal disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Proctalgia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Small intestinal obstruction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stomatitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Barrett's oesophagus	0	1 (<0.1)		1 (<0.1)
Chronic gastritis	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Dry mouth	4 (<0.1)	1 (<0.1)		5 (<0.1)
Duodenal ulcer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysphagia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Faeces discoloured	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gingival disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Gingival pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Melaena	0	1 (<0.1)		1 (<0.1)
Noninfective gingivitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Paraesthesia oral	4 (<0.1)	1 (<0.1)		5 (<0.1)
Poor dental condition	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal fissure	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Saliva altered	1 (<0.1)	1 (<0.1)		2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue ulceration	0	1 (<0.1)		1 (<0.1)
Abdominal rigidity	2 (<0.1)	0		2 (<0.1)
Anal fistula	1 (<0.1)	0		1 (<0.1)
Ascites	2 (<0.1)	0		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Eosinophilic oesophagitis	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric polyps	2 (<0.1)	0		2 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival recession	1 (<0.1)	0		1 (<0.1)
Glossodynia	2 (<0.1)	0		2 (<0.1)
Hypertrophy of tongue papillae	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Intussusception	1 (<0.1)	0		1 (<0.1)
Lip blister	1 (<0.1)	0		1 (<0.1)
Odynophagia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Oral disorder	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Palatal disorder	1 (<0.1)	0		1 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Terminal ileitis	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Tongue dry	1 (<0.1)	0		1 (<0.1)
Uvulitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	17 (0.1)	20 (0.2)		37 (0.2)
Cholelithiasis	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.63)	17 (<0.1)
Cholecystitis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Hepatic steatosis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Jaundice	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Hepatic cyst	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders	283 (2.5)	287 (2.5)		570 (2.5)
Urticaria	37 (0.3)	40 (0.4)	1.08 (0.69, 1.68)	77 (0.3)
Rash	42 (0.4)	32 (0.3)	0.76 (0.48, 1.20)	74 (0.3)
Dermatitis contact	28 (0.2)	26 (0.2)	0.93 (0.55, 1.57)	54 (0.2)
Pruritus	18 (0.2)	20 (0.2)	1.11 (0.59, 2.08)	38 (0.2)
Eczema	8 (<0.1)	18 (0.2)	2.25 (1.00, 5.06)	26 (0.1)
Acne	18 (0.2)	15 (0.1)	0.83 (0.43, 1.63)	33 (0.1)
Hyperhidrosis	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Night sweats	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Alopecia	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Dermatitis	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Rash maculo-papular	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Rash papular	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Erythema	5 (<0.1)	6 (<0.1)		11 (<0.1)
Psoriasis	1 (<0.1)	6 (<0.1)		7 (<0.1)
Ecchymosis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Rosacea	2 (<0.1)	5 (<0.1)		7 (<0.1)
Actinic keratosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Rash pruritic	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Angioedema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blister	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dermatitis allergic	5 (<0.1)	3 (<0.1)		8 (<0.1)
Dermatitis atopic	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.14)	12 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dry skin	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hidradenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pain of skin	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pityriasis rosea	0	3 (<0.1)		3 (<0.1)
Rash erythematous	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rash macular	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin ulcer	0	3 (<0.1)		3 (<0.1)
Urticaria papular	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Dermal cyst	5 (<0.1)	2 (<0.1)		7 (<0.1)
Diabetic foot	0	2 (<0.1)		2 (<0.1)
Eczema nummular	0	2 (<0.1)		2 (<0.1)
Hand dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Papule	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rash vesicular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Skin lesion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Blood blister	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	0	1 (<0.1)		1 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Onychoclasis	0	1 (<0.1)		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Vitiligo	0	1 (<0.1)		1 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Decubitus ulcer	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Hyperkeratosis	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Intertrigo	3 (<0.1)	0		3 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Miliaria	1 (<0.1)	0		1 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	2 (<0.1)	0		2 (<0.1)
Skin fissures	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin wrinkling	1 (<0.1)	0		1 (<0.1)
Solar lentigo	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	958 (8.4)	925 (8.1)		1883 (8.2)
Myalgia	362 (3.2)	329 (2.9)	0.91 (0.78, 1.05)	691 (3.0)
Arthralgia	314 (2.8)	312 (2.7)	0.99 (0.85, 1.16)	626 (2.7)
Back pain	134 (1.2)	120 (1.1)	0.90 (0.70, 1.14)	254 (1.1)
Pain in extremity	72 (0.6)	57 (0.5)	0.79 (0.56, 1.12)	129 (0.6)
Musculoskeletal pain	37 (0.3)	50 (0.4)	1.35 (0.89, 2.06)	87 (0.4)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Neck pain	38 (0.3)	47 (0.4)	1.24 (0.81, 1.89)	85 (0.4)
Muscle spasms	31 (0.3)	32 (0.3)	1.03 (0.63, 1.68)	63 (0.3)
Osteoarthritis	31 (0.3)	30 (0.3)	0.97 (0.59, 1.59)	61 (0.3)
Intervertebral disc protrusion	8 (<0.1)	17 (0.1)	2.12 (0.94, 4.81)	25 (0.1)
Musculoskeletal chest pain	18 (0.2)	16 (0.1)	0.89 (0.46, 1.72)	34 (0.1)
Tendonitis	14 (0.1)	16 (0.1)	1.14 (0.57, 2.31)	30 (0.1)
Rotator cuff syndrome	15 (0.1)	15 (0.1)	1.00 (0.50, 2.01)	30 (0.1)
Bursitis	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Musculoskeletal stiffness	13 (0.1)	8 (<0.1)	0.62 (0.26, 1.45)	21 (<0.1)
Groin pain	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Arthritis	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Muscle tightness	2 (<0.1)	5 (<0.1)		7 (<0.1)
Pain in jaw	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Plantar fasciitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Spinal pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Costochondritis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Joint range of motion decreased	0	4 (<0.1)		4 (<0.1)
Joint swelling	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Limb discomfort	2 (<0.1)	4 (<0.1)		6 (<0.1)
Spinal osteoarthritis	5 (<0.1)	4 (<0.1)		9 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Temporomandibular joint syndrome	2 (<0.1)	4 (<0.1)		6 (<0.1)
Trigger finger	3 (<0.1)	4 (<0.1)		7 (<0.1)
Limb mass	1 (<0.1)	3 (<0.1)		4 (<0.1)
Muscular weakness	6 (<0.1)	3 (<0.1)		9 (<0.1)
Osteoporosis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Periarthritis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Synovial cyst	4 (<0.1)	3 (<0.1)		7 (<0.1)
Axillary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Exostosis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Fibromyalgia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Flank pain	4 (<0.1)	2 (<0.1)		6 (<0.1)
Intervertebral disc degeneration	4 (<0.1)	2 (<0.1)		6 (<0.1)
Muscle twitching	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Osteopenia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rheumatoid arthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Compartment syndrome	0	1 (<0.1)		1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)		1 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Foot deformity	4 (<0.1)	1 (<0.1)		5 (<0.1)
Joint noise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint stiffness	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ligament pain	0	1 (<0.1)		1 (<0.1)
Medial tibial stress syndrome	0	1 (<0.1)		1 (<0.1)
Muscle fatigue	0	1 (<0.1)		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteonecrosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	0	1 (<0.1)		1 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Trismus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fasciitis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Joint effusion	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	2 (<0.1)	0		2 (<0.1)
Synovitis	2 (<0.1)	0		2 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Tendon disorder	1 (<0.1)	0		1 (<0.1)
Tenosynovitis stenosans	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Renal and urinary disorders	52 (0.5)	49 (0.4)		101 (0.4)
Nephrolithiasis	23 (0.2)	15 (0.1)	0.65 (0.34, 1.24)	38 (0.2)
Dysuria	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Acute kidney injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypertonic bladder	0	3 (<0.1)		3 (<0.1)
Polyuria	0	3 (<0.1)		3 (<0.1)
Bladder pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chronic kidney disease	2 (<0.1)	2 (<0.1)		4 (<0.1)
Haematuria	10 (<0.1)	2 (<0.1)	0.20 (0.05, 0.81)	12 (<0.1)
Hydronephrosis	0	2 (<0.1)		2 (<0.1)
Urinary incontinence	0	2 (<0.1)		2 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Calculus bladder	0	1 (<0.1)		1 (<0.1)
Chromaturia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Micturition urgency	0	1 (<0.1)		1 (<0.1)
Nocturia	0	1 (<0.1)		1 (<0.1)
Pollakiuria	4 (<0.1)	1 (<0.1)		5 (<0.1)
Renal disorder	0	1 (<0.1)		1 (<0.1)
Renal failure	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Renal tubular necrosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Renal and urinary disorders (Cont.)				
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal cyst	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	3 (<0.1)	3 (<0.1)		6 (<0.1)
Abortion spontaneous	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)		1 (<0.1)
Morning sickness	0	1 (<0.1)		1 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	102 (0.9)	85 (0.7)		187 (0.8)
Pelvic pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Prostatitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Dysmenorrhoea	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.40)	15 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Erectile dysfunction	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Menorrhagia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Benign prostatic hyperplasia	12 (0.1)	4 (<0.1)	0.33 (0.11, 0.98)	16 (<0.1)
Ovarian cyst	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Vaginal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Breast cyst	2 (<0.1)	3 (<0.1)		5 (<0.1)
Menopausal symptoms	2 (<0.1)	3 (<0.1)		5 (<0.1)
Uterine polyp	3 (<0.1)	3 (<0.1)		6 (<0.1)
Breast hyperplasia	0	2 (<0.1)		2 (<0.1)
Breast pain	5 (<0.1)	2 (<0.1)		7 (<0.1)
Breast ulceration	0	2 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	2 (<0.1)		4 (<0.1)
Postmenopausal haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rectocele	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Adnexa uteri pain	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Artificial menopause	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast fibrosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Breast mass	4 (<0.1)	1 (<0.1)		5 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical polyp	0	1 (<0.1)		1 (<0.1)
Cystocele	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)		2 (<0.1)
Endometriosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibrocystic breast disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Polymenorrhoea	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	3 (<0.1)	1 (<0.1)		4 (<0.1)
Testicular pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaginal cyst	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vaginal prolapse	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Vulva cyst	0	1 (<0.1)		1 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	3 (<0.1)	0		3 (<0.1)
Dyspareunia	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Nipple pain	1 (<0.1)	0		1 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Peyronie's disease	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	3 (<0.1)	0		3 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Testicular swelling	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Congenital, familial and genetic disorders	5 (<0.1)	6 (<0.1)		11 (<0.1)
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Preauricular cyst	0	1 (<0.1)		1 (<0.1)
Type IIa hyperlipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Von Willebrand's disease	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1007 (8.8)	1374 (12.0)		2381 (10.4)
Fatigue	633 (5.5)	658 (5.8)	1.04 (0.93, 1.16)	1291 (5.7)
Injection site pain	104 (0.9)	204 (1.8)	1.96 (1.55, 2.48)	308 (1.3)
Chills	125 (1.1)	135 (1.2)	1.08 (0.85, 1.37)	260 (1.1)
Pyrexia	94 (0.8)	124 (1.1)	1.32 (1.01, 1.72)	218 (1.0)
Injection site erythema	23 (0.2)	102 (0.9)	4.43 (2.83, 6.94)	125 (0.5)
Pain	107 (0.9)	102 (0.9)	0.95 (0.73, 1.25)	209 (0.9)
Injection site swelling	19 (0.2)	86 (0.8)	4.52 (2.77, 7.40)	105 (0.5)
Injection site pruritus	11 (<0.1)	63 (0.6)	5.73 (3.05, 10.75)	74 (0.3)
Injection site lymphadenopathy	15 (0.1)	61 (0.5)	4.07 (2.33, 7.10)	76 (0.3)
Injection site induration	11 (<0.1)	43 (0.4)	3.91 (2.04, 7.49)	54 (0.2)
Injection site macule	3 (<0.1)	31 (0.3)	10.33 (3.36, 31.81)	34 (0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Injection site urticaria	0	27 (0.2)		27 (0.1)
Axillary pain	14 (0.1)	24 (0.2)	1.71 (0.90, 3.27)	38 (0.2)
Chest discomfort	19 (0.2)	19 (0.2)	1.00 (0.53, 1.87)	38 (0.2)
Injection site rash	1 (<0.1)	19 (0.2)	18.99 (3.23, 111.55)	20 (<0.1)
Injection site bruising	12 (0.1)	15 (0.1)	1.25 (0.60, 2.62)	27 (0.1)
Malaise	9 (<0.1)	15 (0.1)	1.67 (0.75, 3.72)	24 (0.1)
Chest pain	10 (<0.1)	14 (0.1)	1.40 (0.63, 3.08)	24 (0.1)
Non-cardiac chest pain	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Peripheral swelling	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Injection site papule	1 (<0.1)	12 (0.1)	12.00 (2.00, 71.91)	13 (<0.1)
Oedema peripheral	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Reactogenicity event	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Swelling face	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Feeling hot	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site paraesthesia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)		6 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Feeling abnormal	4 (<0.1)	4 (<0.1)		8 (<0.1)
Injection site haemorrhage	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site joint pain	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Asthenia	6 (<0.1)	3 (<0.1)		9 (<0.1)
Influenza like illness	5 (<0.1)	3 (<0.1)		8 (<0.1)
Injection site haematoma	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site hypoaesthesia	0	3 (<0.1)		3 (<0.1)
Injection site mass	0	3 (<0.1)		3 (<0.1)
Injury associated with device	0	3 (<0.1)		3 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Vaccination site pain	5 (<0.1)	3 (<0.1)		8 (<0.1)
Adverse drug reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site irritation	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cyst	3 (<0.1)	1 (<0.1)		4 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Early satiety	0	1 (<0.1)		1 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	5 (<0.1)	1 (<0.1)		6 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Hangover	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Xerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Capsular contracture associated with breast implant	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Injection site discolouration	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Precancerous condition	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	2 (<0.1)	0		2 (<0.1)
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations	119 (1.0)	113 (1.0)		232 (1.0)
Blood pressure increased	41 (0.4)	30 (0.3)	0.73 (0.46, 1.17)	71 (0.3)
Blood pressure systolic increased	12 (0.1)	13 (0.1)	1.08 (0.50, 2.33)	25 (0.1)
Blood pressure diastolic increased	8 (<0.1)	11 (<0.1)	1.37 (0.57, 3.32)	19 (<0.1)
Hepatic enzyme increased	4 (<0.1)	6 (<0.1)		10 (<0.1)
Blood cholesterol increased	6 (<0.1)	5 (<0.1)		11 (<0.1)
Body temperature increased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Blood glucose increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Heart rate increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Transaminases increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Weight decreased	0	3 (<0.1)		3 (<0.1)
Blood potassium decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood triglycerides increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrocardiogram QT prolonged	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	6 (<0.1)	2 (<0.1)		8 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Antinuclear antibody positive	0	1 (<0.1)		1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Blood parathyroid hormone increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood uric acid increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
C-reactive protein increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac murmur	6 (<0.1)	1 (<0.1)		7 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Glycosylated haemoglobin increased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Haemoglobin decreased	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Liver function test increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Respiratory rate increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stool analysis abnormal	0	1 (<0.1)		1 (<0.1)
Streptococcus test negative	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Troponin increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Vitamin D decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Weight increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Blood urine present	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Haematocrit increased	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Pregnancy test positive	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
SARS-CoV-2 test positive	1 (<0.1)	0		1 (<0.1)
Viral test positive	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Vitamin B12 decreased	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	458 (4.0)	382 (3.3)		840 (3.7)
Muscle strain	40 (0.4)	41 (0.4)	1.02 (0.67, 1.58)	81 (0.4)
Ligament sprain	44 (0.4)	39 (0.3)	0.89 (0.58, 1.36)	83 (0.4)
Skin laceration	40 (0.4)	24 (0.2)	0.60 (0.36, 0.99)	64 (0.3)
Fall	27 (0.2)	22 (0.2)	0.81 (0.47, 1.42)	49 (0.2)
Arthropod bite	28 (0.2)	19 (0.2)	0.68 (0.38, 1.20)	47 (0.2)
Tooth fracture	24 (0.2)	19 (0.2)	0.79 (0.44, 1.43)	43 (0.2)
Foot fracture	16 (0.1)	15 (0.1)	0.94 (0.47, 1.87)	31 (0.1)
Procedural pain	37 (0.3)	15 (0.1)	0.41 (0.22, 0.73)	52 (0.2)
Animal bite	15 (0.1)	14 (0.1)	0.93 (0.46, 1.90)	29 (0.1)
Contusion	26 (0.2)	14 (0.1)	0.54 (0.28, 1.02)	40 (0.2)
Limb injury	10 (<0.1)	13 (0.1)	1.30 (0.58, 2.90)	23 (0.1)
Joint injury	7 (<0.1)	12 (0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Meniscus injury	11 (<0.1)	12 (0.1)	1.09 (0.49, 2.42)	23 (0.1)
Road traffic accident	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Skin abrasion	20 (0.2)	10 (<0.1)	0.50 (0.24, 1.05)	30 (0.1)
Arthropod sting	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Concussion	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Head injury	0	6 (<0.1)		6 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ankle fracture	6 (<0.1)	5 (<0.1)		11 (<0.1)
Facial bones fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Ligament rupture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Post-traumatic pain	6 (<0.1)	5 (<0.1)		11 (<0.1)
Rib fracture	6 (<0.1)	5 (<0.1)		11 (<0.1)
Back injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Cartilage injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Corneal abrasion	6 (<0.1)	4 (<0.1)		10 (<0.1)
Epicondylitis	6 (<0.1)	4 (<0.1)		10 (<0.1)
Joint dislocation	1 (<0.1)	4 (<0.1)		5 (<0.1)
Stress fracture	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Thermal burn	3 (<0.1)	4 (<0.1)		7 (<0.1)
Upper limb fracture	1 (<0.1)	4 (<0.1)		5 (<0.1)
Alcohol poisoning	0	3 (<0.1)		3 (<0.1)
Clavicle fracture	0	3 (<0.1)		3 (<0.1)
Dental restoration failure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hand fracture	4 (<0.1)	3 (<0.1)		7 (<0.1)
Muscle rupture	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tendon injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Bone contusion	4 (<0.1)	2 (<0.1)		6 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Exposure to SARS-CoV-2	0	2 (<0.1)		2 (<0.1)
Humerus fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypobarism	0	2 (<0.1)		2 (<0.1)
Ligament injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lip injury	0	2 (<0.1)		2 (<0.1)
Post procedural haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tendon rupture	5 (<0.1)	2 (<0.1)		7 (<0.1)
Wound	6 (<0.1)	2 (<0.1)		8 (<0.1)
Wrist fracture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns second degree	3 (<0.1)	1 (<0.1)		4 (<0.1)
Carbon monoxide poisoning	0	1 (<0.1)		1 (<0.1)
Chemical burn	0	1 (<0.1)		1 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Chillblains	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)		1 (<0.1)
Eyelid injury	0	1 (<0.1)		1 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)		1 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Graft complication	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Limb traumatic amputation	0	1 (<0.1)		1 (<0.1)
Lower limb fracture	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)		1 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Neck injury	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Procedural nausea	4 (<0.1)	1 (<0.1)		5 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Product administration interrupted	1 (<0.1)	1 (<0.1)		2 (<0.1)
Radius fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scar	0	1 (<0.1)		1 (<0.1)
Skin wound	3 (<0.1)	1 (<0.1)		4 (<0.1)
Spinal column injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splinter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	2 (<0.1)	1 (<0.1)		3 (<0.1)
Superficial injury of eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Thoracic vertebral fracture	0	1 (<0.1)		1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Traumatic haemorrhage	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Burns first degree	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Fractured coccyx	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	2 (<0.1)	0		2 (<0.1)
Inappropriate schedule of product administration	4 (<0.1)	0		4 (<0.1)
Keratorhexis	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Musculoskeletal foreign body	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	1 (<0.1)	0		1 (<0.1)
Post procedural contusion	1 (<0.1)	0		1 (<0.1)
Post procedural fever	1 (<0.1)	0		1 (<0.1)
Post procedural hypothyroidism	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural vomiting	1 (<0.1)	0		1 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Uterine perforation	1 (<0.1)	0		1 (<0.1)
Vaccination complication	2 (<0.1)	0		2 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	3 (<0.1)	2 (<0.1)		5 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Postmenopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Product issues	0	4 (<0.1)		4 (<0.1)
Device breakage	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1604 (42.8)	1671 (44.3)		3275 (43.6)
Number of Unsolicited Adverse Events	3679	3843		7522
Infections and infestations	477 (12.7)	384 (10.2)		861 (11.4)
Urinary tract infection	68 (1.8)	55 (1.5)	0.80 (0.57, 1.14)	123 (1.6)
Upper respiratory tract infection	35 (0.9)	45 (1.2)	1.28 (0.83, 1.98)	80 (1.1)
Sinusitis	27 (0.7)	31 (0.8)	1.14 (0.69, 1.90)	58 (0.8)
Viral infection	21 (0.6)	27 (0.7)	1.28 (0.73, 2.24)	48 (0.6)
Herpes zoster	5 (0.1)	19 (0.5)	3.78 (1.47, 9.76)	24 (0.3)
Suspected COVID-19	23 (0.6)	19 (0.5)	0.82 (0.45, 1.49)	42 (0.6)
COVID-19	135 (3.6)	18 (0.5)	0.13 (0.08, 0.22)	153 (2.0)
Cellulitis	9 (0.2)	11 (0.3)	1.22 (0.52, 2.86)	20 (0.3)
Rhinovirus infection	10 (0.3)	11 (0.3)	1.09 (0.48, 2.51)	21 (0.3)
Tooth abscess	18 (0.5)	9 (0.2)	0.50 (0.23, 1.08)	27 (0.4)
Tooth infection	12 (0.3)	9 (0.2)	0.75 (0.32, 1.73)	21 (0.3)
Diverticulitis	9 (0.2)	8 (0.2)	0.88 (0.35, 2.22)	17 (0.2)
Hordeolum	8 (0.2)	8 (0.2)	1.00 (0.39, 2.56)	16 (0.2)
Gastroenteritis	5 (0.1)	7 (0.2)	1.39 (0.47, 4.15)	12 (0.2)
Pneumonia	9 (0.2)	7 (0.2)	0.77 (0.30, 2.00)	16 (0.2)
Gingivitis	4 (0.1)	6 (0.2)		10 (0.1)
Onychomycosis	3 (<0.1)	6 (0.2)		9 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Conjunctivitis	4 (0.1)	5 (0.1)		9 (0.1)
Localised infection	4 (0.1)	5 (0.1)		9 (0.1)
Oral herpes	2 (<0.1)	5 (0.1)		7 (<0.1)
Viral upper respiratory tract infection	3 (<0.1)	5 (0.1)		8 (0.1)
Bronchitis	1 (<0.1)	4 (0.1)		5 (<0.1)
Ear infection	6 (0.2)	4 (0.1)		10 (0.1)
Enterovirus infection	0	4 (0.1)		4 (<0.1)
Herpes simplex	1 (<0.1)	4 (0.1)		5 (<0.1)
Laryngitis	1 (<0.1)	4 (0.1)		5 (<0.1)
Pharyngitis	1 (<0.1)	4 (0.1)		5 (<0.1)
Acute sinusitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Appendicitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Clostridium difficile infection	0	3 (<0.1)		3 (<0.1)
Cystitis	8 (0.2)	3 (<0.1)	0.37 (0.11, 1.30)	11 (0.1)
Fungal infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Nasopharyngitis	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.1)
Otitis externa	4 (0.1)	3 (<0.1)		7 (<0.1)
Paronychia	5 (0.1)	3 (<0.1)		8 (0.1)
Postoperative wound infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Staphylococcal infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abdominal abscess	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Chronic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Eye infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis media	1 (<0.1)	2 (<0.1)		3 (<0.1)
Periodontitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Respiratory tract infection	3 (<0.1)	2 (<0.1)		5 (<0.1)
Respiratory tract infection viral	2 (<0.1)	2 (<0.1)		4 (<0.1)
Sepsis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Staphylococcal skin infection	0	2 (<0.1)		2 (<0.1)
Subcutaneous abscess	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tinea infection	0	2 (<0.1)		2 (<0.1)
Vulvovaginal mycotic infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic bacteriuria	0	1 (<0.1)		1 (<0.1)
Atypical mycobacterial infection	0	1 (<0.1)		1 (<0.1)
Atypical pneumonia	0	1 (<0.1)		1 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Colonic abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	0	1 (<0.1)		1 (<0.1)
Coronavirus infection	0	1 (<0.1)		1 (<0.1)
Epididymitis	0	1 (<0.1)		1 (<0.1)
Folliculitis	4 (0.1)	1 (<0.1)		5 (<0.1)
Gastrointestinal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Genital infection fungal	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Rhinitis	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Septic shock	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sialoadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinusitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Skin infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tinea pedis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Viral sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Appendicitis perforated	1 (<0.1)	0		1 (<0.1)
Balanitis candida	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Body tinea	2 (<0.1)	0		2 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	7 (0.2)	0		7 (<0.1)
Candida infection	3 (<0.1)	0		3 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Ear infection fungal	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	1 (<0.1)	0		1 (<0.1)
Fungal skin infection	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Genital herpes simplex	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Helicobacter infection	1 (<0.1)	0		1 (<0.1)
Herpangina	1 (<0.1)	0		1 (<0.1)
Kidney infection	1 (<0.1)	0		1 (<0.1)
Klebsiella bacteraemia	1 (<0.1)	0		1 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Nail infection	1 (<0.1)	0		1 (<0.1)
Nasal vestibulitis	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	4 (0.1)	0		4 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Proteus infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Soft tissue infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea cruris	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)
Wound infection	2 (<0.1)	0		2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	64 (1.7)	60 (1.6)		124 (1.6)
Basal cell carcinoma	19 (0.5)	17 (0.5)	0.89 (0.47, 1.69)	36 (0.5)
Skin cancer	3 (<0.1)	5 (0.1)		8 (0.1)
Malignant melanoma	1 (<0.1)	4 (0.1)		5 (<0.1)
Prostate cancer	5 (0.1)	4 (0.1)		9 (0.1)
Squamous cell carcinoma of skin	4 (0.1)	4 (0.1)		8 (0.1)
Lipoma	2 (<0.1)	3 (<0.1)		5 (<0.1)
Benign hepatic neoplasm	0	2 (<0.1)		2 (<0.1)
Benign neoplasm of skin	0	2 (<0.1)		2 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	2 (<0.1)	1 (<0.1)		3 (<0.1)
Benign salivary gland neoplasm	0	1 (<0.1)		1 (<0.1)
Brain neoplasm	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Nasal cavity cancer	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Seborrhoeic keratosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma	8 (0.2)	1 (<0.1)	0.12 (0.02, 0.77)	9 (0.1)
Benign neoplasm of bladder	1 (<0.1)	0		1 (<0.1)
Bladder cancer	1 (<0.1)	0		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	1 (<0.1)	0		1 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	2 (<0.1)	0		2 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Metastases to bone	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Skin papilloma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Blood and lymphatic system disorders	27 (0.7)	43 (1.1)		70 (0.9)
Lymphadenopathy	16 (0.4)	33 (0.9)	2.05 (1.14, 3.69)	49 (0.7)
Anaemia	6 (0.2)	5 (0.1)		11 (0.1)
Leukocytosis	0	2 (<0.1)		2 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymphadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	1 (<0.1)	0		1 (<0.1)
Splenic calcification	1 (<0.1)	0		1 (<0.1)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)
Immune system disorders	22 (0.6)	25 (0.7)		47 (0.6)
Seasonal allergy	16 (0.4)	15 (0.4)	0.93 (0.47, 1.86)	31 (0.4)
Drug hypersensitivity	2 (<0.1)	4 (0.1)		6 (<0.1)
Hypersensitivity	2 (<0.1)	4 (0.1)		6 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to chemicals	1 (<0.1)	0		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	9 (0.2)	17 (0.5)		26 (0.3)
Hypothyroidism	4 (0.1)	10 (0.3)	2.49 (0.83, 7.49)	14 (0.2)
Goitre	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Endocrine disorders (Cont.)				
Thyroid mass	1 (<0.1)	2 (<0.1)		3 (<0.1)
Basedow's disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperparathyroidism	0	1 (<0.1)		1 (<0.1)
Thyroiditis	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	88 (2.3)	90 (2.4)		178 (2.4)
Hyperlipidaemia	17 (0.5)	17 (0.5)	1.00 (0.51, 1.92)	34 (0.5)
Hypercholesterolaemia	9 (0.2)	12 (0.3)	1.33 (0.57, 3.07)	21 (0.3)
Type 2 diabetes mellitus	8 (0.2)	12 (0.3)	1.49 (0.63, 3.55)	20 (0.3)
Gout	8 (0.2)	9 (0.2)	1.12 (0.45, 2.81)	17 (0.2)
Vitamin D deficiency	8 (0.2)	6 (0.2)	0.75 (0.27, 2.06)	14 (0.2)
Dehydration	6 (0.2)	5 (0.1)		11 (0.1)
Diabetes mellitus	4 (0.1)	5 (0.1)		9 (0.1)
Hyponatraemia	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)
Decreased appetite	5 (0.1)	4 (0.1)		9 (0.1)
Glucose tolerance impaired	0	4 (0.1)		4 (<0.1)
Hypokalaemia	4 (0.1)	3 (<0.1)		7 (<0.1)
Hyperkalaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hypoglycaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Malnutrition	0	2 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)				
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertriglyceridaemia	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypomagnesaemia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Vitamin K deficiency	0	1 (<0.1)		1 (<0.1)
Abnormal loss of weight	2 (<0.1)	0		2 (<0.1)
Fluid overload	1 (<0.1)	0		1 (<0.1)
Fluid retention	1 (<0.1)	0		1 (<0.1)
Hypermagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Magnesium deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	35 (0.9)	54 (1.4)		89 (1.2)
Anxiety	12 (0.3)	19 (0.5)	1.58 (0.78, 3.19)	31 (0.4)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Psychiatric disorders (Cont.)				
Insomnia	13 (0.3)	12 (0.3)	0.92 (0.43, 1.97)	25 (0.3)
Depression	6 (0.2)	10 (0.3)	1.66 (0.63, 4.39)	16 (0.2)
Nightmare	0	3 (<0.1)		3 (<0.1)
Sleep disorder	0	2 (<0.1)		2 (<0.1)
Suicidal ideation	0	2 (<0.1)		2 (<0.1)
Attention deficit hyperactivity disorder	0	1 (<0.1)		1 (<0.1)
Bipolar disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Confusional state	2 (<0.1)	1 (<0.1)		3 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Mental fatigue	0	1 (<0.1)		1 (<0.1)
Mental status changes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Terminal insomnia	0	1 (<0.1)		1 (<0.1)
Abnormal dreams	1 (<0.1)	0		1 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	0		1 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders	256 (6.8)	265 (7.0)		521 (6.9)
Headache	152 (4.1)	162 (4.3)	1.06 (0.85, 1.32)	314 (4.2)
Dizziness	30 (0.8)	26 (0.7)	0.86 (0.51, 1.45)	56 (0.7)
Paraesthesia	4 (0.1)	9 (0.2)	2.24 (0.73, 6.85)	13 (0.2)
Sinus headache	5 (0.1)	9 (0.2)	1.79 (0.63, 5.09)	14 (0.2)
Sciatica	11 (0.3)	8 (0.2)	0.72 (0.30, 1.75)	19 (0.3)
Cervical radiculopathy	0	7 (0.2)		7 (<0.1)
Syncope	12 (0.3)	5 (0.1)	0.41 (0.15, 1.13)	17 (0.2)
Hypoaesthesia	4 (0.1)	4 (0.1)		8 (0.1)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Facial paralysis	0	3 (<0.1)		3 (<0.1)
Lumbar radiculopathy	2 (<0.1)	3 (<0.1)		5 (<0.1)
Migraine	4 (0.1)	3 (<0.1)		7 (<0.1)
Peripheral sensory neuropathy	0	3 (<0.1)		3 (<0.1)
Amnesia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Carpal tunnel syndrome	5 (0.1)	2 (<0.1)		7 (<0.1)
Disturbance in attention	0	2 (<0.1)		2 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia	0	2 (<0.1)		2 (<0.1)
Nerve compression	4 (0.1)	2 (<0.1)		6 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Parosmia	0	2 (<0.1)		2 (<0.1)
Piriformis syndrome	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Post herpetic neuralgia	0	2 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Tension headache	3 (<0.1)	2 (<0.1)		5 (<0.1)
Transient ischaemic attack	0	2 (<0.1)		2 (<0.1)
Tremor	3 (<0.1)	2 (<0.1)		5 (<0.1)
Ageusia	8 (0.2)	1 (<0.1)	0.12 (0.02, 0.77)	9 (0.1)
Anosmia	4 (0.1)	1 (<0.1)		5 (<0.1)
Balance disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Dementia	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dysgeusia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	2 (<0.1)	1 (<0.1)		3 (<0.1)
New daily persistent headache	0	1 (<0.1)		1 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Post-traumatic headache	2 (<0.1)	1 (<0.1)		3 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Intention tremor	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Presyncope	4 (0.1)	0		4 (<0.1)
Restless legs syndrome	3 (<0.1)	0		3 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	2 (<0.1)	0		2 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)
Eye disorders	60 (1.6)	62 (1.6)		122 (1.6)
Cataract	7 (0.2)	9 (0.2)	1.28 (0.49, 3.31)	16 (0.2)
Glaucoma	6 (0.2)	7 (0.2)	1.16 (0.41, 3.29)	13 (0.2)
Dry eye	6 (0.2)	5 (0.1)		11 (0.1)
Eye irritation	0	4 (0.1)		4 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Eye disorders (Cont.)				
Eye pain	1 (<0.1)	4 (0.1)		5 (<0.1)
Chalazion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Eye pruritus	2 (<0.1)	3 (<0.1)		5 (<0.1)
Eye inflammation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Macular degeneration	0	2 (<0.1)		2 (<0.1)
Macular hole	1 (<0.1)	2 (<0.1)		3 (<0.1)
Retinal detachment	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vitreous floaters	2 (<0.1)	2 (<0.1)		4 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blepharitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Conjunctival haemorrhage	3 (<0.1)	1 (<0.1)		4 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foreign body sensation in eyes	0	1 (<0.1)		1 (<0.1)
Keratitis	0	1 (<0.1)		1 (<0.1)
Lacrimation increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lenticular opacities	0	1 (<0.1)		1 (<0.1)
Macular fibrosis	0	1 (<0.1)		1 (<0.1)
Papilloedema	0	1 (<0.1)		1 (<0.1)
Retinal haemorrhage	0	1 (<0.1)		1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Retinopathy hypertensive	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Eye disorders (Cont.)				
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vision blurred	2 (<0.1)	1 (<0.1)		3 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Diplopia	2 (<0.1)	0		2 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	2 (<0.1)	0		2 (<0.1)
Ocular hyperaemia	2 (<0.1)	0		2 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal infarction	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Strabismus	2 (<0.1)	0		2 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Ear and labyrinth disorders	44 (1.2)	42 (1.1)		86 (1.1)
Vertigo	12 (0.3)	19 (0.5)	1.58 (0.78, 3.19)	31 (0.4)
Ear pain	10 (0.3)	7 (0.2)	0.70 (0.27, 1.77)	17 (0.2)
Tinnitus	4 (0.1)	4 (0.1)		8 (0.1)
Vertigo positional	1 (<0.1)	4 (0.1)		5 (<0.1)
Meniere's disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Deafness unilateral	0	2 (<0.1)		2 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear congestion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	0	1 (<0.1)		1 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Ear canal erythema	1 (<0.1)	0		1 (<0.1)
Ear discomfort	5 (0.1)	0		5 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	3 (<0.1)	0		3 (<0.1)
Cardiac disorders	72 (1.9)	82 (2.2)		154 (2.0)
Atrial fibrillation	20 (0.5)	18 (0.5)	0.90 (0.48, 1.67)	38 (0.5)
Coronary artery disease	9 (0.2)	7 (0.2)	0.77 (0.30, 2.00)	16 (0.2)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders (Cont.)				
Angina pectoris	6 (0.2)	6 (0.2)		12 (0.2)
Palpitations	2 (<0.1)	6 (0.2)		8 (0.1)
Ventricular extrasystoles	2 (<0.1)	6 (0.2)		8 (0.1)
Arrhythmia	3 (<0.1)	4 (0.1)		7 (<0.1)
Bradycardia	8 (0.2)	4 (0.1)	0.50 (0.16, 1.55)	12 (0.2)
Cardiac failure congestive	5 (0.1)	4 (0.1)		9 (0.1)
Sinus tachycardia	3 (<0.1)	4 (0.1)		7 (<0.1)
Myocardial infarction	3 (<0.1)	3 (<0.1)		6 (<0.1)
Supraventricular tachycardia	0	3 (<0.1)		3 (<0.1)
Tachycardia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Acute coronary syndrome	0	2 (<0.1)		2 (<0.1)
Acute myocardial infarction	4 (0.1)	2 (<0.1)		6 (<0.1)
Cardiac failure	4 (0.1)	2 (<0.1)		6 (<0.1)
Cardio-respiratory arrest	0	2 (<0.1)		2 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	4 (0.1)	1 (<0.1)		5 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders (Cont.)				
Cardiovascular symptom	0	1 (<0.1)		1 (<0.1)
Pericarditis	0	1 (<0.1)		1 (<0.1)
Sinus bradycardia	0	1 (<0.1)		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac failure acute	1 (<0.1)	0		1 (<0.1)
Cardiac steatosis	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left atrial enlargement	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Mitral valve incompetence	2 (<0.1)	0		2 (<0.1)
Tricuspid valve incompetence	2 (<0.1)	0		2 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	142 (3.8)	129 (3.4)		271 (3.6)
Hypertension	117 (3.1)	89 (2.4)	0.76 (0.58, 0.99)	206 (2.7)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Vascular disorders (Cont.)				
Hot flush	5 (0.1)	7 (0.2)	1.39 (0.47, 4.15)	12 (0.2)
Haematoma	2 (<0.1)	6 (0.2)		8 (0.1)
Deep vein thrombosis	2 (<0.1)	4 (0.1)		6 (<0.1)
Arteriosclerosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypertensive urgency	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypotension	4 (0.1)	3 (<0.1)		7 (<0.1)
Aortic dilatation	0	2 (<0.1)		2 (<0.1)
Flushing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Orthostatic hypotension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Systolic hypertension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aortic aneurysm	3 (<0.1)	1 (<0.1)		4 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive emergency	0	1 (<0.1)		1 (<0.1)
Labile hypertension	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Phlebitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Vascular disorders (Cont.)				
Vascular calcification	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	235 (6.3)	217 (5.8)		452 (6.0)
Rhinorrhoea	57 (1.5)	61 (1.6)	1.07 (0.75, 1.52)	118 (1.6)
Cough	57 (1.5)	59 (1.6)	1.03 (0.72, 1.48)	116 (1.5)
Nasal congestion	50 (1.3)	47 (1.2)	0.94 (0.63, 1.39)	97 (1.3)
Oropharyngeal pain	62 (1.7)	46 (1.2)	0.74 (0.51, 1.08)	108 (1.4)
Dyspnoea	23 (0.6)	16 (0.4)	0.69 (0.37, 1.29)	39 (0.5)
Asthma	7 (0.2)	11 (0.3)	1.56 (0.63, 3.90)	18 (0.2)
Sneezing	4 (0.1)	10 (0.3)	2.49 (0.83, 7.49)	14 (0.2)
Upper-airway cough syndrome	3 (<0.1)	8 (0.2)	2.65 (0.76, 9.21)	11 (0.1)
Rhinitis allergic	8 (0.2)	6 (0.2)	0.75 (0.27, 2.06)	14 (0.2)
Chronic obstructive pulmonary disease	11 (0.3)	5 (0.1)	0.45 (0.16, 1.24)	16 (0.2)
Epistaxis	8 (0.2)	5 (0.1)	0.62 (0.21, 1.80)	13 (0.2)
Respiratory tract congestion	5 (0.1)	5 (0.1)		10 (0.1)
Acute respiratory failure	7 (0.2)	4 (0.1)	0.57 (0.18, 1.82)	11 (0.1)
Respiratory disorder	2 (<0.1)	4 (0.1)		6 (<0.1)
Sinus congestion	9 (0.2)	4 (0.1)	0.44 (0.14, 1.35)	13 (0.2)
Dysphonia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Emphysema	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pharyngeal erythema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Pleural effusion	4 (0.1)	3 (<0.1)		7 (<0.1)
Sleep apnoea syndrome	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tachypnoea	6 (0.2)	3 (<0.1)		9 (0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Dyspnoea exertional	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pulmonary embolism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pulmonary mass	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Throat irritation	4 (0.1)	2 (<0.1)		6 (<0.1)
Atelectasis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Dry throat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lung infiltration	0	1 (<0.1)		1 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)		1 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pneumonia aspiration	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pneumothorax	0	1 (<0.1)		1 (<0.1)
Productive cough	3 (<0.1)	1 (<0.1)		4 (<0.1)
Pulmonary hypertension	0	1 (<0.1)		1 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rhonchi	0	1 (<0.1)		1 (<0.1)
Vasomotor rhinitis	0	1 (<0.1)		1 (<0.1)
Wheezing	3 (<0.1)	1 (<0.1)		4 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Nasal dryness	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Oropharyngeal discomfort	1 (<0.1)	0		1 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Reflux laryngitis	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders	235 (6.3)	243 (6.4)		478 (6.4)
Diarrhoea	80 (2.1)	64 (1.7)	0.80 (0.58, 1.10)	144 (1.9)
Nausea	50 (1.3)	55 (1.5)	1.09 (0.75, 1.60)	105 (1.4)
Gastrooesophageal reflux disease	15 (0.4)	26 (0.7)	1.73 (0.92, 3.22)	41 (0.5)
Vomiting	17 (0.5)	24 (0.6)	1.41 (0.76, 2.59)	41 (0.5)
Toothache	9 (0.2)	13 (0.3)	1.44 (0.63, 3.28)	22 (0.3)
Abdominal pain	6 (0.2)	11 (0.3)	1.82 (0.70, 4.75)	17 (0.2)
Abdominal pain upper	6 (0.2)	9 (0.2)	1.49 (0.55, 4.02)	15 (0.2)
Inguinal hernia	6 (0.2)	9 (0.2)	1.49 (0.55, 4.02)	15 (0.2)
Constipation	15 (0.4)	8 (0.2)	0.53 (0.23, 1.22)	23 (0.3)
Dental caries	10 (0.3)	8 (0.2)	0.80 (0.32, 1.95)	18 (0.2)
Colitis	2 (<0.1)	5 (0.1)		7 (<0.1)
Dyspepsia	3 (<0.1)	5 (0.1)		8 (0.1)
Gastrointestinal haemorrhage	2 (<0.1)	4 (0.1)		6 (<0.1)
Diverticulum intestinal	0	3 (<0.1)		3 (<0.1)
Flatulence	0	3 (<0.1)		3 (<0.1)
Food poisoning	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hiatus hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypoaesthesia oral	0	3 (<0.1)		3 (<0.1)
Large intestine polyp	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.1)
Umbilical hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abdominal pain lower	2 (<0.1)	2 (<0.1)		4 (<0.1)
Barrett's oesophagus	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Dysphagia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastric ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gastritis	6 (0.2)	2 (<0.1)		8 (0.1)
Gingival pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Haemorrhoids	3 (<0.1)	2 (<0.1)		5 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)
Paraesthesia oral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Small intestinal obstruction	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abdominal discomfort	5 (0.1)	1 (<0.1)		6 (<0.1)
Anorectal disorder	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Diverticulum	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry mouth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Duodenitis	0	1 (<0.1)		1 (<0.1)
Faecaloma	0	1 (<0.1)		1 (<0.1)
Faeces discoloured	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastrointestinal pain	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Intussusception	0	1 (<0.1)		1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Melaena	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	0	1 (<0.1)		1 (<0.1)
Oral disorder	0	1 (<0.1)		1 (<0.1)
Oral mucosal blistering	0	1 (<0.1)		1 (<0.1)
Oral mucosal eruption	0	1 (<0.1)		1 (<0.1)
Pancreatic cyst	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal hernia	1 (<0.1)	0		1 (<0.1)
Abdominal tenderness	1 (<0.1)	0		1 (<0.1)
Abdominal wall cyst	1 (<0.1)	0		1 (<0.1)
Anorectal discomfort	1 (<0.1)	0		1 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Colitis microscopic	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Haematochezia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Mouth haemorrhage	1 (<0.1)	0		1 (<0.1)
Obstructive pancreatitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Tooth disorder	3 (<0.1)	0		3 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Upper gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Hepatobiliary disorders	4 (0.1)	11 (0.3)		15 (0.2)
Cholelithiasis	2 (<0.1)	5 (0.1)		7 (<0.1)
Cholecystitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hepatic steatosis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic cyst	0	1 (<0.1)		1 (<0.1)
Hepatic haematoma	1 (<0.1)	0		1 (<0.1)
Hyperbilirubinaemia	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	91 (2.4)	107 (2.8)		198 (2.6)
Urticaria	9 (0.2)	15 (0.4)	1.66 (0.74, 3.70)	24 (0.3)
Rash	5 (0.1)	12 (0.3)	2.39 (0.88, 6.49)	17 (0.2)
Erythema	3 (<0.1)	11 (0.3)	3.65 (1.10, 12.14)	14 (0.2)
Dermatitis contact	13 (0.3)	8 (0.2)	0.61 (0.26, 1.44)	21 (0.3)
Pruritus	11 (0.3)	8 (0.2)	0.72 (0.30, 1.75)	19 (0.3)
Actinic keratosis	3 (<0.1)	5 (0.1)		8 (0.1)
Rash macular	4 (0.1)	5 (0.1)		9 (0.1)
Dermatitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dermatitis atopic	0	3 (<0.1)		3 (<0.1)
Hyperhidrosis	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ingrowing nail	1 (<0.1)	3 (<0.1)		4 (<0.1)
Night sweats	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dry skin	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ecchymosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Precancerous skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rash maculo-papular	0	2 (<0.1)		2 (<0.1)
Rash papular	0	2 (<0.1)		2 (<0.1)
Rash pruritic	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Skin lesion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alopecia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Decubitus ulcer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eczema nummular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Macule	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Psoriasis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin hypopigmentation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Acne	1 (<0.1)	0		1 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Cold sweat	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Eczema	3 (<0.1)	0		3 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin exfoliation	1 (<0.1)	0		1 (<0.1)
Skin ulcer	1 (<0.1)	0		1 (<0.1)
Stasis dermatitis	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	384 (10.2)	390 (10.3)		774 (10.3)
Arthralgia	122 (3.3)	131 (3.5)	1.07 (0.84, 1.36)	253 (3.4)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Myalgia	89 (2.4)	105 (2.8)	1.17 (0.89, 1.55)	194 (2.6)
Back pain	51 (1.4)	43 (1.1)	0.84 (0.56, 1.25)	94 (1.3)
Osteoarthritis	44 (1.2)	31 (0.8)	0.70 (0.45, 1.10)	75 (1.0)
Pain in extremity	29 (0.8)	27 (0.7)	0.93 (0.55, 1.55)	56 (0.7)
Musculoskeletal pain	16 (0.4)	17 (0.5)	1.06 (0.54, 2.06)	33 (0.4)
Neck pain	16 (0.4)	15 (0.4)	0.93 (0.47, 1.86)	31 (0.4)
Muscle spasms	13 (0.3)	11 (0.3)	0.84 (0.39, 1.84)	24 (0.3)
Bursitis	5 (0.1)	10 (0.3)	1.99 (0.71, 5.56)	15 (0.2)
Rotator cuff syndrome	11 (0.3)	10 (0.3)	0.90 (0.39, 2.08)	21 (0.3)
Arthritis	3 (<0.1)	8 (0.2)	2.65 (0.76, 9.21)	11 (0.1)
Musculoskeletal stiffness	3 (<0.1)	7 (0.2)	2.32 (0.66, 8.23)	10 (0.1)
Joint swelling	1 (<0.1)	6 (0.2)		7 (<0.1)
Muscular weakness	2 (<0.1)	6 (0.2)		8 (0.1)
Osteopenia	4 (0.1)	6 (0.2)		10 (0.1)
Osteoporosis	4 (0.1)	5 (0.1)		9 (0.1)
Spinal osteoarthritis	4 (0.1)	5 (0.1)		9 (0.1)
Tendonitis	10 (0.3)	5 (0.1)	0.50 (0.18, 1.39)	15 (0.2)
Flank pain	2 (<0.1)	4 (0.1)		6 (<0.1)
Periarthritis	2 (<0.1)	4 (0.1)		6 (<0.1)
Spinal stenosis	1 (<0.1)	4 (0.1)		5 (<0.1)
Trigger finger	4 (0.1)	4 (0.1)		8 (0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spondylolisthesis	0	3 (<0.1)		3 (<0.1)
Fibromyalgia	0	2 (<0.1)		2 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Muscle twitching	0	2 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	8 (0.2)	2 (<0.1)	0.25 (0.06, 1.03)	10 (0.1)
Cervical spinal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Foot deformity	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)		1 (<0.1)
Joint range of motion decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint stiffness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ligamentum flavum hypertrophy	0	1 (<0.1)		1 (<0.1)
Limb discomfort	0	1 (<0.1)		1 (<0.1)
Muscle tightness	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Pain in jaw	4 (0.1)	1 (<0.1)		5 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Spinal synovial cyst	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spondylitis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tenosynovitis stenosans	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)		1 (<0.1)
Exostosis	4 (0.1)	0		4 (<0.1)
Groin pain	2 (<0.1)	0		2 (<0.1)
Intervertebral disc protrusion	5 (0.1)	0		5 (<0.1)
Kyphosis	1 (<0.1)	0		1 (<0.1)
Limb mass	1 (<0.1)	0		1 (<0.1)
Lumbar spinal stenosis	2 (<0.1)	0		2 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Plantar fasciitis	2 (<0.1)	0		2 (<0.1)
Polyarthritis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Scoliosis	2 (<0.1)	0		2 (<0.1)
Synovial cyst	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Renal and urinary disorders	47 (1.3)	51 (1.4)		98 (1.3)
Nephrolithiasis	11 (0.3)	14 (0.4)	1.27 (0.59, 2.73)	25 (0.3)
Chronic kidney disease	5 (0.1)	5 (0.1)		10 (0.1)
Haematuria	1 (<0.1)	4 (0.1)		5 (<0.1)
Pollakiuria	2 (<0.1)	4 (0.1)		6 (<0.1)
Urinary retention	2 (<0.1)	4 (0.1)		6 (<0.1)
Acute kidney injury	8 (0.2)	3 (<0.1)	0.37 (0.11, 1.30)	11 (0.1)
Nocturia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dysuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertonic bladder	3 (<0.1)	2 (<0.1)		5 (<0.1)
Polyuria	0	2 (<0.1)		2 (<0.1)
Renal cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary incontinence	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetic nephropathy	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder spasm	2 (<0.1)	0		2 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Micturition urgency	3 (<0.1)	0		3 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)				
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	2 (<0.1)	0		2 (<0.1)
Stress urinary incontinence	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	30 (0.8)	30 (0.8)		60 (0.8)
Benign prostatic hyperplasia	10 (0.3)	7 (0.2)	0.70 (0.27, 1.77)	17 (0.2)
Prostatomegaly	3 (<0.1)	4 (0.1)		7 (<0.1)
Erectile dysfunction	2 (<0.1)	3 (<0.1)		5 (<0.1)
Breast cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ovarian cyst	0	2 (<0.1)		2 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Atrophic vulvovaginitis	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast enlargement	0	1 (<0.1)		1 (<0.1)
Breast mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Breast tenderness	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)				
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Postmenopausal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Prostatic cyst	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)		1 (<0.1)
Cervical polyp	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Ovarian mass	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Pelvic floor muscle weakness	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
Prostatitis	3 (<0.1)	0		3 (<0.1)
Pruritus genital	1 (<0.1)	0		1 (<0.1)
Vulvovaginal dryness	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	0	2 (<0.1)		2 (<0.1)
Developmental hip dysplasia	0	1 (<0.1)		1 (<0.1)
Gilbert's syndrome	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions	323 (8.6)	462 (12.3)		785 (10.4)
Fatigue	166 (4.4)	224 (5.9)	1.34 (1.10, 1.63)	390 (5.2)
Injection site pain	37 (1.0)	65 (1.7)	1.75 (1.17, 2.60)	102 (1.4)
Injection site erythema	17 (0.5)	56 (1.5)	3.28 (1.92, 5.60)	73 (1.0)
Pyrexia	26 (0.7)	44 (1.2)	1.68 (1.04, 2.72)	70 (0.9)
Chills	37 (1.0)	40 (1.1)	1.08 (0.69, 1.67)	77 (1.0)
Injection site swelling	12 (0.3)	33 (0.9)	2.74 (1.43, 5.23)	45 (0.6)
Pain	28 (0.7)	31 (0.8)	1.10 (0.67, 1.82)	59 (0.8)
Injection site pruritus	2 (<0.1)	25 (0.7)	12.44 (3.27, 47.41)	27 (0.4)
Injection site macule	1 (<0.1)	14 (0.4)	13.93 (2.34, 82.86)	15 (0.2)
Injection site urticaria	1 (<0.1)	11 (0.3)	10.95 (1.82, 65.95)	12 (0.2)
Injection site induration	7 (0.2)	10 (0.3)	1.42 (0.56, 3.61)	17 (0.2)
Injection site lymphadenopathy	2 (<0.1)	8 (0.2)	3.98 (0.96, 16.56)	10 (0.1)
Oedema peripheral	11 (0.3)	7 (0.2)	0.63 (0.25, 1.58)	18 (0.2)
Injection site rash	0	6 (0.2)		6 (<0.1)
Peripheral swelling	5 (0.1)	6 (0.2)		11 (0.1)
Chest discomfort	6 (0.2)	5 (0.1)		11 (0.1)
Injection site bruising	9 (0.2)	4 (0.1)	0.44 (0.14, 1.35)	13 (0.2)
Malaise	5 (0.1)	4 (0.1)		9 (0.1)
Asthenia	4 (0.1)	3 (<0.1)		7 (<0.1)
Axillary pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site haematoma	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Injection site haemorrhage	3 (<0.1)	2 (<0.1)		5 (<0.1)
Injection site warmth	0	2 (<0.1)		2 (<0.1)
Non-cardiac chest pain	6 (0.2)	2 (<0.1)		8 (0.1)
Precancerous condition	0	2 (<0.1)		2 (<0.1)
Vaccination site pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysplasia	0	1 (<0.1)		1 (<0.1)
Exercise tolerance decreased	0	1 (<0.1)		1 (<0.1)
Feeling abnormal	2 (<0.1)	1 (<0.1)		3 (<0.1)
Feeling hot	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Hangover	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Influenza like illness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site discolouration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site irritation	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site papule	0	1 (<0.1)		1 (<0.1)
Injection site paraesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Medical device site pain	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Swelling	0	1 (<0.1)		1 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug intolerance	1 (<0.1)	0		1 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Granuloma	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Mass	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Reactogenicity event	2 (<0.1)	0		2 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site swelling	1 (<0.1)	0		1 (<0.1)
Investigations	47 (1.3)	59 (1.6)		106 (1.4)
Blood pressure increased	12 (0.3)	11 (0.3)	0.91 (0.41, 2.02)	23 (0.3)
Blood pressure systolic increased	9 (0.2)	8 (0.2)	0.88 (0.35, 2.22)	17 (0.2)
Blood cholesterol increased	5 (0.1)	5 (0.1)		10 (0.1)
Blood creatine increased	0	2 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
C-reactive protein increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiac murmur	2 (<0.1)	2 (<0.1)		4 (<0.1)
Heart rate increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations (Cont.)				
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood testosterone decreased	0	1 (<0.1)		1 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood urine present	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
Body temperature increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 decreased	0	1 (<0.1)		1 (<0.1)
Weight decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations (Cont.)				
Liver function test abnormal	1 (<0.1)	0		1 (<0.1)
Liver function test increased	1 (<0.1)	0		1 (<0.1)
Renal function test abnormal	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Total lung capacity decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	193 (5.1)	189 (5.0)		382 (5.1)
Fall	21 (0.6)	24 (0.6)	1.14 (0.64, 2.02)	45 (0.6)
Contusion	10 (0.3)	16 (0.4)	1.59 (0.74, 3.44)	26 (0.3)
Procedural pain	19 (0.5)	15 (0.4)	0.79 (0.40, 1.53)	34 (0.5)
Skin laceration	13 (0.3)	13 (0.3)	1.00 (0.47, 2.11)	26 (0.3)
Tooth fracture	12 (0.3)	13 (0.3)	1.08 (0.50, 2.32)	25 (0.3)
Muscle strain	11 (0.3)	12 (0.3)	1.09 (0.49, 2.41)	23 (0.3)
Arthropod bite	9 (0.2)	10 (0.3)	1.11 (0.46, 2.64)	19 (0.3)
Ligament sprain	6 (0.2)	10 (0.3)	1.66 (0.63, 4.39)	16 (0.2)
Foot fracture	7 (0.2)	8 (0.2)	1.14 (0.43, 3.01)	15 (0.2)
Limb injury	7 (0.2)	7 (0.2)	1.00 (0.36, 2.72)	14 (0.2)
Meniscus injury	10 (0.3)	6 (0.2)	0.60 (0.23, 1.58)	16 (0.2)
Rib fracture	3 (<0.1)	6 (0.2)		9 (0.1)
Road traffic accident	6 (0.2)	6 (0.2)		12 (0.2)
Post-traumatic pain	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin abrasion	11 (0.3)	5 (0.1)	0.45 (0.16, 1.24)	16 (0.2)
Animal bite	3 (<0.1)	4 (0.1)		7 (<0.1)
Bone contusion	4 (0.1)	3 (<0.1)		7 (<0.1)
Facial bones fracture	0	3 (<0.1)		3 (<0.1)
Head injury	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hip fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Humerus fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Inappropriate schedule of product administration	0	3 (<0.1)		3 (<0.1)
Joint injury	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cervical vertebral fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Clavicle fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hand fracture	0	2 (<0.1)		2 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Muscle rupture	0	2 (<0.1)		2 (<0.1)
Spinal compression fracture	0	2 (<0.1)		2 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Thermal burn	0	2 (<0.1)		2 (<0.1)
Vaccination complication	1 (<0.1)	2 (<0.1)		3 (<0.1)
Wrist fracture	4 (0.1)	2 (<0.1)		6 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Arthropod sting	10 (0.3)	1 (<0.1)	0.10 (0.02, 0.60)	11 (0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Corneal abrasion	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Dental restoration failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dural tear	0	1 (<0.1)		1 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Fractured sacrum	1 (<0.1)	1 (<0.1)		2 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Injury	0	1 (<0.1)		1 (<0.1)
Joint dislocation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Multiple fractures	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Patella fracture	0	1 (<0.1)		1 (<0.1)
Pelvic fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural fever	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Procedural nausea	0	1 (<0.1)		1 (<0.1)
Procedural site reaction	0	1 (<0.1)		1 (<0.1)
Scratch	0	1 (<0.1)		1 (<0.1)
Skin wound	0	1 (<0.1)		1 (<0.1)
Sports injury	0	1 (<0.1)		1 (<0.1)
Stress fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)		1 (<0.1)
Tendon rupture	4 (0.1)	1 (<0.1)		5 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ankle fracture	4 (0.1)	0		4 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	3 (<0.1)	0		3 (<0.1)
Eye injury	2 (<0.1)	0		2 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Gingival injury	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Ligament injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ligament rupture	1 (<0.1)	0		1 (<0.1)
Lip injury	4 (0.1)	0		4 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Mallet finger	1 (<0.1)	0		1 (<0.1)
Multiple injuries	1 (<0.1)	0		1 (<0.1)
Nail injury	2 (<0.1)	0		2 (<0.1)
Periorbital haemorrhage	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Sunburn	1 (<0.1)	0		1 (<0.1)
Tendon injury	1 (<0.1)	0		1 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.2.1.3
Subject Incidence of Unsolicited TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Wound	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	1 (<0.1)		4 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4233 (28.7)	4652 (31.5)		8885 (30.1)
Number of Unsolicited Adverse Events	8382	9332		17714
Infections and infestations	934 (6.3)	758 (5.1)		1692 (5.7)
Urinary tract infection	111 (0.8)	94 (0.6)	0.85 (0.64, 1.11)	205 (0.7)
Upper respiratory tract infection	116 (0.8)	81 (0.5)	0.70 (0.53, 0.93)	197 (0.7)
Sinusitis	45 (0.3)	60 (0.4)	1.33 (0.91, 1.96)	105 (0.4)
Viral infection	50 (0.3)	38 (0.3)	0.76 (0.50, 1.15)	88 (0.3)
Rhinovirus infection	30 (0.2)	35 (0.2)	1.17 (0.72, 1.89)	65 (0.2)
Suspected COVID-19	35 (0.2)	33 (0.2)	0.94 (0.59, 1.51)	68 (0.2)
Tooth infection	18 (0.1)	25 (0.2)	1.39 (0.76, 2.52)	43 (0.1)
Tooth abscess	26 (0.2)	23 (0.2)	0.88 (0.51, 1.54)	49 (0.2)
Herpes zoster	15 (0.1)	21 (0.1)	1.40 (0.73, 2.68)	36 (0.1)
Gastroenteritis	17 (0.1)	19 (0.1)	1.12 (0.59, 2.12)	36 (0.1)
COVID-19	148 (1.0)	18 (0.1)	0.12 (0.07, 0.20)	166 (0.6)
Ear infection	10 (<0.1)	18 (0.1)	1.80 (0.85, 3.83)	28 (<0.1)
Pharyngitis	21 (0.1)	18 (0.1)	0.86 (0.46, 1.59)	39 (0.1)
Pharyngitis streptococcal	21 (0.1)	13 (<0.1)	0.62 (0.31, 1.22)	34 (0.1)
Cellulitis	16 (0.1)	12 (<0.1)	0.75 (0.36, 1.56)	28 (<0.1)
Conjunctivitis	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Hordeolum	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Oral herpes	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Viral upper respiratory tract infection	14 (<0.1)	11 (<0.1)	0.79 (0.36, 1.70)	25 (<0.1)
Diverticulitis	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Fungal infection	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Gingivitis	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Otitis media	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.33)	16 (<0.1)
Bronchitis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Herpes simplex	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Localised infection	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Onychomycosis	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Folliculitis	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Acute sinusitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Bacterial vaginosis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Otitis externa	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vulvovaginal mycotic infection	14 (<0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Abscess limb	1 (<0.1)	5 (<0.1)		6 (<0.1)
Nasopharyngitis	12 (<0.1)	5 (<0.1)	0.42 (0.15, 1.13)	17 (<0.1)
Paronychia	5 (<0.1)	5 (<0.1)		10 (<0.1)
Pneumonia	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)		9 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Enterovirus infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Laryngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Skin infection	4 (<0.1)	4 (<0.1)		8 (<0.1)
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Subcutaneous abscess	2 (<0.1)	4 (<0.1)		6 (<0.1)
Asymptomatic COVID-19	3 (<0.1)	3 (<0.1)		6 (<0.1)
Clostridium difficile infection	0	3 (<0.1)		3 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	10 (<0.1)	3 (<0.1)	0.30 (0.09, 1.01)	13 (<0.1)
Helicobacter infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Lyme disease	0	3 (<0.1)		3 (<0.1)
Staphylococcal infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Cystitis	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Otitis media acute	2 (<0.1)	2 (<0.1)		4 (<0.1)
Respiratory tract infection viral	5 (<0.1)	2 (<0.1)		7 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea pedis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Tonsillitis	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Candida infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rhinitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Tinea cruris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Wound infection	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	2 (<0.1)	0		2 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	55 (0.4)	62 (0.4)		117 (0.4)
Basal cell carcinoma	16 (0.1)	10 (<0.1)	0.62 (0.29, 1.35)	26 (<0.1)
Benign neoplasm of skin	2 (<0.1)	4 (<0.1)		6 (<0.1)
Squamous cell carcinoma	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Uterine leiomyoma	1 (<0.1)	4 (<0.1)		5 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lipoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)		5 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	143 (1.0)	289 (2.0)		432 (1.5)
Lymphadenopathy	122 (0.8)	261 (1.8)	2.14 (1.73, 2.65)	383 (1.3)
Anaemia	6 (<0.1)	10 (<0.1)	1.67 (0.63, 4.41)	16 (<0.1)
Lymph node pain	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Lymphadenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Iron deficiency anaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Blood and lymphatic system disorders (Cont.)				
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	66 (0.4)	47 (0.3)		113 (0.4)
Seasonal allergy	47 (0.3)	33 (0.2)	0.70 (0.45, 1.09)	80 (0.3)
Hypersensitivity	6 (<0.1)	6 (<0.1)		12 (<0.1)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	5 (<0.1)	1 (<0.1)		6 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	0		2 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	17 (0.1)	12 (<0.1)		29 (<0.1)
Hypothyroidism	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Endocrine disorders (Cont.)				
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	109 (0.7)	126 (0.9)		235 (0.8)
Hyperlipidaemia	21 (0.1)	22 (0.1)	1.05 (0.58, 1.89)	43 (0.1)
Type 2 diabetes mellitus	11 (<0.1)	20 (0.1)	1.82 (0.88, 3.73)	31 (0.1)
Decreased appetite	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Hypercholesterolaemia	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Vitamin D deficiency	14 (<0.1)	11 (<0.1)	0.79 (0.36, 1.70)	25 (<0.1)
Dehydration	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.58)	15 (<0.1)
Gout	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Diabetes mellitus	5 (<0.1)	6 (<0.1)		11 (<0.1)
Glucose tolerance impaired	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Hyperglycaemia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Abnormal loss of weight	0	2 (<0.1)		2 (<0.1)
Hypoglycaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypocalcaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	116 (0.8)	155 (1.1)		271 (0.9)
Anxiety	38 (0.3)	52 (0.4)	1.37 (0.90, 2.07)	90 (0.3)
Depression	29 (0.2)	33 (0.2)	1.14 (0.69, 1.86)	62 (0.2)
Insomnia	24 (0.2)	32 (0.2)	1.33 (0.79, 2.25)	56 (0.2)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)
Panic attack	3 (<0.1)	4 (<0.1)		7 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)		4 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress	1 (<0.1)	2 (<0.1)		3 (<0.1)
Suicidal ideation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders (Cont.)				
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Libido decreased	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	3 (<0.1)	0		3 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders (Cont.)				
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	849 (5.8)	984 (6.7)		1833 (6.2)
Headache	660 (4.5)	722 (4.9)	1.09 (0.99, 1.21)	1382 (4.7)
Dizziness	55 (0.4)	72 (0.5)	1.31 (0.92, 1.85)	127 (0.4)
Paraesthesia	26 (0.2)	34 (0.2)	1.31 (0.79, 2.16)	60 (0.2)
Sinus headache	6 (<0.1)	20 (0.1)	3.33 (1.38, 8.06)	26 (<0.1)
Ageusia	10 (<0.1)	15 (0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Migraine	22 (0.1)	14 (<0.1)	0.64 (0.33, 1.23)	36 (0.1)
Dysgeusia	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Hypoaesthesia	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Syncope	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Sciatica	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Anosmia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Cervical radiculopathy	1 (<0.1)	8 (<0.1)	8.00 (1.30, 49.24)	9 (<0.1)
Tension headache	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Hyperaesthesia	0	6 (<0.1)		6 (<0.1)
Presyncope	14 (<0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Carpal tunnel syndrome	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Memory impairment	0	4 (<0.1)		4 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Burning sensation	0	3 (<0.1)		3 (<0.1)
Cerebrovascular accident	0	3 (<0.1)		3 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Nerve compression	3 (<0.1)	3 (<0.1)		6 (<0.1)
Peripheral sensory neuropathy	0	3 (<0.1)		3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	3 (<0.1)		5 (<0.1)
Amnesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neuropathy peripheral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Parosmia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic headache	1 (<0.1)	2 (<0.1)		3 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	3 (<0.1)	0		3 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	67 (0.5)	69 (0.5)		136 (0.5)
Eye irritation	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Eye pruritus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Vision blurred	3 (<0.1)	5 (<0.1)		8 (<0.1)
Dry eye	6 (<0.1)	4 (<0.1)		10 (<0.1)
Eye pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Eye inflammation	0	3 (<0.1)		3 (<0.1)
Glaucoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Retinal detachment	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blepharitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular hyperaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Vitreous floaters	2 (<0.1)	2 (<0.1)		4 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cataract	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Visual impairment	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	79 (0.5)	78 (0.5)		157 (0.5)
Vertigo	18 (0.1)	22 (0.1)	1.22 (0.66, 2.25)	40 (0.1)
Ear pain	18 (0.1)	17 (0.1)	0.94 (0.49, 1.81)	35 (0.1)
Tinnitus	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Ear and labyrinth disorders (Cont.)				
Vertigo positional	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Ear discomfort	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Cerumen impaction	2 (<0.1)	3 (<0.1)		5 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ear canal erythema	4 (<0.1)	2 (<0.1)		6 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ear congestion	4 (<0.1)	1 (<0.1)		5 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniere's disease	0	1 (<0.1)		1 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tympanic membrane perforation	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	74 (0.5)	77 (0.5)		151 (0.5)
Tachycardia	9 (<0.1)	15 (0.1)	1.67 (0.75, 3.72)	24 (<0.1)
Bradycardia	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Atrial fibrillation	11 (<0.1)	12 (<0.1)	1.09 (0.49, 2.42)	23 (<0.1)
Palpitations	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.33)	16 (<0.1)
Angina pectoris	4 (<0.1)	4 (<0.1)		8 (<0.1)
Arrhythmia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Cardiac failure congestive	4 (<0.1)	3 (<0.1)		7 (<0.1)
Coronary artery disease	4 (<0.1)	3 (<0.1)		7 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Sinus tachycardia	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Atrial flutter	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)		4 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	199 (1.3)	193 (1.3)		392 (1.3)
Hypertension	157 (1.1)	148 (1.0)	0.94 (0.75, 1.18)	305 (1.0)
Hot flush	8 (<0.1)	15 (0.1)	1.87 (0.81, 4.31)	23 (<0.1)
Flushing	5 (<0.1)	6 (<0.1)		11 (<0.1)
Haematoma	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hypertensive urgency	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hypotension	4 (<0.1)	4 (<0.1)		8 (<0.1)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Orthostatic hypotension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	654 (4.4)	588 (4.0)		1242 (4.2)
Cough	163 (1.1)	174 (1.2)	1.07 (0.86, 1.32)	337 (1.1)
Oropharyngeal pain	229 (1.6)	155 (1.1)	0.68 (0.55, 0.83)	384 (1.3)
Nasal congestion	161 (1.1)	148 (1.0)	0.92 (0.74, 1.15)	309 (1.0)
Rhinorrhoea	142 (1.0)	127 (0.9)	0.89 (0.70, 1.13)	269 (0.9)
Dyspnoea	40 (0.3)	42 (0.3)	1.05 (0.68, 1.61)	82 (0.3)
Tachypnoea	31 (0.2)	33 (0.2)	1.06 (0.66, 1.73)	64 (0.2)
Respiratory tract congestion	7 (<0.1)	17 (0.1)	2.43 (1.03, 5.70)	24 (<0.1)
Asthma	17 (0.1)	16 (0.1)	0.94 (0.48, 1.84)	33 (0.1)
Sinus congestion	25 (0.2)	16 (0.1)	0.64 (0.35, 1.19)	41 (0.1)
Throat irritation	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Epistaxis	10 (<0.1)	15 (0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Rhinitis allergic	15 (0.1)	12 (<0.1)	0.80 (0.38, 1.68)	27 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Upper-airway cough syndrome	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Sneezing	14 (<0.1)	10 (<0.1)	0.71 (0.32, 1.57)	24 (<0.1)
Chronic obstructive pulmonary disease	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Dysphonia	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Sinus pain	4 (<0.1)	5 (<0.1)		9 (<0.1)
Dry throat	3 (<0.1)	4 (<0.1)		7 (<0.1)
Dyspnoea exertional	1 (<0.1)	4 (<0.1)		5 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)		7 (<0.1)
Pharyngeal erythema	3 (<0.1)	4 (<0.1)		7 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Pleural effusion	4 (<0.1)	3 (<0.1)		7 (<0.1)
Productive cough	6 (<0.1)	3 (<0.1)		9 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)
Wheezing	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory failure	0	2 (<0.1)		2 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	4 (<0.1)	1 (<0.1)		5 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080301.sas 10JUN2021 12:56

Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders	555 (3.8)	590 (4.0)		1145 (3.9)
Diarrhoea	197 (1.3)	199 (1.3)	1.01 (0.83, 1.23)	396 (1.3)
Nausea	161 (1.1)	161 (1.1)	1.00 (0.80, 1.24)	322 (1.1)
Vomiting	51 (0.3)	62 (0.4)	1.21 (0.84, 1.75)	113 (0.4)
Gastrooesophageal reflux disease	26 (0.2)	39 (0.3)	1.50 (0.92, 2.45)	65 (0.2)
Toothache	28 (0.2)	35 (0.2)	1.25 (0.76, 2.04)	63 (0.2)
Abdominal pain	19 (0.1)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.2)
Constipation	20 (0.1)	16 (0.1)	0.80 (0.42, 1.52)	36 (0.1)
Dental caries	11 (<0.1)	15 (0.1)	1.36 (0.64, 2.91)	26 (<0.1)
Dyspepsia	15 (0.1)	14 (<0.1)	0.93 (0.46, 1.90)	29 (<0.1)
Abdominal pain upper	20 (0.1)	13 (<0.1)	0.65 (0.33, 1.29)	33 (0.1)
Food poisoning	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Abdominal pain lower	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Abdominal discomfort	13 (<0.1)	6 (<0.1)	0.46 (0.18, 1.17)	19 (<0.1)
Colitis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Haemorrhoids	4 (<0.1)	5 (<0.1)		9 (<0.1)
Abdominal distension	2 (<0.1)	4 (<0.1)		6 (<0.1)
Gastric ulcer	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hiatus hernia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Inguinal hernia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Flatulence	2 (<0.1)	3 (<0.1)		5 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080301.sas 10JUN2021 12:56

Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)		4 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Large intestine polyp	5 (<0.1)	3 (<0.1)		8 (<0.1)
Paraesthesia oral	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tooth impacted	2 (<0.1)	3 (<0.1)		5 (<0.1)
Umbilical hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)		5 (<0.1)
Dysphagia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastritis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastrointestinal disorder	0	2 (<0.1)		2 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)		4 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)
Proctalgia	0	2 (<0.1)		2 (<0.1)
Rectal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small intestinal obstruction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	5 (<0.1)	0		5 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	4 (<0.1)	13 (<0.1)		17 (<0.1)
Cholelithiasis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Hepatic steatosis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	226 (1.5)	283 (1.9)		509 (1.7)
Urticaria	31 (0.2)	41 (0.3)	1.32 (0.83, 2.10)	72 (0.2)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash	29 (0.2)	34 (0.2)	1.17 (0.72, 1.91)	63 (0.2)
Dermatitis contact	30 (0.2)	24 (0.2)	0.80 (0.47, 1.36)	54 (0.2)
Pruritus	23 (0.2)	24 (0.2)	1.04 (0.59, 1.83)	47 (0.2)
Erythema	4 (<0.1)	15 (0.1)	3.75 (1.31, 10.75)	19 (<0.1)
Hyperhidrosis	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Eczema	3 (<0.1)	10 (<0.1)	3.33 (0.99, 11.22)	13 (<0.1)
Night sweats	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Acne	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Rash maculo-papular	2 (<0.1)	8 (<0.1)	4.00 (0.96, 16.63)	10 (<0.1)
Rash papular	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Alopecia	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Dermatitis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Actinic keratosis	2 (<0.1)	6 (<0.1)		8 (<0.1)
Rash macular	3 (<0.1)	6 (<0.1)		9 (<0.1)
Dermatitis atopic	6 (<0.1)	5 (<0.1)		11 (<0.1)
Psoriasis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Rash pruritic	6 (<0.1)	5 (<0.1)		11 (<0.1)
Ecchymosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)
Rosacea	2 (<0.1)	4 (<0.1)		6 (<0.1)
Blister	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dry skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hidradenitis	0	3 (<0.1)		3 (<0.1)
Macule	0	3 (<0.1)		3 (<0.1)
Pain of skin	0	3 (<0.1)		3 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Angioedema	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hand dermatitis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Rash erythematous	3 (<0.1)	2 (<0.1)		5 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Papule	2 (<0.1)	1 (<0.1)		3 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	4 (<0.1)	0		4 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	987 (6.7)	988 (6.7)		1975 (6.7)
Arthralgia	378 (2.6)	385 (2.6)	1.02 (0.88, 1.17)	763 (2.6)
Myalgia	374 (2.5)	378 (2.6)	1.01 (0.88, 1.16)	752 (2.5)
Back pain	126 (0.9)	103 (0.7)	0.82 (0.63, 1.06)	229 (0.8)
Pain in extremity	76 (0.5)	65 (0.4)	0.85 (0.62, 1.19)	141 (0.5)
Musculoskeletal pain	34 (0.2)	49 (0.3)	1.44 (0.93, 2.22)	83 (0.3)
Neck pain	35 (0.2)	45 (0.3)	1.28 (0.83, 1.99)	80 (0.3)
Muscle spasms	29 (0.2)	34 (0.2)	1.17 (0.72, 1.91)	63 (0.2)
Osteoarthritis	28 (0.2)	23 (0.2)	0.82 (0.48, 1.41)	51 (0.2)
Musculoskeletal chest pain	14 (<0.1)	15 (0.1)	1.07 (0.52, 2.18)	29 (<0.1)
Tendonitis	13 (<0.1)	15 (0.1)	1.15 (0.56, 2.38)	28 (<0.1)
Bursitis	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Musculoskeletal stiffness	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rotator cuff syndrome	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Arthritis	3 (<0.1)	9 (<0.1)	3.00 (0.88, 10.24)	12 (<0.1)
Intervertebral disc protrusion	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Trigger finger	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Groin pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Joint swelling	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Muscular weakness	2 (<0.1)	6 (<0.1)		8 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Muscle tightness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Costochondritis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Fibromyalgia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Osteoporosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pain in jaw	6 (<0.1)	4 (<0.1)		10 (<0.1)
Spinal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Spinal stenosis	0	4 (<0.1)		4 (<0.1)
Flank pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Limb discomfort	2 (<0.1)	3 (<0.1)		5 (<0.1)
Muscle twitching	2 (<0.1)	3 (<0.1)		5 (<0.1)
Neck mass	0	3 (<0.1)		3 (<0.1)
Spinal osteoarthritis	3 (<0.1)	3 (<0.1)		6 (<0.1)

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MedDRA version 23.0.
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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Axillary mass	2 (<0.1)	2 (<0.1)		4 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Plantar fasciitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	4 (<0.1)	1 (<0.1)		5 (<0.1)
Joint stiffness	3 (<0.1)	1 (<0.1)		4 (<0.1)
Limb mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	3 (<0.1)	0		3 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Torticollis	2 (<0.1)	0		2 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	43 (0.3)	49 (0.3)		92 (0.3)
Nephrolithiasis	20 (0.1)	14 (<0.1)	0.70 (0.36, 1.37)	34 (0.1)
Dysuria	1 (<0.1)	4 (<0.1)		5 (<0.1)
Haematuria	6 (<0.1)	3 (<0.1)		9 (<0.1)
Pollakiuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Polyuria	0	3 (<0.1)		3 (<0.1)
Acute kidney injury	4 (<0.1)	2 (<0.1)		6 (<0.1)
Chronic kidney disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertonic bladder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nocturia	0	2 (<0.1)		2 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary incontinence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary retention	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders (Cont.)				
Chromaturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Micturition urgency	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	59 (0.4)	61 (0.4)		120 (0.4)
Benign prostatic hyperplasia	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Dysmenorrhoea	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Erectile dysfunction	3 (<0.1)	5 (<0.1)		8 (<0.1)
Pelvic pain	1 (<0.1)	4 (<0.1)		5 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Prostatitis	6 (<0.1)	3 (<0.1)		9 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Menopausal symptoms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Menstruation irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1036 (7.0)	1577 (10.7)		2613 (8.9)
Fatigue	645 (4.4)	739 (5.0)	1.15 (1.03, 1.27)	1384 (4.7)
Injection site pain	114 (0.8)	252 (1.7)	2.21 (1.77, 2.75)	366 (1.2)
Injection site erythema	39 (0.3)	155 (1.1)	3.97 (2.80, 5.63)	194 (0.7)
Chills	108 (0.7)	129 (0.9)	1.19 (0.93, 1.54)	237 (0.8)
Pyrexia	62 (0.4)	116 (0.8)	1.87 (1.38, 2.54)	178 (0.6)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Injection site swelling	29 (0.2)	114 (0.8)	3.93 (2.62, 5.89)	143 (0.5)
Injection site pruritus	13 (<0.1)	88 (0.6)	6.77 (3.81, 12.01)	101 (0.3)
Pain	65 (0.4)	71 (0.5)	1.09 (0.78, 1.52)	136 (0.5)
Injection site lymphadenopathy	15 (0.1)	65 (0.4)	4.33 (2.49, 7.54)	80 (0.3)
Injection site induration	18 (0.1)	51 (0.3)	2.83 (1.67, 4.81)	69 (0.2)
Injection site macule	4 (<0.1)	45 (0.3)	11.24 (4.21, 30.03)	49 (0.2)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.98 (6.58, 219.09)	39 (0.1)
Axillary pain	14 (<0.1)	26 (0.2)	1.86 (0.98, 3.51)	40 (0.1)
Injection site rash	1 (<0.1)	24 (0.2)	23.99 (4.12, 139.83)	25 (<0.1)
Injection site bruising	20 (0.1)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.1)
Malaise	10 (<0.1)	15 (0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	12.99 (2.18, 77.55)	14 (<0.1)
Chest discomfort	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Peripheral swelling	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Chest pain	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Non-cardiac chest pain	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Reactogenicity event	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haemorrhage	5 (<0.1)	6 (<0.1)		11 (<0.1)
Injection site paraesthesia	3 (<0.1)	6 (<0.1)		9 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Feeling abnormal	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Oedema peripheral	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Vaccination site pain	3 (<0.1)	5 (<0.1)		8 (<0.1)
Feeling hot	3 (<0.1)	4 (<0.1)		7 (<0.1)
Injection site mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site reaction	0	3 (<0.1)		3 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Swelling face	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Asthenia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080301.sas 10JUN2021 12:56

Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Hangover	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Discomfort	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)
Investigations	75 (0.5)	103 (0.7)		178 (0.6)
Blood pressure increased	27 (0.2)	24 (0.2)	0.89 (0.52, 1.53)	51 (0.2)
Blood pressure systolic increased	7 (<0.1)	15 (0.1)	2.14 (0.90, 5.11)	22 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	10 (<0.1)	5.00 (1.23, 20.28)	12 (<0.1)
Body temperature increased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood cholesterol increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hepatic enzyme increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Transaminases increased	0	4 (<0.1)		4 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood triglycerides increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Heart rate increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Blood glucose increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Weight decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Vitamin D decreased	2 (<0.1)	0		2 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	391 (2.7)	325 (2.2)		716 (2.4)
Muscle strain	35 (0.2)	39 (0.3)	1.11 (0.71, 1.75)	74 (0.3)
Ligament sprain	27 (0.2)	29 (0.2)	1.07 (0.64, 1.80)	56 (0.2)
Arthropod bite	31 (0.2)	24 (0.2)	0.77 (0.46, 1.31)	55 (0.2)
Skin laceration	32 (0.2)	23 (0.2)	0.72 (0.42, 1.22)	55 (0.2)
Contusion	28 (0.2)	20 (0.1)	0.71 (0.41, 1.26)	48 (0.2)
Fall	27 (0.2)	20 (0.1)	0.74 (0.42, 1.31)	47 (0.2)
Procedural pain	31 (0.2)	17 (0.1)	0.55 (0.31, 0.98)	48 (0.2)
Tooth fracture	17 (0.1)	17 (0.1)	1.00 (0.52, 1.93)	34 (0.1)
Foot fracture	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Limb injury	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.57)	20 (<0.1)
Road traffic accident	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Skin abrasion	22 (0.1)	11 (<0.1)	0.50 (0.25, 1.01)	33 (0.1)
Arthropod sting	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (<0.1)
Joint injury	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Animal bite	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Post-traumatic pain	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Concussion	3 (<0.1)	5 (<0.1)		8 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Hand fracture	3 (<0.1)	5 (<0.1)		8 (<0.1)
Meniscus injury	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Rib fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Wrist fracture	4 (<0.1)	4 (<0.1)		8 (<0.1)
Bone contusion	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Epicondylitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Head injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Tendon rupture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Thermal burn	3 (<0.1)	3 (<0.1)		6 (<0.1)
Upper limb fracture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Ankle fracture	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Back injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	2 (<0.1)	1 (<0.1)		3 (<0.1)
Wound	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	2 (<0.1)	0		2 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Lip injury	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Product issues	3 (<0.1)	5 (<0.1)		8 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	92 (27.3)	77 (22.2)		169 (24.7)
Number of Unsolicited Adverse Events	193	170		363
Infections and infestations	16 (4.7)	19 (5.5)		35 (5.1)
COVID-19	8 (2.4)	4 (1.2)	0.49 (0.16, 1.50)	12 (1.8)
Viral infection	2 (0.6)	3 (0.9)		5 (0.7)
Asymptomatic COVID-19	0	2 (0.6)		2 (0.3)
Paronychia	0	2 (0.6)		2 (0.3)
Cystitis	0	1 (0.3)		1 (0.1)
Herpes zoster	0	1 (0.3)		1 (0.1)
Otitis externa	0	1 (0.3)		1 (0.1)
Rhinovirus infection	0	1 (0.3)		1 (0.1)
Sinusitis	1 (0.3)	1 (0.3)		2 (0.3)
Subcutaneous abscess	0	1 (0.3)		1 (0.1)
Suspected COVID-19	0	1 (0.3)		1 (0.1)
Upper respiratory tract infection	2 (0.6)	1 (0.3)		3 (0.4)
Vaginal infection	0	1 (0.3)		1 (0.1)
Bacterial vaginosis	1 (0.3)	0		1 (0.1)
Cellulitis	1 (0.3)	0		1 (0.1)
Folliculitis	1 (0.3)	0		1 (0.1)
Pyelonephritis acute	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Infections and infestations (Cont.)				
Septic shock	1 (0.3)	0		1 (0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.3)	0		1 (0.1)
Prostate cancer recurrent	1 (0.3)	0		1 (0.1)
Blood and lymphatic system disorders	5 (1.5)	3 (0.9)		8 (1.2)
Lymphadenopathy	5 (1.5)	3 (0.9)		8 (1.2)
Metabolism and nutrition disorders	4 (1.2)	1 (0.3)		5 (0.7)
Hyperlipidaemia	0	1 (0.3)		1 (0.1)
Type 2 diabetes mellitus	0	1 (0.3)		1 (0.1)
Vitamin D deficiency	0	1 (0.3)		1 (0.1)
Dehydration	1 (0.3)	0		1 (0.1)
Hypercholesterolaemia	1 (0.3)	0		1 (0.1)
Increased appetite	1 (0.3)	0		1 (0.1)
Metabolic acidosis	1 (0.3)	0		1 (0.1)
Psychiatric disorders	0	3 (0.9)		3 (0.4)
Depression	0	1 (0.3)		1 (0.1)
Drug abuse	0	1 (0.3)		1 (0.1)
Libido decreased	0	1 (0.3)		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Psychiatric disorders (Cont.)				
Premature ejaculation	0	1 (0.3)		1 (0.1)
Nervous system disorders	28 (8.3)	21 (6.1)		49 (7.2)
Headache	23 (6.8)	19 (5.5)	0.80 (0.45, 1.43)	42 (6.1)
Dizziness	1 (0.3)	2 (0.6)		3 (0.4)
Hypoaesthesia	0	1 (0.3)		1 (0.1)
Migraine	2 (0.6)	1 (0.3)		3 (0.4)
Sciatica	0	1 (0.3)		1 (0.1)
Dysgeusia	1 (0.3)	0		1 (0.1)
Paraesthesia	1 (0.3)	0		1 (0.1)
Parosmia	1 (0.3)	0		1 (0.1)
Somnolence	1 (0.3)	0		1 (0.1)
Eye disorders	0	1 (0.3)		1 (0.1)
Vision blurred	0	1 (0.3)		1 (0.1)
Ear and labyrinth disorders	4 (1.2)	1 (0.3)		5 (0.7)
Cerumen impaction	0	1 (0.3)		1 (0.1)
Ear pruritus	1 (0.3)	0		1 (0.1)
Tinnitus	2 (0.6)	0		2 (0.3)
Tympanic membrane perforation	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Cardiac disorders	1 (0.3)	2 (0.6)		3 (0.4)
Angina pectoris	0	1 (0.3)		1 (0.1)
Cardiac failure congestive	0	1 (0.3)		1 (0.1)
Acute left ventricular failure	1 (0.3)	0		1 (0.1)
Atrial fibrillation	1 (0.3)	0		1 (0.1)
Vascular disorders	4 (1.2)	3 (0.9)		7 (1.0)
Hypertension	3 (0.9)	3 (0.9)		6 (0.9)
Aortic dilatation	1 (0.3)	0		1 (0.1)
Respiratory, thoracic and mediastinal disorders	12 (3.6)	12 (3.5)		24 (3.5)
Nasal congestion	4 (1.2)	6 (1.7)		10 (1.5)
Cough	2 (0.6)	3 (0.9)		5 (0.7)
Rhinorrhoea	3 (0.9)	3 (0.9)		6 (0.9)
Oropharyngeal pain	3 (0.9)	2 (0.6)		5 (0.7)
Dyspnoea	1 (0.3)	1 (0.3)		2 (0.3)
Epistaxis	1 (0.3)	1 (0.3)		2 (0.3)
Pharyngeal erythema	0	1 (0.3)		1 (0.1)
Productive cough	0	1 (0.3)		1 (0.1)
Respiratory tract congestion	0	1 (0.3)		1 (0.1)
Acute respiratory failure	1 (0.3)	0		1 (0.1)
Haemoptysis	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Sinus congestion	1 (0.3)	0		1 (0.1)
Gastrointestinal disorders	9 (2.7)	6 (1.7)		15 (2.2)
Diarrhoea	1 (0.3)	3 (0.9)		4 (0.6)
Gastrooesophageal reflux disease	3 (0.9)	2 (0.6)		5 (0.7)
Abdominal pain upper	0	1 (0.3)		1 (0.1)
Gastric ulcer	0	1 (0.3)		1 (0.1)
Nausea	2 (0.6)	1 (0.3)		3 (0.4)
Oesophageal ulcer	0	1 (0.3)		1 (0.1)
Abdominal pain	1 (0.3)	0		1 (0.1)
Dyspepsia	1 (0.3)	0		1 (0.1)
Gastritis	1 (0.3)	0		1 (0.1)
Hepatobiliary disorders	1 (0.3)	0		1 (0.1)
Cholelithiasis	1 (0.3)	0		1 (0.1)
Skin and subcutaneous tissue disorders	8 (2.4)	10 (2.9)		18 (2.6)
Urticaria	2 (0.6)	3 (0.9)		5 (0.7)
Hyperhidrosis	0	2 (0.6)		2 (0.3)
Acne	1 (0.3)	1 (0.3)		2 (0.3)
Dermatitis	0	1 (0.3)		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ecchymosis	0	1 (0.3)		1 (0.1)
Rash	1 (0.3)	1 (0.3)		2 (0.3)
Rash macular	0	1 (0.3)		1 (0.1)
Blister	1 (0.3)	0		1 (0.1)
Dermatitis contact	1 (0.3)	0		1 (0.1)
Erythema	1 (0.3)	0		1 (0.1)
Night sweats	1 (0.3)	0		1 (0.1)
Musculoskeletal and connective tissue disorders	28 (8.3)	16 (4.6)		44 (6.4)
Myalgia	12 (3.6)	9 (2.6)	0.73 (0.32, 1.67)	21 (3.1)
Arthralgia	10 (3.0)	6 (1.7)	0.58 (0.22, 1.53)	16 (2.3)
Back pain	4 (1.2)	2 (0.6)		6 (0.9)
Limb discomfort	0	2 (0.6)		2 (0.3)
Muscle spasms	0	1 (0.3)		1 (0.1)
Muscle tightness	0	1 (0.3)		1 (0.1)
Neck pain	3 (0.9)	1 (0.3)		4 (0.6)
Pain in extremity	1 (0.3)	1 (0.3)		2 (0.3)
Arthritis	1 (0.3)	0		1 (0.1)
Axillary mass	1 (0.3)	0		1 (0.1)
Muscle twitching	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Musculoskeletal pain	4 (1.2)	0		4 (0.6)
Musculoskeletal stiffness	1 (0.3)	0		1 (0.1)
Plantar fasciitis	1 (0.3)	0		1 (0.1)
Rotator cuff syndrome	1 (0.3)	0		1 (0.1)
Spinal stenosis	1 (0.3)	0		1 (0.1)
Renal and urinary disorders	3 (0.9)	1 (0.3)		4 (0.6)
Dysuria	0	1 (0.3)		1 (0.1)
Chromaturia	1 (0.3)	0		1 (0.1)
Micturition urgency	1 (0.3)	0		1 (0.1)
Nephrolithiasis	1 (0.3)	0		1 (0.1)
Renal colic	1 (0.3)	0		1 (0.1)
General disorders and administration site conditions	24 (7.1)	22 (6.3)		46 (6.7)
Fatigue	17 (5.0)	10 (2.9)	0.57 (0.27, 1.21)	27 (3.9)
Injection site pain	3 (0.9)	3 (0.9)		6 (0.9)
Chills	3 (0.9)	2 (0.6)		5 (0.7)
Feeling hot	0	2 (0.6)		2 (0.3)
Injection site erythema	0	2 (0.6)		2 (0.3)
Injection site induration	0	2 (0.6)		2 (0.3)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
General disorders and administration site conditions (Cont.)				
Chest pain	0	1 (0.3)		1 (0.1)
Hangover	0	1 (0.3)		1 (0.1)
Injection site bruising	1 (0.3)	1 (0.3)		2 (0.3)
Injection site swelling	0	1 (0.3)		1 (0.1)
Oedema peripheral	0	1 (0.3)		1 (0.1)
Pyrexia	0	1 (0.3)		1 (0.1)
Swelling face	0	1 (0.3)		1 (0.1)
Non-cardiac chest pain	1 (0.3)	0		1 (0.1)
Pain	1 (0.3)	0		1 (0.1)
Investigations	4 (1.2)	4 (1.2)		8 (1.2)
Blood glucose increased	0	1 (0.3)		1 (0.1)
Blood pressure increased	0	1 (0.3)		1 (0.1)
Blood pressure systolic abnormal	0	1 (0.3)		1 (0.1)
Heart rate increased	0	1 (0.3)		1 (0.1)
Blood pressure systolic increased	1 (0.3)	0		1 (0.1)
Heart rate irregular	1 (0.3)	0		1 (0.1)
Hepatic enzyme increased	1 (0.3)	0		1 (0.1)
International normalised ratio increased	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Injury, poisoning and procedural complications	6 (1.8)	4 (1.2)		10 (1.5)
Fall	0	1 (0.3)		1 (0.1)
Head injury	0	1 (0.3)		1 (0.1)
Ligament sprain	2 (0.6)	1 (0.3)		3 (0.4)
Road traffic accident	0	1 (0.3)		1 (0.1)
Animal bite	1 (0.3)	0		1 (0.1)
Concussion	1 (0.3)	0		1 (0.1)
Contusion	1 (0.3)	0		1 (0.1)
Epicondylitis	1 (0.3)	0		1 (0.1)
Procedural anxiety	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	13 (15.5)	23 (26.4)		36 (21.1)
Number of Unsolicited Adverse Events	24	39		63
Infections and infestations	2 (2.4)	6 (6.9)		8 (4.7)
Conjunctivitis	0	1 (1.1)		1 (0.6)
Herpes simplex	0	1 (1.1)		1 (0.6)
Lyme disease	0	1 (1.1)		1 (0.6)
Pharyngitis	0	1 (1.1)		1 (0.6)
Staphylococcal infection	0	1 (1.1)		1 (0.6)
Tooth infection	0	1 (1.1)		1 (0.6)
Sinusitis bacterial	1 (1.2)	0		1 (0.6)
Urinary tract infection	1 (1.2)	0		1 (0.6)
Metabolism and nutrition disorders	0	1 (1.1)		1 (0.6)
Hypercholesterolaemia	0	1 (1.1)		1 (0.6)
Psychiatric disorders	0	1 (1.1)		1 (0.6)
Depression	0	1 (1.1)		1 (0.6)
Nervous system disorders	4 (4.8)	3 (3.4)		7 (4.1)
Headache	4 (4.8)	3 (3.4)		7 (4.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Ear and labyrinth disorders	0	2 (2.3)		2 (1.2)
Meniere's disease	0	1 (1.1)		1 (0.6)
Vertigo	0	1 (1.1)		1 (0.6)
Vascular disorders	1 (1.2)	2 (2.3)		3 (1.8)
Hypertension	1 (1.2)	2 (2.3)		3 (1.8)
Respiratory, thoracic and mediastinal disorders	1 (1.2)	3 (3.4)		4 (2.3)
Nasal congestion	0	1 (1.1)		1 (0.6)
Oropharyngeal pain	0	1 (1.1)		1 (0.6)
Sneezing	0	1 (1.1)		1 (0.6)
Tachypnoea	1 (1.2)	0		1 (0.6)
Gastrointestinal disorders	3 (3.6)	3 (3.4)		6 (3.5)
Diarrhoea	1 (1.2)	2 (2.3)		3 (1.8)
Inguinal hernia	0	1 (1.1)		1 (0.6)
Constipation	1 (1.2)	0		1 (0.6)
Nausea	1 (1.2)	0		1 (0.6)
Vomiting	2 (2.4)	0		2 (1.2)
Skin and subcutaneous tissue disorders	1 (1.2)	2 (2.3)		3 (1.8)
Pruritus	0	1 (1.1)		1 (0.6)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash erythematous	0	1 (1.1)		1 (0.6)
Rash	1 (1.2)	0		1 (0.6)
Musculoskeletal and connective tissue disorders	2 (2.4)	3 (3.4)		5 (2.9)
Back pain	0	1 (1.1)		1 (0.6)
Pain in extremity	0	1 (1.1)		1 (0.6)
Torticollis	0	1 (1.1)		1 (0.6)
Arthralgia	1 (1.2)	0		1 (0.6)
Myalgia	2 (2.4)	0		2 (1.2)
General disorders and administration site conditions	5 (6.0)	7 (8.0)		12 (7.0)
Fatigue	4 (4.8)	3 (3.4)		7 (4.1)
Injection site pain	1 (1.2)	3 (3.4)		4 (2.3)
Injection site lymphadenopathy	0	1 (1.1)		1 (0.6)
Pain	0	1 (1.1)		1 (0.6)
Pyrexia	0	1 (1.1)		1 (0.6)
Investigations	1 (1.2)	0		1 (0.6)
Blood pressure systolic increased	1 (1.2)	0		1 (0.6)

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Table 14.3.1.8.3.1
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Injury, poisoning and procedural complications	0	2 (2.3)		2 (1.2)
Meniscus injury	0	1 (1.1)		1 (0.6)
Procedural pain	0	1 (1.1)		1 (0.6)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6359 (43.1)	6175 (41.9)		12534 (42.5)
Number of Unsolicited Adverse Events	14896	14530		29426
Infections and infestations	2491 (16.9)	1677 (11.4)		4168 (14.1)
Upper respiratory tract infection	306 (2.1)	257 (1.7)	0.84 (0.71, 0.99)	563 (1.9)
Urinary tract infection	200 (1.4)	170 (1.2)	0.85 (0.69, 1.04)	370 (1.3)
Viral infection	156 (1.1)	159 (1.1)	1.02 (0.82, 1.27)	315 (1.1)
Sinusitis	119 (0.8)	129 (0.9)	1.08 (0.85, 1.39)	248 (0.8)
Suspected COVID-19	124 (0.8)	129 (0.9)	1.04 (0.81, 1.33)	253 (0.9)
COVID-19	966 (6.6)	82 (0.6)	0.08 (0.07, 0.11)	1048 (3.6)
Rhinovirus infection	74 (0.5)	82 (0.6)	1.11 (0.81, 1.51)	156 (0.5)
Herpes zoster	21 (0.1)	49 (0.3)	2.33 (1.41, 3.87)	70 (0.2)
Viral upper respiratory tract infection	39 (0.3)	41 (0.3)	1.05 (0.68, 1.62)	80 (0.3)
Tooth infection	36 (0.2)	35 (0.2)	0.97 (0.61, 1.54)	71 (0.2)
Tooth abscess	45 (0.3)	34 (0.2)	0.76 (0.49, 1.17)	79 (0.3)
Gastroenteritis	39 (0.3)	31 (0.2)	0.79 (0.50, 1.27)	70 (0.2)
Pharyngitis	32 (0.2)	31 (0.2)	0.97 (0.59, 1.58)	63 (0.2)
Ear infection	25 (0.2)	30 (0.2)	1.20 (0.71, 2.03)	55 (0.2)
Cellulitis	35 (0.2)	28 (0.2)	0.80 (0.49, 1.31)	63 (0.2)
Bronchitis	33 (0.2)	25 (0.2)	0.76 (0.45, 1.27)	58 (0.2)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Pharyngitis streptococcal	38 (0.3)	24 (0.2)	0.63 (0.38, 1.05)	62 (0.2)
Hordeolum	27 (0.2)	23 (0.2)	0.85 (0.49, 1.47)	50 (0.2)
Otitis media	19 (0.1)	21 (0.1)	1.10 (0.60, 2.03)	40 (0.1)
Conjunctivitis	23 (0.2)	19 (0.1)	0.83 (0.45, 1.50)	42 (0.1)
Diverticulitis	21 (0.1)	18 (0.1)	0.86 (0.46, 1.59)	39 (0.1)
Nasopharyngitis	29 (0.2)	18 (0.1)	0.62 (0.35, 1.11)	47 (0.2)
Oral herpes	18 (0.1)	18 (0.1)	1.00 (0.53, 1.90)	36 (0.1)
Pneumonia	34 (0.2)	18 (0.1)	0.53 (0.30, 0.93)	52 (0.2)
Asymptomatic COVID-19	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Respiratory tract infection	13 (<0.1)	14 (<0.1)	1.08 (0.51, 2.25)	27 (<0.1)
Acute sinusitis	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Fungal infection	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Bacterial vaginosis	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Gingivitis	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Localised infection	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Onychomycosis	6 (<0.1)	12 (<0.1)	2.00 (0.78, 5.14)	18 (<0.1)
Enterovirus infection	4 (<0.1)	11 (<0.1)	2.75 (0.92, 8.17)	15 (<0.1)
Herpes simplex	5 (<0.1)	11 (<0.1)	2.20 (0.80, 6.06)	16 (<0.1)
Otitis externa	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Vulvovaginal mycotic infection	21 (0.1)	10 (<0.1)	0.48 (0.23, 0.99)	31 (0.1)
Folliculitis	15 (0.1)	9 (<0.1)	0.60 (0.27, 1.34)	24 (<0.1)
Skin infection	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Vulvovaginal candidiasis	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.33)	16 (<0.1)
Abscess limb	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Furuncle	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Gastroenteritis viral	17 (0.1)	7 (<0.1)	0.41 (0.18, 0.97)	24 (<0.1)
Laryngitis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Paronychia	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Clostridium difficile infection	1 (<0.1)	6 (<0.1)		7 (<0.1)
Cystitis	18 (0.1)	6 (<0.1)	0.33 (0.14, 0.81)	24 (<0.1)
Oral candidiasis	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Pyelonephritis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Sepsis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Staphylococcal skin infection	1 (<0.1)	6 (<0.1)		7 (<0.1)
Subcutaneous abscess	4 (<0.1)	6 (<0.1)		10 (<0.1)
Appendicitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Helicobacter infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Kidney infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Lyme disease	0	5 (<0.1)		5 (<0.1)
Postoperative wound infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Staphylococcal infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Chlamydial infection	0	4 (<0.1)		4 (<0.1)
Eye infection	6 (<0.1)	4 (<0.1)		10 (<0.1)
Gonorrhoea	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Impetigo	1 (<0.1)	4 (<0.1)		5 (<0.1)
Periodontitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Respiratory tract infection viral	12 (<0.1)	4 (<0.1)	0.33 (0.11, 0.98)	16 (<0.1)
Rhinitis	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Sinusitis bacterial	3 (<0.1)	4 (<0.1)		7 (<0.1)
Viral pharyngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Abdominal abscess	0	3 (<0.1)		3 (<0.1)
Abscess jaw	0	3 (<0.1)		3 (<0.1)
Chronic sinusitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Coronavirus infection	0	3 (<0.1)		3 (<0.1)
Epididymitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Tonsillitis	14 (<0.1)	3 (<0.1)	0.21 (0.07, 0.70)	17 (<0.1)
Wound infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Candida infection	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cat scratch disease	0	2 (<0.1)		2 (<0.1)
Conjunctivitis bacterial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Fungal skin infection	5 (<0.1)	2 (<0.1)		7 (<0.1)
Gastrointestinal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Infected cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nail infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media acute	5 (<0.1)	2 (<0.1)		7 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Peritonitis	0	2 (<0.1)		2 (<0.1)
Pertussis	0	2 (<0.1)		2 (<0.1)
Post procedural infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Pulpitis dental	2 (<0.1)	2 (<0.1)		4 (<0.1)
Septic shock	2 (<0.1)	2 (<0.1)		4 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea cruris	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tinea pedis	5 (<0.1)	2 (<0.1)		7 (<0.1)
Tuberculosis	0	2 (<0.1)		2 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urinary tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urosepsis	0	2 (<0.1)		2 (<0.1)
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Viral sinusitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic bacteriuria	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atypical mycobacterial infection	0	1 (<0.1)		1 (<0.1)
Atypical pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Body tinea	3 (<0.1)	1 (<0.1)		4 (<0.1)
Breast abscess	2 (<0.1)	1 (<0.1)		3 (<0.1)
Breast cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiolitis	0	1 (<0.1)		1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Colonic abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Dacryocystitis	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)
Genital infection fungal	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Gingival abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Groin abscess	0	1 (<0.1)		1 (<0.1)
Helminthic infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	2 (<0.1)	1 (<0.1)		3 (<0.1)
Infected dermal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza	6 (<0.1)	1 (<0.1)		7 (<0.1)
Injection site infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Labyrinthitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Papilloma viral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Perineal abscess	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)

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MedDRA version 23.0.
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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Pyoderma	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin candida	4 (<0.1)	1 (<0.1)		5 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Streptococcal infection	0	1 (<0.1)		1 (<0.1)
Tinea versicolour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Trichomoniasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vulvitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)		1 (<0.1)
Abscess	2 (<0.1)	0		2 (<0.1)
Abscess neck	1 (<0.1)	0		1 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Adenovirus infection	1 (<0.1)	0		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Balanitis candida	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Bronchitis bacterial	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	16 (0.1)	0		16 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cervicitis	2 (<0.1)	0		2 (<0.1)
Cholecystitis infective	2 (<0.1)	0		2 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	2 (<0.1)	0		2 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Ear infection fungal	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
HIV infection	2 (<0.1)	0		2 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Hepatitis C	1 (<0.1)	0		1 (<0.1)
Herpangina	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Infection	1 (<0.1)	0		1 (<0.1)
Klebsiella bacteraemia	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	3 (<0.1)	0		3 (<0.1)
Mastoiditis	3 (<0.1)	0		3 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Nasal vestibulitis	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	2 (<0.1)	0		2 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	2 (<0.1)	0		2 (<0.1)
Proteus infection	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Root canal infection	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	3 (<0.1)	0		3 (<0.1)
Tinea barbae	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Vaginal abscess	1 (<0.1)	0		1 (<0.1)
Vaginitis chlamydial	2 (<0.1)	0		2 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Vestibular neuronitis	1 (<0.1)	0		1 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	123 (0.8)	137 (0.9)		260 (0.9)
Basal cell carcinoma	28 (0.2)	24 (0.2)	0.86 (0.50, 1.47)	52 (0.2)
Prostate cancer	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Uterine leiomyoma	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Benign neoplasm of skin	2 (<0.1)	6 (<0.1)		8 (<0.1)
Skin cancer	4 (<0.1)	6 (<0.1)		10 (<0.1)
Squamous cell carcinoma	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Malignant melanoma	5 (<0.1)	5 (<0.1)		10 (<0.1)
Squamous cell carcinoma of skin	9 (<0.1)	4 (<0.1)	0.44 (0.15, 1.36)	13 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign breast neoplasm	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of thyroid gland	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lipoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Malignant melanoma in situ	1 (<0.1)	3 (<0.1)		4 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin papilloma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Benign hepatic neoplasm	0	2 (<0.1)		2 (<0.1)
Breast cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Invasive ductal breast carcinoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Plasma cell myeloma	0	2 (<0.1)		2 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Adrenal adenoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign ovarian tumour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign salivary gland neoplasm	0	1 (<0.1)		1 (<0.1)
Brain neoplasm	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Breast cancer in situ	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Fibrous histiocytoma	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Intraductal papilloma of breast	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Metastases to bone	1 (<0.1)	1 (<0.1)		2 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Nasal cavity cancer	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)		1 (<0.1)
Prostate cancer stage I	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal neoplasm	0	1 (<0.1)		1 (<0.1)
Seborrhoeic keratosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Benign bone neoplasm	1 (<0.1)	0		1 (<0.1)
Benign neoplasm of eyelid	1 (<0.1)	0		1 (<0.1)
Bladder cancer	1 (<0.1)	0		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Breast neoplasm	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Enchondromatosis	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	3 (<0.1)	0		3 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	194 (1.3)	338 (2.3)		532 (1.8)
Lymphadenopathy	150 (1.0)	284 (1.9)	1.89 (1.56, 2.30)	434 (1.5)
Anaemia	17 (0.1)	21 (0.1)	1.23 (0.66, 2.31)	38 (0.1)
Lymph node pain	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Iron deficiency anaemia	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Lymphadenitis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Thrombocytopenia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Leukocytosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)
Normocytic anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Blood and lymphatic system disorders (Cont.)				
Eosinophilia	0	1 (<0.1)		1 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Nucleated red cells	1 (<0.1)	0		1 (<0.1)
Splenic calcification	1 (<0.1)	0		1 (<0.1)
Immune system disorders	96 (0.7)	89 (0.6)		185 (0.6)
Seasonal allergy	69 (0.5)	59 (0.4)	0.85 (0.61, 1.21)	128 (0.4)
Drug hypersensitivity	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.57)	20 (<0.1)
Hypersensitivity	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Food allergy	2 (<0.1)	4 (<0.1)		6 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Mycotic allergy	0	2 (<0.1)		2 (<0.1)
Allergy to animal	0	1 (<0.1)		1 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	2 (<0.1)	0		2 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Immune system disorders (Cont.)				
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	40 (0.3)	38 (0.3)		78 (0.3)
Hypothyroidism	19 (0.1)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.2)
Thyroid mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Goitre	6 (<0.1)	2 (<0.1)		8 (<0.1)
Hyperparathyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperthyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Basedow's disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypogonadism	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Thyroiditis	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	2 (<0.1)	0		2 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroiditis subacute	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	278 (1.9)	259 (1.8)		537 (1.8)
Type 2 diabetes mellitus	32 (0.2)	42 (0.3)	1.31 (0.83, 2.07)	74 (0.3)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Hyperlipidaemia	52 (0.4)	39 (0.3)	0.75 (0.50, 1.13)	91 (0.3)
Vitamin D deficiency	37 (0.3)	29 (0.2)	0.78 (0.48, 1.27)	66 (0.2)
Hypercholesterolaemia	36 (0.2)	28 (0.2)	0.78 (0.48, 1.27)	64 (0.2)
Decreased appetite	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Dehydration	14 (<0.1)	15 (0.1)	1.07 (0.52, 2.18)	29 (<0.1)
Diabetes mellitus	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Gout	17 (0.1)	13 (<0.1)	0.76 (0.38, 1.55)	30 (0.1)
Glucose tolerance impaired	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Hyponatraemia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Hypokalaemia	17 (0.1)	7 (<0.1)	0.41 (0.18, 0.97)	24 (<0.1)
Hyperglycaemia	6 (<0.1)	5 (<0.1)		11 (<0.1)
Hypertriglyceridaemia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Hypoglycaemia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Vitamin B12 deficiency	4 (<0.1)	4 (<0.1)		8 (<0.1)
Abnormal loss of weight	4 (<0.1)	3 (<0.1)		7 (<0.1)
Diabetes mellitus inadequate control	3 (<0.1)	3 (<0.1)		6 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperkalaemia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Iron deficiency	6 (<0.1)	3 (<0.1)		9 (<0.1)
Obesity	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypocalcaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Insulin resistance	0	2 (<0.1)		2 (<0.1)
Malnutrition	0	2 (<0.1)		2 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dairy intolerance	0	1 (<0.1)		1 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)		4 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Food intolerance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypercalcaemia	0	1 (<0.1)		1 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypomagnesaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Hypophosphataemia	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin K deficiency	0	1 (<0.1)		1 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Fluid overload	1 (<0.1)	0		1 (<0.1)
Fluid retention	1 (<0.1)	0		1 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypermagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	264 (1.8)	312 (2.1)		576 (2.0)
Anxiety	86 (0.6)	107 (0.7)	1.24 (0.94, 1.65)	193 (0.7)
Depression	85 (0.6)	92 (0.6)	1.08 (0.81, 1.45)	177 (0.6)
Insomnia	54 (0.4)	60 (0.4)	1.11 (0.77, 1.60)	114 (0.4)
Attention deficit hyperactivity disorder	24 (0.2)	20 (0.1)	0.83 (0.46, 1.49)	44 (0.1)
Bipolar disorder	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)
Panic attack	6 (<0.1)	4 (<0.1)		10 (<0.1)
Post-traumatic stress disorder	2 (<0.1)	4 (<0.1)		6 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)		4 (<0.1)
Suicidal ideation	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Psychiatric disorders (Cont.)				
Alcohol withdrawal syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bipolar II disorder	0	2 (<0.1)		2 (<0.1)
Generalised anxiety disorder	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	4 (<0.1)	2 (<0.1)		6 (<0.1)
Stress	2 (<0.1)	2 (<0.1)		4 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Alcohol abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Confusional state	3 (<0.1)	1 (<0.1)		4 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Dysphemia	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental fatigue	2 (<0.1)	1 (<0.1)		3 (<0.1)
Mental status changes	4 (<0.1)	1 (<0.1)		5 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders (Cont.)				
Obsessive-compulsive personality disorder	0	1 (<0.1)		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Psychotic disorder	0	1 (<0.1)		1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Social anxiety disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Terminal insomnia	0	1 (<0.1)		1 (<0.1)
Agitation	2 (<0.1)	0		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Delirium	1 (<0.1)	0		1 (<0.1)
Depression suicidal	2 (<0.1)	0		2 (<0.1)
Disorientation	1 (<0.1)	0		1 (<0.1)
Dissociative disorder	1 (<0.1)	0		1 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders (Cont.)				
Mixed anxiety and depressive disorder	1 (<0.1)	0		1 (<0.1)
Nicotine dependence	1 (<0.1)	0		1 (<0.1)
Schizophrenia	2 (<0.1)	0		2 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	1204 (8.2)	1278 (8.7)		2482 (8.4)
Headache	859 (5.8)	879 (6.0)	1.02 (0.93, 1.12)	1738 (5.9)
Dizziness	87 (0.6)	94 (0.6)	1.08 (0.81, 1.44)	181 (0.6)
Paraesthesia	30 (0.2)	43 (0.3)	1.43 (0.90, 2.27)	73 (0.2)
Migraine	40 (0.3)	31 (0.2)	0.77 (0.49, 1.23)	71 (0.2)
Syncope	40 (0.3)	24 (0.2)	0.60 (0.36, 0.99)	64 (0.2)
Sciatica	25 (0.2)	23 (0.2)	0.92 (0.53, 1.61)	48 (0.2)
Ageusia	29 (0.2)	22 (0.1)	0.76 (0.44, 1.31)	51 (0.2)
Sinus headache	12 (<0.1)	21 (0.1)	1.75 (0.87, 3.50)	33 (0.1)
Anosmia	24 (0.2)	18 (0.1)	0.75 (0.41, 1.37)	42 (0.1)
Cervical radiculopathy	2 (<0.1)	17 (0.1)	8.49 (2.18, 33.04)	19 (<0.1)
Hypoaesthesia	14 (<0.1)	16 (0.1)	1.14 (0.57, 2.31)	30 (0.1)
Presyncope	16 (0.1)	15 (0.1)	0.94 (0.47, 1.87)	31 (0.1)
Dysgeusia	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Carpal tunnel syndrome	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Nerve compression	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.33)	16 (<0.1)
Tension headache	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Facial paralysis	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Cerebrovascular accident	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Burning sensation	1 (<0.1)	6 (<0.1)		7 (<0.1)
Hyperaesthesia	0	6 (<0.1)		6 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Lumbar radiculopathy	5 (<0.1)	5 (<0.1)		10 (<0.1)
Memory impairment	1 (<0.1)	5 (<0.1)		6 (<0.1)
Seizure	6 (<0.1)	5 (<0.1)		11 (<0.1)
Parosmia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	4 (<0.1)		7 (<0.1)
Subarachnoid haemorrhage	0	4 (<0.1)		4 (<0.1)
Amnesia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Lethargy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Migraine with aura	3 (<0.1)	3 (<0.1)		6 (<0.1)
Neuralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Neuropathy peripheral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Somnolence	2 (<0.1)	3 (<0.1)		5 (<0.1)
Taste disorder	2 (<0.1)	3 (<0.1)		5 (<0.1)
Transient ischaemic attack	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tremor	5 (<0.1)	3 (<0.1)		8 (<0.1)
Carotid artery stenosis	0	2 (<0.1)		2 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Cubital tunnel syndrome	0	2 (<0.1)		2 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Dizziness postural	0	2 (<0.1)		2 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Morton's neuralgia	0	2 (<0.1)		2 (<0.1)
Optic neuritis	0	2 (<0.1)		2 (<0.1)
Piriformis syndrome	0	2 (<0.1)		2 (<0.1)
Post herpetic neuralgia	0	2 (<0.1)		2 (<0.1)
Post-traumatic headache	2 (<0.1)	2 (<0.1)		4 (<0.1)
Restless legs syndrome	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Aphasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Central nervous system lesion	0	1 (<0.1)		1 (<0.1)
Cerebral atrophy	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Complex regional pain syndrome	0	1 (<0.1)		1 (<0.1)
Dementia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Depressed level of consciousness	0	1 (<0.1)		1 (<0.1)
Diabetic mononeuropathy	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Essential tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Hypersomnia	0	1 (<0.1)		1 (<0.1)
Hyposmia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Loss of consciousness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle contractions involuntary	2 (<0.1)	1 (<0.1)		3 (<0.1)
New daily persistent headache	0	1 (<0.1)		1 (<0.1)
Occipital neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Trigeminal neuralgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	2 (<0.1)	0		2 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Cerebral cyst	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	3 (<0.1)	0		3 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	3 (<0.1)	0		3 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Hypogeusia	4 (<0.1)	0		4 (<0.1)
Intention tremor	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0		1 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Myoclonus	1 (<0.1)	0		1 (<0.1)
Perineurial cyst	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Radicular pain	1 (<0.1)	0		1 (<0.1)
Right hemisphere deficit syndrome	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Speech disorder	2 (<0.1)	0		2 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0		1 (<0.1)
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)
Vocal cord paralysis	1 (<0.1)	0		1 (<0.1)
Eye disorders	124 (0.8)	138 (0.9)		262 (0.9)
Cataract	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Eye pruritus	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Dry eye	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Eye irritation	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Glaucoma	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Retinal detachment	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Eye pain	4 (<0.1)	6 (<0.1)		10 (<0.1)
Vision blurred	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Blepharitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Conjunctival haemorrhage	3 (<0.1)	5 (<0.1)		8 (<0.1)
Chalazion	1 (<0.1)	4 (<0.1)		5 (<0.1)
Swelling of eyelid	1 (<0.1)	4 (<0.1)		5 (<0.1)
Visual impairment	3 (<0.1)	4 (<0.1)		7 (<0.1)
Eye inflammation	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lacrimation increased	4 (<0.1)	3 (<0.1)		7 (<0.1)
Uveitis	0	3 (<0.1)		3 (<0.1)
Vitreous floaters	4 (<0.1)	3 (<0.1)		7 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Eye haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye swelling	5 (<0.1)	2 (<0.1)		7 (<0.1)
Macular degeneration	1 (<0.1)	2 (<0.1)		3 (<0.1)
Macular hole	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular discomfort	0	2 (<0.1)		2 (<0.1)
Ocular hyperaemia	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Photophobia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Diabetic retinopathy	0	1 (<0.1)		1 (<0.1)
Diplopia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye disorder	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Foreign body sensation in eyes	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Keratitis	0	1 (<0.1)		1 (<0.1)
Lenticular opacities	0	1 (<0.1)		1 (<0.1)
Macular fibrosis	0	1 (<0.1)		1 (<0.1)
Macular oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Orbital haematoma	0	1 (<0.1)		1 (<0.1)
Papilloedema	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Presbyopia	0	1 (<0.1)		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Retinopathy hypertensive	0	1 (<0.1)		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eye ulcer	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	3 (<0.1)	0		3 (<0.1)
Nictitating spasm	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	3 (<0.1)	0		3 (<0.1)
Photopsia	2 (<0.1)	0		2 (<0.1)
Retinal infarction	1 (<0.1)	0		1 (<0.1)
Retinal oedema	1 (<0.1)	0		1 (<0.1)
Retinal tear	2 (<0.1)	0		2 (<0.1)
Strabismus	2 (<0.1)	0		2 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	4 (<0.1)	0		4 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Ear and labyrinth disorders	140 (0.9)	131 (0.9)		271 (0.9)
Vertigo	32 (0.2)	45 (0.3)	1.41 (0.90, 2.20)	77 (0.3)
Ear pain	34 (0.2)	29 (0.2)	0.85 (0.52, 1.39)	63 (0.2)
Tinnitus	20 (0.1)	20 (0.1)	1.00 (0.54, 1.84)	40 (0.1)
Vertigo positional	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Ear discomfort	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Meniere's disease	2 (<0.1)	5 (<0.1)		7 (<0.1)
Cerumen impaction	4 (<0.1)	3 (<0.1)		7 (<0.1)
Deafness unilateral	2 (<0.1)	3 (<0.1)		5 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear canal erythema	6 (<0.1)	2 (<0.1)		8 (<0.1)
Ear congestion	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Eustachian tube dysfunction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tympanic membrane perforation	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Ear pruritus	5 (<0.1)	1 (<0.1)		6 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	2 (<0.1)	0		2 (<0.1)
External ear pain	1 (<0.1)	0		1 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Ear and labyrinth disorders (Cont.)				
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	164 (1.1)	163 (1.1)		327 (1.1)
Atrial fibrillation	27 (0.2)	25 (0.2)	0.93 (0.54, 1.58)	52 (0.2)
Palpitations	13 (<0.1)	22 (0.1)	1.69 (0.86, 3.31)	35 (0.1)
Tachycardia	22 (0.1)	21 (0.1)	0.95 (0.53, 1.72)	43 (0.1)
Bradycardia	23 (0.2)	15 (0.1)	0.65 (0.34, 1.23)	38 (0.1)
Angina pectoris	12 (<0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Coronary artery disease	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Ventricular extrasystoles	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.58)	15 (<0.1)
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Sinus tachycardia	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Arrhythmia	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Cardiac failure congestive	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Acute myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Cardiac failure	4 (<0.1)	4 (<0.1)		8 (<0.1)
Supraventricular tachycardia	0	4 (<0.1)		4 (<0.1)
Acute coronary syndrome	0	3 (<0.1)		3 (<0.1)
Atrial flutter	4 (<0.1)	3 (<0.1)		7 (<0.1)
Acute left ventricular failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Cardiomyopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ventricular tachycardia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial enlargement	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiovascular symptom	0	1 (<0.1)		1 (<0.1)
Left ventricular hypertrophy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinus bradycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial tachycardia	2 (<0.1)	0		2 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac disorder	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Cardiac steatosis	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	2 (<0.1)	0		2 (<0.1)
Diastolic dysfunction	1 (<0.1)	0		1 (<0.1)
Extrasystoles	1 (<0.1)	0		1 (<0.1)
Left atrial enlargement	1 (<0.1)	0		1 (<0.1)
Mitral valve incompetence	2 (<0.1)	0		2 (<0.1)
Mitral valve thickening	1 (<0.1)	0		1 (<0.1)
Myocardial ischaemia	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Postural orthostatic tachycardia syndrome	1 (<0.1)	0		1 (<0.1)
Sinus arrest	1 (<0.1)	0		1 (<0.1)
Tricuspid valve incompetence	2 (<0.1)	0		2 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	397 (2.7)	338 (2.3)		735 (2.5)
Hypertension	325 (2.2)	254 (1.7)	0.78 (0.66, 0.92)	579 (2.0)
Hot flush	11 (<0.1)	16 (0.1)	1.45 (0.69, 3.08)	27 (<0.1)
Haematoma	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Deep vein thrombosis	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Flushing	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Hypotension	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Orthostatic hypotension	1 (<0.1)	6 (<0.1)		7 (<0.1)
Hypertensive urgency	2 (<0.1)	5 (<0.1)		7 (<0.1)
Arteriosclerosis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Aortic dilatation	0	2 (<0.1)		2 (<0.1)
Labile hypertension	0	2 (<0.1)		2 (<0.1)
Prehypertension	0	2 (<0.1)		2 (<0.1)
Raynaud's phenomenon	1 (<0.1)	2 (<0.1)		3 (<0.1)
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Diastolic hypotension	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive emergency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pallor	0	1 (<0.1)		1 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Peripheral coldness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Phlebitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	2 (<0.1)	0		2 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	2 (<0.1)	0		2 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Lymphoedema	1 (<0.1)	0		1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral venous disease	1 (<0.1)	0		1 (<0.1)
Secondary hypertension	1 (<0.1)	0		1 (<0.1)
Vascular calcification	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	2 (<0.1)	0		2 (<0.1)
Respiratory, thoracic and mediastinal disorders	1075 (7.3)	949 (6.4)		2024 (6.9)
Cough	303 (2.1)	304 (2.1)	1.00 (0.86, 1.17)	607 (2.1)
Oropharyngeal pain	376 (2.6)	298 (2.0)	0.79 (0.68, 0.92)	674 (2.3)

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Table 14.3.1.8.3.3
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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal congestion	285 (1.9)	262 (1.8)	0.92 (0.78, 1.08)	547 (1.9)
Rhinorrhoea	254 (1.7)	239 (1.6)	0.94 (0.79, 1.12)	493 (1.7)
Dyspnoea	85 (0.6)	88 (0.6)	1.03 (0.77, 1.39)	173 (0.6)
Tachypnoea	41 (0.3)	39 (0.3)	0.95 (0.62, 1.47)	80 (0.3)
Sinus congestion	47 (0.3)	33 (0.2)	0.70 (0.45, 1.09)	80 (0.3)
Asthma	39 (0.3)	32 (0.2)	0.82 (0.52, 1.30)	71 (0.2)
Respiratory tract congestion	18 (0.1)	24 (0.2)	1.33 (0.73, 2.43)	42 (0.1)
Upper-airway cough syndrome	22 (0.1)	23 (0.2)	1.04 (0.59, 1.86)	45 (0.2)
Epistaxis	16 (0.1)	21 (0.1)	1.31 (0.69, 2.49)	37 (0.1)
Rhinitis allergic	26 (0.2)	21 (0.1)	0.81 (0.46, 1.42)	47 (0.2)
Sneezing	22 (0.1)	21 (0.1)	0.95 (0.53, 1.72)	43 (0.1)
Throat irritation	20 (0.1)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.1)
Chronic obstructive pulmonary disease	24 (0.2)	14 (<0.1)	0.58 (0.31, 1.11)	38 (0.1)
Sinus pain	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.33)	16 (<0.1)
Acute respiratory failure	13 (<0.1)	7 (<0.1)	0.54 (0.22, 1.31)	20 (<0.1)
Paranasal sinus discomfort	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Pleural effusion	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Respiratory disorder	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Dysphonia	14 (<0.1)	5 (<0.1)	0.36 (0.13, 0.95)	19 (<0.1)
Dyspnoea exertional	5 (<0.1)	5 (<0.1)		10 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pharyngeal erythema	6 (<0.1)	5 (<0.1)		11 (<0.1)
Sleep apnoea syndrome	6 (<0.1)	5 (<0.1)		11 (<0.1)
Wheezing	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Bronchiectasis	0	4 (<0.1)		4 (<0.1)
Dry throat	5 (<0.1)	4 (<0.1)		9 (<0.1)
Atelectasis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bronchospasm	1 (<0.1)	3 (<0.1)		4 (<0.1)
Emphysema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypoxia	6 (<0.1)	3 (<0.1)		9 (<0.1)
Productive cough	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Allergic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nasal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Paranasal sinus hypersecretion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Choking sensation	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lung infiltration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nasal dryness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal mucosal disorder	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	8 (<0.1)	1 (<0.1)	0.12 (0.02, 0.77)	9 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary congestion	0	1 (<0.1)		1 (<0.1)
Pulmonary hypertension	0	1 (<0.1)		1 (<0.1)
Pulmonary oedema	0	1 (<0.1)		1 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Rhonchi	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	6 (<0.1)	1 (<0.1)		7 (<0.1)
Vasomotor rhinitis	0	1 (<0.1)		1 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Vocal cord thickening	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Bronchial hyperreactivity	1 (<0.1)	0		1 (<0.1)
Haemoptysis	3 (<0.1)	0		3 (<0.1)
Laryngeal stenosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Lung cyst	1 (<0.1)	0		1 (<0.1)
Lung opacity	2 (<0.1)	0		2 (<0.1)
Nasal turbinate hypertrophy	1 (<0.1)	0		1 (<0.1)
Nasal ulcer	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary granuloma	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Rales	2 (<0.1)	0		2 (<0.1)
Reflux laryngitis	1 (<0.1)	0		1 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory symptom	4 (<0.1)	0		4 (<0.1)
Rhinalgia	2 (<0.1)	0		2 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	2 (<0.1)	0		2 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	3 (<0.1)	0		3 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	2 (<0.1)	0		2 (<0.1)
Gastrointestinal disorders	866 (5.9)	888 (6.0)		1754 (5.9)
Diarrhoea	276 (1.9)	274 (1.9)	0.99 (0.84, 1.17)	550 (1.9)
Nausea	239 (1.6)	240 (1.6)	1.00 (0.84, 1.20)	479 (1.6)
Vomiting	82 (0.6)	91 (0.6)	1.11 (0.82, 1.49)	173 (0.6)
Gastrooesophageal reflux disease	55 (0.4)	79 (0.5)	1.44 (1.02, 2.02)	134 (0.5)
Abdominal pain	39 (0.3)	45 (0.3)	1.15 (0.75, 1.76)	84 (0.3)
Toothache	49 (0.3)	45 (0.3)	0.92 (0.61, 1.37)	94 (0.3)
Constipation	38 (0.3)	27 (0.2)	0.71 (0.44, 1.16)	65 (0.2)
Dental caries	29 (0.2)	25 (0.2)	0.86 (0.51, 1.46)	54 (0.2)
Abdominal pain upper	32 (0.2)	24 (0.2)	0.75 (0.44, 1.26)	56 (0.2)
Dyspepsia	22 (0.1)	23 (0.2)	1.04 (0.59, 1.86)	45 (0.2)

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Gastrointestinal disorders (Cont.)				
Food poisoning	15 (0.1)	13 (<0.1)	0.87 (0.42, 1.79)	28 (<0.1)
Abdominal pain lower	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Hiatus hernia	6 (<0.1)	11 (<0.1)	1.83 (0.70, 4.77)	17 (<0.1)
Inguinal hernia	6 (<0.1)	11 (<0.1)	1.83 (0.70, 4.77)	17 (<0.1)
Abdominal discomfort	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (<0.1)
Large intestine polyp	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Colitis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Gastritis	14 (<0.1)	8 (<0.1)	0.57 (0.25, 1.33)	22 (<0.1)
Haemorrhoids	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Irritable bowel syndrome	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Umbilical hernia	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Abdominal distension	2 (<0.1)	6 (<0.1)		8 (<0.1)
Flatulence	3 (<0.1)	6 (<0.1)		9 (<0.1)
Gastric ulcer	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Lip swelling	2 (<0.1)	6 (<0.1)		8 (<0.1)
Tooth impacted	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Diverticulum intestinal	1 (<0.1)	5 (<0.1)		6 (<0.1)
Gastrointestinal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Haematochezia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Oesophagitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Rectal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Small intestinal obstruction	4 (<0.1)	4 (<0.1)		8 (<0.1)

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Gastrointestinal disorders (Cont.)				
Aphthous ulcer	6 (<0.1)	3 (<0.1)		9 (<0.1)
Barrett's oesophagus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diverticulum	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dysphagia	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Faeces soft	0	3 (<0.1)		3 (<0.1)
Gastrointestinal pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Gingival pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypoaesthesia oral	0	3 (<0.1)		3 (<0.1)
Pancreatitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Paraesthesia oral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Periodontal disease	0	3 (<0.1)		3 (<0.1)
Stomatitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Dry mouth	5 (<0.1)	2 (<0.1)		7 (<0.1)
Duodenal ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Faeces discoloured	0	2 (<0.1)		2 (<0.1)
Frequent bowel movements	0	2 (<0.1)		2 (<0.1)
Gastrointestinal disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gingival bleeding	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Intestinal obstruction	0	2 (<0.1)		2 (<0.1)
Melaena	0	2 (<0.1)		2 (<0.1)
Mouth ulceration	4 (<0.1)	2 (<0.1)		6 (<0.1)
Oesophageal spasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Peptic ulcer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Proctalgia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swollen tongue	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anorectal disorder	0	1 (<0.1)		1 (<0.1)
Chronic gastritis	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Duodenitis	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Faecaloma	0	1 (<0.1)		1 (<0.1)
Gingival disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Intussusception	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Noninfective gingivitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral mucosal blistering	0	1 (<0.1)		1 (<0.1)
Oral mucosal eruption	0	1 (<0.1)		1 (<0.1)
Oral pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Pancreatic cyst	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Poor dental condition	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Saliva altered	1 (<0.1)	1 (<0.1)		2 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue ulceration	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Abdominal rigidity	2 (<0.1)	0		2 (<0.1)
Abdominal tenderness	1 (<0.1)	0		1 (<0.1)
Abdominal wall cyst	1 (<0.1)	0		1 (<0.1)
Anal fistula	1 (<0.1)	0		1 (<0.1)
Anorectal discomfort	1 (<0.1)	0		1 (<0.1)
Ascites	2 (<0.1)	0		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Colitis microscopic	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Eosinophilic oesophagitis	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	2 (<0.1)	0		2 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0		1 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival recession	1 (<0.1)	0		1 (<0.1)
Glossodynia	2 (<0.1)	0		2 (<0.1)
Hypertrophy of tongue papillae	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Lip blister	1 (<0.1)	0		1 (<0.1)
Obstructive pancreatitis	1 (<0.1)	0		1 (<0.1)
Odynophagia	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Palatal disorder	1 (<0.1)	0		1 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Terminal ileitis	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Tongue dry	1 (<0.1)	0		1 (<0.1)
Tooth disorder	3 (<0.1)	0		3 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Upper gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Uvulitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	20 (0.1)	31 (0.2)		51 (0.2)
Cholelithiasis	8 (<0.1)	15 (0.1)	1.87 (0.81, 4.31)	23 (<0.1)
Cholecystitis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Hepatic steatosis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Bile duct stone	0	2 (<0.1)		2 (<0.1)
Biliary colic	0	2 (<0.1)		2 (<0.1)
Biliary dyskinesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholecystitis acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Jaundice	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic haematoma	1 (<0.1)	0		1 (<0.1)
Hyperbilirubinaemia	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	362 (2.5)	380 (2.6)		742 (2.5)
Urticaria	43 (0.3)	52 (0.4)	1.21 (0.81, 1.80)	95 (0.3)
Rash	45 (0.3)	43 (0.3)	0.95 (0.63, 1.45)	88 (0.3)
Dermatitis contact	40 (0.3)	34 (0.2)	0.85 (0.54, 1.34)	74 (0.3)
Pruritus	28 (0.2)	27 (0.2)	0.96 (0.57, 1.62)	55 (0.2)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Eczema	11 (<0.1)	18 (0.1)	1.64 (0.79, 3.40)	29 (<0.1)
Erythema	7 (<0.1)	17 (0.1)	2.43 (1.03, 5.70)	24 (<0.1)
Acne	17 (0.1)	14 (<0.1)	0.82 (0.41, 1.65)	31 (0.1)
Hyperhidrosis	12 (<0.1)	13 (<0.1)	1.08 (0.50, 2.33)	25 (<0.1)
Night sweats	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Actinic keratosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Dermatitis	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Rash maculo-papular	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Rash papular	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Alopecia	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Psoriasis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Rash macular	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Rosacea	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Dermatitis atopic	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Ecchymosis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Rash pruritic	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Dry skin	4 (<0.1)	4 (<0.1)		8 (<0.1)
Ingrowing nail	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)
Skin lesion	6 (<0.1)	4 (<0.1)		10 (<0.1)
Angioedema	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Blister	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermal cyst	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Dermatitis allergic	5 (<0.1)	3 (<0.1)		8 (<0.1)
Eczema nummular	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hidradenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Macule	1 (<0.1)	3 (<0.1)		4 (<0.1)
Neurodermatitis	0	3 (<0.1)		3 (<0.1)
Pain of skin	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Diabetic foot	0	2 (<0.1)		2 (<0.1)
Hand dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Papule	2 (<0.1)	2 (<0.1)		4 (<0.1)
Precancerous skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rash erythematous	4 (<0.1)	2 (<0.1)		6 (<0.1)
Rash vesicular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood blister	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Decubitus ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Onychoclasis	0	1 (<0.1)		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin hypopigmentation	0	1 (<0.1)		1 (<0.1)
Skin mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitiligo	0	1 (<0.1)		1 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Hyperkeratosis	1 (<0.1)	0		1 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	4 (<0.1)	0		4 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Miliaria	1 (<0.1)	0		1 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin discolouration	2 (<0.1)	0		2 (<0.1)
Skin fissures	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin wrinkling	1 (<0.1)	0		1 (<0.1)
Stasis dermatitis	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders	1309 (8.9)	1287 (8.7)		2596 (8.8)
Arthralgia	424 (2.9)	436 (3.0)	1.03 (0.90, 1.17)	860 (2.9)
Myalgia	437 (3.0)	423 (2.9)	0.97 (0.85, 1.10)	860 (2.9)
Back pain	181 (1.2)	159 (1.1)	0.88 (0.71, 1.08)	340 (1.2)
Pain in extremity	100 (0.7)	81 (0.5)	0.81 (0.61, 1.08)	181 (0.6)
Musculoskeletal pain	48 (0.3)	65 (0.4)	1.35 (0.93, 1.96)	113 (0.4)
Osteoarthritis	74 (0.5)	61 (0.4)	0.82 (0.59, 1.15)	135 (0.5)
Neck pain	51 (0.3)	60 (0.4)	1.18 (0.81, 1.70)	111 (0.4)
Muscle spasms	44 (0.3)	42 (0.3)	0.95 (0.63, 1.45)	86 (0.3)
Rotator cuff syndrome	25 (0.2)	25 (0.2)	1.00 (0.58, 1.73)	50 (0.2)
Tendonitis	24 (0.2)	21 (0.1)	0.87 (0.49, 1.56)	45 (0.2)
Bursitis	13 (<0.1)	19 (0.1)	1.46 (0.73, 2.92)	32 (0.1)
Musculoskeletal chest pain	26 (0.2)	18 (0.1)	0.69 (0.38, 1.25)	44 (0.1)
Intervertebral disc protrusion	13 (<0.1)	17 (0.1)	1.31 (0.64, 2.65)	30 (0.1)
Musculoskeletal stiffness	15 (0.1)	15 (0.1)	1.00 (0.50, 2.01)	30 (0.1)
Arthritis	10 (<0.1)	14 (<0.1)	1.40 (0.63, 3.08)	24 (<0.1)
Joint swelling	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Muscular weakness	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Osteopenia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Osteoporosis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Trigger finger	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Groin pain	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Periarthritis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Flank pain	6 (<0.1)	6 (<0.1)		12 (<0.1)
Pain in jaw	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Costochondritis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Muscle tightness	2 (<0.1)	5 (<0.1)		7 (<0.1)
Plantar fasciitis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Spinal pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	5 (<0.1)		7 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Fibromyalgia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Intervertebral disc degeneration	6 (<0.1)	4 (<0.1)		10 (<0.1)
Muscle twitching	2 (<0.1)	4 (<0.1)		6 (<0.1)
Spinal stenosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Limb discomfort	2 (<0.1)	3 (<0.1)		5 (<0.1)
Muscle fatigue	0	3 (<0.1)		3 (<0.1)
Neck mass	0	3 (<0.1)		3 (<0.1)
Spondylolisthesis	0	3 (<0.1)		3 (<0.1)
Synovial cyst	6 (<0.1)	3 (<0.1)		9 (<0.1)
Axillary mass	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Cervical spinal stenosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Exostosis	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Foot deformity	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Joint stiffness	3 (<0.1)	2 (<0.1)		5 (<0.1)
Limb mass	2 (<0.1)	2 (<0.1)		4 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rheumatoid arthritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Spondylitis	0	2 (<0.1)		2 (<0.1)
Tenosynovitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Compartment syndrome	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)		1 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)		1 (<0.1)
Joint noise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ligament pain	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Ligamentum flavum hypertrophy	0	1 (<0.1)		1 (<0.1)
Medial tibial stress syndrome	0	1 (<0.1)		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteonecrosis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal synovial cyst	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis stenosans	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)		1 (<0.1)
Fasciitis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Joint effusion	1 (<0.1)	0		1 (<0.1)
Kyphosis	1 (<0.1)	0		1 (<0.1)
Lumbar spinal stenosis	2 (<0.1)	0		2 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Scoliosis	3 (<0.1)	0		3 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Synovitis	2 (<0.1)	0		2 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Torticollis	2 (<0.1)	0		2 (<0.1)
Renal and urinary disorders	95 (0.6)	97 (0.7)		192 (0.7)
Nephrolithiasis	33 (0.2)	28 (0.2)	0.85 (0.52, 1.40)	61 (0.2)
Dysuria	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Acute kidney injury	13 (<0.1)	7 (<0.1)	0.54 (0.22, 1.31)	20 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders (Cont.)				
Chronic kidney disease	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Haematuria	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Urinary retention	4 (<0.1)	6 (<0.1)		10 (<0.1)
Hypertonic bladder	3 (<0.1)	5 (<0.1)		8 (<0.1)
Pollakiuria	5 (<0.1)	5 (<0.1)		10 (<0.1)
Nocturia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Polyuria	0	4 (<0.1)		4 (<0.1)
Urinary incontinence	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hydronephrosis	0	3 (<0.1)		3 (<0.1)
Bladder pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Renal cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Urinary hesitation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder spasm	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calculus bladder	0	1 (<0.1)		1 (<0.1)
Chromaturia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cystitis interstitial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetic nephropathy	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Micturition urgency	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders (Cont.)				
Renal disorder	0	1 (<0.1)		1 (<0.1)
Renal failure	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Renal tubular necrosis	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	2 (<0.1)	0		2 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	2 (<0.1)	0		2 (<0.1)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abortion spontaneous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)		1 (<0.1)
Morning sickness	0	1 (<0.1)		1 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders	128 (0.9)	114 (0.8)		242 (0.8)
Benign prostatic hyperplasia	21 (0.1)	11 (<0.1)	0.52 (0.26, 1.07)	32 (0.1)
Erectile dysfunction	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.76)	19 (<0.1)
Ovarian cyst	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Pelvic pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Prostatitis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Breast cyst	3 (<0.1)	5 (<0.1)		8 (<0.1)
Dysmenorrhoea	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.40)	15 (<0.1)
Menorrhagia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Prostatomegaly	6 (<0.1)	5 (<0.1)		11 (<0.1)
Menopausal symptoms	2 (<0.1)	4 (<0.1)		6 (<0.1)
Vaginal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Uterine polyp	3 (<0.1)	3 (<0.1)		6 (<0.1)
Breast hyperplasia	0	2 (<0.1)		2 (<0.1)
Breast mass	5 (<0.1)	2 (<0.1)		7 (<0.1)
Breast pain	5 (<0.1)	2 (<0.1)		7 (<0.1)
Breast ulceration	0	2 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	3 (<0.1)	2 (<0.1)		5 (<0.1)
Rectocele	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexa uteri pain	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Artificial menopause	0	1 (<0.1)		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast enlargement	0	1 (<0.1)		1 (<0.1)
Breast fibrosis	0	1 (<0.1)		1 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Breast tenderness	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical polyp	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystocele	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)		2 (<0.1)
Endometriosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibrocystic breast disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Menstruation irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Polymenorrhoea	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatic cyst	0	1 (<0.1)		1 (<0.1)
Testicular pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaginal cyst	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vaginal prolapse	0	1 (<0.1)		1 (<0.1)
Vulva cyst	0	1 (<0.1)		1 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	3 (<0.1)	0		3 (<0.1)
Dyspareunia	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Ovarian mass	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Pelvic floor muscle weakness	1 (<0.1)	0		1 (<0.1)
Peyronie's disease	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	3 (<0.1)	0		3 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Pruritus genital	1 (<0.1)	0		1 (<0.1)
Testicular swelling	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	2 (<0.1)	0		2 (<0.1)
Vulvovaginal dryness	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	5 (<0.1)	8 (<0.1)		13 (<0.1)
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Developmental hip dysplasia	0	1 (<0.1)		1 (<0.1)
Gilbert's syndrome	0	1 (<0.1)		1 (<0.1)
Preauricular cyst	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Congenital, familial and genetic disorders (Cont.)				
Type IIa hyperlipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Von Willebrand's disease	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1297 (8.8)	1803 (12.2)		3100 (10.5)
Fatigue	777 (5.3)	867 (5.9)	1.12 (1.02, 1.23)	1644 (5.6)
Injection site pain	137 (0.9)	263 (1.8)	1.92 (1.56, 2.35)	400 (1.4)
Chills	158 (1.1)	172 (1.2)	1.09 (0.88, 1.35)	330 (1.1)
Pyrexia	120 (0.8)	166 (1.1)	1.38 (1.09, 1.75)	286 (1.0)
Injection site erythema	40 (0.3)	156 (1.1)	3.90 (2.76, 5.50)	196 (0.7)
Pain	134 (0.9)	131 (0.9)	0.98 (0.77, 1.24)	265 (0.9)
Injection site swelling	30 (0.2)	118 (0.8)	3.93 (2.64, 5.85)	148 (0.5)
Injection site pruritus	13 (<0.1)	88 (0.6)	6.77 (3.81, 12.01)	101 (0.3)
Injection site lymphadenopathy	17 (0.1)	68 (0.5)	4.00 (2.37, 6.76)	85 (0.3)
Injection site induration	18 (0.1)	51 (0.3)	2.83 (1.67, 4.81)	69 (0.2)
Injection site macule	4 (<0.1)	45 (0.3)	11.24 (4.21, 30.03)	49 (0.2)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.98 (6.58, 219.09)	39 (0.1)
Axillary pain	15 (0.1)	27 (0.2)	1.80 (0.97, 3.35)	42 (0.1)
Injection site rash	1 (<0.1)	25 (0.2)	24.98 (4.29, 145.49)	26 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Chest discomfort	24 (0.2)	24 (0.2)	1.00 (0.57, 1.75)	48 (0.2)
Malaise	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
Peripheral swelling	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
Injection site bruising	20 (0.1)	18 (0.1)	0.90 (0.48, 1.68)	38 (0.1)
Chest pain	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)
Non-cardiac chest pain	15 (0.1)	14 (<0.1)	0.93 (0.46, 1.90)	29 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	12.99 (2.18, 77.55)	14 (<0.1)
Oedema peripheral	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Reactogenicity event	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Asthenia	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haemorrhage	5 (<0.1)	6 (<0.1)		11 (<0.1)
Injection site paraesthesia	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vaccination site swelling	1 (<0.1)	6 (<0.1)		7 (<0.1)
Feeling abnormal	6 (<0.1)	5 (<0.1)		11 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Swelling face	4 (<0.1)	5 (<0.1)		9 (<0.1)
Vaccination site pain	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Feeling hot	3 (<0.1)	4 (<0.1)		7 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Influenza like illness	6 (<0.1)	4 (<0.1)		10 (<0.1)
Injection site mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cyst	6 (<0.1)	3 (<0.1)		9 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site reaction	0	3 (<0.1)		3 (<0.1)
Injury associated with device	0	3 (<0.1)		3 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Adverse drug reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Inflammation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Dysplasia	0	1 (<0.1)		1 (<0.1)
Early satiety	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Facial pain	6 (<0.1)	1 (<0.1)		7 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hangover	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Medical device site pain	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Xerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Capsular contracture associated with breast implant	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Drug intolerance	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Sluggishness	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	4 (<0.1)	0		4 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	2 (<0.1)	0		2 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	2 (<0.1)	0		2 (<0.1)
Investigations	158 (1.1)	167 (1.1)		325 (1.1)
Blood pressure increased	50 (0.3)	40 (0.3)	0.80 (0.53, 1.21)	90 (0.3)
Blood pressure systolic increased	19 (0.1)	21 (0.1)	1.10 (0.60, 2.03)	40 (0.1)
Blood pressure diastolic increased	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Blood cholesterol increased	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Hepatic enzyme increased	4 (<0.1)	6 (<0.1)		10 (<0.1)
Body temperature increased	2 (<0.1)	5 (<0.1)		7 (<0.1)
Prostatic specific antigen increased	2 (<0.1)	5 (<0.1)		7 (<0.1)
Heart rate increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Transaminases increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Weight decreased	1 (<0.1)	4 (<0.1)		5 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Blood glucose increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood triglycerides increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
C-reactive protein increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cardiac murmur	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Blood creatine increased	0	2 (<0.1)		2 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Blood parathyroid hormone increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood potassium decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrocardiogram QT prolonged	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hepatic enzyme abnormal	0	2 (<0.1)		2 (<0.1)
Human rhinovirus test positive	1 (<0.1)	2 (<0.1)		3 (<0.1)
White blood cell count increased	0	2 (<0.1)		2 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Antinuclear antibody positive	0	1 (<0.1)		1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood uric acid increased	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Blood urine present	1 (<0.1)	1 (<0.1)		2 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)		1 (<0.1)
Glycosylated haemoglobin increased	5 (<0.1)	1 (<0.1)		6 (<0.1)
Haemoglobin decreased	0	1 (<0.1)		1 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Liver function test increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stool analysis abnormal	0	1 (<0.1)		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Streptococcus test negative	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Troponin increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Vitamin B12 decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitamin D decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Weight increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Haematocrit increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Liver function test abnormal	1 (<0.1)	0		1 (<0.1)
Pregnancy test positive	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Renal function test abnormal	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
SARS-CoV-2 test positive	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Total lung capacity decreased	1 (<0.1)	0		1 (<0.1)
Viral test positive	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	639 (4.3)	560 (3.8)		1199 (4.1)
Muscle strain	51 (0.3)	53 (0.4)	1.04 (0.71, 1.52)	104 (0.4)
Ligament sprain	48 (0.3)	47 (0.3)	0.98 (0.66, 1.46)	95 (0.3)
Fall	48 (0.3)	44 (0.3)	0.92 (0.61, 1.37)	92 (0.3)
Skin laceration	52 (0.4)	37 (0.3)	0.71 (0.47, 1.08)	89 (0.3)
Tooth fracture	36 (0.2)	32 (0.2)	0.89 (0.55, 1.42)	68 (0.2)
Contusion	35 (0.2)	30 (0.2)	0.86 (0.53, 1.39)	65 (0.2)
Arthropod bite	37 (0.3)	29 (0.2)	0.78 (0.48, 1.27)	66 (0.2)
Procedural pain	54 (0.4)	28 (0.2)	0.52 (0.33, 0.81)	82 (0.3)
Foot fracture	23 (0.2)	23 (0.2)	1.00 (0.57, 1.77)	46 (0.2)
Limb injury	17 (0.1)	20 (0.1)	1.18 (0.62, 2.22)	37 (0.1)
Animal bite	17 (0.1)	18 (0.1)	1.06 (0.55, 2.03)	35 (0.1)
Meniscus injury	21 (0.1)	16 (0.1)	0.76 (0.40, 1.44)	37 (0.1)
Road traffic accident	14 (<0.1)	15 (0.1)	1.07 (0.52, 2.18)	29 (<0.1)
Skin abrasion	30 (0.2)	15 (0.1)	0.50 (0.27, 0.92)	45 (0.2)
Joint injury	9 (<0.1)	14 (<0.1)	1.55 (0.69, 3.51)	23 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Rib fracture	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Arthropod sting	18 (0.1)	10 (<0.1)	0.56 (0.26, 1.18)	28 (<0.1)
Concussion	4 (<0.1)	10 (<0.1)	2.50 (0.83, 7.53)	14 (<0.1)
Post-traumatic pain	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Facial bones fracture	0	8 (<0.1)		8 (<0.1)
Head injury	2 (<0.1)	8 (<0.1)	4.00 (0.96, 16.63)	10 (<0.1)
Thermal burn	3 (<0.1)	6 (<0.1)		9 (<0.1)
Ankle fracture	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.40)	15 (<0.1)
Bone contusion	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Clavicle fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Corneal abrasion	6 (<0.1)	5 (<0.1)		11 (<0.1)
Epicondylitis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Hand fracture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Humerus fracture	3 (<0.1)	5 (<0.1)		8 (<0.1)
Joint dislocation	4 (<0.1)	5 (<0.1)		9 (<0.1)
Ligament rupture	5 (<0.1)	5 (<0.1)		10 (<0.1)
Muscle rupture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Stress fracture	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Upper limb fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Back injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Cartilage injury	5 (<0.1)	4 (<0.1)		9 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Dental restoration failure	2 (<0.1)	4 (<0.1)		6 (<0.1)
Wrist fracture	6 (<0.1)	4 (<0.1)		10 (<0.1)
Alcohol poisoning	0	3 (<0.1)		3 (<0.1)
Craniocerebral injury	0	3 (<0.1)		3 (<0.1)
Hip fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Inappropriate schedule of product administration	3 (<0.1)	3 (<0.1)		6 (<0.1)
Subdural haematoma	0	3 (<0.1)		3 (<0.1)
Tendon injury	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tendon rupture	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.14)	12 (<0.1)
Cervical vertebral fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Exposure to SARS-CoV-2	3 (<0.1)	2 (<0.1)		5 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Hypobarism	0	2 (<0.1)		2 (<0.1)
Ligament injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Lip injury	4 (<0.1)	2 (<0.1)		6 (<0.1)
Lower limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post procedural haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Procedural nausea	4 (<0.1)	2 (<0.1)		6 (<0.1)
Skin wound	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vaccination complication	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	3 (<0.1)	1 (<0.1)		4 (<0.1)
Carbon monoxide poisoning	0	1 (<0.1)		1 (<0.1)
Chemical burn	0	1 (<0.1)		1 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Chillblains	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)		1 (<0.1)
Dural tear	0	1 (<0.1)		1 (<0.1)
Eyelid injury	0	1 (<0.1)		1 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)		1 (<0.1)
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)		1 (<0.1)
Fractured sacrum	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Graft complication	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injury	0	1 (<0.1)		1 (<0.1)
Limb traumatic amputation	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Multiple fractures	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Neck injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural fever	1 (<0.1)	1 (<0.1)		2 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Procedural site reaction	0	1 (<0.1)		1 (<0.1)
Product administration interrupted	1 (<0.1)	1 (<0.1)		2 (<0.1)
Radius fracture	6 (<0.1)	1 (<0.1)		7 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scar	1 (<0.1)	1 (<0.1)		2 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal column injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Splinter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sports injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Superficial injury of eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Traumatic haemorrhage	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound	7 (<0.1)	1 (<0.1)	0.14 (0.02, 0.89)	8 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eye injury	2 (<0.1)	0		2 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	3 (<0.1)	0		3 (<0.1)
Foreign body in ear	2 (<0.1)	0		2 (<0.1)
Fractured coccyx	1 (<0.1)	0		1 (<0.1)
Gingival injury	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Keratorhexis	1 (<0.1)	0		1 (<0.1)
Mallet finger	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Mouth injury	1 (<0.1)	0		1 (<0.1)
Multiple injuries	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Musculoskeletal foreign body	1 (<0.1)	0		1 (<0.1)
Nail injury	2 (<0.1)	0		2 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	2 (<0.1)	0		2 (<0.1)
Post procedural contusion	1 (<0.1)	0		1 (<0.1)
Post procedural hypothyroidism	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural vomiting	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	2 (<0.1)	0		2 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	2 (<0.1)	0		2 (<0.1)
Uterine perforation	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	3 (<0.1)	2 (<0.1)		5 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Postmenopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	5 (<0.1)		8 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	131 (38.9)	105 (30.3)		236 (34.5)
Number of Unsolicited Adverse Events	290	276		566
Infections and infestations	34 (10.1)	29 (8.4)		63 (9.2)
Viral infection	3 (0.9)	5 (1.4)		8 (1.2)
COVID-19	9 (2.7)	4 (1.2)	0.43 (0.14, 1.31)	13 (1.9)
Upper respiratory tract infection	8 (2.4)	4 (1.2)	0.49 (0.16, 1.50)	12 (1.8)
Asymptomatic COVID-19	0	2 (0.6)		2 (0.3)
Otitis externa	0	2 (0.6)		2 (0.3)
Paronychia	0	2 (0.6)		2 (0.3)
Rhinovirus infection	1 (0.3)	2 (0.6)		3 (0.4)
Sinusitis	1 (0.3)	2 (0.6)		3 (0.4)
Cystitis	0	1 (0.3)		1 (0.1)
Herpes zoster	2 (0.6)	1 (0.3)		3 (0.4)
Pharyngitis streptococcal	1 (0.3)	1 (0.3)		2 (0.3)
Pneumonia	0	1 (0.3)		1 (0.1)
Respiratory tract infection	0	1 (0.3)		1 (0.1)
Subcutaneous abscess	0	1 (0.3)		1 (0.1)
Suspected COVID-19	0	1 (0.3)		1 (0.1)
Urinary tract infection	4 (1.2)	1 (0.3)		5 (0.7)
Vaginal infection	0	1 (0.3)		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Infections and infestations (Cont.)				
Acute sinusitis	1 (0.3)	0		1 (0.1)
Bacterial vaginosis	1 (0.3)	0		1 (0.1)
Cellulitis	1 (0.3)	0		1 (0.1)
Folliculitis	1 (0.3)	0		1 (0.1)
Furuncle	1 (0.3)	0		1 (0.1)
Gastroenteritis	2 (0.6)	0		2 (0.3)
Otitis media	1 (0.3)	0		1 (0.1)
Perineal cellulitis	1 (0.3)	0		1 (0.1)
Pyelonephritis	1 (0.3)	0		1 (0.1)
Pyelonephritis acute	1 (0.3)	0		1 (0.1)
Septic shock	1 (0.3)	0		1 (0.1)
Skin infection	1 (0.3)	0		1 (0.1)
Tooth abscess	1 (0.3)	0		1 (0.1)
Viral upper respiratory tract infection	1 (0.3)	0		1 (0.1)
Vulvovaginal candidiasis	1 (0.3)	0		1 (0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.3)	0		1 (0.1)
Prostate cancer recurrent	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Blood and lymphatic system disorders	5 (1.5)	3 (0.9)		8 (1.2)
Lymphadenopathy	5 (1.5)	3 (0.9)		8 (1.2)
Immune system disorders	3 (0.9)	1 (0.3)		4 (0.6)
Hypersensitivity	0	1 (0.3)		1 (0.1)
Seasonal allergy	3 (0.9)	0		3 (0.4)
Metabolism and nutrition disorders	9 (2.7)	3 (0.9)		12 (1.8)
Hyperlipidaemia	0	2 (0.6)		2 (0.3)
Type 2 diabetes mellitus	1 (0.3)	2 (0.6)		3 (0.4)
Vitamin D deficiency	2 (0.6)	1 (0.3)		3 (0.4)
Dehydration	1 (0.3)	0		1 (0.1)
Hypercholesterolaemia	3 (0.9)	0		3 (0.4)
Increased appetite	1 (0.3)	0		1 (0.1)
Metabolic acidosis	1 (0.3)	0		1 (0.1)
Psychiatric disorders	2 (0.6)	6 (1.7)		8 (1.2)
Depression	0	3 (0.9)		3 (0.4)
Anxiety	1 (0.3)	1 (0.3)		2 (0.3)
Drug abuse	0	1 (0.3)		1 (0.1)
Libido decreased	0	1 (0.3)		1 (0.1)
Premature ejaculation	0	1 (0.3)		1 (0.1)
Sleep disorder	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Nervous system disorders	31 (9.2)	27 (7.8)		58 (8.5)
Headache	23 (6.8)	23 (6.6)	0.97 (0.56, 1.69)	46 (6.7)
Dizziness	1 (0.3)	3 (0.9)		4 (0.6)
Ageusia	1 (0.3)	1 (0.3)		2 (0.3)
Anosmia	1 (0.3)	1 (0.3)		2 (0.3)
Dysgeusia	1 (0.3)	1 (0.3)		2 (0.3)
Hypoaesthesia	0	1 (0.3)		1 (0.1)
Migraine	2 (0.6)	1 (0.3)		3 (0.4)
Sciatica	0	1 (0.3)		1 (0.1)
Syncope	0	1 (0.3)		1 (0.1)
Taste disorder	0	1 (0.3)		1 (0.1)
Nerve compression	1 (0.3)	0		1 (0.1)
Paraesthesia	1 (0.3)	0		1 (0.1)
Parosmia	1 (0.3)	0		1 (0.1)
Poor quality sleep	1 (0.3)	0		1 (0.1)
Somnolence	1 (0.3)	0		1 (0.1)
Eye disorders	0	1 (0.3)		1 (0.1)
Vision blurred	0	1 (0.3)		1 (0.1)
Ear and labyrinth disorders	8 (2.4)	1 (0.3)		9 (1.3)
Cerumen impaction	1 (0.3)	1 (0.3)		2 (0.3)
Diplacusis	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Ear and labyrinth disorders (Cont.)				
Ear pain	1 (0.3)	0		1 (0.1)
Ear pruritus	1 (0.3)	0		1 (0.1)
Tinnitus	2 (0.6)	0		2 (0.3)
Tympanic membrane perforation	1 (0.3)	0		1 (0.1)
Vertigo	1 (0.3)	0		1 (0.1)
Cardiac disorders	2 (0.6)	2 (0.6)		4 (0.6)
Angina pectoris	0	1 (0.3)		1 (0.1)
Cardiac failure congestive	0	1 (0.3)		1 (0.1)
Acute left ventricular failure	1 (0.3)	0		1 (0.1)
Atrial fibrillation	1 (0.3)	0		1 (0.1)
Ventricular extrasystoles	1 (0.3)	0		1 (0.1)
Vascular disorders	7 (2.1)	6 (1.7)		13 (1.9)
Hypertension	6 (1.8)	6 (1.7)		12 (1.8)
Aortic dilatation	1 (0.3)	0		1 (0.1)
Respiratory, thoracic and mediastinal disorders	16 (4.7)	16 (4.6)		32 (4.7)
Nasal congestion	5 (1.5)	7 (2.0)	1.36 (0.46, 4.03)	12 (1.8)
Cough	4 (1.2)	5 (1.4)		9 (1.3)
Rhinorrhoea	4 (1.2)	5 (1.4)		9 (1.3)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Oropharyngeal pain	4 (1.2)	4 (1.2)		8 (1.2)
Dyspnoea	1 (0.3)	3 (0.9)		4 (0.6)
Productive cough	0	2 (0.6)		2 (0.3)
Respiratory tract congestion	0	2 (0.6)		2 (0.3)
Dry throat	0	1 (0.3)		1 (0.1)
Epistaxis	1 (0.3)	1 (0.3)		2 (0.3)
Pharyngeal erythema	0	1 (0.3)		1 (0.1)
Throat irritation	0	1 (0.3)		1 (0.1)
Acute respiratory failure	1 (0.3)	0		1 (0.1)
Haemoptysis	1 (0.3)	0		1 (0.1)
Sinus congestion	1 (0.3)	0		1 (0.1)
Tachypnoea	1 (0.3)	0		1 (0.1)
Gastrointestinal disorders	14 (4.2)	13 (3.7)		27 (3.9)
Diarrhoea	3 (0.9)	6 (1.7)		9 (1.3)
Gastrooesophageal reflux disease	4 (1.2)	4 (1.2)		8 (1.2)
Nausea	2 (0.6)	3 (0.9)		5 (0.7)
Abdominal pain upper	0	2 (0.6)		2 (0.3)
Abdominal pain	1 (0.3)	1 (0.3)		2 (0.3)
Gastric ulcer	0	1 (0.3)		1 (0.1)
Oesophageal ulcer	0	1 (0.3)		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Gastrointestinal disorders (Cont.)				
Rectal fissure	0	1 (0.3)		1 (0.1)
Dental caries	2 (0.6)	0		2 (0.3)
Dyspepsia	2 (0.6)	0		2 (0.3)
Gastritis	1 (0.3)	0		1 (0.1)
Periodontal disease	1 (0.3)	0		1 (0.1)
Hepatobiliary disorders	1 (0.3)	0		1 (0.1)
Cholelithiasis	1 (0.3)	0		1 (0.1)
Skin and subcutaneous tissue disorders	11 (3.3)	12 (3.5)		23 (3.4)
Hyperhidrosis	0	3 (0.9)		3 (0.4)
Urticaria	3 (0.9)	3 (0.9)		6 (0.9)
Acne	2 (0.6)	1 (0.3)		3 (0.4)
Dermatitis	1 (0.3)	1 (0.3)		2 (0.3)
Dry skin	0	1 (0.3)		1 (0.1)
Ecchymosis	0	1 (0.3)		1 (0.1)
Rash	1 (0.3)	1 (0.3)		2 (0.3)
Rash macular	0	1 (0.3)		1 (0.1)
Blister	1 (0.3)	0		1 (0.1)
Dermatitis contact	1 (0.3)	0		1 (0.1)
Erythema	1 (0.3)	0		1 (0.1)
Night sweats	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Pruritus	1 (0.3)	0		1 (0.1)
Musculoskeletal and connective tissue disorders	31 (9.2)	23 (6.6)		54 (7.9)
Myalgia	12 (3.6)	10 (2.9)	0.81 (0.36, 1.81)	22 (3.2)
Arthralgia	11 (3.3)	7 (2.0)	0.62 (0.25, 1.53)	18 (2.6)
Back pain	4 (1.2)	3 (0.9)		7 (1.0)
Limb discomfort	0	2 (0.6)		2 (0.3)
Musculoskeletal pain	5 (1.5)	2 (0.6)		7 (1.0)
Neck pain	3 (0.9)	2 (0.6)		5 (0.7)
Bursitis	0	1 (0.3)		1 (0.1)
Limb mass	0	1 (0.3)		1 (0.1)
Muscle spasms	0	1 (0.3)		1 (0.1)
Muscle tightness	0	1 (0.3)		1 (0.1)
Pain in extremity	1 (0.3)	1 (0.3)		2 (0.3)
Arthritis	2 (0.6)	0		2 (0.3)
Axillary mass	1 (0.3)	0		1 (0.1)
Muscle twitching	1 (0.3)	0		1 (0.1)
Musculoskeletal stiffness	1 (0.3)	0		1 (0.1)
Osteoarthritis	1 (0.3)	0		1 (0.1)
Plantar fasciitis	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rotator cuff syndrome	1 (0.3)	0		1 (0.1)
Spinal stenosis	1 (0.3)	0		1 (0.1)
Renal and urinary disorders	4 (1.2)	3 (0.9)		7 (1.0)
Dysuria	1 (0.3)	1 (0.3)		2 (0.3)
Nephrolithiasis	1 (0.3)	1 (0.3)		2 (0.3)
Polyuria	0	1 (0.3)		1 (0.1)
Chromaturia	1 (0.3)	0		1 (0.1)
Micturition urgency	1 (0.3)	0		1 (0.1)
Pollakiuria	1 (0.3)	0		1 (0.1)
Renal colic	1 (0.3)	0		1 (0.1)
Pregnancy, puerperium and perinatal conditions	1 (0.3)	0		1 (0.1)
Abortion spontaneous	1 (0.3)	0		1 (0.1)
Reproductive system and breast disorders	4 (1.2)	1 (0.3)		5 (0.7)
Postmenopausal haemorrhage	0	1 (0.3)		1 (0.1)
Benign prostatic hyperplasia	1 (0.3)	0		1 (0.1)
Breast cyst	1 (0.3)	0		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Reproductive system and breast disorders (Cont.)				
Nipple pain	1 (0.3)	0		1 (0.1)
Pelvic prolapse	1 (0.3)	0		1 (0.1)
General disorders and administration site conditions	28 (8.3)	25 (7.2)		53 (7.7)
Fatigue	18 (5.3)	11 (3.2)	0.59 (0.29, 1.22)	29 (4.2)
Chills	4 (1.2)	3 (0.9)		7 (1.0)
Injection site pain	3 (0.9)	3 (0.9)		6 (0.9)
Feeling hot	0	2 (0.6)		2 (0.3)
Injection site erythema	0	2 (0.6)		2 (0.3)
Injection site induration	0	2 (0.6)		2 (0.3)
Chest pain	0	1 (0.3)		1 (0.1)
Hangover	0	1 (0.3)		1 (0.1)
Injection site bruising	1 (0.3)	1 (0.3)		2 (0.3)
Injection site swelling	1 (0.3)	1 (0.3)		2 (0.3)
Non-cardiac chest pain	1 (0.3)	1 (0.3)		2 (0.3)
Oedema peripheral	1 (0.3)	1 (0.3)		2 (0.3)
Pain	1 (0.3)	1 (0.3)		2 (0.3)
Pyrexia	0	1 (0.3)		1 (0.1)
Swelling face	0	1 (0.3)		1 (0.1)
Vessel puncture site bruise	0	1 (0.3)		1 (0.1)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
General disorders and administration site conditions (Cont.)				
Asthenia	1 (0.3)	0		1 (0.1)
Chest discomfort	1 (0.3)	0		1 (0.1)
Investigations	6 (1.8)	5 (1.4)		11 (1.6)
Blood glucose increased	0	1 (0.3)		1 (0.1)
Blood pressure increased	2 (0.6)	1 (0.3)		3 (0.4)
Blood pressure systolic abnormal	0	1 (0.3)		1 (0.1)
Heart rate increased	0	1 (0.3)		1 (0.1)
Hepatic enzyme increased	1 (0.3)	1 (0.3)		2 (0.3)
Blood pressure systolic increased	1 (0.3)	0		1 (0.1)
Heart rate irregular	1 (0.3)	0		1 (0.1)
International normalised ratio increased	1 (0.3)	0		1 (0.1)
Respiratory rate increased	1 (0.3)	0		1 (0.1)
Injury, poisoning and procedural complications	10 (3.0)	8 (2.3)		18 (2.6)
Fall	0	2 (0.6)		2 (0.3)
Ligament sprain	2 (0.6)	2 (0.6)		4 (0.6)
Head injury	0	1 (0.3)		1 (0.1)
Joint injury	0	1 (0.3)		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301080303.sas 10JUN2021 12:56

Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Injury, poisoning and procedural complications (Cont.)				
Meniscus injury	0	1 (0.3)		1 (0.1)
Procedural pain	1 (0.3)	1 (0.3)		2 (0.3)
Road traffic accident	0	1 (0.3)		1 (0.1)
Spinal compression fracture	0	1 (0.3)		1 (0.1)
Animal bite	1 (0.3)	0		1 (0.1)
Concussion	1 (0.3)	0		1 (0.1)
Contusion	1 (0.3)	0		1 (0.1)
Epicondylitis	1 (0.3)	0		1 (0.1)
Facial bones fracture	1 (0.3)	0		1 (0.1)
Inappropriate schedule of product administration	1 (0.3)	0		1 (0.1)
Procedural anxiety	1 (0.3)	0		1 (0.1)
Skin abrasion	1 (0.3)	0		1 (0.1)
Skin laceration	1 (0.3)	0		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	23 (27.4)	30 (34.5)		53 (31.0)
Number of Unsolicited Adverse Events	43	63		106
Infections and infestations	8 (9.5)	11 (12.6)		19 (11.1)
Sinusitis	0	2 (2.3)		2 (1.2)
Suspected COVID-19	0	2 (2.3)		2 (1.2)
Conjunctivitis	1 (1.2)	1 (1.1)		2 (1.2)
Gastroenteritis viral	0	1 (1.1)		1 (0.6)
Herpes simplex	0	1 (1.1)		1 (0.6)
Infected bite	0	1 (1.1)		1 (0.6)
Lyme disease	0	1 (1.1)		1 (0.6)
Pharyngitis	0	1 (1.1)		1 (0.6)
Pharyngitis streptococcal	0	1 (1.1)		1 (0.6)
Staphylococcal infection	0	1 (1.1)		1 (0.6)
Tooth infection	0	1 (1.1)		1 (0.6)
Upper respiratory tract infection	0	1 (1.1)		1 (0.6)
COVID-19	4 (4.8)	0		4 (2.3)
Sinusitis bacterial	1 (1.2)	0		1 (0.6)
Urinary tract infection	1 (1.2)	0		1 (0.6)
Viral upper respiratory tract infection	1 (1.2)	0		1 (0.6)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.1)		1 (0.6)
Squamous cell carcinoma of skin	0	1 (1.1)		1 (0.6)
Blood and lymphatic system disorders	1 (1.2)	1 (1.1)		2 (1.2)
Iron deficiency anaemia	0	1 (1.1)		1 (0.6)
Lymphadenopathy	1 (1.2)	0		1 (0.6)
Metabolism and nutrition disorders	1 (1.2)	2 (2.3)		3 (1.8)
Hypercholesterolaemia	0	1 (1.1)		1 (0.6)
Hyperlipidaemia	0	1 (1.1)		1 (0.6)
Vitamin D deficiency	1 (1.2)	0		1 (0.6)
Psychiatric disorders	0	1 (1.1)		1 (0.6)
Depression	0	1 (1.1)		1 (0.6)
Nervous system disorders	5 (6.0)	6 (6.9)		11 (6.4)
Headache	4 (4.8)	5 (5.7)		9 (5.3)
Nerve compression	0	1 (1.1)		1 (0.6)
VIth nerve paralysis	1 (1.2)	0		1 (0.6)
Ear and labyrinth disorders	1 (1.2)	2 (2.3)		3 (1.8)
Meniere's disease	0	1 (1.1)		1 (0.6)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Ear and labyrinth disorders (Cont.)				
Vertigo	1 (1.2)	1 (1.1)		2 (1.2)
Cardiac disorders	1 (1.2)	0		1 (0.6)
Tachycardia	1 (1.2)	0		1 (0.6)
Vascular disorders	1 (1.2)	3 (3.4)		4 (2.3)
Hypertension	1 (1.2)	2 (2.3)		3 (1.8)
Hot flush	0	1 (1.1)		1 (0.6)
Respiratory, thoracic and mediastinal disorders	3 (3.6)	5 (5.7)		8 (4.7)
Oropharyngeal pain	1 (1.2)	2 (2.3)		3 (1.8)
Rhinorrhoea	0	2 (2.3)		2 (1.2)
Cough	0	1 (1.1)		1 (0.6)
Dyspnoea	0	1 (1.1)		1 (0.6)
Nasal congestion	1 (1.2)	1 (1.1)		2 (1.2)
Sneezing	0	1 (1.1)		1 (0.6)
Respiratory tract congestion	1 (1.2)	0		1 (0.6)
Tachypnoea	1 (1.2)	0		1 (0.6)
Gastrointestinal disorders	4 (4.8)	3 (3.4)		7 (4.1)
Diarrhoea	1 (1.2)	2 (2.3)		3 (1.8)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Gastrointestinal disorders (Cont.)				
Inguinal hernia	0	1 (1.1)		1 (0.6)
Constipation	1 (1.2)	0		1 (0.6)
Mouth haemorrhage	1 (1.2)	0		1 (0.6)
Nausea	1 (1.2)	0		1 (0.6)
Vomiting	2 (2.4)	0		2 (1.2)
Skin and subcutaneous tissue disorders	1 (1.2)	2 (2.3)		3 (1.8)
Pruritus	0	1 (1.1)		1 (0.6)
Rash erythematous	0	1 (1.1)		1 (0.6)
Rash	1 (1.2)	0		1 (0.6)
Musculoskeletal and connective tissue disorders	2 (2.4)	5 (5.7)		7 (4.1)
Pain in extremity	0	2 (2.3)		2 (1.2)
Back pain	0	1 (1.1)		1 (0.6)
Myalgia	2 (2.4)	1 (1.1)		3 (1.8)
Torticollis	0	1 (1.1)		1 (0.6)
Arthralgia	1 (1.2)	0		1 (0.6)
General disorders and administration site conditions	5 (6.0)	8 (9.2)		13 (7.6)
Fatigue	4 (4.8)	4 (4.6)		8 (4.7)

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Table 14.3.1.8.3.3
Subject Incidence of Unsolicited TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
General disorders and administration site conditions (Cont.)				
Injection site pain	1 (1.2)	3 (3.4)		4 (2.3)
Injection site lymphadenopathy	0	1 (1.1)		1 (0.6)
Pain	0	1 (1.1)		1 (0.6)
Pyrexia	0	1 (1.1)		1 (0.6)
Investigations	2 (2.4)	0		2 (1.2)
Blood pressure increased	1 (1.2)	0		1 (0.6)
Blood pressure systolic increased	1 (1.2)	0		1 (0.6)
Injury, poisoning and procedural complications	2 (2.4)	3 (3.4)		5 (2.9)
Meniscus injury	0	1 (1.1)		1 (0.6)
Procedural pain	1 (1.2)	1 (1.1)		2 (1.2)
Wound	0	1 (1.1)		1 (0.6)
Dental restoration failure	1 (1.2)	0		1 (0.6)

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MedDRA version 23.0.
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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4294 (28.3)	4716 (31.1)		9010 (29.7)
Number of Unsolicited Adverse Events	8452	9401		17853
Infections and infestations	937 (6.2)	774 (5.1)		1711 (5.6)
Urinary tract infection	110 (0.7)	94 (0.6)	0.85 (0.65, 1.12)	204 (0.7)
Upper respiratory tract infection	118 (0.8)	82 (0.5)	0.69 (0.52, 0.92)	200 (0.7)
Sinusitis	46 (0.3)	61 (0.4)	1.32 (0.91, 1.94)	107 (0.4)
Viral infection	52 (0.3)	41 (0.3)	0.79 (0.52, 1.18)	93 (0.3)
Rhinovirus infection	30 (0.2)	36 (0.2)	1.20 (0.74, 1.94)	66 (0.2)
Suspected COVID-19	35 (0.2)	34 (0.2)	0.97 (0.61, 1.55)	69 (0.2)
Tooth infection	18 (0.1)	26 (0.2)	1.44 (0.80, 2.61)	44 (0.1)
Tooth abscess	26 (0.2)	23 (0.2)	0.88 (0.51, 1.54)	49 (0.2)
Herpes zoster	15 (<0.1)	22 (0.1)	1.46 (0.77, 2.79)	37 (0.1)
COVID-19	152 (1.0)	21 (0.1)	0.14 (0.09, 0.22)	173 (0.6)
Gastroenteritis	17 (0.1)	19 (0.1)	1.12 (0.59, 2.12)	36 (0.1)
Pharyngitis	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Ear infection	10 (<0.1)	18 (0.1)	1.80 (0.85, 3.82)	28 (<0.1)
Conjunctivitis	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Pharyngitis streptococcal	20 (0.1)	13 (<0.1)	0.65 (0.33, 1.29)	33 (0.1)
Hordeolum	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Oral herpes	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Cellulitis	17 (0.1)	11 (<0.1)	0.65 (0.31, 1.36)	28 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Viral upper respiratory tract infection	14 (<0.1)	11 (<0.1)	0.78 (0.36, 1.69)	25 (<0.1)
Diverticulitis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Fungal infection	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Gingivitis	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Herpes simplex	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Otitis media	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Bronchitis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Localised infection	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Onychomycosis	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Folliculitis	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Otitis externa	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Paronychia	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Acute sinusitis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Bacterial vaginosis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vulvovaginal mycotic infection	14 (<0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Abscess limb	1 (<0.1)	5 (<0.1)		6 (<0.1)
Asymptomatic COVID-19	3 (<0.1)	5 (<0.1)		8 (<0.1)
Nasopharyngitis	12 (<0.1)	5 (<0.1)	0.42 (0.15, 1.13)	17 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Subcutaneous abscess	2 (<0.1)	5 (<0.1)		7 (<0.1)
Enterovirus infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Laryngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Lyme disease	0	4 (<0.1)		4 (<0.1)
Skin infection	4 (<0.1)	4 (<0.1)		8 (<0.1)
Staphylococcal infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cystitis	11 (<0.1)	3 (<0.1)	0.27 (0.08, 0.91)	14 (<0.1)
Furuncle	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastroenteritis viral	10 (<0.1)	3 (<0.1)	0.30 (0.09, 1.01)	13 (<0.1)
Helicobacter infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gonorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis media acute	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pneumonia	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Respiratory tract infection viral	5 (<0.1)	2 (<0.1)		7 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea pedis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Tonsillitis	11 (<0.1)	2 (<0.1)	0.18 (0.05, 0.73)	13 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	0	1 (<0.1)		1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Candida infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastroenteritis bacterial	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rhinitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Tinea cruris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Trichomoniasis	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Infections and infestations (Cont.)				
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Wound infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Breast abscess	2 (<0.1)	0		2 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	2 (<0.1)	0		2 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Influenza	2 (<0.1)	0		2 (<0.1)
Labyrinthitis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pulpitis dental	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	2 (<0.1)	0		2 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Skin candida	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	48 (0.3)	53 (0.3)		101 (0.3)
Basal cell carcinoma	16 (0.1)	10 (<0.1)	0.62 (0.29, 1.35)	26 (<0.1)
Benign neoplasm of skin	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Squamous cell carcinoma	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Uterine leiomyoma	1 (<0.1)	4 (<0.1)		5 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lipoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Malignant melanoma	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Benign ovarian tumour	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)		5 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	147 (1.0)	291 (1.9)		438 (1.4)
Lymphadenopathy	127 (0.8)	264 (1.7)	2.08 (1.68, 2.56)	391 (1.3)
Anaemia	5 (<0.1)	10 (<0.1)	2.00 (0.71, 5.58)	15 (<0.1)
Lymph node pain	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Lymphadenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Iron deficiency anaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

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Blood and lymphatic system disorders (Cont.)				
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	65 (0.4)	47 (0.3)		112 (0.4)
Seasonal allergy	47 (0.3)	33 (0.2)	0.70 (0.45, 1.09)	80 (0.3)
Hypersensitivity	6 (<0.1)	6 (<0.1)		12 (<0.1)
Food allergy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug hypersensitivity	5 (<0.1)	1 (<0.1)		6 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	17 (0.1)	11 (<0.1)		28 (<0.1)
Hypothyroidism	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)

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Endocrine disorders (Cont.)				
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	109 (0.7)	126 (0.8)		235 (0.8)
Hyperlipidaemia	21 (0.1)	23 (0.2)	1.09 (0.61, 1.96)	44 (0.1)
Type 2 diabetes mellitus	11 (<0.1)	21 (0.1)	1.91 (0.93, 3.89)	32 (0.1)
Hypercholesterolaemia	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Vitamin D deficiency	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Decreased appetite	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Dehydration	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Gout	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Diabetes mellitus	5 (<0.1)	6 (<0.1)		11 (<0.1)
Glucose tolerance impaired	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Hyperglycaemia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hyponatraemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abnormal loss of weight	0	2 (<0.1)		2 (<0.1)
Hypoglycaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Food intolerance	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hyperkalaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	111 (0.7)	154 (1.0)		265 (0.9)
Anxiety	37 (0.2)	52 (0.3)	1.40 (0.92, 2.13)	89 (0.3)
Depression	27 (0.2)	35 (0.2)	1.29 (0.79, 2.13)	62 (0.2)

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Psychiatric disorders (Cont.)				
Insomnia	24 (0.2)	32 (0.2)	1.33 (0.79, 2.25)	56 (0.2)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Attention deficit hyperactivity disorder	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Sleep disorder	0	5 (<0.1)		5 (<0.1)
Panic attack	3 (<0.1)	4 (<0.1)		7 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)		4 (<0.1)
Libido decreased	0	2 (<0.1)		2 (<0.1)
Major depression	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress	1 (<0.1)	2 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)

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Psychiatric disorders (Cont.)				
Reading disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental fatigue	1 (<0.1)	0		1 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	875 (5.8)	1002 (6.6)		1877 (6.2)
Headache	687 (4.5)	744 (4.9)	1.08 (0.98, 1.20)	1431 (4.7)
Dizziness	56 (0.4)	74 (0.5)	1.32 (0.93, 1.86)	130 (0.4)
Paraesthesia	26 (0.2)	34 (0.2)	1.31 (0.79, 2.16)	60 (0.2)
Sinus headache	6 (<0.1)	20 (0.1)	3.33 (1.38, 8.05)	26 (<0.1)
Ageusia	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Migraine	23 (0.2)	15 (<0.1)	0.65 (0.34, 1.23)	38 (0.1)
Hypoaesthesia	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Dysgeusia	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Sciatica	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Syncope	12 (<0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Anosmia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Tension headache	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Cervical radiculopathy	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Hyperaesthesia	0	6 (<0.1)		6 (<0.1)
Presyncope	14 (<0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Carpal tunnel syndrome	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Memory impairment	0	4 (<0.1)		4 (<0.1)
Burning sensation	0	3 (<0.1)		3 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Nerve compression	3 (<0.1)	3 (<0.1)		6 (<0.1)
Peripheral sensory neuropathy	0	3 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	3 (<0.1)		5 (<0.1)
Amnesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Migraine with aura	0	2 (<0.1)		2 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neuropathy peripheral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Parosmia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Post-traumatic headache	1 (<0.1)	2 (<0.1)		3 (<0.1)
Seizure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Somnolence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Dizziness postural	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Post herpetic neuralgia	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Restless legs syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	3 (<0.1)	0		3 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Muscle contractions involuntary	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	66 (0.4)	70 (0.5)		136 (0.4)
Eye irritation	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Eye pruritus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Vision blurred	3 (<0.1)	6 (<0.1)		9 (<0.1)
Dry eye	6 (<0.1)	4 (<0.1)		10 (<0.1)
Eye pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Eye inflammation	0	3 (<0.1)		3 (<0.1)
Glaucoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Retinal detachment	1 (<0.1)	3 (<0.1)		4 (<0.1)
Blepharitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Eye swelling	3 (<0.1)	2 (<0.1)		5 (<0.1)
Lacrimation increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular hyperaemia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Photophobia	0	2 (<0.1)		2 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vitreous floaters	2 (<0.1)	2 (<0.1)		4 (<0.1)
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cataract	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Visual impairment	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Photopsia	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	83 (0.5)	81 (0.5)		164 (0.5)
Vertigo	18 (0.1)	23 (0.2)	1.28 (0.70, 2.34)	41 (0.1)
Ear pain	18 (0.1)	17 (0.1)	0.94 (0.49, 1.81)	35 (0.1)
Tinnitus	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Vertigo positional	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Cerumen impaction	2 (<0.1)	4 (<0.1)		6 (<0.1)
Ear discomfort	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ear canal erythema	4 (<0.1)	2 (<0.1)		6 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ear congestion	4 (<0.1)	1 (<0.1)		5 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)				
Tympanic membrane perforation	6 (<0.1)	1 (<0.1)		7 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Ear pruritus	3 (<0.1)	0		3 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	62 (0.4)	68 (0.4)		130 (0.4)
Tachycardia	9 (<0.1)	15 (<0.1)	1.66 (0.74, 3.72)	24 (<0.1)
Bradycardia	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Atrial fibrillation	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Palpitations	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Angina pectoris	4 (<0.1)	5 (<0.1)		9 (<0.1)
Arrhythmia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Sinus tachycardia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Coronary artery disease	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Cardiac failure	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	196 (1.3)	194 (1.3)		390 (1.3)
Hypertension	160 (1.1)	151 (1.0)	0.94 (0.76, 1.18)	311 (1.0)
Hot flush	8 (<0.1)	15 (<0.1)	1.87 (0.81, 4.31)	23 (<0.1)
Flushing	5 (<0.1)	6 (<0.1)		11 (<0.1)
Haematoma	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hypertensive urgency	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypotension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Orthostatic hypotension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	3 (<0.1)	0		3 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)

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Safety Set

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Vascular disorders (Cont.)				
Diastolic hypertension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	656 (4.3)	595 (3.9)		1251 (4.1)
Cough	165 (1.1)	177 (1.2)	1.07 (0.87, 1.32)	342 (1.1)
Oropharyngeal pain	232 (1.5)	158 (1.0)	0.68 (0.56, 0.83)	390 (1.3)
Nasal congestion	165 (1.1)	155 (1.0)	0.94 (0.75, 1.17)	320 (1.1)
Rhinorrhoea	145 (1.0)	130 (0.9)	0.90 (0.71, 1.13)	275 (0.9)
Dyspnoea	41 (0.3)	42 (0.3)	1.02 (0.67, 1.57)	83 (0.3)
Tachypnoea	32 (0.2)	33 (0.2)	1.03 (0.64, 1.67)	65 (0.2)
Respiratory tract congestion	7 (<0.1)	18 (0.1)	2.57 (1.10, 5.99)	25 (<0.1)
Asthma	17 (0.1)	16 (0.1)	0.94 (0.48, 1.84)	33 (0.1)
Epistaxis	11 (<0.1)	16 (0.1)	1.45 (0.69, 3.07)	27 (<0.1)
Sinus congestion	26 (0.2)	16 (0.1)	0.61 (0.33, 1.13)	42 (0.1)
Throat irritation	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Rhinitis allergic	15 (<0.1)	12 (<0.1)	0.80 (0.38, 1.68)	27 (<0.1)
Upper-airway cough syndrome	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Sneezing	14 (<0.1)	11 (<0.1)	0.78 (0.36, 1.69)	25 (<0.1)
Chronic obstructive pulmonary disease	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Dysphonia	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pharyngeal erythema	3 (<0.1)	5 (<0.1)		8 (<0.1)
Sinus pain	4 (<0.1)	5 (<0.1)		9 (<0.1)
Dry throat	3 (<0.1)	4 (<0.1)		7 (<0.1)
Dyspnoea exertional	1 (<0.1)	4 (<0.1)		5 (<0.1)
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)		7 (<0.1)
Productive cough	6 (<0.1)	4 (<0.1)		10 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Wheezing	4 (<0.1)	3 (<0.1)		7 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pleural effusion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atelectasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Emphysema	0	1 (<0.1)		1 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal dryness	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	4 (<0.1)	1 (<0.1)		5 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	2 (<0.1)	0		2 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	561 (3.7)	589 (3.9)		1150 (3.8)
Diarrhoea	199 (1.3)	203 (1.3)	1.02 (0.84, 1.24)	402 (1.3)
Nausea	163 (1.1)	160 (1.1)	0.98 (0.79, 1.22)	323 (1.1)
Vomiting	52 (0.3)	61 (0.4)	1.17 (0.81, 1.69)	113 (0.4)
Gastrooesophageal reflux disease	29 (0.2)	41 (0.3)	1.41 (0.88, 2.26)	70 (0.2)
Toothache	28 (0.2)	35 (0.2)	1.25 (0.76, 2.04)	63 (0.2)
Abdominal pain	19 (0.1)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.1)
Constipation	21 (0.1)	16 (0.1)	0.76 (0.40, 1.44)	37 (0.1)
Dental caries	11 (<0.1)	15 (<0.1)	1.36 (0.64, 2.91)	26 (<0.1)
Dyspepsia	16 (0.1)	14 (<0.1)	0.87 (0.43, 1.76)	30 (<0.1)
Abdominal pain upper	20 (0.1)	13 (<0.1)	0.65 (0.33, 1.29)	33 (0.1)
Food poisoning	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Abdominal pain lower	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Abdominal discomfort	13 (<0.1)	6 (<0.1)	0.46 (0.18, 1.17)	19 (<0.1)
Gastric ulcer	2 (<0.1)	5 (<0.1)		7 (<0.1)
Haemorrhoids	4 (<0.1)	5 (<0.1)		9 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal distension	2 (<0.1)	4 (<0.1)		6 (<0.1)
Inguinal hernia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Aphthous ulcer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Colitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Flatulence	2 (<0.1)	3 (<0.1)		5 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)		4 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Large intestine polyp	5 (<0.1)	3 (<0.1)		8 (<0.1)
Paraesthesia oral	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tooth impacted	2 (<0.1)	3 (<0.1)		5 (<0.1)
Umbilical hernia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dry mouth	3 (<0.1)	2 (<0.1)		5 (<0.1)
Dysphagia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastritis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastrointestinal disorder	0	2 (<0.1)		2 (<0.1)
Hiatus hernia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)		4 (<0.1)
Mouth ulceration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophagitis	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Proctalgia	0	2 (<0.1)		2 (<0.1)
Rectal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Peptic ulcer	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gastrointestinal pain	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	2 (<0.1)	0		2 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Oral pain	5 (<0.1)	0		5 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Retching	1 (<0.1)	0		1 (<0.1)
Saliva altered	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	5 (<0.1)	10 (<0.1)		15 (<0.1)
Cholelithiasis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Hepatic steatosis	0	2 (<0.1)		2 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	233 (1.5)	293 (1.9)		526 (1.7)
Urticaria	33 (0.2)	44 (0.3)	1.33 (0.85, 2.08)	77 (0.3)
Rash	31 (0.2)	35 (0.2)	1.13 (0.70, 1.82)	66 (0.2)
Pruritus	23 (0.2)	25 (0.2)	1.09 (0.62, 1.90)	48 (0.2)
Dermatitis contact	31 (0.2)	24 (0.2)	0.77 (0.46, 1.31)	55 (0.2)
Erythema	5 (<0.1)	15 (<0.1)	3.00 (1.13, 7.93)	20 (<0.1)
Hyperhidrosis	11 (<0.1)	13 (<0.1)	1.18 (0.54, 2.58)	24 (<0.1)
Eczema	3 (<0.1)	10 (<0.1)	3.33 (0.99, 11.21)	13 (<0.1)
Night sweats	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Acne	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Dermatitis	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash maculo-papular	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Rash papular	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Alopecia	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Rash macular	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Actinic keratosis	2 (<0.1)	6 (<0.1)		8 (<0.1)
Dermatitis atopic	6 (<0.1)	5 (<0.1)		11 (<0.1)
Ecchymosis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Psoriasis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Rash pruritic	6 (<0.1)	5 (<0.1)		11 (<0.1)
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)
Rosacea	2 (<0.1)	4 (<0.1)		6 (<0.1)
Blister	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dry skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hidradenitis	0	3 (<0.1)		3 (<0.1)
Macule	0	3 (<0.1)		3 (<0.1)
Pain of skin	0	3 (<0.1)		3 (<0.1)
Rash erythematous	3 (<0.1)	3 (<0.1)		6 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Hand dermatitis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Angioedema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	4 (<0.1)	1 (<0.1)		5 (<0.1)
Dermatitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Papule	2 (<0.1)	1 (<0.1)		3 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	0	1 (<0.1)		1 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin lesion	4 (<0.1)	0		4 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	1010 (6.7)	1002 (6.6)		2012 (6.6)
Arthralgia	389 (2.6)	391 (2.6)	1.00 (0.87, 1.15)	780 (2.6)
Myalgia	388 (2.6)	387 (2.5)	1.00 (0.87, 1.14)	775 (2.6)
Back pain	130 (0.9)	106 (0.7)	0.81 (0.63, 1.05)	236 (0.8)
Pain in extremity	77 (0.5)	67 (0.4)	0.87 (0.63, 1.20)	144 (0.5)
Musculoskeletal pain	38 (0.3)	49 (0.3)	1.29 (0.85, 1.96)	87 (0.3)
Neck pain	38 (0.3)	46 (0.3)	1.21 (0.79, 1.85)	84 (0.3)
Muscle spasms	29 (0.2)	35 (0.2)	1.21 (0.74, 1.96)	64 (0.2)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Osteoarthritis	23 (0.2)	21 (0.1)	0.91 (0.51, 1.63)	44 (0.1)
Tendonitis	13 (<0.1)	15 (<0.1)	1.15 (0.56, 2.38)	28 (<0.1)
Musculoskeletal chest pain	14 (<0.1)	14 (<0.1)	1.00 (0.48, 2.06)	28 (<0.1)
Bursitis	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Musculoskeletal stiffness	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Rotator cuff syndrome	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Arthritis	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Trigger finger	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Groin pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Intervertebral disc protrusion	4 (<0.1)	6 (<0.1)		10 (<0.1)
Joint swelling	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Muscle tightness	1 (<0.1)	6 (<0.1)		7 (<0.1)
Muscular weakness	2 (<0.1)	6 (<0.1)		8 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Limb discomfort	2 (<0.1)	5 (<0.1)		7 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Costochondritis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Fibromyalgia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Osteoporosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pain in jaw	6 (<0.1)	4 (<0.1)		10 (<0.1)
Spinal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Flank pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Muscle twitching	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Neck mass	0	3 (<0.1)		3 (<0.1)
Spinal osteoarthritis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Axillary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle fatigue	0	2 (<0.1)		2 (<0.1)
Plantar fasciitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Intervertebral disc degeneration	4 (<0.1)	1 (<0.1)		5 (<0.1)
Joint stiffness	2 (<0.1)	1 (<0.1)		3 (<0.1)
Limb mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	3 (<0.1)	0		3 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	0		2 (<0.1)
Scoliosis	2 (<0.1)	0		2 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	45 (0.3)	46 (0.3)		91 (0.3)
Nephrolithiasis	21 (0.1)	11 (<0.1)	0.52 (0.26, 1.07)	32 (0.1)
Dysuria	1 (<0.1)	5 (<0.1)		6 (<0.1)
Haematuria	6 (<0.1)	3 (<0.1)		9 (<0.1)
Pollakiuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Polyuria	0	3 (<0.1)		3 (<0.1)
Hypertonic bladder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nocturia	0	2 (<0.1)		2 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary incontinence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute kidney injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder pain	0	1 (<0.1)		1 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Chromaturia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chronic kidney disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	2 (<0.1)	0		2 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	58 (0.4)	58 (0.4)		116 (0.4)
Dysmenorrhoea	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Erectile dysfunction	3 (<0.1)	5 (<0.1)		8 (<0.1)
Benign prostatic hyperplasia	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Pelvic pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Menorrhagia	0	3 (<0.1)		3 (<0.1)
Prostatitis	6 (<0.1)	3 (<0.1)		9 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Menopausal symptoms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	0	2 (<0.1)		2 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	0	1 (<0.1)		1 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Testicular pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)				
Hydrocele	2 (<0.1)	0		2 (<0.1)
General disorders and administration site conditions	1062 (7.0)	1602 (10.6)		2664 (8.8)
Fatigue	666 (4.4)	752 (5.0)	1.13 (1.02, 1.25)	1418 (4.7)
Injection site pain	118 (0.8)	258 (1.7)	2.18 (1.76, 2.71)	376 (1.2)
Injection site erythema	39 (0.3)	157 (1.0)	4.02 (2.84, 5.69)	196 (0.6)
Chills	111 (0.7)	131 (0.9)	1.18 (0.92, 1.51)	242 (0.8)
Pyrexia	62 (0.4)	118 (0.8)	1.90 (1.40, 2.58)	180 (0.6)
Injection site swelling	29 (0.2)	115 (0.8)	3.96 (2.64, 5.93)	144 (0.5)
Injection site pruritus	13 (<0.1)	88 (0.6)	6.76 (3.81, 12.00)	101 (0.3)
Pain	66 (0.4)	72 (0.5)	1.09 (0.78, 1.52)	138 (0.5)
Injection site lymphadenopathy	15 (<0.1)	66 (0.4)	4.39 (2.53, 7.64)	81 (0.3)
Injection site induration	18 (0.1)	53 (0.3)	2.94 (1.73, 4.99)	71 (0.2)
Injection site macule	4 (<0.1)	45 (0.3)	11.23 (4.21, 30.01)	49 (0.2)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.94 (6.58, 218.91)	39 (0.1)
Axillary pain	14 (<0.1)	26 (0.2)	1.85 (0.98, 3.51)	40 (0.1)
Injection site rash	1 (<0.1)	24 (0.2)	23.97 (4.11, 139.71)	25 (<0.1)
Injection site bruising	21 (0.1)	18 (0.1)	0.86 (0.46, 1.59)	39 (0.1)
Malaise	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	12.98 (2.18, 77.49)	14 (<0.1)
Chest discomfort	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Peripheral swelling	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Chest pain	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Reactogenicity event	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Feeling hot	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haemorrhage	5 (<0.1)	6 (<0.1)		11 (<0.1)
Injection site paraesthesia	3 (<0.1)	6 (<0.1)		9 (<0.1)
Non-cardiac chest pain	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Oedema peripheral	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Feeling abnormal	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Vaccination site pain	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site reaction	0	3 (<0.1)		3 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Hangover	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Asthenia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Swelling face	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	0	1 (<0.1)		1 (<0.1)
Adverse drug reaction	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)
Thirst	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	1 (<0.1)	0		1 (<0.1)
Xerosis	1 (<0.1)	0		1 (<0.1)
Investigations	80 (0.5)	107 (0.7)		187 (0.6)
Blood pressure increased	27 (0.2)	25 (0.2)	0.92 (0.54, 1.58)	52 (0.2)
Blood pressure systolic increased	9 (<0.1)	15 (<0.1)	1.66 (0.74, 3.72)	24 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	10 (<0.1)	4.99 (1.23, 20.26)	12 (<0.1)
Body temperature increased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood cholesterol increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Heart rate increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hepatic enzyme increased	4 (<0.1)	4 (<0.1)		8 (<0.1)
Transaminases increased	0	4 (<0.1)		4 (<0.1)
Blood glucose increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood triglycerides increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Weight decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatine increased	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood uric acid increased	0	1 (<0.1)		1 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac murmur	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	2 (<0.1)	0		2 (<0.1)
Weight increased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications	389 (2.6)	323 (2.1)		712 (2.3)
Muscle strain	35 (0.2)	39 (0.3)	1.11 (0.71, 1.75)	74 (0.2)
Ligament sprain	29 (0.2)	30 (0.2)	1.03 (0.62, 1.71)	59 (0.2)
Arthropod bite	31 (0.2)	24 (0.2)	0.77 (0.46, 1.31)	55 (0.2)
Skin laceration	32 (0.2)	22 (0.1)	0.69 (0.40, 1.17)	54 (0.2)
Contusion	29 (0.2)	20 (0.1)	0.69 (0.39, 1.21)	49 (0.2)
Fall	26 (0.2)	20 (0.1)	0.77 (0.43, 1.36)	46 (0.2)
Procedural pain	31 (0.2)	18 (0.1)	0.58 (0.33, 1.03)	49 (0.2)
Tooth fracture	17 (0.1)	17 (0.1)	1.00 (0.52, 1.93)	34 (0.1)
Foot fracture	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Limb injury	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Road traffic accident	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Skin abrasion	22 (0.1)	11 (<0.1)	0.50 (0.25, 1.01)	33 (0.1)
Arthropod sting	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (<0.1)
Joint injury	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Animal bite	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Meniscus injury	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Post-traumatic pain	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Concussion	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hand fracture	3 (<0.1)	5 (<0.1)		8 (<0.1)
Rib fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Head injury	1 (<0.1)	4 (<0.1)		5 (<0.1)
Bone contusion	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cartilage injury	0	3 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Epicondylitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Facial bones fracture	0	3 (<0.1)		3 (<0.1)
Thermal burn	3 (<0.1)	3 (<0.1)		6 (<0.1)
Wrist fracture	4 (<0.1)	3 (<0.1)		7 (<0.1)
Ankle fracture	4 (<0.1)	2 (<0.1)		6 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tendon injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tendon rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Upper limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)		2 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Vaccination complication	2 (<0.1)	1 (<0.1)		3 (<0.1)
Wound	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Back injury	3 (<0.1)	0		3 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Humerus fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Inappropriate schedule of product administration	2 (<0.1)	0		2 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Lip injury	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural nausea	2 (<0.1)	0		2 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Sports injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	1 (<0.1)		2 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Product issues	2 (<0.1)	5 (<0.1)		7 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.13.1
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Product issues (Cont.)				
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6429 (42.4)	6230 (41.0)		12659 (41.7)
Number of Unsolicited Adverse Events	14790	14468		29258
Infections and infestations	2485 (16.4)	1685 (11.1)		4170 (13.7)
Upper respiratory tract infection	314 (2.1)	261 (1.7)	0.83 (0.71, 0.98)	575 (1.9)
Urinary tract infection	202 (1.3)	170 (1.1)	0.84 (0.69, 1.03)	372 (1.2)
Viral infection	159 (1.0)	163 (1.1)	1.02 (0.82, 1.27)	322 (1.1)
Sinusitis	120 (0.8)	133 (0.9)	1.11 (0.87, 1.41)	253 (0.8)
Suspected COVID-19	124 (0.8)	132 (0.9)	1.06 (0.83, 1.36)	256 (0.8)
COVID-19	941 (6.2)	84 (0.6)	0.09 (0.07, 0.11)	1025 (3.4)
Rhinovirus infection	75 (0.5)	84 (0.6)	1.12 (0.82, 1.52)	159 (0.5)
Herpes zoster	23 (0.2)	50 (0.3)	2.17 (1.33, 3.54)	73 (0.2)
Viral upper respiratory tract infection	41 (0.3)	41 (0.3)	1.00 (0.65, 1.53)	82 (0.3)
Tooth infection	36 (0.2)	36 (0.2)	1.00 (0.63, 1.58)	72 (0.2)
Tooth abscess	46 (0.3)	34 (0.2)	0.74 (0.48, 1.15)	80 (0.3)
Pharyngitis	32 (0.2)	32 (0.2)	1.00 (0.61, 1.62)	64 (0.2)
Gastroenteritis	41 (0.3)	31 (0.2)	0.76 (0.48, 1.20)	72 (0.2)
Ear infection	25 (0.2)	30 (0.2)	1.20 (0.71, 2.02)	55 (0.2)
Pharyngitis streptococcal	38 (0.3)	26 (0.2)	0.68 (0.42, 1.12)	64 (0.2)
Cellulitis	36 (0.2)	25 (0.2)	0.69 (0.42, 1.15)	61 (0.2)
Bronchitis	33 (0.2)	23 (0.2)	0.70 (0.41, 1.18)	56 (0.2)
Hordeolum	27 (0.2)	23 (0.2)	0.85 (0.49, 1.47)	50 (0.2)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Otitis media	20 (0.1)	21 (0.1)	1.05 (0.57, 1.92)	41 (0.1)
Conjunctivitis	24 (0.2)	20 (0.1)	0.83 (0.46, 1.49)	44 (0.1)
Asymptomatic COVID-19	16 (0.1)	19 (0.1)	1.19 (0.62, 2.28)	35 (0.1)
Nasopharyngitis	29 (0.2)	18 (0.1)	0.62 (0.35, 1.11)	47 (0.2)
Oral herpes	18 (0.1)	18 (0.1)	1.00 (0.53, 1.90)	36 (0.1)
Diverticulitis	18 (0.1)	17 (0.1)	0.94 (0.49, 1.81)	35 (0.1)
Respiratory tract infection	13 (<0.1)	15 (<0.1)	1.15 (0.56, 2.38)	28 (<0.1)
Acute sinusitis	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Fungal infection	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Bacterial vaginosis	11 (<0.1)	12 (<0.1)	1.09 (0.49, 2.42)	23 (<0.1)
Gingivitis	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Herpes simplex	5 (<0.1)	12 (<0.1)	2.40 (0.88, 6.52)	17 (<0.1)
Localised infection	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Onychomycosis	6 (<0.1)	12 (<0.1)	2.00 (0.78, 5.13)	18 (<0.1)
Otitis externa	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Enterovirus infection	4 (<0.1)	11 (<0.1)	2.75 (0.92, 8.16)	15 (<0.1)
Pneumonia	23 (0.2)	10 (<0.1)	0.43 (0.21, 0.90)	33 (0.1)
Vulvovaginal mycotic infection	21 (0.1)	10 (<0.1)	0.48 (0.23, 0.99)	31 (0.1)
Folliculitis	16 (0.1)	9 (<0.1)	0.56 (0.25, 1.24)	25 (<0.1)
Paronychia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Skin infection	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Vulvovaginal candidiasis	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Abscess limb	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Cystitis	18 (0.1)	7 (<0.1)	0.39 (0.17, 0.91)	25 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Furuncle	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Gastroenteritis viral	17 (0.1)	7 (<0.1)	0.41 (0.18, 0.97)	24 (<0.1)
Laryngitis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Subcutaneous abscess	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Lyme disease	0	6 (<0.1)		6 (<0.1)
Oral candidiasis	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Pyelonephritis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Staphylococcal infection	3 (<0.1)	6 (<0.1)		9 (<0.1)
Staphylococcal skin infection	1 (<0.1)	6 (<0.1)		7 (<0.1)
Clostridium difficile infection	1 (<0.1)	5 (<0.1)		6 (<0.1)
Helicobacter infection	4 (<0.1)	5 (<0.1)		9 (<0.1)
Kidney infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Chlamydial infection	0	4 (<0.1)		4 (<0.1)
Eye infection	6 (<0.1)	4 (<0.1)		10 (<0.1)
Gonorrhoea	2 (<0.1)	4 (<0.1)		6 (<0.1)
Impetigo	1 (<0.1)	4 (<0.1)		5 (<0.1)
Periodontitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Postoperative wound infection	3 (<0.1)	4 (<0.1)		7 (<0.1)
Respiratory tract infection viral	12 (<0.1)	4 (<0.1)	0.33 (0.11, 0.98)	16 (<0.1)
Rhinitis	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Sinusitis bacterial	4 (<0.1)	4 (<0.1)		8 (<0.1)
Abdominal abscess	0	3 (<0.1)		3 (<0.1)
Abscess jaw	0	3 (<0.1)		3 (<0.1)
Chronic sinusitis	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Coronavirus infection	0	3 (<0.1)		3 (<0.1)
Epididymitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Tonsillitis	14 (<0.1)	3 (<0.1)	0.21 (0.07, 0.69)	17 (<0.1)
Viral pharyngitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Candida infection	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cat scratch disease	0	2 (<0.1)		2 (<0.1)
Conjunctivitis bacterial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Fungal skin infection	5 (<0.1)	2 (<0.1)		7 (<0.1)
Gastrointestinal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Infected bite	2 (<0.1)	2 (<0.1)		4 (<0.1)
Infected cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nail infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media acute	5 (<0.1)	2 (<0.1)		7 (<0.1)
Pertussis	0	2 (<0.1)		2 (<0.1)
Pulpitis dental	2 (<0.1)	2 (<0.1)		4 (<0.1)
Sepsis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Soft tissue infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea cruris	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tinea infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tinea pedis	5 (<0.1)	2 (<0.1)		7 (<0.1)
Tuberculosis	0	2 (<0.1)		2 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Urinary tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Viral rhinitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Viral sinusitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wound infection	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic bacteriuria	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atypical mycobacterial infection	0	1 (<0.1)		1 (<0.1)
Atypical pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacteraemia	0	1 (<0.1)		1 (<0.1)
Bacterial infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Body tinea	3 (<0.1)	1 (<0.1)		4 (<0.1)
Breast abscess	2 (<0.1)	1 (<0.1)		3 (<0.1)
Breast cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiolitis	0	1 (<0.1)		1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Colonic abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Dacryocystitis	0	1 (<0.1)		1 (<0.1)
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Gastrointestinal bacterial overgrowth	0	1 (<0.1)		1 (<0.1)
Genital herpes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)		2 (<0.1)
Genital infection fungal	0	1 (<0.1)		1 (<0.1)
Gingival abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Groin abscess	0	1 (<0.1)		1 (<0.1)
Helminthic infection	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza	6 (<0.1)	1 (<0.1)		7 (<0.1)
Injection site infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Labyrinthitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Papilloma viral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Perineal abscess	0	1 (<0.1)		1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)		1 (<0.1)
Post procedural infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyoderma	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Septic shock	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin candida	4 (<0.1)	1 (<0.1)		5 (<0.1)
Streptococcal infection	0	1 (<0.1)		1 (<0.1)
Tinea versicolour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Trichomoniasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Vulvitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)		1 (<0.1)
Abscess	2 (<0.1)	0		2 (<0.1)
Abscess neck	1 (<0.1)	0		1 (<0.1)
Adenovirus infection	1 (<0.1)	0		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Balanitis candida	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Bronchitis bacterial	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	8 (<0.1)	0		8 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cervicitis	2 (<0.1)	0		2 (<0.1)
Cholecystitis infective	2 (<0.1)	0		2 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Ear infection fungal	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastrointestinal viral infection	1 (<0.1)	0		1 (<0.1)
HIV infection	2 (<0.1)	0		2 (<0.1)
Hepatitis C	1 (<0.1)	0		1 (<0.1)
Herpangina	1 (<0.1)	0		1 (<0.1)
Herpes ophthalmic	1 (<0.1)	0		1 (<0.1)
Herpes virus infection	1 (<0.1)	0		1 (<0.1)
Infection	1 (<0.1)	0		1 (<0.1)
Klebsiella bacteraemia	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	3 (<0.1)	0		3 (<0.1)
Mastoiditis	3 (<0.1)	0		3 (<0.1)
Nasal abscess	1 (<0.1)	0		1 (<0.1)
Nasal vestibulitis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Ophthalmic herpes zoster	1 (<0.1)	0		1 (<0.1)
Oral viral infection	1 (<0.1)	0		1 (<0.1)
Oropharyngeal gonococcal infection	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Perineal cellulitis	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	2 (<0.1)	0		2 (<0.1)
Proteus infection	1 (<0.1)	0		1 (<0.1)
Pustule	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	2 (<0.1)	0		2 (<0.1)
Syphilis	3 (<0.1)	0		3 (<0.1)
Tinea barbae	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Vaginal abscess	1 (<0.1)	0		1 (<0.1)
Vaginitis chlamydial	2 (<0.1)	0		2 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Vestibular neuronitis	1 (<0.1)	0		1 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	101 (0.7)	111 (0.7)		212 (0.7)
Basal cell carcinoma	28 (0.2)	24 (0.2)	0.86 (0.50, 1.47)	52 (0.2)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Uterine leiomyoma	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Benign neoplasm of skin	2 (<0.1)	6 (<0.1)		8 (<0.1)
Skin cancer	4 (<0.1)	6 (<0.1)		10 (<0.1)
Squamous cell carcinoma	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Squamous cell carcinoma of skin	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Malignant melanoma	5 (<0.1)	4 (<0.1)		9 (<0.1)
Benign breast neoplasm	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of thyroid gland	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lipoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Malignant melanoma in situ	1 (<0.1)	3 (<0.1)		4 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Prostate cancer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin papilloma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Benign hepatic neoplasm	0	2 (<0.1)		2 (<0.1)
Breast cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Adrenal adenoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign ovarian tumour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign salivary gland neoplasm	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Brain neoplasm	0	1 (<0.1)		1 (<0.1)
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Breast cancer in situ	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Fibrous histiocytoma	0	1 (<0.1)		1 (<0.1)
Haemangioma of liver	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Intraductal papilloma of breast	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	0	1 (<0.1)		1 (<0.1)
Keratoacanthoma	0	1 (<0.1)		1 (<0.1)
Lip squamous cell carcinoma	0	1 (<0.1)		1 (<0.1)
Lipoma of breast	0	1 (<0.1)		1 (<0.1)
Meningioma benign	0	1 (<0.1)		1 (<0.1)
Nasal cavity cancer	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Prostate cancer stage I	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Renal neoplasm	0	1 (<0.1)		1 (<0.1)
Seborrhoeic keratosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Benign bone neoplasm	1 (<0.1)	0		1 (<0.1)
Benign neoplasm of eyelid	1 (<0.1)	0		1 (<0.1)
Bladder cancer	1 (<0.1)	0		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast neoplasm	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Enchondromatosis	1 (<0.1)	0		1 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Metastases to bone	1 (<0.1)	0		1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0		1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0		1 (<0.1)
Renal hamartoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Blood and lymphatic system disorders	193 (1.3)	339 (2.2)		532 (1.8)
Lymphadenopathy	156 (1.0)	287 (1.9)	1.84 (1.51, 2.23)	443 (1.5)
Anaemia	15 (<0.1)	19 (0.1)	1.26 (0.65, 2.46)	34 (0.1)
Lymph node pain	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Iron deficiency anaemia	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Lymphadenitis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Thrombocytopenia	0	4 (<0.1)		4 (<0.1)
Leukocytosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)
Normocytic anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eosinophilia	0	1 (<0.1)		1 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	0	1 (<0.1)		1 (<0.1)
Nucleated red cells	1 (<0.1)	0		1 (<0.1)
Splenic calcification	1 (<0.1)	0		1 (<0.1)
Immune system disorders	97 (0.6)	90 (0.6)		187 (0.6)
Seasonal allergy	72 (0.5)	59 (0.4)	0.82 (0.58, 1.15)	131 (0.4)
Drug hypersensitivity	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Food allergy	2 (<0.1)	4 (<0.1)		6 (<0.1)
Anaphylactic reaction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Mycotic allergy	0	2 (<0.1)		2 (<0.1)
Allergy to animal	0	1 (<0.1)		1 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Immune system disorders (Cont.)				
Allergy to chemicals	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	2 (<0.1)	0		2 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	40 (0.3)	37 (0.2)		77 (0.3)
Hypothyroidism	19 (0.1)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.1)
Thyroid mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Goitre	6 (<0.1)	2 (<0.1)		8 (<0.1)
Hyperparathyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperthyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypogonadism	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Thyroiditis	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	2 (<0.1)	0		2 (<0.1)
Basedow's disease	2 (<0.1)	0		2 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Oestrogen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroiditis subacute	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders	279 (1.8)	250 (1.6)		529 (1.7)
Hyperlipidaemia	52 (0.3)	42 (0.3)	0.81 (0.54, 1.21)	94 (0.3)
Type 2 diabetes mellitus	32 (0.2)	42 (0.3)	1.31 (0.83, 2.07)	74 (0.2)
Vitamin D deficiency	40 (0.3)	30 (0.2)	0.75 (0.47, 1.20)	70 (0.2)
Hypercholesterolaemia	39 (0.3)	29 (0.2)	0.74 (0.46, 1.19)	68 (0.2)
Decreased appetite	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Diabetes mellitus	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Glucose tolerance impaired	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Gout	16 (0.1)	12 (<0.1)	0.75 (0.36, 1.56)	28 (<0.1)
Dehydration	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Hypokalaemia	16 (0.1)	6 (<0.1)	0.37 (0.15, 0.93)	22 (<0.1)
Hyponatraemia	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Hyperglycaemia	6 (<0.1)	5 (<0.1)		11 (<0.1)
Hypertriglyceridaemia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Vitamin B12 deficiency	4 (<0.1)	4 (<0.1)		8 (<0.1)
Abnormal loss of weight	4 (<0.1)	3 (<0.1)		7 (<0.1)
Diabetes mellitus inadequate control	2 (<0.1)	3 (<0.1)		5 (<0.1)
Iron deficiency	6 (<0.1)	3 (<0.1)		9 (<0.1)
Hyperkalaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hypocalcaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypoglycaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Insulin resistance	0	2 (<0.1)		2 (<0.1)
Malnutrition	0	2 (<0.1)		2 (<0.1)
Obesity	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Metabolism and nutrition disorders (Cont.)				
Dairy intolerance	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)		4 (<0.1)
Food intolerance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypercalcaemia	0	1 (<0.1)		1 (<0.1)
Hypoferritinaemia	0	1 (<0.1)		1 (<0.1)
Hypomagnesaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Hypophosphataemia	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polydipsia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin K deficiency	0	1 (<0.1)		1 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Fluid overload	1 (<0.1)	0		1 (<0.1)
Fluid retention	1 (<0.1)	0		1 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypermagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Increased appetite	1 (<0.1)	0		1 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders	258 (1.7)	307 (2.0)		565 (1.9)
Anxiety	86 (0.6)	108 (0.7)	1.25 (0.95, 1.66)	194 (0.6)
Depression	83 (0.5)	93 (0.6)	1.12 (0.83, 1.50)	176 (0.6)
Insomnia	54 (0.4)	60 (0.4)	1.11 (0.77, 1.60)	114 (0.4)
Attention deficit hyperactivity disorder	24 (0.2)	20 (0.1)	0.83 (0.46, 1.49)	44 (0.1)
Bipolar disorder	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Abnormal dreams	2 (<0.1)	5 (<0.1)		7 (<0.1)
Sleep disorder	1 (<0.1)	5 (<0.1)		6 (<0.1)
Panic attack	6 (<0.1)	4 (<0.1)		10 (<0.1)
Post-traumatic stress disorder	2 (<0.1)	4 (<0.1)		6 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)		5 (<0.1)
Libido decreased	0	3 (<0.1)		3 (<0.1)
Nightmare	1 (<0.1)	3 (<0.1)		4 (<0.1)
Bipolar II disorder	0	2 (<0.1)		2 (<0.1)
Generalised anxiety disorder	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Stress	2 (<0.1)	2 (<0.1)		4 (<0.1)
Suicidal ideation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bruxism	0	1 (<0.1)		1 (<0.1)
Claustrophobia	0	1 (<0.1)		1 (<0.1)
Confusional state	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Depressed mood	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Dysphemia	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Mental fatigue	2 (<0.1)	1 (<0.1)		3 (<0.1)
Obsessive-compulsive personality disorder	0	1 (<0.1)		1 (<0.1)
Persistent depressive disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Premature ejaculation	0	1 (<0.1)		1 (<0.1)
Psychotic disorder	0	1 (<0.1)		1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)		1 (<0.1)
Reading disorder	0	1 (<0.1)		1 (<0.1)
Social anxiety disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Terminal insomnia	0	1 (<0.1)		1 (<0.1)
Agitation	2 (<0.1)	0		2 (<0.1)
Alcohol abuse	1 (<0.1)	0		1 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	0		1 (<0.1)
Delirium	1 (<0.1)	0		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Disorientation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Dissociative disorder	1 (<0.1)	0		1 (<0.1)
Hallucination, visual	1 (<0.1)	0		1 (<0.1)
Mental status changes	3 (<0.1)	0		3 (<0.1)
Mixed anxiety and depressive disorder	1 (<0.1)	0		1 (<0.1)
Nicotine dependence	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	1220 (8.0)	1296 (8.5)		2516 (8.3)
Headache	886 (5.8)	907 (6.0)	1.02 (0.93, 1.12)	1793 (5.9)
Dizziness	87 (0.6)	96 (0.6)	1.10 (0.83, 1.47)	183 (0.6)
Paraesthesia	30 (0.2)	43 (0.3)	1.43 (0.90, 2.27)	73 (0.2)
Migraine	41 (0.3)	32 (0.2)	0.78 (0.49, 1.23)	73 (0.2)
Sciatica	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Ageusia	30 (0.2)	23 (0.2)	0.77 (0.45, 1.31)	53 (0.2)
Sinus headache	12 (<0.1)	21 (0.1)	1.75 (0.87, 3.50)	33 (0.1)
Syncope	33 (0.2)	21 (0.1)	0.64 (0.37, 1.09)	54 (0.2)
Anosmia	25 (0.2)	19 (0.1)	0.76 (0.42, 1.37)	44 (0.1)
Hypoaesthesia	14 (<0.1)	17 (0.1)	1.21 (0.61, 2.42)	31 (0.1)
Cervical radiculopathy	2 (<0.1)	16 (0.1)	7.99 (2.05, 31.19)	18 (<0.1)
Presyncope	16 (0.1)	15 (<0.1)	0.94 (0.47, 1.87)	31 (0.1)
Dysgeusia	8 (<0.1)	13 (<0.1)	1.62 (0.69, 3.81)	21 (<0.1)
Nerve compression	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Carpal tunnel syndrome	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Tension headache	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Facial paralysis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Burning sensation	1 (<0.1)	6 (<0.1)		7 (<0.1)
Hyperaesthesia	0	6 (<0.1)		6 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)		7 (<0.1)
Memory impairment	1 (<0.1)	5 (<0.1)		6 (<0.1)
Lumbar radiculopathy	5 (<0.1)	4 (<0.1)		9 (<0.1)
Parosmia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	4 (<0.1)		7 (<0.1)
Taste disorder	2 (<0.1)	4 (<0.1)		6 (<0.1)
Amnesia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Lethargy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Mental impairment	0	3 (<0.1)		3 (<0.1)
Migraine with aura	3 (<0.1)	3 (<0.1)		6 (<0.1)
Neuralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Neuropathy peripheral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Seizure	5 (<0.1)	3 (<0.1)		8 (<0.1)
Somnolence	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tremor	5 (<0.1)	3 (<0.1)		8 (<0.1)
Cubital tunnel syndrome	0	2 (<0.1)		2 (<0.1)
Diabetic neuropathy	0	2 (<0.1)		2 (<0.1)
Dizziness postural	0	2 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)		2 (<0.1)
Morton's neuralgia	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Piriformis syndrome	0	2 (<0.1)		2 (<0.1)
Post herpetic neuralgia	0	2 (<0.1)		2 (<0.1)
Post-traumatic headache	2 (<0.1)	2 (<0.1)		4 (<0.1)
Restless legs syndrome	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Aura	0	1 (<0.1)		1 (<0.1)
Balance disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Central nervous system lesion	0	1 (<0.1)		1 (<0.1)
Cerebral atrophy	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Cognitive disorder	0	1 (<0.1)		1 (<0.1)
Complex regional pain syndrome	0	1 (<0.1)		1 (<0.1)
Dementia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Depressed level of consciousness	0	1 (<0.1)		1 (<0.1)
Diabetic mononeuropathy	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Essential tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hypersomnia	0	1 (<0.1)		1 (<0.1)
Hyposmia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Loss of consciousness	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Muscle contractions involuntary	2 (<0.1)	1 (<0.1)		3 (<0.1)
New daily persistent headache	0	1 (<0.1)		1 (<0.1)
Occipital neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	1 (<0.1)	1 (<0.1)		2 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trigeminal neuralgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Visual field defect	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	1 (<0.1)	0		1 (<0.1)
Cerebral cyst	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	3 (<0.1)	0		3 (<0.1)
Dyskinesia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hypogeusia	4 (<0.1)	0		4 (<0.1)
Intention tremor	1 (<0.1)	0		1 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0		1 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)
Myoclonus	1 (<0.1)	0		1 (<0.1)
Perineurial cyst	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	2 (<0.1)	0		2 (<0.1)
Radicular pain	1 (<0.1)	0		1 (<0.1)
Right hemisphere deficit syndrome	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0		1 (<0.1)
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
VIth nerve paralysis	1 (<0.1)	0		1 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)
Vocal cord paralysis	1 (<0.1)	0		1 (<0.1)
Eye disorders	123 (0.8)	139 (0.9)		262 (0.9)
Cataract	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Eye pruritus	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Dry eye	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Eye irritation	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Glaucoma	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Retinal detachment	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Vision blurred	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Eye pain	4 (<0.1)	6 (<0.1)		10 (<0.1)
Blepharitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Conjunctival haemorrhage	3 (<0.1)	5 (<0.1)		8 (<0.1)
Chalazion	1 (<0.1)	4 (<0.1)		5 (<0.1)
Swelling of eyelid	1 (<0.1)	4 (<0.1)		5 (<0.1)
Visual impairment	3 (<0.1)	4 (<0.1)		7 (<0.1)
Eye inflammation	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lacrimation increased	4 (<0.1)	3 (<0.1)		7 (<0.1)
Uveitis	0	3 (<0.1)		3 (<0.1)
Vitreous floaters	4 (<0.1)	3 (<0.1)		7 (<0.1)
Blepharospasm	0	2 (<0.1)		2 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Eye haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye swelling	5 (<0.1)	2 (<0.1)		7 (<0.1)
Macular degeneration	1 (<0.1)	2 (<0.1)		3 (<0.1)
Macular hole	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ocular discomfort	0	2 (<0.1)		2 (<0.1)
Ocular hyperaemia	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Photophobia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Xerophthalmia	0	2 (<0.1)		2 (<0.1)
Accommodation disorder	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Conjunctival hyperaemia	0	1 (<0.1)		1 (<0.1)
Diabetic retinopathy	0	1 (<0.1)		1 (<0.1)
Diplopia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye disorder	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Foreign body sensation in eyes	0	1 (<0.1)		1 (<0.1)
Iris disorder	0	1 (<0.1)		1 (<0.1)
Keratitis	0	1 (<0.1)		1 (<0.1)
Lenticular opacities	0	1 (<0.1)		1 (<0.1)
Macular fibrosis	0	1 (<0.1)		1 (<0.1)
Macular oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Orbital haematoma	0	1 (<0.1)		1 (<0.1)
Papilloedema	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Presbyopia	0	1 (<0.1)		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Retinopathy hypertensive	0	1 (<0.1)		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryoadenitis acquired	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye discharge	1 (<0.1)	0		1 (<0.1)
Eye ulcer	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	3 (<0.1)	0		3 (<0.1)
Nictitating spasm	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Open angle glaucoma	1 (<0.1)	0		1 (<0.1)
Orbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	3 (<0.1)	0		3 (<0.1)
Photopsia	2 (<0.1)	0		2 (<0.1)
Retinal infarction	1 (<0.1)	0		1 (<0.1)
Retinal oedema	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Strabismus	2 (<0.1)	0		2 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	4 (<0.1)	0		4 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Ear and labyrinth disorders	149 (1.0)	134 (0.9)		283 (0.9)
Vertigo	34 (0.2)	46 (0.3)	1.35 (0.87, 2.10)	80 (0.3)
Ear pain	35 (0.2)	29 (0.2)	0.83 (0.51, 1.35)	64 (0.2)
Tinnitus	22 (0.1)	20 (0.1)	0.91 (0.50, 1.65)	42 (0.1)
Vertigo positional	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Ear discomfort	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Meniere's disease	2 (<0.1)	6 (<0.1)		8 (<0.1)
Cerumen impaction	5 (<0.1)	4 (<0.1)		9 (<0.1)
Deafness unilateral	2 (<0.1)	3 (<0.1)		5 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear canal erythema	6 (<0.1)	2 (<0.1)		8 (<0.1)
Ear congestion	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Eustachian tube dysfunction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Motion sickness	0	2 (<0.1)		2 (<0.1)
Otorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tympanic membrane perforation	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Ear pruritus	6 (<0.1)	1 (<0.1)		7 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Diplacusis	1 (<0.1)	0		1 (<0.1)
Ear haemorrhage	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	2 (<0.1)	0		2 (<0.1)
External ear pain	1 (<0.1)	0		1 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)				
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	134 (0.9)	138 (0.9)		272 (0.9)
Palpitations	13 (<0.1)	22 (0.1)	1.69 (0.86, 3.31)	35 (0.1)
Tachycardia	23 (0.2)	21 (0.1)	0.91 (0.51, 1.63)	44 (0.1)
Atrial fibrillation	19 (0.1)	20 (0.1)	1.05 (0.57, 1.95)	39 (0.1)
Bradycardia	23 (0.2)	14 (<0.1)	0.61 (0.32, 1.17)	37 (0.1)
Angina pectoris	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Ventricular extrasystoles	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Coronary artery disease	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Sinus tachycardia	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Arrhythmia	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Cardiac failure	2 (<0.1)	3 (<0.1)		5 (<0.1)
Supraventricular tachycardia	0	3 (<0.1)		3 (<0.1)
Cardiac failure congestive	6 (<0.1)	2 (<0.1)		8 (<0.1)
Cardiomyopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ventricular tachycardia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute left ventricular failure	0	1 (<0.1)		1 (<0.1)
Acute myocardial infarction	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial enlargement	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Cardiac flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiovascular symptom	0	1 (<0.1)		1 (<0.1)
Coronary artery occlusion	0	1 (<0.1)		1 (<0.1)
Left ventricular hypertrophy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pericardial effusion	0	1 (<0.1)		1 (<0.1)
Sinus bradycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial tachycardia	2 (<0.1)	0		2 (<0.1)
Cardiac disorder	1 (<0.1)	0		1 (<0.1)
Cardiac steatosis	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	2 (<0.1)	0		2 (<0.1)
Diastolic dysfunction	1 (<0.1)	0		1 (<0.1)
Extrasystoles	1 (<0.1)	0		1 (<0.1)
Left atrial enlargement	1 (<0.1)	0		1 (<0.1)
Mitral valve incompetence	2 (<0.1)	0		2 (<0.1)
Mitral valve thickening	1 (<0.1)	0		1 (<0.1)
Myocardial ischaemia	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Postural orthostatic tachycardia syndrome	1 (<0.1)	0		1 (<0.1)
Sinus arrest	1 (<0.1)	0		1 (<0.1)
Tricuspid valve incompetence	2 (<0.1)	0		2 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders	392 (2.6)	335 (2.2)		727 (2.4)
Hypertension	330 (2.2)	260 (1.7)	0.79 (0.67, 0.92)	590 (1.9)
Hot flush	11 (<0.1)	17 (0.1)	1.54 (0.74, 3.24)	28 (<0.1)
Haematoma	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Flushing	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Orthostatic hypotension	1 (<0.1)	6 (<0.1)		7 (<0.1)
Hypotension	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Deep vein thrombosis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypertensive urgency	1 (<0.1)	3 (<0.1)		4 (<0.1)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Aortic dilatation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arteriosclerosis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Labile hypertension	0	2 (<0.1)		2 (<0.1)
Prehypertension	0	2 (<0.1)		2 (<0.1)
Raynaud's phenomenon	1 (<0.1)	2 (<0.1)		3 (<0.1)
Thrombophlebitis superficial	3 (<0.1)	2 (<0.1)		5 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Diastolic hypotension	0	1 (<0.1)		1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive emergency	0	1 (<0.1)		1 (<0.1)
Pallor	0	1 (<0.1)		1 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders (Cont.)				
Peripheral coldness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Phlebitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	3 (<0.1)	0		3 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Diastolic hypertension	2 (<0.1)	0		2 (<0.1)
Lymphoedema	1 (<0.1)	0		1 (<0.1)
Peripheral venous disease	1 (<0.1)	0		1 (<0.1)
Secondary hypertension	1 (<0.1)	0		1 (<0.1)
Vascular calcification	1 (<0.1)	0		1 (<0.1)
Vasodilatation	1 (<0.1)	0		1 (<0.1)
White coat hypertension	2 (<0.1)	0		2 (<0.1)
Respiratory, thoracic and mediastinal disorders	1070 (7.1)	949 (6.3)		2019 (6.7)
Cough	307 (2.0)	310 (2.0)	1.01 (0.86, 1.18)	617 (2.0)
Oropharyngeal pain	381 (2.5)	304 (2.0)	0.80 (0.69, 0.92)	685 (2.3)
Nasal congestion	291 (1.9)	270 (1.8)	0.93 (0.79, 1.09)	561 (1.8)
Rhinorrhoea	258 (1.7)	246 (1.6)	0.95 (0.80, 1.13)	504 (1.7)
Dyspnoea	86 (0.6)	87 (0.6)	1.01 (0.75, 1.36)	173 (0.6)
Tachypnoea	43 (0.3)	39 (0.3)	0.91 (0.59, 1.39)	82 (0.3)
Sinus congestion	48 (0.3)	33 (0.2)	0.69 (0.44, 1.06)	81 (0.3)
Asthma	38 (0.3)	32 (0.2)	0.84 (0.53, 1.34)	70 (0.2)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory tract congestion	19 (0.1)	26 (0.2)	1.37 (0.76, 2.45)	45 (0.1)
Upper-airway cough syndrome	22 (0.1)	23 (0.2)	1.04 (0.59, 1.86)	45 (0.1)
Epistaxis	17 (0.1)	22 (0.1)	1.29 (0.69, 2.41)	39 (0.1)
Sneezing	22 (0.1)	22 (0.1)	1.00 (0.56, 1.79)	44 (0.1)
Rhinitis allergic	26 (0.2)	21 (0.1)	0.81 (0.46, 1.42)	47 (0.2)
Throat irritation	20 (0.1)	18 (0.1)	0.90 (0.48, 1.68)	38 (0.1)
Chronic obstructive pulmonary disease	18 (0.1)	13 (<0.1)	0.72 (0.36, 1.45)	31 (0.1)
Sinus pain	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Paranasal sinus discomfort	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Pharyngeal erythema	6 (<0.1)	6 (<0.1)		12 (<0.1)
Respiratory disorder	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Dry throat	5 (<0.1)	5 (<0.1)		10 (<0.1)
Dysphonia	14 (<0.1)	5 (<0.1)	0.36 (0.13, 0.95)	19 (<0.1)
Dyspnoea exertional	5 (<0.1)	5 (<0.1)		10 (<0.1)
Productive cough	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Sleep apnoea syndrome	6 (<0.1)	5 (<0.1)		11 (<0.1)
Wheezing	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Bronchiectasis	0	4 (<0.1)		4 (<0.1)
Pleural effusion	5 (<0.1)	4 (<0.1)		9 (<0.1)
Bronchospasm	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypoxia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Allergic cough	0	2 (<0.1)		2 (<0.1)
Allergic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Atelectasis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Emphysema	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nasal discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)		4 (<0.1)
Paranasal sinus hypersecretion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Choking sensation	0	1 (<0.1)		1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Laryngeal oedema	0	1 (<0.1)		1 (<0.1)
Lung infiltration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nasal dryness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal mucosal disorder	0	1 (<0.1)		1 (<0.1)
Nasal pruritus	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	7 (<0.1)	1 (<0.1)	0.14 (0.02, 0.89)	8 (<0.1)
Pneumonia aspiration	0	1 (<0.1)		1 (<0.1)
Pulmonary congestion	0	1 (<0.1)		1 (<0.1)
Pulmonary hypertension	0	1 (<0.1)		1 (<0.1)
Pulmonary mass	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary oedema	0	1 (<0.1)		1 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Rhonchi	0	1 (<0.1)		1 (<0.1)
Sputum increased	0	1 (<0.1)		1 (<0.1)
Tonsillolith	6 (<0.1)	1 (<0.1)		7 (<0.1)
Vasomotor rhinitis	0	1 (<0.1)		1 (<0.1)
Vocal cord disorder	0	1 (<0.1)		1 (<0.1)
Vocal cord thickening	0	1 (<0.1)		1 (<0.1)
Acute respiratory failure	4 (<0.1)	0		4 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Bronchial hyperreactivity	1 (<0.1)	0		1 (<0.1)
Haemoptysis	4 (<0.1)	0		4 (<0.1)
Laryngeal stenosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Lung cyst	1 (<0.1)	0		1 (<0.1)
Lung opacity	2 (<0.1)	0		2 (<0.1)
Nasal turbinate hypertrophy	1 (<0.1)	0		1 (<0.1)
Nasal ulcer	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Pharyngeal paraesthesia	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary granuloma	1 (<0.1)	0		1 (<0.1)
Rales	2 (<0.1)	0		2 (<0.1)
Reflux laryngitis	1 (<0.1)	0		1 (<0.1)
Respiratory symptom	4 (<0.1)	0		4 (<0.1)
Rhinalgia	2 (<0.1)	0		2 (<0.1)
Rhinitis atrophic	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	2 (<0.1)	0		2 (<0.1)
Tonsillar exudate	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	3 (<0.1)	0		3 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract congestion	2 (<0.1)	0		2 (<0.1)
Gastrointestinal disorders	871 (5.7)	884 (5.8)		1755 (5.8)
Diarrhoea	279 (1.8)	280 (1.8)	1.00 (0.85, 1.18)	559 (1.8)
Nausea	239 (1.6)	240 (1.6)	1.00 (0.84, 1.20)	479 (1.6)
Vomiting	82 (0.5)	90 (0.6)	1.10 (0.81, 1.48)	172 (0.6)
Gastrooesophageal reflux disease	59 (0.4)	82 (0.5)	1.39 (1.00, 1.93)	141 (0.5)
Toothache	49 (0.3)	45 (0.3)	0.92 (0.61, 1.37)	94 (0.3)
Abdominal pain	39 (0.3)	44 (0.3)	1.13 (0.73, 1.73)	83 (0.3)
Constipation	39 (0.3)	27 (0.2)	0.69 (0.43, 1.12)	66 (0.2)
Dental caries	31 (0.2)	25 (0.2)	0.81 (0.48, 1.36)	56 (0.2)
Abdominal pain upper	32 (0.2)	24 (0.2)	0.75 (0.44, 1.26)	56 (0.2)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Dyspepsia	24 (0.2)	23 (0.2)	0.96 (0.54, 1.68)	47 (0.2)
Food poisoning	15 (<0.1)	13 (<0.1)	0.87 (0.42, 1.79)	28 (<0.1)
Abdominal pain lower	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Inguinal hernia	6 (<0.1)	11 (<0.1)	1.83 (0.70, 4.77)	17 (<0.1)
Abdominal discomfort	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (<0.1)
Large intestine polyp	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Hiatus hernia	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Haemorrhoids	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Irritable bowel syndrome	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Gastric ulcer	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Gastritis	13 (<0.1)	7 (<0.1)	0.54 (0.22, 1.31)	20 (<0.1)
Umbilical hernia	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Abdominal distension	2 (<0.1)	6 (<0.1)		8 (<0.1)
Flatulence	3 (<0.1)	6 (<0.1)		9 (<0.1)
Lip swelling	2 (<0.1)	6 (<0.1)		8 (<0.1)
Tooth impacted	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Colitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Diverticulum intestinal	1 (<0.1)	5 (<0.1)		6 (<0.1)
Haematochezia	4 (<0.1)	4 (<0.1)		8 (<0.1)
Oesophagitis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Rectal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Aphthous ulcer	6 (<0.1)	3 (<0.1)		9 (<0.1)
Barrett's oesophagus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diverticulum	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Dysphagia	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Faeces soft	0	3 (<0.1)		3 (<0.1)
Gastrointestinal pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Gingival pain	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypoaesthesia oral	0	3 (<0.1)		3 (<0.1)
Paraesthesia oral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Periodontal disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Stomatitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Dry mouth	5 (<0.1)	2 (<0.1)		7 (<0.1)
Faeces discoloured	0	2 (<0.1)		2 (<0.1)
Frequent bowel movements	0	2 (<0.1)		2 (<0.1)
Gastrointestinal disorder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gingival bleeding	0	2 (<0.1)		2 (<0.1)
Melaena	0	2 (<0.1)		2 (<0.1)
Mouth ulceration	4 (<0.1)	2 (<0.1)		6 (<0.1)
Oesophageal ulcer	0	2 (<0.1)		2 (<0.1)
Pancreatitis	0	2 (<0.1)		2 (<0.1)
Peptic ulcer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Proctalgia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swollen tongue	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tongue discolouration	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anorectal disorder	0	1 (<0.1)		1 (<0.1)
Chronic gastritis	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Duodenitis	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Faecaloma	0	1 (<0.1)		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Glossitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intussusception	1 (<0.1)	1 (<0.1)		2 (<0.1)
Leukoplakia oral	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Noninfective gingivitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal spasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oral mucosal blistering	0	1 (<0.1)		1 (<0.1)
Oral mucosal eruption	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Oral pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Pancreatic cyst	0	1 (<0.1)		1 (<0.1)
Poor dental condition	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal fissure	0	1 (<0.1)		1 (<0.1)
Saliva altered	1 (<0.1)	1 (<0.1)		2 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)		1 (<0.1)
Tongue discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue ulceration	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Abdominal rigidity	2 (<0.1)	0		2 (<0.1)
Abdominal tenderness	1 (<0.1)	0		1 (<0.1)
Abdominal wall cyst	1 (<0.1)	0		1 (<0.1)
Anal fistula	1 (<0.1)	0		1 (<0.1)
Anorectal discomfort	1 (<0.1)	0		1 (<0.1)
Ascites	2 (<0.1)	0		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Colitis microscopic	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Eosinophilic oesophagitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric polyps	2 (<0.1)	0		2 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0		1 (<0.1)
Gastrointestinal motility disorder	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival recession	1 (<0.1)	0		1 (<0.1)
Glossodynia	2 (<0.1)	0		2 (<0.1)
Hypertrophy of tongue papillae	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Lip blister	1 (<0.1)	0		1 (<0.1)
Mouth haemorrhage	1 (<0.1)	0		1 (<0.1)
Obstructive pancreatitis	1 (<0.1)	0		1 (<0.1)
Odynophagia	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral discomfort	1 (<0.1)	0		1 (<0.1)
Oral mucosal erythema	1 (<0.1)	0		1 (<0.1)
Palatal disorder	1 (<0.1)	0		1 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Regurgitation	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Terminal ileitis	1 (<0.1)	0		1 (<0.1)
Tongue coated	1 (<0.1)	0		1 (<0.1)
Tongue dry	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Tooth disorder	3 (<0.1)	0		3 (<0.1)
Upper gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Uvulitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	18 (0.1)	26 (0.2)		44 (0.1)
Cholelithiasis	9 (<0.1)	14 (<0.1)	1.55 (0.69, 3.51)	23 (<0.1)
Hepatic steatosis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Cholecystitis	0	4 (<0.1)		4 (<0.1)
Biliary colic	0	2 (<0.1)		2 (<0.1)
Biliary dyskinesia	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Jaundice	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic haematoma	1 (<0.1)	0		1 (<0.1)
Hyperbilirubinaemia	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	372 (2.5)	391 (2.6)		763 (2.5)
Urticaria	46 (0.3)	55 (0.4)	1.19 (0.81, 1.76)	101 (0.3)
Rash	47 (0.3)	43 (0.3)	0.91 (0.61, 1.38)	90 (0.3)
Dermatitis contact	41 (0.3)	34 (0.2)	0.83 (0.53, 1.30)	75 (0.2)
Pruritus	29 (0.2)	28 (0.2)	0.96 (0.58, 1.61)	57 (0.2)
Eczema	11 (<0.1)	18 (0.1)	1.63 (0.78, 3.40)	29 (<0.1)
Erythema	8 (<0.1)	17 (0.1)	2.12 (0.94, 4.80)	25 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Hyperhidrosis	12 (<0.1)	16 (0.1)	1.33 (0.64, 2.77)	28 (<0.1)
Acne	19 (0.1)	15 (<0.1)	0.79 (0.41, 1.53)	34 (0.1)
Night sweats	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Dermatitis	14 (<0.1)	10 (<0.1)	0.71 (0.32, 1.57)	24 (<0.1)
Actinic keratosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Rash maculo-papular	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Rash papular	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Alopecia	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Rash macular	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Ecchymosis	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Psoriasis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Rosacea	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Dermatitis atopic	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Rash pruritic	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Dry skin	4 (<0.1)	5 (<0.1)		9 (<0.1)
Ingrowing nail	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pityriasis rosea	0	4 (<0.1)		4 (<0.1)
Skin lesion	6 (<0.1)	4 (<0.1)		10 (<0.1)
Blister	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dermal cyst	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Dermatitis allergic	5 (<0.1)	3 (<0.1)		8 (<0.1)
Eczema nummular	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hidradenitis	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Macule	1 (<0.1)	3 (<0.1)		4 (<0.1)
Neurodermatitis	0	3 (<0.1)		3 (<0.1)
Pain of skin	1 (<0.1)	3 (<0.1)		4 (<0.1)
Rash erythematous	4 (<0.1)	3 (<0.1)		7 (<0.1)
Skin burning sensation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acne cystic	0	2 (<0.1)		2 (<0.1)
Angioedema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Diabetic foot	0	2 (<0.1)		2 (<0.1)
Hand dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Papule	2 (<0.1)	2 (<0.1)		4 (<0.1)
Precancerous skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood blister	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Cold sweat	1 (<0.1)	1 (<0.1)		2 (<0.1)
Decubitus ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Lichen sclerosus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Onychoclasis	0	1 (<0.1)		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Petechiae	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash vesicular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin exfoliation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin haemorrhage	0	1 (<0.1)		1 (<0.1)
Skin hypopigmentation	0	1 (<0.1)		1 (<0.1)
Skin mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Solar lentigo	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitiligo	0	1 (<0.1)		1 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Hyperkeratosis	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	4 (<0.1)	0		4 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Miliaria	1 (<0.1)	0		1 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin discolouration	2 (<0.1)	0		2 (<0.1)
Skin fissures	1 (<0.1)	0		1 (<0.1)
Skin hyperpigmentation	2 (<0.1)	0		2 (<0.1)
Skin irritation	1 (<0.1)	0		1 (<0.1)
Skin wrinkling	1 (<0.1)	0		1 (<0.1)
Stasis dermatitis	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Telangiectasia	1 (<0.1)	0		1 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	0		1 (<0.1)
Umbilical erythema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	1322 (8.7)	1296 (8.5)		2618 (8.6)
Arthralgia	436 (2.9)	443 (2.9)	1.01 (0.89, 1.16)	879 (2.9)
Myalgia	451 (3.0)	434 (2.9)	0.96 (0.84, 1.09)	885 (2.9)
Back pain	185 (1.2)	162 (1.1)	0.87 (0.71, 1.08)	347 (1.1)
Pain in extremity	101 (0.7)	84 (0.6)	0.83 (0.62, 1.11)	185 (0.6)
Musculoskeletal pain	53 (0.3)	67 (0.4)	1.26 (0.88, 1.81)	120 (0.4)
Neck pain	54 (0.4)	61 (0.4)	1.13 (0.78, 1.62)	115 (0.4)
Osteoarthritis	65 (0.4)	53 (0.3)	0.81 (0.57, 1.17)	118 (0.4)
Muscle spasms	44 (0.3)	43 (0.3)	0.98 (0.64, 1.48)	87 (0.3)
Rotator cuff syndrome	26 (0.2)	25 (0.2)	0.96 (0.56, 1.65)	51 (0.2)
Tendonitis	24 (0.2)	21 (0.1)	0.87 (0.49, 1.56)	45 (0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Bursitis	13 (<0.1)	20 (0.1)	1.54 (0.77, 3.05)	33 (0.1)
Musculoskeletal chest pain	25 (0.2)	17 (0.1)	0.68 (0.37, 1.25)	42 (0.1)
Musculoskeletal stiffness	16 (0.1)	15 (<0.1)	0.94 (0.47, 1.87)	31 (0.1)
Arthritis	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)
Intervertebral disc protrusion	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)
Joint swelling	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Muscular weakness	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Osteopenia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Osteoporosis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Spinal osteoarthritis	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Trigger finger	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Groin pain	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Periarthritis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Muscle tightness	2 (<0.1)	6 (<0.1)		8 (<0.1)
Pain in jaw	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Costochondritis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Flank pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Limb discomfort	2 (<0.1)	5 (<0.1)		7 (<0.1)
Plantar fasciitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Spinal pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	5 (<0.1)		7 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)		5 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Fibromyalgia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Intervertebral disc degeneration	6 (<0.1)	4 (<0.1)		10 (<0.1)
Muscle twitching	3 (<0.1)	4 (<0.1)		7 (<0.1)
Limb mass	2 (<0.1)	3 (<0.1)		5 (<0.1)
Muscle fatigue	0	3 (<0.1)		3 (<0.1)
Neck mass	0	3 (<0.1)		3 (<0.1)
Synovial cyst	6 (<0.1)	3 (<0.1)		9 (<0.1)
Axillary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cervical spinal stenosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Exostosis	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Foot deformity	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Joint stiffness	2 (<0.1)	2 (<0.1)		4 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spondylitis	0	2 (<0.1)		2 (<0.1)
Spondylolisthesis	0	2 (<0.1)		2 (<0.1)
Tenosynovitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Compartment syndrome	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Dupuytren's contracture	0	1 (<0.1)		1 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)		1 (<0.1)
Joint noise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ligament pain	0	1 (<0.1)		1 (<0.1)
Ligamentum flavum hypertrophy	0	1 (<0.1)		1 (<0.1)
Medial tibial stress syndrome	0	1 (<0.1)		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteonecrosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal synovial cyst	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tendon pain	0	1 (<0.1)		1 (<0.1)
Tenosynovitis stenosans	2 (<0.1)	1 (<0.1)		3 (<0.1)
Torticollis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)		1 (<0.1)
Fasciitis	1 (<0.1)	0		1 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0		1 (<0.1)
Joint effusion	1 (<0.1)	0		1 (<0.1)
Kyphosis	1 (<0.1)	0		1 (<0.1)
Lumbar spinal stenosis	2 (<0.1)	0		2 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Scoliosis	3 (<0.1)	0		3 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Synovitis	2 (<0.1)	0		2 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	0		2 (<0.1)
Renal and urinary disorders	90 (0.6)	92 (0.6)		182 (0.6)
Nephrolithiasis	33 (0.2)	24 (0.2)	0.73 (0.43, 1.22)	57 (0.2)
Dysuria	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Chronic kidney disease	5 (<0.1)	6 (<0.1)		11 (<0.1)
Haematuria	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Urinary retention	3 (<0.1)	6 (<0.1)		9 (<0.1)
Hypertonic bladder	3 (<0.1)	5 (<0.1)		8 (<0.1)
Pollakiuria	6 (<0.1)	5 (<0.1)		11 (<0.1)
Polyuria	0	5 (<0.1)		5 (<0.1)
Nocturia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Urinary incontinence	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hydronephrosis	0	3 (<0.1)		3 (<0.1)
Acute kidney injury	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Bladder pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Renal cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Urinary hesitation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bladder diverticulum	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder spasm	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calculus bladder	0	1 (<0.1)		1 (<0.1)
Chromaturia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cystitis interstitial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetic nephropathy	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Micturition urgency	3 (<0.1)	1 (<0.1)		4 (<0.1)
Renal disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Renal failure	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Renal tubular necrosis	0	1 (<0.1)		1 (<0.1)
Stress urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urethral pain	0	1 (<0.1)		1 (<0.1)
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal colic	2 (<0.1)	0		2 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	2 (<0.1)	0		2 (<0.1)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)		1 (<0.1)
Morning sickness	0	1 (<0.1)		1 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abortion spontaneous	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	126 (0.8)	109 (0.7)		235 (0.8)
Benign prostatic hyperplasia	21 (0.1)	10 (<0.1)	0.48 (0.23, 0.99)	31 (0.1)
Erectile dysfunction	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Prostatitis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)

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Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Breast cyst	4 (<0.1)	5 (<0.1)		9 (<0.1)
Dysmenorrhoea	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.39)	15 (<0.1)
Menorrhagia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Ovarian cyst	5 (<0.1)	5 (<0.1)		10 (<0.1)
Prostatomegaly	6 (<0.1)	5 (<0.1)		11 (<0.1)
Menopausal symptoms	2 (<0.1)	4 (<0.1)		6 (<0.1)
Pelvic pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Vaginal haemorrhage	3 (<0.1)	4 (<0.1)		7 (<0.1)
Postmenopausal haemorrhage	3 (<0.1)	3 (<0.1)		6 (<0.1)
Uterine polyp	3 (<0.1)	3 (<0.1)		6 (<0.1)
Breast hyperplasia	0	2 (<0.1)		2 (<0.1)
Breast mass	5 (<0.1)	2 (<0.1)		7 (<0.1)
Breast pain	4 (<0.1)	2 (<0.1)		6 (<0.1)
Breast ulceration	0	2 (<0.1)		2 (<0.1)
Nipple exudate bloody	0	2 (<0.1)		2 (<0.1)
Rectocele	0	2 (<0.1)		2 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexa uteri pain	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Artificial menopause	0	1 (<0.1)		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast calcifications	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast enlargement	0	1 (<0.1)		1 (<0.1)
Breast fibrosis	0	1 (<0.1)		1 (<0.1)
Breast swelling	0	1 (<0.1)		1 (<0.1)
Breast tenderness	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical polyp	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystocele	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ejaculation failure	0	1 (<0.1)		1 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)		2 (<0.1)
Endometriosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibrocystic breast disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Menstruation irregular	3 (<0.1)	1 (<0.1)		4 (<0.1)
Metrorrhagia	0	1 (<0.1)		1 (<0.1)
Nipple pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Perineal rash	0	1 (<0.1)		1 (<0.1)
Polymenorrhoea	0	1 (<0.1)		1 (<0.1)
Priapism	0	1 (<0.1)		1 (<0.1)
Prostatic cyst	0	1 (<0.1)		1 (<0.1)
Testicular pain	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Uterine haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaginal cyst	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vaginal prolapse	0	1 (<0.1)		1 (<0.1)
Vulva cyst	0	1 (<0.1)		1 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pruritus	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	3 (<0.1)	0		3 (<0.1)
Dyspareunia	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Oligomenorrhoea	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Ovarian mass	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Pelvic floor muscle weakness	1 (<0.1)	0		1 (<0.1)
Peyronie's disease	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	3 (<0.1)	0		3 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Pruritus genital	1 (<0.1)	0		1 (<0.1)
Testicular swelling	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Uterine spasm	2 (<0.1)	0		2 (<0.1)
Vulvovaginal discomfort	2 (<0.1)	0		2 (<0.1)
Vulvovaginal dryness	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	4 (<0.1)	8 (<0.1)		12 (<0.1)
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Developmental hip dysplasia	0	1 (<0.1)		1 (<0.1)
Gilbert's syndrome	0	1 (<0.1)		1 (<0.1)
Preauricular cyst	0	1 (<0.1)		1 (<0.1)
Type IIa hyperlipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Von Willebrand's disease	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
General disorders and administration site conditions	1321 (8.7)	1826 (12.0)		3147 (10.4)
Fatigue	799 (5.3)	882 (5.8)	1.10 (1.00, 1.21)	1681 (5.5)
Injection site pain	141 (0.9)	269 (1.8)	1.91 (1.56, 2.33)	410 (1.4)
Chills	162 (1.1)	175 (1.2)	1.08 (0.87, 1.33)	337 (1.1)
Pyrexia	119 (0.8)	168 (1.1)	1.41 (1.12, 1.78)	287 (0.9)
Injection site erythema	40 (0.3)	158 (1.0)	3.94 (2.80, 5.57)	198 (0.7)
Pain	135 (0.9)	133 (0.9)	0.98 (0.78, 1.25)	268 (0.9)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site swelling	31 (0.2)	119 (0.8)	3.83 (2.59, 5.67)	150 (0.5)
Injection site pruritus	13 (<0.1)	88 (0.6)	6.76 (3.81, 12.00)	101 (0.3)
Injection site lymphadenopathy	17 (0.1)	69 (0.5)	4.05 (2.40, 6.85)	86 (0.3)
Injection site induration	18 (0.1)	53 (0.3)	2.94 (1.73, 4.99)	71 (0.2)
Injection site macule	4 (<0.1)	45 (0.3)	11.23 (4.21, 30.01)	49 (0.2)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.94 (6.58, 218.91)	39 (0.1)
Axillary pain	15 (<0.1)	27 (0.2)	1.80 (0.97, 3.34)	42 (0.1)
Injection site rash	1 (<0.1)	25 (0.2)	24.96 (4.29, 145.37)	26 (<0.1)
Chest discomfort	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Injection site bruising	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Malaise	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
Peripheral swelling	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
Chest pain	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	12.98 (2.18, 77.49)	14 (<0.1)
Oedema peripheral	17 (0.1)	13 (<0.1)	0.76 (0.38, 1.55)	30 (<0.1)
Non-cardiac chest pain	14 (<0.1)	12 (<0.1)	0.86 (0.40, 1.82)	26 (<0.1)
Injection site warmth	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Reactogenicity event	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Feeling hot	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haematoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site haemorrhage	5 (<0.1)	6 (<0.1)		11 (<0.1)
Injection site paraesthesia	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vaccination site swelling	1 (<0.1)	6 (<0.1)		7 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Asthenia	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.39)	15 (<0.1)
Feeling abnormal	6 (<0.1)	5 (<0.1)		11 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Vaccination site pain	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Influenza like illness	6 (<0.1)	4 (<0.1)		10 (<0.1)
Injection site mass	1 (<0.1)	4 (<0.1)		5 (<0.1)
Swelling face	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cyst	6 (<0.1)	3 (<0.1)		9 (<0.1)
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site reaction	0	3 (<0.1)		3 (<0.1)
Injury associated with device	0	3 (<0.1)		3 (<0.1)
Tenderness	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Adverse drug reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)		2 (<0.1)
Hangover	1 (<0.1)	2 (<0.1)		3 (<0.1)
Inflammation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site scab	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sensation of foreign body	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Vessel puncture site bruise	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Crying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysplasia	0	1 (<0.1)		1 (<0.1)
Early satiety	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Facial pain	6 (<0.1)	1 (<0.1)		7 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lithiasis	0	1 (<0.1)		1 (<0.1)
Mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Medical device site pain	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vaccination site mass	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Xerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Capsular contracture associated with breast implant	1 (<0.1)	0		1 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Drug intolerance	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hunger	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site joint discomfort	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site oedema	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Nodule	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Polyp	1 (<0.1)	0		1 (<0.1)
Sluggishness	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)
Temperature intolerance	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Thirst	2 (<0.1)	0		2 (<0.1)
Vaccination site bruising	2 (<0.1)	0		2 (<0.1)
Vaccination site inflammation	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Vessel puncture site pain	2 (<0.1)	0		2 (<0.1)
Investigations	165 (1.1)	169 (1.1)		334 (1.1)
Blood pressure increased	53 (0.3)	41 (0.3)	0.77 (0.52, 1.16)	94 (0.3)
Blood pressure systolic increased	21 (0.1)	21 (0.1)	1.00 (0.55, 1.81)	42 (0.1)
Blood pressure diastolic increased	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Blood cholesterol increased	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Body temperature increased	2 (<0.1)	5 (<0.1)		7 (<0.1)
Heart rate increased	3 (<0.1)	5 (<0.1)		8 (<0.1)
Hepatic enzyme increased	5 (<0.1)	5 (<0.1)		10 (<0.1)
Prostatic specific antigen increased	2 (<0.1)	5 (<0.1)		7 (<0.1)
Blood glucose increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Transaminases increased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Weight decreased	1 (<0.1)	4 (<0.1)		5 (<0.1)
Blood testosterone decreased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood triglycerides increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
C-reactive protein increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cardiac murmur	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Blood creatine increased	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Blood creatinine increased	0	2 (<0.1)		2 (<0.1)
Blood parathyroid hormone increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood potassium decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrocardiogram QT prolonged	0	2 (<0.1)		2 (<0.1)
Hepatic enzyme abnormal	0	2 (<0.1)		2 (<0.1)
Human rhinovirus test positive	1 (<0.1)	2 (<0.1)		3 (<0.1)
White blood cell count increased	0	2 (<0.1)		2 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Antinuclear antibody positive	0	1 (<0.1)		1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Blood uric acid increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood urine present	1 (<0.1)	1 (<0.1)		2 (<0.1)
Body temperature decreased	0	1 (<0.1)		1 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)		1 (<0.1)
Glycosylated haemoglobin increased	5 (<0.1)	1 (<0.1)		6 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Haemoglobin decreased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	6 (<0.1)	1 (<0.1)		7 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Liver function test increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Respiratory rate increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stool analysis abnormal	0	1 (<0.1)		1 (<0.1)
Streptococcus test negative	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Troponin increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urine transitional cells present	0	1 (<0.1)		1 (<0.1)
Vitamin B12 decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitamin D decreased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Weight increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	2 (<0.1)	0		2 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Haematocrit increased	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Liver function test abnormal	1 (<0.1)	0		1 (<0.1)
Pregnancy test positive	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Renal function test abnormal	1 (<0.1)	0		1 (<0.1)
SARS-CoV-2 test positive	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Total lung capacity decreased	1 (<0.1)	0		1 (<0.1)
Viral test positive	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	635 (4.2)	554 (3.6)		1189 (3.9)
Muscle strain	51 (0.3)	53 (0.3)	1.04 (0.71, 1.52)	104 (0.3)
Ligament sprain	50 (0.3)	49 (0.3)	0.98 (0.66, 1.45)	99 (0.3)
Fall	43 (0.3)	44 (0.3)	1.02 (0.67, 1.55)	87 (0.3)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin laceration	52 (0.3)	36 (0.2)	0.69 (0.45, 1.05)	88 (0.3)
Tooth fracture	36 (0.2)	32 (0.2)	0.89 (0.55, 1.42)	68 (0.2)
Contusion	36 (0.2)	30 (0.2)	0.83 (0.52, 1.34)	66 (0.2)
Procedural pain	56 (0.4)	30 (0.2)	0.53 (0.34, 0.83)	86 (0.3)
Arthropod bite	37 (0.2)	29 (0.2)	0.78 (0.48, 1.27)	66 (0.2)
Foot fracture	23 (0.2)	23 (0.2)	1.00 (0.56, 1.77)	46 (0.2)
Limb injury	17 (0.1)	20 (0.1)	1.17 (0.62, 2.22)	37 (0.1)
Animal bite	18 (0.1)	18 (0.1)	1.00 (0.53, 1.90)	36 (0.1)
Meniscus injury	21 (0.1)	18 (0.1)	0.86 (0.46, 1.59)	39 (0.1)
Skin abrasion	31 (0.2)	15 (<0.1)	0.48 (0.26, 0.89)	46 (0.2)
Joint injury	8 (<0.1)	14 (<0.1)	1.75 (0.75, 4.06)	22 (<0.1)
Road traffic accident	13 (<0.1)	14 (<0.1)	1.08 (0.51, 2.25)	27 (<0.1)
Arthropod sting	18 (0.1)	10 (<0.1)	0.55 (0.26, 1.18)	28 (<0.1)
Post-traumatic pain	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Rib fracture	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Concussion	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Head injury	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Facial bones fracture	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Thermal burn	3 (<0.1)	6 (<0.1)		9 (<0.1)
Ankle fracture	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Bone contusion	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Clavicle fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Corneal abrasion	6 (<0.1)	5 (<0.1)		11 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Epicondylitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Hand fracture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Joint dislocation	4 (<0.1)	5 (<0.1)		9 (<0.1)
Ligament rupture	5 (<0.1)	5 (<0.1)		10 (<0.1)
Muscle rupture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Stress fracture	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Cartilage injury	4 (<0.1)	4 (<0.1)		8 (<0.1)
Dental restoration failure	3 (<0.1)	4 (<0.1)		7 (<0.1)
Humerus fracture	3 (<0.1)	4 (<0.1)		7 (<0.1)
Upper limb fracture	2 (<0.1)	4 (<0.1)		6 (<0.1)
Alcohol poisoning	0	3 (<0.1)		3 (<0.1)
Back injury	5 (<0.1)	3 (<0.1)		8 (<0.1)
Inappropriate schedule of product administration	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tendon injury	2 (<0.1)	3 (<0.1)		5 (<0.1)
Wrist fracture	6 (<0.1)	3 (<0.1)		9 (<0.1)
Exposure to SARS-CoV-2	3 (<0.1)	2 (<0.1)		5 (<0.1)
Heat exhaustion	0	2 (<0.1)		2 (<0.1)
Hypobarism	0	2 (<0.1)		2 (<0.1)
Ligament injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Lip injury	4 (<0.1)	2 (<0.1)		6 (<0.1)
Lower limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Procedural nausea	4 (<0.1)	2 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin wound	3 (<0.1)	2 (<0.1)		5 (<0.1)
Spinal compression fracture	0	2 (<0.1)		2 (<0.1)
Tendon rupture	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Vaccination complication	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wound	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	3 (<0.1)	1 (<0.1)		4 (<0.1)
Carbon monoxide poisoning	0	1 (<0.1)		1 (<0.1)
Chemical burn	0	1 (<0.1)		1 (<0.1)
Chemical burns of eye	0	1 (<0.1)		1 (<0.1)
Chillblains	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)		1 (<0.1)
Dural tear	0	1 (<0.1)		1 (<0.1)
Eyelid injury	0	1 (<0.1)		1 (<0.1)
Face injury	0	1 (<0.1)		1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)		1 (<0.1)
Fractured sacrum	1 (<0.1)	1 (<0.1)		2 (<0.1)
Graft complication	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injury	0	1 (<0.1)		1 (<0.1)
Limb traumatic amputation	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Multiple fractures	0	1 (<0.1)		1 (<0.1)
Muscle hernia	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Neck injury	0	1 (<0.1)		1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural fever	0	1 (<0.1)		1 (<0.1)
Post procedural haematoma	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural swelling	2 (<0.1)	1 (<0.1)		3 (<0.1)
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural headache	0	1 (<0.1)		1 (<0.1)
Procedural site reaction	0	1 (<0.1)		1 (<0.1)
Product administration interrupted	1 (<0.1)	1 (<0.1)		2 (<0.1)
Radius fracture	6 (<0.1)	1 (<0.1)		7 (<0.1)
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)		3 (<0.1)
Scar	1 (<0.1)	1 (<0.1)		2 (<0.1)
Scratch	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal column injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splinter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sports injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)		1 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thoracic vertebral fracture	0	1 (<0.1)		1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Traumatic haemorrhage	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Buttock injury	1 (<0.1)	0		1 (<0.1)
Cervical vertebral fracture	1 (<0.1)	0		1 (<0.1)
Exposure to toxic agent	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Eye injury	2 (<0.1)	0		2 (<0.1)
Eyelid contusion	1 (<0.1)	0		1 (<0.1)
Foreign body	3 (<0.1)	0		3 (<0.1)
Foreign body in ear	2 (<0.1)	0		2 (<0.1)
Fractured coccyx	1 (<0.1)	0		1 (<0.1)
Gingival injury	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Keratorhexis	1 (<0.1)	0		1 (<0.1)
Mallet finger	1 (<0.1)	0		1 (<0.1)
Mouth injury	1 (<0.1)	0		1 (<0.1)
Multiple injuries	1 (<0.1)	0		1 (<0.1)
Muscle injury	1 (<0.1)	0		1 (<0.1)
Musculoskeletal foreign body	1 (<0.1)	0		1 (<0.1)
Nail injury	2 (<0.1)	0		2 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	2 (<0.1)	0		2 (<0.1)
Post procedural contusion	1 (<0.1)	0		1 (<0.1)
Post procedural hypothyroidism	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	2 (<0.1)	0		2 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.8.13.2
Subject Incidence of Unsolicited Non-Serious TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural vomiting	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Repetitive strain injury	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Skeletal injury	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	2 (<0.1)	0		2 (<0.1)
Trunk injury	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	2 (<0.1)	0		2 (<0.1)
Uterine perforation	1 (<0.1)	0		1 (<0.1)
Venomous sting	1 (<0.1)	0		1 (<0.1)
Social circumstances	2 (<0.1)	2 (<0.1)		4 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Postmenopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Product issues	2 (<0.1)	5 (<0.1)		7 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4338 (28.6)	4752 (31.3)	9090 (30.0)
Mild	2456 (16.2)	2708 (17.8)	5164 (17.0)
Moderate	1629 (10.7)	1768 (11.6)	3397 (11.2)
Severe	233 (1.5)	258 (1.7)	491 (1.6)
Missing	20 (0.1)	18 (0.1)	38 (0.1)
Number of Unsolicited Adverse Events	8599	9541	18140
Mild	5734	6430	12164
Moderate	2502	2702	5204
Severe	291	318	609
Missing	72	91	163
Infections and infestations	952 (6.3)	783 (5.2)	1735 (5.7)
Mild	463 (3.1)	403 (2.7)	866 (2.9)
Moderate	450 (3.0)	356 (2.3)	806 (2.7)
Severe	34 (0.2)	20 (0.1)	54 (0.2)
Missing	5 (<0.1)	4 (<0.1)	9 (<0.1)
Urinary tract infection	112 (0.7)	94 (0.6)	206 (0.7)
Mild	51 (0.3)	56 (0.4)	107 (0.4)
Moderate	57 (0.4)	37 (0.2)	94 (0.3)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Upper respiratory tract infection	118 (0.8)	82 (0.5)	200 (0.7)
Mild	66 (0.4)	45 (0.3)	111 (0.4)
Moderate	51 (0.3)	37 (0.2)	88 (0.3)
Severe	1 (<0.1)	0	1 (<0.1)
Sinusitis	46 (0.3)	61 (0.4)	107 (0.4)
Mild	22 (0.1)	25 (0.2)	47 (0.2)
Moderate	24 (0.2)	34 (0.2)	58 (0.2)
Severe	0	2 (<0.1)	2 (<0.1)
Viral infection	52 (0.3)	41 (0.3)	93 (0.3)
Mild	23 (0.2)	18 (0.1)	41 (0.1)
Moderate	28 (0.2)	23 (0.2)	51 (0.2)
Severe	1 (<0.1)	0	1 (<0.1)
Rhinovirus infection	30 (0.2)	36 (0.2)	66 (0.2)
Mild	14 (<0.1)	21 (0.1)	35 (0.1)
Moderate	16 (0.1)	15 (<0.1)	31 (0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Suspected COVID-19	35 (0.2)	34 (0.2)	69 (0.2)
Mild	16 (0.1)	19 (0.1)	35 (0.1)
Moderate	19 (0.1)	15 (<0.1)	34 (0.1)
Severe	0	0	0
Tooth infection	18 (0.1)	26 (0.2)	44 (0.1)
Mild	6 (<0.1)	11 (<0.1)	17 (<0.1)
Moderate	12 (<0.1)	14 (<0.1)	26 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Tooth abscess	26 (0.2)	23 (0.2)	49 (0.2)
Mild	9 (<0.1)	7 (<0.1)	16 (<0.1)
Moderate	15 (<0.1)	16 (0.1)	31 (0.1)
Severe	2 (<0.1)	0	2 (<0.1)
COVID-19	156 (1.0)	22 (0.1)	178 (0.6)
Mild	70 (0.5)	13 (<0.1)	83 (0.3)
Moderate	79 (0.5)	9 (<0.1)	88 (0.3)
Severe	7 (<0.1)	0	7 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100101.sas 22JUN2021 09:10

Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Herpes zoster	15 (<0.1)	22 (0.1)	37 (0.1)
Mild	5 (<0.1)	10 (<0.1)	15 (<0.1)
Moderate	10 (<0.1)	11 (<0.1)	21 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Gastroenteritis	17 (0.1)	19 (0.1)	36 (0.1)
Mild	10 (<0.1)	10 (<0.1)	20 (<0.1)
Moderate	7 (<0.1)	9 (<0.1)	16 (<0.1)
Severe	0	0	0
Pharyngitis	21 (0.1)	19 (0.1)	40 (0.1)
Mild	16 (0.1)	13 (<0.1)	29 (<0.1)
Moderate	5 (<0.1)	6 (<0.1)	11 (<0.1)
Severe	0	0	0
Ear infection	10 (<0.1)	18 (0.1)	28 (<0.1)
Mild	5 (<0.1)	11 (<0.1)	16 (<0.1)
Moderate	5 (<0.1)	6 (<0.1)	11 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Conjunctivitis	9 (<0.1)	13 (<0.1)	22 (<0.1)
Mild	4 (<0.1)	8 (<0.1)	12 (<0.1)
Moderate	5 (<0.1)	4 (<0.1)	9 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Pharyngitis streptococcal	21 (0.1)	13 (<0.1)	34 (0.1)
Mild	6 (<0.1)	5 (<0.1)	11 (<0.1)
Moderate	13 (<0.1)	7 (<0.1)	20 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Cellulitis	17 (0.1)	12 (<0.1)	29 (<0.1)
Mild	7 (<0.1)	4 (<0.1)	11 (<0.1)
Moderate	8 (<0.1)	6 (<0.1)	14 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Hordeolum	12 (<0.1)	12 (<0.1)	24 (<0.1)
Mild	8 (<0.1)	7 (<0.1)	15 (<0.1)
Moderate	4 (<0.1)	5 (<0.1)	9 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Oral herpes	9 (<0.1)	12 (<0.1)	21 (<0.1)
Mild	6 (<0.1)	8 (<0.1)	14 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	0	0	0
Viral upper respiratory tract infection	14 (<0.1)	11 (<0.1)	25 (<0.1)
Mild	10 (<0.1)	9 (<0.1)	19 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	0	0	0
Diverticulitis	10 (<0.1)	9 (<0.1)	19 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	5 (<0.1)	5 (<0.1)	10 (<0.1)
Severe	4 (<0.1)	1 (<0.1)	5 (<0.1)
Fungal infection	11 (<0.1)	9 (<0.1)	20 (<0.1)
Mild	6 (<0.1)	3 (<0.1)	9 (<0.1)
Moderate	4 (<0.1)	5 (<0.1)	9 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Gingivitis	6 (<0.1)	9 (<0.1)	15 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Herpes simplex	5 (<0.1)	9 (<0.1)	14 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	5 (<0.1)	5 (<0.1)	10 (<0.1)
Severe	0	0	0
Otitis media	7 (<0.1)	9 (<0.1)	16 (<0.1)
Mild	3 (<0.1)	6 (<0.1)	9 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	0	0	0
Bronchitis	9 (<0.1)	8 (<0.1)	17 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Localised infection	8 (<0.1)	8 (<0.1)	16 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	5 (<0.1)	5 (<0.1)	10 (<0.1)
Severe	0	0	0
Onychomycosis	3 (<0.1)	8 (<0.1)	11 (<0.1)
Mild	0	7 (<0.1)	7 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Folliculitis	7 (<0.1)	7 (<0.1)	14 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Otitis externa	11 (<0.1)	7 (<0.1)	18 (<0.1)
Mild	7 (<0.1)	3 (<0.1)	10 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Paronychia	5 (<0.1)	7 (<0.1)	12 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0
Acute sinusitis	4 (<0.1)	6 (<0.1)	10 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Bacterial vaginosis	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Vulvovaginal candidiasis	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	3 (<0.1)	6 (<0.1)	9 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Vulvovaginal mycotic infection	14 (<0.1)	6 (<0.1)	20 (<0.1)
Mild	10 (<0.1)	1 (<0.1)	11 (<0.1)
Moderate	4 (<0.1)	5 (<0.1)	9 (<0.1)
Severe	0	0	0
Abscess limb	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Asymptomatic COVID-19	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasopharyngitis	12 (<0.1)	5 (<0.1)	17 (<0.1)
Mild	9 (<0.1)	4 (<0.1)	13 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Pneumonia	11 (<0.1)	5 (<0.1)	16 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	5 (<0.1)	1 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	2 (<0.1)	3 (<0.1)	5 (<0.1)
Respiratory tract infection	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	0	0	0
Subcutaneous abscess	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	4 (<0.1)	4 (<0.1)
Severe	0	0	0
Enterovirus infection	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Laryngitis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lyme disease	0	4 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Skin infection	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Staphylococcal infection	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100101.sas 22JUN2021 09:10

Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Staphylococcal skin infection	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Clostridium difficile infection	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Cystitis	11 (<0.1)	3 (<0.1)	14 (<0.1)
Mild	7 (<0.1)	2 (<0.1)	9 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	0	0	0
Furuncle	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Gastroenteritis viral	10 (<0.1)	3 (<0.1)	13 (<0.1)
Mild	9 (<0.1)	1 (<0.1)	10 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Helicobacter infection	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Impetigo	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Kidney infection	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Chlamydial infection	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Chronic sinusitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Coronavirus infection	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Epididymitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Gonorrhoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Oral candidiasis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Otitis media acute	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Respiratory tract infection viral	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Soft tissue infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Tinea pedis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Tonsillitis	11 (<0.1)	2 (<0.1)	13 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	6 (<0.1)	1 (<0.1)	7 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100101.sas 22JUN2021 09:10

Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Viral pharyngitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Viral rhinitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Abdominal abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Abscess jaw	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Abscess oral	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Appendicitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Bacteraemia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Bacterial infection	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Body tinea	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Candida infection	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Cat scratch disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Catheter site infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Chest wall abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Conjunctivitis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eye infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Fungal skin infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Gastroenteritis bacterial	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gastrointestinal infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Infected cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Infected dermal cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Injection site infection	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Joint abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Latent tuberculosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Liver abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Lung abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Nail infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Osteomyelitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Parotitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Periodontitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Peritonitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Pharyngitis bacterial	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pneumonia mycoplasmal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Postoperative wound infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Prostate infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Pyelonephritis acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Rash pustular	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rhinitis	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	5 (<0.1)	1 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sepsis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Sialoadenitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Sinusitis fungal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Tinea cruris	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Trichomoniasis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Tuberculosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Upper respiratory tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Urinary tract infection bacterial	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Urosepsis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Uterine infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Wound infection	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Abscess	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Bacterial vulvovaginitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Breast abscess	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Breast cellulitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
COVID-19 pneumonia	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Cholecystitis infective	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Coccidioidomycosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Denture stomatitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gardnerella infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gastrointestinal viral infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gingival abscess	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
HIV infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Herpes ophthalmic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Herpes virus infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Influenza	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Labyrinthitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lower respiratory tract infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Mastoiditis	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Nasal abscess	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Ophthalmic herpes zoster	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Oral viral infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Oropharyngeal gonococcal infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Otitis media chronic	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pneumonia viral	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Post procedural infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pulpitis dental	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Pustule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Root canal infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Septic shock	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Sinusitis bacterial	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Skin bacterial infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Skin candida	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Syphilis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Tinea infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tinea versicolour	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	56 (0.4)	62 (0.4)	118 (0.4)
Mild	23 (0.2)	24 (0.2)	47 (0.2)
Moderate	24 (0.2)	24 (0.2)	48 (0.2)
Severe	9 (<0.1)	9 (<0.1)	18 (<0.1)
Missing	0	5 (<0.1)	5 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Basal cell carcinoma	16 (0.1)	10 (<0.1)	26 (<0.1)
Mild	8 (<0.1)	4 (<0.1)	12 (<0.1)
Moderate	7 (<0.1)	5 (<0.1)	12 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of skin	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Squamous cell carcinoma	8 (<0.1)	4 (<0.1)	12 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Uterine leiomyoma	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Malignant melanoma	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Melanocytic naevus	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Prostate cancer	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Benign breast neoplasm	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lipoma	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Acral lentiginous melanoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Angiolipoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Benign hepatic neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Benign neoplasm of bladder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Benign neoplasm of thyroid gland	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Benign ovarian tumour	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Colorectal cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Haemangioma of liver	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Invasive ductal breast carcinoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lip squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lipoma of breast	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Malignant melanoma in situ	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Meningioma benign	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Metastases to bone	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Metastases to lung	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Nasopharyngeal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Papillary thyroid cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Skin papilloma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Splenic marginal zone lymphoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Throat cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Breast cancer	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Chondromatosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Hepatocellular carcinoma	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Intraductal proliferative breast lesion	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Lung adenocarcinoma	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Prostate cancer recurrent	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Renal cell carcinoma	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Renal hamartoma	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Thyroid cancer recurrent	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	148 (1.0)	292 (1.9)	440 (1.4)
Mild	127 (0.8)	251 (1.7)	378 (1.2)
Moderate	20 (0.1)	37 (0.2)	57 (0.2)
Severe	0	3 (<0.1)	3 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Lymphadenopathy	127 (0.8)	264 (1.7)	391 (1.3)
Mild	112 (0.7)	233 (1.5)	345 (1.1)
Moderate	15 (<0.1)	30 (0.2)	45 (0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Anaemia	6 (<0.1)	10 (<0.1)	16 (<0.1)
Mild	3 (<0.1)	7 (<0.1)	10 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Lymph node pain	9 (<0.1)	9 (<0.1)	18 (<0.1)
Mild	7 (<0.1)	6 (<0.1)	13 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Lymphadenitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Iron deficiency anaemia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Thrombocytopenia	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood loss anaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Normocytic anaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Immune system disorders	66 (0.4)	47 (0.3)	113 (0.4)
Mild	28 (0.2)	22 (0.1)	50 (0.2)
Moderate	34 (0.2)	22 (0.1)	56 (0.2)
Severe	3 (<0.1)	3 (<0.1)	6 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Seasonal allergy	47 (0.3)	33 (0.2)	80 (0.3)
Mild	20 (0.1)	15 (<0.1)	35 (0.1)
Moderate	27 (0.2)	17 (0.1)	44 (0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Hypersensitivity	6 (<0.1)	6 (<0.1)	12 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Food allergy	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Allergy to chemicals	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Drug hypersensitivity	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Sarcoidosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Allergy to metals	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Anaphylactic reaction	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Milk allergy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Serum sickness	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders	17 (0.1)	12 (<0.1)	29 (<0.1)
Mild	8 (<0.1)	6 (<0.1)	14 (<0.1)
Moderate	7 (<0.1)	4 (<0.1)	11 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Hypothyroidism	10 (<0.1)	10 (<0.1)	20 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	5 (<0.1)	4 (<0.1)	9 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Basedow's disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders (Cont.)			
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Autoimmune thyroiditis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Goitre	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hyperparathyroidism primary	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders (Cont.)			
Oestrogen deficiency	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Thyroid mass	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Metabolism and nutrition disorders	113 (0.7)	128 (0.8)	241 (0.8)
Mild	58 (0.4)	63 (0.4)	121 (0.4)
Moderate	48 (0.3)	62 (0.4)	110 (0.4)
Severe	3 (<0.1)	3 (<0.1)	6 (<0.1)
Missing	4 (<0.1)	0	4 (<0.1)
Hyperlipidaemia	21 (0.1)	23 (0.2)	44 (0.1)
Mild	10 (<0.1)	13 (<0.1)	23 (<0.1)
Moderate	11 (<0.1)	10 (<0.1)	21 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Type 2 diabetes mellitus	11 (<0.1)	21 (0.1)	32 (0.1)
Mild	7 (<0.1)	7 (<0.1)	14 (<0.1)
Moderate	4 (<0.1)	14 (<0.1)	18 (<0.1)
Severe	0	0	0
Hypercholesterolaemia	13 (<0.1)	12 (<0.1)	25 (<0.1)
Mild	9 (<0.1)	8 (<0.1)	17 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0
Vitamin D deficiency	14 (<0.1)	12 (<0.1)	26 (<0.1)
Mild	8 (<0.1)	6 (<0.1)	14 (<0.1)
Moderate	6 (<0.1)	6 (<0.1)	12 (<0.1)
Severe	0	0	0
Decreased appetite	9 (<0.1)	11 (<0.1)	20 (<0.1)
Mild	7 (<0.1)	9 (<0.1)	16 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Dehydration	6 (<0.1)	10 (<0.1)	16 (<0.1)
Mild	0	5 (<0.1)	5 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gout	7 (<0.1)	7 (<0.1)	14 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	5 (<0.1)	6 (<0.1)	11 (<0.1)
Severe	0	0	0
Diabetes mellitus	5 (<0.1)	6 (<0.1)	11 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	5 (<0.1)	5 (<0.1)	10 (<0.1)
Severe	0	0	0
Glucose tolerance impaired	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	6 (<0.1)	3 (<0.1)	9 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hyperglycaemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Hypertriglyceridaemia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Hyponatraemia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Abnormal loss of weight	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypoglycaemia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Abnormal weight gain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Diabetes mellitus inadequate control	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Food intolerance	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hyperkalaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hypocalcaemia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypoferritinaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hypokalaemia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Insulin resistance	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Iron deficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Magnesium deficiency	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Obesity	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Polydipsia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dyslipidaemia	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Hyperuricaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypomagnesaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Increased appetite	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Metabolic acidosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders	116 (0.8)	159 (1.0)	275 (0.9)
Mild	40 (0.3)	55 (0.4)	95 (0.3)
Moderate	67 (0.4)	98 (0.6)	165 (0.5)
Severe	8 (<0.1)	2 (<0.1)	10 (<0.1)
Missing	1 (<0.1)	4 (<0.1)	5 (<0.1)
Anxiety	38 (0.3)	52 (0.3)	90 (0.3)
Mild	12 (<0.1)	16 (0.1)	28 (<0.1)
Moderate	23 (0.2)	36 (0.2)	59 (0.2)
Severe	3 (<0.1)	0	3 (<0.1)
Depression	29 (0.2)	35 (0.2)	64 (0.2)
Mild	6 (<0.1)	8 (<0.1)	14 (<0.1)
Moderate	20 (0.1)	26 (0.2)	46 (0.2)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Insomnia	24 (0.2)	32 (0.2)	56 (0.2)
Mild	13 (<0.1)	14 (<0.1)	27 (<0.1)
Moderate	10 (<0.1)	18 (0.1)	28 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Abnormal dreams	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Attention deficit hyperactivity disorder	9 (<0.1)	5 (<0.1)	14 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	0	0	0
Sleep disorder	0	5 (<0.1)	5 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Panic attack	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Bipolar disorder	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	0	0	0
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	0	0	0
Nightmare	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Libido decreased	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Major depression	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Post-traumatic stress disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Stress	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Suicidal ideation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Affect lability	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Alcohol withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Bipolar II disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bruxism	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Claustrophobia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Completed suicide	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Depressed mood	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Drug abuse	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Emotional disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hallucination	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Premature ejaculation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Reading disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Schizoaffective disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Substance abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Agitation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Alcoholism	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Confusional state	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0	4 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Hallucination, visual	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Mental fatigue	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Mental status changes	3 (<0.1)	0	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Persistent depressive disorder	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Schizophrenia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Nervous system disorders	881 (5.8)	1008 (6.6)	1889 (6.2)
Mild	617 (4.1)	698 (4.6)	1315 (4.3)
Moderate	239 (1.6)	278 (1.8)	517 (1.7)
Severe	23 (0.2)	26 (0.2)	49 (0.2)
Missing	2 (<0.1)	6 (<0.1)	8 (<0.1)
Headache	687 (4.5)	744 (4.9)	1431 (4.7)
Mild	504 (3.3)	544 (3.6)	1048 (3.5)
Moderate	172 (1.1)	185 (1.2)	357 (1.2)
Severe	11 (<0.1)	14 (<0.1)	25 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Dizziness	56 (0.4)	74 (0.5)	130 (0.4)
Mild	43 (0.3)	59 (0.4)	102 (0.3)
Moderate	12 (<0.1)	13 (<0.1)	25 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Paraesthesia	27 (0.2)	34 (0.2)	61 (0.2)
Mild	22 (0.1)	27 (0.2)	49 (0.2)
Moderate	5 (<0.1)	7 (<0.1)	12 (<0.1)
Severe	0	0	0
Sinus headache	6 (<0.1)	20 (0.1)	26 (<0.1)
Mild	3 (<0.1)	10 (<0.1)	13 (<0.1)
Moderate	3 (<0.1)	10 (<0.1)	13 (<0.1)
Severe	0	0	0
Ageusia	10 (<0.1)	15 (<0.1)	25 (<0.1)
Mild	6 (<0.1)	11 (<0.1)	17 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0
Migraine	24 (0.2)	15 (<0.1)	39 (0.1)
Mild	9 (<0.1)	4 (<0.1)	13 (<0.1)
Moderate	13 (<0.1)	8 (<0.1)	21 (<0.1)
Severe	2 (<0.1)	3 (<0.1)	5 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Hypoaesthesia	9 (<0.1)	13 (<0.1)	22 (<0.1)
Mild	9 (<0.1)	10 (<0.1)	19 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Dysgeusia	8 (<0.1)	12 (<0.1)	20 (<0.1)
Mild	8 (<0.1)	12 (<0.1)	20 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Syncope	14 (<0.1)	12 (<0.1)	26 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	7 (<0.1)	5 (<0.1)	12 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sciatica	9 (<0.1)	11 (<0.1)	20 (<0.1)
Mild	3 (<0.1)	7 (<0.1)	10 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Anosmia	9 (<0.1)	9 (<0.1)	18 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0
Cervical radiculopathy	1 (<0.1)	8 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	6 (<0.1)	6 (<0.1)
Severe	0	0	0
Tension headache	6 (<0.1)	8 (<0.1)	14 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0
Hyperaesthesia	0	6 (<0.1)	6 (<0.1)
Mild	0	6 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Presyncope	14 (<0.1)	6 (<0.1)	20 (<0.1)
Mild	6 (<0.1)	3 (<0.1)	9 (<0.1)
Moderate	6 (<0.1)	3 (<0.1)	9 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Disturbance in attention	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Carpal tunnel syndrome	7 (<0.1)	4 (<0.1)	11 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	6 (<0.1)	3 (<0.1)	9 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Memory impairment	0	4 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Burning sensation	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cerebrovascular accident	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Mental impairment	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nerve compression	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Peripheral sensory neuropathy	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Seizure	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Taste disorder	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Amnesia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Diabetic neuropathy	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Facial paralysis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Idiopathic intracranial hypertension	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Migraine with aura	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Neuropathy peripheral	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Parosmia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Post-traumatic headache	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Somnolence	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Transient ischaemic attack	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Aura	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Balance disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Carotid artery stenosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Carotid artery thrombosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Cerebral small vessel ischaemic disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cognitive disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cubital tunnel syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dizziness postural	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Dyslexia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Embolic stroke	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Essential tremor	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Head discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Head titubation	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hyposmia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lethargy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lumbar radiculopathy	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Movement disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Piriformis syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Poor quality sleep	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Post herpetic neuralgia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Primary cough headache	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Primary headache associated with sexual activity	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Radiculopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Restless legs syndrome	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Tremor	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vestibular migraine	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Visual field defect	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Aphasia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Dementia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dyskinesia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Encephalopathy	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	0	2 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hypogeusia	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Muscle contractions involuntary	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Occipital neuralgia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Peroneal nerve palsy	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Speech disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Trigeminal neuralgia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eye disorders	67 (0.4)	70 (0.5)	137 (0.5)
Mild	39 (0.3)	46 (0.3)	85 (0.3)
Moderate	25 (0.2)	21 (0.1)	46 (0.2)
Severe	3 (<0.1)	3 (<0.1)	6 (<0.1)
Eye irritation	1 (<0.1)	7 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Eye pruritus	8 (<0.1)	7 (<0.1)	15 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	5 (<0.1)	2 (<0.1)	7 (<0.1)
Severe	0	0	0
Vision blurred	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dry eye	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Eye pain	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Conjunctival haemorrhage	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eye inflammation	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Glaucoma	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Retinal detachment	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Blepharitis	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Blepharospasm	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Eye swelling	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lacrimation increased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Ocular hyperaemia	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	5 (<0.1)	1 (<0.1)	6 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Photophobia	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Scleritis	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Swelling of eyelid	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Vitreous floaters	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Xerophthalmia	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Accommodation disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blindness transient	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Cataract	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Chalazion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Conjunctivitis allergic	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Eyelid cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Iris disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Ocular discomfort	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Retinal vascular occlusion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Uveitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Visual impairment	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Vitreous disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Asthenopia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Blindness	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Dacryoadenitis acquired	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eye discharge	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eyelid ptosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Macular degeneration	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Macular hole	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Macular oedema	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Ocular rosacea	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Open angle glaucoma	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Orbital oedema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Periorbital oedema	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Periorbital swelling	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Photopsia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Retinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Strabismus	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Ulcerative keratitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vitreous detachment	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ear and labyrinth disorders	83 (0.5)	81 (0.5)	164 (0.5)
Mild	55 (0.4)	49 (0.3)	104 (0.3)
Moderate	25 (0.2)	31 (0.2)	56 (0.2)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Vertigo	18 (0.1)	23 (0.2)	41 (0.1)
Mild	7 (<0.1)	12 (<0.1)	19 (<0.1)
Moderate	8 (<0.1)	10 (<0.1)	18 (<0.1)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Ear pain	18 (0.1)	17 (0.1)	35 (0.1)
Mild	12 (<0.1)	12 (<0.1)	24 (<0.1)
Moderate	6 (<0.1)	5 (<0.1)	11 (<0.1)
Severe	0	0	0
Tinnitus	14 (<0.1)	12 (<0.1)	26 (<0.1)
Mild	10 (<0.1)	8 (<0.1)	18 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0
Vertigo positional	1 (<0.1)	7 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	5 (<0.1)	5 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Cerumen impaction	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Ear discomfort	8 (<0.1)	4 (<0.1)	12 (<0.1)
Mild	6 (<0.1)	3 (<0.1)	9 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Deafness neurosensory	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Deafness unilateral	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Ear canal erythema	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Meniere's disease	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Motion sickness	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Otorrhoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Ear congestion	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Middle ear effusion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tympanic membrane perforation	6 (<0.1)	1 (<0.1)	7 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Safety Set

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Ear and labyrinth disorders (Cont.)			
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ear pruritus	3 (<0.1)	0	3 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Excessive cerumen production	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tympanic membrane disorder	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

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Ear and labyrinth disorders (Cont.)			
Tympanic membrane hyperaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cardiac disorders	75 (0.5)	79 (0.5)	154 (0.5)
Mild	28 (0.2)	28 (0.2)	56 (0.2)
Moderate	26 (0.2)	32 (0.2)	58 (0.2)
Severe	12 (<0.1)	15 (<0.1)	27 (<0.1)
Missing	9 (<0.1)	4 (<0.1)	13 (<0.1)
Tachycardia	9 (<0.1)	15 (<0.1)	24 (<0.1)
Mild	6 (<0.1)	9 (<0.1)	15 (<0.1)
Moderate	1 (<0.1)	6 (<0.1)	7 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Bradycardia	16 (0.1)	13 (<0.1)	29 (<0.1)
Mild	6 (<0.1)	6 (<0.1)	12 (<0.1)
Moderate	7 (<0.1)	3 (<0.1)	10 (<0.1)
Severe	3 (<0.1)	4 (<0.1)	7 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Atrial fibrillation	12 (<0.1)	12 (<0.1)	24 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	7 (<0.1)	7 (<0.1)	14 (<0.1)
Severe	3 (<0.1)	4 (<0.1)	7 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Palpitations	7 (<0.1)	9 (<0.1)	16 (<0.1)
Mild	7 (<0.1)	6 (<0.1)	13 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Angina pectoris	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	5 (<0.1)	6 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Arrhythmia	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Cardiac failure congestive	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Coronary artery disease	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Sinus tachycardia	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Acute myocardial infarction	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Arteriosclerosis coronary artery	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Atrial enlargement	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Atrial flutter	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Cardiac flutter	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Ventricular extrasystoles	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Atrial tachycardia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Cardiomegaly	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Left ventricular hypertrophy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pericardial effusion	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Vascular disorders	204 (1.3)	198 (1.3)	402 (1.3)
Mild	77 (0.5)	72 (0.5)	149 (0.5)
Moderate	78 (0.5)	90 (0.6)	168 (0.6)
Severe	44 (0.3)	33 (0.2)	77 (0.3)
Missing	5 (<0.1)	3 (<0.1)	8 (<0.1)
Hypertension	161 (1.1)	153 (1.0)	314 (1.0)
Mild	55 (0.4)	47 (0.3)	102 (0.3)
Moderate	71 (0.5)	76 (0.5)	147 (0.5)
Severe	34 (0.2)	28 (0.2)	62 (0.2)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Hot flush	8 (<0.1)	15 (<0.1)	23 (<0.1)
Mild	7 (<0.1)	11 (<0.1)	18 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Flushing	5 (<0.1)	6 (<0.1)	11 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Haematoma	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Hypertensive urgency	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hypotension	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Systolic hypertension	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	3 (<0.1)	3 (<0.1)	6 (<0.1)
Orthostatic hypotension	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Arteriosclerosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Deep vein thrombosis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Essential hypertension	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Peripheral coldness	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Varicose vein	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Aortic dilatation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Aortic stenosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Diastolic hypertension	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Hypertensive emergency	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Phlebitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Thrombophlebitis superficial	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
White coat hypertension	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Respiratory, thoracic and mediastinal disorders	667 (4.4)	603 (4.0)	1270 (4.2)
Mild	522 (3.4)	454 (3.0)	976 (3.2)
Moderate	128 (0.8)	128 (0.8)	256 (0.8)
Severe	12 (<0.1)	15 (<0.1)	27 (<0.1)
Missing	5 (<0.1)	6 (<0.1)	11 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Cough	165 (1.1)	177 (1.2)	342 (1.1)
Mild	135 (0.9)	147 (1.0)	282 (0.9)
Moderate	29 (0.2)	27 (0.2)	56 (0.2)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Oropharyngeal pain	232 (1.5)	158 (1.0)	390 (1.3)
Mild	201 (1.3)	134 (0.9)	335 (1.1)
Moderate	29 (0.2)	24 (0.2)	53 (0.2)
Severe	2 (<0.1)	0	2 (<0.1)
Nasal congestion	165 (1.1)	155 (1.0)	320 (1.1)
Mild	142 (0.9)	127 (0.8)	269 (0.9)
Moderate	23 (0.2)	26 (0.2)	49 (0.2)
Severe	0	2 (<0.1)	2 (<0.1)
Rhinorrhoea	145 (1.0)	130 (0.9)	275 (0.9)
Mild	127 (0.8)	109 (0.7)	236 (0.8)
Moderate	18 (0.1)	19 (0.1)	37 (0.1)
Severe	0	2 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.
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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Dyspnoea	41 (0.3)	43 (0.3)	84 (0.3)
Mild	31 (0.2)	31 (0.2)	62 (0.2)
Moderate	10 (<0.1)	8 (<0.1)	18 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Tachypnoea	32 (0.2)	33 (0.2)	65 (0.2)
Mild	31 (0.2)	32 (0.2)	63 (0.2)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Respiratory tract congestion	7 (<0.1)	18 (0.1)	25 (<0.1)
Mild	6 (<0.1)	11 (<0.1)	17 (<0.1)
Moderate	1 (<0.1)	7 (<0.1)	8 (<0.1)
Severe	0	0	0
Asthma	17 (0.1)	16 (0.1)	33 (0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	14 (<0.1)	12 (<0.1)	26 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Epistaxis	11 (<0.1)	16 (0.1)	27 (<0.1)
Mild	8 (<0.1)	13 (<0.1)	21 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0
Sinus congestion	26 (0.2)	16 (0.1)	42 (0.1)
Mild	18 (0.1)	11 (<0.1)	29 (<0.1)
Moderate	8 (<0.1)	5 (<0.1)	13 (<0.1)
Severe	0	0	0
Throat irritation	16 (0.1)	16 (0.1)	32 (0.1)
Mild	14 (<0.1)	15 (<0.1)	29 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Rhinitis allergic	15 (<0.1)	12 (<0.1)	27 (<0.1)
Mild	14 (<0.1)	9 (<0.1)	23 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Upper-airway cough syndrome	12 (<0.1)	12 (<0.1)	24 (<0.1)
Mild	10 (<0.1)	9 (<0.1)	19 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Sneezing	14 (<0.1)	11 (<0.1)	25 (<0.1)
Mild	13 (<0.1)	10 (<0.1)	23 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Chronic obstructive pulmonary disease	11 (<0.1)	7 (<0.1)	18 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	6 (<0.1)	6 (<0.1)	12 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Dysphonia	8 (<0.1)	5 (<0.1)	13 (<0.1)
Mild	8 (<0.1)	5 (<0.1)	13 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pharyngeal erythema	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sinus pain	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dry throat	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dyspnoea exertional	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Paranasal sinus discomfort	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Productive cough	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	5 (<0.1)	3 (<0.1)	8 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Bronchiectasis	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Pleural effusion	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary embolism	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Wheezing	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Acute respiratory failure	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	2 (<0.1)	2 (<0.1)	4 (<0.1)
Allergic cough	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Atelectasis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Bronchospasm	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Paranasal sinus hypersecretion	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pleurisy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Respiratory failure	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Emphysema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Hypoxia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal discomfort	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Nasal dryness	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal pruritus	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal septum deviation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Paranasal cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pharyngeal swelling	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pleuritic pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Respiratory disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Respiratory distress	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Sputum increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tonsillolith	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Aphonia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Asthma exercise induced	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Haemoptysis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Laryngeal oedema	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Painful respiration	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pneumonia aspiration	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary fibrosis	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pulmonary infarction	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Pulmonary mass	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rales	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Respiratory symptom	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Rhinalgia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rhinitis atrophic	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Throat tightness	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tonsillar exudate	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Tonsillar hypertrophy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Upper respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gastrointestinal disorders	567 (3.7)	599 (3.9)	1166 (3.8)
Mild	382 (2.5)	376 (2.5)	758 (2.5)
Moderate	165 (1.1)	200 (1.3)	365 (1.2)
Severe	16 (0.1)	21 (0.1)	37 (0.1)
Missing	4 (<0.1)	2 (<0.1)	6 (<0.1)
Diarrhoea	199 (1.3)	204 (1.3)	403 (1.3)
Mild	152 (1.0)	156 (1.0)	308 (1.0)
Moderate	46 (0.3)	45 (0.3)	91 (0.3)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Nausea	164 (1.1)	162 (1.1)	326 (1.1)
Mild	122 (0.8)	118 (0.8)	240 (0.8)
Moderate	40 (0.3)	38 (0.3)	78 (0.3)
Severe	1 (<0.1)	5 (<0.1)	6 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Vomiting	53 (0.3)	62 (0.4)	115 (0.4)
Mild	40 (0.3)	44 (0.3)	84 (0.3)
Moderate	12 (<0.1)	17 (0.1)	29 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Gastrooesophageal reflux disease	29 (0.2)	41 (0.3)	70 (0.2)
Mild	12 (<0.1)	20 (0.1)	32 (0.1)
Moderate	16 (0.1)	21 (0.1)	37 (0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Toothache	28 (0.2)	35 (0.2)	63 (0.2)
Mild	13 (<0.1)	19 (0.1)	32 (0.1)
Moderate	15 (<0.1)	16 (0.1)	31 (0.1)
Severe	0	0	0
Abdominal pain	20 (0.1)	26 (0.2)	46 (0.2)
Mild	12 (<0.1)	14 (<0.1)	26 (<0.1)
Moderate	5 (<0.1)	8 (<0.1)	13 (<0.1)
Severe	2 (<0.1)	4 (<0.1)	6 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Constipation	21 (0.1)	16 (0.1)	37 (0.1)
Mild	14 (<0.1)	7 (<0.1)	21 (<0.1)
Moderate	7 (<0.1)	8 (<0.1)	15 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Dental caries	11 (<0.1)	15 (<0.1)	26 (<0.1)
Mild	6 (<0.1)	5 (<0.1)	11 (<0.1)
Moderate	5 (<0.1)	10 (<0.1)	15 (<0.1)
Severe	0	0	0
Abdominal pain upper	20 (0.1)	14 (<0.1)	34 (0.1)
Mild	16 (0.1)	6 (<0.1)	22 (<0.1)
Moderate	2 (<0.1)	6 (<0.1)	8 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Dyspepsia	16 (0.1)	14 (<0.1)	30 (<0.1)
Mild	11 (<0.1)	10 (<0.1)	21 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Food poisoning	7 (<0.1)	11 (<0.1)	18 (<0.1)
Mild	3 (<0.1)	8 (<0.1)	11 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	0	0	0
Abdominal pain lower	8 (<0.1)	8 (<0.1)	16 (<0.1)
Mild	7 (<0.1)	6 (<0.1)	13 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Abdominal discomfort	13 (<0.1)	6 (<0.1)	19 (<0.1)
Mild	8 (<0.1)	5 (<0.1)	13 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Colitis	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastric ulcer	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Haemorrhoids	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0
Inguinal hernia	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	4 (<0.1)	0	4 (<0.1)
Moderate	0	4 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Abdominal distension	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Hiatus hernia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Aphthous ulcer	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Flatulence	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Haematochezia	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Large intestine polyp	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	5 (<0.1)	3 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Paraesthesia oral	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Tooth impacted	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Umbilical hernia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Anal fissure	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Chapped lips	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Diverticulum intestinal	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dry mouth	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Dysphagia	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Gastritis	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastrointestinal disorder	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hypoaesthesia oral	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Lip swelling	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Mouth ulceration	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oesophagitis	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Proctalgia	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Rectal haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Stomatitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Swollen tongue	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Tongue discolouration	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Abdominal hernia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dental paraesthesia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Duodenal ulcer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Erosive oesophagitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Faeces soft	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Frequent bowel movements	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gastrointestinal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Gingival bleeding	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gingival pain	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Glossitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Impaired gastric emptying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Intestinal obstruction	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Leukoplakia oral	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lip oedema	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Loose tooth	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oesophageal ulcer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Oral disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pancreatitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Peptic ulcer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Periodontal disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Proctitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rectal prolapse	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Salivary hypersecretion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Small intestinal obstruction	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Submaxillary gland enlargement	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ascites	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Dental necrosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Diverticulum	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Gastric perforation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastric polyps	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gastrointestinal motility disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gastrointestinal pain	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Glossodynia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lichenoid dysplasia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Noninfective gingivitis	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Oral cavity fistula	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oral discomfort	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Oral mucosal erythema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Oral pain	5 (<0.1)	0	5 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Regurgitation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Retching	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Saliva altered	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tongue coated	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders	5 (<0.1)	13 (<0.1)	18 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	0	3 (<0.1)	3 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Cholelithiasis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Cholecystitis	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Hepatic steatosis	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Bile duct stone	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)			
Biliary colic	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cholecystitis acute	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hepatic cyst	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders	235 (1.5)	295 (1.9)	530 (1.7)
Mild	165 (1.1)	203 (1.3)	368 (1.2)
Moderate	65 (0.4)	86 (0.6)	151 (0.5)
Severe	2 (<0.1)	6 (<0.1)	8 (<0.1)
Missing	3 (<0.1)	0	3 (<0.1)
Urticaria	33 (0.2)	44 (0.3)	77 (0.3)
Mild	22 (0.1)	20 (0.1)	42 (0.1)
Moderate	10 (<0.1)	23 (0.2)	33 (0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Rash	31 (0.2)	35 (0.2)	66 (0.2)
Mild	25 (0.2)	27 (0.2)	52 (0.2)
Moderate	6 (<0.1)	7 (<0.1)	13 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Pruritus	23 (0.2)	25 (0.2)	48 (0.2)
Mild	17 (0.1)	20 (0.1)	37 (0.1)
Moderate	5 (<0.1)	4 (<0.1)	9 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Dermatitis contact	31 (0.2)	24 (0.2)	55 (0.2)
Mild	22 (0.1)	16 (0.1)	38 (0.1)
Moderate	9 (<0.1)	8 (<0.1)	17 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Erythema	5 (<0.1)	15 (<0.1)	20 (<0.1)
Mild	4 (<0.1)	10 (<0.1)	14 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Hyperhidrosis	11 (<0.1)	13 (<0.1)	24 (<0.1)
Mild	11 (<0.1)	11 (<0.1)	22 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Eczema	3 (<0.1)	10 (<0.1)	13 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	6 (<0.1)	8 (<0.1)
Severe	0	0	0
Night sweats	8 (<0.1)	10 (<0.1)	18 (<0.1)
Mild	7 (<0.1)	10 (<0.1)	17 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Acne	7 (<0.1)	9 (<0.1)	16 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	0	0	0
Dermatitis	5 (<0.1)	8 (<0.1)	13 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Rash maculo-papular	2 (<0.1)	8 (<0.1)	10 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0
Rash papular	4 (<0.1)	8 (<0.1)	12 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100101.sas 22JUN2021 09:10

Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Alopecia	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	3 (<0.1)	7 (<0.1)	10 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Rash macular	3 (<0.1)	7 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Actinic keratosis	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Dermatitis atopic	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	5 (<0.1)	4 (<0.1)	9 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100101.sas 22JUN2021 09:10

Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Ecchymosis	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Psoriasis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Rash pruritic	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	0	0	0
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rosacea	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Blister	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Dry skin	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hidradenitis	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Macule	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Pain of skin	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rash erythematous	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100101.sas 22JUN2021 09:10

Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Urticaria papular	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	4 (<0.1)	3 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Acne cystic	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Angioedema	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Hand dermatitis	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Lichen planus	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Neurodermatitis	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Skin ulcer	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Alopecia areata	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Chronic spontaneous urticaria	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Cold sweat	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dermal cyst	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0
Dermatitis allergic	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ingrowing nail	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Lichen sclerosus	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Mechanical urticaria	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Papule	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Petechiae	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Precancerous skin lesion	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Skin exfoliation	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin mass	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin warm	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Solar lentigo	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dermatitis bullous	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ingrown hair	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Intertrigo	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Livedo reticularis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Perioral dermatitis	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Photosensitivity reaction	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Rash follicular	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rash vesicular	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Scab	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Skin discolouration	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin hyperpigmentation	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin irritation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin lesion	4 (<0.1)	0	4 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Umbilical erythema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Musculoskeletal and connective tissue disorders	1017 (6.7)	1007 (6.6)	2024 (6.7)
Mild	662 (4.4)	641 (4.2)	1303 (4.3)
Moderate	317 (2.1)	337 (2.2)	654 (2.2)
Severe	35 (0.2)	26 (0.2)	61 (0.2)
Missing	3 (<0.1)	3 (<0.1)	6 (<0.1)
Arthralgia	389 (2.6)	391 (2.6)	780 (2.6)
Mild	281 (1.9)	284 (1.9)	565 (1.9)
Moderate	101 (0.7)	99 (0.7)	200 (0.7)
Severe	7 (<0.1)	7 (<0.1)	14 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Myalgia	388 (2.6)	387 (2.5)	775 (2.6)
Mild	313 (2.1)	296 (1.9)	609 (2.0)
Moderate	71 (0.5)	82 (0.5)	153 (0.5)
Severe	4 (<0.1)	9 (<0.1)	13 (<0.1)
Back pain	130 (0.9)	106 (0.7)	236 (0.8)
Mild	69 (0.5)	55 (0.4)	124 (0.4)
Moderate	53 (0.3)	50 (0.3)	103 (0.3)
Severe	7 (<0.1)	1 (<0.1)	8 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Pain in extremity	77 (0.5)	67 (0.4)	144 (0.5)
Mild	52 (0.3)	41 (0.3)	93 (0.3)
Moderate	25 (0.2)	24 (0.2)	49 (0.2)
Severe	0	2 (<0.1)	2 (<0.1)
Musculoskeletal pain	38 (0.3)	49 (0.3)	87 (0.3)
Mild	22 (0.1)	29 (0.2)	51 (0.2)
Moderate	16 (0.1)	20 (0.1)	36 (0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Neck pain	38 (0.3)	46 (0.3)	84 (0.3)
Mild	25 (0.2)	30 (0.2)	55 (0.2)
Moderate	13 (<0.1)	14 (<0.1)	27 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Muscle spasms	29 (0.2)	35 (0.2)	64 (0.2)
Mild	14 (<0.1)	19 (0.1)	33 (0.1)
Moderate	14 (<0.1)	14 (<0.1)	28 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Osteoarthritis	28 (0.2)	23 (0.2)	51 (0.2)
Mild	5 (<0.1)	6 (<0.1)	11 (<0.1)
Moderate	18 (0.1)	16 (0.1)	34 (0.1)
Severe	3 (<0.1)	0	3 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Musculoskeletal chest pain	14 (<0.1)	15 (<0.1)	29 (<0.1)
Mild	10 (<0.1)	9 (<0.1)	19 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Tendonitis	13 (<0.1)	15 (<0.1)	28 (<0.1)
Mild	6 (<0.1)	8 (<0.1)	14 (<0.1)
Moderate	5 (<0.1)	6 (<0.1)	11 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bursitis	7 (<0.1)	12 (<0.1)	19 (<0.1)
Mild	3 (<0.1)	6 (<0.1)	9 (<0.1)
Moderate	4 (<0.1)	6 (<0.1)	10 (<0.1)
Severe	0	0	0
Musculoskeletal stiffness	14 (<0.1)	12 (<0.1)	26 (<0.1)
Mild	11 (<0.1)	10 (<0.1)	21 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Rotator cuff syndrome	12 (<0.1)	11 (<0.1)	23 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	9 (<0.1)	8 (<0.1)	17 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Arthritis	4 (<0.1)	9 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	7 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Intervertebral disc protrusion	5 (<0.1)	7 (<0.1)	12 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	6 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Trigger finger	3 (<0.1)	7 (<0.1)	10 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Groin pain	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Joint swelling	9 (<0.1)	6 (<0.1)	15 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Muscle tightness	1 (<0.1)	6 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Muscular weakness	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	5 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Joint range of motion decreased	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	4 (<0.1)	4 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Limb discomfort	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Bone pain	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Costochondritis	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Fibromyalgia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteoporosis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Pain in jaw	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	6 (<0.1)	3 (<0.1)	9 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Spinal pain	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Spinal stenosis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Flank pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Muscle twitching	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Neck mass	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Spinal osteoarthritis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Axillary mass	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Muscle fatigue	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Plantar fasciitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Polyarthritis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Temporomandibular joint syndrome	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Bone lesion	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bone swelling	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Degenerative bone disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Exostosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Floating patella	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Intervertebral disc degeneration	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Joint stiffness	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Limb mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Myosclerosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Osteitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteopenia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Palindromic rheumatism	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Periarthritis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Plantar fascial fibromatosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Rheumatoid arthritis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Sacroiliitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Spondylitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Tendon disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tendon pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tenosynovitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Torticollis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Trismus	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Undifferentiated connective tissue disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Cervical spinal stenosis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	0	2 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Foot deformity	3 (<0.1)	0	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Intervertebral disc annular tear	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Muscle discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Musculoskeletal discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Musculoskeletal disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Myositis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Osteonecrosis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Psoriatic arthropathy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Scoliosis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Synovial cyst	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Synovitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Vertebral foraminal stenosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Renal and urinary disorders	46 (0.3)	50 (0.3)	96 (0.3)
Mild	15 (<0.1)	21 (0.1)	36 (0.1)
Moderate	26 (0.2)	23 (0.2)	49 (0.2)
Severe	4 (<0.1)	3 (<0.1)	7 (<0.1)
Missing	1 (<0.1)	3 (<0.1)	4 (<0.1)
Nephrolithiasis	21 (0.1)	14 (<0.1)	35 (0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	15 (<0.1)	4 (<0.1)	19 (<0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Missing	1 (<0.1)	4 (<0.1)	5 (<0.1)
Dysuria	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	4 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Haematuria	6 (<0.1)	3 (<0.1)	9 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Pollakiuria	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Polyuria	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Acute kidney injury	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Chronic kidney disease	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hypertonic bladder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Nocturia	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Urinary hesitation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Urinary incontinence	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Urinary retention	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Bladder diverticulum	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bladder pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Bladder spasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Chromaturia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Cystitis interstitial	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Haemorrhage urinary tract	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Hydronephrosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Renal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Renal pain	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Stress urinary incontinence	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Urethral pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bladder prolapse	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Micturition urgency	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Renal colic	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Renal impairment	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders	59 (0.4)	61 (0.4)	120 (0.4)
Mild	33 (0.2)	29 (0.2)	62 (0.2)
Moderate	22 (0.1)	30 (0.2)	52 (0.2)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Benign prostatic hyperplasia	8 (<0.1)	5 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Dysmenorrhoea	7 (<0.1)	5 (<0.1)	12 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Erectile dysfunction	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Pelvic pain	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Menorrhagia	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Prostatitis	6 (<0.1)	3 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Breast cyst	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Menopausal symptoms	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Nipple exudate bloody	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Postmenopausal haemorrhage	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Uterine haemorrhage	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Vaginal haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Adnexal torsion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Breast calcifications	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Breast disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Breast mass	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Breast pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Breast swelling	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Cervical dysplasia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Ejaculation failure	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Menstrual disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Menstruation irregular	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Metrorrhagia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Nipple pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Ovarian cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Perineal rash	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Priapism	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Prostatomegaly	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Rectocele	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Testicular pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Uterine polyp	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Amenorrhoea	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Atrophic vulvovaginitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Bartholin's cyst	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Cystocele	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Endometriosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Fibrocystic breast disease	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Haematospermia	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Oligomenorrhoea	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Polycystic ovaries	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Premenstrual dysphoric disorder	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Uterine spasm	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vulvovaginal discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hydrocele	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Talipes	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions	1065 (7.0)	1606 (10.6)	2671 (8.8)
Mild	829 (5.5)	1250 (8.2)	2079 (6.9)
Moderate	215 (1.4)	300 (2.0)	515 (1.7)
Severe	20 (0.1)	55 (0.4)	75 (0.2)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Fatigue	666 (4.4)	752 (5.0)	1418 (4.7)
Mild	522 (3.4)	581 (3.8)	1103 (3.6)
Moderate	135 (0.9)	150 (1.0)	285 (0.9)
Severe	9 (<0.1)	20 (0.1)	29 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Injection site pain	118 (0.8)	258 (1.7)	376 (1.2)
Mild	99 (0.7)	205 (1.4)	304 (1.0)
Moderate	18 (0.1)	49 (0.3)	67 (0.2)
Severe	1 (<0.1)	4 (<0.1)	5 (<0.1)
Injection site erythema	39 (0.3)	157 (1.0)	196 (0.6)
Mild	36 (0.2)	124 (0.8)	160 (0.5)
Moderate	3 (<0.1)	25 (0.2)	28 (<0.1)
Severe	0	8 (<0.1)	8 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Chills	111 (0.7)	131 (0.9)	242 (0.8)
Mild	91 (0.6)	109 (0.7)	200 (0.7)
Moderate	20 (0.1)	20 (0.1)	40 (0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Pyrexia	62 (0.4)	118 (0.8)	180 (0.6)
Mild	52 (0.3)	86 (0.6)	138 (0.5)
Moderate	10 (<0.1)	30 (0.2)	40 (0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Injection site swelling	29 (0.2)	115 (0.8)	144 (0.5)
Mild	23 (0.2)	88 (0.6)	111 (0.4)
Moderate	6 (<0.1)	24 (0.2)	30 (<0.1)
Severe	0	3 (<0.1)	3 (<0.1)
Injection site pruritus	13 (<0.1)	88 (0.6)	101 (0.3)
Mild	12 (<0.1)	77 (0.5)	89 (0.3)
Moderate	1 (<0.1)	11 (<0.1)	12 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Pain	66 (0.4)	72 (0.5)	138 (0.5)
Mild	45 (0.3)	56 (0.4)	101 (0.3)
Moderate	19 (0.1)	14 (<0.1)	33 (0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Injection site lymphadenopathy	15 (<0.1)	66 (0.4)	81 (0.3)
Mild	13 (<0.1)	56 (0.4)	69 (0.2)
Moderate	1 (<0.1)	7 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Injection site induration	18 (0.1)	53 (0.3)	71 (0.2)
Mild	16 (0.1)	47 (0.3)	63 (0.2)
Moderate	1 (<0.1)	5 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site macule	4 (<0.1)	45 (0.3)	49 (0.2)
Mild	4 (<0.1)	33 (0.2)	37 (0.1)
Moderate	0	6 (<0.1)	6 (<0.1)
Severe	0	6 (<0.1)	6 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site urticaria	1 (<0.1)	38 (0.3)	39 (0.1)
Mild	1 (<0.1)	31 (0.2)	32 (0.1)
Moderate	0	5 (<0.1)	5 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Axillary pain	14 (<0.1)	26 (0.2)	40 (0.1)
Mild	10 (<0.1)	26 (0.2)	36 (0.1)
Moderate	4 (<0.1)	0	4 (<0.1)
Severe	0	0	0
Injection site rash	1 (<0.1)	24 (0.2)	25 (<0.1)
Mild	1 (<0.1)	21 (0.1)	22 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Injection site bruising	21 (0.1)	18 (0.1)	39 (0.1)
Mild	20 (0.1)	18 (0.1)	38 (0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Malaise	10 (<0.1)	15 (<0.1)	25 (<0.1)
Mild	8 (<0.1)	9 (<0.1)	17 (<0.1)
Moderate	2 (<0.1)	5 (<0.1)	7 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	14 (<0.1)
Mild	1 (<0.1)	12 (<0.1)	13 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Chest discomfort	14 (<0.1)	12 (<0.1)	26 (<0.1)
Mild	11 (<0.1)	7 (<0.1)	18 (<0.1)
Moderate	3 (<0.1)	5 (<0.1)	8 (<0.1)
Severe	0	0	0
Chest pain	5 (<0.1)	10 (<0.1)	15 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Peripheral swelling	11 (<0.1)	10 (<0.1)	21 (<0.1)
Mild	7 (<0.1)	7 (<0.1)	14 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	0	0	0
Injection site warmth	1 (<0.1)	7 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	7 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Non-cardiac chest pain	10 (<0.1)	7 (<0.1)	17 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Reactogenicity event	2 (<0.1)	7 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100101.sas 22JUN2021 09:10

Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Feeling hot	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	6 (<0.1)	8 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site haematoma	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	6 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site haemorrhage	5 (<0.1)	6 (<0.1)	11 (<0.1)
Mild	4 (<0.1)	6 (<0.1)	10 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site paraesthesia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	6 (<0.1)	8 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Oedema peripheral	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	6 (<0.1)	5 (<0.1)	11 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Vaccination site swelling	0	6 (<0.1)	6 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Feeling abnormal	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Injection site joint pain	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site pain	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Injection site mass	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Injection site irritation	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site reaction	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Swelling face	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Tenderness	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site erythema	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Cyst	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Exercise tolerance decreased	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hangover	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Injection site scab	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Precancerous condition	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Sensation of foreign body	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site rash	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Asthenia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Crying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Facial pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Feeling cold	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Granuloma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Induration	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Inflammation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Infusion site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site discolouration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injury associated with device	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lithiasis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Mass	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Secretion discharge	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site induration	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vaccination site lymphadenopathy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vaccination site mass	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site pruritus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vessel puncture site bruise	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vessel puncture site haemorrhage	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Adverse drug reaction	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gait disturbance	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Hunger	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Hypothermia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Impaired healing	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Incarcerated hernia	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	0	2 (<0.1)
Influenza like illness	3 (<0.1)	0	3 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site discomfort	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site joint discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection site oedema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site scar	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection site vesicles	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Medical device site inflammation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nodule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Polyp	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sluggishness	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Swelling	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Temperature intolerance	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Thirst	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site bruising	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site inflammation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vessel puncture site pain	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Xerosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Investigations	80 (0.5)	107 (0.7)	187 (0.6)
Mild	44 (0.3)	55 (0.4)	99 (0.3)
Moderate	23 (0.2)	29 (0.2)	52 (0.2)
Severe	13 (<0.1)	23 (0.2)	36 (0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood pressure increased	27 (0.2)	25 (0.2)	52 (0.2)
Mild	10 (<0.1)	10 (<0.1)	20 (<0.1)
Moderate	11 (<0.1)	5 (<0.1)	16 (<0.1)
Severe	6 (<0.1)	10 (<0.1)	16 (<0.1)
Blood pressure systolic increased	9 (<0.1)	15 (<0.1)	24 (<0.1)
Mild	1 (<0.1)	5 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	7 (<0.1)	7 (<0.1)	14 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	10 (<0.1)	12 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	4 (<0.1)	4 (<0.1)
Body temperature increased	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood cholesterol increased	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Heart rate increased	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hepatic enzyme increased	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Transaminases increased	0	4 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood glucose increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood testosterone decreased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Blood triglycerides increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Blood creatinine increased	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Prostatic specific antigen increased	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Weight decreased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood creatine increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

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Investigations (Cont.)			
Blood glucose decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood oestrogen decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood parathyroid hormone increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood potassium decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Blood uric acid increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
C-reactive protein increased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cardiac murmur	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Carotid bruit	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Chest X-ray	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Electrocardiogram QT prolonged	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Heart rate irregular	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Hepatic enzyme abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hormone level abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Human rhinovirus test positive	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Safety Set

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Investigations (Cont.)			
Mammogram abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Oestradiol decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Respiratory rate increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
White blood cell count decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Investigations (Cont.)			
White blood cell count increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Alanine aminotransferase increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood calcium increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood pressure diastolic decreased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood prolactin increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood thyroid stimulating hormone increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Glycosylated haemoglobin increased	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
International normalised ratio increased	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lipase increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Red blood cell count increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Serum ferritin increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vitamin B12 decreased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vitamin D decreased	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Weight increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications	397 (2.6)	331 (2.2)	728 (2.4)
Mild	196 (1.3)	156 (1.0)	352 (1.2)
Moderate	177 (1.2)	151 (1.0)	328 (1.1)
Severe	21 (0.1)	19 (0.1)	40 (0.1)
Missing	3 (<0.1)	5 (<0.1)	8 (<0.1)
Muscle strain	35 (0.2)	39 (0.3)	74 (0.2)
Mild	16 (0.1)	23 (0.2)	39 (0.1)
Moderate	17 (0.1)	15 (<0.1)	32 (0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Ligament sprain	29 (0.2)	30 (0.2)	59 (0.2)
Mild	18 (0.1)	10 (<0.1)	28 (<0.1)
Moderate	9 (<0.1)	19 (0.1)	28 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Arthropod bite	31 (0.2)	24 (0.2)	55 (0.2)
Mild	24 (0.2)	22 (0.1)	46 (0.2)
Moderate	7 (<0.1)	2 (<0.1)	9 (<0.1)
Severe	0	0	0
Skin laceration	32 (0.2)	23 (0.2)	55 (0.2)
Mild	16 (0.1)	10 (<0.1)	26 (<0.1)
Moderate	16 (0.1)	10 (<0.1)	26 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Fall	27 (0.2)	21 (0.1)	48 (0.2)
Mild	13 (<0.1)	13 (<0.1)	26 (<0.1)
Moderate	14 (<0.1)	7 (<0.1)	21 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Contusion	29 (0.2)	20 (0.1)	49 (0.2)
Mild	20 (0.1)	10 (<0.1)	30 (<0.1)
Moderate	9 (<0.1)	10 (<0.1)	19 (<0.1)
Severe	0	0	0
Procedural pain	31 (0.2)	18 (0.1)	49 (0.2)
Mild	10 (<0.1)	6 (<0.1)	16 (<0.1)
Moderate	19 (0.1)	11 (<0.1)	30 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Tooth fracture	17 (0.1)	17 (0.1)	34 (0.1)
Mild	8 (<0.1)	5 (<0.1)	13 (<0.1)
Moderate	9 (<0.1)	12 (<0.1)	21 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Road traffic accident	7 (<0.1)	13 (<0.1)	20 (<0.1)
Mild	4 (<0.1)	6 (<0.1)	10 (<0.1)
Moderate	2 (<0.1)	5 (<0.1)	7 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Foot fracture	13 (<0.1)	12 (<0.1)	25 (<0.1)
Mild	6 (<0.1)	2 (<0.1)	8 (<0.1)
Moderate	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Limb injury	8 (<0.1)	12 (<0.1)	20 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	4 (<0.1)	6 (<0.1)	10 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Skin abrasion	22 (0.1)	11 (<0.1)	33 (0.1)
Mild	20 (0.1)	10 (<0.1)	30 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Arthropod sting	17 (0.1)	10 (<0.1)	27 (<0.1)
Mild	11 (<0.1)	8 (<0.1)	19 (<0.1)
Moderate	6 (<0.1)	2 (<0.1)	8 (<0.1)
Severe	0	0	0
Joint injury	6 (<0.1)	7 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Animal bite	11 (<0.1)	6 (<0.1)	17 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	7 (<0.1)	2 (<0.1)	9 (<0.1)
Severe	0	0	0
Meniscus injury	9 (<0.1)	6 (<0.1)	15 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	4 (<0.1)	5 (<0.1)	9 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post-traumatic pain	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Concussion	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	0	0	0
Hand fracture	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Rib fracture	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Facial bones fracture	0	4 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Head injury	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Wrist fracture	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Bone contusion	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Cartilage injury	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Epicondylitis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Tendon rupture	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Thermal burn	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Upper limb fracture	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Ankle fracture	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	2 (<0.1)	2 (<0.1)
Craniocerebral injury	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Ligament injury	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Ligament rupture	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Muscle rupture	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Tendon injury	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Alcohol poisoning	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Animal scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Back injury	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Bone fragmentation	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Burns first degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Burns second degree	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Chemical burns of eye	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Clavicle fracture	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Corneal abrasion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Exposure to SARS-CoV-2	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Face injury	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypobarism	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Incision site rash	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection related reaction	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Joint dislocation	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Muscle hernia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal injury	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Overdose	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Periorbital haemorrhage	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post procedural swelling	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Post-traumatic neck syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Procedural headache	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Spinal compression fracture	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Stab wound	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	4 (<0.1)	0	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Subdural haematoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Sunburn	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Uterine rupture	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vaccination complication	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Wound	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Anaemia postoperative	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Buttock injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Exposure to toxic agent	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eye injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Eyelid contusion	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Femur fracture	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Foreign body	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Foreign body in ear	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Foreign body in eye	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Humerus fracture	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Iliotibial band syndrome	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Immunisation anxiety related reaction	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Inappropriate schedule of product administration	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Incision site inflammation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lip injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Mouth injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Muscle injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nail injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Patella fracture	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Phrenic nerve injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post procedural haematoma	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Procedural anxiety	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Procedural complication	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Procedural nausea	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pulmonary contusion	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Radius fracture	3 (<0.1)	0	3 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0
Repetitive strain injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Scar	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skeletal injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sports injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Superficial injury of eye	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Trunk injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Ulnar nerve injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Venomous sting	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Social circumstances	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Product issues	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	5 (<0.1)	7 (<0.1)
Severe	0	0	0
Device breakage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.1
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Product issues (Cont.)			
Device dislocation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Device physical property issue	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Embedded device	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Lead dislodgement	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6513 (43.0)	6310 (41.6)	12823 (42.3)
Mild	3078 (20.3)	3054 (20.1)	6132 (20.2)
Moderate	2909 (19.2)	2757 (18.2)	5666 (18.7)
Severe	486 (3.2)	461 (3.0)	947 (3.1)
Missing	40 (0.3)	38 (0.3)	78 (0.3)
Number of Unsolicited Adverse Events	15229	14869	30098
Mild	9212	9215	18427
Moderate	5137	4814	9951
Severe	663	628	1291
Missing	217	212	429
Infections and infestations	2533 (16.7)	1717 (11.3)	4250 (14.0)
Mild	1191 (7.9)	849 (5.6)	2040 (6.7)
Moderate	1208 (8.0)	793 (5.2)	2001 (6.6)
Severe	119 (0.8)	59 (0.4)	178 (0.6)
Missing	15 (<0.1)	16 (0.1)	31 (0.1)
Upper respiratory tract infection	314 (2.1)	262 (1.7)	576 (1.9)
Mild	176 (1.2)	147 (1.0)	323 (1.1)
Moderate	135 (0.9)	110 (0.7)	245 (0.8)
Severe	3 (<0.1)	4 (<0.1)	7 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Urinary tract infection	205 (1.4)	171 (1.1)	376 (1.2)
Mild	88 (0.6)	91 (0.6)	179 (0.6)
Moderate	112 (0.7)	77 (0.5)	189 (0.6)
Severe	4 (<0.1)	3 (<0.1)	7 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Viral infection	159 (1.0)	164 (1.1)	323 (1.1)
Mild	88 (0.6)	82 (0.5)	170 (0.6)
Moderate	70 (0.5)	82 (0.5)	152 (0.5)
Severe	1 (<0.1)	0	1 (<0.1)
Sinusitis	120 (0.8)	133 (0.9)	253 (0.8)
Mild	53 (0.3)	62 (0.4)	115 (0.4)
Moderate	65 (0.4)	69 (0.5)	134 (0.4)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Suspected COVID-19	124 (0.8)	132 (0.9)	256 (0.8)
Mild	76 (0.5)	82 (0.5)	158 (0.5)
Moderate	47 (0.3)	46 (0.3)	93 (0.3)
Severe	1 (<0.1)	4 (<0.1)	5 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
COVID-19	979 (6.5)	86 (0.6)	1065 (3.5)
Mild	456 (3.0)	52 (0.3)	508 (1.7)
Moderate	450 (3.0)	32 (0.2)	482 (1.6)
Severe	58 (0.4)	1 (<0.1)	59 (0.2)
Missing	15 (<0.1)	1 (<0.1)	16 (<0.1)
Rhinovirus infection	75 (0.5)	84 (0.6)	159 (0.5)
Mild	37 (0.2)	52 (0.3)	89 (0.3)
Moderate	37 (0.2)	32 (0.2)	69 (0.2)
Severe	1 (<0.1)	0	1 (<0.1)
Herpes zoster	23 (0.2)	50 (0.3)	73 (0.2)
Mild	7 (<0.1)	18 (0.1)	25 (<0.1)
Moderate	16 (0.1)	31 (0.2)	47 (0.2)
Severe	0	1 (<0.1)	1 (<0.1)
Viral upper respiratory tract infection	41 (0.3)	41 (0.3)	82 (0.3)
Mild	24 (0.2)	31 (0.2)	55 (0.2)
Moderate	15 (<0.1)	10 (<0.1)	25 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Tooth infection	36 (0.2)	36 (0.2)	72 (0.2)
Mild	12 (<0.1)	14 (<0.1)	26 (<0.1)
Moderate	24 (0.2)	20 (0.1)	44 (0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Tooth abscess	46 (0.3)	34 (0.2)	80 (0.3)
Mild	13 (<0.1)	10 (<0.1)	23 (<0.1)
Moderate	31 (0.2)	24 (0.2)	55 (0.2)
Severe	2 (<0.1)	0	2 (<0.1)
Pharyngitis	32 (0.2)	32 (0.2)	64 (0.2)
Mild	23 (0.2)	22 (0.1)	45 (0.1)
Moderate	9 (<0.1)	10 (<0.1)	19 (<0.1)
Severe	0	0	0
Gastroenteritis	41 (0.3)	31 (0.2)	72 (0.2)
Mild	21 (0.1)	13 (<0.1)	34 (0.1)
Moderate	19 (0.1)	16 (0.1)	35 (0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Ear infection	25 (0.2)	30 (0.2)	55 (0.2)
Mild	9 (<0.1)	18 (0.1)	27 (<0.1)
Moderate	16 (0.1)	11 (<0.1)	27 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Cellulitis	36 (0.2)	28 (0.2)	64 (0.2)
Mild	13 (<0.1)	10 (<0.1)	23 (<0.1)
Moderate	19 (0.1)	13 (<0.1)	32 (0.1)
Severe	4 (<0.1)	3 (<0.1)	7 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Pharyngitis streptococcal	39 (0.3)	26 (0.2)	65 (0.2)
Mild	16 (0.1)	10 (<0.1)	26 (<0.1)
Moderate	21 (0.1)	15 (<0.1)	36 (0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bronchitis	33 (0.2)	25 (0.2)	58 (0.2)
Mild	10 (<0.1)	9 (<0.1)	19 (<0.1)
Moderate	19 (0.1)	15 (<0.1)	34 (0.1)
Severe	4 (<0.1)	1 (<0.1)	5 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Hordeolum	27 (0.2)	23 (0.2)	50 (0.2)
Mild	18 (0.1)	12 (<0.1)	30 (<0.1)
Moderate	9 (<0.1)	11 (<0.1)	20 (<0.1)
Severe	0	0	0
Otitis media	20 (0.1)	21 (0.1)	41 (0.1)
Mild	8 (<0.1)	8 (<0.1)	16 (<0.1)
Moderate	12 (<0.1)	13 (<0.1)	25 (<0.1)
Severe	0	0	0
Conjunctivitis	24 (0.2)	20 (0.1)	44 (0.1)
Mild	14 (<0.1)	12 (<0.1)	26 (<0.1)
Moderate	10 (<0.1)	7 (<0.1)	17 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Asymptomatic COVID-19	16 (0.1)	19 (0.1)	35 (0.1)
Mild	14 (<0.1)	16 (0.1)	30 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Pneumonia	34 (0.2)	19 (0.1)	53 (0.2)
Mild	7 (<0.1)	1 (<0.1)	8 (<0.1)
Moderate	17 (0.1)	8 (<0.1)	25 (<0.1)
Severe	6 (<0.1)	6 (<0.1)	12 (<0.1)
Missing	4 (<0.1)	4 (<0.1)	8 (<0.1)
Diverticulitis	21 (0.1)	18 (0.1)	39 (0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	11 (<0.1)	12 (<0.1)	23 (<0.1)
Severe	5 (<0.1)	1 (<0.1)	6 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Nasopharyngitis	29 (0.2)	18 (0.1)	47 (0.2)
Mild	22 (0.1)	13 (<0.1)	35 (0.1)
Moderate	7 (<0.1)	5 (<0.1)	12 (<0.1)
Severe	0	0	0
Oral herpes	18 (0.1)	18 (0.1)	36 (0.1)
Mild	12 (<0.1)	11 (<0.1)	23 (<0.1)
Moderate	6 (<0.1)	7 (<0.1)	13 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Respiratory tract infection	13 (<0.1)	15 (<0.1)	28 (<0.1)
Mild	6 (<0.1)	8 (<0.1)	14 (<0.1)
Moderate	7 (<0.1)	7 (<0.1)	14 (<0.1)
Severe	0	0	0
Acute sinusitis	10 (<0.1)	13 (<0.1)	23 (<0.1)
Mild	3 (<0.1)	6 (<0.1)	9 (<0.1)
Moderate	7 (<0.1)	7 (<0.1)	14 (<0.1)
Severe	0	0	0
Fungal infection	16 (0.1)	13 (<0.1)	29 (<0.1)
Mild	8 (<0.1)	5 (<0.1)	13 (<0.1)
Moderate	7 (<0.1)	7 (<0.1)	14 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Bacterial vaginosis	11 (<0.1)	12 (<0.1)	23 (<0.1)
Mild	6 (<0.1)	6 (<0.1)	12 (<0.1)
Moderate	4 (<0.1)	6 (<0.1)	10 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Gingivitis	9 (<0.1)	12 (<0.1)	21 (<0.1)
Mild	4 (<0.1)	6 (<0.1)	10 (<0.1)
Moderate	3 (<0.1)	5 (<0.1)	8 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Herpes simplex	5 (<0.1)	12 (<0.1)	17 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	5 (<0.1)	8 (<0.1)	13 (<0.1)
Severe	0	0	0
Localised infection	9 (<0.1)	12 (<0.1)	21 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	6 (<0.1)	8 (<0.1)	14 (<0.1)
Severe	0	0	0
Onychomycosis	6 (<0.1)	12 (<0.1)	18 (<0.1)
Mild	1 (<0.1)	9 (<0.1)	10 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Otitis externa	13 (<0.1)	12 (<0.1)	25 (<0.1)
Mild	8 (<0.1)	4 (<0.1)	12 (<0.1)
Moderate	5 (<0.1)	8 (<0.1)	13 (<0.1)
Severe	0	0	0
Enterovirus infection	4 (<0.1)	11 (<0.1)	15 (<0.1)
Mild	3 (<0.1)	8 (<0.1)	11 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Vulvovaginal mycotic infection	21 (0.1)	10 (<0.1)	31 (0.1)
Mild	14 (<0.1)	3 (<0.1)	17 (<0.1)
Moderate	7 (<0.1)	7 (<0.1)	14 (<0.1)
Severe	0	0	0
Folliculitis	16 (0.1)	9 (<0.1)	25 (<0.1)
Mild	9 (<0.1)	7 (<0.1)	16 (<0.1)
Moderate	7 (<0.1)	2 (<0.1)	9 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Paronychia	8 (<0.1)	9 (<0.1)	17 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0
Skin infection	7 (<0.1)	9 (<0.1)	16 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	5 (<0.1)	6 (<0.1)	11 (<0.1)
Severe	0	0	0
Vulvovaginal candidiasis	8 (<0.1)	9 (<0.1)	17 (<0.1)
Mild	5 (<0.1)	8 (<0.1)	13 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Abscess limb	3 (<0.1)	8 (<0.1)	11 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	3 (<0.1)	5 (<0.1)	8 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Gastroenteritis viral	17 (0.1)	8 (<0.1)	25 (<0.1)
Mild	14 (<0.1)	4 (<0.1)	18 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	0	0	0
Cystitis	18 (0.1)	7 (<0.1)	25 (<0.1)
Mild	8 (<0.1)	3 (<0.1)	11 (<0.1)
Moderate	10 (<0.1)	4 (<0.1)	14 (<0.1)
Severe	0	0	0
Furuncle	5 (<0.1)	7 (<0.1)	12 (<0.1)
Mild	5 (<0.1)	4 (<0.1)	9 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Laryngitis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	3 (<0.1)	6 (<0.1)	9 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Subcutaneous abscess	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	6 (<0.1)	8 (<0.1)
Severe	0	0	0
Clostridium difficile infection	1 (<0.1)	6 (<0.1)	7 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Lyme disease	0	6 (<0.1)	6 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Oral candidiasis	8 (<0.1)	6 (<0.1)	14 (<0.1)
Mild	5 (<0.1)	3 (<0.1)	8 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Pyelonephritis	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	3 (<0.1)	2 (<0.1)	5 (<0.1)
Sepsis	6 (<0.1)	6 (<0.1)	12 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Missing	2 (<0.1)	2 (<0.1)	4 (<0.1)
Staphylococcal infection	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	5 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Staphylococcal skin infection	1 (<0.1)	6 (<0.1)	7 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Appendicitis	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	4 (<0.1)	3 (<0.1)	7 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Helicobacter infection	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Kidney infection	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Postoperative wound infection	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Chlamydial infection	0	4 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Eye infection	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Gonorrhoea	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Impetigo	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Periodontitis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Respiratory tract infection viral	12 (<0.1)	4 (<0.1)	16 (<0.1)
Mild	7 (<0.1)	4 (<0.1)	11 (<0.1)
Moderate	5 (<0.1)	0	5 (<0.1)
Severe	0	0	0
Rhinitis	8 (<0.1)	4 (<0.1)	12 (<0.1)
Mild	8 (<0.1)	3 (<0.1)	11 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Sinusitis bacterial	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Viral pharyngitis	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Abdominal abscess	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Abscess jaw	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Chronic sinusitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Coronavirus infection	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Epididymitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Injection site cellulitis	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Tonsillitis	14 (<0.1)	3 (<0.1)	17 (<0.1)
Mild	6 (<0.1)	2 (<0.1)	8 (<0.1)
Moderate	7 (<0.1)	1 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Wound infection	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Candida infection	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Cat scratch disease	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Conjunctivitis bacterial	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Fungal skin infection	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Gastrointestinal infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Infected bite	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Infected cyst	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Nail infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Otitis media acute	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Peritonitis	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	2 (<0.1)	2 (<0.1)
Pertussis	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Post procedural infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Postoperative abscess	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	2 (<0.1)	2 (<0.1)
Pulpitis dental	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Septic shock	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Soft tissue infection	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Tinea cruris	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tinea infection	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tinea pedis	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Tuberculosis	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Upper respiratory tract infection bacterial	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Urinary tract infection bacterial	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Urosepsis	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	2 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Viral rhinitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Viral sinusitis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Abscess oral	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Appendicitis perforated	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Asymptomatic bacteriuria	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Atypical mycobacterial infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Atypical pneumonia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Bacteraemia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Bacterial infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bacterial pyelonephritis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Body tinea	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Breast abscess	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Breast cellulitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bronchiolitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Campylobacter gastroenteritis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Catheter site infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Chest wall abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Colonic abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Conjunctivitis viral	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Dacryocystitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Diabetic foot infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Eyelid infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Genital herpes	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Genital herpes simplex	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Genital infection fungal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Giardiasis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Gingival abscess	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Groin abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Helminthic infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hepatitis A	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Infected dermal cyst	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Influenza	6 (<0.1)	1 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	0	0	0
Injection site infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Joint abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Labyrinthitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Large intestine infection	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Laryngitis viral	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Latent tuberculosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Liver abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Lung abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Osteomyelitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Papilloma viral infection	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Parainfluenzae virus infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Parotitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Perineal abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Pharyngitis bacterial	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pneumonia mycoplasmal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Prostate infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Pyelonephritis acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pyoderma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rash pustular	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Rocky mountain spotted fever	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Salpingitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Sialoadenitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Sinusitis fungal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Skin candida	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Spinal cord abscess	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Streptococcal infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Tinea versicolour	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Toxic shock syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Trichomoniasis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Uterine infection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Vaginal infection	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vulvitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vulvovaginitis trichomonal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Abscess	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Abscess neck	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Adenovirus infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Appendiceal abscess	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Bacterial vulvovaginitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Balanitis candida	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Blastocystis infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Bronchitis bacterial	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Bullous impetigo	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
COVID-19 pneumonia	16 (0.1)	0	16 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	5 (<0.1)	0	5 (<0.1)
Severe	7 (<0.1)	0	7 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Campylobacter infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Cervicitis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Cholecystitis infective	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Clostridium difficile colitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Coccidioidomycosis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Corneal infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Denture stomatitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Ear infection fungal	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Enterococcal bacteraemia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eye infection bacterial	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Gardnerella infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gastrointestinal viral infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
HIV infection	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hepatitis C	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Herpangina	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Herpes ophthalmic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Herpes virus infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Klebsiella bacteraemia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Lower respiratory tract infection	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Mastoiditis	3 (<0.1)	0	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Meningitis aseptic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Nasal abscess	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal vestibulitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Ophthalmic herpes zoster	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Oral viral infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Oropharyngeal gonococcal infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Otitis media chronic	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pelvic abscess	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Perineal cellulitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Perirectal abscess	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Pneumonia bacterial	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Pneumonia viral	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Proteus infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pustule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Root canal infection	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin bacterial infection	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Streptococcal sepsis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Syphilis	3 (<0.1)	0	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Tinea barbae	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Urinary tract infection enterococcal	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Vaginal abscess	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vaginitis chlamydial	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Varicella zoster virus infection	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vestibular neuronitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Infections and infestations (Cont.)			
Viral diarrhoea	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	124 (0.8)	138 (0.9)	262 (0.9)
Mild	45 (0.3)	44 (0.3)	89 (0.3)
Moderate	54 (0.4)	59 (0.4)	113 (0.4)
Severe	22 (0.1)	24 (0.2)	46 (0.2)
Missing	3 (<0.1)	11 (<0.1)	14 (<0.1)
Basal cell carcinoma	28 (0.2)	24 (0.2)	52 (0.2)
Mild	13 (<0.1)	10 (<0.1)	23 (<0.1)
Moderate	13 (<0.1)	13 (<0.1)	26 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Prostate cancer	6 (<0.1)	8 (<0.1)	14 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	2 (<0.1)	4 (<0.1)	6 (<0.1)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Uterine leiomyoma	3 (<0.1)	7 (<0.1)	10 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	5 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Benign neoplasm of skin	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Skin cancer	4 (<0.1)	6 (<0.1)	10 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	3 (<0.1)	5 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Squamous cell carcinoma	10 (<0.1)	6 (<0.1)	16 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	5 (<0.1)	4 (<0.1)	9 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Malignant melanoma	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Squamous cell carcinoma of skin	9 (<0.1)	5 (<0.1)	14 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	6 (<0.1)	4 (<0.1)	10 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Benign breast neoplasm	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Benign neoplasm of thyroid gland	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Lipoma	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Malignant melanoma in situ	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Skin papilloma	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Benign hepatic neoplasm	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Breast cancer	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	0	2 (<0.1)	2 (<0.1)
Invasive ductal breast carcinoma	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Plasma cell myeloma	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	2 (<0.1)	2 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Adrenal adenoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Angiolipoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
B-cell small lymphocytic lymphoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Benign neoplasm of bladder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Benign ovarian tumour	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Benign salivary gland neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Brain neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Breast cancer female	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Breast cancer in situ	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Cancer pain	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Colon cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Colorectal cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Fibrous histiocytoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Gastric cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Gastrointestinal stromal tumour	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Haemangioma of liver	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Intraductal papilloma of breast	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Intraductal proliferative breast lesion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Keratoacanthoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lip squamous cell carcinoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Lipoma of breast	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Liposarcoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Meningioma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Meningioma benign	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Metastases to bone	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Metastases to lung	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Nasal cavity cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Nasopharyngeal neoplasm benign	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Non-Hodgkin's lymphoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Oesophageal carcinoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Pelvic neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Prostate cancer stage I	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Rectal cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Renal cell carcinoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Renal neoplasm	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Seborrhoeic keratosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Splenic marginal zone lymphoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Throat cancer	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Thymoma malignant	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Benign bone neoplasm	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Benign neoplasm of eyelid	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bladder cancer	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Bladder neoplasm	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Breast cancer stage I	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Breast neoplasm	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Chondromatosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Colon cancer stage III	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Enchondromatosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Endometrial cancer	3 (<0.1)	0	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	0	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Hepatic cancer	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Leiomyosarcoma metastatic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Non-small cell lung cancer	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Pancreatic carcinoma stage IV	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Penile cancer	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Prostate cancer metastatic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Prostate cancer recurrent	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Prostate cancer stage IV	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Renal hamartoma	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Thyroid cancer	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Thyroid cancer recurrent	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Blood and lymphatic system disorders	200 (1.3)	342 (2.3)	542 (1.8)
Mild	158 (1.0)	282 (1.9)	440 (1.4)
Moderate	35 (0.2)	51 (0.3)	86 (0.3)
Severe	4 (<0.1)	7 (<0.1)	11 (<0.1)
Missing	3 (<0.1)	2 (<0.1)	5 (<0.1)
Lymphadenopathy	156 (1.0)	287 (1.9)	443 (1.5)
Mild	132 (0.9)	253 (1.7)	385 (1.3)
Moderate	24 (0.2)	33 (0.2)	57 (0.2)
Severe	0	1 (<0.1)	1 (<0.1)
Anaemia	17 (0.1)	21 (0.1)	38 (0.1)
Mild	9 (<0.1)	12 (<0.1)	21 (<0.1)
Moderate	6 (<0.1)	6 (<0.1)	12 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Lymph node pain	9 (<0.1)	10 (<0.1)	19 (<0.1)
Mild	7 (<0.1)	7 (<0.1)	14 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Iron deficiency anaemia	11 (<0.1)	8 (<0.1)	19 (<0.1)
Mild	7 (<0.1)	1 (<0.1)	8 (<0.1)
Moderate	3 (<0.1)	6 (<0.1)	9 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Lymphadenitis	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Thrombocytopenia	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Leukocytosis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Leukopenia	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Normocytic anaemia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood loss anaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Eosinophilia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Splenomegaly	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Thrombocytosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Anaemia macrocytic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Blood and lymphatic system disorders (Cont.)			
Nucleated red cells	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Splenic calcification	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Immune system disorders	99 (0.7)	90 (0.6)	189 (0.6)
Mild	41 (0.3)	42 (0.3)	83 (0.3)
Moderate	53 (0.3)	42 (0.3)	95 (0.3)
Severe	3 (<0.1)	6 (<0.1)	9 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Seasonal allergy	72 (0.5)	59 (0.4)	131 (0.4)
Mild	31 (0.2)	29 (0.2)	60 (0.2)
Moderate	41 (0.3)	28 (0.2)	69 (0.2)
Severe	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Drug hypersensitivity	8 (<0.1)	12 (<0.1)	20 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	3 (<0.1)	6 (<0.1)	9 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)	18 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	6 (<0.1)	3 (<0.1)	9 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Food allergy	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Mycotic allergy	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Allergy to animal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Allergy to arthropod bite	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Allergy to chemicals	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Sarcoidosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Type IV hypersensitivity reaction	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Allergy to metals	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cytokine storm	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Immune system disorders (Cont.)			
Milk allergy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Serum sickness	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Smoke sensitivity	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Endocrine disorders	40 (0.3)	38 (0.3)	78 (0.3)
Mild	22 (0.1)	21 (0.1)	43 (0.1)
Moderate	16 (0.1)	14 (<0.1)	30 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders (Cont.)			
Hypothyroidism	19 (0.1)	26 (0.2)	45 (0.1)
Mild	10 (<0.1)	13 (<0.1)	23 (<0.1)
Moderate	8 (<0.1)	12 (<0.1)	20 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Thyroid mass	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Goitre	6 (<0.1)	2 (<0.1)	8 (<0.1)
Mild	6 (<0.1)	2 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hyperparathyroidism	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders (Cont.)			
Hyperthyroidism	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Basedow's disease	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Hypogonadism	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Thyroid cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders (Cont.)			
Thyroiditis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Androgen deficiency	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Autoimmune thyroiditis	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Hyperparathyroidism primary	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Endocrine disorders (Cont.)			
Oestrogen deficiency	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Thyroiditis subacute	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Metabolism and nutrition disorders	288 (1.9)	264 (1.7)	552 (1.8)
Mild	142 (0.9)	113 (0.7)	255 (0.8)
Moderate	123 (0.8)	134 (0.9)	257 (0.8)
Severe	15 (<0.1)	12 (<0.1)	27 (<0.1)
Missing	8 (<0.1)	5 (<0.1)	13 (<0.1)
Type 2 diabetes mellitus	33 (0.2)	44 (0.3)	77 (0.3)
Mild	12 (<0.1)	11 (<0.1)	23 (<0.1)
Moderate	18 (0.1)	31 (0.2)	49 (0.2)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hyperlipidaemia	52 (0.3)	42 (0.3)	94 (0.3)
Mild	27 (0.2)	20 (0.1)	47 (0.2)
Moderate	25 (0.2)	22 (0.1)	47 (0.2)
Severe	0	0	0
Vitamin D deficiency	40 (0.3)	30 (0.2)	70 (0.2)
Mild	26 (0.2)	15 (<0.1)	41 (0.1)
Moderate	13 (<0.1)	15 (<0.1)	28 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Hypercholesterolaemia	39 (0.3)	29 (0.2)	68 (0.2)
Mild	26 (0.2)	17 (0.1)	43 (0.1)
Moderate	13 (<0.1)	12 (<0.1)	25 (<0.1)
Severe	0	0	0
Decreased appetite	16 (0.1)	17 (0.1)	33 (0.1)
Mild	12 (<0.1)	14 (<0.1)	26 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Dehydration	15 (<0.1)	15 (<0.1)	30 (<0.1)
Mild	2 (<0.1)	7 (<0.1)	9 (<0.1)
Moderate	8 (<0.1)	5 (<0.1)	13 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	4 (<0.1)	2 (<0.1)	6 (<0.1)
Diabetes mellitus	10 (<0.1)	13 (<0.1)	23 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	9 (<0.1)	10 (<0.1)	19 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Gout	17 (0.1)	13 (<0.1)	30 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	10 (<0.1)	10 (<0.1)	20 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Glucose tolerance impaired	12 (<0.1)	12 (<0.1)	24 (<0.1)
Mild	11 (<0.1)	6 (<0.1)	17 (<0.1)
Moderate	1 (<0.1)	5 (<0.1)	6 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hyponatraemia	9 (<0.1)	9 (<0.1)	18 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Hypokalaemia	17 (0.1)	7 (<0.1)	24 (<0.1)
Mild	6 (<0.1)	3 (<0.1)	9 (<0.1)
Moderate	8 (<0.1)	3 (<0.1)	11 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Hyperglycaemia	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Hypertriglyceridaemia	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypoglycaemia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Vitamin B12 deficiency	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Abnormal loss of weight	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Diabetes mellitus inadequate control	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperkalaemia	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Iron deficiency	6 (<0.1)	3 (<0.1)	9 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0
Obesity	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypocalcaemia	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Insulin resistance	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Malnutrition	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Abnormal weight gain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Dairy intolerance	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Diabetic complication	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Dyslipidaemia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Failure to thrive	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Food intolerance	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gluten sensitivity	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hypercalcaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Hypoferritinaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hypomagnesaemia	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Hypophosphataemia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Magnesium deficiency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Polydipsia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vitamin K deficiency	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Calcium deficiency	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Fluid overload	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Fluid retention	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Folate deficiency	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Hypermagnesaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hyperuricaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Increased appetite	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lactic acidosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Metabolic acidosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)			
Vitamin B1 deficiency	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Psychiatric disorders	266 (1.8)	319 (2.1)	585 (1.9)
Mild	87 (0.6)	105 (0.7)	192 (0.6)
Moderate	163 (1.1)	200 (1.3)	363 (1.2)
Severe	13 (<0.1)	9 (<0.1)	22 (<0.1)
Missing	3 (<0.1)	5 (<0.1)	8 (<0.1)
Anxiety	87 (0.6)	108 (0.7)	195 (0.6)
Mild	28 (0.2)	33 (0.2)	61 (0.2)
Moderate	55 (0.4)	74 (0.5)	129 (0.4)
Severe	4 (<0.1)	1 (<0.1)	5 (<0.1)
Depression	85 (0.6)	96 (0.6)	181 (0.6)
Mild	22 (0.1)	25 (0.2)	47 (0.2)
Moderate	59 (0.4)	67 (0.4)	126 (0.4)
Severe	2 (<0.1)	4 (<0.1)	6 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Insomnia	54 (0.4)	60 (0.4)	114 (0.4)
Mild	25 (0.2)	25 (0.2)	50 (0.2)
Moderate	28 (0.2)	35 (0.2)	63 (0.2)
Severe	1 (<0.1)	0	1 (<0.1)
Attention deficit hyperactivity disorder	24 (0.2)	20 (0.1)	44 (0.1)
Mild	13 (<0.1)	9 (<0.1)	22 (<0.1)
Moderate	11 (<0.1)	11 (<0.1)	22 (<0.1)
Severe	0	0	0
Bipolar disorder	8 (<0.1)	7 (<0.1)	15 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	7 (<0.1)	6 (<0.1)	13 (<0.1)
Severe	0	0	0
Abnormal dreams	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Sleep disorder	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Panic attack	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	6 (<0.1)	1 (<0.1)	7 (<0.1)
Severe	0	0	0
Post-traumatic stress disorder	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Adjustment disorder with depressed mood	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Libido decreased	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Nightmare	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Suicidal ideation	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Alcohol withdrawal syndrome	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Bipolar II disorder	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Generalised anxiety disorder	7 (<0.1)	2 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	5 (<0.1)	1 (<0.1)	6 (<0.1)
Severe	0	0	0
Major depression	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Stress	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Affect lability	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Alcohol abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Bruxism	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Claustrophobia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Completed suicide	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Confusional state	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Depressed mood	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Drug abuse	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Drug use disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dysphemia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Emotional disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Grief reaction	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Hallucination	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Intentional self-injury	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Mental fatigue	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Mental status changes	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Obsessive-compulsive personality disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Persistent depressive disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Premature ejaculation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Psychotic disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Reading disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Schizoaffective disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Social anxiety disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Substance abuse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Substance-induced mood disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Suicide attempt	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Terminal insomnia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Agitation	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Alcoholism	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Delirium	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Depression suicidal	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Disorientation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dissociative disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Hallucination, visual	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Mania	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Mixed anxiety and depressive disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Nicotine dependence	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)			
Schizophrenia	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Nervous system disorders	1240 (8.2)	1311 (8.6)	2551 (8.4)
Mild	809 (5.3)	827 (5.4)	1636 (5.4)
Moderate	371 (2.4)	424 (2.8)	795 (2.6)
Severe	51 (0.3)	50 (0.3)	101 (0.3)
Missing	9 (<0.1)	10 (<0.1)	19 (<0.1)
Headache	886 (5.8)	907 (6.0)	1793 (5.9)
Mild	637 (4.2)	638 (4.2)	1275 (4.2)
Moderate	233 (1.5)	247 (1.6)	480 (1.6)
Severe	16 (0.1)	21 (0.1)	37 (0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Dizziness	88 (0.6)	97 (0.6)	185 (0.6)
Mild	65 (0.4)	70 (0.5)	135 (0.4)
Moderate	19 (0.1)	24 (0.2)	43 (0.1)
Severe	4 (<0.1)	2 (<0.1)	6 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Paraesthesia	31 (0.2)	43 (0.3)	74 (0.2)
Mild	24 (0.2)	29 (0.2)	53 (0.2)
Moderate	6 (<0.1)	14 (<0.1)	20 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Migraine	42 (0.3)	32 (0.2)	74 (0.2)
Mild	15 (<0.1)	5 (<0.1)	20 (<0.1)
Moderate	24 (0.2)	22 (0.1)	46 (0.2)
Severe	3 (<0.1)	5 (<0.1)	8 (<0.1)
Syncope	40 (0.3)	25 (0.2)	65 (0.2)
Mild	13 (<0.1)	6 (<0.1)	19 (<0.1)
Moderate	17 (0.1)	9 (<0.1)	26 (<0.1)
Severe	7 (<0.1)	6 (<0.1)	13 (<0.1)
Missing	3 (<0.1)	4 (<0.1)	7 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Sciatica	25 (0.2)	24 (0.2)	49 (0.2)
Mild	8 (<0.1)	12 (<0.1)	20 (<0.1)
Moderate	13 (<0.1)	10 (<0.1)	23 (<0.1)
Severe	3 (<0.1)	2 (<0.1)	5 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Ageusia	30 (0.2)	23 (0.2)	53 (0.2)
Mild	23 (0.2)	15 (<0.1)	38 (0.1)
Moderate	7 (<0.1)	8 (<0.1)	15 (<0.1)
Severe	0	0	0
Sinus headache	12 (<0.1)	21 (0.1)	33 (0.1)
Mild	8 (<0.1)	11 (<0.1)	19 (<0.1)
Moderate	4 (<0.1)	10 (<0.1)	14 (<0.1)
Severe	0	0	0
Anosmia	25 (0.2)	19 (0.1)	44 (0.1)
Mild	18 (0.1)	11 (<0.1)	29 (<0.1)
Moderate	5 (<0.1)	8 (<0.1)	13 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Cervical radiculopathy	2 (<0.1)	17 (0.1)	19 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	12 (<0.1)	13 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Hypoaesthesia	14 (<0.1)	17 (0.1)	31 (0.1)
Mild	13 (<0.1)	13 (<0.1)	26 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0
Presyncope	16 (0.1)	15 (<0.1)	31 (0.1)
Mild	8 (<0.1)	6 (<0.1)	14 (<0.1)
Moderate	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Dysgeusia	8 (<0.1)	13 (<0.1)	21 (<0.1)
Mild	8 (<0.1)	13 (<0.1)	21 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Nerve compression	8 (<0.1)	10 (<0.1)	18 (<0.1)
Mild	4 (<0.1)	3 (<0.1)	7 (<0.1)
Moderate	3 (<0.1)	7 (<0.1)	10 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Carpal tunnel syndrome	11 (<0.1)	9 (<0.1)	20 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	8 (<0.1)	7 (<0.1)	15 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Tension headache	9 (<0.1)	9 (<0.1)	18 (<0.1)
Mild	4 (<0.1)	6 (<0.1)	10 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	0	0	0
Facial paralysis	3 (<0.1)	8 (<0.1)	11 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	3 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Cerebrovascular accident	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	3 (<0.1)	3 (<0.1)	6 (<0.1)
Missing	0	3 (<0.1)	3 (<0.1)
Burning sensation	1 (<0.1)	6 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	5 (<0.1)	6 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hyperaesthesia	0	6 (<0.1)	6 (<0.1)
Mild	0	6 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Disturbance in attention	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Lumbar radiculopathy	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Memory impairment	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Seizure	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Parosmia	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Peripheral sensory neuropathy	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Subarachnoid haemorrhage	0	4 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Taste disorder	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Amnesia	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Lethargy	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Mental impairment	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Migraine with aura	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Neuralgia	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Neuropathy peripheral	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	5 (<0.1)	2 (<0.1)	7 (<0.1)
Severe	0	0	0
Somnolence	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Transient ischaemic attack	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Tremor	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Carotid artery stenosis	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Cubital tunnel syndrome	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Diabetic neuropathy	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dizziness postural	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Embolic stroke	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Idiopathic intracranial hypertension	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Morton's neuralgia	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Optic neuritis	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Piriformis syndrome	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Post herpetic neuralgia	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Post-traumatic headache	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Restless legs syndrome	9 (<0.1)	2 (<0.1)	11 (<0.1)
Mild	5 (<0.1)	1 (<0.1)	6 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Aphasia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Aura	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Autonomic nervous system imbalance	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Balance disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Carotid artery thrombosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Central nervous system lesion	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cerebral atrophy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Cerebral small vessel ischaemic disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cognitive disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Complex regional pain syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dementia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Depressed level of consciousness	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Diabetic mononeuropathy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dyslexia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Essential tremor	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Head discomfort	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Head titubation	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hemiparesis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Hypersomnia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Hyposmia	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Loss of consciousness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Migraine without aura	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Movement disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Multiple sclerosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Muscle contractions involuntary	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
New daily persistent headache	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Occipital neuralgia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Poor quality sleep	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Primary cough headache	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Primary headache associated with sexual activity	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Radiculopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Small fibre neuropathy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Spinal cord compression	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Toxic encephalopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Trigeminal neuralgia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Vestibular migraine	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Visual field defect	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Amyotrophic lateral sclerosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Arachnoid cyst	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Cerebral cyst	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Dysaesthesia	3 (<0.1)	0	3 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Dyskinesia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Encephalopathy	3 (<0.1)	0	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	0	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Horner's syndrome	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hydrocephalus	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Hypogeusia	4 (<0.1)	0	4 (<0.1)
Mild	4 (<0.1)	0	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Intention tremor	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ischaemic stroke	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Myasthenia gravis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Myoclonus	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Perineurial cyst	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Peroneal nerve palsy	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Radicular pain	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Right hemisphere deficit syndrome	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Shift work disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Speech disorder	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Tarsal tunnel syndrome	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Thoracic radiculopathy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Transient global amnesia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
VIth nerve paralysis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Nervous system disorders (Cont.)			
Vertebral artery occlusion	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vocal cord paralysis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eye disorders	124 (0.8)	139 (0.9)	263 (0.9)
Mild	70 (0.5)	78 (0.5)	148 (0.5)
Moderate	51 (0.3)	57 (0.4)	108 (0.4)
Severe	3 (<0.1)	4 (<0.1)	7 (<0.1)
Cataract	9 (<0.1)	13 (<0.1)	22 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Eye pruritus	9 (<0.1)	10 (<0.1)	19 (<0.1)
Mild	4 (<0.1)	7 (<0.1)	11 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	0	0	0
Dry eye	11 (<0.1)	9 (<0.1)	20 (<0.1)
Mild	7 (<0.1)	4 (<0.1)	11 (<0.1)
Moderate	4 (<0.1)	5 (<0.1)	9 (<0.1)
Severe	0	0	0
Eye irritation	3 (<0.1)	8 (<0.1)	11 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	0	4 (<0.1)	4 (<0.1)
Severe	0	0	0
Glaucoma	8 (<0.1)	8 (<0.1)	16 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Retinal detachment	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Vision blurred	10 (<0.1)	7 (<0.1)	17 (<0.1)
Mild	8 (<0.1)	5 (<0.1)	13 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Eye pain	4 (<0.1)	6 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Blepharitis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Conjunctival haemorrhage	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Chalazion	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Swelling of eyelid	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Visual impairment	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Eye inflammation	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Lacrimation increased	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Uveitis	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vitreous floaters	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Blepharospasm	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eye haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eye swelling	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Macular degeneration	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Macular hole	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Ocular discomfort	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Ocular hyperaemia	7 (<0.1)	2 (<0.1)	9 (<0.1)
Mild	7 (<0.1)	1 (<0.1)	8 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Photophobia	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Scleritis	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Xerophthalmia	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Accommodation disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Blindness transient	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Conjunctival hyperaemia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Diabetic retinopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Diplopia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Dry age-related macular degeneration	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Eye disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eyelid cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Foreign body sensation in eyes	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Iris disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Keratitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lenticular opacities	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Macular fibrosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Macular oedema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Noninfective conjunctivitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Orbital haematoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Papilloedema	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Periorbital oedema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Presbyopia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Retinal haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Retinal vascular occlusion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Retinopathy hypertensive	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ulcerative keratitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Vitreous disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Asthenopia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Blindness	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dacryoadenitis acquired	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dacryostenosis acquired	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Eye discharge	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eye ulcer	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Eyelid ptosis	3 (<0.1)	0	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Nictitating spasm	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Ocular rosacea	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Open angle glaucoma	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Orbital oedema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Periorbital pain	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Periorbital swelling	3 (<0.1)	0	3 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Photopsia	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Retinal infarction	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Retinal oedema	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Eye disorders (Cont.)			
Retinal tear	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Strabismus	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Visual acuity reduced	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vitreous detachment	4 (<0.1)	0	4 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders	149 (1.0)	134 (0.9)	283 (0.9)
Mild	100 (0.7)	84 (0.6)	184 (0.6)
Moderate	43 (0.3)	46 (0.3)	89 (0.3)
Severe	5 (<0.1)	3 (<0.1)	8 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Vertigo	34 (0.2)	46 (0.3)	80 (0.3)
Mild	13 (<0.1)	27 (0.2)	40 (0.1)
Moderate	16 (0.1)	16 (0.1)	32 (0.1)
Severe	4 (<0.1)	3 (<0.1)	7 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Ear pain	35 (0.2)	29 (0.2)	64 (0.2)
Mild	25 (0.2)	20 (0.1)	45 (0.1)
Moderate	10 (<0.1)	9 (<0.1)	19 (<0.1)
Severe	0	0	0
Tinnitus	22 (0.1)	20 (0.1)	42 (0.1)
Mild	17 (0.1)	13 (<0.1)	30 (<0.1)
Moderate	5 (<0.1)	7 (<0.1)	12 (<0.1)
Severe	0	0	0
Vertigo positional	4 (<0.1)	8 (<0.1)	12 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	5 (<0.1)	6 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Ear discomfort	11 (<0.1)	7 (<0.1)	18 (<0.1)
Mild	8 (<0.1)	6 (<0.1)	14 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	0	0
Meniere's disease	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Cerumen impaction	5 (<0.1)	4 (<0.1)	9 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Deafness unilateral	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Deafness neurosensory	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Ear canal erythema	6 (<0.1)	2 (<0.1)	8 (<0.1)
Mild	6 (<0.1)	2 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ear congestion	7 (<0.1)	2 (<0.1)	9 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Eustachian tube dysfunction	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Motion sickness	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Otorrhoea	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tympanic membrane perforation	9 (<0.1)	2 (<0.1)	11 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	4 (<0.1)	0	4 (<0.1)
Severe	0	0	0
Ear pruritus	6 (<0.1)	1 (<0.1)	7 (<0.1)
Mild	6 (<0.1)	1 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Hypoacusis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Middle ear effusion	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Diplacusis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ear haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Excessive cerumen production	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
External ear pain	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hyperacusis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tympanic membrane disorder	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)			
Tympanic membrane hyperaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cardiac disorders	167 (1.1)	165 (1.1)	332 (1.1)
Mild	57 (0.4)	53 (0.3)	110 (0.4)
Moderate	61 (0.4)	63 (0.4)	124 (0.4)
Severe	31 (0.2)	35 (0.2)	66 (0.2)
Missing	18 (0.1)	14 (<0.1)	32 (0.1)
Atrial fibrillation	28 (0.2)	25 (0.2)	53 (0.2)
Mild	5 (<0.1)	3 (<0.1)	8 (<0.1)
Moderate	12 (<0.1)	14 (<0.1)	26 (<0.1)
Severe	7 (<0.1)	6 (<0.1)	13 (<0.1)
Missing	4 (<0.1)	2 (<0.1)	6 (<0.1)
Palpitations	13 (<0.1)	22 (0.1)	35 (0.1)
Mild	12 (<0.1)	14 (<0.1)	26 (<0.1)
Moderate	1 (<0.1)	7 (<0.1)	8 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Tachycardia	23 (0.2)	21 (0.1)	44 (0.1)
Mild	13 (<0.1)	11 (<0.1)	24 (<0.1)
Moderate	8 (<0.1)	9 (<0.1)	17 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)
Bradycardia	23 (0.2)	15 (<0.1)	38 (0.1)
Mild	10 (<0.1)	6 (<0.1)	16 (<0.1)
Moderate	8 (<0.1)	3 (<0.1)	11 (<0.1)
Severe	5 (<0.1)	5 (<0.1)	10 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Angina pectoris	12 (<0.1)	11 (<0.1)	23 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	5 (<0.1)	10 (<0.1)	15 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Coronary artery disease	9 (<0.1)	10 (<0.1)	19 (<0.1)
Mild	0	0	0
Moderate	6 (<0.1)	6 (<0.1)	12 (<0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Ventricular extrasystoles	6 (<0.1)	10 (<0.1)	16 (<0.1)
Mild	4 (<0.1)	7 (<0.1)	11 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Myocardial infarction	9 (<0.1)	7 (<0.1)	16 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Missing	6 (<0.1)	4 (<0.1)	10 (<0.1)
Sinus tachycardia	8 (<0.1)	7 (<0.1)	15 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Cardiac failure congestive	9 (<0.1)	6 (<0.1)	15 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	3 (<0.1)	2 (<0.1)	5 (<0.1)
Missing	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Arrhythmia	8 (<0.1)	5 (<0.1)	13 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	5 (<0.1)	2 (<0.1)	7 (<0.1)
Severe	0	0	0
Acute myocardial infarction	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Missing	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cardiac failure	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Supraventricular tachycardia	0	4 (<0.1)	4 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Acute coronary syndrome	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Atrial flutter	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Acute left ventricular failure	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Cardiomyopathy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Coronary artery occlusion	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	2 (<0.1)	2 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Ventricular tachycardia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Angina unstable	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Arteriosclerosis coronary artery	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Atrial enlargement	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Atrioventricular block	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Cardiac arrest	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Cardiac flutter	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Cardiovascular symptom	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Left ventricular hypertrophy	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Sinus bradycardia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Stress cardiomyopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Atrial tachycardia	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Atrioventricular block complete	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Atrioventricular block second degree	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Cardiac disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Cardiac steatosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cardiomegaly	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Diastolic dysfunction	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Extrasystoles	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Left atrial enlargement	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Mitral valve incompetence	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Mitral valve thickening	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Myocardial ischaemia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Paroxysmal arrhythmia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Postural orthostatic tachycardia syndrome	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Cardiac disorders (Cont.)			
Sinus arrest	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Tricuspid valve incompetence	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Ventricular arrhythmia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ventricular fibrillation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders	405 (2.7)	347 (2.3)	752 (2.5)
Mild	139 (0.9)	131 (0.9)	270 (0.9)
Moderate	183 (1.2)	163 (1.1)	346 (1.1)
Severe	75 (0.5)	47 (0.3)	122 (0.4)
Missing	8 (<0.1)	6 (<0.1)	14 (<0.1)
Hypertension	332 (2.2)	262 (1.7)	594 (2.0)
Mild	108 (0.7)	90 (0.6)	198 (0.7)
Moderate	164 (1.1)	137 (0.9)	301 (1.0)
Severe	58 (0.4)	33 (0.2)	91 (0.3)
Missing	2 (<0.1)	2 (<0.1)	4 (<0.1)
Hot flush	11 (<0.1)	17 (0.1)	28 (<0.1)
Mild	9 (<0.1)	13 (<0.1)	22 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	0	0	0
Haematoma	7 (<0.1)	11 (<0.1)	18 (<0.1)
Mild	3 (<0.1)	6 (<0.1)	9 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Deep vein thrombosis	6 (<0.1)	8 (<0.1)	14 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Missing	2 (<0.1)	2 (<0.1)	4 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Flushing	5 (<0.1)	7 (<0.1)	12 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Hypotension	11 (<0.1)	6 (<0.1)	17 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Orthostatic hypotension	1 (<0.1)	6 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Hypertensive urgency	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Arteriosclerosis	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Systolic hypertension	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	3 (<0.1)	3 (<0.1)	6 (<0.1)
Aortic dilatation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Labile hypertension	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Prehypertension	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Raynaud's phenomenon	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Achenbach syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Aortic aneurysm	4 (<0.1)	1 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Arterial occlusive disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Diastolic hypotension	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Embolism venous	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hypertensive emergency	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Pallor	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Peripheral arterial occlusive disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Peripheral coldness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Phlebitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Thrombophlebitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Venous thrombosis limb	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Aortic stenosis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Arterial haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Diastolic hypertension	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Fibromuscular dysplasia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lymphoedema	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Peripheral artery aneurysm	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Peripheral venous disease	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Vascular disorders (Cont.)			
Secondary hypertension	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vascular calcification	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vasodilatation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
White coat hypertension	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders	1094 (7.2)	970 (6.4)	2064 (6.8)
Mild	813 (5.4)	695 (4.6)	1508 (5.0)
Moderate	238 (1.6)	237 (1.6)	475 (1.6)
Severe	33 (0.2)	24 (0.2)	57 (0.2)
Missing	10 (<0.1)	14 (<0.1)	24 (<0.1)
Cough	307 (2.0)	310 (2.0)	617 (2.0)
Mild	247 (1.6)	255 (1.7)	502 (1.7)
Moderate	59 (0.4)	52 (0.3)	111 (0.4)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Oropharyngeal pain	381 (2.5)	304 (2.0)	685 (2.3)
Mild	329 (2.2)	259 (1.7)	588 (1.9)
Moderate	49 (0.3)	45 (0.3)	94 (0.3)
Severe	3 (<0.1)	0	3 (<0.1)
Nasal congestion	291 (1.9)	270 (1.8)	561 (1.8)
Mild	248 (1.6)	206 (1.4)	454 (1.5)
Moderate	42 (0.3)	61 (0.4)	103 (0.3)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Rhinorrhoea	258 (1.7)	246 (1.6)	504 (1.7)
Mild	225 (1.5)	202 (1.3)	427 (1.4)
Moderate	32 (0.2)	41 (0.3)	73 (0.2)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Dyspnoea	86 (0.6)	92 (0.6)	178 (0.6)
Mild	64 (0.4)	60 (0.4)	124 (0.4)
Moderate	21 (0.1)	23 (0.2)	44 (0.1)
Severe	1 (<0.1)	5 (<0.1)	6 (<0.1)
Missing	0	4 (<0.1)	4 (<0.1)
Tachypnoea	43 (0.3)	39 (0.3)	82 (0.3)
Mild	42 (0.3)	38 (0.3)	80 (0.3)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Sinus congestion	48 (0.3)	33 (0.2)	81 (0.3)
Mild	33 (0.2)	26 (0.2)	59 (0.2)
Moderate	15 (<0.1)	7 (<0.1)	22 (<0.1)
Severe	0	0	0
Asthma	39 (0.3)	32 (0.2)	71 (0.2)
Mild	9 (<0.1)	9 (<0.1)	18 (<0.1)
Moderate	24 (0.2)	21 (0.1)	45 (0.1)
Severe	6 (<0.1)	2 (<0.1)	8 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Respiratory tract congestion	19 (0.1)	26 (0.2)	45 (0.1)
Mild	13 (<0.1)	17 (0.1)	30 (<0.1)
Moderate	6 (<0.1)	9 (<0.1)	15 (<0.1)
Severe	0	0	0
Upper-airway cough syndrome	22 (0.1)	23 (0.2)	45 (0.1)
Mild	20 (0.1)	19 (0.1)	39 (0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	0	0	0
Epistaxis	17 (0.1)	22 (0.1)	39 (0.1)
Mild	12 (<0.1)	18 (0.1)	30 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Sneezing	22 (0.1)	22 (0.1)	44 (0.1)
Mild	19 (0.1)	20 (0.1)	39 (0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Rhinitis allergic	26 (0.2)	21 (0.1)	47 (0.2)
Mild	22 (0.1)	14 (<0.1)	36 (0.1)
Moderate	4 (<0.1)	7 (<0.1)	11 (<0.1)
Severe	0	0	0
Throat irritation	20 (0.1)	18 (0.1)	38 (0.1)
Mild	18 (0.1)	17 (0.1)	35 (0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Chronic obstructive pulmonary disease	24 (0.2)	14 (<0.1)	38 (0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	13 (<0.1)	11 (<0.1)	24 (<0.1)
Severe	5 (<0.1)	1 (<0.1)	6 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Sinus pain	7 (<0.1)	9 (<0.1)	16 (<0.1)
Mild	7 (<0.1)	9 (<0.1)	16 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Acute respiratory failure	14 (<0.1)	7 (<0.1)	21 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	5 (<0.1)	2 (<0.1)	7 (<0.1)
Missing	5 (<0.1)	5 (<0.1)	10 (<0.1)
Paranasal sinus discomfort	7 (<0.1)	7 (<0.1)	14 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Pharyngeal erythema	6 (<0.1)	6 (<0.1)	12 (<0.1)
Mild	6 (<0.1)	6 (<0.1)	12 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pleural effusion	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary embolism	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	4 (<0.1)	2 (<0.1)	6 (<0.1)
Missing	3 (<0.1)	3 (<0.1)	6 (<0.1)
Respiratory disorder	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	7 (<0.1)	4 (<0.1)	11 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Dry throat	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dysphonia	14 (<0.1)	5 (<0.1)	19 (<0.1)
Mild	13 (<0.1)	5 (<0.1)	18 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Dyspnoea exertional	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Productive cough	8 (<0.1)	5 (<0.1)	13 (<0.1)
Mild	6 (<0.1)	4 (<0.1)	10 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Sleep apnoea syndrome	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Wheezing	11 (<0.1)	5 (<0.1)	16 (<0.1)
Mild	8 (<0.1)	2 (<0.1)	10 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Bronchiectasis	0	4 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Atelectasis	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Bronchospasm	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Emphysema	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Hypoxia	6 (<0.1)	3 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Allergic cough	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Allergic sinusitis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Nasal discomfort	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Oropharyngeal discomfort	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Paranasal sinus hypersecretion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pleurisy	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Pulmonary mass	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Respiratory failure	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Choking sensation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Increased viscosity of upper respiratory secretion	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Laryngeal oedema	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Lung infiltration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Nasal dryness	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Nasal mucosal disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal pruritus	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Nasal septum deviation	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Paranasal cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Pharyngeal swelling	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pleuritic pain	8 (<0.1)	1 (<0.1)	9 (<0.1)
Mild	5 (<0.1)	1 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0
Pneumonia aspiration	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Pulmonary congestion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary hypertension	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Pulmonary oedema	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Respiratory distress	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rhonchi	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Sputum increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tonsillolith	6 (<0.1)	1 (<0.1)	7 (<0.1)
Mild	5 (<0.1)	1 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vasomotor rhinitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vocal cord disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Vocal cord thickening	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Acute respiratory distress syndrome	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Aphonia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Asthma exercise induced	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Bronchial hyperreactivity	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Haemoptysis	4 (<0.1)	0	4 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Laryngeal stenosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lower respiratory tract congestion	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Lung cyst	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lung opacity	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Nasal turbinate hypertrophy	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal ulcer	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Organising pneumonia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Painful respiration	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pharyngeal paraesthesia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pneumonitis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pulmonary fibrosis	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pulmonary granuloma	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pulmonary infarction	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Rales	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Reflux laryngitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Respiratory symptom	4 (<0.1)	0	4 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Rhinalgia	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Rhinitis atrophic	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Sinus polyp	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Throat tightness	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tonsillar exudate	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Tonsillar hypertrophy	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Tonsillar inflammation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Upper respiratory tract congestion	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gastrointestinal disorders	884 (5.8)	904 (6.0)	1788 (5.9)
Mild	532 (3.5)	518 (3.4)	1050 (3.5)
Moderate	308 (2.0)	336 (2.2)	644 (2.1)
Severe	35 (0.2)	44 (0.3)	79 (0.3)
Missing	9 (<0.1)	6 (<0.1)	15 (<0.1)
Diarrhoea	280 (1.8)	282 (1.9)	562 (1.9)
Mild	212 (1.4)	209 (1.4)	421 (1.4)
Moderate	65 (0.4)	68 (0.4)	133 (0.4)
Severe	2 (<0.1)	5 (<0.1)	7 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Nausea	242 (1.6)	243 (1.6)	485 (1.6)
Mild	175 (1.2)	171 (1.1)	346 (1.1)
Moderate	62 (0.4)	61 (0.4)	123 (0.4)
Severe	3 (<0.1)	10 (<0.1)	13 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Vomiting	84 (0.6)	91 (0.6)	175 (0.6)
Mild	57 (0.4)	63 (0.4)	120 (0.4)
Moderate	24 (0.2)	24 (0.2)	48 (0.2)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Gastrooesophageal reflux disease	59 (0.4)	83 (0.5)	142 (0.5)
Mild	27 (0.2)	36 (0.2)	63 (0.2)
Moderate	31 (0.2)	46 (0.3)	77 (0.3)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Abdominal pain	40 (0.3)	46 (0.3)	86 (0.3)
Mild	19 (0.1)	24 (0.2)	43 (0.1)
Moderate	17 (0.1)	15 (<0.1)	32 (0.1)
Severe	3 (<0.1)	7 (<0.1)	10 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Toothache	49 (0.3)	45 (0.3)	94 (0.3)
Mild	20 (0.1)	22 (0.1)	42 (0.1)
Moderate	29 (0.2)	23 (0.2)	52 (0.2)
Severe	0	0	0
Constipation	39 (0.3)	27 (0.2)	66 (0.2)
Mild	22 (0.1)	11 (<0.1)	33 (0.1)
Moderate	16 (0.1)	15 (<0.1)	31 (0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Abdominal pain upper	32 (0.2)	26 (0.2)	58 (0.2)
Mild	21 (0.1)	10 (<0.1)	31 (0.1)
Moderate	7 (<0.1)	12 (<0.1)	19 (<0.1)
Severe	4 (<0.1)	2 (<0.1)	6 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Dental caries	31 (0.2)	25 (0.2)	56 (0.2)
Mild	12 (<0.1)	7 (<0.1)	19 (<0.1)
Moderate	19 (0.1)	18 (0.1)	37 (0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Dyspepsia	24 (0.2)	23 (0.2)	47 (0.2)
Mild	13 (<0.1)	15 (<0.1)	28 (<0.1)
Moderate	10 (<0.1)	7 (<0.1)	17 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Food poisoning	15 (<0.1)	13 (<0.1)	28 (<0.1)
Mild	8 (<0.1)	8 (<0.1)	16 (<0.1)
Moderate	7 (<0.1)	5 (<0.1)	12 (<0.1)
Severe	0	0	0
Abdominal pain lower	12 (<0.1)	12 (<0.1)	24 (<0.1)
Mild	8 (<0.1)	9 (<0.1)	17 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Inguinal hernia	6 (<0.1)	12 (<0.1)	18 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	2 (<0.1)	7 (<0.1)	9 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Hiatus hernia	6 (<0.1)	11 (<0.1)	17 (<0.1)
Mild	3 (<0.1)	8 (<0.1)	11 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Abdominal discomfort	17 (0.1)	10 (<0.1)	27 (<0.1)
Mild	10 (<0.1)	9 (<0.1)	19 (<0.1)
Moderate	6 (<0.1)	1 (<0.1)	7 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Large intestine polyp	10 (<0.1)	10 (<0.1)	20 (<0.1)
Mild	9 (<0.1)	7 (<0.1)	16 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Colitis	9 (<0.1)	8 (<0.1)	17 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	2 (<0.1)	5 (<0.1)	7 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastritis	15 (<0.1)	8 (<0.1)	23 (<0.1)
Mild	7 (<0.1)	1 (<0.1)	8 (<0.1)
Moderate	5 (<0.1)	5 (<0.1)	10 (<0.1)
Severe	3 (<0.1)	2 (<0.1)	5 (<0.1)
Haemorrhoids	6 (<0.1)	8 (<0.1)	14 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	0	0	0
Irritable bowel syndrome	3 (<0.1)	8 (<0.1)	11 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	7 (<0.1)	9 (<0.1)
Severe	0	0	0
Gastric ulcer	7 (<0.1)	7 (<0.1)	14 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Umbilical hernia	1 (<0.1)	7 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Abdominal distension	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	5 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Flatulence	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Lip swelling	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Tooth impacted	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	0	0	0
Diverticulum intestinal	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	5 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gastrointestinal haemorrhage	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	3 (<0.1)	0	3 (<0.1)
Missing	0	3 (<0.1)	3 (<0.1)
Haematochezia	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oesophagitis	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Rectal haemorrhage	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Small intestinal obstruction	4 (<0.1)	4 (<0.1)	8 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	4 (<0.1)	5 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Aphthous ulcer	6 (<0.1)	3 (<0.1)	9 (<0.1)
Mild	5 (<0.1)	1 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Barrett's oesophagus	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Diverticulum	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dysphagia	7 (<0.1)	3 (<0.1)	10 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Faeces soft	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastrointestinal pain	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Gingival pain	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Hyperaesthesia teeth	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Hypoaesthesia oral	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Pancreatitis	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Paraesthesia oral	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Periodontal disease	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Stomatitis	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Anal fissure	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Chapped lips	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dry mouth	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Duodenal ulcer	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Duodenal ulcer perforation	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Faeces discoloured	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Frequent bowel movements	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gastrointestinal disorder	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gingival bleeding	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Intestinal obstruction	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Melaena	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Mouth ulceration	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oesophageal spasm	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Oesophageal ulcer	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Peptic ulcer	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Proctalgia	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Swollen tongue	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Tongue discolouration	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Abdominal hernia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Anorectal disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Chronic gastritis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Crohn's disease	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Dental paraesthesia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Diabetic gastroparesis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Diverticular perforation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Duodenitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Enteritis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Faecaloma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gingival disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Glossitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Impaired gastric emptying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Intra-abdominal fluid collection	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Intussusception	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Large intestine perforation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Leukoplakia oral	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Lip oedema	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Loose tooth	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Noninfective gingivitis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Oesophageal rupture	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oesophageal stenosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Oral disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Oral mucosal blistering	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Oral mucosal eruption	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oral pain	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Pancreatic cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Pancreatitis acute	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Poor dental condition	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Proctitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rectal fissure	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Rectal prolapse	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Saliva altered	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Salivary gland calculus	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Salivary hypersecretion	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Submaxillary gland enlargement	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Tongue discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tongue disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tongue ulceration	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Tooth discolouration	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Abdominal rigidity	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Abdominal tenderness	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Abdominal wall cyst	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Anal fistula	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Anorectal discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ascites	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Coeliac disease	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Colitis microscopic	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Dental necrosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Duodenal ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Eosinophilic oesophagitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Femoral hernia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastric perforation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Gastric polyps	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gastric ulcer haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Gastrointestinal motility disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gingival discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gingival recession	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Glossodynia	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Hypertrophy of tongue papillae	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ileus paralytic	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lip blister	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Mouth haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Obstructive pancreatitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Odynophagia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Oral cavity fistula	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Oral discomfort	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Oral mucosal erythema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Palatal disorder	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Palatal oedema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Regurgitation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Retching	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Terminal ileitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Tongue coated	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Tongue dry	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tooth disorder	3 (<0.1)	0	3 (<0.1)
Mild	0	0	0
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0
Tooth socket haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Upper gastrointestinal haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)			
Uvulitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Hepatobiliary disorders	21 (0.1)	31 (0.2)	52 (0.2)
Mild	7 (<0.1)	15 (<0.1)	22 (<0.1)
Moderate	8 (<0.1)	7 (<0.1)	15 (<0.1)
Severe	3 (<0.1)	7 (<0.1)	10 (<0.1)
Missing	3 (<0.1)	2 (<0.1)	5 (<0.1)
Cholelithiasis	9 (<0.1)	15 (<0.1)	24 (<0.1)
Mild	4 (<0.1)	7 (<0.1)	11 (<0.1)
Moderate	5 (<0.1)	4 (<0.1)	9 (<0.1)
Severe	0	4 (<0.1)	4 (<0.1)
Cholecystitis	3 (<0.1)	7 (<0.1)	10 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)			
Hepatic steatosis	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Bile duct stone	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Biliary colic	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Biliary dyskinesia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)			
Cholecystitis acute	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Hepatic cyst	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Jaundice	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nonalcoholic fatty liver disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Hepatobiliary disorders (Cont.)			
Hepatic haematoma	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Hyperbilirubinaemia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Skin and subcutaneous tissue disorders	374 (2.5)	394 (2.6)	768 (2.5)
Mild	249 (1.6)	252 (1.7)	501 (1.7)
Moderate	117 (0.8)	133 (0.9)	250 (0.8)
Severe	5 (<0.1)	8 (<0.1)	13 (<0.1)
Missing	3 (<0.1)	1 (<0.1)	4 (<0.1)
Urticaria	46 (0.3)	55 (0.4)	101 (0.3)
Mild	31 (0.2)	25 (0.2)	56 (0.2)
Moderate	12 (<0.1)	29 (0.2)	41 (0.1)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash	47 (0.3)	44 (0.3)	91 (0.3)
Mild	38 (0.3)	33 (0.2)	71 (0.2)
Moderate	9 (<0.1)	9 (<0.1)	18 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Dermatitis contact	41 (0.3)	34 (0.2)	75 (0.2)
Mild	27 (0.2)	21 (0.1)	48 (0.2)
Moderate	14 (<0.1)	13 (<0.1)	27 (<0.1)
Severe	0	0	0
Pruritus	29 (0.2)	28 (0.2)	57 (0.2)
Mild	22 (0.1)	21 (0.1)	43 (0.1)
Moderate	6 (<0.1)	5 (<0.1)	11 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Eczema	11 (<0.1)	18 (0.1)	29 (<0.1)
Mild	6 (<0.1)	7 (<0.1)	13 (<0.1)
Moderate	5 (<0.1)	11 (<0.1)	16 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Erythema	8 (<0.1)	17 (0.1)	25 (<0.1)
Mild	6 (<0.1)	11 (<0.1)	17 (<0.1)
Moderate	2 (<0.1)	5 (<0.1)	7 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Hyperhidrosis	12 (<0.1)	16 (0.1)	28 (<0.1)
Mild	11 (<0.1)	13 (<0.1)	24 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Acne	19 (0.1)	15 (<0.1)	34 (0.1)
Mild	8 (<0.1)	6 (<0.1)	14 (<0.1)
Moderate	11 (<0.1)	9 (<0.1)	20 (<0.1)
Severe	0	0	0
Night sweats	12 (<0.1)	11 (<0.1)	23 (<0.1)
Mild	11 (<0.1)	11 (<0.1)	22 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis	14 (<0.1)	10 (<0.1)	24 (<0.1)
Mild	9 (<0.1)	7 (<0.1)	16 (<0.1)
Moderate	5 (<0.1)	2 (<0.1)	7 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Actinic keratosis	5 (<0.1)	9 (<0.1)	14 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Rash maculo-papular	4 (<0.1)	9 (<0.1)	13 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	5 (<0.1)	6 (<0.1)
Severe	0	0	0
Rash papular	4 (<0.1)	9 (<0.1)	13 (<0.1)
Mild	3 (<0.1)	6 (<0.1)	9 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Alopecia	10 (<0.1)	8 (<0.1)	18 (<0.1)
Mild	7 (<0.1)	8 (<0.1)	15 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0
Rash macular	6 (<0.1)	8 (<0.1)	14 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Ecchymosis	7 (<0.1)	7 (<0.1)	14 (<0.1)
Mild	6 (<0.1)	7 (<0.1)	13 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Psoriasis	3 (<0.1)	7 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	5 (<0.1)	5 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rosacea	3 (<0.1)	7 (<0.1)	10 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Dermatitis atopic	9 (<0.1)	6 (<0.1)	15 (<0.1)
Mild	6 (<0.1)	4 (<0.1)	10 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Rash pruritic	11 (<0.1)	6 (<0.1)	17 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	7 (<0.1)	2 (<0.1)	9 (<0.1)
Severe	0	0	0
Dry skin	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Ingrowing nail	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
Pityriasis rosea	0	4 (<0.1)	4 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Skin lesion	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Angioedema	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Blister	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Dermal cyst	7 (<0.1)	3 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	0	0	0
Dermatitis allergic	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Eczema nummular	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Hidradenitis	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Macule	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Neurodermatitis	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Pain of skin	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Rash erythematous	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Skin burning sensation	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Skin ulcer	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Urticaria papular	5 (<0.1)	3 (<0.1)	8 (<0.1)
Mild	4 (<0.1)	3 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Acne cystic	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Diabetic foot	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Hand dermatitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lichen planus	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Papule	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Precancerous skin lesion	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Rash vesicular	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Alopecia areata	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Androgenetic alopecia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Blood blister	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Chronic spontaneous urticaria	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Cold sweat	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Decubitus ulcer	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Exfoliative rash	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lichen sclerosus	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Mechanical urticaria	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Onychoclasis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Perioral dermatitis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Petechiae	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Skin exfoliation	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin haemorrhage	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin hypopigmentation	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Skin warm	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Solar lentigo	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vitiligo	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Alopecia scarring	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Dermatitis bullous	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Hyperkeratosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ingrown hair	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Intertrigo	4 (<0.1)	0	4 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Lichenoid keratosis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Livedo reticularis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Miliaria	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Photosensitivity reaction	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Rash follicular	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Scab	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin discolouration	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Skin fissures	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Skin hyperpigmentation	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin irritation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Skin wrinkling	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Stasis dermatitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Subcutaneous emphysema	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Telangiectasia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Transient acantholytic dermatosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)			
Umbilical erythema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Musculoskeletal and connective tissue disorders	1342 (8.9)	1315 (8.7)	2657 (8.8)
Mild	781 (5.2)	722 (4.8)	1503 (5.0)
Moderate	505 (3.3)	531 (3.5)	1036 (3.4)
Severe	50 (0.3)	50 (0.3)	100 (0.3)
Missing	6 (<0.1)	12 (<0.1)	18 (<0.1)
Arthralgia	436 (2.9)	443 (2.9)	879 (2.9)
Mild	295 (1.9)	299 (2.0)	594 (2.0)
Moderate	133 (0.9)	131 (0.9)	264 (0.9)
Severe	8 (<0.1)	12 (<0.1)	20 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Myalgia	451 (3.0)	434 (2.9)	885 (2.9)
Mild	353 (2.3)	328 (2.2)	681 (2.2)
Moderate	92 (0.6)	97 (0.6)	189 (0.6)
Severe	6 (<0.1)	9 (<0.1)	15 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Back pain	185 (1.2)	163 (1.1)	348 (1.1)
Mild	92 (0.6)	70 (0.5)	162 (0.5)
Moderate	85 (0.6)	89 (0.6)	174 (0.6)
Severe	7 (<0.1)	3 (<0.1)	10 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Pain in extremity	101 (0.7)	84 (0.6)	185 (0.6)
Mild	64 (0.4)	50 (0.3)	114 (0.4)
Moderate	37 (0.2)	32 (0.2)	69 (0.2)
Severe	0	2 (<0.1)	2 (<0.1)
Musculoskeletal pain	53 (0.3)	67 (0.4)	120 (0.4)
Mild	30 (0.2)	30 (0.2)	60 (0.2)
Moderate	23 (0.2)	36 (0.2)	59 (0.2)
Severe	0	1 (<0.1)	1 (<0.1)
Neck pain	54 (0.4)	62 (0.4)	116 (0.4)
Mild	36 (0.2)	39 (0.3)	75 (0.2)
Moderate	18 (0.1)	19 (0.1)	37 (0.1)
Severe	0	3 (<0.1)	3 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteoarthritis	75 (0.5)	61 (0.4)	136 (0.4)
Mild	16 (0.1)	14 (<0.1)	30 (<0.1)
Moderate	48 (0.3)	37 (0.2)	85 (0.3)
Severe	7 (<0.1)	5 (<0.1)	12 (<0.1)
Missing	4 (<0.1)	5 (<0.1)	9 (<0.1)
Muscle spasms	44 (0.3)	43 (0.3)	87 (0.3)
Mild	19 (0.1)	21 (0.1)	40 (0.1)
Moderate	23 (0.2)	20 (0.1)	43 (0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Rotator cuff syndrome	26 (0.2)	25 (0.2)	51 (0.2)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	21 (0.1)	18 (0.1)	39 (0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Tendonitis	24 (0.2)	21 (0.1)	45 (0.1)
Mild	10 (<0.1)	10 (<0.1)	20 (<0.1)
Moderate	12 (<0.1)	10 (<0.1)	22 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Bursitis	13 (<0.1)	20 (0.1)	33 (0.1)
Mild	5 (<0.1)	9 (<0.1)	14 (<0.1)
Moderate	8 (<0.1)	10 (<0.1)	18 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Musculoskeletal chest pain	26 (0.2)	18 (0.1)	44 (0.1)
Mild	17 (0.1)	10 (<0.1)	27 (<0.1)
Moderate	6 (<0.1)	5 (<0.1)	11 (<0.1)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Intervertebral disc protrusion	13 (<0.1)	17 (0.1)	30 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	8 (<0.1)	12 (<0.1)	20 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	3 (<0.1)	4 (<0.1)
Musculoskeletal stiffness	16 (0.1)	15 (<0.1)	31 (0.1)
Mild	13 (<0.1)	12 (<0.1)	25 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Arthritis	12 (<0.1)	14 (<0.1)	26 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	7 (<0.1)	12 (<0.1)	19 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Joint swelling	11 (<0.1)	10 (<0.1)	21 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	5 (<0.1)	5 (<0.1)	10 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Muscular weakness	8 (<0.1)	9 (<0.1)	17 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)	18 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Osteopenia	5 (<0.1)	8 (<0.1)	13 (<0.1)
Mild	3 (<0.1)	5 (<0.1)	8 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Osteoporosis	8 (<0.1)	8 (<0.1)	16 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	3 (<0.1)	6 (<0.1)	9 (<0.1)
Severe	0	0	0
Trigger finger	7 (<0.1)	8 (<0.1)	15 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	5 (<0.1)	4 (<0.1)	9 (<0.1)
Severe	0	0	0
Groin pain	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Periarthritis	4 (<0.1)	7 (<0.1)	11 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0
Flank pain	6 (<0.1)	6 (<0.1)	12 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Muscle tightness	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Pain in jaw	11 (<0.1)	6 (<0.1)	17 (<0.1)
Mild	9 (<0.1)	4 (<0.1)	13 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Costochondritis	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Joint range of motion decreased	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	4 (<0.1)	4 (<0.1)
Severe	0	0	0
Limb discomfort	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Plantar fasciitis	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Spinal pain	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Bone pain	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Fibromyalgia	5 (<0.1)	4 (<0.1)	9 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	5 (<0.1)	1 (<0.1)	6 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Intervertebral disc degeneration	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Muscle twitching	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Spinal stenosis	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Limb mass	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Muscle fatigue	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Neck mass	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Spondylolisthesis	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Synovial cyst	6 (<0.1)	3 (<0.1)	9 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Axillary mass	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cervical spinal stenosis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Exostosis	8 (<0.1)	2 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	5 (<0.1)	1 (<0.1)	6 (<0.1)
Severe	0	0	0
Facet joint syndrome	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Foot deformity	7 (<0.1)	2 (<0.1)	9 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Joint stiffness	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Rheumatoid arthritis	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Spondylitis	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Tenosynovitis	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Bone lesion	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bone swelling	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Chondrocalcinosis pyrophosphate	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Compartment syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Degenerative bone disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Dupuytren's contracture	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Floating patella	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Fracture nonunion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Joint noise	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Ligament pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ligamentum flavum hypertrophy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Medial tibial stress syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Musculoskeletal discomfort	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Myosclerosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Osteitis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Osteonecrosis	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Palindromic rheumatism	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Plantar fascial fibromatosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Sacroiliitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Spinal synovial cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Spondylolysis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Tendon disorder	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tendon pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Tenosynovitis stenosans	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Torticollis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Trismus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Fasciitis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Femoroacetabular impingement	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Intervertebral disc annular tear	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Joint effusion	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Kyphosis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lumbar spinal stenosis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Muscle discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Musculoskeletal disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Myositis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Polymyalgia rheumatica	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Rhabdomyolysis	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Rheumatic disorder	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Scoliosis	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Sjogren's syndrome	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Synovitis	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)			
Systemic lupus erythematosus	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Renal and urinary disorders	99 (0.7)	100 (0.7)	199 (0.7)
Mild	33 (0.2)	41 (0.3)	74 (0.2)
Moderate	51 (0.3)	44 (0.3)	95 (0.3)
Severe	11 (<0.1)	11 (<0.1)	22 (<0.1)
Missing	4 (<0.1)	4 (<0.1)	8 (<0.1)
Nephrolithiasis	34 (0.2)	29 (0.2)	63 (0.2)
Mild	7 (<0.1)	8 (<0.1)	15 (<0.1)
Moderate	22 (0.1)	11 (<0.1)	33 (0.1)
Severe	4 (<0.1)	6 (<0.1)	10 (<0.1)
Missing	1 (<0.1)	4 (<0.1)	5 (<0.1)
Dysuria	5 (<0.1)	9 (<0.1)	14 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	5 (<0.1)	7 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Acute kidney injury	13 (<0.1)	7 (<0.1)	20 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	5 (<0.1)	1 (<0.1)	6 (<0.1)
Severe	3 (<0.1)	4 (<0.1)	7 (<0.1)
Missing	4 (<0.1)	1 (<0.1)	5 (<0.1)
Chronic kidney disease	7 (<0.1)	7 (<0.1)	14 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Haematuria	11 (<0.1)	6 (<0.1)	17 (<0.1)
Mild	7 (<0.1)	4 (<0.1)	11 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	0	0	0
Urinary retention	4 (<0.1)	6 (<0.1)	10 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Hypertonic bladder	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	0	0
Pollakiuria	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Polyuria	0	5 (<0.1)	5 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Nocturia	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Urinary incontinence	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Hydronephrosis	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Bladder pain	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Renal cyst	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Urinary hesitation	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Bladder diverticulum	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Bladder prolapse	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Bladder spasm	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Calculus bladder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Chromaturia	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Cystitis interstitial	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Diabetic nephropathy	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Haemorrhage urinary tract	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lower urinary tract symptoms	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Micturition urgency	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Renal disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Renal failure	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Renal pain	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Renal tubular necrosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Stress urinary incontinence	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Ureterolithiasis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Urethral pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pelvi-ureteric obstruction	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Renal colic	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)			
Renal impairment	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Urge incontinence	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Urine flow decreased	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Pregnancy, puerperium and perinatal conditions	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions (Cont.)			
Abortion spontaneous	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Morning sickness	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pregnancy	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions (Cont.)			
Ectopic pregnancy	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Reproductive system and breast disorders	132 (0.9)	115 (0.8)	247 (0.8)
Mild	65 (0.4)	53 (0.3)	118 (0.4)
Moderate	57 (0.4)	56 (0.4)	113 (0.4)
Severe	7 (<0.1)	5 (<0.1)	12 (<0.1)
Missing	3 (<0.1)	1 (<0.1)	4 (<0.1)
Benign prostatic hyperplasia	22 (0.1)	11 (<0.1)	33 (0.1)
Mild	7 (<0.1)	4 (<0.1)	11 (<0.1)
Moderate	13 (<0.1)	7 (<0.1)	20 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Erectile dysfunction	11 (<0.1)	8 (<0.1)	19 (<0.1)
Mild	9 (<0.1)	4 (<0.1)	13 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Ovarian cyst	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Pelvic pain	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Prostatitis	7 (<0.1)	6 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	5 (<0.1)	3 (<0.1)	8 (<0.1)
Severe	0	0	0
Breast cyst	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Dysmenorrhoea	10 (<0.1)	5 (<0.1)	15 (<0.1)
Mild	6 (<0.1)	2 (<0.1)	8 (<0.1)
Moderate	3 (<0.1)	3 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Menorrhagia	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Prostatomegaly	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	4 (<0.1)	2 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Menopausal symptoms	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Vaginal haemorrhage	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Postmenopausal haemorrhage	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	3 (<0.1)	0	3 (<0.1)
Severe	0	0	0
Uterine polyp	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Breast hyperplasia	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Breast mass	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Breast pain	5 (<0.1)	2 (<0.1)	7 (<0.1)
Mild	4 (<0.1)	2 (<0.1)	6 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Breast ulceration	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dysfunctional uterine bleeding	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Nipple exudate bloody	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Rectocele	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Uterine haemorrhage	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Adenomyosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Adnexa uteri pain	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Adnexal torsion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Artificial menopause	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Atrophic vulvovaginitis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Balanoposthitis	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Breast calcifications	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Breast disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Breast enlargement	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Breast fibrosis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Breast swelling	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Breast tenderness	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Cervical dysplasia	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Cervical polyp	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Cystocele	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Ejaculation failure	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Endometrial thickening	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Endometriosis	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Fibrocystic breast disease	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Gynaecomastia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Menstrual disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Menstruation irregular	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Metrorrhagia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Nipple pain	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Perineal rash	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Polymenorrhoea	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Priapism	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Prostatic cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Testicular pain	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Vaginal cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaginal discharge	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaginal prolapse	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vulva cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Vulval disorder	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vulvovaginal pruritus	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Amenorrhoea	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Bartholin's cyst	3 (<0.1)	0	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Dyspareunia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Endometrial hyperplasia	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Haematospermia	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Oligomenorrhoea	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ovarian cyst ruptured	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Ovarian mass	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pelvic discomfort	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Pelvic floor muscle weakness	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pelvic prolapse	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Peyronie's disease	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Polycystic ovaries	3 (<0.1)	0	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Premenstrual dysphoric disorder	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pruritus genital	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Testicular swelling	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Uterine cyst	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)			
Uterine spasm	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Vulvovaginal discomfort	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vulvovaginal dryness	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Congenital, familial and genetic disorders	5 (<0.1)	8 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Dermoid cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Developmental hip dysplasia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gilbert's syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Preauricular cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Type IIa hyperlipidaemia	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Von Willebrand's disease	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hydrocele	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)			
Talipes	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
General disorders and administration site conditions	1330 (8.8)	1836 (12.1)	3166 (10.4)
Mild	995 (6.6)	1395 (9.2)	2390 (7.9)
Moderate	298 (2.0)	368 (2.4)	666 (2.2)
Severe	30 (0.2)	68 (0.4)	98 (0.3)
Missing	7 (<0.1)	5 (<0.1)	12 (<0.1)
Fatigue	799 (5.3)	882 (5.8)	1681 (5.5)
Mild	614 (4.0)	679 (4.5)	1293 (4.3)
Moderate	171 (1.1)	177 (1.2)	348 (1.1)
Severe	14 (<0.1)	25 (0.2)	39 (0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Injection site pain	141 (0.9)	269 (1.8)	410 (1.4)
Mild	117 (0.8)	213 (1.4)	330 (1.1)
Moderate	23 (0.2)	50 (0.3)	73 (0.2)
Severe	1 (<0.1)	6 (<0.1)	7 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Chills	162 (1.1)	175 (1.2)	337 (1.1)
Mild	128 (0.8)	148 (1.0)	276 (0.9)
Moderate	32 (0.2)	24 (0.2)	56 (0.2)
Severe	2 (<0.1)	3 (<0.1)	5 (<0.1)
Pyrexia	120 (0.8)	168 (1.1)	288 (0.9)
Mild	95 (0.6)	126 (0.8)	221 (0.7)
Moderate	23 (0.2)	40 (0.3)	63 (0.2)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Injection site erythema	40 (0.3)	158 (1.0)	198 (0.7)
Mild	36 (0.2)	125 (0.8)	161 (0.5)
Moderate	4 (<0.1)	25 (0.2)	29 (<0.1)
Severe	0	8 (<0.1)	8 (<0.1)
Pain	135 (0.9)	133 (0.9)	268 (0.9)
Mild	93 (0.6)	104 (0.7)	197 (0.6)
Moderate	39 (0.3)	26 (0.2)	65 (0.2)
Severe	3 (<0.1)	3 (<0.1)	6 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site swelling	31 (0.2)	119 (0.8)	150 (0.5)
Mild	23 (0.2)	90 (0.6)	113 (0.4)
Moderate	8 (<0.1)	26 (0.2)	34 (0.1)
Severe	0	3 (<0.1)	3 (<0.1)
Injection site pruritus	13 (<0.1)	88 (0.6)	101 (0.3)
Mild	12 (<0.1)	77 (0.5)	89 (0.3)
Moderate	1 (<0.1)	11 (<0.1)	12 (<0.1)
Severe	0	0	0
Injection site lymphadenopathy	17 (0.1)	69 (0.5)	86 (0.3)
Mild	15 (<0.1)	59 (0.4)	74 (0.2)
Moderate	1 (<0.1)	7 (<0.1)	8 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Injection site induration	18 (0.1)	53 (0.3)	71 (0.2)
Mild	16 (0.1)	47 (0.3)	63 (0.2)
Moderate	1 (<0.1)	5 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site macule	4 (<0.1)	45 (0.3)	49 (0.2)
Mild	4 (<0.1)	33 (0.2)	37 (0.1)
Moderate	0	6 (<0.1)	6 (<0.1)
Severe	0	6 (<0.1)	6 (<0.1)
Injection site urticaria	1 (<0.1)	38 (0.3)	39 (0.1)
Mild	1 (<0.1)	31 (0.2)	32 (0.1)
Moderate	0	5 (<0.1)	5 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Axillary pain	15 (<0.1)	27 (0.2)	42 (0.1)
Mild	11 (<0.1)	26 (0.2)	37 (0.1)
Moderate	4 (<0.1)	1 (<0.1)	5 (<0.1)
Severe	0	0	0
Injection site rash	1 (<0.1)	25 (0.2)	26 (<0.1)
Mild	1 (<0.1)	22 (0.1)	23 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Chest discomfort	25 (0.2)	24 (0.2)	49 (0.2)
Mild	16 (0.1)	14 (<0.1)	30 (<0.1)
Moderate	8 (<0.1)	9 (<0.1)	17 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site bruising	21 (0.1)	19 (0.1)	40 (0.1)
Mild	20 (0.1)	19 (0.1)	39 (0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Malaise	14 (<0.1)	19 (0.1)	33 (0.1)
Mild	12 (<0.1)	12 (<0.1)	24 (<0.1)
Moderate	2 (<0.1)	6 (<0.1)	8 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Peripheral swelling	14 (<0.1)	19 (0.1)	33 (0.1)
Mild	8 (<0.1)	11 (<0.1)	19 (<0.1)
Moderate	6 (<0.1)	8 (<0.1)	14 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Chest pain	11 (<0.1)	15 (<0.1)	26 (<0.1)
Mild	4 (<0.1)	5 (<0.1)	9 (<0.1)
Moderate	5 (<0.1)	7 (<0.1)	12 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)
Non-cardiac chest pain	16 (0.1)	15 (<0.1)	31 (0.1)
Mild	9 (<0.1)	8 (<0.1)	17 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	2 (<0.1)	3 (<0.1)	5 (<0.1)
Missing	1 (<0.1)	1 (<0.1)	2 (<0.1)
Oedema peripheral	17 (0.1)	14 (<0.1)	31 (0.1)
Mild	11 (<0.1)	8 (<0.1)	19 (<0.1)
Moderate	5 (<0.1)	5 (<0.1)	10 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Injection site papule	1 (<0.1)	13 (<0.1)	14 (<0.1)
Mild	1 (<0.1)	12 (<0.1)	13 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site warmth	1 (<0.1)	7 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	7 (<0.1)	8 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Reactogenicity event	5 (<0.1)	7 (<0.1)	12 (<0.1)
Mild	3 (<0.1)	3 (<0.1)	6 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	0	0	0
Asthenia	10 (<0.1)	6 (<0.1)	16 (<0.1)
Mild	5 (<0.1)	3 (<0.1)	8 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Feeling hot	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	6 (<0.1)	8 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site haematoma	2 (<0.1)	6 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	6 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site haemorrhage	5 (<0.1)	6 (<0.1)	11 (<0.1)
Mild	4 (<0.1)	6 (<0.1)	10 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site paraesthesia	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	6 (<0.1)	8 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Swelling face	4 (<0.1)	6 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site swelling	1 (<0.1)	6 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Feeling abnormal	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Injection site joint pain	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	5 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site pain	7 (<0.1)	5 (<0.1)	12 (<0.1)
Mild	5 (<0.1)	4 (<0.1)	9 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Death	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	2 (<0.1)	4 (<0.1)	6 (<0.1)
Influenza like illness	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	4 (<0.1)	3 (<0.1)	7 (<0.1)
Severe	0	0	0
Injection site mass	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Cyst	6 (<0.1)	3 (<0.1)	9 (<0.1)
Mild	4 (<0.1)	3 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site hypoaesthesia	1 (<0.1)	3 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Injection site irritation	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Injection site reaction	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injury associated with device	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Tenderness	0	3 (<0.1)	3 (<0.1)
Mild	0	3 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site erythema	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0
Adverse drug reaction	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Exercise tolerance decreased	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Hangover	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Inflammation	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Injection site scab	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Precancerous condition	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Sensation of foreign body	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site rash	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vessel puncture site bruise	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Crying	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Drug withdrawal syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Dysplasia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Early satiety	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Facial discomfort	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Facial pain	6 (<0.1)	1 (<0.1)	7 (<0.1)
Mild	4 (<0.1)	1 (<0.1)	5 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Feeling cold	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Generalised oedema	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Induration	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Infusion site lymphadenopathy	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection site discolouration	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lithiasis	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Mass	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Medical device site pain	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Multiple organ dysfunction syndrome	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Secretion discharge	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Swelling	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site induration	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vaccination site lymphadenopathy	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Vaccination site mass	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site pruritus	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vessel puncture site haematoma	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vessel puncture site haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Xerosis	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Capsular contracture associated with breast implant	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Drug intolerance	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Gait disturbance	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Hunger	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hypothermia	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Impaired healing	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Incarcerated hernia	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	2 (<0.1)	0	2 (<0.1)

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site discomfort	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Injection site joint discomfort	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection site nodule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection site oedema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Injection site scar	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection site vesicles	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Medical device site inflammation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nodule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Oedema	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Pelvic mass	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Polyp	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sluggishness	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Systemic inflammatory response syndrome	4 (<0.1)	0	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	3 (<0.1)	0	3 (<0.1)
Temperature intolerance	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Thirst	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site bruising	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)			
Vaccination site inflammation	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vaccination site nodule	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Vessel puncture site pain	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Investigations	166 (1.1)	172 (1.1)	338 (1.1)
Mild	90 (0.6)	88 (0.6)	178 (0.6)
Moderate	43 (0.3)	51 (0.3)	94 (0.3)
Severe	31 (0.2)	33 (0.2)	64 (0.2)
Missing	2 (<0.1)	0	2 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood pressure increased	53 (0.3)	41 (0.3)	94 (0.3)
Mild	23 (0.2)	20 (0.1)	43 (0.1)
Moderate	18 (0.1)	9 (<0.1)	27 (<0.1)
Severe	12 (<0.1)	12 (<0.1)	24 (<0.1)
Blood pressure systolic increased	21 (0.1)	21 (0.1)	42 (0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	15 (<0.1)	12 (<0.1)	27 (<0.1)
Blood pressure diastolic increased	10 (<0.1)	13 (<0.1)	23 (<0.1)
Mild	5 (<0.1)	6 (<0.1)	11 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	5 (<0.1)	6 (<0.1)	11 (<0.1)
Blood cholesterol increased	11 (<0.1)	10 (<0.1)	21 (<0.1)
Mild	5 (<0.1)	5 (<0.1)	10 (<0.1)
Moderate	6 (<0.1)	5 (<0.1)	11 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Hepatic enzyme increased	5 (<0.1)	7 (<0.1)	12 (<0.1)
Mild	4 (<0.1)	3 (<0.1)	7 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	4 (<0.1)	4 (<0.1)
Body temperature increased	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Heart rate increased	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	3 (<0.1)	4 (<0.1)	7 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Prostatic specific antigen increased	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	4 (<0.1)	5 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood glucose increased	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Transaminases increased	2 (<0.1)	4 (<0.1)	6 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Weight decreased	1 (<0.1)	4 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	2 (<0.1)	3 (<0.1)
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Blood testosterone decreased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood triglycerides increased	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	3 (<0.1)	4 (<0.1)
Severe	0	0	0
C-reactive protein increased	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Cardiac murmur	8 (<0.1)	3 (<0.1)	11 (<0.1)
Mild	6 (<0.1)	3 (<0.1)	9 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Blood creatine increased	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood creatinine increased	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood parathyroid hormone increased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood potassium decreased	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Electrocardiogram QT prolonged	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Heart rate irregular	6 (<0.1)	2 (<0.1)	8 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	2 (<0.1)	0	2 (<0.1)
Hepatic enzyme abnormal	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0
Human rhinovirus test positive	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
White blood cell count increased	0	2 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Antinuclear antibody positive	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Aspartate aminotransferase increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood bilirubin increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood glucose decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood oestrogen decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood pressure systolic abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Blood pressure systolic decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood uric acid increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Blood urine present	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Body temperature decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Carotid bruit	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Chest X-ray	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Electrocardiogram T wave inversion	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Fibrin D dimer increased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Glomerular filtration rate decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Glycosylated haemoglobin increased	5 (<0.1)	1 (<0.1)	6 (<0.1)
Mild	3 (<0.1)	0	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Haemoglobin decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hepatitis C antibody positive	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Hormone level abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Influenza A virus test positive	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Liver function test increased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Lymphocyte count decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Mammogram abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Nerve conduction studies abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Neutrophil count increased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Oestradiol decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Oxygen saturation decreased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Respiratory rate increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Stool analysis abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Streptococcus test negative	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Thyroid function test abnormal	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Troponin increased	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Urine transitional cells present	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Vitamin B12 decreased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Vitamin D decreased	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Weight increased	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
White blood cell count decreased	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood calcium increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Blood iron decreased	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Blood pressure diastolic decreased	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Blood prolactin increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Blood thyroid stimulating hormone increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Brain natriuretic peptide increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Haematocrit increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
International normalised ratio increased	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Lipase increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
Liver function test abnormal	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pregnancy test positive	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Red blood cell count increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Renal function test abnormal	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Investigations (Cont.)			
SARS-CoV-2 test positive	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Serum ferritin increased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Total lung capacity decreased	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Viral test positive	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications	651 (4.3)	571 (3.8)	1222 (4.0)
Mild	286 (1.9)	235 (1.5)	521 (1.7)
Moderate	310 (2.0)	277 (1.8)	587 (1.9)
Severe	47 (0.3)	47 (0.3)	94 (0.3)
Missing	8 (<0.1)	12 (<0.1)	20 (<0.1)
Muscle strain	51 (0.3)	53 (0.3)	104 (0.3)
Mild	21 (0.1)	30 (0.2)	51 (0.2)
Moderate	27 (0.2)	21 (0.1)	48 (0.2)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Ligament sprain	50 (0.3)	49 (0.3)	99 (0.3)
Mild	30 (0.2)	19 (0.1)	49 (0.2)
Moderate	17 (0.1)	28 (0.2)	45 (0.1)
Severe	3 (<0.1)	2 (<0.1)	5 (<0.1)
Fall	48 (0.3)	46 (0.3)	94 (0.3)
Mild	22 (0.1)	23 (0.2)	45 (0.1)
Moderate	22 (0.1)	17 (0.1)	39 (0.1)
Severe	2 (<0.1)	5 (<0.1)	7 (<0.1)
Missing	2 (<0.1)	1 (<0.1)	3 (<0.1)
Skin laceration	53 (0.3)	37 (0.2)	90 (0.3)
Mild	22 (0.1)	14 (<0.1)	36 (0.1)
Moderate	25 (0.2)	18 (0.1)	43 (0.1)
Severe	5 (<0.1)	3 (<0.1)	8 (<0.1)
Missing	1 (<0.1)	2 (<0.1)	3 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Tooth fracture	36 (0.2)	32 (0.2)	68 (0.2)
Mild	15 (<0.1)	12 (<0.1)	27 (<0.1)
Moderate	21 (0.1)	18 (0.1)	39 (0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Contusion	36 (0.2)	30 (0.2)	66 (0.2)
Mild	24 (0.2)	16 (0.1)	40 (0.1)
Moderate	12 (<0.1)	14 (<0.1)	26 (<0.1)
Severe	0	0	0
Procedural pain	56 (0.4)	30 (0.2)	86 (0.3)
Mild	17 (0.1)	7 (<0.1)	24 (<0.1)
Moderate	33 (0.2)	21 (0.1)	54 (0.2)
Severe	6 (<0.1)	2 (<0.1)	8 (<0.1)
Arthropod bite	37 (0.2)	29 (0.2)	66 (0.2)
Mild	28 (0.2)	24 (0.2)	52 (0.2)
Moderate	9 (<0.1)	5 (<0.1)	14 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Foot fracture	23 (0.2)	23 (0.2)	46 (0.2)
Mild	8 (<0.1)	6 (<0.1)	14 (<0.1)
Moderate	11 (<0.1)	16 (0.1)	27 (<0.1)
Severe	4 (<0.1)	1 (<0.1)	5 (<0.1)
Limb injury	17 (0.1)	20 (0.1)	37 (0.1)
Mild	8 (<0.1)	9 (<0.1)	17 (<0.1)
Moderate	8 (<0.1)	8 (<0.1)	16 (<0.1)
Severe	1 (<0.1)	3 (<0.1)	4 (<0.1)
Animal bite	18 (0.1)	18 (0.1)	36 (0.1)
Mild	7 (<0.1)	8 (<0.1)	15 (<0.1)
Moderate	10 (<0.1)	9 (<0.1)	19 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Meniscus injury	21 (0.1)	18 (0.1)	39 (0.1)
Mild	7 (<0.1)	4 (<0.1)	11 (<0.1)
Moderate	12 (<0.1)	13 (<0.1)	25 (<0.1)
Severe	2 (<0.1)	1 (<0.1)	3 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Road traffic accident	14 (<0.1)	16 (0.1)	30 (<0.1)
Mild	5 (<0.1)	6 (<0.1)	11 (<0.1)
Moderate	6 (<0.1)	8 (<0.1)	14 (<0.1)
Severe	3 (<0.1)	1 (<0.1)	4 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Joint injury	9 (<0.1)	15 (<0.1)	24 (<0.1)
Mild	2 (<0.1)	7 (<0.1)	9 (<0.1)
Moderate	5 (<0.1)	7 (<0.1)	12 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Skin abrasion	31 (0.2)	15 (<0.1)	46 (0.2)
Mild	23 (0.2)	14 (<0.1)	37 (0.1)
Moderate	8 (<0.1)	1 (<0.1)	9 (<0.1)
Severe	0	0	0
Rib fracture	9 (<0.1)	11 (<0.1)	20 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	5 (<0.1)	8 (<0.1)	13 (<0.1)
Severe	3 (<0.1)	2 (<0.1)	5 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Arthropod sting	18 (0.1)	10 (<0.1)	28 (<0.1)
Mild	11 (<0.1)	8 (<0.1)	19 (<0.1)
Moderate	7 (<0.1)	2 (<0.1)	9 (<0.1)
Severe	0	0	0
Concussion	5 (<0.1)	10 (<0.1)	15 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	3 (<0.1)	5 (<0.1)	8 (<0.1)
Severe	0	2 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Post-traumatic pain	13 (<0.1)	10 (<0.1)	23 (<0.1)
Mild	4 (<0.1)	6 (<0.1)	10 (<0.1)
Moderate	8 (<0.1)	4 (<0.1)	12 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Head injury	2 (<0.1)	9 (<0.1)	11 (<0.1)
Mild	0	4 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Facial bones fracture	1 (<0.1)	8 (<0.1)	9 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	3 (<0.1)	3 (<0.1)
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Thermal burn	3 (<0.1)	6 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	4 (<0.1)	6 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Ankle fracture	10 (<0.1)	5 (<0.1)	15 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	6 (<0.1)	2 (<0.1)	8 (<0.1)
Severe	2 (<0.1)	2 (<0.1)	4 (<0.1)
Bone contusion	8 (<0.1)	5 (<0.1)	13 (<0.1)
Mild	5 (<0.1)	1 (<0.1)	6 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Clavicle fracture	1 (<0.1)	5 (<0.1)	6 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Corneal abrasion	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	4 (<0.1)	4 (<0.1)	8 (<0.1)
Severe	0	0	0
Epicondylitis	6 (<0.1)	5 (<0.1)	11 (<0.1)
Mild	4 (<0.1)	4 (<0.1)	8 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Hand fracture	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	3 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Humerus fracture	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	3 (<0.1)	1 (<0.1)	4 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	2 (<0.1)	2 (<0.1)
Joint dislocation	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Ligament rupture	5 (<0.1)	5 (<0.1)	10 (<0.1)
Mild	2 (<0.1)	3 (<0.1)	5 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	0	0
Muscle rupture	4 (<0.1)	5 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	4 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Stress fracture	8 (<0.1)	5 (<0.1)	13 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	6 (<0.1)	4 (<0.1)	10 (<0.1)
Severe	0	0	0
Upper limb fracture	2 (<0.1)	5 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	4 (<0.1)	5 (<0.1)
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Back injury	5 (<0.1)	4 (<0.1)	9 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	3 (<0.1)	4 (<0.1)	7 (<0.1)
Severe	0	0	0
Cartilage injury	5 (<0.1)	4 (<0.1)	9 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Dental restoration failure	3 (<0.1)	4 (<0.1)	7 (<0.1)
Mild	1 (<0.1)	3 (<0.1)	4 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Wrist fracture	6 (<0.1)	4 (<0.1)	10 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	3 (<0.1)	2 (<0.1)	5 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Alcohol poisoning	0	3 (<0.1)	3 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Craniocerebral injury	0	3 (<0.1)	3 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Hip fracture	3 (<0.1)	3 (<0.1)	6 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	3 (<0.1)	2 (<0.1)	5 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Inappropriate schedule of product administration	4 (<0.1)	3 (<0.1)	7 (<0.1)
Mild	4 (<0.1)	3 (<0.1)	7 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Subdural haematoma	0	3 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	2 (<0.1)	2 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Tendon injury	2 (<0.1)	3 (<0.1)	5 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Tendon rupture	9 (<0.1)	3 (<0.1)	12 (<0.1)
Mild	3 (<0.1)	1 (<0.1)	4 (<0.1)
Moderate	5 (<0.1)	1 (<0.1)	6 (<0.1)
Severe	1 (<0.1)	0	1 (<0.1)
Missing	0	1 (<0.1)	1 (<0.1)
Cervical vertebral fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	0	2 (<0.1)	2 (<0.1)
Exposure to SARS-CoV-2	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	3 (<0.1)	2 (<0.1)	5 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Heat exhaustion	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Hypobarism	0	2 (<0.1)	2 (<0.1)
Mild	0	2 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Ligament injury	2 (<0.1)	2 (<0.1)	4 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Lip injury	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Lower limb fracture	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post procedural haemorrhage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Procedural nausea	4 (<0.1)	2 (<0.1)	6 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Skin wound	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	2 (<0.1)	4 (<0.1)
Severe	0	0	0
Spinal compression fracture	0	2 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	2 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Vaccination complication	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Wound	7 (<0.1)	2 (<0.1)	9 (<0.1)
Mild	5 (<0.1)	2 (<0.1)	7 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Animal scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Bone fragmentation	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Burns first degree	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Burns second degree	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Carbon monoxide poisoning	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Chemical burn	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Chemical burns of eye	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Chillblains	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Deep vein thrombosis postoperative	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Dislocation of vertebra	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Dural tear	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eyelid injury	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Face injury	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Femoral neck fracture	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Femur fracture	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	1 (<0.1)	1 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Foreign body in respiratory tract	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Fractured sacrum	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Gastrointestinal procedural complication	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Graft complication	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Incarcerated incisional hernia	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Incision site pain	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Incision site rash	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Injection related reaction	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Injury	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Limb traumatic amputation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Meniscus cyst	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Multiple fractures	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Muscle hernia	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nasal injury	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Neck injury	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Overdose	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Pelvic fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Periorbital haematoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Post procedural fever	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Post procedural haematoma	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Post procedural swelling	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Procedural haemorrhage	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Missing	1 (<0.1)	0	1 (<0.1)
Procedural headache	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Procedural site reaction	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Product administration interrupted	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Radius fracture	6 (<0.1)	1 (<0.1)	7 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	6 (<0.1)	0	6 (<0.1)
Severe	0	0	0
Respiratory fume inhalation disorder	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Scar	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Scratch	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Spinal column injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0
Splinter	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sports injury	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	1 (<0.1)	2 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Stab wound	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Sunburn	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	2 (<0.1)	1 (<0.1)	3 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Superficial injury of eye	2 (<0.1)	1 (<0.1)	3 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	1 (<0.1)	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	1 (<0.1)	2 (<0.1)
Tooth injury	3 (<0.1)	1 (<0.1)	4 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	1 (<0.1)	3 (<0.1)
Severe	0	0	0
Traumatic haemorrhage	0	1 (<0.1)	1 (<0.1)
Mild	0	1 (<0.1)	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Traumatic liver injury	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Uterine rupture	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Wound dehiscence	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	0	1 (<0.1)	1 (<0.1)
Anaemia postoperative	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Buttock injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Exposure to toxic agent	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eye injury	2 (<0.1)	0	2 (<0.1)
Mild	2 (<0.1)	0	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Eyelid contusion	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Foreign body	3 (<0.1)	0	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	2 (<0.1)	0	2 (<0.1)
Foreign body in ear	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Fractured coccyx	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Gingival injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Gun shot wound	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Immunisation anxiety related reaction	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Incision site inflammation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Keratorhexis	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Mallet finger	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Mouth injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Multiple injuries	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Muscle injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Musculoskeletal foreign body	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Nail injury	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Phrenic nerve injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Post procedural bile leak	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Post procedural constipation	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Post procedural contusion	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Post procedural hypothyroidism	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Procedural anxiety	2 (<0.1)	0	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Procedural complication	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Procedural vomiting	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Pulmonary contusion	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Repetitive strain injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Scapula fracture	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)
Skeletal injury	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sternal fracture	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Tracheal haemorrhage	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Traumatic haemothorax	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Trunk injury	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Ulna fracture	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)			
Ulnar nerve injury	2 (<0.1)	0	2 (<0.1)
Mild	0	0	0
Moderate	2 (<0.1)	0	2 (<0.1)
Severe	0	0	0
Uterine perforation	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0
Venomous sting	1 (<0.1)	0	1 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Social circumstances	3 (<0.1)	2 (<0.1)	5 (<0.1)
Mild	2 (<0.1)	2 (<0.1)	4 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Social circumstances (Cont.)			
Menopause	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Postmenopause	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	1 (<0.1)	2 (<0.1)
Moderate	0	0	0
Severe	0	0	0
Sexual abuse	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	0	0	0
Severe	0	0	0
Missing	1 (<0.1)	0	1 (<0.1)
Product issues	3 (<0.1)	5 (<0.1)	8 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	2 (<0.1)	5 (<0.1)	7 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Product issues (Cont.)			
Device breakage	1 (<0.1)	2 (<0.1)	3 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	2 (<0.1)	3 (<0.1)
Severe	0	0	0
Device dislocation	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Device physical property issue	1 (<0.1)	1 (<0.1)	2 (<0.1)
Mild	1 (<0.1)	0	1 (<0.1)
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0
Embedded device	0	1 (<0.1)	1 (<0.1)
Mild	0	0	0
Moderate	0	1 (<0.1)	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
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Table 14.3.1.10.1.3
Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term and Severity in Overall Stage
Safety Set

System Organ Class Preferred Term Toxicity Grade	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Product issues (Cont.)			
Lead dislodgement	1 (<0.1)	0	1 (<0.1)
Mild	0	0	0
Moderate	1 (<0.1)	0	1 (<0.1)
Severe	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301100103.sas 22JUN2021 09:10

Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1236 (8.2)	2067 (13.6)		3303 (10.9)
Number of Unsolicited Adverse Events	2220	3704		5924
Infections and infestations	18 (0.1)	23 (0.2)		41 (0.1)
Suspected COVID-19	0	4 (<0.1)		4 (<0.1)
Viral infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Conjunctivitis	0	2 (<0.1)		2 (<0.1)
Herpes zoster	0	2 (<0.1)		2 (<0.1)
Injection site cellulitis	0	2 (<0.1)		2 (<0.1)
Oral herpes	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinusitis	0	2 (<0.1)		2 (<0.1)
COVID-19	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Gingivitis	1 (<0.1)	0		1 (<0.1)
Herpes simplex	1 (<0.1)	0		1 (<0.1)
Onychomycosis	1 (<0.1)	0		1 (<0.1)
Rhinitis	3 (<0.1)	0		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Rhinovirus infection	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	6 (<0.1)	0		6 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	99 (0.7)	225 (1.5)		324 (1.1)
Lymphadenopathy	92 (0.6)	215 (1.4)	2.33 (1.83, 2.97)	307 (1.0)
Lymph node pain	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Lymphadenitis	0	3 (<0.1)		3 (<0.1)
Anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Immune system disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Hypersensitivity	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	7 (<0.1)		10 (<0.1)
Decreased appetite	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	0	1 (<0.1)		1 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	2 (<0.1)	15 (<0.1)		17 (<0.1)
Insomnia	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Abnormal dreams	1 (<0.1)	3 (<0.1)		4 (<0.1)
Sleep disorder	0	2 (<0.1)		2 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	343 (2.3)	525 (3.5)		868 (2.9)
Headache	302 (2.0)	439 (2.9)	1.45 (1.26, 1.68)	741 (2.4)
Dizziness	13 (<0.1)	28 (0.2)	2.15 (1.13, 4.10)	41 (0.1)
Paraesthesia	9 (<0.1)	14 (<0.1)	1.55 (0.69, 3.51)	23 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Dysgeusia	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Hyperaesthesia	0	5 (<0.1)		5 (<0.1)
Hypoaesthesia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Migraine	5 (<0.1)	4 (<0.1)		9 (<0.1)
Disturbance in attention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Syncope	0	3 (<0.1)		3 (<0.1)
Ageusia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)
Memory impairment	0	2 (<0.1)		2 (<0.1)
Mental impairment	0	2 (<0.1)		2 (<0.1)
Sinus headache	0	2 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	2 (<0.1)		4 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Presyncope	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sciatica	0	1 (<0.1)		1 (<0.1)
Anosmia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)
Eye disorders	4 (<0.1)	7 (<0.1)		11 (<0.1)
Vision blurred	0	2 (<0.1)		2 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Photophobia	0	1 (<0.1)		1 (<0.1)
Visual impairment	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	0	1 (<0.1)		1 (<0.1)
Eye pruritus	1 (<0.1)	0		1 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	7 (<0.1)	11 (<0.1)		18 (<0.1)
Tinnitus	1 (<0.1)	5 (<0.1)		6 (<0.1)
Vertigo	4 (<0.1)	3 (<0.1)		7 (<0.1)
Deafness neurosensory	0	1 (<0.1)		1 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Vertigo positional	0	1 (<0.1)		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Ear pain	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	4 (<0.1)	9 (<0.1)		13 (<0.1)
Tachycardia	0	4 (<0.1)		4 (<0.1)
Sinus tachycardia	0	3 (<0.1)		3 (<0.1)
Angina pectoris	0	1 (<0.1)		1 (<0.1)
Palpitations	0	1 (<0.1)		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Bradycardia	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders	17 (0.1)	22 (0.1)		39 (0.1)
Hypertension	12 (<0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Hot flush	3 (<0.1)	6 (<0.1)		9 (<0.1)
Flushing	1 (<0.1)	4 (<0.1)		5 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	42 (0.3)	55 (0.4)		97 (0.3)
Nasal congestion	9 (<0.1)	21 (0.1)	2.33 (1.09, 4.99)	30 (<0.1)
Cough	5 (<0.1)	13 (<0.1)	2.60 (0.96, 6.99)	18 (<0.1)
Rhinorrhoea	8 (<0.1)	13 (<0.1)	1.62 (0.69, 3.81)	21 (<0.1)
Oropharyngeal pain	14 (<0.1)	11 (<0.1)	0.78 (0.36, 1.69)	25 (<0.1)
Dyspnoea	4 (<0.1)	5 (<0.1)		9 (<0.1)
Throat irritation	2 (<0.1)	3 (<0.1)		5 (<0.1)
Asthma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus congestion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Tachypnoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Upper-airway cough syndrome	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Dysphonia	2 (<0.1)	0		2 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Productive cough	2 (<0.1)	0		2 (<0.1)
Rhinitis allergic	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	117 (0.8)	149 (1.0)		266 (0.9)
Nausea	57 (0.4)	78 (0.5)	1.37 (0.97, 1.92)	135 (0.4)
Diarrhoea	32 (0.2)	44 (0.3)	1.37 (0.87, 2.16)	76 (0.3)
Vomiting	17 (0.1)	22 (0.1)	1.29 (0.69, 2.41)	39 (0.1)
Abdominal pain	2 (<0.1)	6 (<0.1)		8 (<0.1)
Abdominal pain upper	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dyspepsia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastrooesophageal reflux disease	0	3 (<0.1)		3 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	2 (<0.1)		2 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Abdominal discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Aphthous ulcer	0	1 (<0.1)		1 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Dry mouth	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Toothache	0	1 (<0.1)		1 (<0.1)
Constipation	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival pain	1 (<0.1)	0		1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	0		1 (<0.1)
Paraesthesia oral	4 (<0.1)	0		4 (<0.1)
Salivary hypersecretion	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	39 (0.3)	93 (0.6)		132 (0.4)
Urticaria	7 (<0.1)	22 (0.1)	3.14 (1.37, 7.17)	29 (<0.1)
Rash	3 (<0.1)	11 (<0.1)	3.66 (1.10, 12.19)	14 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Erythema	0	9 (<0.1)		9 (<0.1)
Hyperhidrosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Pruritus	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Night sweats	3 (<0.1)	6 (<0.1)		9 (<0.1)
Rash maculo-papular	0	5 (<0.1)		5 (<0.1)
Rash pruritic	2 (<0.1)	4 (<0.1)		6 (<0.1)
Rash macular	0	3 (<0.1)		3 (<0.1)
Skin burning sensation	0	3 (<0.1)		3 (<0.1)
Alopecia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angioedema	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Dermatitis atopic	0	1 (<0.1)		1 (<0.1)
Lichen planus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Rash papular	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin warm	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Dermatitis contact	2 (<0.1)	0		2 (<0.1)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	398 (2.6)	458 (3.0)		856 (2.8)
Myalgia	256 (1.7)	282 (1.9)	1.10 (0.93, 1.30)	538 (1.8)
Arthralgia	257 (1.7)	267 (1.8)	1.04 (0.88, 1.23)	524 (1.7)
Pain in extremity	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Neck pain	1 (<0.1)	11 (<0.1)	10.98 (1.82, 66.17)	12 (<0.1)
Back pain	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Musculoskeletal pain	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Muscle spasms	4 (<0.1)	5 (<0.1)		9 (<0.1)
Joint range of motion decreased	0	4 (<0.1)		4 (<0.1)
Limb discomfort	0	3 (<0.1)		3 (<0.1)
Musculoskeletal stiffness	5 (<0.1)	3 (<0.1)		8 (<0.1)
Tendonitis	0	3 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Bone pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Muscular weakness	1 (<0.1)	2 (<0.1)		3 (<0.1)
Axillary mass	0	1 (<0.1)		1 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flank pain	0	1 (<0.1)		1 (<0.1)
Joint stiffness	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Osteoarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Trigger finger	0	1 (<0.1)		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Muscle tightness	1 (<0.1)	0		1 (<0.1)
Muscle twitching	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	0	1 (<0.1)		1 (<0.1)
Chromaturia	0	1 (<0.1)		1 (<0.1)
Reproductive system and breast disorders	4 (<0.1)	4 (<0.1)		8 (<0.1)
Menorrhagia	0	2 (<0.1)		2 (<0.1)
Erectile dysfunction	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	0		2 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)
Menstruation irregular	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	674 (4.4)	1251 (8.2)		1925 (6.3)
Fatigue	457 (3.0)	569 (3.7)	1.24 (1.10, 1.40)	1026 (3.4)
Injection site pain	95 (0.6)	224 (1.5)	2.35 (1.86, 2.99)	319 (1.1)
Injection site erythema	37 (0.2)	147 (1.0)	3.97 (2.77, 5.67)	184 (0.6)
Injection site swelling	28 (0.2)	111 (0.7)	3.96 (2.62, 5.97)	139 (0.5)
Chills	43 (0.3)	81 (0.5)	1.88 (1.30, 2.72)	124 (0.4)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site pruritus	12 (<0.1)	80 (0.5)	6.66 (3.66, 12.10)	92 (0.3)
Pyrexia	16 (0.1)	67 (0.4)	4.18 (2.44, 7.16)	83 (0.3)
Injection site lymphadenopathy	11 (<0.1)	59 (0.4)	5.36 (2.85, 10.08)	70 (0.2)
Injection site induration	18 (0.1)	51 (0.3)	2.83 (1.66, 4.81)	69 (0.2)
Injection site macule	4 (<0.1)	39 (0.3)	9.74 (3.63, 26.15)	43 (0.1)
Injection site urticaria	1 (<0.1)	34 (0.2)	33.95 (5.87, 196.28)	35 (0.1)
Pain	10 (<0.1)	25 (0.2)	2.50 (1.22, 5.12)	35 (0.1)
Injection site rash	1 (<0.1)	21 (0.1)	20.97 (3.58, 122.74)	22 (<0.1)
Axillary pain	6 (<0.1)	19 (0.1)	3.16 (1.30, 7.69)	25 (<0.1)
Injection site papule	1 (<0.1)	12 (<0.1)	11.98 (2.00, 71.83)	13 (<0.1)
Malaise	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Injection site bruising	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Reactogenicity event	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site paraesthesia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)		6 (<0.1)
Injection site haemorrhage	1 (<0.1)	4 (<0.1)		5 (<0.1)
Peripheral swelling	2 (<0.1)	4 (<0.1)		6 (<0.1)
Chest discomfort	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site mass	1 (<0.1)	3 (<0.1)		4 (<0.1)
Non-cardiac chest pain	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Vaccination site pain	0	3 (<0.1)		3 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site haematoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenderness	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Chest pain	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	0	1 (<0.1)		1 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Vaccination site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	0	1 (<0.1)		1 (<0.1)
Asthenia	4 (<0.1)	0		4 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Investigations	7 (<0.1)	15 (<0.1)		22 (<0.1)
Body temperature increased	0	4 (<0.1)		4 (<0.1)
Blood pressure increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood pressure systolic increased	0	2 (<0.1)		2 (<0.1)
Heart rate increased	0	2 (<0.1)		2 (<0.1)
C-reactive protein increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.11.1.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	9 (<0.1)	5 (<0.1)		14 (<0.1)
Contusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Foot fracture	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Tooth fracture	0	1 (<0.1)		1 (<0.1)
Fall	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Wrist fracture	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	945 (8.3)	1580 (13.8)		2525 (11.1)
Number of Unsolicited Adverse Events	1713	2858		4571
Infections and infestations	15 (0.1)	17 (0.1)		32 (0.1)
Suspected COVID-19	0	4 (<0.1)		4 (<0.1)
Viral infection	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site cellulitis	0	2 (<0.1)		2 (<0.1)
Oral herpes	0	2 (<0.1)		2 (<0.1)
Sinusitis	0	2 (<0.1)		2 (<0.1)
Conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Gingivitis	1 (<0.1)	0		1 (<0.1)
Herpes simplex	1 (<0.1)	0		1 (<0.1)
Onychomycosis	1 (<0.1)	0		1 (<0.1)
Rhinitis	2 (<0.1)	0		2 (<0.1)
Rhinovirus infection	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	5 (<0.1)	0		5 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Blood and lymphatic system disorders	92 (0.8)	208 (1.8)		300 (1.3)
Lymphadenopathy	86 (0.8)	200 (1.8)	2.32 (1.81, 2.99)	286 (1.3)
Lymph node pain	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Lymphadenitis	0	2 (<0.1)		2 (<0.1)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Immune system disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Hypersensitivity	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	5 (<0.1)		8 (<0.1)
Decreased appetite	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	0	1 (<0.1)		1 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	1 (<0.1)	10 (<0.1)		11 (<0.1)
Insomnia	1 (<0.1)	6 (<0.1)		7 (<0.1)
Abnormal dreams	0	3 (<0.1)		3 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Sleep disorder	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	278 (2.4)	425 (3.7)		703 (3.1)
Headache	247 (2.2)	357 (3.1)	1.44 (1.23, 1.70)	604 (2.6)
Dizziness	9 (<0.1)	19 (0.2)	2.11 (0.97, 4.57)	28 (0.1)
Paraesthesia	8 (<0.1)	13 (0.1)	1.62 (0.69, 3.82)	21 (<0.1)
Dysgeusia	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Hyperaesthesia	0	4 (<0.1)		4 (<0.1)
Migraine	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hypoaesthesia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Syncope	0	3 (<0.1)		3 (<0.1)
Ageusia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)
Disturbance in attention	2 (<0.1)	2 (<0.1)		4 (<0.1)
Mental impairment	0	2 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Presyncope	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sciatica	0	1 (<0.1)		1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anosmia	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)
Eye disorders	3 (<0.1)	5 (<0.1)		8 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Photophobia	0	1 (<0.1)		1 (<0.1)
Vision blurred	0	1 (<0.1)		1 (<0.1)
Visual impairment	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	0	1 (<0.1)		1 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Ear and labyrinth disorders	5 (<0.1)	7 (<0.1)		12 (<0.1)
Tinnitus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Vertigo	2 (<0.1)	2 (<0.1)		4 (<0.1)
Deafness neurosensory	0	1 (<0.1)		1 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Ear pain	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	1 (<0.1)	8 (<0.1)		9 (<0.1)
Tachycardia	0	4 (<0.1)		4 (<0.1)
Sinus tachycardia	0	2 (<0.1)		2 (<0.1)
Angina pectoris	0	1 (<0.1)		1 (<0.1)
Palpitations	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	7 (<0.1)	12 (0.1)		19 (<0.1)
Hypertension	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hot flush	2 (<0.1)	3 (<0.1)		5 (<0.1)
Flushing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders	30 (0.3)	48 (0.4)		78 (0.3)
Nasal congestion	6 (<0.1)	19 (0.2)	3.17 (1.30, 7.69)	25 (0.1)
Cough	3 (<0.1)	12 (0.1)	4.00 (1.21, 13.18)	15 (<0.1)
Rhinorrhoea	2 (<0.1)	10 (<0.1)	5.00 (1.23, 20.28)	12 (<0.1)
Oropharyngeal pain	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Dyspnoea	3 (<0.1)	5 (<0.1)		8 (<0.1)
Throat irritation	1 (<0.1)	3 (<0.1)		4 (<0.1)
Asthma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus congestion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Upper-airway cough syndrome	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Dysphonia	1 (<0.1)	0		1 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Productive cough	1 (<0.1)	0		1 (<0.1)
Rhinitis allergic	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders	90 (0.8)	115 (1.0)		205 (0.9)
Nausea	46 (0.4)	63 (0.6)	1.37 (0.94, 2.00)	109 (0.5)
Diarrhoea	20 (0.2)	35 (0.3)	1.75 (1.02, 3.01)	55 (0.2)
Vomiting	17 (0.1)	18 (0.2)	1.06 (0.55, 2.03)	35 (0.2)
Abdominal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Dyspepsia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gastrooesophageal reflux disease	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	2 (<0.1)		2 (<0.1)
Abdominal discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abdominal pain upper	2 (<0.1)	1 (<0.1)		3 (<0.1)
Aphthous ulcer	0	1 (<0.1)		1 (<0.1)
Dry mouth	0	1 (<0.1)		1 (<0.1)
Lip swelling	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Toothache	0	1 (<0.1)		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	0		1 (<0.1)
Paraesthesia oral	3 (<0.1)	0		3 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	33 (0.3)	71 (0.6)		104 (0.5)
Urticaria	6 (<0.1)	16 (0.1)	2.67 (1.08, 6.60)	22 (<0.1)
Rash	3 (<0.1)	11 (<0.1)	3.67 (1.10, 12.20)	14 (<0.1)
Hyperhidrosis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Pruritus	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.78)	17 (<0.1)
Night sweats	2 (<0.1)	5 (<0.1)		7 (<0.1)
Erythema	0	4 (<0.1)		4 (<0.1)
Rash maculo-papular	0	4 (<0.1)		4 (<0.1)
Skin burning sensation	0	3 (<0.1)		3 (<0.1)
Alopecia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angioedema	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Rash pruritic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis atopic	0	1 (<0.1)		1 (<0.1)
Lichen planus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash papular	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Dermatitis contact	1 (<0.1)	0		1 (<0.1)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	303 (2.7)	328 (2.9)		631 (2.8)
Myalgia	201 (1.8)	209 (1.8)	1.04 (0.86, 1.26)	410 (1.8)
Arthralgia	193 (1.7)	186 (1.6)	0.96 (0.79, 1.18)	379 (1.7)
Neck pain	1 (<0.1)	10 (<0.1)	10.00 (1.65, 60.58)	11 (<0.1)
Pain in extremity	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Musculoskeletal pain	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Back pain	4 (<0.1)	5 (<0.1)		9 (<0.1)
Joint range of motion decreased	0	3 (<0.1)		3 (<0.1)
Limb discomfort	0	3 (<0.1)		3 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Muscle spasms	3 (<0.1)	3 (<0.1)		6 (<0.1)
Musculoskeletal stiffness	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bone pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tendonitis	0	2 (<0.1)		2 (<0.1)
Axillary mass	0	1 (<0.1)		1 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Osteoarthritis	0	1 (<0.1)		1 (<0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	1 (<0.1)	0		1 (<0.1)
Muscle tightness	1 (<0.1)	0		1 (<0.1)
Muscle twitching	1 (<0.1)	0		1 (<0.1)
Muscular weakness	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Renal and urinary disorders	0	1 (<0.1)		1 (<0.1)
Chromaturia	0	1 (<0.1)		1 (<0.1)
Reproductive system and breast disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Menorrhagia	0	2 (<0.1)		2 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	0		2 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)
Menstruation irregular	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	508 (4.5)	945 (8.3)		1453 (6.4)
Fatigue	357 (3.1)	425 (3.7)	1.19 (1.04, 1.37)	782 (3.4)
Injection site pain	71 (0.6)	173 (1.5)	2.44 (1.85, 3.20)	244 (1.1)
Injection site erythema	22 (0.2)	95 (0.8)	4.32 (2.73, 6.83)	117 (0.5)
Injection site swelling	18 (0.2)	81 (0.7)	4.50 (2.72, 7.45)	99 (0.4)
Chills	32 (0.3)	68 (0.6)	2.12 (1.40, 3.22)	100 (0.4)
Injection site pruritus	10 (<0.1)	60 (0.5)	6.00 (3.11, 11.57)	70 (0.3)
Injection site lymphadenopathy	11 (<0.1)	52 (0.5)	4.73 (2.49, 8.95)	63 (0.3)
Pyrexia	10 (<0.1)	50 (0.4)	5.00 (2.57, 9.73)	60 (0.3)
Injection site induration	11 (<0.1)	43 (0.4)	3.91 (2.04, 7.49)	54 (0.2)
Injection site macule	3 (<0.1)	26 (0.2)	8.66 (2.79, 26.91)	29 (0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Injection site urticaria	0	23 (0.2)		23 (0.1)
Axillary pain	5 (<0.1)	17 (0.1)	3.40 (1.30, 8.87)	22 (<0.1)
Pain	8 (<0.1)	17 (0.1)	2.12 (0.94, 4.81)	25 (0.1)
Injection site rash	1 (<0.1)	16 (0.1)	15.99 (2.71, 94.56)	17 (<0.1)
Injection site papule	1 (<0.1)	11 (<0.1)	11.00 (1.83, 66.25)	12 (<0.1)
Malaise	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.26)	11 (<0.1)
Reactogenicity event	0	7 (<0.1)		7 (<0.1)
Injection site bruising	6 (<0.1)	6 (<0.1)		12 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Injection site paraesthesia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site joint pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Peripheral swelling	2 (<0.1)	4 (<0.1)		6 (<0.1)
Chest discomfort	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site haemorrhage	0	3 (<0.1)		3 (<0.1)
Injection site warmth	1 (<0.1)	3 (<0.1)		4 (<0.1)
Non-cardiac chest pain	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Feeling abnormal	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site irritation	0	2 (<0.1)		2 (<0.1)
Injection site mass	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenderness	0	2 (<0.1)		2 (<0.1)
Vaccination site pain	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Chest pain	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site haematoma	0	1 (<0.1)		1 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	0	1 (<0.1)		1 (<0.1)
Asthenia	3 (<0.1)	0		3 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Investigations	6 (<0.1)	9 (<0.1)		15 (<0.1)
Body temperature increased	0	3 (<0.1)		3 (<0.1)
Blood pressure increased	3 (<0.1)	2 (<0.1)		5 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)		1 (<0.1)
Heart rate increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	6 (<0.1)	4 (<0.1)		10 (<0.1)
Contusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Foot fracture	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	291 (7.8)	487 (12.9)		778 (10.3)
Number of Unsolicited Adverse Events	507	846		1353
Infections and infestations	3 (<0.1)	6 (0.2)		9 (0.1)
Herpes zoster	0	2 (<0.1)		2 (<0.1)
COVID-19	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Oral herpes	1 (<0.1)	0		1 (<0.1)
Rhinitis	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	7 (0.2)	17 (0.5)		24 (0.3)
Lymphadenopathy	6 (0.2)	15 (0.4)	2.49 (1.00, 6.20)	21 (0.3)
Anaemia	0	1 (<0.1)		1 (<0.1)
Lymphadenitis	0	1 (<0.1)		1 (<0.1)
Lymph node pain	1 (<0.1)	0		1 (<0.1)
Immune system disorders	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	0	2 (<0.1)		2 (<0.1)
Decreased appetite	0	2 (<0.1)		2 (<0.1)
Psychiatric disorders	1 (<0.1)	5 (0.1)		6 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Insomnia	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Sleep disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Abnormal dreams	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	65 (1.7)	100 (2.7)		165 (2.2)
Headache	55 (1.5)	82 (2.2)	1.48 (1.06, 2.08)	137 (1.8)
Dizziness	4 (0.1)	9 (0.2)	2.24 (0.73, 6.85)	13 (0.2)
Hypoaesthesia	0	2 (<0.1)		2 (<0.1)
Sinus headache	0	2 (<0.1)		2 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Disturbance in attention	0	1 (<0.1)		1 (<0.1)
Dysgeusia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Taste disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Vision blurred	0	1 (<0.1)		1 (<0.1)
Eye pruritus	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (<0.1)	4 (0.1)		6 (<0.1)
Tinnitus	0	2 (<0.1)		2 (<0.1)
Vertigo	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vertigo positional	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders	3 (<0.1)	1 (<0.1)		4 (<0.1)
Sinus tachycardia	0	1 (<0.1)		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Bradycardia	1 (<0.1)	0		1 (<0.1)
Vascular disorders	10 (0.3)	10 (0.3)		20 (0.3)
Hypertension	8 (0.2)	5 (0.1)	0.62 (0.21, 1.80)	13 (0.2)
Hot flush	1 (<0.1)	3 (<0.1)		4 (<0.1)
Flushing	0	2 (<0.1)		2 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	12 (0.3)	7 (0.2)		19 (0.3)
Oropharyngeal pain	5 (0.1)	4 (0.1)		9 (0.1)
Rhinorrhoea	6 (0.2)	3 (<0.1)		9 (0.1)
Nasal congestion	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cough	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dysphonia	1 (<0.1)	0		1 (<0.1)
Dyspnoea	1 (<0.1)	0		1 (<0.1)
Productive cough	1 (<0.1)	0		1 (<0.1)
Tachypnoea	1 (<0.1)	0		1 (<0.1)
Throat irritation	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders	27 (0.7)	34 (0.9)		61 (0.8)
Nausea	11 (0.3)	15 (0.4)	1.36 (0.64, 2.90)	26 (0.3)
Diarrhoea	12 (0.3)	9 (0.2)	0.75 (0.32, 1.73)	21 (0.3)
Vomiting	0	4 (0.1)		4 (<0.1)
Abdominal pain	0	2 (<0.1)		2 (<0.1)
Abdominal pain upper	0	2 (<0.1)		2 (<0.1)
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Gastrooesophageal reflux disease	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Constipation	1 (<0.1)	0		1 (<0.1)
Gingival pain	1 (<0.1)	0		1 (<0.1)
Paraesthesia oral	1 (<0.1)	0		1 (<0.1)
Salivary hypersecretion	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	6 (0.2)	22 (0.6)		28 (0.4)
Urticaria	1 (<0.1)	6 (0.2)		7 (<0.1)
Erythema	0	5 (0.1)		5 (<0.1)
Hyperhidrosis	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Pruritus	3 (<0.1)	2 (<0.1)		5 (<0.1)
Rash macular	0	2 (<0.1)		2 (<0.1)
Rash pruritic	0	2 (<0.1)		2 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Night sweats	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash maculo-papular	0	1 (<0.1)		1 (<0.1)
Dermatitis contact	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	95 (2.5)	130 (3.4)		225 (3.0)
Arthralgia	64 (1.7)	81 (2.1)	1.26 (0.91, 1.74)	145 (1.9)
Myalgia	55 (1.5)	73 (1.9)	1.32 (0.94, 1.87)	128 (1.7)
Pain in extremity	3 (<0.1)	4 (0.1)		7 (<0.1)
Back pain	0	3 (<0.1)		3 (<0.1)
Muscle spasms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Muscular weakness	0	2 (<0.1)		2 (<0.1)
Fibromyalgia	0	1 (<0.1)		1 (<0.1)
Flank pain	0	1 (<0.1)		1 (<0.1)
Joint range of motion decreased	0	1 (<0.1)		1 (<0.1)
Joint stiffness	0	1 (<0.1)		1 (<0.1)
Musculoskeletal pain	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Neck pain	0	1 (<0.1)		1 (<0.1)
Tendonitis	0	1 (<0.1)		1 (<0.1)
Trigger finger	0	1 (<0.1)		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Musculoskeletal stiffness	2 (<0.1)	0		2 (<0.1)
Osteoarthritis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)		1 (<0.1)
Erectile dysfunction	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	166 (4.4)	306 (8.1)		472 (6.3)
Fatigue	100 (2.7)	144 (3.8)	1.43 (1.12, 1.84)	244 (3.2)
Injection site erythema	15 (0.4)	52 (1.4)	3.45 (1.96, 6.07)	67 (0.9)
Injection site pain	24 (0.6)	51 (1.4)	2.11 (1.31, 3.41)	75 (1.0)
Injection site swelling	10 (0.3)	30 (0.8)	2.99 (1.48, 6.01)	40 (0.5)
Injection site pruritus	2 (<0.1)	20 (0.5)	9.95 (2.59, 38.34)	22 (0.3)
Pyrexia	6 (0.2)	17 (0.5)	2.82 (1.15, 6.93)	23 (0.3)
Chills	11 (0.3)	13 (0.3)	1.18 (0.54, 2.57)	24 (0.3)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Injection site macule	1 (<0.1)	13 (0.3)	12.94 (2.17, 77.22)	14 (0.2)
Injection site urticaria	1 (<0.1)	11 (0.3)	10.95 (1.82, 65.95)	12 (0.2)
Injection site induration	7 (0.2)	8 (0.2)	1.14 (0.43, 3.01)	15 (0.2)
Pain	2 (<0.1)	8 (0.2)	3.98 (0.96, 16.56)	10 (0.1)
Injection site lymphadenopathy	0	7 (0.2)		7 (<0.1)
Injection site rash	0	5 (0.1)		5 (<0.1)
Axillary pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site warmth	0	2 (<0.1)		2 (<0.1)
Feeling hot	0	1 (<0.1)		1 (<0.1)
Injection site bruising	3 (<0.1)	1 (<0.1)		4 (<0.1)
Injection site discolouration	0	1 (<0.1)		1 (<0.1)
Injection site haematoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site irritation	0	1 (<0.1)		1 (<0.1)
Injection site joint pain	0	1 (<0.1)		1 (<0.1)
Injection site mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site papule	0	1 (<0.1)		1 (<0.1)
Malaise	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vaccination site pain	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.2
Subject Incidence of Unsolicited Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Injection site paraesthesia	1 (<0.1)	0		1 (<0.1)
Reactogenicity event	1 (<0.1)	0		1 (<0.1)
Investigations	1 (<0.1)	6 (0.2)		7 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)		1 (<0.1)
Body temperature increased	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	0	1 (<0.1)		1 (<0.1)
Heart rate increased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tooth fracture	0	1 (<0.1)		1 (<0.1)
Fall	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Wrist fracture	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1201 (8.1)	2032 (13.8)		3233 (11.0)
Number of Unsolicited Adverse Events	2150	3638		5788
Infections and infestations	18 (0.1)	22 (0.1)		40 (0.1)
Suspected COVID-19	0	4 (<0.1)		4 (<0.1)
Viral infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Conjunctivitis	0	2 (<0.1)		2 (<0.1)
Herpes zoster	0	2 (<0.1)		2 (<0.1)
Injection site cellulitis	0	2 (<0.1)		2 (<0.1)
Oral herpes	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinusitis	0	2 (<0.1)		2 (<0.1)
COVID-19	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Injection site infection	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Gingivitis	1 (<0.1)	0		1 (<0.1)
Herpes simplex	1 (<0.1)	0		1 (<0.1)
Onychomycosis	1 (<0.1)	0		1 (<0.1)
Rhinitis	3 (<0.1)	0		3 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Rhinovirus infection	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	6 (<0.1)	0		6 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	94 (0.6)	223 (1.5)		317 (1.1)
Lymphadenopathy	87 (0.6)	213 (1.4)	2.45 (1.91, 3.13)	300 (1.0)
Lymph node pain	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Lymphadenitis	0	3 (<0.1)		3 (<0.1)
Anaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Immune system disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Hypersensitivity	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	7 (<0.1)		10 (<0.1)
Decreased appetite	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	0	1 (<0.1)		1 (<0.1)
Polydipsia	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	2 (<0.1)	15 (0.1)		17 (<0.1)
Insomnia	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Abnormal dreams	1 (<0.1)	3 (<0.1)		4 (<0.1)
Sleep disorder	0	2 (<0.1)		2 (<0.1)
Affect lability	0	1 (<0.1)		1 (<0.1)
Depressed mood	0	1 (<0.1)		1 (<0.1)
Emotional disorder	0	1 (<0.1)		1 (<0.1)
Hallucination	0	1 (<0.1)		1 (<0.1)
Nightmare	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	328 (2.2)	510 (3.5)		838 (2.8)
Headache	288 (2.0)	425 (2.9)	1.47 (1.27, 1.71)	713 (2.4)
Dizziness	13 (<0.1)	27 (0.2)	2.08 (1.08, 3.98)	40 (0.1)
Paraesthesia	9 (<0.1)	14 (<0.1)	1.55 (0.69, 3.51)	23 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Dysgeusia	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Hyperaesthesia	0	5 (<0.1)		5 (<0.1)
Hypoaesthesia	1 (<0.1)	5 (<0.1)		6 (<0.1)
Disturbance in attention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Migraine	4 (<0.1)	3 (<0.1)		7 (<0.1)
Syncope	0	3 (<0.1)		3 (<0.1)
Ageusia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Burning sensation	0	2 (<0.1)		2 (<0.1)
Memory impairment	0	2 (<0.1)		2 (<0.1)
Mental impairment	0	2 (<0.1)		2 (<0.1)
Sinus headache	0	2 (<0.1)		2 (<0.1)
Somnolence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Taste disorder	2 (<0.1)	2 (<0.1)		4 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Dyslexia	0	1 (<0.1)		1 (<0.1)
Essential tremor	0	1 (<0.1)		1 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Movement disorder	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Parosmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	0	1 (<0.1)		1 (<0.1)
Poor quality sleep	0	1 (<0.1)		1 (<0.1)
Presyncope	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sciatica	0	1 (<0.1)		1 (<0.1)
Anosmia	1 (<0.1)	0		1 (<0.1)
Dysaesthesia	1 (<0.1)	0		1 (<0.1)
Hypogeusia	2 (<0.1)	0		2 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)
Eye disorders	4 (<0.1)	7 (<0.1)		11 (<0.1)
Vision blurred	0	2 (<0.1)		2 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Photophobia	0	1 (<0.1)		1 (<0.1)
Visual impairment	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	0	1 (<0.1)		1 (<0.1)
Eye pruritus	1 (<0.1)	0		1 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)

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up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Periorbital pain	1 (<0.1)	0		1 (<0.1)
Visual acuity reduced	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	7 (<0.1)	11 (<0.1)		18 (<0.1)
Tinnitus	1 (<0.1)	5 (<0.1)		6 (<0.1)
Vertigo	4 (<0.1)	3 (<0.1)		7 (<0.1)
Deafness neurosensory	0	1 (<0.1)		1 (<0.1)
Deafness unilateral	0	1 (<0.1)		1 (<0.1)
Vertigo positional	0	1 (<0.1)		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Ear pain	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	4 (<0.1)	8 (<0.1)		12 (<0.1)
Tachycardia	0	4 (<0.1)		4 (<0.1)
Sinus tachycardia	0	3 (<0.1)		3 (<0.1)
Palpitations	0	1 (<0.1)		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Bradycardia	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	17 (0.1)	22 (0.1)		39 (0.1)
Hypertension	12 (<0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Hot flush	3 (<0.1)	6 (<0.1)		9 (<0.1)
Flushing	1 (<0.1)	4 (<0.1)		5 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Peripheral coldness	0	1 (<0.1)		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	42 (0.3)	55 (0.4)		97 (0.3)
Nasal congestion	9 (<0.1)	21 (0.1)	2.33 (1.09, 5.00)	30 (0.1)
Cough	5 (<0.1)	13 (<0.1)	2.60 (0.97, 6.99)	18 (<0.1)
Rhinorrhoea	8 (<0.1)	13 (<0.1)	1.62 (0.69, 3.82)	21 (<0.1)
Oropharyngeal pain	14 (<0.1)	11 (<0.1)	0.79 (0.36, 1.70)	25 (<0.1)
Dyspnoea	4 (<0.1)	5 (<0.1)		9 (<0.1)
Throat irritation	2 (<0.1)	3 (<0.1)		5 (<0.1)
Asthma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus discomfort	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sinus congestion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoxia	0	1 (<0.1)		1 (<0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Tachypnoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Upper-airway cough syndrome	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Dysphonia	2 (<0.1)	0		2 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Productive cough	2 (<0.1)	0		2 (<0.1)
Rhinitis allergic	1 (<0.1)	0		1 (<0.1)
Tonsillar inflammation	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	114 (0.8)	148 (1.0)		262 (0.9)
Nausea	55 (0.4)	78 (0.5)	1.42 (1.01, 2.00)	133 (0.5)
Diarrhoea	32 (0.2)	43 (0.3)	1.34 (0.85, 2.11)	75 (0.3)
Vomiting	17 (0.1)	22 (0.1)	1.29 (0.69, 2.41)	39 (0.1)
Abdominal pain	1 (<0.1)	6 (<0.1)		7 (<0.1)
Abdominal pain upper	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dyspepsia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Gastrooesophageal reflux disease	0	3 (<0.1)		3 (<0.1)
Chapped lips	0	2 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	2 (<0.1)		2 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swollen tongue	0	2 (<0.1)		2 (<0.1)
Abdominal discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Aphthous ulcer	0	1 (<0.1)		1 (<0.1)

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Gastrointestinal disorders (Cont.)				
Dental paraesthesia	0	1 (<0.1)		1 (<0.1)
Dry mouth	0	1 (<0.1)		1 (<0.1)
Frequent bowel movements	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth discolouration	0	1 (<0.1)		1 (<0.1)
Toothache	0	1 (<0.1)		1 (<0.1)
Constipation	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Gingival discomfort	1 (<0.1)	0		1 (<0.1)
Gingival pain	1 (<0.1)	0		1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	0		1 (<0.1)
Paraesthesia oral	4 (<0.1)	0		4 (<0.1)
Salivary hypersecretion	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	38 (0.3)	91 (0.6)		129 (0.4)
Urticaria	6 (<0.1)	21 (0.1)	3.50 (1.45, 8.42)	27 (<0.1)
Rash	3 (<0.1)	10 (<0.1)	3.33 (0.99, 11.22)	13 (<0.1)
Erythema	0	9 (<0.1)		9 (<0.1)

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Skin and subcutaneous tissue disorders (Cont.)				
Hyperhidrosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Pruritus	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Night sweats	3 (<0.1)	6 (<0.1)		9 (<0.1)
Rash maculo-papular	0	5 (<0.1)		5 (<0.1)
Rash pruritic	2 (<0.1)	4 (<0.1)		6 (<0.1)
Rash macular	0	3 (<0.1)		3 (<0.1)
Skin burning sensation	0	3 (<0.1)		3 (<0.1)
Alopecia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angioedema	0	2 (<0.1)		2 (<0.1)
Macule	0	2 (<0.1)		2 (<0.1)
Pain of skin	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Dermatitis atopic	0	1 (<0.1)		1 (<0.1)
Lichen planus	0	1 (<0.1)		1 (<0.1)
Mechanical urticaria	0	1 (<0.1)		1 (<0.1)
Pityriasis rosea	0	1 (<0.1)		1 (<0.1)
Rash papular	0	1 (<0.1)		1 (<0.1)
Skin warm	0	1 (<0.1)		1 (<0.1)

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Skin and subcutaneous tissue disorders (Cont.)				
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Dermatitis contact	2 (<0.1)	0		2 (<0.1)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Rash vesicular	1 (<0.1)	0		1 (<0.1)
Skin discolouration	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	383 (2.6)	448 (3.0)		831 (2.8)
Myalgia	245 (1.7)	274 (1.9)	1.12 (0.94, 1.33)	519 (1.8)
Arthralgia	249 (1.7)	263 (1.8)	1.06 (0.89, 1.25)	512 (1.7)
Pain in extremity	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Neck pain	1 (<0.1)	11 (<0.1)	10.99 (1.83, 66.23)	12 (<0.1)
Back pain	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Musculoskeletal pain	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Muscle spasms	4 (<0.1)	5 (<0.1)		9 (<0.1)
Joint range of motion decreased	0	4 (<0.1)		4 (<0.1)
Musculoskeletal stiffness	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tendonitis	0	3 (<0.1)		3 (<0.1)
Bone pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Muscular weakness	1 (<0.1)	2 (<0.1)		3 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Axillary mass	0	1 (<0.1)		1 (<0.1)
Bone lesion	0	1 (<0.1)		1 (<0.1)
Bone swelling	0	1 (<0.1)		1 (<0.1)
Costochondritis	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flank pain	0	1 (<0.1)		1 (<0.1)
Joint stiffness	0	1 (<0.1)		1 (<0.1)
Limb discomfort	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myosclerosis	0	1 (<0.1)		1 (<0.1)
Neck mass	0	1 (<0.1)		1 (<0.1)
Osteoarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Trigger finger	0	1 (<0.1)		1 (<0.1)
Muscle discomfort	1 (<0.1)	0		1 (<0.1)
Muscle tightness	1 (<0.1)	0		1 (<0.1)
Muscle twitching	1 (<0.1)	0		1 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders	0	1 (<0.1)		1 (<0.1)
Chromaturia	0	1 (<0.1)		1 (<0.1)
Reproductive system and breast disorders	4 (<0.1)	4 (<0.1)		8 (<0.1)
Menorrhagia	0	2 (<0.1)		2 (<0.1)
Erectile dysfunction	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	0		2 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)
Menstruation irregular	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	654 (4.4)	1234 (8.4)		1888 (6.4)
Fatigue	440 (3.0)	561 (3.8)	1.27 (1.13, 1.44)	1001 (3.4)
Injection site pain	93 (0.6)	219 (1.5)	2.35 (1.85, 2.99)	312 (1.1)
Injection site erythema	37 (0.3)	145 (1.0)	3.92 (2.74, 5.60)	182 (0.6)
Injection site swelling	28 (0.2)	110 (0.7)	3.93 (2.60, 5.92)	138 (0.5)
Chills	40 (0.3)	80 (0.5)	2.00 (1.37, 2.91)	120 (0.4)
Injection site pruritus	12 (<0.1)	80 (0.5)	6.66 (3.67, 12.11)	92 (0.3)
Pyrexia	16 (0.1)	65 (0.4)	4.06 (2.37, 6.97)	81 (0.3)
Injection site lymphadenopathy	11 (<0.1)	58 (0.4)	5.27 (2.80, 9.93)	69 (0.2)
Injection site induration	18 (0.1)	49 (0.3)	2.72 (1.60, 4.64)	67 (0.2)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Injection site macule	4 (<0.1)	39 (0.3)	9.74 (3.63, 26.17)	43 (0.1)
Injection site urticaria	1 (<0.1)	34 (0.2)	33.98 (5.88, 196.44)	35 (0.1)
Pain	10 (<0.1)	25 (0.2)	2.50 (1.22, 5.12)	35 (0.1)
Injection site rash	1 (<0.1)	21 (0.1)	20.99 (3.59, 122.85)	22 (<0.1)
Axillary pain	6 (<0.1)	19 (0.1)	3.16 (1.30, 7.69)	25 (<0.1)
Injection site papule	1 (<0.1)	12 (<0.1)	11.99 (2.00, 71.89)	13 (<0.1)
Malaise	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Injection site bruising	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Reactogenicity event	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Vaccination site swelling	0	6 (<0.1)		6 (<0.1)
Injection site joint pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Injection site paraesthesia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Injection site warmth	1 (<0.1)	5 (<0.1)		6 (<0.1)
Injection site haemorrhage	1 (<0.1)	4 (<0.1)		5 (<0.1)
Peripheral swelling	2 (<0.1)	4 (<0.1)		6 (<0.1)
Chest discomfort	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site irritation	0	3 (<0.1)		3 (<0.1)
Injection site mass	1 (<0.1)	3 (<0.1)		4 (<0.1)
Non-cardiac chest pain	0	3 (<0.1)		3 (<0.1)
Vaccination site erythema	0	3 (<0.1)		3 (<0.1)
Vaccination site pain	0	3 (<0.1)		3 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Feeling abnormal	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site haematoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenderness	0	2 (<0.1)		2 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)
Chest pain	0	1 (<0.1)		1 (<0.1)
Facial discomfort	0	1 (<0.1)		1 (<0.1)
Feeling cold	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Infusion site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site discolouration	0	1 (<0.1)		1 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site scab	0	1 (<0.1)		1 (<0.1)
Secretion discharge	0	1 (<0.1)		1 (<0.1)
Vaccination site induration	0	1 (<0.1)		1 (<0.1)
Vaccination site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Vaccination site pruritus	0	1 (<0.1)		1 (<0.1)
Asthenia	4 (<0.1)	0		4 (<0.1)
Discomfort	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Injection site discomfort	2 (<0.1)	0		2 (<0.1)
Injection site nodule	1 (<0.1)	0		1 (<0.1)
Injection site scar	1 (<0.1)	0		1 (<0.1)
Injection site vesicles	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Vaccination site nodule	1 (<0.1)	0		1 (<0.1)
Investigations	7 (<0.1)	15 (0.1)		22 (<0.1)
Body temperature increased	0	4 (<0.1)		4 (<0.1)
Blood pressure increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood pressure systolic increased	0	2 (<0.1)		2 (<0.1)
Heart rate increased	0	2 (<0.1)		2 (<0.1)
C-reactive protein increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory rate increased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic abnormal	1 (<0.1)	0		1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications	9 (<0.1)	5 (<0.1)		14 (<0.1)
Contusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Foot fracture	0	1 (<0.1)		1 (<0.1)
Injection related reaction	0	1 (<0.1)		1 (<0.1)
Procedural headache	0	1 (<0.1)		1 (<0.1)
Tooth fracture	0	1 (<0.1)		1 (<0.1)
Fall	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Wrist fracture	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	30 (8.9)	30 (8.6)		60 (8.8)
Number of Unsolicited Adverse Events	60	58		118
Infections and infestations	0	1 (0.3)		1 (0.1)
Viral infection	0	1 (0.3)		1 (0.1)
Blood and lymphatic system disorders	5 (1.5)	2 (0.6)		7 (1.0)
Lymphadenopathy	5 (1.5)	2 (0.6)		7 (1.0)
Nervous system disorders	11 (3.3)	13 (3.7)		24 (3.5)
Headache	10 (3.0)	12 (3.5)	1.17 (0.52, 2.61)	22 (3.2)
Dizziness	0	1 (0.3)		1 (0.1)
Migraine	1 (0.3)	1 (0.3)		2 (0.3)
Cardiac disorders	0	1 (0.3)		1 (0.1)
Angina pectoris	0	1 (0.3)		1 (0.1)
Gastrointestinal disorders	3 (0.9)	1 (0.3)		4 (0.6)
Diarrhoea	0	1 (0.3)		1 (0.1)
Abdominal pain	1 (0.3)	0		1 (0.1)
Nausea	2 (0.6)	0		2 (0.3)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Skin and subcutaneous tissue disorders	1 (0.3)	2 (0.6)		3 (0.4)
Rash	0	1 (0.3)		1 (0.1)
Urticaria	1 (0.3)	1 (0.3)		2 (0.3)
Musculoskeletal and connective tissue disorders	14 (4.2)	10 (2.9)		24 (3.5)
Myalgia	10 (3.0)	8 (2.3)	0.78 (0.32, 1.89)	18 (2.6)
Arthralgia	7 (2.1)	4 (1.2)	0.55 (0.17, 1.76)	11 (1.6)
Limb discomfort	0	2 (0.6)		2 (0.3)
Back pain	1 (0.3)	0		1 (0.1)
Musculoskeletal pain	1 (0.3)	0		1 (0.1)
Musculoskeletal stiffness	1 (0.3)	0		1 (0.1)
General disorders and administration site conditions	16 (4.7)	13 (3.7)		29 (4.2)
Fatigue	13 (3.9)	7 (2.0)	0.52 (0.22, 1.26)	20 (2.9)
Injection site pain	2 (0.6)	3 (0.9)		5 (0.7)
Injection site erythema	0	2 (0.6)		2 (0.3)
Injection site induration	0	2 (0.6)		2 (0.3)
Chills	3 (0.9)	1 (0.3)		4 (0.6)
Injection site swelling	0	1 (0.3)		1 (0.1)
Pyrexia	0	1 (0.3)		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.11.1.3
Subject Incidence of Unsolicited Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	5 (6.0)	5 (5.7)		10 (5.8)
Number of Unsolicited Adverse Events	10	8		18
Nervous system disorders	4 (4.8)	2 (2.3)		6 (3.5)
Headache	4 (4.8)	2 (2.3)		6 (3.5)
Musculoskeletal and connective tissue disorders	1 (1.2)	0		1 (0.6)
Arthralgia	1 (1.2)	0		1 (0.6)
Myalgia	1 (1.2)	0		1 (0.6)
General disorders and administration site conditions	4 (4.8)	4 (4.6)		8 (4.7)
Injection site pain	0	2 (2.3)		2 (1.2)
Fatigue	4 (4.8)	1 (1.1)		5 (2.9)
Injection site lymphadenopathy	0	1 (1.1)		1 (0.6)
Pyrexia	0	1 (1.1)		1 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301110103.sas 10JUN2021 13:04

Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	104 (0.7)	98 (0.6)		202 (0.7)
Number of Unsolicited Adverse Events	147	140		287
Infections and infestations	19 (0.1)	13 (<0.1)		32 (0.1)
Pneumonia	4 (<0.1)	3 (<0.1)		7 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
COVID-19	4 (<0.1)	1 (<0.1)		5 (<0.1)
Cellulitis	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Diverticulitis	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301130101.sas 21JUN2021 14:45

Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	2 (<0.1)	0		2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (<0.1)	9 (<0.1)		17 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Blood and lymphatic system disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	4 (<0.1)	2 (<0.1)		6 (<0.1)
Dehydration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Hyponatraemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	7 (<0.1)	5 (<0.1)		12 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	8 (<0.1)	10 (<0.1)		18 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Syncope	2 (<0.1)	2 (<0.1)		4 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders	17 (0.1)	14 (<0.1)		31 (0.1)
Atrial fibrillation	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cardiac failure congestive	3 (<0.1)	3 (<0.1)		6 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)
Vascular disorders	8 (<0.1)	4 (<0.1)		12 (<0.1)
Hypertension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders	15 (<0.1)	9 (<0.1)		24 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)
Acute respiratory failure	3 (<0.1)	2 (<0.1)		5 (<0.1)
Respiratory failure	0	2 (<0.1)		2 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pleural effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic obstructive pulmonary disease	3 (<0.1)	0		3 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	7 (<0.1)	15 (<0.1)		22 (<0.1)
Colitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hiatus hernia	0	2 (<0.1)		2 (<0.1)
Nausea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal pain upper	0	1 (<0.1)		1 (<0.1)
Diarrhoea	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vomiting	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal pain	2 (<0.1)	0		2 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)		3 (<0.1)
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	12 (<0.1)	9 (<0.1)		21 (<0.1)
Osteoarthritis	6 (<0.1)	2 (<0.1)		8 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Back pain	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Spinal osteoarthritis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	2 (<0.1)	5 (<0.1)		7 (<0.1)
Nephrolithiasis	0	3 (<0.1)		3 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic kidney disease	0	1 (<0.1)		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	5 (<0.1)	4 (<0.1)		9 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	11 (<0.1)	10 (<0.1)		21 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Road traffic accident	0	2 (<0.1)		2 (<0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Fall	1 (<0.1)	1 (<0.1)		2 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.1.1
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tendon rupture	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Rib fracture	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	292 (1.9)	268 (1.8)		560 (1.8)
Number of Unsolicited Adverse Events	439	401		840
Infections and infestations	77 (0.5)	48 (0.3)		125 (0.4)
Pneumonia	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Appendicitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Sepsis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cellulitis	0	3 (<0.1)		3 (<0.1)
Bronchitis	0	2 (<0.1)		2 (<0.1)
COVID-19	40 (0.3)	2 (<0.1)	0.05 (0.01, 0.19)	42 (0.1)
Peritonitis	0	2 (<0.1)		2 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Urosepsis	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Diverticulitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastroenteritis viral	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Septic shock	3 (<0.1)	1 (<0.1)		4 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	5 (<0.1)	1 (<0.1)		6 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
COVID-19 pneumonia	8 (<0.1)	0		8 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Localised infection	1 (<0.1)	0		1 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pyelonephritis	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.2)	27 (0.2)		51 (0.2)
Prostate cancer	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hepatocellular carcinoma	0	2 (<0.1)		2 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	3 (<0.1)	0		3 (<0.1)
Intraductal proliferative breast lesion	3 (<0.1)	0		3 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Uterine leiomyoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	7 (<0.1)	3 (<0.1)		10 (<0.1)
Anaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thrombocytopenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)
Immune system disorders	2 (<0.1)	0		2 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	15 (<0.1)	17 (0.1)		32 (0.1)
Dehydration	4 (<0.1)	4 (<0.1)		8 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyponatraemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypoglycaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Type 2 diabetes mellitus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Diabetes mellitus inadequate control	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	13 (<0.1)	13 (<0.1)		26 (<0.1)
Depression	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental status changes	1 (<0.1)	1 (<0.1)		2 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)
Anxiety disorder	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Major depression	2 (<0.1)	0		2 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	27 (0.2)	31 (0.2)		58 (0.2)
Cerebrovascular accident	4 (<0.1)	6 (<0.1)		10 (<0.1)
Syncope	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aphasia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Dizziness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders	43 (0.3)	36 (0.2)		79 (0.3)
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Atrial fibrillation	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Cardiac failure congestive	3 (<0.1)	4 (<0.1)		7 (<0.1)
Acute coronary syndrome	0	3 (<0.1)		3 (<0.1)
Acute myocardial infarction	6 (<0.1)	3 (<0.1)		9 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)		6 (<0.1)
Atrial flutter	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute left ventricular failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery occlusion	0	1 (<0.1)		1 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Angina pectoris	1 (<0.1)	0		1 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)

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Cardiac disorders (Cont.)				
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)
Vascular disorders	15 (<0.1)	15 (<0.1)		30 (<0.1)
Deep vein thrombosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Haematoma	0	2 (<0.1)		2 (<0.1)
Hypertension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Hypotension	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)

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Respiratory, thoracic and mediastinal disorders	35 (0.2)	25 (0.2)		60 (0.2)
Acute respiratory failure	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Dyspnoea	0	5 (<0.1)		5 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	1 (<0.1)	0.12 (0.02, 0.77)	9 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Asthma	1 (<0.1)	0		1 (<0.1)
Epistaxis	1 (<0.1)	0		1 (<0.1)
Hypoxia	3 (<0.1)	0		3 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	25 (0.2)	36 (0.2)		61 (0.2)
Colitis	4 (<0.1)	3 (<0.1)		7 (<0.1)

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Gastrointestinal disorders (Cont.)				
Gastrointestinal haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Nausea	3 (<0.1)	3 (<0.1)		6 (<0.1)
Small intestinal obstruction	3 (<0.1)	3 (<0.1)		6 (<0.1)
Abdominal pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal pain upper	0	2 (<0.1)		2 (<0.1)
Diarrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Hiatus hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Intestinal obstruction	0	2 (<0.1)		2 (<0.1)
Vomiting	2 (<0.1)	2 (<0.1)		4 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastrooesophageal reflux disease	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	0	1 (<0.1)		1 (<0.1)
Pancreatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal hernia	1 (<0.1)	0		1 (<0.1)
Abdominal pain lower	2 (<0.1)	0		2 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	5 (<0.1)	6 (<0.1)		11 (<0.1)
Cholecystitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bile duct stone	0	2 (<0.1)		2 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	28 (0.2)	24 (0.2)		52 (0.2)
Osteoarthritis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.58)	20 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Intervertebral disc protrusion	2 (<0.1)	3 (<0.1)		5 (<0.1)
Back pain	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Flank pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Spondylolisthesis	0	1 (<0.1)		1 (<0.1)
Vertebral foraminal stenosis	0	1 (<0.1)		1 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	11 (<0.1)	10 (<0.1)		21 (<0.1)
Acute kidney injury	6 (<0.1)	5 (<0.1)		11 (<0.1)
Nephrolithiasis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Chronic kidney disease	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abortion spontaneous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	6 (<0.1)	6 (<0.1)		12 (<0.1)
Pelvic pain	0	2 (<0.1)		2 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions	12 (<0.1)	15 (<0.1)		27 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Non-cardiac chest pain	2 (<0.1)	3 (<0.1)		5 (<0.1)
Chest pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Asthenia	0	1 (<0.1)		1 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Pyrexia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)
Investigations	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	0	1 (<0.1)		1 (<0.1)
Transaminases increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	29 (0.2)	27 (0.2)		56 (0.2)
Hip fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Fall	5 (<0.1)	2 (<0.1)		7 (<0.1)
Road traffic accident	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Concussion	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Humerus fracture	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rib fracture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Skin laceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Superficial injury of eye	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.1.3
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Pelvic fracture	1 (<0.1)	0		1 (<0.1)
Post procedural fever	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	2 (<0.1)	0		2 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	54 (0.5)	59 (0.5)		113 (0.5)
Number of Unsolicited Adverse Events	88	75		163
Infections and infestations	8 (<0.1)	7 (<0.1)		15 (<0.1)
COVID-19	3 (<0.1)	1 (<0.1)		4 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Appendicitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Diverticulitis	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	6 (<0.1)		7 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Prostate cancer	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	1 (<0.1)	0		1 (<0.1)
Anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	0		3 (<0.1)
Dehydration	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Hyponatraemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	6 (<0.1)	5 (<0.1)		11 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	6 (<0.1)	6 (<0.1)		12 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Syncope	1 (<0.1)	1 (<0.1)		2 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	8 (<0.1)	5 (<0.1)		13 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Atrial fibrillation	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)
Vascular disorders	5 (<0.1)	0		5 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Hypertension	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders (Cont.)				
Hypotension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	10 (<0.1)	7 (<0.1)		17 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)		5 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	4 (<0.1)	11 (<0.1)		15 (<0.1)
Colitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hiatus hernia	0	2 (<0.1)		2 (<0.1)
Abdominal pain upper	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Diarrhoea	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal pain	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Nausea	1 (<0.1)	0		1 (<0.1)
Vomiting	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	6 (<0.1)	5 (<0.1)		11 (<0.1)
Back pain	0	1 (<0.1)		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)		2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Musculoskeletal chest pain	0	1 (<0.1)		1 (<0.1)
Osteoarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Spinal osteoarthritis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	0	3 (<0.1)		3 (<0.1)
Nephrolithiasis	0	2 (<0.1)		2 (<0.1)
Acute kidney injury	0	1 (<0.1)		1 (<0.1)
Reproductive system and breast disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions	3 (<0.1)	4 (<0.1)		7 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	8 (<0.1)	4 (<0.1)		12 (<0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Tendon rupture	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Fall	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	50 (1.3)	39 (1.0)		89 (1.2)
Number of Unsolicited Adverse Events	59	65		124
Infections and infestations	11 (0.3)	6 (0.2)		17 (0.2)
Pneumonia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cellulitis	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
COVID-19	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	2 (<0.1)	0		2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (0.2)	3 (<0.1)		10 (0.1)
Prostate cancer	3 (<0.1)	2 (<0.1)		5 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	1 (<0.1)		1 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dehydration	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders	2 (<0.1)	4 (0.1)		6 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Syncope	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	9 (0.2)	9 (0.2)		18 (0.2)
Atrial fibrillation	2 (<0.1)	3 (<0.1)		5 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Vascular disorders	3 (<0.1)	4 (0.1)		7 (<0.1)
Hypertension	0	2 (<0.1)		2 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Vascular disorders (Cont.)				
Hypotension	0	1 (<0.1)		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	5 (0.1)	2 (<0.1)		7 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	2 (<0.1)	0		2 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Pleural effusion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	3 (<0.1)	4 (0.1)		7 (<0.1)
Nausea	0	2 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Abdominal pain	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Hepatobiliary disorders	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	0		2 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	6 (0.2)	4 (0.1)		10 (0.1)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Osteoarthritis	5 (0.1)	1 (<0.1)		6 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Chronic kidney disease	0	1 (<0.1)		1 (<0.1)
Nephrolithiasis	0	1 (<0.1)		1 (<0.1)
Acute kidney injury	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Reproductive system and breast disorders	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	2 (<0.1)	0		2 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	3 (<0.1)	6 (0.2)		9 (0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Fall	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.1
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Rib fracture	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	168 (1.5)	150 (1.3)		318 (1.4)
Number of Unsolicited Adverse Events	257	216		473
Infections and infestations	41 (0.4)	30 (0.3)		71 (0.3)
Pneumonia	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Sepsis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cellulitis	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Appendicitis perforated	0	1 (<0.1)		1 (<0.1)
Bronchitis	0	1 (<0.1)		1 (<0.1)
COVID-19	24 (0.2)	1 (<0.1)	0.04 (0.01, 0.24)	25 (0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Diverticulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastroenteritis viral	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Post procedural infection	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Septic shock	2 (<0.1)	1 (<0.1)		3 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pyelonephritis	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (<0.1)	17 (0.1)		28 (0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Prostate cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal cell carcinoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	2 (<0.1)	0		2 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	4 (<0.1)	1 (<0.1)		5 (<0.1)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Thrombocytopenia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	2 (<0.1)	0		2 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	11 (<0.1)	8 (<0.1)		19 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Hyponatraemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dehydration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Diabetes mellitus inadequate control	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	11 (<0.1)	12 (0.1)		23 (0.1)
Depression	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alcohol withdrawal syndrome	0	2 (<0.1)		2 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)
Anxiety disorder	1 (<0.1)	0		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Major depression	2 (<0.1)	0		2 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	19 (0.2)	18 (0.2)		37 (0.2)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Syncope	5 (<0.1)	3 (<0.1)		8 (<0.1)
Aphasia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Dizziness	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Arachnoid cyst	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	18 (0.2)	11 (<0.1)		29 (0.1)
Myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Atrial flutter	0	2 (<0.1)		2 (<0.1)
Cardiac failure congestive	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronary artery disease	0	2 (<0.1)		2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute myocardial infarction	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Atrial fibrillation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac failure acute	0	1 (<0.1)		1 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Angina pectoris	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)
Vascular disorders	11 (<0.1)	5 (<0.1)		16 (<0.1)
Deep vein thrombosis	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Hypertension	2 (<0.1)	0		2 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Hypotension	2 (<0.1)	0		2 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders (Cont.)				
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	21 (0.2)	15 (0.1)		36 (0.2)
Dyspnoea	0	5 (<0.1)		5 (<0.1)
Pulmonary embolism	5 (<0.1)	4 (<0.1)		9 (<0.1)
Acute respiratory failure	5 (<0.1)	3 (<0.1)		8 (<0.1)
Pleural effusion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	3 (<0.1)	0		3 (<0.1)
Epistaxis	1 (<0.1)	0		1 (<0.1)
Hypoxia	3 (<0.1)	0		3 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumothorax	2 (<0.1)	0		2 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders	14 (0.1)	18 (0.2)		32 (0.1)
Colitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hiatus hernia	0	2 (<0.1)		2 (<0.1)
Abdominal pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal pain upper	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diarrhoea	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Nausea	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vomiting	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abdominal hernia	1 (<0.1)	0		1 (<0.1)
Abdominal pain lower	2 (<0.1)	0		2 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Pancreatitis	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Hepatobiliary disorders	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cholecystitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	0	3 (<0.1)		3 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	15 (0.1)	11 (<0.1)		26 (0.1)
Intervertebral disc protrusion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Osteoarthritis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Back pain	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vertebral foraminal stenosis	0	1 (<0.1)		1 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Flank pain	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Muscular weakness	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	2 (<0.1)	0		2 (<0.1)
Renal and urinary disorders	3 (<0.1)	5 (<0.1)		8 (<0.1)
Nephrolithiasis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Acute kidney injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abortion spontaneous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	4 (<0.1)	5 (<0.1)		9 (<0.1)
Pelvic pain	0	2 (<0.1)		2 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)		1 (<0.1)
Dysfunctional uterine bleeding	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Breast pain	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Ovarian cyst	2 (<0.1)	0		2 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	7 (<0.1)	11 (<0.1)		18 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Chest pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Non-cardiac chest pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	18 (0.2)	13 (0.1)		31 (0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Concussion	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Superficial injury of eye	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Fall	3 (<0.1)	0		3 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Post procedural fever	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Rib fracture	1 (<0.1)	0		1 (<0.1)
Skin laceration	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	124 (3.3)	118 (3.1)		242 (3.2)
Number of Unsolicited Adverse Events	182	185		367
Infections and infestations	36 (1.0)	18 (0.5)		54 (0.7)
Pneumonia	3 (<0.1)	5 (0.1)		8 (0.1)
Appendicitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Bronchitis	0	1 (<0.1)		1 (<0.1)
COVID-19	16 (0.4)	1 (<0.1)	0.06 (0.01, 0.37)	17 (0.2)
Cellulitis	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Sepsis	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	4 (0.1)	1 (<0.1)		5 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	5 (0.1)	0		5 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Diverticulitis	2 (<0.1)	0		2 (<0.1)
Localised infection	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pyelonephritis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (0.3)	10 (0.3)		23 (0.3)
Prostate cancer	3 (<0.1)	4 (0.1)		7 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Intraductal proliferative breast lesion	2 (<0.1)	0		2 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thrombocytopenia	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	4 (0.1)	9 (0.2)		13 (0.2)
Dehydration	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)				
Diabetic ketoacidosis	0	1 (<0.1)		1 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypoglycaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	0	1 (<0.1)		1 (<0.1)
Hyponatraemia	0	1 (<0.1)		1 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Type 2 diabetes mellitus	0	1 (<0.1)		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Mental status changes	0	1 (<0.1)		1 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	8 (0.2)	13 (0.3)		21 (0.3)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Syncope	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)		1 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Dizziness	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	25 (0.7)	25 (0.7)		50 (0.7)
Atrial fibrillation	9 (0.2)	5 (0.1)	0.55 (0.19, 1.57)	14 (0.2)
Myocardial infarction	3 (<0.1)	3 (<0.1)		6 (<0.1)
Acute coronary syndrome	0	2 (<0.1)		2 (<0.1)
Acute myocardial infarction	4 (0.1)	2 (<0.1)		6 (<0.1)
Cardiac failure congestive	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardio-respiratory arrest	0	2 (<0.1)		2 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders (Cont.)				
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Coronary artery disease	3 (<0.1)	1 (<0.1)		4 (<0.1)
Coronary artery occlusion	0	1 (<0.1)		1 (<0.1)
Pericarditis	0	1 (<0.1)		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrial flutter	2 (<0.1)	0		2 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac failure acute	1 (<0.1)	0		1 (<0.1)
Vascular disorders	4 (0.1)	10 (0.3)		14 (0.2)
Deep vein thrombosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypertension	0	2 (<0.1)		2 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Vascular disorders (Cont.)				
Hypotension	0	1 (<0.1)		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	14 (0.4)	10 (0.3)		24 (0.3)
Acute respiratory failure	5 (0.1)	4 (0.1)		9 (0.1)
Pulmonary embolism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Chronic obstructive pulmonary disease	5 (0.1)	1 (<0.1)		6 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	0	1 (<0.1)		1 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asthma	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Pleural effusion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	11 (0.3)	18 (0.5)		29 (0.4)
Gastrointestinal haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Nausea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Small intestinal obstruction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal pain	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal pain upper	0	1 (<0.1)		1 (<0.1)
Colitis	0	1 (<0.1)		1 (<0.1)
Diarrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Gastrooesophageal reflux disease	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Hiatus hernia	1 (<0.1)	0		1 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholecystitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders	2 (<0.1)	0		2 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	13 (0.3)	13 (0.3)		26 (0.3)
Osteoarthritis	10 (0.3)	5 (0.1)	0.50 (0.18, 1.39)	15 (0.2)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Back pain	0	1 (<0.1)		1 (<0.1)
Flank pain	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Muscular weakness	0	1 (<0.1)		1 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Spondylolisthesis	0	1 (<0.1)		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	8 (0.2)	5 (0.1)		13 (0.2)
Acute kidney injury	4 (0.1)	3 (<0.1)		7 (<0.1)
Nephrolithiasis	0	2 (<0.1)		2 (<0.1)
Chronic kidney disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)				
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	5 (0.1)	4 (0.1)		9 (0.1)
Asthenia	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Pyrexia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations (Cont.)				
Transaminases increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	11 (0.3)	14 (0.4)		25 (0.3)
Hip fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Fall	2 (<0.1)	2 (<0.1)		4 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Humerus fracture	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Rib fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Road traffic accident	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Pelvic fracture	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.2.3
Subject Incidence of Serious TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	101 (0.7)	96 (0.7)		197 (0.7)
Number of Unsolicited Adverse Events	139	137		276
Infections and infestations	18 (0.1)	13 (<0.1)		31 (0.1)
Pneumonia	4 (<0.1)	3 (<0.1)		7 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
COVID-19	4 (<0.1)	1 (<0.1)		5 (<0.1)
Cellulitis	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
COVID-19 pneumonia	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Diverticulitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)
Sepsis	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	2 (<0.1)	0		2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (<0.1)	9 (<0.1)		17 (<0.1)
Prostate cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	1 (<0.1)	0		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Dehydration	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Hyponatraemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders	7 (<0.1)	4 (<0.1)		11 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	8 (<0.1)	10 (<0.1)		18 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Syncope	2 (<0.1)	2 (<0.1)		4 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	1 (<0.1)	1 (<0.1)		2 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Encephalopathy	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	16 (0.1)	13 (<0.1)		29 (<0.1)
Atrial fibrillation	2 (<0.1)	3 (<0.1)		5 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiac failure congestive	3 (<0.1)	2 (<0.1)		5 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	0	1 (<0.1)		1 (<0.1)
Atrial flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders	8 (<0.1)	4 (<0.1)		12 (<0.1)
Hypertension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Respiratory, thoracic and mediastinal disorders	14 (<0.1)	9 (<0.1)		23 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Respiratory failure	0	2 (<0.1)		2 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pleural effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic obstructive pulmonary disease	3 (<0.1)	0		3 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	7 (<0.1)	14 (<0.1)		21 (<0.1)
Colitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hiatus hernia	0	2 (<0.1)		2 (<0.1)
Nausea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal pain upper	0	1 (<0.1)		1 (<0.1)
Diarrhoea	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vomiting	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal pain	2 (<0.1)	0		2 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Hepatobiliary disorders	0	3 (<0.1)		3 (<0.1)
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	11 (<0.1)	9 (<0.1)		20 (<0.1)
Osteoarthritis	6 (<0.1)	2 (<0.1)		8 (<0.1)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Back pain	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Spinal osteoarthritis	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders	2 (<0.1)	5 (<0.1)		7 (<0.1)
Nephrolithiasis	0	3 (<0.1)		3 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic kidney disease	0	1 (<0.1)		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Benign prostatic hyperplasia	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	4 (<0.1)	4 (<0.1)		8 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Non-cardiac chest pain	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	11 (<0.1)	10 (<0.1)		21 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Road traffic accident	0	2 (<0.1)		2 (<0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Fall	1 (<0.1)	1 (<0.1)		2 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tendon rupture	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Rib fracture	1 (<0.1)	0		1 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3 (0.9)	1 (0.3)		4 (0.6)
Number of Unsolicited Adverse Events	8	2		10
Infections and infestations	1 (0.3)	0		1 (0.1)
Pyelonephritis acute	1 (0.3)	0		1 (0.1)
Septic shock	1 (0.3)	0		1 (0.1)
Metabolism and nutrition disorders	1 (0.3)	0		1 (0.1)
Metabolic acidosis	1 (0.3)	0		1 (0.1)
Psychiatric disorders	0	1 (0.3)		1 (0.1)
Drug abuse	0	1 (0.3)		1 (0.1)
Cardiac disorders	1 (0.3)	1 (0.3)		2 (0.3)
Cardiac failure congestive	0	1 (0.3)		1 (0.1)
Acute left ventricular failure	1 (0.3)	0		1 (0.1)
Atrial fibrillation	1 (0.3)	0		1 (0.1)
Respiratory, thoracic and mediastinal disorders	1 (0.3)	0		1 (0.1)
Acute respiratory failure	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Musculoskeletal and connective tissue disorders	1 (0.3)	0		1 (0.1)
Spinal stenosis	1 (0.3)	0		1 (0.1)
General disorders and administration site conditions	1 (0.3)	0		1 (0.1)
Non-cardiac chest pain	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.13.3.1
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	1 (1.1)		1 (0.6)
Number of Unsolicited Adverse Events	0	1		1
Gastrointestinal disorders	0	1 (1.1)		1 (0.6)
Inguinal hernia	0	1 (1.1)		1 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	285 (1.9)	266 (1.8)		551 (1.9)
Number of Unsolicited Adverse Events	427	398		825
Infections and infestations	76 (0.5)	48 (0.3)		124 (0.4)
Pneumonia	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Appendicitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Sepsis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cellulitis	0	3 (<0.1)		3 (<0.1)
Bronchitis	0	2 (<0.1)		2 (<0.1)
COVID-19	40 (0.3)	2 (<0.1)	0.05 (0.01, 0.19)	42 (0.1)
Peritonitis	0	2 (<0.1)		2 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Urosepsis	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Diverticulitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gastroenteritis viral	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Septic shock	2 (<0.1)	1 (<0.1)		3 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	5 (<0.1)	1 (<0.1)		6 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
COVID-19 pneumonia	8 (<0.1)	0		8 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Localised infection	1 (<0.1)	0		1 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pyelonephritis	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.2)	27 (0.2)		51 (0.2)
Prostate cancer	4 (<0.1)	5 (<0.1)		9 (<0.1)
Hepatocellular carcinoma	0	2 (<0.1)		2 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Malignant melanoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	3 (<0.1)	0		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Intraductal proliferative breast lesion	3 (<0.1)	0		3 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	7 (<0.1)	3 (<0.1)		10 (<0.1)
Anaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thrombocytopenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Iron deficiency anaemia	1 (<0.1)	0		1 (<0.1)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Immune system disorders	2 (<0.1)	0		2 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	14 (<0.1)	17 (0.1)		31 (0.1)
Dehydration	4 (<0.1)	4 (<0.1)		8 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyponatraemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypoglycaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Type 2 diabetes mellitus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypokalaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Diabetes mellitus inadequate control	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders	13 (<0.1)	12 (<0.1)		25 (<0.1)
Depression	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental status changes	1 (<0.1)	1 (<0.1)		2 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	1 (<0.1)	0		1 (<0.1)
Anxiety disorder	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Major depression	2 (<0.1)	0		2 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	27 (0.2)	31 (0.2)		58 (0.2)
Cerebrovascular accident	4 (<0.1)	6 (<0.1)		10 (<0.1)

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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Syncope	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aphasia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Dizziness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Lumbar radiculopathy	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)

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Nervous system disorders (Cont.)				
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	42 (0.3)	35 (0.2)		77 (0.3)
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Atrial fibrillation	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Acute coronary syndrome	0	3 (<0.1)		3 (<0.1)
Acute myocardial infarction	6 (<0.1)	3 (<0.1)		9 (<0.1)
Cardiac failure congestive	3 (<0.1)	3 (<0.1)		6 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)		6 (<0.1)
Atrial flutter	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Cardiac disorders (Cont.)				
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery occlusion	0	1 (<0.1)		1 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Angina pectoris	1 (<0.1)	0		1 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Sinus tachycardia	2 (<0.1)	0		2 (<0.1)
Vascular disorders	15 (0.1)	15 (0.1)		30 (0.1)
Deep vein thrombosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Haematoma	0	2 (<0.1)		2 (<0.1)
Hypertension	2 (<0.1)	2 (<0.1)		4 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Aortic aneurysm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Hypotension	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	34 (0.2)	25 (0.2)		59 (0.2)
Acute respiratory failure	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Dyspnoea	0	5 (<0.1)		5 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atelectasis	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	1 (<0.1)	0.12 (0.02, 0.77)	9 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Asthma	1 (<0.1)	0		1 (<0.1)
Epistaxis	1 (<0.1)	0		1 (<0.1)
Hypoxia	3 (<0.1)	0		3 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	25 (0.2)	35 (0.2)		60 (0.2)
Colitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Gastrointestinal haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Nausea	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Gastrointestinal disorders (Cont.)				
Small intestinal obstruction	3 (<0.1)	3 (<0.1)		6 (<0.1)
Abdominal pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abdominal pain upper	0	2 (<0.1)		2 (<0.1)
Diarrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Hiatus hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Intestinal obstruction	0	2 (<0.1)		2 (<0.1)
Vomiting	2 (<0.1)	2 (<0.1)		4 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Gastritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastrooesophageal reflux disease	0	1 (<0.1)		1 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	0	1 (<0.1)		1 (<0.1)
Pancreatitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Abdominal hernia	1 (<0.1)	0		1 (<0.1)

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Gastrointestinal disorders (Cont.)				
Abdominal pain lower	2 (<0.1)	0		2 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	5 (<0.1)	6 (<0.1)		11 (<0.1)
Cholecystitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bile duct stone	0	2 (<0.1)		2 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)

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Musculoskeletal and connective tissue disorders	26 (0.2)	24 (0.2)		50 (0.2)
Osteoarthritis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Intervertebral disc protrusion	2 (<0.1)	3 (<0.1)		5 (<0.1)
Back pain	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Flank pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Spondylolisthesis	0	1 (<0.1)		1 (<0.1)
Vertebral foraminal stenosis	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	11 (<0.1)	10 (<0.1)		21 (<0.1)
Acute kidney injury	6 (<0.1)	5 (<0.1)		11 (<0.1)

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Renal and urinary disorders (Cont.)				
Nephrolithiasis	1 (<0.1)	5 (<0.1)		6 (<0.1)
Chronic kidney disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abortion spontaneous	0	1 (<0.1)		1 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	5 (<0.1)	6 (<0.1)		11 (<0.1)
Pelvic pain	0	2 (<0.1)		2 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Breast pain	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)

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Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	11 (<0.1)	15 (0.1)		26 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Non-cardiac chest pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chest pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Asthenia	0	1 (<0.1)		1 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Pyrexia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)
Investigations	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Heart rate irregular	0	1 (<0.1)		1 (<0.1)
Transaminases increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	28 (0.2)	27 (0.2)		55 (0.2)
Hip fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Fall	5 (<0.1)	2 (<0.1)		7 (<0.1)
Road traffic accident	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Back injury	0	1 (<0.1)		1 (<0.1)
Concussion	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Humerus fracture	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Joint injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rib fracture	3 (<0.1)	1 (<0.1)		4 (<0.1)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Superficial injury of eye	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Pelvic fracture	1 (<0.1)	0		1 (<0.1)
Post procedural fever	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Thoracic vertebral fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	2 (<0.1)	0		2 (<0.1)
Social circumstances	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	7 (2.1)	1 (0.3)		8 (1.2)
Number of Unsolicited Adverse Events	12	2		14
Infections and infestations	1 (0.3)	0		1 (0.1)
Pyelonephritis acute	1 (0.3)	0		1 (0.1)
Septic shock	1 (0.3)	0		1 (0.1)
Metabolism and nutrition disorders	1 (0.3)	0		1 (0.1)
Metabolic acidosis	1 (0.3)	0		1 (0.1)
Psychiatric disorders	0	1 (0.3)		1 (0.1)
Drug abuse	0	1 (0.3)		1 (0.1)
Cardiac disorders	1 (0.3)	1 (0.3)		2 (0.3)
Cardiac failure congestive	0	1 (0.3)		1 (0.1)
Acute left ventricular failure	1 (0.3)	0		1 (0.1)
Atrial fibrillation	1 (0.3)	0		1 (0.1)
Respiratory, thoracic and mediastinal disorders	1 (0.3)	0		1 (0.1)
Acute respiratory failure	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Musculoskeletal and connective tissue disorders	2 (0.6)	0		2 (0.3)
Arthritis	1 (0.3)	0		1 (0.1)
Spinal stenosis	1 (0.3)	0		1 (0.1)
Pregnancy, puerperium and perinatal conditions	1 (0.3)	0		1 (0.1)
Abortion spontaneous	1 (0.3)	0		1 (0.1)
Reproductive system and breast disorders	1 (0.3)	0		1 (0.1)
Pelvic prolapse	1 (0.3)	0		1 (0.1)
General disorders and administration site conditions	1 (0.3)	0		1 (0.1)
Non-cardiac chest pain	1 (0.3)	0		1 (0.1)
Injury, poisoning and procedural complications	1 (0.3)	0		1 (0.1)
Skin laceration	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.3.3
Subject Incidence of Serious TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	1 (1.1)		1 (0.6)
Number of Unsolicited Adverse Events	0	1		1
Gastrointestinal disorders	0	1 (1.1)		1 (0.6)
Inguinal hernia	0	1 (1.1)		1 (0.6)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Number of Unsolicited Adverse Events	439	401	840
Infections and infestations	95	54	149
Pneumonia	11	9	20
Appendicitis	5	4	9
Sepsis	4	4	8
Cellulitis	0	3	3
Bronchitis	0	2	2
COVID-19	40	2	42
Peritonitis	0	2	2
Postoperative abscess	0	2	2
Urosepsis	0	2	2
Abscess limb	0	1	1
Appendicitis perforated	1	1	2
Clostridium difficile infection	0	1	1
Diabetic foot infection	0	1	1
Diverticulitis	3	1	4
Gastroenteritis viral	0	1	1
Giardiasis	0	1	1
Hepatitis A	0	1	1
Liver abscess	0	1	1
Lung abscess	0	1	1
Pneumonia mycoplasmal	0	1	1
Pneumonia staphylococcal	0	1	1
Post procedural infection	0	1	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Infections and infestations (Cont.)			
Postoperative wound infection	0	1	1
Pyelonephritis acute	1	1	2
Salpingitis	0	1	1
Septic shock	3	1	4
Spinal cord abscess	0	1	1
Toxic shock syndrome	0	1	1
Upper respiratory tract infection	0	1	1
Urinary tract infection	5	1	6
Viral infection	0	1	1
Viral pharyngitis	0	1	1
Wound infection	0	1	1
COVID-19 pneumonia	8	0	8
Clostridium difficile colitis	1	0	1
Coccidioidomycosis	1	0	1
Enterococcal bacteraemia	1	0	1
Localised infection	1	0	1
Meningitis aseptic	1	0	1
Osteomyelitis	1	0	1
Perirectal abscess	1	0	1
Pharyngitis streptococcal	1	0	1
Pneumonia bacterial	1	0	1
Pneumonia klebsiella	1	0	1
Pyelonephritis	2	0	2
Streptococcal sepsis	1	0	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Infections and infestations (Cont.)			
Tooth abscess	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24	33	57
Prostate cancer	4	5	9
Hepatocellular carcinoma	0	3	3
Thymoma malignant	0	2	2
B-cell small lymphocytic lymphoma	0	1	1
Benign lung neoplasm	0	1	1
Cancer pain	0	1	1
Clear cell renal cell carcinoma	1	1	2
Colorectal cancer	0	1	1
Gastric cancer	0	1	1
Gastrointestinal stromal tumour	0	1	1
Invasive lobular breast carcinoma	0	1	1
Liposarcoma	0	1	1
Malignant melanoma	0	1	1
Meningioma	0	1	1
Metastases to bone	0	1	1
Metastases to lung	0	1	1
Metastatic neoplasm	0	1	1
Non-Hodgkin's lymphoma	0	1	1
Oesophageal carcinoma	0	1	1
Papillary thyroid cancer	1	1	2

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MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)			
Pelvic neoplasm	0	1	1
Plasma cell myeloma	0	1	1
Renal cell carcinoma	1	1	2
Splenic marginal zone lymphoma	0	1	1
Throat cancer	0	1	1
Thyroid cancer metastatic	0	1	1
Adenocarcinoma gastric	1	0	1
Breast cancer stage I	1	0	1
Colon cancer stage III	1	0	1
Endometrial cancer	3	0	3
Intraductal proliferative breast lesion	3	0	3
Invasive ductal breast carcinoma	1	0	1
Leiomyosarcoma metastatic	1	0	1
Lung adenocarcinoma	1	0	1
Non-small cell lung cancer	1	0	1
Pancreatic carcinoma stage IV	1	0	1
Prostate cancer metastatic	1	0	1
Thyroid cancer	1	0	1
Uterine leiomyoma	1	0	1
Blood and lymphatic system disorders	7	4	11
Anaemia	2	2	4
Blood loss anaemia	1	1	2

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Blood and lymphatic system disorders (Cont.)			
Thrombocytopenia	1	1	2
Anaemia macrocytic	1	0	1
Iron deficiency anaemia	1	0	1
Thrombocytosis	1	0	1
Immune system disorders	2	0	2
Anaphylactic reaction	1	0	1
Cytokine storm	1	0	1
Endocrine disorders	0	1	1
Basedow's disease	0	1	1
Metabolism and nutrition disorders	17	20	37
Dehydration	5	4	9
Diabetic ketoacidosis	3	3	6
Hyponatraemia	1	3	4
Hypoglycaemia	1	2	3
Type 2 diabetes mellitus	1	2	3
Diabetic complication	0	1	1
Failure to thrive	0	1	1
Gout	1	1	2
Hyperkalaemia	0	1	1
Hypokalaemia	1	1	2
Obesity	0	1	1

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MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Metabolism and nutrition disorders (Cont.)			
Diabetes mellitus	1	0	1
Diabetes mellitus inadequate control	1	0	1
Hypomagnesaemia	1	0	1
Metabolic acidosis	1	0	1
Psychiatric disorders	17	16	33
Alcohol withdrawal syndrome	1	3	4
Depression	2	3	5
Alcohol abuse	0	1	1
Completed suicide	1	1	2
Drug abuse	0	1	1
Intentional self-injury	0	1	1
Mental status changes	1	1	2
Schizoaffective disorder	1	1	2
Substance-induced mood disorder	0	1	1
Substance-induced psychotic disorder	0	1	1
Suicidal ideation	0	1	1
Suicide attempt	0	1	1
Alcoholism	1	0	1
Anxiety	2	0	2
Anxiety disorder	1	0	1
Confusional state	1	0	1
Depression suicidal	1	0	1
Major depression	3	0	3

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MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Psychiatric disorders (Cont.)			
Mania	1	0	1
Schizophrenia	1	0	1
Nervous system disorders	29	35	64
Cerebrovascular accident	4	6	10
Syncope	7	6	13
Seizure	1	3	4
Subarachnoid haemorrhage	0	3	3
Embolic stroke	0	2	2
Transient ischaemic attack	2	2	4
Aphasia	0	1	1
Autonomic nervous system imbalance	0	1	1
Carotid artery stenosis	0	1	1
Carotid artery thrombosis	0	1	1
Cauda equina syndrome	0	1	1
Cervical radiculopathy	0	1	1
Dizziness	1	1	2
Facial paralysis	0	1	1
Hemiparesis	0	1	1
Lumbar radiculopathy	0	1	1
Multiple sclerosis	1	1	2
Optic neuritis	0	1	1
Spinal cord compression	0	1	1
Amyotrophic lateral sclerosis	1	0	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Nervous system disorders (Cont.)			
Arachnoid cyst	1	0	1
Basal ganglia haemorrhage	1	0	1
Encephalopathy	2	0	2
Hydrocephalus	1	0	1
Ischaemic stroke	1	0	1
Loss of consciousness	1	0	1
Migraine	1	0	1
Nerve compression	1	0	1
Paraesthesia	2	0	2
Speech disorder	1	0	1
Eye disorders	2	0	2
Retinal detachment	1	0	1
Retinal tear	1	0	1
Cardiac disorders	54	43	97
Myocardial infarction	9	7	16
Atrial fibrillation	10	6	16
Cardiac failure congestive	5	4	9
Acute coronary syndrome	0	3	3
Acute myocardial infarction	6	3	9
Coronary artery disease	3	3	6
Atrial flutter	2	2	4
Cardio-respiratory arrest	1	2	3

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Cardiac disorders (Cont.)			
Pericarditis	4	2	6
Acute left ventricular failure	2	1	3
Angina unstable	0	1	1
Bradycardia	0	1	1
Cardiac arrest	0	1	1
Cardiac failure	2	1	3
Cardiac failure acute	1	1	2
Coronary artery occlusion	0	1	1
Pericardial effusion	1	1	2
Stress cardiomyopathy	0	1	1
Supraventricular tachycardia	0	1	1
Ventricular extrasystoles	0	1	1
Angina pectoris	2	0	2
Arrhythmia	1	0	1
Atrioventricular block complete	1	0	1
Atrioventricular block second degree	1	0	1
Paroxysmal arrhythmia	1	0	1
Sinus tachycardia	2	0	2
Vascular disorders	16	17	33
Deep vein thrombosis	1	4	5
Haematoma	0	2	2
Hypertension	2	2	4
Hypertensive urgency	1	2	3

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MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Vascular disorders (Cont.)			
Aortic aneurysm	1	1	2
Arteriosclerosis	0	1	1
Axillary vein thrombosis	0	1	1
Embolism venous	0	1	1
Hypotension	3	1	4
Polyarteritis nodosa	0	1	1
Venous thrombosis limb	0	1	1
Aortic stenosis	1	0	1
Arterial haemorrhage	1	0	1
Fibromuscular dysplasia	1	0	1
Hypertensive emergency	2	0	2
Peripheral artery aneurysm	1	0	1
Peripheral artery occlusion	1	0	1
Thrombophlebitis superficial	1	0	1
Respiratory, thoracic and mediastinal disorders	43	28	71
Acute respiratory failure	10	7	17
Pulmonary embolism	7	7	14
Dyspnoea	0	5	5
Pleural effusion	2	2	4
Respiratory failure	1	2	3
Atelectasis	0	1	1
Chronic obstructive pulmonary disease	8	1	9
Emphysema	1	1	2

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Respiratory, thoracic and mediastinal disorders (Cont.)			
Pneumothorax	2	1	3
Pulmonary mass	0	1	1
Acute respiratory distress syndrome	1	0	1
Asthma	1	0	1
Epistaxis	1	0	1
Hypoxia	3	0	3
Laryngeal oedema	1	0	1
Organising pneumonia	1	0	1
Pleuritic pain	1	0	1
Pneumonia aspiration	1	0	1
Pulmonary fibrosis	1	0	1
Pulmonary infarction	1	0	1
Gastrointestinal disorders	29	40	69
Colitis	4	3	7
Gastrointestinal haemorrhage	2	3	5
Nausea	3	3	6
Small intestinal obstruction	3	3	6
Abdominal pain	2	2	4
Abdominal pain upper	0	2	2
Diarrhoea	1	2	3
Duodenal ulcer perforation	0	2	2
Hiatus hernia	1	2	3

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Gastrointestinal disorders (Cont.)			
Intestinal obstruction	0	2	2
Vomiting	2	2	4
Crohn's disease	0	1	1
Diverticular perforation	0	1	1
Duodenal ulcer	0	1	1
Gastritis	2	1	3
Gastrooesophageal reflux disease	0	1	1
Inguinal hernia	0	1	1
Intra-abdominal fluid collection	0	1	1
Large intestine perforation	0	1	1
Oesophageal rupture	0	1	1
Oesophageal spasm	0	1	1
Pancreatitis	2	1	3
Pancreatitis acute	0	1	1
Rectal prolapse	0	1	1
Retroperitoneal haemorrhage	0	1	1
Abdominal hernia	1	0	1
Abdominal pain lower	2	0	2
Duodenal ulcer haemorrhage	1	0	1
Gastric perforation	1	0	1
Gastric ulcer haemorrhage	1	0	1
Tooth socket haemorrhage	1	0	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Hepatobiliary disorders	5	6	11
Cholecystitis	3	3	6
Bile duct stone	0	2	2
Cholelithiasis	0	1	1
Biliary dyskinesia	1	0	1
Cholecystitis acute	1	0	1
Skin and subcutaneous tissue disorders	2	4	6
Alopecia areata	0	1	1
Angioedema	1	1	2
Rash	0	1	1
Rash vesicular	0	1	1
Dermatitis bullous	1	0	1
Musculoskeletal and connective tissue disorders	28	24	52
Osteoarthritis	12	8	20
Intervertebral disc protrusion	2	3	5
Back pain	0	2	2
Spinal stenosis	2	2	4
Flank pain	1	1	2
Fracture nonunion	0	1	1
Muscular weakness	1	1	2
Musculoskeletal chest pain	1	1	2
Neck pain	0	1	1
Rheumatoid arthritis	0	1	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Musculoskeletal and connective tissue disorders (Cont.)			
Spinal osteoarthritis	3	1	4
Spondylolisthesis	0	1	1
Vertebral foraminal stenosis	0	1	1
Arthritis	1	0	1
Cervical spinal stenosis	1	0	1
Joint stiffness	1	0	1
Osteonecrosis	1	0	1
Polymyalgia rheumatica	1	0	1
Rhabdomyolysis	1	0	1
Renal and urinary disorders	11	13	24
Acute kidney injury	6	6	12
Nephrolithiasis	1	6	7
Chronic kidney disease	2	1	3
Renal impairment	1	0	1
Urinary retention	1	0	1
Pregnancy, puerperium and perinatal conditions	2	1	3
Abortion spontaneous	1	1	2
Ectopic pregnancy	1	0	1
Reproductive system and breast disorders	6	7	13
Pelvic pain	0	2	2

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Reproductive system and breast disorders (Cont.)			
Uterine haemorrhage	0	2	2
Benign prostatic hyperplasia	1	1	2
Dysfunctional uterine bleeding	0	1	1
Ovarian cyst	2	1	3
Breast pain	1	0	1
Endometrial hyperplasia	1	0	1
Pelvic prolapse	1	0	1
Congenital, familial and genetic disorders	1	0	1
Talipes	1	0	1
General disorders and administration site conditions	13	16	29
Death	2	4	6
Non-cardiac chest pain	2	3	5
Chest pain	2	2	4
Swelling face	1	2	3
Asthenia	0	1	1
Drug withdrawal syndrome	0	1	1
Generalised oedema	0	1	1
Multiple organ dysfunction syndrome	0	1	1
Oedema peripheral	0	1	1
Feeling hot	1	0	1
Incarcerated hernia	2	0	2

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
General disorders and administration site conditions (Cont.)			
Pyrexia	1	0	1
Systemic inflammatory response syndrome	2	0	2
Investigations	1	4	5
Heart rate irregular	0	2	2
Hepatic enzyme increased	0	2	2
Transaminases increased	1	0	1
Injury, poisoning and procedural complications	33	35	68
Hip fracture	3	3	6
Cervical vertebral fracture	0	2	2
Craniocerebral injury	0	2	2
Fall	5	2	7
Road traffic accident	1	2	3
Subdural haematoma	0	2	2
Back injury	0	1	1
Concussion	0	1	1
Facial bones fracture	0	1	1
Femoral neck fracture	0	1	1
Femur fracture	2	1	3
Gastrointestinal procedural complication	0	1	1
Head injury	0	1	1
Humerus fracture	0	1	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Injury, poisoning and procedural complications (Cont.)			
Incarcerated incisional hernia	0	1	1
Incision site pain	0	1	1
Joint injury	2	1	3
Overdose	0	1	1
Post procedural haemorrhage	1	1	2
Procedural haemorrhage	1	1	2
Rib fracture	3	1	4
Skin laceration	1	1	2
Superficial injury of eye	0	1	1
Tendon rupture	1	1	2
Traumatic liver injury	0	1	1
Upper limb fracture	0	1	1
Wound dehiscence	0	1	1
Wrist fracture	0	1	1
Ankle fracture	1	0	1
Cartilage injury	1	0	1
Gun shot wound	1	0	1
Immunisation anxiety related reaction	1	0	1
Pelvic fracture	1	0	1
Post procedural fever	1	0	1
Post procedural haematoma	1	0	1
Post-traumatic pain	1	0	1
Sternal fracture	1	0	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.13.4.1
Incidence of Serious TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Injury, poisoning and procedural complications (Cont.)			
Thoracic vertebral fracture	1	0	1
Tracheal haemorrhage	1	0	1
Traumatic haemothorax	2	0	2
Social circumstances	1	0	1
Sexual abuse	1	0	1
Product issues	1	0	1
Lead dislodgement	1	0	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
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Table 14.3.1.14.1.1
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3 (<0.1)	8 (<0.1)		11 (<0.1)
Number of Unsolicited Adverse Events	7	9		16
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.14.1.1
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0		2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.14.1.3
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4 (<0.1)	12 (<0.1)		16 (<0.1)
Number of Unsolicited Adverse Events	13	15		28
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericardial effusion	0	1 (<0.1)		1 (<0.1)
Pericarditis	0	1 (<0.1)		1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.14.1.3
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Atrial fibrillation	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Respiratory failure	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	1 (<0.1)	0		1 (<0.1)
Acute kidney injury	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.14.1.3
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0		2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.14.2.1
Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (<0.1)	6 (<0.1)		8 (<0.1)
Number of Unsolicited Adverse Events	6	6		12
Nervous system disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.14.2.1
Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications	2 (<0.1)	0		2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.14.2.1
Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1 (<0.1)	2 (<0.1)		3 (<0.1)
Number of Unsolicited Adverse Events	1	3		4
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.14.2.3
Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (<0.1)	9 (<0.1)		11 (<0.1)
Number of Unsolicited Adverse Events	6	11		17
Nervous system disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	0	1 (<0.1)		1 (<0.1)
Pericardial effusion	0	1 (<0.1)		1 (<0.1)
Pericarditis	0	1 (<0.1)		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140203.sas 10JUN2021 13:05

Table 14.3.1.14.2.3
Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0		2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140203.sas 10JUN2021 13:05

Table 14.3.1.14.2.3
Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (<0.1)	3 (<0.1)		5 (<0.1)
Number of Unsolicited Adverse Events	7	4		11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	1 (<0.1)	0		1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Respiratory failure	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140203.sas 10JUN2021 13:05

Table 14.3.1.14.2.3
Subject Incidence of Serious Treatment-Related TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	1 (<0.1)	0		1 (<0.1)
Acute kidney injury	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140203.sas 10JUN2021 13:05

Table 14.3.1.14.3.1
Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3 (<0.1)	8 (<0.1)		11 (<0.1)
Number of Unsolicited Adverse Events	7	9		16
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140301.sas 21JUN2021 14:46

Table 14.3.1.14.3.1
Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0		2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140301.sas 21JUN2021 14:46

Table 14.3.1.14.3.1
Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)

There are no observations for this section.

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.14.3.3
Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4 (<0.1)	12 (<0.1)		16 (<0.1)
Number of Unsolicited Adverse Events	13	15		28
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Endocrine disorders	0	1 (<0.1)		1 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	0	1 (<0.1)		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericardial effusion	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140303.sas 10JUN2021 13:05

Table 14.3.1.14.3.3
Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Pericarditis	0	1 (<0.1)		1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Respiratory failure	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Vomiting	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Angioedema	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140303.sas 10JUN2021 13:05

Table 14.3.1.14.3.3
Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders	1 (<0.1)	0		1 (<0.1)
Acute kidney injury	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	0		2 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140303.sas 10JUN2021 13:05

Table 14.3.1.14.3.3
Subject Incidence of Serious Treatment-Related TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)

There are no observations for this section.

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140303.sas 10JUN2021 13:05

Table 14.3.1.14.5.1
Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Number of Unsolicited Adverse Events	7	9	16
Endocrine disorders	0	1	1
Basedow's disease	0	1	1
Nervous system disorders	2	1	3
Autonomic nervous system imbalance	0	1	1
Paraesthesia	2	0	2
Gastrointestinal disorders	0	2	2
Nausea	0	1	1
Vomiting	0	1	1
Skin and subcutaneous tissue disorders	0	2	2
Alopecia areata	0	1	1
Angioedema	0	1	1
Musculoskeletal and connective tissue disorders	1	1	2
Rheumatoid arthritis	0	1	1
Polymyalgia rheumatica	1	0	1
General disorders and administration site conditions	2	2	4
Swelling face	1	2	3
Feeling hot	1	0	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140501.sas 21JUN2021 14:47

Table 14.3.1.14.5.1
Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Number of Events Placebo (N=15162)	 mRNA-1273 (N=15184)	 Total (N=30346)
Injury, poisoning and procedural complications	2	0	2
Immunisation anxiety related reaction	1	0	1
Procedural haemorrhage	1	0	1

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301140501.sas 21JUN2021 14:47

Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	109 (0.7)	74 (0.5)		183 (0.6)
Number of Unsolicited Adverse Events	123	87		210
Infections and infestations	61 (0.4)	25 (0.2)		86 (0.3)
COVID-19	53 (0.3)	14 (<0.1)	0.26 (0.15, 0.47)	67 (0.2)
Asymptomatic COVID-19	0	3 (<0.1)		3 (<0.1)
Pneumonia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes simplex	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Suspected COVID-19	0	1 (<0.1)		1 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Diverticulitis	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403011501.sas 10JUN2021 13:05

Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	3 (<0.1)		4 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymphadenopathy	0	2 (<0.1)		2 (<0.1)
Psychiatric disorders	6 (<0.1)	4 (<0.1)		10 (<0.1)
Bipolar disorder	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Anxiety	2 (<0.1)	0		2 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403011501.sas 10JUN2021 13:05

Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders	6 (<0.1)	6 (<0.1)		12 (<0.1)
Ageusia	0	1 (<0.1)		1 (<0.1)
Anosmia	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Headache	2 (<0.1)	1 (<0.1)		3 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Amnesia	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	2 (<0.1)	0		2 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (<0.1)	0		2 (<0.1)
Vertigo	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	6 (<0.1)	3 (<0.1)		9 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Tachycardia	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	4 (<0.1)	4 (<0.1)		8 (<0.1)
Hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	6 (<0.1)	3 (<0.1)		9 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0		1 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abdominal pain lower	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	4 (<0.1)	9 (<0.1)		13 (<0.1)
Urticaria	2 (<0.1)	5 (<0.1)		7 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal and connective tissue disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Arthralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthritis	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Back pain	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	0		1 (<0.1)
Pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	3 (<0.1)	6 (<0.1)		9 (<0.1)
Injection site erythema	0	2 (<0.1)		2 (<0.1)
Injection site swelling	0	2 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Injection site macule	0	1 (<0.1)		1 (<0.1)
Injection site urticaria	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure increased	1 (<0.1)	0		1 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications	5 (<0.1)	4 (<0.1)		9 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Product issues	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	82 (0.7)	59 (0.5)		141 (0.6)
Number of Unsolicited Adverse Events	85	69		154
Infections and infestations	53 (0.5)	20 (0.2)		73 (0.3)
COVID-19	50 (0.4)	10 (<0.1)	0.20 (0.10, 0.39)	60 (0.3)
Asymptomatic COVID-19	0	3 (<0.1)		3 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes simplex	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Pneumonia	0	1 (<0.1)		1 (<0.1)
Suspected COVID-19	0	1 (<0.1)		1 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	3 (<0.1)		4 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymphadenopathy	0	2 (<0.1)		2 (<0.1)
Psychiatric disorders	5 (<0.1)	4 (<0.1)		9 (<0.1)
Bipolar disorder	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Anxiety	2 (<0.1)	0		2 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	2 (<0.1)	4 (<0.1)		6 (<0.1)
Ageusia	0	1 (<0.1)		1 (<0.1)
Anosmia	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Headache	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Eye disorders	2 (<0.1)	0		2 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0		1 (<0.1)
Vertigo	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cardiac failure congestive	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders	4 (<0.1)	1 (<0.1)		5 (<0.1)
Pulmonary embolism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0		1 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	0	2 (<0.1)		2 (<0.1)
Abdominal pain lower	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	3 (<0.1)	7 (<0.1)		10 (<0.1)
Urticaria	1 (<0.1)	4 (<0.1)		5 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal and connective tissue disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Arthralgia	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Back pain	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Synovitis	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	0		1 (<0.1)
Pregnancy	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	6 (<0.1)		7 (<0.1)
Injection site erythema	0	2 (<0.1)		2 (<0.1)
Injection site swelling	0	2 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Injection site macule	0	1 (<0.1)		1 (<0.1)
Injection site urticaria	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	0		1 (<0.1)
Investigations	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications	3 (<0.1)	2 (<0.1)		5 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Product issues	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	27 (0.7)	15 (0.4)		42 (0.6)
Number of Unsolicited Adverse Events	38	18		56
Infections and infestations	8 (0.2)	5 (0.1)		13 (0.2)
COVID-19	3 (<0.1)	4 (0.1)		7 (<0.1)
Pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Diverticulitis	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	4 (0.1)	2 (<0.1)		6 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Amnesia	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0		1 (<0.1)
Vertigo	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	5 (0.1)	0		5 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Cardiac failure congestive	1 (<0.1)	0		1 (<0.1)
Tachycardia	1 (<0.1)	0		1 (<0.1)
Vascular disorders	0	1 (<0.1)		1 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal and connective tissue disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Arthritis	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Arthralgia	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.2
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Age Group, System Organ Class and Preferred Term
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions	2 (<0.1)	0		2 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	0		1 (<0.1)
Blood pressure increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hip fracture	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	101 (0.7)	67 (0.5)		168 (0.6)
Number of Unsolicited Adverse Events	115	79		194
Infections and infestations	54 (0.4)	19 (0.1)		73 (0.2)
COVID-19	47 (0.3)	10 (<0.1)	0.21 (0.11, 0.42)	57 (0.2)
Asymptomatic COVID-19	0	2 (<0.1)		2 (<0.1)
Pneumonia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Suspected COVID-19	0	1 (<0.1)		1 (<0.1)
Viral infection	0	1 (<0.1)		1 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Diverticulitis	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Varicella zoster virus infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	3 (<0.1)		4 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymphadenopathy	0	2 (<0.1)		2 (<0.1)
Psychiatric disorders	6 (<0.1)	3 (<0.1)		9 (<0.1)
Bipolar disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Anxiety	2 (<0.1)	0		2 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders	6 (<0.1)	6 (<0.1)		12 (<0.1)
Ageusia	0	1 (<0.1)		1 (<0.1)
Anosmia	0	1 (<0.1)		1 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Headache	2 (<0.1)	1 (<0.1)		3 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Neuropathy peripheral	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Amnesia	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Migraine	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Eye disorders	2 (<0.1)	0		2 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (<0.1)	0		2 (<0.1)
Vertigo	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	6 (<0.1)	2 (<0.1)		8 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Acute myocardial infarction	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	2 (<0.1)	0		2 (<0.1)
Cardiac failure congestive	1 (<0.1)	0		1 (<0.1)
Tachycardia	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	4 (<0.1)	4 (<0.1)		8 (<0.1)
Hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Orthostatic hypotension	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	6 (<0.1)	3 (<0.1)		9 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0		1 (<0.1)
Pleurisy	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abdominal pain lower	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Cholelithiasis	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	4 (<0.1)	9 (<0.1)		13 (<0.1)
Urticaria	2 (<0.1)	5 (<0.1)		7 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal and connective tissue disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Arthralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthritis	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	0	1 (<0.1)		1 (<0.1)
Back pain	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	0		1 (<0.1)
Pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site erythema	0	2 (<0.1)		2 (<0.1)
Injection site swelling	0	2 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Injection site macule	0	1 (<0.1)		1 (<0.1)
Injection site urticaria	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure increased	1 (<0.1)	0		1 (<0.1)
Heart rate irregular	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	5 (<0.1)	4 (<0.1)		9 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Product issues	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	8 (2.4)	6 (1.7)		14 (2.0)
Number of Unsolicited Adverse Events	8	7		15
Infections and infestations	7 (2.1)	5 (1.4)		12 (1.8)
COVID-19	6 (1.8)	4 (1.2)		10 (1.5)
Asymptomatic COVID-19	0	1 (0.3)		1 (0.1)
Pyelonephritis acute	1 (0.3)	0		1 (0.1)
Psychiatric disorders	0	1 (0.3)		1 (0.1)
Drug abuse	0	1 (0.3)		1 (0.1)
Cardiac disorders	0	1 (0.3)		1 (0.1)
Cardiac failure congestive	0	1 (0.3)		1 (0.1)
General disorders and administration site conditions	1 (0.3)	0		1 (0.1)
Non-cardiac chest pain	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.15.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Study Vaccine by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	1 (1.1)		1 (0.6)
Number of Unsolicited Adverse Events	0	1		1
Infections and infestations	0	1 (1.1)		1 (0.6)
Herpes simplex	0	1 (1.1)		1 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.16.1.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6 (<0.1)	9 (<0.1)		15 (<0.1)
Number of Unsolicited Adverse Events	6	10		16
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	0	3 (<0.1)		3 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Cardiac disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160101.sas 21JUN2021 14:49

Table 14.3.1.16.1.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Investigations	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160101.sas 21JUN2021 14:49

Table 14.3.1.16.1.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	23 (0.2)	26 (0.2)		49 (0.2)
Number of Unsolicited Adverse Events	24	30		54
Infections and infestations	3 (<0.1)	1 (<0.1)		4 (<0.1)
COVID-19	3 (<0.1)	1 (<0.1)		4 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	3 (<0.1)		4 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	0	1 (<0.1)		1 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160103.sas 21JUN2021 14:49

Table 14.3.1.16.1.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders	2 (<0.1)	0		2 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Seizure	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0		1 (<0.1)
Vertigo	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	5 (<0.1)	7 (<0.1)		12 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Myocardial infarction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Vascular disorders	1 (<0.1)	0		1 (<0.1)
Hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	4 (<0.1)		4 (<0.1)
Acute respiratory failure	0	1 (<0.1)		1 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160103.sas 21JUN2021 14:49

Table 14.3.1.16.1.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastrointestinal haemorrhage	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	4 (<0.1)	6 (<0.1)		10 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160103.sas 21JUN2021 14:49

Table 14.3.1.16.1.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term in Overall Stage
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Hip fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160103.sas 21JUN2021 14:49

Table 14.3.1.16.2.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3 (<0.1)	7 (<0.1)		10 (<0.1)
Number of Unsolicited Adverse Events	3	8		11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	0	3 (<0.1)		3 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Cardiac disorders	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160201.sas 21JUN2021 14:49

Table 14.3.1.16.2.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Investigations	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160201.sas 21JUN2021 14:49

Table 14.3.1.16.2.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3 (<0.1)	2 (<0.1)		5 (<0.1)
Number of Unsolicited Adverse Events	3	2		5
Cardiac disorders	0	1 (<0.1)		1 (<0.1)
Cardio-respiratory arrest	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160201.sas 21JUN2021 14:49

Table 14.3.1.16.2.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	15 (0.1)	15 (0.1)		30 (0.1)
Number of Unsolicited Adverse Events	15	17		32
Infections and infestations	3 (<0.1)	0		3 (<0.1)
COVID-19	3 (<0.1)	0		3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	3 (<0.1)		3 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Metabolism and nutrition disorders	0	1 (<0.1)		1 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160203.sas 21JUN2021 14:50

Table 14.3.1.16.2.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders	1 (<0.1)	0		1 (<0.1)
Seizure	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0		1 (<0.1)
Vertigo	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	3 (<0.1)	1 (<0.1)		4 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Myocardial infarction	2 (<0.1)	0		2 (<0.1)
Vascular disorders	1 (<0.1)	0		1 (<0.1)
Hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160203.sas 21JUN2021 14:50

Table 14.3.1.16.2.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions	2 (<0.1)	5 (<0.1)		7 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Investigations	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160203.sas 21JUN2021 14:50

Table 14.3.1.16.2.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	8 (0.2)	11 (0.3)		19 (0.3)
Number of Unsolicited Adverse Events	9	13		22
Infections and infestations	0	1 (<0.1)		1 (<0.1)
COVID-19	0	1 (<0.1)		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	0		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	1 (<0.1)	0		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	2 (<0.1)	6 (0.2)		8 (0.1)
Cardio-respiratory arrest	0	2 (<0.1)		2 (<0.1)
Myocardial infarction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160203.sas 21JUN2021 14:50

Table 14.3.1.16.2.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Age Group, System Organ Class and Preferred Term in Overall Stage
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders	0	3 (<0.1)		3 (<0.1)
Acute respiratory failure	0	1 (<0.1)		1 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastrointestinal haemorrhage	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	2 (<0.1)	1 (<0.1)		3 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160203.sas 21JUN2021 14:50

Table 14.3.1.16.3.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6 (<0.1)	9 (<0.1)		15 (<0.1)
Number of Unsolicited Adverse Events	6	10		16
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	0	3 (<0.1)		3 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Cardiac disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160301.sas 21JUN2021 14:50

Table 14.3.1.16.3.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)
Investigations	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160301.sas 21JUN2021 14:50

Table 14.3.1.16.3.1
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)

There are no observations for this section.

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160301.sas 21JUN2021 14:50

Table 14.3.1.16.3.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	23 (0.2)	26 (0.2)		49 (0.2)
Number of Unsolicited Adverse Events	24	30		54
Infections and infestations	3 (<0.1)	1 (<0.1)		4 (<0.1)
COVID-19	3 (<0.1)	1 (<0.1)		4 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (<0.1)	3 (<0.1)		4 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	0	1 (<0.1)		1 (<0.1)
Diabetic complication	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Completed suicide	1 (<0.1)	1 (<0.1)		2 (<0.1)
Schizoaffective disorder	0	1 (<0.1)		1 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.16.3.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders (Cont.)				
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	2 (<0.1)	0		2 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Seizure	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0		1 (<0.1)
Vertigo	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	5 (<0.1)	7 (<0.1)		12 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Myocardial infarction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cardiac arrest	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	0	1 (<0.1)		1 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Vascular disorders	1 (<0.1)	0		1 (<0.1)
Hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	4 (<0.1)		4 (<0.1)
Acute respiratory failure	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160303.sas 21JUN2021 14:51

Table 14.3.1.16.3.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Pulmonary mass	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastrointestinal haemorrhage	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Dermatitis allergic	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	4 (<0.1)	6 (<0.1)		10 (<0.1)
Death	2 (<0.1)	4 (<0.1)		6 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Incarcerated hernia	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160303.sas 21JUN2021 14:51

Table 14.3.1.16.3.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Systemic inflammatory response syndrome	1 (<0.1)	0		1 (<0.1)
Investigations	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160303.sas 21JUN2021 14:51

Table 14.3.1.16.3.3
Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)

There are no observations for this section.

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301160303.sas 21JUN2021 14:51

Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	233 (1.5)	258 (1.7)		491 (1.6)
Number of Unsolicited Adverse Events	291	318		609
Infections and infestations	34 (0.2)	20 (0.1)		54 (0.2)
Sinusitis	0	2 (<0.1)		2 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cellulitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis	0	1 (<0.1)		1 (<0.1)
Diverticulitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Fungal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingivitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Tooth infection	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301170101.sas 21JUN2021 14:51

Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Urinary tract infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bacterial vaginosis	1 (<0.1)	0		1 (<0.1)
Bronchitis	2 (<0.1)	0		2 (<0.1)
COVID-19	7 (<0.1)	0		7 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Tooth abscess	2 (<0.1)	0		2 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Viral infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (<0.1)	9 (<0.1)		18 (<0.1)
Prostate cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Basal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Malignant melanoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	3 (<0.1)		3 (<0.1)
Anaemia	0	1 (<0.1)		1 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Immune system disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Food allergy	0	1 (<0.1)		1 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Drug hypersensitivity	2 (<0.1)	0		2 (<0.1)
Endocrine disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypothyroidism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301170101.sas 21JUN2021 14:51

Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Decreased appetite	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Glucose tolerance impaired	0	1 (<0.1)		1 (<0.1)
Dehydration	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	8 (<0.1)	2 (<0.1)		10 (<0.1)
Depression	2 (<0.1)	1 (<0.1)		3 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	3 (<0.1)	0		3 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Insomnia	1 (<0.1)	0		1 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	23 (0.2)	26 (0.2)		49 (0.2)
Headache	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)
Migraine	2 (<0.1)	3 (<0.1)		5 (<0.1)
Syncope	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dizziness	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301170101.sas 21JUN2021 14:51

Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Sciatica	1 (<0.1)	1 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Carpal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Presyncope	2 (<0.1)	0		2 (<0.1)
Seizure	1 (<0.1)	0		1 (<0.1)
Eye disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Scleritis	0	1 (<0.1)		1 (<0.1)
Blepharitis	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vertigo	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cardiac disorders	12 (<0.1)	15 (<0.1)		27 (<0.1)
Atrial fibrillation	3 (<0.1)	4 (<0.1)		7 (<0.1)
Bradycardia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Coronary artery disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301170101.sas 21JUN2021 14:51

Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Cardiac failure	1 (<0.1)	0		1 (<0.1)
Tachycardia	2 (<0.1)	0		2 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	44 (0.3)	33 (0.2)		77 (0.3)
Hypertension	34 (0.2)	28 (0.2)	0.82 (0.50, 1.35)	62 (0.2)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	1 (<0.1)	0		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	12 (<0.1)	15 (<0.1)		27 (<0.1)
Cough	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dyspnoea	0	2 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal congestion	0	2 (<0.1)		2 (<0.1)
Pleural effusion	0	2 (<0.1)		2 (<0.1)
Rhinorrhoea	0	2 (<0.1)		2 (<0.1)
Asthma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	0	1 (<0.1)		1 (<0.1)
Pleurisy	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	2 (<0.1)	0		2 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	16 (0.1)	21 (0.1)		37 (0.1)
Nausea	1 (<0.1)	5 (<0.1)		6 (<0.1)
Abdominal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diarrhoea	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal pain upper	2 (<0.1)	1 (<0.1)		3 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Enteritis	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Umbilical hernia	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastritis	2 (<0.1)	0		2 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrooesophageal reflux disease	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)		3 (<0.1)
Cholelithiasis	0	2 (<0.1)		2 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	6 (<0.1)		8 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Erythema	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	35 (0.2)	26 (0.2)		61 (0.2)
Myalgia	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Arthralgia	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Muscle spasms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Neck pain	0	2 (<0.1)		2 (<0.1)
Pain in extremity	0	2 (<0.1)		2 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Temporomandibular joint syndrome	0	2 (<0.1)		2 (<0.1)
Back pain	7 (<0.1)	1 (<0.1)	0.14 (0.02, 0.89)	8 (<0.1)
Rotator cuff syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tendonitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Costochondritis	1 (<0.1)	0		1 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Joint swelling	1 (<0.1)	0		1 (<0.1)
Musculoskeletal chest pain	2 (<0.1)	0		2 (<0.1)
Osteoarthritis	3 (<0.1)	0		3 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Nephrolithiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	0		1 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	20 (0.1)	55 (0.4)		75 (0.2)
Fatigue	9 (<0.1)	20 (0.1)	2.22 (1.03, 4.78)	29 (<0.1)
Injection site erythema	0	8 (<0.1)		8 (<0.1)
Injection site macule	0	6 (<0.1)		6 (<0.1)
Injection site pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site swelling	0	3 (<0.1)		3 (<0.1)
Chills	0	2 (<0.1)		2 (<0.1)
Injection site urticaria	0	2 (<0.1)		2 (<0.1)
Pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pyrexia	0	2 (<0.1)		2 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site induration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Investigations	13 (<0.1)	23 (0.2)		36 (0.1)
Blood pressure increased	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Blood pressure systolic increased	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Blood pressure diastolic increased	0	4 (<0.1)		4 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	21 (0.1)	19 (0.1)		40 (0.1)
Limb injury	0	2 (<0.1)		2 (<0.1)
Skin laceration	0	2 (<0.1)		2 (<0.1)
Ankle fracture	0	1 (<0.1)		1 (<0.1)
Burns second degree	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Foot fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ligament injury	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.1
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ligament sprain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle strain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Procedural pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Road traffic accident	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Tendon injury	0	1 (<0.1)		1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Joint dislocation	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Meniscus injury	1 (<0.1)	0		1 (<0.1)
Muscle rupture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	152 (1.3)	177 (1.6)		329 (1.4)
Number of Unsolicited Adverse Events	190	225		415
Infections and infestations	21 (0.2)	17 (0.1)		38 (0.2)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis	0	1 (<0.1)		1 (<0.1)
Diverticulitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Fungal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumonia	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Sinusitis	0	1 (<0.1)		1 (<0.1)
Tooth infection	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Appendicitis	1 (<0.1)	0		1 (<0.1)
Bacterial vaginosis	1 (<0.1)	0		1 (<0.1)
Bronchitis	2 (<0.1)	0		2 (<0.1)
COVID-19	6 (<0.1)	0		6 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
Gingivitis	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Viral infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (<0.1)	5 (<0.1)		8 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	3 (<0.1)		3 (<0.1)
Anaemia	0	1 (<0.1)		1 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Immune system disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Food allergy	0	1 (<0.1)		1 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Drug hypersensitivity	2 (<0.1)	0		2 (<0.1)
Endocrine disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypothyroidism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Decreased appetite	0	1 (<0.1)		1 (<0.1)
Glucose tolerance impaired	0	1 (<0.1)		1 (<0.1)
Dehydration	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	7 (<0.1)	1 (<0.1)		8 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	3 (<0.1)	0		3 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Insomnia	1 (<0.1)	0		1 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	18 (0.2)	21 (0.2)		39 (0.2)
Headache	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Migraine	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dizziness	1 (<0.1)	2 (<0.1)		3 (<0.1)
Syncope	1 (<0.1)	2 (<0.1)		3 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Presyncope	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Seizure	1 (<0.1)	0		1 (<0.1)
Eye disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Scleritis	0	1 (<0.1)		1 (<0.1)
Blepharitis	1 (<0.1)	0		1 (<0.1)
Retinal detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertigo	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac disorders	5 (<0.1)	8 (<0.1)		13 (<0.1)
Bradycardia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Atrial fibrillation	1 (<0.1)	0		1 (<0.1)
Tachycardia	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders	26 (0.2)	16 (0.1)		42 (0.2)
Hypertension	20 (0.2)	15 (0.1)	0.75 (0.39, 1.45)	35 (0.2)
Systolic hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	1 (<0.1)	0		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	9 (<0.1)	13 (0.1)		22 (<0.1)
Cough	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dyspnoea	0	2 (<0.1)		2 (<0.1)
Nasal congestion	0	2 (<0.1)		2 (<0.1)
Rhinorrhoea	0	2 (<0.1)		2 (<0.1)
Asthma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Pleurisy	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	11 (<0.1)	19 (0.2)		30 (0.1)
Abdominal pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diarrhoea	1 (<0.1)	3 (<0.1)		4 (<0.1)
Nausea	0	3 (<0.1)		3 (<0.1)
Abdominal pain upper	1 (<0.1)	1 (<0.1)		2 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Enteritis	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Umbilical hernia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal discomfort	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrooesophageal reflux disease	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	2 (<0.1)		2 (<0.1)
Cholelithiasis	0	2 (<0.1)		2 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	25 (0.2)	15 (0.1)		40 (0.2)
Myalgia	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Arthralgia	6 (<0.1)	4 (<0.1)		10 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Temporomandibular joint syndrome	0	2 (<0.1)		2 (<0.1)
Muscle spasms	1 (<0.1)	1 (<0.1)		2 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Pain in extremity	0	1 (<0.1)		1 (<0.1)
Tendonitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Back pain	7 (<0.1)	0		7 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Costochondritis	1 (<0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Joint swelling	1 (<0.1)	0		1 (<0.1)
Musculoskeletal chest pain	2 (<0.1)	0		2 (<0.1)
Spinal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute kidney injury	0	1 (<0.1)		1 (<0.1)
Nephrolithiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	0		1 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	15 (0.1)	42 (0.4)		57 (0.2)
Fatigue	6 (<0.1)	16 (0.1)	2.67 (1.08, 6.60)	22 (<0.1)
Injection site erythema	0	5 (<0.1)		5 (<0.1)
Injection site pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site macule	0	3 (<0.1)		3 (<0.1)
Chills	0	2 (<0.1)		2 (<0.1)
Injection site swelling	0	2 (<0.1)		2 (<0.1)
Pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site induration	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Injection site rash	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Investigations	8 (<0.1)	15 (0.1)		23 (0.1)
Blood pressure increased	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Blood pressure systolic increased	4 (<0.1)	4 (<0.1)		8 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Injury, poisoning and procedural complications	13 (0.1)	14 (0.1)		27 (0.1)
Limb injury	0	2 (<0.1)		2 (<0.1)
Ankle fracture	0	1 (<0.1)		1 (<0.1)
Burns second degree	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Ligament injury	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ligament sprain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle strain	0	1 (<0.1)		1 (<0.1)
Procedural pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Road traffic accident	0	1 (<0.1)		1 (<0.1)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Tendon injury	0	1 (<0.1)		1 (<0.1)
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Foot fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Meniscus injury	1 (<0.1)	0		1 (<0.1)
Muscle rupture	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	81 (2.2)	81 (2.1)		162 (2.2)
Number of Unsolicited Adverse Events	101	93		194
Infections and infestations	13 (0.3)	3 (<0.1)		16 (0.2)
Appendicitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gingivitis	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Sinusitis	0	1 (<0.1)		1 (<0.1)
COVID-19	1 (<0.1)	0		1 (<0.1)
Cellulitis	1 (<0.1)	0		1 (<0.1)
Diverticulitis	2 (<0.1)	0		2 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	1 (<0.1)	0		1 (<0.1)
Pneumonia	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Urinary tract infection	3 (<0.1)	0		3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (0.2)	4 (0.1)		10 (0.1)
Prostate cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Basal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Immune system disorders	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Endocrine disorders	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Psychiatric disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Depression	0	1 (<0.1)		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	5 (0.1)	5 (0.1)		10 (0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Headache	2 (<0.1)	1 (<0.1)		3 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Sciatica	1 (<0.1)	1 (<0.1)		2 (<0.1)
Syncope	0	1 (<0.1)		1 (<0.1)
Carpal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Presyncope	1 (<0.1)	0		1 (<0.1)
Eye disorders	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal detachment	0	1 (<0.1)		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (<0.1)	0		2 (<0.1)
Vertigo	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	7 (0.2)	7 (0.2)		14 (0.2)
Atrial fibrillation	2 (<0.1)	4 (0.1)		6 (<0.1)
Coronary artery disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Bradycardia	2 (<0.1)	0		2 (<0.1)
Cardiac failure	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Vascular disorders	18 (0.5)	17 (0.5)		35 (0.5)
Hypertension	14 (0.4)	13 (0.3)	0.92 (0.44, 1.93)	27 (0.4)
Systolic hypertension	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Nasal septum deviation	0	1 (<0.1)		1 (<0.1)
Pleural effusion	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	1 (<0.1)	0		1 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	5 (0.1)	2 (<0.1)		7 (<0.1)
Nausea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal pain	1 (<0.1)	0		1 (<0.1)
Abdominal pain upper	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Hepatobiliary disorders	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Erythema	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	10 (0.3)	11 (0.3)		21 (0.3)
Arthralgia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Myalgia	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Back pain	0	1 (<0.1)		1 (<0.1)
Muscle spasms	0	1 (<0.1)		1 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Pain in extremity	0	1 (<0.1)		1 (<0.1)
Rotator cuff syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	0		1 (<0.1)
Osteoarthritis	3 (<0.1)	0		3 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Tendonitis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	3 (<0.1)	1 (<0.1)		4 (<0.1)
Nephrolithiasis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute kidney injury	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
General disorders and administration site conditions	5 (0.1)	13 (0.3)		18 (0.2)
Fatigue	3 (<0.1)	4 (0.1)		7 (<0.1)
Injection site erythema	0	3 (<0.1)		3 (<0.1)
Injection site macule	0	3 (<0.1)		3 (<0.1)
Injection site urticaria	0	2 (<0.1)		2 (<0.1)
Pyrexia	0	2 (<0.1)		2 (<0.1)
Injection site swelling	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Pain	1 (<0.1)	0		1 (<0.1)
Investigations	5 (0.1)	8 (0.2)		13 (0.2)
Blood pressure systolic increased	3 (<0.1)	3 (<0.1)		6 (<0.1)
Blood pressure diastolic increased	0	2 (<0.1)		2 (<0.1)
Blood pressure increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	8 (0.2)	5 (0.1)		13 (0.2)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Foot fracture	0	1 (<0.1)		1 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin laceration	0	1 (<0.1)		1 (<0.1)
Joint dislocation	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Muscle strain	2 (<0.1)	0		2 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.2
Subject Incidence of Unsolicited Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Procedural pain	1 (<0.1)	0		1 (<0.1)
Road traffic accident	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	225 (1.5)	256 (1.7)		481 (1.6)
Number of Unsolicited Adverse Events	280	316		596
Infections and infestations	34 (0.2)	20 (0.1)		54 (0.2)
Sinusitis	0	2 (<0.1)		2 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cellulitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis	0	1 (<0.1)		1 (<0.1)
Diverticulitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Fungal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingivitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Tooth infection	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Bacterial vaginosis	1 (<0.1)	0		1 (<0.1)
Bronchitis	2 (<0.1)	0		2 (<0.1)
COVID-19	7 (<0.1)	0		7 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Tooth abscess	2 (<0.1)	0		2 (<0.1)
Upper respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Viral infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (<0.1)	9 (<0.1)		18 (<0.1)
Prostate cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Basal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Malignant melanoma	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	3 (<0.1)		3 (<0.1)
Anaemia	0	1 (<0.1)		1 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Immune system disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Food allergy	0	1 (<0.1)		1 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Immune system disorders (Cont.)				
Drug hypersensitivity	2 (<0.1)	0		2 (<0.1)
Endocrine disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypothyroidism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	2 (<0.1)	3 (<0.1)		5 (<0.1)
Decreased appetite	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Glucose tolerance impaired	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	8 (<0.1)	2 (<0.1)		10 (<0.1)
Depression	2 (<0.1)	1 (<0.1)		3 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	3 (<0.1)	0		3 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Insomnia	1 (<0.1)	0		1 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders	23 (0.2)	26 (0.2)		49 (0.2)
Headache	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)
Migraine	2 (<0.1)	3 (<0.1)		5 (<0.1)
Syncope	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dizziness	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Sciatica	1 (<0.1)	1 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Carpal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Presyncope	2 (<0.1)	0		2 (<0.1)
Seizure	1 (<0.1)	0		1 (<0.1)
Eye disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Scleritis	0	1 (<0.1)		1 (<0.1)
Blepharitis	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Ear and labyrinth disorders	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vertigo	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cardiac disorders	11 (<0.1)	15 (0.1)		26 (<0.1)
Atrial fibrillation	2 (<0.1)	4 (<0.1)		6 (<0.1)
Bradycardia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Coronary artery disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Cardiac failure	1 (<0.1)	0		1 (<0.1)
Tachycardia	2 (<0.1)	0		2 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	44 (0.3)	33 (0.2)		77 (0.3)
Hypertension	34 (0.2)	28 (0.2)	0.82 (0.50, 1.35)	62 (0.2)
Systolic hypertension	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Hypertensive emergency	1 (<0.1)	0		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
White coat hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	12 (<0.1)	15 (0.1)		27 (<0.1)
Cough	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dyspnoea	0	2 (<0.1)		2 (<0.1)
Nasal congestion	0	2 (<0.1)		2 (<0.1)
Pleural effusion	0	2 (<0.1)		2 (<0.1)
Rhinorrhoea	0	2 (<0.1)		2 (<0.1)
Asthma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	0	1 (<0.1)		1 (<0.1)
Pleurisy	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Chronic obstructive pulmonary disease	2 (<0.1)	0		2 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Hypoxia	1 (<0.1)	0		1 (<0.1)
Oropharyngeal pain	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	16 (0.1)	20 (0.1)		36 (0.1)
Nausea	1 (<0.1)	5 (<0.1)		6 (<0.1)
Abdominal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diarrhoea	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abdominal pain upper	2 (<0.1)	1 (<0.1)		3 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Enteritis	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Umbilical hernia	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastritis	2 (<0.1)	0		2 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrooesophageal reflux disease	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)		3 (<0.1)
Cholelithiasis	0	2 (<0.1)		2 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	2 (<0.1)	6 (<0.1)		8 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Erythema	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders	32 (0.2)	26 (0.2)		58 (0.2)
Myalgia	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Arthralgia	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Muscle spasms	1 (<0.1)	2 (<0.1)		3 (<0.1)
Neck pain	0	2 (<0.1)		2 (<0.1)
Pain in extremity	0	2 (<0.1)		2 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	0	2 (<0.1)		2 (<0.1)
Temporomandibular joint syndrome	0	2 (<0.1)		2 (<0.1)
Back pain	6 (<0.1)	1 (<0.1)		7 (<0.1)
Rotator cuff syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tendonitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Costochondritis	1 (<0.1)	0		1 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Joint swelling	1 (<0.1)	0		1 (<0.1)
Musculoskeletal chest pain	2 (<0.1)	0		2 (<0.1)
Osteoarthritis	3 (<0.1)	0		3 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Nephrolithiasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	0		1 (<0.1)
Dysmenorrhoea	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	19 (0.1)	55 (0.4)		74 (0.3)
Fatigue	9 (<0.1)	20 (0.1)	2.22 (1.03, 4.78)	29 (<0.1)
Injection site erythema	0	8 (<0.1)		8 (<0.1)
Injection site macule	0	6 (<0.1)		6 (<0.1)
Injection site pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Injection site swelling	0	3 (<0.1)		3 (<0.1)
Chills	0	2 (<0.1)		2 (<0.1)
Injection site urticaria	0	2 (<0.1)		2 (<0.1)
Pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pyrexia	0	2 (<0.1)		2 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site hypoaesthesia	0	1 (<0.1)		1 (<0.1)
Injection site induration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Investigations	11 (<0.1)	22 (0.1)		33 (0.1)
Blood pressure increased	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Blood pressure systolic increased	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Blood pressure diastolic increased	0	4 (<0.1)		4 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Blood pressure systolic decreased	0	1 (<0.1)		1 (<0.1)
Injury, poisoning and procedural complications	21 (0.1)	19 (0.1)		40 (0.1)
Limb injury	0	2 (<0.1)		2 (<0.1)
Skin laceration	0	2 (<0.1)		2 (<0.1)
Ankle fracture	0	1 (<0.1)		1 (<0.1)
Burns second degree	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Foot fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ligament injury	0	1 (<0.1)		1 (<0.1)
Ligament sprain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle strain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Procedural pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Road traffic accident	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stab wound	0	1 (<0.1)		1 (<0.1)
Tendon injury	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tibia fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Joint dislocation	1 (<0.1)	0		1 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Meniscus injury	1 (<0.1)	0		1 (<0.1)
Muscle rupture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	7 (2.1)	1 (0.3)		8 (1.2)
Number of Unsolicited Adverse Events	10	1		11
Metabolism and nutrition disorders	1 (0.3)	0		1 (0.1)
Dehydration	1 (0.3)	0		1 (0.1)
Cardiac disorders	1 (0.3)	0		1 (0.1)
Acute left ventricular failure	1 (0.3)	0		1 (0.1)
Atrial fibrillation	1 (0.3)	0		1 (0.1)
Musculoskeletal and connective tissue disorders	3 (0.9)	0		3 (0.4)
Arthritis	1 (0.3)	0		1 (0.1)
Back pain	1 (0.3)	0		1 (0.1)
Spinal stenosis	1 (0.3)	0		1 (0.1)
Renal and urinary disorders	1 (0.3)	0		1 (0.1)
Nephrolithiasis	1 (0.3)	0		1 (0.1)
Renal colic	1 (0.3)	0		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
General disorders and administration site conditions	1 (0.3)	0		1 (0.1)
Non-cardiac chest pain	1 (0.3)	0		1 (0.1)
Investigations	1 (0.3)	1 (0.3)		2 (0.3)
Blood pressure increased	0	1 (0.3)		1 (0.1)
Blood pressure systolic increased	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.17.1.3
Subject Incidence of Unsolicited Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1 (1.2)	1 (1.1)		2 (1.2)
Number of Unsolicited Adverse Events	1	1		2
Gastrointestinal disorders	0	1 (1.1)		1 (0.6)
Inguinal hernia	0	1 (1.1)		1 (0.6)
Investigations	1 (1.2)	0		1 (0.6)
Blood pressure systolic increased	1 (1.2)	0		1 (0.6)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301170103.sas 21JUN2021 14:51

Table 14.3.1.18.1.1
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	31 (0.2)	83 (0.5)		114 (0.4)
Number of Unsolicited Adverse Events	39	101		140
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Immune system disorders	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	8 (<0.1)	13 (<0.1)		21 (<0.1)
Headache	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Migraine	0	2 (<0.1)		2 (<0.1)
Dizziness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Syncope	0	1 (<0.1)		1 (<0.1)
Ear and labyrinth disorders	0	1 (<0.1)		1 (<0.1)
Vertigo	0	1 (<0.1)		1 (<0.1)
Vascular disorders	9 (<0.1)	6 (<0.1)		15 (<0.1)
Hypertension	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301180101.sas 21JUN2021 14:54

Table 14.3.1.18.1.1
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	0	3 (<0.1)		3 (<0.1)
Nausea	0	2 (<0.1)		2 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	4 (<0.1)		4 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	7 (<0.1)	14 (<0.1)		21 (<0.1)
Myalgia	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Arthralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Muscle spasms	0	2 (<0.1)		2 (<0.1)
Pain in extremity	0	2 (<0.1)		2 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Back pain	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301180101.sas 21JUN2021 14:54

Table 14.3.1.18.1.1
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions	10 (<0.1)	42 (0.3)		52 (0.2)
Fatigue	6 (<0.1)	16 (0.1)	2.66 (1.08, 6.59)	22 (<0.1)
Injection site erythema	0	8 (<0.1)		8 (<0.1)
Injection site macule	0	6 (<0.1)		6 (<0.1)
Injection site pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site swelling	0	3 (<0.1)		3 (<0.1)
Chills	0	2 (<0.1)		2 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site urticaria	0	2 (<0.1)		2 (<0.1)
Injection site induration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Pyrexia	0	1 (<0.1)		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Investigations	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood pressure increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.18.1.2
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	20 (0.2)	59 (0.5)		79 (0.3)
Number of Unsolicited Adverse Events	26	73		99
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	7 (<0.1)	11 (<0.1)		18 (<0.1)
Headache	6 (<0.1)	6 (<0.1)		12 (<0.1)
Migraine	0	2 (<0.1)		2 (<0.1)
Dizziness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Syncope	0	1 (<0.1)		1 (<0.1)
Ear and labyrinth disorders	0	1 (<0.1)		1 (<0.1)
Vertigo	0	1 (<0.1)		1 (<0.1)
Vascular disorders	1 (<0.1)	3 (<0.1)		4 (<0.1)
Hypertension	1 (<0.1)	3 (<0.1)		4 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.18.1.2
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	0	2 (<0.1)		2 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	6 (<0.1)	10 (<0.1)		16 (<0.1)
Myalgia	2 (<0.1)	6 (<0.1)		8 (<0.1)
Arthralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Muscle spasms	0	1 (<0.1)		1 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Pain in extremity	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Back pain	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.18.1.2
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions	8 (<0.1)	31 (0.3)		39 (0.2)
Fatigue	4 (<0.1)	13 (0.1)	3.25 (1.12, 9.46)	17 (<0.1)
Injection site erythema	0	5 (<0.1)		5 (<0.1)
Injection site macule	0	3 (<0.1)		3 (<0.1)
Injection site pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chills	0	2 (<0.1)		2 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site swelling	0	2 (<0.1)		2 (<0.1)
Injection site induration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)
Investigations	1 (<0.1)	3 (<0.1)		4 (<0.1)
Blood pressure increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.18.1.2
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	11 (0.3)	24 (0.6)		35 (0.5)
Number of Unsolicited Adverse Events	13	28		41
Immune system disorders	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Vascular disorders	8 (0.2)	3 (<0.1)		11 (0.1)
Hypertension	8 (0.2)	3 (<0.1)	0.37 (0.11, 1.30)	11 (0.1)
Gastrointestinal disorders	0	1 (<0.1)		1 (<0.1)
Nausea	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	2 (<0.1)		2 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.18.1.2
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders	1 (<0.1)	4 (0.1)		5 (<0.1)
Myalgia	0	2 (<0.1)		2 (<0.1)
Muscle spasms	0	1 (<0.1)		1 (<0.1)
Pain in extremity	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	2 (<0.1)	11 (0.3)		13 (0.2)
Fatigue	2 (<0.1)	3 (<0.1)		5 (<0.1)
Injection site erythema	0	3 (<0.1)		3 (<0.1)
Injection site macule	0	3 (<0.1)		3 (<0.1)
Injection site urticaria	0	2 (<0.1)		2 (<0.1)
Injection site swelling	0	1 (<0.1)		1 (<0.1)
Pyrexia	0	1 (<0.1)		1 (<0.1)
Investigations	0	2 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure increased	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.18.1.3
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	30 (0.2)	83 (0.6)		113 (0.4)
Number of Unsolicited Adverse Events	38	101		139
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Immune system disorders	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Nervous system disorders	8 (<0.1)	13 (<0.1)		21 (<0.1)
Headache	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Migraine	0	2 (<0.1)		2 (<0.1)
Dizziness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Movement disorder	0	1 (<0.1)		1 (<0.1)
Syncope	0	1 (<0.1)		1 (<0.1)
Ear and labyrinth disorders	0	1 (<0.1)		1 (<0.1)
Vertigo	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301180103.sas 21JUN2021 14:54

Table 14.3.1.18.1.3
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders	9 (<0.1)	6 (<0.1)		15 (<0.1)
Hypertension	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Respiratory, thoracic and mediastinal disorders	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorders	0	3 (<0.1)		3 (<0.1)
Nausea	0	2 (<0.1)		2 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	0	4 (<0.1)		4 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Musculoskeletal and connective tissue disorders	6 (<0.1)	14 (<0.1)		20 (<0.1)
Myalgia	2 (<0.1)	8 (<0.1)	4.00 (0.96, 16.63)	10 (<0.1)
Arthralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Muscle spasms	0	2 (<0.1)		2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.18.1.3
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in extremity	0	2 (<0.1)		2 (<0.1)
Neck pain	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	10 (<0.1)	42 (0.3)		52 (0.2)
Fatigue	6 (<0.1)	16 (0.1)	2.67 (1.08, 6.60)	22 (<0.1)
Injection site erythema	0	8 (<0.1)		8 (<0.1)
Injection site macule	0	6 (<0.1)		6 (<0.1)
Injection site pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Injection site swelling	0	3 (<0.1)		3 (<0.1)
Chills	0	2 (<0.1)		2 (<0.1)
Injection site lymphadenopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site urticaria	0	2 (<0.1)		2 (<0.1)
Injection site induration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Malaise	0	1 (<0.1)		1 (<0.1)
Pyrexia	0	1 (<0.1)		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.18.1.3
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood pressure increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.18.1.3
Subject Incidence of Unsolicited Treatment-Related Severe TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1 (0.3)	0		1 (0.1)
Number of Unsolicited Adverse Events	1	0		1
Musculoskeletal and connective tissue disorders	1 (0.3)	0		1 (0.1)
Back pain	1 (0.3)	0		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1940 (12.8)	1819 (12.0)		3759 (12.4)
Number of Unsolicited Adverse Events	2863	2715		5578
Infections and infestations	705 (4.6)	547 (3.6)		1252 (4.1)
Urinary tract infection	94 (0.6)	71 (0.5)	0.75 (0.56, 1.02)	165 (0.5)
Upper respiratory tract infection	74 (0.5)	50 (0.3)	0.67 (0.47, 0.96)	124 (0.4)
Sinusitis	35 (0.2)	46 (0.3)	1.31 (0.85, 2.03)	81 (0.3)
Suspected COVID-19	30 (0.2)	29 (0.2)	0.97 (0.58, 1.60)	59 (0.2)
Viral infection	33 (0.2)	24 (0.2)	0.73 (0.43, 1.22)	57 (0.2)
COVID-19	139 (0.9)	20 (0.1)	0.14 (0.09, 0.23)	159 (0.5)
Rhinovirus infection	19 (0.1)	20 (0.1)	1.05 (0.57, 1.95)	39 (0.1)
Tooth abscess	21 (0.1)	20 (0.1)	0.95 (0.52, 1.74)	41 (0.1)
Tooth infection	14 (<0.1)	20 (0.1)	1.43 (0.73, 2.79)	34 (0.1)
Herpes zoster	10 (<0.1)	17 (0.1)	1.70 (0.79, 3.64)	27 (<0.1)
Pharyngitis streptococcal	19 (0.1)	13 (<0.1)	0.68 (0.34, 1.36)	32 (0.1)
Ear infection	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Pharyngitis	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)	21 (<0.1)
Gastroenteritis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Cellulitis	13 (<0.1)	8 (<0.1)	0.61 (0.26, 1.44)	21 (<0.1)
Diverticulitis	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Localised infection	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Otitis externa	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Bronchitis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Conjunctivitis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Fungal infection	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Hordeolum	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Otitis media	5 (<0.1)	6 (<0.1)		11 (<0.1)
Paronychia	4 (<0.1)	6 (<0.1)		10 (<0.1)
Abscess limb	0	5 (<0.1)		5 (<0.1)
Acute sinusitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Folliculitis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Herpes simplex	3 (<0.1)	5 (<0.1)		8 (<0.1)
Onychomycosis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Pneumonia	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Viral upper respiratory tract infection	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Bacterial vaginosis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Gingivitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cystitis	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Enterovirus infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Helicobacter infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Oral herpes	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin infection	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Staphylococcal infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Staphylococcal skin infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subcutaneous abscess	0	3 (<0.1)		3 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Impetigo	0	2 (<0.1)		2 (<0.1)
Laryngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis media acute	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tonsillitis	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vulvovaginal mycotic infection	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Candida infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Furuncle	0	1 (<0.1)		1 (<0.1)
Gastroenteritis viral	4 (<0.1)	1 (<0.1)		5 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Gonorrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	0	1 (<0.1)		1 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Nasopharyngitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection	4 (<0.1)	1 (<0.1)		5 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tinea cruris	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Breast abscess	1 (<0.1)	0		1 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	5 (<0.1)	0		5 (<0.1)
Rhinitis	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Sinusitis bacterial	2 (<0.1)	0		2 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea pedis	2 (<0.1)	0		2 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	50 (0.3)	51 (0.3)		101 (0.3)
Basal cell carcinoma	16 (0.1)	9 (<0.1)	0.56 (0.25, 1.24)	25 (<0.1)
Benign neoplasm of skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Malignant melanoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Prostate cancer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Squamous cell carcinoma	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Uterine leiomyoma	0	3 (<0.1)		3 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)		5 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Haemangioma of liver	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	24 (0.2)	39 (0.3)		63 (0.2)
Lymphadenopathy	15 (<0.1)	24 (0.2)	1.60 (0.85, 3.01)	39 (0.1)
Anaemia	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Iron deficiency anaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Lymphadenitis	1 (<0.1)	0		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Immune system disorders	22 (0.1)	13 (<0.1)		35 (0.1)
Seasonal allergy	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Hypersensitivity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	0		2 (<0.1)
Drug hypersensitivity	2 (<0.1)	0		2 (<0.1)
Food allergy	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	11 (<0.1)	10 (<0.1)		21 (<0.1)
Hypothyroidism	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	79 (0.5)	85 (0.6)		164 (0.5)
Hyperlipidaemia	15 (<0.1)	17 (0.1)	1.13 (0.57, 2.24)	32 (0.1)
Type 2 diabetes mellitus	7 (<0.1)	16 (0.1)	2.28 (0.96, 5.40)	23 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Vitamin D deficiency	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Hypercholesterolaemia	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.75)	19 (<0.1)
Dehydration	6 (<0.1)	6 (<0.1)		12 (<0.1)
Diabetes mellitus	5 (<0.1)	5 (<0.1)		10 (<0.1)
Glucose tolerance impaired	6 (<0.1)	5 (<0.1)		11 (<0.1)
Gout	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Decreased appetite	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypokalaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypoglycaemia	2 (<0.1)	0		2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	73 (0.5)	90 (0.6)		163 (0.5)
Anxiety	28 (0.2)	36 (0.2)	1.28 (0.79, 2.09)	64 (0.2)
Depression	20 (0.1)	30 (0.2)	1.50 (0.86, 2.62)	50 (0.2)
Insomnia	6 (<0.1)	6 (<0.1)		12 (<0.1)
Attention deficit hyperactivity disorder	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	2 (<0.1)		4 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic stress disorder	0	2 (<0.1)		2 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Drug abuse	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Panic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Mental status changes	3 (<0.1)	0		3 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	140 (0.9)	156 (1.0)		296 (1.0)
Headache	70 (0.5)	70 (0.5)	1.00 (0.72, 1.39)	140 (0.5)
Paraesthesia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Dizziness	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Migraine	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Syncope	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Anosmia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Ageusia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cervical radiculopathy	0	4 (<0.1)		4 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Sciatica	6 (<0.1)	4 (<0.1)		10 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	3 (<0.1)		7 (<0.1)
Cerebrovascular accident	0	3 (<0.1)		3 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoaesthesia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nerve compression	1 (<0.1)	2 (<0.1)		3 (<0.1)
Neuralgia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Presyncope	5 (<0.1)	2 (<0.1)		7 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)

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Nervous system disorders (Cont.)				
Hyposmia	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinus headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Tension headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)

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Safety Set

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Nervous system disorders (Cont.)				
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Neuropathy peripheral	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Tremor	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	30 (0.2)	26 (0.2)		56 (0.2)
Dry eye	3 (<0.1)	3 (<0.1)		6 (<0.1)
Eye irritation	0	3 (<0.1)		3 (<0.1)
Glaucoma	2 (<0.1)	3 (<0.1)		5 (<0.1)
Retinal detachment	2 (<0.1)	3 (<0.1)		5 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Cataract	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye pruritus	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Eye disorders (Cont.)				
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vision blurred	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blepharitis	4 (<0.1)	0		4 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)

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Safety Set

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Ear and labyrinth disorders	35 (0.2)	32 (0.2)		67 (0.2)
Vertigo	3 (<0.1)	9 (<0.1)	3.00 (0.88, 10.23)	12 (<0.1)
Ear pain	6 (<0.1)	6 (<0.1)		12 (<0.1)
Vertigo positional	1 (<0.1)	6 (<0.1)		7 (<0.1)
Cerumen impaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Tinnitus	5 (<0.1)	2 (<0.1)		7 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear canal erythema	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Ear congestion	2 (<0.1)	0		2 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	3 (<0.1)	0		3 (<0.1)
Cardiac disorders	38 (0.3)	48 (0.3)		86 (0.3)
Atrial fibrillation	11 (<0.1)	12 (<0.1)	1.09 (0.49, 2.42)	23 (<0.1)
Palpitations	1 (<0.1)	6 (<0.1)		7 (<0.1)
Cardiac failure congestive	4 (<0.1)	4 (<0.1)		8 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Angina pectoris	3 (<0.1)	3 (<0.1)		6 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)		6 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Sinus tachycardia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tachycardia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arrhythmia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Atrial flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders	117 (0.8)	101 (0.7)		218 (0.7)
Hypertension	96 (0.6)	86 (0.6)	0.89 (0.67, 1.19)	182 (0.6)
Hypertensive urgency	2 (<0.1)	3 (<0.1)		5 (<0.1)
Haematoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hot flush	2 (<0.1)	2 (<0.1)		4 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Flushing	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	3 (<0.1)	0		3 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Orthostatic hypotension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	192 (1.3)	155 (1.0)		347 (1.1)
Cough	60 (0.4)	56 (0.4)	0.93 (0.65, 1.34)	116 (0.4)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal congestion	44 (0.3)	44 (0.3)	1.00 (0.66, 1.51)	88 (0.3)
Rhinorrhoea	38 (0.3)	36 (0.2)	0.95 (0.60, 1.49)	74 (0.2)
Oropharyngeal pain	49 (0.3)	27 (0.2)	0.55 (0.35, 0.88)	76 (0.3)
Dyspnoea	18 (0.1)	14 (<0.1)	0.78 (0.39, 1.54)	32 (0.1)
Asthma	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Respiratory tract congestion	4 (<0.1)	6 (<0.1)		10 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Sinus congestion	6 (<0.1)	4 (<0.1)		10 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rhinitis allergic	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Acute respiratory failure	3 (<0.1)	2 (<0.1)		5 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchiectasis	0	2 (<0.1)		2 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory failure	0	2 (<0.1)		2 (<0.1)
Sinus pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sneezing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Upper-airway cough syndrome	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wheezing	3 (<0.1)	2 (<0.1)		5 (<0.1)
Dysphonia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Epistaxis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	3 (<0.1)	1 (<0.1)		4 (<0.1)
Pleuritic pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Productive cough	0	1 (<0.1)		1 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Throat irritation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Dry throat	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	168 (1.1)	181 (1.2)		349 (1.2)
Nausea	33 (0.2)	34 (0.2)	1.03 (0.64, 1.65)	67 (0.2)
Diarrhoea	32 (0.2)	33 (0.2)	1.03 (0.64, 1.67)	65 (0.2)
Gastrooesophageal reflux disease	16 (0.1)	21 (0.1)	1.31 (0.69, 2.48)	37 (0.1)
Dental caries	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Vomiting	8 (<0.1)	13 (<0.1)	1.62 (0.69, 3.81)	21 (<0.1)
Toothache	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Abdominal pain	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Constipation	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Abdominal pain upper	4 (<0.1)	6 (<0.1)		10 (<0.1)
Abdominal pain lower	5 (<0.1)	5 (<0.1)		10 (<0.1)
Inguinal hernia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Colitis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Gastric ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Hiatus hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Large intestine polyp	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tooth impacted	1 (<0.1)	3 (<0.1)		4 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Dyspepsia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Food poisoning	3 (<0.1)	2 (<0.1)		5 (<0.1)
Haemorrhoids	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rectal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Umbilical hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal discomfort	3 (<0.1)	1 (<0.1)		4 (<0.1)
Abdominal distension	0	1 (<0.1)		1 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Flatulence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gingival pain	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Stomatitis	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastritis	4 (<0.1)	0		4 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Lip swelling	2 (<0.1)	0		2 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	4 (<0.1)	12 (<0.1)		16 (<0.1)
Cholelithiasis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	90 (0.6)	88 (0.6)		178 (0.6)
Urticaria	10 (<0.1)	14 (<0.1)	1.40 (0.63, 3.08)	24 (<0.1)
Dermatitis contact	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.58)	20 (<0.1)
Pruritus	6 (<0.1)	6 (<0.1)		12 (<0.1)
Acne	5 (<0.1)	5 (<0.1)		10 (<0.1)
Actinic keratosis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Dermatitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Eczema	0	3 (<0.1)		3 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermatitis atopic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hidradenitis	0	2 (<0.1)		2 (<0.1)
Hyperhidrosis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Psoriasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rash maculo-papular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Blister	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermal cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dermatitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Rash erythematous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rash pruritic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angioedema	3 (<0.1)	0		3 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ecchymosis	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Night sweats	2 (<0.1)	0		2 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Skin mass	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders	236 (1.6)	249 (1.6)		485 (1.6)
Arthralgia	41 (0.3)	39 (0.3)	0.95 (0.62, 1.47)	80 (0.3)
Myalgia	29 (0.2)	32 (0.2)	1.10 (0.67, 1.81)	61 (0.2)
Back pain	36 (0.2)	25 (0.2)	0.69 (0.42, 1.15)	61 (0.2)
Osteoarthritis	19 (0.1)	18 (0.1)	0.95 (0.50, 1.78)	37 (0.1)
Muscle spasms	14 (<0.1)	16 (0.1)	1.14 (0.57, 2.30)	30 (<0.1)
Neck pain	8 (<0.1)	16 (0.1)	2.00 (0.88, 4.56)	24 (<0.1)
Musculoskeletal pain	12 (<0.1)	15 (<0.1)	1.25 (0.59, 2.62)	27 (<0.1)
Pain in extremity	20 (0.1)	11 (<0.1)	0.55 (0.27, 1.13)	31 (0.1)
Bursitis	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Tendonitis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Rotator cuff syndrome	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Arthritis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Trigger finger	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Musculoskeletal chest pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Joint swelling	0	4 (<0.1)		4 (<0.1)
Spinal stenosis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Muscle tightness	0	3 (<0.1)		3 (<0.1)
Musculoskeletal stiffness	0	3 (<0.1)		3 (<0.1)
Osteoporosis	0	3 (<0.1)		3 (<0.1)
Joint range of motion decreased	0	2 (<0.1)		2 (<0.1)
Muscular weakness	0	2 (<0.1)		2 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spinal osteoarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibromyalgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Flank pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Groin pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intervertebral disc degeneration	3 (<0.1)	1 (<0.1)		4 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Plantar fasciitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Axillary mass	2 (<0.1)	0		2 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Costochondritis	3 (<0.1)	0		3 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	2 (<0.1)	0		2 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Pain in jaw	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	0		1 (<0.1)
Torticollis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders	36 (0.2)	32 (0.2)		68 (0.2)
Nephrolithiasis	19 (0.1)	11 (<0.1)	0.58 (0.28, 1.20)	30 (<0.1)
Acute kidney injury	3 (<0.1)	2 (<0.1)		5 (<0.1)
Chronic kidney disease	0	2 (<0.1)		2 (<0.1)
Dysuria	0	2 (<0.1)		2 (<0.1)
Haematuria	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hypertonic bladder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary retention	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders	38 (0.3)	37 (0.2)		75 (0.2)
Benign prostatic hyperplasia	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Pelvic pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Prostatitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Breast cyst	0	2 (<0.1)		2 (<0.1)
Dysmenorrhoea	0	2 (<0.1)		2 (<0.1)
Erectile dysfunction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Menorrhagia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Rectocele	0	1 (<0.1)		1 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Testicular pain	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Vaginal haemorrhage	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)				
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	125 (0.8)	152 (1.0)		277 (0.9)
Fatigue	52 (0.3)	55 (0.4)	1.06 (0.73, 1.54)	107 (0.4)
Pain	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
Chills	17 (0.1)	14 (<0.1)	0.82 (0.41, 1.64)	31 (0.1)
Injection site pain	4 (<0.1)	14 (<0.1)	3.49 (1.21, 10.09)	18 (<0.1)
Pyrexia	13 (<0.1)	14 (<0.1)	1.08 (0.51, 2.25)	27 (<0.1)
Injection site erythema	1 (<0.1)	7 (<0.1)	6.99 (1.12, 43.54)	8 (<0.1)
Injection site induration	0	7 (<0.1)		7 (<0.1)
Injection site lymphadenopathy	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Injection site rash	0	6 (<0.1)		6 (<0.1)
Injection site swelling	0	6 (<0.1)		6 (<0.1)
Non-cardiac chest pain	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Chest pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site macule	0	4 (<0.1)		4 (<0.1)
Injection site pruritus	0	4 (<0.1)		4 (<0.1)
Oedema peripheral	4 (<0.1)	3 (<0.1)		7 (<0.1)
Reactogenicity event	0	3 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chest discomfort	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site papule	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Peripheral swelling	4 (<0.1)	2 (<0.1)		6 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vaccination site pain	0	2 (<0.1)		2 (<0.1)
Axillary pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Malaise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Asthenia	2 (<0.1)	0		2 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hangover	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site bruising	3 (<0.1)	0		3 (<0.1)
Injection site haemorrhage	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	0		1 (<0.1)
Investigations	37 (0.2)	42 (0.3)		79 (0.3)
Blood cholesterol increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hepatic enzyme increased	3 (<0.1)	4 (<0.1)		7 (<0.1)
Transaminases increased	0	4 (<0.1)		4 (<0.1)
Blood pressure increased	5 (<0.1)	3 (<0.1)		8 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood triglycerides increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Weight decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190101.sas 21JUN2021 14:54

Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Heart rate increased	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	227 (1.5)	192 (1.3)		419 (1.4)
Ligament sprain	8 (<0.1)	20 (0.1)	2.50 (1.12, 5.55)	28 (<0.1)
Skin laceration	28 (0.2)	20 (0.1)	0.71 (0.41, 1.26)	48 (0.2)
Muscle strain	15 (<0.1)	15 (<0.1)	1.00 (0.50, 2.01)	30 (<0.1)
Foot fracture	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.52)	21 (<0.1)
Procedural pain	16 (0.1)	11 (<0.1)	0.69 (0.32, 1.45)	27 (<0.1)
Fall	12 (<0.1)	10 (<0.1)	0.83 (0.37, 1.88)	22 (<0.1)
Tooth fracture	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Limb injury	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Arthropod bite	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Road traffic accident	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Meniscus injury	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Concussion	4 (<0.1)	5 (<0.1)		9 (<0.1)
Rib fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Hand fracture	3 (<0.1)	4 (<0.1)		7 (<0.1)
Joint injury	4 (<0.1)	4 (<0.1)		8 (<0.1)
Wrist fracture	4 (<0.1)	4 (<0.1)		8 (<0.1)
Animal bite	10 (<0.1)	3 (<0.1)	0.30 (0.09, 1.01)	13 (<0.1)
Arthropod sting	4 (<0.1)	3 (<0.1)		7 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Contusion	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Post-traumatic pain	4 (<0.1)	3 (<0.1)		7 (<0.1)
Upper limb fracture	0	3 (<0.1)		3 (<0.1)
Ankle fracture	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Epicondylitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Head injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tendon rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Back injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone contusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Skin abrasion	6 (<0.1)	1 (<0.1)		7 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tendon injury	0	1 (<0.1)		1 (<0.1)
Thermal burn	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural nausea	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)		7 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.1
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Product issues (Cont.)				
Embedded device	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4131 (27.2)	3468 (22.8)		7599 (25.0)
Number of Unsolicited Adverse Events	7272	6145		13417
Infections and infestations	2069 (13.6)	1329 (8.8)		3398 (11.2)
Upper respiratory tract infection	209 (1.4)	177 (1.2)	0.85 (0.69, 1.03)	386 (1.3)
Urinary tract infection	180 (1.2)	137 (0.9)	0.76 (0.61, 0.95)	317 (1.0)
Suspected COVID-19	96 (0.6)	113 (0.7)	1.18 (0.90, 1.54)	209 (0.7)
Viral infection	115 (0.8)	112 (0.7)	0.97 (0.75, 1.26)	227 (0.7)
Sinusitis	99 (0.7)	108 (0.7)	1.09 (0.83, 1.43)	207 (0.7)
COVID-19	892 (5.9)	79 (0.5)	0.09 (0.07, 0.11)	971 (3.2)
Rhinovirus infection	49 (0.3)	57 (0.4)	1.16 (0.80, 1.70)	106 (0.3)
Herpes zoster	17 (0.1)	40 (0.3)	2.35 (1.34, 4.11)	57 (0.2)
Tooth abscess	39 (0.3)	30 (0.2)	0.77 (0.48, 1.23)	69 (0.2)
Tooth infection	30 (0.2)	30 (0.2)	1.00 (0.61, 1.65)	60 (0.2)
Pharyngitis streptococcal	36 (0.2)	25 (0.2)	0.69 (0.42, 1.15)	61 (0.2)
Viral upper respiratory tract infection	23 (0.2)	24 (0.2)	1.04 (0.59, 1.83)	47 (0.2)
Cellulitis	28 (0.2)	23 (0.2)	0.82 (0.48, 1.41)	51 (0.2)
Ear infection	21 (0.1)	22 (0.1)	1.05 (0.58, 1.89)	43 (0.1)
Bronchitis	30 (0.2)	20 (0.1)	0.67 (0.38, 1.16)	50 (0.2)
Gastroenteritis	20 (0.1)	19 (0.1)	0.95 (0.51, 1.76)	39 (0.1)
Pharyngitis	19 (0.1)	19 (0.1)	1.00 (0.53, 1.87)	38 (0.1)
Pneumonia	33 (0.2)	19 (0.1)	0.57 (0.33, 1.00)	52 (0.2)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Otitis media	17 (0.1)	18 (0.1)	1.06 (0.55, 2.03)	35 (0.1)
Diverticulitis	19 (0.1)	15 (<0.1)	0.79 (0.41, 1.53)	34 (0.1)
Hordeolum	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Conjunctivitis	16 (0.1)	12 (<0.1)	0.75 (0.36, 1.56)	28 (<0.1)
Otitis externa	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Enterovirus infection	2 (<0.1)	10 (<0.1)	4.99 (1.23, 20.26)	12 (<0.1)
Fungal infection	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Localised infection	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Acute sinusitis	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Onychomycosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Respiratory tract infection	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Abscess limb	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Bacterial vaginosis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Herpes simplex	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Nasopharyngitis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.58)	20 (<0.1)
Paronychia	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Asymptomatic COVID-19	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Cystitis	14 (<0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Gingivitis	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Skin infection	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Vulvovaginal candidiasis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Folliculitis	12 (<0.1)	6 (<0.1)	0.50 (0.19, 1.28)	18 (<0.1)
Lyme disease	0	6 (<0.1)		6 (<0.1)
Pyelonephritis	6 (<0.1)	6 (<0.1)		12 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Sepsis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Appendicitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Clostridium difficile infection	0	5 (<0.1)		5 (<0.1)
Gastroenteritis viral	6 (<0.1)	5 (<0.1)		11 (<0.1)
Kidney infection	2 (<0.1)	5 (<0.1)		7 (<0.1)
Oral candidiasis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Oral herpes	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Postoperative wound infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Staphylococcal infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Staphylococcal skin infection	1 (<0.1)	5 (<0.1)		6 (<0.1)
Chlamydial infection	0	4 (<0.1)		4 (<0.1)
Eye infection	6 (<0.1)	4 (<0.1)		10 (<0.1)
Furuncle	0	4 (<0.1)		4 (<0.1)
Helicobacter infection	4 (<0.1)	4 (<0.1)		8 (<0.1)
Laryngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Periodontitis	0	4 (<0.1)		4 (<0.1)
Sinusitis bacterial	4 (<0.1)	4 (<0.1)		8 (<0.1)
Subcutaneous abscess	2 (<0.1)	4 (<0.1)		6 (<0.1)
Viral pharyngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Vulvovaginal mycotic infection	13 (<0.1)	4 (<0.1)	0.31 (0.11, 0.89)	17 (<0.1)
Abdominal abscess	0	3 (<0.1)		3 (<0.1)
Chronic sinusitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Coronavirus infection	0	3 (<0.1)		3 (<0.1)
Gonorrhoea	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Rhinitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tonsillitis	11 (<0.1)	3 (<0.1)	0.27 (0.08, 0.91)	14 (<0.1)
Wound infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Candida infection	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cat scratch disease	0	2 (<0.1)		2 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Fungal skin infection	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastrointestinal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Infected bite	1 (<0.1)	2 (<0.1)		3 (<0.1)
Infected cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nail infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media acute	5 (<0.1)	2 (<0.1)		7 (<0.1)
Peritonitis	0	2 (<0.1)		2 (<0.1)
Pertussis	0	2 (<0.1)		2 (<0.1)
Post procedural infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Pulpitis dental	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory tract infection viral	10 (<0.1)	2 (<0.1)	0.20 (0.05, 0.81)	12 (<0.1)
Septic shock	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tinea cruris	0	2 (<0.1)		2 (<0.1)
Tinea infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tuberculosis	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Upper respiratory tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urinary tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urosepsis	0	2 (<0.1)		2 (<0.1)
Viral sinusitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic bacteriuria	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atypical mycobacterial infection	0	1 (<0.1)		1 (<0.1)
Atypical pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Body tinea	2 (<0.1)	1 (<0.1)		3 (<0.1)
Breast abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiolitis	0	1 (<0.1)		1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Colonic abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	4 (<0.1)	1 (<0.1)		5 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Dacryocystitis	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Genital infection fungal	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Gingival abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Groin abscess	0	1 (<0.1)		1 (<0.1)
Helminthic infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza	4 (<0.1)	1 (<0.1)		5 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Labyrinthitis	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Papilloma viral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin candida	3 (<0.1)	1 (<0.1)		4 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Streptococcal infection	0	1 (<0.1)		1 (<0.1)
Tinea versicolour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Vulvitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)		1 (<0.1)
Abscess neck	1 (<0.1)	0		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Balanitis candida	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Bronchitis bacterial	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	16 (0.1)	0		16 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cervicitis	2 (<0.1)	0		2 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	2 (<0.1)	0		2 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Ear infection fungal	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Hepatitis C	1 (<0.1)	0		1 (<0.1)
Herpangina	1 (<0.1)	0		1 (<0.1)
Injection site infection	1 (<0.1)	0		1 (<0.1)
Klebsiella bacteraemia	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	2 (<0.1)	0		2 (<0.1)
Mastoiditis	3 (<0.1)	0		3 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Nasal vestibulitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Perineal cellulitis	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	2 (<0.1)	0		2 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	2 (<0.1)	0		2 (<0.1)
Proteus infection	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	3 (<0.1)	0		3 (<0.1)
Tinea barbae	1 (<0.1)	0		1 (<0.1)
Tinea pedis	3 (<0.1)	0		3 (<0.1)
Trichomoniasis	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Vaginal abscess	1 (<0.1)	0		1 (<0.1)
Vaginitis chlamydial	2 (<0.1)	0		2 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	116 (0.8)	123 (0.8)		239 (0.8)
Basal cell carcinoma	28 (0.2)	22 (0.1)	0.78 (0.45, 1.36)	50 (0.2)
Prostate cancer	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Skin cancer	4 (<0.1)	6 (<0.1)		10 (<0.1)
Uterine leiomyoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Benign neoplasm of skin	2 (<0.1)	5 (<0.1)		7 (<0.1)
Malignant melanoma	5 (<0.1)	5 (<0.1)		10 (<0.1)
Squamous cell carcinoma	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Squamous cell carcinoma of skin	9 (<0.1)	5 (<0.1)	0.55 (0.20, 1.58)	14 (<0.1)
Benign breast neoplasm	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of thyroid gland	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lipoma	2 (<0.1)	3 (<0.1)		5 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin papilloma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Benign hepatic neoplasm	0	2 (<0.1)		2 (<0.1)
Breast cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Malignant melanoma in situ	1 (<0.1)	2 (<0.1)		3 (<0.1)
Plasma cell myeloma	0	2 (<0.1)		2 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Adrenal adenoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign neoplasm of bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign salivary gland neoplasm	0	1 (<0.1)		1 (<0.1)
Brain neoplasm	0	1 (<0.1)		1 (<0.1)
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Breast cancer in situ	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Fibrous histiocytoma	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Intraductal papilloma of breast	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Invasive ductal breast carcinoma	2 (<0.1)	1 (<0.1)		3 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Meningioma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	1 (<0.1)	1 (<0.1)		2 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)		1 (<0.1)
Prostate cancer stage I	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal neoplasm	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Benign bone neoplasm	1 (<0.1)	0		1 (<0.1)
Benign neoplasm of eyelid	1 (<0.1)	0		1 (<0.1)
Benign ovarian tumour	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Breast neoplasm	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Enchondromatosis	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	3 (<0.1)	0		3 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0		1 (<0.1)
Haemangioma of liver	2 (<0.1)	0		2 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0		1 (<0.1)
Seborrhoeic keratosis	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Blood and lymphatic system disorders	56 (0.4)	73 (0.5)		129 (0.4)
Lymphadenopathy	29 (0.2)	38 (0.3)	1.31 (0.81, 2.11)	67 (0.2)
Anaemia	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Iron deficiency anaemia	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Thrombocytopenia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Leukocytosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymphadenitis	1 (<0.1)	0		1 (<0.1)
Nucleated red cells	1 (<0.1)	0		1 (<0.1)
Splenic calcification	1 (<0.1)	0		1 (<0.1)
Immune system disorders	41 (0.3)	38 (0.3)		79 (0.3)
Seasonal allergy	25 (0.2)	23 (0.2)	0.92 (0.53, 1.61)	48 (0.2)
Drug hypersensitivity	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Hypersensitivity	5 (<0.1)	4 (<0.1)		9 (<0.1)
Mycotic allergy	0	2 (<0.1)		2 (<0.1)
Allergy to animal	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Immune system disorders (Cont.)				
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	33 (0.2)	33 (0.2)		66 (0.2)
Hypothyroidism	15 (<0.1)	22 (0.1)	1.46 (0.77, 2.79)	37 (0.1)
Thyroid mass	1 (<0.1)	3 (<0.1)		4 (<0.1)
Goitre	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hyperparathyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Basedow's disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperthyroidism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypogonadism	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Thyroiditis	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Thyroiditis subacute	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	222 (1.5)	191 (1.3)		413 (1.4)
Hyperlipidaemia	44 (0.3)	35 (0.2)	0.79 (0.51, 1.23)	79 (0.3)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Type 2 diabetes mellitus	25 (0.2)	33 (0.2)	1.32 (0.79, 2.20)	58 (0.2)
Vitamin D deficiency	27 (0.2)	25 (0.2)	0.92 (0.54, 1.58)	52 (0.2)
Hypercholesterolaemia	30 (0.2)	21 (0.1)	0.70 (0.40, 1.21)	51 (0.2)
Diabetes mellitus	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.52)	21 (<0.1)
Glucose tolerance impaired	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Dehydration	14 (<0.1)	9 (<0.1)	0.64 (0.28, 1.45)	23 (<0.1)
Gout	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Hyponatraemia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Hypokalaemia	16 (0.1)	5 (<0.1)	0.31 (0.12, 0.82)	21 (<0.1)
Hyperglycaemia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Decreased appetite	4 (<0.1)	3 (<0.1)		7 (<0.1)
Diabetes mellitus inadequate control	2 (<0.1)	3 (<0.1)		5 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperkalaemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypertriglyceridaemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Iron deficiency	4 (<0.1)	3 (<0.1)		7 (<0.1)
Obesity	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypocalcaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypoglycaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Insulin resistance	0	2 (<0.1)		2 (<0.1)
Malnutrition	0	2 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abnormal loss of weight	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)		4 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypercalcaemia	0	1 (<0.1)		1 (<0.1)
Hypomagnesaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Hypophosphataemia	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitamin K deficiency	0	1 (<0.1)		1 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Fluid overload	1 (<0.1)	0		1 (<0.1)
Fluid retention	1 (<0.1)	0		1 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypermagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	193 (1.3)	224 (1.5)		417 (1.4)
Depression	70 (0.5)	84 (0.6)	1.20 (0.87, 1.64)	154 (0.5)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Anxiety	67 (0.4)	81 (0.5)	1.21 (0.88, 1.66)	148 (0.5)
Insomnia	23 (0.2)	23 (0.2)	1.00 (0.56, 1.77)	46 (0.2)
Attention deficit hyperactivity disorder	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Bipolar disorder	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	4 (<0.1)		5 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	2 (<0.1)		4 (<0.1)
Alcohol withdrawal syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bipolar II disorder	0	2 (<0.1)		2 (<0.1)
Generalised anxiety disorder	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Major depression	4 (<0.1)	2 (<0.1)		6 (<0.1)
Suicidal ideation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Confusional state	2 (<0.1)	1 (<0.1)		3 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Dysphemia	0	1 (<0.1)		1 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental status changes	4 (<0.1)	1 (<0.1)		5 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Obsessive-compulsive personality disorder	0	1 (<0.1)		1 (<0.1)
Panic attack	4 (<0.1)	1 (<0.1)		5 (<0.1)
Persistent depressive disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Psychotic disorder	0	1 (<0.1)		1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Social anxiety disorder	0	1 (<0.1)		1 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Delirium	1 (<0.1)	0		1 (<0.1)
Depression suicidal	2 (<0.1)	0		2 (<0.1)
Dissociative disorder	1 (<0.1)	0		1 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Mixed anxiety and depressive disorder	1 (<0.1)	0		1 (<0.1)
Nicotine dependence	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders	322 (2.1)	319 (2.1)		641 (2.1)
Headache	142 (0.9)	132 (0.9)	0.93 (0.73, 1.17)	274 (0.9)
Dizziness	25 (0.2)	18 (0.1)	0.72 (0.40, 1.31)	43 (0.1)
Migraine	19 (0.1)	18 (0.1)	0.95 (0.50, 1.78)	37 (0.1)
Sciatica	19 (0.1)	17 (0.1)	0.89 (0.47, 1.70)	36 (0.1)
Paraesthesia	13 (<0.1)	16 (0.1)	1.23 (0.60, 2.52)	29 (<0.1)
Syncope	24 (0.2)	16 (0.1)	0.67 (0.36, 1.24)	40 (0.1)
Cervical radiculopathy	1 (<0.1)	12 (<0.1)	11.98 (2.00, 71.83)	13 (<0.1)
Anosmia	6 (<0.1)	10 (<0.1)	1.66 (0.63, 4.40)	16 (<0.1)
Ageusia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Nerve compression	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Cerebrovascular accident	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Facial paralysis	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Carpal tunnel syndrome	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Hypoaesthesia	5 (<0.1)	5 (<0.1)		10 (<0.1)
Lumbar radiculopathy	1 (<0.1)	5 (<0.1)		6 (<0.1)
Seizure	6 (<0.1)	5 (<0.1)		11 (<0.1)
Subarachnoid haemorrhage	0	4 (<0.1)		4 (<0.1)
Neuralgia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Peripheral sensory neuropathy	2 (<0.1)	3 (<0.1)		5 (<0.1)
Presyncope	5 (<0.1)	3 (<0.1)		8 (<0.1)
Transient ischaemic attack	4 (<0.1)	3 (<0.1)		7 (<0.1)
Amnesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Carotid artery stenosis	0	2 (<0.1)		2 (<0.1)
Cubital tunnel syndrome	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Memory impairment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Optic neuritis	0	2 (<0.1)		2 (<0.1)
Piriformis syndrome	0	2 (<0.1)		2 (<0.1)
Restless legs syndrome	6 (<0.1)	2 (<0.1)		8 (<0.1)
Aphasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burning sensation	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Central nervous system lesion	0	1 (<0.1)		1 (<0.1)
Cerebral atrophy	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Complex regional pain syndrome	0	1 (<0.1)		1 (<0.1)
Depressed level of consciousness	0	1 (<0.1)		1 (<0.1)
Head discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Hypersomnia	0	1 (<0.1)		1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine with aura	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Morton's neuralgia	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle contractions involuntary	0	1 (<0.1)		1 (<0.1)
Occipital neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Sinus headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Tension headache	2 (<0.1)	1 (<0.1)		3 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Tremor	3 (<0.1)	1 (<0.1)		4 (<0.1)
Trigeminal neuralgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	2 (<0.1)	0		2 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Cerebral cyst	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	3 (<0.1)	0		3 (<0.1)
Essential tremor	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Hypogeusia	1 (<0.1)	0		1 (<0.1)
Intention tremor	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0		1 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)
Neuropathy peripheral	5 (<0.1)	0		5 (<0.1)
Perineurial cyst	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Poor quality sleep	1 (<0.1)	0		1 (<0.1)
Radicular pain	1 (<0.1)	0		1 (<0.1)
Right hemisphere deficit syndrome	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0		1 (<0.1)
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
VIth nerve paralysis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)
Vocal cord paralysis	1 (<0.1)	0		1 (<0.1)
Eye disorders	70 (0.5)	80 (0.5)		150 (0.5)
Cataract	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.29)	22 (<0.1)
Dry eye	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Retinal detachment	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Glaucoma	5 (<0.1)	6 (<0.1)		11 (<0.1)
Chalazion	1 (<0.1)	4 (<0.1)		5 (<0.1)
Eye irritation	1 (<0.1)	4 (<0.1)		5 (<0.1)
Uveitis	0	3 (<0.1)		3 (<0.1)
Blepharitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Eye haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye pruritus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Macular degeneration	1 (<0.1)	2 (<0.1)		3 (<0.1)
Macular hole	1 (<0.1)	2 (<0.1)		3 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Vision blurred	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetic retinopathy	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Eye pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Foreign body sensation in eyes	0	1 (<0.1)		1 (<0.1)
Keratitis	0	1 (<0.1)		1 (<0.1)
Lenticular opacities	0	1 (<0.1)		1 (<0.1)
Macular fibrosis	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Orbital haematoma	0	1 (<0.1)		1 (<0.1)
Papilloedema	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	0	1 (<0.1)		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Retinopathy hypertensive	0	1 (<0.1)		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	3 (<0.1)	1 (<0.1)		4 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Diplopia	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Eye disorders (Cont.)				
Eye inflammation	4 (<0.1)	0		4 (<0.1)
Eye swelling	2 (<0.1)	0		2 (<0.1)
Eye ulcer	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	3 (<0.1)	0		3 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photophobia	2 (<0.1)	0		2 (<0.1)
Retinal oedema	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	4 (<0.1)	0		4 (<0.1)
Ear and labyrinth disorders	71 (0.5)	61 (0.4)		132 (0.4)
Vertigo	13 (<0.1)	22 (0.1)	1.69 (0.86, 3.31)	35 (0.1)
Ear pain	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Tinnitus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Vertigo positional	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Meniere's disease	2 (<0.1)	5 (<0.1)		7 (<0.1)
Cerumen impaction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear discomfort	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Ear and labyrinth disorders (Cont.)				
Deafness unilateral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ear canal erythema	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear pruritus	4 (<0.1)	1 (<0.1)		5 (<0.1)
Eustachian tube dysfunction	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hypoacusis	0	1 (<0.1)		1 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Tympanic membrane perforation	6 (<0.1)	1 (<0.1)		7 (<0.1)
Diplacusis	1 (<0.1)	0		1 (<0.1)
Ear congestion	2 (<0.1)	0		2 (<0.1)
Excessive cerumen production	2 (<0.1)	0		2 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	114 (0.8)	118 (0.8)		232 (0.8)
Atrial fibrillation	27 (0.2)	25 (0.2)	0.92 (0.54, 1.58)	52 (0.2)
Palpitations	6 (<0.1)	14 (<0.1)	2.33 (0.93, 5.86)	20 (<0.1)
Ventricular extrasystoles	4 (<0.1)	10 (<0.1)	2.50 (0.83, 7.52)	14 (<0.1)
Coronary artery disease	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Angina pectoris	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Cardiac failure congestive	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Myocardial infarction	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.06)	14 (<0.1)
Sinus tachycardia	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Tachycardia	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Acute myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Cardiac failure	3 (<0.1)	4 (<0.1)		7 (<0.1)
Supraventricular tachycardia	0	4 (<0.1)		4 (<0.1)
Acute coronary syndrome	0	3 (<0.1)		3 (<0.1)
Atrial flutter	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bradycardia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arrhythmia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiomyopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ventricular tachycardia	0	2 (<0.1)		2 (<0.1)
Acute left ventricular failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial enlargement	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardiovascular symptom	0	1 (<0.1)		1 (<0.1)
Left ventricular hypertrophy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Sinus bradycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial tachycardia	2 (<0.1)	0		2 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac disorder	1 (<0.1)	0		1 (<0.1)
Cardiac steatosis	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	2 (<0.1)	0		2 (<0.1)
Diastolic dysfunction	1 (<0.1)	0		1 (<0.1)
Extrasystoles	1 (<0.1)	0		1 (<0.1)
Mitral valve incompetence	2 (<0.1)	0		2 (<0.1)
Mitral valve thickening	1 (<0.1)	0		1 (<0.1)
Myocardial ischaemia	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Postural orthostatic tachycardia syndrome	1 (<0.1)	0		1 (<0.1)
Sinus arrest	1 (<0.1)	0		1 (<0.1)
Tricuspid valve incompetence	2 (<0.1)	0		2 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	264 (1.7)	222 (1.5)		486 (1.6)
Hypertension	218 (1.4)	176 (1.2)	0.81 (0.66, 0.98)	394 (1.3)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders (Cont.)				
Haematoma	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Deep vein thrombosis	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Hypertensive urgency	2 (<0.1)	4 (<0.1)		6 (<0.1)
Orthostatic hypotension	1 (<0.1)	4 (<0.1)		5 (<0.1)
Hot flush	4 (<0.1)	3 (<0.1)		7 (<0.1)
Hypotension	6 (<0.1)	3 (<0.1)		9 (<0.1)
Aortic dilatation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arteriosclerosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flushing	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive emergency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Phlebitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Raynaud's phenomenon	1 (<0.1)	1 (<0.1)		2 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders (Cont.)				
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis superficial	3 (<0.1)	1 (<0.1)		4 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	2 (<0.1)	0		2 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Lymphoedema	1 (<0.1)	0		1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral venous disease	1 (<0.1)	0		1 (<0.1)
Secondary hypertension	1 (<0.1)	0		1 (<0.1)
Vascular calcification	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	409 (2.7)	329 (2.2)		738 (2.4)
Cough	122 (0.8)	112 (0.7)	0.92 (0.71, 1.18)	234 (0.8)
Nasal congestion	91 (0.6)	91 (0.6)	1.00 (0.75, 1.33)	182 (0.6)
Rhinorrhoea	75 (0.5)	76 (0.5)	1.01 (0.74, 1.39)	151 (0.5)
Oropharyngeal pain	104 (0.7)	73 (0.5)	0.70 (0.52, 0.94)	177 (0.6)
Dyspnoea	46 (0.3)	41 (0.3)	0.89 (0.59, 1.35)	87 (0.3)
Asthma	28 (0.2)	20 (0.1)	0.71 (0.41, 1.26)	48 (0.2)
Chronic obstructive pulmonary disease	18 (0.1)	10 (<0.1)	0.55 (0.26, 1.18)	28 (<0.1)
Sinus congestion	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Respiratory tract congestion	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Acute respiratory failure	14 (<0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Rhinitis allergic	12 (<0.1)	7 (<0.1)	0.58 (0.24, 1.43)	19 (<0.1)
Upper-airway cough syndrome	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Sinus pain	1 (<0.1)	6 (<0.1)		7 (<0.1)
Pleural effusion	5 (<0.1)	5 (<0.1)		10 (<0.1)
Sneezing	2 (<0.1)	5 (<0.1)		7 (<0.1)
Respiratory disorder	5 (<0.1)	4 (<0.1)		9 (<0.1)
Sleep apnoea syndrome	6 (<0.1)	4 (<0.1)		10 (<0.1)
Atelectasis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Emphysema	1 (<0.1)	3 (<0.1)		4 (<0.1)
Paranasal sinus discomfort	0	3 (<0.1)		3 (<0.1)
Epistaxis	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hypoxia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Pharyngeal erythema	6 (<0.1)	2 (<0.1)		8 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Productive cough	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Wheezing	5 (<0.1)	2 (<0.1)		7 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchospasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Choking sensation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dysphonia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dyspnoea exertional	4 (<0.1)	1 (<0.1)		5 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lung infiltration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal mucosal disorder	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	6 (<0.1)	1 (<0.1)		7 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pulmonary hypertension	0	1 (<0.1)		1 (<0.1)
Pulmonary oedema	0	1 (<0.1)		1 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Throat irritation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vasomotor rhinitis	0	1 (<0.1)		1 (<0.1)
Vocal cord thickening	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Bronchial hyperreactivity	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dry throat	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Laryngeal stenosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Lung cyst	1 (<0.1)	0		1 (<0.1)
Lung opacity	2 (<0.1)	0		2 (<0.1)
Nasal dryness	1 (<0.1)	0		1 (<0.1)
Nasal turbinate hypertrophy	1 (<0.1)	0		1 (<0.1)
Nasal ulcer	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary granuloma	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	2 (<0.1)	0		2 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders	371 (2.4)	382 (2.5)		753 (2.5)
Nausea	65 (0.4)	69 (0.5)	1.06 (0.76, 1.48)	134 (0.4)
Diarrhoea	60 (0.4)	61 (0.4)	1.02 (0.71, 1.45)	121 (0.4)
Gastrooesophageal reflux disease	37 (0.2)	51 (0.3)	1.38 (0.90, 2.09)	88 (0.3)
Abdominal pain	21 (0.1)	25 (0.2)	1.19 (0.67, 2.11)	46 (0.2)
Dental caries	29 (0.2)	23 (0.2)	0.79 (0.46, 1.36)	52 (0.2)
Toothache	27 (0.2)	20 (0.1)	0.74 (0.42, 1.31)	47 (0.2)
Vomiting	21 (0.1)	19 (0.1)	0.90 (0.49, 1.66)	40 (0.1)
Constipation	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Abdominal pain upper	10 (<0.1)	15 (<0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Inguinal hernia	5 (<0.1)	11 (<0.1)	2.20 (0.80, 6.05)	16 (<0.1)
Large intestine polyp	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Hiatus hernia	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Irritable bowel syndrome	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Abdominal pain lower	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Colitis	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Dyspepsia	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Gastritis	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Gastric ulcer	6 (<0.1)	5 (<0.1)		11 (<0.1)
Tooth impacted	6 (<0.1)	5 (<0.1)		11 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)		6 (<0.1)
Rectal haemorrhage	2 (<0.1)	4 (<0.1)		6 (<0.1)
Small intestinal obstruction	4 (<0.1)	4 (<0.1)		8 (<0.1)
Umbilical hernia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Barrett's oesophagus	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Diverticulum	3 (<0.1)	3 (<0.1)		6 (<0.1)
Food poisoning	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Gastrointestinal haemorrhage	3 (<0.1)	3 (<0.1)		6 (<0.1)
Gingival pain	0	3 (<0.1)		3 (<0.1)
Haematochezia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Oesophagitis	0	3 (<0.1)		3 (<0.1)
Pancreatitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Periodontal disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abdominal discomfort	5 (<0.1)	2 (<0.1)		7 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Dysphagia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastrointestinal pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Intestinal obstruction	0	2 (<0.1)		2 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oesophageal spasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oesophageal ulcer	0	2 (<0.1)		2 (<0.1)
Stomatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal hernia	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Chronic gastritis	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Duodenitis	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Faecaloma	0	1 (<0.1)		1 (<0.1)
Faeces discoloured	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Intussusception	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Melaena	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	3 (<0.1)	1 (<0.1)		4 (<0.1)
Noninfective gingivitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Oesophageal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pancreatic cyst	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peptic ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Proctalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal fissure	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	0	1 (<0.1)		1 (<0.1)
Swollen tongue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue disorder	0	1 (<0.1)		1 (<0.1)
Tongue ulceration	0	1 (<0.1)		1 (<0.1)
Abdominal rigidity	1 (<0.1)	0		1 (<0.1)
Abdominal tenderness	1 (<0.1)	0		1 (<0.1)
Anal fistula	1 (<0.1)	0		1 (<0.1)
Anorectal discomfort	1 (<0.1)	0		1 (<0.1)
Aphthous ulcer	2 (<0.1)	0		2 (<0.1)
Ascites	2 (<0.1)	0		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Colitis microscopic	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Dry mouth	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0		1 (<0.1)
Gingival recession	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Mouth haemorrhage	1 (<0.1)	0		1 (<0.1)
Obstructive pancreatitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Terminal ileitis	1 (<0.1)	0		1 (<0.1)
Tooth disorder	2 (<0.1)	0		2 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Upper gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Uvulitis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Hepatobiliary disorders	17 (0.1)	27 (0.2)		44 (0.1)
Cholelithiasis	7 (<0.1)	13 (<0.1)	1.85 (0.76, 4.51)	20 (<0.1)
Cholecystitis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Hepatic steatosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bile duct stone	0	2 (<0.1)		2 (<0.1)
Biliary colic	0	2 (<0.1)		2 (<0.1)
Biliary dyskinesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholecystitis acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic haematoma	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	180 (1.2)	155 (1.0)		335 (1.1)
Urticaria	17 (0.1)	21 (0.1)	1.23 (0.66, 2.31)	38 (0.1)
Dermatitis contact	20 (0.1)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.1)
Rash	20 (0.1)	13 (<0.1)	0.65 (0.33, 1.29)	33 (0.1)
Eczema	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Acne	17 (0.1)	9 (<0.1)	0.53 (0.24, 1.16)	26 (<0.1)
Actinic keratosis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Pruritus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Rosacea	3 (<0.1)	6 (<0.1)		9 (<0.1)
Dermatitis	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Ingrowing nail	1 (<0.1)	4 (<0.1)		5 (<0.1)
Psoriasis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Skin lesion	3 (<0.1)	4 (<0.1)		7 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dermal cyst	5 (<0.1)	3 (<0.1)		8 (<0.1)
Dermatitis allergic	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermatitis atopic	4 (<0.1)	3 (<0.1)		7 (<0.1)
Dry skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Eczema nummular	0	3 (<0.1)		3 (<0.1)
Hyperhidrosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Neurodermatitis	0	3 (<0.1)		3 (<0.1)
Rash maculo-papular	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetic foot	0	2 (<0.1)		2 (<0.1)
Erythema	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hidradenitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Precancerous skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rash macular	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alopecia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blister	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood blister	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Decubitus ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Hand dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Papule	0	1 (<0.1)		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Rash erythematous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rash pruritic	6 (<0.1)	1 (<0.1)		7 (<0.1)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Angioedema	3 (<0.1)	0		3 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ecchymosis	3 (<0.1)	0		3 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	3 (<0.1)	0		3 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Night sweats	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin exfoliation	1 (<0.1)	0		1 (<0.1)
Skin fissures	1 (<0.1)	0		1 (<0.1)
Skin mass	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin wrinkling	1 (<0.1)	0		1 (<0.1)
Solar lentigo	1 (<0.1)	0		1 (<0.1)
Stasis dermatitis	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	467 (3.1)	484 (3.2)		951 (3.1)
Arthralgia	65 (0.4)	68 (0.4)	1.04 (0.75, 1.46)	133 (0.4)
Back pain	73 (0.5)	62 (0.4)	0.85 (0.61, 1.19)	135 (0.4)
Osteoarthritis	57 (0.4)	52 (0.3)	0.91 (0.63, 1.32)	109 (0.4)
Myalgia	60 (0.4)	50 (0.3)	0.83 (0.57, 1.21)	110 (0.4)
Musculoskeletal pain	20 (0.1)	29 (0.2)	1.45 (0.83, 2.54)	49 (0.2)
Neck pain	14 (<0.1)	25 (0.2)	1.78 (0.94, 3.39)	39 (0.1)
Muscle spasms	25 (0.2)	22 (0.1)	0.88 (0.50, 1.55)	47 (0.2)
Pain in extremity	26 (0.2)	22 (0.1)	0.84 (0.48, 1.48)	48 (0.2)
Rotator cuff syndrome	19 (0.1)	20 (0.1)	1.05 (0.57, 1.95)	39 (0.1)
Intervertebral disc protrusion	10 (<0.1)	17 (0.1)	1.70 (0.79, 3.64)	27 (<0.1)
Bursitis	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)
Tendonitis	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Arthritis	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Spinal osteoarthritis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Trigger finger	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Musculoskeletal chest pain	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Periarthritis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Joint swelling	1 (<0.1)	6 (<0.1)		7 (<0.1)
Osteoporosis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Muscular weakness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Osteopenia	5 (<0.1)	5 (<0.1)		10 (<0.1)
Flank pain	5 (<0.1)	4 (<0.1)		9 (<0.1)
Intervertebral disc degeneration	5 (<0.1)	4 (<0.1)		9 (<0.1)
Musculoskeletal stiffness	0	4 (<0.1)		4 (<0.1)
Spinal stenosis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Muscle tightness	0	3 (<0.1)		3 (<0.1)
Plantar fasciitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Spinal pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Spondylolisthesis	0	3 (<0.1)		3 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cervical spinal stenosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Exostosis	6 (<0.1)	2 (<0.1)		8 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Foot deformity	6 (<0.1)	2 (<0.1)		8 (<0.1)
Joint range of motion decreased	0	2 (<0.1)		2 (<0.1)
Limb mass	0	2 (<0.1)		2 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in jaw	3 (<0.1)	2 (<0.1)		5 (<0.1)
Rheumatoid arthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenosynovitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Compartment syndrome	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Groin pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)		1 (<0.1)
Joint stiffness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ligament pain	0	1 (<0.1)		1 (<0.1)
Ligamentum flavum hypertrophy	0	1 (<0.1)		1 (<0.1)
Medial tibial stress syndrome	0	1 (<0.1)		1 (<0.1)
Muscle twitching	0	1 (<0.1)		1 (<0.1)
Musculoskeletal discomfort	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteonecrosis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Polyarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal synovial cyst	0	1 (<0.1)		1 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Synovial cyst	5 (<0.1)	1 (<0.1)		6 (<0.1)
Tendon disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tenosynovitis stenosans	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)		1 (<0.1)
Axillary mass	2 (<0.1)	0		2 (<0.1)
Costochondritis	4 (<0.1)	0		4 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Kyphosis	1 (<0.1)	0		1 (<0.1)
Lumbar spinal stenosis	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Scoliosis	2 (<0.1)	0		2 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Torticollis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	78 (0.5)	71 (0.5)		149 (0.5)
Nephrolithiasis	30 (0.2)	23 (0.2)	0.77 (0.45, 1.31)	53 (0.2)
Acute kidney injury	12 (<0.1)	7 (<0.1)	0.58 (0.24, 1.43)	19 (<0.1)
Chronic kidney disease	6 (<0.1)	6 (<0.1)		12 (<0.1)
Haematuria	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Hypertonic bladder	3 (<0.1)	5 (<0.1)		8 (<0.1)
Urinary retention	4 (<0.1)	5 (<0.1)		9 (<0.1)
Dysuria	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hydronephrosis	0	3 (<0.1)		3 (<0.1)
Pollakiuria	2 (<0.1)	3 (<0.1)		5 (<0.1)
Renal cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Urinary hesitation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder spasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Calculus bladder	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Renal and urinary disorders (Cont.)				
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Diabetic nephropathy	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyuria	0	1 (<0.1)		1 (<0.1)
Renal disorder	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Micturition urgency	3 (<0.1)	0		3 (<0.1)
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	2 (<0.1)	0		2 (<0.1)
Stress urinary incontinence	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	3 (<0.1)	3 (<0.1)		6 (<0.1)
Abortion spontaneous	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)		1 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders	100 (0.7)	85 (0.6)		185 (0.6)
Benign prostatic hyperplasia	20 (0.1)	8 (<0.1)	0.40 (0.18, 0.89)	28 (<0.1)
Ovarian cyst	6 (<0.1)	6 (<0.1)		12 (<0.1)
Prostatitis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Breast cyst	3 (<0.1)	5 (<0.1)		8 (<0.1)
Erectile dysfunction	8 (<0.1)	5 (<0.1)	0.62 (0.21, 1.81)	13 (<0.1)
Pelvic pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Prostatomegaly	5 (<0.1)	5 (<0.1)		10 (<0.1)
Menopausal symptoms	1 (<0.1)	3 (<0.1)		4 (<0.1)
Menorrhagia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Breast mass	5 (<0.1)	2 (<0.1)		7 (<0.1)
Breast pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Breast ulceration	0	2 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dysmenorrhoea	2 (<0.1)	2 (<0.1)		4 (<0.1)
Postmenopausal haemorrhage	3 (<0.1)	2 (<0.1)		5 (<0.1)
Rectocele	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Uterine polyp	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vaginal haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexa uteri pain	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Artificial menopause	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Atrophic vulvovaginitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast enlargement	0	1 (<0.1)		1 (<0.1)
Breast hyperplasia	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical polyp	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystocele	1 (<0.1)	1 (<0.1)		2 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibrocystic breast disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Prostatic cyst	0	1 (<0.1)		1 (<0.1)
Vaginal cyst	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vaginal prolapse	0	1 (<0.1)		1 (<0.1)
Vulva cyst	0	1 (<0.1)		1 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	3 (<0.1)	0		3 (<0.1)
Dyspareunia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders (Cont.)				
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Endometriosis	2 (<0.1)	0		2 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Ovarian mass	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Pelvic floor muscle weakness	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
Peyronie's disease	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	2 (<0.1)	0		2 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Pruritus genital	1 (<0.1)	0		1 (<0.1)
Testicular pain	2 (<0.1)	0		2 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Vulvovaginal dryness	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	5 (<0.1)	5 (<0.1)		10 (<0.1)
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Preauricular cyst	0	1 (<0.1)		1 (<0.1)
Von Willebrand's disease	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Congenital, familial and genetic disorders (Cont.)				
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
Type IIa hyperlipidaemia	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	240 (1.6)	265 (1.7)		505 (1.7)
Fatigue	104 (0.7)	104 (0.7)	1.00 (0.76, 1.31)	208 (0.7)
Pain	45 (0.3)	40 (0.3)	0.89 (0.58, 1.35)	85 (0.3)
Chills	34 (0.2)	29 (0.2)	0.85 (0.52, 1.39)	63 (0.2)
Pyrexia	33 (0.2)	28 (0.2)	0.85 (0.51, 1.39)	61 (0.2)
Injection site pain	6 (<0.1)	15 (<0.1)	2.50 (1.00, 6.23)	21 (<0.1)
Non-cardiac chest pain	12 (<0.1)	12 (<0.1)	1.00 (0.46, 2.18)	24 (<0.1)
Chest pain	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.32)	16 (<0.1)
Oedema peripheral	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Injection site lymphadenopathy	2 (<0.1)	8 (<0.1)	3.99 (0.96, 16.62)	10 (<0.1)
Chest discomfort	14 (<0.1)	7 (<0.1)	0.50 (0.21, 1.20)	21 (<0.1)
Injection site erythema	2 (<0.1)	7 (<0.1)	3.49 (0.83, 14.79)	9 (<0.1)
Injection site induration	0	7 (<0.1)		7 (<0.1)
Injection site rash	0	7 (<0.1)		7 (<0.1)
Injection site swelling	0	7 (<0.1)		7 (<0.1)
Peripheral swelling	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Asthenia	6 (<0.1)	4 (<0.1)		10 (<0.1)
Influenza like illness	4 (<0.1)	4 (<0.1)		8 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site macule	0	4 (<0.1)		4 (<0.1)
Injection site pruritus	0	4 (<0.1)		4 (<0.1)
Swelling face	1 (<0.1)	4 (<0.1)		5 (<0.1)
Cyst	5 (<0.1)	3 (<0.1)		8 (<0.1)
Injury associated with device	0	3 (<0.1)		3 (<0.1)
Malaise	2 (<0.1)	3 (<0.1)		5 (<0.1)
Reactogenicity event	2 (<0.1)	3 (<0.1)		5 (<0.1)
Adverse drug reaction	0	2 (<0.1)		2 (<0.1)
Axillary pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site papule	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vaccination site pain	0	2 (<0.1)		2 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Dysplasia	0	1 (<0.1)		1 (<0.1)
Early satiety	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Capsular contracture associated with breast implant	1 (<0.1)	0		1 (<0.1)
Death	1 (<0.1)	0		1 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Feeling abnormal	2 (<0.1)	0		2 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hangover	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site bruising	3 (<0.1)	0		3 (<0.1)
Injection site haemorrhage	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	4 (<0.1)	0		4 (<0.1)
Vaccination site lymphadenopathy	3 (<0.1)	0		3 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations	85 (0.6)	88 (0.6)		173 (0.6)
Blood cholesterol increased	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Blood pressure increased	17 (0.1)	8 (<0.1)	0.47 (0.21, 1.06)	25 (<0.1)
Hepatic enzyme increased	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	5 (<0.1)		6 (<0.1)
Blood pressure systolic increased	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Transaminases increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Cardiac murmur	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood glucose increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood potassium decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood pressure diastolic increased	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood triglycerides increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
C-reactive protein increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrocardiogram QT prolonged	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hepatic enzyme abnormal	0	2 (<0.1)		2 (<0.1)
Weight decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Antinuclear antibody positive	0	1 (<0.1)		1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Blood parathyroid hormone increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood urine present	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)		1 (<0.1)
Glycosylated haemoglobin increased	4 (<0.1)	1 (<0.1)		5 (<0.1)
Haemoglobin decreased	0	1 (<0.1)		1 (<0.1)
Heart rate increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Liver function test increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stool analysis abnormal	0	1 (<0.1)		1 (<0.1)
Streptococcus test negative	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Troponin increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin D decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	2 (<0.1)	0		2 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Blood uric acid increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Haematocrit increased	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Liver function test abnormal	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
SARS-CoV-2 test positive	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Total lung capacity decreased	1 (<0.1)	0		1 (<0.1)
Viral test positive	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	2 (<0.1)	0		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications	425 (2.8)	392 (2.6)		817 (2.7)
Skin laceration	47 (0.3)	34 (0.2)	0.72 (0.47, 1.12)	81 (0.3)
Ligament sprain	22 (0.1)	32 (0.2)	1.45 (0.85, 2.48)	54 (0.2)
Fall	25 (0.2)	26 (0.2)	1.04 (0.60, 1.79)	51 (0.2)
Muscle strain	24 (0.2)	25 (0.2)	1.04 (0.60, 1.81)	49 (0.2)
Procedural pain	34 (0.2)	22 (0.1)	0.65 (0.38, 1.10)	56 (0.2)
Tooth fracture	30 (0.2)	22 (0.1)	0.73 (0.43, 1.26)	52 (0.2)
Foot fracture	18 (0.1)	20 (0.1)	1.11 (0.59, 2.08)	38 (0.1)
Meniscus injury	19 (0.1)	18 (0.1)	0.95 (0.50, 1.78)	37 (0.1)
Animal bite	15 (<0.1)	15 (<0.1)	1.00 (0.50, 2.01)	30 (<0.1)
Arthropod bite	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Limb injury	11 (<0.1)	13 (<0.1)	1.18 (0.54, 2.58)	24 (<0.1)
Joint injury	7 (<0.1)	12 (<0.1)	1.71 (0.70, 4.22)	19 (<0.1)
Road traffic accident	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Concussion	5 (<0.1)	10 (<0.1)	2.00 (0.71, 5.58)	15 (<0.1)
Rib fracture	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.65)	19 (<0.1)
Contusion	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Facial bones fracture	1 (<0.1)	8 (<0.1)	7.99 (1.30, 49.20)	9 (<0.1)
Post-traumatic pain	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)	17 (<0.1)
Head injury	2 (<0.1)	6 (<0.1)		8 (<0.1)
Clavicle fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Corneal abrasion	5 (<0.1)	5 (<0.1)		10 (<0.1)
Humerus fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Ligament rupture	5 (<0.1)	5 (<0.1)		10 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Muscle rupture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Stress fracture	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Upper limb fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Ankle fracture	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Cartilage injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Epicondylitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hand fracture	4 (<0.1)	4 (<0.1)		8 (<0.1)
Joint dislocation	3 (<0.1)	4 (<0.1)		7 (<0.1)
Skin abrasion	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Wrist fracture	6 (<0.1)	4 (<0.1)		10 (<0.1)
Arthropod sting	5 (<0.1)	3 (<0.1)		8 (<0.1)
Back injury	4 (<0.1)	3 (<0.1)		7 (<0.1)
Craniocerebral injury	0	3 (<0.1)		3 (<0.1)
Dental restoration failure	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hip fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Subdural haematoma	0	3 (<0.1)		3 (<0.1)
Alcohol poisoning	0	2 (<0.1)		2 (<0.1)
Bone contusion	5 (<0.1)	2 (<0.1)		7 (<0.1)
Cervical vertebral fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ligament injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Lower limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post procedural haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Procedural nausea	3 (<0.1)	2 (<0.1)		5 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Skin wound	2 (<0.1)	2 (<0.1)		4 (<0.1)
Spinal compression fracture	0	2 (<0.1)		2 (<0.1)
Tendon rupture	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Burns second degree	3 (<0.1)	1 (<0.1)		4 (<0.1)
Chillblains	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)		1 (<0.1)
Dural tear	0	1 (<0.1)		1 (<0.1)
Eyelid injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)		1 (<0.1)
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)		1 (<0.1)
Fractured sacrum	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Graft complication	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injury	0	1 (<0.1)		1 (<0.1)
Limb traumatic amputation	0	1 (<0.1)		1 (<0.1)
Lip injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Multiple fractures	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Neck injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural fever	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Procedural site reaction	0	1 (<0.1)		1 (<0.1)
Radius fracture	6 (<0.1)	1 (<0.1)		7 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Scar	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal column injury	0	1 (<0.1)		1 (<0.1)
Splinter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sports injury	0	1 (<0.1)		1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)		1 (<0.1)
Superficial injury of eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tendon injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thermal burn	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Traumatic haemorrhage	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound	6 (<0.1)	1 (<0.1)		7 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Foreign body	3 (<0.1)	0		3 (<0.1)
Foreign body in ear	2 (<0.1)	0		2 (<0.1)
Fractured coccyx	1 (<0.1)	0		1 (<0.1)
Gingival injury	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Injection related reaction	1 (<0.1)	0		1 (<0.1)
Keratorhexis	1 (<0.1)	0		1 (<0.1)
Mallet finger	1 (<0.1)	0		1 (<0.1)
Multiple injuries	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	2 (<0.1)	0		2 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural hypothyroidism	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	2 (<0.1)	0		2 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural vomiting	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.1.3
Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Traumatic haemothorax	2 (<0.1)	0		2 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	2 (<0.1)	0		2 (<0.1)
Uterine perforation	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Social circumstances	3 (<0.1)	1 (<0.1)		4 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Postmenopause	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)		7 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1419 (12.4)	1311 (11.5)		2730 (12.0)
Number of Unsolicited Adverse Events	2104	1970		4074
Infections and infestations	555 (4.9)	430 (3.8)		985 (4.3)
Urinary tract infection	60 (0.5)	53 (0.5)	0.88 (0.61, 1.27)	113 (0.5)
Upper respiratory tract infection	66 (0.6)	41 (0.4)	0.62 (0.42, 0.91)	107 (0.5)
Sinusitis	28 (0.2)	39 (0.3)	1.39 (0.86, 2.25)	67 (0.3)
Suspected COVID-19	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Viral infection	29 (0.3)	21 (0.2)	0.72 (0.42, 1.26)	50 (0.2)
Rhinovirus infection	17 (0.1)	17 (0.1)	1.00 (0.52, 1.93)	34 (0.1)
COVID-19	124 (1.1)	15 (0.1)	0.12 (0.07, 0.21)	139 (0.6)
Tooth infection	11 (<0.1)	15 (0.1)	1.36 (0.64, 2.91)	26 (0.1)
Pharyngitis streptococcal	17 (0.1)	13 (0.1)	0.76 (0.38, 1.55)	30 (0.1)
Tooth abscess	12 (0.1)	13 (0.1)	1.08 (0.50, 2.33)	25 (0.1)
Herpes zoster	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Ear infection	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Pharyngitis	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Gastroenteritis	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Bronchitis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Cellulitis	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Diverticulitis	4 (<0.1)	5 (<0.1)		9 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Folliculitis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Fungal infection	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Hordeolum	6 (<0.1)	5 (<0.1)		11 (<0.1)
Otitis externa	5 (<0.1)	5 (<0.1)		10 (<0.1)
Otitis media	5 (<0.1)	5 (<0.1)		10 (<0.1)
Abscess limb	0	4 (<0.1)		4 (<0.1)
Acute sinusitis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Bacterial vaginosis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Conjunctivitis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Localised infection	3 (<0.1)	4 (<0.1)		7 (<0.1)
Lyme disease	0	4 (<0.1)		4 (<0.1)
Paronychia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Viral upper respiratory tract infection	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Helicobacter infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	0	3 (<0.1)		3 (<0.1)
Oral herpes	2 (<0.1)	3 (<0.1)		5 (<0.1)
Staphylococcal skin infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Enterovirus infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Herpes simplex	2 (<0.1)	2 (<0.1)		4 (<0.1)
Onychomycosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Oral candidiasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pneumonia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Skin infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tonsillitis	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vulvovaginal mycotic infection	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Body tinea	0	1 (<0.1)		1 (<0.1)
Candida infection	0	1 (<0.1)		1 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Chronic sinusitis	0	1 (<0.1)		1 (<0.1)
Cystitis	6 (<0.1)	1 (<0.1)		7 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Fungal skin infection	0	1 (<0.1)		1 (<0.1)
Furuncle	0	1 (<0.1)		1 (<0.1)
Gastroenteritis viral	4 (<0.1)	1 (<0.1)		5 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Gingivitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Gonorrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)
Infected bite	0	1 (<0.1)		1 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Nasopharyngitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	0	1 (<0.1)		1 (<0.1)
Staphylococcal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Subcutaneous abscess	0	1 (<0.1)		1 (<0.1)
Tinea cruris	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Wound infection	0	1 (<0.1)		1 (<0.1)
Appendicitis	1 (<0.1)	0		1 (<0.1)
Breast abscess	1 (<0.1)	0		1 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Laryngitis	1 (<0.1)	0		1 (<0.1)
Latent tuberculosis	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	4 (<0.1)	0		4 (<0.1)
Rhinitis	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sepsis	1 (<0.1)	0		1 (<0.1)
Septic shock	1 (<0.1)	0		1 (<0.1)
Sialoadenitis	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	20 (0.2)	26 (0.2)		46 (0.2)
Basal cell carcinoma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Uterine leiomyoma	0	3 (<0.1)		3 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Benign neoplasm of skin	2 (<0.1)	2 (<0.1)		4 (<0.1)
Squamous cell carcinoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	2 (<0.1)	1 (<0.1)		3 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Prostate cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Haemangioma of liver	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Skin cancer	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	0		2 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	21 (0.2)	30 (0.3)		51 (0.2)
Lymphadenopathy	13 (0.1)	19 (0.2)	1.46 (0.73, 2.92)	32 (0.1)
Anaemia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Iron deficiency anaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Blood and lymphatic system disorders (Cont.)				
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	0		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	20 (0.2)	7 (<0.1)		27 (0.1)
Seasonal allergy	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Hypersensitivity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Anaphylactic reaction	2 (<0.1)	0		2 (<0.1)
Drug hypersensitivity	2 (<0.1)	0		2 (<0.1)
Food allergy	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	8 (<0.1)	8 (<0.1)		16 (<0.1)
Hypothyroidism	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders	59 (0.5)	48 (0.4)		107 (0.5)
Hyperlipidaemia	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Type 2 diabetes mellitus	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)
Vitamin D deficiency	6 (<0.1)	5 (<0.1)		11 (<0.1)
Diabetes mellitus	2 (<0.1)	4 (<0.1)		6 (<0.1)
Glucose tolerance impaired	6 (<0.1)	4 (<0.1)		10 (<0.1)
Dehydration	4 (<0.1)	3 (<0.1)		7 (<0.1)
Gout	4 (<0.1)	3 (<0.1)		7 (<0.1)
Decreased appetite	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypokalaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypercholesterolaemia	10 (<0.1)	0		10 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypoglycaemia	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyponatraemia	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	63 (0.6)	78 (0.7)		141 (0.6)
Anxiety	23 (0.2)	29 (0.3)	1.26 (0.73, 2.16)	52 (0.2)
Depression	19 (0.2)	28 (0.2)	1.47 (0.83, 2.62)	47 (0.2)
Attention deficit hyperactivity disorder	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Insomnia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	2 (<0.1)		3 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic stress disorder	0	2 (<0.1)		2 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Drug abuse	0	1 (<0.1)		1 (<0.1)
Panic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	3 (<0.1)	0		3 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	111 (1.0)	115 (1.0)		226 (1.0)
Headache	60 (0.5)	54 (0.5)	0.90 (0.62, 1.30)	114 (0.5)
Paraesthesia	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Migraine	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Anosmia	2 (<0.1)	5 (<0.1)		7 (<0.1)
Syncope	5 (<0.1)	5 (<0.1)		10 (<0.1)
Ageusia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Dizziness	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Sciatica	5 (<0.1)	3 (<0.1)		8 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Carpal tunnel syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cervical radiculopathy	0	2 (<0.1)		2 (<0.1)
Hypoaesthesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nerve compression	0	2 (<0.1)		2 (<0.1)
Presyncope	3 (<0.1)	2 (<0.1)		5 (<0.1)
Seizure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Facial paralysis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Neuralgia	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Tension headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Transient ischaemic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Sinus headache	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Eye disorders	13 (0.1)	16 (0.1)		29 (0.1)
Dry eye	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Eye irritation	0	2 (<0.1)		2 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye pruritus	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vision blurred	1 (<0.1)	1 (<0.1)		2 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blepharitis	2 (<0.1)	0		2 (<0.1)
Cataract	1 (<0.1)	0		1 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Vitreous floaters	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	23 (0.2)	22 (0.2)		45 (0.2)
Ear pain	5 (<0.1)	6 (<0.1)		11 (<0.1)
Vertigo	0	6 (<0.1)		6 (<0.1)
Vertigo positional	1 (<0.1)	3 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Tinnitus	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear canal erythema	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear discomfort	0	1 (<0.1)		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Ear pruritus	1 (<0.1)	0		1 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	0		1 (<0.1)
Middle ear effusion	3 (<0.1)	0		3 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	20 (0.2)	19 (0.2)		39 (0.2)
Atrial fibrillation	2 (<0.1)	3 (<0.1)		5 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Palpitations	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cardiac failure congestive	3 (<0.1)	2 (<0.1)		5 (<0.1)
Sinus tachycardia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tachycardia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angina pectoris	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Cardiac failure	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Arrhythmia	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular extrasystoles	2 (<0.1)	0		2 (<0.1)
Vascular disorders	77 (0.7)	61 (0.5)		138 (0.6)
Hypertension	66 (0.6)	55 (0.5)	0.83 (0.58, 1.19)	121 (0.5)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders (Cont.)				
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Flushing	1 (<0.1)	1 (<0.1)		2 (<0.1)
Haematoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	2 (<0.1)	0		2 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	149 (1.3)	121 (1.1)		270 (1.2)
Cough	49 (0.4)	45 (0.4)	0.92 (0.61, 1.37)	94 (0.4)
Nasal congestion	32 (0.3)	36 (0.3)	1.12 (0.70, 1.80)	68 (0.3)
Rhinorrhoea	31 (0.3)	29 (0.3)	0.94 (0.57, 1.54)	60 (0.3)
Oropharyngeal pain	40 (0.4)	23 (0.2)	0.57 (0.35, 0.95)	63 (0.3)
Dyspnoea	14 (0.1)	11 (<0.1)	0.79 (0.36, 1.70)	25 (0.1)
Asthma	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Chronic obstructive pulmonary disease	4 (<0.1)	4 (<0.1)		8 (<0.1)
Respiratory tract congestion	3 (<0.1)	4 (<0.1)		7 (<0.1)
Sinus congestion	5 (<0.1)	4 (<0.1)		9 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchiectasis	0	2 (<0.1)		2 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary embolism	3 (<0.1)	2 (<0.1)		5 (<0.1)
Sinus pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sneezing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Wheezing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Pleural effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pleuritic pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Productive cough	0	1 (<0.1)		1 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Rhinitis allergic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Throat irritation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Dysphonia	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Nasal septum deviation	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pharyngeal erythema	2 (<0.1)	0		2 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Respiratory disorder	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Upper-airway cough syndrome	2 (<0.1)	0		2 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders	113 (1.0)	134 (1.2)		247 (1.1)
Diarrhoea	19 (0.2)	30 (0.3)	1.58 (0.90, 2.78)	49 (0.2)
Nausea	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Gastrooesophageal reflux disease	10 (<0.1)	16 (0.1)	1.60 (0.74, 3.46)	26 (0.1)
Abdominal pain	7 (<0.1)	9 (<0.1)	1.29 (0.50, 3.33)	16 (<0.1)
Vomiting	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Dental caries	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Constipation	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Toothache	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Abdominal pain lower	4 (<0.1)	5 (<0.1)		9 (<0.1)
Abdominal pain upper	3 (<0.1)	3 (<0.1)		6 (<0.1)
Colitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tooth impacted	1 (<0.1)	3 (<0.1)		4 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Dyspepsia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Food poisoning	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastric ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hiatus hernia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Inguinal hernia	0	2 (<0.1)		2 (<0.1)
Large intestine polyp	0	2 (<0.1)		2 (<0.1)
Umbilical hernia	0	2 (<0.1)		2 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal distension	0	1 (<0.1)		1 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Flatulence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Haemorrhoids	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)

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Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastritis	3 (<0.1)	0		3 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Lip swelling	1 (<0.1)	0		1 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	4 (<0.1)	7 (<0.1)		11 (<0.1)
Cholelithiasis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders	69 (0.6)	64 (0.6)		133 (0.6)
Urticaria	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Dermatitis contact	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Rash	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Acne	5 (<0.1)	5 (<0.1)		10 (<0.1)
Pruritus	5 (<0.1)	5 (<0.1)		10 (<0.1)
Eczema	0	3 (<0.1)		3 (<0.1)
Dermatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hidradenitis	0	2 (<0.1)		2 (<0.1)
Hyperhidrosis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Psoriasis	0	2 (<0.1)		2 (<0.1)
Rosacea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Actinic keratosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Blister	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dermatitis atopic	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Rash erythematous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash maculo-papular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Angioedema	2 (<0.1)	0		2 (<0.1)
Dry skin	1 (<0.1)	0		1 (<0.1)
Ecchymosis	1 (<0.1)	0		1 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Night sweats	2 (<0.1)	0		2 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash pruritic	4 (<0.1)	0		4 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	164 (1.4)	172 (1.5)		336 (1.5)
Arthralgia	30 (0.3)	27 (0.2)	0.90 (0.54, 1.50)	57 (0.2)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Myalgia	25 (0.2)	25 (0.2)	1.00 (0.58, 1.73)	50 (0.2)
Back pain	26 (0.2)	18 (0.2)	0.69 (0.38, 1.25)	44 (0.2)
Neck pain	7 (<0.1)	14 (0.1)	2.00 (0.83, 4.81)	21 (<0.1)
Muscle spasms	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Musculoskeletal pain	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)	18 (<0.1)
Osteoarthritis	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Pain in extremity	12 (0.1)	7 (<0.1)	0.58 (0.24, 1.44)	19 (<0.1)
Tendonitis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Rotator cuff syndrome	5 (<0.1)	6 (<0.1)		11 (<0.1)
Musculoskeletal chest pain	3 (<0.1)	4 (<0.1)		7 (<0.1)
Arthritis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bursitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Muscle tightness	0	3 (<0.1)		3 (<0.1)
Trigger finger	1 (<0.1)	3 (<0.1)		4 (<0.1)
Joint range of motion decreased	0	2 (<0.1)		2 (<0.1)
Joint swelling	0	2 (<0.1)		2 (<0.1)
Musculoskeletal stiffness	0	2 (<0.1)		2 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Spinal osteoarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Bone pain	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibromyalgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Flank pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Groin pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intervertebral disc degeneration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscular weakness	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteoporosis	0	1 (<0.1)		1 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fasciitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarthritis	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)
Axillary mass	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Costochondritis	3 (<0.1)	0		3 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Pain in jaw	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	2 (<0.1)	0		2 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	0		1 (<0.1)
Torticollis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	18 (0.2)	15 (0.1)		33 (0.1)
Nephrolithiasis	12 (0.1)	6 (<0.1)	0.50 (0.19, 1.28)	18 (<0.1)
Acute kidney injury	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Renal and urinary disorders (Cont.)				
Dysuria	0	2 (<0.1)		2 (<0.1)
Hypertonic bladder	0	2 (<0.1)		2 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Haematuria	3 (<0.1)	1 (<0.1)		4 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	31 (0.3)	29 (0.3)		60 (0.3)
Pelvic pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Prostatitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dysmenorrhoea	0	2 (<0.1)		2 (<0.1)
Erectile dysfunction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Benign prostatic hyperplasia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Breast cyst	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Menorrhagia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Postmenopausal haemorrhage	0	1 (<0.1)		1 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Ovarian cyst	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Testicular pain	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Vaginal haemorrhage	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	100 (0.9)	121 (1.1)		221 (1.0)
Fatigue	43 (0.4)	42 (0.4)	0.98 (0.64, 1.49)	85 (0.4)
Pain	11 (<0.1)	14 (0.1)	1.27 (0.59, 2.75)	25 (0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Chills	14 (0.1)	12 (0.1)	0.86 (0.40, 1.82)	26 (0.1)
Injection site pain	4 (<0.1)	12 (0.1)	3.00 (1.02, 8.82)	16 (<0.1)
Pyrexia	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Injection site erythema	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.59)	8 (<0.1)
Injection site induration	0	7 (<0.1)		7 (<0.1)
Injection site lymphadenopathy	2 (<0.1)	6 (<0.1)		8 (<0.1)
Injection site swelling	0	6 (<0.1)		6 (<0.1)
Non-cardiac chest pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Chest pain	1 (<0.1)	4 (<0.1)		5 (<0.1)
Injection site rash	0	4 (<0.1)		4 (<0.1)
Injection site macule	0	3 (<0.1)		3 (<0.1)
Injection site pruritus	0	3 (<0.1)		3 (<0.1)
Reactogenicity event	0	3 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	3 (<0.1)		4 (<0.1)
Chest discomfort	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Injection site papule	0	2 (<0.1)		2 (<0.1)
Peripheral swelling	1 (<0.1)	2 (<0.1)		3 (<0.1)
Axillary pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Malaise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Oedema peripheral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vaccination site pain	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Asthenia	2 (<0.1)	0		2 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Hangover	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site bruising	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Precancerous condition	1 (<0.1)	0		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations	27 (0.2)	31 (0.3)		58 (0.3)
Hepatic enzyme increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Blood pressure increased	2 (<0.1)	3 (<0.1)		5 (<0.1)
Transaminases increased	0	3 (<0.1)		3 (<0.1)
Blood cholesterol increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood testosterone decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Weight decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood pressure systolic increased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Cardiac murmur	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Heart rate increased	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications	152 (1.3)	130 (1.1)		282 (1.2)
Ligament sprain	7 (<0.1)	16 (0.1)	2.28 (0.97, 5.41)	23 (0.1)
Skin laceration	23 (0.2)	13 (0.1)	0.57 (0.29, 1.10)	36 (0.2)
Muscle strain	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.53)	21 (<0.1)
Foot fracture	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Tooth fracture	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Limb injury	2 (<0.1)	6 (<0.1)		8 (<0.1)
Fall	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Meniscus injury	6 (<0.1)	5 (<0.1)		11 (<0.1)
Procedural pain	6 (<0.1)	5 (<0.1)		11 (<0.1)
Arthropod bite	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Concussion	3 (<0.1)	4 (<0.1)		7 (<0.1)
Joint injury	3 (<0.1)	4 (<0.1)		7 (<0.1)
Road traffic accident	2 (<0.1)	4 (<0.1)		6 (<0.1)
Animal bite	8 (<0.1)	3 (<0.1)	0.37 (0.11, 1.30)	11 (<0.1)
Arthropod sting	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Ankle fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Contusion	6 (<0.1)	2 (<0.1)		8 (<0.1)
Facial bones fracture	0	2 (<0.1)		2 (<0.1)
Hand fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ligament rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Upper limb fracture	0	2 (<0.1)		2 (<0.1)
Wrist fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Back injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Epicondylitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Joint dislocation	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)		1 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Muscle rupture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Post-traumatic pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rib fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Skin abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Tendon injury	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Bone contusion	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural nausea	1 (<0.1)	0		1 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Thermal burn	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	0	3 (<0.1)		3 (<0.1)
Device breakage	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	521 (13.9)	508 (13.5)		1029 (13.7)
Number of Unsolicited Adverse Events	759	745		1504
Infections and infestations	150 (4.0)	117 (3.1)		267 (3.6)
Urinary tract infection	34 (0.9)	18 (0.5)	0.53 (0.30, 0.92)	52 (0.7)
Upper respiratory tract infection	8 (0.2)	9 (0.2)	1.12 (0.45, 2.81)	17 (0.2)
Sinusitis	7 (0.2)	7 (0.2)	1.00 (0.36, 2.72)	14 (0.2)
Tooth abscess	9 (0.2)	7 (0.2)	0.77 (0.30, 2.00)	16 (0.2)
Herpes zoster	3 (<0.1)	6 (0.2)		9 (0.1)
COVID-19	15 (0.4)	5 (0.1)	0.33 (0.13, 0.88)	20 (0.3)
Suspected COVID-19	5 (0.1)	5 (0.1)		10 (0.1)
Tooth infection	3 (<0.1)	5 (0.1)		8 (0.1)
Gingivitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Herpes simplex	1 (<0.1)	3 (<0.1)		4 (<0.1)
Localised infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Onychomycosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pneumonia	6 (0.2)	3 (<0.1)		9 (0.1)
Rhinovirus infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Viral infection	4 (0.1)	3 (<0.1)		7 (<0.1)
Cellulitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Conjunctivitis	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Cystitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Diverticulitis	4 (0.1)	2 (<0.1)		6 (<0.1)
Ear infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Laryngitis	0	2 (<0.1)		2 (<0.1)
Otitis externa	3 (<0.1)	2 (<0.1)		5 (<0.1)
Paronychia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Staphylococcal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subcutaneous abscess	0	2 (<0.1)		2 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Acute sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Appendicitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chronic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Enterovirus infection	0	1 (<0.1)		1 (<0.1)
Fungal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hordeolum	1 (<0.1)	1 (<0.1)		2 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	0	1 (<0.1)		1 (<0.1)
Otitis media	0	1 (<0.1)		1 (<0.1)
Otitis media acute	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Sepsis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sialoadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Skin infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)
Viral upper respiratory tract infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vulvovaginal candidiasis	0	1 (<0.1)		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Body tinea	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
Candida infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Folliculitis	2 (<0.1)	0		2 (<0.1)
Fungal skin infection	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastroenteritis	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Helicobacter infection	1 (<0.1)	0		1 (<0.1)
Kidney infection	1 (<0.1)	0		1 (<0.1)
Nasopharyngitis	1 (<0.1)	0		1 (<0.1)
Oral candidiasis	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pharyngitis	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	0		2 (<0.1)
Postoperative wound infection	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Soft tissue infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)
Wound infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	30 (0.8)	25 (0.7)		55 (0.7)
Basal cell carcinoma	12 (0.3)	6 (0.2)	0.50 (0.19, 1.28)	18 (0.2)
Skin cancer	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Lipoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Malignant melanoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostate cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of skin	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma	6 (0.2)	1 (<0.1)		7 (<0.1)
Squamous cell carcinoma of skin	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Blood and lymphatic system disorders	3 (<0.1)	9 (0.2)		12 (0.2)
Lymphadenopathy	2 (<0.1)	5 (0.1)		7 (<0.1)
Anaemia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	0	1 (<0.1)		1 (<0.1)
Lymphadenitis	1 (<0.1)	0		1 (<0.1)
Immune system disorders	2 (<0.1)	6 (0.2)		8 (0.1)
Seasonal allergy	2 (<0.1)	4 (0.1)		6 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Endocrine disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypothyroidism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	20 (0.5)	37 (1.0)		57 (0.8)
Hypercholesterolaemia	1 (<0.1)	8 (0.2)	7.96 (1.29, 49.03)	9 (0.1)
Hyperlipidaemia	4 (0.1)	8 (0.2)	1.99 (0.64, 6.21)	12 (0.2)
Type 2 diabetes mellitus	2 (<0.1)	7 (0.2)	3.48 (0.82, 14.74)	9 (0.1)
Vitamin D deficiency	0	5 (0.1)		5 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)				
Dehydration	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hyponatraemia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetes mellitus	3 (<0.1)	1 (<0.1)		4 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Glucose tolerance impaired	0	1 (<0.1)		1 (<0.1)
Gout	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Decreased appetite	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypocalcaemia	1 (<0.1)	0		1 (<0.1)
Hypoglycaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	10 (0.3)	12 (0.3)		22 (0.3)
Anxiety	5 (0.1)	7 (0.2)	1.39 (0.47, 4.15)	12 (0.2)
Depression	1 (<0.1)	2 (<0.1)		3 (<0.1)
Insomnia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Psychiatric disorders (Cont.)				
Adjustment disorder with depressed mood	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0		1 (<0.1)
Mental status changes	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	29 (0.8)	41 (1.1)		70 (0.9)
Headache	10 (0.3)	16 (0.4)	1.59 (0.74, 3.44)	26 (0.3)
Dizziness	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cerebrovascular accident	0	2 (<0.1)		2 (<0.1)
Cervical radiculopathy	0	2 (<0.1)		2 (<0.1)
Paraesthesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Carpal tunnel syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Facial paralysis	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Migraine	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Sciatica	1 (<0.1)	1 (<0.1)		2 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Sinus headache	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Syncope	3 (<0.1)	1 (<0.1)		4 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	0	1 (<0.1)		1 (<0.1)
Ageusia	1 (<0.1)	0		1 (<0.1)
Anosmia	1 (<0.1)	0		1 (<0.1)
Hypoaesthesia	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Neuropathy peripheral	1 (<0.1)	0		1 (<0.1)
Presyncope	2 (<0.1)	0		2 (<0.1)
Restless legs syndrome	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tremor	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Eye disorders	17 (0.5)	10 (0.3)		27 (0.4)
Glaucoma	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cataract	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Dry eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eye irritation	0	1 (<0.1)		1 (<0.1)
Eye pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	0	1 (<0.1)		1 (<0.1)
Blepharitis	2 (<0.1)	0		2 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Ear and labyrinth disorders	12 (0.3)	10 (0.3)		22 (0.3)
Vertigo	3 (<0.1)	3 (<0.1)		6 (<0.1)
Vertigo positional	0	3 (<0.1)		3 (<0.1)
Meniere's disease	0	2 (<0.1)		2 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	0	1 (<0.1)		1 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Ear discomfort	1 (<0.1)	0		1 (<0.1)
Ear pain	1 (<0.1)	0		1 (<0.1)
Ear pruritus	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tinnitus	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	18 (0.5)	29 (0.8)		47 (0.6)
Atrial fibrillation	9 (0.2)	9 (0.2)	1.00 (0.41, 2.43)	18 (0.2)
Coronary artery disease	3 (<0.1)	3 (<0.1)		6 (<0.1)
Palpitations	0	3 (<0.1)		3 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Angina pectoris	2 (<0.1)	2 (<0.1)		4 (<0.1)
Arrhythmia	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders (Cont.)				
Cardiac failure congestive	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardio-respiratory arrest	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Sinus tachycardia	0	1 (<0.1)		1 (<0.1)
Tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Atrial flutter	1 (<0.1)	0		1 (<0.1)
Cardiac failure	2 (<0.1)	0		2 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	40 (1.1)	40 (1.1)		80 (1.1)
Hypertension	30 (0.8)	31 (0.8)	1.03 (0.63, 1.69)	61 (0.8)
Hot flush	2 (<0.1)	2 (<0.1)		4 (<0.1)
Aortic aneurysm	3 (<0.1)	1 (<0.1)		4 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Haematoma	0	1 (<0.1)		1 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Vascular disorders (Cont.)				
Hypotension	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Orthostatic hypotension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	43 (1.1)	34 (0.9)		77 (1.0)
Cough	11 (0.3)	11 (0.3)	1.00 (0.44, 2.24)	22 (0.3)
Nasal congestion	12 (0.3)	8 (0.2)	0.66 (0.28, 1.58)	20 (0.3)
Rhinorrhoea	7 (0.2)	7 (0.2)	1.00 (0.36, 2.72)	14 (0.2)
Asthma	2 (<0.1)	4 (0.1)		6 (<0.1)
Oropharyngeal pain	9 (0.2)	4 (0.1)	0.44 (0.14, 1.35)	13 (0.2)
Dyspnoea	4 (0.1)	3 (<0.1)		7 (<0.1)
Respiratory tract congestion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rhinitis allergic	3 (<0.1)	2 (<0.1)		5 (<0.1)
Upper-airway cough syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chronic obstructive pulmonary disease	4 (0.1)	1 (<0.1)		5 (<0.1)
Dysphonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Epistaxis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal septum deviation	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pleural effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pulmonary embolism	0	1 (<0.1)		1 (<0.1)
Respiratory disorder	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)
Dry throat	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Sinus congestion	1 (<0.1)	0		1 (<0.1)
Wheezing	2 (<0.1)	0		2 (<0.1)
Gastrointestinal disorders	55 (1.5)	47 (1.2)		102 (1.4)
Nausea	8 (0.2)	10 (0.3)	1.24 (0.51, 3.05)	18 (0.2)
Dental caries	2 (<0.1)	5 (0.1)		7 (<0.1)
Gastrooesophageal reflux disease	6 (0.2)	5 (0.1)		11 (0.1)
Toothache	2 (<0.1)	5 (0.1)		7 (<0.1)
Vomiting	2 (<0.1)	4 (0.1)		6 (<0.1)
Abdominal pain upper	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diarrhoea	13 (0.3)	3 (<0.1)	0.23 (0.07, 0.75)	16 (0.2)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Inguinal hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Colitis	0	1 (<0.1)		1 (<0.1)
Constipation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dysphagia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastric ulcer	0	1 (<0.1)		1 (<0.1)
Gingival pain	0	1 (<0.1)		1 (<0.1)
Haemorrhoids	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hiatus hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	4 (0.1)	1 (<0.1)		5 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	0	1 (<0.1)		1 (<0.1)
Stomatitis	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	2 (<0.1)	0		2 (<0.1)
Abdominal pain	1 (<0.1)	0		1 (<0.1)
Abdominal pain lower	1 (<0.1)	0		1 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Food poisoning	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastritis	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Lip swelling	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	0		1 (<0.1)
Umbilical hernia	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	5 (0.1)		5 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Cholelithiasis	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	21 (0.6)	24 (0.6)		45 (0.6)
Actinic keratosis	1 (<0.1)	4 (0.1)		5 (<0.1)
Urticaria	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dermatitis contact	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Rash	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis atopic	0	1 (<0.1)		1 (<0.1)
Dry skin	0	1 (<0.1)		1 (<0.1)
Erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ingrowing nail	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Pruritus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash maculo-papular	0	1 (<0.1)		1 (<0.1)
Rash pruritic	0	1 (<0.1)		1 (<0.1)
Rosacea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermal cyst	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ecchymosis	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Psoriasis	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin mass	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	72 (1.9)	77 (2.0)		149 (2.0)
Arthralgia	11 (0.3)	12 (0.3)	1.09 (0.49, 2.41)	23 (0.3)
Osteoarthritis	10 (0.3)	8 (0.2)	0.80 (0.32, 1.95)	18 (0.2)
Back pain	10 (0.3)	7 (0.2)	0.70 (0.27, 1.77)	17 (0.2)
Myalgia	4 (0.1)	7 (0.2)	1.74 (0.55, 5.56)	11 (0.1)
Bursitis	3 (<0.1)	6 (0.2)		9 (0.1)
Musculoskeletal pain	4 (0.1)	5 (0.1)		9 (0.1)
Arthritis	0	4 (0.1)		4 (<0.1)
Pain in extremity	8 (0.2)	4 (0.1)	0.50 (0.16, 1.55)	12 (0.2)
Spinal stenosis	0	4 (0.1)		4 (<0.1)
Trigger finger	0	4 (0.1)		4 (<0.1)
Muscle spasms	5 (0.1)	3 (<0.1)		8 (0.1)
Joint swelling	0	2 (<0.1)		2 (<0.1)
Neck pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Osteoporosis	0	2 (<0.1)		2 (<0.1)
Rotator cuff syndrome	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tendonitis	4 (0.1)	2 (<0.1)		6 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Muscular weakness	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Musculoskeletal stiffness	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cervical spinal stenosis	1 (<0.1)	0		1 (<0.1)
Flank pain	1 (<0.1)	0		1 (<0.1)
Foot deformity	1 (<0.1)	0		1 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Osteopenia	1 (<0.1)	0		1 (<0.1)
Polyarthritis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Spinal osteoarthritis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	18 (0.5)	17 (0.5)		35 (0.5)
Nephrolithiasis	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)				
Chronic kidney disease	0	2 (<0.1)		2 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haematuria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary hesitation	0	1 (<0.1)		1 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acute kidney injury	3 (<0.1)	0		3 (<0.1)
Hypertonic bladder	1 (<0.1)	0		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	7 (0.2)	8 (0.2)		15 (0.2)
Benign prostatic hyperplasia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast cyst	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Reproductive system and breast disorders (Cont.)				
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	0	1 (<0.1)		1 (<0.1)
Erectile dysfunction	1 (<0.1)	0		1 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Prostatitis	2 (<0.1)	0		2 (<0.1)
General disorders and administration site conditions	25 (0.7)	31 (0.8)		56 (0.7)
Fatigue	9 (0.2)	13 (0.3)	1.44 (0.63, 3.28)	22 (0.3)
Pain	3 (<0.1)	5 (0.1)		8 (0.1)
Pyrexia	2 (<0.1)	5 (0.1)		7 (<0.1)
Chills	3 (<0.1)	2 (<0.1)		5 (<0.1)
Injection site pain	0	2 (<0.1)		2 (<0.1)
Injection site rash	0	2 (<0.1)		2 (<0.1)
Oedema peripheral	2 (<0.1)	2 (<0.1)		4 (<0.1)
Precancerous condition	0	2 (<0.1)		2 (<0.1)
Cyst	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Injection site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site macule	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Injection site pruritus	0	1 (<0.1)		1 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Vaccination site pain	0	1 (<0.1)		1 (<0.1)
Chest discomfort	1 (<0.1)	0		1 (<0.1)
Chest pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site bruising	2 (<0.1)	0		2 (<0.1)
Injection site haemorrhage	1 (<0.1)	0		1 (<0.1)
Non-cardiac chest pain	2 (<0.1)	0		2 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Peripheral swelling	3 (<0.1)	0		3 (<0.1)
Investigations	10 (0.3)	11 (0.3)		21 (0.3)
Blood cholesterol increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)		1 (<0.1)
Blood testosterone decreased	0	1 (<0.1)		1 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac murmur	0	1 (<0.1)		1 (<0.1)

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Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations (Cont.)				
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure increased	3 (<0.1)	0		3 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Weight decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	75 (2.0)	62 (1.6)		137 (1.8)
Skin laceration	5 (0.1)	7 (0.2)	1.39 (0.47, 4.15)	12 (0.2)
Procedural pain	10 (0.3)	6 (0.2)	0.60 (0.23, 1.58)	16 (0.2)
Fall	5 (0.1)	5 (0.1)		10 (0.1)
Arthropod bite	2 (<0.1)	4 (0.1)		6 (<0.1)
Ligament sprain	1 (<0.1)	4 (0.1)		5 (<0.1)
Muscle strain	5 (0.1)	4 (0.1)		9 (0.1)
Rib fracture	1 (<0.1)	4 (0.1)		5 (<0.1)
Road traffic accident	2 (<0.1)	4 (0.1)		6 (<0.1)
Limb injury	4 (0.1)	3 (<0.1)		7 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Tooth fracture	6 (0.2)	3 (<0.1)		9 (0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Facial bones fracture	0	2 (<0.1)		2 (<0.1)
Foot fracture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hand fracture	0	2 (<0.1)		2 (<0.1)
Post-traumatic pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Wrist fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Bone contusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Contusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Head injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hip fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Muscle rupture	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Overdose	0	1 (<0.1)		1 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tendon rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thermal burn	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	0	1 (<0.1)		1 (<0.1)
Animal bite	2 (<0.1)	0		2 (<0.1)
Ankle fracture	1 (<0.1)	0		1 (<0.1)
Arthropod sting	2 (<0.1)	0		2 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Joint dislocation	2 (<0.1)	0		2 (<0.1)
Joint injury	1 (<0.1)	0		1 (<0.1)
Ligament rupture	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Skin abrasion	3 (<0.1)	0		3 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	1 (<0.1)		4 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3089 (27.1)	2457 (21.5)		5546 (24.3)
Number of Unsolicited Adverse Events	5364	4370		9734
Infections and infestations	1677 (14.7)	1024 (9.0)		2701 (11.8)
Upper respiratory tract infection	185 (1.6)	141 (1.2)	0.76 (0.61, 0.95)	326 (1.4)
Suspected COVID-19	79 (0.7)	96 (0.8)	1.21 (0.90, 1.63)	175 (0.8)
Urinary tract infection	119 (1.0)	94 (0.8)	0.79 (0.60, 1.03)	213 (0.9)
Viral infection	97 (0.9)	90 (0.8)	0.93 (0.70, 1.23)	187 (0.8)
Sinusitis	76 (0.7)	83 (0.7)	1.09 (0.80, 1.49)	159 (0.7)
COVID-19	772 (6.8)	63 (0.6)	0.08 (0.06, 0.11)	835 (3.7)
Rhinovirus infection	41 (0.4)	49 (0.4)	1.19 (0.79, 1.80)	90 (0.4)
Herpes zoster	13 (0.1)	25 (0.2)	1.92 (1.00, 3.71)	38 (0.2)
Pharyngitis streptococcal	33 (0.3)	25 (0.2)	0.76 (0.45, 1.27)	58 (0.3)
Tooth infection	19 (0.2)	22 (0.2)	1.16 (0.63, 2.12)	41 (0.2)
Viral upper respiratory tract infection	21 (0.2)	22 (0.2)	1.05 (0.58, 1.89)	43 (0.2)
Tooth abscess	24 (0.2)	21 (0.2)	0.87 (0.49, 1.56)	45 (0.2)
Ear infection	17 (0.1)	19 (0.2)	1.12 (0.59, 2.12)	36 (0.2)
Bronchitis	29 (0.3)	18 (0.2)	0.62 (0.35, 1.11)	47 (0.2)
Pharyngitis	18 (0.2)	18 (0.2)	1.00 (0.53, 1.90)	36 (0.2)
Gastroenteritis	18 (0.2)	17 (0.1)	0.94 (0.49, 1.81)	35 (0.2)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Otitis media	16 (0.1)	16 (0.1)	1.00 (0.51, 1.97)	32 (0.1)
Cellulitis	21 (0.2)	15 (0.1)	0.71 (0.37, 1.37)	36 (0.2)
Pneumonia	24 (0.2)	12 (0.1)	0.50 (0.25, 0.99)	36 (0.2)
Hordeolum	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)
Diverticulitis	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Otitis externa	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)
Bacterial vaginosis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Conjunctivitis	12 (0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Fungal infection	12 (0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Respiratory tract infection	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Abscess limb	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Enterovirus infection	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Nasopharyngitis	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Acute sinusitis	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Asymptomatic COVID-19	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Folliculitis	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Lyme disease	0	6 (<0.1)		6 (<0.1)
Skin infection	3 (<0.1)	6 (<0.1)		9 (<0.1)
Vulvovaginal candidiasis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Gastroenteritis viral	6 (<0.1)	5 (<0.1)		11 (<0.1)
Kidney infection	1 (<0.1)	5 (<0.1)		6 (<0.1)
Localised infection	3 (<0.1)	5 (<0.1)		8 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Oral herpes	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Paronychia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Pyelonephritis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Chlamydial infection	0	4 (<0.1)		4 (<0.1)
Cystitis	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)	12 (<0.1)
Furuncle	0	4 (<0.1)		4 (<0.1)
Gingivitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Helicobacter infection	3 (<0.1)	4 (<0.1)		7 (<0.1)
Herpes simplex	2 (<0.1)	4 (<0.1)		6 (<0.1)
Onychomycosis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Sepsis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Clostridium difficile infection	0	3 (<0.1)		3 (<0.1)
Gonorrhoea	2 (<0.1)	3 (<0.1)		5 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Oral candidiasis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rhinitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Sinusitis bacterial	3 (<0.1)	3 (<0.1)		6 (<0.1)
Staphylococcal infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Staphylococcal skin infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Tonsillitis	11 (<0.1)	3 (<0.1)	0.27 (0.08, 0.91)	14 (<0.1)
Viral pharyngitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Vulvovaginal mycotic infection	12 (0.1)	3 (<0.1)	0.25 (0.08, 0.82)	15 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Wound infection	0	3 (<0.1)		3 (<0.1)
Appendicitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Candida infection	0	2 (<0.1)		2 (<0.1)
Cat scratch disease	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Eye infection	5 (<0.1)	2 (<0.1)		7 (<0.1)
Fungal skin infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Impetigo	0	2 (<0.1)		2 (<0.1)
Infected bite	1 (<0.1)	2 (<0.1)		3 (<0.1)
Laryngitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nail infection	0	2 (<0.1)		2 (<0.1)
Periodontitis	0	2 (<0.1)		2 (<0.1)
Pertussis	0	2 (<0.1)		2 (<0.1)
Postoperative wound infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulpitis dental	1 (<0.1)	2 (<0.1)		3 (<0.1)
Subcutaneous abscess	0	2 (<0.1)		2 (<0.1)
Tinea cruris	0	2 (<0.1)		2 (<0.1)
Tuberculosis	0	2 (<0.1)		2 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urinary tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	0	1 (<0.1)		1 (<0.1)
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiolitis	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Chronic sinusitis	0	1 (<0.1)		1 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Dacryocystitis	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Gingival abscess	0	1 (<0.1)		1 (<0.1)
Groin abscess	0	1 (<0.1)		1 (<0.1)
Helminthic infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Infected cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza	4 (<0.1)	1 (<0.1)		5 (<0.1)
Labyrinthitis	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	0	1 (<0.1)		1 (<0.1)
Otitis media acute	5 (<0.1)	1 (<0.1)		6 (<0.1)
Papilloma viral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection viral	8 (<0.1)	1 (<0.1)	0.12 (0.02, 0.77)	9 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Septic shock	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Skin candida	3 (<0.1)	1 (<0.1)		4 (<0.1)
Soft tissue infection	0	1 (<0.1)		1 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Streptococcal infection	0	1 (<0.1)		1 (<0.1)
Tinea versicolour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Viral sinusitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vulvitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)		1 (<0.1)
Abscess neck	1 (<0.1)	0		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Asymptomatic bacteriuria	2 (<0.1)	0		2 (<0.1)
Atypical pneumonia	1 (<0.1)	0		1 (<0.1)
Bronchitis bacterial	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	9 (<0.1)	0		9 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cervicitis	2 (<0.1)	0		2 (<0.1)
Coccidioidomycosis	2 (<0.1)	0		2 (<0.1)
Conjunctivitis bacterial	4 (<0.1)	0		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Corneal infection	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	1 (<0.1)	0		1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Hepatitis C	1 (<0.1)	0		1 (<0.1)
Infected dermal cyst	1 (<0.1)	0		1 (<0.1)
Injection site infection	1 (<0.1)	0		1 (<0.1)
Latent tuberculosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	2 (<0.1)	0		2 (<0.1)
Mastoiditis	3 (<0.1)	0		3 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Perineal cellulitis	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	2 (<0.1)	0		2 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Pyelonephritis acute	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sialoadenitis	1 (<0.1)	0		1 (<0.1)
Sinusitis fungal	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Infections and infestations (Cont.)				
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Syphilis	3 (<0.1)	0		3 (<0.1)
Tinea barbae	1 (<0.1)	0		1 (<0.1)
Tinea infection	1 (<0.1)	0		1 (<0.1)
Tinea pedis	2 (<0.1)	0		2 (<0.1)
Trichomoniasis	1 (<0.1)	0		1 (<0.1)
Vaginal abscess	1 (<0.1)	0		1 (<0.1)
Vaginitis chlamydial	2 (<0.1)	0		2 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	58 (0.5)	71 (0.6)		129 (0.6)
Basal cell carcinoma	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Uterine leiomyoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Prostate cancer	1 (<0.1)	4 (<0.1)		5 (<0.1)
Squamous cell carcinoma	2 (<0.1)	4 (<0.1)		6 (<0.1)
Benign breast neoplasm	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of skin	2 (<0.1)	3 (<0.1)		5 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin papilloma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of thyroid gland	2 (<0.1)	2 (<0.1)		4 (<0.1)
Breast cancer	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Malignant melanoma in situ	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Adrenal adenoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Breast cancer in situ	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Fibrous histiocytoma	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Intraductal papilloma of breast	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma	4 (<0.1)	1 (<0.1)		5 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Prostate cancer stage I	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	0	1 (<0.1)		1 (<0.1)
Renal neoplasm	0	1 (<0.1)		1 (<0.1)
Skin cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Squamous cell carcinoma of skin	5 (<0.1)	1 (<0.1)		6 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign bone neoplasm	1 (<0.1)	0		1 (<0.1)
Benign neoplasm of eyelid	1 (<0.1)	0		1 (<0.1)
Benign ovarian tumour	1 (<0.1)	0		1 (<0.1)
Breast neoplasm	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Enchondromatosis	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	2 (<0.1)	0		2 (<0.1)
Haemangioma of liver	2 (<0.1)	0		2 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	45 (0.4)	55 (0.5)		100 (0.4)
Lymphadenopathy	25 (0.2)	28 (0.2)	1.12 (0.66, 1.91)	53 (0.2)
Anaemia	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.63)	17 (<0.1)
Iron deficiency anaemia	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Thrombocytopenia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Blood and lymphatic system disorders (Cont.)				
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	0	1 (<0.1)		1 (<0.1)
Nucleated red cells	1 (<0.1)	0		1 (<0.1)
Immune system disorders	30 (0.3)	24 (0.2)		54 (0.2)
Seasonal allergy	18 (0.2)	15 (0.1)	0.83 (0.43, 1.63)	33 (0.1)
Drug hypersensitivity	3 (<0.1)	5 (<0.1)		8 (<0.1)
Hypersensitivity	3 (<0.1)	2 (<0.1)		5 (<0.1)
Mycotic allergy	0	2 (<0.1)		2 (<0.1)
Allergy to animal	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Endocrine disorders	27 (0.2)	18 (0.2)		45 (0.2)
Hypothyroidism	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Hyperparathyroidism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperthyroidism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypogonadism	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Thyroid mass	0	1 (<0.1)		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Basedow's disease	1 (<0.1)	0		1 (<0.1)
Goitre	3 (<0.1)	0		3 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Thyroiditis subacute	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	152 (1.3)	117 (1.0)		269 (1.2)
Type 2 diabetes mellitus	19 (0.2)	22 (0.2)	1.16 (0.63, 2.12)	41 (0.2)
Hyperlipidaemia	28 (0.2)	21 (0.2)	0.75 (0.43, 1.31)	49 (0.2)
Vitamin D deficiency	20 (0.2)	19 (0.2)	0.95 (0.51, 1.76)	39 (0.2)
Hypercholesterolaemia	25 (0.2)	11 (<0.1)	0.44 (0.22, 0.88)	36 (0.2)
Diabetes mellitus	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Glucose tolerance impaired	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Dehydration	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Hyponatraemia	2 (<0.1)	4 (<0.1)		6 (<0.1)
Decreased appetite	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Gout	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Hyperglycaemia	4 (<0.1)	3 (<0.1)		7 (<0.1)
Diabetes mellitus inadequate control	2 (<0.1)	2 (<0.1)		4 (<0.1)
Diabetic ketoacidosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hypertriglyceridaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypokalaemia	13 (0.1)	2 (<0.1)	0.15 (0.04, 0.61)	15 (<0.1)
Iron deficiency	3 (<0.1)	2 (<0.1)		5 (<0.1)
Obesity	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abnormal loss of weight	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)		4 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypercalcaemia	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoglycaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypophosphataemia	0	1 (<0.1)		1 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Metabolism and nutrition disorders (Cont.)				
Dyslipidaemia	4 (<0.1)	0		4 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypomagnesaemia	2 (<0.1)	0		2 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Metabolic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	168 (1.5)	196 (1.7)		364 (1.6)
Depression	66 (0.6)	78 (0.7)	1.18 (0.85, 1.64)	144 (0.6)
Anxiety	57 (0.5)	69 (0.6)	1.21 (0.85, 1.71)	126 (0.6)
Attention deficit hyperactivity disorder	21 (0.2)	18 (0.2)	0.86 (0.46, 1.59)	39 (0.2)
Insomnia	16 (0.1)	18 (0.2)	1.12 (0.58, 2.18)	34 (0.1)
Bipolar disorder	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	4 (<0.1)		5 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bipolar II disorder	0	2 (<0.1)		2 (<0.1)
Generalised anxiety disorder	6 (<0.1)	2 (<0.1)		8 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Major depression	4 (<0.1)	2 (<0.1)		6 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Drug abuse	0	1 (<0.1)		1 (<0.1)
Dysphemia	0	1 (<0.1)		1 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Obsessive-compulsive personality disorder	0	1 (<0.1)		1 (<0.1)
Panic attack	4 (<0.1)	1 (<0.1)		5 (<0.1)
Persistent depressive disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Psychotic disorder	0	1 (<0.1)		1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Social anxiety disorder	0	1 (<0.1)		1 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Psychiatric disorders (Cont.)				
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Delirium	1 (<0.1)	0		1 (<0.1)
Depression suicidal	2 (<0.1)	0		2 (<0.1)
Dissociative disorder	1 (<0.1)	0		1 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Mental status changes	2 (<0.1)	0		2 (<0.1)
Mixed anxiety and depressive disorder	1 (<0.1)	0		1 (<0.1)
Nicotine dependence	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	244 (2.1)	235 (2.1)		479 (2.1)
Headache	123 (1.1)	105 (0.9)	0.85 (0.66, 1.10)	228 (1.0)
Migraine	17 (0.1)	15 (0.1)	0.88 (0.45, 1.74)	32 (0.1)
Dizziness	12 (0.1)	13 (0.1)	1.08 (0.50, 2.33)	25 (0.1)
Paraesthesia	11 (<0.1)	12 (0.1)	1.09 (0.49, 2.42)	23 (0.1)
Syncope	14 (0.1)	12 (0.1)	0.86 (0.40, 1.82)	26 (0.1)
Sciatica	12 (0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (0.1)
Ageusia	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Anosmia	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Cervical radiculopathy	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.59)	8 (<0.1)
Nerve compression	3 (<0.1)	6 (<0.1)		9 (<0.1)
Hypoaesthesia	3 (<0.1)	5 (<0.1)		8 (<0.1)
Carpal tunnel syndrome	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cerebrovascular accident	1 (<0.1)	4 (<0.1)		5 (<0.1)
Facial paralysis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Seizure	6 (<0.1)	4 (<0.1)		10 (<0.1)
Presyncope	3 (<0.1)	3 (<0.1)		6 (<0.1)
Lumbar radiculopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Memory impairment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Restless legs syndrome	4 (<0.1)	2 (<0.1)		6 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Aphasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Burning sensation	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Central nervous system lesion	0	1 (<0.1)		1 (<0.1)
Cerebral atrophy	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Complex regional pain syndrome	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Depressed level of consciousness	0	1 (<0.1)		1 (<0.1)
Head discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Hypersomnia	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Morton's neuralgia	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle contractions involuntary	0	1 (<0.1)		1 (<0.1)
Neuralgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Occipital neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Tension headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Transient ischaemic attack	4 (<0.1)	1 (<0.1)		5 (<0.1)
Trigeminal neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Arachnoid cyst	2 (<0.1)	0		2 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Cerebral cyst	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	3 (<0.1)	0		3 (<0.1)
Essential tremor	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Hypogeusia	1 (<0.1)	0		1 (<0.1)
Hyposmia	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0		1 (<0.1)
Migraine with aura	1 (<0.1)	0		1 (<0.1)
Neuropathy peripheral	3 (<0.1)	0		3 (<0.1)
Perineurial cyst	1 (<0.1)	0		1 (<0.1)
Peripheral sensory neuropathy	2 (<0.1)	0		2 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Nervous system disorders (Cont.)				
Poor quality sleep	1 (<0.1)	0		1 (<0.1)
Radicular pain	1 (<0.1)	0		1 (<0.1)
Right hemisphere deficit syndrome	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Sinus headache	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0		1 (<0.1)
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
Tremor	1 (<0.1)	0		1 (<0.1)
VIth nerve paralysis	1 (<0.1)	0		1 (<0.1)
Vocal cord paralysis	1 (<0.1)	0		1 (<0.1)
Eye disorders	30 (0.3)	38 (0.3)		68 (0.3)
Retinal detachment	1 (<0.1)	5 (<0.1)		6 (<0.1)
Cataract	2 (<0.1)	4 (<0.1)		6 (<0.1)
Dry eye	2 (<0.1)	4 (<0.1)		6 (<0.1)
Eye haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye irritation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye pruritus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Uveitis	0	2 (<0.1)		2 (<0.1)
Vision blurred	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Blepharitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Conjunctival haemorrhage	0	1 (<0.1)		1 (<0.1)
Diabetic retinopathy	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye disorder	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Orbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	0	1 (<0.1)		1 (<0.1)
Ulcerative keratitis	0	1 (<0.1)		1 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Eye inflammation	2 (<0.1)	0		2 (<0.1)
Eye pain	1 (<0.1)	0		1 (<0.1)
Eye swelling	2 (<0.1)	0		2 (<0.1)
Eye ulcer	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Eye disorders (Cont.)				
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Photophobia	2 (<0.1)	0		2 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Retinal oedema	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	4 (<0.1)	0		4 (<0.1)
Vitreous floaters	2 (<0.1)	0		2 (<0.1)
Ear and labyrinth disorders	49 (0.4)	41 (0.4)		90 (0.4)
Vertigo	9 (<0.1)	13 (0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Ear pain	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Tinnitus	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Meniere's disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Vertigo positional	2 (<0.1)	3 (<0.1)		5 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear discomfort	0	2 (<0.1)		2 (<0.1)
Cerumen impaction	3 (<0.1)	1 (<0.1)		4 (<0.1)
Deafness unilateral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ear canal erythema	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear pruritus	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Ear and labyrinth disorders (Cont.)				
Hypoacusis	0	1 (<0.1)		1 (<0.1)
Tympanic membrane perforation	4 (<0.1)	1 (<0.1)		5 (<0.1)
Diplacusis	1 (<0.1)	0		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Eustachian tube dysfunction	2 (<0.1)	0		2 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Middle ear effusion	3 (<0.1)	0		3 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	57 (0.5)	46 (0.4)		103 (0.5)
Palpitations	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Atrial fibrillation	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Myocardial infarction	5 (<0.1)	4 (<0.1)		9 (<0.1)
Tachycardia	11 (<0.1)	4 (<0.1)	0.36 (0.12, 1.08)	15 (<0.1)
Ventricular extrasystoles	3 (<0.1)	4 (<0.1)		7 (<0.1)
Angina pectoris	5 (<0.1)	3 (<0.1)		8 (<0.1)
Sinus tachycardia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Acute myocardial infarction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Atrial flutter	0	2 (<0.1)		2 (<0.1)
Cardiac failure	0	2 (<0.1)		2 (<0.1)
Cardiac failure congestive	4 (<0.1)	2 (<0.1)		6 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Cardiac failure acute	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coronary artery disease	0	1 (<0.1)		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Arrhythmia	4 (<0.1)	0		4 (<0.1)
Arteriosclerosis coronary artery	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiac disorder	1 (<0.1)	0		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Diastolic dysfunction	1 (<0.1)	0		1 (<0.1)
Extrasystoles	1 (<0.1)	0		1 (<0.1)
Mitral valve thickening	1 (<0.1)	0		1 (<0.1)
Myocardial ischaemia	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Cardiac disorders (Cont.)				
Postural orthostatic tachycardia syndrome	1 (<0.1)	0		1 (<0.1)
Sinus arrest	1 (<0.1)	0		1 (<0.1)
Sinus bradycardia	1 (<0.1)	0		1 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	0		1 (<0.1)
Vascular disorders	169 (1.5)	130 (1.1)		299 (1.3)
Hypertension	139 (1.2)	110 (1.0)	0.79 (0.62, 1.01)	249 (1.1)
Deep vein thrombosis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Haematoma	2 (<0.1)	3 (<0.1)		5 (<0.1)
Orthostatic hypotension	0	3 (<0.1)		3 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Flushing	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hot flush	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypotension	4 (<0.1)	1 (<0.1)		5 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis superficial	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Vascular disorders (Cont.)				
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Aortic dilatation	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Arteriosclerosis	2 (<0.1)	0		2 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Lymphoedema	1 (<0.1)	0		1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)
Peripheral venous disease	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Raynaud's phenomenon	1 (<0.1)	0		1 (<0.1)
Secondary hypertension	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	314 (2.8)	240 (2.1)		554 (2.4)
Cough	100 (0.9)	88 (0.8)	0.88 (0.66, 1.17)	188 (0.8)
Nasal congestion	72 (0.6)	75 (0.7)	1.04 (0.76, 1.44)	147 (0.6)
Oropharyngeal pain	88 (0.8)	62 (0.5)	0.70 (0.51, 0.97)	150 (0.7)
Rhinorrhoea	65 (0.6)	61 (0.5)	0.94 (0.66, 1.33)	126 (0.6)
Dyspnoea	32 (0.3)	33 (0.3)	1.03 (0.64, 1.67)	65 (0.3)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Asthma	22 (0.2)	12 (0.1)	0.55 (0.27, 1.09)	34 (0.1)
Sinus congestion	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Chronic obstructive pulmonary disease	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Respiratory tract congestion	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Sinus pain	1 (<0.1)	5 (<0.1)		6 (<0.1)
Pulmonary embolism	5 (<0.1)	4 (<0.1)		9 (<0.1)
Rhinitis allergic	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Sneezing	2 (<0.1)	4 (<0.1)		6 (<0.1)
Acute respiratory failure	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Upper-airway cough syndrome	4 (<0.1)	3 (<0.1)		7 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Paranasal sinus discomfort	0	2 (<0.1)		2 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sleep apnoea syndrome	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wheezing	3 (<0.1)	2 (<0.1)		5 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Choking sensation	0	1 (<0.1)		1 (<0.1)
Dyspnoea exertional	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypoxia	4 (<0.1)	1 (<0.1)		5 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nasal mucosal disorder	0	1 (<0.1)		1 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Productive cough	0	1 (<0.1)		1 (<0.1)
Pulmonary oedema	0	1 (<0.1)		1 (<0.1)
Respiratory disorder	5 (<0.1)	1 (<0.1)		6 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Throat irritation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vocal cord thickening	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Bronchial hyperreactivity	1 (<0.1)	0		1 (<0.1)
Bronchospasm	1 (<0.1)	0		1 (<0.1)
Dysphonia	2 (<0.1)	0		2 (<0.1)
Epistaxis	2 (<0.1)	0		2 (<0.1)
Laryngeal stenosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Lung cyst	1 (<0.1)	0		1 (<0.1)
Lung infiltration	2 (<0.1)	0		2 (<0.1)
Lung opacity	2 (<0.1)	0		2 (<0.1)
Nasal septum deviation	2 (<0.1)	0		2 (<0.1)
Nasal turbinate hypertrophy	1 (<0.1)	0		1 (<0.1)
Nasal ulcer	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pharyngeal erythema	4 (<0.1)	0		4 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pneumothorax	2 (<0.1)	0		2 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary granuloma	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	2 (<0.1)	0		2 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Tonsillar hypertrophy	2 (<0.1)	0		2 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	250 (2.2)	262 (2.3)		512 (2.2)
Nausea	48 (0.4)	54 (0.5)	1.12 (0.76, 1.65)	102 (0.4)
Diarrhoea	41 (0.4)	49 (0.4)	1.19 (0.79, 1.80)	90 (0.4)
Gastrooesophageal reflux disease	25 (0.2)	35 (0.3)	1.40 (0.84, 2.32)	60 (0.3)
Abdominal pain	17 (0.1)	18 (0.2)	1.06 (0.55, 2.03)	35 (0.2)
Dental caries	20 (0.2)	15 (0.1)	0.75 (0.39, 1.45)	35 (0.2)
Vomiting	14 (0.1)	14 (0.1)	1.00 (0.48, 2.06)	28 (0.1)
Constipation	8 (<0.1)	12 (0.1)	1.50 (0.63, 3.57)	20 (<0.1)
Toothache	22 (0.2)	12 (0.1)	0.55 (0.27, 1.09)	34 (0.1)
Abdominal pain upper	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Abdominal pain lower	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Dyspepsia	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Irritable bowel syndrome	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Large intestine polyp	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Hiatus hernia	2 (<0.1)	6 (<0.1)		8 (<0.1)
Tooth impacted	6 (<0.1)	5 (<0.1)		11 (<0.1)
Gastritis	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Colitis	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Gastric ulcer	5 (<0.1)	3 (<0.1)		8 (<0.1)
Haematochezia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Inguinal hernia	0	3 (<0.1)		3 (<0.1)
Rectal haemorrhage	1 (<0.1)	3 (<0.1)		4 (<0.1)
Umbilical hernia	0	3 (<0.1)		3 (<0.1)
Abdominal discomfort	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Diverticulum	1 (<0.1)	2 (<0.1)		3 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Food poisoning	5 (<0.1)	2 (<0.1)		7 (<0.1)
Gastrointestinal pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Haemorrhoids	0	2 (<0.1)		2 (<0.1)
Lip swelling	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oesophageal ulcer	0	2 (<0.1)		2 (<0.1)
Pancreatitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Periodontal disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Small intestinal obstruction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Barrett's oesophagus	0	1 (<0.1)		1 (<0.1)
Chronic gastritis	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gingival pain	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mouth ulceration	3 (<0.1)	1 (<0.1)		4 (<0.1)
Noninfective gingivitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Peptic ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Proctalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal fissure	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Stomatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Tongue disorder	0	1 (<0.1)		1 (<0.1)
Tongue ulceration	0	1 (<0.1)		1 (<0.1)
Abdominal rigidity	1 (<0.1)	0		1 (<0.1)
Anal fistula	1 (<0.1)	0		1 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Ascites	2 (<0.1)	0		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	0		1 (<0.1)
Dry mouth	1 (<0.1)	0		1 (<0.1)
Dysphagia	3 (<0.1)	0		3 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Gastrointestinal disorders (Cont.)				
Gingival recession	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Intussusception	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Paraesthesia oral	1 (<0.1)	0		1 (<0.1)
Terminal ileitis	1 (<0.1)	0		1 (<0.1)
Uvulitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	15 (0.1)	16 (0.1)		31 (0.1)
Cholelithiasis	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Cholecystitis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	1 (<0.1)	0		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Hepatic cyst	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders	132 (1.2)	119 (1.0)		251 (1.1)
Urticaria	14 (0.1)	17 (0.1)	1.21 (0.61, 2.43)	31 (0.1)
Dermatitis contact	17 (0.1)	15 (0.1)	0.88 (0.45, 1.74)	32 (0.1)
Eczema	4 (<0.1)	10 (<0.1)	2.50 (0.83, 7.53)	14 (<0.1)
Acne	16 (0.1)	9 (<0.1)	0.56 (0.25, 1.25)	25 (0.1)
Rash	18 (0.2)	8 (<0.1)	0.44 (0.20, 1.00)	26 (0.1)
Pruritus	6 (<0.1)	6 (<0.1)		12 (<0.1)
Rosacea	2 (<0.1)	5 (<0.1)		7 (<0.1)
Psoriasis	0	4 (<0.1)		4 (<0.1)
Actinic keratosis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermatitis	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Dermatitis allergic	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hyperhidrosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin ulcer	0	3 (<0.1)		3 (<0.1)
Dermal cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Dermatitis atopic	4 (<0.1)	2 (<0.1)		6 (<0.1)
Diabetic foot	0	2 (<0.1)		2 (<0.1)
Dry skin	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eczema nummular	0	2 (<0.1)		2 (<0.1)
Hidradenitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Rash maculo-papular	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Skin lesion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alopecia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blister	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood blister	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hand dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ingrowing nail	0	1 (<0.1)		1 (<0.1)
Neurodermatitis	0	1 (<0.1)		1 (<0.1)
Papule	0	1 (<0.1)		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Rash erythematous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash macular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	0	1 (<0.1)		1 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Angioedema	2 (<0.1)	0		2 (<0.1)
Decubitus ulcer	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ecchymosis	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	2 (<0.1)	0		2 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Night sweats	2 (<0.1)	0		2 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash pruritic	5 (<0.1)	0		5 (<0.1)
Skin fissures	1 (<0.1)	0		1 (<0.1)
Skin wrinkling	1 (<0.1)	0		1 (<0.1)
Solar lentigo	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	315 (2.8)	319 (2.8)		634 (2.8)
Arthralgia	44 (0.4)	49 (0.4)	1.11 (0.74, 1.67)	93 (0.4)
Back pain	53 (0.5)	42 (0.4)	0.79 (0.53, 1.18)	95 (0.4)
Myalgia	53 (0.5)	41 (0.4)	0.77 (0.52, 1.16)	94 (0.4)
Osteoarthritis	24 (0.2)	25 (0.2)	1.04 (0.60, 1.81)	49 (0.2)
Musculoskeletal pain	14 (0.1)	22 (0.2)	1.57 (0.81, 3.03)	36 (0.2)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Neck pain	11 (<0.1)	20 (0.2)	1.82 (0.89, 3.73)	31 (0.1)
Intervertebral disc protrusion	7 (<0.1)	17 (0.1)	2.43 (1.03, 5.70)	24 (0.1)
Muscle spasms	16 (0.1)	17 (0.1)	1.06 (0.54, 2.07)	33 (0.1)
Pain in extremity	18 (0.2)	13 (0.1)	0.72 (0.36, 1.45)	31 (0.1)
Rotator cuff syndrome	12 (0.1)	13 (0.1)	1.08 (0.50, 2.33)	25 (0.1)
Tendonitis	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Musculoskeletal chest pain	6 (<0.1)	6 (<0.1)		12 (<0.1)
Arthritis	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Bursitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Spinal osteoarthritis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Trigger finger	3 (<0.1)	4 (<0.1)		7 (<0.1)
Muscle tightness	0	3 (<0.1)		3 (<0.1)
Musculoskeletal stiffness	0	3 (<0.1)		3 (<0.1)
Periarthritis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Plantar fasciitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Spinal pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Exostosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Flank pain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Intervertebral disc degeneration	4 (<0.1)	2 (<0.1)		6 (<0.1)
Joint range of motion decreased	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Joint swelling	1 (<0.1)	2 (<0.1)		3 (<0.1)
Limb mass	0	2 (<0.1)		2 (<0.1)
Muscular weakness	1 (<0.1)	2 (<0.1)		3 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Osteopenia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Osteoporosis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Rheumatoid arthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Compartment syndrome	0	1 (<0.1)		1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Foot deformity	4 (<0.1)	1 (<0.1)		5 (<0.1)
Groin pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Joint stiffness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ligament pain	0	1 (<0.1)		1 (<0.1)
Medial tibial stress syndrome	0	1 (<0.1)		1 (<0.1)
Muscle twitching	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Musculoskeletal discomfort	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteonecrosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pain in jaw	1 (<0.1)	1 (<0.1)		2 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Synovial cyst	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tenosynovitis	0	1 (<0.1)		1 (<0.1)
Trismus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Axillary mass	2 (<0.1)	0		2 (<0.1)
Costochondritis	4 (<0.1)	0		4 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Spinal stenosis	2 (<0.1)	0		2 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Tendon disorder	1 (<0.1)	0		1 (<0.1)
Tenosynovitis stenosans	1 (<0.1)	0		1 (<0.1)
Torticollis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	38 (0.3)	33 (0.3)		71 (0.3)
Nephrolithiasis	20 (0.2)	12 (0.1)	0.60 (0.30, 1.21)	32 (0.1)
Acute kidney injury	4 (<0.1)	4 (<0.1)		8 (<0.1)
Dysuria	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypertonic bladder	0	3 (<0.1)		3 (<0.1)
Chronic kidney disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Haematuria	6 (<0.1)	2 (<0.1)		8 (<0.1)
Hydronephrosis	0	2 (<0.1)		2 (<0.1)
Urinary retention	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Renal and urinary disorders (Cont.)				
Calculus bladder	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Polyuria	0	1 (<0.1)		1 (<0.1)
Renal disorder	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary incontinence	0	1 (<0.1)		1 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Chromaturia	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal cyst	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	3 (<0.1)	3 (<0.1)		6 (<0.1)
Abortion spontaneous	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)		1 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders	73 (0.6)	65 (0.6)		138 (0.6)
Prostatitis	3 (<0.1)	6 (<0.1)		9 (<0.1)
Pelvic pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Benign prostatic hyperplasia	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Erectile dysfunction	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Ovarian cyst	6 (<0.1)	4 (<0.1)		10 (<0.1)
Breast cyst	1 (<0.1)	3 (<0.1)		4 (<0.1)
Menopausal symptoms	1 (<0.1)	3 (<0.1)		4 (<0.1)
Menorrhagia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Breast pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Breast ulceration	0	2 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dysmenorrhoea	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rectocele	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Uterine polyp	3 (<0.1)	2 (<0.1)		5 (<0.1)
Vaginal haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Adnexa uteri pain	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Artificial menopause	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast hyperplasia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Breast mass	4 (<0.1)	1 (<0.1)		5 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical polyp	0	1 (<0.1)		1 (<0.1)
Cystocele	1 (<0.1)	1 (<0.1)		2 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibrocystic breast disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Postmenopausal haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Prostatomegaly	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vaginal cyst	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vaginal prolapse	0	1 (<0.1)		1 (<0.1)
Vulva cyst	0	1 (<0.1)		1 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	3 (<0.1)	0		3 (<0.1)
Dyspareunia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Reproductive system and breast disorders (Cont.)				
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Endometriosis	2 (<0.1)	0		2 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Peyronie's disease	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	2 (<0.1)	0		2 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Testicular pain	2 (<0.1)	0		2 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	5 (<0.1)	5 (<0.1)		10 (<0.1)
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Preauricular cyst	0	1 (<0.1)		1 (<0.1)
Von Willebrand's disease	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
Type IIa hyperlipidaemia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions	185 (1.6)	205 (1.8)		390 (1.7)
Fatigue	89 (0.8)	79 (0.7)	0.89 (0.66, 1.20)	168 (0.7)
Pain	39 (0.3)	30 (0.3)	0.77 (0.48, 1.23)	69 (0.3)
Chills	27 (0.2)	22 (0.2)	0.81 (0.47, 1.42)	49 (0.2)
Pyrexia	27 (0.2)	21 (0.2)	0.78 (0.44, 1.36)	48 (0.2)
Injection site pain	4 (<0.1)	13 (0.1)	3.25 (1.12, 9.46)	17 (<0.1)
Non-cardiac chest pain	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.63)	17 (<0.1)
Chest pain	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Injection site erythema	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.59)	8 (<0.1)
Injection site induration	0	7 (<0.1)		7 (<0.1)
Injection site lymphadenopathy	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Injection site swelling	0	6 (<0.1)		6 (<0.1)
Peripheral swelling	3 (<0.1)	6 (<0.1)		9 (<0.1)
Chest discomfort	10 (<0.1)	5 (<0.1)	0.50 (0.18, 1.40)	15 (<0.1)
Injection site rash	0	5 (<0.1)		5 (<0.1)
Swelling face	1 (<0.1)	4 (<0.1)		5 (<0.1)
Influenza like illness	3 (<0.1)	3 (<0.1)		6 (<0.1)
Injection site macule	0	3 (<0.1)		3 (<0.1)
Injection site pruritus	0	3 (<0.1)		3 (<0.1)
Injury associated with device	0	3 (<0.1)		3 (<0.1)
Oedema peripheral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Reactogenicity event	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Adverse drug reaction	0	2 (<0.1)		2 (<0.1)
Asthenia	4 (<0.1)	2 (<0.1)		6 (<0.1)
Axillary pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site papule	0	2 (<0.1)		2 (<0.1)
Malaise	2 (<0.1)	2 (<0.1)		4 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Early satiety	0	1 (<0.1)		1 (<0.1)
Feeling hot	1 (<0.1)	1 (<0.1)		2 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)
Mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vaccination site pain	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Capsular contracture associated with breast implant	1 (<0.1)	0		1 (<0.1)
Death	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
General disorders and administration site conditions (Cont.)				
Facial pain	1 (<0.1)	0		1 (<0.1)
Feeling abnormal	2 (<0.1)	0		2 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Hangover	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Inflammation	1 (<0.1)	0		1 (<0.1)
Injection site bruising	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Precancerous condition	1 (<0.1)	0		1 (<0.1)
Swelling	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)
Vaccination site lymphadenopathy	3 (<0.1)	0		3 (<0.1)
Investigations	60 (0.5)	61 (0.5)		121 (0.5)
Blood pressure increased	12 (0.1)	7 (<0.1)	0.58 (0.24, 1.44)	19 (<0.1)
Hepatic enzyme increased	3 (<0.1)	6 (<0.1)		9 (<0.1)
Blood cholesterol increased	5 (<0.1)	5 (<0.1)		10 (<0.1)
Prostatic specific antigen increased	0	3 (<0.1)		3 (<0.1)
Transaminases increased	1 (<0.1)	3 (<0.1)		4 (<0.1)
Blood glucose increased	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Blood potassium decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood pressure diastolic increased	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blood pressure systolic increased	5 (<0.1)	2 (<0.1)		7 (<0.1)
Electrocardiogram QT prolonged	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	4 (<0.1)	2 (<0.1)		6 (<0.1)
Weight decreased	0	2 (<0.1)		2 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Antinuclear antibody positive	0	1 (<0.1)		1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood testosterone decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
C-reactive protein increased	0	1 (<0.1)		1 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)		2 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Glycosylated haemoglobin increased	3 (<0.1)	1 (<0.1)		4 (<0.1)
Haemoglobin decreased	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Liver function test increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stool analysis abnormal	0	1 (<0.1)		1 (<0.1)
Streptococcus test negative	0	1 (<0.1)		1 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Troponin increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin D decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Blood uric acid increased	1 (<0.1)	0		1 (<0.1)
Blood urine present	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Investigations (Cont.)				
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Haematocrit increased	1 (<0.1)	0		1 (<0.1)
Heart rate increased	1 (<0.1)	0		1 (<0.1)
International normalised ratio increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
SARS-CoV-2 test positive	1 (<0.1)	0		1 (<0.1)
Viral test positive	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	2 (<0.1)	0		2 (<0.1)
Injury, poisoning and procedural complications	291 (2.6)	262 (2.3)		553 (2.4)
Ligament sprain	21 (0.2)	25 (0.2)	1.19 (0.67, 2.11)	46 (0.2)
Skin laceration	36 (0.3)	22 (0.2)	0.61 (0.36, 1.03)	58 (0.3)
Muscle strain	16 (0.1)	19 (0.2)	1.19 (0.62, 2.28)	35 (0.2)
Tooth fracture	21 (0.2)	15 (0.1)	0.71 (0.37, 1.37)	36 (0.2)
Foot fracture	11 (<0.1)	14 (0.1)	1.27 (0.59, 2.75)	25 (0.1)
Animal bite	13 (0.1)	12 (0.1)	0.92 (0.43, 1.98)	25 (0.1)
Fall	13 (0.1)	12 (0.1)	0.92 (0.43, 1.98)	25 (0.1)
Meniscus injury	11 (<0.1)	12 (0.1)	1.09 (0.49, 2.42)	23 (0.1)
Joint injury	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.59)	15 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Procedural pain	17 (0.1)	10 (<0.1)	0.59 (0.27, 1.26)	27 (0.1)
Concussion	4 (<0.1)	9 (<0.1)	2.25 (0.74, 6.88)	13 (<0.1)
Limb injury	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.12)	14 (<0.1)
Arthropod bite	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.76)	19 (<0.1)
Contusion	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Road traffic accident	3 (<0.1)	6 (<0.1)		9 (<0.1)
Facial bones fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Ligament rupture	4 (<0.1)	5 (<0.1)		9 (<0.1)
Ankle fracture	6 (<0.1)	4 (<0.1)		10 (<0.1)
Cartilage injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Corneal abrasion	5 (<0.1)	4 (<0.1)		9 (<0.1)
Head injury	0	4 (<0.1)		4 (<0.1)
Rib fracture	6 (<0.1)	4 (<0.1)		10 (<0.1)
Stress fracture	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.83)	11 (<0.1)
Upper limb fracture	0	4 (<0.1)		4 (<0.1)
Arthropod sting	3 (<0.1)	3 (<0.1)		6 (<0.1)
Back injury	4 (<0.1)	3 (<0.1)		7 (<0.1)
Clavicle fracture	0	3 (<0.1)		3 (<0.1)
Epicondylitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Joint dislocation	0	3 (<0.1)		3 (<0.1)
Muscle rupture	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Alcohol poisoning	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Dental restoration failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hand fracture	4 (<0.1)	2 (<0.1)		6 (<0.1)
Humerus fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Ligament injury	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post procedural haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post-traumatic pain	5 (<0.1)	2 (<0.1)		7 (<0.1)
Skin abrasion	6 (<0.1)	2 (<0.1)		8 (<0.1)
Wrist fracture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bone contusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns second degree	3 (<0.1)	1 (<0.1)		4 (<0.1)
Chillblains	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)		1 (<0.1)
Eyelid injury	0	1 (<0.1)		1 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)		1 (<0.1)
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)		1 (<0.1)

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Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Graft complication	0	1 (<0.1)		1 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Limb traumatic amputation	0	1 (<0.1)		1 (<0.1)
Lip injury	0	1 (<0.1)		1 (<0.1)
Lower limb fracture	0	1 (<0.1)		1 (<0.1)
Lumbar vertebral fracture	0	1 (<0.1)		1 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Neck injury	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural nausea	3 (<0.1)	1 (<0.1)		4 (<0.1)
Radius fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Scar	0	1 (<0.1)		1 (<0.1)
Skin wound	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Spinal column injury	0	1 (<0.1)		1 (<0.1)
Splinter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Superficial injury of eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tendon injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tendon rupture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Thoracic vertebral fracture	0	1 (<0.1)		1 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Traumatic haemorrhage	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound	6 (<0.1)	1 (<0.1)		7 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Fibula fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Fractured coccyx	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Hip fracture	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Injury, poisoning and procedural complications (Cont.)				
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Injection related reaction	1 (<0.1)	0		1 (<0.1)
Keratorhexis	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	1 (<0.1)	0		1 (<0.1)
Post procedural fever	1 (<0.1)	0		1 (<0.1)
Post procedural hypothyroidism	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural vomiting	1 (<0.1)	0		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Thermal burn	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Uterine perforation	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=18 and <65 Years

System Organ Class Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Social circumstances	3 (<0.1)	1 (<0.1)		4 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Postmenopause	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	0	3 (<0.1)		3 (<0.1)
Device breakage	0	1 (<0.1)		1 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1042 (27.8)	1011 (26.8)		2053 (27.3)
Number of Unsolicited Adverse Events	1908	1775		3683
Infections and infestations	392 (10.5)	305 (8.1)		697 (9.3)
Urinary tract infection	61 (1.6)	43 (1.1)	0.70 (0.48, 1.03)	104 (1.4)
Upper respiratory tract infection	24 (0.6)	36 (1.0)	1.49 (0.90, 2.48)	60 (0.8)
Sinusitis	23 (0.6)	25 (0.7)	1.08 (0.62, 1.89)	48 (0.6)
Viral infection	18 (0.5)	22 (0.6)	1.22 (0.66, 2.24)	40 (0.5)
Suspected COVID-19	17 (0.5)	17 (0.5)	1.00 (0.51, 1.92)	34 (0.5)
COVID-19	120 (3.2)	16 (0.4)	0.13 (0.08, 0.22)	136 (1.8)
Herpes zoster	4 (0.1)	15 (0.4)	3.73 (1.30, 10.70)	19 (0.3)
Tooth abscess	15 (0.4)	9 (0.2)	0.60 (0.27, 1.33)	24 (0.3)
Cellulitis	7 (0.2)	8 (0.2)	1.14 (0.43, 3.01)	15 (0.2)
Rhinovirus infection	8 (0.2)	8 (0.2)	1.00 (0.39, 2.56)	16 (0.2)
Tooth infection	11 (0.3)	8 (0.2)	0.72 (0.30, 1.75)	19 (0.3)
Pneumonia	9 (0.2)	7 (0.2)	0.77 (0.30, 2.00)	16 (0.2)
Diverticulitis	9 (0.2)	6 (0.2)	0.66 (0.25, 1.79)	15 (0.2)
Localised infection	4 (0.1)	5 (0.1)		9 (0.1)
Onychomycosis	2 (<0.1)	5 (0.1)		7 (<0.1)
Conjunctivitis	4 (0.1)	4 (0.1)		8 (0.1)
Herpes simplex	1 (<0.1)	4 (0.1)		5 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Acute sinusitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Appendicitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Cystitis	6 (0.2)	3 (<0.1)		9 (0.1)
Ear infection	4 (0.1)	3 (<0.1)		7 (<0.1)
Enterovirus infection	0	3 (<0.1)		3 (<0.1)
Gingivitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Paronychia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Postoperative wound infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abdominal abscess	0	2 (<0.1)		2 (<0.1)
Bronchitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Eye infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Fungal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gastroenteritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hordeolum	5 (0.1)	2 (<0.1)		7 (<0.1)
Laryngitis	0	2 (<0.1)		2 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis externa	4 (0.1)	2 (<0.1)		6 (<0.1)
Otitis media	1 (<0.1)	2 (<0.1)		3 (<0.1)
Periodontitis	0	2 (<0.1)		2 (<0.1)
Postoperative abscess	0	2 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Sepsis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Staphylococcal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Staphylococcal skin infection	0	2 (<0.1)		2 (<0.1)
Subcutaneous abscess	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tinea infection	0	2 (<0.1)		2 (<0.1)
Viral upper respiratory tract infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Asymptomatic COVID-19	0	1 (<0.1)		1 (<0.1)
Asymptomatic bacteriuria	0	1 (<0.1)		1 (<0.1)
Atypical mycobacterial infection	0	1 (<0.1)		1 (<0.1)
Atypical pneumonia	0	1 (<0.1)		1 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)
Colonic abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	0	1 (<0.1)		1 (<0.1)
Coronavirus infection	0	1 (<0.1)		1 (<0.1)
Epididymitis	0	1 (<0.1)		1 (<0.1)
Gastrointestinal infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Genital infection fungal	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Impetigo	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	0	1 (<0.1)		1 (<0.1)
Nasopharyngitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Otitis media acute	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Post procedural infection	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory tract infection viral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Septic shock	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sialoadenitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinusitis bacterial	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Skin infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Vaginal infection	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Viral pharyngitis	0	1 (<0.1)		1 (<0.1)
Viral sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vulvovaginal candidiasis	0	1 (<0.1)		1 (<0.1)
Vulvovaginal mycotic infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Appendicitis perforated	1 (<0.1)	0		1 (<0.1)
Balanitis candida	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Body tinea	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	7 (0.2)	0		7 (<0.1)
Candida infection	3 (<0.1)	0		3 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Ear infection fungal	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	1 (<0.1)	0		1 (<0.1)
Folliculitis	2 (<0.1)	0		2 (<0.1)
Fungal skin infection	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)
Helicobacter infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Infections and infestations (Cont.)				
Herpangina	1 (<0.1)	0		1 (<0.1)
Kidney infection	1 (<0.1)	0		1 (<0.1)
Klebsiella bacteraemia	1 (<0.1)	0		1 (<0.1)
Nail infection	1 (<0.1)	0		1 (<0.1)
Nasal vestibulitis	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pharyngitis streptococcal	3 (<0.1)	0		3 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Proteus infection	1 (<0.1)	0		1 (<0.1)
Rhinitis	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Soft tissue infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Tinea pedis	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)
Wound infection	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	58 (1.5)	52 (1.4)		110 (1.5)
Basal cell carcinoma	19 (0.5)	15 (0.4)	0.79 (0.40, 1.53)	34 (0.5)
Skin cancer	3 (<0.1)	5 (0.1)		8 (0.1)
Malignant melanoma	1 (<0.1)	4 (0.1)		5 (<0.1)
Prostate cancer	4 (0.1)	4 (0.1)		8 (0.1)
Squamous cell carcinoma of skin	4 (0.1)	4 (0.1)		8 (0.1)
Lipoma	2 (<0.1)	3 (<0.1)		5 (<0.1)
Benign hepatic neoplasm	0	2 (<0.1)		2 (<0.1)
Benign neoplasm of skin	0	2 (<0.1)		2 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	2 (<0.1)	1 (<0.1)		3 (<0.1)
Benign salivary gland neoplasm	0	1 (<0.1)		1 (<0.1)
Brain neoplasm	0	1 (<0.1)		1 (<0.1)
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Hepatocellular carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma	7 (0.2)	1 (<0.1)	0.14 (0.02, 0.89)	8 (0.1)
Benign neoplasm of bladder	1 (<0.1)	0		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	1 (<0.1)	0		1 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0		1 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	2 (<0.1)	0		2 (<0.1)
Invasive ductal breast carcinoma	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Metastases to bone	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Prostate cancer stage IV	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Seborrhoeic keratosis	1 (<0.1)	0		1 (<0.1)
Skin papilloma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	11 (0.3)	18 (0.5)		29 (0.4)
Lymphadenopathy	4 (0.1)	10 (0.3)	2.49 (0.83, 7.49)	14 (0.2)
Anaemia	3 (<0.1)	5 (0.1)		8 (0.1)
Leukocytosis	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thrombocytopenia	0	1 (<0.1)		1 (<0.1)
Lymphadenitis	1 (<0.1)	0		1 (<0.1)
Splenic calcification	1 (<0.1)	0		1 (<0.1)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)
Immune system disorders	11 (0.3)	14 (0.4)		25 (0.3)
Seasonal allergy	7 (0.2)	8 (0.2)	1.14 (0.43, 3.01)	15 (0.2)
Drug hypersensitivity	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypersensitivity	2 (<0.1)	2 (<0.1)		4 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Immune system disorders (Cont.)				
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	6 (0.2)	15 (0.4)		21 (0.3)
Hypothyroidism	1 (<0.1)	8 (0.2)	7.96 (1.29, 49.03)	9 (0.1)
Goitre	2 (<0.1)	2 (<0.1)		4 (<0.1)
Thyroid mass	1 (<0.1)	2 (<0.1)		3 (<0.1)
Basedow's disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperparathyroidism	0	1 (<0.1)		1 (<0.1)
Thyroiditis	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	70 (1.9)	74 (2.0)		144 (1.9)
Hyperlipidaemia	16 (0.4)	14 (0.4)	0.87 (0.43, 1.76)	30 (0.4)
Type 2 diabetes mellitus	6 (0.2)	11 (0.3)	1.82 (0.70, 4.75)	17 (0.2)
Hypercholesterolaemia	5 (0.1)	10 (0.3)	1.99 (0.71, 5.56)	15 (0.2)
Gout	6 (0.2)	6 (0.2)		12 (0.2)
Vitamin D deficiency	7 (0.2)	6 (0.2)	0.85 (0.30, 2.42)	13 (0.2)
Hyponatraemia	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)
Dehydration	5 (0.1)	4 (0.1)		9 (0.1)
Diabetes mellitus	4 (0.1)	4 (0.1)		8 (0.1)
Glucose tolerance impaired	0	4 (0.1)		4 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypokalaemia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperkalaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Malnutrition	0	2 (<0.1)		2 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Diabetic ketoacidosis	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Hyperglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertriglyceridaemia	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypomagnesaemia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Vitamin B12 deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin K deficiency	0	1 (<0.1)		1 (<0.1)
Abnormal loss of weight	1 (<0.1)	0		1 (<0.1)
Decreased appetite	2 (<0.1)	0		2 (<0.1)
Fluid overload	1 (<0.1)	0		1 (<0.1)
Fluid retention	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Metabolism and nutrition disorders (Cont.)				
Hypermagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Magnesium deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	25 (0.7)	28 (0.7)		53 (0.7)
Anxiety	10 (0.3)	12 (0.3)	1.19 (0.53, 2.70)	22 (0.3)
Depression	4 (0.1)	6 (0.2)		10 (0.1)
Insomnia	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)
Attention deficit hyperactivity disorder	0	1 (<0.1)		1 (<0.1)
Bipolar disorder	0	1 (<0.1)		1 (<0.1)
Confusional state	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Mental status changes	2 (<0.1)	1 (<0.1)		3 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Adjustment disorder with depressed mood	1 (<0.1)	0		1 (<0.1)
Alcohol withdrawal syndrome	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders	78 (2.1)	84 (2.2)		162 (2.2)
Headache	19 (0.5)	27 (0.7)	1.41 (0.79, 2.52)	46 (0.6)
Sciatica	7 (0.2)	6 (0.2)	0.85 (0.30, 2.42)	13 (0.2)
Cervical radiculopathy	0	5 (0.1)		5 (<0.1)
Dizziness	13 (0.3)	5 (0.1)	0.38 (0.14, 1.03)	18 (0.2)
Paraesthesia	2 (<0.1)	4 (0.1)		6 (<0.1)
Syncope	10 (0.3)	4 (0.1)	0.40 (0.13, 1.20)	14 (0.2)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Facial paralysis	0	3 (<0.1)		3 (<0.1)
Lumbar radiculopathy	0	3 (<0.1)		3 (<0.1)
Migraine	2 (<0.1)	3 (<0.1)		5 (<0.1)
Peripheral sensory neuropathy	0	3 (<0.1)		3 (<0.1)
Amnesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Carpal tunnel syndrome	4 (0.1)	2 (<0.1)		6 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Nerve compression	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neuralgia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Piriformis syndrome	0	2 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Transient ischaemic attack	0	2 (<0.1)		2 (<0.1)
Anosmia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Seizure	0	1 (<0.1)		1 (<0.1)
Sinus headache	0	1 (<0.1)		1 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Tremor	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ageusia	3 (<0.1)	0		3 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Hypoaesthesia	2 (<0.1)	0		2 (<0.1)
Intention tremor	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)
Neuropathy peripheral	2 (<0.1)	0		2 (<0.1)
Presyncope	2 (<0.1)	0		2 (<0.1)
Restless legs syndrome	2 (<0.1)	0		2 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tension headache	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Nervous system disorders (Cont.)				
Trigeminal neuralgia	2 (<0.1)	0		2 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)
Eye disorders	40 (1.1)	42 (1.1)		82 (1.1)
Cataract	7 (0.2)	9 (0.2)	1.28 (0.49, 3.31)	16 (0.2)
Glaucoma	5 (0.1)	5 (0.1)		10 (0.1)
Dry eye	5 (0.1)	4 (0.1)		9 (0.1)
Chalazion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Eye irritation	0	2 (<0.1)		2 (<0.1)
Macular degeneration	0	2 (<0.1)		2 (<0.1)
Macular hole	1 (<0.1)	2 (<0.1)		3 (<0.1)
Retinal detachment	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blepharitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foreign body sensation in eyes	0	1 (<0.1)		1 (<0.1)
Keratitis	0	1 (<0.1)		1 (<0.1)
Lenticular opacities	0	1 (<0.1)		1 (<0.1)
Macular fibrosis	0	1 (<0.1)		1 (<0.1)
Papilloedema	0	1 (<0.1)		1 (<0.1)
Retinal haemorrhage	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Eye disorders (Cont.)				
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Retinopathy hypertensive	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Diplopia	2 (<0.1)	0		2 (<0.1)
Eye inflammation	2 (<0.1)	0		2 (<0.1)
Eyelid ptosis	2 (<0.1)	0		2 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Vision blurred	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	22 (0.6)	20 (0.5)		42 (0.6)
Vertigo	4 (0.1)	9 (0.2)	2.24 (0.73, 6.85)	13 (0.2)
Vertigo positional	1 (<0.1)	4 (0.1)		5 (<0.1)
Ear pain	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Ear and labyrinth disorders (Cont.)				
Meniere's disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cerumen impaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Middle ear effusion	0	1 (<0.1)		1 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Ear congestion	1 (<0.1)	0		1 (<0.1)
Ear discomfort	3 (<0.1)	0		3 (<0.1)
Ear pruritus	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tinnitus	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	57 (1.5)	72 (1.9)		129 (1.7)
Atrial fibrillation	20 (0.5)	18 (0.5)	0.90 (0.48, 1.67)	38 (0.5)
Coronary artery disease	8 (0.2)	7 (0.2)	0.87 (0.33, 2.31)	15 (0.2)
Ventricular extrasystoles	1 (<0.1)	6 (0.2)		7 (<0.1)
Palpitations	2 (<0.1)	5 (0.1)		7 (<0.1)
Cardiac failure congestive	5 (0.1)	4 (0.1)		9 (0.1)
Angina pectoris	4 (0.1)	3 (<0.1)		7 (<0.1)
Bradycardia	3 (<0.1)	3 (<0.1)		6 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders (Cont.)				
Sinus tachycardia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Supraventricular tachycardia	0	3 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	2 (<0.1)		2 (<0.1)
Acute myocardial infarction	4 (0.1)	2 (<0.1)		6 (<0.1)
Arrhythmia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardiac failure	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cardio-respiratory arrest	0	2 (<0.1)		2 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Myocardial infarction	3 (<0.1)	2 (<0.1)		5 (<0.1)
Tachycardia	0	2 (<0.1)		2 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial flutter	3 (<0.1)	1 (<0.1)		4 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Cardiovascular symptom	0	1 (<0.1)		1 (<0.1)
Pericarditis	0	1 (<0.1)		1 (<0.1)
Sinus bradycardia	0	1 (<0.1)		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Cardiac disorders (Cont.)				
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac failure acute	1 (<0.1)	0		1 (<0.1)
Cardiac steatosis	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Mitral valve incompetence	2 (<0.1)	0		2 (<0.1)
Tricuspid valve incompetence	2 (<0.1)	0		2 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	95 (2.5)	92 (2.4)		187 (2.5)
Hypertension	79 (2.1)	66 (1.8)	0.83 (0.60, 1.15)	145 (1.9)
Haematoma	2 (<0.1)	5 (0.1)		7 (<0.1)
Deep vein thrombosis	2 (<0.1)	4 (0.1)		6 (<0.1)
Aortic dilatation	0	2 (<0.1)		2 (<0.1)
Arteriosclerosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hot flush	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypotension	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Vascular disorders (Cont.)				
Aortic aneurysm	3 (<0.1)	1 (<0.1)		4 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive emergency	0	1 (<0.1)		1 (<0.1)
Orthostatic hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)		1 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Phlebitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)		1 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Vascular calcification	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	95 (2.5)	89 (2.4)		184 (2.4)
Cough	22 (0.6)	24 (0.6)	1.09 (0.61, 1.92)	46 (0.6)
Nasal congestion	19 (0.5)	16 (0.4)	0.84 (0.44, 1.61)	35 (0.5)
Rhinorrhoea	10 (0.3)	15 (0.4)	1.49 (0.69, 3.25)	25 (0.3)
Oropharyngeal pain	16 (0.4)	11 (0.3)	0.68 (0.32, 1.45)	27 (0.4)
Asthma	6 (0.2)	8 (0.2)	1.33 (0.48, 3.66)	14 (0.2)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dyspnoea	14 (0.4)	8 (0.2)	0.57 (0.24, 1.32)	22 (0.3)
Acute respiratory failure	7 (0.2)	4 (0.1)	0.57 (0.18, 1.82)	11 (0.1)
Chronic obstructive pulmonary disease	9 (0.2)	4 (0.1)	0.44 (0.14, 1.35)	13 (0.2)
Upper-airway cough syndrome	2 (<0.1)	4 (0.1)		6 (<0.1)
Emphysema	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pleural effusion	3 (<0.1)	3 (<0.1)		6 (<0.1)
Respiratory disorder	0	3 (<0.1)		3 (<0.1)
Respiratory tract congestion	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rhinitis allergic	5 (0.1)	3 (<0.1)		8 (0.1)
Epistaxis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Pharyngeal erythema	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pulmonary embolism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pulmonary mass	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sleep apnoea syndrome	3 (<0.1)	2 (<0.1)		5 (<0.1)
Atelectasis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bronchospasm	0	1 (<0.1)		1 (<0.1)
Dysphonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoxia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lung infiltration	0	1 (<0.1)		1 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Pneumonia aspiration	0	1 (<0.1)		1 (<0.1)
Pneumothorax	0	1 (<0.1)		1 (<0.1)
Productive cough	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pulmonary hypertension	0	1 (<0.1)		1 (<0.1)
Respiratory failure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinus pain	0	1 (<0.1)		1 (<0.1)
Sneezing	0	1 (<0.1)		1 (<0.1)
Vasomotor rhinitis	0	1 (<0.1)		1 (<0.1)
Dry throat	1 (<0.1)	0		1 (<0.1)
Dyspnoea exertional	2 (<0.1)	0		2 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)
Nasal dryness	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Pleuritic pain	1 (<0.1)	0		1 (<0.1)
Sinus congestion	1 (<0.1)	0		1 (<0.1)
Throat irritation	1 (<0.1)	0		1 (<0.1)
Wheezing	2 (<0.1)	0		2 (<0.1)
Gastrointestinal disorders	121 (3.2)	120 (3.2)		241 (3.2)
Gastrooesophageal reflux disease	12 (0.3)	16 (0.4)	1.33 (0.64, 2.76)	28 (0.4)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Nausea	17 (0.5)	15 (0.4)	0.88 (0.44, 1.73)	32 (0.4)
Diarrhoea	19 (0.5)	12 (0.3)	0.63 (0.31, 1.27)	31 (0.4)
Dental caries	9 (0.2)	8 (0.2)	0.88 (0.35, 2.22)	17 (0.2)
Inguinal hernia	5 (0.1)	8 (0.2)	1.59 (0.55, 4.62)	13 (0.2)
Toothache	5 (0.1)	8 (0.2)	1.59 (0.55, 4.62)	13 (0.2)
Abdominal pain	4 (0.1)	7 (0.2)	1.74 (0.55, 5.56)	11 (0.1)
Abdominal pain upper	3 (<0.1)	7 (0.2)	2.32 (0.66, 8.23)	10 (0.1)
Vomiting	7 (0.2)	5 (0.1)	0.71 (0.24, 2.12)	12 (0.2)
Colitis	2 (<0.1)	4 (0.1)		6 (<0.1)
Constipation	8 (0.2)	4 (0.1)	0.50 (0.16, 1.55)	12 (0.2)
Gastrointestinal haemorrhage	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hiatus hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Large intestine polyp	7 (0.2)	3 (<0.1)	0.43 (0.12, 1.51)	10 (0.1)
Barrett's oesophagus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Diverticulum intestinal	0	2 (<0.1)		2 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Dysphagia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastric ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Gastritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Gingival pain	0	2 (<0.1)		2 (<0.1)
Haemorrhoids	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Oesophagitis	0	2 (<0.1)		2 (<0.1)
Small intestinal obstruction	3 (<0.1)	2 (<0.1)		5 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Diverticulum	2 (<0.1)	1 (<0.1)		3 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Duodenitis	0	1 (<0.1)		1 (<0.1)
Faecaloma	0	1 (<0.1)		1 (<0.1)
Faeces discoloured	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Food poisoning	2 (<0.1)	1 (<0.1)		3 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Intussusception	0	1 (<0.1)		1 (<0.1)
Irritable bowel syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Melaena	0	1 (<0.1)		1 (<0.1)
Oesophageal spasm	0	1 (<0.1)		1 (<0.1)
Pancreatic cyst	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	0	1 (<0.1)		1 (<0.1)
Stomatitis	0	1 (<0.1)		1 (<0.1)
Umbilical hernia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abdominal discomfort	2 (<0.1)	0		2 (<0.1)
Abdominal hernia	1 (<0.1)	0		1 (<0.1)
Abdominal pain lower	1 (<0.1)	0		1 (<0.1)
Abdominal tenderness	1 (<0.1)	0		1 (<0.1)
Anorectal discomfort	1 (<0.1)	0		1 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)
Colitis microscopic	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Lip swelling	1 (<0.1)	0		1 (<0.1)
Mouth haemorrhage	1 (<0.1)	0		1 (<0.1)
Obstructive pancreatitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Swollen tongue	1 (<0.1)	0		1 (<0.1)
Tooth disorder	2 (<0.1)	0		2 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Gastrointestinal disorders (Cont.)				
Upper gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	2 (<0.1)	11 (0.3)		13 (0.2)
Cholelithiasis	1 (<0.1)	5 (0.1)		6 (<0.1)
Cholecystitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hepatic steatosis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)
Biliary dyskinesia	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic cyst	0	1 (<0.1)		1 (<0.1)
Hepatic haematoma	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	48 (1.3)	36 (1.0)		84 (1.1)
Rash	2 (<0.1)	5 (0.1)		7 (<0.1)
Actinic keratosis	3 (<0.1)	4 (0.1)		7 (<0.1)
Urticaria	3 (<0.1)	4 (0.1)		7 (<0.1)
Ingrowing nail	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dermatitis contact	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Precancerous skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Decubitus ulcer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermal cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis atopic	0	1 (<0.1)		1 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eczema nummular	0	1 (<0.1)		1 (<0.1)
Erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pruritus	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rash macular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rash maculo-papular	0	1 (<0.1)		1 (<0.1)
Rash pruritic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rosacea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Acne	1 (<0.1)	0		1 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ecchymosis	1 (<0.1)	0		1 (<0.1)
Eczema	3 (<0.1)	0		3 (<0.1)
Intertrigo	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Night sweats	1 (<0.1)	0		1 (<0.1)
Psoriasis	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Scab	1 (<0.1)	0		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	0		1 (<0.1)
Skin exfoliation	1 (<0.1)	0		1 (<0.1)
Skin mass	2 (<0.1)	0		2 (<0.1)
Skin ulcer	1 (<0.1)	0		1 (<0.1)
Stasis dermatitis	1 (<0.1)	0		1 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	152 (4.1)	165 (4.4)		317 (4.2)
Osteoarthritis	33 (0.9)	27 (0.7)	0.81 (0.49, 1.34)	60 (0.8)
Back pain	20 (0.5)	20 (0.5)	1.00 (0.54, 1.83)	40 (0.5)
Arthralgia	21 (0.6)	19 (0.5)	0.90 (0.49, 1.66)	40 (0.5)
Bursitis	5 (0.1)	9 (0.2)	1.79 (0.63, 5.09)	14 (0.2)
Myalgia	7 (0.2)	9 (0.2)	1.28 (0.49, 3.31)	16 (0.2)
Pain in extremity	8 (0.2)	9 (0.2)	1.12 (0.45, 2.81)	17 (0.2)
Arthritis	1 (<0.1)	7 (0.2)	6.97 (1.12, 43.39)	8 (0.1)
Musculoskeletal pain	6 (0.2)	7 (0.2)	1.16 (0.41, 3.29)	13 (0.2)
Rotator cuff syndrome	7 (0.2)	7 (0.2)	1.00 (0.36, 2.72)	14 (0.2)
Muscle spasms	9 (0.2)	5 (0.1)	0.55 (0.19, 1.57)	14 (0.2)
Neck pain	3 (<0.1)	5 (0.1)		8 (0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Joint swelling	0	4 (0.1)		4 (<0.1)
Osteoporosis	2 (<0.1)	4 (0.1)		6 (<0.1)
Periarthritis	2 (<0.1)	4 (0.1)		6 (<0.1)
Spinal osteoarthritis	3 (<0.1)	4 (0.1)		7 (<0.1)
Spinal stenosis	1 (<0.1)	4 (0.1)		5 (<0.1)
Trigger finger	2 (<0.1)	4 (0.1)		6 (<0.1)
Muscular weakness	0	3 (<0.1)		3 (<0.1)
Osteopenia	4 (0.1)	3 (<0.1)		7 (<0.1)
Spondylolisthesis	0	3 (<0.1)		3 (<0.1)
Flank pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Intervertebral disc degeneration	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tendonitis	7 (0.2)	2 (<0.1)	0.28 (0.07, 1.20)	9 (0.1)
Cervical spinal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Foot deformity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)		1 (<0.1)
Ligamentum flavum hypertrophy	0	1 (<0.1)		1 (<0.1)
Musculoskeletal chest pain	4 (0.1)	1 (<0.1)		5 (<0.1)
Musculoskeletal stiffness	0	1 (<0.1)		1 (<0.1)
Pain in jaw	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Spinal synovial cyst	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tenosynovitis stenosans	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)		1 (<0.1)
Exostosis	3 (<0.1)	0		3 (<0.1)
Groin pain	1 (<0.1)	0		1 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	0		3 (<0.1)
Kyphosis	1 (<0.1)	0		1 (<0.1)
Lumbar spinal stenosis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Plantar fasciitis	1 (<0.1)	0		1 (<0.1)
Polyarthritis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	2 (<0.1)	0		2 (<0.1)
Renal and urinary disorders	40 (1.1)	38 (1.0)		78 (1.0)
Nephrolithiasis	10 (0.3)	11 (0.3)	1.09 (0.48, 2.51)	21 (0.3)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Renal and urinary disorders (Cont.)				
Chronic kidney disease	5 (0.1)	4 (0.1)		9 (0.1)
Acute kidney injury	8 (0.2)	3 (<0.1)	0.37 (0.11, 1.30)	11 (0.1)
Haematuria	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pollakiuria	2 (<0.1)	3 (<0.1)		5 (<0.1)
Urinary retention	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypertonic bladder	3 (<0.1)	2 (<0.1)		5 (<0.1)
Renal cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Bladder prolapse	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Diabetic nephropathy	0	1 (<0.1)		1 (<0.1)
Dysuria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary hesitation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder spasm	1 (<0.1)	0		1 (<0.1)
Micturition urgency	3 (<0.1)	0		3 (<0.1)
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal impairment	2 (<0.1)	0		2 (<0.1)
Stress urinary incontinence	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Reproductive system and breast disorders	27 (0.7)	20 (0.5)		47 (0.6)
Benign prostatic hyperplasia	10 (0.3)	4 (0.1)	0.40 (0.13, 1.20)	14 (0.2)
Prostatomegaly	2 (<0.1)	4 (0.1)		6 (<0.1)
Breast cyst	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ovarian cyst	0	2 (<0.1)		2 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Atrophic vulvovaginitis	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast enlargement	0	1 (<0.1)		1 (<0.1)
Breast mass	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erectile dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Postmenopausal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Prostatic cyst	0	1 (<0.1)		1 (<0.1)
Cervical polyp	1 (<0.1)	0		1 (<0.1)
Haematospermia	1 (<0.1)	0		1 (<0.1)
Ovarian mass	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Pelvic floor muscle weakness	1 (<0.1)	0		1 (<0.1)
Pelvic prolapse	1 (<0.1)	0		1 (<0.1)
Prostatitis	3 (<0.1)	0		3 (<0.1)
Pruritus genital	1 (<0.1)	0		1 (<0.1)
Vulvovaginal dryness	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions	55 (1.5)	60 (1.6)		115 (1.5)
Fatigue	15 (0.4)	25 (0.7)	1.66 (0.89, 3.11)	40 (0.5)
Pain	6 (0.2)	10 (0.3)	1.66 (0.63, 4.39)	16 (0.2)
Chills	7 (0.2)	7 (0.2)	1.00 (0.36, 2.72)	14 (0.2)
Pyrexia	6 (0.2)	7 (0.2)	1.16 (0.41, 3.29)	13 (0.2)
Oedema peripheral	7 (0.2)	6 (0.2)	0.85 (0.30, 2.42)	13 (0.2)
Asthenia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Chest discomfort	4 (0.1)	2 (<0.1)		6 (<0.1)
Cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Injection site pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site rash	0	2 (<0.1)		2 (<0.1)
Non-cardiac chest pain	5 (0.1)	2 (<0.1)		7 (<0.1)
Precancerous condition	0	2 (<0.1)		2 (<0.1)
Dysplasia	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Influenza like illness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site macule	0	1 (<0.1)		1 (<0.1)
Injection site pruritus	0	1 (<0.1)		1 (<0.1)
Injection site reaction	0	1 (<0.1)		1 (<0.1)
Injection site swelling	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
General disorders and administration site conditions (Cont.)				
Malaise	0	1 (<0.1)		1 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Swelling	0	1 (<0.1)		1 (<0.1)
Vaccination site pain	0	1 (<0.1)		1 (<0.1)
Chest pain	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Granuloma	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site bruising	2 (<0.1)	0		2 (<0.1)
Injection site erythema	1 (<0.1)	0		1 (<0.1)
Injection site haemorrhage	1 (<0.1)	0		1 (<0.1)
Mass	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Peripheral swelling	4 (0.1)	0		4 (<0.1)
Reactogenicity event	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations	25 (0.7)	27 (0.7)		52 (0.7)
Blood cholesterol increased	3 (<0.1)	4 (0.1)		7 (<0.1)
Blood pressure systolic increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardiac murmur	1 (<0.1)	2 (<0.1)		3 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood pressure increased	5 (0.1)	1 (<0.1)		6 (<0.1)
Blood testosterone decreased	0	1 (<0.1)		1 (<0.1)
Blood triglycerides increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood urine present	0	1 (<0.1)		1 (<0.1)
C-reactive protein increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)		1 (<0.1)
Heart rate increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hepatic enzyme increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)		1 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Transaminases increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Investigations (Cont.)				
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	1 (<0.1)	0		1 (<0.1)
Liver function test abnormal	1 (<0.1)	0		1 (<0.1)
Liver function test increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Total lung capacity decreased	1 (<0.1)	0		1 (<0.1)
Weight decreased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	134 (3.6)	130 (3.4)		264 (3.5)
Fall	12 (0.3)	14 (0.4)	1.16 (0.55, 2.46)	26 (0.3)
Procedural pain	17 (0.5)	12 (0.3)	0.70 (0.34, 1.45)	29 (0.4)
Skin laceration	11 (0.3)	12 (0.3)	1.09 (0.49, 2.41)	23 (0.3)
Ligament sprain	1 (<0.1)	7 (0.2)	6.97 (1.12, 43.39)	8 (0.1)
Tooth fracture	9 (0.2)	7 (0.2)	0.77 (0.30, 2.00)	16 (0.2)
Foot fracture	7 (0.2)	6 (0.2)	0.85 (0.30, 2.42)	13 (0.2)
Meniscus injury	8 (0.2)	6 (0.2)	0.75 (0.27, 2.06)	14 (0.2)
Muscle strain	8 (0.2)	6 (0.2)	0.75 (0.27, 2.06)	14 (0.2)
Rib fracture	3 (<0.1)	6 (0.2)		9 (0.1)
Arthropod bite	5 (0.1)	5 (0.1)		10 (0.1)
Post-traumatic pain	5 (0.1)	5 (0.1)		10 (0.1)
Road traffic accident	6 (0.2)	5 (0.1)		11 (0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Limb injury	6 (0.2)	4 (0.1)		10 (0.1)
Animal bite	2 (<0.1)	3 (<0.1)		5 (<0.1)
Facial bones fracture	0	3 (<0.1)		3 (<0.1)
Hip fracture	2 (<0.1)	3 (<0.1)		5 (<0.1)
Humerus fracture	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cervical vertebral fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Clavicle fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hand fracture	0	2 (<0.1)		2 (<0.1)
Head injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Joint injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Muscle rupture	0	2 (<0.1)		2 (<0.1)
Skin abrasion	4 (0.1)	2 (<0.1)		6 (<0.1)
Spinal compression fracture	0	2 (<0.1)		2 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Wrist fracture	4 (0.1)	2 (<0.1)		6 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Bone contusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Concussion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Contusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Corneal abrasion	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Dental restoration failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dural tear	0	1 (<0.1)		1 (<0.1)
Epicondylitis	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Fractured sacrum	1 (<0.1)	1 (<0.1)		2 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Injury	0	1 (<0.1)		1 (<0.1)
Joint dislocation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Multiple fractures	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Patella fracture	0	1 (<0.1)		1 (<0.1)
Pelvic fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural fever	0	1 (<0.1)		1 (<0.1)
Procedural haemorrhage	0	1 (<0.1)		1 (<0.1)
Procedural nausea	0	1 (<0.1)		1 (<0.1)
Procedural site reaction	0	1 (<0.1)		1 (<0.1)
Skin wound	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190203.sas 21JUN2021 14:55

Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Sports injury	0	1 (<0.1)		1 (<0.1)
Stress fracture	0	1 (<0.1)		1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)		1 (<0.1)
Tendon rupture	4 (0.1)	1 (<0.1)		5 (<0.1)
Thermal burn	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Upper limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ankle fracture	4 (0.1)	0		4 (<0.1)
Arthropod sting	2 (<0.1)	0		2 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Gingival injury	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Ligament injury	1 (<0.1)	0		1 (<0.1)
Ligament rupture	1 (<0.1)	0		1 (<0.1)
Lip injury	3 (<0.1)	0		3 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Mallet finger	1 (<0.1)	0		1 (<0.1)
Multiple injuries	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.2.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Age Group, System Organ Class and Preferred Term in Overall Stage Safety Set

Age Group: >=65 Years

System Organ Class Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Injury, poisoning and procedural complications (Cont.)				
Nail injury	1 (<0.1)	0		1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Scar	1 (<0.1)	0		1 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	1 (<0.1)		4 (<0.1)
Device breakage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190203.sas 21JUN2021 14:55

Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	1902 (12.9)	1782 (12.1)		3684 (12.5)
Number of Unsolicited Adverse Events	2801	2656		5457
Infections and infestations	692 (4.7)	529 (3.6)		1221 (4.1)
Urinary tract infection	93 (0.6)	71 (0.5)	0.76 (0.56, 1.04)	164 (0.6)
Upper respiratory tract infection	72 (0.5)	49 (0.3)	0.68 (0.47, 0.98)	121 (0.4)
Sinusitis	34 (0.2)	45 (0.3)	1.32 (0.85, 2.06)	79 (0.3)
Suspected COVID-19	30 (0.2)	28 (0.2)	0.93 (0.56, 1.55)	58 (0.2)
Viral infection	32 (0.2)	24 (0.2)	0.75 (0.44, 1.26)	56 (0.2)
Tooth abscess	21 (0.1)	20 (0.1)	0.95 (0.52, 1.74)	41 (0.1)
Rhinovirus infection	19 (0.1)	19 (0.1)	1.00 (0.53, 1.87)	38 (0.1)
Tooth infection	14 (<0.1)	19 (0.1)	1.36 (0.69, 2.67)	33 (0.1)
COVID-19	134 (0.9)	16 (0.1)	0.12 (0.07, 0.20)	150 (0.5)
Herpes zoster	10 (<0.1)	16 (0.1)	1.60 (0.74, 3.46)	26 (<0.1)
Pharyngitis streptococcal	19 (0.1)	13 (<0.1)	0.68 (0.34, 1.36)	32 (0.1)
Ear infection	9 (<0.1)	12 (<0.1)	1.33 (0.58, 3.08)	21 (<0.1)
Gastroenteritis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Pharyngitis	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)	20 (<0.1)
Cellulitis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Diverticulitis	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Localised infection	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Bronchitis	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Fungal infection	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Hordeolum	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Otitis externa	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Otitis media	5 (<0.1)	6 (<0.1)		11 (<0.1)
Abscess limb	0	5 (<0.1)		5 (<0.1)
Acute sinusitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Conjunctivitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Folliculitis	4 (<0.1)	5 (<0.1)		9 (<0.1)
Herpes simplex	3 (<0.1)	5 (<0.1)		8 (<0.1)
Onychomycosis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Paronychia	4 (<0.1)	5 (<0.1)		9 (<0.1)
Pneumonia	11 (<0.1)	5 (<0.1)	0.45 (0.16, 1.25)	16 (<0.1)
Viral upper respiratory tract infection	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Bacterial vaginosis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Gingivitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Vulvovaginal candidiasis	1 (<0.1)	4 (<0.1)		5 (<0.1)
Enterovirus infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Helicobacter infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Kidney infection	1 (<0.1)	3 (<0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Lyme disease	0	3 (<0.1)		3 (<0.1)
Oral herpes	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Staphylococcal skin infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Asymptomatic COVID-19	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chlamydial infection	0	2 (<0.1)		2 (<0.1)
Chronic sinusitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	2 (<0.1)		2 (<0.1)
Coronavirus infection	0	2 (<0.1)		2 (<0.1)
Cystitis	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Impetigo	0	2 (<0.1)		2 (<0.1)
Laryngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Oral candidiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Otitis media acute	2 (<0.1)	2 (<0.1)		4 (<0.1)
Staphylococcal infection	2 (<0.1)	2 (<0.1)		4 (<0.1)
Subcutaneous abscess	0	2 (<0.1)		2 (<0.1)
Tonsillitis	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Viral pharyngitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vulvovaginal mycotic infection	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Body tinea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Candida infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cat scratch disease	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Epididymitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye infection	3 (<0.1)	1 (<0.1)		4 (<0.1)
Fungal skin infection	2 (<0.1)	1 (<0.1)		3 (<0.1)
Furuncle	0	1 (<0.1)		1 (<0.1)
Gastroenteritis viral	4 (<0.1)	1 (<0.1)		5 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Gonorrhoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	0	1 (<0.1)		1 (<0.1)
Infected cyst	0	1 (<0.1)		1 (<0.1)
Infected dermal cyst	0	1 (<0.1)		1 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Lung abscess	0	1 (<0.1)		1 (<0.1)
Nail infection	0	1 (<0.1)		1 (<0.1)
Nasopharyngitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Periodontitis	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Postoperative wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Respiratory tract infection	4 (<0.1)	1 (<0.1)		5 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Sepsis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	0	1 (<0.1)		1 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Tinea cruris	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Tuberculosis	0	1 (<0.1)		1 (<0.1)
Upper respiratory tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urinary tract infection bacterial	0	1 (<0.1)		1 (<0.1)
Urosepsis	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Wound infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Breast abscess	1 (<0.1)	0		1 (<0.1)
Breast cellulitis	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	3 (<0.1)	0		3 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Conjunctivitis bacterial	1 (<0.1)	0		1 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
Gingival abscess	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
HIV infection	1 (<0.1)	0		1 (<0.1)
Influenza	1 (<0.1)	0		1 (<0.1)
Mastoiditis	2 (<0.1)	0		2 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Pneumonia viral	1 (<0.1)	0		1 (<0.1)
Post procedural infection	1 (<0.1)	0		1 (<0.1)
Respiratory tract infection viral	5 (<0.1)	0		5 (<0.1)
Rhinitis	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Sinusitis bacterial	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	1 (<0.1)	0		1 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	1 (<0.1)	0		1 (<0.1)
Tinea pedis	2 (<0.1)	0		2 (<0.1)
Tinea versicolour	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	50 (0.3)	51 (0.3)		101 (0.3)
Basal cell carcinoma	16 (0.1)	9 (<0.1)	0.56 (0.25, 1.25)	25 (<0.1)
Benign neoplasm of skin	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Malignant melanoma	3 (<0.1)	3 (<0.1)		6 (<0.1)
Melanocytic naevus	0	3 (<0.1)		3 (<0.1)
Prostate cancer	2 (<0.1)	3 (<0.1)		5 (<0.1)
Skin cancer	3 (<0.1)	3 (<0.1)		6 (<0.1)
Squamous cell carcinoma	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Uterine leiomyoma	0	3 (<0.1)		3 (<0.1)
Benign breast neoplasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lipoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
Benign hepatic neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of thyroid gland	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Papillary thyroid cancer	0	1 (<0.1)		1 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Skin papilloma	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Squamous cell carcinoma of skin	4 (<0.1)	1 (<0.1)		5 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Haemangioma of liver	1 (<0.1)	0		1 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	0		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Renal cell carcinoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	24 (0.2)	39 (0.3)		63 (0.2)
Lymphadenopathy	15 (0.1)	24 (0.2)	1.60 (0.85, 3.01)	39 (0.1)
Anaemia	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Iron deficiency anaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	0	1 (<0.1)		1 (<0.1)
Leukocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Lymphadenitis	1 (<0.1)	0		1 (<0.1)
Normocytic anaemia	1 (<0.1)	0		1 (<0.1)
Immune system disorders	22 (0.1)	13 (<0.1)		35 (0.1)
Seasonal allergy	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Hypersensitivity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)

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Safety Set

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Immune system disorders (Cont.)				
Anaphylactic reaction	2 (<0.1)	0		2 (<0.1)
Drug hypersensitivity	2 (<0.1)	0		2 (<0.1)
Food allergy	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	11 (<0.1)	10 (<0.1)		21 (<0.1)
Hypothyroidism	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Basedow's disease	0	1 (<0.1)		1 (<0.1)
Hypogonadism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Goitre	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	77 (0.5)	83 (0.6)		160 (0.5)
Hyperlipidaemia	15 (0.1)	16 (0.1)	1.07 (0.53, 2.13)	31 (0.1)
Type 2 diabetes mellitus	7 (<0.1)	15 (0.1)	2.14 (0.90, 5.11)	22 (<0.1)
Vitamin D deficiency	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Hypercholesterolaemia	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)

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Metabolism and nutrition disorders (Cont.)				
Dehydration	5 (<0.1)	6 (<0.1)		11 (<0.1)
Diabetes mellitus	5 (<0.1)	5 (<0.1)		10 (<0.1)
Glucose tolerance impaired	6 (<0.1)	5 (<0.1)		11 (<0.1)
Gout	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hyponatraemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Decreased appetite	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hyperglycaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypertriglyceridaemia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abnormal loss of weight	0	1 (<0.1)		1 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Electrolyte imbalance	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hyperkalaemia	0	1 (<0.1)		1 (<0.1)
Hypocalcaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypokalaemia	4 (<0.1)	1 (<0.1)		5 (<0.1)
Insulin resistance	0	1 (<0.1)		1 (<0.1)
Iron deficiency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Magnesium deficiency	0	1 (<0.1)		1 (<0.1)
Obesity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Calcium deficiency	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Dyslipidaemia	3 (<0.1)	0		3 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Hypoglycaemia	2 (<0.1)	0		2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	73 (0.5)	87 (0.6)		160 (0.5)
Anxiety	28 (0.2)	36 (0.2)	1.28 (0.79, 2.09)	64 (0.2)
Depression	20 (0.1)	28 (0.2)	1.40 (0.79, 2.46)	48 (0.2)
Insomnia	6 (<0.1)	6 (<0.1)		12 (<0.1)
Attention deficit hyperactivity disorder	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Bipolar disorder	5 (<0.1)	3 (<0.1)		8 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	2 (<0.1)		4 (<0.1)
Major depression	2 (<0.1)	2 (<0.1)		4 (<0.1)
Post-traumatic stress disorder	0	2 (<0.1)		2 (<0.1)
Alcohol withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	0	1 (<0.1)		1 (<0.1)
Bipolar II disorder	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders (Cont.)				
Completed suicide	0	1 (<0.1)		1 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Panic attack	2 (<0.1)	1 (<0.1)		3 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Suicidal ideation	0	1 (<0.1)		1 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Generalised anxiety disorder	4 (<0.1)	0		4 (<0.1)
Mental status changes	3 (<0.1)	0		3 (<0.1)
Persistent depressive disorder	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	136 (0.9)	153 (1.0)		289 (1.0)
Headache	67 (0.5)	68 (0.5)	1.01 (0.73, 1.42)	135 (0.5)
Paraesthesia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Dizziness	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.78)	17 (<0.1)
Migraine	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Syncope	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Anosmia	3 (<0.1)	5 (<0.1)		8 (<0.1)

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Nervous system disorders (Cont.)				
Ageusia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Cervical radiculopathy	0	4 (<0.1)		4 (<0.1)
Carpal tunnel syndrome	4 (<0.1)	3 (<0.1)		7 (<0.1)
Cerebrovascular accident	0	3 (<0.1)		3 (<0.1)
Sciatica	6 (<0.1)	3 (<0.1)		9 (<0.1)
Seizure	1 (<0.1)	3 (<0.1)		4 (<0.1)
Subarachnoid haemorrhage	0	3 (<0.1)		3 (<0.1)
Facial paralysis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoaesthesia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Nerve compression	1 (<0.1)	2 (<0.1)		3 (<0.1)
Neuralgia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Peripheral sensory neuropathy	0	2 (<0.1)		2 (<0.1)
Presyncope	5 (<0.1)	2 (<0.1)		7 (<0.1)
Transient ischaemic attack	2 (<0.1)	2 (<0.1)		4 (<0.1)
Amnesia	0	1 (<0.1)		1 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	0	1 (<0.1)		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cubital tunnel syndrome	0	1 (<0.1)		1 (<0.1)

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Nervous system disorders (Cont.)				
Embolic stroke	0	1 (<0.1)		1 (<0.1)
Head discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Hyposmia	0	1 (<0.1)		1 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar radiculopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Memory impairment	0	1 (<0.1)		1 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Piriformis syndrome	0	1 (<0.1)		1 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Restless legs syndrome	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinus headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Tension headache	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Nervous system disorders (Cont.)				
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Neuropathy peripheral	1 (<0.1)	0		1 (<0.1)
Occipital neuralgia	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Tremor	1 (<0.1)	0		1 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	30 (0.2)	25 (0.2)		55 (0.2)
Dry eye	3 (<0.1)	3 (<0.1)		6 (<0.1)
Eye irritation	0	3 (<0.1)		3 (<0.1)
Glaucoma	2 (<0.1)	3 (<0.1)		5 (<0.1)
Retinal detachment	2 (<0.1)	3 (<0.1)		5 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)

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Eye disorders (Cont.)				
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Cataract	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chalazion	0	1 (<0.1)		1 (<0.1)
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye pruritus	0	1 (<0.1)		1 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	1 (<0.1)	1 (<0.1)		2 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blepharitis	4 (<0.1)	0		4 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctival haemorrhage	1 (<0.1)	0		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Eye swelling	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Macular degeneration	1 (<0.1)	0		1 (<0.1)
Macular hole	1 (<0.1)	0		1 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	0		1 (<0.1)
Vision blurred	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	34 (0.2)	31 (0.2)		65 (0.2)
Vertigo	3 (<0.1)	9 (<0.1)	3.00 (0.88, 10.24)	12 (<0.1)
Ear pain	6 (<0.1)	6 (<0.1)		12 (<0.1)
Vertigo positional	1 (<0.1)	6 (<0.1)		7 (<0.1)
Cerumen impaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Tinnitus	5 (<0.1)	2 (<0.1)		7 (<0.1)
Deafness unilateral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ear canal erythema	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniere's disease	0	1 (<0.1)		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Ear and labyrinth disorders (Cont.)				
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Ear congestion	2 (<0.1)	0		2 (<0.1)
Ear pruritus	2 (<0.1)	0		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	0		1 (<0.1)
Excessive cerumen production	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	0		2 (<0.1)
Cardiac disorders	37 (0.3)	47 (0.3)		84 (0.3)
Atrial fibrillation	10 (<0.1)	12 (<0.1)	1.20 (0.53, 2.71)	22 (<0.1)
Palpitations	1 (<0.1)	6 (<0.1)		7 (<0.1)
Angina pectoris	3 (<0.1)	3 (<0.1)		6 (<0.1)
Cardiac failure congestive	4 (<0.1)	3 (<0.1)		7 (<0.1)
Coronary artery disease	3 (<0.1)	3 (<0.1)		6 (<0.1)
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Sinus tachycardia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Tachycardia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Acute myocardial infarction	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arrhythmia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Acute left ventricular failure	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	0	1 (<0.1)		1 (<0.1)
Atrial enlargement	0	1 (<0.1)		1 (<0.1)
Atrial flutter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bradycardia	0	1 (<0.1)		1 (<0.1)
Cardiac failure	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ventricular extrasystoles	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atrial tachycardia	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	1 (<0.1)	0		1 (<0.1)
Left ventricular hypertrophy	1 (<0.1)	0		1 (<0.1)
Pericardial effusion	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	114 (0.8)	98 (0.7)		212 (0.7)
Hypertension	94 (0.6)	83 (0.6)	0.88 (0.66, 1.18)	177 (0.6)
Hypertensive urgency	2 (<0.1)	3 (<0.1)		5 (<0.1)
Haematoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hot flush	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Vascular disorders (Cont.)				
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arteriosclerosis	0	1 (<0.1)		1 (<0.1)
Essential hypertension	0	1 (<0.1)		1 (<0.1)
Flushing	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypotension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)
Varicose vein	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	3 (<0.1)	0		3 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	2 (<0.1)	0		2 (<0.1)
Orthostatic hypotension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	189 (1.3)	151 (1.0)		340 (1.2)
Cough	60 (0.4)	55 (0.4)	0.92 (0.64, 1.32)	115 (0.4)
Nasal congestion	43 (0.3)	42 (0.3)	0.98 (0.64, 1.49)	85 (0.3)
Rhinorrhoea	38 (0.3)	34 (0.2)	0.89 (0.57, 1.41)	72 (0.2)
Oropharyngeal pain	48 (0.3)	26 (0.2)	0.54 (0.34, 0.87)	74 (0.3)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Dyspnoea	18 (0.1)	14 (<0.1)	0.78 (0.39, 1.54)	32 (0.1)
Asthma	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Respiratory tract congestion	4 (<0.1)	6 (<0.1)		10 (<0.1)
Chronic obstructive pulmonary disease	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Sinus congestion	6 (<0.1)	4 (<0.1)		10 (<0.1)
Pulmonary embolism	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rhinitis allergic	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Acute respiratory failure	2 (<0.1)	2 (<0.1)		4 (<0.1)
Atelectasis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchiectasis	0	2 (<0.1)		2 (<0.1)
Pleural effusion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory failure	0	2 (<0.1)		2 (<0.1)
Sinus pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Sneezing	1 (<0.1)	2 (<0.1)		3 (<0.1)
Upper-airway cough syndrome	3 (<0.1)	2 (<0.1)		5 (<0.1)
Wheezing	3 (<0.1)	2 (<0.1)		5 (<0.1)
Dysphonia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dyspnoea exertional	0	1 (<0.1)		1 (<0.1)
Emphysema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Epistaxis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal septum deviation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Paranasal sinus discomfort	0	1 (<0.1)		1 (<0.1)
Pharyngeal erythema	3 (<0.1)	1 (<0.1)		4 (<0.1)
Pleuritic pain	4 (<0.1)	1 (<0.1)		5 (<0.1)
Productive cough	0	1 (<0.1)		1 (<0.1)
Respiratory disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Throat irritation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Dry throat	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pneumonia aspiration	1 (<0.1)	0		1 (<0.1)

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Respiratory, thoracic and mediastinal disorders (Cont.)				
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Pulmonary mass	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	166 (1.1)	179 (1.2)		345 (1.2)
Nausea	33 (0.2)	34 (0.2)	1.03 (0.64, 1.65)	67 (0.2)
Diarrhoea	32 (0.2)	33 (0.2)	1.03 (0.64, 1.67)	65 (0.2)
Gastrooesophageal reflux disease	15 (0.1)	20 (0.1)	1.33 (0.69, 2.57)	35 (0.1)
Dental caries	10 (<0.1)	13 (<0.1)	1.30 (0.58, 2.90)	23 (<0.1)
Vomiting	8 (<0.1)	13 (<0.1)	1.62 (0.69, 3.82)	21 (<0.1)
Toothache	13 (<0.1)	12 (<0.1)	0.92 (0.43, 1.98)	25 (<0.1)
Abdominal pain	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Constipation	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Abdominal pain upper	4 (<0.1)	6 (<0.1)		10 (<0.1)
Abdominal pain lower	5 (<0.1)	5 (<0.1)		10 (<0.1)
Colitis	3 (<0.1)	4 (<0.1)		7 (<0.1)
Inguinal hernia	3 (<0.1)	4 (<0.1)		7 (<0.1)
Haematochezia	0	3 (<0.1)		3 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Hiatus hernia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Irritable bowel syndrome	2 (<0.1)	3 (<0.1)		5 (<0.1)
Large intestine polyp	4 (<0.1)	3 (<0.1)		7 (<0.1)
Tooth impacted	1 (<0.1)	3 (<0.1)		4 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Dyspepsia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Food poisoning	3 (<0.1)	2 (<0.1)		5 (<0.1)
Gastric ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Haemorrhoids	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rectal haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Umbilical hernia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal discomfort	3 (<0.1)	1 (<0.1)		4 (<0.1)
Abdominal distension	0	1 (<0.1)		1 (<0.1)
Abdominal hernia	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dysphagia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	0	1 (<0.1)		1 (<0.1)
Flatulence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gingival pain	0	1 (<0.1)		1 (<0.1)

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Gastrointestinal disorders (Cont.)				
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Hypoaesthesia oral	0	1 (<0.1)		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intestinal obstruction	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mouth ulceration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophagitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	0	1 (<0.1)		1 (<0.1)
Periodontal disease	0	1 (<0.1)		1 (<0.1)
Proctalgia	0	1 (<0.1)		1 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Stomatitis	0	1 (<0.1)		1 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Aphthous ulcer	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190301.sas 21JUN2021 14:56

Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Ascites	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Diverticulum	1 (<0.1)	0		1 (<0.1)
Diverticulum intestinal	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastritis	4 (<0.1)	0		4 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Lip swelling	2 (<0.1)	0		2 (<0.1)
Noninfective gingivitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	3 (<0.1)	12 (<0.1)		15 (<0.1)
Cholelithiasis	2 (<0.1)	6 (<0.1)		8 (<0.1)
Cholecystitis	0	2 (<0.1)		2 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Biliary colic	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Hepatobiliary disorders (Cont.)				
Cholecystitis acute	0	1 (<0.1)		1 (<0.1)
Hepatic steatosis	0	1 (<0.1)		1 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	87 (0.6)	86 (0.6)		173 (0.6)
Urticaria	9 (<0.1)	14 (<0.1)	1.55 (0.69, 3.51)	23 (<0.1)
Dermatitis contact	12 (<0.1)	11 (<0.1)	0.92 (0.41, 2.03)	23 (<0.1)
Rash	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.76)	19 (<0.1)
Acne	4 (<0.1)	5 (<0.1)		9 (<0.1)
Actinic keratosis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Pruritus	6 (<0.1)	5 (<0.1)		11 (<0.1)
Dermatitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Eczema	0	3 (<0.1)		3 (<0.1)
Rosacea	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermatitis atopic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hidradenitis	0	2 (<0.1)		2 (<0.1)
Hyperhidrosis	0	2 (<0.1)		2 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Neurodermatitis	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Psoriasis	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash maculo-papular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Skin ulcer	0	2 (<0.1)		2 (<0.1)
Alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Blister	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Dermal cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dermatitis allergic	2 (<0.1)	1 (<0.1)		3 (<0.1)
Dry skin	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erythema	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hand dermatitis	0	1 (<0.1)		1 (<0.1)
Ingrowing nail	0	1 (<0.1)		1 (<0.1)
Precancerous skin lesion	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rash pruritic	4 (<0.1)	1 (<0.1)		5 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Angioedema	3 (<0.1)	0		3 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ecchymosis	2 (<0.1)	0		2 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Night sweats	2 (<0.1)	0		2 (<0.1)
Perioral dermatitis	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin lesion	1 (<0.1)	0		1 (<0.1)
Skin mass	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	228 (1.5)	246 (1.7)		474 (1.6)
Arthralgia	41 (0.3)	38 (0.3)	0.93 (0.60, 1.43)	79 (0.3)
Myalgia	28 (0.2)	32 (0.2)	1.14 (0.69, 1.89)	60 (0.2)
Back pain	33 (0.2)	24 (0.2)	0.73 (0.43, 1.22)	57 (0.2)
Osteoarthritis	19 (0.1)	18 (0.1)	0.95 (0.50, 1.78)	37 (0.1)
Muscle spasms	14 (<0.1)	16 (0.1)	1.14 (0.57, 2.31)	30 (0.1)
Neck pain	6 (<0.1)	16 (0.1)	2.67 (1.08, 6.60)	22 (<0.1)
Musculoskeletal pain	11 (<0.1)	15 (0.1)	1.36 (0.64, 2.91)	26 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Pain in extremity	20 (0.1)	11 (<0.1)	0.55 (0.27, 1.13)	31 (0.1)
Bursitis	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Tendonitis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Rotator cuff syndrome	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Arthritis	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Intervertebral disc protrusion	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Trigger finger	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Musculoskeletal chest pain	5 (<0.1)	5 (<0.1)		10 (<0.1)
Joint swelling	0	4 (<0.1)		4 (<0.1)
Spinal stenosis	0	4 (<0.1)		4 (<0.1)
Musculoskeletal stiffness	0	3 (<0.1)		3 (<0.1)
Osteoporosis	0	3 (<0.1)		3 (<0.1)
Joint range of motion decreased	0	2 (<0.1)		2 (<0.1)
Muscle tightness	0	2 (<0.1)		2 (<0.1)
Muscular weakness	0	2 (<0.1)		2 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Spinal osteoarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Exostosis	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Fibromyalgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Flank pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Groin pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intervertebral disc degeneration	3 (<0.1)	1 (<0.1)		4 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteopenia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Plantar fasciitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyarthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Tendon disorder	0	1 (<0.1)		1 (<0.1)
Tenosynovitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Trismus	0	1 (<0.1)		1 (<0.1)
Undifferentiated connective tissue disease	0	1 (<0.1)		1 (<0.1)

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Musculoskeletal and connective tissue disorders (Cont.)				
Axillary mass	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Costochondritis	3 (<0.1)	0		3 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Foot deformity	2 (<0.1)	0		2 (<0.1)
Joint stiffness	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Osteonecrosis	2 (<0.1)	0		2 (<0.1)
Pain in jaw	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Scoliosis	1 (<0.1)	0		1 (<0.1)
Synovial cyst	3 (<0.1)	0		3 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	0		1 (<0.1)
Torticollis	1 (<0.1)	0		1 (<0.1)
Vertebral foraminal stenosis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	33 (0.2)	32 (0.2)		65 (0.2)
Nephrolithiasis	18 (0.1)	11 (<0.1)	0.61 (0.29, 1.27)	29 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders (Cont.)				
Acute kidney injury	3 (<0.1)	2 (<0.1)		5 (<0.1)
Chronic kidney disease	0	2 (<0.1)		2 (<0.1)
Dysuria	0	2 (<0.1)		2 (<0.1)
Haematuria	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hypertonic bladder	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pollakiuria	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary hesitation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary retention	3 (<0.1)	2 (<0.1)		5 (<0.1)
Bladder spasm	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Hydronephrosis	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Renal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Urinary incontinence	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder prolapse	1 (<0.1)	0		1 (<0.1)
Micturition urgency	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders	38 (0.3)	37 (0.3)		75 (0.3)
Benign prostatic hyperplasia	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Pelvic pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Prostatitis	5 (<0.1)	3 (<0.1)		8 (<0.1)
Breast cyst	0	2 (<0.1)		2 (<0.1)
Dysmenorrhoea	0	2 (<0.1)		2 (<0.1)
Erectile dysfunction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Uterine haemorrhage	0	2 (<0.1)		2 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Breast pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical dysplasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	1 (<0.1)		3 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menopausal symptoms	0	1 (<0.1)		1 (<0.1)
Menorrhagia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Postmenopausal haemorrhage	0	1 (<0.1)		1 (<0.1)
Prostatomegaly	0	1 (<0.1)		1 (<0.1)
Rectocele	0	1 (<0.1)		1 (<0.1)
Uterine polyp	0	1 (<0.1)		1 (<0.1)
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	1 (<0.1)	0		1 (<0.1)
Cystocele	1 (<0.1)	0		1 (<0.1)
Endometriosis	1 (<0.1)	0		1 (<0.1)
Fibrocystic breast disease	1 (<0.1)	0		1 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Testicular pain	1 (<0.1)	0		1 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)
Vaginal haemorrhage	1 (<0.1)	0		1 (<0.1)
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190301.sas 21JUN2021 14:56

Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Congenital, familial and genetic disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arnold-Chiari malformation	0	2 (<0.1)		2 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	122 (0.8)	147 (1.0)		269 (0.9)
Fatigue	51 (0.3)	55 (0.4)	1.08 (0.74, 1.57)	106 (0.4)
Pain	14 (<0.1)	18 (0.1)	1.28 (0.65, 2.55)	32 (0.1)
Chills	17 (0.1)	14 (<0.1)	0.82 (0.41, 1.65)	31 (0.1)
Pyrexia	13 (<0.1)	14 (<0.1)	1.08 (0.51, 2.25)	27 (<0.1)
Injection site pain	3 (<0.1)	13 (<0.1)	4.33 (1.32, 14.16)	16 (<0.1)
Injection site erythema	1 (<0.1)	7 (<0.1)	7.00 (1.12, 43.58)	8 (<0.1)
Injection site induration	0	7 (<0.1)		7 (<0.1)
Injection site lymphadenopathy	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Injection site rash	0	6 (<0.1)		6 (<0.1)
Injection site swelling	0	6 (<0.1)		6 (<0.1)
Non-cardiac chest pain	6 (<0.1)	5 (<0.1)		11 (<0.1)
Chest pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Injection site macule	0	4 (<0.1)		4 (<0.1)
Injection site pruritus	0	4 (<0.1)		4 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Reactogenicity event	0	3 (<0.1)		3 (<0.1)
Chest discomfort	8 (<0.1)	2 (<0.1)	0.25 (0.06, 1.04)	10 (<0.1)
Cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Injection site papule	0	2 (<0.1)		2 (<0.1)
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Oedema peripheral	4 (<0.1)	2 (<0.1)		6 (<0.1)
Peripheral swelling	4 (<0.1)	2 (<0.1)		6 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Swelling face	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vaccination site pain	0	2 (<0.1)		2 (<0.1)
Axillary pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Granuloma	0	1 (<0.1)		1 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	0	1 (<0.1)		1 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)
Injury associated with device	0	1 (<0.1)		1 (<0.1)
Malaise	1 (<0.1)	1 (<0.1)		2 (<0.1)
Mass	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Asthenia	2 (<0.1)	0		2 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hangover	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Influenza like illness	3 (<0.1)	0		3 (<0.1)
Injection site bruising	3 (<0.1)	0		3 (<0.1)
Injection site haemorrhage	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Vaccination site lymphadenopathy	1 (<0.1)	0		1 (<0.1)
Investigations	35 (0.2)	42 (0.3)		77 (0.3)
Blood cholesterol increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hepatic enzyme increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Transaminases increased	0	4 (<0.1)		4 (<0.1)
Blood pressure increased	5 (<0.1)	3 (<0.1)		8 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Blood triglycerides increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Prostatic specific antigen increased	0	2 (<0.1)		2 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood glucose increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood potassium decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)		1 (<0.1)
Blood pressure systolic increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac murmur	1 (<0.1)	1 (<0.1)		2 (<0.1)
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram QT prolonged	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Heart rate irregular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hepatic enzyme abnormal	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Weight decreased	1 (<0.1)	1 (<0.1)		2 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	0		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	1 (<0.1)	0		1 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
C-reactive protein increased	1 (<0.1)	0		1 (<0.1)
Glycosylated haemoglobin increased	2 (<0.1)	0		2 (<0.1)
Heart rate increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	1 (<0.1)	0		1 (<0.1)
Vitamin D decreased	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications	223 (1.5)	189 (1.3)		412 (1.4)
Ligament sprain	7 (<0.1)	20 (0.1)	2.86 (1.24, 6.59)	27 (<0.1)
Skin laceration	28 (0.2)	20 (0.1)	0.71 (0.41, 1.26)	48 (0.2)
Muscle strain	15 (0.1)	15 (0.1)	1.00 (0.50, 2.01)	30 (0.1)
Foot fracture	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.53)	21 (<0.1)
Procedural pain	16 (0.1)	11 (<0.1)	0.69 (0.32, 1.45)	27 (<0.1)
Tooth fracture	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Fall	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Limb injury	6 (<0.1)	9 (<0.1)	1.50 (0.56, 4.04)	15 (<0.1)
Arthropod bite	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Road traffic accident	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Concussion	3 (<0.1)	5 (<0.1)		8 (<0.1)
Meniscus injury	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Rib fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Facial bones fracture	0	4 (<0.1)		4 (<0.1)
Hand fracture	3 (<0.1)	4 (<0.1)		7 (<0.1)
Joint injury	4 (<0.1)	4 (<0.1)		8 (<0.1)
Wrist fracture	4 (<0.1)	4 (<0.1)		8 (<0.1)
Animal bite	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.14)	12 (<0.1)
Arthropod sting	4 (<0.1)	3 (<0.1)		7 (<0.1)
Cartilage injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Contusion	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)

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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post-traumatic pain	4 (<0.1)	3 (<0.1)		7 (<0.1)
Upper limb fracture	0	3 (<0.1)		3 (<0.1)
Ankle fracture	4 (<0.1)	2 (<0.1)		6 (<0.1)
Cervical vertebral fracture	0	2 (<0.1)		2 (<0.1)
Craniocerebral injury	0	2 (<0.1)		2 (<0.1)
Epicondylitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ligament injury	0	2 (<0.1)		2 (<0.1)
Ligament rupture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Muscle rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tendon rupture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Back injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone contusion	2 (<0.1)	1 (<0.1)		3 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Burns second degree	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Corneal abrasion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Head injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Joint dislocation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lower limb fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	0	1 (<0.1)		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	0	1 (<0.1)		1 (<0.1)
Skin abrasion	6 (<0.1)	1 (<0.1)		7 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Stress fracture	5 (<0.1)	1 (<0.1)		6 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Tendon injury	0	1 (<0.1)		1 (<0.1)
Thermal burn	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Femur fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Foreign body in ear	1 (<0.1)	0		1 (<0.1)
Foreign body in eye	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Patella fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	2 (<0.1)	0		2 (<0.1)
Procedural nausea	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Radius fracture	3 (<0.1)	0		3 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Scar	1 (<0.1)	0		1 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Superficial injury of eye	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	1 (<0.1)	0		1 (<0.1)
Wound	1 (<0.1)	0		1 (<0.1)
Social circumstances	2 (<0.1)	1 (<0.1)		3 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)		7 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	35 (10.4)	25 (7.2)		60 (8.8)
Number of Unsolicited Adverse Events	59	41		100
Infections and infestations	11 (3.3)	13 (3.7)		24 (3.5)
COVID-19	5 (1.5)	4 (1.2)		9 (1.3)
Cystitis	0	1 (0.3)		1 (0.1)
Herpes zoster	0	1 (0.3)		1 (0.1)
Otitis externa	0	1 (0.3)		1 (0.1)
Paronychia	0	1 (0.3)		1 (0.1)
Rhinovirus infection	0	1 (0.3)		1 (0.1)
Sinusitis	1 (0.3)	1 (0.3)		2 (0.3)
Subcutaneous abscess	0	1 (0.3)		1 (0.1)
Suspected COVID-19	0	1 (0.3)		1 (0.1)
Upper respiratory tract infection	2 (0.6)	1 (0.3)		3 (0.4)
Vaginal infection	0	1 (0.3)		1 (0.1)
Cellulitis	1 (0.3)	0		1 (0.1)
Folliculitis	1 (0.3)	0		1 (0.1)
Pyelonephritis acute	1 (0.3)	0		1 (0.1)
Septic shock	1 (0.3)	0		1 (0.1)
Viral infection	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190301.sas 21JUN2021 14:56

Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Metabolism and nutrition disorders	2 (0.6)	1 (0.3)		3 (0.4)
Hyperlipidaemia	0	1 (0.3)		1 (0.1)
Type 2 diabetes mellitus	0	1 (0.3)		1 (0.1)
Vitamin D deficiency	0	1 (0.3)		1 (0.1)
Dehydration	1 (0.3)	0		1 (0.1)
Metabolic acidosis	1 (0.3)	0		1 (0.1)
Psychiatric disorders	0	2 (0.6)		2 (0.3)
Depression	0	1 (0.3)		1 (0.1)
Drug abuse	0	1 (0.3)		1 (0.1)
Nervous system disorders	4 (1.2)	2 (0.6)		6 (0.9)
Headache	3 (0.9)	1 (0.3)		4 (0.6)
Sciatica	0	1 (0.3)		1 (0.1)
Migraine	1 (0.3)	0		1 (0.1)
Eye disorders	0	1 (0.3)		1 (0.1)
Vision blurred	0	1 (0.3)		1 (0.1)
Ear and labyrinth disorders	1 (0.3)	0		1 (0.1)
Tympanic membrane perforation	1 (0.3)	0		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Cardiac disorders	1 (0.3)	1 (0.3)		2 (0.3)
Cardiac failure congestive	0	1 (0.3)		1 (0.1)
Acute left ventricular failure	1 (0.3)	0		1 (0.1)
Atrial fibrillation	1 (0.3)	0		1 (0.1)
Vascular disorders	3 (0.9)	1 (0.3)		4 (0.6)
Hypertension	2 (0.6)	1 (0.3)		3 (0.4)
Aortic dilatation	1 (0.3)	0		1 (0.1)
Respiratory, thoracic and mediastinal disorders	3 (0.9)	2 (0.6)		5 (0.7)
Rhinorrhoea	0	2 (0.6)		2 (0.3)
Cough	0	1 (0.3)		1 (0.1)
Nasal congestion	1 (0.3)	1 (0.3)		2 (0.3)
Acute respiratory failure	1 (0.3)	0		1 (0.1)
Oropharyngeal pain	1 (0.3)	0		1 (0.1)
Gastrointestinal disorders	1 (0.3)	1 (0.3)		2 (0.3)
Gastric ulcer	0	1 (0.3)		1 (0.1)
Gastrooesophageal reflux disease	1 (0.3)	1 (0.3)		2 (0.3)
Oesophageal ulcer	0	1 (0.3)		1 (0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Hepatobiliary disorders	1 (0.3)	0		1 (0.1)
Cholelithiasis	1 (0.3)	0		1 (0.1)
Skin and subcutaneous tissue disorders	3 (0.9)	0		3 (0.4)
Acne	1 (0.3)	0		1 (0.1)
Rash	1 (0.3)	0		1 (0.1)
Urticaria	1 (0.3)	0		1 (0.1)
Musculoskeletal and connective tissue disorders	8 (2.4)	3 (0.9)		11 (1.6)
Arthralgia	0	1 (0.3)		1 (0.1)
Back pain	3 (0.9)	1 (0.3)		4 (0.6)
Muscle tightness	0	1 (0.3)		1 (0.1)
Arthritis	1 (0.3)	0		1 (0.1)
Axillary mass	1 (0.3)	0		1 (0.1)
Musculoskeletal pain	1 (0.3)	0		1 (0.1)
Myalgia	1 (0.3)	0		1 (0.1)
Neck pain	2 (0.6)	0		2 (0.3)
Spinal stenosis	1 (0.3)	0		1 (0.1)
Renal and urinary disorders	3 (0.9)	0		3 (0.4)
Chromaturia	1 (0.3)	0		1 (0.1)
Micturition urgency	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Renal and urinary disorders (Cont.)				
Nephrolithiasis	1 (0.3)	0		1 (0.1)
Renal colic	1 (0.3)	0		1 (0.1)
General disorders and administration site conditions	3 (0.9)	4 (1.2)		7 (1.0)
Feeling hot	0	1 (0.3)		1 (0.1)
Injection site pain	1 (0.3)	1 (0.3)		2 (0.3)
Oedema peripheral	0	1 (0.3)		1 (0.1)
Swelling face	0	1 (0.3)		1 (0.1)
Fatigue	1 (0.3)	0		1 (0.1)
Non-cardiac chest pain	1 (0.3)	0		1 (0.1)
Investigations	2 (0.6)	0		2 (0.3)
Hepatic enzyme increased	1 (0.3)	0		1 (0.1)
International normalised ratio increased	1 (0.3)	0		1 (0.1)
Injury, poisoning and procedural complications	4 (1.2)	2 (0.6)		6 (0.9)
Fall	0	1 (0.3)		1 (0.1)
Head injury	0	1 (0.3)		1 (0.1)
Animal bite	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Injury, poisoning and procedural complications (Cont.)				
Concussion	1 (0.3)	0		1 (0.1)
Contusion	1 (0.3)	0		1 (0.1)
Ligament sprain	1 (0.3)	0		1 (0.1)
Procedural anxiety	1 (0.3)	0		1 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	3 (3.6)	12 (13.8)		15 (8.8)
Number of Unsolicited Adverse Events	3	18		21
Infections and infestations	2 (2.4)	5 (5.7)		7 (4.1)
Conjunctivitis	0	1 (1.1)		1 (0.6)
Lyme disease	0	1 (1.1)		1 (0.6)
Pharyngitis	0	1 (1.1)		1 (0.6)
Staphylococcal infection	0	1 (1.1)		1 (0.6)
Tooth infection	0	1 (1.1)		1 (0.6)
Sinusitis bacterial	1 (1.2)	0		1 (0.6)
Urinary tract infection	1 (1.2)	0		1 (0.6)
Metabolism and nutrition disorders	0	1 (1.1)		1 (0.6)
Hypercholesterolaemia	0	1 (1.1)		1 (0.6)
Psychiatric disorders	0	1 (1.1)		1 (0.6)
Depression	0	1 (1.1)		1 (0.6)
Nervous system disorders	0	1 (1.1)		1 (0.6)
Headache	0	1 (1.1)		1 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Ear and labyrinth disorders	0	1 (1.1)		1 (0.6)
Meniere's disease	0	1 (1.1)		1 (0.6)
Vascular disorders	0	2 (2.3)		2 (1.2)
Hypertension	0	2 (2.3)		2 (1.2)
Respiratory, thoracic and mediastinal disorders	0	2 (2.3)		2 (1.2)
Nasal congestion	0	1 (1.1)		1 (0.6)
Oropharyngeal pain	0	1 (1.1)		1 (0.6)
Gastrointestinal disorders	1 (1.2)	1 (1.1)		2 (1.2)
Inguinal hernia	0	1 (1.1)		1 (0.6)
Constipation	1 (1.2)	0		1 (0.6)
Skin and subcutaneous tissue disorders	0	2 (2.3)		2 (1.2)
Pruritus	0	1 (1.1)		1 (0.6)
Rash erythematous	0	1 (1.1)		1 (0.6)
General disorders and administration site conditions	0	1 (1.1)		1 (0.6)
Pain	0	1 (1.1)		1 (0.6)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.1
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Injury, poisoning and procedural complications	0	1 (1.1)		1 (0.6)
Meniscus injury	0	1 (1.1)		1 (0.6)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4054 (27.5)	3397 (23.0)		7451 (25.3)
Number of Unsolicited Adverse Events	7134	6017		13151
Infections and infestations	2038 (13.8)	1299 (8.8)		3337 (11.3)
Upper respiratory tract infection	204 (1.4)	173 (1.2)	0.85 (0.69, 1.04)	377 (1.3)
Urinary tract infection	176 (1.2)	137 (0.9)	0.78 (0.62, 0.97)	313 (1.1)
Viral infection	113 (0.8)	111 (0.8)	0.98 (0.76, 1.27)	224 (0.8)
Suspected COVID-19	96 (0.7)	110 (0.7)	1.15 (0.87, 1.50)	206 (0.7)
Sinusitis	98 (0.7)	104 (0.7)	1.06 (0.81, 1.40)	202 (0.7)
COVID-19	883 (6.0)	75 (0.5)	0.08 (0.07, 0.11)	958 (3.2)
Rhinovirus infection	48 (0.3)	55 (0.4)	1.15 (0.78, 1.68)	103 (0.3)
Herpes zoster	15 (0.1)	39 (0.3)	2.60 (1.45, 4.67)	54 (0.2)
Tooth abscess	38 (0.3)	30 (0.2)	0.79 (0.49, 1.27)	68 (0.2)
Tooth infection	30 (0.2)	29 (0.2)	0.97 (0.58, 1.60)	59 (0.2)
Viral upper respiratory tract infection	22 (0.1)	24 (0.2)	1.09 (0.62, 1.93)	46 (0.2)
Cellulitis	27 (0.2)	23 (0.2)	0.85 (0.49, 1.47)	50 (0.2)
Pharyngitis streptococcal	35 (0.2)	23 (0.2)	0.66 (0.39, 1.10)	58 (0.2)
Ear infection	21 (0.1)	22 (0.1)	1.05 (0.58, 1.89)	43 (0.1)
Bronchitis	30 (0.2)	20 (0.1)	0.67 (0.38, 1.16)	50 (0.2)
Gastroenteritis	19 (0.1)	19 (0.1)	1.00 (0.53, 1.87)	38 (0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Otitis media	16 (0.1)	18 (0.1)	1.12 (0.58, 2.18)	34 (0.1)
Pharyngitis	19 (0.1)	18 (0.1)	0.95 (0.50, 1.78)	37 (0.1)
Pneumonia	33 (0.2)	18 (0.1)	0.55 (0.31, 0.96)	51 (0.2)
Diverticulitis	19 (0.1)	15 (0.1)	0.79 (0.41, 1.53)	34 (0.1)
Hordeolum	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Conjunctivitis	15 (0.1)	11 (<0.1)	0.73 (0.34, 1.57)	26 (<0.1)
Enterovirus infection	2 (<0.1)	10 (<0.1)	5.00 (1.23, 20.28)	12 (<0.1)
Fungal infection	13 (<0.1)	10 (<0.1)	0.77 (0.34, 1.71)	23 (<0.1)
Localised infection	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Acute sinusitis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Onychomycosis	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Otitis externa	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Abscess limb	2 (<0.1)	8 (<0.1)	4.00 (0.96, 16.63)	10 (<0.1)
Bacterial vaginosis	9 (<0.1)	8 (<0.1)	0.89 (0.35, 2.23)	17 (<0.1)
Herpes simplex	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Nasopharyngitis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.59)	20 (<0.1)
Respiratory tract infection	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Asymptomatic COVID-19	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Gingivitis	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Paronychia	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Skin infection	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Vulvovaginal candidiasis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Cystitis	14 (<0.1)	6 (<0.1)	0.43 (0.17, 1.08)	20 (<0.1)
Folliculitis	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Pyelonephritis	5 (<0.1)	6 (<0.1)		11 (<0.1)
Sepsis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Appendicitis	6 (<0.1)	5 (<0.1)		11 (<0.1)
Clostridium difficile infection	0	5 (<0.1)		5 (<0.1)
Kidney infection	2 (<0.1)	5 (<0.1)		7 (<0.1)
Lyme disease	0	5 (<0.1)		5 (<0.1)
Oral candidiasis	5 (<0.1)	5 (<0.1)		10 (<0.1)
Oral herpes	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Postoperative wound infection	3 (<0.1)	5 (<0.1)		8 (<0.1)
Staphylococcal skin infection	1 (<0.1)	5 (<0.1)		6 (<0.1)
Chlamydial infection	0	4 (<0.1)		4 (<0.1)
Eye infection	6 (<0.1)	4 (<0.1)		10 (<0.1)
Furuncle	0	4 (<0.1)		4 (<0.1)
Gastroenteritis viral	6 (<0.1)	4 (<0.1)		10 (<0.1)
Helicobacter infection	4 (<0.1)	4 (<0.1)		8 (<0.1)
Laryngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Periodontitis	0	4 (<0.1)		4 (<0.1)
Sinusitis bacterial	3 (<0.1)	4 (<0.1)		7 (<0.1)
Staphylococcal infection	3 (<0.1)	4 (<0.1)		7 (<0.1)
Viral pharyngitis	2 (<0.1)	4 (<0.1)		6 (<0.1)

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Table 14.3.1.19.3.3
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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Vulvovaginal mycotic infection	13 (<0.1)	4 (<0.1)	0.31 (0.11, 0.90)	17 (<0.1)
Abdominal abscess	0	3 (<0.1)		3 (<0.1)
Chronic sinusitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Coronavirus infection	0	3 (<0.1)		3 (<0.1)
Gonorrhoea	2 (<0.1)	3 (<0.1)		5 (<0.1)
Impetigo	0	3 (<0.1)		3 (<0.1)
Injection site cellulitis	0	3 (<0.1)		3 (<0.1)
Rhinitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Subcutaneous abscess	2 (<0.1)	3 (<0.1)		5 (<0.1)
Tonsillitis	11 (<0.1)	3 (<0.1)	0.27 (0.08, 0.91)	14 (<0.1)
Wound infection	1 (<0.1)	3 (<0.1)		4 (<0.1)
Candida infection	3 (<0.1)	2 (<0.1)		5 (<0.1)
Cat scratch disease	0	2 (<0.1)		2 (<0.1)
Epididymitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Fungal skin infection	4 (<0.1)	2 (<0.1)		6 (<0.1)
Gastrointestinal infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Infected cyst	1 (<0.1)	2 (<0.1)		3 (<0.1)
Nail infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Otitis media acute	5 (<0.1)	2 (<0.1)		7 (<0.1)
Peritonitis	0	2 (<0.1)		2 (<0.1)
Pertussis	0	2 (<0.1)		2 (<0.1)
Post procedural infection	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Postoperative abscess	0	2 (<0.1)		2 (<0.1)
Pulpitis dental	1 (<0.1)	2 (<0.1)		3 (<0.1)
Respiratory tract infection viral	10 (<0.1)	2 (<0.1)	0.20 (0.05, 0.81)	12 (<0.1)
Septic shock	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tinea cruris	0	2 (<0.1)		2 (<0.1)
Tinea infection	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tuberculosis	0	2 (<0.1)		2 (<0.1)
Upper respiratory tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urinary tract infection bacterial	0	2 (<0.1)		2 (<0.1)
Urosepsis	0	2 (<0.1)		2 (<0.1)
Viral sinusitis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abscess jaw	0	1 (<0.1)		1 (<0.1)
Abscess oral	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Asymptomatic bacteriuria	2 (<0.1)	1 (<0.1)		3 (<0.1)
Atypical mycobacterial infection	0	1 (<0.1)		1 (<0.1)
Atypical pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Body tinea	2 (<0.1)	1 (<0.1)		3 (<0.1)
Breast abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast cellulitis	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Bronchiolitis	0	1 (<0.1)		1 (<0.1)
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)
Catheter site infection	0	1 (<0.1)		1 (<0.1)
Chest wall abscess	0	1 (<0.1)		1 (<0.1)
Colonic abscess	0	1 (<0.1)		1 (<0.1)
Conjunctivitis bacterial	4 (<0.1)	1 (<0.1)		5 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Dacryocystitis	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Gastrointestinal bacterial overgrowth	0	1 (<0.1)		1 (<0.1)
Genital herpes simplex	0	1 (<0.1)		1 (<0.1)
Genital infection fungal	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Gingival abscess	1 (<0.1)	1 (<0.1)		2 (<0.1)
Groin abscess	0	1 (<0.1)		1 (<0.1)
Helminthic infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Infected bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Infected dermal cyst	1 (<0.1)	1 (<0.1)		2 (<0.1)
Influenza	4 (<0.1)	1 (<0.1)		5 (<0.1)
Joint abscess	0	1 (<0.1)		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Labyrinthitis	0	1 (<0.1)		1 (<0.1)
Large intestine infection	0	1 (<0.1)		1 (<0.1)
Laryngitis viral	0	1 (<0.1)		1 (<0.1)
Latent tuberculosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Liver abscess	0	1 (<0.1)		1 (<0.1)
Lung abscess	0	1 (<0.1)		1 (<0.1)
Oral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteomyelitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Papilloma viral infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Parainfluenzae virus infection	0	1 (<0.1)		1 (<0.1)
Parotitis	0	1 (<0.1)		1 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Pneumonia staphylococcal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Prostate infection	0	1 (<0.1)		1 (<0.1)
Pyelonephritis acute	0	1 (<0.1)		1 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rocky mountain spotted fever	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Sexually transmitted disease	0	1 (<0.1)		1 (<0.1)
Sialoadenitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sinusitis fungal	1 (<0.1)	1 (<0.1)		2 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Infections and infestations (Cont.)				
Skin candida	3 (<0.1)	1 (<0.1)		4 (<0.1)
Soft tissue infection	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal cord abscess	0	1 (<0.1)		1 (<0.1)
Streptococcal infection	0	1 (<0.1)		1 (<0.1)
Tinea versicolour	1 (<0.1)	1 (<0.1)		2 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Uterine infection	0	1 (<0.1)		1 (<0.1)
Vulvitis	0	1 (<0.1)		1 (<0.1)
Vulvovaginitis trichomonal	0	1 (<0.1)		1 (<0.1)
Abscess neck	1 (<0.1)	0		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Balanitis candida	1 (<0.1)	0		1 (<0.1)
Blastocystis infection	1 (<0.1)	0		1 (<0.1)
Bronchitis bacterial	1 (<0.1)	0		1 (<0.1)
Bullous impetigo	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	16 (0.1)	0		16 (<0.1)
Campylobacter infection	1 (<0.1)	0		1 (<0.1)
Cervicitis	2 (<0.1)	0		2 (<0.1)
Cholecystitis infective	1 (<0.1)	0		1 (<0.1)
Clostridium difficile colitis	1 (<0.1)	0		1 (<0.1)
Coccidioidomycosis	2 (<0.1)	0		2 (<0.1)
Corneal infection	1 (<0.1)	0		1 (<0.1)

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Infections and infestations (Cont.)				
Denture stomatitis	1 (<0.1)	0		1 (<0.1)
Ear infection fungal	1 (<0.1)	0		1 (<0.1)
Enterococcal bacteraemia	1 (<0.1)	0		1 (<0.1)
Escherichia bacteraemia	1 (<0.1)	0		1 (<0.1)
Eye infection bacterial	2 (<0.1)	0		2 (<0.1)
Gardnerella infection	1 (<0.1)	0		1 (<0.1)
Gastroenteritis bacterial	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
HIV infection	1 (<0.1)	0		1 (<0.1)
Hepatitis C	1 (<0.1)	0		1 (<0.1)
Herpangina	1 (<0.1)	0		1 (<0.1)
Injection site infection	1 (<0.1)	0		1 (<0.1)
Klebsiella bacteraemia	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract infection	2 (<0.1)	0		2 (<0.1)
Mastoiditis	3 (<0.1)	0		3 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Nasal vestibulitis	1 (<0.1)	0		1 (<0.1)
Otitis media chronic	1 (<0.1)	0		1 (<0.1)
Pelvic abscess	1 (<0.1)	0		1 (<0.1)
Perirectal abscess	2 (<0.1)	0		2 (<0.1)
Pneumonia bacterial	1 (<0.1)	0		1 (<0.1)
Pneumonia klebsiella	1 (<0.1)	0		1 (<0.1)

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Infections and infestations (Cont.)				
Pneumonia viral	2 (<0.1)	0		2 (<0.1)
Proteus infection	1 (<0.1)	0		1 (<0.1)
Root canal infection	1 (<0.1)	0		1 (<0.1)
Skin bacterial infection	2 (<0.1)	0		2 (<0.1)
Streptococcal sepsis	1 (<0.1)	0		1 (<0.1)
Syphilis	3 (<0.1)	0		3 (<0.1)
Tinea barbae	1 (<0.1)	0		1 (<0.1)
Tinea pedis	3 (<0.1)	0		3 (<0.1)
Trichomoniasis	1 (<0.1)	0		1 (<0.1)
Urinary tract infection enterococcal	1 (<0.1)	0		1 (<0.1)
Vaginal abscess	1 (<0.1)	0		1 (<0.1)
Vaginitis chlamydial	2 (<0.1)	0		2 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Viral rhinitis	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	116 (0.8)	122 (0.8)		238 (0.8)
Basal cell carcinoma	28 (0.2)	22 (0.1)	0.79 (0.45, 1.36)	50 (0.2)
Prostate cancer	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Skin cancer	4 (<0.1)	6 (<0.1)		10 (<0.1)
Uterine leiomyoma	2 (<0.1)	6 (<0.1)		8 (<0.1)
Benign neoplasm of skin	2 (<0.1)	5 (<0.1)		7 (<0.1)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Malignant melanoma	5 (<0.1)	5 (<0.1)		10 (<0.1)
Squamous cell carcinoma	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Squamous cell carcinoma of skin	9 (<0.1)	4 (<0.1)	0.44 (0.15, 1.36)	13 (<0.1)
Benign breast neoplasm	3 (<0.1)	3 (<0.1)		6 (<0.1)
Benign neoplasm of thyroid gland	4 (<0.1)	3 (<0.1)		7 (<0.1)
Lipoma	2 (<0.1)	3 (<0.1)		5 (<0.1)
Melanocytic naevus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin papilloma	4 (<0.1)	3 (<0.1)		7 (<0.1)
Benign hepatic neoplasm	0	2 (<0.1)		2 (<0.1)
Breast cancer	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hepatocellular carcinoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Malignant melanoma in situ	1 (<0.1)	2 (<0.1)		3 (<0.1)
Plasma cell myeloma	0	2 (<0.1)		2 (<0.1)
Acral lentiginous melanoma	0	1 (<0.1)		1 (<0.1)
Adrenal adenoma	0	1 (<0.1)		1 (<0.1)
Angiolipoma	0	1 (<0.1)		1 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Benign lung neoplasm	0	1 (<0.1)		1 (<0.1)
Benign neoplasm of bladder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Benign salivary gland neoplasm	0	1 (<0.1)		1 (<0.1)

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Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Brain neoplasm	0	1 (<0.1)		1 (<0.1)
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Breast cancer in situ	0	1 (<0.1)		1 (<0.1)
Cancer pain	0	1 (<0.1)		1 (<0.1)
Chronic myelomonocytic leukaemia	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Colorectal cancer	0	1 (<0.1)		1 (<0.1)
Cutaneous lymphoma	0	1 (<0.1)		1 (<0.1)
Fibrous histiocytoma	0	1 (<0.1)		1 (<0.1)
Gastric cancer	0	1 (<0.1)		1 (<0.1)
Gastrointestinal stromal tumour	0	1 (<0.1)		1 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Intraductal papilloma of breast	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Invasive ductal breast carcinoma	2 (<0.1)	1 (<0.1)		3 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Liposarcoma	0	1 (<0.1)		1 (<0.1)

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Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190303.sas 21JUN2021 14:57

Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Meningioma	0	1 (<0.1)		1 (<0.1)
Metastases to bone	1 (<0.1)	1 (<0.1)		2 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Nasopharyngeal neoplasm benign	0	1 (<0.1)		1 (<0.1)
Non-Hodgkin's lymphoma	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic neoplasm	0	1 (<0.1)		1 (<0.1)
Pituitary tumour benign	0	1 (<0.1)		1 (<0.1)
Prostate cancer stage I	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal neoplasm	0	1 (<0.1)		1 (<0.1)
Splenic marginal zone lymphoma	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Thyroid cancer metastatic	0	1 (<0.1)		1 (<0.1)
Adenocarcinoma gastric	1 (<0.1)	0		1 (<0.1)
Benign bone neoplasm	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Benign neoplasm of eyelid	1 (<0.1)	0		1 (<0.1)
Benign ovarian tumour	1 (<0.1)	0		1 (<0.1)
Bladder neoplasm	1 (<0.1)	0		1 (<0.1)
Breast cancer stage I	1 (<0.1)	0		1 (<0.1)
Breast neoplasm	1 (<0.1)	0		1 (<0.1)
Chondromatosis	1 (<0.1)	0		1 (<0.1)
Colon cancer stage III	1 (<0.1)	0		1 (<0.1)
Enchondromatosis	1 (<0.1)	0		1 (<0.1)
Endometrial cancer	3 (<0.1)	0		3 (<0.1)
Essential thrombocythaemia	1 (<0.1)	0		1 (<0.1)
Haemangioma of liver	2 (<0.1)	0		2 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Leiomyosarcoma metastatic	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Naevus haemorrhage	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Pancreatic carcinoma stage IV	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prolactin-producing pituitary tumour	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Prostate cancer stage IV	1 (<0.1)	0		1 (<0.1)
Seborrhoeic keratosis	1 (<0.1)	0		1 (<0.1)
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	56 (0.4)	72 (0.5)		128 (0.4)
Lymphadenopathy	29 (0.2)	38 (0.3)	1.31 (0.81, 2.11)	67 (0.2)
Anaemia	10 (<0.1)	15 (0.1)	1.50 (0.69, 3.27)	25 (<0.1)
Iron deficiency anaemia	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Thrombocytopenia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Leukocytosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)
Blood loss anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Normocytic anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Splenomegaly	0	1 (<0.1)		1 (<0.1)
Thrombocytosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lymphadenitis	1 (<0.1)	0		1 (<0.1)
Nucleated red cells	1 (<0.1)	0		1 (<0.1)
Splenic calcification	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Immune system disorders	40 (0.3)	37 (0.3)		77 (0.3)
Seasonal allergy	24 (0.2)	23 (0.2)	0.96 (0.54, 1.68)	47 (0.2)
Drug hypersensitivity	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Hypersensitivity	5 (<0.1)	3 (<0.1)		8 (<0.1)
Mycotic allergy	0	2 (<0.1)		2 (<0.1)
Allergy to animal	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	2 (<0.1)	1 (<0.1)		3 (<0.1)
Food allergy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Allergy to metals	1 (<0.1)	0		1 (<0.1)
Cytokine storm	1 (<0.1)	0		1 (<0.1)
Milk allergy	1 (<0.1)	0		1 (<0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Smoke sensitivity	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	33 (0.2)	33 (0.2)		66 (0.2)
Hypothyroidism	15 (0.1)	22 (0.1)	1.47 (0.77, 2.79)	37 (0.1)
Thyroid mass	1 (<0.1)	3 (<0.1)		4 (<0.1)
Goitre	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hyperparathyroidism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Basedow's disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hyperthyroidism	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Endocrine disorders (Cont.)				
Hypogonadism	3 (<0.1)	1 (<0.1)		4 (<0.1)
Thyroid cyst	0	1 (<0.1)		1 (<0.1)
Thyroiditis	0	1 (<0.1)		1 (<0.1)
Androgen deficiency	1 (<0.1)	0		1 (<0.1)
Autoimmune thyroiditis	1 (<0.1)	0		1 (<0.1)
Hyperparathyroidism primary	1 (<0.1)	0		1 (<0.1)
Thyroiditis subacute	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	217 (1.5)	186 (1.3)		403 (1.4)
Hyperlipidaemia	44 (0.3)	32 (0.2)	0.73 (0.46, 1.14)	76 (0.3)
Type 2 diabetes mellitus	25 (0.2)	31 (0.2)	1.24 (0.74, 2.09)	56 (0.2)
Vitamin D deficiency	25 (0.2)	24 (0.2)	0.96 (0.55, 1.67)	49 (0.2)
Hypercholesterolaemia	29 (0.2)	20 (0.1)	0.69 (0.39, 1.21)	49 (0.2)
Diabetes mellitus	10 (<0.1)	11 (<0.1)	1.10 (0.48, 2.53)	21 (<0.1)
Glucose tolerance impaired	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Dehydration	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Gout	13 (<0.1)	9 (<0.1)	0.69 (0.30, 1.58)	22 (<0.1)
Hyponatraemia	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Hypokalaemia	16 (0.1)	5 (<0.1)	0.31 (0.12, 0.82)	21 (<0.1)
Hyperglycaemia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Decreased appetite	4 (<0.1)	3 (<0.1)		7 (<0.1)
Diabetes mellitus inadequate control	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Hyperkalaemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypertriglyceridaemia	2 (<0.1)	3 (<0.1)		5 (<0.1)
Iron deficiency	4 (<0.1)	3 (<0.1)		7 (<0.1)
Obesity	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hypocalcaemia	2 (<0.1)	2 (<0.1)		4 (<0.1)
Hypoglycaemia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Insulin resistance	0	2 (<0.1)		2 (<0.1)
Malnutrition	0	2 (<0.1)		2 (<0.1)
Vitamin B12 deficiency	3 (<0.1)	2 (<0.1)		5 (<0.1)
Abnormal loss of weight	2 (<0.1)	1 (<0.1)		3 (<0.1)
Abnormal weight gain	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Electrolyte imbalance	3 (<0.1)	1 (<0.1)		4 (<0.1)
Failure to thrive	0	1 (<0.1)		1 (<0.1)
Gluten sensitivity	0	1 (<0.1)		1 (<0.1)
Hypercalcaemia	0	1 (<0.1)		1 (<0.1)
Hypomagnesaemia	5 (<0.1)	1 (<0.1)		6 (<0.1)
Hypophosphataemia	0	1 (<0.1)		1 (<0.1)
Magnesium deficiency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vitamin K deficiency	0	1 (<0.1)		1 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Metabolism and nutrition disorders (Cont.)				
Calcium deficiency	1 (<0.1)	0		1 (<0.1)
Fluid overload	1 (<0.1)	0		1 (<0.1)
Fluid retention	1 (<0.1)	0		1 (<0.1)
Folate deficiency	1 (<0.1)	0		1 (<0.1)
Hypermagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyperuricaemia	1 (<0.1)	0		1 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	192 (1.3)	218 (1.5)		410 (1.4)
Anxiety	66 (0.4)	80 (0.5)	1.21 (0.88, 1.67)	146 (0.5)
Depression	70 (0.5)	80 (0.5)	1.14 (0.83, 1.57)	150 (0.5)
Insomnia	23 (0.2)	23 (0.2)	1.00 (0.57, 1.77)	46 (0.2)
Attention deficit hyperactivity disorder	21 (0.1)	19 (0.1)	0.90 (0.49, 1.67)	40 (0.1)
Bipolar disorder	7 (<0.1)	7 (<0.1)	1.00 (0.37, 2.73)	14 (<0.1)
Post-traumatic stress disorder	1 (<0.1)	4 (<0.1)		5 (<0.1)
Adjustment disorder with depressed mood	2 (<0.1)	2 (<0.1)		4 (<0.1)
Alcohol withdrawal syndrome	2 (<0.1)	2 (<0.1)		4 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Psychiatric disorders (Cont.)				
Bipolar II disorder	0	2 (<0.1)		2 (<0.1)
Generalised anxiety disorder	7 (<0.1)	2 (<0.1)	0.29 (0.07, 1.21)	9 (<0.1)
Major depression	4 (<0.1)	2 (<0.1)		6 (<0.1)
Suicidal ideation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alcohol abuse	0	1 (<0.1)		1 (<0.1)
Anxiety disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Completed suicide	0	1 (<0.1)		1 (<0.1)
Confusional state	2 (<0.1)	1 (<0.1)		3 (<0.1)
Drug use disorder	0	1 (<0.1)		1 (<0.1)
Dysphemia	0	1 (<0.1)		1 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental status changes	4 (<0.1)	1 (<0.1)		5 (<0.1)
Obsessive-compulsive personality disorder	0	1 (<0.1)		1 (<0.1)
Panic attack	4 (<0.1)	1 (<0.1)		5 (<0.1)
Persistent depressive disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Psychotic disorder	0	1 (<0.1)		1 (<0.1)
Rapid eye movement sleep behaviour disorder	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Social anxiety disorder	0	1 (<0.1)		1 (<0.1)

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Psychiatric disorders (Cont.)				
Stress	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance abuse	0	1 (<0.1)		1 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)
Substance-induced psychotic disorder	0	1 (<0.1)		1 (<0.1)
Suicide attempt	0	1 (<0.1)		1 (<0.1)
Agitation	1 (<0.1)	0		1 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Delirium	1 (<0.1)	0		1 (<0.1)
Depression suicidal	2 (<0.1)	0		2 (<0.1)
Dissociative disorder	1 (<0.1)	0		1 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Mixed anxiety and depressive disorder	1 (<0.1)	0		1 (<0.1)
Nicotine dependence	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Seasonal affective disorder	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	315 (2.1)	312 (2.1)		627 (2.1)
Headache	139 (0.9)	126 (0.9)	0.91 (0.71, 1.15)	265 (0.9)
Dizziness	25 (0.2)	18 (0.1)	0.72 (0.40, 1.31)	43 (0.1)
Migraine	18 (0.1)	18 (0.1)	1.00 (0.53, 1.90)	36 (0.1)
Paraesthesia	13 (<0.1)	16 (0.1)	1.23 (0.60, 2.52)	29 (<0.1)
Sciatica	19 (0.1)	16 (0.1)	0.84 (0.44, 1.62)	35 (0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Syncope	24 (0.2)	16 (0.1)	0.67 (0.36, 1.24)	40 (0.1)
Cervical radiculopathy	1 (<0.1)	12 (<0.1)	11.99 (2.00, 71.89)	13 (<0.1)
Anosmia	6 (<0.1)	10 (<0.1)	1.67 (0.63, 4.41)	16 (<0.1)
Ageusia	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Nerve compression	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Cerebrovascular accident	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Facial paralysis	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Carpal tunnel syndrome	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Hypoaesthesia	5 (<0.1)	5 (<0.1)		10 (<0.1)
Lumbar radiculopathy	1 (<0.1)	5 (<0.1)		6 (<0.1)
Seizure	6 (<0.1)	5 (<0.1)		11 (<0.1)
Subarachnoid haemorrhage	0	4 (<0.1)		4 (<0.1)
Neuralgia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Peripheral sensory neuropathy	2 (<0.1)	3 (<0.1)		5 (<0.1)
Presyncope	5 (<0.1)	3 (<0.1)		8 (<0.1)
Transient ischaemic attack	4 (<0.1)	3 (<0.1)		7 (<0.1)
Amnesia	1 (<0.1)	2 (<0.1)		3 (<0.1)
Carotid artery stenosis	0	2 (<0.1)		2 (<0.1)
Cubital tunnel syndrome	0	2 (<0.1)		2 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Memory impairment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Optic neuritis	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Piriformis syndrome	0	2 (<0.1)		2 (<0.1)
Restless legs syndrome	6 (<0.1)	2 (<0.1)		8 (<0.1)
Aphasia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autonomic nervous system imbalance	0	1 (<0.1)		1 (<0.1)
Balance disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burning sensation	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cauda equina syndrome	0	1 (<0.1)		1 (<0.1)
Central nervous system lesion	0	1 (<0.1)		1 (<0.1)
Cerebral atrophy	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Complex regional pain syndrome	0	1 (<0.1)		1 (<0.1)
Depressed level of consciousness	0	1 (<0.1)		1 (<0.1)
Head discomfort	2 (<0.1)	1 (<0.1)		3 (<0.1)
Head titubation	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Hyperaesthesia	0	1 (<0.1)		1 (<0.1)
Hypersomnia	0	1 (<0.1)		1 (<0.1)
Hyposmia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Idiopathic intracranial hypertension	0	1 (<0.1)		1 (<0.1)
Lethargy	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.3.3
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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Migraine with aura	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine without aura	0	1 (<0.1)		1 (<0.1)
Morton's neuralgia	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle contractions involuntary	0	1 (<0.1)		1 (<0.1)
Occipital neuralgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic headache	0	1 (<0.1)		1 (<0.1)
Primary cough headache	0	1 (<0.1)		1 (<0.1)
Primary headache associated with sexual activity	0	1 (<0.1)		1 (<0.1)
Radiculopathy	0	1 (<0.1)		1 (<0.1)
Sinus headache	1 (<0.1)	1 (<0.1)		2 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Spinal cord compression	0	1 (<0.1)		1 (<0.1)
Tardive dyskinesia	0	1 (<0.1)		1 (<0.1)
Tension headache	2 (<0.1)	1 (<0.1)		3 (<0.1)
Toxic encephalopathy	0	1 (<0.1)		1 (<0.1)
Tremor	3 (<0.1)	1 (<0.1)		4 (<0.1)
Trigeminal neuralgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	2 (<0.1)	0		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Cerebral cyst	1 (<0.1)	0		1 (<0.1)
Dementia	1 (<0.1)	0		1 (<0.1)
Encephalopathy	3 (<0.1)	0		3 (<0.1)
Essential tremor	2 (<0.1)	0		2 (<0.1)
Horner's syndrome	1 (<0.1)	0		1 (<0.1)
Hydrocephalus	1 (<0.1)	0		1 (<0.1)
Hypogeusia	1 (<0.1)	0		1 (<0.1)
Intention tremor	1 (<0.1)	0		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Loss of consciousness	1 (<0.1)	0		1 (<0.1)
Metabolic encephalopathy	1 (<0.1)	0		1 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)
Neuropathy peripheral	5 (<0.1)	0		5 (<0.1)
Perineurial cyst	1 (<0.1)	0		1 (<0.1)
Peroneal nerve palsy	1 (<0.1)	0		1 (<0.1)
Radicular pain	1 (<0.1)	0		1 (<0.1)
Right hemisphere deficit syndrome	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Speech disorder	1 (<0.1)	0		1 (<0.1)
Tarsal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Thoracic radiculopathy	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Nervous system disorders (Cont.)				
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)
Vocal cord paralysis	1 (<0.1)	0		1 (<0.1)
Eye disorders	70 (0.5)	79 (0.5)		149 (0.5)
Cataract	9 (<0.1)	13 (<0.1)	1.44 (0.63, 3.30)	22 (<0.1)
Dry eye	7 (<0.1)	8 (<0.1)	1.14 (0.43, 3.03)	15 (<0.1)
Retinal detachment	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Glaucoma	5 (<0.1)	6 (<0.1)		11 (<0.1)
Chalazion	1 (<0.1)	4 (<0.1)		5 (<0.1)
Eye irritation	1 (<0.1)	4 (<0.1)		5 (<0.1)
Uveitis	0	3 (<0.1)		3 (<0.1)
Blepharitis	4 (<0.1)	2 (<0.1)		6 (<0.1)
Conjunctival haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Eye haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Eye pruritus	1 (<0.1)	2 (<0.1)		3 (<0.1)
Macular degeneration	1 (<0.1)	2 (<0.1)		3 (<0.1)
Macular hole	1 (<0.1)	2 (<0.1)		3 (<0.1)
Scleritis	0	2 (<0.1)		2 (<0.1)
Blepharospasm	0	1 (<0.1)		1 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetic retinopathy	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Dry age-related macular degeneration	0	1 (<0.1)		1 (<0.1)
Eye disorder	0	1 (<0.1)		1 (<0.1)
Eye pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eyelid cyst	0	1 (<0.1)		1 (<0.1)
Foreign body sensation in eyes	0	1 (<0.1)		1 (<0.1)
Keratitis	0	1 (<0.1)		1 (<0.1)
Lenticular opacities	0	1 (<0.1)		1 (<0.1)
Macular fibrosis	0	1 (<0.1)		1 (<0.1)
Noninfective conjunctivitis	0	1 (<0.1)		1 (<0.1)
Ocular discomfort	0	1 (<0.1)		1 (<0.1)
Orbital haematoma	0	1 (<0.1)		1 (<0.1)
Papilloedema	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	0	1 (<0.1)		1 (<0.1)
Retinal haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Retinal vascular occlusion	0	1 (<0.1)		1 (<0.1)
Retinopathy hypertensive	0	1 (<0.1)		1 (<0.1)
Ulcerative keratitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vision blurred	4 (<0.1)	1 (<0.1)		5 (<0.1)
Visual impairment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitreous disorder	0	1 (<0.1)		1 (<0.1)
Vitreous floaters	3 (<0.1)	1 (<0.1)		4 (<0.1)
Xerophthalmia	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Eye disorders (Cont.)				
Asthenopia	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Conjunctivochalasis	1 (<0.1)	0		1 (<0.1)
Dacryostenosis acquired	1 (<0.1)	0		1 (<0.1)
Diplopia	2 (<0.1)	0		2 (<0.1)
Eye inflammation	4 (<0.1)	0		4 (<0.1)
Eye swelling	2 (<0.1)	0		2 (<0.1)
Eye ulcer	1 (<0.1)	0		1 (<0.1)
Eyelid ptosis	3 (<0.1)	0		3 (<0.1)
Macular oedema	1 (<0.1)	0		1 (<0.1)
Ocular hyperaemia	1 (<0.1)	0		1 (<0.1)
Ocular rosacea	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Photophobia	2 (<0.1)	0		2 (<0.1)
Retinal oedema	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Strabismus	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	1 (<0.1)	0		1 (<0.1)
Vitreous detachment	4 (<0.1)	0		4 (<0.1)
Ear and labyrinth disorders	67 (0.5)	60 (0.4)		127 (0.4)
Vertigo	11 (<0.1)	22 (0.1)	2.00 (0.98, 4.06)	33 (0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Ear and labyrinth disorders (Cont.)				
Ear pain	10 (<0.1)	10 (<0.1)	1.00 (0.43, 2.34)	20 (<0.1)
Tinnitus	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Vertigo positional	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Meniere's disease	2 (<0.1)	4 (<0.1)		6 (<0.1)
Cerumen impaction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Ear discomfort	3 (<0.1)	2 (<0.1)		5 (<0.1)
Deafness unilateral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ear canal erythema	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear pruritus	4 (<0.1)	1 (<0.1)		5 (<0.1)
Eustachian tube dysfunction	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hypoacusis	0	1 (<0.1)		1 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Motion sickness	0	1 (<0.1)		1 (<0.1)
Tympanic membrane perforation	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear congestion	2 (<0.1)	0		2 (<0.1)
Excessive cerumen production	2 (<0.1)	0		2 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Otorrhoea	1 (<0.1)	0		1 (<0.1)
Tympanic membrane hyperaemia	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders	113 (0.8)	117 (0.8)		230 (0.8)
Atrial fibrillation	26 (0.2)	25 (0.2)	0.96 (0.56, 1.65)	51 (0.2)
Palpitations	6 (<0.1)	14 (<0.1)	2.33 (0.93, 5.87)	20 (<0.1)
Ventricular extrasystoles	4 (<0.1)	10 (<0.1)	2.50 (0.83, 7.53)	14 (<0.1)
Coronary artery disease	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Angina pectoris	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Myocardial infarction	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Sinus tachycardia	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Tachycardia	11 (<0.1)	6 (<0.1)	0.55 (0.21, 1.42)	17 (<0.1)
Cardiac failure congestive	9 (<0.1)	5 (<0.1)	0.56 (0.20, 1.58)	14 (<0.1)
Acute myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Cardiac failure	3 (<0.1)	4 (<0.1)		7 (<0.1)
Supraventricular tachycardia	0	4 (<0.1)		4 (<0.1)
Acute coronary syndrome	0	3 (<0.1)		3 (<0.1)
Atrial flutter	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bradycardia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Arrhythmia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cardiomyopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Pericarditis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Ventricular tachycardia	0	2 (<0.1)		2 (<0.1)
Acute left ventricular failure	1 (<0.1)	1 (<0.1)		2 (<0.1)

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Angina unstable	0	1 (<0.1)		1 (<0.1)
Aortic valve stenosis	0	1 (<0.1)		1 (<0.1)
Arteriosclerosis coronary artery	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial enlargement	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)
Cardiac failure acute	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardiovascular symptom	0	1 (<0.1)		1 (<0.1)
Left ventricular hypertrophy	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pericardial effusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sinus bradycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular extrasystoles	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atrial tachycardia	2 (<0.1)	0		2 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)
Cardiac disorder	1 (<0.1)	0		1 (<0.1)
Cardiac steatosis	1 (<0.1)	0		1 (<0.1)
Cardiomegaly	2 (<0.1)	0		2 (<0.1)
Diastolic dysfunction	1 (<0.1)	0		1 (<0.1)
Extrasystoles	1 (<0.1)	0		1 (<0.1)
Mitral valve incompetence	2 (<0.1)	0		2 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Cardiac disorders (Cont.)				
Mitral valve thickening	1 (<0.1)	0		1 (<0.1)
Myocardial ischaemia	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Postural orthostatic tachycardia syndrome	1 (<0.1)	0		1 (<0.1)
Sinus arrest	1 (<0.1)	0		1 (<0.1)
Tricuspid valve incompetence	2 (<0.1)	0		2 (<0.1)
Ventricular arrhythmia	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	258 (1.8)	215 (1.5)		473 (1.6)
Hypertension	213 (1.4)	170 (1.2)	0.80 (0.65, 0.97)	383 (1.3)
Haematoma	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.24)	12 (<0.1)
Deep vein thrombosis	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Hypertensive urgency	2 (<0.1)	4 (<0.1)		6 (<0.1)
Orthostatic hypotension	1 (<0.1)	4 (<0.1)		5 (<0.1)
Hypotension	6 (<0.1)	3 (<0.1)		9 (<0.1)
Aortic dilatation	0	2 (<0.1)		2 (<0.1)
Arteriosclerosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Hot flush	4 (<0.1)	2 (<0.1)		6 (<0.1)
Varicose vein	1 (<0.1)	2 (<0.1)		3 (<0.1)
Achenbach syndrome	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Aortic aneurysm	4 (<0.1)	1 (<0.1)		5 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Essential hypertension	1 (<0.1)	1 (<0.1)		2 (<0.1)
Flushing	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypertensive emergency	2 (<0.1)	1 (<0.1)		3 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Phlebitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Raynaud's phenomenon	1 (<0.1)	1 (<0.1)		2 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis superficial	3 (<0.1)	1 (<0.1)		4 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Aortic stenosis	2 (<0.1)	0		2 (<0.1)
Arterial haemorrhage	1 (<0.1)	0		1 (<0.1)
Fibromuscular dysplasia	1 (<0.1)	0		1 (<0.1)
Lymphoedema	1 (<0.1)	0		1 (<0.1)
Peripheral artery aneurysm	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Vascular disorders (Cont.)				
Peripheral venous disease	1 (<0.1)	0		1 (<0.1)
Secondary hypertension	1 (<0.1)	0		1 (<0.1)
Vascular calcification	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	402 (2.7)	320 (2.2)		722 (2.4)
Cough	120 (0.8)	108 (0.7)	0.90 (0.69, 1.16)	228 (0.8)
Nasal congestion	87 (0.6)	88 (0.6)	1.01 (0.75, 1.36)	175 (0.6)
Rhinorrhoea	74 (0.5)	72 (0.5)	0.97 (0.70, 1.34)	146 (0.5)
Oropharyngeal pain	102 (0.7)	71 (0.5)	0.70 (0.51, 0.94)	173 (0.6)
Dyspnoea	46 (0.3)	39 (0.3)	0.85 (0.56, 1.29)	85 (0.3)
Asthma	28 (0.2)	20 (0.1)	0.71 (0.41, 1.26)	48 (0.2)
Chronic obstructive pulmonary disease	18 (0.1)	10 (<0.1)	0.56 (0.26, 1.18)	28 (<0.1)
Sinus congestion	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)	21 (<0.1)
Acute respiratory failure	13 (<0.1)	7 (<0.1)	0.54 (0.22, 1.31)	20 (<0.1)
Respiratory tract congestion	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Rhinitis allergic	12 (<0.1)	7 (<0.1)	0.58 (0.24, 1.44)	19 (<0.1)
Upper-airway cough syndrome	6 (<0.1)	7 (<0.1)	1.17 (0.41, 3.31)	13 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Sinus pain	1 (<0.1)	6 (<0.1)		7 (<0.1)
Pleural effusion	5 (<0.1)	5 (<0.1)		10 (<0.1)
Sneezing	2 (<0.1)	5 (<0.1)		7 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Respiratory disorder	5 (<0.1)	4 (<0.1)		9 (<0.1)
Sleep apnoea syndrome	6 (<0.1)	4 (<0.1)		10 (<0.1)
Atelectasis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bronchiectasis	0	3 (<0.1)		3 (<0.1)
Emphysema	1 (<0.1)	3 (<0.1)		4 (<0.1)
Paranasal sinus discomfort	0	3 (<0.1)		3 (<0.1)
Epistaxis	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hypoxia	6 (<0.1)	2 (<0.1)		8 (<0.1)
Pharyngeal erythema	6 (<0.1)	2 (<0.1)		8 (<0.1)
Pleurisy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary mass	3 (<0.1)	2 (<0.1)		5 (<0.1)
Respiratory failure	1 (<0.1)	2 (<0.1)		3 (<0.1)
Wheezing	5 (<0.1)	2 (<0.1)		7 (<0.1)
Allergic sinusitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchospasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Choking sensation	0	1 (<0.1)		1 (<0.1)
Dysphonia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Dyspnoea exertional	4 (<0.1)	1 (<0.1)		5 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lung infiltration	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nasal discomfort	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Nasal mucosal disorder	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	2 (<0.1)	1 (<0.1)		3 (<0.1)
Paranasal cyst	0	1 (<0.1)		1 (<0.1)
Pleuritic pain	6 (<0.1)	1 (<0.1)		7 (<0.1)
Pneumonia aspiration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumothorax	2 (<0.1)	1 (<0.1)		3 (<0.1)
Productive cough	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pulmonary hypertension	0	1 (<0.1)		1 (<0.1)
Pulmonary oedema	0	1 (<0.1)		1 (<0.1)
Respiratory distress	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Throat irritation	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tonsillolith	3 (<0.1)	1 (<0.1)		4 (<0.1)
Vasomotor rhinitis	0	1 (<0.1)		1 (<0.1)
Vocal cord thickening	0	1 (<0.1)		1 (<0.1)
Acute respiratory distress syndrome	1 (<0.1)	0		1 (<0.1)
Aphonia	1 (<0.1)	0		1 (<0.1)
Asthma exercise induced	1 (<0.1)	0		1 (<0.1)
Bronchial hyperreactivity	1 (<0.1)	0		1 (<0.1)
Dry throat	1 (<0.1)	0		1 (<0.1)
Haemoptysis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Laryngeal stenosis	1 (<0.1)	0		1 (<0.1)
Lower respiratory tract congestion	1 (<0.1)	0		1 (<0.1)
Lung cyst	1 (<0.1)	0		1 (<0.1)
Lung opacity	2 (<0.1)	0		2 (<0.1)
Nasal dryness	1 (<0.1)	0		1 (<0.1)
Nasal turbinate hypertrophy	1 (<0.1)	0		1 (<0.1)
Nasal ulcer	1 (<0.1)	0		1 (<0.1)
Organising pneumonia	1 (<0.1)	0		1 (<0.1)
Painful respiration	2 (<0.1)	0		2 (<0.1)
Paranasal sinus hypersecretion	1 (<0.1)	0		1 (<0.1)
Pneumonitis	1 (<0.1)	0		1 (<0.1)
Pulmonary fibrosis	2 (<0.1)	0		2 (<0.1)
Pulmonary granuloma	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Rales	1 (<0.1)	0		1 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Sinus polyp	1 (<0.1)	0		1 (<0.1)
Throat tightness	1 (<0.1)	0		1 (<0.1)
Tonsillar hypertrophy	2 (<0.1)	0		2 (<0.1)
Upper respiratory tract congestion	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders	362 (2.5)	375 (2.5)		737 (2.5)
Nausea	65 (0.4)	68 (0.5)	1.05 (0.75, 1.47)	133 (0.5)
Diarrhoea	59 (0.4)	60 (0.4)	1.02 (0.71, 1.45)	119 (0.4)
Gastrooesophageal reflux disease	35 (0.2)	49 (0.3)	1.40 (0.91, 2.15)	84 (0.3)
Abdominal pain	21 (0.1)	24 (0.2)	1.14 (0.64, 2.03)	45 (0.2)
Dental caries	27 (0.2)	23 (0.2)	0.85 (0.49, 1.47)	50 (0.2)
Toothache	27 (0.2)	20 (0.1)	0.74 (0.42, 1.31)	47 (0.2)
Vomiting	21 (0.1)	19 (0.1)	0.90 (0.49, 1.67)	40 (0.1)
Constipation	15 (0.1)	16 (0.1)	1.07 (0.53, 2.13)	31 (0.1)
Abdominal pain upper	10 (<0.1)	14 (<0.1)	1.40 (0.63, 3.08)	24 (<0.1)
Inguinal hernia	5 (<0.1)	10 (<0.1)	2.00 (0.72, 5.58)	15 (<0.1)
Large intestine polyp	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Hiatus hernia	5 (<0.1)	9 (<0.1)	1.80 (0.63, 5.11)	14 (<0.1)
Irritable bowel syndrome	3 (<0.1)	8 (<0.1)	2.67 (0.77, 9.25)	11 (<0.1)
Abdominal pain lower	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Colitis	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Dyspepsia	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Gastritis	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)	16 (<0.1)
Tooth impacted	6 (<0.1)	5 (<0.1)		11 (<0.1)
Gastric ulcer	6 (<0.1)	4 (<0.1)		10 (<0.1)
Haemorrhoids	2 (<0.1)	4 (<0.1)		6 (<0.1)
Rectal haemorrhage	2 (<0.1)	4 (<0.1)		6 (<0.1)
Small intestinal obstruction	4 (<0.1)	4 (<0.1)		8 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Umbilical hernia	1 (<0.1)	4 (<0.1)		5 (<0.1)
Barrett's oesophagus	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diverticulum	3 (<0.1)	3 (<0.1)		6 (<0.1)
Food poisoning	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)	10 (<0.1)
Gastrointestinal haemorrhage	3 (<0.1)	3 (<0.1)		6 (<0.1)
Gingival pain	0	3 (<0.1)		3 (<0.1)
Haematochezia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Oesophagitis	0	3 (<0.1)		3 (<0.1)
Pancreatitis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Periodontal disease	0	3 (<0.1)		3 (<0.1)
Abdominal discomfort	5 (<0.1)	2 (<0.1)		7 (<0.1)
Abdominal distension	1 (<0.1)	2 (<0.1)		3 (<0.1)
Anal fissure	0	2 (<0.1)		2 (<0.1)
Diverticulum intestinal	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Duodenal ulcer perforation	0	2 (<0.1)		2 (<0.1)
Dysphagia	5 (<0.1)	2 (<0.1)		7 (<0.1)
Flatulence	2 (<0.1)	2 (<0.1)		4 (<0.1)
Gastrointestinal pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypoaesthesia oral	0	2 (<0.1)		2 (<0.1)
Intestinal obstruction	0	2 (<0.1)		2 (<0.1)
Lip swelling	2 (<0.1)	2 (<0.1)		4 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Oesophageal spasm	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stomatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal hernia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Chronic gastritis	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Diabetic gastroparesis	0	1 (<0.1)		1 (<0.1)
Diverticular perforation	0	1 (<0.1)		1 (<0.1)
Duodenitis	0	1 (<0.1)		1 (<0.1)
Enteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Erosive oesophagitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Faecaloma	0	1 (<0.1)		1 (<0.1)
Faeces discoloured	0	1 (<0.1)		1 (<0.1)
Faeces soft	0	1 (<0.1)		1 (<0.1)
Gastrointestinal disorder	0	1 (<0.1)		1 (<0.1)
Gingival bleeding	0	1 (<0.1)		1 (<0.1)
Gingival disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperaesthesia teeth	0	1 (<0.1)		1 (<0.1)
Impaired gastric emptying	1 (<0.1)	1 (<0.1)		2 (<0.1)
Intra-abdominal fluid collection	0	1 (<0.1)		1 (<0.1)
Intussusception	1 (<0.1)	1 (<0.1)		2 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Loose tooth	1 (<0.1)	1 (<0.1)		2 (<0.1)
Melaena	0	1 (<0.1)		1 (<0.1)
Mouth ulceration	3 (<0.1)	1 (<0.1)		4 (<0.1)
Noninfective gingivitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal rupture	0	1 (<0.1)		1 (<0.1)
Oesophageal stenosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oesophageal ulcer	0	1 (<0.1)		1 (<0.1)
Pancreatic cyst	0	1 (<0.1)		1 (<0.1)
Pancreatitis acute	0	1 (<0.1)		1 (<0.1)
Paraesthesia oral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peptic ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Proctalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Proctitis	0	1 (<0.1)		1 (<0.1)
Rectal prolapse	0	1 (<0.1)		1 (<0.1)
Retroperitoneal haemorrhage	0	1 (<0.1)		1 (<0.1)
Salivary gland calculus	0	1 (<0.1)		1 (<0.1)
Salivary hypersecretion	0	1 (<0.1)		1 (<0.1)
Swollen tongue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tongue disorder	0	1 (<0.1)		1 (<0.1)
Tongue ulceration	0	1 (<0.1)		1 (<0.1)
Abdominal rigidity	1 (<0.1)	0		1 (<0.1)
Abdominal tenderness	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Anal fistula	1 (<0.1)	0		1 (<0.1)
Anorectal discomfort	1 (<0.1)	0		1 (<0.1)
Aphthous ulcer	2 (<0.1)	0		2 (<0.1)
Ascites	2 (<0.1)	0		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Colitis microscopic	1 (<0.1)	0		1 (<0.1)
Dental necrosis	1 (<0.1)	0		1 (<0.1)
Dry mouth	1 (<0.1)	0		1 (<0.1)
Duodenal ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric perforation	1 (<0.1)	0		1 (<0.1)
Gastric polyps	1 (<0.1)	0		1 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal inflammation	1 (<0.1)	0		1 (<0.1)
Gingival recession	1 (<0.1)	0		1 (<0.1)
Glossodynia	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Lichenoid dysplasia	1 (<0.1)	0		1 (<0.1)
Obstructive pancreatitis	1 (<0.1)	0		1 (<0.1)
Oral cavity fistula	1 (<0.1)	0		1 (<0.1)
Oral pain	2 (<0.1)	0		2 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Gastrointestinal disorders (Cont.)				
Retching	1 (<0.1)	0		1 (<0.1)
Terminal ileitis	1 (<0.1)	0		1 (<0.1)
Tooth disorder	2 (<0.1)	0		2 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Upper gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Uvulitis	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	16 (0.1)	27 (0.2)		43 (0.1)
Cholelithiasis	6 (<0.1)	13 (<0.1)	2.17 (0.85, 5.50)	19 (<0.1)
Cholecystitis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.27)	10 (<0.1)
Hepatic steatosis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bile duct stone	0	2 (<0.1)		2 (<0.1)
Biliary colic	0	2 (<0.1)		2 (<0.1)
Biliary dyskinesia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cholecystitis acute	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatic cyst	2 (<0.1)	1 (<0.1)		3 (<0.1)
Nonalcoholic fatty liver disease	0	1 (<0.1)		1 (<0.1)
Hepatic haematoma	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	175 (1.2)	152 (1.0)		327 (1.1)
Urticaria	15 (0.1)	21 (0.1)	1.40 (0.73, 2.68)	36 (0.1)
Dermatitis contact	20 (0.1)	17 (0.1)	0.85 (0.45, 1.60)	37 (0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Rash	19 (0.1)	13 (<0.1)	0.68 (0.34, 1.36)	32 (0.1)
Eczema	7 (<0.1)	10 (<0.1)	1.43 (0.56, 3.62)	17 (<0.1)
Acne	15 (0.1)	9 (<0.1)	0.60 (0.27, 1.34)	24 (<0.1)
Actinic keratosis	5 (<0.1)	7 (<0.1)	1.40 (0.47, 4.17)	12 (<0.1)
Pruritus	8 (<0.1)	6 (<0.1)	0.75 (0.27, 2.07)	14 (<0.1)
Rosacea	3 (<0.1)	6 (<0.1)		9 (<0.1)
Dermatitis	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Ingrowing nail	1 (<0.1)	4 (<0.1)		5 (<0.1)
Psoriasis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Skin lesion	3 (<0.1)	4 (<0.1)		7 (<0.1)
Dermal cyst	5 (<0.1)	3 (<0.1)		8 (<0.1)
Dermatitis allergic	2 (<0.1)	3 (<0.1)		5 (<0.1)
Dermatitis atopic	4 (<0.1)	3 (<0.1)		7 (<0.1)
Eczema nummular	0	3 (<0.1)		3 (<0.1)
Hyperhidrosis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Neurodermatitis	0	3 (<0.1)		3 (<0.1)
Rash maculo-papular	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin ulcer	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diabetic foot	0	2 (<0.1)		2 (<0.1)
Dry skin	2 (<0.1)	2 (<0.1)		4 (<0.1)
Erythema	4 (<0.1)	2 (<0.1)		6 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Hidradenitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Pityriasis rosea	0	2 (<0.1)		2 (<0.1)
Precancerous skin lesion	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rash macular	3 (<0.1)	2 (<0.1)		5 (<0.1)
Alopecia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blister	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood blister	0	1 (<0.1)		1 (<0.1)
Chronic spontaneous urticaria	0	1 (<0.1)		1 (<0.1)
Decubitus ulcer	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hand dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Papule	0	1 (<0.1)		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Rash papular	2 (<0.1)	1 (<0.1)		3 (<0.1)
Rash pruritic	6 (<0.1)	1 (<0.1)		7 (<0.1)
Rash vesicular	0	1 (<0.1)		1 (<0.1)
Seborrhoeic dermatitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Angioedema	3 (<0.1)	0		3 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Ecchymosis	3 (<0.1)	0		3 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Ingrown hair	1 (<0.1)	0		1 (<0.1)
Intertrigo	3 (<0.1)	0		3 (<0.1)
Lichenoid keratosis	1 (<0.1)	0		1 (<0.1)
Livedo reticularis	1 (<0.1)	0		1 (<0.1)
Night sweats	3 (<0.1)	0		3 (<0.1)
Photosensitivity reaction	1 (<0.1)	0		1 (<0.1)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Scab	1 (<0.1)	0		1 (<0.1)
Skin exfoliation	1 (<0.1)	0		1 (<0.1)
Skin fissures	1 (<0.1)	0		1 (<0.1)
Skin mass	2 (<0.1)	0		2 (<0.1)
Skin wrinkling	1 (<0.1)	0		1 (<0.1)
Solar lentigo	1 (<0.1)	0		1 (<0.1)
Stasis dermatitis	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Transient acantholytic dermatosis	1 (<0.1)	0		1 (<0.1)
Urticaria papular	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders	457 (3.1)	475 (3.2)		932 (3.2)
Arthralgia	65 (0.4)	67 (0.5)	1.03 (0.73, 1.45)	132 (0.4)
Back pain	70 (0.5)	60 (0.4)	0.86 (0.61, 1.21)	130 (0.4)
Osteoarthritis	56 (0.4)	52 (0.4)	0.93 (0.64, 1.35)	108 (0.4)
Myalgia	59 (0.4)	48 (0.3)	0.81 (0.56, 1.19)	107 (0.4)
Musculoskeletal pain	19 (0.1)	28 (0.2)	1.47 (0.83, 2.62)	47 (0.2)
Neck pain	12 (<0.1)	24 (0.2)	2.00 (1.01, 3.94)	36 (0.1)
Muscle spasms	25 (0.2)	22 (0.1)	0.88 (0.50, 1.55)	47 (0.2)
Pain in extremity	26 (0.2)	22 (0.1)	0.85 (0.48, 1.48)	48 (0.2)
Rotator cuff syndrome	19 (0.1)	20 (0.1)	1.05 (0.57, 1.95)	39 (0.1)
Intervertebral disc protrusion	10 (<0.1)	17 (0.1)	1.70 (0.79, 3.64)	27 (<0.1)
Bursitis	11 (<0.1)	14 (<0.1)	1.27 (0.59, 2.75)	25 (<0.1)
Tendonitis	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Arthritis	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.57)	20 (<0.1)
Spinal osteoarthritis	8 (<0.1)	8 (<0.1)	1.00 (0.39, 2.57)	16 (<0.1)
Trigger finger	5 (<0.1)	8 (<0.1)	1.60 (0.55, 4.64)	13 (<0.1)
Musculoskeletal chest pain	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.78)	17 (<0.1)
Periarthritis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Joint swelling	1 (<0.1)	6 (<0.1)		7 (<0.1)
Osteoporosis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Muscular weakness	1 (<0.1)	5 (<0.1)		6 (<0.1)
Osteopenia	5 (<0.1)	5 (<0.1)		10 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Flank pain	5 (<0.1)	4 (<0.1)		9 (<0.1)
Intervertebral disc degeneration	5 (<0.1)	4 (<0.1)		9 (<0.1)
Musculoskeletal stiffness	0	4 (<0.1)		4 (<0.1)
Spinal stenosis	2 (<0.1)	4 (<0.1)		6 (<0.1)
Plantar fasciitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Spinal pain	1 (<0.1)	3 (<0.1)		4 (<0.1)
Spondylolisthesis	0	3 (<0.1)		3 (<0.1)
Temporomandibular joint syndrome	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cervical spinal stenosis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Exostosis	6 (<0.1)	2 (<0.1)		8 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Foot deformity	6 (<0.1)	2 (<0.1)		8 (<0.1)
Joint range of motion decreased	0	2 (<0.1)		2 (<0.1)
Muscle tightness	0	2 (<0.1)		2 (<0.1)
Neck mass	0	2 (<0.1)		2 (<0.1)
Pain in jaw	3 (<0.1)	2 (<0.1)		5 (<0.1)
Rheumatoid arthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tenosynovitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bone pain	0	1 (<0.1)		1 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Compartment syndrome	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Degenerative bone disease	0	1 (<0.1)		1 (<0.1)
Dupuytren's contracture	0	1 (<0.1)		1 (<0.1)
Fibromyalgia	3 (<0.1)	1 (<0.1)		4 (<0.1)
Floating patella	0	1 (<0.1)		1 (<0.1)
Fracture nonunion	0	1 (<0.1)		1 (<0.1)
Groin pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Intervertebral disc disorder	0	1 (<0.1)		1 (<0.1)
Joint stiffness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Ligament pain	0	1 (<0.1)		1 (<0.1)
Ligamentum flavum hypertrophy	0	1 (<0.1)		1 (<0.1)
Limb mass	0	1 (<0.1)		1 (<0.1)
Medial tibial stress syndrome	0	1 (<0.1)		1 (<0.1)
Muscle twitching	0	1 (<0.1)		1 (<0.1)
Musculoskeletal discomfort	0	1 (<0.1)		1 (<0.1)
Osteitis	0	1 (<0.1)		1 (<0.1)
Osteonecrosis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Plantar fascial fibromatosis	0	1 (<0.1)		1 (<0.1)
Polyarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal synovial cyst	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spondylitis	0	1 (<0.1)		1 (<0.1)
Spondylolysis	0	1 (<0.1)		1 (<0.1)
Synovial cyst	5 (<0.1)	1 (<0.1)		6 (<0.1)
Tendon disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tenosynovitis stenosans	2 (<0.1)	1 (<0.1)		3 (<0.1)
Trismus	1 (<0.1)	1 (<0.1)		2 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vertebral foraminal stenosis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Vertebral lateral recess stenosis	0	1 (<0.1)		1 (<0.1)
Axillary mass	1 (<0.1)	0		1 (<0.1)
Costochondritis	4 (<0.1)	0		4 (<0.1)
Femoroacetabular impingement	1 (<0.1)	0		1 (<0.1)
Kyphosis	1 (<0.1)	0		1 (<0.1)
Lumbar spinal stenosis	1 (<0.1)	0		1 (<0.1)
Musculoskeletal disorder	1 (<0.1)	0		1 (<0.1)
Myositis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190303.sas 21JUN2021 14:57

Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Scoliosis	2 (<0.1)	0		2 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Synovitis	1 (<0.1)	0		1 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Torticollis	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	75 (0.5)	71 (0.5)		146 (0.5)
Nephrolithiasis	29 (0.2)	23 (0.2)	0.79 (0.46, 1.36)	52 (0.2)
Acute kidney injury	12 (<0.1)	7 (<0.1)	0.58 (0.24, 1.44)	19 (<0.1)
Chronic kidney disease	6 (<0.1)	6 (<0.1)		12 (<0.1)
Haematuria	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Hypertonic bladder	3 (<0.1)	5 (<0.1)		8 (<0.1)
Urinary retention	4 (<0.1)	5 (<0.1)		9 (<0.1)
Dysuria	3 (<0.1)	4 (<0.1)		7 (<0.1)
Hydronephrosis	0	3 (<0.1)		3 (<0.1)
Pollakiuria	2 (<0.1)	3 (<0.1)		5 (<0.1)
Renal cyst	3 (<0.1)	2 (<0.1)		5 (<0.1)
Urinary hesitation	2 (<0.1)	2 (<0.1)		4 (<0.1)
Urinary incontinence	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bladder prolapse	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bladder spasm	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Renal and urinary disorders (Cont.)				
Calculus bladder	0	1 (<0.1)		1 (<0.1)
Cystitis interstitial	0	1 (<0.1)		1 (<0.1)
Diabetic nephropathy	0	1 (<0.1)		1 (<0.1)
Haemorrhage urinary tract	0	1 (<0.1)		1 (<0.1)
Lower urinary tract symptoms	0	1 (<0.1)		1 (<0.1)
Nocturia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Polyuria	0	1 (<0.1)		1 (<0.1)
Renal disorder	0	1 (<0.1)		1 (<0.1)
Renal pain	0	1 (<0.1)		1 (<0.1)
Ureterolithiasis	0	1 (<0.1)		1 (<0.1)
Micturition urgency	2 (<0.1)	0		2 (<0.1)
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal impairment	2 (<0.1)	0		2 (<0.1)
Stress urinary incontinence	1 (<0.1)	0		1 (<0.1)
Urge incontinence	1 (<0.1)	0		1 (<0.1)
Urine flow decreased	1 (<0.1)	0		1 (<0.1)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	3 (<0.1)		5 (<0.1)
Abortion spontaneous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperemesis gravidarum	0	1 (<0.1)		1 (<0.1)
Pregnancy	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Pregnancy, puerperium and perinatal conditions (Cont.)				
Ectopic pregnancy	1 (<0.1)	0		1 (<0.1)
Reproductive system and breast disorders	97 (0.7)	84 (0.6)		181 (0.6)
Benign prostatic hyperplasia	19 (0.1)	8 (<0.1)	0.42 (0.19, 0.94)	27 (<0.1)
Ovarian cyst	6 (<0.1)	6 (<0.1)		12 (<0.1)
Prostatitis	6 (<0.1)	6 (<0.1)		12 (<0.1)
Breast cyst	2 (<0.1)	5 (<0.1)		7 (<0.1)
Erectile dysfunction	8 (<0.1)	5 (<0.1)	0.62 (0.22, 1.81)	13 (<0.1)
Pelvic pain	2 (<0.1)	5 (<0.1)		7 (<0.1)
Prostatomegaly	5 (<0.1)	5 (<0.1)		10 (<0.1)
Menopausal symptoms	1 (<0.1)	3 (<0.1)		4 (<0.1)
Menorrhagia	1 (<0.1)	3 (<0.1)		4 (<0.1)
Breast mass	5 (<0.1)	2 (<0.1)		7 (<0.1)
Breast pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Breast ulceration	0	2 (<0.1)		2 (<0.1)
Dysfunctional uterine bleeding	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dysmenorrhoea	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rectocele	0	2 (<0.1)		2 (<0.1)
Uterine haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Uterine polyp	3 (<0.1)	2 (<0.1)		5 (<0.1)

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Safety Set

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System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Vaginal haemorrhage	2 (<0.1)	2 (<0.1)		4 (<0.1)
Adenomyosis	0	1 (<0.1)		1 (<0.1)
Adnexa uteri pain	0	1 (<0.1)		1 (<0.1)
Adnexal torsion	0	1 (<0.1)		1 (<0.1)
Artificial menopause	0	1 (<0.1)		1 (<0.1)
Atrophic vulvovaginitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Balanoposthitis	0	1 (<0.1)		1 (<0.1)
Breast disorder	0	1 (<0.1)		1 (<0.1)
Breast enlargement	0	1 (<0.1)		1 (<0.1)
Breast hyperplasia	0	1 (<0.1)		1 (<0.1)
Cervical dysplasia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cervical polyp	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cystocele	1 (<0.1)	1 (<0.1)		2 (<0.1)
Endometrial thickening	1 (<0.1)	1 (<0.1)		2 (<0.1)
Fibrocystic breast disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gynaecomastia	0	1 (<0.1)		1 (<0.1)
Menstrual disorder	0	1 (<0.1)		1 (<0.1)
Nipple exudate bloody	0	1 (<0.1)		1 (<0.1)
Postmenopausal haemorrhage	3 (<0.1)	1 (<0.1)		4 (<0.1)
Prostatic cyst	0	1 (<0.1)		1 (<0.1)
Vaginal cyst	0	1 (<0.1)		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Reproductive system and breast disorders (Cont.)				
Vaginal discharge	0	1 (<0.1)		1 (<0.1)
Vaginal prolapse	0	1 (<0.1)		1 (<0.1)
Vulva cyst	0	1 (<0.1)		1 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Vulvovaginal pain	0	1 (<0.1)		1 (<0.1)
Amenorrhoea	1 (<0.1)	0		1 (<0.1)
Bartholin's cyst	3 (<0.1)	0		3 (<0.1)
Dyspareunia	1 (<0.1)	0		1 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Endometriosis	2 (<0.1)	0		2 (<0.1)
Haematospermia	2 (<0.1)	0		2 (<0.1)
Ovarian cyst ruptured	2 (<0.1)	0		2 (<0.1)
Ovarian mass	1 (<0.1)	0		1 (<0.1)
Pelvic discomfort	1 (<0.1)	0		1 (<0.1)
Pelvic floor muscle weakness	1 (<0.1)	0		1 (<0.1)
Peyronie's disease	1 (<0.1)	0		1 (<0.1)
Polycystic ovaries	2 (<0.1)	0		2 (<0.1)
Premenstrual dysphoric disorder	1 (<0.1)	0		1 (<0.1)
Pruritus genital	1 (<0.1)	0		1 (<0.1)
Testicular pain	2 (<0.1)	0		2 (<0.1)
Uterine cyst	1 (<0.1)	0		1 (<0.1)

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Safety Set

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Reproductive system and breast disorders (Cont.)				
Vulvovaginal discomfort	1 (<0.1)	0		1 (<0.1)
Vulvovaginal dryness	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	5 (<0.1)	5 (<0.1)		10 (<0.1)
Arnold-Chiari malformation	1 (<0.1)	2 (<0.1)		3 (<0.1)
Dermoid cyst	0	1 (<0.1)		1 (<0.1)
Preauricular cyst	0	1 (<0.1)		1 (<0.1)
Von Willebrand's disease	0	1 (<0.1)		1 (<0.1)
Hydrocele	2 (<0.1)	0		2 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
Type IIa hyperlipidaemia	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	234 (1.6)	257 (1.7)		491 (1.7)
Fatigue	102 (0.7)	102 (0.7)	1.00 (0.76, 1.31)	204 (0.7)
Pain	45 (0.3)	39 (0.3)	0.87 (0.57, 1.32)	84 (0.3)
Chills	33 (0.2)	29 (0.2)	0.88 (0.54, 1.44)	62 (0.2)
Pyrexia	33 (0.2)	28 (0.2)	0.85 (0.52, 1.40)	61 (0.2)
Injection site pain	5 (<0.1)	14 (<0.1)	2.80 (1.05, 7.46)	19 (<0.1)
Non-cardiac chest pain	11 (<0.1)	11 (<0.1)	1.00 (0.44, 2.25)	22 (<0.1)

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General disorders and administration site conditions (Cont.)				
Chest pain	7 (<0.1)	9 (<0.1)	1.28 (0.50, 3.33)	16 (<0.1)
Injection site lymphadenopathy	2 (<0.1)	8 (<0.1)	4.00 (0.96, 16.63)	10 (<0.1)
Oedema peripheral	11 (<0.1)	8 (<0.1)	0.73 (0.30, 1.76)	19 (<0.1)
Chest discomfort	13 (<0.1)	7 (<0.1)	0.54 (0.22, 1.31)	20 (<0.1)
Injection site erythema	2 (<0.1)	7 (<0.1)	3.50 (0.83, 14.81)	9 (<0.1)
Injection site induration	0	7 (<0.1)		7 (<0.1)
Injection site rash	0	7 (<0.1)		7 (<0.1)
Injection site swelling	0	7 (<0.1)		7 (<0.1)
Peripheral swelling	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)
Asthenia	5 (<0.1)	4 (<0.1)		9 (<0.1)
Influenza like illness	4 (<0.1)	4 (<0.1)		8 (<0.1)
Injection site macule	0	4 (<0.1)		4 (<0.1)
Injection site pruritus	0	4 (<0.1)		4 (<0.1)
Cyst	5 (<0.1)	3 (<0.1)		8 (<0.1)
Injury associated with device	0	3 (<0.1)		3 (<0.1)
Malaise	2 (<0.1)	3 (<0.1)		5 (<0.1)
Reactogenicity event	2 (<0.1)	3 (<0.1)		5 (<0.1)
Swelling face	1 (<0.1)	3 (<0.1)		4 (<0.1)
Adverse drug reaction	0	2 (<0.1)		2 (<0.1)
Axillary pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Injection site papule	0	2 (<0.1)		2 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Injection site reaction	0	2 (<0.1)		2 (<0.1)
Precancerous condition	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vaccination site pain	0	2 (<0.1)		2 (<0.1)
Crying	0	1 (<0.1)		1 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Dysplasia	0	1 (<0.1)		1 (<0.1)
Early satiety	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Granuloma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Induration	0	1 (<0.1)		1 (<0.1)
Inflammation	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site warmth	0	1 (<0.1)		1 (<0.1)
Mass	2 (<0.1)	1 (<0.1)		3 (<0.1)
Multiple organ dysfunction syndrome	0	1 (<0.1)		1 (<0.1)
Sensation of foreign body	0	1 (<0.1)		1 (<0.1)
Swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vessel puncture site haematoma	0	1 (<0.1)		1 (<0.1)
Capsular contracture associated with breast implant	1 (<0.1)	0		1 (<0.1)
Death	1 (<0.1)	0		1 (<0.1)
Facial pain	1 (<0.1)	0		1 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
General disorders and administration site conditions (Cont.)				
Feeling abnormal	2 (<0.1)	0		2 (<0.1)
Feeling hot	1 (<0.1)	0		1 (<0.1)
Gait disturbance	2 (<0.1)	0		2 (<0.1)
Hangover	1 (<0.1)	0		1 (<0.1)
Hypothermia	1 (<0.1)	0		1 (<0.1)
Impaired healing	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Injection site bruising	3 (<0.1)	0		3 (<0.1)
Injection site haemorrhage	1 (<0.1)	0		1 (<0.1)
Medical device site inflammation	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pelvic mass	1 (<0.1)	0		1 (<0.1)
Systemic inflammatory response syndrome	4 (<0.1)	0		4 (<0.1)
Vaccination site lymphadenopathy	3 (<0.1)	0		3 (<0.1)
Investigations	82 (0.6)	87 (0.6)		169 (0.6)
Blood cholesterol increased	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)	17 (<0.1)
Blood pressure increased	16 (0.1)	8 (<0.1)	0.50 (0.22, 1.14)	24 (<0.1)
Hepatic enzyme increased	3 (<0.1)	6 (<0.1)		9 (<0.1)
Prostatic specific antigen increased	1 (<0.1)	5 (<0.1)		6 (<0.1)

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Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Blood pressure systolic increased	7 (<0.1)	4 (<0.1)	0.57 (0.18, 1.82)	11 (<0.1)
Transaminases increased	2 (<0.1)	4 (<0.1)		6 (<0.1)
Cardiac murmur	2 (<0.1)	3 (<0.1)		5 (<0.1)
Blood glucose increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood potassium decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Blood pressure diastolic increased	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blood testosterone decreased	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blood triglycerides increased	2 (<0.1)	2 (<0.1)		4 (<0.1)
C-reactive protein increased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Electrocardiogram QT prolonged	0	2 (<0.1)		2 (<0.1)
Heart rate irregular	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hepatic enzyme abnormal	0	2 (<0.1)		2 (<0.1)
Weight decreased	1 (<0.1)	2 (<0.1)		3 (<0.1)
Alanine aminotransferase increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Antinuclear antibody positive	0	1 (<0.1)		1 (<0.1)
Aspartate aminotransferase increased	0	1 (<0.1)		1 (<0.1)
Blood bilirubin increased	0	1 (<0.1)		1 (<0.1)
Blood creatinine increased	0	1 (<0.1)		1 (<0.1)
Blood glucose decreased	0	1 (<0.1)		1 (<0.1)
Blood oestrogen decreased	0	1 (<0.1)		1 (<0.1)
Blood parathyroid hormone increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood urine present	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Carotid bruit	0	1 (<0.1)		1 (<0.1)
Chest X-ray	0	1 (<0.1)		1 (<0.1)
Electrocardiogram T wave inversion	0	1 (<0.1)		1 (<0.1)
Fibrin D dimer increased	0	1 (<0.1)		1 (<0.1)
Glomerular filtration rate decreased	0	1 (<0.1)		1 (<0.1)
Glycosylated haemoglobin increased	4 (<0.1)	1 (<0.1)		5 (<0.1)
Haemoglobin decreased	0	1 (<0.1)		1 (<0.1)
Heart rate increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hepatitis C antibody positive	0	1 (<0.1)		1 (<0.1)
Hormone level abnormal	0	1 (<0.1)		1 (<0.1)
Human rhinovirus test positive	0	1 (<0.1)		1 (<0.1)
Influenza A virus test positive	0	1 (<0.1)		1 (<0.1)
Liver function test increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Mammogram abnormal	0	1 (<0.1)		1 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neutrophil count increased	0	1 (<0.1)		1 (<0.1)
Oestradiol decreased	0	1 (<0.1)		1 (<0.1)
Oxygen saturation decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Smear cervix abnormal	1 (<0.1)	1 (<0.1)		2 (<0.1)
Stool analysis abnormal	0	1 (<0.1)		1 (<0.1)
Streptococcus test negative	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Investigations (Cont.)				
Thyroid function test abnormal	0	1 (<0.1)		1 (<0.1)
Troponin increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vitamin D decreased	2 (<0.1)	1 (<0.1)		3 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)
White blood cell count increased	0	1 (<0.1)		1 (<0.1)
Blood calcium increased	1 (<0.1)	0		1 (<0.1)
Blood iron decreased	2 (<0.1)	0		2 (<0.1)
Blood pressure diastolic decreased	2 (<0.1)	0		2 (<0.1)
Blood prolactin increased	1 (<0.1)	0		1 (<0.1)
Blood thyroid stimulating hormone increased	1 (<0.1)	0		1 (<0.1)
Blood uric acid increased	1 (<0.1)	0		1 (<0.1)
Brain natriuretic peptide increased	1 (<0.1)	0		1 (<0.1)
Haematocrit increased	1 (<0.1)	0		1 (<0.1)
Lipase increased	1 (<0.1)	0		1 (<0.1)
Liver function test abnormal	1 (<0.1)	0		1 (<0.1)
Red blood cell count increased	1 (<0.1)	0		1 (<0.1)
SARS-CoV-2 test positive	1 (<0.1)	0		1 (<0.1)
Serum ferritin increased	1 (<0.1)	0		1 (<0.1)
Total lung capacity decreased	1 (<0.1)	0		1 (<0.1)
Viral test positive	1 (<0.1)	0		1 (<0.1)
Vitamin B12 decreased	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications	417 (2.8)	385 (2.6)		802 (2.7)
Skin laceration	46 (0.3)	34 (0.2)	0.74 (0.48, 1.15)	80 (0.3)
Ligament sprain	21 (0.1)	32 (0.2)	1.52 (0.88, 2.62)	53 (0.2)
Fall	25 (0.2)	25 (0.2)	1.00 (0.58, 1.73)	50 (0.2)
Muscle strain	24 (0.2)	25 (0.2)	1.04 (0.60, 1.81)	49 (0.2)
Tooth fracture	30 (0.2)	22 (0.1)	0.73 (0.43, 1.26)	52 (0.2)
Procedural pain	33 (0.2)	21 (0.1)	0.64 (0.37, 1.09)	54 (0.2)
Foot fracture	18 (0.1)	20 (0.1)	1.11 (0.59, 2.08)	38 (0.1)
Meniscus injury	19 (0.1)	16 (0.1)	0.84 (0.44, 1.62)	35 (0.1)
Animal bite	14 (<0.1)	15 (0.1)	1.07 (0.52, 2.18)	29 (<0.1)
Arthropod bite	16 (0.1)	13 (<0.1)	0.81 (0.40, 1.66)	29 (<0.1)
Limb injury	11 (<0.1)	13 (<0.1)	1.18 (0.54, 2.58)	24 (<0.1)
Joint injury	7 (<0.1)	11 (<0.1)	1.57 (0.63, 3.92)	18 (<0.1)
Road traffic accident	9 (<0.1)	11 (<0.1)	1.22 (0.52, 2.87)	20 (<0.1)
Concussion	4 (<0.1)	10 (<0.1)	2.50 (0.83, 7.53)	14 (<0.1)
Rib fracture	9 (<0.1)	10 (<0.1)	1.11 (0.46, 2.66)	19 (<0.1)
Contusion	10 (<0.1)	9 (<0.1)	0.90 (0.38, 2.15)	19 (<0.1)
Facial bones fracture	0	8 (<0.1)		8 (<0.1)
Post-traumatic pain	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.78)	17 (<0.1)
Clavicle fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Corneal abrasion	5 (<0.1)	5 (<0.1)		10 (<0.1)
Head injury	2 (<0.1)	5 (<0.1)		7 (<0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Humerus fracture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Ligament rupture	5 (<0.1)	5 (<0.1)		10 (<0.1)
Muscle rupture	2 (<0.1)	5 (<0.1)		7 (<0.1)
Stress fracture	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Upper limb fracture	1 (<0.1)	5 (<0.1)		6 (<0.1)
Ankle fracture	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Cartilage injury	5 (<0.1)	4 (<0.1)		9 (<0.1)
Epicondylitis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Hand fracture	4 (<0.1)	4 (<0.1)		8 (<0.1)
Joint dislocation	3 (<0.1)	4 (<0.1)		7 (<0.1)
Skin abrasion	9 (<0.1)	4 (<0.1)	0.44 (0.15, 1.36)	13 (<0.1)
Wrist fracture	6 (<0.1)	4 (<0.1)		10 (<0.1)
Arthropod sting	5 (<0.1)	3 (<0.1)		8 (<0.1)
Back injury	4 (<0.1)	3 (<0.1)		7 (<0.1)
Craniocerebral injury	0	3 (<0.1)		3 (<0.1)
Dental restoration failure	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hip fracture	3 (<0.1)	3 (<0.1)		6 (<0.1)
Subdural haematoma	0	3 (<0.1)		3 (<0.1)
Alcohol poisoning	0	2 (<0.1)		2 (<0.1)
Bone contusion	5 (<0.1)	2 (<0.1)		7 (<0.1)
Cervical vertebral fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Ligament injury	2 (<0.1)	2 (<0.1)		4 (<0.1)
Lower limb fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Post procedural haemorrhage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Procedural nausea	3 (<0.1)	2 (<0.1)		5 (<0.1)
Skin wound	2 (<0.1)	2 (<0.1)		4 (<0.1)
Tendon rupture	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Animal scratch	0	1 (<0.1)		1 (<0.1)
Bone fragmentation	0	1 (<0.1)		1 (<0.1)
Burns first degree	0	1 (<0.1)		1 (<0.1)
Burns second degree	3 (<0.1)	1 (<0.1)		4 (<0.1)
Chillblains	0	1 (<0.1)		1 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Dislocation of vertebra	0	1 (<0.1)		1 (<0.1)
Dural tear	0	1 (<0.1)		1 (<0.1)
Eyelid injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Fibula fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Foreign body in eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Foreign body in respiratory tract	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Foreign body in skin or subcutaneous tissue	0	1 (<0.1)		1 (<0.1)
Fractured sacrum	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Graft complication	0	1 (<0.1)		1 (<0.1)
Hypobarism	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Incision site pain	0	1 (<0.1)		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injury	0	1 (<0.1)		1 (<0.1)
Limb traumatic amputation	0	1 (<0.1)		1 (<0.1)
Lip injury	3 (<0.1)	1 (<0.1)		4 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniscus cyst	0	1 (<0.1)		1 (<0.1)
Multiple fractures	0	1 (<0.1)		1 (<0.1)
Nasal injury	0	1 (<0.1)		1 (<0.1)
Neck injury	0	1 (<0.1)		1 (<0.1)
Overdose	0	1 (<0.1)		1 (<0.1)
Patella fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pelvic fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Periorbital haematoma	0	1 (<0.1)		1 (<0.1)
Periorbital haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural fever	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post procedural swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Post-traumatic neck syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	2 (<0.1)	1 (<0.1)		3 (<0.1)
Procedural site reaction	0	1 (<0.1)		1 (<0.1)
Radius fracture	6 (<0.1)	1 (<0.1)		7 (<0.1)
Scar	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal column injury	0	1 (<0.1)		1 (<0.1)
Spinal compression fracture	0	1 (<0.1)		1 (<0.1)
Splinter	1 (<0.1)	1 (<0.1)		2 (<0.1)
Sports injury	0	1 (<0.1)		1 (<0.1)
Subcutaneous haematoma	0	1 (<0.1)		1 (<0.1)
Superficial injury of eye	2 (<0.1)	1 (<0.1)		3 (<0.1)
Tendon injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thermal burn	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thoracic vertebral fracture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tooth injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Traumatic haemorrhage	0	1 (<0.1)		1 (<0.1)
Traumatic liver injury	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Uterine rupture	0	1 (<0.1)		1 (<0.1)
Wound dehiscence	0	1 (<0.1)		1 (<0.1)
Anaemia postoperative	1 (<0.1)	0		1 (<0.1)
Exposure to SARS-CoV-2	1 (<0.1)	0		1 (<0.1)
Eye injury	1 (<0.1)	0		1 (<0.1)
Foreign body	3 (<0.1)	0		3 (<0.1)
Foreign body in ear	2 (<0.1)	0		2 (<0.1)
Fractured coccyx	1 (<0.1)	0		1 (<0.1)
Gingival injury	1 (<0.1)	0		1 (<0.1)
Gun shot wound	1 (<0.1)	0		1 (<0.1)
Iliotibial band syndrome	1 (<0.1)	0		1 (<0.1)
Immunisation anxiety related reaction	1 (<0.1)	0		1 (<0.1)
Incision site inflammation	1 (<0.1)	0		1 (<0.1)
Injection related reaction	1 (<0.1)	0		1 (<0.1)
Keratorhexis	1 (<0.1)	0		1 (<0.1)
Mallet finger	1 (<0.1)	0		1 (<0.1)
Multiple injuries	1 (<0.1)	0		1 (<0.1)
Nail injury	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural bile leak	1 (<0.1)	0		1 (<0.1)
Post procedural constipation	2 (<0.1)	0		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Injury, poisoning and procedural complications (Cont.)				
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural hypothyroidism	1 (<0.1)	0		1 (<0.1)
Procedural anxiety	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural vomiting	1 (<0.1)	0		1 (<0.1)
Pulmonary contusion	1 (<0.1)	0		1 (<0.1)
Respiratory fume inhalation disorder	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Scratch	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)
Tracheal haemorrhage	1 (<0.1)	0		1 (<0.1)
Traumatic haemothorax	2 (<0.1)	0		2 (<0.1)
Ulna fracture	1 (<0.1)	0		1 (<0.1)
Ulnar nerve injury	2 (<0.1)	0		2 (<0.1)
Uterine perforation	1 (<0.1)	0		1 (<0.1)
Vaccination complication	1 (<0.1)	0		1 (<0.1)
Wound	6 (<0.1)	0		6 (<0.1)
Social circumstances	3 (<0.1)	1 (<0.1)		4 (<0.1)
Menopause	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Negative

System Organ Class Preferred Term	Placebo (N=14741) n (%)	mRNA-1273 (N=14750) n (%)	Rate Ratio (95% CI)	Total (N=29491) n (%)
Social circumstances (Cont.)				
Postmenopause	1 (<0.1)	0		1 (<0.1)
Sexual abuse	1 (<0.1)	0		1 (<0.1)
Product issues	3 (<0.1)	4 (<0.1)		7 (<0.1)
Device breakage	1 (<0.1)	2 (<0.1)		3 (<0.1)
Device dislocation	0	1 (<0.1)		1 (<0.1)
Embedded device	0	1 (<0.1)		1 (<0.1)
Device physical property issue	1 (<0.1)	0		1 (<0.1)
Lead dislodgement	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	65 (19.3)	51 (14.7)		116 (17.0)
Number of Unsolicited Adverse Events	124	88		212
Infections and infestations	25 (7.4)	20 (5.8)		45 (6.6)
COVID-19	6 (1.8)	4 (1.2)		10 (1.5)
Upper respiratory tract infection	5 (1.5)	3 (0.9)		8 (1.2)
Otitis externa	0	2 (0.6)		2 (0.3)
Rhinovirus infection	1 (0.3)	2 (0.6)		3 (0.4)
Sinusitis	1 (0.3)	2 (0.6)		3 (0.4)
Cystitis	0	1 (0.3)		1 (0.1)
Herpes zoster	2 (0.6)	1 (0.3)		3 (0.4)
Paronychia	0	1 (0.3)		1 (0.1)
Pharyngitis streptococcal	1 (0.3)	1 (0.3)		2 (0.3)
Pneumonia	0	1 (0.3)		1 (0.1)
Respiratory tract infection	0	1 (0.3)		1 (0.1)
Subcutaneous abscess	0	1 (0.3)		1 (0.1)
Suspected COVID-19	0	1 (0.3)		1 (0.1)
Vaginal infection	0	1 (0.3)		1 (0.1)
Viral infection	2 (0.6)	1 (0.3)		3 (0.4)
Acute sinusitis	1 (0.3)	0		1 (0.1)
Cellulitis	1 (0.3)	0		1 (0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Infections and infestations (Cont.)				
Folliculitis	1 (0.3)	0		1 (0.1)
Gastroenteritis	1 (0.3)	0		1 (0.1)
Otitis media	1 (0.3)	0		1 (0.1)
Perineal cellulitis	1 (0.3)	0		1 (0.1)
Pyelonephritis	1 (0.3)	0		1 (0.1)
Pyelonephritis acute	1 (0.3)	0		1 (0.1)
Septic shock	1 (0.3)	0		1 (0.1)
Skin infection	1 (0.3)	0		1 (0.1)
Tooth abscess	1 (0.3)	0		1 (0.1)
Urinary tract infection	3 (0.9)	0		3 (0.4)
Viral upper respiratory tract infection	1 (0.3)	0		1 (0.1)
Vulvovaginal candidiasis	1 (0.3)	0		1 (0.1)
Immune system disorders	1 (0.3)	1 (0.3)		2 (0.3)
Hypersensitivity	0	1 (0.3)		1 (0.1)
Seasonal allergy	1 (0.3)	0		1 (0.1)
Metabolism and nutrition disorders	5 (1.5)	3 (0.9)		8 (1.2)
Hyperlipidaemia	0	2 (0.6)		2 (0.3)
Type 2 diabetes mellitus	0	2 (0.6)		2 (0.3)
Vitamin D deficiency	2 (0.6)	1 (0.3)		3 (0.4)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Metabolism and nutrition disorders (Cont.)				
Dehydration	1 (0.3)	0		1 (0.1)
Hypercholesterolaemia	1 (0.3)	0		1 (0.1)
Metabolic acidosis	1 (0.3)	0		1 (0.1)
Psychiatric disorders	1 (0.3)	5 (1.4)		6 (0.9)
Depression	0	3 (0.9)		3 (0.4)
Anxiety	1 (0.3)	1 (0.3)		2 (0.3)
Drug abuse	0	1 (0.3)		1 (0.1)
Nervous system disorders	6 (1.8)	4 (1.2)		10 (1.5)
Headache	3 (0.9)	3 (0.9)		6 (0.9)
Sciatica	0	1 (0.3)		1 (0.1)
Migraine	1 (0.3)	0		1 (0.1)
Nerve compression	1 (0.3)	0		1 (0.1)
Poor quality sleep	1 (0.3)	0		1 (0.1)
Eye disorders	0	1 (0.3)		1 (0.1)
Vision blurred	0	1 (0.3)		1 (0.1)
Ear and labyrinth disorders	3 (0.9)	0		3 (0.4)
Diplacusis	1 (0.3)	0		1 (0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Ear and labyrinth disorders (Cont.)				
Tympanic membrane perforation	1 (0.3)	0		1 (0.1)
Vertigo	1 (0.3)	0		1 (0.1)
Cardiac disorders	1 (0.3)	1 (0.3)		2 (0.3)
Cardiac failure congestive	0	1 (0.3)		1 (0.1)
Acute left ventricular failure	1 (0.3)	0		1 (0.1)
Atrial fibrillation	1 (0.3)	0		1 (0.1)
Vascular disorders	6 (1.8)	4 (1.2)		10 (1.5)
Hypertension	5 (1.5)	4 (1.2)		9 (1.3)
Aortic dilatation	1 (0.3)	0		1 (0.1)
Respiratory, thoracic and mediastinal disorders	6 (1.8)	5 (1.4)		11 (1.6)
Cough	2 (0.6)	3 (0.9)		5 (0.7)
Nasal congestion	3 (0.9)	2 (0.6)		5 (0.7)
Rhinorrhoea	1 (0.3)	2 (0.6)		3 (0.4)
Dyspnoea	0	1 (0.3)		1 (0.1)
Productive cough	0	1 (0.3)		1 (0.1)
Respiratory tract congestion	0	1 (0.3)		1 (0.1)
Acute respiratory failure	1 (0.3)	0		1 (0.1)
Oropharyngeal pain	2 (0.6)	0		2 (0.3)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Gastrointestinal disorders	7 (2.1)	6 (1.7)		13 (1.9)
Gastrooesophageal reflux disease	2 (0.6)	2 (0.6)		4 (0.6)
Abdominal pain	0	1 (0.3)		1 (0.1)
Abdominal pain upper	0	1 (0.3)		1 (0.1)
Diarrhoea	1 (0.3)	1 (0.3)		2 (0.3)
Gastric ulcer	0	1 (0.3)		1 (0.1)
Nausea	0	1 (0.3)		1 (0.1)
Oesophageal ulcer	0	1 (0.3)		1 (0.1)
Rectal fissure	0	1 (0.3)		1 (0.1)
Dental caries	2 (0.6)	0		2 (0.3)
Dyspepsia	1 (0.3)	0		1 (0.1)
Periodontal disease	1 (0.3)	0		1 (0.1)
Hepatobiliary disorders	1 (0.3)	0		1 (0.1)
Cholelithiasis	1 (0.3)	0		1 (0.1)
Skin and subcutaneous tissue disorders	5 (1.5)	1 (0.3)		6 (0.9)
Dry skin	0	1 (0.3)		1 (0.1)
Acne	2 (0.6)	0		2 (0.3)
Dermatitis	1 (0.3)	0		1 (0.1)
Rash	1 (0.3)	0		1 (0.1)
Urticaria	2 (0.6)	0		2 (0.3)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Musculoskeletal and connective tissue disorders	10 (3.0)	8 (2.3)		18 (2.6)
Back pain	3 (0.9)	2 (0.6)		5 (0.7)
Arthralgia	0	1 (0.3)		1 (0.1)
Limb mass	0	1 (0.3)		1 (0.1)
Muscle tightness	0	1 (0.3)		1 (0.1)
Musculoskeletal pain	1 (0.3)	1 (0.3)		2 (0.3)
Myalgia	1 (0.3)	1 (0.3)		2 (0.3)
Neck pain	2 (0.6)	1 (0.3)		3 (0.4)
Arthritis	2 (0.6)	0		2 (0.3)
Axillary mass	1 (0.3)	0		1 (0.1)
Osteoarthritis	1 (0.3)	0		1 (0.1)
Spinal stenosis	1 (0.3)	0		1 (0.1)
Renal and urinary disorders	3 (0.9)	0		3 (0.4)
Chromaturia	1 (0.3)	0		1 (0.1)
Micturition urgency	1 (0.3)	0		1 (0.1)
Nephrolithiasis	1 (0.3)	0		1 (0.1)
Renal colic	1 (0.3)	0		1 (0.1)
Pregnancy, puerperium and perinatal conditions	1 (0.3)	0		1 (0.1)
Abortion spontaneous	1 (0.3)	0		1 (0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Reproductive system and breast disorders	3 (0.9)	1 (0.3)		4 (0.6)
Postmenopausal haemorrhage	0	1 (0.3)		1 (0.1)
Benign prostatic hyperplasia	1 (0.3)	0		1 (0.1)
Breast cyst	1 (0.3)	0		1 (0.1)
Pelvic prolapse	1 (0.3)	0		1 (0.1)
General disorders and administration site conditions	6 (1.8)	6 (1.7)		12 (1.8)
Fatigue	2 (0.6)	1 (0.3)		3 (0.4)
Feeling hot	0	1 (0.3)		1 (0.1)
Injection site pain	1 (0.3)	1 (0.3)		2 (0.3)
Non-cardiac chest pain	1 (0.3)	1 (0.3)		2 (0.3)
Oedema peripheral	1 (0.3)	1 (0.3)		2 (0.3)
Swelling face	0	1 (0.3)		1 (0.1)
Asthenia	1 (0.3)	0		1 (0.1)
Chest discomfort	1 (0.3)	0		1 (0.1)
Chills	1 (0.3)	0		1 (0.1)
Investigations	3 (0.9)	1 (0.3)		4 (0.6)
Hepatic enzyme increased	1 (0.3)	1 (0.3)		2 (0.3)
Blood pressure increased	1 (0.3)	0		1 (0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Positive

System Organ Class Preferred Term	Placebo (N=337) n (%)	mRNA-1273 (N=347) n (%)	Rate Ratio (95% CI)	Total (N=684) n (%)
Investigations (Cont.)				
International normalised ratio increased	1 (0.3)	0		1 (0.1)
Injury, poisoning and procedural complications	6 (1.8)	5 (1.4)		11 (1.6)
Fall	0	1 (0.3)		1 (0.1)
Head injury	0	1 (0.3)		1 (0.1)
Joint injury	0	1 (0.3)		1 (0.1)
Meniscus injury	0	1 (0.3)		1 (0.1)
Procedural pain	0	1 (0.3)		1 (0.1)
Spinal compression fracture	0	1 (0.3)		1 (0.1)
Animal bite	1 (0.3)	0		1 (0.1)
Concussion	1 (0.3)	0		1 (0.1)
Contusion	1 (0.3)	0		1 (0.1)
Facial bones fracture	1 (0.3)	0		1 (0.1)
Ligament sprain	1 (0.3)	0		1 (0.1)
Procedural anxiety	1 (0.3)	0		1 (0.1)
Skin abrasion	1 (0.3)	0		1 (0.1)
Skin laceration	1 (0.3)	0		1 (0.1)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	12 (14.3)	20 (23.0)		32 (18.7)
Number of Unsolicited Adverse Events	14	40		54
Infections and infestations	6 (7.1)	10 (11.5)		16 (9.4)
Sinusitis	0	2 (2.3)		2 (1.2)
Suspected COVID-19	0	2 (2.3)		2 (1.2)
Conjunctivitis	1 (1.2)	1 (1.1)		2 (1.2)
Gastroenteritis viral	0	1 (1.1)		1 (0.6)
Infected bite	0	1 (1.1)		1 (0.6)
Lyme disease	0	1 (1.1)		1 (0.6)
Pharyngitis	0	1 (1.1)		1 (0.6)
Pharyngitis streptococcal	0	1 (1.1)		1 (0.6)
Staphylococcal infection	0	1 (1.1)		1 (0.6)
Tooth infection	0	1 (1.1)		1 (0.6)
Upper respiratory tract infection	0	1 (1.1)		1 (0.6)
COVID-19	3 (3.6)	0		3 (1.8)
Sinusitis bacterial	1 (1.2)	0		1 (0.6)
Urinary tract infection	1 (1.2)	0		1 (0.6)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.1)		1 (0.6)
Squamous cell carcinoma of skin	0	1 (1.1)		1 (0.6)
Blood and lymphatic system disorders	0	1 (1.1)		1 (0.6)
Iron deficiency anaemia	0	1 (1.1)		1 (0.6)
Metabolism and nutrition disorders	0	2 (2.3)		2 (1.2)
Hypercholesterolaemia	0	1 (1.1)		1 (0.6)
Hyperlipidaemia	0	1 (1.1)		1 (0.6)
Psychiatric disorders	0	1 (1.1)		1 (0.6)
Depression	0	1 (1.1)		1 (0.6)
Nervous system disorders	1 (1.2)	3 (3.4)		4 (2.3)
Headache	0	3 (3.4)		3 (1.8)
VIth nerve paralysis	1 (1.2)	0		1 (0.6)
Ear and labyrinth disorders	1 (1.2)	1 (1.1)		2 (1.2)
Meniere's disease	0	1 (1.1)		1 (0.6)
Vertigo	1 (1.2)	0		1 (0.6)

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Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Vascular disorders	0	3 (3.4)		3 (1.8)
Hypertension	0	2 (2.3)		2 (1.2)
Hot flush	0	1 (1.1)		1 (0.6)
Respiratory, thoracic and mediastinal disorders	1 (1.2)	4 (4.6)		5 (2.9)
Oropharyngeal pain	0	2 (2.3)		2 (1.2)
Rhinorrhoea	0	2 (2.3)		2 (1.2)
Cough	0	1 (1.1)		1 (0.6)
Dyspnoea	0	1 (1.1)		1 (0.6)
Nasal congestion	1 (1.2)	1 (1.1)		2 (1.2)
Respiratory tract congestion	1 (1.2)	0		1 (0.6)
Gastrointestinal disorders	2 (2.4)	1 (1.1)		3 (1.8)
Inguinal hernia	0	1 (1.1)		1 (0.6)
Constipation	1 (1.2)	0		1 (0.6)
Mouth haemorrhage	1 (1.2)	0		1 (0.6)
Skin and subcutaneous tissue disorders	0	2 (2.3)		2 (1.2)
Pruritus	0	1 (1.1)		1 (0.6)
Rash erythematous	0	1 (1.1)		1 (0.6)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190303.sas 21JUN2021 14:57

Table 14.3.1.19.3.3
Subject Incidence of Unsolicited Medically-Attended TEAE by Baseline SARS-CoV-2 Status, System Organ Class and Preferred Term in Overall Stage
Safety Set

Baseline SARS-CoV-2 Status: Missing

System Organ Class Preferred Term	Placebo (N=84) n (%)	mRNA-1273 (N=87) n (%)	Rate Ratio (95% CI)	Total (N=171) n (%)
Musculoskeletal and connective tissue disorders	0	1 (1.1)		1 (0.6)
Myalgia	0	1 (1.1)		1 (0.6)
General disorders and administration site conditions	0	2 (2.3)		2 (1.2)
Fatigue	0	1 (1.1)		1 (0.6)
Pain	0	1 (1.1)		1 (0.6)
Injury, poisoning and procedural complications	2 (2.4)	2 (2.3)		4 (2.3)
Meniscus injury	0	1 (1.1)		1 (0.6)
Wound	0	1 (1.1)		1 (0.6)
Dental restoration failure	1 (1.2)	0		1 (0.6)
Procedural pain	1 (1.2)	0		1 (0.6)

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MedDRA version 23.0.
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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	157 (1.0)	140 (0.9)		297 (1.0)
Number of Unsolicited Adverse Events	193	172		365
Infections and infestations	31 (0.2)	19 (0.1)		50 (0.2)
Sinusitis	0	2 (<0.1)		2 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Appendicitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Cellulitis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis	0	1 (<0.1)		1 (<0.1)
Diverticulitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Fungal infection	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Peritonitis	0	1 (<0.1)		1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pneumonia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Tooth infection	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Urinary tract infection	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Bacterial vaginosis	1 (<0.1)	0		1 (<0.1)
Bronchitis	2 (<0.1)	0		2 (<0.1)
COVID-19	7 (<0.1)	0		7 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
Gingivitis	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Viral infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (<0.1)	8 (<0.1)		16 (<0.1)
Prostate cancer	1 (<0.1)	2 (<0.1)		3 (<0.1)
Basal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Plasma cell myeloma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	0	1 (<0.1)		1 (<0.1)
Breast cancer	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Malignant melanoma	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	0	2 (<0.1)		2 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Immune system disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Drug hypersensitivity	2 (<0.1)	0		2 (<0.1)
Endocrine disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypothyroidism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)
Metabolism and nutrition disorders	3 (<0.1)	2 (<0.1)		5 (<0.1)
Decreased appetite	0	1 (<0.1)		1 (<0.1)
Diabetes mellitus inadequate control	0	1 (<0.1)		1 (<0.1)
Dehydration	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders (Cont.)				
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Hypokalaemia	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	7 (<0.1)	1 (<0.1)		8 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Alcoholism	1 (<0.1)	0		1 (<0.1)
Anxiety	3 (<0.1)	0		3 (<0.1)
Confusional state	1 (<0.1)	0		1 (<0.1)
Depression	2 (<0.1)	0		2 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	14 (<0.1)	10 (<0.1)		24 (<0.1)
Headache	3 (<0.1)	3 (<0.1)		6 (<0.1)
Syncope	1 (<0.1)	2 (<0.1)		3 (<0.1)
Cerebrovascular accident	0	1 (<0.1)		1 (<0.1)
Dizziness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Migraine	2 (<0.1)	1 (<0.1)		3 (<0.1)
Migraine with aura	0	1 (<0.1)		1 (<0.1)
Sciatica	1 (<0.1)	1 (<0.1)		2 (<0.1)
Subarachnoid haemorrhage	0	1 (<0.1)		1 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Carpal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)

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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Presyncope	1 (<0.1)	0		1 (<0.1)
Seizure	1 (<0.1)	0		1 (<0.1)
Eye disorders	3 (<0.1)	3 (<0.1)		6 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Retinal detachment	1 (<0.1)	1 (<0.1)		2 (<0.1)
Scleritis	0	1 (<0.1)		1 (<0.1)
Blepharitis	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	1 (<0.1)	0		1 (<0.1)
Vertigo	1 (<0.1)	0		1 (<0.1)
Cardiac disorders	7 (<0.1)	11 (<0.1)		18 (<0.1)
Atrial fibrillation	3 (<0.1)	4 (<0.1)		7 (<0.1)
Coronary artery disease	1 (<0.1)	2 (<0.1)		3 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Cardiac failure congestive	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Cardiac failure	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Vascular disorders	18 (0.1)	7 (<0.1)		25 (<0.1)
Hypertension	12 (<0.1)	4 (<0.1)	0.33 (0.11, 0.98)	16 (<0.1)
Hypertensive urgency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Deep vein thrombosis	1 (<0.1)	0		1 (<0.1)
Hypertensive emergency	1 (<0.1)	0		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Respiratory, thoracic and mediastinal disorders	10 (<0.1)	12 (<0.1)		22 (<0.1)
Cough	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pleural effusion	0	2 (<0.1)		2 (<0.1)
Asthma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Nasal congestion	0	1 (<0.1)		1 (<0.1)
Nasal septum deviation	0	1 (<0.1)		1 (<0.1)
Pleurisy	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	2 (<0.1)	1 (<0.1)		3 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Rhinorrhoea	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Acute respiratory failure	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)				
Chronic obstructive pulmonary disease	2 (<0.1)	0		2 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Hypoxia	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	0		1 (<0.1)
Gastrointestinal disorders	14 (<0.1)	19 (0.1)		33 (0.1)
Abdominal pain	2 (<0.1)	4 (<0.1)		6 (<0.1)
Colitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Diarrhoea	0	3 (<0.1)		3 (<0.1)
Nausea	1 (<0.1)	3 (<0.1)		4 (<0.1)
Abdominal pain upper	1 (<0.1)	1 (<0.1)		2 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Enteritis	0	1 (<0.1)		1 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Pancreatitis	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Small intestinal obstruction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Umbilical hernia	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	1 (<0.1)	0		1 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastritis	2 (<0.1)	0		2 (<0.1)
Gastrointestinal haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrooesophageal reflux disease	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	0	3 (<0.1)		3 (<0.1)
Cholelithiasis	0	2 (<0.1)		2 (<0.1)
Cholecystitis	0	1 (<0.1)		1 (<0.1)
Skin and subcutaneous tissue disorders	1 (<0.1)	5 (<0.1)		6 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	0	1 (<0.1)		1 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	23 (0.2)	13 (<0.1)		36 (0.1)
Arthralgia	3 (<0.1)	3 (<0.1)		6 (<0.1)
Neck pain	0	2 (<0.1)		2 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)

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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Spinal stenosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Back pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Muscle spasms	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myalgia	0	1 (<0.1)		1 (<0.1)
Rotator cuff syndrome	1 (<0.1)	1 (<0.1)		2 (<0.1)
Tendonitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Costochondritis	1 (<0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Musculoskeletal chest pain	2 (<0.1)	0		2 (<0.1)
Osteoarthritis	3 (<0.1)	0		3 (<0.1)
Osteonecrosis	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	4 (<0.1)	3 (<0.1)		7 (<0.1)
Nephrolithiasis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Acute kidney injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Urinary retention	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Reproductive system and breast disorders	1 (<0.1)	2 (<0.1)		3 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	10 (<0.1)	18 (0.1)		28 (<0.1)
Injection site pain	0	3 (<0.1)		3 (<0.1)
Fatigue	3 (<0.1)	2 (<0.1)		5 (<0.1)
Injection site erythema	0	2 (<0.1)		2 (<0.1)
Injection site macule	0	2 (<0.1)		2 (<0.1)
Pain	1 (<0.1)	2 (<0.1)		3 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Non-cardiac chest pain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Oedema peripheral	0	1 (<0.1)		1 (<0.1)
Pyrexia	0	1 (<0.1)		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	1 (<0.1)	0		1 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190401.sas 21JUN2021 14:57

Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Investigations	2 (<0.1)	3 (<0.1)		5 (<0.1)
Hepatic enzyme increased	0	2 (<0.1)		2 (<0.1)
Blood pressure increased	1 (<0.1)	1 (<0.1)		2 (<0.1)
Blood pressure systolic increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	19 (0.1)	14 (<0.1)		33 (0.1)
Limb injury	0	2 (<0.1)		2 (<0.1)
Skin laceration	0	2 (<0.1)		2 (<0.1)
Ankle fracture	0	1 (<0.1)		1 (<0.1)
Burns second degree	0	1 (<0.1)		1 (<0.1)
Facial bones fracture	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Hip fracture	2 (<0.1)	1 (<0.1)		3 (<0.1)
Ligament injury	0	1 (<0.1)		1 (<0.1)
Ligament sprain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle strain	2 (<0.1)	1 (<0.1)		3 (<0.1)
Road traffic accident	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190401.sas 21JUN2021 14:57

Table 14.3.1.19.4.1
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days After Any Injection
Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	0		1 (<0.1)
Foot fracture	1 (<0.1)	0		1 (<0.1)
Foreign body	1 (<0.1)	0		1 (<0.1)
Joint dislocation	1 (<0.1)	0		1 (<0.1)
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Meniscus injury	1 (<0.1)	0		1 (<0.1)
Muscle rupture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Procedural haemorrhage	1 (<0.1)	0		1 (<0.1)
Procedural pain	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)

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MedDRA version 23.0.
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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	373 (2.5)	326 (2.1)		699 (2.3)
Number of Unsolicited Adverse Events	507	448		955
Infections and infestations	110 (0.7)	56 (0.4)		166 (0.5)
Pneumonia	6 (<0.1)	6 (<0.1)		12 (<0.1)
Appendicitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Cellulitis	4 (<0.1)	3 (<0.1)		7 (<0.1)
Sepsis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Suspected COVID-19	1 (<0.1)	3 (<0.1)		4 (<0.1)
Upper respiratory tract infection	2 (<0.1)	3 (<0.1)		5 (<0.1)
Urinary tract infection	3 (<0.1)	3 (<0.1)		6 (<0.1)
Peritonitis	0	2 (<0.1)		2 (<0.1)
Pyelonephritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Septic shock	2 (<0.1)	2 (<0.1)		4 (<0.1)
Sinusitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Tooth infection	0	2 (<0.1)		2 (<0.1)
Abdominal abscess	0	1 (<0.1)		1 (<0.1)
Abscess limb	0	1 (<0.1)		1 (<0.1)
Appendicitis perforated	1 (<0.1)	1 (<0.1)		2 (<0.1)
Atypical pneumonia	0	1 (<0.1)		1 (<0.1)
Bacterial pyelonephritis	0	1 (<0.1)		1 (<0.1)
Bronchitis	4 (<0.1)	1 (<0.1)		5 (<0.1)
COVID-19	55 (0.4)	1 (<0.1)	0.02 (0.00, 0.10)	56 (0.2)

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MedDRA version 23.0.
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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Campylobacter gastroenteritis	0	1 (<0.1)		1 (<0.1)
Clostridium difficile infection	0	1 (<0.1)		1 (<0.1)
Conjunctivitis	0	1 (<0.1)		1 (<0.1)
Conjunctivitis viral	0	1 (<0.1)		1 (<0.1)
Diabetic foot infection	0	1 (<0.1)		1 (<0.1)
Diverticulitis	5 (<0.1)	1 (<0.1)		6 (<0.1)
Ear infection	0	1 (<0.1)		1 (<0.1)
Eyelid infection	0	1 (<0.1)		1 (<0.1)
Fungal infection	0	1 (<0.1)		1 (<0.1)
Furuncle	0	1 (<0.1)		1 (<0.1)
Gastroenteritis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Gastrointestinal infection	0	1 (<0.1)		1 (<0.1)
Giardiasis	0	1 (<0.1)		1 (<0.1)
Hepatitis A	0	1 (<0.1)		1 (<0.1)
Herpes zoster	0	1 (<0.1)		1 (<0.1)
Pharyngitis streptococcal	2 (<0.1)	1 (<0.1)		3 (<0.1)
Pneumonia mycoplasmal	0	1 (<0.1)		1 (<0.1)
Proctitis chlamydial	0	1 (<0.1)		1 (<0.1)
Salpingitis	0	1 (<0.1)		1 (<0.1)
Toxic shock syndrome	0	1 (<0.1)		1 (<0.1)
Appendiceal abscess	1 (<0.1)	0		1 (<0.1)
Bacterial vaginosis	1 (<0.1)	0		1 (<0.1)
COVID-19 pneumonia	7 (<0.1)	0		7 (<0.1)
Coccidioidomycosis	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Infections and infestations (Cont.)				
Gastroenteritis bacterial	1 (<0.1)	0		1 (<0.1)
Genital herpes	1 (<0.1)	0		1 (<0.1)
Gingivitis	2 (<0.1)	0		2 (<0.1)
Meningitis aseptic	1 (<0.1)	0		1 (<0.1)
Osteomyelitis	1 (<0.1)	0		1 (<0.1)
Rhinovirus infection	1 (<0.1)	0		1 (<0.1)
Staphylococcal infection	1 (<0.1)	0		1 (<0.1)
Tonsillitis	1 (<0.1)	0		1 (<0.1)
Tooth abscess	1 (<0.1)	0		1 (<0.1)
Viral diarrhoea	1 (<0.1)	0		1 (<0.1)
Viral infection	1 (<0.1)	0		1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21 (0.1)	22 (0.1)		43 (0.1)
Prostate cancer	1 (<0.1)	4 (<0.1)		5 (<0.1)
Plasma cell myeloma	0	2 (<0.1)		2 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)		1 (<0.1)
Basal cell carcinoma	2 (<0.1)	1 (<0.1)		3 (<0.1)
Breast cancer	1 (<0.1)	1 (<0.1)		2 (<0.1)
Breast cancer female	0	1 (<0.1)		1 (<0.1)
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Colon cancer	0	1 (<0.1)		1 (<0.1)
Intraductal proliferative breast lesion	1 (<0.1)	1 (<0.1)		2 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Invasive ductal breast carcinoma	0	1 (<0.1)		1 (<0.1)
Invasive lobular breast carcinoma	0	1 (<0.1)		1 (<0.1)
Malignant melanoma in situ	0	1 (<0.1)		1 (<0.1)
Meningioma	0	1 (<0.1)		1 (<0.1)
Metastases to lung	0	1 (<0.1)		1 (<0.1)
Metastatic neoplasm	0	1 (<0.1)		1 (<0.1)
Oesophageal carcinoma	0	1 (<0.1)		1 (<0.1)
Rectal cancer	0	1 (<0.1)		1 (<0.1)
Throat cancer	0	1 (<0.1)		1 (<0.1)
Thymoma malignant	0	1 (<0.1)		1 (<0.1)
Uterine leiomyoma	1 (<0.1)	1 (<0.1)		2 (<0.1)
Endometrial cancer	2 (<0.1)	0		2 (<0.1)
Hepatic cancer	1 (<0.1)	0		1 (<0.1)
Lung adenocarcinoma	1 (<0.1)	0		1 (<0.1)
Malignant melanoma	1 (<0.1)	0		1 (<0.1)
Non-small cell lung cancer	1 (<0.1)	0		1 (<0.1)
Papillary thyroid cancer	1 (<0.1)	0		1 (<0.1)
Penile cancer	1 (<0.1)	0		1 (<0.1)
Prostate cancer metastatic	1 (<0.1)	0		1 (<0.1)
Skin cancer	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma	1 (<0.1)	0		1 (<0.1)
Squamous cell carcinoma of skin	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (Cont.)				
Thyroid cancer	1 (<0.1)	0		1 (<0.1)
Thyroid cancer recurrent	1 (<0.1)	0		1 (<0.1)
Blood and lymphatic system disorders	3 (<0.1)	6 (<0.1)		9 (<0.1)
Leukocytosis	0	2 (<0.1)		2 (<0.1)
Anaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Iron deficiency anaemia	0	1 (<0.1)		1 (<0.1)
Lymph node pain	0	1 (<0.1)		1 (<0.1)
Lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Blood loss anaemia	1 (<0.1)	0		1 (<0.1)
Thrombocytosis	1 (<0.1)	0		1 (<0.1)
Immune system disorders	3 (<0.1)	4 (<0.1)		7 (<0.1)
Drug hypersensitivity	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypersensitivity	0	1 (<0.1)		1 (<0.1)
Seasonal allergy	0	1 (<0.1)		1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Anaphylactic reaction	1 (<0.1)	0		1 (<0.1)
Endocrine disorders	2 (<0.1)	1 (<0.1)		3 (<0.1)
Hypothyroidism	1 (<0.1)	1 (<0.1)		2 (<0.1)
Thyroid mass	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Metabolism and nutrition disorders	14 (<0.1)	9 (<0.1)		23 (<0.1)
Diabetic ketoacidosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Decreased appetite	0	1 (<0.1)		1 (<0.1)
Dehydration	1 (<0.1)	1 (<0.1)		2 (<0.1)
Diabetes mellitus inadequate control	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypoglycaemia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypokalaemia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Malnutrition	0	1 (<0.1)		1 (<0.1)
Obesity	0	1 (<0.1)		1 (<0.1)
Dyslipidaemia	1 (<0.1)	0		1 (<0.1)
Gout	2 (<0.1)	0		2 (<0.1)
Hypomagnesaemia	1 (<0.1)	0		1 (<0.1)
Hyponatraemia	1 (<0.1)	0		1 (<0.1)
Lactic acidosis	1 (<0.1)	0		1 (<0.1)
Type 2 diabetes mellitus	3 (<0.1)	0		3 (<0.1)
Vitamin B1 deficiency	1 (<0.1)	0		1 (<0.1)
Psychiatric disorders	12 (<0.1)	8 (<0.1)		20 (<0.1)
Depression	2 (<0.1)	3 (<0.1)		5 (<0.1)
Anxiety	4 (<0.1)	1 (<0.1)		5 (<0.1)
Grief reaction	0	1 (<0.1)		1 (<0.1)
Intentional self-injury	0	1 (<0.1)		1 (<0.1)
Mental status changes	0	1 (<0.1)		1 (<0.1)
Schizoaffective disorder	1 (<0.1)	1 (<0.1)		2 (<0.1)
Substance-induced mood disorder	0	1 (<0.1)		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Psychiatric disorders (Cont.)				
Alcoholism	1 (<0.1)	0		1 (<0.1)
Confusional state	2 (<0.1)	0		2 (<0.1)
Depression suicidal	1 (<0.1)	0		1 (<0.1)
Major depression	1 (<0.1)	0		1 (<0.1)
Mania	1 (<0.1)	0		1 (<0.1)
Schizophrenia	1 (<0.1)	0		1 (<0.1)
Nervous system disorders	37 (0.2)	31 (0.2)		68 (0.2)
Headache	6 (<0.1)	7 (<0.1)	1.16 (0.41, 3.30)	13 (<0.1)
Syncope	5 (<0.1)	5 (<0.1)		10 (<0.1)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Facial paralysis	0	3 (<0.1)		3 (<0.1)
Migraine	3 (<0.1)	3 (<0.1)		6 (<0.1)
Lumbar radiculopathy	0	2 (<0.1)		2 (<0.1)
Sciatica	3 (<0.1)	2 (<0.1)		5 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Cervical radiculopathy	0	1 (<0.1)		1 (<0.1)
Dizziness	4 (<0.1)	1 (<0.1)		5 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Migraine with aura	1 (<0.1)	1 (<0.1)		2 (<0.1)
Seizure	1 (<0.1)	1 (<0.1)		2 (<0.1)
Anosmia	2 (<0.1)	0		2 (<0.1)
Aphasia	1 (<0.1)	0		1 (<0.1)
Arachnoid cyst	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Nervous system disorders (Cont.)				
Carpal tunnel syndrome	1 (<0.1)	0		1 (<0.1)
Encephalopathy	2 (<0.1)	0		2 (<0.1)
Nerve compression	1 (<0.1)	0		1 (<0.1)
Neuralgia	1 (<0.1)	0		1 (<0.1)
Paraesthesia	1 (<0.1)	0		1 (<0.1)
Presyncope	1 (<0.1)	0		1 (<0.1)
Shift work disorder	1 (<0.1)	0		1 (<0.1)
Transient global amnesia	1 (<0.1)	0		1 (<0.1)
Transient ischaemic attack	2 (<0.1)	0		2 (<0.1)
Trigeminal neuralgia	1 (<0.1)	0		1 (<0.1)
Eye disorders	3 (<0.1)	4 (<0.1)		7 (<0.1)
Retinal detachment	1 (<0.1)	2 (<0.1)		3 (<0.1)
Glaucoma	0	1 (<0.1)		1 (<0.1)
Scleritis	0	1 (<0.1)		1 (<0.1)
Blepharitis	1 (<0.1)	0		1 (<0.1)
Blindness	1 (<0.1)	0		1 (<0.1)
Retinal tear	1 (<0.1)	0		1 (<0.1)
Ear and labyrinth disorders	2 (<0.1)	2 (<0.1)		4 (<0.1)
Vertigo	2 (<0.1)	2 (<0.1)		4 (<0.1)
Cardiac disorders	25 (0.2)	31 (0.2)		56 (0.2)
Atrial fibrillation	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Myocardial infarction	1 (<0.1)	3 (<0.1)		4 (<0.1)
Cardiac failure congestive	3 (<0.1)	2 (<0.1)		5 (<0.1)
Coronary artery disease	2 (<0.1)	2 (<0.1)		4 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Acute coronary syndrome	0	1 (<0.1)		1 (<0.1)
Acute myocardial infarction	3 (<0.1)	1 (<0.1)		4 (<0.1)
Angina unstable	0	1 (<0.1)		1 (<0.1)
Atrial flutter	0	1 (<0.1)		1 (<0.1)
Atrioventricular block	0	1 (<0.1)		1 (<0.1)
Bradycardia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiac failure acute	0	1 (<0.1)		1 (<0.1)
Cardiac flutter	0	1 (<0.1)		1 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Left ventricular hypertrophy	0	1 (<0.1)		1 (<0.1)
Palpitations	0	1 (<0.1)		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Supraventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Tachycardia	0	1 (<0.1)		1 (<0.1)
Ventricular extrasystoles	0	1 (<0.1)		1 (<0.1)
Ventricular tachycardia	0	1 (<0.1)		1 (<0.1)
Acute left ventricular failure	1 (<0.1)	0		1 (<0.1)
Angina pectoris	2 (<0.1)	0		2 (<0.1)
Atrioventricular block complete	1 (<0.1)	0		1 (<0.1)
Atrioventricular block second degree	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Cardiac disorders (Cont.)				
Cardiac failure	1 (<0.1)	0		1 (<0.1)
Paroxysmal arrhythmia	1 (<0.1)	0		1 (<0.1)
Pericarditis	1 (<0.1)	0		1 (<0.1)
Ventricular fibrillation	1 (<0.1)	0		1 (<0.1)
Vascular disorders	32 (0.2)	18 (0.1)		50 (0.2)
Hypertension	21 (0.1)	7 (<0.1)	0.33 (0.14, 0.76)	28 (<0.1)
Deep vein thrombosis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Haematoma	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypertensive urgency	1 (<0.1)	2 (<0.1)		3 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Hypertensive emergency	1 (<0.1)	1 (<0.1)		2 (<0.1)
Peripheral vascular disorder	0	1 (<0.1)		1 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Systolic hypertension	0	1 (<0.1)		1 (<0.1)
Aortic aneurysm	1 (<0.1)	0		1 (<0.1)
Aortic stenosis	1 (<0.1)	0		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Phlebitis	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis superficial	1 (<0.1)	0		1 (<0.1)
Varicose vein	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Respiratory, thoracic and mediastinal disorders	29 (0.2)	21 (0.1)		50 (0.2)
Cough	1 (<0.1)	3 (<0.1)		4 (<0.1)
Dyspnoea	1 (<0.1)	3 (<0.1)		4 (<0.1)
Pleural effusion	1 (<0.1)	3 (<0.1)		4 (<0.1)
Acute respiratory failure	5 (<0.1)	2 (<0.1)		7 (<0.1)
Asthma	5 (<0.1)	2 (<0.1)		7 (<0.1)
Nasal congestion	1 (<0.1)	2 (<0.1)		3 (<0.1)
Pulmonary embolism	4 (<0.1)	2 (<0.1)		6 (<0.1)
Rhinorrhoea	1 (<0.1)	2 (<0.1)		3 (<0.1)
Bronchiectasis	0	1 (<0.1)		1 (<0.1)
Chronic obstructive pulmonary disease	5 (<0.1)	1 (<0.1)		6 (<0.1)
Nasal septum deviation	0	1 (<0.1)		1 (<0.1)
Pleurisy	0	1 (<0.1)		1 (<0.1)
Pneumothorax	0	1 (<0.1)		1 (<0.1)
Respiratory failure	0	1 (<0.1)		1 (<0.1)
Tachypnoea	0	1 (<0.1)		1 (<0.1)
Emphysema	1 (<0.1)	0		1 (<0.1)
Epistaxis	1 (<0.1)	0		1 (<0.1)
Hypoxia	2 (<0.1)	0		2 (<0.1)
Oropharyngeal pain	1 (<0.1)	0		1 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Rhinalgia	1 (<0.1)	0		1 (<0.1)
Sleep apnoea syndrome	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders	31 (0.2)	41 (0.3)		72 (0.2)
Abdominal pain	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Nausea	3 (<0.1)	6 (<0.1)		9 (<0.1)
Colitis	2 (<0.1)	5 (<0.1)		7 (<0.1)
Diarrhoea	0	5 (<0.1)		5 (<0.1)
Small intestinal obstruction	1 (<0.1)	4 (<0.1)		5 (<0.1)
Abdominal pain upper	3 (<0.1)	2 (<0.1)		5 (<0.1)
Gastritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Pancreatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Vomiting	1 (<0.1)	2 (<0.1)		3 (<0.1)
Abdominal pain lower	0	1 (<0.1)		1 (<0.1)
Barrett's oesophagus	0	1 (<0.1)		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer	0	1 (<0.1)		1 (<0.1)
Duodenal ulcer perforation	0	1 (<0.1)		1 (<0.1)
Dyspepsia	0	1 (<0.1)		1 (<0.1)
Enteritis	0	1 (<0.1)		1 (<0.1)
Faeces discoloured	0	1 (<0.1)		1 (<0.1)
Gastrooesophageal reflux disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Inguinal hernia	0	1 (<0.1)		1 (<0.1)
Large intestine perforation	0	1 (<0.1)		1 (<0.1)
Large intestine polyp	0	1 (<0.1)		1 (<0.1)
Rectal haemorrhage	0	1 (<0.1)		1 (<0.1)
Umbilical hernia	0	1 (<0.1)		1 (<0.1)
Abdominal discomfort	1 (<0.1)	0		1 (<0.1)

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Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Gastrointestinal disorders (Cont.)				
Abdominal hernia	2 (<0.1)	0		2 (<0.1)
Dysphagia	1 (<0.1)	0		1 (<0.1)
Femoral hernia	1 (<0.1)	0		1 (<0.1)
Gastric ulcer	1 (<0.1)	0		1 (<0.1)
Gastric ulcer haemorrhage	1 (<0.1)	0		1 (<0.1)
Gastrointestinal haemorrhage	3 (<0.1)	0		3 (<0.1)
Hiatus hernia	1 (<0.1)	0		1 (<0.1)
Ileus paralytic	1 (<0.1)	0		1 (<0.1)
Oesophageal stenosis	1 (<0.1)	0		1 (<0.1)
Retching	1 (<0.1)	0		1 (<0.1)
Tooth socket haemorrhage	1 (<0.1)	0		1 (<0.1)
Hepatobiliary disorders	3 (<0.1)	7 (<0.1)		10 (<0.1)
Cholelithiasis	0	4 (<0.1)		4 (<0.1)
Cholecystitis	1 (<0.1)	3 (<0.1)		4 (<0.1)
Bile duct stone	0	1 (<0.1)		1 (<0.1)
Cholecystitis acute	1 (<0.1)	0		1 (<0.1)
Hepatic cyst	1 (<0.1)	0		1 (<0.1)
Skin and subcutaneous tissue disorders	4 (<0.1)	7 (<0.1)		11 (<0.1)
Rash	0	2 (<0.1)		2 (<0.1)
Actinic keratosis	0	1 (<0.1)		1 (<0.1)
Dermatitis	0	1 (<0.1)		1 (<0.1)
Hidradenitis	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Skin and subcutaneous tissue disorders (Cont.)				
Pruritus	0	1 (<0.1)		1 (<0.1)
Rash macular	0	1 (<0.1)		1 (<0.1)
Urticaria	2 (<0.1)	1 (<0.1)		3 (<0.1)
Angioedema	1 (<0.1)	0		1 (<0.1)
Subcutaneous emphysema	1 (<0.1)	0		1 (<0.1)
Musculoskeletal and connective tissue disorders	37 (0.2)	35 (0.2)		72 (0.2)
Arthralgia	4 (<0.1)	6 (<0.1)		10 (<0.1)
Osteoarthritis	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Back pain	5 (<0.1)	3 (<0.1)		8 (<0.1)
Neck pain	0	3 (<0.1)		3 (<0.1)
Flank pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rotator cuff syndrome	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spinal pain	0	2 (<0.1)		2 (<0.1)
Spinal stenosis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Spondylolisthesis	0	2 (<0.1)		2 (<0.1)
Bursitis	0	1 (<0.1)		1 (<0.1)
Foot deformity	0	1 (<0.1)		1 (<0.1)
Muscle spasms	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscular weakness	1 (<0.1)	1 (<0.1)		2 (<0.1)
Musculoskeletal chest pain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Musculoskeletal pain	0	1 (<0.1)		1 (<0.1)

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Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Musculoskeletal and connective tissue disorders (Cont.)				
Myalgia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Osteonecrosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Spinal osteoarthritis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Tendonitis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Arthritis	1 (<0.1)	0		1 (<0.1)
Cervical spinal stenosis	2 (<0.1)	0		2 (<0.1)
Costochondritis	1 (<0.1)	0		1 (<0.1)
Intervertebral disc protrusion	1 (<0.1)	0		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Rhabdomyolysis	1 (<0.1)	0		1 (<0.1)
Undifferentiated connective tissue disease	1 (<0.1)	0		1 (<0.1)
Renal and urinary disorders	11 (<0.1)	11 (<0.1)		22 (<0.1)
Nephrolithiasis	4 (<0.1)	6 (<0.1)		10 (<0.1)
Acute kidney injury	3 (<0.1)	4 (<0.1)		7 (<0.1)
Urinary retention	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urinary incontinence	0	1 (<0.1)		1 (<0.1)
Chronic kidney disease	1 (<0.1)	0		1 (<0.1)
Pelvi-ureteric obstruction	1 (<0.1)	0		1 (<0.1)
Renal colic	1 (<0.1)	0		1 (<0.1)
Renal impairment	1 (<0.1)	0		1 (<0.1)

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Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Pregnancy, puerperium and perinatal conditions	1 (<0.1)	1 (<0.1)		2 (<0.1)
Abortion spontaneous	1 (<0.1)	1 (<0.1)		2 (<0.1)
Reproductive system and breast disorders	6 (<0.1)	5 (<0.1)		11 (<0.1)
Breast mass	0	1 (<0.1)		1 (<0.1)
Ovarian cyst	0	1 (<0.1)		1 (<0.1)
Pelvic pain	0	1 (<0.1)		1 (<0.1)
Uterine haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Vulval disorder	0	1 (<0.1)		1 (<0.1)
Benign prostatic hyperplasia	2 (<0.1)	0		2 (<0.1)
Endometrial hyperplasia	1 (<0.1)	0		1 (<0.1)
Menorrhagia	1 (<0.1)	0		1 (<0.1)
Prostatomegaly	1 (<0.1)	0		1 (<0.1)
Congenital, familial and genetic disorders	1 (<0.1)	0		1 (<0.1)
Talipes	1 (<0.1)	0		1 (<0.1)
General disorders and administration site conditions	19 (0.1)	27 (0.2)		46 (0.2)
Fatigue	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)
Injection site pain	0	4 (<0.1)		4 (<0.1)
Non-cardiac chest pain	2 (<0.1)	3 (<0.1)		5 (<0.1)

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Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
General disorders and administration site conditions (Cont.)				
Injection site erythema	0	2 (<0.1)		2 (<0.1)
Injection site macule	0	2 (<0.1)		2 (<0.1)
Pain	2 (<0.1)	2 (<0.1)		4 (<0.1)
Adverse drug reaction	0	1 (<0.1)		1 (<0.1)
Chest discomfort	1 (<0.1)	1 (<0.1)		2 (<0.1)
Chest pain	1 (<0.1)	1 (<0.1)		2 (<0.1)
Drug withdrawal syndrome	0	1 (<0.1)		1 (<0.1)
Generalised oedema	0	1 (<0.1)		1 (<0.1)
Injection site lymphadenopathy	0	1 (<0.1)		1 (<0.1)
Injection site rash	0	1 (<0.1)		1 (<0.1)
Oedema peripheral	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pyrexia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Asthenia	2 (<0.1)	0		2 (<0.1)
Chills	1 (<0.1)	0		1 (<0.1)
Gait disturbance	1 (<0.1)	0		1 (<0.1)
Incarcerated hernia	2 (<0.1)	0		2 (<0.1)
Investigations	8 (<0.1)	8 (<0.1)		16 (<0.1)
Hepatic enzyme increased	0	4 (<0.1)		4 (<0.1)
Blood pressure systolic increased	4 (<0.1)	2 (<0.1)		6 (<0.1)
Blood pressure diastolic increased	2 (<0.1)	1 (<0.1)		3 (<0.1)
Blood pressure increased	2 (<0.1)	1 (<0.1)		3 (<0.1)

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Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Investigations (Cont.)				
Heart rate irregular	0	1 (<0.1)		1 (<0.1)
Transaminases increased	1 (<0.1)	0		1 (<0.1)
Injury, poisoning and procedural complications	45 (0.3)	42 (0.3)		87 (0.3)
Fall	2 (<0.1)	5 (<0.1)		7 (<0.1)
Limb injury	1 (<0.1)	3 (<0.1)		4 (<0.1)
Skin laceration	5 (<0.1)	3 (<0.1)		8 (<0.1)
Ankle fracture	2 (<0.1)	2 (<0.1)		4 (<0.1)
Concussion	0	2 (<0.1)		2 (<0.1)
Facial bones fracture	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hip fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Ligament sprain	3 (<0.1)	2 (<0.1)		5 (<0.1)
Rib fracture	3 (<0.1)	2 (<0.1)		5 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Tooth fracture	0	2 (<0.1)		2 (<0.1)
Alcohol poisoning	0	1 (<0.1)		1 (<0.1)
Animal bite	1 (<0.1)	1 (<0.1)		2 (<0.1)
Burns second degree	0	1 (<0.1)		1 (<0.1)
Cartilage injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Clavicle fracture	0	1 (<0.1)		1 (<0.1)
Craniocerebral injury	0	1 (<0.1)		1 (<0.1)
Femoral neck fracture	0	1 (<0.1)		1 (<0.1)
Femur fracture	0	1 (<0.1)		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190402.sas 21JUN2021 14:58

Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Fibula fracture	0	1 (<0.1)		1 (<0.1)
Gastrointestinal procedural complication	0	1 (<0.1)		1 (<0.1)
Head injury	0	1 (<0.1)		1 (<0.1)
Humerus fracture	0	1 (<0.1)		1 (<0.1)
Incarcerated incisional hernia	0	1 (<0.1)		1 (<0.1)
Joint injury	0	1 (<0.1)		1 (<0.1)
Ligament injury	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lower limb fracture	0	1 (<0.1)		1 (<0.1)
Meniscus injury	2 (<0.1)	1 (<0.1)		3 (<0.1)
Muscle rupture	1 (<0.1)	1 (<0.1)		2 (<0.1)
Muscle strain	3 (<0.1)	1 (<0.1)		4 (<0.1)
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural haemorrhage	1 (<0.1)	1 (<0.1)		2 (<0.1)
Procedural nausea	0	1 (<0.1)		1 (<0.1)
Procedural pain	5 (<0.1)	1 (<0.1)		6 (<0.1)
Road traffic accident	3 (<0.1)	1 (<0.1)		4 (<0.1)
Superficial injury of eye	0	1 (<0.1)		1 (<0.1)
Wrist fracture	0	1 (<0.1)		1 (<0.1)
Foot fracture	4 (<0.1)	0		4 (<0.1)
Foreign body	2 (<0.1)	0		2 (<0.1)
Hand fracture	1 (<0.1)	0		1 (<0.1)
Joint dislocation	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190402.sas 21JUN2021 14:58

Table 14.3.1.19.4.2
Subject Incidence of Unsolicited Severe Medically-Attended TEAE by System Organ Class and Preferred Term in Overall Stage Safety Set

System Organ Class Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Injury, poisoning and procedural complications (Cont.)				
Lumbar vertebral fracture	1 (<0.1)	0		1 (<0.1)
Phrenic nerve injury	1 (<0.1)	0		1 (<0.1)
Post procedural haematoma	1 (<0.1)	0		1 (<0.1)
Post-traumatic pain	1 (<0.1)	0		1 (<0.1)
Procedural complication	1 (<0.1)	0		1 (<0.1)
Scapula fracture	1 (<0.1)	0		1 (<0.1)
Sternal fracture	1 (<0.1)	0		1 (<0.1)
Tendon rupture	1 (<0.1)	0		1 (<0.1)
Tibia fracture	1 (<0.1)	0		1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190402.sas 21JUN2021 14:58

Table 14.3.1.19.5.1
Summary of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of 1st Vaccination
Safety Set (Dose 1)

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	68 (0.4)	74 (0.5)	142 (0.5)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	10 (<0.1)	10 (<0.1)	20 (<0.1)
Leading to Discontinuation from Study Vaccine	2 (<0.1)	0	2 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	8 (<0.1)	4 (<0.1)	12 (<0.1)
Unsolicited TEAEs Related to Study Vaccination			
All	24 (0.2)	28 (0.2)	52 (0.2)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	4 (<0.1)	2 (<0.1)	6 (<0.1)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (<0.1)	0	1 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
N: Number of participants in Safety Set who received 1st injection
n: Number of participants who reported AEs in specified category
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190501.sas 10JUN2021 13:00

Table 14.3.1.19.5.2
Summary of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of 2nd Vaccination
Safety Set (Dose 2)

	Placebo (N=14631) n (%)	mRNA-1273 (N=14731) n (%)	Total (N=29362) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	41 (0.3)	47 (0.3)	88 (0.3)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (<0.1)	0	5 (<0.1)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	3 (<0.1)	4 (<0.1)	7 (<0.1)
Unsolicited TEAEs Related to Study Vaccination			
All	21 (0.1)	23 (0.2)	44 (0.1)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	2 (<0.1)	0	2 (<0.1)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	0	2 (<0.1)	2 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
N: Number of participants in Safety Set who received 2nd injection
n: Number of participants who reported AEs in specified category
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190502.sas 10JUN2021 13:00

Table 14.3.1.19.5.3
Summary of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination
Safety Set

	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination			
All	105 (0.7)	118 (0.8)	223 (0.7)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	14 (<0.1)	10 (<0.1)	24 (<0.1)
Leading to Discontinuation from Study Vaccine	2 (<0.1)	0	2 (<0.1)
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	11 (<0.1)	8 (<0.1)	19 (<0.1)
Unsolicited TEAEs Related to Study Vaccination			
All	44 (0.3)	50 (0.3)	94 (0.3)
Serious	0	0	0
Fatal	0	0	0
Medically-Attended	5 (<0.1)	2 (<0.1)	7 (<0.1)
Leading to Discontinuation from Study Vaccine	0	0	0
Leading to Discontinuation from Participation in the Study	0	0	0
Severe	1 (<0.1)	2 (<0.1)	3 (<0.1)

A treatment-emergent adverse event (TEAE) is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure.
N: Number of participants in Safety Set who received any injection
n: Number of participants who reported AEs in specified category
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190503.sas 21JUN2021 14:58

Table 14.3.1.19.6.1
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of First Vaccination by Preferred Term
Safety Set (Dose 1)

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Number of Subjects with Immediate Unsolicited Adverse Events	68 (0.4)	8 (<0.1)	74 (0.5)	4 (<0.1)	142 (0.5)	12 (<0.1)
Number of Immediate Unsolicited Adverse Events	74	8	84	4	158	12
Hypertension	15 (<0.1)	5 (<0.1)	13 (<0.1)	2 (<0.1)	28 (<0.1)	7 (<0.1)
Tachypnoea	16 (0.1)	0	13 (<0.1)	0	29 (<0.1)	0
Injection site pain	2 (<0.1)	0	5 (<0.1)	0	7 (<0.1)	0
Bradycardia	3 (<0.1)	0	4 (<0.1)	1 (<0.1)	7 (<0.1)	1 (<0.1)
Arthralgia	2 (<0.1)	0	3 (<0.1)	0	5 (<0.1)	0
Blood pressure increased	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	6 (<0.1)	2 (<0.1)
Dizziness	5 (<0.1)	0	3 (<0.1)	0	8 (<0.1)	0
Fatigue	7 (<0.1)	0	3 (<0.1)	0	10 (<0.1)	0
Headache	2 (<0.1)	0	3 (<0.1)	0	5 (<0.1)	0
Hypoaesthesia	0	0	2 (<0.1)	0	2 (<0.1)	0

N: Number of participants in Safety Set who received 1st injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190601.sas 10JUN2021 13:01

Table 14.3.1.19.6.1
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of First Vaccination by Preferred Term
Safety Set (Dose 1)

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Injection site haematoma	0	0	2 (<0.1)	0	2 (<0.1)	0
Injection site swelling	0	0	2 (<0.1)	0	2 (<0.1)	0
Presyncope	3 (<0.1)	0	2 (<0.1)	0	5 (<0.1)	0
Tachycardia	2 (<0.1)	0	2 (<0.1)	0	4 (<0.1)	0
Blood pressure systolic abnormal	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Blood pressure systolic increased	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)	1 (<0.1)
Chills	0	0	1 (<0.1)	0	1 (<0.1)	0
Feeling hot	0	0	1 (<0.1)	0	1 (<0.1)	0
Flushing	0	0	1 (<0.1)	0	1 (<0.1)	0
Haematoma	0	0	1 (<0.1)	0	1 (<0.1)	0
Hyperhidrosis	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Hypersensitivity	0	0	1 (<0.1)	0	1 (<0.1)	0

N: Number of participants in Safety Set who received 1st injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190601.sas 10JUN2021 13:01

Table 14.3.1.19.6.1
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of First Vaccination by Preferred Term
Safety Set (Dose 1)

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Hypoaesthesia oral	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site bruising	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site paraesthesia	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site pruritus	0	0	1 (<0.1)	0	1 (<0.1)	0
Limb discomfort	0	0	1 (<0.1)	0	1 (<0.1)	0
Musculoskeletal chest pain	0	0	1 (<0.1)	0	1 (<0.1)	0
Musculoskeletal pain	0	0	1 (<0.1)	0	1 (<0.1)	0
Myalgia	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Non-cardiac chest pain	0	0	1 (<0.1)	0	1 (<0.1)	0
Oxygen saturation decreased	0	0	1 (<0.1)	0	1 (<0.1)	0
Pruritus	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Salivary hypersecretion	0	0	1 (<0.1)	0	1 (<0.1)	0

N: Number of participants in Safety Set who received 1st injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190601.sas 10JUN2021 13:01

Table 14.3.1.19.6.1
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of First Vaccination by Preferred Term
Safety Set (Dose 1)

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Syncope	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Vessel puncture site haemorrhage	0	0	1 (<0.1)	0	1 (<0.1)	0
COVID-19	1 (<0.1)	0	0	0	1 (<0.1)	0
Dysgeusia	2 (<0.1)	0	0	0	2 (<0.1)	0
Hypotension	1 (<0.1)	0	0	0	1 (<0.1)	0
Paraesthesia	1 (<0.1)	0	0	0	1 (<0.1)	0
Procedural nausea	1 (<0.1)	0	0	0	1 (<0.1)	0
Systolic hypertension	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

N: Number of participants in Safety Set who received 1st injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190601.sas 10JUN2021 13:01

Table 14.3.1.19.6.2
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Second Vaccination by Preferred Term
Safety Set (Dose 2)

	Placebo (N=14631)		mRNA-1273 (N=14731)		Total (N=29362)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Number of Subjects with Immediate Unsolicited Adverse Events	41 (0.3)	3 (<0.1)	47 (0.3)	4 (<0.1)	88 (0.3)	7 (<0.1)
Number of Immediate Unsolicited Adverse Events	50	3	53	5	103	8
Dizziness	4 (<0.1)	0	6 (<0.1)	0	10 (<0.1)	0
Hypertension	8 (<0.1)	3 (<0.1)	6 (<0.1)	1 (<0.1)	14 (<0.1)	4 (<0.1)
Fatigue	3 (<0.1)	0	5 (<0.1)	1 (<0.1)	8 (<0.1)	1 (<0.1)
Blood pressure increased	1 (<0.1)	0	4 (<0.1)	1 (<0.1)	5 (<0.1)	1 (<0.1)
Injection site pain	1 (<0.1)	0	4 (<0.1)	0	5 (<0.1)	0
Bradycardia	4 (<0.1)	0	3 (<0.1)	0	7 (<0.1)	0
Headache	4 (<0.1)	0	3 (<0.1)	0	7 (<0.1)	0
Arthralgia	6 (<0.1)	0	2 (<0.1)	0	8 (<0.1)	0
Chills	0	0	2 (<0.1)	0	2 (<0.1)	0
Dysgeusia	1 (<0.1)	0	2 (<0.1)	0	3 (<0.1)	0

N: Number of participants in Safety Set who received 2nd injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190602.sas 10JUN2021 13:01

Table 14.3.1.19.6.2
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Second Vaccination by Preferred Term
Safety Set (Dose 2)

	Placebo (N=14631)		mRNA-1273 (N=14731)		Total (N=29362)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Injection site erythema	1 (<0.1)	0	2 (<0.1)	0	3 (<0.1)	0
Tachycardia	0	0	2 (<0.1)	0	2 (<0.1)	0
Asymptomatic COVID-19	0	0	1 (<0.1)	0	1 (<0.1)	0
Blood pressure systolic increased	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site bruising	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site haematoma	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site haemorrhage	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site induration	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Injection site swelling	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Limb discomfort	0	0	1 (<0.1)	0	1 (<0.1)	0
Malaise	0	0	1 (<0.1)	0	1 (<0.1)	0
Myalgia	3 (<0.1)	0	1 (<0.1)	0	4 (<0.1)	0

N: Number of participants in Safety Set who received 2nd injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190602.sas 10JUN2021 13:01

Table 14.3.1.19.6.2
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Second Vaccination by Preferred Term
Safety Set (Dose 2)

	Placebo (N=14631)		mRNA-1273 (N=14731)		Total (N=29362)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Palpitations	0	0	1 (<0.1)	0	1 (<0.1)	0
Paraesthesia	0	0	1 (<0.1)	0	1 (<0.1)	0
Anxiety	1 (<0.1)	0	0	0	1 (<0.1)	0
Disturbance in attention	1 (<0.1)	0	0	0	1 (<0.1)	0
Feeling abnormal	1 (<0.1)	0	0	0	1 (<0.1)	0
Hypotension	1 (<0.1)	0	0	0	1 (<0.1)	0
Injection site pruritus	1 (<0.1)	0	0	0	1 (<0.1)	0
Musculoskeletal chest pain	1 (<0.1)	0	0	0	1 (<0.1)	0
Nausea	2 (<0.1)	0	0	0	2 (<0.1)	0
Pain in extremity	1 (<0.1)	0	0	0	1 (<0.1)	0
Pruritus	2 (<0.1)	0	0	0	2 (<0.1)	0

N: Number of participants in Safety Set who received 2nd injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190602.sas 10JUN2021 13:01

Table 14.3.1.19.6.3
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term
Safety Set

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Number of Subjects with Immediate Unsolicited Adverse Events	105 (0.7)	11 (<0.1)	118 (0.8)	8 (<0.1)	223 (0.7)	19 (<0.1)
Number of Immediate Unsolicited Adverse Events	124	11	137	9	261	20
Hypertension	22 (0.1)	8 (<0.1)	19 (0.1)	3 (<0.1)	41 (0.1)	11 (<0.1)
Tachypnoea	16 (0.1)	0	13 (<0.1)	0	29 (<0.1)	0
Injection site pain	3 (<0.1)	0	9 (<0.1)	0	12 (<0.1)	0
Dizziness	9 (<0.1)	0	8 (<0.1)	0	17 (<0.1)	0
Fatigue	10 (<0.1)	0	8 (<0.1)	1 (<0.1)	18 (<0.1)	1 (<0.1)
Blood pressure increased	4 (<0.1)	1 (<0.1)	7 (<0.1)	2 (<0.1)	11 (<0.1)	3 (<0.1)
Bradycardia	6 (<0.1)	0	6 (<0.1)	1 (<0.1)	12 (<0.1)	1 (<0.1)
Headache	6 (<0.1)	0	6 (<0.1)	0	12 (<0.1)	0
Arthralgia	8 (<0.1)	0	5 (<0.1)	0	13 (<0.1)	0
Tachycardia	2 (<0.1)	0	4 (<0.1)	0	6 (<0.1)	0

N: Number of participants in Safety Set who received any injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190603.sas 21JUN2021 14:58

Table 14.3.1.19.6.3
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term
Safety Set

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Chills	0	0	3 (<0.1)	0	3 (<0.1)	0
Injection site haematoma	0	0	3 (<0.1)	0	3 (<0.1)	0
Injection site swelling	0	0	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)
Blood pressure systolic increased	2 (<0.1)	1 (<0.1)	2 (<0.1)	0	4 (<0.1)	1 (<0.1)
Dysgeusia	3 (<0.1)	0	2 (<0.1)	0	5 (<0.1)	0
Hypoaesthesia	0	0	2 (<0.1)	0	2 (<0.1)	0
Injection site bruising	2 (<0.1)	0	2 (<0.1)	0	4 (<0.1)	0
Injection site erythema	1 (<0.1)	0	2 (<0.1)	0	3 (<0.1)	0
Limb discomfort	0	0	2 (<0.1)	0	2 (<0.1)	0
Myalgia	4 (<0.1)	0	2 (<0.1)	0	6 (<0.1)	0
Presyncope	3 (<0.1)	0	2 (<0.1)	0	5 (<0.1)	0
Asymptomatic COVID-19	0	0	1 (<0.1)	0	1 (<0.1)	0

N: Number of participants in Safety Set who received any injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190603.sas 21JUN2021 14:58

Table 14.3.1.19.6.3
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term
Safety Set

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Blood pressure systolic abnormal	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Feeling hot	0	0	1 (<0.1)	0	1 (<0.1)	0
Flushing	0	0	1 (<0.1)	0	1 (<0.1)	0
Haematoma	0	0	1 (<0.1)	0	1 (<0.1)	0
Hyperhidrosis	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Hypersensitivity	0	0	1 (<0.1)	0	1 (<0.1)	0
Hypoaesthesia oral	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site haemorrhage	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Injection site induration	0	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Injection site paraesthesia	0	0	1 (<0.1)	0	1 (<0.1)	0
Injection site pruritus	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Malaise	0	0	1 (<0.1)	0	1 (<0.1)	0

N: Number of participants in Safety Set who received any injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190603.sas 21JUN2021 14:58

Table 14.3.1.19.6.3
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term
Safety Set

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Musculoskeletal chest pain	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Musculoskeletal pain	0	0	1 (<0.1)	0	1 (<0.1)	0
Non-cardiac chest pain	0	0	1 (<0.1)	0	1 (<0.1)	0
Oxygen saturation decreased	0	0	1 (<0.1)	0	1 (<0.1)	0
Palpitations	0	0	1 (<0.1)	0	1 (<0.1)	0
Paraesthesia	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Pruritus	2 (<0.1)	0	1 (<0.1)	0	3 (<0.1)	0
Salivary hypersecretion	0	0	1 (<0.1)	0	1 (<0.1)	0
Syncope	1 (<0.1)	0	1 (<0.1)	0	2 (<0.1)	0
Vessel puncture site haemorrhage	0	0	1 (<0.1)	0	1 (<0.1)	0
Anxiety	1 (<0.1)	0	0	0	1 (<0.1)	0
COVID-19	1 (<0.1)	0	0	0	1 (<0.1)	0

N: Number of participants in Safety Set who received any injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190603.sas 21JUN2021 14:58

Table 14.3.1.19.6.3
Subject Incidence of Immediate Unsolicited Adverse Event Occurring within 30 Minutes of Any Vaccination by Preferred Term
Safety Set

	Placebo (N=15162)		mRNA-1273 (N=15184)		Total (N=30346)	
	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)	Any n (%)	Severe n (%)
Disturbance in attention	1 (<0.1)	0	0	0	1 (<0.1)	0
Feeling abnormal	1 (<0.1)	0	0	0	1 (<0.1)	0
Hypotension	2 (<0.1)	0	0	0	2 (<0.1)	0
Nausea	2 (<0.1)	0	0	0	2 (<0.1)	0
Pain in extremity	1 (<0.1)	0	0	0	1 (<0.1)	0
Procedural nausea	1 (<0.1)	0	0	0	1 (<0.1)	0
Systolic hypertension	1 (<0.1)	1 (<0.1)	0	0	1 (<0.1)	1 (<0.1)

N: Number of participants in Safety Set who received any injection; n: Number of participants who reported AEs in specified category; %=n/N*100.
MedDRA version 23.0.
Preferred term is sorted by descending frequency in mRNA-1273 Any column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301190603.sas 21JUN2021 14:58

Table 14.3.1.21.1.3.1
Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After First Injection
Safety Set (Dose 1)

	>=18 and <65 Years			>=65 Years			Overall		
Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Solicited Adverse Reaction [1]	406 (3.6)	484 (4.2)	890 (3.9)	92 (2.5)	143 (3.8)	235 (3.1)	498 (3.3)	627 (4.1)	1125 (3.7)
Number of Subjects Reporting Solicited Local Adverse Reaction [1]	23 (0.2)	144 (1.3)	167 (0.7)	10 (0.3)	44 (1.2)	54 (0.7)	33 (0.2)	188 (1.2)	221 (0.7)
Number of Subjects Reporting Solicited Systemic Adverse Reaction [1]	388 (3.4)	365 (3.2)	753 (3.3)	83 (2.2)	106 (2.8)	189 (2.5)	471 (3.1)	471 (3.1)	942 (3.1)
Number of Subjects Reporting Solicited Injection Site Reaction [2]	20 (0.2)	131 (1.1)	151 (0.7)	9 (0.2)	43 (1.1)	52 (0.7)	29 (0.2)	174 (1.1)	203 (0.7)
Number of Solicited Adverse Reactions [1]	584	705	1289	130	195	325	714	900	1614
Pain	14 (0.1)	54 (0.5)	68 (0.3)	3 (<0.1)	12 (0.3)	15 (0.2)	17 (0.1)	66 (0.4)	83 (0.3)
Erythema (Redness)	5 (<0.1)	62 (0.5)	67 (0.3)	4 (0.1)	27 (0.7)	31 (0.4)	9 (<0.1)	89 (0.6)	98 (0.3)

Percentages are based on the number of safety subjects.
[1] Solicited adverse reaction (AR) limits to terms collected on eDiary, i.e., local solicited AR includes Pain, Erythema, Swelling, and Axillary Swelling or Tenderness, and systemic solicited AR includes Fever, Headache, Fatigue, Myalgia, Arthralgia, Nausea/Vomiting, and Chills.
[2] Solicited injection site reaction includes Pain, Erythema, and Swelling.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030121010301.sas 10JUN2021 13:01

Table 14.3.1.21.1.3.1
Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After First Injection
Safety Set (Dose 1)

	>=18 and <65 Years			>=65 Years			Overall		
Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Swelling (Hardness)	4 (<0.1)	51 (0.4)	55 (0.2)	2 (<0.1)	11 (0.3)	13 (0.2)	6 (<0.1)	62 (0.4)	68 (0.2)
Axillary Swelling or Tenderness	4 (<0.1)	15 (0.1)	19 (<0.1)	1 (<0.1)	1 (<0.1)	2 (<0.1)	5 (<0.1)	16 (0.1)	21 (<0.1)
Fever	21 (0.2)	18 (0.2)	39 (0.2)	5 (0.1)	8 (0.2)	13 (0.2)	26 (0.2)	26 (0.2)	52 (0.2)
Headache	189 (1.7)	162 (1.4)	351 (1.5)	34 (0.9)	33 (0.9)	67 (0.9)	223 (1.5)	195 (1.3)	418 (1.4)
Fatigue	110 (1.0)	113 (1.0)	223 (1.0)	16 (0.4)	31 (0.8)	47 (0.6)	126 (0.8)	144 (0.9)	270 (0.9)
Myalgia	64 (0.6)	73 (0.6)	137 (0.6)	18 (0.5)	23 (0.6)	41 (0.5)	82 (0.5)	96 (0.6)	178 (0.6)
Arthralgia	56 (0.5)	57 (0.5)	113 (0.5)	21 (0.6)	22 (0.6)	43 (0.6)	77 (0.5)	79 (0.5)	156 (0.5)
Nausea/Vomiting	56 (0.5)	47 (0.4)	103 (0.5)	12 (0.3)	16 (0.4)	28 (0.4)	68 (0.4)	63 (0.4)	131 (0.4)
Chills	22 (0.2)	23 (0.2)	45 (0.2)	8 (0.2)	7 (0.2)	15 (0.2)	30 (0.2)	30 (0.2)	60 (0.2)

Percentages are based on the number of safety subjects.
[1] Solicited adverse reaction (AR) limits to terms collected on eDiary, i.e., local solicited AR includes Pain, Erythema, Swelling, and Axillary Swelling or Tenderness, and systemic solicited AR includes Fever, Headache, Fatigue, Myalgia, Arthralgia, Nausea/Vomiting, and Chills.
[2] Solicited injection site reaction includes Pain, Erythema, and Swelling.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030121010301.sas 10JUN2021 13:01

Table 14.3.1.21.1.3.2
Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After Second Injection
Safety Set (Dose 2)

	>=18 and <65 Years			>=65 Years			Overall		
Term	Placebo (N=10964) n (%)	mRNA-1273 (N=11027) n (%)	Total (N=21991) n (%)	Placebo (N=3667) n (%)	mRNA-1273 (N=3704) n (%)	Total (N=7371) n (%)	Placebo (N=14631) n (%)	mRNA-1273 (N=14731) n (%)	Total (N=29362) n (%)
Number of Subjects Reporting Solicited Adverse Reaction [1]	639 (5.8)	566 (5.1)	1205 (5.5)	192 (5.2)	186 (5.0)	378 (5.1)	831 (5.7)	752 (5.1)	1583 (5.4)
Number of Subjects Reporting Solicited Local Adverse Reaction [1]	58 (0.5)	34 (0.3)	92 (0.4)	19 (0.5)	21 (0.6)	40 (0.5)	77 (0.5)	55 (0.4)	132 (0.4)
Number of Subjects Reporting Solicited Systemic Adverse Reaction [1]	599 (5.5)	541 (4.9)	1140 (5.2)	179 (4.9)	169 (4.6)	348 (4.7)	778 (5.3)	710 (4.8)	1488 (5.1)
Number of Subjects Reporting Solicited Injection Site Reaction [2]	53 (0.5)	29 (0.3)	82 (0.4)	19 (0.5)	20 (0.5)	39 (0.5)	72 (0.5)	49 (0.3)	121 (0.4)
Number of Solicited Adverse Reactions [1]	1146	986	2132	313	306	619	1459	1292	2751
Pain	45 (0.4)	25 (0.2)	70 (0.3)	15 (0.4)	12 (0.3)	27 (0.4)	60 (0.4)	37 (0.3)	97 (0.3)
Erythema (Redness)	5 (<0.1)	4 (<0.1)	9 (<0.1)	3 (<0.1)	6 (0.2)	9 (0.1)	8 (<0.1)	10 (<0.1)	18 (<0.1)

Percentages are based on the number of safety subjects.
[1] Solicited adverse reaction (AR) limits to terms collected on eDiary, i.e., local solicited AR includes Pain, Erythema, Swelling, and Axillary Swelling or Tenderness, and systemic solicited AR includes Fever, Headache, Fatigue, Myalgia, Arthralgia, Nausea/Vomiting, and Chills.
[2] Solicited injection site reaction includes Pain, Erythema, and Swelling.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030121010302.sas 10JUN2021 13:01

Table 14.3.1.21.1.3.2
Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After Second Injection
Safety Set (Dose 2)

	>=18 and <65 Years			>=65 Years			Overall		
Term	Placebo (N=10964) n (%)	mRNA-1273 (N=11027) n (%)	Total (N=21991) n (%)	Placebo (N=3667) n (%)	mRNA-1273 (N=3704) n (%)	Total (N=7371) n (%)	Placebo (N=14631) n (%)	mRNA-1273 (N=14731) n (%)	Total (N=29362) n (%)
Swelling (Hardness)	3 (<0.1)	3 (<0.1)	6 (<0.1)	3 (<0.1)	5 (0.1)	8 (0.1)	6 (<0.1)	8 (<0.1)	14 (<0.1)
Axillary Swelling or Tenderness	6 (<0.1)	5 (<0.1)	11 (<0.1)	0	1 (<0.1)	1 (<0.1)	6 (<0.1)	6 (<0.1)	12 (<0.1)
Fever	68 (0.6)	51 (0.5)	119 (0.5)	17 (0.5)	18 (0.5)	35 (0.5)	85 (0.6)	69 (0.5)	154 (0.5)
Headache	338 (3.1)	297 (2.7)	635 (2.9)	73 (2.0)	64 (1.7)	137 (1.9)	411 (2.8)	361 (2.5)	772 (2.6)
Fatigue	186 (1.7)	153 (1.4)	339 (1.5)	47 (1.3)	61 (1.6)	108 (1.5)	233 (1.6)	214 (1.5)	447 (1.5)
Myalgia	155 (1.4)	128 (1.2)	283 (1.3)	42 (1.1)	35 (0.9)	77 (1.0)	197 (1.3)	163 (1.1)	360 (1.2)
Arthralgia	56 (0.5)	75 (0.7)	131 (0.6)	31 (0.8)	26 (0.7)	57 (0.8)	87 (0.6)	101 (0.7)	188 (0.6)
Nausea/Vomiting	110 (1.0)	99 (0.9)	209 (1.0)	35 (1.0)	31 (0.8)	66 (0.9)	145 (1.0)	130 (0.9)	275 (0.9)
Chills	68 (0.6)	47 (0.4)	115 (0.5)	23 (0.6)	17 (0.5)	40 (0.5)	91 (0.6)	64 (0.4)	155 (0.5)

Percentages are based on the number of safety subjects.
[1] Solicited adverse reaction (AR) limits to terms collected on eDiary, i.e., local solicited AR includes Pain, Erythema, Swelling, and Axillary Swelling or Tenderness, and systemic solicited AR includes Fever, Headache, Fatigue, Myalgia, Arthralgia, Nausea/Vomiting, and Chills.
[2] Solicited injection site reaction includes Pain, Erythema, and Swelling.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030121010302.sas 10JUN2021 13:01

Table 14.3.1.21.1.3.3
Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After Any Injection
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Number of Subjects Reporting Solicited Adverse Reaction [1]	979 (8.6)	1001 (8.8)	1980 (8.7)	271 (7.2)	312 (8.3)	583 (7.8)	1250 (8.2)	1313 (8.6)	2563 (8.4)
Number of Subjects Reporting Solicited Local Adverse Reaction [1]	80 (0.7)	174 (1.5)	254 (1.1)	29 (0.8)	64 (1.7)	93 (1.2)	109 (0.7)	238 (1.6)	347 (1.1)
Number of Subjects Reporting Solicited Systemic Adverse Reaction [1]	930 (8.2)	864 (7.6)	1794 (7.9)	251 (6.7)	261 (6.9)	512 (6.8)	1181 (7.8)	1125 (7.4)	2306 (7.6)
Number of Subjects Reporting Solicited Injection Site Reaction [2]	72 (0.6)	156 (1.4)	228 (1.0)	28 (0.7)	63 (1.7)	91 (1.2)	100 (0.7)	219 (1.4)	319 (1.1)
Number of Solicited Adverse Reactions [1]	1730	1691	3421	443	501	944	2173	2192	4365
Pain	58 (0.5)	75 (0.7)	133 (0.6)	18 (0.5)	24 (0.6)	42 (0.6)	76 (0.5)	99 (0.7)	175 (0.6)
Erythema (Redness)	10 (<0.1)	66 (0.6)	76 (0.3)	7 (0.2)	33 (0.9)	40 (0.5)	17 (0.1)	99 (0.7)	116 (0.4)

Percentages are based on the number of safety subjects.
[1] Solicited adverse reaction (AR) limits to terms collected on eDiary, i.e., local solicited AR includes Pain, Erythema, Swelling, and Axillary Swelling or Tenderness, and systemic solicited AR includes Fever, Headache, Fatigue, Myalgia, Arthralgia, Nausea/Vomiting, and Chills.
[2] Solicited injection site reaction includes Pain, Erythema, and Swelling.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030121010303.sas 10JUN2021 13:02

Table 14.3.1.21.1.3.3
Subject Incidence of Solicited Adverse Reaction [1] with Onset Day after Day 7 After Any Injection
Safety Set

	>=18 and <65 Years			>=65 Years			Overall		
Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Total (N=22826) n (%)	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Total (N=7520) n (%)	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Total (N=30346) n (%)
Swelling (Hardness)	7 (<0.1)	54 (0.5)	61 (0.3)	5 (0.1)	16 (0.4)	21 (0.3)	12 (<0.1)	70 (0.5)	82 (0.3)
Axillary Swelling or Tenderness	10 (<0.1)	20 (0.2)	30 (0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	11 (<0.1)	22 (0.1)	33 (0.1)
Fever	88 (0.8)	69 (0.6)	157 (0.7)	22 (0.6)	26 (0.7)	48 (0.6)	110 (0.7)	95 (0.6)	205 (0.7)
Headache	504 (4.4)	444 (3.9)	948 (4.2)	104 (2.8)	94 (2.5)	198 (2.6)	608 (4.0)	538 (3.5)	1146 (3.8)
Fatigue	291 (2.6)	260 (2.3)	551 (2.4)	61 (1.6)	89 (2.4)	150 (2.0)	352 (2.3)	349 (2.3)	701 (2.3)
Myalgia	218 (1.9)	191 (1.7)	409 (1.8)	59 (1.6)	57 (1.5)	116 (1.5)	277 (1.8)	248 (1.6)	525 (1.7)
Arthralgia	112 (1.0)	126 (1.1)	238 (1.0)	49 (1.3)	47 (1.2)	96 (1.3)	161 (1.1)	173 (1.1)	334 (1.1)
Nausea/Vomiting	163 (1.4)	146 (1.3)	309 (1.4)	45 (1.2)	47 (1.2)	92 (1.2)	208 (1.4)	193 (1.3)	401 (1.3)
Chills	90 (0.8)	70 (0.6)	160 (0.7)	29 (0.8)	24 (0.6)	53 (0.7)	119 (0.8)	94 (0.6)	213 (0.7)

Percentages are based on the number of safety subjects.
[1] Solicited adverse reaction (AR) limits to terms collected on eDiary, i.e., local solicited AR includes Pain, Erythema, Swelling, and Axillary Swelling or Tenderness, and systemic solicited AR includes Fever, Headache, Fatigue, Myalgia, Arthralgia, Nausea/Vomiting, and Chills.
[2] Solicited injection site reaction includes Pain, Erythema, and Swelling.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030121010303.sas 10JUN2021 13:02

Table 14.3.1.21.1.4
Summary of Subjects with Local Adverse Reactions that Occurs at Day 8 or beyond of Each Injection
Solicited Safety Set

	Vaccination 1		Vaccination 2	
Category	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)
Subjects with any Local Adverse Reactions Occurs at Day 8 or beyond	158 (1.0)	514 (3.4)	199 (1.4)	356 (2.4)
Started within 7-day of the injection and continuing beyond 7 days	130 (0.9)	351 (2.3)	122 (0.8)	308 (2.1)
Had solicited AR within 7 days, and re-started on Day 8 or afterwards	10 (<0.1)	83 (0.5)	20 (0.1)	38 (0.3)
No solicited AR within 7 days, and had AR started on Day 8 or afterwards	18 (0.1)	80 (0.5)	57 (0.4)	10 (<0.1)
Subjects with Pain Occurs at Day 8 or beyond	70 (0.5)	156 (1.0)	116 (0.8)	186 (1.3)
Started within 7-day of the injection and continuing beyond 7 days	56 (0.4)	102 (0.7)	58 (0.4)	155 (1.1)
Had solicited AR within 7 days, and re-started on Day 8 or afterwards	6 (<0.1)	53 (0.3)	17 (0.1)	31 (0.2)
No solicited AR within 7 days, and had AR started on Day 8 or afterwards	8 (<0.1)	1 (<0.1)	41 (0.3)	0

Subjects with adverse reactions on Day 8 or beyond, independent of the start date.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301210104.sas 24JUN2021 05:58

Table 14.3.1.21.1.4
Summary of Subjects with Local Adverse Reactions that Occurs at Day 8 or beyond of Each Injection
Solicited Safety Set

	Vaccination 1		Vaccination 2	
Category	Placebo (N=15151) n (%)	mRNA-1273 (N=15166) n (%)	Placebo (N=14578) n (%)	mRNA-1273 (N=14691) n (%)
Subjects with Erythema (Redness) Occurs at Day 8 or beyond	27 (0.2)	117 (0.8)	21 (0.1)	78 (0.5)
Started within 7-day of the injection and continuing beyond 7 days	20 (0.1)	34 (0.2)	13 (<0.1)	70 (0.5)
Had solicited AR within 7 days, and re-started on Day 8 or afterwards	0	15 (<0.1)	0	2 (<0.1)
No solicited AR within 7 days, and had AR started on Day 8 or afterwards	7 (<0.1)	68 (0.4)	8 (<0.1)	6 (<0.1)
Subjects with Swelling (Hardness) Occurs at Day 8 or beyond	25 (0.2)	88 (0.6)	22 (0.2)	76 (0.5)
Started within 7-day of the injection and continuing beyond 7 days	22 (0.1)	33 (0.2)	16 (0.1)	70 (0.5)
Had solicited AR within 7 days, and re-started on Day 8 or afterwards	0	19 (0.1)	0	2 (<0.1)
No solicited AR within 7 days, and had AR started on Day 8 or afterwards	3 (<0.1)	36 (0.2)	6 (<0.1)	4 (<0.1)
Subjects with Axillary Swelling or Tenderness Occurs at Day 8 or beyond	62 (0.4)	243 (1.6)	57 (0.4)	101 (0.7)
Started within 7-day of the injection and continuing beyond 7 days	54 (0.4)	223 (1.5)	48 (0.3)	90 (0.6)
Had solicited AR within 7 days, and re-started on Day 8 or afterwards	5 (<0.1)	12 (<0.1)	4 (<0.1)	7 (<0.1)
No solicited AR within 7 days, and had AR started on Day 8 or afterwards	3 (<0.1)	8 (<0.1)	5 (<0.1)	4 (<0.1)

Subjects with adverse reactions on Day 8 or beyond, independent of the start date.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t140301210104.sas 24JUN2021 05:58

Table 14.3.1.22.1
Subject Incidence of Vasculitis [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Vasculitis [1]	1 (<0.1)	1 (<0.1)		2 (<0.1)
Number of Vasculitis [1]	1	1		2
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Vasculitis is identified through selected SMQ.
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Table 14.3.1.22.1
Subject Incidence of Vasculitis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Vasculitis [1]	0	1 (<0.1)		1 (<0.1)
Number of Vasculitis [1]	0	1		1
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Vasculitis is identified through selected SMQ.
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Table 14.3.1.22.1
Subject Incidence of Vasculitis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Vasculitis [1]	1 (<0.1)	0		1 (<0.1)
Number of Vasculitis [1]	1	0		1
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Vasculitis is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Hypersensitivity [1]	278 (1.8)	336 (2.2)		614 (2.0)
Number of Hypersensitivity [1]	301	382		683
Allergic cough	0	2 (<0.1)		2 (<0.1)
Allergic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Angioedema	3 (<0.1)	3 (<0.1)		6 (<0.1)
Bronchospasm	1 (<0.1)	3 (<0.1)		4 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)		4 (<0.1)
Dermatitis	14 (<0.1)	10 (<0.1)	0.71 (0.32, 1.57)	24 (<0.1)
Dermatitis allergic	5 (<0.1)	3 (<0.1)		8 (<0.1)
Dermatitis atopic	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.79)	15 (<0.1)
Dermatitis bullous	2 (<0.1)	0		2 (<0.1)
Dermatitis contact	41 (0.3)	34 (0.2)	0.83 (0.53, 1.30)	75 (0.2)
Drug hypersensitivity	8 (<0.1)	12 (<0.1)	1.50 (0.63, 3.56)	20 (<0.1)
Eczema	11 (<0.1)	18 (0.1)	1.63 (0.78, 3.40)	29 (<0.1)
Eczema nummular	1 (<0.1)	3 (<0.1)		4 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Eye swelling	5 (<0.1)	2 (<0.1)		7 (<0.1)
Hand dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	1 (<0.1)	25 (0.2)	24.96 (4.29, 145.37)	26 (<0.1)
Injection site urticaria	1 (<0.1)	38 (0.3)	37.94 (6.58, 218.91)	39 (0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	2 (<0.1)	6 (<0.1)		8 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)		1 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital swelling	3 (<0.1)	0		3 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Rash	47 (0.3)	44 (0.3)	0.93 (0.62, 1.41)	91 (0.3)
Rash erythematous	4 (<0.1)	3 (<0.1)		7 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash macular	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Rash maculo-papular	4 (<0.1)	9 (<0.1)	2.25 (0.73, 6.88)	13 (<0.1)
Rash pruritic	11 (<0.1)	6 (<0.1)	0.54 (0.21, 1.42)	17 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rash vesicular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rhinitis allergic	26 (0.2)	21 (0.1)	0.81 (0.46, 1.42)	47 (0.2)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Swelling face	4 (<0.1)	6 (<0.1)		10 (<0.1)
Swelling of eyelid	1 (<0.1)	4 (<0.1)		5 (<0.1)
Swollen tongue	1 (<0.1)	2 (<0.1)		3 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Urticaria	46 (0.3)	55 (0.4)	1.19 (0.81, 1.76)	101 (0.3)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Hypersensitivity [1]	217 (1.9)	248 (2.2)		465 (2.0)
Number of Hypersensitivity [1]	237	284		521
Allergic cough	0	2 (<0.1)		2 (<0.1)
Allergic sinusitis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Angioedema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Bronchospasm	1 (<0.1)	1 (<0.1)		2 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis	11 (<0.1)	7 (<0.1)	0.64 (0.25, 1.59)	18 (<0.1)
Dermatitis allergic	5 (<0.1)	3 (<0.1)		8 (<0.1)
Dermatitis atopic	9 (<0.1)	3 (<0.1)	0.33 (0.10, 1.14)	12 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Dermatitis contact	28 (0.2)	26 (0.2)	0.93 (0.55, 1.57)	54 (0.2)
Drug hypersensitivity	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Eczema	8 (<0.1)	18 (0.2)	2.25 (1.00, 5.06)	26 (0.1)
Eczema nummular	0	2 (<0.1)		2 (<0.1)
Exfoliative rash	0	1 (<0.1)		1 (<0.1)
Eye swelling	4 (<0.1)	1 (<0.1)		5 (<0.1)
Hand dermatitis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Hypersensitivity	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)	12 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Incision site rash	0	1 (<0.1)		1 (<0.1)
Injection related reaction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Injection site rash	1 (<0.1)	19 (0.2)	18.99 (3.23, 111.55)	20 (<0.1)
Injection site urticaria	0	27 (0.2)		27 (0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	5 (<0.1)		6 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Perioral dermatitis	3 (<0.1)	1 (<0.1)		4 (<0.1)
Periorbital oedema	0	1 (<0.1)		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Rash	42 (0.4)	32 (0.3)	0.76 (0.48, 1.20)	74 (0.3)
Rash erythematous	3 (<0.1)	3 (<0.1)		6 (<0.1)
Rash follicular	1 (<0.1)	0		1 (<0.1)
Rash macular	2 (<0.1)	3 (<0.1)		5 (<0.1)
Rash maculo-papular	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.59)	11 (<0.1)
Rash pruritic	10 (<0.1)	4 (<0.1)	0.40 (0.13, 1.20)	14 (<0.1)
Rash pustular	0	1 (<0.1)		1 (<0.1)
Rash vesicular	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rhinitis allergic	18 (0.2)	15 (0.1)	0.83 (0.43, 1.63)	33 (0.1)
Serum sickness	1 (<0.1)	0		1 (<0.1)
Swelling face	3 (<0.1)	6 (<0.1)		9 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Swelling of eyelid	1 (<0.1)	3 (<0.1)		4 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Urticaria	37 (0.3)	40 (0.4)	1.08 (0.69, 1.68)	77 (0.3)
Urticaria papular	4 (<0.1)	3 (<0.1)		7 (<0.1)
Vaccination site rash	0	2 (<0.1)		2 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Hypersensitivity [1]	61 (1.6)	88 (2.3)		149 (2.0)
Number of Hypersensitivity [1]	64	98		162
Angioedema	1 (<0.1)	0		1 (<0.1)
Bronchospasm	0	2 (<0.1)		2 (<0.1)
Conjunctivitis allergic	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dermatitis	3 (<0.1)	3 (<0.1)		6 (<0.1)
Dermatitis atopic	0	3 (<0.1)		3 (<0.1)
Dermatitis bullous	1 (<0.1)	0		1 (<0.1)
Dermatitis contact	13 (0.3)	8 (0.2)	0.61 (0.26, 1.44)	21 (0.3)
Drug hypersensitivity	2 (<0.1)	4 (0.1)		6 (<0.1)
Eczema	3 (<0.1)	0		3 (<0.1)
Eczema nummular	1 (<0.1)	1 (<0.1)		2 (<0.1)
Eye swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hypersensitivity	2 (<0.1)	4 (0.1)		6 (<0.1)
Injection site rash	0	6 (0.2)		6 (<0.1)
Injection site urticaria	1 (<0.1)	11 (0.3)	10.95 (1.82, 65.95)	12 (0.2)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)		1 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.2
Subject Incidence of Hypersensitivity [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Rash	5 (0.1)	12 (0.3)	2.39 (0.88, 6.49)	17 (0.2)
Rash erythematous	1 (<0.1)	0		1 (<0.1)
Rash macular	4 (0.1)	5 (0.1)		9 (0.1)
Rash maculo-papular	0	2 (<0.1)		2 (<0.1)
Rash pruritic	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rhinitis allergic	8 (0.2)	6 (0.2)	0.75 (0.27, 2.06)	14 (0.2)
Swelling face	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Swollen tongue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)		1 (<0.1)
Urticaria	9 (0.2)	15 (0.4)	1.66 (0.74, 3.70)	24 (0.3)
Urticaria papular	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hypersensitivity is identified through selected SMQ.
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Table 14.3.1.22.3
Subject Incidence of Arthritis [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Arthritis [1]	125 (0.8)	118 (0.8)		243 (0.8)
Number of Arthritis [1]	132	124		256
Arthritis	12 (<0.1)	14 (<0.1)	1.16 (0.55, 2.47)	26 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Gout	17 (0.1)	13 (<0.1)	0.76 (0.38, 1.55)	30 (<0.1)
Osteoarthritis	75 (0.5)	61 (0.4)	0.81 (0.58, 1.14)	136 (0.4)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Periarthritis	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)	1.00 (0.41, 2.44)	18 (<0.1)
Spondylitis	0	2 (<0.1)		2 (<0.1)
Synovitis	2 (<0.1)	0		2 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	5 (<0.1)		7 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Arthritis is identified through selected SMQ.
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Table 14.3.1.22.3
Subject Incidence of Arthritis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Arthritis [1]	63 (0.6)	59 (0.5)		122 (0.5)
Number of Arthritis [1]	64	64		128
Arthritis	9 (<0.1)	6 (<0.1)	0.67 (0.25, 1.80)	15 (<0.1)
Chondrocalcinosis pyrophosphate	0	1 (<0.1)		1 (<0.1)
Facet joint syndrome	0	2 (<0.1)		2 (<0.1)
Gout	9 (<0.1)	4 (<0.1)	0.44 (0.15, 1.36)	13 (<0.1)
Osteoarthritis	31 (0.3)	30 (0.3)	0.97 (0.59, 1.59)	61 (0.3)
Palindromic rheumatism	0	1 (<0.1)		1 (<0.1)
Periarthritis	2 (<0.1)	3 (<0.1)		5 (<0.1)
Polyarthritis	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rheumatic disorder	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Sacroiliitis	0	1 (<0.1)		1 (<0.1)
Spinal osteoarthritis	5 (<0.1)	4 (<0.1)		9 (<0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Synovitis	2 (<0.1)	0		2 (<0.1)
Temporomandibular joint syndrome	2 (<0.1)	4 (<0.1)		6 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Arthritis is identified through selected SMQ.
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Table 14.3.1.22.3
Subject Incidence of Arthritis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Arthritis [1]	62 (1.7)	59 (1.6)		121 (1.6)
Number of Arthritis [1]	68	60		128
Arthritis	3 (<0.1)	8 (0.2)	2.65 (0.76, 9.21)	11 (0.1)
Gout	8 (0.2)	9 (0.2)	1.12 (0.45, 2.81)	17 (0.2)
Osteoarthritis	44 (1.2)	31 (0.8)	0.70 (0.45, 1.10)	75 (1.0)
Periarthritis	2 (<0.1)	4 (0.1)		6 (<0.1)
Polyarthritis	1 (<0.1)	0		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Spinal osteoarthritis	4 (0.1)	5 (0.1)		9 (0.1)
Spondylitis	0	1 (<0.1)		1 (<0.1)
Temporomandibular joint syndrome	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Arthritis is identified through selected SMQ.
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Table 14.3.1.22.4
Subject Incidence of Angioedema [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Angioedema [1]	71 (0.5)	82 (0.5)		153 (0.5)
Number of Angioedema [1]	79	91		170
Angioedema	3 (<0.1)	3 (<0.1)		6 (<0.1)
Eye swelling	5 (<0.1)	2 (<0.1)		7 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	2 (<0.1)	6 (<0.1)		8 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital swelling	3 (<0.1)	0		3 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Swelling face	4 (<0.1)	6 (<0.1)		10 (<0.1)
Swelling of eyelid	1 (<0.1)	4 (<0.1)		5 (<0.1)
Swollen tongue	1 (<0.1)	2 (<0.1)		3 (<0.1)
Urticaria	46 (0.3)	55 (0.4)	1.19 (0.81, 1.76)	101 (0.3)
Urticaria papular	5 (<0.1)	3 (<0.1)		8 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Angioedema is identified through selected SMQ.
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Table 14.3.1.22.4
Subject Incidence of Angioedema [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Angioedema [1]	54 (0.5)	63 (0.6)		117 (0.5)
Number of Angioedema [1]	61	69		130
Angioedema	2 (<0.1)	3 (<0.1)		5 (<0.1)
Eye swelling	4 (<0.1)	1 (<0.1)		5 (<0.1)
Idiopathic urticaria	1 (<0.1)	0		1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	5 (<0.1)		6 (<0.1)
Palatal oedema	1 (<0.1)	0		1 (<0.1)
Periorbital oedema	0	1 (<0.1)		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Swelling face	3 (<0.1)	6 (<0.1)		9 (<0.1)
Swelling of eyelid	1 (<0.1)	3 (<0.1)		4 (<0.1)
Swollen tongue	0	1 (<0.1)		1 (<0.1)
Urticaria	37 (0.3)	40 (0.4)	1.08 (0.69, 1.68)	77 (0.3)
Urticaria papular	4 (<0.1)	3 (<0.1)		7 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Angioedema is identified through selected SMQ.
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Table 14.3.1.22.4
Subject Incidence of Angioedema [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Angioedema [1]	17 (0.5)	19 (0.5)		36 (0.5)
Number of Angioedema [1]	18	22		40
Angioedema	1 (<0.1)	0		1 (<0.1)
Eye swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Pharyngeal swelling	0	1 (<0.1)		1 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)
Swollen tongue	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	9 (0.2)	15 (0.4)	1.66 (0.74, 3.70)	24 (0.3)
Urticaria papular	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Angioedema is identified through selected SMQ.
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Table 14.3.1.22.5
Subject Incidence of Peripheral Neuropathy [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Peripheral Neuropathy [1]	13 (<0.1)	12 (<0.1)		25 (<0.1)
Number of Peripheral Neuropathy [1]	14	12		26
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neuralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Neuropathy peripheral	5 (<0.1)	3 (<0.1)		8 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	4 (<0.1)		7 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Peripheral Neuropathy is identified through selected SMQ.
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Table 14.3.1.22.5
Subject Incidence of Peripheral Neuropathy [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Peripheral Neuropathy [1]	8 (<0.1)	6 (<0.1)		14 (<0.1)
Number of Peripheral Neuropathy [1]	8	6		14
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neuralgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Neuropathy peripheral	3 (<0.1)	2 (<0.1)		5 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	1 (<0.1)		4 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Peripheral Neuropathy is identified through selected SMQ.
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Table 14.3.1.22.5
Subject Incidence of Peripheral Neuropathy [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Peripheral Neuropathy [1]	5 (0.1)	6 (0.2)		11 (0.1)
Number of Peripheral Neuropathy [1]	6	6		12
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neuropathy peripheral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Peripheral sensory neuropathy	0	3 (<0.1)		3 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Peripheral Neuropathy is identified through selected SMQ.
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Table 14.3.1.22.6
Subject Incidence of Demyelinating Disease of Central Nervous System [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Demyelinating Disease of Central Nervous System [1]	1 (<0.1)	3 (<0.1)		4 (<0.1)
Number of Demyelinating Disease of Central Nervous System [1]	1	4		5
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	2 (<0.1)		2 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Demyelinating Disease of Central Nervous System is identified through selected SMQ.
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Table 14.3.1.22.6
Subject Incidence of Demyelinating Disease of Central Nervous System [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Demyelinating Disease of Central Nervous System [1]	1 (<0.1)	2 (<0.1)		3 (<0.1)
Number of Demyelinating Disease of Central Nervous System [1]	1	3		4
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Demyelinating Disease of Central Nervous System is identified through selected SMQ.
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Table 14.3.1.22.6
Subject Incidence of Demyelinating Disease of Central Nervous System [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Demyelinating Disease of Central Nervous System [1]	0	1 (<0.1)		1 (<0.1)
Number of Demyelinating Disease of Central Nervous System [1]	0	1		1
Optic neuritis	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Demyelinating Disease of Central Nervous System is identified through selected SMQ.
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Table 14.3.1.22.7
Subject Incidence of Convulsions [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Convulsions [1]	6 (<0.1)	5 (<0.1)		11 (<0.1)
Number of Convulsions [1]	6	6		12
Seizure	6 (<0.1)	5 (<0.1)		11 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Convulsions is identified through selected SMQ.
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Table 14.3.1.22.7
Subject Incidence of Convulsions [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Convulsions [1]	6 (<0.1)	4 (<0.1)		10 (<0.1)
Number of Convulsions [1]	6	5		11
Seizure	6 (<0.1)	4 (<0.1)		10 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Convulsions is identified through selected SMQ.
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Table 14.3.1.22.7
Subject Incidence of Convulsions [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Convulsions [1]	0	1 (<0.1)		1 (<0.1)
Number of Convulsions [1]	0	1		1
Seizure	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Convulsions is identified through selected SMQ.
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Table 14.3.1.22.8
Subject Incidence of Anaphylaxis [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Anaphylaxis [1]	8 (<0.1)	5 (<0.1)		13 (<0.1)
Number of Anaphylaxis [1]	18	9		27
Anaphylactic reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Asthma	2 (<0.1)	0		2 (<0.1)
Cough	1 (<0.1)	1 (<0.1)		2 (<0.1)
Dyspnoea	2 (<0.1)	1 (<0.1)		3 (<0.1)
Eye pruritus	0	1 (<0.1)		1 (<0.1)
Hypotension	3 (<0.1)	0		3 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pruritus	1 (<0.1)	0		1 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Tachypnoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wheezing	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Anaphylaxis is identified through selected SMQ.
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Table 14.3.1.22.8
Subject Incidence of Anaphylaxis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Anaphylaxis [1]	6 (<0.1)	4 (<0.1)		10 (<0.1)
Number of Anaphylaxis [1]	12	7		19
Anaphylactic reaction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Asthma	2 (<0.1)	0		2 (<0.1)
Cough	1 (<0.1)	0		1 (<0.1)
Dyspnoea	0	1 (<0.1)		1 (<0.1)
Hypotension	2 (<0.1)	0		2 (<0.1)
Swelling face	0	1 (<0.1)		1 (<0.1)
Tachypnoea	1 (<0.1)	1 (<0.1)		2 (<0.1)
Urticaria	1 (<0.1)	1 (<0.1)		2 (<0.1)
Wheezing	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Anaphylaxis is identified through selected SMQ.
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Table 14.3.1.22.8
Subject Incidence of Anaphylaxis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Anaphylaxis [1]	2 (<0.1)	1 (<0.1)		3 (<0.1)
Number of Anaphylaxis [1]	6	2		8
Cough	0	1 (<0.1)		1 (<0.1)
Dyspnoea	2 (<0.1)	0		2 (<0.1)
Eye pruritus	0	1 (<0.1)		1 (<0.1)
Hypotension	1 (<0.1)	0		1 (<0.1)
Oedema	1 (<0.1)	0		1 (<0.1)
Pruritus	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Anaphylaxis is identified through selected SMQ.
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Table 14.3.1.22.9
Subject Incidence of Autoimmune Disorder by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Autoimmune Disorder [1]	49 (0.3)	56 (0.4)		105 (0.3)
Number of Autoimmune Disorder [1]	52	57		109
Alopecia	10 (<0.1)	8 (<0.1)	0.80 (0.33, 1.96)	18 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autoimmune thyroiditis	2 (<0.1)	0		2 (<0.1)
Basedow's disease	2 (<0.1)	1 (<0.1)		3 (<0.1)
Cardiomyopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Facial paralysis	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neuralgia	5 (<0.1)	3 (<0.1)		8 (<0.1)
Neuropathy peripheral	5 (<0.1)	3 (<0.1)		8 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.22.9
Subject Incidence of Autoimmune Disorder by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Optic neuritis	0	2 (<0.1)		2 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	4 (<0.1)		7 (<0.1)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriasis	3 (<0.1)	7 (<0.1)	2.33 (0.66, 8.26)	10 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Raynaud's phenomenon	1 (<0.1)	2 (<0.1)		3 (<0.1)
Rheumatoid arthritis	3 (<0.1)	2 (<0.1)		5 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Uveitis	0	3 (<0.1)		3 (<0.1)
Vitiligo	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012209.sas 10JUN2021 13:13

Table 14.3.1.22.9
Subject Incidence of Autoimmune Disorder by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Autoimmune Disorder [1]	35 (0.3)	39 (0.3)		74 (0.3)
Number of Autoimmune Disorder [1]	37	40		77
Alopecia	8 (<0.1)	7 (<0.1)	0.87 (0.33, 2.32)	15 (<0.1)
Alopecia areata	0	1 (<0.1)		1 (<0.1)
Alopecia scarring	1 (<0.1)	0		1 (<0.1)
Androgenetic alopecia	1 (<0.1)	1 (<0.1)		2 (<0.1)
Autoimmune thyroiditis	2 (<0.1)	0		2 (<0.1)
Basedow's disease	1 (<0.1)	0		1 (<0.1)
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)
Coeliac disease	1 (<0.1)	0		1 (<0.1)
Crohn's disease	0	1 (<0.1)		1 (<0.1)
Facial paralysis	3 (<0.1)	5 (<0.1)		8 (<0.1)
Hypergammaglobulinaemia benign monoclonal	0	1 (<0.1)		1 (<0.1)
Lichen planus	0	2 (<0.1)		2 (<0.1)
Multiple sclerosis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Nerve conduction studies abnormal	0	1 (<0.1)		1 (<0.1)
Neuralgia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Neuropathy peripheral	3 (<0.1)	2 (<0.1)		5 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Peripheral sensory neuropathy	3 (<0.1)	1 (<0.1)		4 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.22.9
Subject Incidence of Autoimmune Disorder by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Polyarteritis nodosa	0	1 (<0.1)		1 (<0.1)
Psoriasis	1 (<0.1)	6 (<0.1)		7 (<0.1)
Psoriatic arthropathy	1 (<0.1)	0		1 (<0.1)
Raynaud's phenomenon	1 (<0.1)	1 (<0.1)		2 (<0.1)
Rheumatoid arthritis	2 (<0.1)	2 (<0.1)		4 (<0.1)
Sjogren's syndrome	1 (<0.1)	0		1 (<0.1)
Small fibre neuropathy	0	1 (<0.1)		1 (<0.1)
Systemic lupus erythematosus	2 (<0.1)	0		2 (<0.1)
Type 1 diabetes mellitus	2 (<0.1)	0		2 (<0.1)
Uveitis	0	2 (<0.1)		2 (<0.1)
Vitiligo	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
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Table 14.3.1.22.9
Subject Incidence of Autoimmune Disorder by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Autoimmune Disorder [1]	14 (0.4)	17 (0.5)		31 (0.4)
Number of Autoimmune Disorder [1]	15	17		32
Alopecia	2 (<0.1)	1 (<0.1)		3 (<0.1)
Amyotrophic lateral sclerosis	1 (<0.1)	0		1 (<0.1)
Basedow's disease	1 (<0.1)	1 (<0.1)		2 (<0.1)
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Facial paralysis	0	3 (<0.1)		3 (<0.1)
Myasthenia gravis	1 (<0.1)	0		1 (<0.1)
Neuralgia	3 (<0.1)	2 (<0.1)		5 (<0.1)
Neuropathy peripheral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Optic neuritis	0	1 (<0.1)		1 (<0.1)
Peripheral sensory neuropathy	0	3 (<0.1)		3 (<0.1)
Polymyalgia rheumatica	1 (<0.1)	0		1 (<0.1)
Psoriasis	2 (<0.1)	1 (<0.1)		3 (<0.1)
Raynaud's phenomenon	0	1 (<0.1)		1 (<0.1)
Rheumatoid arthritis	1 (<0.1)	0		1 (<0.1)
Sarcoidosis	0	1 (<0.1)		1 (<0.1)
Uveitis	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.22.10
Subject Incidence of Central Nervous System Vascular Disorders [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Central Nervous System Vascular Disorders [1]	11 (<0.1)	21 (0.1)		32 (0.1)
Number of Central Nervous System Vascular Disorders [1]	11	24		35
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Carotid artery stenosis	0	2 (<0.1)		2 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Subarachnoid haemorrhage	0	4 (<0.1)		4 (<0.1)
Subdural haematoma	0	3 (<0.1)		3 (<0.1)
Transient ischaemic attack	4 (<0.1)	3 (<0.1)		7 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Central Nervous System Vascular Disorders are identified through selected SMQ.
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Table 14.3.1.22.10
Subject Incidence of Central Nervous System Vascular Disorders [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Central Nervous System Vascular Disorders [1]	7 (<0.1)	10 (<0.1)		17 (<0.1)
Number of Central Nervous System Vascular Disorders [1]	7	11		18
Basal ganglia haemorrhage	1 (<0.1)	0		1 (<0.1)
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Cerebral small vessel ischaemic disease	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	2 (<0.1)	4 (<0.1)		6 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Subdural haematoma	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	4 (<0.1)	1 (<0.1)		5 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Central Nervous System Vascular Disorders are identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012210.sas 30JUN2021 09:47

Table 14.3.1.22.10
Subject Incidence of Central Nervous System Vascular Disorders [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Central Nervous System Vascular Disorders [1]	4 (0.1)	11 (0.3)		15 (0.2)
Number of Central Nervous System Vascular Disorders [1]	4	13		17
Carotid artery stenosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Subarachnoid haemorrhage	0	2 (<0.1)		2 (<0.1)
Subdural haematoma	0	2 (<0.1)		2 (<0.1)
Transient ischaemic attack	0	2 (<0.1)		2 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Central Nervous System Vascular Disorders are identified through selected SMQ.
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Table 14.3.1.22.11
Subject Incidence of Dermal Filler Reaction Post Vaccination by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Dermal Filler Reaction Post Vaccination [1]	14 (<0.1)	20 (0.1)		34 (0.1)
Number of Dermal Filler Reaction Post Vaccination [1]	17	21		38
Eye swelling	5 (<0.1)	2 (<0.1)		7 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	2 (<0.1)	6 (<0.1)		8 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital swelling	3 (<0.1)	0		3 (<0.1)
Swelling face	4 (<0.1)	6 (<0.1)		10 (<0.1)
Swelling of eyelid	1 (<0.1)	4 (<0.1)		5 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012211.sas 10JUN2021 13:13

Table 14.3.1.22.11
Subject Incidence of Dermal Filler Reaction Post Vaccination by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Dermal Filler Reaction Post Vaccination [1]	9 (<0.1)	17 (0.1)		26 (0.1)
Number of Dermal Filler Reaction Post Vaccination [1]	12	18		30
Eye swelling	4 (<0.1)	1 (<0.1)		5 (<0.1)
Lip oedema	0	1 (<0.1)		1 (<0.1)
Lip swelling	1 (<0.1)	5 (<0.1)		6 (<0.1)
Periorbital oedema	0	1 (<0.1)		1 (<0.1)
Periorbital swelling	2 (<0.1)	0		2 (<0.1)
Swelling face	3 (<0.1)	6 (<0.1)		9 (<0.1)
Swelling of eyelid	1 (<0.1)	3 (<0.1)		4 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012211.sas 10JUN2021 13:13

Table 14.3.1.22.11
Subject Incidence of Dermal Filler Reaction Post Vaccination by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Dermal Filler Reaction Post Vaccination [1]	5 (0.1)	3 (<0.1)		8 (0.1)
Number of Dermal Filler Reaction Post Vaccination [1]	5	3		8
Eye swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Lip swelling	1 (<0.1)	1 (<0.1)		2 (<0.1)
Periorbital oedema	1 (<0.1)	0		1 (<0.1)
Periorbital swelling	1 (<0.1)	0		1 (<0.1)
Swelling face	1 (<0.1)	0		1 (<0.1)
Swelling of eyelid	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
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Table 14.3.1.22.12
Subject Incidence of Embolic and Thrombotic Events [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Embolic and Thrombotic Events [1]	43 (0.3)	47 (0.3)		90 (0.3)
Number of Embolic and Thrombotic Events [1]	45	54		99
Acute myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	4 (<0.1)	7 (<0.1)	1.75 (0.55, 5.58)	11 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Deep vein thrombosis	6 (<0.1)	8 (<0.1)	1.33 (0.48, 3.67)	14 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)	16 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)		2 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)	13 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Embolic and Thrombotic Events are identified through selected SMQ.
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Table 14.3.1.22.12
Subject Incidence of Embolic and Thrombotic Events [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Retinal infarction	1 (<0.1)	0		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Transient ischaemic attack	4 (<0.1)	3 (<0.1)		7 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Embolic and Thrombotic Events are identified through selected SMQ.
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Table 14.3.1.22.12
Subject Incidence of Embolic and Thrombotic Events [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Embolic and Thrombotic Events [1]	28 (0.2)	26 (0.2)		54 (0.2)
Number of Embolic and Thrombotic Events [1]	29	29		58
Acute myocardial infarction	2 (<0.1)	2 (<0.1)		4 (<0.1)
Blindness transient	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	2 (<0.1)	4 (<0.1)		6 (<0.1)
Deep vein thrombosis	4 (<0.1)	4 (<0.1)		8 (<0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)		1 (<0.1)
Embolism venous	0	1 (<0.1)		1 (<0.1)
Hemiparesis	0	1 (<0.1)		1 (<0.1)
Myocardial infarction	6 (<0.1)	4 (<0.1)		10 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	0		1 (<0.1)
Pulmonary embolism	5 (<0.1)	4 (<0.1)		9 (<0.1)
Pulmonary infarction	1 (<0.1)	0		1 (<0.1)
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)		6 (<0.1)
Transient ischaemic attack	4 (<0.1)	1 (<0.1)		5 (<0.1)
Venous thrombosis limb	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Embolic and Thrombotic Events are identified through selected SMQ.
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Table 14.3.1.22.12
Subject Incidence of Embolic and Thrombotic Events [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Embolic and Thrombotic Events [1]	15 (0.4)	21 (0.6)		36 (0.5)
Number of Embolic and Thrombotic Events [1]	16	25		41
Acute myocardial infarction	4 (0.1)	2 (<0.1)		6 (<0.1)
Arterial occlusive disease	0	1 (<0.1)		1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)		1 (<0.1)
Carotid artery thrombosis	0	1 (<0.1)		1 (<0.1)
Cerebrovascular accident	2 (<0.1)	3 (<0.1)		5 (<0.1)
Coronary artery occlusion	0	2 (<0.1)		2 (<0.1)
Deep vein thrombosis	2 (<0.1)	4 (0.1)		6 (<0.1)
Embolic stroke	0	2 (<0.1)		2 (<0.1)
Ischaemic stroke	1 (<0.1)	0		1 (<0.1)
Myocardial infarction	3 (<0.1)	3 (<0.1)		6 (<0.1)
Peripheral artery occlusion	0	1 (<0.1)		1 (<0.1)
Pulmonary embolism	2 (<0.1)	2 (<0.1)		4 (<0.1)
Retinal infarction	1 (<0.1)	0		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Transient ischaemic attack	0	2 (<0.1)		2 (<0.1)
Vertebral artery occlusion	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Embolic and Thrombotic Events are identified through selected SMQ.
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Table 14.3.1.22.13
Subject Incidence of Hearing and Vestibular Disorders [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Hearing and Vestibular Disorders [1]	81 (0.5)	88 (0.6)		169 (0.6)
Number of Hearing and Vestibular Disorders [1]	88	92		180
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	2 (<0.1)	3 (<0.1)		5 (<0.1)
Diplacusis	1 (<0.1)	0		1 (<0.1)
Eustachian tube dysfunction	4 (<0.1)	2 (<0.1)		6 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniere's disease	2 (<0.1)	6 (<0.1)		8 (<0.1)
Middle ear effusion	3 (<0.1)	1 (<0.1)		4 (<0.1)
Tinnitus	22 (0.1)	20 (0.1)	0.91 (0.50, 1.65)	42 (0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	9 (<0.1)	2 (<0.1)	0.22 (0.05, 0.91)	11 (<0.1)
Vertigo	34 (0.2)	46 (0.3)	1.35 (0.87, 2.10)	80 (0.3)
Vertigo positional	4 (<0.1)	8 (<0.1)	2.00 (0.64, 6.23)	12 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Vestibular neuronitis	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hearing and Vestibular Disorders are identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012213.sas 30JUN2021 09:47

Table 14.3.1.22.13
Subject Incidence of Hearing and Vestibular Disorders [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Hearing and Vestibular Disorders [1]	58 (0.5)	56 (0.5)		114 (0.5)
Number of Hearing and Vestibular Disorders [1]	64	58		122
Deafness neurosensory	0	2 (<0.1)		2 (<0.1)
Deafness unilateral	2 (<0.1)	1 (<0.1)		3 (<0.1)
Diplacusis	1 (<0.1)	0		1 (<0.1)
Eustachian tube dysfunction	3 (<0.1)	1 (<0.1)		4 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)		2 (<0.1)
Meniere's disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Middle ear effusion	3 (<0.1)	0		3 (<0.1)
Tinnitus	18 (0.2)	16 (0.1)	0.89 (0.46, 1.72)	34 (0.1)
Tympanic membrane disorder	1 (<0.1)	0		1 (<0.1)
Tympanic membrane perforation	6 (<0.1)	2 (<0.1)		8 (<0.1)
Vertigo	22 (0.2)	27 (0.2)	1.23 (0.70, 2.14)	49 (0.2)
Vertigo positional	3 (<0.1)	4 (<0.1)		7 (<0.1)
Vestibular migraine	0	1 (<0.1)		1 (<0.1)
Vestibular neuronitis	1 (<0.1)	0		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hearing and Vestibular Disorders are identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012213.sas 30JUN2021 09:47

Table 14.3.1.22.13
Subject Incidence of Hearing and Vestibular Disorders [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Hearing and Vestibular Disorders [1]	23 (0.6)	32 (0.8)		55 (0.7)
Number of Hearing and Vestibular Disorders [1]	24	34		58
Deafness unilateral	0	2 (<0.1)		2 (<0.1)
Eustachian tube dysfunction	1 (<0.1)	1 (<0.1)		2 (<0.1)
Hyperacusis	1 (<0.1)	0		1 (<0.1)
Meniere's disease	1 (<0.1)	3 (<0.1)		4 (<0.1)
Middle ear effusion	0	1 (<0.1)		1 (<0.1)
Tinnitus	4 (0.1)	4 (0.1)		8 (0.1)
Tympanic membrane perforation	3 (<0.1)	0		3 (<0.1)
Vertigo	12 (0.3)	19 (0.5)	1.58 (0.78, 3.19)	31 (0.4)
Vertigo positional	1 (<0.1)	4 (0.1)		5 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Hearing and Vestibular Disorders are identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012213.sas 30JUN2021 09:47

Table 14.3.1.22.14
Subject Incidence of Thrombophlebitis [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Thrombophlebitis [1]	4 (<0.1)	3 (<0.1)		7 (<0.1)
Number of Thrombophlebitis [1]	4	3		7
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)		6 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Thrombophlebitis is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012214.sas 30JUN2021 09:48

Table 14.3.1.22.14
Subject Incidence of Thrombophlebitis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Thrombophlebitis [1]	4 (<0.1)	3 (<0.1)		7 (<0.1)
Number of Thrombophlebitis [1]	4	3		7
Thrombophlebitis	0	1 (<0.1)		1 (<0.1)
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)		6 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Thrombophlebitis is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012214.sas 30JUN2021 09:48

Table 14.3.1.22.14
Subject Incidence of Thrombophlebitis [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)

There are no observations for this section.

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Thrombophlebitis is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012214.sas 30JUN2021 09:48

Table 14.3.1.22.15
Subject Incidence of Haematopoietic Cytopenias [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Haematopoietic Cytopenias [1]	2 (<0.1)	9 (<0.1)		11 (<0.1)
Number of Haematopoietic Cytopenias [1]	2	9		11
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Thrombocytopenia	1 (<0.1)	5 (<0.1)		6 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Haematopoietic Cytopenias is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012215.sas 30JUN2021 09:48

Table 14.3.1.22.15
Subject Incidence of Haematopoietic Cytopenias [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Haematopoietic Cytopenias [1]	2 (<0.1)	6 (<0.1)		8 (<0.1)
Number of Haematopoietic Cytopenias [1]	2	6		8
Anaemia macrocytic	1 (<0.1)	0		1 (<0.1)
Leukopenia	0	2 (<0.1)		2 (<0.1)
Thrombocytopenia	1 (<0.1)	3 (<0.1)		4 (<0.1)
White blood cell count decreased	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Haematopoietic Cytopenias is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012215.sas 30JUN2021 09:48

Table 14.3.1.22.15
Subject Incidence of Haematopoietic Cytopenias [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Haematopoietic Cytopenias [1]	0	3 (<0.1)		3 (<0.1)
Number of Haematopoietic Cytopenias [1]	0	3		3
Lymphocyte count decreased	0	1 (<0.1)		1 (<0.1)
Thrombocytopenia	0	2 (<0.1)		2 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Haematopoietic Cytopenias is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012215.sas 30JUN2021 09:48

Table 14.3.1.22.16
Subject Incidence of Cardiomyopathy [1] by Preferred Term by Age Group
Safety Set

Age Group: Overall

Preferred Term	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)	Total (N=30346) n (%)
Number of Subjects Reporting Cardiomyopathy [1]	1 (<0.1)	3 (<0.1)		4 (<0.1)
Number of Cardiomyopathy [1]	1	3		4
Cardiomyopathy	1 (<0.1)	2 (<0.1)		3 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Cardiomyopathy is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012216.sas 30JUN2021 09:48

Table 14.3.1.22.16
Subject Incidence of Cardiomyopathy [1] by Preferred Term by Age Group
Safety Set

Age Group: >=18 and <65 Years

Preferred Term	Placebo (N=11411) n (%)	mRNA-1273 (N=11415) n (%)	Rate Ratio (95% CI)	Total (N=22826) n (%)
Number of Subjects Reporting Cardiomyopathy [1]	1 (<0.1)	1 (<0.1)		2 (<0.1)
Number of Cardiomyopathy [1]	1	1		2
Cardiomyopathy	1 (<0.1)	1 (<0.1)		2 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Cardiomyopathy is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012216.sas 30JUN2021 09:48

Table 14.3.1.22.16
Subject Incidence of Cardiomyopathy [1] by Preferred Term by Age Group
Safety Set

Age Group: >=65 Years

Preferred Term	Placebo (N=3751) n (%)	mRNA-1273 (N=3769) n (%)	Rate Ratio (95% CI)	Total (N=7520) n (%)
Number of Subjects Reporting Cardiomyopathy [1]	0	2 (<0.1)		2 (<0.1)
Number of Cardiomyopathy [1]	0	2		2
Cardiomyopathy	0	1 (<0.1)		1 (<0.1)
Stress cardiomyopathy	0	1 (<0.1)		1 (<0.1)

Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in Placebo. The 95% CI is calculated using the Miettinen and Nurminen method.
MedDRA version 23.0.
[1] Cardiomyopathy is identified through selected SMQ.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012216.sas 30JUN2021 09:48

Table 14.3.1.23.1
Summary of Death
Safety Set

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Number of Deaths, n (%)	16 (0.1)	16 (0.1)	32 (0.1)
From Randomization up to 14 Days After First Injection	2	0	2
>=14 up to 21 Days After First Injection	0	2	2
>=21 Days After First Injection up to Second Injection	1	2	3
From Second Injection up to 7 Days After Second Injection	0	0	0
>=7 up to 14 Days After Second Injection	0	0	0
>=14 up to 28 Days After Second Injection	0	0	0
>=28 up to 56 Days After Second Injection	2	2	4
>=56 up to 84 Days After Second Injection	2	4	6
>=84 up to 112 Days After Second Injection	6	3	9
>=112 Days After Second Injection	3	3	6

Percentages are based on the number of subjects in Safety Set.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t1403012301.sas 24JUN2021 07:03

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Baseline			
n	15145	15165	30310
Mean (SD)	78.9 (9.53)	79.0 (9.63)	79.0 (9.58)
Median	79.0	79.0	79.0
Min, Max	37, 121	14, 119	14, 121
Day 1 - 30 Minutes Postdose			
Absolute Result			
n	15100	15128	30228
Mean (SD)	79.1 (9.54)	79.2 (9.59)	79.2 (9.57)
Median	79.0	80.0	79.0
Min, Max	37, 133	37, 129	37, 133
Change from Baseline			
n	15087	15109	30196
Mean (SD)	0.2 (8.06)	0.2 (8.02)	0.2 (8.04)
Median	0.0	0.0	0.0
Min, Max	-59, 50	-41, 67	-59, 67
Day 29			
Absolute Result			
n	14827	14898	29725
Mean (SD)	78.1 (9.60)	78.1 (9.57)	78.1 (9.59)
Median	78.0	78.0	78.0
Min, Max	32, 121	23, 127	23, 127
Change from Baseline			
n	14811	14880	29691
Mean (SD)	-0.8 (9.23)	-0.9 (9.28)	-0.9 (9.26)
Median	-1.0	-1.0	-1.0
Min, Max	-54, 43	-61, 65	-61, 65

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Day 57			
Absolute Result			
n	11603	11785	23388
Mean (SD)	77.7 (9.57)	77.8 (9.63)	77.8 (9.60)
Median	78.0	78.0	78.0
Min, Max	12, 118	40, 126	12, 126
Change from Baseline			
n	11589	11769	23358
Mean (SD)	-1.1 (9.21)	-1.1 (9.36)	-1.1 (9.29)
Median	-1.0	-1.0	-1.0
Min, Max	-87, 49	-41, 68	-87, 68
Day 209			
Absolute Result			
n	14	13	27
Mean (SD)	77.8 (8.79)	84.4 (12.78)	81.0 (11.19)
Median	76.5	87.0	80.0
Min, Max	60, 96	51, 100	51, 100
Change from Baseline			
n	14	12	26
Mean (SD)	-1.3 (8.44)	2.7 (13.85)	0.5 (11.20)
Median	-5.0	5.0	3.0
Min, Max	-12, 12	-37, 17	-37, 17

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Baseline			
n	15145	15164	30309
Mean (SD)	71.9 (11.84)	72.1 (11.97)	72.0 (11.91)
Median	71.0	71.0	71.0
Min, Max	36, 137	40, 138	36, 138
Day 1 - 30 Minutes Postdose			
Absolute Result			
n	15091	15125	30216
Mean (SD)	68.8 (11.34)	69.0 (11.27)	68.9 (11.31)
Median	68.0	68.0	68.0
Min, Max	14, 130	16, 130	14, 130
Change from Baseline			
n	15078	15105	30183
Mean (SD)	-3.1 (8.34)	-3.1 (8.26)	-3.1 (8.30)
Median	-3.0	-3.0	-3.0
Min, Max	-55, 67	-94, 57	-94, 67
Day 29			
Absolute Result			
n	14828	14897	29725
Mean (SD)	69.4 (11.48)	69.5 (11.27)	69.5 (11.38)
Median	68.0	68.0	68.0
Min, Max	7, 140	32, 131	7, 140
Change from Baseline			
n	14812	14879	29691
Mean (SD)	-2.4 (10.40)	-2.6 (10.20)	-2.5 (10.30)
Median	-2.0	-2.0	-2.0
Min, Max	-67, 63	-56, 46	-67, 63

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Day 57			
Absolute Result			
n	11602	11782	23384
Mean (SD)	73.4 (11.87)	73.6 (11.83)	73.5 (11.85)
Median	72.0	73.0	72.0
Min, Max	35, 130	40, 144	35, 144
Change from Baseline			
n	11588	11765	23353
Mean (SD)	1.4 (10.68)	1.3 (10.70)	1.3 (10.69)
Median	1.0	1.0	1.0
Min, Max	-53, 56	-53, 75	-53, 75
Day 209			
Absolute Result			
n	14	13	27
Mean (SD)	73.9 (9.29)	84.1 (11.07)	78.8 (11.24)
Median	71.5	82.0	80.0
Min, Max	60, 88	70, 112	60, 112
Change from Baseline			
n	14	12	26
Mean (SD)	2.8 (7.71)	8.0 (12.23)	5.2 (10.18)
Median	3.0	8.0	5.0
Min, Max	-12, 20	-13, 27	-13, 27

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Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Baseline			
n	15118	15144	30262
Mean (SD)	15.6 (2.38)	15.6 (2.09)	15.6 (2.24)
Median	16.0	16.0	16.0
Min, Max	8, 152	8, 28	8, 152
Day 1 - 30 Minutes Postdose			
Absolute Result			
n	15079	15116	30195
Mean (SD)	15.6 (2.43)	15.6 (2.05)	15.6 (2.25)
Median	16.0	16.0	16.0
Min, Max	8, 150	8, 50	8, 150
Change from Baseline			
n	15039	15077	30116
Mean (SD)	0.0 (2.68)	0.0 (2.03)	0.0 (2.38)
Median	0.0	0.0	0.0
Min, Max	-138, 134	-11, 34	-138, 134
Day 29			
Absolute Result			
n	14826	14896	29722
Mean (SD)	15.5 (1.99)	15.5 (1.93)	15.5 (1.96)
Median	16.0	16.0	16.0
Min, Max	9, 83	9, 28	9, 83
Change from Baseline			
n	14783	14857	29640
Mean (SD)	-0.1 (2.64)	-0.1 (2.33)	-0.1 (2.49)
Median	0.0	0.0	0.0
Min, Max	-136, 67	-12, 12	-136, 67

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Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Day 57			
Absolute Result			
n	11600	11774	23374
Mean (SD)	15.5 (2.23)	15.5 (2.00)	15.5 (2.11)
Median	16.0	16.0	16.0
Min, Max	10, 135	8, 68	8, 135
Change from Baseline			
n	11560	11738	23298
Mean (SD)	-0.1 (2.51)	-0.1 (2.33)	-0.1 (2.42)
Median	0.0	0.0	0.0
Min, Max	-12, 117	-12, 48	-12, 117
Day 209			
Absolute Result			
n	14	13	27
Mean (SD)	15.4 (1.15)	14.2 (1.63)	14.8 (1.50)
Median	16.0	14.0	14.0
Min, Max	14, 17	12, 17	12, 17
Change from Baseline			
n	14	12	26
Mean (SD)	0.4 (2.24)	-1.7 (2.50)	-0.5 (2.55)
Median	1.0	-1.0	0.0
Min, Max	-4, 4	-6, 1	-6, 4

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Baseline			
n	15144	15165	30309
Mean (SD)	127.1 (15.19)	127.1 (15.14)	127.1 (15.16)
Median	126.0	127.0	126.0
Min, Max	75, 203	79, 212	75, 212
Day 1 - 30 Minutes Postdose			
Absolute Result			
n	15100	15128	30228
Mean (SD)	127.3 (15.45)	127.5 (15.29)	127.4 (15.37)
Median	126.0	127.0	127.0
Min, Max	59, 214	78, 221	59, 221
Change from Baseline			
n	15086	15109	30195
Mean (SD)	0.3 (11.62)	0.4 (11.63)	0.3 (11.63)
Median	0.0	0.0	0.0
Min, Max	-67, 67	-107, 79	-107, 79
Day 29			
Absolute Result			
n	14827	14898	29725
Mean (SD)	125.0 (14.75)	125.1 (14.81)	125.1 (14.78)
Median	124.0	124.0	124.0
Min, Max	75, 206	76, 222	75, 222
Change from Baseline			
n	14810	14880	29690
Mean (SD)	-2.1 (13.68)	-2.0 (13.99)	-2.0 (13.84)
Median	-2.0	-2.0	-2.0
Min, Max	-85, 72	-114, 73	-114, 73

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Day 57			
Absolute Result			
n	11603	11785	23388
Mean (SD)	125.3 (14.86)	125.6 (14.90)	125.5 (14.88)
Median	125.0	125.0	125.0
Min, Max	81, 198	75, 205	75, 205
Change from Baseline			
n	11588	11769	23357
Mean (SD)	-1.6 (13.99)	-1.6 (14.04)	-1.6 (14.02)
Median	-1.0	-2.0	-1.0
Min, Max	-73, 70	-89, 76	-89, 76
Day 209			
Absolute Result			
n	14	13	27
Mean (SD)	118.5 (15.43)	130.9 (12.26)	124.5 (15.12)
Median	116.5	134.0	126.0
Min, Max	96, 153	96, 144	96, 153
Change from Baseline			
n	14	12	26
Mean (SD)	-4.3 (11.55)	0.8 (14.39)	-1.9 (12.93)
Median	-5.0	2.0	-1.0
Min, Max	-20, 19	-28, 28	-28, 28

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Baseline			
n	15141	15161	30302
Mean (SD)	36.71 (0.345)	36.71 (0.343)	36.71 (0.344)
Median	36.72	36.72	36.72
Min, Max	26.3, 38.3	31.1, 38.8	26.3, 38.8
Day 1 - 30 Minutes Postdose			
Absolute Result			
n	15091	15125	30216
Mean (SD)	36.64 (0.609)	36.63 (0.373)	36.64 (0.505)
Median	36.67	36.67	36.67
Min, Max	33.8, 96.2	34.1, 38.6	33.8, 96.2
Change from Baseline			
n	15074	15102	30176
Mean (SD)	-0.07 (0.621)	-0.08 (0.388)	-0.07 (0.518)
Median	-0.06	-0.06	-0.06
Min, Max	-2.8, 59.7	-2.8, 5.7	-2.8, 59.7
Day 29			
Absolute Result			
n	14828	14897	29725
Mean (SD)	36.69 (0.329)	36.69 (0.329)	36.69 (0.329)
Median	36.72	36.70	36.72
Min, Max	34.5, 38.8	34.1, 39.9	34.1, 39.9
Change from Baseline			
n	14808	14875	29683
Mean (SD)	-0.02 (0.396)	-0.02 (0.393)	-0.02 (0.394)
Median	0.00	0.00	0.00
Min, Max	-2.6, 9.9	-2.9, 5.3	-2.9, 9.9

Table 14.3.2.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Placebo (N=15162)	mRNA-1273 (N=15184)	Total (N=30346)
Day 57			
Absolute Result			
n	11595	11772	23367
Mean (SD)	36.68 (0.323)	36.68 (0.319)	36.68 (0.321)
Median	36.70	36.70	36.70
Min, Max	30.4, 38.7	33.7, 37.7	30.4, 38.7
Change from Baseline			
n	11577	11753	23330
Mean (SD)	-0.04 (0.401)	-0.03 (0.405)	-0.04 (0.403)
Median	-0.06	-0.06	-0.06
Min, Max	-6.2, 3.2	-2.8, 5.2	-6.2, 5.2
Day 209			
Absolute Result			
n	14	13	27
Mean (SD)	36.73 (0.216)	36.76 (0.223)	36.75 (0.216)
Median	36.69	36.72	36.72
Min, Max	36.3, 37.1	36.4, 37.2	36.3, 37.2
Change from Baseline			
n	14	12	26
Mean (SD)	0.04 (0.411)	-0.05 (0.315)	0.00 (0.365)
Median	-0.06	-0.08	-0.06
Min, Max	-0.8, 0.8	-0.5, 0.6	-0.8, 0.8

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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	4 (<0.1)	51 (0.3)	4 (<0.1)	3 (<0.1)	0	0	62 (0.4)
Grade 0	12 (<0.1)	12761 (84.2)	562 (3.7)	193 (1.3)	32 (0.2)	0	13560 (89.4)
Grade 1	1 (<0.1)	604 (4.0)	185 (1.2)	106 (0.7)	30 (0.2)	0	926 (6.1)
Grade 2	0	189 (1.2)	88 (0.6)	97 (0.6)	28 (0.2)	0	402 (2.7)
Grade 3	0	50 (0.3)	40 (0.3)	58 (0.4)	62 (0.4)	0	210 (1.4)
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	17 (0.1)	13657 (90.1)	879 (5.8)	457 (3.0)	152 (1.0)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	306 (2.0)	20 (0.1)	3 (<0.1)	5 (<0.1)	0	335 (2.2)
Grade 0	16 (0.1)	12180 (80.3)	532 (3.5)	209 (1.4)	45 (0.3)	0	12982 (85.6)
Grade 1	0	774 (5.1)	191 (1.3)	109 (0.7)	32 (0.2)	0	1106 (7.3)
Grade 2	0	323 (2.1)	97 (0.6)	88 (0.6)	24 (0.2)	0	532 (3.5)
Grade 3	0	74 (0.5)	39 (0.3)	48 (0.3)	46 (0.3)	0	207 (1.4)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	13657 (90.1)	879 (5.8)	457 (3.0)	152 (1.0)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3223 (21.3)	202 (1.3)	103 (0.7)	28 (0.2)	0	3559 (23.5)
Grade 0	14 (<0.1)	9934 (65.5)	494 (3.3)	204 (1.3)	56 (0.4)	0	10702 (70.6)
Grade 1	0	318 (2.1)	106 (0.7)	85 (0.6)	27 (0.2)	0	536 (3.5)
Grade 2	0	146 (1.0)	58 (0.4)	46 (0.3)	21 (0.1)	0	271 (1.8)
Grade 3	0	36 (0.2)	19 (0.1)	19 (0.1)	20 (0.1)	0	94 (0.6)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	13657 (90.1)	879 (5.8)	457 (3.0)	152 (1.0)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	17 (0.1)	13644 (90.0)	878 (5.8)	457 (3.0)	152 (1.0)	0	15148 (>99.9)
Grade 0	0	13 (<0.1)	0	0	0	0	13 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	1 (<0.1)	0	0	0	1 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	13657 (90.1)	879 (5.8)	457 (3.0)	152 (1.0)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	1 (<0.1)	1 (<0.1)	0	0	0	0	2 (<0.1)
Grade 0	15 (<0.1)	11669 (77.0)	362 (2.4)	95 (0.6)	19 (0.1)	0	12160 (80.2)
Grade 1	1 (<0.1)	1278 (8.4)	260 (1.7)	124 (0.8)	22 (0.1)	0	1685 (11.1)
Grade 2	0	563 (3.7)	170 (1.1)	139 (0.9)	31 (0.2)	0	903 (6.0)
Grade 3	0	144 (0.9)	87 (0.6)	99 (0.7)	80 (0.5)	0	410 (2.7)
Grade 4	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Total	17 (0.1)	13657 (90.1)	879 (5.8)	457 (3.0)	152 (1.0)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	4 (<0.1)	65 (0.4)	1 (<0.1)	1 (<0.1)	0	0	71 (0.5)
Grade 0	12 (<0.1)	13447 (88.7)	242 (1.6)	27 (0.2)	5 (<0.1)	0	13733 (90.6)
Grade 1	1 (<0.1)	657 (4.3)	261 (1.7)	42 (0.3)	4 (<0.1)	0	965 (6.4)
Grade 2	0	125 (0.8)	113 (0.7)	58 (0.4)	12 (<0.1)	0	308 (2.0)
Grade 3	0	20 (0.1)	12 (<0.1)	28 (0.2)	25 (0.2)	0	85 (0.6)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14314 (94.4)	629 (4.1)	156 (1.0)	46 (0.3)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	318 (2.1)	12 (<0.1)	3 (<0.1)	0	0	334 (2.2)
Grade 0	16 (0.1)	13103 (86.4)	287 (1.9)	43 (0.3)	5 (<0.1)	0	13454 (88.7)
Grade 1	0	706 (4.7)	237 (1.6)	50 (0.3)	9 (<0.1)	0	1002 (6.6)
Grade 2	0	155 (1.0)	80 (0.5)	44 (0.3)	13 (<0.1)	0	292 (1.9)
Grade 3	0	32 (0.2)	13 (<0.1)	16 (0.1)	19 (0.1)	0	80 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14314 (94.4)	629 (4.1)	156 (1.0)	46 (0.3)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3351 (22.1)	158 (1.0)	44 (0.3)	4 (<0.1)	0	3560 (23.5)
Grade 0	12 (<0.1)	10689 (70.5)	360 (2.4)	58 (0.4)	17 (0.1)	0	11136 (73.4)
Grade 1	2 (<0.1)	218 (1.4)	80 (0.5)	34 (0.2)	7 (<0.1)	0	341 (2.2)
Grade 2	0	50 (0.3)	27 (0.2)	15 (<0.1)	8 (<0.1)	0	100 (0.7)
Grade 3	0	6 (<0.1)	4 (<0.1)	5 (<0.1)	10 (<0.1)	0	25 (0.2)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14314 (94.4)	629 (4.1)	156 (1.0)	46 (0.3)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	17 (0.1)	14300 (94.3)	629 (4.1)	156 (1.0)	46 (0.3)	0	15148 (>99.9)
Grade 0	0	14 (<0.1)	0	0	0	0	14 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14314 (94.4)	629 (4.1)	156 (1.0)	46 (0.3)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	1 (<0.1)	2 (<0.1)	0	0	0	0	3 (<0.1)
Grade 0	14 (<0.1)	12812 (84.5)	141 (0.9)	15 (<0.1)	1 (<0.1)	0	12983 (85.6)
Grade 1	2 (<0.1)	1179 (7.8)	298 (2.0)	34 (0.2)	4 (<0.1)	0	1517 (10.0)
Grade 2	0	265 (1.7)	161 (1.1)	64 (0.4)	10 (<0.1)	0	500 (3.3)
Grade 3	0	56 (0.4)	29 (0.2)	43 (0.3)	31 (0.2)	0	159 (1.0)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14314 (94.4)	629 (4.1)	156 (1.0)	46 (0.3)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	4 (<0.1)	66 (0.4)	1 (<0.1)	0	0	0	71 (0.5)
Grade 0	13 (<0.1)	14826 (97.8)	145 (1.0)	3 (<0.1)	0	0	14987 (98.8)
Grade 1	0	44 (0.3)	49 (0.3)	2 (<0.1)	0	0	95 (0.6)
Grade 2	0	3 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	0	9 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14939 (98.5)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	330 (2.2)	3 (<0.1)	0	0	0	334 (2.2)
Grade 0	16 (0.1)	14390 (94.9)	140 (0.9)	1 (<0.1)	1 (<0.1)	0	14548 (96.0)
Grade 1	0	199 (1.3)	51 (0.3)	4 (<0.1)	1 (<0.1)	0	255 (1.7)
Grade 2	0	18 (0.1)	3 (<0.1)	1 (<0.1)	0	0	22 (0.1)
Grade 3	0	2 (<0.1)	0	1 (<0.1)	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14939 (98.5)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3523 (23.2)	32 (0.2)	2 (<0.1)	0	0	3560 (23.5)
Grade 0	14 (<0.1)	11276 (74.4)	125 (0.8)	3 (<0.1)	1 (<0.1)	0	11419 (75.3)
Grade 1	0	129 (0.9)	39 (0.3)	1 (<0.1)	1 (<0.1)	0	170 (1.1)
Grade 2	0	11 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	13 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14939 (98.5)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	17 (0.1)	14925 (98.4)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15148 (>99.9)
Grade 0	0	14 (<0.1)	0	0	0	0	14 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14939 (98.5)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	1 (<0.1)	2 (<0.1)	0	0	0	0	3 (<0.1)
Grade 0	16 (0.1)	14573 (96.1)	98 (0.6)	1 (<0.1)	0	0	14688 (96.9)
Grade 1	0	331 (2.2)	93 (0.6)	3 (<0.1)	0	0	427 (2.8)
Grade 2	0	31 (0.2)	6 (<0.1)	2 (<0.1)	2 (<0.1)	0	41 (0.3)
Grade 3	0	2 (<0.1)	0	1 (<0.1)	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	17 (0.1)	14939 (98.5)	197 (1.3)	7 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	4 (<0.1)	58 (0.4)	20 (0.1)	1 (<0.1)	0	0	83 (0.5)
Grade 0	35 (0.2)	10217 (67.4)	1353 (8.9)	43 (0.3)	3 (<0.1)	0	11651 (76.8)
Grade 1	4 (<0.1)	1323 (8.7)	1925 (12.7)	59 (0.4)	1 (<0.1)	0	3312 (21.8)
Grade 2	1 (<0.1)	47 (0.3)	37 (0.2)	22 (0.1)	0	0	107 (0.7)
Grade 3	0	5 (<0.1)	1 (<0.1)	2 (<0.1)	1 (<0.1)	0	9 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	44 (0.3)	11650 (76.8)	3336 (22.0)	127 (0.8)	5 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	263 (1.7)	69 (0.5)	3 (<0.1)	0	0	336 (2.2)
Grade 0	30 (0.2)	9029 (59.6)	1458 (9.6)	47 (0.3)	3 (<0.1)	0	10567 (69.7)
Grade 1	13 (<0.1)	2305 (15.2)	1758 (11.6)	69 (0.5)	2 (<0.1)	0	4147 (27.4)
Grade 2	0	49 (0.3)	49 (0.3)	8 (<0.1)	0	0	106 (0.7)
Grade 3	0	4 (<0.1)	2 (<0.1)	0	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	44 (0.3)	11650 (76.8)	3336 (22.0)	127 (0.8)	5 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	4 (<0.1)	2799 (18.5)	727 (4.8)	30 (0.2)	2 (<0.1)	0	3562 (23.5)
Grade 0	37 (0.2)	7674 (50.6)	1455 (9.6)	55 (0.4)	2 (<0.1)	0	9223 (60.8)
Grade 1	3 (<0.1)	1162 (7.7)	1129 (7.4)	40 (0.3)	1 (<0.1)	0	2335 (15.4)
Grade 2	0	14 (<0.1)	23 (0.2)	1 (<0.1)	0	0	38 (0.3)
Grade 3	0	1 (<0.1)	2 (<0.1)	1 (<0.1)	0	0	4 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	44 (0.3)	11650 (76.8)	3336 (22.0)	127 (0.8)	5 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	44 (0.3)	11638 (76.8)	3334 (22.0)	127 (0.8)	5 (<0.1)	0	15148 (>99.9)
Grade 0	0	10 (<0.1)	2 (<0.1)	0	0	0	12 (<0.1)
Grade 1	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	44 (0.3)	11650 (76.8)	3336 (22.0)	127 (0.8)	5 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	1 (<0.1)	2 (<0.1)	0	0	0	0	3 (<0.1)
Grade 0	25 (0.2)	8048 (53.1)	699 (4.6)	21 (0.1)	1 (<0.1)	0	8794 (58.0)
Grade 1	17 (0.1)	3482 (23.0)	2532 (16.7)	73 (0.5)	3 (<0.1)	0	6107 (40.3)
Grade 2	1 (<0.1)	108 (0.7)	100 (0.7)	30 (0.2)	0	0	239 (1.6)
Grade 3	0	10 (<0.1)	5 (<0.1)	3 (<0.1)	1 (<0.1)	0	19 (0.1)
Grade 4	0	0	0	0	0	0	0
Total	44 (0.3)	11650 (76.8)	3336 (22.0)	127 (0.8)	5 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	4 (<0.1)	58 (0.4)	0	0	0	0	62 (0.4)
Grade 0	14 (<0.1)	15024 (99.1)	28 (0.2)	6 (<0.1)	2 (<0.1)	0	15074 (99.4)
Grade 1	0	21 (0.1)	0	0	0	0	21 (0.1)
Grade 2	0	1 (<0.1)	1 (<0.1)	0	0	0	2 (<0.1)
Grade 3	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	15107 (99.6)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	334 (2.2)	0	0	0	0	335 (2.2)
Grade 0	17 (0.1)	14719 (97.1)	26 (0.2)	6 (<0.1)	1 (<0.1)	0	14769 (97.4)
Grade 1	0	35 (0.2)	2 (<0.1)	0	0	0	37 (0.2)
Grade 2	0	14 (<0.1)	0	0	1 (<0.1)	0	15 (<0.1)
Grade 3	0	5 (<0.1)	1 (<0.1)	0	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	15107 (99.6)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3550 (23.4)	6 (<0.1)	0	0	0	3559 (23.5)
Grade 0	15 (<0.1)	11534 (76.1)	21 (0.1)	6 (<0.1)	2 (<0.1)	0	11578 (76.4)
Grade 1	0	17 (0.1)	1 (<0.1)	0	0	0	18 (0.1)
Grade 2	0	6 (<0.1)	1 (<0.1)	0	0	0	7 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	15107 (99.6)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	18 (0.1)	15093 (99.5)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15148 (>99.9)
Grade 0	0	14 (<0.1)	0	0	0	0	14 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	15107 (99.6)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	1 (<0.1)	1 (<0.1)	0	0	0	0	2 (<0.1)
Grade 0	17 (0.1)	15015 (99.0)	24 (0.2)	6 (<0.1)	1 (<0.1)	0	15063 (99.3)
Grade 1	0	63 (0.4)	3 (<0.1)	0	0	0	66 (0.4)
Grade 2	0	20 (0.1)	1 (<0.1)	0	1 (<0.1)	0	22 (0.1)
Grade 3	0	8 (<0.1)	1 (<0.1)	0	0	0	9 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	15107 (99.6)	29 (0.2)	6 (<0.1)	2 (<0.1)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	4 (<0.1)	42 (0.3)	12 (<0.1)	1 (<0.1)	3 (<0.1)	0	62 (0.4)
Grade 0	12 (<0.1)	11377 (75.0)	854 (5.6)	131 (0.9)	101 (0.7)	0	12475 (82.3)
Grade 1	0	811 (5.3)	535 (3.5)	109 (0.7)	129 (0.9)	0	1584 (10.4)
Grade 2	2 (<0.1)	133 (0.9)	130 (0.9)	50 (0.3)	51 (0.3)	0	366 (2.4)
Grade 3	0	138 (0.9)	171 (1.1)	85 (0.6)	278 (1.8)	0	672 (4.4)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	3 (<0.1)
Total	18 (0.1)	12502 (82.5)	1703 (11.2)	377 (2.5)	562 (3.7)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	291 (1.9)	28 (0.2)	7 (<0.1)	8 (<0.1)	0	335 (2.2)
Grade 0	16 (0.1)	10731 (70.8)	891 (5.9)	137 (0.9)	154 (1.0)	0	11929 (78.7)
Grade 1	0	1106 (7.3)	483 (3.2)	109 (0.7)	121 (0.8)	0	1819 (12.0)
Grade 2	0	200 (1.3)	126 (0.8)	55 (0.4)	65 (0.4)	0	446 (2.9)
Grade 3	1 (<0.1)	174 (1.1)	175 (1.2)	69 (0.5)	214 (1.4)	0	633 (4.2)
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	12502 (82.5)	1703 (11.2)	377 (2.5)	562 (3.7)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	2930 (19.3)	425 (2.8)	88 (0.6)	113 (0.7)	0	3559 (23.5)
Grade 0	14 (<0.1)	8795 (58.0)	839 (5.5)	164 (1.1)	199 (1.3)	0	10011 (66.0)
Grade 1	1 (<0.1)	571 (3.8)	283 (1.9)	60 (0.4)	102 (0.7)	0	1017 (6.7)
Grade 2	0	85 (0.6)	71 (0.5)	24 (0.2)	42 (0.3)	0	222 (1.5)
Grade 3	0	121 (0.8)	85 (0.6)	41 (0.3)	106 (0.7)	0	353 (2.3)
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	12502 (82.5)	1703 (11.2)	377 (2.5)	562 (3.7)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	18 (0.1)	12488 (82.4)	1703 (11.2)	377 (2.5)	562 (3.7)	0	15148 (>99.9)
Grade 0	0	13 (<0.1)	0	0	0	0	13 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	18 (0.1)	12502 (82.5)	1703 (11.2)	377 (2.5)	562 (3.7)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	1 (<0.1)	0	1 (<0.1)	0	0	0	2 (<0.1)
Grade 0	15 (<0.1)	9957 (65.7)	472 (3.1)	55 (0.4)	42 (0.3)	0	10541 (69.5)
Grade 1	0	1825 (12.0)	658 (4.3)	112 (0.7)	96 (0.6)	0	2691 (17.7)
Grade 2	1 (<0.1)	337 (2.2)	218 (1.4)	64 (0.4)	56 (0.4)	0	676 (4.5)
Grade 3	1 (<0.1)	382 (2.5)	353 (2.3)	145 (1.0)	368 (2.4)	0	1249 (8.2)
Grade 4	0	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	3 (<0.1)
Total	18 (0.1)	12502 (82.5)	1703 (11.2)	377 (2.5)	562 (3.7)	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	4 (<0.1)	67 (0.4)	0	0	0	0	71 (0.5)
Grade 0	17 (0.1)	15070 (99.4)	1 (<0.1)	0	0	0	15088 (99.5)
Grade 1	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Total	21 (0.1)	15140 (99.9)	1 (<0.1)	0	0	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	333 (2.2)	0	0	0	0	334 (2.2)
Grade 0	20 (0.1)	14801 (97.6)	1 (<0.1)	0	0	0	14822 (97.8)
Grade 1	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 2	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	21 (0.1)	15140 (99.9)	1 (<0.1)	0	0	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3564 (23.5)	0	0	0	0	3567 (23.5)
Grade 0	18 (0.1)	11571 (76.3)	1 (<0.1)	0	0	0	11590 (76.4)
Grade 1	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 2	0	4 (<0.1)	0	0	0	0	4 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	21 (0.1)	15140 (99.9)	1 (<0.1)	0	0	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	21 (0.1)	15126 (99.8)	1 (<0.1)	0	0	0	15148 (>99.9)
Grade 0	0	14 (<0.1)	0	0	0	0	14 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	21 (0.1)	15140 (99.9)	1 (<0.1)	0	0	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: Placebo (N=15162)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	1 (<0.1)	2 (<0.1)	0	0	0	0	3 (<0.1)
Grade 0	20 (0.1)	15124 (99.7)	1 (<0.1)	0	0	0	15145 (99.9)
Grade 1	0	6 (<0.1)	0	0	0	0	6 (<0.1)
Grade 2	0	7 (<0.1)	0	0	0	0	7 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Total	21 (0.1)	15140 (99.9)	1 (<0.1)	0	0	0	15162 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	0	51 (0.3)	3 (<0.1)	1 (<0.1)	1 (<0.1)	0	56 (0.4)
Grade 0	19 (0.1)	12736 (83.9)	578 (3.8)	176 (1.2)	44 (0.3)	0	13553 (89.3)
Grade 1	0	582 (3.8)	206 (1.4)	104 (0.7)	27 (0.2)	0	919 (6.1)
Grade 2	0	199 (1.3)	125 (0.8)	104 (0.7)	33 (0.2)	0	461 (3.0)
Grade 3	0	61 (0.4)	29 (0.2)	46 (0.3)	59 (0.4)	0	195 (1.3)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	13629 (89.8)	941 (6.2)	431 (2.8)	164 (1.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	258 (1.7)	17 (0.1)	5 (<0.1)	5 (<0.1)	0	286 (1.9)
Grade 0	17 (0.1)	12199 (80.3)	595 (3.9)	197 (1.3)	61 (0.4)	0	13069 (86.1)
Grade 1	1 (<0.1)	764 (5.0)	189 (1.2)	104 (0.7)	24 (0.2)	0	1082 (7.1)
Grade 2	0	321 (2.1)	103 (0.7)	81 (0.5)	32 (0.2)	0	537 (3.5)
Grade 3	0	87 (0.6)	37 (0.2)	44 (0.3)	42 (0.3)	0	210 (1.4)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	13629 (89.8)	941 (6.2)	431 (2.8)	164 (1.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3071 (20.2)	213 (1.4)	79 (0.5)	33 (0.2)	0	3399 (22.4)
Grade 0	16 (0.1)	9988 (65.8)	531 (3.5)	212 (1.4)	69 (0.5)	0	10816 (71.2)
Grade 1	0	377 (2.5)	137 (0.9)	78 (0.5)	24 (0.2)	0	616 (4.1)
Grade 2	0	147 (1.0)	39 (0.3)	42 (0.3)	17 (0.1)	0	245 (1.6)
Grade 3	0	46 (0.3)	21 (0.1)	20 (0.1)	21 (0.1)	0	108 (0.7)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	13629 (89.8)	941 (6.2)	431 (2.8)	164 (1.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	18 (0.1)	13619 (89.7)	941 (6.2)	429 (2.8)	164 (1.1)	0	15171 (>99.9)
Grade 0	1 (<0.1)	6 (<0.1)	0	0	0	0	7 (<0.1)
Grade 1	0	3 (<0.1)	0	2 (<0.1)	0	0	5 (<0.1)
Grade 2	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	13629 (89.8)	941 (6.2)	431 (2.8)	164 (1.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 0	18 (0.1)	11587 (76.3)	386 (2.5)	91 (0.6)	20 (0.1)	0	12102 (79.7)
Grade 1	1 (<0.1)	1294 (8.5)	290 (1.9)	106 (0.7)	23 (0.2)	0	1714 (11.3)
Grade 2	0	571 (3.8)	190 (1.3)	145 (1.0)	40 (0.3)	0	946 (6.2)
Grade 3	0	176 (1.2)	75 (0.5)	89 (0.6)	81 (0.5)	0	421 (2.8)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	13629 (89.8)	941 (6.2)	431 (2.8)	164 (1.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	0	56 (0.4)	2 (<0.1)	1 (<0.1)	0	0	59 (0.4)
Grade 0	19 (0.1)	13539 (89.2)	258 (1.7)	26 (0.2)	6 (<0.1)	0	13848 (91.2)
Grade 1	1 (<0.1)	646 (4.3)	243 (1.6)	45 (0.3)	3 (<0.1)	0	938 (6.2)
Grade 2	0	103 (0.7)	94 (0.6)	63 (0.4)	7 (<0.1)	0	267 (1.8)
Grade 3	0	23 (0.2)	15 (<0.1)	18 (0.1)	16 (0.1)	0	72 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14367 (94.6)	612 (4.0)	153 (1.0)	32 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	2 (<0.1)	277 (1.8)	7 (<0.1)	1 (<0.1)	0	0	287 (1.9)
Grade 0	17 (0.1)	13196 (86.9)	310 (2.0)	46 (0.3)	7 (<0.1)	0	13576 (89.4)
Grade 1	1 (<0.1)	720 (4.7)	179 (1.2)	44 (0.3)	4 (<0.1)	0	948 (6.2)
Grade 2	0	149 (1.0)	96 (0.6)	43 (0.3)	9 (<0.1)	0	297 (2.0)
Grade 3	0	25 (0.2)	20 (0.1)	19 (0.1)	12 (<0.1)	0	76 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14367 (94.6)	612 (4.0)	153 (1.0)	32 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3210 (21.1)	147 (1.0)	35 (0.2)	7 (<0.1)	0	3402 (22.4)
Grade 0	17 (0.1)	10902 (71.8)	353 (2.3)	64 (0.4)	10 (<0.1)	0	11346 (74.7)
Grade 1	0	218 (1.4)	88 (0.6)	26 (0.2)	6 (<0.1)	0	338 (2.2)
Grade 2	0	32 (0.2)	20 (0.1)	23 (0.2)	8 (<0.1)	0	83 (0.5)
Grade 3	0	5 (<0.1)	4 (<0.1)	5 (<0.1)	1 (<0.1)	0	15 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14367 (94.6)	612 (4.0)	153 (1.0)	32 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	19 (0.1)	14355 (94.5)	612 (4.0)	153 (1.0)	32 (0.2)	0	15171 (>99.9)
Grade 0	1 (<0.1)	12 (<0.1)	0	0	0	0	13 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14367 (94.6)	612 (4.0)	153 (1.0)	32 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 0	18 (0.1)	12901 (85.0)	164 (1.1)	14 (<0.1)	2 (<0.1)	0	13099 (86.3)
Grade 1	2 (<0.1)	1180 (7.8)	257 (1.7)	36 (0.2)	4 (<0.1)	0	1479 (9.7)
Grade 2	0	240 (1.6)	157 (1.0)	69 (0.5)	9 (<0.1)	0	475 (3.1)
Grade 3	0	45 (0.3)	34 (0.2)	34 (0.2)	17 (0.1)	0	130 (0.9)
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14367 (94.6)	612 (4.0)	153 (1.0)	32 (0.2)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	0	57 (0.4)	1 (<0.1)	1 (<0.1)	0	0	59 (0.4)
Grade 0	20 (0.1)	14819 (97.6)	170 (1.1)	11 (<0.1)	0	0	15020 (98.9)
Grade 1	0	39 (0.3)	47 (0.3)	12 (<0.1)	0	0	98 (0.6)
Grade 2	0	2 (<0.1)	2 (<0.1)	2 (<0.1)	1 (<0.1)	0	7 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14917 (98.2)	220 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	2 (<0.1)	276 (1.8)	7 (<0.1)	2 (<0.1)	0	0	287 (1.9)
Grade 0	17 (0.1)	14407 (94.9)	146 (1.0)	15 (<0.1)	0	0	14585 (96.1)
Grade 1	0	218 (1.4)	59 (0.4)	5 (<0.1)	1 (<0.1)	0	283 (1.9)
Grade 2	1 (<0.1)	14 (<0.1)	8 (<0.1)	3 (<0.1)	0	0	26 (0.2)
Grade 3	0	2 (<0.1)	0	1 (<0.1)	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14917 (98.2)	220 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3347 (22.0)	47 (0.3)	5 (<0.1)	0	0	3402 (22.4)
Grade 0	17 (0.1)	11422 (75.2)	142 (0.9)	14 (<0.1)	1 (<0.1)	0	11596 (76.4)
Grade 1	0	137 (0.9)	26 (0.2)	5 (<0.1)	0	0	168 (1.1)
Grade 2	0	10 (<0.1)	5 (<0.1)	2 (<0.1)	0	0	17 (0.1)
Grade 3	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14917 (98.2)	220 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	19 (0.1)	14905 (98.2)	220 (1.4)	26 (0.2)	1 (<0.1)	0	15171 (>99.9)
Grade 0	1 (<0.1)	11 (<0.1)	0	0	0	0	12 (<0.1)
Grade 1	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14917 (98.2)	220 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 0	19 (0.1)	14538 (95.7)	122 (0.8)	6 (<0.1)	0	0	14685 (96.7)
Grade 1	0	352 (2.3)	84 (0.6)	13 (<0.1)	0	0	449 (3.0)
Grade 2	1 (<0.1)	23 (0.2)	14 (<0.1)	6 (<0.1)	1 (<0.1)	0	45 (0.3)
Grade 3	0	3 (<0.1)	0	1 (<0.1)	0	0	4 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	20 (0.1)	14917 (98.2)	220 (1.4)	26 (0.2)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	1 (<0.1)	47 (0.3)	20 (0.1)	0	0	0	68 (0.4)
Grade 0	32 (0.2)	10212 (67.3)	1391 (9.2)	31 (0.2)	1 (<0.1)	0	11667 (76.8)
Grade 1	6 (<0.1)	1357 (8.9)	1929 (12.7)	41 (0.3)	2 (<0.1)	0	3335 (22.0)
Grade 2	1 (<0.1)	38 (0.3)	41 (0.3)	26 (0.2)	0	0	106 (0.7)
Grade 3	0	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	0	8 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	40 (0.3)	11657 (76.8)	3382 (22.3)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	222 (1.5)	63 (0.4)	1 (<0.1)	1 (<0.1)	0	288 (1.9)
Grade 0	31 (0.2)	9057 (59.6)	1524 (10.0)	47 (0.3)	0	0	10659 (70.2)
Grade 1	8 (<0.1)	2319 (15.3)	1736 (11.4)	43 (0.3)	3 (<0.1)	0	4109 (27.1)
Grade 2	0	55 (0.4)	58 (0.4)	9 (<0.1)	0	0	122 (0.8)
Grade 3	0	4 (<0.1)	1 (<0.1)	1 (<0.1)	0	0	6 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	40 (0.3)	11657 (76.8)	3382 (22.3)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	4 (<0.1)	2677 (17.6)	716 (4.7)	11 (<0.1)	2 (<0.1)	0	3410 (22.5)
Grade 0	28 (0.2)	7736 (50.9)	1510 (9.9)	54 (0.4)	1 (<0.1)	0	9329 (61.4)
Grade 1	8 (<0.1)	1223 (8.1)	1139 (7.5)	34 (0.2)	1 (<0.1)	0	2405 (15.8)
Grade 2	0	19 (0.1)	16 (0.1)	2 (<0.1)	0	0	37 (0.2)
Grade 3	0	2 (<0.1)	1 (<0.1)	0	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	40 (0.3)	11657 (76.8)	3382 (22.3)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	39 (0.3)	11647 (76.7)	3380 (22.3)	101 (0.7)	4 (<0.1)	0	15171 (>99.9)
Grade 0	0	9 (<0.1)	2 (<0.1)	0	0	0	11 (<0.1)
Grade 1	1 (<0.1)	1 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	40 (0.3)	11657 (76.8)	3382 (22.3)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	0	0	1 (<0.1)	0	0	0	1 (<0.1)
Grade 0	24 (0.2)	7994 (52.6)	725 (4.8)	11 (<0.1)	0	0	8754 (57.7)
Grade 1	15 (<0.1)	3549 (23.4)	2545 (16.8)	54 (0.4)	3 (<0.1)	0	6166 (40.6)
Grade 2	1 (<0.1)	106 (0.7)	108 (0.7)	33 (0.2)	0	0	248 (1.6)
Grade 3	0	8 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)	0	15 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	40 (0.3)	11657 (76.8)	3382 (22.3)	101 (0.7)	4 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	0	56 (0.4)	0	0	0	0	56 (0.4)
Grade 0	19 (0.1)	15065 (99.2)	17 (0.1)	6 (<0.1)	1 (<0.1)	0	15108 (99.5)
Grade 1	0	13 (<0.1)	1 (<0.1)	0	0	0	14 (<0.1)
Grade 2	0	3 (<0.1)	1 (<0.1)	0	0	0	4 (<0.1)
Grade 3	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	15139 (99.7)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	284 (1.9)	0	1 (<0.1)	0	0	286 (1.9)
Grade 0	17 (0.1)	14811 (97.5)	15 (<0.1)	5 (<0.1)	0	0	14848 (97.8)
Grade 1	1 (<0.1)	30 (0.2)	2 (<0.1)	0	1 (<0.1)	0	34 (0.2)
Grade 2	0	12 (<0.1)	2 (<0.1)	0	0	0	14 (<0.1)
Grade 3	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	15139 (99.7)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	3393 (22.3)	1 (<0.1)	1 (<0.1)	1 (<0.1)	0	3399 (22.4)
Grade 0	16 (0.1)	11715 (77.2)	16 (0.1)	5 (<0.1)	0	0	11752 (77.4)
Grade 1	0	21 (0.1)	1 (<0.1)	0	0	0	22 (0.1)
Grade 2	0	8 (<0.1)	0	0	0	0	8 (<0.1)
Grade 3	0	2 (<0.1)	1 (<0.1)	0	0	0	3 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	15139 (99.7)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	18 (0.1)	15127 (99.6)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15171 (>99.9)
Grade 0	1 (<0.1)	12 (<0.1)	0	0	0	0	13 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	15139 (99.7)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 0	18 (0.1)	15055 (99.2)	14 (<0.1)	6 (<0.1)	0	0	15093 (99.4)
Grade 1	1 (<0.1)	55 (0.4)	2 (<0.1)	0	1 (<0.1)	0	59 (0.4)
Grade 2	0	22 (0.1)	2 (<0.1)	0	0	0	24 (0.2)
Grade 3	0	6 (<0.1)	1 (<0.1)	0	0	0	7 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	15139 (99.7)	19 (0.1)	6 (<0.1)	1 (<0.1)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	0	49 (0.3)	5 (<0.1)	1 (<0.1)	1 (<0.1)	0	56 (0.4)
Grade 0	19 (0.1)	11310 (74.5)	844 (5.6)	120 (0.8)	96 (0.6)	0	12389 (81.6)
Grade 1	0	890 (5.9)	552 (3.6)	122 (0.8)	137 (0.9)	0	1701 (11.2)
Grade 2	0	138 (0.9)	147 (1.0)	67 (0.4)	67 (0.4)	0	419 (2.8)
Grade 3	0	131 (0.9)	165 (1.1)	87 (0.6)	236 (1.6)	0	619 (4.1)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	12518 (82.4)	1713 (11.3)	397 (2.6)	537 (3.5)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	246 (1.6)	22 (0.1)	7 (<0.1)	10 (<0.1)	0	286 (1.9)
Grade 0	14 (<0.1)	10702 (70.5)	879 (5.8)	157 (1.0)	133 (0.9)	0	11885 (78.3)
Grade 1	3 (<0.1)	1163 (7.7)	489 (3.2)	116 (0.8)	148 (1.0)	0	1919 (12.6)
Grade 2	0	202 (1.3)	131 (0.9)	48 (0.3)	64 (0.4)	0	445 (2.9)
Grade 3	1 (<0.1)	205 (1.4)	192 (1.3)	69 (0.5)	182 (1.2)	0	649 (4.3)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	12518 (82.4)	1713 (11.3)	397 (2.6)	537 (3.5)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	3 (<0.1)	2790 (18.4)	427 (2.8)	96 (0.6)	84 (0.6)	0	3400 (22.4)
Grade 0	15 (<0.1)	8923 (58.8)	844 (5.6)	157 (1.0)	192 (1.3)	0	10131 (66.7)
Grade 1	0	573 (3.8)	265 (1.7)	80 (0.5)	110 (0.7)	0	1028 (6.8)
Grade 2	0	111 (0.7)	75 (0.5)	27 (0.2)	40 (0.3)	0	253 (1.7)
Grade 3	1 (<0.1)	121 (0.8)	102 (0.7)	37 (0.2)	111 (0.7)	0	372 (2.4)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	12518 (82.4)	1713 (11.3)	397 (2.6)	537 (3.5)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	18 (0.1)	12508 (82.4)	1711 (11.3)	397 (2.6)	537 (3.5)	0	15171 (>99.9)
Grade 0	1 (<0.1)	8 (<0.1)	2 (<0.1)	0	0	0	11 (<0.1)
Grade 1	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	12518 (82.4)	1713 (11.3)	397 (2.6)	537 (3.5)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
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Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 0	15 (<0.1)	9867 (65.0)	475 (3.1)	53 (0.3)	32 (0.2)	0	10442 (68.8)
Grade 1	3 (<0.1)	1873 (12.3)	652 (4.3)	113 (0.7)	106 (0.7)	0	2747 (18.1)
Grade 2	0	373 (2.5)	229 (1.5)	81 (0.5)	67 (0.4)	0	750 (4.9)
Grade 3	1 (<0.1)	404 (2.7)	357 (2.4)	150 (1.0)	332 (2.2)	0	1244 (8.2)
Grade 4	0	0	0	0	0	0	0
Total	19 (0.1)	12518 (82.4)	1713 (11.3)	397 (2.6)	537 (3.5)	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 1 - 30 Minutes Postdose							
UNK	0	59 (0.4)	0	0	0	0	59 (0.4)
Grade 0	23 (0.2)	15097 (99.4)	1 (<0.1)	1 (<0.1)	0	0	15122 (99.6)
Grade 1	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 2	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	23 (0.2)	15159 (99.8)	1 (<0.1)	1 (<0.1)	0	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 29							
UNK	1 (<0.1)	286 (1.9)	0	0	0	0	287 (1.9)
Grade 0	22 (0.1)	14868 (97.9)	1 (<0.1)	1 (<0.1)	0	0	14892 (98.1)
Grade 1	0	3 (<0.1)	0	0	0	0	3 (<0.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	23 (0.2)	15159 (99.8)	1 (<0.1)	1 (<0.1)	0	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 57							
UNK	4 (<0.1)	3407 (22.4)	0	1 (<0.1)	0	0	3412 (22.5)
Grade 0	19 (0.1)	11752 (77.4)	1 (<0.1)	0	0	0	11772 (77.5)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	23 (0.2)	15159 (99.8)	1 (<0.1)	1 (<0.1)	0	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	22 (0.1)	15147 (99.8)	1 (<0.1)	1 (<0.1)	0	0	15171 (>99.9)
Grade 0	1 (<0.1)	12 (<0.1)	0	0	0	0	13 (<0.1)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	23 (0.2)	15159 (99.8)	1 (<0.1)	1 (<0.1)	0	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

Table 14.3.2.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Treatment Group: mRNA-1273 (N=15184)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Worst Post-Baseline							
UNK	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 0	23 (0.2)	15150 (99.8)	1 (<0.1)	1 (<0.1)	0	0	15175 (>99.9)
Grade 1	0	5 (<0.1)	0	0	0	0	5 (<0.1)
Grade 2	0	1 (<0.1)	0	0	0	0	1 (<0.1)
Grade 3	0	2 (<0.1)	0	0	0	0	2 (<0.1)
Grade 4	0	0	0	0	0	0	0
Total	23 (0.2)	15159 (99.8)	1 (<0.1)	1 (<0.1)	0	0	15184 (100)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.
Program Path: \\wilbtia\wilbtia01\Moderna MODMRNA1273P301_U\BLA\TLF\t14030202.sas 25JUN2021 12:40

15 NARRATIVES OF DEATHS, OTHER SERIOUS ADVERSE EVENTS, AND CERTAIN OTHER CLINICALLY MEANINGFUL ADVERSE EVENTS

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3002031		X			X	
US3002046		X		X	X	
US3002122						X
US3002131		X				
US3002259		X				
US3002302					X	
US3012096		X				
US3012098		X				
US3012131		X				
US3012263		X				
US3012329			X			
US3022012					X	
US3022021					X	
US3022031		X			X	
US3022052		X				
US3022063		X				
US3022103		X				
US3022186		X				
US3022193		X				
US3022208		X			X	
US3022233			X			
US3022246		X				
US3022276		X				
US3022291		X				
US3032110			X			
US3032112						X
US3032112_a		X				
US3032115		X				
US3032171					X	
US3032172					X	
US3032187		X	X			
US3032204	X	X	X	X		
US3032211					X	

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3032242		X				
US3032263		X				
US3032277		X		X	X	
US3032305					X	
US3032320					X	
US3032323		X				X
US3032337		X				
US3042032				X	X	
US3042047			X			
US3042177						X
US3042187			X			
US3042190		X		X	X	
US3042192				X	X	
US3042203		X				
US3042209					X	
US3042210		X				
US3042213		X				
US3042241			X			
US3042264		X				
US3042288		X	X			
US3042295				X	X	
US3052020						X
US3052028		X				
US3052044		X				
US3052220		X				
US3052295		X				
US3052315		X				
US3052380		X				
US3062018		X				
US3062019		X				
US3062048		X				
US3062075		X				
US3062079		X				
US3062128		X				
US3062151		X				
US3062167		X				
US3062265		X				
US3082051		X		X	X	

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3082081		X				
US3082136		X				
US3082247					X	
US3082269	X	X		X		
US3092021		X				
US3092022		X				
US3092043		X				
US3092047		X				
US3092099						X
US3092112		X				
US3092245		X				
US3102052		X				
US3102061		X				
US3102082		X				
US3102283		X	X			
US3102311		X				
US3112030		X				
US3112071		X				
US3112121		X				
US3112128		X			X	
US3112145		X				
US3112164		X				
US3112192		X				
US3112210		X				
US3112219			X			
US3112223		X				
US3112266					X	
US3112267					X	
US3112365		X				
US3112389		X				
US3122010		X			X	
US3122047					X	
US3122085		X				
US3132019		X				
US3132037		X				
US3132084			X			
US3132111		X				
US3132149		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3142013			X			
US3142034			X			
US3142043			X			
US3142056			X			
US3142100			X			
US3142161		X				
US3142185		X				
US3142243					X	
US3142252			X			
US3142255			X			
US3142268		X				
US3152025					X	
US3152136		X				
US3152194		X				
US3152523			X			
US3162003		X				
US3162006		X	X			
US3162007		X				
US3162028			X			
US3162037		X				
US3162078			X		X	
US3162159			X		X	
US3172028		X				
US3172038		X			X	
US3172114		X				
US3172185		X			X	
US3172224		X				
US3172250		X				
US3172265					X	
US3172322		X				
US3172333		X				
US3172349		X				X
US3172360					X	
US3172467					X	
US3172469		X				
US3182006			X			
US3182012			X			
US3182025		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3182145			X			
US3182151						X
US3182158		X				
US3182166		X				
US3182192		X				
US3182227		X				
US3182236		X				
US3182292					X	
US3192006		X				
US3192086					X	
US3192291		X				
US3192345		X				
US3192486		X				
US3192569	X	X		X		
US3192614		X				
US3192730					X	
US3192734		X				
US3202036		X				
US3202049		X	X			
US3202085		X				
US3202191		X				
US3202197		X				
US3202231		X				
US3202304		X				
US3202310		X				
US3202366						X
US3212004		X				
US3212013		X				
US3212028		X				
US3212066					X	
US3212100		X				
US3212112			X		X	
US3212182						X
US3212326		X				
US3212394		X				
US3222004		X				
US3222013		X				
US3222032		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3222059		X				
US3222061					X	
US3222068		X				
US3222077		X				
US3222089		X				
US3222117		X				
US3222143		X				
US3222189		X				
US3222220		X				
US3222296		X				
US3222299		X				
US3222311		X				
US3222315		X				
US3222367		X				
US3222388		X				
US3222424					X	
US3222452		X				
US3222462		X				
US3222554		X				
US3222611		X				
US3232021					X	
US3232048	X	X		X		
US3232056		X	X			
US3232157			X			
US3242002					X	
US3242003			X			
US3242017		X				
US3242051		X				
US3242107		X				
US3242231		X				
US3242258					X	
US3242264		X				
US3242269		X				
US3242288					X	
US3242314		X				
US3242370		X		X	X	
US3242397			X			
US3252009						X

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3252020					X	
US3252075					X	
US3252119		X				
US3252127		X				
US3252166		X				
US3252261		X				
US3252516		X				
US3252553		X			X	
US3252602		X				
US3252638					X	
US3262007			X			
US3262055		X				
US3262099			X			
US3262145		X	X			
US3262275			X			
US3272005		X				
US3272026		X	X			
US3272031		X				
US3272070	X	X		X		
US3272085		X				
US3272104			X			
US3272144		X	X			
US3272169		X				
US3272195		X	X			
US3272196			X			
US3272260					X	
US3272342			X			
US3272357			X			
US3272377		X				
US3282113		X				
US3292023	X	X		X		
US3292103		X				
US3292127		X				
US3292236		X				
US3292241					X	
US3292245		X				
US3292259		X				
US3292304		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3292312		X				
US3292316		X				
US3292320		X				
US3292324		X				
US3292339		X				
US3292365		X				
US3292412					X	
US3302212		X				
US3302345						X
US3302379		X	X			
US3302383		X	X		X	
US3302395	X	X		X		
US3302472		X				
US3312023		X				
US3312046		X				
US3312063					X	
US3312068					X	
US3312095		X				
US3312130		X				
US3312187		X				
US3312197		X			X	
US3312201					X	
US3312212		X			X	
US3312225		X				
US3312249		X				
US3312291		X				
US3312325		X				
US3312330			X			
US3312395		X				
US3312434		X				
US3312465		X				
US3312548					X	
US3312573						X
US3312587					X	
US3312605		X	X			
US3312629		X				
US3312637		X			X	
US3322006			X		X	

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3322013		X				
US3322061					X	
US3322199	X	X		X		
US3322302		X				
US3322329		X				
US3322341		X				
US3322353		X				
US3322388			X			
US3322429		X				
US3332001			X			
US3332033		X				
US3332034		X				
US3332060					X	
US3332089					X	
US3332101			X			
US3342023		X				
US3342046			X			
US3342088		X			X	
US3342142						X
US3342182			X			
US3342199		X				
US3342200		X				
US3342239					X	
US3342253					X	
US3342256	X	X		X		
US3342259				X	X	
US3342281		X				
US3342286					X	
US3342323					X	
US3342343		X			X	
US3342354		X				
US3352033		X				
US3352070		X				
US3352072					X	
US3352200						X
US3352299		X				
US3352424		X				
US3362023					X	

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3362069		X				
US3362071		X				
US3362083					X	
US3362099		X				
US3362124					X	
US3362166		X				
US3362210		X				
US3362222		X				
US3362244		X			X	
US3362285		X				
US3372005		X				
US3372059		X	X			
US3372060		X				
US3372092					X	
US3372110					X	
US3372137		X				
US3372184		X				
US3372209		X				
US3372228	X	X		X		
US3372229					X	X
US3372274		X				
US3372284		X				
US3372394		X				
US3382035					X	
US3382085				X		
US3382284		X		X	X	
US3392049		X				
US3392112		X				
US3392120		X				
US3392149		X			X	
US3392251		X				
US3402029		X	X			
US3402042		X				
US3402139		X				
US3402194		X	X			
US3402196			X			
US3402211		X				
US3402212		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3402284		X				
US3402299		X				
US3402300					X	
US3402316						X
US3402332			X			
US3402381		X				
US3402382		X				
US3402425		X				
US3402430					X	
US3402448		X				
US3412012			X			
US3412013		X				
US3412016		X				
US3412067		X				
US3412081		X				
US3412118		X				
US3412125		X				
US3412126		X			X	
US3412127		X				
US3412129					X	
US3412184		X				
US3412205		X				
US3412208			X			
US3412224			X			
US3412240		X				
US3412243		X				
US3412259			X			
US3412300			X			
US3412304			X			
US3412328		X				
US3422135		X				
US3422244	X	X		X		
US3422281		X				
US3432016		X				
US3432023		X			X	
US3432081		X				
US3432094		X				
US3432202		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3432208		X				
US3432229		X				
US3432242		X				
US3432295	X	X		X	X	
US3432334					X	
US3432517		X				
US3432627		X				
US3442024		X				
US3442031		X				
US3442051		X				
US3442060		X				
US3442068		X				
US3442096			X			
US3442113		X				
US3442173			X			
US3452203			X			
US3452232			X			
US3452295					X	
US3452332			X			
US3462076						X
US3462091		X				
US3462101		X				
US3462111		X				
US3462116		X				
US3462133		X				
US3462213		X				
US3462255		X				
US3462374			X			
US3462388		X				
US3472001	X	X		X		
US3472013		X				
US3472096					X	
US3472130			X		X	
US3482023		X				
US3482064					X	
US3482094			X			
US3482145		X				
US3482267		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3482284		X			X	
US3482286			X			
US3482302		X				
US3492064		X				
US3492078		X				
US3492085		X				
US3492117					X	
US3492178		X				
US3492237					X	
US3492242					X	
US3492243		X				
US3492273		X				
US3492281		X				
US3492299					X	
US3502045		X				
US3502142		X				
US3512036		X				
US3512042	X	X		X		
US3512176					X	
US3512193		X				
US3512199					X	
US3512217		X				
US3522042					X	
US3522077		X				
US3522109		X				
US3522128		X				
US3522200		X				
US3522227		X				
US3522269		X				
US3522297					X	
US3522513		X				
US3522529		X				
US3522664					X	
US3532002		X				
US3532020					X	
US3532063		X				
US3532170		X			X	
US3532192		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3532212		X			X	
US3532231		X				
US3532279					X	
US3532281		X				
US3542043					X	
US3542090					X	
US3542108		X				
US3542168		X			X	
US3542199		X				
US3542309		X				
US3542332		X			X	
US3552024		X				
US3552035					X	
US3552053		X				
US3552087					X	
US3552103					X	
US3552140		X			X	
US3552189		X				
US3552191		X				
US3552232		X			X	
US3552273					X	
US3552331		X			X	
US3552371		X			X	
US3552444					X	
US3552473		X				
US3552497					X	
US3552499		X				
US3562015			X			
US3562040			X			
US3562157		X		X	X	
US3562205		X				
US3562230		X			X	
US3572086	X	X		X		
US3572116		X				
US3572120		X				
US3572125		X				
US3572134		X				
US3572181		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3572199		X				
US3572324			X			
US3592075			X			
US3592111		X				
US3592127			X			
US3592196					X	
US3592226		X				
US3592229		X				
US3592232		X				
US3592247		X				
US3602004		X				
US3602008					X	
US3602030		X				
US3602051		X				
US3602074		X	X			
US3602111					X	
US3612010		X				
US3612031			X			
US3622012					X	
US3622116		X				
US3622169	X	X		X		
US3622197		X				
US3622211		X				
US3622282		X				
US3632022		X				
US3632032		X				
US3632064		X				
US3632107			X			
US3632127		X				
US3632154			X			
US3642024		X				
US3642035		X				
US3642072		X				
US3642261					X	
US3642268					X	
US3642333		X				
US3652038		X			X	
US3652039					X	

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3662033		X				
US3662156			X			
US3662181		X				
US3672092					X	
US3672097					X	
US3672151					X	
US3672163				X	X	
US3672187					X	
US3672199		X				
US3672203	X	X		X		
US3672251					X	
US3672278		X			X	
US3672333					X	
US3672377					X	
US3672388		X				
US3672407					X	
US3682001		X				
US3682017		X				
US3682018			X			
US3682040					X	
US3682134		X				
US3692001		X				
US3692016		X				
US3692141		X				
US3702010	X	X	X	X		
US3702051			X			
US3712013		X				
US3712032		X				
US3712035		X				
US3712064		X				
US3712094		X				
US3712114		X				
US3712271		X	X			
US3712308			X			
US3722034		X				
US3722066		X	X			
US3722239						X
US3722305						X

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3722338		X				
US3722406		X				
US3732094		X				
US3732110		X				
US3732176		X	X			
US3732207					X	
US3732235		X				
US3732249		X				
US3732262					X	
US3732304		X				
US3732311					X	
US3742022		X				
US3742076		X				
US3742077		X				
US3742123			X			
US3742132		X				
US3742169		X			X	
US3742253					X	
US3742330		X				
US3742342		X				
US3742357			X			
US3742364		X				
US3742384		X				
US3742395					X	
US3742477					X	
US3752025		X	X			
US3752129		X				
US3752162			X			
US3752173	X	X		X		
US3752229			X			
US3752245		X				
US3752259		X				
US3752366					X	
US3762161		X				
US3762175		X				
US3762177					X	
US3772035			X			
US3772037		X	X			

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3772051		X		X	X	
US3772103		X				
US3772159			X			
US3772187		X				
US3782073					X	
US3782100		X				
US3782153		X				
US3782162		X				
US3782198					X	
US3792080		X				
US3792090		X				
US3792094		X				
US3802034			X			
US3802046		X	X			
US3802109			X			
US3802149		X				
US3802185			X			
US3802218		X				
US3812010		X				
US3812059		X				
US3812060	X	X		X		
US3812062		X				
US3812085		X				
US3812098		X				
US3812132		X				
US3812169		X				
US3812174					X	
US3812197					X	
US3812257					X	
US3812270		X				
US3812280		X				
US3812291		X				
US3822003		X				
US3822006					X	
US3822015		X				
US3822043		X				
US3822119		X				
US3822154		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3822278		X				
US3822443	X	X		X		
US3832014		X				
US3832043		X				
US3832055		X				
US3832074		X				
US3832150		X				
US3832211		X				
US3832237	X	X		X		
US3832250						X
US3842027		X				
US3842040			X			
US3842060					X	
US3852122			X			
US3852200		X				
US3862020		X				
US3862021		X				
US3862044					X	
US3862050					X	
US3862053		X				
US3862086						X
US3862098					X	
US3862099		X				
US3862119		X				
US3862141	X	X		X		
US3862175					X	
US3862286					X	
US3872001		X				
US3872016		X				
US3872062		X				
US3872090		X				
US3872095		X	X			
US3872118		X				
US3872138					X	
US3872173		X				
US3872213						X
US3872223			X			
US3872318	X	X		X		

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3872345						X
US3872377			X			
US3872402		X				
US3872496	X	X		X		
US3872501					X	
US3882011	X	X		X		
US3882016		X				
US3882049					X	
US3892033		X				
US3892034		X				
US3892059			X			
US3902015			X			
US3902019					X	
US3902020		X				
US3902021		X				
US3902030					X	
US3902064					X	
US3912024	X	X		X		
US3912114		X				
US3912121		X				
US3912163		X				
US3912241		X			X	
US3922067		X			X	
US3922074					X	
US3922080		X			X	
US3932003					X	
US3932005		X				
US3932018		X				
US3932051		X				
US3932066		X	X			
US3932077		X				
US3932083		X	X			
US3932118			X			
US3932147		X			X	
US3932151		X				
US3932182		X				
US3932192		X				
US3932197	X	X		X		

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3932206		X				
US3932215		X				
US3932238					X	
US3932246	X	X		X		
US3932286		X	X			
US3932296		X				
US3942001		X				
US3942021		X		X	X	
US3942027		X				X
US3942036		X				
US3942044					X	
US3942079			X		X	
US3942151		X			X	
US3952004		X				
US3952033		X	X		X	
US3952052		X				
US3952094	X	X	X	X		
US3952104		X			X	
US3952116					X	
US3952141		X				
US3952158					X	
US3952216					X	
US3962016			X			
US3962042		X				
US3962063		X				
US3962066			X			
US3962094	X	X		X		
US3972010	X	X		X		
US3972045	X	X		X		
US3972049		X				
US3972064		X				
US3972097		X				
US3972104		X				
US3972116		X				
US3972210						X
US3972225					X	
US3982022		X				
US3982031		X				

Participant Number	Death	Other SAE	Severe COVID-19	Unsolicited AE Leading to Discontinuation of Study	Unsolicited AE Leading to Discontinuation of Vaccine	Pregnancy
US3982050		X				
US3982069		X				
US3982088		X				
US3982125		X				
US3982144		X				
US3982151		X				
US3982158					X	
US3982169		X				
US3982213					X	
US3982244		X				
US3982246		X				
US3982256		X				
US3982269		X				
US3982272		X				
US3742148						X

Abbreviations: AE=adverse event; SAE= serious adverse event.

Participant Number:	US323-2048 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Amyotrophic Lateral Sclerosis/Complication Of Amyotrophic Lateral Sclerosis	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	05 Nov 2020 (Study Day 77) – 12 Dec 2020 (Study Day 114)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US323-2048, a 73-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 18 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Nov 2020 (Study Day 77), 76 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of amyotrophic lateral sclerosis. Action taken with the IP was not applicable. The event of complication of amyotrophic lateral sclerosis lasted for 38 days, after which it was considered to be fatal on 12 Dec 2020 (Study Day 114). The investigator assessed the event of amyotrophic lateral sclerosis to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Nov 2020 (Study Day 77), the participant experienced a serious adverse event of complication of amyotrophic lateral sclerosis (ALS). The participant was placed in hospice care at home on 19 Nov 2020 (Study Day 91) secondary to dysphagia and progression of ALS. Treatment included a percutaneous endoscopic gastrostomy tube placement.

Action taken with study IP in response to the event of ALS was not applicable, as the participant had already received both scheduled doses.

The event, ALS, was considered fatal on 12 Dec 2020 (Study Day 114). The cause of death was reported as ALS. An autopsy was not requested by the participant's spouse. A death certificate was

issued on 13 Jan 2021 (Study Day 146) and the cause of death was documented as complications from ALS.

The investigator assessed the event, of ALS, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001092	Amyotrophic lateral sclerosis

Study Completion/Discontinuation

On 12 Dec 2020 (Study Day 114), the participant discontinued from the study due to death. On 12 Dec 2020 (Study Day 114), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Astigmatism	Astigmatism bilateral (eyeglasses)	1959 - Ongoing
Inguinal hernia	Inguinal hernia	2013 - 2013
Hypertension	High blood pressure	18 Dec 2013 (Study Day -2438) - Ongoing
Atrial fibrillation	Atrial fibrillation	19 Dec 2013 (Study Day -2437) - 2014
Benign prostatic hyperplasia	BPH	19 Dec 2013 (Study Day -2437) - 23 Nov 2015 (Study Day -1733)
Erectile dysfunction	Erectile dysfunction	2015 - Ongoing
Memory impairment	Memory changes	2017 - Ongoing
Heart rate irregular	Irregular heart beat	16 May 2019 (Study Day -463) - 16 May 2019 (Study Day -463)
Gastrooesophageal reflux disease	GERD	24 Sep 2019 (Study Day -332) - Ongoing
Amyotrophic lateral sclerosis	Amyotrophic lateral sclerosis	02 Dec 2019 (Study Day -263) - Ongoing
Insomnia	Insomnia	04 Feb 2020 (Study Day -199) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	14 Apr 2016 (Study Day -1590) - 12 Dec 2020 (Study Day 114)	Cardiac Prophylactic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2019 - 12 Dec 2020 (Study Day 114)	Maintenance
Guanfacine	06 Dec 2019 (Study Day -259) - 12 Dec 2020 (Study Day 114)	Hypertension
Carvedilol	17 Dec 2019 (Study Day -248) - 12 Dec 2020 (Study Day 114)	Hypertension
Riluzole	17 Dec 2019 (Study Day -248) - 12 Dec 2020 (Study Day 114)	ALS
Quetiapine	04 Feb 2020 (Study Day -199) - 12 Dec 2020 (Study Day 114)	Insomnia
Magnesium	03 Mar 2020 (Study Day -171) - 12 Dec 2020 (Study Day 114)	Maintenance
Probiotics NOS	03 Mar 2020 (Study Day -171) - 12 Dec 2020 (Study Day 114)	Maintenance
Vitamins NOS	03 Mar 2020 (Study Day -171) - 12 Dec 2020 (Study Day 114)	Maintenance
Colecalciferol	12 May 2020 (Study Day -101) - 12 Dec 2020 (Study Day 114)	Maintenance
Hyoscyamine sulfate	23 Sep 2020 (Study Day 34) - 12 Dec 2020 (Study Day 114)	Secretions
Influenza vaccine inact split 3v	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Influenza Vaccine
Patient received percutaneous endoscopic gastrostomy tube*	10 Dec 2020 (Study Day 112) - 10 Dec 2020 (Study Day 112)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Salivary Hypersecretion	Grade 2/moderate	Not related	23 Sep 2020 (Study Day 34) - 12 Dec 2020 (Study Day 114)
Dysphagia	Grade 2/moderate	Not related	10 Dec 2020 (Study Day 112) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2070 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/ Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	01 Oct 2020 (Study Day 57) – 01 Oct 2020 (Study Day 57)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2070, a 74-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Oct 2020 (Study Day 57), 56 days after the first dose and 28 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction was considered to be fatal on 01 Oct 2020 (Study Day 57). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 01 Oct 2020 (Study Day 57), the participant experienced a fatal serious adverse event of myocardial infarction (MI) and was hospitalized. The participant's initial rhythm was irregular narrow complexes on the monitor without pulse, and pulseless electrical activity arrest. An endotracheal tube (ET) tube was placed and cardiopulmonary resuscitation (CPR) was initiated. Return of spontaneous circulation was achieved with advanced cardiovascular life support (ACLS) for approximately 20 minutes. The participant presented to hospital via emergency medical services as a cardiac arrest. Initially, the participant was mentally confused but able to answer questions and was moderately lethargic. The participant had several episodes of emesis and desaturation, and rapid sequence intubation was performed. Relevant laboratory and diagnostic test results showed sodium 139 mmol/L, potassium 4.0 mmol/L, chloride 105 mmol/L (no

reference ranges were reported), troponin 0.45 ng/mL (reference range ≤ 0.04 ng/mL), oxygen saturation 94%, and heart rate 116 beats/minute. A chest x-ray showed low lung volumes with patchy pulmonary consolidation and interstitial thickening. Additionally, the participant was given ketamine, rocuronium, and propofol via IV drip. Electrocardiogram results showed global ischemia and ST elevation in augmented vector right. The participant was taken to catheterization laboratory. Approximately, 30 to 45 minutes later, code blue was activated. The participant was also given epinephrine IV in accordance with ACLS. The participant presented with agonal rhythm and no palpated pulse. Additionally, an arterial line had excellent waveform during compressions but no pressure during pulse checks. The ET remained in place while the cardiologist was performing coronary catheterization during CPR. Calcium was given but the participant did not regain pulses and was confirmed dead. Additional treatment for the event included acetylsalicylic acid rectal, verapamil, nitroglycerin, and heparin intra-arterial; propofol IV; sodium chloride 0.9% IV; and phenylephrine, iopamidol, norepinephrine, and vasopressin. It was noted by the investigator that the participant had numerous cardiovascular risk factors that precipitated the event, which included diabetes mellitus, hypertension, and hyperlipidemia.

Action taken with the study IP was not applicable in response to the event.

The participant died on 01 Oct 2020 (Study Day 57). The cause of death was reported as MI.

The investigator assessed the event, MI, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000399	Myocardial infarction

Study Completion/Discontinuation

On 01 Oct 2020 (Study Day 57), the participant discontinued from the study due to death. On 01 Oct 2020 (Study Day 57), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Chronic obstructive pulmonary disease	COPD	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1987 - Ongoing	Cardiac Prophylaxis
Metformin	1987 - Ongoing	Diabetes Mellitus Type 2
Insulin	2000 - Ongoing	Diabetes Mellitus Type 2
Gabapentin	2008 - Ongoing	Diabetes Mellitus Type 2
Amitriptyline	2010 - Ongoing	Type 2 Diabetes Mellitus
Colecalciferol	2010 - Ongoing	Hypercholesterolemia
Cyanocobalamin	2010 - Ongoing	Nutritional Supplement
Simvastatin	2010 - Ongoing	Hypercholesterolemia
Hydrochlorothiazide	2017 - Ongoing	Hypertension
Losartan	2018 - Ongoing	Hypertension
Empagliflozin	2019 - Ongoing	Diabetes Mellitus Type 2
Acetylsalicylic acid	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Arterial line insertion*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Central venous catheter insertion*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Coronary catheterization*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Epinephrine	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Glyceryl trinitrate	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Heparin	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Intubation*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Iopamidol	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Mechanical ventilaton*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Norepinephrine	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Phenylephrine	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Propofol	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Sodium chloride	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Vasopressin	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction
Verapamil	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Myocardial Infarction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US329-2023 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diabetic Ketoacidosis/Diabetic Ketoacidosis	SAE	Grade 3/ severe	Not related	22 Oct 2020 (Study Day 80) – 26 Oct 2020 (Study Day 84)	Recovered/ resolved
Cardiac Failure Congestive/End Stage Congestive Heart Failure	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	19 Dec 2020 (Study Day 138) – 23 Jan 2021 (Study Day 173)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2023, an 80-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Oct 2020 (Study Day 80), 79 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diabetic ketoacidosis. Action taken with the IP was not applicable. The event of diabetic ketoacidosis lasted for 5 days, after which it was considered to be recovered/resolved on 26 Oct 2020 (Study Day 84). The investigator assessed the event of diabetic ketoacidosis to be not related to the IP.

On 19 Dec 2020 (Study Day 138), 137 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of end stage congestive heart failure lasted for 36 days, after which it was considered to be fatal on 23 Jan 2021 (Study Day 173). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 22 Oct 2020 (Study Day 80), the participant experienced a serious adverse event of diabetic ketoacidosis. On the same day, the participant was not feeling well due to an insulin pump that

was not functioning correctly. Scar tissue in the participant's skin was preventing the flow of insulin. The participant had been waiting for a replacement pump that was overdue for delivery. The participant checked their blood sugar which had been registering between 500 and 700 (no units or reference range reported) with the lowest reading of 468 (no units). After realizing that their glucose levels were not dropping to normal levels, they contacted emergency medical services and were transported to the hospital where they were evaluated by emergency department physicians and were hospitalized for diabetic ketoacidosis. Treatment included an insulin drip. There was no COVID-19 testing performed.

On 26 Oct 2020 (Study Day 84), the participant was discharged from the hospital in stable condition.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The event, diabetic ketoacidosis, was reported as resolved on 26 Oct 2020 (Study Day 84).

The investigator assessed the event, diabetic ketoacidosis, as not related to study IP or study procedure.

On 19 Dec 2020 (Study Day 138), the participant experienced a fatal serious adverse event of cardiac failure congestive. The participant was initially admitted to the hospital with diabetic ketoacidosis (DKA), lactic acidosis, hyperkalemia, acute kidney injury (AKI), and met the severe sepsis criteria in addition to a femur fracture that they sustained from a fall prior to hospital admission. Per the participant’s spouse, the participant had been having many fluctuations in their glucose levels over the few days. The participant became confused when their glucose was abnormal; lost their balance and fell. An electrocardiogram (ECG) on admission showed mild ST depressions in inferior leads. Troponin was normal on admission but ultimately increased to >50 (no units or reference range reported) on 20 Jan 2021 (Study Day 170). On presentation with DKA, the participant’s creatinine had been up to 2.4 (no units or reference range reported). Persistent AMS was suspected due to metabolic encephalopathy but stroke or other causes like central nervous system (CNS) infection could not be ruled out. On admission, the AMS was likely due to DKA, but the participant's mentation did not improve. On an unspecified date, a computerized tomography (CT) scan of the head was negative; the scan was repeated on an unspecified date and was also negative. It was reported that prior to admission, the participant was mentally functional. The participant continued to have AMS and was not able to tolerate a magnetic resonance imaging (MRI)/CT scan due to agitation. The participant was on empiric antibiotic coverage with meropenem and in case the AMS was due to meningitis, as doctors were unable to perform a lumbar puncture (LP) per an infectious disease (ID) condition; the participant's mental status was not improving. The participant had no agitation since they had been on quetiapine but was still

confused. An electroencephalogram (EEG) was negative. Treatment for end stage congestive heart failure included ceftriaxone IV.

On 20 Dec 2020 (Day 139), the participant developed acute hypoxemic respiratory failure and cardiogenic shock due to an ST-elevation myocardial infarction (STEMI) and was found to have a severely depressed ejection fraction (EF) of 20% due to acute systolic congestive heart failure (CHF)/dilated cardiomyopathy. The participant underwent a percutaneous coronary intervention (PCI) and drug-eluting stent (DES) implantation × 2 to the ostial proximal diagonal artery (PDA) and proximal and mid-PDA. A repeat ECG showed ST elevations in lateral and inferior leads. An echocardiogram showed a severely reduced ejection fraction (EF) of about 20% (no reference range reported), with severe global hypokinesis of the left ventricle. The participant was to continue acetylsalicylic acid, clopidogrel, atorvastatin, and carvedilol (starting time of all medications unknown); as the participant was unable to take anything by mouth (PO) due to dysphagia, a Dobhoff tube was in place to administer these medications as the participant had shown no improvement in mentation and had failed a swallow study due to persistent AMS; the participant was then followed by speech therapy. Carvedilol was also indicated for the participant's dilated cardiomyopathy (nonischemic > ischemic)/acute systolic CHF. The participant had also been receiving furosemide IV intermittently. On this date, the participant was also intubated due to acute respiratory failure with hypoxia, likely related to aspiration pneumonia (status post treatment).

On 21 Dec 2020 (Day 140), the participant underwent cardioversion for ventricular tachycardia and continued on amiodarone.

On 26 Dec 2020 (Day 145), the participant completed their course of piperacillin/tazobactam for aspiration pneumonia on admission, with recurrence.

On 27 Dec 2020 (Day 146), the participant was extubated.

On 01 Jan 2021 (Day 151), the participant was started on piperacillin/tazobactam for persistent leukocytosis without a clear source despite aggressive antibiotics/antivirals IV.

On 05 Jan 2021 (Day 155), the participant was started on doxycycline for persistent leukocytosis. The participant's dose of amiodarone was changed to 200 mg daily per cardiologist's recommendations. The participant was awaiting medical stability for surgical intervention of the left hip. Despite the *Enterococcus*, doctors were reluctant to add vancomycin to the participant's treatment regimen as they were at high risk for AKI. The plan was to re-culture blood and urine and add doxycycline, which would provide some broad-spectrum coverage (including *Staphylococcus* in the participant's lungs and perhaps *Enterococcus* in their wound). Since the participant's most recent urine culture was negative and a CT scan of the chest was negative, it

was hoped that those were not areas of active infection. The participant's procalcitonin was 0.16 (no units or reference range reported), which seemed to indicate a lack of acute sepsis.

On 12 Jan 2021 (Day 162), the participant's piperacillin/tazobactam was changed to meropenem for persistent leukocytosis. Treatment also included acyclovir for meningitis empiric coverage.

On 15 Jan 2021 (Day 165), the participant's hypernatremia was not improving with free water flushes; the concern was that the participant was on high-volume free water and also tube feedings (TF). It was decided that the participant would be started on a low dose of ¼ normal saline (NS). The plan was to monitor renal function and adjust the free water flushes as well as IV fluids and when not needed, discontinue IV fluids.

On 19 Jan 2021 (Day 169), the overall hospital course was discussed with the participant's child and included no improvement in the participant's mental status; hospice was discussed and the consent for hospice was signed. On this date, the participant pulled out the Dobhoff tube; this had happened multiple times, and it was ultimately left out since the participant was being discharged to hospice. Vital signs at 11:55 included temperature 97.7°F (low), respiratory rate (RR) 17 breaths per minute, and oxygen saturation (SpO_2) 100%; at 15:09 included diastolic blood pressure (DBP) 72 mm Hg; at 19:36 included temperature 97°F (low), heart rate (HR) 69 beats per minute (bpm), RR 18 breaths per minute; at 23:33 included HR 55 bpm (low), systolic blood pressure (SBP) 117 mm Hg, and DBP 59 mm hg (low).

On 20 Jan 2021 (Day 170), the participant was discharged from the hospital with diagnoses of diabetic ketoacidosis with underlying type 1 diabetes mellitus (resolved), acute respiratory failure with hypoxia/respiratory arrest requiring mechanical ventilation (resolved), AKI (resolved), lactic acidosis on admission (resolved), cardiogenic shock on admission (resolved), STEMI status post DES × 2 (diagonal/PDA), acute systolic CHF/dilated cardiomyopathy with EF 20%, acute aspiration pneumonia with recurrence, acute and persistent metabolic encephalopathy, left commuted displaced femur fracture related to a mechanical fall prior to admission, acute thrombocytosis (improving), atrial flutter (paroxysmal), ventricular tachycardia (paroxysmal), acute hypernatremia (resolved), dysphagia, community acquired sacral deep tissue injury (DTI) with progression to unstageable, severe protein-calorie malnutrition with a prealbumin of 7 (no units or reference range reported). The participant's doxycycline and acyclovir were discontinued upon discharge to hospice. There was no improvement to mentation or leukocytosis with the antibiotic regimen. A repeat blood culture was negative. A CT scan of abdomen/pelvis showed no abscess, but a 2 cm nodule in the left upper renal pole was identified (incidental finding), that was concerning for neoplasm, it also showed a chronic L4 compression fracture, increased anasarca, and persistent bilateral layering pleural effusions with partial compressive lower lobe atelectasis. The participant's thrombocytosis was reactive due to inflammation/infection. The participant's platelet count peaked at over 1100 (no units or reference range reported), but it was trending down

upon discharge. The participant's heart was in sinus rhythm, continuing on amiodarone, and carvedilol for paroxysmal atrial flutter (CHA2DS2-VASc score was 5). The participant's type 1 diabetes with DKA on admission had resolved, and they were off the insulin drip. The participant's hemoglobin was stable and would continue to be monitored. The participant was not ready for surgery on their left comminuted displaced femur fracture related to a fall prior to admission at the time of discharge, it was considered for the following week, pending evaluations by cardiology and orthopedics; the patient would remain as a high-risk surgical candidate regardless of timing of procedure. The participant was continued on levothyroxine for their hypothyroidism. The wound care service had been following the participant for their community acquired DTI which had progressed to unstageable sacral/coccyx pressure ulcer which extended to the bilateral buttocks and a new left lateral malleolus stage 2 pressure ulcer. The participant also was on a low air loss mattress, and the sites were offloaded. The participant's hypernatremia was resolving, and the water flush was stopped. Laboratory test results from samples collected at 02:37 included sodium 147, potassium 3.8, chloride 110, carbon dioxide 28, anion gap 13, glucose level 81, calcium 8.1 (low), blood urea nitrogen 39 (high), creatinine 1.07, magnesium 2.3, phosphate 2.9, white blood cells 17.83 (high), red blood cells 3.67 (low), hemoglobin 11.6 (low), hematocrit 37.5 (low), mean cell volume 102.2 (high), mean cell hemoglobin 31.6, mean corpuscular hemoglobin concentration 30.9 (low), red cell distribution width (RDW-CV) 17.2 (high), platelet count 325 (adequate), mean platelet volume 10.4, nucleated red blood cells (NRBC) auto absolute < 0.01, NRBC% 0.0 (no units or reference ranges reported). Vital signs taken at 04:17 included SpO_2 94%, at 07:18 included temperature 97.8°F (low), HR 65 bpm, RR 18 breaths per minute, SBP 142 mm Hg (high), DBP 65 mm Hg, and SpO2 94% (on room air). A physical examination was normal except for decreased breath sounds in the lungs and confusion. The participant's condition at discharge was stable, their discharge activity level was bedrest, and the discharge diet was pleasure feeds. The participant was discharged to hospice. A COVID-19 PCR test completed during the participant's hospitalization resulted as "not detected".

On 23 Jan 2021 (Day 173) at 09:45, the participant died. The coroner arrived to find the participant absent of vital signs. The oxygen and Foley catheter were removed. The cause of death was end stage heart failure. An autopsy was not performed.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The event, cardiac failure congestive, was reported as fatal on 23 Jan 2021. The cause of death was reported as end stage heart failure.

The investigator assessed the event, cardiac failure congestive, as not related to study IP or study procedure.

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
CIOMS MOD-2020-000556	Diabetic ketoacidosis
CIOMS MOD-2021-017317	Cardiac failure congestive

Study Completion/Discontinuation

On 23 Jan 2021 (Study Day 173), the participant discontinued from the study due to death. On 23 Jan 2021 (Study Day 173), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug delivery device implantation	Insulin pump	Not reported - Ongoing
Tonsillectomy	Tonsillectomy	1946 - 1946
Tonsillitis	Tonsilitis	1946 - 1946
Appendicectomy	Appendectomy	1958 - 1958
Appendicitis	Appendicitis	1958 - 1958
Penile operation	Peyronie's plaque surgery	1982 - 1982
Peyronie's disease	Peyronie's plaque	1982 - 1988
Penile operation	Surgery to penis	1988 - 1988
Mycotic allergy	Seasonal allergy: mold	1990 - Ongoing
Seasonal allergy	Seasonal allergy: mountain cedar	1990 - Ongoing
Spinal fracture	Fractured back	1990 - 1990
Spinal operation	Back surgery	1990 - 1990
Type 1 diabetes mellitus	Type i diabetes	1999 - Ongoing
Renal stone removal	Kidney surgery - remove benign spot on kidney	2006 - 2006
Arthralgia	Knee pain	2007 - Ongoing
Chondroplasty	Bilateral cartilage buildup in knees	2007 - 2009
Glaucoma	Bilateral glacoma	2007 - Ongoing
Knee operation	Knee surgery - left knee	2007 - 2007
Dermatitis atopic	Atopic dermitis on face	2009 - Ongoing
Knee arthroplasty	Knee replacement - left knee	2009 - 2009
Hypothyroidism	Hypothyroid	2010 - Ongoing
Coronary artery disease	Coronary artery disease	2012 - Ongoing
Stent placement	Stent placement	2012 - 2012
Diabetic neuropathy	Diabetic peripheral neuropathy	2013 - Ongoing
Drug intolerance	Intolerant to aricept	2013 - Ongoing
Depression	Depression	2017 - Ongoing
Vitamin D deficiency	Vitamin d deficency	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin lispro	Not reported - Ongoing	Type 1 Diabetes
Glucose	1999 - Ongoing	Type 1 Diabetes
Lisinopril	2000 - Ongoing	Kidney Disease Prevention
Brimonidine tartrate; timolol maleate	2007 - Ongoing	Bilateral Glaucoma
Latanoprost	2007 - Ongoing	Bilateral Glaucoma
Latanoprost; netarsudil mesilate	2007 - Ongoing	Bilateral Glaucoma
Tramadol	2007 - Ongoing	Left Knee Pain
Triamcinolone	2009 - Ongoing	Facial Atopic Dermatitis
Levothyroxine	2010 - Ongoing	Hypothyroid
Gabapentin	2013 - Ongoing	Diabetic Peripheral Neuropathy
Ascorbic acid	2016 - Ongoing	Supplement
Doxycycline	2016 - Ongoing	Dental Infection
Vitamin b12 nos	2016 - Ongoing	Preventative
Duloxetine	2017 - Ongoing	Depression
Ergocalciferol	2019 - Ongoing	Vitamin D Deficiency
Influenza vaccine	23 Sep 2020 (Study Day 51) - 23 Sep 2020 (Study Day 51)	Influenza
Glucose	22 Oct 2020 (Study Day 80) - 22 Oct 2020 (Study Day 80)	Diabetic Ketoacidosis
Insulin	22 Oct 2020 (Study Day 80) - 22 Oct 2020 (Study Day 80)	Diabetic Ketoacidosis
Sodium bicarbonate; sodium chloride	22 Oct 2020 (Study Day 80) - 22 Oct 2020 (Study Day 80)	Diabetic Ketoacidosis
Sodium chloride	22 Oct 2020 (Study Day 80) - 22 Oct 2020 (Study Day 80)	Diabetic Ketoacidosis
Tooth extraction*	30 Nov 2020 (Study Day 119) - 30 Nov 2020 (Study Day 119)	Adverse Event
Ceftriaxone	19 Dec 2020 (Study Day 138) - 19 Dec 2020 (Study Day 138)	End Stage Congestive Heart Failure
Piperacillin; tazobactam	19 Dec 2020 (Study Day 138) - 19 Dec 2020 (Study Day 138)	End Stage Congestive Heart Failure
Doxycycline	Jan 2021 - Jan 2021	End Stage Congestive Heart Failure
Piperacillin sodium; tazobactam sodium	Jan 2021 - Jan 2021	End Stage Congestive Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tooth Infection	Grade 2/moderate	Not related	27 Nov 2020 (Study Day 116) - 30 Nov 2020 (Study Day 119)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3377927

Participant Number:	US330-2395 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	04 Jan 2021 (Study Day 131) – 04 Jan 2021 (Study Day 131)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2395, a 67-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Jan 2021 (Study Day 131), 130 days after the first dose and 102 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction was considered to be fatal on 04 Jan 2021 (Study Day 131). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 04 Jan 2021 (Study Day 131), the participant experienced a fatal serious adverse event of myocardial infarction (MI). The participant was found deceased at home, and MI was determined to be the cause. The participant did not have any risk factors for MI. The participant's child requested unblinding of the participant's actual study IP, and the site let the family know that the participant had received placebo. The participant's child agreed to send a copy of death certificate when available.

According to the participant's child, no medical intervention was given for the event of MI, as the participant was found deceased.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 04 Jan 2021 (Study Day 131). The cause of death was reported as MI.

The investigator assessed the event, MI, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006670	Myocardial infarction

Study Completion/Discontinuation

On 04 Jan 2021 (Study Day 131), the participant discontinued from the study due to death. On 04 Jan 2021 (Study Day 131), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	2017 - Ongoing
Peripheral sensorimotor neuropathy	Sensorimotor neuropathy in bilateral feet	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	2017 - Ongoing	Insomnia
Gabapentin	2019 - Ongoing	Neuropathy In Feet

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US332-2199 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 30)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Fatal Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	16 Nov 2020 (Study Day 76) – 16 Nov 2020 (Study Day 76)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2199, a 64-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Nov 2020 (Study Day 76), 75 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction was considered to be fatal on 16 Nov 2020 (Study Day 76). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 16 Nov 2020 (Study Day 76), the participant suffered a fatal serious adverse event of myocardial infarction. The participant had multiple known cardiac risk factors. All communication methods have been tried to get further information and medical records from the family with no success.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses prior to the event.

The participant died on 16 Nov 2020 (Study Day 76). The cause of death was reported as myocardial infarction.

The investigator assessed the event, myocardial infarction, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000870	Myocardial infarction

Study Completion/Discontinuation

On 16 Nov 2020 (Study Day 76), the participant discontinued from the study due to death. On 16 Nov 2020 (Study Day 76), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Exostosis	Bone spur	Not reported - 2012
Obesity	Obesity	Not reported - Ongoing
Drug hypersensitivity	Penicillin allergy	1959 - Ongoing
Bundle branch block left	Left bundle branch block	1976 - Ongoing
Bone lesion excision	Bone spur surgery	2012 - 2012
Eczema	Eczema	Sep 2016 - Ongoing
Spinal operation	Back surgery	31 Oct 2017 (Study Day -1037) - 31 Oct 2017 (Study Day -1037)
Hypertension	Hypertension	Sep 2018 - Ongoing
Hypercholesterolaemia	Hypercholesteremia	Jan 2019 - Ongoing
Supraventricular tachycardia	Arrhythmia (supraventricular tachycardia)	Jan 2019 - Ongoing
Glucose tolerance impaired	Pre-diabetes	Feb 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Jan 2019 - Ongoing	Cardiac Prophylaxis
Atenolol	Jan 2019 - Ongoing	Arythmia/Hypertension
Atorvastatin	Jan 2019 - Ongoing	Hypercholestremia
Amlodipine	Oct 2019 - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US334-2256 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardio-Respiratory Arrest/Cardiopulmonary Arrest	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	20 Sep 2020 (Study Day 7) – 20 Sep 2020 (Study Day 7)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2256, a 43-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 5 serious adverse event of cardio-respiratory arrest. On 20 Sep 2020 (Study Day 7), the IP dose was discontinued due to death. The event of cardiopulmonary arrest was considered to be fatal on 20 Sep 2020 (Study Day 7). The investigator assessed the event of cardio-respiratory arrest to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 20 Sep 2020 (Study Day 7), the participant experienced a fatal serious adverse event of cardiorespiratory arrest. The participant presented to the emergency department (ED) with chest pain and shortness of breath. The participant had a witnessed collapse in the ED with cardiopulmonary arrest. The participant underwent endotracheal intubation, defibrillation, an electrocardiogram, and IV catheterization via the right antecubital fossa. Resuscitation was unsuccessful.

Action taken with the study IP was not applicable in response to the event.

The participant died on 20 Sep 2020 (Study Day 7). The cause of death was reported as atherosclerotic and hypertensive cardiovascular disease.

On 21 Sep 2020 (Study Day 8), an autopsy demonstrated a well-developed, obese person without significant injuries. The heart showed cardiomegaly, and there was left ventricular hypertrophy. There was an atherosclerosis and stenosis of the coronary arteries. The participant had 75% coronary artery stenosis (CAS), 50% left mainstem CAS, 75% left anterior CAS, and 40% left circumflex CAS. The right ventricle free wall thickness was 0.3 cm, left ventricular free wall thickness was 1.8 cm, and interventricular septal thickness was 1.7 cm (no reference ranges provided). There was arterionephrosclerosis commonly observed with hypertension. The autopsy also showed mild fatty streaks in the atherosclerosis of the aorta. The defibrillator pads and the electrocardiogram electrode pads were affixed to the torso and upper extremities. Injuries related to resuscitative attempts included bilateral anterolateral rib fractures with associated intercostal muscle hemorrhage and hemorrhage in the pancreatic tail without overt necrosis. The participant had a marked amount of blood and frothy fluid, indicative of pulmonary congestion and edema. There was an intravascular catheter protruding from the right antecubital fossa with scattered abrasions of the posterior left hand (ranging from 0.5 to 1 cm in the greatest dimension). A 0.7 by 0.3 cm crusted abrasion of the right ankle was seen. Postmortem toxicology testing showed a femoral blood ethanol result of 0.05% and a vitreous fluid ethanol result of 0.06% (no reference ranges provided). A postmortem computerized tomography scan revealed bilateral anterolateral rib fractures, cardiomegaly, and focal coronary artery calcification. There was no mention of COVID-19 testing per the medical examiner report.

On 08 Oct 2020 (Study Day 25), the participant's spouse called the site to inform the site staff of the participant's death.

The investigator assessed the event, cardio-respiratory arrest, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000433	Cardio-respiratory arrest

Study Completion/Discontinuation

On 20 Sep 2020 (Study Day 7), the participant discontinued from the study due to death. On 20 Sep 2020 (Study Day 7), the participant died due to adverse event. An autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiomegaly	Cardiomegaly	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Left ventricular hypertrophy	Left ventricular hypertrophy	Not reported - Ongoing
Nephrosclerosis	Arterionephrosclerosis	Not reported - Ongoing
Obesity	Obesity	Not reported - Ongoing
Headache	Headaches	2007 - Ongoing
Diverticulum	Diverticulosis	2010 - Ongoing
Gastrectomy	Gastric sleeve surgery	May 2014 - May 2014
Tooth infection	Tooth infection	Jun 2020 - Jul 2020
Tooth extraction	Tooth extraction	Jul 2020 - Jul 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2008 - Ongoing	Headaches
Defibrillation*	20 Sep 2020 (Study Day 7) - 20 Sep 2020 (Study Day 7)	Adverse Event
Electrocardiogram*	20 Sep 2020 (Study Day 7) - 20 Sep 2020 (Study Day 7)	Adverse Event
Endotracheal intubation*	20 Sep 2020 (Study Day 7) - 20 Sep 2020 (Study Day 7)	Adverse Event
Intravascular catheterization right antecubital fossa*	20 Sep 2020 (Study Day 7) - 20 Sep 2020 (Study Day 7)	Adverse Event
Postmortem CT scan*	21 Sep 2020 (Study Day 8) - 21 Sep 2020 (Study Day 8)	Adverse Event
Toxicology labs postmortem*	02 Oct 2020 (Study Day 19) - 02 Oct 2020 (Study Day 19)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US337-2228 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 36)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Death/Death-Unknown Cause	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	25 Jan 2021 (Study Day 155) – 25 Jan 2021 (Study Day 155)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2228, a 55-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Jan 2021 (Study Day 155), 154 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of death. Action taken with the IP was not applicable. The event of death-unknown cause was considered to be fatal on 25 Jan 2021 (Study Day 155). The investigator assessed the event of death to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 20 Jan 2021 (Day 150), the participant underwent a cervical fusion and was discharged home after the procedure with no complications.

On 25 Jan 2021 (Day 155), the participant experienced a fatal serious adverse event of death. The participant's spouse called the site to report that the participant had died. The spouse went to help the participant out of bed that night; the participant was awake at the time, then took a breath and died. The underlying cause of death is unknown.

Action taken with the study IP was not applicable in response to the event, as the participant had received both scheduled doses.

The participant died on 25 Jan 2021 (Study Day 155). The cause of death was unknown.

The investigator assessed the event, death, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009157	Death

Study Completion/Discontinuation

On 25 Jan 2021 (Study Day 155), the participant discontinued from the study due to death. On 25 Jan 2021 (Study Day 155), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic tonsillitis	Tonsillitis - chronic	1984 - 1986
Tonsillectomy	Tonsillectomy	1986 - 1986
Depression	Depression	1990 - Ongoing
Insomnia	Insomnia	1990 - Ongoing
Bursitis	Bursitis left elbow	1994 - 1994
Joint fluid drainage	Left elbow bursa sac drainage	1994 - 1994
Intervertebral disc protrusion	Herniated disc thoracic spine	1996 - 2016
Lipoma	Right armpit benign lipoma	1996 - 1996
Lipoma excision	Right armpit lipoma enucleation	1996 - 1996
Staphylococcal infection	Left foot mrsa infection	1996 - 1996
Cholecystectomy	Cholecystectomy	2008 - 2008
Cholelithiasis	Cholelithiasis	2008 - 2008
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2008 - Ongoing
Sinusitis	Sinusitis	2013 - 2014
Functional endoscopic sinus surgery	Left nostril sinus endoscopic	2014 - 2014
Hypertension	Hypertension	2014 - Ongoing
Hypogonadism male	Male hypogonadism	2014 - Ongoing
Meniscus injury	Torn meniscus right knee	2014 - 2016
Type 2 diabetes mellitus	Diabetes mellitus type ii	2014 - Ongoing
Bursitis	Bursitis left elbow	2015 - 2016
Arthritis infective	Left elbow mycobacterium infection	2016 - 2016
Arthroscopy	Arthroscopy right knee	2016 - 2016
Bursa removal	Left elbow bursectomy	2016 - 2016
Cartilage injury	Torn cartilage right knee	2016 - 2016
Intervertebral disc protrusion	Herniated disc cervical spine	2016 - Ongoing
Spinal fusion surgery	Thoracic spine fusion	2016 - 2016
Arthroscopy	Arthroscopy left knee	2018 - 2018

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Meniscus injury	Torn meniscus left knee	2018 - 2018
Obesity	Obesity	2019 - Ongoing
Vitamin B12 deficiency	Vitamin b12 deficiency	Aug 2019 - Ongoing
Osteoarthritis	Generalized osteoarthritis	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Eszopiclone	1990 - Ongoing	Insomnia`
Trazodone	1990 - Ongoing	Depression
Amlodipine	2000 - Ongoing	Hypertension
Atenolol	2000 - Ongoing	Hypertension
Lisinopril	2000 - Ongoing	Hypertension
Omeprazole	2008 - Ongoing	Gastroesophageal Reflux Disease
Diphtheria vaccine toxoid; pertussis vaccine; tetanus vaccine toxoid	2012 - 2012	Diphtheria Tetanus And Acellular Pertussis Prophylaxis/Prevention
Acetylsalicylic acid	2014 - Ongoing	Cardiac Prophylaxis
Folic acid	2014 - Ongoing	Dietary Supplement
Metformin	2014 - Ongoing	Diabetes Mellitus Type Ii
Testosterone cipionate	2014 - Ongoing	Male Hypogonadism
Pneumococcal vaccine	2015 - 2015	Pneumonia Prophylaxis/Prevention
Varicella zoster vaccine	Jan 2019 - Jan 2019	Herpes Zoster Prophylaxis/Prevention
Influenza vaccine	Aug 2019 - Aug 2019	Influenza Prophylaxis/Prevention
Vitamin b12 nos	Aug 2019 - Ongoing	Vitamin B12 Deficiency
Ascorbic acid	Jan 2020 - Ongoing	Dietary Supplement
Vitamin d nos	Jan 2020 - Ongoing	Dietary Supplement
Oxycodone hydrochloride; paracetamol	Jun 2020 - Ongoing	Generalized Osteoarthritis
Cervical fusion*	20 Jan 2021 (Study Day 150) - 20 Jan 2021 (Study Day 150)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US347-2001 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 32)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/ Provisional Diagnosis Only - Sudden Fatal Event, Likely Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	27 Nov 2020 (Study Day 89) – 27 Nov 2020 (Study Day 89)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US347-2001, a 70-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 01 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Nov 2020 (Study Day 89), 88 days after the first dose and 57 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of provisional diagnosis only - sudden fatal event, likely myocardial infarction was considered to be fatal on 27 Nov 2020 (Study Day 89). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 27 Nov 2020 (Study Day 89), the participant experienced a fatal serious adverse event of myocardial infarction. On the same day, the participant was found dead on the bathroom floor. The time of death and cause of death have not yet been determined. Per the investigator, the sudden fatal event was likely a myocardial infarction. The investigator requested family permission to conduct limited postmortem exam, but the family refused an autopsy.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 27 Nov 2020 (Study Day 89). The cause of death has not yet been determined and the site was unable to obtain the death certificate.

The investigator assessed the event, myocardial infarction, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000914	Myocardial infarction

Study Completion/Discontinuation

On 27 Nov 2020 (Study Day 89), the participant discontinued from the study due to death. On 27 Nov 2020 (Study Day 89), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Essential hypertension	Essential hypertension	2005 - Ongoing
Obesity	Morbid obesity	2005 - Ongoing
Osteoarthritis	Osteoarthritis in both lower extremities	2005 - Ongoing
Wolff-Parkinson-White syndrome	Wolf Parkinson white syndrome	2005 - Ongoing
Constipation	Constipation	2010 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2012 - Ongoing
Renal cyst	Benign renal cyst	Aug 2012 - Ongoing
Aortic stenosis	Mild aortic stenosis	2016 - Ongoing
Atrial fibrillation	Atrial fibrillation	2016 - Ongoing
Left ventricular hypertrophy	Left ventricular hypertrophy	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; losartan potassium	2005 - Ongoing	Hypertension
Metoprolol	2005 - Ongoing	Hypertension
Atorvastatin	2010 - Ongoing	Hyperlipidemia
Bisacodyl	2010 - Ongoing	Constipation
Docusate sodium	2010 - Ongoing	Constipation
Apixaban	2016 - Ongoing	Prophylaxis For Vte

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b nos	Sep 2019 - Ongoing	Health Promotion
Influenza vaccine	15 Sep 2020 (Study Day 16) - 15 Sep 2020 (Study Day 16)	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hepatitis C Antibody Positive	Grade 1/mild	Not related	29 Sep 2020 (Study Day 30) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US351-2042 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardio-Respiratory Arrest/Cardiopulmonary Arrest	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	01 Sep 2020 (Study Day 21) – 01 Sep 2020 (Study Day 21)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2042, a 78-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Sep 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 5 serious adverse event of cardio-respiratory arrest. On 01 Sep 2020 (Study Day 21), the IP dose was discontinued due to death. The event of cardiopulmonary arrest was considered to be fatal on 01 Sep 2020 (Study Day 21). The investigator assessed the event of cardio-respiratory arrest to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

The participant tolerated the study vaccine well with only minimal local injection site tenderness and was scheduled to undergo an elective cochlear implant on 03 Sep 2020 (Study Day 23) and stopped taking acetylsalicylic acid 2 to 5 days prior to surgery.

On 30 Aug 2020 (Study Day 19), the participant was sick. On 31 Aug 2020 (Study Day 20), the participant had 3 episodes of vomiting and nausea. The participant did not have a fever, weight change, swelling or any other symptoms. The participant went to bed separately from their spouse.

On 01 Sep 2020 (Study Day 21), the participant experienced a fatal serious adverse event of cardio-respiratory arrest. In the morning of that day, the spouse found the participant who had died at home.

There was no action taken with the study IP in response to the event.

The participant died on 01 Sep 2020 (Study Day 21). Per the death certificate, cause of death was cardiopulmonary arrest due to hypertension/hyperlipidemia. No autopsy was performed.

The investigator assessed the event, cardio-respiratory arrest, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
CIOMS MOD-2020-000244	Cardio-respiratory arrest

Study Completion/Discontinuation

On 01 Sep 2020 (Study Day 21), the participant discontinued from the study due to death. On 01 Sep 2020 (Study Day 21), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1947 - Ongoing
Tremor	Right hand tremor	1990 - Ongoing
Dyspepsia	Heartburn	1998 - Ongoing
Gastric ulcer	Gastric ulcer gastric	1998 - 1998
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1998 - Ongoing
Cataract	Bilateral cataracts	2000 - 2010
Hypersensitivity	Environmental allergies	2000 - Ongoing
Blood cholesterol increased	High cholesterol	2005 - Ongoing
Drug hypersensitivity	Allergy to penicillin	2005 - Ongoing
Drug hypersensitivity	Allergy to sulfa	2005 - Ongoing
Hypertension	High blood pressure	2005 - Ongoing
Deafness bilateral	Bilateral hearing loss	2010 - Ongoing
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Intraocular lens implant	Bilateral lens implant	2010 - 2010
Sleep apnoea syndrome	Sleep apnea	2012 - Ongoing
Spinal stenosis	Spinal stenosis	2013 - Ongoing
Atrial fibrillation	Paroxysmal atrial fibrillation	2015 - Ongoing
Cerebrovascular accident	Stroke	27 Jun 2016 (Study Day -1507) - 27 Jun 2016 (Study Day -1507)
Retinal vascular thrombosis	Left side ocular thrombosis	27 Jun 2016 (Study Day -1507) - 27 Jun 2016 (Study Day -1507)
Anxiety	Anxiety	2019 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cholecystitis chronic	Chronic cholecystitis	2019 - Ongoing
Constipation	Constipation	2019 - Ongoing
Depression	Depression	2019 - Ongoing
Hip fracture	Fracture left hip	2019 - 2019
Insomnia	Insomnia	2019 - Ongoing
Osteoarthritis	Generalized unspecified joint osteoarthritis	2019 - Ongoing
Pelvic fracture	Broken pelvis secondary to fall	02 Aug 2019 (Study Day -376) - 08 Aug 2019 (Study Day -370)
Pelvic operation	Pelvic repair surgery	08 Aug 2019 (Study Day -370) - 08 Aug 2019 (Study Day -370)
Acetabulum fracture	Acetabular fracture	Nov 2019 - Dec 2019
Hip surgery	Acetabular surgery	Nov 2019 - Nov 2019
Prostatomegaly	Enlarged prostate	Nov 2019 - Ongoing
Hip surgery	Acetabular surgery	Dec 2019 - Dec 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	2000 - Ongoing	Seasonal Allergies
Losartan potassium	2005 - Ongoing	High Blood Pressure
Atorvastatin	2010 - Ongoing	High Cholesterol
Hydrochlorothiazide	2015 - Ongoing	High Blood Pressure
Acetylsalicylic acid	2016 - Ongoing	Post Stroke
Paracetamol	2019 - Ongoing	Osteoarthritis Hip
Mirtazapine	Nov 2019 - Ongoing	Depression
Tamsulosin hydrochloride	Nov 2019 - Ongoing	Benign Prostatic Hyperplasia
Hydrocodone	Dec 2019 - Ongoing	Hip Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Malaise	Grade 2/moderate	Not related	30 Aug 2020 (Study Day 19) - 01 Sep 2020 (Study Day 21)
Nausea	Grade 2/moderate	Not related	30 Aug 2020 (Study Day 19) - 01 Sep 2020 (Study Day 21)
Vomiting	Grade 1/mild	Not related	31 Aug 2020 (Study Day 20) - 31 Aug 2020 (Study Day 20)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US352-2109 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pericardial Effusion/Pericardial Effusion	SAE	Grade 4	Related	16 Nov 2020 (Study Day 96) – 22 Feb 2021 (Study Day 194)	Recovered/ resolved
Pericarditis/Pericarditis	SAE	Grade 2/ moderate	Related	16 Nov 2020 (Study Day 96) – 22 Feb 2021 (Study Day 194)	Recovered/ resolved
Pleural Effusion/ Pleural Effusions (Bilateral)	SAE	Grade 4	Related	17 Nov 2020 (Study Day 97) – 22 Feb 2021 (Study Day 194)	Recovered/ resolved
Atrial Flutter/Episodic Atrial Flutter	SAE	Grade 1/mild	Not related	26 Nov 2020 (Study Day 106) – 01 Dec 2020 (Study Day 111)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2109, a 59-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Nov 2020 (Study Day 96), 95 days after the first dose and 67 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pericardial effusion. Action taken with the IP was not applicable. The event of pericardial effusion lasted for 99 days, after which it was considered to be recovered/resolved on 22 Feb 2021 (Study Day 194). The investigator assessed the event of pericardial effusion to be related to the IP.

On 16 Nov 2020 (Study Day 96), 95 days after the first dose and 67 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pericarditis. Action taken with the IP was not applicable. The event of pericarditis lasted for 99 days, after which it was considered to be recovered/resolved on 22 Feb 2021 (Study Day 194). The investigator assessed the event of pericarditis to be related to the IP.

On 17 Nov 2020 (Study Day 97), 96 days after the first dose and 68 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pleural effusion. Action taken with the IP was not applicable. The event of pleural effusions (bilateral) lasted for 98 days, after which it was considered to be recovered/resolved on 22 Feb 2021 (Study Day 194). The investigator assessed the event of pleural effusion to be related to the IP.

On 26 Nov 2020 (Study Day 106), 105 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of atrial flutter. Action taken with the IP was not applicable. The event of episodic atrial flutter lasted for 6 days, after which it was considered to be recovered/resolved on 01 Dec 2020 (Study Day 111). The investigator assessed the event of atrial flutter to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 15 Sep 2020 (Study Day 34), the participant experienced acute shortness of breath along with chest discomfort and presented to the emergency department (ED). Laboratory test results included white blood cell (WBC) count $10.4 \times 10^3/\mu L$ (reference range 3.8 to $10.6 \times 10^3/\mu L$), red blood cell count $4.79 \times 10^6/\mu L$ (reference range 4.15 to $5.55 \times 10^6/\mu L$), absolute monocytes $1.0 \times 10^3/\mu L$ (reference range 0.00 to $0.80 \times 10^3/\mu L$), potassium 3.4 mmol/L (reference range 3.5 to 5.0 mmol/L), blood urea nitrogen 28 mg/dL (reference range 10 to 25 mg/dL), quantitative D-dimer 1.01 µg/mL fibrinogen equivalent units (reference range < 0.59 µg/mL), troponin < 18 ng/L (reference range < 19 ng/L), prothrombin time (PT) 12.9 seconds (reference range 12.1 to 14.5 seconds), and partial thromboplastin time (PTT) 33 seconds (reference range 22 to 36 seconds). A chest x-ray revealed no pneumothorax; pulmonary vasculature, cardiac, and mediastinal silhouettes were within normal limits; lungs were clear; osseous structures were intact; no evidence of pulmonary embolism or pericardial effusion; and no acute process. The participant was discharged from the ED.

On 05 Oct 2020 (Study Day 54), the participant developed sinus congestion.

On 13 Oct 2020 (Study Day 62), the participant received Flublok RIV4 vaccination for influenza prophylaxis.

On 15 Nov 2020 (Study Day 95), the participant experienced chest heaviness and pain and felt chest pressure when leaning forward. The participant had a spell of nausea and “passed out” after kneeling on the floor. The participant reported that their heart rate was between 84 to 117 beats per minute (bpm).

On 16 Nov 2020 (Study Day 96), the participant experienced serious adverse events (SAEs) of pericardial effusion and pericarditis while visiting their primary care physician concerning the symptoms they had been experiencing. The participant's heart rate was 114 bpm and they were referred to a cardiologist for additional work-up.

On 17 Nov 2020 (Study Day 97), the participant experienced an SAE of pleural effusion. A computed tomography (CT) angiography scan showed stable minimal to mild dilatation of the ascending aorta and new small bilateral pleural effusions, left greater than right, and moderate pericardial effusion with diffuse pericardial enhancement, a correlate for pericarditis.

On 18 Nov 2020 (Study Day 98), an echocardiogram (ECHO) showed a normal left ventricular ejection fraction of 60 to 65%, small pericardial effusion circumferentially around the entire heart with no evidence of cardiac tamponade. Etiology was suspected to be reactive (viral or inflammatory). The participant's erythrocyte sedimentation rate (ESR) was 34 mm/hr (reference range 0 to 20 mm/hr). Treatment included high-dose acetylsalicylic acid and colchicine.

On 23 Nov 2020 (Study Day 103), SARS-CoV-2 RT-PCR testing was negative.

On 26 Nov 2020 (Study Day 106), the participant experienced an SAE of atrial flutter. The participant presented to the ED for chest pain, epigastric pain, and rising fatigue. An episodic atrial flutter was noted, which was considered secondary to pericarditis. A CT scan showed no pulmonary embolism, no lung consolidation, mild to moderate left- and right-sided pleural effusions, underlying compressive atelectasis in the lungs, and mild to moderate pericardial effusion. Laboratory test results included ESR 101 mm/hr, procalcitonin 0.38 ng/mL (reference range < 0.25 ng/mL), antinuclear antibodies were negative, platelets 492 × 10^3/µL (reference range 150 to 450 × 10^3/µL), troponin < 4, brain natriuretic peptide 112 pg/mL (reference range < 50 pg/mL), and WBC 20.0 × 10^3/µL. The participant was admitted to the hospital.

On 27 Nov 2020 (Study Day 107), an ECHO showed improvement in the participant's pericardial effusion. Relevant laboratory results included C-reactive protein (CRP) 24.4 mg/dL (reference range < 0.5 mg/dL), WBC 14.3 × 10^3/µL, hemoglobin (Hgb) 10.8 g/dL (reference range 12 to 15 g/dL), hematocrit (Hct) 32.9% (reference range 36 to 46%), and platelets 454 × 10^3/µL; human immunodeficiency virus antigen and antibody testing was nonreactive, urine *Histoplasma* antigen testing was negative, and blood cultures showed no growth. A respiratory virus panel PCR test on a nasopharyngeal sample, which included adenovirus, respiratory syncytial virus, parainfluenza, coronavirus (excluding COVID-19), and influenza, was negative for all pathogens tested. Treatment with methocarbamol and paracetamol were started for pericarditis.

On 28 Nov 2020 (Study Day 108), laboratory test results included free thyroxine 1.05 ng/dL (reference range 0.61 to 1.44 ng/dL), thyroid stimulating hormone 3.16 µIU/mL (reference range 0.45 to 5.33 µIU/mL), PT 16 seconds, and PTT 50 seconds.

On 30 Nov 2020 (Study Day 110), laboratory test results included WBC 9.6 × 10^3/µL, Hgb 10.7 g/dL, Hct 30.5%, and platelets 474 × 10^3/µL. A left-side thoracentesis was performed, removing 450 mL of clear yellow fluid. Results of pleural fluid analyses were consistent with

transudate and included cultures negative for bacteria and fungi, with a lactate dehydrogenase of 78 IU/L (reference range < 220 IU/L) and protein of 3.3 g/dL (reference range < 8.3 g/dL).

Infectious disease was consulted and did not have a strong suspicion for infection. The participant was given ketorolac and prednisone for pericarditis.

On 01 Dec 2020 (Study Day 111), the participant was feeling better, sitting upright with no conversational dyspnea, on room air; still had fatigue, but it was improving, overall. Vital signs included blood pressure 129/74 mm Hg, pulse 67 bpm, temperature 36.4°C, respiratory rate 18 breaths per minute, and oxygen saturation 96%. The participant was discharged home in stable condition. The participant was treated with diphenhydramine. Treatment for the events continued on discharge included metoprolol for atrial flutter, and colchicine and prednisone for pericarditis.

On 02 Dec 2020 (Study Day 112), the participant started low-dose acetylsalicylic acid for pericarditis.

On 04 Dec 2020 (Study Day 114), during the post-hospitalization follow-up, atrial flutter was not observed, and the participant was not reporting any shortness of breath or pleurodynia. Relevant laboratory test results included WBC 14 × 10^3/µL, Hgb 11.7 g/dL, Hct 35.5%, platelets 555 × 10^3/µL, CRP 2.2 mg/dL, and ESR 49 mm/hr. A cardiology follow-up was scheduled for 16 Dec 2020 (Study Day 126).

On 07 Dec 2020 (Study Day 117), the participant remained on a prednisone taper for pericarditis.

On 13 Jan 2021 (Study Day 154), the participant had a follow-up visit with cardiology. The participant had not experienced any symptoms related to atrial flutter since hospitalization but remained on metoprolol as a precaution. The cardiologist believed the irritation from the pericarditis caused the atrial flutter and that it had now resolved. There was no pericardial rub on examination, however, the participant had occasional chest and upper abdominal pain that was likely related to the pericardial fluid. Prednisone tapering was continued, and the participant was instructed to follow up with rheumatology in January 2021 and cardiology again in April 2021.

On 18 Jan 2021 (Study Day 159), during a follow-up visit, the physician noted the participant still experienced serositis (pericarditis and small bilateral pleural effusion).

On 22 Feb 2021 (Study Day 194), the participant was weaned off prednisone and was asymptomatic with no shortness of breath or chest pain. No pulmonology follow-up appointment was scheduled.

Action taken with study IP in response to the events of pericardial effusion, pericarditis, pleural effusion, and atrial flutter, was not applicable, as the participant had already received both scheduled doses.

The event of atrial flutter was considered resolved on 01 Dec 2020 (Study Day 111). The events of pericardial effusion, pericarditis, and pleural effusion were considered resolved on 22 Feb 2021 (Study Day 194).

The investigator assessed the events of pericardial effusion, pericarditis, and pleural effusion as related to study IP, based on the timing of chest pain after the study dosing and diagnosis with etiology matching an inflammatory response. The event of atrial flutter was assessed as not related to the study IP. The events of pericardial effusion, pericarditis, pleural effusion, and atrial flutter were assessed as not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000916	Pericardial effusion
MOD-2020-000916	Pericarditis
MOD-2020-000916	Pleural effusion
MOD-2020-000916	Atrial flutter

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthritis	Right knee arthritis	Not reported - Ongoing
Asthma	Mild asthma	Not reported - Ongoing
Basal cell carcinoma	Basal cell carcinoma chest	Not reported
Basal cell carcinoma	Basal cell carcinoma nose	Not reported
Eyelid ptosis	Droopy eyelids interfering with vision	Not reported - Ongoing
Migraine	Migraine headaches	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Arthralgia	Migratory pains in joints of knees, legs (saw rhematologist, no diagnosis)	2013 - 2013
Osteoarthritis	Knee replacement surgery (due to osteoarthritis)	2013 - 2013
Postmenopause	Post menopause	24 Jan 2013 (Study Day -2758) - Ongoing
Aortic aneurysm	Enlarged descending aorta	2017 - 2017
Joint swelling	Middle finger of left hand joint swelling, no known cause	2019 - 2019
Facial paralysis	Bell's palsy	Feb 2019 - Feb 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	Not reported - Ongoing	Knee Pain
Salbutamol	Not reported - Ongoing	Asthma
Basic metabolic profile*	15 Sep 2020 (Study Day 34) - 15 Sep 2020 (Study Day 34)	Diagnostic
Cbc and differential*	15 Sep 2020 (Study Day 34) - 15 Sep 2020 (Study Day 34)	Diagnostic
Ct chest with iv contrast pulmonary embolism*	15 Sep 2020 (Study Day 34) - 15 Sep 2020 (Study Day 34)	Diagnostic
D-dimer, quantitative*	15 Sep 2020 (Study Day 34) - 15 Sep 2020 (Study Day 34)	Diagnostic
Pt/inr/ptt*	15 Sep 2020 (Study Day 34) - 15 Sep 2020 (Study Day 34)	Diagnostic
Troponin i*	15 Sep 2020 (Study Day 34) - 15 Sep 2020 (Study Day 34)	Diagnostic
Fluticasone	05 Oct 2020 (Study Day 54) - Ongoing	Sinus Congestion
Influenza vaccine rha 4v (baculovirus)	13 Oct 2020 (Study Day 62) - 13 Oct 2020 (Study Day 62)	Flu Prevention
Excision biopsy of left shoulder and left cheek skin lesions*	05 Nov 2020 (Study Day 85) - 05 Nov 2020 (Study Day 85)	Diagnostic
Photodynamic therapy (red light)*	13 Nov 2020 (Study Day 93) - 13 Nov 2020 (Study Day 93)	Adverse Event
Ecg 12 lead*	16 Nov 2020 (Study Day 96) - 16 Nov 2020 (Study Day 96)	Diagnostic
Ct angiography chest gated with iv contrast (**non-coronary**)*	17 Nov 2020 (Study Day 97) - 17 Nov 2020 (Study Day 97)	Diagnostic
Acetylsalicylic acid	18 Nov 2020 (Study Day 98) - 25 Nov 2020 (Study Day 105)	Pericarditis
Ana screen and titer*	18 Nov 2020 (Study Day 98) - 18 Nov 2020 (Study Day 98)	Diagnostic
Bnp*	18 Nov 2020 (Study Day 98) - 18 Nov 2020 (Study Day 98)	Diagnostic
Colchicine	18 Nov 2020 (Study Day 98) - Ongoing	Pericarditis
Erythrocyte sedimentation rate*	18 Nov 2020 (Study Day 98) - 18 Nov 2020 (Study Day 98)	Diagnostic
Troponin i*	18 Nov 2020 (Study Day 98) - 18 Nov 2020 (Study Day 98)	Diagnostic
2019 ncoronavirus, pcr (covid-19)*	25 Nov 2020 (Study Day 105) - 25 Nov 2020 (Study Day 105)	Diagnostic
Acetylsalicylic acid	25 Nov 2020 (Study Day 105) - 01 Dec 2020 (Study Day 111)	Pericarditis/ Pericardial Effusion
Aluminium hydroxide; magnesium hydroxide; simeticone	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Gastro Esophageal Reflux Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Basic metabolic profile*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Bnp*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Cbc and differential*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Ct chest with iv contrast pulmonary embolism*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Cxr-pal*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Ecg 12 lead 1 of 2*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Ecg 12 lead 2 of 2*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Ecg*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Erythrocyte sedimentation rate*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Lidocaine hydrochloride	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Gastro Esophageal Reflux Disease
Magnesium*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Procalcitonin*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Troponin i*	26 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 106)	Diagnostic
Ana screen and titer*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Basic metabolic profile*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Blood culture*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
C-reactive protein*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Cbc*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Citric acid; potassium bicarbonate	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Prevention Of Issues During Hospitalization: Electrolyte Replacement
Ecg 12 lead*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Echocardiogram*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Enoxaparin sodium	27 Nov 2020 (Study Day 107) - 01 Dec 2020 (Study Day 111)	Venous Thromboembolism Prophylaxis
Histoplasma ag, quant*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Hiv 4th generation antigen/antibody combo*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Magnesium*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Methocarbamol	27 Nov 2020 (Study Day 107) - 01 Dec 2020 (Study Day 111)	Pericarditis
Paracetamol	27 Nov 2020 (Study Day 107) - 01 Dec 2020 (Study Day 111)	Pericarditis
Phosphorus*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Telemetry monitoring (until 01dec2020)*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Troponin i*	27 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 107)	Diagnostic
Basic metabolic profile*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Cbc and differential*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Ecg 12 lead*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Flu a/b and rsv pcr, nasopharynx*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Liver profile*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Macrogol	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Prevention Of Constipation
Magnesium*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Phosphorus*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Potassium chloride	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Prevention Of Issues During Hospitalization: Electrolyte Replacement
Pt/inr/ptt*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Respiratory virus panel pcr*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
T4, free*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Tsh*	28 Nov 2020 (Study Day 108) - 28 Nov 2020 (Study Day 108)	Diagnostic
Basic metabolic profile*	29 Nov 2020 (Study Day 109) - 29 Nov 2020 (Study Day 109)	Diagnostic
Cbc and differential*	29 Nov 2020 (Study Day 109) - 29 Nov 2020 (Study Day 109)	Diagnostic
Chest marking (for thoracentesis)*	29 Nov 2020 (Study Day 109) - 29 Nov 2020 (Study Day 109)	Adverse Event
Magnesium*	29 Nov 2020 (Study Day 109) - 29 Nov 2020 (Study Day 109)	Diagnostic
Pantoprazole sodium sesquihydrate	29 Nov 2020 (Study Day 109) - 22 Feb 2021 (Study Day 194)	Gastro Esophageal Reflux Disease
Phosphorus*	29 Nov 2020 (Study Day 109) - 29 Nov 2020 (Study Day 109)	Diagnostic
Adenosine deaminase, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Afb culture, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Basic metabolic profile*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Cbc and differential*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Cell count and differential, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Chest 1 view (including portable)*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Adverse Event
Cytology pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Fluid culture, non-csf (anaerobic/aerobic) with gram stain*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Fungal culture, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Glucose, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Ketorolac tromethamine	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Pericarditis
Ldh, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Magnesium*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Ph, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Phosphorus*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Protein, pleural fluid*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Diagnostic
Thoracentesis*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Adverse Event
Basic metabolic profile*	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Diagnostic
Covid-19 antibody, igg*	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Diagnostic
Diphenhydramine hydrochloride	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Pericarditis
Diphenhydramine; zinc acetate	01 Dec 2020 (Study Day 111) - Ongoing	Itching Secondary To Seasonal Allergies
Lactulose	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Prevention Of Constipation
Ldh, total*	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Diagnostic
Magnesium*	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Diagnostic
Metoprolol tartrate	01 Dec 2020 (Study Day 111) - Ongoing	Episodic Atrial Flutter
Phosphorus*	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	01 Dec 2020 (Study Day 111) - 08 Dec 2020 (Study Day 118)	Pericarditis
Acetylsalicylic acid	02 Dec 2020 (Study Day 112) - Ongoing	Pericarditis
C-reactive protein*	04 Dec 2020 (Study Day 114) - 04 Dec 2020 (Study Day 114)	Diagnostic
Cbc and differential*	04 Dec 2020 (Study Day 114) - 04 Dec 2020 (Study Day 114)	Diagnostic
Erythrocyte sedimentation rate*	04 Dec 2020 (Study Day 114) - 04 Dec 2020 (Study Day 114)	Diagnostic
Prednisone	08 Dec 2020 (Study Day 118) - 15 Dec 2020 (Study Day 125)	Pericarditis
Prednisone	15 Dec 2020 (Study Day 125) - 22 Dec 2020 (Study Day 132)	Pericarditis
Prednisone	21 Dec 2020 (Study Day 131) - 03 Jan 2021 (Study Day 144)	Pericarditis
Prednisone	30 Dec 2020 (Study Day 140) - 05 Jan 2021 (Study Day 146)	Pericarditis
Prednisone	05 Jan 2021 (Study Day 146) - 13 Jan 2021 (Study Day 154)	Pericarditis
Prednisone	13 Jan 2021 (Study Day 154) - 15 Jan 2021 (Study Day 156)	Pericarditis
Prednisone	15 Jan 2021 (Study Day 156) - 17 Jan 2021 (Study Day 158)	Pericarditis
Prednisone	18 Jan 2021 (Study Day 159) - 25 Jan 2021 (Study Day 166)	Pericarditis
Prednisone	25 Jan 2021 (Study Day 166) - Ongoing	Pericarditis
Prednisone	25 Jan 2021 (Study Day 166) - 28 Jan 2021 (Study Day 169)	Pericarditis
Prednisone	28 Jan 2021 (Study Day 169) - 31 Jan 2021 (Study Day 172)	Pericarditis
Prednisone	31 Jan 2021 (Study Day 172) - 03 Feb 2021 (Study Day 175)	Pericarditis
Prednisone	03 Feb 2021 (Study Day 175) - 07 Feb 2021 (Study Day 179)	Pericarditis
Prednisone	07 Feb 2021 (Study Day 179) - 10 Feb 2021 (Study Day 182)	Pericarditis
Prednisone	10 Feb 2021 (Study Day 182) - 16 Feb 2021 (Study Day 188)	Pericarditis
Prednisone	16 Feb 2021 (Study Day 188) - 22 Feb 2021 (Study Day 194)	Pericarditis
Blepharoplasty*	17 Feb 2021 (Study Day 189) - 17 Feb 2021 (Study Day 189)	Medical History
Diagnostic ultrasound bilateral hands*	02 Mar 2021 (Study Day 202) - 02 Mar 2021 (Study Day 202)	Diagnostic
Botulinum toxin type a	15 Mar 2021 (Study Day 215) - 15 Mar 2021 (Study Day 215)	Facial Rhytides (Glabella And Crows Feet)
Hyaluronic acid	15 Mar 2021 (Study Day 215) - 15 Mar 2021 (Study Day 215)	Cosmetic (Face)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chest Pain	Grade 4	Related	13 Sep 2020 (Study Day 32) - 15 Sep 2020 (Study Day 34)
Fatigue	Grade 2/moderate	Related	13 Sep 2020 (Study Day 32) - 18 Sep 2020 (Study Day 37)
Chest Discomfort	Grade 2/moderate	Related	30 Sep 2020 (Study Day 49) - 03 Oct 2020 (Study Day 52)
Headache	Grade 1/mild	Not related	30 Sep 2020 (Study Day 49) - 03 Oct 2020 (Study Day 52)
Actinic Keratosis	Grade 3/severe	Not related	22 Oct 2020 (Study Day 71) - 13 Nov 2020 (Study Day 93)
Malignant Melanoma In Situ	Grade 3/severe	Not related	22 Oct 2020 (Study Day 71) - 05 Nov 2020 (Study Day 85)
Fatigue	Grade 3/severe	Related	15 Nov 2020 (Study Day 95) - 02 Dec 2020 (Study Day 112)
Nausea	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 95) - 15 Nov 2020 (Study Day 95)
Pericardial Effusion	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 95) - 16 Feb 2021 (Study Day 188)
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	01 Dec 2020 (Study Day 111) - 22 Feb 2021 (Study Day 194)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US362-2169 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 4	Not related	06 Dec 2020 (Study Day 89) – 04 Jan 2021 (Study Day 118)	Recovered/ resolved
Hepatocellular Carcinoma/Metastatic Hepatocellular Carcinoma	SAE	Grade 4	Not related	30 Dec 2020 (Study Day 113) – 04 Jan 2021 (Study Day 118)	Recovered/ resolved with sequelae
Hepatocellular Carcinoma/Worsening Metastatic Hepatocellular Carcinoma	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	16 Jan 2021 (Study Day 130) – 21 Jan 2021 (Study Day 135)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2169, a 56-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Dec 2020 (Study Day 89), 88 days after the first dose and 60 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 30 days, after which it was considered to be recovered/resolved on 04 Jan 2021 (Study Day 118). The investigator assessed the event of pneumonia to be not related to the IP.

On 30 Dec 2020 (Study Day 113), 112 days after the first dose and 84 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hepatocellular carcinoma. Action taken with the IP was not applicable. The event of metastatic hepatocellular carcinoma lasted for 6 days, after which it was considered to be recovered/resolved with sequelae on 04 Jan 2021 (Study Day 118). The investigator assessed the event of hepatocellular carcinoma to be not related to the IP.

On 16 Jan 2021 (Study Day 130), 129 days after the first dose and 101 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of hepatocellular carcinoma. Action taken with the IP was not applicable. The event of worsening metastatic hepatocellular carcinoma lasted for 6 days, after which it was considered to be fatal on 21 Jan 2021 (Study Day 135). The investigator assessed the event of hepatocellular carcinoma to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 29 Nov 2020 (Study Day 82), the participant experienced a nonserious adverse events of nasal congestion and worsening dyspnea.

On 03 Dec 2020 (Study Day 86), the participant was contacted for the Month 3 safety call. The participant continued to experience nasal congestion and worsening dyspnea and was scheduled for an illness visit on 04 Dec 2020 (Study Day 87).

On 04 Dec 2020 (Study Day 87), the participant did not go to the illness visit and continued experiencing symptoms of nasal congestion and worsening dyspnea.

On 06 Dec 2020 (Study Day 89), the participant experienced a serious adverse event (SAE) of pneumonia. The participant presented to the emergency department with chief complaints of shortness of breath, weakness, and abdominal pain for 3 days. The participant's oxygen saturation was 89 to 90% on room air and their respiratory rate was 24 breaths per minute. The participant was admitted to the hospital in intensive care unit (ICU) for pneumonia. On the same day, a computerized tomography (CT) scan revealed liver lesions and multiple lung nodules suggestive of hepatocellular carcinoma with lung metastases. Relevant laboratory test results included platelet count 99 (low), calcium 8.4 (low), alkaline phosphatase 240 (high), total bilirubin 1.9 (high), alanine aminotransferase (ALT) 55 (high), and aspartate aminotransferase (AST) 94 (high) (no units or reference ranges reported). A chest x-ray revealed a right large pleural effusion.

On 11 Dec 2020 (Study Day 94), the participant underwent right thoracentesis (amount and type of fluid was not reported).

On 15 Dec 2020 (Study Day 98), a right pleural drain was placed under ultrasound guidance.

On 28 Dec 2020 (Study Day 111), relevant laboratory test results included sodium 131 (low); calcium 8.0 (low); AST 7.2 (high); *Mycoplasma pneumoniae* IgM was positive; SARS antigen was negative; and COVID-19 RT-PCR was negative. A chest x-ray showed bilateral lung infiltrates; right greater than left and the infiltrates were stable.

On 30 Dec 2020 (Study Day 113), the participant experienced an SAE of hepatocellular carcinoma (metastatic hepatocellular carcinoma), which was confirmed with a CT-guided liver biopsy.

On 31 Dec 2020 (Study Day 114), a chest x-ray showed decreasing vascular congestion and small bilateral plural effusions with bibasilar atelectasis and/or infiltrate.

On 04 Jan 2021 (Study Day 118), a chest x-ray showed bilateral lung infiltrate.

Treatment for the events included oxygen; azithromycin, ceftriaxone, piperacillin/tazobactam, vancomycin, calcium chloride, methylprednisolone, furosemide, sodium chloride (all IV), albuterol/ipratropium intranasal; azithromycin, furosemide, montelukast, spironolactone, and paracetamol (all PO).

The event of pneumonia was considered resolved on 04 Jan 2021 (Study Day 118), the event of hepatocellular carcinoma (metastatic hepatocellular carcinoma), was considered resolved with sequelae on 04 Jan 2021 (Study Day 118), and the participant was discharged from the hospital on the same day.

On 16 Jan 2021 (Study Day 130), the participant experienced an SAE of hepatocellular carcinoma (worsening metastatic hepatocellular carcinoma). The participant presented to the hospital with complaints of multiple syncopal episodes, worsening edema, worsening shortness of breath, right upper quadrant pain, and fatigue. The participant was admitted to the ICU for 4 days. The participant had a negative COVID-19 test. Subsequent hospital events included anasarca and sepsis. Treatment for the event of hepatocellular carcinoma (worsening metastatic hepatocellular carcinoma) included rifaximin, sodium bicarbonate, lactulose, famotidine (all PO); vancomycin, daptomycin, micafungin, albumin, sodium bicarbonate, hydromorphone, cefepime, metronidazole, vasopressin, meropenem, ceftriaxone, norepinephrine, octreotide, albuterol/ipratropium, and methylprednisolone (all IV).

On 21 Jan 2021 (Study Day 135), the participant experienced cardiopulmonary arrest and died. The cause of death was reported as hepatocellular carcinoma (worsening metastatic hepatocellular carcinoma).

Action taken with study IP was not applicable in response to the events as the participant had already received both scheduled doses.

The investigator assessed the events, pneumonia and hepatocellular carcinoma (metastatic hepatocellular carcinoma and worsening metastatic hepatocellular carcinoma), as not related to the study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001051	Pneumonia
MOD-2020-001051	Hepatocellular carcinoma metastatic (worsening)
MOD-2020-001051	Hepatocellular carcinoma metastatic

Study Completion/Discontinuation

On 21 Jan 2021 (Study Day 135), the participant discontinued from the study due to death. On 21 Jan 2021 (Study Day 135), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1985 - Ongoing
Fluid retention	Fluid retention	1991 - Ongoing
Obesity	Severe obesity (BMI 49.6)	2008 - Ongoing
Diabetes mellitus	Diabetes	2014 - Ongoing
Dyspnoea	Dyspnea	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	2017 - Ongoing	Fluid Retention
Spironolactone	2017 - Ongoing	Fluid Retention
Salbutamol	2018 - Ongoing	Dyspnea
Influenza vaccine	25 Aug 2020 (Study Day -15) - Ongoing	Influenza Prophylaxis
Abdominal ultrasound*	06 Dec 2020 (Study Day 89) - 06 Dec 2020 (Study Day 89)	Diagnostic
Ascorbic acid	06 Dec 2020 (Study Day 89) - 04 Jan 2021 (Study Day 118)	Vitamin Supplementation
Azithromycin	06 Dec 2020 (Study Day 89) - 15 Dec 2020 (Study Day 98)	Pneumonia
Calcium chloride	06 Dec 2020 (Study Day 89) - 06 Dec 2020 (Study Day 89)	Unknown
Ceftriaxone	06 Dec 2020 (Study Day 89) - 06 Dec 2020 (Study Day 89)	Pneumonia
CTA chest*	06 Dec 2020 (Study Day 89) - 06 Dec 2020 (Study Day 89)	Diagnostic
EKG*	06 Dec 2020 (Study Day 89) - 06 Dec 2020 (Study Day 89)	Diagnostic
Famotidine	06 Dec 2020 (Study Day 89) - 04 Jan 2021 (Study Day 118)	Reflux Prevention
Furosemide	06 Dec 2020 (Study Day 89) - 22 Dec 2020 (Study Day 105)	Unknown
Heparin	06 Dec 2020 (Study Day 89) - 11 Dec 2020 (Study Day 94)	Unknown
Iopamidol	06 Dec 2020 (Study Day 89) - 09 Dec 2020 (Study Day 92)	Unknown
Ipratropium bromide; salbutamol sulfate	06 Dec 2020 (Study Day 89) - 04 Jan 2021 (Study Day 118)	Pneumonia
Methylprednisolone sodium succinate	06 Dec 2020 (Study Day 89) - 06 Dec 2020 (Study Day 89)	Unknown

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Methylprednisolone sodium succinate	06 Dec 2020 (Study Day 89) - 11 Dec 2020 (Study Day 94)	Unknown
Oxygen	06 Dec 2020 (Study Day 89) - 04 Jan 2021 (Study Day 118)	Dyspnea, Pneumonia
Spironolactone	06 Dec 2020 (Study Day 89) - 22 Dec 2020 (Study Day 105)	Unknown
X-ray*	06 Dec 2020 (Study Day 89) - 06 Dec 2020 (Study Day 89)	Diagnostic
Zinc sulfate	06 Dec 2020 (Study Day 89) - 04 Jan 2021 (Study Day 118)	Vitamin Supplementation
Chest x-ray*	07 Dec 2020 (Study Day 90) - 07 Dec 2020 (Study Day 90)	Diagnostic
Colecalciferol	07 Dec 2020 (Study Day 90) - 04 Jan 2021 (Study Day 118)	Vitamin Supplementation
Echocardiogram*	07 Dec 2020 (Study Day 90) - 07 Dec 2020 (Study Day 90)	Diagnostic
Paracetamol	07 Dec 2020 (Study Day 90) - 04 Jan 2021 (Study Day 118)	Unknown
Azithromycin	08 Dec 2020 (Study Day 91) - 03 Jan 2021 (Study Day 117)	Pneumonia
Ceftriaxone	08 Dec 2020 (Study Day 91) - 11 Dec 2020 (Study Day 94)	Pneumonia
Lactulose	08 Dec 2020 (Study Day 91) - 04 Jan 2021 (Study Day 118)	Unknown
Quetiapine	08 Dec 2020 (Study Day 91) - 03 Jan 2021 (Study Day 117)	Unknown
Chest x-ray*	09 Dec 2020 (Study Day 92) - 09 Dec 2020 (Study Day 92)	Diagnostic
Ct abd/pelvis w/wo contrast*	09 Dec 2020 (Study Day 92) - 09 Dec 2020 (Study Day 92)	Diagnostic
Lorazepam	09 Dec 2020 (Study Day 92) - 03 Jan 2021 (Study Day 117)	Unknown (According To Medical Records)
Chest x-ray*	10 Dec 2020 (Study Day 93) - 10 Dec 2020 (Study Day 93)	Diagnostic
Chest x-ray*	11 Dec 2020 (Study Day 94) - 11 Dec 2020 (Study Day 94)	Diagnostic
Codeine; guaifenesin	11 Dec 2020 (Study Day 94) - 04 Jan 2021 (Study Day 118)	Cough
Right thoracentesis*	11 Dec 2020 (Study Day 94) - 11 Dec 2020 (Study Day 94)	Diagnostic
Nadolol	12 Dec 2020 (Study Day 95) - 31 Dec 2020 (Study Day 114)	Unknown
Chest x-ray*	13 Dec 2020 (Study Day 96) - 13 Dec 2020 (Study Day 96)	Diagnostic
Chest x-ray*	14 Dec 2020 (Study Day 97) - 14 Dec 2020 (Study Day 97)	Diagnostic
Chest x-ray*	15 Dec 2020 (Study Day 98) - 15 Dec 2020 (Study Day 98)	Diagnostic
Right pleural drain placement under US guidance*	15 Dec 2020 (Study Day 98) - 15 Dec 2020 (Study Day 98)	Diagnostic
Albumin human	16 Dec 2020 (Study Day 99) - 22 Dec 2020 (Study Day 105)	Unknown
Chest x-ray*	19 Dec 2020 (Study Day 102) - 19 Dec 2020 (Study Day 102)	Diagnostic
Chest x-ray*	21 Dec 2020 (Study Day 104) - 21 Dec 2020 (Study Day 104)	Diagnostic
Piperacillin sodium; tazobactam sodium	21 Dec 2020 (Study Day 104) - 23 Dec 2020 (Study Day 106)	Pneumonia
Chest x-ray*	23 Dec 2020 (Study Day 106) - 23 Dec 2020 (Study Day 106)	Diagnostic
Chest x-ray*	24 Dec 2020 (Study Day 107) - 24 Dec 2020 (Study Day 107)	Diagnostic
Ondansetron	24 Dec 2020 (Study Day 107) - 04 Jan 2021 (Study Day 118)	Nausea
Vancomycin	24 Dec 2020 (Study Day 107) - 26 Dec 2020 (Study Day 109)	Pneumonia
Chest x-ray*	25 Dec 2020 (Study Day 108) - 25 Dec 2020 (Study Day 108)	Diagnostic
Chest x-ray*	26 Dec 2020 (Study Day 109) - 26 Dec 2020 (Study Day 109)	Diagnostic
Vancomycin	26 Dec 2020 (Study Day 109) - 03 Jan 2021 (Study Day 117)	Pneumonia
Venous duplex ultrasound UE right*	26 Dec 2020 (Study Day 109) - 26 Dec 2020 (Study Day 109)	Diagnostic
CTA chest*	27 Dec 2020 (Study Day 110) - 27 Dec 2020 (Study Day 110)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x-ray*	28 Dec 2020 (Study Day 111) - 28 Dec 2020 (Study Day 111)	Diagnostic
Chest x-ray*	29 Dec 2020 (Study Day 112) - 29 Dec 2020 (Study Day 112)	Diagnostic
CT guided liver biopsy*	30 Dec 2020 (Study Day 113) - 30 Dec 2020 (Study Day 113)	Diagnostic
Chest x-ray*	31 Dec 2020 (Study Day 114) - 31 Dec 2020 (Study Day 114)	Diagnostic
Echocardiogram*	31 Dec 2020 (Study Day 114) - 31 Dec 2020 (Study Day 114)	Diagnostic
Chest x-ray*	01 Jan 2021 (Study Day 115) - 01 Jan 2021 (Study Day 115)	Diagnostic
Midodrine	01 Jan 2021 (Study Day 115) - 04 Jan 2021 (Study Day 118)	Hypotension
Chest x-ray*	03 Jan 2021 (Study Day 117) - 03 Jan 2021 (Study Day 117)	Diagnostic
Chest x-ray*	04 Jan 2021 (Study Day 118) - 04 Jan 2021 (Study Day 118)	Diagnostic
Furosemide	10 Jan 2021 (Study Day 124) - 10 Jan 2021 (Study Day 124)	Metastatic Hepatocellular Carcinoma
Abdominal ultrasound*	16 Jan 2021 (Study Day 130) - 16 Jan 2021 (Study Day 130)	Diagnostic
Albumin NOS	16 Jan 2021 (Study Day 130) - 20 Jan 2021 (Study Day 134)	Sepsis
Cefepime	16 Jan 2021 (Study Day 130) - 18 Jan 2021 (Study Day 132)	Sepsis
Central venous line placement*	16 Jan 2021 (Study Day 130) - 16 Jan 2021 (Study Day 130)	Diagnostic
Chest x-ray*	16 Jan 2021 (Study Day 130) - 16 Jan 2021 (Study Day 130)	Diagnostic
CT chest, abdomen, pelvis*	16 Jan 2021 (Study Day 130) - 16 Jan 2021 (Study Day 130)	Diagnostic
Norepinephrine	16 Jan 2021 (Study Day 130) - 20 Jan 2021 (Study Day 134)	Sepsis
Ondansetron	16 Jan 2021 (Study Day 130) - 21 Jan 2021 (Study Day 135)	Nausea Prevention
Vancomycin	16 Jan 2021 (Study Day 130) - 18 Jan 2021 (Study Day 132)	Sepsis
Vasopressin	16 Jan 2021 (Study Day 130) - 18 Jan 2021 (Study Day 132)	Sepsis
Albumin NOS	17 Jan 2021 (Study Day 131) - 17 Jan 2021 (Study Day 131)	Sepsis
CT abdomen pelvis w/wo contrast*	17 Jan 2021 (Study Day 131) - 17 Jan 2021 (Study Day 131)	Diagnostic
Lactulose	17 Jan 2021 (Study Day 131) - 20 Jan 2021 (Study Day 134)	Sepsis
Meropenem	17 Jan 2021 (Study Day 131) - 18 Jan 2021 (Study Day 132)	Sepsis
Metronidazole	17 Jan 2021 (Study Day 131) - 20 Jan 2021 (Study Day 134)	Sepsis
Octreotide	17 Jan 2021 (Study Day 131) - 20 Jan 2021 (Study Day 134)	Sepsis
Rifaximin	17 Jan 2021 (Study Day 131) - 20 Jan 2021 (Study Day 134)	Sepsis
Chest x-ray*	18 Jan 2021 (Study Day 132) - 18 Jan 2021 (Study Day 132)	Diagnostic
Daptomycin	18 Jan 2021 (Study Day 132) - 20 Jan 2021 (Study Day 134)	Sepsis
Enoxaparin sodium	18 Jan 2021 (Study Day 132) - 20 Jan 2021 (Study Day 134)	Prevention Of Blood Clots
Famotidine	18 Jan 2021 (Study Day 132) - 20 Jan 2021 (Study Day 134)	Unknown
Micafungin	18 Jan 2021 (Study Day 132) - 20 Jan 2021 (Study Day 134)	Sepsis
Sodium bicarbonate	18 Jan 2021 (Study Day 132) - 20 Jan 2021 (Study Day 134)	Sepsis
Echocardiogram*	19 Jan 2021 (Study Day 133) - 19 Jan 2021 (Study Day 133)	Diagnostic
Lorazepam	19 Jan 2021 (Study Day 133) - 19 Jan 2021 (Study Day 133)	Unknown (According To Medical Records)
Sodium bicarbonate	19 Jan 2021 (Study Day 133) - 19 Jan 2021 (Study Day 133)	Sepsis
Glycopyrronium	20 Jan 2021 (Study Day 134) - 21 Jan 2021 (Study Day 135)	Unknown (According To Medical Records)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydromorphone hydrochloride	20 Jan 2021 (Study Day 134) - 21 Jan 2021 (Study Day 135)	Metastatic Hepatocellular Carcinoma
Ipratropium; salbutamol	20 Jan 2021 (Study Day 134) - 21 Jan 2021 (Study Day 135)	Unknown
Nystatin	20 Jan 2021 (Study Day 134) - 21 Jan 2021 (Study Day 135)	Unknown

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspnoea	Grade 2/moderate	Not related	29 Nov 2020 (Study Day 82) - 21 Jan 2021 (Study Day 135)
Nasal Congestion	Grade 1/mild	Not related	29 Nov 2020 (Study Day 82) - 21 Jan 2021 (Study Day 135)
Sepsis	Grade 3/severe	Not related	16 Jan 2021 (Study Day 130) - 21 Jan 2021 (Study Day 135)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2173 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 30)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/ Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	01 Nov 2020 (Study Day 74) – 01 Nov 2020 (Study Day 74)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2173, a 77-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 74), 73 days after the first dose and 44 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction was considered to be fatal on 01 Nov 2020 (Study Day 74). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 01 Nov 2020 (Study Day 74), the participant experienced a fatal serious adverse event of myocardial infarction. The participant's child reported that they died of a "massive heart attack". No treatment was given for the event because the participant died at home.

Action taken with the study IP was not applicable in response to the event.

The participant died on 01 Nov 2020 (Study Day 74).

The investigator assessed the event, myocardial infarction, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000604	Myocardial infarction

Study Completion/Discontinuation

On 01 Nov 2020 (Study Day 74), the participant discontinued from the study due to death. On 01 Nov 2020 (Study Day 74), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Skin graft	Island Peticoh transplant left hand	Not reported
Limb reconstructive surgery	Reconstructive left-hand surgery	1979 - 1979
Gastrooesophageal reflux disease	Gerd/reflux	2002 - Ongoing
Prostatomegaly	Prostate enlargement	2004 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2005 - Ongoing
Deafness bilateral	Bilateral hearing loss	2005 - Ongoing
Back pain	Low back pain	2015 - Ongoing
Cardiomyopathy	Cardiomyopathy	2015 - Ongoing
Cholecystectomy	Cholecystectomy for cholecystitis	2015 - 2015
Cholecystitis	Cholecystitis	2015 - 2015
Gout	Gout (location unknown)	2015 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Myocardial infarction	Myocardial infarction	2015 - 2015
Catheterisation cardiac	Cardiac catheterization	06 Nov 2015 (Study Day -1749) - 06 Nov 2015 (Study Day -1749)
Coronary artery disease	Coronary artery disease	Dec 2015 - Ongoing
Basal cell carcinoma	Basal cell cancer on face	2019 - 2019
Cataract	Cataracts	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fish oil	May 2005 - 01 Nov 2020 (Study Day 74)	Prophylaxis For Cardiac Disease
Omeprazole	Jan 2010 - 01 Nov 2020 (Study Day 74)	GERD
Acetylsalicylic acid	Jun 2015 - 01 Nov 2020 (Study Day 74)	Prophylaxis For Cardiac Disease
Atorvastatin	Jun 2015 - 01 Nov 2020 (Study Day 74)	Hyperlipidemia
Budesonide; formoterol fumarate	Jun 2015 - 01 Nov 2020 (Study Day 74)	Chronic Obstructive Pulmonary Disease
Carvedilol	Jun 2015 - 01 Nov 2020 (Study Day 74)	Hypertension
Fluticasone	Jun 2015 - 01 Nov 2020 (Study Day 74)	Chronic Obstructive Pulmonary Disease
Allopurinol	Jul 2018 - 01 Nov 2020 (Study Day 74)	Gout
Vitamins nos	Feb 2019 - 01 Nov 2020 (Study Day 74)	Supplement
Tamsulosin	Aug 2019 - 01 Nov 2020 (Study Day 74)	Enlarged Prostate
Guaifenesin	Jan 2020 - 01 Nov 2020 (Study Day 74)	Chronic Obstructive Pulmonary Disease
Salbutamol	Jan 2020 - 01 Nov 2020 (Study Day 74)	Chronic Obstructive Pulmonary Disease
Influenza vaccine	20 Oct 2020 (Study Day 62) - 20 Oct 2020 (Study Day 62)	Prophylaxis For Seasonal Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US383-2237 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Death/Death (Unknown Cause)	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	19 Nov 2020 (Study Day 92) – 19 Nov 2020 (Study Day 92)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2237, a 50-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Nov 2020 (Study Day 92), 91 days after the first dose and 63 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of death. Action taken with the IP was not applicable. The event of death was considered to be fatal on 19 Nov 2020 (Study Day 92). The investigator assessed the event of death to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 19 Nov 2020 (Study Day 92), the participant experienced a fatal serious adverse event of death. Per the participant's spouse, the participant was found dead by the local authorities. The participant's spouse suspected that the participant's past history of severe alcohol addiction, mental health problems, and suicidal tendencies contributed to the participant's death. No treatment was reported.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 19 Nov 2020 (Study Day 92). The cause of death was reported as unknown.

The investigator assessed the event, death, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000959	Death

Study Completion/Discontinuation

On 19 Nov 2020 (Study Day 92), the participant discontinued from the study due to death. On 19 Nov 2020 (Study Day 92), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1978 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Gastrooesophageal reflux disease	Acid reflux with nausea	2017 - Ongoing
Insomnia	Insomnia	2018 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2014 - 08 Oct 2020 (Study Day 50)	Hypertension
Sertraline	2016 - Ongoing	Anxiety
Diphenhydramine hydrochloride	2017 - Ongoing	Acid Reflux With Nausea
Clonidine	Dec 2019 - Ongoing	Insomnia
Metoprolol	Dec 2019 - Ongoing	Hypertension
Buspirone hydrochloride	Jan 2020 - Ongoing	Anxiety
Colecalciferol	Apr 2020 - Ongoing	Vitamin D3 Deficiency
Losartan	08 Oct 2020 (Study Day 50) - Ongoing	Worsening Of Hypertension
Influenza vaccine	13 Oct 2020 (Study Day 55) - 13 Oct 2020 (Study Day 55)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 1/mild	Not related	08 Oct 2020 (Study Day 50) - 15 Oct 2020 (Study Day 57)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US388-2011 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 30)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Seizure/Seizure	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	06 Jan 2021 (Study Day 126) – 06 Jan 2021 (Study Day 126)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US388-2011, a 59-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Jan 2021 (Study Day 126), 125 days after the first dose and 96 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of seizure. Action taken with the IP was not applicable. The event of seizure was considered to be fatal on 06 Jan 2021 (Study Day 126). The investigator assessed the event of seizure to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 06 Jan 2021 (Study Day 126), the participant experienced a fatal serious adverse event of seizure. The participant resided in a short-term care facility. The nursing station was notified that the participant experienced chest pain on a scale of 10 out of 10 that radiated to their shoulder blades and complained of indigestion (likely angina). Emergency services were called, and the participant was in full arrest. An electrocardiogram showed normal sinus rhythm. The participant had seizure-like activity (likely myoclonic jerking) followed by full cardiac arrest. A bag valve mask ventilator, chest compressions, and electric shock were attempted for the participant's ventricular fibrillation. The participant coded in the emergency department for approximately 27 minutes and was reportedly shocked multiple times, but a pulse was not able to be recovered.

There was no evidence of acute trauma, and the manner of death was natural. An enzyme-linked immunosorbent assay drug screen was presumptively positive for methamphetamine and methylenedioxymethamphetamine. All other results were negative. A blood alcohol test result was negative.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 06 Jan 2021 (Study Day 126). An autopsy revealed the cause of death was due to sudden cardiac death as a result of hypertensive heart disease, complicated by diabetes mellitus and obesity. Additional cause of death per coroner report was acute myocardial infarction with ventricular fibrillation.

The investigator assessed the event, seizure, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002295	Seizure

Study Completion/Discontinuation

On 06 Jan 2021 (Study Day 126), the participant discontinued from the study due to death. On 06 Jan 2021 (Study Day 126), the participant died due to adverse event. An autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic low back pain	14 Feb 2018 (Study Day -932) - Ongoing
Deafness	Hearing loss	14 Feb 2018 (Study Day -932) - Ongoing
Dental caries	Dental caries	14 Feb 2018 (Study Day -932) - Ongoing
Drug abuse	Nondependent cannabis abuse	14 Feb 2018 (Study Day -932) - Ongoing
Erectile dysfunction	Erectile dysfunction	14 Feb 2018 (Study Day -932) - Ongoing
Homeless	Homeless	14 Feb 2018 (Study Day -932) - Not reported
Hypertension	HTN - hypertension	14 Feb 2018 (Study Day -932) - Ongoing
Hypothyroidism	Hypothyroidism	14 Feb 2018 (Study Day -932) - Ongoing
Mixed anxiety and depressive disorder	Mood disorder; depression and anxiety	14 Feb 2018 (Study Day -932) - Ongoing
Obesity	Obesity	14 Feb 2018 (Study Day -932) - Ongoing
Osteoarthritis	Osteoarthritis of knee	14 Feb 2018 (Study Day -932) - Ongoing
Tinnitus	Tinnitus	14 Feb 2018 (Study Day -932) - Ongoing
Tobacco user	Tobacco user	14 Feb 2018 (Study Day -932) - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	14 Feb 2018 (Study Day -932) - Ongoing
Type V hyperlipidaemia	Mixed hyperlipidemia	14 Feb 2018 (Study Day -932) - Ongoing
Drug dependence	Methamphetamine dependence	02 Aug 2020 (Study Day -32) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	Not reported - Ongoing	Prophylaxis For Health Promotion
Duloxetine hydrochloride	Not reported - Ongoing	Mood - Depression
Fish oil	Not reported - Ongoing	Supplementation
Hydroxyzine hydrochloride	Not reported - Ongoing	Anxiety
Ibuprofen	Not reported - Ongoing	General Body Pain
Levothyroxine sodium	Not reported - Ongoing	Thyroid/Hypothyroidism
Lisinopril	Not reported - Ongoing	High Blood Pressure
Paracetamol	Not reported - Ongoing	General Body Pain
Simvastatin	Not reported - Ongoing	High Cholesterol (Hyperlipidemia)
Varenicline	17 Oct 2020 (Study Day 45) - Ongoing	Smoking Cessation
Loperamide	16 Nov 2020 (Study Day 75) - 03 Dec 2020 (Study Day 92)	Stomach Flu With Diarrhea
Ondansetron	16 Nov 2020 (Study Day 75) - 03 Dec 2020 (Study Day 92)	Stomach Flu With Nausea
EKG*	06 Jan 2021 (Study Day 126) - 06 Jan 2021 (Study Day 126)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastroenteritis Viral	Grade 1/mild	Not related	16 Nov 2020 (Study Day 75) - 03 Dec 2020 (Study Day 92)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US391-2024 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 28)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/ Obstructing Nephrolithiasis	SAE	Grade 3/ severe	Not related	31 Oct 2020 (Study Day 65) – 04 Nov 2020 (Study Day 69)	Recovered/ resolved
Acute Kidney Injury/Acute Renal Failure	SAE	Grade 3/ severe	Not related	03 Nov 2020 (Study Day 68) – Ongoing	Not recovered/not resolved
Flank Pain/Flank Pain (Left)	SAE	Grade 3/ severe	Not related	03 Nov 2020 (Study Day 68) – Ongoing	Not recovered/not resolved
Thrombocytopenia/ Thrombocytopenia	SAE	Grade 4	Not related	03 Nov 2020 (Study Day 68) – Ongoing	Not recovered/not resolved
Duodenal Ulcer Perforation/Perforated Duodenal Ulcer	SAE	Grade 3/ severe	Not related	08 Nov 2020 (Study Day 73) – 08 Nov 2020 (Study Day 73)	Recovered/ resolved with sequelae
Gastrointestinal Haemorrhage/Gi Bleed	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	08 Nov 2020 (Study Day 73) – 22 Nov 2020 (Study Day 87)	Fatal
Generalised Oedema/Anasarca	SAE	Grade 3/ severe	Not related	08 Nov 2020 (Study Day 73) – Ongoing	Not recovered/ not resolved
Intra-Abdominal Fluid Collection/Intraabdominal Fluid	SAE	Grade 2/ moderate	Not related	08 Nov 2020 (Study Day 73) – Ongoing	Not recovered/ not resolved
Anaemia/Anemia	SAE	Grade 3/ severe	Not related	15 Nov 2020 (Study Day 80) – Ongoing	Not recovered/ not resolved
Acute Respiratory Failure/Acute Hypoxic Respiratory Failure	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	20 Nov 2020 (Study Day 85) – 22 Nov 2020 (Study Day 87)	Fatal
Multiple Organ Dysfunction Syndrome/Multisystem Organ Failure	Death, SAE, AE leading to study	Grade 5	Not related	20 Nov 2020 (Study Day 85) – 22 Nov 2020 (Study Day 87)	Fatal

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MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
	discontinuation				

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2024, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Oct 2020 (Study Day 65), 64 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of obstructing nephrolithiasis lasted for 5 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 69). The investigator assessed the event of nephrolithiasis to be not related to the IP.

On 03 Nov 2020 (Study Day 68), 67 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute renal failure was considered to be ongoing. The investigator assessed the event of acute kidney injury to be not related to the IP.

On 03 Nov 2020 (Study Day 68), 67 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of flank pain. Action taken with the IP was not applicable. The event of flank pain (left) was considered to be ongoing. The investigator assessed the event of flank pain to be not related to the IP.

On 03 Nov 2020 (Study Day 68), 67 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of thrombocytopenia. Action taken with the IP was not applicable. The event of thrombocytopenia was considered to be ongoing. The investigator assessed the event of thrombocytopenia to be not related to the IP.

On 08 Nov 2020 (Study Day 73), 72 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of duodenal ulcer perforation. Action taken with the IP was not applicable. The event of perforated duodenal ulcer lasted for 1 day, after which it was considered to be recovered/resolved with sequelae on 08 Nov 2020 (Study Day 73). The investigator assessed the event of duodenal ulcer perforation to be not related to the IP.

On 08 Nov 2020 (Study Day 73), 72 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of gastrointestinal haemorrhage.

Action taken with the IP was not applicable. The event of gi bleed lasted for 15 days, after which it was considered to be fatal on 22 Nov 2020 (Study Day 87). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

On 08 Nov 2020 (Study Day 73), 72 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of generalised oedema. Action taken with the IP was not applicable. The event of anasarca was considered to be ongoing. The investigator assessed the event of generalised oedema to be not related to the IP.

On 08 Nov 2020 (Study Day 73), 72 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of intra-abdominal fluid collection. Action taken with the IP was not applicable. The event of intraabdominal fluid was considered to be ongoing. The investigator assessed the event of intra-abdominal fluid collection to be not related to the IP.

On 15 Nov 2020 (Study Day 80), 79 days after the first dose and 52 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of anaemia. Action taken with the IP was not applicable. The event of anemia was considered to be ongoing. The investigator assessed the event of anaemia to be not related to the IP.

On 20 Nov 2020 (Study Day 85), 84 days after the first dose and 57 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute hypoxic respiratory failure lasted for 3 days, after which it was considered to be fatal on 22 Nov 2020 (Study Day 87). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 20 Nov 2020 (Study Day 85), 84 days after the first dose and 57 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of multiple organ dysfunction syndrome. Action taken with the IP was not applicable. The event of multisystem organ failure lasted for 3 days, after which it was considered to be fatal on 22 Nov 2020 (Study Day 87). The investigator assessed the event of multiple organ dysfunction syndrome to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 31 Oct 2020 (Study Day 65), the participant experienced a serious adverse event (SAE) of nephrolithiasis. The participant was initially assessed with ureteral stones.

On 03 Nov 2020 (Study Day 68), the participant experienced SAEs of flank pain, thrombocytopenia, and acute kidney injury. On the same day, the participant presented to the emergency department for worsened abdominal pain in the left flank. Upon arrival, the participant's platelets were low (value not reported), and this was considered life threatening; hemoglobin (Hgb) was stable at 12.6 g/dL (reference range 13.0 to 17.0 g/dL). The participant was

subsequently hospitalized for thrombocytopenia and acute kidney failure secondary to nephrolithiasis. On 03 Nov 2020 (Study Day 68), 04 Nov 2020 (Study Day 69), and 05 Nov 2020 (Study Day 70), the participant's creatinine levels were 3.5 mg/dL, 3.1 mg/dL, and 3.3 mg/dL (reference range 0.6 to 1.3 mg/dL), respectively. On 03 Nov 2020 (Study Day 68), an abdominal and pelvic computerized tomography (CT) scan revealed the proximal portion of left ureter was obstructed by stones measuring up to 9 mm in size; mild hydronephrosis; and worsened edema in the left renal region. Based on the findings, pyelonephritis was suspected, and a left renal stone was diagnosed. The participant had a ureteral stent inserted. Treatment medications included piperacillin/tazobactam IV and hydromorphone (route not reported). On 04 Nov 2020 (Study Day 69), the event of acute kidney injury worsened to acute renal failure. Treatment medications included oxycodone and sennoside (both PO); ceftriaxone, tamsulosin, morphine, and midazolam (all IV); and heparin SC. On 05 Nov 2020 (Study Day 70), the participant reported ongoing abdominal pain. Later, on the same day, their platelet count decreased from $79 \times 10^3/\mu L$ to $73 \times 10^3/\mu L$ and then dropped to $59 \times 10^3/\mu L$ (reference range not reported). No sign of active bleeding was reported. Treatment medications included meropenem IV and hydrocodone/paracetamol PO. On 06 Nov 2020 (Study Day 71), a follow-up renal ultrasound revealed no hydronephrosis.

On 08 Nov 2020 (Study Day 73), the participant experienced SAEs of duodenal ulcer perforation, gastrointestinal hemorrhage, generalized edema, and intra-abdominal fluid collection. On 08 Nov 2020 (Study Day 73), the participant had worsened lower abdominal pain that was more constant and severe, along with decreased appetite and nausea. Their Hgb dropped to 10.9 g/dL. An abdominal and pelvic CT on the same day showed increased atelectasis consolidation in both lower lobes with new patchy infiltrate in the posterior right upper lobe; a moderately large volume of free fluid with a large amount in the pneumoperitoneum and acute massive free air and fluid were found in the intra-abdominal and the intraperitoneal spaces, respectively. Perforation was suspected, but the site could not be identified. The participant had an exploratory laparotomy, and post-operative results showed closure of a duodenal ulcer with a Graham patch, extensive lysis of adhesions, and drainage of peritoneal abscesses. A drain was brought out through the incision in the right upper quadrant and then was placed posterior and superior to the actual ulcer. A follow-up CT on an unreported date was performed to ensure there was no leak or obstruction. Comorbidities for the perforated ulcer included Crohn's disease, multiple/recurrent small bowel obstruction/resection, colon resection, nonalcoholic cirrhosis status post transjugular intrahepatic portosystemic shunt, and a hepatic stent.

On 09 Nov 2020 (Study Day 74), the participant's Hgb was 8.7 g/dL. On 12 Nov 2020 (Study Day 77), the participant received ferric sodium gluconate complex IV for anemia. On 13 Nov 2020 (Study Day 78), the participant continued to have dark brown fluid leaking from the

right-side Jackson Pratt drain. On the same day, an abdominal and pelvic CT revealed interval placement of a surgical drain in the subhepatic space with a diminishing volume of ascites, residual gravity dependent fluid in the pelvis, post-surgical change in the ventral abdominal wall, edematous changes in the omentum, small loculations of fluid adjacent to the descending colon, worsening bilateral pulmonary infiltrates and pleural effusions, and worsening soft tissue anasarca.

On 15 Nov 2020 (Study Day 80), the participant experienced an SAE of anemia due to the perforated duodenal ulcer. On the same day, their Hgb dropped to 6.2 g/dL. While hospitalized, the participant was treated with multiple transfusions of packed red blood cells (RBCs) and potassium chloride. After the transfusions, the participant's platelets improved but never recovered. On 17 Nov 2020 (Study Day 82), the relevant laboratory results showed Hgb 7.8 g/dL, hematocrit (Hct) 23.7% (reference range 37 to 49%), and platelet count 31 × 10^3/µL (no reference range provided).

On 18 Nov 2020 (Study Day 83), a single-view chest x-ray revealed a clinical indication for renal failure, fluid overload, development of diffuse bilateral interstitial infiltrates or edema, volume loss at the lung bases, and trace pleural fluid at the costophrenic angles. Treatment medication included furosemide IV for fluid overload due to acute renal failure. On 19 Nov 2020 (Study Day 84), an abdominal and pelvic CT revealed diffuse water density; simple appearing loculated collections of fluid throughout the peritoneal cavity, the largest of which extended from the left upper quadrant caudally into the pelvis; and no associated inflammatory changes or free air.

On 20 Nov 2020 (Study Day 85), the participant experienced SAEs of multiple organ dysfunction syndrome and acute respiratory failure. The participant underwent CT guided drainage as opposed to draining through the existing drain. Due to the suspicion of post-operative bleeding, monitoring for ongoing bleeding continued. On the same day, the participant experienced a code blue for an acute hypoxic respiratory failure with bradycardia secondary to airway blockage from oral bleeding. During the rescue measures, the participant was noted to have active bleeding in the back of the mouth and the presence of dried blood. Blood in the urine was also noted. The oxygen saturation (SpO_2) dropped to 23% (reference range not reported), with a heart rate of 52 beats/minute (bpm). The laboratory test results on 20 Nov 2020 (Study Day 85) included blood gas pH 7.234 (at 20:10) and 7.346 (at 22:30) (reference range 7.35 to 7.45); pO_2 147.4 mm Hg and 261.5 mm Hg (reference range 80 to 100 mm Hg); bicarbonate 18.5 mmol/L and 21.7 mmol/L (reference range 22 to 26 mmol/L); arterial blood gas (ABG) base excess -8.4 L and -3.6 L (reference range -2 to 2 L); Allen test positive; sodium 151 mmol/L (reference range 135 to 143 mmol/L); chloride 123 mmol/L (reference range 95 to 110 mmol/L); urea 64 mg/dL (reference range 5 to 20 mg/dL); estimated creatinine clearance 28.73 mL/min (reference range >30 mL/min); estimated glomerular filtration rate (eGFR) (non-African American) 28 (reference

range >60; units not reported); bilirubin 2.1 mg/dL (reference range 0.0 to 1.3 mg/dL); total protein 5.8 g/dL (reference range 6.4 to 8.2 g/dL); albumin 1.8 g/dL (reference range 3.4 to 5.0 g/dL); and creatinine 2.3 mg/dL and 2.4 mg/dL (reference range 0.6 to 1.3 mg/dL). Efforts to recover from decreasing platelets and down-trending Hgb failed, as the participant had Hgb 6.0 g/dL, Hct 19.9% (reference ranges not reported), and RBC 1.98 (no units or reference range reported). After intubation and treatment in the intensive care unit, the participant's SpO_2 and heart rate improved to 96% and 126 bpm, respectively. Treatment included ventilation with sedation (propofol/fentanyl), paracetamol, albumin human IV, alteplase, amiodarone, calcium carbonate, diatrizoate, enoxaparin, fentanyl IV, hydrocodone/paracetamol, ipratropium, calcium chloride dihydrate/potassium chloride, levalbuterol, melatonin, metoprolol, morphine, mupirocin, naloxone, nitroglycerine, norepinephrine, ondansetron, pantoprazole, piperacillin/tazobactam, potassium chloride, and total parenteral nutrition.

On 21 Nov 2020 (Study Day 86), laboratory test results included blood gas pH 7.291, pO_2 143.4 mm Hg, bicarbonate standard 20.7 mmol/L, ABG base excess –5.4 L, Allen test positive, creatinine 2.1 mg/dL, sodium 144, (no unit reported) potassium 5.4 mmol/L (reference range 3.5 to 5.1 mmol/L), chloride 118 mmol/L, urea 61 mg/dL, eGFR (non-African American) 33 (no units provided), calcium 8.4 mg/dL (reference range 8.8 to 10.5 mg/dL), bilirubin 2.3 mg/dL, total protein 4.9 g/dL, albumin 1.6 g/dL, Hgb 5.7 g/dL, and Hct 18.7%. Treatment included 1 unit of packed RBCs and albumin.

On 22 Nov 2020 (Study Day 87), the participant's family decided to discontinue any life-saving measures. The participant was taken off the ventilator and died the same day.

Action taken with the study IP in response to the events was reported as not applicable as both doses had already been administered.

The event, nephrolithiasis, was considered resolved on 04 Nov 2020 (Study Day 69). The event, duodenal ulcer perforation, was considered resolved with sequelae of anemia on 08 Nov 2020 (Study Day 73). The events of thrombocytopenia, flank pain (left), anemia, intra-abdominal fluid collection, acute kidney failure, and generalized oedema were ongoing at the time of death. The events of gastrointestinal hemorrhage, acute respiratory failure, and multiple organ dysfunction syndrome were considered fatal on 22 Nov 2020 (Study Day 87).

The participant died on 22 Nov 2020 (Study Day 87). The cause of death was reported as gastrointestinal hemorrhage, acute respiratory failure, and multiple organ dysfunction syndrome. No autopsy was performed.

The investigator assessed the events of thrombocytopenia, anemia, acute respiratory failure, multiple organ dysfunction syndrome, acute kidney failure, nephrolithiasis, duodenal ulcer perforation, flank pain (left), intra-abdominal fluid collection, gastrointestinal hemorrhage, and generalized oedema as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000787	Nephrolithiasis
MOD-2020-000787	Acute Kidney Injury
MOD-2020-000787	Flank Pain
MOD-2020-000787	Thrombocytopenia
MOD-2020-000787	Duodenal Ulcer Perforation
MOD-2020-000787	Gastrointestinal Haemorrhage
MOD-2020-000787	Generalised Oedema
MOD-2020-000787	Intra-Abdominal Fluid Collection
MOD-2020-000787	Anaemia
MOD-2020-000787	Acute Respiratory Failure
MOD-2020-000787	Multiple Organ Dysfunction Syndrome

Study Completion/Discontinuation

On 22 Nov 2020 (Study Day 87), the participant discontinued from the study due to death. On 22 Nov 2020 (Study Day 87), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies (nasal drainage, cough)	1971 - Ongoing
Colectomy	Partial colectomy	1985 - 1985
Crohn's disease	Chron's disease	1985 - Ongoing
Short-bowel syndrome	Short bowel syndrome	1998 - Ongoing
Anxiety	Anxiety	2012 - Ongoing
Arthritis	Arthritis	2012 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diclofenac	2012 - Ongoing	Arthritis Pain
Hydroxyzine	2012 - Ongoing	Anxiety
Tamsulosin	2016 - Ongoing	Benign Prostatic Hyperplasia
Dextromethorphan; guaifenesin	2017 - Ongoing	Seasonal Allergies
Ascorbic acid; betacarotene; cupric oxide; tocopheryl acetate; zinc oxide	Aug 2019 - Ongoing	Vision Loss
Levocetirizine dihydrochloride	01 Jul 2020 (Study Day -58) - Ongoing	Seasonal Allergies
Sodium chloride	02 Sep 2020 (Study Day 6) - Ongoing	Seasonal Allergies
Influenza vaccine	23 Oct 2020 (Study Day 57) - 23 Oct 2020 (Study Day 57)	Flu Prevention
Ct of abdomen/pelvis*	03 Nov 2020 (Study Day 68) - 03 Nov 2020 (Study Day 68)	Diagnostic
Hydromorphone hydrochloride	03 Nov 2020 (Study Day 68) - 10 Nov 2020 (Study Day 75)	Obstructing Nephrolithiasis
Piperacillin sodium; tazobactam sodium	03 Nov 2020 (Study Day 68) - 17 Nov 2020 (Study Day 82)	Klebsiella Complicated Pyelonephritis
Ureteral stent*	03 Nov 2020 (Study Day 68) - 03 Nov 2020 (Study Day 68)	Adverse Event
X-ray cystogram*	03 Nov 2020 (Study Day 68) - 03 Nov 2020 (Study Day 68)	Diagnostic
Bifidobacterium bifidum; lactobacillus acidophilus; lactobacillus bulgaricus; streptococcus thermophilus	04 Nov 2020 (Study Day 69) - 08 Nov 2020 (Study Day 73)	To Maintain Gut Health
Ceftriaxone	04 Nov 2020 (Study Day 69) - 06 Nov 2020 (Study Day 71)	Klebsiella Complicated Pyelonephritis
Cystourethroscopy with left retrograde ureteropyelogram*	04 Nov 2020 (Study Day 69) - 04 Nov 2020 (Study Day 69)	Adverse Event
Docusate sodium; senna alexandrina	04 Nov 2020 (Study Day 69) - 05 Nov 2020 (Study Day 70)	Obstructing Nephrolithiasis
Heparin	04 Nov 2020 (Study Day 69) - 04 Nov 2020 (Study Day 69)	To Prevent Clotting
Melatonin	04 Nov 2020 (Study Day 69) - 04 Nov 2020 (Study Day 69)	Insomnia Following Laparotomy For Obstructing Nephrolithiasis
Midazolam hydrochloride	04 Nov 2020 (Study Day 69) - 20 Nov 2020 (Study Day 85)	Anxiety
Morphine sulfate	04 Nov 2020 (Study Day 69) - 05 Nov 2020 (Study Day 70)	Obstructing Nephrolithiasis
Oxycodone	04 Nov 2020 (Study Day 69) - 04 Nov 2020 (Study Day 69)	Obstructing Nephrolithiasis
Tamsulosin hydrochloride	04 Nov 2020 (Study Day 69) - 04 Nov 2020 (Study Day 69)	Benign Prostatic Hypertrophy
Hydrocodone bitartrate; paracetamol	05 Nov 2020 (Study Day 70) - 05 Nov 2020 (Study Day 70)	Pain Associated With Perforated Duodenal Ulcer

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ipratropium bromide	05 Nov 2020 (Study Day 70) - 05 Nov 2020 (Study Day 70)	Atelectasis, Bilateral Lower Lobes
Levosalbutamol hydrochloride	05 Nov 2020 (Study Day 70) - 05 Nov 2020 (Study Day 70)	Atelectasis, Bilateral Lower Lobes
Meropenem	05 Nov 2020 (Study Day 70) - 05 Nov 2020 (Study Day 70)	Klebsiella Complicated Pyelonephritis
Macrogol 3350	06 Nov 2020 (Study Day 71) - 06 Nov 2020 (Study Day 71)	Crohn's Disease
Renal ultrasound*	06 Nov 2020 (Study Day 71) - 06 Nov 2020 (Study Day 71)	Diagnostic
Sodium bicarbonate	06 Nov 2020 (Study Day 71) - 10 Nov 2020 (Study Day 75)	Currently Unknown
Magnesium citrate	07 Nov 2020 (Study Day 72) - 07 Nov 2020 (Study Day 72)	Currently Unknown
Omeprazole	07 Nov 2020 (Study Day 72) - 09 Nov 2020 (Study Day 74)	Gi Protection
Ct of abdomen/pelvis without contrast*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Diagnostic
Drain placement posterior superior to the perforated duodenal ulcer*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Exploratory laparotomy with closure of duodenal ulcer*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Graham patch*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Lysis of adhesions from abdominal wall*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Platelet transfusion*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Albumin human	09 Nov 2020 (Study Day 74) - 20 Nov 2020 (Study Day 85)	Protein Replacement Due To Cirrhosis
Enoxaparin sodium	09 Nov 2020 (Study Day 74) - 10 Nov 2020 (Study Day 75)	Clot Prevention
Fluconazole	10 Nov 2020 (Study Day 75) - 10 Nov 2020 (Study Day 75)	Post Op Infection Prophylaxis
X-ray upper gi*	11 Nov 2020 (Study Day 76) - 11 Nov 2020 (Study Day 76)	Diagnostic
Ferric sodium gluconate complex	12 Nov 2020 (Study Day 77) - 12 Nov 2020 (Study Day 77)	Anemia
Metoprolol tartrate	12 Nov 2020 (Study Day 77) - 16 Nov 2020 (Study Day 81)	Hypertension
Solutions for parenteral nutrition	12 Nov 2020 (Study Day 77) - 20 Nov 2020 (Study Day 85)	Prophylaxis For Malnutrition
Ct of abdomen/pelvis without contrast*	13 Nov 2020 (Study Day 78) - 13 Nov 2020 (Study Day 78)	Diagnostic
Packed red blood cells*	15 Nov 2020 (Study Day 80) - 15 Nov 2020 (Study Day 80)	Adverse Event
Potassium chloride	15 Nov 2020 (Study Day 80) - 20 Nov 2020 (Study Day 85)	Hypernatremia /Low Potassium, Ongoing Acute Renal Failure
X-ray abdomen /kidneys, ureter, bladder*	15 Nov 2020 (Study Day 80) - 15 Nov 2020 (Study Day 80)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Potassium phosphate dibasic	16 Nov 2020 (Study Day 81) - 16 Nov 2020 (Study Day 81)	Corrective Supplement
Platelet transfusion*	17 Nov 2020 (Study Day 82) - 17 Nov 2020 (Study Day 82)	Adverse Event
Furosemide	18 Nov 2020 (Study Day 83) - 18 Nov 2020 (Study Day 83)	Fluid Overload Due To Acute Renal Failure
X-ray chest*	18 Nov 2020 (Study Day 83) - 18 Nov 2020 (Study Day 83)	Adverse Event
Ct abdomen/pelvis without contrast*	19 Nov 2020 (Study Day 84) - 19 Nov 2020 (Study Day 84)	Diagnostic
Ct guided drain placement*	20 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 85)	Adverse Event
Fentanyl	20 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 85)	Multi-System Organ Failure
Mupirocin	20 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 85)	Restore Moisture
Propofol	20 Nov 2020 (Study Day 85) - 21 Nov 2020 (Study Day 86)	Sedation For Mechanical Ventilation
X-ray chest*	20 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 85)	Diagnostic
Intubation*	21 Nov 2020 (Study Day 86) - 21 Nov 2020 (Study Day 86)	Adverse Event
Norepinephrine bitartrate	21 Nov 2020 (Study Day 86) - 21 Nov 2020 (Study Day 86)	Currently Unknown
Packed red blood cells*	21 Nov 2020 (Study Day 86) - 21 Nov 2020 (Study Day 86)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	17 Oct 2020 (Study Day 51) - 19 Oct 2020 (Study Day 53)
Vomiting	Grade 2/moderate	Not related	17 Oct 2020 (Study Day 51) - 19 Oct 2020 (Study Day 53)
Rhonchi	Grade 1/mild	Not related	22 Oct 2020 (Study Day 56) - 27 Oct 2020 (Study Day 61)
Bacterial Pyelonephritis	Grade 3/severe	Not related	03 Nov 2020 (Study Day 68) - 17 Nov 2020 (Study Day 82)
Atelectasis	Grade 2/moderate	Not related	05 Nov 2020 (Study Day 70) - Ongoing
Lung Infiltration	Grade 2/moderate	Not related	08 Nov 2020 (Study Day 73) - Ongoing
Pleural Effusion	Grade 3/severe	Not related	18 Nov 2020 (Study Day 83) - Ongoing
Malnutrition	Grade 3/severe	Not related	20 Nov 2020 (Study Day 85) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2197 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	27 Oct 2020 (Study Day 32)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Death/Death Of Unknown Origin*	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	13 Mar 2021 (Study Day 169) – 13 Mar 2021 (Study Day 169)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

* According to the safety database, the preferred term was "Toxicity to various agents" and the verbatim term was "Death due to combination of fentanyl and ethanol intoxication".

Participant US393-2197, a 37-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 26 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Mar 2021 (Study Day 169), 168 days after the first dose and 137 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of death. Action taken with the IP was not applicable. The event of death was considered to be fatal on 13 Mar 2021 (Study Day 169). The investigator assessed the event of death to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 13 Mar 2021 (Study Day 169), the participant experienced a fatal serious adverse event due to a combination of fentanyl and ethanol intoxication. On 03 Apr 2021 (Study Day 190), the participant's parent called the site and told them their child had died. The participant's parent was contacted and could not provide any information but gave another child's contact information for follow-up. The participant's sibling was contacted and reported that the participant was found dead alone in their home on 13 Mar 2021 (Study Day 169). The sibling also stated that the participant had depression and noted that the paramedics found a bottle of fentanyl in the participant's home.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 13 Mar 2021 (Study Day 169). The primary cause of death was reported as combined fentanyl and ethanol intoxication.

The investigator assessed the event, death due to combination of fentanyl and ethanol intoxication, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-070499	Death

Study Completion/Discontinuation

On 13 Mar 2021 (Study Day 169), the participant discontinued from the study due to death. On 13 Mar 2021 (Study Day 169), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anaemia	Anemia	2000 - 2000

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	26 Sep 2020 (Study Day 1) - 26 Sep 2020 (Study Day 1)	Pain At Injection Site
Paracetamol	28 Oct 2020 (Study Day 33) - 29 Oct 2020 (Study Day 34)	Body Aches And Headaches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US396-2094 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Head Injury/Head Trauma	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	15 Oct 2020 (Study Day 37) – 15 Oct 2020 (Study Day 37)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US396-2094, a 56-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 09 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Oct 2020 (Study Day 37), 36 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 5 serious adverse event of head injury. On 06 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of head trauma was considered to be fatal on 15 Oct 2020 (Study Day 37). The investigator assessed the event of head injury to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 12 Oct 2020 (Study Day 34), the site contacted the participant's sibling (emergency contact) after several unsuccessful attempts were made via telephone, email, and certified letter to reach the participant.

On 14 Oct 2020 (Study Day 36), the participant's sibling contacted the police for a wellness check for the participant.

On 15 Oct 2020 (Study Day 37), the participant experienced a fatal serious adverse event of head injury. The site received a voice mail message that stated the participant had died and no autopsy was done. The police found the participant deceased on the bathroom floor and reported the participant had head trauma from a fall.

There was no action taken with the study IP in response to the event.

The participant died on 15 Oct 2020 (Study Day 37). The cause of death was reported as head injury.

The investigator assessed the event, head injury, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000491	Head trauma

Study Completion/Discontinuation

On 15 Oct 2020 (Study Day 37), the participant discontinued from the study due to death. On 15 Oct 2020 (Study Day 37), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to chemicals	Pine tar allergy	1970 - Ongoing
Food allergy	Capsicum allergy	1970 - Ongoing
Seasonal allergy	Seasonal allergies	1982 - Ongoing
Glaucoma	Glaucoma both eyes	1995 - Ongoing
Fluid retention	Water retention	1998 - Ongoing
Muscle spasms	Muscle spasms	2000 - Ongoing
Carpal tunnel syndrome	Bilateral carpal tunnel syndrome	2012 - Ongoing
Arthralgia	Chronic pain knee	2013 - Ongoing
Back pain	Chronic pain back	2013 - Ongoing
Hysterectomy	Hysterectomy	2013 - 2013
Musculoskeletal pain	Chronic pain shoulder	2013 - Ongoing
Ovarian cancer	Ovarian cancer	2013 - 2013
Uterine cancer	Uterine cancer	2013 - 2013
Hypertension	Hypertension	2015 - Ongoing
Intervertebral disc protrusion	Herniated disc	2015 - 2015
Muscle spasms	Leg spasms	2015 - Ongoing
Osteoarthritis	Osteoarthritis knees	2015 - Ongoing
Osteoarthritis	Osteoarthritis shoulder	2015 - Ongoing
Spinal osteoarthritis	Osteoarthritis back	2015 - Ongoing
Blood cholesterol increased	High cholesterol	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pseudoephedrine hydrochloride	1982 - Ongoing	Seasonal Allergies
Vitamins nos	1990 - Ongoing	Dietary Supplement
Latanoprost	1995 - Ongoing	Glaucoma
Hypericum perforatum	1997 - Ongoing	Dietary Supplement
Hydrochlorothiazide	1998 - Ongoing	Water Retention
Diclofenac	2000 - Ongoing	Muscle Spasms
Colecalciferol	2010 - Ongoing	Dietary Supplement
Iron	2010 - Ongoing	Dietary Supplement
Hydrocodone bitartrate; paracetamol	2013 - Ongoing	Chronic Pain - Back, Knees And Shoulders
Gabapentin	2014 - Ongoing	Chronic Pain Back, Knees And Shoulders
Lisinopril	2015 - Ongoing	Hypertension
Potassium chloride	2015 - Ongoing	Leg Spasms
Methocarbamol	2018 - Ongoing	Chronic Pain
Pravastatin	2019 - Ongoing	High Cholesterol
Fish oil	12 Sep 2020 (Study Day 4) - Ongoing	High Triglycerides

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	07 Oct 2020 (Study Day 29) - Ongoing
Fall	Grade 1/mild	Not related	15 Oct 2020 (Study Day 37) - 15 Oct 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US397-2010 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Death/Undetermined Cause Pending Autopsy	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	08 Jan 2021 (Study Day 138) – 08 Jan 2021 (Study Day 138)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2010, a 59-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Jan 2021 (Study Day 138), 137 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of death. Action taken with the IP was not applicable. The event of undetermined cause pending autopsy was considered to be fatal on 08 Jan 2021 (Study Day 138). The investigator assessed the event of death to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 08 Jan 2021 (Study Day 138), the participant experienced a fatal serious adverse event of death.

The participant was due for a safety call but did not respond to voicemail or email. The participant's emergency contact was called on 22 Jan 2021 (Study Day 152) and informed the site that the participant had been found dead on 08 Jan 2021 (Study Day 138). The participant's emergency contact refused to give additional details but was willing to send a copy of the autopsy result when they received it.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The investigator assessed the event, death, as not related to study IP and not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006644	Death

Study Completion/Discontinuation

On 08 Jan 2021 (Study Day 138), the participant discontinued from the study due to death. On 08 Jan 2021 (Study Day 138), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US303-2204 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 32)
Reason for Narrative:	Death, SAE, Severe COVID-19, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	Death, SAE, COVID-19, , AE leading to study discontinuation	Grade 5	Not related	09 Nov 2020 (Study Day 88) – 16 Nov 2020 (Study Day 95)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US303-2204, a 54-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 09 Nov 2020 (Study Day 88), 87 days after the first dose and 56 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 32, 14 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Nov 2020 (Study Day 90), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 88)	Chills	Mild
09 Nov 2020 (Study Day 88)	Fatigue	Severe
09 Nov 2020 (Study Day 88)	Headache	Mild

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 88)	Nausea	Mild
09 Nov 2020 (Study Day 88)	Vomiting	Mild
10 Nov 2020 (Study Day 89)	Chills	Mild
10 Nov 2020 (Study Day 89)	Fatigue	Severe
10 Nov 2020 (Study Day 89)	Headache	Mild
10 Nov 2020 (Study Day 89)	Nausea	Mild
10 Nov 2020 (Study Day 89)	Vomiting	Mild
11 Nov 2020 (Study Day 90)	Chills	Mild
11 Nov 2020 (Study Day 90)	Fatigue	Severe
11 Nov 2020 (Study Day 90)	Headache	Mild
11 Nov 2020 (Study Day 90)	Nausea	Mild
11 Nov 2020 (Study Day 90)	Vomiting	Mild
12 Nov 2020 (Study Day 91)	Fatigue	Severe
12 Nov 2020 (Study Day 91)	Headache	Mild
12 Nov 2020 (Study Day 91)	Nausea	Mild
13 Nov 2020 (Study Day 92)	Chills	Mild
13 Nov 2020 (Study Day 92)	Cough	Mild
13 Nov 2020 (Study Day 92)	Fatigue	Severe
13 Nov 2020 (Study Day 92)	Headache	Mild
14 Nov 2020 (Study Day 93)	Body Aches	Mild
14 Nov 2020 (Study Day 93)	Cough	Severe
14 Nov 2020 (Study Day 93)	Diarrhea	Moderate
14 Nov 2020 (Study Day 93)	Difficulty Breathing	Severe
14 Nov 2020 (Study Day 93)	Fatigue	Severe
14 Nov 2020 (Study Day 93)	Muscle Aches (Myalgia)	Mild
14 Nov 2020 (Study Day 93)	Nausea	Severe
14 Nov 2020 (Study Day 93)	O2 Saturation (%)	87
14 Nov 2020 (Study Day 93)	Shortness of Breath	Severe
14 Nov 2020 (Study Day 93)	Vomiting	Moderate
15 Nov 2020 (Study Day 94)	Body Aches	Mild
15 Nov 2020 (Study Day 94)	Cough	Moderate
15 Nov 2020 (Study Day 94)	Difficulty Breathing	Moderate
15 Nov 2020 (Study Day 94)	Fatigue	Severe
15 Nov 2020 (Study Day 94)	Muscle Aches (Myalgia)	Mild
15 Nov 2020 (Study Day 94)	Nausea	Severe
15 Nov 2020 (Study Day 94)	O2 Saturation (%)	91
15 Nov 2020 (Study Day 94)	Shortness of Breath	Moderate
16 Nov 2020 (Study Day 95)	Body Aches	Mild
16 Nov 2020 (Study Day 95)	Chills	Mild
16 Nov 2020 (Study Day 95)	Cough	Moderate
16 Nov 2020 (Study Day 95)	Fatigue	Severe
16 Nov 2020 (Study Day 95)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 95)	Nausea	Mild

Symptom Date	Symptom	Result
16 Nov 2020 (Study Day 95)	O2 Saturation (%)	93
16 Nov 2020 (Study Day 95)	Shortness of Breath	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
14 Nov 2020 (Study Day 93)	Oxygen Saturation	87%
14 Nov 2020 - 16 Nov 2020 (Study Day 93-95)	Oxygen Saturation of SpO2 <= 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 8 days, after which it was considered to be fatal on 16 Nov 2020 (Study Day 95). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 09 Nov 2020 (Study Day 88), the participant experienced a fatal serious adverse event of COVID-19. The participant was symptomatic and had a positive SARS-CoV-2 RT-PCR nasopharyngeal swab collected on 11 Nov 2020 (Study Day 90). Treatment included acetylsalicylic acid PO.

From 09 Nov 2020 (Study Day 88) through 16 Nov 2020 (Study Day 95), the participant intermittently experienced mild to severe chills, cough, shortness of breath, difficulty breathing, fatigue, muscle aches, body aches, headache, nausea, vomiting, and diarrhea. The participant denied loss of taste, loss of smell, nasal congestion, runny nose, or sore throat.

On 10 Nov 2020 (Study Day 89), treatment included azithromycin, methylprednisolone, and ondansetron all PO.

On 14 Nov 2020 (Study Day 93), treatment included salbutamol inhalation.

From 14 Nov 2020 (Study Day 93) through 16 Nov 2020 (Study Day 95), the participant's oxygen saturation ranged from 87 to 93%.

Action taken with the study IP was not applicable as the participant had already received both scheduled doses.

On 16 Nov 2020 (Study Day 95), the participant was brought to the hospital emergency department and was dead on arrival. The cause of death was reported as symptomatic COVID-19.

The investigator assessed the event, COVID-19, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000822	COVID-19

Study Completion/Discontinuation

On 16 Nov 2020 (Study Day 95), the participant discontinued from the study due to death. On 16 Nov 2020 (Study Day 95), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 1 diabetes mellitus	Type 1 diabetic	1986 - 17 Nov 2020 (Study Day 96)
Hypothyroidism	Hypothyroidism	2017 - 17 Nov 2020 (Study Day 96)
Headache	Headaches	Jan 2019 - May 2019
Hypercholesterolaemia	Hypercholesterolemia	Jan 2019 - 17 Nov 2020 (Study Day 96)
Contusion	Head contusion due to fall on ice	Mar 2019 - Mar 2019
Intervertebral disc operation	C 8-9 taken out, replaced with a plate	May 2019 - May 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Jan 2019 - Ongoing	Medical History: Hypercholesterolemia
Metoprolol succinate	Jan 2019 - May 2019	Medical History: Headaches
Thyroid	Jan 2019 - Ongoing	Medical History: Hypothyroidism
Insulin degludec	Mar 2019 - Ongoing	Medical History: Type 1 Diabetes
Insulin aspart	Jun 2019 - Ongoing	Medical History: Diabetes Type 1
Thyroid	Nov 2019 - Ongoing	Medical History: Hypothyroidism
Influenza vaccine	30 Sep 2020 (Study Day 48) - 30 Sep 2020 (Study Day 48)	Prophylaxis For Seasonal Influenza
Acetylsalicylic acid	09 Nov 2020 (Study Day 88) - Ongoing	COVID-Like Illness
Azithromycin	10 Nov 2020 (Study Day 89) - 10 Nov 2020 (Study Day 89)	COVID-Like Illness
Methylprednisolone	10 Nov 2020 (Study Day 89) - 10 Nov 2020 (Study Day 89)	COVID-Like Illness
Ondansetron	10 Nov 2020 (Study Day 89) - Ongoing	COVID-Like Illness

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	11 Nov 2020 (Study Day 90) - 14 Nov 2020 (Study Day 93)	COVID Like Illness
Methylprednisolone	11 Nov 2020 (Study Day 90) - 11 Nov 2020 (Study Day 90)	COVID-Like Illness
Methylprednisolone	12 Nov 2020 (Study Day 91) - 12 Nov 2020 (Study Day 91)	COVID-Like Illness
Methylprednisolone	13 Nov 2020 (Study Day 92) - 13 Nov 2020 (Study Day 92)	COVID-Like Illness
Methylprednisolone	14 Nov 2020 (Study Day 93) - 14 Nov 2020 (Study Day 93)	COVID-Like Illness
Salbutamol	14 Nov 2020 (Study Day 93) - 16 Nov 2020 (Study Day 95)	COVID-Like Illness
Methylprednisolone	15 Nov 2020 (Study Day 94) - 15 Nov 2020 (Study Day 94)	COVID-Like Illness

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US308-2269 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastric Perforation/Intra-Abdominal Perforation	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	02 Oct 2020 (Study Day 12) – 03 Oct 2020 (Study Day 13)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US308-2269, a 75-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 21 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 12), 11 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 5 serious adverse event of gastric perforation. On 03 Oct 2020 (Study Day 13), the IP dose was discontinued due to death. The event of intra-abdominal perforation lasted for 2 days, after which it was considered to be fatal on 03 Oct 2020 (Study Day 13). The investigator assessed the event of gastric perforation to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 01 Oct 2020 (Study Day 11), the participant began having abdominal pain in the evening. On 02 Oct 2020 (Study Day 12), the participant complained of abdominal pain and dyspnea that morning. The participant went to their primary care physician's (PCP) office with palpitations and shortness of breath. While at the PCP, the participant was found to have uncontrolled atrial fibrillation (AF), hypoxia with oxygen of 45% (no reference range reported), and hypotension. The participant denied chest pains that morning but did have chest pains later in the day. A review of systems showed no chills, fatigue, or fever, and they did not have congestion, ear pain, rhinorrhea, sore throat, or eye pain. The participant did have shortness of breath without a cough, chest pains, and palpitations. There were no seizures, weakness, or headaches. At 11:23, acetylsalicylic acid 81 mg PO was administered.

On 02 Oct 2020 (Day 12), the participant experienced a serious adverse event of gastric perforation. On the same day, emergency medical services (EMS) was called, and the participant was transported to a hospital. Emergency medical services were unable to get a blood pressure (BP) reading while in transit and the participant's heart rate (HR) ranged from 50 to 156 beats per minute en route. On presentation to the emergency department (ED), the participant was tachycardic with a HR in the 140s, hypotensive, dyspneic, and mentating; they also experienced bradycardia, AF with a rapid ventricular rate, and ventricular arrhythmia. The participant reported no history of AF and stated they were significantly short of breath and was in a tripod position. The participant denied nausea and vomiting, was on 15 L of oxygen via a no-rebreather and was saturating well. While in the ED, the participant was electively intubated. A nasogastric tube was placed to decompress the participant's stomach. The participant's AF improved following rapid pressure infusion of normal saline, diltiazem IV and comfort improved with use of the nonrebreather. Pulmonary embolism was presumed due to the new onset of AF, shortness of breath, and hypoxia.

Physical examination showed that the participant appeared well-developed and well-nourished, and in no distress. Their head was normocephalic and atraumatic, eyes had normal conjunctivae, no sclera icterus, and the neck was supple with no thyromegaly present. The participant's heart rhythm was tachycardic and irregular, and the participant was in respiratory distress. An electrocardiogram (ECG) showed normal sinus rhythm with no signs of acute ischemia. A second ECG showed sinus tachycardia, rightward axis, and an inferior infarct could not be ruled out (cited on or before 02 Oct 2020 [Study Day 12]). This was an abnormal ECG (when compared with ECG of 02 Oct 2020 [Study Day 12] at 11:50) in which premature ventricular complexes were no longer present. The participant's ECG showed that they were not in sinus rhythm "was no longer with junctional escape complexes", and the QT interval was shortened. A chest x-ray showed severe pneumoperitoneum, low lung volumes, and probable atelectasis and/or scarring along the diaphragmatic domes. A nasogastric tube appeared to terminate near the gastroesophageal junction in the proper place. A computerized tomography angiogram (CTA) scan of the chest showed no evidence of pulmonary emboli, and a tremendous amount of pneumoperitoneum was noted. The CTA was reviewed with concerns for significant amounts of free air, decreasing lung volumes and intrathoracic pathology. The participant was later reported to be in pulseless electrical activity – ventricular arrythmia. Advanced Cardiovascular Life Support was initiated with medication, defibrillation, and intubation. The participant received 6 rounds of epinephrine, cardioversion, calcium chloride, and sodium bicarbonate and was also treated with 100 units of vasopressin in sodium chloride 0.9% infusion. Return of spontaneous circulation was achieved. The participant responded well to diltiazem (both IV and PO) and rhythm was obtained after defibrillation. The fraction of inspired oxygen was at 100%. Vital signs on 02 Oct 2020 (Study Day 12) are presented in the table below.

Time on 02 Oct 2020 (Study Day 12)	Blood Pressure (mm Hg)	Pulse (beats per minute)	O_2 saturation (%)	Respiratory Rate (breaths per minute)
Unreported time (supine)	109/69	-	88	-
11:32	84/69	142	92	23
15:08	93/64	98	89	23
16:15	79/54	135	88	24

Abbreviations: BP = blood pressure; RR = respiratory rate.

The participant's oral temperature was 97.5°F (36.4°C) at an unreported time and 97.7°F (36.5°C) at 12:49.

Laboratory test results included arterial blood gases that showed significant metabolic acidosis with "pH of 6.8, arterial pH 6.88 and 7.24" (reference range 7.35 to 7.45), arterial partial carbon dioxide 74 mm Hg and 52 mm Hg (reference range 35 to 48 mm Hg), arterial partial oxygen 72 mm Hg (reference range 83 to 108 mm Hg), bicarbonate 8.8 mmol/L (reference range 18 to 23 mmol/L), arterial oxygen saturation 81% and 23% (reference range 95 to 98%), arterial base excess < –5.0 mmol/L (reference range –2 to 2 mmol/L), blood lactic acid 11.6 mmol/L (reference range 0.5 to 2.2 mmol/L). A complete blood count showed signs of leukocytosis, with neutrophils 76.5% (reference range 42 to 75%), mean corpuscular hemoglobin 23.4 pg (reference range 26 to 34 pg), mean corpuscular hemoglobin concentration 29.3 g/dL (reference range 31 to 35.5 g/dL), and mean platelet volume 8.9% (reference range 9 to 12.5%). A coagulation profile included prothrombin time 11.6 seconds and 12.9 seconds (reference range 9.3 to 11.5 seconds), international normalized ratio 1.2 (reference range 0.9 to 1.1), and activated partial thromboplastin time 24.1 (no units or reference range). Blood chemistry laboratory test results included carbon dioxide 18 mmol/L (reference range 24 to 31 mmol/L), glucose 310 mg/dL and 172 mg/dL (reference range 75 to 110 mg/dL), creatinine 1.6 mg/dL and 2.9 mg/dL (reference range 0.5 to 1.4 mg/dL), blood urea nitrogen 23 mg/dL and 29 mg/dL (reference range 8 to 21 mg/dL), anion gap 17 mmol/L and 19 mmol/L (reference range 5 to 16 mmol/L), osmolality 297.0 mOsm/kg and 304.0 mOsm/kg (reference range 267 to 293 mOsm/kg), lipase 181 (no units or reference range), troponin 50.9 ng/L and 134.8 ng/L (reference range ≤ 47 ng/L), total protein 5.7 g/dL (reference range 6 to 8 g/dL), globulin 1.9 g/dL (reference range 2.2 to 4.0 g/dL), aspartate aminotransferase 91 IU/L (reference range 10 to 40 IU/L), alanine aminotransferase 68 IU/L (reference range 3 to 38 IU/L) and hemoglobin A1c 6.3 (no units or reference range). A urinalysis showed trace protein and glucose (both reference ranges were negative). Microscopic urinalysis only showed few bacteria (reference range none), and red blood cells were 5 to 10 (reference range 0 to 2). A COVID-19 SARS Coronavirus test by nasopharyngeal swab was negative.

General surgery was consulted, and it was advised that the participant be transferred to a tertiary care center due to the type of perforation with intrathoracic abdominal contents, however the participant was not stable enough for transfer. A plan of care was discussed. The participant's spouse desired that the participant be made comfortable instead of going through surgery and it was decided to maintain intubation and the participant was made 'do-not-resuscitate' in the event of ventricular arrhythmia. The participant was admitted to the intensive care unit to wait for family to arrive and withdraw care. On 03 Oct 2020 (Study Day 13), treatment included fentanyl IV for abdominal pain. The participant expired on 03 Oct 2020 (Study Day 13) at 03:20.

Problem list included an intra-abdominal perforation, pneumoperitoneum, cardiac arrest, cardiogenic shock, AF with rapid ventricular response, severe metabolic acidosis, and respiratory acidosis.

The cause of death was reported as pneumoperitoneum, presumed intra-abdominal perforation that led to cardiac arrest. An autopsy was performed and confirmed that the result of intra-abdominal perforation (stomach and colon) was cardiac arrest.

The investigator assessed the event, gastric perforation, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000415	Gastric perforation

Study Completion/Discontinuation

On 03 Oct 2020 (Study Day 13), the participant discontinued from the study due to death. On 03 Oct 2020 (Study Day 13), the participant died due to adverse event. An autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gout	Gout (both feet)	2018 - Ongoing
Erectile dysfunction	Erectile dysfunction	2019 - Ongoing
Urinary retention	Urinary retention	2019 - Ongoing
Hiatus hernia	Hiatal hernia	21 Feb 2020 (Study Day -213) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colchicine	2018 - Ongoing	Gout (Both Feet)
Tadalafil	2019 - Ongoing	Erectile Dysfunction
Tamsulosin	2019 - Ongoing	Urinary Retention
Acetylsalicylic acid	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Abdominal Pain
Albumin human	02 Oct 2020 (Study Day 12) - 03 Oct 2020 (Study Day 13)	Shock R/T SAE #1
Atropine	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Atrial Fibrillation
Central line placement*	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Adverse Event
Chest x-ray*	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Adverse Event
Ct angiogram of the chest*	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Adverse Event
Diltiazem	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Atrial Fibrillation
Etomidate	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Anaesthetic For SAE
Intubation*	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Adverse Event
Iopamidol	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Ct Imaging Contrast / Used To Diagnose Pneumoperitoneum
Norepinephrine	02 Oct 2020 (Study Day 12) - 03 Oct 2020 (Study Day 13)	Blood Pressure
Phenylephrine	02 Oct 2020 (Study Day 12) - 03 Oct 2020 (Study Day 13)	Blood Pressure
Piperacillin sodium; tazobactam sodium	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Infection Preventative
Rocuronium	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Paralytic
Sodium bicarbonate	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Electrolyte Replacement
Sodium bicarbonate	02 Oct 2020 (Study Day 12) - 03 Oct 2020 (Study Day 13)	Electrolyte Replacement
Sodium chloride	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Replacing Fluids
Vancomycin	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Infection Prevention
Vasopressin	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Blood Pressure
Calcium chloride; potassium chloride; sodium lactate	03 Oct 2020 (Study Day 13) - 03 Oct 2020 (Study Day 13)	Replacing Fluids/Electrolytes
Fentanyl	03 Oct 2020 (Study Day 13) - 03 Oct 2020 (Study Day 13)	Abdominal Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium bicarbonate	03 Oct 2020 (Study Day 13) - 03 Oct 2020 (Study Day 13)	Electrolyte Replacement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atrial Fibrillation	Grade 4	Not related	02 Oct 2020 (Study Day 12) - 03 Oct 2020 (Study Day 13)
Hyperglycaemia	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 12) - 03 Oct 2020 (Study Day 13)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US319-2569 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	29 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	26 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hepatic Cancer/Liver Cancer	AE leading to study discontinuation	Grade 3/ severe	Not related	26 Jan 2021 (Study Day 151) – Ongoing	Not recovered/ not resolved
Pancreatic Carcinoma Stage IV/ Stage 4 Pancreatic Cancer	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	26 Jan 2021 (Study Day 151) – 17 Feb 2021 (Study Day 173)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2569, a 76-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 26 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Jan 2021 (Study Day 151), 150 days after the first dose and 122 days after the second dose of the IP, the participant experienced a Grade 3/severe nonserious adverse event of hepatic cancer. Action taken with the IP was not applicable. The event of liver cancer was considered to be ongoing. The investigator assessed the event of hepatic cancer to be not related to the IP.

On 26 Jan 2021 (Study Day 151), 150 days after the first dose and 122 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of pancreatic carcinoma stage IV. Action taken with the IP was not applicable. The event of stage IV pancreatic cancer lasted for 23 days, after which it was considered to be fatal on 17 Feb 2021 (Study Day 173). The investigator assessed the event of pancreatic carcinoma stage IV to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 26 Jan 2021 (Study Day 151), the participant experienced a fatal serious adverse event of pancreatic carcinoma stage IV and was hospitalized on a reported date. Treatment medication for the event included oxycodone/paracetamol.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The participant died on 17 Feb 2021 (Study Day 173). According to the death certificate, the cause of death was malignant neoplasm of the pancreas with metastases.

The investigator assessed the event, pancreatic carcinoma stage IV, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-016694	Pancreatic cancer stage IV

Study Completion/Discontinuation

On 10 Feb 2021 (Study Day 166), the participant discontinued from the study due to adverse event. On 17 Feb 2021 (Study Day 173), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1995 - Ongoing
Hypothyroidism	Hypothyroidism	1995 - Ongoing
Type 1 diabetes mellitus	Type i diabetes	2000 - Ongoing
Hip arthroplasty	Left hip replacement	2012 - 2012
Constipation	Chronic constipation	2017 - Ongoing
Hip arthroplasty	Right hip replacement	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	1995 - Ongoing	Hypothyroidism
Ramipril	1995 - Ongoing	Hypertension
Insulin glargine	2000 - Ongoing	Type I Diabetes
Insulin lispro	2000 - Ongoing	Type I Diabetes
Linaclotide	2017 - Ongoing	Constipation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	03 Jan 2021 (Study Day 128) - 08 Jan 2021 (Study Day 133)	Symptomatic COVID-19
Hydroxychloroquine	03 Jan 2021 (Study Day 128) - 10 Jan 2021 (Study Day 135)	Symptomatic COVID-19
Ct scan*	26 Jan 2021 (Study Day 151) - 26 Jan 2021 (Study Day 151)	Adverse Event
Oxycodone hydrochloride; paracetamol	01 Feb 2021 (Study Day 157) - Ongoing	Pain From Pancreatic And Liver Cancer
Mri*	02 Feb 2021 (Study Day 158) - 02 Feb 2021 (Study Day 158)	Adverse Event
Liver biopsy*	08 Feb 2021 (Study Day 164) - 08 Feb 2021 (Study Day 164)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	02 Jan 2021 (Study Day 127) - 21 Jan 2021 (Study Day 146)
Hepatic Cancer	Grade 3/severe	Not related	26 Jan 2021 (Study Day 151) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US342-2244 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Arrest/ Cardiac Arrest	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	03 Jan 2021 (Study Day 117) – 03 Jan 2021 (Study Day 117)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US342-2244, a 65-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Jan 2021 (Study Day 117), 116 days after the first dose and 88 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of cardiac arrest. Action taken with the IP was not applicable. The event of cardiac arrest was considered to be fatal on 03 Jan 2021 (Study Day 117). The investigator assessed the event of cardiac arrest to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 03 Jan 2021 (Study Day 117), the participant experienced a fatal serious adverse event of cardiac arrest. The participant was found deceased at home by their spouse. The last contact with the participant via eDiary reported no issues on 01 Jan 2021 (Study Day 115).

Action taken with study IP in response to the event, cardiac arrest, was not applicable as the participant received both scheduled doses.

The participant died on 03 Jan 2021 (Study Day 117). The cause of death was reported as cardiac arrest. Toxicology and autopsy reports were pending at the time of this report.

The investigator assessed the event, cardiac arrest, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005920	Cardiac arrest

Study Completion/Discontinuation

On 03 Jan 2021 (Study Day 117), the participant discontinued from the study due to death. On 03 Jan 2021 (Study Day 117), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis	30 Jun 1975 (Study Day -16508) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	01 Jan 2020 (Study Day -252) - Ongoing	Osteoarthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US343-2295 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Death, SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dermatitis Bullous/Diffuse Bullous Rash (Non-Urticarial)	SAE	Grade 4	Not related	12 Sep 2020 (Study Day 18) – Ongoing	Not recovered/ not resolved
Systemic Inflammatory Response Syndrome/ Severe Systemic Inflammatory Syndrome In The Setting Of CLL	Death, SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 5	Not related	01 Oct 2020 (Study Day 37) – 02 Oct 2020 (Study Day 38)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2295, an 83-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Sep 2020 (Study Day 18), 17 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of dermatitis bullous. On 02 Oct 2020 (Study Day 38), the IP dose was discontinued due to death. The event of diffuse bullous rash (non-urticarial) was considered to be ongoing. The investigator assessed the event of dermatitis bullous to be not related to the IP.

On 01 Oct 2020 (Study Day 37), 36 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 5 serious adverse event of systemic inflammatory response syndrome. On 02 Oct 2020 (Study Day 38), the IP dose was discontinued due to death. The event of severe systemic inflammatory syndrome in the setting of CLL lasted for 2 days, after which it was considered to be fatal on 02 Oct 2020 (Study Day 38). The investigator assessed the event of systemic inflammatory response syndrome to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

One month prior to the first administration of study IP, the participant began to experience new symptoms consistent with chronic lymphocytic leukemia (CLL) progression, including night sweats and fatigue. A positron emission tomography with computerized tomography (PET-CT) scan was performed on 04 Aug 2020 (Study Day –23) to further evaluate these symptoms and their potential relationship to the participant's disease transformation. Primary findings included uptake/avidity at the left base of the tongue, posterior right greater trochanter, right humeral head, right femoral head, left femoroacetabular joint space, and the right axillary lymph nodes, which were noted by the radiologist as atypical for a squamous cell carcinoma metastasis and was more compatible with a lymphoma. Splenomegaly (16 cm along the craniocaudal axis) was also observed.

On 04 Sep 2020 (Study Day 10), an ultrasound-guided lymph node biopsy of the right axilla was performed. Histopathology was consistent with a B-cell lymphoproliferative disorder.

On 12 Sep 2020 (Study Day 18), the participant experienced a serious adverse event (SAE) of dermatitis bullous. The participant developed a raised, red papular rash on their ankles that spread up both legs and body over the following days.

On 15 Sep 2020 (Study Day 21), the participant had a virtual visit with their primary care physician and then a dermatologist. The blistering rash had spread to involve more of their body. Treatment included triamcinolone acetonide cream and ciclopirox cream, both topical.

On 17 Sep 2020 (Study Day 23), the participant presented to the emergency department (ED) due to progression of the rash, which had become painful and itchy, forming large, weeping blisters. They denied mucosal lesions, fevers, chills, nausea, vomiting, abdominal pain, and diarrhea. The participant also denied recently starting any new medications. Initial vital signs in the ED were temperature 96.4°F, heart rate 88 beats/minute, blood pressure 128/57 mm Hg, respiratory rate 20 breaths/minute, and oxygen saturation 98% on room air. A physical examination was notable for a diffuse papular/vesicular/bullae rash with open blisters and yellowish serous drainage, much more confluent over the groin and torso, extending into the axillae bilaterally. The rash was more vesicular over the bilateral lower extremities with confluence towards the ankles and there were several areas of skin tearing on the participant’s back and in the inguinal folds. There were no lesions seen on examination of the oral mucosa, genitals, and palms. Initial laboratory results included white blood cell (WBC) count 25.7×10^3 (units not provided), neutrophils 46%, lymphocytes 42%, monocytes 9%, eosinophils 2%, atypical cells 1%, absolute neutrophil count 11.82×10^3 (units not provided), absolute lymphocyte count 11.05×10^3 (units not provided), absolute monocyte count $2.31 \times 10^3/\mu L$, platelet count (Plt) 176×10^3 (units not provided), blood urea nitrogen (BUN) 53, creatine 2.2 (baseline 1.1) (no units were provided), potassium 6.1 mmol/L then 5.4 mmol/L on repeat (no reference ranges were provided), and a negative

COVID-19 polymerase chain reaction (PCR) test result. An electrocardiogram (ECG) showed sinus rate 74 beats/minute, right bundle branch block with left anterior fascicular block, and T-wave flattening in lateral leads without ST depressions or elevations.

Dermatology was consulted and they assessed the participant's presentation as consistent with bullous vasculitis, neutrophilic dermatosis, or autoimmune bullous disease. A skin biopsy showed mixed spongiotic, interface, and focally acantholytic dermatitis with mid to upper dermal perivascular and interstitial lympho-eosinophilic infiltrate and upper dermal edema. There was no intraepidermal or basement membrane deposition of immunoglobulin (Ig)G, IgG4, IgA, IgM, C3, or fibrinogen seen. Periodic-acid Schiff stain was negative for fungi and showed areas of vacuolar degeneration of the basement membrane zone. Immunostain for *Varicella zoster* antigen was negative. The pathologist suggested diagnostic considerations of atypical/extensive Grover's disease secondary to a paraneoplastic process or a Grover's disease-like hypersensitivity reaction. Treatment included clobetasol propionate 0.05% topical.

On 18 Sep 2020 (Study Day 24), blood cultures were collected and showed no growth on the final report. Relevant laboratory test results included alanine aminotransferase (ALT) 14, aspartate aminotransferase (AST) 22, alkaline phosphatase (ALP) 97, total bilirubin 0.8, and lactate dehydrogenase (LDH) 381 (no units or reference ranges provided). The participant had no new symptoms and was improving.

On 22 Sep 2020 (Study Day 28), magnetic resonance imaging of the neck was performed at the request of the otolaryngology specialist, who was consulted to evaluate the potential biopsy of the lesion at the base of the participant's tongue noted on the 04 Aug 2020 (Study Day –23) PET-CT scan. There was no mass or abnormal enhancement in the region of the left tongue to correlate with the PET-CT scan finding. There was conglomerate right axillary and supraclavicular lymphadenopathy with possible contact with the brachial plexus. An ultrasound of the neck was also performed for biopsy planning and showed asymmetric, edematous soft tissue thickening in the left tonsillar fossa, likely correlating to the previously seen area of avidity on prior PET-CT scan, and no well-defined mass was identified. Ultimately, a biopsy was not collected from the base of the tongue/left tonsillar fossa upon otolaryngology specialist's evaluation.

On 23 Sep 2020 (Study Day 29), a right upper extremity venous ultrasound was performed to investigate swelling and showed no evidence of deep vein thrombosis.

On 24 Sep 2020 (Study Day 30), the participant's rash was improved overall upon examination. Laboratory test results included WBC 27.7×10^3 (units not provided), red blood cell (RBC) 3.26×10^6 (units not provided), hemoglobin (Hgb) 10.0 g/dL, hematocrit 31.4%, BUN 35, Plt 155×10^3 (units not provided), and uric acid 7.6 (no units or reference ranges reported). The participant was discharged on allopurinol PO on the same day.

The participant had been doing well and their rash had continued to improve since being discharged until, on 29 Sep 2020 (Study Day 35), they noted that the rash had progressed to a confluent erythematous rash on their right chest, extending into the axilla.

On 30 Sep 2020 (Study Day 36), the participant presented to the ED and was later admitted to the hospital with high-grade fevers, up to 104°F at home and maximum temperature of 102.2°F in ED, with diarrhea, and shortness of breath. The participant's initial vital signs were temperature 101.1°F, heart rate 100 beats/minute, blood pressure 137/66 mm Hg, respiratory rate 18 breaths/minute, and oxygen saturation of 94% on room air. Significant laboratory results included D-dimer 6750 ng/mL, fibrinogen 324 mg/dL, WBC 37.4×10^3 (units not provided), Hgb 11.2 (units not provided), lactate 1.9 (units not provided), Plt $130 \times 10^3/\mu L$, prothrombin time (PT) 18.1 seconds, international normalized ratio (INR) 1.7, BUN 30, sodium 133, uric acid 5.9, troponin 0.34, ALT 41, AST 48, ALP 227, albumin 3.2, calcium 8.2 (no units or reference ranges were provided), positive hepatitis A antibodies (negative IgM, denoted no active infection), and creatinine 1.7. A COVID-19 PCR test with a nasal swab was negative. A chest, abdomen, and pelvis CT showed considerable adenopathy in the chest and abdomen located in the bilateral axillae, retroperitoneum, pelvis, and inguinal regions (increased since the prior PET-CT scan on 04 Aug 2020 [Study Day -23]), new moderate left pleural effusion, and stable lung nodules. There was further increase in splenomegaly, which measured 21.7 cm, with multiple low-density lesions present. A cystic lesion in the pancreatic neck, measuring 1.2×0.7 cm, was noted. Treatment included ceftriaxone/azithromycin PO and paracetamol PO. Preadmission medications were levothyroxine, prednisolone, tamsulosin, fluticasone, allopurinol, triamcinolone 0.1%, and hydroxyzine.

On 01 Oct 2020 (Study Day 37), the participant's lungs were clear to auscultation bilaterally with an increased respiratory rate and increased work of breathing. The participant had a diffuse, resolving, macular rash involving the entire body with small patches of desquamation throughout, scattered, small, fluid-filled bullae on the dorsum of the right foot, and a large area of confluent erythema over their right chest, extending into the axilla. The participant's condition deteriorated throughout the day with the development of acute respiratory failure, requiring intubation and mechanical ventilation. The participant was transferred to the intensive care unit and their condition continued to worsen with pneumothorax and purpura fulminans, which covered almost all of their body. The PCR test results were negative for COVID-19, adenovirus, coronavirus (non-COVID-19), human metapneumovirus, human rhinovirus/enterovirus, all influenza, all parainfluenza, respiratory syncytial virus A and B, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae*.

On 02 Oct 2020 (Study Day 38), the participant experienced a fatal SAE of systemic inflammatory response syndrome. On the morning of 02 Oct 2020 (Study Day 38), the participant experienced cardiac arrest with pulseless electrical activity and was resuscitated. A hematologist was consulted

and confirmed the participant's diagnosis of purpura fulminans based on their examination and review of laboratory results. Due to the severity of their condition and poor prognosis, the participant's family elected to pursue comfort-focused care. The participant died that afternoon at 16:45. During this admission, the participant's laboratory test results were significant for increase in D-dimer from 6750 ng/mL to 21,600 ng/mL, decrease in fibrinogen from 324 mg/dL to 151 mg/dL, decrease in Plt from $130 \times 10^3/\mu L$ to $68 \times 10^3/\mu L$, and a progressive coagulopathy with increase in INR from 2.2 to 4.2, PT from 18.1 seconds to 46.1 seconds, schistocytes on smear, and eventually purpura fulminans/disseminated intravascular coagulation. The participant had elevated markers of inflammation, ferritin 1729 ng/mL, and lactate dehydrogenase 537 IU/L (no reference ranges were provided). The participant had a component of heart failure detected on chest x-ray and pro-brain natriuretic peptide of 18,965 pg/mL (no reference range provided). Electrocardiogram and creatine kinase-MB did not indicate myocardial infarction.

Study IP was delayed in response to the event of dermatitis bullous. Study IP was withdrawn in response to the event of severe systemic inflammatory syndrome in the setting of CLL.

The participant died on 02 Oct 2020 (Study Day 38). The cause of death, per autopsy report from 29 Oct 2020 (Study Day 65), was severe systemic inflammatory response syndrome in the setting of CLL. An infiltrate composed of T-cells (CD4+ predominant) and eosinophils was present in all major organs causing a myocarditis in the heart, vacuolar interface dermatitis in the skin, necrosis and histiocytic aggregates in the bone marrow and lymph nodes, and portal-based inflammation in the liver with biliary injury and endotheliitis of the portal and central veins. Infiltrates were also prominent in the bowel wall without mucosal involvement. The spleen was massively enlarged with prominent sinusoidal histiocytes present on histology.

The liver and kidney also showed acute ischemic injury. Microthrombi were seen in the skin but were likely secondary to the inflammation rather than a primary vasculitis. The participant's CLL was present in the nodes and marrow but were displaced by the inflammatory infiltrate. Sections of multiple nodes and marrow did not show large cell transformation. The lungs were heavy with edema and focal acute and organizing pneumonia, but no source of sepsis was identified, and postmortem blood and lung culture did not show significant growth. The conclusion of the autopsy report was that there was a massive immune response that was difficult to classify. There was no evidence of high-grade transformation or progression of the CLL or a source of infection that could account for the histologic picture. The trigger for this reaction was unclear, and a relationship to participant's recent vaccination could not be excluded based on the findings. At the time of the participant's death, the event of dermatitis bullous was considered not resolved.

The investigator assessed the events, dermatitis bullous and systemic inflammatory response syndrome (in the setting of CLL), as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000325	Dermatitis bullous
MOD-2020-000325	Systemic inflammatory response syndrome

Study Completion/Discontinuation

On 02 Oct 2020 (Study Day 38), the participant discontinued from the study due to death. On 02 Oct 2020 (Study Day 38), the participant died due to adverse event. An autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Aortic dilatation	Aortic root dilation	Not reported - Ongoing
Chronic kidney disease	CKD stage 3	Not reported - Ongoing
Corneal dystrophy	Fuchs' dystrophy	Not reported - Ongoing
Lymphadenopathy	Right axillary lympthodenopathy	Not reported - Ongoing
Night sweats	Night sweats	Not reported - Ongoing
Open angle glaucoma	Open angle glaucoma	Not reported - Ongoing
Renal cyst	Renal cyst	Not reported - Ongoing
Sleep apnoea syndrome	OSA	Not reported - Ongoing
Tonsillar hypertrophy	Soft tissue thickening in l tonsillar fossa	Not reported - Ongoing
Rhinitis	Idiopathic rhinitis	1990 - Ongoing
Bradycardia	Bradycardia	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017 - Ongoing
Chronic lymphocytic leukaemia	Chronic lymphocytic leukemia (no therapy, monitored)	2019 - Ongoing
Cataract	Cataracts	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydroxyzine	Not reported - 02 Oct 2020 (Study Day 38)	Pruitis (Entire Body)
Levothyroxine sodium	Not reported - 02 Oct 2020 (Study Day 38)	Hypothyroidism
Prednisolone acetate	Not reported - 02 Oct 2020 (Study Day 38)	Unk
Fluticasone	2000 - Ongoing	Idiopathic Rhinitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2005 - Ongoing	Hypothyroidism
Tamsulosin	2017 - Ongoing	Benign Prostatic Hyperplasia
Cataract surgery*	02 Sep 2020 (Study Day 8) - 02 Sep 2020 (Study Day 8)	Medical History
Axillary biopsy*	04 Sep 2020 (Study Day 10) - 04 Sep 2020 (Study Day 10)	Medical History
Ciclopirox	15 Sep 2020 (Study Day 21) - 02 Oct 2020 (Study Day 38)	Diffuse Bullous Rash (Non-Urticarial)
Triamcinolone acetonide	15 Sep 2020 (Study Day 21) - Ongoing	Diffuse Bullous Rash (Non-Urticarial)
Clobetasol	17 Sep 2020 (Study Day 23) - 17 Sep 2020 (Study Day 23)	Diffuse Bullous Rash (Non-Urticarial)
EKG*	17 Sep 2020 (Study Day 23) - 17 Sep 2020 (Study Day 23)	Medical History
Skin biopsy*	17 Sep 2020 (Study Day 23) - 17 Sep 2020 (Study Day 23)	Adverse Event
MRI- neck*	22 Sep 2020 (Study Day 28) - 22 Sep 2020 (Study Day 28)	Adverse Event
Ultrasound- neck*	22 Sep 2020 (Study Day 28) - 22 Sep 2020 (Study Day 28)	Adverse Event
Allopurinol	24 Sep 2020 (Study Day 30) - 02 Oct 2020 (Study Day 38)	Diffuse Bullous Rash (Non-Urticarial)
Azithromycin	30 Sep 2020 (Study Day 36) - 30 Sep 2020 (Study Day 36)	Rash (Diffuse Bullous Rash Non-Urticarial)
Ceftriaxone	30 Sep 2020 (Study Day 36) - 30 Sep 2020 (Study Day 36)	Rash (Diffuse Bullous Rash Non-Urticarial)
Ct scan (chest, abdomen, pelvis)*	30 Sep 2020 (Study Day 36) - 30 Sep 2020 (Study Day 36)	Medical History
Paracetamol	30 Sep 2020 (Study Day 36) - 30 Sep 2020 (Study Day 36)	Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphadenopathy	Grade 1/mild	Not related	22 Sep 2020 (Study Day 28) - 02 Oct 2020 (Study Day 38)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378011

Participant Number:	US355-2191 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Basedow's Disease/Graves' Disease	SAE	Grade 4	Related	30 Sep 2020 (Study Day 36) – 01 Feb 2021 (Study Day 160)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2191, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Sep 2020 (Study Day 36), 35 days after the first dose and 7 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of Basedow's disease. Action taken with the IP was not applicable. The event of Basedow's disease lasted for 125 days, after which it was considered to be recovered/resolved with sequelae on 01 Feb 2021 (Study Day 160). The investigator assessed the event of Basedow's disease to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 30 Sep 2020 (Study Day 36), the participant experienced a serious adverse event (SAE) of Basedow's disease. The participant reported shortness of breath on exertion, fatigue, and swollen ankles.

On 07 Oct 2020 (Study Day 43), the participant continued to experience shortness of breath.

On 09 Oct 2020 (Study Day 45), the participant presented to the emergency department (ED) and was hospitalized overnight. Treatment for shortness of breath and swollen ankles included single dose of furosemide IV. An electrocardiogram showed sinus tachycardia and no evidence of injury pattern. A computed tomography of the chest showed no evidence of pulmonary embolism. An

x-ray was without significant or acute findings. On 10 Oct 2020 (Study Day 46), participant was discharged.

On 12 Oct 2020 (Study Day 48), an echocardiogram showed no pathologic processes.

On 23 Oct 2020 (Study Day 59), the participant informed the physician that recent laboratory results included free T4 4.16 ng/mL (reference range 0.7 to 1.48 ng/mL) and total T3 451 ng/mL (reference range 0.58 to 1.59 ng/mL).

On 26 Oct 2020 (Study Day 62), carvedilol PO for tachycardia and methimazole PO for the event of Basedow's disease were started, and on 30 Oct 2020 (Study Day 66), atenolol PO for tachycardia was also started.

On 09 Nov 2020 (Study Day 76), laboratory results included total T3 245.52 ng/dL, thyroid stimulating hormone (TSH) <0.003 µIU/mL (reference range 0.47 to 5 µIU/mL), and free T4 1.64 ng/mL, and dosing of methimazole PO was increased.

On 11 Nov 2020 (Study Day 78), the participant's peripheral edema had resolved, and their shortness of breath remained ongoing, which was retrospectively consistent with hyperthyroidism.

On 18 Nov 2020 (Study Day 85), the participant reported that their peripheral edema remained resolved, and their shortness of breath was still ongoing.

On 19 Nov 2020 (Study Day 86), laboratory results included thyroid stimulating immunoglobulins 498% baseline (reference range <140%), thyroid peroxidase antibody 18 IU/mL (reference range <9 IU/mL), total T3 74.5 ng/dL (0.745 ng/mL), free T4 1.03 ng/mL, and TSH <0.003 µIU/mL. The participant developed a rash and stopped treatment with methimazole. Treatment with prednisone PO was started.

On 24 Nov 2020 (Study Day 91), thyroid imaging revealed normal overall size of the thyroid, with the right lobe of the thyroid larger than the left lobe. There was a uniform distribution of radioiodine throughout both lobes, which was consistent with Basedow's disease.

On 01 Dec 2020 (Study Day 98), the participant was treated with radioiodine I-131 therapy.

On 03 Dec 2020 (Study Day 100), treatment included propranolol PO.

On 17 Dec 2020 (Study Day 114), free T4 was 1.01 ng/mL and total T3 was 74.5 ng/dL (0.745 ng/mL).

Action taken with study IP was not applicable in response to the events, as the participant had already received both scheduled doses.

The event, Basedow's disease, was considered resolved with sequelae of ongoing fatigue and need for medications on 01 Feb 2021 (Study Day 160).

The investigator assessed the event, Basedow's disease, as related to the study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001843	Basedow's disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	Not reported - Ongoing
Drug hypersensitivity	Medication allergy: tolectin	1987 - Ongoing
Intervertebral disc protrusion	Herniated disc	1987 - Ongoing
Osteoarthritis	Osteoarthritis	1987 - Ongoing
Depression	Depression	1990 - Ongoing
Rosacea	Rosacea	1990 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Menopause	Menopause	2003 - Ongoing
Breast cancer	Breast cancer	Jan 2007 - Jan 2012
Vitamin D deficiency	Vitamin d deficiency	2012 - Ongoing
Meniere's disease	Meniere's disease	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	Jun 2018 - Ongoing
Constipation	Constipation	2019 - Ongoing
Tendonitis	Left heel achilles tendonitis	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Venlafaxine	1990 - Ongoing	Mild Depression
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Colecalciferol	2012 - Ongoing	Vitamin D Deficiency

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2014 - Ongoing	Health Promotion
Hydrochlorothiazide; triamterene	2015 - Ongoing	Meniere's Disease
Gabapentin	2016 - Ongoing	Osteoarthritis
Cetirizine	2017 - Ongoing	Seasonal Allergies
Metformin	Jun 2018 - Ongoing	Type 2 Diabetes Mellitus
Vitamin b12 nos	Jun 2018 - Ongoing	Replacement For Or Preventative Of Metformin Depletion
Magnesium citrate	2019 - Ongoing	Constipation
Furosemide	09 Oct 2020 (Study Day 45) - 09 Oct 2020 (Study Day 45)	Graves' Disease
Carvedilol	26 Oct 2020 (Study Day 62) - 30 Oct 2020 (Study Day 66)	Tachycardia
Thiamazole	26 Oct 2020 (Study Day 62) - 08 Nov 2020 (Study Day 75)	Graves' Disease
Atenolol	30 Oct 2020 (Study Day 66) - 08 Nov 2020 (Study Day 75)	Tachycardia
Influenza vaccine	30 Oct 2020 (Study Day 66) - 30 Oct 2020 (Study Day 66)	Influenza Prophylaxis
Atenolol	09 Nov 2020 (Study Day 76) - 02 Dec 2020 (Study Day 99)	Tachycardia
Diphenhydramine hydrochloride	09 Nov 2020 (Study Day 76) - Ongoing	Generalized Itching
Thiamazole	09 Nov 2020 (Study Day 76) - 18 Nov 2020 (Study Day 85)	Graves' Disease
Prednisone	19 Nov 2020 (Study Day 86) - 18 Dec 2020 (Study Day 115)	Graves' Disease
Radioactive iodine uptake scan*	24 Nov 2020 (Study Day 91) - 24 Nov 2020 (Study Day 91)	Diagnostic
Thyroid ablation*	01 Dec 2020 (Study Day 98) - 01 Dec 2020 (Study Day 98)	Adverse Event
Propranolol	02 Dec 2020 (Study Day 99) - 17 Jan 2021 (Study Day 145)	Graves' Disease
Prednisone	19 Dec 2020 (Study Day 116) - 23 Dec 2020 (Study Day 120)	Grave's Disease
Propranolol	19 Dec 2020 (Study Day 116) - 19 Jan 2021 (Study Day 147)	Grave's Disease
Prednisone	24 Dec 2020 (Study Day 121) - 30 Dec 2020 (Study Day 127)	Graves' Disease
Prednisone	31 Dec 2020 (Study Day 128) - 06 Jan 2021 (Study Day 134)	Graves' Disease
Prednisone	07 Jan 2021 (Study Day 135) - 13 Jan 2021 (Study Day 141)	Graves' Disease
Prednisone	14 Jan 2021 (Study Day 142) - 19 Jan 2021 (Study Day 147)	Graves' Disease
Levothyroxine	01 Feb 2021 (Study Day 160) - Ongoing	Graves' Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	24 Sep 2020 (Study Day 30) - 01 Feb 2021 (Study Day 160)
Cough	Grade 1/mild	Related	08 Oct 2020 (Study Day 44) - 08 Oct 2020 (Study Day 44)
Headache	Grade 1/mild	Related	08 Oct 2020 (Study Day 44) - 08 Oct 2020 (Study Day 44)
Oropharyngeal Pain	Grade 1/mild	Related	08 Oct 2020 (Study Day 44) - 08 Oct 2020 (Study Day 44)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anaemia	Grade 2/moderate	Related	09 Oct 2020 (Study Day 45) - 20 Oct 2020 (Study Day 56)
Muscular Weakness	Grade 2/moderate	Related	09 Oct 2020 (Study Day 45) - 22 Dec 2020 (Study Day 119)
Sinus Tachycardia	Grade 1/mild	Related	09 Oct 2020 (Study Day 45) - 09 Nov 2020 (Study Day 76)
Pruritus	Grade 2/moderate	Related	09 Nov 2020 (Study Day 76) - 01 Feb 2021 (Study Day 160)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378016

Participant Number:	US357-2086 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 30)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/CVA	SAE	Grade 3/ severe	Not related	31 Dec 2020 (Study Day 129) – 13 Jan 2021 (Study Day 142)	Recovered/ resolved
COVID-19/ COVID-19	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	03 Jan 2021 (Study Day 132) – 12 Feb 2021 (Study Day 172)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee

Participant US357-2086, a 63-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 23 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Dec 2020 (Study Day 129), 128 days after the first dose and 99 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of CVA lasted for 14 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 142). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

On 03 Jan 2021 (Study Day 132), 131 days after the first dose and 102 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of COVID-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 41 days, after which it was considered to be fatal on 12 Feb 2021 (Study Day 172). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 31 Dec 2020 (Study Day 129), the participant experienced a serious adverse event (SAE) of cerebrovascular accident. The participant presented to the hospital with headache, neck pain,

upper back pain, and pelvic pain status after a fall on 25 Dec 2020 (Study Day 123); reason for the fall was unclear. The participant denied loss of consciousness and presented with facial drooping to right side of face. The participant was admitted for neurological signs of stroke that had been present for 3 days before admission. The participant was convinced by their caretaker to come to the hospital. After being assessed in the emergency department (ED), the participant was found to be COVID-19 positive and was admitted to the COVID unit for supportive therapy and neurology was consulted.

On 03 Jan 2021 (Study Day 132), a computed tomography (CT) of head revealed postoperative changes related to a left frontal temporal craniotomy and aneurysm clip in the region of the terminal left internal carotid artery/middle cerebral artery segment of the middle cerebral artery and persistent areas of encephalomalacia involving the left frontal, temporal, and parietal lobes. Otherwise, no significant interval intracranial findings were observed. Relevant laboratory results included prothrombin time (PT) 10.8 and international normalized ratio (INR) 0.95 (no units and reference ranges reported). Treatment for the event of cerebrovascular accident included levofloxacin.

On 05 Jan 2021 (Study Day 134), laboratory results included hemoglobin (Hgb) 11.7 (low), hematocrit (Hct) 35 (low), platelet count 316, sodium 140, potassium 3.4 (low), carbon dioxide 27, chloride 106, creatinine (Cr) 0.59 (low), blood urea 11.57, glucose 146 (high), phosphorus 3.2, and calcium 8.5 (low) (no units and reference ranges reported).

On 06 Jan 2021 (Study Day 135), laboratory results included Hgb normalized to 17.10, Hct normalized to 51.2, Cr normalized to 0.63, magnesium 2.2, PT increased to 24 (high), INR increased to 2.0 (high), activated partial thromboplastin time 31.2, and troponin < 0.01 (no units and reference ranges reported).

On 07 Jan 2021 (Study Day 136), relevant laboratory results included Hgb dropped to 11.7 (low), Hct dropped to 35.3 (low), white blood cell 3.44 (low) (no unit and reference range reported), potassium 3.6, Cr dropped to 0.56 (low), glucose 136 (high), and calcium 8.2 (low).

On 08 Jan 2021 (Study Day 137), laboratory results showed PT remained elevated at 15.6 (high) and INR normalized at 1.3.

During hospitalization, the participant remained hemodynamically stable, stated weakness and mild shortness of breath for which oxygen supplement was provided with alleviation of symptoms. There was suspicion of some deconditioning, and an incentive spirometry was ordered (no results provided). The participant received remdesivir for 5 days and convalescent plasma for asymptomatic COVID-19 and levofloxacin PO for cerebrovascular accident.

On 13 Jan 2021 (Study Day 142), the participant was deemed ready for discharge to a nursing and rehabilitation center for ongoing physical and occupational therapy. Upon discharge, physical examination revealed right facial droop, right hand paresis, and left hand and lower extremities with decreased strength. Discharge medications included alprazolam PO, amlodipine PO, acetylsalicylic acid, atorvastatin, cholecalciferol, guaifenesin, labetalol PO, and losartan. Discharge diagnosis included cerebrovascular accident, pneumonia due to COVID-19, ambulatory dysfunction, benign essential hypertension, bicytopenia, fall, and left ankle sprain.

The event, cerebrovascular accident, was considered resolved on 13 Jan 2021 (Study Day 142).

On 03 Jan 2021 (Study Day 132), the participant experienced a fatal SAE of COVID-19. The participant tested positive for SARS-CoV-2 by real-time RT-PCR reaction nasopharyngeal swab. The participant presented to ED with progressive shortness of breath, was afebrile, tachycardic with a pulse of 91 beats/minute, which increased to as high as 114 beats/minute, and was tachypneic at 26 breaths/minute, which increased to as high as 40 breaths/minute. Pulse oximeter result was 78% on room air and improved to 98% on 15 large non-rebreather mask. Decreased breath sounds were reported. Laboratory results included lymphocytes 6.8%, glucose 126, and albumin 2.9 (no units and reference range reported), and showed no leukocytosis and stable electrolytes, creatinine, and liver function tests. A CT scan of the chest showed moderate to severe COVID-19 pneumonia. Criteria for sepsis was met. Treatment included fluid bolus, cefepime, vancomycin, and levofloxacin for sepsis (all IV).

On 17 Jan 2021 (Study Day 146), treatment with levofloxacin 500 mg QD for 10 days for COVID-19 pneumonia was started.

On 23 Jan 2021 (Study Day 152), the participant was admitted to a COVID-19 unit at a nursing home.

On 08 Feb 2021 (Study Day 168), a respiratory viral panel and COVID-19 PCR were negative. The participant had a protracted hospital course and continued to deteriorate from the time of admission. No significant complications or iatrogenic injury was reported during the hospital stay. The participant's radiographic, laboratory, and other diagnostic data showed progressive worsening of COVID-19 pneumonia and the participant's prognosis was discussed with their family, who decided to change the code status to a do-not-resuscitate order. The participant continued to be hemodynamically unstable, requiring 3 vasopressors to support their blood pressure, and they continued to desaturate on ventilator despite being on 100% FiO_2, blood O_2 saturations dropped into the 40s. The participant was hypothermic, tachycardic, tachypneic, and completely unresponsive. After consulting with the family, they decided to withdraw all aggressive care and place the participant on comfort measures only. All aggressive care was

withdrawn at 11:40. The participant began to experience progressively worsening bradycardia and expired at 11:44 on 12 Feb 2021.

Action taken with the study IP was not applicable as the participant had already received both scheduled doses.

The participant died on 12 Feb 2021 (Study Day 172). The cause of death was reported as COVID-19. It was not known whether an autopsy was performed.

The investigator assessed the events, cerebrovascular accident and COVID-19, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004768	Cerebrovascular accident
MOD-2021-059237	COVID-19

Study Completion/Discontinuation

On 12 Feb 2021 (Study Day 172), the participant discontinued from the study due to death. On 12 Feb 2021 (Study Day 172), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Cerebrovascular accident	Cerebrovascular accident (CVA)	2004 - 2004
Hypertension	Hypertension	2004 - Ongoing
Cerebrovascular accident	Cerebrovascular accident (CVA)	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Feb 2020 - Ongoing	CVA
Influenza vaccine	21 Oct 2020 (Study Day 58) - 21 Oct 2020 (Study Day 58)	Flu Prevention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Incentive spirometry*	01 Jan 2021 (Study Day 130) - 01 Jan 2021 (Study Day 130)	Adverse Event
O2 supplement*	01 Jan 2021 (Study Day 130) - 01 Jan 2021 (Study Day 130)	Adverse Event
Remdesivir administered for 5 days*	01 Jan 2021 (Study Day 130) - 01 Jan 2021 (Study Day 130)	Adverse Event
Levofloxacin hemihydrate	03 Jan 2021 (Study Day 132) - 12 Feb 2021 (Study Day 172)	CVA
Covid19 plasma*	05 Jan 2021 (Study Day 134) - 05 Jan 2021 (Study Day 134)	Other, COVID19 Positive
Physical and occupational therapy following CVA*	13 Jan 2021 (Study Day 142) - 13 Jan 2021 (Study Day 142)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	23 Sep 2020 (Study Day 30) - 12 Feb 2021 (Study Day 172)
Pneumonia	Grade 3/severe	Not related	03 Jan 2021 (Study Day 132) - 13 Jan 2021 (Study Day 142)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US360-2030 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	16 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Immunisation Anxiety Related Reaction/Anxiety Related To The Vaccine	SAE	Grade 2/ moderate	Related	17 Sep 2020 (Study Day 7) – 07 Oct 2020 (Study Day 27)	Recovered/ resolved
Paraesthesia/Tingling On Right Side Of Face	SAE	Grade 2/ moderate	Related	17 Sep 2020 (Study Day 7) – 28 Sep 2020 (Study Day 18)	Recovered/ resolved
Swelling Face/Swelling To The Right Side Of The Face	SAE	Grade 2/ moderate	Related	17 Sep 2020 (Study Day 7) – 27 Sep 2020 (Study Day 17)	Recovered/ resolved
Pleuritic Pain/Left Sided Pleuritic Chest Pain	SAE	Grade 1/ mild	Not related	27 Sep 2020 (Study Day 17) – 29 Sep 2020 (Study Day 19)	Recovered/ resolved
Feeling Hot/Left Sided Chest Wall Warmth	SAE	Grade 2/ moderate	Related	06 Oct 2020 (Study Day 26) – 16 Oct 2020 (Study Day 36)	Recovered/ resolved
Paraesthesia/Left Sided Tingling	SAE	Grade 2/ moderate	Related	06 Oct 2020 (Study Day 26) – 16 Oct 2020 (Study Day 36)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US360-2030, a 41-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 16 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Sep 2020 (Study Day 7), 6 days after the first dose and 29 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of immunisation anxiety related reaction. The IP dose was not changed due to the anxiety related to the vaccine. The event of anxiety related to the vaccine lasted for 21 days, after which it was considered to be recovered/resolved on 07 Oct 2020 (Study Day 27). The investigator assessed the event of immunisation anxiety related reaction to be related to the IP.

On 17 Sep 2020 (Study Day 7), 6 days after the first dose and 29 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of paraesthesia. The IP dose was not changed due to the tingling on right side of face. The event of tingling on right

side of face lasted for 12 days, after which it was considered to be recovered/resolved on 28 Sep 2020 (Study Day 18). The investigator assessed the event of paraesthesia to be related to the IP.

On 17 Sep 2020 (Study Day 7), 6 days after the first dose and 29 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of swelling face. The IP dose was not changed due to the swelling to the right side of the face. The event of swelling to the right side of the face lasted for 11 days, after which it was considered to be recovered/resolved on 27 Sep 2020 (Study Day 17). The investigator assessed the event of swelling face to be related to the IP.

On 27 Sep 2020 (Study Day 17), 16 days after the first dose and 19 days before the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of pleuritic pain. The IP dose was not changed due to the left sided pleuritic chest pain. The event of left sided pleuritic chest pain lasted for 3 days, after which it was considered to be recovered/resolved on 29 Sep 2020 (Study Day 19). The investigator assessed the event of pleuritic pain to be not related to the IP.

On 06 Oct 2020 (Study Day 26), 25 days after the first dose and 10 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of feeling hot. The IP dose was delayed due to the left sided chest wall warmth. The event of left sided chest wall warmth lasted for 11 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 36). The investigator assessed the event of feeling hot to be related to the IP.

On 06 Oct 2020 (Study Day 26), 25 days after the first dose and 10 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of paraesthesia. The IP dose was delayed due to the left sided tingling. The event of left sided tingling lasted for 11 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 36). The investigator assessed the event of paraesthesia to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 06 Aug 2020 (Study Day –36), the participant had their teeth cleaned.

On 28 Aug 2020 (Study Day –18), the participant had a root canal.

On 17 Sep 2020 (Study Day 7), the participant experienced serious adverse events (SAEs) of immunization anxiety related reaction, paraesthesia (tingling on right side of face), and swelling face. The participant had pain chewing on the back teeth due to root canal.

On 18 Sep 2020 (Study Day 8), the participant developed increased tingling and numbness along the jaw line (along the mandibular nerve distribution of the trigeminal nerve) and increased swelling and fullness over the maxilla. The participant did not have nasal discharge. Over the next 2 days, the participant's pain persisted.

On 21 Sep 2020 (Study Day 11), the participant visited their dentist, who did not find any issues with the tooth that had the root canal and felt that the participant could have shingles or some other medical issues leading to the jaw pain.

On 22 Sep 2020 (Study Day 12), the participant's vital signs included body temperature 96.4°F, blood pressure 128/81 mm Hg, pulse oximetry 100%, heart rate 98 beats per min, respiratory rate 12 breaths per min, and body mass index 38.4 kg/m^2. The participant had swelling in their cheek and jaw area but did not have redness of the face, tooth decay, pain on palpation of the tooth with the recent root canal, swelling of the jaw, facial droop, nasal congestion, or nasal redness.

On an unspecified date, as recommended, the participant consulted an ear, nose, and throat (ENT) specialist, who did not find a clear explanation for the events but suspected an odontogenic infection and referred the participant to an oral surgeon and recommended a sinus computerized tomography (CT) scan. The participant did not undergo the CT scan but did see an oral surgeon who thought the pain might be caused by an issue related to a dental crown at the same site as the recent root canal. The radiograph results were unremarkable.

On 27 Sep 2020 (Study Day 17), the participant's symptoms of facial swelling and numbness and tooth pain resolved. On the same day, the participant experienced an SAE of pleuritic pain. The participant reported left sided back pain, thoracic and pleuritic chest pain, and was evaluated by a cardiologist, who recommended an echocardiogram (ECHO) and stress test. The cardiologist confirmed that the chest pain was not cardiac related. The participant also had complaints of right-sided chest wall numbness and requested to be withdrawn from the next dose of the IP. Additionally, the participant requested unblinding of IP to lessen their anxiety while undergoing evaluation of symptoms. No additional medications or treatment was provided. The participant was recommended to continue to follow-up with cardiologist.

On 28 Sep 2020 (Study Day 18), the participant went to their primary care physician and had an electrocardiogram (ECG) and chest x-ray; results of both were normal.

On 06 Oct 2020 (Study Day 26), the participant experienced SAEs of feeling hot, described as left-sided chest wall warmth while lying down, and paraesthesia, described as left-sided tingling.

On 10 OCT 2020 (Study Day 30), a regular cardiac stress test showed no ischemia.

On 13 Oct 2020 (Study Day 33), an ECG showed normal size of left ventricle cavity, normal global wall motion, visual ejection fraction 55 to 60% (no reference range provided), doppler evidence of grade 1 (impaired), diastolic dysfunction, and a structurally normal trileaflet aortic valve with mild grade 1 regurgitation.

No action was taken with the study IP in response to the events of immunization anxiety related reaction, paraesthesia (tingling on right side of face), swelling face, and pleuritic pain. Study IP dose was delayed in response to the events of feeling hot and paresthesia (left-sided tingling).

The event of swelling face was considered resolved on 27 Sep 2020 (Study Day 17). The event of paresthesia (tingling on right side of face) was considered resolved on 28 Sep 2020 (Study Day 18). The event of pleuritic pain was considered resolved on 29 Sep 2020 (Study Day 19). The event of immunization anxiety related reaction was considered resolved on 07 Oct 2020 (Study Day 27). The events of feeling hot and paresthesia (left sided tingling) were considered resolved on 16 Oct 2020 (Study Day 36).

The investigator assessed the events of immunization anxiety related reaction, paraesthesia (tingling on right side of face), and swelling face as related to study IP and not related to study procedure. The investigator assessed the event, pleuritic pain, as not related to study IP or study procedure. The investigator assessed the events of feeling hot and paresthesia (left sided tingling) as related to study IP or study procedure.

The company assessed all of the events as unrelated to the study IP. The events might be explained by the participant's recent dental surgery and medical history of sinus surgery.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000323	Immunisation anxiety related reaction
MOD-2020-000323	Paraesthesia
MOD-2020-000323	Swelling face
MOD-2020-000323	Pleuritic pain
MOD-2020-000323	Feeling hot
MOD-2020-000323	Paraesthesia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Endometriosis	Endometriosis s/p stripping	Not reported - Ongoing
Osteoarthritis	Left knee osteoarthritis	Not reported - Ongoing
Rhinitis	Non-allergic rhinitis	Not reported - Ongoing
Sinus operation	Multiple sinus surgeries	Not reported

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vitamin D deficiency	Vitamin d insufficiency	Not reported - Ongoing
Asthma	Asthma	1995 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Dry eye	Dry eye syndrome	2012 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Dental cleaning	Tooth cleaning	06 Aug 2020 (Study Day -36) - 06 Aug 2020 (Study Day -36)
Alopecia	Hair thinning	11 Aug 2020 (Study Day -31) - Ongoing
Endodontic procedure	Root canal	28 Aug 2020 (Study Day -14) - 28 Aug 2020 (Study Day -14)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ciclosporin	Not reported - Ongoing	Dry Eye
Diclofenac	Not reported - Ongoing	Left Knee OA
Esomeprazole magnesium	Not reported - Ongoing	Acid Reflux
Fluticasone propionate	Not reported - Ongoing	Non- Allergic Rhinitis
Melatonin	Not reported - Ongoing	Insomnia
Probiotics nos	Not reported - Ongoing	Good Gi Health
Vitamin d nos	Not reported - Ongoing	Maintain Good Level
Vitamins nos	Not reported - Ongoing	Good Health
Fluticasone propionate; salmeterol xinafoate	2004 - Ongoing	Asthma
Azelastine hydrochloride	2005 - Ongoing	Non- Allergic Rhinitis
Telmisartan	2012 - Ongoing	HTN
Etonogestrel	24 Jun 2020 (Study Day -79) - Ongoing	Contraception And Endometriosis
Biotin	Aug 2020 - Ongoing	Thinning Of Hair
Dentist visit*	21 Sep 2020 (Study Day 11) - 21 Sep 2020 (Study Day 11)	Adverse Event
Chest x-ray (CXR)*	07 Oct 2020 (Study Day 27) - 07 Oct 2020 (Study Day 27)	Adverse Event
EKG*	07 Oct 2020 (Study Day 27) - 07 Oct 2020 (Study Day 27)	Adverse Event
Stress test*	07 Oct 2020 (Study Day 27) - 07 Oct 2020 (Study Day 27)	Adverse Event
Paracetamol	18 Oct 2020 (Study Day 38) - 18 Oct 2020 (Study Day 38)	Headache
Acetylsalicylic acid; caffeine; paracetamol	23 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 43)	Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid; caffeine; paracetamol	02 Nov 2020 (Study Day 53) - 02 Nov 2020 (Study Day 53)	Headache
Acetylsalicylic acid; caffeine; paracetamol	04 Nov 2020 (Study Day 55) - 04 Nov 2020 (Study Day 55)	Headache
Cefalexin	04 Feb 2021 (Study Day 147) - 16 Feb 2021 (Study Day 159)	Right Maxillary Sinus Pain/Congestion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Toothache	Grade 1/mild	Not related	17 Sep 2020 (Study Day 7) - 22 Sep 2020 (Study Day 12)
Headache	Grade 1/mild	Related	18 Oct 2020 (Study Day 38) - 24 Oct 2020 (Study Day 44)
Migraine	Grade 1/mild	Related	02 Nov 2020 (Study Day 53) - 03 Nov 2020 (Study Day 54)
Migraine	Grade 1/mild	Related	04 Nov 2020 (Study Day 55) - 04 Nov 2020 (Study Day 55)
Sinus Congestion	Grade 1/mild	Not related	04 Feb 2021 (Study Day 147) - 17 Feb 2021 (Study Day 160)
Sinus Pain	Grade 1/mild	Not related	04 Feb 2021 (Study Day 147) - 17 Feb 2021 (Study Day 160)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2203 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 31)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Completed Suicide/Committed Suicide	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	13 Dec 2020 (Study Day 117) – 13 Dec 2020 (Study Day 117)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2203, a 25-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Dec 2020 (Study Day 117), 116 days after the first dose and 86 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of completed suicide. Action taken with the IP was not applicable. The event of committed suicide was considered to be fatal on 13 Dec 2020 (Study Day 117). The investigator assessed the event of completed suicide to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 13 Dec 2020 (Study Day 117), the participant experienced a fatal serious adverse event of completed suicide. The site was informed after speaking with the participant's parent.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The event, completed suicide, was considered fatal and serious. The participant died on 13 Dec 2020 (Study Day 117).

The investigator assessed the event, completed suicide, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005702	Completed suicide

Study Completion/Discontinuation

On 13 Dec 2020 (Study Day 117), the participant discontinued from the study due to death. On 13 Dec 2020 (Study Day 117), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Amoxicillin allergy	2000 - Ongoing
Anxiety	Anxiety	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	Jan 2020 - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US370-2010 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Death, SAE, Severe COVID-19, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Infection (Onset 1/1/2021, Diagnosis 1/5/2021)	Death, SAE, COVID-19, AE leading to study discontinuation	Grade 5	Not related	01 Jan 2021 (Study Day 120) – 25 Feb 2021 (Study Day 175)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US370-2010, a 74-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 01 Jan 2021 (Study Day 120), 119 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 5 serious adverse event of COVID-19 infection (onset 1/1/2021, diagnosis 1/5/2021).

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 02 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 08 Jan 2021 (Study Day 127), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
01 Jan 2021 (Study Day 120)	Chills	Mild
01 Jan 2021 (Study Day 120)	Cough	Moderate
01 Jan 2021 (Study Day 120)	Fatigue	Mild
01 Jan 2021 (Study Day 120)	Nasal Congestion	Severe

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 121)	Chills	Mild
02 Jan 2021 (Study Day 121)	Cough	Moderate
02 Jan 2021 (Study Day 121)	Fatigue	Mild
02 Jan 2021 (Study Day 121)	Nasal Congestion	Severe
03 Jan 2021 (Study Day 122)	Chills	Mild
03 Jan 2021 (Study Day 122)	Cough	Moderate
03 Jan 2021 (Study Day 122)	Fatigue	Mild
03 Jan 2021 (Study Day 122)	Nasal Congestion	Severe
04 Jan 2021 (Study Day 123)	Chills	Mild
04 Jan 2021 (Study Day 123)	Cough	Moderate
04 Jan 2021 (Study Day 123)	Diarrhea	Mild
04 Jan 2021 (Study Day 123)	Fatigue	Mild
04 Jan 2021 (Study Day 123)	Nasal Congestion	Severe
04 Jan 2021 (Study Day 123)	Nausea	Mild
04 Jan 2021 (Study Day 123)	Vomiting	Mild
05 Jan 2021 (Study Day 124)	Chills	Mild
05 Jan 2021 (Study Day 124)	Cough	Moderate
05 Jan 2021 (Study Day 124)	Diarrhea	Mild
05 Jan 2021 (Study Day 124)	Difficulty Breathing	Severe
05 Jan 2021 (Study Day 124)	Fatigue	Mild
05 Jan 2021 (Study Day 124)	Nasal Congestion	Severe
05 Jan 2021 (Study Day 124)	Nausea	Mild
05 Jan 2021 (Study Day 124)	O2 Saturation (%)	90
05 Jan 2021 (Study Day 124)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 124)	Temperature (°F)	38.3
05 Jan 2021 (Study Day 124)	Vomiting	Mild
06 Jan 2021 (Study Day 125)	Cough	Mild
06 Jan 2021 (Study Day 125)	Difficulty Breathing	Mild
06 Jan 2021 (Study Day 125)	Fatigue	Mild
06 Jan 2021 (Study Day 125)	Nasal Congestion	Moderate
06 Jan 2021 (Study Day 125)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 126)	Cough	Mild
07 Jan 2021 (Study Day 126)	Difficulty Breathing	Mild
07 Jan 2021 (Study Day 126)	Fatigue	Mild
07 Jan 2021 (Study Day 126)	Nasal Congestion	Moderate
07 Jan 2021 (Study Day 126)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 127)	Cough	Mild
08 Jan 2021 (Study Day 127)	Difficulty Breathing	Mild
08 Jan 2021 (Study Day 127)	Fatigue	Mild
08 Jan 2021 (Study Day 127)	Nasal Congestion	Moderate
08 Jan 2021 (Study Day 127)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 128)	Cough	Mild
09 Jan 2021 (Study Day 128)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
09 Jan 2021 (Study Day 128)	Fatigue	Mild
09 Jan 2021 (Study Day 128)	Nasal Congestion	Moderate
09 Jan 2021 (Study Day 128)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 129)	Cough	Mild
10 Jan 2021 (Study Day 129)	Difficulty Breathing	Mild
10 Jan 2021 (Study Day 129)	Fatigue	Mild
10 Jan 2021 (Study Day 129)	Nasal Congestion	Moderate
10 Jan 2021 (Study Day 129)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 130)	Cough	Mild
11 Jan 2021 (Study Day 130)	Fatigue	Mild
11 Jan 2021 (Study Day 130)	Nasal Congestion	Moderate
11 Jan 2021 (Study Day 130)	O2 Saturation (%)	93
12 Jan 2021 (Study Day 131)	Cough	Mild
12 Jan 2021 (Study Day 131)	Fatigue	Mild
12 Jan 2021 (Study Day 131)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 132)	Difficulty Breathing	Mild
13 Jan 2021 (Study Day 132)	Shortness of Breath	Mild
14 Jan 2021 (Study Day 133)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 134)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 135)	Cough	Mild
16 Jan 2021 (Study Day 135)	Difficulty Breathing	Mild
16 Jan 2021 (Study Day 135)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 136)	Chills	Mild
17 Jan 2021 (Study Day 136)	Cough	Mild
17 Jan 2021 (Study Day 136)	Difficulty Breathing	Mild
17 Jan 2021 (Study Day 136)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 136)	O2 Saturation (%)	93
18 Jan 2021 (Study Day 137)	Chills	Mild
18 Jan 2021 (Study Day 137)	Cough	Mild
18 Jan 2021 (Study Day 137)	Difficulty Breathing	Mild
18 Jan 2021 (Study Day 137)	Nasal Congestion	Mild
18 Jan 2021 (Study Day 137)	Temperature (°F)	100.8
19 Jan 2021 (Study Day 138)	Chills	Mild
19 Jan 2021 (Study Day 138)	Cough	Mild
19 Jan 2021 (Study Day 138)	Difficulty Breathing	Mild
19 Jan 2021 (Study Day 138)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
05 Jan 2021 (Study Day 124)	Heart Rate >= 125 per Minute	Yes
05 Jan 2021 (Study Day 124)	Oxygen Saturation	90%

Dates	Severity Indication	Result
05 Jan 2021 (Study Day 124)	PaO2/FIO2 Ratio < 300 mm Hg	Yes
05 Jan 2021 (Study Day 124)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes
05 Jan 2021 (Study Day 124)	Vasopressors Required	Yes
05 Jan 2021 - 05 Jan 2021 (Study Day 124-124)	Clinical Evidence of Pneumonia	Yes
05 Jan 2021 - 05 Jan 2021 (Study Day 124-124)	Oxygen Saturation of SpO2 <= 93% on room air at sea level	Yes
05 Jan 2021 - 05 Jan 2021 (Study Day 124-124)	Radiographical Evidence of Pneumonia	Yes
20 Jan 2021 - 20 Jan 2021 (Study Day 139-139)	Acute Respiratory Distress Syndrome (ARDS)	Yes
20 Jan 2021 - 24 Jan 2021 (Study Day 139-143)	High-Flow Oxygen	Yes
21 Jan 2021 - 24 Jan 2021 (Study Day 140-143)	Non-Invasive Ventilation	Yes
24 Jan 2021 - 25 Feb 2021 (Study Day 143-175)	Admission to an intensive care unit due to SARS-CoV-2	Yes
24 Jan 2021 - 25 Feb 2021 (Study Day 143-175)	Mechanical Ventilation	Yes
24 Jan 2021 - 24 Jan 2021 (Study Day 143-143)	Respiratory Failure	Yes

On 01 Oct 2020 (Study Day 28), the IP dose was discontinued due to other. The event of COVID-19 infection (onset 1/1/2021, diagnosis 1/5/2021) lasted for 56 days, after which it was considered to be fatal on 25 Feb 2021 (Study Day 175). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 01 Jan 2021 (Study Day 120), the participant experienced a fatal serious adverse event of COVID-19 infection with symptom onset the same day and diagnosed on 05 Jan 2021 (Study Day 124) with a positive SARS-CoV-2 RT-PCR test result via nasopharyngeal swab collected on 08 Jan 2021 (Study Day 127).

From 01 Jan 2021 (Study Day 120) through 19 Jan 2021 (Study Day 138), the participant intermittently experienced mild chills, shortness of breath, fatigue, nausea, vomiting and diarrhea; mild to moderate cough; mild to severe nasal congestion, and difficulty breathing. The participant denied muscle aches, body aches, headache, loss of taste, loss of smell, runny nose, or sore throat.

On 02 Jan 2021 (Study Day 121), the participant took ibuprofen PO for a fever.

On 05 Jan 2021 (Study Day 124), the participant was seen for symptoms suggestive of COVID-19 including fever, cough, and dyspnea on exertion. At the visit, the participant was noted to be coughing and short of breath with exertion; emergency medical services (EMS) was called and the participant was hospitalized. COVID-19 pneumonia was diagnosed, with clinical and

radiographical evidence including pulmonary infiltrates, hypoxemia, and a positive RT-PCR for SARS-CoV2. The participant had an oxygen saturation of 90% on room air at sea level, was hypoxic with ambulation (O_2 saturation 89%) but was otherwise medically stable with no end organ damage. The participant's temperature was noted as 38.3°C, which returned to normal 36.8°C on the following day. The participant did not require intensive care unit (ICU) admission or mechanical ventilation. The participant received remdesivir IV, and dexamethasone, enoxaparin SC, ibuprofen, and *Senna alexandrina* (all PO) for treatment of the event and ceftriaxone IV and ibuprofen PO for fever.

On 06 Jan 2021 (Study Day 125), participant's treatment included remdesivir IV, benzonatate, and dexamethasone PO.

On 11 Jan 2021(Study Day 130), the participant was discharged from the hospital. On the same day, the participant was re-hospitalized and treated with a 5-day course of remdesivir and dexamethasone. The participant's O_2 saturation was 93% and returned to 94% the following day.

On 15 Jan 2021 (Study Day 134), the participant was discharged from the hospital, for the second time, and was stable until the participant discontinued dexamethasone.

On 16 Jan 2021 (Study Day 135), the participant noted fevers, worsening hypoxia, and shortness of breath.

On 17 Jan 2021 (Study Day 136), the participant's O_2 saturation was 93%.

On 18 Jan 2021(Study Day 137), the participant's O_2 saturation returned to normal, 97%; temperature 100.8°F and normalized to 100.1°F the following day.

On 19 Jan 2021 (Study Day 138), the participant took paracetamol PO for the event.

On 20 Jan 2021 (Study Day 139), the participant called EMS and was re-admitted to the hospital for acute respiratory failure secondary to pneumonia, requiring high flow oxygen and bilevel noninvasive positive pressure ventilation. Despite reinstitution of steroids, empiric treatment for bacterial pneumonia, and empiric coverage for *Pneumocystis jirovecii* pneumonia, the participant developed worsening hypoxemia.

On 24 Jan 2021 (Study Day 143), the participant was intubated and transferred to the ICU. During the stay, the participant was sedated and paralyzed on mechanical ventilation with high ventilatory requirements and persistent hypoxemia. The participant had recurrent supraventricular tachycardia, treated with amiodarone and cardioversion. Additionally, the participant had electrolyte disturbances. Work-up revealed no other microbial explanation for pneumonia/acute respiratory distress syndrome (ARDS) other than SARS-CoV2 as the participant remained RT-PCR positive on 31 Jan 2021 (Study Day 150) and 25 Feb 2021 (Study Day 175). After

several weeks with no improvement, and given the severity of the lung damage, the participant's family elected to sign a do-not-resuscitate order.

On an unspecified date, the participant had a PaO_2/FIO_2 ratio less than 300 mm Hg and evidence of shock requiring vasopressors with systolic blood pressure less than 90 mm Hg and diastolic blood pressure less than 60 mm Hg and heart rate of more than or equal to 125 beats per minute.

On 21 Feb 2021 (Study Day 171), the participant's relevant laboratory test results showed white blood cell (WBC) count 21.97 (high), hemoglobin (Hgb) 9.8 (low), hematocrit (Hct) 33.8 (low), and platelets 70 (low) (no units or reference range provided).

On 23 Feb 2021 (Study Day 173), the participant's relevant laboratory test results showed creatinine 1.19 (high), blood urea nitrogen (BUN) 111 (high), glucose 151 (high), calcium 8.1 (low), WBC 18.77 (high), Hct 33.2 (low), and prothrombin time (PT) 13.3 (high) (no units or reference range provided).

On 24 Feb 2021 (Study Day 174), the participant's relevant laboratory test results showed creatinine 1.31 (high) and BUN 114 (high) (no units or reference range provided).

On 25 Feb 2021 (Study Day 175), the participant's relevant laboratory test results showed WBC 23.11 (high), Hgb 10.5 (low), Hct 35.1 (low), platelets 120 (low), potassium 5.3 and 5.5 (high), creatinine 1.57 (high), BUN 129 (high), magnesium 2.5 and 2.6 (high), phosphate 5.9 (high), and calcium 8.0 (low) (no units or reference range provided). The participant died from ARDS with the only identified causative organism being SARS-CoV2.

Action taken with study IP in response to the event was not applicable, as the participant refused to receive a second dose.

The event, COVID-19 infection, was reported as fatal on 25 Feb 2021 (Study Day 175). The cause of death was reported as ARDS due to COVID-19.

The investigator assessed the event, COVID-19 infection, as not related to the study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002834	COVID-19 infection

Study Completion/Discontinuation

On 25 Feb 2021 (Study Day 175), the participant discontinued from the study due to death. On 25 Feb 2021 (Study Day 175), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Constipation	Constipation	Not reported - Ongoing
HIV infection	Human immunodeficiency virus infection	Not reported - Ongoing
Insulin resistance	Insulin resistance	Not reported - Ongoing
Depression	Depression	2000 - Ongoing
Herpes simplex	Herpes simplex	2000 - Ongoing
Hepatic cirrhosis	Cirrhosis of liver due to hepatitis c	2007 - Ongoing
Hypertension	Hypertension	2007 - Ongoing
Lipodystrophy acquired	Lipodystrophy due to aids antiretroviral therapy	2007 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia associated with nocturia	2010 - Ongoing
Bundle branch block right	Exercise-induced right bundle branch block during exercise stress test - asymptomatic	2012 - Ongoing
Large intestine polyp	Colonic polyps	2013 - Not reported
Hepatitis C	Hepatitis c	2015 - 2015
Oesophageal variceal ligation	Esophageal varices with h/o banding	2016 - Ongoing
Portal hypertensive gastropathy	Portal hypertensive gastropathy	10 Oct 2019 (Study Day -330) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bisacodyl	28 Apr 2016 (Study Day -1590) - Ongoing	Constipation
Valaciclovir hydrochloride	07 Jun 2017 (Study Day -1185) - Ongoing	Hsv
Azelastine hydrochloride	24 Sep 2018 (Study Day -711) - Ongoing	Allergies
Clotrimazole	12 Nov 2018 (Study Day -662) - Ongoing	Unknown
Bictegravir sodium; emtricitabine; tenofovir alafenamide fumarate	20 Apr 2020 (Study Day -137) - Ongoing	Hiv
Escitalopram	20 Apr 2020 (Study Day -137) - Ongoing	Depression

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	20 Apr 2020 (Study Day -137) - Ongoing	Esophageal Varices, Portal Hypertensive Gastropathy
Vitamins nos	20 Apr 2020 (Study Day -137) - Ongoing	Nutritional Supplement
Influenza vaccine	02 Oct 2020 (Study Day 29) - 02 Oct 2020 (Study Day 29)	Influenza Prophylaxis
Ibuprofen	02 Jan 2021 (Study Day 121) - 03 Jan 2021 (Study Day 122)	Fever (COVID-19 Symptoms)
Ceftriaxone	05 Jan 2021 (Study Day 124) - 05 Jan 2021 (Study Day 124)	Fever (Related To COVID-19)
Dexamethasone	05 Jan 2021 (Study Day 124) - 16 Jan 2021 (Study Day 135)	COVID-19
Enoxaparin sodium	05 Jan 2021 (Study Day 124) - 11 Jan 2021 (Study Day 130)	COVID-19
Ibuprofen	05 Jan 2021 (Study Day 124) - 05 Jan 2021 (Study Day 124)	COVID-19
Remdesivir	05 Jan 2021 (Study Day 124) - 05 Jan 2021 (Study Day 124)	COVID-19
Sennoside a+b	05 Jan 2021 (Study Day 124) - 11 Jan 2021 (Study Day 130)	COVID-19
Benzonatate	06 Jan 2021 (Study Day 125) - 11 Jan 2021 (Study Day 130)	COVID-19
Dexamethasone	06 Jan 2021 (Study Day 125) - 15 Jan 2021 (Study Day 134)	COVID-19
Remdesivir	06 Jan 2021 (Study Day 125) - 09 Jan 2021 (Study Day 128)	COVID-19
Melatonin	09 Jan 2021 (Study Day 128) - 09 Jan 2021 (Study Day 128)	Insomnia
Paracetamol	19 Jan 2021 (Study Day 138) - 19 Jan 2021 (Study Day 138)	COVID-19
Hi-flow oxygen and bi-level non-invasive positive pressure ventilation*	20 Jan 2021 (Study Day 139) - 20 Jan 2021 (Study Day 139)	Adverse Event
Intubation*	24 Jan 2021 (Study Day 143) - 24 Jan 2021 (Study Day 143)	Adverse Event
Cardioversion*	12 Feb 2021 (Study Day 162) - 12 Feb 2021 (Study Day 162)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 3/severe	Related	04 Sep 2020 (Study Day 1) - 11 Sep 2020 (Study Day 8)
Fatigue	Grade 3/severe	Related	05 Sep 2020 (Study Day 2) - 11 Sep 2020 (Study Day 8)
Fatigue	Grade 1/mild	Related	11 Sep 2020 (Study Day 8) - 02 Oct 2020 (Study Day 29)
Abdominal Pain Lower	Grade 1/mild	Not related	23 Oct 2020 (Study Day 50) - 26 Oct 2020 (Study Day 53)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2060 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 26)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	24 Nov 2020 (Study Day 111) – 24 Nov 2020 (Study Day 111)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2060, a 62-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 31 Aug 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Nov 2020 (Study Day 111), 110 days after the first dose and 85 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction was considered to be fatal on 24 Nov 2020 (Study Day 111). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 24 Nov 2020 (Study Day 111), the participant experienced a fatal serious adverse event of myocardial infarction (MI).

On 04 Dec 2020 (Study Day 121), the site contacted the participant's sibling who reported that the participant was found dead on 30 Nov 2020 (Study Day 117) but may have expired 1 week prior.

Action taken with study IP in response to the event was not applicable as the participant had already received both scheduled doses.

The participant died on 24 Nov 2020 (Study Day 111). According to the participant's death certificate, the cause of death was reported as probable MI.

The investigator assessed the event, MI, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001025	Myocardial infarction

Study Completion/Discontinuation

On 24 Nov 2020 (Study Day 111), the participant discontinued from the study due to death. On 24 Nov 2020 (Study Day 111), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Inguinal hernia	Left side inguinal hernia	(b) (6) 1958 (Study Day (b) (6) - 1966
Inguinal hernia repair	Left side inguinal hernia operation	1966 - 1966
Anxiety	Anxiety	1967 - Ongoing
Blood cholesterol increased	High cholesterol	1998 - Ongoing
Depression	Depression	2000 - Ongoing
Colon adenoma	Tubular adenoma of colon	2019 - Ongoing
Presbyacusis	Presbycusis both side	2019 - Ongoing
Tinnitus	Tinnitis	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion hydrochloride	2005 - Ongoing	Depression
Colecalciferol	2005 - Ongoing	General Health
Duloxetine hydrochloride	2005 - Ongoing	Depression
Atorvastatin	2018 - Ongoing	High Cholesterol
Other alimentary tract and metabolism products	Aug 2019 - Ongoing	General Health
Vitamins nos	Aug 2019 - Ongoing	General Health
Influenza vaccine	22 Sep 2020 (Study Day 48) - 22 Sep 2020 (Study Day 48)	Flu Prevention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride; paracetamol	16 Oct 2020 (Study Day 72) - 16 Oct 2020 (Study Day 72)	COVID-Like Illness
Diphenhydramine hydrochloride; paracetamol	17 Oct 2020 (Study Day 73) - 17 Oct 2020 (Study Day 73)	COVID-Like Illness
Zinc acetate; zinc gluconate	17 Oct 2020 (Study Day 73) - 17 Oct 2020 (Study Day 73)	COVID-Like Illness
Diphenhydramine hydrochloride; paracetamol	18 Oct 2020 (Study Day 74) - 18 Oct 2020 (Study Day 74)	COVID-Like Illness
Zinc acetate; zinc gluconate	18 Oct 2020 (Study Day 74) - 18 Oct 2020 (Study Day 74)	COVID-Like Illness
Zinc acetate; zinc gluconate	19 Oct 2020 (Study Day 75) - 19 Oct 2020 (Study Day 75)	COVID-Like Illness

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hordeolum	Grade 1/mild	Not related	29 Sep 2020 (Study Day 55) - 01 Oct 2020 (Study Day 57)
Suspected COVID-19	Grade 2/moderate	Not related	16 Oct 2020 (Study Day 72) - 21 Oct 2020 (Study Day 77)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2141 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardio-Respiratory Arrest/Cardiopulmonary Arrest	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	09 Mar 2021 (Study Day 183) – 09 Mar 2021 (Study Day 183)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2141, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Mar 2021 (Study Day 183), 182 days after the first dose and 154 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of cardio-respiratory arrest. Action taken with the IP was not applicable. The event of cardiopulmonary arrest was considered to be fatal on 09 Mar 2021 (Study Day 183). The investigator assessed the event of cardio-respiratory arrest to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 09 Mar 2021 (Study Day 183), the participant experienced a fatal serious adverse event of cardio-respiratory arrest. On the same day, the participant was hospitalized for a cardiopulmonary arrest related to the underlying medical conditions of coronary artery disease and atrial fibrillation requiring implantable cardioverter defibrillator. Earlier in the day, the participant had a leak in the house and ran upstairs quickly to check. After the rapid movement, their heart was racing, and they collapsed and lost consciousness. They briefly regained consciousness but then quickly lost consciousness again. The participant had no other complaints, seizure activity, or "holding chest." Their family began bystander cardiopulmonary resuscitation (CPR) 2 minutes after they collapsed. The participant was transported to the emergency department (ED) via emergency medical services (EMS). The EMS reported that the participant's initial rhythm was pulseless electrical activity

(PEA), thus they placed a supraglottic airway device (i-gel) and put them on an automated active compression-decompression CPR device (LUCAS) to continue CPR. The EMS administered 5 rounds of epinephrine on route to the ED with no return of pulses; the participant's blood glucose was noted to be 165 mg/dL (reference range 70 to 99 mg/dL).

Upon arrival in the ED, the participant's rhythm was PEA and CPR was continued using the LUCAS. They were given 2 doses of calcium, 2 grams of magnesium, and 1 more dose of epinephrine in the ED with good effect; return of spontaneous circulation (ROSC) was obtained at 07:47. The participant was intubated. They had an episode of ventricular tachycardia and were defibrillated at 200 joules. The participant briefly lost pulses again at 07:53 and compressions were resumed, with return of their pulse at 07:55. Vital signs included blood pressure 126/76 mm Hg at 08:09, oxygen saturation 98% with FiO_2 100% at 07:58. Physical examination revealed ill appearance; cool skin; nonreactive pupils; no spontaneous circulation; i-gel in place, ventilated respirations; Glasgow coma scale included eyes open 1/4, verbal response 1/5, motor response 1/6, and total score 3; and the rest of the physical examination results were normal. Laboratory data at 08:36 included potassium 4.8 mmol/L (reference range 3.5 to 5.1 mmol/L), magnesium 3.8 mg/dL (high) (reference range 1.8 to 2.4 mg/dL), lactic acid 6.7 mmol/L (high) (reference range 0.5 to 2.2 mmol/L), carbon dioxide 17 mmol/L (low) (reference range 24 to 31 mmol/L), anion gap 14.8 mmol/L (reference range 10 to 20 mmol/L), blood glucose 342 mg/dL (high) (reference range 70 to 99 mg/dL), calcium 16.1 mg/dL (high) (reference range 8.5 to 10.5 mg/dL), total creatine kinase 385 U/L (high) (reference 12 to 191 U/L), troponin-I 0.35 ng/mL (reference range 0 to 0.40 ng/mL). Blood gas results showed pH 7.10 (low) (reference range 7.35 to 7.45), pCO_2 45 mm Hg (reference range 35 to 45 mm Hg), pO_2 271 mm Hg (high) (reference range 80 to 100 mm Hg), bicarbonate 14 mmol/L (low) (reference range 22 to 26 mmol/L), base excess -15 mmol/L (low) (reference range -2 to 2 mmol/L), arterial oxygen saturation 99.8% (reference range 95 to 100%). Electrocardiogram (ECG) at 08:54 showed ventricular rate 63 beats per minute (bpm) with electronic ventricular pacemaker replacing sinus rhythm. A COVID-19 nucleic acid amplification test was negative. There was no clear history to suggest pulmonary coronary thrombosis, and the participant's ECG was without signs of ST-elevation myocardial infarction (STEMI). The participant was not hypothermic. They had hyperkalemia, which was possible given their response to the administration of calcium. There were no signs on bedside ultrasound of cardiac tamponade or tension pneumothorax. There was no reported serious trauma to suggest hypovolemic shock and blood loss. The participant did not have any history that would suggest ingestion, and nothing in their history to suggest severe acidosis. Laboratory test result data were notable for a mild troponin elevation (value and time of test not reported) after initially being negative; this elevation could have been due to CPR for non-STEMI. The participant was acidotic with lactic acidosis, suspected to be secondary to tissue hypoperfusion in the setting of arrest. The participant had hyperglycemia, however, with only a mild gap that could be explained

by their lactic acidosis. Treatment included cefepime IV in sterile water and vancomycin/sodium chloride IV. Vital signs at 09:32 included blood pressure 185/77 mm Hg, peripheral pulse rate 69 bpm, respiratory rate 19 breaths per minute, and oxygen saturation 100%.

Laboratory data at 10:13 included potassium 5.4 mmol/L (high), magnesium 3.3 mg/dL (high), lactic acid 2.8 mmol/L (high), carbon dioxide 20 mmol/L (low), anion gap 11.4 mmol/L, blood glucose 263 mg/dL (high), calcium 13.6 mg/dL, and troponin-I 5.28 ng/mL (high). Blood gas showed pH 7.21 (low), pCO_2 40 mm Hg, pO_2 330 mm Hg (high), bicarbonate 17 mmol/L (low), base excess -11 mmol/L (low), and arterial oxygen saturation 99.9%. A computerized tomography scan of the brain without contrast revealed no intracranial abnormality, mild deep white matter periventricular ischemic changes, and paranasal sinus mucosal disease. After speaking with the participant's outpatient cardiologist, the participant was transferred to the intensive care unit (ICU) and started on sedation and cooling. A review of systems was not obtained due to the participant's clinical condition and altered mental status. Blood gas at 12:33 showed pH 7.19 (low), pCO_2 44 mm Hg, pO_2 159 mm Hg (high), bicarbonate 17 mmol/L (low), base excess -11 mmol/L (low), and arterial oxygen saturation 99%. Laboratory data at 12:35 included potassium 5.4 mmol/L (high), magnesium 3.1 mg/dL (high), carbon dioxide 18 mmol/L (low), anion gap 15.4 mmol/L, blood glucose 259 mg/dL (high), calcium 13.3 mg/dL (high), and troponin-I 17.80 ng/mL (high). Laboratory data at 12:36 included lactic acid 1.6 mmol/L. An ECG at 13:13 showed no ST-T changes, normal PR and QRS intervals, and a paced rhythm without any significant ST segment discordance or concordance. Vital signs at 13:15 included temperature 95.1°F degrees (rectal), apical heart rate 69 bpm, respiratory rate 10 breaths per minute (low), systolic blood pressure 163 mm Hg (high). Physical examination revealed no acute distress; the participant was not alert and oriented; respirations nonlabored with support of ventilator; heart rate normal; altered level of consciousness (comatose), abnormal movements: myoclonus and tics (bilateral upper and lower extremities); not cooperative; and palliative performance scale 10 (no reference range provided). Electrophysiology was consulted for interrogation of the participant's defibrillator, as the participant had what appeared to be ventricular tachycardia without activation of their implanted defibrillator. Vital signs included pulse 66 bpm, rhythm A-sensed biventricular paced, blood pressure 107/79 mm Hg, and oxygen saturation 98% (intubated). Interrogation of biventricular pacemaker defibrillator revealed normal function, and no arrhythmias were noted, with only an episode of nonsustained ventricular tachycardia. Transthoracic echocardiogram with Doppler was performed that showed left ventricular ejection fraction of 25 to 30%, blood pressure 133/80 mm Hg, and heart rate 66 bpm. Laboratory data at 16:27 included blood glucose 232 mg/dL (high). Laboratory data at 17:58 included troponin-I 26.40 ng/mL (high). Blood gas included pH 7.17 (low), pCO_2 43 mm Hg, pO_2 83 mm Hg, bicarbonate 16 mmol/L (low), base excess -12 mmol/L (low), and arterial oxygen saturation 92.7% (low).

After being transferred to the ICU, the participant again had a cardiac arrest that evening. A code blue was called, and CPR was started. The participant received advanced cardiac life support medications with brief ROSC; unfortunately, the participant's systolic blood pressure remained in the 40s mm Hg despite maximum norepinephrine/dopamine/epinephrine drips. Vasoactive and bicarbonate drips were ordered. The participant subsequently went into ventricular fibrillation with defibrillation given as well as their own automatic implantable cardioverter-defibrillator (AICD) firing. Maximal efforts were given with bicarbonate/epinephrine/calcium chloride pushes and subsequent defibrillations as well as the participant's own defibrillator firing. The participant deteriorated to sustained ventricular fibrillation with their own AICD firing. No heart sounds could be auscultated. There were no palpable pulses via the right carotid artery or right radial artery. Asystole was shown on telemetry with flat A-line. When the ventilator was turned off, there was no chest rise and no auscultated breath sounds. The participant's pupils were fixed and dilated. The time of death was declared to be 19:52.

Action taken with the study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The participant died on 09 Mar 2021 (Study Day 183). The causes of death reported were ventricular fibrillation arrest and nonischemic cardiomyopathy.

The investigator assessed the event, cardio-respiratory arrest secondary to ventricular fibrillation, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-038453	Cardio-respiratory arrest

Study Completion/Discontinuation

On 09 Mar 2021 (Study Day 183), the participant discontinued from the study due to death. On 09 Mar 2021 (Study Day 183), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	1990 - Ongoing
Hypothyroidism	Hypothyroidism	1995 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial fibrillation	Atrial fibrillation	2004 - Ongoing
Cardiac failure congestive	Congestive heart failure	2004 - Ongoing
Hypertension	Hypertension	2004 - Ongoing
Coronary artery disease	Coronary artery disease	2005 - Ongoing
Insomnia	Insomnia	2008 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Gout	Gout of both feet	2016 - Ongoing
Peptic ulcer	Peptic ulcer	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1995 - Ongoing	Hypothyroidism
Carvedilol	2004 - Ongoing	Congestive Heart Failure
Furosemide	2004 - Ongoing	Congestive Heart Failure
Acetylsalicylic acid	2005 - Ongoing	Coronary Artery Disease
Atorvastatin	2005 - Ongoing	Coronary Artery Disease
Alprazolam	2008 - Ongoing	Insomnia
Allopurinol	2016 - Ongoing	Gout
Colecalciferol	2016 - Ongoing	Supplement
Insulin	2016 - Ongoing	Diabetes Mellitus Type 2
Pantoprazole	2016 - Ongoing	Peptic Ulcer
Vitamins nos	2016 - Ongoing	Supplement
Amiodarone	Jan 2020 - Ongoing	Atrial Fibrillation
Apixaban	Jan 2020 - 15 Jan 2021 (Study Day 130)	Atrial Fibrillation
Influenza vaccine inact split 3v	14 Aug 2020 (Study Day -25) - 14 Aug 2020 (Study Day -25)	Prophylaxis For Influenza
Paracetamol	08 Oct 2020 (Study Day 31) - 08 Oct 2020 (Study Day 31)	Injection Site Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US387-2318 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Completed Suicide/Suicide	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	16 Sep 2020 (Study Day 21) – 16 Sep 2020 (Study Day 21)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2318, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 27 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 5 serious adverse event of completed suicide. On 16 Sep 2020 (Study Day 21), the IP dose was discontinued due to death. The event of suicide was considered to be fatal on 16 Sep 2020 (Study Day 21). The investigator assessed the event of completed suicide to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 20 Aug 2020 (Study Day –8), per the participant's family, the participant complained of stomach pain, constipation, and diarrhea.

On 16 Sep 2020 (Study Day 21), the participant experienced a fatal serious adverse event of suicide. The participant's family member contacted the site and indicated that their parent had committed suicide. The participant seemed to have had an obsessive concern about cancer and was convinced that a recent episode of constipation requiring an emergency department evaluation was due to concerns of cancer and the participant was relieved to know that the constipation was not due to cancer. The participant was prescribed bisacodyl suppositories and polyethylene glycol/electrolytes PO. The participant's family member suspected that their parent may have

purchased diet pills prior to their death, which contained caffeine. The family member also believed that their parent suffered from depression and may have thought about suicide before.

Action taken with the study IP in response to the event was not applicable.

The participant died on 16 Sep 2020 (Study Day 21). Per the death certificate, the cause of death was reported as multiple blunt force injuries.

The investigator assessed the event, completed suicide, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000304	Suicide

Study Completion/Discontinuation

On 16 Sep 2020 (Study Day 21), the participant discontinued from the study due to death. On 16 Sep 2020 (Study Day 21), the participant died due to adverse event. An autopsy was not performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rotator cuff repair	Left rotator cuff repair	1976 - 1976
Rotator cuff syndrome	Rotator cuff tear	1976 - 1976
Allergy to animal	Allergy to dogs	2010 - Ongoing
Umbilical hernia	Umbilical hernia	2017 - Ongoing
Umbilical hernia repair	Umbilical hernia repair	2017 - 2017
Constipation	Constipation	22 Aug 2020 (Study Day -5) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	2010 - Ongoing	Dog Allergies

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US387-2496 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 31)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Death/Death (Details Unknown)	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	17 Dec 2020 (Study Day 100) – 17 Dec 2020 (Study Day 100)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2496, a 61-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Dec 2020 (Study Day 100), 99 days after the first dose and 69 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of death. Action taken with the IP was not applicable. The event of death (details unknown) was considered to be fatal on 17 Dec 2020 (Study Day 100). The investigator assessed the event of death to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On an unspecified date, the participant was admitted to the hospital. No treatment information was reported by the investigator.

On an unspecified date in April 2021, the participant's emergency contact was called, and they reported that the participant had died in early December 2020.

Action taken with the study IP was not applicable in response to the event as the participant had already received both scheduled doses.

The participant died on 17 Dec 2020 (Study Day 100). The cause of death was unknown.

The investigator assessed the event, death (details unknown), as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-073412	Death

Study Completion/Discontinuation

On 17 Dec 2020 (Study Day 100), the participant discontinued from the study due to death. On 17 Dec 2020 (Study Day 100), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Intervertebral disc disorder	Damaged cervical disk	2004 - Ongoing
Musculoskeletal pain	Occasional generalized musculoskeletal pain	2004 - Ongoing
Neck pain	Occasional disc pain neck	2004 - Ongoing
Hypertension	Hypertension	2008 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	2014 - Ongoing
Asthma	Asthma	2016 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	2004 - Ongoing	Disc Pain
Enalapril	2008 - Ongoing	Hypertension
Gabapentin	2016 - Ongoing	Disc Pain
Metformin	2016 - Ongoing	Diabetes Mellitus Type Ii
Salbutamol	2016 - Ongoing	Asthma
Labetalol	2017 - Ongoing	Hypertension
Beclometasone dipropionate	2018 - Ongoing	Copd
Exenatide	Mar 2020 - 28 Sep 2020 (Study Day 20)	Diabetes Mellitus Type Ii

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dulaglutide	05 Oct 2020 (Study Day 27) - Ongoing	Type Ii Dm
Acetylsalicylic acid	10 Oct 2020 (Study Day 32) - 12 Oct 2020 (Study Day 34)	Injection Site Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US393-2147 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	16 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/Worsening Of Congestive Heart Failure	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	05 Oct 2020 (Study Day 20) – 11 Oct 2020 (Study Day 26)	Recovered/ resolved
Chronic Obstructive Pulmonary Disease/ Exacerbated COPD Caused By Worsening Congestive Heart Failure	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	05 Oct 2020 (Study Day 20) – 05 Nov 2020 (Study Day 51)	Recovered /resolved
Atrial Fibrillation/ Atrial Fibrillation	SAE	Grade 3/ severe	Not related	29 Dec 2020 (Study Day 105) – Ongoing	Not recovered/ not resolved
Cardiac Failure Congestive/Worsening Of Congestive Heart Failure	SAE	Grade 4	Not related	29 Dec 2020 (Study Day 105) – Ongoing	Not recovered/ not resolved
Chronic Kidney Disease/Worsening Of Chronic Kidney Disease	SAE	Grade 4	Not related	29 Dec 2020 (Study Day 105) – Ongoing	Not recovered/ not resolved
Acute Respiratory Failure/Acute Respiratory Failure	SAE	Grade 4	Not related	03 Jan 2021 (Study Day 110) – Ongoing	Not recovered/ not resolved
Blood Loss Anaemia/Anemia Secondary To Gi Bleed	SAE	Grade 3/ severe	Not related	06 Jan 2021 (Study Day 113) – Ongoing	Not recovered/ not resolved
COVID-19/COVID 19	SAE	Grade 4	Not related	06 Jan 2021 (Study Day 113) – Ongoing	Not recovered/ not resolved
Gastrointestinal Haemorrhage/Gi Bleed Of Unknown Cause	SAE	Grade 3/ severe	Not related	06 Jan 2021 (Study Day 113) – Ongoing	Not recovered/ not resolved
COVID-19 Pneumonia/Pneumonia Secondary To COVID-19	SAE	Grade 3/ severe	Not related	08 Jan 2021 (Study Day 115) – Not reported	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2147, an 84-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 16 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Oct 2020 (Study Day 20), 19 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of cardiac failure congestive. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of worsening of congestive heart failure lasted for 7 days, after which it was considered to be recovered/resolved on 11 Oct 2020 (Study Day 26). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

On 05 Oct 2020 (Study Day 20), 19 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of chronic obstructive pulmonary disease. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of exacerbated copd caused by worsening congestive heart failure lasted for 32 days, after which it was considered to be recovered/resolved on 05 Nov 2020 (Study Day 51). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

On 29 Dec 2020 (Study Day 105), 104 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of atrial fibrillation was considered to be ongoing. The investigator assessed the event of atrial fibrillation to be not related to the IP.

On 29 Dec 2020 (Study Day 105), 104 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of cardiac failure congestive. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of worsening of congestive heart failure was considered to be ongoing. The investigator assessed the event of cardiac failure congestive to be not related to the IP.

On 29 Dec 2020 (Study Day 105), 104 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of chronic kidney disease. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of worsening of chronic kidney disease was considered to be ongoing. The investigator assessed the event of chronic kidney disease to be not related to the IP.

On 03 Jan 2021 (Study Day 110), 109 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of acute respiratory failure. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute respiratory failure was considered to be ongoing. The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 06 Jan 2021 (Study Day 113), 112 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of blood loss anaemia. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of anemia secondary to gi bleed was considered to be ongoing. The investigator assessed the event of blood loss anaemia to be not related to the IP.

On 06 Jan 2021 (Study Day 113), 112 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of COVID-19. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of COVID 19 was considered to be ongoing. The investigator assessed the event of COVID-19 to be not related to the IP.

On 06 Jan 2021 (Study Day 113), 112 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of gastrointestinal haemorrhage. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of gi bleed of unknown cause was considered to be ongoing. The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

On 08 Jan 2021 (Study Day 115), 114 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of covid-19 pneumonia. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of pneumonia secondary to COVID-19 was considered to be ongoing. The investigator assessed the event of covid-19 pneumonia to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Oct 2020 (Study Day 20), the participant experienced serious adverse events (SAEs) of cardiac failure congestive and chronic obstructive pulmonary disease (COPD). On the same day, the participant experienced shortness of breath, nonradiating chest pressure without chills or fever and was hospitalized. The participant had complained of a dry cough for 2 weeks. An electrocardiogram (ECG) determined that the participant had worsening of congestive heart failure (CHF) which led to exacerbation of COPD. A chest x-ray was consistent with CHF. Both pulmonology and cardiology were consulted on admission. The participant's troponin was high at 19 ng/L (no reference range provided). A COVID-19 test result was negative. Treatment for exacerbated COPD included antibiotics IV and steroids IV. Treatment for worsening of CHF included nifedipine PO and furosemide IV. The participant's shortness of breath improved, but the participant developed an acute kidney injury. The kidney injury improved after stopping diuretics on an unreported date.

On 08 Oct 2020 (Study Day 23), an echocardiogram confirmed that the participant had worsening of their CHF which led to exacerbation of their COPD. On 09 Oct 2020 (Study Day 24), laboratory

test results included albumin 4.2, alkaline phosphatase 90, aspartate aminotransferase 36, alanine aminotransferase 23, and total bilirubin 0.2 (no units or reference range provided). On 10 Oct 2020 (Study Day 25), the participant's vital signs included temperature (oral) 36.6°C and laboratory test results included magnesium 2.6 (no units or reference range provided).

On 11 Oct 2020 (Study Day 26), the participant's vital signs included blood pressure 157/74 mm Hg, respiratory rate 18 breaths per minute, oxygen saturation 98%, temperature oral 36.4°C (97.5°F), and heart rate 74 beats/minute (bpm). Laboratory test results included white blood cell (WBC) 9.0, red blood cell 3.48, hemoglobin (Hgb) 10.6, hematocrit 34.0, mean corpuscular Hgb concentration 31.2, mean corpuscular volume 98, platelet count 195, blood sodium 141, blood potassium 4.7, chloride 102, carbon dioxide 29, blood glucose 138, blood urea nitrogen 85, creatinine 1.54, and calcium 9.0 (no units and reference ranges provided). On 11 Oct 2020 (Study Day 26), the participant was stable and discharged from the hospital on furosemide, metoprolol, nifedipine, prednisone, acetylsalicylic acid, cyanocobalamin, montelukast, glyceryl trinitrate, and pramipexole (all PO), and albuterol and albuterol-ipratropium (both inhaled). The participant was ambulating dependently without difficulty, and their dyspnea on exertion had improved. The participant's oxygen saturation was consistent with the participant's baseline oxygen saturation on oxygen at 3 L/min. The participant was advised to eat a heart healthy diet with less than 2 g of sodium per day and was scheduled for follow-up with primary care physician, nephrology, and pulmonology.

The study IP was discontinued in response to these events.

The event, cardiac failure congestive, was reported as resolved on 11 Oct 2020 (Study Day 26). The event, COPD, was reported as resolved on 05 Nov 2020 (Study Day 51).

The investigator assessed the events, COPD and cardiac failure congestive, as not related to study IP or study procedure.

From 05 Dec 2020 (Study Day 81) through 28 Dec 2020 (Study Day 104), the participant intermittently experienced mild to moderate chills; and mild to severe cough, shortness of breath, difficulty breathing, fatigue, and body aches. The participant denied muscle aches, headache, new loss of taste or smell, nasal congestion, runny nose, nausea, vomiting, diarrhea, and sore throat.

On 18 Dec 2020 (Study Day 94), a SARS-CoV-2 RT-PCR nasopharyngeal swab was negative.

On 29 Dec 2020 (Study Day 105), the participant experienced SAEs of atrial fibrillation, cardiac failure congestive, and chronic kidney disease and was hospitalized. The participant presented to an emergency department (ED) with a complaint of chest pain and palpitations. They reported that the pain started approximately 2 hours prior to the ED visit, and they took 10 tablets of acetylsalicylic acids (baby aspirin) for any alleviation of their pain. The participant's heart rate was up to 160 bpm. The participant felt better, and their chest pain improved after receiving

diltiazem IV and oxygen. The participant's oxygen saturation was >92%. In the ED, laboratory test results showed leukocytosis with WBC $14 \times 10^3/\mu L$, stable Hgb with chronic anemia, stable renal function (serum creatinine 1.4), an elevated brain natriuretic peptide (NT-pro BNP) of 45000 pg/mL, and elevated troponin T of 360 (previously 162) (no units or reference ranges provided). An ECG showed atrial fibrillation but no acute ischemia. A chest x-ray showed mild pulmonary congestion with trace left pleural effusion and atelectasis, but there was no sign of pneumonia. The participant's glomerular filtration rate ranged from 10 to 40 mL/min/1.73m^2 (reference range ≥69 mL/min/1.73m^2). The participant was treated with apixaban IV for worsening CHF, epoetin alfa PO for chronic kidney disease, and amiodarone PO for worsening CHF. No medications were given for atrial fibrillation. The participant had progressed to acute renal failure and required dialysis starting on 29 Dec 2020 (Study Day 105).

On 01 Jan 2021 (Study Day 108), the participant was given regadenoson IV for worsening of CHF. The participant's troponin ranged from 40 to 300 ng/L (reference range ≥11 ng/L).

On 03 Jan 2021 (Study Day 110), the participant experienced an SAE of acute respiratory failure and had a positive test result for COVID-19. The participant was given guaifenesin PO and *Plantago ovata* PO for pneumonia caused by COVID-19, and 3 L of oxygen.

On 04 Jan 2021 (Study Day 111), the participant was given ondansetron IV and tiotropium inhalation for COVID-19. A computerized tomography (CT) scan of the chest without contrast and a retro-peritoneal ultrasound were performed.

On 06 Jan 2021 (Study Day 113), the participant experienced SAEs of blood loss anemia, COVID-19, and gastrointestinal (GI) hemorrhage. On the same day, a nurse practitioner from the hospital requested an emergency unblinding due to the participant contracting COVID-19 in the hospital. On the same day, the participant Hgb values continued to drop. Blood transfusions were given on 07 Jan 2021 (Study Day 114), 08 Jan 2021 (Study Day 115), 11 Jan 2021 (Study Day 118), 16 Jan 2021 (Study Day 123), and 19 Jan 2021 (Study Day 126).

On 08 Jan 2021 (Study Day 115), the participant developed an SAE of COVID-19 pneumonia found in both lungs. The participant completed remdesivir IV and dexamethasone IV on an unreported date. The participant was seen by pulmonology and cardiology specialists and was on high flow oxygen that was eventually weaned to 4 L. On an unreported date, the participant developed chest pain. No catheterization intervention was performed as the participant required anticoagulation and there was a high bleeding risk with their significant drop in Hgb. The participant was also too high risk for an endoscopy.

During this hospitalization, 3 additional chest x-rays were performed on 06 Jan 2021 (Study Day 113), 08 Jan 2021 (Study Day 115), and 18 Jan 2021 (Study Day 125); a CT scan of the chest and abdomen and a nuclear medicine myocardial perfusion scan were performed on 01 Jan 2021

(Study Day 108); and echocardiograms were performed on 30 Dec 2020 (Study Day 106), 01 Jan 2021 (Study Day 108), 07 Jan 2021 (Study Day 114), and 17 Jan 2021 (Study Day 124); no results were reported for any of these tests.

Action taken with study IP in response to the events was not applicable.

The events, cardiac failure congestive, chronic kidney disease, atrial fibrillation, acute respiratory failure, blood loss anemia, COVID-19, COVID-19 pneumonia, and GI hemorrhage, were reported as not resolved.

The investigator assessed the events, CHF, chronic kidney disease, atrial fibrillation, acute respiratory failure, blood loss anemia, COVID-19, COVID-19 pneumonia, and GI hemorrhage, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001757	Atrial fibrillation
MOD-2021-001757	Cardiac failure congestive
MOD-2021-001757	Chronic kidney disease
MOD-2021-001757	Acute respiratory failure
MOD-2021-001757	Blood loss anaemia
MOD-2021-001757	COVID-19
MOD-2021-001757	Gastrointestinal haemorrhage
MOD-2021-001757	COVID-19 pneumonia
MOD-2020-000422	Chronic obstructive pulmonary disease
MOD-2020-000422	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug intolerance	Ambien intolerance	Not reported - Ongoing
Drug intolerance	Coticosteroid intolerance	Not reported - Ongoing
Cardiac murmur	Heart murmur - unknown etiology	(b) (6) 1936 - Ongoing
Asthma	Asthma	1939 - Ongoing
Migraine	Migraines	1945 - 2010
Uterine leiomyoma	Fibroid tumors	1950 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to morphine, codeine, and demerol	1956 - Ongoing
Drug hypersensitivity	Penicillin allergy	1956 - Ongoing
Drug hypersensitivity	Statin medication allergy	1956 - Ongoing
Hypertension	Hypertension	1956 - Ongoing
Nephrolithiasis	Kidney stones	1959 - 1959
Pneumonia	Lung infection	1960 - 1960
Blood cholesterol increased	High cholesterol	1984 - Ongoing
Hepatic enzyme increased	Liver enzyme elevation	1984 - 1984
Postmenopause	Post-menopausal	1989 - Ongoing
Chronic kidney disease	Chronic kidney disease	2000 - Ongoing
Upper limb fracture	Left arm fracture	2000 - 2000
Cataract	Bilateral cataracts	2009 - 2009
Renal cyst	Bilateral kidney cysts benign	2010 - Ongoing
Restless legs syndrome	Restless leg syndrome	2010 - Ongoing
Obesity	Obesity	2011 - Ongoing
Cardiac failure congestive	Congestive heart failure	2014 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2014 - Ongoing
Emphysema	Emphysema	2014 - Ongoing
Poor peripheral circulation	Poor circulation in legs	2014 - Ongoing
Upper limb fracture	Left shoulder fracture	2015 - 2015
Deafness bilateral	Bilateral hearing loss	2016 - Ongoing
Fluid retention	Bilateral ankle/ feet fluid retention	2016 - Ongoing
Urinary incontinence	Bladder incontinence	2016 - Ongoing
Intestinal ischaemia	Ischemic bowel disease	2017 - 2017
Myalgia	Muscle aches	2017 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Transfusion	Blood transfusion	2017 - 2017
Abdominal hernia	Abdominal hernia	2019 - Ongoing
Herpes zoster	Shingles	2019 - 2019
Constipation	Constipation	2020 - Ongoing
Anaemia	Anemia	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2000 - Ongoing	Emphysema/COPD/Asthma
Metoprolol	2010 - Ongoing	Hypertension
Pramipexole	2016 - Ongoing	Restless Leg Syndrome
Fluticasone	2017 - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Umeclidinium bromide; vilanterol trifenatate	2017 - Ongoing	Emphysema
Ipratropium; salbutamol	2018 - Ongoing	Emphysema/ COPD/Asthma
Vitamin B12 NOS	2018 - Ongoing	Vitamin Supplement
Docusate sodium	Apr 2020 - Ongoing	Constipation
Ferrous sulfate	Apr 2020 - Ongoing	Anemia
Hydralazine	May 2020 - Ongoing	Hypertension
Verapamil	May 2020 - Ongoing	Hypertension
Furosemide	Sep 2020 - Ongoing	Bilateral Ankle/ Feet fluid Retention
Potassium	Sep 2020 - Ongoing	Bilateral Ankle/ Feet fluid Retention
Chest x ray*	05 Oct 2020 (Study Day 20) - 05 Oct 2020 (Study Day 20)	Adverse Event
ECG*	05 Oct 2020 (Study Day 20) - 05 Oct 2020 (Study Day 20)	Adverse Event
Pramipexole dihydrochloride	05 Oct 2020 (Study Day 20) - Ongoing	Restless Leg Syndrome
Electrocardiogram*	07 Oct 2020 (Study Day 22) - 07 Oct 2020 (Study Day 22)	Adverse Event
Echocardiogram*	08 Oct 2020 (Study Day 23) - 08 Oct 2020 (Study Day 23)	Adverse Event
Glyceryl trinitrate	11 Oct 2020 (Study Day 26) - Ongoing	Worsening CHF
Nifedipine	11 Oct 2020 (Study Day 26) - Ongoing	Worsening Congestive Heart Failure
Doxycycline hyclate	22 Dec 2020 (Study Day 98) - Ongoing	Unknown Indication
Prednisone	22 Dec 2020 (Study Day 98) - Ongoing	COPD
Amiodarone	29 Dec 2020 (Study Day 105) - Ongoing	Worsening CHF
Apixaban	29 Dec 2020 (Study Day 105) - 06 Jan 2021 (Study Day 113)	Worsening CHF
Chest x-ray*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Dialysis*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Diltiazem	29 Dec 2020 (Study Day 105) - Ongoing	Worsening CHF
Echocardiogram*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Electrocardiogram*	29 Dec 2020 (Study Day 105) - 29 Dec 2020 (Study Day 105)	Adverse Event
Epoetin alfa	29 Dec 2020 (Study Day 105) - Ongoing	Chronic Kidney Disease
Glucagon	29 Dec 2020 (Study Day 105) - Ongoing	Diabetes Mellitus
Glucose	29 Dec 2020 (Study Day 105) - Ongoing	Diabetes Mellitus Type 2
Insulin	29 Dec 2020 (Study Day 105) - Ongoing	Diabetes Mellitus Type 2
Methylprednisolone	29 Dec 2020 (Study Day 105) - Ongoing	Worsening COPD
Pantoprazole	29 Dec 2020 (Study Day 105) - 06 Jan 2021 (Study Day 113)	GERD
Electrocardiogram*	30 Dec 2020 (Study Day 106) - 30 Dec 2020 (Study Day 106)	Adverse Event
Electrocardiogram*	01 Jan 2021 (Study Day 108) - 01 Jan 2021 (Study Day 108)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Nuclear medicine myocardial perfusion scan*	01 Jan 2021 (Study Day 108) - 01 Jan 2021 (Study Day 108)	Adverse Event
Regadenoson	01 Jan 2021 (Study Day 108) - 01 Jan 2021 (Study Day 108)	Worsening Of CHF
Guaifenesin	03 Jan 2021 (Study Day 110) - Ongoing	Pneumonia Caused By COVID
Oxygen	03 Jan 2021 (Study Day 110) - 21 Jan 2021 (Study Day 128)	Acute Respiratory Failure
Plantago ovata	03 Jan 2021 (Study Day 110) - Ongoing	Pneumonia Caused By COVID
CT chest without contrast*	04 Jan 2021 (Study Day 111) - 04 Jan 2021 (Study Day 111)	Adverse Event
Ondansetron	04 Jan 2021 (Study Day 111) - Ongoing	COVID-19
Retro-peritoneal ultrasound*	04 Jan 2021 (Study Day 111) - 04 Jan 2021 (Study Day 111)	Adverse Event
Tiotropium	04 Jan 2021 (Study Day 111) - Ongoing	COVID-19
Chest x-ray*	06 Jan 2021 (Study Day 113) - 06 Jan 2021 (Study Day 113)	Adverse Event
Blood transfusion*	07 Jan 2021 (Study Day 114) - 07 Jan 2021 (Study Day 114)	Adverse Event
Electrocardiogram*	07 Jan 2021 (Study Day 114) - 07 Jan 2021 (Study Day 114)	Adverse Event
Blood transfusion*	08 Jan 2021 (Study Day 115) - 08 Jan 2021 (Study Day 115)	Adverse Event
Chest x-ray*	08 Jan 2021 (Study Day 115) - 08 Jan 2021 (Study Day 115)	Adverse Event
Blood transfusion*	11 Jan 2021 (Study Day 118) - 11 Jan 2021 (Study Day 118)	Adverse Event
Blood transfusion*	16 Jan 2021 (Study Day 123) - 16 Jan 2021 (Study Day 123)	Adverse Event
Electrocardiogram*	17 Jan 2021 (Study Day 124) - 17 Jan 2021 (Study Day 124)	Adverse Event
Chest x-ray*	18 Jan 2021 (Study Day 125) - 18 Jan 2021 (Study Day 125)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)
Diarrhoea	Grade 1/mild	Not related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)
Dyspnoea	Grade 1/mild	Not related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)
Fatigue	Grade 1/mild	Not related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)
Headache	Grade 1/mild	Related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)
Myalgia	Grade 1/mild	Related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)
Nasal Congestion	Grade 1/mild	Not related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)
Rhinorrhoea	Grade 1/mild	Not related	20 Sep 2020 (Study Day 5) - 27 Sep 2020 (Study Day 12)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acute Kidney Injury	Grade 2/moderate	Not related	05 Oct 2020 (Study Day 20) - 11 Oct 2020 (Study Day 26)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 122) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2246 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	13 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	10 Nov 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Death/Death-Pending Autopsy*	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	02 Jan 2021 (Study Day 82) – 02 Jan 2021 (Study Day 82)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

* According to information from the safety database, the preferred term was "Illicit drug intoxication" and the verbatim term was "death due to toxic effects of fentanyl".

Participant US393-2246, a 37-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 10 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Jan 2021 (Study Day 82), 81 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of death. Action taken with the IP was not applicable. The event of death-pending autopsy was considered to be fatal on 02 Jan 2021 (Study Day 82). The investigator assessed the event of death to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 02 Jan 2021 (Study Day 82), the participant experienced a fatal serious adverse event of illicit drug intoxication. On that day, the participant was found unresponsive. The emergency personnel responded and death was pronounced on scene. The participant was last known alive on the evening of 01 Jan 2021 (Study Day 81) and had no complaints at that time. No trauma or homicide was suspected. Per the participant's family member, the participant was not ill or had recent hospitalization.

On 04 Jan 2021 (Study Day 84), an autopsy was performed. The cause of death was listed as toxic effects of fentanyl. The manner of death was accident and the injury occurred via use of fentanyl. Internal examination findings included toxic effects of fentanyl (pulmonary edema and congestion; moderate cerebral edema), obesity (cardiomegaly, 475 g, with biventricular dilation; cholesterosis), nephrosclerosis, and polycystic ovaries. Postmortem examination showed no significant trauma. Postmortem toxicology revealed fentanyl as well as hydroxyzine, venlafaxine, nicotine, and caffeine. Based on the findings, reported circumstances of death, and all other investigative information received, it was the medical examiner's opinion that the cause of death was the toxic effects of fentanyl.

Samples of cardiac blood, iliac blood, vitreous fluid, and urine were collected and submitted for toxicological analysis. Positive findings from the toxicology report (from iliac blood sample) included despropionyl fentanyl positive (report limit 0.10 ng/mL), caffeine positive (report limit 0.20 µg/mL), cotinine positive (report limit 200 ng/mL), nicotine positive (report limit 100 ng/mL), venlafaxine 24 ng/mL (report limit 20 ng/mL), O-desmethylvenlafaxine 290 ng/mL (report limit 20 ng/mL), hydroxyzine 31 ng/mL (report limit 5.0 ng/mL), fentanyl 16 ng/mL (report limit 0.10 ng/mL), and norfentanyl 7.7 ng/mL (report limit 0.20 ng/mL). The examination of the specimens submitted did not reveal any additional positive findings of toxicological significance.

Action taken with the study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The participant died on 02 Jan 2021 (Study Day 82). The cause of death was reported as toxic effects of fentanyl.

The investigator assessed the event, toxicity to various agents, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001844	Illicit drug intoxication

Study Completion/Discontinuation

On 02 Jan 2021 (Study Day 82), the participant discontinued from the study due to death. On 02 Jan 2021 (Study Day 82), the participant died due to adverse event. An autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	Not reported - Ongoing
Lactose intolerance	Lactose intolerance	1993 - Ongoing
Female sterilisation	Bilateral tubal ligation	22 Nov 2011 (Study Day -3248) - 22 Nov 2020 (Study Day 41)
Anxiety	Anxiety	2015 - Ongoing
Depression	Depression	2015 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	2015 - Ongoing
Psoriasis	Psoriasis - elbows	2015 - Ongoing
Psoriasis	Psoriasis - knees	2015 - Ongoing
Umbilical hernia	Umbilical hernia	2018 - 2018
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disorder	Dec 2019 - Ongoing
Nephrolithiasis	Kidney stone	Dec 2019 - Dec 2019
Nephrolithiasis	Kidney stone	Feb 2020 - Feb 2020
Hypothyroidism	Hypothyroidism	Sep 2020 - Ongoing
Cervicitis	Cervicitis	02 Oct 2020 (Study Day -11) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	Jun 2020 - Ongoing	Post Traumatic Stress Disorder
Hydroxyzine	Jun 2020 - Ongoing	Anxiety
Venlafaxine	Jun 2020 - Ongoing	Post Traumatic Stress Disorder, Anxiety
Fluticasone propionate; salmeterol xinafoate	25 Sep 2020 (Study Day -18) - Ongoing	Chronic Obstructive Pulmonary Disease
Levothyroxine	25 Sep 2020 (Study Day -18) - Ongoing	Hypothyroidism
Salbutamol sulfate	25 Sep 2020 (Study Day -18) - Ongoing	Chronic Obstructive Pulmonary Disease
Doxycycline	02 Oct 2020 (Study Day -11) - 16 Oct 2020 (Study Day 4)	Cervicitis
Metronidazole	02 Oct 2020 (Study Day -11) - 16 Oct 2020 (Study Day 4)	Cervicitis
Paracetamol	02 Oct 2020 (Study Day -11) - Ongoing	Cervical Infection Pain
Levonorgestrel	26 Oct 2020 (Study Day 14) - Ongoing	Birth Control

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	10 Nov 2020 (Study Day 29) - 21 Nov 2020 (Study Day 40)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378065

Participant Number:	US395-2094 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	15 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	14 Oct 2020 (Study Day 30)
Reason for Narrative:	Death, SAE, Severe COVID-19, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ SARS-Cov-2 Infection	Death, SAE, COVID-19, AE leading to study discontinuation	Grade 5	Not related	24 Dec 2020 (Study Day 101) – 30 Jan 2021 (Study Day 138)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US395-2094, a 57-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Dec 2020 (Study Day 101), 100 days after the first dose and 71 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of covid-19. Action taken with the IP was not applicable. The event of SARS-CoV-2 infection lasted for 38 days, after which it was considered to be fatal on 30 Jan 2021 (Study Day 138). The investigator assessed the event of covid-19 to be not related to the IP.

Severe COVID-19 Details

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 14 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 24 Dec 2020 (Study Day 101), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
01 Jan 2020 (Study Day -258)	Cough	Mild
01 Jan 2020 (Study Day -258)	Shortness of Breath	Mild
22 Dec 2020 (Study Day 99)	Cough	Mild
22 Dec 2020 (Study Day 99)	Shortness of Breath	Mild
23 Dec 2020 (Study Day 100)	Cough	Mild
23 Dec 2020 (Study Day 100)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 101)	New Loss of Smell	Mild
24 Dec 2020 (Study Day 101)	O2 Saturation (%)	89
24 Dec 2020 (Study Day 101)	Runny Nose (Rhinorrhea)	Mild
24 Dec 2020 (Study Day 101)	Temperature (°F)	39.0
25 Dec 2020 (Study Day 102)	Cough	Mild
25 Dec 2020 (Study Day 102)	New Loss of Smell	Mild
25 Dec 2020 (Study Day 102)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 103)	Cough	Mild
26 Dec 2020 (Study Day 103)	New Loss of Smell	Mild
26 Dec 2020 (Study Day 103)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 104)	Cough	Mild
27 Dec 2020 (Study Day 104)	New Loss of Smell	Mild
27 Dec 2020 (Study Day 104)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 105)	Cough	Mild
28 Dec 2020 (Study Day 105)	New Loss of Smell	Mild
28 Dec 2020 (Study Day 105)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 106)	Cough	Mild
29 Dec 2020 (Study Day 106)	New Loss of Smell	Mild
29 Dec 2020 (Study Day 106)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 107)	Cough	Mild
30 Dec 2020 (Study Day 107)	New Loss of Smell	Mild
30 Dec 2020 (Study Day 107)	Shortness of Breath	Mild
31 Dec 2020 (Study Day 108)	Cough	Mild
31 Dec 2020 (Study Day 108)	Shortness of Breath	Mild
02 Jan 2021 (Study Day 110)	Cough	Mild
02 Jan 2021 (Study Day 110)	Diarrhea	Mild
02 Jan 2021 (Study Day 110)	Shortness of Breath	Mild
03 Jan 2021 (Study Day 111)	Cough	Mild
03 Jan 2021 (Study Day 111)	Diarrhea	Mild
03 Jan 2021 (Study Day 111)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 112)	Cough	Mild
04 Jan 2021 (Study Day 112)	Diarrhea	Mild
04 Jan 2021 (Study Day 112)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 113)	Cough	Mild
05 Jan 2021 (Study Day 113)	Diarrhea	Mild
05 Jan 2021 (Study Day 113)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
06 Jan 2021 (Study Day 114)	Cough	Mild
06 Jan 2021 (Study Day 114)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 115)	Cough	Mild
07 Jan 2021 (Study Day 115)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 116)	Cough	Mild
08 Jan 2021 (Study Day 116)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 117)	Cough	Mild
10 Jan 2021 (Study Day 118)	Cough	Mild
10 Jan 2021 (Study Day 118)	Temperature (°F)	102.2
11 Jan 2021 (Study Day 119)	Cough	Mild
12 Jan 2021 (Study Day 120)	Cough	Mild
12 Jan 2021 (Study Day 120)	Shortness of Breath	Mild
13 Jan 2021 (Study Day 121)	Temperature (°F)	39.1
14 Jan 2021 (Study Day 122)	Cough	Mild
14 Jan 2021 (Study Day 122)	Shortness of Breath	Severe
15 Jan 2021 (Study Day 123)	O2 Saturation (%)	85
15 Jan 2021 (Study Day 123)	Shortness of Breath	Mild
26 Jan 2021 (Study Day 134)	O2 Saturation (%)	91

The participant had the following indications of Severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
19 Jan 2021 (Study Day 127)	Oxygen Saturation	74%
13 Jan 2021 (Study Day 121)	Respiratory Rate	46 breaths/min
24 Dec 2020 - 24 Dec 2020 (Study Day 101-101)	Clinical Evidence of Pneumonia	Yes
24 Dec 2020 - 13 Jan 2021 (Study Day 101-121)	Non-Invasive Ventilation	Yes
24 Dec 2020 - 24 Dec 2020 (Study Day 101-101)	Radiographical Evidence of Pneumonia	Yes
13 Jan 2021 - 19 Jan 2021 (Study Day 121-127)	High-Flow Oxygen	Yes
13 Jan 2021 - 30 Jan 2021 (Study Day 121-138)	Respiratory Rates >= 30 per Minute	Yes
19 Jan 2021 - 19 Jan 2021 (Study Day 127-127)	Acute Respiratory Distress Syndrome (ARDS)	Yes
19 Jan 2021 - 30 Jan 2021 (Study Day 127-138)	Admission to an intensive care unit due to SARS-CoV-2	Yes
19 Jan 2021 - 30 Jan 2021 (Study Day 127-138)	Mechanical Ventilation	Yes
19 Jan 2021 - 30 Jan 2021 (Study Day 127-138)	Oxygen Saturation of SpO2 <= 93% on room air at sea level	Yes
19 Jan 2021 - 19 Jan 2021 (Study Day 127-127)	Respiratory Failure	Yes

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 24 Dec 2020 (Study Day 101), the participant experienced a serious adverse event of COVID-19. The participant tested positive for SARS-CoV-2 by RT-PCR nasopharyngeal swab and presented to the emergency department with cough, shortness of breath with chest pain, and fever. The participant was hypoxic with an oxygen saturation of 89%, heart rate of 108 beats per

minute, and respiratory rate of 24 breaths per minute, and they required 2 L of oxygen to maintain adequate oxygenation. The participant was given paracetamol PO for the fever, and dexamethasone IV was started because COVID-19 was suspected. A chest x-ray and computerized tomography (CT) scan were consistent with COVID-19. A cardiac work-up was performed for the chest pain; the participant's troponin result was negative, and no ischemia was seen on the electrocardiogram. Test results for influenza A/B and respiratory syncytial virus were all negative. Additional treatment included azithromycin PO, ceftriaxone IV, and enoxaparin SC. Over the course of the hospitalization, the participant needed up to 15 L/min oxygen via a non-rebreather. The participant completed a 5-day course of remdesivir IV and a 10-day course of dexamethasone IV.

On 05 Jan 2021 (Study Day 113), the participant had a CT angiography pulmonary done with unreported results.

On 13 Jan 2021 (Study Day 121), the participant had worsening shortness of breath, with tachypnea of over 40 breaths per minute, and a worsening chest x-ray, and was started on vancomycin IV and piperacillin/tazobactam IV for new sepsis due to hospital-acquired pneumonia. On the same day, the participant was triaged to the surgical intensive care unit for acute hypoxic respiratory insufficiency requiring high-flow nasal cannula of 60 L of 100% oxygen. The hospital course was complicated by *Clostridium difficile* infection, for which the participant received vancomycin PO.

From 24 Dec 2020 (Study Day 101) through 15 Jan 2021 (Study Day 123), the participant intermittently experienced mild cough, shortness of breath, new loss of smell, runny nose, and diarrhea. The participant denied experiencing chills, difficulty breathing, muscle aches, body aches, fatigue, headache, new loss of taste, nasal congestion, nausea, vomiting, or sore throat.

On 19 Jan 2021 (Study Day 127), the participant was intubated.

On 26 Jan 2021 (Study Day 134), palliative care was consulted.

On 27 Jan 2021 (Study Day 135), a bronchoscopy was performed emergently for potential airway occlusion; however, the participant's airways were found to be patent.

On 28 Jan 2021 (Study Day 136), the participant received a blood transfusion.

On 30 Jan 2021 (Study Day 138) at 02:07, the participant died. The cause of death was reported as COVID-19. As updated by the investigator, it was highly unlikely that an autopsy would be performed. There was no known COVID-19 exposure prior to this event.

Action taken with study IP was not applicable in response to the event, as the participant had already received both scheduled doses.

The investigator assessed the event, COVID-19, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001545	SARS-CoV-2 infection

Study Completion/Discontinuation

On 30 Jan 2021 (Study Day 138), the participant discontinued from the study due to death. On 30 Jan 2021 (Study Day 138), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diabetes mellitus	Diabetes	2000 - Ongoing
Intervertebral disc protrusion	Neck hernia	2008 - Ongoing
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Arthralgia	Left knee pain	27 Feb 2020 (Study Day -201) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2010 - Ongoing	Hypertension
Simvastatin	2015 - Ongoing	High Cholesterol
Metformin hydrochloride; sitagliptin	2019 - Ongoing	Diabetes
Meloxicam	Mar 2020 - Ongoing	Left Knee Pain
Influenza vaccine	23 Aug 2020 (Study Day -23) - 23 Aug 2020 (Study Day -23)	Flu Prevention
Hydrocortisone	09 Oct 2020 (Study Day 25) - 09 Oct 2020 (Study Day 25)	Left Knee Pain
Paracetamol	24 Dec 2020 (Study Day 101) - 30 Jan 2021 (Study Day 138)	SARS-CoV-2 Infection
X-ray of chest*	24 Dec 2020 (Study Day 101) - 24 Dec 2020 (Study Day 101)	Adverse Event
Azithromycin	25 Dec 2020 (Study Day 102) - 29 Dec 2020 (Study Day 106)	SARS-CoV-2 Infection
Ceftriaxone	25 Dec 2020 (Study Day 102) - 25 Dec 2020 (Study Day 102)	SARS-CoV-2 Infection
CT of chest*	25 Dec 2020 (Study Day 102) - 25 Dec 2020 (Study Day 102)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexamethasone	25 Dec 2020 (Study Day 102) - 25 Dec 2020 (Study Day 102)	SARS-CoV-2 Infection
Dexamethasone	25 Dec 2020 (Study Day 102) - 03 Jan 2021 (Study Day 111)	SARS-CoV-2 Infection
Enoxaparin	25 Dec 2020 (Study Day 102) - 30 Jan 2021 (Study Day 138)	SARS-CoV-2 Infection
Remdesivir	25 Dec 2020 (Study Day 102) - 29 Dec 2020 (Study Day 106)	SARS-CoV-2 Infection
Vancomycin	04 Jan 2021 (Study Day 112) - 17 Jan 2021 (Study Day 125)	Clostridium Difficile
CT angiography pulmonary*	05 Jan 2021 (Study Day 113) - 05 Jan 2021 (Study Day 113)	Adverse Event
Piperacillin sodium; tazobactam sodium	13 Jan 2021 (Study Day 121) - 22 Jan 2021 (Study Day 130)	Hospital Acquired Pneumonia
Vancomycin	13 Jan 2021 (Study Day 121) - 22 Jan 2021 (Study Day 130)	Hospital Acquired Pneumonia
X-ray of the chest*	13 Jan 2021 (Study Day 121) - 13 Jan 2021 (Study Day 121)	Adverse Event
Intubation*	19 Jan 2021 (Study Day 127) - 19 Jan 2021 (Study Day 127)	Adverse Event
X-ray of the chest*	26 Jan 2021 (Study Day 134) - 26 Jan 2021 (Study Day 134)	Adverse Event
Bronchoscopy*	27 Jan 2021 (Study Day 135) - 27 Jan 2021 (Study Day 135)	Adverse Event
Blood transfusion*	28 Jan 2021 (Study Day 136) - 28 Jan 2021 (Study Day 136)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Clostridium Difficile Infection	Grade 2/moderate	Not related	03 Jan 2021 (Study Day 111) - 17 Jan 2021 (Study Day 125)
Pneumonia	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 121) - 22 Jan 2021 (Study Day 130)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US397-2045 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 29)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/Death Suspected Due To Coronary Artery Disease	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	03 Dec 2020 (Study Day 99) – 03 Dec 2020 (Study Day 99)	Fatal
Diabetic Complication/ Death Probably To Complications Of Diabetes Mellitus	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	03 Dec 2020 (Study Day 99) – 03 Dec 2020 (Study Day 99)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2045, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Dec 2020 (Study Day 99), 98 days after the first dose and 70 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of coronary artery disease. The IP dose was not changed due to the death suspected due to coronary artery disease. The event of death suspected due to coronary artery disease was considered to be fatal on 03 Dec 2020 (Study Day 99). The investigator assessed the event of coronary artery disease to be not related to the IP.

On 03 Dec 2020 (Study Day 99), 98 days after the first dose and 70 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of diabetic complication. Action taken with the IP was not applicable. The event of death probably to complications of diabetes mellitus was considered to be fatal on 03 Dec 2020 (Study Day 99). The investigator assessed the event of diabetic complication to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 24 Nov 2020 (Study Day 90), the safety call for Study Day 85 was completed. This was the last contact the site had with the participant.

On an unspecified day in December 2020, a safety call for Study Day 119 was attempted but the participant did not answer the phone. The coordinator searched the internet for the participant's name and an obituary report was found confirming they had died on 03 Dec 2020 (Study Day 99). The emergency contact person was called but did not answer, and a voice message was left to call the site back.

On 04 Jan 2021 (Study Day 131), the investigator reported that the participant had severe type 2 diabetes and had the complication of a foot ulcer for the previous 4 years. They had recently undergone a foot surgery. On 21 Oct 2020 (Study Day 56), they had been diagnosed with diabetic gastroparesis (nonserious adverse event). The participant's emergency contact person returned the call to the investigator and reported that the participant was found deceased in their home on 03 Dec 2020 (Study Day 99). A "light autopsy" confirmed the cause of death was complications of diabetes mellitus and coronary artery disease.

Action taken with the study IP was not applicable as the participant had already received both scheduled doses.

The participant died on 03 Dec 2020 (Study Day 99). The cause of death was reported on 06 Jan 2021 (Study Day 133) as diabetic complication and coronary artery disease.

The investigator assessed the events, fatal diabetic complication and fatal coronary artery disease, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001305	Coronary artery disease
MOD-2020-001305	Diabetic complication

Study Completion/Discontinuation

On 03 Dec 2020 (Study Day 99), the participant discontinued from the study due to death. On 03 Dec 2020 (Study Day 99), the participant died due to adverse event. An autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetic mellitus type 2	1993 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Blood cholesterol increased	High cholesterol	2016 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diabetic foot	Diabetic ulcer (l) foot	2016 - Ongoing
Ligament rupture	Torn ACL right knee	2017 - 2017
Localised infection	Infected toes right foot	Jan 2017 - Jan 2017
Diabetic neuropathy	L foot diabetic neuropathy	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	1993 - Ongoing	Diabetes Mellitus Ii
Insulin glargine	1993 - Ongoing	Diabetes Mellitus Ii
Lisinopril	2014 - Ongoing	Hypertension
Atorvastatin	2016 - Ongoing	Hypercholesterolemia
Gabapentin	2018 - Ongoing	Left Foot Diabetic Neuropathy
Ibuprofen	2018 - Ongoing	Left Foot Diabetic Neuropathy
Omeprazole	21 Oct 2020 (Study Day 56) - Ongoing	Diabetic Gastroparesis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diabetic Gastroparesis	Grade 1/mild	Not related	21 Oct 2020 (Study Day 56) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US382-2443 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine in Part A:	28 Sep 2020 (Study Day 1)
Second Dose of Vaccine in Part A:	27 Oct 2020 (Study Day 30)
Reason for Narrative:	Death, SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain/Abdominal Pain	SAE	Grade 3/ severe	Not related	04 Dec 2020 (Study Day 68) – 14 Dec 2020 (Study Day 78)	Recovered/ resolved
Pulmonary Mass/Right Lower Lobe Pulmonary Nodule Concerning For Primary Lung Malignancy	Death, SAE, AE leading to study discontinuation	Grade 5	Not related	11 Jan 2021 (Study Day 106) – 11 Feb 2021 (Study Day 137)	Fatal

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2443, a 75-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Dec 2020 (Study Day 68), 67 days after the first dose and 38 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abdominal pain. Action taken with the IP was not applicable. The event of abdominal pain lasted for 11 days, after which it was considered to be recovered/resolved on 14 Dec 2020 (Study Day 78). The investigator assessed the event of abdominal pain to be not related to the IP.

On 11 Jan 2021 (Study Day 106), 105 days after the first dose and 76 days after the second dose of the IP, the participant experienced a Grade 5 serious adverse event of pulmonary mass. Action taken with the IP was not applicable. The event of right lower lobe pulmonary nodule concerning for primary lung malignancy lasted for 32 days, after which it was considered to be fatal on 11 Feb 2021 (Study Day 137). The investigator assessed the event of pulmonary mass to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 04 Dec 2020 (Study Day 68), the participant experienced a serious adverse event of abdominal pain. The participant presented to the emergency department and was admitted with complaints of

leg swelling, abdominal pain, nausea, poor appetite, and vomiting that lasted for 4 days. The participant's troponin was 34 (no unit and reference range reported). A computerized tomography of the abdomen and pelvis with contrast showed partial imaging of a pulmonary nodule in the right lower lobe; minimal pleural effusions with atelectatic change; passive congestion of liver; status of post-cholecystectomy; stable cyst of 5.8 cm in size in the right lobe of liver; small amount of free intraperitoneal fluid in the pelvis; and stable small cystic lesion at the head of pancreas. A 2-view chest x-ray showed chronic obstructive pulmonary disease with emphysematous changes with no localized infiltrates. Positron emission tomography scan showed a hypermetabolic lesion of 1.6 × 1.8 cm in size in the right lower lung, a hypermetabolic lesion of 2.5 × 2 cm in size in the hepatic flexure of the colon near the liver cyst but separate, increased uptake in the left adrenal gland suggestive of hyperplasia.

On 10 Dec 2020 (Study Day 74), a single-view chest x-ray showed hyperinflation of the lungs consistent with emphysema; a partial consolidation at both lung bases and small bilateral pleural effusions, possibly pneumonia; and a cardiac silhouette within normal limits. Relevant laboratory test results included red blood cell (RBC) 3.60 × 10^6/μL (reference range 3.72 to 4.93 × 10^6/μL), hemoglobin (Hgb) 10.0 g/dL (reference range 11.5 to 15.0 g/dL), and hematocrit (Hct) 31% (reference range 34 to 44%).

On 12 Dec 2020 (Study Day 76), the COVID-19 test was negative. The participant's abdominal pain with nausea and vomiting was felt to be multifocal with fluid overload from cor pulmonale and possibly surgery related to the colonic mass. Treatment for the event included furosemide IV.

On 13 Dec 2020 (Study Day 77), relevant laboratory test results included RBC 3.7 × 10^6/μL, Hgb 10.2 g/dL, Hct 32%, chloride 97 mmol/L (reference range 98 to 107 mmol/L), carbon dioxide (CO_2) 42 mmol/L (reference range 21 to 31 mmol/L), and anion gap 4 mmol/L (reference range 3 to 15 mmol/L).

On 14 Dec 2020 (Study Day 78), relevant laboratory test results included chloride 94 mmol/L, CO_2 44 mmol/L, and anion gap 2 mmol/L. The participant was discharged from the hospital in stable condition.

Action taken with the study IP in response to the event of abdominal pain was not applicable, as the participant had already received both scheduled doses.

The event, abdominal pain, was considered resolved on 14 Dec 2020 (Study Day 78).

On 11 Jan 2021 (Study Day 106), the participant experienced a fatal SAE of pulmonary mass. The participant had a pulmonary nodule in the right lower lobe, concerning for primary lung malignancy.

On 11 Feb 2021 (Study Day 137), the participant's spouse reported that the participant died, and the cause of death was likely the participant's recent diagnosis of possible right lower lobe pulmonary nodule concerning for primary lung malignancy.

Action taken with the study IP in response to the event of pulmonary mass was not applicable, as the participant had already received both scheduled doses.

The participant died on 11 Feb 2021 (Study Day 137). The cause of death was likely the pulmonary mass.

The investigator assessed the events, abdominal pain and pulmonary mass, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001303	Abdominal pain
MOD-2021-014149	Pulmonary mass

Study Completion/Discontinuation

On 11 Feb 2021 (Study Day 137), the participant discontinued from the study due to death. On 11 Feb 2021 (Study Day 137), the participant died due to adverse event. It is unknown if an autopsy was performed.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Tubal ligation	1976 - Ongoing
Myopia	Nearsighted	1990 - Ongoing
Intervertebral disc protrusion	Herniated disc	1997 - 2014
Chronic obstructive pulmonary disease	Copd	2006 - Ongoing
Chronic obstructive pulmonary disease	Shortness of breath related to copd	2006 - Ongoing
Pneumonia	Pneumonia	2008 - 2012
Dysphagia	Trouble swallowing	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Sinusitis	Sinus infections	2010 - Ongoing
Anxiety	Anxiety	2014 - Ongoing
Atrial fibrillation	Atrial fibillilation	2014 - Ongoing
Intervertebral disc operation	Back surgery for herniated disc	2014 - Ongoing
Dyspepsia	Heartburn	2015 - Ongoing
Dyspepsia	Indigestion	2015 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrointestinal ulcer haemorrhage	Ulcers - gi hemmorhage	2015 - 2015
Gastrooesophageal reflux disease	Acid reflux	2015 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Increased tendency to bruise	Easy brusing	2017 - Ongoing
Osteoporosis	Osteoporosis	2018 - Ongoing
Hypertonic bladder	Overactive bladder	2019 - Ongoing
Urinary incontinence	Urinary incontinence	2019 - Ongoing
Constipation	Frequent constipation	Mar 2020 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	Mar 2020 - Ongoing
Chest discomfort	Chest discomfort	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2010 - Ongoing	Copd, Shortness Of Breath
Digoxin	2014 - Ongoing	Atrial Fibrillation
Duloxetine	2014 - Ongoing	Anxiety
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	28 May 2014 (Study Day -2315) - 28 May 2014 (Study Day -2315)	Vaccine
Levosalbutamol	2015 - Ongoing	Copd
Pantoprazole	2015 - Ongoing	Acid Reflux
Vitamins nos	2015 - Ongoing	Supplement
Budesonide	2016 - Ongoing	Copd
Diltiazem	2016 - Ongoing	Hypertension
Pneumococcal vaccine	14 Apr 2016 (Study Day -1628) - 14 Apr 2016 (Study Day -1628)	Vaccine
Acetylsalicylic acid	2017 - Ongoing	Supplement
Dextromethorphan hydrobromide; guaifenesin	2017 - Ongoing	Seasonal Allergies
Montelukast	2017 - Ongoing	Shortness Of Breath, Copd
Denosumab	2018 - Ongoing	Osteoporosis
Ipratropium bromide	2018 - Ongoing	Seasonal Allergies
Calcium carbonate	2019 - Ongoing	Supplement
Cod-liver oil	2019 - Ongoing	Supplement
Colecalciferol	2019 - Ongoing	Supplement
Formoterol fumarate	2019 - Ongoing	Copd
Prednisone	2019 - Ongoing	Copd
Vitamin e nos	2019 - Ongoing	Supplement
Influenza vaccine	15 Oct 2019 (Study Day -349) - 15 Oct 2019 (Study Day -349)	Vaccine

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Linaclotide	2020 - Ongoing	Constipation
Revefenacin	Jan 2020 - Ongoing	Copd
Macrogol 3350	Feb 2020 - Ongoing	Constipation
Furosemide	04 Dec 2020 (Study Day 68) - 05 Dec 2020 (Study Day 69)	Abdominal Pain And Swollen Feet
Oxygen	04 Dec 2020 (Study Day 68) - Ongoing	Copd
Metoprolol	06 Dec 2020 (Study Day 70) - Ongoing	Hypertension
Furosemide	12 Dec 2020 (Study Day 76) - 12 Dec 2020 (Study Day 76)	Abdominal Pain
Prednisone	14 Dec 2020 (Study Day 78) - 19 Dec 2020 (Study Day 83)	Copd

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain In Extremity	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 48) - 15 Nov 2020 (Study Day 49)
Peripheral Swelling	Grade 2/moderate	Not related	02 Dec 2020 (Study Day 66) - 08 Dec 2020 (Study Day 72)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US300-2122 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	21 Nov 2020 (Study Day 107) – 21 Nov 2020 (Study Day 107)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2122, a 25-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	07 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	04 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 21 Nov 2020 (Study Day 107), the participant had a positive pregnancy test. The participant reported using condoms as a means of contraception. The first day of the participant's last menstrual period was on 19 Oct 2020 (Study Day 74). The estimated date of conception was unknown, and the due date was estimated as 28 Jul 2021 (Study Day 356).

Action taken with study IP in response to the event of pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026742	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Intermittent headache	2010 - Ongoing
Depression	Depression	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2010 - Ongoing	Intermittent Headaches
Sertraline hydrochloride	Dec 2019 - Ongoing	Depression
Phentermine	24 Aug 2020 (Study Day 18) - 21 Nov 2020 (Study Day 107)	Weight Gain
Influenza vaccine	24 Nov 2020 (Study Day 110) - 24 Nov 2020 (Study Day 110)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Weight Increased	Grade 1/mild	Not related	24 Aug 2020 (Study Day 18) - Ongoing
Myalgia	Grade 1/mild	Related	29 Aug 2020 (Study Day 23) - 29 Aug 2020 (Study Day 23)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2323 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 34)
Reason for Narrative:	Pregnancy, SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Vaccine exposure before pregnancy/Vaccine exposure before pregnancy	Pregnancy	Nonserious	Not applicable	25 Jan 2021 (Study Day 157) – 02 Feb 2021 (Study Day 165)	Recovered/ resolved
Abortion Spontaneous/Spontaneous Abortion Of Pregnancy	SAE, Pregnancy	Grade 3/ severe	Not related	02 Feb 2021 (Study Day 165) – 02 Feb 2021 (Study Day 165)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2323, a 19-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 24 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Feb 2021 (Study Day 165), 164 days after the first dose and 131 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abortion spontaneous. Action taken with the IP was not applicable. The event of spontaneous abortion of pregnancy lasted for 1 day, after which it was considered to be recovered/resolved on 02 Feb 2021 (Study Day 165). The investigator assessed the event of abortion spontaneous to be not related to the IP.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	22 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	24 Sep 2020 (Study Day 34)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 25 Jan 2021 (Study Day 157), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was unknown due to a history of irregular menstrual cycles. The estimated date of conception was reported as an unknown day in November 2020 and the estimated due date was reported as not applicable.

On an unknown date, the participant experienced bloating and nausea that were symptoms of the pregnancy. The participant also had some upper respiratory symptoms (not specified) and saw their primary care provider who performed a COVID-19 test, which was negative, and a pregnancy test, which was positive.

On 02 Feb 2021 (Study Day 165), the participant experienced a serious adverse event of spontaneous abortion as evidenced by heavy cramping and bleeding. The participant contacted an obstetrician/gynecologist who confirmed a spontaneous miscarriage had occurred at an estimated 12 weeks of gestation. There was no history of any trauma prior to the event. The participant was blood type A– and was given a one-time dose of anti-D immunoglobulin IM on 03 Feb 2021 (Study Day 166). The participant reported that there had not been an ultrasound prior to the miscarriage and that they were not using contraception.

Action taken with study IP in response to the events, vaccine exposure before pregnancy and abortion spontaneous, was not applicable, as the participant had already received both scheduled doses.

The events, vaccine exposure before pregnancy and spontaneous abortion, were reported as resolved on 02 Feb 2021 (Study Day 165).

The investigator's assessment of the relationship between the event of vaccine exposure before pregnancy and the study IP or study procedure was not reported. The investigator assessed the event, spontaneous abortion, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy and serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-020781	Vaccine exposure before pregnancy
MOD-2021-020781	Abortion spontaneous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2001 - Ongoing
Menstruation irregular	Irregular menstral cycle	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Drospirenone; ethinylestradiol	2018 - Ongoing	Birth Control
Anti-D immunoglobulin	03 Feb 2021 (Study Day 166) - 03 Feb 2021 (Study Day 166)	Postpartum Rh Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not related	15 Jan 2021 (Study Day 147) - 23 Jan 2021 (Study Day 155)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2177 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Exposure during pregnancy/Drug exposure during pregnancy	Pregnancy	Nonserious	Not applicable	10 Sep 2020 (Study Day 29) – 10 Sep 2020 (Study Day 29)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2177, a 22-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 22 Oct 2020 (Study Day 71).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	13 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	10 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	22 Oct 2020 (Study Day 71)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 15 Oct 2020 (Study Day 64), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was unknown as the participant was postpartum. The participant reported using condoms as a contraceptive method during the postpartum period. The estimated date of conception was 29 Aug 2020 (Study Day 17) and the estimated due date was 22 May 2021 (Study Day 283).

On 22 Oct 2020 (Study Day 71), a urine pregnancy test was positive.

On an unspecified date, an ultrasound confirmed twin gestation with a due date of 22 May 2021 (Study Day 283).

The participant had completed the study IP dosing and therefore, no action was taken with the study IP as a result of the pregnancy.

The outcome of the event, exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000511	Exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	11 Sep 2020 (Study Day 30) - 12 Sep 2020 (Study Day 31)	Headache And Pain At Injection Site
Paracetamol	11 Sep 2020 (Study Day 30) - 12 Sep 2020 (Study Day 31)	Headache And Pain At Injection Site
Influenza vaccine	19 Nov 2020 (Study Day 99) - 19 Nov 2020 (Study Day 99)	Influenza Prevention
Paracetamol	21 Nov 2020 (Study Day 101) - 24 Nov 2020 (Study Day 104)	Viral Syndrome Of Unknown Etiology
Fluoxetine	13 Jan 2021 (Study Day 154) - Ongoing	Depression
Ciprofloxacin hydrochloride; dexamethasone	19 Mar 2021 (Study Day 219) - Ongoing	Eczema-Right External Ear Canal
Pantoprazole	19 Mar 2021 (Study Day 219) - Ongoing	Gastroesophageal Reflux Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Seasonal Allergy	Grade 1/mild	Not related	01 Sep 2020 (Study Day 20) - Ongoing
Viral Infection	Grade 1/mild	Not related	31 Oct 2020 (Study Day 80) - 10 Nov 2020 (Study Day 90)
Viral Infection	Grade 1/mild	Not related	16 Nov 2020 (Study Day 96) - 24 Nov 2020 (Study Day 104)
Depression	Grade 1/mild	Not related	13 Jan 2021 (Study Day 154) - Ongoing
Gestational Diabetes	Grade 1/mild	Not related	09 Feb 2021 (Study Day 181) - Ongoing
Eczema	Grade 1/mild	Not related	19 Mar 2021 (Study Day 219) - Ongoing
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	19 Mar 2021 (Study Day 219) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US305-2020 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	30 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	26 Aug 2020 (Study Day 28)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	04 Dec 2020 (Study Day 128) – 14 Jan 2021 (Study Day 169)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2020, a 26-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	30 Jul 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	26 Aug 2020 (Study Day 28)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 04 Jan 2021 (Study Day 159), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was on 20 Nov 2020 (Study Day 114). The estimated date of conception was 04 Dec 2020 (Study Day 128) and the estimated due date was 27 Aug 2021 (Study Day 394).

On 06 Jan 2021 (Study Day 161), the participant experienced a serious adverse event of abortion spontaneous and was seen in the emergency department for first trimester vaginal bleeding. An ultrasound scan showed a single intrauterine pregnancy with no fetal pole or cardiac activity. A laboratory test result for beta human chorionic gonadotropin was 7367 (no units and reference range provided). It was unknown if the participant had a history of subfertility or if the participant had prenatal care, prenatal testing, or investigations done.

Action taken with study IP in response to drug exposure before pregnancy and abortion spontaneous was not applicable, as the participant had already received both scheduled doses.

On 14 Jan 2021 (Study Day 169), the participant's vaginal bleeding had resolved. The participant was 6 weeks pregnant, and had a spontaneous abortion not otherwise specified, which had resolved as well.

The investigator's assessment of the relationship between the events of drug exposure before pregnancy and abortion spontaneous and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002171	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsilectomy	2006 - 2006
Appendicectomy	Appendectomy	2014 - 2014
Anxiety	Anxiety	26 Aug 2019 (Study Day -339) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	26 Aug 2020 (Study Day 28) - 26 Aug 2020 (Study Day 28)	Headache After 2nd Injection
Venlafaxine	26 Aug 2020 (Study Day 28) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US309-2099 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	09 Sep 2020 (Study Day 31) – 09 Sep 2020 (Study Day 31)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2099, a 19-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 09 Sep 2020 (Study Day 31).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	10 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	09 Sep 2020 (Study Day 31)	Positive
Choriogonadotropin Beta	05 Nov 2020 (Study Day 88)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 07 Sep 2020 (Study Day 29), the participant had a positive urine pregnancy test, prior to their second dose. An additional urine pregnancy test was performed, which was also positive. Additionally, a blood sample was collected to confirm pregnancy, which was positive. An ultrasound was scheduled. The date of the participant's last menstrual period was 25 Jul 2020 (Study Day –17). The estimated date of conception and estimated due date were not reported.

Action taken with the study IP was withdrawn as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000282	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	10 Aug 2020 (Study Day 1) - 10 Aug 2020 (Study Day 1)	Pain At Injection Site
Vitamins nos	Jan 2021 - Ongoing	Abnormal/Unhealthy Pregnancy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US317-2349 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ectopic Pregnancy/Ectopic Pregnancy	SAE, Pregnancy	Grade 2/ moderate	Not related	06 Oct 2020 (Study Day 42) – 13 Oct 2020 (Study Day 49)	Recovered/ resolved
Spontaneous abortion/ spontaneous abortion	Pregnancy	Grade 2/ moderate	Not related	31 Aug 2020 (Study Day 6) - 13 Oct 2020 (Study Day 49)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2349, a 35-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Oct 2020 (Study Day 42), 41 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of ectopic pregnancy. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to pregnancy. The event of ectopic pregnancy ended in miscarriage lasted for 8 days, after which it was considered to be recovered/resolved on 13 Oct 2020 (Study Day 49). The investigator assessed the event of ectopic pregnancy to be not related to the IP.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 23 Sep 2020 (Study Day 29).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	26 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	23 Sep 2020 (Study Day 29)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 22 Sep 2020 (Study Day 28), the participant had a positive home urine pregnancy test. The first day of the participant's last menstrual period was on 25 Aug 2020 (Study Day –1). The estimated date of conception was 31 Aug 2020 (Study Day 6), and the estimated due date was 26 May 2021 (Study Day 274). The participant reported using condoms with spermicide and ethinylestradiol/norgestimate as dual means of contraception.

On 23 Sep 2020 (Study Day 29), the participant arrived at the clinic and reported the pregnancy. The participant reported that they missed their menses that month and decided to perform a urine pregnancy test the day prior, which was positive. Urine was collected and a pregnancy test was performed, which was positive. Additionally, blood was collected for a qualitative/quantitative test and sent out to the local laboratory for final confirmation, which resulted positive.

Study IP was discontinued as a result of the pregnancy and the second dose was not administered.

On 06 Oct 2020 (Study Day 42), the participant experienced serious adverse events of ectopic pregnancy and spontaneous abortion. The participant noted having a small amount of vaginal bleeding.

On 07 Oct 2020 (Study Day 43), the participant presented to the emergency department with complaint of vaginal bleeding and abdominal pain since the previous day. The participant had some brown spotting from the vagina in the previous week, which resolved during the weekend, but started again with a brighter red color on the morning of 07 Oct 2020 (Study Day 43). The participant denied passing any clots. The participant's vital signs were stable. An obstetric ultrasound showed a uterus empty of a gestational sac and no uterine masses were identified, with normal ovaries. Laboratory results showed normal prothrombin time of 12.1 seconds, normal international normalized ratio of 1.05, normal partial thromboplastin time of 37.2 seconds, low hematocrit level of 36.7%, high mean platelet volume of 10.7 fL, and high quantitative human chorionic gonadotropin of 1292.30 mIU/mL (no reference ranges reported); "an antibody screen was negative". The participant was hemodynamically stable, feeling much better, and was discharged home with information regarding ectopic pregnancy, threatened miscarriage, and miscarriage. Upon discharge, the participant was instructed to not take part in any physical activity, have pelvic rest, no sexual intercourse for 2 weeks, and stay hydrated.

Action taken with study IP was not applicable for the events, ectopic pregnancy and spontaneous abortion.

The events, ectopic pregnancy and spontaneous abortion, were reported as resolved on 13 Oct 2020 (Study Day 49).

The investigator assessed the events, ectopic pregnancy and spontaneous abortion, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000360	Ectopic pregnancy
MOD-2020-000360	Abortion spontaneous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	2008 - Ongoing
Back pain	Back pain	2017 - Ongoing
Caesarean section	Cesarean section	04 Apr 2017 (Study Day -1240) - 04 Apr 2017 (Study Day -1240)
Ovarian cyst	Right ovarian cyst benign	Aug 2019 - Sep 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; norgestimate	Aug 2019 - 22 Sep 2020 (Study Day 28)	Contraception
Paracetamol	09 Sep 2020 (Study Day 15) - 09 Sep 2020 (Study Day 15)	Back Pain
Rest observation*	06 Oct 2020 (Study Day 42) - 06 Oct 2020 (Study Day 42)	Adverse Event
Ethinylestradiol; norgestimate	15 Nov 2020 (Study Day 82) - Ongoing	Contraception

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abortion Spontaneous	Grade 2/moderate	Not related	06 Oct 2020 (Study Day 42) - 13 Oct 2020 (Study Day 49)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2151 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy.	Pregnancy	Nonserious	Not applicable	02 Sep 2020 (Study Day 30) – 02 Sep 2020 (Study Day 30)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2151, a 41-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 29 Sep 2020 (Study Day 57).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	04 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	01 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	29 Sep 2020 (Study Day 57)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 28 Sep 2020 (Study Day 56), the participant had a positive urine home pregnancy test. The first day of the participant's last menstrual period was on 19 Aug 2020 (Study Day 16). The estimated date of conception was on 02 Sep 2020 (Study Day 30) and the estimated due date as 26 May 2021 (Study Day 296). The participant was using condom with spermicide for contraception and this was not a planned pregnancy. The participant began taking prenatal vitamins PO, cyanocobalamin PO, and folic acid PO.

On 29 Sep 2020 (Study Day 57), the participant had a positive urine pregnancy test and scheduled their obstetrics and gynecology appointment for 12 Oct 2020 (Study Day 70).

The participant had completed the study IP dosing and therefore, no action was taken with the study IP as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000380	Drug exposure before pregnancy

Study Completion/Discontinuation

On 24 Mar 2021 (Study Day 233), the participant discontinued from the study due to pregnancy.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1999 - Ongoing
Gastric bypass	Gastric bypass	2009 - 2009
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Myopia	Bilateral myopia	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	2010 - Ongoing	Seasonal Allergies
Vitamins NOS	May 2020 - 27 Sep 2020 (Study Day 55)	Health Maintenance
Paracetamol	06 Aug 2020 (Study Day 3) - 06 Aug 2020 (Study Day 3)	Headache
Paracetamol	10 Aug 2020 (Study Day 7) - 10 Aug 2020 (Study Day 7)	Joint Aches
Folic acid	28 Sep 2020 (Study Day 56) - Ongoing	Health Maintenance
Vitamin B12 NOS	28 Sep 2020 (Study Day 56) - Ongoing	Health Maintenance

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins NOS	28 Sep 2020 (Study Day 56) - Ongoing	Health Maintenance

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US320-2366 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	11 Oct 2020 (Study Day 42) – 11 Oct 2020 (Study Day 42)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2366, a 30-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	31 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	28 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 25 Oct 2020 (Study Day 56), the participant had a positive urine pregnancy test at home.

On 02 Dec 2020 (Study Day 94), an ultrasound performed per their obstetrician confirmed the participant was approximately 7 weeks pregnant. The first day of the participant's last menstrual period was 05 Oct 2020 (Study Day 36). The estimated date of conception was 11 Oct 2020 (Study Day 42) and the estimated due date as 18 Jul 2021 (Study Day 322). The participant reported using double barrier contraception without fail.

The participant had completed study IP dosing; therefore, action taken with study IP was not applicable as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy and serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001036	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Eczema	Eczema	2000 - Ongoing
Drug eruption	Allergy to keflex reaction- entire body rash	2010 - Ongoing
Fatigue	Chronic fatigue	2015 - Ongoing
Gastrooesophageal reflux disease	Chronic acid reflux	2015 - Ongoing
Menorrhagia	Heavy menstrual bleeding	2015 - Ongoing
Hiatus hernia	Hiatal hernia	Aug 2015 - Ongoing
Diarrhoea	Chronic diarrhea- controlled with diet	2018 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome- controlled with diet	2018 - Ongoing
Glucose tolerance impaired	Pre-diabetes	Jul 2018 - Ongoing
Ovarian cyst	Left ovarian cyst	2019 - Ongoing
Uterine leiomyoma	Uterine fibroid	2019 - Ongoing
Blood testosterone increased	Elevated testosterone level	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Biotin	2010 - Ongoing	General Health Supplement
Vitamins nos	2010 - 01 Dec 2020 (Study Day 93)	General Health Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2015 - Ongoing	Heavy Menstrual Bleeding
Fexofenadine hydrochloride	May 2017 - 15 Feb 2021 (Study Day 169)	Seasonal Allergies
Metformin	Jul 2018 - 15 Feb 2021 (Study Day 169)	Pre-Diabetes
Fluticasone propionate	Apr 2020 - Ongoing	Seasonal Allergies
Magnesium	Jun 2020 - Ongoing	General Health Supplement
Fluconazole	03 Sep 2020 (Study Day 4) - 03 Sep 2020 (Study Day 4)	Vaginal Candidiasis
Sulfamethoxazole; trimethoprim	03 Sep 2020 (Study Day 4) - 08 Sep 2020 (Study Day 9)	Urinary Tract Infection
Urine pregnancy test*	02 Dec 2020 (Study Day 94) - 02 Dec 2020 (Study Day 94)	Other, Confirmation Of Pregnancy
Vaginal ultrasound*	02 Dec 2020 (Study Day 94) - 02 Dec 2020 (Study Day 94)	Other, Confirmation Of Pregnancy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	31 Aug 2020 (Study Day 1) - 08 Sep 2020 (Study Day 9)
Urinary Tract Infection	Grade 2/moderate	Not related	02 Sep 2020 (Study Day 3) - 08 Sep 2020 (Study Day 9)
Vulvovaginal Candidiasis	Grade 1/mild	Not related	02 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 4)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US321-2182 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	17 Aug 2020 (Study Day 4) – 17 Aug 2020 (Study Day 4)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2182, a 20-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 11 Sep 2020 (Study Day 29).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	14 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	11 Sep 2020 (Study Day 29)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 11 Sep 2020 (Study Day 29), the participant had a positive urine pregnancy test. The participant and their partner were using condoms with spermicide as a method of contraception. The first day of the participant's last menstrual period was 12 Aug 2020 (Study Day -2). The estimated date of conception was 17 Aug 2020 (Study Day 4) and the estimated due date was in May 2021.

Action taken with the study IP was withdrawn as a result of the event of drug exposure before pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the nonserious event and pregnancy are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000287	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	2002 - Ongoing
Appendicectomy	Appendectomy	2016 - 2016
Appendicitis	Appendicitis	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2002 - Ongoing	Asthma Rescue
Vitamins nos	14 Sep 2020 (Study Day 32) - Ongoing	Pregnancy
Influenza vaccine	16 Oct 2020 (Study Day 64) - 16 Oct 2020 (Study Day 64)	Immunization
Phenoxymethylpenicillin potassium	21 Oct 2020 (Study Day 69) - 25 Oct 2020 (Study Day 73)	Group B Streptococcal Infection (Gbs Positive)
Brompheniramine maleate; dextromethorphan hydrobromide; phenylephrine hydrochloride	18 Jan 2021 (Study Day 158) - 12 Feb 2021 (Study Day 183)	Cough
Other cough suppressants	18 Jan 2021 (Study Day 158) - 12 Feb 2021 (Study Day 183)	Cough
Ferrous sulfate	05 Mar 2021 (Study Day 204) - Ongoing	Anemia
Ondansetron	23 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 222)	Gastroenteritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Morning Sickness	Grade 1/mild	Not related	13 Sep 2020 (Study Day 31) - 26 Oct 2020 (Study Day 74)
Streptococcal Infection	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 63) - 25 Oct 2020 (Study Day 73)
Hyperemesis Gravidarum	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 74) - Ongoing
Cough	Grade 1/mild	Not related	18 Jan 2021 (Study Day 158) - Ongoing
COVID-19	Grade 2/moderate	Not related	28 Jan 2021 (Study Day 168) - 06 Feb 2021 (Study Day 177)
Iron Deficiency Anaemia	Grade 2/moderate	Not related	04 Mar 2021 (Study Day 203) - Ongoing
Gastroenteritis	Grade 2/moderate	Not related	23 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 222)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US325-2009 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure during pregnancy/ Maternal exposure during pregnancy, first trimester	Pregnancy	Nonserious	Not related	03 Aug 2020 (Study Day 1) - 03 Aug 2020 (Study Day 1)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2009, a 33-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 01 Sep 2020 (Study Day 30).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	03 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	01 Sep 2020 (Study Day 30)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 03 Aug 2020 (Study Day 1), at screening, the participant had a negative urine pregnancy test.

On 29 Aug 2020 (Study Day 27), the participant had a positive home urine pregnancy test. On 01 Sep 2020 (Study Day 30), during the Day 29 visit, the participant reported findings of the home pregnancy test. A serum human chorionic gonadotropin pregnancy test was performed, which was positive. The date of the last menstrual period was on 10 Jun 2020 (Study Day –55), the estimated date of conception was 27 Jul 2020 (Study Day –8) and the estimated due date was 01 Apr 2021 (Study Day 242). The participant's form of contraception included ethinylestradiol/norgestimate

PO, and the participant reported compliance with this method. At the time of the report, the participant has not had any problems during pregnancy.

Study IP was withdrawn in response to the event.

The outcome of the event, maternal exposure during pregnancy, was not reported.

The event of maternal exposure during pregnancy was considered unrelated to the study IP according to the investigator's assessment.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000250	Maternal exposure during pregnancy

Study Completion/Discontinuation

On 13 Jan 2021 (Study Day 164), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; norgestimate	Apr 2020 - Ongoing	Contraceptive
Vitamins nos	14 Sep 2020 (Study Day 43) - Ongoing	Pregnancy
Influenza vaccine	16 Sep 2020 (Study Day 45) - 16 Sep 2020 (Study Day 45)	Flu Vaccine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US330-2345 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	01 Nov 2020 (Study Day 70) – 01 Nov 2020 (Study Day 70)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2345, a 26-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	24 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	21 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 19 Nov 2020 (Study Day 88), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was on 27 Oct 2020 (Study Day 65). The estimated date of conception was 01 Nov 2020 (Study Day 70) and the due date was estimated as 03 Aug 2021 (Study Day 345). The participant reported taking an oral contraceptive; however, they missed 1 dose. The participant reported that their pregnancy was going "great".

The participant had completed study IP dosing; therefore, no action was taken with study IP as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011804	Drug exposure before pregnancy

Study Completion/Discontinuation

On 02 Feb 2021 (Study Day 163), the participant discontinued from the study due to pregnancy.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2018 - Ongoing	Birth Control
Escitalopram oxalate	2020 - Ongoing	Anxiety
Paracetamol	25 Aug 2020 (Study Day 2) - 26 Aug 2020 (Study Day 3)	Injection Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US331-2573 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure during pregnancy/Maternal exposure during pregnancy	Pregnancy	Nonserious	Not applicable	13 Sep 2020 (Study Day 5) – 07 Oct 2020 (Study Day 29)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2573, a 34-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	09 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	07 Oct 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 07 Oct 2020 (Study Day 29), the participant had a urine pregnancy test prior to the second dose of blinded IP. The pregnancy test was read at 4 minutes from the start of the test and was negative. The pregnancy test was left on the counter and was noted to be positive over an hour later when the staff was cleaning the counter. By then, the participant had been dosed and was about to leave the building. The subinvestigator notified the participant, confirmed history and dates of etonogestrel use, and a urine pregnancy test was repeated on a new sample. This pregnancy test was positive and gave the positive signal within the product specification time frame. A quantitative human chorionic gonadotropin blood test was measured as 6747 mIU/mL

(no reference range provided). The participant was referred to their primary care provider regarding possible etonogestrel failure. The first day of the participant's last menstrual period was on 30 Aug 2020 (Study Day –11). The estimated date of conception was on 13 Sep 2020 (Study Day 5), and the estimated due date was 06 Jun 2021 (Study Day 271).

The participant had completed study IP dosing; therefore, no action was taken with study IP as a result of the pregnancy.

The outcome of the event, maternal exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of maternal exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000435	Maternal exposure during pregnancy

Study Completion/Discontinuation

On 31 Oct 2020 (Study Day 53), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Etonogestrel	Jan 2019 - Ongoing	Birth Control

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US334-2142 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure before pregnancy/Maternal exposure before pregnancy	Pregnancy	Nonserious	Not applicable	15 Oct 2020 (Study Day 53) – 15 Oct 2020 (Study Day 53)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2142, a 37-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	24 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	21 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 11 Nov 2020 (Study Day 80), the participant had a positive urine pregnancy test. On an unspecified date, the participant had a second positive urine pregnancy test. The first day of the participant's last menstrual period was 04 Oct 2020 (Study Day 42). The estimated date of conception was 15 Oct 2020 (Study Day 53), and the estimated due date was 10 Jul 2021 (Study Day 321). The participant reported no problems with the pregnancy thus far and was scheduled for an appointment with the obstetrician/gynecologist in the coming week.

The participant had completed study IP dosing; therefore, no action was taken with study IP as a result of the pregnancy.

The outcome of the event, maternal exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of maternal exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000863	Maternal exposure before pregnancy

Study Completion/Discontinuation

On 19 Jan 2021 (Study Day 149), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ventricular septal defect	Ventricular septal defect	(b) (6) 1983 (Study Day (b) (6) - 1985
Genital herpes simplex	Herpes simplex virus i (genital)	2003 - Ongoing
Supraventricular tachycardia	Supraventricular tachycardia	2014 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2016 - Ongoing	Seasonal Allergies
Ibuprofen	24 Sep 2020 (Study Day 32) - 25 Sep 2020 (Study Day 33)	Headache
Influenza vaccine	11 Nov 2020 (Study Day 80) - 11 Nov 2020 (Study Day 80)	Influenza Prophylaxis
Other viral vaccines	12 Jan 2021 (Study Day 142) - 12 Jan 2021 (Study Day 142)	COVID-19 Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US335-2200 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine in Part A:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine in Part A:	19 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Not applicable	Not applicable	12 Jan 2021 (Study Day 144) - 12 Jan 2021 (Study Day 144)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2200, a 36-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 19 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 26 Jan 2021 (Study Day 158).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	22 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	19 Sep 2020 (Study Day 29)	Negative
Choriogonadotropin Beta	26 Jan 2021 (Study Day 158)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 12 Jan 2021 (Study Day 144), the participant had a positive urine pregnancy test. On 26 Jan 2021 (Study Day 158), the participant had another positive urine pregnancy test. The participant's last menstrual period was on 07 Nov 2020 (Study Day 78). The estimated date of conception was not reported, and the estimated due date was 15 Aug 2021 (Study Day 359). The participant reported that they had been using a barrier method contraception. The participant began mineral/vitamin PO for the pregnancy.

On 09 Mar 2021 (Study Day 200), the participant had an ultrasound, and the findings were reported as single live intrauterine pregnancy of 17 weeks 2 days, amniotic fluid volume appeared normal, no gross fetal abnormality visualized. An expected delivery date in correspondence with the findings was 15 Aug 2021 (Study Day 359).

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008625	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	2005 - Ongoing
Myopia	Nearsighted	2005 - Ongoing
Inguinal hernia	Right inguinal hernia	2011 - 2011
Inguinal hernia repair	Right inguinal hernia repair	2011 - 2011
Caesarean section	C section	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2015 - Ongoing	Migraines
Paracetamol	23 Aug 2020 (Study Day 2) - 23 Aug 2020 (Study Day 2)	Headache
Paracetamol	20 Sep 2020 (Study Day 30) - 20 Sep 2020 (Study Day 30)	Fever
Paracetamol	20 Sep 2020 (Study Day 30) - 20 Sep 2020 (Study Day 30)	Headache
Vitamins nos	20 Jan 2021 (Study Day 152) - Ongoing	Multivitamin

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US337-2229 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Pregnancy, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pregnancy/Pregnancy	Pregnancy, AE leading to withdrawal from study vaccine	Nonserious	Not related	25 Sep 2020 (Study Day 33) – Not reported	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2229, a 34-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 28 Sep 2020 (Study Day 36).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	24 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	28 Sep 2020 (Study Day 36)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 25 Sep 2020 (Study Day 33), the participant had a positive home urine pregnancy test. The estimated date of conception was on an unknown date in August 2020. The first day of their last menstrual period was around 26 Aug 2020 (Study Day 3), and the estimated due date was not provided. The participant was using condoms with spermicide for contraception.

On 28 Sep 2020 (Study Day 36), at the site, the participant had a positive urine pregnancy test.

Action taken with the study IP was withdrawn as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator assessed the event of pregnancy to be not related to the study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000374	Drug exposure before pregnancy

Study Completion/Discontinuation

On 01 Mar 2021 (Study Day 190), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Myopia (near sighted)	1995 - 2009
Breast enlargement	Macromastia	2002 - 2005
Depression	Depression	2004 - Ongoing
Mammoplasty	Bilateral reduction mammoplasty	2005 - 2005
Photorefractive keratectomy	Bilateral photorefractive keratectomy	2009 - 2009
Caesarean section	Cesarean section	22 Nov 2017 (Study Day -1006) - 22 Nov 2017 (Study Day -1006)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Japanese encephalitis vaccine	2013 - 2013	Japanese Encephalitis Prophylaxis/Prevention
Rabies vaccine	2013 - 2013	Rabies Prophylactic
Diphtheria vaccine; pertussis vaccine	2017 - 2017	Diphtheria/Tetanus And Acellular Pertussis Prophylaxis/Prevention
Influenza vaccine	Sep 2018 - Sep 2018	Influenza Prophylaxis/Prevention
Fluoxetine hydrochloride	Feb 2019 - Ongoing	Depression
Ondansetron	30 Oct 2020 (Study Day 68) - Ongoing	Hyperemesis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Other viral vaccines	14 Feb 2021 (Study Day 175) - 14 Feb 2021 (Study Day 175)	COVID-19 Prevention / Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pregnancy	Grade 1/mild	Not related	25 Sep 2020 (Study Day 33) - Ongoing
Dehydration	Grade 2/moderate	Not related	30 Oct 2020 (Study Day 68) - 30 Oct 2020 (Study Day 68)
Vomiting	Grade 2/moderate	Not related	30 Oct 2020 (Study Day 68) - Not reported
Cough	Grade 1/mild	Not related	12 Jan 2021 (Study Day 142) - 19 Jan 2021 (Study Day 149)
Nasal Congestion	Grade 1/mild	Not related	12 Jan 2021 (Study Day 142) - 18 Jan 2021 (Study Day 148)
Oropharyngeal Pain	Grade 1/mild	Not related	12 Jan 2021 (Study Day 142) - 17 Jan 2021 (Study Day 147)
Rhinorrhoea	Grade 1/mild	Not related	12 Jan 2021 (Study Day 142) - 18 Jan 2021 (Study Day 148)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2316 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 34)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pregnancy/Pregnancy	Pregnancy	Nonserious	Not applicable	18 Oct 2020 (Study Day 71) – 18 Oct 2020 (Study Day 71)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2316, a 29-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 09 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	09 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	11 Sep 2020 (Study Day 34)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 25 Oct 2020 (Study Day 78), the participant had a positive home pregnancy test. The first day of the participant's last menstrual period was on 25 Sep 2020 (Study Day 48). The estimated date of conception was 18 Oct 2020 (Study Day 71), and the estimated due date was 30 Jun 2021 (Study Day 326). The participant reported that they missed reinserting their ethinylestradiol/ etonogestrel ring by 1 day and had unprotected coitus on that particular day.

On 08 Dec 2020 (Study Day 122), the participant had an appointment scheduled with their gynecologist.

The participant had completed study IP dosing; therefore, action taken with study IP was not applicable as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy and nonserious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000533	Drug exposure before pregnancy
MOD-2020-000487	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Binge eating	Binge eating disorder	2000 - Ongoing
Drug hypersensitivity	Allergy to morphine	2015 - Ongoing
Anxiety	Anxiety	Dec 2019 - Ongoing
Depression	Depression	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; etonogestrel	2018 - Ongoing	Birth Control
Bupropion hydrochloride	Dec 2019 - Ongoing	Anxiety And Depression
Citalopram hydrobromide	Jul 2020 - Ongoing	Anxiety And Depression
Ciprofloxacin	10 Sep 2020 (Study Day 33) - 16 Sep 2020 (Study Day 39)	Urinary Tract Infection
Influenza vaccine	10 Sep 2020 (Study Day 33) - 10 Sep 2020 (Study Day 33)	Flu Prevention
Paracetamol	12 Sep 2020 (Study Day 35) - Ongoing	Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 32) - 16 Sep 2020 (Study Day 39)
Fatigue	Grade 1/mild	Related	11 Sep 2020 (Study Day 34) - 20 Sep 2020 (Study Day 43)
COVID-19	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 65) - 26 Oct 2020 (Study Day 79)
Pregnancy	Grade 1/mild	Not related	24 Oct 2020 (Study Day 77) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US346-2076 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Exposure during pregnancy/Exposure during pregnancy	Pregnancy	Nonserious	Not applicable	04 Sep 2020 (Study Day 29) – 04 Sep 2020 (Study Day 29)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2076, a 28-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	07 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	04 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 07 Sep 2020 (Study Day 32), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was 11 Aug 2020 (Study Day 5). The estimated date of conception was 25 Aug 2020 (Study Day 19), and the estimated due date was 16 May 2021 (Study Day 283). The participant had been on etonogestrel implant at Study Visit 0/Visit 1. Per the participant, etonogestrel may have been removed without the site's knowledge on 16 Aug 2020 (Study Day 10) when the participant switched to oral contraceptive pills. It was assessed that the participant became pregnant during the switch in contraceptive method.

The participant had completed study IP dosing; therefore, action taken with study IP was not applicable as a result of the pregnancy.

The outcome of the event, exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000267	Exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eczema	Eczema	2017 - Ongoing
Rhinitis perennial	Perennial allergic rhinitis	2019 - Ongoing
Pain	Occasional body pain	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Etonogestrel	Aug 2019 - Ongoing	Birth Control
Paracetamol	Jan 2020 - Ongoing	Occasional Body Pain
Vitamins nos	May 2020 - Ongoing	Supplement
Norethisterone	16 Aug 2020 (Study Day 10) - 07 Sep 2020 (Study Day 32)	Birth Control
Paracetamol	17 Aug 2020 (Study Day 11) - 18 Aug 2020 (Study Day 12)	Upper Respiratory Tract Infection
Paracetamol	04 Sep 2020 (Study Day 29) - 06 Sep 2020 (Study Day 31)	Injection Site Pain
Ondansetron	02 Oct 2020 (Study Day 57) - Ongoing	Nausea

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	15 Aug 2020 (Study Day 9) - 21 Aug 2020 (Study Day 15)
Ligament Sprain	Grade 3/severe	Not related	07 Sep 2020 (Study Day 32) - 22 Sep 2020 (Study Day 47)
Nausea	Grade 1/mild	Not related	25 Sep 2020 (Study Day 50) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US372-2239 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	18 Nov 2020 (Study Day 98) – 18 Nov 2020 (Study Day 98)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2239, a 20-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	13 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	10 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 05 Dec 2020 (Study Day 115), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was on 05 Nov 2020 (Study Day 85). The estimated date of conception was 18 Nov 2020 (Study Day 98), and the estimated due date was 22 Jun 2021 (Study Day 314). The participant reported not using contraception.

On 10 Dec 2020 (Study Day 120), the participant was seen by a physician for the pregnancy.

The participant had completed study IP dosing; therefore, action taken with study IP was not applicable as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001110	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2017 - Ongoing
Migraine	Migraines	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline hydrochloride	2017 - Ongoing	Anxiety
Gabapentin	2018 - Ongoing	Migraines
Ibuprofen	14 Aug 2020 (Study Day 2) - 16 Aug 2020 (Study Day 4)	Pain At Injection Site
Ibuprofen	11 Sep 2020 (Study Day 30) - 18 Sep 2020 (Study Day 37)	Fever, Pain At Injection Site, Muscle Aches, Generalized Joint Aches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 3/severe	Not related	10 Sep 2020 (Study Day 29) - 11 Sep 2020 (Study Day 30)
Pyrexia	Grade 2/moderate	Related	10 Sep 2020 (Study Day 29) - 11 Sep 2020 (Study Day 30)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US372-2305 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	24 Sep 2020 (Study Day 37) – 24 Sep 2020 (Study Day 37)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2305, a 34-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	19 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	16 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 01 Oct 2020 (Study Day 44), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was 19 Sep 2020 (Study Day 32). The participant reported not using any contraceptive method. The estimated date of conception was 24 Sep 2020 (Study Day 37), and the estimated due date was 19 Jun 2021 (Study Day 305).

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both doses of study IP per protocol.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002711	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Migraine	Migraine headaches	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2010 - Ongoing	Hypothyroidism
Amitriptyline hydrochloride	2019 - Ongoing	Migraine Headaches
Paracetamol	20 Aug 2020 (Study Day 2) - 21 Aug 2020 (Study Day 3)	Headache, Pain At Injection Site
Ibuprofen	17 Sep 2020 (Study Day 30) - 20 Sep 2020 (Study Day 33)	Headache, Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US374-2148 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	16 Jan 2021 (Study Day 142) – 29 Jan 2021 (Study Day 155	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2148, a 24-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	28 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	25 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 16 Jan 2021 (Study Day 142), the participant had positive home urine pregnancy tests on 16 Jan 2021 (Study Day 142) and 17 Jan 2021 (Study Day 143). The first day of the participant's last menstrual period was on 16 Dec 2020 (Study Day 111). The estimated date of conception and estimated due date were not reported.

On 29 Jan 2021 (Study Day 155), at an estimated sixth week of pregnancy, the participant experienced a serious adverse event of spontaneous abortion. The participant reported suffering a miscarriage and consulted their obstetrician/gynecologist, who confirmed the miscarriage on the same date; the cause was not otherwise specified.

Action taken with the study IP in response to the events, drug exposure before pregnancy and spontaneous abortion, was not applicable, as the participant had already received both scheduled doses.

The events, drug exposure before pregnancy and spontaneous abortion, were reported as resolved on 29 Jan 2021 (Study Day 155).

The investigator assessed the event, spontaneous abortion, as not related to study IP or study procedure. The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the serious event and pregnancy are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005522	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2016 - Ongoing
Depression	Depression	2016 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	Nov 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	30 Aug 2020 (Study Day 3) - 01 Sep 2020 (Study Day 5)	Headache
Influenza vaccine	20 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 85)	Flu Prophylaxis
Nitrofurantoin	21 Feb 2021 (Study Day 178) - Ongoing	Urinary Tract Infection
Escitalopram	07 Mar 2021 (Study Day 192) - Ongoing	Depression

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prazosin	07 Mar 2021 (Study Day 192) - Ongoing	Post Traumatic Stress Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	21 Feb 2021 (Study Day 178) - 28 Feb 2021 (Study Day 185)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US383-2250 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure before pregnancy/ Maternal exposure before pregnancy	Pregnancy	Nonserious	Not applicable	12 Sep 2020 (Study Day 20) – 21 Sep 2020 (Study Day 29)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2250, a 28-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 21 Sep 2020 (Study Day 29).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	24 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	21 Sep 2020 (Study Day 29)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 21 Sep 2020 (Study Day 29), the participant had a positive urine pregnancy test prior to the scheduled second dose of the study IP. The first day of the participant's last menstrual period was 31 Aug 2020 (Study Day 8). The estimated date of conception was 12 Sep 2020 (Study Day 20), and the estimated due date was 18 Jun 2021 (Study Day 299).

The participant was initially compliant with their IUD contraception. However, they had removed the IUD prior to the intercourse due to discomfort and inserted a new device following intercourse. The participant denied any problems with the pregnancy.

Action taken with the study IP was withdrawn as a result of the pregnancy.

The outcome of the event, maternal exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of maternal exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000330	Maternal exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicitis	Appendicitis	2005 - 2005
Cholecystitis	Cholecystitis	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; etonogestrel	2019 - 21 Sep 2020 (Study Day 29)	Contraception
Promethazine	02 Oct 2020 (Study Day 40) - Ongoing	Ae- Nausea

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Not related	31 Aug 2020 (Study Day 8) - 01 Sep 2020 (Study Day 9)
Nausea	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 40) - 20 Oct 2020 (Study Day 58)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2086 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/ Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	28 Aug 2020 (Study Day 1) – 09 Oct 2020 (Study Day 42)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2086, a 28-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The participant had at least one positive test result for pregnancy, with first positive pregnancy reported on 25 Sep 2020 (Study Day 29).

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	28 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	25 Sep 2020 (Study Day 29)	Positive

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 25 Sep 2020 (Study Day 29), the participant had a positive urine pregnancy test at the Dose 2 visit. The first day of the participant's last menstrual period was 31 Aug 2020 (Study Day 4). The estimated date of conception was 28 Aug 2020 (Study Day 1), and the estimated due date was not reported.

Between 08 Oct 2020 (Study Day 42) and 09 Oct 2020 (Study Day 43), the participant underwent an elective medical termination of intrauterine pregnancy. No complications were reported during the pregnancy or termination. The number of weeks of pregnancy was unknown per the investigator. Treatment medications provided for the elective termination of pregnancy included

oral mifepristone 200 mg on 08 Oct 2020 (Study Day 42) and buccal misoprostol 800 mg on 09 Oct 2020 (Study Day 43).

Action taken with the study IP was withdrawn as a result of the pregnancy.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the events of drug exposure before pregnancy and abortion elective and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000362	Drug exposure before pregnancy

Study Completion/Discontinuation

On 14 Jan 2021 (Study Day 140), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eczema	Eczema	1995 - Ongoing
Migraine	Migraines	2006 - Ongoing
Drug hypersensitivity	Allergy to pcn	2008 - Ongoing
Arthroscopy	Left knee arthroscopy	Feb 2008 - Feb 2008
Asthma exercise induced	Exercise induced asthma	2012 - Ongoing
Endometriosis	Endometriosis	2014 - Ongoing
Tonsillectomy	Tonsillectomy	Aug 2015 - Aug 2015
Uterine dilation and curettage	Endometrial excision	Jul 2017 - Jul 2017
Depression	Depression	2018 - Ongoing
Anxiety	Anxiety	2019 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Seasonal allergy	Seasonal allergies	2019 - Ongoing
Drug hypersensitivity	Allergy to ribavirin	20 Mar 2019 (Study Day -527) - Ongoing
Exposure to communicable disease	Exposure to hepatitis c	20 Mar 2019 (Study Day -527) - 20 Mar 2019 (Study Day -527)
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2012 - Ongoing	Asthma
Cetirizine hydrochloride	Mar 2019 - Ongoing	Seasonal Allergies
Alprazolam	Jul 2019 - Ongoing	Anxiety And Insomnia
Venlafaxine	Jul 2019 - Ongoing	Depression
Zolpidem	Jul 2019 - Ongoing	Insomnia
Lansoprazole	2020 - Ongoing	Gastroesophageal Reflux Disease
Elective medical termination of intrauterine pregnancy*	08 Oct 2020 (Study Day 42) - 08 Oct 2020 (Study Day 42)	Other, Pregnancy
Mifepristone	08 Oct 2020 (Study Day 42) - 08 Oct 2020 (Study Day 42)	Elective Termination Of Pregnancy
Misoprostol	09 Oct 2020 (Study Day 43) - 09 Oct 2020 (Study Day 43)	Elective Termination Of Pregnancy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US387-2213 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 30)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	18 Jan 2021 (Study Day 155) – 18 Jan 2021 (Study Day 155)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2213, a 36-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	17 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	15 Sep 2020 (Study Day 30)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 03 Mar 2021 (Study Day 199), the participant had a positive urine human chorionic gonadotropin pregnancy test. The participant reported using condoms with spermicide as a means of contraception. The first day of the participant's last menstrual period was 04 Jan 2021 (Study Day 141). The estimated date of conception was 18 Jan 2021 (Study Day 155), and the due date was estimated as 07 Oct 2021 (Study Day 417).

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event of drug exposure before pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-033970	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	15 May 2020 (Study Day -94) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	15 May 2020 (Study Day -94) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rhinorrhoea	Grade 1/mild	Not related	21 Sep 2020 (Study Day 36) - 01 Oct 2020 (Study Day 46)
Cough	Grade 1/mild	Not related	23 Sep 2020 (Study Day 38) - 06 Nov 2020 (Study Day 82)
Fatigue	Grade 1/mild	Not related	27 Sep 2020 (Study Day 42) - 01 Nov 2020 (Study Day 77)
Headache	Grade 1/mild	Not related	27 Sep 2020 (Study Day 42) - 30 Sep 2020 (Study Day 45)
Rhinorrhoea	Grade 1/mild	Not related	03 Oct 2020 (Study Day 48) - 10 Oct 2020 (Study Day 55)
Oropharyngeal Pain	Grade 1/mild	Not related	07 Oct 2020 (Study Day 52) - 11 Oct 2020 (Study Day 56)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nasal Congestion	Grade 1/mild	Not related	10 Oct 2020 (Study Day 55) - 15 Oct 2020 (Study Day 60)
Rhinorrhoea	Grade 1/mild	Not related	15 Oct 2020 (Study Day 60) - 17 Oct 2020 (Study Day 62)
Nasal Congestion	Grade 1/mild	Not related	17 Oct 2020 (Study Day 62) - 18 Oct 2020 (Study Day 63)
Rhinorrhoea	Grade 1/mild	Not related	18 Oct 2020 (Study Day 63) - 19 Oct 2020 (Study Day 64)
Nasal Congestion	Grade 1/mild	Not related	19 Oct 2020 (Study Day 64) - 23 Oct 2020 (Study Day 68)
Cough	Grade 1/mild	Not related	28 Dec 2020 (Study Day 134) - 13 Apr 2021 (Study Day 240)
Nasal Congestion	Grade 1/mild	Not related	20 Feb 2021 (Study Day 188) - 13 Apr 2021 (Study Day 240)
Exposure During Pregnancy	Grade 3/severe	Not applicable	03 Mar 2021 (Study Day 199) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2345 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	01 Oct 2020 (Study Day 35) – 09 Jan 2021 (Study Day 135)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2345, a 36-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	28 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	25 Sep 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 31 Dec 2020 (Study Day 126), the participant had a positive urine pregnancy test. The participant reported using condoms with spermicide as a means of contraception. The first day of the participant's last menstrual period was unknown. The estimated date of conception was 01 Oct 2020 (Study Day 35), and the estimated due date was 30 Apr 2021 (Study Day 246). The participant did not realize they were pregnant until 31 Dec 2020 (Study Day 126), when they believed they were approximately 20 weeks pregnant. The participant did not know for sure when their last period was because they had a history of irregular periods. The pregnancy was not planned.

On 09 Jan 2021 (Study Day 135), the participant experienced a serious adverse event of abortion elective. At approximately 20 weeks of pregnancy, the participant chose to terminate the pregnancy with an elective abortion. There were no complications following the procedure. The outcome of the pregnancy was elective termination without congenital anomaly.

On 19 Feb 2021 (Study Day 176), the participant reported the pregnancy to the site.

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the events, drug exposure before pregnancy and elective abortion, was not reported.

The investigator's assessment of the relationship between the events of drug exposure before pregnancy and elective abortion and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy and serious adverse event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-017500	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	11 Dec 2020 (Study Day 106) - 11 Dec 2020 (Study Day 106)	Prophylactic Influenza
Pregnancy fermentation*	09 Jan 2021 (Study Day 135) - 09 Jan 2021 (Study Day 135)	Other, Unwanted Pregnancy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Insomnia	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 96) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378141

Participant Number:	US394-2027 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE, Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	10 Dec 2020 (Study Day 104) – 17 Dec 2020 (Study Day 111)	Recovered/ resolved
Abortion Spontaneous/ Spontaneous Abortion	SAE, Pregnancy	Grade 3/ severe	Not related	10 Dec 2020 (Study Day 104) – 17 Dec 2020 (Study Day 111)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2027, a 23-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 10 Dec 2020 (Study Day 104), 103 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abortion spontaneous. Action taken with the IP was not applicable. The event of spontaneous abortion lasted for 8 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 111). The investigator assessed the event of abortion spontaneous to be not related to the IP.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	29 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	24 Sep 2020 (Study Day 27)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 10 Dec 2020 (Study Day 104), the participant had a positive pregnancy test. The first day of the participant's last menstrual period was on 08 Nov 2020 (Study Day 72). The estimated date of conception was in December 2020.

On 14 Dec 2020 (Study Day 108), human chorionic gonadotropin (HCG) quantitative level was 112.5 (no unit or reference range reported).

On 17 Dec 2020 (Study Day 111), the participant presented to the emergency department, where it was confirmed that they had experienced a spontaneous abortion. The participant's HCG quantitative level was 38.1 (no units or reference range). No treatment was given.

Action taken with the study IP was not applicable in response to the events, as the participant had already received both scheduled doses.

The events, drug exposure before pregnancy and spontaneous abortion, were considered resolved on 17 Dec 2020 (Study Day 111).

The investigator's assessment of the relationship of the event, drug exposure before pregnancy, and the study IP or study procedure was not reported. The investigator assessed the event, abortion spontaneous, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the pregnancy and serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001223	Drug exposure before pregnancy
MOD-2020-001223	Abortion spontaneous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pre-eclampsia	Preeclampsia	2016 - 2016
Toothache	Tooth ache	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen sodium	Feb 2020 - Ongoing	Tooth Ache
Nitrofurantoin	14 Dec 2020 (Study Day 108) - 21 Dec 2020 (Study Day 115)	Urinary Tract Infection
Ob ultrasound*	17 Dec 2020 (Study Day 111) - 17 Dec 2020 (Study Day 111)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	14 Dec 2020 (Study Day 108) - 21 Dec 2020 (Study Day 115)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US397-2210 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	20 Oct 2020 (Study Day 29)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug exposure before pregnancy/Drug exposure before pregnancy	Pregnancy	Nonserious	Not applicable	22 Apr 2021 (Study Day 213) – 22 Apr 2021 (Study Day 213)	Ongoing

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2210, a 28-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 22 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 20 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	22 Sep 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	20 Oct 2020 (Study Day 29)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 22 Apr 2021 (Study Day 213), the participant had a positive urine pregnancy test. The first day of the participant's last menstrual period was on 29 Mar 2021 (Study Day 189). After speaking with the principal investigator, the participant confirmed their pregnancy but did not elaborate due to the planned site visit on 26 Apr 2021 (Study Day 217). The estimated date of conception was 22 Apr 2021 (Study Day 213), and the estimated due date was 03 Jan 2022 (Study Day 469).

Action taken with study IP in response to the pregnancy was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, drug exposure before pregnancy, was not reported.

The investigator's assessment of the relationship between the event, drug exposure before pregnancy, and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-089803	Drug exposure before pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1996 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Norethisterone	Aug 2020 - Ongoing	Birth Control Pregnancy Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US303-2112 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 30)
Reason for Narrative:	Pregnancy

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Maternal exposure during pregnancy	Pregnancy	Nonserious	Not applicable	03 Sep 2020 (Study Day 30) – 03 Sep 2020 (Study Day 30)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2112, a 30-year-old race not reported female, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Pregnancy Details

The laboratory test results for pregnancy are reported in the table below:

Laboratory Results:

Test Name	Test Date	Result
Choriogonadotropin Beta	05 Aug 2020 (Study Day 1)	Negative
Choriogonadotropin Beta	03 Sep 2020 (Study Day 30)	Negative

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 03 Sep 2020 (Study Day 30), the participant had a positive pregnancy test performed in December 2020. The first day of the participant's last menstrual period was 11 Aug 2020 (Study Day 7). The estimated date of conception was 25 Aug 2020 (Study Day 21), and the estimated due date was 18 May 2021 (Study Day 287). The participant reported using condoms with spermicide as a method of contraception.

On 08 Oct 2020 (Study Day 65), the participant's ultrasound (8 weeks and 2 days of gestational age) showed a singleton live intrauterine pregnancy (IUP) with fetal heart rate 148 beats per minute (bpm). On the ultrasound, the yolk sac and embryo were seen. The cervix, adnexa, and uterus appeared normal. The participant tested negative for syphilis, human immunodeficiency virus, hepatitis B virus, human papillomavirus, *Neisseria gonorrhoeae*, and *Chlamydia trachomatis*.

On 22 Jan 2021 (Study Day 171), the participant stated their pregnancy was progressing well.

On 28 Apr 2021 (Study Day 267), at 37 weeks 1 day of gestational age, the participant was induced due to polyhydramnios and gestational diabetes and was given hydration IV and antiemetics. Artificial rupture of membranes was performed. The participant utilized an epidural. The birth was spontaneous vaginal without complication. Oxytocin was used for augmentation of labor. After approximately 15 minutes of second stage of labor, a viable male was born. The infant was noted to have bilateral club feet (previously noted in ultrasound). Nuchal cord was checked, and no nuchal cord was noted. Third stage of labor was without complication. There were no perineal lacerations noted. Time elapsed between rupture of membrane and delivery was 7 hours 55 minutes. Postpartum period was uncomplicated. Infant was bottle fed using infant formula with iron. During the review of medical records, infant's weight was 3895 gm, length was 53.34 cm, and head circumference was 34.29 cm. Apgar score at 1 minute was 8, and at 5 minutes was 9. The infant had 2 preauricular skin tags on right ear. On an unspecified day in May 2021, a retroperitoneal ultrasound on the infant showed minimal hydronephrosis on the left, otherwise bilateral kidneys, and urinary bladder were within normal limits.

Action taken with study IP in response to the event, maternal exposure during pregnancy, was not applicable, as the participant had already received both scheduled doses.

The outcome of the event, maternal exposure during pregnancy, was not reported.

The investigator's assessment of the relationship between the event of maternal exposure during pregnancy and the study IP or study procedure was not reported.

Additional Information From the Safety Database

Additional details for the pregnancy are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-007678	Maternal exposure during pregnancy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy	1992 - Ongoing
Urticaria	Allergy to sulfa-hives	1992 - Ongoing
Urticaria	Allergy to levaquin-hives	2010 - Ongoing
Genital herpes	Genital herpes	2014 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mammary duct ectasia	Mammary duct ectasia left	2018 - Ongoing
Abscess drainage	Abscess drained in right breast	May 2020 - May 2020
Breast abscess	Absess right breast	May 2020 - May 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aciclovir	08 Oct 2020 (Study Day 65) - Ongoing	Genital Herpes
Ultrasound*	31 Dec 2020 (Study Day 149) - 31 Dec 2020 (Study Day 149)	Adverse Event
Glibenclamide	05 Feb 2021 (Study Day 185) - 28 Apr 2021 (Study Day 267)	Gestational Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gestational Diabetes	Grade 1/mild	Not related	05 Feb 2021 (Study Day 185) - 28 Apr 2021 (Study Day 267)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2112_a (Part A) (Fetus/Infant Narrative)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Talipes/Bilateral Talipes Equinovarus Of Fetus*	SAE	Grade 3/ severe	Not related	11 Aug 2020 (Study Day 7) – Ongoing	Not recovered/ not resolved

* This narrative is a description of the event related to the fetus/infant of Participant US303-2112.

Event Details

On 11 Aug 2020 (Study Day 7), 6 days after the first dose and 23 days before the second dose of the IP, the fetus/infant of participant experienced a Grade 3/severe serious adverse event of talipes. Action taken with the IP was not applicable. The event of bilateral talipes equinovarus of fetus was considered to be ongoing. The investigator assessed the event of talipes to be not related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 31 Dec 2020 (Study Day 149), the participant's fetus experienced a serious adverse event of talipes (bilateral talipes equinovarus of fetus). On the same day, the participant's ultrasound (20 weeks and 2 days of gestational age) showed a singleton live intrauterine pregnancy with cervical length 4.68 cm, nuchal fold 7.8 mm, fetal heart rate 154 bpm, and in transverse position with normal amniotic fluid. Fetal heart chambers were not seen well. It also showed abnormal face profile, frontal bossing (present in some views and in other views appears normal), and bilateral talipes equinovarus (club feet). The participant had noninvasive prenatal testing (NIPT) done.

On 05 Jan 2021 (Study Day 154), the participant had an ultrasound (21 weeks and 0 days of gestational age) at the perinatal center that showed the fetus had a nuchal fold that measured 9.4 mm (abnormal), left and right club feet, and levorotation of the cardiac axis. The participant's cervical length was 5.13 cm. The fetal heart rate was 159 bpm. The remainder of the ultrasound was normal with fetus in breech position. The participant reported feeling well and denied any obstetrical complaints. Differential diagnosis included trisomy 18, other obstetrical aneuploidy, nonaneuploid syndrome, and/or congenital anomaly without underlying genetic abnormality. The perinatal physician discussed the risks and benefits of an amniocentesis. After discussion, the plan of care was to wait for the NIPT results. If NIPT results were negative, then they would defer

diagnostic genetics until the newborn period. If NIPT results were positive, then they would continue with counseling with the genetic counselor to finalize a decision to proceed with or decline amniocentesis. The participant's NIPT showed no aneuploidy detected and the fetal sex was male.

On 28 Apr 2021 (Study Day 267), at 37 weeks 1 day of gestational age, infant was born and noted to have bilateral club feet (previously noted in ultrasound).

Action taken with study IP in response to the event, talipes, was not applicable, as the participant had already received both scheduled doses.

The event, talipes, was considered as not recovered/not resolved on 25 Mar 2021 (Study Day 233).

The investigator assessed the event, talipes, as not related to study IP or study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-117184	Talipes

Participant Number:	US321-2326 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Autonomic Nervous System Imbalance/ Autonomic Dysfunction	SAE	Grade 2/ moderate	Related	25 Sep 2020 (Study Day 30) – 01 Mar 2021 (Study Day 187)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2326, a 46-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 30), 29 days after the first dose and on the day of the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of autonomic nervous system imbalance. Action taken with the IP was not applicable. The event of autonomic dysfunction lasted for 158 days, after which it was considered to be recovered/resolved with sequelae on 01 Mar 2021 (Study Day 187). The investigator assessed the event of autonomic nervous system imbalance to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 25 Sep 2020 (Study Day 30), the participant experienced a serious adverse event of autonomic nervous system imbalance after receiving the second dose of study IP. While driving home, about 30 minutes after the second dose, the participant had a strange feeling in their head. The participant reported not being able to think right. They wanted to pull over to the side of the road but did not because of the traffic. The participant kept driving home and when they got home, they had a fever with a maximum temperature of 102.5°F for 2 days. The participant reported feeling better after the fever resolved. Treatment for the fever/pain reactogenicity included paracetamol PO.

On 18 Oct 2021 (Study Day 53), the participant reported intense vertigo upon standing with no prior history of vertigo. They awoke the next morning with persistent vertigo. On an unknown

date, the participant went to their primary care provider (PCP) who prescribed amoxicillin/clavulanate PO (taken from 25 Oct 2020 [Study Day 60] to 30 Oct 2020 [Study Day 65]) for possible sinus congestion. The PCP did not find any sinus or ear problems. The participant reported menstrual periods every 15 days. The participant's hemoglobin was 13.1 (no units or reference range provided), and a complete metabolic panel, thyroid levels, and D-dimer were all normal. The participant reported symptoms of intermittent palpitations and intermittent dizziness. They were unable to tolerate their usual level of activity/exercise; they were typically able to run 10 miles without problems, but recently, they could run only a mile and developed heart palpitations (heart pounding) and dizziness if they walked a block. The participant denied spinning sensation, syncope, and depression. The participant's vertigo had mostly resolved, but they continued to have shortness of breath, palpitations, and lack of stamina. Treatment for the event included formoterol inhalation.

On 03 Nov 2020 (Study Day 69), the participant was treated with meclizine PO for autonomic dysfunction.

On 18 Nov 2020 (Study Day 84), an electrocardiogram was normal. Additional diagnostic test results reported, without dates, included a magnetic resonance imaging scan of the brain that showed no acute changes with cerebral spinal fluid collection at the right cerebellomedullary angle suggestive of an arachnoid cyst; chest x-ray was normal; thyroid-stimulating hormone, complete blood count, chemistries, aspartate aminotransferase, alanine aminotransferase, and D-dimer were normal. A Hallpike maneuver was negative with no nystagmus (they were briefly dizzy); blood pressure was 118/79 mm Hg and pulse 71 beats per minute (bpm) while supine and 111/77 mm Hg and pulse 76 bpm while standing. The participant reported having intermittent dizziness and vertigo often precipitated by exercise. The participant was referred to get a Holter monitor and cardiology evaluation with encouragement from the investigator and an additional recommendation for a neurology evaluation as they continued to have symptoms of fatigue and dizziness that limited their exercise and activities.

On 16 Dec 2020 (Study Day 112), the participant had an echocardiogram which showed normal left ventricular systolic function with an ejection fraction of greater than 55%, normal left ventricular wall thickness, mild mitral regurgitation, normal aortic and tricuspid valve, and no pericardial effusion. The participant also had a stress test which was interpreted to be a normal maximum stress test; predicted maximum heart rate was 174 bpm, 80% target heart rate was 148 bpm; cardiac and pulmonary examinations were normal.

Action taken with the study IP was not applicable in response to the event as the participant received both doses of study IP.

The event, autonomic nervous system imbalance, was reported as resolved with sequelae (palpitations) on 01 Mar 2021 (Study Day 187).

The investigator assessed the event, autonomic nervous system imbalance, as related to study IP and not related to study procedure.

The investigator stated that the participant's symptoms of fatigue, dizziness, and palpitations were possibly related to the study IP based on a temporal relationship and no other cause had been identified despite medical check-ups with physicians.

The investigator assessed the event, autonomic nervous system imbalance, as related to study IP. The sponsor considered the event to be unrelated to the study IP, as the symptoms described were relatively common and nonspecific in this subject with multiple confounders, including concomitant sinus infection and thyroid dysfunction, which would provide more plausible explanations for the symptoms experienced.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000862	Autonomic nervous system imbalance

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	2005 - 2005
Benign neoplasm of thyroid gland	Left thyroid nodule, benign	2006 - 2006
Hypothyroidism	Hypothyroidism	2006 - Ongoing
Thyroidectomy	Left thyroidectomy	2006 - 2006
Plantar fasciitis	Plantar fasciitis left foot	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	Jun 2006 - Ongoing	Hypothyroidism

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fish oil	2014 - Ongoing	Deficiency; General Health
Xantofyl; zeaxanthin	2017 - Ongoing	Eye Health; General Health
Ascorbic acid; folic acid; vitamin b complex	Jan 2020 - Ongoing	Deficiency; General Health
Calcium carbonate; colecalciferol	Jan 2020 - Ongoing	Deficiency; General Health
Paracetamol	25 Sep 2020 (Study Day 30) - 26 Sep 2020 (Study Day 31)	Fever/Pain Reactogenicity
Formoterol	21 Oct 2020 (Study Day 56) - 21 Oct 2020 (Study Day 56)	Autonomic Dysfunction
Amoxicillin sodium; clavulanate potassium	25 Oct 2020 (Study Day 60) - 30 Oct 2020 (Study Day 65)	Acute Non-Recurrent Pansinusitis
Meclozine	03 Nov 2020 (Study Day 69) - 03 Nov 2020 (Study Day 69)	Autonomic Dysfunction
Chest x-ray*	07 Dec 2020 (Study Day 103) - 07 Dec 2020 (Study Day 103)	Adverse Event
Mri head*	07 Dec 2020 (Study Day 103) - 07 Dec 2020 (Study Day 103)	Adverse Event
Cardiac stress test*	16 Dec 2020 (Study Day 112) - 16 Dec 2020 (Study Day 112)	Adverse Event
Echocardiogram*	16 Dec 2020 (Study Day 112) - 16 Dec 2020 (Study Day 112)	Adverse Event
Holter monitor (ambulatory ekg)*	16 Dec 2020 (Study Day 112) - 16 Dec 2020 (Study Day 112)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	20 Oct 2020 (Study Day 55) - 24 Dec 2020 (Study Day 120)
Sinusitis	Grade 1/mild	Not related	23 Oct 2020 (Study Day 58) - 02 Nov 2020 (Study Day 68)
Upper-Airway Cough Syndrome	Grade 1/mild	Not related	25 Oct 2020 (Study Day 60) - 24 Dec 2020 (Study Day 120)
Polymenorrhoea	Grade 1/mild	Related	08 Nov 2020 (Study Day 74) - 27 Dec 2020 (Study Day 123)
Palpitations	Grade 1/mild	Related	01 Mar 2021 (Study Day 187) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US332-2329 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Swelling Face/Facial Swelling	SAE	Grade 3/ severe	Related	17 Oct 2020 (Study Day 36) – 22 Oct 2020 (Study Day 41)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2329, a 51-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Oct 2020 (Study Day 36), 35 days after the first dose and 2 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of swelling face. Action taken with the IP was not applicable. The event of facial swelling lasted for 6 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 41). The investigator assessed the event of swelling face to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 02 Oct 2020 (Study Day 21), the participant had cosmetic injections in their cheeks. They were injected with a Botox/Filler combination consisting of 60 units of BOTOX® (onabotulinumtoxinA) Cosmetic, 1 unit of Juvederm® Ultra Plus XC, and 3 units of Juvederm® Voluma SC.

On 15 Oct 2020 (Study Day 34), the participant presented to the site for their second dose visit and their physical examination, including a skin assessment, which was normal.

On 17 Oct 2020 (Study Day 36), the participant experienced a serious adverse event of swelling face, which was considered medically significant. The participant developed injection site swelling/hardness measuring 125 mm with mild deltoid tenderness at the site of study IP administration, but they denied trouble moving the affected arm. That night, they experienced bilateral facial swelling, which was greater on the left side than the right. The participant contacted

the doctor who performed the cosmetic procedure with concerns of moderate facial swelling and was prescribed a 5-day course of prednisolone PO (initial dose of 25 mg, followed by 40 mg daily) as the treatment.

On 18 Oct 2020 (Study Day 37), the area of swelling/hardness at the study IP injection site reduced to 55 mm.

On 20 Oct 2020 (Study Day 39), the participant reported that their facial swelling was almost completely resolved, with minimal swelling remaining under the left eye.

Action taken with study IP in response to the event was not applicable as the participant had already received both scheduled doses.

The event, swelling face, was considered resolved on 22 Oct 2020 (Study Day 41).

The investigator assessed the event, swelling face, as related to study IP and not related to study procedure. The investigator noted that facial swelling was a known potential side effect of Voluma dermal filler injections and stated that the injection of dermal filler was believed to be a contributing factor to the participant's development of facial swelling. However, since the participant developed facial swelling almost 2 weeks after the dermal filler injections and only 2 days after administration of study IP, the investigator concluded that the temporal relationship provided a reasonable probability of a causal relationship between the participant's facial swelling and receipt of the IP.

The sponsor cannot rule out a possible cause and effect relationship between administration of study IP and the occurrence facial swelling. After review of the clinical details and investigator comments pertaining to this adverse event, and based upon experience to date, the sponsor does not believe that changes to the conduct of this clinical trial are warranted.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000515	Swelling face

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cervical dysplasia	Cervical dysplasia	2007 - 2007
Hysterectomy	Hysterectomy	2007 - 2007
Postmenopause	Post menopausal	2014 - Ongoing
Foot operation	Foot surgery	2018 - 2018
Sports injury	Tennis injury-left foot	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	2014 - Ongoing	Post Menopausal
Testosterone	2014 - Ongoing	Post Menopausal
Naproxen	16 Sep 2020 (Study Day 5) - 16 Sep 2020 (Study Day 5)	Generalized Myalgia
Botulinum toxin type a	Oct 2020 - Oct 2020	Facial Cosmetic Injection(Wrinkles)
Dermal filler injection*	02 Oct 2020 (Study Day 21) - 02 Oct 2020 (Study Day 21)	Other, Cosmetic
Hyaluronic acid	02 Oct 2020 (Study Day 21) - 02 Oct 2020 (Study Day 21)	Cosmetic Procedure
Naproxen	16 Oct 2020 (Study Day 35) - 16 Oct 2020 (Study Day 35)	Headache, Left Arm Injection Site Swelling
Amoxicillin; clavulanic acid	17 Oct 2020 (Study Day 36) - 21 Nov 2020 (Study Day 71)	Facial Swelling
Prednisolone	17 Oct 2020 (Study Day 36) - 17 Oct 2020 (Study Day 36)	Facial Swelling
Prednisolone	18 Oct 2020 (Study Day 37) - Ongoing	Facial Swelling
Influenza vaccine	23 Nov 2020 (Study Day 73) - 23 Nov 2020 (Study Day 73)	Preventative Healthcare

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	17 Nov 2020 (Study Day 67) - 01 Dec 2020 (Study Day 81)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	11 Jan 2021 (Study Day 122) - 14 Jan 2021 (Study Day 125)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2023 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Polymyalgia Rheumatica/Possible Polymyalgia Rheumatica	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Related	20 Aug 2020 (Study Day 16) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2023, an 83-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Aug 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of polymyalgia rheumatica. On 01 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of possible polymyalgia rheumatica was considered to be ongoing. The investigator assessed the event of polymyalgia rheumatica to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 07 Aug 2020 (Study Day 3), the participant returned to the clinic for an unscheduled visit, due to a complaint of mild body aches. They had a negative nasopharyngeal RT-PCR SARS-CoV-2 test.

On 20 Aug 2020 (Study Day 16), the participant experienced a serious adverse event of polymyalgia rheumatica (PMR). The participant presented to the emergency department and was hospitalized due to generalized weakness and severe myalgias that lasted for 3 days. In the days leading up to the hospitalization, the participant developed progressive, migratory myalgias of bilateral lumbar/sacroiliac joint, bilateral deltoid, right occiput, cervical paraspinal muscles which had worsened over 2 weeks; and progressive weakness until they were unable to get out of bed. The participant reported difficulty abducting bilateral upper extremities due to weakness and

pain. In addition, they experienced headache, which was relieved by paracetamol. The participant denied fever or chills. The participant did not experience vertigo, unilateral weakness/numbness or speech changes; thus, stroke was excluded.

On an unspecified date in August, laboratory test results included C-reactive protein at 96.9 mg/L (reference range 0.0 to 5.0 mg/L); erythrocyte sedimentation rate of 56 mm/h (reference range 0 to 15 mm/h); troponin 30 then 29 (no units or reference range provided), creatinine 2.6 (participant's baseline level was 1.9 to 2.1; no units or reference range provided), and magnesium 2.0 (no unit or reference range reported). An infectious disease work-up was negative including an unremarkable urinalysis, negative COVID-19 test, and negative chest x-ray. An electrocardiogram (ECG) was unchanged from the prior ECG.

The admitting physician, primary investigator, and infectious disease consultant originally assessed that the myalgias were unlikely related to study IP, given the timing of onset of symptoms and insignificant findings in clinic 7 days after study IP dose. Rheumatologists were consulted and provided a possible diagnosis of PMR; however, a vaccine side effect was also suspected. Their recommendation included a one-time dose of prednisone of 15 mg. After the one-time dose was administered, the participant's pain resolved.

On 21 Aug 2020 (Study Day 17), the participant reported feeling much better; however, they still had mild tenderness over right occiput, deltoid and cervical paraspinal areas on examination. Their range of motion (ROM) had improved; they were able to fully abduct their shoulders; and ROM of cervical spine was intact. Their sensation and strength were equal bilaterally, with no focal deficits. The abnormal laboratory results on the same day included chloride 113 (high), carbon dioxide 15 (low), blood urea nitrogen 37 (high), creatinine 2.03 (high), glucose 125 (high), red blood cell count 2.61 (low), hemoglobin 7.5 (low), hematocrit 22.9 (low), and platelet count 125 (low) (no units and reference ranges reported). Vital signs included temperature 97.9°F, heart rate 59 beats per minute, respiratory rate 18 breaths per minute, blood pressure 153/65 mm Hg, and oxygen saturation 97% on room air. On the same day, the participant was discharged on a 15-day prednisone taper (starting dose of 20 mg daily) with plans to follow-up on symptoms and laboratory tests after the taper was completed.

On 26 Aug 2020 (Study Day 22), the participant reported feeling good during the day, however, upon waking up in the morning, they experienced some pain in their shoulders and neck. The pain went away approximately 2 hours after taking prednisone.

On 04 Sep 2020 (Study Day 31), the participant completed their prednisone taper; however, they experienced recurrence of axial myalgias.

On 09 Sep 2020 (Study Day 36), the participant was seen by a rheumatologist as an outpatient. Laboratory test results included antinuclear antibody <1:40 (no units, reference range <1:40) and

rheumatoid factor <10 IU/mL (reference range 0 to 15 IU/mL). Prednisone was restarted at 20 mg for 2 weeks, followed by slow taper.

During study follow-up visits on 01 Oct 2020 (Study Day 58) and 13 Oct 2020 (Study Day 70), the participant responded well on the prednisone regimen. They planned to continue follow-up with rheumatology for the speed of their prednisone taper and overall condition.

Study IP was discontinued in response to the event, as the investigator was concerned that administering the next scheduled study IP dose might interfere with symptom assessment of PMR due to the participant's ongoing prednisone taper.

The event, PMR, was considered resolving.

The investigator assessed the event, PMR, as related to study IP and not related to study procedure. Per the investigator, there may be a possible relationship due to the symptomatology described as polymyalgia and weakness that developed after the study IP was administered.

Based on review of available data, the sponsor cannot rule out a possible cause and effect relationship between administration of study IP and the occurrence of polymyalgia rheumatica.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000211	Polymyalgia rheumatica

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy (serum sickness)	1960 – Ongoing
Depression	Mild depression	1980 – Ongoing
Hyperlipidaemia	Hyperlipidemia	1980 – Ongoing
Back pain	Chronic low back pain with intermittent flare	2000 – Ongoing
Hypothyroidism	Hypothyroidism	2005 – Ongoing
Hypertension	Hypertension (well controlled)	2010 – Ongoing
Pneumonia pneumococcal	Pneumococcal pneumonia	2010 – 2010
Seasonal allergy	Seasonal allergies	2010 – Ongoing
Ventricular extrasystoles	Premature ventricular complex	2010 – Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cerebrovascular accident	Stroke	2011 – 2011
Anaemia	Chronic anemia	2012 – Ongoing
Hypergammaglobulinaemia benign monoclonal	Monoclonal gammopathy of undetermined significance	2012 – Ongoing
Renal failure	Mild renal failure	2013 – Ongoing
Aortic stenosis	Aortic stenosis	Jun 2019 – Ongoing
Cardiac failure congestive	Congestive heart failure	Jun 2019 – Ongoing
Transcatheter aortic valve implantation	Tavr for aortic stenosis	Jun 2019 - Jun 2019
Coronary artery disease	Coronary heart disease	Nov 2019 – Ongoing
Constipation	Constipation	Jan 2020 – Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion	1980 – Ongoing	Depression
Acetylsalicylic acid	2000 – Ongoing	Chronic Low Back Pain With Intermittent Flare
Levothyroxine	2005 – Ongoing	Hypothyroidism
Atenolol	2010 – Ongoing	Premature Ventricular Complex
Fluticasone propionate	2010 – Ongoing	Seasonal Allergies
Acetylsalicylic acid	2011 – Ongoing	Stroke
Clopidogrel bisulfate	2011 – Ongoing	Stroke
Calcium	2015 – Ongoing	General Health
Vitamin d nos	2015 – Ongoing	General Health
Vitamins nos	2015 – Ongoing	General Health
Bisoprolol	2016 - Jul 2020	Heart Failure/Htn
Rosuvastatin	2018 – Ongoing	Hyperlipidemia
Docusate sodium	Jan 2020 - Ongoing	Constipation
Prednisone	20 Aug 2020 (Study Day 16) - 20 Aug 2020 (Study Day 16)	Possible Polymyalgia Rheumatica
Prednisone	21 Aug 2020 (Study Day 17) - 04 Sep 2020 (Study Day 31)	Possible Polymyalgia Rheumatica
Prednisone	11 Sep 2020 (Study Day 38) - Ongoing	Polymyalgia Rheumatica
Influenza vaccine	25 Sep 2020 (Study Day 52) - 25 Sep 2020 (Study Day 52)	Prophylaxis For Influenza
Cardiac ultrasound*	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Adverse Event
Chest xr*	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Adverse Event
Ct head*	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Methylprednisolone	29 Jan 2021 (Study Day 178) - 06 Feb 2021 (Study Day 186)	Pmr
Methylprednisolone	29 Jan 2021 (Study Day 178) - 08 Feb 2021 (Study Day 188)	Pmr
Ondansetron	29 Jan 2021 (Study Day 178) - 16 Feb 2021 (Study Day 196)	Nausea
Methylprednisolone	30 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 188)	Pmr
Aminophylline	31 Jan 2021 (Study Day 180) - 31 Jan 2021 (Study Day 180)	Idiopathic Interstitial Pneumonitis
Myocardial perfusion spect study*	31 Jan 2021 (Study Day 180) - 31 Jan 2021 (Study Day 180)	Adverse Event
Plantago ovata	31 Jan 2021 (Study Day 180) - 16 Feb 2021 (Study Day 196)	Constipation
Lung ventilation and perfusion scan*	02 Feb 2021 (Study Day 182) - 02 Feb 2021 (Study Day 182)	Adverse Event
Oxymetazoline	02 Feb 2021 (Study Day 182) - 05 Feb 2021 (Study Day 185)	Idiopathic Interstitial Pneumonitis
Ct chest*	03 Feb 2021 (Study Day 183) - 03 Feb 2021 (Study Day 183)	Adverse Event
Guaifenesin	03 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 196)	Cough
Heparin	03 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 196)	Coagulant Prophylaxis
Salbutamol	03 Feb 2021 (Study Day 183) - 16 Feb 2021 (Study Day 196)	Wheezing Associated With Idiopathic Interstitial Pneumonitis
Paracetamol	04 Feb 2021 (Study Day 184) - 16 Feb 2021 (Study Day 196)	Pain And Fever
Atovaquone	08 Feb 2021 (Study Day 188) - 11 Feb 2021 (Study Day 191)	Pjp Prophylaxis
Methylprednisolone sodium succinate	08 Feb 2021 (Study Day 188) - 11 Feb 2021 (Study Day 191)	Pmr
Prednisone	11 Feb 2021 (Study Day 191) - 15 Feb 2021 (Study Day 195)	Pmr
Prednisone	15 Feb 2021 (Study Day 195) - 03 Mar 2021 (Study Day 211)	Pmr
Abdomen ultrasound*	16 Feb 2021 (Study Day 196) - 16 Feb 2021 (Study Day 196)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US354-2108 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Swelling Face/Cheek Swelling, Bilateral	SAE	Grade 2/ moderate	Related	30 Sep 2020 (Study Day 31) – 05 Oct 2020 (Study Day 36)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2108, a 46-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Sep 2020 (Study Day 31), 30 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of swelling face. Action taken with the IP was not applicable. The event of cheek swelling, bilateral lasted for 6 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 36). The investigator assessed the event of swelling face to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 29 Sep 2020 (Study Day 30), the participant experienced injection site pain from the second vaccination at night through the next day.

On 30 Sep 2020 (Study Day 31), the participant experienced a serious adverse event of swelling face that was considered a medically important event. The participant woke up with significant bilateral cheek swelling; no rash, pain, tenderness, oral or respiratory symptoms were reported. The participant had no fever or chills and felt well aside from unsightly cheek swelling. The participant had no new medications, foods, creams, toothpaste, etc.

On 01 Oct 2020 (Study Day 32), treatment included diphenhydramine 50 mg QD PO with no relief. On 03 Oct 2020 (Study Day 34), the participant started methylprednisolone 4 mg PO.

On 04 Oct 2020 (Study Day 35), the participant's face swelling had improved considerably.

Action taken with IP in response to the event was not applicable, as the participant had already received both doses per protocol.

The event, swelling face, was considered resolved on 05 Oct 2020 (Study Day 36) and there was no recurrence.

The investigator assessed the event, swelling face, as related to IP and not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000656	Swelling face

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	C section	13 Oct 2005 (Study Day -5436) - 13 Oct 2005 (Study Day -5436)
Caesarean section	C section	30 Jun 2008 (Study Day -4445) - 30 Jun 2008 (Study Day -4445)
Mastectomy	Mastectomy - flap reconstruction	Apr 2017 - Apr 2017
Anxiety	Anxiety	2018 - Ongoing
Dermal filler injection	Dermal filler (voluma) cheek injections, bilaterl	Mar 2020 - Mar 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine hydrochloride	2018 - Ongoing	Anxiety
Paracetamol	30 Sep 2020 (Study Day 31) - 03 Oct 2020 (Study Day 34)	Headache And Myalgias
Diphenhydramine hydrochloride	01 Oct 2020 (Study Day 32) - 03 Oct 2020 (Study Day 34)	Cheek Swelling
Methylprednisolone sodium succinate	03 Oct 2020 (Study Day 34) - 07 Oct 2020 (Study Day 38)	Cheek Swelling

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	17 Oct 2020 (Study Day 48) - 17 Oct 2020 (Study Day 48)	Ocular Pruritus
Influenza vaccine	26 Oct 2020 (Study Day 57) - 26 Oct 2020 (Study Day 57)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Eye Pruritus	Grade 1/mild	Not related	17 Oct 2020 (Study Day 48) - 17 Oct 2020 (Study Day 48)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2053 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nausea/Nausea	SAE	Grade 4	Related	15 Sep 2020 (Study Day 30) – 21 Sep 2020 (Study Day 36)	Recovered/ resolved
Vomiting/Intractable Vomiting	SAE	Grade 4	Related	15 Sep 2020 (Study Day 30) – 21 Sep 2020 (Study Day 36)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2053, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Sep 2020 (Study Day 30), 29 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of nausea. Action taken with the IP was not applicable. The event of nausea lasted for 7 days, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 36). The investigator assessed the event of nausea to be related to the IP.

On 15 Sep 2020 (Study Day 30), 29 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of vomiting. Action taken with the IP was not applicable. The event of intractable vomiting lasted for 7 days, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 36). The investigator assessed the event of vomiting to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 15 Sep 2020 (Study Day 30), the participant experienced serious adverse events (SAEs) of nausea and vomiting. The participant described the events as intractable vomiting and mild nausea, accompanied by fever, with a maximum temperature of 101°F, and moderate headache. The participant had not been able to drink much and was not able to keep food down. The participant drank 22 ounces of fluid with no food and experienced an interference with activity.

On 16 Sep 2020 (Study Day 31), the participant reported mild headache and severe nausea and stated that, since the time of contact with the site that day, their oral intake was "only a few sips of fluids." The participant's fever resolved with a recorded temperature of 98°F. That evening of the same day, the participant visited an urgent care and received treatment with fluids and ondansetron for the event of intractable nausea with vomiting. The participant was provided a prescription for ondansetron for ongoing treatment at home.

In the morning of 17 Sep 2020 (Study Day 32), the participant felt better, and both the headache and nausea improved to mild. The participant reported not filling the ondansetron prescription provided the day before. That evening, the participant's symptoms worsened again. The participant's spouse reported that they were unable to keep fluids down and wanted to go to the emergency department (ED). The ondansetron prescription had been filled and the participant took a dose "a few minutes" before the call to the site without any improvement. The participant's spouse also reported that they had a prior history of headaches with severe nausea that had led to hospital admissions in the past.

In the evening of 17 Sep 2020 (Study Day 32), the participant presented to the ED with intractable nausea and vomiting and was admitted to the hospital. Vital signs included blood pressure 162/70 mm Hg, respiratory rate 18 breaths per minute, and heart rate 63 beats per minute. Laboratory results included glucose 121 mg/dL (high), white blood cell (WBC) count $6.2 \times 10^3/\mu L$, red blood cell count (RBC) $4.40 \times 10^6/\mu L$, hemoglobin (Hgb) 13.5 g/dL, hematocrit (Hct) 40%, platelet count $228 \times 10^3/\mu L$, potassium 4.2 mmol/L, blood urea nitrogen (BUN) 13 mg/dL, creatinine 0.8 mg/dL, calcium 9.6 mg/dL, albumin 4.4 g/dL, and alkaline phosphate 86 U/L (no reference ranges reported). Urinalysis revealed hazy clarity and trace ketones but was otherwise within normal limits. While hospitalized, no COVID-19 testing was done. Treatment for the event included IV fluids and ondansetron.

On 18 Sep 2020 (Study Day 33), the participant's symptoms had improved and they were discharged from the hospital. Relevant laboratory results included WBC $7.2 \times 10^3/\mu L$, RBC $4.07 \times 10^6/\mu L$, Hgb 12.4 g/dL, Hct 37.3%, platelet count $203 \times 10^3/\mu L$, potassium 4.2 mmol/L, BUN 11 mg/dL, creatinine 0.9 mg/dL, calcium 9.0 mg/dL, albumin 3.8 g/dL, and alkaline phosphatase 74 U/L. Ongoing treatment prescribed at discharge included metoclopramide and ondansetron. The participant reported not taking the treatment medications prescribed at discharge.

On 21 Sep 2020 (Study Day 36), the participant was symptom free. Throughout the course of illness, the participant denied taking any over-the-counter or prescription medications to treat symptoms at home, outside of the single dose of ondansetron on 17 Sep 2020.

Action taken with the IP was reported as not applicable in response to the events of intractable vomiting and nausea, as the participant had already received both scheduled doses.

The events, nausea and vomiting, were considered resolved on 21 Sep 2020 (Study Day 36).

The investigator assessed the events, nausea and vomiting, as related to IP. Per the investigator, the events were related to IP because the participant developed a headache during the "diary card period" (designated period to collect solicited reactogenicity events) after receiving the second injection. The headache contributed to the nausea and vomiting, which necessitated the hospitalization. Since the headache was experienced in the "diary card" (reactogenicity) period, this caused the investigator to assess the events as related. The investigator assessed the events, nausea and vomiting, as not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000306	Nausea
MOD-2020-000306	Vomiting

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Irritable bowel syndrome	Irritable bowel disease	Not reported - Ongoing
Mitral valve prolapse	Mitral valve prolapse	Not reported - Ongoing
Nausea	Nausea	Not reported - Ongoing
Supraventricular tachycardia	Cardiac arrythmia - paroxysmal supraventricular tachycardia	Not reported - Ongoing
Endometriosis	Endometriosis	1985 - Aug 1996
Uveitis	Chronic right uveitis	1989 - Ongoing
Hysterectomy	Hysterectomy	Aug 1996 - Aug 1996
Hemiparesis	Left sided weakness	Jan 2007 - Ongoing
Insomnia	Insomnia	Jan 2007 - Ongoing
Headache	Headaches	Oct 2007 - Ongoing
Hypoaesthesia	Left calf numbness	Oct 2007 - Ongoing
Nephrolithiasis	Kidney stones	Oct 2007 - Ongoing
Spinal fusion surgery	Spinal fusion	Oct 2007 - Oct 2007
Synovial cyst	Benign synovial cyst	Oct 2007 - Oct 2007
Synovial cyst removal	Synovial cyst removal	Oct 2007 - Oct 2007
Bunion operation	Bunionectomy left first metatarsal and 5th metatarsal	2018 - 2018

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Bunion operation	Bunionectomy right first metatarsal and 5th metatarsal	2018 - 2018
Foot deformity	Bunions: left first metatarsal and 5th metatarsal, right first metatarsal and 5th metatarsal	2018 - 2018
Skin wrinkling	Rhytids	2018 - Ongoing
Meniscus injury	Left meniscus tear	Jan 2020 - May 2020
Meniscus operation	Left meniscus arthroscopic repair	May 2020 - May 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisolone acetate	1989 - Ongoing	Chronic Right Eye Uveitis
Diphenhydramine hydrochloride	2015 - Ongoing	Insomnia
Melatonin	2015 - Ongoing	Insomnia
Cefalexin	28 Aug 2020 (Study Day 12) - 04 Sep 2020 (Study Day 19)	Toothache
Ondansetron	16 Sep 2020 (Study Day 31) - 16 Sep 2020 (Study Day 31)	Nausea, Intractable Vomiting
I.v. solutions	17 Sep 2020 (Study Day 32) - 18 Sep 2020 (Study Day 33)	Nausea, Intractable Vomiting
Ondansetron	18 Sep 2020 (Study Day 33) - 18 Sep 2020 (Study Day 33)	Nausea, Intractable Vomiting

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Toothache	Grade 2/moderate	Not related	28 Aug 2020 (Study Day 12) - 04 Sep 2020 (Study Day 19)
Diarrhoea	Grade 1/mild	Related	19 Sep 2020 (Study Day 34) - 19 Sep 2020 (Study Day 34)
Supraventricular Tachycardia	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 86) - 14 Dec 2020 (Study Day 120)
Migraine	Grade 2/moderate	Not related	19 Nov 2020 (Study Day 95) - 10 Dec 2020 (Study Day 116)
Mitral Valve Incompetence	Grade 1/mild	Not related	19 Nov 2020 (Study Day 95) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2232 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	29 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 4	Related	26 Sep 2020 (Study Day 29) – 08 Oct 2020 (Study Day 41)	Recovered/ resolved
Acute Myocardial Infarction/Non-ST Elevated Myocardial Infarction	SAE	Grade 4	Related	26 Sep 2020 (Study Day 29) – 26 Sep 2020 (Study Day 29)	Recovered/ resolved
Atrial Fibrillation/Paroxysmal Atrial Fibrillation	SAE	Grade 4	Related	26 Sep 2020 (Study Day 29) – 30 Oct 2020 (Study Day 63)	Recovered/ resolved with sequelae
Hypomagnesaemia/ Hypomagnesia	SAE	Grade 4	Related	26 Sep 2020 (Study Day 29) – 08 Oct 2020 (Study Day 41)	Recovered/ resolved
Organising Pneumonia/Cryptogenic Organizing Pneumonia	SAE	Grade 4	Related	26 Sep 2020 (Study Day 29) – 19 Nov 2020 (Study Day 83)	Recovered/ resolved
Respiratory Failure/Respiratory Failure	SAE, AE leading to withdrawal from study vaccine	Grade 4	Related	28 Sep 2020 (Study Day 31) – 19 Nov 2020 (Study Day 83)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2232, a 70-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Sep 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of acute kidney injury. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute kidney injury lasted for 13 days, after which it was considered to be recovered/resolved on 08 Oct 2020 (Study Day 41). The investigator assessed the event of acute kidney injury to be related to the IP.

On 26 Sep 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of non-st elevated myocardial infarction lasted for 1 day, after which it was considered to be recovered/resolved on 26 Sep 2020 (Study Day 29). The investigator assessed the event of acute myocardial infarction to be related to the IP.

On 26 Sep 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of atrial fibrillation. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of paroxysmal atrial fibrillation lasted for 35 days, after which it was considered to be recovered/resolved with sequelae on 30 Oct 2020 (Study Day 63). The investigator assessed the event of atrial fibrillation to be related to the IP.

On 26 Sep 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of hypomagnesaemia. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of hypomagnesia lasted for 13 days, after which it was considered to be recovered/resolved on 08 Oct 2020 (Study Day 41). The investigator assessed the event of hypomagnesaemia to be related to the IP.

On 26 Sep 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of organising pneumonia. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of cryptogenic organizing pneumonia lasted for 55 days, after which it was considered to be recovered/resolved on 19 Nov 2020 (Study Day 83). The investigator assessed the event of organising pneumonia to be related to the IP.

On 28 Sep 2020 (Study Day 31), 30 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of respiratory failure. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of respiratory failure lasted for 53 days, after which it was considered to be recovered/resolved on 19 Nov 2020 (Study Day 83). The investigator assessed the event of respiratory failure to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 22 Sep 2020 (Study Day 25), the participant experienced a cough and took dextromethorphan/ chlorpheniramine.

On 25 Sep 2020 (Study Day 28), the participant reported typical allergy symptoms of sniffles, postnasal drainage, and a cough. They were advised to call back if symptoms worsened or changed. Further reported symptoms included general body aches, headache, chest tightness, and fatigue.

On 26 Sep 2020 (Study Day 29), the participant experienced serious adverse events (SAEs) of acute kidney injury (AKI), acute myocardial infarction (MI), atrial fibrillation (AFib), hypomagnesemia, and organizing pneumonia. The participant experienced a worsening cough, fever of 101°F, new onset paroxysmal AFib with rapid ventricular response, and a non-ST elevated MI and was admitted to the hospital. The participant's troponin values were elevated on admission, with a peak of 2.415 ng/mL (reference range <0.038 ng/mL), likely secondary to demand ischemia from rapid AFib. Further laboratory test results included sodium 135 mmol/L (reference range 138 to 145 mmol/L), carbon dioxide (CO2) 18 mmol/L (reference range 23 to 31 mmol/L), blood urea nitrogen (BUN) 47 mg/dL (reference range 8.4 to 25.7 mg/dL), creatinine (Cr) 2.59 mg/dL (reference range 0.72 to 1.25 mg/dL), glucose 466 mg/dL (reference range 70 to 105 mg/dL), white blood cell (WBC) count 10.8 × 109/L (reference range 4.4 to 10.7 × 109/L), red blood cell (RBC) count 3.72 × 1012/L (reference range 3.80 to 5.40 × 1012/L), hemoglobin (Hgb) 11.3 g/dL (reference range 12.0 to 17.6 g/dL), hematocrit (Hct) 33.5% (reference range 35.2 to 51.7%), neutrophils 90.5% (reference range 44.0 to 73.0%), lymphocytes 2.2% (reference range 20.0 to 43.0%), absolute neutrophil count (ANC) 9.75 × 109/L (reference range 2.01 to 7.14 × 109/L), absolute lymphocyte count 0.24 × 109/L (reference range 1.07 to 3.94 × 109/L), magnesium 1.0 mg/dL (reference range 1.6 to 2.6 mg/dL), and procalcitonin 2.76 ng/mL (reference range <0.10 ng/mL). A chest x-ray showed bilateral infiltrates consistent with multifocal pneumonia, which was a pattern suggestive of, but not a diagnostic for, COVID-19 pneumonia. The first blood culture showed Staphylococcus hominis and the second showed no growth; the S hominis was considered a likely contaminant. A urine culture revealed <10,000 CFU/mL of urogenital flora. A urinalysis revealed color yellow, protein 3+, blood 1+, leukocyte trace, glucose 3+, and WBC count >100 (no reference ranges reported). A respiratory panel was negative. Initial treatment included ceftriaxone and azithromycin, which were stopped as the diagnosis was likely cryptogenic organizing pneumonia. Treatment for AKI included IV fluids. Further treatment included acetylsalicylic acid, magnesium, enoxaparin, insulin aspart, and dexamethasone.

On 27 Sep 2020 (Study Day 30), vital signs included blood pressure (BP) 142/61 mm Hg, pulse 96 beats per minute (bpm), respiratory rate 25 breaths per minute (breaths/min), temperature 98.1°F, and oxygen saturation 76% at 01:56, which improved to 93% at 01:58. Laboratory test results included troponin I 1.643 ng/mL, WBC count 14.5 × 109/L, RBC count 3.63 × 1012/L, Hgb 11.0 g/dL, Hct 33.8%, neutrophils 91.0%, lymphocytes 2.7%, ANC 13.21 × 109/L, absolute lymphocyte count 0.38 × 109/L, Hgb A1c 9.0% (reference range 4.2 to 5.6%), glucose 120 mg/dL, CO2 20 mmol/L, BUN 48 mg/dL, Cr 2.40 mg/dL, total protein 6.2 g/dL (reference range 6.4 to

8.3 g/dL), and albumin 3.1 g/dL (reference range 3.2 to 4.6 g/dL). Paroxysmal AFib was noted. The participant self-converted to sinus rhythm with Bachmann's bundle. A nasopharyngeal swab was negative for COVID-19. Treatment included ondansetron for nausea, benzonatate for cough, and acetylsalicylic acid. The participant's type II diabetes was uncontrolled, and their insulin glargine dose was increased.

On 28 Sep 2020 (Study Day 31), the participant experienced an SAE of respiratory failure secondary to bilateral pulmonary infiltrates with ongoing cough and fever of 101°F. A physical examination revealed diminished breath sounds with coarse crackles and lower extremity edema. The participant was treated with 6 L of oxygen and remained hospitalized. A cardiology workup was performed. An echocardiogram (ECHO) showed cardiomyopathy with an ejection fraction (EF) of 30 to 35% (no reference range provided). A chest x-ray showed increasing bilateral patchy airspace consolidation, right greater than left. Laboratory test results for ferritin was 334 ng/mL (reference range 22 to 276 ng/mL) and C-reactive protein was 31.37 mg/dL (reference range ≤0.50 mg/dL). Treatment included levofloxacin PO.

On 29 Sep 2020 (Study Day 32), the participant's condition worsened, and they were treated with 8 L/min of oxygen. Vital signs included BP 171/95 mm Hg, pulse 72 bpm, respiratory rate 24 breaths/min, temperature 97.4°F, and oxygen saturation 97%. Laboratory test results included chloride (Cl) 110 mmol/L (reference range 98 to 107 mmol/L), CO2 17 mmol/L, BUN 63 mg/dL, Cr 2.25 mg/dL, glucose 160 mg/dL, WBC count 20.9 × 109/L, RBC count 3.69 × 1012/L, Hgb 11.2 g/dL, Hct 34.6%, neutrophils 94.6%, lymphocytes 1.5%, monocytes 2.4%, ANC 19.80 × 109/L, and absolute lymphocytes count 0.02 × 109/L. A computerized tomogram (CT) of the chest showed findings in keeping with multifocal pneumonia, no lobe was spared; small bilateral pleural effusions were noted, with right greater than left; and nonspecific esophageal wall thickening was considered to be correlated with esophageal reflux. A follow-up chest CT was recommended after the appropriate course of therapy to document resolution of these findings. An ECHO showed the left ventricle was normal in size, systolic left ventricular function was moderately to markedly reduced, EF of 30 to 35%, left ventricle wall thickness was normal, no regional wall motion abnormalities, left ventricular diastolic function parameters were normal, and right ventricular systolic pressure was 30 mm Hg. Urine Streptococcus pneumoniae and Legionella spp antigens test results were negative. Treatment included a course of steroids, hydrocodone/paracetamol, and dextromethorphan/guaifenesin.

On 30 Sep 2020 (Study Day 33), the participant underwent a bronchoscopy, which showed unresolved bilateral infiltrates. Bronchial washing Gram stain and culture were obtained from the endobronchial tree, and bronchoalveolar lavage Gram stain was performed from the right upper lobe and right middle lobe; there was no evidence of diffuse alveolar hemorrhage, and culture

results showed moderate polymorphonuclear (PMN) cells and no organisms. The WBC differential from the manual bronchoalveolar lavage showed neutrophils 45%, lymphocytes 73%, macrophages 32%, and cells counted 100 (no reference ranges provided). Laboratory test results included WBC count 15.9 × 109/L, Hgb 10.1 g/dL, Hct 30.9%, Cl 111 mmol/L, CO2 20 mmol/L, BUN 56 mg/dL, Cr 1.98 mg/dL, glucose 116 mg/dL, and calcium (Ca) 8.1 mg/dL (reference range 8.1 to 10.4 mg/dL). A respiratory panel was negative. The participant was weaned to 3 L of oxygen. Treatment included salbutamol 0.5%, lidocaine 4%, and levalbuterol.

On 01 Oct 2020 (Study Day 34), treatment included enoxaparin and diltiazem. Bronchoalveolar lavage culture, Gram stain, and bronchial washing culture and Gram stain showed no growth, moderate PMN cells, and no organisms were seen. Blood culture showed no growth. A bronchoalveolar lavage pathology smear revealed no malignancy.

On 02 Oct 2020 (Study Day 35), bronchoalveolar lavage culture and Gram stain and bronchial washing culture and Gram stain showed no growth, moderate PMN cells, and no organisms were seen. Blood culture showed growth of S hominis, which was a possible contaminant unless multiple cultures were positive for the same isolate. Bronchial washing cytology showed no cytological diagnosis and was negative for malignancy. Treatment for pneumonia included prednisone PO.

On 03 Oct 2020 (Study Day 36), vital signs included BP 159/90 mm Hg, pulse 97 bpm, respiratory rate 20 breaths/min, temperature 97.2°F, and oxygen saturation 95%. Physical examination revealed diminished breath sounds with coarse crackles; tachycardia, irregular rhythm; and lower extremity edema.

On 04 Oct 2020 (Study Day 37), a PCR test for Herpes simplex types 1 and 2 was negative.

On 05 Oct 2020 (Study Day 38), the participant's Foley catheter was removed, and they were able to void. Treatment included digoxin and amiodarone. A bronchoalveolar lavage acid-fast bacilli smear showed no acid-fast bacilli. A fungal culture and smear of bronchial washing showed no fungi isolated, no yeast or hyphae seen, and Pneumocystis jirovecii was not detected.

On 06 Oct 2020 (Study Day 39), a chest x-ray showed bilateral infiltrates mildly increased on the right. Laboratory test results included WBC count 12.6 × 109/L, RBC count 3.60 × 1012/L, Hgb 10.9 g/dL, Hct 34.0%, Cl 108 mmol/L, CO2 20 mmol/L, BUN 47 mg/dL, Cr 1.58 mg/dL, glucose 148 mg/dL, Ca 8.1 mg/dL, neutrophils 76.8%, lymphocytes 11.2%, and ANC 9.67 × 109/L.

On 07 Oct 2020 (Study Day 40), a limited ECHO showed and EF of 35 to 45%. A cardiac LifeVest™ was considered. A bronchoalveolar lavage culture for Legionella spp was negative.

On 08 Oct 2020 (Study Day 41), vital signs included BP 168/86 mm Hg, pulse 92 bpm, respiratory rate 20 breaths/min, temperature 97.8°F, and oxygen saturation 94%. Physical examination revealed coarse breath sounds, irregular rhythm, and minimal lower extremity edema. Treatment included amiodarone and apixaban for paroxysmal AFib, prednisone for pneumonia, metoprolol and furosemide for hypertension, and clopidogrel was stopped. Venlafaxine was started for depression. Acute kidney injury secondary to acute tubular necrosis and nonanion gap metabolic acidosis improved. Hypertension was increasing and hydralazine was resumed. The participant was discharged from the hospital in good condition with 2 L of supplemental oxygen and a Holter monitor for 30 days. Discharge diagnoses included community acquired pneumonia, elevated troponin, AFib with rapid ventricular response, sepsis, and chest pain.

On 09 Oct 2020 (Study Day 42), Cytomegalovirus was not detected using a PCR of bronchoalveolar lavage fluid.

On 12 Oct 2020 (Study Day 45), the participant reported they were on 4 L of supplemental oxygen and remained on prednisone.

On 15 Oct 2020 (Study Day 48), the participant was rehospitalized for AFib. The participant presented with atrial flutter/rapid ventricular response and symptoms of shortness of breath. Cardiology and pulmonary were consulted. A chest x-ray showed extensive bilateral infiltrates consistent with multifocal pneumonia slightly improved in the interval. Treatment included benzonatate PO for cough, diltiazem IV and amiodarone IV for paroxysmal AFib, and enoxaparin SC for coronary artery disease.

On 16 Oct 2020 (Study Day 49), the participant was lying in bed, appeared comfortable, and continued with an amiodarone IV drip and 4 L of oxygen via nasal cannula. Laboratory test results included RBC count 3.57 × 1012/L, Hgb 10.6 g/dL, Hct 32.9%, sodium 133 mmol/L, Cr 1.51 mg/dL, glucose 222 mg/dL, Ca 8.0 mg/dL, albumin 2.7 g/dL, total protein 4.8 g/dL, and Hgb A1c 9.5%. Treatment included insulin aspart SC for diabetes type II.

On 17 Oct 2020 (Study Day 50), the participant was discharged from the hospital. Discharge diagnoses included AFib/rapid ventricular response, nonischemic cardiomyopathy, acute hypoxemic respiratory failure, diabetes, and AKI. As recommended by cardiology, apixaban was given upon discharge. Treatment also included prednisone PO for pneumonia.

On 19 Nov 2020 (Study Day 83), the investigator reported that as per pulmonology reports, the participant was recovering and would follow up in 3 months.

There was no action taken with study IP in response to the events of organizing pneumonia, AFib, acute MI, hypomagnesia, and AKI. Study IP was discontinued in response to the event of respiratory failure.

The event, acute MI, was reported as resolved on 26 Sep 2020 (Study Day 29). The events, hypomagnesia and AKI, were reported as resolved on 08 Oct 2020 (Study Day 41). The event, AFib, was reported as resolved with sequelae on 30 Oct 2020 (Study Day 63); the participant was in sinus rhythm but could intermittently go in and out of AFib and on medication and was following up with their primary care physician to control and monitor. The events of organizing pneumonia and respiratory failure were reported as resolved on 19 Nov 2020 (Study Day 83).

The investigator assessed the events, organizing pneumonia, respiratory failure, AFib, acute MI, hypomagnesia, and AKI, as related to study IP and not related to study procedure.

The sponsor assessed the events as unrelated to the study IP, noting that the events are more likely explained by the subject's comorbid conditions.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000369	Acute kidney injury
MOD-2020-000369	Acute myocardial infarction
MOD-2020-000369	Atrial fibrillation
MOD-2020-000369	Hypomagnesaemia
MOD-2020-000369	Organising pneumonia
MOD-2020-000369	Respiratory failure
MOD-2021-009983	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Exposure to communicable disease	Tuberculosis exposure	Not reported
Urinary tract infection	Recurrent urinary tract infections	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	1951 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Joint dislocation	Right shoulder dislocation	1975 - 1975
Hypertension	Hypertension	1992 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	1992 - Ongoing
Depression	Depression	13 Jun 2008 (Study Day -4460) - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Gastritis	Gastritis	10 Oct 2011 (Study Day -3246) - 31 Oct 2011 (Study Day -3225)
Helicobacter infection	H. pylori infection	12 Oct 2011 (Study Day -3244) - 31 Oct 2011 (Study Day -3225)
Chronic kidney disease	Chronic kidney disease	24 Jan 2012 (Study Day -3140) - Ongoing
Coronary artery disease	Coronary artery disease	2013 - Ongoing
Cellulitis	Right lower extremity cellulitis	08 Jan 2014 (Study Day -2425) - Not reported
Pulmonary embolism	Pulmonary embolism	08 Jan 2014 (Study Day -2425) - 18 Jan 2014 (Study Day -2415)
Pyuria	Pyuria	08 Jan 2014 (Study Day -2425) - 18 Jan 2014 (Study Day -2415)
Iron deficiency anaemia	Iron deficiency anemia	13 Jan 2014 (Study Day -2420) - Ongoing
Diabetic neuropathy	Sensory diabetic neuropathy	21 Jul 2014 (Study Day -2231) - Ongoing
Back pain	Low back pain	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Mitral valve incompetence	Mitral valve regurgitation	28 Apr 2016 (Study Day -1584) - Ongoing
Staphylococcus test positive	Mrsa positive	2017 - 2017
Coronary arterial stent insertion	Coronary artery stent	20 Apr 2018 (Study Day -862) - 20 Apr 2018 (Study Day -862)
Diabetic retinopathy	Diabetic retinopathy left eye	2019 - Ongoing
Lens disorder	Left lens erosion	2019 - Ongoing
Colon adenoma	Adenomatous colon polyp	17 Jun 2019 (Study Day -439) - 17 Jun 2019 (Study Day -439)
Colonoscopy	Colonscopy	17 Jun 2019 (Study Day -439) - 17 Jun 2019 (Study Day -439)
Diverticulum intestinal	Diverticulosis of colon	17 Jun 2019 (Study Day -439) - 30 Jun 2019 (Study Day -426)
Benign prostatic hyperplasia	Benign prostatic hypertrophy	Nov 2019 - Ongoing
Urinary retention	Urinary retention	Nov 2019 - Ongoing
Myocardial infarction	Myocardial infarction	01 Nov 2019 (Study Day -302) - 01 Nov 2019 (Study Day -302)
Wound	Wound right elbow	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	2010 - Ongoing	Insomnia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2013 - 25 Sep 2020 (Study Day 28)	Coronary Artery Disease
Amlodipine	2013 - 15 Oct 2020 (Study Day 48)	Coronary Artery Disease
Clopidogrel bisulfate	2013 - 08 Oct 2020 (Study Day 41)	Coronary Artery Disease
Atorvastatin	2015 - Ongoing	Hyperlipidemia
Metformin	2015 - 08 Oct 2020 (Study Day 41)	Type 2 Diabetes
Liraglutide	2017 - Ongoing	Type 2 Diabetes
Insulin glargine	2018 - Ongoing	Type 2 Diabetes
Finasteride	Nov 2019 - Ongoing	Benign Prostatic Hypertension
Hydralazine	Feb 2020 - 29 Mar 2021 (Study Day 213)	Hypertension
Tamsulosin hydrochloride	Feb 2020 - Ongoing	Urinary Retention
Chlorphenamine maleate; dextromethorphan hydrobromide	22 Sep 2020 (Study Day 25) - 26 Sep 2020 (Study Day 29)	Seasonal Allergies/Nasal Congestion
Acetylsalicylic acid	26 Sep 2020 (Study Day 29) - 26 Sep 2020 (Study Day 29)	Non-St Elevated Myocardial Infarction
Azithromycin	26 Sep 2020 (Study Day 29) - 28 Sep 2020 (Study Day 31)	Pneumonia, Respiratory Failure
Ceftriaxone	26 Sep 2020 (Study Day 29) - 28 Sep 2020 (Study Day 31)	Pneumonia, Respiratory Failure
Dexamethasone	26 Sep 2020 (Study Day 29) - 27 Sep 2020 (Study Day 30)	Pneumonia, Respiratory Failure
Enoxaparin sodium	26 Sep 2020 (Study Day 29) - 28 Sep 2020 (Study Day 31)	Coagulation Prophylaxis
Insulin aspart	26 Sep 2020 (Study Day 29) - 08 Oct 2020 (Study Day 41)	Type 2 Diabetes
Magnesium	26 Sep 2020 (Study Day 29) - 26 Sep 2020 (Study Day 29)	Hypomagnesia
Acetylsalicylic acid	27 Sep 2020 (Study Day 30) - Ongoing	Coronary Artery Disease
Benzonatate	27 Sep 2020 (Study Day 30) - 29 Sep 2020 (Study Day 32)	Cough
Ondansetron	27 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 30)	Nausea
Levofloxacin	28 Sep 2020 (Study Day 31) - 28 Sep 2020 (Study Day 31)	Pneumonia, Respiratory Failure
Dextromethorphan hydrobromide; guaifenesin	29 Sep 2020 (Study Day 32) - 08 Oct 2020 (Study Day 41)	Pneumonia
Hydrocodone bitartrate; paracetamol	29 Sep 2020 (Study Day 32) - 01 Oct 2020 (Study Day 34)	Pneumonia
Bronchoscopy*	30 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 33)	Diagnostic
Levosalbutamol	30 Sep 2020 (Study Day 33) - 02 Oct 2020 (Study Day 35)	Pneumonia, Respiratory Failure
Lidocaine	30 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 33)	Bronchoscopy
Salbutamol	30 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 33)	Bronchoscopy
Diltiazem	01 Oct 2020 (Study Day 34) - 01 Oct 2020 (Study Day 34)	Paroxysmal Atrial Fibrillation
Enoxaparin sodium	01 Oct 2020 (Study Day 34) - 02 Oct 2020 (Study Day 35)	Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	02 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 48)	Pneumonia, Respiratory Failure
Amiodarone	05 Oct 2020 (Study Day 38) - 05 Oct 2020 (Study Day 38)	Paroxysmal Atrial Fibrillation
Amiodarone	05 Oct 2020 (Study Day 38) - 06 Oct 2020 (Study Day 39)	Paroxysmal Atrial Fibrillation
Digoxin	05 Oct 2020 (Study Day 38) - 05 Oct 2020 (Study Day 38)	Paroxysmal Atrial Fibrillation
Amiodarone	06 Oct 2020 (Study Day 39) - Ongoing	Paroxysmal Atrial Fibrillation
Apixaban	08 Oct 2020 (Study Day 41) - Ongoing	Paroxysmal Atrial Fibrillation
Furosemide	08 Oct 2020 (Study Day 41) - 08 Oct 2020 (Study Day 41)	Hypertension
Metoprolol	08 Oct 2020 (Study Day 41) - Ongoing	Atrial Fibrillation
Venlafaxine hydrochloride	08 Oct 2020 (Study Day 41) - Ongoing	Depression
Amiodarone	15 Oct 2020 (Study Day 48) - 15 Oct 2020 (Study Day 48)	Paroxysmal Atrial Fibrillation
Benzonatate	15 Oct 2020 (Study Day 48) - 20 Nov 2020 (Study Day 84)	Cough
Diltiazem	15 Oct 2020 (Study Day 48) - 15 Oct 2020 (Study Day 48)	Paroxysmal Atrial Fibrillation
Enoxaparin sodium	15 Oct 2020 (Study Day 48) - 17 Oct 2020 (Study Day 50)	Coronary Artery Disease
Insulin aspart	16 Oct 2020 (Study Day 49) - 17 Oct 2020 (Study Day 50)	Diabetes Type 2
Prednisone	17 Oct 2020 (Study Day 50) - 24 Oct 2020 (Study Day 57)	Pneumonia, Respiratory Failure
Prednisone	25 Oct 2020 (Study Day 58) - 01 Nov 2020 (Study Day 65)	Pneumonia
Influenza vaccine	14 Dec 2020 (Study Day 108) - 14 Dec 2020 (Study Day 108)	Influenza Prophylaxis
Codeine phosphate; paracetamol	Jan 2021 - 29 Mar 2021 (Study Day 213)	Back Pain
Chlorphenamine maleate; dextromethorphan hydrobromide	18 Jan 2021 (Study Day 143) - 01 Feb 2021 (Study Day 157)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 2/moderate	Related	27 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 30)
COVID-19	Grade 2/moderate	Not related	18 Jan 2021 (Study Day 143) - 31 Jan 2021 (Study Day 156)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US360-2051 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	14 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Aortic Stenosis/Worsening Of Aortic Stenosis	SAE	Grade 4	Not related	28 Oct 2020 (Study Day 42) – 02 Nov 2020 (Study Day 47)	Recovered/ resolved with sequelae
Procedural Haemorrhage/Increased Bleeding Intra Operative Time	SAE	Grade 4	Related	29 Oct 2020 (Study Day 43) – 29 Oct 2020 (Study Day 43)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US360-2051, a 52-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Oct 2020 (Study Day 42), 41 days after the first dose and 14 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of aortic stenosis. Action taken with the IP was not applicable. The event of worsening of aortic stenosis lasted for 6 days, after which it was considered to be recovered/resolved with sequelae on 02 Nov 2020 (Study Day 47). The investigator assessed the event of aortic stenosis to be not related to the IP.

On 29 Oct 2020 (Study Day 43), 42 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of procedural haemorrhage. Action taken with the IP was not applicable. The event of increased bleeding intra operative time lasted for 1 days, after which it was considered to be recovered/resolved on 29 Oct 2020 (Study Day 43). The investigator assessed the event of procedural haemorrhage to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 19 Oct 2020 (Study Day 33), the participant experienced a nonserious adverse event (AE) of aortic stenosis. On the same day, an echocardiogram showed normal left ventricular systolic function, ejection fraction estimated at 65-70%, grade 1 (mild) left ventricular diastolic dysfunction, moderate concentric hypertrophy, mildly dilated left atrium, aortic valve showed that

a bicuspid valve could not be excluded, there was heavy calcification of the aortic valve, and severe stenosis. Trace regurgitation was revealed on pulsed-wave (PW) color-flow doppler; atrioventricular (AV) peak gradient was 107.0 mmHg, AV mean gradient was 82.0 mmHg, aortic valve area measured 0.49 cm^2 (no reference ranges were provided), and the pulmonic valve showed trace regurgitation on PW color-flow doppler, and minimal coronary artery disease.

On 27 Oct 2020 (Study Day 41), an electrocardiogram (ECG) was abnormal, and a SARS-CoV-2 RT-PCR nasopharyngeal swab result was negative.

On 28 Oct 2020 (Study Day 42), the participant experienced a serious adverse event (SAE) of aortic stenosis. The participant experienced rib pain at a level of 8/10 bilaterally and experienced recurrent syncope with exertion. The participant was given acetylsalicylic acid PO prior to aortic valve replacement (AVR) surgery. According to the Primary Investigator's assessment, a single dose of acetylsalicylic acid taken the day before surgery was probably not solely responsible for the bleeding seen after the AVR. Laboratory test results included partial thromboplastin time (PTT) 14.6 seconds (reference range 12.2 to 14.4 seconds), PTT 29.9 seconds (reference range 23.4 to 38.9 seconds), and international normalized ratio (INR) 1.16 (reference range 0.80 – 1.20).

On 29 Oct 2020 (Study Day 43), the participant experienced an SAE of procedural hemorrhage. On the same day, the participant was admitted to the hospital for AVR surgery and was noted to bleed profusely after undergoing AVR. Medications received for the surgical procedure included aztreonam, fentanyl, ketorolac, paracetamol, midazolam, morphine, prochlorperazine, vancomycin, and warfarin (all IV); diazepam and metoprolol tartrate PO. The participant had an additional abnormal ECG. A post-surgical transesophageal echocardiogram showed the valve was well seated without evidence of paravalvular leak. Treatment included a fresh frozen plasma (FFP) transfusion, and the participant was placed in the intensive care unit for 2 days. After the surgical incision had been closed despite heparin reversal with protamine and the activated clotting time returned to 116 (approximately baseline; no units or reference rang provided), there was continued mediastinal bleeding of an unknown source with notably very poor clot formation; however, despite giving a unit of FFP and platelets, coagulopathy was not corrected and there was significant bleeding from sternal edges. The participant's chest tube output was monitored. Laboratory test results included PTT 17.9 seconds, INR 1.52, hemoglobin (Hgb) 8.8 g/dL (reference range 13.0 to 17.0 g/dL), hematocrit (Hct) 24.7% (reference range 38.7 to 50.0%) and platelets $127 \times 10^3/\mu L$ (reference range 135 to $430 \times 10^3/\mu L$).

On 30 Oct 2020 (Study Day 44), the participant was transferred to the cardiac stepdown unit. An ECG was again abnormal. Laboratory test results included PTT 15.1 seconds, PTT 33.7 seconds, INR 1.21, Hgb 8.8 g/dL, Hct 25.1%, and platelets $142 \times 10^3/\mu L$. Treatment included acetylsalicylic acid.

On 01 Nov 2020 (Study Day 46), laboratory test results included Hgb 8.4 g/dL, Hct 24.6%, and platelets 131 × 10^3/µL. On 02 Nov 2020 (Study Day 47), the participant was discharged from the hospital with treatment medication including bacitracin topical for incision care and apixaban PO for non-valvular atrial fibrillation prophylaxis following AVR surgery. Activity instructions were as tolerated, no lifting, driving, or strenuous exercise until specified and planned post-surgical follow-up in 1 and 2 weeks.

Action taken with the study IP was not applicable as the participant had already received both scheduled doses.

The SAE, increased bleeding intraoperative time, was reported as resolved on 29 Oct 2020 (Study Day 43). The SAE, worsening of aortic stenosis, was reported as resolved with sequelae (participant with open-heart surgery and post-operative recovery ongoing) on 02 Nov 2020 (Study Day 47).

The investigator assessed the event, aortic stenosis, as not related to study IP or study procedure.

The investigator assessed the event, procedural hemorrhage, as related to study IP and not related to study procedure. The surgeon felt that that there was no known cause and raised the possibility of association of the bleeding risk with the use of a study IP.

The event, worsening aortic stenosis, was considered resolved with sequelae on Study Day 47, 3 days after the surgical intervention, and the event, intraoperative bleeding, was considered resolved on the same day it occurred (Study Day 43).

The event of procedural hemorrhage (increased bleeding intraoperative time) was considered unrelated to IP by the company and related to study IP by the investigator. The event of procedural hemorrhage may be explained by the participant's intake of acetylsalicylic acid prior to the surgical intervention.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000664	Aortic stenosis
MOD-2020-000664	Procedural haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Non-specific cardiac murmur (diagnosed a few years ago)	Not reported - Ongoing
Rotator cuff repair	Rotator cuff repair (right)	1996 - 1996
Rotator cuff syndrome	Rotator cuff tear (right)	1996 - 1996
Tobacco user	Smoking	2000 - Mar 2020
Tension headache	Headaches (type: tension)	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2008 - Ongoing
Polyarthritis	Arthritis (type: unknown; location: knees bilaterally, neck)	2011 - Ongoing
Genital herpes	Genital herpes (last outbreak july 2020)	2012 - Ongoing
Knee arthroplasty	Knee replacement	2012 - 2012
Bronchitis	Bronchitis (mild)	2015 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015 - Ongoing
Syncope	Syncope (recurrent)	2018 - Ongoing
Aortic stenosis	Aortic stenosis	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2005 - Jul 2020	Headaches
Atorvastatin	2011 - Ongoing	HLD
Salbutamol sulfate	2015 - Ongoing	COPD Exacerbation/Wheezing
Umeclidinium bromide	2015 - Ongoing	COPD
Vitamins nos	2015 - Ongoing	General Good Health
Ascorbic acid	2016 - Ongoing	General Good Health
Vitamin D1	2016 - Ongoing	General Good Health
Fish oil	2018 - Ongoing	General Good Health
Nicotine	Mar 2020 - Ongoing	Smoking Cessation
Zinc	Jun 2020 - Ongoing	General Good Health
Aciclovir	Jul 2020 - Jul 2020	Genital Herpes (Outbreak)
Ibuprofen	14 Oct 2020 (Study Day 28) - 14 Oct 2020 (Study Day 28)	Headache
Color-flow pw echocardiogram*	19 Oct 2020 (Study Day 33) - 19 Oct 2020 (Study Day 33)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Electrocardiogram (EKG)*	27 Oct 2020 (Study Day 41) - 27 Oct 2020 (Study Day 41)	Diagnostic
Acetylsalicylic acid	28 Oct 2020 (Study Day 42) - 28 Oct 2020 (Study Day 42)	Unk (Taken Prior To Atrial Valve Replacement Surgery)
Cardiac catheterization*	28 Oct 2020 (Study Day 42) - 28 Oct 2020 (Study Day 42)	Adverse Event
Diazepam	28 Oct 2020 (Study Day 42) - 28 Oct 2020 (Study Day 42)	Unknown
Diphenhydramine hydrochloride	28 Oct 2020 (Study Day 42) - 28 Oct 2020 (Study Day 42)	Insomnia
Physical therapy (prior to AVR surgery)*	28 Oct 2020 (Study Day 42) - 28 Oct 2020 (Study Day 42)	Adverse Event
Aortic valve replacement surgery*	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Adverse Event
Aztreonam	29 Oct 2020 (Study Day 43) - 31 Oct 2020 (Study Day 45)	Anti-Biotic (Surgical Prophylaxis)
Blood/platelet/cryoprecipitate transfusion (intraoperative, AVR surgery)*	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Adverse Event
Electrocardiogram (EKG)*	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Diagnostic
Fentanyl	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Pain Control (RVA Surgery)
Metoprolol tartrate	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	R/T To RVA Surgery
Midazolam hydrochloride	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Sedation (R/T RVA Surgery
Morphine	29 Oct 2020 (Study Day 43) - 30 Oct 2020 (Study Day 44)	Moderate Pain (R/T RVA Surgery)
Morphine	29 Oct 2020 (Study Day 43) - 30 Oct 2020 (Study Day 44)	Severe Pain (8-10) R/T RVA Surgery
Ondansetron	29 Oct 2020 (Study Day 43) - 30 Oct 2020 (Study Day 44)	Prophylaxis For Nausea/Vomiting (S/P AVR Surgery)
Paracetamol	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Pain (Musculoskeletal And Connective Tissue Related Chest Pain Due To AVR Surgery Related Incision)
Paracetamol	29 Oct 2020 (Study Day 43) - 30 Oct 2020 (Study Day 44)	Pain Control R/T AVR Surgery Due To SAE Worsening Of Aortic Stenosis
Pethidine	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Shivering (S/P RVA Surgery)
Prochlorperazine edisylate	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Unknown (Administered During RVA Surgery)
Vancomycin hydrochloride	29 Oct 2020 (Study Day 43) - 30 Oct 2020 (Study Day 44)	Anti-Biotic To Prevent Infection R/T Arv Surgery Due To Worsening Of Aortic Stenosis
Acetylsalicylic acid	30 Oct 2020 (Study Day 44) - Ongoing	S/P Cardiac Surgery
Electrocardiogram (EKG)*	30 Oct 2020 (Study Day 44) - 30 Oct 2020 (Study Day 44)	Diagnostic
Ketorolac tromethamine	31 Oct 2020 (Study Day 45) - 31 Oct 2020 (Study Day 45)	Pain Control (S/P RVA Surgery)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tramadol hydrochloride	31 Oct 2020 (Study Day 45) - 02 Nov 2020 (Study Day 47)	Moderate Pain (4-7) In Chest R/T S/P AVR Surgery Due To Worsening Of Aortic Stenosis
Warfarin sodium	31 Oct 2020 (Study Day 45) - 31 Oct 2020 (Study Day 45)	Anticoagulant (S/P AVR Surgery)
Warfarin sodium	01 Nov 2020 (Study Day 46) - 01 Nov 2020 (Study Day 46)	Anticoagulant (S/P AVR Surgery)
Apixaban	02 Nov 2020 (Study Day 47) - Ongoing	Non-Valvular Atrial Fibrillation
Bacitracin	02 Nov 2020 (Study Day 47) - Ongoing	Incision Care
Ferrous sulfate	02 Nov 2020 (Study Day 47) - Ongoing	Anemia From Inadequate Iron In The Body (S/P AVR)
Oxycodone hydrochloride	02 Nov 2020 (Study Day 47) - Ongoing	Pain
Physical therapy (following AVR surgery prior to discharge)*	02 Nov 2020 (Study Day 47) - 02 Nov 2020 (Study Day 47)	Adverse Event
Simvastatin	30 Nov 2020 (Study Day 75) - Ongoing	Hyperlipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Musculoskeletal Chest Pain	Grade 3/severe	Not related	27 Oct 2020 (Study Day 41) - 31 Oct 2020 (Study Day 45)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378186

Participant Number:	US365-2038 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	25 Oct 2020 (Study Day 31) – 06 Nov 2020 (Study Day 43)	Recovered/ resolved
Cerebrovascular Accident/Cryptogenic Stroke (Official Diagnosis On 12/4, Symptoms Beginning On 11/30)	SAE	Grade 3/ severe	Related	30 Nov 2020 (Study Day 67) – 15 Dec 2020 (Study Day 82)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US365-2038, a 34-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Oct 2020 (Study Day 31), 30 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 22 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of COVID-19 lasted for 13 days, after which it was considered to be recovered/resolved on 06 Nov 2020 (Study Day 43). The investigator assessed the event of covid-19 to be not related to the IP.

On 30 Nov 2020 (Study Day 67), 66 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. On 22 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of cryptogenic stroke (official diagnosis on 12/4, symptoms beginning on 11/30) lasted for 16 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 82). The investigator assessed the event of cerebrovascular accident to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 22 Oct 2020 (Study Day 28), a rapid test and a SARS-CoV-2 RT-PCR nasopharyngeal swab at a local urgent care was negative.

On 25 Oct 2020 (Study Day 31), the participant experienced a nonserious adverse event of COVID-19 with a positive SARS-CoV-2 RT-PCR nasopharyngeal swab collected on 26 Oct 2020 (Study Day 32). The participant was exposed by their childcare provider who tested positive on 21 Oct 2020 (Study Day 27), and their child tested positive on 22 Oct 2020 (Study Day 28).

From 25 Oct 2020 (Study Day 31) to 04 Nov 2020 (Study Day 41), the participant intermittently experienced mild fatigue, loss of smell, nasal congestion, nausea, and diarrhea. They denied chills, cough, shortness of breath, difficulty breathing, muscle aches, body aches, headache, loss of taste, runny nose, vomiting, or sore throat. Saliva was collected per protocol on days 3, 5, 7, 9, 14, and 21 after the positive SARS-CoV-2 test. On days 3 and 7, after the positive SARS-CoV-2 test, saliva resulted in positive tests. On days 5 and 9, after the positive SARS-CoV-2 test, saliva results were reported as not detected and on days 14 and 21, after the positive SARS-CoV-2 test, saliva results were “did not result”.

On 28 Oct 2020 (Study Day 34), the participant reported that their symptoms had resolved. No medical intervention was given for their symptoms.

On 31 Oct 2020 (Study Day 37), the participant had another positive COVID-19 test. The participant was monitored via telehealth visits for the next 14 days.

Study IP was discontinued in response to the event.

The event, COVID-19, was reported as resolved on 06 Nov 2020 (Study Day 43).

The investigator assessed the event, COVID-19, as not related to study IP or study procedure.

On 30 Nov 2020 (Study Day 67), the participant experienced a serious adverse event of cerebrovascular accident. The participant was seen in the emergency department after developing acute symptoms of nausea, vomiting, and difficulty walking due to a sensation of being pulled to one side. The participant was treated with metoclopramide PO and ondansetron PO. The participant was discharged on meclizine PO with a presumed diagnosis of vertigo. The participant’s symptoms were improving but they continued to have some vertigo with associated headache and nausea.

On 01 Dec 2020 (Study Day 68), the participant began treatment with meclizine PO.

On 02 Dec 2020 (Study Day 69), the participant had a follow-up appointment with a neurologist and all laboratory test results including a complete blood panel and C-reactive protein were normal. At that time, the participant was given a working diagnosis of vestibular neuritis and a magnetic resonance imaging (MRI) scan was scheduled to rule out other conditions.

On 04 Dec 2020 (Study Day 71), the participant was admitted to the neurology intensive care unit (ICU) for a second opinion. They spent 5 days in the ICU. An MRI scan showed an acute left posterior inferior cerebellar artery (PICA) territory infarct with a mass effect on the fourth ventricle. A magnetic resonance angiography of the head and neck was unremarkable. A computed tomography angiogram of the head and neck with contrast showed a questionable focal occlusion of the PICA just left of midline. A transesophageal echocardiogram showed a patent foremen ovale (PFO) with right to left shunting. Hypercoagulability laboratory test results showed no suggestion of a current hypercoagulable state. A lumbar puncture and lower extremities ultrasound were negative. The final diagnosis was a cryptogenic stroke with a prominent PFO. Due to the participant's age, a stroke could not completely exclude a paradoxical/embolic etiology, and a PFO with concerning features, a decision was made to close the PFO.

On 05 Dec 2020 (Study Day 72), laboratory test results of cerebral spinal fluid included red blood cells 40/µL (abnormal), protein 29.5 mg/dL, and lymphocytes 71% (no reference ranges provided).

On 06 Dec 2020 (Study Day 73), laboratory test results included thrombin time 16.8 seconds, C-reactive protein 0.4 mg/mL, factor II 93%, fibrinogen 280 mg/dL, D-dimer 0.27 µg/mL, and factor V level 88% (no reference ranges provided). A Doppler of the extremities indicated no evidence of deep venous thrombus in the right or left femoral-popliteal venous system.

On 07 Dec 2020 (Study Day 74), the participant underwent closure of their PFO. Treatment included atorvastatin, apixaban, and acetylsalicylic acid (all PO) for stroke prevention. The participant's vital signs included blood pressure 99/85 mm Hg, pulse 99 beats per minute, respiratory rate 14 breaths per minute, and oxygen saturation 100%. Laboratory test results included international normalized ratio 1.1 (no reference range provided) and prothrombin time 13.6 seconds (reference range 12.3 to 14.9 seconds). A meningitis panel was negative. A cerebral angiogram with right radial access was performed indicating no evidence of central nervous system vasculopathy or vasculitis. The participant was sedated with midazolam and fentanyl for the procedure. Heparin, verapamil, and nitroglycerine were used for radial access.

On 08 Dec 2020 (Study Day 75), the participant was discharged from the hospital.

Action taken with study IP in response to the event was not applicable as the participant experienced a previous nonserious event of COVID-19 and was not able to receive the second dose of study IP.

The event, cerebrovascular accident, was reported as resolved on 15 Dec 2020 (Study Day 82).

The investigator assessed the event, cerebrovascular accident, as related to study IP and not related to study procedure. The investigator could not reasonably exclude that the vaccine did not, with or without the addition of mild COVID-19, contribute to their stroke that did have a temporal factor. Markers typically seen with COVID-19-related clotting were not elevated in the participant.

Although the participant's PFO was treated, there were discordant results on the bubble studies. The presence of 1 positive test would reasonably support treatment for PFO given the clinical event, but the discordance is enough to place some reasonable doubt that it is the full cause of the event.

The investigator assessed the event of cerebrovascular accident as related to the study vaccine; however, the sponsor considered the event unrelated to the study vaccine noting the PFO, which is associated with cryptogenic stroke and increases the risk of stroke.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000622	COVID-19
MOD-2020-001032	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	Jan 2019 - Ongoing	Supplement
Ibuprofen	26 Sep 2020 (Study Day 2) - 26 Sep 2020 (Study Day 2)	Pain At Injection Site Left Arm (Ediary Symptoms)
Metoclopramide	30 Nov 2020 (Study Day 67) - 30 Nov 2020 (Study Day 67)	Pica Territory Infarct Mass Effect
Ondansetron	30 Nov 2020 (Study Day 67) - 04 Dec 2020 (Study Day 71)	Nausea And Vomiting (Related To Cryptogenic Stroke)
Ondansetron	30 Nov 2020 (Study Day 67) - 30 Nov 2020 (Study Day 67)	Pica Territory Infarct Mass Effect
Meclozine	01 Dec 2020 (Study Day 68) - Ongoing	Pica Territory Infarct Mass Effect
Bloodwork*	02 Dec 2020 (Study Day 69) - 02 Dec 2020 (Study Day 69)	Adverse Event
Ascorbic acid	04 Dec 2020 (Study Day 71) - Ongoing	Supplementation
Ferrous sulfate	04 Dec 2020 (Study Day 71) - Ongoing	Supplementation
Hypercoagulability labs.*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mr brain without contrast*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event
Mra head without contrast*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event
Mra neck without contrast*	04 Dec 2020 (Study Day 71) - 04 Dec 2020 (Study Day 71)	Adverse Event
Apixaban	05 Dec 2020 (Study Day 72) - Ongoing	Stroke Prevention
Atorvastatin	05 Dec 2020 (Study Day 72) - 07 Dec 2020 (Study Day 74)	Stroke Prevention
Lumbar puncture*	05 Dec 2020 (Study Day 72) - 05 Dec 2020 (Study Day 72)	Adverse Event
Transthoracic echocardiogram*	05 Dec 2020 (Study Day 72) - 05 Dec 2020 (Study Day 72)	Adverse Event
Doppler ultrasound (lower extremity)*	06 Dec 2020 (Study Day 73) - 06 Dec 2020 (Study Day 73)	Adverse Event
Acetylsalicylic acid	07 Dec 2020 (Study Day 74) - Ongoing	Stroke Prevention
Closure of the patent foramen ovale*	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Adverse Event
Fentanyl	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Anesthesia For Procedure Related To Cryptogenic Stroke
Midazolam	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Anesthesia For Procedure Related To Cryptogenic Stroke
Ondansetron	07 Dec 2020 (Study Day 74) - 07 Dec 2020 (Study Day 74)	Anesthesia For Procedure Related To Cryptogenic Stroke
Cefazolin	08 Dec 2020 (Study Day 75) - 08 Dec 2020 (Study Day 75)	Antibiotic Prophylaxis For Procedure Related To Cryptogenic Stroke

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 13) - 07 Oct 2020 (Study Day 13)
COVID-19	Grade 1/mild	Not related	25 Oct 2020 (Study Day 31) - 06 Nov 2020 (Study Day 43)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2077 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angioedema/Angioedema [lips]	SAE	Grade 2/ moderate	Related	23 Sep 2020 (Study Day 30) – 25 Sep 2020 (Study Day 32)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2077, a 29-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Sep 2020 (Study Day 30), 29 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of angioedema. Action taken with the IP was not applicable. The event of angioedema [lips] lasted for 3 days, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 32). The investigator assessed the event of angioedema to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 23 Sep 2020 (Study Day 30), the participant experienced a serious adverse event of angioedema (angioedema [lips]). The participant developed reactogenicity symptoms of fever 10 hours after their second dose of study IP on 22 Sep 2020 (Study Day 29), with highest temperature of 103.1°F, accompanied by chills (Grade 2), headache and fatigue (Grade 3), and nausea (Grade 1). Treatment for lip angioedema included diphenhydramine PO and famotidine PO.

On 24 Sep 2020 (Study Day 31), the participant woke up with severe lip angioedema without hives, rash, tongue or mouth swelling, dysphagia, dyspnea, wheeze, or stridor. They also complained of painful muscles in the back of their neck and mental fogginess. All symptoms resolved within 48 hours. The participant had no known allergies or family history of angioedema, but approximately 1 year ago, they had experienced similar lip angioedema following a flu vaccine.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The event, angioedema, was considered resolved on 25 Sep 2020 (Study Day 32).

The investigator assessed the event, angioedema, as related to study IP and not related to study procedure.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000921	Angioedema

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	2007 - Ongoing
Angioedema	Angioedema	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Drospirenone; ethinylestradiol	2010 - Ongoing	Birth Control
Botulinum toxin type a	2019 - 2019	Cosmetic To Forehead
Hyaluronic acid	May 2019 - Oct 2019	Cosmetic To Lips
Hyaluronic acid	Dec 2019 - Sep 2020	Cosmetic To Bilateral Eyes
Botulinum toxin type a	2020 - 2020	Cosmetic To Forehead
Hyaluronic acid; lidocaine hydrochloride	Jul 2020 - Jul 2020	Cosmetic To Lips
Hyaluronic acid; lidocaine hydrochloride	Jul 2020 - Jul 2020	Cosmetic To Naso Labial Folds Bilaterally
Paracetamol	26 Aug 2020 (Study Day 2) - 26 Aug 2020 (Study Day 2)	Pain At Vaccination Site
Diphenhydramine hydrochloride	23 Sep 2020 (Study Day 30) - 26 Sep 2020 (Study Day 33)	Angioedema

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	23 Sep 2020 (Study Day 30) - 26 Sep 2020 (Study Day 33)	Angioedema
Paracetamol	23 Sep 2020 (Study Day 30) - 24 Sep 2020 (Study Day 31)	Fever Reactogencity
Influenza vaccine	14 Oct 2020 (Study Day 51) - 14 Oct 2020 (Study Day 51)	Flu Prevention
Hyaluronic acid	Nov 2020 - Nov 2020	Cosmetic To Cheeks Bilaterally
Doxycycline	13 Nov 2020 (Study Day 81) - 13 Dec 2020 (Study Day 111)	Acne
Microneedling with radiofrequency*	13 Nov 2020 (Study Day 81) - 13 Nov 2020 (Study Day 81)	Other, Acne Scarring
Bupropion hydrochloride	04 Dec 2020 (Study Day 102) - Ongoing	Situational Depression
Spironolactone	12 Feb 2021 (Study Day 172) - Ongoing	Acne

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Adjustment Disorder With Depressed Mood	Grade 2/moderate	Not related	15 Sep 2020 (Study Day 22) - 01 Mar 2021 (Study Day 189)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2169 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rheumatoid Arthritis/ Rheumatoid Arthritis	SAE, AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	31 Aug 2020 (Study Day 1) – Ongoing	Recovering /resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2169, a 57-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 31 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of rheumatoid arthritis. On 27 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of rheumatoid arthritis was considered to be ongoing. The investigator assessed the event of rheumatoid arthritis to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database

On 31 Aug 2020 (Study Day 1), the participant experienced a serious adverse event of rheumatoid arthritis. On the same day, the participant received their first and only dose of mRNA-1273. Later that same day, through 06 Sep 2020 (Study Day 7), the participant reported muscle and joint aches/pain (Vaccine Toxicity Scale Grades 1 to 2 in severity) in the eDiary. The participant also experienced tinnitus, insomnia, and constipation post-vaccination.

During the time period starting around 10 Sep 2020 (Study Day 11) through the last week of September 2020, the participant experienced recurrent muscle and joint aches/pain. The quality of the pain was different from the joint aches/pain previously reported, mainly with the left knee and right shoulder. The pain was constant regardless of rest or activity and was not worse at any particular time of the day. The participant also experienced joint stiffness in the mornings, which

improved with a shower and movement. They denied joint swelling. Additionally, they had intermittent pain at base of their neck. The participant treated their symptoms with paracetamol and diclofenac, which reduced the pain; diclofenac was only used at the peak of pain for a few days.

On 25 Sep 2020 (Study Day 26), a review of systems was positive for weight gain, weakness, hearing loss, tinnitus, wheezing, constipation, nausea, headache, insomnia, joint pain, and muscle weakness. Relevant laboratory test results, on the same day, included complement factor C3 of 194 (high) (no units and reference range reported), rheumatoid factor (RF) 62.5 IU/mL (reference range 0 to 13 IU/mL), cyclic citrullinated peptide (CCP) antibody >250 units (reference range <20 units), complement factor C4 of 32 (no units and reference range reported), an antinuclear antibody test was negative, erythrocyte sedimentation rate (ESR) 4 mm/hour (no reference range reported), and C-reactive protein (CRP) <0.1 (no unit, reference range 1 to 3).

On 29 Sep 2020 (Study Day 30), the participant's rheumatologist noted that the participant reported ongoing mild pain in the left elbow when lifting objects, right shoulder, and right knee. They reported feeling a little weak at the peak of their pain and denied shortness of breath, chest pain, rash, and fevers during their arthralgias. The participant also felt their heart rate was higher than usual; in the 80 beats per minute (bpm) range, when it was typically in the 50 to 60 bpm range. Vital signs during the visit included blood pressure 124/71 mm Hg, heart rate 70 bpm, body mass index (BMI) 29.78 kg/m^2, and a pain score of 6.5. Physical examination findings included 5/5 strength in bilateral upper and lower extremities, mild left elbow discomfort with extreme flexion and with lifting a box of surgical gloves, tenderness in bilateral elbows at the lateral epicondyles, and no other findings of musculoskeletal tenderness, swelling, effusion, or limitations to range of motion. The rheumatologist's initial assessment was that the participant had reactive arthritis based on mild symptoms and tenderness over their lateral epicondyles. However, after reviewing the laboratory test results, the rheumatologist was concerned about the possibility of rheumatoid arthritis (RA) due to the high level of CCP antibody and RF. Diagnoses included RA and lateral epicondylitis. No new medications or treatment were prescribed.

On 20 Oct 2020 (Study Day 51), the participant had a follow-up visit with a rheumatologist, where they reported recurrence of pain in both elbows and arms starting about 6 days prior and right knee pain. The pain was worse on the left side and with activities, such as lifting weights. The back of their hand hurt with fist clenching and they had forearm pain with lifting their laptop. The participant noted that the base of their neck was painful at times and they felt this caused their right arm to feel weak, but they denied numbness, tingling, or burning pain in the right arm. The right hip was still bothering them, though not as bad as before. They had noticed twitching in the left index finger when at rest in the past week and denied joint stiffness or swelling. The participant had taken paracetamol for a couple of days preceding the follow-up visit and noted that their pain

was much improved. Vital signs included blood pressure 119/77 mm Hg, pulse 70 bpm, BMI 30.55 kg/m^2, and pain scale 2/10. Review of systems was positive for weight gain, joint pain, joint swelling, muscle cramping, myalgia, neck pain, and neck stiffness. Physical examination findings included right lateral neck tenderness with cervical spine range of motion and on palpation, assessed as possibly muscular. Hand grip caused lateral and medial elbow pain bilaterally and the participant felt nauseated and had to lay down. They had lateral and medial epicondyle tenderness of both elbows. Laboratory test results included CRP 0.88 (reference range 1 to 3, no unit reported) and ESR 13 (no unit reported, reference range 0 to 20). A joint examination did not reveal active inflammatory arthritis, though they still had arthralgias to varying degrees by history. The rheumatologist noted that early RA can manifest in a palindromic pattern, consistent with participant's presentation. The participant began treatment with meloxicam PO and was instructed to use elbow straps during activities. A cervical spine x-ray was ordered, and they were instructed to follow-up in 4 weeks.

On 20 Nov 2020 (Study Day 82), a magnetic resonance imaging (MRI) scan of the right elbow revealed mild distal triceps tendinosis and no findings to suggest RA. An MRI scan of the left elbow revealed medial and lateral epicondylitis, low grade insertional tearing of the common extensor tendon, and distal long head biceps tendinosis without evidence of tear. A cervical spine x-ray with flexion/extension views revealed overall mild multilevel, multifactorial degenerative changes, normal alignment, and no listhesis with flexion or extension.

On 04 Dec 2020 (Study Day 96), the participant had a follow-up visit with a rheumatologist, where they reported ongoing elbow pain that was exacerbated with movement and interfered with their sleep. Use of forearm straps, meloxicam, and ice helped to relieve their elbow pain during the day but they woke up with elbow pain at night despite use of elbow straps at night. They felt that meloxicam was helping with all of their other pains. Vital signs included blood pressure 127/75 mm Hg, pulse 59 bpm, BMI 30.4 kg/m^2, and pain scale 7/10. During the review of systems, the participant reported weight gain, dyspnea, constipation, bowel changes, polydipsia, headache, sleep disturbances, joint pain, joint tenderness, morning stiffness, neck pain, and neck stiffness. During the physical examination, a hand grip test caused lateral and medial elbow pain bilaterally, which led to the participant to feeling nauseated, without dizziness, and they had to lay down. Physical examination revealed right shoulder joint tenderness; right elbow moderate medial epicondyle tenderness; and left elbow severe medial and moderate lateral epicondyle tenderness. No other joint swelling, tenderness, effusion, or decreased range of motion was noted. The participant’s Clinical Disease Activity Index score was 8 out of 76. Laboratory test results included CCP 103.0 (reference range 0.0 to 6.9), RF Immunoglobulin (Ig) A 118 (reference range 0 to 35), RF IgG 42 (reference range 0 to 20), RF IgM 64 (reference range 0 to 25), CRP 1.74 (reference

range 1 to 3) and ESR 12 (units not reported). Meloxicam was discontinued due to incomplete pain relief and treatment with celecoxib 200 mg BID was prescribed.

On 17 Dec 2020 (Study Day 109), the participant had a follow-up visit with a rheumatologist, where they reported they felt better in general after taking celecoxib; however, the past few days they had recurrent left elbow and mild right elbow pain. They reported that the left elbow pain was both lateral and medial, and hurt when they used their arm, straightening their elbow, it hurt overnight when they were still for a while and when they moved to turn over or pull up the covers. They were having significant morning stiffness, though it improved when they moved around. Their neck felt much better with celecoxib and their right ankle was felt like it was "giving out" on them intermittently. They reported that they did not lift much. Their pain assessment was 6/10. There was no change from the prior visit to the participant's review of systems or physical examination. A triamcinolone 40 mg injection was given in left elbow, medial and lateral epicondyles. Additional treatment of hydroxychloroquine 200 mg BID was started.

Action taken with the study IP was withdrawn in response to the event.

The event of RA was considered resolving.

The investigator assessed the event of RA to be related to study IP and not related to study procedure. The provider was suspicious of a positive causal relationship to study IP due to the participant's lack of symptoms prior to study IP administration.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000411	Rheumatoid arthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypersensitivity	Environmental allergies	1990 - Ongoing
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Asthma	Asthma	2000 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Pain in extremity	Left outer thigh pain	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1990 - Ongoing	Hypothyroidism
Montelukast	1990 - Ongoing	Environmental Allergies
Salbutamol	2000 - Ongoing	Asthma
Rabeprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Enalapril	2018 - Ongoing	Hypertension
Levocetirizine	2018 - Ongoing	Environmental Allergies
Fluticasone furoate; vilanterol trifenatate	Aug 2020 - Ongoing	Asthma
Fibre, dietary	15 Sep 2020 (Study Day 16) - Ongoing	Constipation
Paracetamol	16 Sep 2020 (Study Day 17) - 24 Sep 2020 (Study Day 25)	Rheumatoid Arthritis
Phenylephrine hydrochloride; theobroma cacao oil	16 Sep 2020 (Study Day 17) - 16 Sep 2020 (Study Day 17)	Constipation
Probiotics nos	23 Sep 2020 (Study Day 24) - Ongoing	Constipation
Paracetamol	09 Oct 2020 (Study Day 40) - Ongoing	Rheumatoid Arthritis
Meloxicam	20 Oct 2020 (Study Day 51) - Ongoing	Rheumatoid Arthritis
Levocetirizine dihydrochloride	31 Oct 2020 (Study Day 62) - 14 Nov 2020 (Study Day 76)	Viral Illness Unspecified
Influenza vaccine	02 Nov 2020 (Study Day 64) - 02 Nov 2020 (Study Day 64)	Viral Illness Unspecified
Mri of left hip*	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Other, Viral Illness Unspecified
X-ray of neck*	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Other, Viral Illness Unspecified
Celecoxib	07 Dec 2020 (Study Day 99) - Ongoing	Rheumatoid Arthritis
Triamcinolone acetonide	17 Dec 2020 (Study Day 109) - 17 Dec 2020 (Study Day 109)	Elbow Pain R/T Rheumatoid Arthritis
Hydroxychloroquine	19 Mar 2021 (Study Day 201) - Ongoing	Rheumatoid Arthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Insomnia	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 8) - 25 Sep 2020 (Study Day 26)
Constipation	Grade 2/moderate	Not related	13 Sep 2020 (Study Day 14) - 25 Sep 2020 (Study Day 26)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vomiting	Grade 1/mild	Not related	19 Sep 2020 (Study Day 20) - 20 Sep 2020 (Study Day 21)
Tinnitus	Grade 2/moderate	Not related	20 Sep 2020 (Study Day 21) - 22 Sep 2020 (Study Day 23)
Constipation	Grade 2/moderate	Not related	22 Oct 2020 (Study Day 53) - 09 Jan 2021 (Study Day 132)
Viral Infection	Grade 2/moderate	Not related	31 Oct 2020 (Study Day 62) - 14 Nov 2020 (Study Day 76)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2085 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Alopecia Areata/ Alopecia Areata	SAE	Grade 1/ mild	Related	10 Sep 2020 (Study Day 34) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2085, a 31-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Sep 2020 (Study Day 34), 33 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of alopecia areata. Action taken with the IP was not applicable. The event of alopecia areata was considered to be ongoing. The investigator assessed the event of alopecia areata to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 10 Sep 2020 (Study Day 34), the participant experienced a serious adverse event of alopecia areata, which was considered medically significant. On 26 Oct 2020 (Study Day 80), the participant first reported thinning of their beard to the site staff.

On 15 Dec 2020 (Study Day 130), the participant was diagnosed with alopecia areata by their dermatologist. Their hair loss was moderate in severity and sudden in onset. They denied any scalp symptoms and washed their hair 3 times a week. They were on minoxidil and reported they switched their medication emtricitabine/tenofovir disoproxil fumarate to emtricitabine/tenofovir alafenamide fumarate and participated in clinical trials for COVID-19. They believed that these events had something to do with hair loss. The participant denied family history of alopecia areata. An examination was performed including the scalp (including hair inspection), head (including face), and neck. General appearance of the participant was well developed and well nourished.

There were discrete nonscarring patches of hair loss distributed on the face. Treatment included 0.5% betamethasone topical. They were provided with counselling on topical steroids, skin care, expectations for treatment and were advised to contact the doctor's office if the alopecia areata did not improve or worsened despite treatment and follow-up in 1 month.

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The event of alopecia areata was reported as not resolved.

The investigator assessed the event of alopecia areata to be related to study IP as the participant received their second dose 8 days prior to event onset and not related to study procedure.

The sponsor considered the event of alopecia areata to be not related to study IP as the condition reported is not uncommon in the general population, and therefore, this single report does not provide sufficient evidence of a relationship to study IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009195	Alopecia areata

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Herpes simplex	Herpes simplex virus type 2	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Emtricitabine; tenofovir disoproxil fumarate	May 2019 - 01 Oct 2020 (Study Day 55)	Hiv Preventative
Aciclovir	Apr 2020 - Ongoing	Herpes Simplex Virus Type 2
Ibuprofen	03 Sep 2020 (Study Day 27) - 04 Sep 2020 (Study Day 28)	Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Emtricitabine; tenofovir alafenamide fumarate	02 Oct 2020 (Study Day 56) - Ongoing	Hiv Preventative
Betamethasone dipropionate	15 Dec 2020 (Study Day 130) - Ongoing	Alopecia Areata

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US381-2291 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Multiple Sclerosis/Multiple Sclerosis	SAE	Grade 2/ moderate	Related	08 Dec 2020 (Study Day 103) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2291, a 36-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Dec 2020 (Study Day 103), 102 days after the first dose and 71 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of multiple sclerosis. Action taken with the IP was not applicable. The event of multiple sclerosis was considered to be ongoing. The investigator assessed the event of multiple sclerosis to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 08 Dec 2020 (Study Day 103), the participant experienced a serious adverse event of multiple sclerosis (MS). The participant developed symptoms of pain, light sensitivity, and motion sensitivity of their eye (later diagnosed as MS). The participant also experienced left eye pain and decreased peripheral vision starting on the same day.

On 14 Dec 2020 (Study Day 109), the participant was evaluated by an ophthalmologist, who ordered an optic nerve magnetic resonance imaging (MRI) scan, which was performed on 17 Dec 2020 (Study Day 112). The results of the optic nerve MRI scan were abnormal, and the participant was diagnosed with MS. Treatment with methylprednisolone PO was initiated. On the same day, the participant also underwent an MRI of the brain and orbits. The final report revealed left optic neuritis and scattered white matter cerebral lesions that were consistent with MS.

Treatment for the event included methylprednisolone, temazepam, escitalopram, and cetirizine (all PO). The participant was given multiple options for disease-modifying therapy but had not yet started any of them.

On 19 Dec 2020 (Study Day 114), a cervical and thoracic spinal MRI scan was performed that revealed demyelinating disease that was consistent in both the cervical and thoracic spinal cord. The participant reported that the initial symptoms were ongoing but denied any additional changes in their health.

On 15 Feb 2021 (Study Day 172), the participant began treatment with prednisone PO and stopped treatment on 20 Feb 2021 (Study Day 177).

Action taken with study IP in response to the event was not applicable, as the participant had already received both scheduled doses.

The event of MS was considered not resolved.

The investigator assessed the event of MS to be related to study IP and not related to study procedure. The rationale provided by the investigator for assessing the event as related was that this new diagnosis of MS occurred within a plausible timeframe of study IP administration and that there were no other possible etiologies known at the time of assessment.

The sponsor considered the event of MS as not related to study IP, as there was insufficient supporting evidence to suggest a reasonable possibility that the study IP caused the adverse event. Additionally, in 2017 the prevalence of adults with MS in the United States has been estimated to be about 362 cases per 100,000, with a 3:1 female to male ratio, and MS most often appears in young adulthood (National Multiple Sclerosis Society, 2020). Although a temporal relationship exists between the study IP administration and the diagnosis of MS, epidemiological data support an already greater likelihood for this participant, as 1 of more than 30,000 people, to be diagnosed with MS, independent of their participation in this study.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001212	Multiple sclerosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	2003 - 2003
Tonsillitis	Tonsillitis	2003 - 2003
Rubber sensitivity	Latex allergy	2005 - Ongoing
Anxiety	Anxiety	2015 - Ongoing
Mammoplasty	Bilateral breast augmentation	2015 - 2015
Aphthous ulcer	Recurrent oral aphthous ulcers	2018 - Ongoing
Myalgia	Intermittent generalized muscle aches	2018 - Ongoing
Rhinitis allergic	Allergic rhinitis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Botulinum toxin type a	2010 - 2010	Wrinkle Prevention
Escitalopram oxalate	2015 - Ongoing	Anxiety
Melatonin	2015 - Ongoing	Sleep Health
Cetirizine hydrochloride	2018 - Ongoing	Environmental Allergies
Ibuprofen	2018 - 27 Aug 2020 (Study Day -1)	Intermittent Generalized Muschle Aches
Levonorgestrel	2019 - Ongoing	Contraception
Montelukast sodium	01 Sep 2020 (Study Day 5) - Ongoing	Environmental Allergies
Ibuprofen	29 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 34)	Headache
Paracetamol	29 Sep 2020 (Study Day 33) - 29 Sep 2020 (Study Day 33)	Fever
Doxycycline	06 Oct 2020 (Study Day 40) - Ongoing	Facial Acne
Influenza vaccine	14 Oct 2020 (Study Day 48) - 14 Oct 2020 (Study Day 48)	Influenza Prevention
Brain and orbits mri*	17 Dec 2020 (Study Day 112) - 17 Dec 2020 (Study Day 112)	Adverse Event
Methylprednisolone	17 Dec 2020 (Study Day 112) - 23 Dec 2020 (Study Day 118)	Multiple Sclerosis
Temazepam	17 Dec 2020 (Study Day 112) - Ongoing	Multiple Sclerosis
Cervical and thoracic spine mri*	19 Dec 2020 (Study Day 114) - 19 Dec 2020 (Study Day 114)	Adverse Event
Prednisone	15 Feb 2021 (Study Day 172) - 20 Feb 2021 (Study Day 177)	Multiple Sclerosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acne	Grade 1/mild	Not related	01 Oct 2020 (Study Day 35) - Ongoing
Optic Neuritis	Grade 2/moderate	Related	08 Dec 2020 (Study Day 103) - 01 Jan 2021 (Study Day 127)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US382-2043 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
B-Cell Small Lymphocytic Lymphoma/Small Lymphocytic Lymphoma	SAE	Grade 3/ severe	Related	02 Oct 2020 (Study Day 57) – 22 Dec 2020 (Study Day 138)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2043, a 75-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 57), 56 days after the first dose and 30 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of b-cell small lymphocytic lymphoma. Action taken with the IP was not applicable. The event of small lymphocytic lymphoma lasted for 82 days, after which it was considered to be recovered/resolved with sequelae on 22 Dec 2020 (Study Day 138). The investigator assessed the event of b-cell small lymphocytic lymphoma to be related to the IP.

Additional Relevant Information From the Safety/Pharmacovigilance Database:

On 05 Sep 2020 (Study Day 30), the participant was scheduled for a routine computed tomography (CT) scan of the chest to screen for lung cancer. The CT revealed new enlarged left axillary lymph nodes; the partially solid 11-mm nodule in the right upper lobe was stable as it remained unchanged since 26 Jun 2018 (Study Day -804). Due to the findings, the participant was scheduled for an ultrasound guided biopsy.

On 02 Oct 2020 (Study Day 57), the participant experienced a serious adverse event of B-cell small lymphocytic lymphoma. On the same day, the participant underwent a biopsy of the left axillary lymph node that revealed partial involvement by small B-cell lymphocytic lymphoma

(chronic lymphocytic leukemia), which was considered a medically significant. The participant had no known risk factors for the event and remained asymptomatic.

On 21 Oct 2020 (Study Day 76), the participant was seen by an oncologist. A physical examination showed no lymphadenopathy of the neck, axilla, or groin. On the same day, the relevant laboratory test results included white blood cell count $8.9 \times 10^3/\mu L$, red blood cell count $4.21 \times 10^6/\mu L$, and red cell distribution width 11.7% (low) (no reference ranges reported). The serology testing, including B2 macroglobulin, low lactate dehydrogenase, and complete blood count, did not reveal lymphocytosis. No treatment was provided for the event. The participant's prognosis was considered positive, but this remained to be seen if any treatment would be required for this malignancy.

Action taken with the study IP was not applicable in response to the event.

The event, B-cell small lymphocytic lymphoma, was considered resolved with sequelae of stable disease on 22 Dec 2020 (Study Day 138). Per the investigator, the participant would be monitored via regular CT scans for disease progression as they did not currently meet criteria to initiate the first-line treatment.

The investigator assessed the event, B-cell small lymphocytic lymphoma, as related to study IP or study procedure as the event occurred approximately 1 month after the second dose of study IP.

The sponsor considered the event of B-cell small lymphocytic lymphoma as unrelated to the study medication, noting the short latency between study medication dosing and the event onset. Causality of the event was also confounded by the participant's prior history of neoplastic disease (stage IV non-small cell lung cancer, lung nodule, bone metastasis, stage IIA invasive mammary carcinoma, and basal cell carcinoma).

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000540	B-cell small lymphocytic lymphoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Metastases to bone	Bone metastasis	Not reported
Non-small cell lung cancer stage IV	Stage iv non small cell lung cancer	Not reported
Postmenopause	Post menopausal	1969 - Ongoing
Mixed anxiety and depressive disorder	Mixed anxiety and depressive disorder	1996 - Ongoing
Type V hyperlipidaemia	Mixed hyperlipidemia	2009 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2012 - Ongoing
Rhinitis allergic	Allergic rhinitis	2012 - Ongoing
Juvenile melanoma benign	Pre melanoma left forearm	2014 - 2014
Skin neoplasm excision	Skin cancer surgery for removal of pre melonoma on left forearm (mohs surgery)	2014 - 2014
Pulmonary mass	Lung nodule	05 Feb 2014 (Study Day -2375) - Ongoing
Basal cell carcinoma	Basal cell carcinoma	2015 - 2015
Hypertension	Hypertension	2015 - Ongoing
Skin neoplasm excision	Skin cancer surgery for removal of basal cell carcinoma (mohs surgery)	2015 - 2015
Osteoporosis	Osteoporosis	2017 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive lung disease	06 Nov 2018 (Study Day -640) - Ongoing
Diverticulum	Diverticulosis	06 Nov 2018 (Study Day -640) - Ongoing
Restless legs syndrome	Restless leg syndrome	06 Nov 2018 (Study Day -640) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	1997 - Ongoing	Depression And Anxiety
Simvastatin	2009 - Ongoing	Mixed Hyperlipidemia
Calcium	2010 - Ongoing	Supplement
Colecalciferol	2010 - Ongoing	Supplement
Vitamins nos	2010 - Ongoing	Supplement
Acetylsalicylic acid	2011 - Ongoing	Cardiac Health
Ipratropium bromide	2012 - Ongoing	Allergic Rhinitis
Omeprazole	2012 - Ongoing	Gastroesophageal Reflux Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphtheria vaccine toxoid; pertussis vaccine; tetanus vaccine toxoid	01 May 2012 (Study Day -3020) - 01 May 2012 (Study Day -3020)	Vaccine
Amlodipine	2015 - Ongoing	Hypertension
Pneumococcal vaccine	09 Feb 2016 (Study Day -1641) - 09 Feb 2016 (Study Day -1641)	Vaccine
Denosumab	2017 - Ongoing	Osteoporosis
Budesonide	2018 - Ongoing	Copd
Fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	2018 - Ongoing	Copd
Ipratropium; salbutamol	2018 - Ongoing	Copd
Lorazepam	2018 - Ongoing	Restless Leg
Probiotics nos	2018 - Ongoing	Supplement
Salbutamol	2018 - Ongoing	Copd
Influenza vaccine	20 Oct 2018 (Study Day -657) - 20 Oct 2018 (Study Day -657)	Vaccine
Varicella zoster vaccine rge (cho)	21 Feb 2019 (Study Day -533) - 21 Feb 2019 (Study Day -533)	Vaccine
Ct chest for lung cancer screening - moderate centrilobular emphysema, moderate-severe coronary arterial calcifications. normal heart size.*	05 Sep 2020 (Study Day 30) - 05 Sep 2020 (Study Day 30)	Medical History
Ultrasounds guided core biopsy*	02 Oct 2020 (Study Day 57) - 02 Oct 2020 (Study Day 57)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arteriosclerosis Coronary Artery	Grade 2/moderate	Not related	05 Sep 2020 (Study Day 30) - Ongoing
Emphysema	Grade 2/moderate	Not related	05 Sep 2020 (Study Day 30) - Ongoing
Lymphadenopathy	Grade 2/moderate	Related	05 Sep 2020 (Study Day 30) - 06 Oct 2020 (Study Day 61)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US300-2046 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hip Fracture/Left Hip Fracture	SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 3/severe	Not related	12 Aug 2020 (Study Day 15) – 14 Aug 2020 (Study Day 17)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2046, a 60-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Aug 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of hip fracture. On 25 Aug 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of left hip fracture lasted for 3 days, after which it was considered to be recovered/resolved on 14 Aug 2020 (Study Day 17). The investigator assessed the event of hip fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000255	Hip fracture

Study Completion/Discontinuation

On 06 Nov 2020 (Study Day 101), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post- menopausal	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Left hip fracture repair*	14 Aug 2020 (Study Day 17) - 14 Aug 2020 (Study Day 17)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US300-2131 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Embolism Venous/Venous Thromboembolism	SAE	Grade 4	Not related	07 Dec 2020 (Study Day 123) – 12 Dec 2020 (Study Day 128)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2131, a 51-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Dec 2020 (Study Day 123), 122 days after the first dose and 94 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of embolism venous. Action taken with the IP was not applicable. The event of venous thromboembolism lasted for 6 days, after which it was considered to be recovered/resolved on 12 Dec 2020 (Study Day 128). The investigator assessed the event of embolism venous to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001082	Embolism venous

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ventricular septal defect	Ventricular foramen (hole in lower left ventricle)	1969 - 1971
Ventricular septal defect repair	Repair of ventricular foramen	1971 - 1971
Obesity	Obesity	1998 - Ongoing
Cardiomyopathy	Cardiomyopathy	2001 - 2013
Cardiac murmur	Grade 1 systolic murmur	07 Aug 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	01 Dec 2020 (Study Day 117) - Ongoing	Hypertension
Doppler of left leg*	07 Dec 2020 (Study Day 123) - 07 Dec 2020 (Study Day 123)	Adverse Event
Ferrous sulfate	11 Dec 2020 (Study Day 127) - Ongoing	Anemia Prophylaxis
Rivaroxaban	12 Dec 2020 (Study Day 128) - Ongoing	Venous Thromboembolism Prevention
Uterine ablation*	13 Jan 2021 (Study Day 160) - 13 Jan 2021 (Study Day 160)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Uterine Leiomyoma	Grade 3/severe	Not related	30 Sep 2020 (Study Day 55) - 13 Jan 2021 (Study Day 160)
Anaemia	Grade 1/mild	Not related	01 Dec 2020 (Study Day 117) - 12 Dec 2020 (Study Day 128)
Hypertension	Grade 1/mild	Not related	01 Dec 2020 (Study Day 117) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US300-2259 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hydrocephalus/Hydrocephalus	SAE	Grade 4	Not related	06 Dec 2020 (Study Day 90) – 15 Dec 2020 (Study Day 99)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2259, a 64-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Dec 2020 (Study Day 90), 89 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hydrocephalus. Action taken with the IP was not applicable. The event of hydrocephalus lasted for 10 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 99). The investigator assessed the event of hydrocephalus to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001069	COVID-19
MOD-2020-001069	Hydrocephalus

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Back pain	Chronic back pain	2015 - Ongoing
Diverticulum	Diverticulosis	Jul 2019 - Ongoing
Small intestinal obstruction	Small bowel obstruction	Jul 2019 - Jul 2019
Small intestinal resection	Small bowel resection	Jul 2019 - Jul 2019
Anxiety	Anxiety	Jun 2020 - Ongoing
Muscular weakness	Bilateral leg weakness	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2005 - Ongoing	Hypertension
Metoprolol	2005 - Ongoing	Hypertension
Hydrochlorothiazide	2008 - Ongoing	Hypertension
Paracetamol	2015 - Ongoing	Chronic Back Pain
Escitalopram	Jun 2020 - Ongoing	Anxiety
Influenza vaccine	23 Oct 2020 (Study Day 46) - 23 Oct 2020 (Study Day 46)	Influenza Prevention
Methylprednisolone sodium succinate	10 Dec 2020 (Study Day 94) - 14 Dec 2020 (Study Day 98)	Hydrocephalus
Foley catheter placement*	15 Dec 2020 (Study Day 99) - 15 Dec 2020 (Study Day 99)	Adverse Event
Ventriculoperitoneal shunt placement*	15 Dec 2020 (Study Day 99) - 15 Dec 2020 (Study Day 99)	Adverse Event
Tamsulosin hydrochloride	22 Dec 2020 (Study Day 106) - Ongoing	Urinary Retention
Thiamine	22 Dec 2020 (Study Day 106) - Ongoing	Vitamin B-12 Deficiency
Apixaban	25 Dec 2020 (Study Day 109) - Ongoing	Atrial Fibrillation
Amlodipine	25 Jan 2021 (Study Day 140) - 17 Feb 2021 (Study Day 163)	Worsening Of Hypertension
Varicella zoster vaccine	03 Feb 2021 (Study Day 149) - 03 Feb 2021 (Study Day 149)	Shingles Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Muscular Weakness	Grade 2/moderate	Not related	19 Nov 2020 (Study Day 73) - Ongoing
COVID-19	Grade 2/moderate	Not related	04 Dec 2020 (Study Day 88) - 19 Dec 2020 (Study Day 103)
Atrial Fibrillation	Grade 1/mild	Not related	06 Dec 2020 (Study Day 90) - Ongoing
Urinary Retention	Grade 2/moderate	Not related	16 Dec 2020 (Study Day 100) - Ongoing
Vitamin B12 Deficiency	Grade 1/mild	Not related	16 Dec 2020 (Study Day 100) - Ongoing
Hypertension	Grade 1/mild	Not related	25 Jan 2021 (Study Day 140) - 17 Feb 2021 (Study Day 163)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US301-2096 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Crohn's Disease/Crohn's Disease	SAE	Grade 3/severe	Not related	03 Nov 2020 (Study Day 86) – 27 Apr 2021 (Study Day 261)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US301-2096, a 59-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Nov 2020 (Study Day 86), 85 days after the first dose and 56 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of crohn's disease. Action taken with the IP was not applicable. The event of crohn's disease lasted for 176 days, after which it was considered to be recovered/resolved with sequelae on 27 Apr 2021 (Study Day 261). The investigator assessed the event of crohn's disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068030	Crohn's Disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1995 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Hysterectomy	Hysterectomy	1996 - 1996
Postmenopause	Post menopausal	1996 - Ongoing
Uterine leiomyoma	Uterine fibroids	1996 - 1996
Bipolar disorder	Bipolar disorder	2008 - Ongoing
Depression	Depressioin	2008 - Ongoing
Type 2 diabetes mellitus	Diabetes, type ii	2010 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Intervertebral disc protrusion	Herniated disc : l4	2014 - Ongoing
Muscle spasms	Back spasms	2014 - Ongoing
Gastrooesophageal reflux disease	Gerd	2017 - Ongoing
Peripheral sensory neuropathy	Neuropathy (sensor), bilateral feet	2017 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Chronic obstructive pulmonary disease	Copd	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2010 - Ongoing	Diabetes, Type Ii
Amlodipine	2012 - Ongoing	Hypertension
Lisinopril	2012 - Ongoing	Hypertension
Duloxetine	2014 - Ongoing	Depression
Hydrocodone bitartrate; paracetamol	2014 - Ongoing	Pain, Back And Feet, Due To Neuropathy
Gabapentin	2017 - Ongoing	Neuropathy, Bilateral Feet
Omeprazole	2017 - Ongoing	Gerd
Ziprasidone	2017 - Ongoing	Bipolar Depression
Atorvastatin	2018 - Ongoing	Hypercholesterolemia
Tizanidine	2018 - Ongoing	Back Spasms
Diphenhydramine hydrochloride	2019 - Ongoing	Seasonal Allergies
Fluticasone	2019 - Ongoing	Seasonal Allergies
Colecalciferol	May 2019 - Ongoing	Nutritional Supplement
Hydrocodone bitartrate; paracetamol	09 Sep 2020 (Study Day 31) - 09 Sep 2020 (Study Day 31)	Pain At Injection Site

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	01 Oct 2020 (Study Day 53) - 01 Oct 2020 (Study Day 53)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US301-2098 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colitis/Colitis	SAE	Grade 3/severe	Not related	24 Sep 2020 (Study Day 46) – 30 Sep 2020 (Study Day 52)	Recovered/ resolved
Acute Respiratory Failure/Acute Hypoxic Respiratory Failure	SAE	Grade 4	Not related	29 Sep 2020 (Study Day 51) – 12 Oct 2020 (Study Day 64)	Recovered/ resolved
Cardiac Failure Congestive/Exacerbation Of Diastolic Chf	SAE	Grade 3/severe	Not related	29 Sep 2020 (Study Day 51) – 12 Oct 2020 (Study Day 64)	Recovered/ resolved
Clostridium Difficile Infection/Clostridium Difficile	SAE	Grade 3/severe	Not related	29 Sep 2020 (Study Day 51) – 25 Oct 2020 (Study Day 77)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US301-2098, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Sep 2020 (Study Day 46), 45 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of colitis. Action taken with the IP was not applicable. The event of colitis lasted for 7 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 52). The investigator assessed the event of colitis to be not related to the IP.

On 29 Sep 2020 (Study Day 51), 50 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute hypoxic respiratory failure lasted for 14 days, after which it was considered to be recovered/resolved on 12 Oct 2020 (Study Day 64). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 29 Sep 2020 (Study Day 51), 50 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of exacerbation of diastolic chf lasted for 14 days, after which it was considered to be recovered/resolved on 12 Oct 2020 (Study Day 64). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

On 29 Sep 2020 (Study Day 51), 50 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of clostridium difficile infection. Action taken with the IP was not applicable. The event of clostridium difficile lasted for 27 days, after which it was considered to be recovered/resolved on 25 Oct 2020 (Study Day 77). The investigator assessed the event of clostridium difficile infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000395	Colitis
MOD-2020-000395	Acute respiratory failure
MOD-2020-000395	Cardiac failure congestive
MOD-2020-000395	Clostridium difficile infection

Study Completion/Discontinuation

On 02 Dec 2020 (Study Day 115), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1980 - Ongoing
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Umbilical hernia	Umbilical hernia	1997 - Ongoing
Drug hypersensitivity	Keflex allergy	1999 - Ongoing
Drug hypersensitivity	Lithium allergy	1999 - Ongoing
Drug hypersensitivity	Lyrica allergy	1999 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Back pain	Back pain lumbar region	2000 - Ongoing
Bipolar disorder	Bipolar disorder	2000 - Ongoing
Depression	Depression	2000 - Ongoing
Dyspepsia	Heartburn	2000 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Fibromyalgia	Fibromyalgia	2000 - Ongoing
Gastrooesophageal reflux disease	Gerd	2000 - Ongoing
Insomnia	Insomnia	2000 - Ongoing
Panic attack	Panic attacks	2000 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Hypertonic bladder	Overactive bladder	2005 - Ongoing
Menopause	Menopause	2005 - Ongoing
Diverticulitis	Diverticulitis	2010 - Ongoing
Osteoarthritis	Osteoarthritis (lower back, lower neck)	2010 - Ongoing
Chronic obstructive pulmonary disease	Copd	Mar 2018 - Ongoing
Cardiac failure congestive	Diastolic congestive heart failure	2019 - Ongoing
Emphysema	Emphysema	2019 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aripiprazole	2000 - Ongoing	Depression
Clonidine	2000 - Ongoing	Anxiety, Hypertension
Hydrocodone bitartrate; paracetamol	2000 - Ongoing	Osteoarthritis
Chondroitin; glucosamine	2015 - Ongoing	Nutritional Supplement
Diprophylline	2015 - Ongoing	Emphysema
Doxepin	2015 - Ongoing	Anxiety
Fish oil	2015 - Ongoing	Nutritional Supplement
Fluticasone propionate	2015 - Ongoing	Seasonal Allergies
Dexlansoprazole	2017 - Ongoing	Diverticulitis
Iron	2017 - Ongoing	Nutritional Supplement
Montelukast	2017 - Ongoing	Seasonal Allergies
Topiramate	2017 - Ongoing	Fibromyalgia
Hydroxyzine	2018 - Ongoing	Insomnia
Lamotrigine	2018 - Ongoing	Bipolar Disorder
Levothyroxine	2018 - Ongoing	Hypothyroidism
Metoprolol	2018 - Ongoing	Hypertension
Atorvastatin	2019 - Ongoing	Hypercholesterolemia
Salbutamol	2019 - Ongoing	Emphysema
Vortioxetine hydrobromide	2019 - Ongoing	Depression
Ondansetron	28 Sep 2020 (Study Day 50) - Ongoing	Nausea
Chest ct for pulmonary embolus, negative*	29 Sep 2020 (Study Day 51) - 29 Sep 2020 (Study Day 51)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct scan - abdomen/pelvis for diagnosis, normal*	29 Sep 2020 (Study Day 51) - 29 Sep 2020 (Study Day 51)	Adverse Event
Dicycloverine	29 Sep 2020 (Study Day 51) - 12 Oct 2020 (Study Day 64)	Colitis (Ae #1)
Electrocardiogram*	29 Sep 2020 (Study Day 51) - 29 Sep 2020 (Study Day 51)	Adverse Event
Furosemide	29 Sep 2020 (Study Day 51) - 01 Oct 2020 (Study Day 53)	Diuretic, From Hospitalization
Gi panel- bacteria pcr - negative*	29 Sep 2020 (Study Day 51) - 29 Sep 2020 (Study Day 51)	Diagnostic
Macrogol	29 Sep 2020 (Study Day 51) - 12 Oct 2020 (Study Day 64)	Pain In Abdomen Dx Colitis
Metronidazole	29 Sep 2020 (Study Day 51) - 01 Oct 2020 (Study Day 53)	Uti Treatment Part Of Hospitalization
Metronidazole	29 Sep 2020 (Study Day 51) - 01 Oct 2020 (Study Day 53)	Uti Treatment Pre-Emptive Part Of Hospitalization
Morphine sulfate	29 Sep 2020 (Study Day 51) - 13 Oct 2020 (Study Day 65)	Pain In Abdomen Part Of Hospitalization (Diagnosed As Colitis)
Pantoprazole sodium sesquihydrate	29 Sep 2020 (Study Day 51) - 12 Oct 2020 (Study Day 64)	Gerd During Hospitalization
Tramadol hydrochloride	29 Sep 2020 (Study Day 51) - 12 Oct 2020 (Study Day 64)	Pain In Abdomen Dx Colitis During Hospitalization
Umeclidinium; vilanterol	29 Sep 2020 (Study Day 51) - 12 Oct 2020 (Study Day 64)	Copd- During Hospitalization
Vancomycin	29 Sep 2020 (Study Day 51) - 22 Oct 2020 (Study Day 74)	C-Diff
Vortioxetine	29 Sep 2020 (Study Day 51) - 12 Oct 2020 (Study Day 64)	Depression - During Hospitalization
Chest ct for pulmonary embolus, negative*	30 Sep 2020 (Study Day 52) - 30 Sep 2020 (Study Day 52)	Adverse Event
Transthoracic echocardiograph*	30 Sep 2020 (Study Day 52) - 30 Sep 2020 (Study Day 52)	Adverse Event
Benzocaine	10 Oct 2020 (Study Day 62) - Ongoing	Cracked Tongue , Fever Blister
Dimeticone	10 Oct 2020 (Study Day 62) - Ongoing	Body Aches/Weakness
Dicycloverine	13 Oct 2020 (Study Day 65) - Ongoing	Colitis Prevention
Sars-cov-2 test (nasal, negative)*	14 Oct 2020 (Study Day 66) - 14 Oct 2020 (Study Day 66)	Adverse Event
Influenza vaccine	23 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 75)	Influenza Prevention
Varicella zoster vaccine	27 Oct 2020 (Study Day 79) - 27 Oct 2020 (Study Day 79)	Shingles Prevention
Mirabegron	03 Nov 2020 (Study Day 86) - Ongoing	Overactive Bladder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US301-2131 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Stroke	SAE	Grade 3/severe	Not related	11 Dec 2020 (Study Day 121) – 11 Dec 2020 (Study Day 121)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US301-2131, a 75-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Dec 2020 (Study Day 121), 120 days after the first dose and 92 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of stroke lasted for 1 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 121). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001127	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to penicillin	1988 - Ongoing
Postmenopause	Postmenopausal	1997 - Ongoing
Complex regional pain syndrome	Reflux sympathetic distrophy, left wrist	2010 - Ongoing
Macular degeneration	Macular degeneration, bilateral	2010 - Ongoing
Osteoporosis	Osteoporosis	2010 - Ongoing
Vertigo positional	Bppv	2010 - Ongoing
Neuroprosthesis implantation	Implanted neurostimulator, due to reflux sympathetic dystrophy, left wrist	2012 - Ongoing
Complex regional pain syndrome	Nerve pain, due to reflux sympathetic dystrophy	2015 - Ongoing
Insomnia	Insomnia	2015 - Ongoing
Fatigue	Chronic fatigue	2016 - Ongoing
Hypoacusis	Decreased hearing, bilateral	2016 - Ongoing
Glaucoma	Glaucoma, bilateral	2019 - Ongoing
Myalgia	General myalgias	Jul 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Doxepin	2015 - Ongoing	Insomnia
Gabapentin	2015 - Ongoing	Nerve Pain, Due To Reflux Sympathetic Dystrophy
Aflibercept	2016 - Ongoing	Macular Degeneration, Bilateral
Calcium citrate; colecalciferol	2016 - Ongoing	Osteoporosis
Colecalciferol	2016 - Ongoing	Osteoporosis
Denosumab	2016 - Ongoing	Osteoporosis
Vitamin b complex	2016 - Ongoing	Chronic Fatigue
Vitamins nos	2016 - Ongoing	Macular Degeneration, Bilateral
Timolol maleate	2019 - Ongoing	Glaucoma, Bilateral
Paracetamol	Jul 2019 - Ongoing	General Myalgias
Influenza vaccine	28 Sep 2020 (Study Day 47) - 28 Sep 2020 (Study Day 47)	Influenza Prophylaxis
Tenecteplase	11 Dec 2020 (Study Day 121) - 11 Dec 2020 (Study Day 121)	Stroke
Acetylsalicylic acid	13 Dec 2020 (Study Day 123) - Ongoing	Cardiac Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	13 Dec 2020 (Study Day 123) - Ongoing	Prophylaxis After Episode Of Cva/Stroke
Clindamycin	08 Mar 2021 (Study Day 208) - Ongoing	Tooth Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US301-2263 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gun Shot Wound/ Gunshot Wound, Right Shoulder And Spine	SAE	Grade 4	Not related	08 Nov 2020 (Study Day 68) – 01 Mar 2021 (Study Day 181)	Recovered/ resolved
Pneumothorax/Bilateral Lung Collapse	SAE	Grade 4	Not related	09 Nov 2020 (Study Day 69) – 15 Nov 2020 (Study Day 75)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US301-2263, a 50-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Nov 2020 (Study Day 68), 67 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of gun shot wound. Action taken with the IP was not applicable. The event of gunshot wound, right shoulder and spine lasted for 114 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 181). The investigator assessed the event of gun shot wound to be not related to the IP.

On 09 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumothorax. Action taken with the IP was not applicable. The event of bilateral lung collapse lasted for 7 days, after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 75). The investigator assessed the event of pneumothorax to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000731	Gun shot wound
MOD-2020-000731	Pneumothorax

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myalgia	General myalgias, secondary to work	2005 - Ongoing
Hypertension	Hypertension	2008 - Ongoing
Type 2 diabetes mellitus	Diabetes, type II	2008 - Ongoing
Dental caries	Dental caries, left molar	2018 - Ongoing
Diabetic neuropathy	Diabetic neuropathy, left foot sensory	Feb 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2005 - Ongoing	General Myalgias
Glibenclamide; metformin hydrochloride	2008 - Ongoing	Diabetes, Type II
Lisinopril	2008 - Ongoing	Hypertension
Ibuprofen	Feb 2019 - Ongoing	Diabetic Neuropathy L Foot Sensory
Gabapentin	22 Jun 2020 (Study Day -72) - Ongoing	Diabetic Neuropathy L Foot Sensory
Paracetamol	07 Sep 2020 (Study Day 6) - 07 Sep 2020 (Study Day 6)	Chills
Amoxicillin	16 Sep 2020 (Study Day 15) - Ongoing	Molar Extraction
Hydrocodone bitartrate; paracetamol	16 Sep 2020 (Study Day 15) - Ongoing	Molar Extraction
Molar extraction*	16 Sep 2020 (Study Day 15) - 16 Sep 2020 (Study Day 15)	Adverse Event
Bilateral chest tube placement*	09 Nov 2020 (Study Day 69) - 09 Nov 2020 (Study Day 69)	Adverse Event
Ct scan - abdomen and pelvis*	09 Nov 2020 (Study Day 69) - 09 Nov 2020 (Study Day 69)	Adverse Event
Ct scan - chest*	09 Nov 2020 (Study Day 69) - 09 Nov 2020 (Study Day 69)	Adverse Event
Glipizide	09 Nov 2020 (Study Day 69) - 15 Nov 2020 (Study Day 75)	Diabetes, Type II (While Hospitalized)
Insulin	09 Nov 2020 (Study Day 69) - 15 Nov 2020 (Study Day 75)	Diabetes, Type II (While Hospitalized)
Methocarbamol	09 Nov 2020 (Study Day 69) - 15 Nov 2020 (Study Day 75)	Pain, Due To Gunshot Wound (Ae #2)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	09 Nov 2020 (Study Day 69) - Ongoing	Pain, Due To Gunshot Wound (Ae #2)
Chest xray*	11 Nov 2020 (Study Day 71) - 11 Nov 2020 (Study Day 71)	Adverse Event
Chest xray*	12 Nov 2020 (Study Day 72) - 12 Nov 2020 (Study Day 72)	Adverse Event
Clotrimazole	15 Nov 2020 (Study Day 75) - 22 Nov 2020 (Study Day 82)	Rash From Laying In Hospital Bed (Ae #5)
Tramadol	15 Nov 2020 (Study Day 75) - 15 Dec 2020 (Study Day 105)	Pain, Due To Gunshot Wound (Ae #2)
Alprazolam	18 Nov 2020 (Study Day 78) - 15 Dec 2020 (Study Day 105)	Anxiety (Ae #4)
Methocarbamol	18 Nov 2020 (Study Day 78) - 15 Dec 2020 (Study Day 105)	Pain, Due To Gunshot Wound (Ae #2)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Loose Tooth	Grade 1/mild	Not related	15 Sep 2020 (Study Day 14) - 16 Sep 2020 (Study Day 15)
Anxiety	Grade 1/mild	Not related	09 Nov 2020 (Study Day 69) - Ongoing
Rib Fracture	Grade 3/severe	Not related	09 Nov 2020 (Study Day 69) - Ongoing
Subcutaneous Emphysema	Grade 3/severe	Not related	09 Nov 2020 (Study Day 69) - 15 Nov 2020 (Study Day 75)
Rash	Grade 1/mild	Not related	15 Nov 2020 (Study Day 75) - 22 Nov 2020 (Study Day 82)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2021 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Orthostatic Hypotension/Orthostatic Hyotension	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	14 Sep 2020 (Study Day 48) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2021, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 29 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Sep 2020 (Study Day 48), 47 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of orthostatic hypotension. On 25 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of orthostatic hyotension was considered to be ongoing. The investigator assessed the event of orthostatic hypotension to be not related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	1993 - Ongoing
Dermal filler injection	Dermal fillers/cosmetic injection	2020 - 2020

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Basal cell carcinoma	Basal cell carcinoma	15 Jul 2020 (Study Day -14) - 15 Jul 2020 (Study Day -14)
Squamous cell carcinoma	Squamous cell carcinoma	15 Jul 2020 (Study Day -14) - 15 Jul 2020 (Study Day -14)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	2019 - Ongoing	Post Menopausal
Progesterone	2019 - Ongoing	Post Menopausal
Testosterone	2019 - Ongoing	Post Menopausal
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	24 Aug 2020 (Study Day 27) - 24 Aug 2020 (Study Day 27)	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Orthostatic Hypotension	Grade 2/moderate	Not related	14 Sep 2020 (Study Day 48) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2031 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Overdose/Overdose Of Klonopin	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	10 Aug 2020 (Study Day 15) – 19 Aug 2020 (Study Day 24)	Recovered/resolved
Pneumonia/Pnuemonia	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	10 Aug 2020 (Study Day 15) – 19 Aug 2020 (Study Day 24)	Recovered/resolved
Respiratory Failure/Lung Failure	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	10 Aug 2020 (Study Day 15) – 19 Aug 2020 (Study Day 24)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2031, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 27 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Aug 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of overdose. On 23 Aug 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of overdose of klonopin lasted for 10 days, after which it was considered to be recovered/resolved on 19 Aug 2020 (Study Day 24). The investigator assessed the event of overdose to be not related to the IP.

On 10 Aug 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of pneumonia. On 23 Aug 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of pnuemonia lasted for 10 days, after which it was considered to be recovered/resolved on 19 Aug 2020 (Study Day 24). The investigator assessed the event of pneumonia to be not related to the IP.

On 10 Aug 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of respiratory failure. On 23 Aug 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of lung failure lasted for 10 days, after which it was considered to be recovered/resolved on 19 Aug 2020 (Study Day 24). The investigator assessed the event of respiratory failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000220	Overdose
MOD-2020-000220	Pneumonia
MOD-2020-000220	Respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Limb operation	Right leg surgery	1976 - 1976
Explorative laparotomy	Exploratory laparotomy	1981 - 1981
Gun shot wound	Gunshot wound	1981 - 1981
Antiphospholipid antibodies positive	Lupus anticoagulant positive	1991 - Ongoing
Deep vein thrombosis	Deep vein thrombosis	1991 - 1991
Deep vein thrombosis	Dvt	1991 - 1992
Hypercoagulation	Hypercoagulable state	1991 - Ongoing
Pulmonary embolism	Pulmonary embolism	1991 - 1991
Alcoholism	Alcohol dependence	2007 - Ongoing
Anxiety	Anxiety	2007 - Ongoing
Depression	Depression	2007 - Ongoing
Nightmare	Nightmares	2007 - Ongoing
Road traffic accident	Tractor trailer accident	2007 - 2007
Post-traumatic stress disorder	Ptsd	Jan 2007 - Ongoing
Schizoaffective disorder	Schizoaffective disorder	Jun 2007 - Ongoing
Back pain	Back pain	2012 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rivaroxaban	1991 - Ongoing	Hypercoagulable Stables
Oxycodone; paracetamol	2016 - Ongoing	Back Pain
Amlodipine	2019 - Ongoing	Hypertension
Atorvastatin	2019 - 09 Aug 2020 (Study Day 14)	Hyperlipidemia
Prazosin	Jun 2020 - Ongoing	Nightmares
Chest xray*	10 Aug 2020 (Study Day 15) - 10 Aug 2020 (Study Day 15)	Adverse Event
Clonazepam	10 Aug 2020 (Study Day 15) - 19 Aug 2020 (Study Day 24)	Anxiety
Ct scan of chest*	10 Aug 2020 (Study Day 15) - 10 Aug 2020 (Study Day 15)	Adverse Event
Mechanical ventilator*	10 Aug 2020 (Study Day 15) - 10 Aug 2020 (Study Day 15)	Adverse Event
Aripiprazole	17 Aug 2020 (Study Day 22) - Ongoing	Schizoaffective Disorder
Duloxetine	17 Aug 2020 (Study Day 22) - Ongoing	Schizophrenia/Ptsd
Fluoxetine	17 Aug 2020 (Study Day 22) - 15 Jan 2021 (Study Day 173)	Schizophernia/ Ptsd
Influenza vaccine	Sep 2020 - Sep 2020	Influenza Prevention
Duloxetine	16 Jan 2021 (Study Day 174) - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US302-2052 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 46)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Oesophageal Carcinoma/ Esophageal Cancer	SAE	Grade 3/ severe	Not related	15 Oct 2020 (Study Day 80) – Ongoing	Not recovered/ not resolved
Oesophageal Rupture/Esophageal Tear	SAE	Grade 4	Not related	15 Oct 2020 (Study Day 80) – 18 Oct 2020 (Study Day 83)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2052, a 55-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 28 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 11 Sep 2020 (Study Day 46). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Oct 2020 (Study Day 80), 79 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of oesophageal carcinoma. Action taken with the IP was not applicable. The event of esophageal cancer was considered to be ongoing. The investigator assessed the event of oesophageal carcinoma to be not related to the IP.

On 15 Oct 2020 (Study Day 80), 79 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of oesophageal rupture. Action taken with the IP was not applicable. The event of esophageal tear lasted for 4 days, after which it was considered to be recovered/resolved on 18 Oct 2020 (Study Day 83). The investigator assessed the event of oesophageal rupture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000655	Oesophageal rupture
MOD-2020-000655	Oesophageal carcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pharyngitis streptococcal	Chronic strep throat	1977 - 1977
Tonsillectomy	Tonsillectomy	1977 - 1977
Hyperlipidaemia	Hyperlipidemia	2013 - Ongoing
Hypothyroidism	Hypothyroidism	2014 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	2014 - Ongoing
Dysphagia	Dysphagia	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rosuvastatin	2013 - Ongoing	Hyperlipidemia
Levothyroxine sodium	2014 - Ongoing	Hypothyroidism
Metformin	2014 - Ongoing	Type 2 Diabetes
Sitagliptin	2014 - Ongoing	Type 2 Diabetes
Lisinopril	2017 - Ongoing	Hypertension
Ibuprofen	13 Sep 2020 (Study Day 48) - 13 Sep 2020 (Study Day 48)	Pain At Injection Site
Esophageal tissue biopsy*	15 Oct 2020 (Study Day 80) - 15 Oct 2020 (Study Day 80)	Adverse Event
Esophagogastro-duodenoscopy*	15 Oct 2020 (Study Day 80) - 15 Oct 2020 (Study Day 80)	Adverse Event
Pantoprazole	15 Oct 2020 (Study Day 80) - Ongoing	Esophageal Cancer
Bronchoscopy*	16 Oct 2020 (Study Day 81) - 16 Oct 2020 (Study Day 81)	Adverse Event
Chest tube placement*	16 Oct 2020 (Study Day 81) - 16 Oct 2020 (Study Day 81)	Adverse Event
Esophageal stent placement*	16 Oct 2020 (Study Day 81) - 16 Oct 2020 (Study Day 81)	Adverse Event
Esophagogastro-duodenoscopy*	16 Oct 2020 (Study Day 81) - 16 Oct 2020 (Study Day 81)	Adverse Event
Mediastinal drainage*	16 Oct 2020 (Study Day 81) - 16 Oct 2020 (Study Day 81)	Adverse Event
Right thoracoscopic evacuation pleural effusion*	16 Oct 2020 (Study Day 81) - 16 Oct 2020 (Study Day 81)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Thoracic cavity field block*	16 Oct 2020 (Study Day 81) - 16 Oct 2020 (Study Day 81)	Adverse Event
Amoxicillin; clavulanic acid	19 Oct 2020 (Study Day 84) - 25 Oct 2020 (Study Day 90)	Esophageal Tear
Influenza vaccine	26 Oct 2020 (Study Day 91) - 26 Oct 2020 (Study Day 91)	Prophylaxis
Pneumococcal vaccine	26 Oct 2020 (Study Day 91) - 26 Oct 2020 (Study Day 91)	Prophylaxis
Lansoprazole	02 Nov 2020 (Study Day 98) - Ongoing	Esophageal Cancer
Metoclopramide	02 Nov 2020 (Study Day 98) - Ongoing	Esophageal Cancer
Esophagectomy*	09 Nov 2020 (Study Day 105) - 09 Nov 2020 (Study Day 105)	Adverse Event
Gastrostomy tube*	09 Nov 2020 (Study Day 105) - 09 Nov 2020 (Study Day 105)	Adverse Event
Gastrostomy tube removed*	10 Feb 2021 (Study Day 198) - 10 Feb 2021 (Study Day 198)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Barrett's Oesophagus	Grade 3/severe	Not related	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378239

Participant Number:	US302-2103 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	23 Nov 2020 (Study Day 116)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain Upper/ Intermittent Epigastric Pain	SAE	Grade 4	Not related	16 Aug 2020 (Study Day 17) – 09 Nov 2020 (Study Day 102)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2103, a 59-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 23 Nov 2020 (Study Day 116). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Aug 2020 (Study Day 17), 16 days after the first dose and 99 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of abdominal pain upper. The IP dose was not changed due to the intermittent epigastric pain. The event of intermittent epigastric pain lasted for 86 days, after which it was considered to be recovered/resolved on 09 Nov 2020 (Study Day 102). The investigator assessed the event of abdominal pain upper to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000247	Abdominal pain upper

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2003 - Ongoing
Postmenopause	Post menopausal	2010 - Ongoing
Onychomycosis	Bilateral onychomycosis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone	2003 - Ongoing	Seasonal Allergies
Ketoconazole	2018 - Ongoing	Onychomycosis Bilateral
Ibuprofen	15 Aug 2020 (Study Day 16) - 16 Aug 2020 (Study Day 17)	Neck Pain
Ct abdomen pelvis with contrast*	16 Aug 2020 (Study Day 17) - 16 Aug 2020 (Study Day 17)	Adverse Event
Pantoprazole	16 Aug 2020 (Study Day 17) - 09 Nov 2020 (Study Day 102)	Epigastric Pain
Sucralfate	16 Aug 2020 (Study Day 17) - 09 Nov 2020 (Study Day 102)	Epigastric Pain
Mri of the abdomen*	15 Sep 2020 (Study Day 47) - 15 Sep 2020 (Study Day 47)	Adverse Event
Paracetamol	24 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 117)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Neck Pain	Grade 2/moderate	Not related	14 Aug 2020 (Study Day 15) - 17 Aug 2020 (Study Day 18)
Hepatic Enzyme Increased	Grade 3/severe	Not related	17 Aug 2020 (Study Day 18) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2186 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dehydration/Dehydration	SAE	Grade 4	Not related	11 Oct 2020 (Study Day 53) – 14 Oct 2020 (Study Day 56)	Recovered/ resolved
Rib Fracture/Fracture Ribs	SAE	Grade 4	Not related	11 Oct 2020 (Study Day 53) – Ongoing	Not recovered/ not resolved
Syncope/Syncope	SAE	Grade 4	Not related	11 Oct 2020 (Study Day 53) – 11 Oct 2020 (Study Day 53)	Recovered/ resolved
Dehydration/Dehydration	SAE	Grade 4	Not related	11 Nov 2020 (Study Day 84) – 13 Nov 2020 (Study Day 86)	Recovered/ resolved
Diarrhoea/Diarrhea	SAE	Grade 4	Not related	11 Nov 2020 (Study Day 84) – 13 Nov 2020 (Study Day 86)	Recovered/ resolved
Non-Small Cell Lung Cancer/Non- Small Cell Carcinoma Of The Lung	SAE	Grade 3/ severe	Not related	14 Jan 2021 (Study Day 148) – 14 Jan 2021 (Study Day 148)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2186, a 66-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Oct 2020 (Study Day 53), 52 days after the first dose and 17 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration lasted for 4 days, after which it was considered to be recovered/resolved on 14 Oct 2020 (Study Day 56). The investigator assessed the event of dehydration to be not related to the IP.

On 11 Oct 2020 (Study Day 53), 52 days after the first dose and 17 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of rib fracture. Action taken with the IP was not applicable. The event of fracture ribs was considered to be ongoing. The investigator assessed the event of rib fracture to be not related to the IP.

On 11 Oct 2020 (Study Day 53), 52 days after the first dose and 17 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 1 days, after which it was considered to be recovered/resolved on 11 Oct 2020 (Study Day 53). The investigator assessed the event of syncope to be not related to the IP.

On 11 Nov 2020 (Study Day 84), 83 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration lasted for 3 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 86). The investigator assessed the event of dehydration to be not related to the IP.

On 11 Nov 2020 (Study Day 84), 83 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of diarrhoea. Action taken with the IP was not applicable. The event of diarrhea lasted for 3 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 86). The investigator assessed the event of diarrhoea to be not related to the IP.

On 14 Jan 2021 (Study Day 148), 147 days after the first dose and 112 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of non-small cell lung cancer. Action taken with the IP was not applicable. The event of non- small cell carcinoma of the lung lasted for 1 days, after which it was considered to be recovered/resolved on 14 Jan 2021 (Study Day 148). The investigator assessed the event of non-small cell lung cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-017181	Non-small cell lung cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant’s medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Right knee osteoarthritis	1976 - 2018
Allergy to arthropod sting	Wasp allergy	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Left knee osteoarthritis	2010 - 2017
Knee arthroplasty	Left knee replacement	Nov 2017 - Nov 2017
Anxiety	Anxiety	2018 - Ongoing
Knee arthroplasty	Right knee replacement	Dec 2018 - Dec 2018
Diarrhoea	Chronic diarrhea	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Valsartan	2000 - 22 Oct 2020 (Study Day 64)	Hypertension
Fluoxetine hydrochloride	2018 - Ongoing	Anxiety
Influenza vaccine	10 Oct 2020 (Study Day 52) - 10 Oct 2020 (Study Day 52)	Influenza Prophylaxis
Metronidazole	14 Oct 2020 (Study Day 56) - Ongoing	Broken Ribs
Ascorbic acid; chromium; selenium; vanadyl sulfate	22 Oct 2020 (Study Day 64) - 01 Feb 2021 (Study Day 166)	Hypertension
Nitazoxanide	11 Nov 2020 (Study Day 84) - Ongoing	Diarrhea
Ct of abdomen*	12 Nov 2020 (Study Day 85) - 12 Nov 2020 (Study Day 85)	Adverse Event
Colonoscopy*	11 Dec 2020 (Study Day 114) - 11 Dec 2020 (Study Day 114)	Adverse Event
Budesonide	16 Dec 2020 (Study Day 119) - Ongoing	Lymphocytic Colitis
Lung lobectomy*	14 Jan 2021 (Study Day 148) - 14 Jan 2021 (Study Day 148)	Adverse Event
Chlormezanone; ibuprofen; metamizole sodium	02 Feb 2021 (Study Day 167) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Colitis Microscopic	Grade 1/mild	Not related	16 Dec 2020 (Study Day 119) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2193 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ovarian Cyst/Ovarian Cysts (Right)	SAE	Grade 2/moderate	Not related	17 Sep 2020 (Study Day 29) – 07 Oct 2020 (Study Day 49)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2193, a 70-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Sep 2020 (Study Day 29), 28 days after the first dose and on the day of the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of ovarian cyst. The IP dose was not changed due to the ovarian cysts (right). The event of ovarian cysts (right) lasted for 21 days, after which it was considered to be recovered/resolved on 07 Oct 2020 (Study Day 49). The investigator assessed the event of ovarian cyst to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000438	Ovarian cyst

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	1980 - Ongoing
Headache	Intermittent headache	2000 - Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Osteopenia	Osteopenia	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1980 - Ongoing	Hypothyroidism
Alendronate sodium	2010 - Ongoing	Osteopenia
Paracetamol	2015 - Ongoing	Headache Pain
Docusate sodium	06 Oct 2020 (Study Day 48) - 10 Oct 2020 (Study Day 52)	Ovarian Cysts
Ibuprofen	06 Oct 2020 (Study Day 48) - 08 Oct 2020 (Study Day 50)	Ovarian Cysts
Oxycodone	06 Oct 2020 (Study Day 48) - 10 Oct 2020 (Study Day 52)	Ovarian Cysts
Hysterectomy*	07 Oct 2020 (Study Day 49) - 07 Oct 2020 (Study Day 49)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dermatitis Atopic	Grade 1/mild	Not related	06 Oct 2020 (Study Day 48) - 13 Oct 2020 (Study Day 55)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2208 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/Congestive Heart Failure	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	07 Sep 2020 (Study Day 19) – 14 Sep 2020 (Study Day 26)	Recovered/ resolved
Drug Abuse/Cocaine Abuse	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	10 Sep 2020 (Study Day 22) – 10 Sep 2020 (Study Day 22)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2208, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 07 Sep 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of cardiac failure congestive. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of congestive heart failure lasted for 8 days, after which it was considered to be recovered/resolved on 14 Sep 2020 (Study Day 26). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

On 10 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of drug abuse. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of cocaine abuse lasted for 1 days, after which it was considered to be recovered/resolved on 10 Sep 2020 (Study Day 22). The investigator assessed the event of drug abuse to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000292	Cardiac failure congestive

CIOMS Number	MedDRA Preferred Term
MOD-2020-000292	Drug abuse

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	1965 - 1965
Bipolar disorder	Bipolar disorder	1975 - Ongoing
Depression	Depression	1975 - Ongoing
Insomnia	Insomnia	1975 - Ongoing
Tonsillectomy	Tonsillectomy	1975 - 1975
Drug hypersensitivity	Codeine allergy	1980 - Ongoing
Drug hypersensitivity	Morphine sulfate allergy	1980 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Breast cancer	Breast cancer	2014 - 2014
Constipation	Chronic constiption	2014 - Ongoing
Hepatitis C	Hepatitis c	2014 - Ongoing
Mastectomy	Masectomy	2014 - 2014
Pain	Chronic pain generalized	2014 - Ongoing
Abdominal operation	Abdominal surgery	2015 - 2015
Small intestinal obstruction	Small bowel obstruction	2015 - Ongoing
Postmenopause	Post menopausal	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Anastrozole	2014 - Ongoing	Breast Cancer
Hydrocodone bitartrate; paracetamol	2014 - Ongoing	Chronic Pain
Macrogol	2014 - Ongoing	Chronic Constiption
Amlodipine	2015 - Jul 2020	Hypertension
Gabapentin	2018 - Ongoing	Chronic Generalized Pain
Paracetamol	21 Aug 2020 (Study Day 2) - 21 Aug 2020 (Study Day 2)	Pain At The Injection Site/ Underarm Swelling
Echocardiogram*	11 Sep 2020 (Study Day 23) - 11 Sep 2020 (Study Day 23)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Electrocardiogram*	11 Sep 2020 (Study Day 23) - 11 Sep 2020 (Study Day 23)	Adverse Event
Furosemide	14 Sep 2020 (Study Day 26) - Ongoing	Congestive Heart Failure
Potassium chloride	14 Sep 2020 (Study Day 26) - Ongoing	Congestive Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US302-2246 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Of Left Hip Osteoarthritis	SAE	Grade 4	Not related	14 Nov 2020 (Study Day 86) – 15 Nov 2020 (Study Day 87)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2246, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Nov 2020 (Study Day 86), 85 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening of left hip osteoarthritis lasted for 2 days, after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 87). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000830	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthritis	Left hip arthritis	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2010 - Ongoing	Hyperlipidemia
Levothyroxine	2015 - Ongoing	Hypothyroidism
Ibuprofen	2019 - Ongoing	Left Hip Osteoarthritis
Acetylsalicylic acid	14 Nov 2020 (Study Day 86) - 20 Nov 2020 (Study Day 92)	Cardiac Prophylaxis
Cilastatin sodium; imipenem	14 Nov 2020 (Study Day 86) - Ongoing	Worsening Of Left Hip Osteoarthritis
Docusate sodium	14 Nov 2020 (Study Day 86) - Ongoing	Worsening Of Left Osteoarthritis
Left hip relacement*	14 Nov 2020 (Study Day 86) - 14 Nov 2020 (Study Day 86)	Adverse Event
Oxycodone hydrochloride; paracetamol	14 Nov 2020 (Study Day 86) - Ongoing	Worsening Of Left Hip Arthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US302-2276 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Injury/Worsening Of Back Injury	SAE	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 43) – 03 Oct 2020 (Study Day 44)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2276, a 45-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 24 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 43), 42 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of back injury. Action taken with the IP was not applicable. The event of worsening of back injury lasted for 2 days, after which it was considered to be recovered/resolved on 03 Oct 2020 (Study Day 44). The investigator assessed the event of back injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000439	Back injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	1986 - Ongoing
Asthma	Asthma	1992 - Ongoing
Conjunctivitis allergic	Allergic conjunctivitis	1996 - Ongoing
Seasonal allergy	Seasonal allergies	1996 - Ongoing
Back injury	Back injury	2002 - Ongoing
Endometriosis	Endometriosis	2002 - 2015
Anxiety	Anxiety	2003 - Ongoing
Bipolar disorder	Bipolar disorder	2003 - Ongoing
Depression	Depression	2003 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2003 - Ongoing
Osteoarthritis	Osteoarthritis	2003 - Ongoing
Hysterectomy	Partial hysterectomy	2004 - 2004
Ovarian cyst	Ovarian cysts - bilateral benign	2004 - 2015
Type 2 diabetes mellitus	Type 2 diabetes	2004 - Ongoing
Hysterectomy	Complete hysterectomy	2015 - 2015
Postmenopause	Post menopausal	2015 - Ongoing
Epicondylitis	Golfers elbow	2019 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2019 - Ongoing
Vitamin B12 deficiency	Vitamin b-12 deficiency	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1988 - Ongoing	Asthma
Budesonide; formoterol fumarate	1992 - Ongoing	Asthma
Omeprazole	2003 - Ongoing	Gastroesophageal Reflux Disease
Empagliflozin	2005 - Ongoing	Diabetes
Glipizide	2005 - Ongoing	Diabetes
Insulin aspart	2005 - Ongoing	Diabetes
Metformin	2005 - Ongoing	Diabetes
Escitalopram oxalate	2015 - 20 Sep 2020 (Study Day 31)	Anxiety
Estradiol	2015 - 31 Aug 2020 (Study Day 11)	Hormone Replacement
Norethisterone	2015 - 31 Aug 2020 (Study Day 11)	Endometriosis
Topiramate	2015 - Ongoing	Bipolar
Cyanocobalamin	2018 - Ongoing	Vitamin B-12 Deficiency

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Varenicline	2018 - Ongoing	Smoking Cessation
Fexofenadine	2019 - Ongoing	Seasonal Allergies
Montelukast	2019 - Ongoing	Seasonal Allergies
Olopatadine hydrochloride	2019 - Ongoing	Allergic Conjunctivitis
Rosuvastatin	2019 - 31 Aug 2020 (Study Day 11)	Hyperlipidemia
Paracetamol	23 Aug 2020 (Study Day 3) - 23 Aug 2020 (Study Day 3)	Headache
Ibuprofen	25 Sep 2020 (Study Day 36) - 25 Sep 2020 (Study Day 36)	Headaches & Pain At Injection Site
Ibuprofen	30 Sep 2020 (Study Day 41) - 30 Sep 2020 (Study Day 41)	Headache
Back surgery*	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Adverse Event
Celecoxib	02 Oct 2020 (Study Day 43) - Ongoing	Worsening Of Back Injury
Methocarbamol	02 Oct 2020 (Study Day 43) - Ongoing	Worsening Of Back Injury
Oxycodone	02 Oct 2020 (Study Day 43) - Ongoing	Worsening Of Back Injury
Paracetamol	02 Oct 2020 (Study Day 43) - Ongoing	Worsening Of Back Injury
Influenza vaccine	03 Oct 2020 (Study Day 44) - 03 Oct 2020 (Study Day 44)	Flu Vaccine
Sulfamethoxazole; trimethoprim	20 Oct 2020 (Study Day 61) - Ongoing	Antibiotic/ Prevent Infection
Buspirone	02 Feb 2021 (Study Day 166) - Ongoing	Anxiety
Spironolactone	12 Mar 2021 (Study Day 204) - Ongoing	Post Menopausal

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US302-2291 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthritis/Worsening Of Right Knee Arthritis	SAE	Grade 4	Not related	09 Nov 2020 (Study Day 78) – 12 Nov 2020 (Study Day 81)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2291, a 45-year-old race not reported female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 09 Nov 2020 (Study Day 78), 77 days after the first dose and 42 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of arthritis. Action taken with the IP was not applicable. The event of worsening of right knee arthritis lasted for 4 days, after which it was considered to be recovered/resolved on 12 Nov 2020 (Study Day 81). The investigator assessed the event of arthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000874	Arthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	(b) (6) 1975 - Ongoing
Asthma	Asthma	1980 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Female sterilisation	Tubal ligation	2006 - 2006
Gastric bypass	Gastric bypass	2008 - 2008
Insomnia	Insomnia	2014 - Ongoing
Depression	Depression	2015 - Ongoing
Gastric ulcer	Stomach ulcer	2016 - 2016
Gastric ulcer surgery	Stomach ulcer surgery	2016 - 2016
Osteoarthritis	Right knee osteoarthritis	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine	2018 - Ongoing	Depression
Celecoxib	2019 - Ongoing	Right Knee Arthritis
Diclofenac	2019 - Ongoing	Right Knee Arthritis
Olmesartan	Jan 2020 - Ongoing	Hypertension
Apixaban	09 Nov 2020 (Study Day 78) – 12 Nov 2020 (Study Day 81)	Worsening Right Knee Arthritis
Oxycodone hydrochloride; paracetamol	09 Nov 2020 (Study Day 78) – 16 Nov 2020 (Study Day 85)	Worsening Right Knee Otsteoarthritis
Right knee replacement*	09 Nov 2020 (Study Day 78) – 09 Nov 2020 (Study Day 78)	Adverse Event
Zolpidem tartrate	28 Jan 2021 (Study Day 158) - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US303-2115 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Sepsis Of Unknown Origin	SAE	Grade 4	Not related	21 Dec 2020 (Study Day 138) – 24 Dec 2020 (Study Day 141)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2115, a 60-year-old race not reported female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Dec 2020 (Study Day 138), 137 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis of unknown origin lasted for 4 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 141). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001544	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1965 - Ongoing
Allergy to chemicals	Allergy to alcohol, rash	1983 - Ongoing
Abortion spontaneous	Recurring miscarriages	1984 - 1984
Hysterectomy	Hysterectomy	1984 - 1984
Postmenopause	Postmenopausal	1984 - Ongoing
Insomnia	Insomnia	2006 - Ongoing
Atrial fibrillation	Paroxysmal atrial fibrillation	2007 - Ongoing
Pulmonary embolism	Pulmonary embolism of left lung	2008 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2012 - Ongoing
Aortic aneurysm	Aortic aneurysm	2013 - 2013
Cerebrovascular accident	Cerebrovascular accident	2013 - 2013
Hypertension	Hypertension	2013 - Ongoing
Myocardial infarction	Myocardial infraction	2013 - Ongoing
Visual impairment	Vision changes	2013 - Ongoing
Peripheral sensory neuropathy	Sensory neuropathy of right arm, neck, and hand	2019 - Ongoing
Back pain	Back pain-lower lumbar	05 Aug 2019 (Study Day -367) - Ongoing
Fractured coccyx	Broken tailbone	05 Aug 2019 (Study Day -367) - 05 Aug 2019 (Study Day -367)
Lumbar vertebral fracture	Fractured vertebrae-lumbar	05 Aug 2019 (Study Day -367) - 05 Aug 2019 (Study Day -367)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2004 - Ongoing	Cardiac Prophylaxis
Omeprazole	2010 - Ongoing	Medical History: Acid Reflux
Alprazolam	2012 - Ongoing	Medical History: Anxiety
Pravastatin	2012 - Ongoing	Medical History: Hypercholesterolemia
Amlodipine	2013 - Ongoing	Medical History: Hypertension
Clopidogrel bisulfate	2013 - Ongoing	Medical History: Aortic Aneurism

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Isosorbide mononitrate	2013 - Ongoing	Medical History: Aortic Aneurysm
Losartan	2013 - Ongoing	Medical History: Hypertension
Sotalol hydrochloride	2013 - Ongoing	Aeortic Aneurism
Tramadol	05 Aug 2019 (Study Day -367) - Ongoing	Medical History: Lower Lumbar Pain
Evolocumab	Oct 2020 - Ongoing	Homozygous Familial Hypercholesterolemia
Benzonatate	09 Dec 2020 (Study Day 126) - 21 Dec 2020 (Study Day 138)	Bilateral Pneumonia
Dexamethasone	09 Dec 2020 (Study Day 126) - 18 Dec 2020 (Study Day 135)	Bilateral Pneumonia
Salbutamol	09 Dec 2020 (Study Day 126) - 24 Dec 2020 (Study Day 141)	Bilateral Pneumonia
Study-related covid-19 test*	09 Dec 2020 (Study Day 126) - 09 Dec 2020 (Study Day 126)	Adverse Event
Rapid covid-19 test*	10 Dec 2020 (Study Day 127) - 10 Dec 2020 (Study Day 127)	Adverse Event
Levofloxacin	14 Dec 2020 (Study Day 131) - 21 Dec 2020 (Study Day 138)	Bilateral Pneumonia
Covid-19 pcr test*	18 Dec 2020 (Study Day 135) - 18 Dec 2020 (Study Day 135)	Adverse Event
Aztreonam	21 Dec 2020 (Study Day 138) - 24 Dec 2020 (Study Day 141)	Sepsis
Enoxaparin sodium	21 Dec 2020 (Study Day 138) - 24 Dec 2020 (Study Day 141)	Sepsis
Sodium chloride	21 Dec 2020 (Study Day 138) - 24 Dec 2020 (Study Day 141)	Sepsis
Vancomycin	21 Dec 2020 (Study Day 138) - 24 Dec 2020 (Study Day 141)	Sepsis
Aspergillus galactomannan testing*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Blood cultures*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Complete blood count*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Complete metabolic panel*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Covid-19 antibody*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Covid-19 pcr*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Ct abdomen/pelvis*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Ct angiogram of chest*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Ct of soft tissue of neck*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
D-dimer*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fungitell testing*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Hiv testing*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Influenza testing*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Lactic acid*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Procalcitonin*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Respiratory viral panel*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event
Troponin*	22 Dec 2020 (Study Day 139) - 22 Dec 2020 (Study Day 139)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Type IIa Hyperlipidaemia	Grade 1/mild	Not related	15 Oct 2020 (Study Day 71) - 16 Mar 2021 (Study Day 223)
Pneumonia	Grade 2/moderate	Not related	05 Dec 2020 (Study Day 122) - 20 Dec 2020 (Study Day 137)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2242 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Endometrial Cancer/ Endometrial Cancer	SAE	Grade 3/severe	Not related	29 Dec 2020 (Study Day 133) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2242, a 72-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Dec 2020 (Study Day 133), 132 days after the first dose and 102 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of endometrial cancer. Action taken with the IP was not applicable. The event of endometrial cancer was considered to be ongoing. The investigator assessed the event of endometrial cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011618	Endometrial cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	1995 - Ongoing
Obesity	Severe obesity	2000 - Ongoing
Arthralgia	Right knee pain	2010 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Osteoarthritis	Osterarthritis right knee	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Famotidine	2010 - Ongoing	Gastroesophageal Reflux Disease
Hydrochlorothiazide	2010 - Ongoing	Hypertension
Lisinopril	2010 - Ongoing	Hypertension
Pantoprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Ibuprofen	2016 - 25 Jan 2021 (Study Day 160)	Knee Pain
Endometrial biopsy*	23 Sep 2020 (Study Day 36) - 23 Sep 2020 (Study Day 36)	Adverse Event
Influenza vaccine	02 Oct 2020 (Study Day 45) - 02 Oct 2020 (Study Day 45)	Flu Vaccine
Complete blood count*	22 Dec 2020 (Study Day 126) - 22 Dec 2020 (Study Day 126)	Adverse Event
Medroxyprogesterone	22 Dec 2020 (Study Day 126) - 01 Jan 2021 (Study Day 136)	Postmenopausal Vaginal Bleeding
Pelvic ultrasound*	22 Dec 2020 (Study Day 126) - 22 Dec 2020 (Study Day 126)	Adverse Event
Colposcopy*	23 Dec 2020 (Study Day 127) - 23 Dec 2020 (Study Day 127)	Adverse Event
Local excision of cervical polyp*	23 Dec 2020 (Study Day 127) - 23 Dec 2020 (Study Day 127)	Adverse Event
Ct of abdomen*	14 Jan 2021 (Study Day 149) - 14 Jan 2021 (Study Day 149)	Adverse Event
Bilateral salpingo-oophorectomy*	01 Feb 2021 (Study Day 167) - 01 Feb 2021 (Study Day 167)	Adverse Event
Colecalciferol	01 Feb 2021 (Study Day 167) - Ongoing	Endometrial Cancer
Excision of a left vulvar intradermal melanocytic nevus*	01 Feb 2021 (Study Day 167) - 01 Feb 2021 (Study Day 167)	Adverse Event
Foley catheter*	01 Feb 2021 (Study Day 167) - 01 Feb 2021 (Study Day 167)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hysterectomy*	01 Feb 2021 (Study Day 167) - 01 Feb 2021 (Study Day 167)	Adverse Event
Paracetamol	01 Feb 2021 (Study Day 167) - Ongoing	Knee Pain
Right pelvic sentinel lymph node biopsy*	01 Feb 2021 (Study Day 167) - 01 Feb 2021 (Study Day 167)	Adverse Event
Ropivacaine	01 Feb 2021 (Study Day 167) - 01 Feb 2021 (Study Day 167)	Hysterectomy
Sodium chloride	01 Feb 2021 (Study Day 167) - 01 Feb 2021 (Study Day 167)	Hysterectomy
Tramadol	01 Feb 2021 (Study Day 167) - 15 Feb 2021 (Study Day 181)	Hysterectomy
Docusate sodium	02 Feb 2021 (Study Day 168) - 15 Feb 2021 (Study Day 181)	Hysterectomy
Ct of chest*	15 Feb 2021 (Study Day 181) - 15 Feb 2021 (Study Day 181)	Adverse Event
Radiation to pelvic region*	22 Mar 2021 (Study Day 216) - 22 Mar 2021 (Study Day 216)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Postmenopausal Haemorrhage	Grade 2/moderate	Not related	23 Nov 2020 (Study Day 97) - 01 Feb 2021 (Study Day 167)
Cervical Polyp	Grade 1/mild	Not related	23 Dec 2020 (Study Day 127) - 23 Dec 2020 (Study Day 127)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2263 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE	Grade 4	Not related	04 Dec 2020 (Study Day 107) – 17 Dec 2020 (Study Day 120)	Recovered/resolved
Atrioventricular Block Second Degree/Second Degree Mobitz Ii Av Block, Intermittent	SAE	Grade 3/severe	Not related	07 Dec 2020 (Study Day 110) – 08 Jan 2021 (Study Day 142)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2263, a 65-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Dec 2020 (Study Day 107), 106 days after the first dose and 73 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 14 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 120). The investigator assessed the event of covid-19 to be not related to the IP.

On 07 Dec 2020 (Study Day 110), 109 days after the first dose and 76 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrioventricular block second degree. Action taken with the IP was not applicable. The event of second degree mobitz ii av block, intermittent lasted for 33 days, after which it was considered to be recovered/resolved on 08 Jan 2021 (Study Day 142). The investigator assessed the event of atrioventricular block second degree to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010823	COVID-19
MOD-2021-010823	Second Degree Mobitz II AV Block, Intermittent

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rheumatic fever	Rheumatic fever	1960 - 1960
Tonsillectomy	Tonsilectomy	1971 - 1971
Tonsillitis	Tonsilitis	1971 - 1971
Endometrial hyperplasia	Atypical endometrial hyperplasia	1991 - 1991
Hormone level abnormal	Hormone deficiency	1991 - Ongoing
Hysterectomy	Hysterectomy	1991 - 1991
Postmenopause	Postmenopausal	1991 - Ongoing
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Colonoscopy	Colonoscopy	2014 - 2014
Anxiety	Anxiety	2017 - Ongoing
Chronic obstructive pulmonary disease	Acute exacerbation of chronic obstructive airway disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	1991 - Ongoing	Medical History: Hormone Replacement
Levothyroxine	2005 - Ongoing	Medical History: Hypothyroidism
Omeprazole	2010 - Ongoing	Medical History: Acid Reflux
Clonazepam	2017 - Ongoing	Medical History: Anxiety
Montelukast	2018 - Ongoing	Acute Exacerbation Of Chronic Obstructive Airway Disease
Budesonide; formoterol fumarate	Oct 2019 - Ongoing	Acute Exacerbation Of Chronic Obstructive Airway Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	04 Dec 2020 (Study Day 107) - 04 Dec 2020 (Study Day 107)	Suspected COVID-19
Paracetamol	04 Dec 2020 (Study Day 107) - 17 Dec 2020 (Study Day 120)	Suspected COVID-19
Sars-cov-2 pcr*	04 Dec 2020 (Study Day 107) - 04 Dec 2020 (Study Day 107)	Adverse Event
Azithromycin	05 Dec 2020 (Study Day 108) - 07 Dec 2020 (Study Day 110)	Suspected COVID-19
Chest x-ray*	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	Adverse Event
Clonazepam	07 Dec 2020 (Study Day 110) - 17 Dec 2020 (Study Day 120)	Anxiety
Complete blood count*	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	Adverse Event
Comprehensive metabolic panel*	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	Adverse Event
Creatine kinase*	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	Adverse Event
D-dimer*	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	Adverse Event
Enoxaparin	07 Dec 2020 (Study Day 110) - 11 Dec 2020 (Study Day 114)	COVID-19
Furosemide	07 Dec 2020 (Study Day 110) - 11 Dec 2020 (Study Day 114)	Second Degree Mobitz Ii Block
Plasma	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	COVID-19
Remdesivir	07 Dec 2020 (Study Day 110) - 11 Dec 2020 (Study Day 114)	COVID-19
Sars-cov-2 antigen test*	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	Adverse Event
Troponin*	07 Dec 2020 (Study Day 110) - 07 Dec 2020 (Study Day 110)	Adverse Event
Guaifenesin	08 Dec 2020 (Study Day 111) - 17 Dec 2020 (Study Day 120)	COVID-19
Procalcitonin*	08 Dec 2020 (Study Day 111) - 08 Dec 2020 (Study Day 111)	Adverse Event
Transthoracic echocardiogram*	08 Dec 2020 (Study Day 111) - 08 Dec 2020 (Study Day 111)	Adverse Event
Magnesium sulfate	09 Dec 2020 (Study Day 112) - 09 Dec 2020 (Study Day 112)	Hypomagnesemia
Potassium chloride	10 Dec 2020 (Study Day 113) - Ongoing	Prophylaxis For Hypokalemia Associated With Furosemide Use
Permanent pacemaker placement*	08 Jan 2021 (Study Day 142) - 08 Jan 2021 (Study Day 142)	Adverse Event
Apixaban	08 Feb 2021 (Study Day 173) - Ongoing	Blood Clot Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 1/mild	Not related	07 Dec 2020 (Study Day 110) - 17 Dec 2020 (Study Day 120)
Pneumonia Viral	Grade 2/moderate	Not related	07 Dec 2020 (Study Day 110) - 17 Dec 2020 (Study Day 120)
Mitral Valve Incompetence	Grade 2/moderate	Not related	08 Dec 2020 (Study Day 111) - 08 Jan 2021 (Study Day 142)
Hypomagnesaemia	Grade 1/mild	Not related	09 Dec 2020 (Study Day 112) - 09 Dec 2020 (Study Day 112)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2277 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Duodenal Ulcer Haemorrhage/Acute Duodenal Ulcer With Hemorrhage	SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 4	Not related	12 Sep 2020 (Study Day 24) – 17 Sep 2020 (Study Day 29)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2277, a 90-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of duodenal ulcer haemorrhage. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute duodenal ulcer with hemorrhage lasted for 6 days, after which it was considered to be recovered/resolved on 17 Sep 2020 (Study Day 29). The investigator assessed the event of duodenal ulcer haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000293	Duodenal ulcer haemorrhage

Study Completion/Discontinuation

On 01 Oct 2020 (Study Day 43), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Capoten allergy	1982 - Ongoing
Anaemia	Anemia	1989 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2005 - Ongoing
Prostatomegaly	Enlarged prostate	2005 - Ongoing
Renal failure	Kidney failure	2005 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2005 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Thrombosis	Blood clot-right lower leg	2013 - 2013
Gout	Gout bilateral feet	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b12 nos	1998 - Ongoing	Nutritional Supplement
Ipratropium bromide	2000 - Ongoing	Seasonal Allergies
Finasteride	2005 - Ongoing	Enlarged Prostate
Glimepiride	2005 - Ongoing	Diabetes Mellitus Type 2
Amlodipine	2010 - Ongoing	Hypertension
Carvedilol	2010 - Ongoing	Hypertension
Losartan	2010 - Ongoing	Hypertension
Pravastatin	2010 - Ongoing	Hypercholesterolemia
Acetylsalicylic acid	2013 - Ongoing	Blood Clots
Allopurinol	2019 - Ongoing	Gout Bilateral Feet
Pantoprazole	12 Sep 2020 (Study Day 24) - 17 Sep 2020 (Study Day 29)	Acute Duodenal Ulcer With Hemorrhage
Pantoprazole	13 Sep 2020 (Study Day 25) - 16 Sep 2020 (Study Day 28)	Acute Duodenal Ulcer With Hemorrhage
Red blood cells, concentrated	13 Sep 2020 (Study Day 25) - 15 Sep 2020 (Study Day 27)	Acute Duodenal Ulcer With Hemorrhage
Colonoscopy*	14 Sep 2020 (Study Day 26) - 14 Sep 2020 (Study Day 26)	Adverse Event
Esophagastroduodenalscopy*	14 Sep 2020 (Study Day 26) - 14 Sep 2020 (Study Day 26)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Transfusion of packed red blood cells*	14 Sep 2020 (Study Day 26) - 14 Sep 2020 (Study Day 26)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US303-2337 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Seizure/Seizure	SAE	Grade 2/moderate	Not related	14 Mar 2021 (Study Day 202) – 14 Mar 2021 (Study Day 202)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2337, a 20-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Mar 2021 (Study Day 202), 201 days after the first dose and 173 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of seizure. Action taken with the IP was not applicable. The event of seizure lasted for 1 day, after which it was considered to be recovered/resolved on 14 Mar 2021 (Study Day 202). The investigator assessed the event of seizure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-050501	Seizure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seizure	History of seizures	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	22 Sep 2020 (Study Day 29) - 23 Sep 2020 (Study Day 30)	Slight Injection Site Pain
Basal metabolic panel*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Blood alcohol level*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Chest x-ray*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Complete blood count with differential*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Creatine kinase*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Ct cervical spine wo contrast*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Ct head without contrast*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Drugs of abuse screen, urine*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Electrocardiogram 12-lead*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Finger stick glucose*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Levetiracetam	14 Mar 2021 (Study Day 202) - Ongoing	Seizure
Levetiracetam	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Seizure
Mri brain with wo contrast*	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Adverse Event
Sodium chloride	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)	Seizure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not related	27 Dec 2020 (Study Day 125) - 12 Jan 2021 (Study Day 141)
Loss Of Consciousness	Grade 1/mild	Not applicable	05 Mar 2021 (Study Day 193) - 05 Mar 2021 (Study Day 193)
Alcohol Poisoning	Grade 1/mild	Not related	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)
Central Nervous System Lesion	Grade 1/mild	Not related	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)
Fall	Grade 2/moderate	Not related	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)
Sinus Tachycardia	Grade 1/mild	Not related	14 Mar 2021 (Study Day 202) - 14 Mar 2021 (Study Day 202)
Traumatic Haemorrhage	Grade 1/mild	Not related	14 Mar 2021 (Study Day 202) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2032 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea/Exacerbation Of Chronic Dyspnea	AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 1/ mild	Not related	27 Aug 2020 (Study Day 30) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2032, a 81-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 29 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Aug 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of dyspnoea. On 25 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of exacerbation of chronic dyspnea was considered to be ongoing. The investigator assessed the event of dyspnoea to be not related to the IP.

Additional Information From The Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 27 Aug 2020 (Study Day 30), the participant discontinued from the study due to adverse event.

FDA-CBER-2022-1614-3378274

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2005 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Essential tremor	Bilateral hands essential tremor	2015 - Ongoing
Dyspnoea	Chronic dyspnea	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Finasteride	2005 - Ongoing	Hypertension
Losartan	2005 - Ongoing	Hypertension
Metoprolol	2005 - Ongoing	Hypertension
Omeprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Primidone	2015 - Ongoing	Bilateral Hand Essential Tremor

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspnoea	Grade 1/mild	Not related	27 Aug 2020 (Study Day 30) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2190 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/Multiple Pulmonary Emboli	SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 28) – 10 Sep 2020 (Study Day 29)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2190, a 27-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Sep 2020 (Study Day 28), 27 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of pulmonary embolism. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of multiple pulmonary emboli lasted for 2 days, after which it was considered to be recovered/resolved on 10 Sep 2020 (Study Day 29). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000279	Pulmonary embolism

Study Completion/Discontinuation

On 17 Sep 2020 (Study Day 36), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2018 - Ongoing
Female sterilisation	Bilateral tubal ligation	Jun 2020 - Jun 2020
Uterine haemorrhage	Uterine/vaginal bleeding	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	2019 - Ongoing	Anxiety
Hydroxyzine hydrochloride	2019 - Ongoing	Anxiety
Levonorgestrel	Jun 2020 - 09 Sep 2020 (Study Day 28)	Contraception
Apixaban	10 Sep 2020 (Study Day 29) - Ongoing	Multiple Pulmonary Emboli
Progesterone	10 Sep 2020 (Study Day 29) - Ongoing	Multiple Pulmonary Emboli

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US304-2192 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hepatic Enzyme Increased/Elevated Liver Enzymes	AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 1/ mild	Not related	31 Aug 2020 (Study Day 18) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2192, a 40-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Aug 2020 (Study Day 18), 17 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of hepatic enzyme increased. On 10 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of elevated liver enzymes was considered to be ongoing. The investigator assessed the event of hepatic enzyme increased to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 14 Sep 2020 (Study Day 32), the participant discontinued from the study due to adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	1985 - Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Hypothyroidism	Hypothyroidism	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	1985 - Ongoing	Seasonal Allergies
Salbutamol	1985 - Ongoing	Asthma
Levothyroxine	2018 - Ongoing	Hypothyroidism
Ibuprofen	15 Aug 2020 (Study Day 2) - 21 Aug 2020 (Study Day 8)	Solicited Symptoms-Body And Joint Aches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hepatic Enzyme Increased	Grade 1/mild	Not related	31 Aug 2020 (Study Day 18) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2203 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumothorax/Right Collapsed Lung	SAE	Grade 2/moderate	Not related	30 Nov 2020 (Study Day 109) – 14 Dec 2020 (Study Day 123)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2203, a 59-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Nov 2020 (Study Day 109), 108 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pneumothorax. Action taken with the IP was not applicable. The event of right collapsed lung lasted for 15 days, after which it was considered to be recovered/resolved on 14 Dec 2020 (Study Day 123). The investigator assessed the event of pneumothorax to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000960	Pneumothorax

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015 - Ongoing
Cystic lung disease	Right lung bullas	2016 - 2016
Insomnia	Insomnia	2016 - Ongoing
Cystic lung disease	Left lung bullas	2018 - 2018
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Neuropathy peripheral	Left chest neuropathy	2018 - Ongoing
Pulmonary resection	Left partial lobectomy	2018 - 2018
Seasonal allergy	Seasonal allergies	2020 - Ongoing
Depression	Depression	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide; formoterol fumarate	2015 - Ongoing	Chronic Obstructive Pulmonary Disease
Tiotropium bromide	2015 - Ongoing	Chronic Obstructive Pulmonary Disease
Quetiapine fumarate	2016 - Ongoing	Insomnia
Atorvastatin	2018 - Ongoing	Hypercholesterolemia
Gabapentin	2018 - Ongoing	Left Side Neuropathy
Nabumetone	2018 - Ongoing	Neuropathy
Cetirizine hydrochloride	Apr 2020 - Ongoing	Seasonal Allergies
Vortioxetine hydrobromide	May 2020 - Ongoing	Depression
Pleurodesis*	09 Dec 2020 (Study Day 118) - 09 Dec 2020 (Study Day 118)	Adverse Event
Ibuprofen	14 Dec 2020 (Study Day 123) - Ongoing	Post-Procedural Pain-Back

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US304-2210 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arachnoid Cyst/Growing/Worsening Of Arachnoid Cyst On Lumbar Spine	SAE	Grade 3/ severe	Not related	01 Nov 2020 (Study Day 77) – 03 Nov 2020 (Study Day 79)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2210, a 62-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 77), 76 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of arachnoid cyst. Action taken with the IP was not applicable. The event of growing/worsening of arachnoid cyst on lumbar spine lasted for 3 days, after which it was considered to be recovered/resolved on 03 Nov 2020 (Study Day 79). The investigator assessed the event of arachnoid cyst to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000931	Arachnoid cyst

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2010 - Ongoing
Arachnoid cyst	Archnoid cyst on lumbar spine	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atenolol	2010 - Ongoing	Hypertension
Levothyroxine	2015 - Ongoing	Hypothyroidism
Atorvastatin	2017 - Ongoing	Hyperlipidemia
Lisinopril	2017 - Ongoing	Hypertension
Paracetamol	17 Sep 2020 (Study Day 32) - 20 Sep 2020 (Study Day 35)	Solicited Symptom-Headache
Duloxetine hydrochloride	03 Nov 2020 (Study Day 79) - Ongoing	Bilateral Lower Leg Neuralgia
Gabapentin	03 Nov 2020 (Study Day 79) - Ongoing	Bilateral Lower Leg Neuralgia
Surgical excision of arachnoid cyst over lumber spine*	03 Nov 2020 (Study Day 79) - 03 Nov 2020 (Study Day 79)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Neuralgia	Grade 1/mild	Not related	03 Nov 2020 (Study Day 79) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2213 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	SAE	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 152) – 15 Jan 2021 (Study Day 152)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2213, a 52-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Jan 2021 (Study Day 152), 151 days after the first dose and 123 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 1 days, after which it was considered to be recovered/resolved on 15 Jan 2021 (Study Day 152). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005767	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	2010 - Ongoing
Erectile dysfunction	Erectile dysfunction	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Anxiety	Anxiety	2017 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactive disorder	2018 - Ongoing
Nephrolithiasis	Left nephrolithiasis	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Zolpidem tartrate	2010 - Ongoing	Insomnia
Amlodipine	2016 - Ongoing	Hypertension
Vardenafil hydrochloride	2016 - Ongoing	Erectile Dysfunction
Nebivolol hydrochloride	2017 - Ongoing	Hypertension
Citalopram	Jan 2017 - Ongoing	Anxiety
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	Dec 2018 - Ongoing	Attention Deficit Hyperactive Disorder
Tamsulosin	Apr 2020 - Ongoing	Nephrolithiasis
Ibuprofen	19 Sep 2020 (Study Day 34) - 19 Sep 2020 (Study Day 34)	Solicited Symptom-Headache, Generalized Muscle And Generalized Joint Aches
Cardiac stent placement x4*	19 Jan 2021 (Study Day 156) - 19 Jan 2021 (Study Day 156)	Adverse Event
Acetylsalicylic acid	20 Jan 2021 (Study Day 157) - Ongoing	Cardiac Prophylaxis
Atorvastatin	20 Jan 2021 (Study Day 157) - Ongoing	Cardiac Prophylaxis
Clopidogrel bisulfate	20 Jan 2021 (Study Day 157) - Ongoing	Myocardial Infarction
Cyclobenzaprine	20 Jan 2021 (Study Day 157) - Ongoing	Herniated L4 Disc
Lisinopril	20 Jan 2021 (Study Day 157) - Ongoing	Myocardial Infarction
Pregabalin	20 Jan 2021 (Study Day 157) - Ongoing	Herniated L4 Disc
Cardiac stent placement x2*	05 Feb 2021 (Study Day 173) - 05 Feb 2021 (Study Day 173)	Adverse Event
Amoxicillin	07 Feb 2021 (Study Day 175) - Ongoing	Prophylaxis Post Cardiac Stent Placement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	18 Nov 2020 (Study Day 94) - 21 Dec 2020 (Study Day 127)
Intervertebral Disc Protrusion	Grade 1/mild	Not related	11 Jan 2021 (Study Day 148) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2264 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intervertebral Disc Protrusion/3 Ruptured Discs In Lumbar Spine	SAE	Grade 1/mild	Not related	26 Oct 2020 (Study Day 68) – 07 Dec 2020 (Study Day 110)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2264, a 68-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Oct 2020 (Study Day 68), 67 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of intervertebral disc protrusion. Action taken with the IP was not applicable. The event of 3 ruptured discs in lumbar spine lasted for 43 days, after which it was considered to be recovered/resolved on 07 Dec 2020 (Study Day 110). The investigator assessed the event of intervertebral disc protrusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000568	Invertebral disc protrusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hepatitis A	Hepatitis a	1991 - 1991
Type 2 diabetes mellitus	Diabetes type 2	1993 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Peptic ulcer	Peptic ulcer	2010 - Ongoing
Peripheral sensory neuropathy	Bilateral foot neuropathy-sensory	2010 - Ongoing
Osteoarthritis	Osteoarthritis	2015 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Nov 2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	1993 - Ongoing	Diabetes Type 2
Hydrochlorothiazide	1995 - Ongoing	Hypertension
Lisinopril	1995 - Ongoing	Hypertension
Glimepiride	2000 - Ongoing	Diabetes Type 2
Atorvastatin	2005 - Ongoing	Hyperlipidemia
Gemfibrozil	2005 - Ongoing	Hyperlipidemia
Gabapentin	2010 - Ongoing	Bilateral Foot Neuropathy-Sensory
Omeprazole	2010 - Ongoing	Acid Reflux
Sucralfate	2010 - Ongoing	Peptic Ulcer
Hydrocodone; paracetamol	2015 - Ongoing	Osteoarthritis
Tamsulosin	2015 - Ongoing	Benign Prostatic Hyperplasia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US304-2295 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Vertigo/Vertigo	AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 1/ mild	Not related	21 Sep 2020 (Study Day 32) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2295, a 61-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 32), 31 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of vertigo. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of vertigo was considered to be ongoing. The investigator assessed the event of vertigo to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 21 Sep 2020 (Study Day 32), the participant discontinued from the study due to adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menorrhagia	Menorrhagia	1990 - 1999
Hysterectomy	Complete hysterectomy	1999 - 1999

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	2010 - Ongoing	Hypothyroidism
Atorvastatin	2019 - Ongoing	Hypercholesterolemia
Guaifenesin	21 Sep 2020 (Study Day 32) - Ongoing	Vertigo
Loratadine	21 Sep 2020 (Study Day 32) - Ongoing	Vertigo

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cystitis	Grade 1/mild	Not related	24 Aug 2020 (Study Day 4) - 07 Sep 2020 (Study Day 18)
Headache	Grade 1/mild	Related	24 Aug 2020 (Study Day 4) - 29 Aug 2020 (Study Day 9)
Vertigo	Grade 1/mild	Not related	21 Sep 2020 (Study Day 32) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US305-2028 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	30 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	25 Aug 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Chest Pain Nos	SAE	Grade 3/severe	Not related	05 Aug 2020 (Study Day 7) – 06 Aug 2020 (Study Day 8)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2028, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 25 Aug 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Aug 2020 (Study Day 7), 6 days after the first dose and 20 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of chest pain. The IP dose was not changed due to the chest pain nos. The event of chest pain nos lasted for 2 days, after which it was considered to be recovered/resolved on 06 Aug 2020 (Study Day 8). The investigator assessed the event of chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000195	Musculoskeletal chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	Not reported - Ongoing
Cataract	Cataracts	Not reported - Ongoing
Depression	Anxiety/depression	Not reported - Ongoing
Diabetes mellitus	Diabetes	Not reported - Ongoing
Drug hypersensitivity	Allergy to anti reflux medications	Not reported - Ongoing
Drug hypersensitivity	Allergy to erythomyacin	Not reported - Ongoing
Dyspepsia	Heartburn	Not reported
Fistula	Sinus fistula	Not reported - Ongoing
Herpes virus infection	Herpes	Not reported - Ongoing
Hiatus hernia	Hiatal hernia	Not reported
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Incontinence	Mild incontenence	Not reported - Ongoing
Large intestine benign neoplasm	Benign colon mass	Not reported - Ongoing
Muscle spasms	Muscle spasms in back	Not reported - Ongoing
Post-traumatic stress disorder	Ptsd	Not reported - Ongoing
Postmenopause	Post menopausal	Not reported - Ongoing
Uterine dilation and curettage	Dilatation and curettage	1984 - Not reported
Caesarean section	C-section	1989 - 1989
Hysteropexy	Uterine suspension surgery	1991 - 1991
Laparoscopy	Abdominal laparoscopy	1991 - 1991
Caesarean section	C-section	1992 - 1992
Sinus operation	Nose & sinus surgery	1992 - 1993
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Transient ischaemic attack	Transient ischemic attack	2013 - 2013
Transient ischaemic attack	Transient ischemic attack	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glimepiride	Not reported - Ongoing	Diabetes
Lysine	Not reported - Ongoing	Herpes
Methocarbamol	Not reported - Ongoing	Muscle Spasms
Glipizide	2008 - Ongoing	Diabetes Militus
Pioglitazone	2008 - Ongoing	Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pioglitazone	2008 - Ongoing	Diabetes Millitus
Levothyroxine	2013 - Ongoing	Hypothroidism
Fluticasone propionate	05 Aug 2020 (Study Day 7) - Ongoing	Seasonal Allergies
Glyceryl trinitrate	05 Aug 2020 (Study Day 7) - 05 Aug 2020 (Study Day 7)	Chest Pain Nos
Cholecystectomy*	10 Mar 2021 (Study Day 224) - 10 Mar 2021 (Study Day 224)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US305-2044 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	26 Aug 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Obstructive Pulmonary Disease/Copd Exacerbation	SAE	Grade 3/severe	Not related	06 Dec 2020 (Study Day 129) – 10 Dec 2020 (Study Day 133)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2044, a 64-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Dec 2020 (Study Day 129), 128 days after the first dose and 102 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. The IP dose was not changed due to the copd exacerbation. The event of copd exacerbation lasted for 5 days, after which it was considered to be recovered/resolved on 10 Dec 2020 (Study Day 133). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074408	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic sinusitis	Chronic sinusitis	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Inguinal hernia	Inguinal hernia	Not reported
Vertigo	Vertigo	Not reported - Ongoing
Chronic obstructive pulmonary disease	Copd due to asbestos exposure	1995 - Ongoing
Exposure to chemical pollution	Asbestos exposure	1995 - Ongoing
Malignant melanoma	Melanoma - middle toe on right foot	1995 - 1995
Skin neoplasm excision	Melanoma removal surgery - middle toe right foot	1995 - 1995
Rotator cuff repair	Rotator cuff surgery - left shoulder	2002 - 2002
Type 1 diabetes mellitus	Diabetes with insulin pump	2002 - Ongoing
Malignant melanoma	Melanoma - left chest	2005 - 2005
Rotator cuff syndrome	Rotator cuff injury - right shoulder	2005 - 2005
Skin neoplasm excision	Melanoma removal surgery - left chest	2005 - 2005
Hypertension	Hypertension	2007 - Ongoing
Coronary artery stenosis	Cardiac blood vessel stricture	2009 - 2015
Coronary artery bypass	Cabg surgery	05 Apr 2009 (Study Day -4135) – 05 Apr 2009 (Study Day -4135)
Dupuytren's contracture	B/l dupuytren's disease - both hands	2013 - Ongoing
Coronary arterial stent insertion	Stent placement - heart	2014 - Ongoing
Coronary arterial stent insertion	Stent placement - heart	2015 - Ongoing
Dupuytren's contracture operation	Duputryen's disease surgery - both hands	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	History Of Cabg
Amlodipine	Not reported - Ongoing	History Of Cabg
Atorvastatin	Not reported - Ongoing	History Of Cabg
Carvedilol	Not reported - Ongoing	History Of Cabg
Clopidogrel bisulfate	Not reported - Ongoing	History Of Cabg
Ezetimibe	Not reported - Ongoing	History Of Cabg
Fish oil	Not reported - Ongoing	Maintenence
Fluticasone propionate	Not reported - Ongoing	Sinusitis
Insulin aspart	Not reported - Ongoing	Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Isosorbide dinitrate	Not reported - Ongoing	History Of Cabg
Losartan	Not reported - Ongoing	Hypertension
Meclozine	Not reported - Ongoing	Vertigo
Montelukast	Not reported - Ongoing	Chronic Sinusitis
Ranolazine	Not reported - Ongoing	History Of Cabg
Salbutamol	Not reported - Ongoing	Copd

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US305-2220 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Thyroid Cancer/Thyroid Cancer	SAE	Grade 3/severe	Not related	22 Oct 2020 (Study Day 70) – 14 Apr 2021 (Study Day 244)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2220, a 68-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Oct 2020 (Study Day 70), 69 days after the first dose and 35 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of thyroid cancer. Action taken with the IP was not applicable. The event of thyroid cancer lasted for 175 days, after which it was considered to be recovered/resolved on 14 Apr 2021 (Study Day 244). The investigator assessed the event of thyroid cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026526	Thyroid cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Acid reflux	1990 - Ongoing
Laryngeal cancer	Vocal cord cancer	1990 - 1990
Sleep apnoea syndrome	Sleep apnea	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alprazolam	Not reported - Ongoing	Unknown
Clonazepam	Not reported - Ongoing	Unknown
Omeprazole	Not reported - Ongoing	Unknown
Temazepam	Not reported - Ongoing	Unknown
Venlafaxine hydrochloride	Not reported - Ongoing	Unknown
Brow lift*	01 Sep 2020 (Study Day 19) - 01 Sep 2020 (Study Day 19)	Other, Cosmetic
Influenza vaccine	08 Sep 2020 (Study Day 26) - 08 Sep 2020 (Study Day 26)	Seasonal Vaccine
Amoxicillin; clavulanic acid	03 Oct 2020 (Study Day 51) - 13 Oct 2020 (Study Day 61)	Left-Sided Lymphadenitis Of The Salivary Gland
Biopsy of nodule in thyroid*	22 Oct 2020 (Study Day 70) - 22 Oct 2020 (Study Day 70)	Diagnostic
Ultrasound*	22 Oct 2020 (Study Day 70) - 22 Oct 2020 (Study Day 70)	Adverse Event
Levothyroxine sodium	Jan 2021 - Ongoing	Thyroid Cancer
Thyroidectomy*	04 Jan 2021 (Study Day 144) - 04 Jan 2021 (Study Day 144)	Adverse Event
Radiotherapy*	12 Feb 2021 (Study Day 183) - 12 Feb 2021 (Study Day 183)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphadenitis	Grade 1/mild	Not related	01 Oct 2020 (Study Day 49) - 13 Oct 2020 (Study Day 61)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US305-2295 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Syncope/Syncope	SAE	Grade 3/severe	Not related	24 Sep 2020 (Study Day 32) – 25 Sep 2020 (Study Day 33)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2295, a 38-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Sep 2020 (Study Day 32), 31 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 2 days, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 33). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000388	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Wisdom teeth removal	Wisdom teeth removal	Not reported
Mitral valve prolapse	Mitral valve prolapse	1994 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Cervical conisation	Conization of the cervix	2003 - 2003
Anxiety	Anxiety	2010 - Ongoing
Female sterilisation	Bilateral tubal ligation	2018 - 2018
Transfusion	Blood transfusion	2018 - 2018
Blood cholesterol increased	High cholesterol	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2000 - Ongoing	Seasonal Allergies
Fexofenadine hydrochloride	2000 - Ongoing	Seasonal Allergies
Fluticasone propionate	2000 - Ongoing	Seasonal Allergies
Sertraline	2010 - Ongoing	Anxiety
Acetylsalicylic acid	2020 - Ongoing	Health Maintenance
Atorvastatin	2020 - Ongoing	High Cholesterol
Ct scan*	24 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 32)	Adverse Event
Eeg*	24 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 32)	Adverse Event
Mri*	24 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 32)	Adverse Event
Transthoracic echo*	24 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 32)	Adverse Event
Ultrasound carotid doppler bilateral*	24 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 32)	Adverse Event
2d echocardiogram*	25 Sep 2020 (Study Day 33) - 25 Sep 2020 (Study Day 33)	Adverse Event
Enoxaparin	25 Sep 2020 (Study Day 33) - 01 Oct 2020 (Study Day 39)	Deep Vein Thrombosis Prevention
Sennoside a+b	25 Sep 2020 (Study Day 33) - 01 Oct 2020 (Study Day 39)	Constipation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Constipation	Grade 1/mild	Not related	25 Sep 2020 (Study Day 33) - 01 Oct 2020 (Study Day 39)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378301

Participant Number:	US305-2315 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE	Grade 3/severe	Not related	27 Nov 2020 (Study Day 92) – 18 Dec 2020 (Study Day 113)	Recovered/resolved
Acute Respiratory Failure/Acute Respiratory Failure With Hypoxia	SAE	Grade 3/severe	Not applicable	09 Dec 2020 (Study Day 104) – 18 Dec 2020 (Study Day 113)	Recovered/resolved
COVID-19 Pneumonia/Bilateral Pneumonia Due To COVID-19	SAE	Grade 3/severe	Not applicable	09 Dec 2020 (Study Day 104) – 18 Dec 2020 (Study Day 113)	Recovered/resolved
Thrombocytosis/Thrombocytosis	SAE	Grade 3/severe	Not applicable	09 Dec 2020 (Study Day 104) – 18 Dec 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2315, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Nov 2020 (Study Day 92), 91 days after the first dose and 63 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 22 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 113). The investigator assessed the event of covid-19 to be not related to the IP.

On 09 Dec 2020 (Study Day 104), 103 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute respiratory failure with hypoxia lasted for 10 days, after which it was considered to be recovered/resolved on 18 Dec 2020

(Study Day 113). The investigator assessed the event of acute respiratory failure to be not applicable to the IP.

On 09 Dec 2020 (Study Day 104), 103 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of covid-19 pneumonia. Action taken with the IP was not applicable. The event of bilateral pneumonia due to COVID-19 lasted for 10 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 113). The investigator assessed the event of covid-19 pneumonia to be not applicable to the IP.

On 09 Dec 2020 (Study Day 104), 103 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of thrombocytosis. Action taken with the IP was not applicable. The event of thrombocytosis lasted for 10 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 113). The investigator assessed the event of thrombocytosis to be not applicable to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001232	COVID-19
MOD-2020-001232	Acute respiratory failure
MOD-2020-001232	COVID-19 pneumonia
MOD-2020-001232	Thrombocytosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial septal defect	Congenital atrial septal defect	1980 - Ongoing
Intervertebral disc protrusion	Herniated disc in neck	1995 - 1995
Spinal fusion surgery	Disc fusion in neck	1995 - 1995
Rotator cuff repair	Shoulder surgery (right)- rotator cuff	2006 - 2006
Back pain	Chronic back pain	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Curcuma longa	Aug 2020 - Ongoing	Chronic Back Pain
Zinc	08 Dec 2020 (Study Day 103) - Ongoing	Sars-Cov-2
Dexamethasone	09 Dec 2020 (Study Day 104) - 18 Dec 2020 (Study Day 113)	Thrombocytosis
Remdesivir	09 Dec 2020 (Study Day 104) - 18 Dec 2020 (Study Day 113)	COVID-19
Oxygen	18 Dec 2020 (Study Day 113) - Ongoing	Sars-Cov-2

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US305-2380 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intervertebral Disc Protrusion/Herneated Disks	SAE	Grade 3/severe	Not related	15 Sep 2020 (Study Day 8) – 18 Feb 2021 (Study Day 164)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US305-2380, a 51-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Sep 2020 (Study Day 8), 7 days after the first dose and 23 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of intervertebral disc protrusion. The IP dose was not changed due to the herneated disks. The event of herneated disks lasted for 157 days, after which it was considered to be recovered/resolved on 18 Feb 2021 (Study Day 164). The investigator assessed the event of intervertebral disc protrusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-055156	Intervertebral disc protrusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Bilateral knee pain	Not reported - Ongoing
Back pain	Back pain	Not reported - Ongoing
Musculoskeletal pain	Shoulder pain	Not reported - Ongoing
Neck pain	Neck pain	Not reported - Ongoing
Sleep apnoea syndrome	Cpap (sleep apnea)	Not reported - Ongoing
Knee operation	Left knee surgery	1990 - 1990
Shoulder operation	Right shoulder surgery	2006 - 2006
Bipolar disorder	Bipolar disorder	2016 - Ongoing
Hepatitis C	Hepatitis c	2016 - 2016
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Ischaemic stroke	Stroke (ischemic)	2016 - 2016
Sleep apnoea syndrome	Sleep apnea	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ledipasvir; sofosbuvir	Not reported - 2016	Hepatitis C
Acetylsalicylic acid	2016 - Ongoing	Heart Health
Atorvastatin	2016 - Ongoing	Hld
Hydrochlorothiazide; telmisartan	2016 - Ongoing	Htn
Magnesium	2016 - Ongoing	Vitamin
Oxycodone hydrochloride; paracetamol	2016 - Ongoing	Bilateral Knee Pain/Neck Back, Shoulder Pain
Valproate semisodium	2016 - Ongoing	Bipolar Disorder
Discectomy*	18 Feb 2021 (Study Day 164) - 18 Feb 2021 (Study Day 164)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US306-2018 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Tooth Abscess/Worsening Of Dental Abscess	SAE	Grade 4	Not related	12 Dec 2020 (Study Day 135) – 20 Dec 2020 (Study Day 143)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2018, a 31-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Dec 2020 (Study Day 135), 134 days after the first dose and 106 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of tooth abscess. Action taken with the IP was not applicable. The event of worsening of dental abscess lasted for 9 days, after which it was considered to be recovered/resolved on 20 Dec 2020 (Study Day 143). The investigator assessed the event of tooth abscess to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001142	Tooth abscess

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1991 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Obesity	Obesity	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Rizatriptan	2013 - Ongoing	Migraines/ Headache
Lamotrigine	2016 - Ongoing	Migraines
Ethinylestradiol; norgestimate	2019 - Ongoing	Birth Control
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	29 Sep 2020 (Study Day 61) - 05 Oct 2020 (Study Day 67)	Upper Respiratory Infectiuon
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	29 Sep 2020 (Study Day 61) - 05 Oct 2020 (Study Day 67)	Upper Respiratory Infection
Acetylsalicylic acid; caffeine; paracetamol	24 Nov 2020 (Study Day 117) - 29 Nov 2020 (Study Day 122)	Upper Respiratory Infection
Amoxicillin	11 Dec 2020 (Study Day 134) - 13 Dec 2020 (Study Day 136)	Dental Abscess
Hydrocodone bitartrate; paracetamol	11 Dec 2020 (Study Day 134) - 20 Dec 2020 (Study Day 143)	Dental Abscess
Diphenhydramine hydrochloride	12 Dec 2020 (Study Day 135) - 12 Dec 2020 (Study Day 135)	Dental Abscess
Lidocaine hydrochloride	12 Dec 2020 (Study Day 135) - 13 Dec 2020 (Study Day 136)	Worsening Of Dental Abscess
Ceftriaxone	13 Dec 2020 (Study Day 136) - 13 Dec 2020 (Study Day 136)	Worsening Of Dental Abscess
Clindamycin	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)	Worsening Of Dental Abscess
Ct maxillofacial without contrast*	13 Dec 2020 (Study Day 136) - 13 Dec 2020 (Study Day 136)	Adverse Event
Metronidazole	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)	Worsening Of Dental Abscess
Morphine	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)	Worsening Of Dental Abcess
Ondansetron	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)	Nausea
Paracetamol	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)	Worsening Of Dental Abscess

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Potassium chloride	13 Dec 2020 (Study Day 136) - 13 Dec 2020 (Study Day 136)	Hypokalemia
Sodium chloride	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)	Worsening Of Dental Abcess
Clindamycin	14 Dec 2020 (Study Day 137) - 20 Dec 2020 (Study Day 143)	Worsening Of Dental Abscess
Lactobacillus nos	14 Dec 2020 (Study Day 137) - 20 Dec 2020 (Study Day 143)	Worsening Of Dental Abscess
Tooth extraction*	14 Dec 2020 (Study Day 137) - 14 Dec 2020 (Study Day 137)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not related	28 Sep 2020 (Study Day 60) - 05 Oct 2020 (Study Day 67)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	21 Nov 2020 (Study Day 114) - 29 Nov 2020 (Study Day 122)
Tooth Abscess	Grade 2/moderate	Not related	10 Dec 2020 (Study Day 133) - 11 Dec 2020 (Study Day 134)
Cellulitis	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)
Hypokalaemia	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)
Nausea	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)
Trismus	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 137)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	02 Jan 2021 (Study Day 156) - 09 Jan 2021 (Study Day 163)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US306-2019 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cellulitis/Cellulitis Left Knee	SAE	Grade 4	Not related	18 Sep 2020 (Study Day 50) – 11 Oct 2020 (Study Day 73)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2019, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 28 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Sep 2020 (Study Day 50), 49 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cellulitis. Action taken with the IP was not applicable. The event of cellulitis left knee lasted for 24 days, after which it was considered to be recovered/resolved on 11 Oct 2020 (Study Day 73). The investigator assessed the event of cellulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000348	Cellulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

FDA-CBER-2022-1614-3378310

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	01 Jan 1969 (Study Day -18839) - Ongoing
Obesity	Obesity	1970 - Ongoing
Polyarthritis	Generalized arthritis, unspecified, non autoimmune	01 Jan 1993 (Study Day -10073) - Ongoing
Type 2 diabetes mellitus	Typer ii diabetes mellitus	01 Jan 1997 (Study Day -8612) - Ongoing
Hypothyroidism	Hypothyroidism	01 Jan 2000 (Study Day -7517) - Ongoing
Postmenopause	Postmenopausal	2005 - Ongoing
Hysterectomy	Hysterectomy	01 Jan 2005 (Study Day -5690) - 01 Jan 2005 (Study Day -5690)
Oedema peripheral	Edema bilateral lower extremities	01 Jan 2005 (Study Day -5690) - Ongoing
Ovarian cyst	Right ovarian cyst	01 Jan 2005 (Study Day -5690) - 01 Jan 2005 (Study Day -5690)
Hypertonic bladder	Overactive bladder	01 Apr 2005 (Study Day -5600) - Ongoing
Seasonal allergy	Allergic rhinitis, seasonal	01 Feb 2008 (Study Day -4564) - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	03 Aug 2009 (Study Day -4015) - Ongoing
Knee arthroplasty	Total left knee replacement	13 Aug 2019 (Study Day -353) - 13 Aug 2019 (Study Day -353)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1993 - Ongoing	Generalized Arthritis, Unspecified, Non Autoimmune
Glipizide	2000 - Ongoing	Type Ii Diabetes Mellitus
Iron	2000 - 21 Sep 2020 (Study Day 53)	Nutritional Supplement
Levothyroxine	2000 - Ongoing	Hypothyroidism
Metformin	2000 - Ongoing	Type Ii Diabetes Mellitus
Oxybutynin	2005 - Ongoing	Overactive Bladder
Lovastatin	03 Aug 2009 (Study Day -4015) - Ongoing	Hypercholesterolemia
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Vitamins nos	2015 - Ongoing	Nutritional Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxybutynin	2016 - Ongoing	Overactive Bladder
Zingiber officinale root	2018 - Ongoing	Nutritional Supplement
Colecalciferol	2019 - Ongoing	Nutritional Supplement
Ascorbic acid	Jan 2020 - Ongoing	Nutritional Supplement
Lisinopril	07 Aug 2020 (Study Day 8) - Ongoing	Hypertenstion
Cefalexin	21 Sep 2020 (Study Day 53) - 23 Sep 2020 (Study Day 55)	Cellulitis Left Knee
Sulfamethoxazole; trimethoprim	21 Sep 2020 (Study Day 53) - 23 Sep 2020 (Study Day 55)	Cellulitis Left Knee
Blood culture*	22 Sep 2020 (Study Day 54) - 22 Sep 2020 (Study Day 54)	Adverse Event
Clindamycin	22 Sep 2020 (Study Day 54) - 23 Sep 2020 (Study Day 55)	Cellulitis Left Knee
Ferrous sulfate	22 Sep 2020 (Study Day 54) - Ongoing	Nutritional Supplement
Fluid knee culture*	22 Sep 2020 (Study Day 54) - 22 Sep 2020 (Study Day 54)	Adverse Event
Ipratropium bromide; salbutamol sulfate	22 Sep 2020 (Study Day 54) - 26 Sep 2020 (Study Day 58)	Asthma-Mild
Paracetamol	22 Sep 2020 (Study Day 54) - 11 Oct 2020 (Study Day 73)	Cellulitis Left Knee
Sodium chloride	22 Sep 2020 (Study Day 54) - 25 Sep 2020 (Study Day 57)	Dehydration
Vancomycin	22 Sep 2020 (Study Day 54) - 26 Sep 2020 (Study Day 58)	Cellulitis Left Knee
X-ray, left knee*	22 Sep 2020 (Study Day 54) - 22 Sep 2020 (Study Day 54)	Adverse Event
Dextromethorphan	23 Sep 2020 (Study Day 55) - 26 Sep 2020 (Study Day 58)	Chronic Cough
Enoxaparin sodium	23 Sep 2020 (Study Day 55) - 23 Sep 2020 (Study Day 55)	Celluitus Left Knee
Insulin lispro	23 Sep 2020 (Study Day 55) - 26 Sep 2020 (Study Day 58)	Diabetes Mellitus Ii
Piperacillin sodium; tazobactam sodium	23 Sep 2020 (Study Day 55) - 23 Sep 2020 (Study Day 55)	Celllulitis Left Knee
Sodium chloride	23 Sep 2020 (Study Day 55) - 23 Sep 2020 (Study Day 55)	Cellulitis Left Knee
Acetylsalicylic acid	24 Sep 2020 (Study Day 56) - 25 Sep 2020 (Study Day 57)	Cardiac Prophylaxis
Blood culture*	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Adverse Event
Cefazolin	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Ceftriaxone	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Chest x-ray*	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Adverse Event
Dexamethasone	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Echocardiogram*	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fentanyl	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Fluticasone	24 Sep 2020 (Study Day 56) - Ongoing	Allergic Rhinitis, Seasonal
Hydrocodone bitartrate; paracetamol	24 Sep 2020 (Study Day 56) - 11 Oct 2020 (Study Day 73)	Cellulitis Left Knee
Hyoscine	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Irrigation and debridement of abscess*	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Adverse Event
Lidocaine	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Ondansetron	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Nausea
Propofol	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Rocuronium	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Sugammadex	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Suxamethonium	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Cellulitis Left Knee
Tissue knee culture*	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)	Adverse Event
Atorvastatin	25 Sep 2020 (Study Day 57) - 25 Sep 2020 (Study Day 57)	Hypercholesterolemia
Azithromycin	25 Sep 2020 (Study Day 57) - 29 Sep 2020 (Study Day 61)	Cellulitis Left Knee
Chest x-ray*	25 Sep 2020 (Study Day 57) - 25 Sep 2020 (Study Day 57)	Adverse Event
Daptomycin	25 Sep 2020 (Study Day 57) - 26 Sep 2020 (Study Day 58)	Cellulitis Left Knee
Furosemide	25 Sep 2020 (Study Day 57) - 25 Sep 2020 (Study Day 57)	Edema Bilateral Lower Extremity
Azithromycin	26 Sep 2020 (Study Day 58) - 26 Sep 2020 (Study Day 58)	Cellulitis Left Knee
Chest x-ray*	26 Sep 2020 (Study Day 58) - 26 Sep 2020 (Study Day 58)	Adverse Event
Cyanocobalamin	26 Sep 2020 (Study Day 58) - 26 Sep 2020 (Study Day 58)	Nutritional Supplement
Echocardiogram*	26 Sep 2020 (Study Day 58) - 26 Sep 2020 (Study Day 58)	Adverse Event
Influenza vaccine	26 Sep 2020 (Study Day 58) - 26 Sep 2020 (Study Day 58)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	04 Aug 2020 (Study Day 5) - Ongoing
Dehydration	Grade 1/mild	Not related	22 Sep 2020 (Study Day 54) - 25 Sep 2020 (Study Day 57)
Joint Abscess	Grade 1/mild	Not related	22 Sep 2020 (Study Day 54) - 16 Oct 2020 (Study Day 78)
Cardiac Murmur	Grade 1/mild	Not related	23 Sep 2020 (Study Day 55) - Ongoing
Nausea	Grade 1/mild	Not related	24 Sep 2020 (Study Day 56) - 24 Sep 2020 (Study Day 56)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US306-2048 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Lumbar Radiculopathy/Lumbar Radiculopathy Involving The Left S1 Nerve Root	SAE	Grade 4	Not related	11 Jan 2021 (Study Day 162) – 12 Jan 2021 (Study Day 163)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2048, a 70-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Jan 2021 (Study Day 162), 161 days after the first dose and 133 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of lumbar radiculopathy. Action taken with the IP was not applicable. The event of lumbar radiculopathy involving the left s1 nerve root lasted for 2 days, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 163). The investigator assessed the event of lumbar radiculopathy to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003669	Lumbar radiculopathy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Low back pain	1964 - Ongoing
Sciatica	Sciatia, left	1964 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Hyperlipidaemia	Hyperlipidemia	28 Apr 2016 (Study Day -1558) - Ongoing
Physiotherapy	Physical therapy	12 Jun 2020 (Study Day -52) - 20 Jun 2020 (Study Day -44)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2001 - Ongoing	Sciatica, Left
Vitamins nos	2005 - Ongoing	Nutritional Supplement
Chondroitin; glucosamine	2010 - Ongoing	Nutritional Supplement
Amlodipine	2016 - Ongoing	Hypertension
Benazepril	29 Apr 2016 (Study Day -1557) - Ongoing	Hypertension
Atorvastatin	02 May 2016 (Study Day -1554) - Ongoing	Hyperlipidemia
Spironolactone	Jul 2018 - Ongoing	Hypertension
Methylprednisolone	01 Nov 2020 (Study Day 91) - 01 Nov 2020 (Study Day 91)	Low Back Pain
Cyclobenzaprine	05 Nov 2020 (Study Day 95) - Ongoing	Low Back Pain
Diclofenac sodium	05 Nov 2020 (Study Day 95) - Ongoing	Low Back Pain
Methylprednisolone acetate	05 Nov 2020 (Study Day 95) - 05 Nov 2020 (Study Day 95)	Low Back Pain
Lumbar epidural*	11 Nov 2020 (Study Day 101) - 11 Nov 2020 (Study Day 101)	Medical History
Bupivacaine	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Calcium chloride; potassium chloride; sodium lactate	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Cefazolin sodium	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Ethanol	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Excision of l5-s1 facet synovial cyst*	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Adverse Event
Gelatin	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Left l5-s1 hemilaminotomy decompression with partial facetectomy*	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Adverse Event
Mri*	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Adverse Event
Other drugs for constipation	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Incidental Durotomy
Paracetamol	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Sodium chloride	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Thrombin	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Vancomycin	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
X-ray*	11 Jan 2021 (Study Day 162) - 11 Jan 2021 (Study Day 162)	Adverse Event
Acetylsalicylic acid	12 Jan 2021 (Study Day 163) - 12 Jan 2021 (Study Day 163)	Lumbar Radiculopathy Involving The Left S1 Nerve Root
Tramadol hydrochloride	12 Jan 2021 (Study Day 163) - 12 Jan 2021 (Study Day 163)	Lumbar Radiculopathy Involving The Left S1 Nerve Root

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dural Tear	Grade 1/mild	Not related	11 Jan 2021 (Study Day 162) - 12 Jan 2021 (Study Day 163)
Headache	Grade 1/mild	Not related	11 Jan 2021 (Study Day 162) - 12 Jan 2021 (Study Day 163)
Intervertebral Disc Degeneration	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 162) - Ongoing
Ligamentum Flavum Hypertrophy	Grade 1/mild	Not related	11 Jan 2021 (Study Day 162) - Ongoing
Spinal Synovial Cyst	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 162) - 12 Jan 2021 (Study Day 163)
Vertebral Lateral Recess Stenosis	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 162) - 12 Jan 2021 (Study Day 163)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US306-2075 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pelvic Fracture/Fracture Of Superior Rim Right Pubis	SAE	Grade 4	Not related	27 Dec 2020 (Study Day 146) – 11 Mar 2021 (Study Day 220)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2075, a 77-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Dec 2020 (Study Day 146), 145 days after the first dose and 117 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pelvic fracture. Action taken with the IP was not applicable. The event of fracture of superior rim right pubis lasted for 75 days, after which it was considered to be recovered/resolved on 11 Mar 2021 (Study Day 220). The investigator assessed the event of pelvic fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001509	Pelvic fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Complete hysterectomy	01 Jan 1982 (Study Day -14095) - 01 Jan 1982 (Study Day -14095)
Uterine leiomyoma	Fibroid tumor	01 Jan 1982 (Study Day -14095) - 01 Jan 1982 (Study Day -14095)
Hypothyroidism	Hypothyroidism	01 Jan 1990 (Study Day -11173) - Ongoing
Hyperlipidaemia	Hyperlipidemia	01 Jan 2005 (Study Day -5694) - Ongoing
Palpitations	Cardiac palpitaion	01 Jan 2005 (Study Day -5694) - Ongoing
Depression	Depression	01 Jan 2015 (Study Day -2042) - Ongoing
Back pain	Chronic back pain	01 Nov 2018 (Study Day -642) - Ongoing
Back pain	Dorsalgia	13 Jan 2019 (Study Day -569) - Ongoing
Insomnia	Insomnia	13 Jan 2019 (Study Day -569) - Ongoing
Muscle spasms	General muscle cramping	13 Jan 2019 (Study Day -569) - Ongoing
Muscle spasms	General muscle spasm	13 Jan 2019 (Study Day -569) - Ongoing
Pulmonary hypertension	Pulmonary hypertension	13 Jan 2019 (Study Day -569) - Ongoing
Hypertension	Hypertension	15 Jan 2019 (Study Day -567) - Ongoing
Osteoporosis	Osteoporosis	15 Jan 2019 (Study Day -567) - Ongoing
Constipation	Constipation, recurrent	18 Jan 2019 (Study Day -564) - Ongoing
Abdominal rebound tenderness	Rebound abdominal tenderness	22 Jan 2019 (Study Day -560) - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	01 Jul 2020 (Study Day -34) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	01 Jan 1990 (Study Day -11173) - 09 Jan 2021 (Study Day 159)	Hypothyroidism

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	01 Jan 2005 (Study Day -5694) - Ongoing	Hyperlipidemia
Metoprolol	01 Jan 2005 (Study Day -5694) - 11 Jan 2021 (Study Day 161)	Cardiac Palpitation
Lidocaine	13 Jan 2019 (Study Day -569) - 09 Jan 2021 (Study Day 159)	Chronic Back Pain
Duloxetine hydrochloride	21 Jan 2019 (Study Day -561) - 09 Jan 2021 (Study Day 159)	Depression
Metaxalone	28 Jan 2019 (Study Day -554) - 09 Jan 2021 (Study Day 159)	Generalized Muscle Cramping
Gabapentin	29 Dec 2019 (Study Day -219) - 09 Jan 2021 (Study Day 159)	Chronic Back Pain
Famotidine	01 Jul 2020 (Study Day -34) - Ongoing	Gastroesophageal Reflux Disease
Paroxetine	17 Aug 2020 (Study Day 14) - 11 Jan 2021 (Study Day 161)	Depression
Influenza vaccine	13 Oct 2020 (Study Day 71) - 13 Oct 2020 (Study Day 71)	Influenza Prophylaxis
Chest x-ray*	28 Dec 2020 (Study Day 147) - 28 Dec 2020 (Study Day 147)	Adverse Event
Morphine	28 Dec 2020 (Study Day 147) - 28 Dec 2020 (Study Day 147)	Generalized Pain
Ondansetron	28 Dec 2020 (Study Day 147) - 28 Dec 2020 (Study Day 147)	Generalized Nausea
Bisacodyl	29 Dec 2020 (Study Day 148) - 09 Jan 2021 (Study Day 159)	Constipation, Recurrent
Calcium carbonate; colecalciferol	29 Dec 2020 (Study Day 148) - 11 Mar 2021 (Study Day 220)	Fracture Of Superior Rim Right Pubis
Chest x-ray with contrast*	29 Dec 2020 (Study Day 148) - 29 Dec 2020 (Study Day 148)	Adverse Event
Chest x-ray without contrast*	29 Dec 2020 (Study Day 148) - 29 Dec 2020 (Study Day 148)	Adverse Event
Hydrocodone bitartrate; paracetamol	29 Dec 2020 (Study Day 148) - 29 Dec 2020 (Study Day 148)	Generalized Pain
Hydrocodone bitartrate; paracetamol	29 Dec 2020 (Study Day 148) - 09 Jan 2021 (Study Day 159)	Generalized Pain
Hydrocodone bitartrate; paracetamol	29 Dec 2020 (Study Day 148) - 17 Feb 2021 (Study Day 198)	Generalized Pain
Hydromorphone hydrochloride	29 Dec 2020 (Study Day 148) - 29 Dec 2020 (Study Day 148)	Generalized Pain
Mirtazapine	29 Dec 2020 (Study Day 148) - 11 Jan 2021 (Study Day 161)	Depression
Morphine	29 Dec 2020 (Study Day 148) - 29 Dec 2020 (Study Day 148)	Generalized Pain
Bisacodyl	30 Dec 2020 (Study Day 149) - 30 Dec 2020 (Study Day 149)	Constipation, Recurrent
Chest ct*	30 Dec 2020 (Study Day 149) - 30 Dec 2020 (Study Day 149)	Adverse Event
Metoprolol	30 Dec 2020 (Study Day 149) - 01 Jan 2021 (Study Day 151)	Hypertension
Ipratropium; salbutamol	31 Dec 2020 (Study Day 150) - Ongoing	Acute Respiratory Failure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Water for injection	31 Dec 2020 (Study Day 150) - 08 Jan 2021 (Study Day 158)	Fracture Of Superior Rim Right Pubis
Benzocaine; menthol	01 Jan 2021 (Study Day 151) - 01 Jan 2021 (Study Day 151)	Fracture Or Superior Rim Right Pubis
Echo with doppler*	01 Jan 2021 (Study Day 151) - 01 Jan 2021 (Study Day 151)	Adverse Event
Hydrocodone bitartrate; paracetamol	01 Jan 2021 (Study Day 151) - 09 Jan 2021 (Study Day 159)	Generalized Pain
Levosalbutamol hydrochloride	01 Jan 2021 (Study Day 151) - 09 Jan 2021 (Study Day 159)	Acute Respiratory Failure
Tramadol	01 Jan 2021 (Study Day 151) - 11 Mar 2021 (Study Day 220)	Generalized Pain
Chest x-ray*	02 Jan 2021 (Study Day 152) - 02 Jan 2021 (Study Day 152)	Adverse Event
Furosemide	02 Jan 2021 (Study Day 152) - 02 Jan 2021 (Study Day 152)	Hypoxia
Methylprednisolone	02 Jan 2021 (Study Day 152) - 04 Jan 2021 (Study Day 154)	Hypoxia
Furosemide	03 Jan 2021 (Study Day 153) - 03 Jan 2021 (Study Day 153)	Hypoxia
Amlodipine	04 Jan 2021 (Study Day 154) - Ongoing	Hypertension
Hydralazine	04 Jan 2021 (Study Day 154) - Ongoing	Hypertension
Prednisone	05 Jan 2021 (Study Day 155) - 15 Feb 2021 (Study Day 196)	Fracture Of Superior Rim Right Pubis
Paracetamol	09 Jan 2021 (Study Day 159) - 16 Jan 2021 (Study Day 166)	Generalized Pain
Levothyroxine	10 Jan 2021 (Study Day 160) - Ongoing	Hypothyroidism
Metoprolol	12 Jan 2021 (Study Day 162) - Ongoing	Hypertension
Mirtazapine	12 Jan 2021 (Study Day 162) - 10 Feb 2021 (Study Day 191)	Worsening Depression
Ranitidine hydrochloride	12 Jan 2021 (Study Day 162) - Ongoing	Gerd
Occupational therapy*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Adverse Event
Physical therapy*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Adverse Event
Bisacodyl	18 Jan 2021 (Study Day 168) - Ongoing	Constipation, Recurrent
Docusate sodium	18 Jan 2021 (Study Day 168) - Ongoing	Constipation, Recurrent
Macrogol 3350	21 Jan 2021 (Study Day 171) - Ongoing	Constipation, Recurrent

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fractured Sacrum	Grade 1/mild	Not related	27 Dec 2020 (Study Day 146) - 11 Mar 2021 (Study Day 220)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pelvic Fracture	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 146) - 11 Mar 2021 (Study Day 220)
Nausea	Grade 1/mild	Not related	28 Dec 2020 (Study Day 147) - 28 Dec 2020 (Study Day 147)
Pain	Grade 1/mild	Not related	28 Dec 2020 (Study Day 147) - 11 Mar 2021 (Study Day 220)
Arteriosclerosis	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Atelectasis	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Cardiac Steatosis	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Kyphosis	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Scoliosis	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Spinal Osteoarthritis	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Splenic Calcification	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Vascular Calcification	Grade 1/mild	Not related	29 Dec 2020 (Study Day 148) - Ongoing
Acute Respiratory Failure	Grade 1/mild	Not related	31 Dec 2020 (Study Day 150) - Ongoing
Atelectasis	Grade 1/mild	Not related	02 Jan 2021 (Study Day 152) - Ongoing
Cardiomegaly	Grade 1/mild	Not related	02 Jan 2021 (Study Day 152) - Ongoing
Hypoxia	Grade 1/mild	Not related	02 Jan 2021 (Study Day 152) - 20 Jan 2021 (Study Day 170)
Total Lung Capacity Decreased	Grade 1/mild	Not related	02 Jan 2021 (Study Day 152) - Ongoing
Atrial Enlargement	Grade 1/mild	Not related	03 Jan 2021 (Study Day 153) - Ongoing
Left Ventricular Hypertrophy	Grade 1/mild	Not related	03 Jan 2021 (Study Day 153) - Ongoing
Mitral Valve Incompetence	Grade 1/mild	Not related	03 Jan 2021 (Study Day 153) - Ongoing
Tricuspid Valve Incompetence	Grade 1/mild	Not related	03 Jan 2021 (Study Day 153) - Ongoing
Depression	Grade 2/moderate	Not related	12 Jan 2021 (Study Day 162) - Ongoing
Oedema Peripheral	Grade 1/mild	Not related	15 Jan 2021 (Study Day 165) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378322

Participant Number:	US306-2079 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Worsening Of Nephrolithiasis Recurrent	SAE	Grade 4	Not related	07 Sep 2020 (Study Day 35) – 10 Sep 2020 (Study Day 38)	Recovered/ resolved
Nephrolithiasis/Worsening Of Recurrent Nephrolithiasis	SAE	Grade 4	Not related	03 Nov 2020 (Study Day 92) – 11 Dec 2020 (Study Day 130)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2079, a 40-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 35), 34 days after the first dose and 3 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of worsening of nephrolithiasis recurrent lasted for 4 days, after which it was considered to be recovered/resolved on 10 Sep 2020 (Study Day 38). The investigator assessed the event of nephrolithiasis to be not related to the IP.

On 03 Nov 2020 (Study Day 92), 91 days after the first dose and 60 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of worsening of recurrent nephrolithiasis lasted for 39 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 130). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000289	Nephrolithiasis
MOD-2021-008915	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Small intestinal obstruction	Small bowel obstruction	1995 - 1995
Muscle spasms	Muscle spasms	1998 - Ongoing
Nephrolithiasis	Nephrolithiasis, recurrent	1998 - Ongoing
Migraine	Migraines	2000 - Ongoing
Anxiety	Anxiety	2013 - Ongoing
Bipolar disorder	Bipolar depression	2013 - Ongoing
Insomnia	Insomnia	2013 - Ongoing
Neuropathy peripheral	Neuropathy, unspecified bilateral hands	2017 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome- constipation	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Buspirone	2013 - Ongoing	Anxiety
Lamotrigine	2013 - Ongoing	Anxiety
Propranolol hydrochloride	2013 - Ongoing	Migraines
Trazodone	2013 - Ongoing	Insomnia
Vilazodone hydrochloride	2013 - Ongoing	Bipolar Depression
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2018 - Ongoing	Contrception
Cefixime	2019 - Ongoing	Muscle Spasms Legs
Docusate sodium	2019 - Ongoing	Irritable Bowel Syndrome-Constipation
Macrogol 3350	2019 - Ongoing	Ibs- Constipation
Gabapentin	Jan 2020 - Ongoing	Neuropathy-Bilateral Hands, Unspecified
Vitamins nos	Mar 2020 - Ongoing	Nutritional Supplement
Aripiprazole	13 May 2020 (Study Day -83) - 29 Sep 2020 (Study Day 57)	Bipolar Depression
Paracetamol	05 Sep 2020 (Study Day 33) - 11 Sep 2020 (Study Day 39)	Headache
Ct abdomen/pelvis with contrast*	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Docusate sodium; sennoside a+b	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Ibs- Constipation
Hydrocodone bitartrate; paracetamol	07 Sep 2020 (Study Day 35) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Morphine	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Ondansetron	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Bilateral Nephrolithiasis
Prochlorperazine	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Bilateral Nephrolithiasis
Sodium chloride	07 Sep 2020 (Study Day 35) - 07 Sep 2020 (Study Day 35)	Bilateral Nephrolithiasis
Sodium chloride	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Tamsulosin hydrochloride	07 Sep 2020 (Study Day 35) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Guaifenesin	08 Sep 2020 (Study Day 36) - Ongoing	Seasonal Allergies
Levofloxacin	08 Sep 2020 (Study Day 36) - 10 Sep 2020 (Study Day 38)	Bilateral Nephrolithiasis
Calcium chloride; potassium chloride; sodium lactate	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Cefazolin sodium	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Hydrocodone bitartrate; paracetamol	09 Sep 2020 (Study Day 37) - 16 Sep 2020 (Study Day 44)	Post Op Pain
Hydromorphone hydrochloride	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Iohexol	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Bilateral Nephrolithiasis
Placement of rental stent*	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Adverse Event
Right ureteroscopy with laser lithotripsy*	09 Sep 2020 (Study Day 37) - 09 Sep 2020 (Study Day 37)	Adverse Event
Aripiprazole	30 Sep 2020 (Study Day 58) - Ongoing	Bipolar Depression
Atropa belladonna extract; papaver somniferum powder	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain Generalized
Calcium chloride; potassium chloride; sodium lactate	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Cartilage; hyaluronic acid	03 Nov 2020 (Study Day 92) - 06 Nov 2020 (Study Day 95)	Nausea, Generalized
Cefazolin	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Urinary Tract Infection
Dexamethasone	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Fentanyl	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain- Generalized
Heparin	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Iv Patency
Hydrocodone bitartrate; paracetamol	03 Nov 2020 (Study Day 92) - 11 Dec 2020 (Study Day 130)	Worsening Of Recurrent Nephrolithiasis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydromorphone hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain- Generalized
Lidocaine	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Lithotripsy*	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Adverse Event
Midazolam hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Morphine	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain Generalized
Ondansetron	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Nausea- Generalized
Oxybutynin hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Oxycodone hydrochloride; paracetamol	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain Generalized
Pethidine hydrochloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Pain- Generalized
Phenylephrine	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Propofol	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Sodium chloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Suxamethonium chloride	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Worsening Of Recurrent Nephrolithiasis
Ureteral stent*	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)	Adverse Event
Percutaneous nephrolithotomy*	10 Dec 2020 (Study Day 129) - 10 Dec 2020 (Study Day 129)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hydronephrosis	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 35) - Ongoing
Transaminases Increased	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 35) - Ongoing
Ureterolithiasis	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 35) - 09 Sep 2020 (Study Day 37)
Procedural Pain	Grade 1/mild	Not related	09 Sep 2020 (Study Day 37) - 16 Sep 2020 (Study Day 44)
Calculus Bladder	Grade 1/mild	Not related	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)
Nausea	Grade 1/mild	Not related	03 Nov 2020 (Study Day 92) - 06 Nov 2020 (Study Day 95)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain	Grade 1/mild	Not related	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)
Urinary Tract Infection	Grade 1/mild	Not related	03 Nov 2020 (Study Day 92) - 03 Nov 2020 (Study Day 92)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378327

Participant Number:	US306-2128 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Osteoarthritis Right Knee	SAE	Grade 4	Not related	03 Dec 2020 (Study Day 120) – 04 Dec 2020 (Study Day 121)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2128, a 77-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Dec 2020 (Study Day 120), 119 days after the first dose and 91 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening osteoarthritis right knee lasted for 2 days, after which it was considered to be recovered/resolved on 04 Dec 2020 (Study Day 121). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001084	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Jan 1975 - Ongoing
Postmenopause	Post menopausal	Jan 1988 - Ongoing
Hypertension	Hypertension	Jan 2003 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disorder	Jan 2010 - Ongoing
Osteopenia	Osteopenia	Jan 2010 - Ongoing
Insomnia	Insomnia	Jan 2015 - Ongoing
Osteoarthritis	Osteoarthritis, generalized	Jan 2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Jan 1988 - Ongoing	Cardiac Prophylaxis
Calcium; vitamin d nos	Jan 1988 - Ongoing	Nutritional Supplement
Fish oil	Jan 1988 - Ongoing	Nutritional Supplement
Lysine	Jan 1988 - Ongoing	Nutritional Supplement
Magnesium	Jan 1988 - Ongoing	Nutritional Supplement
Xantofyl	Jan 1988 - Ongoing	Nutritional Supplement
Hydrochlorothiazide	Jan 2003 - Ongoing	Hypertension
Loratadine	Jan 2005 - Ongoing	Seasonal Allergies
Ibandronate sodium	Jan 2010 - Ongoing	Osteopenia
Ranitidine	Jan 2010 - Ongoing	Gastroesophageal Reflux Disorder
Potassium	Jun 2014 - Ongoing	Nutritional Supplement
Ibuprofen	Jan 2015 - Ongoing	Osteoarthritis, Generalized
Diphenhydramine	Jun 2019 - Ongoing	Insomnia
Meloxicam	12 Aug 2020 (Study Day 7) - 01 Sep 2020 (Study Day 27)	Osteoarthritis, Generalized
Meloxicam	02 Sep 2020 (Study Day 28) - Ongoing	Osteoarthritis-Generalized
Influenza vaccine	19 Sep 2020 (Study Day 45) - 19 Sep 2020 (Study Day 45)	Influenza Prophalyxis
Amitriptyline	25 Nov 2020 (Study Day 112) - Ongoing	Interstital Cystitis
Amitriptyline hydrochloride	30 Nov 2020 (Study Day 117) - Ongoing	Insomnia
Sulfamethoxazole; trimethoprim	30 Nov 2020 (Study Day 117) - 03 Dec 2020 (Study Day 120)	Bladder Infection
Calcium chloride; potassium chloride; sodium lactate	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Worsening Osteoarthritis Right Knee
Cefazolin sodium	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Worsening Osteoarthritis Right Knee

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexamethasone	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Nausea-Recurrent
Docusate sodium	03 Dec 2020 (Study Day 120) - 04 Dec 2020 (Study Day 121)	Post Operative Constipation
Famotidine	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Nausea-Recurrent
Metoclopramide	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Nausea- Recurrent
Nystatin; zinc oxide	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Infection Prophylaxis
Ondansetron	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Nausea-Recurrent
Paracetamol	03 Dec 2020 (Study Day 120) - 01 Jan 2021 (Study Day 149)	Post Operative Pain
Right knee replacement*	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Adverse Event
Sennoside a+b	03 Dec 2020 (Study Day 120) - 04 Dec 2020 (Study Day 121)	Post Operative Constipation
Sodium chloride	03 Dec 2020 (Study Day 120) - 04 Dec 2020 (Study Day 121)	Worsening Osteoarthritis Right Knee
Tramadol	03 Dec 2020 (Study Day 120) - 01 Jan 2021 (Study Day 149)	Postoperative Pain
Vancomycin	03 Dec 2020 (Study Day 120) - 03 Dec 2020 (Study Day 120)	Worsening Osteoarthritis Right Knee
Acetylsalicylic acid	04 Dec 2020 (Study Day 121) - 04 Dec 2020 (Study Day 121)	Worsening Osteoarthritis Right Knee
Hydrochlorothiazide	04 Dec 2020 (Study Day 121) - Ongoing	Hypertention
Macrogol 3350	04 Dec 2020 (Study Day 121) - 04 Dec 2020 (Study Day 121)	Post Operative Constipation
Magnesium oxide	04 Dec 2020 (Study Day 121) - 04 Dec 2020 (Study Day 121)	Post Operative Constipation
Potassium chloride	04 Dec 2020 (Study Day 121) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Restless Legs Syndrome	Grade 1/mild	Not related	02 Nov 2020 (Study Day 89) - Ongoing
Cystitis Interstitial	Grade 1/mild	Not related	12 Nov 2020 (Study Day 99) - Ongoing
Cystitis	Grade 1/mild	Not related	30 Nov 2020 (Study Day 117) - 03 Dec 2020 (Study Day 120)
Nausea	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 120) - 04 Dec 2020 (Study Day 121)
Post Procedural Constipation	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 120) - 04 Dec 2020 (Study Day 121)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 120) - 01 Jan 2021 (Study Day 149)
Anaemia	Grade 1/mild	Not related	04 Dec 2020 (Study Day 121) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US306-2151 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Left Hip Osteoarthritis	SAE	Grade 4	Not related	14 Oct 2020 (Study Day 69) – 15 Oct 2020 (Study Day 70)	Recovered/ resolved
Postoperative Wound Infection/ Post Op Wound Infection, L Hip	SAE	Grade 4	Not related	20 Oct 2020 (Study Day 75) – 12 Dec 2020 (Study Day 128)	Recovered/ resolved
Gastrointestinal Haemorrhage/ Gastrointestinal Bleed	SAE	Grade 4	Not related	21 Oct 2020 (Study Day 76) – 21 Nov 2020 (Study Day 107)	Recovered/ resolved
Non-Cardiac Chest Pain/Non Cardiac Chest Pain	SAE	Grade 4	Not related	23 Oct 2020 (Study Day 78) – 23 Oct 2020 (Study Day 78)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2151, a 72-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Oct 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of left hip osteoarthritis lasted for 2 days, after which it was considered to be recovered/resolved on 15 Oct 2020 (Study Day 70). The investigator assessed the event of osteoarthritis to be not related to the IP.

On 20 Oct 2020 (Study Day 75), 74 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of postoperative wound infection. Action taken with the IP was not applicable. The event of post op wound infection, l hip lasted for 54 days, after which it was considered to be recovered/resolved on 12 Dec 2020 (Study Day 128). The investigator assessed the event of postoperative wound infection to be not related to the IP.

On 21 Oct 2020 (Study Day 76), 75 days after the first dose and 47 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of gastrointestinal haemorrhage.

Action taken with the IP was not applicable. The event of gastrointestinal bleed lasted for 32 days, after which it was considered to be recovered/resolved on 21 Nov 2020 (Study Day 107). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

On 23 Oct 2020 (Study Day 78), 77 days after the first dose and 49 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of non-cardiac chest pain. Action taken with the IP was not applicable. The event of non cardiac chest pain lasted for 1 day, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 78). The investigator assessed the event of non-cardiac chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000509	Osteoarthritis
MOD-2020-000509	Postoperative wound infection
MOD-2020-000509	Gastrointestinal haemorrhage
MOD-2020-000509	Non-cardiac chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1990 - Ongoing
Back pain	Low back pain	1990 - Ongoing
Depression	Depression	1990 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	1990 - Ongoing
Osteoarthritis	Osteoarthritis, bilateral hips	1990 - Ongoing
Arthralgia	Arthralgia, generalized	2000 - Ongoing
Muscle spasms	Leg cramps, recurrent	2000 - Ongoing
Osteopenia	Osteopenia	2000 - Ongoing
Spinal stenosis	Spinal stenosis	2000 - Ongoing
Postmenopause	Post menopausal	2005 - Ongoing
Peripheral sensory neuropathy	Neuropathy, sensory	Jan 2012 - Ongoing
Gastrooesophageal reflux disease	Gerd	Jan 2015 - Ongoing
Urinary incontinence	Incontinence, urinary	2017 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Celecoxib	2019 - 13 Oct 2020 (Study Day 68)	Osteoarthritis Bilateral Hips And Knees
Dietary supplement	Feb 2020 - Ongoing	Nutritional Supplement
Other urologicals	Jul 2020 - 15 Dec 2020 (Study Day 131)	Incontinence, Urinary
Unspecified herbal and traditional medicine	Jul 2020 - Ongoing	Osteoarthritis, Bilateral Hips And Knees
Hydrocodone bitartrate; paracetamol	01 Sep 2020 (Study Day 26) - 06 Nov 2020 (Study Day 92)	Osteoarthritis, Bilateral Knees
Influenza vaccine	26 Sep 2020 (Study Day 51) - 26 Sep 2020 (Study Day 51)	Influenza Prophylaxis
Acetylsalicylic acid	14 Oct 2020 (Study Day 69) - 22 Oct 2020 (Study Day 77)	Osteoarthritis Bilateral Hips
Bupivacaine hydrochloride; epinephrine	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthrits
Calcium chloride; potassium chloride; sodium lactate	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthritis
Cefazolin sodium	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthrits
Celecoxib	14 Oct 2020 (Study Day 69) - 20 Oct 2020 (Study Day 75)	Osteoarthritis Bilateral Hips
Dexamethasone	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthritis
Docusate sodium	14 Oct 2020 (Study Day 69) - 15 Jan 2021 (Study Day 162)	Constipation
Hyoscine	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthritis
Ketorolac tromethamine	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthritis
Left hip replacement*	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Adverse Event
Ondansetron	14 Oct 2020 (Study Day 69) - 30 Oct 2020 (Study Day 85)	Post Op Nausea
Oxycodone hydrochloride; paracetamol	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hips Osteoarthritis
Oxycodone hydrochloride; paracetamol	14 Oct 2020 (Study Day 69) - 19 Oct 2020 (Study Day 74)	Postoperative Pain, Generalized
Paracetamol	14 Oct 2020 (Study Day 69) - 15 Oct 2020 (Study Day 70)	Left Hip Osteoarthritis
Pneumococcal vaccine	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Pneumonia Prophylaxis
Sodium chloride	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthritis
Tranexamic acid	14 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 69)	Left Hip Osteoarthritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	15 Oct 2020 (Study Day 70) - 15 Oct 2020 (Study Day 70)	Postoperative Nausea
Hydroxyzine	15 Oct 2020 (Study Day 70) - 15 Oct 2020 (Study Day 70)	Anxiety
Hydroxyzine	15 Oct 2020 (Study Day 70) - 15 Oct 2020 (Study Day 70)	Postoperative Nausea Recurrent
Sodium chloride	15 Oct 2020 (Study Day 70) - 15 Oct 2020 (Study Day 70)	Left Hip Osteoarthritis
Ascorbic acid	20 Oct 2020 (Study Day 75) - Ongoing	Nutritional Supplement
Baclofen	20 Oct 2020 (Study Day 75) - Ongoing	Post Operative Pain Pain, Generalized
Hydroxyzine	20 Oct 2020 (Study Day 75) - 28 Oct 2020 (Study Day 83)	Abdominal Pain
Pantoprazole	20 Oct 2020 (Study Day 75) - 20 Oct 2020 (Study Day 75)	Post Op Nausea
Computerized tomography scan, abdominal*	21 Oct 2020 (Study Day 76) - 21 Oct 2020 (Study Day 76)	Adverse Event
Ipratropium; salbutamol	21 Oct 2020 (Study Day 76) - 26 Oct 2020 (Study Day 81)	Chronic Obstructive Pulmonary Disease
Oxycodone hydrochloride; paracetamol	21 Oct 2020 (Study Day 76) - 21 Oct 2020 (Study Day 76)	Post Operative Pain, Generalized
Oxycodone hydrochloride; paracetamol	21 Oct 2020 (Study Day 76) - 25 Oct 2020 (Study Day 80)	Post Operative Pain, Generalized
Pantoprazole sodium sesquihydrate	21 Oct 2020 (Study Day 76) - 21 Nov 2020 (Study Day 107)	Gastrointestinal Bleed
Red blood cells, concentrated	21 Oct 2020 (Study Day 76) - 26 Oct 2020 (Study Day 81)	Gastrointestinal Bleed
Esophagogastroduodenoscopy*	22 Oct 2020 (Study Day 77) - 22 Oct 2020 (Study Day 77)	Adverse Event
Lidocaine	22 Oct 2020 (Study Day 77) - 27 Oct 2020 (Study Day 82)	Post Operative Pain, Generalized
Nicotine	22 Oct 2020 (Study Day 77) - 28 Oct 2020 (Study Day 83)	Withdrawal Prophylaxis
Propofol	22 Oct 2020 (Study Day 77) - 22 Oct 2020 (Study Day 77)	Gastrointestinal Bleed
Sertraline	22 Oct 2020 (Study Day 77) - Ongoing	Depression
Acetylsalicylic acid	23 Oct 2020 (Study Day 78) - 15 Dec 2020 (Study Day 131)	Cardiac Prophylaxis
Cefepime	23 Oct 2020 (Study Day 78) - 24 Oct 2020 (Study Day 79)	Post Operative Infection, Left Hip
Electrocardiogram*	23 Oct 2020 (Study Day 78) - 23 Oct 2020 (Study Day 78)	Adverse Event
Ondansetron	23 Oct 2020 (Study Day 78) - 30 Oct 2020 (Study Day 85)	Post Operative Nausea, Recurrent
Oxygen	23 Oct 2020 (Study Day 78) - 25 Oct 2020 (Study Day 80)	Chronic Obstructive Pulmonary Disease
Paracetamol	23 Oct 2020 (Study Day 78) - 06 Nov 2020 (Study Day 92)	Post Operative Pain, Generalized
Vancomycin	23 Oct 2020 (Study Day 78) - 23 Oct 2020 (Study Day 78)	Post Operative Infection, Left Hip

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocodone bitartrate; paracetamol	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Post Op Pain
Hydromorphone	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Post Operative Pain, Generalized
Hydromorphone hydrochloride	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Post Operative Pain, Generalized
Lidocaine	24 Oct 2020 (Study Day 79) - 25 Oct 2020 (Study Day 80)	Post Operative Pain, Generalized
Lidocaine	24 Oct 2020 (Study Day 79) - 28 Oct 2020 (Study Day 83)	Post Operative Pain, Generalized
Piperacillin sodium; tazobactam sodium	24 Oct 2020 (Study Day 79) - 26 Oct 2020 (Study Day 81)	Post Operative Infection, Left Hip
Revision left hip replacement*	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Adverse Event
Sodium chloride	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Hypotension
Vancomycin	24 Oct 2020 (Study Day 79) - 25 Oct 2020 (Study Day 80)	Post Operative Infection, Left Hip
Azithromycin	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Infection, Left Hip
Calcium chloride; potassium chloride; sodium lactate	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Infection, Left Hip
Dexamethasone	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Infection, Left Hip
Docusate sodium	25 Oct 2020 (Study Day 80) - 28 Oct 2020 (Study Day 83)	Constipation
Exchange of the poly and femoral head of the implants*	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Adverse Event
Fentanyl	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Pain, Generalized
Hydrocodone bitartrate; paracetamol	25 Oct 2020 (Study Day 80) - 06 Nov 2020 (Study Day 92)	Post Operative, Generalized
Irrigation and debridement of left hip*	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Adverse Event
Midazolam	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Infection, Left Hip
Phenylephrine	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Hypotension
Propofol	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Gastrointestinal Bleed
Rocuronium	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Infection, Left Hip
Saccharated iron oxide	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Anemia
Sodium phosphate monobasic (anhydrous)	25 Oct 2020 (Study Day 80) - 28 Oct 2020 (Study Day 83)	Constipation
Suxamethonium	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Infection, Left Hip
Tobramycin	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Post Operative Pain, Generalized

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tranexamic acid	25 Oct 2020 (Study Day 80) - 25 Oct 2020 (Study Day 80)	Gastrointestinal Bleed
Vancomycin	25 Oct 2020 (Study Day 80) - 26 Oct 2020 (Study Day 81)	Post Operative Infection, Left Hip
Ascorbic acid	26 Oct 2020 (Study Day 81) - 12 Dec 2020 (Study Day 128)	Post Operative Infection, Left Hip
Docusate sodium; sennoside a+b	26 Oct 2020 (Study Day 81) - 26 Oct 2020 (Study Day 81)	Constipation
Folic acid; minerals nos; vitamins nos	26 Oct 2020 (Study Day 81) - 28 Oct 2020 (Study Day 83)	Nutritional Deficiency
Macrogol 3350	26 Oct 2020 (Study Day 81) - 26 Oct 2020 (Study Day 81)	Constipation
Picc line insertion*	26 Oct 2020 (Study Day 81) - 26 Oct 2020 (Study Day 81)	Adverse Event
Ceftriaxone	27 Oct 2020 (Study Day 82) - 28 Oct 2020 (Study Day 83)	Post Operative Infection Left Hip
Ceftriaxone	27 Oct 2020 (Study Day 82) - 28 Oct 2020 (Study Day 83)	Postoperative Wound Infection, Left Hip
Saccharated iron oxide	27 Oct 2020 (Study Day 82) - 27 Oct 2020 (Study Day 82)	Anemia
Ceftriaxone	28 Oct 2020 (Study Day 83) - 07 Jan 2021 (Study Day 154)	Post Op Wound Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anaemia	Grade 1/mild	Not related	14 Oct 2020 (Study Day 69) - Ongoing
Constipation	Grade 1/mild	Not related	14 Oct 2020 (Study Day 69) - 15 Oct 2020 (Study Day 70)
Procedural Nausea	Grade 3/severe	Not related	14 Oct 2020 (Study Day 69) - 30 Oct 2020 (Study Day 85)
Abdominal Pain	Grade 1/mild	Not related	19 Oct 2020 (Study Day 74) - 28 Oct 2020 (Study Day 83)
Diverticulum Intestinal	Grade 1/mild	Not related	21 Oct 2020 (Study Day 76) - Ongoing
Haematoma	Grade 1/mild	Not related	21 Oct 2020 (Study Day 76) - 28 Oct 2020 (Study Day 83)
Suicidal Ideation	Grade 1/mild	Not related	21 Oct 2020 (Study Day 76) - 21 Oct 2020 (Study Day 76)
Asthenia	Grade 1/mild	Not related	22 Oct 2020 (Study Day 77) - 28 Oct 2020 (Study Day 83)
Duodenal Ulcer	Grade 1/mild	Not related	22 Oct 2020 (Study Day 77) - 03 Dec 2020 (Study Day 119)
Duodenitis	Grade 1/mild	Not related	22 Oct 2020 (Study Day 77) - 05 Nov 2020 (Study Day 91)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastritis	Grade 1/mild	Not related	22 Oct 2020 (Study Day 77) - 30 Oct 2020 (Study Day 85)
Hiatus Hernia	Grade 1/mild	Not related	22 Oct 2020 (Study Day 77) - Ongoing
Oesophagitis	Grade 1/mild	Not related	22 Oct 2020 (Study Day 77) - 05 Nov 2020 (Study Day 91)
Sinus Tachycardia	Grade 1/mild	Not related	22 Oct 2020 (Study Day 77) - 25 Oct 2020 (Study Day 80)
Confusional State	Grade 1/mild	Not related	24 Oct 2020 (Study Day 79) - 28 Oct 2020 (Study Day 83)
Hypotension	Grade 1/mild	Not related	24 Oct 2020 (Study Day 79) - 25 Oct 2020 (Study Day 80)
Oedema Peripheral	Grade 1/mild	Not related	24 Oct 2020 (Study Day 79) - 25 Oct 2020 (Study Day 80)
Procedural Pain	Grade 3/severe	Not related	24 Oct 2020 (Study Day 79) - 12 Dec 2020 (Study Day 128)
Skin Abrasion	Grade 1/mild	Not related	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)
Malnutrition	Grade 1/mild	Not related	26 Oct 2020 (Study Day 81) - Ongoing
Syncope	Grade 1/mild	Not related	27 Oct 2020 (Study Day 82) - 27 Oct 2020 (Study Day 82)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US306-2167 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE	Grade 4	Not related	16 Oct 2020 (Study Day 70) – 08 Jan 2021 (Study Day 154)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2167, a 56-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Oct 2020 (Study Day 70), 69 days after the first dose and 38 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate cancer lasted for 85 days, after which it was considered to be recovered/resolved on 08 Jan 2021 (Study Day 154). The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001196	COVID-19
MOD-2020-000610	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	2010 - Ongoing
Osteoarthritis	Osteoarthritis-bilateral hands, shoulders	2012 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes mellitus	01 May 2020 (Study Day -99) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Zolpidem	2010 - Ongoing	Insomnia
Meloxicam	2017 - Ongoing	Osteoarthritis- Bilateral Hands, Shoulders
Metformin	01 May 2020 (Study Day -99) - Ongoing	Type 2 Diabetes Mellitus
Psa level*	10 Aug 2020 (Study Day 3) - 10 Aug 2020 (Study Day 3)	Diagnostic
Prostate biopsy*	16 Oct 2020 (Study Day 70) - 16 Oct 2020 (Study Day 70)	Adverse Event
Transrectal ultrasound of the prostate*	16 Oct 2020 (Study Day 70) - 16 Oct 2020 (Study Day 70)	Adverse Event
Sildenafil	20 Nov 2020 (Study Day 105) - Ongoing	Erectile Dysfunction
Guaifenesin	08 Dec 2020 (Study Day 123) - 22 Dec 2020 (Study Day 137)	COVID 19
Paracetamol	08 Dec 2020 (Study Day 123) - 22 Dec 2020 (Study Day 137)	COVID 19
Phenylephrine hydrochloride	08 Dec 2020 (Study Day 123) - 22 Dec 2020 (Study Day 137)	COVID 19
Bilateral pelvic lymphadenectomy*	08 Jan 2021 (Study Day 154) - 08 Jan 2021 (Study Day 154)	Adverse Event
Cefradine	08 Jan 2021 (Study Day 154) - 08 Jan 2021 (Study Day 154)	Infection Prophylaxis
Heparin	08 Jan 2021 (Study Day 154) - 08 Jan 2021 (Study Day 154)	Deep Vein Thrombosis Prophylaxis
Robotic assisted laparoscopic radical prostatectomy*	08 Jan 2021 (Study Day 154) - 08 Jan 2021 (Study Day 154)	Adverse Event
Suprapubic tube placement*	08 Jan 2021 (Study Day 154) - 08 Jan 2021 (Study Day 154)	Adverse Event
Hydrocodone bitartrate; paracetamol	09 Jan 2021 (Study Day 155) - 11 Jan 2021 (Study Day 157)	Post Operative Pain Generalized
Naproxen sodium	11 Jan 2021 (Study Day 157) - 14 Jan 2021 (Study Day 160)	Post Operative Pain Generalized
Cefalexin	17 Jan 2021 (Study Day 163) - 23 Jan 2021 (Study Day 169)	Infection Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tadalafil	02 Mar 2021 (Study Day 207) - Ongoing	Erectile Dysfunction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Erectile Dysfunction	Grade 1/mild	Not related	20 Nov 2020 (Study Day 105) - Ongoing
COVID-19	Grade 2/moderate	Not related	08 Dec 2020 (Study Day 123) - 23 Dec 2020 (Study Day 138)
Procedural Pain	Grade 1/mild	Not related	09 Jan 2021 (Study Day 155) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US306-2265 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	15 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 40)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Alcohol Abuse/Worsening Of Alcohol Abuse	SAE	Grade 4	Not related	17 Sep 2020 (Study Day 34) – 23 Sep 2020 (Study Day 40)	Recovered/ resolved
Alcohol Withdrawal Syndrome/ Alcohol Withdrawal Symptoms	SAE	Grade 4	Not related	13 Oct 2020 (Study Day 60) – 20 Oct 2020 (Study Day 67)	Recovered/ resolved
Musculoskeletal Chest Pain/ Chest Pain - Musculoskeletal	SAE	Grade 4	Not related	13 Oct 2020 (Study Day 60) – 14 Oct 2020 (Study Day 61)	Recovered/ resolved
Alcohol Withdrawal Syndrome/ Alcohol Withdrawal Symptoms	SAE	Grade 4	Not related	27 Oct 2020 (Study Day 74) – 02 Nov 2020 (Study Day 80)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US306-2265, a 56-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 15 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 40). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Sep 2020 (Study Day 34), 33 days after the first dose and 6 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of alcohol abuse. The IP dose was not changed due to the worsening of alcohol abuse. The event of worsening of alcohol abuse lasted for 7 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 40). The investigator assessed the event of alcohol abuse to be not related to the IP.

On 13 Oct 2020 (Study Day 60), 59 days after the first dose and 20 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of alcohol withdrawal syndrome. Action taken with the IP was not applicable. The event of alcohol withdrawal symptoms lasted for 8 days, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 67). The investigator assessed the event of alcohol withdrawal syndrome to be not related to the IP.

On 13 Oct 2020 (Study Day 60), 59 days after the first dose and 20 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of musculoskeletal chest pain. Action taken with the IP was not applicable. The event of chest pain - musculoskeletal lasted for 2 days, after which it was considered to be recovered/resolved on 14 Oct 2020 (Study Day 61). The investigator assessed the event of musculoskeletal chest pain to be not related to the IP.

On 27 Oct 2020 (Study Day 74), 73 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of alcohol withdrawal syndrome. Action taken with the IP was not applicable. The event of alcohol withdrawal symptoms lasted for 7 days, after which it was considered to be recovered/resolved on 02 Nov 2020 (Study Day 80). The investigator assessed the event of alcohol withdrawal syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD- 2020-000347	Alcohol abuse
MOD-2020-000504	Alcohol withdrawal syndrome
MOD2020-000504	Musculoskeletal chest pain
MOD-2020-000709	Alcohol withdrawal syndrome

Study Completion/Discontinuation

On 20 Nov 2020 (Study Day 98), the participant discontinued from the study due to physician decision (inaccurate data and to allow time for subject to get health in order).

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol abuse	Alcohol abuse	2000 - Ongoing
Alcoholic seizure	Alcohol withdrawal seizures, recurrent	2000 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Pain in extremity	Right leg pain	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Carvedilol	Feb 2020 - Ongoing	Hypertension
Pregabalin	01 Jun 2020 (Study Day -75) - Ongoing	Right Leg Pain
Acetylsalicylic acid	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Chest Pain - Musculoskeletal
Arformoterol tartrate	13 Oct 2020 (Study Day 60) - 20 Oct 2020 (Study Day 67)	Wheezing
Budesonide	13 Oct 2020 (Study Day 60) - 20 Oct 2020 (Study Day 67)	Wheezing
Carvedilol	13 Oct 2020 (Study Day 60) - Ongoing	Hypertension
Chest x-ray*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ct abdomen/pelvis*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ct cervical spine without contrast*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ct head without contrast*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ct left elbow*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ct lumbar spine without contrast*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ct maxillofacial without contrast*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ct thoracic spine without contrast*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Ekg*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Fentanyl	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Generalized Pain
Folic acid	13 Oct 2020 (Study Day 60) - 20 Oct 2020 (Study Day 67)	Alcohol Withdrawal Symptoms
Lorazepam	13 Oct 2020 (Study Day 60) - 18 Oct 2020 (Study Day 65)	Alcohol Withdrawal Symptoms
Magnesium	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Acute Alcohol Intoxication
Morphine sulfate	13 Oct 2020 (Study Day 60) - 14 Oct 2020 (Study Day 61)	Generalized Pain
Ondansetron	13 Oct 2020 (Study Day 60) - 19 Oct 2020 (Study Day 66)	Nausea
Oxycodone hydrochloride; paracetamol	13 Oct 2020 (Study Day 60) - Ongoing	Generalized Pain
Potassium chloride	13 Oct 2020 (Study Day 60) - 14 Oct 2020 (Study Day 61)	Acute Alcohol Intoxication
Potassium chloride	13 Oct 2020 (Study Day 60) - 16 Oct 2020 (Study Day 63)	Alcohol Withdrawal Symptoms

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Wheezing
Salbutamol	13 Oct 2020 (Study Day 60) - 20 Oct 2020 (Study Day 67)	Wheezing
Sodium chloride	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Acute Alcohol Intoxication
Vitamins nos	13 Oct 2020 (Study Day 60) - 20 Oct 2020 (Study Day 67)	Nutritional Supplement
Vitamins with minerals	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Acute Alcohol Intoxication
X-ray left elbow*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
X-ray right elbow*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Diagnostic
X-ray right hip*	13 Oct 2020 (Study Day 60) - 13 Oct 2020 (Study Day 60)	Adverse Event
Enoxaparin sodium	14 Oct 2020 (Study Day 61) - 15 Oct 2020 (Study Day 62)	Alcohol Withdrawal Symptoms
Lidocaine	14 Oct 2020 (Study Day 61) - 20 Oct 2020 (Study Day 67)	Generalized Pain
Pantoprazole sodium sesquihydrate	14 Oct 2020 (Study Day 61) - 20 Oct 2020 (Study Day 67)	Alcohol Withdrawal Symptoms
Potassium chloride	14 Oct 2020 (Study Day 61) - 14 Oct 2020 (Study Day 61)	Acute Alcohol Intoxication
Paracetamol	17 Oct 2020 (Study Day 64) - 20 Oct 2020 (Study Day 67)	Generalized Pain
Vitamin b1 nos	17 Oct 2020 (Study Day 64) - 20 Oct 2020 (Study Day 67)	Alcohol Withdrawal Symptoms
Hydralazine hydrochloride	19 Oct 2020 (Study Day 66) - 19 Oct 2020 (Study Day 66)	Hypertension
Arformoterol tartrate	27 Oct 2020 (Study Day 74) - 01 Nov 2020 (Study Day 79)	Wheezing
Calcium chloride; potassium chloride; sodium lactate	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Acute Alcohol Intoxication
Chest x-ray*	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Adverse Event
Ct abdomin/pelvis*	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Adverse Event
Ct cervical spine*	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Adverse Event
Ct head*	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Adverse Event
Ct thoracic spine*	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Adverse Event
Ketorolac tromethamine	27 Oct 2020 (Study Day 74) - 01 Nov 2020 (Study Day 79)	Generalized Pain
Lidocaine	27 Oct 2020 (Study Day 74) - 01 Nov 2020 (Study Day 79)	Generalized Pain
Lorazepam	27 Oct 2020 (Study Day 74) - 29 Oct 2020 (Study Day 76)	Alcohol Withdrawal Symptoms

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Acute Alcohol Intoxication
Oxazepam	27 Oct 2020 (Study Day 74) - 31 Oct 2020 (Study Day 78)	Alcohol Withdrawal Symptoms
Pantoprazole	27 Oct 2020 (Study Day 74) - 30 Oct 2020 (Study Day 77)	Alcohol Withdrawal Symptoms
Pregabalin	27 Oct 2020 (Study Day 74) - 01 Nov 2020 (Study Day 79)	Generalized Pain
Sodium chloride	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Acute Alcohol Intoxication
Vitamins nos	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Acute Alcohol Intoxication
X-ray right shoulder*	27 Oct 2020 (Study Day 74) - 27 Oct 2020 (Study Day 74)	Adverse Event
Foley catheter placement*	28 Oct 2020 (Study Day 75) - 28 Oct 2020 (Study Day 75)	Adverse Event
Folic acid	28 Oct 2020 (Study Day 75) - 02 Nov 2020 (Study Day 80)	Nutritional Supplement
Hydromorphone hydrochloride	28 Oct 2020 (Study Day 75) - 28 Oct 2020 (Study Day 75)	Generalized Pain
Morphine sulfate	28 Oct 2020 (Study Day 75) - 01 Nov 2020 (Study Day 79)	Generalized Pain
Oxycodone	28 Oct 2020 (Study Day 75) - 02 Nov 2020 (Study Day 80)	Generalized Pain
Paracetamol	28 Oct 2020 (Study Day 75) - 02 Nov 2020 (Study Day 80)	Generalized Pain
Potassium chloride	28 Oct 2020 (Study Day 75) - 28 Oct 2020 (Study Day 75)	Hypokalemia
Potassium phosphate dibasic	28 Oct 2020 (Study Day 75) - 29 Oct 2020 (Study Day 76)	Generalized Pain
Tamsulosin hydrochloride	28 Oct 2020 (Study Day 75) - 01 Nov 2020 (Study Day 79)	Urinary Retention
Vitamin b1 nos	28 Oct 2020 (Study Day 75) - 02 Nov 2020 (Study Day 80)	Nutritional Supplement
Vitamins nos	28 Oct 2020 (Study Day 75) - 02 Nov 2020 (Study Day 80)	Nutritional Supplement
Enoxaparin sodium	29 Oct 2020 (Study Day 76) - 02 Nov 2020 (Study Day 80)	Alcohol Withdrawal Symptoms
Magnesium oxide	29 Oct 2020 (Study Day 76) - 02 Nov 2020 (Study Day 80)	Alcohol Withdrawal Symptoms
Pantoprazole sodium sesquihydrate	01 Nov 2020 (Study Day 79) - 02 Nov 2020 (Study Day 80)	Alcohol Withdrawal Symptoms
Vitamin b12 nos	01 Nov 2020 (Study Day 79) - 02 Nov 2020 (Study Day 80)	Alcohol Withdrawal Symptoms

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Alcohol Poisoning	Grade 4	Not related	13 Oct 2020 (Study Day 60) - 14 Oct 2020 (Study Day 61)
Chronic Sinusitis	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Hyperglycaemia	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Hypokalaemia	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Osteoarthritis	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Pain	Grade 3/severe	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Periorbital Haematoma	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Periorbital Haemorrhage	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Skin Laceration	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Spinal Osteoarthritis	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Thrombocytopenia	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Transaminases Increased	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Upper Limb Fracture	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Vertigo	Grade 1/mild	Not related	13 Oct 2020 (Study Day 60) - Ongoing
Wheezing	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 60) - 20 Oct 2020 (Study Day 67)
Vomiting	Grade 2/moderate	Not related	14 Oct 2020 (Study Day 61) - 14 Oct 2020 (Study Day 61)
Alcohol Poisoning	Grade 3/severe	Not related	27 Oct 2020 (Study Day 74) - 28 Oct 2020 (Study Day 75)
Clavicle Fracture	Grade 1/mild	Not related	27 Oct 2020 (Study Day 74) - Ongoing
Thoracic Vertebral Fracture	Grade 1/mild	Not related	27 Oct 2020 (Study Day 74) - Ongoing
Wheezing	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 74) - 01 Nov 2020 (Study Day 79)
Arthralgia	Grade 3/severe	Not related	28 Oct 2020 (Study Day 75) - Ongoing
Back Pain	Grade 1/mild	Not related	28 Oct 2020 (Study Day 75) - Ongoing
Hyponatraemia	Grade 1/mild	Not related	28 Oct 2020 (Study Day 75) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypophosphataemia	Grade 2/moderate	Not related	28 Oct 2020 (Study Day 75) - 29 Oct 2020 (Study Day 76)
Urinary Retention	Grade 3/severe	Not related	28 Oct 2020 (Study Day 75) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US308-2051 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bile Duct Stone/Choledocholithiasis	SAE	Grade 4	Not related	26 Aug 2020 (Study Day 9) – 30 Sep 2020 (Study Day 44)	Recovered/ resolved
Pancreatitis Acute/Acute Pancreatitis	SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 4	Not related	26 Aug 2020 (Study Day 9) – 30 Sep 2020 (Study Day 44)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US308-2051, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 18 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of bile duct stone. On 07 Sep 2020 (Study Day 21), the IP dose was discontinued due to serious adverse event. The event of choledocholithiasis lasted for 36 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 44). The investigator assessed the event of bile duct stone to be not related to the IP.

On 26 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of pancreatitis acute. On 07 Sep 2020 (Study Day 21), the IP dose was discontinued due to serious adverse event. The event of acute pancreatitis lasted for 36 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 44). The investigator assessed the event of pancreatitis acute to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000266	Bile duct stone
MOD-2020-000266	Pancreatitis acute

Study Completion/Discontinuation

On 08 Sep 2020 (Study Day 22), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	Jan 2008 - Ongoing
Hepatic cirrhosis	Cirrhosis of liver	2014 - Ongoing
Acute kidney injury	Acute renal failure	May 2014 - May 2014
Cholecystectomy	Cholecystectomy	May 2014 - May 2014
Cholecystitis acute	Acute cholecystitis	May 2014 - May 2014
Encephalopathy	Acute encephalopathy	11 May 2014 (Study Day -2291) - 11 May 2014 (Study Day -2291)
Varices oesophageal	Esophageal varices	18 Jun 2014 (Study Day -2253) - Ongoing
Hepatitis C	Hepatitis c	Jul 2014 - Oct 2014
Benign prostatic hyperplasia	Benign prostatic hypertrophy	Jan 2019 - Ongoing
Neuralgia	Abdominal nerve pain	Jan 2019 - Ongoing
Headache	Headache	Jun 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	Jan 2008 - 09 Jul 2020 (Study Day -40)	Hypothyroidism
Gabapentin	15 Jan 2019 (Study Day -581) - Ongoing	Nerve Pain [abdominal]
Rivaroxaban	15 Jan 2019 (Study Day -581) - Ongoing	Stroke Prevention
Tamsulosin	18 Jan 2019 (Study Day -578) - Ongoing	Benign Prostatic Hypertrophy
Finasteride	19 Jan 2019 (Study Day -577) - Ongoing	Benign Prostatic Hypertrophy
Sumatriptan	Jun 2019 - Ongoing	Moderate Headaches

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	24 Aug 2020 (Study Day 7) - 24 Aug 2020 (Study Day 7)	Epigastric Abdominal Pain (Ae #6)
Ciprofloxacin hydrochloride	26 Aug 2020 (Study Day 9) - Ongoing	Acute Pancreatitis
Docusate	26 Aug 2020 (Study Day 9) - Ongoing	Constipation
Enoxaparin sodium	26 Aug 2020 (Study Day 9) - 08 Sep 2020 (Study Day 22)	Prevention Of Emboli
Hydromorphone	26 Aug 2020 (Study Day 9) - 26 Aug 2020 (Study Day 9)	Abdominal Pain (Ae #6)
Iohexol	26 Aug 2020 (Study Day 9) - 26 Aug 2020 (Study Day 9)	Contrast For Procedure
Iopamidol	26 Aug 2020 (Study Day 9) - 26 Aug 2020 (Study Day 9)	Contrast For A Procedure
Meropenem	26 Aug 2020 (Study Day 9) - 26 Aug 2020 (Study Day 9)	Bacterial Infection (Sepsis)
Nicotine	26 Aug 2020 (Study Day 9) - Ongoing	Smoking Cessation
Paracetamol	26 Aug 2020 (Study Day 9) - 08 Sep 2020 (Study Day 22)	Abdominal Pain (Ae #6)
Propranolol	26 Aug 2020 (Study Day 9) - Ongoing	Epigastric Abdominal Pain/Headache
Endoscopic retrograde cholangiopancreatography with sphincterotomy, balloon extraction, balloon sweep, and pd stent placement.*	28 Aug 2020 (Study Day 11) - 28 Aug 2020 (Study Day 11)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain Upper	Grade 2/moderate	Not related	24 Aug 2020 (Study Day 7) - 30 Sep 2020 (Study Day 44)
Headache	Grade 2/moderate	Not related	26 Aug 2020 (Study Day 9) - 30 Sep 2020 (Study Day 44)
Sepsis	Grade 2/moderate	Not related	26 Aug 2020 (Study Day 9) - 26 Aug 2020 (Study Day 9)
Benign Hepatic Neoplasm	Grade 2/moderate	Not related	27 Aug 2020 (Study Day 10) - 30 Sep 2020 (Study Day 44)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US308-2081 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis	SAE	Grade 3/severe	Not related	02 Oct 2020 (Study Day 43) – 19 Oct 2020 (Study Day 60)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US308-2081, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 43), 42 days after the first dose and 11 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 18 days, after which it was considered to be recovered/resolved on 19 Oct 2020 (Study Day 60). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000813	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Malignant melanoma	Skin melanoma left arm	Jan 2013 - Jan 2013
Squamous cell carcinoma	Squamous cell melanoma right finger	Feb 2015 - Feb 2015
Oesophagitis	Esophagitis	Jan 2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexlansoprazole	01 Jan 2017 (Study Day -1328) - Ongoing	Esophsgitis
Ibuprofen	22 Aug 2020 (Study Day 2) - 22 Aug 2020 (Study Day 2)	Injection Site Pain
Ibuprofen	23 Aug 2020 (Study Day 3) - Ongoing	General Pain Preventative
Corticosteroid nos	11 Sep 2020 (Study Day 22) - 11 Sep 2020 (Study Day 22)	R Arm/Shoulder Bursitis
Naproxen sodium	11 Sep 2020 (Study Day 22) - 14 Sep 2020 (Study Day 25)	R Arm/Shoulder Bursitis
Prednisone	12 Sep 2020 (Study Day 23) - 17 Sep 2020 (Study Day 28)	R Arm/Shoulder Bursitis
Diphenhydramine hydrochloride	01 Oct 2020 (Study Day 42) - 02 Oct 2020 (Study Day 43)	Hives (Arms & Legs)
Aluminium hydroxide; magnesium hydroxide; simeticone	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Ae #2 [cholecystitis]
Enoxaparin sodium	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Thrombosis Prophylaxis (From Sae)
Fentanyl	02 Oct 2020 (Study Day 43) - 03 Oct 2020 (Study Day 44)	Abdominal Pain From Cholecystitis (From Sae)
Hydromorphone hydrochloride	02 Oct 2020 (Study Day 43) - 05 Oct 2020 (Study Day 46)	Abdominal Pain From Cholecystitis (From Sae)
Hyoscyamine	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Cholecystitis
Iopamidol	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Contrast Agent
Lidocaine hydrochloride	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Local Anesthetic
Oxycodone	02 Oct 2020 (Study Day 43) - 05 Oct 2020 (Study Day 46)	Abdominal Pain From Cholecystitis (From Sae)
Pantoprazole	02 Oct 2020 (Study Day 43) - 05 Oct 2020 (Study Day 46)	Ae #2 [cholecystitis]
Paracetamol	02 Oct 2020 (Study Day 43) - 05 Oct 2020 (Study Day 46)	Abdominal Pain (From Sae)
Promethazine	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Nausea Prophylaxis (From Sae)
Bupivacaine; lidocaine	03 Oct 2020 (Study Day 44) - 03 Oct 2020 (Study Day 44)	Local (Abdomin) Anesthesia
Cefotetan	03 Oct 2020 (Study Day 44) - 03 Oct 2020 (Study Day 44)	Ae #2 (Cholecystitis)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cholecystectomy*	03 Oct 2020 (Study Day 44) - 03 Oct 2020 (Study Day 44)	Adverse Event
Hydromorphone hydrochloride	03 Oct 2020 (Study Day 44) - 03 Oct 2020 (Study Day 44)	Abdominal Pain From Cholecystitis (From Sae)
Methocarbamol	03 Oct 2020 (Study Day 44) - 05 Oct 2020 (Study Day 46)	Ae #2 [cholecystitis]
Midazolam	03 Oct 2020 (Study Day 44) - 03 Oct 2020 (Study Day 44)	Anesthesia (From Cholecystectomy)
Enoxaparin sodium	04 Oct 2020 (Study Day 45) - 04 Oct 2020 (Study Day 45)	Thrombosis Prophylaxis (From Sae)
Lorazepam	04 Oct 2020 (Study Day 45) - 04 Oct 2020 (Study Day 45)	Anxiolytic (Anxiety)
Oxycodone	05 Oct 2020 (Study Day 46) - 19 Oct 2020 (Study Day 60)	Pain Reliever For Cholecystitis
Paracetamol	05 Oct 2020 (Study Day 46) - Ongoing	Pain Reliever For Cholecystitis
Sennoside a+b	05 Oct 2020 (Study Day 46) - 04 Nov 2020 (Study Day 76)	Constipation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Bursitis	Grade 2/moderate	Not related	10 Sep 2020 (Study Day 21) - 17 Sep 2020 (Study Day 28)
Urticaria	Grade 2/moderate	Related	01 Oct 2020 (Study Day 42) - 05 Oct 2020 (Study Day 46)
Constipation	Grade 2/moderate	Not related	05 Oct 2020 (Study Day 46) - 04 Nov 2020 (Study Day 76)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US308-2136 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Invasive Ductal Breast Carcinoma/Stage 1a, T1c, Pn0, M0, Her2 Positive, Estrogen Negative, Invasive Ductal Carcinoma Of The Left Breast	SAE	Grade 2/ moderate	Not related	19 Nov 2020 (Study Day 84) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US308-2136, a 44-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 28 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Nov 2020 (Study Day 84), 83 days after the first dose and 52 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of invasive ductal breast carcinoma. Action taken with the IP was not applicable. The event of stage 1a, t1c, pn0, m0, her2 positive, estrogen negative, invasive ductal carcinoma of the left breast was considered to be ongoing. The investigator assessed the event of invasive ductal breast carcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009930	Invasive ductal breast carcinoma

Study Completion/Discontinuation

On 07 Jan 2021 (Study Day 133), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Fibrocystic breast disease	Cystic breasts	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levonorgestrel	2016 - Ongoing	Birth Control
Influenza vaccine	14 Oct 2020 (Study Day 48) - 14 Oct 2020 (Study Day 48)	Prophylaxis
Ibuprofen	20 Oct 2020 (Study Day 54) - 20 Oct 2020 (Study Day 54)	Headache
Ibuprofen	21 Oct 2020 (Study Day 55) - 21 Oct 2020 (Study Day 55)	Headache
Cabazitaxel	08 Dec 2020 (Study Day 103) - Ongoing	Breast Cancer (Left)
Docetaxel	08 Dec 2020 (Study Day 103) - Ongoing	Breast Cancer (Left)
Pertuzumab	08 Dec 2020 (Study Day 103) - Ongoing	Breast Cancer (Left)
Trastuzumab	08 Dec 2020 (Study Day 103) - Ongoing	Breast Cancer (Left)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 2/moderate	Not related	20 Oct 2020 (Study Day 54) - 21 Oct 2020 (Study Day 55)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US309-2021 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Obstructive Pulmonary Disease/Copd Exacebration	SAE	Grade 3/severe	Not related	15 Nov 2020 (Study Day 103) – 17 Nov 2020 (Study Day 105)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2021, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Nov 2020 (Study Day 103), 102 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of copd exacebration lasted for 3 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 105). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002074	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2002 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2005 - Ongoing
Arthralgia	Left knee pain	2011 - Ongoing
Hypertension	Hypertension	2011 - Ongoing
Knee arthroplasty	Left knee arthoplasty	2011 - 2011
Spinal osteoarthritis	Osteoarthritis arthritis in back	2011 - Ongoing
Neuropathy peripheral	Neuropathy legs and hands	2013 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Chronic obstructive pulmonary disease	Copd	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hypecholesterlemia
Insulin degludec	Not reported - Ongoing	Diabetes
Losartan	Not reported - Ongoing	Hypertension
Omeprazole	Not reported - Ongoing	Gastroesophageal Relux Disease
Insulin aspart	2008 - Ongoing	Diabetes
Hydrocodone bitartrate; paracetamol	2011 - Ongoing	Left Knee Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US309-2022 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dizziness/Worsening Dizziness	SAE	Grade 4	Not related	03 Oct 2020 (Study Day 60) – 06 Oct 2020 (Study Day 63)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2022, a 57-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Oct 2020 (Study Day 60), 59 days after the first dose and 31 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dizziness. Action taken with the IP was not applicable. The event of worsening dizziness lasted for 4 days, after which it was considered to be recovered/resolved on 06 Oct 2020 (Study Day 63). The investigator assessed the event of dizziness to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000419	Dizziness

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Prostate cancer	Prostate cancer	2010 - Not reported
Prostatectomy	Prostatectomy	2010 - Not reported
Limb injury	Left shoulder injury	2012 - 2012
Shoulder operation	Left shoulder surgery (due to injury)	2012 - 2012
Limb injury	Left shoulder pain due to injury	Dec 2012 - Ongoing
Foot fracture	Right foot fracture	2015 - 2015
Medical device implantation	Right metatarsal rod to repair fracture	2015 - 2015
Wound	Chronic right foot wound (s/p multiple surgeries)	2015 - Ongoing
Peripheral sensory neuropathy	Sensory neuropathy bilateral feet	2016 - Ongoing
Anxiety	Anxiety	2017 - Ongoing
Back injury	Back pain due to injury	2017 - Ongoing
Bradycardia	Bradycardia	2017 - Ongoing
Dizziness	History of dizziness secondary to neck injury sustained in military	2017 - Ongoing
Neck injury	Chronic neck pain due to injury	2017 - Ongoing
Neck injury	Neck injury (sustained in military)	2017 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2018 - Ongoing
Hypertension	Hypertension	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Etodolac	2016 - Ongoing	Left Shoulder Pain
Gabapentin	2016 - Ongoing	Neuropathy Bilateral Feet
Clonazepam	2017 - Ongoing	Anxiety
Atorvastatin	2018 - Ongoing	Hyperlpidemia
Lisinopril	2018 - 04 Oct 2020 (Study Day 61)	Hypertension
Second metatarsal replacement*	22 Sep 2020 (Study Day 49) - 22 Sep 2020 (Study Day 49)	Adverse Event
Ceftriaxone; vancomycin	03 Oct 2020 (Study Day 60) - 06 Oct 2020 (Study Day 63)	Right 2nd Toe Staphaloccoccus Infection
Morphine	03 Oct 2020 (Study Day 60) - 06 Oct 2020 (Study Day 63)	Right Foot Pain
Amoxicillin	06 Oct 2020 (Study Day 63) - 13 Oct 2020 (Study Day 70)	Right 2nd Toe Staphaloccoccus Infection

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diclofenac sodium	06 Oct 2020 (Study Day 63) - 05 Nov 2020 (Study Day 93)	Right 2nd Toe Staphaloccoccus Infection
Doxycycline hyclate	06 Oct 2020 (Study Day 63) - 13 Oct 2020 (Study Day 70)	Right 2nd Toe Staphaloccoccus Infection
Lidocaine	06 Oct 2020 (Study Day 63) - 05 Nov 2020 (Study Day 93)	Right 2nd Toe Staphaloccoccus Infection
Lisinopril	06 Oct 2020 (Study Day 63) - Ongoing	Hypertension
Right rotator cuff reattachment*	15 Dec 2020 (Study Day 133) - 15 Dec 2020 (Study Day 133)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Limb Injury	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 49) - 22 Sep 2020 (Study Day 49)
Staphylococcal Skin Infection	Grade 1/mild	Not related	22 Sep 2020 (Study Day 49) - 06 Oct 2020 (Study Day 63)
Acute Kidney Injury	Grade 1/mild	Not related	03 Oct 2020 (Study Day 60) - 05 Oct 2020 (Study Day 62)
Lethargy	Grade 1/mild	Not related	03 Oct 2020 (Study Day 60) - 06 Oct 2020 (Study Day 63)
Rotator Cuff Syndrome	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 133) - 15 Dec 2020 (Study Day 133)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US309-2043 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asthma/Asthma Exacerbation	SAE	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 58) – 10 Nov 2020 (Study Day 97)	Recovered/resolved
Chronic Obstructive Pulmonary Disease/Chronic Obstructive Pulmonary Disease Exacerbation	SAE	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 58) – 10 Nov 2020 (Study Day 97)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2043, a 69-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 58), 57 days after the first dose and 29 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of asthma. Action taken with the IP was not applicable. The event of asthma exacerbation lasted for 40 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 97). The investigator assessed the event of asthma to be not related to the IP.

On 02 Oct 2020 (Study Day 58), 57 days after the first dose and 29 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of chronic obstructive pulmonary disease exacerbation lasted for 40 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 97). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000739	Asthma
MOD-2020-000739	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1954 - Ongoing
Female sterilisation	Tubal ligation	1977 - 1977
Insomnia	Insomnia	1990 - Ongoing
Seasonal allergy	Mid seasonal allergies	1995 - Ongoing
Uterine leiomyoma	Uterine fibroids	1998 - Jan 1998
Hysterectomy	Hysterectomy	Jan 1998 - Jan 1998
Hypertension	Hereditary hypertension	2000 - Ongoing
Bronchitis chronic	Chronic bronchitis	Dec 2019 - Ongoing
Chronic obstructive pulmonary disease	Copd	Dec 2019 - Ongoing
Emphysema	Emphysema	16 Jul 2020 (Study Day -21) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2006 - 28 Aug 2020 (Study Day 23)	Hypertension
Montelukast	2019 - Ongoing	Mid Seasonal Allergic Rhinitis
Roflumilast	Dec 2019 - 07 Sep 2020 (Study Day 33)	Chronic Obstructive Pulmonary Disease
Omalizumab	23 Sep 2020 (Study Day 49) - Ongoing	Asthma/Chronic Obstructive Pulmonary Disease
Losartan	Oct 2020 - Ongoing	Hypertension
Hepatitis a vaccine; hepatitis b vaccine	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Prophylaxis Hepatitis A & B
Influenza vaccine	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Prophylaxis Influenza

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tetanus vaccine	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Prophylaxis Tetanus
Varicella zoster vaccine	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Prophylaxis Shingles
Prednisone	02 Oct 2020 (Study Day 58) - 09 Oct 2020 (Study Day 65)	Asthma/Copd Exacerbation
Prednisone	04 Nov 2020 (Study Day 91) - 12 Nov 2020 (Study Day 99)	Asthma/Copd Exacerbation
Benzonatate	12 Nov 2020 (Study Day 99) - Ongoing	Cough Due To Asthma/Copd Exacerbation
Guaifenesin	12 Nov 2020 (Study Day 99) - 19 Nov 2020 (Study Day 106)	Asthma/Copd
Pantoprazole sodium sesquihydrate	12 Nov 2020 (Study Day 99) - Ongoing	Cough Due To Exacerbated Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US309-2047 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 40)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Obstructive Pulmonary Disease/Copd Exacerbation	SAE	Grade 3/severe	Not related	14 Mar 2021 (Study Day 221) – 18 Mar 2021 (Study Day 225)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2047, a 47-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 40). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Mar 2021 (Study Day 221), 220 days after the first dose and 181 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of copd exacerbation lasted for 5 days, after which it was considered to be recovered/resolved on 18 Mar 2021 (Study Day 225). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-047384	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	Not reported - Ongoing
Asthma	Moderate asthma	1994 - Ongoing
Type 2 diabetes mellitus	Dmt2	2002 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	Not reported - Ongoing	Diabetes
Insulin glargine	Not reported - Ongoing	Diabetes
Salbutamol	Not reported - Ongoing	Asthma
Paracetamol	10 Aug 2020 (Study Day 5) - 13 Aug 2020 (Study Day 8)	Chest Pain
Paracetamol	12 Aug 2020 (Study Day 7) - 12 Aug 2020 (Study Day 7)	Headache
Influenza vaccine	19 Oct 2020 (Study Day 75) - 19 Oct 2020 (Study Day 75)	Flu Prevention
Methocarbamol	13 Mar 2021 (Study Day 220) - Ongoing	Chronic Low Back Pain
Torasemide	13 Mar 2021 (Study Day 220) - Not reported	Copd Exarcebation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chronic Obstructive Pulmonary Disease	Grade 1/mild	Not related	Not reported - Ongoing
Cough	Grade 1/mild	Not related	10 Aug 2020 (Study Day 5) - 13 Aug 2020 (Study Day 8)
Musculoskeletal Chest Pain	Grade 1/mild	Not related	10 Aug 2020 (Study Day 5) - 13 Aug 2020 (Study Day 8)
Headache	Grade 1/mild	Related	12 Aug 2020 (Study Day 7) - 14 Aug 2020 (Study Day 9)
Cough	Grade 1/mild	Not related	09 Oct 2020 (Study Day 65) - 09 Nov 2020 (Study Day 96)
Pain	Grade 1/mild	Not related	09 Oct 2020 (Study Day 65) - 09 Nov 2020 (Study Day 96)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US309-2112 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 50)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Pain/Worsening Of Back Pain	SAE	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 175) – 06 Feb 2021 (Study Day 180)	Recovered/resolved with sequelae
Gout/Worsening Of Bilateral Foot Pain (Secondary To Gout)	SAE	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 175) – 06 Feb 2021 (Study Day 180)	Recovered/resolved
Oedema Peripheral/Bilateral Foot Edema	SAE	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 175) – 06 Feb 2021 (Study Day 180)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2112, a 68-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 29 Sep 2020 (Study Day 50). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Feb 2021 (Study Day 175), 174 days after the first dose and 125 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of back pain. Action taken with the IP was not applicable. The event of worsening of back pain lasted for 6 days, after which it was considered to be recovered/resolved with sequelae on 06 Feb 2021 (Study Day 180). The investigator assessed the event of back pain to be not related to the IP.

On 01 Feb 2021 (Study Day 175), 174 days after the first dose and 125 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of gout. Action taken with the IP was not applicable. The event of worsening of bilateral foot pain (secondary to gout) lasted for 6 days, after which it was considered to be recovered/resolved on 06 Feb 2021 (Study Day 180). The investigator assessed the event of gout to be not related to the IP.

On 01 Feb 2021 (Study Day 175), 174 days after the first dose and 125 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of oedema peripheral. Action taken with the IP was not applicable. The event of bilateral foot edema lasted for 6 days, after which it was considered to be recovered/resolved on 06 Feb 2021 (Study Day 180). The investigator assessed the event of gout to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-022252	Back pain
MOD-2021-022252	Gout
MOD-2021-022252	Oedema peripheral

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Spinal fracture	Spinal fracture	Not reported - Ongoing
Temporomandibular joint syndrome	Temporomandibular joint dysfunction	1979 - Ongoing
Postmenopause	Post-menopausal	2002 - Ongoing
Cerebrovascular accident	Massive stroke	2008 - 2008
Hypertension	Hypertension	2015 - Ongoing
Back pain	Chronic back pain	2016 - Ongoing
Gout	Intermittent bilateral foot pain secondary to gout	2016 - Ongoing
Gout	Intermittent gout (bilateral feet)	2016 - Ongoing
Kidney infection	Intermittent kidney infections	2016 - Ongoing
Sepsis	Sepsis	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diazepam	1985 - Ongoing	Tempormandibular Joint Dysfunction
Lisinopril	2016 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atropine sulfate; diphenoxylate hydrochloride	15 Sep 2020 (Study Day 36) - 17 Sep 2020 (Study Day 38)	Diarrhea
Naproxen sodium	18 Oct 2020 (Study Day 69) - 19 Oct 2020 (Study Day 70)	Low Grade Fever <100.4
Dexamethasone	01 Feb 2021 (Study Day 175) - Ongoing	Bilateral Foot Pain/ Bilateral Edema/Worsening Of Back Pain
Tramadol	01 Feb 2021 (Study Day 175) - 06 Feb 2021 (Study Day 180)	Bilateral Foot Pain
Physical therapy*	20 Feb 2021 (Study Day 194) - 20 Feb 2021 (Study Day 194)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 1/mild	Not related	15 Sep 2020 (Study Day 36) - 17 Sep 2020 (Study Day 38)
Nausea	Grade 1/mild	Related	15 Sep 2020 (Study Day 36) - 17 Sep 2020 (Study Day 38)
Pyrexia	Grade 1/mild	Not related	18 Oct 2020 (Study Day 69) - 19 Oct 2020 (Study Day 70)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US309-2245 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post-Traumatic Pain/Chest Pain Traumatic Due To Motor Vehicle Accident	SAE	Grade 2/moderate	Not related	21 Nov 2020 (Study Day 87) – 25 Nov 2020 (Study Day 91)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US309-2245, a 66-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Nov 2020 (Study Day 87), 86 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of post-traumatic pain. Action taken with the IP was not applicable. The event of chest pain traumatic due to motor vehicle accident lasted for 5 days, after which it was considered to be recovered/resolved on 25 Nov 2020 (Study Day 91). The investigator assessed the event of post-traumatic pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000901	Post-traumatic pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Partial hysterectomy	2001 - 2001
Postmenopause	Post menopausal	2001 - Ongoing
Dyspnoea	Intermittent shortness of breath	2010 - Ongoing
Arthralgia	Bilateral ankle pain	2015 - Ongoing
Arthralgia	Bilateral knee pain	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Depression	Depression	2017 - Ongoing
Flank pain	Upper left torso pain secondary to shingles	2017 - Ongoing
Glaucoma	Bilateral glaucoma	2017 - Ongoing
Herpes zoster	Shingles	2017 - 2017
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Muscle spasms	Muscle spasms bilateral legs	2017 - Ongoing
Hypertonic bladder	Overactive bladder	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2015 - Ongoing	Hypertension
Hydrochlorothiazide; lisinopril	2015 - Ongoing	Hypertension
Ibuprofen	2015 - Ongoing	Bilateral Knee And Ankle Pain
Naproxen sodium	2015 - Ongoing	Bilateral Knee Pain
Paracetamol	2015 - Ongoing	Back Knee Pain Back Ankle Pain
Atorvastatin	2017 - Ongoing	Hypercholesterolemia
Gabapentin	2017 - Ongoing	Upper Right Torso Pain Secondary To Shingles
Sertraline	2017 - Ongoing	Depression
Travoprost	2017 - Ongoing	Glaucoma
Varicella zoster vaccine	Feb 2020 - Feb 2020	Prophylaxis
Cyclobenzaprine	Jun 2020 - Ongoing	Muscle Spasms Bilateral Legs
Oxybutynin	20 Jun 2020 (Study Day -68) - 09 Mar 2021 (Study Day 195)	Overactive Bladder
Ibuprofen	30 Sep 2020 (Study Day 35) - 04 Oct 2020 (Study Day 39)	Body/Muscle Aches
Naproxen sodium	30 Sep 2020 (Study Day 35) - 04 Oct 2020 (Study Day 39)	Body/Muscle Aches

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	30 Sep 2020 (Study Day 35) - 04 Oct 2020 (Study Day 39)	Body/Muscle Ache
Occupational therapy*	22 Nov 2020 (Study Day 88) - 22 Nov 2020 (Study Day 88)	Adverse Event
Physical therapy*	22 Nov 2020 (Study Day 88) - 22 Nov 2020 (Study Day 88)	Adverse Event
Tramadol	01 Dec 2020 (Study Day 97) - Ongoing	Motor Vehicle Accident
Codeine phosphate; paracetamol	01 Jan 2021 (Study Day 128) - 14 Jan 2021 (Study Day 141)	Secondary/Motor Vehicle Accident
Amitriptyline	19 Jan 2021 (Study Day 146) - Ongoing	Sleep Aide From Mva Due To Pain Left Upper And Lower Extremities & Lbp
Urodynamics testing*	03 Mar 2021 (Study Day 189) - 03 Mar 2021 (Study Day 189)	Adverse Event
Cytoscopy*	09 Mar 2021 (Study Day 195) - 09 Mar 2021 (Study Day 195)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Post-Traumatic Pain	Grade 1/mild	Not related	21 Nov 2020 (Study Day 87) - Ongoing
Road Traffic Accident	Grade 2/moderate	Not related	21 Nov 2020 (Study Day 87) - 21 Nov 2020 (Study Day 87)
Hypertonic Bladder	Grade 1/mild	Not related	15 Dec 2020 (Study Day 111) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US310-2052 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	25 Aug 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arrhythmia/Arrhythmia (Unknown Type, Worsening)	SAE	Grade 2/moderate	Not related	19 Oct 2020 (Study Day 83) – 23 Dec 2020 (Study Day 148)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US310-2052, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 25 Aug 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Oct 2020 (Study Day 83), 82 days after the first dose and 55 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of arrhythmia. Action taken with the IP was not applicable. The event of arrhythmia (unknown type, worsening) lasted for 66 days, after which it was considered to be recovered/resolved on 23 Dec 2020 (Study Day 148). The investigator assessed the event of arrhythmia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009568	Arrhythmia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	1956 - Ongoing
Vasectomy	Vasectomy	1986 - 1986
Intervertebral disc protrusion	Herniated disc	1991 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Insomnia	Insomnia	2005 - Ongoing
Arteriosclerosis	Ateriosclerosis	2008 - Ongoing
Coronary arterial stent insertion	Cardiac stent insertion	2008 - 2008
Drug hypersensitivity	Lipitor allergy	2008 - Ongoing
Myocardial infarction	Myocardial infarction	2008 - 2008
Coronary arterial stent insertion	Cardiac stent insertion	2010 - 2010
Drug hypersensitivity	Lisinopril allergy	2010 - Ongoing
Rotator cuff syndrome	Torn rotator cuffs, bilateral shoulders	2016 - Ongoing
Dyspepsia	Heartburn	2018 - Ongoing
Hepatitis C	Hepatitis c	Feb 2018 - Feb 2018
Arrhythmia	Arrhythmia (unknown type)	2019 - Ongoing
Chronic kidney disease	Kidney disease stage 1	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	2005 - 19 Jan 2021 (Study Day 175)	Sleep Aid
Isosorbide mononitrate	2009 - 16 Dec 2020 (Study Day 141)	Heart Preventative (Arrhythmia)
Budesonide	2017 - Ongoing	Allergic Rhinitis
Pantoprazole	2018 - Ongoing	Heartburn
Acetylsalicylic acid	Mar 2020 - Ongoing	Herniated Disc
Amlodipine	Mar 2020 - Ongoing	Hypertension
Metoprolol	20 Oct 2020 (Study Day 84) - 30 Nov 2020 (Study Day 125)	Arrhythmia, Unknown Type (Worsening)
Angiogram*	30 Nov 2020 (Study Day 125) - 30 Nov 2020 (Study Day 125)	Adverse Event
Metoprolol	30 Nov 2020 (Study Day 125) - 19 Jan 2021 (Study Day 175)	Arrhythmia
Echocardiogram*	16 Dec 2020 (Study Day 141) - 16 Dec 2020 (Study Day 141)	Adverse Event
Quadruple bypass*	16 Dec 2020 (Study Day 141) - 16 Dec 2020 (Study Day 141)	Adverse Event
Metoprolol	19 Jan 2021 (Study Day 175) - Ongoing	Arrythmia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pregabalin	19 Jan 2021 (Study Day 175) - Ongoing	Pain - Herniated Disc
Trazodone	19 Jan 2021 (Study Day 175) - Ongoing	Sleep Aid (For Insomnia)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ageusia	Grade 1/mild	Not related	19 Oct 2020 (Study Day 83) - 22 Oct 2020 (Study Day 86)
Cough	Grade 1/mild	Not related	19 Oct 2020 (Study Day 83) - 24 Oct 2020 (Study Day 88)
Dyspnoea	Grade 1/mild	Not related	19 Oct 2020 (Study Day 83) - 24 Oct 2020 (Study Day 88)
Dyspnoea	Grade 1/mild	Not related	19 Oct 2020 (Study Day 83) - 23 Oct 2020 (Study Day 87)
Fatigue	Grade 2/moderate	Not related	19 Oct 2020 (Study Day 83) - 23 Oct 2020 (Study Day 87)
Headache	Grade 1/mild	Not related	19 Oct 2020 (Study Day 83) - 23 Oct 2020 (Study Day 87)
Nasal Congestion	Grade 1/mild	Not related	19 Oct 2020 (Study Day 83) - 23 Oct 2020 (Study Day 87)
Rhinorrhoea	Grade 1/mild	Not related	20 Oct 2020 (Study Day 84) - 23 Oct 2020 (Study Day 87)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US310-2061 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	30 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Atrial Fibrillation With Rvr	SAE	Grade 3/severe	Not related	20 Aug 2020 (Study Day 22) – 23 Aug 2020 (Study Day 25)	Recovered/resolved
Hypertensive Urgency/Hypertensive Urgency	SAE	Grade 3/severe	Not related	20 Aug 2020 (Study Day 22) – 23 Aug 2020 (Study Day 25)	Recovered/resolved
Nausea/Nausea	SAE	Grade 3/severe	Not related	20 Aug 2020 (Study Day 22) – 23 Aug 2020 (Study Day 25)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US310-2061, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Aug 2020 (Study Day 22), 21 days after the first dose and 12 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. The IP dose was delayed due to the atrial fibrillation with rvr. The event of atrial fibrillation with rvr lasted for 4 days, after which it was considered to be recovered/resolved on 23 Aug 2020 (Study Day 25). The investigator assessed the event of atrial fibrillation to be not related to the IP.

On 20 Aug 2020 (Study Day 22), 21 days after the first dose and 12 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypertensive urgency. The IP dose was delayed due to the hypertensive urgency. The event of hypertensive urgency lasted for 4 days, after which it was considered to be recovered/resolved on 23 Aug 2020

(Study Day 25). The investigator assessed the event of hypertensive urgency to be not related to the IP.

On 20 Aug 2020 (Study Day 22), 21 days after the first dose and 12 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of nausea. The IP dose was delayed due to the nausea. The event of nausea lasted for 4 days, after which it was considered to be recovered/resolved on 23 Aug 2020 (Study Day 25). The investigator assessed the event of nausea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000225	Atrial fibrillation
MOD-2020-000225	Hypertensive urgency
MOD-2020-000225	Nausea

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nausea	Nausea	1990 - Ongoing
Substance use	Marijuana use	1990 - Ongoing
Aortic aneurysm	Abdominal aortic aneurysm	2015 - 2015
Milk allergy	Allergic to milk	2015 - Ongoing
Urticaria	Allergic to aspirin - hives reaction	2015 - Ongoing
Coronary artery disease	Coronary artery disease	2016 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Myocardial infarction	Myocardial infarction	2016 - 2016
Depression	Depression - mild	2018 - Ongoing
Knee arthroplasty	Left knee replacement	2018 - 2018
Atrial fibrillation	Arrhythmia (atrial fibrillation)	2019 - Ongoing
Dementia	Dementia	2019 - Ongoing
Seasonal allergy	Allergic rhinitis: seasonal	2019 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease (gerd)	2020 - Ongoing
Basal cell carcinoma	Basal cell carcinoma (forehead)	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2016 - Ongoing	Hypertension
Atorvastatin	2016 - 21 Sep 2020 (Study Day 54)	Hyperlipidemia
Clopidogrel	2016 - Ongoing	Coronary Artery Disease
Metoprolol succinate	2016 - Ongoing	Hypertension
Ubidecarenone	2016 - Ongoing	High Blood Pressure, Migraines
Trazodone	2018 - Ongoing	Mild Depression
Apixaban	2019 - Ongoing	Atrial Fibrillation
Cetirizine	2019 - Ongoing	Seasonal Allergies
Fluticasone	2019 - Ongoing	Seasonal Allergies
Memantine	2019 - Ongoing	Dementia
Vitamins nos	2019 - Ongoing	Supplement
Chest x ray*	20 Aug 2020 (Study Day 22) - 20 Aug 2020 (Study Day 22)	Diagnostic
Ct abdomen + pelvis*	20 Aug 2020 (Study Day 22) - 20 Aug 2020 (Study Day 22)	Diagnostic
Ct angio abdomen + pelvis*	20 Aug 2020 (Study Day 22) - 20 Aug 2020 (Study Day 22)	Diagnostic
Ct angio chest*	20 Aug 2020 (Study Day 22) - 20 Aug 2020 (Study Day 22)	Diagnostic
Ekg*	20 Aug 2020 (Study Day 22) - 20 Aug 2020 (Study Day 22)	Diagnostic
Ekg*	22 Aug 2020 (Study Day 24) - 22 Aug 2020 (Study Day 24)	Diagnostic
Buspirone	23 Aug 2020 (Study Day 25) - Oct 2020	Anxiety
Ondansetron	23 Aug 2020 (Study Day 25) - Oct 2020	Nausea
Pantoprazole	23 Aug 2020 (Study Day 25) - 06 Mar 2021 (Study Day 220)	Acid Reflux
Atorvastatin	21 Sep 2020 (Study Day 54) - Ongoing	Hyperlipidemia
Fluorouracil	12 Oct 2020 (Study Day 75) - Ongoing	Basal Cell Carcinoma
Pantoprazole	06 Mar 2021 (Study Day 220) - Ongoing	Acid Reflux

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 1/mild	Not related	20 Aug 2020 (Study Day 22) - 23 Aug 2020 (Study Day 25)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US310-2082 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatitis/Pancreatitis	SAE	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 100) – 16 Nov 2020 (Study Day 106)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US310-2082, a 65-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Nov 2020 (Study Day 100), 99 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pancreatitis. Action taken with the IP was not applicable. The event of pancreatitis lasted for 7 days, after which it was considered to be recovered/resolved on 16 Nov 2020 (Study Day 106). The investigator assessed the event of pancreatitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000778	Pancreatitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergic to penicillin	1960 - Ongoing
Tobacco user	Tobacco use - cigars	2005 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus - type ii	2010 - Ongoing
Alcohol use	Alcohol use (3 drinks per day every day)	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Ppx
Lisinopril	2010 - Ongoing	Hypertension
Metformin	2010 - Ongoing	Diabetes Type Ii
Rosuvastatin	2010 - Ongoing	Hypercholesterolemia
Calcium chloride; potassium chloride; sodium lactate	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Pancreatitis
Ceftriaxone	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Pancreatitis
Citric acid; potassium bicarbonate	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Hypokalemia Ppx
Ct abdomen + pelvis with iv contrast*	11 Nov 2020 (Study Day 101) - 11 Nov 2020 (Study Day 101)	Diagnostic
Glucagon	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Type Ii Diabetes
Glucose	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Type Ii Diabetes
Hydrocodone bitartrate; paracetamol	11 Nov 2020 (Study Day 101) - Ongoing	Pancreatitis
Magnesium oxide	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Hypomagnesemia Ppx
Magnesium sulfate	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Hypomagnesemia Ppx
Metronidazole	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Pancreatitis
Morphine sulfate	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Pancreatitis
Ondansetron	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Nausea/Vomiting Ppx
Potassium chloride	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Hypokalemia Ppx
Sodium chloride	11 Nov 2020 (Study Day 101) - 16 Nov 2020 (Study Day 106)	Pancreatitis
Enoxaparin sodium	12 Nov 2020 (Study Day 102) - 16 Nov 2020 (Study Day 106)	Dvt Ppx

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Xray chest*	12 Nov 2020 (Study Day 102) - 12 Nov 2020 (Study Day 102)	Diagnostic
Hepatobiliary scan*	13 Nov 2020 (Study Day 103) - 13 Nov 2020 (Study Day 103)	Diagnostic
Ct abdomen + pelvis with iv contrast*	14 Nov 2020 (Study Day 104) - 14 Nov 2020 (Study Day 104)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain	Grade 1/mild	Not related	10 Nov 2020 (Study Day 100) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378381

Participant Number:	US310-2311 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bile Duct Stone/Choledocholithiasis	SAE	Grade 3/severe	Not related	13 Jan 2021 (Study Day 135) – 17 Jan 2021 (Study Day 139)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US310-2311, a 37-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Jan 2021 (Study Day 135), 134 days after the first dose and 106 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of bile duct stone. Action taken with the IP was not applicable. The event of choledocholithiasis lasted for 5 days, after which it was considered to be recovered/resolved on 17 Jan 2021 (Study Day 139). The investigator assessed the event of bile duct stone to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005999	Bile duct stone

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tobacco user	Tobacco use - cigarettes	1990 - 2006
Facial paralysis	Bells palsy, facial rt side	2011 - 2011
Dermal filler injection	Juviderm (cosmetic)	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levonorgestrel	2017 - Ongoing	Birth Control Prophylaxis
Cbc - serial throughout hospital stay*	13 Jan 2021 (Study Day 135) - 13 Jan 2021 (Study Day 135)	Adverse Event
Chem panel - serial throughout hospital stay*	13 Jan 2021 (Study Day 135) - 13 Jan 2021 (Study Day 135)	Adverse Event
Urinalysis*	13 Jan 2021 (Study Day 135) - 13 Jan 2021 (Study Day 135)	Adverse Event
Abdominal ultrasound*	14 Jan 2021 (Study Day 136) - 14 Jan 2021 (Study Day 136)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	14 Jan 2021 (Study Day 136) - 14 Jan 2021 (Study Day 136)	Choledocholithiasis
Ct abdomen and pelvis*	14 Jan 2021 (Study Day 136) - 14 Jan 2021 (Study Day 136)	Adverse Event
Fentanyl	14 Jan 2021 (Study Day 136) - 14 Jan 2021 (Study Day 136)	Choledocholithiasis
Ondansetron	14 Jan 2021 (Study Day 136) - 14 Jan 2021 (Study Day 136)	Choledocholithiasis
Paracetamol	14 Jan 2021 (Study Day 136) - 14 Jan 2021 (Study Day 136)	Choledocholithiasis
Endoscopic retrograde cholangiopancreatography (ecrp)*	15 Jan 2021 (Study Day 137) - 15 Jan 2021 (Study Day 137)	Adverse Event
Glucagon	15 Jan 2021 (Study Day 137) - 15 Jan 2021 (Study Day 137)	Surgical Ecrp
Indometacin	15 Jan 2021 (Study Day 137) - 15 Jan 2021 (Study Day 137)	Surgical Use Ecrp
Metronidazole	15 Jan 2021 (Study Day 137) - 20 Jan 2021 (Study Day 142)	Gallbladder Surgery
Midazolam hydrochloride	15 Jan 2021 (Study Day 137) - 15 Jan 2021 (Study Day 137)	Sedation For Ercp
Mr abdomen*	15 Jan 2021 (Study Day 137) - 15 Jan 2021 (Study Day 137)	Adverse Event
Pethidine hydrochloride	15 Jan 2021 (Study Day 137) - 15 Jan 2021 (Study Day 137)	Sedation For Ercp

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cholecystectomy with pathology review*	17 Jan 2021 (Study Day 139) - 17 Jan 2021 (Study Day 139)	Adverse Event
Levofloxacin	20 Jan 2021 (Study Day 142) - 20 Jan 2021 (Study Day 142)	Gall Bladder Surgery

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Adrenal Adenoma	Grade 1/mild	Not related	14 Jan 2021 (Study Day 136) - Ongoing
Renal Disorder	Grade 1/mild	Not related	14 Jan 2021 (Study Day 136) - Ongoing
Pancreatitis	Grade 3/severe	Not related	15 Jan 2021 (Study Day 137) - 17 Jan 2021 (Study Day 139)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2030 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	30 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	27 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nerve Compression/Pinched Nerve Secondary To Surgical Complication	SAE	Grade 3/severe	Not related	26 Oct 2020 (Study Day 89) – 28 Oct 2020 (Study Day 91)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2030, a 71-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 27 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Oct 2020 (Study Day 89), 88 days after the first dose and 60 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of nerve compression. Action taken with the IP was not applicable. The event of pinched nerve secondary to surgical complication lasted for 3 days, after which it was considered to be recovered/resolved with sequelae on 28 Oct 2020 (Study Day 91). The investigator assessed the event of nerve compression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003417	Nerve compression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dental caries	Tooth cavity	Not reported - 11 Dec 2020 (Study Day 135)
Osteoarthritis	Bilateral knee osteoarthritis	Sep 1987 - Ongoing
Scoliosis	Scoliosis t-spine	Apr 1988 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	Apr 1988 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	Jan 1993 - Ongoing
Erectile dysfunction	Erectile dysfunction	Jul 2004 - Ongoing
Diabetic retinopathy	Bilateral diabetic retinopathy	Aug 2007 - Ongoing
Constipation	Constipation	2009 - Ongoing
Seasonal allergy	Hay fever	2009 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Jan 2009 - Jul 2012
Arthralgia	Bilateral knee pain	2010 - Ongoing
Peripheral sensory neuropathy	Bilateral feet peripheral sensory neuropathy	Mar 2010 - Ongoing
Asthma	Moderate asthma	Apr 2010 - Ongoing
Intervertebral disc protrusion	Herniated c5 and c6	Jun 2010 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2012 - Ongoing
Transurethral prostatectomy	Transurethral resection of the prostate	Jul 2012 - Jul 2012
Hypertension	Hypertension	2016 - Ongoing
Dry eye	Dry eyes	2018 - Ongoing
Hypertonic bladder	Overactive bladder	Dec 2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Jan 2019 - Ongoing
Knee arthroplasty	Left total knee replacement	31 Jul 2019 (Study Day -365) - 31 Jul 2019 (Study Day -365)
Rash	Intermittent skin rash l shoulder	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2009 - Ongoing	Hayfever
Sildenafil	2010 - Ongoing	Erectile Dysfunction
Chondroitin; glucosamine	15 Mar 2010 (Study Day -3790) - Ongoing	Supplement
Glucosamine sulfate	15 Mar 2010 (Study Day -3790) - Ongoing	Supplement
Diclofenac	28 Jan 2012 (Study Day -3106) - Ongoing	Bilateral Knee Pain
Omeprazole	19 Oct 2012 (Study Day -2841) - Ongoing	Gerd
Insulin human	14 Apr 2014 (Study Day -2299) - Ongoing	Dmii

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin human	14 Aug 2014 (Study Day -2177) - Ongoing	Dmii
Gabapentin	02 Sep 2014 (Study Day -2158) - Ongoing	Peripheral Sensory Nephropathy
Gabapentin	02 Sep 2014 (Study Day -2158) - Ongoing	Peripheral Sensory Neuropathy
Plantago psyllium	25 Apr 2015 (Study Day -1923) - Ongoing	Supplement
Hydrochlorothiazide	2016 - Ongoing	Hypertension
Lisinopril	2016 - Ongoing	Hypertension
Empagliflozin	27 Feb 2017 (Study Day -1249) – 24 Aug 2020 (Study Day 26)	Dmii
Ipratropium bromide; salbutamol sulfate	04 May 2017 (Study Day -1183) - Ongoing	Asthma
Carmellose sodium	2018 - Ongoing	Dry Eyes
Metformin hydrochloride; sitagliptin	16 Jun 2018 (Study Day -775) - Ongoing	Dmii
Solifenacin succinate	22 Dec 2018 (Study Day -586) - Ongoing	Oab
Docusate sodium	2019 - Ongoing	Constipation
Rosuvastatin calcium	16 Jan 2019 (Study Day -561) - Ongoing	Hyperlipidemia
Triamcinolone acetonide	08 Feb 2020 (Study Day -173) - Ongoing	Skin Rash L Shoulder
Acetylsalicylic acid	09 Apr 2020 (Study Day -112) - Ongoing	Cardiac Prophylaxis
Ferrous sulfate	Jul 2020 - Ongoing	Supplement
Empagliflozin	25 Aug 2020 (Study Day 27) - Ongoing	Dmii
Insulin human	17 Oct 2020 (Study Day 80) - 19 Oct 2020 (Study Day 82)	Dm 2
Varenicline tartrate	20 Oct 2020 (Study Day 83) - Ongoing	Smoking Cessation Aid
Cefazolin	23 Oct 2020 (Study Day 86) - 23 Oct 2020 (Study Day 86)	Pinched Nerve
Atorvastatin	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)	Hyperlipidemia
Bacitracin	26 Oct 2020 (Study Day 89) - 26 Oct 2020 (Study Day 89)	Wound Infection Prophylaxis
Bupivacaine; epinephrine	26 Oct 2020 (Study Day 89) - 26 Oct 2020 (Study Day 89)	Pinched Nerve
Cefazolin	26 Oct 2020 (Study Day 89) - 26 Oct 2020 (Study Day 89)	Pinched Nerve
Cefazolin	26 Oct 2020 (Study Day 89) - 27 Oct 2020 (Study Day 90)	Pinched Nerve
Cervical decompression*	26 Oct 2020 (Study Day 89) - 26 Oct 2020 (Study Day 89)	Medical History
Fentanyl	26 Oct 2020 (Study Day 89) - 26 Oct 2020 (Study Day 89)	Pinched Nerve
Hydromorphone hydrochloride	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)	Pinched Nerve
Loratadine	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)	Hayfever
Macrogol 3350	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)	Constipation
Methocarbamol	26 Oct 2020 (Study Day 89) - 28 Oct 2020 (Study Day 91)	Pinched Nerve
Ondansetron	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)	Pinched Nerve

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxybutynin	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)	Bph
Oxycodone hydrochloride	26 Oct 2020 (Study Day 89) - 28 Oct 2020 (Study Day 91)	Pinched Nerve
Povidone-iodine	26 Oct 2020 (Study Day 89) - 26 Oct 2020 (Study Day 89)	Pinched Nerve
Sennoside a+b	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)	Constipation
Vancomycin	26 Oct 2020 (Study Day 89) - 26 Oct 2020 (Study Day 89)	Pinched Nerve
Cefazolin	27 Oct 2020 (Study Day 90) - 29 Oct 2020 (Study Day 92)	Pinched Nerve
Dexamethasone	27 Oct 2020 (Study Day 90) - 29 Oct 2020 (Study Day 92)	Pinched Nerve
Insulin glargine	27 Oct 2020 (Study Day 90) - 27 Oct 2020 (Study Day 90)	Type 2 Diabetes
Oxycodone hydrochloride; paracetamol	27 Oct 2020 (Study Day 90) - 27 Oct 2020 (Study Day 90)	Pinched Nerve
Pantoprazole	27 Oct 2020 (Study Day 90) - 27 Oct 2020 (Study Day 90)	Gerd
Bacitracin	28 Oct 2020 (Study Day 91) - 28 Oct 2020 (Study Day 91)	Wound Infection Prophylaxis
Bupivacaine; epinephrine	28 Oct 2020 (Study Day 91) - 28 Oct 2020 (Study Day 91)	Pinched Nerve
Corrective back surgery*	28 Oct 2020 (Study Day 91) - 28 Oct 2020 (Study Day 91)	Adverse Event
Famotidine	28 Oct 2020 (Study Day 91) - 30 Oct 2020 (Study Day 93)	Gerd
Fentanyl	28 Oct 2020 (Study Day 91) - 28 Oct 2020 (Study Day 91)	Pinched Nerve
Insulin glargine	28 Oct 2020 (Study Day 91) - 28 Oct 2020 (Study Day 91)	Type 2 Diabetes
Vancomycin	28 Oct 2020 (Study Day 91) - 28 Oct 2020 (Study Day 91)	Pinched Nerve
Fluticasone propionate	30 Oct 2020 (Study Day 93) - 30 Oct 2020 (Study Day 93)	Rhinitis
Tooth extractions x3*	11 Dec 2020 (Study Day 135) - 11 Dec 2020 (Study Day 135)	Medical History
Varicella zoster vaccine	11 Mar 2021 (Study Day 225) - 11 Mar 2021 (Study Day 225)	Shingles Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dizziness	Grade 1/mild	Not related	30 Jul 2020 (Study Day 1) - 30 Jul 2020 (Study Day 1)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rhinitis	Grade 1/mild	Not related	26 Oct 2020 (Study Day 89) - 30 Oct 2020 (Study Day 93)
Tooth Fracture	Grade 2/moderate	Not related	23 Feb 2021 (Study Day 209) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2071 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Sepsis	SAE	Grade 4	Not related	18 Jan 2021 (Study Day 169) – 31 Jan 2021 (Study Day 182)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2071, a 55-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Jan 2021 (Study Day 169), 168 days after the first dose and 140 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis lasted for 14 days, after which it was considered to be recovered/resolved on 31 Jan 2021 (Study Day 182). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006656	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2015 - Ongoing
Arthralgia	Bilateral ankle pain	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin hydrochloride	2015 - Ongoing	Benign Prostatic Hyperplasia
Testosterone	15 Jul 2020 (Study Day -19) - Ongoing	Health Supplement
Ibuprofen	01 Aug 2020 (Study Day -2) - 09 Aug 2020 (Study Day 7)	Ankle Pain-Bilateral
Influenza vaccine	05 Oct 2020 (Study Day 64) - 05 Oct 2020 (Study Day 64)	Influenza Virus Prophylaxis
Ceftriaxone	18 Jan 2021 (Study Day 169) - 18 Jan 2021 (Study Day 169)	Sepsis
Paracetamol	18 Jan 2021 (Study Day 169) - 18 Jan 2021 (Study Day 169)	Sepsis
Ciprofloxacin	22 Jan 2021 (Study Day 173) - 31 Jan 2021 (Study Day 182)	Sepsis
Ciprofloxacin	04 Feb 2021 (Study Day 186) - 22 Feb 2021 (Study Day 204)	Prostatitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pyelonephritis	Grade 3/severe	Not related	18 Jan 2021 (Study Day 169) - Ongoing
Hypobarism	Grade 1/mild	Not related	22 Jan 2021 (Study Day 173) - 22 Jan 2021 (Study Day 173)
Prostatitis	Grade 2/moderate	Not related	04 Feb 2021 (Study Day 186) - 22 Feb 2021 (Study Day 204)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2121 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Malignant Melanoma/Melanoma	SAE	Grade 4	Not related	09 Sep 2020 (Study Day 36) – 21 Sep 2020 (Study Day 48)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2121, a 54-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Sep 2020 (Study Day 36), 35 days after the first dose and 7 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of malignant melanoma. Action taken with the IP was not applicable. The event of melanoma lasted for 13 days, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 48). The investigator assessed the event of malignant melanoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000396	Malignant melanoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1976 - Ongoing
Malignant melanoma	Melanoma (abd)	Dec 2010 - Dec 2010
Bone operation	Pubis resection	Dec 2017 - Dec 2017
Hip surgery	Hip repair, torn labrum	Dec 2017 - Dec 2017
Malignant melanoma	Melanoma (left bicep)	20 Nov 2019 (Study Day -259) - 20 Nov 2019 (Study Day -259)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Melanoma excised*	21 Sep 2020 (Study Day 48) - 21 Sep 2020 (Study Day 48)	Adverse Event
Influenza vaccine	30 Sep 2020 (Study Day 57) - 30 Sep 2020 (Study Day 57)	Flu Vaccine
Doxycycline	21 Oct 2020 (Study Day 78) - 28 Oct 2020 (Study Day 85)	Surgical Site Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Viral Infection	Grade 2/moderate	Not related	03 Oct 2020 (Study Day 60) - 06 Oct 2020 (Study Day 63)
Postoperative Wound Infection	Grade 1/mild	Not related	21 Oct 2020 (Study Day 78) - 28 Oct 2020 (Study Day 85)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2128 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain Lower/Intermittent Right Lower Quadrant Pain	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	12 Aug 2020 (Study Day 7) – Ongoing	Not recovered/ not resolved
Diabetic Ketoacidosis/Diabetic Ketoacidosis	SAE	Grade 4	Not related	22 Nov 2020 (Study Day 109) – 22 Nov 2020 (Study Day 109)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2128, a 30-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Aug 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of abdominal pain lower. On 02 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of intermittent right lower quadrant pain was considered to be ongoing. The investigator assessed the event of abdominal pain lower to be not related to the IP.

On 22 Nov 2020 (Study Day 109), 108 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of diabetic ketoacidosis. On 02 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of diabetic ketoacidosis lasted for 1 day, after which it was considered to be recovered/resolved on 22 Nov 2020 (Study Day 109). The investigator assessed the event of diabetic ketoacidosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001382	Diabetic ketoacidosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1993 - 1993
Tonsillitis	Tonsillitis	1993 - Ongoing
Gastrooesophageal reflux disease	Gerd	1997 - Ongoing
Bipolar disorder	Bipolar disorder	1999 - Ongoing
Lacrimal duct procedure	Lacrimal duct dilation	2002 - 2002
Type 1 diabetes mellitus	Type 1 diabetes	2002 - Ongoing
Ovarian cyst	Ovarian cyst	2006 - 2006
Drug hypersensitivity	Sulfa allergy	2010 - Ongoing
Drug hypersensitivity	Vancomycin allergy	2010 - Ongoing
Adenoidectomy	Adenoidectomy	2013 - 2013
Pilonidal cyst	Pilonidal cyst	2013 - 2013
Pilonidal cyst	Pilonidal cyst	2016 - 2016
Sinus operation	Nasal sinus surgery	2016 - 2016
Arthropod bite	Bilateral ankle flea bites	Jul 2020 - Ongoing
Conjunctivitis allergic	Bilateral allergic conjunctivitis	02 Aug 2020 (Study Day -4) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin lispro	2002 - Ongoing	Type 1 Diabetes
Bupropion hydrochloride	2018 - 22 Nov 2020 (Study Day 109)	Bipolar Disorder
Lithium	2018 - Ongoing	Bipolar Disorder
Insulin degludec	2019 - Ongoing	Type 1 Diabetes
Norethisterone	May 2020 - Ongoing	Birth Control
Cyclopentolate hydrochloride	Aug 2020 - 07 Aug 2020 (Study Day 2)	Bilateral Conjunctivitis Allergies
Difluprednate	Aug 2020 - 07 Aug 2020 (Study Day 2)	Bilateral Conjunctivitis Allergic
Ceftriaxone	12 Aug 2020 (Study Day 7) - 12 Aug 2020 (Study Day 7)	Uti
Ceftriaxone	12 Aug 2020 (Study Day 7) - 22 Aug 2020 (Study Day 17)	Uti
Doxycycline	12 Aug 2020 (Study Day 7) - 26 Aug 2020 (Study Day 21)	Preventative For Potential Pid (Per Medical Records)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Morphine	12 Aug 2020 (Study Day 7) - 13 Aug 2020 (Study Day 8)	Rlq Pain
Influenza vaccine	16 Oct 2020 (Study Day 72) - 16 Oct 2020 (Study Day 72)	Flu Prophylaxis
Ibuprofen	25 Oct 2020 (Study Day 81) - 25 Oct 2020 (Study Day 81)	Viral Syndrome
Ceftriaxone	22 Nov 2020 (Study Day 109) - 24 Nov 2020 (Study Day 111)	Uti Leukocytosis
Insulin glargine	22 Nov 2020 (Study Day 109) - 23 Nov 2020 (Study Day 110)	Diabetic Ketoacidosis
Bupropion hydrochloride	23 Nov 2020 (Study Day 110) - Ongoing	Bipolar Disorder
Fluconazole	23 Nov 2020 (Study Day 110) - 27 Nov 2020 (Study Day 114)	Vaginal Candidiasis
Cefalexin	24 Nov 2020 (Study Day 111) - 01 Dec 2020 (Study Day 118)	Uti Leukocytosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain Lower	Grade 2/moderate	Not related	12 Aug 2020 (Study Day 7) - Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	12 Aug 2020 (Study Day 7) - 22 Aug 2020 (Study Day 17)
Pyrexia	Grade 1/mild	Not related	13 Sep 2020 (Study Day 39) - 13 Sep 2020 (Study Day 39)
Viral Infection	Grade 2/moderate	Not related	25 Oct 2020 (Study Day 81) - 19 Nov 2020 (Study Day 106)
Concussion	Grade 3/severe	Not related	22 Nov 2020 (Study Day 109) - 10 Jan 2021 (Study Day 158)
Leukocytosis	Grade 3/severe	Not related	22 Nov 2020 (Study Day 109) - 01 Dec 2020 (Study Day 118)
Vulvovaginal Candidiasis	Grade 2/moderate	Not related	23 Nov 2020 (Study Day 110) - 27 Nov 2020 (Study Day 114)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2145 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis	SAE	Grade 4	Not related	08 Dec 2020 (Study Day 124) – 04 Feb 2021 (Study Day 182)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2145, a 42-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Dec 2020 (Study Day 124), 123 days after the first dose and 95 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 59 days, after which it was considered to be recovered/resolved on 04 Feb 2021 (Study Day 182). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012087	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Generalised anxiety disorder	General anxiety disorder	1990 - Ongoing
Rubber sensitivity	Allergy to latex	1990 - Ongoing
Headache	Non migraine headaches	1997 - Ongoing
Squamous cell carcinoma	Squamous cell carcinoma-left chest	2012 - 2012
Hypersensitivity	Environmental allergies	2016 - Ongoing
Eczema	Eczema	2018 - Ongoing
Insomnia	Insomnia	2018 - Ongoing
Bronchitis bacterial	Acute bacterial bronchitis	Jan 2020 - 2020
Drug hypersensitivity	Allergy to augmentin	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine	2013 - Ongoing	Anxiety
Trazodone	2018 - Ongoing	Insomnia
Vitamins nos	2019 - Ongoing	Health Supplement
Paracetamol	10 Aug 2020 (Study Day 4) - 14 Aug 2020 (Study Day 8)	Fever
Paracetamol	10 Aug 2020 (Study Day 4) - 14 Aug 2020 (Study Day 8)	Headache And Axillary Lymphadenopathy
Influenza vaccine	08 Oct 2020 (Study Day 63) - 08 Oct 2020 (Study Day 63)	Influenza Virus Prophylaxis
Sulfamethoxazole; trimethoprim	10 Nov 2020 (Study Day 96) - 23 Nov 2020 (Study Day 109)	Cough And Congestion Due To Viral Syndrome
Ibuprofen	18 Nov 2020 (Study Day 104) - Ongoing	Headache Due To R Upper Extremity Tingling/ Neck Pain
Lorazepam	20 Nov 2020 (Study Day 106) - 21 Nov 2020 (Study Day 107)	Insomnia
Aluminium hydroxide; magnesium hydroxide; simeticone	04 Jan 2021 (Study Day 151) - Ongoing	Gi Discomfort
Omeprazole	04 Jan 2021 (Study Day 151) - Ongoing	Gi Discomfort
Simeticone	04 Jan 2021 (Study Day 151) - Ongoing	Gi Discomfort
Cholecystectomy*	04 Feb 2021 (Study Day 182) - 04 Feb 2021 (Study Day 182)	Adverse Event
Fentanyl	04 Feb 2021 (Study Day 182) - 04 Feb 2021 (Study Day 182)	Cholecystitis
Morphine	04 Feb 2021 (Study Day 182) - 04 Feb 2021 (Study Day 182)	Cholecystitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	04 Feb 2021 (Study Day 182) - 04 Feb 2021 (Study Day 182)	Cholecystitis
Piperacillin sodium; tazobactam sodium	04 Feb 2021 (Study Day 182) - 04 Feb 2021 (Study Day 182)	Cholecystitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 2/moderate	Related	07 Aug 2020 (Study Day 1) - 18 Aug 2020 (Study Day 12)
Fatigue	Grade 2/moderate	Related	07 Aug 2020 (Study Day 1) - 20 Aug 2020 (Study Day 14)
Myalgia	Grade 2/moderate	Related	07 Aug 2020 (Study Day 1) - 16 Aug 2020 (Study Day 10)
Lymphadenopathy	Grade 1/mild	Related	09 Aug 2020 (Study Day 3) - 19 Aug 2020 (Study Day 13)
Headache	Grade 1/mild	Related	10 Aug 2020 (Study Day 4) - 23 Aug 2020 (Study Day 17)
Fatigue	Grade 1/mild	Related	05 Sep 2020 (Study Day 30) - 14 Sep 2020 (Study Day 39)
Headache	Grade 1/mild	Related	09 Sep 2020 (Study Day 34) - 12 Sep 2020 (Study Day 37)
Viral Infection	Grade 1/mild	Not related	16 Oct 2020 (Study Day 71) - 23 Nov 2020 (Study Day 109)
Headache	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 101) - 29 Nov 2020 (Study Day 115)
Neck Pain	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 101) - Ongoing
Paraesthesia	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 101) - Ongoing
Abdominal Discomfort	Grade 2/moderate	Not related	04 Jan 2021 (Study Day 151) - Ongoing
Cholelithiasis	Grade 1/mild	Not related	26 Jan 2021 (Study Day 173) - 04 Feb 2021 (Study Day 182)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2164 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/ Severe Coronary Artery Disease	SAE	Grade 4	Not related	16 Sep 2020 (Study Day 38) – 24 Sep 2020 (Study Day 46)	Recovered/ resolved
Pleural Effusion/Pleural Effusion	SAE	Grade 4	Not related	02 Oct 2020 (Study Day 54) – 02 Oct 2020 (Study Day 54)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2164, a 76-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 38), 37 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of severe coronary artery disease lasted for 9 days, after which it was considered to be recovered/resolved on 24 Sep 2020 (Study Day 46). The investigator assessed the event of coronary artery disease to be not related to the IP.

On 02 Oct 2020 (Study Day 54), 53 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pleural effusion. Action taken with the IP was not applicable. The event of pleural effusion lasted for 1 day, after which it was considered to be recovered/resolved on 02 Oct 2020 (Study Day 54). The investigator assessed the event of pleural effusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000355	Coronary artery disease
MOD-2020-000355	Pleural effusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Carpal tunnel syndrome	Carpal tunnel	2014 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Osteoarthritis	Osteoarthritis	2014 - Ongoing
Hypercholesterolaemia	Hypercholesterolermia	2017 - Ongoing
Benign prostatic hyperplasia	Benign prostrate hyperplasia	2018 - Ongoing
Insomnia	Insomnia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2010 - Ongoing	Hypothyroidism
Atenolol	2014 - 17 Sep 2020 (Study Day 39)	Hypertension
Gabapentin	2014 - Ongoing	Carpal Tunnel
Tramadol	2014 - Ongoing	Osteoarthritis Pain Relief
Rosuvastatin calcium	2017 - Ongoing	Hypercholesterolemia
Amlodipine	2018 - Ongoing	Hypertension
Norfloxacin	2018 - Ongoing	Benign Prostatic Hyperplasia
Zolpidem tartrate	2019 - Ongoing	Insomnia
Paracetamol	09 Sep 2020 (Study Day 31) - 09 Sep 2020 (Study Day 31)	Pain At Injection Site
Acetylsalicylic acid; caffeine; paracetamol	11 Sep 2020 (Study Day 33) - 11 Sep 2020 (Study Day 33)	Headache
Acetylsalicylic acid	18 Sep 2020 (Study Day 40) - Ongoing	Cardiac Event Prophylaxis
Amiodarone	18 Sep 2020 (Study Day 40) - 02 Oct 2020 (Study Day 54)	Cad
Angiogram*	18 Sep 2020 (Study Day 40) - 18 Sep 2020 (Study Day 40)	Medical History
Apixaban	18 Sep 2020 (Study Day 40) - Ongoing	Cad
Atenolol	18 Sep 2020 (Study Day 40) - Ongoing	Hypertension
Bumetanide	18 Sep 2020 (Study Day 40) - 02 Oct 2020 (Study Day 54)	Severe Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cabg x3*	18 Sep 2020 (Study Day 40) - 18 Sep 2020 (Study Day 40)	Adverse Event
Colchicine	18 Sep 2020 (Study Day 40) - Ongoing	Cad
Docusate sodium	18 Sep 2020 (Study Day 40) - 24 Sep 2020 (Study Day 46)	Severe Coronary Artery Disease
Ezetimibe	18 Sep 2020 (Study Day 40) - Ongoing	Hypercholesterolemia
Potassium chloride	18 Sep 2020 (Study Day 40) - 02 Oct 2020 (Study Day 54)	Severe Coronary Artery Disease
Tramadol	18 Sep 2020 (Study Day 40) - Ongoing	Post Op Pain Management
Left chest tube*	02 Oct 2020 (Study Day 54) - 02 Oct 2020 (Study Day 54)	Adverse Event
Levofloxacin	02 Oct 2020 (Study Day 54) - 09 Oct 2020 (Study Day 61)	Pleural Effusion
Amiodarone	03 Oct 2020 (Study Day 55) - 17 Oct 2020 (Study Day 69)	Cad
Amiodarone	18 Oct 2020 (Study Day 70) - Ongoing	Cad

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US311-2192 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Paroxysmal Atrial Fibrillation	SAE	Grade 4	Not related	17 Oct 2020 (Study Day 68) – 20 Oct 2020 (Study Day 71)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2192, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 11 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Oct 2020 (Study Day 68), 67 days after the first dose and 36 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of paroxysmal atrial fibrillation lasted for 4 days, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 71). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000527	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Neck pain	Chronic neck pain	2012 - Ongoing
Cholecystectomy	Cholecystectomy	2013 - 2013
Cholelithiasis	Gall stones	2013 - 2013
Depression	Depression	2016 - Ongoing
Large intestine polyp	Colon polyps	2017 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Atrial fibrillation	Atrial fibrillation	Apr 2020 - Ongoing
Hypertension	Hypertension	Apr 2020 - Ongoing
Intestinal obstruction	Bowel blockage	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone	Not reported - Ongoing	Seasonal Allergies
Loratadine	Not reported - Ongoing	Seasonal Allergies
Montelukast	Not reported - Ongoing	Asthma
Vitamins nos	2000 - Ongoing	Supplement
Ascorbic acid	2005 - Ongoing	Supplement
Macrogol 3350	2019 - Ongoing	Hiatal Hernia
Amlodipine	12 Apr 2020 (Study Day -121) - 23 Sep 2020 (Study Day 44)	Hypertension
Apixaban	12 Apr 2020 (Study Day -121) - Ongoing	Atrial Fibrillation
Losartan	12 Apr 2020 (Study Day -121) - Ongoing	Hypertension
Paracetamol	11 Aug 2020 (Study Day 1) - 13 Aug 2020 (Study Day 3)	Body Aches Prior To Injection
Hydrocodone bitartrate; paracetamol	02 Sep 2020 (Study Day 23) - 16 Sep 2020 (Study Day 37)	Left Knee Contusion Secondary To Mechanical Fall
Hydrocodone bitartrate; paracetamol	02 Sep 2020 (Study Day 23) - 16 Sep 2020 (Study Day 37)	Left Shoulder Contusion Secondary To Mechanical Fall
Morphine	02 Sep 2020 (Study Day 23) - 16 Sep 2020 (Study Day 37)	Left Knee Contusion Secondary To Mechanical Fall
Morphine	02 Sep 2020 (Study Day 23) - 16 Sep 2020 (Study Day 37)	Left Shoulder Contusion Secondary To Mechanical Fall
Atorvastatin	25 Sep 2020 (Study Day 46) - Ongoing	Hypercholesterolemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	18 Oct 2020 (Study Day 69) - 18 Oct 2020 (Study Day 69)	Paroxysmal Atrial Fibrillation
Amiodarone	18 Oct 2020 (Study Day 69) - Ongoing	Atrial Fibrillation
Salbutamol	18 Oct 2020 (Study Day 69) - Ongoing	Seasonal Allergies
Duloxetine	20 Oct 2020 (Study Day 71) - Ongoing	Depression
Fluticasone	21 Oct 2020 (Study Day 72) - Ongoing	Seasonal Allergies
Heart ablation*	23 Feb 2021 (Study Day 197) - 23 Feb 2021 (Study Day 197)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Contusion	Grade 2/moderate	Not related	01 Sep 2020 (Study Day 22) - 16 Sep 2020 (Study Day 37)
Contusion	Grade 2/moderate	Not related	01 Sep 2020 (Study Day 22) - 21 Sep 2020 (Study Day 42)
Arthralgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 32) - 01 Oct 2020 (Study Day 52)
Fatigue	Grade 2/moderate	Related	11 Sep 2020 (Study Day 32) - 29 Sep 2020 (Study Day 50)
Myalgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 32) - 01 Oct 2020 (Study Day 52)
Atrial Fibrillation	Grade 3/severe	Not related	30 Dec 2020 (Study Day 142) - 23 Feb 2021 (Study Day 197)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2210 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Endometrial Cancer/ Endometrial Cancer	SAE	Grade 4	Not related	11 Jan 2021 (Study Day 153) – 27 Jan 2021 (Study Day 169)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2210, a 62-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Jan 2021 (Study Day 153), 152 days after the first dose and 124 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of endometrial cancer. Action taken with the IP was not applicable. The event of endometrial cancer lasted for 17 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 169). The investigator assessed the event of endometrial cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006558	Endometrial cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mammoplasty	Bilateral breast augmentation	2004 - 2004
Presbyopia	Presbyopia	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	13 Sep 2020 (Study Day 33) - 13 Sep 2020 (Study Day 33)	Headache
Influenza vaccine	29 Sep 2020 (Study Day 49) - 29 Sep 2020 (Study Day 49)	Influenza Prophylaxis
Gabapentin	26 Jan 2021 (Study Day 168) - 03 Feb 2021 (Study Day 176)	Pre And Post Operative Pain Relief (Endometrial Cancer Treatment)
Laparoscopic hysterectomy bilateral salpingo oophorectomy with stage, bilateral pelvic lymph node dissection bilateral uretrolysis.*	27 Jan 2021 (Study Day 169) - 27 Jan 2021 (Study Day 169)	Adverse Event
Docusate sodium	28 Jan 2021 (Study Day 170) - 03 Feb 2021 (Study Day 176)	Stool Softener Post Op (Endometrial Cancer Treatment)
Excisional biopsy*	19 Mar 2021 (Study Day 220) - 19 Mar 2021 (Study Day 220)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Basal Cell Carcinoma	Grade 2/moderate	Not related	19 Mar 2021 (Study Day 220) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2223 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 42)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pharyngitis Streptococcal/Strep-Pharyngitis	SAE	Grade 3/severe	Not related	01 Sep 2020 (Study Day 20) – 14 Sep 2020 (Study Day 33)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2223, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 42). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Sep 2020 (Study Day 20), 19 days after the first dose and 22 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pharyngitis streptococcal. The IP dose was delayed due to the strep-pharyngitis. The event of strep-pharyngitis lasted for 14 days, after which it was considered to be recovered/resolved on 14 Sep 2020 (Study Day 33). The investigator assessed the event of pharyngitis streptococcal to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000258	Pharyngitis streptococcal

Study Completion/Discontinuation

On 14 Jan 2021 (Study Day 155), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1980 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Herpes simplex	Herpes simplex virus, recurrent	2010 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2010 - Ongoing
Gout	Gout	2015 - Ongoing
Prostate cancer	Prostate cancer	Apr 2015 - 03 Jul 2015 (Study Day -1868)
Prostatectomy	Prostatectomy	03 Jul 2015 (Study Day -1868) - 03 Jul 2015 (Study Day -1868)
Extrasystoles	Trigiminy cardiac arrythimia	2017 - 14 Oct 2019 (Study Day -304)
Coronary artery disease	Coronary artery disease	2019 - Ongoing
Coronary arterial stent insertion	Cardiac stent	14 Oct 2019 (Study Day -304) - 14 Oct 2019 (Study Day -304)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Berberine	2010 - Ongoing	Health Supplement
Losartan	2010 - Ongoing	Hypertension
Valaciclovir hydrochloride	2010 - Ongoing	Herpes Simplex Virus
Valsartan	2010 - Ongoing	Hypertension
Allopurinol	2015 - Ongoing	Gout
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
Rosuvastatin calcium	2018 - Ongoing	Hypercholesterol
Clopidogrel bisulfate	2019 - Ongoing	Cad S/P Stent
Magnesium	01 Jan 2020 (Study Day -225) - Ongoing	Health Supplement
Amoxicillin	02 Sep 2020 (Study Day 21) - 14 Sep 2020 (Study Day 33)	Strepp-Pharyngitis
In-patient covid pcr*	02 Sep 2020 (Study Day 21) - 02 Sep 2020 (Study Day 21)	Adverse Event
Paracetamol	02 Sep 2020 (Study Day 21) - 02 Sep 2020 (Study Day 21)	Fever Reduction
Influenza vaccine	19 Oct 2020 (Study Day 68) - 19 Oct 2020 (Study Day 68)	Influenza Virus Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US311-2365 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Thoracic Vertebral Fracture/T12 Fracture	SAE	Grade 4	Not related	28 Oct 2020 (Study Day 66) – 02 Nov 2020 (Study Day 71)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2365, a 69-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Oct 2020 (Study Day 66), 65 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of thoracic vertebral fracture. Action taken with the IP was not applicable. The event of T12 fracture lasted for 6 days, after which it was considered to be recovered/resolved on 02 Nov 2020 (Study Day 71). The investigator assessed the event of thoracic vertebral fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000794	Thoracic vertebral fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Acid reflux	1987 - Ongoing
Prostate cancer	Prostate cancer	2002 - 2002
Hypercholesterolaemia	Hypercholesterolemia	2003 - Ongoing
Hypertension	Hypertension	2003 - Ongoing
Gastrooesophageal reflux disease	Gerd	2005 - Ongoing
Osteoarthritis	Osteoarthritis-bilateral knees	2010 - Ongoing
Asthma	Asthma	2012 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2014 - Ongoing
Cholecystectomy	Cholecystectomy	2015 - 2015
Cholelithiasis	Cholelithiasis	2015 - 2015
Hepatic steatosis	Fatty liver	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2015 - Ongoing	Hypertension
Pravastatin	2015 - Ongoing	Hypercholesterolemia
Beclometasone dipropionate	2016 - Ongoing	Asthma
Salbutamol sulfate	2016 - Ongoing	Asthma
Omeprazole	2018 - Ongoing	Acid Reflux
Influenza vaccine	09 Oct 2020 (Study Day 47) - 09 Oct 2020 (Study Day 47)	Influenza Virus Prophylaxis
Chest xray*	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	Adverse Event
Covid-19 rapid test*	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	Adverse Event
Ct 2d reconstruction*	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	Adverse Event
Ct abdomen with contrast*	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	Adverse Event
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	Prophylaxis
Hydromorphone hydrochloride	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	T12 Fracture
Iohexol	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	T12 Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Morphine	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	T12 Fracture
Ondansetron	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	T12 Fracture
Sodium chloride	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	T12 Fracture
Thoracic mri without contrast*	02 Nov 2020 (Study Day 71) - 02 Nov 2020 (Study Day 71)	Adverse Event
Ceftriaxone	27 Nov 2020 (Study Day 96) - 27 Nov 2020 (Study Day 96)	Cellulitis Lle
Covid-19 rapid test*	27 Nov 2020 (Study Day 96) - 27 Nov 2020 (Study Day 96)	Adverse Event
Ecg*	27 Nov 2020 (Study Day 96) - 27 Nov 2020 (Study Day 96)	Adverse Event
Ibuprofen	27 Nov 2020 (Study Day 96) - 27 Nov 2020 (Study Day 96)	Cellulitis Lle
Iohexol	27 Nov 2020 (Study Day 96) - 27 Nov 2020 (Study Day 96)	Cellulitis Lle
Paracetamol	27 Nov 2020 (Study Day 96) - 27 Nov 2020 (Study Day 96)	Cellulitis Lle
Vancomycin	27 Nov 2020 (Study Day 96) - 27 Nov 2020 (Study Day 96)	Cellulitis Lle
Cefalexin	28 Nov 2020 (Study Day 97) - 06 Dec 2020 (Study Day 105)	Cellulitis Lle

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cellulitis	Grade 3/severe	Not related	27 Nov 2020 (Study Day 96) - 06 Dec 2020 (Study Day 105)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2389 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Liposarcoma/Left Thigh Liposarcoma	SAE	Grade 4	Not related	02 Dec 2020 (Study Day 99) – 09 Mar 2021 (Study Day 196)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2389, a 69-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Dec 2020 (Study Day 99), 98 days after the first dose and 70 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of liposarcoma. Action taken with the IP was not applicable. The event of left thigh liposarcoma lasted for 98 days, after which it was considered to be recovered/resolved on 09 Mar 2021 (Study Day 196). The investigator assessed the event of liposarcoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-058692	Liposarcoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menopausal symptoms	Post menopausal hot flashes	2019 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2020 - Ongoing
Limb mass	Left thigh mass	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	Supplement
Ascorbic acid	2015 - Ongoing	Supplement
Glucosamine	2015 - Ongoing	Supplement
Hyaluronic acid	2015 - 2015	Cosmetic
Vitamin e nos	2015 - Ongoing	Supplement
Botulinum toxin type a	2017 - 2017	Cosmetic
Vitamin d nos	2018 - Ongoing	Supplement
Estradiol	2019 - Ongoing	Post Menopausal Hot Flashes
Pravastatin	2020 - Ongoing	Hypercholesterolemia
Influenza vaccine	20 Oct 2020 (Study Day 56) - 20 Oct 2020 (Study Day 56)	Flu Prophylaxis
Nitrofurantoin	10 Nov 2020 (Study Day 77) - 15 Nov 2020 (Study Day 82)	Uti
Pneumococcal vaccine	02 Dec 2020 (Study Day 99) - 02 Dec 2020 (Study Day 99)	Pneumonia Prevention Prophylaxis
Liposarcoma excision*	09 Mar 2021 (Study Day 196) - 09 Mar 2021 (Study Day 196)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	10 Nov 2020 (Study Day 77) - 15 Nov 2020 (Study Day 82)
Viral Infection	Grade 1/mild	Not related	15 Jan 2021 (Study Day 143) - 24 Jan 2021 (Study Day 152)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378414

Participant Number:	US312-2010 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Metastases To Lung/Metastases To Lungs [recurrence Of Throat Cance]	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	12 Aug 2020 (Study Day 17) – Ongoing	Not recovered/ not resolved
Throat Cancer/Recurrence Of Throat Cancer [with Metastases To Lungs]	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	12 Aug 2020 (Study Day 17) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US312-2010, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 27 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Aug 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of metastases to lung. On 23 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of metastases to lungs [recurrence of throat cance] was considered to be ongoing. The investigator assessed the event of metastases to lung to be not related to the IP.

On 12 Aug 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of throat cancer. On 23 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of recurrence of throat cancer [with metastases to lungs] was considered to be ongoing. The investigator assessed the event of throat cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000206	Throat cancer
MOD-2020-000206	Metastases to lung

Study Completion/Discontinuation

On 25 Nov 2020 (Study Day 122), the participant discontinued from the study due to physician decision (reoccurrence of throat cancer resulted in unblinding; subject could continue safety follow up at physician's discretion which was removed on 11/25/20).

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	1970 - Ongoing
Nephrolithiasis	Kidney stones occasional	2004 - Ongoing
Urticaria	Allergy to hydrochlorothiazide - hives	2016 - Ongoing
Benign neoplasm of thyroid gland	Thyroid nodules - benign	2019 - Ongoing
Influenza	Shingles vaccine - flu symptoms	2019 - 2019
Throat cancer	Throat cancer	Feb 2019 - Jun 2019
Chemotherapy	Chemotherapy (for throat cancer)	Mar 2019 - Jun 2019
Radiation therapy to ear, nose, or throat	Radiation therapy (for throat cancer)	Mar 2019 - Jun 2019
Dry mouth	Severe dry mouth	Apr 2019 - Ongoing
Pulmonary embolism	Pulmonary embolism	30 May 2019 (Study Day -424) - 30 May 2019 (Study Day -424)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	1975 - Ongoing	Seasonal Allergies
Atorvastatin	1990 - Ongoing	Hyperlipidemia
Probenecid	1996 - Ongoing	Gout Prevention
Ct chest wo contrast in img ct hbr*	12 Aug 2020 (Study Day 17) - 12 Aug 2020 (Study Day 17)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Guided lung biopsy: positive for squamous cell carcinoma consistent with metastasis , cps 2, p40/p16 and hrhpv positive*	28 Aug 2020 (Study Day 33) - 28 Aug 2020 (Study Day 33)	Adverse Event
Pembrolizumab	24 Sep 2020 (Study Day 60) - Ongoing	Throat Cancer , Metastases To Lungs

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US312-2085 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	26 Aug 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/Diverticulitis	SAE	Grade 3/severe	Not related	08 Jan 2021 (Study Day 165) – 13 Jan 2021 (Study Day 170)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US312-2085, a 69-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 28 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 26 Aug 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Jan 2021 (Study Day 165), 164 days after the first dose and 135 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diverticulitis. Action taken with the IP was not applicable. The event of diverticulitis lasted for 6 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 170). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012114	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	1979 - 1979
Depression	Depression	1995 - Ongoing
Gastrooesophageal reflux disease	Gerd	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Gastric banding	Gastric banding surgery	2001 - 2001
Hyperlipidaemia	Hyperlipidemia	2002 - Ongoing
Diverticulitis	Diverticulitis	2006 - Ongoing
Axillary lymphadenectomy	Axillary lymph node removal (secondary to skin cancer removal)	2011 - 2011
Malignant melanoma	Melanoma - back	2011 - 2011
Skin neoplasm excision	Melanoma removal - back	2011 - 2011
Rosacea	Rosacea	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	1995 - Ongoing	Depression
Metoprolol	2000 - Ongoing	Hypertension
Omeprazole	2000 - Ongoing	Gerd
Bupropion hydrochloride	2005 - Ongoing	Depression
Ezetimibe	2005 - Ongoing	Hyperlipidemia
Simvastatin	2005 - Ongoing	Hyperlipidemia
Acetylsalicylic acid	2019 - Ongoing	Cardiac Health
Nicotinamide	2019 - Ongoing	Rosacea - Face
Sulfacetamide sodium	2019 - Ongoing	Rosacea - Face
Loratadine	Jun 2020 - Ongoing	Seasonal Allergies
Influenza vaccine	17 Nov 2020 (Study Day 113) - 17 Nov 2020 (Study Day 113)	Flu Prevention
Varicella zoster vaccine rge (cho)	17 Nov 2020 (Study Day 113) - 17 Nov 2020 (Study Day 113)	Shingles Prevention
Tetanus vaccine	11 Dec 2020 (Study Day 137) - 11 Dec 2020 (Study Day 137)	Tetanus Prevention
Bloodwork*	08 Jan 2021 (Study Day 165) - 08 Jan 2021 (Study Day 165)	Adverse Event
Cat scan*	08 Jan 2021 (Study Day 165) - 08 Jan 2021 (Study Day 165)	Adverse Event
Montelukast sodium	10 Mar 2021 (Study Day 226) - Ongoing	Seasonal Allergies
Varicella zoster vaccine rge (cho)	23 Mar 2021 (Study Day 239) - 23 Mar 2021 (Study Day 239)	Shingles Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US313-2019 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis Perforated/Appendicitis Perforated	SAE	Grade 3/severe	Not related	18 Nov 2020 (Study Day 94) – 27 Nov 2020 (Study Day 103)	Recovered/resolved
Peritonitis/Localized Peritonitis	SAE	Grade 3/severe	Not related	18 Nov 2020 (Study Day 94) – 27 Nov 2020 (Study Day 103)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US313-2019, a 29-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Nov 2020 (Study Day 94), 93 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis perforated. Action taken with the IP was not applicable. The event of appendicitis perforated lasted for 10 days, after which it was considered to be recovered/resolved on 27 Nov 2020 (Study Day 103). The investigator assessed the event of appendicitis perforated to be not related to the IP.

On 18 Nov 2020 (Study Day 94), 93 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of peritonitis. Action taken with the IP was not applicable. The event of localized peritonitis lasted for 10 days, after which it was considered to be recovered/resolved on 27 Nov 2020 (Study Day 103). The investigator assessed the event of peritonitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000928	Appendicitis perforated

CIOMS Number	MedDRA Preferred Term
MOD-2020-000928	Peritonitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2009 - Ongoing
Glomerulonephritis	Glomerulonephritis	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine	2009 - Ongoing	Seasonal Allergies
Triamcinolone	2009 - Ongoing	Seasonal Allergies
Lisinopril	2013 - Ongoing	Glomerulonephritis
Paracetamol	18 Aug 2020 (Study Day 2) - 18 Aug 2020 (Study Day 2)	Headache
Paracetamol	19 Sep 2020 (Study Day 34) - 20 Sep 2020 (Study Day 35)	Headaches/ Muscle Aches
Ondansetron	23 Nov 2020 (Study Day 99) - 23 Nov 2020 (Study Day 99)	Appendicitis, Perforated
Sodium chloride	23 Nov 2020 (Study Day 99) - 24 Nov 2020 (Study Day 100)	Appendicitis, Perforated
Ct scan abdomen and pelvic*	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Adverse Event
Iopamidol	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Ct Scan Abdomen
Piperacillin; tazobactam	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Appendectomy
Laparoscopic appendectomy*	25 Nov 2020 (Study Day 101) - 25 Nov 2020 (Study Day 101)	Adverse Event
Ibuprofen	26 Nov 2020 (Study Day 102) - 30 Nov 2020 (Study Day 106)	Appendicitis, Perforated
Paracetamol	26 Nov 2020 (Study Day 102) - 03 Dec 2020 (Study Day 109)	Appendicitis, Perforated
Benzocaine	27 Nov 2020 (Study Day 103) - 03 Dec 2020 (Study Day 109)	Sore Throat

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin; clavulanic acid	28 Nov 2020 (Study Day 104) - 04 Dec 2020 (Study Day 110)	Infection Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oropharyngeal Pain	Grade 1/mild	Not related	27 Nov 2020 (Study Day 103) - 03 Dec 2020 (Study Day 109)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US313-2037 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute On Chronic End Stage Renal Disease	SAE	Grade 3/severe	Not related	16 Oct 2020 (Study Day 45) – 24 Nov 2020 (Study Day 84)	Recovered/resolved with sequelae
Cardiac Failure Acute/Acute On Chronic Combined Systolic And Diastolic Heart Failure	SAE	Grade 3/severe	Not related	22 Dec 2020 (Study Day 112) – 03 Jan 2021 (Study Day 124)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US313-2037, a 54-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Oct 2020 (Study Day 45), 44 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute on chronic end stage renal disease lasted for 40 days, after which it was considered to be recovered/resolved with sequelae on 24 Nov 2020 (Study Day 84). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 22 Dec 2020 (Study Day 112), 111 days after the first dose and 83 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cardiac failure acute. Action taken with the IP was not applicable. The event of acute on chronic combined systolic and diastolic heart failure lasted for 13 days, after which it was considered to be recovered/resolved

with sequelae on 03 Jan 2021 (Study Day 124). The investigator assessed the event of cardiac failure acute to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001445	Acute kidney injury
MOD-2021-010272	Cardiac failure acute

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diabetic retinopathy	Diabetic retinopathay	Not reported - Ongoing
Osteomyelitis	Osteomyelitis	Not reported
Staphylococcal infection	Methicillin resistant staphylococcus aureus (mrsa)	Not reported
Type 2 diabetes mellitus	Diabetes type ii	1994 - Ongoing
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Coronary artery bypass	Double bypass surgery	2012 - 2012
Hypertension	Hypertension	2012 - Ongoing
Peripheral vascular disorder	Peripheral vascular disease	2017 - Ongoing
Constipation	Constipation	2018 - Ongoing
Drug hypersensitivity	Daptomycin allergy	2018 - Ongoing
Toe amputation	Right toe amputation surgical	2018 - 2018
Vitamin D deficiency	Vitamin d deficiency	2018 - Ongoing
Cardiac failure congestive	Congestive heart failure	2019 - Ongoing
Coronary artery disease	Coronary artery disease	2019 - Ongoing
Deep vein thrombosis	Deep vein thrombosis	2019 - 2019
Diabetic neuropathy	Diabetic neuropathy to bilateral extremities from calf to feet - sensory	2019 - Ongoing
End stage renal disease	End stage renal disease bilateral	2019 - Ongoing
Myocardial infarction	Heart attack	2019 - 2019
Skin ulcer	Right foot ulcer	2019 - Ongoing
Appendicectomy	Appendectomy	Mar 2020 - Mar 2020
Appendicitis perforated	Ruptured appendix	Mar 2020 - Mar 2020
Gout	Gout bilat feet	Mar 2020 - Ongoing
Gout	Gout bilat hands	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin glargine	2010 - 19 Nov 2020 (Study Day 79)	Type 2 Diabetes
Insulin lispro	2010 - 19 Nov 2020 (Study Day 79)	Type 2 Diabetes
Amlodipine	2015 - Ongoing	Hypertension
Atorvastatin	2015 - Ongoing	High Cholesterol
Acetylsalicylic acid	2018 - Ongoing	Cardiac Prophylaxis
Ergocalciferol	2018 - 13 Nov 2020 (Study Day 73)	Vitamin D Deficiency
Hydralazine	2018 - Ongoing	Hypertension
Isosorbide	2018 - Ongoing	Hypertension
Labetalol	2018 - Ongoing	Hypertension
Metolazone	2018 - Ongoing	Hypertension
Bumetanide	2019 - Ongoing	Hypertension
Clonidine	2019 - Ongoing	Hypertension
Clopidogrel	2019 - Ongoing	Cardiac Prophylaxis
Gabapentin	2019 - Ongoing	Neuropathy To Bilateral Extremities From Calf To Feet
Allopurinol	Apr 2020 - 14 Nov 2020 (Study Day 74)	Gout
Paracetamol	01 Oct 2020 (Study Day 30) - 01 Oct 2020 (Study Day 30)	Fever
Cefalexin	13 Oct 2020 (Study Day 42) - 22 Oct 2020 (Study Day 51)	Sinus Infection
Furosemide	16 Oct 2020 (Study Day 45) - 21 Oct 2020 (Study Day 50)	Acute On Chronic End Stage Renal Disease
Furosemide	22 Oct 2020 (Study Day 51) - 14 Nov 2020 (Study Day 74)	Acute On Chronic End Stage Renal Disease
Furosemide	Nov 2020 - Nov 2020	Bilateral Lower Extremity Swelling Endstage Renal Disease
Epoetin alfa	12 Nov 2020 (Study Day 72) - 12 Nov 2020 (Study Day 72)	Anemia
Acetylsalicylic acid	14 Nov 2020 (Study Day 74) - 14 Nov 2020 (Study Day 74)	Cardiac Prophylaxis
Bumetanide	14 Nov 2020 (Study Day 74) - 15 Nov 2020 (Study Day 75)	Acute On Chronic End Stage Renal Disease
Calcitriol	14 Nov 2020 (Study Day 74) - Ongoing	Acute On Chronic End Stage Renal Disease
Chest xray*	14 Nov 2020 (Study Day 74) - 14 Nov 2020 (Study Day 74)	Diagnostic
Ct scan*	14 Nov 2020 (Study Day 74) - 14 Nov 2020 (Study Day 74)	Diagnostic
Docusate sodium	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)	Obstipation
Ecg*	14 Nov 2020 (Study Day 74) - 14 Nov 2020 (Study Day 74)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Epoetin zeta	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)	Anemia
Furosemide	14 Nov 2020 (Study Day 74) - 14 Nov 2020 (Study Day 74)	Acute On Chronic End Stage Renal Disease
Furosemide	14 Nov 2020 (Study Day 74) - 15 Nov 2020 (Study Day 75)	Acute On Chronic End Stage Renal Disease
Glucagon	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)	Diabetes Type 2
Glucose	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)	Diabetes Type 2
Heparin	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)	Blood Clots Prophylaxis
Lactulose	14 Nov 2020 (Study Day 74) - 17 Nov 2020 (Study Day 77)	Obstipation
Ondansetron	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)	Nausea Prophylaxis
Sodium chloride	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)	Acute On Chronic End Stage Renal Disease
Transthoracic echocardiogram*	15 Nov 2020 (Study Day 75) - 15 Nov 2020 (Study Day 75)	Diagnostic
Ct scan*	16 Nov 2020 (Study Day 76) - 16 Nov 2020 (Study Day 76)	Diagnostic
Chest xray*	17 Nov 2020 (Study Day 77) - 17 Nov 2020 (Study Day 77)	Diagnostic
Hemodialysisi*	17 Nov 2020 (Study Day 77) - 17 Nov 2020 (Study Day 77)	Adverse Event
Ir non tunneled cv catheter replacement*	17 Nov 2020 (Study Day 77) - 17 Nov 2020 (Study Day 77)	Adverse Event
Lidocaine	17 Nov 2020 (Study Day 77) - 17 Nov 2020 (Study Day 77)	Hd Catheter Placement
Pantoprazole	17 Nov 2020 (Study Day 77) - 17 Nov 2020 (Study Day 77)	Gastrointestinal Prophylaxis
Ultra sound abdomen*	17 Nov 2020 (Study Day 77) - 17 Nov 2020 (Study Day 77)	Diagnostic
Hemodialysisi*	18 Nov 2020 (Study Day 78) - 18 Nov 2020 (Study Day 78)	Adverse Event
Macrogol; potassium chloride; sodium bicarbonate; sodium chloride; sodium sulfate	18 Nov 2020 (Study Day 78) - 18 Nov 2020 (Study Day 78)	Ostipation
Oxycodone	18 Nov 2020 (Study Day 78) - 24 Nov 2020 (Study Day 84)	Acute On Chronic End Stage Renal Disease
Paracetamol	18 Nov 2020 (Study Day 78) - 24 Nov 2020 (Study Day 84)	Acute On Chronic End Stage Renal Disease
Insulin glargine	19 Nov 2020 (Study Day 79) - Ongoing	Type Ii Diabetes Mellitus
Insulin lispro	19 Nov 2020 (Study Day 79) - Ongoing	Diabetes Type 2
Ultra sound lower extremities*	19 Nov 2020 (Study Day 79) - 19 Nov 2020 (Study Day 79)	Diagnostic
Chest xray*	20 Nov 2020 (Study Day 80) - 20 Nov 2020 (Study Day 80)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ecg*	21 Nov 2020 (Study Day 81) - 21 Nov 2020 (Study Day 81)	Diagnostic
Epinephrine; lidocaine	21 Nov 2020 (Study Day 81) - 21 Nov 2020 (Study Day 81)	Procedure Pain Prophylaxis
Fentanyl	21 Nov 2020 (Study Day 81) - 21 Nov 2020 (Study Day 81)	Procedure Pain Prophylaxis Ir Tunnel Cv Catheter
Ir tunneled cv catheter*	21 Nov 2020 (Study Day 81) - 21 Nov 2020 (Study Day 81)	Adverse Event
Midazolam	21 Nov 2020 (Study Day 81) - 21 Nov 2020 (Study Day 81)	Anxiety Prophylaxis
Temporary tunneled hd catheter placement*	21 Nov 2020 (Study Day 81) - 21 Nov 2020 (Study Day 81)	Adverse Event
Allopurinol	25 Nov 2020 (Study Day 85) - Ongoing	Gout
Ergocalciferol	25 Nov 2020 (Study Day 85) - Ongoing	Vitamin D Deficiency
Ferrous sulfate	25 Nov 2020 (Study Day 85) - Ongoing	Anemia
Acetylsalicylic acid	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Cardiac Prophylaxis
Ceftriaxone	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Pneumonia
Ct scan*	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Diagnostic
Echocardiogram transthoracic*	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Diagnostic
Furosemide	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Acute On Chronic Combined Systolica And Diastolic Heart Failure
Heparin	24 Dec 2020 (Study Day 114) - 03 Jan 2021 (Study Day 124)	Dvt Prophylaxis
Lactulose	24 Dec 2020 (Study Day 114) - 03 Jan 2021 (Study Day 124)	Constipation
Levofloxacin	24 Dec 2020 (Study Day 114) - 25 Dec 2020 (Study Day 115)	Pneumonia
Trialysis catheter placement*	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Adverse Event
Epinephrine; lidocaine	25 Dec 2020 (Study Day 115) - 25 Dec 2020 (Study Day 115)	Tunneled Dialysis Catheter Placement
Fentanyl	25 Dec 2020 (Study Day 115) - 25 Dec 2020 (Study Day 115)	Tunneled Dyalisis Catheter Placement
Lidocaine	25 Dec 2020 (Study Day 115) - 25 Dec 2020 (Study Day 115)	Tunneled Dyalysis Catheter Placement
Transthoracic echocardiogram*	25 Dec 2020 (Study Day 115) - 25 Dec 2020 (Study Day 115)	Adverse Event
Tunneled dialysis catheter*	25 Dec 2020 (Study Day 115) - 25 Dec 2020 (Study Day 115)	Adverse Event
Lidocaine	26 Dec 2020 (Study Day 116) - 26 Dec 2020 (Study Day 116)	Trialysis Cv Catheter Placement
Abdomen plus pelvic ct scan*	27 Dec 2020 (Study Day 117) - 27 Dec 2020 (Study Day 117)	Diagnostic
Epinephrine; lidocaine	30 Dec 2020 (Study Day 120) - 30 Dec 2020 (Study Day 120)	Ir Tunneled Cv Catheter Placement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fentanyl	30 Dec 2020 (Study Day 120) - 30 Dec 2020 (Study Day 120)	Ir Tunneled Catheter Placement
Ir non tunneled catheter placement*	30 Dec 2020 (Study Day 120) - 30 Dec 2020 (Study Day 120)	Adverse Event
Lidocaine	30 Dec 2020 (Study Day 120) - 30 Dec 2020 (Study Day 120)	Ir Tunneled Cv Catheter Placement
Lidocaine	30 Dec 2020 (Study Day 120) - 30 Dec 2020 (Study Day 120)	Trialysis Catheter Placement
Ultrasound thoracentesis*	30 Dec 2020 (Study Day 120) - 30 Dec 2020 (Study Day 120)	Diagnostic
Left lung thoracentesis*	31 Dec 2020 (Study Day 121) - 31 Dec 2020 (Study Day 121)	Adverse Event
Left thoracentesis*	31 Dec 2020 (Study Day 121) - 31 Dec 2020 (Study Day 121)	Adverse Event
Lidocaine	31 Dec 2020 (Study Day 121) - 31 Dec 2020 (Study Day 121)	Trialysis Catheter
Xr esophagram*	31 Dec 2020 (Study Day 121) - 31 Dec 2020 (Study Day 121)	Adverse Event
Carvedilol	03 Jan 2021 (Study Day 124) - Ongoing	Acute On Chronic Combined Systolic And Diastolic Heart Failure
Ferrous sulfate	03 Jan 2021 (Study Day 124) - Ongoing	Dietary Supplement
Furosemide	03 Jan 2021 (Study Day 124) - Ongoing	Acute On Chronic Combined Systolic And Diastolic Heart Failure
Levofloxacin	03 Jan 2021 (Study Day 124) - 09 Jan 2021 (Study Day 130)	Pneumonia
Ondansetron	03 Jan 2021 (Study Day 124) - Ongoing	Nausea Prophylaxis
Salbutamol	03 Jan 2021 (Study Day 124) - Ongoing	Acute On Chronic Combined Systolic And Diastolic Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Sinusitis	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 42) - 22 Oct 2020 (Study Day 51)
Type 2 Diabetes Mellitus	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 61) - Ongoing
Acute Left Ventricular Failure	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 67) - 24 Nov 2020 (Study Day 84)
Anaemia	Grade 2/moderate	Not related	08 Nov 2020 (Study Day 68) - Ongoing
Constipation	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 74) - 24 Nov 2020 (Study Day 84)
Hiatus Hernia	Grade 1/mild	Not related	14 Nov 2020 (Study Day 74) - Ongoing
Renal Tubular Necrosis	Grade 1/mild	Not related	14 Nov 2020 (Study Day 74) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pneumonia	Grade 2/moderate	Not related	24 Dec 2020 (Study Day 114) - 09 Jan 2021 (Study Day 130)
Acute Myocardial Infarction	Grade 2/moderate	Not related	25 Dec 2020 (Study Day 115) - 25 Dec 2020 (Study Day 115)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US313-2111 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	10 Nov 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Osteoarthritis/Exacerbation Of Degenerative Joint Disease Lumbar Spine	SAE	Grade 3/severe	Not related	28 Dec 2020 (Study Day 81) – 14 Mar 2021 (Study Day 157)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US313-2111, a 56-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 09 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 10 Nov 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Dec 2020 (Study Day 81), 80 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of spinal osteoarthritis. Action taken with the IP was not applicable. The event of exacerbation of degenerative joint disease lumbar spine lasted for 77 days, after which it was considered to be recovered/resolved with sequelae on 14 Mar 2021 (Study Day 157). The investigator assessed the event of spinal osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-050357	Spinal osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	1981 - Ongoing
Obesity	Obesity	1991 - Ongoing
Dysmenorrhoea	Dysmenorhhea	2000 - 2001
Hysterectomy	Hysterectomy	2001 - 2001
Menopausal symptoms	Postmenopausal syndrome	2001 - Ongoing
Intervertebral disc protrusion	Herniated disc l4,l5, s1	2016 - 2017
Lumbar radiculopathy	Lumbar radiculopathy	2016 - Ongoing
Scoliosis	Scoliosis	2016 - Ongoing
Spinal osteoarthritis	Degenerative joint disease lumbar spine	2016 - Ongoing
Spinal stenosis	Spinal stenosis	2016 - Ongoing
Irritable bowel syndrome	Ibs	2017 - Ongoing
Spinal fusion surgery	L4,l5,s1 infusion	2017 - 2017
Osteoarthritis	Osteoarthritis bilateral hands	2020 - Ongoing
Tendonitis	Left ankle pain achilles tendonitis	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b12 nos	2010 - Ongoing	Dietary Supplement
Vitamins nos	2010 - Ongoing	Dietary Supplement
Cannabis sativa	2017 - Ongoing	Insomnia
Docusate sodium	2019 - Ongoing	Ibs
Phentermine	Jan 2020 - Ongoing	Obesity
Dexamethasone	19 Mar 2020 (Study Day -204) - 21 Mar 2020 (Study Day -202)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Naproxen sodium	Aug 2020 - Ongoing	Bilateral Hands Osteoarthritis
Calcium carbonate	Sep 2020 - Ongoing	Ibs
Melatonin	Sep 2020 - Ongoing	Insomnia
Meloxicam	Sep 2020 - Sep 2020	Degenerative Joint Disease Lumbar Spine
Simeticone	Sep 2020 - Ongoing	Ibs
Influenza vaccine	16 Sep 2020 (Study Day -23) - 16 Sep 2020 (Study Day -23)	Flu Prophylaxis
Diclofenac potassium	25 Oct 2020 (Study Day 17) - 27 Nov 2020 (Study Day 50)	Left Ankle Achilles Tendonitis Pain
Naproxen sodium	16 Nov 2020 (Study Day 39) - 16 Nov 2020 (Study Day 39)	Muscle Aches

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ketorolac tromethamine	28 Dec 2020 (Study Day 81) - 28 Dec 2020 (Study Day 81)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Methylprednisolone	28 Dec 2020 (Study Day 81) - 30 Dec 2020 (Study Day 83)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Diclofenac	30 Dec 2020 (Study Day 83) - Ongoing	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Gabapentin	30 Dec 2020 (Study Day 83) - 15 Jan 2021 (Study Day 99)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Paracetamol	30 Dec 2020 (Study Day 83) - Ongoing	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Tizanidine	15 Jan 2021 (Study Day 99) - Ongoing	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Gabapentin	16 Jan 2021 (Study Day 100) - Ongoing	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Celecoxib	21 Jan 2021 (Study Day 105) - Ongoing	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Hydrocortisone	05 Feb 2021 (Study Day 120) - 05 Feb 2021 (Study Day 120)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Morphine	14 Mar 2021 (Study Day 157) - 14 Mar 2021 (Study Day 157)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Ondansetron	14 Mar 2021 (Study Day 157) - 14 Mar 2021 (Study Day 157)	Nausea Prophylaxis
Bupivacaine	16 Mar 2021 (Study Day 159) - 16 Mar 2021 (Study Day 159)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Lidocaine	16 Mar 2021 (Study Day 159) - 17 Mar 2021 (Study Day 160)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Bupivacaine	17 Mar 2021 (Study Day 160) - 17 Mar 2021 (Study Day 160)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
L1-s1 posterior decompression*	17 Mar 2021 (Study Day 160) - 17 Mar 2021 (Study Day 160)	Adverse Event
L4-l5 posterior fusion*	17 Mar 2021 (Study Day 160) - 17 Mar 2021 (Study Day 160)	Adverse Event
Cyclobenzaprine	19 Mar 2021 (Study Day 162) - 29 Mar 2021 (Study Day 172)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Oxycodone	19 Mar 2021 (Study Day 162) - 26 Mar 2021 (Study Day 169)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Dexamethasone	22 Mar 2021 (Study Day 165) - 24 Mar 2021 (Study Day 167)	Exacerbation Of Degenerative Joint Disease Lumbar Spine
Dexamethasone	25 Mar 2021 (Study Day 168) - 27 Mar 2021 (Study Day 170)	Exacerbation Of Degenerative Joint Disease Lumbar Spine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US336-2071 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain/Abdominal Pain	SAE	Grade 3/ severe	Not related	23 Nov 2020 (Study Day 109) – 04 Dec 2020 (Study Day 120)	Recovered/ resolved
Dyspnoea/Shortness Of Breath	SAE	Grade 4	Not related	23 Nov 2020 (Study Day 109) – 05 Dec 2020 (Study Day 121)	Recovered/ resolved
Upper Respiratory Tract Infection/Upper Respiratory Infection	SAE	Grade 4	Not related	23 Nov 2020 (Study Day 109) – 30 Dec 2020 (Study Day 146)	Recovered/ resolved
Dehydration/Dehydration	SAE	Grade 4	Not related	03 Dec 2020 (Study Day 119) – 05 Dec 2020 (Study Day 121)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2071, a 52-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Nov 2020 (Study Day 109), 108 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abdominal pain. Action taken with the IP was not applicable. The event of abdominal pain lasted for 12 days, after which it was considered to be recovered/resolved on 04 Dec 2020 (Study Day 120). The investigator assessed the event of abdominal pain to be not related to the IP.

On 23 Nov 2020 (Study Day 109), 108 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dyspnoea. Action taken with the IP was not applicable. The event of shortness of breath lasted for 13 days, after which it was considered to be recovered/resolved on 05 Dec 2020 (Study Day 121). The investigator assessed the event of dyspnoea to be not related to the IP.

On 23 Nov 2020 (Study Day 109), 108 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of upper respiratory tract

infection. Action taken with the IP was not applicable. The event of upper respiratory infection lasted for 38 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 146). The investigator assessed the event of upper respiratory tract infection to be not related to the IP.

On 03 Dec 2020 (Study Day 119), 118 days after the first dose and 90 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration lasted for 3 days, after which it was considered to be recovered/resolved on 05 Dec 2020 (Study Day 121). The investigator assessed the event of dehydration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001073	Upper respiratory tract infection
MOD-2020-001073	Dyspnoea
MOD-2020-001073	Dehydration
MOD-2020-001073	Abdominal pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Congestive cardiomyopathy	Dilated cardiomyopathy	Not reported - Ongoing
Appendicectomy	Appendectomy	1978 - 1978
Colonoscopy	Colonoscopy	2000 - 2000
Acute myocardial infarction	Non-stemi myocardial infarcation	2015 - 2015
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Cardiac failure congestive	Systolic chf	14 Jun 2016 (Study Day -1515) - Ongoing
Chronic kidney disease	Chronic kidney disease	14 Jun 2016 (Study Day -1515) - Ongoing
Phaeochromocytoma	Pheochromocytoma	14 Jun 2016 (Study Day -1515) - Ongoing
Pulmonary hypertension	Pulmonary hypertension	14 Jun 2016 (Study Day -1515) - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	14 Jul 2016 (Study Day -1485) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2015 - Ongoing	History Of Non-Stemi Myocardial Infarct
Amlodipine	2015 - Ongoing	Hypertension
Fish oil	2015 - Ongoing	Hyperlipidemia
Lisinopril	2015 - Ongoing	Hypertension
Spironolactone	2016 - Ongoing	Systolic Congestive Heart Failure
Amoxicillin; clavulanate potassium	03 Dec 2020 (Study Day 119) - 08 Dec 2020 (Study Day 124)	Ae Upper Respiratory Infection
Colonoscopy*	03 Dec 2020 (Study Day 119) - 03 Dec 2020 (Study Day 119)	Diagnostic
Dicycloverine	03 Dec 2020 (Study Day 119) - Ongoing	Abdominal Pain
Dicycloverine hydrochloride	03 Dec 2020 (Study Day 119) - Ongoing	Gastroesophageal Reflux Disease
Salbutamol	03 Dec 2020 (Study Day 119) - 30 Dec 2020 (Study Day 146)	Shortness Of Breath
Sodium bicarbonate	03 Dec 2020 (Study Day 119) - 05 Dec 2020 (Study Day 121)	Principal Ae:dehydration
Vitamin d nos	03 Dec 2020 (Study Day 119) - Ongoing	Nutritional Support
Pantoprazole sodium sesquihydrate	25 Jan 2021 (Study Day 172) - Ongoing	Gastroesophageal Reflux Disease
Carvedilol	05 Mar 2021 (Study Day 211) - Ongoing	Dissecting Aorta
Hydralazine	05 Mar 2021 (Study Day 211) - Ongoing	Dissecting Aorta

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not applicable	03 Dec 2020 (Study Day 119) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2627 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	18 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Inguinal Hernia/Hernia S/P Left Inguinal Hernia Repair	SAE	Grade 3/severe	Not related	23 Nov 2020 (Study Day 34) – 24 Nov 2020 (Study Day 35)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2627, a 33-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was Not reported.

Event Details

On 23 Nov 2020 (Study Day 34), 33 days after the first dose and 5 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of inguinal hernia. Action taken with the IP was not applicable. The event of hernia s/p left inguinal hernia repair lasted for 2 days, after which it was considered to be recovered/resolved on 24 Nov 2020 (Study Day 35). The investigator assessed the event of inguinal hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000902	Inguinal hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Craniocerebral injury	Traumatic brain injury	2010 - Ongoing
Migraine	Migraines	2010 - Ongoing
Asthma	Mild asthma	2012 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2012 - Ongoing	Asthma
Paracetamol	19 Nov 2020 (Study Day 30) - 19 Nov 2020 (Study Day 30)	Headache
Celecoxib	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Pain From Hernia Repair
Hernia repair*	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Adverse Event
Oxycodone	23 Nov 2020 (Study Day 34) - 28 Nov 2020 (Study Day 39)	Pain After Left Inguinal Hernia Repair
Paracetamol	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Pain From Hernia Repair
Paracetamol	24 Nov 2020 (Study Day 35) - 02 Dec 2020 (Study Day 43)	Pain From Hernia Repair

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pruritus	Grade 1/mild	Not related	21 Oct 2020 (Study Day 1) - 21 Oct 2020 (Study Day 1)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US313-2149 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	18 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Fall/Fall	SAE	Grade 3/severe	Not related	27 Dec 2020 (Study Day 68) – 27 Dec 2020 (Study Day 68)	Recovered/resolved
Hip Fracture/Right Hip Fracture	SAE	Grade 3/severe	Not related	27 Dec 2020 (Study Day 68) – 28 Dec 2020 (Study Day 69)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US313-2149, a 72-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Dec 2020 (Study Day 68), 67 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of fall. Action taken with the IP was not applicable. The event of fall lasted for 1 day, after which it was considered to be recovered/resolved on 27 Dec 2020 (Study Day 68). The investigator assessed the event of fall to be not related to the IP.

On 27 Dec 2020 (Study Day 68), 67 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hip fracture. Action taken with the IP was not applicable. The event of right hip fracture lasted for 2 days, after which it was considered to be recovered/resolved on 28 Dec 2020 (Study Day 69). The investigator assessed the event of hip fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004578	Fall
MOD-2021-004578	Hip Fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menopausal symptoms	Postmenopausal syndrome	1976 - Ongoing
Spinal osteoarthritis	Osteoarthritis neck	2002 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	2005 - Ongoing
Back pain	Chronic back pain	2017 - Ongoing
Fluid retention	Water retension due to ankle swelling	2017 - Ongoing
Gastric ulcer	Stomach ulcers	2017 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Osteoporosis	Osteoporosis	2017 - Ongoing
Osteoarthritis	Osteoarthritis bilateral hands	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	Not reported - Ongoing	Not reported
Alendronate sodium	2017 - Ongoing	Osteoporosis
Pantoprazole	2017 - Ongoing	Stomach Ulcers
Rosuvastatin	2017 - Ongoing	Hypercholesterolemia
Sucralfate	2017 - Ongoing	Stomach Ulcers
Torasemide	2017 - Ongoing	Water Retention
Codeine; paracetamol	2018 - Ongoing	Osteoarthritis Bilateral Hands
Diclofenac	Sep 2020 - Ongoing	Osteoarthritis Neck
Calcium carbonate	27 Dec 2020 (Study Day 68) - 30 Dec 2020 (Study Day 71)	Stomach Prophylaxis
Chest x-ray*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct scan of cervical spine*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event
Ct scan of head/brain*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event
Fentanyl	27 Dec 2020 (Study Day 68) - 30 Dec 2020 (Study Day 71)	Right Hip Fracture
Magnesium sulfate	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Right Hip Fracture
Oxycodone hydrochloride; paracetamol	27 Dec 2020 (Study Day 68) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Potassium chloride	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Hypokalemia
Right hip ct*	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Adverse Event
Thiamine	27 Dec 2020 (Study Day 68) - 27 Dec 2020 (Study Day 68)	Right Hip Fracture
Bupivacaine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Calcium chloride; potassium chloride; sodium lactate	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Cefazolin	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Infection Prophylaxis
Dexamethasone	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Dexmedetomidine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Ekg*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event
Famotidine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Stomach Prophylaxis
Famotidine	28 Dec 2020 (Study Day 69) - 29 Dec 2020 (Study Day 70)	Stomach Prophylaxis
Ferrous sulfate	28 Dec 2020 (Study Day 69) - 15 Jan 2021 (Study Day 87)	Dietary Supplement
Ketorolac	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Lidocaine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Morphine	28 Dec 2020 (Study Day 69) - 29 Dec 2020 (Study Day 70)	Right Hip Pain
Ondansetron	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Nausea Prophylaxis
Oxycodone	28 Dec 2020 (Study Day 69) - 15 Jan 2021 (Study Day 87)	Right Hip Pain
Paracetamol	28 Dec 2020 (Study Day 69) - 30 Dec 2020 (Study Day 71)	Right Hip Pain
Peng block*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event
Phenylephrine	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Potassium chloride	28 Dec 2020 (Study Day 69) - 09 Jan 2021 (Study Day 81)	Hypokalemia
Propofol	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Right hip xray*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event
Right total hip arthroplasty*	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Adverse Event
Rocuronium	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Suxamethonium	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Tobramycin	28 Dec 2020 (Study Day 69) - 30 Dec 2020 (Study Day 71)	Infection Prophylaxis
Tranexamic acid	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Right Hip Fracture
Vancomycin	28 Dec 2020 (Study Day 69) - 28 Dec 2020 (Study Day 69)	Infection Prophylaxis
Vitamins nos	28 Dec 2020 (Study Day 69) - 30 Dec 2020 (Study Day 71)	Dietary Supplement
Acetylsalicylic acid	29 Dec 2020 (Study Day 70) - 15 Jan 2021 (Study Day 87)	Cardiac Prophylaxis
Docusate sodium	29 Dec 2020 (Study Day 70) - 15 Jan 2021 (Study Day 87)	Constipation Prophylaxis
Enoxaparin	29 Dec 2020 (Study Day 70) - 29 Dec 2020 (Study Day 70)	Dvt Prophylaxis
Influenza vaccine	29 Dec 2020 (Study Day 70) - 29 Dec 2020 (Study Day 70)	Influenza Prophylaxis
Diclofenac sodium	30 Dec 2020 (Study Day 71) - 06 Jan 2021 (Study Day 78)	Right Hip Pain
Lidocaine	30 Dec 2020 (Study Day 71) - 02 Jan 2021 (Study Day 74)	Right Hip Pain
Vitamin d nos	30 Dec 2020 (Study Day 71) - 15 Jan 2021 (Study Day 87)	Dietary Supplement
Other viral vaccines	05 Jan 2021 (Study Day 77) - 05 Jan 2021 (Study Day 77)	COVID19 Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypocalcaemia	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 68) - 28 Dec 2020 (Study Day 69)
Hypokalaemia	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 68) - 28 Dec 2020 (Study Day 69)
Hypomagnesaemia	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 68) - 28 Dec 2020 (Study Day 69)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 2/moderate	Not related	28 Dec 2020 (Study Day 69) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US314-2161 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Stroke	SAE	Grade 2/moderate	Not related	23 Nov 2020 (Study Day 108) – 23 Nov 2020 (Study Day 108)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US314-2161, a 72-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Nov 2020 (Study Day 108), 107 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of stroke lasted for 1 day, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 108). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-007926	Cerebrovascular accident

Study Completion/Discontinuation

On 24 Feb 2021 (Study Day 201), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillitis	Tonsillitis	1952 - 1952
Asthma	Asthma	2002 - Ongoing
Postmenopause	Post menopausal	2002 - Ongoing
Osteoarthritis	Oa	2005 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2007 - Ongoing
Hypertension	High blood pressure	2007 - Ongoing
Cataract	Bilateral cataracts	2010 - 2010
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Upper-airway cough syndrome	Postnasal drip	2010 - Ongoing
Increased tendency to bruise	Bruise easily	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide; formoterol fumarate	2002 - Ongoing	Asthma
Salbutamol	2002 - Ongoing	Asthma
Pravastatin	2007 - Ongoing	High Cholesterol
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Acetylsalicylic acid	2013 - Ongoing	General Heart Health
Losartan	2013 - Ongoing	Hypertension
Influenza vaccine	20 Oct 2020 (Study Day 74) - 20 Oct 2020 (Study Day 74)	Flu Prevention
Apixaban	23 Nov 2020 (Study Day 108) - Ongoing	Stroke Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US314-2185 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 37)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intestinal Obstruction/Closed Loop Bowel Obstruction	SAE	Grade 2/moderate	Not related	18 Sep 2020 (Study Day 39) – 18 Sep 2020 (Study Day 39)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US314-2185, a 73-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 37). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Sep 2020 (Study Day 39), 38 days after the first dose and 2 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of intestinal obstruction. Action taken with the IP was not applicable. The event of closed loop bowel obstruction lasted for 1 day, after which it was considered to be recovered/resolved on 18 Sep 2020 (Study Day 39). The investigator assessed the event of intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000322	Intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillitis	Tonsillitis	1951 - 1951
Astigmatism	Astigmatism	1963 - Ongoing
Myopia	Bilateral nearsighted	1963 - Ongoing
Anxiety	Anxiety	1987 - Ongoing
Hypertension	Hypertension	1987 - Ongoing
Hernia	Hernias (location unknown)	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Dyspepsia	Heartburn	2003 - Ongoing
Seasonal allergy	Seasonal allergies	2006 - Ongoing
Dental implantation	Dental implants	2010 - Ongoing
Tinnitus	Ringing in ears, bilateral	2010 - Ongoing
Cough	Chronic cough	2012 - Ongoing
Hypothyroidism	Hypothyroidism	2012 - Ongoing
Osteoarthritis	Oa in knees	2013 - Ongoing
Bronchitis	Bronchitis	2015 - 2015
Pneumonia	Pneumonia	2015 - Ongoing
Back pain	Back pain	2016 - Ongoing
Intervertebral disc protrusion	Herniated disk	2016 - Ongoing
Thrombosis	Blood clots	2016 - 2016
Vertigo	Vertigo	2016 - 2019
Deafness bilateral	Bilateral hearing loss	2017 - Ongoing
Cataract	Bilateral cataracts	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; lisinopril	1990 - Ongoing	Hypertension
Simvastatin	2000 - Ongoing	Hypercholesterolemia
Omeprazole	2003 - Ongoing	Heartburn
Diphenhydramine	2006 - Ongoing	Seasonal Allergies
Levothyroxine sodium	2012 - Ongoing	Hypothyroidism
Dextrin	2015 - Ongoing	General Health
Acetylsalicylic acid	2016 - Ongoing	Heart Health
Ibuprofen	2016 - Ongoing	Herniated Disc
Lycopene	2018 - Ongoing	General Health

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Punica granatum	2018 - Ongoing	General Health
Hydrocortisone	Dec 2019 - Ongoing	Osteoarthritis
Naproxen	Jun 2020 - Ongoing	Osteoarthritis
Anesthetics, general	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Closed Loop Bowel Obstruction
Ceftriaxone	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Closed Loop Bowel Obstruction
Fentanyl	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Closed Loop Bowel Obstruction
Hydromorphone hydrochloride	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Closed Loop Bowel Obstruction
Iohexol	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Closed Loop Bowel Obstruction
Laparoscopic open, small bowel resection*	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Adverse Event
Morphine	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Closed Loop Bowel Obstruction
Sodium chloride	18 Sep 2020 (Study Day 39) - 18 Sep 2020 (Study Day 39)	Closed Loop Bowel Obstruction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US314-2268 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Duodenal Ulcer/Duodenal Ulcer	SAE	Grade 3/severe	Not related	22 Oct 2020 (Study Day 49) – 01 Mar 2021 (Study Day 179)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US314-2268, a 60-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Oct 2020 (Study Day 49), 48 days after the first dose and 22 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of duodenal ulcer. Action taken with the IP was not applicable. The event of duodenal ulcer lasted for 131 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 179). The investigator assessed the event of duodenal ulcer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000542	Duodenal ulcer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypogonadism	Hypogonadism	Not reported - Ongoing
Migraine	Migraines	1972 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Testis cancer	Testicular cancer	1997 - 1997
Back pain	Back pain	2000 - Ongoing
Cataract	Cataracts	2012 - 2012
Hypertension	High blood pressure	2015 - Ongoing
Irritable bowel syndrome	Ibs	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Testosterone	Not reported - Ongoing	Hormone Replacement
Cetirizine hydrochloride	1995 - Ongoing	Seasonal Allergies
Fluticasone propionate	1995 - Ongoing	Seasonal Allergies
Sumatriptan	2000 - Ongoing	Migraines
Testosterone	2016 - Ongoing	Hypogonadism
Probiotics nos	2019 - Ongoing	General Health
Paracetamol	2020 - Ongoing	Unspecified Pain
Pyridoxine hydrochloride	2020 - Ongoing	General Health
Vitamin b12 nos	2020 - Ongoing	General Health
Paracetamol	03 Oct 2020 (Study Day 30) - 03 Oct 2020 (Study Day 30)	Injection Site Pain
Paracetamol	03 Oct 2020 (Study Day 30) - 03 Oct 2020 (Study Day 30)	Injection Site Pain After Second Vaccination
Promethazine	13 Oct 2020 (Study Day 40) - 13 Oct 2020 (Study Day 40)	Intermittent Neausea
Promethazine	13 Oct 2020 (Study Day 40) - 13 Oct 2020 (Study Day 40)	Nausea
Pantoprazole sodium sesquihydrate	22 Oct 2020 (Study Day 49) - 22 Oct 2020 (Study Day 49)	Duodenal Ulcer
Colonoscopy*	23 Oct 2020 (Study Day 50) - 23 Oct 2020 (Study Day 50)	Adverse Event
Ct abdomen and pelvis with contrast*	23 Oct 2020 (Study Day 50) - 23 Oct 2020 (Study Day 50)	Adverse Event
Egd*	23 Oct 2020 (Study Day 50) - 23 Oct 2020 (Study Day 50)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole sodium sesquihydrate	23 Oct 2020 (Study Day 50) - 23 Oct 2020 (Study Day 50)	Ulcer
Sodium chloride	23 Oct 2020 (Study Day 50) - 23 Oct 2020 (Study Day 50)	Prophylaxis Dehydration

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Not related	02 Oct 2020 (Study Day 29) - 01 Nov 2020 (Study Day 59)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US315-2136 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Sternal Pain	SAE	Grade 4	Not related	03 Nov 2020 (Study Day 85) – 10 Feb 2021 (Study Day 184)	Recovered/ resolved
Sternal Fracture/Non-Displaced Closed Fracture Lower Sternum	SAE	Grade 3/ severe	Not related	03 Nov 2020 (Study Day 85) – 12 Mar 2021 (Study Day 214)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2136, a 50-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Nov 2020 (Study Day 85), 84 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of chest pain. Action taken with the IP was not applicable. The event of sternal pain lasted for 100 days, after which it was considered to be recovered/resolved on 10 Feb 2021 (Study Day 184). The investigator assessed the event of chest pain to be not related to the IP.

On 03 Nov 2020 (Study Day 85), 84 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of sternal fracture. Action taken with the IP was not applicable. The event of non-displaced closed fracture lower sternum lasted for 130 days, after which it was considered to be recovered/resolved on 12 Mar 2021 (Study Day 214). The investigator assessed the event of sternal fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004516	Chest pain
MOD-2021-004516	Sternal fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Von Willebrand's disease	Von willebrand disease	1996 - Ongoing
Asthma	Mild asthma	2004 - Ongoing
Vitamin B12 deficiency	Vitamin b12 deficiency	2004 - Ongoing
Anxiety disorder	Anxiety disorder	2015 - Ongoing
Allergy to chemicals	Blue dye allergy	2016 - Ongoing
Nephrolithiasis	Kidney stones	2016 - 2016
Asthma	Asthma exacerbation	01 Aug 2020 (Study Day -10) - 08 Aug 2020 (Study Day -3)
Headache	Headache	01 Aug 2020 (Study Day -10) - 01 Aug 2020 (Study Day -10)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Montelukast sodium	2004 - Ongoing	Mild Asthma
Salbutamol sulfate	2004 - Ongoing	Mild Asthma
Vitamin b12 nos	2004 - Ongoing	B12 Deficiency
Citalopram	2015 - Ongoing	Anxiety Disorder
Fluticasone propionate; salmeterol xinafoate	01 Aug 2020 (Study Day -10) - 08 Aug 2020 (Study Day -3)	Asthma Exacerbation
Paracetamol	01 Aug 2020 (Study Day -10) - 01 Aug 2020 (Study Day -10)	Headache
Paracetamol	12 Aug 2020 (Study Day 2) - 12 Aug 2020 (Study Day 2)	Headache
Paracetamol	27 Oct 2020 (Study Day 78) - 31 Oct 2020 (Study Day 82)	Upper Respiratory Tract Infection

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct scan of the chest without contrast*	03 Nov 2020 (Study Day 85) - 03 Nov 2020 (Study Day 85)	Adverse Event
Lidocaine	03 Nov 2020 (Study Day 85) - 03 Dec 2020 (Study Day 115)	Severed Sternum
Lidocaine; prilocaine	03 Nov 2020 (Study Day 85) - 03 Dec 2020 (Study Day 115)	Sternal Pain
Morphine	03 Nov 2020 (Study Day 85) - 03 Nov 2020 (Study Day 85)	Sternal Pain
Ondansetron	03 Nov 2020 (Study Day 85) - 03 Nov 2020 (Study Day 85)	Sternal Pain
Oxycodone	03 Nov 2020 (Study Day 85) - 13 Nov 2020 (Study Day 95)	Sternal Pain
Paracetamol	03 Nov 2020 (Study Day 85) - 03 Dec 2020 (Study Day 115)	Sternal Pain
Tramadol	03 Nov 2020 (Study Day 85) - 13 Nov 2020 (Study Day 95)	Sternal Pain
Influenza vaccine	04 Nov 2020 (Study Day 86) - 04 Nov 2020 (Study Day 86)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 78) - 31 Oct 2020 (Study Day 82)
Fall	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 85) - 03 Nov 2020 (Study Day 85)
Rib Fracture	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 85) - 28 Jan 2021 (Study Day 171)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US315-2194 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/Bilateral Pulmonary Embolism	SAE	Grade 3/severe	Not related	21 Sep 2020 (Study Day 39) – 16 Oct 2020 (Study Day 64)	Recovered/resolved with sequelae
Pulmonary Infarction/Bilateral Pulmonary Infarcts	SAE	Grade 3/severe	Not related	02 Oct 2020 (Study Day 50) – 16 Oct 2020 (Study Day 64)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2194, a 54-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 39), 38 days after the first dose and 10 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of bilateral pulmonary embolism lasted for 26 days, after which it was considered to be recovered/resolved with sequelae on 16 Oct 2020 (Study Day 64). The investigator assessed the event of pulmonary embolism to be not related to the IP.

On 02 Oct 2020 (Study Day 50), 49 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary infarction. Action taken with the IP was not applicable. The event of bilateral pulmonary infarcts lasted for 15 days, after which it was considered to be recovered/resolved with sequelae on 16 Oct 2020 (Study Day 64). The investigator assessed the event of pulmonary infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000408	Pulmonary embolism
MOD-2020-000408	Pulmonary infarction

Study Completion/Discontinuation

On 15 Jan 2021 (Study Day 155), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2008 - Ongoing
Intervertebral disc protrusion	L4-l5 disc bulge impingement	2016 - Aug 2017
Intervertebral disc operation	L4-l5 discectomy	Aug 2017 - Aug 2017
Autoimmune thyroiditis	Hashimoto's thyroiditis	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Carvedilol	2019 - Ongoing	Hypertension
Vitamin b12 nos	2019 - Ongoing	Nutritional Supplement
Bifidobacterium infantis	Feb 2020 - Ongoing	Nutritional Supplement
Calcium	Apr 2020 - Ongoing	Nutritional Supplement
Methylprednisolone	21 Sep 2020 (Study Day 39) - 27 Sep 2020 (Study Day 45)	Unspecified Right Chest Pain
Magnetic resonance imaging thoracic spine without contrast*	22 Sep 2020 (Study Day 40) - 22 Sep 2020 (Study Day 40)	Adverse Event
Antithrombin iii antigen panel*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Beta 2 glycoprotein 1*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Cardiolipin antibody panel*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Cbc with auto differentials*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Comprehensive metabolic panel*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Computed tomography chest with contrast*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Enoxaparin sodium	02 Oct 2020 (Study Day 50) - 16 Oct 2020 (Study Day 64)	Bilateral Pulmonary Emboli With Pulmonary Infarcts
Factor v leiden*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Homocysteine panel*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Lupus anticoagulant panel*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Protein c*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Protein s*	02 Oct 2020 (Study Day 50) - 02 Oct 2020 (Study Day 50)	Adverse Event
Computed tomography abdomen and pelvis with contrast*	06 Oct 2020 (Study Day 54) - 06 Oct 2020 (Study Day 54)	Adverse Event
Venous doppler ultrasound dvt protocol bilateral legs*	07 Oct 2020 (Study Day 55) - 07 Oct 2020 (Study Day 55)	Adverse Event
Echocardiogram*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Rivaroxaban	16 Oct 2020 (Study Day 64) - Ongoing	Pulmonary Embolism Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chest Pain	Grade 2/moderate	Not related	21 Sep 2020 (Study Day 39) - 21 Sep 2020 (Study Day 39)
Pleural Effusion	Grade 1/mild	Not related	22 Sep 2020 (Study Day 40) - 02 Oct 2020 (Study Day 50)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US316-2003 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	24 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Acute Myocardial Infarction	SAE	Grade 4	Not related	07 Sep 2020 (Study Day 43) – 08 Sep 2020 (Study Day 44)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2003, a 75-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 27 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 24 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 43), 42 days after the first dose and 14 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of acute myocardial infarction lasted for 2 days, after which it was considered to be recovered/resolved on 08 Sep 2020 (Study Day 44). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000275	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ex-tobacco user	Previous smoker	1961 - 2019
Menopause	Menopausal	Jul 1988 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disorder	2005 - Ongoing
Hyperlipidaemia	Hyperlipidema	2005 - Ongoing
Intervertebral disc disorder	Cervical disc disease	Dec 2008 - Ongoing
Wrist fracture	Left wrist fracture	Oct 2011 - Mar 2012

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	Health Maintenance
Acetylsalicylic acid	2005 - Ongoing	Health Maintenance
Atorvastatin	2005 - 08 Sep 2020 (Study Day 44)	Hyperlipidemia
Chondroitin; glucosamine	2010 - Ongoing	Cervical Disc Disease
Omega-3 nos	2010 - 2020	Health Maintenance
Oxygen	2010 - Ongoing	Chronic Obstructive Pulmonary Disease
Salbutamol sulfate	2010 - Ongoing	Chronic Obstructive Pulmonary Disease
Vitamin e nos	2010 - Ongoing	Health Maintenance
Fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	2019 - Ongoing	Chronic Obstructive Pulmonary Disease
Tramadol	10 Jul 2020 (Study Day -17) - Ongoing	Cervical Disc Disease
Paracetamol	07 Sep 2020 (Study Day 43) - 07 Sep 2020 (Study Day 43)	Acute Myocardial Infarction
Tramadol	07 Sep 2020 (Study Day 43) - 08 Sep 2020 (Study Day 44)	Acute Myocardial Infarction
Acetylsalicylic acid	08 Sep 2020 (Study Day 44) - 08 Sep 2020 (Study Day 44)	Acute Myocardial Infarction
Glyceryl trinitrate	08 Sep 2020 (Study Day 44) - Ongoing	Acute Myocardial Infarction
Heparin	08 Sep 2020 (Study Day 44) - 08 Sep 2020 (Study Day 44)	Acute Myocardial Infarction
Morphine sulfate	08 Sep 2020 (Study Day 44) - 08 Sep 2020 (Study Day 44)	Acute Myocardial Infarction
Ondansetron	08 Sep 2020 (Study Day 44) - 08 Sep 2020 (Study Day 44)	Nausea Due To Acute Myocardial Infarction
Balloon angioplasty of mid-right coronary artery*	09 Sep 2020 (Study Day 45) - 09 Sep 2020 (Study Day 45)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Left and right coronary angiography*	09 Sep 2020 (Study Day 45) - 09 Sep 2020 (Study Day 45)	Adverse Event
Left heart catheterization*	09 Sep 2020 (Study Day 45) - 09 Sep 2020 (Study Day 45)	Adverse Event
Atorvastatin	11 Sep 2020 (Study Day 47) - Ongoing	Hyperlipidemia
Carvedilol	11 Sep 2020 (Study Day 47) - 21 Sep 2020 (Study Day 57)	Coronary Artery Disease
Ticagrelor	11 Sep 2020 (Study Day 47) - Ongoing	Coronary Artery Disease
Influenza vaccine	15 Oct 2020 (Study Day 81) - 15 Oct 2020 (Study Day 81)	Influenza Prevention
Clopidogrel bisulfate	10 Nov 2020 (Study Day 107) - Ongoing	Coronary Artery Disease
Hydrochlorothiazide; triamterene	15 Dec 2020 (Study Day 142) - Ongoing	Bilateral Lower Extremity Edema

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cholecystitis Acute	Grade 4	Not related	27 Aug 2020 (Study Day 32) - 27 Aug 2020 (Study Day 32)
Biliary Colic	Grade 1/mild	Not related	01 Sep 2020 (Study Day 37) - Ongoing
Nausea	Grade 2/moderate	Not related	08 Sep 2020 (Study Day 44) - 08 Sep 2020 (Study Day 44)
Coronary Artery Disease	Grade 3/severe	Not related	09 Sep 2020 (Study Day 45) - Ongoing
Dyspnoea	Grade 2/moderate	Not related	11 Sep 2020 (Study Day 47) - 22 Sep 2020 (Study Day 58)
Oedema Peripheral	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 142) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US316-2007 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Mild Cerebrovascular Accident	SAE	Grade 3/severe	Not related	30 Jul 2020 (Study Day 4) – 31 Jul 2020 (Study Day 5)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2007, a 68-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 27 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Jul 2020 (Study Day 4), 3 days after the first dose and 32 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. The IP dose was not changed due to the mild cerebrovascular accident. The event of mild cerebrovascular accident lasted for 2 days, after which it was considered to be recovered/resolved on 31 Jul 2020 (Study Day 5). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000193	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Uterine leiomyoma	Uterine firbroids	1999 - 1999
Hypertension	Hypertension	2013 - Ongoing
Gastrooesophageal reflux disease	Acid reflux disease	2014 - Ongoing
Sinus bradycardia	Sinus bradycardia	2014 - Ongoing
Vitamin B12 deficiency	Vitamin b12 deficiency	2014 - Ongoing
Osteoarthritis	Osteoarthritis (bilateral hands, bilateral knees, neck)	2016 - Ongoing
Osteoporosis	Osteoporosis	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2013 - 07 Aug 2020 (Study Day 12)	Hypertension
Omeprazole	2015 - Ongoing	Acid Reflux Disease
Meloxicam	2016 - Ongoing	Osteoarthritis Bilateral Hands, Bilateral Knees, Neck
Cpk 227*	30 Jul 2020 (Study Day 4) - 30 Jul 2020 (Study Day 4)	Adverse Event
Methocarbamol	30 Jul 2020 (Study Day 4) - 01 Aug 2020 (Study Day 6)	Occipital Headache
Mri brain and brainstem with and without contrast*	30 Jul 2020 (Study Day 4) - 30 Jul 2020 (Study Day 4)	Adverse Event
Acetylsalicylic acid	31 Jul 2020 (Study Day 5) - 15 Aug 2020 (Study Day 20)	Mild Cerebrovascular Accident
Ct venogram of head with and without contrast*	31 Jul 2020 (Study Day 5) - 31 Jul 2020 (Study Day 5)	Adverse Event
Gadobutrol	31 Jul 2020 (Study Day 5) - 31 Jul 2020 (Study Day 5)	Contrast For Mri Procedure
Iohexol	31 Jul 2020 (Study Day 5) - 31 Jul 2020 (Study Day 5)	Contrast For Ct Venogram Of Head
Transthoracic echocardiogram*	31 Jul 2020 (Study Day 5) - 31 Jul 2020 (Study Day 5)	Adverse Event
Ultrasound duplex scan bilateral extracranial carotid arteries*	31 Jul 2020 (Study Day 5) - 31 Jul 2020 (Study Day 5)	Adverse Event
Atorvastatin	01 Aug 2020 (Study Day 6) - 08 Aug 2020 (Study Day 13)	Mild Cerebrovascular Accident
Vitamin b12 nos	05 Aug 2020 (Study Day 10) - Ongoing	Vitamin B12 Deficiency
Diphenhydramine	08 Aug 2020 (Study Day 13) - Ongoing	Urticaria
Losartan	08 Aug 2020 (Study Day 13) - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	11 Aug 2020 (Study Day 16) - Ongoing	Urticaria
Hydrocortisone	11 Aug 2020 (Study Day 16) - Ongoing	Urticaria
Clopidogrel bisulfate	17 Aug 2020 (Study Day 22) - Ongoing	Stroke Prophylaxis
Cardiac event monitor (holter)*	24 Aug 2020 (Study Day 29) - 24 Aug 2020 (Study Day 29)	Adverse Event
Prednisone	21 Sep 2020 (Study Day 57) - 28 Sep 2020 (Study Day 64)	Urticaria On Abdomen
Triamcinolone	21 Sep 2020 (Study Day 57) - Ongoing	Urticaria On Abdomen

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Amnesia	Grade 2/moderate	Not related	29 Jul 2020 (Study Day 3) - Ongoing
Headache	Grade 2/moderate	Not related	30 Jul 2020 (Study Day 4) - 01 Aug 2020 (Study Day 6)
Urticaria	Grade 2/moderate	Not related	06 Aug 2020 (Study Day 11) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US316-2037 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteonecrosis/Developing Avascular Necrosis Of Left Hip	SAE	Grade 4	Not related	08 Dec 2020 (Study Day 131) – 08 Feb 2021 (Study Day 193)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US316-2037, a 68-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 28 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Dec 2020 (Study Day 131), 130 days after the first dose and 102 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteonecrosis. Action taken with the IP was not applicable. The event of developing avascular necrosis of left hip lasted for 63 days, after which it was considered to be recovered/resolved on 08 Feb 2021 (Study Day 193). The investigator assessed the event of osteonecrosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014410	Osteonecrosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tinnitus	Bilateral tinnitus	1965 - Ongoing
Drug hypersensitivity	Erythromycin allergy	1990 - Ongoing
Drug hypersensitivity	Penicillin allergy	1990 - Ongoing
Drug hypersensitivity	Sulfa allergy	1990 - Ongoing
Drug hypersensitivity	Tetracycline allergy	1990 - Ongoing
Appendicitis	Appendicitis	1996 - 1996
Small intestinal obstruction	Small bowel obstruction	1997 - 1997
Depression	Depression	1999 - Ongoing
Insomnia	Insomnia	1999 - Ongoing
Menopause	Natural menopause	2005 - Ongoing
Sinus bradycardia	Asymptomatic sinus bradycardia	2014 - Ongoing
Abdominal hernia	Recurrent ventral hernia	2015 - 2015
Spinal osteoarthritis	Osteoarthritis lower back	2015 - Ongoing
Atrial fibrillation	Intermittent atrial fibrillation	Mar 2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Mar 2018 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease c5, c6, c7	Mar 2018 - Ongoing
Osteopenia	Osteopenia	Mar 2018 - Ongoing
Restless legs syndrome	Restless leg syndrome, bilateral	May 2018 - Ongoing
Hypertension	Hypertension	Jun 2018 - Ongoing
Arthralgia	Right hip pain	Feb 2020 - Ongoing
Arthralgia	Left hip pain	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alendronate sodium	Mar 2018 - Ongoing	Osteopenia
Fluoxetine	Mar 2018 - Ongoing	Depression
Hydrocodone bitartrate; paracetamol	Mar 2018 - Ongoing	Osteoarthritis Lower Back
Pravastatin	Mar 2018 - Ongoing	Hyperlipidemia
Rivaroxaban	Mar 2018 - Ongoing	Atrial Fibrillation
Pramipexole	May 2018 - Ongoing	Restless Leg Syndrome, Bilateral
Metoprolol tartrate	Jun 2018 - Ongoing	Hypertension
Dronedarone	May 2019 - Ongoing	Atrial Fibrillation
Ibuprofen	18 Dec 2019 (Study Day -226) - Ongoing	Osteoarthritis Lower Back (Left And Right Hip Pain)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	07 Aug 2020 (Study Day 8) - 07 Aug 2020 (Study Day 8)	Headache
Celecoxib	17 Aug 2020 (Study Day 18) - 07 Feb 2021 (Study Day 192)	Left And Right Hip Pain
Naproxen	23 Aug 2020 (Study Day 24) - 13 Nov 2020 (Study Day 106)	Left Shoulder Pain
Triamcinolone acetonide	16 Sep 2020 (Study Day 48) - 16 Sep 2020 (Study Day 48)	Osteoarthritis (Lower Back)
Triamcinolone acetonide	16 Sep 2020 (Study Day 48) - 16 Sep 2020 (Study Day 48)	Right Hip Pain
Triamcinolone acetonide	22 Sep 2020 (Study Day 54) - 22 Sep 2020 (Study Day 54)	Worsening Of Left Hip Pain
Codeine phosphate; paracetamol	13 Nov 2020 (Study Day 106) - Ongoing	Left And Right Hip Pain
Mri of the left hip without contrast*	13 Nov 2020 (Study Day 106) - 13 Nov 2020 (Study Day 106)	Medical History
Hydrocodone bitartrate; paracetamol	20 Nov 2020 (Study Day 113) - Ongoing	Right Hip Pain And Worsening Of Left Hip Pain
Xray of pelvis and bilateral hips*	08 Jan 2021 (Study Day 162) - 08 Jan 2021 (Study Day 162)	Adverse Event
Bupivacaine	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Local Anesthesia For Left Total Hip Arthroplasty
Calcium chloride; potassium chloride; sodium lactate	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Intraoperative Hydration For Left Total Hip Arthroplasty
Celecoxib	08 Feb 2021 (Study Day 193) - Ongoing	Pain From Left Hip Replacement
Clindamycin	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Prevent Infection From Left Total Hip Arthroplasty
Dexamethasone	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Prevent Inflammation From Left Total Hip Arthroplasty
Ephedrine	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Prevention Of Bronchospasm During Left Total Hip Arthroplasty
Fentanyl	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	General Anesthesia For Left Total Hip Arthroplasty
Ketamine	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	General Anesthesia For Left Total Hip Arthroplasty
Left hip arthroplasty*	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Adverse Event
Lidocaine	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Regional Anesthesia For Left Total Hip Arthroplasty
Midazolam hydrochloride	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Sedation For Left Total Hip Arthroplasty
Ondansetron	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Prevention Of Nausea/Vomiting During Left Total Hip Arthroplasty
Oxycodone; paracetamol	08 Feb 2021 (Study Day 193) - 19 Mar 2021 (Study Day 232)	Pain From Left Hip Replacement
Phenylephrine	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	Prevent Intraoperative Hypotension During Left Total Hip Arthroplasty
Propofol	08 Feb 2021 (Study Day 193) - 08 Feb 2021 (Study Day 193)	General Anesthesia For Left Total Hip Arthroplasty

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 2/moderate	Not related	07 Aug 2020 (Study Day 8) - 07 Aug 2020 (Study Day 8)
Musculoskeletal Pain	Grade 2/moderate	Not related	23 Aug 2020 (Study Day 24) - 15 Jan 2021 (Study Day 169)
Arthralgia	Grade 3/severe	Not related	01 Sep 2020 (Study Day 33) - 08 Feb 2021 (Study Day 193)
Osteoarthritis	Grade 3/severe	Not related	08 Jan 2021 (Study Day 162) - 08 Feb 2021 (Study Day 193)
Procedural Pain	Grade 3/severe	Not related	08 Feb 2021 (Study Day 193) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2028 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Paroxysmal Arrhythmia/ Cardiac Arrhythmia Paroxysmal	SAE	Grade 3/ severe	Not related	08 Dec 2020 (Study Day 120) – 11 Dec 2020 (Study Day 123)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2028, a 54-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Dec 2020 (Study Day 120), 119 days after the first dose and 91 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of paroxysmal arrhythmia. Action taken with the IP was not applicable. The event of cardiac arrhythmia paroxysmal lasted for 4 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 123). The investigator assessed the event of paroxysmal arrhythmia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074251	Atrial fibrillation
MOD-2021-001866	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caffeine consumption	Caffeine consumption	1974 - Ongoing
Alcohol use	Alcohol consumption	1982 - Ongoing
Ex-tobacco user	Past tobacco user	1982 - 2019
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2010 - Ongoing
Presbyopia	Presbyopia	2015 - Ongoing
Drug abuse	Cocaine abuse	2018 - Ongoing
Dyslipidaemia	Dyslipidemia	2018 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2018 - Ongoing
Vitamin B1 deficiency	Thiamine deficiency	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2010 - 10 Dec 2020 (Study Day 122)	Hypertension
Metformin	2010 - Ongoing	Diabetes Type 2
Amlodipine	2015 - Ongoing	Hypertension
Radiology chest single view xr*	05 Dec 2020 (Study Day 117) - 05 Dec 2020 (Study Day 117)	Adverse Event
Cardiac cath procedure*	08 Dec 2020 (Study Day 120) - 08 Dec 2020 (Study Day 120)	Adverse Event
Ekg-stress*	08 Dec 2020 (Study Day 120) - 08 Dec 2020 (Study Day 120)	Adverse Event
Magnesium sulfate	08 Dec 2020 (Study Day 120) - 08 Dec 2020 (Study Day 120)	Hypomagnesemia
Glyceryl trinitrate	09 Dec 2020 (Study Day 121) - 09 Dec 2020 (Study Day 121)	Ct Scan Test
Iodine	09 Dec 2020 (Study Day 121) - 09 Dec 2020 (Study Day 121)	Computed Tomography
Radiology: coronary cta w ca score \t\ func*	09 Dec 2020 (Study Day 121) - 09 Dec 2020 (Study Day 121)	Adverse Event
Apixaban	10 Dec 2020 (Study Day 122) - Ongoing	Prophylaxis Atrial Fibrillation
Atorvastatin	10 Dec 2020 (Study Day 122) - Ongoing	Cardiovascular Disease Precaution
Carvedilol	10 Dec 2020 (Study Day 122) - Ongoing	Cardiac Heart Failure
Clopidogrel	10 Dec 2020 (Study Day 122) - Ongoing	Coronary Artery Disease
Diltiazem	10 Dec 2020 (Study Day 122) - Ongoing	Atrial Fibrillation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Empagliflozin	10 Dec 2020 (Study Day 122) - Ongoing	Worsening Diabetes Type Ii
Folic acid	10 Dec 2020 (Study Day 122) - 05 Apr 2021 (Study Day 238)	Nutritional Supplement
Glimepiride	10 Dec 2020 (Study Day 122) - Ongoing	Diabetes Type 2
Losartan	10 Dec 2020 (Study Day 122) - Ongoing	Worsening Hypertension
Myocardial spect mult w ef wm*	10 Dec 2020 (Study Day 122) - 10 Dec 2020 (Study Day 122)	Adverse Event
Regadenoson	10 Dec 2020 (Study Day 122) - 10 Dec 2020 (Study Day 122)	Nuclear Myocardia Sect
Simvastatin	10 Dec 2020 (Study Day 122) - Ongoing	Hypercholesterol
Spironolactone	10 Dec 2020 (Study Day 122) - 06 Apr 2021 (Study Day 239)	Worsening Hypertension
Thiamine	10 Dec 2020 (Study Day 122) - Ongoing	Thiamine Deficiency

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Paroxysmal Arrhythmia	Grade 1/mild	Not related	05 Dec 2020 (Study Day 117) - 05 Dec 2020 (Study Day 117)
Hypertension	Grade 3/severe	Not related	08 Dec 2020 (Study Day 120) - 10 Dec 2020 (Study Day 122)
Hypomagnesaemia	Grade 3/severe	Not related	08 Dec 2020 (Study Day 120) - 10 Dec 2020 (Study Day 122)
Type 2 Diabetes Mellitus	Grade 3/severe	Not related	08 Dec 2020 (Study Day 120) - 10 Dec 2020 (Study Day 122)
Vitamin B1 Deficiency	Grade 3/severe	Not related	08 Dec 2020 (Study Day 120) - 10 Dec 2020 (Study Day 122)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2038 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Respiratory Failure/Acute Hypoxemic Respiratoy Failure	SAE	Grade 4	Not related	01 Sep 2020 (Study Day 22) – 03 Sep 2020 (Study Day 24)	Recovered/ resolved
Metabolic Acidosis/Profound Metabolic Acidosis	SAE	Grade 4	Not related	01 Sep 2020 (Study Day 22) – 03 Sep 2020 (Study Day 24)	Recovered/ resolved
Pyelonephritis Acute/Acute Pyelonephritis (Right Kidney)	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	01 Sep 2020 (Study Day 22) – 26 Sep 2020 (Study Day 47)	Recovered/ resolved
Septic Shock/Septic Shock	SAE	Grade 4	Not related	01 Sep 2020 (Study Day 22) – 03 Sep 2020 (Study Day 24)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2038, a 34-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 01 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of acute respiratory failure. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute hypoxemic respiratoy failure lasted for 3 days, after which it was considered to be recovered/resolved on 03 Sep 2020 (Study Day 24). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 01 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of metabolic acidosis. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of profound

metabolic acidosis lasted for 3 days, after which it was considered to be recovered/resolved on 03 Sep 2020 (Study Day 24). The investigator assessed the event of metabolic acidosis to be not related to the IP.

On 01 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of pyelonephritis acute. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute pyelonephritis (right kidney) lasted for 26 days, after which it was considered to be recovered/resolved on 26 Sep 2020 (Study Day 47). The investigator assessed the event of pyelonephritis acute to be not related to the IP.

On 01 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of septic shock. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of septic shock lasted for 3 days, after which it was considered to be recovered/resolved on 03 Sep 2020 (Study Day 24). The investigator assessed the event of septic shock to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000245	Acute pyelonephritis
MOD-2020-000245	Septic shock
MOD-2020-000245	Acute respiratory failure
MOD-2020-000245	Metabolic acidosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mammoplasty	Breast augmentation	2009 - 2009
Female sterilisation	Tubal ligation	2012 - 2012
Mammoplasty	Breast augmentation	2017 - 2017
Obesity	Obese	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	29 Aug 2020 (Study Day 19) - 31 Aug 2020 (Study Day 21)	Vomiting
Adenosine	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Tachychardia
Amiodarone	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Tachychardia
Calcium chloride; potassium chloride; sodium lactate	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Metabolic Acidosis
Cefepime	01 Sep 2020 (Study Day 22) - 02 Sep 2020 (Study Day 23)	Pyelonephritis/Septic Shock
Chest x-ray*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Ct brain*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Ct chest, abdomen/pelvis*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Famotidine	01 Sep 2020 (Study Day 22) - 03 Sep 2020 (Study Day 24)	Vomiting/Nausea
Fentanyl	01 Sep 2020 (Study Day 22) - 02 Sep 2020 (Study Day 23)	Right Upper Quadrant Pain Abdomen
Intubated*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Ketorolac tromethamine	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Right Upper Quadrant Abdomen Pain
Nephrostogram antegrade urography.*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Norepinephrine	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Anesthesia For Respiratory Tube Placement
Paracetamol	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Fever
Percutaneous nephrostomy tube*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Percutaneous nephrostomy*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Potassium chloride	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Metabolic Acidosis
Propofol	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Anesthesia For Respiratory Tube Placement
Right uretral stent placement*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Schedule a urethoscopy*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event
Secondary hydronephorosis*	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium bicarbonate	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Metabolic Acidosis
Sodium chloride	01 Sep 2020 (Study Day 22) - 02 Sep 2020 (Study Day 23)	Hydration (Open Line For Medication Administration)
Vancomycin	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Pnelonephritis/Septic Shock
Vasopressin	01 Sep 2020 (Study Day 22) - 01 Sep 2020 (Study Day 22)	Tachycardia/Hypotension
Ceftriaxone	03 Sep 2020 (Study Day 24) - 04 Sep 2020 (Study Day 25)	Pyelonephritis
Sulfamethoxazole; trimethoprim	04 Sep 2020 (Study Day 25) - 18 Sep 2020 (Study Day 39)	Pyelonephritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nephrolithiasis	Grade 3/severe	Not related	29 Aug 2020 (Study Day 19) - Ongoing
Renal Colic	Grade 3/severe	Not related	29 Aug 2020 (Study Day 19) - 30 Aug 2020 (Study Day 20)
Pyelonephritis	Grade 3/severe	Not related	22 Sep 2020 (Study Day 43) - 26 Sep 2020 (Study Day 47)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2114 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 3/severe	Not related	15 Nov 2020 (Study Day 94) – 17 Nov 2020 (Study Day 96)	Recovered/resolved
Syncope/Syncope And Collapse (Primary)	SAE	Grade 3/severe	Not related	15 Nov 2020 (Study Day 94) – 17 Nov 2020 (Study Day 96)	Recovered/resolved
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 3/severe	Not related	04 Dec 2020 (Study Day 113) – 10 Dec 2020 (Study Day 119)	Recovered/resolved
Syncope/Syncope	SAE	Grade 3/severe	Not related	04 Dec 2020 (Study Day 113) – 11 Dec 2020 (Study Day 120)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2114, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Nov 2020 (Study Day 94), 93 days after the first dose and 60 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute kidney injury lasted for 3 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 96). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 15 Nov 2020 (Study Day 94), 93 days after the first dose and 60 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of syncope. Action taken

with the IP was not applicable. The event of syncope and collapse (primary) lasted for 3 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 96). The investigator assessed the event of syncope to be not related to the IP.

On 04 Dec 2020 (Study Day 113), 112 days after the first dose and 79 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute kidney injury lasted for 7 days, after which it was considered to be recovered/resolved on 10 Dec 2020 (Study Day 119). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 04 Dec 2020 (Study Day 113), 112 days after the first dose and 79 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 8 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 120). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001120	Acute kidney injury
MOD-2020-001120	Syncope
MOD-2020-001125	Acute kidney injury
MOD-2020-001125	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hip fracture	Right hip fracture	1975 - 1975
Hip surgery	Right hip surgery	1975 - 1975
Rhinitis allergic	Allergic rhinitis	2007 - Ongoing
Asthma	Moderate asthma	2015 - Ongoing
Chronic obstructive pulmonary disease	Copd	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone	2007 - 27 Dec 2020 (Study Day 136)	Allergic Rhinitis
Lisinopril	2015 - 15 Nov 2020 (Study Day 94)	Hypertension
Metformin	2015 - Ongoing	Diabetes Type 2
Salbutamol	2015 - Ongoing	Chronic Obstructive Pulmonary Disease (2 Puffs)
Amlodipine	18 Nov 2020 (Study Day 97) - Ongoing	Hypertension
Diphenhydramine	18 Nov 2020 (Study Day 97) - 20 Nov 2020 (Study Day 99)	Lower Lip Swelling
Famotidine	18 Nov 2020 (Study Day 97) - 23 Nov 2020 (Study Day 102)	Lower Lip Swelling
Ferrous sulfate	18 Nov 2020 (Study Day 97) - Ongoing	Anemia
Fluticasone; salmeterol	18 Nov 2020 (Study Day 97) - 27 Dec 2020 (Study Day 136)	Chronic Obstructive Pulmonary Disease
Folic acid	18 Nov 2020 (Study Day 97) - Ongoing	Nutritional Supplement
Carvedilol	11 Dec 2020 (Study Day 120) - Ongoing	Hypertension
Dicycloverine	11 Dec 2020 (Study Day 120) - Ongoing	Bloating
Loperamide	11 Dec 2020 (Study Day 120) - 20 Dec 2020 (Study Day 129)	Diarrhea
Methylprednisolone	22 Dec 2020 (Study Day 131) - 27 Dec 2020 (Study Day 136)	Copd Exacerbation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lip Swelling	Grade 1/mild	Not related	15 Nov 2020 (Study Day 94) - 17 Nov 2020 (Study Day 96)
Normocytic Anaemia	Grade 1/mild	Not related	15 Nov 2020 (Study Day 94) - Ongoing
Sinusitis	Grade 1/mild	Not related	15 Nov 2020 (Study Day 94) - 27 Dec 2020 (Study Day 136)
Inguinal Hernia	Grade 1/mild	Not related	23 Nov 2020 (Study Day 102) - Ongoing
Syncope	Grade 2/moderate	Not related	23 Nov 2020 (Study Day 102) - 23 Nov 2020 (Study Day 102)
Diarrhoea	Grade 1/mild	Not related	04 Dec 2020 (Study Day 113) - 20 Dec 2020 (Study Day 129)
Chronic Obstructive Pulmonary Disease	Grade 2/moderate	Not related	23 Dec 2020 (Study Day 132) - 28 Dec 2020 (Study Day 137)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2185 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Left Ventricular Failure/Acute Exacerbation Of Systolic Heart Failure	SAE	Grade 3/severe	Not related	07 Sep 2020 (Study Day 21) – 15 Sep 2020 (Study Day 29)	Recovered/resolved
Atrial Fibrillation/Atrial Fibrilation With Rapid Ventricular Rate	SAE	Grade 3/severe	Not related	07 Sep 2020 (Study Day 21) – 15 Sep 2020 (Study Day 29)	Recovered/resolved
Non-Cardiac Chest Pain/Non Cardiac Chest Pain	SAE, AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	07 Sep 2020 (Study Day 21) – 15 Sep 2020 (Study Day 29)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2185, a 61-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 18 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 07 Sep 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of acute left ventricular failure. On 14 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute exacerbation of systolic heart failure lasted for 9 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 29). The investigator assessed the event of acute left ventricular failure to be not related to the IP.

On 07 Sep 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. On 14 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of atrial fibrilation with rapid ventricular rate lasted for 9 days, after which it was considered to be

recovered/resolved on 15 Sep 2020 (Study Day 29). The investigator assessed the event of atrial fibrillation to be not related to the IP.

On 07 Sep 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of non-cardiac chest pain. On 14 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of non cardiac chest pain lasted for 9 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 29). The investigator assessed the event of non-cardiac chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000297	Acute left ventricular failure
MOD-2020-000297	Atrial fibrillation
MOD-2020-000297	Non-cardiac chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rheumatoid arthritis	Rheumatoid arthritis	2000 - Ongoing
Dyspepsia	Heartburn	2008 - Ongoing
Obesity	Obese	2008 - Ongoing
Presbyopia	Presbyopia	2015 - Ongoing
Umbilical hernia	Unbilical hernia	2015 - Ongoing
Mitral valve incompetence	Mitral valve insufficiency	2016 - 2016
Mitral valve incompetence	Mitral valve regurgitation	2016 - Dec 2017
Anaemia	Anemia	2017 - Jul 2020
Cardiac failure chronic	Chronic heart failure	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2017 - Ongoing
Atrial fibrillation	Atrial fibrillation	Dec 2017 - Ongoing
Mitral valve replacement	Mitrla valve replacement	Dec 2017 - Dec 2017
Mitral valve stenosis	Mitral valve resterosis	2019 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2020 - Ongoing
COVID-19	Covid 19 infection	04 Jul 2020 (Study Day -45) - 18 Aug 2020 (Study Day 1)

Preferred Term	Condition	Start Date – Stop Date/Ongoing
COVID-19 pneumonia	Pneumonia secondary to covid19	04 Jul 2020 (Study Day -45) - 26 Jul 2020 (Study Day -23)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ferrous sulfate	2017 - Ongoing	Anemia
Lisinopril	2017 - Ongoing	Hypertension
Metformin	2017 - 21 Oct 2020 (Study Day 65)	Diabetes Type 2
Metoprolol	2017 - Ongoing	Chf/Afib
Prednisone	2017 - 26 Mar 2021 (Study Day 221)	Rheumatisms
Furosemide	23 Dec 2017 (Study Day -969) - Ongoing	Chronic Heart Failure
Metoprolol	23 Dec 2017 (Study Day -969) - Ongoing	Chronic Heart Failure / Atrial Fibrillation
Metoprolol	23 Dec 2017 (Study Day -969) - Jan 2021	Congestive Heart Failure / Atrial Fibrillation
Amiodarone	13 Jul 2018 (Study Day -767) - Ongoing	Atrial Fibrillation
Warfarin	2019 - 07 Sep 2020 (Study Day 21)	Afib
Candesartan	07 Sep 2020 (Study Day 21) - Ongoing	Congestive Heart Failure - Chf
Chest x-ray*	07 Sep 2020 (Study Day 21) - 07 Sep 2020 (Study Day 21)	Adverse Event
Electrocardiogram*	07 Sep 2020 (Study Day 21) - 07 Sep 2020 (Study Day 21)	Adverse Event
Enoxaparin	07 Sep 2020 (Study Day 21) - 11 Sep 2020 (Study Day 25)	Atrial Fibrillation
Furosemide	07 Sep 2020 (Study Day 21) - 11 Sep 2020 (Study Day 25)	Congestive Heart Failure
Insulin lispro	07 Sep 2020 (Study Day 21) - 15 Sep 2020 (Study Day 29)	Type 2 Diabetes
Labetalol	07 Sep 2020 (Study Day 21) - 07 Sep 2020 (Study Day 21)	Acute Chronic Heart Failure
Prednisone	07 Sep 2020 (Study Day 21) - 26 Mar 2021 (Study Day 221)	Rheumatoid Arthristis
Adult echocardiogram (ae 2d echo*	09 Sep 2020 (Study Day 23) - 09 Sep 2020 (Study Day 23)	Adverse Event
Chest x-ray*	11 Sep 2020 (Study Day 25) - 11 Sep 2020 (Study Day 25)	Adverse Event
Ferrous sulfate	11 Sep 2020 (Study Day 25) - Ongoing	Anemia
Metformin	11 Sep 2020 (Study Day 25) - Ongoing	Diabetes Type Ii
Metformin	11 Sep 2020 (Study Day 25) - Ongoing	Type 2 Diabetes
Transesesophageal echocardiogram*	11 Sep 2020 (Study Day 25) - 11 Sep 2020 (Study Day 25)	Adverse Event
Warfarin sodium	11 Sep 2020 (Study Day 25) - Jan 2021	Atrial Fibrillation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cardiac catheterization*	14 Sep 2020 (Study Day 28) - 14 Sep 2020 (Study Day 28)	Adverse Event
Apixaban	Jan 2021 - Ongoing	Afib
Quetiapine fumarate	Jan 2021 - Ongoing	Chronic Heat Failure
Rosuvastatin calcium	Jan 2021 - Ongoing	Hypocholesterolemia
Sacubitril valsartan sodium hydrate	Jan 2021 - Ongoing	Hypertension
Atorvastatin	26 Mar 2021 (Study Day 221) - Ongoing	Cholesterol
Pantoprazole	26 Mar 2021 (Study Day 221) - Ongoing	Heartburn
Prednisone	26 Mar 2021 (Study Day 221) - Ongoing	Rheumatisms

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
International Normalised Ratio Increased	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 21) - 11 Sep 2020 (Study Day 25)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2224 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rib Fracture/Right Rib Cage Multiple Fractures	SAE	Grade 3/severe	Not related	23 Jan 2021 (Study Day 158) – 01 Mar 2021 (Study Day 195)	Recovered/resolved
Traumatic Haemothorax/Hemopneumothorax - Secondary To Rib Cage Multiple Fractures.	SAE	Grade 2/ moderate	Not related	23 Jan 2021 (Study Day 158) – 27 Jan 2021 (Study Day 162)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2224, a 50-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Jan 2021 (Study Day 158), 157 days after the first dose and 129 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of rib fracture. Action taken with the IP was not applicable. The event of right rib cage multiple fractures lasted for 38 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 195). The investigator assessed the event of rib fracture to be not related to the IP.

On 23 Jan 2021 (Study Day 158), 157 days after the first dose and 129 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of traumatic haemothorax. Action taken with the IP was not applicable. The event of hemopneumothorax - secondary to rib cage multiple fractures lasted for 5 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 162). The investigator assessed the event of traumatic haemothorax to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009647	Traumatic haemothorax
MOD-2021-009647	Rib fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Back pain	1995 - Ongoing
Hypermetropia	Hypermetrophia	2000 - Ongoing
Dyspepsia	Heartburn	2010 - Ongoing
Nephrolithiasis	Left kidney stones	2015 - 2015
Upper limb fracture	Right elbow fracture	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1995 - 19 Aug 2020 (Study Day 1)	Back Pain
Ibuprofen	1995 - 16 Oct 2020 (Study Day 59)	Historical Back Pain
Famotidine	2010 - Ongoing	Heartburn
Enoxaparin sodium	23 Jan 2021 (Study Day 158) - 27 Jan 2021 (Study Day 162)	Right Rib Cage Pain
Gabapentin	23 Jan 2021 (Study Day 158) - 15 Mar 2021 (Study Day 209)	Right Rib Cage Pain
Ibuprofen	23 Jan 2021 (Study Day 158) - Ongoing	Right Rib Cage Pain - Fractures
Ketorolac tromethamine	23 Jan 2021 (Study Day 158) - 27 Jan 2021 (Study Day 162)	Right Rib Cage Pain
Oxycodone	23 Jan 2021 (Study Day 158) - 27 Jan 2021 (Study Day 162)	Right Rib Cage Pain
Paracetamol	23 Jan 2021 (Study Day 158) - Ongoing	Right Rib Cage Pain - Fractures

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Skin Abrasion	Grade 2/moderate	Not related	23 Jan 2021 (Study Day 158) - 03 Mar 2021 (Study Day 197)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2250 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/Acute Exacerbation Of Congestion Heart Failure	SAE	Grade 3/severe	Not related	12 Sep 2020 (Study Day 24) – 16 Sep 2020 (Study Day 28)	Recovered/resolved
Cardiac Failure Congestive/Acute Exacerbation Of Chronic Congestive Heart Failure	SAE	Grade 3/severe	Not related	08 Feb 2021 (Study Day 173) – 16 Feb 2021 (Study Day 181)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2250, a 59-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Sep 2020 (Study Day 24), 23 days after the first dose and 6 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of acute exacerbation of congestion heart failure lasted for 5 days, after which it was considered to be recovered/resolved on 16 Sep 2020 (Study Day 28). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

On 08 Feb 2021 (Study Day 173), 172 days after the first dose and 143 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cardiac failure congestive. Action taken with the IP was not applicable. The event of acute exacerbation of chronic congestive heart failure lasted for 9 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 181). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000754	Cardiac failure congestive
MOD-2021-015902	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ectrodactyly	Congenital ectrodoctylia	(b) (6) 1961 (Study Day - (b) (6) - Ongoing
Hypertension	Hypertension mild	1986 - Ongoing
Atrial fibrillation	Paroxysmal atrial fibrillation	2008 - Ongoing
Implantable defibrillator insertion	Post automated implantable cardioverter defibrillator congestive heart failure	2008 - Ongoing
Ischaemic cardiomyopathy	Ischemic cardiomyopathy	2008 - Ongoing
Implantable defibrillator insertion	Defibrillator	04 Dec 2008 (Study Day -4277) - 04 Dec 2016 (Study Day -1355)
Catheterisation cardiac	Cardiac catheter	2012 - 2012
Erectile dysfunction	Erectile dysfunction	2015 - 2015
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2015 - Ongoing
Obesity	Severe obesity	2015 - Ongoing
Sciatica	Left sciatica	2015 - Ongoing
Sciatica	Left side sciatica	2015 - 2015
Type 2 diabetes mellitus	Diabetes type ii	2015 - Ongoing
Catheterisation cardiac	Cardiac catheter	2016 - 2016
Cholecystectomy	Laparascopic cholecystectomy	2016 - 2016
Cholelithiasis	Gallstones	2016 - 2016
Cardiac resynchronisation therapy	Biventriculor dual chamber	04 Dec 2016 (Study Day -1355) - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Myocardial infarction	Heart attack	2017 - 2017
Penile prosthesis insertion	Penile implant	2017 - 2017
Sleep apnoea syndrome	Sleep apnea	2017 - Ongoing
Back pain	Back pain	2018 - Ongoing
Catheterisation cardiac	Cardiac catheter	2018 - 2018
Diabetic neuropathy	Sensorial diabetic peripheral neuropathy	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ischaemic stroke	Stroke vs. transient ischemic attacks	Apr 2020 - Apr 2020
Device related infection	Penile implant infection and removal of prosthesis	19 May 2020 (Study Day -93) - 30 Jun 2020 (Study Day -51)
Cerebrovascular accident	Cerebrovascular accident	04 Jul 2020 (Study Day -47) - 04 Jul 2020 (Study Day -47)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bumetanide	2008 - 12 Feb 2021 (Study Day 177)	Chronic Heart Failure Diuretic
Amiodarone	2015 - Ongoing	Paroxysmal Atrial Fibrillation
Apixaban	2015 - 12 Feb 2021 (Study Day 177)	Anticoagulant Atrial Fibrillation
Furosemide	2015 - Aug 2020	Hypertension
Lisinopril	2015 - 16 Sep 2020 (Study Day 28)	Hypertension
Metformin	2015 - Ongoing	Diabetes Type Ii
Pantoprazole	2015 - Ongoing	Gastroesophageal Reflux Disease
Atorvastatin	2016 - Ongoing	Hyperlipidemia
Baclofen	2018 - Ongoing	Left Sciatic Pain
Diclofenac	2018 - Ongoing	Left Sciatic Pain
Gabapentin	2018 - Ongoing	Chronic Lower Back Pain
Oxycodone	2018 - Ongoing	Left Sciatic Exacerbation
Paracetamol	2018 - Ongoing	Chronic Lower Back Pain
Carvedilol	Feb 2020 - 12 Feb 2021 (Study Day 177)	Hypertension
Potassium chloride	Feb 2020 - Mar 2021	Chronic Heart Failure
Sacubitril valsartan sodium hydrate	Jun 2020 - Ongoing	Hypertension
Ct angio pulmonary arteries*	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Adverse Event
Ekg*	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Adverse Event
Furosemide	12 Sep 2020 (Study Day 24) - 16 Sep 2020 (Study Day 28)	Diuretic
Sodium chloride	12 Sep 2020 (Study Day 24) - 14 Sep 2020 (Study Day 26)	Flush Iv Catheter
Sodium chloride	12 Sep 2020 (Study Day 24) - 16 Sep 2020 (Study Day 28)	Flush Iv Catheter
Tramadol	12 Sep 2020 (Study Day 24) - 19 Sep 2020 (Study Day 31)	Chronic Lower Back Pain
X-ray - ra ches*	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Adverse Event
Ct lumbar spine*	13 Sep 2020 (Study Day 25) - 13 Sep 2020 (Study Day 25)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
X-ray - ra chest*	13 Sep 2020 (Study Day 25) - 13 Sep 2020 (Study Day 25)	Adverse Event
Us guidance paracentesis*	15 Sep 2020 (Study Day 27) - 15 Sep 2020 (Study Day 27)	Adverse Event
Acetylsalicylic acid	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Cardiac Prophylaxis
Apixaban	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Atrial Fibrillation
Bumetanide	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Chronic Heart Failure Exacerbation
Bumetanide	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Chronic Heart Failure Exacerbation
Carvedilol	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Hypertension
Carvedilol	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Hypertension
Clopidogrel bisulfate	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Acute Coronary Syndrome
Enoxaparin sodium	13 Feb 2021 (Study Day 178) - Ongoing	Heart Attack Prophylaxis
Glucagon	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Diabetes Type Ii
Glucose	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Severe Hypoglycemia Prophylaxis
Glucose; heparin sodium	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Atrial Fibrillation
Glyceryl trinitrate	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Chest Pain
Insulin	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Diabetes Type II
Insulin glargine	13 Feb 2021 (Study Day 178) - Ongoing	Diabetes Type II
Insulin lispro	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Diabetes Type II
Morphine	13 Feb 2021 (Study Day 178) - Ongoing	Left Sciatic Pain
Potassium chloride	13 Feb 2021 (Study Day 178) - Ongoing	Hypopotassemia Prophylaxis
Sodium chloride	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Flush Iv Catheter
Spironolactone	13 Feb 2021 (Study Day 178) - Ongoing	Chronic Heart Failure Exacerbation
Tramadol	13 Feb 2021 (Study Day 178) - Ongoing	Left Sciatic Pain
Acetylsalicylic acid	14 Feb 2021 (Study Day 179) - Ongoing	Cardiac Prophylaxis
Carvedilol	14 Feb 2021 (Study Day 179) - Ongoing	Hypertension
Acetylsalicylic acid	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Non St Myocardia Infarction
Atorvastatin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Coronary Artery Disease
Clonidine	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Hypertension Emergency
Clopidogrel	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Non St Myocardial Infarction

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Docusate	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Constipation Prophylaxis
Enoxaparin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Deep Venous Thrombosis Prophylaxis (Dvt)
Glucagon	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Severe Hypoglycemia Prophylaxes
Glucose	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Severe Hypoglycemia Prophylaxis
Glyceryl trinitrate	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Chest Pain
Hydromorphone	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Chest Pain / Sciatica
Insulin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Diabetes Mellitus
Ketorolac	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Sciatica
Lorazepam	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Anxiety
Ondansetron	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Emisis Prophylaxis
Paracetamol	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Left Sciatica
Rosuvastatin	26 Feb 2021 (Study Day 191) - 04 Mar 2021 (Study Day 197)	Coronary Artery Disease Dyslipidemia
Spironolactone	26 Feb 2021 (Study Day 191) - 25 Mar 2021 (Study Day 218)	Chronic Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ascites	Grade 2/moderate	Not related	12 Sep 2020 (Study Day 24) - 15 Sep 2020 (Study Day 27)
Cardiomegaly	Grade 1/mild	Not related	12 Sep 2020 (Study Day 24) - Ongoing
Chronic Kidney Disease	Grade 1/mild	Not related	13 Sep 2020 (Study Day 25) - Ongoing
Intervertebral Disc Degeneration	Grade 2/moderate	Not related	13 Sep 2020 (Study Day 25) - Ongoing
Anaemia	Grade 1/mild	Not related	16 Sep 2020 (Study Day 28) - Ongoing
Asymptomatic COVID-19	Grade 1/mild	Not related	28 Feb 2021 (Study Day 193) - 11 Mar 2021 (Study Day 204)
Liver Function Test Increased	Grade 1/mild	Not related	01 Mar 2021 (Study Day 194) - Ongoing
Hepatomegaly	Grade 1/mild	Not related	05 Mar 2021 (Study Day 198) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2322 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Obstructive Pulmonary Disease/ Worsening Of Chronic Obstructive Pulmonary Disease	SAE	Grade 3/ severe	Not related	10 Oct 2020 (Study Day 47) – 12 Nov 2020 (Study Day 80)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2322, a 51-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Oct 2020 (Study Day 47), 46 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of worsening of chronic obstructive pulmonary disease lasted for 34 days, after which it was considered to be recovered/resolved on 12 Nov 2020 (Study Day 80). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000475	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1977 - 1977
Tonsillitis	Tonsillitis	1977 - 1977
Female sterilisation	Tubal ligation bilateral	2002 - 2002
Umbilical hernia	Umbilical hernia	2002 - 2002
Umbilical hernia repair	Umbilical hernia surgery	2002 - 2002
Chronic obstructive pulmonary disease	Mild chronic obstructive pulmonary disease	2010 - Ongoing
Headache	Chronic headache	17 Apr 2010 (Study Day -3783) - Ongoing
Spinal operation	Lumbar surgery	2012 - 2012
Hypertension	Hypertension	2015 - Ongoing
Back pain	Chronic back pain	2016 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	2016 - Ongoing
Osteoarthritis	Generalized osteoarthritis	2016 - Ongoing
Osteoporosis	Osteoporosis	2016 - Ongoing
Spinal operation	Sacral surgery	2016 - 2016
Lumbar radiculopathy	Lumbar radiculopathy	29 Apr 2016 (Study Day -1579) - Ongoing
Sciatica	Chronic left sided sciatica	29 Apr 2016 (Study Day -1579) - Ongoing
Presbyopia	Presbyopia	2018 - Ongoing
Diabetic neuropathy	Diabetic peripheral neuropathy	2019 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2019 - Ongoing
Obesity	Severe obesity	2020 - Ongoing
Joint abscess	Left hip abscess	07 Mar 2020 (Study Day -171) - 20 Mar 2020 (Study Day -158)
Tendon pain	Right shoulder calcific tendon pain	07 Aug 2020 (Study Day -18) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2010 - Ongoing	Chronic Obstructive Pulmonary Disease
Metformin	2019 - Ongoing	Diabetes Type Ii
Budesonide; formoterol fumarate	16 Dec 2019 (Study Day -253) - Ongoing	Chronic Obstructive Pulmonary Disease
Gabapentin	16 Dec 2019 (Study Day -253) - Ongoing	Diabetic Peripheral Neuropathy

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	16 Dec 2019 (Study Day -253) - Ongoing	Hypertension
Lisinopril	16 Dec 2019 (Study Day -253) - Ongoing	Hypertension
Ibuprofen	25 Sep 2020 (Study Day 32) - 28 Sep 2020 (Study Day 35)	Headache/Fever
Paracetamol	25 Sep 2020 (Study Day 32) - 12 Nov 2020 (Study Day 80)	Headache/Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chronic Obstructive Pulmonary Disease	Grade 1/mild	Not related	07 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 47)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378492

Participant Number:	US317-2333 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Salpingitis/Bilateral Acute Salpingitis	SAE	Grade 3/severe	Not related	09 Nov 2020 (Study Day 77) – 26 Nov 2020 (Study Day 94)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2333, a 29-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Nov 2020 (Study Day 77), 76 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of salpingitis. Action taken with the IP was not applicable. The event of bilateral acute salpingitis lasted for 18 days, after which it was considered to be recovered/resolved on 26 Nov 2020 (Study Day 94). The investigator assessed the event of salpingitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000872	Salpingitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypermetropia	Hyperopia	2001 - Ongoing
Liposuction	Liposuction	2017 - 2017
Ectopic pregnancy	Ectopic pregnancy	2018 - 2018
Kidney infection	Recurrent left kidney infection	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	26 Aug 2020 (Study Day 2) - 27 Aug 2020 (Study Day 3)	Headache / Left Deltoid Pain
Ibuprofen	25 Sep 2020 (Study Day 32) - 25 Sep 2020 (Study Day 32)	Headache (Solicited Adverse Reaction, Not An A/E)
Doxycycline	12 Nov 2020 (Study Day 80) - 26 Nov 2020 (Study Day 94)	Acute Salpingitis
Metronidazole	12 Nov 2020 (Study Day 80) - 26 Nov 2020 (Study Day 94)	Acute Salpingitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US317-2469 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	18 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Metastases To Bone/Bone Metastasis Manifested By Intractible Left Thigh Pain Radiation To Left Knee	SAE	Grade 4	Not related	11 Dec 2020 (Study Day 52) – Ongoing	Not recovered/ not resolved
Prostate Cancer/Prostate Cancer	SAE	Grade 4	Not related	11 Dec 2020 (Study Day 52) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2469, a 59-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Dec 2020 (Study Day 52), 51 days after the first dose and 23 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of metastases to bone. Action taken with the IP was not applicable. The event of bone metastasis manifested by intractible left thigh pain radiation to left knee was considered to be ongoing. The investigator assessed the event of metastases to bone to be not related to the IP.

On 11 Dec 2020 (Study Day 52), 51 days after the first dose and 23 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011756	Metastases to bone
MOD-2021-011756	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	1966 - Ongoing
Appendicectomy	Appendectomy	1982 - 1982
Appendicitis	Acute appendicitis	1982 - 1982
Presbyopia	Bilateral presbyopia	2013 - Ongoing
Deafness bilateral	Hearing loss mild bilateral	2015 - Ongoing
Pain in extremity	Left thigh pain (secondary to fall)	03 Sep 2020 (Study Day -48) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1999 - Ongoing	Mild Asthma
Ibuprofen	14 Nov 2020 (Study Day 25) - Ongoing	Left Thigh Pain
Bicalutamide	18 Dec 2020 (Study Day 59) - Ongoing	Prostate Cancer
Gabapentin	18 Dec 2020 (Study Day 59) - Ongoing	Bilateral Left Extremities Numbness
Oxycodone hydrochloride	18 Dec 2020 (Study Day 59) - Ongoing	Left Thigh Pain
Diclofenac	21 Jan 2021 (Study Day 93) - Ongoing	Knee Pain
Leuprorelin acetate	22 Jan 2021 (Study Day 94) - Ongoing	Prostate Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain In Extremity	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 25) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2025 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	24 Aug 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dysfunctional Uterine Bleeding/ Dysfunctional Uterine Bleeding	SAE	Grade 4	Not related	20 Nov 2020 (Study Day 116) – 08 Jan 2021 (Study Day 165)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2025, a 30-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 24 Aug 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Nov 2020 (Study Day 116), 115 days after the first dose and 88 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dysfunctional uterine bleeding. Action taken with the IP was not applicable. The event of dysfunctional uterine bleeding lasted for 50 days, after which it was considered to be recovered/resolved on 08 Jan 2021 (Study Day 165). The investigator assessed the event of dysfunctional uterine bleeding to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-057074	Abnormal uterine bleeding

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Allergy to apples	(b) (6) 1990 - Ongoing
Perennial allergy	Perennial allergies	(b) (6) 1990 - Ongoing
Seasonal allergy	Seasonal allergies	(b) (6) 1990 - Ongoing
Presbyopia	Presbyopia	2000 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Depression	Depression	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Vitamin d nos	2015 - Ongoing	Health Maintenance
Intrauterine contraceptive device	2017 - 07 Jan 2021 (Study Day 164)	Birth Control
Fluticasone	2018 - Ongoing	Seasonal Allergies
Ethinylestradiol; etonogestrel	15 Jun 2020 (Study Day -43) - Ongoing	Birth Control
Acetylsalicylic acid; caffeine; paracetamol	24 Aug 2020 (Study Day 28) - 25 Aug 2020 (Study Day 29)	Fever/Headache
Paracetamol	24 Aug 2020 (Study Day 28) - 25 Aug 2020 (Study Day 29)	Fever/Headache
Contrast media	14 Dec 2020 (Study Day 140) - 14 Dec 2020 (Study Day 140)	For Ct Scan
Iohexol	14 Dec 2020 (Study Day 140) - 14 Dec 2020 (Study Day 140)	Abdominal Cramping
Ketorolac	14 Dec 2020 (Study Day 140) - 28 Dec 2020 (Study Day 154)	Abdominal Cramping
Ketorolac	14 Dec 2020 (Study Day 140) - 14 Dec 2020 (Study Day 140)	Abdominal Pain
Ondansetron	14 Dec 2020 (Study Day 140) - 14 Dec 2020 (Study Day 140)	Nausea
Estradiol	24 Dec 2020 (Study Day 150) - 24 Dec 2020 (Study Day 150)	Dysfunctional Uterine Bleeding
Estradiol	24 Dec 2020 (Study Day 150) - 25 Dec 2020 (Study Day 151)	Dysfunctional Uterine Bleeding
Iron	24 Dec 2020 (Study Day 150) - 25 Dec 2020 (Study Day 151)	Dysfunctional Uterine Bleeding/Anemia
Iron	24 Dec 2020 (Study Day 150) - 24 Dec 2020 (Study Day 150)	Iron Deficiency Anemia
Paracetamol	24 Dec 2020 (Study Day 150) - 28 Dec 2020 (Study Day 154)	Abdominal Cramping

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Red blood cells, concentrated	24 Dec 2020 (Study Day 150) - 24 Dec 2020 (Study Day 150)	Dysfunctional Uterine Bleeding/Anemia
Red blood cells, concentrated	24 Dec 2020 (Study Day 150) - 25 Dec 2020 (Study Day 151)	Dysfunctional Uterine Bleeding/Anemia
Red blood cells, concentrated	24 Dec 2020 (Study Day 150) - 24 Dec 2020 (Study Day 150)	Iron Deficiency Anemia
Paracetamol	28 Dec 2020 (Study Day 154) - 28 Dec 2020 (Study Day 154)	Abdominal Pain
Cefalexin	29 Dec 2020 (Study Day 155) - 04 Jan 2021 (Study Day 161)	Thrombophlebitis
Cefazolin	29 Dec 2020 (Study Day 155) - 29 Dec 2020 (Study Day 155)	Thrombophlebitis
Ferrous sulfate	29 Dec 2020 (Study Day 155) - Ongoing	Iron Deficiency Anemia
Dilation and curettage*	07 Jan 2021 (Study Day 164) - 07 Jan 2021 (Study Day 164)	Adverse Event
Hydromorphone	07 Jan 2021 (Study Day 164) - 07 Jan 2021 (Study Day 164)	Pain Secondary To D&c
Ibuprofen	07 Jan 2021 (Study Day 164) - Ongoing	Pain Secondary To D&c
Promethazine	07 Jan 2021 (Study Day 164) - 07 Jan 2021 (Study Day 164)	Nausea
Docusate sodium	08 Jan 2021 (Study Day 165) - 17 Jan 2021 (Study Day 174)	Prophylaxis
Ibuprofen	08 Jan 2021 (Study Day 165) - 17 Jan 2021 (Study Day 174)	Pain Secondary To Dysfunctional Uterine Bleeding
Fluconazole	15 Jan 2021 (Study Day 172) - Ongoing	Uterine Yeast Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 139) - 14 Dec 2020 (Study Day 140)
Diarrhoea	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 139) - 14 Dec 2020 (Study Day 140)
Nausea	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 139) - 14 Dec 2020 (Study Day 140)
Iron Deficiency Anaemia	Grade 3/severe	Not related	24 Dec 2020 (Study Day 150) - 06 Apr 2021 (Study Day 253)
Pain	Grade 2/moderate	Not related	24 Dec 2020 (Study Day 150) - 24 Dec 2020 (Study Day 150)
Abdominal Pain	Grade 2/moderate	Not related	28 Dec 2020 (Study Day 154) - 28 Dec 2020 (Study Day 154)
Thrombophlebitis	Grade 2/moderate	Not related	28 Dec 2020 (Study Day 154) - 07 Jan 2021 (Study Day 164)
Dizziness	Grade 2/moderate	Not related	07 Jan 2021 (Study Day 164) - 08 Jan 2021 (Study Day 165)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vulvovaginal Mycotic Infection	Grade 1/mild	Not related	15 Jan 2021 (Study Day 172) - 25 Jan 2021 (Study Day 182)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2158 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intervertebral Disc Protrusion/Herniated Disc	SAE	Grade 4	Not related	12 Dec 2020 (Study Day 131) – 13 Jan 2021 (Study Day 163)	Recovered/resolved
Aphasia/Dysphasia	SAE	Grade 4	Not related	15 Jan 2021 (Study Day 165) – 18 Jan 2021 (Study Day 168)	Recovered/resolved
Dyspnoea/Difficulty Breathing	SAE	Grade 4	Not related	15 Jan 2021 (Study Day 165) – 18 Jan 2021 (Study Day 168)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2158, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Dec 2020 (Study Day 131), 130 days after the first dose and 102 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of intervertebral disc protrusion. Action taken with the IP was not applicable. The event of herniated disc lasted for 33 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 163). The investigator assessed the event of intervertebral disc protrusion to be not related to the IP.

On 15 Jan 2021 (Study Day 165), 164 days after the first dose and 136 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of aphasia. Action taken with the IP was not applicable. The event of dysphasia lasted for 4 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 168). The investigator assessed the event of aphasia to be not related to the IP.

On 15 Jan 2021 (Study Day 165), 164 days after the first dose and 136 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dyspnoea. Action taken with the IP was not applicable. The event of difficulty breathing lasted for 4 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 168). The investigator assessed the event of dyspnoea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-059043	Aphasia
MOD-2021-059043	Dyspnoea
MOD-2021-008600	Intervertebral disc protrusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Benign neoplasm of thymus	Benign thynoma	1993 - 1993
Blood cholesterol increased	High cholesterol	1993 - Ongoing
Dysplasia	Right ventricle dysplasia	1999 - Ongoing
Asthma	Asthma	2000 - Ongoing
Bipolar II disorder	Bipolar 2	2006 - Ongoing
Coronary arterial stent insertion	Cardiac stents	2010 - 2010
Nerve compression	Pinched nerve in neck	2018 - Ongoing
Prostatomegaly	Enlarged prostate	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lamotrigine	2007 - Ongoing	Bipolar Disorder
Salbutamol	2010 - Ongoing	Asthma
Topiramate	2011 - Ongoing	Bipolar Disorder
Rosuvastatin	2017 - Ongoing	High Cholesterol
Ubidecarenone	May 2019 - Ongoing	Health Maintenance

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin hydrochloride	Jun 2019 - Ongoing	Enlarged Prostate
Colecalciferol	May 2020 - Ongoing	Health Maintenance
Ezetimibe	May 2020 - Ongoing	High Cholesterol
Prednisone	28 Sep 2020 (Study Day 56) - 01 Oct 2020 (Study Day 59)	Pain From Pinched Nerve In Neck
Influenza vaccine	05 Oct 2020 (Study Day 63) - 05 Oct 2020 (Study Day 63)	Health Maintenance
Anterior cervical discectomy/decompression*	12 Jan 2021 (Study Day 162) - 12 Jan 2021 (Study Day 162)	Adverse Event
X-ray*	12 Jan 2021 (Study Day 162) - 12 Jan 2021 (Study Day 162)	Diagnostic
Docusate sodium	13 Jan 2021 (Study Day 163) - 25 Jan 2021 (Study Day 175)	Constipation Prophylaxis
Glyceryl trinitrate	13 Jan 2021 (Study Day 163) - Ongoing	Prophylaxis
Macrogol	13 Jan 2021 (Study Day 163) - 25 Jan 2021 (Study Day 175)	Post Procedure Constipation Prophylaxis
Ondansetron	13 Jan 2021 (Study Day 163) - 25 Jan 2021 (Study Day 175)	Post Procedure Nausea Prophylaxis
Oxycodone	13 Jan 2021 (Study Day 163) - 20 Jan 2021 (Study Day 170)	Pain Secondary To Anterior Cervical Discectomy
Paracetamol	13 Jan 2021 (Study Day 163) - 25 Jan 2021 (Study Day 175)	Pain Secondary To Anterior Cervical Discectomy
Cbc panel*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Diagnostic
Chest x-ray*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Diagnostic
Cmp panel*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Diagnostic
Coag panel*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Diagnostic
Ct (neck)*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Diagnostic
Ct (pe)*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Diagnostic
Type and screen labs*	16 Jan 2021 (Study Day 166) - 16 Jan 2021 (Study Day 166)	Diagnostic
Prednisone	23 Jan 2021 (Study Day 173) - 25 Jan 2021 (Study Day 175)	Post Surgical Inflammation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nerve Compression	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 37) - 12 Jan 2021 (Study Day 162)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378503

Participant Number:	US318-2166 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cancer Pain/General Chest Pain Secondary To Small Cell Carcinoma	SAE	Grade 4	Not related	21 Nov 2020 (Study Day 109) – 21 Nov 2020 (Study Day 109)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2166, an 80-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Nov 2020 (Study Day 109), 108 days after the first dose and 78 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cancer pain. Action taken with the IP was not applicable. The event of general chest pain secondary to small cell carcinoma lasted for 1 day, after which it was considered to be recovered/resolved on 21 Nov 2020 (Study Day 109). The investigator assessed the event of cancer pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-016774	Cancer pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Blood cholesterol increased	High cholesterol	2005 - Ongoing
Depression	Depression	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2011 - Ongoing
Bradycardia	Bradycardia	2015 - Ongoing
Cardiac pacemaker insertion	Pacemaker	2015 - 2015
Hypermetropia	Bilateral hyperopia	2017 - Ongoing
Macular degeneration	Bilateral macular degeneration	2019 - Ongoing
Coronary artery disease	Coronary artery disease	14 Jan 2020 (Study Day -204) - Ongoing
Myocardial infarction	Heart attack	14 Jan 2020 (Study Day -204) - 14 Jan 2020 (Study Day -204)
Coronary arterial stent insertion	Stent placement-lad	15 Jan 2020 (Study Day -203) - 15 Jan 2020 (Study Day -203)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2005 - Ongoing	Heart Health
Fluoxetine	2010 - Ongoing	Depression
Salbutamol	2011 - Ongoing	Chronic Obstructive Pulmonary Disease
Vitamins nos	2019 - Ongoing	Macular Degeneration
Atorvastatin	Jan 2020 - Ongoing	High Cholesterol
Carvedilol	Jan 2020 - Ongoing	Hypertension/Coronary Artery Disease
Fish oil	Jan 2020 - Ongoing	Health Maintenance
Ticagrelor	Jan 2020 - Ongoing	Coronary Artery Disease
Paracetamol	05 Sep 2020 (Study Day 32) - 05 Sep 2020 (Study Day 32)	Injection Site Pain/Headache
Influenza vaccine	19 Oct 2020 (Study Day 76) - 19 Oct 2020 (Study Day 76)	Health Maintenance

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US318-2192 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Epistaxis/Severe Epistaxis Secondary To Nasal Surgical Complication	SAE	Grade 4	Not related	22 Nov 2020 (Study Day 109) – 23 Nov 2020 (Study Day 110)	Recovered/resolved
Hypoxia/Hypoxia Secondary To Chronic Obstructive Pulmonary Disease And Asthma	SAE	Grade 4	Not related	24 Nov 2020 (Study Day 111) – 25 Nov 2020 (Study Day 112)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2192, a 63-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Nov 2020 (Study Day 109), 108 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of epistaxis. Action taken with the IP was not applicable. The event of severe epistaxis secondary to nasal surgical complication lasted for 2 days, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 110). The investigator assessed the event of epistaxis to be not related to the IP.

On 24 Nov 2020 (Study Day 111), 110 days after the first dose and 82 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hypoxia. Action taken with the IP was not applicable. The event of hypoxia secondary to chronic obstructive pulmonary disease and asthma lasted for 2 days, after which it was considered to be recovered/resolved on 25 Nov 2020 (Study Day 112). The investigator assessed the event of hypoxia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000917	Epistaxis
MOD-2020-000917	Hypoxia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1960 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Goitre	Goiter	2000 - 2000
Hypertension	Hypertension	2000 - Ongoing
Appendicectomy	Appendectomy	2008 - 2008
Appendicitis	Appendicitis	2008 - 2008
Gastrooesophageal reflux disease	Acid reflux	2009 - Ongoing
Haemorrhoids	Hemorrhoids	2012 - Ongoing
Asthma	Moderate asthma	2014 - Ongoing
Osteoarthritis	Osteoarthritis-right knee	2015 - Ongoing
Osteopenia	Osteopenia	2015 - Ongoing
Nasal septum deviation	Deviated septum	17 Jan 2018 (Study Day -932) - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Trigeminal neuralgia	Trigeminal neuralgia	Oct 2019 - Mar 2020
Gastrooesophageal reflux disease	Gerd	May 2020 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	19 May 2020 (Study Day -79) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Citalopram	2000 - Ongoing	Anxiety
Lisinopril	2000 - Ongoing	Hypertension
Amlodipine	2002 - Ongoing	Hypertension
Metoprolol	2003 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2005 - Ongoing	Seasonal Allergies
Loratadine	2005 - Ongoing	Seasonal Allergies
Vitamins nos	2005 - Ongoing	Health Maintenance
Colecalciferol	2009 - Ongoing	Health Maintenance
Glucosamine	2009 - Ongoing	Health Maintenance
Omeprazole	2009 - Ongoing	Acid Reflux
Hydrocortisone	2012 - Ongoing	Hemorrhoids
Fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	2014 - Ongoing	Asthma/Chronic Obstructive Pulmonary Disease
Salbutamol	2014 - Ongoing	Asthma
Vitamins nos	2014 - Ongoing	Health Maintenance
Ascorbic acid	2019 - Ongoing	Health Maintenance
Menaquinone	2019 - Ongoing	Health Maintenance
Vitamin b12 nos	2019 - Ongoing	Health Maintenance
Zolpidem	2019 - Ongoing	Insomnia
Clonazepam	13 May 2020 (Study Day -85) - Ongoing	Anxiety
Macrogol 3350	23 Aug 2020 (Study Day 18) - Ongoing	Stool Softener/Constipation Prophylaxis
Diclofenac	15 Sep 2020 (Study Day 41) - Ongoing	Osteoarthritis
Covid test*	24 Oct 2020 (Study Day 80) - 24 Oct 2020 (Study Day 80)	Diagnostic
Influenza vaccine	26 Oct 2020 (Study Day 82) - 26 Oct 2020 (Study Day 82)	Health Maintenance
Chest x-ray*	11 Nov 2020 (Study Day 98) - 11 Nov 2020 (Study Day 98)	Diagnostic
Doxycycline	11 Nov 2020 (Study Day 98) - 21 Nov 2020 (Study Day 108)	Prophylaxis Septoplasty
Septoplasty*	11 Nov 2020 (Study Day 98) - 11 Nov 2020 (Study Day 98)	Medical History
Ct scan*	22 Nov 2020 (Study Day 109) - 22 Nov 2020 (Study Day 109)	Diagnostic
Ekg*	22 Nov 2020 (Study Day 109) - 22 Nov 2020 (Study Day 109)	Diagnostic
Labwork*	22 Nov 2020 (Study Day 109) - 22 Nov 2020 (Study Day 109)	Diagnostic
Ondansetron	22 Nov 2020 (Study Day 109) - 23 Nov 2020 (Study Day 110)	Prophylacitc
Sodium chloride	22 Nov 2020 (Study Day 109) - 23 Nov 2020 (Study Day 110)	Prophylacitc
Ct scan*	23 Nov 2020 (Study Day 110) - 23 Nov 2020 (Study Day 110)	Diagnostic
Cta of head and neck*	23 Nov 2020 (Study Day 110) - 23 Nov 2020 (Study Day 110)	Diagnostic
Hydrocodone bitartrate; paracetamol	23 Nov 2020 (Study Day 110) - 01 Dec 2020 (Study Day 118)	Septoplasty Pain
Iohexol	23 Nov 2020 (Study Day 110) - 23 Nov 2020 (Study Day 110)	Cta Of Head And Neck
Omega-3 fatty acids	23 Nov 2020 (Study Day 110) - Ongoing	Health Maintenance

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	23 Nov 2020 (Study Day 110) - 01 Dec 2020 (Study Day 118)	Septoplasty Pain
Sodium chloride	24 Nov 2020 (Study Day 111) - Ongoing	Post Septoplasty Prophylactic
Echocardiogram*	25 Nov 2020 (Study Day 112) - 25 Nov 2020 (Study Day 112)	Diagnostic
Ferrous sulfate	26 Nov 2020 (Study Day 113) - 10 Dec 2020 (Study Day 127)	Anemia
Phenylephrine hydrochloride	26 Nov 2020 (Study Day 113) - 29 Nov 2020 (Study Day 116)	Nosebleed (Epistaxis)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Epistaxis	Grade 3/severe	Not related	20 Nov 2020 (Study Day 107) - 20 Nov 2020 (Study Day 107)
Anaemia	Grade 2/moderate	Not related	22 Nov 2020 (Study Day 109) - Ongoing
Chest Discomfort	Grade 2/moderate	Not related	22 Nov 2020 (Study Day 109) - 22 Nov 2020 (Study Day 109)
Syncope	Grade 1/mild	Not related	22 Nov 2020 (Study Day 109) - 22 Nov 2020 (Study Day 109)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2227 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Non-Cardiac Chest Pain/Chest Pain (Non-Cardiac)	SAE	Grade 4	Not related	06 Oct 2020 (Study Day 61) – 09 Oct 2020 (Study Day 64)	Recovered/ resolved
Dehydration/Dehydration	SAE	Grade 4	Not related	24 Oct 2020 (Study Day 79) – 26 Oct 2020 (Study Day 81)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2227, a 69-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 08 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Oct 2020 (Study Day 61), 60 days after the first dose and 28 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of non-cardiac chest pain. Action taken with the IP was not applicable. The event of chest pain (non-cardiac) lasted for 4 days, after which it was considered to be recovered/resolved on 09 Oct 2020 (Study Day 64). The investigator assessed the event of non-cardiac chest pain to be not related to the IP.

On 24 Oct 2020 (Study Day 79), 78 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration lasted for 3 days, after which it was considered to be recovered/resolved on 26 Oct 2020 (Study Day 81). The investigator assessed the event of dehydration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000582	Chest pain (non-cardiac)
MOD-2020-000582	Dehydration

Study Completion/Discontinuation

On 02 Mar 2021 (Study Day 208), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Tubal ligation	1983 - 1983
Coronary artery disease	Coronary artery disease	1998 - Ongoing
Hypertension	Hypertension	1998 - Ongoing
Myocardial infarction	Heart attack	1998 - 1998
Menopause	Menopause	2005 - Ongoing
Presbyopia	Presbyopia	2005 - Ongoing
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Purpura senile	Senile pupura bilateral arms	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1998 - Ongoing	Heart Health
Lisinopril	1998 - 07 Oct 2020 (Study Day 62)	Hypertension
Atorvastatin	2010 - Ongoing	High Cholesterol
Levothyroxine	2013 - Ongoing	Hypothyroidism
Vitamin d nos	2015 - Ongoing	Health Maintenance
Oxycodone	Oct 2020 - Oct 2020	Pain Secondary To Left Arthoplasty
Acetylsalicylic acid	06 Oct 2020 (Study Day 61) - 06 Oct 2020 (Study Day 61)	Chest Pain, Non Cardiac.
Bloodwork (troponin)*	06 Oct 2020 (Study Day 61) - 06 Oct 2020 (Study Day 61)	Diagnostic
Chest ct with contrast*	06 Oct 2020 (Study Day 61) - 06 Oct 2020 (Study Day 61)	Diagnostic
Left shoulder arthroplasty*	06 Oct 2020 (Study Day 61) - 06 Oct 2020 (Study Day 61)	Adverse Event
Cardiac catherization*	07 Oct 2020 (Study Day 62) - 07 Oct 2020 (Study Day 62)	Adverse Event
Chest x-ray*	08 Oct 2020 (Study Day 63) - 08 Oct 2020 (Study Day 63)	Diagnostic
Chest ct with contrast*	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x-ray*	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Diagnostic
Ct of brain*	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Diagnostic
Ekg*	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Diagnostic
I.v. solutions	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)	Dehydration

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rotator Cuff Syndrome	Grade 3/severe	Not related	25 Sep 2020 (Study Day 50) - 06 Oct 2020 (Study Day 61)
Atelectasis	Grade 2/moderate	Not related	06 Oct 2020 (Study Day 61) - Ongoing
Bradycardia	Grade 3/severe	Not related	06 Oct 2020 (Study Day 61) - 06 Oct 2020 (Study Day 61)
Asthenia	Grade 2/moderate	Not related	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)
Syncope	Grade 3/severe	Not related	24 Oct 2020 (Study Day 79) - 24 Oct 2020 (Study Day 79)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2236 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Of Left Knee Osteoarthritis	SAE	Grade 3/severe	Not related	18 Jan 2021 (Study Day 165) – 18 Jan 2021 (Study Day 165)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2236, a 60-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Jan 2021 (Study Day 165), 164 days after the first dose and 130 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening of left knee osteoarthritis lasted for 1 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 165). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-061486	Knee osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypermetropia	Bilateral hyperopia	1967 - Ongoing
Food allergy	Allergy to seafood	1977 - Ongoing
Drug hypersensitivity	Allergy to diflucan	1989 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Facial bones fracture	Fractured nose	2001 - 2001
Rhinoplasty	Rhinoplasty	2001 - 2001
Hypothyroidism	Hypothyroidism	2008 - Ongoing
Thrombosis	Blood clot-right foot	2010 - 2010
Sinuplasty	Sinuplasty	2012 - 2012
Sinus congestion	Blocked sinuses	2012 - 2012
Osteoarthritis	Osteoarthritis-back/ bilateral feet/ bilateral knees/ bilateral elbows/ bilateral shoulders	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Guaifenesin	1995 - Ongoing	Seasonal Allergies
Iron	1997 - Ongoing	Health Maintenance
Levothyroxine	2010 - Ongoing	Hypothyroidism
Biotin	2014 - Ongoing	Health Maintenance
Hydrocortisone	2016 - Ongoing	Osteoarthritis-Back/ Bilateral Feet/ Bilateral Knees/ Bilateral Elbows/ Bilateral Shoulders
Naproxen	2016 - Ongoing	Osteoarthritis
Omeprazole	2016 - Ongoing	Health Maintenance For Stomach Protection
Total left knee replacement*	18 Jan 2021 (Study Day 165) - 18 Jan 2021 (Study Day 165)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US319-2006 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Kidney Disease/Worsening Chronic Kidney Disease	SAE	Grade 2/ moderate	Not related	16 Aug 2020 (Study Day 16) – 17 Aug 2020 (Study Day 17)	Recovered/resolved
Dehydration/Dehydration	SAE	Grade 4	Not related	16 Aug 2020 (Study Day 16) – 17 Aug 2020 (Study Day 17)	Recovered/resolved
Hyperkalaemia/Hyperkalemia	SAE	Grade 2/ moderate	Not related	16 Aug 2020 (Study Day 16) – 17 Aug 2020 (Study Day 17)	Recovered/resolved
Hypotension/Hypotension	SAE	Grade 4	Not related	16 Aug 2020 (Study Day 16) – 17 Aug 2020 (Study Day 17)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2006, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 01 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 29 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Aug 2020 (Study Day 16), 15 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of chronic kidney disease. The IP dose was not changed due to the worsening chronic kidney disease. The event of worsening chronic kidney disease lasted for 2 days, after which it was considered to be recovered/resolved on 17 Aug 2020 (Study Day 17). The investigator assessed the event of chronic kidney disease to be not related to the IP.

On 16 Aug 2020 (Study Day 16), 15 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. The IP dose was not changed due to the dehydration. The event of dehydration lasted for 2 days, after which it

was considered to be recovered/resolved on 17 Aug 2020 (Study Day 17). The investigator assessed the event of dehydration to be not related to the IP.

On 16 Aug 2020 (Study Day 16), 15 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of hyperkalaemia. The IP dose was not changed due to the hyperkalemia. The event of hyperkalemia lasted for 2 days, after which it was considered to be recovered/resolved on 17 Aug 2020 (Study Day 17). The investigator assessed the event of hyperkalaemia to be not related to the IP.

On 16 Aug 2020 (Study Day 16), 15 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hypotension. The IP dose was not changed due to the hypotension. The event of hypotension lasted for 2 days, after which it was considered to be recovered/resolved on 17 Aug 2020 (Study Day 17). The investigator assessed the event of hypotension to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000231	Dehydration
MOD-2020-000231	Hypotension
MOD-2020-000231	Chronic kidney disease
MOD-2020-000231	Hyperkalemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Blood testosterone decreased	Low testosterone	20 Apr 2012 (Study Day -3025) - Ongoing
Hyperlipidaemia	Hyperlipidemia	20 Apr 2012 (Study Day -3025) - Ongoing
Hypertension	Hypertension	20 Apr 2012 (Study Day -3025) - Ongoing
Hypothyroidism	Hypothyroidism	20 Apr 2012 (Study Day -3025) - Ongoing
Type 2 diabetes mellitus	Type II diabetes	20 Apr 2012 (Study Day -3025) - Ongoing
Chronic kidney disease	Chronic kidney disease	14 Jul 2020 (Study Day -18) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2012 - Ongoing	Preventative
Levothyroxine	2012 - Ongoing	Hypothyroidism
Lisinopril	2012 - 16 Aug 2020 (Study Day 16)	Hypertension
Chondroitin; glucosamine	2015 - Ongoing	Preventative
Glucosamine	2015 - Ongoing	Preventative
Hydrochlorothiazide	2015 - 16 Aug 2020 (Study Day 16)	Hypertension
Metformin	2015 - Ongoing	Diabetes Mellitus II
Testosterone cipionate	2015 - Ongoing	Low Testosterone
Fish oil	2016 - Ongoing	Preventative
Vitamin d nos	2016 - Ongoing	Preventative
Lovastatin	14 Jul 2020 (Study Day -18) - Ongoing	Hyperlipidemia
Calcium chloride; potassium chloride; sodium lactate	16 Aug 2020 (Study Day 16) - 17 Aug 2020 (Study Day 17)	Dehydration
Glucagon	16 Aug 2020 (Study Day 16) - 16 Aug 2020 (Study Day 16)	Prophylaxis For Hypoglycemia
Glucose	16 Aug 2020 (Study Day 16) - 16 Aug 2020 (Study Day 16)	Hyperkalemia
Lisinopril	16 Aug 2020 (Study Day 16) - Ongoing	Hypertension
Ondansetron	16 Aug 2020 (Study Day 16) - 16 Aug 2020 (Study Day 16)	Prophylactic For Nausea/Vomiting

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US319-2291 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	16 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	12 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Clostridium Difficile Colitis/C-Diff - Colitiis	SAE	Grade 4	Not related	02 Nov 2020 (Study Day 79) – 10 Nov 2020 (Study Day 87)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2291, a 70-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 16 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 12 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Nov 2020 (Study Day 79), 78 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of clostridium difficile colitis. Action taken with the IP was not applicable. The event of c-diff - colitiis lasted for 9 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 87). The investigator assessed the event of clostridium difficile colitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000783	Clostridium difficile colitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	Not reported
Benign breast neoplasm	Benign breast lesion	Not reported
Anxiety	Anxiety	1990 - Ongoing
Bipolar II disorder	Bipolar ii	1990 - Ongoing
Depression	Depression	1990 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1990 - Ongoing
Obsessive-compulsive disorder	Obsessive compulsive disorder	1990 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Osteoarthritis	Osteoarthritis	1995 - Ongoing
Osteopenia	Osteopenia	1995 - Ongoing
Postmenopause	Post menopausal	1995 - Ongoing
Urinary tract infection	Urinary tract infection	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lamotrigine	1990 - Ongoing	Biploar Disorder
Rosuvastatin calcium	1990 - Ongoing	Hypercholesterolemia
Valproate semisodium	1992 - Ongoing	Bipolar Disorder
Clomipramine hydrochloride	1995 - Ongoing	Bipolar Disorder
Estradiol	1995 - Ongoing	Post Menopausal
Meloxicam	1995 - Ongoing	Osteoarthritis
Metoprolol	1995 - Ongoing	Hypertension
Progesterone	1995 - Ongoing	Postmenopausal
Spironolactone	1995 - Ongoing	Hypertension
Gabapentin	2015 - Ongoing	Obsessive Compulsive Disorder/Bipolar Disorder
Buspirone hydrochloride	2019 - Ongoing	Bipolar Disorder
Hydrocodone bitartrate; paracetamol	2019 - Ongoing	Osteoarthritis
Progesterone	2019 - Ongoing	Post Menopause
Nitrofurantoin	13 Aug 2020 (Study Day -3) - 19 Aug 2020 (Study Day 4)	Urinary Tract Infection
Dental bridge procedure*	27 Oct 2020 (Study Day 73) - 27 Oct 2020 (Study Day 73)	Other, Dental Work
Tooth extraction*	27 Oct 2020 (Study Day 73) - 27 Oct 2020 (Study Day 73)	Other, Dental

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	28 Oct 2020 (Study Day 74) - 29 Oct 2020 (Study Day 75)	Chills, Fever
Paracetamol	28 Oct 2020 (Study Day 74) - 29 Oct 2020 (Study Day 75)	Chills, Fever
Ondansetron	01 Nov 2020 (Study Day 78) - 02 Nov 2020 (Study Day 79)	Nausea/Vomiting
Amlodipine besilate	02 Nov 2020 (Study Day 79) - 04 Jan 2021 (Study Day 142)	Hypertension
Amlodipine besilate	02 Nov 2020 (Study Day 79) - 04 Jan 2021 (Study Day 142)	Worsening Hypertension
Vancomycin	02 Nov 2020 (Study Day 79) - 10 Nov 2020 (Study Day 87)	C-Diff
All other therapeutic products	03 Nov 2020 (Study Day 80) - 03 Nov 2020 (Study Day 80)	Hydration/Nausea/Vomiting
Chest x-ray*	03 Nov 2020 (Study Day 80) - 03 Nov 2020 (Study Day 80)	Diagnostic
Clomipramine	03 Nov 2020 (Study Day 80) - 09 Nov 2020 (Study Day 86)	Ocd
Ekg*	03 Nov 2020 (Study Day 80) - 03 Nov 2020 (Study Day 80)	Diagnostic
Glucose	03 Nov 2020 (Study Day 80) - 07 Nov 2020 (Study Day 84)	Dehydration
Heparin	03 Nov 2020 (Study Day 80) - 09 Nov 2020 (Study Day 86)	Prevention Of Blood Clots
Lorazepam	03 Nov 2020 (Study Day 80) - 09 Nov 2020 (Study Day 86)	Anxiety
Nuclear medicine pulmonary ventilation and perfusion study*	03 Nov 2020 (Study Day 80) - 03 Nov 2020 (Study Day 80)	Diagnostic
Ondansetron	03 Nov 2020 (Study Day 80) - 03 Nov 2020 (Study Day 80)	Nausea/Vomiting
Paracetamol	03 Nov 2020 (Study Day 80) - 07 Nov 2020 (Study Day 84)	Abdominal Pain
Ultrasound retroperitoneal kidney*	03 Nov 2020 (Study Day 80) - 03 Nov 2020 (Study Day 80)	Diagnostic
Ct abdomen w/o contrast*	04 Nov 2020 (Study Day 81) - 04 Nov 2020 (Study Day 81)	Diagnostic
Amlodipine	08 Nov 2020 (Study Day 85) - Ongoing	Worsening Hypertension
Chest x-ray*	09 Nov 2020 (Study Day 86) - 09 Nov 2020 (Study Day 86)	Diagnostic
Furosemide	09 Nov 2020 (Study Day 86) - Ongoing	Severe Tricuspid Regurgitation/Edema
Magnesium sulfate	09 Nov 2020 (Study Day 86) - 10 Nov 2020 (Study Day 87)	Electrolyte Replacement
Solifenacin	09 Nov 2020 (Study Day 86) - 10 Nov 2020 (Study Day 87)	Bladder Spasms
Echo*	10 Nov 2020 (Study Day 87) - 10 Nov 2020 (Study Day 87)	Diagnostic
Vancomycin	10 Nov 2020 (Study Day 87) - 20 Nov 2020 (Study Day 97)	C.Diff Colitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	24 Nov 2020 (Study Day 101) - 29 Nov 2020 (Study Day 106)	Vomiting
Potassium chloride	24 Nov 2020 (Study Day 101) - 29 Nov 2020 (Study Day 106)	Mild Hyponatremia
All other therapeutic products	26 Nov 2020 (Study Day 103) - 26 Nov 2020 (Study Day 103)	Hydration

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 73) - 10 Nov 2020 (Study Day 87)
Vomiting	Grade 2/moderate	Not related	28 Oct 2020 (Study Day 74) - 10 Nov 2020 (Study Day 87)
Fatigue	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 75) - 04 Nov 2020 (Study Day 81)
Pyrexia	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 75) - 04 Nov 2020 (Study Day 81)
Abdominal Pain	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 10 Nov 2020 (Study Day 87)
Acute Kidney Injury	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 10 Nov 2020 (Study Day 87)
Diarrhoea	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 10 Nov 2020 (Study Day 87)
Dyspnoea	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 08 Nov 2020 (Study Day 85)
Gastroenteritis	Grade 3/severe	Not related	03 Nov 2020 (Study Day 80) - 10 Nov 2020 (Study Day 87)
Hypokalaemia	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 10 Nov 2020 (Study Day 87)
Hyponatraemia	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 08 Nov 2020 (Study Day 85)
Hypotension	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 08 Nov 2020 (Study Day 85)
Mental Status Changes	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 05 Nov 2020 (Study Day 82)
Vomiting	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 80) - 05 Nov 2020 (Study Day 82)
Irritable Bowel Syndrome	Grade 1/mild	Not related	05 Nov 2020 (Study Day 82) - Ongoing
Hypotension	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 84) - 08 Nov 2020 (Study Day 85)
Bladder Spasm	Grade 1/mild	Not related	08 Nov 2020 (Study Day 85) - 09 Nov 2020 (Study Day 86)
Hypertension	Grade 2/moderate	Not related	09 Nov 2020 (Study Day 86) - 10 Nov 2020 (Study Day 87)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oedema	Grade 1/mild	Not related	09 Nov 2020 (Study Day 86) - 10 Nov 2020 (Study Day 87)
Tricuspid Valve Incompetence	Grade 2/moderate	Not related	09 Nov 2020 (Study Day 86) - 10 Nov 2020 (Study Day 87)
Asthenia	Grade 2/moderate	Not related	24 Nov 2020 (Study Day 101) - 29 Nov 2020 (Study Day 106)
Hyponatraemia	Grade 1/mild	Not related	24 Nov 2020 (Study Day 101) - 29 Nov 2020 (Study Day 106)
Vomiting	Grade 2/moderate	Not related	24 Nov 2020 (Study Day 101) - 29 Nov 2020 (Study Day 106)
Diarrhoea	Grade 2/moderate	Not related	26 Nov 2020 (Study Day 103) - 29 Nov 2020 (Study Day 106)
Drug Hypersensitivity	Grade 1/mild	Not related	14 Dec 2020 (Study Day 121) - 09 Jan 2021 (Study Day 147)
Injection Site Pain	Grade 1/mild	Related	22 Jan 2021 (Study Day 160) - 22 Jan 2021 (Study Day 160)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US319-2345 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	23 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	20 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pyelonephritis Acute/Acute Pyelonephritis	SAE	Grade 4	Not related	27 Aug 2020 (Study Day 5) – 04 Sep 2020 (Study Day 13)	Recovered/resolved
Urosepsis/Urosepsis	SAE	Grade 4	Not related	27 Aug 2020 (Study Day 5) – 04 Sep 2020 (Study Day 13)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2345, a 67-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 23 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 20 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Aug 2020 (Study Day 5), 4 days after the first dose and 24 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pyelonephritis acute. The IP dose was not changed due to the acute pyelonephritis. The event of acute pyelonephritis lasted for 9 days, after which it was considered to be recovered/resolved on 04 Sep 2020 (Study Day 13). The investigator assessed the event of pyelonephritis acute to be not related to the IP.

On 27 Aug 2020 (Study Day 5), 4 days after the first dose and 24 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of urosepsis. The IP dose was not changed due to the urosepsis. The event of urosepsis lasted for 9 days, after which it was considered to be recovered/resolved on 04 Sep 2020 (Study Day 13). The investigator assessed the event of urosepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000316	Pyelonephritis acute
MOD-2020-000316	Urosepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	Jan 1980 - Ongoing
Hysterectomy	Hysterectomy	1991 - 1991
Botulinum toxin injection	Botox	2010 - 2010
Vitamin D deficiency	Vitamin d deficient	Jan 2015 - Ongoing
Stress cardiomyopathy	Stress cardiomyopathy	2019 - Ongoing
Hypertension	Hypertension	Sep 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Esomeprazole magnesium	Jan 1995 - Ongoing	Gastroesophageal Reflux Disease
Vitamin d nos	Jan 2015 - Ongoing	Vitamin D Deficient
Acetylsalicylic acid	Sep 2019 - Ongoing	Cardiac Preventative
Hydrochlorothiazide; losartan potassium	Sep 2019 - Ongoing	Hypertension
Antibiotics	28 Aug 2020 (Study Day 6) - 04 Sep 2020 (Study Day 13)	Acute Pyelonephritis
Ceftriaxone	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Urinary Tract Infection/Bacteremia
Chest x-ray*	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Diagnostic
Ct abdomen & pelvis with contrast*	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Diagnostic
Ekg*	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Diagnostic
Ketorolac tromethamine	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Methocarbamol	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Body Aches
Ondansetron	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Intractable Nausea/Vomiting
Paracetamol	28 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 6)	Fever
Paracetamol	28 Aug 2020 (Study Day 6) - 02 Sep 2020 (Study Day 11)	Fever, Headache, Generalized Muscle Aches, Joint Aches. Pain At Injection Site
Furosemide	01 Sep 2020 (Study Day 10) - 02 Sep 2020 (Study Day 11)	Fluid Retention
Ciprofloxacin	02 Sep 2020 (Study Day 11) - 09 Sep 2020 (Study Day 18)	Pyelonephritis
Ibuprofen	21 Sep 2020 (Study Day 30) - 23 Sep 2020 (Study Day 32)	Fever, Headache, Generalized Muscle Aches, Joint Aches. Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Myalgia	Grade 1/mild	Not related	26 Aug 2020 (Study Day 4) - 05 Sep 2020 (Study Day 14)
Urinary Tract Infection	Grade 2/moderate	Not related	26 Aug 2020 (Study Day 4) - 02 Sep 2020 (Study Day 11)
Chills	Grade 1/mild	Not related	27 Aug 2020 (Study Day 5) - 31 Aug 2020 (Study Day 9)
Fatigue	Grade 1/mild	Not related	27 Aug 2020 (Study Day 5) - 05 Sep 2020 (Study Day 14)
Nausea	Grade 1/mild	Not related	27 Aug 2020 (Study Day 5) - 02 Sep 2020 (Study Day 11)
Pyrexia	Grade 1/mild	Not related	27 Aug 2020 (Study Day 5) - 29 Aug 2020 (Study Day 7)
Vomiting	Grade 1/mild	Not related	27 Aug 2020 (Study Day 5) - 30 Aug 2020 (Study Day 8)
Headache	Grade 1/mild	Not related	28 Aug 2020 (Study Day 6) - 02 Sep 2020 (Study Day 11)
Hypertension	Grade 2/moderate	Not related	28 Aug 2020 (Study Day 6) - 01 Sep 2020 (Study Day 10)
Nausea	Grade 1/mild	Not related	28 Aug 2020 (Study Day 6) - 02 Sep 2020 (Study Day 11)
Bacteraemia	Grade 2/moderate	Not related	29 Aug 2020 (Study Day 7) - 01 Sep 2020 (Study Day 10)
Hyponatraemia	Grade 1/mild	Not related	29 Aug 2020 (Study Day 7) - 01 Sep 2020 (Study Day 10)
Arthralgia	Grade 1/mild	Not related	30 Aug 2020 (Study Day 8) - 01 Sep 2020 (Study Day 10)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US319-2486 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deep Vein Thrombosis/Deep Vein Thrombosis	SAE	Grade 4	Not related	02 Nov 2020 (Study Day 69) – 08 Nov 2020 (Study Day 75)	Recovered/resolved
Gastrointestinal Haemorrhage/Gastrointestinal Bleed	SAE	Grade 4	Not related	02 Nov 2020 (Study Day 69) – 08 Nov 2020 (Study Day 75)	Recovered/resolved
Pulmonary Embolism/Pulmonary Embolism	SAE	Grade 4	Not related	02 Nov 2020 (Study Day 69) – 08 Nov 2020 (Study Day 75)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2486, a 73-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of deep vein thrombosis. Action taken with the IP was not applicable. The event of deep vein thrombosis lasted for 7 days, after which it was considered to be recovered/resolved on 08 Nov 2020 (Study Day 75). The investigator assessed the event of deep vein thrombosis to be not related to the IP.

On 02 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of gastrointestinal haemorrhage. Action taken with the IP was not applicable. The event of gastrointestinal bleed lasted for 7 days, after which it was considered to be recovered/resolved on 08 Nov 2020 (Study Day 75). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

On 02 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolism lasted for 7 days, after which it was considered to be recovered/resolved on 08 Nov 2020 (Study Day 75). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000867	Deep vein thrombosis
MOD-2020-000867	Gastrointestinal haemorrhage
MOD-2020-000867	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	1970 - Ongoing
Anxiety	Anxiety	1975 - Ongoing
Appendicectomy	Appendectomy	1980 - 1980
Cholecystectomy	Cholecystectomy	2000 - 2000
Arthroscopic surgery	Left knee arthroscopic surgery	2005 - 2005
Pancreatitis chronic	Chronic pancratitis	2005 - Ongoing
Arthroscopic surgery	Right knee arthroscopic surgery	2010 - 2010
Osteoarthritis	Osteoarthritis	2010 - Ongoing
Pain	Chronic pain	2010 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Hypothyroidism	Hypothyroidism	2017 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2018 - Ongoing
Anaemia	Anemia	2019 - Ongoing
Neuropathy peripheral	Peripheral neuropathy	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Celecoxib	2010 - Ongoing	Osteoarthritis
Lisinopril	2015 - Ongoing	Hypertension
Levothyroxine sodium	2017 - Ongoing	Hypothyroidism
Buspirone	2018 - Ongoing	Anxiety
Oxycodone	2018 - Ongoing	Chronic Pain
Pantoprazole	2018 - Ongoing	Gastroesophageal Reflux Disease
Quetiapine	2018 - Ongoing	Post Traumatic Stress Disorder
Valproate semisodium	2018 - Ongoing	Post Traumatic Stress Disorder
Ferrous sulfate	2019 - Ongoing	Anemia
Metformin	2019 - Ongoing	Diabetes Type 2
Pregabalin	2019 - Ongoing	Peripheral Neuropathy/Chronic Pain
Influenza vaccine	16 Oct 2020 (Study Day 52) - 16 Oct 2020 (Study Day 52)	Flu Prevention
Colonoscopy*	02 Nov 2020 (Study Day 69) - 02 Nov 2020 (Study Day 69)	Diagnostic
Endoscopy*	02 Nov 2020 (Study Day 69) - 02 Nov 2020 (Study Day 69)	Diagnostic
Heparin	02 Nov 2020 (Study Day 69) - 03 Nov 2020 (Study Day 70)	Treatment Of Pulmonary Embolism And Deep Vein Thrombosis
Pancreatic stent placement*	02 Nov 2020 (Study Day 69) - 02 Nov 2020 (Study Day 69)	Adverse Event
Blood transfusion*	03 Nov 2020 (Study Day 70) - 03 Nov 2020 (Study Day 70)	Adverse Event
Warfarin sodium	03 Nov 2020 (Study Day 70) - Ongoing	Treatment Of Pulmonary Embolism And Deep Vein Thrombosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US319-2614 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pericardial Effusion/Pericarditis Effusion	SAE	Grade 4	Not related	11 Sep 2020 (Study Day 12) – 15 Sep 2020 (Study Day 16)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2614, a 60-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Sep 2020 (Study Day 12), 11 days after the first dose and 18 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pericardial effusion. The IP dose was not changed due to the pericarditis effusion. The event of pericarditis effusion lasted for 5 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 16). The investigator assessed the event of pericardial effusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000302	Pericardial effusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Goitre	Goiter	Feb 2010 - Not reported
Osteoarthritis	Osteoarthritis	Feb 2010 - Ongoing
Blood cholesterol increased	High cholesterol	Feb 2011 - Ongoing
Hypertension	Hypertension	Feb 2011 - Ongoing
Diabetes mellitus	Diabetes	Jan 2015 - Ongoing
Erectile dysfunction	Erectile dysfunction	Jan 2015 - Ongoing
Muscle spasms	Muscle spasms	Jan 2015 - Ongoing
Neuralgia	Nerve pain	Jan 2015 - Ongoing
Anxiety	Anxiety	Feb 2018 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	Feb 2018 - Ongoing
Hypertension	High blood pressure	Feb 2018 - Ongoing
Acute myocardial infarction	Non-st segment elevation myocardial infarction	Apr 2018 - Ongoing
Atrial fibrillation	Atrial fibrillation	Apr 2018 - Ongoing
Tachycardia	Tachycardia	Apr 2018 - Ongoing
Ventricular fibrillation	Ventricular fibrillation	Apr 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone hydrochloride	Feb 2010 - Ongoing	Osteoarthritis
Atorvastatin	Feb 2011 - Ongoing	High Cholesterol
Carvedilol	Feb 2011 - Ongoing	Hypertension
Hydrochlorothiazide; losartan potassium	Feb 2011 - Ongoing	Hypertension
Duloxetine	Jan 2015 - Ongoing	Osteoarthritis
Gabapentin	Jan 2015 - Ongoing	Nerve Pain
Glipizide	Jan 2015 - Ongoing	Diabetes
Metformin	Jan 2015 - Ongoing	Diabetes
Sildenafil	Jan 2015 - Ongoing	Erectile Dysfunction
Tizanidine	Jan 2015 - Ongoing	Muscle Spasm
Alprazolam	Feb 2018 - Ongoing	Anxiety
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	Feb 2018 - Ongoing	Attention Deficit Disorder
Amiodarone	Apr 2018 - Ongoing	Ventricular Fibrillation/Tachycardia
Tamsulosin	Apr 2018 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	31 Aug 2020 (Study Day 1) - Ongoing	Pain On Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	12 Feb 2021 (Study Day 166) - 18 Feb 2021 (Study Day 172)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US319-2730 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Tachycardia/Worsening Of Tachycardia	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	18 Oct 2020 (Study Day 15) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2730, a 68-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Oct 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of tachycardia. On 31 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening of tachycardia was considered to be ongoing. The investigator assessed the event of tachycardia to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tachycardia	Tachycardia	Not reported - Ongoing
Uterine leiomyoma	Fibroids	1995 - 2000
Hysterectomy	Hysterectomy	2000 - 2000

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Breast cancer	Breast cancer	31 Jul 2008 (Study Day -4448) - Apr 2010
Mastectomy	Double mastectomy	Apr 2010 - Apr 2010
Botulinum toxin injection	Botox	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Anastrozole	Apr 2009 - Ongoing	Breast Cancer Recurrence Prevention
Botulinum toxin type a	15 Oct 2020 (Study Day 12) - 15 Oct 2020 (Study Day 12)	Cosmetic Injections
Botulinum toxin type a	01 Feb 2021 (Study Day 121) - 01 Feb 2021 (Study Day 121)	Cosmetic Injections
Paracetamol	12 Feb 2021 (Study Day 132) - 12 Feb 2021 (Study Day 132)	Joint Pain Post Injection
Ibuprofen	13 Feb 2021 (Study Day 133) - 13 Feb 2021 (Study Day 133)	Joint Pain Post Injection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tachycardia	Grade 2/moderate	Not related	18 Oct 2020 (Study Day 15) - Ongoing
Arthralgia	Grade 1/mild	Related	12 Feb 2021 (Study Day 132) - 15 Feb 2021 (Study Day 135)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US319-2734 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	04 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	02 Nov 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Fibrosis/Worsening Of Chronic Pulmonary Fibrosis	SAE	Grade 2/moderate	Not related	11 Nov 2020 (Study Day 39) – 22 Nov 2020 (Study Day 50)	Recovered/resolved
Hypoxia/Hypoxia Due To Rll Pneumonia	SAE	Grade 3/severe	Not related	18 Nov 2020 (Study Day 46) – 25 Nov 2020 (Study Day 53)	Recovered/resolved
Pneumonia/Rll Pneumonia	SAE	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 46) – 25 Nov 2020 (Study Day 53)	Recovered/resolved
Coccidioidomycosis/Valley Fever	SAE	Grade 3/severe	Not related	21 Nov 2020 (Study Day 49) – 02 Dec 2020 (Study Day 60)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2734, a 58-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 02 Nov 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Nov 2020 (Study Day 39), 38 days after the first dose and 9 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pulmonary fibrosis. The IP dose was not changed due to the worsening of chronic pulmonary fibrosis. The event of worsening of chronic pulmonary fibrosis lasted for 12 days, after which it was considered to be recovered/resolved on 22 Nov 2020 (Study Day 50). The investigator assessed the event of pulmonary fibrosis to be not related to the IP.

On 18 Nov 2020 (Study Day 46), 45 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypoxia. Action taken with the IP was not applicable. The event of hypoxia due to rll pneumonia lasted for 8 days, after

which it was considered to be recovered/resolved on 25 Nov 2020 (Study Day 53). The investigator assessed the event of hypoxia to be not related to the IP.

On 18 Nov 2020 (Study Day 46), 45 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of rll pneumonia lasted for 8 days, after which it was considered to be recovered/resolved on 25 Nov 2020 (Study Day 53). The investigator assessed the event of pneumonia to be not related to the IP.

On 21 Nov 2020 (Study Day 49), 48 days after the first dose and 19 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of coccidioidomycosis. The IP dose was not changed due to the valley fever. The event of valley fever lasted for 12 days, after which it was considered to be recovered/resolved on 02 Dec 2020 (Study Day 60). The investigator assessed the event of coccidioidomycosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006706	Pulmonary fibrosis
MOD-2021-006706	Hypoxia
MOD-2021-006706	Pneumonia
MOD-2021-006706	Coccidioidomycosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hodgkin's disease	Hodgkin's lymphoma	1999 - 1999
Radiotherapy	Radiation for lymphoma	1999 - 1999
Pulmonary fibrosis	Obstructive airway limitation/chronic pulmonary fibrosis	Jun 1999 - Ongoing
Cholecystectomy	Cholecystectomy	2001 - 2001
Cholelithiasis	Gallstones	2001 - 2001
Breast cancer	Left breast cancer	2008 - 2008
Mastectomy	Left mastectomy	2008 - 2008
Hysterectomy	Hysterectomy	2012 - 2012
Uterine leiomyoma	Fibroids	2012 - 2012
Insomnia	Insomnia	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sinus tachycardia	Sinus tachycardia	Jun 2019 - Ongoing
Hypertension	Hypertension	Sep 2019 - Ongoing
Deafness bilateral	Bilateral hearing loss	Oct 2019 - Ongoing
Anxiety	Anxiety	Mar 2020 - Ongoing
Depression	Depression	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Melatonin	2018 - Ongoing	Insomnia
Fish oil	Jun 2018 - Ongoing	Supplement
Vitamin d nos	Jun 2018 - Ongoing	Supplement
Vitamins nos	Jun 2018 - Ongoing	Supplement
Hydrochlorothiazide	Sep 2019 - Ongoing	Hypertension
Propranolol	Sep 2019 - Ongoing	Sinus Tachycardia
Alprazolam	Mar 2020 - Ongoing	Anxiety/Insomnia
Venlafaxine	Mar 2020 - Ongoing	Anxiety/Depression
Influenza vaccine	18 Oct 2020 (Study Day 15) - 18 Oct 2020 (Study Day 15)	Flu Prevention
Ibuprofen	05 Nov 2020 (Study Day 33) - 18 Nov 2020 (Study Day 46)	Body Aches From Injection
Paracetamol	10 Nov 2020 (Study Day 38) - 16 Nov 2020 (Study Day 44)	Headache
Acetylsalicylic acid	11 Nov 2020 (Study Day 39) - 13 Nov 2020 (Study Day 41)	Headache From The Pneumonia
Cephalosporin nos	18 Nov 2020 (Study Day 46) - 23 Nov 2020 (Study Day 51)	Rll Pneumonia
Levofloxacin	18 Nov 2020 (Study Day 46) - 18 Nov 2020 (Study Day 46)	Rll Pneumonia
Levofloxacin	18 Nov 2020 (Study Day 46) - 25 Nov 2020 (Study Day 53)	Rll Pneumonia
Metronidazole	18 Nov 2020 (Study Day 46) - 23 Nov 2020 (Study Day 51)	Rll Pneumonia
Oxygen	18 Nov 2020 (Study Day 46) - 25 Nov 2020 (Study Day 53)	Hypoxia And Pneumonia
Salbutamol	18 Nov 2020 (Study Day 46) - 23 Nov 2020 (Study Day 51)	Rll Pneumonia
Vancomycin	18 Nov 2020 (Study Day 46) - 23 Nov 2020 (Study Day 51)	Rll Pneumonia
Fluconazole	21 Nov 2020 (Study Day 49) - 05 Jan 2021 (Study Day 94)	Valley Fever
Ibuprofen	02 Mar 2021 (Study Day 150) - 02 Mar 2021 (Study Day 150)	Sore Arm Post Injection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	03 Nov 2020 (Study Day 31) - 02 Dec 2020 (Study Day 60)
Arthralgia	Grade 1/mild	Related	05 Nov 2020 (Study Day 33) - 16 Nov 2020 (Study Day 44)
Headache	Grade 2/moderate	Not related	05 Nov 2020 (Study Day 33) - 18 Nov 2020 (Study Day 46)
Pain	Grade 2/moderate	Related	05 Nov 2020 (Study Day 33) - 18 Nov 2020 (Study Day 46)
Chills	Grade 2/moderate	Not related	11 Nov 2020 (Study Day 39) - 11 Nov 2020 (Study Day 39)
Injection Site Pain	Grade 1/mild	Related	30 Jan 2021 (Study Day 119) - 31 Jan 2021 (Study Day 120)
Fatigue	Grade 1/mild	Related	02 Mar 2021 (Study Day 150) - 03 Mar 2021 (Study Day 151)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US320-2036 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Incarcerated Incisional Hernia/Worsening Of Incarcerated Recurrent Incisional Ventral Hernia	SAE	Grade 3/severe	Not related	09 Jan 2021 (Study Day 157) – 12 Jan 2021 (Study Day 160)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2036, a 66-year-old race not reported female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Jan 2021 (Study Day 157), 156 days after the first dose and 128 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of incarcerated incisional hernia. Action taken with the IP was not applicable. The event of worsening of incarcerated recurrent incisional ventral hernia lasted for 4 days, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 160). The investigator assessed the event of incarcerated incisional hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003240	Incarcerated incisional hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	1959 - Ongoing
Appendicectomy	Appendectomy	1961 - 1961
Endometriosis	Endometriosis	1982 - 1986
Hysterectomy	Total hysterectomy	1986 - 1986
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Spinal operation	Neuropathy caused by back surgery	2003 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes mellitus	2015 - Ongoing
Incarcerated incisional hernia	Incarcerated recurrent incisional ventral hernia	2016 - Ongoing
Gastrooesophageal reflux disease	Gerd	2018 - Ongoing
Back pain	Back pain	2019 - Ongoing
Hyperlipidaemia	Hyperlipedema	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dulaglutide	2015 - Ongoing	Type 2 Diabetes Mellitus
Gabapentin	2017 - 10 Jan 2021 (Study Day 158)	Sensory Neuropathy
Pantoprazole	2018 - 10 Jan 2021 (Study Day 158)	Gerd
Calcium	2019 - Ongoing	Vitamin Supplement
Colecalciferol	2019 - Ongoing	Vitamin Supplement
Fluticasone	2019 - Ongoing	Seasonal Allergies
Tizanidine	2019 - Ongoing	Back Pain
Ubidecarenone	2019 - Ongoing	Vitamin Supplement
Vaccinium macrocarpon	2019 - Ongoing	To Prevent Utis
Vitamin b complex	2019 - Ongoing	Vitamin Supplement
Vitamin e nos	2019 - Ongoing	Vitamin Supplement
Rosuvastatin	May 2020 - Ongoing	Hld
Calcium chloride; potassium chloride; sodium lactate	10 Jan 2021 (Study Day 158) - 14 Jan 2021 (Study Day 162)	Prevention Of Dehydration, Keep Vein Open For Iv Medication Administration
Hydromorphone	10 Jan 2021 (Study Day 158) - 10 Jan 2021 (Study Day 158)	Incarcerated Ventral Hernia
Hydromorphone hydrochloride	10 Jan 2021 (Study Day 158) - 10 Jan 2021 (Study Day 158)	Incarcerated Ventral Hernia
Nasogastric tube placement*	10 Jan 2021 (Study Day 158) - 10 Jan 2021 (Study Day 158)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	10 Jan 2021 (Study Day 158) - 10 Jan 2021 (Study Day 158)	Incarcerated Ventral Hernia
Phenol	10 Jan 2021 (Study Day 158) - 10 Jan 2021 (Study Day 158)	Improve Nasogastric Tube Insertion Procedure
Gabapentin	11 Jan 2021 (Study Day 159) - Ongoing	Sensory Neuropathy
Pantoprazole sodium sesquihydrate	11 Jan 2021 (Study Day 159) - 12 Jan 2021 (Study Day 160)	Gastroesophageal Reflux Disease
Paracetamol	11 Jan 2021 (Study Day 159) - 11 Jan 2021 (Study Day 159)	Incarcerated Ventral Hernia
Anesthetics, general	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Incarcerated Recurrent Incisional Ventral Hernia (Surgical Repair Procedure)
Bupivacaine hydrochloride; epinephrine	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Incarcerated Ventral Hernia
Hydromorphone hydrochloride	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Incarcerated Ventral Hernia
Hydromorphone hydrochloride	12 Jan 2021 (Study Day 160) - 13 Jan 2021 (Study Day 161)	Incarcerated Ventral Hernia
Insulin human; insulin human injection, isophane	12 Jan 2021 (Study Day 160) - 13 Jan 2021 (Study Day 161)	Type 2 Diabetes Mellitus
Methocarbamol	12 Jan 2021 (Study Day 160) - 15 Jan 2021 (Study Day 163)	Incarcerated Ventral Hernia
Oxycodone hydrochloride	12 Jan 2021 (Study Day 160) - 15 Jan 2021 (Study Day 163)	Incarcerated Ventral Hernia
Paracetamol	12 Jan 2021 (Study Day 160) - 15 Jan 2021 (Study Day 163)	Incarcerated Ventral Hernia
Ventral hernia repair surgery*	12 Jan 2021 (Study Day 160) - 12 Jan 2021 (Study Day 160)	Adverse Event
Pantoprazole sodium sesquihydrate	13 Jan 2021 (Study Day 161) - Ongoing	Gastresophageal Reflux Disease
Melatonin	14 Jan 2021 (Study Day 162) - 14 Jan 2021 (Study Day 162)	Supplement
Enoxaparin sodium	15 Jan 2021 (Study Day 163) - 15 Jan 2021 (Study Day 163)	Prevention Of Blood Clots Post Surgically
Bismuth subsalicylate	28 Feb 2021 (Study Day 207) - 01 Mar 2021 (Study Day 208)	Diarrhea/Vomiting

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 1/mild	Not related	28 Feb 2021 (Study Day 207) - 01 Mar 2021 (Study Day 208)
Vomiting	Grade 1/mild	Not related	28 Feb 2021 (Study Day 207) - 01 Mar 2021 (Study Day 208)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US320-2085 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 41)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Renal Failure Unspecified	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 160) – 26 Jan 2021 (Study Day 171)	Recovered/ resolved
Acute Respiratory Failure/ Acute Hypoxic Respiratory Failure	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 160) – 30 Jan 2021 (Study Day 175)	Recovered/ resolved
Diabetic Ketoacidosis/Diabetic Ketoacidosis	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 160) – 09 Feb 2021 (Study Day 185)	Recovered/ resolved
Pancreatitis/Pancreatitis	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 160) – 09 Feb 2021 (Study Day 185)	Recovered/ resolved
Pneumonia/Pneumonia	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 160) – 05 Feb 2021 (Study Day 181)	Recovered/ resolved
Sepsis/Sepsis	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 160) – 09 Feb 2021 (Study Day 185)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2085, a 39-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 09 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 41). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Jan 2021 (Study Day 160), 159 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute renal failure unspecified lasted for 12 days, after which it was considered to be recovered/resolved on 26 Jan 2021 (Study Day 171). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 15 Jan 2021 (Study Day 160), 159 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute hypoxic respiratory failure lasted for 16 days, after which it was considered to be recovered/resolved on 30 Jan 2021 (Study

Day 175). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 15 Jan 2021 (Study Day 160), 159 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diabetic ketoacidosis. Action taken with the IP was not applicable. The event of diabetic ketoacidosis lasted for 26 days, after which it was considered to be recovered/resolved on 09 Feb 2021 (Study Day 185). The investigator assessed the event of diabetic ketoacidosis to be not related to the IP.

On 15 Jan 2021 (Study Day 160), 159 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pancreatitis. Action taken with the IP was not applicable. The event of pancreatitis lasted for 26 days, after which it was considered to be recovered/resolved on 09 Feb 2021 (Study Day 185). The investigator assessed the event of pancreatitis to be not related to the IP.

On 15 Jan 2021 (Study Day 160), 159 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 22 days, after which it was considered to be recovered/resolved on 05 Feb 2021 (Study Day 181). The investigator assessed the event of pneumonia to be not related to the IP.

On 15 Jan 2021 (Study Day 160), 159 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis lasted for 26 days, after which it was considered to be recovered/resolved on 09 Feb 2021 (Study Day 185). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-017319	Acute kidney injury
MOD-2021-017319	Acute respiratory failure
MOD-2021-017319	Diabetic ketoacidosis
MOD-2021-017319	Pancreatitis
MOD-2021-017319	Pneumonia
MOD-2021-017319	Sepsis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	27 Sep 1995 (Study Day -9083) - Ongoing
Depression	Depression	12 Apr 2004 (Study Day -5963) - Ongoing
Alcohol abuse	Alcohol abuse	2010 - Ongoing
Migraine	Migraines	12 Apr 2013 (Study Day -2676) - Ongoing
Botulinum toxin injection	Botox for migraines	2015 - 2015
Basedow's disease	Hyperthyroidism (grave's disease)	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Propranolol	10 Apr 2019 (Study Day -487) - 15 Jan 2021 (Study Day 160)	Migraine
Thiamazole	05 Jun 2020 (Study Day -65) - Ongoing	Hyperthyroid
Topiramate	17 Jun 2020 (Study Day -53) - 15 Jan 2021 (Study Day 160)	Migraine
Mirtazapine	15 Oct 2020 (Study Day 68) - Ongoing	Post Traumatic Stress Disorder
Azithromycin	15 Jan 2021 (Study Day 160) - 15 Jan 2021 (Study Day 160)	Sepsis
Ceftriaxone	15 Jan 2021 (Study Day 160) - 15 Jan 2021 (Study Day 160)	Sepsis
Famotidine	15 Jan 2021 (Study Day 160) - 09 Feb 2021 (Study Day 185)	Gastritis
Fenofibrate	15 Jan 2021 (Study Day 160) - 15 Jan 2021 (Study Day 160)	Hypertriglyceridemia
Glucose; potassium chloride; sodium chloride	15 Jan 2021 (Study Day 160) - 16 Jan 2021 (Study Day 161)	Intermittent Electrolyte
Heparin sodium	15 Jan 2021 (Study Day 160) - 16 Jan 2021 (Study Day 161)	Prophylaxis
Hydromorphone hydrochloride	15 Jan 2021 (Study Day 160) - 16 Jan 2021 (Study Day 161)	Pancreatitis
Insulin human	15 Jan 2021 (Study Day 160) - 18 Jan 2021 (Study Day 163)	Diabetes Mellitus T2
Iodine	15 Jan 2021 (Study Day 160) - 16 Jan 2021 (Study Day 161)	Infection Prevention
Lorazepam	15 Jan 2021 (Study Day 160) - 16 Jan 2021 (Study Day 161)	Acute Hypoxic Respiratory Failure
Salbutamol sulfate	15 Jan 2021 (Study Day 160) - 16 Jan 2021 (Study Day 161)	Acute Hypoxic Respiratory Failure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	15 Jan 2021 (Study Day 160) - 15 Jan 2021 (Study Day 160)	Intermittent Electrolyte Imbalance
Sodium chloride	15 Jan 2021 (Study Day 160) - 16 Jan 2021 (Study Day 161)	Intermittent Electrolyte Imbalance
Calcium gluconate	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Intermittent Electrolyte Imbalance
Ceftriaxone	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Sepsis
Dexmedetomidine hydrochloride	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Acute Hypoxic Respiratory Failure
Etomidate	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Acute Hypoxic Respiratory Failure
Fentanyl	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Pancreatitis
Metoprolol tartrate	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Acute Renal Failure
Metronidazole	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Sepsis
Midazolam hydrochloride	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Acute Hypoxic Respiratory Failure
Morphine sulfate	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Pancreatitis
Norepinephrine	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Sepsis
Propofol	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Pancreatitis
Sodium phosphate	16 Jan 2021 (Study Day 161) - 16 Jan 2021 (Study Day 161)	Intermittent Electrolyte Imbalance
Albumin human	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Sepsis
Aphoresis*	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Sepsis
Chlordiazepoxide	17 Jan 2021 (Study Day 162) - 25 Jan 2021 (Study Day 170)	Alcohol Withdrawal
Dexmedetomidine hydrochloride	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Acute Hypoxic Respiratory Failure
Diphenhydramine hydrochloride	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Prophylaxis During Dialysis
Fentanyl citrate	17 Jan 2021 (Study Day 162) - 09 Feb 2021 (Study Day 185)	Pancreatitis
Glucose; sodium chloride	17 Jan 2021 (Study Day 162) - 18 Jan 2021 (Study Day 163)	Sepsis
Intubation*	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Adverse Event
Magnesium sulfate	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Intermittent Electrolyte Imbalances
Mechanical ventilation*	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mupirocin	17 Jan 2021 (Study Day 162) - 22 Jan 2021 (Study Day 167)	Prophylaxis-(In Hospital When Intubated)
Paracetamol	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Sepsis
Piperacillin sodium; tazobactam sodium	17 Jan 2021 (Study Day 162) - 17 Jan 2021 (Study Day 162)	Sepsis
Piperacillin sodium; tazobactam sodium	17 Jan 2021 (Study Day 162) - 02 Feb 2021 (Study Day 178)	Sepsis
Sodium chloride	17 Jan 2021 (Study Day 162) - 09 Feb 2021 (Study Day 185)	Intermittent Electrolyte Imbalances
Dialysis*	18 Jan 2021 (Study Day 163) - 18 Jan 2021 (Study Day 163)	Adverse Event
Heparin	18 Jan 2021 (Study Day 163) - 30 Jan 2021 (Study Day 175)	Dvt Prophylaxis
Paracetamol	18 Jan 2021 (Study Day 163) - 18 Jan 2021 (Study Day 163)	Sepsis
Calcium chloride; potassium chloride; sodium lactate	19 Jan 2021 (Study Day 164) - 09 Feb 2021 (Study Day 185)	Sepsis
Docusate sodium	19 Jan 2021 (Study Day 164) - 09 Feb 2021 (Study Day 185)	Constipation
Glucose	19 Jan 2021 (Study Day 164) - 09 Feb 2021 (Study Day 185)	Hypoglycemia Prophylaxis
Hydromorphone hydrochloride	19 Jan 2021 (Study Day 164) - 19 Jan 2021 (Study Day 164)	Pancreatitis
Labetalol	19 Jan 2021 (Study Day 164) - 09 Feb 2021 (Study Day 185)	Acute Rental Failure Unspecified
Ondansetron	19 Jan 2021 (Study Day 164) - 19 Jan 2021 (Study Day 164)	Unspecified Gastritis
Potassium chloride	19 Jan 2021 (Study Day 164) - 19 Jan 2021 (Study Day 164)	Intermittent Electrolyte Imbalances
Sennoside a+b	19 Jan 2021 (Study Day 164) - 09 Feb 2021 (Study Day 185)	Constipation
Glucose; sodium chloride	20 Jan 2021 (Study Day 165) - 09 Feb 2021 (Study Day 185)	Intermittent Electrolyte Imbalances
Bisacodyl	21 Jan 2021 (Study Day 166) - 21 Jan 2021 (Study Day 166)	Constipation
Diazepam	21 Jan 2021 (Study Day 166) - 21 Jan 2021 (Study Day 166)	Alcohol (Etoh) Withdrawal
Insulin glargine	21 Jan 2021 (Study Day 166) - 27 Jan 2021 (Study Day 172)	Diabetes Mellitus T2
Insulin lispro	21 Jan 2021 (Study Day 166) - 09 Feb 2021 (Study Day 185)	Dm T2
Macrogol 3350	21 Jan 2021 (Study Day 166) - 09 Feb 2021 (Study Day 185)	Constipation
Oxycodone hydrochloride	21 Jan 2021 (Study Day 166) - 02 Feb 2021 (Study Day 178)	Pancreatitis
Clonidine	22 Jan 2021 (Study Day 167) - 09 Feb 2021 (Study Day 185)	Acute Renal Failure
Potassium chloride	23 Jan 2021 (Study Day 168) - 23 Jan 2021 (Study Day 168)	Intermittent Electrolyte Imbalance

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metronidazole	24 Jan 2021 (Study Day 169) - 24 Jan 2021 (Study Day 169)	Sepsis
Vancomycin	26 Jan 2021 (Study Day 171) - 29 Jan 2021 (Study Day 174)	Sepsis
Amino acids nos; carbohydrates nos; electrolytes nos	27 Jan 2021 (Study Day 172) - 08 Feb 2021 (Study Day 184)	Pancreatitis
Carvedilol	27 Jan 2021 (Study Day 172) - 09 Feb 2021 (Study Day 185)	Hypertension
Insulin human	27 Jan 2021 (Study Day 172) - 09 Feb 2021 (Study Day 185)	Diabetes T2
Pantoprazole	27 Jan 2021 (Study Day 172) - 08 Feb 2021 (Study Day 184)	Gastric Ulcer
Ultrasound guided paracentesis*	27 Jan 2021 (Study Day 172) - 27 Jan 2021 (Study Day 172)	Adverse Event
Chlorothiazide	28 Jan 2021 (Study Day 173) - 28 Jan 2021 (Study Day 173)	Loculated Ascites
Decompression colonoscopy*	28 Jan 2021 (Study Day 173) - 28 Jan 2021 (Study Day 173)	Adverse Event
Furosemide	28 Jan 2021 (Study Day 173) - 28 Jan 2021 (Study Day 173)	Loculated Ascites
Atorvastatin	30 Jan 2021 (Study Day 175) - Ongoing	Hypertriglyceridemia
Guaifenesin	02 Feb 2021 (Study Day 178) - 09 Feb 2021 (Study Day 185)	Mucolytic- Subj Had Pneumonia
Ipratropium bromide; salbutamol sulfate	07 Feb 2021 (Study Day 183) - 09 Mar 2021 (Study Day 213)	1.) Pneumonia 2.) Dyspnea
Salbutamol	07 Feb 2021 (Study Day 183) - 09 Feb 2021 (Study Day 185)	1.) Dyspnea 2.) Pneumonia
Insulin human; insulin human injection, isophane	09 Feb 2021 (Study Day 185) - Ongoing	Diabetes T2
Pantoprazole	09 Feb 2021 (Study Day 185) - 09 Feb 2021 (Study Day 185)	Gastric Ulcer
Salbutamol	09 Feb 2021 (Study Day 185) - Ongoing	Dyspnea
Omeprazole	10 Feb 2021 (Study Day 186) - Ongoing	Gastric Ulcer
Lisinopril	08 Mar 2021 (Study Day 212) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Post-Traumatic Stress Disorder	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 68) - Ongoing
Alcohol Withdrawal Syndrome	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 160) - 09 Feb 2021 (Study Day 185)
Constipation	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 160) - 29 Jan 2021 (Study Day 174)
Electrolyte Imbalance	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 160) - 09 Feb 2021 (Study Day 185)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastric Ulcer	Grade 1/mild	Not related	15 Jan 2021 (Study Day 160) - Ongoing
Gastritis	Grade 1/mild	Not related	15 Jan 2021 (Study Day 160) - 09 Feb 2021 (Study Day 185)
Hypertriglyceridaemia	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 160) - Ongoing
Ileus Paralytic	Grade 3/severe	Not related	15 Jan 2021 (Study Day 160) - 09 Feb 2021 (Study Day 185)
Suicidal Ideation	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 160) - 22 Jan 2021 (Study Day 167)
Type 2 Diabetes Mellitus	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 160) - Ongoing
Ascites	Grade 2/moderate	Not related	27 Jan 2021 (Study Day 172) - 04 Feb 2021 (Study Day 180)
Hypertension	Grade 1/mild	Not related	27 Jan 2021 (Study Day 172) - Ongoing
Dysphonia	Grade 1/mild	Not related	30 Jan 2021 (Study Day 175) - 27 Mar 2021 (Study Day 231)
Dyspnoea	Grade 2/moderate	Not related	06 Feb 2021 (Study Day 182) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US320-2191 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 42)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asthenia/Weakness	SAE	Grade 1/mild	Not related	29 Oct 2020 (Study Day 77) – 03 Nov 2020 (Study Day 82)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2191, a 77-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 42). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Oct 2020 (Study Day 77), 76 days after the first dose and 35 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of asthenia. Action taken with the IP was not applicable. The event of weakness lasted for 6 days, after which it was considered to be recovered/resolved on 03 Nov 2020 (Study Day 82). The investigator assessed the event of asthenia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000869	Asthenia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cerebellar infarction	Chronic infarction in left cerebellar hemisphere	Not reported - Ongoing
Cerebral infarction	Subacute chronic infarction in left posterior lobe	Not reported - Ongoing
Anosmia	Anosmia	1943 - Ongoing
Obesity	Obesity	1950 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease lumbar spine	1983 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1999 - Ongoing
Hiatus hernia	Hiatal hernia	2000 - Ongoing
Osteoarthritis	Osteoarthritis in shoulders bilateral	2004 - Ongoing
Osteoarthritis	Osteoarthritis right ankle	2004 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2012 - Ongoing
Blood cholesterol increased	High cholesterol	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Oedema peripheral	Episodic edema bilateral legs	2016 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2018 - Ongoing
Fatigue	Fatigue	2018 - Ongoing
Axonal neuropathy	Axonal neuropathy	Jun 2019 - Ongoing
Cerebrovascular accident	Cerebral vascular accident	Jun 2019 - Jun 2019
Gait disturbance	Gait disturbance	Jun 2019 - Ongoing
Atrial fibrillation	Atrial fibrillation	Sep 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoclopramide	1999 - Ongoing	Gastroesophageal Reflux Disease
Celecoxib	2004 - 03 Nov 2020 (Study Day 82)	Osteoarthritis
Esomeprazole magnesium	2004 - Ongoing	Gerd
Dutasteride; tamsulosin hydrochloride	21 Nov 2012 (Study Day -2823) - Ongoing	Benign Prostatic Hyperplasia
Atorvastatin	11 Feb 2016 (Study Day -1646) - Ongoing	High Cholesterol
Hydrocodone bitartrate; paracetamol	06 Apr 2018 (Study Day -861) - Ongoing	Chronic Back Pain
Lisinopril	18 Jun 2018 (Study Day -788) - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	27 Jun 2018 (Study Day -779) - Ongoing	Hypertension
Apixaban	15 Sep 2019 (Study Day -334) - Ongoing	Atrial Fibrillation
Sotalol	15 Sep 2019 (Study Day -334) - Ongoing	Atrial Fibrillation
Umeclidinium bromide; vilanterol trifenatate	11 Feb 2020 (Study Day -185) - Ongoing	Chronic Obstructive Pulmonary Disease
Sulfamethoxazole; trimethoprim	08 Oct 2020 (Study Day 56) - 29 Oct 2020 (Study Day 77)	Laceration Of Right Elbow
Incision and drainage of olecranon bursa*	27 Oct 2020 (Study Day 75) - 27 Oct 2020 (Study Day 75)	Adverse Event
Diphenhydramine	31 Oct 2020 (Study Day 79) - 02 Nov 2020 (Study Day 81)	Prevention Of Sleeplessness
Doxycycline	03 Nov 2020 (Study Day 82) - 08 Dec 2020 (Study Day 117)	Right Olecranon Bursitis
Lidocaine	03 Nov 2020 (Study Day 82) - Ongoing	Back Pain Osteoarthritis
Left cubital tunnel release*	02 Feb 2021 (Study Day 173) - 02 Feb 2021 (Study Day 173)	Adverse Event
Resuture of left cubital tunnel release surgery*	09 Mar 2021 (Study Day 208) - 09 Mar 2021 (Study Day 208)	Adverse Event
Doxycycline	10 Mar 2021 (Study Day 209) - Ongoing	Dehiscence Of Left Cubital Tunnel Release Sutures

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	14 Aug 2020 (Study Day 1) - 12 Sep 2020 (Study Day 30)
Myalgia	Grade 1/mild	Related	14 Aug 2020 (Study Day 1) - 12 Sep 2020 (Study Day 30)
Fatigue	Grade 1/mild	Related	15 Aug 2020 (Study Day 2) - 12 Sep 2020 (Study Day 30)
Skin Laceration	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)
Bursitis	Grade 3/severe	Not related	27 Oct 2020 (Study Day 75) - 15 Nov 2020 (Study Day 94)
Urinary Retention	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 75) - Ongoing
Cubital Tunnel Syndrome	Grade 2/moderate	Not related	02 Dec 2020 (Study Day 111) - 02 Feb 2021 (Study Day 173)
Wound Dehiscence	Grade 1/mild	Not related	09 Mar 2021 (Study Day 208) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US320-2197 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	15 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Carotid Artery Stenosis/Right Carotid Stenosis	SAE	Grade 2/moderate	Not related	21 Oct 2020 (Study Day 68) – 21 Oct 2020 (Study Day 68)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2197, a 73-year-old race not reported male, received the first dose of mRNA-1273 in the left arm on 15 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Oct 2020 (Study Day 68), 67 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of carotid artery stenosis. Action taken with the IP was not applicable. The event of right carotid stenosis lasted for 1 day, after which it was considered to be recovered/resolved on 21 Oct 2020 (Study Day 68). The investigator assessed the event of carotid artery stenosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068011	Carotid artery stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Chronic hip pain bilateral	Not reported - Ongoing
Back pain	Chronic back pain	Not reported - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Gastrooesophageal reflux disease	Heartburn/acid reflux	2000 - Ongoing
Sleep apnoea syndrome	Sleep apnea- uses a c-pap	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2001 - Ongoing
Gout	General gout	2005 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Drug hypersensitivity	Allergic to statins- caused kidney disease	2011 - Ongoing
Nephropathy toxic	Kidney disease- caused by allergic reaction to statins	2011 - Ongoing
Aortic aneurysm	Abdominal aortic aneurysm	2014 - 2014
Cardiac pacemaker insertion	Placement of cardiac pacemaker	2014 - 2014
Coronary artery disease	Coronary artery disease	2014 - Ongoing
Implantable defibrillator insertion	Placement of cardiac pacemaker defibrillator	2015 - 2015
Carotid artery stenosis	Left carotid artery stenosis	Jan 2020 - Ongoing
Carotid artery stenosis	Right carotid artery stenosis	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole sodium sesquihydrate	2000 - Ongoing	Acid Reflux
Allopurinol	2005 - Ongoing	Gouty Arthritis
Levothyroxine	2011 - Ongoing	Hypothyroidism
Terazosin	2011 - Ongoing	Benign Prostatic Hyperplasia
Carvedilol	2015 - Ongoing	Hypertension
Lisinopril	2015 - Ongoing	Hypertension
Anesthetics, general	21 Oct 2020 (Study Day 68) - 21 Oct 2020 (Study Day 68)	Right Carotid Stenosis
Heparin	21 Oct 2020 (Study Day 68) - 21 Oct 2020 (Study Day 68)	Right Carotid Endarterectomy Procedural Prophylaxis
Right carotid endartarectomy with bovine patch angioplasty*	21 Oct 2020 (Study Day 68) - 21 Oct 2020 (Study Day 68)	Medical History

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Anesthetics, general	19 Jan 2021 (Study Day 158) - 19 Jan 2021 (Study Day 158)	Left Carotid Stenosis (Procedural Anesthesia For Left Carotid Endarterectomy)
Heparin	19 Jan 2021 (Study Day 158) - 19 Jan 2021 (Study Day 158)	Left Carotid Endarterectomy Procedural Prophylaxis
Left carotid endarterectomy with bovine patch angioplasty*	19 Jan 2021 (Study Day 158) - 19 Jan 2021 (Study Day 158)	Medical History
Alirocumab	08 Feb 2021 (Study Day 178) - Ongoing	Hyperlipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US320-2231 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Embolic Stroke/Embolic Stroke	SAE	Grade 2/moderate	Not related	31 Oct 2020 (Study Day 76) – 31 Oct 2020 (Study Day 76)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2231, a 77-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Oct 2020 (Study Day 76), 75 days after the first dose and 47 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of embolic stroke. Action taken with the IP was not applicable. The event of embolic stroke lasted for 1 days, after which it was considered to be recovered/resolved on 31 Oct 2020 (Study Day 76). The investigator assessed the event of embolic stroke to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000682	Embolic stroke

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1958 - Ongoing
Female sterilisation	Tubal ligation	1977 - 1977
Hypertension	Htn	1983 - Ongoing
Osteoarthritis	Osteoarthritis left shoulder	2000 - Ongoing
Vitamin B complex deficiency	Vitamin b deficiency	2000 - Ongoing
Insomnia	Insomnia	2015 - Ongoing
Psoriasis	Psoriasis- general	2018 - Ongoing
Psoriatic arthropathy	Psoriatic arthritis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Folic acid	1977 - Ongoing	Supplement
Hydrochlorothiazide	1988 - Ongoing	Htn
Vitamin b complex	2000 - Ongoing	Supplement
Fish oil	2010 - Ongoing	Supplement
Melatonin	2015 - Ongoing	Insomnia
Apremilast	2018 - Ongoing	Psoriatic Arthritis
Curcuma longa	2018 - Ongoing	General Supplement
Vitamin d nos	2018 - Ongoing	General Supplement
Xantofyl	2018 - Ongoing	Supplement
Fexofenadine hydrochloride	2019 - Ongoing	Seasonal Allergies
Paracetamol	15 Sep 2020 (Study Day 30) - 18 Sep 2020 (Study Day 33)	1) Fever 2) Pain
Acetylsalicylic acid	31 Oct 2020 (Study Day 76) - Ongoing	Cardiovascular Prophylaxis/ Stroke Prevention
Rosuvastatin calcium	31 Oct 2020 (Study Day 76) - Ongoing	Embolic Stroke

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US320-2304 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Benign Prostatic Hyperplasia/Worsening Of Enlarged Prostate (Benign Prostatic Hyperplasia)	SAE	Grade 3/severe	Not related	01 Dec 2020 (Study Day 96) – 18 Dec 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2304, a 76-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Dec 2020 (Study Day 96), 95 days after the first dose and 67 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of benign prostatic hyperplasia. Action taken with the IP was not applicable. The event of worsening of enlarged prostate (benign prostatic hyperplasia) lasted for 18 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 113). The investigator assessed the event of benign prostatic hyperplasia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001233	Benign prostatic hyperplasia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Erectile dysfunction	Erectile dysfunction	Not reported - Ongoing
Haemorrhoids	Hemorrhoids	Not reported - Ongoing
Heart rate irregular	Irregular heartbeat	Not reported - Ongoing
Hypogonadism	Hypogonadism	1962 - Ongoing
Benign prostatic hyperplasia	Enlarged prostate (benign prostatic hyperplasia)	2004 - Ongoing
Hypertension	Hypertension (borderline)	2018 - Ongoing
Depression	Depression	Jan 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tadalafil	Not reported - Ongoing	Erectile Dysfunction
Tamsulosin	2004 - 17 Dec 2020 (Study Day 112)	Enlarged Prostate
Testosterone	2014 - Ongoing	Hypogonadism
Losartan	2018 - 14 Jan 2021 (Study Day 140)	Borderline Hypertension
Citalopram	Jan 2019 - Ongoing	Depression
Influenza vaccine	18 Oct 2020 (Study Day 52) - 18 Oct 2020 (Study Day 52)	Flu Prevention
Docusate	17 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 115)	Prevent Constipation Post Op
Oxybutynin	17 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 115)	Prophylaxis Of Bladder Spasms Post-Prostatectomy
Oxycodone hydrochloride; paracetamol	17 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 115)	Post Op Pain
Prostatectomy complete laser enucleation of prostate*	17 Dec 2020 (Study Day 112) - 17 Dec 2020 (Study Day 112)	Adverse Event
Sulfamethoxazole; trimethoprim	17 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 115)	Prevent Post Op Infection
Amoxicillin	28 Dec 2020 (Study Day 123) - 06 Jan 2021 (Study Day 132)	Strep Infection- Throat``
Cefalexin	14 Jan 2021 (Study Day 140) - 24 Jan 2021 (Study Day 150)	Laceration To Both Hands

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pharyngitis Streptococcal	Grade 1/mild	Not related	28 Dec 2020 (Study Day 123) - 06 Jan 2021 (Study Day 132)
Skin Laceration	Grade 3/severe	Not related	14 Jan 2021 (Study Day 140) - 14 Jan 2021 (Study Day 140)
Syncope	Grade 2/moderate	Not related	14 Jan 2021 (Study Day 140) - 14 Jan 2021 (Study Day 140)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US320-2310 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hiatus Hernia/Worsening Of Hiatal Hernia	SAE	Grade 2/moderate	Not related	06 Oct 2020 (Study Day 43) – 24 Oct 2020 (Study Day 61)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US320-2310, a 63-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Oct 2020 (Study Day 43), 42 days after the first dose and 13 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of hiatus hernia. Action taken with the IP was not applicable. The event of worsening of hiatal hernia lasted for 19 days, after which it was considered to be recovered/resolved on 24 Oct 2020 (Study Day 61). The investigator assessed the event of hiatus hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000565	Hiatus hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol use	Alcohol intake- 4 drinks per week	Not reported - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1980 - Ongoing
Hiatus hernia	Hiatal hernia	1993 - Ongoing
Hysterectomy	Total vaginal hysterectomy	1999 - 1999
Uterine leiomyoma	Benign uterine fibroid tumors	1999 - 1999
Type 2 diabetes mellitus	Type 2 diabetes mellitus	2015 - 2017
Gastritis	Gastritis	Mar 2020 - Ongoing
Iron deficiency anaemia	Iron-deficiency anemia	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hypercholesterolemia
Omeprazole	Mar 2020 - Ongoing	Gastritis
Ibuprofen	06 Oct 2020 (Study Day 43) - 24 Oct 2020 (Study Day 61)	Worsening Of Hiatal Hernia
Ondansetron	06 Oct 2020 (Study Day 43) - 24 Oct 2020 (Study Day 61)	Worsening Of Hiatal Hernia
Anesthetics, general	23 Oct 2020 (Study Day 60) - 23 Oct 2020 (Study Day 60)	Worsening Of Hiatal Hernia
Cefazolin sodium	23 Oct 2020 (Study Day 60) - 23 Oct 2020 (Study Day 60)	Surgery Infection Prophylaxis
Davinci hiatal hernia repair*	23 Oct 2020 (Study Day 60) - 23 Oct 2020 (Study Day 60)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US321-2004 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	SAE	Not reported	Not reported	01 Dec 2020 (Study Day 121) – 17 Dec 2020 (Study Day 137)	Recovered/resolved
COVID-19 Pneumonia/COVID 19 (Pneumonia)	SAE	Grade 3/severe	Not related	01 Dec 2020 (Study Day 121) – 17 Dec 2020 (Study Day 137)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2004, a 38-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Dec 2020 (Study Day 121), 120 days after the first dose and 92 days after the second dose of the IP, the participant experienced an AE grade not reported serious adverse event of covid-19. Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 137). The investigator assessed the event of covid-19 to be relationship to IP not reported.

On 01 Dec 2020 (Study Day 121), 120 days after the first dose and 92 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of covid-19 pneumonia. Action taken with the IP was not applicable. The event of COVID-19 (pneumonia) lasted for 17 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 137). The investigator assessed the event of covid-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001068	COVID-19
MOD-2020-001068	COVID-19 pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cleft palate	Cleft palate	(b) (6) 1982 - Dec 1982
Lip repair	Cheiloplasty	(b) (6) 1982 - (b) (6) 1982
Palatoplasty	Palatoplasty	(b) (6) 1982 - (b) (6) 1982
Cleft lip	Cleft lip	(b) (6) 1982 (Study Day (b) (6)) - Dec 1982
Menorrhagia	Menorrhagia	2004 - 2017
Female sterilisation	Bilateral tubal ligation	02 Aug 2004 (Study Day -5845) - 02 Aug 2004 (Study Day -5845)
Asthma	Mild asthma	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2013 - Ongoing	Asthma
Ethinylestradiol; levonorgestrel	2017 - Ongoing	Menorrhagia
Fluticasone furoate; vilanterol	2018 - Ongoing	Mild Asthma
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	01 Dec 2020 (Study Day 121) - 15 Dec 2020 (Study Day 135)	COVID-19
Ibuprofen	01 Dec 2020 (Study Day 121) - 01 Dec 2020 (Study Day 121)	COVID-19
Paracetamol	01 Dec 2020 (Study Day 121) - 20 Apr 2021 (Study Day 261)	COVID-19
Ct chest with contrast*	07 Dec 2020 (Study Day 127) - 07 Dec 2020 (Study Day 127)	Adverse Event
Dexamethasone	07 Dec 2020 (Study Day 127) - 10 Dec 2020 (Study Day 130)	COVID19 (Pneumonia)
Remdesivir	07 Dec 2020 (Study Day 127) - 10 Dec 2020 (Study Day 130)	COVID19 (Pneumonia)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexamethasone	10 Dec 2020 (Study Day 130) - 17 Dec 2020 (Study Day 137)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	09 Aug 2020 (Study Day 7) - 11 Aug 2020 (Study Day 9)
Fatigue	Grade 1/mild	Related	09 Aug 2020 (Study Day 7) - 11 Aug 2020 (Study Day 9)
Myalgia	Grade 1/mild	Related	09 Aug 2020 (Study Day 7) - 11 Aug 2020 (Study Day 9)
Liver Function Test Increased	Grade 1/mild	Not related	07 Dec 2020 (Study Day 127) - 05 Apr 2021 (Study Day 246)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US321-2013 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 66)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Uterine Haemorrhage/Abnormal Uterine Bleeding	SAE	Grade 3/severe	Not related	27 Aug 2020 (Study Day 25) – 28 Aug 2020 (Study Day 26)	Recovered/resolved
Uterine Haemorrhage/Abnormal Uterine Bleeding	SAE	Grade 3/severe	Not related	22 Sep 2020 (Study Day 51) – 22 Sep 2020 (Study Day 51)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2013, a 45-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 66). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Aug 2020 (Study Day 25), 24 days after the first dose and 41 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of uterine haemorrhage. The IP dose was delayed due to the abnormal uterine bleeding. The event of abnormal uterine bleeding lasted for 2 days, after which it was considered to be recovered/resolved on 28 Aug 2020 (Study Day 26). The investigator assessed the event of uterine haemorrhage to be not related to the IP.

On 22 Sep 2020 (Study Day 51), 50 days after the first dose and 15 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of uterine haemorrhage. The IP dose was delayed due to the abnormal uterine bleeding. The event of abnormal uterine bleeding lasted for 1 day, after which it was considered to be recovered/resolved on 22 Sep 2020 (Study Day 51). The investigator assessed the event of uterine haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000237	Uterine haemorrhage
MOD-2020-000908	Uterine haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	Cesarean section	08 Dec 1993 (Study Day -9735) - 08 Dec 1993 (Study Day -9735)
Caesarean section	Cesarean section	31 Aug 1998 (Study Day -8008) - 31 Aug 1998 (Study Day -8008)
Caesarean section	Cesarean section	25 Jun 2002 (Study Day -6614) - 25 Jun 2002 (Study Day -6614)
Female sterilisation	Bilateral tubal ligation	25 Jun 2002 (Study Day -6614) - 25 Jun 2002 (Study Day -6614)
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Uterine leiomyoma	Intramural uterine fibroids	2012 - 22 Sep 2020 (Study Day 51)
Cholecystectomy	Cholecystectomy	2016 - 2016
Cholelithiasis	Cholelithiasis	2016 - 2016
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2017 - Ongoing
Iron deficiency anaemia	Iron deficiency anemia	2018 - Ongoing
Urinary incontinence	Urinary incontinence	2019 - Ongoing
Muscle strain	Peroneal tear	Feb 2020 - Feb 2020
Tenoplasty	Peroneal tendon repair	Feb 2020 - Feb 2020
Obesity	Obesity	03 Aug 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Fexofenadine	2010 - Ongoing	Seasonal Allergies
Ferrous sulfate	2018 - Aug 2020	Iron Deficiency
Esomeprazole magnesium	2019 - Ongoing	Gastroesophageal Reflux Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxybutynin	2019 - Ongoing	Urinary Incontinence
Blood transfusion*	27 Aug 2020 (Study Day 25) - 27 Aug 2020 (Study Day 25)	Adverse Event
Ferrous sulfate	27 Aug 2020 (Study Day 25) - Ongoing	Fe Deficiency Anemia
Medroxyprogesterone acetate	28 Aug 2020 (Study Day 26) - 29 Aug 2020 (Study Day 27)	Uterine Bleeding
Ethinylestradiol; norgestimate	29 Aug 2020 (Study Day 27) - 04 Sep 2020 (Study Day 33)	Uterine Bleeding
Ethinylestradiol; levonorgestrel	05 Sep 2020 (Study Day 34) - 21 Sep 2020 (Study Day 50)	Abnormal Uterine Bleeding
Elective hysterectomy*	22 Sep 2020 (Study Day 51) - 22 Sep 2020 (Study Day 51)	Medical History
Hydrocodone bitartrate; paracetamol	22 Sep 2020 (Study Day 51) - 07 Oct 2020 (Study Day 66)	Postoperative Pain
Docusate sodium	23 Sep 2020 (Study Day 52) - 07 Oct 2020 (Study Day 66)	Prevention Of Constipation With Postoperative Opioid Use; Hysterectomy
Ibuprofen	23 Sep 2020 (Study Day 52) - 07 Oct 2020 (Study Day 66)	Postoperative Pain
Paracetamol	23 Sep 2020 (Study Day 52) - 07 Oct 2020 (Study Day 66)	Postoperative Pain
Amoxicillin; clavulanic acid	12 Oct 2020 (Study Day 71) - 19 Oct 2020 (Study Day 78)	Urinary Tract Infection
Influenza vaccine	14 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 73)	Immunization
Fluconazole	20 Oct 2020 (Study Day 79) - 20 Oct 2020 (Study Day 79)	Vaginal Candidiasis
Nystatin	28 Oct 2020 (Study Day 87) - Ongoing	Vaginal Candidiasis
Prednisone	28 Oct 2020 (Study Day 87) - Ongoing	Foot Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	12 Oct 2020 (Study Day 71) - 19 Oct 2020 (Study Day 78)
Vulvovaginal Candidiasis	Grade 1/mild	Not related	20 Oct 2020 (Study Day 79) - Ongoing
Plantar Fasciitis	Grade 2/moderate	Not related	22 Oct 2020 (Study Day 81) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US321-2028 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Coronary Syndrome/ Acute Coronary Syndrome (Non St Elevated Myocardial Infarction)	SAE	Grade 3/ severe	Not related	20 Oct 2020 (Study Day 78) – 20 Oct 2020 (Study Day 78)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2028, a 67-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Oct 2020 (Study Day 78), 77 days after the first dose and 49 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute coronary syndrome. Action taken with the IP was not applicable. The event of acute coronary syndrome (non st elevated myocardial infarction) lasted for 1 day, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 78). The investigator assessed the event of acute coronary syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000569	Acute coronary syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Developmental hip dysplasia	Genetic bilateral hip dysplasia	(b) (6) 1953 (Study Day (b) (6) - 10 Apr 2018 (Study Day -847)
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2017 - Ongoing
Nephrolithiasis	Nephrolithiasis (left)	Oct 2017 - Oct 2017
Hip arthroplasty	Bilateral total hip replacement	10 Apr 2018 (Study Day -847) - 10 Apr 2018 (Study Day -847)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2000 - 29 Oct 2020 (Study Day 87)	Hypercholesterolemia
Chondroitin; glucosamine	2000 - Ongoing	Joint; General Health
Colecalciferol	2000 - Ongoing	Vitamin D Deficiency Prophylaxis
Folic acid	2000 - Ongoing	Folic Acid Deficiency Prophylaxis
Hydrochlorothiazide; triamterene	2000 - Ongoing	Hypertension
Vitamins nos	2000 - Ongoing	Illness Prophylaxis
Acetylsalicylic acid	2005 - Ongoing	Cardiac Prophylaxis
Hydrochlorothiazide; triamterene	2010 - Ongoing	Hypertension
Levothyroxine	2017 - Ongoing	Hypothyroidism
Ibuprofen	02 Sep 2020 (Study Day 30) - 02 Sep 2020 (Study Day 30)	Fever/Pain Reactogenicity
Influenza vaccine	16 Sep 2020 (Study Day 44) - 16 Sep 2020 (Study Day 44)	Immunization
Coronary artery bypass graft*	23 Oct 2020 (Study Day 81) - 23 Oct 2020 (Study Day 81)	Adverse Event
Gabapentin	28 Oct 2020 (Study Day 86) - 11 Nov 2020 (Study Day 100)	Post Operative Pain, Coronary Artery Bypass Graft
Pantoprazole sodium sesquihydrate	28 Oct 2020 (Study Day 86) - 11 Nov 2020 (Study Day 100)	Gastroesophageal Reflux Disease
Amiodarone	29 Oct 2020 (Study Day 87) - Ongoing	Coronary Artery Disease
Atorvastatin	29 Oct 2020 (Study Day 87) - Ongoing	Hypercholesterolemia
Metoprolol	29 Oct 2020 (Study Day 87) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 81) - 11 Nov 2020 (Study Day 100)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	28 Oct 2020 (Study Day 86) - Ongoing
Hypercholesterolaemia	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 87) - Ongoing
Hypertension	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 87) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US321-2100 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pelvic Pain/Pelvic Pain	SAE	Grade 2/ moderate	Not related	15 Dec 2020 (Study Day 128) – 27 Dec 2020 (Study Day 140)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2100, a 38-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Dec 2020 (Study Day 128), 127 days after the first dose and 98 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pelvic pain. Action taken with the IP was not applicable. The event of pelvic pain lasted for 13 days, after which it was considered to be recovered/resolved on 27 Dec 2020 (Study Day 140). The investigator assessed the event of pelvic pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001529	Pelvic pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergic rhinitis	2000 - Ongoing
Glucose tolerance impaired	Prediabetes	2007 - Ongoing
Cholecystectomy	Cholecystectomy	2008 - 2008
Cholecystitis	Cholecystitis	2008 - 2008
Uterine leiomyoma	Leiomyoma of uterus	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Seasonal Allergic Rhinitis, Fever/Pain Reactogenicity
Vitamins nos	2005 - Ongoing	Wellness
Metformin	2007 - Ongoing	Glucose Intolerance
Isoleucine; leucine; valine	2017 - Ongoing	Muscle Building
Ascorbic acid	2019 - Ongoing	Preventative
Ethinylestradiol; ferrous fumarate; norethisterone acetate	01 Mar 2020 (Study Day -162) - 10 Dec 2020 (Study Day 123)	Birth Control
Pelvic ultrasound*	17 Sep 2020 (Study Day 39) - 17 Sep 2020 (Study Day 39)	Adverse Event
Clindamycin	17 Nov 2020 (Study Day 100) - 28 Nov 2020 (Study Day 111)	Skin Rash Of Right Breast
Pelvic ultrasound*	01 Dec 2020 (Study Day 114) - 01 Dec 2020 (Study Day 114)	Medical History
Total abdominal hysterectomy*	15 Dec 2020 (Study Day 128) - 15 Dec 2020 (Study Day 128)	Other, Medical History ((Leiomyoma Of Uterus) And Adverse Event (Pelvic Pain)
Hydrocodone bitartrate; paracetamol	17 Dec 2020 (Study Day 130) - 19 Dec 2020 (Study Day 132)	Pelvic Pain
Ibuprofen	17 Dec 2020 (Study Day 130) - 27 Dec 2020 (Study Day 140)	Pelvic Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	10 Aug 2020 (Study Day 1) - 20 Aug 2020 (Study Day 11)
Back Pain	Grade 2/moderate	Not related	14 Aug 2020 (Study Day 5) - 01 Sep 2020 (Study Day 23)
Pain In Jaw	Grade 1/mild	Not related	14 Aug 2020 (Study Day 5) - 29 Aug 2020 (Study Day 20)
Injection Site Bruising	Grade 1/mild	Related	16 Aug 2020 (Study Day 7) - 21 Aug 2020 (Study Day 12)
Rash	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 99) - 20 Nov 2020 (Study Day 103)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US321-2394 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	12 Oct 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea/Dyspnea	SAE	Grade 3/severe	Not related	15 Nov 2020 (Study Day 66) – 30 Nov 2020 (Study Day 81)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2394, a 62-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 12 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Nov 2020 (Study Day 66), 65 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of dyspnoea. Action taken with the IP was not applicable. The event of dyspnea lasted for 16 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 81). The investigator assessed the event of dyspnoea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000913	Dyspnoea

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	Cesarean section	1985 - 1985
Uterine leiomyoma	Uterine fibroids	1990 - 1995
Myomectomy	Myomectomy	1995 - 1995
Appendicectomy	Appendectomy	1998 - 1998
Appendicitis	Appendicitis	1998 - 1998
Postmenopause	Post-menopausal	2000 - Ongoing
Cardiac murmur	Heart murmur	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1975 - Ongoing	Dietary Supplement
Naproxen sodium	15 Sep 2020 (Study Day 5) - 15 Sep 2020 (Study Day 5)	Injection Site Pain
Paracetamol	15 Sep 2020 (Study Day 5) - 15 Sep 2020 (Study Day 5)	Injection Site Pain
Amoxicillin	04 Nov 2020 (Study Day 55) - 13 Nov 2020 (Study Day 64)	Otitis
Chest ct*	19 Nov 2020 (Study Day 70) - 19 Nov 2020 (Study Day 70)	Adverse Event
Levofloxacin	21 Nov 2020 (Study Day 72) - 22 Nov 2020 (Study Day 73)	Dyspnea
Azithromycin	25 Nov 2020 (Study Day 76) - 30 Nov 2020 (Study Day 81)	Dyspnea

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	11 Sep 2020 (Study Day 1) - 19 Sep 2020 (Study Day 9)
Otitis Media	Grade 1/mild	Not related	02 Nov 2020 (Study Day 53) - 18 Nov 2020 (Study Day 69)
Faeces Discoloured	Grade 1/mild	Not related	12 Nov 2020 (Study Day 63) - 19 Nov 2020 (Study Day 70)
Fatigue	Grade 2/moderate	Not related	12 Nov 2020 (Study Day 63) - 30 Nov 2020 (Study Day 81)
Abdominal Discomfort	Grade 1/mild	Not related	13 Nov 2020 (Study Day 64) - 23 Nov 2020 (Study Day 74)
Headache	Grade 2/moderate	Not related	13 Nov 2020 (Study Day 64) - 23 Nov 2020 (Study Day 74)
Tachycardia	Grade 3/severe	Not related	15 Nov 2020 (Study Day 66) - 30 Nov 2020 (Study Day 81)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2004 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Uncontrolled Hypertension	SAE	Grade 4	Not related	01 Oct 2020 (Study Day 57) – 02 Oct 2020 (Study Day 58)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2004, a 69-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Oct 2020 (Study Day 57), 56 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hypertension. Action taken with the IP was not applicable. The event of uncontrolled hypertension lasted for 2 days, after which it was considered to be recovered/resolved on 02 Oct 2020 (Study Day 58). The investigator assessed the event of hypertension to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000418	Hypertension

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial flutter	Atrial flutter	1960 - Ongoing
Ex-tobacco user	Ex-smoker	1967 - 1975
Muscle spasms	Muscle spasms	1970 - Ongoing
Caesarean section	Cesarean section	1977 - Ongoing
Fibromyalgia	Fibromyalgia	1980 - Ongoing
Tension headache	Tension headache	1980 - Ongoing
Tension headache	Tension headaches	1980 - Ongoing
Rhinoplasty	Rhinoplasty	1995 - 1995
Uterine dilation and curettage	Dilation and curettage	1995 - Ongoing
Depression	Depression	2000 - Ongoing
Hypoparathyroidism	Hypoparathyroidism	2000 - Ongoing
Insomnia	Insomnia	2000 - Ongoing
Osteoarthritis	Osteoarthritis	2000 - Ongoing
Rosacea	Rosacea	2000 - Ongoing
Drug hypersensitivity	Levaquin allergy	2005 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2005 - Ongoing
Postmenopause	Postmenopausal	2010 - Ongoing
Colonoscopy	Colonoscopy	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Not reported - Ongoing	Headaches
Omega-3 nos	Not reported - Ongoing	Supplement
Vitamins nos	Not reported - Ongoing	Supplement
Meloxicam	2000 - Ongoing	Fibromyalgia
Venlafaxine	2000 - Ongoing	Depression Over Fibromyalgia
Doxycycline	2005 - Ongoing	Rosacea
Hydrocodone	2005 - Ongoing	Fibromyalgia
Nortriptyline	2005 - Ongoing	Muscle Spasms
Tizanidine	2005 - Ongoing	Muscle Spasms
Liothyronine	2010 - Ongoing	Hypoparathyroidism
Tramadol	2010 - Ongoing	Fibromyalgia
Levothyroxine	2015 - Ongoing	Hypoparathyroidism
Influenza vaccine	24 Sep 2020 (Study Day 50) - 24 Sep 2020 (Study Day 50)	Influenza

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
2d echo*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Blood work for troponins*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Stress test*	01 Oct 2020 (Study Day 57) - 01 Oct 2020 (Study Day 57)	Adverse Event
Losartan	02 Oct 2020 (Study Day 58) - Ongoing	Hypertension
Losartan	06 Jan 2021 (Study Day 154) - Ongoing	Hypertension
Chondroitin sulfate; glucosamine sulfate; methylsulfonylmethane	03 Feb 2021 (Study Day 182) - Ongoing	Cartilage Support - Prophylaxis.

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2013 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Atrial Fibrillation - Worsening	SAE	Grade 4	Not related	14 Nov 2020 (Study Day 101) – 16 Nov 2020 (Study Day 103)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2013, a 68-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 04 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Nov 2020 (Study Day 101), 100 days after the first dose and 71 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of atrial fibrillation - worsening lasted for 3 days, after which it was considered to be recovered/resolved on 16 Nov 2020 (Study Day 103). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000824	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypercholesterolaemia	Hypercholesterolemia	01 Jan 1995 (Study Day -9349) - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Hypertonic bladder	Overactive bladder	2018 - Ongoing
Seasonal allergy	Seasonal allergy	2018 - Ongoing
Atrial fibrillation	Atrial fibrillation	01 Jan 2019 (Study Day -583) - Ongoing
Amnesia	Memory loss	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lovastatin	2000 - Ongoing	Hypercholesterolemia
Omeprazole	2010 - Ongoing	Gerd
Montelukast	2018 - Ongoing	Seasonal Allergy
Tamsulosin	2018 - Ongoing	Overactive Bladder
Donepezil	2020 - Ongoing	Memory Loss
Fenofibrate	2020 - Ongoing	Hypercholesterolemia
Metoprolol	2020 - Ongoing	Atrial Fibrillation
Influenza vaccine	16 Sep 2020 (Study Day 42) - 16 Sep 2020 (Study Day 42)	Seasonal Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2032 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hepatic Enzyme Increased/ Elevated Liver Enzymes	SAE	Grade 3/severe	Not related	13 Dec 2020 (Study Day 129) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2032, a 73-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Dec 2020 (Study Day 129), 128 days after the first dose and 100 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hepatic enzyme increased. Action taken with the IP was not applicable. The event of elevated liver enzymes was considered to be ongoing. The investigator assessed the event of hepatic enzyme increased to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001140	Hepatic enzyme increased

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic back pain	1980 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1980 - Ongoing
Hypertension	Hypertension	1980 - Ongoing
Hypothyroidism	Hypothyroidism	1981 - Ongoing
Female sterilisation	Tubal ligation	1986 - 1986
Postmenopause	Postmenopausal	1998 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2000 - Ongoing
Menorrhagia	Menorrhagia	2002 - 2005
Hysterectomy	Hysterectomy	2005 - 2005
Amnesia	Memory loss	2018 - Ongoing
Osteoarthritis	Osteoarthritis-knees - no official dx at this time.	2019 - Ongoing
Cholecystectomy	Cholecystectomy	Jan 2020 - Jan 2020
Cholecystitis	Cholesystitis	Jan 2020 - Jan 2020
Abdominal pain	Abdominal pain	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	01 Jan 1980 (Study Day -14829) - Ongoing	Hypertension
Atorvastatin	01 Jan 1980 (Study Day -14829) - Ongoing	Hypercholesterolemia
Carvedilol	01 Jan 1980 (Study Day -14829) - Ongoing	Hypertension
Cyclobenzaprine hydrochloride	01 Jan 1980 (Study Day -14829) - Ongoing	Chronic Back Pain
Losartan	01 Jan 1980 (Study Day -14829) - Ongoing	Hypertension
Levothyroxine	01 Jan 1981 (Study Day -14463) - Ongoing	Hypothyroidism
Omeprazole	01 Jan 2000 (Study Day -7524) - Ongoing	Acid Reflux
Venlafaxine	01 Jan 2000 (Study Day -7524) - Ongoing	Anxiety
Gabapentin	01 Jan 2010 (Study Day -3871) - Ongoing	Chronic Back Pain
Morphine	01 Jan 2015 (Study Day -2045) - Ongoing	Chronic Back Pain
Oxycodone	01 Jan 2015 (Study Day -2045) - Ongoing	Chronic Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2059 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 38)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/New Onset-Atrial Fibrillation	SAE	Grade 3/severe	Not related	03 Sep 2020 (Study Day 27) – 05 Sep 2020 (Study Day 29)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2059, a 84-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 38). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Sep 2020 (Study Day 27), 26 days after the first dose and 11 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. The IP dose was delayed due to the new onset-atrial fibrillation. The event of new onset-atrial fibrillation lasted for 3 days, after which it was considered to be recovered/resolved on 05 Sep 2020 (Study Day 29). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000264	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Measles	Measles-childhood	Not reported
Mumps	Mumps-childhood	Not reported
Non-tobacco user	Non-smoker	Not reported
Rubella	Rubella-childhood	Not reported
Varicella	Chicken pox- childhood	Not reported
Postmenopause	Post-menopausal	01 Jan 1967 (Study Day -19578) - Not reported
Osteoarthritis	Osteoarthritis - knees bilateral	01 Jan 1990 (Study Day -11177) - Ongoing
Gastrooesophageal reflux disease	Gerd	01 Jan 1992 (Study Day -10447) - Ongoing
Hiatus hernia	Hiatal hernia	01 Jan 1992 (Study Day -10447) - Ongoing
Meningitis	Meningitis	01 Jan 1996 (Study Day -8986) - Ongoing
Cataract operation	Cataract surgery - bilateral	01 Jan 1998 (Study Day -8255) - 01 Jan 1998 (Study Day -8255)
Osteoarthritis	Osteoarthritis - hands bilateral	01 Jan 2000 (Study Day -7525) - Ongoing
Hypersensitivity	Allergies, environmental	01 Jan 2001 (Study Day -7159) - Ongoing
Rhinitis allergic	Allergic rhinitis	01 Jan 2001 (Study Day -7159) - Ongoing
Seasonal allergy	Allergies- seasonal	01 Jan 2001 (Study Day -7159) - Ongoing
Bronchitis	Bronchitis	01 Jan 2004 (Study Day -6064) - 01 Jan 2019 (Study Day -585)
Back disorder	Back problems	01 Jan 2006 (Study Day -5333) - Ongoing
Sinusitis	Sinusitis	2009 - Ongoing
Tinea versicolour	Tinea versicolor - upper back	01 Jan 2010 (Study Day -3872) - Ongoing
Knee arthroplasty	Knee replacement-left	01 Jan 2013 (Study Day -2776) - 01 Jan 2013 (Study Day -2776)
Hypercholesterolaemia	Hypercholesterolemia	01 Jan 2019 (Study Day -585) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	21 Sep 2000 (Study Day -7261) - Ongoing	Osteoarthritis - Knees - B/L
Fexofenadine hydrochloride	01 Jan 2009 (Study Day -4237) - Ongoing	Sinusitis
Pantoprazole sodium sesquihydrate	01 Jan 2010 (Study Day -3872) - Ongoing	Gerd
Salbutamol	01 Jan 2016 (Study Day -1681) - Ongoing	Allergic Rhinitis
Apixaban	05 Sep 2020 (Study Day 29) - Ongoing	A-Fib
Diltiazem	05 Sep 2020 (Study Day 29) - Ongoing	A-Fib
Metoprolol	05 Sep 2020 (Study Day 29) - Ongoing	A-Fib/Essential Htn

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Essential Hypertension	Grade 1/mild	Not related	05 Sep 2020 (Study Day 29) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2061 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Breast Mass/Mass On Right Breast Positive For Cancer	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	04 Sep 2020 (Study Day 26) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2061, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Sep 2020 (Study Day 26), 25 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of breast mass. On 06 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of mass on right breast possitive for cancer was considered to be ongoing. The investigator assessed the event of breast mass to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	01 Jan 2000 (Study Day -7527) - Ongoing
Chronic obstructive pulmonary disease	Copd- chronic plumonary disease	01 Jan 2006 (Study Day -5335) - Ongoing
Emphysema	Emphysema	01 Jan 2006 (Study Day -5335) - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	01 Jan 2010 (Study Day -3874) - Ongoing
Lung neoplasm malignant	Lung cancer	01 Jan 2015 (Study Day -2048) - Not reported
Seasonal allergy	Allergies - seasonal	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	01 Jan 2005 (Study Day -5700) - Ongoing	Hyperlipidemia
Fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	01 Jan 2006 (Study Day -5335) - Ongoing	Copd/Emphasema
Salbutamol	01 Jan 2006 (Study Day -5335) - Ongoing	Copd/Emphasema
Losartan	01 Jan 2010 (Study Day -3874) - Ongoing	Hypertension
Metoprolol	01 Jan 2018 (Study Day -952) - Ongoing	Hypertension
Fluticasone propionate	2020 - Ongoing	Seasonal Allergies
Influenza vaccine	11 Sep 2020 (Study Day 33) - 11 Sep 2020 (Study Day 33)	Seasonal Influenza
Mastectomy right breast*	12 Feb 2021 (Study Day 187) - 12 Feb 2021 (Study Day 187)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Breast Mass	Grade 3/severe	Not related	04 Sep 2020 (Study Day 26) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2068 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Respiratory Failure/Acute On Chronic Hypoxic Respiratory Failure	SAE	Grade 4	Not related	24 Sep 2020 (Study Day 46) – 05 Oct 2020 (Study Day 57)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2068, a 71-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Sep 2020 (Study Day 46), 45 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute on chronic hypoxic respiratory failure lasted for 12 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 57). The investigator assessed the event of acute respiratory failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000428	Acute respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to animal	Cat dandere allergy	Not reported - Ongoing
Drug hypersensitivity	Codeine allergy	Not reported - Ongoing
Drug hypersensitivity	Gemfibrozil allergy	Not reported - Ongoing
Seasonal allergy	Grass allergy	Not reported - Ongoing
Seasonal allergy	Pollen allergy	Not reported - Ongoing
Back pain	Chronic back pain	01 Jan 1993 (Study Day -10083) - Ongoing
Umbilical hernia repair	Hernia surgery, umbilical	01 Jan 2004 (Study Day -6066) - 01 Jan 2004 (Study Day -6066)
Hypertension	Hypertension	01 Jan 2005 (Study Day -5700) - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	01 Jan 2005 (Study Day -5700) - Ongoing
Knee arthroplasty	Knee replacement - bilat	01 Jan 2006 (Study Day -5335) - 01 Jan 2006 (Study Day -5335)
Hypercholesterolaemia	Hypercholesterolemia	01 Jan 2010 (Study Day -3874) - Ongoing
Prostate cancer	Prostate cancer	01 Jan 2010 (Study Day -3874) - 01 Jan 2010 (Study Day -3874)
Spinal operation	Back surgery	01 Jan 2010 (Study Day -3874) - 01 Jan 2010 (Study Day -3874)
Atrial fibrillation	Atrial fibrillation	01 Jan 2015 (Study Day -2048) - Ongoing
Hypothyroidism	Hypothyroidism	01 Jan 2015 (Study Day -2048) - Ongoing
Oedema peripheral	Edema - bilat pedal edema	01 Jan 2018 (Study Day -952) - Ongoing
Anxiety	Anxiety	01 Sep 2019 (Study Day -344) - Ongoing
Pulmonary fibrosis	Plumonary fibrosis	01 Sep 2019 (Study Day -344) - Ongoing
Rhinitis allergic	Allergic rhinitis	01 Sep 2019 (Study Day -344) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	01 Jan 2005 (Study Day -5700) - Ongoing	Hypertension
Metformin	01 Jan 2005 (Study Day -5700) - Ongoing	Diabetes
Metoprolol	01 Jan 2010 (Study Day -3874) - Ongoing	Hypertension
Levothyroxine	01 Jan 2015 (Study Day -2048) - Ongoing	Hypothyroidism
Rivaroxaban	01 Jan 2015 (Study Day -2048) - Ongoing	Atrial Fibrillation
Morphine	01 Jan 2018 (Study Day -952) - Ongoing	Back Pain
Furosemide	01 Mar 2020 (Study Day -162) - Ongoing	Edema - Bilat Pedal Edema
Pirfenidone	Apr 2020 - Ongoing	Pulmonry Fibrosis
Salmeterol	Apr 2020 - Ongoing	Pulmonary Fibrosis
Clonazepam	01 May 2020 (Study Day -101) - Ongoing	Anxiety

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	24 Sep 2020 (Study Day 46) - Ongoing	Hypercholesterolemia
Electro cardio gram*	24 Sep 2020 (Study Day 46) - 24 Sep 2020 (Study Day 46)	Adverse Event
Glyceryl trinitrate	24 Sep 2020 (Study Day 46) - Ongoing	Angina
Ipratropium; salbutamol	24 Sep 2020 (Study Day 46) - Ongoing	Shortness Of Breath
Isosorbide mononitrate	24 Sep 2020 (Study Day 46) - 05 Oct 2020 (Study Day 57)	Angina
Ondansetron	24 Sep 2020 (Study Day 46) - 05 Oct 2020 (Study Day 57)	Nausea And Vomiting
Paracetamol	24 Sep 2020 (Study Day 46) - Ongoing	Pain
Acetylsalicylic acid	25 Sep 2020 (Study Day 47) - Ongoing	Cardiac Prophylaxis
Arterial blood gas*	25 Sep 2020 (Study Day 47) - 25 Sep 2020 (Study Day 47)	Adverse Event
Ct of chest*	25 Sep 2020 (Study Day 47) - 25 Sep 2020 (Study Day 47)	Adverse Event
Diltiazem	25 Sep 2020 (Study Day 47) - Ongoing	Hypertension
Emergency bloodwork*	25 Sep 2020 (Study Day 47) - 25 Sep 2020 (Study Day 47)	Adverse Event
Furosemide	25 Sep 2020 (Study Day 47) - Ongoing	Hypertension
Insulin lispro	25 Sep 2020 (Study Day 47) - 05 Oct 2020 (Study Day 57)	Diabetes Type 2
Methylprednisolone	25 Sep 2020 (Study Day 47) - 05 Oct 2020 (Study Day 57)	Pneumonia
Nasal cannula*	25 Sep 2020 (Study Day 47) - 25 Sep 2020 (Study Day 47)	Adverse Event
Oxygen	25 Sep 2020 (Study Day 47) - 26 Sep 2020 (Study Day 48)	O2 Needed During Procedure, Broncholavage
Piperacillin; tazobactam	25 Sep 2020 (Study Day 47) - 01 Oct 2020 (Study Day 53)	Respiratory Failure.
Spironolactone	25 Sep 2020 (Study Day 47) - Ongoing	Hypertension
Xr chest*	27 Sep 2020 (Study Day 49) - 27 Sep 2020 (Study Day 49)	Adverse Event
Bronch lavage right middle lobe of lung*	01 Oct 2020 (Study Day 53) - 01 Oct 2020 (Study Day 53)	Adverse Event
Barium swallow*	02 Oct 2020 (Study Day 54) - 02 Oct 2020 (Study Day 54)	Adverse Event
Benzonatate	05 Oct 2020 (Study Day 57) - 10 Oct 2020 (Study Day 62)	Cough
Colecalciferol	05 Oct 2020 (Study Day 57) - Ongoing	Supplement
Fluconazole	05 Oct 2020 (Study Day 57) - 15 Oct 2020 (Study Day 67)	Fungal Infection
Guaifenesin	05 Oct 2020 (Study Day 57) - 10 Oct 2020 (Study Day 62)	Cough
Lorazepam	05 Oct 2020 (Study Day 57) - 10 Oct 2020 (Study Day 62)	Anxiety
Macrogol 3350	05 Oct 2020 (Study Day 57) - 15 Oct 2020 (Study Day 67)	Constipation
Metoprolol	05 Oct 2020 (Study Day 57) - 04 Nov 2020 (Study Day 87)	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Minerals nos; vitamins nos	05 Oct 2020 (Study Day 57) - Ongoing	Supplement
Pantoprazole	05 Oct 2020 (Study Day 57) - 04 Nov 2020 (Study Day 87)	Supplement
Prednisone	05 Oct 2020 (Study Day 57) - 21 Oct 2020 (Study Day 73)	Pneumonia
Ranolazine	05 Oct 2020 (Study Day 57) - 04 Nov 2020 (Study Day 87)	Angina
Xr of chest*	24 Oct 2020 (Study Day 76) - 24 Oct 2020 (Study Day 76)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2077 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Kidney Stones	SAE	Grade 4	Not related	15 Sep 2020 (Study Day 37) – 02 Oct 2020 (Study Day 54)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2077, a 73-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Sep 2020 (Study Day 37), 36 days after the first dose and 6 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of kidney stones lasted for 18 days, after which it was considered to be recovered/resolved on 02 Oct 2020 (Study Day 54). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000363	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	01 Jan 1966 (Study Day -19945) - 01 Jan 1966 (Study Day -19945)
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	2002 - Ongoing
Nephrolithiasis	Nephrolithiasis	2010 - Not reported
Hypercholesterolaemia	Hypercholesterolemia	01 Jan 2010 (Study Day -3874) - Ongoing
Benign lung neoplasm	Lung nodule benign	01 Jan 2014 (Study Day -2413) - Ongoing
Chronic obstructive pulmonary disease	Copd-chronic obstructive pulmonary disease	01 Jan 2014 (Study Day -2413) - Ongoing
Cardiac failure congestive	Congestive heart failure	2018 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	01 Jan 2018 (Study Day -952) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine	01 Jan 1995 (Study Day -9353) - Ongoing	Seasonal Allergies
Acetylsalicylic acid	01 Jan 2000 (Study Day -7527) - Ongoing	Congestive Heart Failure
Vitamin b complex	2002 - Ongoing	Supplement
Vitamins nos	2002 - Ongoing	Supplement
Lovastatin	01 Jan 2010 (Study Day -3874) - Ongoing	Hypercholesterolemia
Metformin	01 Jan 2013 (Study Day -2778) - Ongoing	Diabetes Mellitus Type 2
Fluticasone furoate; vilanterol trifenatate	01 Jan 2014 (Study Day -2413) - Ongoing	Chronic Obstructive Pulmonary Disease
Atenolol	2018 - Ongoing	Congestive Heart Failure
Alfuzosin	01 Jan 2018 (Study Day -952) - Ongoing	Benign Prostate Hyperplasia
Furosemide	01 Jan 2018 (Study Day -952) - Ongoing	Congestive Heart Failure
Potassium	01 Jan 2018 (Study Day -952) - Ongoing	Supplement
Salbutamol	01 Jan 2018 (Study Day -952) - Ongoing	Chronic Obstructive Pulmonary Disease
Finasteride	01 Jan 2019 (Study Day -587) - Ongoing	Benign Prostate Hyperplasia
Morphine	15 Sep 2020 (Study Day 37) - 15 Sep 2020 (Study Day 37)	Kidney Stones
Oxycodone hydrochloride	18 Sep 2020 (Study Day 40) - 02 Oct 2020 (Study Day 54)	Kidney Stones
Antibiotics	22 Sep 2020 (Study Day 44) - 23 Sep 2020 (Study Day 45)	Urinary Tract Infection
I.v. solutions	22 Sep 2020 (Study Day 44) - 23 Sep 2020 (Study Day 45)	Kidney Stones

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Morphine	22 Sep 2020 (Study Day 44) - 23 Sep 2020 (Study Day 45)	Renal Pain Secondary To Kidney Stone
Lithotripsy*	02 Oct 2020 (Study Day 54) - 02 Oct 2020 (Study Day 54)	Adverse Event
Influenza vaccine	27 Oct 2020 (Study Day 79) - 27 Oct 2020 (Study Day 79)	Vaccine
Lisinopril	24 Jan 2021 (Study Day 168) - Ongoing	Congestive Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	10 Sep 2020 (Study Day 32) - 11 Oct 2020 (Study Day 63)
Myalgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 33) - 17 Sep 2020 (Study Day 39)
Vomiting	Grade 1/mild	Related	15 Sep 2020 (Study Day 37) - 26 Sep 2020 (Study Day 48)
Urinary Tract Infection	Grade 1/mild	Not related	22 Sep 2020 (Study Day 44) - 23 Sep 2020 (Study Day 45)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2089 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	12 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Left Ventricular Failure/Primary Sae Acute Diastolic Heart Failure	SAE	Grade 4	Not related	23 Jan 2021 (Study Day 166) – 27 Jan 2021 (Study Day 170)	Recovered/resolved
Chronic Obstructive Pulmonary Disease/Copd Exacerbation	SAE	Grade 4	Not related	23 Jan 2021 (Study Day 166) – 27 Jan 2021 (Study Day 170)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2089, a 72-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 12 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Jan 2021 (Study Day 166), 165 days after the first dose and 133 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute left ventricular failure. Action taken with the IP was not applicable. The event of primary sae acute diastolic heart failure lasted for 5 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 170). The investigator assessed the event of acute left ventricular failure to be not related to the IP.

On 23 Jan 2021 (Study Day 166), 165 days after the first dose and 133 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of copd exacerbation lasted for 5 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 170). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008062	Chronic obstructive pulmonary disease
MOD-2021-008062	Acute left ventricular failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	Not reported - Ongoing
Major depression	Major depression	Not reported - Ongoing
Hypertension	Hypertension	01 Jan 1995 (Study Day -9354) - Ongoing
Seasonal allergy	Seasonal allergies	2001 - Ongoing
Hysterectomy	Hysterectomy	2002 - 2002
Chronic obstructive pulmonary disease	Copd	2014 - Ongoing
Postmenopause	Postmenopausal	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	Not reported - Ongoing	Copd
Metoprolol	Not reported - Ongoing	Hypertension
Spironolactone	Not reported - Ongoing	Copd
Chlorphenamine maleate	2001 - Ongoing	Seasonal Allergies
Penicillin nos	31 Oct 2020 (Study Day 82) - 04 Nov 2020 (Study Day 86)	Sore Throat
Influenza vaccine	11 Nov 2020 (Study Day 93) - 11 Nov 2020 (Study Day 93)	Vaccine
Aripiprazole	23 Jan 2021 (Study Day 166) - 27 Jan 2021 (Study Day 170)	Major Depression
Alprazolam	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Anxiety
Ascorbic acid	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Supplement
Azithromycin	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Benzonatate	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Budesonide	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Codeine; guaifenesin	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Diphenhydramine	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Preventative

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Docusate sodium	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Preventative (Constipation)
Doxepin	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Depression
Famotidine	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Preventative
Formoterol	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Furosemide	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Acute Diastolic Heart Failure
Guaifenesin	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Ipratropium	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Iron; vitamins nos	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Macrogol 3350	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Preventative
Methylprednisolone	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Copd Exacerbation
Metoprolol tartrate	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Acute Diastolic Heart Failure
Nicotine	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Preventative
Ondansetron	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Preventative
Paracetamol	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Fever Or Pain
Sodium chloride	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Keep Vain Open
Sodium chloride	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Keep Vein Open
Sodium chloride	24 Jan 2021 (Study Day 167) - 24 Jan 2021 (Study Day 167)	Preventative
Spironolactone	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Acute Diastolic Heart Failure
Valsartan	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Acute Diastolic Heart Failure
Venlafaxine	24 Jan 2021 (Study Day 167) - 27 Jan 2021 (Study Day 170)	Major Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oropharyngeal Pain	Grade 1/mild	Not related	31 Oct 2020 (Study Day 82) - 04 Nov 2020 (Study Day 86)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2117 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Obstructive Pulmonary Disease/Copd Exacerbation	SAE	Grade 3/severe	Not related	11 Dec 2020 (Study Day 122) – 15 Dec 2020 (Study Day 126)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2117, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Dec 2020 (Study Day 122), 121 days after the first dose and 92 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of copd exacerbation lasted for 5 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 126). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001109	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1991 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Chronic obstructive pulmonary disease	Copd	2002 - Ongoing
Seasonal allergy	Allergies - seasonal	2002 - Ongoing
Restless legs syndrome	Restless leg syndrome - bilateral	2005 - Ongoing
Diabetic neuropathy	Diabetic neuropathy - (hands and feet) bilateral, sensory	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2012 - Ongoing
Cardiac failure congestive	Congestive heart failure	2015 - Ongoing
Insomnia	Insomnia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1980 - Ongoing	Cardiac Supplement
Lisinopril	1991 - Ongoing	Hypertension
Rosuvastatin	2000 - Ongoing	Hypercholesterlemia
Fluticasone propionate; salmeterol xinafoate	2002 - Ongoing	Copd
Montelukast sodium	2002 - Ongoing	Allergies - Seasonal
Bisoprolol	2004 - Ongoing	Hypertension
Gabapentin	2010 - Ongoing	Diabetic Neuropathy - (Hands And Feet)
Insulin aspart	2013 - Ongoing	Diabetes
Insulin glargine	2013 - Ongoing	Diabetes
Pramipexole	2015 - Ongoing	Restless Leg Syndrome
Trazodone	2015 - Ongoing	Insomnia
Clopidogrel bisulfate	2016 - Ongoing	Blood Clot Prevention
Spironolactone	2016 - Ongoing	Hypertension
Furosemide	2017 - Ongoing	Copd
Cefuroxime	11 Dec 2020 (Study Day 122) - 17 Dec 2020 (Study Day 128)	Bacterial Infection
Hydrocodone; paracetamol	11 Dec 2020 (Study Day 122) - 12 Dec 2020 (Study Day 123)	Chest Pain/ Chronic Obstructive Pulmonary Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	11 Dec 2020 (Study Day 122) - 13 Dec 2020 (Study Day 124)	Shortness Of Breath

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	13 Nov 2020 (Study Day 94) - 17 Dec 2020 (Study Day 128)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2143 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Benign Lung Neoplasm/Lung Nodules Benign	SAE	Grade 2/moderate	Not related	11 Dec 2020 (Study Day 120) – Ongoing	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2143, a 37-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Dec 2020 (Study Day 120), 119 days after the first dose and 86 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of benign lung neoplasm. The IP dose was not changed due to the lung nodules benign. The event of lung nodules benign was considered to be ongoing. The investigator assessed the event of benign lung neoplasm to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001188	Benign lung neoplasm

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	01 Jan 2010 (Study Day -3878) - Ongoing
Cyst removal	Cyst removed- right wrist	01 Jan 2010 (Study Day -3878) - 01 Jan 2010 (Study Day -3878)
Endometriosis	Endometriosis	01 Jan 2011 (Study Day -3513) - Ongoing
Caesarean section	Cesarean section	01 Jan 2012 (Study Day -3148) - 01 Jan 2012 (Study Day -3148)
Endometrial disorder	Endometrial cysts - benign	01 Jan 2013 (Study Day -2782) - 01 Jan 2013 (Study Day -2782)
Laparoscopy	Laparoscopy	01 Jan 2013 (Study Day -2782) - 01 Jan 2013 (Study Day -2782)
Carpal tunnel decompression	Carpal tunnel surgery- right wrist	01 Jan 2014 (Study Day -2417) - 01 Jan 2014 (Study Day -2417)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; norethisterone acetate	2018 - Ongoing	Birth Control
Amitriptyline	Mar 2020 - Ongoing	Anxiety
Alprazolam	Apr 2020 - Ongoing	Anxiety
Paracetamol	18 Sep 2020 (Study Day 36) - 20 Sep 2020 (Study Day 38)	Headache
Influenza vaccine	23 Nov 2020 (Study Day 102) - 23 Nov 2020 (Study Day 102)	Vaccine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2189 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Alcoholism/Chronic Alcoholic Relapse	SAE	Grade 3/ severe	Not related	02 Oct 2020 (Study Day 47) – Ongoing	Not recovered/ not resolved
Encephalopathy/Encephalopathy	SAE	Grade 3/ severe	Not related	02 Oct 2020 (Study Day 47) – 03 Oct 2020 (Study Day 48)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2189, a 57-year-old race unknown male, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 47), 46 days after the first dose and 14 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of alcoholism. Action taken with the IP was not applicable. The event of chronic alcoholic relapse was considered to be ongoing. The investigator assessed the event of alcoholism to be not related to the IP.

On 02 Oct 2020 (Study Day 47), 46 days after the first dose and 14 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of encephalopathy. Action taken with the IP was not applicable. The event of encephalopathy lasted for 2 days, after which it was considered to be recovered/resolved on 03 Oct 2020 (Study Day 48). The investigator assessed the event of encephalopathy to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000420	Alcoholism
MOD-2020-000420	Encephalopathy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Bipolar disorder	Bipolar disorder	Not reported - Ongoing
Gastrooesophageal reflux disease	Gerd	Not reported - Ongoing
Umbilical hernia	Hernia - umbilical	2012 - 2012
Shoulder operation	Shoulder surgery from an unknown cause	2015 - Not reported
Alcoholism	Chronic alcoholic	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Other dermatologicals	Not reported - Not reported	Unknow Reason For Dermal Filler
Calcium	2015 - Ongoing	Supplement
Curcuma longa	2015 - Ongoing	Supplement
Fish oil	2015 - Ongoing	Supplement
Folic acid	2015 - Ongoing	Supplement
Potassium	2015 - Ongoing	Supplement
Vitamin d nos	2015 - Ongoing	Supplement
Vitamins nos	2015 - Ongoing	Supplement
Ct of head*	02 Oct 2020 (Study Day 47) - 02 Oct 2020 (Study Day 47)	Adverse Event
Electrolytes nos	02 Oct 2020 (Study Day 47) - 02 Oct 2020 (Study Day 47)	Ae: Acute Kidney Injury: (Creatinine Was Elevated To A 2 And Fluids Dropped It To A 1.26.)
Sulfamethoxazole; trimethoprim	21 Dec 2020 (Study Day 127) - 30 Dec 2020 (Study Day 136)	Urinary Tract Infection
Cefalexin	24 Feb 2021 (Study Day 192) - 07 Mar 2021 (Study Day 203)	Ae: Urinary Tract Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acute Kidney Injury	Grade 1/mild	Not related	02 Oct 2020 (Study Day 47) - 03 Oct 2020 (Study Day 48)
Bipolar Disorder	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 47) - Ongoing
Hallucination, Visual	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 47) - 03 Oct 2020 (Study Day 48)
Substance Abuse	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 47) - Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	21 Dec 2020 (Study Day 127) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2220 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arterial Haemorrhage/Temporal Artery Bleeding	SAE	Grade 4	Not related	11 Mar 2021 (Study Day 205) – 15 Mar 2021 (Study Day 209)	Recovered/resolved
Fall/Fall	SAE	Grade 4	Not related	12 Mar 2021 (Study Day 206) – Ongoing	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2220, a 63-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 17 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Mar 2021 (Study Day 205), 204 days after the first dose and 175 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of arterial haemorrhage. Action taken with the IP was not applicable. The event of temporal artery bleeding lasted for 5 days, after which it was considered to be recovered/resolved on 15 Mar 2021 (Study Day 209). The investigator assessed the event of arterial haemorrhage to be not related to the IP.

On 12 Mar 2021 (Study Day 206), 205 days after the first dose and 176 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of fall. Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of fall to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-047049	Arterial haemorrhage
MOD-2021-047049	Fall

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergies, tramadol	Not reported - Ongoing
Postmenopause	Postmenopausal	Not reported - Ongoing
Gastrooesophageal reflux disease	Gerd	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole sodium sesquihydrate	2019 - Ongoing	Gerd

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2296 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Thymoma Malignant/Invasive Thymoma	SAE	Grade 3/severe	Not related	04 Dec 2020 (Study Day 104) – 11 Dec 2020 (Study Day 111)	Recovered/resolved
Thymoma Malignant/Invasive Thymoma	SAE	Grade 3/severe	Not related	14 Jan 2021 (Study Day 145) – 21 Jan 2021 (Study Day 152)	Recovered/resolved
Viral Infection/Norovirus	SAE	Grade 2/moderate	Not related	31 Jan 2021 (Study Day 162) – 04 Feb 2021 (Study Day 166)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2296, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 23 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Dec 2020 (Study Day 104), 103 days after the first dose and 73 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of thymoma malignant. The IP dose was not changed due to the invasive thymoma. The event of invasive thymoma lasted for 8 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 111). The investigator assessed the event of thymoma malignant to be not related to the IP.

On 14 Jan 2021 (Study Day 145), 144 days after the first dose and 114 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of thymoma malignant. The IP dose was not changed due to the invasive thymoma. The event of invasive thymoma lasted for 8 days, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 152). The investigator assessed the event of thymoma malignant to be not related to the IP.

On 31 Jan 2021 (Study Day 162), 161 days after the first dose and 131 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of viral infection. Action taken with the IP was not applicable. The event of norovirus lasted for 5 days, after which it was considered to be recovered/resolved on 04 Feb 2021 (Study Day 166). The investigator assessed the event of viral infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012028	Thymoma malignant
MOD-2021-012062	Viral infection
MOD-2021-068010	Thymoma malignant

Study Completion/Discontinuation

On 12 Feb 2021 (Study Day 174), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	2001 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin	23 Sep 2020 (Study Day 32) - 29 Sep 2020 (Study Day 38)	Pneumonia
Azithromycin	23 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 36)	Pneumonia
Ct chest*	04 Oct 2020 (Study Day 43) - 04 Oct 2020 (Study Day 43)	Diagnostic
Prednisone	11 Nov 2020 (Study Day 81) - 17 Nov 2020 (Study Day 87)	Ae # 5 Maculopapular
Triamcinolone	11 Nov 2020 (Study Day 81) - 17 Nov 2020 (Study Day 87)	Ae # 5 Maculopapular
Metoprolol	12 Dec 2020 (Study Day 112) - Ongoing	Htn
Ct abdomen and pelvis*	31 Jan 2021 (Study Day 162) - 31 Jan 2021 (Study Day 162)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxybutynin	31 Jan 2021 (Study Day 162) - Ongoing	Overactive Bladder
Oxycodone	31 Jan 2021 (Study Day 162) - Ongoing	Ae 2 Invasive Thymoma
Sertraline hydrochloride	31 Jan 2021 (Study Day 162) - Ongoing	Depression
Thymectomy*	31 Jan 2021 (Study Day 162) - 31 Jan 2021 (Study Day 162)	Adverse Event
Venlafaxine	31 Jan 2021 (Study Day 162) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pneumonia	Grade 3/severe	Not related	23 Sep 2020 (Study Day 32) - 20 Oct 2020 (Study Day 59)
Rash Maculo-Papular	Grade 2/moderate	Not related	11 Nov 2020 (Study Day 81) - 17 Nov 2020 (Study Day 87)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2299 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/Small Bowel Obstruction	SAE	Grade 3/severe	Not related	03 Oct 2020 (Study Day 42) – 05 Oct 2020 (Study Day 44)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2299, a 57-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 23 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Oct 2020 (Study Day 42), 41 days after the first dose and 10 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of small intestinal obstruction. Action taken with the IP was not applicable. The event of small bowel obstruction lasted for 3 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 44). The investigator assessed the event of small intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000431	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	Not reported - Ongoing
Osteoarthritis	Osteoarthritis-right toe	1998 - 10 Sep 2020 (Study Day 19)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	24 Sep 2020 (Study Day 33) - 25 Sep 2020 (Study Day 34)	Body Aches
Cat scan of abdomen and pelvis*	03 Oct 2020 (Study Day 42) - 03 Oct 2020 (Study Day 42)	Adverse Event
Famotidine	03 Oct 2020 (Study Day 42) - 05 Oct 2020 (Study Day 44)	Abdominal Pain Secondary To Small Bowel Obstruction
Glucose; sodium chloride	03 Oct 2020 (Study Day 42) - 03 Oct 2020 (Study Day 42)	Supplement
Morphine	03 Oct 2020 (Study Day 42) - 04 Oct 2020 (Study Day 43)	General Pain
Ondansetron	03 Oct 2020 (Study Day 42) - 05 Oct 2020 (Study Day 44)	Nausea
Oxycodone hydrochloride; paracetamol	03 Oct 2020 (Study Day 42) - 05 Oct 2020 (Study Day 44)	General Pain
Paracetamol	03 Oct 2020 (Study Day 42) - 05 Oct 2020 (Study Day 44)	General Pain
Sodium chloride	03 Oct 2020 (Study Day 42) - 05 Oct 2020 (Study Day 44)	Dvt Prophylaxis
X-ray abdomen flat/upright with chest*	03 Oct 2020 (Study Day 42) - 03 Oct 2020 (Study Day 42)	Adverse Event
Exploratory laparotomy*	04 Oct 2020 (Study Day 43) - 04 Oct 2020 (Study Day 43)	Diagnostic
Piperacillin sodium; tazobactam sodium	04 Oct 2020 (Study Day 43) - 04 Oct 2020 (Study Day 43)	Small Bowel Obstruction
Influenza vaccine	16 Oct 2020 (Study Day 55) - 16 Oct 2020 (Study Day 55)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	23 Aug 2020 (Study Day 1) - 31 Aug 2020 (Study Day 9)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378612

Participant Number:	US322-2311 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urinary Tract Infection/ Urinary Tract Infection	SAE	Grade 4	Not related	28 Sep 2020 (Study Day 36) – 30 Sep 2020 (Study Day 38)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2311, a 68-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Sep 2020 (Study Day 36), 35 days after the first dose and 5 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of urinary tract infection lasted for 3 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 38). The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000448	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis bilateral hips	Not reported - Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	Not reported - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Urinary incontinence	Urinary incontinence	2006 - Ongoing
Cerebrovascular accident	Cva	01 Apr 2006 (Study Day -5259) - Ongoing
Gastroduodenal ulcer	Gastroduodenal ulcer	01 Apr 2006 (Study Day -5259) - Ongoing
Muscle spasms	Muscle spasms	01 Apr 2006 (Study Day -5259) - Ongoing
Postmenopause	Postmenopausal	2007 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Dementia	Dementia	2013 - Ongoing
Transient ischaemic attack	Tia	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2018 - Ongoing
Hip surgery	Hip surgery	02 Oct 2018 (Study Day -692) - 02 Oct 2018 (Study Day -692)
Hip arthroplasty	Right hip replacement	12 Feb 2020 (Study Day -194) - 12 Feb 2020 (Study Day -194)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	2000 - Ongoing	Hypertension
Acetylsalicylic acid	01 Jan 2006 (Study Day -5349) - Ongoing	Cardiac Prophylaxis
Rosuvastatin	01 Jan 2006 (Study Day -5349) - Ongoing	Hyperlipidemia
Tolterodine l-tartrate	01 Jan 2006 (Study Day -5349) - Ongoing	Urinary Incontinence
Baclofen	01 Apr 2006 (Study Day -5259) - Ongoing	Muscle Spasms
Furosemide	01 Jan 2011 (Study Day -3523) - Ongoing	Hypertension
Donepezil	2013 - Ongoing	Dementia
Duloxetine	01 Jan 2013 (Study Day -2792) - 30 Sep 2020 (Study Day 38)	Anxiety
Memantine hydrochloride	01 Jan 2013 (Study Day -2792) - Ongoing	Dementia
Valproate semisodium	01 Jan 2013 (Study Day -2792) - Ongoing	Anxiety
Levothyroxine	01 Jan 2018 (Study Day -966) - Ongoing	Hypoparathyroid
Omeprazole	01 Apr 2020 (Study Day -145) - Ongoing	Gastroduodenal Ulcer
Tramadol	29 Sep 2020 (Study Day 37) - 12 Oct 2020 (Study Day 50)	Postoperative Hip Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cefdinir	30 Sep 2020 (Study Day 38) - 05 Oct 2020 (Study Day 43)	Urinary Tract Infection
Sulfamethoxazole; trimethoprim	05 Oct 2020 (Study Day 43) - 12 Oct 2020 (Study Day 50)	Uti
Levofloxacin	05 Dec 2020 (Study Day 104) - 15 Dec 2020 (Study Day 114)	Uti
Tramadol	15 Dec 2020 (Study Day 114) - 15 Dec 2020 (Study Day 114)	Knee Pain
Influenza vaccine	22 Dec 2020 (Study Day 121) - 22 Dec 2020 (Study Day 121)	Prophylaxis Seasonal Influenza
Cefalexin	01 Feb 2021 (Study Day 162) - 02 Feb 2021 (Study Day 163)	Pre-Op Mohs Surgery Basal Cell Carcinoma Excised From Cheak.
Doxycycline	02 Feb 2021 (Study Day 163) - 07 Feb 2021 (Study Day 168)	Mohs Surgery For Basal Cell Removed
Mohs surgery*	02 Feb 2021 (Study Day 163) - 02 Feb 2021 (Study Day 163)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fall	Grade 1/mild	Not applicable	30 Sep 2020 (Study Day 38) - 30 Sep 2020 (Study Day 38)
Urinary Tract Infection	Grade 1/mild	Not related	04 Dec 2020 (Study Day 103) - 15 Dec 2020 (Study Day 114)
Arthralgia	Grade 1/mild	Not related	15 Dec 2020 (Study Day 114) - 15 Dec 2020 (Study Day 114)
Micrographic Skin Surgery	Grade 2/moderate	Not related	02 Feb 2021 (Study Day 163) - 02 Feb 2021 (Study Day 163)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2315 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Osteoarthritis Right Hip	SAE	Grade 4	Not related	09 Sep 2020 (Study Day 17) – 10 Sep 2020 (Study Day 18)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2315, a 72-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 22 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Sep 2020 (Study Day 17), 16 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. The IP dose was not changed due to the osteoarthritis right hip. The event of osteoarthritis right hip lasted for 2 days, after which it was considered to be recovered/resolved on 10 Sep 2020 (Study Day 18). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000337	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Carpal tunnel decompression	Bilateral carpal tunnel release	Not reported
Carpal tunnel syndrome	Bilateral carpal tunnel syndrome	Not reported
Cataract	Bilateral cataracts	Not reported
Cholecystectomy	Cholecystectomy	Not reported
Cholecystitis	Cholecystitis	Not reported
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	Not reported - Ongoing
Drug hypersensitivity	Allergy to diclofenac	Not reported - Ongoing
Fibromyalgia	Fibromyalgia	Not reported - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	Not reported - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Not reported - Ongoing
Intraocular lens implant	Intraoccular lens implants-bilateral	Not reported
Nephrolithiasis	Renal calculi	Not reported
Osteoarthritis	Osteoarthritis left shoulder	Not reported
Shoulder arthroplasty	Left shoulder replaced	Not reported
Drug hypersensitivity	Allergies, morphine	1980 - Ongoing
Drug hypersensitivity	Allergy, codeine	1980 - Ongoing
Drug hypersensitivity	Allergy, hydrocodone	1980 - Ongoing
Seasonal allergy	Allergies, seasonal	1980 - Ongoing
Type 2 diabetes mellitus	Diabetes, type ii	1980 - Ongoing
Osteoarthritis	Osteoarthritis - right hip	1998 - Ongoing
Hysterectomy	Hysterectomy	2005 - 2005
Postmenopause	Postmenopausal	2005 - Ongoing
Depression	Depression	2013 - Ongoing
Hypertension	Hypertension	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	Not reported - Ongoing	Fibromyalgia Pain
Paracetamol	2008 - Ongoing	Degenerative Osteoarthritis Joint Disease
Paroxetine	2013 - Ongoing	Depression
Hydrochlorothiazide; triamterene	2014 - Ongoing	Hypertension
Preop - chest x-ray*	03 Sep 2020 (Study Day 11) - 03 Sep 2020 (Study Day 11)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hip replacement - right hip*	09 Sep 2020 (Study Day 17) - 09 Sep 2020 (Study Day 17)	Medical History
Levofloxacin hemihydrate	09 Sep 2020 (Study Day 17) - Ongoing	Post Operative Anti Coagulant
Ondansetron	09 Sep 2020 (Study Day 17) - 10 Sep 2020 (Study Day 18)	Nausea Prophylaxis
Preoperative bloodwork*	09 Sep 2020 (Study Day 17) - 09 Sep 2020 (Study Day 17)	Adverse Event
Xray- pelvis*	09 Sep 2020 (Study Day 17) - 09 Sep 2020 (Study Day 17)	Adverse Event
Tramadol	11 Sep 2020 (Study Day 19) - Ongoing	Right Hip Surgical Pain Secondary To Osteoarthritis
Apixaban	12 Sep 2020 (Study Day 20) - Ongoing	Right Arthroplasty Secondary To Right Hip Osteoarthritis
Azithromycin	12 Sep 2020 (Study Day 20) - Ongoing	Urinary Tract Pain
Celecoxib	12 Sep 2020 (Study Day 20) - Ongoing	Osteoarthritis Rt Hip
Oxycodone hydrochloride; paracetamol	12 Sep 2020 (Study Day 20) - Ongoing	Right Hip Arthroplasty Pain Secondary To Right Hip Osteoarthritis
Influenza vaccine	21 Oct 2020 (Study Day 59) - 21 Oct 2020 (Study Day 59)	Seasonal Influenza
Varicella zoster vaccine	21 Oct 2020 (Study Day 59) - 21 Oct 2020 (Study Day 59)	Shingles

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	26 Aug 2020 (Study Day 3) - 10 Sep 2020 (Study Day 18)
Headache	Grade 1/mild	Related	26 Aug 2020 (Study Day 3) - 10 Sep 2020 (Study Day 18)
Myalgia	Grade 1/mild	Related	26 Aug 2020 (Study Day 3) - 10 Sep 2020 (Study Day 18)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2367 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 2/moderate	Not related	24 Nov 2020 (Study Day 90) – 27 Nov 2020 (Study Day 93)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2367, a 39-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Nov 2020 (Study Day 90), 89 days after the first dose and 57 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 4 days, after which it was considered to be recovered/resolved on 27 Nov 2020 (Study Day 93). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000903	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

FDA-CBER-2022-1614-3378619

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Type 1 diabetes mellitus	Diabetes type i	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2018 - Ongoing	Hypertension
Insulin glargine	2018 - Ongoing	Diabetes Type 2
Insulin lispro	2018 - Ongoing	Diabetes Type 2
Losartan	2018 - Ongoing	Hypertension
Rosuvastatin	2018 - Ongoing	Hypercholesterolemia
Paracetamol	02 Sep 2020 (Study Day 7) - 02 Sep 2020 (Study Day 7)	Headache - Postdose
Influenza vaccine	03 Sep 2020 (Study Day 8) - 03 Sep 2020 (Study Day 8)	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2388 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Oct 2020 (Study Day 51)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Vertebral Foraminal Stenosis/Lumbar Canal And Foramina Stenosis	SAE	Grade 4	Not related	25 Sep 2020 (Study Day 29) – 30 Sep 2020 (Study Day 34)	Recovered/resolved
Incision Site Pain/Lumbar Pain At Surgery Site.	SAE	Grade 4	Not related	08 Oct 2020 (Study Day 42) – 09 Oct 2020 (Study Day 43)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2388, a 59-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 17 Oct 2020 (Study Day 51). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 29), 28 days after the first dose and 22 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of vertebral foraminal stenosis. The IP dose was delayed due to the lumbar canal and foramina stenosis. The event of lumbar canal and foramina stenosis lasted for 6 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 34). The investigator assessed the event of vertebral foraminal stenosis to be not related to the IP.

On 08 Oct 2020 (Study Day 42), 41 days after the first dose and 9 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of incision site pain. The IP dose was delayed due to the lumbar pain at surgery site.. The event of lumbar pain at surgery site. lasted for 2 days, after which it was considered to be recovered/resolved on 09 Oct 2020 (Study Day 43). The investigator assessed the event of incision site pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000391	Vertebral foraminal stenosis
MOD-2020-000391	Incision site pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Spinal osteoarthritis	Advanced multilevel degenerative changes spondylosis of the lumbar spine	Not reported - Ongoing
Vertebral foraminal stenosis	Multilevel foraminal lumbar stenosis	Not reported - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Neuropathy peripheral	Neuropathy with feet	2005 - Ongoing
Gastrooesophageal reflux disease	Gerd	2015 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atenolol	2015 - Ongoing	Hypertension
Lisinopril	2015 - Ongoing	Hypertension
Omeprazole	2015 - 30 Sep 2020 (Study Day 34)	Gerd
Gabapentin	2018 - Ongoing	Neuropathy To Feet
Ct abd and pelvis w/c*	14 Sep 2020 (Study Day 18) - 14 Sep 2020 (Study Day 18)	Diagnostic
Ct l spine w/o contrast*	14 Sep 2020 (Study Day 18) - 14 Sep 2020 (Study Day 18)	Diagnostic
Laminectomy*	25 Sep 2020 (Study Day 29) - 25 Sep 2020 (Study Day 29)	Adverse Event
Diazepam	27 Sep 2020 (Study Day 31) - Ongoing	Lumbar Canal And Foramina Stenosis
Amlodipine	30 Sep 2020 (Study Day 34) - Ongoing	Hypertension
Dexamethasone	30 Sep 2020 (Study Day 34) - 06 Oct 2020 (Study Day 40)	Lumbar Canal And Foramina Stenosis
Dicycloverine	30 Sep 2020 (Study Day 34) - Ongoing	Cholelithiasis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fentanyl	30 Sep 2020 (Study Day 34) - Ongoing	S/P Laminectomy Pain Management
Melatonin	30 Sep 2020 (Study Day 34) - Ongoing	Insomnia
Omeprazole	30 Sep 2020 (Study Day 34) - Ongoing	Gerd
Oxycodone; paracetamol	30 Sep 2020 (Study Day 34) - Ongoing	Lumbar Canal And Foramina Stenosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diverticulum Intestinal	Grade 1/mild	Not related	01 Sep 2020 (Study Day 5) - 17 Oct 2020 (Study Day 51)
Cholelithiasis	Grade 1/mild	Not related	14 Sep 2020 (Study Day 18) - Ongoing
Hepatic Steatosis	Grade 1/mild	Not related	14 Sep 2020 (Study Day 18) - Ongoing
Hiatus Hernia	Grade 1/mild	Not related	14 Sep 2020 (Study Day 18) - Ongoing
Hypertension	Grade 2/moderate	Not related	30 Sep 2020 (Study Day 34) - 17 Oct 2020 (Study Day 51)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2452 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cervical Vertebral Fracture/C3 Cervical Fracture	SAE	Grade 4	Not related	26 Oct 2020 (Study Day 55) – 30 Oct 2020 (Study Day 59)	Recovered/resolved
Facial Bones Fracture/Nasal Fracture	SAE	Grade 4	Not related	26 Oct 2020 (Study Day 55) – 30 Oct 2020 (Study Day 59)	Recovered/resolved
Fall/Fall	SAE	Grade 4	Not related	26 Oct 2020 (Study Day 55) – 26 Oct 2020 (Study Day 55)	Recovered/resolved
Skin Laceration/Facial Laceration	SAE	Grade 4	Not related	26 Oct 2020 (Study Day 55) – 30 Oct 2020 (Study Day 59)	Recovered/resolved
Subdural Haematoma/Subdural Hematoma	SAE	Grade 4	Not related	26 Oct 2020 (Study Day 55) – 30 Oct 2020 (Study Day 59)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2452, a 80-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 02 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Oct 2020 (Study Day 55), 54 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of fall. Action taken with the IP was not applicable. The event of fall lasted for 1 day, after which it was considered to be recovered/resolved on 26 Oct 2020 (Study Day 55). The investigator assessed the event of fall to be not related to the IP.

On 26 Oct 2020 (Study Day 55), 54 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cervical vertebral fracture. Action taken with the IP was not applicable. The event of c3 cervical fracture lasted for 5 days, after which it was considered to be recovered/resolved on 30 Oct 2020 (Study Day 59). The investigator assessed the event of cervical vertebral fracture to be not related to the IP.

On 26 Oct 2020 (Study Day 55), 54 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of facial bones fracture. Action taken with the IP was not applicable. The event of nasal fracture lasted for 5 days, after which it was considered to be recovered/resolved on 30 Oct 2020 (Study Day 59). The investigator assessed the event of facial bones fracture to be not related to the IP.

On 26 Oct 2020 (Study Day 55), 54 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of skin laceration. Action taken with the IP was not applicable. The event of facial laceration lasted for 5 days, after which it was considered to be recovered/resolved on 30 Oct 2020 (Study Day 59). The investigator assessed the event of skin laceration to be not related to the IP.

On 26 Oct 2020 (Study Day 55), 54 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of subdural haematoma. Action taken with the IP was not applicable. The event of subdural hematoma lasted for 5 days, after which it was considered to be recovered/resolved on 30 Oct 2020 (Study Day 59). The investigator assessed the event of subdural haematoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000578	Cervical vertebral fracture
MOD-2020-000578	Facial bones fracture
MOD-2020-000578	Fall
MOD-2020-000578	Skin laceration
MOD-2020-000578	Subdural haematoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	Not reported - Ongoing
Skin cosmetic procedure	Unknown cosmetic procedure	Not reported
Depression	Depression	01 Jan 1970 (Study Day -18507) - Ongoing
Hypercholesterolaemia	Hypercholesterolemi	01 Jan 1980 (Study Day -14855) - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	01 Jan 1980 (Study Day -14855) - Ongoing
Neuropathy peripheral	Neuropathy	01 Jan 2005 (Study Day -5723) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Other dermatologicals	Not reported - Not reported	Cosmetic
Atorvastatin	01 Jan 1980 (Study Day -14855) - Ongoing	Hyperlipidemia
Lisinopril	01 Jan 1980 (Study Day -14855) - 30 Oct 2020 (Study Day 59)	Hypertension
Buspirone	01 Jan 2000 (Study Day -7550) - 30 Oct 2020 (Study Day 59)	Depression
Duloxetine	01 Jan 2005 (Study Day -5723) - Ongoing	Neuropathy (Motor) (Lower Extremity)
Glucosamine	01 Jan 2005 (Study Day -5723) - Ongoing	Supplement
Vitamins nos	01 Jan 2007 (Study Day -4993) - Ongoing	Supplement
Acetylsalicylic acid	01 Jan 2010 (Study Day -3897) - Ongoing	Cardiac
Ascorbic acid; betacarotene; cupric oxide; tocopheryl acetate; zinc oxide	01 Jan 2019 (Study Day -610) - Ongoing	Supplement
Paracetamol	03 Oct 2020 (Study Day 32) - 03 Oct 2020 (Study Day 32)	Soreness At Injection Site
Cat scan head and brain*	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Adverse Event
Ceftriaxone	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Ae # 1 Infection Preventative
Cervical collar*	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Adverse Event
Ct cervial spine without contrast*	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Adverse Event
Ct maxillofacial without contracet*	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Adverse Event
Flexion extension x-ray of cervical spine*	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Adverse Event
Occupational therapy*	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Adverse Event
Physical therapy*	26 Oct 2020 (Study Day 55) - 26 Oct 2020 (Study Day 55)	Adverse Event
Labetalol	27 Oct 2020 (Study Day 56) - 27 Oct 2020 (Study Day 56)	Hypertension
Lisinopril	27 Oct 2020 (Study Day 56) - 27 Oct 2020 (Study Day 56)	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Morphine	27 Oct 2020 (Study Day 56) - 28 Oct 2020 (Study Day 57)	Pain Prn- Cervical Spine Pain, Nasal Fracture And Facial Laceration Secondary To Fall
Nicardipine	27 Oct 2020 (Study Day 56) - 28 Oct 2020 (Study Day 57)	Subdural Hematoma
Ondansetron	27 Oct 2020 (Study Day 56) - 28 Oct 2020 (Study Day 57)	Nausea Due To Subdural Hematoma
Sodium chloride	27 Oct 2020 (Study Day 56) - 29 Oct 2020 (Study Day 58)	Dihydration -
Sodium chloride	27 Oct 2020 (Study Day 56) - 29 Oct 2020 (Study Day 58)	Laceration Secondary To Fall
Buspirone	28 Oct 2020 (Study Day 57) - 30 Oct 2020 (Study Day 59)	Anxiety
Hydrocodone; paracetamol	28 Oct 2020 (Study Day 57) - 29 Oct 2020 (Study Day 58)	Subdural Hematoma, Nasal Fracture, And Facial Laceration Pain - Prophylaxis
Lisinopril	28 Oct 2020 (Study Day 57) - 28 Oct 2020 (Study Day 57)	Hypertension
Sodium chloride	28 Oct 2020 (Study Day 57) - 28 Oct 2020 (Study Day 57)	Dihydration - Prophylaxis
Famotidine	29 Oct 2020 (Study Day 58) - 29 Oct 2020 (Study Day 58)	Heartburn Preventative
Buspirone	30 Oct 2020 (Study Day 59) - Ongoing	Anxiety
Lisinopril	30 Oct 2020 (Study Day 59) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 1/mild	Not related	30 Oct 2020 (Study Day 59) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378627

Participant Number:	US322-2462 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urosepsis/Bladder Infection/ Urosepsis	SAE	Grade 4	Not related	25 Jan 2021 (Study Day 146) – Ongoing	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2462, a 63-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Jan 2021 (Study Day 146), 145 days after the first dose and 115 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of urosepsis. Action taken with the IP was not applicable. The event of bladder infection/ urosepsis was considered to be ongoing. The investigator assessed the event of urosepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010353	Urosepsis
MOD-2021-117004	Bacterial infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myalgia	Generalized muscle pain	01 Jan 2005 (Study Day -5723) - Ongoing
Hepatic cirrhosis	Cirrhosis	01 Aug 2013 (Study Day -2589) - Ongoing
Drug hypersensitivity	Allergies, bactrim	01 Aug 2014 (Study Day -2224) - Ongoing
Hypertension	Hypertension	01 Aug 2014 (Study Day -2224) - Ongoing
Atrial fibrillation	Atrial fibrillation	01 Aug 2015 (Study Day -1859) - Ongoing
Cholecystectomy	Cholescyctectomy	01 Aug 2015 (Study Day -1859) - 01 Aug 2015 (Study Day -1859)
Cholecystitis	Cholecystitis	01 Aug 2015 (Study Day -1859) - 01 Aug 2015 (Study Day -1859)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diltiazem hydrochloride	Not reported - Ongoing	Atrial Fibrillation
Ibuprofen	01 Jan 2005 (Study Day -5723) - Ongoing	Generalized Muscle Pain
Lisinopril	2014 - Ongoing	Hypertension
Metoprolol	2015 - Ongoing	Hypertension
Acetylsalicylic acid	01 Jan 2018 (Study Day -975) - Ongoing	Cardiac Health
Ibuprofen	03 Sep 2020 (Study Day 2) - 03 Sep 2020 (Study Day 2)	Fever
Influenza vaccine	21 Oct 2020 (Study Day 50) - 21 Oct 2020 (Study Day 50)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US322-2554 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/Diverticulitis	SAE	Grade 4	Not related	24 Jan 2021 (Study Day 140) – 07 Feb 2021 (Study Day 154)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2554, a 69-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Jan 2021 (Study Day 140), 139 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of diverticulitis. Action taken with the IP was not applicable. The event of diverticulitis lasted for 15 days, after which it was considered to be recovered/resolved on 07 Feb 2021 (Study Day 154). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009946	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	1985 - 1985
Hypertension	Hypertension	1995 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Insomnia	Insomnia	Jan 2005 - Ongoing
Constipation	Constipation	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine hydrochloride	2004 - Ongoing	Back Pain
Meloxicam	2004 - Ongoing	Back Pain
Lisinopril	2005 - Ongoing	Hypertension
Pravastatin	2005 - Ongoing	Hyperlipidemia
Zolpidem tartrate	2005 - Ongoing	Insomnia
Docusate sodium	2010 - Ongoing	Constipation
Acetylsalicylic acid	03 Jan 2010 (Study Day -3900) - Ongoing	Cardiac
Influenza vaccine	22 Oct 2020 (Study Day 46) - 22 Oct 2020 (Study Day 46)	Seasonal Influenza
Abd/pelvis w/cont-ct scan*	28 Jan 2021 (Study Day 144) - 28 Jan 2021 (Study Day 144)	Adverse Event
Magnesium hydroxide	29 Jan 2021 (Study Day 145) - 30 Jan 2021 (Study Day 146)	Constipation
Morphine	29 Jan 2021 (Study Day 145) - 29 Jan 2021 (Study Day 145)	Diverticulitis
Oxycodone hydrochloride	29 Jan 2021 (Study Day 145) - 30 Jan 2021 (Study Day 146)	Diverticulitis
Piperacillin sodium; tazobactam sodium	29 Jan 2021 (Study Day 145) - 29 Jan 2021 (Study Day 145)	Diverticulitis
Ciprofloxacin	31 Jan 2021 (Study Day 147) - 07 Feb 2021 (Study Day 154)	Diverticulitis
Metronidazole	31 Jan 2021 (Study Day 147) - 07 Feb 2021 (Study Day 154)	Diverticulitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Musculoskeletal Chest Pain	Grade 1/mild	Not related	14 Feb 2021 (Study Day 161) - Ongoing
Myalgia	Grade 1/mild	Not related	14 Feb 2021 (Study Day 161) - 24 Feb 2021 (Study Day 171)
Ear Pain	Grade 1/mild	Not related	14 Feb 2021 (Study Day 161) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2611 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Basal Ganglia Haemorrhage/Left Basal Ganglia Hemorrhage	SAE	Grade 4	Not related	29 Oct 2020 (Study Day 43) – 10 Nov 2020 (Study Day 55)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2611, a 55-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Oct 2020 (Study Day 43), 42 days after the first dose and 14 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of basal ganglia haemorrhage. Action taken with the IP was not applicable. The event of left basal ganglia hemorrhage lasted for 13 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 55). The investigator assessed the event of basal ganglia haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000591	Basal ganglia hemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gerd	2014 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2014 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2014 - Ongoing
Insomnia	Insomnia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dapagliflozin propanediol monohydrate; metformin hydrochloride	2014 - Ongoing	Diabetes Type Ii
Dulaglutide	2014 - Ongoing	Diabetestype Ii
Metformin	2014 - Ongoing	Diabetes Type Ii
Omeprazole	2014 - Ongoing	Gerd
Rosuvastatin	2014 - Ongoing	Hypercholesterolemia/ Dyslipidemia
Zolpidem tartrate	2019 - Ongoing	Insomnia
Color/spectral doppler*	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Adverse Event
Ct scan of the brain*	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Adverse Event
Ecg*	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Adverse Event
Famotidine	29 Oct 2020 (Study Day 43) - Ongoing	Gerd
Glucose	29 Oct 2020 (Study Day 43) - 30 Oct 2020 (Study Day 44)	Diabetes Type Ii
Nicardipine	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Hypertension
Sonogram - lower right extremities*	29 Oct 2020 (Study Day 43) - 29 Oct 2020 (Study Day 43)	Adverse Event
Chemistry, pt, ptt, and complete blood count*	31 Oct 2020 (Study Day 45) - 31 Oct 2020 (Study Day 45)	Adverse Event
Mra*	31 Oct 2020 (Study Day 45) - 31 Oct 2020 (Study Day 45)	Adverse Event
Mri head and neck*	31 Oct 2020 (Study Day 45) - 31 Oct 2020 (Study Day 45)	Adverse Event
Amitriptyline	12 Jan 2021 (Study Day 118) - Ongoing	Nerve Pain From Stroke He Recently Had
Baclofen	12 Jan 2021 (Study Day 118) - Ongoing	Nerve Pain From Stroke He Recently Had

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	12 Jan 2021 (Study Day 118) - Ongoing	Nerve Pain From Stroke He Recently Had
Tramadol	12 Jan 2021 (Study Day 118) - Ongoing	Nerve Pain Secondary To Stroke

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Aphasia	Grade 3/severe	Not related	29 Oct 2020 (Study Day 43) - 10 Nov 2020 (Study Day 55)
Dyslipidaemia	Grade 3/severe	Not related	29 Oct 2020 (Study Day 43) - 15 Nov 2020 (Study Day 60)
Gait Disturbance	Grade 3/severe	Not related	29 Oct 2020 (Study Day 43) - 10 Nov 2020 (Study Day 55)
Hypertension	Grade 3/severe	Not related	29 Oct 2020 (Study Day 43) - 10 Nov 2020 (Study Day 55)
Neuralgia	Grade 3/severe	Not related	12 Jan 2021 (Study Day 118) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US324-2017 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bronchitis/Acute Bronchitis	SAE	Grade 3/severe	Not related	17 Oct 2020 (Study Day 72) – 27 Oct 2020 (Study Day 82)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2017, a 64-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Oct 2020 (Study Day 72), 71 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of bronchitis. Action taken with the IP was not applicable. The event of acute bronchitis lasted for 11 days, after which it was considered to be recovered/resolved on 27 Oct 2020 (Study Day 82). The investigator assessed the event of bronchitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000508	Bronchitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Obesity	Obesity	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atenolol	2015 - Ongoing	Hypertension
Hydrochlorothiazide; triamterene	2015 - Ongoing	Hypertension
Tamsulosin	2019 - Ongoing	Benign Prostatic Hyperplasia
Paracetamol	08 Sep 2020 (Study Day 33) - 08 Sep 2020 (Study Day 33)	Injection Site Pain
Azithromycin	18 Oct 2020 (Study Day 73) - 20 Oct 2020 (Study Day 75)	Acute Bronchitis
Brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride	18 Oct 2020 (Study Day 73) - 20 Oct 2020 (Study Day 75)	Acute Bronchitis
Salbutamol	18 Oct 2020 (Study Day 73) - 26 Oct 2020 (Study Day 81)	Acute Bronchitis
Azithromycin	19 Oct 2020 (Study Day 74) - 20 Oct 2020 (Study Day 75)	Acute Bronchitis
Paracetamol	19 Oct 2020 (Study Day 74) - 21 Oct 2020 (Study Day 76)	Bronchitis
Codeine; promethazine	21 Oct 2020 (Study Day 76) - 27 Oct 2020 (Study Day 82)	Acute Bronchitis
Benzonatate	22 Oct 2020 (Study Day 77) - 27 Oct 2020 (Study Day 82)	Acute Bronchitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US324-2051 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ankle Fracture/Trimalleolar Ankle Fracture, Right	SAE	Grade 3/severe	Not related	01 Nov 2020 (Study Day 86) – 31 Mar 2021 (Study Day 236)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2051, a 54-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 86), 85 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of ankle fracture. Action taken with the IP was not applicable. The event of trimalleolar ankle fracture, right lasted for 151 days, after which it was considered to be recovered/resolved on 31 Mar 2021 (Study Day 236). The investigator assessed the event of ankle fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000721	Ankle fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Drug allergy-codeine	2000 - Ongoing
Anxiety	Anxiety	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2006 - Ongoing
Insomnia	Insomnia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram	2005 - Ongoing	Anxiety
Pravastatin	2006 - Ongoing	Hyperlipidemia
Hyaluronic acid	2015 - 2016	Cosmetic
Trazodone	2015 - Ongoing	Insomnia
Amoxicillin	22 Sep 2020 (Study Day 46) - 02 Oct 2020 (Study Day 56)	Acute Otitis Media, Right
Ibuprofen	22 Sep 2020 (Study Day 46) - 02 Oct 2020 (Study Day 56)	Acute Otitis Media, Right
Ofloxacin	22 Sep 2020 (Study Day 46) - 02 Oct 2020 (Study Day 56)	Acute Otitis Media, Right
Calcium chloride; potassium chloride; sodium lactate	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Trimalleolar Ankle Fracture (Prophylaxis)
Computerized tomography*	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Adverse Event
Ekg*	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Adverse Event
Ondansetron	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Trimalleolar Ankle Fracture/Nausea
Sodium chloride	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Trimalleolar Ankle Fracture, Prophylaxis
Splint, right ankle (pre-surgery)*	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Adverse Event
Sutures*	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Adverse Event
Xray, right ankle*	02 Nov 2020 (Study Day 87) - 02 Nov 2020 (Study Day 87)	Adverse Event
Anesthetics, general	03 Nov 2020 (Study Day 88) - 03 Nov 2020 (Study Day 88)	Trimalleolar Ankle Fracture, Right
Ankle repair, right (small fragment plate and screws)*	03 Nov 2020 (Study Day 88) - 03 Nov 2020 (Study Day 88)	Adverse Event
Splint, right ankle (post surgery)*	03 Nov 2020 (Study Day 88) - 03 Nov 2020 (Study Day 88)	Adverse Event
Acetylsalicylic acid	05 Nov 2020 (Study Day 90) - 23 Dec 2020 (Study Day 138)	Trimalleolar Ankle Fracture, Right
Bisacodyl	05 Nov 2020 (Study Day 90) - 12 Nov 2020 (Study Day 97)	Constipation After Surgery

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	05 Nov 2020 (Study Day 90) - Ongoing	Trimalleolar Ankle Fracture, Right
Oxycodone	05 Nov 2020 (Study Day 90) - 12 Nov 2020 (Study Day 97)	Trimalleolar Ankle Fracture, Right
Paracetamol	05 Nov 2020 (Study Day 90) - 30 Dec 2020 (Study Day 145)	Trimalleolar Ankle Fracture, Right
Meloxicam	07 Jan 2021 (Study Day 153) - Ongoing	Trimalleolar Ankle Fracture, Right

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Otitis Media Acute	Grade 2/moderate	Not related	19 Sep 2020 (Study Day 43) - 02 Oct 2020 (Study Day 56)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378640

Participant Number:	US324-2107 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	15 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Cerebrovascular Accident	SAE	Grade 3/severe	Not related	09 Jan 2021 (Study Day 148) – 09 Jan 2021 (Study Day 148)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2107, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 15 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 14 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Jan 2021 (Study Day 148), 147 days after the first dose and 117 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of cerebrovascular accident lasted for 1 day, after which it was considered to be recovered/resolved on 09 Jan 2021 (Study Day 148). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003274	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	1970 - 1970
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	01 Jan 1998 (Study Day -8262) - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Cholecystectomy	Cholecystectomy	Nov 2019 - Nov 2019
Cholelithiasis	Gallstones	Nov 2019 - Nov 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	01 Jan 1998 (Study Day -8262) - Ongoing	Gastroesophageal Reflux Disease
Vitamins nos	01 Jan 2008 (Study Day -4610) - Ongoing	Diet Supplement
Influenza vaccine	10 Oct 2020 (Study Day 57) - 10 Oct 2020 (Study Day 57)	Prophylaxis For Influenza
Acetylsalicylic acid	09 Jan 2021 (Study Day 148) - 12 Jan 2021 (Study Day 151)	Cerebral Vascular Accident
Alteplase	09 Jan 2021 (Study Day 148) - 09 Jan 2021 (Study Day 148)	Celebral Vascular Accident
Aluminium hydroxide; magnesium hydroxide; simeticone	09 Jan 2021 (Study Day 148) - 12 Jan 2021 (Study Day 151)	Cerebral Vascular Accident
Calcium gluconate; sodium chloride	09 Jan 2021 (Study Day 148) - 09 Jan 2021 (Study Day 148)	Cerebral Vascular Accident
Ct/head and neck*	09 Jan 2021 (Study Day 148) - 09 Jan 2021 (Study Day 148)	Adverse Event
Echo*	09 Jan 2021 (Study Day 148) - 09 Jan 2021 (Study Day 148)	Adverse Event
Glucose	09 Jan 2021 (Study Day 148) - 12 Jan 2021 (Study Day 151)	Cerebral Vascular Accident
Insulin lispro	09 Jan 2021 (Study Day 148) - 12 Jan 2021 (Study Day 151)	Cerebral Vascular Accident
Iopamidol	09 Jan 2021 (Study Day 148) - 09 Jan 2021 (Study Day 148)	Cerebral Vascular Accident
Methylprednisolone sodium succinate	09 Jan 2021 (Study Day 148) - 12 Jan 2021 (Study Day 151)	Cerebral Vascular Accident
Mri*	09 Jan 2021 (Study Day 148) - 09 Jan 2021 (Study Day 148)	Adverse Event
Paracetamol	09 Jan 2021 (Study Day 148) - 12 Jan 2021 (Study Day 151)	Cerebral Vascular Accident

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	09 Jan 2021 (Study Day 148) - 09 Jan 2021 (Study Day 148)	Cerebral Vascular Accident
Acetylsalicylic acid	10 Jan 2021 (Study Day 149) - Ongoing	Post Cerebrovascular Accident, Prophylaxis For Heart Health
Atorvastatin	10 Jan 2021 (Study Day 149) - Ongoing	Hyperlipidemia
Heparin	11 Jan 2021 (Study Day 150) - 12 Jan 2021 (Study Day 151)	Cerebral Vascular Accident
Perflutren	11 Jan 2021 (Study Day 150) - 11 Jan 2021 (Study Day 150)	Cerebral Vascular Accident
Clopidogrel	12 Jan 2021 (Study Day 151) - Ongoing	Post Cerebrovascular Accident, Prophylaxis For Heart Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US324-2231 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Uncontrolled Hypertension	SAE	Grade 2/moderate	Not related	08 Sep 2020 (Study Day 13) – 09 Sep 2020 (Study Day 14)	Recovered/resolved
Aortic Aneurysm/Worsening Aortic Aneurysm	SAE	Grade 4	Not related	08 Oct 2020 (Study Day 43) – 28 Oct 2020 (Study Day 63)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2231, a 76-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 13), 12 days after the first dose and 17 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of hypertension. The IP dose was not changed due to the uncontrolled hypertension. The event of uncontrolled hypertension lasted for 2 days, after which it was considered to be recovered/resolved on 09 Sep 2020 (Study Day 14). The investigator assessed the event of hypertension to be not related to the IP.

On 08 Oct 2020 (Study Day 43), 42 days after the first dose and 13 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of aortic aneurysm. Action taken with the IP was not applicable. The event of worsening aortic aneurysm lasted for 21 days, after which it was considered to be recovered/resolved on 28 Oct 2020 (Study Day 63). The investigator assessed the event of aortic aneurysm to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000285	Hypertension
MOD-2020-000818	Aortic aneurysm

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Endometriosis	Endometriosis	1970 - 1975
Hysterectomy	Hysterectomy	1975 - 1975
Postmenopause	Postmenopausal	1976 - Ongoing
Drug hypersensitivity	Drug allergy-ibuprofen	01 Jan 1990 (Study Day -11196) - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	2015 - Ongoing
Hepatic steatosis	Fatty liver	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	24 Oct 2016 (Study Day -1403) - Ongoing
Obesity	Obesity	24 Oct 2016 (Study Day -1403) - Ongoing
Aortic aneurysm	Thoracic aortic aneurysm without rupture	2017 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Headache	Headaches, occasional	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	01 Jan 2011 (Study Day -3526) - Ongoing	Heart Health
Amlodipine	01 Jan 2016 (Study Day -1700) - 09 Sep 2020 (Study Day 14)	Hypertension
Metoprolol succinate	01 Jan 2016 (Study Day -1700) - Ongoing	Hypertension
Paracetamol	2018 - Ongoing	Headaches, Occasional
Omeprazole	01 Feb 2018 (Study Day -938) - Ongoing	Gastroesophageal Reflux Disease
Ezetimibe	01 Sep 2020 (Study Day 6) - 08 Feb 2021 (Study Day 166)	Hyperlipidemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	09 Sep 2020 (Study Day 14) - 06 Nov 2020 (Study Day 72)	Hypertension
Prazosin	09 Sep 2020 (Study Day 14) - Ongoing	Hypertension
Paracetamol	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Injection Site Pain, Left Arm
Cardiac catheterization*	09 Oct 2020 (Study Day 44) - 09 Oct 2020 (Study Day 44)	Adverse Event
Chlorhexidine	27 Oct 2020 (Study Day 62) - 31 Oct 2020 (Study Day 66)	Worsening Aortic Aneurysm
Chlorhexidine gluconate	27 Oct 2020 (Study Day 62) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Heparin	27 Oct 2020 (Study Day 62) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Metoprolol tartrate	27 Oct 2020 (Study Day 62) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Mupirocin	27 Oct 2020 (Study Day 62) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
1-v coronary artery bypass graft*	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Adverse Event
Acetylsalicylic acid	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Albumin human	28 Oct 2020 (Study Day 63) - 01 Nov 2020 (Study Day 67)	Worsening Of Aortic Aneurysm
Aminocaproic acid	28 Oct 2020 (Study Day 63) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Anticoagulant citrate dextrose	28 Oct 2020 (Study Day 63) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Ascending aortic replacement*	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Adverse Event
Bacitracin	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Bupivacaine	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Calcium chloride	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Calcium chloride; potassium chloride; sodium lactate	28 Oct 2020 (Study Day 63) - 31 Oct 2020 (Study Day 66)	Worsening Aortic Aneurysm
Cefazolin	28 Oct 2020 (Study Day 63) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Dexmedetomidine	28 Oct 2020 (Study Day 63) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Electrolyte solutions [umbrella term]	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Electrolytes nos	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Epinephrine	28 Oct 2020 (Study Day 63) - 01 Nov 2020 (Study Day 67)	Worsening Aortic Aneurysm
Fentanyl	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glucose	28 Oct 2020 (Study Day 63) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Hydromorphone	28 Oct 2020 (Study Day 63) - 04 Nov 2020 (Study Day 70)	Worsening Aortic Aneurysm
Insulin	28 Oct 2020 (Study Day 63) - 31 Oct 2020 (Study Day 66)	Worsening Aortic Aneurysm
Lidocaine	28 Oct 2020 (Study Day 63) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Magnesium sulfate	28 Oct 2020 (Study Day 63) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Mannitol	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Milrinone	28 Oct 2020 (Study Day 63) - 01 Nov 2020 (Study Day 67)	Worsening Aortic Aneurysm
Norepinephrine bitartrate	28 Oct 2020 (Study Day 63) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Paracetamol	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Paracetamol	28 Oct 2020 (Study Day 63) - 01 Nov 2020 (Study Day 67)	Worsening Aortic Aneurysm
Phenylephrine	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Potassium chloride	28 Oct 2020 (Study Day 63) - 01 Nov 2020 (Study Day 67)	Worsening Aortic Aneurysm
Potassium chloride	28 Oct 2020 (Study Day 63) - 03 Nov 2020 (Study Day 69)	Worsening Aortic Aneurysm
Propofol	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Sodium bicarbonate	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Sodium chloride	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Vancomycin	28 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 63)	Worsening Aortic Aneurysm
Vasopressin	28 Oct 2020 (Study Day 63) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Acetylsalicylic acid	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Ascorbic acid	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Docusate sodium	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Esomeprazole	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Ezetimibe	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Glucose	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Macrogol	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	29 Oct 2020 (Study Day 64) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Oxycodone	29 Oct 2020 (Study Day 64) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Pantoprazole	29 Oct 2020 (Study Day 64) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Potassium chloride	29 Oct 2020 (Study Day 64) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Sodium phosphate	29 Oct 2020 (Study Day 64) - 29 Oct 2020 (Study Day 64)	Worsening Aortic Aneurysm
Clopidogrel	30 Oct 2020 (Study Day 65) - Ongoing	Prophylaxis, Antiplatelet, Post Cabg Procedure
Dexamethasone	30 Oct 2020 (Study Day 65) - 30 Oct 2020 (Study Day 65)	Worsening Aortic Aneurysm
Ferrous sulfate	30 Oct 2020 (Study Day 65) - Ongoing	Prophylaxis, Anemia, Post Cabg Procedure
Furosemide	30 Oct 2020 (Study Day 65) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Insulin detemir	30 Oct 2020 (Study Day 65) - 02 Nov 2020 (Study Day 68)	Worsening Aortic Aneurysm
Insulin lispro	30 Oct 2020 (Study Day 65) - 03 Nov 2020 (Study Day 69)	Worsening Aortic Aneurysm
Pantoprazole	30 Oct 2020 (Study Day 65) - 30 Oct 2020 (Study Day 65)	Worsening Aortic Aneurysm
Bumetanide	31 Oct 2020 (Study Day 66) - 31 Oct 2020 (Study Day 66)	Worsening Aortic Aneurysm
Hydrocortisone sodium succinate	31 Oct 2020 (Study Day 66) - 31 Oct 2020 (Study Day 66)	Worsening Aortic Aneurysm
Magnesium sulfate	31 Oct 2020 (Study Day 66) - 31 Oct 2020 (Study Day 66)	Worsening Aortic Aneurysm
Midodrine	31 Oct 2020 (Study Day 66) - 01 Nov 2020 (Study Day 67)	Worsening Aortic Aneurysm
Bumetanide	01 Nov 2020 (Study Day 67) - 01 Nov 2020 (Study Day 67)	Worsening Aortic Aneurysm
Hydralazine	01 Nov 2020 (Study Day 67) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Magnesium sulfate	01 Nov 2020 (Study Day 67) - 01 Nov 2020 (Study Day 67)	Worsening Aortic Aneurysm
Paracetamol	01 Nov 2020 (Study Day 67) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Salbutamol	01 Nov 2020 (Study Day 67) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Atorvastatin	02 Nov 2020 (Study Day 68) - Ongoing	Hypercholesterolemia
Potassium chloride	02 Nov 2020 (Study Day 68) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Losartan	03 Nov 2020 (Study Day 69) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Melatonin	03 Nov 2020 (Study Day 69) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bacitracin	04 Nov 2020 (Study Day 70) - 06 Feb 2021 (Study Day 164)	Worsening Aortic Aneurysm
Piperacillin; tazobactam	04 Nov 2020 (Study Day 70) - 06 Nov 2020 (Study Day 72)	Worsening Aortic Aneurysm
Amoxicillin; clavulanic acid	06 Nov 2020 (Study Day 72) - 12 Nov 2020 (Study Day 78)	Prophylaxis For Post Surgery Infection
Bacitracin	06 Nov 2020 (Study Day 72) - 15 Nov 2020 (Study Day 81)	Prophylaxis, Wound Infection Post Procedure
Losartan	06 Nov 2020 (Study Day 72) - Ongoing	Hypertension
Paracetamol	06 Nov 2020 (Study Day 72) - 01 Dec 2020 (Study Day 97)	Pain, Procedure Coronary Artery Bypass Graft
Tramadol	06 Nov 2020 (Study Day 72) - 20 Nov 2020 (Study Day 86)	Pain, Post Coronary Artery Bypass Graft Procedure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Grade 1/mild	Not related	01 Sep 2020 (Study Day 6) - 08 Feb 2021 (Study Day 166)
Coronary Artery Disease	Grade 3/severe	Not related	15 Oct 2020 (Study Day 50) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378649

Participant Number:	US324-2258 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Community Acquired Pneumonia	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	15 Sep 2020 (Study Day 16) – 22 Oct 2020 (Study Day 53)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2258, a 76-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Sep 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of pneumonia. On 27 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of community acquired pneumonia lasted for 38 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 53). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Chronic asthma	01 Jan 1970 (Study Day -18505) - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	2000 - Ongoing
Osteopenia	Osteopenia	2010 - Ongoing
Drug hypersensitivity	Drug allergy-lisinopril	2012 - Ongoing
Bronchitis chronic	Chronic bronchitis	2015 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Colon cancer	Colon cancer	2019 - 2019
Colon operation	Colon surgery	2019 - 2019
Coronary artery disease	Coronary artery disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2010 - Ongoing	Copd
Acetylsalicylic acid	2015 - Ongoing	Prophylaxis For Heart Health
Calcium	2015 - Ongoing	Prophylaxis For Bone Health
Atorvastatin	01 Jan 2015 (Study Day -2069) - Ongoing	Coronary Artery Disease
Azithromycin	16 Sep 2020 (Study Day 17) - 16 Sep 2020 (Study Day 17)	Pneumonia
Brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride	16 Sep 2020 (Study Day 17) - 22 Oct 2020 (Study Day 53)	Pneumonia
Guaifenesin	16 Sep 2020 (Study Day 17) - 22 Oct 2020 (Study Day 53)	Pneumonia
Azithromycin	17 Sep 2020 (Study Day 18) - 20 Sep 2020 (Study Day 21)	Pneumonia
Doxycycline monohydrate	05 Oct 2020 (Study Day 36) - 15 Oct 2020 (Study Day 46)	Asthma
Prednisone	05 Oct 2020 (Study Day 36) - 09 Oct 2020 (Study Day 40)	Asthma
Budesonide; formoterol	08 Oct 2020 (Study Day 39) - Ongoing	Asthma
Prednisone	10 Oct 2020 (Study Day 41) - 12 Oct 2020 (Study Day 43)	Asthma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pneumonia	Grade 3/severe	Not related	15 Sep 2020 (Study Day 16) - 22 Oct 2020 (Study Day 53)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asthma	Grade 3/severe	Not related	05 Oct 2020 (Study Day 36) - 22 Oct 2020 (Study Day 53)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378652

Participant Number:	US324-2264 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Skin Laceration/Head Laceration	SAE	Grade 3/severe	Not related	20 Nov 2020 (Study Day 81) – 30 Nov 2020 (Study Day 91)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2264, a 49-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 20 Nov 2020 (Study Day 81), 80 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of skin laceration. Action taken with the IP was not applicable. The event of head laceration lasted for 11 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 91). The investigator assessed the event of skin laceration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000905	Skin laceration

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Back pain	1990 - Ongoing
Vasectomy	Vasectomy	1995 - 1995
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1990 - Ongoing	Back Pain
Levothyroxine sodium	2010 - Ongoing	Hypothyroidism
Lisinopril	2015 - Ongoing	Hypertension
Atorvastatin	2017 - Ongoing	Hyperlipidemia
Hyaluronic acid	2019 - 2019	Cosmetic
Influenza vaccine	13 Aug 2020 (Study Day -19) - 13 Aug 2020 (Study Day -19)	Flu Prevention
Lidocaine	20 Nov 2020 (Study Day 81) - 30 Nov 2020 (Study Day 91)	Head Laceration
Mupirocin	20 Nov 2020 (Study Day 81) - Ongoing	Head Laceration
Sutures,head*	20 Nov 2020 (Study Day 81) - 20 Nov 2020 (Study Day 81)	Adverse Event
Nasal reduction*	24 Nov 2020 (Study Day 85) - 24 Nov 2020 (Study Day 85)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Viral Infection	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 40) - 17 Oct 2020 (Study Day 47)
Facial Bones Fracture	Grade 3/severe	Not related	20 Nov 2020 (Study Day 81) - 30 Nov 2020 (Study Day 91)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US324-2269 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hepatocellular Carcinoma/ Hepatocellular Carcinoma	SAE	Grade 4	Not related	07 Dec 2020 (Study Day 98) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2269, a 77-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Dec 2020 (Study Day 98), 97 days after the first dose and 68 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hepatocellular carcinoma. Action taken with the IP was not applicable. The event of hepatocellular carcinoma was considered to be ongoing. The investigator assessed the event of hepatocellular carcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001136	Hepatocellular carcinoma

Study Completion/Discontinuation

On 22 Jan 2021 (Study Day 144), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma, episodic	1985 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	01 Jan 2008 (Study Day -4627) - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Atrial fibrillation	Atrial fibrillation	01 Jan 2011 (Study Day -3531) - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	01 Jan 2017 (Study Day -1339) - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	01 Apr 2018 (Study Day -884) - Ongoing
Diverticulum	Diverticulosis	10 Jul 2020 (Study Day -53) - 20 Jul 2020 (Study Day -43)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diltiazem	01 Jan 2010 (Study Day -3896) - Ongoing	Hypertension
Simvastatin	01 Jan 2010 (Study Day -3896) - Ongoing	Hypercholesterolemia
Flecainide	2011 - Ongoing	Atrial Fibrillation
Pantoprazole	01 Jan 2017 (Study Day -1339) - Ongoing	Gastroesophageal Reflux Disease
Apixaban	01 May 2018 (Study Day -854) - Ongoing	Atrial Fibrillation
Levocetirizine dihydrochloride	15 Sep 2020 (Study Day 15) - Ongoing	Seasonal Allergic Rhinitis
Fluticasone propionate	22 Oct 2020 (Study Day 52) - 30 Oct 2020 (Study Day 60)	Asthma Exacerbation
Guaifenesin	22 Oct 2020 (Study Day 52) - 28 Oct 2020 (Study Day 58)	Asthma Exacerbation
Prednisone	22 Oct 2020 (Study Day 52) - 28 Oct 2020 (Study Day 58)	Asthma Exacerbation
Salbutamol	22 Oct 2020 (Study Day 52) - 07 Dec 2020 (Study Day 98)	Asthma Exacerbation
Amoxicillin; clavulanic acid	31 Oct 2020 (Study Day 61) - 11 Nov 2020 (Study Day 72)	Acute Frontal Sinusitis
Azithromycin	31 Oct 2020 (Study Day 61) - 31 Oct 2020 (Study Day 61)	Acute Frontal Sinusitis
Brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride	31 Oct 2020 (Study Day 61) - 06 Nov 2020 (Study Day 67)	Acute Frontal Sinusitis
Ceftriaxone	31 Oct 2020 (Study Day 61) - 31 Oct 2020 (Study Day 61)	Acute Frontal Sinusitis
Dexamethasone	31 Oct 2020 (Study Day 61) - 31 Oct 2020 (Study Day 61)	Acute Frontal Sinusitis
Azithromycin	01 Nov 2020 (Study Day 62) - 04 Nov 2020 (Study Day 65)	Acute Frontal Sinusitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Liver biopsy*	03 Dec 2020 (Study Day 94) - 03 Dec 2020 (Study Day 94)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Foot Fracture	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 32) - 02 Nov 2020 (Study Day 63)
Asthma	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 45) - 07 Dec 2020 (Study Day 98)
Acute Sinusitis	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 59) - 06 Nov 2020 (Study Day 67)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US325-2261 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure/Heart Failure	SAE	Grade 4	Not related	01 Nov 2020 (Study Day 74) – 03 Nov 2020 (Study Day 76)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2261, a 75-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 74), 73 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cardiac failure. Action taken with the IP was not applicable. The event of heart failure lasted for 3 days, after which it was considered to be recovered/resolved on 03 Nov 2020 (Study Day 76). The investigator assessed the event of cardiac failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000738	Cardiac failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies (pollen, dust)	1960 - Ongoing
Menorrhagia	Menorrhagia	1974 - 1985
Female sterilisation	Bilateral tubal ligation	Jan 1980 - Jan 1980
Hysterectomy	Cervical hysterectomy	Jan 1985 - Jan 1985
Asthma	Asthma	1995 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Montelukast	1995 - Ongoing	Asthma
Amlodipine	2005 - 09 Nov 2020 (Study Day 82)	Hypertension
Cetirizine	2005 - Ongoing	Seasonal Allergy
Fluticasone propionate; salmeterol xinafoate	2005 - Ongoing	Asthma
Hydrochlorothiazide; losartan potassium	2005 - 09 Nov 2020 (Study Day 82)	Hypertension
Levothyroxine	2005 - Ongoing	Hypothyroidism
Metoprolol	2005 - 09 Nov 2020 (Study Day 82)	Hypertension
Simvastatin	2005 - Ongoing	Hyperlipidemia
Vitamin b12 nos	2005 - Ongoing	Dietary Supplement
Vitamin d nos	2005 - Ongoing	Dietary Supplement
Vitamins nos	2005 - Ongoing	Dietary Supplement
Acetylsalicylic acid	2013 - Ongoing	Heart Health
Pantoprazole	2020 - Ongoing	Gastroesophageal Reflux Disease
Carvedilol	03 Nov 2020 (Study Day 76) - Ongoing	Heart Failure
Furosemide	03 Nov 2020 (Study Day 76) - Ongoing	Heart Failure
Olmesartan	03 Nov 2020 (Study Day 76) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US336-2099 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hip Fracture/Left Hip Fracture	SAE	Grade 4	Not related	26 Jan 2021 (Study Day 170) – 28 Jan 2021 (Study Day 172)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2099, a 68-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Jan 2021 (Study Day 170), 169 days after the first dose and 138 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hip fracture. Action taken with the IP was not applicable. The event of left hip fracture lasted for 3 days, after which it was considered to be recovered/resolved on 28 Jan 2021 (Study Day 172). The investigator assessed the event of hip fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-017323	Hip fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	2002 - Ongoing
Osteoporosis	Osteoporisis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Zoledronic acid	25 Jan 2021 (Study Day 169) - 25 Jan 2021 (Study Day 169)	Osteoporosis
Calcium chloride; potassium chloride; sodium lactate	26 Jan 2021 (Study Day 170) - 28 Jan 2021 (Study Day 172)	Left Hip Fracture
Cannulated screw fixation of left femoral fracture*	26 Jan 2021 (Study Day 170) - 26 Jan 2021 (Study Day 170)	Adverse Event
Hydrocodone; paracetamol	26 Jan 2021 (Study Day 170) - 27 Jan 2021 (Study Day 171)	Left Hip Fracture
Hydromorphone	26 Jan 2021 (Study Day 170) - 27 Jan 2021 (Study Day 171)	Left Hip Fracture
Melatonin	26 Jan 2021 (Study Day 170) - 27 Jan 2021 (Study Day 171)	Left Hip Fracture
Morphine	26 Jan 2021 (Study Day 170) - 26 Jan 2021 (Study Day 170)	Left Hip Fracture
Morphine	26 Jan 2021 (Study Day 170) - 28 Jan 2021 (Study Day 172)	Left Hip Fracture
Ondansetron	26 Jan 2021 (Study Day 170) - 26 Jan 2021 (Study Day 170)	Left Hip Fracture
Oxycodone hydrochloride; paracetamol	26 Jan 2021 (Study Day 170) - 27 Jan 2021 (Study Day 171)	Left Hip Fracture
Paracetamol	26 Jan 2021 (Study Day 170) - 28 Jan 2021 (Study Day 172)	Left Hip Fracture
Cefazolin; glucose	27 Jan 2021 (Study Day 171) - 27 Jan 2021 (Study Day 171)	Left Hip Fracture

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dizziness	Grade 2/moderate	Not related	03 Jan 2021 (Study Day 147) - 03 Jan 2021 (Study Day 147)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US324-2314 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostatic Adenocarcinoma (Gleason Score 3+4+=7)	SAE	Grade 4	Not related	06 Nov 2020 (Study Day 58) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2314, a 75-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Nov 2020 (Study Day 58), 57 days after the first dose and 28 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostatic adenocarcinoma (gleason score 3+4+=7) was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000776	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1994 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Obesity	Obesity	2016 - Ongoing
Rhinitis perennial	Perennial allergic rhinitis	2016 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	2016 - Ongoing
Erectile dysfunction	Erectile dysfunction	03 Aug 2017 (Study Day -1134) - Ongoing
Chronic kidney disease	Chronic kidney disease, stage 2	01 Jun 2019 (Study Day -467) - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	27 Jun 2019 (Study Day -441) - Ongoing
Prostatic specific antigen increased	Elevated prostate specific antigen	27 Jun 2019 (Study Day -441) - Ongoing
Optic ischaemic neuropathy	Ischemic optic neuropathy	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	1994 - Ongoing	Hypertension
Lisinopril	1994 - Ongoing	Hypertension
Levothyroxine	2000 - Ongoing	Hypothyroidism
Cetirizine hydrochloride	2016 - Ongoing	Seasonal And Perennial Allergic Rhinitis
Acetylsalicylic acid	Jan 2020 - Ongoing	Heart Health
Paracetamol	10 Oct 2020 (Study Day 31) - 10 Oct 2020 (Study Day 31)	Chills / Body Aches
Alfuzosin	31 Oct 2020 (Study Day 52) - 27 Jan 2021 (Study Day 140)	Benign Prostatic Hyperplasia
Ciprofloxacin	02 Nov 2020 (Study Day 54) - 11 Nov 2020 (Study Day 63)	Prophylaxis For Prostate Biopsy
Prostate biopsy*	04 Nov 2020 (Study Day 56) - 04 Nov 2020 (Study Day 56)	Adverse Event
Prostatectomy*	27 Jan 2021 (Study Day 140) - 27 Jan 2021 (Study Day 140)	Adverse Event
Docusate sodium	28 Jan 2021 (Study Day 141) - 28 Feb 2021 (Study Day 172)	Post Procedure, Prostatectomy
Ciprofloxacin	03 Feb 2021 (Study Day 147) - 05 Feb 2021 (Study Day 149)	Post Procedure, Prophylaxis For Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US324-2370 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Schizoaffective Disorder/Worsening Of Schizoaffective Disorder	SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 3/severe	Not related	29 Sep 2020 (Study Day 7) – 03 Oct 2020 (Study Day 11)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2370, a 28-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 23 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of schizoaffective disorder. On 18 Oct 2020 (Study Day 26), the IP dose was discontinued due to serious adverse event. The event of worsening of schizoaffective disorder lasted for 5 days, after which it was considered to be recovered/resolved on 03 Oct 2020 (Study Day 11). The investigator assessed the event of schizoaffective disorder to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000451	Schizoaffective disorder

Study Completion/Discontinuation

On 19 Oct 2020 (Study Day 27), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Schizoaffective disorder	Schizoaffective disorder	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Haloperidol lactate	26 Sep 2020 (Study Day 4) - 26 Sep 2020 (Study Day 4)	Schizoaffective Disorder
Fluoxetine hydrochloride	01 Oct 2020 (Study Day 9) - Ongoing	Schizoaffective Disorder
Quetiapine fumarate	01 Oct 2020 (Study Day 9) - Ongoing	Schizoaffective Disorder
Valproate semisodium	01 Oct 2020 (Study Day 9) - Ongoing	Schizoaffective Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US325-2119 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	SAE	Grade 4	Not related	14 Oct 2020 (Study Day 65) – 20 Oct 2020 (Study Day 71)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2119, a 57-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Oct 2020 (Study Day 65), 64 days after the first dose and 36 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 7 days, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 71). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000507	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	Jan 2000 - Jan 2000
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Type 2 diabetes mellitus	Type II diabetes	2016 - Ongoing
Localised infection	Left foot infection	Nov 2016 - Nov 2016
Toe amputation	Removal of fifth left toe	Nov 2016 - Nov 2016
Localised infection	Left foot infection	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Liraglutide	2016 - Ongoing	Type II Diabetes
Lisinopril	2016 - Ongoing	Hypertension
Simvastatin	2016 - Ongoing	Hyperlipidemia
Insulin glargine	2018 - Ongoing	Type II Diabetes
Acetylsalicylic acid	12 Jun 2019 (Study Day -426) - Ongoing	General Health
Atorvastatin calcium	15 Oct 2019 (Study Day -301) - 20 Oct 2020 (Study Day 71)	Hyperlipidemia
Famotidine	15 Oct 2019 (Study Day -301) - 20 Oct 2020 (Study Day 71)	Gastroesophageal Reflux Disease
Zolpidem tartrate	15 Oct 2019 (Study Day -301) - 20 Oct 2020 (Study Day 71)	Nausea
Metronidazole	Apr 2020 - 11 Aug 2020 (Study Day 1)	Left Foot Infection
Cefdinir	04 Aug 2020 (Study Day -7) - 15 Sep 2020 (Study Day 36)	Antibiotics For Foot Infection
Attempted percutaneous coronary intervention to the ramus unable to cross*	14 Oct 2020 (Study Day 65) - 14 Oct 2020 (Study Day 65)	Adverse Event
Emergent left heart catherization*	14 Oct 2020 (Study Day 65) - 14 Oct 2020 (Study Day 65)	Adverse Event
Percutaneous coronary intervention to the circumflex and left posterior descending artery*	14 Oct 2020 (Study Day 65) - 14 Oct 2020 (Study Day 65)	Adverse Event
Amiodarone hydrochloride	15 Oct 2020 (Study Day 66) - 20 Oct 2020 (Study Day 71)	Acute Coronary Syndrome
Glucagon	15 Oct 2020 (Study Day 66) - 20 Oct 2020 (Study Day 71)	Hypoglycaemia
Glucose	15 Oct 2020 (Study Day 66) - 20 Oct 2020 (Study Day 71)	Dehydration

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	15 Oct 2020 (Study Day 66) - 15 Oct 2020 (Study Day 66)	General Health
Insulin	15 Oct 2020 (Study Day 66) - 20 Oct 2020 (Study Day 71)	Type 2 Diabetes
Mupirocin	15 Oct 2020 (Study Day 66) - 20 Oct 2020 (Study Day 71)	Prophylaxis For Mrsa
Ondansetron	15 Oct 2020 (Study Day 66) - 20 Oct 2020 (Study Day 71)	Nausea
Paracetamol	15 Oct 2020 (Study Day 66) - 20 Oct 2020 (Study Day 71)	Injection Site Pain
Percutaneous coronary intervention to left anterior descending artery*	15 Oct 2020 (Study Day 66) - 15 Oct 2020 (Study Day 66)	Adverse Event
Pneumococcal vaccine	15 Oct 2020 (Study Day 66) - 15 Oct 2020 (Study Day 66)	General Health
Ticagrelor	15 Oct 2020 (Study Day 66) - Ongoing	Acute Coronary Syndrome
Carvedilol	20 Oct 2020 (Study Day 71) - Ongoing	Prophylaxis For Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US325-2127 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 4	Not related	28 Oct 2020 (Study Day 79) – 29 Oct 2020 (Study Day 80)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2127, a 68-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Oct 2020 (Study Day 79), 78 days after the first dose and 50 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 2 days, after which it was considered to be recovered/resolved on 29 Oct 2020 (Study Day 80). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000632	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2009 - Ongoing
Carotid arteriosclerosis	Carotid atherosclerosis	2009 - Ongoing
Asthma	Asthma	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Osteoarthritis	Osteoarthritis of hands	2010 - Ongoing
Chronic sinusitis	Chronic sinusitis	2015 - Ongoing
Trigger finger	Acquired trigger finger	2017 - Ongoing
Vitamin D deficiency	Vitamin d defi	2017 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	2018 - Ongoing
Gastritis	Gastritis	2018 - Ongoing
Colonoscopy	Colonoscopy	Aug 2018 - Aug 2018
Constipation	Chronic idiopathic constipation	2019 - Ongoing
Hypothyroidism	Hypothyroid	2019 - Ongoing
Endoscopy	Endoscopy	Jan 2020 - Jan 2020
Cerebral atrophy	General cerebral atrophy	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2009 - Ongoing	Carotid Atherosclerosis
Finasteride	2009 - Ongoing	Enlarged Prostate
Sitosterol	2009 - Ongoing	Benign Prostatic Hyperplasia
Vitamins nos	2009 - Ongoing	Dietary Supplement
Amlodipine	2010 - Ongoing	Hypertension
Diclofenac	2010 - Ongoing	Osteoarthritis Of Hands
Fenofibrate	2010 - Ongoing	Hypercholesteremia
Fluticasone propionate	2010 - Ongoing	Asthma
Metoprolol	2010 - Ongoing	Hypertension
Montelukast	2010 - Ongoing	Asthma
Pravastatin	2010 - Ongoing	Hypercholesterol
Zolpidem	2010 - Ongoing	Insomnia
Doxazosin mesilate	2018 - Ongoing	Hypertension
Levothyroxine sodium	2019 - Ongoing	Hypothyroid

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Linaclotide	2019 - Ongoing	Constipation
Omeprazole	07 Sep 2020 (Study Day 28) - 29 Sep 2020 (Study Day 50)	Gastritis
Paracetamol	09 Sep 2020 (Study Day 30) - 11 Sep 2020 (Study Day 32)	Pain In Injection Site
Influenza vaccine	29 Sep 2020 (Study Day 50) - 29 Sep 2020 (Study Day 50)	General Health
Esomeprazole	30 Sep 2020 (Study Day 51) - Ongoing	Gastritis
Sucralfate	30 Sep 2020 (Study Day 51) - Ongoing	Gastritis
Appendectomy*	28 Oct 2020 (Study Day 79) - 28 Oct 2020 (Study Day 79)	Adverse Event
Amoxicillin; clavulanic acid	29 Oct 2020 (Study Day 80) - Ongoing	Appendicitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US325-2166 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Thyroid Cancer Metastatic/Metastatic Papillary Thyroid Carcinoma	SAE	Grade 4	Not related	22 Sep 2020 (Study Day 41) – 30 Oct 2020 (Study Day 79)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2166, a 50-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Sep 2020 (Study Day 41), 40 days after the first dose and 12 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of thyroid cancer metastatic. Action taken with the IP was not applicable. The event of metastatic papillary thyroid carcinoma lasted for 39 days, after which it was considered to be recovered/resolved on 30 Oct 2020 (Study Day 79). The investigator assessed the event of thyroid cancer metastatic to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000670	Thyroid cancer metastatic

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	Cesarean section	Oct 2002 - Oct 2002
Cholecystectomy	Cholecystectomy	Jan 2007 - Jan 2007
Cholecystitis	Cholecystitis	Jan 2007 - Jan 2007
Caesarean section	Cesarean section	Oct 2007 - Oct 2007
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2010 - Ongoing
Allergy to animal	Allergy to pets	Jan 2010 - Jan 2010
Seasonal allergy	Seasonal allergies	Jan 2010 - Ongoing
Hypersensitivity	Environmental allergies	2015 - Ongoing
Hysterectomy	Hysterectomy	Jan 2017 - Jan 2017
Uterine leiomyoma	Uterine myoma	Jan 2017 - Jan 2017
Hypertriglyceridaemia	Hypertriglyceridemia	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2010 - Ongoing	Type 2 Diabetes
Metoprolol	2010 - Ongoing	Hypertension
Lovastatin	Jan 2020 - Ongoing	Hypertriglyceridemia
Montelukast	Jan 2020 - Ongoing	Seasonal Allergies
Influenza vaccine	26 Aug 2020 (Study Day 14) - 26 Aug 2020 (Study Day 14)	Influenza Virus
Paracetamol	12 Sep 2020 (Study Day 31) - 13 Sep 2020 (Study Day 32)	Headache
Left cervical lymph node excision*	22 Sep 2020 (Study Day 41) - 22 Sep 2020 (Study Day 41)	Adverse Event
Levothyroxine	30 Oct 2020 (Study Day 79) - Ongoing	Hypothyroidism
Tyroidectomy*	30 Oct 2020 (Study Day 79) - 30 Oct 2020 (Study Day 79)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypothyroidism	Grade 1/mild	Not related	30 Oct 2020 (Study Day 79) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378675

Participant Number:	US325-2553 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis Acute/Acute Cholecystitis	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	23 Oct 2020 (Study Day 30) – 04 Nov 2020 (Study Day 42)	Recovered/ resolved
Cholecystitis Infective/Acute Ganrenous Cholecystitis	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	23 Oct 2020 (Study Day 30) – 04 Nov 2020 (Study Day 42)	Recovered/ resolved
Cholelithiasis/ Cholelithiasis	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	23 Oct 2020 (Study Day 30) – 04 Nov 2020 (Study Day 42)	Recovered/ resolved
Escherichia Bacteraemia/ Escherichia Coli Bactermia	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	23 Oct 2020 (Study Day 30) – 04 Nov 2020 (Study Day 42)	Recovered/ resolved
Post Procedural Bile Leak/Biliary Leak Status Post Stent Placement	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	23 Oct 2020 (Study Day 30) – 04 Nov 2020 (Study Day 42)	Recovered/ resolved
Septic Shock/Septic Shock	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	23 Oct 2020 (Study Day 30) – 04 Nov 2020 (Study Day 42)	Recovered/ resolved
Urinary Tract Infection Enterococcal/ Enterococcus Faecalis Urinary Tract Infection	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	23 Oct 2020 (Study Day 30) – 04 Nov 2020 (Study Day 42)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2553, a 74-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 24 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of cholecystitis acute. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of acute cholecystitis lasted for 13 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 42). The investigator assessed the event of cholecystitis acute to be not related to the IP.

On 23 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of cholecystitis infective. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of acute ganrenous cholecystitis lasted for 13 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 42). The investigator assessed the event of cholecystitis infective to be not related to the IP.

On 23 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of cholelithiasis. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of cholelithiasis lasted for 13 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 42). The investigator assessed the event of cholelithiasis to be not related to the IP.

On 23 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of escherichia bacteraemia. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of escherichia coli bactermia lasted for 13 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 42). The investigator assessed the event of escherichia bacteraemia to be not related to the IP.

On 23 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of post procedural bile leak. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of biliary leak status post stent placement lasted for 13 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 42). The investigator assessed the event of post procedural bile leak to be not related to the IP.

On 23 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of septic shock. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of septic shock

lasted for 13 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 42). The investigator assessed the event of septic shock to be not related to the IP.

On 23 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of urinary tract infection enterococcal. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of enterococcus faecalis urinary tract infection lasted for 13 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 42). The investigator assessed the event of urinary tract infection enterococcal to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000564	Septic shock
MOD-2020-000564	Cholecystitis acute

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2000 - Ongoing
Bradycardia	Bradycardia	2018 - 2018
Cardiac pacemaker insertion	Pacemaker	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2005 - Ongoing	Hypertension
Acetylsalicylic acid	2015 - Ongoing	Prophylaxis For Cardiovascular Disease
Hydrochlorothiazide	2019 - Ongoing	Hypertension
Metoprolol	2019 - Ongoing	Hypertension
Cefalexin	13 Oct 2020 (Study Day 20) - 23 Oct 2020 (Study Day 30)	Nondisplaced Fracture Of The Right Scaphoid
Paracetamol	13 Oct 2020 (Study Day 20) - 05 Mar 2021 (Study Day 163)	Nondisplaced Fracture Of The Right Scaphoid

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
X-rays of right wrist, right knee, and right ankle*	14 Oct 2020 (Study Day 21) - 14 Oct 2020 (Study Day 21)	Adverse Event
X-rays of right wrist, right knee, and right ankle*	19 Oct 2020 (Study Day 26) - 19 Oct 2020 (Study Day 26)	Adverse Event
Laparoscopic converted to open subtotal cholecystectomy*	23 Oct 2020 (Study Day 30) - 23 Oct 2020 (Study Day 30)	Adverse Event
Piperacillin sodium; tazobactam sodium	23 Oct 2020 (Study Day 30) - 04 Nov 2020 (Study Day 42)	Acute Cholecystitis And Sepsis
Abdominal lavage*	25 Oct 2020 (Study Day 32) - 25 Oct 2020 (Study Day 32)	Adverse Event
Control of cystic duct with clips*	25 Oct 2020 (Study Day 32) - 25 Oct 2020 (Study Day 32)	Adverse Event
Exploratory laparotomy*	25 Oct 2020 (Study Day 32) - 25 Oct 2020 (Study Day 32)	Adverse Event
Fascial closure*	25 Oct 2020 (Study Day 32) - 25 Oct 2020 (Study Day 32)	Adverse Event
Partial cholecystectomy (posterior wall)*	25 Oct 2020 (Study Day 32) - 25 Oct 2020 (Study Day 32)	Adverse Event
Midline placement*	29 Oct 2020 (Study Day 36) - 29 Oct 2020 (Study Day 36)	Adverse Event
X-rays of right wrist and right ankle*	13 Nov 2020 (Study Day 51) - 13 Nov 2020 (Study Day 51)	Adverse Event
X-rays of right ankle*	25 Nov 2020 (Study Day 63) - 25 Nov 2020 (Study Day 63)	Adverse Event
X-rays of right wrist and right ankle*	16 Dec 2020 (Study Day 84) - 16 Dec 2020 (Study Day 84)	Adverse Event
X-rays of right wrist and right ankle*	13 Jan 2021 (Study Day 112) - 13 Jan 2021 (Study Day 112)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Wrist Fracture	Grade 1/mild	Not related	13 Oct 2020 (Study Day 20) - 05 Mar 2021 (Study Day 163)
Ankle Fracture	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 20) - 05 Mar 2021 (Study Day 163)
Cholecystitis Infective	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 30) - 04 Nov 2020 (Study Day 42)
Cholelithiasis	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 30) - 04 Nov 2020 (Study Day 42)
Escherichia Bacteraemia	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 30) - 04 Nov 2020 (Study Day 42)
Post Procedural Bile Leak	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 30) - 04 Nov 2020 (Study Day 42)
Urinary Tract Infection Enterococcal	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 30) - 04 Nov 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378680

Participant Number:	US325-2602 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	30 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 3/ severe	Not related	06 Nov 2020 (Study Day 36) – 06 Nov 2020 (Study Day 36)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2602, a 52-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 02 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 30 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Nov 2020 (Study Day 36), 35 days after the first dose and 7 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 1 days, after which it was considered to be recovered/resolved on 06 Nov 2020 (Study Day 36). The investigator assessed the event of appendicitis to be not related to the IP.

On 03 Dec 2020 (Study Day 63), 62 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 2/moderate non-serious adverse event of covid-19. The IP dose was not changed due to the covid-19. The event of COVID-19 lasted for 33 days, after which it was considered to be recovered/resolved on 04 Jan 2021 (Study Day 95). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000674	Appendicitis
MOD-2021-002863	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign breast neoplasm	Benign tumor on left breast	Sep 2001 - Sep 2001
Breast tumour excision	Extraction of benign tumor on left breast	Sep 2001 - Sep 2001
Drug hypersensitivity	Allergy to bactrim	Sep 2004 - Ongoing
Lumbar radiculopathy	Lumbar radiculopathy	Sep 2010 - Ongoing
Benign uterine neoplasm	Benign uterine tumor	Sep 2012 - Sep 2012
Hysterectomy	Hysterectomy	Sep 2012 - Sep 2012
Oophorectomy	Oophorectomy	Sep 2012 - Sep 2012
Osteopenia	Osteopenia	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	Jan 2018 - Ongoing	Lumbar Radiculopathy
Alendronate sodium	23 Sep 2020 (Study Day -9) - Ongoing	Osteopenia
Gabapentin	23 Sep 2020 (Study Day -9) - Ongoing	Lumbar Radiculopathy
Cyclobenzaprine	28 Sep 2020 (Study Day -4) - Ongoing	Lumbar Radiculopathy
Naproxen	07 Oct 2020 (Study Day 6) - 07 Oct 2020 (Study Day 6)	Headache
Naproxen	09 Oct 2020 (Study Day 8) - 09 Oct 2020 (Study Day 8)	Underarm Gland Swelling
Appendectomy*	06 Nov 2020 (Study Day 36) - 06 Nov 2020 (Study Day 36)	Adverse Event
Hydralazine	06 Nov 2020 (Study Day 36) - 06 Nov 2020 (Study Day 36)	Appendicitis
Morphine	06 Nov 2020 (Study Day 36) - 07 Nov 2020 (Study Day 37)	Appendicitis
Pantoprazole	06 Nov 2020 (Study Day 36) - 06 Nov 2020 (Study Day 36)	Appendicitis
Promethazine	06 Nov 2020 (Study Day 36) - 07 Nov 2020 (Study Day 37)	Appendicitis
Tramadol	06 Nov 2020 (Study Day 36) - 07 Nov 2020 (Study Day 37)	Appendicitis
Amoxicillin; clavulanic acid	07 Nov 2020 (Study Day 37) - 14 Nov 2020 (Study Day 44)	Post Appendectomy
Hydrocodone bitartrate; paracetamol	07 Nov 2020 (Study Day 37) - 11 Nov 2020 (Study Day 41)	Post Appendectomy
Ondansetron	07 Nov 2020 (Study Day 37) - 11 Nov 2020 (Study Day 41)	Nausea
Cetirizine	18 Dec 2020 (Study Day 78) - 24 Dec 2020 (Study Day 84)	COVID-19
Famotidine	18 Dec 2020 (Study Day 78) - 24 Dec 2020 (Study Day 84)	COVID-19
Azithromycin	19 Dec 2020 (Study Day 79) - 24 Dec 2020 (Study Day 84)	COVID-19
Ivermectin	19 Dec 2020 (Study Day 79) - 19 Dec 2020 (Study Day 79)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 63) - 04 Jan 2021 (Study Day 95)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378683

Participant Number:	US325-2638 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	24 Oct 2020 (Study Day 18) – 24 Nov 2020 (Study Day 49)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2638, a 41-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 07 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Oct 2020 (Study Day 18), 17 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 03 Nov 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of COVID-19 lasted for 32 days, after which it was considered to be recovered/resolved on 24 Nov 2020 (Study Day 49). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000617	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy	2008 - 2008
Menorrhagia	Menorrhagia	2008 - 2008

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Guaifenesin	24 Oct 2020 (Study Day 18) - 13 Nov 2020 (Study Day 38)	COVID-19
Paracetamol	24 Oct 2020 (Study Day 18) - 13 Nov 2020 (Study Day 38)	COVID-19
Acetylsalicylic acid	28 Oct 2020 (Study Day 22) - 13 Nov 2020 (Study Day 38)	Prophylaxis For Cardiac Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	24 Oct 2020 (Study Day 18) - 24 Nov 2020 (Study Day 49)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US326-2055 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	30 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Metastatic Neoplasm/Sequelae From Metastatic Malignancy Of Unknown Origin	SAE	Grade 3/severe	Not related	05 Feb 2021 (Study Day 191) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US326-2055, a 64-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Feb 2021 (Study Day 191), 190 days after the first dose and 161 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of metastatic neoplasm. Action taken with the IP was not applicable. The event of sequelae from metastatic malignancy of unknown origin was considered to be ongoing. The investigator assessed the event of metastatic neoplasm to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-023182	Hodgkin's disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mitral valve prolapse	Mitral valve prolapse	1974 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Megestrol acetate	10 Feb 2021 (Study Day 196) - Ongoing	Decreased Appetite

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Decreased Appetite	Grade 2/moderate	Not related	10 Feb 2021 (Study Day 196) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2005 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Iron Deficiency Anaemia/Worsening Iron-Deficiency Anemia	SAE	Grade 4	Not related	12 Jan 2021 (Study Day 168) – 15 Jan 2021 (Study Day 171)	Recovered/resolved
Syncope/Syncope	SAE	Grade 4	Not related	12 Jan 2021 (Study Day 168) – 12 Jan 2021 (Study Day 168)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2005, a 45-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Jan 2021 (Study Day 168), 167 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of iron deficiency anaemia. On 25 Aug 2020 (Study Day 28), the IP dose was discontinued due to other. The event of worsening iron-deficiency anemia lasted for 4 days, after which it was considered to be recovered/resolved on 15 Jan 2021 (Study Day 171). The investigator assessed the event of iron deficiency anaemia to be not related to the IP.

On 12 Jan 2021 (Study Day 168), 167 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of syncope. On 25 Aug 2020 (Study Day 28), the IP dose was discontinued due to other. The event of syncope lasted for 1 day, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 168). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005879	Iron deficiency anaemia

CIOMS Number	MedDRA Preferred Term
MOD-2021-005879	Syncope
MOD-2020-001174	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Allergy to eggs	Sep 2001 - Ongoing
Drug hypersensitivity	Allergy to singular	Apr 2005 - Ongoing
Seasonal allergy	Hayfever	2008 - Ongoing
Drug hypersensitivity	Allergy to rocephin	Aug 2013 - Ongoing
Menorrhagia	Menorrhagia	2016 - 2016
Hysterectomy	Complete hysterectomy	Sep 2016 - Sep 2016
Iron deficiency anaemia	Iron-deficient anemia	2017 - Ongoing
Asthma	Severe asthma	2018 - Ongoing
Hyperthyroidism	Hyperthyroidism	May 2018 - Ongoing
Hypothyroidism	Hypothyroidism	May 2018 - Ongoing
Thyroidectomy	Thyroidectomy	May 2018 - May 2018
Blood oestrogen decreased	Low estrogen	10 Feb 2020 (Study Day -170) - Ongoing
Blood oestrogen decreased	Low estrogen	10 Feb 2020 (Study Day -170) - Ongoing
Anxiety	Anxiety	30 Mar 2020 (Study Day -121) - Ongoing
Depression	Depression	30 Mar 2020 (Study Day -121) - Ongoing
Osteoarthritis	Osteoarthritis (generalized)	04 May 2020 (Study Day -86) - Ongoing
Abdominal pain	Abdominal pain	25 Jun 2020 (Study Day -34) - Ongoing
Neuralgia	Generalized neuralgia	25 Jun 2020 (Study Day -34) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2008 - Ongoing	Hayfever
Formoterol fumarate; mometasone furoate	2018 - Ongoing	Asthma
Tiotropium bromide	2018 - Ongoing	Asthma
Levothyroxine sodium	May 2018 - Ongoing	Hypothyroidism

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Thyroid	May 2018 - 31 Jan 2021 (Study Day 187)	Hypothyroidism
Immunoglobulin human normal	Jan 2020 - Ongoing	Asthma
Estrogens conjugated	10 Feb 2020 (Study Day -170) - Ongoing	Low Estrogen
Sertraline hydrochloride	30 Mar 2020 (Study Day -121) - Ongoing	Depression
Meloxicam	04 May 2020 (Study Day -86) - 14 Jan 2021 (Study Day 170)	Osteroarthritis (Generalized)
Vitamin d nos	04 May 2020 (Study Day -86) - Ongoing	Nutritional Supplement
Ascorbic acid	08 May 2020 (Study Day -82) - Ongoing	Nutritional Supplement
Ferrous sulfate	08 May 2020 (Study Day -82) - Ongoing	Nutritional Supplement
Benralizumab	17 Jun 2020 (Study Day -42) - Ongoing	Asthma
Gabapentin	25 Jun 2020 (Study Day -34) - Ongoing	Generalized Neuralgia
Pantoprazole sodium sesquihydrate	25 Jun 2020 (Study Day -34) - Ongoing	Abdominal Pain
Cyclobenzaprine	17 Jul 2020 (Study Day -12) - Ongoing	Osteroarthritis (Generalized)
Acetylsalicylic acid; caffeine; paracetamol	30 Jul 2020 (Study Day 2) - 03 Aug 2020 (Study Day 6)	Solicited Event On Ediary Headache
Azithromycin	18 Aug 2020 (Study Day 21) - 21 Aug 2020 (Study Day 24)	Upper Respiratory Infection
Methylprednisolone acetate	18 Aug 2020 (Study Day 21) - 18 Aug 2020 (Study Day 21)	Upper Respiratory Infection
Levofloxacin	02 Sep 2020 (Study Day 36) - 09 Sep 2020 (Study Day 43)	Upper Respiratory Infection
Amoxicillin	09 Nov 2020 (Study Day 104) - 19 Nov 2020 (Study Day 114)	Sinus Infection
Fluconazole	15 Nov 2020 (Study Day 110) - 22 Nov 2020 (Study Day 117)	Oral Candidiasis
Methylrosanilinium chloride	16 Nov 2020 (Study Day 111) - 16 Nov 2020 (Study Day 111)	Oral Candidiasis
Fluconazole	17 Nov 2020 (Study Day 112) - 20 Nov 2020 (Study Day 115)	Sinus Infection
Chlorphenamine maleate; dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	11 Dec 2020 (Study Day 136) - 09 Jan 2021 (Study Day 165)	COVID 19
Pantoprazole sodium sesquihydrate	12 Jan 2021 (Study Day 168) - 13 Jan 2021 (Study Day 169)	Syncope Secondary To Iron-Deficiency Anemia
Chest-xray*	13 Jan 2021 (Study Day 169) - 13 Jan 2021 (Study Day 169)	Adverse Event
D-dimer*	13 Jan 2021 (Study Day 169) - 13 Jan 2021 (Study Day 169)	Adverse Event
Ekg*	13 Jan 2021 (Study Day 169) - 13 Jan 2021 (Study Day 169)	Adverse Event
Esophagogastroduodenoscopy*	13 Jan 2021 (Study Day 169) - 13 Jan 2021 (Study Day 169)	Adverse Event
Transthoracic echocardiogram*	13 Jan 2021 (Study Day 169) - 13 Jan 2021 (Study Day 169)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 1/mild	Not related	30 Jul 2020 (Study Day 2) - 02 Aug 2020 (Study Day 5)
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	30 Jul 2020 (Study Day 2) - 21 Aug 2020 (Study Day 24)
Suspected COVID-19	Grade 2/moderate	Not related	18 Aug 2020 (Study Day 21) - 21 Aug 2020 (Study Day 24)
Suspected COVID-19	Grade 2/moderate	Not related	18 Sep 2020 (Study Day 52) - 22 Sep 2020 (Study Day 56)
Fatigue	Grade 1/mild	Not related	08 Nov 2020 (Study Day 103) - 01 Dec 2020 (Study Day 126)
Myalgia	Grade 1/mild	Not related	08 Nov 2020 (Study Day 103) - 01 Dec 2020 (Study Day 126)
Nasal Congestion	Grade 1/mild	Not related	08 Nov 2020 (Study Day 103) - 01 Dec 2020 (Study Day 126)
Pain	Grade 1/mild	Not related	08 Nov 2020 (Study Day 103) - 15 Dec 2020 (Study Day 140)
Sinusitis	Grade 1/mild	Not related	08 Nov 2020 (Study Day 103) - 01 Dec 2020 (Study Day 126)
Suspected COVID-19	Grade 1/mild	Not related	08 Nov 2020 (Study Day 103) - 19 Nov 2020 (Study Day 114)
Cough	Grade 1/mild	Not related	09 Nov 2020 (Study Day 104) - 01 Dec 2020 (Study Day 126)
Dyspnoea	Grade 1/mild	Not related	09 Nov 2020 (Study Day 104) - 01 Dec 2020 (Study Day 126)
Dyspnoea	Grade 1/mild	Not related	09 Nov 2020 (Study Day 104) - 01 Dec 2020 (Study Day 126)
Nausea	Grade 1/mild	Not related	09 Nov 2020 (Study Day 104) - 01 Dec 2020 (Study Day 126)
Headache	Grade 1/mild	Not related	10 Nov 2020 (Study Day 105) - 15 Nov 2020 (Study Day 110)
Oral Candidiasis	Grade 1/mild	Not related	15 Nov 2020 (Study Day 110) - 21 Nov 2020 (Study Day 116)
COVID-19	Grade 3/severe	Not related	08 Dec 2020 (Study Day 133) - 09 Jan 2021 (Study Day 165)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2031 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Breast Cancer Stage I/Stage 1 Left Breast Cancer	SAE	Grade 2/ moderate	Not related	17 Aug 2020 (Study Day 17) – 27 Aug 2020 (Study Day 27)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2031, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 01 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Aug 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of breast cancer stage I. On 28 Aug 2020 (Study Day 28), the IP dose was discontinued due to other. The event of stage 1 left breast cancer lasted for 11 days, after which it was considered to be recovered/resolved on 27 Aug 2020 (Study Day 27). The investigator assessed the event of breast cancer stage I to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000207	Breast cancer stage I

Study Completion/Discontinuation

On 20 Jan 2021 (Study Day 173), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Oral herpes	Oral herpes simplex 1	1975 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Hysterectomy	Total hysterectomy	2002 - 2002
Menorrhagia	Menorrhagia	2002 - 2002
Postmenopause	Postmenopausal	2002 - Ongoing
Basedow's disease	Graves disease	2006 - Ongoing
Arthralgia	Bilateral knee pain	2014 - 06 Aug 2019 (Study Day -361)
Cholecystectomy	Cholecystectomy	2015 - 2015
Cholecystitis	Cholecystitis	2015 - 2015
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Obesity	Severe obesity	2015 - Ongoing
Knee arthroplasty	Total left knee replacement	Oct 2016 - Oct 2016
Lichen sclerosus	Lichen sclerosus bilateral lower extremities	2018 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2018 - Ongoing
Knee arthroplasty	Total right knee replacement	06 Aug 2019 (Study Day -361) - 06 Aug 2019 (Study Day -361)
Emphysema	Emphysema	15 May 2020 (Study Day -78) - Ongoing
Mammogram	Mammogram	28 Jul 2020 (Study Day -4) - 28 Jul 2020 (Study Day -4)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lysine	1975 - Ongoing	Herpes Simplex 1
Diphenhydramine hydrochloride	2000 - Ongoing	Seasonal Allergies
Levothyroxine	2006 - Ongoing	Graves Disease
Vitamins nos	2013 - Ongoing	Nutritional Supplement
Hydrochlorothiazide; losartan potassium	2015 - Ongoing	Hypertension
Omeprazole	2015 - Ongoing	Gastroesophageal Reflux Disease
Cimicifuga racemosa	2018 - Ongoing	Vasomotor Symptoms
Clobetasol propionate	2018 - Ongoing	Lichen Scleroses
Clobetasol propionate	2018 - Ongoing	Lichen Sclerosus
Metformin hydrochloride	2018 - Ongoing	Type 2 Diabetes
Budesonide; formoterol fumarate	15 May 2020 (Study Day -78) - Ongoing	Emphysema

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	15 Jul 2020 (Study Day -17) - Ongoing	Nutritional Supplement
Vitamin b nos	15 Jul 2020 (Study Day -17) - Ongoing	Nutritional Supplement
Biopsy on left breast*	05 Aug 2020 (Study Day 5) - 05 Aug 2020 (Study Day 5)	Diagnostic
Lumpectomy*	26 Aug 2020 (Study Day 26) - 26 Aug 2020 (Study Day 26)	Adverse Event
Influenza vaccine	22 Sep 2020 (Study Day 53) - 22 Sep 2020 (Study Day 53)	Influenza Prophylaxis
Letrozole	01 Nov 2020 (Study Day 93) - Ongoing	Stage 1 Breast Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US327-2085 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Musculoskeletal Chest Pain/Worsening Intermittent Chest Wall Pain Non Cardiac	SAE	Grade 3/severe	Not related	07 Oct 2020 (Study Day 62) – 31 Dec 2020 (Study Day 147)	Recovered/ resolved
Syncope/Syncope	SAE	Grade 4	Not related	31 Dec 2020 (Study Day 147) – 31 Dec 2020 (Study Day 147)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2085, a 58-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Oct 2020 (Study Day 62), 61 days after the first dose and 33 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of musculoskeletal chest pain. Action taken with the IP was not applicable. The event of worsening intermittent chest wall pain non cardiac lasted for 86 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 147). The investigator assessed the event of musculoskeletal chest pain to be not related to the IP.

On 31 Dec 2020 (Study Day 147), 146 days after the first dose and 118 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 1 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 147). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000477	Musculoskeletal chest pain
MOD-2021-099074	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy/ anaphylaxis	1970 - Ongoing
Transient ischaemic attack	Transient ischemic attacks	2007 - 29 May 2013 (Study Day -2627)
Type 2 diabetes mellitus	Type 2 diabetes	2007 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2009 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Osteoarthritis	Osteoarthritis	2010 - Ongoing
Atrial septal defect	Patent foramen ovale	2011 - 29 May 2013 (Study Day -2627)
Hypercholesterolaemia	Hypercholesterolemia	2012 - Ongoing
Device occlusion	Amplatzer cribriform occluder device	29 May 2013 (Study Day -2627) - Ongoing
Diarrhoea	Diarrhea	2015 - Ongoing
Pericarditis	Pericarditis	Jun 2019 - Jul 2019
Musculoskeletal chest pain	Intermittent chest wall pain	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2007 - 06 Jan 2021 (Study Day 153)	Diabetes
Omeprazole	2009 - Ongoing	Gastroesophageal Reflux Disease
Losartan	2010 - Ongoing	Hypertension
Meloxicam	2010 - Ongoing	Osteoarthritis
Pioglitazone	2010 - Ongoing	Type 2 Diabetes
Atorvastatin	2012 - Ongoing	Hypercholesterolemia
Acetylsalicylic acid	2013 - Ongoing	Cardiac Prophylaxis
Nebivolol hydrochloride	2013 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colestipol	2015 - Ongoing	Diarrhea
Hydrochlorothiazide	2019 - Ongoing	Hypertension
Colchicine	14 Oct 2020 (Study Day 69) - Ongoing	Worsening Intermittent Chest Wall Pain
Hydrocodone bitartrate; paracetamol	14 Oct 2020 (Study Day 69) - Ongoing	Worsening Intermittent Chest Wall Pain
Cefepime	31 Dec 2020 (Study Day 147) - 01 Jan 2021 (Study Day 148)	Lactic Acidosis
Levetiracetam	31 Dec 2020 (Study Day 147) - Ongoing	Syncope
Negative procalcitonin*	31 Dec 2020 (Study Day 147) - 31 Dec 2020 (Study Day 147)	Adverse Event
Work up for sepsis*	31 Dec 2020 (Study Day 147) - 31 Dec 2020 (Study Day 147)	Adverse Event
X-ray*	31 Dec 2020 (Study Day 147) - 31 Dec 2020 (Study Day 147)	Adverse Event
Ekg*	01 Jan 2021 (Study Day 148) - 01 Jan 2021 (Study Day 148)	Adverse Event
Mri*	02 Jan 2021 (Study Day 149) - 02 Jan 2021 (Study Day 149)	Adverse Event
Electroencephalogram*	04 Jan 2021 (Study Day 151) - 04 Jan 2021 (Study Day 151)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	05 Nov 2020 (Study Day 91) - 13 Nov 2020 (Study Day 99)
Lactic Acidosis	Grade 3/severe	Not related	31 Dec 2020 (Study Day 147) - 07 Jan 2021 (Study Day 154)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2169 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	15 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rectal Prolapse/Rectal Prolapse	SAE	Grade 4	Not related	08 Sep 2020 (Study Day 25) – 19 Oct 2020 (Study Day 66)	Recovered/resolved
Gastrointestinal Procedural Complication/Rectal Prolapse Repair Complication Due To Constipation	SAE	Grade 3/severe	Not related	04 Nov 2020 (Study Day 82) – 07 Nov 2020 (Study Day 85)	Recovered/resolved
Hyponatraemia/Hyponatremia	SAE	Grade 2/moderate	Not related	05 Nov 2020 (Study Day 83) – 07 Nov 2020 (Study Day 85)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2169, a 47-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 15 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 25), 24 days after the first dose and 8 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of rectal prolapse. The IP dose was not changed due to the rectal prolapse. The event of rectal prolapse lasted for 42 days, after which it was considered to be recovered/resolved on 19 Oct 2020 (Study Day 66). The investigator assessed the event of rectal prolapse to be not related to the IP.

On 04 Nov 2020 (Study Day 82), 81 days after the first dose and 49 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of gastrointestinal procedural complication. Action taken with the IP was not applicable. The event of rectal prolapse repair complication due to constipation lasted for 4 days, after which it was considered to be recovered/resolved on 07 Nov 2020 (Study Day 85). The investigator assessed the event of gastrointestinal procedural complication to be not related to the IP.

On 05 Nov 2020 (Study Day 83), 82 days after the first dose and 50 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of hyponatraemia. Action taken with the IP was not applicable. The event of hyponatremia lasted for 3 days, after which it was considered to be recovered/resolved on 07 Nov 2020 (Study Day 85). The investigator assessed the event of hyponatraemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000766	Rectal prolapse
MOD-2020-000766	Gastrointestinal procedural complication
MOD-2020-000766	Hyponatremia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Adenoiditis	Adenoiditis	1975 - 1975
Adenotonsillectomy	Tonsillectomy/adenoidectomy	1975 - 1975
Seasonal allergy	Seasonal allergies	1975 - Ongoing
Tonsillitis	Tonsillitis	1975 - 1975
Asthma	Mild asthma	1978 - Ongoing
Substance abuse	Substance abuse	1988 - 2012
Drug hypersensitivity	Allergy to codeine	1990 - Ongoing
Gun shot wound	Trauma surgery (post gun shot wound left armpit)	1991 - 1991
Post-traumatic stress disorder	Post traumatic stress disorder	1991 - Ongoing
Drug hypersensitivity	Allergy to aspirin	1994 - Ongoing
Endometriosis	Endometriosis	1994 - 1999
Iodine allergy	Allergy to iodine	1994 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1997 - Ongoing
Drug hypersensitivity	Allergy to toradol	1999 - Ongoing
Hysterectomy	Full hysterectomy	1999 - 1999
Drug hypersensitivity	Allergy to morphine	2007 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Borderline personality disorder	Border line personality disorder	2010 - Ongoing
Osteoporosis	Osteoporosis	2012 - Ongoing
Cataract	Cataract (left eye)	2013 - May 2014

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Catheterisation cardiac	Heart cath	2013 - 2013
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2013 - Ongoing
Hypotension	Hypotension	2013 - Ongoing
Mitral valve prolapse	Mitral valve prolapse	2013 - Ongoing
Peripheral sensory neuropathy	Neuropathy in neck (sensory)	2013 - Ongoing
Supraventricular tachycardia	Supra ventricular tachycardia (svt)	2013 - Ongoing
Spinal fusion surgery	Anterior fusion 3-7 pseudoarthrosis (c4-c7)	2014 - 2014
Cataract operation	Cataract surgery (left eye)	May 2014 - May 2014
Bone graft	Left hip graft	2016 - 2016
Spinal fusion surgery	Anterior fusion 3-7 pseudoarthrosis (c4-c7)	2016 - 2016
Syncope	Syncope	16 Jul 2017 (Study Day -1126) - 16 Jul 2017 (Study Day -1126)
Atrial fibrillation	Arrhythmia (irregular heart beat) (atrial fibrillation)	2018 - Ongoing
Botulinum toxin injection	Botox injection, facial	2018 - 2018
Cardiac ablation	Cardiac ablation	2018 - 2018
Catheterisation cardiac	Heart cath	2018 - 2018
Depression	Depression	2018 - Ongoing
Bipolar disorder	Bipolar disorder	2019 - Ongoing
Drug hypersensitivity	Allergy to dilaudid	2019 - Ongoing
Hypertonic bladder	Overactive bladder	2019 - Ongoing
Abdominal pain	Abdominal pain	May 2020 - Ongoing
Vitreous disorder	Vitreous humor (left eye) (details unknown)	May 2020 - 08 Oct 2020 (Study Day 55)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2000 - Ongoing	Mild Asthma
Cyclobenzaprine hydrochloride	2013 - Ongoing	Neuropathy In Neck
Pregabalin	2014 - Ongoing	Neuropathy In Neck
Citalopram hydrobromide	2018 - Ongoing	Depression And Anxiety
Metoprolol	2018 - Ongoing	Arrhythmia (Irregular Heart Beat) Atrial Fibrillation
Solifenacin succinate	2019 - Ongoing	Overactive Bladder
Cetirizine hydrochloride	Apr 2020 - Ongoing	Seasonal Allergies
Omeprazole	Apr 2020 - Ongoing	Gastroesophageal Reflux Disease
Cariprazine hydrochloride	Jun 2020 - Ongoing	Depression
Vitamin e nos	Jun 2020 - Ongoing	Nutritional Supplement
Paracetamol	16 Aug 2020 (Study Day 2) - 19 Aug 2020 (Study Day 5)	Injection Site Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metronidazole	20 Aug 2020 (Study Day 6) - 31 Aug 2020 (Study Day 17)	Gastroenteritis
Sulfamethoxazole; trimethoprim	20 Aug 2020 (Study Day 6) - 31 Aug 2020 (Study Day 17)	Gastroenteritis
Melatonin	02 Sep 2020 (Study Day 19) - Ongoing	Nutritional Supplement
Esophagogastroduodenoscopy (egd)*	04 Sep 2020 (Study Day 21) - 04 Sep 2020 (Study Day 21)	Adverse Event
Ct imaging (abdomen/pelvis)*	07 Sep 2020 (Study Day 24) - 07 Sep 2020 (Study Day 24)	Adverse Event
Ibuprofen	08 Sep 2020 (Study Day 25) - Ongoing	Rectal Prolapse
Routine colonoscopy*	08 Sep 2020 (Study Day 25) - 08 Sep 2020 (Study Day 25)	Diagnostic
Tramadol	08 Sep 2020 (Study Day 25) - 07 Nov 2020 (Study Day 85)	Rectal Prolapse Repair
Yag laser posterior capsulotomy (left eye)*	08 Oct 2020 (Study Day 55) - 08 Oct 2020 (Study Day 55)	Medical History
Prednisolone acetate	09 Oct 2020 (Study Day 56) - 11 Oct 2020 (Study Day 58)	Yag Laser Posterior Capsulotomy (Left Eye
Chest x-ray*	15 Oct 2020 (Study Day 62) - 15 Oct 2020 (Study Day 62)	Other, Pre-Op Physical
Electrocardiogram*	15 Oct 2020 (Study Day 62) - 15 Oct 2020 (Study Day 62)	Other, Pre-Op Physical
Rectal prolapse repair*	19 Oct 2020 (Study Day 66) - 19 Oct 2020 (Study Day 66)	Adverse Event
Magnesium citrate	01 Nov 2020 (Study Day 79) - Ongoing	Constipation
Sodium phosphate	01 Nov 2020 (Study Day 79) - 07 Nov 2020 (Study Day 85)	Constipation
Docusate	03 Nov 2020 (Study Day 81) - Ongoing	Constipation
Docusate sodium	03 Nov 2020 (Study Day 81) - Ongoing	Constipation
Macrogol 3350	03 Nov 2020 (Study Day 81) - Ongoing	Constipation
Magnesium hydroxide	03 Nov 2020 (Study Day 81) - Ongoing	Constipation
Ct imaging (abdomen/pelvis)*	04 Nov 2020 (Study Day 82) - 04 Nov 2020 (Study Day 82)	Adverse Event
Docusate sodium; sennoside a+b	04 Nov 2020 (Study Day 82) - 07 Nov 2020 (Study Day 85)	Constipation
Methylprednisolone sodium succinate	04 Nov 2020 (Study Day 82) - 04 Nov 2020 (Study Day 82)	Iv Contrast
Metoclopramide	04 Nov 2020 (Study Day 82) - Ongoing	Nausea/Vomitting
Ondansetron	04 Nov 2020 (Study Day 82) - 04 Nov 2020 (Study Day 82)	Iv Contrast
Ct imaging (abdomen/pelvis)*	05 Nov 2020 (Study Day 83) - 05 Nov 2020 (Study Day 83)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastroenteritis	Grade 1/mild	Not related	20 Aug 2020 (Study Day 6) - 31 Aug 2020 (Study Day 17)
Rectal Haemorrhage	Grade 3/severe	Not related	02 Sep 2020 (Study Day 19) - 19 Oct 2020 (Study Day 66)
Rectocele	Grade 2/moderate	Not related	04 Sep 2020 (Study Day 21) - 19 Oct 2020 (Study Day 66)
Abdominal Pain	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 24) - 19 Oct 2020 (Study Day 66)
Fatigue	Grade 2/moderate	Not related	16 Sep 2020 (Study Day 33) - 02 Oct 2020 (Study Day 49)
Headache	Grade 3/severe	Not related	16 Sep 2020 (Study Day 33) - 01 Oct 2020 (Study Day 48)
Myalgia	Grade 1/mild	Not related	17 Sep 2020 (Study Day 34) - 03 Oct 2020 (Study Day 50)
Diarrhoea	Grade 2/moderate	Not related	17 Sep 2020 (Study Day 34) - 30 Sep 2020 (Study Day 47)
Constipation	Grade 2/moderate	Not related	19 Oct 2020 (Study Day 66) - Ongoing
Nausea	Grade 3/severe	Not related	04 Nov 2020 (Study Day 82) - 25 Nov 2020 (Study Day 103)
Vomiting	Grade 1/mild	Not related	04 Nov 2020 (Study Day 82) - 25 Nov 2020 (Study Day 103)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2377 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	15 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	16 Nov 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suicidal Ideation/Suicidal Ideation	SAE	Grade 4	Not related	21 Nov 2020 (Study Day 38) – 30 Nov 2020 (Study Day 47)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2377, a 48-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 15 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 16 Nov 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Nov 2020 (Study Day 38), 37 days after the first dose and 5 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of suicidal ideation. Action taken with the IP was not applicable. The event of suicidal ideation lasted for 10 days, after which it was considered to be recovered/resolved with sequelae on 30 Nov 2020 (Study Day 47). The investigator assessed the event of suicidal ideation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000918	Suicidal ideation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol use disorder	Severe alcohol use disorder- not in remission	Not reported - Ongoing
Drug use disorder	Severe stimulant use disorder	Not reported - Ongoing
Major depression	Major depressive disorder recurrent, severe, with psychotic features	Not reported - Ongoing
Substance abuse	Substance abuse	Not reported - Ongoing
Suicide attempt	Suicide attempt, previous	Not reported - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1998 - Ongoing
Obesity	Severe obesity	2012 - Ongoing
Back pain	Lumbar pain	11 Jun 2012 (Study Day -3048) - Ongoing
Neck pain	Chronic cervical pain	11 Jun 2012 (Study Day -3048) - Ongoing
Spinal fusion surgery	Lumbar single level surgical fusion	27 Nov 2012 (Study Day -2879) - 27 Nov 2012 (Study Day -2879)
Spinal fusion surgery	Single level cervical surgical fusion	14 Feb 2013 (Study Day -2800) - 14 Feb 2013 (Study Day -2800)
Hypertension	Hypertension	2016 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2016 - Ongoing
Schizoaffective disorder bipolar type	Schizoaffective disorder bipolar type	05 Nov 2017 (Study Day -1075) - Ongoing
Chronic kidney disease	Chronic kidney disease	06 Nov 2017 (Study Day -1074) - Ongoing
Hyperlipidaemia	Hyperlipidemia	06 Nov 2017 (Study Day -1074) - Ongoing
Hypokalaemia	Hypokalemia	06 Nov 2017 (Study Day -1074) - Ongoing
Spinal fusion surgery	Single level cervical surgical fusion	14 Feb 2018 (Study Day -974) - 14 Feb 2018 (Study Day -974)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amitriptyline	Not reported - 22 Nov 2020 (Study Day 39)	Severe, Major Recurrent Depression
Bupropion	Not reported - 30 Nov 2020 (Study Day 47)	Major Depressive Disorder
Famotidine	Not reported - 22 Nov 2020 (Study Day 39)	Gastroesophageal Reflux Disease
Hydrocodone bitartrate; paracetamol	Not reported - 22 Nov 2020 (Study Day 39)	Chronic Lumbar Pain, Chronic Cervical Pain
Naproxen	Not reported - 30 Nov 2020 (Study Day 47)	Chronic Neck And Chronic Back Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2016 - Ongoing	Hypertension
Metformin	2016 - Ongoing	Diabetes Mellitus Type 2
Omeprazole	2016 - Ongoing	Gastroesophageal Reflux Disease
Ibuprofen	18 Nov 2017 (Study Day -1062) - 22 Nov 2020 (Study Day 39)	Chronic Lumbar Pain, Chronic Cervical Pain
Vitamin b complex	2019 - Ongoing	Nutritional Supplement
Paracetamol	18 Oct 2020 (Study Day 4) - Ongoing	Fever
Aripiprazole	30 Nov 2020 (Study Day 47) - Ongoing	Suicidal Ideation
Nortriptyline	30 Nov 2020 (Study Day 47) - Ongoing	Suicidal Ideation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US328-2113 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	16 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	19 Nov 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/Coronary Artery Disease	SAE	Grade 4	Not related	23 Oct 2020 (Study Day 8) – Ongoing	Not recovered/not resolved
Pulmonary Embolism/ Multiple Subsegmental Pulmonary Emboli	SAE	Grade 4	Not related	06 Nov 2020 (Study Day 22) – 08 Dec 2020 (Study Day 54)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US328-2113, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 16 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 19 Nov 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Oct 2020 (Study Day 8), 7 days after the first dose and 27 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of coronary artery disease. The IP dose was not changed due to the coronary artery disease. The event of coronary artery disease was considered to be ongoing. The investigator assessed the event of coronary artery disease to be not related to the IP.

On 06 Nov 2020 (Study Day 22), 21 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pulmonary embolism. The IP dose was not changed due to the multiple subsegmental pulmonary emboli. The event of multiple subsegmental pulmonary emboli lasted for 33 days, after which it was considered to be recovered/resolved on 08 Dec 2020 (Study Day 54). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000563	Coronary artery disease
MOD-2020-000563	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Angina pectoris	Intermittent midsternal chest pain, cardiac	2010 - 02 Nov 2020 (Study Day 18)
Dermal filler injection	Unknown dermal filler to face	2014 - 2014
Sleep apnoea syndrome	Obstructive sleep apnea	2014 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Hypothyroidism	Hypothyroidism	2017 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Sep 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ipratropium bromide	2015 – Ongoing	Seasonal Allergies
Atorvastatin	2017 - 23 Oct 2020 (Study Day 8)	Hyperlipidemia
Levothyroxine	2017 - 23 Oct 2020 (Study Day 8)	Hypothyroidism
Tamsulosin	Sep 2018 – Ongoing	Benign Prostatic Hyperplasia
Ct coronay angiography*	23 Oct 2020 (Study Day 8) - 23 Oct 2020 (Study Day 8)	Adverse Event
Sodium chloride	23 Oct 2020 (Study Day 8) - 23 Oct 2020 (Study Day 8)	Coronary Artery Disease
Atorvastatin	24 Oct 2020 (Study Day 9) – Ongoing	Coronary Artery Disease
Levothyroxine	24 Oct 2020 (Study Day 9) – Ongoing	Hypothyroidism
Losartan	24 Oct 2020 (Study Day 9) - 06 Nov 2020 (Study Day 22)	Congestive Heart Failure
Metoprolol	24 Oct 2020 (Study Day 9) – Ongoing	Congestive Heart Failure
Cardiac catheterization*	27 Oct 2020 (Study Day 12) - 27 Oct 2020 (Study Day 12)	Adverse Event
Ekg*	30 Oct 2020 (Study Day 15) - 30 Oct 2020 (Study Day 15)	Adverse Event
Acetylsalicylic acid	Nov 2020 – Ongoing	Anti-Coagulation Post Cabg

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	Nov 2020 - 16 Nov 2020 (Study Day 32)	Pulmonary Thromboembolism
Heparin	Nov 2020 - Nov 2020	Pulmonary Thromboembolism
Oxycodone	Nov 2020 - 16 Nov 2020 (Study Day 32)	Post Cabg Pain
Coronary artery bypass graft*	02 Nov 2020 (Study Day 18) - 02 Nov 2020 (Study Day 18)	Adverse Event
Pneumococcal vaccine polysacch 23v	10 Nov 2020 (Study Day 26) - 10 Nov 2020 (Study Day 26)	Pneumonia Phophylaxis
Apixaban	17 Nov 2020 (Study Day 33) - Ongoing	Multiple Subsegmental Pulmonary Emboli

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cardiac Failure Congestive	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 8) - Ongoing
Musculoskeletal Chest Pain	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 8) - 23 Oct 2020 (Study Day 8)
Renal Cyst	Grade 1/mild	Not related	23 Oct 2020 (Study Day 8) - Ongoing
Procedural Pain	Grade 2/moderate	Not related	02 Nov 2020 (Study Day 18) - 08 Jan 2021 (Study Day 85)
Pleural Effusion	Grade 3/severe	Not related	06 Nov 2020 (Study Day 22) - 10 Nov 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2103 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	05 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Subdural Haematoma/Subdural Hematoma	SAE	Grade 3/severe	Not related	14 Nov 2020 (Study Day 99) – 26 Jan 2021 (Study Day 172)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2103, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 05 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Nov 2020 (Study Day 99), 98 days after the first dose and 70 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of subdural haematoma. Action taken with the IP was not applicable. The event of subdural hematoma lasted for 74 days, after which it was considered to be recovered/resolved on 26 Jan 2021 (Study Day 172). The investigator assessed the event of subdural haematoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000871	Subdural hematoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Visual acuity reduced	Bilateral decreased visual acuity	1963 - Ongoing
Rheumatoid arthritis	Bilateral hip rheumatoid arthritis	1967 - 1999
Medical device implantation	Harrington rod implant	1974 - 1974
Scoliosis	Scoliosis	1974 - 1974
Caesarean section	C-section	Apr 1984 - Apr 1984
Caesarean section	C-section	Aug 1988 - Aug 1988
Hypersensitivity	Environmental cedar allergy	1990 - Ongoing
Hip arthroplasty	Total hip replacement	1999 - 1999
Arthralgia	Chronic generalized joint pain	2000 - Ongoing
Gastrooesophageal reflux disease	Esophageal reflux (gerd)	2000 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Postmenopause	Post menopausal	2007 - Ongoing
Hypercholesterolaemia	Hypercholersterolemia	2015 - Ongoing
Hypothyroidism	Hypothyroid	2015 - Ongoing
Progesterone decreased	Low progesterone	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Esomeprazole magnesium	2000 - Ongoing	Gerd
Paracetamol	2000 - Ongoing	Generalized Joint Pain
Amlodipine	2005 - Ongoing	Hypertension
Losartan	2005 - Ongoing	Hypertension
Metoprolol	2005 - Ongoing	Hypertension
Magnesium citrate	2014 - Ongoing	General Health
Atorvastatin	2015 - Ongoing	Hypercholesterolemia
Calcium	2015 - Ongoing	General Health
Colecalciferol	2015 - Ongoing	General Health
Fish oil	2015 - Ongoing	General Health
Progesterone	2015 - Ongoing	Low Progesterone
Thyroid	2015 - Ongoing	Hypothyroid
Vitamin b nos	2015 - Ongoing	General Health
Vitamin k nos	2015 - Ongoing	General Health
Vitamins nos	2015 - Ongoing	General Health
Fexofenadine hydrochloride	2019 - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	06 Oct 2020 (Study Day 60) - 06 Oct 2020 (Study Day 60)	Prophylaxis For Flu Prevention
Levetiracetam	14 Nov 2020 (Study Day 99) - 22 Nov 2020 (Study Day 107)	Seizure Prevention Following Subdural Hematoma
Head ct*	15 Nov 2020 (Study Day 100) - 15 Nov 2020 (Study Day 100)	Adverse Event
Tetanus vaccine	15 Nov 2020 (Study Day 100) - 15 Nov 2020 (Study Day 100)	Vaccine For Tetanus
Head ct*	17 Nov 2020 (Study Day 102) - 17 Nov 2020 (Study Day 102)	Adverse Event
Head ct*	10 Dec 2020 (Study Day 125) - 10 Dec 2020 (Study Day 125)	Adverse Event
Pneumococcal vaccine polysacch 23v	16 Dec 2020 (Study Day 131) - 16 Dec 2020 (Study Day 131)	Vaccine For Pneumonia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fall	Grade 3/severe	Not related	14 Nov 2020 (Study Day 99) - 14 Nov 2020 (Study Day 99)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2127 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Road Traffic Accident/Motor Vehicle Accident	SAE	Grade 3/severe	Not related	25 Nov 2020 (Study Day 107) – 25 Nov 2020 (Study Day 107)	Recovered/ resolved
Gastrointestinal Haemorrhage/Internal Gi Hemorrhage - Motor Vehical Accident	SAE	Grade 3/severe	Not related	13 Dec 2020 (Study Day 125) – 11 Jan 2021 (Study Day 154)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2127, a 74-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Nov 2020 (Study Day 107), 106 days after the first dose and 78 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of road traffic accident. Action taken with the IP was not applicable. The event of motor vehicle accident lasted for 1 days, after which it was considered to be recovered/resolved on 25 Nov 2020 (Study Day 107). The investigator assessed the event of road traffic accident to be not related to the IP.

On 13 Dec 2020 (Study Day 125), 124 days after the first dose and 96 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of gastrointestinal haemorrhage. Action taken with the IP was not applicable. The event of internal gi hemorrhage - motor vehical accident lasted for 30 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 154). The investigator assessed the event of gastrointestinal haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000989	Road traffic accident
MOD-2020-000989	Gastrointestinal haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Visual acuity reduced	Decreased visual acuity	1953 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Prophylaxis For The General Cardiac Health
Vitamin d nos	2010 - Ongoing	Supplement
Vitamins nos	2010 - Ongoing	Supplement
Amlodipine	2013 - Ongoing	Hypertension
Hydrochlorothiazide	2013 - Ongoing	Hypertension
Lisinopril	2013 - Ongoing	Hypertension
Potassium	2013 - Ongoing	Supplement
Simvastatin	2016 - Ongoing	Hypercholesterol
Ct abdominal pelvis*	25 Nov 2020 (Study Day 107) - 25 Nov 2020 (Study Day 107)	Adverse Event
Four compartment fasciotomy (rle)*	25 Nov 2020 (Study Day 107) - 25 Nov 2020 (Study Day 107)	Adverse Event
Ondansetron	25 Nov 2020 (Study Day 107) - 04 Dec 2020 (Study Day 116)	Motor Vehicle Accident
Morphine sulfate	26 Nov 2020 (Study Day 108) - 04 Dec 2020 (Study Day 116)	Motor Vehicle Accident
Hydromorphone	27 Nov 2020 (Study Day 109) - 27 Nov 2020 (Study Day 109)	Pain From Motor Vehicle Accident

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Debridement rle wound vac placement*	28 Nov 2020 (Study Day 110) - 28 Nov 2020 (Study Day 110)	Adverse Event
Docusate sodium	30 Nov 2020 (Study Day 112) - 04 Dec 2020 (Study Day 116)	Motor Vehicle Accident
Enoxaparin	30 Nov 2020 (Study Day 112) - 04 Dec 2020 (Study Day 116)	Motor Vehicle Accident
Tramadol	30 Nov 2020 (Study Day 112) - 04 Jan 2021 (Study Day 147)	General Localized Pain From Motor Vehicle Accident
Excisional debridement rle wound vac placement*	01 Dec 2020 (Study Day 113) - 01 Dec 2020 (Study Day 113)	Adverse Event
Chest x-ray*	17 Dec 2020 (Study Day 129) - 17 Dec 2020 (Study Day 129)	Diagnostic
Dexamethasone	17 Dec 2020 (Study Day 129) - 11 Jan 2021 (Study Day 154)	Motor Vehicle Accident
Doppler ultrasound*	17 Dec 2020 (Study Day 129) - 17 Dec 2020 (Study Day 129)	Diagnostic
Gabapentin	17 Dec 2020 (Study Day 129) - 11 Jan 2021 (Study Day 154)	Pain From Motor Vehicle Accident
Iohexol	17 Dec 2020 (Study Day 129) - 17 Dec 2020 (Study Day 129)	Motor Vehicle Accident
Senna alexandrina glycoside extract	17 Dec 2020 (Study Day 129) - 11 Jan 2021 (Study Day 154)	Internal Gi Hemorrhage - Motor Vehical Accident
Simvastatin	17 Dec 2020 (Study Day 129) - 11 Jan 2021 (Study Day 154)	Motor Vehicle Accident
Solutions for parenteral nutrition	17 Dec 2020 (Study Day 129) - 11 Jan 2021 (Study Day 154)	Internal Gi Hemorrhage - Motor Vehical Accident
Debridement of wound*	18 Dec 2020 (Study Day 130) - 18 Dec 2020 (Study Day 130)	Adverse Event
Egd*	19 Dec 2020 (Study Day 131) - 19 Dec 2020 (Study Day 131)	Diagnostic
Blood transfusion*	20 Dec 2020 (Study Day 132) - 20 Dec 2020 (Study Day 132)	Adverse Event
Colonoscopy*	21 Dec 2020 (Study Day 133) - 21 Dec 2020 (Study Day 133)	Diagnostic
Egd*	21 Dec 2020 (Study Day 133) - 21 Dec 2020 (Study Day 133)	Diagnostic
Hemostatic clips*	21 Dec 2020 (Study Day 133) - 21 Dec 2020 (Study Day 133)	Adverse Event
Blood transfusion*	22 Dec 2020 (Study Day 134) - 22 Dec 2020 (Study Day 134)	Adverse Event
Blood transfusion*	23 Dec 2020 (Study Day 135) - 23 Dec 2020 (Study Day 135)	Adverse Event
Blood transfusion*	25 Dec 2020 (Study Day 137) - 25 Dec 2020 (Study Day 137)	Adverse Event
Blood transfusion*	27 Dec 2020 (Study Day 139) - 27 Dec 2020 (Study Day 139)	Adverse Event
Blood transfusion*	28 Dec 2020 (Study Day 140) - 28 Dec 2020 (Study Day 140)	Adverse Event
Chest x-ray*	28 Dec 2020 (Study Day 140) - 28 Dec 2020 (Study Day 140)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Egd*	28 Dec 2020 (Study Day 140) - 28 Dec 2020 (Study Day 140)	Diagnostic
Hemostatic clips*	28 Dec 2020 (Study Day 140) - 28 Dec 2020 (Study Day 140)	Adverse Event
Chest x-ray*	29 Dec 2020 (Study Day 141) - 29 Dec 2020 (Study Day 141)	Diagnostic
Ct-abdomen*	29 Dec 2020 (Study Day 141) - 29 Dec 2020 (Study Day 141)	Diagnostic
Embolization*	29 Dec 2020 (Study Day 141) - 29 Dec 2020 (Study Day 141)	Adverse Event
Chest x-ray*	30 Dec 2020 (Study Day 142) - 30 Dec 2020 (Study Day 142)	Diagnostic
Doppler ultrasound*	01 Jan 2021 (Study Day 144) - 01 Jan 2021 (Study Day 144)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Haematoma	Grade 3/severe	Not related	25 Nov 2020 (Study Day 107) - 04 Jan 2021 (Study Day 147)
Ligament Injury	Grade 3/severe	Not related	25 Nov 2020 (Study Day 107) - Ongoing
Limb Injury	Grade 3/severe	Not related	25 Nov 2020 (Study Day 107) - Ongoing
Pleural Effusion	Grade 3/severe	Not related	25 Nov 2020 (Study Day 107) - 08 Jan 2021 (Study Day 151)
Post-Traumatic Pain	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 107) - 04 Jan 2021 (Study Day 147)
Prostatomegaly	Grade 3/severe	Not related	25 Nov 2020 (Study Day 107) - 01 Jan 2021 (Study Day 144)
Skin Laceration	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 107) - 14 Dec 2020 (Study Day 126)
Skin Laceration	Grade 3/severe	Not related	25 Nov 2020 (Study Day 107) - 07 Jan 2021 (Study Day 150)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2236 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Fibromuscular Dysplasia/Fibromuscular Dysplasia	SAE	Grade 2/ moderate	Not related	04 Sep 2020 (Study Day 16) – 05 Sep 2020 (Study Day 17)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2236, a 80-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Sep 2020 (Study Day 16), 15 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of fibromuscular dysplasia. The IP dose was not changed due to the fibromuscular dysplasia. The event of fibromuscular dysplasia lasted for 2 days, after which it was considered to be recovered/resolved on 05 Sep 2020 (Study Day 17). The investigator assessed the event of fibromuscular dysplasia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000272	Fibromuscular dysplasia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1972 - Ongoing
Hysterectomy	Hysterectomy	1979 - 1979
Uterine leiomyoma	Uterine fibroids	1979 - 1979
Cataract	Cataracts ou	1986 - 2016
Gastric ulcer	Stomach ulcer	1986 - 1986
Upper gastrointestinal haemorrhage	Upper gi bleed	1986 - 1986
Food allergy	Allergies to soy	1987 - Ongoing
Migraine	Migraine headaches	1987 - Ongoing
Deafness bilateral	Bilateral hearing loss	1990 - Ongoing
Pneumonia	Hospitalization - pneumonia	1990 - 1990
Osteopenia	Osteopenia	2000 - Ongoing
Squamous cell carcinoma	Squamous cell cancer - rle	2000 - 2000
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Cataract operation	Cataract removal ou - bilateral	2016 - 2016
Pneumonia	Hospitalization - pneumonia	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sumatriptan	1985 - Ongoing	Migraine Headaches
Calcium	2000 - Ongoing	Osteopenia
Curcuma longa	2015 - Ongoing	Nutritional Supplement
Fish oil	2015 - Ongoing	Hyperlipidemia
Magnesium	2015 - Ongoing	Nutritional Supplement
Potassium	2015 - Ongoing	Nutritional Supplement
Ubidecarenone	2017 - Ongoing	Nutritional Supplement
Botulinum toxin type a	Apr 2020 - Apr 2020	Cosmetic Facial Injection
Erenumab	21 Aug 2020 (Study Day 2) - 21 Aug 2020 (Study Day 2)	Migraine Headaches
Brain mra*	04 Sep 2020 (Study Day 16) - 04 Sep 2020 (Study Day 16)	Diagnostic
Brain mri*	04 Sep 2020 (Study Day 16) - 04 Sep 2020 (Study Day 16)	Diagnostic
Meclozine	04 Sep 2020 (Study Day 16) - 05 Sep 2020 (Study Day 17)	Vertigo

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vertigo	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 15) - 04 Sep 2020 (Study Day 16)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378718

Participant Number:	US329-2245 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE	Grade 3/severe	Not related	01 Nov 2020 (Study Day 74) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2245, a 67-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 74), 73 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. The IP dose was not changed due to the prostate cancer. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-096154	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic back pain	1990 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Vitiligo	Vitiligo	2010 - Ongoing
Hypertension	Hypertension	May 2016 - Ongoing
Myocardial infarction	Myocardial infarction	May 2016 - May 2016
Stent placement	Stent placement - x3	May 2016 - May 2016
Myocardial infarction	Myocardial infarction	09 Jan 2018 (Study Day -954) - 09 Jan 2018 (Study Day -954)
Stent placement	Stent placement - x1	09 Jan 2018 (Study Day -954) - 09 Jan 2018 (Study Day -954)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1990 - Ongoing	Cardiac Prophylaxis
Glucosamine	2000 - Ongoing	Nutritional Supplement
Vitamins nos	2000 - Ongoing	Nutritional Supplement
Krill oil	2010 - Ongoing	Nutritional Supplement
Ubidecarenone	2015 - Ongoing	Nutritional Supplement
Atorvastatin	May 2016 - Ongoing	Hyperlipidemia
Carvedilol	May 2016 - Ongoing	Hypertension
Losartan	May 2016 - Ongoing	Hypertension
Prasugrel	May 2016 - Ongoing	Clotting Prophylaxis
Cetyl myristoleate	Apr 2020 - Ongoing	Nutritional Supplement
Crataegus spp. extract	Apr 2020 - Ongoing	Nutritional Supplement
Prasterone	Apr 2020 - Ongoing	Nutritional Supplement
Resveratrol	Apr 2020 - Ongoing	Nutritional Supplement
Zinc	Apr 2020 - Ongoing	Nutritional Supplement
Influenza vaccine	21 Oct 2020 (Study Day 63) - 21 Oct 2020 (Study Day 63)	Flu Pervetion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US329-2259 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Hernia/Abdominal Hernia	SAE	Grade 3/severe	Not related	29 Dec 2020 (Study Day 132) – 29 Dec 2020 (Study Day 132)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2259, a 50-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Dec 2020 (Study Day 132), 131 days after the first dose and 103 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abdominal hernia. Action taken with the IP was not applicable. The event of abdominal hernia lasted for 1 days, after which it was considered to be recovered/resolved on 29 Dec 2020 (Study Day 132). The investigator assessed the event of abdominal hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004569	Abdominal hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Low back pain	1998 - Ongoing
Spinal operation	Low back surgery	1998 - 1998
Spinal operation	Low back surgery	1999 - 1999
Abdominal hernia	Ventral hernia	2009 - 2017
Abdominal hernia repair	Ventral hernia repair	2011 - 2011
Abdominal hernia repair	Ventral hernia repair	2017 - 2017
Type 2 diabetes mellitus	Diabetes type ii	Nov 2019 - Ongoing
Contusion	Head contusion	15 May 2020 (Study Day -97) - 15 May 2020 (Study Day -97)
Headache	Headaches secondary to head contusion	15 May 2020 (Study Day -97) - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	15 Aug 2020 (Study Day -5) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocodone bitartrate; paracetamol	1998 - Ongoing	Low Back Pain
Sitagliptin	Nov 2019 - Ongoing	Diabetes Type Ii
Topiramate	09 Aug 2020 (Study Day -11) - Ongoing	Headache
Atorvastatin	15 Aug 2020 (Study Day -5) - Ongoing	Hypercholesterolemia
Paracetamol	21 Aug 2020 (Study Day 2) - 25 Aug 2020 (Study Day 6)	Mild Fever
Prednisolone	01 Sep 2020 (Study Day 13) - 17 Sep 2020 (Study Day 29)	Eye Infection
Baclofen	07 Nov 2020 (Study Day 80) - Ongoing	Muscle Aches
Baclofen	07 Nov 2020 (Study Day 80) - 16 Nov 2020 (Study Day 89)	Muscle Soreness
Varicella zoster vaccine	06 Dec 2020 (Study Day 109) - 06 Dec 2020 (Study Day 109)	Prophylaxis
Varicella zoster vaccine	06 Dec 2020 (Study Day 109) - 06 Dec 2020 (Study Day 109)	Shingles
Bilat myocut flaps*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Exploratory laparotomy*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Omentectomy*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Removal of fb*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Ventral hernia repair*	29 Dec 2020 (Study Day 132) - 29 Dec 2020 (Study Day 132)	Adverse Event
Paracetamol	28 Jan 2021 (Study Day 162) - Ongoing	Pain At Injection Site
Cat scan - abdomen/pelvis*	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Adverse Event
Cefepime hydrochloride	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Ceftriaxone	13 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 178)	Abdominal Hernia Repair Infection
Glucagon	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Hydrocodone; paracetamol	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Insulin lispro	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Magnesium oxide	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Magnesium sulfate	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Metronidazole	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Morphine sulfate	13 Feb 2021 (Study Day 178) - 15 Feb 2021 (Study Day 180)	Abdominal Hernia Repair Infection
Ondansetron hydrochloride	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Paracetamol	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Potassium chloride	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Sodium chloride	13 Feb 2021 (Study Day 178) - 16 Feb 2021 (Study Day 181)	Abdominal Hernia Repair Infection
Vancomycin	13 Feb 2021 (Study Day 178) - 18 Feb 2021 (Study Day 183)	Abdominal Hernia Repair Infection
Ultrasound guided needle aspiration*	15 Feb 2021 (Study Day 180) - 15 Feb 2021 (Study Day 180)	Adverse Event
Ciprofloxacin	17 Feb 2021 (Study Day 182) - 26 Feb 2021 (Study Day 191)	Abdominal Hernia Repair Infection
Metronidazole	17 Feb 2021 (Study Day 182) - 26 Feb 2021 (Study Day 191)	Abdominal Hernia Repair Infection
Broken incisor repair*	20 Mar 2021 (Study Day 213) - 20 Mar 2021 (Study Day 213)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Eye Infection	Grade 1/mild	Not related	30 Aug 2020 (Study Day 11) - 17 Sep 2020 (Study Day 29)
Chills	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 80) - 17 Dec 2020 (Study Day 120)
Fatigue	Grade 3/severe	Not related	07 Nov 2020 (Study Day 80) - 21 Nov 2020 (Study Day 94)
Headache	Grade 1/mild	Not related	07 Nov 2020 (Study Day 80) - 23 Dec 2020 (Study Day 126)
Myalgia	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 80) - 16 Nov 2020 (Study Day 89)
Nausea	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 91)
Pain	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 80) - 24 Dec 2020 (Study Day 127)
Cough	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 89) - 22 Dec 2020 (Study Day 125)
Diarrhoea	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 89) - 19 Nov 2020 (Study Day 92)
Dyspnoea	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 89) - 17 Dec 2020 (Study Day 120)
Dyspnoea	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 89) - 17 Nov 2020 (Study Day 90)
Nasal Congestion	Grade 1/mild	Not related	16 Nov 2020 (Study Day 89) - 17 Nov 2020 (Study Day 90)
Oropharyngeal Pain	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 89) - 21 Nov 2020 (Study Day 94)
Pyrexia	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 89) - 17 Nov 2020 (Study Day 90)
Rhinorrhoea	Grade 1/mild	Not related	18 Nov 2020 (Study Day 91) - 21 Nov 2020 (Study Day 94)
Fatigue	Grade 3/severe	Not related	22 Dec 2020 (Study Day 125) - 23 Dec 2020 (Study Day 126)
Myalgia	Grade 3/severe	Not related	22 Dec 2020 (Study Day 125) - 23 Dec 2020 (Study Day 126)
Nausea	Grade 2/moderate	Not related	22 Dec 2020 (Study Day 125) - 23 Dec 2020 (Study Day 126)
Dyspnoea	Grade 1/mild	Not related	25 Dec 2020 (Study Day 128) - 26 Dec 2020 (Study Day 129)
Nasal Congestion	Grade 1/mild	Not related	26 Dec 2020 (Study Day 129) - Ongoing
Rhinorrhoea	Grade 1/mild	Not related	26 Dec 2020 (Study Day 129) - Ongoing
Abdominal Pain	Grade 2/moderate	Not related	29 Dec 2020 (Study Day 132) - Ongoing
Tooth Fracture	Grade 2/moderate	Not related	29 Dec 2020 (Study Day 132) - 20 Mar 2021 (Study Day 213)
Injection Site Pain	Grade 2/moderate	Related	28 Jan 2021 (Study Day 162) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2304 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Large Intestine Perforation/Perforated Colon	SAE	Grade 3/severe	Not related	04 Oct 2020 (Study Day 41) – 06 Oct 2020 (Study Day 43)	Recovered/ resolved
Pulmonary Embolism/Pulmonary Embolism	SAE	Grade 3/severe	Not related	07 Oct 2020 (Study Day 44) – 01 Apr 2021 (Study Day 220)	Recovered/ resolved
Pulmonary Embolism/Right Lung Pulmonary Emboli	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 144) – 01 Apr 2021 (Study Day 220)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2304, a 35-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Oct 2020 (Study Day 41), 40 days after the first dose and 12 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of large intestine perforation. Action taken with the IP was not applicable. The event of perforated colon lasted for 3 days, after which it was considered to be recovered/resolved on 06 Oct 2020 (Study Day 43). The investigator assessed the event of large intestine perforation to be not related to the IP.

On 07 Oct 2020 (Study Day 44), 43 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolism lasted for 177 days, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 220). The investigator assessed the event of pulmonary embolism to be not related to the IP.

On 15 Jan 2021 (Study Day 144), 143 days after the first dose and 115 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary

embolism. Action taken with the IP was not applicable. The event of right lung pulmonary emboli lasted for 77 days, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 220). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000427	Large intestine perforation
MOD-2020-000427	Pulmonary embolism
MOD-2021-005683	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cleft lip repair	Cleft lip repair	(b) (6) 1985 - (b) (6) 1985
Cleft lip	Cleft lip	(b) (6) 1985 (Study Day (b) (6)) - (b) (6) 1985 (Study Day (b) (6))
Food allergy	Pecan allergy	1992 - Ongoing
Hypersensitivity	Environmental allergies	1992 - Ongoing
Acne	Adult facial acne	2000 - Ongoing
Meniscus injury	Torn meniscus right knee	2003 - 2003
Meniscus operation	Orthoscopic meniscus repair	2003 - 2003
Wisdom teeth removal	Wisdom teeth removal	2004 - 2004
Intervertebral disc protrusion	L4-l5 bulging discs	2005 - 2005
Intrathecal injection	Steroid injection due to inflammed disks in back due to motorcycle accident	2005 - 2005
Abdominal pain upper	Stomach pain	2007 - 2007
Endoscopy	Endoscopy	2007 - 2007
Diverticulum	Diverticulosis	Mar 2019 - Ongoing
Colonoscopy	Colonoscopy	Apr 2019 - Apr 2019
Large intestinal polypectomy	Small polyp removal in colon	Apr 2019 - Apr 2019
Depression	Depression	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2000 - Ongoing	Seasonal Allergies
Montelukast sodium	2010 - Ongoing	Seasonal Allergies
Curcuma longa	2019 - 04 Oct 2020 (Study Day 41)	Health Supplement
Paracetamol	2019 - Ongoing	Pain Preventative
Probiotics nos	Feb 2020 - Ongoing	Digestion Supplement
Vitamins nos	May 2020 - Ongoing	Health Supplement
Zingiber officinale	May 2020 - 04 Oct 2020 (Study Day 41)	Health Supplement
Dicycloverine	Jul 2020 - 04 Oct 2020 (Study Day 41)	Diverticulosis
Methylcellulose	Aug 2020 - 04 Oct 2020 (Study Day 41)	Supplement
Paracetamol	23 Sep 2020 (Study Day 30) - 23 Sep 2020 (Study Day 30)	Headache (Reactogenicity)
Ileostomy*	06 Oct 2020 (Study Day 43) - 06 Oct 2020 (Study Day 43)	Adverse Event
Rivaroxaban	22 Oct 2020 (Study Day 59) - 15 Jan 2021 (Study Day 144)	Prophylaxis
Warfarin	16 Jan 2021 (Study Day 145) - Ongoing	Prophylaxis
Pantoprazole sodium sesquihydrate	17 Jan 2021 (Study Day 146) - Ongoing	Health Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US329-2312 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Stroke	SAE	Grade 4	Not related	25 Oct 2020 (Study Day 62) – 25 Oct 2020 (Study Day 62)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2312, a 56-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Oct 2020 (Study Day 62), 61 days after the first dose and 33 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of stroke lasted for 1 days, after which it was considered to be recovered/resolved on 25 Oct 2020 (Study Day 62). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000547	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	1995 - 1995
Coronary artery disease	Coronary artery disease	2009 - Ongoing
Stent placement	Stent placement	2009 - 2009
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertriglyceridaemia	Hypertriglyceridemia	Feb 2010 - Ongoing
Diverticulitis	Diverticulitis	2015 - 2015
Blood testosterone decreased	Low testosterone	2019 - Ongoing
Visual acuity reduced	Bilateral decreased visual acuity	2019 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	Jan 2019 - Ongoing
Hypertension	Hypertension	Feb 2019 - Ongoing
Oedema due to cardiac disease	Cardiac edema (cad)	Feb 2019 - Ongoing
Coronary artery bypass	Cabg	26 Feb 2019 (Study Day -546) - 26 Feb 2019 (Study Day -546)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Heart Health
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Clopidogrel bisulfate	2010 - Ongoing	Cad
Carvedilol	28 Feb 2019 (Study Day -544) - Ongoing	Hypertension
Eicosapentaenoic acid ethyl ester	28 Feb 2019 (Study Day -544) - Ongoing	Hypertriglyceridemia
Bumetanide	Mar 2019 - Ongoing	Cardiac Edema
Lisinopril	Mar 2019 - Ongoing	Hypertension/Cardiac Edema
Empagliflozin; metformin hydrochloride	Jun 2019 - Ongoing	Type 2 Diabetes
Eplerenone	30 Jun 2020 (Study Day -56) - Ongoing	Hypertension
Alteplase	Oct 2020 - Oct 2020	Acute Cva
Vancomycin	Oct 2020 - Oct 2020	Prophylaxis Of Infection
Alteplase	25 Oct 2020 (Study Day 62) - 25 Oct 2020 (Study Day 62)	Stroke
Bisacodyl	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)	Constipation
Chest x-ray*	25 Oct 2020 (Study Day 62) - 25 Oct 2020 (Study Day 62)	Diagnostic
Cta-head and neck*	25 Oct 2020 (Study Day 62) - 25 Oct 2020 (Study Day 62)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)	Gerd
Head ct*	25 Oct 2020 (Study Day 62) - 25 Oct 2020 (Study Day 62)	Diagnostic
Iopamidol	25 Oct 2020 (Study Day 62) - 25 Oct 2020 (Study Day 62)	Acute Cva (Cta)
Magnesium hydroxide	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)	Constipation
Naloxone	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)	Arousal Difficulty
Ondansetron	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)	Nausea
Sodium chloride	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)	Prophylaxis (Infection)
Ceftriaxone	26 Oct 2020 (Study Day 63) - 29 Oct 2020 (Study Day 66)	Uti
Echocardiogram*	26 Oct 2020 (Study Day 63) - 26 Oct 2020 (Study Day 63)	Adverse Event
Head ct*	26 Oct 2020 (Study Day 63) - 26 Oct 2020 (Study Day 63)	Diagnostic
Mri*	26 Oct 2020 (Study Day 63) - 26 Oct 2020 (Study Day 63)	Diagnostic
Vancomycin	26 Oct 2020 (Study Day 63) - 29 Oct 2020 (Study Day 66)	Prophylaxis Of Infection
Carotid doppler*	27 Oct 2020 (Study Day 64) - 27 Oct 2020 (Study Day 64)	Diagnostic
Transesophageal*	28 Oct 2020 (Study Day 65) - 28 Oct 2020 (Study Day 65)	Diagnostic
Apixaban	30 Oct 2020 (Study Day 67) - Ongoing	Prophylaxis For Stroke
Testosterone	30 Oct 2020 (Study Day 67) - Ongoing	Low Testosterone
Ticagrelor	30 Oct 2020 (Study Day 67) - Ongoing	Prophylaxis For Stroke
Influenza vaccine	14 Nov 2020 (Study Day 82) - 14 Nov 2020 (Study Day 82)	Prophylaxis
Aicd insertion*	30 Dec 2020 (Study Day 128) - 30 Dec 2020 (Study Day 128)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atrial Fibrillation	Grade 3/severe	Not related	25 Oct 2020 (Study Day 62) - 25 Oct 2020 (Study Day 62)
Cardiac Failure	Grade 2/moderate	Not related	25 Oct 2020 (Study Day 62) - 25 Oct 2020 (Study Day 62)
Constipation	Grade 2/moderate	Not related	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Depressed Level Of Consciousness	Grade 2/moderate	Not related	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)
Nausea	Grade 2/moderate	Not related	25 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 66)
Urinary Tract Infection	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 63) - 29 Oct 2020 (Study Day 66)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2316 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abscess Limb/Right Glute Abscess	SAE	Grade 3/severe	Not related	03 Jan 2021 (Study Day 132) – 25 Jan 2021 (Study Day 154)	Recovered/ resolved
Diabetic Ketoacidosis/Diabetic Ketoacidosis	SAE	Grade 3/severe	Not related	09 Jan 2021 (Study Day 138) – 15 Jan 2021 (Study Day 144)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2316, a 39-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Jan 2021 (Study Day 132), 131 days after the first dose and 103 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abscess limb. Action taken with the IP was not applicable. The event of right glute abscess lasted for 23 days, after which it was considered to be recovered/resolved on 25 Jan 2021 (Study Day 154). The investigator assessed the event of abscess limb to be not related to the IP.

On 09 Jan 2021 (Study Day 138), 137 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diabetic ketoacidosis. Action taken with the IP was not applicable. The event of diabetic ketoacidosis lasted for 7 days, after which it was considered to be recovered/resolved on 15 Jan 2021 (Study Day 144). The investigator assessed the event of diabetic ketoacidosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002930	Abscess limb
MOD-2021-002930	Diabetic ketoacidosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1981 - Ongoing
Tonsillectomy	Tonsillectomy	1984 - 1984
Tonsillitis	Tonsillitis	1984 - 1984
Scoliosis	Scoliosis	1985 - Ongoing
Myopia	Myopia	1986 - 2005
Headache	Headaches	1994 - Ongoing
Post-traumatic stress disorder	Ptsd	1995 - Ongoing
Delivery	Vaginal delivery	1996 - 1996
Hypothyroidism	Hypothyroid	1997 - Ongoing
Delivery	Vaginal delivery	2000 - 2000
Factor II deficiency	Factor ii deficiency	2001 - Ongoing
Delivery	Vaginal delivery	2003 - 2003
Type 2 diabetes mellitus	Type ii diabetes	2003 - Ongoing
Keratomileusis	Bilateral lasik surgery	2005 - 2005
Nonalcoholic fatty liver disease	Nonalcoholic fatty liver disease	2006 - Ongoing
Caesarean section	C-section	2010 - 2010
Female sterilisation	Tubal ligation (bilateral)	2010 - 2010
Diabetic neuropathy	Diabetic peripheral neuropathy (hands and feet)	2015 - Ongoing
Anxiety	Anxiety	2017 - Ongoing
Bipolar I disorder	Bipolar i	2017 - Ongoing
Drug hypersensitivity	Penicillin allergy	2017 - Ongoing
Allergy to animal	Pet dander allergy	2018 - Ongoing
Dust allergy	Environmental dust allergy	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1994 - Ongoing	Headaches
Levothyroxine	1997 - Ongoing	Hypothyroid
Gabapentin	2015 - Ongoing	Dpn

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lorazepam	2017 - Ongoing	Anxiety
Risperidone	2017 - 30 Jun 2020 (Study Day -56)	Bipolar
Insulin detemir	2019 - 07 Jan 2021 (Study Day 136)	Type Ii Diabetes
Insulin lispro	2019 - 07 Jan 2021 (Study Day 136)	Type Ii Diabetes
Influenza vaccine	13 Oct 2020 (Study Day 50) - 13 Oct 2020 (Study Day 50)	Influenza Prophylaxis
Sulfamethoxazole; trimethoprim	16 Oct 2020 (Study Day 53) - 20 Oct 2020 (Study Day 57)	Left Foot Abscess
Cefuroxime axetil	21 Oct 2020 (Study Day 58) - 30 Oct 2020 (Study Day 67)	Left Foot Abscess
Liraglutide	02 Nov 2020 (Study Day 70) - 16 Nov 2020 (Study Day 84)	Type Ii Diabetes
Liraglutide	17 Nov 2020 (Study Day 85) - Ongoing	Type Ii Diabetes
Paracetamol	12 Dec 2020 (Study Day 110) - 18 Dec 2020 (Study Day 116)	Sore Throat
Azithromycin	13 Dec 2020 (Study Day 111) - 17 Dec 2020 (Study Day 115)	Sinus Infection
Sulfamethoxazole	13 Dec 2020 (Study Day 111) - 15 Dec 2020 (Study Day 113)	Sinus Infection
Paracetamol	15 Dec 2020 (Study Day 113) - 15 Dec 2020 (Study Day 113)	Fever
Cefalexin	06 Jan 2021 (Study Day 135) - 07 Jan 2021 (Study Day 136)	Prophylaxis R Glute Abscess
Codeine phosphate; paracetamol	07 Jan 2021 (Study Day 136) - 09 Jan 2021 (Study Day 138)	R Glute Abscess Pain
Ibuprofen	07 Jan 2021 (Study Day 136) - 09 Jan 2021 (Study Day 138)	R Glute Abscess (Sae)
Sulfamethoxazole; trimethoprim	07 Jan 2021 (Study Day 136) - 09 Jan 2021 (Study Day 138)	R Glute Abscess (Sae)
Ct/ pelvis*	08 Jan 2021 (Study Day 137) - 08 Jan 2021 (Study Day 137)	Adverse Event
R glute abscess surgical debridement*	09 Jan 2021 (Study Day 138) - 09 Jan 2021 (Study Day 138)	Adverse Event
Chest xray*	13 Jan 2021 (Study Day 142) - 13 Jan 2021 (Study Day 142)	Adverse Event
Insulin glargine	16 Jan 2021 (Study Day 145) - Ongoing	Diabetec Ketoacidosis
Insulin lispro	16 Jan 2021 (Study Day 145) - Ongoing	Diabetic Ketoacidosis
Linezolid	16 Jan 2021 (Study Day 145) - 25 Jan 2021 (Study Day 154)	R Glute Abscess
Metronidazole	16 Jan 2021 (Study Day 145) - 25 Jan 2021 (Study Day 154)	R Glute Abscess

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abscess Limb	Grade 2/moderate	Not related	11 Oct 2020 (Study Day 48) - 18 Oct 2020 (Study Day 55)
Oropharyngeal Pain	Grade 1/mild	Not related	12 Dec 2020 (Study Day 110) - 18 Dec 2020 (Study Day 116)
Sinus Congestion	Grade 1/mild	Not related	12 Dec 2020 (Study Day 110) - 15 Dec 2020 (Study Day 113)
Sinusitis	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 111) - 18 Dec 2020 (Study Day 116)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspnoea	Grade 1/mild	Not related	15 Dec 2020 (Study Day 113) - 15 Dec 2020 (Study Day 113)
Fatigue	Grade 1/mild	Not related	15 Dec 2020 (Study Day 113) - 15 Dec 2020 (Study Day 113)
Pyrexia	Grade 1/mild	Not related	15 Dec 2020 (Study Day 113) - 15 Dec 2020 (Study Day 113)
Rhinorrhoea	Grade 1/mild	Not related	15 Dec 2020 (Study Day 113) - 15 Dec 2020 (Study Day 113)
Sepsis	Grade 2/moderate	Not related	08 Mar 2021 (Study Day 196) - 25 Mar 2021 (Study Day 213)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2320 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cartilage Injury/Left Hip Labrum Tear	SAE	Grade 3/ severe	Not related	27 Aug 2020 (Study Day 3) – 31 Dec 2020 (Study Day 129)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2320, a 54-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Aug 2020 (Study Day 3), 2 days after the first dose and 26 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cartilage injury. The IP dose was not changed due to the left hip labrum tear. The event of left hip labrum tear lasted for 127 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 129). The investigator assessed the event of cartilage injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000336	Cartilage injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Low back pain	1991 - Ongoing
Arthralgia	R shoulder joint pain	2004 - Ongoing
Dermatitis contact	Adhesive allergy	2005 - 2005
Limb injury	Injury to left big toe	2005 - 2005
Toe operation	Left toe surgery	2005 - 2005
Cervical radiculopathy	Cervical radiculopathy	2008 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2008 - Ongoing
Spinal osteoarthritis	Spinal osteoarthritis	2008 - Ongoing
Large intestine polyp	Colonic polyp	2016 - Ongoing
Nasal septum deviation	Deviated septun	2017 - 2017
Sinus operation	Sinus surgery	2017 - 2017
Blood testosterone decreased	Low testosterone	2018 - Ongoing
Constipation	Constipation	2018 - 2018
Hyperlipidaemia	Hyperlipidemia	2018 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Hypogonadism	Hypogonadism	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2008 - Ongoing	Spinal Osteoarthritis
Ibuprofen	2008 - Ongoing	Generalized Osteoarthritis Pain
Testosterone	2008 - Ongoing	Low Testosterone
Amlodipine	2018 - Ongoing	Hypertension
Atorvastatin	2018 - Ongoing	Hypercholesterolemia
Acetylsalicylic acid	2019 - Ongoing	Preventative Heart Health
Catheter placement*	30 Aug 2020 (Study Day 6) - 30 Aug 2020 (Study Day 6)	Adverse Event
Lumbar/hip mri*	02 Sep 2020 (Study Day 9) - 02 Sep 2020 (Study Day 9)	Adverse Event
Cyclobenzaprine	05 Sep 2020 (Study Day 12) - 08 Sep 2020 (Study Day 15)	Tear In Left Hip Labrum
Cyclobenzaprine hydrochloride	05 Sep 2020 (Study Day 12) - 08 Sep 2020 (Study Day 15)	Tear In Left Hip Labrium
Methylprednisolone	05 Sep 2020 (Study Day 12) - 10 Sep 2020 (Study Day 17)	Tear In Left Hip Labruim

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clindamycin	19 Jan 2021 (Study Day 148) - 02 Feb 2021 (Study Day 162)	L25 Tooth Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Bursitis	Grade 2/moderate	Not related	30 Aug 2020 (Study Day 6) - 31 Dec 2020 (Study Day 129)
Iliotibial Band Syndrome	Grade 2/moderate	Not related	30 Aug 2020 (Study Day 6) - 10 Sep 2020 (Study Day 17)
Leukocytosis	Grade 2/moderate	Not related	30 Aug 2020 (Study Day 6) - 04 Sep 2020 (Study Day 11)
Urinary Retention	Grade 2/moderate	Not related	30 Aug 2020 (Study Day 6) - 04 Sep 2020 (Study Day 11)
Vertebral Foraminal Stenosis	Grade 2/moderate	Not related	30 Aug 2020 (Study Day 6) - 10 Sep 2020 (Study Day 17)
COVID-19	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 83) - 07 Dec 2020 (Study Day 105)
Nasopharyngitis	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 83) - 07 Dec 2020 (Study Day 105)
Tooth Infection	Grade 2/moderate	Not related	19 Jan 2021 (Study Day 148) - 04 Feb 2021 (Study Day 164)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2324 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Femur Fracture/ R Broken Femur	SAE	Grade 3/severe	Not related	03 Nov 2020 (Study Day 69) – 22 Dec 2020 (Study Day 118)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2324, a 66-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of femur fracture. Action taken with the IP was not applicable. The event of r broken femur lasted for 50 days, after which it was considered to be recovered/resolved on 22 Dec 2020 (Study Day 118). The investigator assessed the event of femur fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000633	Femur fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - 2008
Osteoarthritis	Osteoarthritis bilateral knees	1973 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	1999 - Ongoing
Knee arthroplasty	Total left knee replacement	2000 - 2000
Hysterectomy	Hysterectomy	2005 - 2005
Uterine leiomyoma	Uterine fibroids	2005 - 2005
Gastric bypass	Gastric bypass surgery	2008 - 2008
Drug hypersensitivity	Fenofibrate allergy	2010 - Ongoing
Visual acuity reduced	Bilateral decreased visual acuity	2010 - Ongoing
Intraductal proliferative breast lesion	Bilateral breast ductal carcinoma in situ	2014 - 2014
Mastectomy	Mastectomy - bilateral	2014 - 2014
Osteopenia	Osteopenia	2014 - Ongoing
Papillary thyroid cancer	Thyroid gland papillary cancer	2014 - 2014
Thyroidectomy	Thyroidectomy	2014 - 2014
Bone operation	Left femur reconstruction	2015 - 2015
Femur fracture	Left femur fracture	2015 - 2015
Cholecystectomy	Cholecystectomy	2017 - 2017
Cholelithiasis	Cholelithiasis	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2010 - Ongoing	Nutritional Supplement
Levothyroxine sodium	2014 - Ongoing	Thyroid Cancer
Vitamin b12 nos	2015 - Ongoing	Nutritional Supplement
Biotin	20 Aug 2020 (Study Day -7) - Ongoing	Nutritional Supplement
Aciclovir	14 Sep 2020 (Study Day 19) - 24 Sep 2020 (Study Day 29)	Shingles
Sulfamethoxazole	16 Sep 2020 (Study Day 21) - 26 Sep 2020 (Study Day 31)	Urinary Tract Infection
Paracetamol	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Fever/Pain (Ediary)
Right femur repair*	04 Nov 2020 (Study Day 70) - 04 Nov 2020 (Study Day 70)	Adverse Event
Ibandronate sodium	19 Mar 2021 (Study Day 205) - Ongoing	Osteopenia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Zoster	Grade 2/moderate	Not related	14 Sep 2020 (Study Day 19) - 24 Sep 2020 (Study Day 29)
Urinary Tract Infection	Grade 1/mild	Not related	16 Sep 2020 (Study Day 21) - 26 Sep 2020 (Study Day 31)
Fall	Grade 3/severe	Not related	03 Nov 2020 (Study Day 69) - 03 Nov 2020 (Study Day 69)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2339 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angioedema/Angioedema	SAE	Grade 4	Not related	16 Sep 2020 (Study Day 21) – 18 Sep 2020 (Study Day 23)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2339, a 70-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 21), 20 days after the first dose and 15 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of angioedema. The IP dose was not changed due to the angioedema. The event of angioedema lasted for 3 days, after which it was considered to be recovered/resolved on 18 Sep 2020 (Study Day 23). The investigator assessed the event of angioedema to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000315	Angioedema

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1975 - Ongoing
Ureteric stenosis	Ureteral stricture	2000 - 2000
Urostomy	Ureterostomy	2000 - 2000
Varicella	Varicella	2000 - Ongoing
Seasonal allergy	Seasonal allergy	2015 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2016 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Inguinal hernia	Groin hernia	2019 - Ongoing
Idiopathic pulmonary fibrosis	Idiopathic pulmonary fibrosis	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Heart Health
Aciclovir	2010 - Ongoing	Varicella
Ascorbic acid	2010 - Ongoing	Nutritional Suppliment
Colecalciferol	2010 - Ongoing	Nutritional Suppliment
Fish oil	2010 - Ongoing	Nutritional Suppliment
Lisinopril	2018 - 17 Sep 2020 (Study Day 22)	Hypertension
Montelukast	2019 - 01 Oct 2020 (Study Day 36)	Seasonal Allergy
Pirfenidone	Jan 2020 - Ongoing	Idiopathic Pulmonary Fibrosis
Metformin hydrochloride; sitagliptin	Apr 2020 - Ongoing	Type 2 Diabetes
Chest x-ray*	17 Sep 2020 (Study Day 22) - 17 Sep 2020 (Study Day 22)	Adverse Event
Diphenhydramine hydrochloride	17 Sep 2020 (Study Day 22) - 17 Sep 2020 (Study Day 22)	Angioedema
Epinephrine	17 Sep 2020 (Study Day 22) - 17 Sep 2020 (Study Day 22)	Angioedema
Famotidine	17 Sep 2020 (Study Day 22) - 17 Sep 2020 (Study Day 22)	Angioedema
Iopamidol	17 Sep 2020 (Study Day 22) - 22 Sep 2020 (Study Day 27)	Ct Contrast
Methylprednisolone	17 Sep 2020 (Study Day 22) - 17 Sep 2020 (Study Day 22)	Angioedema
Neck/maxillofacial ct*	17 Sep 2020 (Study Day 22) - 17 Sep 2020 (Study Day 22)	Adverse Event
Methylprednisolone	18 Sep 2020 (Study Day 23) - 23 Sep 2020 (Study Day 28)	Angioedema

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mirtazapine	01 Oct 2020 (Study Day 36) - Ongoing	Depression
Sulfamethoxazole	01 Oct 2020 (Study Day 36) - 20 Oct 2020 (Study Day 55)	Urinary Tract Infection
Amoxicillin; clavulanic acid	11 Oct 2020 (Study Day 46) - 19 Jan 2021 (Study Day 146)	Urinary Tract Infection/Bladder Prostate Health
Sulfamethoxazole; trimethoprim	14 Oct 2020 (Study Day 49) - 20 Oct 2020 (Study Day 55)	Urinary Tract Infection
Tamsulosin	16 Oct 2020 (Study Day 51) - 20 Oct 2020 (Study Day 55)	Urinary Tract Infection
Influenza vaccine	16 Nov 2020 (Study Day 82) - 16 Nov 2020 (Study Day 82)	Prophylaxis
Sulfamethoxazole; trimethoprim	08 Dec 2020 (Study Day 104) - 09 Jan 2021 (Study Day 136)	Urinary Tract Infection
Codeine; paracetamol	02 Feb 2021 (Study Day 160) - 04 Feb 2021 (Study Day 162)	Pain From Concomitant Procedure, Groin Hernia Repair
Hernia repair*	02 Feb 2021 (Study Day 160) - 02 Feb 2021 (Study Day 160)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	01 Oct 2020 (Study Day 36) - 20 Oct 2020 (Study Day 55)
Fatigue	Grade 1/mild	Related	02 Oct 2020 (Study Day 37) - 09 Oct 2020 (Study Day 44)
Injection Site Pain	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 47) - 20 Oct 2020 (Study Day 55)
Injection Site Hypoaesthesia	Grade 1/mild	Not related	16 Oct 2020 (Study Day 51) - 30 Dec 2020 (Study Day 126)
Urinary Tract Infection	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 67) - 19 Jan 2021 (Study Day 146)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2365 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	26 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Invasive Lobular Breast Carcinoma/Invasive Lobular Breast Carcinoma	SAE	Grade 3/severe	Not related	09 Nov 2020 (Study Day 73) – 14 Jan 2021 (Study Day 139)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2365, a 58-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 26 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Nov 2020 (Study Day 73), 72 days after the first dose and 44 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of invasive lobular breast carcinoma. Action taken with the IP was not applicable. The event of invasive lobular breast carcinoma lasted for 67 days, after which it was considered to be recovered/resolved on 14 Jan 2021 (Study Day 139). The investigator assessed the event of invasive lobular breast carcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000718	Invasive lobular breast carcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	1970 - Ongoing
Cough	Chronic cough	1977 - Ongoing
Allergy to arthropod sting	Bee sting allergy	1981 - Ongoing
Allergy to plants	Oak allergy	1984 - Ongoing
Mycotic allergy	Mold allergy	1984 - Ongoing
Hymenectomy	Hymenectomy	1985 - 1985
Septate hymen	Thick/septate hymen	1985 - 1985
Caesarean section	C-section	1989 - 1989
Migraine	Migraines	1993 - Ongoing
Endometriosis	Endometriosis	1997 - 1997
Endometriosis	Laparoscopy for endometriosis	1997 - 1997
Asthma	Asthma	1998 - Ongoing
Visual acuity reduced	Bilateral decreased visual acuity	2005 - Ongoing
Hot flush	Hot flashes	2008 - Ongoing
Cancer surgery	Left hand squamous cell removal	2009 - 2009
Squamous cell carcinoma	Left hand squamous cell carcinoma	2009 - 2009
Anxiety	Anxiety	2010 - Ongoing
Large intestine polyp	Colon polyp benign	2012 - 2015
Postmenopause	Post-menopausal	2014 - Ongoing
Colonoscopy	Colonoscopy	2015 - 2015
Ovarian cyst	Benign left overian cyst	2015 - Ongoing
Polypectomy	Polyp removal	2015 - 2015
Basal cell carcinoma	Left hand and foot basal cell carcinoma	2017 - 2017
Skin neoplasm excision	Left hand and foot basal cell removal	2017 - 2017
Pain	General aches	Aug 2020 - Ongoing
Keratomileusis	Right eye lasik	06 Aug 2020 (Study Day -23) - 06 Aug 2020 (Study Day -23)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tretinoin	1997 - Ongoing	Acne
Sumatriptan succinate	2000 - Ongoing	Migraine
Montelukast sodium	2005 - Ongoing	Asthma
Salbutamol sulfate	2005 - Ongoing	Asthma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - 11 Nov 2020 (Study Day 75)	Prophylaxis For Cardiac Preventative
Estradiol	2014 - 12 Nov 2020 (Study Day 76)	Menopause
Progesterone	2014 - 12 Nov 2020 (Study Day 76)	Hot Flashes
Duloxetine hydrochloride	2015 - Ongoing	Anxiety
Fluticasone furoate	2015 - Ongoing	Asthma
Zinc	Jul 2020 - Ongoing	General Health Suppliment
Acetylsalicylic acid	Aug 2020 - 11 Nov 2020 (Study Day 75)	General Aches
Ascorbic acid	Aug 2020 - Ongoing	General Health Suppliment
Mammogram*	08 Oct 2020 (Study Day 41) - 08 Oct 2020 (Study Day 41)	Diagnostic
Mammogram*	29 Oct 2020 (Study Day 62) - 29 Oct 2020 (Study Day 62)	Diagnostic
Left breast biopsy*	03 Nov 2020 (Study Day 67) - 03 Nov 2020 (Study Day 67)	Diagnostic
Mastectomy*	14 Jan 2021 (Study Day 139) - 14 Jan 2021 (Study Day 139)	Adverse Event
Tobramycin	23 Feb 2021 (Study Day 179) - 09 Mar 2021 (Study Day 193)	Conjunctivitis
Anastrozole	25 Mar 2021 (Study Day 209) - Ongoing	Invasive Lobular Carcinoma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Conjunctivitis	Grade 2/moderate	Not related	23 Feb 2021 (Study Day 179) - 08 Mar 2021 (Study Day 192)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378747

Participant Number:	US330-2212 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cervical Radiculopathy/Worsening Cervical Radiculopathy	SAE	Grade 2 /moderate	Not related	28 Sep 2020 (Study Day 46) – 30 Sep 2020 (Study Day 48)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2212, a 34-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Sep 2020 (Study Day 46), 45 days after the first dose and 17 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of cervical radiculopathy. Action taken with the IP was not applicable. The event of worsening cervical radiculopathy lasted for 3 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 48). The investigator assessed the event of cervical radiculopathy to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000423	Cervical radiculopathy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

FDA-CBER-2022-1614-3378748

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cervical radiculopathy	Cervical radiculopathy	Apr 2020 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	Apr 2020 - Ongoing
Cervical spinal stenosis	Cervical stenosis	05 Aug 2020 (Study Day -9) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium chloride; potassium chloride; sodium lactate	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Prep
Cefazolin	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Cervical fusion*	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Adverse Event
Dexamethasone	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Ephedrine	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Fentanyl	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Glycopyrronium	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Hydromorphone	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Ketamine	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Lidocaine	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Midazolam	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Ondansetron	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Oxycodone	28 Sep 2020 (Study Day 46) - 30 Sep 2020 (Study Day 48)	Worsening Cervical Radiculopathy
Paracetamol	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Phenylephrine	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Propofol	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Remifentanil	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Rocuronium	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia
Suxamethonium	28 Sep 2020 (Study Day 46) - 28 Sep 2020 (Study Day 46)	Surgical Procedure Anesthesia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US330-2383 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19, AE leading to withdrawal from study vaccine	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 28) – 29 Sep 2020 (Study Day 35)	Recovered/resolved
COVID-19 Pneumonia/Pneumonia (Due To COVID-19)	COVID-19	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 28) – 29 Sep 2020 (Study Day 35)	Recovered/resolved
Acute Respiratory Failure/Acute Respiratory Failure	SAE, AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	26 Sep 2020 (Study Day 32) – 28 Sep 2020 (Study Day 34)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US330-2383, a 54-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Sep 2020 (Study Day 32), 31 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of acute respiratory failure. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of acute respiratory failure lasted for 3 days, after which it was considered to be recovered/resolved on 28 Sep 2020 (Study Day 34). The investigator assessed the event of acute respiratory failure to be not related to the IP.

Severe COVID-19 Details

On 22 Sep 2020 (Study Day 28), 27 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On 22 Sep 2020 (Study Day 28), 27 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/Moderate non-serious adverse event of pneumonia (due to COVID-19).

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 22 Sep 2020 (Study Day 28), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
22 Sep 2020 (Study Day 28)	Fatigue	Mild
22 Sep 2020 (Study Day 28)	Nausea	Mild
23 Sep 2020 (Study Day 29)	Fatigue	Mild
23 Sep 2020 (Study Day 29)	Nausea	Mild
23 Sep 2020 (Study Day 29)	Temperature (°F)	100.4

The participant had no reported indications of Severe COVID-19 infection.

On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 8 days, after which it was considered to be recovered/resolved on 29 Sep 2020 (Study Day 35). The investigator assessed the event of COVID-19 to be not related to the IP.

On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of pneumonia (due to COVID-19) lasted for 8 days, after which it was considered to be recovered/resolved on 29 Sep 2020 (Study Day 35). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000372	COVID-19
MOD-2020-000372	Acute respiratory failure

Study Completion/Discontinuation

On 19 Oct 2020 (Study Day 55), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Tourette's disorder	Tourette's syndrome	2008 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Citalopram	2008 - Ongoing	Tourette's Syndrome
Clonazepam	2008 - Ongoing	Tourette's Syndrome
Atorvastatin	2015 - Ongoing	Hyperlipidemia
Montelukast	2018 - Ongoing	Seasonal Allergies
Chest x-ray*	26 Sep 2020 (Study Day 32) - 26 Sep 2020 (Study Day 32)	Adverse Event
Convalescent plasma*	26 Sep 2020 (Study Day 32) - 26 Sep 2020 (Study Day 32)	Adverse Event
Oxygen	26 Sep 2020 (Study Day 32) - 28 Sep 2020 (Study Day 34)	Ae (Acute Respiratory Failure)
Remdesivir	26 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 33)	Sae - Acute Respiratory Failure
Ascorbic acid	29 Sep 2020 (Study Day 35) - Ongoing	Supplement
Atorvastatin	29 Sep 2020 (Study Day 35) - Ongoing	Hyperlipidemia
Benzonatate	29 Sep 2020 (Study Day 35) - 29 Sep 2020 (Study Day 35)	COVID-19
Dexamethasone	29 Sep 2020 (Study Day 35) - 06 Oct 2020 (Study Day 42)	Ae - Acute Respiratory Failure
Guaifenesin	29 Sep 2020 (Study Day 35) - 06 Oct 2020 (Study Day 42)	COVID-19
Salbutamol	29 Sep 2020 (Study Day 35) - 29 Sep 2020 (Study Day 35)	COVID-19
Thiamine	29 Sep 2020 (Study Day 35) - Ongoing	COVID-19
Zinc	29 Sep 2020 (Study Day 35) - Ongoing	Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 28) - 29 Sep 2020 (Study Day 35)
COVID-19 Pneumonia	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 28) - 29 Sep 2020 (Study Day 35)
Hyperlipidaemia	Grade 2/moderate	Not related	29 Sep 2020 (Study Day 35) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US330-2472 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	12 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	11 Nov 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE	Grade 3/severe	Not related	22 Dec 2020 (Study Day 72) – 30 Dec 2020 (Study Day 80)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US330-2472, a 71-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 12 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 11 Nov 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Dec 2020 (Study Day 72), 71 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 9 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 80). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010310	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1970 - Ongoing
Depression	Depression	1984 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	1984 - Ongoing
Monoplegia	Paralysis - left leg	1984 - 1984
Female sterilisation	Bilateral tubal ligation	Oct 1990 - Oct 1990
Emphysema	Emphysema	2000 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus - type 2	2003 - Ongoing
Osteoarthritis	Osteoarthritis	2008 - Ongoing
Osteoporosis	Osteoporosis	2008 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Muscle spasms	Spasm - muscle	2016 - Ongoing
Bundle branch block left	Cardiac arrhythmia - left bundle branch block	2018 - Ongoing
Oral candidiasis	Candidiasis - oral	2018 - 2018
Chest pain	Chest pain - unk	2019 - Ongoing
Coronary artery disease	Cad (coronary artery disease)	2019 - Ongoing
Myocardial infarction	Heart attack	2019 - 2019
Oedema peripheral	Edema (bilateral upper and lower extremities)	2019 - Ongoing
Implantable defibrillator insertion	Defibrillator implant	Oct 2019 - Oct 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2000 - Ongoing	Emphysema
Budesonide; formoterol fumarate	2010 - Ongoing	Emphysema
Diclofenac	2010 - Ongoing	Osteoarthritis
Tiotropium bromide	2017 - Ongoing	Emphysema
Furosemide	2019 - 22 Dec 2020 (Study Day 72)	Edema - Bilateral Upper And Lower Extremities
Ivabradine hydrochloride	2019 - 22 Dec 2020 (Study Day 72)	Chest Pain - Unk
Rivaroxaban	2019 - 22 Dec 2020 (Study Day 72)	Cad
Sacubitril valsartan sodium hydrate	2019 - 22 Dec 2020 (Study Day 72)	Cad (Coronary Artery Disease)
Dapagliflozin propanediol monohydrate	Jan 2020 - 22 Dec 2020 (Study Day 72)	Diabetes Type 2
Furosemide	03 Jan 2020 (Study Day -283) - 30 Dec 2020 (Study Day 80)	Edema (Bilateral Upper And Lower Extremities)
Montelukast sodium	Mar 2020 - Ongoing	Emphysema
Rosuvastatin calcium	Mar 2020 - Ongoing	Hypercholesterolemia
Denosumab	Jul 2020 - Ongoing	Osteoporosis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	14 Oct 2020 (Study Day 3) - 14 Oct 2020 (Study Day 3)	Injection Pain
Calcium chloride; potassium chloride; sodium lactate	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	COVID-19
Ibuprofen	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	COVID-19
Ipratropium	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	Emphysema
Ipratropium	22 Dec 2020 (Study Day 72) - 23 Dec 2020 (Study Day 73)	Emphysema
Methylprednisolone	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	COVID-19
Oxygen	22 Dec 2020 (Study Day 72) - 06 Jan 2021 (Study Day 87)	COVID-19
Paracetamol	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	COVID-19
Paracetamol	22 Dec 2020 (Study Day 72) - 30 Dec 2020 (Study Day 80)	COVID-19
Salbutamol	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	COVID-19
Salbutamol sulfate	22 Dec 2020 (Study Day 72) - Ongoing	Emphysema
Sodium chloride	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	COVID-19
Vancomycin	22 Dec 2020 (Study Day 72) - 22 Dec 2020 (Study Day 72)	COVID-19
Salbutamol	23 Dec 2020 (Study Day 73) - 23 Dec 2020 (Study Day 73)	Emphysema
Vancomycin	23 Dec 2020 (Study Day 73) - 25 Dec 2020 (Study Day 75)	COVID-19
Ascorbic acid	24 Dec 2020 (Study Day 74) - 24 Dec 2020 (Study Day 74)	COVID-19
Ascorbic acid	24 Dec 2020 (Study Day 74) - 30 Dec 2020 (Study Day 80)	COVID-19
Remdesivir	24 Dec 2020 (Study Day 74) - 24 Dec 2020 (Study Day 74)	COVID-19
Sodium chloride	24 Dec 2020 (Study Day 74) - 24 Dec 2020 (Study Day 74)	COVID-19
Remdesivir	25 Dec 2020 (Study Day 75) - 28 Dec 2020 (Study Day 78)	COVID-19
Vancomycin	26 Dec 2020 (Study Day 76) - 26 Dec 2020 (Study Day 76)	COVID-19
Tuberculin	28 Dec 2020 (Study Day 78) - 28 Dec 2020 (Study Day 78)	Tb Skin Test
Colecalciferol	30 Dec 2020 (Study Day 80) - 06 Jan 2021 (Study Day 87)	COVID-19
Dexamethasone	30 Dec 2020 (Study Day 80) - 31 Dec 2020 (Study Day 81)	COVID-19
Nicotine	30 Dec 2020 (Study Day 80) - Ongoing	Smoking Cessation
Rivaroxaban	03 Jan 2021 (Study Day 84) - Ongoing	Cad

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	02 Feb 2021 (Study Day 114) - 02 Feb 2021 (Study Day 114)	Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acute Respiratory Failure	Grade 2/moderate	Not related	22 Dec 2020 (Study Day 72) - 06 Jan 2021 (Study Day 87)
Chronic Obstructive Pulmonary Disease	Grade 2/moderate	Not related	22 Dec 2020 (Study Day 72) - 06 Jan 2021 (Study Day 87)
Decreased Appetite	Grade 2/moderate	Not related	22 Dec 2020 (Study Day 72) - 06 Jan 2021 (Study Day 87)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2023 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Stress Cardiomyopathy/Takotsubo Cardiomyopathy	SAE	Grade 3/severe	Not related	18 Dec 2020 (Study Day 130) – 25 Feb 2021 (Study Day 199)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2023, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Dec 2020 (Study Day 130), 129 days after the first dose and 101 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of stress cardiomyopathy. Action taken with the IP was not applicable. The event of takotsubo cardiomyopathy lasted for 70 days, after which it was considered to be recovered/resolved on 25 Feb 2021 (Study Day 199). The investigator assessed the event of stress cardiomyopathy to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001374	Stress cardiomyopathy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Postmenopause	Post menopausal	2010 - Ongoing
Spinal osteoarthritis	Lumbar arthritis (osteoarthritis)	2017 - Ongoing
Back pain	Occasional lower back pain	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Citalopram hydrobromide	2000 - Ongoing	Anxiety
Atorvastatin	2010 - Ongoing	Hyperlipidemia
Lisinopril	2010 - 18 Dec 2020 (Study Day 130)	Hypertension
Gabapentin	2017 - Ongoing	Osteoarthritis
Tramadol	02 May 2020 (Study Day -101) - Ongoing	Lower Back Pain
Hydrocodone bitartrate; paracetamol	15 Aug 2020 (Study Day 5) - 21 Aug 2020 (Study Day 11)	Left Wrist Fracture
Surgical repair left wrist fracture*	19 Aug 2020 (Study Day 9) - 19 Aug 2020 (Study Day 9)	Adverse Event
Naproxen	21 Aug 2020 (Study Day 11) - 25 Sep 2020 (Study Day 46)	Left Wrist Fracture
Ibuprofen	07 Oct 2020 (Study Day 58) - 12 Oct 2020 (Study Day 63)	Sinusitis/Headache
Levofloxacin	08 Oct 2020 (Study Day 59) - 17 Oct 2020 (Study Day 68)	Sinusitis
Influenza vaccine	27 Oct 2020 (Study Day 78) - 27 Oct 2020 (Study Day 78)	Seasonal Influenza Prophylaxis
Acetylsalicylic acid	18 Dec 2020 (Study Day 130) - Ongoing	Cardiac Prophylaxis
Cardiac catheterization*	18 Dec 2020 (Study Day 130) - 18 Dec 2020 (Study Day 130)	Adverse Event
Enoxaparin sodium	18 Dec 2020 (Study Day 130) - 18 Dec 2020 (Study Day 130)	Takotsubo Cardiomyopathy
Fentanyl	18 Dec 2020 (Study Day 130) - 18 Dec 2020 (Study Day 130)	Takotsubo Cardiomyopathy
Glyceryl trinitrate	18 Dec 2020 (Study Day 130) - 18 Dec 2020 (Study Day 130)	Takotsubo Cardiomyopathy
Metoprolol	18 Dec 2020 (Study Day 130) - Ongoing	Hypertension
Midazolam hydrochloride	18 Dec 2020 (Study Day 130) - 18 Dec 2020 (Study Day 130)	Takotsubo Cardiomyopathy

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Echocardiogram*	19 Dec 2020 (Study Day 131) - 19 Dec 2020 (Study Day 131)	Adverse Event
Pantoprazole	20 Dec 2020 (Study Day 132) - Ongoing	Gastroesophageal Reflux Disease Prophylaxis
Lisinopril	31 Dec 2020 (Study Day 143) - 12 Feb 2021 (Study Day 186)	Hypertension
Paracetamol	05 Feb 2021 (Study Day 179) - 14 Feb 2021 (Study Day 188)	Sinusitis
Amoxicillin; clavulanic acid	11 Feb 2021 (Study Day 185) - 18 Feb 2021 (Study Day 192)	Sinusitis
Lisinopril	13 Feb 2021 (Study Day 187) - Ongoing	Hypertention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Wrist Fracture	Grade 2/moderate	Not related	14 Aug 2020 (Study Day 4) - 25 Sep 2020 (Study Day 46)
Cough	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 19 Oct 2020 (Study Day 70)
Dyspnoea	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 06 Oct 2020 (Study Day 57)
Fatigue	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 15 Oct 2020 (Study Day 66)
Headache	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 06 Oct 2020 (Study Day 57)
Myalgia	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 06 Oct 2020 (Study Day 57)
Nasal Congestion	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 06 Oct 2020 (Study Day 57)
Pain	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 06 Oct 2020 (Study Day 57)
Rhinorrhoea	Grade 1/mild	Not related	02 Oct 2020 (Study Day 53) - 06 Oct 2020 (Study Day 57)
Anosmia	Grade 1/mild	Not related	08 Oct 2020 (Study Day 59) - 15 Oct 2020 (Study Day 66)
Dyspnoea	Grade 1/mild	Not related	08 Oct 2020 (Study Day 59) - 15 Oct 2020 (Study Day 66)
Headache	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 59) - 19 Oct 2020 (Study Day 70)
Nasal Congestion	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 59) - 15 Oct 2020 (Study Day 66)
Oropharyngeal Pain	Grade 1/mild	Not related	08 Oct 2020 (Study Day 59) - 15 Oct 2020 (Study Day 66)
Pain	Grade 1/mild	Not related	08 Oct 2020 (Study Day 59) - 15 Oct 2020 (Study Day 66)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rhinorrhoea	Grade 1/mild	Not related	08 Oct 2020 (Study Day 59) - 15 Oct 2020 (Study Day 66)
Sinusitis	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 59) - 17 Oct 2020 (Study Day 68)
Sinusitis	Grade 1/mild	Not related	05 Feb 2021 (Study Day 179) - 18 Feb 2021 (Study Day 192)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2046 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Viral Pharyngitis/Viral Pharyngitis	SAE	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 57) – 15 Nov 2020 (Study Day 96)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2046, a 82-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Oct 2020 (Study Day 57), 56 days after the first dose and 28 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of viral pharyngitis. Action taken with the IP was not applicable. The event of viral pharyngitis lasted for 40 days, after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 96). The investigator assessed the event of viral pharyngitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000470	Viral pharyngitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Congenital systolic heart murmur	(b) (6) 1937 - Ongoing
Hysterectomy	Partial hysterectomy	1985 - 1985
Menorrhagia	Menorrhagia	1985 - 1985
Back pain	Lower back pain	2000 - Ongoing
Lumbar vertebral fracture	L5 vertebral fracture	2000 - 2000
Spinal fusion surgery	L4-5 vertebral fusion	2000 - 2000
Postmenopause	Post menopausal	2002 - Ongoing
Deafness bilateral	Bilateral hearing loss	2009 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2000 - Ongoing	Lower Back Pain
Paracetamol	11 Sep 2020 (Study Day 31) - 12 Sep 2020 (Study Day 32)	Injection Site Pain
Ibuprofen	07 Oct 2020 (Study Day 57) - 17 Oct 2020 (Study Day 67)	Viral Pharyngitis
Paracetamol	07 Oct 2020 (Study Day 57) - 17 Oct 2020 (Study Day 67)	Viral Pharyngitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Not related	07 Oct 2020 (Study Day 57) - 07 Oct 2020 (Study Day 57)
Nausea	Grade 1/mild	Not related	07 Oct 2020 (Study Day 57) - 19 Oct 2020 (Study Day 69)
Oropharyngeal Pain	Grade 1/mild	Not related	07 Oct 2020 (Study Day 57) - 16 Oct 2020 (Study Day 66)
Pyrexia	Grade 1/mild	Not related	07 Oct 2020 (Study Day 57) - 14 Oct 2020 (Study Day 64)
Vomiting	Grade 1/mild	Not related	07 Oct 2020 (Study Day 57) - 07 Oct 2020 (Study Day 57)
Fatigue	Grade 1/mild	Not related	09 Oct 2020 (Study Day 59) - Ongoing
Pain	Grade 1/mild	Not related	18 Oct 2020 (Study Day 68) - 18 Oct 2020 (Study Day 68)
Rhinorrhoea	Grade 1/mild	Not related	18 Oct 2020 (Study Day 68) - 20 Oct 2020 (Study Day 70)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2063 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ageusia/New Loss Of Taste	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	21 Aug 2020 (Study Day 9) – 15 Sep 2020 (Study Day 34)	Recovered/resolved
Anosmia/New Loss Of Smell	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	21 Aug 2020 (Study Day 9) – 15 Sep 2020 (Study Day 34)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2063, a 44-year-old race unknown male, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of ageusia. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of new loss of taste lasted for 26 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 34). The investigator assessed the event of ageusia to be not related to the IP.

On 21 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of anosmia. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of new loss of smell lasted for 26 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 34). The investigator assessed the event of anosmia to be not related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Surgical repair of left humerus fracture*	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ageusia	Grade 2/moderate	Not related	21 Aug 2020 (Study Day 9) - 15 Sep 2020 (Study Day 34)
Anosmia	Grade 2/moderate	Not related	21 Aug 2020 (Study Day 9) - 15 Sep 2020 (Study Day 34)
Diarrhoea	Grade 2/moderate	Not related	21 Aug 2020 (Study Day 9) - 28 Aug 2020 (Study Day 16)
Fatigue	Grade 1/mild	Not related	21 Aug 2020 (Study Day 9) - 27 Aug 2020 (Study Day 15)
Myalgia	Grade 2/moderate	Not related	21 Aug 2020 (Study Day 9) - 15 Sep 2020 (Study Day 34)
Nasal Congestion	Grade 2/moderate	Not related	21 Aug 2020 (Study Day 9) - 27 Aug 2020 (Study Day 15)
Nausea	Grade 2/moderate	Not related	21 Aug 2020 (Study Day 9) - 28 Aug 2020 (Study Day 16)
Pain	Grade 1/mild	Not related	21 Aug 2020 (Study Day 9) - 28 Aug 2020 (Study Day 16)
Vomiting	Grade 2/moderate	Not related	21 Aug 2020 (Study Day 9) - 26 Aug 2020 (Study Day 14)
Chills	Grade 1/mild	Not related	25 Aug 2020 (Study Day 13) - 28 Aug 2020 (Study Day 16)
Rhinorrhoea	Grade 1/mild	Not related	25 Aug 2020 (Study Day 13) - 26 Aug 2020 (Study Day 14)
Cough	Grade 1/mild	Not related	26 Aug 2020 (Study Day 14) - 26 Aug 2020 (Study Day 14)
Humerus Fracture	Grade 3/severe	Not related	30 Nov 2020 (Study Day 110) - 30 Nov 2020 (Study Day 110)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2095 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Meningitis Aseptic/Aseptic Meningitis	SAE	Grade 3/ severe	Not related	12 Feb 2021 (Study Day 180) – 06 Mar 2021 (Study Day 202)	Recovered/ resolved with sequelae
Pneumonia/Pneumonia	SAE	Grade 3/ severe	Not related	12 Feb 2021 (Study Day 180) – 24 Feb 2021 (Study Day 192)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2095, a 23-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Feb 2021 (Study Day 180), 179 days after the first dose and 144 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of meningitis aseptic. Action taken with the IP was not applicable. The event of aseptic meningitis lasted for 23 days, after which it was considered to be recovered/resolved with sequelae on 06 Mar 2021 (Study Day 202). The investigator assessed the event of meningitis aseptic to be not related to the IP.

On 12 Feb 2021 (Study Day 180), 179 days after the first dose and 144 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 13 days, after which it was considered to be recovered/resolved with sequelae on 24 Feb 2021 (Study Day 192). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-020940	Meningitis aseptic

CIOMS Number	MedDRA Preferred Term
MOD-2021-020940	Pneumonia
MOD-2020-001052	COVID-19

Study Completion/Discontinuation

On 10 Mar 2021 (Study Day 206), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2007 - Ongoing
Asthma exercise induced	Exercise induced asthma	2014 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2015 - Ongoing	Health Maintenance
Levonorgestrel	2018 - Ongoing	Birth Control
Vitamin d nos	2019 - Ongoing	Health Maintenance
Influenza vaccine	05 Sep 2020 (Study Day 20) - 05 Sep 2020 (Study Day 20)	Seasonal Influenza Prophylaxis
Amoxicillin; clavulanic acid	12 Feb 2021 (Study Day 180) - 19 Feb 2021 (Study Day 187)	Pneumonia
Cyclobenzaprine	12 Feb 2021 (Study Day 180) - Ongoing	Aseptic Meningitis
Ibuprofen	12 Feb 2021 (Study Day 180) - 19 Feb 2021 (Study Day 187)	Aseptic Meningitis
Paracetamol	12 Feb 2021 (Study Day 180) - 06 Mar 2021 (Study Day 202)	Pneumonia Aseptic Meningitis
Azithromycin	17 Feb 2021 (Study Day 185) - 17 Feb 2021 (Study Day 185)	Pneumonia
Azithromycin	18 Feb 2021 (Study Day 186) - 19 Feb 2021 (Study Day 187)	Pneumonia
Dexamethasone	19 Feb 2021 (Study Day 187) - 22 Feb 2021 (Study Day 190)	Pneumonia
Docusate	19 Feb 2021 (Study Day 187) - Ongoing	Constipation
Fentanyl	19 Feb 2021 (Study Day 187) - 19 Feb 2021 (Study Day 187)	Pneumonia, Aseptic Meningitis
Levofloxacin	19 Feb 2021 (Study Day 187) - 25 Feb 2021 (Study Day 193)	Pneumonia
Ondansetron	19 Feb 2021 (Study Day 187) - 19 Feb 2021 (Study Day 187)	Pneumonia, Aseptic Meningitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	19 Feb 2021 (Study Day 187) - 23 Feb 2021 (Study Day 191)	Pneumonia, Aseptic Meningitis
Oxygen	19 Feb 2021 (Study Day 187) - 22 Feb 2021 (Study Day 190)	Pneumonia
Pantoprazole	19 Feb 2021 (Study Day 187) - Ongoing	Gastritis Prophylaxis
Piperacillin sodium; tazobactam sodium	19 Feb 2021 (Study Day 187) - 21 Feb 2021 (Study Day 189)	Pneumonia
Sodium chloride	19 Feb 2021 (Study Day 187) - 19 Feb 2021 (Study Day 187)	Pneumonia, Aseptic Meningitis
Sodium chloride	19 Feb 2021 (Study Day 187) - 20 Feb 2021 (Study Day 188)	Pneumonia, Aseptic Meningitis
Vancomycin	19 Feb 2021 (Study Day 187) - 21 Feb 2021 (Study Day 189)	Pneumonia
Ibuprofen	22 Feb 2021 (Study Day 190) - 06 Mar 2021 (Study Day 202)	Aseptic Meningitis
Dexamethasone	23 Feb 2021 (Study Day 191) - 28 Feb 2021 (Study Day 196)	Pneumonia
Meclozine	23 Feb 2021 (Study Day 191) - 25 Feb 2021 (Study Day 193)	Aseptic Meningitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	03 Dec 2020 (Study Day 109) - 12 Dec 2020 (Study Day 118)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2130 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angina Pectoris/Chest Pain (Cardiac Related)	SAE	Grade 3/ severe	Not related	15 Dec 2020 (Study Day 120) – 18 Dec 2020 (Study Day 123)	Recovered/ resolved
Diabetes Mellitus Inadequate Control/Uncontrolled Diabetes Mellitus Ii	SAE	Grade 3/ severe	Not related	16 Dec 2020 (Study Day 121) – 18 Dec 2020 (Study Day 123)	Recovered/ resolved
Hypertension/Uncontrolled Hypertension	SAE	Grade 3/ severe	Not related	16 Dec 2020 (Study Day 121) – 18 Dec 2020 (Study Day 123)	Recovered/ resolved
Angina Pectoris/Angina	SAE	Grade 3/ severe	Not related	10 Feb 2021 (Study Day 177) – 13 Feb 2021 (Study Day 180)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2130, a 50-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 18 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Dec 2020 (Study Day 120), 119 days after the first dose and 88 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of angina pectoris. Action taken with the IP was not applicable. The event of chest pain (cardiac related) lasted for 4 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 123). The investigator assessed the event of angina pectoris to be not related to the IP.

On 16 Dec 2020 (Study Day 121), 120 days after the first dose and 89 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diabetes mellitus inadequate control. Action taken with the IP was not applicable. The event of uncontrolled diabetes mellitus ii lasted for 3 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 123). The investigator assessed the event of diabetes mellitus inadequate control to be not related to the IP.

On 16 Dec 2020 (Study Day 121), 120 days after the first dose and 89 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypertension.

Action taken with the IP was not applicable. The event of uncontrolled hypertension lasted for 3 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 123). The investigator assessed the event of hypertension to be not related to the IP.

On 10 Feb 2021 (Study Day 177), 176 days after the first dose and 145 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of angina pectoris. Action taken with the IP was not applicable. The event of angina lasted for 4 days, after which it was considered to be recovered/resolved on 13 Feb 2021 (Study Day 180). The investigator assessed the event of angina pectoris to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001177	Angina pectoris
MOD-2020-001177	Diabetes mellitus inadequate control
MOD-2020-001177	Hypertension
MOD-2020-001177	COVID-19
MOD-2021-015222	Angina pectoris

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septum deviation	Deviated septum	1988 - Ongoing
Cholecystectomy	Cholecystectomy	2000 - 2000
Cholelithiasis	Cholelithiasis	2000 - 2000
Anxiety	Anxiety	2005 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease (lumbar)	2010 - Ongoing
Spinal osteoarthritis	Lumbosacral spondylosis	2010 - Ongoing
Substance abuse	Polysubstance abuse	2010 - 2017
Type 2 diabetes mellitus	Diabetes mellitus type ii	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Migraine	Migraine headaches	2015 - Ongoing
Angina unstable	Unstable angina	2017 - Apr 2018
Coronary arterial stent insertion	Stent x2 lad	2017 - 2017

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	2017 - Ongoing
Angioplasty	Angioplasty	13 Nov 2017 (Study Day -1009) - 13 Nov 2017 (Study Day -1009)
Rotator cuff repair	Right rotator cuff repair	Dec 2018 - Dec 2018
Rotator cuff syndrome	Right rotator cuff tear	Dec 2018 - Dec 2018
Tendon rupture	Right bicep tendon tear	Dec 2018 - Dec 2018
Tenoplasty	Right bicep tendon repair	Dec 2018 - Dec 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	13 Nov 2017 (Study Day -1009) - Ongoing	Coronary Artery Disease
Carvedilol	13 Nov 2017 (Study Day -1009) - Ongoing	Hypertension
Metformin	13 Nov 2017 (Study Day -1009) - Ongoing	Diabetes Mellitus Type Ii
Glipizide	01 Jan 2019 (Study Day -595) - 11 Feb 2021 (Study Day 178)	Diabetes Mellitus Type Ii
Dapagliflozin propanediol monohydrate	19 Feb 2020 (Study Day -181) - 11 Feb 2021 (Study Day 178)	Diabetes Mellitus Type Ii
Paracetamol	15 Dec 2020 (Study Day 120) - 25 Dec 2020 (Study Day 130)	Symptomatic COVID-19
Acetylsalicylic acid	16 Dec 2020 (Study Day 121) - 17 Dec 2020 (Study Day 122)	Chest Pain
Glucose	16 Dec 2020 (Study Day 121) - 18 Dec 2020 (Study Day 123)	Acute Kidney Injury On Chronic Kidney Disease
Glyceryl trinitrate	16 Dec 2020 (Study Day 121) - 17 Dec 2020 (Study Day 122)	Chest Pain - Cardiac Related
Insulin	16 Dec 2020 (Study Day 121) - 17 Dec 2020 (Study Day 122)	Untreated Diabetes
Labetalol	16 Dec 2020 (Study Day 121) - 16 Dec 2020 (Study Day 121)	Uncontrolled Hypertension
Acetylsalicylic acid	11 Feb 2021 (Study Day 178) - 11 Feb 2021 (Study Day 178)	Unstable Angina
Clonidine	11 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 180)	Unstable Angina
Glyceryl trinitrate	11 Feb 2021 (Study Day 178) - 11 Feb 2021 (Study Day 178)	Unstable Angina
Lisinopril	11 Feb 2021 (Study Day 178) - Ongoing	Hypertention
Metoprolol	11 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 180)	Unstable Angina
Ondansetron	11 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 180)	Unstable Angina
Promethazine	11 Feb 2021 (Study Day 178) - 13 Feb 2021 (Study Day 180)	Unstable Angina
Atorvastatin	12 Feb 2021 (Study Day 179) - Ongoing	Hyperlipidemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bivalirudin	12 Feb 2021 (Study Day 179) - 12 Feb 2021 (Study Day 179)	Unstable Angina
Clopidogrel	12 Feb 2021 (Study Day 179) - Ongoing	Thrombus Prophylaxis
Coronary stent placement*	12 Feb 2021 (Study Day 179) - 12 Feb 2021 (Study Day 179)	Adverse Event
Isosorbide mononitrate	12 Feb 2021 (Study Day 179) - Ongoing	Hypertention
Liraglutide	10 Mar 2021 (Study Day 205) - Ongoing	Diabetes Mellitus Type Ii

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Blood Pressure Systolic Increased	Grade 3/severe	Not related	16 Oct 2020 (Study Day 60) - Ongoing
COVID-19	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 120) - 25 Dec 2020 (Study Day 130)
Acute Kidney Injury	Grade 2/moderate	Not related	16 Dec 2020 (Study Day 121) - 17 Dec 2020 (Study Day 122)
Hyponatraemia	Grade 3/severe	Not related	16 Dec 2020 (Study Day 121) - 18 Dec 2020 (Study Day 123)
Pulmonary Granuloma	Grade 1/mild	Not related	16 Dec 2020 (Study Day 121) - Ongoing
Heart Rate Irregular	Grade 2/moderate	Not related	05 Feb 2021 (Study Day 172) - Ongoing
Spinal Osteoarthritis	Grade 1/mild	Not related	11 Feb 2021 (Study Day 178) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2187 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rhabdomyolysis/ Rhabdomyolisis	SAE	Grade 3/severe	Not related	08 Nov 2020 (Study Day 81) – 12 Jan 2021 (Study Day 146)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2187, a 31-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Nov 2020 (Study Day 81), 80 days after the first dose and 52 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of rhabdomyolysis. Action taken with the IP was not applicable. The event of rhabdomyolisis lasted for 66 days, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 146). The investigator assessed the event of rhabdomyolysis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000790	Rhabdomyolysis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	08 Nov 2020 (Study Day 81) - 09 Nov 2020 (Study Day 82)	Rhabdomyloysis
Sodium chloride	12 Nov 2020 (Study Day 85) - 14 Nov 2020 (Study Day 87)	Rhabdomyolosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US331-2197 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cervical Radiculopathy/Exacerbation Of Left Cervical Radiculopathy	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	06 Sep 2020 (Study Day 18) – 09 Oct 2020 (Study Day 51)	Recovered/ resolved
Pneumonia/Pneumonia	SAE	Grade 3/ severe	Not related	22 Nov 2020 (Study Day 95) – 09 Dec 2020 (Study Day 112)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2197, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Sep 2020 (Study Day 18), 17 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of cervical radiculopathy. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of exacerbation of left cervical radiculopathy lasted for 34 days, after which it was considered to be recovered/resolved on 09 Oct 2020 (Study Day 51). The investigator assessed the event of cervical radiculopathy to be not related to the IP.

On 22 Nov 2020 (Study Day 95), 94 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of pneumonia. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of pneumonia lasted for 18 days, after which it was considered to be recovered/resolved on 09 Dec 2020 (Study Day 112). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000930	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anosmia	Anosmia	1969 - Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Sleep apnoea syndrome	Sleep apnea	1990 - Ongoing
Spinal stenosis	Spinal stenosis	1990 - 2012
Anxiety	Anxiety	2000 - Ongoing
Depression	Depression	2000 - Ongoing
Osteoarthritis	Osteoarthritis of neck and shoulders	2000 - Ongoing
Carpal tunnel decompression	Bilateral carpal tunnel repair	2007 - 2007
Carpal tunnel syndrome	Bilateral carpal tunnel	2007 - 2007
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Spinal laminectomy	Spinal laminectomy	2012 - 2012
Intervertebral disc compression	Compressed cervical disc	2014 - Ongoing
Atrial fibrillation	Atril fibrillation	2017 - Ongoing
Coronary artery disease	Coronary artery disease	2017 - Ongoing
Coronary arterial stent insertion	Cardiac stent placement	May 2017 - May 2017
Myocardial infarction	Myocardial infarction	May 2017 - May 2017
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2018 - Ongoing
Cervical radiculopathy	Left cervical radiculopathy	2018 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Gynaecomastia	Gynecomastia	2018 - Ongoing
Blood testosterone decreased	Low testosterone levels	Jan 2019 - Ongoing
Rotator cuff syndrome	Right rotator cuff tear	Mar 2020 - Mar 2020
Rotator cuff repair	Right rotator cuff repair	May 2020 - May 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine	2000 - Ongoing	Anxiety
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
All other non-therapeutic products	2017 - Ongoing	Sleep Apnea
Apixaban	2017 - Ongoing	Atril Fibrillation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Carvedilol	2017 - Ongoing	Hypertension
Cetirizine hydrochloride	2017 - Ongoing	Seasonal Allergies
Spironolactone	2017 - 27 Aug 2020 (Study Day 8)	Hypertension
Atorvastatin	2018 - Ongoing	Hyperlipidemia
Montelukast	2018 - Ongoing	Seasonal Allergies
Pantoprazole	2018 - Ongoing	Gastroesophageal Reflux Disease
Tamsulosin hydrochloride	2018 - Ongoing	Benign Prostatic Hyperplasia
Vitamin d nos	May 2020 - Ongoing	Health Prophylaxis
Testosterone	04 Jun 2020 (Study Day -77) - Ongoing	Low Testosterone Levels
Chlortalidone	28 Aug 2020 (Study Day 9) - Ongoing	Hypertension
Ibuprofen	12 Sep 2020 (Study Day 24) - 13 Sep 2020 (Study Day 25)	Exacerbation Of Left Cervial Radiculopathy
Naproxen	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Exacerabation Of Left Cervial Radiculopathy
Paracetamol	12 Sep 2020 (Study Day 24) - 12 Sep 2020 (Study Day 24)	Exacerbation Of Left Radiculopathy
Oxycodone hydrochloride; paracetamol	14 Sep 2020 (Study Day 26) - 18 Sep 2020 (Study Day 30)	Exacerbation Of Left Cervical Radiculopathy
Cyclobenzaprine	30 Sep 2020 (Study Day 42) - 09 Oct 2020 (Study Day 51)	Exacerbation Of Left Cervical Radiculopathy
Influenza vaccine	06 Nov 2020 (Study Day 79) - 06 Nov 2020 (Study Day 79)	Seasonal Influenza Prophylaxis
Naproxen	22 Nov 2020 (Study Day 95) - 27 Nov 2020 (Study Day 100)	Pneumonia
Pectin	22 Nov 2020 (Study Day 95) - 30 Nov 2020 (Study Day 103)	Pneumonia
Phenol	22 Nov 2020 (Study Day 95) - 30 Nov 2020 (Study Day 103)	Penumonia
Amoxicillin; clavulanic acid	25 Nov 2020 (Study Day 98) - 30 Nov 2020 (Study Day 103)	Pneumonia
Azithromycin	28 Nov 2020 (Study Day 101) - 01 Dec 2020 (Study Day 104)	Pneumonia
Ceftriaxone	28 Nov 2020 (Study Day 101) - 01 Dec 2020 (Study Day 104)	Pneumonia
Chest x-ray*	28 Nov 2020 (Study Day 101) - 28 Nov 2020 (Study Day 101)	Adverse Event
Diphenhydramine hydrochloride	28 Nov 2020 (Study Day 101) - 28 Nov 2020 (Study Day 101)	Pneumonia
Electrocardiogram*	28 Nov 2020 (Study Day 101) - 28 Nov 2020 (Study Day 101)	Adverse Event
Methylprednisolone sodium succinate	28 Nov 2020 (Study Day 101) - 28 Nov 2020 (Study Day 101)	Pneumonia
Oxygen	28 Nov 2020 (Study Day 101) - 30 Nov 2020 (Study Day 103)	Pneumonia
Metformin hydrochloride	29 Dec 2020 (Study Day 132) - Ongoing	Pre-Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	25 Aug 2020 (Study Day 6) - 25 Aug 2020 (Study Day 6)
Cervical Radiculopathy	Grade 2/moderate	Not related	06 Sep 2020 (Study Day 18) - 09 Oct 2020 (Study Day 51)
Glucose Tolerance Impaired	Grade 1/mild	Not related	28 Dec 2020 (Study Day 131) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2201 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/ Diverticulitis	AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	24 Aug 2020 (Study Day 5) – 09 Oct 2020 (Study Day 51)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2201, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Aug 2020 (Study Day 5), 4 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of diverticulitis. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of diverticulitis lasted for 47 days, after which it was considered to be recovered/resolved on 09 Oct 2020 (Study Day 51). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cervical vertebral fracture	Cervical fracture	2001 - 2001

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Spinal fusion surgery	Cervical fusion	2001 - 2001
Back pain	Back pain	2010 - Ongoing
Intervertebral disc protrusion	Herniated l2, l3, l4, l5 disc	2010 - 2013
Spinal fusion surgery	Lumbar fusion l2-l5	2013 - 2013
Abdominal pain	Intermittent abdominal pain	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocodone	2010 - Ongoing	L2-L5 Herniated Disc
Oxycodone	Mar 2020 - Ongoing	L2-L5 Herniated Lumbar Disc
Ciprofloxacin	28 Aug 2020 (Study Day 9) - 06 Sep 2020 (Study Day 18)	Diverticullitis
Polypectomy*	09 Oct 2020 (Study Day 51) - 09 Oct 2020 (Study Day 51)	Adverse Event
Corticosteroid nos	11 Mar 2021 (Study Day 204) - 11 Mar 2021 (Study Day 204)	Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diverticulitis	Grade 3/severe	Not related	24 Aug 2020 (Study Day 5) - 09 Oct 2020 (Study Day 51)
Large Intestine Polyp	Grade 2/moderate	Not related	09 Oct 2020 (Study Day 51) - 09 Oct 2020 (Study Day 51)
Blood Pressure Diastolic Increased	Grade 3/severe	Not related	28 Oct 2020 (Study Day 70) - 28 Jan 2021 (Study Day 162)
Blood Pressure Systolic Increased	Grade 3/severe	Not related	28 Oct 2020 (Study Day 70) - 28 Jan 2021 (Study Day 162)
Skin Abrasion	Grade 1/mild	Not related	10 Jan 2021 (Study Day 144) - 19 Jan 2021 (Study Day 153)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2212 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteomyelitis/Left Great Toe Osteomyelitis	SAE, AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	04 Sep 2020 (Study Day 15) – 16 Oct 2020 (Study Day 57)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2212, a 71-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Sep 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of osteomyelitis. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of left great toe osteomyelitis lasted for 43 days, after which it was considered to be recovered/resolved with sequelae on 16 Oct 2020 (Study Day 57). The investigator assessed the event of osteomyelitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000262	Osteomyelitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Type ii diabetes mellitus	1985 - Ongoing
Rotator cuff repair	Right rotator cuff repair	1995 - 1995
Rotator cuff syndrome	Right rotator cuff tear injury	1995 - 1995
Postmenopause	Post menopausal	Oct 1995 - Ongoing
Osteoarthritis	Osteoarthritis	1998 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Knee arthroplasty	Right total knee replacement	01 Apr 2000 (Study Day -7447) - 01 Apr 2000 (Study Day -7447)
Drug hypersensitivity	Allergy to naproxen	2010 - Ongoing
Restless legs syndrome	Restless leg syndrome	2010 - Ongoing
Joint dislocation	Left shoulder dislocation	2011 - 2011
Shoulder arthroplasty	Left shoulder replacement	2011 - 2011
Upper limb fracture	Left shoulder fracture	2011 - 2011
Spinal fusion surgery	Lower back fusion	2012 - 2012
Hypertension	Hypertension	2015 - Ongoing
Chronic left ventricular failure	Chronic diastolic heart failure	2016 - Ongoing
Wound	Recurrent right foot wound	2016 - 2016
Acute myocardial infarction	Non st elevation myocardial infarction	2017 - 2017
Cardiac valve disease	Valvular heart disease	2017 - Ongoing
Chronic kidney disease	Stage iv chronic renal disease	2018 - Ongoing
Osteotomy	Osteotomy right foot	24 May 2019 (Study Day -455) - 24 May 2019 (Study Day -455)
Lymphoedema	Lymphadema (bilateral lower extremities)	Nov 2019 - Ongoing
Wound	Chronic wound left toe	2020 - Ongoing
Osteomyelitis	Osteomyelitis	Jul 2020 - Jul 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	1990 – Ongoing	Type Ii Diabetes Mellitus
Insulin glargine	1990 – Ongoing	Type Ii Diabetes Mellitus
Acetylsalicylic acid	1995 – Ongoing	Cardiac Prophylaxis
Paracetamol	1998 – Ongoing	Osteoarthritis
Rosuvastatin	2000 – Ongoing	Hypercholesterolemia
Baclofen	2010 – Ongoing	Restless Leg Syndrome

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pramipexole	2010 – Ongoing	Restless Leg Syndrome
Furosemide	2015 – Ongoing	Hypertension
Losartan	2015 – Ongoing	Hypertension
Metoprolol	2015 – Ongoing	Hypertension
Spironolactone	2015 – Ongoing	Hypertension
Colecalciferol	2017 – Ongoing	Health Maintenance
Dulaglutide	2017 - 01 Oct 2020 (Study Day 42)	Diabetes Mellitus Type Ii
Empagliflozin	2017 - 05 Oct 2020 (Study Day 46)	Type Ii Diabetes Mellitus
Aciclovir	04 Sep 2020 (Study Day 15) - 08 Sep 2020 (Study Day 19)	Herpes Zoster
Ceftaroline	04 Sep 2020 (Study Day 15) - 15 Oct 2020 (Study Day 56)	Left Great Toe Osteomyelitis
Left great toe amputation*	04 Sep 2020 (Study Day 15) - 04 Sep 2020 (Study Day 15)	Adverse Event
Hydrocortisone	10 Sep 2020 (Study Day 21) - 24 Sep 2020 (Study Day 35)	Herpes Zoster
Influenza vaccine	03 Oct 2020 (Study Day 44) - 03 Oct 2020 (Study Day 44)	Seasonal Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Zoster	Grade 2/moderate	Not related	28 Aug 2020 (Study Day 8) - 06 Nov 2020 (Study Day 78)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2225 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Transient Ischaemic Attack/Transient Ischemic Attack	SAE	Grade 3/severe	Not related	24 Jan 2021 (Study Day 154) – 17 Feb 2021 (Study Day 178)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2225, a 54-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Jan 2021 (Study Day 154), 153 days after the first dose and 125 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of transient ischaemic attack. Action taken with the IP was not applicable. The event of transient ischemic attack lasted for 25 days, after which it was considered to be recovered/resolved on 17 Feb 2021 (Study Day 178). The investigator assessed the event of transient ischaemic attack to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011147	Transient ischaemic attack
MOD-2020-000706	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to penicillin	1982 - Ongoing
Arteriosclerosis	Atherosclerosis	2010 - 2010
Coronary artery bypass	Quadruple bypass surgery	2010 - 2010
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Androgen deficiency	Hypotestosteronism	2015 - Ongoing
Dyspepsia	Heartburn	2015 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2017 - Ongoing
Hypothyroidism	Hypothyroidism	2018 - 24 Aug 2020 (Study Day 1)
Type 2 diabetes mellitus	Diabetes mellitus type ii	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiovascular Prophylaxis
Atorvastatin	2010 - Nov 2020	Hyperlipidemia
Fenofibrate	2010 - Ongoing	Hyperlipidemia
Lisinopril	2010 - Ongoing	Hypertension
Clindamycin	2011 - Ongoing	Prevent Rash After Haircut
Calcium carbonate	2015 - Jan 2021	Heartburn
Testosterone	2015 - Ongoing	Hypotestosteronemia
Ubidecarenone	2015 - Ongoing	Health Maintenance
Ascorbic acid	2017 - 19 Nov 2020 (Study Day 88)	Health Maintenance
Colecalciferol	2017 - 19 Nov 2020 (Study Day 88)	Health Maintenance
Carvedilol	2018 - Ongoing	Hypertension
Evolocumab	2018 - Ongoing	Hyperlipidemia
Insulin degludec	2018 - Ongoing	Type 2 Diabetes Mellitus
Levothyroxine	2018 - Ongoing	Hypothyroidism
Metformin	2018 - Ongoing	Type 2 Diabetes Mellitus
Empagliflozin	2019 - Ongoing	Diabetes Mellitus Type 2
Eicosapentaenoic acid	15 Oct 2020 (Study Day 53) - Ongoing	Worsening Of Hyperlipidemia
Influenza vaccine	26 Oct 2020 (Study Day 64) - 26 Oct 2020 (Study Day 64)	Seasonal Influenza Vaccine
Atorvastatin	Nov 2020 - Ongoing	Worsening Of Hyperlipidemia
Paracetamol	08 Nov 2020 (Study Day 77) - 19 Nov 2020 (Study Day 88)	Syptomatic COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium citrate; colecalciferol	09 Nov 2020 (Study Day 78) - 19 Nov 2020 (Study Day 88)	Health Maintenance
Dexamethasone	09 Nov 2020 (Study Day 78) - 19 Nov 2020 (Study Day 88)	Symptomatic COVID-19
Zinc	09 Nov 2020 (Study Day 78) - 19 Nov 2020 (Study Day 88)	Health Maintenance
Erythromycin	13 Nov 2020 (Study Day 82) - 18 Nov 2020 (Study Day 87)	Symptomatic COVID-19
Hydroxychloroquine	13 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 89)	Symptomatic COVID-19
Omeprazole	Jan 2021 - Ongoing	Heartburn
Clopidogrel	26 Jan 2021 (Study Day 156) - Ongoing	Transient Ischaemic Attack

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 53) - Ongoing
COVID-19	Grade 2/moderate	Not related	04 Nov 2020 (Study Day 73) - 17 Nov 2020 (Study Day 86)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2249 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deep Vein Thrombosis/Left Lower Extremity Deep Vein Thrombosis	SAE	Grade 3/severe	Not related	02 Jan 2021 (Study Day 132) – 01 Apr 2021 (Study Day 221)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2249, a 65-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Jan 2021 (Study Day 132), 131 days after the first dose and 96 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of deep vein thrombosis. Action taken with the IP was not applicable. The event of left lower extremity deep vein thrombosis lasted for 90 days, after which it was considered to be recovered/resolved on 01 Apr 2021 (Study Day 221). The investigator assessed the event of deep vein thrombosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002256	Deep vein thrombosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Joint injury	Radioscaphoidal impingement	2005 - 2010
Tenosynovitis stenosans	Right radial styloid impingement	2009 - 2010
Ostectomy	Right radial styloidectomy	2010 - 2010
Osteoarthritis	Osteoarthtitis	2010 - Ongoing
Rotator cuff repair	Right rotator cuff repair	2013 - 2013
Rotator cuff syndrome	Right rotator cuff tear	2013 - 2013
Hip arthroplasty	Left hip arthroplasty	2015 - 2015
Hypertension	Hypertension	2017 - Ongoing
Gastrointestinal bacterial overgrowth	Small bowel bacterial overgrowth	Jan 2020 - Ongoing
Rotator cuff syndrome	Right rotator cuff tear	Jan 2020 - Apr 2020
Rotator cuff repair	Right rotator cuff repair	Apr 2020 - Apr 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylaxis
Pantoprazole	2000 - Ongoing	Gastroesophageal Reflux Disease
Pravastatin	2000 - Ongoing	Hyperlipidemia
Vitamins nos	2000 - Ongoing	Health Maintenance
Ubidecarenone	2012 - Ongoing	Health Maintenance
Chondroitin sulfate; glucosamine; methylsulfonylmethane	2015 - Ongoing	Osteoarthritis
Ascophyllum nodosum; ascorbic acid; betacarotene; borago officinalis; capsicum annuum; petroselinum crispum; pyridoxine hydrochloride; serenoa repens; tocopheryl acetate; zea mays style; zinc oxide	2016 - Ongoing	Health Maintenance
Losartan	2017 - Ongoing	Hypertension
Propranolol	2017 - Ongoing	Hypertension
Linaclotide	18 Sep 2020 (Study Day 26) - 21 Sep 2020 (Study Day 29)	Small Bowel Bacterial Overgrowth
Sulfamethoxazole; trimethoprim	23 Sep 2020 (Study Day 31) - 02 Oct 2020 (Study Day 40)	Intestinal Infection
Ibuprofen	29 Sep 2020 (Study Day 37) - 29 Sep 2020 (Study Day 37)	Muscle Aches/Joint Aches

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	03 Oct 2020 (Study Day 41) - 03 Oct 2020 (Study Day 41)	Muscle Aches/Joint Aches
Influenza vaccine	25 Oct 2020 (Study Day 63) - 25 Oct 2020 (Study Day 63)	Seasonal Influenza Vaccine
Rivaroxaban	04 Jan 2021 (Study Day 134) - 25 Jan 2021 (Study Day 155)	Left Calf Venous Thrombosis
Rivaroxaban	26 Jan 2021 (Study Day 156) - Ongoing	Left Calf Venous Thrombosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Rash	Grade 1/mild	Not related	01 Sep 2020 (Study Day 9) - 04 Sep 2020 (Study Day 12)
Gastrointestinal Infection	Grade 3/severe	Not related	23 Sep 2020 (Study Day 31) - 03 Oct 2020 (Study Day 41)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2291 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis	SAE	Grade 3/severe	Not related	27 Nov 2020 (Study Day 94) – 28 Nov 2020 (Study Day 95)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2291, a 63-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Nov 2020 (Study Day 94), 93 days after the first dose and 65 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 2 days, after which it was considered to be recovered/resolved on 28 Nov 2020 (Study Day 95). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001224	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy	2006 - 2006
Menorrhagia	Menorrhagia	2006 - 2006
Salpingo-oophorectomy bilateral	Bilateral salpingo-oophorectomy	2006 - 2006
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Insomnia	Insomnia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Zolpidem tartrate	2015 - Ongoing	Insomnia
Influenza vaccine	28 Oct 2020 (Study Day 64) - 28 Oct 2020 (Study Day 64)	Seasonal Influenza Prophylaxis
Varicella zoster vaccine rge (cho)	05 Nov 2020 (Study Day 72) - 05 Nov 2020 (Study Day 72)	Shingles Prophylaxis
Hydrochlorothiazide; lisinopril	10 Nov 2020 (Study Day 77) - 17 Dec 2020 (Study Day 114)	Hypertension
Acetylsalicylic acid; citric acid; sodium bicarbonate	27 Nov 2020 (Study Day 94) - 27 Nov 2020 (Study Day 94)	Cholecystitis
Bismuth subsalicylate	27 Nov 2020 (Study Day 94) - 27 Nov 2020 (Study Day 94)	Cholecystitis
Naproxen sodium	27 Nov 2020 (Study Day 94) - 27 Nov 2020 (Study Day 94)	Cholecystitis
Ketorolac	28 Nov 2020 (Study Day 95) - 28 Nov 2020 (Study Day 95)	Cholecystitis
Laparoscopic cholecystectomy*	28 Nov 2020 (Study Day 95) - 28 Nov 2020 (Study Day 95)	Adverse Event
Sulfamethoxazole; trimethoprim	11 Dec 2020 (Study Day 108) - 16 Dec 2020 (Study Day 113)	Lower Urinary Tract Infection
Losartan	18 Dec 2020 (Study Day 115) - 18 Dec 2020 (Study Day 115)	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Not related	30 Oct 2020 (Study Day 66) - 04 Nov 2020 (Study Day 71)
Oropharyngeal Pain	Grade 1/mild	Not related	30 Oct 2020 (Study Day 66) - Ongoing
Blood Pressure Systolic Increased	Grade 3/severe	Not related	02 Nov 2020 (Study Day 69) - 09 Nov 2020 (Study Day 76)
Cough	Grade 1/mild	Not related	03 Nov 2020 (Study Day 70) - 04 Nov 2020 (Study Day 71)
Hypertension	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 77) - Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	11 Dec 2020 (Study Day 108) - 16 Dec 2020 (Study Day 113)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2325 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pelvic Prolapse/ Worsening Of Pelvic Organ Prolapse	SAE	Grade 2/ moderate	Not related	11 Nov 2020 (Study Day 77) – 11 Dec 2020 (Study Day 107)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2325, a 71-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 11 Nov 2020 (Study Day 77), 76 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pelvic prolapse. Action taken with the IP was not applicable. The event of worsening of pelvic organ prolapse lasted for 31 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 107). The investigator assessed the event of pelvic prolapse to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001164	Pelvic prolapse

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1970 - Ongoing
Rhinitis allergic	Allergic rhinitis	1970 - Ongoing
Drug hypersensitivity	Allergy to tetracycline	1975 - Ongoing
Drug hypersensitivity	Allergy to codeine	1980 - Ongoing
Hysterectomy	Hysterectomy	1996 - 1996
Salpingo-oophorectomy bilateral	Bilateral salpingo-oophorectomy	1996 - 1996
Uterine leiomyoma	Uterine fibroid tumors	1996 - 1996
Neurectomy	Right foot neuroma removal	2008 - 2008
Neuroma	Right foot neuroma	2008 - 2008
Insomnia	Insomnia	2010 - Ongoing
Cystocele	Cystocele	2015 - Ongoing
Osteoarthritis	Osteoarthritis	2015 - Ongoing
Rectocele	Rectocele	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1970 - Ongoing	Asthma
Doxylamine succinate	2010 - Ongoing	Insomnia
Paracetamol	2015 - Ongoing	Osteoarthritis
Vitamin d nos	2018 - Ongoing	General Health Maintenance
Budesonide; formoterol fumarate	Jul 2018 - Ongoing	Asthma
Cetirizine	Mar 2020 - Ongoing	Allergy To Rhinitis
Collagen	Mar 2020 - Ongoing	General Health Maintenance
Influenza vaccine	25 Oct 2020 (Study Day 60) - 25 Oct 2020 (Study Day 60)	Seasonal Influenza Prophylaxis
Sulfamethoxazole; trimethoprim	31 Oct 2020 (Study Day 66) - 02 Nov 2020 (Study Day 68)	Urinary Tract Infection
Botulinum toxin type a haemagglutinin complex	Nov 2020 - Nov 2020	Cosmetic Prophylaxis
Celecoxib	11 Dec 2020 (Study Day 107) - 13 Dec 2020 (Study Day 109)	Worsening Of Pelvic Organ Prolapsa
Cystoscopy*	11 Dec 2020 (Study Day 107) - 11 Dec 2020 (Study Day 107)	Adverse Event
Perineorrhaphy*	11 Dec 2020 (Study Day 107) - 11 Dec 2020 (Study Day 107)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rectocele/cystocele repair*	11 Dec 2020 (Study Day 107) - 11 Dec 2020 (Study Day 107)	Adverse Event
Sacrospinous fixation*	11 Dec 2020 (Study Day 107) - 11 Dec 2020 (Study Day 107)	Adverse Event
Sulfamethoxazole; trimethoprim	17 Dec 2020 (Study Day 113) - 21 Dec 2020 (Study Day 117)	Post Surgery Infection Prophylaxis
Estradiol	16 Jan 2021 (Study Day 143) - 29 Jan 2021 (Study Day 156)	Rectocele Repair
Estradiol	30 Jan 2021 (Study Day 157) - Ongoing	Rectocele Repair

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	31 Oct 2020 (Study Day 66) - 02 Nov 2020 (Study Day 68)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378796

Participant Number:	US331-2395 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Mania/Manic Episode	SAE	Grade 3/severe	Not related	02 Feb 2021 (Study Day 156) – 15 Feb 2021 (Study Day 169)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2395, a 55-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Feb 2021 (Study Day 156), 155 days after the first dose and 127 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of mania. Action taken with the IP was not applicable. The event of manic episode lasted for 14 days, after which it was considered to be recovered/resolved on 15 Feb 2021 (Study Day 169). The investigator assessed the event of mania to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015270	Mania

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hepatitis C	Hepatitis c virus	1984 - 2016
Osteoarthritis	Osteoarthritis	1989 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	1990 - Ongoing
Bipolar disorder	Bipolar disorder	1990 - Ongoing
Drug hypersensitivity	Allergy to morphine	1990 - Ongoing
Drug hypersensitivity	Allergy to oxycontin	1990 - Ongoing
Fasciotomy	Fasciotomy right leg (left leg donor site)	2010 - 2010
Gun shot wound	Gunshot wound right leg	2010 - 2010
Pneumonia staphylococcal	Methicillin-resistant staphylococcus aureus	2015 - 2015
Parkinsonism	Neuroleptic parkinsonism	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine	14 Sep 2020 (Study Day 15) - 05 Oct 2020 (Study Day 36)	Cervicalgia
Ketorolac tromethamine	14 Sep 2020 (Study Day 15) - 14 Sep 2020 (Study Day 15)	Cervicalgia
Methylprednisolone	14 Sep 2020 (Study Day 15) - 14 Sep 2020 (Study Day 15)	Cervicalgia
Naproxen	14 Sep 2020 (Study Day 15) - 05 Oct 2020 (Study Day 36)	Cervicalgia
Methylprednisolone	15 Sep 2020 (Study Day 16) - 15 Sep 2020 (Study Day 16)	Cervicalgia
Methylprednisolone	16 Sep 2020 (Study Day 17) - 16 Sep 2020 (Study Day 17)	Cervicalgia
Methylprednisolone	17 Sep 2020 (Study Day 18) - 17 Sep 2020 (Study Day 18)	Cervicalgia
Methylprednisolone	18 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 19)	Cervicalgia
Methylprednisolone	19 Sep 2020 (Study Day 20) - 19 Sep 2020 (Study Day 20)	Cervicalgia
Olanzapine	02 Feb 2021 (Study Day 156) - 20 Apr 2021 (Study Day 233)	Bipolar/Manic Episode
Valproate semisodium	02 Feb 2021 (Study Day 156) - 20 Apr 2021 (Study Day 233)	Bipolar/Manic Episode

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Zolpidem	02 Feb 2021 (Study Day 156) - 20 Apr 2021 (Study Day 233)	Bipolar/Manic Episode

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Neck Pain	Grade 2/moderate	Not related	12 Sep 2020 (Study Day 13) - Ongoing
Nasal Congestion	Grade 1/mild	Not related	22 Mar 2021 (Study Day 204) - 27 Mar 2021 (Study Day 209)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2434 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Osteoarthritis Right Hip	SAE	Grade 3/severe	Not related	15 Oct 2020 (Study Day 45) – 03 Feb 2021 (Study Day 156)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2434, a 69-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Oct 2020 (Study Day 45), 44 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening osteoarthritis right hip lasted for 112 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 156). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-016894	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Osteoarthritis	Osteoarthritis left knee	2010 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Osteoporosis	Osteoporosis	2018 - Ongoing
Osteoarthritis	Osteoarthritis right hip	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2017 - Ongoing	Health Maintenance
Alendronate sodium	2018 - Ongoing	Osteoporosis
Calcium	2018 - Ongoing	Health Maintenance
Lisinopril	2018 - Ongoing	Hypertension
Colecalciferol	15 Jun 2020 (Study Day -78) - Ongoing	Health Maintenance
Naproxen	26 Jun 2020 (Study Day -67) - Ongoing	Osteoarthritis Left Knee
Paracetamol	26 Jun 2020 (Study Day -67) - Ongoing	Osteoarthritis Left Knee
Influenza vaccine	16 Oct 2020 (Study Day 46) - 16 Oct 2020 (Study Day 46)	Seasonal Influenza Vaccine
Lisinopril	20 Oct 2020 (Study Day 50) - Ongoing	Hypertension
Hydrochlorothiazide	Nov 2020 - 03 Feb 2021 (Study Day 156)	Hypertension
Amlodipine	22 Nov 2020 (Study Day 83) - Ongoing	Hypertension
Anesthetics, local	01 Feb 2021 (Study Day 154) - 01 Feb 2021 (Study Day 154)	Worsening Osteoarthritis Right Hip
Cefazolin sodium	01 Feb 2021 (Study Day 154) - 01 Feb 2021 (Study Day 154)	Perioperative Prophylaxis
Enoxaparin sodium	01 Feb 2021 (Study Day 154) - 02 Feb 2021 (Study Day 155)	Worsening Osteoarthritis Right Hip
I.v. solutions	01 Feb 2021 (Study Day 154) - 02 Feb 2021 (Study Day 155)	Worsening Osteoarthritis Right Hip
Right hip replacement*	01 Feb 2021 (Study Day 154) - 01 Feb 2021 (Study Day 154)	Adverse Event
Meloxicam	02 Feb 2021 (Study Day 155) - 16 Feb 2021 (Study Day 169)	Worsening Osteoarthritis Right Hip
Paracetamol	02 Feb 2021 (Study Day 155) - 07 Mar 2021 (Study Day 188)	Worsening Osteoarthritis Right Hip
Oxycodone	03 Feb 2021 (Study Day 156) - 10 Feb 2021 (Study Day 163)	Post-Op Pain (Right Hip Replacement)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	04 Feb 2021 (Study Day 157) - Ongoing	Deep Vein Thrombosis Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nasal Congestion	Grade 1/mild	Not related	10 Sep 2020 (Study Day 10) - 11 Sep 2020 (Study Day 11)
Rhinorrhoea	Grade 1/mild	Not related	10 Sep 2020 (Study Day 10) - 11 Sep 2020 (Study Day 11)
Blood Pressure Systolic Increased	Grade 3/severe	Not related	29 Sep 2020 (Study Day 29) - 27 Oct 2020 (Study Day 57)
Osteonecrosis	Grade 3/severe	Not related	15 Oct 2020 (Study Day 45) - 01 Feb 2021 (Study Day 154)
Hypertension	Grade 2/moderate	Not related	11 Nov 2020 (Study Day 72) - 03 Feb 2021 (Study Day 156)
Procedural Pain	Grade 3/severe	Not related	01 Feb 2021 (Study Day 154) - 07 Mar 2021 (Study Day 188)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378802

Participant Number:	US331-2465 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression/Exacerbation Of Depression	SAE	Grade 3/severe	Not related	15 Dec 2020 (Study Day 105) – 31 Mar 2021 (Study Day 211)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2465, a 18-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Dec 2020 (Study Day 105), 104 days after the first dose and 76 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of depression. Action taken with the IP was not applicable. The event of exacerbation of depression lasted for 107 days, after which it was considered to be recovered/resolved on 31 Mar 2021 (Study Day 211). The investigator assessed the event of depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-060230	Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2010 - Ongoing
Drug hypersensitivity	Adderall allergy	2010 - Ongoing
Alcohol use disorder	Alcohol use disorder	2016 - Ongoing
Anxiety	Anxiety	2016 - Ongoing
Depression	Depression	2016 - Ongoing
Drug abuse	Benzodiazepineabuse	2016 - Ongoing
Panic attack	Panic attacks	2016 - Ongoing
Social anxiety disorder	Social anxiety disorder	2016 - Ongoing
Substance use disorder	Cannibis use disorder	2016 - Ongoing
Suicide attempt	Suicide attempt (x4)	2016 - 2020
Asthma	Asthma	2018 - Ongoing
Bronchitis	Bronchitis	2018 - 2018
Blister	Right second finger blister	31 Aug 2020 (Study Day -2) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2018 - Ongoing	Asthma
Clonazepam	Apr 2020 - 02 Mar 2021 (Study Day 182)	Anxiety
Alprazolam	30 Sep 2020 (Study Day 29) - 02 Mar 2021 (Study Day 182)	Anxiety
Fluoxetine	02 Feb 2021 (Study Day 154) - 05 Feb 2021 (Study Day 157)	Exacerbation Of Depression
Trazodone	02 Feb 2021 (Study Day 154) - 01 Mar 2021 (Study Day 181)	Exacerbation Of Depression
Fluoxetine	06 Feb 2021 (Study Day 158) - 05 Mar 2021 (Study Day 185)	Exacerbation Of Depression
Hydroxyzine	02 Mar 2021 (Study Day 182) - Ongoing	Exacerbation Of Depression
Trazodone	02 Mar 2021 (Study Day 182) - Ongoing	Exacerbation Of Depression
Gabapentin	03 Mar 2021 (Study Day 183) - Ongoing	Exacerbation Of Depression
Fluoxetine	05 Mar 2021 (Study Day 185) - Ongoing	Exacerbation Of Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US331-2629 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	13 Oct 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/Small Bowel Obstruction	SAE	Grade 3/severe	Not related	06 Nov 2020 (Study Day 57) – 10 Nov 2020 (Study Day 61)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2629, a 53-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Nov 2020 (Study Day 57), 56 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of small intestinal obstruction. Action taken with the IP was not applicable. The event of small bowel obstruction lasted for 5 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 61). The investigator assessed the event of small intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000715	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	1981 - 1981
Appendicitis	Appendicitis	1981 - 1981
Drug hypersensitivity	Codeine allergy	1995 - Ongoing
Carpal tunnel decompression	Right carpal tunnel surgery	2000 - 2000
Carpal tunnel syndrome	Right carpal tunnel syndrome	2000 - 2000
Duodenal ulcer	Duodenal ulcer	2000 - 2000
Migraine	Migraines	2000 - Ongoing
Cholecystectomy	Cholecystectomy	2001 - 2001
Cholecystitis	Cholecystitis	2001 - 2001
Carpal tunnel decompression	Left carpal tunnel surgery	2005 - 2005
Carpal tunnel syndrome	Left carpal tunnel syndrome	2005 - 2005
Diverticulum	Diverticulosis	Jun 2005 - 2015
Drug hypersensitivity	Tramadol allergy	2008 - Ongoing
Peripheral nerve decompression	Left release of ulnar nerve in guyon's canal	2008 - 2008
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Sinusitis	Sinus infections	2010 - Ongoing
Rotator cuff repair	Right rotator cuff repair	2011 - 2011
Rotator cuff syndrome	Right rotator cuff tear	2011 - 2011
Colectomy	Partial colectomy	Jun 2015 - Jun 2015
Gastrooesophageal reflux disease	Acid reflux	2016 - Ongoing
Hiatus hernia	Current hiatal hernia	2016 - Ongoing
Erosive oesophagitis	Erosive esophagitis	2017 - 2017
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2017 - Ongoing
Inguinal hernia	Inguinal hernia	2017 - 2017
Gastrectomy	Laparoscopic sleeve gastrectomy	Jan 2017 - Jan 2017
Obesity	Obesity	Jan 2017 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Postmenopause	Post menopausal	2018 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Barrett's oesophagus	Irregular z line esophagus	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1990 - Ongoing	General Health

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Migraines
Paracetamol	2000 - Ongoing	Migraines
Fish oil	2005 - Ongoing	General Health
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Calcium	2010 - Ongoing	General Health Maintenance
Vitamin b nos	2015 - Ongoing	General Health
Famotidine	2016 - Ongoing	Acid Reflux
Pantoprazole	2016 - Ongoing	Current Hiatal Hernia
Escitalopram	2018 - Ongoing	Anxiety
Fluticasone	2018 - Ongoing	Seasonal Allergies
Loratadine	2018 - Ongoing	Seasonal Allergies
Montelukast	2018 - Ongoing	Seasonal Allergies
Amitriptyline	Feb 2020 - Ongoing	Migraines
Sumatriptan	Feb 2020 - Ongoing	Migraines
Liraglutide	01 Jun 2020 (Study Day -102) - Ongoing	Obesity
Ibuprofen	15 Oct 2020 (Study Day 35) - 04 Nov 2020 (Study Day 55)	Left Tennis Elbow
Hydrocortisone	05 Nov 2020 (Study Day 56) - 05 Nov 2020 (Study Day 56)	Left Tennis Elbow
Fentanyl	06 Nov 2020 (Study Day 57) - 08 Nov 2020 (Study Day 59)	Small Bowel Obstruction
Glucose; sodium chloride	06 Nov 2020 (Study Day 57) - 10 Nov 2020 (Study Day 61)	Small Bowel Obstruction
Ketorolac tromethamine	06 Nov 2020 (Study Day 57) - 08 Nov 2020 (Study Day 59)	Small Bowel Obstruction
Influenza vaccine	08 Nov 2020 (Study Day 59) - 08 Nov 2020 (Study Day 59)	Seasonal Influneza Prophylaxis
Potassium	10 Nov 2020 (Study Day 61) - 10 Nov 2020 (Study Day 61)	Hypokalemia
Docusate	11 Nov 2020 (Study Day 62) - Ongoing	Small Bowel Obstruction Prophylaxis
Paracetamol	21 Nov 2020 (Study Day 72) - 30 Nov 2020 (Study Day 81)	Upper Respitory Infection
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	22 Nov 2020 (Study Day 73) - 30 Nov 2020 (Study Day 81)	Upper Respitory Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Epicondylitis	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 35) - 06 Nov 2020 (Study Day 57)
Normocytic Anaemia	Grade 1/mild	Not related	09 Nov 2020 (Study Day 60) - 10 Nov 2020 (Study Day 61)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypokalaemia	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 61) - 10 Nov 2020 (Study Day 61)
Gastroenteritis	Grade 2/moderate	Not related	21 Nov 2020 (Study Day 72) - 26 Nov 2020 (Study Day 77)
Viral Upper Respiratory Tract Infection	Grade 2/moderate	Not related	21 Nov 2020 (Study Day 72) - 30 Nov 2020 (Study Day 81)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2637 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/Exacerbation Of Coronary Artery Disease	SAE, AE leading to withdrawal from study vaccine	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 35) – 16 Oct 2020 (Study Day 36)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2637, a 57-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Oct 2020 (Study Day 35), 34 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of coronary artery disease. On 08 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of exacerbation of coronary artery disease lasted for 2 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 36). The investigator assessed the event of coronary artery disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000503	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Supraventricular tachycardia	Supraventricular tachycardia	1980 - Ongoing
Sarcoidosis	Sarcoidosis	1986 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1990 - Ongoing
Umbilical hernia	Umbilical hernia	2000 - Ongoing
Cholecystectomy	Cholecystectomy	2001 - 2001
Cholelithiasis	Cholelithiasis	2001 - 2001
Depression	Depression	2001 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2001 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2015 - Ongoing
Back pain	Low back pain	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Insomnia	Difficulty sleeping	2017 - Ongoing
Sciatica	Sciatica	2017 - Ongoing
Fracture treatment	Left humerous compound fracture surgical repair	06 Sep 2017 (Study Day -1101) - 06 Sep 2017 (Study Day -1101)
Humerus fracture	Left humerous compound fracture	06 Sep 2017 (Study Day -1101) - 06 Sep 2017 (Study Day -1101)
Intervertebral disc protrusion	L4-l5 bulging disc	06 Sep 2017 (Study Day -1101) - 06 Sep 2017 (Study Day -1101)
Angina pectoris	Angina	2018 - Ongoing
Coronary artery disease	Coronary artery disease	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine hydrochloride	2001 - Ongoing	Depression
Omeprazole	2001 - Ongoing	Gastroesophageal Reflux Disease
Quetiapine fumarate	2001 - Ongoing	Depression
All other non-therapeutic products	2015 - Ongoing	Sleep Apnea
Trazodone	2017 - Ongoing	Difficulty Sleeping
Paracetamol	16 Sep 2020 (Study Day 6) - 16 Sep 2020 (Study Day 6)	Muscle Aches
Glyceryl trinitrate	09 Oct 2020 (Study Day 29) - Ongoing	Angina
Cardiac catheterization with stent*	15 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 35)	Adverse Event
Prasugrel	15 Oct 2020 (Study Day 35) - 15 Oct 2020 (Study Day 35)	Coranary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	16 Oct 2020 (Study Day 36) - Ongoing	Cardiac Prophylaxis
Famotidine	16 Oct 2020 (Study Day 36) - Ongoing	Gastroesophageal Reflux Disease
Prasugrel	16 Oct 2020 (Study Day 36) - Ongoing	Coronary Artery Disease
Rosuvastatin	16 Oct 2020 (Study Day 36) - Ongoing	Hypercholesterolemia
Hydrocodone bitartrate; paracetamol	30 Dec 2020 (Study Day 111) - 06 Jan 2021 (Study Day 118)	Umbilical Hernia
Umbilical hernia repair*	30 Dec 2020 (Study Day 111) - 30 Dec 2020 (Study Day 111)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US332-2013 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Syncope/Convulsive Syncope	SAE	Grade 3/severe	Not related	14 Sep 2020 (Study Day 29) – 14 Sep 2020 (Study Day 29)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2013, a 61-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Sep 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of syncope. On 13 Sep 2020 (Study Day 28), the IP dose was discontinued due to lost to follow-up. The event of convulsive syncope lasted for 1 days, after which it was considered to be recovered/resolved on 14 Sep 2020 (Study Day 29). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000295	Syncope

Study Completion/Discontinuation

On 14 Sep 2020 (Study Day 29), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	2010 - Ongoing
Arthritis	Right knee arthritis	Jan 2015 - Jun 2015
Knee arthroplasty	Partial right knee replacement	Jun 2015 - Jun 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2010 - Ongoing	General Health
Ammonia	14 Sep 2020 (Study Day 29) - 14 Sep 2020 (Study Day 29)	Convulsive Syncope
Oxygen	14 Sep 2020 (Study Day 29) - 14 Sep 2020 (Study Day 29)	Convulsive Syncope

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dizziness	Grade 1/mild	Not related	17 Aug 2020 (Study Day 1) - 17 Aug 2020 (Study Day 1)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US332-2302 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Wrist Fracture/Right Scaphoid Fracture	SAE	Grade 3/ severe	Not related	22 Oct 2020 (Study Day 43) – 10 Dec 2020 (Study Day 92)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2302, a 37-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Oct 2020 (Study Day 43), 42 days after the first dose and 14 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of wrist fracture. Action taken with the IP was not applicable. The event of right scaphoid fracture lasted for 50 days, after which it was considered to be recovered/resolved on 10 Dec 2020 (Study Day 92). The investigator assessed the event of wrist fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000730	Wrist fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	2000 - 2010
Appendiceectomy	Appendectomy	2000 - 2000
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Tendonitis	Tendonitis	2000 - 2000
Drug hypersensitivity	Morphine allergy	2011 - Ongoing
Lung lobectomy	Left lung lower lobectomy	2011 - 2011
Pulmonary haemorrhage	Idiopathic pulmonary hemorrhage	2011 - 2011
Anxiety	Anxiety	2012 - Ongoing
Depression	Depression	2012 - Ongoing
Gastric ulcer	Gastric ulcer	2016 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2000 - Ongoing	Seasonal Allergies
Vitamins nos	2015 - Ongoing	General Health
Bupropion	2017 - Ongoing	Depression
Escitalopram	2017 - Ongoing	Depression
Famotidine	2017 - Ongoing	Acid Reflux
Ibuprofen	08 Oct 2020 (Study Day 29) - 09 Oct 2020 (Study Day 30)	Headache And Injection Site Pain
Doxycycline	28 Oct 2020 (Study Day 49) - 30 Oct 2020 (Study Day 51)	Right Scaphoid Fracture
Hydrocodone bitartrate; paracetamol	28 Oct 2020 (Study Day 49) - 29 Oct 2020 (Study Day 50)	Right Scaphoid Fracture
Right scaphoid surgery*	28 Oct 2020 (Study Day 49) - 28 Oct 2020 (Study Day 49)	Adverse Event
Influenza vaccine	03 Nov 2020 (Study Day 55) - 03 Nov 2020 (Study Day 55)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US332-2341 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	29 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post Procedural Haemorrhage/Post-Op Vaginal Hemorrhage	SAE	Grade 3/ severe	Not related	13 Jan 2021 (Study Day 105) – 14 Jan 2021 (Study Day 106)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2341, a 46-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 29 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Jan 2021 (Study Day 105), 104 days after the first dose and 76 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of post procedural haemorrhage. Action taken with the IP was not applicable. The event of post-op vaginal hemorrhage lasted for 2 days, after which it was considered to be recovered/resolved on 14 Jan 2021 (Study Day 106). The investigator assessed the event of post procedural haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004454	Post procedural haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy (hives)	1978 - 1994
Seasonal allergy	Seasonal allergies	1979 - Ongoing
Malocclusion	Cross bite	1984 - 1995
Bunion operation	Right toe bunion excision	1995 - 1995
Foot deformity	Bunion on right toe	1995 - 1995
Jaw operation	Jaw realignment surgery	1995 - 1995
Arthralgia	Right knee pain	1996 - 1997
Arthroscopic surgery	Right knee arthroscopic lateral release surgery	1997 - 1997
Asthma	Asthma	2005 - Ongoing
Cubital tunnel syndrome	Right elbow cubital tunnel syndrome	2005 - 2005
Insomnia	Insomnia	2005 - Ongoing
Peripheral nerve decompression	Cubital tunnel release surgery	2005 - 2005
Wrist fracture	Broken left wrist	2013 - 2013
Ankle fracture	Broken left ankle	2017 - 2017
Lumbar vertebral fracture	L1 fracture	2017 - 2017
Liposuction	Liposuction	2018 - 2018
Menstruation irregular	Irregular menstruation	Feb 2020 - Ongoing
Uterine leiomyoma	Uterine fibroid (submucosal leiomyoma)	Feb 2020 - 28 Dec 2020 (Study Day 89)
Skin cosmetic procedure	Face tightening cosmetic procedure, elective	31 Aug 2020 (Study Day -31) - 31 Aug 2020 (Study Day -31)
Seasonal allergy	Exacerbation of seasonal allergies	28 Sep 2020 (Study Day -3) - 30 Sep 2020 (Study Day -1)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Biotin	2005 - Ongoing	General Health
Vitamins nos	2005 - Ongoing	General Health
Salbutamol	Feb 2005 - Ongoing	Asthma
Chlorphenamine maleate	Jun 2005 - Ongoing	Seasonal Allergies
Chromium picolinate	2018 - Ongoing	Weight Loss Aid
Levocarnitine	2018 - Ongoing	General Health
Linoleic acid	2018 - Ongoing	Weight Loss Aid
Probiotics nos	2018 - Ongoing	General Health
Calcium citrate; magnesium citrate	Mar 2020 - Ongoing	General Health

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
I.v. solutions	Mar 2020 - 23 Oct 2020 (Study Day 23)	General Health
Linum usitatissimum seed oil	Mar 2020 - Ongoing	General Health
Moringa oleifera	Mar 2020 - Ongoing	General Health
Nicotinamide	Mar 2020 - Ongoing	General Health
Testosterone	Mar 2020 - Ongoing	General Health
Vitamin b1 nos	Mar 2020 - Ongoing	General Health
Algae nos	May 2020 - Ongoing	General Health
Pseudoephedrine hydrochloride	28 Sep 2020 (Study Day -3) - 01 Oct 2020 (Study Day 1)	Sinus Headache Sinus Headache (Exacerbation Of Seasonal Allergies)
Paracetamol	30 Sep 2020 (Study Day -1) - 30 Sep 2020 (Study Day -1)	Sinus Headache (Exacerbation Of Seasonal Allergies)
Codeine; paracetamol	28 Dec 2020 (Study Day 89) - 29 Dec 2020 (Study Day 90)	Hysterectomy
Ibuprofen	28 Dec 2020 (Study Day 89) - 29 Dec 2020 (Study Day 90)	Hysterectomy
Robotic laparoscopic-assisted hysterectomy, bilateral salpingectomy*	28 Dec 2020 (Study Day 89) - 28 Dec 2020 (Study Day 89)	Other, Elective
Other dermatologicals	2021 - 2021	Cosmetic
Metronidazole	13 Jan 2021 (Study Day 105) - 14 Feb 2021 (Study Day 137)	Vaginal Bleeding
Suture reinforcement of the vaginal cuff for hemostasis*	14 Jan 2021 (Study Day 106) - 14 Jan 2021 (Study Day 106)	Adverse Event
Abdominoplasty and abdominal muscle repair*	22 Feb 2021 (Study Day 145) - 22 Feb 2021 (Study Day 145)	Other, Elective Procedure
Methocarbamol	22 Feb 2021 (Study Day 145) - 24 Feb 2021 (Study Day 147)	Abdominoplasty And Abdominal Muscle Repair/Abdominal Pain Due To Abdominoplasty
Metoprolol	22 Feb 2021 (Study Day 145) - Ongoing	Hypertension
Ciprofloxacin	24 Feb 2021 (Study Day 147) - 02 Mar 2021 (Study Day 153)	Abdominoplasty And Abdominal Muscle Repair
Clindamycin	24 Feb 2021 (Study Day 147) - 02 Mar 2021 (Study Day 153)	Abdominoplasty And Abdominal Muscle Repair
Gabapentin	24 Feb 2021 (Study Day 147) - 24 Feb 2021 (Study Day 147)	Abdominoplasty And Abdominal Muscle Repair

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	22 Feb 2021 (Study Day 145) - Ongoing
Procedural Pain	Grade 2/moderate	Not related	22 Feb 2021 (Study Day 145) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US332-2353 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	15 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	13 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Adenocarcinoma	SAE	Grade 3/severe	Not related	16 Oct 2020 (Study Day 32) – 08 Dec 2020 (Study Day 85)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2353, a 73-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Oct 2020 (Study Day 32), 31 days after the first dose and 3 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate adenocarcinoma lasted for 54 days, after which it was considered to be recovered/resolved with sequelae on 08 Dec 2020 (Study Day 85). The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000571	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Erectile dysfunction	Erectile dysfunction	1984 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	1990 - Ongoing
Hernia hiatus repair	Hiatal hernia surgery	1995 - 1995
Inguinal hernia repair	Indirect inguinal hernia surgery	1997 - 1997
Biopsy prostate normal	Prostatic biopsy for hyperplasia - negative	2015 - 2015
Irritable bowel syndrome	Irritable bowel syndrome	2015 - Ongoing
Prostatic specific antigen increased	Elevation of prostate-specific antigen	2015 - Ongoing
Haemorrhoids	Internal hemorrhoids	2016 - Ongoing
Haemorrhoid operation	Internal hemorrhoid ligation procedure	2018 - 2018
Urinary incontinence	Urinary incontinence	2018 - Ongoing
Haemorrhoid operation	Internal hemorrhoid ligation procedure	2019 - 2019
Pulmonary hypertension	Pulmonary hypertension	2019 - Ongoing
Oedema peripheral	Pedal edema	2020 - Ongoing
Hearing aid user	Hearing aids	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bone scan*	Not reported - Not reported	Diagnostic
Computerized tomography (ct) of abdomen/pelvis*	Not reported - Not reported	Diagnostic
Vacuum erection device*	Not reported - Not reported	Medical History
Vitamins nos	1975 - Ongoing	General Health
Folic acid	1985 - Ongoing	General Health
Testosterone cipionate	1987 - Ongoing	Erectile Dysfunction
Sildenafil	1998 - 16 Oct 2020 (Study Day 32)	Erectile Dysfunction
Alfuzosin	2014 - Ongoing	Benign Prostatic Hyperplasia
Finasteride	2014 - Ongoing	Benign Prostatic Hyperplasia
Plantago psyllium	2015 - Ongoing	Irritable Bowel Syndrome
Loperamide hydrochloride	2016 - 20 Sep 2020 (Study Day 6)	Irritable Bowel Syndrome
Sildenafil	19 Nov 2019 (Study Day -301) - Ongoing	Pulmonary Hypertension
Triamterene	May 2020 - Ongoing	Pedal Edema
Prostate magnetic resonance imaging with or with out contrast*	25 Sep 2020 (Study Day 11) - 25 Sep 2020 (Study Day 11)	Diagnostic
Ciprofloxacin	29 Sep 2020 (Study Day 15) - 02 Oct 2020 (Study Day 18)	Lower Urinary Tract Symptoms

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gentamicin sulfate	29 Sep 2020 (Study Day 15) - 29 Sep 2020 (Study Day 15)	Lower Urinary Tract Symptoms
Metronidazole	29 Sep 2020 (Study Day 15) - 02 Oct 2020 (Study Day 18)	Lower Urinary Tract Symptoms
Desmopressin	06 Oct 2020 (Study Day 22) - Ongoing	Urinary Incontinence
Prostate biopsy*	16 Oct 2020 (Study Day 32) - 16 Oct 2020 (Study Day 32)	Diagnostic
Omeprazole	04 Nov 2020 (Study Day 51) - Ongoing	Gastroesophageal Reflux Disease
Influenza vaccine	14 Nov 2020 (Study Day 61) - 14 Nov 2020 (Study Day 61)	Prophylaxis Of Influenza
Robotic assisted prostatectomy, bilateral pelvic lymph node dissection, neuroplasty, bladder suspension*	08 Dec 2020 (Study Day 85) - 08 Dec 2020 (Study Day 85)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Bladder Diverticulum	Grade 1/mild	Not related	25 Sep 2020 (Study Day 11) - Ongoing
Diverticulum Intestinal	Grade 1/mild	Not related	25 Sep 2020 (Study Day 11) - Ongoing
Lower Urinary Tract Symptoms	Grade 2/moderate	Not related	29 Sep 2020 (Study Day 15) - 02 Oct 2020 (Study Day 18)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 50) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US332-2429 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	10 Nov 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastrointestinal Stromal Tumour/Gatrointestinal Stromal Tumor	SAE	Grade 2/ moderate	Not related	31 Dec 2020 (Study Day 79) – 31 Dec 2020 (Study Day 79)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2429, a 44-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 14 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 10 Nov 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Dec 2020 (Study Day 79), 78 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of gastrointestinal stromal tumour. Action taken with the IP was not applicable. The event of gatrointestinal stromal tumor lasted for 1 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 79). The investigator assessed the event of gastrointestinal stromal tumour to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011777	Gastrointestinal stromal tumour

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	2009 - 2009
Hypothyroidism	Hypothyroidism	2018 - Ongoing
Rotator cuff repair	Rotator cuff repair	2018 - 2018
Rotator cuff syndrome	Rotator cuff injury -right	2018 - Mar 2018
Weight increased	Leptin resistance (weight gain)	2018 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	2018 - Ongoing	Hypothyroidism
Liraglutide	2018 - Ongoing	Leptin Resistance (Weight Control)
Lisdexamfetamine mesilate	2019 - Ongoing	Attention Deficit Disorder
Ibuprofen	11 Nov 2020 (Study Day 29) - 11 Nov 2020 (Study Day 29)	Injection Site Pain And Myalgia
Paracetamol	11 Nov 2020 (Study Day 29) - 11 Nov 2020 (Study Day 29)	Fever
Ibuprofen	12 Nov 2020 (Study Day 30) - 12 Nov 2020 (Study Day 30)	Injection Site Pain
Esophagogastroduodenoscopy*	13 Nov 2020 (Study Day 31) - 13 Nov 2020 (Study Day 31)	Diagnostic
Pcr covid-19 test*	20 Nov 2020 (Study Day 38) - 20 Nov 2020 (Study Day 38)	Diagnostic
Pcr covid-19 test*	04 Dec 2020 (Study Day 52) - 04 Dec 2020 (Study Day 52)	Diagnostic
Pantoprazole	21 Dec 2020 (Study Day 69) - 01 Jan 2021 (Study Day 80)	Reflux
Paracetamol	21 Dec 2020 (Study Day 69) - 05 Jan 2021 (Study Day 84)	Gastrointestinal Stromal Tumor
Enoxaparin	31 Dec 2020 (Study Day 79) - 01 Jan 2021 (Study Day 80)	Gastrointestinal Stromal Tumor
Gastric bypass (elective)*	31 Dec 2020 (Study Day 79) - 31 Dec 2020 (Study Day 79)	Medical History
Hydromorphone	31 Dec 2020 (Study Day 79) - 01 Jan 2021 (Study Day 80)	Gastrointestinal Stromal Tumor
Ketorolac	31 Dec 2020 (Study Day 79) - 01 Jan 2021 (Study Day 80)	Gastrointestinal Stromal Tumor
Ondansetron	31 Dec 2020 (Study Day 79) - 01 Jan 2021 (Study Day 80)	Nausea And Vomiting

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Promethazine	31 Dec 2020 (Study Day 79) - 01 Jan 2021 (Study Day 80)	Nausea/ Vomiting
Removal of gastrointestinal stromal tumor*	31 Dec 2020 (Study Day 79) - 31 Dec 2020 (Study Day 79)	Adverse Event
Tramadol	31 Dec 2020 (Study Day 79) - 01 Jan 2021 (Study Day 80)	Gastrointestinal Stromal Tumor
Ct scan with contrast (of lungs)*	08 Jan 2021 (Study Day 87) - 08 Jan 2021 (Study Day 87)	Diagnostic
Rapid covid-19 test (negative)*	08 Jan 2021 (Study Day 87) - 08 Jan 2021 (Study Day 87)	Diagnostic
Omeprazole	12 Jan 2021 (Study Day 91) - Ongoing	Treatment Of Gerd
Sucralfate	12 Jan 2021 (Study Day 91) - Ongoing	Prevent Ulcers
Ursodeoxycholic acid	12 Jan 2021 (Study Day 91) - Ongoing	Prevention Of Gallstones
Oral covid-19 test (results pending)*	13 Jan 2021 (Study Day 92) - 13 Jan 2021 (Study Day 92)	Diagnostic
Suture repair of left lower leg laceration*	19 Feb 2021 (Study Day 129) - 19 Feb 2021 (Study Day 129)	Adverse Event
Pcr covid-19 (nasal swab test) negative*	25 Feb 2021 (Study Day 135) - 25 Feb 2021 (Study Day 135)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Swelling	Grade 1/mild	Related	10 Nov 2020 (Study Day 28) - 19 Nov 2020 (Study Day 37)
Rhinorrhoea	Grade 1/mild	Not related	08 Dec 2020 (Study Day 56) - 08 Dec 2020 (Study Day 56)
Cough	Grade 2/moderate	Not related	08 Jan 2021 (Study Day 87) - Ongoing
Dyspnoea	Grade 2/moderate	Not related	08 Jan 2021 (Study Day 87) - 09 Jan 2021 (Study Day 88)
Skin Laceration	Grade 2/moderate	Not related	19 Feb 2021 (Study Day 129) - Ongoing
American Trypanosomiasis	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 150) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US333-2033 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Syncope/Syncope	SAE	Grade 4	Not related	12 Dec 2020 (Study Day 125) – 12 Dec 2020 (Study Day 125)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US333-2033, a 77-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Dec 2020 (Study Day 125), 124 days after the first dose and 92 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 1 days, after which it was considered to be recovered/resolved on 12 Dec 2020 (Study Day 125). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008099	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	2012 - Ongoing
Erectile dysfunction	Erectile dysfunction	2012 - Ongoing
Coronary artery disease	Coronary artery disease	2016 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2016 - Ongoing
Coronary arterial stent insertion	Cardiac stent placement	29 Sep 2016 (Study Day -1411) - 29 Sep 2016 (Study Day -1411)
Myocardial infarction	Myocardial infarction	29 Sep 2016 (Study Day -1411) - 29 Sep 2016 (Study Day -1411)
Dyspnoea	Shortness of breath intermittent	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2017 - 26 Feb 2021 (Study Day 201)	Hypercholesterolemia
Clopidogrel	2017 - 30 Sep 2020 (Study Day 52)	Cardiac Prophylaxis
Losartan	2017 - 12 Dec 2020 (Study Day 125)	Hypertension
Metformin	2017 - Ongoing	Prediabetes
Metoprolol	2017 - 26 Feb 2021 (Study Day 201)	Hypertension
Sildenafil	2017 - Ongoing	Erectile Dysfunction
Influenza vaccine	17 Nov 2020 (Study Day 100) - 17 Nov 2020 (Study Day 100)	Influenza Prophylaxis
Calcium chloride; potassium chloride; sodium lactate	12 Dec 2020 (Study Day 125) - 12 Dec 2020 (Study Day 125)	Syncope
Cefalexin	12 Dec 2020 (Study Day 125) - 19 Dec 2020 (Study Day 132)	Urinary Tract Infection
Ceftriaxone	12 Dec 2020 (Study Day 125) - 12 Dec 2020 (Study Day 125)	Urinary Tract Infection
Losartan	12 Dec 2020 (Study Day 125) - 26 Feb 2021 (Study Day 201)	Hypertension
Ciprofloxacin	20 Jan 2021 (Study Day 164) - 06 Feb 2021 (Study Day 181)	Urinary Tract Infection
Tamsulosin	20 Jan 2021 (Study Day 164) - Ongoing	Uti Prophylaxis
Atorvastatin	26 Feb 2021 (Study Day 201) - Ongoing	Worsening Of Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cardiac stent placement*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Chest x ray*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Echocardiogram*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Ekg*	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Adverse Event
Heparin	26 Feb 2021 (Study Day 201) - 05 Mar 2021 (Study Day 208)	Blood Clot Prophylaxis
Losartan	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Worsening Of Coronary Artery Disease
Metoprolol succinate	26 Feb 2021 (Study Day 201) - Ongoing	Worsening Of Coronary Artery Disease
Sodium chloride	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Surgical Prophylaxis
Tirofiban	26 Feb 2021 (Study Day 201) - 26 Feb 2021 (Study Day 201)	Blood Clot Prophylaxis
Coronary artery bypass graft x 2*	01 Mar 2021 (Study Day 204) - 01 Mar 2021 (Study Day 204)	Adverse Event
Norepinephrine	01 Mar 2021 (Study Day 204) - 01 Mar 2021 (Study Day 204)	Worsening Of Coronary Artery Disease
Protamine	01 Mar 2021 (Study Day 204) - 01 Mar 2021 (Study Day 204)	Hemorrhage Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 1/mild	Not related	11 Sep 2020 (Study Day 33) - Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	12 Dec 2020 (Study Day 125) - 19 Dec 2020 (Study Day 132)
Urinary Tract Infection	Grade 2/moderate	Not related	18 Jan 2021 (Study Day 162) - 06 Feb 2021 (Study Day 181)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US333-2034 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Biliary Dyskinesia/Biliary Dyskinesia	SAE	Grade 4	Not related	01 Nov 2020 (Study Day 84) – 31 Dec 2020 (Study Day 144)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US333-2034, a 31-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 84), 83 days after the first dose and 58 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of biliary dyskinesia. Action taken with the IP was not applicable. The event of biliary dyskinesia lasted for 61 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 144). The investigator assessed the event of biliary dyskinesia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001768	Biliary dyskinesia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mitral valve incompetence	Mitral valve regurgitation	2005 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Mitral valve repair	Mitral valve repair	17 Jun 2010 (Study Day -3707) - 17 Jun 2010 (Study Day -3707)
Insomnia	Insomnia	2014 - Ongoing
Anxiety	Anxiety	2015 - Ongoing
Mitral valve repair	Mitral valve repair	14 Mar 2017 (Study Day -1245) - 14 Mar 2017 (Study Day -1245)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Levonorgestrel	Nov 2015 - 09 Nov 2020 (Study Day 92)	Pregnancy Prophylaxis
Citalopram hydrobromide	2016 - Ongoing	Anxiety
Trazodone	Apr 2020 - Ongoing	Insomnia
Influenza vaccine	12 Oct 2020 (Study Day 64) - 12 Oct 2020 (Study Day 64)	Influenza Prophylaxis
Levonorgestrel	09 Nov 2020 (Study Day 92) - Ongoing	Pregnancy Prophylaxis
Paracetamol	18 Nov 2020 (Study Day 101) - 29 Nov 2020 (Study Day 112)	COVID-Like Illness
Ibuprofen	19 Nov 2020 (Study Day 102) - 29 Nov 2020 (Study Day 112)	COVID-Like Illness
Clonazepam	21 Nov 2020 (Study Day 104) - 21 Nov 2020 (Study Day 104)	COVID-Like Illness
Omeprazole	07 Dec 2020 (Study Day 120) - Ongoing	Gastro Esophageal Reflux Disease
Hydromorphone	15 Dec 2020 (Study Day 128) - 15 Dec 2020 (Study Day 128)	Biliary Diskinesia
Ondansetron	15 Dec 2020 (Study Day 128) - 15 Dec 2020 (Study Day 128)	Nausea Prophylaxis
Ondansetron	15 Dec 2020 (Study Day 128) - 01 Jan 2021 (Study Day 145)	Nausea Prophylaxis
Calcium chloride; potassium chloride; sodium lactate	31 Dec 2020 (Study Day 144) - 31 Dec 2020 (Study Day 144)	Cholecystectomy Surgical Prophylaxis
Laparoscopic cholecystectomy*	31 Dec 2020 (Study Day 144) - 31 Dec 2020 (Study Day 144)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	01 Oct 2020 (Study Day 53) - Ongoing
Suspected COVID-19	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 101) - 11 Dec 2020 (Study Day 124)
Conjunctivitis	Grade 2/moderate	Not related	21 Nov 2020 (Study Day 104) - 22 Nov 2020 (Study Day 105)
Haemangioma Of Liver	Grade 1/mild	Not related	15 Dec 2020 (Study Day 128) - Ongoing
Tachycardia	Grade 1/mild	Not related	24 Mar 2021 (Study Day 227) - 24 Mar 2021 (Study Day 227)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2023 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/R Knee Osteoarthritis	SAE	Grade 4	Not related	23 Sep 2020 (Study Day 44) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2023, a 69-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Sep 2020 (Study Day 44), 43 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of r knee osteoarthritis was considered to be ongoing. The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068079	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Seasonal allergy	Cedar fever	Dec 2000 - Dec 2000
Hypertension	Hypertension	2017 - Ongoing
Osteoarthritis	Osteoarthritis (fingers of bilateral hands)	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	Dec 2000 - Ongoing	Cedar Fever
Lisinopril	2017 - Ongoing	Hypertension
Meloxicam	2017 - Ongoing	Osteoarthritis
Ibuprofen	23 Sep 2020 (Study Day 44) - Ongoing	Right Meniscal Tear (Ae)
Hydrocortisone	24 Sep 2020 (Study Day 45) - 24 Sep 2020 (Study Day 45)	Right Meniscal Tear (Ae)
Influenza vaccine	18 Oct 2020 (Study Day 69) - 18 Oct 2020 (Study Day 69)	Influenza Prevention
Celecoxib	20 Oct 2020 (Study Day 71) - 20 Nov 2020 (Study Day 102)	Right Meniscal Tear (Ae)
Right meniscus surgery*	02 Nov 2020 (Study Day 84) - 02 Nov 2020 (Study Day 84)	Adverse Event
Hydrochlorothiazide	16 Feb 2021 (Study Day 190) - Ongoing	Ae: Worsening Symptoms Of Hypertension
Sertraline hydrochloride	16 Feb 2021 (Study Day 190) - Ongoing	Ae: Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Meniscus Injury	Grade 2/moderate	Not related	23 Sep 2020 (Study Day 44) - 02 Nov 2020 (Study Day 84)
Osteoarthritis	Grade 1/mild	Not related	23 Sep 2020 (Study Day 44) - Ongoing
Depression	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 190) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 190) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2088 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colon Cancer Stage III/Stage III Colon Cancer	SAE, AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	15 Sep 2020 (Study Day 30) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2088, a 50-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 17 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Sep 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of colon cancer stage III. On 13 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of stage III colon cancer was considered to be ongoing. The investigator assessed the event of colon cancer stage III to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000305	Colon cancer stage III

Study Completion/Discontinuation

On 22 Jan 2021 (Study Day 159), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Limb traumatic amputation	Traumatic amputation of l 3rd distal end of digit	1980 - 1980
Drug eruption	Sulfa drug allergy (rash)	1990 - Ongoing
Tarsal tunnel decompression	Tarsal tunnel surgery right foot	2018 - 2018
Tarsal tunnel syndrome	Tarsal tunnel syndrome right foot	2018 - 2018
Skin abrasion	Minor abrasion left ue from burn from grease fryer	12 Aug 2020 (Study Day -5) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colonoscopy*	31 Aug 2020 (Study Day 15) - 31 Aug 2020 (Study Day 15)	Diagnostic
Egd*	31 Aug 2020 (Study Day 15) - 31 Aug 2020 (Study Day 15)	Diagnostic
Ct scan (chest, abd, pelv) with contrast*	22 Sep 2020 (Study Day 37) - 22 Sep 2020 (Study Day 37)	Diagnostic
Influenza vaccine	24 Sep 2020 (Study Day 39) - 24 Sep 2020 (Study Day 39)	Wellness
Colonic tumor resection*	30 Sep 2020 (Study Day 45) - 30 Sep 2020 (Study Day 45)	Adverse Event
Ileostomy*	30 Sep 2020 (Study Day 45) - 30 Sep 2020 (Study Day 45)	Adverse Event
Paracetamol	30 Sep 2020 (Study Day 45) - 03 Oct 2020 (Study Day 48)	Post Operative Pain (Colonic Tumor Resection)
Mri power-port (for chemotherapy) right subclavian.*	16 Oct 2020 (Study Day 61) - 16 Oct 2020 (Study Day 61)	Adverse Event
Other viral vaccines	2021 - 2021	COVID-19
Other viral vaccines	22 Jan 2021 (Study Day 159) - 22 Jan 2021 (Study Day 159)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US334-2199 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colitis/Acute Focal Colitis	SAE	Grade 3/severe	Not related	13 Sep 2020 (Study Day 10) – 25 Sep 2020 (Study Day 22)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2199, a 59-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Sep 2020 (Study Day 10), 9 days after the first dose and 18 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of colitis. The IP dose was not changed due to the acute focal colitis. The event of acute focal colitis lasted for 13 days, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 22). The investigator assessed the event of colitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000314	Colitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Herpes simplex	Herpes simplex virus type 1	24 Aug 2015 (Study Day -1838) - Ongoing
Haemochromatosis	Hemochromatosis	2018 - Ongoing
Insomnia	Insomnia	2018 - Ongoing
Renal cancer	Cancer of the kidney (encapsulated tumor)	Jun 2019 - 24 Aug 2019 (Study Day -377)
Renal tumour excision	Tumor removal right kidney	24 Aug 2019 (Study Day -377) - 24 Aug 2019 (Study Day -377)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pseudoephedrine	1985 - Ongoing	Seasonal Allergies
Aciclovir	24 Aug 2015 (Study Day -1838) - Ongoing	Herpes Simplex Virus Type 1
Zolpidem	2018 - Ongoing	Insomnia
Allopurinol	Sep 2019 - Feb 2020	Maintainence Drug For Post Partial Nephrectomy
Naproxen	06 Sep 2020 (Study Day 3) - 06 Sep 2020 (Study Day 3)	Headache
Cbc labs*	13 Sep 2020 (Study Day 10) - 13 Sep 2020 (Study Day 10)	Adverse Event
Ciprofloxacin	13 Sep 2020 (Study Day 10) - 24 Sep 2020 (Study Day 21)	Ae Acute Focal Colitis
Codeine; paracetamol	13 Sep 2020 (Study Day 10) - 25 Sep 2020 (Study Day 22)	Ae Acute Focal Colitis
Ct scan abdomen/pelvis*	13 Sep 2020 (Study Day 10) - 13 Sep 2020 (Study Day 10)	Adverse Event
Famotidine	13 Sep 2020 (Study Day 10) - 25 Sep 2020 (Study Day 22)	Ae Acute Focal Colitis
Metronidazole	13 Sep 2020 (Study Day 10) - 20 Sep 2020 (Study Day 17)	Ae Acute Focal Colitis
Piperacillin sodium; tazobactam sodium	13 Sep 2020 (Study Day 10) - 13 Sep 2020 (Study Day 10)	Ae Acute Focal Colitis
Routine chemistry*	13 Sep 2020 (Study Day 10) - 13 Sep 2020 (Study Day 10)	Adverse Event
Ceftriaxone	14 Sep 2020 (Study Day 11) - 14 Sep 2020 (Study Day 11)	Ae Acute Focal Colitis
Routine chemistry*	14 Sep 2020 (Study Day 11) - 14 Sep 2020 (Study Day 11)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cbc labs*	15 Sep 2020 (Study Day 12) - 15 Sep 2020 (Study Day 12)	Adverse Event
Routine chemistry*	15 Sep 2020 (Study Day 12) - 15 Sep 2020 (Study Day 12)	Adverse Event
Colonoscopy*	25 Sep 2020 (Study Day 22) - 25 Sep 2020 (Study Day 22)	Adverse Event
Influenza vaccine	16 Oct 2020 (Study Day 43) - 16 Oct 2020 (Study Day 43)	Yearly Flu Prevention
Varicella zoster vaccine	09 Nov 2020 (Study Day 67) - 09 Nov 2020 (Study Day 67)	Shingles Prophylaxis
Ciprofloxacin	08 Mar 2021 (Study Day 186) - 15 Mar 2021 (Study Day 193)	Acute Focal Colitis #2 Ae
Metronidazole	08 Mar 2021 (Study Day 186) - 15 Mar 2021 (Study Day 193)	Acute Focal Colitis #2 Ae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphadenopathy	Grade 1/mild	Related	10 Feb 2021 (Study Day 160) - 11 Feb 2021 (Study Day 161)
Colitis	Grade 2/moderate	Not related	07 Mar 2021 (Study Day 185) - 15 Mar 2021 (Study Day 193)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2200 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intraductal Proliferative Breast Lesion/Ductal Carcinoma In Situ Right Breast	SAE	Grade 3/severe	Not related	20 Nov 2020 (Study Day 78) – 13 Jan 2021 (Study Day 132)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2200, a 44-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Nov 2020 (Study Day 78), 77 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of intraductal proliferative breast lesion. Action taken with the IP was not applicable. The event of ductal carcinoma in situ right breast lasted for 55 days, after which it was considered to be recovered/resolved with sequelae on 13 Jan 2021 (Study Day 132). The investigator assessed the event of intraductal proliferative breast lesion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000888	Intraductal proliferative breast lesion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dermatitis atopic	Atopic dermatitis	1990 - Ongoing
Rubber sensitivity	Latex allergy - hives	1993 - Ongoing
Seasonal allergy	Seasonal allergies	1993 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Precancerous cells present	Precancerous cervical cells	2018 - 12 Nov 2018 (Study Day -662)
Hysterectomy	Hysterectomy	12 Nov 2018 (Study Day -662) - 12 Nov 2018 (Study Day -662)
Nephrolithiasis	Kidney stones	2019 - 2019
Arthralgia	Joint pain bilateral lower extremities	May 2020 - Ongoing
Arthralgia	Joint pain bilateral shoulders	May 2020 - Ongoing
Mammogram	Mammogram	Jul 2020 - Jul 2020
Benign breast neoplasm	Right breast lump benign	Aug 2020 - Aug 2020
Biopsy breast	Right breast lump biopsy	Aug 2020 - Aug 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Triamcinolone	2000 - Ongoing	Atopic Dermatitis
Montelukast sodium	2010 - Ongoing	Seasonal Allergies
Vitamin d nos	2015 - Ongoing	Vitamin D Deficiency
Influenza vaccine	05 Aug 2020 (Study Day -30) - 05 Aug 2020 (Study Day -30)	Influenza Prevention
Paracetamol	03 Oct 2020 (Study Day 30) - 03 Oct 2020 (Study Day 30)	Headache (Solicited Reaction - Vaccine #2)
Right breast ultrasound*	06 Nov 2020 (Study Day 64) - 06 Nov 2020 (Study Day 64)	Diagnostic
Right breast lumpectomy*	18 Nov 2020 (Study Day 76) - 18 Nov 2020 (Study Day 76)	Adverse Event
Radiation therapy*	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Adverse Event
Sulfadiazine silver	21 Jan 2021 (Study Day 140) - 11 Feb 2021 (Study Day 161)	Radiation Dermatitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dermatitis Atopic	Grade 1/mild	Not related	04 Sep 2020 (Study Day 1) - 16 Oct 2020 (Study Day 43)
Fatigue	Grade 1/mild	Related	04 Oct 2020 (Study Day 31) - 16 Oct 2020 (Study Day 43)
Myalgia	Grade 1/mild	Related	05 Oct 2020 (Study Day 32) - 16 Oct 2020 (Study Day 43)
Radiation Skin Injury	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 140) - 11 Feb 2021 (Study Day 161)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2239 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Head Injury/Head Trauma	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	13 Oct 2020 (Study Day 34) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2239, a 30-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Oct 2020 (Study Day 34), 33 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of head injury. On 07 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of head trauma was considered to be ongoing. The investigator assessed the event of head injury to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 11 Nov 2020 (Study Day 63), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	02 Mar 2012 (Study Day -3114) - 02 Mar 2012 (Study Day -3114)

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	Jan 2018 - Ongoing
Hypertension	Hypertension	Jun 2018 - Ongoing
Cholelithiasis	Gallstones	Mar 2019 - Ongoing
Intervertebral disc disorder	L5 defective disc	Mar 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Buspirone hydrochloride	Jan 2018 - Jun 2018	Anxiety
Buspirone	Jun 2018 - Feb 2019	Anxiety
Gabapentin	Jun 2018 - Feb 2019	Anxiety
Naproxen	11 Sep 2020 (Study Day 2) - 12 Sep 2020 (Study Day 3)	Injection Site Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Head Injury	Grade 1/mild	Not related	13 Oct 2020 (Study Day 34) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2259 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression Suicidal/Depression With Suicidal Ideation	AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 3/ severe	Not related	14 Oct 2020 (Study Day 31) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2259, a 41-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Oct 2020 (Study Day 31), 30 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of depression suicidal. On 11 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of depression with suicidal ideation was considered to be ongoing. The investigator assessed the event of depression suicidal to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 16 Oct 2020 (Study Day 33), the participant discontinued from the study due to adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	Jan 2020 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisdexamfetamine mesilate	Jan 2020 - Ongoing	Attention Deficit Disorder
Zolpidem tartrate	Jan 2020 - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pharyngitis	Grade 1/mild	Not related	14 Sep 2020 (Study Day 1) - 14 Sep 2020 (Study Day 1)
Migraine	Grade 1/mild	Not related	14 Sep 2020 (Study Day 1) - Ongoing
Depression Suicidal	Grade 3/severe	Not related	14 Oct 2020 (Study Day 31) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2281 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	27 Oct 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Concussion/Concussion	SAE	Grade 4	Not related	27 Oct 2020 (Study Day 34) – 20 Nov 2020 (Study Day 58)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2281, a 42-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 24 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Oct 2020 (Study Day 34), 33 days after the first dose and on the day of the second dose of the IP, the participant experienced a Grade 4 serious adverse event of concussion. The IP dose was not changed due to the concussion. The event of concussion lasted for 25 days, after which it was considered to be recovered/resolved on 20 Nov 2020 (Study Day 58). The investigator assessed the event of concussion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000623	Concussion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Glucose tolerance impaired	Pre-diabetes mellitus type 2	2012 - 2013
Hyperlipidaemia	Hyperlipidemia	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	2015 - Ongoing	Seasonal Allergies
Hydrocortisone	09 Oct 2020 (Study Day 16) - 13 Oct 2020 (Study Day 20)	Pityriasis Rosea
Magnesium hydroxide	16 Oct 2020 (Study Day 23) - 16 Oct 2020 (Study Day 23)	Ae Bacterial Gastroenteritis
Paracetamol	27 Oct 2020 (Study Day 34) - 30 Oct 2020 (Study Day 37)	Headache
Levetiracetam	30 Oct 2020 (Study Day 37) - 07 Nov 2020 (Study Day 45)	Concussion: Ae
Methocarbamol	30 Oct 2020 (Study Day 37) - 07 Nov 2020 (Study Day 45)	Concussion: Ae
Paracetamol	30 Oct 2020 (Study Day 37) - 20 Nov 2020 (Study Day 58)	Concussion: Ae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pityriasis Rosea	Grade 1/mild	Not related	08 Oct 2020 (Study Day 15) - Ongoing
Gastroenteritis Bacterial	Grade 1/mild	Not related	16 Oct 2020 (Study Day 23) - 17 Oct 2020 (Study Day 24)
Lip Injury	Grade 1/mild	Not related	27 Oct 2020 (Study Day 34) - 29 Oct 2020 (Study Day 36)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2286 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Hypertension (Unspecified)	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	21 Oct 2020 (Study Day 26) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2286, a 37-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 26 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Oct 2020 (Study Day 26), 25 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of hypertension. On 23 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of hypertension (unspecified) was considered to be ongoing. The investigator assessed the event of hypertension to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pain	Generalized pain	2000 - Ongoing
Neck surgery	Surgery for right neck stabbing	2010 - 2010
Stab wound	Right neck stabbing (~ 4 in deep)	2010 - 2010

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Generalized Pain
Diphenhydramine	2020 - Ongoing	Seasonal Allergies
Lisinopril	25 Jan 2021 (Study Day 122) - 19 Mar 2021 (Study Day 175)	Hypertension Unspecified

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	21 Oct 2020 (Study Day 26) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2343 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Osteoarthritis/Worsening Of Osteoarthritis Of Cervical Spine	SAE	Grade 2/ moderate	Not related	19 Oct 2020 (Study Day 8) – 02 Apr 2021 (Study Day 173)	Recovered/ resolved
Synovitis/New Onset Of Symmetrical Synovitis Of Hands And Feet	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	26 Oct 2020 (Study Day 15) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2343, a 61-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 12 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Oct 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of spinal osteoarthritis. On 08 Nov 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening of osteoarthritis of cervical spine lasted for 166 days, after which it was considered to be recovered/resolved on 02 Apr 2021 (Study Day 173). The investigator assessed the event of spinal osteoarthritis to be not related to the IP.

On 26 Oct 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of synovitis. On 08 Nov 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of new onset of symmetrical synovitis of hands and feet was considered to be ongoing. The investigator assessed the event of synovitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-068993	Spinal osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy (due to uterine fibroids)	1985 - 1985
Uterine leiomyoma	Fibroids of the uterus	1985 - 1985
Hip arthroplasty	Left hip replacement	2003 - 2003
Sports injury	Left hip sports induced injury	2003 - 2003
Osteoarthritis	Osteoarthritis of bilateral hips and bilateral wrists	2010 - Ongoing
Spinal osteoarthritis	Osteoarthritis of the cervical spine	2010 - Ongoing
Headache	Headaches	06 Sep 2019 (Study Day -402) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mri - cervical spine*	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Adverse Event
Corticosteroid nos	21 Oct 2020 (Study Day 10) - 21 Oct 2020 (Study Day 10)	Cervical Disc Disease Ae
Ibuprofen	31 Oct 2020 (Study Day 20) - Ongoing	Osteoarthritis
Ketorolac tromethamine	31 Oct 2020 (Study Day 20) - Ongoing	New Onset Of Symmetrical Synovitis Of Hands And Feet
Lisinopril	04 Jan 2021 (Study Day 85) - Ongoing	Hypertension Ae
Ibuprofen	11 Mar 2021 (Study Day 151) - 11 Mar 2021 (Study Day 151)	Allergic Rhinitis Ae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Viral Infection	Grade 1/mild	Not related	13 Oct 2020 (Study Day 2) - 28 Oct 2020 (Study Day 17)
Synovitis	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 15) - Ongoing
Hypertension	Grade 1/mild	Not related	04 Jan 2021 (Study Day 85) - Ongoing
Rhinitis Allergic	Grade 1/mild	Not related	07 Mar 2021 (Study Day 147) - 15 Mar 2021 (Study Day 155)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2354 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	13 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	12 Nov 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diabetic Ketoacidosis/Diabetic Ketoacidosis	SAE	Grade 4	Not related	11 Dec 2020 (Study Day 60) – 13 Dec 2020 (Study Day 62)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2354, a 51-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 13 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 12 Nov 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Dec 2020 (Study Day 60), 59 days after the first dose and 29 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of diabetic ketoacidosis. Action taken with the IP was not applicable. The event of diabetic ketoacidosis lasted for 3 days, after which it was considered to be recovered/resolved on 13 Dec 2020 (Study Day 62). The investigator assessed the event of diabetic ketoacidosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001121	Diabetic ketoacidosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	1985 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2013 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2013 - Ongoing
Postmenopause	Postmenopausal	2016 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Depression	Depression	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1985 - Ongoing	Headaches
Amlodipine	2013 - Ongoing	Hypercholesterolemia
Insulin human; insulin human injection, isophane	2013 - 11 Dec 2020 (Study Day 60)	Type II Diabetes
Metformin	2013 - Ongoing	Type II Diabetes
Pravastatin	2013 - 20 Apr 2021 (Study Day 190)	Hypertension
Sitagliptin	2013 - 11 Dec 2020 (Study Day 60)	Type II Diabetes
Bupropion	2018 - Ongoing	Anxiety & Depression
Fluoxetine	2018 - Ongoing	Anxiety & Depression
Ibuprofen	14 Nov 2020 (Study Day 33) - 14 Nov 2020 (Study Day 33)	Headache Post Vaccine #2 Ar
Abdominal/pelvis ct with contrast*	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Adverse Event
Ceftriaxone sodium	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Chest xray*	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Adverse Event
Insulin	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Insulin human	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Iopamidol	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Ondansetron	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae
Sodium chloride	12 Dec 2020 (Study Day 61) - 12 Dec 2020 (Study Day 61)	Diabetic Ketoacidosis Ae

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	13 Dec 2020 (Study Day 62) - Ongoing	Type II Diabetes Mellitus
Sitagliptin	13 Dec 2020 (Study Day 62) - Ongoing	Type II Diabetes Mellitus
Oxcarbazepine	05 Jan 2021 (Study Day 85) - Ongoing	Anxiety And Depression Exacerbation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	23 Dec 2020 (Study Day 72) - Ongoing
Depression	Grade 2/moderate	Not related	23 Dec 2020 (Study Day 72) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US335-2033 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Acute Inferior Wall Myocardial Infarction	SAE	Grade 4	Not related	05 Nov 2020 (Study Day 92) – 05 Nov 2020 (Study Day 92)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2033, a 61-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Nov 2020 (Study Day 92), 91 days after the first dose and 56 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of acute inferior wall myocardial infarction lasted for 1 days, after which it was considered to be recovered/resolved on 05 Nov 2020 (Study Day 92). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000689	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1963 - 1963
Tonsillitis	Tonsillitis (recurring)	1963 - 1963
Presbyopia	Presbyopia	2005 - Ongoing
Neck pain	Neck pain	2014 - Ongoing
Migraine	Migraines	2015 - Ongoing
Foot fracture	Left big toe rislal phalanx fracture	2018 - 2018
Hyperlipidaemia	Hyperlipidemia	01 Jul 2018 (Study Day -767) - Ongoing
Hypertension	Hypertension	01 Jul 2018 (Study Day -767) - Ongoing
Arthrodesis	Arthrodesis l5-l6	2019 - 2019
Intervertebral disc protrusion	Discal hernia l5-l6	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2014 - Ongoing	Neck Pain
Ibuprofen	2015 - Ongoing	Migraines
Chest xray*	05 Nov 2020 (Study Day 92) - 05 Nov 2020 (Study Day 92)	Adverse Event
Ticagrelor	05 Nov 2020 (Study Day 92) - Ongoing	Cardiovascular Prophylaxis
Transthoracic echocardiogram*	05 Nov 2020 (Study Day 92) - 05 Nov 2020 (Study Day 92)	Adverse Event
Two angioplasty with stent*	05 Nov 2020 (Study Day 92) - 05 Nov 2020 (Study Day 92)	Adverse Event
Lidocaine	09 Nov 2020 (Study Day 96) - 09 Nov 2020 (Study Day 96)	Angioplasty Anesthetic
Two angioplasty with stent*	09 Nov 2020 (Study Day 96) - 09 Nov 2020 (Study Day 96)	Adverse Event
Acetylsalicylic acid	10 Nov 2020 (Study Day 97) - Ongoing	Cardiovascular Prohylaxis
Atorvastatin	10 Nov 2020 (Study Day 97) - Ongoing	Hyperlipidemia
Metoprolol	10 Nov 2020 (Study Day 97) - Ongoing	Hypertension
Paracetamol	04 Feb 2021 (Study Day 183) - 04 Feb 2021 (Study Day 183)	Pain At Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US335-2070 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Wound Infection/Wound Infection	SAE	Grade 4	Not related	20 Dec 2020 (Study Day 130) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2070, a 54-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Dec 2020 (Study Day 130), 129 days after the first dose and 103 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of wound infection. Action taken with the IP was not applicable. The event of wound infection was considered to be ongoing. The investigator assessed the event of wound infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-077358	Wound infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol abuse	Alcohol abuse	Not reported

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cough	Chronic cough	Not reported
Malignant melanoma	Melanoma of the lower back	Not reported
Mastoiditis	Unspecified mastoiditis bilateral	Not reported
Otorrhoea	Purulent otorrhea of right ear	Not reported
Astigmatism	Astigmatism bilateral	1969 - Ongoing
Tobacco user	Current tobacco user	1983 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	01 Oct 2020 (Study Day 50) - Ongoing	Left Distal Tibia Fracture
Oxycodone hydrochloride; paracetamol	01 Oct 2020 (Study Day 50) - Ongoing	Left Distal Tibia Fracture
Influenza vaccine	11 Dec 2020 (Study Day 121) - 11 Dec 2020 (Study Day 121)	Flu Prevention
Covid 19 antigen bd*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Diagnostic
Ct angiogram of pulmonary arteries with contrast*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Adverse Event
Ecg*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Diagnostic
Ra chest 1 view*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Diagnostic
Us doppler lower extremety venous left.*	10 Mar 2021 (Study Day 210) - 10 Mar 2021 (Study Day 210)	Adverse Event
Cefepime hydrochloride	11 Mar 2021 (Study Day 211) - Ongoing	Cellulitis Of Right Leg
Clindamycin	11 Mar 2021 (Study Day 211) - Ongoing	Sepsis
Diazepam	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Enoxaparin sodium	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Ketorolac tromethamine	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Ondansetron	11 Mar 2021 (Study Day 211) - Ongoing	Nausea
Oxycodone hydrochloride; paracetamol	11 Mar 2021 (Study Day 211) - Ongoing	Left Popliteal Deep Vein Thrombosis
Ra ankle portable left*	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Adverse Event
Sodium chloride; vancomycin hydrochloride	11 Mar 2021 (Study Day 211) - Ongoing	Sepsis
Vancomycin	11 Mar 2021 (Study Day 211) - 17 Mar 2021 (Study Day 217)	Sepsis
Zolpidem tartrate	11 Mar 2021 (Study Day 211) - Ongoing	Sleep
Irrigation and debridement left ankle*	13 Mar 2021 (Study Day 213) - 13 Mar 2021 (Study Day 213)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mri ankle with and without contrast left*	13 Mar 2021 (Study Day 213) - 13 Mar 2021 (Study Day 213)	Adverse Event
Removal of harware ankle surgery*	13 Mar 2021 (Study Day 213) - 13 Mar 2021 (Study Day 213)	Adverse Event
Mri left foot with and without contrast.*	14 Mar 2021 (Study Day 214) - 14 Mar 2021 (Study Day 214)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tibia Fracture	Grade 3/severe	Not related	25 Sep 2020 (Study Day 44) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US335-2299 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rash Vesicular/Disseminated Vesicular Reaction	SAE	Grade 4	Not related	08 Nov 2020 (Study Day 69) – 13 Nov 2020 (Study Day 74)	Recovered/resolved
Hepatic Enzyme Increased/Elevated Liver Transaminase Level	SAE	Grade 3/severe	Not related	11 Nov 2020 (Study Day 72) – 13 Nov 2020 (Study Day 74)	Recovered/resolved
Rash/Generalized Rash Skin Eruption	SAE	Grade 3/severe	Not related	11 Nov 2020 (Study Day 72) – 15 Dec 2020 (Study Day 106)	Recovered/resolved
Pulmonary Embolism/Bilateral Pulmonary Embolism	SAE	Grade 4	Not related	29 Nov 2020 (Study Day 90) – 01 Dec 2020 (Study Day 92)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2299, a 48-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of rash vesicular. Action taken with the IP was not applicable. The event of disseminated vesicular reaction lasted for 6 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 74). The investigator assessed the event of rash vesicular to be not related to the IP.

On 11 Nov 2020 (Study Day 72), 71 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hepatic enzyme increased. Action taken with the IP was not applicable. The event of elevated liver transaminase level lasted for 3 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 74). The investigator assessed the event of hepatic enzyme increased to be not related to the IP.

On 11 Nov 2020 (Study Day 72), 71 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of rash. Action taken with the IP was not applicable. The event of generalized rash skin eruption lasted for 35 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 106). The investigator assessed the event of rash to be not related to the IP.

On 29 Nov 2020 (Study Day 90), 89 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of bilateral pulmonary embolism lasted for 3 days, after which it was considered to be recovered/resolved on 01 Dec 2020 (Study Day 92). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000753	Rash vesicular
MOD-2020-000753	Hepatic enzyme increased
MOD-2020-000753	Rash
MOD-2020-001065	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Astigmatism	Astigmatism	1986 - Ongoing
Hypermetropia	Hyperopia	1986 - Ongoing
Myopia	Myopia	1986 - Ongoing
Fracture treatment	Surgery - right tibia fracture repair	1998 - 1998
Keratomileusis	Surgery - bilateral lasik	1998 - 1998
Shoulder operation	Left shoulder internal fixation duet dislocation	1998 - 1998
Shoulder operation	Surgery - left shoulder dislocated (fixation)	1998 - 1998
Tibia fracture	Right tibia fracture	1998 - 1998
Bradycardia	Bradycardia	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Arthroscopy	Surgery - left knee arthroscopy	2008 - 2008
Meniscus injury	Left knee meniscus lesion	2008 - 2008
Nephrolithiasis	Kidney stones	2012 - 2012
Vasectomy	Surgery - vasectomy	2014 - 2014

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pulmonary embolism	Pulmonary embolism	2018 - 2018
Nephrolithiasis	Kidney stones	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	2005 - Ongoing	Hypothyroidism
Famotidine	11 Nov 2020 (Study Day 72) - 13 Nov 2020 (Study Day 74)	Gastric Prophylaxis
Hydromorphone	11 Nov 2020 (Study Day 72) - 11 Nov 2020 (Study Day 72)	Generalized Rash Skin Eruption
Hydromorphone hydrochloride	11 Nov 2020 (Study Day 72) - 13 Nov 2020 (Study Day 74)	Generalized Rash Skin Eruption
Loratadine	11 Nov 2020 (Study Day 72) - 13 Nov 2020 (Study Day 74)	Generalized Rask Skin Eruption
Ondansetron	11 Nov 2020 (Study Day 72) - 11 Nov 2020 (Study Day 72)	Generalized Rash Skin Eruption
Other dermatologicals	11 Nov 2020 (Study Day 72) - 13 Nov 2020 (Study Day 74)	Generalized Rash Skin Eruption
Paracetamol	11 Nov 2020 (Study Day 72) - 11 Nov 2020 (Study Day 72)	Generalized Rash Skin Eruption
Prednisone	11 Nov 2020 (Study Day 72) - 12 Nov 2020 (Study Day 73)	Generalized Rash Skin Eruption
Punch biopsy*	11 Nov 2020 (Study Day 72) - 11 Nov 2020 (Study Day 72)	Adverse Event
Sodium chloride	11 Nov 2020 (Study Day 72) - 12 Nov 2020 (Study Day 73)	Generalized Rash Skin Eruption
Triamcinolone	11 Nov 2020 (Study Day 72) - 13 Nov 2020 (Study Day 74)	Generalized Rash Skin Eruption
Valaciclovir hydrochloride	11 Nov 2020 (Study Day 72) - 15 Nov 2020 (Study Day 76)	Genralized Rash Skin Eruption
Skin biopsy*	12 Nov 2020 (Study Day 73) - 12 Nov 2020 (Study Day 73)	Adverse Event
Betamethasone	13 Nov 2020 (Study Day 74) - 15 Dec 2020 (Study Day 106)	Generalized Rask Skin Eruption
Prednisone	13 Nov 2020 (Study Day 74) - 15 Nov 2020 (Study Day 76)	Generalized Rash Skin Eruption
Skin biopsy right arm*	13 Nov 2020 (Study Day 74) - 13 Nov 2020 (Study Day 74)	Adverse Event
Prednisone	16 Nov 2020 (Study Day 77) - 18 Nov 2020 (Study Day 79)	Generalized Rash Skin Eruption
Prednisone	19 Nov 2020 (Study Day 80) - 20 Nov 2020 (Study Day 81)	Generalized Rash Skin Eruption
Prednisone	21 Nov 2020 (Study Day 82) - Ongoing	Generalized Rash Skin Eruption.

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	29 Nov 2020 (Study Day 90) - 29 Nov 2020 (Study Day 90)	Pneumonia
Ceftriaxone	29 Nov 2020 (Study Day 90) - 29 Nov 2020 (Study Day 90)	Pneumonia
Chest ct with contrast*	29 Nov 2020 (Study Day 90) - 29 Nov 2020 (Study Day 90)	Adverse Event
Chest x ray 2 views*	29 Nov 2020 (Study Day 90) - 29 Nov 2020 (Study Day 90)	Adverse Event
Iopamidol	29 Nov 2020 (Study Day 90) - 29 Nov 2020 (Study Day 90)	Bilateral Pulmonary Embolism
Morphine	29 Nov 2020 (Study Day 90) - 30 Nov 2020 (Study Day 91)	Pulmonary Embolism
Rivaroxaban	29 Nov 2020 (Study Day 90) - 15 Dec 2020 (Study Day 106)	Pulmonay Embolism
Echo doppler*	30 Nov 2020 (Study Day 91) - 30 Nov 2020 (Study Day 91)	Adverse Event
Ekg*	30 Nov 2020 (Study Day 91) - 30 Nov 2020 (Study Day 91)	Adverse Event
Glucose	30 Nov 2020 (Study Day 91) - 30 Nov 2020 (Study Day 91)	Bilateral Pulmonary Embolism
Glucose	30 Nov 2020 (Study Day 91) - 01 Dec 2020 (Study Day 92)	Bilateral Pulmonary Embolism
Heparin	30 Nov 2020 (Study Day 91) - 30 Nov 2020 (Study Day 91)	Bilateral Pulmonary Embolism
Heparin	30 Nov 2020 (Study Day 91) - 01 Dec 2020 (Study Day 92)	Bilateral Pulmonary Embolism
Methylprednisolone	01 Dec 2020 (Study Day 92) - 01 Dec 2020 (Study Day 92)	Bilateral Pulmonary Embolism
Omeprazole	01 Dec 2020 (Study Day 92) - 03 Dec 2020 (Study Day 94)	Gastroesophageal Reflux Disease,
Venous doppler bilateral lower extremeties*	01 Dec 2020 (Study Day 92) - 01 Dec 2020 (Study Day 92)	Adverse Event
Methylprednisolone	02 Dec 2020 (Study Day 93) - 02 Dec 2020 (Study Day 93)	Bilateral Pulmonary Embolism
Methylprednisolone	03 Dec 2020 (Study Day 94) - 03 Dec 2020 (Study Day 94)	Bilateral Pulmonary Embolism
Methylprednisolone	04 Dec 2020 (Study Day 95) - 04 Dec 2020 (Study Day 95)	Bilateral Pulmonary Embolism
Methylprednisolone	05 Dec 2020 (Study Day 96) - 05 Dec 2020 (Study Day 96)	Bilateral Pulmonary Embolism
Methylprednisolone	06 Dec 2020 (Study Day 97) - 06 Dec 2020 (Study Day 97)	Bilateral Pulmonary Embolism
Rivaroxaban	16 Dec 2020 (Study Day 107) - Ongoing	Pulmonary Embolism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pneumonia	Grade 1/mild	Not related	29 Nov 2020 (Study Day 90) - 01 Dec 2020 (Study Day 92)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378865

Participant Number:	US335-2424 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	27 Oct 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Worsening Of Hypertension	SAE	Grade 4	Not related	05 Oct 2020 (Study Day 12) – 18 Oct 2020 (Study Day 25)	Recovered/ resolved
Sinus Tachycardia/Sinus Tachycardia	SAE	Grade 4	Not related	05 Oct 2020 (Study Day 12) – 18 Oct 2020 (Study Day 25)	Recovered/ resolved
Hypokalaemia/ Hypokalemia	SAE	Grade 4	Not related	17 Oct 2020 (Study Day 24) – 18 Oct 2020 (Study Day 25)	Recovered/ resolved
Hyponatraemia/ Hyponatremia	SAE	Grade 4	Not related	17 Oct 2020 (Study Day 24) – 18 Oct 2020 (Study Day 25)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2424, a 53-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 24 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 27 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Oct 2020 (Study Day 12), 11 days after the first dose and 22 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hypertension. The IP dose was not changed due to the worsening of hypertension. The event of worsening of hypertension lasted for 14 days, after which it was considered to be recovered/resolved on 18 Oct 2020 (Study Day 25). The investigator assessed the event of hypertension to be not related to the IP.

On 05 Oct 2020 (Study Day 12), 11 days after the first dose and 22 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of sinus tachycardia. The IP dose was not changed due to the sinus tachycardia. The event of sinus tachycardia lasted for 14 days, after which it was considered to be recovered/resolved on 18 Oct 2020 (Study Day 25). The investigator assessed the event of sinus tachycardia to be not related to the IP.

On 17 Oct 2020 (Study Day 24), 23 days after the first dose and 10 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hypokalaemia. The IP dose was not changed due to the hypokalemia. The event of hypokalemia lasted for 2 days, after

which it was considered to be recovered/resolved on 18 Oct 2020 (Study Day 25). The investigator assessed the event of hypokalaemia to be not related to the IP.

On 17 Oct 2020 (Study Day 24), 23 days after the first dose and 10 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hyponatraemia. The IP dose was not changed due to the hyponatremia. The event of hyponatremia lasted for 2 days, after which it was considered to be recovered/resolved on 18 Oct 2020 (Study Day 25). The investigator assessed the event of hyponatraemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000514	Sinus tachycardia
MOD-2020-000514	Hypertension
MOD-2020-000514	Hypokalaemia
MOD-2020-000514	Hyponatraemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Myopia	1973 - Ongoing
Keratomileusis	Surgery - lasik (bilateral)	2009 - 2009
Anxiety	Anxiety	2010 - Ongoing
Bipolar disorder	Bipolar	2010 - Ongoing
Depression	Depression	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	23 Sep 2020 (Study Day -1) - Ongoing
Hypertension	Hypertension	23 Sep 2020 (Study Day -1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Quetiapine fumarate	2010 - Ongoing	Depression
Valproate semisodium	2015 - Ongoing	Bipolar
Acetylsalicylic acid	05 Oct 2020 (Study Day 12) - Ongoing	Cardiovascular Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chlortalidone	05 Oct 2020 (Study Day 12) - 17 Oct 2020 (Study Day 24)	Hypertension
Ezetimibe; simvastatin	05 Oct 2020 (Study Day 12) - Ongoing	Hyperlipidemia
Gemfibrozil	05 Oct 2020 (Study Day 12) - Ongoing	Hyperlipidemia
Losartan potassium	05 Oct 2020 (Study Day 12) - 18 Oct 2020 (Study Day 25)	Hypertesion
Losartan potassium	05 Oct 2020 (Study Day 12) - 18 Oct 2020 (Study Day 25)	Sinus Tachycardia
Omeprazole	05 Oct 2020 (Study Day 12) - Ongoing	Gastro Reflux Prevention
Terazosin	13 Oct 2020 (Study Day 20) - Ongoing	Hypertension
12-lead ecg*	17 Oct 2020 (Study Day 24) - 17 Oct 2020 (Study Day 24)	Diagnostic
Acetylsalicylic acid	17 Oct 2020 (Study Day 24) - 17 Oct 2020 (Study Day 24)	Hypertension
Chest x-ray*	17 Oct 2020 (Study Day 24) - 17 Oct 2020 (Study Day 24)	Diagnostic
Citric acid; potassium bicarbonate	17 Oct 2020 (Study Day 24) - 17 Oct 2020 (Study Day 24)	Hypokalemia
Safety labs*	17 Oct 2020 (Study Day 24) - 17 Oct 2020 (Study Day 24)	Adverse Event
Sodium chloride	17 Oct 2020 (Study Day 24) - 17 Oct 2020 (Study Day 24)	Hyponatremia
Echocardiogram*	18 Oct 2020 (Study Day 25) - 18 Oct 2020 (Study Day 25)	Diagnostic
Metoprolol	23 Oct 2020 (Study Day 30) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US336-2069 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intestinal Obstruction/Partial Bowel Obstruction -Ileum	SAE	Grade 4	Not related	06 Dec 2020 (Study Day 122) – 11 Dec 2020 (Study Day 127)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2069, a 63-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Dec 2020 (Study Day 122), 121 days after the first dose and 93 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of intestinal obstruction. Action taken with the IP was not applicable. The event of partial bowel obstruction -ileum lasted for 6 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 127). The investigator assessed the event of intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001081	Intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Basal cell carcinoma	Basal cell of the scalp	2000 - 2000
Gout	Gout- multiple locations	2010 - Ongoing
Constipation	Constipation	2014 - Ongoing
Insomnia	Insomnia	2014 - Ongoing
Pericardial excision	Pericardectomy	2014 - 2014
Pericarditis	Pericarditis	2014 - 2014
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Back pain	Lower back pain	2017 - Ongoing
Hypogonadism	Hypogonadism	2017 - Ongoing
Appendicectomy	Appendectomy	2018 - 2018
Skin neoplasm excision	Right cheek excision of melanoma	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	2010 - Ongoing	General Gout
Rhamnus purshiana	2014 - Ongoing	Constipation
Zolpidem tartrate	2014 - 26 Mar 2021 (Study Day 232)	Insomnia
Lisinopril	2015 - Ongoing	Hypertension
Simvastatin	2015 - Ongoing	Hyperlipidemia
Ibuprofen	2017 - Ongoing	Lower Back Pain
Testosterone	2017 - Ongoing	Hypogonadism
Ibuprofen	04 Sep 2020 (Study Day 29) - 04 Sep 2020 (Study Day 29)	Reaction (E-Diary Day 1 And 2) To Treat Pain/Fever
Mohs surgery for basal cell carcinoma*	16 Dec 2020 (Study Day 132) - 16 Dec 2020 (Study Day 132)	Medical History
Amoxicillin	21 Jan 2021 (Study Day 168) - 26 Jan 2021 (Study Day 173)	Tooth Implant
Dental implant*	22 Jan 2021 (Study Day 169) - 22 Jan 2021 (Study Day 169)	Adverse Event
Eszopiclone	26 Mar 2021 (Study Day 232) - Ongoing	Insomnia
Lifitegrast	26 Mar 2021 (Study Day 232) - Ongoing	Dry Eyes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Poor Dental Condition	Grade 2/moderate	Not related	22 Jan 2021 (Study Day 169) - 26 Jan 2021 (Study Day 173)
Dry Eye	Grade 2/moderate	Not related	26 Mar 2021 (Study Day 232) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378871

Participant Number:	US340-2332 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 35)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	27 Nov 2020 (Study Day 108) – 03 Dec 2020 (Study Day 114)	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US340-2332, a 39-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 27 Nov 2020 (Study Day 108), 107 days after the first dose and 73 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 35, 15 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 03 Dec 2020 (Study Day 114), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
27 Nov 2020 (Study Day 108)	Muscle Aches (Myalgia)	Mild
27 Nov 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Mild
28 Nov 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 110)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 111)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 114)	Difficulty Breathing	Mild
03 Dec 2020 (Study Day 114)	Fatigue	Mild
03 Dec 2020 (Study Day 114)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 114)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 114)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
03 Dec 2020 (Study Day 114)	Heart Rate	135 beats/min
03 Dec 2020 - 03 Dec 2020 (Study Day 114-114)	Heart Rate ≥125 per Minute	Yes

Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001050	COVID-19

Study Completion/Discontinuation

On 03 Dec 2020 (Study Day 114), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Lower back pain	1990 - Ongoing
Carpal tunnel syndrome	Bilateral carpal tunnel	2000 - Ongoing
Drug hypersensitivity	Allergy to penicillan	2000 - Ongoing
Drug hypersensitivity	Allergy to ciproflaxin	2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	13 Aug 2020 (Study Day 2) - 22 Aug 2020 (Study Day 11)
COVID-19	Grade 2/moderate	Not related	27 Nov 2020 (Study Day 108) - 03 Dec 2020 (Study Day 114)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2012 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	26 Aug 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID - 19	COVID-19	Grade 1/mild	Not related	25 Dec 2020 (Study Day 150) – 19 Jan 2021 (Study Day 175)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US341-2012, a 46-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 26 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 25 Dec 2020 (Study Day 150), 149 days after the first dose and 121 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 26 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Dec 2020 (Study Day 153), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
25 Dec 2020 (Study Day 150)	Cough	Mild
25 Dec 2020 (Study Day 150)	Fatigue	Mild
28 Dec 2020 (Study Day 153)	Body Aches	Mild

Symptom Date	Symptom	Result
28 Dec 2020 (Study Day 153)	Chills	Mild
28 Dec 2020 (Study Day 153)	Cough	Mild
28 Dec 2020 (Study Day 153)	Difficulty Breathing	Mild
28 Dec 2020 (Study Day 153)	Fatigue	Moderate
28 Dec 2020 (Study Day 153)	Muscle Aches (Myalgia)	Mild
28 Dec 2020 (Study Day 153)	Nasal Congestion	Moderate
28 Dec 2020 (Study Day 153)	New Loss of Smell	Moderate
28 Dec 2020 (Study Day 153)	New Loss of Taste	Moderate
28 Dec 2020 (Study Day 153)	Runny Nose (Rhinorrhea)	Moderate
28 Dec 2020 (Study Day 153)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 154)	Cough	Mild
29 Dec 2020 (Study Day 154)	Difficulty Breathing	Mild
29 Dec 2020 (Study Day 154)	Fatigue	Moderate
29 Dec 2020 (Study Day 154)	Headache	Mild
29 Dec 2020 (Study Day 154)	Nasal Congestion	Moderate
29 Dec 2020 (Study Day 154)	New Loss of Smell	Moderate
29 Dec 2020 (Study Day 154)	New Loss of Taste	Moderate
29 Dec 2020 (Study Day 154)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 155)	Cough	Mild
30 Dec 2020 (Study Day 155)	Difficulty Breathing	Mild
30 Dec 2020 (Study Day 155)	Fatigue	Moderate
30 Dec 2020 (Study Day 155)	Nasal Congestion	Moderate
30 Dec 2020 (Study Day 155)	Nausea	Mild
30 Dec 2020 (Study Day 155)	New Loss of Smell	Severe
30 Dec 2020 (Study Day 155)	New Loss of Taste	Severe
30 Dec 2020 (Study Day 155)	Shortness of Breath	Mild
31 Dec 2020 (Study Day 156)	Cough	Mild
31 Dec 2020 (Study Day 156)	Difficulty Breathing	Mild
31 Dec 2020 (Study Day 156)	Fatigue	Moderate
31 Dec 2020 (Study Day 156)	Nasal Congestion	Moderate
31 Dec 2020 (Study Day 156)	Nausea	Mild
31 Dec 2020 (Study Day 156)	New Loss of Smell	Severe
31 Dec 2020 (Study Day 156)	New Loss of Taste	Severe
31 Dec 2020 (Study Day 156)	Runny Nose (Rhinorrhea)	Moderate
31 Dec 2020 (Study Day 156)	Shortness of Breath	Mild
31 Dec 2020 (Study Day 156)	Vomiting	Mild
01 Jan 2021 (Study Day 157)	Cough	Mild
01 Jan 2021 (Study Day 157)	Difficulty Breathing	Mild
01 Jan 2021 (Study Day 157)	Fatigue	Mild
01 Jan 2021 (Study Day 157)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 157)	New Loss of Smell	Mild
01 Jan 2021 (Study Day 157)	New Loss of Taste	Mild
01 Jan 2021 (Study Day 157)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 158)	Cough	Mild
02 Jan 2021 (Study Day 158)	Difficulty Breathing	Mild
02 Jan 2021 (Study Day 158)	Fatigue	Mild
02 Jan 2021 (Study Day 158)	New Loss of Smell	Mild
02 Jan 2021 (Study Day 158)	New Loss of Taste	Mild
02 Jan 2021 (Study Day 158)	Shortness of Breath	Mild
03 Jan 2021 (Study Day 159)	Diarrhea	Mild
03 Jan 2021 (Study Day 159)	Difficulty Breathing	Mild
03 Jan 2021 (Study Day 159)	Fatigue	Mild
03 Jan 2021 (Study Day 159)	New Loss of Taste	Mild
03 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 160)	Fatigue	Mild
04 Jan 2021 (Study Day 160)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 161)	Fatigue	Mild
06 Jan 2021 (Study Day 162)	Difficulty Breathing	Mild
06 Jan 2021 (Study Day 162)	Fatigue	Mild
06 Jan 2021 (Study Day 162)	O2 Saturation (%)	92
06 Jan 2021 (Study Day 162)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 163)	Difficulty Breathing	Mild
07 Jan 2021 (Study Day 163)	Fatigue	Mild
07 Jan 2021 (Study Day 163)	New Loss of Smell	Moderate
07 Jan 2021 (Study Day 163)	New Loss of Taste	Moderate
07 Jan 2021 (Study Day 163)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 164)	Difficulty Breathing	Mild
08 Jan 2021 (Study Day 164)	Fatigue	Moderate
08 Jan 2021 (Study Day 164)	Headache	Mild
08 Jan 2021 (Study Day 164)	New Loss of Smell	Moderate
08 Jan 2021 (Study Day 164)	New Loss of Taste	Moderate
08 Jan 2021 (Study Day 164)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 165)	Difficulty Breathing	Mild
09 Jan 2021 (Study Day 165)	New Loss of Smell	Mild
09 Jan 2021 (Study Day 165)	New Loss of Taste	Mild
09 Jan 2021 (Study Day 165)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 166)	Difficulty Breathing	Mild
10 Jan 2021 (Study Day 166)	New Loss of Smell	Mild
10 Jan 2021 (Study Day 166)	New Loss of Taste	Mild
10 Jan 2021 (Study Day 166)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 167)	Difficulty Breathing	Mild
11 Jan 2021 (Study Day 167)	New Loss of Smell	Mild
11 Jan 2021 (Study Day 167)	New Loss of Taste	Mild
11 Jan 2021 (Study Day 167)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 168)	Difficulty Breathing	Mild
12 Jan 2021 (Study Day 168)	Fatigue	Moderate

Symptom Date	Symptom	Result
12 Jan 2021 (Study Day 168)	New Loss of Smell	Mild
12 Jan 2021 (Study Day 168)	New Loss of Taste	Mild
12 Jan 2021 (Study Day 168)	Shortness of Breath	Mild
13 Jan 2021 (Study Day 169)	Difficulty Breathing	Mild
13 Jan 2021 (Study Day 169)	Fatigue	Moderate
13 Jan 2021 (Study Day 169)	Nausea	Moderate
13 Jan 2021 (Study Day 169)	Shortness of Breath	Mild
14 Jan 2021 (Study Day 170)	New Loss of Smell	Mild
14 Jan 2021 (Study Day 170)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 171)	Fatigue	Moderate
16 Jan 2021 (Study Day 172)	Fatigue	Moderate
18 Jan 2021 (Study Day 174)	O2 Saturation (%)	91
18 Jan 2021 (Study Day 174)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
06 Jan 2021 (Study Day 162)	Oxygen Saturation	91%
06 Jan 2021 - 18 Jan 2021 (Study Day 162-174)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID - 19 lasted for 26 days, after which it was considered to be recovered/resolved on 19 Jan 2021 (Study Day 175). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002026	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hepatitis A	Hepatitis a	1986 - 1986
Endometriosis	Endometriosis	1990 - 2016

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug use disorder	Opiod use disorder remission	2007 - Ongoing
Nausea	Nausea associated with meds	2007 - Ongoing
Anxiety	Anxiety	2010 - 2016
Depression	Depression	2010 - 2016
Anaemia	Anemia	2017 - 2017
Oedema peripheral	Chronic swelling lower extremities non pitting edema	2017 - Ongoing
Obesity	Obesity	29 Jul 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Buprenorphine hydrochloride; naloxone hydrochloride	2007 - Ongoing	Opioid Abuse Remission
Botulinum toxin type a	2018 - 2018	Cosmetic
Bumetanide	2018 - Ongoing	Lower Extremity Edema
Probiotics nos	01 Jan 2019 (Study Day -575) - Ongoing	General Health
Vitamins nos	01 Jan 2019 (Study Day -575) - Ongoing	General Health
Ondansetron	01 Feb 2020 (Study Day -179) - Ongoing	Nausea
Biotin	01 Apr 2020 (Study Day -119) - Ongoing	General Health
Ibuprofen	01 Aug 2020 (Study Day 4) - 01 Aug 2020 (Study Day 4)	Myalgias, Arthalgias Generalized (Solicited)
Ibuprofen	01 Aug 2020 (Study Day 4) - 01 Aug 2020 (Study Day 4)	Solicited Myalgia, Arthralgias
Metformin	20 Nov 2020 (Study Day 115) - Ongoing	Obesity / Weight Loss / Border Line Diabetic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Breast Pain	Grade 1/mild	Not related	01 Aug 2020 (Study Day 4) - 05 Aug 2020 (Study Day 8)
Glucose Tolerance Impaired	Grade 1/mild	Not related	30 Nov 2020 (Study Day 125) - Ongoing
COVID-19	Grade 1/mild	Not related	25 Dec 2020 (Study Day 150) - 19 Jan 2021 (Study Day 175)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2208 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	06 Dec 2020 (Study Day 118) – 23 Dec 2020 (Study Day 135)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US341-2208, a 75-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 06 Dec 2020 (Study Day 118), 117 days after the first dose and 89 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 10 Dec 2020 (Study Day 122), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
06 Dec 2020 (Study Day 118)	Body Aches	Mild
06 Dec 2020 (Study Day 118)	Cough	Mild
06 Dec 2020 (Study Day 118)	Fatigue	Moderate

Symptom Date	Symptom	Result
06 Dec 2020 (Study Day 118)	Nausea	Mild
06 Dec 2020 (Study Day 118)	New Loss of Smell	Moderate
06 Dec 2020 (Study Day 118)	New Loss of Taste	Moderate
06 Dec 2020 (Study Day 118)	Runny Nose (Rhinorrhea)	Moderate
07 Dec 2020 (Study Day 119)	Body Aches	Mild
07 Dec 2020 (Study Day 119)	Cough	Mild
07 Dec 2020 (Study Day 119)	Fatigue	Moderate
07 Dec 2020 (Study Day 119)	Nausea	Mild
07 Dec 2020 (Study Day 119)	New Loss of Smell	Moderate
07 Dec 2020 (Study Day 119)	New Loss of Taste	Moderate
07 Dec 2020 (Study Day 119)	Runny Nose (Rhinorrhea)	Moderate
08 Dec 2020 (Study Day 120)	Body Aches	Mild
08 Dec 2020 (Study Day 120)	Cough	Mild
08 Dec 2020 (Study Day 120)	Fatigue	Moderate
08 Dec 2020 (Study Day 120)	Nausea	Mild
08 Dec 2020 (Study Day 120)	New Loss of Smell	Moderate
08 Dec 2020 (Study Day 120)	New Loss of Taste	Moderate
08 Dec 2020 (Study Day 120)	Runny Nose (Rhinorrhea)	Moderate
09 Dec 2020 (Study Day 121)	Body Aches	Mild
09 Dec 2020 (Study Day 121)	Cough	Mild
09 Dec 2020 (Study Day 121)	Fatigue	Moderate
09 Dec 2020 (Study Day 121)	Nausea	Mild
09 Dec 2020 (Study Day 121)	New Loss of Smell	Moderate
09 Dec 2020 (Study Day 121)	New Loss of Taste	Moderate
09 Dec 2020 (Study Day 121)	Runny Nose (Rhinorrhea)	Moderate
10 Dec 2020 (Study Day 122)	Body Aches	Mild
10 Dec 2020 (Study Day 122)	Cough	Mild
10 Dec 2020 (Study Day 122)	Diarrhea	Moderate
10 Dec 2020 (Study Day 122)	Fatigue	Moderate
10 Dec 2020 (Study Day 122)	Headache	Mild
10 Dec 2020 (Study Day 122)	Muscle Aches (Myalgia)	Mild
10 Dec 2020 (Study Day 122)	Nausea	Mild
10 Dec 2020 (Study Day 122)	New Loss of Smell	Moderate
10 Dec 2020 (Study Day 122)	New Loss of Taste	Moderate
10 Dec 2020 (Study Day 122)	Runny Nose (Rhinorrhea)	Moderate
11 Dec 2020 (Study Day 123)	Body Aches	Mild
11 Dec 2020 (Study Day 123)	Cough	Mild
11 Dec 2020 (Study Day 123)	Diarrhea	Mild
11 Dec 2020 (Study Day 123)	Fatigue	Moderate
11 Dec 2020 (Study Day 123)	Headache	Severe
11 Dec 2020 (Study Day 123)	Muscle Aches (Myalgia)	Mild
11 Dec 2020 (Study Day 123)	Nasal Congestion	Moderate
11 Dec 2020 (Study Day 123)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 123)	New Loss of Taste	Mild
11 Dec 2020 (Study Day 123)	Runny Nose (Rhinorrhea)	Moderate
12 Dec 2020 (Study Day 124)	Body Aches	Mild
12 Dec 2020 (Study Day 124)	Cough	Mild
12 Dec 2020 (Study Day 124)	Fatigue	Mild
12 Dec 2020 (Study Day 124)	Muscle Aches (Myalgia)	Mild
12 Dec 2020 (Study Day 124)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
13 Dec 2020 (Study Day 125)	Body Aches	Mild
13 Dec 2020 (Study Day 125)	Cough	Mild
13 Dec 2020 (Study Day 125)	Diarrhea	Moderate
13 Dec 2020 (Study Day 125)	Fatigue	Mild
13 Dec 2020 (Study Day 125)	Muscle Aches (Myalgia)	Mild
13 Dec 2020 (Study Day 125)	O2 Saturation (%)	90
13 Dec 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
14 Dec 2020 (Study Day 126)	Body Aches	Mild
14 Dec 2020 (Study Day 126)	Fatigue	Mild
14 Dec 2020 (Study Day 126)	Muscle Aches (Myalgia)	Mild
14 Dec 2020 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
15 Dec 2020 (Study Day 127)	Body Aches	Mild
15 Dec 2020 (Study Day 127)	Cough	Mild
15 Dec 2020 (Study Day 127)	Fatigue	Mild
15 Dec 2020 (Study Day 127)	Headache	Moderate
15 Dec 2020 (Study Day 127)	Muscle Aches (Myalgia)	Mild
15 Dec 2020 (Study Day 127)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 127)	New Loss of Smell	Mild
15 Dec 2020 (Study Day 127)	New Loss of Taste	Mild
16 Dec 2020 (Study Day 128)	Fatigue	Mild
16 Dec 2020 (Study Day 128)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 128)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 128)	Nausea	Mild
16 Dec 2020 (Study Day 128)	New Loss of Smell	Mild
16 Dec 2020 (Study Day 128)	New Loss of Taste	Mild
16 Dec 2020 (Study Day 128)	O2 Saturation (%)	93
17 Dec 2020 (Study Day 129)	Body Aches	Mild
17 Dec 2020 (Study Day 129)	Cough	Mild
17 Dec 2020 (Study Day 129)	Fatigue	Mild
17 Dec 2020 (Study Day 129)	Headache	Mild
17 Dec 2020 (Study Day 129)	Muscle Aches (Myalgia)	Mild
17 Dec 2020 (Study Day 129)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 129)	New Loss of Smell	Mild
17 Dec 2020 (Study Day 129)	New Loss of Taste	Mild
18 Dec 2020 (Study Day 130)	Cough	Mild

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 130)	Fatigue	Moderate
18 Dec 2020 (Study Day 130)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 130)	New Loss of Smell	Mild
18 Dec 2020 (Study Day 130)	New Loss of Taste	Mild
18 Dec 2020 (Study Day 130)	Runny Nose (Rhinorrhea)	Mild
19 Dec 2020 (Study Day 131)	Body Aches	Mild
19 Dec 2020 (Study Day 131)	Cough	Mild
19 Dec 2020 (Study Day 131)	Fatigue	Mild
19 Dec 2020 (Study Day 131)	Muscle Aches (Myalgia)	Mild
19 Dec 2020 (Study Day 131)	Nasal Congestion	Mild
19 Dec 2020 (Study Day 131)	New Loss of Smell	Mild
19 Dec 2020 (Study Day 131)	New Loss of Taste	Mild
19 Dec 2020 (Study Day 131)	Runny Nose (Rhinorrhea)	Mild
20 Dec 2020 (Study Day 132)	Fatigue	Mild
21 Dec 2020 (Study Day 133)	Fatigue	Mild
22 Dec 2020 (Study Day 134)	Runny Nose (Rhinorrhea)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
13 Dec 2020 (Study Day 125)	Oxygen Saturation	90%
13 Dec 2020 - 16 Dec 2020 (Study Day 125-128)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 18 days, after which it was considered to be recovered/resolved on 23 Dec 2020 (Study Day 135). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001124	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	Not reported - Ongoing
Seasonal allergy	Allergic rhinitis - seasonal	1950 - Ongoing
Osteoarthritis	Osteoarthritis (right knee)	2002 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2019 - Ongoing
Rash	Rash from mask	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1995 - Ongoing	Headaches For Seasonal Allergies
Colecalciferol	2005 - Ongoing	General Health / Bone Health
Atorvastatin	2010 - Ongoing	Hyperlipidemia
Vitamins nos	2010 - Ongoing	General Health
Meloxicam	2017 - Ongoing	Osteoarthritis Knee
Diclofenac	2018 - Ongoing	Osteoarthritis
Levothyroxine	Dec 2019 - Ongoing	Hypothyroid
Triamcinolone	2020 - Ongoing	Rash From Mask
Paracetamol	07 Jan 2021 (Study Day 150) - Ongoing	Injection Pain Left Shoulder
Melatonin	04 Feb 2021 (Study Day 178) - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Insomnia	Grade 1/mild	Not related	24 Nov 2020 (Study Day 106) - Ongoing
COVID-19	Grade 1/mild	Not related	06 Dec 2020 (Study Day 118) - 23 Dec 2020 (Study Day 135)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2224 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	23 Nov 2020 (Study Day 102) – 08 Dec 2020 (Study Day 117)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US341-2224, a 54-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 23 Nov 2020 (Study Day 102), 101 days after the first dose and 73 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 11 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 25 Nov 2020 (Study Day 104), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
23 Nov 2020 (Study Day 102)	Cough	Mild
23 Nov 2020 (Study Day 102)	Headache	Mild
23 Nov 2020 (Study Day 102)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 103)	Cough	Mild
24 Nov 2020 (Study Day 103)	Headache	Mild

Symptom Date	Symptom	Result
24 Nov 2020 (Study Day 103)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 104)	Cough	Mild
25 Nov 2020 (Study Day 104)	Headache	Moderate
25 Nov 2020 (Study Day 104)	Nasal Congestion	Moderate
25 Nov 2020 (Study Day 104)	Runny Nose (Rhinorrhea)	Moderate
25 Nov 2020 (Study Day 104)	Sore Throat	Mild
27 Nov 2020 (Study Day 106)	Cough	Moderate
27 Nov 2020 (Study Day 106)	Fatigue	Mild
27 Nov 2020 (Study Day 106)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 106)	New Loss of Smell	Moderate
27 Nov 2020 (Study Day 106)	New Loss of Taste	Moderate
28 Nov 2020 (Study Day 107)	Cough	Moderate
28 Nov 2020 (Study Day 107)	Fatigue	Mild
28 Nov 2020 (Study Day 107)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 107)	New Loss of Smell	Moderate
28 Nov 2020 (Study Day 107)	New Loss of Taste	Moderate
28 Nov 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 108)	Cough	Moderate
29 Nov 2020 (Study Day 108)	Fatigue	Mild
29 Nov 2020 (Study Day 108)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 108)	New Loss of Smell	Moderate
29 Nov 2020 (Study Day 108)	New Loss of Taste	Moderate
30 Nov 2020 (Study Day 109)	Body Aches	Mild
30 Nov 2020 (Study Day 109)	Cough	Mild
30 Nov 2020 (Study Day 109)	Fatigue	Moderate
30 Nov 2020 (Study Day 109)	Headache	Moderate
30 Nov 2020 (Study Day 109)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 109)	New Loss of Smell	Moderate
30 Nov 2020 (Study Day 109)	New Loss of Taste	Moderate
30 Nov 2020 (Study Day 109)	O2 Saturation (%)	93
30 Nov 2020 (Study Day 109)	Sore Throat	Mild
01 Dec 2020 (Study Day 110)	Cough	Moderate
01 Dec 2020 (Study Day 110)	Fatigue	Mild
01 Dec 2020 (Study Day 110)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 110)	New Loss of Smell	Moderate
01 Dec 2020 (Study Day 110)	New Loss of Taste	Moderate
02 Dec 2020 (Study Day 111)	Cough	Mild
02 Dec 2020 (Study Day 111)	Fatigue	Moderate
02 Dec 2020 (Study Day 111)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 112)	Cough	Mild
03 Dec 2020 (Study Day 112)	Fatigue	Mild
03 Dec 2020 (Study Day 112)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 112)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
04 Dec 2020 (Study Day 113)	Cough	Mild
04 Dec 2020 (Study Day 113)	Fatigue	Mild
04 Dec 2020 (Study Day 113)	Nasal Congestion	Mild
04 Dec 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
05 Dec 2020 (Study Day 114)	Cough	Mild
05 Dec 2020 (Study Day 114)	Fatigue	Mild
05 Dec 2020 (Study Day 114)	Runny Nose (Rhinorrhea)	Mild
06 Dec 2020 (Study Day 115)	Cough	Mild
06 Dec 2020 (Study Day 115)	Nasal Congestion	Mild
07 Dec 2020 (Study Day 116)	Cough	Mild
07 Dec 2020 (Study Day 116)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
30 Nov 2020 (Study Day 109)	Oxygen Saturation	93%
30 Nov 2020 - 30 Nov 2020 (Study Day 109-109)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 16 days, after which it was considered to be recovered/resolved on 08 Dec 2020 (Study Day 117). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001386	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Alergic to penicillin	1966 - Ongoing
Drug hypersensitivity	Alergic to sulfa drugs	1966 - Ongoing
Seasonal allergy	Allergic rhinitis - seasonal	1975 - Ongoing
Temporomandibular joint surgery	Tmj surgery	1988 - 1988

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Temporomandibular joint syndrome	Tmj disorder	1988 - 1988
Depression	Depression	1995 - Ongoing
Migraine	Headaches/migraines	2000 - Ongoing
Hysterectomy	Hysterectomy	2004 - 2004
Insomnia	Insomnia	2004 - Ongoing
Postmenopause	Post -menopausal	2004 - Ongoing
Bursitis	Bursitis	2007 - 2007
Shoulder operation	Right shoulder surgery (bursitis)	2007 - 2007
Osteoporosis	Osteoporosis	2008 - Ongoing
Benign tumour excision	Right benign tumor (on carotid) removal	2010 - 2010
Drug hypersensitivity	Alergic to naproxen	2010 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Immune thrombocytopenia	Idiopathic thrombocytopenic purpura (stable)	2010 - Ongoing
Paraganglion neoplasm benign	Benign neoplasm on carotid (right)	2010 - 2010
Diplopia	Bilateral diplopia	2012 - Ongoing
Cholecystitis	Cholecystitis	2014 - 2014
Cholecystitis	Cholecystitis	2014 - 2014
Essential tremor	Essential tremors in bilateral hands and neck	2014 - Ongoing
Overweight	Overweight	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Headaches
Fluoxetine	2004 - Ongoing	Depression
Vitamin d nos	2004 - Ongoing	General Health
Estrogens conjugated	2005 - Ongoing	Hormone Replacement For Hysterectomy
Fexofenadine hydrochloride	2005 - Ongoing	Seasonal Allergies
Fluticasone	2005 - Ongoing	Seasonal Allergies
Ibandronate sodium	2008 - Ongoing	Osteoporosis
Melatonin	2010 - Ongoing	Insomnia
Ranitidine hydrochloride	2010 - 09 Jan 2021 (Study Day 149)	Gastroesophageal Reflux Disease
Rizatriptan benzoate	2010 - Ongoing	Migraines
Baclofen	2012 - Ongoing	Migraines
Magnesium	2012 - Ongoing	General Health
Riboflavin	2012 - Ongoing	Headaches
Ubidecarenone	2012 - Ongoing	General Health

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Propranolol	2015 - Ongoing	Essential Tremors
Sumatriptan	2015 - Ongoing	Migraines
Folic acid	2016 - Ongoing	Headaches
Trazodone	2016 - Ongoing	Insomnia
Acetylsalicylic acid	2018 - Ongoing	General Health
Pyridoxine hydrochloride	2018 - Ongoing	General Health
Ascorbic acid	2019 - Ongoing	General Health
Collagen	2019 - Ongoing	General Health
Phentermine	Jan 2020 - Ongoing	Weight Loss
Galcanezumab	May 2020 - Ongoing	Migraines
Clindamycin	18 Aug 2020 (Study Day 5) - 28 Aug 2020 (Study Day 15)	Infection - Right Index Finger
Influenza vaccine	25 Sep 2020 (Study Day 43) - 25 Sep 2020 (Study Day 43)	Influenza Prophylaxis
Pseudoephedrine hydrochloride	23 Nov 2020 (Study Day 102) - 28 Nov 2020 (Study Day 107)	Uri / COVID-19
Meclozine	05 Jan 2021 (Study Day 145) - 07 Jan 2021 (Study Day 147)	Vertigo
Famotidine	10 Jan 2021 (Study Day 150) - Ongoing	Gerd
Atomoxetine hydrochloride	08 Mar 2021 (Study Day 207) - Ongoing	Attention Deficit Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Localised Infection	Grade 2/moderate	Not related	17 Aug 2020 (Study Day 4) - 08 Oct 2020 (Study Day 56)
COVID-19	Grade 1/mild	Not related	23 Nov 2020 (Study Day 102) - 08 Dec 2020 (Study Day 117)
Vertigo	Grade 1/mild	Not related	05 Jan 2021 (Study Day 145) - 07 Jan 2021 (Study Day 147)
Attention Deficit Hyperactivity Disorder	Grade 1/mild	Not related	18 Mar 2021 (Study Day 217) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2259 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 36)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	03 Nov 2020 (Study Day 79) – 17 Nov 2020 (Study Day 93)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US341-2259, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 03 Nov 2020 (Study Day 79), 78 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 36, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 09 Nov 2020 (Study Day 85), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
03 Nov 2020 (Study Day 79)	Sore Throat	Mild
04 Nov 2020 (Study Day 80)	Sore Throat	Mild
05 Nov 2020 (Study Day 81)	Body Aches	Mild

Symptom Date	Symptom	Result
05 Nov 2020 (Study Day 81)	Nasal Congestion	Mild
05 Nov 2020 (Study Day 81)	Runny Nose (Rhinorrhea)	Mild
06 Nov 2020 (Study Day 82)	Nasal Congestion	Mild
06 Nov 2020 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
07 Nov 2020 (Study Day 83)	Nasal Congestion	Mild
07 Nov 2020 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
08 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
08 Nov 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
09 Nov 2020 (Study Day 85)	Body Aches	Moderate
09 Nov 2020 (Study Day 85)	Cough	Mild
09 Nov 2020 (Study Day 85)	Fatigue	Mild
09 Nov 2020 (Study Day 85)	Muscle Aches (Myalgia)	Moderate
09 Nov 2020 (Study Day 85)	Nasal Congestion	Moderate
09 Nov 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Moderate
09 Nov 2020 (Study Day 85)	Sore Throat	Mild
10 Nov 2020 (Study Day 86)	Cough	Mild
11 Nov 2020 (Study Day 87)	Fatigue	Mild
11 Nov 2020 (Study Day 87)	O2 Saturation (%)	93
11 Nov 2020 (Study Day 87)	Runny Nose (Rhinorrhea)	Mild
12 Nov 2020 (Study Day 88)	Fatigue	Mild
12 Nov 2020 (Study Day 88)	O2 Saturation (%)	91
13 Nov 2020 (Study Day 89)	Fatigue	Mild
13 Nov 2020 (Study Day 89)	Headache	Moderate
13 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 90)	Fatigue	Mild
14 Nov 2020 (Study Day 90)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 90)	Runny Nose (Rhinorrhea)	Mild
15 Nov 2020 (Study Day 91)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 91)	Runny Nose (Rhinorrhea)	Mild
16 Nov 2020 (Study Day 92)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 92)	Runny Nose (Rhinorrhea)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
11 Nov 2020 (Study Day 87)	Oxygen Saturation	91%
11 Nov 2020 - 12 Nov 2020 (Study Day 87-88)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 93). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000848	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Headahce migraine	1963 - Ongoing
Ovarian cancer	Cancer history (ovarian)	2002 - 2003
Hysterectomy	Hysterectomy	2003 - 2003
Osteoarthritis	Osteoarthritis right shoulder	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid; caffeine; paracetamol	1988 - Ongoing	Migrain
Sumatriptan	2010 - Ongoing	Migraine
Celecoxib	12 Jan 2020 (Study Day -218) - Ongoing	Oa-Shoulder Pain
Influenza vaccine	08 Oct 2020 (Study Day 53) - 08 Oct 2020 (Study Day 53)	General Health
Pseudoephedrine hydrochloride	08 Nov 2020 (Study Day 84) - 09 Nov 2020 (Study Day 85)	Symptomatic COVID-19 - Runny Nose And Congestion
Methylprednisolone	05 Dec 2020 (Study Day 111) - 05 Dec 2020 (Study Day 111)	Right Shoulder Pain
Pneumococcal vaccine polysacch 23v	05 Dec 2020 (Study Day 111) - 05 Dec 2020 (Study Day 111)	Pneumonia Prophylaxis
Terbinafine hydrochloride	02 Mar 2021 (Study Day 198) - Ongoing	Onychomycosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	03 Nov 2020 (Study Day 79) - 17 Nov 2020 (Study Day 93)
Onychomycosis	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 198) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2300 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID -19	COVID-19	Grade 1/mild	Not related	02 Nov 2020 (Study Day 71) – 04 Nov 2020 (Study Day 73)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US341-2300, a 59-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 02 Nov 2020 (Study Day 71), 70 days after the first dose and 42 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID -19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 04 Nov 2020 (Study Day 73), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
02 Nov 2020 (Study Day 71)	Cough	Mild
02 Nov 2020 (Study Day 71)	Headache	Mild
02 Nov 2020 (Study Day 71)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
02 Nov 2020 (Study Day 71)	Runny Nose (Rhinorrhea)	Mild
10 Nov 2020 (Study Day 79)	O2 Saturation (%)	85

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
10 Nov 2020 (Study Day 79)	Oxygen Saturation	85%
10 Nov 2020 - 10 Nov 2020 (Study Day 79-79)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID -19 lasted for 3 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 73). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000719	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	2010 - Ongoing
Drug hypersensitivity	Allergic - medications - tetrarycline and doxicycline	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	07 Dec 2020 (Study Day 106) - 07 Dec 2020 (Study Day 106)	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	02 Nov 2020 (Study Day 71) - 04 Nov 2020 (Study Day 73)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378896

Participant Number:	US341-2304 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	03 Nov 2020 (Study Day 72) – 28 Nov 2020 (Study Day 97)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US341-2304, a 70-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 03 Nov 2020 (Study Day 72), 71 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 05 Nov 2020 (Study Day 74), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
05 Nov 2020 (Study Day 74)	Body Aches	Mild
05 Nov 2020 (Study Day 74)	Cough	Mild
05 Nov 2020 (Study Day 74)	Fatigue	Mild

Symptom Date	Symptom	Result
05 Nov 2020 (Study Day 74)	Headache	Mild
05 Nov 2020 (Study Day 74)	Muscle Aches (Myalgia)	Mild
06 Nov 2020 (Study Day 75)	Cough	Mild
06 Nov 2020 (Study Day 75)	Fatigue	Mild
06 Nov 2020 (Study Day 75)	Headache	Mild
06 Nov 2020 (Study Day 75)	Nasal Congestion	Moderate
06 Nov 2020 (Study Day 75)	Runny Nose (Rhinorrhea)	Mild
07 Nov 2020 (Study Day 76)	O2 Saturation (%)	92
09 Nov 2020 (Study Day 78)	Cough	Mild
09 Nov 2020 (Study Day 78)	Fatigue	Moderate
09 Nov 2020 (Study Day 78)	Headache	Mild
09 Nov 2020 (Study Day 78)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 79)	Cough	Mild
10 Nov 2020 (Study Day 79)	Fatigue	Mild
10 Nov 2020 (Study Day 79)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 79)	O2 Saturation (%)	92
10 Nov 2020 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild
11 Nov 2020 (Study Day 80)	Cough	Mild
11 Nov 2020 (Study Day 80)	Fatigue	Moderate
11 Nov 2020 (Study Day 80)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 81)	Cough	Mild
12 Nov 2020 (Study Day 81)	Fatigue	Severe
13 Nov 2020 (Study Day 82)	Cough	Severe
13 Nov 2020 (Study Day 82)	Fatigue	Moderate
13 Nov 2020 (Study Day 82)	O2 Saturation (%)	93
13 Nov 2020 (Study Day 82)	Shortness of Breath	Moderate
13 Nov 2020 (Study Day 82)	Temperature (°F)	100.6
14 Nov 2020 (Study Day 83)	Cough	Severe
14 Nov 2020 (Study Day 83)	Fatigue	Severe
14 Nov 2020 (Study Day 83)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
14 Nov 2020 (Study Day 83)	Shortness of Breath	Moderate
14 Nov 2020 (Study Day 83)	Sore Throat	Mild
15 Nov 2020 (Study Day 84)	Cough	Mild
15 Nov 2020 (Study Day 84)	Fatigue	Mild
15 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 84)	O2 Saturation (%)	93
16 Nov 2020 (Study Day 85)	Cough	Mild
16 Nov 2020 (Study Day 85)	Fatigue	Mild
16 Nov 2020 (Study Day 85)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 85)	O2 Saturation (%)	93
17 Nov 2020 (Study Day 86)	Fatigue	Mild
17 Nov 2020 (Study Day 86)	O2 Saturation (%)	93

Symptom Date	Symptom	Result
18 Nov 2020 (Study Day 87)	Fatigue	Mild
18 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 88)	Fatigue	Mild
19 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 88)	O2 Saturation (%)	93
20 Nov 2020 (Study Day 89)	Fatigue	Mild
20 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 90)	Cough	Mild
21 Nov 2020 (Study Day 90)	Fatigue	Mild
21 Nov 2020 (Study Day 90)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 90)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 91)	Fatigue	Mild
22 Nov 2020 (Study Day 91)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 92)	Fatigue	Mild
23 Nov 2020 (Study Day 92)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 93)	Fatigue	Mild
24 Nov 2020 (Study Day 93)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 94)	Fatigue	Mild
25 Nov 2020 (Study Day 94)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 95)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
07 Nov 2020 (Study Day 76)	Oxygen Saturation	92%
07 Nov 2020 - 19 Nov 2020 (Study Day 76-88)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 26 days, after which it was considered to be recovered/resolved on 28 Nov 2020 (Study Day 97). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000724	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Allergic rhinitis - shrimp	1955 - Ongoing
Type 2 diabetes mellitus	Diabetes - type ii	2000 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Hyperglycaemia	Hyperglycemia	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Osteoarthritis	Osteoarthritis - left foot and lower back	2012 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rosuvastatin calcium	2010 - Ongoing	Hyperlipidemia
Acetylsalicylic acid	2012 - Ongoing	Hypertension
Glibenclamide; metformin	2012 - Ongoing	Hyperglycemia
Glucosamine	2012 - Ongoing	Osteoarthritis - Left Foot And Lower Back
Ramipril	2012 - Ongoing	Hypertension
Omeprazole	2014 - Ongoing	Gerd
Vitamins nos	2014 - Ongoing	General Health
Meloxicam	2015 - Ongoing	Osteoarthritis
Semaglutide	08 Sep 2020 (Study Day 16) - Ongoing	Type Two Diabetes
Influenza vaccine	10 Oct 2020 (Study Day 48) - 10 Oct 2020 (Study Day 48)	Influenza Prophylactic
Dextromethorphan hydrobromide; guaifenesin	13 Nov 2020 (Study Day 82) - 13 Nov 2020 (Study Day 82)	Symptomatic COVID-19
Pseudoephedrine hydrochloride	16 Nov 2020 (Study Day 85) - 20 Nov 2020 (Study Day 89)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	03 Nov 2020 (Study Day 72) - 28 Nov 2020 (Study Day 97)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US344-2096 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 26)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	20 Dec 2020 (Study Day 116) – 30 Jan 2021 (Study Day 157)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US344-2096, a 44-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 20 Dec 2020 (Study Day 116), 115 days after the first dose and 90 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 26, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Dec 2020 (Study Day 124), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
20 Dec 2020 (Study Day 116)	Cough	Mild
20 Dec 2020 (Study Day 116)	Fatigue	Mild
20 Dec 2020 (Study Day 116)	Headache	Mild

Symptom Date	Symptom	Result
20 Dec 2020 (Study Day 116)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 116)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 117)	Cough	Mild
21 Dec 2020 (Study Day 117)	Fatigue	Mild
21 Dec 2020 (Study Day 117)	Headache	Mild
21 Dec 2020 (Study Day 117)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 117)	Runny Nose (Rhinorrhea)	Mild
22 Dec 2020 (Study Day 118)	Cough	Mild
22 Dec 2020 (Study Day 118)	Fatigue	Mild
22 Dec 2020 (Study Day 118)	Headache	Mild
22 Dec 2020 (Study Day 118)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 118)	Runny Nose (Rhinorrhea)	Mild
23 Dec 2020 (Study Day 119)	Cough	Mild
23 Dec 2020 (Study Day 119)	Fatigue	Mild
23 Dec 2020 (Study Day 119)	Headache	Mild
23 Dec 2020 (Study Day 119)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 119)	Runny Nose (Rhinorrhea)	Mild
24 Dec 2020 (Study Day 120)	Cough	Mild
24 Dec 2020 (Study Day 120)	Fatigue	Mild
24 Dec 2020 (Study Day 120)	Headache	Mild
24 Dec 2020 (Study Day 120)	Nasal Congestion	Mild
24 Dec 2020 (Study Day 120)	Runny Nose (Rhinorrhea)	Mild
25 Dec 2020 (Study Day 121)	Cough	Mild
25 Dec 2020 (Study Day 121)	Diarrhea	Mild
25 Dec 2020 (Study Day 121)	Fatigue	Mild
25 Dec 2020 (Study Day 121)	Headache	Mild
25 Dec 2020 (Study Day 121)	Nasal Congestion	Mild
25 Dec 2020 (Study Day 121)	Runny Nose (Rhinorrhea)	Mild
25 Dec 2020 (Study Day 121)	Vomiting	Mild
26 Dec 2020 (Study Day 122)	Cough	Mild
26 Dec 2020 (Study Day 122)	Diarrhea	Mild
26 Dec 2020 (Study Day 122)	Fatigue	Mild
26 Dec 2020 (Study Day 122)	Headache	Mild
26 Dec 2020 (Study Day 122)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 122)	Runny Nose (Rhinorrhea)	Mild
26 Dec 2020 (Study Day 122)	Vomiting	Mild
27 Dec 2020 (Study Day 123)	Cough	Mild
27 Dec 2020 (Study Day 123)	Fatigue	Mild
27 Dec 2020 (Study Day 123)	Headache	Mild
27 Dec 2020 (Study Day 123)	Nasal Congestion	Mild
27 Dec 2020 (Study Day 123)	Runny Nose (Rhinorrhea)	Mild
27 Dec 2020 (Study Day 123)	Vomiting	Mild
28 Dec 2020 (Study Day 124)	Cough	Mild

Symptom Date	Symptom	Result
28 Dec 2020 (Study Day 124)	Fatigue	Mild
28 Dec 2020 (Study Day 124)	Headache	Mild
28 Dec 2020 (Study Day 124)	Nasal Congestion	Mild
28 Dec 2020 (Study Day 124)	O2 Saturation (%)	92
28 Dec 2020 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 124)	Vomiting	Mild
29 Dec 2020 (Study Day 125)	Cough	Mild
29 Dec 2020 (Study Day 125)	Diarrhea	Mild
29 Dec 2020 (Study Day 125)	Fatigue	Mild
29 Dec 2020 (Study Day 125)	Headache	Mild
29 Dec 2020 (Study Day 125)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 125)	Vomiting	Moderate
30 Dec 2020 (Study Day 126)	Cough	Mild
30 Dec 2020 (Study Day 126)	Diarrhea	Mild
30 Dec 2020 (Study Day 126)	Fatigue	Mild
30 Dec 2020 (Study Day 126)	Headache	Mild
30 Dec 2020 (Study Day 126)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
30 Dec 2020 (Study Day 126)	Vomiting	Moderate
31 Dec 2020 (Study Day 127)	Cough	Mild
31 Dec 2020 (Study Day 127)	Diarrhea	Mild
31 Dec 2020 (Study Day 127)	Fatigue	Mild
31 Dec 2020 (Study Day 127)	Headache	Mild
31 Dec 2020 (Study Day 127)	Nasal Congestion	Mild
31 Dec 2020 (Study Day 127)	Runny Nose (Rhinorrhea)	Mild
31 Dec 2020 (Study Day 127)	Vomiting	Moderate
01 Jan 2021 (Study Day 128)	Cough	Mild
01 Jan 2021 (Study Day 128)	Diarrhea	Mild
01 Jan 2021 (Study Day 128)	Fatigue	Mild
01 Jan 2021 (Study Day 128)	Headache	Mild
01 Jan 2021 (Study Day 128)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 128)	Runny Nose (Rhinorrhea)	Mild
01 Jan 2021 (Study Day 128)	Vomiting	Moderate
02 Jan 2021 (Study Day 129)	Cough	Mild
02 Jan 2021 (Study Day 129)	Diarrhea	Mild
02 Jan 2021 (Study Day 129)	Fatigue	Mild
02 Jan 2021 (Study Day 129)	Nasal Congestion	Mild
02 Jan 2021 (Study Day 129)	Runny Nose (Rhinorrhea)	Mild
02 Jan 2021 (Study Day 129)	Vomiting	Moderate
03 Jan 2021 (Study Day 130)	Cough	Mild
03 Jan 2021 (Study Day 130)	Diarrhea	Mild
03 Jan 2021 (Study Day 130)	Fatigue	Mild

Symptom Date	Symptom	Result
03 Jan 2021 (Study Day 130)	Nasal Congestion	Mild
03 Jan 2021 (Study Day 130)	Runny Nose (Rhinorrhea)	Mild
03 Jan 2021 (Study Day 130)	Vomiting	Mild
04 Jan 2021 (Study Day 131)	Cough	Mild
04 Jan 2021 (Study Day 131)	Diarrhea	Mild
04 Jan 2021 (Study Day 131)	Fatigue	Mild
04 Jan 2021 (Study Day 131)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 131)	Runny Nose (Rhinorrhea)	Mild
04 Jan 2021 (Study Day 131)	Vomiting	Mild
05 Jan 2021 (Study Day 132)	Cough	Mild
05 Jan 2021 (Study Day 132)	Diarrhea	Mild
05 Jan 2021 (Study Day 132)	Fatigue	Mild
05 Jan 2021 (Study Day 132)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 132)	Runny Nose (Rhinorrhea)	Mild
05 Jan 2021 (Study Day 132)	Vomiting	Mild
06 Jan 2021 (Study Day 133)	Cough	Mild
07 Jan 2021 (Study Day 134)	Cough	Mild
08 Jan 2021 (Study Day 135)	Cough	Mild
09 Jan 2021 (Study Day 136)	Cough	Mild
10 Jan 2021 (Study Day 137)	Cough	Mild
10 Jan 2021 (Study Day 137)	O2 Saturation (%)	91
11 Jan 2021 (Study Day 138)	Cough	Mild
12 Jan 2021 (Study Day 139)	Cough	Mild
13 Jan 2021 (Study Day 140)	Cough	Mild
14 Jan 2021 (Study Day 141)	Cough	Mild
15 Jan 2021 (Study Day 142)	Cough	Mild
16 Jan 2021 (Study Day 143)	Cough	Mild
17 Jan 2021 (Study Day 144)	Cough	Mild
18 Jan 2021 (Study Day 145)	Cough	Mild
19 Jan 2021 (Study Day 146)	Cough	Mild
20 Jan 2021 (Study Day 147)	Cough	Mild
21 Jan 2021 (Study Day 148)	Cough	Mild
22 Jan 2021 (Study Day 149)	Cough	Mild
23 Jan 2021 (Study Day 150)	Cough	Mild
24 Jan 2021 (Study Day 151)	Cough	Mild
25 Jan 2021 (Study Day 152)	Cough	Mild
26 Jan 2021 (Study Day 153)	Cough	Mild
27 Jan 2021 (Study Day 154)	Cough	Mild
28 Jan 2021 (Study Day 155)	Cough	Mild
29 Jan 2021 (Study Day 156)	Cough	Mild
30 Jan 2021 (Study Day 157)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
28 Dec 2020 (Study Day 124)	Oxygen Saturation	91%
28 Dec 2020 - 11 Jan 2021 (Study Day 124-138)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 42 days, after which it was considered to be recovered/resolved on 30 Jan 2021 (Study Day 157). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002614	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	1985 - Ongoing
Back pain	Back pain	1998 - Ongoing
Osteoarthritis	Osteoarthritis	1998 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2014 - Ongoing
Ligament operation	Acl repair	Jan 2015 - Jan 2015
Ligament rupture	Torn acl	Jan 2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Benzocaine; menthol	20 Dec 2020 (Study Day 116) - 30 Jan 2021 (Study Day 157)	COVID-19
Chlorphenamine maleate; paracetamol; phenylephrine hydrochloride	20 Dec 2020 (Study Day 116) - 06 Jan 2021 (Study Day 133)	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dextromethorphan hydrobromide; guaifenesin	20 Dec 2020 (Study Day 116) - 06 Jan 2021 (Study Day 133)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	20 Dec 2020 (Study Day 116) - 30 Jan 2021 (Study Day 157)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US344-2173 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	16 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 30)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 1/mild	Not related	04 Dec 2020 (Study Day 80) – 15 Dec 2020 (Study Day 91)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US344-2173, a 52-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 04 Dec 2020 (Study Day 80), 79 days after the first dose and 50 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 15 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 07 Dec 2020 (Study Day 83), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
04 Dec 2020 (Study Day 80)	Cough	Mild
04 Dec 2020 (Study Day 80)	Headache	Mild
04 Dec 2020 (Study Day 80)	Nasal Congestion	Mild
04 Dec 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
05 Dec 2020 (Study Day 81)	Body Aches	Mild

Symptom Date	Symptom	Result
05 Dec 2020 (Study Day 81)	Chills	Mild
05 Dec 2020 (Study Day 81)	Cough	Mild
05 Dec 2020 (Study Day 81)	Fatigue	Mild
05 Dec 2020 (Study Day 81)	Headache	Mild
05 Dec 2020 (Study Day 81)	Nasal Congestion	Mild
05 Dec 2020 (Study Day 81)	Runny Nose (Rhinorrhea)	Mild
06 Dec 2020 (Study Day 82)	Body Aches	Mild
06 Dec 2020 (Study Day 82)	Cough	Mild
06 Dec 2020 (Study Day 82)	Fatigue	Mild
06 Dec 2020 (Study Day 82)	Headache	Mild
06 Dec 2020 (Study Day 82)	Nasal Congestion	Mild
06 Dec 2020 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
07 Dec 2020 (Study Day 83)	Body Aches	Mild
07 Dec 2020 (Study Day 83)	Cough	Mild
07 Dec 2020 (Study Day 83)	Fatigue	Mild
07 Dec 2020 (Study Day 83)	Headache	Mild
07 Dec 2020 (Study Day 83)	Nasal Congestion	Mild
07 Dec 2020 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 84)	Cough	Mild
08 Dec 2020 (Study Day 84)	Fatigue	Mild
08 Dec 2020 (Study Day 84)	Nasal Congestion	Mild
09 Dec 2020 (Study Day 85)	Cough	Mild
09 Dec 2020 (Study Day 85)	Headache	Mild
09 Dec 2020 (Study Day 85)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 86)	Fatigue	Mild
10 Dec 2020 (Study Day 86)	Nasal Congestion	Mild
11 Dec 2020 (Study Day 87)	Fatigue	Mild
11 Dec 2020 (Study Day 87)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 88)	Fatigue	Mild
12 Dec 2020 (Study Day 88)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 88)	O2 Saturation (%)	92
13 Dec 2020 (Study Day 89)	Fatigue	Mild
13 Dec 2020 (Study Day 89)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 90)	Fatigue	Mild
14 Dec 2020 (Study Day 90)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 91)	O2 Saturation (%)	92

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
12 Dec 2020 (Study Day 88)	Oxygen Saturation	92%

Dates	Severity Indication	Result
12 Dec 2020 - 15 Dec 2020 (Study Day 88-91)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 12 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 91). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-007841	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy: hives rash	1980 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1994 - Ongoing
Tonsillitis	Tonsillitis	1995 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Depression	Depression	2000 - Ongoing
Dyspepsia	Heartburn	2000 - Ongoing
Gastrooesophageal reflux disease	Gerd	2000 - Ongoing
Cholecystectomy	Gall bladder removal	2008 - 2008
Cholelithiasis	Cholelithiasis	2008 - 2008
Cataract	Cataracts	2014 - 2014
Cataract operation	Cataract removal	2014 - 2014
Chronic obstructive pulmonary disease	Copd	2014 - Ongoing
Hot flush	Hot flashes	2017 - Ongoing
Hysterectomy	Hysterectomy	2017 - 2017
Menorrhagia	Menorrhagia	2017 - 2017
Back pain	Lumbar back pain	2018 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2018 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	2014 - Ongoing	Copd
Vortioxetine hydrobromide	2016 - Ongoing	Depression
Aripiprazole	2018 - Ongoing	Depression
Rosuvastatin	2019 - Ongoing	Hypercholesterolemia
Suvorexant	Oct 2019 - Ongoing	Insomnia
Semaglutide	04 Mar 2020 (Study Day -196) - Ongoing	Diabetes Type 2
Ibuprofen	29 Sep 2020 (Study Day 14) - 12 Oct 2020 (Study Day 27)	Broken Toes: Right 3rd And 4th
Influenza vaccine	05 Nov 2020 (Study Day 51) - 05 Nov 2020 (Study Day 51)	Influenza
Quetiapine fumarate	23 Feb 2021 (Study Day 161) - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Foot Fracture	Grade 2/moderate	Not related	28 Sep 2020 (Study Day 13) - 16 Nov 2020 (Study Day 62)
COVID-19	Grade 1/mild	Not related	04 Dec 2020 (Study Day 80) - 15 Dec 2020 (Study Day 91)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US345-2203 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 31)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	COVID-19	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 106) – 25 Nov 2020 (Study Day 114)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US345-2203, a 80-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 03 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 17 Nov 2020 (Study Day 106), 105 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 31, 03 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 17 Nov 2020 (Study Day 106), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 106)	Cough	Mild
17 Nov 2020 (Study Day 106)	O2 Saturation (%)	93
17 Nov 2020 (Study Day 106)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 106)	Shortness of Breath	Mild
18 Nov 2020 (Study Day 107)	Cough	Mild
18 Nov 2020 (Study Day 107)	O2 Saturation (%)	92
18 Nov 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 108)	Cough	Mild
19 Nov 2020 (Study Day 108)	Difficulty Breathing	Mild
19 Nov 2020 (Study Day 108)	O2 Saturation (%)	91
19 Nov 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Mild
20 Nov 2020 (Study Day 109)	Cough	Mild
20 Nov 2020 (Study Day 109)	Difficulty Breathing	Mild
20 Nov 2020 (Study Day 109)	O2 Saturation (%)	91
20 Nov 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
21 Nov 2020 (Study Day 110)	Diarrhea	Mild
21 Nov 2020 (Study Day 110)	O2 Saturation (%)	93
21 Nov 2020 (Study Day 110)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 111)	Diarrhea	Mild
22 Nov 2020 (Study Day 111)	Difficulty Breathing	Mild
22 Nov 2020 (Study Day 111)	O2 Saturation (%)	93
22 Nov 2020 (Study Day 111)	Runny Nose (Rhinorrhea)	Mild
23 Nov 2020 (Study Day 112)	Diarrhea	Mild
23 Nov 2020 (Study Day 112)	Difficulty Breathing	Mild
23 Nov 2020 (Study Day 112)	O2 Saturation (%)	93
23 Nov 2020 (Study Day 112)	Runny Nose (Rhinorrhea)	Mild
24 Nov 2020 (Study Day 113)	Difficulty Breathing	Mild
24 Nov 2020 (Study Day 113)	O2 Saturation (%)	93
25 Nov 2020 (Study Day 114)	O2 Saturation (%)	93
26 Nov 2020 (Study Day 115)	O2 Saturation (%)	93
27 Nov 2020 (Study Day 116)	O2 Saturation (%)	93
28 Nov 2020 (Study Day 117)	O2 Saturation (%)	93
29 Nov 2020 (Study Day 118)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
17 Nov 2020 (Study Day 106)	Oxygen Saturation	91%
17 Nov 2020 - 30 Nov 2020 (Study Day 106-119)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 9 days, after which it was considered to be recovered/resolved on 25 Nov 2020 (Study Day 114). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000934	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	1970 - Ongoing
Drug hypersensitivity	Allergy to sulfa	1976 - Ongoing
Drug hypersensitivity	Allergy to codeine/morphine	1985 - Ongoing
Drug hypersensitivity	Allergy to nar-can	1985 - Ongoing
Dysmenorrhoea	Painful periods	1985 - 1985
Hysterectomy	Complete hysterectomy	1985 - 1985
Cholecystectomy	Cholecystectomy	1994 - 1994
Cholelithiasis	Gallstones	1994 - 1994
Benign gastrointestinal neoplasm	Non-cancerous growth in bowel	2001 - 2001
Intestinal resection	Bowel resection	2001 - 2001
Bunion operation	Bunions removed from both feet	2003 - 2003
Knee arthroplasty	Left knee replacement surgery	2005 - 2005
Knee arthroplasty	Right knee replacement	2007 - 2007
Rotator cuff repair	Rotator cuff repair of right shoulder	2009 - 2009
Nasal operation	Nasal reconstruction due to injury	2010 - 2010
Glaucoma	Glaucoma	2012 - 2012
Hypocholesterolaemia	Hypocholesterolemia	2015 - Ongoing
Restless legs syndrome	Rls	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Gastrooesophageal reflux disease	Gerd	2016 - Ongoing
Hypertension	High blood pressure	2016 - Ongoing
Peripheral sensory neuropathy	Sensory neuropathy of bilateral extremities	2017 - Ongoing
Osteoarthritis	Osteoarthritis all joints	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1970 - Ongoing	Hypothyroidism
Ezetimibe	2015 - Ongoing	High Cholesterol
Loratadine	2015 - Ongoing	Seasonal Allergies
Ropinirole	2015 - Ongoing	Rls
Pantoprazole	2016 - Ongoing	Gerd
Spironolactone	2016 - Ongoing	High Blood Pressure
Thyroid	2016 - Ongoing	Hypothyroidism
Gabapentin	2017 - Ongoing	Sensory Neuropathy Of Bilateral Extremities
Tramadol	2017 - Ongoing	Osteoarthritis
Diclofenac	2018 - Ongoing	Osteoarthritis
Diclofenac sodium	Apr 2020 - Ongoing	Oa/Joint Inflammation
Unspecified herbal and traditional medicine	Apr 2020 - Ongoing	Joint Inflammation All Joints Due To Oa
Prednisone	17 Nov 2020 (Study Day 106) - 24 Nov 2020 (Study Day 113)	Sob Caused By COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 106) - 25 Nov 2020 (Study Day 114)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US345-2232 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 35)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 1/mild	Not related	11 Dec 2020 (Study Day 129) – 12 Jan 2021 (Study Day 161)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US345-2232, a 37-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 11 Dec 2020 (Study Day 129), 128 days after the first dose and 94 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 35, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 15 Dec 2020 (Study Day 133), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 129)	Nasal Congestion	Mild
11 Dec 2020 (Study Day 129)	Runny Nose (Rhinorrhea)	Mild
12 Dec 2020 (Study Day 130)	Body Aches	Mild
12 Dec 2020 (Study Day 130)	Cough	Mild
12 Dec 2020 (Study Day 130)	Fatigue	Mild

Symptom Date	Symptom	Result
12 Dec 2020 (Study Day 130)	Sore Throat	Mild
13 Dec 2020 (Study Day 131)	Body Aches	Mild
13 Dec 2020 (Study Day 131)	Cough	Mild
13 Dec 2020 (Study Day 131)	Diarrhea	Moderate
13 Dec 2020 (Study Day 131)	Fatigue	Mild
13 Dec 2020 (Study Day 131)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 131)	Sore Throat	Mild
14 Dec 2020 (Study Day 132)	Body Aches	Moderate
14 Dec 2020 (Study Day 132)	Cough	Mild
14 Dec 2020 (Study Day 132)	Fatigue	Mild
14 Dec 2020 (Study Day 132)	Muscle Aches (Myalgia)	Mild
14 Dec 2020 (Study Day 132)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 132)	New Loss of Taste	Mild
14 Dec 2020 (Study Day 132)	Sore Throat	Mild
15 Dec 2020 (Study Day 133)	Body Aches	Moderate
15 Dec 2020 (Study Day 133)	Cough	Mild
15 Dec 2020 (Study Day 133)	Fatigue	Mild
15 Dec 2020 (Study Day 133)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 133)	New Loss of Taste	Mild
15 Dec 2020 (Study Day 133)	Sore Throat	Mild
16 Dec 2020 (Study Day 134)	Cough	Mild
16 Dec 2020 (Study Day 134)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 134)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 134)	Shortness of Breath	Mild
16 Dec 2020 (Study Day 134)	Sore Throat	Mild
17 Dec 2020 (Study Day 135)	Cough	Mild
17 Dec 2020 (Study Day 135)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 135)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 135)	Sore Throat	Mild
18 Dec 2020 (Study Day 136)	Cough	Moderate
18 Dec 2020 (Study Day 136)	Nasal Congestion	Moderate
18 Dec 2020 (Study Day 136)	New Loss of Smell	Moderate
18 Dec 2020 (Study Day 136)	New Loss of Taste	Moderate
18 Dec 2020 (Study Day 136)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 137)	Cough	Moderate
19 Dec 2020 (Study Day 137)	New Loss of Smell	Mild
19 Dec 2020 (Study Day 137)	New Loss of Taste	Mild
19 Dec 2020 (Study Day 137)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 138)	Body Aches	Moderate
20 Dec 2020 (Study Day 138)	Cough	Moderate
20 Dec 2020 (Study Day 138)	Nasal Congestion	Moderate
20 Dec 2020 (Study Day 138)	Sore Throat	Mild
21 Dec 2020 (Study Day 139)	Cough	Moderate

Symptom Date	Symptom	Result
21 Dec 2020 (Study Day 139)	Headache	Moderate
21 Dec 2020 (Study Day 139)	Nasal Congestion	Moderate
22 Dec 2020 (Study Day 140)	Cough	Moderate
22 Dec 2020 (Study Day 140)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 140)	Shortness of Breath	Moderate
22 Dec 2020 (Study Day 140)	Temperature (°F)	100.5
23 Dec 2020 (Study Day 141)	Body Aches	Moderate
23 Dec 2020 (Study Day 141)	Cough	Moderate
23 Dec 2020 (Study Day 141)	Headache	Mild
23 Dec 2020 (Study Day 141)	O2 Saturation (%)	88
23 Dec 2020 (Study Day 141)	Shortness of Breath	Moderate
23 Dec 2020 (Study Day 141)	Temperature (°F)	101.6
24 Dec 2020 (Study Day 142)	Body Aches	Moderate
24 Dec 2020 (Study Day 142)	Cough	Moderate
24 Dec 2020 (Study Day 142)	Headache	Mild
24 Dec 2020 (Study Day 142)	O2 Saturation (%)	88
24 Dec 2020 (Study Day 142)	Shortness of Breath	Moderate
24 Dec 2020 (Study Day 142)	Temperature (°F)	101.7
25 Dec 2020 (Study Day 143)	Body Aches	Moderate
25 Dec 2020 (Study Day 143)	Cough	Moderate
25 Dec 2020 (Study Day 143)	Shortness of Breath	Moderate
25 Dec 2020 (Study Day 143)	Temperature (°F)	101.0
26 Dec 2020 (Study Day 144)	Cough	Moderate
26 Dec 2020 (Study Day 144)	Fatigue	Moderate
26 Dec 2020 (Study Day 144)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 144)	O2 Saturation (%)	86
26 Dec 2020 (Study Day 144)	Shortness of Breath	Moderate
27 Dec 2020 (Study Day 145)	Cough	Moderate
27 Dec 2020 (Study Day 145)	O2 Saturation (%)	88
27 Dec 2020 (Study Day 145)	Shortness of Breath	Moderate
27 Dec 2020 (Study Day 145)	Sore Throat	Mild
28 Dec 2020 (Study Day 146)	Cough	Mild
28 Dec 2020 (Study Day 146)	Headache	Moderate
28 Dec 2020 (Study Day 146)	O2 Saturation (%)	93
28 Dec 2020 (Study Day 146)	Shortness of Breath	Moderate
29 Dec 2020 (Study Day 147)	Cough	Mild
29 Dec 2020 (Study Day 147)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 148)	Cough	Mild
30 Dec 2020 (Study Day 148)	O2 Saturation (%)	93
30 Dec 2020 (Study Day 148)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 148)	Sore Throat	Mild
31 Dec 2020 (Study Day 149)	Cough	Mild
31 Dec 2020 (Study Day 149)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
01 Jan 2021 (Study Day 150)	Cough	Mild
01 Jan 2021 (Study Day 150)	O2 Saturation (%)	90
01 Jan 2021 (Study Day 150)	Shortness of Breath	Mild
02 Jan 2021 (Study Day 151)	Cough	Mild
02 Jan 2021 (Study Day 151)	O2 Saturation (%)	90
02 Jan 2021 (Study Day 151)	Shortness of Breath	Mild
03 Jan 2021 (Study Day 152)	Cough	Mild
03 Jan 2021 (Study Day 152)	O2 Saturation (%)	93
03 Jan 2021 (Study Day 152)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 153)	Cough	Mild
04 Jan 2021 (Study Day 153)	O2 Saturation (%)	90
04 Jan 2021 (Study Day 153)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 154)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 155)	Diarrhea	Mild
06 Jan 2021 (Study Day 155)	O2 Saturation (%)	92
06 Jan 2021 (Study Day 155)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 155)	Sore Throat	Mild
06 Jan 2021 (Study Day 155)	Vomiting	Mild
07 Jan 2021 (Study Day 156)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 157)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 158)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 160)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 161)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
23 Dec 2020 (Study Day 141)	Oxygen Saturation	86%
23 Dec 2020 - 06 Jan 2021 (Study Day 141-155)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 33 days, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 161). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001146	COVID-19

Study Completion/Discontinuation

On 22 Feb 2021 (Study Day 202), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to keflex	1987 - Ongoing
Dyspepsia	Heartburn	2010 - Ongoing
Back pain	Back pain	2015 - Ongoing
Headache	Headaches	2017 - Ongoing
Migraine	Migraines	2017 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Hypermetropia	Farsighted	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	2017 - Ongoing	Intermittent Heartburn
Montelukast	2018 - Ongoing	Intermittent Seasonal Allergies
Dexamethasone	23 Dec 2020 (Study Day 141) - 28 Dec 2020 (Study Day 146)	COVID-19
Ivermectin	23 Dec 2020 (Study Day 141) - 23 Dec 2020 (Study Day 141)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	11 Dec 2020 (Study Day 129) - 12 Jan 2021 (Study Day 161)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US345-2332 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 28)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	COVID-19	Grade 1/mild	Not related	26 Oct 2020 (Study Day 81) – 23 Nov 2020 (Study Day 109)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US345-2332, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 03 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 26 Oct 2020 (Study Day 81), 80 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 03 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 26 Oct 2020 (Study Day 81), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
26 Oct 2020 (Study Day 81)	Body Aches	Mild
26 Oct 2020 (Study Day 81)	Fatigue	Mild
26 Oct 2020 (Study Day 81)	Muscle Aches (Myalgia)	Mild
27 Oct 2020 (Study Day 82)	Body Aches	Mild
27 Oct 2020 (Study Day 82)	Chills	Mild

Symptom Date	Symptom	Result
27 Oct 2020 (Study Day 82)	Fatigue	Mild
27 Oct 2020 (Study Day 82)	Muscle Aches (Myalgia)	Mild
28 Oct 2020 (Study Day 83)	Body Aches	Mild
28 Oct 2020 (Study Day 83)	Chills	Mild
28 Oct 2020 (Study Day 83)	Cough	Mild
28 Oct 2020 (Study Day 83)	Fatigue	Mild
28 Oct 2020 (Study Day 83)	Muscle Aches (Myalgia)	Mild
29 Oct 2020 (Study Day 84)	Fatigue	Mild
29 Oct 2020 (Study Day 84)	New Loss of Smell	Mild
29 Oct 2020 (Study Day 84)	New Loss of Taste	Mild
30 Oct 2020 (Study Day 85)	Body Aches	Moderate
30 Oct 2020 (Study Day 85)	Chills	Moderate
30 Oct 2020 (Study Day 85)	Cough	Moderate
30 Oct 2020 (Study Day 85)	Diarrhea	Mild
30 Oct 2020 (Study Day 85)	Fatigue	Moderate
30 Oct 2020 (Study Day 85)	Headache	Moderate
30 Oct 2020 (Study Day 85)	Muscle Aches (Myalgia)	Mild
30 Oct 2020 (Study Day 85)	Nasal Congestion	Moderate
30 Oct 2020 (Study Day 85)	Nausea	Mild
30 Oct 2020 (Study Day 85)	New Loss of Smell	Moderate
30 Oct 2020 (Study Day 85)	New Loss of Taste	Moderate
30 Oct 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Moderate
30 Oct 2020 (Study Day 85)	Shortness of Breath	Mild
30 Oct 2020 (Study Day 85)	Sore Throat	Mild
30 Oct 2020 (Study Day 85)	Temperature (°F)	101.2
31 Oct 2020 (Study Day 86)	Body Aches	Moderate
31 Oct 2020 (Study Day 86)	Chills	Moderate
31 Oct 2020 (Study Day 86)	Cough	Moderate
31 Oct 2020 (Study Day 86)	Difficulty Breathing	Moderate
31 Oct 2020 (Study Day 86)	Fatigue	Moderate
31 Oct 2020 (Study Day 86)	Headache	Moderate
31 Oct 2020 (Study Day 86)	Muscle Aches (Myalgia)	Moderate
31 Oct 2020 (Study Day 86)	Nasal Congestion	Moderate
31 Oct 2020 (Study Day 86)	New Loss of Smell	Mild
31 Oct 2020 (Study Day 86)	New Loss of Taste	Moderate
31 Oct 2020 (Study Day 86)	O2 Saturation (%)	91
31 Oct 2020 (Study Day 86)	Runny Nose (Rhinorrhea)	Moderate
31 Oct 2020 (Study Day 86)	Shortness of Breath	Mild
31 Oct 2020 (Study Day 86)	Sore Throat	Mild
31 Oct 2020 (Study Day 86)	Temperature (°F)	101.2
01 Nov 2020 (Study Day 87)	Body Aches	Moderate
01 Nov 2020 (Study Day 87)	Chills	Mild
01 Nov 2020 (Study Day 87)	Cough	Mild

Symptom Date	Symptom	Result
01 Nov 2020 (Study Day 87)	Fatigue	Moderate
01 Nov 2020 (Study Day 87)	Headache	Moderate
01 Nov 2020 (Study Day 87)	Muscle Aches (Myalgia)	Moderate
01 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
01 Nov 2020 (Study Day 87)	New Loss of Smell	Moderate
01 Nov 2020 (Study Day 87)	New Loss of Taste	Moderate
01 Nov 2020 (Study Day 87)	Temperature (°F)	100.4
02 Nov 2020 (Study Day 88)	Body Aches	Moderate
02 Nov 2020 (Study Day 88)	Fatigue	Moderate
02 Nov 2020 (Study Day 88)	Headache	Moderate
02 Nov 2020 (Study Day 88)	Muscle Aches (Myalgia)	Moderate
02 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
02 Nov 2020 (Study Day 88)	New Loss of Smell	Mild
02 Nov 2020 (Study Day 88)	New Loss of Taste	Moderate
03 Nov 2020 (Study Day 89)	Fatigue	Mild
03 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
03 Nov 2020 (Study Day 89)	New Loss of Taste	Mild
03 Nov 2020 (Study Day 89)	O2 Saturation (%)	93
04 Nov 2020 (Study Day 90)	Body Aches	Mild
04 Nov 2020 (Study Day 90)	Fatigue	Mild
04 Nov 2020 (Study Day 90)	Muscle Aches (Myalgia)	Mild
04 Nov 2020 (Study Day 90)	New Loss of Smell	Mild
04 Nov 2020 (Study Day 90)	New Loss of Taste	Mild
05 Nov 2020 (Study Day 91)	Fatigue	Mild
05 Nov 2020 (Study Day 91)	Muscle Aches (Myalgia)	Mild
05 Nov 2020 (Study Day 91)	New Loss of Smell	Mild
05 Nov 2020 (Study Day 91)	New Loss of Taste	Mild
06 Nov 2020 (Study Day 92)	Fatigue	Mild
06 Nov 2020 (Study Day 92)	Headache	Mild
06 Nov 2020 (Study Day 92)	New Loss of Smell	Mild
06 Nov 2020 (Study Day 92)	New Loss of Taste	Mild
06 Nov 2020 (Study Day 92)	Shortness of Breath	Mild
07 Nov 2020 (Study Day 93)	Fatigue	Mild
07 Nov 2020 (Study Day 93)	New Loss of Smell	Mild
07 Nov 2020 (Study Day 93)	New Loss of Taste	Mild
08 Nov 2020 (Study Day 94)	Fatigue	Mild
08 Nov 2020 (Study Day 94)	Headache	Mild
08 Nov 2020 (Study Day 94)	New Loss of Smell	Mild
08 Nov 2020 (Study Day 94)	New Loss of Taste	Mild
09 Nov 2020 (Study Day 95)	Fatigue	Mild
09 Nov 2020 (Study Day 95)	New Loss of Smell	Mild
09 Nov 2020 (Study Day 95)	New Loss of Taste	Mild
10 Nov 2020 (Study Day 96)	Fatigue	Mild

Symptom Date	Symptom	Result
10 Nov 2020 (Study Day 96)	New Loss of Smell	Mild
10 Nov 2020 (Study Day 96)	New Loss of Taste	Mild
11 Nov 2020 (Study Day 97)	New Loss of Smell	Mild
11 Nov 2020 (Study Day 97)	New Loss of Taste	Mild
12 Nov 2020 (Study Day 98)	New Loss of Smell	Mild
12 Nov 2020 (Study Day 98)	New Loss of Taste	Mild
13 Nov 2020 (Study Day 99)	New Loss of Smell	Mild
13 Nov 2020 (Study Day 99)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
31 Oct 2020 (Study Day 86)	Oxygen Saturation	91%
31 Oct 2020 - 03 Nov 2020 (Study Day 86-89)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 29 days, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 109). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000603	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	1985 - Ongoing
Drug hypersensitivity	Allergy to penicillin	1995 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Myocardial infarction	Heart attack	1995 - 1995
Oedema peripheral	Edema both feet	1995 - Ongoing
Vasectomy	Vasectomy	1997 - 1997
Seasonal allergy	Seasonal allergies	2001 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2005 - Ongoing
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Back pain	Back pain	2015 - Ongoing
Intervertebral disc operation	Disc repair of back	2016 - 2016
Gastrooesophageal reflux disease	Gerd	2018 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	Jun 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Digoxin	1995 - Ongoing	Hypertension
Furosemide	1995 - Ongoing	Edema Both Feet
Alprazolam	2005 - Ongoing	Anxiety
Amlodipine	2005 - Ongoing	High Blood Pressure
Rosuvastatin	2010 - Ongoing	High Cholesterol
Ibuprofen	2015 - Ongoing	Back Pain
Metformin	Jun 2019 - Ongoing	Diabetes Type Ii

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	03 Sep 2020 (Study Day 28) - 22 Oct 2020 (Study Day 77)
Myalgia	Grade 1/mild	Related	06 Sep 2020 (Study Day 31) - 22 Oct 2020 (Study Day 77)
COVID-19	Grade 1/mild	Not related	26 Oct 2020 (Study Day 81) - 23 Nov 2020 (Study Day 109)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US346-2374 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 128) – 17 Jan 2021 (Study Day 144)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US346-2374, a 39-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 01 Jan 2021 (Study Day 128), 127 days after the first dose and 99 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 24 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 04 Jan 2021 (Study Day 131), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
01 Jan 2021 (Study Day 128)	Cough	Mild
01 Jan 2021 (Study Day 128)	Headache	Mild
01 Jan 2021 (Study Day 128)	Muscle Aches (Myalgia)	Mild
01 Jan 2021 (Study Day 128)	Sore Throat	Mild
01 Jan 2021 (Study Day 128)	Temperature (°F)	101

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 129)	Cough	Mild
02 Jan 2021 (Study Day 129)	Diarrhea	Mild
02 Jan 2021 (Study Day 129)	Headache	Mild
02 Jan 2021 (Study Day 129)	Muscle Aches (Myalgia)	Mild
02 Jan 2021 (Study Day 129)	Sore Throat	Mild
02 Jan 2021 (Study Day 129)	Temperature (°F)	101
03 Jan 2021 (Study Day 130)	Cough	Mild
03 Jan 2021 (Study Day 130)	Diarrhea	Mild
03 Jan 2021 (Study Day 130)	Headache	Mild
03 Jan 2021 (Study Day 130)	Muscle Aches (Myalgia)	Mild
04 Jan 2021 (Study Day 131)	Body Aches	Moderate
04 Jan 2021 (Study Day 131)	Cough	Mild
04 Jan 2021 (Study Day 131)	Diarrhea	Mild
04 Jan 2021 (Study Day 131)	Headache	Mild
04 Jan 2021 (Study Day 131)	Muscle Aches (Myalgia)	Moderate
04 Jan 2021 (Study Day 131)	New Loss of Smell	Moderate
04 Jan 2021 (Study Day 131)	New Loss of Taste	Moderate
05 Jan 2021 (Study Day 132)	Body Aches	Moderate
05 Jan 2021 (Study Day 132)	Cough	Mild
05 Jan 2021 (Study Day 132)	Headache	Mild
05 Jan 2021 (Study Day 132)	Muscle Aches (Myalgia)	Moderate
05 Jan 2021 (Study Day 132)	New Loss of Smell	Moderate
05 Jan 2021 (Study Day 132)	New Loss of Taste	Moderate
06 Jan 2021 (Study Day 133)	Body Aches	Moderate
06 Jan 2021 (Study Day 133)	Cough	Mild
06 Jan 2021 (Study Day 133)	Fatigue	Moderate
06 Jan 2021 (Study Day 133)	Headache	Mild
06 Jan 2021 (Study Day 133)	Muscle Aches (Myalgia)	Moderate
06 Jan 2021 (Study Day 133)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 133)	New Loss of Smell	Severe
06 Jan 2021 (Study Day 133)	New Loss of Taste	Severe
07 Jan 2021 (Study Day 134)	Fatigue	Moderate
07 Jan 2021 (Study Day 134)	Headache	Mild
07 Jan 2021 (Study Day 134)	New Loss of Smell	Severe
07 Jan 2021 (Study Day 134)	New Loss of Taste	Severe
08 Jan 2021 (Study Day 135)	Fatigue	Mild
08 Jan 2021 (Study Day 135)	Headache	Mild
08 Jan 2021 (Study Day 135)	New Loss of Smell	Severe
08 Jan 2021 (Study Day 135)	New Loss of Taste	Severe
08 Jan 2021 (Study Day 135)	O2 Saturation (%)	93
09 Jan 2021 (Study Day 136)	Fatigue	Mild
09 Jan 2021 (Study Day 136)	Headache	Mild
09 Jan 2021 (Study Day 136)	New Loss of Smell	Severe

Symptom Date	Symptom	Result
09 Jan 2021 (Study Day 136)	New Loss of Taste	Severe
10 Jan 2021 (Study Day 137)	Fatigue	Mild
10 Jan 2021 (Study Day 137)	Headache	Mild
10 Jan 2021 (Study Day 137)	New Loss of Smell	Severe
10 Jan 2021 (Study Day 137)	New Loss of Taste	Severe
11 Jan 2021 (Study Day 138)	Fatigue	Mild
11 Jan 2021 (Study Day 138)	New Loss of Smell	Severe
11 Jan 2021 (Study Day 138)	New Loss of Taste	Severe
12 Jan 2021 (Study Day 139)	Fatigue	Mild
12 Jan 2021 (Study Day 139)	New Loss of Smell	Moderate
12 Jan 2021 (Study Day 139)	New Loss of Taste	Moderate
13 Jan 2021 (Study Day 140)	Fatigue	Mild
13 Jan 2021 (Study Day 140)	New Loss of Smell	Moderate
13 Jan 2021 (Study Day 140)	New Loss of Taste	Moderate
14 Jan 2021 (Study Day 141)	New Loss of Smell	Moderate
14 Jan 2021 (Study Day 141)	New Loss of Taste	Moderate
15 Jan 2021 (Study Day 142)	New Loss of Smell	Mild
15 Jan 2021 (Study Day 142)	New Loss of Taste	Mild
16 Jan 2021 (Study Day 143)	New Loss of Smell	Mild
16 Jan 2021 (Study Day 143)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
08 Jan 2021 (Study Day 135)	Oxygen Saturation	93%
08 Jan 2021 - 08 Jan 2021 (Study Day 135-135)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 17 Jan 2021 (Study Day 144). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002254	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal and perennial allergic rhinitis	1999 - Ongoing
Depression	Mild depression	2000 - Ongoing
Urethral operation	Urethral enlargement surgery	2018 - 2018
Urethral stenosis	Narrow urethral opening	2018 - 2018
Vasectomy	Vasectomy	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	27 Aug 2020 (Study Day 1) - 27 Aug 2020 (Study Day 1)	Injection Site Pain
Escitalopram oxalate	23 Oct 2020 (Study Day 58) - Ongoing	Mild Depression
Ibuprofen	01 Jan 2021 (Study Day 128) - 03 Jan 2021 (Study Day 130)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 128) - 17 Jan 2021 (Study Day 144)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US347-2130 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	23 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19, AE leading to withdrawal from study vaccine	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 12) – 17 Nov 2020 (Study Day 26)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US347-2130, a 46-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 23 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 03 Nov 2020 (Study Day 12), 11 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 09 Nov 2020 (Study Day 18), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
06 Nov 2020 (Study Day 15)	Chills	Mild
06 Nov 2020 (Study Day 15)	Headache	Moderate
06 Nov 2020 (Study Day 15)	Muscle Aches (Myalgia)	Moderate
09 Nov 2020 (Study Day 18)	Chills	Mild
09 Nov 2020 (Study Day 18)	Fatigue	Moderate
09 Nov 2020 (Study Day 18)	Headache	Moderate

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 18)	Muscle Aches (Myalgia)	Moderate
09 Nov 2020 (Study Day 18)	Sore Throat	Moderate
10 Nov 2020 (Study Day 19)	Chills	Mild
10 Nov 2020 (Study Day 19)	Fatigue	Moderate
10 Nov 2020 (Study Day 19)	Headache	Mild
10 Nov 2020 (Study Day 19)	Muscle Aches (Myalgia)	Moderate
10 Nov 2020 (Study Day 19)	Sore Throat	Moderate
10 Nov 2020 (Study Day 19)	Temperature (°F)	101.3
11 Nov 2020 (Study Day 20)	Chills	Mild
11 Nov 2020 (Study Day 20)	Fatigue	Moderate
11 Nov 2020 (Study Day 20)	Muscle Aches (Myalgia)	Moderate
11 Nov 2020 (Study Day 20)	Sore Throat	Moderate
12 Nov 2020 (Study Day 21)	Chills	Mild
12 Nov 2020 (Study Day 21)	Fatigue	Moderate
12 Nov 2020 (Study Day 21)	Headache	Mild
12 Nov 2020 (Study Day 21)	Muscle Aches (Myalgia)	Moderate
12 Nov 2020 (Study Day 21)	O2 Saturation (%)	93
12 Nov 2020 (Study Day 21)	Sore Throat	Moderate
13 Nov 2020 (Study Day 22)	Chills	Mild
13 Nov 2020 (Study Day 22)	Fatigue	Moderate
13 Nov 2020 (Study Day 22)	Muscle Aches (Myalgia)	Moderate
13 Nov 2020 (Study Day 22)	O2 Saturation (%)	93
14 Nov 2020 (Study Day 23)	Fatigue	Mild
14 Nov 2020 (Study Day 23)	Nausea	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
12 Nov 2020 (Study Day 21)	Oxygen Saturation	93%
12 Nov 2020 - 14 Nov 2020 (Study Day 21-23)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

On 19 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 26). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000769	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Bicuspid aortic valve	Bicuspid aortic valve syndrome	(b) (6) 1973 (Study Day (b) (6)) - Ongoing
Mitral valve prolapse	Mitral valve prolapse	1983 - Ongoing
Sleep apnoea syndrome	Sleep apnea	Sep 2012 - Ongoing
Sciatica	Sciatica	May 2013 - Ongoing
Major depression	Major depressive disorder	Sep 2019 - Ongoing
Erectile dysfunction	Erectile dysfunction	Jun 2020 - Ongoing
Insomnia	Insomnia	Jun 2020 - Ongoing
Obesity	Obesity, class ii	Oct 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	May 2013 - Ongoing	Sciatica
Bupropion	Oct 2019 - Ongoing	Depression
Tadalafil	Jun 2020 - Ongoing	Erectile Dysfunction
Zolpidem tartrate	Oct 2020 - Ongoing	Insomnia
Influenza vaccine	05 Oct 2020 (Study Day -18) - 05 Oct 2020 (Study Day -18)	Prophylaxis For Influenza
Ibuprofen	03 Nov 2020 (Study Day 12) - 04 Nov 2020 (Study Day 13)	COVID-19
Paracetamol; phenylephrine hydrochloride	03 Nov 2020 (Study Day 12) - 17 Nov 2020 (Study Day 26)	COVID-19
Ibuprofen	04 Nov 2020 (Study Day 13) - 17 Nov 2020 (Study Day 26)	COVID-19
Paracetamol	06 Nov 2020 (Study Day 15) - 17 Nov 2020 (Study Day 26)	COVID-19
Endoscopy*	10 Feb 2021 (Study Day 111) - 10 Feb 2021 (Study Day 111)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Erythema	Grade 1/mild	Related	23 Oct 2020 (Study Day 1) - 03 Nov 2020 (Study Day 12)
COVID-19	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 12) - 17 Nov 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US348-2094 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 34)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 3/severe	Not related	09 Dec 2020 (Study Day 112) – 05 Jan 2021 (Study Day 139)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US348-2094, a 48-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 22 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 09 Dec 2020 (Study Day 112), 111 days after the first dose and 78 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 34, 22 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 17 Dec 2020 (Study Day 120), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
10 Oct 2020 (Study Day 52)	Body Aches	Moderate
10 Oct 2020 (Study Day 52)	Chills	Moderate
10 Oct 2020 (Study Day 52)	Cough	Moderate
10 Oct 2020 (Study Day 52)	Fatigue	Moderate
10 Oct 2020 (Study Day 52)	Headache	Moderate

Symptom Date	Symptom	Result
10 Oct 2020 (Study Day 52)	Nasal Congestion	Moderate
10 Oct 2020 (Study Day 52)	Runny Nose (Rhinorrhea)	Moderate
10 Oct 2020 (Study Day 52)	Sore Throat	Moderate
11 Oct 2020 (Study Day 53)	Body Aches	Moderate
11 Oct 2020 (Study Day 53)	Chills	Moderate
11 Oct 2020 (Study Day 53)	Cough	Moderate
11 Oct 2020 (Study Day 53)	Fatigue	Moderate
11 Oct 2020 (Study Day 53)	Headache	Moderate
11 Oct 2020 (Study Day 53)	Nasal Congestion	Moderate
11 Oct 2020 (Study Day 53)	Runny Nose (Rhinorrhea)	Moderate
11 Oct 2020 (Study Day 53)	Sore Throat	Moderate
12 Oct 2020 (Study Day 54)	Body Aches	Moderate
12 Oct 2020 (Study Day 54)	Chills	Moderate
12 Oct 2020 (Study Day 54)	Cough	Moderate
12 Oct 2020 (Study Day 54)	Fatigue	Moderate
12 Oct 2020 (Study Day 54)	Headache	Moderate
12 Oct 2020 (Study Day 54)	Nasal Congestion	Moderate
12 Oct 2020 (Study Day 54)	Runny Nose (Rhinorrhea)	Moderate
12 Oct 2020 (Study Day 54)	Sore Throat	Moderate
13 Oct 2020 (Study Day 55)	Fatigue	Mild
13 Oct 2020 (Study Day 55)	Headache	Mild
13 Oct 2020 (Study Day 55)	Muscle Aches (Myalgia)	Mild
13 Oct 2020 (Study Day 55)	Nasal Congestion	Mild
13 Oct 2020 (Study Day 55)	Runny Nose (Rhinorrhea)	Mild
13 Oct 2020 (Study Day 55)	Sore Throat	Mild
14 Oct 2020 (Study Day 56)	Body Aches	Mild
14 Oct 2020 (Study Day 56)	Cough	Mild
14 Oct 2020 (Study Day 56)	Fatigue	Mild
14 Oct 2020 (Study Day 56)	Muscle Aches (Myalgia)	Mild
14 Oct 2020 (Study Day 56)	Nasal Congestion	Mild
14 Oct 2020 (Study Day 56)	Runny Nose (Rhinorrhea)	Mild
15 Oct 2020 (Study Day 57)	Body Aches	Mild
15 Oct 2020 (Study Day 57)	Cough	Mild
15 Oct 2020 (Study Day 57)	Fatigue	Mild
15 Oct 2020 (Study Day 57)	Muscle Aches (Myalgia)	Mild
15 Oct 2020 (Study Day 57)	Nasal Congestion	Mild
15 Oct 2020 (Study Day 57)	Runny Nose (Rhinorrhea)	Mild
16 Oct 2020 (Study Day 58)	Cough	Mild
16 Oct 2020 (Study Day 58)	Fatigue	Mild
16 Oct 2020 (Study Day 58)	Headache	Mild
16 Oct 2020 (Study Day 58)	Muscle Aches (Myalgia)	Mild
16 Oct 2020 (Study Day 58)	Nasal Congestion	Mild
16 Oct 2020 (Study Day 58)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
16 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 89)	Runny Nose (Rhinorrhea)	Mild
17 Nov 2020 (Study Day 90)	Headache	Mild
17 Nov 2020 (Study Day 90)	Nasal Congestion	Mild
17 Nov 2020 (Study Day 90)	Runny Nose (Rhinorrhea)	Mild
17 Nov 2020 (Study Day 90)	Sore Throat	Mild
18 Nov 2020 (Study Day 91)	Headache	Mild
18 Nov 2020 (Study Day 91)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 92)	Headache	Mild
19 Nov 2020 (Study Day 92)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 93)	Headache	Mild
09 Dec 2020 (Study Day 112)	Body Aches	Moderate
09 Dec 2020 (Study Day 112)	Fatigue	Moderate
09 Dec 2020 (Study Day 112)	Headache	Moderate
09 Dec 2020 (Study Day 112)	Runny Nose (Rhinorrhea)	Moderate
09 Dec 2020 (Study Day 112)	Sore Throat	Moderate
10 Dec 2020 (Study Day 113)	Body Aches	Moderate
10 Dec 2020 (Study Day 113)	Fatigue	Moderate
10 Dec 2020 (Study Day 113)	Headache	Moderate
10 Dec 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Moderate
10 Dec 2020 (Study Day 113)	Sore Throat	Moderate
11 Dec 2020 (Study Day 114)	Body Aches	Moderate
11 Dec 2020 (Study Day 114)	Fatigue	Moderate
11 Dec 2020 (Study Day 114)	Headache	Moderate
11 Dec 2020 (Study Day 114)	Runny Nose (Rhinorrhea)	Moderate
11 Dec 2020 (Study Day 114)	Sore Throat	Moderate
12 Dec 2020 (Study Day 115)	Body Aches	Moderate
12 Dec 2020 (Study Day 115)	Fatigue	Moderate
12 Dec 2020 (Study Day 115)	Headache	Moderate
12 Dec 2020 (Study Day 115)	Runny Nose (Rhinorrhea)	Moderate
12 Dec 2020 (Study Day 115)	Sore Throat	Moderate
13 Dec 2020 (Study Day 116)	Body Aches	Moderate
13 Dec 2020 (Study Day 116)	Fatigue	Moderate
13 Dec 2020 (Study Day 116)	Headache	Moderate
13 Dec 2020 (Study Day 116)	Runny Nose (Rhinorrhea)	Moderate
13 Dec 2020 (Study Day 116)	Sore Throat	Moderate
14 Dec 2020 (Study Day 117)	Body Aches	Moderate
14 Dec 2020 (Study Day 117)	Fatigue	Moderate
14 Dec 2020 (Study Day 117)	Headache	Moderate
14 Dec 2020 (Study Day 117)	Runny Nose (Rhinorrhea)	Moderate
14 Dec 2020 (Study Day 117)	Sore Throat	Moderate
15 Dec 2020 (Study Day 118)	Body Aches	Moderate
15 Dec 2020 (Study Day 118)	Fatigue	Moderate

Symptom Date	Symptom	Result
15 Dec 2020 (Study Day 118)	Headache	Moderate
15 Dec 2020 (Study Day 118)	Runny Nose (Rhinorrhea)	Moderate
15 Dec 2020 (Study Day 118)	Sore Throat	Moderate
16 Dec 2020 (Study Day 119)	Body Aches	Moderate
16 Dec 2020 (Study Day 119)	Fatigue	Moderate
16 Dec 2020 (Study Day 119)	Headache	Moderate
16 Dec 2020 (Study Day 119)	Runny Nose (Rhinorrhea)	Moderate
16 Dec 2020 (Study Day 119)	Sore Throat	Moderate
17 Dec 2020 (Study Day 120)	Body Aches	Moderate
17 Dec 2020 (Study Day 120)	Chills	Mild
17 Dec 2020 (Study Day 120)	Fatigue	Moderate
17 Dec 2020 (Study Day 120)	Headache	Mild
17 Dec 2020 (Study Day 120)	Muscle Aches (Myalgia)	Moderate
17 Dec 2020 (Study Day 120)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 120)	New Loss of Smell	Mild
17 Dec 2020 (Study Day 120)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 120)	Shortness of Breath	Moderate
17 Dec 2020 (Study Day 120)	Sore Throat	Moderate
18 Dec 2020 (Study Day 121)	Body Aches	Mild
18 Dec 2020 (Study Day 121)	Cough	Mild
18 Dec 2020 (Study Day 121)	Fatigue	Moderate
18 Dec 2020 (Study Day 121)	Muscle Aches (Myalgia)	Mild
18 Dec 2020 (Study Day 121)	New Loss of Smell	Mild
18 Dec 2020 (Study Day 121)	New Loss of Taste	Mild
18 Dec 2020 (Study Day 121)	Sore Throat	Mild
19 Dec 2020 (Study Day 122)	Body Aches	Moderate
19 Dec 2020 (Study Day 122)	Chills	Moderate
19 Dec 2020 (Study Day 122)	Difficulty Breathing	Mild
19 Dec 2020 (Study Day 122)	Fatigue	Moderate
19 Dec 2020 (Study Day 122)	Muscle Aches (Myalgia)	Mild
19 Dec 2020 (Study Day 122)	New Loss of Smell	Mild
19 Dec 2020 (Study Day 122)	New Loss of Taste	Mild
19 Dec 2020 (Study Day 122)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 122)	Temperature (°F)	101
20 Dec 2020 (Study Day 123)	Body Aches	Moderate
20 Dec 2020 (Study Day 123)	Chills	Mild
20 Dec 2020 (Study Day 123)	Fatigue	Moderate
20 Dec 2020 (Study Day 123)	Muscle Aches (Myalgia)	Moderate
20 Dec 2020 (Study Day 123)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 123)	Temperature (°F)	101.5
21 Dec 2020 (Study Day 124)	Body Aches	Mild
21 Dec 2020 (Study Day 124)	Cough	Mild
21 Dec 2020 (Study Day 124)	Fatigue	Moderate

Symptom Date	Symptom	Result
21 Dec 2020 (Study Day 124)	Muscle Aches (Myalgia)	Mild
21 Dec 2020 (Study Day 124)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 124)	Shortness of Breath	Moderate
21 Dec 2020 (Study Day 124)	Temperature (°F)	100.7
22 Dec 2020 (Study Day 125)	Body Aches	Moderate
22 Dec 2020 (Study Day 125)	Chills	Severe
22 Dec 2020 (Study Day 125)	Difficulty Breathing	Moderate
22 Dec 2020 (Study Day 125)	Headache	Mild
22 Dec 2020 (Study Day 125)	Muscle Aches (Myalgia)	Moderate
22 Dec 2020 (Study Day 125)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 125)	Nausea	Mild
22 Dec 2020 (Study Day 125)	New Loss of Smell	Mild
22 Dec 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
22 Dec 2020 (Study Day 125)	Shortness of Breath	Moderate
22 Dec 2020 (Study Day 125)	Temperature (°F)	103.0
23 Dec 2020 (Study Day 126)	Body Aches	Moderate
23 Dec 2020 (Study Day 126)	Chills	Moderate
23 Dec 2020 (Study Day 126)	Cough	Mild
23 Dec 2020 (Study Day 126)	Difficulty Breathing	Moderate
23 Dec 2020 (Study Day 126)	Headache	Mild
23 Dec 2020 (Study Day 126)	Muscle Aches (Myalgia)	Moderate
23 Dec 2020 (Study Day 126)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 126)	New Loss of Smell	Mild
23 Dec 2020 (Study Day 126)	New Loss of Taste	Mild
23 Dec 2020 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
23 Dec 2020 (Study Day 126)	Shortness of Breath	Moderate
23 Dec 2020 (Study Day 126)	Temperature (°F)	103.5
24 Dec 2020 (Study Day 127)	Body Aches	Moderate
24 Dec 2020 (Study Day 127)	Chills	Moderate
24 Dec 2020 (Study Day 127)	Cough	Mild
24 Dec 2020 (Study Day 127)	Difficulty Breathing	Moderate
24 Dec 2020 (Study Day 127)	Headache	Mild
24 Dec 2020 (Study Day 127)	Muscle Aches (Myalgia)	Moderate
24 Dec 2020 (Study Day 127)	Nasal Congestion	Mild
24 Dec 2020 (Study Day 127)	New Loss of Smell	Mild
24 Dec 2020 (Study Day 127)	New Loss of Taste	Mild
24 Dec 2020 (Study Day 127)	Runny Nose (Rhinorrhea)	Mild
24 Dec 2020 (Study Day 127)	Shortness of Breath	Moderate
24 Dec 2020 (Study Day 127)	Temperature (°F)	103.3
25 Dec 2020 (Study Day 128)	Chills	Mild
25 Dec 2020 (Study Day 128)	Cough	Mild
25 Dec 2020 (Study Day 128)	Fatigue	Moderate

Symptom Date	Symptom	Result
25 Dec 2020 (Study Day 128)	Headache	Mild
25 Dec 2020 (Study Day 128)	New Loss of Smell	Moderate
25 Dec 2020 (Study Day 128)	New Loss of Taste	Mild
25 Dec 2020 (Study Day 128)	O2 Saturation (%)	93
25 Dec 2020 (Study Day 128)	Shortness of Breath	Moderate
26 Dec 2020 (Study Day 129)	Cough	Mild
26 Dec 2020 (Study Day 129)	Fatigue	Mild
26 Dec 2020 (Study Day 129)	Headache	Mild
26 Dec 2020 (Study Day 129)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 129)	New Loss of Smell	Moderate
26 Dec 2020 (Study Day 129)	Shortness of Breath	Moderate
27 Dec 2020 (Study Day 130)	Body Aches	Mild
27 Dec 2020 (Study Day 130)	Cough	Mild
27 Dec 2020 (Study Day 130)	Fatigue	Mild
27 Dec 2020 (Study Day 130)	Headache	Mild
27 Dec 2020 (Study Day 130)	O2 Saturation (%)	93
27 Dec 2020 (Study Day 130)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 131)	Fatigue	Mild
28 Dec 2020 (Study Day 131)	Headache	Mild
28 Dec 2020 (Study Day 131)	Muscle Aches (Myalgia)	Mild
28 Dec 2020 (Study Day 131)	Nasal Congestion	Mild
28 Dec 2020 (Study Day 131)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 131)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 132)	Body Aches	Mild
29 Dec 2020 (Study Day 132)	Cough	Mild
29 Dec 2020 (Study Day 132)	Fatigue	Mild
29 Dec 2020 (Study Day 132)	Headache	Mild
29 Dec 2020 (Study Day 132)	Muscle Aches (Myalgia)	Mild
29 Dec 2020 (Study Day 132)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 132)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 132)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 132)	Sore Throat	Mild
29 Dec 2020 (Study Day 132)	Temperature (°F)	102.0
30 Dec 2020 (Study Day 133)	Body Aches	Mild
30 Dec 2020 (Study Day 133)	Fatigue	Mild
30 Dec 2020 (Study Day 133)	Headache	Mild
30 Dec 2020 (Study Day 133)	Muscle Aches (Myalgia)	Mild
30 Dec 2020 (Study Day 133)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 133)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 133)	Sore Throat	Mild
31 Dec 2020 (Study Day 134)	Body Aches	Mild
31 Dec 2020 (Study Day 134)	Cough	Mild
31 Dec 2020 (Study Day 134)	Fatigue	Mild

Symptom Date	Symptom	Result
31 Dec 2020 (Study Day 134)	Headache	Mild
31 Dec 2020 (Study Day 134)	Muscle Aches (Myalgia)	Mild
31 Dec 2020 (Study Day 134)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 135)	Cough	Mild
01 Jan 2021 (Study Day 135)	Shortness of Breath	Mild
02 Jan 2021 (Study Day 136)	Cough	Mild
02 Jan 2021 (Study Day 136)	Fatigue	Mild
02 Jan 2021 (Study Day 136)	Shortness of Breath	Mild
03 Jan 2021 (Study Day 137)	Fatigue	Mild
04 Jan 2021 (Study Day 138)	Muscle Aches (Myalgia)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
25 Dec 2020 (Study Day 128)	Oxygen Saturation	93%
25 Dec 2020 - 27 Dec 2020 (Study Day 128-130)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 28 days, after which it was considered to be recovered/resolved on 05 Jan 2021 (Study Day 139). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001236	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract operation	Cataract surgery	1984 - 1984
Gastrooesophageal reflux disease	Acid reflux	1995 - Ongoing
Hernia repair	Hernia repair	2004 - 2004
Appendicectomy	Appendectomy	2014 - 2014

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexchlorpheniramine maleate; phenylephrine hydrochloride	12 Oct 2020 (Study Day 54) - 14 Oct 2020 (Study Day 56)	Upper Respiratory (Uri) Symptoms
Ascorbic acid; herbal nos; levoglutamide; lysine; magnesium; manganese; retinol; riboflavin; selenium; tocopherol; zinc	16 Dec 2020 (Study Day 119) - 30 Dec 2020 (Study Day 133)	Health Promotion
Vitamins nos	16 Dec 2020 (Study Day 119) - Ongoing	Health Promotion
Acetylsalicylic acid	17 Dec 2020 (Study Day 120) - 11 Feb 2021 (Study Day 176)	COVID-19
Methylprednisolone	17 Dec 2020 (Study Day 120) - 17 Dec 2020 (Study Day 120)	COVID-19
Paracetamol	17 Dec 2020 (Study Day 120) - 17 Dec 2020 (Study Day 120)	Body Aches (COVID-19)
Cetirizine	18 Dec 2020 (Study Day 121) - 07 Jan 2021 (Study Day 141)	COVID-19
Methylprednisolone	18 Dec 2020 (Study Day 121) - 18 Dec 2020 (Study Day 121)	COVID-19
Methylprednisolone	19 Dec 2020 (Study Day 122) - 19 Dec 2020 (Study Day 122)	COVID-19
Azithromycin	20 Dec 2020 (Study Day 123) - 20 Dec 2020 (Study Day 123)	Treatment For Possible Secondary Infection Due To Continued High Fever
Methylprednisolone	20 Dec 2020 (Study Day 123) - 20 Dec 2020 (Study Day 123)	COVID-19
Azithromycin	21 Dec 2020 (Study Day 124) - 24 Dec 2020 (Study Day 127)	Treatment For Possible Secondary Infection Due To Continued High Fever
Methylprednisolone	21 Dec 2020 (Study Day 124) - 21 Dec 2020 (Study Day 124)	COVID-19
Dexamethasone	22 Dec 2020 (Study Day 125) - 27 Dec 2020 (Study Day 130)	COVID19
Methylprednisolone	22 Dec 2020 (Study Day 125) - 22 Dec 2020 (Study Day 125)	COVID-19
Paracetamol	22 Dec 2020 (Study Day 125) - 03 Jan 2021 (Study Day 137)	Fever Related To COVID19
Salbutamol	23 Dec 2020 (Study Day 126) - 05 Jan 2021 (Study Day 139)	COVID 19
Chest xray*	24 Dec 2020 (Study Day 127) - 24 Dec 2020 (Study Day 127)	Adverse Event
Doxycycline	24 Dec 2020 (Study Day 127) - 03 Jan 2021 (Study Day 137)	Treatment For Possible Secondary Infection Due To Continued High Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 52) - 19 Oct 2020 (Study Day 61)
Fatigue	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 52) - 18 Oct 2020 (Study Day 60)
Headache	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 52) - 16 Oct 2020 (Study Day 58)
Myalgia	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 52) - 19 Oct 2020 (Study Day 61)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	10 Oct 2020 (Study Day 52) - 19 Oct 2020 (Study Day 61)
COVID-19	Grade 3/severe	Not related	09 Dec 2020 (Study Day 112) - 05 Jan 2021 (Study Day 139)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378941

Participant Number:	US348-2286 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	12 Nov 2020 (Study Day 31)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 3/severe	Not related	04 Jan 2021 (Study Day 84) – 14 Jan 2021 (Study Day 94)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US348-2286, a 52-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 13 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 12 Nov 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 04 Jan 2021 (Study Day 84), 83 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 31, 12 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 08 Jan 2021 (Study Day 88), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
04 Jan 2021 (Study Day 84)	Body Aches	Mild
04 Jan 2021 (Study Day 84)	Cough	Mild
04 Jan 2021 (Study Day 84)	Fatigue	Mild
04 Jan 2021 (Study Day 84)	Headache	Mild
05 Jan 2021 (Study Day 85)	Body Aches	Mild
05 Jan 2021 (Study Day 85)	Cough	Mild

Symptom Date	Symptom	Result
05 Jan 2021 (Study Day 85)	Fatigue	Mild
06 Jan 2021 (Study Day 86)	Body Aches	Mild
06 Jan 2021 (Study Day 86)	Cough	Mild
06 Jan 2021 (Study Day 86)	Fatigue	Mild
07 Jan 2021 (Study Day 87)	Cough	Mild
08 Jan 2021 (Study Day 88)	Cough	Mild
08 Jan 2021 (Study Day 88)	O2 Saturation (%)	93
09 Jan 2021 (Study Day 89)	Cough	Mild
10 Jan 2021 (Study Day 90)	Body Aches	Mild
10 Jan 2021 (Study Day 90)	Cough	Mild
11 Jan 2021 (Study Day 91)	Body Aches	Mild
11 Jan 2021 (Study Day 91)	Cough	Mild
11 Jan 2021 (Study Day 91)	Fatigue	Mild
12 Jan 2021 (Study Day 92)	Body Aches	Severe
12 Jan 2021 (Study Day 92)	Chills	Moderate
12 Jan 2021 (Study Day 92)	Cough	Mild
12 Jan 2021 (Study Day 92)	Fatigue	Severe
12 Jan 2021 (Study Day 92)	Muscle Aches (Myalgia)	Severe
12 Jan 2021 (Study Day 92)	Temperature (°F)	101.5
13 Jan 2021 (Study Day 93)	Fatigue	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
08 Jan 2021 (Study Day 88)	Oxygen Saturation	93%
08 Jan 2021 - 08 Jan 2021 (Study Day 88-88)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 11 days, after which it was considered to be recovered/resolved on 14 Jan 2021 (Study Day 94). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010478	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Blood pressure increased	Elevated blood pressure	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	04 Jan 2021 (Study Day 84) - 28 Jan 2021 (Study Day 108)	Supplementation
Ibuprofen	04 Jan 2021 (Study Day 84) - 06 Jan 2021 (Study Day 86)	Body Aches Related To COVID-19
Vitamin d nos	04 Jan 2021 (Study Day 84) - 28 Jan 2021 (Study Day 108)	Supplementation
Zinc	04 Jan 2021 (Study Day 84) - 28 Jan 2021 (Study Day 108)	Supplementation
Ibuprofen	10 Jan 2021 (Study Day 90) - 15 Jan 2021 (Study Day 95)	Body Aches Related To COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	04 Jan 2021 (Study Day 84) - 14 Jan 2021 (Study Day 94)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US356-2015 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19 Infection	COVID-19	Grade 2/moderate	Not related	30 Dec 2020 (Study Day 147) – 18 Jan 2021 (Study Day 166)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US356-2015, a 48-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 30 Dec 2020 (Study Day 147), 146 days after the first dose and 118 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID 19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 03 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 31 Dec 2020 (Study Day 148), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
30 Dec 2020 (Study Day 147)	Nasal Congestion	Mild
31 Dec 2020 (Study Day 148)	Body Aches	Mild
31 Dec 2020 (Study Day 148)	Cough	Mild
31 Dec 2020 (Study Day 148)	Difficulty Breathing	Mild
31 Dec 2020 (Study Day 148)	Fatigue	Mild
31 Dec 2020 (Study Day 148)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
31 Dec 2020 (Study Day 148)	Nasal Congestion	Mild
31 Dec 2020 (Study Day 148)	Runny Nose (Rhinorrhea)	Mild
31 Dec 2020 (Study Day 148)	Shortness of Breath	Mild
31 Dec 2020 (Study Day 148)	Sore Throat	Mild
01 Jan 2021 (Study Day 149)	Body Aches	Mild
01 Jan 2021 (Study Day 149)	Fatigue	Mild
01 Jan 2021 (Study Day 149)	Muscle Aches (Myalgia)	Mild
01 Jan 2021 (Study Day 149)	Sore Throat	Moderate
02 Jan 2021 (Study Day 150)	Body Aches	Mild
02 Jan 2021 (Study Day 150)	Fatigue	Mild
02 Jan 2021 (Study Day 150)	Muscle Aches (Myalgia)	Mild
02 Jan 2021 (Study Day 150)	Nasal Congestion	Mild
02 Jan 2021 (Study Day 150)	Sore Throat	Mild
03 Jan 2021 (Study Day 151)	Body Aches	Mild
03 Jan 2021 (Study Day 151)	Fatigue	Mild
03 Jan 2021 (Study Day 151)	Muscle Aches (Myalgia)	Mild
03 Jan 2021 (Study Day 151)	Nasal Congestion	Mild
03 Jan 2021 (Study Day 151)	New Loss of Smell	Mild
03 Jan 2021 (Study Day 151)	New Loss of Taste	Mild
03 Jan 2021 (Study Day 151)	Sore Throat	Mild
04 Jan 2021 (Study Day 152)	Body Aches	Mild
04 Jan 2021 (Study Day 152)	Fatigue	Mild
04 Jan 2021 (Study Day 152)	Muscle Aches (Myalgia)	Mild
04 Jan 2021 (Study Day 152)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 152)	New Loss of Smell	Mild
04 Jan 2021 (Study Day 152)	New Loss of Taste	Mild
04 Jan 2021 (Study Day 152)	Sore Throat	Mild
05 Jan 2021 (Study Day 153)	Body Aches	Mild
05 Jan 2021 (Study Day 153)	Fatigue	Mild
05 Jan 2021 (Study Day 153)	Muscle Aches (Myalgia)	Mild
05 Jan 2021 (Study Day 153)	New Loss of Smell	Moderate
05 Jan 2021 (Study Day 153)	New Loss of Taste	Moderate
05 Jan 2021 (Study Day 153)	Sore Throat	Mild
06 Jan 2021 (Study Day 154)	Body Aches	Mild
06 Jan 2021 (Study Day 154)	Cough	Mild
06 Jan 2021 (Study Day 154)	Diarrhea	Mild
06 Jan 2021 (Study Day 154)	Fatigue	Moderate
06 Jan 2021 (Study Day 154)	Headache	Mild
06 Jan 2021 (Study Day 154)	Muscle Aches (Myalgia)	Mild
06 Jan 2021 (Study Day 154)	New Loss of Smell	Moderate
06 Jan 2021 (Study Day 154)	New Loss of Taste	Moderate
06 Jan 2021 (Study Day 154)	Sore Throat	Mild
07 Jan 2021 (Study Day 155)	Body Aches	Mild

Symptom Date	Symptom	Result
07 Jan 2021 (Study Day 155)	Cough	Mild
07 Jan 2021 (Study Day 155)	Diarrhea	Mild
07 Jan 2021 (Study Day 155)	Fatigue	Moderate
07 Jan 2021 (Study Day 155)	Headache	Mild
07 Jan 2021 (Study Day 155)	Muscle Aches (Myalgia)	Mild
07 Jan 2021 (Study Day 155)	New Loss of Smell	Mild
07 Jan 2021 (Study Day 155)	New Loss of Taste	Mild
07 Jan 2021 (Study Day 155)	Runny Nose (Rhinorrhea)	Moderate
07 Jan 2021 (Study Day 155)	Sore Throat	Mild
08 Jan 2021 (Study Day 156)	Body Aches	Moderate
08 Jan 2021 (Study Day 156)	Chills	Mild
08 Jan 2021 (Study Day 156)	Cough	Moderate
08 Jan 2021 (Study Day 156)	Diarrhea	Moderate
08 Jan 2021 (Study Day 156)	Difficulty Breathing	Moderate
08 Jan 2021 (Study Day 156)	Fatigue	Moderate
08 Jan 2021 (Study Day 156)	Headache	Moderate
08 Jan 2021 (Study Day 156)	Muscle Aches (Myalgia)	Moderate
08 Jan 2021 (Study Day 156)	Nasal Congestion	Moderate
08 Jan 2021 (Study Day 156)	New Loss of Smell	Moderate
08 Jan 2021 (Study Day 156)	New Loss of Taste	Moderate
08 Jan 2021 (Study Day 156)	O2 Saturation (%)	92
08 Jan 2021 (Study Day 156)	Runny Nose (Rhinorrhea)	Moderate
08 Jan 2021 (Study Day 156)	Shortness of Breath	Moderate
08 Jan 2021 (Study Day 156)	Sore Throat	Mild
08 Jan 2021 (Study Day 156)	Temperature (°F)	102.8
09 Jan 2021 (Study Day 157)	Body Aches	Moderate
09 Jan 2021 (Study Day 157)	Chills	Moderate
09 Jan 2021 (Study Day 157)	Cough	Moderate
09 Jan 2021 (Study Day 157)	Diarrhea	Mild
09 Jan 2021 (Study Day 157)	Difficulty Breathing	Mild
09 Jan 2021 (Study Day 157)	Fatigue	Moderate
09 Jan 2021 (Study Day 157)	Headache	Moderate
09 Jan 2021 (Study Day 157)	Muscle Aches (Myalgia)	Moderate
09 Jan 2021 (Study Day 157)	Nasal Congestion	Moderate
09 Jan 2021 (Study Day 157)	New Loss of Smell	Moderate
09 Jan 2021 (Study Day 157)	New Loss of Taste	Moderate
09 Jan 2021 (Study Day 157)	Runny Nose (Rhinorrhea)	Moderate
09 Jan 2021 (Study Day 157)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 157)	Sore Throat	Mild
10 Jan 2021 (Study Day 158)	Body Aches	Moderate
10 Jan 2021 (Study Day 158)	Chills	Moderate
10 Jan 2021 (Study Day 158)	Cough	Moderate
10 Jan 2021 (Study Day 158)	Diarrhea	Mild

Symptom Date	Symptom	Result
10 Jan 2021 (Study Day 158)	Difficulty Breathing	Mild
10 Jan 2021 (Study Day 158)	Fatigue	Moderate
10 Jan 2021 (Study Day 158)	Muscle Aches (Myalgia)	Moderate
10 Jan 2021 (Study Day 158)	Nasal Congestion	Moderate
10 Jan 2021 (Study Day 158)	New Loss of Smell	Mild
10 Jan 2021 (Study Day 158)	New Loss of Taste	Mild
10 Jan 2021 (Study Day 158)	Runny Nose (Rhinorrhea)	Moderate
10 Jan 2021 (Study Day 158)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 158)	Sore Throat	Mild
11 Jan 2021 (Study Day 159)	Body Aches	Mild
11 Jan 2021 (Study Day 159)	Cough	Moderate
11 Jan 2021 (Study Day 159)	Diarrhea	Mild
11 Jan 2021 (Study Day 159)	Fatigue	Moderate
11 Jan 2021 (Study Day 159)	Headache	Mild
11 Jan 2021 (Study Day 159)	Muscle Aches (Myalgia)	Mild
11 Jan 2021 (Study Day 159)	Nasal Congestion	Moderate
11 Jan 2021 (Study Day 159)	New Loss of Smell	Mild
11 Jan 2021 (Study Day 159)	New Loss of Taste	Mild
11 Jan 2021 (Study Day 159)	Runny Nose (Rhinorrhea)	Mild
11 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 159)	Sore Throat	Mild
12 Jan 2021 (Study Day 160)	Body Aches	Mild
12 Jan 2021 (Study Day 160)	Cough	Moderate
12 Jan 2021 (Study Day 160)	Diarrhea	Mild
12 Jan 2021 (Study Day 160)	Difficulty Breathing	Mild
12 Jan 2021 (Study Day 160)	Fatigue	Moderate
12 Jan 2021 (Study Day 160)	Headache	Mild
12 Jan 2021 (Study Day 160)	Muscle Aches (Myalgia)	Mild
12 Jan 2021 (Study Day 160)	Nasal Congestion	Moderate
12 Jan 2021 (Study Day 160)	New Loss of Smell	Mild
12 Jan 2021 (Study Day 160)	New Loss of Taste	Mild
12 Jan 2021 (Study Day 160)	Runny Nose (Rhinorrhea)	Mild
12 Jan 2021 (Study Day 160)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 160)	Sore Throat	Mild
13 Jan 2021 (Study Day 161)	Body Aches	Mild
13 Jan 2021 (Study Day 161)	Cough	Mild
13 Jan 2021 (Study Day 161)	Diarrhea	Mild
13 Jan 2021 (Study Day 161)	Difficulty Breathing	Mild
13 Jan 2021 (Study Day 161)	Fatigue	Moderate
13 Jan 2021 (Study Day 161)	Headache	Mild
13 Jan 2021 (Study Day 161)	Muscle Aches (Myalgia)	Mild
13 Jan 2021 (Study Day 161)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 161)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
13 Jan 2021 (Study Day 161)	New Loss of Taste	Mild
13 Jan 2021 (Study Day 161)	Runny Nose (Rhinorrhea)	Mild
13 Jan 2021 (Study Day 161)	Shortness of Breath	Mild
13 Jan 2021 (Study Day 161)	Sore Throat	Mild
14 Jan 2021 (Study Day 162)	Cough	Mild
14 Jan 2021 (Study Day 162)	Difficulty Breathing	Mild
14 Jan 2021 (Study Day 162)	Fatigue	Mild
14 Jan 2021 (Study Day 162)	Nasal Congestion	Mild
14 Jan 2021 (Study Day 162)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 163)	Cough	Mild
15 Jan 2021 (Study Day 163)	Difficulty Breathing	Mild
15 Jan 2021 (Study Day 163)	Fatigue	Mild
15 Jan 2021 (Study Day 163)	Nasal Congestion	Mild
15 Jan 2021 (Study Day 163)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 164)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
08 Jan 2021 (Study Day 156)	Oxygen Saturation	92%
08 Jan 2021 - 09 Jan 2021 (Study Day 156-157)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 infection lasted for 20 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 166). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002691	COVID-19

Study Completion/Discontinuation

On 23 Mar 2021 (Study Day 230), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1993 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2011 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2011 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2014 - Ongoing
Prostatomegaly	Enlarged prostate	2014 - Ongoing
Seasonal allergy	Seasonal allergies	2016 - Ongoing
Hepatic steatosis	Fatty liver	2017 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2017 - Ongoing
Depression	Depression	2020 - Ongoing
Haemorrhoids	Internal hemorrhoids	Jan 2020 - Jan 2020
Euglycaemic diabetic ketoacidosis	Euglycemic dka	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin hydrochloride	2011 - Ongoing	Diabetes Type Ii
Atorvastatin calcium	2014 - Ongoing	Hyperlipidemia
Linagliptin	2014 - Ongoing	Diabetes Type Ii
Tamsulosin	2014 - Ongoing	Enlarged Prostate
Fluticasone propionate	2016 - Ongoing	Seasonal Allergies
Aripiprazole	2020 - Ongoing	Depression
Loratadine	2020 - Ongoing	Seasonal Allergies
Sertraline hydrochloride	2020 - Ongoing	Depression
Insulin lispro	Jan 2020 - Ongoing	Diabetes Type Ii
Insulin glargine	Feb 2020 - Ongoing	Diabetes Type Ii
Cetirizine hydrochloride; pseudoephedrine hydrochloride	07 Jan 2021 (Study Day 155) - 17 Jan 2021 (Study Day 165)	COVID 19 Infection
Ibuprofen	08 Jan 2021 (Study Day 156) - 08 Jan 2021 (Study Day 156)	COVID 19 Infection
Other antivirals	08 Jan 2021 (Study Day 156) - 08 Jan 2021 (Study Day 156)	COVID 19 Infection
Paracetamol	08 Jan 2021 (Study Day 156) - 08 Jan 2021 (Study Day 156)	COVID 19 Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	30 Dec 2020 (Study Day 147) - 18 Jan 2021 (Study Day 166)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3378951

Participant Number:	US356-2040 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 36)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19 Infection	COVID-19	Grade 2/moderate	Not related	26 Nov 2020 (Study Day 105) – 15 Dec 2020 (Study Day 124)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US356-2040, a 45-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 26 Nov 2020 (Study Day 105), 104 days after the first dose and 69 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID 19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 36, 18 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 02 Dec 2020 (Study Day 111), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
26 Nov 2020 (Study Day 105)	Headache	Mild
27 Nov 2020 (Study Day 106)	Cough	Mild
27 Nov 2020 (Study Day 106)	Fatigue	Mild
27 Nov 2020 (Study Day 106)	Headache	Mild
27 Nov 2020 (Study Day 106)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 106)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
28 Nov 2020 (Study Day 107)	Cough	Mild
28 Nov 2020 (Study Day 107)	Fatigue	Mild
28 Nov 2020 (Study Day 107)	Headache	Mild
28 Nov 2020 (Study Day 107)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 108)	Cough	Mild
29 Nov 2020 (Study Day 108)	Fatigue	Mild
29 Nov 2020 (Study Day 108)	Headache	Mild
29 Nov 2020 (Study Day 108)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 109)	Cough	Mild
30 Nov 2020 (Study Day 109)	Fatigue	Mild
30 Nov 2020 (Study Day 109)	Headache	Mild
30 Nov 2020 (Study Day 109)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
01 Dec 2020 (Study Day 110)	Cough	Mild
01 Dec 2020 (Study Day 110)	Fatigue	Mild
01 Dec 2020 (Study Day 110)	Headache	Mild
01 Dec 2020 (Study Day 110)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 110)	Runny Nose (Rhinorrhea)	Mild
02 Dec 2020 (Study Day 111)	Fatigue	Mild
02 Dec 2020 (Study Day 111)	Headache	Mild
02 Dec 2020 (Study Day 111)	Nasal Congestion	Mild
02 Dec 2020 (Study Day 111)	New Loss of Smell	Mild
02 Dec 2020 (Study Day 111)	New Loss of Taste	Mild
02 Dec 2020 (Study Day 111)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 112)	Cough	Mild
03 Dec 2020 (Study Day 112)	Fatigue	Moderate
03 Dec 2020 (Study Day 112)	Headache	Mild
03 Dec 2020 (Study Day 112)	Muscle Aches (Myalgia)	Moderate
03 Dec 2020 (Study Day 112)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 112)	Nausea	Mild
03 Dec 2020 (Study Day 112)	New Loss of Taste	Moderate
04 Dec 2020 (Study Day 113)	Cough	Mild
04 Dec 2020 (Study Day 113)	Fatigue	Mild
04 Dec 2020 (Study Day 113)	Muscle Aches (Myalgia)	Mild
04 Dec 2020 (Study Day 113)	Nasal Congestion	Mild
04 Dec 2020 (Study Day 113)	New Loss of Taste	Moderate
05 Dec 2020 (Study Day 114)	Body Aches	Mild
05 Dec 2020 (Study Day 114)	Cough	Mild
05 Dec 2020 (Study Day 114)	Fatigue	Mild
05 Dec 2020 (Study Day 114)	Nasal Congestion	Mild
05 Dec 2020 (Study Day 114)	New Loss of Taste	Moderate

Symptom Date	Symptom	Result
06 Dec 2020 (Study Day 115)	Body Aches	Mild
06 Dec 2020 (Study Day 115)	Cough	Mild
06 Dec 2020 (Study Day 115)	Fatigue	Mild
06 Dec 2020 (Study Day 115)	Headache	Mild
06 Dec 2020 (Study Day 115)	Nasal Congestion	Mild
06 Dec 2020 (Study Day 115)	New Loss of Taste	Moderate
07 Dec 2020 (Study Day 116)	Cough	Mild
07 Dec 2020 (Study Day 116)	Difficulty Breathing	Mild
07 Dec 2020 (Study Day 116)	Fatigue	Mild
07 Dec 2020 (Study Day 116)	New Loss of Taste	Moderate
07 Dec 2020 (Study Day 116)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 117)	Fatigue	Mild
08 Dec 2020 (Study Day 117)	New Loss of Smell	Mild
08 Dec 2020 (Study Day 117)	New Loss of Taste	Mild
08 Dec 2020 (Study Day 117)	Shortness of Breath	Mild
09 Dec 2020 (Study Day 118)	Fatigue	Mild
09 Dec 2020 (Study Day 118)	New Loss of Smell	Moderate
09 Dec 2020 (Study Day 118)	New Loss of Taste	Moderate
10 Dec 2020 (Study Day 119)	Fatigue	Mild
10 Dec 2020 (Study Day 119)	New Loss of Smell	Moderate
10 Dec 2020 (Study Day 119)	New Loss of Taste	Moderate
11 Dec 2020 (Study Day 120)	New Loss of Smell	Mild
11 Dec 2020 (Study Day 120)	New Loss of Taste	Mild
14 Dec 2020 (Study Day 123)	New Loss of Smell	Mild
14 Dec 2020 (Study Day 123)	New Loss of Taste	Mild

The participant had no reported indications of Severe COVID-19 infection.

Action taken with the IP was not applicable. The event of COVID 19 infection lasted for 20 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 124). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001048	COVID-19

Study Completion/Discontinuation

On 04 Jan 2021 (Study Day 144), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Attention deficit hyperactivity disorder	Attention-deficit/hyperactivity disorder	2010 - Ongoing
Anxiety	Anxiety	2015 - Ongoing
Depression	Depression	2015 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine	2010 - Ongoing	Seasonal Allergies
Bupropion	2018 - Ongoing	Depression
Lisdexamfetamine mesilate	2018 - Ongoing	Attention Deficit Hyperactivity Disorder
Sertraline	2018 - Ongoing	Depression
Clonazepam	2019 - Ongoing	Anxiety
Ibuprofen	14 Aug 2020 (Study Day 1) - 14 Aug 2020 (Study Day 1)	Headaches
Influenza vaccine	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Flu Prophylaxis
Other viral vaccines	Dec 2020 - Dec 2020	COVID 19 Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	26 Nov 2020 (Study Day 105) - 15 Dec 2020 (Study Day 124)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US357-2324 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	21 Oct 2020 (Study Day 30)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	21 Dec 2020 (Study Day 91) – 20 Jan 2021 (Study Day 121)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US357-2324, a 41-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 22 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 21 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 21 Dec 2020 (Study Day 91), 90 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 21 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 25 Dec 2020 (Study Day 95), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
21 Dec 2020 (Study Day 91)	Diarrhea	Mild
22 Dec 2020 (Study Day 92)	Body Aches	Mild
22 Dec 2020 (Study Day 92)	Chills	Mild
22 Dec 2020 (Study Day 92)	Diarrhea	Mild
23 Dec 2020 (Study Day 93)	Body Aches	Mild
23 Dec 2020 (Study Day 93)	Chills	Mild
23 Dec 2020 (Study Day 93)	Diarrhea	Mild

Symptom Date	Symptom	Result
24 Dec 2020 (Study Day 94)	Body Aches	Mild
24 Dec 2020 (Study Day 94)	Chills	Mild
24 Dec 2020 (Study Day 94)	Diarrhea	Mild
25 Dec 2020 (Study Day 95)	Body Aches	Mild
25 Dec 2020 (Study Day 95)	Chills	Mild
25 Dec 2020 (Study Day 95)	Diarrhea	Mild
25 Dec 2020 (Study Day 95)	O2 Saturation (%)	93
26 Dec 2020 (Study Day 96)	Body Aches	Mild
26 Dec 2020 (Study Day 96)	Chills	Mild
26 Dec 2020 (Study Day 96)	Diarrhea	Mild
27 Dec 2020 (Study Day 97)	Body Aches	Mild
27 Dec 2020 (Study Day 97)	Chills	Mild
27 Dec 2020 (Study Day 97)	Diarrhea	Mild
28 Dec 2020 (Study Day 98)	Body Aches	Mild
28 Dec 2020 (Study Day 98)	Chills	Mild
28 Dec 2020 (Study Day 98)	Diarrhea	Mild
29 Dec 2020 (Study Day 99)	Body Aches	Mild
29 Dec 2020 (Study Day 99)	Chills	Mild
30 Dec 2020 (Study Day 100)	Body Aches	Mild
30 Dec 2020 (Study Day 100)	Chills	Mild
31 Dec 2020 (Study Day 101)	Body Aches	Mild
31 Dec 2020 (Study Day 101)	Chills	Mild
31 Dec 2020 (Study Day 101)	Cough	Mild
31 Dec 2020 (Study Day 101)	Diarrhea	Mild
31 Dec 2020 (Study Day 101)	Headache	Mild
31 Dec 2020 (Study Day 101)	New Loss of Smell	Mild
31 Dec 2020 (Study Day 101)	New Loss of Taste	Mild
01 Jan 2021 (Study Day 102)	Body Aches	Mild
01 Jan 2021 (Study Day 102)	Chills	Mild
01 Jan 2021 (Study Day 102)	Cough	Mild
01 Jan 2021 (Study Day 102)	Diarrhea	Mild
01 Jan 2021 (Study Day 102)	Headache	Mild
01 Jan 2021 (Study Day 102)	New Loss of Smell	Mild
01 Jan 2021 (Study Day 102)	New Loss of Taste	Mild
02 Jan 2021 (Study Day 103)	Cough	Mild
02 Jan 2021 (Study Day 103)	Diarrhea	Mild
02 Jan 2021 (Study Day 103)	Headache	Mild
03 Jan 2021 (Study Day 104)	Cough	Mild
03 Jan 2021 (Study Day 104)	Diarrhea	Mild
03 Jan 2021 (Study Day 104)	Fatigue	Mild
03 Jan 2021 (Study Day 104)	Headache	Mild
04 Jan 2021 (Study Day 105)	Cough	Mild
04 Jan 2021 (Study Day 105)	Diarrhea	Mild

Symptom Date	Symptom	Result
04 Jan 2021 (Study Day 105)	Fatigue	Mild
04 Jan 2021 (Study Day 105)	Headache	Mild
05 Jan 2021 (Study Day 106)	Diarrhea	Mild
05 Jan 2021 (Study Day 106)	Fatigue	Mild
05 Jan 2021 (Study Day 106)	Headache	Mild
06 Jan 2021 (Study Day 107)	Diarrhea	Mild
06 Jan 2021 (Study Day 107)	Fatigue	Mild
06 Jan 2021 (Study Day 107)	Headache	Mild
07 Jan 2021 (Study Day 108)	Diarrhea	Mild
07 Jan 2021 (Study Day 108)	Headache	Mild
08 Jan 2021 (Study Day 109)	Diarrhea	Mild
08 Jan 2021 (Study Day 109)	Headache	Mild
09 Jan 2021 (Study Day 110)	Diarrhea	Mild
09 Jan 2021 (Study Day 110)	Headache	Mild
10 Jan 2021 (Study Day 111)	Diarrhea	Mild
10 Jan 2021 (Study Day 111)	Headache	Mild
11 Jan 2021 (Study Day 112)	Diarrhea	Mild
11 Jan 2021 (Study Day 112)	Headache	Mild
12 Jan 2021 (Study Day 113)	Diarrhea	Mild
12 Jan 2021 (Study Day 113)	Headache	Mild
13 Jan 2021 (Study Day 114)	Diarrhea	Mild
13 Jan 2021 (Study Day 114)	Headache	Mild
14 Jan 2021 (Study Day 115)	Diarrhea	Mild
14 Jan 2021 (Study Day 115)	Headache	Mild
15 Jan 2021 (Study Day 116)	Diarrhea	Mild
15 Jan 2021 (Study Day 116)	Headache	Mild
16 Jan 2021 (Study Day 117)	Diarrhea	Mild
16 Jan 2021 (Study Day 117)	Headache	Mild
17 Jan 2021 (Study Day 118)	Diarrhea	Mild
17 Jan 2021 (Study Day 118)	Headache	Mild
19 Jan 2021 (Study Day 120)	Headache	Mild
20 Jan 2021 (Study Day 121)	Headache	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
25 Dec 2020 (Study Day 95)	Oxygen Saturation	93%
25 Dec 2020 - 25 Dec 2020 (Study Day 95-95)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 31 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 121). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Dyslipidaemia	Dyslipidemia	2016 - Ongoing
Urticaria	Hives	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	09 Nov 2020 (Study Day 49) - 09 Nov 2020 (Study Day 49)	Vaccination

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	21 Dec 2020 (Study Day 91) - 20 Jan 2021 (Study Day 121)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2075 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	05 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	23 Dec 2020 (Study Day 138) – 11 Jan 2021 (Study Day 157)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US359-2075, a 65-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 05 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 23 Dec 2020 (Study Day 138), 137 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 05 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Dec 2020 (Study Day 143), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
23 Dec 2020 (Study Day 138)	Headache	Mild
24 Dec 2020 (Study Day 139)	Headache	Mild
25 Dec 2020 (Study Day 140)	Cough	Mild
25 Dec 2020 (Study Day 140)	Headache	Mild
25 Dec 2020 (Study Day 140)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
25 Dec 2020 (Study Day 140)	Nasal Congestion	Mild
25 Dec 2020 (Study Day 140)	Runny Nose (Rhinorrhea)	Mild
25 Dec 2020 (Study Day 140)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 141)	Cough	Mild
26 Dec 2020 (Study Day 141)	Headache	Mild
26 Dec 2020 (Study Day 141)	Muscle Aches (Myalgia)	Mild
26 Dec 2020 (Study Day 141)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 141)	Runny Nose (Rhinorrhea)	Mild
26 Dec 2020 (Study Day 141)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 142)	Cough	Mild
27 Dec 2020 (Study Day 142)	Headache	Mild
27 Dec 2020 (Study Day 142)	Muscle Aches (Myalgia)	Mild
27 Dec 2020 (Study Day 142)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 143)	Cough	Mild
28 Dec 2020 (Study Day 143)	Headache	Mild
28 Dec 2020 (Study Day 143)	Muscle Aches (Myalgia)	Mild
28 Dec 2020 (Study Day 143)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 144)	Cough	Mild
29 Dec 2020 (Study Day 144)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 145)	Body Aches	Mild
30 Dec 2020 (Study Day 145)	Cough	Moderate
30 Dec 2020 (Study Day 145)	Diarrhea	Mild
30 Dec 2020 (Study Day 145)	Fatigue	Mild
30 Dec 2020 (Study Day 145)	Muscle Aches (Myalgia)	Mild
30 Dec 2020 (Study Day 145)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 145)	Runny Nose (Rhinorrhea)	Mild
30 Dec 2020 (Study Day 145)	Sore Throat	Mild
31 Dec 2020 (Study Day 146)	Cough	Mild
31 Dec 2020 (Study Day 146)	Diarrhea	Mild
31 Dec 2020 (Study Day 146)	Fatigue	Mild
31 Dec 2020 (Study Day 146)	Nasal Congestion	Mild
31 Dec 2020 (Study Day 146)	New Loss of Taste	Mild
01 Jan 2021 (Study Day 147)	Cough	Mild
01 Jan 2021 (Study Day 147)	Fatigue	Moderate
01 Jan 2021 (Study Day 147)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 147)	New Loss of Taste	Mild
02 Jan 2021 (Study Day 148)	Cough	Mild
02 Jan 2021 (Study Day 148)	Diarrhea	Mild
02 Jan 2021 (Study Day 148)	New Loss of Taste	Mild
03 Jan 2021 (Study Day 149)	Cough	Mild
03 Jan 2021 (Study Day 149)	Fatigue	Moderate
03 Jan 2021 (Study Day 149)	New Loss of Taste	Mild
04 Jan 2021 (Study Day 150)	Diarrhea	Mild

Symptom Date	Symptom	Result
04 Jan 2021 (Study Day 150)	Fatigue	Mild
04 Jan 2021 (Study Day 150)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 150)	O2 Saturation (%)	91
05 Jan 2021 (Study Day 151)	Cough	Mild
05 Jan 2021 (Study Day 151)	Diarrhea	Mild
05 Jan 2021 (Study Day 151)	Fatigue	Mild
05 Jan 2021 (Study Day 151)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 152)	Cough	Mild
06 Jan 2021 (Study Day 152)	Diarrhea	Mild
06 Jan 2021 (Study Day 152)	Nasal Congestion	Mild
07 Jan 2021 (Study Day 153)	Cough	Mild
07 Jan 2021 (Study Day 153)	Diarrhea	Mild
07 Jan 2021 (Study Day 153)	Fatigue	Mild
09 Jan 2021 (Study Day 155)	Cough	Mild
10 Jan 2021 (Study Day 156)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
04 Jan 2021 (Study Day 150)	Oxygen Saturation	91%
04 Jan 2021 - 04 Jan 2021 (Study Day 150-150)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 157). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015312	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1960 - Ongoing
Depression	Depression	1985 - Ongoing
Neuropathy peripheral	Idiopathic neuropathy bilateral feet	1988 - Ongoing
Peripheral sensory neuropathy	Idiopathic neuropathy bilateral legs sensory	1988 - Ongoing
Hypertension	Hypertension	1990 - Ongoing
Hyperglycaemia	Hyperglycemia	1993 - Ongoing
Hysterectomy	Total hysterectomy	2009 - 2009
Oestrogen deficiency	Estrogen deficiency	2009 - Ongoing
Uterine leiomyoma	Uterine fibroids	2009 - 2009
Osteoarthritis	Osteoarthritis bilateral thumbs, left knee	2010 - Ongoing
Upper respiratory tract infection	Recurrent upper respiratory infection	2014 - Ongoing
Deafness unilateral	Hearing loss right ear	2015 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	2018 - Ongoing
Joint injury	Injured left knee	2020 - Ongoing
Hypertonic bladder	Overactive bladder	Feb 2020 - Ongoing
Oedema peripheral	Edema left lower leg	Feb 2020 - Ongoing
Hypertonic bladder	Overactive bladder	08 Aug 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diltiazem	1990 - Ongoing	Hypertension
Paroxetine	2005 - Ongoing	Depression
Metformin	2006 - Ongoing	Hyperglycemia
Meloxicam	2010 - Ongoing	Osteoarthritis Bilateral Thumbs, Left Knee
Oxybutynin	Mar 2020 - Ongoing	Overactive Bladder
Lisinopril	30 Aug 2020 (Study Day 23) - 15 Sep 2020 (Study Day 39)	Hypertension
Paracetamol	05 Sep 2020 (Study Day 29) - 08 Sep 2020 (Study Day 32)	Headache
Lisinopril	16 Sep 2020 (Study Day 40) - Ongoing	Worsening Of Hypertension
Betamethasone	07 Oct 2020 (Study Day 61) - 07 Oct 2020 (Study Day 61)	Osteoarthritis Left Knee
Bupivacaine	07 Oct 2020 (Study Day 61) - 07 Oct 2020 (Study Day 61)	Osteoarthritis Left Knee
Lidocaine	07 Oct 2020 (Study Day 61) - 07 Oct 2020 (Study Day 61)	Osteoarthritis Left Knee
Influenza vaccine	25 Oct 2020 (Study Day 79) - 25 Oct 2020 (Study Day 79)	Influenza Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	23 Dec 2020 (Study Day 138) - 23 Dec 2020 (Study Day 138)	Swollen Right Eye
Polymyxin b	23 Dec 2020 (Study Day 138) - Ongoing	Swollen Right Eye
Azithromycin	24 Dec 2020 (Study Day 139) - 28 Dec 2020 (Study Day 143)	Swollen Right Eye

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	10 Sep 2020 (Study Day 34) - 30 Sep 2020 (Study Day 54)
COVID-19	Grade 1/mild	Not related	23 Dec 2020 (Study Day 138) - 11 Jan 2021 (Study Day 157)
Eye Swelling	Grade 1/mild	Not related	23 Dec 2020 (Study Day 138) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2127 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 31)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	11 Nov 2020 (Study Day 93) – 30 Nov 2020 (Study Day 112)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US359-2127, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 11 Nov 2020 (Study Day 93), 92 days after the first dose and 62 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 31, 10 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 13 Nov 2020 (Study Day 95), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Nov 2020 (Study Day 93)	Body Aches	Mild
11 Nov 2020 (Study Day 93)	Chills	Severe
11 Nov 2020 (Study Day 93)	Fatigue	Moderate
11 Nov 2020 (Study Day 93)	Headache	Moderate
11 Nov 2020 (Study Day 93)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
11 Nov 2020 (Study Day 93)	Runny Nose (Rhinorrhea)	Mild
11 Nov 2020 (Study Day 93)	Shortness of Breath	Moderate
12 Nov 2020 (Study Day 94)	Diarrhea	Mild
12 Nov 2020 (Study Day 94)	Fatigue	Moderate
12 Nov 2020 (Study Day 94)	Headache	Moderate
12 Nov 2020 (Study Day 94)	Runny Nose (Rhinorrhea)	Mild
13 Nov 2020 (Study Day 95)	Diarrhea	Mild
13 Nov 2020 (Study Day 95)	Fatigue	Moderate
13 Nov 2020 (Study Day 95)	Headache	Mild
13 Nov 2020 (Study Day 95)	Runny Nose (Rhinorrhea)	Mild
13 Nov 2020 (Study Day 95)	Sore Throat	Mild
14 Nov 2020 (Study Day 96)	Body Aches	Mild
14 Nov 2020 (Study Day 96)	Cough	Mild
14 Nov 2020 (Study Day 96)	Fatigue	Mild
14 Nov 2020 (Study Day 96)	Headache	Moderate
14 Nov 2020 (Study Day 96)	Muscle Aches (Myalgia)	Mild
14 Nov 2020 (Study Day 96)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 96)	O2 Saturation (%)	93
14 Nov 2020 (Study Day 96)	Runny Nose (Rhinorrhea)	Moderate
14 Nov 2020 (Study Day 96)	Sore Throat	Mild
15 Nov 2020 (Study Day 97)	Cough	Mild
15 Nov 2020 (Study Day 97)	Nausea	Mild
15 Nov 2020 (Study Day 97)	Runny Nose (Rhinorrhea)	Mild
15 Nov 2020 (Study Day 97)	Sore Throat	Mild
15 Nov 2020 (Study Day 97)	Vomiting	Mild
16 Nov 2020 (Study Day 98)	Cough	Mild
16 Nov 2020 (Study Day 98)	Headache	Moderate
16 Nov 2020 (Study Day 98)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 98)	Runny Nose (Rhinorrhea)	Mild
16 Nov 2020 (Study Day 98)	Sore Throat	Mild
17 Nov 2020 (Study Day 99)	Cough	Mild
17 Nov 2020 (Study Day 99)	Nasal Congestion	Mild
17 Nov 2020 (Study Day 99)	Runny Nose (Rhinorrhea)	Mild
18 Nov 2020 (Study Day 100)	Cough	Mild
18 Nov 2020 (Study Day 100)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 101)	Cough	Mild
19 Nov 2020 (Study Day 101)	Runny Nose (Rhinorrhea)	Mild
20 Nov 2020 (Study Day 102)	Cough	Mild
20 Nov 2020 (Study Day 102)	Runny Nose (Rhinorrhea)	Mild
21 Nov 2020 (Study Day 103)	Cough	Mild
21 Nov 2020 (Study Day 103)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 104)	Runny Nose (Rhinorrhea)	Mild
23 Nov 2020 (Study Day 105)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
24 Nov 2020 (Study Day 106)	Runny Nose (Rhinorrhea)	Mild
25 Nov 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
27 Nov 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
28 Nov 2020 (Study Day 110)	Runny Nose (Rhinorrhea)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
14 Nov 2020 (Study Day 96)	Oxygen Saturation	93%
14 Nov 2020 - 14 Nov 2020 (Study Day 96-96)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 112). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000836	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2008 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2008 - Ongoing
Hypermetropia	Hyperopia	2009 - Ongoing
Menorrhagia	Menorrhagia	2009 - Feb 2019
Myopia	Myopia	2009 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Osteoarthritis	Bilateral knee osteoarthritis	2010 - Ongoing
Neuropathy peripheral	Bilateral feet neuropathy, idiopathic	2012 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	2013 - Ongoing
Rhinitis allergic	Allergic rhinitis	2015 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Carpal tunnel syndrome	Bilateral carpal tunnel	2016 - Jun 2020
Anxiety	Anxiety	2018 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	Dec 2018 - Ongoing
Hysterectomy	Hysterectomy	Feb 2019 - Feb 2019
Iron deficiency	Iron deficiency	Feb 2019 - Ongoing
Hypertonic bladder	Overactive bladder	May 2019 - Ongoing
Carpal tunnel decompression	Right carpal tunnel surgery	Aug 2019 - Aug 2019
Lumbar spinal stenosis	Spinal stenosis lumbar	Apr 2020 - Ongoing
Carpal tunnel decompression	Left carpal tunnel surgery	Jun 2020 - Jun 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2008 - Ongoing	Nutritional Supplement
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Pantoprazole sodium sesquihydrate	2010 - Ongoing	Acid Reflux
Rosuvastatin calcium	2010 - Ongoing	Hyperlipidemia
Fluticasone propionate	2015 - Ongoing	Allergic Rhinitis
Venlafaxine hydrochloride	2015 - Ongoing	Depression
Celecoxib	2018 - Ongoing	Bilateral Knee Osteoarthritis
Probiotics nos	2018 - Ongoing	Irritable Bowel Syndrome
Semaglutide	Feb 2019 - Ongoing	Diabetes Mellitus Type Ii
Oxybutynin	Jun 2019 - Ongoing	Overactive Bladder
Vitamins nos	Aug 2019 - Ongoing	Nutritional Supplement
Ascorbic acid; boswellia serrata; chondroitin sulfate sodium; colecalciferol; glucosamine sulfate potassium chloride; manganese sulfate; methylsulfonylmethane; sodium borate	Jan 2020 - Ongoing	Bilateral Knee Osteoarthritis
Chondroitin sulfate; glucosamine sulfate; methylsulfonylmethane	Jan 2020 - Ongoing	Bilateral Knee Ostearthritis
Influenza vaccine	20 Oct 2020 (Study Day 71) - 20 Oct 2020 (Study Day 71)	Influenza Prophylaxis
Liraglutide	03 Nov 2020 (Study Day 85) - Ongoing	Diabetes Type 2
Paracetamol	11 Nov 2020 (Study Day 93) - Ongoing	Headache, COVID 19
Ascorbic acid	13 Nov 2020 (Study Day 95) - Ongoing	Nutritional Supplement
Melatonin	13 Nov 2020 (Study Day 95) - Ongoing	Anxiety
Zinc	13 Nov 2020 (Study Day 95) - Ongoing	Nutritional Supplement
Total left knee replacement*	04 Dec 2020 (Study Day 116) - 04 Dec 2020 (Study Day 116)	Medical History
Oxycodone	05 Dec 2020 (Study Day 117) - Ongoing	Left Knee Pain Post Surgical
Paracetamol	05 Dec 2020 (Study Day 117) - Ongoing	Left Knee Pain Post Surgical

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	11 Nov 2020 (Study Day 93) - 30 Nov 2020 (Study Day 112)
Procedural Pain	Grade 1/mild	Not related	04 Dec 2020 (Study Day 116) - 15 Dec 2020 (Study Day 127)
Tinnitus	Grade 1/mild	Not related	15 Dec 2020 (Study Day 127) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US360-2074 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	19 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID - 19	SAE, COVID-19	Grade 3/severe	Not related	29 Nov 2020 (Study Day 70) – 11 Feb 2021 (Study Day 144)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US360-2074, a 50-year-old race unknown male, received the first dose of placebo in the left arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 19 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 29 Nov 2020 (Study Day 70), 69 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of symptomatic COVID - 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 19 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 02 Dec 2020 (Study Day 73), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
29 Nov 2020 (Study Day 70)	Sore Throat	Mild
30 Nov 2020 (Study Day 71)	Sore Throat	Mild
01 Dec 2020 (Study Day 72)	Chills	Moderate
01 Dec 2020 (Study Day 72)	Fatigue	Mild
01 Dec 2020 (Study Day 72)	Sore Throat	Mild
01 Dec 2020 (Study Day 72)	Temperature (°F)	102.0

Symptom Date	Symptom	Result
02 Dec 2020 (Study Day 73)	Chills	Moderate
02 Dec 2020 (Study Day 73)	Fatigue	Mild
02 Dec 2020 (Study Day 73)	Sore Throat	Mild
03 Dec 2020 (Study Day 74)	Chills	Mild
03 Dec 2020 (Study Day 74)	Fatigue	Mild
03 Dec 2020 (Study Day 74)	Headache	Mild
03 Dec 2020 (Study Day 74)	Sore Throat	Mild
03 Dec 2020 (Study Day 74)	Temperature (°F)	101
04 Dec 2020 (Study Day 75)	Cough	Mild
04 Dec 2020 (Study Day 75)	Fatigue	Mild
04 Dec 2020 (Study Day 75)	Sore Throat	Mild
05 Dec 2020 (Study Day 76)	Cough	Mild
05 Dec 2020 (Study Day 76)	Fatigue	Mild
05 Dec 2020 (Study Day 76)	Headache	Mild
05 Dec 2020 (Study Day 76)	Muscle Aches (Myalgia)	Mild
05 Dec 2020 (Study Day 76)	Temperature (°F)	102.2
06 Dec 2020 (Study Day 77)	Cough	Mild
06 Dec 2020 (Study Day 77)	Fatigue	Mild
06 Dec 2020 (Study Day 77)	Headache	Moderate
07 Dec 2020 (Study Day 78)	Body Aches	Mild
07 Dec 2020 (Study Day 78)	Cough	Mild
07 Dec 2020 (Study Day 78)	Headache	Mild
07 Dec 2020 (Study Day 78)	Muscle Aches (Myalgia)	Mild
08 Dec 2020 (Study Day 79)	Body Aches	Mild
08 Dec 2020 (Study Day 79)	Chills	Mild
08 Dec 2020 (Study Day 79)	Cough	Mild
08 Dec 2020 (Study Day 79)	Headache	Mild
08 Dec 2020 (Study Day 79)	Muscle Aches (Myalgia)	Mild
08 Dec 2020 (Study Day 79)	Nasal Congestion	Mild
08 Dec 2020 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 79)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 79)	Temperature (°F)	101
09 Dec 2020 (Study Day 80)	Body Aches	Mild
09 Dec 2020 (Study Day 80)	Chills	Mild
09 Dec 2020 (Study Day 80)	Cough	Mild
09 Dec 2020 (Study Day 80)	Muscle Aches (Myalgia)	Mild
09 Dec 2020 (Study Day 80)	Nasal Congestion	Mild
09 Dec 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
09 Dec 2020 (Study Day 80)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
10 Dec 2020 (Study Day 81)	Oxygen Saturation	83%
10 Dec 2020 - 10 Dec 2020 (Study Day 81-81)	Clinical Evidence of Pneumonia	Yes
10 Dec 2020 - 10 Dec 2020 (Study Day 81-81)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
10 Dec 2020 - 10 Dec 2020 (Study Day 81-81)	Radiographical Evidence of Pneumonia	Yes
10 Dec 2020 - 10 Dec 2020 (Study Day 81-81)	Respiratory Failure	Yes
11 Dec 2020 - 19 Dec 2020 (Study Day 82-90)	High-Flow Oxygen	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID - 19 lasted for 75 days, after which it was considered to be recovered/resolved with sequelae on 11 Feb 2021 (Study Day 144). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001108	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vitamin D deficiency	Vitamin d deficiency	Not reported - Ongoing
Tuberculin test positive	Positive ppdâ (purified protein derivative) tb test (due to bcg vaccine in childhood)	Jul 2020 - Jul 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2015 - Ongoing	Preventive Health
Zeaxanthin	2015 - Ongoing	For Eye Strength Preventative
Naproxen sodium	24 Oct 2020 (Study Day 34) - 24 Oct 2020 (Study Day 34)	Slight Headache
Azithromycin	30 Nov 2020 (Study Day 71) - 30 Nov 2020 (Study Day 71)	Sore Throat - Listed On Symptom Tracker Log
Azithromycin	01 Dec 2020 (Study Day 72) - 05 Dec 2020 (Study Day 76)	Sore Throat - Listed On Symptom Tracker Log
Naproxen sodium	02 Dec 2020 (Study Day 73) - 02 Dec 2020 (Study Day 73)	Fever - Listed On Symptom Tracker Log
Paracetamol	02 Dec 2020 (Study Day 73) - 02 Dec 2020 (Study Day 73)	Fever - Listed On Symptom Tracker Log
Ascorbic acid	03 Dec 2020 (Study Day 74) - Ongoing	Dietary/Nutritional Supplement
Naproxen sodium	03 Dec 2020 (Study Day 74) - 06 Dec 2020 (Study Day 77)	Headache - Listed In Sympton Tracker Log
Vitamin d nos	03 Dec 2020 (Study Day 74) - Ongoing	Dietary/Nutritional Supplement
Zinc	03 Dec 2020 (Study Day 74) - Ongoing	Dietary/Nutritional Supplement
Benzonatate	08 Dec 2020 (Study Day 79) - Ongoing	Cough
Salbutamol	08 Dec 2020 (Study Day 79) - Ongoing	Spasm Of Lung Air Passages And Wheezing
Azithromycin	10 Dec 2020 (Study Day 81) - 10 Dec 2020 (Study Day 81)	Pneumonia
Benzonatate	10 Dec 2020 (Study Day 81) - 20 Dec 2020 (Study Day 91)	Cough
Ceftriaxone	10 Dec 2020 (Study Day 81) - 16 Dec 2020 (Study Day 87)	Pneumonia
Chest x-ray*	10 Dec 2020 (Study Day 81) - 10 Dec 2020 (Study Day 81)	Adverse Event
Codeine phosphate; promethazine hydrochloride	10 Dec 2020 (Study Day 81) - 20 Dec 2020 (Study Day 91)	Cough
Dexamethasone	10 Dec 2020 (Study Day 81) - 10 Dec 2020 (Study Day 81)	COVID
Dexamethasone	10 Dec 2020 (Study Day 81) - 11 Dec 2020 (Study Day 82)	COVID
Dexamethasone	10 Dec 2020 (Study Day 81) - 17 Dec 2020 (Study Day 88)	COVID
Enoxaparin sodium	10 Dec 2020 (Study Day 81) - 14 Dec 2020 (Study Day 85)	Prevention Of Clots
Famotidine	10 Dec 2020 (Study Day 81) - 20 Dec 2020 (Study Day 91)	Gerd
Oxygen	10 Dec 2020 (Study Day 81) - 11 Feb 2021 (Study Day 144)	Due To COVID-19 (While Being Hospitalized)
Paracetamol	10 Dec 2020 (Study Day 81) - 20 Dec 2020 (Study Day 91)	Fever Relief
Remdesivir	10 Dec 2020 (Study Day 81) - 10 Dec 2020 (Study Day 81)	COVID
Salbutamol	10 Dec 2020 (Study Day 81) - 20 Dec 2020 (Study Day 91)	Dyspnea

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Remdesivir	11 Dec 2020 (Study Day 82) - 14 Dec 2020 (Study Day 85)	COVID
Tramadol hydrochloride	11 Dec 2020 (Study Day 82) - 20 Dec 2020 (Study Day 91)	Pain Relief
Melatonin	12 Dec 2020 (Study Day 83) - 19 Dec 2020 (Study Day 90)	Insomnia
Vancomycin hydrochloride	12 Dec 2020 (Study Day 83) - 13 Dec 2020 (Study Day 84)	Bacteremia
Loperamide hydrochloride	13 Dec 2020 (Study Day 84) - 20 Dec 2020 (Study Day 91)	Diarrhea
Vancomycin	13 Dec 2020 (Study Day 84) - 13 Dec 2020 (Study Day 84)	Bacteremia
Chest x-ray*	14 Dec 2020 (Study Day 85) - 14 Dec 2020 (Study Day 85)	Adverse Event
Enoxaparin sodium	14 Dec 2020 (Study Day 85) - 20 Dec 2020 (Study Day 91)	Prevention Of Blood Clots
Docusate sodium	16 Dec 2020 (Study Day 87) - 20 Dec 2020 (Study Day 91)	Constipation
Macrogol 3350	17 Dec 2020 (Study Day 88) - 20 Dec 2020 (Study Day 91)	Constipation
Dexamethasone	18 Dec 2020 (Study Day 89) - 20 Dec 2020 (Study Day 91)	COVID
Melatonin	19 Dec 2020 (Study Day 90) - 20 Dec 2020 (Study Day 91)	Insomnia
Chest x-ray*	20 Dec 2020 (Study Day 91) - 20 Dec 2020 (Study Day 91)	Adverse Event
Acetylsalicylic acid	21 Dec 2020 (Study Day 92) - Ongoing	Prevention Of Clots
Promethazine	21 Dec 2020 (Study Day 92) - Ongoing	Cough Suppressant - Captured In Illness Visit
Paracetamol	19 Jan 2021 (Study Day 121) - 19 Jan 2021 (Study Day 121)	Low Grade Fever Of 99.2 - Captured In Ediary The Day After Ip Was Administered

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Not related	29 Nov 2020 (Study Day 70) - 13 Dec 2020 (Study Day 84)
Dizziness	Grade 1/mild	Not related	05 Dec 2020 (Study Day 76) - 05 Dec 2020 (Study Day 76)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US361-2031 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 27)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	26 Dec 2020 (Study Day 108) – 08 Jan 2021 (Study Day 121)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US361-2031, a 67-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 26 Dec 2020 (Study Day 108), 107 days after the first dose and 81 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 27, 06 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Dec 2020 (Study Day 110), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
26 Dec 2020 (Study Day 108)	Body Aches	Mild
26 Dec 2020 (Study Day 108)	Chills	Mild
26 Dec 2020 (Study Day 108)	Cough	Moderate
26 Dec 2020 (Study Day 108)	Diarrhea	Moderate
26 Dec 2020 (Study Day 108)	Fatigue	Mild

Symptom Date	Symptom	Result
26 Dec 2020 (Study Day 108)	Headache	Severe
26 Dec 2020 (Study Day 108)	Muscle Aches (Myalgia)	Mild
26 Dec 2020 (Study Day 108)	Nasal Congestion	Moderate
26 Dec 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Moderate
26 Dec 2020 (Study Day 108)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 108)	Sore Throat	Mild
27 Dec 2020 (Study Day 109)	Chills	Mild
27 Dec 2020 (Study Day 109)	Cough	Mild
27 Dec 2020 (Study Day 109)	Diarrhea	Mild
27 Dec 2020 (Study Day 109)	Fatigue	Mild
27 Dec 2020 (Study Day 109)	Headache	Moderate
27 Dec 2020 (Study Day 109)	Nasal Congestion	Mild
27 Dec 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 110)	Chills	Mild
28 Dec 2020 (Study Day 110)	Cough	Mild
28 Dec 2020 (Study Day 110)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 111)	Cough	Mild
29 Dec 2020 (Study Day 111)	Headache	Moderate
29 Dec 2020 (Study Day 111)	Nasal Congestion	Moderate
29 Dec 2020 (Study Day 111)	New Loss of Smell	Moderate
29 Dec 2020 (Study Day 111)	New Loss of Taste	Moderate
30 Dec 2020 (Study Day 112)	Headache	Mild
30 Dec 2020 (Study Day 112)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 112)	New Loss of Smell	Mild
30 Dec 2020 (Study Day 112)	New Loss of Taste	Mild
31 Dec 2020 (Study Day 113)	Chills	Moderate
31 Dec 2020 (Study Day 113)	Fatigue	Mild
31 Dec 2020 (Study Day 113)	Headache	Moderate
31 Dec 2020 (Study Day 113)	Nasal Congestion	Moderate
31 Dec 2020 (Study Day 113)	New Loss of Smell	Mild
31 Dec 2020 (Study Day 113)	New Loss of Taste	Mild
31 Dec 2020 (Study Day 113)	O2 Saturation (%)	93
01 Jan 2021 (Study Day 114)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 114)	New Loss of Smell	Mild
01 Jan 2021 (Study Day 114)	New Loss of Taste	Mild
02 Jan 2021 (Study Day 115)	Nasal Congestion	Mild
02 Jan 2021 (Study Day 115)	New Loss of Smell	Mild
02 Jan 2021 (Study Day 115)	New Loss of Taste	Mild
03 Jan 2021 (Study Day 116)	Diarrhea	Mild
03 Jan 2021 (Study Day 116)	Fatigue	Mild
03 Jan 2021 (Study Day 116)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 117)	Diarrhea	Mild
04 Jan 2021 (Study Day 117)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
05 Jan 2021 (Study Day 118)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
31 Dec 2020 (Study Day 113)	Oxygen Saturation	93%
31 Dec 2020 - 31 Dec 2020 (Study Day 113-113)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 14 days, after which it was considered to be recovered/resolved on 08 Jan 2021 (Study Day 121). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002891	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis of knees	Oct 2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Indometacin	06 Sep 2020 (Study Day -4) - 06 Sep 2020 (Study Day -4)	Osteoarthritits Of Bilateral Knees
Montelukast	19 Sep 2020 (Study Day 10) - 22 Sep 2020 (Study Day 13)	Sinus Infection
Sulfamethoxazole; trimethoprim	19 Sep 2020 (Study Day 10) - 28 Sep 2020 (Study Day 19)	Sinus Infection

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	27 Oct 2020 (Study Day 48) - 09 Nov 2020 (Study Day 61)	Wheezing
Methylprednisolone	02 Nov 2020 (Study Day 54) - 07 Nov 2020 (Study Day 59)	Wheezing
Acetylsalicylic acid; caffeine; paracetamol	26 Dec 2020 (Study Day 108) - 05 Jan 2021 (Study Day 118)	Symptomatic COVID19
Ketorolac	13 Jan 2021 (Study Day 126) - 16 Jan 2021 (Study Day 129)	Neck Pain
Colecalciferol	12 Feb 2021 (Study Day 156) - Ongoing	Supplement
Lisinopril	12 Feb 2021 (Study Day 156) - Ongoing	Tachycardia
Metoprolol	12 Feb 2021 (Study Day 156) - Ongoing	Tachycardia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Sinusitis	Grade 1/mild	Not related	18 Sep 2020 (Study Day 9) - 28 Sep 2020 (Study Day 19)
Wheezing	Grade 1/mild	Not related	23 Oct 2020 (Study Day 44) - 09 Nov 2020 (Study Day 61)
COVID-19	Grade 1/mild	Not related	26 Dec 2020 (Study Day 108) - 08 Jan 2021 (Study Day 121)
Neck Pain	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 126) - 16 Jan 2021 (Study Day 129)
Tachycardia	Grade 2/moderate	Not related	12 Feb 2021 (Study Day 156) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US363-2107 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	20 Oct 2020 (Study Day 27)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	17 Nov 2020 (Study Day 55) – 12 Dec 2020 (Study Day 80)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US363-2107, a 46-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 24 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 20 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 17 Nov 2020 (Study Day 55), 54 days after the first dose and 28 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 27, 20 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 24 Nov 2020 (Study Day 62), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 55)	Chills	Moderate
17 Nov 2020 (Study Day 55)	Headache	Moderate
18 Nov 2020 (Study Day 56)	Chills	Moderate
18 Nov 2020 (Study Day 56)	Cough	Mild
18 Nov 2020 (Study Day 56)	Fatigue	Moderate
18 Nov 2020 (Study Day 56)	Headache	Moderate

Symptom Date	Symptom	Result
19 Nov 2020 (Study Day 57)	Chills	Mild
19 Nov 2020 (Study Day 57)	Cough	Mild
19 Nov 2020 (Study Day 57)	Fatigue	Mild
19 Nov 2020 (Study Day 57)	Headache	Mild
20 Nov 2020 (Study Day 58)	Chills	Mild
20 Nov 2020 (Study Day 58)	Cough	Mild
20 Nov 2020 (Study Day 58)	Fatigue	Mild
20 Nov 2020 (Study Day 58)	Headache	Mild
20 Nov 2020 (Study Day 58)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 58)	New Loss of Smell	Severe
21 Nov 2020 (Study Day 59)	Chills	Mild
21 Nov 2020 (Study Day 59)	Cough	Mild
21 Nov 2020 (Study Day 59)	Fatigue	Mild
21 Nov 2020 (Study Day 59)	Headache	Mild
21 Nov 2020 (Study Day 59)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 59)	New Loss of Smell	Severe
22 Nov 2020 (Study Day 60)	Body Aches	Mild
22 Nov 2020 (Study Day 60)	Chills	Mild
22 Nov 2020 (Study Day 60)	Cough	Mild
22 Nov 2020 (Study Day 60)	Fatigue	Mild
22 Nov 2020 (Study Day 60)	Muscle Aches (Myalgia)	Mild
22 Nov 2020 (Study Day 60)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 60)	New Loss of Smell	Severe
23 Nov 2020 (Study Day 61)	Body Aches	Mild
23 Nov 2020 (Study Day 61)	Cough	Mild
23 Nov 2020 (Study Day 61)	Muscle Aches (Myalgia)	Mild
23 Nov 2020 (Study Day 61)	New Loss of Smell	Severe
24 Nov 2020 (Study Day 62)	Body Aches	Mild
24 Nov 2020 (Study Day 62)	Cough	Mild
24 Nov 2020 (Study Day 62)	Muscle Aches (Myalgia)	Mild
24 Nov 2020 (Study Day 62)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 62)	New Loss of Smell	Severe
25 Nov 2020 (Study Day 63)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 63)	New Loss of Smell	Mild
27 Nov 2020 (Study Day 65)	Cough	Mild
27 Nov 2020 (Study Day 65)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 65)	New Loss of Smell	Mild
28 Nov 2020 (Study Day 66)	New Loss of Smell	Mild
29 Nov 2020 (Study Day 67)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 67)	New Loss of Smell	Mild
30 Nov 2020 (Study Day 68)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 69)	Nasal Congestion	Mild
02 Dec 2020 (Study Day 70)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 71)	Cough	Mild
03 Dec 2020 (Study Day 71)	Runny Nose (Rhinorrhea)	Mild
04 Dec 2020 (Study Day 72)	Runny Nose (Rhinorrhea)	Mild
05 Dec 2020 (Study Day 73)	Difficulty Breathing	Mild
05 Dec 2020 (Study Day 73)	Nasal Congestion	Mild
05 Dec 2020 (Study Day 73)	New Loss of Smell	Mild
05 Dec 2020 (Study Day 73)	O2 Saturation (%)	89
05 Dec 2020 (Study Day 73)	Runny Nose (Rhinorrhea)	Mild
05 Dec 2020 (Study Day 73)	Shortness of Breath	Mild
06 Dec 2020 (Study Day 74)	Nasal Congestion	Mild
07 Dec 2020 (Study Day 75)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 76)	Nasal Congestion	Mild
08 Dec 2020 (Study Day 76)	Runny Nose (Rhinorrhea)	Mild
09 Dec 2020 (Study Day 77)	Runny Nose (Rhinorrhea)	Mild
10 Dec 2020 (Study Day 78)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
05 Dec 2020 (Study Day 73)	Oxygen Saturation	89%
05 Dec 2020 - 05 Dec 2020 (Study Day 73-73)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 26 days, after which it was considered to be recovered/resolved on 12 Dec 2020 (Study Day 80). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000972	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Inguinal hernia repair	Hernia (left inguinal, surgery)	1980 - 1980

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2018 - Ongoing	Dietary Supplement
Fish oil	2018 - Ongoing	Dietary Supplement
Glucosamine	2018 - Ongoing	Dietary Supplement
Iron	2018 - Ongoing	Dietary Supplement
Melatonin	2018 - Ongoing	Dietary Supplement
Vitamin b12 nos	2018 - Ongoing	Dietary Supplement
Vitamin d nos	2018 - Ongoing	Dietary Supplement
Ibuprofen	28 Sep 2020 (Study Day 5) - 28 Sep 2020 (Study Day 5)	Muscle Aches
Paracetamol	28 Sep 2020 (Study Day 5) - 28 Sep 2020 (Study Day 5)	Muscle Aches
Acetylsalicylic acid	19 Nov 2020 (Study Day 57) - 22 Nov 2020 (Study Day 60)	COVID 19 Symptoms
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	19 Nov 2020 (Study Day 57) - 22 Nov 2020 (Study Day 60)	COVID 19 Symptoms
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	19 Nov 2020 (Study Day 57) - 22 Nov 2020 (Study Day 60)	COVID 19 Symptoms
Menthol	19 Nov 2020 (Study Day 57) - 22 Nov 2020 (Study Day 60)	COVID 19 Symptoms
Paracetamol	19 Nov 2020 (Study Day 57) - 22 Nov 2020 (Study Day 60)	COVID 19 Symptoms

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	17 Nov 2020 (Study Day 55) - 12 Dec 2020 (Study Day 80)
Rectal Haemorrhage	Grade 1/mild	Not related	23 Nov 2020 (Study Day 61) - 07 Dec 2020 (Study Day 75)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US363-2154 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	22 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	19 Nov 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 2/ moderate	Not related	08 Dec 2020 (Study Day 48) – 22 Dec 2020 (Study Day 62)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US363-2154, a 38-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 22 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 19 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 08 Dec 2020 (Study Day 48), 47 days after the first dose and 19 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 19 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 10 Dec 2020 (Study Day 50), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
08 Dec 2020 (Study Day 48)	Body Aches	Moderate
08 Dec 2020 (Study Day 48)	Cough	Moderate
08 Dec 2020 (Study Day 48)	Difficulty Breathing	Mild
08 Dec 2020 (Study Day 48)	Muscle Aches (Myalgia)	Moderate
08 Dec 2020 (Study Day 48)	Nasal Congestion	Moderate

Symptom Date	Symptom	Result
08 Dec 2020 (Study Day 48)	New Loss of Smell	Mild
08 Dec 2020 (Study Day 48)	New Loss of Taste	Mild
08 Dec 2020 (Study Day 48)	Runny Nose (Rhinorrhea)	Moderate
09 Dec 2020 (Study Day 49)	Body Aches	Moderate
09 Dec 2020 (Study Day 49)	Cough	Severe
09 Dec 2020 (Study Day 49)	Difficulty Breathing	Severe
09 Dec 2020 (Study Day 49)	Muscle Aches (Myalgia)	Moderate
09 Dec 2020 (Study Day 49)	Nasal Congestion	Moderate
09 Dec 2020 (Study Day 49)	New Loss of Smell	Severe
09 Dec 2020 (Study Day 49)	New Loss of Taste	Severe
09 Dec 2020 (Study Day 49)	Runny Nose (Rhinorrhea)	Moderate
10 Dec 2020 (Study Day 50)	Body Aches	Moderate
10 Dec 2020 (Study Day 50)	Cough	Moderate
10 Dec 2020 (Study Day 50)	Difficulty Breathing	Moderate
10 Dec 2020 (Study Day 50)	Fatigue	Severe
10 Dec 2020 (Study Day 50)	Headache	Mild
10 Dec 2020 (Study Day 50)	Muscle Aches (Myalgia)	Moderate
10 Dec 2020 (Study Day 50)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 50)	New Loss of Smell	Severe
10 Dec 2020 (Study Day 50)	New Loss of Taste	Severe
10 Dec 2020 (Study Day 50)	Runny Nose (Rhinorrhea)	Mild
10 Dec 2020 (Study Day 50)	Shortness of Breath	Moderate
11 Dec 2020 (Study Day 51)	Body Aches	Severe
11 Dec 2020 (Study Day 51)	Chills	Mild
11 Dec 2020 (Study Day 51)	Cough	Moderate
11 Dec 2020 (Study Day 51)	Difficulty Breathing	Moderate
11 Dec 2020 (Study Day 51)	Fatigue	Moderate
11 Dec 2020 (Study Day 51)	Muscle Aches (Myalgia)	Severe
11 Dec 2020 (Study Day 51)	Nasal Congestion	Moderate
11 Dec 2020 (Study Day 51)	New Loss of Smell	Moderate
11 Dec 2020 (Study Day 51)	New Loss of Taste	Moderate
11 Dec 2020 (Study Day 51)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 51)	Shortness of Breath	Moderate
12 Dec 2020 (Study Day 52)	Body Aches	Moderate
12 Dec 2020 (Study Day 52)	Chills	Moderate
12 Dec 2020 (Study Day 52)	Cough	Mild
12 Dec 2020 (Study Day 52)	Difficulty Breathing	Moderate
12 Dec 2020 (Study Day 52)	Fatigue	Moderate
12 Dec 2020 (Study Day 52)	Headache	Mild
12 Dec 2020 (Study Day 52)	Muscle Aches (Myalgia)	Moderate
12 Dec 2020 (Study Day 52)	New Loss of Smell	Severe
12 Dec 2020 (Study Day 52)	New Loss of Taste	Moderate
12 Dec 2020 (Study Day 52)	Shortness of Breath	Moderate

Symptom Date	Symptom	Result
13 Dec 2020 (Study Day 53)	Body Aches	Moderate
13 Dec 2020 (Study Day 53)	Chills	Mild
13 Dec 2020 (Study Day 53)	Cough	Moderate
13 Dec 2020 (Study Day 53)	Difficulty Breathing	Moderate
13 Dec 2020 (Study Day 53)	Fatigue	Moderate
13 Dec 2020 (Study Day 53)	Headache	Moderate
13 Dec 2020 (Study Day 53)	Muscle Aches (Myalgia)	Moderate
13 Dec 2020 (Study Day 53)	New Loss of Smell	Severe
13 Dec 2020 (Study Day 53)	New Loss of Taste	Severe
13 Dec 2020 (Study Day 53)	Shortness of Breath	Moderate
14 Dec 2020 (Study Day 54)	Body Aches	Mild
14 Dec 2020 (Study Day 54)	Chills	Moderate
14 Dec 2020 (Study Day 54)	Cough	Mild
14 Dec 2020 (Study Day 54)	Difficulty Breathing	Moderate
14 Dec 2020 (Study Day 54)	Fatigue	Mild
14 Dec 2020 (Study Day 54)	Headache	Mild
14 Dec 2020 (Study Day 54)	Muscle Aches (Myalgia)	Mild
14 Dec 2020 (Study Day 54)	New Loss of Smell	Severe
14 Dec 2020 (Study Day 54)	New Loss of Taste	Severe
14 Dec 2020 (Study Day 54)	Shortness of Breath	Moderate
15 Dec 2020 (Study Day 55)	Body Aches	Mild
15 Dec 2020 (Study Day 55)	Chills	Mild
15 Dec 2020 (Study Day 55)	Cough	Mild
15 Dec 2020 (Study Day 55)	Difficulty Breathing	Moderate
15 Dec 2020 (Study Day 55)	Fatigue	Mild
15 Dec 2020 (Study Day 55)	Headache	Moderate
15 Dec 2020 (Study Day 55)	Muscle Aches (Myalgia)	Mild
15 Dec 2020 (Study Day 55)	New Loss of Smell	Severe
15 Dec 2020 (Study Day 55)	New Loss of Taste	Moderate
15 Dec 2020 (Study Day 55)	O2 Saturation (%)	92
15 Dec 2020 (Study Day 55)	Shortness of Breath	Moderate
16 Dec 2020 (Study Day 56)	Body Aches	Mild
16 Dec 2020 (Study Day 56)	Chills	Moderate
16 Dec 2020 (Study Day 56)	Cough	Mild
16 Dec 2020 (Study Day 56)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 56)	Fatigue	Mild
16 Dec 2020 (Study Day 56)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 56)	New Loss of Smell	Severe
16 Dec 2020 (Study Day 56)	New Loss of Taste	Moderate
16 Dec 2020 (Study Day 56)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 57)	Chills	Moderate
17 Dec 2020 (Study Day 57)	New Loss of Smell	Severe
17 Dec 2020 (Study Day 57)	New Loss of Taste	Moderate

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 58)	Difficulty Breathing	Mild
18 Dec 2020 (Study Day 58)	New Loss of Smell	Severe
18 Dec 2020 (Study Day 58)	New Loss of Taste	Moderate
18 Dec 2020 (Study Day 58)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 59)	New Loss of Smell	Severe
19 Dec 2020 (Study Day 59)	New Loss of Taste	Moderate
20 Dec 2020 (Study Day 60)	New Loss of Smell	Severe
20 Dec 2020 (Study Day 60)	New Loss of Taste	Moderate
21 Dec 2020 (Study Day 61)	New Loss of Smell	Moderate
21 Dec 2020 (Study Day 61)	New Loss of Taste	Moderate
22 Dec 2020 (Study Day 62)	Headache	Mild
22 Dec 2020 (Study Day 62)	New Loss of Smell	Moderate
22 Dec 2020 (Study Day 62)	New Loss of Taste	Moderate
23 Dec 2020 (Study Day 63)	New Loss of Smell	Severe
23 Dec 2020 (Study Day 63)	New Loss of Taste	Moderate
26 Dec 2020 (Study Day 66)	New Loss of Smell	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
15 Dec 2020 (Study Day 55)	Oxygen Saturation	92%
15 Dec 2020 - 15 Dec 2020 (Study Day 55-55)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 22 Dec 2020 (Study Day 62). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001145	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Severe obesity (bmi: 40.57184)	Not reported - Ongoing
Tonsillectomy	Tonsillectomy	1990 - 1990
Migraine	Migranes	01 Jan 1990 (Study Day -11252) - Ongoing
Asthma	Mild asthma	01 Jan 1992 (Study Day -10522) - Ongoing
Acne	Facial acne	1994 - Ongoing
Allergy to vaccine	Tb shot allergy	01 Jan 1997 (Study Day -8695) - Ongoing
Hidradenitis	Hidradenitis suppurativa	01 Jan 1997 (Study Day -8695) - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	01 Jan 1997 (Study Day -8695) - Ongoing
Drug hypersensitivity	Erythromycin allergy	01 Jan 2000 (Study Day -7600) - Ongoing
Muscle spasms	Intermittent back spasms	01 Jun 2005 (Study Day -5622) - Ongoing
Schizoaffective disorder bipolar type	Schizoaffective bipolar	01 Jan 2009 (Study Day -4312) - Ongoing
Seasonal allergy	Seasonal allergies	01 Jan 2011 (Study Day -3582) - Ongoing
Drug hypersensitivity	Abilify allergy	01 Jan 2017 (Study Day -1390) - Ongoing
Herpes simplex	Herpes simplex virus 2	01 Jan 2018 (Study Day -1025) - Ongoing
Plantar fasciitis	Plantar fascitis	01 May 2020 (Study Day -174) - Ongoing
Dermal filler injection	Derma filler injection	Aug 2020 - Aug 2020
Neck pain	Neck pain	01 Sep 2020 (Study Day -51) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Eletriptan hydrobromide	2005 - Ongoing	Migraines
Ketorolac tromethamine	2005 - Ongoing	Migraines
Prochlorperazine edisylate	2005 - Ongoing	Migraines
Tizanidine hydrochloride	2005 - Ongoing	Migraines, Back Spasms
Naproxen sodium	2010 - Ongoing	Migraines
Indometacin	2012 - Ongoing	Migraines
Cyclobenzaprine hydrochloride	2013 - Ongoing	Back Spams, Back Pain
Salbutamol	2013 - Ongoing	Mild Asthma
Botulinum toxin type a	2014 - Ongoing	Migraines
Docusate sodium	2017 - Ongoing	Irritable Bowel Syndrome

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Magnesium	2017 - Ongoing	Migraines
Benzatropine mesilate	01 Oct 2017 (Study Day -1117) - Ongoing	Schizoaffective Bipolar
Lithium	01 Oct 2017 (Study Day -1117) - Ongoing	Schizoaffective Bipolar
Paliperidone palmitate	01 Oct 2017 (Study Day -1117) - Ongoing	Schizoaffective Bipolar
Quetiapine fumarate	01 Oct 2017 (Study Day -1117) - 06 Mar 2021 (Study Day 136)	Schizoaffective Bipolar
Benzoyl peroxide	2018 - Ongoing	Hidradenitis Suppurativa
Cetirizine hydrochloride	2018 - Ongoing	Seasonal Allergies
Clindamycin	2018 - Ongoing	Hidradenitis Suppurativa
Memantine hydrochloride	2018 - Ongoing	Migraines
Nystatin	2018 - Ongoing	Hidradenitis Suppurativa
Silybum marianum	2018 - Ongoing	General Health
Triamcinolone	2018 - Ongoing	Hidradenitis Suppurativa
Aciclovir	01 Jun 2018 (Study Day -874) - Ongoing	Herpes Simplex 2
Emtricitabine; tenofovir disoproxil fumarate	2019 - Ongoing	Prevent Hiv Infection
Other alimentary tract and metabolism products	01 Mar 2020 (Study Day -235) - Ongoing	Women Health's
Probiotics nos	01 May 2020 (Study Day -174) - Ongoing	Irritable Bowel Syndrome
Isotretinoin	01 Aug 2020 (Study Day -82) - Ongoing	Hidradenitis Suppurativa
Pearl	01 Aug 2020 (Study Day -82) - Ongoing	Facial Acne
Cervical spine x-ray*	29 Oct 2020 (Study Day 8) - 29 Oct 2020 (Study Day 8)	Adverse Event
Thoracic spine x-ray*	29 Oct 2020 (Study Day 8) - 29 Oct 2020 (Study Day 8)	Adverse Event
Intrauterine device insertion*	03 Nov 2020 (Study Day 13) - 03 Nov 2020 (Study Day 13)	Other, Participant Had Mirena Intrauterine Device Insertion.
Chest x-ray*	05 Nov 2020 (Study Day 15) - 05 Nov 2020 (Study Day 15)	Adverse Event
Methylprednisolone	05 Nov 2020 (Study Day 15) - 12 Nov 2020 (Study Day 22)	Neck Pain
Hydrocortisone	19 Nov 2020 (Study Day 29) - Ongoing	Facial Acne
Thoracentesis*	25 Nov 2020 (Study Day 35) - 25 Nov 2020 (Study Day 35)	Adverse Event
Codeine	09 Dec 2020 (Study Day 49) - 09 Dec 2020 (Study Day 49)	Symptomatic COVID 19
Naproxen sodium	12 Dec 2020 (Study Day 52) - 12 Dec 2020 (Study Day 52)	Migraines
Fremanezumab	18 Feb 2021 (Study Day 120) - Ongoing	Migraines

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pleural Effusion	Grade 1/mild	Not related	05 Nov 2020 (Study Day 15) - 27 Nov 2020 (Study Day 37)
COVID-19	Grade 2/moderate	Not related	08 Dec 2020 (Study Day 48) - 22 Dec 2020 (Study Day 62)
Chest Discomfort	Grade 2/moderate	Not related	09 Dec 2020 (Study Day 49) - 22 Dec 2020 (Study Day 62)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US366-2156 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	02 Nov 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 3/ severe	Not related	23 Nov 2020 (Study Day 50) – 14 Dec 2020 (Study Day 71)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US366-2156, a 49-year-old Hispanic or Latino female, received the first dose of placebo in the right arm on 05 Oct 2020 (Study Day 1). The second dose was administered in the right arm on 02 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 23 Nov 2020 (Study Day 50), 49 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 02 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Nov 2020 (Study Day 50), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
06 Oct 2020 (Study Day 2)	Difficulty Breathing	Mild
06 Oct 2020 (Study Day 2)	Fatigue	Mild
06 Oct 2020 (Study Day 2)	Headache	Mild
06 Oct 2020 (Study Day 2)	Muscle Aches (Myalgia)	Mild
07 Oct 2020 (Study Day 3)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
07 Oct 2020 (Study Day 3)	Fatigue	Mild
07 Oct 2020 (Study Day 3)	Headache	Mild
07 Oct 2020 (Study Day 3)	Muscle Aches (Myalgia)	Mild
08 Oct 2020 (Study Day 4)	Difficulty Breathing	Mild
08 Oct 2020 (Study Day 4)	Fatigue	Mild
08 Oct 2020 (Study Day 4)	Headache	Mild
08 Oct 2020 (Study Day 4)	Muscle Aches (Myalgia)	Mild
08 Oct 2020 (Study Day 4)	Sore Throat	Mild
09 Oct 2020 (Study Day 5)	Chills	Mild
09 Oct 2020 (Study Day 5)	Difficulty Breathing	Mild
09 Oct 2020 (Study Day 5)	Fatigue	Mild
09 Oct 2020 (Study Day 5)	Headache	Mild
09 Oct 2020 (Study Day 5)	Muscle Aches (Myalgia)	Mild
09 Oct 2020 (Study Day 5)	Nausea	Mild
09 Oct 2020 (Study Day 5)	Sore Throat	Mild
10 Oct 2020 (Study Day 6)	Chills	Mild
10 Oct 2020 (Study Day 6)	Fatigue	Mild
10 Oct 2020 (Study Day 6)	Headache	Mild
10 Oct 2020 (Study Day 6)	Muscle Aches (Myalgia)	Mild
10 Oct 2020 (Study Day 6)	Nausea	Mild
10 Oct 2020 (Study Day 6)	Sore Throat	Mild
11 Oct 2020 (Study Day 7)	Chills	Mild
11 Oct 2020 (Study Day 7)	Fatigue	Mild
11 Oct 2020 (Study Day 7)	Headache	Mild
11 Oct 2020 (Study Day 7)	Muscle Aches (Myalgia)	Mild
11 Oct 2020 (Study Day 7)	Nausea	Mild
11 Oct 2020 (Study Day 7)	Sore Throat	Mild
12 Oct 2020 (Study Day 8)	Chills	Mild
12 Oct 2020 (Study Day 8)	Fatigue	Mild
12 Oct 2020 (Study Day 8)	Headache	Mild
12 Oct 2020 (Study Day 8)	Muscle Aches (Myalgia)	Moderate
12 Oct 2020 (Study Day 8)	Shortness of Breath	Mild
12 Oct 2020 (Study Day 8)	Sore Throat	Mild
13 Oct 2020 (Study Day 9)	Chills	Mild
13 Oct 2020 (Study Day 9)	Fatigue	Mild
13 Oct 2020 (Study Day 9)	Headache	Mild
13 Oct 2020 (Study Day 9)	Muscle Aches (Myalgia)	Mild
13 Oct 2020 (Study Day 9)	Shortness of Breath	Mild
13 Oct 2020 (Study Day 9)	Sore Throat	Mild
14 Oct 2020 (Study Day 10)	Chills	Mild
14 Oct 2020 (Study Day 10)	Cough	Mild
14 Oct 2020 (Study Day 10)	Fatigue	Mild
14 Oct 2020 (Study Day 10)	Headache	Moderate

Symptom Date	Symptom	Result
14 Oct 2020 (Study Day 10)	Muscle Aches (Myalgia)	Mild
14 Oct 2020 (Study Day 10)	Shortness of Breath	Moderate
14 Oct 2020 (Study Day 10)	Sore Throat	Mild
15 Oct 2020 (Study Day 11)	Body Aches	Moderate
15 Oct 2020 (Study Day 11)	Chills	Moderate
15 Oct 2020 (Study Day 11)	Cough	Mild
15 Oct 2020 (Study Day 11)	Difficulty Breathing	Mild
15 Oct 2020 (Study Day 11)	Fatigue	Moderate
15 Oct 2020 (Study Day 11)	Headache	Moderate
15 Oct 2020 (Study Day 11)	Muscle Aches (Myalgia)	Moderate
15 Oct 2020 (Study Day 11)	Nausea	Mild
15 Oct 2020 (Study Day 11)	Shortness of Breath	Moderate
16 Oct 2020 (Study Day 12)	Body Aches	Mild
16 Oct 2020 (Study Day 12)	Cough	Mild
16 Oct 2020 (Study Day 12)	Headache	Moderate
16 Oct 2020 (Study Day 12)	Muscle Aches (Myalgia)	Mild
16 Oct 2020 (Study Day 12)	Shortness of Breath	Mild
17 Oct 2020 (Study Day 13)	Chills	Moderate
17 Oct 2020 (Study Day 13)	Cough	Mild
17 Oct 2020 (Study Day 13)	Fatigue	Moderate
17 Oct 2020 (Study Day 13)	Headache	Moderate
17 Oct 2020 (Study Day 13)	Shortness of Breath	Mild
18 Oct 2020 (Study Day 14)	Cough	Mild
18 Oct 2020 (Study Day 14)	Headache	Moderate
18 Oct 2020 (Study Day 14)	Shortness of Breath	Moderate
19 Oct 2020 (Study Day 15)	Cough	Mild
19 Oct 2020 (Study Day 15)	Runny Nose (Rhinorrhea)	Mild
19 Oct 2020 (Study Day 15)	Shortness of Breath	Mild
19 Oct 2020 (Study Day 15)	Sore Throat	Mild
03 Nov 2020 (Study Day 30)	Muscle Aches (Myalgia)	Moderate
04 Nov 2020 (Study Day 31)	Muscle Aches (Myalgia)	Moderate
05 Nov 2020 (Study Day 32)	Muscle Aches (Myalgia)	Moderate
06 Nov 2020 (Study Day 33)	Muscle Aches (Myalgia)	Moderate
07 Nov 2020 (Study Day 34)	Muscle Aches (Myalgia)	Moderate
08 Nov 2020 (Study Day 35)	Muscle Aches (Myalgia)	Moderate
09 Nov 2020 (Study Day 36)	Muscle Aches (Myalgia)	Moderate
10 Nov 2020 (Study Day 37)	Muscle Aches (Myalgia)	Moderate
11 Nov 2020 (Study Day 38)	Chills	Mild
11 Nov 2020 (Study Day 38)	Cough	Mild
11 Nov 2020 (Study Day 38)	Fatigue	Mild
11 Nov 2020 (Study Day 38)	Headache	Moderate
11 Nov 2020 (Study Day 38)	Muscle Aches (Myalgia)	Moderate
12 Nov 2020 (Study Day 39)	Chills	Mild

Symptom Date	Symptom	Result
12 Nov 2020 (Study Day 39)	Cough	Mild
12 Nov 2020 (Study Day 39)	Fatigue	Mild
12 Nov 2020 (Study Day 39)	Headache	Moderate
12 Nov 2020 (Study Day 39)	Muscle Aches (Myalgia)	Moderate
13 Nov 2020 (Study Day 40)	Chills	Mild
13 Nov 2020 (Study Day 40)	Cough	Mild
13 Nov 2020 (Study Day 40)	Fatigue	Mild
13 Nov 2020 (Study Day 40)	Headache	Moderate
13 Nov 2020 (Study Day 40)	Muscle Aches (Myalgia)	Moderate
14 Nov 2020 (Study Day 41)	Chills	Mild
14 Nov 2020 (Study Day 41)	Cough	Mild
14 Nov 2020 (Study Day 41)	Fatigue	Mild
14 Nov 2020 (Study Day 41)	Headache	Moderate
14 Nov 2020 (Study Day 41)	Muscle Aches (Myalgia)	Moderate
15 Nov 2020 (Study Day 42)	Chills	Mild
15 Nov 2020 (Study Day 42)	Cough	Mild
15 Nov 2020 (Study Day 42)	Fatigue	Mild
15 Nov 2020 (Study Day 42)	Headache	Moderate
15 Nov 2020 (Study Day 42)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 43)	Chills	Mild
16 Nov 2020 (Study Day 43)	Cough	Mild
16 Nov 2020 (Study Day 43)	Fatigue	Mild
16 Nov 2020 (Study Day 43)	Headache	Moderate
16 Nov 2020 (Study Day 43)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 43)	Sore Throat	Mild
17 Nov 2020 (Study Day 44)	Chills	Mild
17 Nov 2020 (Study Day 44)	Cough	Mild
17 Nov 2020 (Study Day 44)	Diarrhea	Mild
17 Nov 2020 (Study Day 44)	Fatigue	Mild
17 Nov 2020 (Study Day 44)	Headache	Moderate
17 Nov 2020 (Study Day 44)	Muscle Aches (Myalgia)	Moderate
17 Nov 2020 (Study Day 44)	New Loss of Smell	Mild
17 Nov 2020 (Study Day 44)	Sore Throat	Mild
18 Nov 2020 (Study Day 45)	Chills	Mild
18 Nov 2020 (Study Day 45)	Cough	Mild
18 Nov 2020 (Study Day 45)	Diarrhea	Mild
18 Nov 2020 (Study Day 45)	Fatigue	Mild
18 Nov 2020 (Study Day 45)	Muscle Aches (Myalgia)	Moderate
18 Nov 2020 (Study Day 45)	Runny Nose (Rhinorrhea)	Moderate
18 Nov 2020 (Study Day 45)	Sore Throat	Mild
19 Nov 2020 (Study Day 46)	Cough	Moderate
19 Nov 2020 (Study Day 46)	Diarrhea	Mild
19 Nov 2020 (Study Day 46)	Fatigue	Mild

Symptom Date	Symptom	Result
19 Nov 2020 (Study Day 46)	Headache	Mild
19 Nov 2020 (Study Day 46)	Muscle Aches (Myalgia)	Mild
19 Nov 2020 (Study Day 46)	Nausea	Moderate
19 Nov 2020 (Study Day 46)	Runny Nose (Rhinorrhea)	Mild
20 Nov 2020 (Study Day 47)	Fatigue	Mild
20 Nov 2020 (Study Day 47)	Nausea	Moderate
21 Nov 2020 (Study Day 48)	Headache	Moderate
21 Nov 2020 (Study Day 48)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 49)	Headache	Moderate
22 Nov 2020 (Study Day 49)	Nausea	Mild
24 Nov 2020 (Study Day 51)	Body Aches	Severe
24 Nov 2020 (Study Day 51)	Chills	Severe
24 Nov 2020 (Study Day 51)	Headache	Severe
24 Nov 2020 (Study Day 51)	Muscle Aches (Myalgia)	Severe
24 Nov 2020 (Study Day 51)	Temperature (°F)	100.5
25 Nov 2020 (Study Day 52)	Body Aches	Severe
25 Nov 2020 (Study Day 52)	Chills	Severe
25 Nov 2020 (Study Day 52)	Cough	Mild
25 Nov 2020 (Study Day 52)	Fatigue	Moderate
25 Nov 2020 (Study Day 52)	Headache	Severe
25 Nov 2020 (Study Day 52)	Muscle Aches (Myalgia)	Severe
26 Nov 2020 (Study Day 53)	Body Aches	Moderate
26 Nov 2020 (Study Day 53)	Chills	Mild
26 Nov 2020 (Study Day 53)	Cough	Mild
26 Nov 2020 (Study Day 53)	Diarrhea	Moderate
26 Nov 2020 (Study Day 53)	Fatigue	Mild
26 Nov 2020 (Study Day 53)	Headache	Moderate
26 Nov 2020 (Study Day 53)	Muscle Aches (Myalgia)	Moderate
27 Nov 2020 (Study Day 54)	Body Aches	Mild
27 Nov 2020 (Study Day 54)	Cough	Mild
27 Nov 2020 (Study Day 54)	Diarrhea	Moderate
27 Nov 2020 (Study Day 54)	Fatigue	Mild
27 Nov 2020 (Study Day 54)	Headache	Mild
27 Nov 2020 (Study Day 54)	Muscle Aches (Myalgia)	Mild
28 Nov 2020 (Study Day 55)	Body Aches	Mild
28 Nov 2020 (Study Day 55)	Cough	Mild
28 Nov 2020 (Study Day 55)	Diarrhea	Mild
28 Nov 2020 (Study Day 55)	Fatigue	Mild
28 Nov 2020 (Study Day 55)	Headache	Mild
28 Nov 2020 (Study Day 55)	Muscle Aches (Myalgia)	Mild
28 Nov 2020 (Study Day 55)	New Loss of Smell	Moderate
28 Nov 2020 (Study Day 55)	O2 Saturation (%)	93
29 Nov 2020 (Study Day 56)	Body Aches	Mild

Symptom Date	Symptom	Result
29 Nov 2020 (Study Day 56)	Cough	Mild
29 Nov 2020 (Study Day 56)	Diarrhea	Mild
29 Nov 2020 (Study Day 56)	Fatigue	Mild
29 Nov 2020 (Study Day 56)	Headache	Mild
29 Nov 2020 (Study Day 56)	Muscle Aches (Myalgia)	Mild
29 Nov 2020 (Study Day 56)	New Loss of Smell	Moderate
30 Nov 2020 (Study Day 57)	Body Aches	Moderate
30 Nov 2020 (Study Day 57)	Fatigue	Moderate
30 Nov 2020 (Study Day 57)	Muscle Aches (Myalgia)	Moderate
30 Nov 2020 (Study Day 57)	New Loss of Smell	Mild
30 Nov 2020 (Study Day 57)	New Loss of Taste	Mild
30 Nov 2020 (Study Day 57)	Sore Throat	Mild
01 Dec 2020 (Study Day 58)	Body Aches	Mild
01 Dec 2020 (Study Day 58)	Cough	Moderate
01 Dec 2020 (Study Day 58)	Diarrhea	Mild
01 Dec 2020 (Study Day 58)	Fatigue	Moderate
01 Dec 2020 (Study Day 58)	Muscle Aches (Myalgia)	Mild
01 Dec 2020 (Study Day 58)	Nausea	Mild
01 Dec 2020 (Study Day 58)	New Loss of Smell	Severe
01 Dec 2020 (Study Day 58)	New Loss of Taste	Severe
01 Dec 2020 (Study Day 58)	Runny Nose (Rhinorrhea)	Mild
01 Dec 2020 (Study Day 58)	Shortness of Breath	Mild
01 Dec 2020 (Study Day 58)	Sore Throat	Mild
02 Dec 2020 (Study Day 59)	Body Aches	Mild
02 Dec 2020 (Study Day 59)	Chills	Mild
02 Dec 2020 (Study Day 59)	Cough	Moderate
02 Dec 2020 (Study Day 59)	Difficulty Breathing	Moderate
02 Dec 2020 (Study Day 59)	Fatigue	Mild
02 Dec 2020 (Study Day 59)	Headache	Moderate
02 Dec 2020 (Study Day 59)	Muscle Aches (Myalgia)	Mild
02 Dec 2020 (Study Day 59)	New Loss of Smell	Mild
02 Dec 2020 (Study Day 59)	New Loss of Taste	Mild
02 Dec 2020 (Study Day 59)	O2 Saturation (%)	88
02 Dec 2020 (Study Day 59)	Runny Nose (Rhinorrhea)	Mild
02 Dec 2020 (Study Day 59)	Shortness of Breath	Moderate
02 Dec 2020 (Study Day 59)	Sore Throat	Mild
03 Dec 2020 (Study Day 60)	Body Aches	Moderate
03 Dec 2020 (Study Day 60)	Chills	Mild
03 Dec 2020 (Study Day 60)	Cough	Moderate
03 Dec 2020 (Study Day 60)	Difficulty Breathing	Mild
03 Dec 2020 (Study Day 60)	Fatigue	Mild
03 Dec 2020 (Study Day 60)	Headache	Mild
03 Dec 2020 (Study Day 60)	Muscle Aches (Myalgia)	Moderate

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 60)	New Loss of Smell	Moderate
03 Dec 2020 (Study Day 60)	New Loss of Taste	Mild
03 Dec 2020 (Study Day 60)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 60)	Shortness of Breath	Mild
03 Dec 2020 (Study Day 60)	Sore Throat	Mild
04 Dec 2020 (Study Day 61)	Cough	Mild
04 Dec 2020 (Study Day 61)	Difficulty Breathing	Mild
04 Dec 2020 (Study Day 61)	Fatigue	Mild
04 Dec 2020 (Study Day 61)	Headache	Mild
04 Dec 2020 (Study Day 61)	New Loss of Smell	Moderate
04 Dec 2020 (Study Day 61)	New Loss of Taste	Moderate
04 Dec 2020 (Study Day 61)	Runny Nose (Rhinorrhea)	Mild
04 Dec 2020 (Study Day 61)	Shortness of Breath	Mild
04 Dec 2020 (Study Day 61)	Sore Throat	Mild
05 Dec 2020 (Study Day 62)	Cough	Mild
05 Dec 2020 (Study Day 62)	Fatigue	Mild
05 Dec 2020 (Study Day 62)	Headache	Mild
05 Dec 2020 (Study Day 62)	New Loss of Smell	Moderate
05 Dec 2020 (Study Day 62)	New Loss of Taste	Moderate
05 Dec 2020 (Study Day 62)	Runny Nose (Rhinorrhea)	Mild
05 Dec 2020 (Study Day 62)	Sore Throat	Mild
06 Dec 2020 (Study Day 63)	Chills	Mild
06 Dec 2020 (Study Day 63)	Fatigue	Mild
06 Dec 2020 (Study Day 63)	New Loss of Smell	Moderate
06 Dec 2020 (Study Day 63)	New Loss of Taste	Moderate
06 Dec 2020 (Study Day 63)	O2 Saturation (%)	92
06 Dec 2020 (Study Day 63)	Runny Nose (Rhinorrhea)	Mild
06 Dec 2020 (Study Day 63)	Shortness of Breath	Mild
06 Dec 2020 (Study Day 63)	Sore Throat	Mild
07 Dec 2020 (Study Day 64)	Chills	Mild
07 Dec 2020 (Study Day 64)	Cough	Moderate
07 Dec 2020 (Study Day 64)	Difficulty Breathing	Mild
07 Dec 2020 (Study Day 64)	Fatigue	Mild
07 Dec 2020 (Study Day 64)	Muscle Aches (Myalgia)	Mild
07 Dec 2020 (Study Day 64)	Nausea	Mild
07 Dec 2020 (Study Day 64)	New Loss of Smell	Moderate
07 Dec 2020 (Study Day 64)	New Loss of Taste	Moderate
07 Dec 2020 (Study Day 64)	O2 Saturation (%)	88
07 Dec 2020 (Study Day 64)	Shortness of Breath	Mild
07 Dec 2020 (Study Day 64)	Sore Throat	Mild
08 Dec 2020 (Study Day 65)	Chills	Mild
08 Dec 2020 (Study Day 65)	Cough	Mild
08 Dec 2020 (Study Day 65)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
08 Dec 2020 (Study Day 65)	Fatigue	Mild
08 Dec 2020 (Study Day 65)	Headache	Moderate
08 Dec 2020 (Study Day 65)	Nasal Congestion	Mild
08 Dec 2020 (Study Day 65)	Nausea	Mild
08 Dec 2020 (Study Day 65)	New Loss of Smell	Moderate
08 Dec 2020 (Study Day 65)	New Loss of Taste	Moderate
08 Dec 2020 (Study Day 65)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 65)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 65)	Sore Throat	Mild
09 Dec 2020 (Study Day 66)	Cough	Mild
09 Dec 2020 (Study Day 66)	Headache	Moderate
09 Dec 2020 (Study Day 66)	Nasal Congestion	Mild
09 Dec 2020 (Study Day 66)	New Loss of Smell	Mild
09 Dec 2020 (Study Day 66)	New Loss of Taste	Mild
09 Dec 2020 (Study Day 66)	Runny Nose (Rhinorrhea)	Mild
09 Dec 2020 (Study Day 66)	Shortness of Breath	Mild
09 Dec 2020 (Study Day 66)	Sore Throat	Moderate
10 Dec 2020 (Study Day 67)	Cough	Mild
10 Dec 2020 (Study Day 67)	Difficulty Breathing	Mild
10 Dec 2020 (Study Day 67)	Fatigue	Mild
10 Dec 2020 (Study Day 67)	Headache	Moderate
10 Dec 2020 (Study Day 67)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 67)	New Loss of Smell	Moderate
10 Dec 2020 (Study Day 67)	New Loss of Taste	Moderate
10 Dec 2020 (Study Day 67)	Shortness of Breath	Mild
10 Dec 2020 (Study Day 67)	Sore Throat	Mild
11 Dec 2020 (Study Day 68)	Body Aches	Mild
11 Dec 2020 (Study Day 68)	Nausea	Mild
11 Dec 2020 (Study Day 68)	New Loss of Smell	Moderate
11 Dec 2020 (Study Day 68)	New Loss of Taste	Moderate
11 Dec 2020 (Study Day 68)	Sore Throat	Mild
12 Dec 2020 (Study Day 69)	Body Aches	Mild
12 Dec 2020 (Study Day 69)	Chills	Mild
12 Dec 2020 (Study Day 69)	Cough	Mild
12 Dec 2020 (Study Day 69)	Diarrhea	Mild
12 Dec 2020 (Study Day 69)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 69)	Nausea	Mild
12 Dec 2020 (Study Day 69)	New Loss of Smell	Moderate
12 Dec 2020 (Study Day 69)	New Loss of Taste	Moderate
12 Dec 2020 (Study Day 69)	Shortness of Breath	Mild
12 Dec 2020 (Study Day 69)	Sore Throat	Mild
13 Dec 2020 (Study Day 70)	Chills	Mild
13 Dec 2020 (Study Day 70)	Cough	Mild

Symptom Date	Symptom	Result
13 Dec 2020 (Study Day 70)	Diarrhea	Mild
13 Dec 2020 (Study Day 70)	Nausea	Mild
13 Dec 2020 (Study Day 70)	New Loss of Smell	Moderate
13 Dec 2020 (Study Day 70)	New Loss of Taste	Moderate
13 Dec 2020 (Study Day 70)	Sore Throat	Mild
14 Dec 2020 (Study Day 71)	Chills	Mild
14 Dec 2020 (Study Day 71)	Cough	Mild
14 Dec 2020 (Study Day 71)	Diarrhea	Moderate
14 Dec 2020 (Study Day 71)	Difficulty Breathing	Mild
14 Dec 2020 (Study Day 71)	Headache	Moderate
14 Dec 2020 (Study Day 71)	Nausea	Moderate
14 Dec 2020 (Study Day 71)	New Loss of Smell	Moderate
14 Dec 2020 (Study Day 71)	New Loss of Taste	Moderate
16 Dec 2020 (Study Day 73)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 73)	Fatigue	Mild
16 Dec 2020 (Study Day 73)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 73)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 73)	Nausea	Moderate
16 Dec 2020 (Study Day 73)	New Loss of Smell	Moderate
16 Dec 2020 (Study Day 73)	New Loss of Taste	Moderate
16 Dec 2020 (Study Day 73)	Runny Nose (Rhinorrhea)	Mild
16 Dec 2020 (Study Day 73)	Shortness of Breath	Mild
16 Dec 2020 (Study Day 73)	Sore Throat	Mild
16 Dec 2020 (Study Day 73)	Vomiting	Moderate
17 Dec 2020 (Study Day 74)	Body Aches	Mild
17 Dec 2020 (Study Day 74)	Chills	Moderate
17 Dec 2020 (Study Day 74)	Diarrhea	Moderate
17 Dec 2020 (Study Day 74)	Difficulty Breathing	Mild
17 Dec 2020 (Study Day 74)	Fatigue	Mild
17 Dec 2020 (Study Day 74)	Headache	Mild
17 Dec 2020 (Study Day 74)	Nausea	Moderate
17 Dec 2020 (Study Day 74)	New Loss of Smell	Moderate
17 Dec 2020 (Study Day 74)	New Loss of Taste	Moderate
17 Dec 2020 (Study Day 74)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 74)	Vomiting	Moderate
18 Dec 2020 (Study Day 75)	Body Aches	Mild
18 Dec 2020 (Study Day 75)	Chills	Mild
18 Dec 2020 (Study Day 75)	Fatigue	Mild
18 Dec 2020 (Study Day 75)	Headache	Mild
18 Dec 2020 (Study Day 75)	Muscle Aches (Myalgia)	Mild
18 Dec 2020 (Study Day 75)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 75)	New Loss of Smell	Moderate
18 Dec 2020 (Study Day 75)	New Loss of Taste	Moderate

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 75)	Sore Throat	Mild
19 Dec 2020 (Study Day 76)	Body Aches	Mild
19 Dec 2020 (Study Day 76)	Chills	Moderate
19 Dec 2020 (Study Day 76)	Fatigue	Moderate
19 Dec 2020 (Study Day 76)	Headache	Moderate
19 Dec 2020 (Study Day 76)	New Loss of Smell	Moderate
19 Dec 2020 (Study Day 76)	New Loss of Taste	Moderate
19 Dec 2020 (Study Day 76)	Sore Throat	Mild
20 Dec 2020 (Study Day 77)	Chills	Mild
20 Dec 2020 (Study Day 77)	Cough	Mild
20 Dec 2020 (Study Day 77)	Difficulty Breathing	Mild
20 Dec 2020 (Study Day 77)	Fatigue	Mild
20 Dec 2020 (Study Day 77)	Headache	Mild
20 Dec 2020 (Study Day 77)	New Loss of Smell	Moderate
20 Dec 2020 (Study Day 77)	New Loss of Taste	Moderate
20 Dec 2020 (Study Day 77)	Sore Throat	Moderate
21 Dec 2020 (Study Day 78)	Body Aches	Mild
21 Dec 2020 (Study Day 78)	Chills	Mild
21 Dec 2020 (Study Day 78)	Fatigue	Mild
21 Dec 2020 (Study Day 78)	Headache	Mild
21 Dec 2020 (Study Day 78)	New Loss of Smell	Moderate
21 Dec 2020 (Study Day 78)	New Loss of Taste	Mild
21 Dec 2020 (Study Day 78)	Sore Throat	Moderate
22 Dec 2020 (Study Day 79)	Body Aches	Mild
22 Dec 2020 (Study Day 79)	Chills	Mild
22 Dec 2020 (Study Day 79)	Fatigue	Mild
22 Dec 2020 (Study Day 79)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 79)	New Loss of Smell	Moderate
22 Dec 2020 (Study Day 79)	New Loss of Taste	Moderate
22 Dec 2020 (Study Day 79)	Sore Throat	Moderate
23 Dec 2020 (Study Day 80)	Chills	Moderate
23 Dec 2020 (Study Day 80)	Headache	Mild
23 Dec 2020 (Study Day 80)	New Loss of Smell	Moderate
23 Dec 2020 (Study Day 80)	New Loss of Taste	Moderate
23 Dec 2020 (Study Day 80)	Sore Throat	Moderate
24 Dec 2020 (Study Day 81)	Body Aches	Moderate
24 Dec 2020 (Study Day 81)	Cough	Moderate
24 Dec 2020 (Study Day 81)	Fatigue	Mild
24 Dec 2020 (Study Day 81)	Headache	Mild
24 Dec 2020 (Study Day 81)	Nasal Congestion	Mild
24 Dec 2020 (Study Day 81)	New Loss of Smell	Moderate
24 Dec 2020 (Study Day 81)	New Loss of Taste	Moderate
24 Dec 2020 (Study Day 81)	Sore Throat	Moderate

Symptom Date	Symptom	Result
25 Dec 2020 (Study Day 82)	Body Aches	Mild
25 Dec 2020 (Study Day 82)	Chills	Mild
25 Dec 2020 (Study Day 82)	Cough	Mild
25 Dec 2020 (Study Day 82)	Headache	Mild
25 Dec 2020 (Study Day 82)	New Loss of Smell	Moderate
25 Dec 2020 (Study Day 82)	New Loss of Taste	Moderate
25 Dec 2020 (Study Day 82)	Sore Throat	Moderate
26 Dec 2020 (Study Day 83)	Cough	Mild
26 Dec 2020 (Study Day 83)	Headache	Mild
26 Dec 2020 (Study Day 83)	New Loss of Smell	Moderate
26 Dec 2020 (Study Day 83)	New Loss of Taste	Moderate
26 Dec 2020 (Study Day 83)	Sore Throat	Mild
27 Dec 2020 (Study Day 84)	Body Aches	Mild
27 Dec 2020 (Study Day 84)	Chills	Moderate
27 Dec 2020 (Study Day 84)	Headache	Mild
27 Dec 2020 (Study Day 84)	New Loss of Smell	Moderate
27 Dec 2020 (Study Day 84)	New Loss of Taste	Moderate
28 Dec 2020 (Study Day 85)	Body Aches	Mild
28 Dec 2020 (Study Day 85)	Chills	Mild
28 Dec 2020 (Study Day 85)	New Loss of Smell	Moderate
28 Dec 2020 (Study Day 85)	New Loss of Taste	Moderate
28 Dec 2020 (Study Day 85)	Sore Throat	Mild
29 Dec 2020 (Study Day 86)	Body Aches	Moderate
29 Dec 2020 (Study Day 86)	Chills	Mild
29 Dec 2020 (Study Day 86)	Cough	Mild
29 Dec 2020 (Study Day 86)	Fatigue	Mild
29 Dec 2020 (Study Day 86)	Headache	Mild
29 Dec 2020 (Study Day 86)	New Loss of Smell	Moderate
29 Dec 2020 (Study Day 86)	New Loss of Taste	Moderate
29 Dec 2020 (Study Day 86)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 86)	Sore Throat	Moderate
30 Dec 2020 (Study Day 87)	Body Aches	Mild
30 Dec 2020 (Study Day 87)	Chills	Moderate
30 Dec 2020 (Study Day 87)	Fatigue	Mild
30 Dec 2020 (Study Day 87)	New Loss of Smell	Moderate
30 Dec 2020 (Study Day 87)	New Loss of Taste	Moderate
30 Dec 2020 (Study Day 87)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 87)	Sore Throat	Moderate
31 Dec 2020 (Study Day 88)	Body Aches	Mild
31 Dec 2020 (Study Day 88)	Chills	Mild
31 Dec 2020 (Study Day 88)	Headache	Mild
31 Dec 2020 (Study Day 88)	New Loss of Smell	Moderate
31 Dec 2020 (Study Day 88)	New Loss of Taste	Moderate

Symptom Date	Symptom	Result
31 Dec 2020 (Study Day 88)	Sore Throat	Moderate
01 Jan 2021 (Study Day 89)	Body Aches	Mild
01 Jan 2021 (Study Day 89)	Chills	Mild
01 Jan 2021 (Study Day 89)	Headache	Mild
01 Jan 2021 (Study Day 89)	New Loss of Smell	Moderate
01 Jan 2021 (Study Day 89)	New Loss of Taste	Moderate
01 Jan 2021 (Study Day 89)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 89)	Sore Throat	Moderate
02 Jan 2021 (Study Day 90)	Body Aches	Mild
02 Jan 2021 (Study Day 90)	Chills	Mild
02 Jan 2021 (Study Day 90)	Fatigue	Moderate
02 Jan 2021 (Study Day 90)	Headache	Mild
02 Jan 2021 (Study Day 90)	New Loss of Smell	Moderate
02 Jan 2021 (Study Day 90)	New Loss of Taste	Moderate
02 Jan 2021 (Study Day 90)	Sore Throat	Mild
03 Jan 2021 (Study Day 91)	Body Aches	Mild
03 Jan 2021 (Study Day 91)	Chills	Mild
03 Jan 2021 (Study Day 91)	Difficulty Breathing	Moderate
03 Jan 2021 (Study Day 91)	Fatigue	Moderate
03 Jan 2021 (Study Day 91)	Headache	Mild
03 Jan 2021 (Study Day 91)	Muscle Aches (Myalgia)	Moderate
03 Jan 2021 (Study Day 91)	New Loss of Smell	Moderate
03 Jan 2021 (Study Day 91)	New Loss of Taste	Moderate
03 Jan 2021 (Study Day 91)	Shortness of Breath	Moderate
03 Jan 2021 (Study Day 91)	Sore Throat	Mild
04 Jan 2021 (Study Day 92)	Body Aches	Moderate
04 Jan 2021 (Study Day 92)	Difficulty Breathing	Mild
04 Jan 2021 (Study Day 92)	Fatigue	Mild
04 Jan 2021 (Study Day 92)	Headache	Moderate
04 Jan 2021 (Study Day 92)	Muscle Aches (Myalgia)	Mild
04 Jan 2021 (Study Day 92)	New Loss of Smell	Moderate
04 Jan 2021 (Study Day 92)	New Loss of Taste	Moderate
04 Jan 2021 (Study Day 92)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 92)	Sore Throat	Mild
05 Jan 2021 (Study Day 93)	Body Aches	Mild
05 Jan 2021 (Study Day 93)	Cough	Mild
05 Jan 2021 (Study Day 93)	Difficulty Breathing	Mild
05 Jan 2021 (Study Day 93)	Fatigue	Mild
05 Jan 2021 (Study Day 93)	Headache	Mild
05 Jan 2021 (Study Day 93)	New Loss of Smell	Moderate
05 Jan 2021 (Study Day 93)	New Loss of Taste	Moderate
05 Jan 2021 (Study Day 93)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 93)	Sore Throat	Mild

Symptom Date	Symptom	Result
06 Jan 2021 (Study Day 94)	Body Aches	Moderate
06 Jan 2021 (Study Day 94)	Cough	Mild
06 Jan 2021 (Study Day 94)	Difficulty Breathing	Moderate
06 Jan 2021 (Study Day 94)	Fatigue	Mild
06 Jan 2021 (Study Day 94)	Headache	Moderate
06 Jan 2021 (Study Day 94)	New Loss of Smell	Moderate
06 Jan 2021 (Study Day 94)	New Loss of Taste	Moderate
06 Jan 2021 (Study Day 94)	Shortness of Breath	Moderate
06 Jan 2021 (Study Day 94)	Sore Throat	Moderate
07 Jan 2021 (Study Day 95)	Body Aches	Mild
07 Jan 2021 (Study Day 95)	Difficulty Breathing	Mild
07 Jan 2021 (Study Day 95)	Fatigue	Mild
07 Jan 2021 (Study Day 95)	New Loss of Smell	Moderate
07 Jan 2021 (Study Day 95)	New Loss of Taste	Moderate
07 Jan 2021 (Study Day 95)	Sore Throat	Mild
08 Jan 2021 (Study Day 96)	Cough	Mild
08 Jan 2021 (Study Day 96)	Fatigue	Mild
08 Jan 2021 (Study Day 96)	New Loss of Smell	Moderate
08 Jan 2021 (Study Day 96)	New Loss of Taste	Moderate
08 Jan 2021 (Study Day 96)	O2 Saturation (%)	93
08 Jan 2021 (Study Day 96)	Sore Throat	Mild
09 Jan 2021 (Study Day 97)	Fatigue	Mild
09 Jan 2021 (Study Day 97)	Headache	Mild
09 Jan 2021 (Study Day 97)	Nasal Congestion	Mild
09 Jan 2021 (Study Day 97)	New Loss of Smell	Moderate
09 Jan 2021 (Study Day 97)	New Loss of Taste	Moderate
09 Jan 2021 (Study Day 97)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 97)	Sore Throat	Mild
10 Jan 2021 (Study Day 98)	Fatigue	Mild
10 Jan 2021 (Study Day 98)	New Loss of Smell	Moderate
10 Jan 2021 (Study Day 98)	New Loss of Taste	Moderate
10 Jan 2021 (Study Day 98)	Sore Throat	Mild
11 Jan 2021 (Study Day 99)	Body Aches	Mild
11 Jan 2021 (Study Day 99)	Sore Throat	Mild
12 Jan 2021 (Study Day 100)	Diarrhea	Mild
12 Jan 2021 (Study Day 100)	Fatigue	Mild
12 Jan 2021 (Study Day 100)	Headache	Mild
12 Jan 2021 (Study Day 100)	Muscle Aches (Myalgia)	Mild
12 Jan 2021 (Study Day 100)	New Loss of Smell	Moderate
12 Jan 2021 (Study Day 100)	New Loss of Taste	Moderate
12 Jan 2021 (Study Day 100)	Sore Throat	Mild
13 Jan 2021 (Study Day 101)	Body Aches	Mild
13 Jan 2021 (Study Day 101)	Diarrhea	Moderate

Symptom Date	Symptom	Result
13 Jan 2021 (Study Day 101)	Sore Throat	Mild
14 Jan 2021 (Study Day 102)	Diarrhea	Mild
14 Jan 2021 (Study Day 102)	Fatigue	Mild
14 Jan 2021 (Study Day 102)	Sore Throat	Mild
15 Jan 2021 (Study Day 103)	Body Aches	Mild
15 Jan 2021 (Study Day 103)	Diarrhea	Mild
15 Jan 2021 (Study Day 103)	Difficulty Breathing	Mild
15 Jan 2021 (Study Day 103)	Fatigue	Mild
15 Jan 2021 (Study Day 103)	Sore Throat	Mild
16 Jan 2021 (Study Day 104)	Body Aches	Mild
16 Jan 2021 (Study Day 104)	Difficulty Breathing	Mild
16 Jan 2021 (Study Day 104)	Fatigue	Mild
16 Jan 2021 (Study Day 104)	Headache	Mild
16 Jan 2021 (Study Day 104)	New Loss of Smell	Mild
16 Jan 2021 (Study Day 104)	New Loss of Taste	Mild
16 Jan 2021 (Study Day 104)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 104)	Sore Throat	Mild
17 Jan 2021 (Study Day 105)	Body Aches	Mild
17 Jan 2021 (Study Day 105)	Cough	Mild
17 Jan 2021 (Study Day 105)	Fatigue	Mild
17 Jan 2021 (Study Day 105)	Headache	Mild
17 Jan 2021 (Study Day 105)	New Loss of Smell	Mild
17 Jan 2021 (Study Day 105)	New Loss of Taste	Mild
17 Jan 2021 (Study Day 105)	Shortness of Breath	Mild
17 Jan 2021 (Study Day 105)	Sore Throat	Moderate
18 Jan 2021 (Study Day 106)	Fatigue	Mild
18 Jan 2021 (Study Day 106)	Headache	Mild
18 Jan 2021 (Study Day 106)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 106)	New Loss of Taste	Mild
18 Jan 2021 (Study Day 106)	Sore Throat	Moderate
19 Jan 2021 (Study Day 107)	Cough	Mild
19 Jan 2021 (Study Day 107)	Fatigue	Mild
19 Jan 2021 (Study Day 107)	Headache	Moderate
19 Jan 2021 (Study Day 107)	Nasal Congestion	Mild
19 Jan 2021 (Study Day 107)	New Loss of Smell	Mild
19 Jan 2021 (Study Day 107)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 107)	Sore Throat	Moderate
20 Jan 2021 (Study Day 108)	Fatigue	Moderate
20 Jan 2021 (Study Day 108)	Headache	Mild
20 Jan 2021 (Study Day 108)	Nasal Congestion	Mild
20 Jan 2021 (Study Day 108)	New Loss of Smell	Mild
20 Jan 2021 (Study Day 108)	New Loss of Taste	Mild
20 Jan 2021 (Study Day 108)	Sore Throat	Moderate

Symptom Date	Symptom	Result
21 Jan 2021 (Study Day 109)	Body Aches	Mild
21 Jan 2021 (Study Day 109)	Fatigue	Mild
21 Jan 2021 (Study Day 109)	Headache	Mild
21 Jan 2021 (Study Day 109)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 109)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 109)	Sore Throat	Mild
22 Jan 2021 (Study Day 110)	Fatigue	Mild
22 Jan 2021 (Study Day 110)	Headache	Moderate
22 Jan 2021 (Study Day 110)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 110)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 110)	Sore Throat	Mild
23 Jan 2021 (Study Day 111)	Body Aches	Moderate
23 Jan 2021 (Study Day 111)	Chills	Mild
23 Jan 2021 (Study Day 111)	Fatigue	Moderate
23 Jan 2021 (Study Day 111)	Headache	Moderate
23 Jan 2021 (Study Day 111)	Nasal Congestion	Mild
23 Jan 2021 (Study Day 111)	New Loss of Smell	Mild
23 Jan 2021 (Study Day 111)	New Loss of Taste	Mild
23 Jan 2021 (Study Day 111)	Runny Nose (Rhinorrhea)	Mild
23 Jan 2021 (Study Day 111)	Sore Throat	Severe
24 Jan 2021 (Study Day 112)	Headache	Moderate
24 Jan 2021 (Study Day 112)	Nasal Congestion	Mild
24 Jan 2021 (Study Day 112)	Sore Throat	Moderate
25 Jan 2021 (Study Day 113)	Body Aches	Mild
25 Jan 2021 (Study Day 113)	Chills	Mild
25 Jan 2021 (Study Day 113)	Cough	Mild
25 Jan 2021 (Study Day 113)	Fatigue	Mild
25 Jan 2021 (Study Day 113)	Headache	Mild
25 Jan 2021 (Study Day 113)	New Loss of Smell	Mild
25 Jan 2021 (Study Day 113)	New Loss of Taste	Mild
25 Jan 2021 (Study Day 113)	Sore Throat	Moderate
26 Jan 2021 (Study Day 114)	Body Aches	Moderate
26 Jan 2021 (Study Day 114)	Cough	Mild
26 Jan 2021 (Study Day 114)	Fatigue	Mild
26 Jan 2021 (Study Day 114)	Headache	Mild
26 Jan 2021 (Study Day 114)	Nasal Congestion	Mild
26 Jan 2021 (Study Day 114)	New Loss of Smell	Mild
26 Jan 2021 (Study Day 114)	Runny Nose (Rhinorrhea)	Mild
26 Jan 2021 (Study Day 114)	Shortness of Breath	Mild
26 Jan 2021 (Study Day 114)	Sore Throat	Mild
27 Jan 2021 (Study Day 115)	Body Aches	Moderate
27 Jan 2021 (Study Day 115)	Chills	Moderate
27 Jan 2021 (Study Day 115)	Headache	Mild

Symptom Date	Symptom	Result
27 Jan 2021 (Study Day 115)	Nasal Congestion	Mild
27 Jan 2021 (Study Day 115)	New Loss of Smell	Mild
27 Jan 2021 (Study Day 115)	Sore Throat	Mild
28 Jan 2021 (Study Day 116)	Body Aches	Mild
28 Jan 2021 (Study Day 116)	Chills	Mild
28 Jan 2021 (Study Day 116)	Headache	Mild
28 Jan 2021 (Study Day 116)	Nasal Congestion	Mild
28 Jan 2021 (Study Day 116)	New Loss of Smell	Mild
28 Jan 2021 (Study Day 116)	Sore Throat	Mild
29 Jan 2021 (Study Day 117)	Body Aches	Mild
29 Jan 2021 (Study Day 117)	Chills	Mild
29 Jan 2021 (Study Day 117)	New Loss of Smell	Mild
29 Jan 2021 (Study Day 117)	Sore Throat	Mild
30 Jan 2021 (Study Day 118)	Body Aches	Mild
30 Jan 2021 (Study Day 118)	Fatigue	Mild
30 Jan 2021 (Study Day 118)	Headache	Mild
30 Jan 2021 (Study Day 118)	New Loss of Smell	Mild
30 Jan 2021 (Study Day 118)	Sore Throat	Mild
31 Jan 2021 (Study Day 119)	Body Aches	Mild
31 Jan 2021 (Study Day 119)	Headache	Mild
31 Jan 2021 (Study Day 119)	New Loss of Smell	Mild
31 Jan 2021 (Study Day 119)	Sore Throat	Mild
01 Feb 2021 (Study Day 120)	Body Aches	Mild
01 Feb 2021 (Study Day 120)	Fatigue	Mild
01 Feb 2021 (Study Day 120)	Headache	Mild
01 Feb 2021 (Study Day 120)	New Loss of Smell	Mild
01 Feb 2021 (Study Day 120)	Sore Throat	Mild
02 Feb 2021 (Study Day 121)	Body Aches	Mild
02 Feb 2021 (Study Day 121)	Headache	Mild
02 Feb 2021 (Study Day 121)	New Loss of Smell	Mild
02 Feb 2021 (Study Day 121)	Runny Nose (Rhinorrhea)	Mild
02 Feb 2021 (Study Day 121)	Sore Throat	Mild
09 Feb 2021 (Study Day 128)	Headache	Mild
09 Feb 2021 (Study Day 128)	New Loss of Smell	Mild
18 Feb 2021 (Study Day 137)	Headache	Mild
18 Feb 2021 (Study Day 137)	New Loss of Smell	Mild
25 Feb 2021 (Study Day 144)	Body Aches	Mild
25 Feb 2021 (Study Day 144)	Headache	Mild
25 Feb 2021 (Study Day 144)	Muscle Aches (Myalgia)	Mild
25 Feb 2021 (Study Day 144)	Sore Throat	Mild
04 Mar 2021 (Study Day 151)	Body Aches	Mild
04 Mar 2021 (Study Day 151)	Cough	Mild
04 Mar 2021 (Study Day 151)	Headache	Mild

Symptom Date	Symptom	Result
04 Mar 2021 (Study Day 151)	Muscle Aches (Myalgia)	Mild
04 Mar 2021 (Study Day 151)	Nasal Congestion	Mild
04 Mar 2021 (Study Day 151)	Runny Nose (Rhinorrhea)	Moderate
04 Mar 2021 (Study Day 151)	Sore Throat	Mild
19 Mar 2021 (Study Day 166)	Cough	Mild
19 Mar 2021 (Study Day 166)	Nasal Congestion	Mild
19 Mar 2021 (Study Day 166)	Runny Nose (Rhinorrhea)	Mild
26 Mar 2021 (Study Day 173)	Headache	Mild
26 Mar 2021 (Study Day 173)	Nasal Congestion	Mild
26 Mar 2021 (Study Day 173)	New Loss of Smell	Mild
26 Mar 2021 (Study Day 173)	New Loss of Taste	Mild
26 Mar 2021 (Study Day 173)	Runny Nose (Rhinorrhea)	Moderate
01 Apr 2021 (Study Day 179)	Nasal Congestion	Mild
01 Apr 2021 (Study Day 179)	New Loss of Taste	Mild
01 Apr 2021 (Study Day 179)	Runny Nose (Rhinorrhea)	Mild
08 Apr 2021 (Study Day 186)	Chills	Mild
08 Apr 2021 (Study Day 186)	Difficulty Breathing	Mild
08 Apr 2021 (Study Day 186)	Fatigue	Moderate
08 Apr 2021 (Study Day 186)	Headache	Moderate
08 Apr 2021 (Study Day 186)	Muscle Aches (Myalgia)	Moderate
08 Apr 2021 (Study Day 186)	Nasal Congestion	Moderate
08 Apr 2021 (Study Day 186)	New Loss of Smell	Moderate
08 Apr 2021 (Study Day 186)	New Loss of Taste	Mild
08 Apr 2021 (Study Day 186)	Runny Nose (Rhinorrhea)	Moderate
08 Apr 2021 (Study Day 186)	Sore Throat	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
28 Nov 2020 (Study Day 55)	Oxygen Saturation	88%
28 Nov 2020 - 07 Dec 2020 (Study Day 55-64)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 22 days, after which it was considered to be recovered/resolved with sequelae on 14 Dec 2020 (Study Day 71). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001003	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vitamin D decreased	Low vitamin d	15 Jan 2000 (Study Day -7569) - Ongoing
Asthma	Mild intermittent asthma	15 Apr 2001 (Study Day -7113) - Ongoing
Seasonal allergy	Seasonal allergies	15 Apr 2001 (Study Day -7113) - Ongoing
Gastrooesophageal reflux disease	Gastro-esophageal reflux disease	15 Jun 2017 (Study Day -1208) - Ongoing
Insomnia	Difficulty sleeping	15 Jun 2019 (Study Day -478) - Ongoing
Postmenopause	Post menopausal	26 Aug 2019 (Study Day -406) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	15 Apr 2001 (Study Day -7113) - 16 Nov 2020 (Study Day 43)	Seasonal Allergies
Calcium carbonate; colecalciferol; cupric oxide; magnesium oxide; manganese sulfate; sodium borate; zinc oxide	15 Jul 2015 (Study Day -1909) - Ongoing	Supplement
Vitamin b12 nos	15 Jul 2015 (Study Day -1909) - Ongoing	Supplement
Vitamin d nos	15 Jul 2015 (Study Day -1909) - 17 Dec 2020 (Study Day 74)	Low Vitamin D
Omeprazole	15 Jul 2017 (Study Day -1178) - 17 Dec 2020 (Study Day 74)	Gerd
Salbutamol	15 Jul 2017 (Study Day -1178) - Ongoing	Asthma
Melatonin	15 Jul 2019 (Study Day -448) - Ongoing	Trouble Sleeping
Ascorbic acid	15 Apr 2020 (Study Day -173) - Ongoing	Supplement
Influenza vaccine	07 Sep 2020 (Study Day -28) - 07 Sep 2020 (Study Day -28)	Annual Vaccine
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	08 Oct 2020 (Study Day 4) - 08 Oct 2020 (Study Day 4)	Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mammogram*	08 Oct 2020 (Study Day 4) - 08 Oct 2020 (Study Day 4)	Diagnostic
Acetylsalicylic acid; caffeine; paracetamol	13 Oct 2020 (Study Day 9) - 13 Oct 2020 (Study Day 9)	Headache
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	15 Oct 2020 (Study Day 11) - 15 Oct 2020 (Study Day 11)	Headache
Paracetamol	16 Oct 2020 (Study Day 12) - 16 Oct 2020 (Study Day 12)	Headache
Paracetamol	17 Oct 2020 (Study Day 13) - 18 Oct 2020 (Study Day 14)	Headache
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	18 Oct 2020 (Study Day 14) - 18 Oct 2020 (Study Day 14)	Cough
Paracetamol	19 Oct 2020 (Study Day 15) - Ongoing	Headache
Vitamins nos	25 Oct 2020 (Study Day 21) - 17 Dec 2020 (Study Day 74)	Supplement
Paracetamol	05 Nov 2020 (Study Day 32) - 08 Nov 2020 (Study Day 35)	Headache
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	11 Nov 2020 (Study Day 38) - 18 Nov 2020 (Study Day 45)	Myalgia
Loratadine	17 Nov 2020 (Study Day 44) - Ongoing	Seasonal Allergies
Ciprofloxacin	19 Nov 2020 (Study Day 46) - 24 Nov 2020 (Study Day 51)	Urinary Tract Infection
Simeticone	20 Nov 2020 (Study Day 47) - 28 Nov 2020 (Study Day 55)	Stomach Bloating
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	25 Nov 2020 (Study Day 52) - 27 Nov 2020 (Study Day 54)	Myalgia, Generalized
Paracetamol	28 Nov 2020 (Study Day 55) - 28 Nov 2020 (Study Day 55)	Myalgia
Ibuprofen	30 Nov 2020 (Study Day 57) - 30 Nov 2020 (Study Day 57)	Myalgia
Ibuprofen	02 Dec 2020 (Study Day 59) - 03 Dec 2020 (Study Day 60)	Body Aches
Monoclonal antibody infusion*	03 Dec 2020 (Study Day 60) - 03 Dec 2020 (Study Day 60)	Adverse Event
Other antivirals	03 Dec 2020 (Study Day 60) - 03 Dec 2020 (Study Day 60)	Symptomatic COVID-19
Dextromethorphan hydrobromide; doxylamine succinate	07 Dec 2020 (Study Day 64) - Ongoing	Cough
Dextromethorphan hydrobromide; guaifenesin	08 Dec 2020 (Study Day 65) - Ongoing	Cough
Ibuprofen	08 Dec 2020 (Study Day 65) - 08 Dec 2020 (Study Day 65)	Headache
Aluminium hydroxide; magnesium trisilicate	15 Dec 2020 (Study Day 72) - 16 Dec 2020 (Study Day 73)	Left Upper Quadrant Pain And Bloating
Calcium carbonate; magnesium hydroxide; simeticone	17 Dec 2020 (Study Day 74) - 21 Dec 2020 (Study Day 78)	Worsening Gerd
Omeprazole	18 Dec 2020 (Study Day 75) - Ongoing	Worsening Gerd

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Valaciclovir hydrochloride	07 Jan 2021 (Study Day 95) - 08 Jan 2021 (Study Day 96)	Cold Sores
Calcium carbonate; magnesium hydroxide; simeticone	08 Jan 2021 (Study Day 96) - 09 Jan 2021 (Study Day 97)	Worsening Gerd
Amylase; cellulase; dehydrocholic acid; dimeticone; lipase; metoclopramide hydrochloride; pancreatin; pepsin	11 Jan 2021 (Study Day 99) - 20 Jan 2021 (Study Day 108)	Gastritis
Otilonium bromide	11 Jan 2021 (Study Day 99) - 20 Jan 2021 (Study Day 108)	Gastritis
Pantoprazole	11 Jan 2021 (Study Day 99) - 03 Feb 2021 (Study Day 122)	Gastritis
Saccharomyces cerevisiae	11 Jan 2021 (Study Day 99) - 15 Jan 2021 (Study Day 103)	Gastritis
Bismuth subsalicylate	13 Jan 2021 (Study Day 101) - 20 Jan 2021 (Study Day 108)	Gastritis
Endoscopy*	13 Jan 2021 (Study Day 101) - 13 Jan 2021 (Study Day 101)	Adverse Event
Rifaximin	13 Jan 2021 (Study Day 101) - 18 Jan 2021 (Study Day 106)	H. Pylori
Stomach biopsy*	13 Jan 2021 (Study Day 101) - 13 Jan 2021 (Study Day 101)	Adverse Event
Stomach ultrasound*	13 Jan 2021 (Study Day 101) - 13 Jan 2021 (Study Day 101)	Adverse Event
Amoxicillin	21 Jan 2021 (Study Day 109) - 03 Feb 2021 (Study Day 122)	H. Pylori
Clarithromycin	21 Jan 2021 (Study Day 109) - 03 Feb 2021 (Study Day 122)	H. Pylori
Silybum marianum	24 Jan 2021 (Study Day 112) - Ongoing	Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Not related	06 Oct 2020 (Study Day 2) - 14 Oct 2020 (Study Day 10)
Headache	Grade 2/moderate	Not related	06 Oct 2020 (Study Day 2) - 15 Oct 2020 (Study Day 11)
Myalgia	Grade 1/mild	Not related	06 Oct 2020 (Study Day 2) - 14 Oct 2020 (Study Day 10)
Paraesthesia	Grade 1/mild	Not related	06 Oct 2020 (Study Day 2) - 07 Oct 2020 (Study Day 3)
Vertigo Positional	Grade 1/mild	Not related	24 Oct 2020 (Study Day 20) - 31 Oct 2020 (Study Day 27)
Ear Pruritus	Grade 1/mild	Not related	29 Oct 2020 (Study Day 25) - 18 Nov 2020 (Study Day 45)
Fatigue	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 30) - 09 Nov 2020 (Study Day 36)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Back Pain	Grade 1/mild	Not related	11 Nov 2020 (Study Day 38) - 18 Nov 2020 (Study Day 45)
Chest Discomfort	Grade 1/mild	Not related	11 Nov 2020 (Study Day 38) - 20 Nov 2020 (Study Day 47)
Pleuritic Pain	Grade 1/mild	Not related	11 Nov 2020 (Study Day 38) - 18 Nov 2020 (Study Day 45)
Abdominal Pain Upper	Grade 1/mild	Not related	12 Nov 2020 (Study Day 39) - 22 Nov 2020 (Study Day 49)
Pharyngeal Erythema	Grade 1/mild	Not related	17 Nov 2020 (Study Day 44) - 11 Feb 2021 (Study Day 130)
Urinary Tract Infection	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 45) - 24 Nov 2020 (Study Day 51)
Abdominal Distension	Grade 1/mild	Not related	19 Nov 2020 (Study Day 46) - 30 Nov 2020 (Study Day 57)
Heart Rate Increased	Grade 1/mild	Not related	19 Nov 2020 (Study Day 46) - 19 Nov 2020 (Study Day 46)
COVID-19	Grade 3/severe	Not related	23 Nov 2020 (Study Day 50) - 14 Dec 2020 (Study Day 71)
Chest Discomfort	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 52) - 22 Jan 2021 (Study Day 110)
Chest Discomfort	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 52) - 15 Dec 2020 (Study Day 72)
Decreased Appetite	Grade 1/mild	Not related	25 Nov 2020 (Study Day 52) - 12 Mar 2021 (Study Day 159)
Arthralgia	Grade 2/moderate	Not related	02 Dec 2020 (Study Day 59) - 03 Dec 2020 (Study Day 60)
Eye Pain	Grade 1/mild	Not related	08 Dec 2020 (Study Day 65) - 13 Dec 2020 (Study Day 70)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	10 Dec 2020 (Study Day 67) - 05 Feb 2021 (Study Day 124)
Abdominal Distension	Grade 2/moderate	Not related	11 Dec 2020 (Study Day 68) - 01 Mar 2021 (Study Day 148)
Abdominal Pain Upper	Grade 2/moderate	Not related	11 Dec 2020 (Study Day 68) - 08 Jan 2021 (Study Day 96)
Arthralgia	Grade 1/mild	Not related	11 Dec 2020 (Study Day 68) - Ongoing
Oral Herpes	Grade 2/moderate	Not related	11 Dec 2020 (Study Day 68) - 12 Dec 2020 (Study Day 69)
Vision Blurred	Grade 1/mild	Not related	13 Dec 2020 (Study Day 70) - 21 Dec 2020 (Study Day 78)
Lymphadenopathy	Grade 1/mild	Not related	14 Dec 2020 (Study Day 71) - 30 Dec 2020 (Study Day 87)
Systemic Inflammatory Response Syndrome	Grade 1/mild	Not related	15 Dec 2020 (Study Day 72) - Ongoing
Dizziness	Grade 1/mild	Not related	17 Dec 2020 (Study Day 74) - 21 Dec 2020 (Study Day 78)
Tongue Disorder	Grade 1/mild	Not related	22 Dec 2020 (Study Day 79) - 30 Dec 2020 (Study Day 87)
Tongue Disorder	Grade 1/mild	Not related	22 Dec 2020 (Study Day 79) - 30 Dec 2020 (Study Day 87)

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Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tongue Dry	Grade 1/mild	Not related	22 Dec 2020 (Study Day 79) - Ongoing
Peripheral Coldness	Grade 1/mild	Not related	27 Dec 2020 (Study Day 84) - 03 Jan 2021 (Study Day 91)
Peripheral Coldness	Grade 1/mild	Not related	27 Dec 2020 (Study Day 84) - 03 Jan 2021 (Study Day 91)
Constipation	Grade 1/mild	Not related	28 Dec 2020 (Study Day 85) - 11 Jan 2021 (Study Day 99)
Abdominal Pain Upper	Grade 1/mild	Not related	03 Jan 2021 (Study Day 91) - 05 Jan 2021 (Study Day 93)
Agitation	Grade 1/mild	Not related	03 Jan 2021 (Study Day 91) - 07 Jan 2021 (Study Day 95)
Bladder Pain	Grade 1/mild	Not related	03 Jan 2021 (Study Day 91) - 05 Jan 2021 (Study Day 93)
Muscle Spasms	Grade 1/mild	Not related	03 Jan 2021 (Study Day 91) - 07 Jan 2021 (Study Day 95)
Pollakiuria	Grade 1/mild	Not related	03 Jan 2021 (Study Day 91) - 05 Jan 2021 (Study Day 93)
Vision Blurred	Grade 1/mild	Not related	04 Jan 2021 (Study Day 92) - 05 Jan 2021 (Study Day 93)
Dizziness	Grade 1/mild	Not related	05 Jan 2021 (Study Day 93) - 05 Jan 2021 (Study Day 93)
Heart Rate Increased	Grade 1/mild	Not related	05 Jan 2021 (Study Day 93) - 07 Jan 2021 (Study Day 95)
Bladder Pain	Grade 1/mild	Not related	07 Jan 2021 (Study Day 95) - Ongoing
Oral Herpes	Grade 2/moderate	Not related	07 Jan 2021 (Study Day 95) - 08 Jan 2021 (Study Day 96)
Pollakiuria	Grade 1/mild	Not related	07 Jan 2021 (Study Day 95) - Ongoing
Speech Disorder	Grade 1/mild	Not related	08 Jan 2021 (Study Day 96) - Ongoing
Gastritis	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 99) - 03 Feb 2021 (Study Day 122)
Helicobacter Infection	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 101) - Ongoing
Throat Irritation	Grade 1/mild	Not related	19 Jan 2021 (Study Day 107) - 22 Jan 2021 (Study Day 110)
Ear Congestion	Grade 1/mild	Not related	26 Jan 2021 (Study Day 114) - 27 Jan 2021 (Study Day 115)
Peripheral Coldness	Grade 2/moderate	Not related	26 Jan 2021 (Study Day 114) - 01 Feb 2021 (Study Day 120)
Abdominal Pain Lower	Grade 1/mild	Not related	11 Feb 2021 (Study Day 130) - 26 Feb 2021 (Study Day 145)
Muscle Tightness	Grade 1/mild	Not related	11 Feb 2021 (Study Day 130) - 02 Mar 2021 (Study Day 149)
Peripheral Coldness	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 130) - 15 Feb 2021 (Study Day 134)
Abdominal Pain Lower	Grade 1/mild	Not related	19 Mar 2021 (Study Day 166) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US368-2018 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	COVID-19	Grade 1/mild	Not related	09 Dec 2020 (Study Day 106) – 19 Dec 2020 (Study Day 116)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2018, a 40-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 09 Dec 2020 (Study Day 106), 105 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 23 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Dec 2020 (Study Day 108), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
09 Dec 2020 (Study Day 106)	Body Aches	Mild
09 Dec 2020 (Study Day 106)	Chills	Mild
09 Dec 2020 (Study Day 106)	Cough	Mild
09 Dec 2020 (Study Day 106)	Fatigue	Mild
09 Dec 2020 (Study Day 106)	Headache	Mild
09 Dec 2020 (Study Day 106)	Muscle Aches (Myalgia)	Mild
10 Dec 2020 (Study Day 107)	Body Aches	Mild
10 Dec 2020 (Study Day 107)	Chills	Mild

Symptom Date	Symptom	Result
10 Dec 2020 (Study Day 107)	Diarrhea	Mild
10 Dec 2020 (Study Day 107)	Fatigue	Mild
10 Dec 2020 (Study Day 107)	Headache	Mild
10 Dec 2020 (Study Day 107)	Muscle Aches (Myalgia)	Mild
11 Dec 2020 (Study Day 108)	Body Aches	Mild
11 Dec 2020 (Study Day 108)	Diarrhea	Mild
11 Dec 2020 (Study Day 108)	Fatigue	Mild
11 Dec 2020 (Study Day 108)	Muscle Aches (Myalgia)	Mild
12 Dec 2020 (Study Day 109)	Body Aches	Mild
12 Dec 2020 (Study Day 109)	Fatigue	Mild
12 Dec 2020 (Study Day 109)	Temperature (°F)	101.1
13 Dec 2020 (Study Day 110)	Body Aches	Mild
13 Dec 2020 (Study Day 110)	Fatigue	Mild
13 Dec 2020 (Study Day 110)	Temperature (°F)	100.7
14 Dec 2020 (Study Day 111)	Body Aches	Mild
14 Dec 2020 (Study Day 111)	Chills	Mild
14 Dec 2020 (Study Day 111)	Cough	Mild
14 Dec 2020 (Study Day 111)	Fatigue	Moderate
14 Dec 2020 (Study Day 111)	Headache	Mild
14 Dec 2020 (Study Day 111)	Muscle Aches (Myalgia)	Mild
14 Dec 2020 (Study Day 111)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 111)	Nausea	Mild
15 Dec 2020 (Study Day 112)	Body Aches	Mild
15 Dec 2020 (Study Day 112)	Chills	Mild
15 Dec 2020 (Study Day 112)	Cough	Mild
15 Dec 2020 (Study Day 112)	Diarrhea	Mild
15 Dec 2020 (Study Day 112)	Fatigue	Moderate
15 Dec 2020 (Study Day 112)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 113)	Fatigue	Mild
16 Dec 2020 (Study Day 113)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 113)	O2 Saturation (%)	93
17 Dec 2020 (Study Day 114)	Fatigue	Mild
18 Dec 2020 (Study Day 115)	Fatigue	Mild
02 Feb 2021 (Study Day 161)	Sore Throat	Mild
03 Feb 2021 (Study Day 162)	Fatigue	Mild
03 Feb 2021 (Study Day 162)	Sore Throat	Mild
03 Feb 2021 (Study Day 162)	Temperature (°F)	100.5
04 Feb 2021 (Study Day 163)	Fatigue	Mild
04 Feb 2021 (Study Day 163)	Sore Throat	Mild
05 Feb 2021 (Study Day 164)	Sore Throat	Mild
06 Feb 2021 (Study Day 165)	Sore Throat	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
16 Dec 2020 (Study Day 113)	Oxygen Saturation	93%
16 Dec 2020 - 16 Dec 2020 (Study Day 113-113)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 11 days, after which it was considered to be recovered/resolved on 19 Dec 2020 (Study Day 116). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001135	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	Not reported - Ongoing	Supplement
Azithromycin	03 Feb 2021 (Study Day 162) - 03 Feb 2021 (Study Day 162)	Strep Â throat
Azithromycin	04 Feb 2021 (Study Day 163) - 07 Feb 2021 (Study Day 166)	Strep Throat
Methylprednisolone	18 Mar 2021 (Study Day 205) - 23 Mar 2021 (Study Day 210)	Right Arm/Shoulder Pain
Valaciclovir hydrochloride	18 Mar 2021 (Study Day 205) - 19 Mar 2021 (Study Day 206)	Oral Hsv Outbreak

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Not related	14 Sep 2020 (Study Day 20) - 15 Sep 2020 (Study Day 21)
Oropharyngeal Pain	Grade 1/mild	Not related	14 Sep 2020 (Study Day 20) - 15 Sep 2020 (Study Day 21)
Vomiting	Grade 1/mild	Not related	14 Sep 2020 (Study Day 20) - 15 Sep 2020 (Study Day 21)
COVID-19	Grade 1/mild	Not related	09 Dec 2020 (Study Day 106) - 19 Dec 2020 (Study Day 116)
Pharyngitis Streptococcal	Grade 2/moderate	Not related	02 Feb 2021 (Study Day 161) - 07 Feb 2021 (Study Day 166)
Musculoskeletal Pain	Grade 2/moderate	Not related	13 Mar 2021 (Study Day 200) - Ongoing
Pain In Extremity	Grade 2/moderate	Not related	13 Mar 2021 (Study Day 200) - Ongoing
Oral Herpes	Grade 2/moderate	Not related	18 Mar 2021 (Study Day 205) - 19 Mar 2021 (Study Day 206)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US370-2051 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	02 Nov 2020 (Study Day 32)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	02 Jan 2021 (Study Day 93) – 07 Feb 2021 (Study Day 129)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US370-2051, a 43-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 02 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 02 Nov 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 02 Jan 2021 (Study Day 93), 92 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 32, 02 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 06 Jan 2021 (Study Day 97), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 93)	Body Aches	Moderate
02 Jan 2021 (Study Day 93)	Fatigue	Moderate
02 Jan 2021 (Study Day 93)	Headache	Moderate
02 Jan 2021 (Study Day 93)	Muscle Aches (Myalgia)	Mild
03 Jan 2021 (Study Day 94)	Body Aches	Moderate
03 Jan 2021 (Study Day 94)	Fatigue	Moderate

Symptom Date	Symptom	Result
03 Jan 2021 (Study Day 94)	Headache	Moderate
03 Jan 2021 (Study Day 94)	Muscle Aches (Myalgia)	Mild
03 Jan 2021 (Study Day 94)	Nasal Congestion	Moderate
03 Jan 2021 (Study Day 94)	Sore Throat	Mild
04 Jan 2021 (Study Day 95)	Body Aches	Moderate
04 Jan 2021 (Study Day 95)	Cough	Mild
04 Jan 2021 (Study Day 95)	Fatigue	Moderate
04 Jan 2021 (Study Day 95)	Headache	Moderate
04 Jan 2021 (Study Day 95)	Muscle Aches (Myalgia)	Mild
04 Jan 2021 (Study Day 95)	Nasal Congestion	Moderate
04 Jan 2021 (Study Day 95)	New Loss of Smell	Severe
04 Jan 2021 (Study Day 95)	New Loss of Taste	Severe
04 Jan 2021 (Study Day 95)	Runny Nose (Rhinorrhea)	Mild
04 Jan 2021 (Study Day 95)	Sore Throat	Mild
05 Jan 2021 (Study Day 96)	Diarrhea	Mild
05 Jan 2021 (Study Day 96)	Fatigue	Mild
05 Jan 2021 (Study Day 96)	Headache	Moderate
05 Jan 2021 (Study Day 96)	Muscle Aches (Myalgia)	Mild
05 Jan 2021 (Study Day 96)	Nasal Congestion	Severe
05 Jan 2021 (Study Day 96)	Nausea	Mild
05 Jan 2021 (Study Day 96)	New Loss of Smell	Moderate
05 Jan 2021 (Study Day 96)	New Loss of Taste	Moderate
05 Jan 2021 (Study Day 96)	Runny Nose (Rhinorrhea)	Moderate
05 Jan 2021 (Study Day 96)	Temperature (°F)	101
06 Jan 2021 (Study Day 97)	Body Aches	Moderate
06 Jan 2021 (Study Day 97)	Cough	Mild
06 Jan 2021 (Study Day 97)	Diarrhea	Mild
06 Jan 2021 (Study Day 97)	Fatigue	Moderate
06 Jan 2021 (Study Day 97)	Headache	Moderate
06 Jan 2021 (Study Day 97)	Muscle Aches (Myalgia)	Mild
06 Jan 2021 (Study Day 97)	Nasal Congestion	Moderate
06 Jan 2021 (Study Day 97)	Nausea	Mild
06 Jan 2021 (Study Day 97)	New Loss of Smell	Severe
06 Jan 2021 (Study Day 97)	New Loss of Taste	Severe
06 Jan 2021 (Study Day 97)	Runny Nose (Rhinorrhea)	Mild
06 Jan 2021 (Study Day 97)	Sore Throat	Mild
07 Jan 2021 (Study Day 98)	Cough	Mild
07 Jan 2021 (Study Day 98)	Fatigue	Moderate
07 Jan 2021 (Study Day 98)	Headache	Mild
07 Jan 2021 (Study Day 98)	Nasal Congestion	Severe
07 Jan 2021 (Study Day 98)	New Loss of Smell	Severe
07 Jan 2021 (Study Day 98)	New Loss of Taste	Severe
07 Jan 2021 (Study Day 98)	Sore Throat	Mild

Symptom Date	Symptom	Result
08 Jan 2021 (Study Day 99)	Diarrhea	Mild
08 Jan 2021 (Study Day 99)	Nasal Congestion	Mild
08 Jan 2021 (Study Day 99)	New Loss of Smell	Moderate
08 Jan 2021 (Study Day 99)	New Loss of Taste	Moderate
09 Jan 2021 (Study Day 100)	Cough	Mild
09 Jan 2021 (Study Day 100)	Headache	Mild
09 Jan 2021 (Study Day 100)	Nasal Congestion	Moderate
09 Jan 2021 (Study Day 100)	New Loss of Smell	Moderate
09 Jan 2021 (Study Day 100)	New Loss of Taste	Moderate
09 Jan 2021 (Study Day 100)	Sore Throat	Mild
10 Jan 2021 (Study Day 101)	Diarrhea	Mild
10 Jan 2021 (Study Day 101)	Fatigue	Mild
10 Jan 2021 (Study Day 101)	Headache	Mild
10 Jan 2021 (Study Day 101)	Nasal Congestion	Moderate
10 Jan 2021 (Study Day 101)	New Loss of Smell	Moderate
10 Jan 2021 (Study Day 101)	New Loss of Taste	Moderate
10 Jan 2021 (Study Day 101)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 101)	Sore Throat	Mild
11 Jan 2021 (Study Day 102)	Cough	Mild
11 Jan 2021 (Study Day 102)	Diarrhea	Mild
11 Jan 2021 (Study Day 102)	Nasal Congestion	Moderate
11 Jan 2021 (Study Day 102)	New Loss of Smell	Moderate
11 Jan 2021 (Study Day 102)	New Loss of Taste	Moderate
11 Jan 2021 (Study Day 102)	O2 Saturation (%)	93
11 Jan 2021 (Study Day 102)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 102)	Sore Throat	Mild
12 Jan 2021 (Study Day 103)	Body Aches	Moderate
12 Jan 2021 (Study Day 103)	Cough	Moderate
12 Jan 2021 (Study Day 103)	Headache	Moderate
12 Jan 2021 (Study Day 103)	Muscle Aches (Myalgia)	Moderate
12 Jan 2021 (Study Day 103)	Nasal Congestion	Moderate
12 Jan 2021 (Study Day 103)	New Loss of Smell	Moderate
12 Jan 2021 (Study Day 103)	New Loss of Taste	Moderate
12 Jan 2021 (Study Day 103)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 103)	Sore Throat	Moderate
13 Jan 2021 (Study Day 104)	Body Aches	Mild
13 Jan 2021 (Study Day 104)	Cough	Mild
13 Jan 2021 (Study Day 104)	Headache	Mild
13 Jan 2021 (Study Day 104)	Muscle Aches (Myalgia)	Mild
13 Jan 2021 (Study Day 104)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 104)	New Loss of Smell	Mild
13 Jan 2021 (Study Day 104)	New Loss of Taste	Mild
13 Jan 2021 (Study Day 104)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
13 Jan 2021 (Study Day 104)	Sore Throat	Mild
13 Jan 2021 (Study Day 104)	Temperature (°F)	101
14 Jan 2021 (Study Day 105)	Body Aches	Mild
14 Jan 2021 (Study Day 105)	Cough	Mild
14 Jan 2021 (Study Day 105)	Fatigue	Mild
14 Jan 2021 (Study Day 105)	Headache	Mild
14 Jan 2021 (Study Day 105)	Muscle Aches (Myalgia)	Mild
14 Jan 2021 (Study Day 105)	Nasal Congestion	Mild
14 Jan 2021 (Study Day 105)	New Loss of Smell	Mild
14 Jan 2021 (Study Day 105)	New Loss of Taste	Mild
14 Jan 2021 (Study Day 105)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 106)	Body Aches	Mild
15 Jan 2021 (Study Day 106)	Cough	Mild
15 Jan 2021 (Study Day 106)	Headache	Mild
15 Jan 2021 (Study Day 106)	Nasal Congestion	Mild
15 Jan 2021 (Study Day 106)	New Loss of Smell	Mild
15 Jan 2021 (Study Day 106)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 106)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 106)	Sore Throat	Mild
16 Jan 2021 (Study Day 107)	Cough	Moderate
16 Jan 2021 (Study Day 107)	Headache	Mild
16 Jan 2021 (Study Day 107)	Nasal Congestion	Mild
16 Jan 2021 (Study Day 107)	New Loss of Smell	Mild
16 Jan 2021 (Study Day 107)	New Loss of Taste	Mild
17 Jan 2021 (Study Day 108)	Cough	Moderate
17 Jan 2021 (Study Day 108)	Fatigue	Mild
17 Jan 2021 (Study Day 108)	Headache	Moderate
17 Jan 2021 (Study Day 108)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 108)	New Loss of Smell	Mild
17 Jan 2021 (Study Day 108)	New Loss of Taste	Mild
18 Jan 2021 (Study Day 109)	Cough	Moderate
18 Jan 2021 (Study Day 109)	Fatigue	Mild
18 Jan 2021 (Study Day 109)	Headache	Moderate
18 Jan 2021 (Study Day 109)	Nasal Congestion	Mild
18 Jan 2021 (Study Day 109)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 109)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 110)	Cough	Moderate
19 Jan 2021 (Study Day 110)	New Loss of Smell	Mild
19 Jan 2021 (Study Day 110)	New Loss of Taste	Mild
20 Jan 2021 (Study Day 111)	Cough	Mild
20 Jan 2021 (Study Day 111)	Headache	Mild
20 Jan 2021 (Study Day 111)	New Loss of Smell	Mild
20 Jan 2021 (Study Day 111)	New Loss of Taste	Mild

Symptom Date	Symptom	Result
21 Jan 2021 (Study Day 112)	Cough	Moderate
21 Jan 2021 (Study Day 112)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 112)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 112)	Shortness of Breath	Mild
22 Jan 2021 (Study Day 113)	Cough	Moderate
22 Jan 2021 (Study Day 113)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 113)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 113)	Shortness of Breath	Mild
23 Jan 2021 (Study Day 114)	Cough	Mild
23 Jan 2021 (Study Day 114)	New Loss of Smell	Mild
23 Jan 2021 (Study Day 114)	New Loss of Taste	Mild
23 Jan 2021 (Study Day 114)	Shortness of Breath	Mild
24 Jan 2021 (Study Day 115)	Cough	Mild
24 Jan 2021 (Study Day 115)	New Loss of Smell	Mild
24 Jan 2021 (Study Day 115)	New Loss of Taste	Mild
25 Jan 2021 (Study Day 116)	Cough	Mild
25 Jan 2021 (Study Day 116)	Headache	Mild
25 Jan 2021 (Study Day 116)	New Loss of Smell	Mild
25 Jan 2021 (Study Day 116)	New Loss of Taste	Mild
26 Jan 2021 (Study Day 117)	Cough	Mild
26 Jan 2021 (Study Day 117)	Headache	Mild
26 Jan 2021 (Study Day 117)	New Loss of Smell	Mild
26 Jan 2021 (Study Day 117)	New Loss of Taste	Mild
27 Jan 2021 (Study Day 118)	Cough	Mild
27 Jan 2021 (Study Day 118)	Headache	Mild
27 Jan 2021 (Study Day 118)	New Loss of Smell	Mild
27 Jan 2021 (Study Day 118)	New Loss of Taste	Mild
29 Jan 2021 (Study Day 120)	Cough	Mild
29 Jan 2021 (Study Day 120)	New Loss of Smell	Mild
29 Jan 2021 (Study Day 120)	New Loss of Taste	Mild
30 Jan 2021 (Study Day 121)	Cough	Mild
30 Jan 2021 (Study Day 121)	New Loss of Smell	Mild
30 Jan 2021 (Study Day 121)	New Loss of Taste	Mild
30 Jan 2021 (Study Day 121)	Shortness of Breath	Moderate
31 Jan 2021 (Study Day 122)	Cough	Mild
01 Feb 2021 (Study Day 123)	Cough	Mild
02 Feb 2021 (Study Day 124)	Cough	Mild
03 Feb 2021 (Study Day 125)	Cough	Mild
04 Feb 2021 (Study Day 126)	Cough	Mild
06 Feb 2021 (Study Day 128)	Cough	Mild
07 Feb 2021 (Study Day 129)	Cough	Mild
09 Feb 2021 (Study Day 131)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
11 Jan 2021 (Study Day 102)	Oxygen Saturation	93%
11 Jan 2021 - 11 Jan 2021 (Study Day 102-102)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 37 days, after which it was considered to be recovered/resolved on 07 Feb 2021 (Study Day 129). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002895	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to animal	Pet allergy	Not reported - Ongoing
Migraine	Migraines	Not reported
Obesity	Severe obesity	Not reported - Ongoing
Seasonal allergy	Seasonal allergies (nasal congestion)	Not reported - Ongoing
Seasonal allergy	Seasonal allergies (skin itching)	Not reported - Ongoing
Adnexal torsion	Ovarian torsion (l)	2014 - Not reported
Meniscus injury	Right knee injury (meniscus tear)	08 May 2020 (Study Day -147) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine	Not reported - Ongoing	Seasonal Allergies (Nasal Congestion And Skin Itchiing)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	Not reported - Ongoing	Seasonal Allergies (Nasal Congestion And Skin Itchiing)
Vitamins nos	Not reported - Ongoing	Nutritional Supplement
Arthroscopic surgery (right knee)*	22 Oct 2020 (Study Day 21) - 22 Oct 2020 (Study Day 21)	Medical History
Hydrocodone; paracetamol	22 Oct 2020 (Study Day 21) - 04 Nov 2020 (Study Day 34)	Right Knee Pain And Swelling (Related To Right Knee Injury)
Meloxicam	22 Oct 2020 (Study Day 21) - 04 Nov 2020 (Study Day 34)	Right Knee Pain And Swelling (Related To Right Knee Injury)
Dextromethorphan; pheniramine; phenylephrine	04 Jan 2021 (Study Day 95) - Ongoing	Cough And Stuffy Nose (Related To COVID-19)
Ibuprofen	12 Jan 2021 (Study Day 103) - Ongoing	Body Aches And Fever (COVID-19 Symptoms)
Dexamethasone	30 Jan 2021 (Study Day 121) - 30 Jan 2021 (Study Day 121)	Rash (Hives)
Diphenhydramine	30 Jan 2021 (Study Day 121) - Ongoing	Rash (Itch)
Famotidine	30 Jan 2021 (Study Day 121) - 30 Jan 2021 (Study Day 121)	Stomach Prophylaxis With Steroid In Er
Dexamethasone	31 Jan 2021 (Study Day 122) - 03 Feb 2021 (Study Day 125)	Rash (Hives)
Fexofenadine	04 Feb 2021 (Study Day 126) - Ongoing	Seasonal Allergies (Nasal Congestion And Skin Itchiing)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 1/mild	Not related	02 Oct 2020 (Study Day 1) - 01 Dec 2020 (Study Day 61)
Joint Swelling	Grade 3/severe	Not related	22 Oct 2020 (Study Day 21) - 21 Nov 2020 (Study Day 51)
Procedural Pain	Grade 3/severe	Not related	22 Oct 2020 (Study Day 21) - 21 Nov 2020 (Study Day 51)
COVID-19	Grade 2/moderate	Not related	02 Jan 2021 (Study Day 93) - 07 Feb 2021 (Study Day 129)
Urticaria	Grade 3/severe	Not related	29 Jan 2021 (Study Day 120) - 08 Feb 2021 (Study Day 130)
Injection Site Pain	Grade 1/mild	Related	12 Feb 2021 (Study Day 134) - 14 Feb 2021 (Study Day 136)
Headache	Grade 1/mild	Related	13 Feb 2021 (Study Day 135) - 14 Feb 2021 (Study Day 136)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US371-2271 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	22 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	19 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 1/mild	Not related	11 Dec 2020 (Study Day 51) – 30 Dec 2020 (Study Day 70)	Recovered/resolved
Pneumonia/Bilateral Pneumonia	SAE	Grade 2/moderate	Not related	21 Dec 2020 (Study Day 61) – 24 Dec 2020 (Study Day 64)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US371-2271, a 45-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 22 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 19 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Dec 2020 (Study Day 61), 60 days after the first dose and 32 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of bilateral pneumonia lasted for 4 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 64). The investigator assessed the event of pneumonia to be not related to the IP.

Severe COVID-19 Details

On 11 Dec 2020 (Study Day 51), 50 days after the first dose and 22 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 19 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 14 Dec 2020 (Study Day 54), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 51)	Body Aches	Mild
11 Dec 2020 (Study Day 51)	Cough	Mild
11 Dec 2020 (Study Day 51)	Headache	Mild
11 Dec 2020 (Study Day 51)	Nasal Congestion	Mild
11 Dec 2020 (Study Day 51)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 51)	Sore Throat	Mild
12 Dec 2020 (Study Day 52)	Body Aches	Mild
12 Dec 2020 (Study Day 52)	Cough	Mild
12 Dec 2020 (Study Day 52)	Fatigue	Mild
12 Dec 2020 (Study Day 52)	Headache	Mild
12 Dec 2020 (Study Day 52)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 52)	Runny Nose (Rhinorrhea)	Mild
12 Dec 2020 (Study Day 52)	Sore Throat	Mild
13 Dec 2020 (Study Day 53)	Body Aches	Mild
13 Dec 2020 (Study Day 53)	Chills	Mild
13 Dec 2020 (Study Day 53)	Cough	Mild
13 Dec 2020 (Study Day 53)	Fatigue	Mild
13 Dec 2020 (Study Day 53)	Headache	Mild
13 Dec 2020 (Study Day 53)	Muscle Aches (Myalgia)	Mild
13 Dec 2020 (Study Day 53)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 53)	Runny Nose (Rhinorrhea)	Mild
13 Dec 2020 (Study Day 53)	Sore Throat	Mild
14 Dec 2020 (Study Day 54)	Body Aches	Mild
14 Dec 2020 (Study Day 54)	Chills	Mild
14 Dec 2020 (Study Day 54)	Cough	Mild
14 Dec 2020 (Study Day 54)	Fatigue	Mild
14 Dec 2020 (Study Day 54)	Headache	Mild
14 Dec 2020 (Study Day 54)	Muscle Aches (Myalgia)	Mild
14 Dec 2020 (Study Day 54)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 54)	Nausea	Mild
14 Dec 2020 (Study Day 54)	Runny Nose (Rhinorrhea)	Mild
14 Dec 2020 (Study Day 54)	Shortness of Breath	Mild
14 Dec 2020 (Study Day 54)	Sore Throat	Mild
15 Dec 2020 (Study Day 55)	Body Aches	Mild
15 Dec 2020 (Study Day 55)	Chills	Mild
15 Dec 2020 (Study Day 55)	Cough	Mild
15 Dec 2020 (Study Day 55)	Fatigue	Mild
15 Dec 2020 (Study Day 55)	Headache	Mild
15 Dec 2020 (Study Day 55)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
15 Dec 2020 (Study Day 55)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 55)	New Loss of Smell	Mild
15 Dec 2020 (Study Day 55)	Runny Nose (Rhinorrhea)	Mild
15 Dec 2020 (Study Day 55)	Temperature (°F)	100.7
16 Dec 2020 (Study Day 56)	Body Aches	Mild
16 Dec 2020 (Study Day 56)	Chills	Mild
16 Dec 2020 (Study Day 56)	Cough	Mild
16 Dec 2020 (Study Day 56)	Fatigue	Mild
16 Dec 2020 (Study Day 56)	Headache	Mild
16 Dec 2020 (Study Day 56)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 56)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 56)	New Loss of Smell	Mild
16 Dec 2020 (Study Day 56)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 57)	Body Aches	Mild
17 Dec 2020 (Study Day 57)	Chills	Mild
17 Dec 2020 (Study Day 57)	Cough	Mild
17 Dec 2020 (Study Day 57)	Fatigue	Mild
17 Dec 2020 (Study Day 57)	Headache	Mild
17 Dec 2020 (Study Day 57)	Muscle Aches (Myalgia)	Mild
17 Dec 2020 (Study Day 57)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 57)	New Loss of Smell	Mild
17 Dec 2020 (Study Day 57)	Runny Nose (Rhinorrhea)	Mild
18 Dec 2020 (Study Day 58)	Body Aches	Mild
18 Dec 2020 (Study Day 58)	Chills	Mild
18 Dec 2020 (Study Day 58)	Cough	Mild
18 Dec 2020 (Study Day 58)	Fatigue	Mild
18 Dec 2020 (Study Day 58)	Headache	Mild
18 Dec 2020 (Study Day 58)	Muscle Aches (Myalgia)	Mild
18 Dec 2020 (Study Day 58)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 58)	New Loss of Smell	Mild
18 Dec 2020 (Study Day 58)	New Loss of Taste	Mild
18 Dec 2020 (Study Day 58)	Runny Nose (Rhinorrhea)	Mild
18 Dec 2020 (Study Day 58)	Shortness of Breath	Mild
18 Dec 2020 (Study Day 58)	Sore Throat	Mild
18 Dec 2020 (Study Day 58)	Temperature (°F)	101.4
19 Dec 2020 (Study Day 59)	Body Aches	Mild
19 Dec 2020 (Study Day 59)	Chills	Mild
19 Dec 2020 (Study Day 59)	Cough	Mild
19 Dec 2020 (Study Day 59)	Difficulty Breathing	Mild
19 Dec 2020 (Study Day 59)	Fatigue	Mild
19 Dec 2020 (Study Day 59)	Headache	Mild
19 Dec 2020 (Study Day 59)	Muscle Aches (Myalgia)	Mild
19 Dec 2020 (Study Day 59)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
19 Dec 2020 (Study Day 59)	New Loss of Smell	Mild
19 Dec 2020 (Study Day 59)	New Loss of Taste	Mild
19 Dec 2020 (Study Day 59)	O2 Saturation (%)	92
19 Dec 2020 (Study Day 59)	Runny Nose (Rhinorrhea)	Mild
19 Dec 2020 (Study Day 59)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 59)	Sore Throat	Mild
20 Dec 2020 (Study Day 60)	Body Aches	Mild
20 Dec 2020 (Study Day 60)	Chills	Mild
20 Dec 2020 (Study Day 60)	Cough	Mild
20 Dec 2020 (Study Day 60)	Difficulty Breathing	Mild
20 Dec 2020 (Study Day 60)	Fatigue	Mild
20 Dec 2020 (Study Day 60)	Headache	Mild
20 Dec 2020 (Study Day 60)	Muscle Aches (Myalgia)	Mild
20 Dec 2020 (Study Day 60)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 60)	Nausea	Mild
20 Dec 2020 (Study Day 60)	New Loss of Smell	Mild
20 Dec 2020 (Study Day 60)	New Loss of Taste	Mild
20 Dec 2020 (Study Day 60)	O2 Saturation (%)	92
20 Dec 2020 (Study Day 60)	Runny Nose (Rhinorrhea)	Mild
20 Dec 2020 (Study Day 60)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 60)	Sore Throat	Mild
20 Dec 2020 (Study Day 60)	Temperature (°F)	101.4
21 Dec 2020 (Study Day 61)	Body Aches	Mild
21 Dec 2020 (Study Day 61)	Chills	Mild
21 Dec 2020 (Study Day 61)	Cough	Mild
21 Dec 2020 (Study Day 61)	Difficulty Breathing	Mild
21 Dec 2020 (Study Day 61)	Fatigue	Mild
21 Dec 2020 (Study Day 61)	Headache	Mild
21 Dec 2020 (Study Day 61)	Muscle Aches (Myalgia)	Mild
21 Dec 2020 (Study Day 61)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 61)	Nausea	Mild
21 Dec 2020 (Study Day 61)	New Loss of Smell	Mild
21 Dec 2020 (Study Day 61)	New Loss of Taste	Mild
21 Dec 2020 (Study Day 61)	O2 Saturation (%)	80
21 Dec 2020 (Study Day 61)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 61)	Shortness of Breath	Mild
21 Dec 2020 (Study Day 61)	Sore Throat	Mild
21 Dec 2020 (Study Day 61)	Temperature (°F)	102.4
22 Dec 2020 (Study Day 62)	Body Aches	Mild
22 Dec 2020 (Study Day 62)	Chills	Mild
22 Dec 2020 (Study Day 62)	Cough	Moderate
22 Dec 2020 (Study Day 62)	Difficulty Breathing	Mild
22 Dec 2020 (Study Day 62)	Fatigue	Mild

Symptom Date	Symptom	Result
22 Dec 2020 (Study Day 62)	Headache	Mild
22 Dec 2020 (Study Day 62)	Muscle Aches (Myalgia)	Mild
22 Dec 2020 (Study Day 62)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 62)	New Loss of Smell	Mild
22 Dec 2020 (Study Day 62)	New Loss of Taste	Mild
22 Dec 2020 (Study Day 62)	Shortness of Breath	Moderate
23 Dec 2020 (Study Day 63)	Body Aches	Mild
23 Dec 2020 (Study Day 63)	Chills	Mild
23 Dec 2020 (Study Day 63)	Cough	Moderate
23 Dec 2020 (Study Day 63)	Difficulty Breathing	Mild
23 Dec 2020 (Study Day 63)	Fatigue	Mild
23 Dec 2020 (Study Day 63)	Headache	Mild
23 Dec 2020 (Study Day 63)	Muscle Aches (Myalgia)	Mild
23 Dec 2020 (Study Day 63)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 63)	New Loss of Smell	Mild
23 Dec 2020 (Study Day 63)	New Loss of Taste	Mild
23 Dec 2020 (Study Day 63)	Shortness of Breath	Moderate
23 Dec 2020 (Study Day 63)	Sore Throat	Mild
24 Dec 2020 (Study Day 64)	Fatigue	Mild
25 Dec 2020 (Study Day 65)	Fatigue	Mild
26 Dec 2020 (Study Day 66)	Fatigue	Mild
27 Dec 2020 (Study Day 67)	Fatigue	Mild
28 Dec 2020 (Study Day 68)	Fatigue	Mild
29 Dec 2020 (Study Day 69)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
19 Dec 2020 (Study Day 59)	Oxygen Saturation	80%
19 Dec 2020 - 21 Dec 2020 (Study Day 59-61)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 70). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001325	COVID-19

CIOMS Number	MedDRA Preferred Term
MOD-2020-001325	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Myopia	1985 - Ongoing
Angioedema	Allergy to hydralazine angioedema	1995 - Ongoing
Diarrhoea	Chronic diarrhea	1995 - Ongoing
Drug hypersensitivity	Allergy to avelox	1995 - Ongoing
Drug hypersensitivity	Allergy to levaquin	1995 - Ongoing
Adenoidectomy	Adenoidectomy	1998 - 1998
Adenoiditis	Adenoiditis	1998 - 1998
Tooth impacted	Wisdom teeth impaction	1999 - 1999
Wisdom teeth removal	Wisdom teeth extraction	1999 - 1999
Hypertension	Hypertension	2000 - Ongoing
Sinus tachycardia	Sinus tachycardia	2000 - Ongoing
Anxiety	Anxiety	2004 - Ongoing
Drug hypersensitivity	Allergy to morphine	2005 - Ongoing
Tonsillectomy	Tonsillectomy	2005 - 2005
Tonsillitis	Tonsillitis	2005 - 2005
Drug hypersensitivity	Allergy to statins	2008 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2008 - Ongoing
Fatigue	Fatigue	2010 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2012 - Ongoing
Appendicectomy	Appendectomy	2013 - 2013
Appendicitis	Appendicitis	2013 - 2013
Hysterectomy	Hysterectomy	2013 - 2013
Menorrhagia	Heavy menses	2013 - 2013
Sleep apnoea syndrome	Obstructive sleep apnea	2013 - Ongoing
Drug hypersensitivity	Allergy to hydralazine	2015 - Ongoing
Drug hypersensitivity	Allergy to lisinopril	2015 - Ongoing
Cholecystectomy	Cholecystectomy	2016 - 2016
Cholecystitis	Cholecystitis	2016 - 2016
Restless legs syndrome	Restless legs syndrome	2017 - Ongoing
Insomnia	Insomnia	2018 - Ongoing
Trigger finger	Trigger finger	01 Jan 2020 (Study Day -295) - 01 Sep 2020 (Study Day -51)

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Mild osteoarthritis (hands)	Feb 2020 - Ongoing
Tendon sheath incision	Trigger finger repair	01 Sep 2020 (Study Day -51) - 01 Sep 2020 (Study Day -51)
Obesity	Obesity	20 Oct 2020 (Study Day -2) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atenolol	2000 - Ongoing	Hypertension
Venlafaxine hydrochloride	2004 - Ongoing	Anxiety
Vitamin d nos	2008 - Ongoing	Supplement
Pantoprazole sodium sesquihydrate	2010 - Ongoing	Acid Reflux
Amlodipine	2015 - Ongoing	Hypertension
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
Insulin glargine	2017 - Ongoing	Diabetes Mellitus Type 2
Ropinirole hydrochloride	2017 - Ongoing	Restless Leg Syndrome
Tizanidine	2017 - Ongoing	Restless Leg
Insulin lispro	2018 - Ongoing	Diabetes Mellitus Type 2
Mirtazapine	2018 - Ongoing	Insomnia
Vitamin b nos	2018 - Ongoing	Supplement
Metformin	2019 - Ongoing	Diabetes
Semaglutide	01 Sep 2020 (Study Day -51) - Ongoing	Diabetes Mellitus Type 2
Ezetimibe	01 Oct 2020 (Study Day -21) - 01 Dec 2020 (Study Day 41)	Hyperlipidemia
Ezetimibe	19 Nov 2020 (Study Day 29) - Ongoing	Hypercholesterolemia
Ascorbic acid	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Treatment Of COVID-19 While Hospitalization
Calcium chloride; potassium chloride; sodium lactate	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Prevention Of Dehydration While Hospitalized
Ceftriaxone	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Treatment Of Pneumonia Bacteriuria And Sepsis While Hospitalized
Chest ct*	21 Dec 2020 (Study Day 61) - 21 Dec 2020 (Study Day 61)	Adverse Event
Chest x-ray*	21 Dec 2020 (Study Day 61) - 21 Dec 2020 (Study Day 61)	Adverse Event
Dexamethasone	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Treatment Of Pneumonia Due To COVID-19 While Hospitalized
Enoxaparin	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Deep Vein Thrombosis Prophylaxis While Hospitalized
Ergocalciferol	21 Dec 2020 (Study Day 61) - 21 Dec 2020 (Study Day 61)	Treatment Of COVID-19 While Hospitalized

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Prevention Of Gastroesophageal Reflux Disease While Hospitalized
Insulin glargine	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Treatment Of Diabetes Mellitus During Hospitalized
Insulin lispro	21 Dec 2020 (Study Day 61) - 21 Dec 2020 (Study Day 61)	Treatment Of Diabetes Mellitus During Hospitalized
Insulin lispro	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Treatment Of Diabetes Mellitus During Hospitalized
Iohexol	21 Dec 2020 (Study Day 61) - 21 Dec 2020 (Study Day 61)	Contrast Used For Imaging While Hospitalized
Levosalbutamol	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Treatment Of Pneumonia / Respiratory Failure Due To COVID-19 While Hospitalized
Paracetamol	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Prevention Of Fever While Hospitalized
Paracetamol	21 Dec 2020 (Study Day 61) - 21 Dec 2020 (Study Day 61)	Prevention Of Pain While Hospitalized
Remdesivir	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Treatment Of COVID-19 While Hospitalized
Sodium chloride	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)	Prevention Of Dehydration During Hospitalization
Vitamins nos	21 Dec 2020 (Study Day 61) - Ongoing	Supplement
Zinc gluconate	21 Dec 2020 (Study Day 61) - Ongoing	Treatment Of COVID-19 While Hospitalized/ Prevention Of COVID
Dexamethasone	24 Dec 2020 (Study Day 64) - 30 Dec 2020 (Study Day 70)	Treatment Of Pneumonia After Hospitalization
Oxygen	24 Dec 2020 (Study Day 64) - 07 Jan 2021 (Study Day 78)	Treatment Of Acute Respiratory Failure Due To COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diverticulum Intestinal	Grade 1/mild	Not related	24 Nov 2020 (Study Day 34) - Ongoing
Pulmonary Mass	Grade 1/mild	Not related	24 Nov 2020 (Study Day 34) - Ongoing
COVID-19	Grade 1/mild	Not related	11 Dec 2020 (Study Day 51) - 30 Dec 2020 (Study Day 70)
Asymptomatic Bacteriuria	Grade 1/mild	Not related	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)
Lung Opacity	Grade 2/moderate	Not related	21 Dec 2020 (Study Day 61) - Ongoing
Sepsis	Grade 2/moderate	Not related	21 Dec 2020 (Study Day 61) - 24 Dec 2020 (Study Day 64)
Transaminases Increased	Grade 1/mild	Not related	21 Dec 2020 (Study Day 61) - Ongoing
Acute Respiratory Failure	Grade 2/moderate	Not related	23 Dec 2020 (Study Day 63) - 24 Dec 2020 (Study Day 64)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US371-2308 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	23 Nov 2020 (Study Day 32)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	COVID-19	Grade 2/moderate	Not related	04 Jan 2021 (Study Day 74) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US371-2308, a 46-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 23 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 23 Nov 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 04 Jan 2021 (Study Day 74), 73 days after the first dose and 42 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 32, 23 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 07 Jan 2021 (Study Day 77), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
04 Jan 2021 (Study Day 74)	Cough	Mild
04 Jan 2021 (Study Day 74)	Headache	Mild
04 Jan 2021 (Study Day 74)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 74)	Sore Throat	Mild
05 Jan 2021 (Study Day 75)	Cough	Mild

Symptom Date	Symptom	Result
05 Jan 2021 (Study Day 75)	Headache	Mild
05 Jan 2021 (Study Day 75)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 75)	Sore Throat	Mild
06 Jan 2021 (Study Day 76)	Body Aches	Mild
06 Jan 2021 (Study Day 76)	Cough	Mild
06 Jan 2021 (Study Day 76)	Diarrhea	Mild
06 Jan 2021 (Study Day 76)	Fatigue	Mild
06 Jan 2021 (Study Day 76)	Headache	Mild
06 Jan 2021 (Study Day 76)	Muscle Aches (Myalgia)	Mild
06 Jan 2021 (Study Day 76)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 76)	Nausea	Mild
06 Jan 2021 (Study Day 76)	New Loss of Smell	Mild
06 Jan 2021 (Study Day 76)	New Loss of Taste	Mild
06 Jan 2021 (Study Day 76)	Runny Nose (Rhinorrhea)	Mild
06 Jan 2021 (Study Day 76)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 76)	Sore Throat	Mild
07 Jan 2021 (Study Day 77)	Body Aches	Mild
07 Jan 2021 (Study Day 77)	Cough	Mild
07 Jan 2021 (Study Day 77)	Diarrhea	Mild
07 Jan 2021 (Study Day 77)	Fatigue	Mild
07 Jan 2021 (Study Day 77)	Headache	Mild
07 Jan 2021 (Study Day 77)	Muscle Aches (Myalgia)	Mild
07 Jan 2021 (Study Day 77)	Nasal Congestion	Mild
07 Jan 2021 (Study Day 77)	Nausea	Mild
07 Jan 2021 (Study Day 77)	New Loss of Smell	Mild
07 Jan 2021 (Study Day 77)	New Loss of Taste	Mild
07 Jan 2021 (Study Day 77)	Runny Nose (Rhinorrhea)	Mild
07 Jan 2021 (Study Day 77)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 77)	Sore Throat	Mild
08 Jan 2021 (Study Day 78)	Body Aches	Mild
08 Jan 2021 (Study Day 78)	Cough	Mild
08 Jan 2021 (Study Day 78)	Diarrhea	Mild
08 Jan 2021 (Study Day 78)	Fatigue	Mild
08 Jan 2021 (Study Day 78)	Headache	Mild
08 Jan 2021 (Study Day 78)	Muscle Aches (Myalgia)	Mild
08 Jan 2021 (Study Day 78)	Nasal Congestion	Mild
08 Jan 2021 (Study Day 78)	Nausea	Mild
08 Jan 2021 (Study Day 78)	New Loss of Smell	Mild
08 Jan 2021 (Study Day 78)	New Loss of Taste	Mild
08 Jan 2021 (Study Day 78)	Runny Nose (Rhinorrhea)	Mild
08 Jan 2021 (Study Day 78)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 78)	Sore Throat	Mild
09 Jan 2021 (Study Day 79)	Body Aches	Mild

Symptom Date	Symptom	Result
09 Jan 2021 (Study Day 79)	Cough	Mild
09 Jan 2021 (Study Day 79)	Diarrhea	Mild
09 Jan 2021 (Study Day 79)	Fatigue	Mild
09 Jan 2021 (Study Day 79)	Headache	Mild
09 Jan 2021 (Study Day 79)	Muscle Aches (Myalgia)	Mild
09 Jan 2021 (Study Day 79)	Nasal Congestion	Mild
09 Jan 2021 (Study Day 79)	Nausea	Mild
09 Jan 2021 (Study Day 79)	New Loss of Smell	Mild
09 Jan 2021 (Study Day 79)	New Loss of Taste	Mild
09 Jan 2021 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild
09 Jan 2021 (Study Day 79)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 79)	Sore Throat	Mild
10 Jan 2021 (Study Day 80)	Body Aches	Mild
10 Jan 2021 (Study Day 80)	Cough	Mild
10 Jan 2021 (Study Day 80)	Diarrhea	Mild
10 Jan 2021 (Study Day 80)	Fatigue	Mild
10 Jan 2021 (Study Day 80)	Headache	Mild
10 Jan 2021 (Study Day 80)	Muscle Aches (Myalgia)	Mild
10 Jan 2021 (Study Day 80)	Nasal Congestion	Mild
10 Jan 2021 (Study Day 80)	Nausea	Mild
10 Jan 2021 (Study Day 80)	New Loss of Smell	Mild
10 Jan 2021 (Study Day 80)	New Loss of Taste	Mild
10 Jan 2021 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
10 Jan 2021 (Study Day 80)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 80)	Sore Throat	Mild
11 Jan 2021 (Study Day 81)	Body Aches	Mild
11 Jan 2021 (Study Day 81)	Cough	Mild
11 Jan 2021 (Study Day 81)	Diarrhea	Mild
11 Jan 2021 (Study Day 81)	Fatigue	Mild
11 Jan 2021 (Study Day 81)	Headache	Mild
11 Jan 2021 (Study Day 81)	Muscle Aches (Myalgia)	Mild
11 Jan 2021 (Study Day 81)	Nasal Congestion	Mild
11 Jan 2021 (Study Day 81)	Nausea	Mild
11 Jan 2021 (Study Day 81)	New Loss of Smell	Mild
11 Jan 2021 (Study Day 81)	New Loss of Taste	Mild
11 Jan 2021 (Study Day 81)	Runny Nose (Rhinorrhea)	Mild
11 Jan 2021 (Study Day 81)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 81)	Sore Throat	Mild
12 Jan 2021 (Study Day 82)	Body Aches	Mild
12 Jan 2021 (Study Day 82)	Cough	Mild
12 Jan 2021 (Study Day 82)	Diarrhea	Mild
12 Jan 2021 (Study Day 82)	Fatigue	Mild
12 Jan 2021 (Study Day 82)	Headache	Mild

Symptom Date	Symptom	Result
12 Jan 2021 (Study Day 82)	Muscle Aches (Myalgia)	Mild
12 Jan 2021 (Study Day 82)	Nasal Congestion	Mild
12 Jan 2021 (Study Day 82)	Nausea	Mild
12 Jan 2021 (Study Day 82)	New Loss of Smell	Mild
12 Jan 2021 (Study Day 82)	New Loss of Taste	Mild
12 Jan 2021 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
12 Jan 2021 (Study Day 82)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 82)	Sore Throat	Mild
13 Jan 2021 (Study Day 83)	Body Aches	Mild
13 Jan 2021 (Study Day 83)	Cough	Mild
13 Jan 2021 (Study Day 83)	Diarrhea	Mild
13 Jan 2021 (Study Day 83)	Fatigue	Mild
13 Jan 2021 (Study Day 83)	Headache	Mild
13 Jan 2021 (Study Day 83)	Muscle Aches (Myalgia)	Mild
13 Jan 2021 (Study Day 83)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 83)	Nausea	Mild
13 Jan 2021 (Study Day 83)	New Loss of Smell	Mild
13 Jan 2021 (Study Day 83)	New Loss of Taste	Mild
13 Jan 2021 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
13 Jan 2021 (Study Day 83)	Shortness of Breath	Mild
13 Jan 2021 (Study Day 83)	Sore Throat	Mild
14 Jan 2021 (Study Day 84)	Body Aches	Mild
14 Jan 2021 (Study Day 84)	Cough	Mild
14 Jan 2021 (Study Day 84)	Diarrhea	Mild
14 Jan 2021 (Study Day 84)	Fatigue	Mild
14 Jan 2021 (Study Day 84)	Headache	Mild
14 Jan 2021 (Study Day 84)	Muscle Aches (Myalgia)	Mild
14 Jan 2021 (Study Day 84)	Nasal Congestion	Mild
14 Jan 2021 (Study Day 84)	Nausea	Mild
14 Jan 2021 (Study Day 84)	New Loss of Smell	Mild
14 Jan 2021 (Study Day 84)	New Loss of Taste	Mild
14 Jan 2021 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
14 Jan 2021 (Study Day 84)	Shortness of Breath	Mild
14 Jan 2021 (Study Day 84)	Sore Throat	Mild
15 Jan 2021 (Study Day 85)	Body Aches	Mild
15 Jan 2021 (Study Day 85)	Cough	Mild
15 Jan 2021 (Study Day 85)	Diarrhea	Mild
15 Jan 2021 (Study Day 85)	Difficulty Breathing	Moderate
15 Jan 2021 (Study Day 85)	Fatigue	Mild
15 Jan 2021 (Study Day 85)	Headache	Mild
15 Jan 2021 (Study Day 85)	Muscle Aches (Myalgia)	Mild
15 Jan 2021 (Study Day 85)	Nasal Congestion	Mild
15 Jan 2021 (Study Day 85)	Nausea	Mild

Symptom Date	Symptom	Result
15 Jan 2021 (Study Day 85)	New Loss of Smell	Mild
15 Jan 2021 (Study Day 85)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 85)	O2 Saturation (%)	88
15 Jan 2021 (Study Day 85)	Runny Nose (Rhinorrhea)	Mild
15 Jan 2021 (Study Day 85)	Shortness of Breath	Moderate
15 Jan 2021 (Study Day 85)	Sore Throat	Mild
16 Jan 2021 (Study Day 86)	Body Aches	Mild
16 Jan 2021 (Study Day 86)	Cough	Mild
16 Jan 2021 (Study Day 86)	Diarrhea	Mild
16 Jan 2021 (Study Day 86)	Difficulty Breathing	Moderate
16 Jan 2021 (Study Day 86)	Fatigue	Mild
16 Jan 2021 (Study Day 86)	Headache	Mild
16 Jan 2021 (Study Day 86)	Muscle Aches (Myalgia)	Mild
16 Jan 2021 (Study Day 86)	Nasal Congestion	Mild
16 Jan 2021 (Study Day 86)	Nausea	Mild
16 Jan 2021 (Study Day 86)	New Loss of Smell	Mild
16 Jan 2021 (Study Day 86)	New Loss of Taste	Mild
16 Jan 2021 (Study Day 86)	O2 Saturation (%)	90
16 Jan 2021 (Study Day 86)	Runny Nose (Rhinorrhea)	Mild
16 Jan 2021 (Study Day 86)	Shortness of Breath	Moderate
16 Jan 2021 (Study Day 86)	Sore Throat	Mild
17 Jan 2021 (Study Day 87)	Body Aches	Mild
17 Jan 2021 (Study Day 87)	Cough	Mild
17 Jan 2021 (Study Day 87)	Diarrhea	Mild
17 Jan 2021 (Study Day 87)	Difficulty Breathing	Moderate
17 Jan 2021 (Study Day 87)	Fatigue	Mild
17 Jan 2021 (Study Day 87)	Headache	Mild
17 Jan 2021 (Study Day 87)	Muscle Aches (Myalgia)	Mild
17 Jan 2021 (Study Day 87)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 87)	Nausea	Mild
17 Jan 2021 (Study Day 87)	New Loss of Smell	Mild
17 Jan 2021 (Study Day 87)	New Loss of Taste	Mild
17 Jan 2021 (Study Day 87)	O2 Saturation (%)	90
17 Jan 2021 (Study Day 87)	Runny Nose (Rhinorrhea)	Mild
17 Jan 2021 (Study Day 87)	Shortness of Breath	Moderate
17 Jan 2021 (Study Day 87)	Sore Throat	Mild
18 Jan 2021 (Study Day 88)	Body Aches	Mild
18 Jan 2021 (Study Day 88)	Cough	Mild
18 Jan 2021 (Study Day 88)	Diarrhea	Mild
18 Jan 2021 (Study Day 88)	Difficulty Breathing	Mild
18 Jan 2021 (Study Day 88)	Fatigue	Mild
18 Jan 2021 (Study Day 88)	Headache	Mild
18 Jan 2021 (Study Day 88)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
18 Jan 2021 (Study Day 88)	Nasal Congestion	Mild
18 Jan 2021 (Study Day 88)	Nausea	Mild
18 Jan 2021 (Study Day 88)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 88)	New Loss of Taste	Mild
18 Jan 2021 (Study Day 88)	Runny Nose (Rhinorrhea)	Mild
18 Jan 2021 (Study Day 88)	Shortness of Breath	Mild
18 Jan 2021 (Study Day 88)	Sore Throat	Mild
19 Jan 2021 (Study Day 89)	Body Aches	Mild
19 Jan 2021 (Study Day 89)	Cough	Mild
19 Jan 2021 (Study Day 89)	Diarrhea	Mild
19 Jan 2021 (Study Day 89)	Difficulty Breathing	Mild
19 Jan 2021 (Study Day 89)	Fatigue	Mild
19 Jan 2021 (Study Day 89)	Headache	Mild
19 Jan 2021 (Study Day 89)	Muscle Aches (Myalgia)	Mild
19 Jan 2021 (Study Day 89)	Nasal Congestion	Mild
19 Jan 2021 (Study Day 89)	Nausea	Mild
19 Jan 2021 (Study Day 89)	New Loss of Smell	Mild
19 Jan 2021 (Study Day 89)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 89)	Runny Nose (Rhinorrhea)	Mild
19 Jan 2021 (Study Day 89)	Shortness of Breath	Mild
19 Jan 2021 (Study Day 89)	Sore Throat	Mild
20 Jan 2021 (Study Day 90)	Body Aches	Mild
20 Jan 2021 (Study Day 90)	Cough	Mild
20 Jan 2021 (Study Day 90)	Diarrhea	Mild
20 Jan 2021 (Study Day 90)	Difficulty Breathing	Mild
20 Jan 2021 (Study Day 90)	Fatigue	Mild
20 Jan 2021 (Study Day 90)	Headache	Mild
20 Jan 2021 (Study Day 90)	Muscle Aches (Myalgia)	Mild
20 Jan 2021 (Study Day 90)	Nasal Congestion	Mild
20 Jan 2021 (Study Day 90)	New Loss of Smell	Mild
20 Jan 2021 (Study Day 90)	New Loss of Taste	Mild
20 Jan 2021 (Study Day 90)	O2 Saturation (%)	92
20 Jan 2021 (Study Day 90)	Runny Nose (Rhinorrhea)	Mild
20 Jan 2021 (Study Day 90)	Shortness of Breath	Mild
20 Jan 2021 (Study Day 90)	Sore Throat	Mild
20 Jan 2021 (Study Day 90)	Vomiting	Mild
21 Jan 2021 (Study Day 91)	Body Aches	Mild
21 Jan 2021 (Study Day 91)	Cough	Mild
21 Jan 2021 (Study Day 91)	Diarrhea	Mild
21 Jan 2021 (Study Day 91)	Difficulty Breathing	Mild
21 Jan 2021 (Study Day 91)	Fatigue	Mild
21 Jan 2021 (Study Day 91)	Headache	Mild
21 Jan 2021 (Study Day 91)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
21 Jan 2021 (Study Day 91)	Nasal Congestion	Mild
21 Jan 2021 (Study Day 91)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 91)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 91)	O2 Saturation (%)	93
21 Jan 2021 (Study Day 91)	Runny Nose (Rhinorrhea)	Mild
21 Jan 2021 (Study Day 91)	Shortness of Breath	Mild
21 Jan 2021 (Study Day 91)	Sore Throat	Mild
21 Jan 2021 (Study Day 91)	Vomiting	Mild
22 Jan 2021 (Study Day 92)	Body Aches	Mild
22 Jan 2021 (Study Day 92)	Cough	Mild
22 Jan 2021 (Study Day 92)	Diarrhea	Mild
22 Jan 2021 (Study Day 92)	Difficulty Breathing	Mild
22 Jan 2021 (Study Day 92)	Fatigue	Mild
22 Jan 2021 (Study Day 92)	Headache	Mild
22 Jan 2021 (Study Day 92)	Muscle Aches (Myalgia)	Mild
22 Jan 2021 (Study Day 92)	Nasal Congestion	Mild
22 Jan 2021 (Study Day 92)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 92)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 92)	O2 Saturation (%)	92
22 Jan 2021 (Study Day 92)	Runny Nose (Rhinorrhea)	Mild
22 Jan 2021 (Study Day 92)	Shortness of Breath	Mild
22 Jan 2021 (Study Day 92)	Sore Throat	Mild
22 Jan 2021 (Study Day 92)	Vomiting	Mild
23 Jan 2021 (Study Day 93)	Body Aches	Mild
23 Jan 2021 (Study Day 93)	Cough	Mild
23 Jan 2021 (Study Day 93)	Difficulty Breathing	Mild
23 Jan 2021 (Study Day 93)	Fatigue	Mild
23 Jan 2021 (Study Day 93)	Headache	Mild
23 Jan 2021 (Study Day 93)	Muscle Aches (Myalgia)	Mild
23 Jan 2021 (Study Day 93)	Nasal Congestion	Mild
23 Jan 2021 (Study Day 93)	New Loss of Smell	Mild
23 Jan 2021 (Study Day 93)	New Loss of Taste	Mild
23 Jan 2021 (Study Day 93)	O2 Saturation (%)	92
23 Jan 2021 (Study Day 93)	Runny Nose (Rhinorrhea)	Mild
23 Jan 2021 (Study Day 93)	Shortness of Breath	Mild
23 Jan 2021 (Study Day 93)	Sore Throat	Mild
24 Jan 2021 (Study Day 94)	Body Aches	Mild
24 Jan 2021 (Study Day 94)	Cough	Mild
24 Jan 2021 (Study Day 94)	Difficulty Breathing	Mild
24 Jan 2021 (Study Day 94)	Fatigue	Mild
24 Jan 2021 (Study Day 94)	Headache	Mild
24 Jan 2021 (Study Day 94)	Muscle Aches (Myalgia)	Mild
24 Jan 2021 (Study Day 94)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
24 Jan 2021 (Study Day 94)	New Loss of Smell	Mild
24 Jan 2021 (Study Day 94)	New Loss of Taste	Mild
24 Jan 2021 (Study Day 94)	Runny Nose (Rhinorrhea)	Mild
24 Jan 2021 (Study Day 94)	Shortness of Breath	Mild
24 Jan 2021 (Study Day 94)	Sore Throat	Mild
26 Jan 2021 (Study Day 96)	Body Aches	Mild
26 Jan 2021 (Study Day 96)	Difficulty Breathing	Mild
26 Jan 2021 (Study Day 96)	Fatigue	Mild
26 Jan 2021 (Study Day 96)	Headache	Mild
26 Jan 2021 (Study Day 96)	Muscle Aches (Myalgia)	Mild
26 Jan 2021 (Study Day 96)	Nasal Congestion	Mild
26 Jan 2021 (Study Day 96)	New Loss of Smell	Mild
26 Jan 2021 (Study Day 96)	New Loss of Taste	Mild
26 Jan 2021 (Study Day 96)	Runny Nose (Rhinorrhea)	Mild
26 Jan 2021 (Study Day 96)	Shortness of Breath	Mild
26 Jan 2021 (Study Day 96)	Sore Throat	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
15 Jan 2021 (Study Day 85)	Oxygen Saturation	88%
15 Jan 2021 - 17 Jan 2021 (Study Day 85-87)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 was considered to be ongoing. The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tooth impacted	Wisdom teeth impaction	1993 - 1993
Wisdom teeth removal	Wisdom teeth extraction	1993 - 1993
Migraine	Migraines	1998 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to levaquin	2006 - Ongoing
Mammoplasty	Breast implants placed	2006 - 2006
Gastrooesophageal reflux disease	Acid reflux	2008 - Ongoing
Hypertension	Hypertension	2008 - Ongoing
Seasonal allergy	Seasonal allergies	2008 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Asthma	Bronchitis induced asthma	2010 - Ongoing
Bronchitis	Occasional bronchitis	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Ankle fracture	Left ankle fracture	2015 - 2015
Ankle operation	Left ankle repair	2015 - 2015
Obesity	Obesity	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; etonogestrel	2000 - Ongoing	Birth Control
Cetirizine hydrochloride	2008 - Ongoing	Seasonal Allergies
Omeprazole	2008 - Ongoing	Acid Reflux
Omeprazole	2008 - 13 Nov 2020 (Study Day 22)	Acid Reflux
Levothyroxine	2010 - Ongoing	Hypothyroidism
Bupropion hydrochloride	2012 - Ongoing	Anxiety
Citalopram hydrobromide	2012 - Ongoing	Anxiety
Montelukast sodium	2016 - Ongoing	Seasonal Allergies
Hydrochlorothiazide; valsartan	2017 - Ongoing	Hypertension
Phentermine	2019 - Ongoing	Weight Loss
Botulinum toxin type a	Oct 2020 - Oct 2020	Elective Cosmetic
Esomeprazole magnesium	15 Nov 2020 (Study Day 24) - Ongoing	Acid Reflux
Ibuprofen	04 Jan 2021 (Study Day 74) - Ongoing	COVID 19
Meloxicam	23 Mar 2021 (Study Day 152) - Ongoing	Si Joint Inflammation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Related	23 Oct 2020 (Study Day 1) - 03 Nov 2020 (Study Day 12)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Myalgia	Grade 1/mild	Related	29 Oct 2020 (Study Day 7) - 01 Nov 2020 (Study Day 10)
Myalgia	Grade 1/mild	Related	28 Nov 2020 (Study Day 37) - 02 Dec 2020 (Study Day 41)
COVID-19	Grade 2/moderate	Not related	04 Jan 2021 (Study Day 74) - Ongoing
Arthritis	Grade 1/mild	Not related	23 Mar 2021 (Study Day 152) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US372-2066 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 26)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Positive COVID 19	COVID-19	Grade 3/ severe	Not related	11 Nov 2020 (Study Day 101) – 30 Dec 2020 (Study Day 150)	Recovered/resolved
COVID-19/Worsening Of COVID-19	SAE, COVID-19	Grade 3/ severe	Not related	16 Nov 2020 (Study Day 106) – 24 Dec 2020 (Study Day 144)	Recovered/resolved
COVID-19 Pneumonia/COVID-19 Pneumonia	SAE	Grade 3/ severe	Not related	16 Nov 2020 (Study Day 106) – 24 Dec 2020 (Study Day 144)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US372-2066, a 67-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 11 Nov 2020 (Study Day 101), 100 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of positive COVID 19.

On 16 Nov 2020 (Study Day 106), 105 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of worsening of COVID-19.

On 16 Nov 2020 (Study Day 106), 105 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID-19 pneumonia.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 26, 28 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 16 Nov 2020 (Study Day 106), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Nov 2020 (Study Day 101)	Body Aches	Moderate
11 Nov 2020 (Study Day 101)	Chills	Moderate
11 Nov 2020 (Study Day 101)	Difficulty Breathing	Severe
11 Nov 2020 (Study Day 101)	Muscle Aches (Myalgia)	Moderate
11 Nov 2020 (Study Day 101)	Shortness of Breath	Severe
12 Nov 2020 (Study Day 102)	Body Aches	Moderate
12 Nov 2020 (Study Day 102)	Chills	Moderate
12 Nov 2020 (Study Day 102)	Difficulty Breathing	Severe
12 Nov 2020 (Study Day 102)	Muscle Aches (Myalgia)	Moderate
12 Nov 2020 (Study Day 102)	Shortness of Breath	Severe
13 Nov 2020 (Study Day 103)	Body Aches	Moderate
13 Nov 2020 (Study Day 103)	Chills	Moderate
13 Nov 2020 (Study Day 103)	Difficulty Breathing	Severe
13 Nov 2020 (Study Day 103)	Muscle Aches (Myalgia)	Moderate
13 Nov 2020 (Study Day 103)	Shortness of Breath	Severe
14 Nov 2020 (Study Day 104)	Body Aches	Moderate
14 Nov 2020 (Study Day 104)	Chills	Moderate
14 Nov 2020 (Study Day 104)	Difficulty Breathing	Severe
14 Nov 2020 (Study Day 104)	Muscle Aches (Myalgia)	Moderate
14 Nov 2020 (Study Day 104)	Shortness of Breath	Severe
15 Nov 2020 (Study Day 105)	Body Aches	Moderate
15 Nov 2020 (Study Day 105)	Chills	Moderate
15 Nov 2020 (Study Day 105)	Difficulty Breathing	Severe
15 Nov 2020 (Study Day 105)	Muscle Aches (Myalgia)	Moderate
15 Nov 2020 (Study Day 105)	Shortness of Breath	Severe
16 Nov 2020 (Study Day 106)	Body Aches	Moderate
16 Nov 2020 (Study Day 106)	Chills	Moderate
16 Nov 2020 (Study Day 106)	Difficulty Breathing	Severe
16 Nov 2020 (Study Day 106)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 106)	O2 Saturation (%)	86
16 Nov 2020 (Study Day 106)	Shortness of Breath	Severe

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
16 Nov 2020 (Study Day 106)	Oxygen Saturation	86%
16 Nov 2020 - 16 Nov 2020 (Study Day 106-106)	Clinical Evidence of Pneumonia	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 106-106)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of positive COVID 19 lasted for 50 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 150). The investigator assessed the event of COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of worsening of COVID-19 lasted for 39 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 144). The investigator assessed the event of COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of COVID-19 pneumonia lasted for 39 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 144). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001325	COVID-19
MOD-2020-001325	COVID-19 pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1956 - Ongoing
Seasonal allergy	Seasonal allergies	1956 - Ongoing
Rotator cuff syndrome	Tore rotator cuff left shoulder	1972 - 2017
Rotator cuff syndrome	Tore rotator cuff right shoulder	1972 - 2015
Vasectomy	Vasectomy	1988 - Ongoing
Hypercholesterolaemia	Hypercholesterol	1990 - Ongoing
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Osteoarthritis	Osteoarthritis in right knee and hip, bilateral thumbs and shoulders	1990 - Ongoing
Gastrooesophageal reflux disease	Gerd	Jul 1990 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Iron deficiency anaemia	Iron deficiency anemia	1995 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Abdominal hernia	Abdominal hernia	2006 - 2006
Chronic kidney disease	Chronic kidney disease stage 3	2010 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	05 May 2014 (Study Day -2282) - Ongoing
Restless legs syndrome	Restless leg syndrome	2015 - Ongoing
Rhinorrhoea	Rhinorrhea	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	1990 - Ongoing	Hypercholesterolemia
Fluticasone propionate	1990 - Ongoing	Asthma
Levothyroxine	1990 - Ongoing	Hypothyroidism
Montelukast	1990 - Ongoing	Seasonal Allergies
Omeprazole	1990 - Ongoing	Gerd
Ferrous sulfate	1995 - Ongoing	Iron Deficiency Anemia
Amlodipine besilate	2005 - Ongoing	Hypertension
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Colecalciferol	2014 - Ongoing	Supplement
Ropinirole	2015 - Ongoing	Restless Leg Syndrome
Valsartan	2016 - Ongoing	Hypertension
Gabapentin	Jul 2016 - Ongoing	Restless Leg Syndrome
Paracetamol	2018 - Ongoing	Osteoarthritis
Ubidecarenone	2018 - Ongoing	Supplement
Indapamide	2019 - Ongoing	Hypertension
Ipratropium	2019 - Ongoing	Rhinorrhea
Gabapentin	03 Aug 2020 (Study Day 1) - Ongoing	Restless Leg Syndrom
Azithromycin	16 Nov 2020 (Study Day 106) - 21 Nov 2020 (Study Day 111)	Viral Pneumonia
Ceftriaxone	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Sepsis
Ct of chest*	16 Nov 2020 (Study Day 106) - 16 Nov 2020 (Study Day 106)	Adverse Event
Echocardiogram*	16 Nov 2020 (Study Day 106) - 16 Nov 2020 (Study Day 106)	Adverse Event
Enoxaparin	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Worsening COVID 19
Enoxaparin sodium	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Anxiety Secondary To COVID 19
Furosemide	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Ae Of COVID 19
Guaifenesin	16 Nov 2020 (Study Day 106) - Ongoing	For Nasal And Chest Congestion Due To COVID 19
Lorazepam	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Anxiety Related To COVID 19
Macrogol 3350	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID 19
Ondansetron	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID 19
Oxygen	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID-19
Paracetamol	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID 19
Potassium chloride	16 Nov 2020 (Study Day 106) - 16 Nov 2020 (Study Day 106)	Worsening Of COVID 19
Promethazine	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID 19
Rotigotine	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Restless Leg Syndrome
Salbutamol	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID 19
Sodium chloride	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	COVID 19
Sodium chloride	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Hyponatremia
Sodium chloride	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)	Worsening Of COVID 19
Ascorbic acid	17 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 117)	Supplement
Guaifenesin	17 Nov 2020 (Study Day 107) - 24 Nov 2020 (Study Day 114)	Worsening Of COVID 19
Rotigotine	17 Nov 2020 (Study Day 107) - 26 Nov 2020 (Study Day 116)	Worsening Of COVID 19
Valsartan	17 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 117)	Worsening Of COVID 19
Zinc	17 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 117)	Supplement
Zinc sulfate	17 Nov 2020 (Study Day 107) - 27 Nov 2020 (Study Day 117)	Worsening Of COVID 19
Zolpidem	17 Nov 2020 (Study Day 107) - 23 Nov 2020 (Study Day 113)	Worsening Of COVID 19
Hyperglycemia correction*	19 Nov 2020 (Study Day 109) - 19 Nov 2020 (Study Day 109)	Adverse Event
Plasma	19 Nov 2020 (Study Day 109) - 19 Nov 2020 (Study Day 109)	Hyponatremia
Furosemide	22 Nov 2020 (Study Day 112) - 24 Nov 2020 (Study Day 114)	Worsening Of COVID 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ceftriaxone	23 Nov 2020 (Study Day 113) - 27 Nov 2020 (Study Day 117)	COVID 19
Iopamidol	23 Nov 2020 (Study Day 113) - 23 Nov 2020 (Study Day 113)	Worsening Of COVID 19
Sodium chloride	23 Nov 2020 (Study Day 113) - 23 Nov 2020 (Study Day 113)	Worsening Of COVID 19
Escitalopram oxalate	24 Nov 2020 (Study Day 114) - 27 Nov 2020 (Study Day 117)	Worsening Of COVID 19
Guaifenesin	24 Nov 2020 (Study Day 114) - 27 Nov 2020 (Study Day 117)	Worsening Of COVID 19
Potassium chloride	24 Nov 2020 (Study Day 114) - 24 Nov 2020 (Study Day 114)	Worsening Of COVID 19
Furosemide	26 Nov 2020 (Study Day 116) - 27 Nov 2020 (Study Day 117)	Worsening Of COVID 19
Oxygen	19 Dec 2020 (Study Day 139) - 24 Jan 2021 (Study Day 175)	Pneumonia Due To COVID 19
Salbutamol	19 Dec 2020 (Study Day 139) - 24 Dec 2020 (Study Day 144)	Worsening Of COVID 19
Sodium chloride	19 Dec 2020 (Study Day 139) - 24 Jan 2021 (Study Day 175)	Pneumonia Due To COVID 19
Xr chest*	19 Dec 2020 (Study Day 139) - 19 Dec 2020 (Study Day 139)	Adverse Event
Ascorbic acid	20 Dec 2020 (Study Day 140) - 24 Dec 2020 (Study Day 144)	Worsening Of COVID 19
Colecalciferol	20 Dec 2020 (Study Day 140) - 24 Dec 2020 (Study Day 144)	Worsening Of COVID 19
Convalescent plasma*	20 Dec 2020 (Study Day 140) - 20 Dec 2020 (Study Day 140)	Adverse Event
Dexamethasone	20 Dec 2020 (Study Day 140) - 26 Dec 2020 (Study Day 146)	COVID 19
Dexamethasone	20 Dec 2020 (Study Day 140) - 29 Dec 2020 (Study Day 149)	COVID 19
Remdesivir	20 Dec 2020 (Study Day 140) - 24 Dec 2020 (Study Day 144)	COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	11 Nov 2020 (Study Day 101) - 30 Dec 2020 (Study Day 150)
Anxiety	Grade 2/moderate	Not applicable	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)
Hypokalaemia	Grade 2/moderate	Not applicable	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)
Hyponatraemia	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 106) - 19 Nov 2020 (Study Day 109)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Sepsis	Grade 2/moderate	Not applicable	16 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 117)
Fluid Overload	Grade 2/moderate	Not applicable	19 Dec 2020 (Study Day 139) - 24 Dec 2020 (Study Day 144)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2110 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Lead Dislodgement/Displaced Automated Implantable Cardioverter Defibrillator Lead	SAE	Grade 2/ moderate	Not related	08 Oct 2020 (Study Day 50) – 08 Oct 2020 (Study Day 50)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2110, a 81-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Oct 2020 (Study Day 50), 49 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of lead dislodgement. Action taken with the IP was not applicable. The event of displaced automated implantable cardioverter defibrillator lead lasted for 1 day, after which it was considered to be recovered/resolved on 08 Oct 2020 (Study Day 50). The investigator assessed the event of lead dislodgement to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000483	Lead dislodgement

Study Completion/Discontinuation

On 03 Feb 2021 (Study Day 168), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1958 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1980 - Ongoing
Actinic keratosis	Actinic keratosis - scalp	1990 - Ongoing
Gout	Gout right big toe	1990 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Atrial fibrillation	Atrial fibrillation	2000 - Ongoing
Drug hypersensitivity	Lisinopril drug allergy	2000 - Ongoing
Drug hypersensitivity	Naproxen drug allergy	2000 - Ongoing
Drug hypersensitivity	Sotalol drug allergy	2000 - Ongoing
Drug hypersensitivity	Vicodin drug allergy	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Implantable defibrillator insertion	Automatic implantable cardioverter defibrillator	2000 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	2015 - Ongoing
Cataract	Cataracts - right eye	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1980 - Ongoing	Cardiac Health
Simvastatin	1980 - Ongoing	Hyperlipidemia
Allopurinol	1990 - Ongoing	Gout Right Big Toe
Thioctic acid	1990 - Ongoing	Vitamin Deficiency
Metoprolol succinate	1995 - Ongoing	Hypertension
Flecainide acetate	2000 - Ongoing	Arrhythmia Ventricular Tachycardia
Levothyroxine	2000 - Ongoing	Hypothyroidism
Tamsulosin hydrochloride	2015 - Ongoing	Benign Prostatic Hyperplasia
Automated implantable cardioverter defibrillator lead replacement*	08 Oct 2020 (Study Day 50) - 08 Oct 2020 (Study Day 50)	Medical History
Cefalexin	08 Oct 2020 (Study Day 50) - 16 Oct 2020 (Study Day 58)	Pacemaker Replacement Procedure
Pacemaker replacement*	08 Oct 2020 (Study Day 50) - 08 Oct 2020 (Study Day 50)	Medical History
Paracetamol	08 Oct 2020 (Study Day 50) - 16 Oct 2020 (Study Day 58)	Pacemaker Replacement Procedure
Colchicine	01 Nov 2020 (Study Day 74) - Ongoing	Gout Right Big Toe

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Other viral vaccines	24 Jan 2021 (Study Day 158) - 24 Jan 2021 (Study Day 158)	COVID-19 Vaccine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 50) - 29 Oct 2020 (Study Day 71)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2176 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	SAE, COVID-19	Grade 4	Not related	15 Nov 2020 (Study Day 82) – 12 Jan 2021 (Study Day 140)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US373-2176, a 85-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 15 Nov 2020 (Study Day 82), 81 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 23 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 22 Nov 2020 (Study Day 89), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
15 Nov 2020 (Study Day 82)	Chills	Mild
15 Nov 2020 (Study Day 82)	Fatigue	Mild
15 Nov 2020 (Study Day 82)	Sore Throat	Mild
16 Nov 2020 (Study Day 83)	Chills	Mild
16 Nov 2020 (Study Day 83)	Fatigue	Mild
16 Nov 2020 (Study Day 83)	Sore Throat	Mild

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 84)	Chills	Mild
17 Nov 2020 (Study Day 84)	Fatigue	Mild
17 Nov 2020 (Study Day 84)	Sore Throat	Mild
18 Nov 2020 (Study Day 85)	Chills	Mild
18 Nov 2020 (Study Day 85)	Fatigue	Mild
18 Nov 2020 (Study Day 85)	Sore Throat	Mild
19 Nov 2020 (Study Day 86)	Chills	Mild
19 Nov 2020 (Study Day 86)	Fatigue	Mild
19 Nov 2020 (Study Day 86)	Sore Throat	Mild
20 Nov 2020 (Study Day 87)	Chills	Mild
20 Nov 2020 (Study Day 87)	Fatigue	Mild
20 Nov 2020 (Study Day 87)	Headache	Mild
20 Nov 2020 (Study Day 87)	Shortness of Breath	Mild
20 Nov 2020 (Study Day 87)	Sore Throat	Moderate
21 Nov 2020 (Study Day 88)	Chills	Mild
21 Nov 2020 (Study Day 88)	Fatigue	Moderate
21 Nov 2020 (Study Day 88)	Headache	Mild
21 Nov 2020 (Study Day 88)	Sore Throat	Mild
22 Nov 2020 (Study Day 89)	Chills	Mild
22 Nov 2020 (Study Day 89)	Fatigue	Moderate
22 Nov 2020 (Study Day 89)	Sore Throat	Mild
23 Nov 2020 (Study Day 90)	Chills	Moderate
23 Nov 2020 (Study Day 90)	Difficulty Breathing	Mild
23 Nov 2020 (Study Day 90)	Fatigue	Mild
23 Nov 2020 (Study Day 90)	O2 Saturation (%)	93
23 Nov 2020 (Study Day 90)	Shortness of Breath	Mild
30 Nov 2020 (Study Day 97)	Shortness of Breath	Mild
01 Dec 2020 (Study Day 98)	Shortness of Breath	Mild
02 Dec 2020 (Study Day 99)	Shortness of Breath	Mild
03 Dec 2020 (Study Day 100)	Shortness of Breath	Mild
04 Dec 2020 (Study Day 101)	Shortness of Breath	Mild
05 Dec 2020 (Study Day 102)	Shortness of Breath	Mild
06 Dec 2020 (Study Day 103)	Shortness of Breath	Mild
07 Dec 2020 (Study Day 104)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 105)	Fatigue	Mild
09 Dec 2020 (Study Day 106)	Fatigue	Mild
10 Dec 2020 (Study Day 107)	Fatigue	Mild
11 Dec 2020 (Study Day 108)	Difficulty Breathing	Mild
11 Dec 2020 (Study Day 108)	Fatigue	Mild
11 Dec 2020 (Study Day 108)	Shortness of Breath	Mild
12 Dec 2020 (Study Day 109)	Fatigue	Mild
20 Dec 2020 (Study Day 117)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
30 Nov 2020 - 30 Nov 2020 (Study Day 97-97)	Clinical Evidence of Pneumonia	Yes
03 Dec 2020 - 03 Dec 2020 (Study Day 100-100)	Radiographical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 59 days, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 140). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000952	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	1948 - 1979
Cholecystitis	Cholecystitis	1974 - 2005
Drug hypersensitivity	Demerol drug allergy	1979 - Ongoing
Drug hypersensitivity	Clarithromycin allergy	1980 - Ongoing
Hypersensitivity	Environmental allergies	1980 - 1989
Drug hypersensitivity	Antihistamine drug allergy	1985 - Ongoing
Drug hypersensitivity	Codeine sulfate allergy	1985 - Ongoing
Hysterectomy	Complete hysterectomy	1987 - 1987
Urinary bladder suspension	Pubovaginal sling surgery	1987 - 1987
Type 2 diabetes mellitus	Type 2 diabetes	1990 - Ongoing
Spinal corpectomy	Anterior cervical corpectomy	1995 - 1995
Dyslipidaemia	Dyslipidemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Cholecystectomy	Cholecystectomy	2015 - 2015
Osteoarthritis	Osteoarthritis	2015 - Ongoing
Presbyopia	Presbyopia - bilaterl	2017 - Ongoing
Presbyacusis	Presbycusis - bilateral	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pneumonia	Pneumonia	21 Feb 2020 (Study Day -187) - 28 Feb 2020 (Study Day -180)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	1990 - Ongoing	Type 2 Diabetes
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Paracetamol	2015 - Ongoing	Osteoarthritis
Lisinopril	2016 - Jun 2020	Hypertension
Lidocaine	31 Aug 2020 (Study Day 6) - 23 Oct 2020 (Study Day 59)	Dermatitis Bilateral Upper And Lower Extremities
Lisinopril	Sep 2020 - Ongoing	Hypertension
Paracetamol	27 Sep 2020 (Study Day 33) - 27 Sep 2020 (Study Day 33)	Dermatitis Bilateral Upper And Lower Extremities
Hydrocortisone	30 Sep 2020 (Study Day 36) - 23 Oct 2020 (Study Day 59)	Deramtitis Bilateral Upper And Lower Extremities
Paracetamol	15 Nov 2020 (Study Day 82) - 11 Jan 2021 (Study Day 139)	Viral Illness
Cefuroxime	24 Nov 2020 (Study Day 91) - 01 Dec 2020 (Study Day 98)	Symptomatic COVID-19
Lisinopril	30 Nov 2020 (Study Day 97) - 30 Nov 2020 (Study Day 97)	Symptomatic COVID-19
Nystatin	08 Feb 2021 (Study Day 167) - 22 Feb 2021 (Study Day 181)	Vaginal Yeast Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthropod Bite	Grade 1/mild	Not related	31 Aug 2020 (Study Day 6) - 31 Aug 2020 (Study Day 6)
Dermatitis	Grade 2/moderate	Not related	31 Aug 2020 (Study Day 6) - 23 Oct 2020 (Study Day 59)
Vulvovaginal Candidiasis	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 167) - 22 Feb 2021 (Study Day 181)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2123 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 36)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/ moderate	Not related	20 Oct 2020 (Study Day 48) – 11 Nov 2020 (Study Day 70)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US374-2123, a 36-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 20 Oct 2020 (Study Day 48), 47 days after the first dose and 12 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 36, 08 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 21 Oct 2020 (Study Day 49), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
20 Oct 2020 (Study Day 48)	Cough	Mild
20 Oct 2020 (Study Day 48)	Fatigue	Severe
20 Oct 2020 (Study Day 48)	Headache	Moderate
21 Oct 2020 (Study Day 49)	Cough	Mild
21 Oct 2020 (Study Day 49)	Fatigue	Severe
21 Oct 2020 (Study Day 49)	Headache	Moderate
21 Oct 2020 (Study Day 49)	Muscle Aches (Myalgia)	Moderate

Symptom Date	Symptom	Result
21 Oct 2020 (Study Day 49)	Nasal Congestion	Mild
21 Oct 2020 (Study Day 49)	Runny Nose (Rhinorrhea)	Mild
22 Oct 2020 (Study Day 50)	Cough	Moderate
22 Oct 2020 (Study Day 50)	Fatigue	Severe
22 Oct 2020 (Study Day 50)	Headache	Mild
22 Oct 2020 (Study Day 50)	Muscle Aches (Myalgia)	Moderate
22 Oct 2020 (Study Day 50)	Nasal Congestion	Mild
22 Oct 2020 (Study Day 50)	Runny Nose (Rhinorrhea)	Mild
22 Oct 2020 (Study Day 50)	Sore Throat	Mild
23 Oct 2020 (Study Day 51)	Cough	Mild
23 Oct 2020 (Study Day 51)	Fatigue	Severe
23 Oct 2020 (Study Day 51)	Headache	Severe
23 Oct 2020 (Study Day 51)	Muscle Aches (Myalgia)	Moderate
23 Oct 2020 (Study Day 51)	Nasal Congestion	Mild
23 Oct 2020 (Study Day 51)	Runny Nose (Rhinorrhea)	Mild
24 Oct 2020 (Study Day 52)	Cough	Mild
24 Oct 2020 (Study Day 52)	Fatigue	Severe
24 Oct 2020 (Study Day 52)	Headache	Moderate
24 Oct 2020 (Study Day 52)	Muscle Aches (Myalgia)	Moderate
24 Oct 2020 (Study Day 52)	Nasal Congestion	Mild
24 Oct 2020 (Study Day 52)	New Loss of Smell	Moderate
24 Oct 2020 (Study Day 52)	New Loss of Taste	Moderate
24 Oct 2020 (Study Day 52)	Runny Nose (Rhinorrhea)	Mild
25 Oct 2020 (Study Day 53)	Cough	Mild
25 Oct 2020 (Study Day 53)	Fatigue	Severe
25 Oct 2020 (Study Day 53)	Headache	Moderate
25 Oct 2020 (Study Day 53)	Muscle Aches (Myalgia)	Moderate
25 Oct 2020 (Study Day 53)	Nasal Congestion	Mild
25 Oct 2020 (Study Day 53)	New Loss of Smell	Moderate
25 Oct 2020 (Study Day 53)	New Loss of Taste	Moderate
25 Oct 2020 (Study Day 53)	Runny Nose (Rhinorrhea)	Mild
26 Oct 2020 (Study Day 54)	Cough	Mild
26 Oct 2020 (Study Day 54)	Fatigue	Severe
26 Oct 2020 (Study Day 54)	Headache	Mild
26 Oct 2020 (Study Day 54)	Muscle Aches (Myalgia)	Mild
26 Oct 2020 (Study Day 54)	New Loss of Smell	Moderate
26 Oct 2020 (Study Day 54)	New Loss of Taste	Moderate
26 Oct 2020 (Study Day 54)	Temperature (°F)	101.3
27 Oct 2020 (Study Day 55)	Cough	Mild
27 Oct 2020 (Study Day 55)	Fatigue	Moderate
27 Oct 2020 (Study Day 55)	Headache	Mild
27 Oct 2020 (Study Day 55)	Muscle Aches (Myalgia)	Mild
27 Oct 2020 (Study Day 55)	Nausea	Mild

Symptom Date	Symptom	Result
27 Oct 2020 (Study Day 55)	New Loss of Smell	Mild
27 Oct 2020 (Study Day 55)	New Loss of Taste	Mild
27 Oct 2020 (Study Day 55)	O2 Saturation (%)	93
28 Oct 2020 (Study Day 56)	Cough	Mild
28 Oct 2020 (Study Day 56)	Difficulty Breathing	Mild
28 Oct 2020 (Study Day 56)	Fatigue	Moderate
28 Oct 2020 (Study Day 56)	Headache	Severe
28 Oct 2020 (Study Day 56)	New Loss of Smell	Mild
28 Oct 2020 (Study Day 56)	New Loss of Taste	Mild
28 Oct 2020 (Study Day 56)	Shortness of Breath	Mild
29 Oct 2020 (Study Day 57)	Cough	Mild
29 Oct 2020 (Study Day 57)	Fatigue	Mild
29 Oct 2020 (Study Day 57)	New Loss of Smell	Mild
29 Oct 2020 (Study Day 57)	New Loss of Taste	Mild
30 Oct 2020 (Study Day 58)	Cough	Mild
30 Oct 2020 (Study Day 58)	Fatigue	Mild
30 Oct 2020 (Study Day 58)	New Loss of Smell	Mild
30 Oct 2020 (Study Day 58)	New Loss of Taste	Mild
31 Oct 2020 (Study Day 59)	Cough	Mild
31 Oct 2020 (Study Day 59)	Fatigue	Mild
31 Oct 2020 (Study Day 59)	Headache	Mild
31 Oct 2020 (Study Day 59)	Nausea	Mild
31 Oct 2020 (Study Day 59)	New Loss of Smell	Mild
31 Oct 2020 (Study Day 59)	New Loss of Taste	Mild
01 Nov 2020 (Study Day 60)	Cough	Mild
01 Nov 2020 (Study Day 60)	Fatigue	Mild
01 Nov 2020 (Study Day 60)	Nausea	Mild
01 Nov 2020 (Study Day 60)	New Loss of Smell	Mild
01 Nov 2020 (Study Day 60)	New Loss of Taste	Mild
02 Nov 2020 (Study Day 61)	Cough	Mild
02 Nov 2020 (Study Day 61)	Fatigue	Mild
02 Nov 2020 (Study Day 61)	Headache	Mild
02 Nov 2020 (Study Day 61)	Nausea	Mild
02 Nov 2020 (Study Day 61)	New Loss of Smell	Mild
02 Nov 2020 (Study Day 61)	New Loss of Taste	Mild
03 Nov 2020 (Study Day 62)	Cough	Mild
03 Nov 2020 (Study Day 62)	Fatigue	Mild
03 Nov 2020 (Study Day 62)	Nausea	Mild
03 Nov 2020 (Study Day 62)	New Loss of Smell	Mild
03 Nov 2020 (Study Day 62)	New Loss of Taste	Mild
04 Nov 2020 (Study Day 63)	Fatigue	Mild
04 Nov 2020 (Study Day 63)	New Loss of Smell	Mild
04 Nov 2020 (Study Day 63)	New Loss of Taste	Mild

Symptom Date	Symptom	Result
05 Nov 2020 (Study Day 64)	Fatigue	Mild
05 Nov 2020 (Study Day 64)	New Loss of Smell	Mild
05 Nov 2020 (Study Day 64)	New Loss of Taste	Mild
06 Nov 2020 (Study Day 65)	Fatigue	Mild
06 Nov 2020 (Study Day 65)	New Loss of Smell	Mild
06 Nov 2020 (Study Day 65)	New Loss of Taste	Mild
07 Nov 2020 (Study Day 66)	Fatigue	Mild
07 Nov 2020 (Study Day 66)	New Loss of Smell	Mild
07 Nov 2020 (Study Day 66)	New Loss of Taste	Mild
08 Nov 2020 (Study Day 67)	Fatigue	Mild
08 Nov 2020 (Study Day 67)	New Loss of Smell	Mild
08 Nov 2020 (Study Day 67)	New Loss of Taste	Mild
09 Nov 2020 (Study Day 68)	Fatigue	Mild
09 Nov 2020 (Study Day 68)	New Loss of Smell	Mild
09 Nov 2020 (Study Day 68)	New Loss of Taste	Mild
10 Nov 2020 (Study Day 69)	Fatigue	Mild
10 Nov 2020 (Study Day 69)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
27 Oct 2020 (Study Day 55)	Oxygen Saturation	93%
27 Oct 2020 - 27 Oct 2020 (Study Day 55-55)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 23 days, after which it was considered to be recovered/resolved on 11 Nov 2020 (Study Day 70). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000587	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol; fish oil	13 Oct 2020 (Study Day 41) - Ongoing	Prevention/Wellness
Vitamin d and analogues	13 Oct 2020 (Study Day 41) - Ongoing	Prevention/Wellness
Paracetamol	21 Oct 2020 (Study Day 49) - 03 Nov 2020 (Study Day 62)	Symptomatic COVID-19 Infection
Ibuprofen	23 Oct 2020 (Study Day 51) - 03 Nov 2020 (Study Day 62)	Symptomatic COVID Infection
Influenza vaccine	19 Nov 2020 (Study Day 78) - 19 Nov 2020 (Study Day 78)	Prophylaxis Flu Vaccine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urticaria	Grade 1/mild	Not related	05 Oct 2020 (Study Day 33) - 09 Oct 2020 (Study Day 37)
COVID-19	Grade 2/moderate	Not related	20 Oct 2020 (Study Day 48) - 11 Nov 2020 (Study Day 70)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2357 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	24 Dec 2020 (Study Day 99) – 08 Jan 2021 (Study Day 114)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US374-2357, a 53-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 24 Dec 2020 (Study Day 99), 98 days after the first dose and 70 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 15 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Dec 2020 (Study Day 103), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
05 Dec 2020 (Study Day 80)	Body Aches	Severe
05 Dec 2020 (Study Day 80)	Nasal Congestion	Mild
05 Dec 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
06 Dec 2020 (Study Day 81)	Difficulty Breathing	Mild
06 Dec 2020 (Study Day 81)	Nasal Congestion	Mild
06 Dec 2020 (Study Day 81)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
07 Dec 2020 (Study Day 82)	Difficulty Breathing	Mild
07 Dec 2020 (Study Day 82)	Nasal Congestion	Mild
07 Dec 2020 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 83)	Nasal Congestion	Mild
08 Dec 2020 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
09 Dec 2020 (Study Day 84)	Fatigue	Mild
09 Dec 2020 (Study Day 84)	Muscle Aches (Myalgia)	Mild
09 Dec 2020 (Study Day 84)	Nasal Congestion	Mild
09 Dec 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
10 Dec 2020 (Study Day 85)	Fatigue	Mild
10 Dec 2020 (Study Day 85)	Muscle Aches (Myalgia)	Mild
10 Dec 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 86)	Muscle Aches (Myalgia)	Mild
11 Dec 2020 (Study Day 86)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 86)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 99)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 100)	Cough	Mild
25 Dec 2020 (Study Day 100)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 101)	Headache	Mild
26 Dec 2020 (Study Day 101)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 101)	Nausea	Mild
26 Dec 2020 (Study Day 101)	Runny Nose (Rhinorrhea)	Mild
26 Dec 2020 (Study Day 101)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 101)	Sore Throat	Mild
27 Dec 2020 (Study Day 102)	Diarrhea	Mild
27 Dec 2020 (Study Day 102)	Nasal Congestion	Mild
27 Dec 2020 (Study Day 102)	Runny Nose (Rhinorrhea)	Mild
27 Dec 2020 (Study Day 102)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 102)	Sore Throat	Mild
28 Dec 2020 (Study Day 103)	Cough	Mild
28 Dec 2020 (Study Day 103)	Diarrhea	Mild
28 Dec 2020 (Study Day 103)	Nasal Congestion	Mild
28 Dec 2020 (Study Day 103)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 103)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 103)	Sore Throat	Mild
29 Dec 2020 (Study Day 104)	Headache	Mild
29 Dec 2020 (Study Day 104)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 104)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 104)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 105)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 105)	Runny Nose (Rhinorrhea)	Mild
30 Dec 2020 (Study Day 105)	Shortness of Breath	Mild
31 Dec 2020 (Study Day 106)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
01 Jan 2021 (Study Day 107)	Headache	Mild
01 Jan 2021 (Study Day 107)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 107)	O2 Saturation (%)	93
02 Jan 2021 (Study Day 108)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 111)	Diarrhea	Mild
06 Jan 2021 (Study Day 112)	Diarrhea	Mild
06 Jan 2021 (Study Day 112)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 113)	Headache	Mild
08 Jan 2021 (Study Day 114)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 117)	Chills	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
01 Jan 2021 (Study Day 107)	Oxygen Saturation	93%
01 Jan 2021 - 01 Jan 2021 (Study Day 107-107)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 16 days, after which it was considered to be recovered/resolved on 08 Jan 2021 (Study Day 114). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002253	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gerd gastro esophageal reflux disease	15 Mar 2019 (Study Day -552) - Ongoing
Botulinum toxin injection	Botox injections	Jun 2019 - Dec 2019
Migraine	Migraines	Jun 2019 - Dec 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	2019 - Ongoing	Gerd
Ascorbic acid	Sep 2019 - Ongoing	Prophylaxis Supplement
Zinc	Sep 2019 - Ongoing	Prophylaxis Supplement
Naproxen	06 Oct 2020 (Study Day 20) - 06 Oct 2020 (Study Day 20)	Generalized Body Aches
Cefalexin	15 Oct 2020 (Study Day 29) - 21 Oct 2020 (Study Day 35)	Prophylaxis Infection
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol; phenylephrine hydrochloride	06 Dec 2020 (Study Day 81) - 06 Jan 2021 (Study Day 112)	Unspecified Viral Illness
Menthol; methyl salicylate	09 Dec 2020 (Study Day 84) - 10 Dec 2020 (Study Day 85)	Viral Illness Unspecified

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain	Grade 1/mild	Not related	06 Oct 2020 (Study Day 20) - 06 Oct 2020 (Study Day 20)
Skin Laceration	Grade 1/mild	Not related	13 Oct 2020 (Study Day 27) - 02 Nov 2020 (Study Day 47)
Viral Infection	Grade 1/mild	Not related	05 Dec 2020 (Study Day 80) - 13 Dec 2020 (Study Day 88)
COVID-19	Grade 1/mild	Not related	24 Dec 2020 (Study Day 99) - 08 Jan 2021 (Study Day 114)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2025 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 43)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE, COVID-19	Grade 4	Not related	08 Nov 2020 (Study Day 91) – 30 Nov 2020 (Study Day 113)	Recovered/resolved
Hypotension/Hypotension	SAE	Grade 4	Not related	10 Nov 2020 (Study Day 93) – 13 Nov 2020 (Study Day 96)	Recovered/resolved
Clear Cell Renal Cell Carcinoma/Clear Cell Renal Carcinoma	SAE	Grade 3/severe	Not related	22 Jan 2021 (Study Day 166) – 23 Jan 2021 (Study Day 167)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US375-2025, a 58-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 43). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Nov 2020 (Study Day 93), 92 days after the first dose and 50 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hypotension. Action taken with the IP was not applicable. The event of hypotension lasted for 4 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 96). The investigator assessed the event of hypotension to be not related to the IP.

On 22 Jan 2021 (Study Day 166), 165 days after the first dose and 123 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of clear cell renal cell carcinoma. Action taken with the IP was not applicable. The event of clear cell renal carcinoma lasted for 2 days, after which it was considered to be recovered/resolved on 23 Jan 2021 (Study Day 167). The investigator assessed the event of clear cell renal cell carcinoma to be not related to the IP.

Severe COVID-19 Details

On 08 Nov 2020 (Study Day 91), 90 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 43, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 10 Nov 2020 (Study Day 93), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
10 Oct 2020 (Study Day 62)	Cough	Mild
11 Oct 2020 (Study Day 63)	Cough	Mild
08 Nov 2020 (Study Day 91)	Headache	Mild
09 Nov 2020 (Study Day 92)	Headache	Severe
10 Nov 2020 (Study Day 93)	Headache	Severe
10 Nov 2020 (Study Day 93)	O2 Saturation (%)	92
11 Nov 2020 (Study Day 94)	Headache	Severe
11 Nov 2020 (Study Day 94)	New Loss of Smell	Severe
11 Nov 2020 (Study Day 94)	New Loss of Taste	Severe
12 Nov 2020 (Study Day 95)	Headache	Severe
12 Nov 2020 (Study Day 95)	New Loss of Smell	Severe
12 Nov 2020 (Study Day 95)	New Loss of Taste	Severe
13 Nov 2020 (Study Day 96)	Headache	Moderate
13 Nov 2020 (Study Day 96)	New Loss of Smell	Severe
13 Nov 2020 (Study Day 96)	New Loss of Taste	Severe
13 Nov 2020 (Study Day 96)	O2 Saturation (%)	91
14 Nov 2020 (Study Day 97)	Headache	Moderate
14 Nov 2020 (Study Day 97)	New Loss of Smell	Severe
14 Nov 2020 (Study Day 97)	New Loss of Taste	Severe
15 Nov 2020 (Study Day 98)	Headache	Moderate
15 Nov 2020 (Study Day 98)	New Loss of Smell	Severe
15 Nov 2020 (Study Day 98)	New Loss of Taste	Severe
16 Nov 2020 (Study Day 99)	Headache	Moderate
16 Nov 2020 (Study Day 99)	New Loss of Smell	Severe
16 Nov 2020 (Study Day 99)	New Loss of Taste	Severe
17 Nov 2020 (Study Day 100)	Body Aches	Mild
17 Nov 2020 (Study Day 100)	Cough	Mild
17 Nov 2020 (Study Day 100)	Fatigue	Moderate
17 Nov 2020 (Study Day 100)	Headache	Mild
17 Nov 2020 (Study Day 100)	New Loss of Smell	Severe

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 100)	New Loss of Taste	Severe
17 Nov 2020 (Study Day 100)	O2 Saturation (%)	93
17 Nov 2020 (Study Day 100)	Shortness of Breath	Mild
18 Nov 2020 (Study Day 101)	Body Aches	Mild
18 Nov 2020 (Study Day 101)	Cough	Mild
18 Nov 2020 (Study Day 101)	Fatigue	Moderate
18 Nov 2020 (Study Day 101)	Headache	Mild
18 Nov 2020 (Study Day 101)	New Loss of Smell	Severe
18 Nov 2020 (Study Day 101)	New Loss of Taste	Severe
18 Nov 2020 (Study Day 101)	Shortness of Breath	Mild
19 Nov 2020 (Study Day 102)	Body Aches	Mild
19 Nov 2020 (Study Day 102)	Cough	Moderate
19 Nov 2020 (Study Day 102)	Fatigue	Moderate
19 Nov 2020 (Study Day 102)	Headache	Moderate
19 Nov 2020 (Study Day 102)	Nasal Congestion	Moderate
19 Nov 2020 (Study Day 102)	New Loss of Smell	Moderate
19 Nov 2020 (Study Day 102)	New Loss of Taste	Moderate
19 Nov 2020 (Study Day 102)	Shortness of Breath	Mild
20 Nov 2020 (Study Day 103)	Body Aches	Mild
20 Nov 2020 (Study Day 103)	Cough	Mild
20 Nov 2020 (Study Day 103)	Fatigue	Moderate
20 Nov 2020 (Study Day 103)	Headache	Moderate
20 Nov 2020 (Study Day 103)	Nasal Congestion	Moderate
20 Nov 2020 (Study Day 103)	New Loss of Smell	Moderate
20 Nov 2020 (Study Day 103)	New Loss of Taste	Moderate
20 Nov 2020 (Study Day 103)	Shortness of Breath	Mild
21 Nov 2020 (Study Day 104)	Body Aches	Mild
21 Nov 2020 (Study Day 104)	Cough	Mild
21 Nov 2020 (Study Day 104)	Fatigue	Moderate
21 Nov 2020 (Study Day 104)	Headache	Moderate
21 Nov 2020 (Study Day 104)	Nasal Congestion	Moderate
21 Nov 2020 (Study Day 104)	New Loss of Smell	Moderate
21 Nov 2020 (Study Day 104)	New Loss of Taste	Moderate
21 Nov 2020 (Study Day 104)	Shortness of Breath	Mild
22 Nov 2020 (Study Day 105)	Body Aches	Mild
22 Nov 2020 (Study Day 105)	Cough	Mild
22 Nov 2020 (Study Day 105)	Fatigue	Moderate
22 Nov 2020 (Study Day 105)	Headache	Moderate
22 Nov 2020 (Study Day 105)	Nasal Congestion	Moderate
22 Nov 2020 (Study Day 105)	New Loss of Smell	Moderate
22 Nov 2020 (Study Day 105)	New Loss of Taste	Moderate
22 Nov 2020 (Study Day 105)	Shortness of Breath	Mild
23 Nov 2020 (Study Day 106)	Cough	Mild

Symptom Date	Symptom	Result
23 Nov 2020 (Study Day 106)	Fatigue	Mild
23 Nov 2020 (Study Day 106)	Headache	Mild
23 Nov 2020 (Study Day 106)	Nasal Congestion	Moderate
23 Nov 2020 (Study Day 106)	New Loss of Smell	Moderate
23 Nov 2020 (Study Day 106)	New Loss of Taste	Moderate
23 Nov 2020 (Study Day 106)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 107)	Fatigue	Mild
24 Nov 2020 (Study Day 107)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 107)	New Loss of Smell	Moderate
24 Nov 2020 (Study Day 107)	New Loss of Taste	Moderate
24 Nov 2020 (Study Day 107)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 108)	Body Aches	Mild
25 Nov 2020 (Study Day 108)	Cough	Mild
25 Nov 2020 (Study Day 108)	Diarrhea	Moderate
25 Nov 2020 (Study Day 108)	Fatigue	Moderate
25 Nov 2020 (Study Day 108)	Headache	Mild
25 Nov 2020 (Study Day 108)	Muscle Aches (Myalgia)	Mild
25 Nov 2020 (Study Day 108)	New Loss of Smell	Moderate
25 Nov 2020 (Study Day 108)	New Loss of Taste	Moderate
25 Nov 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Mild
25 Nov 2020 (Study Day 108)	Shortness of Breath	Mild
26 Nov 2020 (Study Day 109)	Fatigue	Mild
26 Nov 2020 (Study Day 109)	New Loss of Smell	Mild
26 Nov 2020 (Study Day 109)	New Loss of Taste	Mild
27 Nov 2020 (Study Day 110)	Fatigue	Mild
27 Nov 2020 (Study Day 110)	New Loss of Smell	Mild
27 Nov 2020 (Study Day 110)	New Loss of Taste	Mild
28 Nov 2020 (Study Day 111)	New Loss of Smell	Mild
28 Nov 2020 (Study Day 111)	New Loss of Taste	Mild
29 Nov 2020 (Study Day 112)	New Loss of Smell	Mild
29 Nov 2020 (Study Day 112)	New Loss of Taste	Mild
30 Nov 2020 (Study Day 113)	New Loss of Smell	Mild
30 Nov 2020 (Study Day 113)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
10 Nov 2020 (Study Day 93)	Oxygen Saturation	92%
10 Nov 2020 - 17 Nov 2020 (Study Day 93-100)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
10 Nov 2020 - 13 Nov 2020 (Study Day 93-96)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 23 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 113). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000749	COVID-19
MOD-2020-000749	Hypotension
MOD-2021-011056	Clear cell renal cell carcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	Not reported - Ongoing
Back pain	Chronic back pain	Not reported - Ongoing
Biopsy breast	Right breast biopsies x 4	Not reported
Cholecystectomy	Cholecystectomy	Not reported
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disorder	Not reported - Ongoing
Depression	Depression	Not reported - Ongoing
Female sterilisation	Tubal ligation	Not reported
Headache	Generalized headaches	Not reported - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	Not reported - Ongoing
Pollakiuria	Urinary frequency	Not reported - Ongoing
Sleep apnoea syndrome	Sleep apnea	Not reported - Ongoing
Spinal osteoarthritis	0steoarthritis back	Not reported - Ongoing
Tobacco abuse	Tobacco abuse	Not reported - Ongoing
Wisdom teeth removal	Wisdom tooth extraction	Not reported
Tonsillectomy	Tonsillectomy	1978 - 1978
Endometriosis	Endometriosis	1989 - Not reported
Hysterectomy	Laparoscopic hysterectomy for endometriosis	1989 - 1989
Hysterectomy	Surgical sterilization/hysterectomy	1989 - 1989
Spinal operation	Back surgery (associated condition unknown)	1989 - 1989
Cholecystectomy	Cholecystectomy (associated condition unknown)	2004 - 2004
Aortic aneurysm	Aortic aneurysm	2017 - 2017

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gerd/reflux	2017 - Ongoing
Anxiety	Anxiety	2019 - Ongoing
Spinal operation	Back surgery (associated condition unknown)	2019 - 2019
Hypercholesterolaemia	Hypercholesterolemia	2020 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	2020 - Ongoing
Renal mass	Left renal mass	20 Jul 2020 (Study Day -21) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide; formoterol fumarate	Not reported - Ongoing	Asthma/Copd
Colecalciferol	Not reported - Ongoing	Supplement
Gabapentin	Not reported - Ongoing	Chronic Back Pain
Salbutamol	Not reported - Ongoing	Asthma/Copd
Pantoprazole sodium sesquihydrate	2017 - Ongoing	Gastroesophageal Reflux Disease
Sertraline	2019 - 02 Mar 2021 (Study Day 205)	Anxiety
Atorvastatin	2020 - Ongoing	Hyperlipidemia
Insulin detemir	2020 - 02 Sep 2020 (Study Day 24)	Diabetes Mellitus Type Ii
Metformin	2020 - Ongoing	Diabetes Mellitus Type 2
Influenza vaccine	03 Sep 2020 (Study Day 25) - 03 Sep 2020 (Study Day 25)	Prophylaxis For Seasonal Influenza
Varenicline tartrate	21 Sep 2020 (Study Day 43) - 21 Oct 2020 (Study Day 73)	Smoking Cessation
Insulin lispro	15 Oct 2020 (Study Day 67) - Nov 2020	Diabetes Mellitus Type 2
Zolpidem tartrate	19 Oct 2020 (Study Day 71) - Ongoing	Sleep Apnea
Ct chest without contrast*	21 Oct 2020 (Study Day 73) - 21 Oct 2020 (Study Day 73)	Diagnostic
Myocardial perfusion/pharmacologic stress test*	21 Oct 2020 (Study Day 73) - 21 Oct 2020 (Study Day 73)	Diagnostic
Insulin lispro	Nov 2020 - Ongoing	Diabetes Ii
Calcium chloride; potassium chloride; sodium lactate	10 Nov 2020 (Study Day 93) - 13 Nov 2020 (Study Day 96)	COVID-19
Calcium chloride; potassium chloride; sodium lactate	10 Nov 2020 (Study Day 93) - 10 Nov 2020 (Study Day 93)	Hypotension
Chest xray 1 view portable ap*	10 Nov 2020 (Study Day 93) - 10 Nov 2020 (Study Day 93)	Adverse Event
Ct head without contrast*	10 Nov 2020 (Study Day 93) - 10 Nov 2020 (Study Day 93)	Adverse Event
Cyclobenzaprine	10 Nov 2020 (Study Day 93) - 11 Nov 2020 (Study Day 94)	COVID-19
Fentanyl	10 Nov 2020 (Study Day 93) - 13 Nov 2020 (Study Day 96)	COVID 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin	10 Nov 2020 (Study Day 93) - 13 Nov 2020 (Study Day 96)	Type Ii Diabetes Mellitus
Cyclobenzaprine	11 Nov 2020 (Study Day 94) - Ongoing	COVID-19
Ketorolac	11 Nov 2020 (Study Day 94) - 11 Nov 2020 (Study Day 94)	COVID- 19
Ketorolac	11 Nov 2020 (Study Day 94) - 13 Nov 2020 (Study Day 96)	COVID-19
Morphine	11 Nov 2020 (Study Day 94) - 11 Nov 2020 (Study Day 94)	COVID-19
Paracetamol	11 Nov 2020 (Study Day 94) - Ongoing	COVID-19
Paracetamol	11 Nov 2020 (Study Day 94) - 13 Nov 2020 (Study Day 96)	COVID-19
Naproxen sodium	13 Nov 2020 (Study Day 96) - Ongoing	COVID-19
Ramipril	13 Jan 2021 (Study Day 157) - Ongoing	Hypertension
Verapamil	13 Jan 2021 (Study Day 157) - Ongoing	Intractable Headache
Docusate sodium	22 Jan 2021 (Study Day 166) - 02 Feb 2021 (Study Day 177)	Prevention Of Constipation
Hydromorphone	22 Jan 2021 (Study Day 166) - 22 Jan 2021 (Study Day 166)	Pain Prevention
Ketorolac	22 Jan 2021 (Study Day 166) - 22 Jan 2021 (Study Day 166)	Pain Prevention
Metoclopramide	22 Jan 2021 (Study Day 166) - 22 Jan 2021 (Study Day 166)	Prevention Of Nausea Related To Anesthesia
Midazolam	22 Jan 2021 (Study Day 166) - 22 Jan 2021 (Study Day 166)	Prevention Of Anxiety Related To Procedure
Ondansetron hydrochloride	22 Jan 2021 (Study Day 166) - 22 Jan 2021 (Study Day 166)	Prevention Of Anesthesia Related Nausea
Oxycodone	22 Jan 2021 (Study Day 166) - 02 Feb 2021 (Study Day 177)	Post Procedural Pain
Paracetamol	22 Jan 2021 (Study Day 166) - 22 Jan 2021 (Study Day 166)	Post Procedure Pain
Paracetamol	22 Jan 2021 (Study Day 166) - 02 Feb 2021 (Study Day 177)	Post Procedure Pain
Robotic assisted laparoscopic left retroperitoneal partial nephrectomy*	22 Jan 2021 (Study Day 166) - 22 Jan 2021 (Study Day 166)	Medical History
Sodium chloride	22 Jan 2021 (Study Day 166) - 23 Jan 2021 (Study Day 167)	Prevention Of Fluid Imbalance
Insulin	23 Jan 2021 (Study Day 167) - 23 Jan 2021 (Study Day 167)	Type Ii Diabetes Mellitus
Oxycodone	23 Jan 2021 (Study Day 167) - 23 Jan 2021 (Study Day 167)	Post Procedure Pain
Cannabidiol	22 Feb 2021 (Study Day 197) - Ongoing	Chronic Pain Prevention
Cannabis sativa	22 Feb 2021 (Study Day 197) - Ongoing	Chronic Pain Prevention
Colecalciferol	Mar 2021 - Ongoing	Bone Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chest Discomfort	Grade 1/mild	Not related	02 Oct 2020 (Study Day 54) - 09 Oct 2020 (Study Day 61)
Cough	Grade 1/mild	Not related	02 Oct 2020 (Study Day 54) - 11 Oct 2020 (Study Day 63)
Headache	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 155) - Ongoing
Hypertension	Grade 2/moderate	Not related	19 Jan 2021 (Study Day 163) - Ongoing
Procedural Pain	Grade 2/moderate	Not related	22 Jan 2021 (Study Day 166) - 02 Feb 2021 (Study Day 177)
Rhonchi	Grade 1/mild	Not related	09 Mar 2021 (Study Day 212) - 07 Apr 2021 (Study Day 241)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2162 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	17 Oct 2020 (Study Day 60) – 02 Nov 2020 (Study Day 76)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US375-2162, a 70-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 17 Oct 2020 (Study Day 60), 59 days after the first dose and 31 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 16 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 27 Oct 2020 (Study Day 70), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
17 Oct 2020 (Study Day 60)	Body Aches	Moderate
17 Oct 2020 (Study Day 60)	Cough	Moderate
17 Oct 2020 (Study Day 60)	Headache	Moderate
18 Oct 2020 (Study Day 61)	Fatigue	Severe
18 Oct 2020 (Study Day 61)	O2 Saturation (%)	88
19 Oct 2020 (Study Day 62)	Body Aches	Mild

Symptom Date	Symptom	Result
19 Oct 2020 (Study Day 62)	Cough	Mild
19 Oct 2020 (Study Day 62)	Fatigue	Moderate
19 Oct 2020 (Study Day 62)	Muscle Aches (Myalgia)	Mild
20 Oct 2020 (Study Day 63)	Cough	Moderate
20 Oct 2020 (Study Day 63)	Fatigue	Moderate
20 Oct 2020 (Study Day 63)	Shortness of Breath	Mild
21 Oct 2020 (Study Day 64)	Cough	Mild
21 Oct 2020 (Study Day 64)	Fatigue	Moderate
21 Oct 2020 (Study Day 64)	Runny Nose (Rhinorrhea)	Mild
21 Oct 2020 (Study Day 64)	Shortness of Breath	Mild
22 Oct 2020 (Study Day 65)	Cough	Mild
22 Oct 2020 (Study Day 65)	Fatigue	Moderate
22 Oct 2020 (Study Day 65)	New Loss of Smell	Severe
22 Oct 2020 (Study Day 65)	New Loss of Taste	Severe
22 Oct 2020 (Study Day 65)	Runny Nose (Rhinorrhea)	Mild
23 Oct 2020 (Study Day 66)	Cough	Mild
23 Oct 2020 (Study Day 66)	Fatigue	Moderate
23 Oct 2020 (Study Day 66)	New Loss of Smell	Moderate
23 Oct 2020 (Study Day 66)	New Loss of Taste	Moderate
24 Oct 2020 (Study Day 67)	Chills	Mild
24 Oct 2020 (Study Day 67)	Cough	Moderate
24 Oct 2020 (Study Day 67)	Diarrhea	Mild
24 Oct 2020 (Study Day 67)	Fatigue	Moderate
25 Oct 2020 (Study Day 68)	Chills	Mild
25 Oct 2020 (Study Day 68)	Cough	Mild
25 Oct 2020 (Study Day 68)	Fatigue	Moderate
26 Oct 2020 (Study Day 69)	Cough	Mild
26 Oct 2020 (Study Day 69)	Fatigue	Moderate
27 Oct 2020 (Study Day 70)	Cough	Mild
27 Oct 2020 (Study Day 70)	Fatigue	Moderate
28 Oct 2020 (Study Day 71)	Cough	Mild
28 Oct 2020 (Study Day 71)	Fatigue	Moderate
29 Oct 2020 (Study Day 72)	Cough	Mild
29 Oct 2020 (Study Day 72)	Fatigue	Moderate
30 Oct 2020 (Study Day 73)	Cough	Mild
30 Oct 2020 (Study Day 73)	Fatigue	Mild
31 Oct 2020 (Study Day 74)	Cough	Mild
31 Oct 2020 (Study Day 74)	Fatigue	Mild
01 Nov 2020 (Study Day 75)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
18 Oct 2020 (Study Day 61)	Oxygen Saturation	88%
18 Oct 2020 - 18 Oct 2020 (Study Day 61-61)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 02 Nov 2020 (Study Day 76). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000586	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rotator cuff repair	Rotator cuff repair	Not reported
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Vasectomy	Vasectomy	Not reported
Hypertriglyceridaemia	Hypertriglyceridemia	1976 - Ongoing
Colonoscopy	Colonoscopy (underlying condition unknown)	1985 - 1985
Corrective lens user	Wears glasses (unknown diagnosis)	1990 - Ongoing
Gastrooesophageal reflux disease	Gerd/reflux	1990 - Ongoing
Visual impairment	Vision disturbance: (unknown diagnosis)	1990 - Ongoing
Asthma	Asthma	2000 - Ongoing
Cholecystectomy	Cholecystectomy (associated condition unknown)	2013 - 2013
Back pain	Low back pain	2015 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder without hyperactivity	13 Oct 2017 (Study Day -1041) - Ongoing
Cataract	Bilateral cataracts	2018 - 2018
Cataract operation	Bilateral cataract surgery	2018 - 2018

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gilbert's syndrome	Gilbert's syndrome	16 May 2018 (Study Day -826) - Ongoing
Vertigo	Vertigo	2019 - Ongoing
Prostatomegaly	Prostate enlargement	2020 - Ongoing
Skin lesion removal	Skin cancer removal right hand (unknown if benign or malignant)	2020 - 2020
Atrial fibrillation	Paroxysmal atrial fibrillation	16 May 2020 (Study Day -95) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin	Feb 2020 - Ongoing	Prostate Enlargement
Mri lumbar w/o contrast*	02 Sep 2020 (Study Day 15) - 02 Sep 2020 (Study Day 15)	Diagnostic
Lumbar f/e x-ray*	30 Sep 2020 (Study Day 43) - 30 Sep 2020 (Study Day 43)	Diagnostic
Cefalexin	15 Oct 2020 (Study Day 58) - 17 Oct 2020 (Study Day 60)	Post Op Medication After Hemilaminectomy
Docusate	15 Oct 2020 (Study Day 58) - Ongoing	Constipation Prophylaxis After Surgery
Hydrocodone	15 Oct 2020 (Study Day 58) - 23 Oct 2020 (Study Day 66)	Treatment Of Post-Operative Pain From Laminectomy
Ibuprofen	15 Oct 2020 (Study Day 58) - Ongoing	Post Op Pain After Hemilaminectomy
L5 s1 discectomy with right lateral hemilaminectomy*	15 Oct 2020 (Study Day 58) - 15 Oct 2020 (Study Day 58)	Medical History
Loratadine	15 Oct 2020 (Study Day 58) - Ongoing	Seasonal Allergies
Methocarbamol	15 Oct 2020 (Study Day 58) - Ongoing	Post Op Medication After Hemilaminectomy
Methocarbamol	15 Oct 2020 (Study Day 58) - 23 Oct 2020 (Study Day 66)	Treat Post-Operative Pain
Paracetamol	17 Oct 2020 (Study Day 60) - 31 Oct 2020 (Study Day 74)	Treatment Of Symptoms Related To COVID-19
Acetylsalicylic acid	20 Oct 2020 (Study Day 63) - 23 Oct 2020 (Study Day 66)	Prophylaxis For Deep Venous Thrombosis Following Laminectomy
Diphenhydramine; paracetamol	20 Oct 2020 (Study Day 63) - 20 Oct 2020 (Study Day 63)	Treatment Of Symptoms Related COVID-19/Sleep Aid
Famotidine	20 Oct 2020 (Study Day 63) - 05 Nov 2020 (Study Day 79)	Shorten Duration/Decrease Severity Of Symptoms Related To COVID-19
Zinc acetate; zinc gluconate	22 Oct 2020 (Study Day 65) - 05 Nov 2020 (Study Day 79)	Shorten Duration Of COVID Symptoms
Ascorbic acid	28 Oct 2020 (Study Day 71) - 05 Nov 2020 (Study Day 79)	Treatment Of Symptoms Related To COVID-19
Vitamin d nos	28 Oct 2020 (Study Day 71) - 05 Nov 2020 (Study Day 79)	Treatment Of Symptoms Related To COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clindamycin	04 Jan 2021 (Study Day 139) - 14 Jan 2021 (Study Day 149)	Insect Bites Right Lower Extremities
Bupropion hydrochloride	24 Mar 2021 (Study Day 218) - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Foot Fracture	Grade 2/moderate	Not related	16 Sep 2020 (Study Day 29) - 01 Dec 2020 (Study Day 105)
Road Traffic Accident	Grade 2/moderate	Not related	16 Sep 2020 (Study Day 29) - 16 Sep 2020 (Study Day 29)
Pulmonary Contusion	Grade 2/moderate	Not related	16 Sep 2020 (Study Day 29) - 26 Nov 2020 (Study Day 100)
Back Pain	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 58) - 15 Oct 2020 (Study Day 58)
COVID-19	Grade 2/moderate	Not related	17 Oct 2020 (Study Day 60) - 02 Nov 2020 (Study Day 76)
Arthropod Bite	Grade 1/mild	Not related	18 Nov 2020 (Study Day 92) - Ongoing
Depression	Grade 2/moderate	Not related	17 Mar 2021 (Study Day 211) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2229 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID 19	COVID-19	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 61) – 12 Nov 2020 (Study Day 81)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US375-2229, a 45-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 23 Oct 2020 (Study Day 61), 60 days after the first dose and 32 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 27 Oct 2020 (Study Day 65), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
23 Oct 2020 (Study Day 61)	Sore Throat	Mild
24 Oct 2020 (Study Day 62)	Body Aches	Moderate
24 Oct 2020 (Study Day 62)	Cough	Moderate
24 Oct 2020 (Study Day 62)	Headache	Moderate
25 Oct 2020 (Study Day 63)	Body Aches	Moderate

Symptom Date	Symptom	Result
25 Oct 2020 (Study Day 63)	Cough	Moderate
25 Oct 2020 (Study Day 63)	Headache	Moderate
26 Oct 2020 (Study Day 64)	Body Aches	Moderate
26 Oct 2020 (Study Day 64)	Cough	Moderate
26 Oct 2020 (Study Day 64)	Headache	Moderate
27 Oct 2020 (Study Day 65)	Body Aches	Moderate
27 Oct 2020 (Study Day 65)	Cough	Moderate
27 Oct 2020 (Study Day 65)	Headache	Moderate
28 Oct 2020 (Study Day 66)	Body Aches	Moderate
28 Oct 2020 (Study Day 66)	Cough	Moderate
28 Oct 2020 (Study Day 66)	Fatigue	Moderate
28 Oct 2020 (Study Day 66)	Headache	Moderate
28 Oct 2020 (Study Day 66)	Muscle Aches (Myalgia)	Moderate
28 Oct 2020 (Study Day 66)	Nasal Congestion	Moderate
28 Oct 2020 (Study Day 66)	Nausea	Mild
28 Oct 2020 (Study Day 66)	New Loss of Smell	Severe
28 Oct 2020 (Study Day 66)	New Loss of Taste	Severe
28 Oct 2020 (Study Day 66)	Sore Throat	Moderate
28 Oct 2020 (Study Day 66)	Temperature (°F)	101.9
29 Oct 2020 (Study Day 67)	Body Aches	Mild
29 Oct 2020 (Study Day 67)	Cough	Mild
29 Oct 2020 (Study Day 67)	Fatigue	Moderate
29 Oct 2020 (Study Day 67)	Headache	Mild
29 Oct 2020 (Study Day 67)	Muscle Aches (Myalgia)	Mild
29 Oct 2020 (Study Day 67)	New Loss of Smell	Severe
29 Oct 2020 (Study Day 67)	New Loss of Taste	Severe
29 Oct 2020 (Study Day 67)	Temperature (°F)	102.0
30 Oct 2020 (Study Day 68)	Cough	Moderate
30 Oct 2020 (Study Day 68)	Fatigue	Moderate
30 Oct 2020 (Study Day 68)	Headache	Moderate
30 Oct 2020 (Study Day 68)	Nausea	Mild
30 Oct 2020 (Study Day 68)	New Loss of Smell	Severe
30 Oct 2020 (Study Day 68)	New Loss of Taste	Severe
30 Oct 2020 (Study Day 68)	Runny Nose (Rhinorrhea)	Mild
30 Oct 2020 (Study Day 68)	Temperature (°F)	101.2
31 Oct 2020 (Study Day 69)	Cough	Mild
31 Oct 2020 (Study Day 69)	Fatigue	Moderate
31 Oct 2020 (Study Day 69)	Headache	Mild
31 Oct 2020 (Study Day 69)	Nausea	Mild
31 Oct 2020 (Study Day 69)	New Loss of Smell	Severe
31 Oct 2020 (Study Day 69)	New Loss of Taste	Severe
31 Oct 2020 (Study Day 69)	Temperature (°F)	100.4
01 Nov 2020 (Study Day 70)	Cough	Mild

Symptom Date	Symptom	Result
01 Nov 2020 (Study Day 70)	Fatigue	Mild
01 Nov 2020 (Study Day 70)	Nausea	Mild
01 Nov 2020 (Study Day 70)	New Loss of Smell	Severe
01 Nov 2020 (Study Day 70)	New Loss of Taste	Severe
01 Nov 2020 (Study Day 70)	Temperature (°F)	100.4
01 Nov 2020 (Study Day 70)	Vomiting	Mild
02 Nov 2020 (Study Day 71)	Body Aches	Moderate
02 Nov 2020 (Study Day 71)	Chills	Moderate
02 Nov 2020 (Study Day 71)	Cough	Moderate
02 Nov 2020 (Study Day 71)	Fatigue	Moderate
02 Nov 2020 (Study Day 71)	Headache	Moderate
02 Nov 2020 (Study Day 71)	Muscle Aches (Myalgia)	Moderate
02 Nov 2020 (Study Day 71)	Nasal Congestion	Moderate
02 Nov 2020 (Study Day 71)	Nausea	Mild
02 Nov 2020 (Study Day 71)	New Loss of Smell	Severe
02 Nov 2020 (Study Day 71)	New Loss of Taste	Severe
02 Nov 2020 (Study Day 71)	O2 Saturation (%)	92
02 Nov 2020 (Study Day 71)	Sore Throat	Moderate
02 Nov 2020 (Study Day 71)	Temperature (°F)	102.0
03 Nov 2020 (Study Day 72)	Cough	Mild
03 Nov 2020 (Study Day 72)	Fatigue	Moderate
03 Nov 2020 (Study Day 72)	Headache	Moderate
03 Nov 2020 (Study Day 72)	Nasal Congestion	Mild
03 Nov 2020 (Study Day 72)	Nausea	Mild
03 Nov 2020 (Study Day 72)	New Loss of Smell	Severe
03 Nov 2020 (Study Day 72)	New Loss of Taste	Severe
03 Nov 2020 (Study Day 72)	Runny Nose (Rhinorrhea)	Mild
03 Nov 2020 (Study Day 72)	Sore Throat	Mild
03 Nov 2020 (Study Day 72)	Vomiting	Mild
04 Nov 2020 (Study Day 73)	Cough	Mild
04 Nov 2020 (Study Day 73)	Fatigue	Mild
04 Nov 2020 (Study Day 73)	Headache	Moderate
04 Nov 2020 (Study Day 73)	Nasal Congestion	Mild
04 Nov 2020 (Study Day 73)	New Loss of Smell	Severe
04 Nov 2020 (Study Day 73)	New Loss of Taste	Severe
05 Nov 2020 (Study Day 74)	Cough	Moderate
05 Nov 2020 (Study Day 74)	Fatigue	Mild
05 Nov 2020 (Study Day 74)	New Loss of Smell	Severe
05 Nov 2020 (Study Day 74)	New Loss of Taste	Severe
06 Nov 2020 (Study Day 75)	Cough	Mild
06 Nov 2020 (Study Day 75)	New Loss of Smell	Severe
06 Nov 2020 (Study Day 75)	New Loss of Taste	Severe
07 Nov 2020 (Study Day 76)	Cough	Mild

Symptom Date	Symptom	Result
07 Nov 2020 (Study Day 76)	Headache	Mild
07 Nov 2020 (Study Day 76)	New Loss of Smell	Severe
07 Nov 2020 (Study Day 76)	New Loss of Taste	Severe
08 Nov 2020 (Study Day 77)	Cough	Mild
08 Nov 2020 (Study Day 77)	Headache	Moderate
08 Nov 2020 (Study Day 77)	New Loss of Smell	Moderate
08 Nov 2020 (Study Day 77)	New Loss of Taste	Moderate
09 Nov 2020 (Study Day 78)	Cough	Mild
09 Nov 2020 (Study Day 78)	New Loss of Smell	Moderate
09 Nov 2020 (Study Day 78)	New Loss of Taste	Moderate
10 Nov 2020 (Study Day 79)	Fatigue	Mild
11 Nov 2020 (Study Day 80)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
02 Nov 2020 (Study Day 71)	Oxygen Saturation	92%
02 Nov 2020 - 02 Nov 2020 (Study Day 71-71)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID 19 lasted for 21 days, after which it was considered to be recovered/resolved on 12 Nov 2020 (Study Day 81). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000590	COVID-19

Study Completion/Discontinuation

On 22 Dec 2020 (Study Day 121), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tinnitus	Tinnitus	Not reported - Ongoing
Drug hypersensitivity	Penicillin allergy	1979 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	1985 - 1985
Appendicitis	Appendicitis	1985 - 1985
Headache	Headaches	1990 - Ongoing
Caesarean section	Cesarean section	2000 - 2000
Cholecystectomy	Cholecystectomy (unknown associated condition)	2000 - 2000
Cholelithiasis	Gallstones	2000 - 2000
Anxiety	Anxiety/panic attacks	2002 - Ongoing
Hyperthyroidism	Hyperthyroidism	2003 - Not reported
Gastric banding	Intestinal surgery consisting of lap band procedure	2004 - 2004
Obesity	Obesity	2004 - 2004
Caesarean section	Cesarean section	2005 - 2005
Hypertension	Hypertension	2005 - Ongoing
Osteoarthritis	Osteoarthritis with back pain	Jul 2006 - Ongoing
Anaemia	Anemia	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Carpal tunnel decompression	Carpal tunnel release right	2013 - 2013
Carpal tunnel syndrome	Carpal tunnel syndrome (r)	2013 - 2013
Hysterectomy	Hysterectomy (unknown associated condition)	2013 - 2013
Urinary incontinence	Urinary incontinence	2013 - Ongoing
Uterine haemorrhage	Severe uterine bleeding	2013 - 2013
Gastrooesophageal reflux disease	Gerd/reflux	2018 - Ongoing
Adhesiolysis	Lysis of adhesions laparotomy (unknown associated condition)	2019 - 2019
Arrhythmia	Cardiac arrhythmia (unknown type)	2019 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2020 - Ongoing
Insomnia	Insomnia	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	2002 - Ongoing	Anxiety
Gabapentin	2006 - Ongoing	Back Pain
Hydrochlorothiazide; olmesartan	2006 - Ongoing	Hypertension
Hydrocodone	2006 - Ongoing	Back Pain
Metaxalone	2016 - Ongoing	Back Pain
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	2020 - Ongoing	Attention Deficit Disorder
Amitriptyline	Jan 2020 - Ongoing	Insomnia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	Jan 2020 - Ongoing	Hypertension
Ibuprofen	02 Oct 2020 (Study Day 40) - 02 Oct 2020 (Study Day 40)	Headache
Ibuprofen	26 Oct 2020 (Study Day 64) - 12 Nov 2020 (Study Day 81)	Symptomatic COVID 19
Azithromycin	02 Nov 2020 (Study Day 71) - 06 Nov 2020 (Study Day 75)	Symptomatic COVID 19
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	02 Nov 2020 (Study Day 71) - 09 Nov 2020 (Study Day 78)	Symptomatic COVID19
Benzonatate	05 Nov 2020 (Study Day 74) - 10 Nov 2020 (Study Day 79)	Symptomatic COVID-19
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	05 Nov 2020 (Study Day 74) - 09 Nov 2020 (Study Day 78)	Symptomatic COVID-19
Other viral vaccines	16 Dec 2020 (Study Day 115) - 16 Dec 2020 (Study Day 115)	COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	28 Aug 2020 (Study Day 5) - 01 Sep 2020 (Study Day 9)
COVID-19	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 61) - 12 Nov 2020 (Study Day 81)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US377-2035 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 36)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 1/mild	Not related	13 Nov 2020 (Study Day 96) – 19 Dec 2020 (Study Day 132)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US377-2035, a 32-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 13 Nov 2020 (Study Day 96), 95 days after the first dose and 60 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 36, 14 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 16 Nov 2020 (Study Day 99), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
16 Nov 2020 (Study Day 99)	Body Aches	Mild
16 Nov 2020 (Study Day 99)	Cough	Mild
16 Nov 2020 (Study Day 99)	Fatigue	Mild
16 Nov 2020 (Study Day 99)	Headache	Mild
16 Nov 2020 (Study Day 99)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
16 Nov 2020 (Study Day 99)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 99)	Nausea	Mild
16 Nov 2020 (Study Day 99)	Runny Nose (Rhinorrhea)	Mild
16 Nov 2020 (Study Day 99)	Sore Throat	Mild
18 Nov 2020 (Study Day 101)	Fatigue	Moderate
18 Nov 2020 (Study Day 101)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 101)	New Loss of Smell	Mild
18 Nov 2020 (Study Day 101)	New Loss of Taste	Mild
18 Nov 2020 (Study Day 101)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 102)	Body Aches	Mild
19 Nov 2020 (Study Day 102)	Cough	Mild
19 Nov 2020 (Study Day 102)	Headache	Mild
19 Nov 2020 (Study Day 102)	Muscle Aches (Myalgia)	Mild
19 Nov 2020 (Study Day 102)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 102)	New Loss of Smell	Moderate
19 Nov 2020 (Study Day 102)	Runny Nose (Rhinorrhea)	Mild
20 Nov 2020 (Study Day 103)	Cough	Mild
20 Nov 2020 (Study Day 103)	Fatigue	Mild
20 Nov 2020 (Study Day 103)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 103)	New Loss of Smell	Moderate
20 Nov 2020 (Study Day 103)	New Loss of Taste	Moderate
20 Nov 2020 (Study Day 103)	Runny Nose (Rhinorrhea)	Mild
21 Nov 2020 (Study Day 104)	Cough	Mild
21 Nov 2020 (Study Day 104)	Fatigue	Mild
21 Nov 2020 (Study Day 104)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 104)	New Loss of Smell	Moderate
21 Nov 2020 (Study Day 104)	New Loss of Taste	Moderate
21 Nov 2020 (Study Day 104)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 105)	Cough	Mild
22 Nov 2020 (Study Day 105)	Fatigue	Moderate
22 Nov 2020 (Study Day 105)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 105)	New Loss of Smell	Severe
22 Nov 2020 (Study Day 105)	New Loss of Taste	Severe
22 Nov 2020 (Study Day 105)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 105)	Shortness of Breath	Moderate
23 Nov 2020 (Study Day 106)	Cough	Mild
23 Nov 2020 (Study Day 106)	Fatigue	Mild
23 Nov 2020 (Study Day 106)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 106)	New Loss of Smell	Mild
23 Nov 2020 (Study Day 106)	New Loss of Taste	Mild
24 Nov 2020 (Study Day 107)	Fatigue	Mild
24 Nov 2020 (Study Day 107)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 107)	New Loss of Smell	Moderate

Symptom Date	Symptom	Result
24 Nov 2020 (Study Day 107)	New Loss of Taste	Moderate
24 Nov 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
25 Nov 2020 (Study Day 108)	Fatigue	Mild
25 Nov 2020 (Study Day 108)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 108)	New Loss of Smell	Moderate
25 Nov 2020 (Study Day 108)	New Loss of Taste	Moderate
25 Nov 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Mild
26 Nov 2020 (Study Day 109)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 109)	New Loss of Smell	Mild
26 Nov 2020 (Study Day 109)	New Loss of Taste	Mild
26 Nov 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
27 Nov 2020 (Study Day 110)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 110)	New Loss of Smell	Moderate
27 Nov 2020 (Study Day 110)	New Loss of Taste	Moderate
27 Nov 2020 (Study Day 110)	Runny Nose (Rhinorrhea)	Mild
28 Nov 2020 (Study Day 111)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 111)	New Loss of Smell	Mild
28 Nov 2020 (Study Day 111)	New Loss of Taste	Mild
29 Nov 2020 (Study Day 112)	New Loss of Smell	Mild
29 Nov 2020 (Study Day 112)	New Loss of Taste	Mild
30 Nov 2020 (Study Day 113)	Diarrhea	Mild
30 Nov 2020 (Study Day 113)	Nausea	Mild
30 Nov 2020 (Study Day 113)	New Loss of Smell	Mild
30 Nov 2020 (Study Day 113)	New Loss of Taste	Mild
30 Nov 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 113)	Sore Throat	Mild
30 Nov 2020 (Study Day 113)	Vomiting	Mild
01 Dec 2020 (Study Day 114)	New Loss of Smell	Mild
01 Dec 2020 (Study Day 114)	New Loss of Taste	Mild
12 Dec 2020 (Study Day 125)	New Loss of Smell	Mild
12 Dec 2020 (Study Day 125)	New Loss of Taste	Mild
13 Dec 2020 (Study Day 126)	New Loss of Smell	Mild
13 Dec 2020 (Study Day 126)	New Loss of Taste	Mild
14 Dec 2020 (Study Day 127)	New Loss of Smell	Mild
14 Dec 2020 (Study Day 127)	New Loss of Taste	Mild
15 Dec 2020 (Study Day 128)	New Loss of Smell	Mild
15 Dec 2020 (Study Day 128)	New Loss of Taste	Mild

The participant had no reported indications of severe COVID-19 infection.

Action taken with the IP was not applicable. The event of COVID-19 lasted for 37 days, after which it was considered to be recovered/resolved on 19 Dec 2020 (Study Day 132). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000925	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2018 - Ongoing
Erectile dysfunction	Erectile dysfuntion	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2018 - 25 Sep 2020 (Study Day 47)	Cardiac Prophylaxis
Bupropion hydrochloride	2018 - Ongoing	Depression
Citalopram hydrobromide	2018 - Ongoing	Depression
Anastrozole	2020 - Ongoing	Erectile Dysfunction
Chorionic gonadotrophin	2020 - Ongoing	Erectile Dysfunction
Testosterone	2020 - Ongoing	Erectile Dysfuntion
Atorvastatin	24 Aug 2020 (Study Day 15) - Ongoing	Hyperlipidemia
Influenza vaccine	12 Nov 2020 (Study Day 95) - 12 Nov 2020 (Study Day 95)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Grade 1/mild	Not related	24 Aug 2020 (Study Day 15) - Ongoing
COVID-19	Grade 1/mild	Not related	13 Nov 2020 (Study Day 96) - 19 Dec 2020 (Study Day 132)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US377-2037 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	06 Nov 2020 (Study Day 88) – 20 Nov 2020 (Study Day 102)	Recovered/resolved
Acute Respiratory Failure/Acute Hypoxic Respiratory Failure Due To COVID-19 Infection	SAE	Grade 4	Not related	08 Nov 2020 (Study Day 90) – 12 Nov 2020 (Study Day 94)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US377-2037, a 72-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 06 Nov 2020 (Study Day 88), 87 days after the first dose and 59 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On 08 Nov 2020 (Study Day 90), 89 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute hypoxic respiratory failure due to COVID-19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 06 Nov 2020 (Study Day 88), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
07 Nov 2020 (Study Day 89)	Cough	Mild
07 Nov 2020 (Study Day 89)	Diarrhea	Mild
07 Nov 2020 (Study Day 89)	Nausea	Mild
07 Nov 2020 (Study Day 89)	Runny Nose (Rhinorrhea)	Mild
07 Nov 2020 (Study Day 89)	Sore Throat	Mild
07 Nov 2020 (Study Day 89)	Vomiting	Mild
13 Nov 2020 (Study Day 95)	Cough	Mild
13 Nov 2020 (Study Day 95)	Diarrhea	Mild
13 Nov 2020 (Study Day 95)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 95)	Runny Nose (Rhinorrhea)	Mild
13 Nov 2020 (Study Day 95)	Sore Throat	Mild
14 Nov 2020 (Study Day 96)	Cough	Mild
16 Nov 2020 (Study Day 98)	Cough	Mild
16 Nov 2020 (Study Day 98)	Difficulty Breathing	Mild
17 Nov 2020 (Study Day 99)	Sore Throat	Mild
18 Nov 2020 (Study Day 100)	Difficulty Breathing	Mild
18 Nov 2020 (Study Day 100)	O2 Saturation (%)	91
19 Nov 2020 (Study Day 101)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
07 Nov 2020 (Study Day 89)	Oxygen Saturation	88%
07 Nov 2020 - 12 Nov 2020 (Study Day 89-94)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
08 Nov 2020 - 10 Nov 2020 (Study Day 90-92)	High-Flow Oxygen	Yes
08 Nov 2020 - 08 Nov 2020 (Study Day 90-90)	Respiratory Failure	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 20 Nov 2020 (Study Day 102). The investigator assessed the event of COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of acute hypoxic respiratory failure due to COVID-19 infection lasted for 5 days, after which it was considered to be recovered/resolved on 12 Nov 2020 (Study Day 94). The investigator assessed the event of acute respiratory failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000699	COVID-19
MOD-2020-000699	Acute respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Endometriosis	Endometriosis	1975 - 1992
Hysterectomy	Complete hysterectomy	1992 - 1992
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Hypokalaemia	Hypokalemia	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Ankle fracture	Right ankle fracture	19 Sep 2012 (Study Day -2883) - 19 Sep 2012 (Study Day -2883)
Peripheral sensory neuropathy	Nueropathy (due to right ankle fracture) (sensory)	2014 - Ongoing
Asthma	Asthma (moderate)	2015 - Ongoing
Botulinum toxin injection	Cosmetic botox facial injection	Mar 2017 - Mar 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2010 - Ongoing	Hypertension
Hydrochlorothiazide	2010 - Ongoing	Hypertension
Levothyroxine	2010 - Ongoing	Hypothyroidism
Potassium chloride	2010 - Ongoing	Kypokalemia
Rosuvastatin	2010 - Ongoing	Hyperlipidemia
Gabapentin	2014 - Ongoing	Neuropathy (Right Ankle)
Budesonide; formoterol fumarate	2015 - Ongoing	Asthma
Paracetamol	13 Aug 2020 (Study Day 3) - 13 Aug 2020 (Study Day 3)	Pain At Injection Site

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	27 Oct 2020 (Study Day 78) - 27 Oct 2020 (Study Day 78)	Influenza Prophylaxis
Cefdinir	05 Nov 2020 (Study Day 87) - 07 Nov 2020 (Study Day 89)	Sinusitis
Ibuprofen	05 Nov 2020 (Study Day 87) - 05 Nov 2020 (Study Day 87)	Sinusitis
Dexamethasone	07 Nov 2020 (Study Day 89) - 12 Nov 2020 (Study Day 94)	COVID-19
Ipratropium bromide; salbutamol sulfate	07 Nov 2020 (Study Day 89) - 07 Nov 2020 (Study Day 89)	COVID-19
Oxygen	08 Nov 2020 (Study Day 90) - 10 Nov 2020 (Study Day 92)	COVID-19
Dexamethasone	13 Nov 2020 (Study Day 95) - 16 Nov 2020 (Study Day 98)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Sinusitis	Grade 2/moderate	Not related	04 Nov 2020 (Study Day 86) - 09 Nov 2020 (Study Day 91)
COVID-19	Grade 2/moderate	Not related	06 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 102)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US377-2159 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 30)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	COVID-19	Grade 1/mild	Not related	03 Dec 2020 (Study Day 99) – 31 Dec 2020 (Study Day 127)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US377-2159, a 76-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 03 Dec 2020 (Study Day 99), 98 days after the first dose and 69 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 25 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 03 Dec 2020 (Study Day 99), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 99)	Body Aches	Mild
03 Dec 2020 (Study Day 99)	Cough	Mild
03 Dec 2020 (Study Day 99)	Headache	Mild
03 Dec 2020 (Study Day 99)	Muscle Aches (Myalgia)	Mild
03 Dec 2020 (Study Day 99)	Nausea	Mild

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 99)	Sore Throat	Mild
04 Dec 2020 (Study Day 100)	Body Aches	Mild
04 Dec 2020 (Study Day 100)	Cough	Mild
04 Dec 2020 (Study Day 100)	Headache	Mild
04 Dec 2020 (Study Day 100)	Muscle Aches (Myalgia)	Mild
04 Dec 2020 (Study Day 100)	Nausea	Mild
04 Dec 2020 (Study Day 100)	Sore Throat	Mild
05 Dec 2020 (Study Day 101)	Body Aches	Mild
05 Dec 2020 (Study Day 101)	Cough	Mild
05 Dec 2020 (Study Day 101)	Muscle Aches (Myalgia)	Mild
05 Dec 2020 (Study Day 101)	Temperature (°F)	100.6
06 Dec 2020 (Study Day 102)	Body Aches	Mild
06 Dec 2020 (Study Day 102)	Cough	Mild
06 Dec 2020 (Study Day 102)	Muscle Aches (Myalgia)	Mild
07 Dec 2020 (Study Day 103)	Body Aches	Mild
07 Dec 2020 (Study Day 103)	Cough	Mild
07 Dec 2020 (Study Day 103)	Difficulty Breathing	Mild
07 Dec 2020 (Study Day 103)	Muscle Aches (Myalgia)	Mild
08 Dec 2020 (Study Day 104)	Body Aches	Mild
08 Dec 2020 (Study Day 104)	Cough	Moderate
08 Dec 2020 (Study Day 104)	Difficulty Breathing	Mild
08 Dec 2020 (Study Day 104)	Muscle Aches (Myalgia)	Mild
08 Dec 2020 (Study Day 104)	O2 Saturation (%)	93
09 Dec 2020 (Study Day 105)	Body Aches	Mild
09 Dec 2020 (Study Day 105)	Cough	Moderate
09 Dec 2020 (Study Day 105)	Difficulty Breathing	Mild
09 Dec 2020 (Study Day 105)	Muscle Aches (Myalgia)	Mild
09 Dec 2020 (Study Day 105)	O2 Saturation (%)	90
10 Dec 2020 (Study Day 106)	Body Aches	Mild
10 Dec 2020 (Study Day 106)	Cough	Moderate
10 Dec 2020 (Study Day 106)	Difficulty Breathing	Mild
10 Dec 2020 (Study Day 106)	Headache	Mild
10 Dec 2020 (Study Day 106)	Muscle Aches (Myalgia)	Mild
10 Dec 2020 (Study Day 106)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 106)	New Loss of Smell	Mild
10 Dec 2020 (Study Day 106)	New Loss of Taste	Mild
10 Dec 2020 (Study Day 106)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 107)	Body Aches	Mild
11 Dec 2020 (Study Day 107)	Cough	Mild
11 Dec 2020 (Study Day 107)	Difficulty Breathing	Mild
11 Dec 2020 (Study Day 107)	Headache	Mild
11 Dec 2020 (Study Day 107)	Muscle Aches (Myalgia)	Mild
11 Dec 2020 (Study Day 107)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 107)	New Loss of Smell	Mild
11 Dec 2020 (Study Day 107)	New Loss of Taste	Mild
11 Dec 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
13 Dec 2020 (Study Day 109)	Body Aches	Mild
13 Dec 2020 (Study Day 109)	Cough	Mild
13 Dec 2020 (Study Day 109)	Difficulty Breathing	Mild
13 Dec 2020 (Study Day 109)	Muscle Aches (Myalgia)	Mild
13 Dec 2020 (Study Day 109)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 109)	New Loss of Smell	Mild
13 Dec 2020 (Study Day 109)	New Loss of Taste	Mild
13 Dec 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
14 Dec 2020 (Study Day 110)	Body Aches	Mild
14 Dec 2020 (Study Day 110)	Cough	Mild
14 Dec 2020 (Study Day 110)	Difficulty Breathing	Moderate
14 Dec 2020 (Study Day 110)	Muscle Aches (Myalgia)	Mild
14 Dec 2020 (Study Day 110)	Nasal Congestion	Moderate
14 Dec 2020 (Study Day 110)	Runny Nose (Rhinorrhea)	Mild
15 Dec 2020 (Study Day 111)	Cough	Mild
15 Dec 2020 (Study Day 111)	Difficulty Breathing	Mild
15 Dec 2020 (Study Day 111)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 111)	Runny Nose (Rhinorrhea)	Mild
16 Dec 2020 (Study Day 112)	Cough	Mild
16 Dec 2020 (Study Day 112)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 112)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 112)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 113)	Cough	Mild
17 Dec 2020 (Study Day 113)	Difficulty Breathing	Mild
17 Dec 2020 (Study Day 113)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
18 Dec 2020 (Study Day 114)	Cough	Mild
18 Dec 2020 (Study Day 114)	Difficulty Breathing	Mild
18 Dec 2020 (Study Day 114)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 114)	Runny Nose (Rhinorrhea)	Mild
19 Dec 2020 (Study Day 115)	Cough	Mild
19 Dec 2020 (Study Day 115)	Difficulty Breathing	Mild
19 Dec 2020 (Study Day 115)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 116)	Cough	Mild
20 Dec 2020 (Study Day 116)	Difficulty Breathing	Mild
20 Dec 2020 (Study Day 116)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 118)	Cough	Mild
22 Dec 2020 (Study Day 118)	Difficulty Breathing	Mild
22 Dec 2020 (Study Day 118)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 119)	Cough	Mild

Symptom Date	Symptom	Result
23 Dec 2020 (Study Day 119)	Difficulty Breathing	Mild
23 Dec 2020 (Study Day 119)	Nasal Congestion	Mild
24 Dec 2020 (Study Day 120)	Cough	Mild
24 Dec 2020 (Study Day 120)	Difficulty Breathing	Mild
24 Dec 2020 (Study Day 120)	Nasal Congestion	Mild
27 Dec 2020 (Study Day 123)	Cough	Mild
27 Dec 2020 (Study Day 123)	Difficulty Breathing	Mild
27 Dec 2020 (Study Day 123)	Nasal Congestion	Moderate
28 Dec 2020 (Study Day 124)	Cough	Mild
28 Dec 2020 (Study Day 124)	Difficulty Breathing	Mild
28 Dec 2020 (Study Day 124)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 125)	Difficulty Breathing	Mild
29 Dec 2020 (Study Day 125)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 126)	Difficulty Breathing	Mild
30 Dec 2020 (Study Day 126)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
08 Dec 2020 (Study Day 104)	Oxygen Saturation	90%
08 Dec 2020 - 09 Dec 2020 (Study Day 104-105)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 29 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 127). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006090	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma moderate	1945 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1975 - Ongoing
Postmenopause	Post menopausal	1985 - Ongoing
Anxiety	Anxiety	1990 - Ongoing
Depression	Depression	1990 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1950 - Ongoing	Asthma Moderate
Fluticasone propionate; salmeterol	1960 - Ongoing	Asthma Moderate
Omeprazole	1985 - 22 Jan 2021 (Study Day 149)	Gastroesophageal Reflux Disease
Citalopram	1990 - Ongoing	Anxiety
Levothyroxine	2000 - Ongoing	Hypothyroidism
Diphenhydramine hydrochloride; paracetamol	29 Aug 2020 (Study Day 3) - 29 Aug 2020 (Study Day 3)	Headache
Influenza vaccine	01 Dec 2020 (Study Day 97) - 01 Dec 2020 (Study Day 97)	Influenxa Prophylaxis
Atorvastatin	19 Feb 2021 (Study Day 177) - Ongoing	Hyperlipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Related	28 Aug 2020 (Study Day 2) - 04 Sep 2020 (Study Day 9)
Fatigue	Grade 2/moderate	Related	28 Aug 2020 (Study Day 2) - 04 Sep 2020 (Study Day 9)
Myalgia	Grade 1/mild	Related	30 Aug 2020 (Study Day 4) - 04 Sep 2020 (Study Day 9)
Fatigue	Grade 1/mild	Not related	03 Sep 2020 (Study Day 8) - 04 Sep 2020 (Study Day 9)
Fatigue	Grade 1/mild	Related	26 Sep 2020 (Study Day 31) - 07 Nov 2020 (Study Day 73)
Nausea	Grade 1/mild	Related	26 Sep 2020 (Study Day 31) - 03 Oct 2020 (Study Day 38)
Headache	Grade 1/mild	Related	29 Sep 2020 (Study Day 34) - 07 Nov 2020 (Study Day 73)
Myalgia	Grade 1/mild	Related	29 Sep 2020 (Study Day 34) - 03 Oct 2020 (Study Day 38)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	03 Dec 2020 (Study Day 99) - 31 Dec 2020 (Study Day 127)
Hyperlipidaemia	Grade 1/mild	Not related	12 Feb 2021 (Study Day 170) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US380-2034 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 28)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID 19	COVID-19	Grade 1/mild	Not related	05 Nov 2020 (Study Day 73) – 03 Dec 2020 (Study Day 101)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US380-2034, a 70-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 05 Nov 2020 (Study Day 73), 72 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 05 Nov 2020 (Study Day 73), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
05 Nov 2020 (Study Day 73)	Cough	Moderate
05 Nov 2020 (Study Day 73)	Fatigue	Mild
05 Nov 2020 (Study Day 73)	Headache	Mild
05 Nov 2020 (Study Day 73)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
06 Nov 2020 (Study Day 74)	Cough	Mild
06 Nov 2020 (Study Day 74)	Nasal Congestion	Mild
06 Nov 2020 (Study Day 74)	Sore Throat	Mild
07 Nov 2020 (Study Day 75)	Cough	Mild
07 Nov 2020 (Study Day 75)	Fatigue	Mild
07 Nov 2020 (Study Day 75)	Headache	Mild
07 Nov 2020 (Study Day 75)	Nasal Congestion	Mild
07 Nov 2020 (Study Day 75)	Sore Throat	Mild
08 Nov 2020 (Study Day 76)	Cough	Mild
08 Nov 2020 (Study Day 76)	Fatigue	Mild
08 Nov 2020 (Study Day 76)	Headache	Moderate
08 Nov 2020 (Study Day 76)	Nasal Congestion	Moderate
08 Nov 2020 (Study Day 76)	New Loss of Smell	Mild
08 Nov 2020 (Study Day 76)	New Loss of Taste	Mild
08 Nov 2020 (Study Day 76)	Sore Throat	Mild
09 Nov 2020 (Study Day 77)	Cough	Mild
09 Nov 2020 (Study Day 77)	Fatigue	Mild
09 Nov 2020 (Study Day 77)	Headache	Moderate
09 Nov 2020 (Study Day 77)	Nasal Congestion	Mild
09 Nov 2020 (Study Day 77)	New Loss of Smell	Moderate
09 Nov 2020 (Study Day 77)	New Loss of Taste	Moderate
09 Nov 2020 (Study Day 77)	Runny Nose (Rhinorrhea)	Mild
09 Nov 2020 (Study Day 77)	Sore Throat	Mild
10 Nov 2020 (Study Day 78)	Chills	Mild
10 Nov 2020 (Study Day 78)	Cough	Mild
10 Nov 2020 (Study Day 78)	Fatigue	Mild
10 Nov 2020 (Study Day 78)	Headache	Moderate
10 Nov 2020 (Study Day 78)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 78)	New Loss of Smell	Moderate
10 Nov 2020 (Study Day 78)	New Loss of Taste	Moderate
10 Nov 2020 (Study Day 78)	Runny Nose (Rhinorrhea)	Mild
10 Nov 2020 (Study Day 78)	Sore Throat	Mild
11 Nov 2020 (Study Day 79)	Cough	Mild
11 Nov 2020 (Study Day 79)	Fatigue	Mild
11 Nov 2020 (Study Day 79)	Headache	Mild
11 Nov 2020 (Study Day 79)	Nasal Congestion	Mild
11 Nov 2020 (Study Day 79)	New Loss of Smell	Moderate
11 Nov 2020 (Study Day 79)	New Loss of Taste	Moderate
11 Nov 2020 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild
11 Nov 2020 (Study Day 79)	Sore Throat	Mild
12 Nov 2020 (Study Day 80)	Body Aches	Mild
12 Nov 2020 (Study Day 80)	Cough	Mild
12 Nov 2020 (Study Day 80)	Fatigue	Moderate

Symptom Date	Symptom	Result
12 Nov 2020 (Study Day 80)	Headache	Mild
12 Nov 2020 (Study Day 80)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 80)	New Loss of Smell	Moderate
12 Nov 2020 (Study Day 80)	New Loss of Taste	Moderate
12 Nov 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
12 Nov 2020 (Study Day 80)	Sore Throat	Mild
13 Nov 2020 (Study Day 81)	Body Aches	Mild
13 Nov 2020 (Study Day 81)	Cough	Moderate
13 Nov 2020 (Study Day 81)	Fatigue	Mild
13 Nov 2020 (Study Day 81)	Headache	Mild
13 Nov 2020 (Study Day 81)	Nasal Congestion	Moderate
13 Nov 2020 (Study Day 81)	New Loss of Smell	Mild
13 Nov 2020 (Study Day 81)	New Loss of Taste	Mild
13 Nov 2020 (Study Day 81)	O2 Saturation (%)	90
13 Nov 2020 (Study Day 81)	Sore Throat	Mild
14 Nov 2020 (Study Day 82)	Body Aches	Mild
14 Nov 2020 (Study Day 82)	Cough	Mild
14 Nov 2020 (Study Day 82)	Fatigue	Moderate
14 Nov 2020 (Study Day 82)	Headache	Moderate
14 Nov 2020 (Study Day 82)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 82)	New Loss of Smell	Mild
14 Nov 2020 (Study Day 82)	New Loss of Taste	Mild
14 Nov 2020 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
14 Nov 2020 (Study Day 82)	Sore Throat	Mild
15 Nov 2020 (Study Day 83)	Cough	Mild
15 Nov 2020 (Study Day 83)	Headache	Mild
15 Nov 2020 (Study Day 83)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 83)	Sore Throat	Mild
16 Nov 2020 (Study Day 84)	Cough	Mild
16 Nov 2020 (Study Day 84)	Fatigue	Mild
16 Nov 2020 (Study Day 84)	Headache	Mild
16 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
16 Nov 2020 (Study Day 84)	Sore Throat	Mild
17 Nov 2020 (Study Day 85)	Cough	Mild
17 Nov 2020 (Study Day 85)	Fatigue	Mild
17 Nov 2020 (Study Day 85)	Headache	Moderate
17 Nov 2020 (Study Day 85)	Nasal Congestion	Mild
17 Nov 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Mild
17 Nov 2020 (Study Day 85)	Sore Throat	Mild
18 Nov 2020 (Study Day 86)	Headache	Mild
18 Nov 2020 (Study Day 86)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 86)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
19 Nov 2020 (Study Day 87)	Cough	Mild
19 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 89)	Cough	Mild
21 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 90)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 91)	Headache	Mild
23 Nov 2020 (Study Day 91)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 91)	Sore Throat	Mild
24 Nov 2020 (Study Day 92)	Sore Throat	Mild
25 Nov 2020 (Study Day 93)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 93)	Sore Throat	Mild
26 Nov 2020 (Study Day 94)	Cough	Mild
26 Nov 2020 (Study Day 94)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 94)	Sore Throat	Mild
27 Nov 2020 (Study Day 95)	Cough	Mild
27 Nov 2020 (Study Day 95)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 95)	Sore Throat	Mild
28 Nov 2020 (Study Day 96)	Cough	Mild
28 Nov 2020 (Study Day 96)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 96)	Sore Throat	Mild
29 Nov 2020 (Study Day 97)	Cough	Mild
30 Nov 2020 (Study Day 98)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 99)	Nasal Congestion	Mild
02 Dec 2020 (Study Day 100)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
13 Nov 2020 (Study Day 81)	Oxygen Saturation	90%
13 Nov 2020 - 13 Nov 2020 (Study Day 81-81)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID 19 lasted for 29 days, after which it was considered to be recovered/resolved on 03 Dec 2020 (Study Day 101). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000703	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Acid reflux	Not reported - Ongoing
Headache	Headache	Not reported - Ongoing
Myalgia	General muscle pain	Not reported - Ongoing
Postmenopause	Post menopausal	Not reported - Ongoing
Asthma	Asthma	2000 - Ongoing
Foot fracture	Right foot fracture	2005 - 2005
Hypertension	Hypertension	2010 - Ongoing
Urinary tract infection	Frequent uti	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mometasone furoate	Not reported - Ongoing	Asthma
Ibuprofen	1990 - Ongoing	Headache And Generalized Muscle Pain
Colecalciferol	2000 - Ongoing	Supplement
Salbutamol	2000 - Ongoing	Asthma
Hydrochlorothiazide	2010 - Ongoing	Hypertension
Famotidine	2018 - Ongoing	Acid Reflux
Ibuprofen	27 Aug 2020 (Study Day 3) - 27 Aug 2020 (Study Day 3)	Headache
Influenza vaccine	12 Oct 2020 (Study Day 49) - 12 Oct 2020 (Study Day 49)	Prevent Influenza Infection
Amoxicillin	29 Oct 2020 (Study Day 66) - 07 Nov 2020 (Study Day 75)	Tooth Infection
Methylprednisolone	29 Oct 2020 (Study Day 66) - 02 Nov 2020 (Study Day 70)	Tooth Infection
Acetylsalicylic acid	05 Nov 2020 (Study Day 73) - Ongoing	Prevent Heart Disease
Guaifenesin	05 Nov 2020 (Study Day 73) - 03 Dec 2020 (Study Day 101)	Congestion, Sore Throat, And Cough As Related To COVID 19 Infection
Paracetamol	08 Nov 2020 (Study Day 76) - 08 Nov 2020 (Study Day 76)	Headache Due To COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	06 Jan 2021 (Study Day 135) - 09 Jan 2021 (Study Day 138)	Body Aches, Injection Site Pain, Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tooth Infection	Grade 1/mild	Not related	29 Oct 2020 (Study Day 66) - 31 Oct 2020 (Study Day 68)
COVID-19	Grade 1/mild	Not related	05 Nov 2020 (Study Day 73) - 03 Dec 2020 (Study Day 101)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US380-2046 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID 19	SAE, COVID-19	Grade 3/ severe	Not related	13 Nov 2020 (Study Day 80) – 06 Jan 2021 (Study Day 134)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US380-2046, a 70-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 13 Nov 2020 (Study Day 80), 79 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of symptomatic COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 23 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 13 Nov 2020 (Study Day 80), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
13 Nov 2020 (Study Day 80)	Body Aches	Severe
13 Nov 2020 (Study Day 80)	Chills	Mild
13 Nov 2020 (Study Day 80)	Cough	Moderate
13 Nov 2020 (Study Day 80)	Diarrhea	Mild

Symptom Date	Symptom	Result
13 Nov 2020 (Study Day 80)	Difficulty Breathing	Mild
13 Nov 2020 (Study Day 80)	Fatigue	Moderate
13 Nov 2020 (Study Day 80)	Headache	Severe
13 Nov 2020 (Study Day 80)	Muscle Aches (Myalgia)	Severe
13 Nov 2020 (Study Day 80)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
13 Nov 2020 (Study Day 80)	Shortness of Breath	Mild
14 Nov 2020 (Study Day 81)	Body Aches	Mild
14 Nov 2020 (Study Day 81)	Cough	Moderate
14 Nov 2020 (Study Day 81)	Diarrhea	Severe
14 Nov 2020 (Study Day 81)	Fatigue	Severe
14 Nov 2020 (Study Day 81)	Headache	Moderate
14 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Mild
14 Nov 2020 (Study Day 81)	Nasal Congestion	Moderate
14 Nov 2020 (Study Day 81)	Nausea	Mild
14 Nov 2020 (Study Day 81)	Temperature (°F)	101
15 Nov 2020 (Study Day 82)	Body Aches	Moderate
15 Nov 2020 (Study Day 82)	Cough	Mild
15 Nov 2020 (Study Day 82)	Diarrhea	Moderate
15 Nov 2020 (Study Day 82)	Fatigue	Severe
15 Nov 2020 (Study Day 82)	Headache	Moderate
15 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
15 Nov 2020 (Study Day 82)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 82)	Nausea	Moderate
15 Nov 2020 (Study Day 82)	Shortness of Breath	Mild
16 Nov 2020 (Study Day 83)	Body Aches	Moderate
16 Nov 2020 (Study Day 83)	Cough	Moderate
16 Nov 2020 (Study Day 83)	Diarrhea	Mild
16 Nov 2020 (Study Day 83)	Fatigue	Moderate
16 Nov 2020 (Study Day 83)	Headache	Mild
16 Nov 2020 (Study Day 83)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 83)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 83)	Nausea	Mild
16 Nov 2020 (Study Day 83)	Shortness of Breath	Mild
17 Nov 2020 (Study Day 84)	Body Aches	Moderate
17 Nov 2020 (Study Day 84)	Cough	Moderate
17 Nov 2020 (Study Day 84)	Diarrhea	Moderate
17 Nov 2020 (Study Day 84)	Fatigue	Moderate
17 Nov 2020 (Study Day 84)	Headache	Moderate
17 Nov 2020 (Study Day 84)	Muscle Aches (Myalgia)	Moderate
17 Nov 2020 (Study Day 84)	Nasal Congestion	Moderate
17 Nov 2020 (Study Day 84)	Nausea	Moderate
17 Nov 2020 (Study Day 84)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
18 Nov 2020 (Study Day 85)	Body Aches	Moderate
18 Nov 2020 (Study Day 85)	Cough	Mild
18 Nov 2020 (Study Day 85)	Diarrhea	Severe
18 Nov 2020 (Study Day 85)	Fatigue	Moderate
18 Nov 2020 (Study Day 85)	Headache	Mild
18 Nov 2020 (Study Day 85)	Muscle Aches (Myalgia)	Moderate
18 Nov 2020 (Study Day 85)	Nausea	Mild
19 Nov 2020 (Study Day 86)	Body Aches	Moderate
19 Nov 2020 (Study Day 86)	Cough	Mild
19 Nov 2020 (Study Day 86)	Diarrhea	Mild
19 Nov 2020 (Study Day 86)	Fatigue	Moderate
19 Nov 2020 (Study Day 86)	Headache	Mild
19 Nov 2020 (Study Day 86)	Muscle Aches (Myalgia)	Moderate
19 Nov 2020 (Study Day 86)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 86)	Nausea	Mild
20 Nov 2020 (Study Day 87)	Body Aches	Mild
20 Nov 2020 (Study Day 87)	Cough	Mild
20 Nov 2020 (Study Day 87)	Fatigue	Mild
20 Nov 2020 (Study Day 87)	Muscle Aches (Myalgia)	Mild
20 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 87)	Nausea	Mild
21 Nov 2020 (Study Day 88)	Body Aches	Mild
21 Nov 2020 (Study Day 88)	Cough	Mild
21 Nov 2020 (Study Day 88)	Fatigue	Moderate
21 Nov 2020 (Study Day 88)	Muscle Aches (Myalgia)	Mild
21 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 88)	Nausea	Mild
24 Nov 2020 (Study Day 91)	Body Aches	Mild
24 Nov 2020 (Study Day 91)	Cough	Mild
24 Nov 2020 (Study Day 91)	Difficulty Breathing	Mild
24 Nov 2020 (Study Day 91)	Fatigue	Moderate
24 Nov 2020 (Study Day 91)	Headache	Mild
24 Nov 2020 (Study Day 91)	Muscle Aches (Myalgia)	Mild
24 Nov 2020 (Study Day 91)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 91)	Nausea	Mild
24 Nov 2020 (Study Day 91)	O2 Saturation (%)	90
24 Nov 2020 (Study Day 91)	Shortness of Breath	Moderate
25 Nov 2020 (Study Day 92)	Body Aches	Moderate
25 Nov 2020 (Study Day 92)	Cough	Moderate
25 Nov 2020 (Study Day 92)	Difficulty Breathing	Mild
25 Nov 2020 (Study Day 92)	Fatigue	Moderate
25 Nov 2020 (Study Day 92)	Headache	Mild
25 Nov 2020 (Study Day 92)	Muscle Aches (Myalgia)	Moderate

Symptom Date	Symptom	Result
25 Nov 2020 (Study Day 92)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 92)	Nausea	Mild
25 Nov 2020 (Study Day 92)	Shortness of Breath	Moderate
26 Nov 2020 (Study Day 93)	Body Aches	Mild
26 Nov 2020 (Study Day 93)	Cough	Mild
26 Nov 2020 (Study Day 93)	Difficulty Breathing	Mild
26 Nov 2020 (Study Day 93)	Fatigue	Moderate
26 Nov 2020 (Study Day 93)	Headache	Mild
26 Nov 2020 (Study Day 93)	Muscle Aches (Myalgia)	Mild
26 Nov 2020 (Study Day 93)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 93)	Nausea	Mild
26 Nov 2020 (Study Day 93)	Shortness of Breath	Mild
27 Nov 2020 (Study Day 94)	Body Aches	Mild
27 Nov 2020 (Study Day 94)	Cough	Moderate
27 Nov 2020 (Study Day 94)	Difficulty Breathing	Mild
27 Nov 2020 (Study Day 94)	Fatigue	Moderate
27 Nov 2020 (Study Day 94)	Muscle Aches (Myalgia)	Mild
27 Nov 2020 (Study Day 94)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 94)	Shortness of Breath	Moderate
28 Nov 2020 (Study Day 95)	Body Aches	Mild
28 Nov 2020 (Study Day 95)	Cough	Mild
28 Nov 2020 (Study Day 95)	Difficulty Breathing	Mild
28 Nov 2020 (Study Day 95)	Fatigue	Moderate
28 Nov 2020 (Study Day 95)	Muscle Aches (Myalgia)	Mild
28 Nov 2020 (Study Day 95)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 95)	Shortness of Breath	Mild
29 Nov 2020 (Study Day 96)	Body Aches	Mild
29 Nov 2020 (Study Day 96)	Difficulty Breathing	Mild
29 Nov 2020 (Study Day 96)	Fatigue	Moderate
29 Nov 2020 (Study Day 96)	Muscle Aches (Myalgia)	Mild
29 Nov 2020 (Study Day 96)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 96)	Shortness of Breath	Mild
30 Nov 2020 (Study Day 97)	Body Aches	Mild
30 Nov 2020 (Study Day 97)	Cough	Mild
30 Nov 2020 (Study Day 97)	Difficulty Breathing	Mild
30 Nov 2020 (Study Day 97)	Fatigue	Mild
30 Nov 2020 (Study Day 97)	Muscle Aches (Myalgia)	Mild
30 Nov 2020 (Study Day 97)	Shortness of Breath	Mild
01 Dec 2020 (Study Day 98)	Body Aches	Mild
01 Dec 2020 (Study Day 98)	Cough	Mild
01 Dec 2020 (Study Day 98)	Difficulty Breathing	Mild
01 Dec 2020 (Study Day 98)	Fatigue	Mild
01 Dec 2020 (Study Day 98)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
01 Dec 2020 (Study Day 98)	Shortness of Breath	Mild
02 Dec 2020 (Study Day 99)	Body Aches	Mild
02 Dec 2020 (Study Day 99)	Cough	Mild
02 Dec 2020 (Study Day 99)	Difficulty Breathing	Mild
02 Dec 2020 (Study Day 99)	Fatigue	Mild
02 Dec 2020 (Study Day 99)	Muscle Aches (Myalgia)	Mild
02 Dec 2020 (Study Day 99)	Shortness of Breath	Mild
03 Dec 2020 (Study Day 100)	Body Aches	Mild
03 Dec 2020 (Study Day 100)	Fatigue	Moderate
03 Dec 2020 (Study Day 100)	Muscle Aches (Myalgia)	Mild
03 Dec 2020 (Study Day 100)	Shortness of Breath	Mild
04 Dec 2020 (Study Day 101)	Body Aches	Mild
04 Dec 2020 (Study Day 101)	Cough	Mild
04 Dec 2020 (Study Day 101)	Fatigue	Mild
04 Dec 2020 (Study Day 101)	Muscle Aches (Myalgia)	Mild
05 Dec 2020 (Study Day 102)	Body Aches	Mild
05 Dec 2020 (Study Day 102)	Cough	Mild
05 Dec 2020 (Study Day 102)	Fatigue	Mild
05 Dec 2020 (Study Day 102)	Muscle Aches (Myalgia)	Mild
06 Dec 2020 (Study Day 103)	Body Aches	Mild
06 Dec 2020 (Study Day 103)	Cough	Mild
06 Dec 2020 (Study Day 103)	Fatigue	Moderate
06 Dec 2020 (Study Day 103)	Muscle Aches (Myalgia)	Mild
06 Dec 2020 (Study Day 103)	Shortness of Breath	Mild
07 Dec 2020 (Study Day 104)	Body Aches	Mild
07 Dec 2020 (Study Day 104)	Cough	Mild
07 Dec 2020 (Study Day 104)	Difficulty Breathing	Mild
07 Dec 2020 (Study Day 104)	Fatigue	Moderate
07 Dec 2020 (Study Day 104)	Muscle Aches (Myalgia)	Mild
07 Dec 2020 (Study Day 104)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 105)	Body Aches	Mild
08 Dec 2020 (Study Day 105)	Cough	Moderate
08 Dec 2020 (Study Day 105)	Fatigue	Moderate
08 Dec 2020 (Study Day 105)	Muscle Aches (Myalgia)	Mild
08 Dec 2020 (Study Day 105)	Shortness of Breath	Mild
09 Dec 2020 (Study Day 106)	Body Aches	Moderate
09 Dec 2020 (Study Day 106)	Cough	Mild
09 Dec 2020 (Study Day 106)	Difficulty Breathing	Mild
09 Dec 2020 (Study Day 106)	Fatigue	Moderate
09 Dec 2020 (Study Day 106)	Muscle Aches (Myalgia)	Moderate
10 Dec 2020 (Study Day 107)	Body Aches	Mild
10 Dec 2020 (Study Day 107)	Cough	Mild
10 Dec 2020 (Study Day 107)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
10 Dec 2020 (Study Day 107)	Fatigue	Moderate
10 Dec 2020 (Study Day 107)	Muscle Aches (Myalgia)	Mild
11 Dec 2020 (Study Day 108)	Body Aches	Mild
11 Dec 2020 (Study Day 108)	Difficulty Breathing	Mild
11 Dec 2020 (Study Day 108)	Fatigue	Mild
11 Dec 2020 (Study Day 108)	Muscle Aches (Myalgia)	Mild
12 Dec 2020 (Study Day 109)	Body Aches	Mild
12 Dec 2020 (Study Day 109)	Cough	Mild
12 Dec 2020 (Study Day 109)	Difficulty Breathing	Mild
12 Dec 2020 (Study Day 109)	Fatigue	Moderate
12 Dec 2020 (Study Day 109)	Muscle Aches (Myalgia)	Mild
12 Dec 2020 (Study Day 109)	New Loss of Taste	Moderate
12 Dec 2020 (Study Day 109)	Shortness of Breath	Mild
13 Dec 2020 (Study Day 110)	Body Aches	Mild
13 Dec 2020 (Study Day 110)	Difficulty Breathing	Mild
13 Dec 2020 (Study Day 110)	Fatigue	Moderate
13 Dec 2020 (Study Day 110)	Muscle Aches (Myalgia)	Mild
13 Dec 2020 (Study Day 110)	New Loss of Taste	Moderate
14 Dec 2020 (Study Day 111)	Body Aches	Moderate
14 Dec 2020 (Study Day 111)	Fatigue	Moderate
14 Dec 2020 (Study Day 111)	Muscle Aches (Myalgia)	Moderate
14 Dec 2020 (Study Day 111)	New Loss of Taste	Moderate
14 Dec 2020 (Study Day 111)	Shortness of Breath	Mild
15 Dec 2020 (Study Day 112)	Body Aches	Moderate
15 Dec 2020 (Study Day 112)	Cough	Mild
15 Dec 2020 (Study Day 112)	Difficulty Breathing	Mild
15 Dec 2020 (Study Day 112)	Fatigue	Moderate
15 Dec 2020 (Study Day 112)	Muscle Aches (Myalgia)	Moderate
15 Dec 2020 (Study Day 112)	New Loss of Taste	Mild
16 Dec 2020 (Study Day 113)	Body Aches	Moderate
16 Dec 2020 (Study Day 113)	Cough	Mild
16 Dec 2020 (Study Day 113)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 113)	Fatigue	Moderate
16 Dec 2020 (Study Day 113)	Muscle Aches (Myalgia)	Moderate
16 Dec 2020 (Study Day 113)	New Loss of Taste	Mild
16 Dec 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
16 Dec 2020 (Study Day 113)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 114)	Body Aches	Moderate
17 Dec 2020 (Study Day 114)	Fatigue	Moderate
17 Dec 2020 (Study Day 114)	Muscle Aches (Myalgia)	Moderate
17 Dec 2020 (Study Day 114)	New Loss of Taste	Mild
17 Dec 2020 (Study Day 114)	Shortness of Breath	Mild
18 Dec 2020 (Study Day 115)	Body Aches	Mild

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 115)	Fatigue	Mild
18 Dec 2020 (Study Day 115)	Muscle Aches (Myalgia)	Mild
18 Dec 2020 (Study Day 115)	New Loss of Taste	Mild
18 Dec 2020 (Study Day 115)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 116)	Body Aches	Moderate
19 Dec 2020 (Study Day 116)	Fatigue	Moderate
19 Dec 2020 (Study Day 116)	Muscle Aches (Myalgia)	Moderate
19 Dec 2020 (Study Day 116)	New Loss of Taste	Mild
19 Dec 2020 (Study Day 116)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 117)	Body Aches	Mild
20 Dec 2020 (Study Day 117)	Fatigue	Moderate
20 Dec 2020 (Study Day 117)	Muscle Aches (Myalgia)	Mild
20 Dec 2020 (Study Day 117)	New Loss of Taste	Mild
20 Dec 2020 (Study Day 117)	Shortness of Breath	Mild
21 Dec 2020 (Study Day 118)	Body Aches	Mild
21 Dec 2020 (Study Day 118)	Fatigue	Moderate
21 Dec 2020 (Study Day 118)	Muscle Aches (Myalgia)	Mild
21 Dec 2020 (Study Day 118)	New Loss of Taste	Moderate
21 Dec 2020 (Study Day 118)	Shortness of Breath	Mild
22 Dec 2020 (Study Day 119)	Body Aches	Severe
22 Dec 2020 (Study Day 119)	Cough	Mild
22 Dec 2020 (Study Day 119)	Fatigue	Severe
22 Dec 2020 (Study Day 119)	Muscle Aches (Myalgia)	Severe
22 Dec 2020 (Study Day 119)	New Loss of Taste	Mild
22 Dec 2020 (Study Day 119)	Shortness of Breath	Mild
23 Dec 2020 (Study Day 120)	Body Aches	Mild
23 Dec 2020 (Study Day 120)	Fatigue	Mild
23 Dec 2020 (Study Day 120)	Muscle Aches (Myalgia)	Mild
23 Dec 2020 (Study Day 120)	New Loss of Taste	Mild
23 Dec 2020 (Study Day 120)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 121)	Body Aches	Mild
24 Dec 2020 (Study Day 121)	Fatigue	Mild
24 Dec 2020 (Study Day 121)	Muscle Aches (Myalgia)	Mild
24 Dec 2020 (Study Day 121)	New Loss of Taste	Mild
24 Dec 2020 (Study Day 121)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 122)	Body Aches	Mild
25 Dec 2020 (Study Day 122)	Fatigue	Mild
25 Dec 2020 (Study Day 122)	Muscle Aches (Myalgia)	Mild
25 Dec 2020 (Study Day 122)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 123)	Body Aches	Mild
26 Dec 2020 (Study Day 123)	Fatigue	Mild
26 Dec 2020 (Study Day 123)	Muscle Aches (Myalgia)	Mild
26 Dec 2020 (Study Day 123)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
27 Dec 2020 (Study Day 124)	Body Aches	Moderate
27 Dec 2020 (Study Day 124)	Cough	Mild
27 Dec 2020 (Study Day 124)	Fatigue	Moderate
27 Dec 2020 (Study Day 124)	Muscle Aches (Myalgia)	Moderate
27 Dec 2020 (Study Day 124)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 125)	Body Aches	Mild
28 Dec 2020 (Study Day 125)	Fatigue	Mild
28 Dec 2020 (Study Day 125)	Muscle Aches (Myalgia)	Mild
29 Dec 2020 (Study Day 126)	Body Aches	Mild
29 Dec 2020 (Study Day 126)	Fatigue	Moderate
29 Dec 2020 (Study Day 126)	Muscle Aches (Myalgia)	Mild
30 Dec 2020 (Study Day 127)	Body Aches	Moderate
30 Dec 2020 (Study Day 127)	Fatigue	Moderate
30 Dec 2020 (Study Day 127)	Muscle Aches (Myalgia)	Moderate
31 Dec 2020 (Study Day 128)	Body Aches	Mild
31 Dec 2020 (Study Day 128)	Cough	Moderate
31 Dec 2020 (Study Day 128)	Difficulty Breathing	Mild
31 Dec 2020 (Study Day 128)	Fatigue	Mild
31 Dec 2020 (Study Day 128)	Muscle Aches (Myalgia)	Mild
31 Dec 2020 (Study Day 128)	Runny Nose (Rhinorrhea)	Mild
31 Dec 2020 (Study Day 128)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 129)	Body Aches	Mild
01 Jan 2021 (Study Day 129)	Fatigue	Mild
01 Jan 2021 (Study Day 129)	Muscle Aches (Myalgia)	Mild
01 Jan 2021 (Study Day 129)	Shortness of Breath	Mild
02 Jan 2021 (Study Day 130)	Body Aches	Mild
02 Jan 2021 (Study Day 130)	Fatigue	Mild
02 Jan 2021 (Study Day 130)	Muscle Aches (Myalgia)	Mild
03 Jan 2021 (Study Day 131)	Body Aches	Moderate
03 Jan 2021 (Study Day 131)	Cough	Mild
03 Jan 2021 (Study Day 131)	Fatigue	Moderate
03 Jan 2021 (Study Day 131)	Muscle Aches (Myalgia)	Moderate
03 Jan 2021 (Study Day 131)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 132)	Body Aches	Mild
04 Jan 2021 (Study Day 132)	Fatigue	Mild
04 Jan 2021 (Study Day 132)	Muscle Aches (Myalgia)	Mild
05 Jan 2021 (Study Day 133)	Body Aches	Moderate
05 Jan 2021 (Study Day 133)	Fatigue	Moderate
05 Jan 2021 (Study Day 133)	Muscle Aches (Myalgia)	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
24 Nov 2020 (Study Day 91)	Oxygen Saturation	90%
24 Nov 2020 - 24 Nov 2020 (Study Day 91-91)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID 19 lasted for 55 days, after which it was considered to be recovered/resolved on 06 Jan 2021 (Study Day 134). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000777	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	Not reported - Ongoing
Dyspepsia	Acid indigestion	Not reported - Ongoing
Postmenopause	Post menopausal	Not reported - Ongoing
Skin lesion	Lesion on back	Not reported - Ongoing
Drug hypersensitivity	Allergies cephalosporin	1980 - Ongoing
Drug hypersensitivity	Allergies sulfa	2000 - Ongoing
Depression	Depression	2005 - Ongoing
Osteoporosis	Osteoporosis	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	2000 - Ongoing	Acid Indigestion
Buspirone hydrochloride	2005 - Ongoing	Anxiety
Fluoxetine hydrochloride	2005 - Ongoing	Mild Depression
Ibandronate sodium	2017 - Ongoing	Mild Osteoporosis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cryosurgery*	17 Sep 2020 (Study Day 23) - 17 Sep 2020 (Study Day 23)	Medical History
Influenza vaccine	20 Oct 2020 (Study Day 56) - 20 Oct 2020 (Study Day 56)	Prevent Flu
Paracetamol	13 Nov 2020 (Study Day 80) - Ongoing	COVID 19
Acetylsalicylic acid	14 Nov 2020 (Study Day 81) - Ongoing	Dvt Prevention
Vitamin d nos	14 Nov 2020 (Study Day 81) - Ongoing	COVID 19
Ibuprofen	17 Nov 2020 (Study Day 84) - Ongoing	Generalized Body And Muscle Aches Due To COVID-19
Chest x ray*	21 Nov 2020 (Study Day 88) - 21 Nov 2020 (Study Day 88)	Adverse Event
Ct angiography of the chest*	21 Nov 2020 (Study Day 88) - 21 Nov 2020 (Study Day 88)	Adverse Event
Ecg*	21 Nov 2020 (Study Day 88) - 21 Nov 2020 (Study Day 88)	Adverse Event
Dexamethasone	22 Nov 2020 (Study Day 89) - 01 Dec 2020 (Study Day 98)	COVID 19 Pna
Fluticasone propionate	09 Dec 2020 (Study Day 106) - Ongoing	COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US380-2109 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 31)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID19	COVID-19	Grade 1/mild	Not related	11 Jan 2021 (Study Day 132) – 02 Mar 2021 (Study Day 182)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US380-2109, a 22-year-old Hispanic or Latino female, received the first dose of placebo in the right arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 02 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 11 Jan 2021 (Study Day 132), 131 days after the first dose and 101 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 31, 02 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Jan 2021 (Study Day 132), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 132)	Body Aches	Moderate
11 Jan 2021 (Study Day 132)	Chills	Mild
11 Jan 2021 (Study Day 132)	Cough	Moderate
11 Jan 2021 (Study Day 132)	Diarrhea	Mild

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 132)	Fatigue	Moderate
11 Jan 2021 (Study Day 132)	Headache	Moderate
11 Jan 2021 (Study Day 132)	Muscle Aches (Myalgia)	Moderate
11 Jan 2021 (Study Day 132)	Nasal Congestion	Moderate
11 Jan 2021 (Study Day 132)	Nausea	Mild
11 Jan 2021 (Study Day 132)	New Loss of Taste	Moderate
11 Jan 2021 (Study Day 132)	Runny Nose (Rhinorrhea)	Moderate
11 Jan 2021 (Study Day 132)	Sore Throat	Moderate
12 Jan 2021 (Study Day 133)	Body Aches	Moderate
12 Jan 2021 (Study Day 133)	Chills	Mild
12 Jan 2021 (Study Day 133)	Cough	Severe
12 Jan 2021 (Study Day 133)	Fatigue	Severe
12 Jan 2021 (Study Day 133)	Headache	Severe
12 Jan 2021 (Study Day 133)	Muscle Aches (Myalgia)	Moderate
12 Jan 2021 (Study Day 133)	Nasal Congestion	Moderate
12 Jan 2021 (Study Day 133)	Nausea	Severe
12 Jan 2021 (Study Day 133)	New Loss of Smell	Severe
12 Jan 2021 (Study Day 133)	New Loss of Taste	Severe
12 Jan 2021 (Study Day 133)	Runny Nose (Rhinorrhea)	Moderate
12 Jan 2021 (Study Day 133)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 133)	Sore Throat	Mild
13 Jan 2021 (Study Day 134)	Body Aches	Moderate
13 Jan 2021 (Study Day 134)	Chills	Mild
13 Jan 2021 (Study Day 134)	Cough	Moderate
13 Jan 2021 (Study Day 134)	Fatigue	Severe
13 Jan 2021 (Study Day 134)	Headache	Mild
13 Jan 2021 (Study Day 134)	Muscle Aches (Myalgia)	Moderate
13 Jan 2021 (Study Day 134)	Nasal Congestion	Moderate
13 Jan 2021 (Study Day 134)	Nausea	Severe
13 Jan 2021 (Study Day 134)	New Loss of Smell	Severe
13 Jan 2021 (Study Day 134)	New Loss of Taste	Severe
13 Jan 2021 (Study Day 134)	Runny Nose (Rhinorrhea)	Severe
13 Jan 2021 (Study Day 134)	Shortness of Breath	Mild
13 Jan 2021 (Study Day 134)	Sore Throat	Mild
14 Jan 2021 (Study Day 135)	Body Aches	Moderate
14 Jan 2021 (Study Day 135)	Cough	Moderate
14 Jan 2021 (Study Day 135)	Difficulty Breathing	Mild
14 Jan 2021 (Study Day 135)	Fatigue	Severe
14 Jan 2021 (Study Day 135)	Headache	Severe
14 Jan 2021 (Study Day 135)	Muscle Aches (Myalgia)	Moderate
14 Jan 2021 (Study Day 135)	Nasal Congestion	Severe
14 Jan 2021 (Study Day 135)	Nausea	Severe
14 Jan 2021 (Study Day 135)	New Loss of Smell	Severe

Symptom Date	Symptom	Result
14 Jan 2021 (Study Day 135)	New Loss of Taste	Moderate
14 Jan 2021 (Study Day 135)	Runny Nose (Rhinorrhea)	Severe
14 Jan 2021 (Study Day 135)	Shortness of Breath	Moderate
14 Jan 2021 (Study Day 135)	Sore Throat	Mild
14 Jan 2021 (Study Day 135)	Vomiting	Severe
15 Jan 2021 (Study Day 136)	Body Aches	Severe
15 Jan 2021 (Study Day 136)	Chills	Severe
15 Jan 2021 (Study Day 136)	Cough	Severe
15 Jan 2021 (Study Day 136)	Difficulty Breathing	Moderate
15 Jan 2021 (Study Day 136)	Fatigue	Severe
15 Jan 2021 (Study Day 136)	Headache	Severe
15 Jan 2021 (Study Day 136)	Muscle Aches (Myalgia)	Severe
15 Jan 2021 (Study Day 136)	Nasal Congestion	Moderate
15 Jan 2021 (Study Day 136)	Nausea	Severe
15 Jan 2021 (Study Day 136)	New Loss of Smell	Severe
15 Jan 2021 (Study Day 136)	New Loss of Taste	Moderate
15 Jan 2021 (Study Day 136)	Runny Nose (Rhinorrhea)	Moderate
15 Jan 2021 (Study Day 136)	Shortness of Breath	Moderate
15 Jan 2021 (Study Day 136)	Sore Throat	Moderate
15 Jan 2021 (Study Day 136)	Temperature (°F)	102.8
16 Jan 2021 (Study Day 137)	Body Aches	Severe
16 Jan 2021 (Study Day 137)	Chills	Severe
16 Jan 2021 (Study Day 137)	Cough	Severe
16 Jan 2021 (Study Day 137)	Difficulty Breathing	Mild
16 Jan 2021 (Study Day 137)	Fatigue	Severe
16 Jan 2021 (Study Day 137)	Headache	Severe
16 Jan 2021 (Study Day 137)	Muscle Aches (Myalgia)	Severe
16 Jan 2021 (Study Day 137)	Nasal Congestion	Severe
16 Jan 2021 (Study Day 137)	Nausea	Severe
16 Jan 2021 (Study Day 137)	New Loss of Smell	Severe
16 Jan 2021 (Study Day 137)	New Loss of Taste	Moderate
16 Jan 2021 (Study Day 137)	Runny Nose (Rhinorrhea)	Severe
16 Jan 2021 (Study Day 137)	Shortness of Breath	Severe
16 Jan 2021 (Study Day 137)	Temperature (°F)	102.2
17 Jan 2021 (Study Day 138)	Body Aches	Severe
17 Jan 2021 (Study Day 138)	Chills	Severe
17 Jan 2021 (Study Day 138)	Cough	Severe
17 Jan 2021 (Study Day 138)	Difficulty Breathing	Moderate
17 Jan 2021 (Study Day 138)	Fatigue	Severe
17 Jan 2021 (Study Day 138)	Headache	Severe
17 Jan 2021 (Study Day 138)	Muscle Aches (Myalgia)	Severe
17 Jan 2021 (Study Day 138)	Nasal Congestion	Severe
17 Jan 2021 (Study Day 138)	Nausea	Severe

Symptom Date	Symptom	Result
17 Jan 2021 (Study Day 138)	New Loss of Smell	Severe
17 Jan 2021 (Study Day 138)	New Loss of Taste	Mild
17 Jan 2021 (Study Day 138)	O2 Saturation (%)	91
17 Jan 2021 (Study Day 138)	Runny Nose (Rhinorrhea)	Severe
17 Jan 2021 (Study Day 138)	Shortness of Breath	Severe
17 Jan 2021 (Study Day 138)	Sore Throat	Mild
17 Jan 2021 (Study Day 138)	Temperature (°F)	101.6
18 Jan 2021 (Study Day 139)	Body Aches	Moderate
18 Jan 2021 (Study Day 139)	Chills	Moderate
18 Jan 2021 (Study Day 139)	Cough	Severe
18 Jan 2021 (Study Day 139)	Difficulty Breathing	Mild
18 Jan 2021 (Study Day 139)	Fatigue	Moderate
18 Jan 2021 (Study Day 139)	Headache	Moderate
18 Jan 2021 (Study Day 139)	Muscle Aches (Myalgia)	Moderate
18 Jan 2021 (Study Day 139)	Nasal Congestion	Moderate
18 Jan 2021 (Study Day 139)	Nausea	Moderate
18 Jan 2021 (Study Day 139)	New Loss of Smell	Moderate
18 Jan 2021 (Study Day 139)	New Loss of Taste	Mild
18 Jan 2021 (Study Day 139)	Runny Nose (Rhinorrhea)	Severe
18 Jan 2021 (Study Day 139)	Shortness of Breath	Moderate
18 Jan 2021 (Study Day 139)	Sore Throat	Mild
18 Jan 2021 (Study Day 139)	Vomiting	Moderate
19 Jan 2021 (Study Day 140)	Body Aches	Moderate
19 Jan 2021 (Study Day 140)	Chills	Mild
19 Jan 2021 (Study Day 140)	Cough	Severe
19 Jan 2021 (Study Day 140)	Difficulty Breathing	Moderate
19 Jan 2021 (Study Day 140)	Fatigue	Moderate
19 Jan 2021 (Study Day 140)	Headache	Moderate
19 Jan 2021 (Study Day 140)	Muscle Aches (Myalgia)	Moderate
19 Jan 2021 (Study Day 140)	Nasal Congestion	Moderate
19 Jan 2021 (Study Day 140)	Nausea	Severe
19 Jan 2021 (Study Day 140)	New Loss of Smell	Moderate
19 Jan 2021 (Study Day 140)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 140)	Runny Nose (Rhinorrhea)	Severe
19 Jan 2021 (Study Day 140)	Shortness of Breath	Severe
19 Jan 2021 (Study Day 140)	Sore Throat	Moderate
20 Jan 2021 (Study Day 141)	Body Aches	Mild
20 Jan 2021 (Study Day 141)	Cough	Severe
20 Jan 2021 (Study Day 141)	Difficulty Breathing	Moderate
20 Jan 2021 (Study Day 141)	Fatigue	Moderate
20 Jan 2021 (Study Day 141)	Headache	Severe
20 Jan 2021 (Study Day 141)	Muscle Aches (Myalgia)	Mild
20 Jan 2021 (Study Day 141)	Nasal Congestion	Moderate

Symptom Date	Symptom	Result
20 Jan 2021 (Study Day 141)	Nausea	Mild
20 Jan 2021 (Study Day 141)	New Loss of Smell	Moderate
20 Jan 2021 (Study Day 141)	New Loss of Taste	Mild
20 Jan 2021 (Study Day 141)	Runny Nose (Rhinorrhea)	Moderate
20 Jan 2021 (Study Day 141)	Shortness of Breath	Moderate
20 Jan 2021 (Study Day 141)	Sore Throat	Moderate
21 Jan 2021 (Study Day 142)	Body Aches	Mild
21 Jan 2021 (Study Day 142)	Chills	Mild
21 Jan 2021 (Study Day 142)	Cough	Severe
21 Jan 2021 (Study Day 142)	Difficulty Breathing	Mild
21 Jan 2021 (Study Day 142)	Fatigue	Moderate
21 Jan 2021 (Study Day 142)	Headache	Moderate
21 Jan 2021 (Study Day 142)	Muscle Aches (Myalgia)	Mild
21 Jan 2021 (Study Day 142)	Nasal Congestion	Moderate
21 Jan 2021 (Study Day 142)	Nausea	Moderate
21 Jan 2021 (Study Day 142)	New Loss of Smell	Moderate
21 Jan 2021 (Study Day 142)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 142)	Runny Nose (Rhinorrhea)	Moderate
21 Jan 2021 (Study Day 142)	Shortness of Breath	Moderate
21 Jan 2021 (Study Day 142)	Sore Throat	Mild
22 Jan 2021 (Study Day 143)	Body Aches	Mild
22 Jan 2021 (Study Day 143)	Cough	Severe
22 Jan 2021 (Study Day 143)	Diarrhea	Mild
22 Jan 2021 (Study Day 143)	Difficulty Breathing	Mild
22 Jan 2021 (Study Day 143)	Fatigue	Moderate
22 Jan 2021 (Study Day 143)	Headache	Moderate
22 Jan 2021 (Study Day 143)	Muscle Aches (Myalgia)	Mild
22 Jan 2021 (Study Day 143)	Nasal Congestion	Moderate
22 Jan 2021 (Study Day 143)	Nausea	Moderate
22 Jan 2021 (Study Day 143)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 143)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 143)	Runny Nose (Rhinorrhea)	Moderate
22 Jan 2021 (Study Day 143)	Shortness of Breath	Moderate
22 Jan 2021 (Study Day 143)	Sore Throat	Mild
23 Jan 2021 (Study Day 144)	Body Aches	Mild
23 Jan 2021 (Study Day 144)	Chills	Mild
23 Jan 2021 (Study Day 144)	Cough	Severe
23 Jan 2021 (Study Day 144)	Diarrhea	Moderate
23 Jan 2021 (Study Day 144)	Difficulty Breathing	Mild
23 Jan 2021 (Study Day 144)	Fatigue	Moderate
23 Jan 2021 (Study Day 144)	Muscle Aches (Myalgia)	Mild
23 Jan 2021 (Study Day 144)	Nasal Congestion	Moderate
23 Jan 2021 (Study Day 144)	Nausea	Moderate

Symptom Date	Symptom	Result
23 Jan 2021 (Study Day 144)	New Loss of Smell	Mild
23 Jan 2021 (Study Day 144)	New Loss of Taste	Mild
23 Jan 2021 (Study Day 144)	Runny Nose (Rhinorrhea)	Moderate
23 Jan 2021 (Study Day 144)	Shortness of Breath	Moderate
23 Jan 2021 (Study Day 144)	Sore Throat	Mild
24 Jan 2021 (Study Day 145)	Body Aches	Mild
24 Jan 2021 (Study Day 145)	Cough	Severe
24 Jan 2021 (Study Day 145)	Diarrhea	Mild
24 Jan 2021 (Study Day 145)	Difficulty Breathing	Mild
24 Jan 2021 (Study Day 145)	Fatigue	Mild
24 Jan 2021 (Study Day 145)	Headache	Mild
24 Jan 2021 (Study Day 145)	Muscle Aches (Myalgia)	Mild
24 Jan 2021 (Study Day 145)	Nasal Congestion	Moderate
24 Jan 2021 (Study Day 145)	Nausea	Moderate
24 Jan 2021 (Study Day 145)	New Loss of Smell	Mild
24 Jan 2021 (Study Day 145)	New Loss of Taste	Mild
24 Jan 2021 (Study Day 145)	Runny Nose (Rhinorrhea)	Moderate
24 Jan 2021 (Study Day 145)	Shortness of Breath	Mild
24 Jan 2021 (Study Day 145)	Sore Throat	Mild
25 Jan 2021 (Study Day 146)	Body Aches	Mild
25 Jan 2021 (Study Day 146)	Cough	Severe
25 Jan 2021 (Study Day 146)	Difficulty Breathing	Mild
25 Jan 2021 (Study Day 146)	Fatigue	Mild
25 Jan 2021 (Study Day 146)	Headache	Mild
25 Jan 2021 (Study Day 146)	Muscle Aches (Myalgia)	Mild
25 Jan 2021 (Study Day 146)	Nasal Congestion	Moderate
25 Jan 2021 (Study Day 146)	Nausea	Mild
25 Jan 2021 (Study Day 146)	New Loss of Smell	Mild
25 Jan 2021 (Study Day 146)	New Loss of Taste	Mild
25 Jan 2021 (Study Day 146)	Runny Nose (Rhinorrhea)	Moderate
25 Jan 2021 (Study Day 146)	Shortness of Breath	Mild
25 Jan 2021 (Study Day 146)	Sore Throat	Mild
26 Jan 2021 (Study Day 147)	Body Aches	Mild
26 Jan 2021 (Study Day 147)	Cough	Severe
26 Jan 2021 (Study Day 147)	Difficulty Breathing	Mild
26 Jan 2021 (Study Day 147)	Fatigue	Moderate
26 Jan 2021 (Study Day 147)	Headache	Severe
26 Jan 2021 (Study Day 147)	Muscle Aches (Myalgia)	Mild
26 Jan 2021 (Study Day 147)	Nasal Congestion	Moderate
26 Jan 2021 (Study Day 147)	Nausea	Moderate
26 Jan 2021 (Study Day 147)	New Loss of Smell	Mild
26 Jan 2021 (Study Day 147)	New Loss of Taste	Mild
26 Jan 2021 (Study Day 147)	Runny Nose (Rhinorrhea)	Moderate

Symptom Date	Symptom	Result
26 Jan 2021 (Study Day 147)	Shortness of Breath	Moderate
26 Jan 2021 (Study Day 147)	Sore Throat	Mild
27 Jan 2021 (Study Day 148)	Body Aches	Mild
27 Jan 2021 (Study Day 148)	Cough	Severe
27 Jan 2021 (Study Day 148)	Difficulty Breathing	Mild
27 Jan 2021 (Study Day 148)	Fatigue	Moderate
27 Jan 2021 (Study Day 148)	Headache	Severe
27 Jan 2021 (Study Day 148)	Muscle Aches (Myalgia)	Mild
27 Jan 2021 (Study Day 148)	Nasal Congestion	Moderate
27 Jan 2021 (Study Day 148)	Nausea	Moderate
27 Jan 2021 (Study Day 148)	New Loss of Smell	Mild
27 Jan 2021 (Study Day 148)	New Loss of Taste	Mild
27 Jan 2021 (Study Day 148)	Runny Nose (Rhinorrhea)	Moderate
27 Jan 2021 (Study Day 148)	Shortness of Breath	Mild
28 Jan 2021 (Study Day 149)	Body Aches	Moderate
28 Jan 2021 (Study Day 149)	Cough	Severe
28 Jan 2021 (Study Day 149)	Difficulty Breathing	Mild
28 Jan 2021 (Study Day 149)	Fatigue	Moderate
28 Jan 2021 (Study Day 149)	Headache	Moderate
28 Jan 2021 (Study Day 149)	Muscle Aches (Myalgia)	Moderate
28 Jan 2021 (Study Day 149)	Nasal Congestion	Moderate
28 Jan 2021 (Study Day 149)	Nausea	Moderate
28 Jan 2021 (Study Day 149)	New Loss of Smell	Mild
28 Jan 2021 (Study Day 149)	New Loss of Taste	Mild
28 Jan 2021 (Study Day 149)	Runny Nose (Rhinorrhea)	Moderate
28 Jan 2021 (Study Day 149)	Shortness of Breath	Mild
29 Jan 2021 (Study Day 150)	Body Aches	Severe
29 Jan 2021 (Study Day 150)	Cough	Severe
29 Jan 2021 (Study Day 150)	Difficulty Breathing	Mild
29 Jan 2021 (Study Day 150)	Fatigue	Moderate
29 Jan 2021 (Study Day 150)	Headache	Mild
29 Jan 2021 (Study Day 150)	Muscle Aches (Myalgia)	Severe
29 Jan 2021 (Study Day 150)	Nasal Congestion	Moderate
29 Jan 2021 (Study Day 150)	Nausea	Mild
29 Jan 2021 (Study Day 150)	New Loss of Smell	Mild
29 Jan 2021 (Study Day 150)	New Loss of Taste	Mild
29 Jan 2021 (Study Day 150)	Runny Nose (Rhinorrhea)	Moderate
29 Jan 2021 (Study Day 150)	Shortness of Breath	Mild
30 Jan 2021 (Study Day 151)	Body Aches	Severe
30 Jan 2021 (Study Day 151)	Cough	Moderate
30 Jan 2021 (Study Day 151)	Difficulty Breathing	Mild
30 Jan 2021 (Study Day 151)	Fatigue	Moderate
30 Jan 2021 (Study Day 151)	Headache	Severe

Symptom Date	Symptom	Result
30 Jan 2021 (Study Day 151)	Muscle Aches (Myalgia)	Severe
30 Jan 2021 (Study Day 151)	Nasal Congestion	Moderate
30 Jan 2021 (Study Day 151)	Nausea	Moderate
30 Jan 2021 (Study Day 151)	New Loss of Smell	Mild
30 Jan 2021 (Study Day 151)	New Loss of Taste	Mild
30 Jan 2021 (Study Day 151)	Runny Nose (Rhinorrhea)	Moderate
30 Jan 2021 (Study Day 151)	Shortness of Breath	Mild
31 Jan 2021 (Study Day 152)	Body Aches	Moderate
31 Jan 2021 (Study Day 152)	Cough	Moderate
31 Jan 2021 (Study Day 152)	Difficulty Breathing	Mild
31 Jan 2021 (Study Day 152)	Fatigue	Moderate
31 Jan 2021 (Study Day 152)	Headache	Severe
31 Jan 2021 (Study Day 152)	Muscle Aches (Myalgia)	Moderate
31 Jan 2021 (Study Day 152)	Nasal Congestion	Moderate
31 Jan 2021 (Study Day 152)	Nausea	Mild
31 Jan 2021 (Study Day 152)	New Loss of Smell	Mild
31 Jan 2021 (Study Day 152)	New Loss of Taste	Mild
31 Jan 2021 (Study Day 152)	Runny Nose (Rhinorrhea)	Moderate
31 Jan 2021 (Study Day 152)	Shortness of Breath	Mild
01 Feb 2021 (Study Day 153)	Body Aches	Moderate
01 Feb 2021 (Study Day 153)	Cough	Moderate
01 Feb 2021 (Study Day 153)	Difficulty Breathing	Mild
01 Feb 2021 (Study Day 153)	Fatigue	Mild
01 Feb 2021 (Study Day 153)	Headache	Severe
01 Feb 2021 (Study Day 153)	Muscle Aches (Myalgia)	Moderate
01 Feb 2021 (Study Day 153)	Nasal Congestion	Moderate
01 Feb 2021 (Study Day 153)	Nausea	Mild
01 Feb 2021 (Study Day 153)	New Loss of Smell	Mild
01 Feb 2021 (Study Day 153)	New Loss of Taste	Mild
01 Feb 2021 (Study Day 153)	Runny Nose (Rhinorrhea)	Moderate
01 Feb 2021 (Study Day 153)	Shortness of Breath	Mild
01 Feb 2021 (Study Day 153)	Sore Throat	Mild
02 Feb 2021 (Study Day 154)	Body Aches	Mild
02 Feb 2021 (Study Day 154)	Cough	Moderate
02 Feb 2021 (Study Day 154)	Difficulty Breathing	Mild
02 Feb 2021 (Study Day 154)	Fatigue	Mild
02 Feb 2021 (Study Day 154)	Headache	Severe
02 Feb 2021 (Study Day 154)	Muscle Aches (Myalgia)	Mild
02 Feb 2021 (Study Day 154)	Nasal Congestion	Moderate
02 Feb 2021 (Study Day 154)	Nausea	Mild
02 Feb 2021 (Study Day 154)	New Loss of Smell	Mild
02 Feb 2021 (Study Day 154)	New Loss of Taste	Mild
02 Feb 2021 (Study Day 154)	Runny Nose (Rhinorrhea)	Moderate

Symptom Date	Symptom	Result
02 Feb 2021 (Study Day 154)	Shortness of Breath	Mild
02 Feb 2021 (Study Day 154)	Sore Throat	Moderate
03 Feb 2021 (Study Day 155)	Body Aches	Mild
03 Feb 2021 (Study Day 155)	Cough	Moderate
03 Feb 2021 (Study Day 155)	Difficulty Breathing	Mild
03 Feb 2021 (Study Day 155)	Fatigue	Moderate
03 Feb 2021 (Study Day 155)	Headache	Severe
03 Feb 2021 (Study Day 155)	Muscle Aches (Myalgia)	Mild
03 Feb 2021 (Study Day 155)	Nasal Congestion	Moderate
03 Feb 2021 (Study Day 155)	Nausea	Mild
03 Feb 2021 (Study Day 155)	New Loss of Smell	Mild
03 Feb 2021 (Study Day 155)	New Loss of Taste	Mild
03 Feb 2021 (Study Day 155)	Runny Nose (Rhinorrhea)	Moderate
03 Feb 2021 (Study Day 155)	Shortness of Breath	Mild
03 Feb 2021 (Study Day 155)	Sore Throat	Mild
04 Feb 2021 (Study Day 156)	Body Aches	Mild
04 Feb 2021 (Study Day 156)	Cough	Moderate
04 Feb 2021 (Study Day 156)	Difficulty Breathing	Mild
04 Feb 2021 (Study Day 156)	Fatigue	Moderate
04 Feb 2021 (Study Day 156)	Headache	Severe
04 Feb 2021 (Study Day 156)	Muscle Aches (Myalgia)	Mild
04 Feb 2021 (Study Day 156)	Nasal Congestion	Moderate
04 Feb 2021 (Study Day 156)	Nausea	Mild
04 Feb 2021 (Study Day 156)	New Loss of Smell	Mild
04 Feb 2021 (Study Day 156)	New Loss of Taste	Mild
04 Feb 2021 (Study Day 156)	Runny Nose (Rhinorrhea)	Moderate
04 Feb 2021 (Study Day 156)	Shortness of Breath	Mild
04 Feb 2021 (Study Day 156)	Sore Throat	Mild
05 Feb 2021 (Study Day 157)	Body Aches	Mild
05 Feb 2021 (Study Day 157)	Cough	Moderate
05 Feb 2021 (Study Day 157)	Difficulty Breathing	Mild
05 Feb 2021 (Study Day 157)	Fatigue	Moderate
05 Feb 2021 (Study Day 157)	Headache	Severe
05 Feb 2021 (Study Day 157)	Muscle Aches (Myalgia)	Mild
05 Feb 2021 (Study Day 157)	Nasal Congestion	Mild
05 Feb 2021 (Study Day 157)	Nausea	Moderate
05 Feb 2021 (Study Day 157)	New Loss of Smell	Mild
05 Feb 2021 (Study Day 157)	New Loss of Taste	Mild
05 Feb 2021 (Study Day 157)	Runny Nose (Rhinorrhea)	Moderate
05 Feb 2021 (Study Day 157)	Shortness of Breath	Mild
05 Feb 2021 (Study Day 157)	Sore Throat	Mild
06 Feb 2021 (Study Day 158)	Cough	Moderate
06 Feb 2021 (Study Day 158)	Fatigue	Moderate

Symptom Date	Symptom	Result
06 Feb 2021 (Study Day 158)	Headache	Severe
06 Feb 2021 (Study Day 158)	Muscle Aches (Myalgia)	Mild
06 Feb 2021 (Study Day 158)	Nasal Congestion	Mild
06 Feb 2021 (Study Day 158)	Nausea	Moderate
06 Feb 2021 (Study Day 158)	New Loss of Smell	Mild
06 Feb 2021 (Study Day 158)	New Loss of Taste	Mild
06 Feb 2021 (Study Day 158)	Runny Nose (Rhinorrhea)	Moderate
06 Feb 2021 (Study Day 158)	Shortness of Breath	Mild
06 Feb 2021 (Study Day 158)	Sore Throat	Mild
07 Feb 2021 (Study Day 159)	Cough	Moderate
07 Feb 2021 (Study Day 159)	Fatigue	Moderate
07 Feb 2021 (Study Day 159)	Headache	Moderate
07 Feb 2021 (Study Day 159)	Muscle Aches (Myalgia)	Mild
07 Feb 2021 (Study Day 159)	Nasal Congestion	Moderate
07 Feb 2021 (Study Day 159)	Nausea	Moderate
07 Feb 2021 (Study Day 159)	New Loss of Smell	Mild
07 Feb 2021 (Study Day 159)	New Loss of Taste	Mild
07 Feb 2021 (Study Day 159)	Runny Nose (Rhinorrhea)	Moderate
07 Feb 2021 (Study Day 159)	Shortness of Breath	Mild
08 Feb 2021 (Study Day 160)	Cough	Moderate
08 Feb 2021 (Study Day 160)	Fatigue	Moderate
08 Feb 2021 (Study Day 160)	Headache	Moderate
08 Feb 2021 (Study Day 160)	Muscle Aches (Myalgia)	Mild
08 Feb 2021 (Study Day 160)	Nasal Congestion	Mild
08 Feb 2021 (Study Day 160)	Nausea	Moderate
08 Feb 2021 (Study Day 160)	New Loss of Smell	Mild
08 Feb 2021 (Study Day 160)	New Loss of Taste	Mild
08 Feb 2021 (Study Day 160)	Runny Nose (Rhinorrhea)	Moderate
08 Feb 2021 (Study Day 160)	Shortness of Breath	Mild
08 Feb 2021 (Study Day 160)	Sore Throat	Mild
10 Feb 2021 (Study Day 162)	Body Aches	Moderate
10 Feb 2021 (Study Day 162)	Cough	Moderate
10 Feb 2021 (Study Day 162)	Fatigue	Moderate
10 Feb 2021 (Study Day 162)	Headache	Mild
10 Feb 2021 (Study Day 162)	Muscle Aches (Myalgia)	Moderate
10 Feb 2021 (Study Day 162)	Nasal Congestion	Mild
10 Feb 2021 (Study Day 162)	Nausea	Moderate
10 Feb 2021 (Study Day 162)	New Loss of Smell	Mild
10 Feb 2021 (Study Day 162)	New Loss of Taste	Mild
10 Feb 2021 (Study Day 162)	Runny Nose (Rhinorrhea)	Moderate
10 Feb 2021 (Study Day 162)	Shortness of Breath	Mild
10 Feb 2021 (Study Day 162)	Sore Throat	Mild
11 Feb 2021 (Study Day 163)	Cough	Moderate

Symptom Date	Symptom	Result
11 Feb 2021 (Study Day 163)	Fatigue	Moderate
11 Feb 2021 (Study Day 163)	Headache	Moderate
11 Feb 2021 (Study Day 163)	Muscle Aches (Myalgia)	Mild
11 Feb 2021 (Study Day 163)	Nasal Congestion	Mild
11 Feb 2021 (Study Day 163)	Nausea	Severe
11 Feb 2021 (Study Day 163)	New Loss of Smell	Mild
11 Feb 2021 (Study Day 163)	New Loss of Taste	Mild
11 Feb 2021 (Study Day 163)	Runny Nose (Rhinorrhea)	Moderate
11 Feb 2021 (Study Day 163)	Shortness of Breath	Mild
12 Feb 2021 (Study Day 164)	Cough	Moderate
12 Feb 2021 (Study Day 164)	Fatigue	Mild
12 Feb 2021 (Study Day 164)	Headache	Mild
12 Feb 2021 (Study Day 164)	Nasal Congestion	Mild
12 Feb 2021 (Study Day 164)	Nausea	Mild
12 Feb 2021 (Study Day 164)	New Loss of Smell	Mild
12 Feb 2021 (Study Day 164)	New Loss of Taste	Mild
12 Feb 2021 (Study Day 164)	Runny Nose (Rhinorrhea)	Moderate
12 Feb 2021 (Study Day 164)	Shortness of Breath	Mild
13 Feb 2021 (Study Day 165)	Body Aches	Mild
13 Feb 2021 (Study Day 165)	Cough	Moderate
13 Feb 2021 (Study Day 165)	Fatigue	Mild
13 Feb 2021 (Study Day 165)	Headache	Mild
13 Feb 2021 (Study Day 165)	Muscle Aches (Myalgia)	Mild
13 Feb 2021 (Study Day 165)	Nasal Congestion	Mild
13 Feb 2021 (Study Day 165)	Nausea	Moderate
13 Feb 2021 (Study Day 165)	New Loss of Smell	Mild
13 Feb 2021 (Study Day 165)	New Loss of Taste	Mild
13 Feb 2021 (Study Day 165)	Runny Nose (Rhinorrhea)	Moderate
13 Feb 2021 (Study Day 165)	Shortness of Breath	Mild
14 Feb 2021 (Study Day 166)	Body Aches	Moderate
14 Feb 2021 (Study Day 166)	Cough	Moderate
14 Feb 2021 (Study Day 166)	Fatigue	Moderate
14 Feb 2021 (Study Day 166)	Muscle Aches (Myalgia)	Moderate
14 Feb 2021 (Study Day 166)	Nasal Congestion	Mild
14 Feb 2021 (Study Day 166)	Nausea	Mild
14 Feb 2021 (Study Day 166)	New Loss of Smell	Mild
14 Feb 2021 (Study Day 166)	Runny Nose (Rhinorrhea)	Moderate
14 Feb 2021 (Study Day 166)	Shortness of Breath	Mild
15 Feb 2021 (Study Day 167)	Body Aches	Mild
15 Feb 2021 (Study Day 167)	Cough	Moderate
15 Feb 2021 (Study Day 167)	Fatigue	Moderate
15 Feb 2021 (Study Day 167)	Muscle Aches (Myalgia)	Mild
15 Feb 2021 (Study Day 167)	Nausea	Mild

Symptom Date	Symptom	Result
15 Feb 2021 (Study Day 167)	New Loss of Smell	Mild
15 Feb 2021 (Study Day 167)	Runny Nose (Rhinorrhea)	Moderate
15 Feb 2021 (Study Day 167)	Shortness of Breath	Mild
16 Feb 2021 (Study Day 168)	Body Aches	Severe
16 Feb 2021 (Study Day 168)	Chills	Moderate
16 Feb 2021 (Study Day 168)	Cough	Mild
16 Feb 2021 (Study Day 168)	Fatigue	Severe
16 Feb 2021 (Study Day 168)	Headache	Severe
16 Feb 2021 (Study Day 168)	Muscle Aches (Myalgia)	Severe
16 Feb 2021 (Study Day 168)	Nausea	Severe
16 Feb 2021 (Study Day 168)	New Loss of Smell	Mild
16 Feb 2021 (Study Day 168)	Runny Nose (Rhinorrhea)	Mild
16 Feb 2021 (Study Day 168)	Shortness of Breath	Mild
16 Feb 2021 (Study Day 168)	Sore Throat	Mild
17 Feb 2021 (Study Day 169)	Body Aches	Severe
17 Feb 2021 (Study Day 169)	Cough	Moderate
17 Feb 2021 (Study Day 169)	Fatigue	Severe
17 Feb 2021 (Study Day 169)	Headache	Moderate
17 Feb 2021 (Study Day 169)	Muscle Aches (Myalgia)	Severe
17 Feb 2021 (Study Day 169)	Nasal Congestion	Mild
17 Feb 2021 (Study Day 169)	Nausea	Moderate
17 Feb 2021 (Study Day 169)	Runny Nose (Rhinorrhea)	Mild
17 Feb 2021 (Study Day 169)	Shortness of Breath	Moderate
18 Feb 2021 (Study Day 170)	Body Aches	Mild
18 Feb 2021 (Study Day 170)	Cough	Mild
18 Feb 2021 (Study Day 170)	Fatigue	Severe
18 Feb 2021 (Study Day 170)	Headache	Moderate
18 Feb 2021 (Study Day 170)	Muscle Aches (Myalgia)	Mild
18 Feb 2021 (Study Day 170)	Nausea	Mild
18 Feb 2021 (Study Day 170)	Runny Nose (Rhinorrhea)	Mild
18 Feb 2021 (Study Day 170)	Shortness of Breath	Mild
19 Feb 2021 (Study Day 171)	Cough	Mild
19 Feb 2021 (Study Day 171)	Fatigue	Severe
19 Feb 2021 (Study Day 171)	Headache	Severe
19 Feb 2021 (Study Day 171)	Muscle Aches (Myalgia)	Mild
19 Feb 2021 (Study Day 171)	Nasal Congestion	Mild
19 Feb 2021 (Study Day 171)	Nausea	Moderate
19 Feb 2021 (Study Day 171)	Runny Nose (Rhinorrhea)	Mild
19 Feb 2021 (Study Day 171)	Shortness of Breath	Mild
19 Feb 2021 (Study Day 171)	Vomiting	Moderate
20 Feb 2021 (Study Day 172)	Cough	Mild
20 Feb 2021 (Study Day 172)	Fatigue	Moderate
20 Feb 2021 (Study Day 172)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
20 Feb 2021 (Study Day 172)	Nasal Congestion	Mild
20 Feb 2021 (Study Day 172)	Nausea	Moderate
20 Feb 2021 (Study Day 172)	Runny Nose (Rhinorrhea)	Mild
20 Feb 2021 (Study Day 172)	Shortness of Breath	Mild
21 Feb 2021 (Study Day 173)	Cough	Mild
21 Feb 2021 (Study Day 173)	Fatigue	Moderate
21 Feb 2021 (Study Day 173)	Muscle Aches (Myalgia)	Mild
21 Feb 2021 (Study Day 173)	Nausea	Severe
21 Feb 2021 (Study Day 173)	Runny Nose (Rhinorrhea)	Mild
21 Feb 2021 (Study Day 173)	Shortness of Breath	Mild
22 Feb 2021 (Study Day 174)	Cough	Mild
22 Feb 2021 (Study Day 174)	Fatigue	Moderate
22 Feb 2021 (Study Day 174)	Muscle Aches (Myalgia)	Mild
22 Feb 2021 (Study Day 174)	Nausea	Severe
22 Feb 2021 (Study Day 174)	Runny Nose (Rhinorrhea)	Mild
23 Feb 2021 (Study Day 175)	Cough	Mild
23 Feb 2021 (Study Day 175)	Fatigue	Moderate
23 Feb 2021 (Study Day 175)	Nausea	Severe
23 Feb 2021 (Study Day 175)	Runny Nose (Rhinorrhea)	Mild
24 Feb 2021 (Study Day 176)	Cough	Mild
24 Feb 2021 (Study Day 176)	Fatigue	Moderate
24 Feb 2021 (Study Day 176)	Headache	Mild
24 Feb 2021 (Study Day 176)	Nausea	Moderate
24 Feb 2021 (Study Day 176)	Runny Nose (Rhinorrhea)	Mild
25 Feb 2021 (Study Day 177)	Fatigue	Moderate
25 Feb 2021 (Study Day 177)	Headache	Mild
25 Feb 2021 (Study Day 177)	Nausea	Moderate
25 Feb 2021 (Study Day 177)	Runny Nose (Rhinorrhea)	Mild
26 Feb 2021 (Study Day 178)	Fatigue	Mild
26 Feb 2021 (Study Day 178)	Nausea	Moderate
26 Feb 2021 (Study Day 178)	Runny Nose (Rhinorrhea)	Mild
27 Feb 2021 (Study Day 179)	Fatigue	Moderate
27 Feb 2021 (Study Day 179)	Headache	Mild
27 Feb 2021 (Study Day 179)	Nausea	Severe
28 Feb 2021 (Study Day 180)	Fatigue	Mild
28 Feb 2021 (Study Day 180)	Nausea	Moderate
01 Mar 2021 (Study Day 181)	Fatigue	Mild
01 Mar 2021 (Study Day 181)	Nausea	Mild
01 Mar 2021 (Study Day 181)	Runny Nose (Rhinorrhea)	Mild
02 Mar 2021 (Study Day 182)	Fatigue	Mild
02 Mar 2021 (Study Day 182)	Headache	Mild
02 Mar 2021 (Study Day 182)	Nausea	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
17 Jan 2021 (Study Day 138)	Oxygen Saturation	91%
17 Jan 2021 - 18 Jan 2021 (Study Day 138-139)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
19 Jan 2021 - 19 Jan 2021 (Study Day 140-140)	Radiographical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID19 lasted for 51 days, after which it was considered to be recovered/resolved on 02 Mar 2021 (Study Day 182). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004604	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Generalized joint pain	Not reported - Ongoing
Drug hypersensitivity	Compazine allergy	Not reported - Ongoing
Polycystic ovaries	Polycystic ovary syndrome	2014 - Ongoing
Nausea	Nausea	2017 - Ongoing
Fibromyalgia	Fibromyalgia	2018 - Ongoing
Gastrooesophageal reflux disease	Acid reflex	2018 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2018 - Ongoing
Migraine	Migraines	2019 - Ongoing
Drug resistance	Lepton resistance	2020 - Ongoing
Clostridium difficile infection	C. diff infection	17 Aug 2020 (Study Day -16) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Iron	Not reported - Ongoing	Supplement - Mineral
Vitamin d nos	Not reported - Ongoing	Supplement - Vitamin
Vitamins nos	Not reported - Ongoing	Supplement - Vitamin
Ethinylestradiol; norgestimate	2014 - Ongoing	Pcos
Ondansetron	2017 - Ongoing	Nausea
Esomeprazole magnesium	2018 - Ongoing	Acid Reflex
Pregabalin	2018 - 10 Oct 2020 (Study Day 39)	Fibromyalgia
Sucralfate	2018 - 15 Mar 2021 (Study Day 195)	Acid Reflex
Baclofen	2019 - 17 Mar 2021 (Study Day 197)	Acid Reflex
Zonisamide	2019 - Ongoing	Migraines
Meloxicam	2020 - Ongoing	Generalized Joint Pain
Ubidecarenone	2020 - Ongoing	Supplement For Leptin
Vancomycin	17 Aug 2020 (Study Day -16) - 22 Sep 2020 (Study Day 21)	C. Diff Infection
Acetylsalicylic acid; caffeine; paracetamol	02 Sep 2020 (Study Day 1) - 05 Sep 2020 (Study Day 4)	Muscle Aches
Paracetamol	02 Sep 2020 (Study Day 1) - 05 Sep 2020 (Study Day 4)	Muscle Aches
Acetylsalicylic acid; caffeine; paracetamol	02 Oct 2020 (Study Day 31) - Ongoing	Body Aches, Generalized Joint Pain, Headache, And Fatigue
Ketorolac tromethamine	02 Oct 2020 (Study Day 31) - Ongoing	Fatigue, Body Aches, Generalized Joint Pain, And Headache
Paracetamol	02 Oct 2020 (Study Day 31) - Ongoing	Body Aches,generalized Â joint Paint, Headache, Fatigue
Oxycodone	12 Oct 2020 (Study Day 41) - 19 Oct 2020 (Study Day 48)	Generalized Muscle Pain
Dexamethasone	15 Oct 2020 (Study Day 44) - 25 Oct 2020 (Study Day 54)	Generalized Joint Pain
Nortriptyline	22 Oct 2020 (Study Day 51) - Ongoing	Fibromyalgia
Cefpodoxime	12 Nov 2020 (Study Day 72) - 22 Nov 2020 (Study Day 82)	Sinus Infection And Ear Infection
Monoclonal antibodies	Jan 2021 - Jan 2021	Symptomatic COVID-19
Cxr*	16 Jan 2021 (Study Day 137) - 16 Jan 2021 (Study Day 137)	Adverse Event
Ekg*	16 Jan 2021 (Study Day 137) - 16 Jan 2021 (Study Day 137)	Adverse Event
Metoclopramide	16 Jan 2021 (Study Day 137) - 05 Feb 2021 (Study Day 157)	Nausea Related To COVID-19
Other antivirals	16 Jan 2021 (Study Day 137) - 16 Jan 2021 (Study Day 137)	COVID-19
Benzonatate	17 Jan 2021 (Study Day 138) - 25 Feb 2021 (Study Day 177)	Symptomatic COVID-19 Cough
Ct chest angiogram*	19 Jan 2021 (Study Day 140) - 19 Jan 2021 (Study Day 140)	Adverse Event
Ekg*	19 Jan 2021 (Study Day 140) - 19 Jan 2021 (Study Day 140)	Adverse Event
Fluticasone propionate	23 Jan 2021 (Study Day 144) - Ongoing	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	03 Feb 2021 (Study Day 155) - 03 Feb 2021 (Study Day 155)	COVID-19
Prednisone	04 Feb 2021 (Study Day 156) - 04 Feb 2021 (Study Day 156)	COVID-19
Olanzapine	05 Feb 2021 (Study Day 157) - Ongoing	Migraines
Prednisone	05 Feb 2021 (Study Day 157) - 05 Feb 2021 (Study Day 157)	COVID-19
Prednisone	06 Feb 2021 (Study Day 158) - 06 Feb 2021 (Study Day 158)	COVID-19
Prednisone	07 Feb 2021 (Study Day 159) - 07 Feb 2021 (Study Day 159)	COVID-19
Galcanezumab	04 Mar 2021 (Study Day 184) - Ongoing	Migraines
Baclofen	17 Mar 2021 (Study Day 197) - Ongoing	Acid Reflux
Colestyramine	17 Mar 2021 (Study Day 197) - 17 Mar 2021 (Study Day 197)	Bile Reflux
Linaclotide	17 Mar 2021 (Study Day 197) - Ongoing	Bile Reflux
Colestipol hydrochloride	23 Mar 2021 (Study Day 203) - Ongoing	Bile Reflux

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	12 Oct 2020 (Study Day 41) - 15 Nov 2020 (Study Day 75)
Fibromyalgia	Grade 2/moderate	Related	12 Oct 2020 (Study Day 41) - 15 Nov 2020 (Study Day 75)
Nausea	Grade 2/moderate	Related	12 Oct 2020 (Study Day 41) - 15 Nov 2020 (Study Day 75)
Ear Infection	Grade 2/moderate	Not related	12 Nov 2020 (Study Day 72) - 22 Nov 2020 (Study Day 82)
Sinusitis	Grade 2/moderate	Not related	12 Nov 2020 (Study Day 72) - 22 Nov 2020 (Study Day 82)
COVID-19	Grade 1/mild	Not related	11 Jan 2021 (Study Day 132) - 02 Mar 2021 (Study Day 182)
COVID-19 Pneumonia	Grade 1/mild	Not related	19 Jan 2021 (Study Day 140) - 02 Mar 2021 (Study Day 182)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	16 Mar 2021 (Study Day 196) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US380-2185 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	12 Oct 2020 (Study Day 34)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID 19	COVID-19	Grade 1/mild	Not related	11 Nov 2020 (Study Day 64) – 02 Dec 2020 (Study Day 85)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US380-2185, a 52-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 12 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 11 Nov 2020 (Study Day 64), 63 days after the first dose and 30 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 34, 12 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Nov 2020 (Study Day 64), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Nov 2020 (Study Day 64)	Nasal Congestion	Moderate
11 Nov 2020 (Study Day 64)	Runny Nose (Rhinorrhea)	Moderate
12 Nov 2020 (Study Day 65)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 65)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
12 Nov 2020 (Study Day 65)	Sore Throat	Mild
13 Nov 2020 (Study Day 66)	Fatigue	Moderate
13 Nov 2020 (Study Day 66)	Nasal Congestion	Moderate
13 Nov 2020 (Study Day 66)	Runny Nose (Rhinorrhea)	Moderate
13 Nov 2020 (Study Day 66)	Sore Throat	Mild
14 Nov 2020 (Study Day 67)	Body Aches	Mild
14 Nov 2020 (Study Day 67)	Chills	Mild
14 Nov 2020 (Study Day 67)	Cough	Mild
14 Nov 2020 (Study Day 67)	Difficulty Breathing	Mild
14 Nov 2020 (Study Day 67)	Fatigue	Severe
14 Nov 2020 (Study Day 67)	Headache	Mild
14 Nov 2020 (Study Day 67)	Muscle Aches (Myalgia)	Mild
14 Nov 2020 (Study Day 67)	Nasal Congestion	Moderate
14 Nov 2020 (Study Day 67)	O2 Saturation (%)	89
14 Nov 2020 (Study Day 67)	Runny Nose (Rhinorrhea)	Moderate
14 Nov 2020 (Study Day 67)	Shortness of Breath	Moderate
14 Nov 2020 (Study Day 67)	Sore Throat	Mild
15 Nov 2020 (Study Day 68)	Body Aches	Moderate
15 Nov 2020 (Study Day 68)	Chills	Moderate
15 Nov 2020 (Study Day 68)	Cough	Moderate
15 Nov 2020 (Study Day 68)	Difficulty Breathing	Moderate
15 Nov 2020 (Study Day 68)	Fatigue	Severe
15 Nov 2020 (Study Day 68)	Headache	Moderate
15 Nov 2020 (Study Day 68)	Muscle Aches (Myalgia)	Moderate
15 Nov 2020 (Study Day 68)	Nasal Congestion	Moderate
15 Nov 2020 (Study Day 68)	O2 Saturation (%)	92
15 Nov 2020 (Study Day 68)	Runny Nose (Rhinorrhea)	Moderate
15 Nov 2020 (Study Day 68)	Shortness of Breath	Moderate
15 Nov 2020 (Study Day 68)	Sore Throat	Mild
16 Nov 2020 (Study Day 69)	Body Aches	Moderate
16 Nov 2020 (Study Day 69)	Chills	Moderate
16 Nov 2020 (Study Day 69)	Cough	Moderate
16 Nov 2020 (Study Day 69)	Difficulty Breathing	Moderate
16 Nov 2020 (Study Day 69)	Fatigue	Severe
16 Nov 2020 (Study Day 69)	Headache	Mild
16 Nov 2020 (Study Day 69)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 69)	Nasal Congestion	Moderate
16 Nov 2020 (Study Day 69)	Runny Nose (Rhinorrhea)	Moderate
16 Nov 2020 (Study Day 69)	Shortness of Breath	Moderate
16 Nov 2020 (Study Day 69)	Sore Throat	Mild
17 Nov 2020 (Study Day 70)	Body Aches	Mild
17 Nov 2020 (Study Day 70)	Chills	Mild
17 Nov 2020 (Study Day 70)	Cough	Mild

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 70)	Difficulty Breathing	Moderate
17 Nov 2020 (Study Day 70)	Fatigue	Moderate
17 Nov 2020 (Study Day 70)	Headache	Mild
17 Nov 2020 (Study Day 70)	Muscle Aches (Myalgia)	Mild
17 Nov 2020 (Study Day 70)	Nasal Congestion	Moderate
17 Nov 2020 (Study Day 70)	Runny Nose (Rhinorrhea)	Moderate
17 Nov 2020 (Study Day 70)	Shortness of Breath	Moderate
17 Nov 2020 (Study Day 70)	Sore Throat	Mild
17 Nov 2020 (Study Day 70)	Temperature (°F)	100.5
18 Nov 2020 (Study Day 71)	Body Aches	Mild
18 Nov 2020 (Study Day 71)	Chills	Mild
18 Nov 2020 (Study Day 71)	Cough	Mild
18 Nov 2020 (Study Day 71)	Difficulty Breathing	Moderate
18 Nov 2020 (Study Day 71)	Fatigue	Moderate
18 Nov 2020 (Study Day 71)	Headache	Mild
18 Nov 2020 (Study Day 71)	Muscle Aches (Myalgia)	Mild
18 Nov 2020 (Study Day 71)	Nasal Congestion	Moderate
18 Nov 2020 (Study Day 71)	Runny Nose (Rhinorrhea)	Moderate
18 Nov 2020 (Study Day 71)	Shortness of Breath	Moderate
18 Nov 2020 (Study Day 71)	Sore Throat	Mild
19 Nov 2020 (Study Day 72)	Body Aches	Moderate
19 Nov 2020 (Study Day 72)	Chills	Mild
19 Nov 2020 (Study Day 72)	Cough	Mild
19 Nov 2020 (Study Day 72)	Difficulty Breathing	Moderate
19 Nov 2020 (Study Day 72)	Fatigue	Severe
19 Nov 2020 (Study Day 72)	Headache	Mild
19 Nov 2020 (Study Day 72)	Muscle Aches (Myalgia)	Moderate
19 Nov 2020 (Study Day 72)	Nasal Congestion	Moderate
19 Nov 2020 (Study Day 72)	Runny Nose (Rhinorrhea)	Moderate
19 Nov 2020 (Study Day 72)	Shortness of Breath	Moderate
19 Nov 2020 (Study Day 72)	Sore Throat	Mild
20 Nov 2020 (Study Day 73)	Body Aches	Moderate
20 Nov 2020 (Study Day 73)	Chills	Mild
20 Nov 2020 (Study Day 73)	Cough	Moderate
20 Nov 2020 (Study Day 73)	Difficulty Breathing	Moderate
20 Nov 2020 (Study Day 73)	Fatigue	Moderate
20 Nov 2020 (Study Day 73)	Headache	Mild
20 Nov 2020 (Study Day 73)	Muscle Aches (Myalgia)	Moderate
20 Nov 2020 (Study Day 73)	Nasal Congestion	Moderate
20 Nov 2020 (Study Day 73)	Runny Nose (Rhinorrhea)	Moderate
20 Nov 2020 (Study Day 73)	Shortness of Breath	Moderate
20 Nov 2020 (Study Day 73)	Sore Throat	Mild
21 Nov 2020 (Study Day 74)	Body Aches	Mild

Symptom Date	Symptom	Result
21 Nov 2020 (Study Day 74)	Cough	Moderate
21 Nov 2020 (Study Day 74)	Difficulty Breathing	Moderate
21 Nov 2020 (Study Day 74)	Fatigue	Moderate
21 Nov 2020 (Study Day 74)	Headache	Mild
21 Nov 2020 (Study Day 74)	Muscle Aches (Myalgia)	Mild
21 Nov 2020 (Study Day 74)	Nasal Congestion	Moderate
21 Nov 2020 (Study Day 74)	Runny Nose (Rhinorrhea)	Moderate
21 Nov 2020 (Study Day 74)	Shortness of Breath	Moderate
21 Nov 2020 (Study Day 74)	Sore Throat	Mild
22 Nov 2020 (Study Day 75)	Body Aches	Mild
22 Nov 2020 (Study Day 75)	Cough	Moderate
22 Nov 2020 (Study Day 75)	Difficulty Breathing	Moderate
22 Nov 2020 (Study Day 75)	Fatigue	Moderate
22 Nov 2020 (Study Day 75)	Headache	Mild
22 Nov 2020 (Study Day 75)	Muscle Aches (Myalgia)	Mild
22 Nov 2020 (Study Day 75)	Nasal Congestion	Moderate
22 Nov 2020 (Study Day 75)	Runny Nose (Rhinorrhea)	Moderate
22 Nov 2020 (Study Day 75)	Shortness of Breath	Moderate
22 Nov 2020 (Study Day 75)	Sore Throat	Mild
23 Nov 2020 (Study Day 76)	Body Aches	Moderate
23 Nov 2020 (Study Day 76)	Cough	Moderate
23 Nov 2020 (Study Day 76)	Difficulty Breathing	Moderate
23 Nov 2020 (Study Day 76)	Fatigue	Moderate
23 Nov 2020 (Study Day 76)	Headache	Mild
23 Nov 2020 (Study Day 76)	Muscle Aches (Myalgia)	Moderate
23 Nov 2020 (Study Day 76)	Nasal Congestion	Moderate
23 Nov 2020 (Study Day 76)	Runny Nose (Rhinorrhea)	Moderate
23 Nov 2020 (Study Day 76)	Shortness of Breath	Moderate
23 Nov 2020 (Study Day 76)	Sore Throat	Mild
24 Nov 2020 (Study Day 77)	Body Aches	Moderate
24 Nov 2020 (Study Day 77)	Cough	Moderate
24 Nov 2020 (Study Day 77)	Difficulty Breathing	Moderate
24 Nov 2020 (Study Day 77)	Fatigue	Moderate
24 Nov 2020 (Study Day 77)	Headache	Mild
24 Nov 2020 (Study Day 77)	Muscle Aches (Myalgia)	Moderate
24 Nov 2020 (Study Day 77)	Nasal Congestion	Moderate
24 Nov 2020 (Study Day 77)	Runny Nose (Rhinorrhea)	Moderate
24 Nov 2020 (Study Day 77)	Shortness of Breath	Moderate
24 Nov 2020 (Study Day 77)	Sore Throat	Mild
25 Nov 2020 (Study Day 78)	Body Aches	Mild
25 Nov 2020 (Study Day 78)	Cough	Moderate
25 Nov 2020 (Study Day 78)	Difficulty Breathing	Moderate
25 Nov 2020 (Study Day 78)	Fatigue	Moderate

Symptom Date	Symptom	Result
25 Nov 2020 (Study Day 78)	Headache	Mild
25 Nov 2020 (Study Day 78)	Muscle Aches (Myalgia)	Mild
25 Nov 2020 (Study Day 78)	Nasal Congestion	Moderate
25 Nov 2020 (Study Day 78)	Runny Nose (Rhinorrhea)	Moderate
25 Nov 2020 (Study Day 78)	Shortness of Breath	Moderate
25 Nov 2020 (Study Day 78)	Sore Throat	Mild
26 Nov 2020 (Study Day 79)	Body Aches	Mild
26 Nov 2020 (Study Day 79)	Cough	Moderate
26 Nov 2020 (Study Day 79)	Difficulty Breathing	Moderate
26 Nov 2020 (Study Day 79)	Fatigue	Moderate
26 Nov 2020 (Study Day 79)	Headache	Mild
26 Nov 2020 (Study Day 79)	Muscle Aches (Myalgia)	Mild
26 Nov 2020 (Study Day 79)	Nasal Congestion	Moderate
26 Nov 2020 (Study Day 79)	Runny Nose (Rhinorrhea)	Moderate
26 Nov 2020 (Study Day 79)	Shortness of Breath	Moderate
26 Nov 2020 (Study Day 79)	Sore Throat	Mild
27 Nov 2020 (Study Day 80)	Cough	Mild
27 Nov 2020 (Study Day 80)	Difficulty Breathing	Moderate
27 Nov 2020 (Study Day 80)	Fatigue	Moderate
27 Nov 2020 (Study Day 80)	Headache	Mild
27 Nov 2020 (Study Day 80)	Nasal Congestion	Moderate
27 Nov 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Moderate
27 Nov 2020 (Study Day 80)	Shortness of Breath	Moderate
28 Nov 2020 (Study Day 81)	Cough	Mild
28 Nov 2020 (Study Day 81)	Difficulty Breathing	Moderate
28 Nov 2020 (Study Day 81)	Fatigue	Moderate
28 Nov 2020 (Study Day 81)	Headache	Mild
28 Nov 2020 (Study Day 81)	Nasal Congestion	Moderate
28 Nov 2020 (Study Day 81)	Runny Nose (Rhinorrhea)	Moderate
28 Nov 2020 (Study Day 81)	Shortness of Breath	Moderate
29 Nov 2020 (Study Day 82)	Cough	Mild
29 Nov 2020 (Study Day 82)	Difficulty Breathing	Mild
29 Nov 2020 (Study Day 82)	Fatigue	Mild
29 Nov 2020 (Study Day 82)	Headache	Mild
29 Nov 2020 (Study Day 82)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 82)	Shortness of Breath	Mild
30 Nov 2020 (Study Day 83)	Cough	Mild
30 Nov 2020 (Study Day 83)	Difficulty Breathing	Mild
30 Nov 2020 (Study Day 83)	Fatigue	Mild
30 Nov 2020 (Study Day 83)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 83)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
01 Dec 2020 (Study Day 84)	Cough	Mild
01 Dec 2020 (Study Day 84)	Difficulty Breathing	Mild
01 Dec 2020 (Study Day 84)	Fatigue	Mild
01 Dec 2020 (Study Day 84)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
01 Dec 2020 (Study Day 84)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
14 Nov 2020 (Study Day 67)	Oxygen Saturation	89%
14 Nov 2020 - 15 Nov 2020 (Study Day 67-68)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID 19 lasted for 22 days, after which it was considered to be recovered/resolved on 02 Dec 2020 (Study Day 85). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000771	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Tonsillectomy	Tonsils removed	1983 - Not reported
Wrist fracture	Left wrist fracture	2005 - Not reported
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Skin neoplasm excision	Basal cell removal	2010 - Not reported
Asthma	Allergy related asthma	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	1975 - Ongoing	Seasonal Allergies
Atorvastatin	2010 - Ongoing	High Cholesterol
Calcium; colecalciferol	2010 - Ongoing	Supplement
Montelukast sodium	2010 - Ongoing	Seasonal Allergies
Omeprazole	2010 - Ongoing	Gerd
Colecalciferol	2015 - Ongoing	Supplement
Hydrochlorothiazide	2015 - Ongoing	Fluid Retention
Krill oil	2015 - Ongoing	High Cholesterol
Norethisterone	2015 - Ongoing	Birth Control
Salbutamol	2020 - Ongoing	Allergy Related Asthma
Ascorbic acid	Mar 2020 - Ongoing	Supplement
Cefalexin	07 Oct 2020 (Study Day 29) - 10 Oct 2020 (Study Day 32)	Post Opp Surgery
Liposuction*	07 Oct 2020 (Study Day 29) - 07 Oct 2020 (Study Day 29)	Other, Elective
Paracetamol	14 Nov 2020 (Study Day 67) - Ongoing	Headache
Acetylsalicylic acid	17 Nov 2020 (Study Day 70) - Ongoing	Dvt Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	11 Nov 2020 (Study Day 64) - 02 Dec 2020 (Study Day 85)
Haemoptysis	Grade 1/mild	Not related	20 Nov 2020 (Study Day 73) - 20 Nov 2020 (Study Day 73)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US384-2040 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	18 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	16 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 42) – 04 Dec 2020 (Study Day 78)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US384-2040, a 49-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 18 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 16 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 29 Oct 2020 (Study Day 42), 41 days after the first dose and 13 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 16 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 03 Nov 2020 (Study Day 47), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
03 Nov 2020 (Study Day 47)	Body Aches	Mild
03 Nov 2020 (Study Day 47)	Cough	Mild
03 Nov 2020 (Study Day 47)	Fatigue	Mild
03 Nov 2020 (Study Day 47)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
03 Nov 2020 (Study Day 47)	Sore Throat	Mild
04 Nov 2020 (Study Day 48)	Body Aches	Moderate
04 Nov 2020 (Study Day 48)	Chills	Mild
04 Nov 2020 (Study Day 48)	Cough	Mild
04 Nov 2020 (Study Day 48)	Difficulty Breathing	Mild
04 Nov 2020 (Study Day 48)	Fatigue	Moderate
04 Nov 2020 (Study Day 48)	Headache	Moderate
04 Nov 2020 (Study Day 48)	Muscle Aches (Myalgia)	Moderate
04 Nov 2020 (Study Day 48)	Nasal Congestion	Moderate
04 Nov 2020 (Study Day 48)	Runny Nose (Rhinorrhea)	Moderate
04 Nov 2020 (Study Day 48)	Shortness of Breath	Mild
05 Nov 2020 (Study Day 49)	Body Aches	Moderate
05 Nov 2020 (Study Day 49)	Chills	Mild
05 Nov 2020 (Study Day 49)	Cough	Mild
05 Nov 2020 (Study Day 49)	Difficulty Breathing	Mild
05 Nov 2020 (Study Day 49)	Fatigue	Mild
05 Nov 2020 (Study Day 49)	Headache	Moderate
05 Nov 2020 (Study Day 49)	Muscle Aches (Myalgia)	Moderate
05 Nov 2020 (Study Day 49)	Nasal Congestion	Mild
05 Nov 2020 (Study Day 49)	Nausea	Mild
05 Nov 2020 (Study Day 49)	New Loss of Smell	Mild
05 Nov 2020 (Study Day 49)	New Loss of Taste	Mild
05 Nov 2020 (Study Day 49)	Runny Nose (Rhinorrhea)	Mild
05 Nov 2020 (Study Day 49)	Shortness of Breath	Mild
06 Nov 2020 (Study Day 50)	Body Aches	Moderate
06 Nov 2020 (Study Day 50)	Chills	Moderate
06 Nov 2020 (Study Day 50)	Cough	Mild
06 Nov 2020 (Study Day 50)	Difficulty Breathing	Mild
06 Nov 2020 (Study Day 50)	Fatigue	Mild
06 Nov 2020 (Study Day 50)	Headache	Moderate
06 Nov 2020 (Study Day 50)	Muscle Aches (Myalgia)	Moderate
06 Nov 2020 (Study Day 50)	Nasal Congestion	Mild
06 Nov 2020 (Study Day 50)	New Loss of Smell	Mild
06 Nov 2020 (Study Day 50)	New Loss of Taste	Mild
06 Nov 2020 (Study Day 50)	Runny Nose (Rhinorrhea)	Mild
06 Nov 2020 (Study Day 50)	Shortness of Breath	Mild
07 Nov 2020 (Study Day 51)	Body Aches	Moderate
07 Nov 2020 (Study Day 51)	Chills	Moderate
07 Nov 2020 (Study Day 51)	Cough	Moderate
07 Nov 2020 (Study Day 51)	Difficulty Breathing	Moderate
07 Nov 2020 (Study Day 51)	Fatigue	Moderate
07 Nov 2020 (Study Day 51)	Headache	Moderate
07 Nov 2020 (Study Day 51)	Muscle Aches (Myalgia)	Moderate

Symptom Date	Symptom	Result
07 Nov 2020 (Study Day 51)	Nasal Congestion	Mild
07 Nov 2020 (Study Day 51)	Nausea	Mild
07 Nov 2020 (Study Day 51)	New Loss of Smell	Moderate
07 Nov 2020 (Study Day 51)	New Loss of Taste	Moderate
07 Nov 2020 (Study Day 51)	Runny Nose (Rhinorrhea)	Mild
07 Nov 2020 (Study Day 51)	Shortness of Breath	Moderate
08 Nov 2020 (Study Day 52)	Body Aches	Moderate
08 Nov 2020 (Study Day 52)	Chills	Moderate
08 Nov 2020 (Study Day 52)	Cough	Moderate
08 Nov 2020 (Study Day 52)	Difficulty Breathing	Moderate
08 Nov 2020 (Study Day 52)	Fatigue	Moderate
08 Nov 2020 (Study Day 52)	Headache	Moderate
08 Nov 2020 (Study Day 52)	Muscle Aches (Myalgia)	Moderate
08 Nov 2020 (Study Day 52)	Nasal Congestion	Mild
08 Nov 2020 (Study Day 52)	Nausea	Mild
08 Nov 2020 (Study Day 52)	New Loss of Smell	Moderate
08 Nov 2020 (Study Day 52)	New Loss of Taste	Moderate
08 Nov 2020 (Study Day 52)	O2 Saturation (%)	92
08 Nov 2020 (Study Day 52)	Shortness of Breath	Moderate
09 Nov 2020 (Study Day 53)	Body Aches	Moderate
09 Nov 2020 (Study Day 53)	Chills	Moderate
09 Nov 2020 (Study Day 53)	Cough	Moderate
09 Nov 2020 (Study Day 53)	Difficulty Breathing	Moderate
09 Nov 2020 (Study Day 53)	Fatigue	Moderate
09 Nov 2020 (Study Day 53)	Headache	Moderate
09 Nov 2020 (Study Day 53)	Muscle Aches (Myalgia)	Moderate
09 Nov 2020 (Study Day 53)	Nausea	Moderate
09 Nov 2020 (Study Day 53)	New Loss of Smell	Moderate
09 Nov 2020 (Study Day 53)	New Loss of Taste	Moderate
09 Nov 2020 (Study Day 53)	Shortness of Breath	Moderate
10 Nov 2020 (Study Day 54)	Body Aches	Moderate
10 Nov 2020 (Study Day 54)	Chills	Mild
10 Nov 2020 (Study Day 54)	Cough	Moderate
10 Nov 2020 (Study Day 54)	Difficulty Breathing	Moderate
10 Nov 2020 (Study Day 54)	Fatigue	Moderate
10 Nov 2020 (Study Day 54)	Headache	Moderate
10 Nov 2020 (Study Day 54)	Muscle Aches (Myalgia)	Moderate
10 Nov 2020 (Study Day 54)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 54)	New Loss of Smell	Mild
10 Nov 2020 (Study Day 54)	New Loss of Taste	Mild
10 Nov 2020 (Study Day 54)	O2 Saturation (%)	93
10 Nov 2020 (Study Day 54)	Runny Nose (Rhinorrhea)	Mild
10 Nov 2020 (Study Day 54)	Shortness of Breath	Moderate

Symptom Date	Symptom	Result
11 Nov 2020 (Study Day 55)	Body Aches	Mild
11 Nov 2020 (Study Day 55)	Cough	Moderate
11 Nov 2020 (Study Day 55)	Difficulty Breathing	Moderate
11 Nov 2020 (Study Day 55)	Fatigue	Mild
11 Nov 2020 (Study Day 55)	Headache	Mild
11 Nov 2020 (Study Day 55)	Muscle Aches (Myalgia)	Mild
11 Nov 2020 (Study Day 55)	New Loss of Smell	Mild
11 Nov 2020 (Study Day 55)	New Loss of Taste	Mild
11 Nov 2020 (Study Day 55)	Runny Nose (Rhinorrhea)	Mild
11 Nov 2020 (Study Day 55)	Shortness of Breath	Moderate
12 Nov 2020 (Study Day 56)	Body Aches	Mild
12 Nov 2020 (Study Day 56)	Cough	Moderate
12 Nov 2020 (Study Day 56)	Difficulty Breathing	Moderate
12 Nov 2020 (Study Day 56)	Fatigue	Mild
12 Nov 2020 (Study Day 56)	Muscle Aches (Myalgia)	Mild
12 Nov 2020 (Study Day 56)	New Loss of Smell	Mild
12 Nov 2020 (Study Day 56)	New Loss of Taste	Mild
12 Nov 2020 (Study Day 56)	Runny Nose (Rhinorrhea)	Mild
12 Nov 2020 (Study Day 56)	Shortness of Breath	Moderate
13 Nov 2020 (Study Day 57)	Body Aches	Mild
13 Nov 2020 (Study Day 57)	Chills	Mild
13 Nov 2020 (Study Day 57)	Cough	Moderate
13 Nov 2020 (Study Day 57)	Difficulty Breathing	Moderate
13 Nov 2020 (Study Day 57)	Fatigue	Mild
13 Nov 2020 (Study Day 57)	Headache	Moderate
13 Nov 2020 (Study Day 57)	Muscle Aches (Myalgia)	Mild
13 Nov 2020 (Study Day 57)	New Loss of Smell	Mild
13 Nov 2020 (Study Day 57)	New Loss of Taste	Mild
13 Nov 2020 (Study Day 57)	Runny Nose (Rhinorrhea)	Mild
13 Nov 2020 (Study Day 57)	Shortness of Breath	Moderate
14 Nov 2020 (Study Day 58)	Body Aches	Mild
14 Nov 2020 (Study Day 58)	Chills	Mild
14 Nov 2020 (Study Day 58)	Cough	Moderate
14 Nov 2020 (Study Day 58)	Difficulty Breathing	Moderate
14 Nov 2020 (Study Day 58)	Fatigue	Mild
14 Nov 2020 (Study Day 58)	Headache	Moderate
14 Nov 2020 (Study Day 58)	Muscle Aches (Myalgia)	Mild
14 Nov 2020 (Study Day 58)	New Loss of Smell	Mild
14 Nov 2020 (Study Day 58)	New Loss of Taste	Mild
14 Nov 2020 (Study Day 58)	Runny Nose (Rhinorrhea)	Mild
14 Nov 2020 (Study Day 58)	Shortness of Breath	Moderate
15 Nov 2020 (Study Day 59)	Body Aches	Mild
15 Nov 2020 (Study Day 59)	Chills	Mild

Symptom Date	Symptom	Result
15 Nov 2020 (Study Day 59)	Cough	Moderate
15 Nov 2020 (Study Day 59)	Difficulty Breathing	Moderate
15 Nov 2020 (Study Day 59)	Fatigue	Mild
15 Nov 2020 (Study Day 59)	Headache	Moderate
15 Nov 2020 (Study Day 59)	Muscle Aches (Myalgia)	Mild
15 Nov 2020 (Study Day 59)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 59)	New Loss of Smell	Mild
15 Nov 2020 (Study Day 59)	New Loss of Taste	Mild
15 Nov 2020 (Study Day 59)	Runny Nose (Rhinorrhea)	Mild
15 Nov 2020 (Study Day 59)	Shortness of Breath	Moderate
16 Nov 2020 (Study Day 60)	Body Aches	Mild
16 Nov 2020 (Study Day 60)	Chills	Mild
16 Nov 2020 (Study Day 60)	Cough	Moderate
16 Nov 2020 (Study Day 60)	Difficulty Breathing	Moderate
16 Nov 2020 (Study Day 60)	Fatigue	Mild
16 Nov 2020 (Study Day 60)	Headache	Moderate
16 Nov 2020 (Study Day 60)	Muscle Aches (Myalgia)	Mild
16 Nov 2020 (Study Day 60)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 60)	New Loss of Smell	Mild
16 Nov 2020 (Study Day 60)	New Loss of Taste	Mild
16 Nov 2020 (Study Day 60)	Runny Nose (Rhinorrhea)	Mild
16 Nov 2020 (Study Day 60)	Shortness of Breath	Moderate
17 Nov 2020 (Study Day 61)	Cough	Moderate
17 Nov 2020 (Study Day 61)	Fatigue	Mild
17 Nov 2020 (Study Day 61)	Headache	Moderate
17 Nov 2020 (Study Day 61)	Nasal Congestion	Mild
17 Nov 2020 (Study Day 61)	New Loss of Smell	Mild
17 Nov 2020 (Study Day 61)	New Loss of Taste	Mild
17 Nov 2020 (Study Day 61)	Runny Nose (Rhinorrhea)	Mild
18 Nov 2020 (Study Day 62)	Cough	Mild
18 Nov 2020 (Study Day 62)	Fatigue	Mild
18 Nov 2020 (Study Day 62)	Headache	Moderate
18 Nov 2020 (Study Day 62)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 62)	New Loss of Smell	Mild
18 Nov 2020 (Study Day 62)	New Loss of Taste	Mild
18 Nov 2020 (Study Day 62)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 63)	Cough	Mild
19 Nov 2020 (Study Day 63)	Difficulty Breathing	Mild
19 Nov 2020 (Study Day 63)	Fatigue	Mild
19 Nov 2020 (Study Day 63)	Headache	Moderate
19 Nov 2020 (Study Day 63)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 63)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 63)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
20 Nov 2020 (Study Day 64)	Cough	Mild
20 Nov 2020 (Study Day 64)	Difficulty Breathing	Mild
20 Nov 2020 (Study Day 64)	Fatigue	Mild
20 Nov 2020 (Study Day 64)	Headache	Moderate
20 Nov 2020 (Study Day 64)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 64)	Runny Nose (Rhinorrhea)	Mild
20 Nov 2020 (Study Day 64)	Shortness of Breath	Mild
21 Nov 2020 (Study Day 65)	Cough	Mild
21 Nov 2020 (Study Day 65)	Difficulty Breathing	Mild
21 Nov 2020 (Study Day 65)	Fatigue	Mild
21 Nov 2020 (Study Day 65)	Headache	Moderate
21 Nov 2020 (Study Day 65)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 65)	Runny Nose (Rhinorrhea)	Mild
21 Nov 2020 (Study Day 65)	Shortness of Breath	Mild
22 Nov 2020 (Study Day 66)	Cough	Mild
22 Nov 2020 (Study Day 66)	Difficulty Breathing	Mild
22 Nov 2020 (Study Day 66)	Fatigue	Mild
22 Nov 2020 (Study Day 66)	Headache	Moderate
22 Nov 2020 (Study Day 66)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 66)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 66)	Shortness of Breath	Mild
23 Nov 2020 (Study Day 67)	Cough	Mild
23 Nov 2020 (Study Day 67)	Difficulty Breathing	Mild
23 Nov 2020 (Study Day 67)	Fatigue	Mild
23 Nov 2020 (Study Day 67)	Headache	Moderate
23 Nov 2020 (Study Day 67)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 67)	Runny Nose (Rhinorrhea)	Mild
23 Nov 2020 (Study Day 67)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 68)	Cough	Mild
24 Nov 2020 (Study Day 68)	Difficulty Breathing	Mild
24 Nov 2020 (Study Day 68)	Fatigue	Mild
24 Nov 2020 (Study Day 68)	Headache	Mild
24 Nov 2020 (Study Day 68)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 68)	Runny Nose (Rhinorrhea)	Mild
24 Nov 2020 (Study Day 68)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 69)	Cough	Mild
25 Nov 2020 (Study Day 69)	Difficulty Breathing	Mild
25 Nov 2020 (Study Day 69)	Fatigue	Mild
25 Nov 2020 (Study Day 69)	Headache	Moderate
25 Nov 2020 (Study Day 69)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 69)	Runny Nose (Rhinorrhea)	Mild
25 Nov 2020 (Study Day 69)	Shortness of Breath	Mild
26 Nov 2020 (Study Day 70)	Cough	Mild

Symptom Date	Symptom	Result
26 Nov 2020 (Study Day 70)	Difficulty Breathing	Mild
26 Nov 2020 (Study Day 70)	Fatigue	Mild
26 Nov 2020 (Study Day 70)	Headache	Moderate
26 Nov 2020 (Study Day 70)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 70)	Runny Nose (Rhinorrhea)	Mild
26 Nov 2020 (Study Day 70)	Shortness of Breath	Mild
27 Nov 2020 (Study Day 71)	Cough	Mild
27 Nov 2020 (Study Day 71)	Difficulty Breathing	Mild
27 Nov 2020 (Study Day 71)	Fatigue	Mild
27 Nov 2020 (Study Day 71)	Headache	Moderate
27 Nov 2020 (Study Day 71)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 71)	Runny Nose (Rhinorrhea)	Mild
27 Nov 2020 (Study Day 71)	Shortness of Breath	Mild
28 Nov 2020 (Study Day 72)	Cough	Mild
28 Nov 2020 (Study Day 72)	Difficulty Breathing	Mild
28 Nov 2020 (Study Day 72)	Fatigue	Mild
28 Nov 2020 (Study Day 72)	Headache	Moderate
28 Nov 2020 (Study Day 72)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 72)	Runny Nose (Rhinorrhea)	Mild
28 Nov 2020 (Study Day 72)	Shortness of Breath	Mild
29 Nov 2020 (Study Day 73)	Cough	Mild
29 Nov 2020 (Study Day 73)	Difficulty Breathing	Mild
29 Nov 2020 (Study Day 73)	Fatigue	Mild
29 Nov 2020 (Study Day 73)	Headache	Moderate
29 Nov 2020 (Study Day 73)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 73)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 73)	Shortness of Breath	Mild
30 Nov 2020 (Study Day 74)	Cough	Mild
30 Nov 2020 (Study Day 74)	Difficulty Breathing	Mild
30 Nov 2020 (Study Day 74)	Fatigue	Mild
30 Nov 2020 (Study Day 74)	Headache	Moderate
30 Nov 2020 (Study Day 74)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 74)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 74)	Shortness of Breath	Mild
02 Dec 2020 (Study Day 76)	Cough	Mild
02 Dec 2020 (Study Day 76)	Difficulty Breathing	Mild
02 Dec 2020 (Study Day 76)	Fatigue	Mild
02 Dec 2020 (Study Day 76)	Headache	Moderate
02 Dec 2020 (Study Day 76)	Nasal Congestion	Mild
02 Dec 2020 (Study Day 76)	Runny Nose (Rhinorrhea)	Mild
02 Dec 2020 (Study Day 76)	Shortness of Breath	Mild
03 Dec 2020 (Study Day 77)	Cough	Mild
03 Dec 2020 (Study Day 77)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 77)	Fatigue	Mild
03 Dec 2020 (Study Day 77)	Headache	Moderate
03 Dec 2020 (Study Day 77)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 77)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 77)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
08 Nov 2020 (Study Day 52)	Oxygen Saturation	92%
08 Nov 2020 - 10 Nov 2020 (Study Day 52-54)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
09 Nov 2020 - 09 Nov 2020 (Study Day 53-53)	Radiographical Evidence of Pneumonia	Yes
10 Nov 2020 - 10 Nov 2020 (Study Day 54-54)	Clinical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 37 days, after which it was considered to be recovered/resolved on 04 Dec 2020 (Study Day 78). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000641	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tension headache	Occasional tension headache	1979 - Ongoing
Asthma	Asthma (moderate)	1986 - Ongoing
Rubber sensitivity	Latex allergy	1995 - Ongoing
Food allergy	Mango allergy	1998 - Ongoing
Seasonal allergy	Seasonal allergies	2005 - Ongoing
Osteoarthritis	Bilateral osteoarthritis	2010 - Ongoing
Hypertension	Hypertension	2012 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2013 - Ongoing
Hypercholesterolaemia	Hypercholesterol	2014 - Ongoing
Blepharospasm	Blepharospasm	2015 - 2015
Gastrooesophageal reflux disease	Acid reflux	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1979 - 17 Feb 2021 (Study Day 153)	Occasional Tension Headaches
Salbutamol	1986 - Ongoing	Asthma
Fluticasone propionate	2005 - Ongoing	Seasonal Allergies
Fexofenadine hydrochloride	2010 - Ongoing	Seasonal Allergies
Hyaluronate sodium	2011 - Ongoing	Osteoarthritis Bilateral Knee's
Amlodipine besilate	01 Mar 2012 (Study Day -3123) - Ongoing	Hypertension
Metformin	2013 - Ongoing	Diabetes Mellitus Type 2
Atorvastatin	2014 - Ongoing	Hypercholesterol
Losartan	Apr 2016 - Ongoing	Hypertension
Esomeprazole magnesium	2019 - Ongoing	Acid Reflux
Fluticasone propionate; salmeterol	2019 - Ongoing	Asthma
Montelukast sodium	2019 - Ongoing	Asthma
Budesonide; formoterol fumarate	01 Jan 2020 (Study Day -261) - Ongoing	Asthma
Paracetamol	19 Oct 2020 (Study Day 32) - 22 Oct 2020 (Study Day 35)	Body Aches
Lansoprazole	Nov 2020 - 16 Nov 2020 (Study Day 60)	Heart Burn
Omeprazole	Nov 2020 - 16 Nov 2020 (Study Day 60)	Heart Burn
Acetylsalicylic acid	01 Nov 2020 (Study Day 45) - 22 Mar 2021 (Study Day 186)	Anticoagulant (COVID)
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	01 Nov 2020 (Study Day 45) - 20 Nov 2020 (Study Day 64)	Nasal Congestion
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	01 Nov 2020 (Study Day 45) - 20 Nov 2020 (Study Day 64)	Runny Nose
Paracetamol	02 Nov 2020 (Study Day 46) - 17 Dec 2020 (Study Day 91)	Headache
Ibuprofen	03 Nov 2020 (Study Day 47) - 16 Dec 2020 (Study Day 90)	Headache
Budesonide; formoterol fumarate	07 Nov 2020 (Study Day 51) - 17 Feb 2021 (Study Day 153)	Shortness Of Breath
Ondansetron	09 Nov 2020 (Study Day 53) - 16 Nov 2020 (Study Day 60)	Nausea
Benzonatate	10 Nov 2020 (Study Day 54) - 16 Nov 2020 (Study Day 60)	Cough
Methylprednisolone	10 Nov 2020 (Study Day 54) - 15 Nov 2020 (Study Day 59)	COVID19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	10 Nov 2020 (Study Day 54) - 17 Nov 2020 (Study Day 61)	Shortness Of Breath
Paracetamol	11 Nov 2020 (Study Day 55) - 17 Feb 2021 (Study Day 153)	Headache
Famotidine	14 Nov 2020 (Study Day 58) - Ongoing	Heartburn
Botulinum toxin type a	Dec 2020 - Ongoing	Cosmetic
Ibuprofen	17 Feb 2021 (Study Day 153) - Ongoing	Body Aches, Muscle Aches
Paracetamol	21 Feb 2021 (Study Day 157) - 08 Mar 2021 (Study Day 172)	Sore Throat, Headache, Chills, Body Aches
Tiotropium bromide	20 Mar 2021 (Study Day 184) - Ongoing	Asthma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain	Grade 1/mild	Related	19 Oct 2020 (Study Day 32) - 22 Oct 2020 (Study Day 35)
Vertigo	Grade 2/moderate	Related	23 Oct 2020 (Study Day 36) - 24 Oct 2020 (Study Day 37)
COVID-19	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 42) - 04 Dec 2020 (Study Day 78)
Palpitations	Grade 1/mild	Not related	01 Nov 2020 (Study Day 45) - 15 Dec 2020 (Study Day 89)
Nausea	Grade 1/mild	Not related	09 Nov 2020 (Study Day 53) - 16 Nov 2020 (Study Day 60)
Pneumonia Viral	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 54) - 15 Dec 2020 (Study Day 89)
Dyspepsia	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 58) - Ongoing
Ocular Hyperaemia	Grade 1/mild	Not related	29 Nov 2020 (Study Day 73) - 03 Dec 2020 (Study Day 77)
Cardiac Murmur	Grade 1/mild	Not related	14 Dec 2020 (Study Day 88) - Ongoing
Tinnitus	Grade 2/moderate	Related	24 Jan 2021 (Study Day 129) - Ongoing
Influenza Like Illness	Grade 1/mild	Related	16 Feb 2021 (Study Day 152) - 08 Mar 2021 (Study Day 172)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US385-2122 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	05 Oct 2020 (Study Day 28)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	18 Dec 2020 (Study Day 102) – 18 Jan 2021 (Study Day 133)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US385-2122, a 63-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 18 Dec 2020 (Study Day 102), 101 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 05 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 22 Dec 2020 (Study Day 106), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 102)	Cough	Mild
18 Dec 2020 (Study Day 102)	Diarrhea	Mild
18 Dec 2020 (Study Day 102)	Muscle Aches (Myalgia)	Mild
19 Dec 2020 (Study Day 103)	Cough	Mild

Symptom Date	Symptom	Result
19 Dec 2020 (Study Day 103)	Diarrhea	Mild
19 Dec 2020 (Study Day 103)	Muscle Aches (Myalgia)	Mild
20 Dec 2020 (Study Day 104)	Cough	Mild
20 Dec 2020 (Study Day 104)	Diarrhea	Mild
20 Dec 2020 (Study Day 104)	Muscle Aches (Myalgia)	Mild
21 Dec 2020 (Study Day 105)	Cough	Mild
21 Dec 2020 (Study Day 105)	Diarrhea	Mild
21 Dec 2020 (Study Day 105)	Muscle Aches (Myalgia)	Mild
22 Dec 2020 (Study Day 106)	Cough	Mild
22 Dec 2020 (Study Day 106)	Diarrhea	Mild
22 Dec 2020 (Study Day 106)	Muscle Aches (Myalgia)	Mild
23 Dec 2020 (Study Day 107)	Chills	Mild
23 Dec 2020 (Study Day 107)	Cough	Mild
23 Dec 2020 (Study Day 107)	Diarrhea	Mild
23 Dec 2020 (Study Day 107)	Fatigue	Mild
23 Dec 2020 (Study Day 107)	Headache	Mild
23 Dec 2020 (Study Day 107)	Muscle Aches (Myalgia)	Mild
23 Dec 2020 (Study Day 107)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 107)	Nausea	Mild
23 Dec 2020 (Study Day 107)	O2 Saturation (%)	91
23 Dec 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
23 Dec 2020 (Study Day 107)	Sore Throat	Mild
24 Dec 2020 (Study Day 108)	Chills	Mild
24 Dec 2020 (Study Day 108)	Cough	Mild
24 Dec 2020 (Study Day 108)	Diarrhea	Mild
24 Dec 2020 (Study Day 108)	Fatigue	Mild
24 Dec 2020 (Study Day 108)	Headache	Mild
24 Dec 2020 (Study Day 108)	Muscle Aches (Myalgia)	Mild
24 Dec 2020 (Study Day 108)	Nasal Congestion	Mild
24 Dec 2020 (Study Day 108)	Nausea	Mild
24 Dec 2020 (Study Day 108)	O2 Saturation (%)	91
24 Dec 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Mild
25 Dec 2020 (Study Day 109)	Chills	Mild
25 Dec 2020 (Study Day 109)	Cough	Mild
25 Dec 2020 (Study Day 109)	Diarrhea	Mild
25 Dec 2020 (Study Day 109)	Fatigue	Mild
25 Dec 2020 (Study Day 109)	Headache	Mild
25 Dec 2020 (Study Day 109)	Muscle Aches (Myalgia)	Mild
25 Dec 2020 (Study Day 109)	Nasal Congestion	Mild
25 Dec 2020 (Study Day 109)	Nausea	Mild
25 Dec 2020 (Study Day 109)	New Loss of Taste	Mild
25 Dec 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
26 Dec 2020 (Study Day 110)	Chills	Mild

Symptom Date	Symptom	Result
26 Dec 2020 (Study Day 110)	Cough	Mild
26 Dec 2020 (Study Day 110)	Diarrhea	Mild
26 Dec 2020 (Study Day 110)	Fatigue	Mild
26 Dec 2020 (Study Day 110)	Headache	Mild
26 Dec 2020 (Study Day 110)	Muscle Aches (Myalgia)	Mild
26 Dec 2020 (Study Day 110)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 110)	Nausea	Mild
26 Dec 2020 (Study Day 110)	New Loss of Taste	Mild
26 Dec 2020 (Study Day 110)	Runny Nose (Rhinorrhea)	Mild
27 Dec 2020 (Study Day 111)	Chills	Mild
27 Dec 2020 (Study Day 111)	Cough	Mild
27 Dec 2020 (Study Day 111)	Diarrhea	Mild
27 Dec 2020 (Study Day 111)	Fatigue	Mild
27 Dec 2020 (Study Day 111)	Nasal Congestion	Mild
27 Dec 2020 (Study Day 111)	Nausea	Mild
27 Dec 2020 (Study Day 111)	New Loss of Smell	Moderate
27 Dec 2020 (Study Day 111)	New Loss of Taste	Mild
27 Dec 2020 (Study Day 111)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 112)	Chills	Mild
28 Dec 2020 (Study Day 112)	Diarrhea	Mild
28 Dec 2020 (Study Day 112)	Fatigue	Mild
28 Dec 2020 (Study Day 112)	Nasal Congestion	Mild
28 Dec 2020 (Study Day 112)	Nausea	Mild
28 Dec 2020 (Study Day 112)	New Loss of Smell	Moderate
28 Dec 2020 (Study Day 112)	New Loss of Taste	Mild
28 Dec 2020 (Study Day 112)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 113)	Cough	Mild
29 Dec 2020 (Study Day 113)	Diarrhea	Mild
29 Dec 2020 (Study Day 113)	Fatigue	Mild
29 Dec 2020 (Study Day 113)	Nausea	Mild
29 Dec 2020 (Study Day 113)	New Loss of Smell	Moderate
29 Dec 2020 (Study Day 113)	New Loss of Taste	Mild
29 Dec 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
30 Dec 2020 (Study Day 114)	Fatigue	Mild
30 Dec 2020 (Study Day 114)	Nausea	Mild
30 Dec 2020 (Study Day 114)	New Loss of Smell	Moderate
30 Dec 2020 (Study Day 114)	New Loss of Taste	Mild
31 Dec 2020 (Study Day 115)	Fatigue	Mild
31 Dec 2020 (Study Day 115)	Nausea	Mild
31 Dec 2020 (Study Day 115)	New Loss of Smell	Moderate
31 Dec 2020 (Study Day 115)	New Loss of Taste	Mild
01 Jan 2021 (Study Day 116)	Fatigue	Mild
01 Jan 2021 (Study Day 116)	New Loss of Smell	Moderate

Symptom Date	Symptom	Result
01 Jan 2021 (Study Day 116)	New Loss of Taste	Mild
02 Jan 2021 (Study Day 117)	Fatigue	Mild
02 Jan 2021 (Study Day 117)	New Loss of Smell	Moderate
02 Jan 2021 (Study Day 117)	New Loss of Taste	Mild
03 Jan 2021 (Study Day 118)	Fatigue	Mild
03 Jan 2021 (Study Day 118)	New Loss of Smell	Moderate
03 Jan 2021 (Study Day 118)	New Loss of Taste	Mild
04 Jan 2021 (Study Day 119)	Fatigue	Mild
04 Jan 2021 (Study Day 119)	New Loss of Smell	Moderate
04 Jan 2021 (Study Day 119)	New Loss of Taste	Mild
05 Jan 2021 (Study Day 120)	Fatigue	Mild
05 Jan 2021 (Study Day 120)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 120)	New Loss of Smell	Moderate
05 Jan 2021 (Study Day 120)	New Loss of Taste	Mild
06 Jan 2021 (Study Day 121)	Fatigue	Mild
06 Jan 2021 (Study Day 121)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 121)	New Loss of Smell	Moderate
06 Jan 2021 (Study Day 121)	New Loss of Taste	Mild
07 Jan 2021 (Study Day 122)	Fatigue	Mild
07 Jan 2021 (Study Day 122)	Nasal Congestion	Mild
07 Jan 2021 (Study Day 122)	New Loss of Smell	Moderate
07 Jan 2021 (Study Day 122)	New Loss of Taste	Mild
08 Jan 2021 (Study Day 123)	Fatigue	Mild
08 Jan 2021 (Study Day 123)	Nasal Congestion	Mild
08 Jan 2021 (Study Day 123)	New Loss of Smell	Moderate
08 Jan 2021 (Study Day 123)	New Loss of Taste	Mild
09 Jan 2021 (Study Day 124)	Fatigue	Mild
09 Jan 2021 (Study Day 124)	New Loss of Smell	Moderate
09 Jan 2021 (Study Day 124)	New Loss of Taste	Mild
10 Jan 2021 (Study Day 125)	Fatigue	Mild
10 Jan 2021 (Study Day 125)	New Loss of Smell	Moderate
10 Jan 2021 (Study Day 125)	New Loss of Taste	Mild
11 Jan 2021 (Study Day 126)	Fatigue	Mild
11 Jan 2021 (Study Day 126)	New Loss of Smell	Moderate
11 Jan 2021 (Study Day 126)	New Loss of Taste	Mild
12 Jan 2021 (Study Day 127)	Fatigue	Mild
12 Jan 2021 (Study Day 127)	New Loss of Taste	Mild
13 Jan 2021 (Study Day 128)	Fatigue	Mild
13 Jan 2021 (Study Day 128)	New Loss of Taste	Mild
14 Jan 2021 (Study Day 129)	Fatigue	Mild
14 Jan 2021 (Study Day 129)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 130)	Fatigue	Mild
16 Jan 2021 (Study Day 131)	Fatigue	Mild

Symptom Date	Symptom	Result
17 Jan 2021 (Study Day 132)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
23 Dec 2020 (Study Day 107)	Oxygen Saturation	91%
22 Dec 2020 - 19 Jan 2021 (Study Day 106-134)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes
23 Dec 2020 - 24 Dec 2020 (Study Day 107-108)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 32 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 133). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001209	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Pruritus	Chronic itching-generalized	2017 - Ongoing
Depression	Depression	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	Not reported - Ongoing	Hypothyroid
Naltrexone	Not reported - Ongoing	Chronic Itching-Generalized
Rosuvastatin calcium	Not reported - Ongoing	Hyperlipidemia
Carvedilol	2017 - Ongoing	Hypertension
Influenza vaccine	19 Oct 2020 (Study Day 42) - 19 Oct 2020 (Study Day 42)	Prophylaxis For Influenza
Dextromethorphan hydrobromide; guaifenesin	23 Dec 2020 (Study Day 107) - 30 Dec 2020 (Study Day 114)	COVID-19
Paracetamol	23 Dec 2020 (Study Day 107) - 30 Dec 2020 (Study Day 114)	COVID-19
Loperamide hydrochloride	29 Dec 2020 (Study Day 113) - 30 Dec 2020 (Study Day 114)	Diarrhea
Cefepime	12 Mar 2021 (Study Day 186) - 02 Apr 2021 (Study Day 207)	Pseudomonas Left Ring Finger

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	18 Dec 2020 (Study Day 102) - 18 Jan 2021 (Study Day 133)
Fungal Skin Infection	Grade 2/moderate	Not related	10 Feb 2021 (Study Day 156) - Ongoing
Pseudomonas Infection	Grade 2/moderate	Not related	10 Feb 2021 (Study Day 156) - 02 Apr 2021 (Study Day 207)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2095 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	SAE, COVID-19	Grade 4	Not related	16 Dec 2020 (Study Day 132) – 20 Jan 2021 (Study Day 167)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US387-2095, a 68-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 16 Dec 2020 (Study Day 132), 131 days after the first dose and 103 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 04 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Dec 2020 (Study Day 139), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

On 30 Dec 2020 (Study Day 146), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
16 Dec 2020 (Study Day 132)	Body Aches	Mild
16 Dec 2020 (Study Day 132)	Chills	Mild
16 Dec 2020 (Study Day 132)	Cough	Moderate

Symptom Date	Symptom	Result
16 Dec 2020 (Study Day 132)	Difficulty Breathing	Moderate
16 Dec 2020 (Study Day 132)	Fatigue	Moderate
16 Dec 2020 (Study Day 132)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 132)	Shortness of Breath	Moderate
17 Dec 2020 (Study Day 133)	Body Aches	Mild
17 Dec 2020 (Study Day 133)	Chills	Moderate
17 Dec 2020 (Study Day 133)	Cough	Moderate
17 Dec 2020 (Study Day 133)	Difficulty Breathing	Moderate
17 Dec 2020 (Study Day 133)	Fatigue	Moderate
17 Dec 2020 (Study Day 133)	Shortness of Breath	Moderate
18 Dec 2020 (Study Day 134)	Body Aches	Mild
18 Dec 2020 (Study Day 134)	Chills	Moderate
18 Dec 2020 (Study Day 134)	Cough	Moderate
18 Dec 2020 (Study Day 134)	Difficulty Breathing	Moderate
18 Dec 2020 (Study Day 134)	Fatigue	Moderate
18 Dec 2020 (Study Day 134)	Shortness of Breath	Moderate
19 Dec 2020 (Study Day 135)	Body Aches	Mild
19 Dec 2020 (Study Day 135)	Chills	Moderate
19 Dec 2020 (Study Day 135)	Cough	Moderate
19 Dec 2020 (Study Day 135)	Difficulty Breathing	Moderate
19 Dec 2020 (Study Day 135)	Fatigue	Moderate
19 Dec 2020 (Study Day 135)	Shortness of Breath	Moderate
20 Dec 2020 (Study Day 136)	Body Aches	Mild
20 Dec 2020 (Study Day 136)	Chills	Moderate
20 Dec 2020 (Study Day 136)	Cough	Moderate
20 Dec 2020 (Study Day 136)	Difficulty Breathing	Moderate
20 Dec 2020 (Study Day 136)	Fatigue	Moderate
20 Dec 2020 (Study Day 136)	Shortness of Breath	Moderate
21 Dec 2020 (Study Day 137)	Body Aches	Mild
21 Dec 2020 (Study Day 137)	Chills	Moderate
21 Dec 2020 (Study Day 137)	Cough	Moderate
21 Dec 2020 (Study Day 137)	Difficulty Breathing	Moderate
21 Dec 2020 (Study Day 137)	Fatigue	Moderate
21 Dec 2020 (Study Day 137)	Shortness of Breath	Moderate
22 Dec 2020 (Study Day 138)	Body Aches	Mild
22 Dec 2020 (Study Day 138)	Chills	Moderate
22 Dec 2020 (Study Day 138)	Cough	Moderate
22 Dec 2020 (Study Day 138)	Difficulty Breathing	Moderate
22 Dec 2020 (Study Day 138)	Fatigue	Moderate
22 Dec 2020 (Study Day 138)	Shortness of Breath	Moderate
23 Dec 2020 (Study Day 139)	Body Aches	Mild
23 Dec 2020 (Study Day 139)	Chills	Moderate
23 Dec 2020 (Study Day 139)	Cough	Moderate

Symptom Date	Symptom	Result
23 Dec 2020 (Study Day 139)	Difficulty Breathing	Moderate
23 Dec 2020 (Study Day 139)	Fatigue	Moderate
23 Dec 2020 (Study Day 139)	Shortness of Breath	Moderate
24 Dec 2020 (Study Day 140)	Body Aches	Mild
24 Dec 2020 (Study Day 140)	Chills	Moderate
24 Dec 2020 (Study Day 140)	Cough	Moderate
24 Dec 2020 (Study Day 140)	Difficulty Breathing	Moderate
24 Dec 2020 (Study Day 140)	Fatigue	Moderate
24 Dec 2020 (Study Day 140)	Shortness of Breath	Moderate
25 Dec 2020 (Study Day 141)	Body Aches	Mild
25 Dec 2020 (Study Day 141)	Chills	Moderate
25 Dec 2020 (Study Day 141)	Cough	Moderate
25 Dec 2020 (Study Day 141)	Difficulty Breathing	Moderate
25 Dec 2020 (Study Day 141)	Fatigue	Moderate
25 Dec 2020 (Study Day 141)	Shortness of Breath	Moderate
26 Dec 2020 (Study Day 142)	Cough	Moderate
26 Dec 2020 (Study Day 142)	Difficulty Breathing	Moderate
26 Dec 2020 (Study Day 142)	Shortness of Breath	Moderate
27 Dec 2020 (Study Day 143)	Cough	Moderate
27 Dec 2020 (Study Day 143)	Difficulty Breathing	Moderate
27 Dec 2020 (Study Day 143)	Shortness of Breath	Moderate
28 Dec 2020 (Study Day 144)	Cough	Mild
28 Dec 2020 (Study Day 144)	Difficulty Breathing	Moderate
28 Dec 2020 (Study Day 144)	Shortness of Breath	Moderate
29 Dec 2020 (Study Day 145)	Cough	Mild
29 Dec 2020 (Study Day 145)	Difficulty Breathing	Moderate
29 Dec 2020 (Study Day 145)	Shortness of Breath	Moderate
30 Dec 2020 (Study Day 146)	Cough	Mild
30 Dec 2020 (Study Day 146)	Difficulty Breathing	Moderate
30 Dec 2020 (Study Day 146)	Shortness of Breath	Moderate
31 Dec 2020 (Study Day 147)	Cough	Mild
31 Dec 2020 (Study Day 147)	Difficulty Breathing	Moderate
01 Jan 2021 (Study Day 148)	Cough	Mild
01 Jan 2021 (Study Day 148)	Difficulty Breathing	Moderate
01 Jan 2021 (Study Day 148)	Fatigue	Mild
02 Jan 2021 (Study Day 149)	Difficulty Breathing	Moderate
02 Jan 2021 (Study Day 149)	Fatigue	Mild
03 Jan 2021 (Study Day 150)	Difficulty Breathing	Moderate
03 Jan 2021 (Study Day 150)	Fatigue	Mild
04 Jan 2021 (Study Day 151)	Difficulty Breathing	Moderate
04 Jan 2021 (Study Day 151)	Fatigue	Mild
04 Jan 2021 (Study Day 151)	O2 Saturation (%)	82
05 Jan 2021 (Study Day 152)	Cough	Mild

Symptom Date	Symptom	Result
05 Jan 2021 (Study Day 152)	Difficulty Breathing	Moderate
05 Jan 2021 (Study Day 152)	Fatigue	Moderate
06 Jan 2021 (Study Day 153)	Cough	Mild
06 Jan 2021 (Study Day 153)	Difficulty Breathing	Moderate
06 Jan 2021 (Study Day 153)	Fatigue	Mild
06 Jan 2021 (Study Day 153)	O2 Saturation (%)	89
07 Jan 2021 (Study Day 154)	Cough	Mild
07 Jan 2021 (Study Day 154)	Difficulty Breathing	Moderate
07 Jan 2021 (Study Day 154)	Fatigue	Mild
08 Jan 2021 (Study Day 155)	Cough	Mild
08 Jan 2021 (Study Day 155)	Difficulty Breathing	Moderate
08 Jan 2021 (Study Day 155)	Fatigue	Mild
09 Jan 2021 (Study Day 156)	Cough	Mild
09 Jan 2021 (Study Day 156)	Difficulty Breathing	Moderate
09 Jan 2021 (Study Day 156)	Fatigue	Mild
09 Jan 2021 (Study Day 156)	Runny Nose (Rhinorrhea)	Mild
10 Jan 2021 (Study Day 157)	Cough	Mild
10 Jan 2021 (Study Day 157)	Difficulty Breathing	Moderate
10 Jan 2021 (Study Day 157)	Fatigue	Mild
10 Jan 2021 (Study Day 157)	O2 Saturation (%)	93
11 Jan 2021 (Study Day 158)	Cough	Mild
11 Jan 2021 (Study Day 158)	Difficulty Breathing	Moderate
11 Jan 2021 (Study Day 158)	Fatigue	Mild
11 Jan 2021 (Study Day 158)	O2 Saturation (%)	92
12 Jan 2021 (Study Day 159)	Fatigue	Mild
13 Jan 2021 (Study Day 160)	Cough	Mild
13 Jan 2021 (Study Day 160)	Difficulty Breathing	Mild
13 Jan 2021 (Study Day 160)	O2 Saturation (%)	92
14 Jan 2021 (Study Day 161)	Cough	Mild
14 Jan 2021 (Study Day 161)	Fatigue	Mild
15 Jan 2021 (Study Day 162)	Cough	Mild
15 Jan 2021 (Study Day 162)	Fatigue	Mild
16 Jan 2021 (Study Day 163)	Cough	Mild
16 Jan 2021 (Study Day 163)	Difficulty Breathing	Mild
16 Jan 2021 (Study Day 163)	Fatigue	Mild
16 Jan 2021 (Study Day 163)	O2 Saturation (%)	93
17 Jan 2021 (Study Day 164)	Cough	Mild
17 Jan 2021 (Study Day 164)	Difficulty Breathing	Mild
17 Jan 2021 (Study Day 164)	Fatigue	Mild
17 Jan 2021 (Study Day 164)	O2 Saturation (%)	93
18 Jan 2021 (Study Day 165)	Cough	Mild
18 Jan 2021 (Study Day 165)	Difficulty Breathing	Mild
18 Jan 2021 (Study Day 165)	Fatigue	Mild

Symptom Date	Symptom	Result
18 Jan 2021 (Study Day 165)	O2 Saturation (%)	88
19 Jan 2021 (Study Day 166)	Cough	Mild
19 Jan 2021 (Study Day 166)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
04 Jan 2021 (Study Day 151)	Oxygen Saturation	82%
23 Dec 2020 - 23 Dec 2020 (Study Day 139-139)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes
04 Jan 2021 - 18 Jan 2021 (Study Day 151-165)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 36 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 167). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001311	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tendon rupture	Achilles tendon rupture	2000 - 2000
Tenoplasty	Achilles tendon repair	2000 - 2000
Nephrolithiasis	Kidney stones	2003 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2008 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Rash	Occasional skin rashes	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	2005 - Ongoing	Prophylactic Kidney Stones
Metformin	2005 - Ongoing	Diabetes Type 2
Atorvastatin	2010 - Ongoing	Hyperlipidemia
Lisinopril	2010 - Ongoing	Hypertension
Acetylsalicylic acid	2015 - Ongoing	Health Maintenace
Ascorbic acid	2015 - Ongoing	Health Maintenance
Colecalciferol	2015 - Ongoing	Health Maintenance
Fish oil	2015 - Ongoing	Health Maintenance
Triamcinolone	2015 - Ongoing	General Skin Rash
Ubidecarenone	2015 - Ongoing	Health Maintenance
Vitamin e nos	2015 - Ongoing	Health Maintenance
Insulin human	2018 - Ongoing	Diabetes Type 2
Influenza vaccine inact split 3v	25 Sep 2020 (Study Day 50) - 25 Sep 2020 (Study Day 50)	Prophylactic Influenza
Diphenhydramine hydrochloride	17 Oct 2020 (Study Day 72) - 17 Oct 2020 (Study Day 72)	Urticarial Rash And Itchiness On Arms
Azithromycin	23 Dec 2020 (Study Day 139) - 28 Dec 2020 (Study Day 144)	COVID-19
Chest x ray*	23 Dec 2020 (Study Day 139) - 23 Dec 2020 (Study Day 139)	Adverse Event
Ecg*	23 Dec 2020 (Study Day 139) - 23 Dec 2020 (Study Day 139)	Adverse Event
Insulin	23 Dec 2020 (Study Day 139) - 30 Dec 2020 (Study Day 146)	Diabetes Mellitus Ii
Vancomycin	23 Dec 2020 (Study Day 139) - 28 Dec 2020 (Study Day 144)	COVID 19
Remdesivir	24 Dec 2020 (Study Day 140) - 28 Dec 2020 (Study Day 144)	COVID 19
Chest xray*	25 Dec 2020 (Study Day 141) - 25 Dec 2020 (Study Day 141)	Adverse Event
Cefdinir	29 Dec 2020 (Study Day 145) - 30 Dec 2020 (Study Day 146)	COVID 19
Dexamethasone	29 Dec 2020 (Study Day 145) - 02 Jan 2021 (Study Day 149)	COVID 19
Formoterol fumarate; mometasone furoate	29 Dec 2020 (Study Day 145) - 13 Jan 2021 (Study Day 160)	COVID 19
Varicella zoster vaccine	17 Feb 2021 (Study Day 195) - 17 Feb 2021 (Study Day 195)	Shingles Prophylaxis
Paracetamol	19 Mar 2021 (Study Day 225) - 20 Mar 2021 (Study Day 226)	Body Aches And Headaches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pruritus	Grade 1/mild	Not related	17 Oct 2020 (Study Day 72) - 17 Oct 2020 (Study Day 72)
Urticaria	Grade 1/mild	Not related	17 Oct 2020 (Study Day 72) - 17 Oct 2020 (Study Day 72)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2223 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	21 Sep 2020 (Study Day 34) – 28 Oct 2020 (Study Day 71)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US387-2223, a 48-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 21 Sep 2020 (Study Day 34), 33 days after the first dose and 5 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 16 Sep 2020, a nasal swab tested by RT-PCR was positive for SARS-CoV-2.

On 16 Sep 2020 (Study Day 29), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

On 28 Sep 2020 (Study Day 41), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
21 Sep 2020 (Study Day 34)	Body Aches	Mild

Symptom Date	Symptom	Result
21 Sep 2020 (Study Day 34)	Cough	Mild
21 Sep 2020 (Study Day 34)	Fatigue	Mild
21 Sep 2020 (Study Day 34)	Headache	Mild
21 Sep 2020 (Study Day 34)	Runny Nose (Rhinorrhea)	Mild
22 Sep 2020 (Study Day 35)	Cough	Mild
22 Sep 2020 (Study Day 35)	Fatigue	Mild
22 Sep 2020 (Study Day 35)	Headache	Mild
22 Sep 2020 (Study Day 35)	Runny Nose (Rhinorrhea)	Mild
23 Sep 2020 (Study Day 36)	Cough	Mild
23 Sep 2020 (Study Day 36)	Fatigue	Mild
23 Sep 2020 (Study Day 36)	Headache	Mild
23 Sep 2020 (Study Day 36)	Runny Nose (Rhinorrhea)	Mild
24 Sep 2020 (Study Day 37)	Cough	Mild
24 Sep 2020 (Study Day 37)	Fatigue	Mild
24 Sep 2020 (Study Day 37)	Headache	Mild
24 Sep 2020 (Study Day 37)	Runny Nose (Rhinorrhea)	Mild
25 Sep 2020 (Study Day 38)	Cough	Mild
25 Sep 2020 (Study Day 38)	Diarrhea	Mild
25 Sep 2020 (Study Day 38)	Fatigue	Mild
25 Sep 2020 (Study Day 38)	Nausea	Mild
25 Sep 2020 (Study Day 38)	New Loss of Smell	Mild
25 Sep 2020 (Study Day 38)	New Loss of Taste	Mild
25 Sep 2020 (Study Day 38)	Shortness of Breath	Mild
25 Sep 2020 (Study Day 38)	Vomiting	Mild
26 Sep 2020 (Study Day 39)	Cough	Mild
26 Sep 2020 (Study Day 39)	Diarrhea	Mild
26 Sep 2020 (Study Day 39)	Fatigue	Mild
26 Sep 2020 (Study Day 39)	Nausea	Mild
26 Sep 2020 (Study Day 39)	New Loss of Smell	Mild
26 Sep 2020 (Study Day 39)	New Loss of Taste	Mild
26 Sep 2020 (Study Day 39)	Shortness of Breath	Mild
26 Sep 2020 (Study Day 39)	Vomiting	Mild
27 Sep 2020 (Study Day 40)	Cough	Mild
27 Sep 2020 (Study Day 40)	Diarrhea	Mild
27 Sep 2020 (Study Day 40)	Fatigue	Mild
27 Sep 2020 (Study Day 40)	New Loss of Smell	Mild
27 Sep 2020 (Study Day 40)	New Loss of Taste	Mild
27 Sep 2020 (Study Day 40)	Shortness of Breath	Mild
28 Sep 2020 (Study Day 41)	Cough	Mild
28 Sep 2020 (Study Day 41)	Diarrhea	Mild
28 Sep 2020 (Study Day 41)	Fatigue	Mild
28 Sep 2020 (Study Day 41)	New Loss of Smell	Mild
28 Sep 2020 (Study Day 41)	New Loss of Taste	Mild

Symptom Date	Symptom	Result
28 Sep 2020 (Study Day 41)	Shortness of Breath	Mild
29 Sep 2020 (Study Day 42)	Cough	Moderate
29 Sep 2020 (Study Day 42)	Fatigue	Mild
29 Sep 2020 (Study Day 42)	Headache	Mild
29 Sep 2020 (Study Day 42)	Runny Nose (Rhinorrhea)	Mild
29 Sep 2020 (Study Day 42)	Shortness of Breath	Moderate
30 Sep 2020 (Study Day 43)	Cough	Moderate
30 Sep 2020 (Study Day 43)	Diarrhea	Mild
30 Sep 2020 (Study Day 43)	Fatigue	Mild
30 Sep 2020 (Study Day 43)	New Loss of Smell	Mild
30 Sep 2020 (Study Day 43)	New Loss of Taste	Mild
30 Sep 2020 (Study Day 43)	Shortness of Breath	Moderate
01 Oct 2020 (Study Day 44)	Cough	Moderate
01 Oct 2020 (Study Day 44)	Diarrhea	Mild
01 Oct 2020 (Study Day 44)	Fatigue	Moderate
01 Oct 2020 (Study Day 44)	Shortness of Breath	Moderate
02 Oct 2020 (Study Day 45)	Cough	Moderate
02 Oct 2020 (Study Day 45)	Diarrhea	Mild
02 Oct 2020 (Study Day 45)	Fatigue	Moderate
02 Oct 2020 (Study Day 45)	Shortness of Breath	Moderate
03 Oct 2020 (Study Day 46)	Cough	Mild
03 Oct 2020 (Study Day 46)	Diarrhea	Mild
03 Oct 2020 (Study Day 46)	Fatigue	Mild
03 Oct 2020 (Study Day 46)	Shortness of Breath	Mild
04 Oct 2020 (Study Day 47)	Cough	Mild
04 Oct 2020 (Study Day 47)	Diarrhea	Mild
04 Oct 2020 (Study Day 47)	Fatigue	Mild
04 Oct 2020 (Study Day 47)	Shortness of Breath	Mild
05 Oct 2020 (Study Day 48)	Cough	Mild
05 Oct 2020 (Study Day 48)	Diarrhea	Mild
05 Oct 2020 (Study Day 48)	Fatigue	Moderate
05 Oct 2020 (Study Day 48)	Headache	Mild
05 Oct 2020 (Study Day 48)	Shortness of Breath	Mild
06 Oct 2020 (Study Day 49)	Body Aches	Mild
06 Oct 2020 (Study Day 49)	Cough	Mild
06 Oct 2020 (Study Day 49)	Fatigue	Mild
06 Oct 2020 (Study Day 49)	Muscle Aches (Myalgia)	Mild
07 Oct 2020 (Study Day 50)	Cough	Moderate
07 Oct 2020 (Study Day 50)	Diarrhea	Mild
07 Oct 2020 (Study Day 50)	Fatigue	Mild
07 Oct 2020 (Study Day 50)	Shortness of Breath	Mild
08 Oct 2020 (Study Day 51)	Cough	Mild
08 Oct 2020 (Study Day 51)	Diarrhea	Mild

Symptom Date	Symptom	Result
08 Oct 2020 (Study Day 51)	Fatigue	Moderate
08 Oct 2020 (Study Day 51)	Shortness of Breath	Mild
09 Oct 2020 (Study Day 52)	Cough	Mild
09 Oct 2020 (Study Day 52)	Fatigue	Mild
09 Oct 2020 (Study Day 52)	Shortness of Breath	Mild
10 Oct 2020 (Study Day 53)	Cough	Moderate
10 Oct 2020 (Study Day 53)	Fatigue	Moderate
10 Oct 2020 (Study Day 53)	Shortness of Breath	Mild
11 Oct 2020 (Study Day 54)	Cough	Moderate
11 Oct 2020 (Study Day 54)	Fatigue	Moderate
11 Oct 2020 (Study Day 54)	Shortness of Breath	Mild
12 Oct 2020 (Study Day 55)	Cough	Mild
12 Oct 2020 (Study Day 55)	Fatigue	Moderate
12 Oct 2020 (Study Day 55)	Headache	Mild
12 Oct 2020 (Study Day 55)	Nasal Congestion	Mild
12 Oct 2020 (Study Day 55)	Shortness of Breath	Mild
13 Oct 2020 (Study Day 56)	Cough	Mild
13 Oct 2020 (Study Day 56)	Fatigue	Moderate
13 Oct 2020 (Study Day 56)	Shortness of Breath	Mild
14 Oct 2020 (Study Day 57)	Cough	Mild
14 Oct 2020 (Study Day 57)	Fatigue	Moderate
14 Oct 2020 (Study Day 57)	Shortness of Breath	Mild
15 Oct 2020 (Study Day 58)	Cough	Moderate
15 Oct 2020 (Study Day 58)	Fatigue	Moderate
15 Oct 2020 (Study Day 58)	Shortness of Breath	Moderate
16 Oct 2020 (Study Day 59)	Cough	Moderate
16 Oct 2020 (Study Day 59)	Fatigue	Moderate
16 Oct 2020 (Study Day 59)	Shortness of Breath	Moderate
17 Oct 2020 (Study Day 60)	Cough	Moderate
17 Oct 2020 (Study Day 60)	Fatigue	Mild
17 Oct 2020 (Study Day 60)	Shortness of Breath	Moderate
18 Oct 2020 (Study Day 61)	Cough	Mild
18 Oct 2020 (Study Day 61)	Fatigue	Moderate
18 Oct 2020 (Study Day 61)	O2 Saturation (%)	92
18 Oct 2020 (Study Day 61)	Shortness of Breath	Mild
19 Oct 2020 (Study Day 62)	Cough	Mild
19 Oct 2020 (Study Day 62)	Fatigue	Moderate
19 Oct 2020 (Study Day 62)	O2 Saturation (%)	93
19 Oct 2020 (Study Day 62)	Shortness of Breath	Mild
20 Oct 2020 (Study Day 63)	Cough	Mild
20 Oct 2020 (Study Day 63)	Fatigue	Moderate
20 Oct 2020 (Study Day 63)	O2 Saturation (%)	92
20 Oct 2020 (Study Day 63)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
21 Oct 2020 (Study Day 64)	Cough	Mild
21 Oct 2020 (Study Day 64)	Fatigue	Moderate
21 Oct 2020 (Study Day 64)	Shortness of Breath	Mild
22 Oct 2020 (Study Day 65)	Cough	Moderate
22 Oct 2020 (Study Day 65)	Fatigue	Moderate
22 Oct 2020 (Study Day 65)	O2 Saturation (%)	93
22 Oct 2020 (Study Day 65)	Shortness of Breath	Moderate
23 Oct 2020 (Study Day 66)	Cough	Moderate
23 Oct 2020 (Study Day 66)	Fatigue	Moderate
23 Oct 2020 (Study Day 66)	Shortness of Breath	Moderate
24 Oct 2020 (Study Day 67)	Cough	Moderate
24 Oct 2020 (Study Day 67)	Fatigue	Moderate
24 Oct 2020 (Study Day 67)	O2 Saturation (%)	92
24 Oct 2020 (Study Day 67)	Shortness of Breath	Mild
25 Oct 2020 (Study Day 68)	Cough	Moderate
25 Oct 2020 (Study Day 68)	Difficulty Breathing	Mild
25 Oct 2020 (Study Day 68)	Fatigue	Moderate
25 Oct 2020 (Study Day 68)	Headache	Moderate
25 Oct 2020 (Study Day 68)	O2 Saturation (%)	92
25 Oct 2020 (Study Day 68)	Shortness of Breath	Mild
26 Oct 2020 (Study Day 69)	Cough	Moderate
26 Oct 2020 (Study Day 69)	Difficulty Breathing	Mild
26 Oct 2020 (Study Day 69)	Fatigue	Mild
26 Oct 2020 (Study Day 69)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
18 Oct 2020 (Study Day 61)	Oxygen Saturation	92%
18 Oct 2020 - 24 Oct 2020 (Study Day 61-67)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 38 days, after which it was considered to be recovered/resolved on 28 Oct 2020 (Study Day 71). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000526	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dermoid cyst	Dermoid cyst benign	1986 - 1997
Hysterectomy	Complete hysterectomy	1997 - 1997
Postmenopause	Postmenopausal	1997 - Ongoing
Spinal fracture	L5, s1 fracture	2017 - 2017
Spinal fusion surgery	L5, s1 spinal fusion	2017 - 2017
Type 2 diabetes mellitus	Diabetes type 2	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2019 - Ongoing	Diabetes Type 2
Semaglutide	2019 - Ongoing	Diabetes Type 2
Ibuprofen	21 Sep 2020 (Study Day 34) - 25 Sep 2020 (Study Day 38)	Fever And Headache
Paracetamol	21 Sep 2020 (Study Day 34) - 25 Sep 2020 (Study Day 38)	Fever And Headache
Bismuth subsalicylate	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	COVID 19
Azithromycin	30 Sep 2020 (Study Day 43) - 04 Oct 2020 (Study Day 47)	Left Lower Lung Pneumonia Related To COVID
Budesonide; formoterol	30 Sep 2020 (Study Day 43) - 28 Oct 2020 (Study Day 71)	COVID 19
Guaifenesin	30 Sep 2020 (Study Day 43) - 14 Oct 2020 (Study Day 57)	COVID 19
Salbutamol sulfate	30 Sep 2020 (Study Day 43) - 28 Oct 2020 (Study Day 71)	COVID 19
Influenza vaccine	16 Oct 2020 (Study Day 59) - 16 Oct 2020 (Study Day 59)	Influenza Infection Prophylaxis
Hepatitis b vaccine	11 Mar 2021 (Study Day 205) - 11 Mar 2021 (Study Day 205)	Hepatitis Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	21 Sep 2020 (Study Day 34) - 28 Oct 2020 (Study Day 71)
Petechiae	Grade 1/mild	Not related	23 Sep 2020 (Study Day 36) - 24 Sep 2020 (Study Day 37)
COVID-19 Pneumonia	Grade 1/mild	Not related	30 Sep 2020 (Study Day 43) - 04 Oct 2020 (Study Day 47)
Tympanic Membrane Perforation	Grade 1/mild	Not related	13 Oct 2020 (Study Day 56) - 14 Oct 2020 (Study Day 57)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2377 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	05 Oct 2020 (Study Day 36)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/ moderate	Not related	19 Nov 2020 (Study Day 81) – 06 Dec 2020 (Study Day 98)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US387-2377, a 36-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 19 Nov 2020 (Study Day 81), 80 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 36, 05 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 24 Nov 2020 (Study Day 86), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
19 Nov 2020 (Study Day 81)	Sore Throat	Moderate
20 Nov 2020 (Study Day 82)	Sore Throat	Moderate
21 Nov 2020 (Study Day 83)	Cough	Mild
21 Nov 2020 (Study Day 83)	Nasal Congestion	Moderate
21 Nov 2020 (Study Day 83)	Sore Throat	Moderate

Symptom Date	Symptom	Result
22 Nov 2020 (Study Day 84)	Cough	Mild
22 Nov 2020 (Study Day 84)	Nasal Congestion	Moderate
22 Nov 2020 (Study Day 84)	Sore Throat	Moderate
23 Nov 2020 (Study Day 85)	Cough	Mild
23 Nov 2020 (Study Day 85)	Nasal Congestion	Moderate
23 Nov 2020 (Study Day 85)	New Loss of Smell	Mild
23 Nov 2020 (Study Day 85)	New Loss of Taste	Mild
24 Nov 2020 (Study Day 86)	Chills	Mild
24 Nov 2020 (Study Day 86)	Cough	Mild
24 Nov 2020 (Study Day 86)	Nasal Congestion	Moderate
24 Nov 2020 (Study Day 86)	New Loss of Smell	Mild
24 Nov 2020 (Study Day 86)	New Loss of Taste	Mild
25 Nov 2020 (Study Day 87)	Chills	Mild
25 Nov 2020 (Study Day 87)	Cough	Mild
25 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 87)	New Loss of Smell	Mild
25 Nov 2020 (Study Day 87)	New Loss of Taste	Mild
26 Nov 2020 (Study Day 88)	Chills	Mild
26 Nov 2020 (Study Day 88)	Cough	Mild
26 Nov 2020 (Study Day 88)	Fatigue	Mild
26 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 88)	New Loss of Smell	Mild
26 Nov 2020 (Study Day 88)	New Loss of Taste	Mild
27 Nov 2020 (Study Day 89)	Chills	Mild
27 Nov 2020 (Study Day 89)	Cough	Mild
27 Nov 2020 (Study Day 89)	Fatigue	Mild
27 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 89)	New Loss of Smell	Mild
27 Nov 2020 (Study Day 89)	New Loss of Taste	Mild
28 Nov 2020 (Study Day 90)	Chills	Mild
28 Nov 2020 (Study Day 90)	Cough	Mild
28 Nov 2020 (Study Day 90)	Fatigue	Mild
28 Nov 2020 (Study Day 90)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 90)	New Loss of Smell	Mild
28 Nov 2020 (Study Day 90)	New Loss of Taste	Mild
29 Nov 2020 (Study Day 91)	Chills	Mild
29 Nov 2020 (Study Day 91)	Fatigue	Mild
29 Nov 2020 (Study Day 91)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 91)	New Loss of Smell	Mild
29 Nov 2020 (Study Day 91)	New Loss of Taste	Mild
30 Nov 2020 (Study Day 92)	Fatigue	Mild
30 Nov 2020 (Study Day 92)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 92)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
30 Nov 2020 (Study Day 92)	New Loss of Taste	Mild
01 Dec 2020 (Study Day 93)	Fatigue	Mild
01 Dec 2020 (Study Day 93)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 93)	New Loss of Smell	Mild
01 Dec 2020 (Study Day 93)	New Loss of Taste	Mild
02 Dec 2020 (Study Day 94)	Nasal Congestion	Mild
02 Dec 2020 (Study Day 94)	New Loss of Smell	Mild
02 Dec 2020 (Study Day 94)	New Loss of Taste	Mild
03 Dec 2020 (Study Day 95)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 95)	New Loss of Smell	Mild
03 Dec 2020 (Study Day 95)	New Loss of Taste	Mild
04 Dec 2020 (Study Day 96)	Nasal Congestion	Mild
04 Dec 2020 (Study Day 96)	New Loss of Smell	Mild
04 Dec 2020 (Study Day 96)	New Loss of Taste	Mild
05 Dec 2020 (Study Day 97)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 105)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
13 Dec 2020 (Study Day 105)	Oxygen Saturation	93%
13 Dec 2020 - 13 Dec 2020 (Study Day 105-105)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
13 Dec 2020 - 13 Dec 2020 (Study Day 105-105)	Respiratory Rates >= 30 per Minute	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 18 days, after which it was considered to be recovered/resolved on 06 Dec 2020 (Study Day 98). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001166	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	23 Nov 2020 (Study Day 85) - 23 Nov 2020 (Study Day 85)	Flu Prevention
Ibuprofen	24 Nov 2020 (Study Day 86) - 24 Nov 2020 (Study Day 86)	Left Arm Pain (Flu Vaccine Site)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	19 Nov 2020 (Study Day 81) - 06 Dec 2020 (Study Day 98)
Vaccination Site Pain	Grade 2/moderate	Not applicable	24 Nov 2020 (Study Day 86) - 25 Nov 2020 (Study Day 87)
Oxygen Saturation Decreased	Grade 1/mild	Not related	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US388-2016 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Substance-Induced Psychotic Disorder/Acute Substance Induced Psychosis	SAE	Grade 4	Not related	11 Nov 2020 (Study Day 69) – 07 Dec 2020 (Study Day 95)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US388-2016, a 56-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of substance-induced psychotic disorder. Action taken with the IP was not applicable. The event of acute substance induced psychosis lasted for 27 days, after which it was considered to be recovered/resolved on 07 Dec 2020 (Study Day 95). The investigator assessed the event of substance-induced psychotic disorder to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009889	Substance-induced psychotic disorder

Study Completion/Discontinuation

On 04 Mar 2021 (Study Day 182), the participant discontinued from the study due to physician decision (non compliant).

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	Not reported - Ongoing
Colostomy	Colostomy present	20 Nov 2003 (Study Day -6133) - Ongoing
Diabetes mellitus	Diabetes mellitus	16 Mar 2016 (Study Day -1633) - Ongoing
Post-traumatic stress disorder	Chronic post-traumatic stress disorder	30 Nov 2016 (Study Day -1374) - Ongoing
Arthritis	Arthritis of left hip	16 Feb 2017 (Study Day -1296) - Ongoing
Arthritis	Arthritis of right hip	16 Feb 2017 (Study Day -1296) - Ongoing
Myocardial infarction	Mi - myocardial infarction	02 Mar 2017 (Study Day -1282) - Ongoing
HIV infection	Human immunodeficiency virus infection	21 Jun 2018 (Study Day -806) - Ongoing
Nicotine dependence	Nicotine dependence	09 Jul 2018 (Study Day -788) - Ongoing
Alcoholism	Alcohol dependence	15 Aug 2018 (Study Day -751) - Ongoing
Drug dependence	Cocaine dependence	15 Aug 2018 (Study Day -751) - Ongoing
Victim of sexual abuse	Adult victim of (b) (6) (b) (6)	15 Jan 2019 (Study Day -598) - Ongoing
Delusion	Psychotic disorder with delusions caused by stimulant	03 Feb 2020 (Study Day -214) - Ongoing
Suicide attempt	H/o: attempted suicide	07 May 2020 (Study Day -120) - Ongoing
Drug abuse	Methamphetamine abuse	26 May 2020 (Study Day -101) - Ongoing
Presbyopia	Presbyopia	07 Jun 2020 (Study Day -89) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Stroke/Heart Attack Prevention
Alogliptin	Not reported - 27 Oct 2020 (Study Day 54)	Diabetes
Atorvastatin	Not reported - Ongoing	Mi - Myocardial Infarction
Gabapentin	Not reported - Ongoing	General Body Pain
Metoprolol succinate	Not reported - Ongoing	Mi - Myocardial Infarction
Paracetamol	Not reported - Ongoing	General Body Pain
Sertraline	Not reported - 06 Jan 2021 (Study Day 125)	Mood (Chronic Post-Traumatic Stress Disorder)
Trazodone	Not reported - 08 Oct 2020 (Study Day 35)	Insomnia
Ekg*	26 Oct 2020 (Study Day 53) - 26 Oct 2020 (Study Day 53)	Diagnostic
Hydroxyzine	07 Dec 2020 (Study Day 95) - Ongoing	As Needed For Insomnia
Metformin	07 Dec 2020 (Study Day 95) - Ongoing	Diabetes
Naltrexone	07 Dec 2020 (Study Day 95) - Ongoing	Alcohol Dependence

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Quetiapine fumarate	07 Dec 2020 (Study Day 95) - Ongoing	Psychotic Disorder With Delusions
Semaglutide	07 Dec 2020 (Study Day 95) - Ongoing	Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chest Pain	Grade 1/mild	Not related	26 Oct 2020 (Study Day 53) - 26 Oct 2020 (Study Day 53)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US389-2033 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Subarachnoid Haemorrhage/ Subarachnoid Hemorrhage	SAE	Grade 3/ severe	Not related	20 Dec 2020 (Study Day 112) – 22 Dec 2020 (Study Day 114)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US389-2033, a 73-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Dec 2020 (Study Day 112), 111 days after the first dose and 83 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of subarachnoid haemorrhage. Action taken with the IP was not applicable. The event of subarachnoid hemorrhage lasted for 3 days, after which it was considered to be recovered/resolved with sequelae on 22 Dec 2020 (Study Day 114). The investigator assessed the event of subarachnoid haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001380	Subarachnoid haemorrhage

Study Completion/Discontinuation

On 27 Jan 2021 (Study Day 150), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	1985 - Ongoing
Bipolar disorder	Bipolar disorder	1990 - Ongoing
Deafness bilateral	Hearing loss (bilateral)	1990 - Ongoing
Drug dependence	History opioid dependence	2004 - 2004
Atrial fibrillation	Intermittent atrial fibrillation	2014 - Ongoing
Cardiac failure	Heart failure	2014 - Ongoing
Coronary artery disease	Coronary artery disease	2014 - Ongoing
Urinary retention	Urinary retention	2014 - Ongoing
Back pain	Chronic low back pain	2018 - Ongoing
Clavicle fracture	Displaced clavical (right)	2018 - 2018
Musculoskeletal pain	Chronic right shoulder pain	2018 - Ongoing
Osteoarthritis	Osteoarthritis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1985 - Ongoing	Headaches
Duloxetine hydrochloride	2010 - Ongoing	Bipolar Disorder
Amiodarone	2014 - 19 Dec 2020 (Study Day 111)	Intermittent Atrial Fibrillation
Carvedilol	2014 - 19 Dec 2020 (Study Day 111)	Heart Failure
Finasteride	2014 - Ongoing	Urinary Retention
Furosemide	2014 - Ongoing	Heart Failure
Isosorbide	2014 - Ongoing	Heart Failure
Potassium	2014 - Ongoing	Heart Failure
Acetylsalicylic acid; caffeine; paracetamol	2018 - Ongoing	Generalized Osteoarthritis
Ibuprofen	01 Sep 2020 (Study Day 2) - 06 Sep 2020 (Study Day 7)	Fatigue
Influenza vaccine	14 Sep 2020 (Study Day 15) - 14 Sep 2020 (Study Day 15)	Influenza
Amiodarone	20 Dec 2020 (Study Day 112) - Ongoing	Atrial Fibrilation
Atorvastatin	20 Dec 2020 (Study Day 112) - Ongoing	Coronary Artery Disease
Bisacodyl	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Bowel Prophylaxis
Carvedilol	20 Dec 2020 (Study Day 112) - Ongoing	Heart Failure
Chest x-ray*	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct brain*	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)	Adverse Event
Ct spine cervical without contrast*	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)	Diagnostic
Docusate	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Bowel Prophylaxis
Hydralazine	20 Dec 2020 (Study Day 112) - Ongoing	Heart Failure
Hydralazine	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Heart Failure
Hydrocodone bitartrate; paracetamol	20 Dec 2020 (Study Day 112) - Ongoing	Left Clavicular Fracture
Hydrocodone bitartrate; paracetamol	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Subarachnoid Hemorrhage
Levothyroxine	20 Dec 2020 (Study Day 112) - Ongoing	Thyroid Nodule
Melatonin	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Insomnia Prophylaxis
Ondansetron	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Nausea Prophylaxis
Oxycodone	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Left Clavicular Fracture
Paracetamol	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	L Clavicle Fracture
Shoulder x-ray left*	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)	Adverse Event
Spironolactone	20 Dec 2020 (Study Day 112) - 22 Dec 2020 (Study Day 114)	Heart Failure
X-ray pelvis*	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)	Diagnostic
X-ray tibia/fibula (right)*	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)	Adverse Event
Ct brain*	21 Dec 2020 (Study Day 113) - 21 Dec 2020 (Study Day 113)	Adverse Event
Debridement r leg hematoma*	21 Dec 2020 (Study Day 113) - 21 Dec 2020 (Study Day 113)	Adverse Event
Cyclobenzaprine	23 Dec 2020 (Study Day 115) - Ongoing	Left Clavicle Fracture
Lidocaine hydrochloride	23 Dec 2020 (Study Day 115) - Ongoing	Left Clavicle Fracture
Other viral vaccines	06 Jan 2021 (Study Day 129) - 06 Jan 2021 (Study Day 129)	COVID-19 Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 3/severe	Related	01 Sep 2020 (Study Day 2) - 09 Sep 2020 (Study Day 10)
Headache	Grade 2/moderate	Related	01 Sep 2020 (Study Day 2) - 11 Sep 2020 (Study Day 12)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chronic Kidney Disease	Grade 1/mild	Not related	20 Dec 2020 (Study Day 112) - Ongoing
Clavicle Fracture	Grade 3/severe	Not related	20 Dec 2020 (Study Day 112) - Ongoing
Fall	Grade 3/severe	Not related	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)
Haematoma	Grade 3/severe	Not related	20 Dec 2020 (Study Day 112) - 21 Dec 2020 (Study Day 113)
Subcutaneous Haematoma	Grade 2/moderate	Not related	20 Dec 2020 (Study Day 112) - Ongoing
Thyroid Mass	Grade 1/mild	Not related	20 Dec 2020 (Study Day 112) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US389-2034 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Craniocerebral Injury/ Traumatic Brain Injury	SAE	Grade 3/ severe	Not related	07 Jan 2021 (Study Day 130) – 08 Jan 2021 (Study Day 131)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US389-2034, a 59-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Jan 2021 (Study Day 130), 129 days after the first dose and 101 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of craniocerebral injury. Action taken with the IP was not applicable. The event of traumatic brain injury lasted for 2 days, after which it was considered to be recovered/resolved with sequelae on 08 Jan 2021 (Study Day 131). The investigator assessed the event of craniocerebral injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004338	Craniocerebral injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Keratoconus	Left keratoconus	(b) (6) 1960 (Study Day (b) (6)) - 1981
Keratoconus	Right keratoconus	(b) (6) 1960 (Study Day (b) (6) - 1977
Corneal transplant	Right corneal transplant	1977 - 1977
Corneal transplant	Left corneal transplant	1981 - 1981
Drug hypersensitivity	Pred forte allergy	1981 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Depression	Depression	2018 - Ongoing
Cataract	Cataracts bilateral	Dec 2018 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2019 - Ongoing
Seasonal allergy	Seasonal allergies	2019 - Ongoing
Tooth disorder	Odontogenic disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin hydrochloride	Aug 2019 - Ongoing	Benign Prostatic Hyperplasia
Plantago ovata	May 2020 - Ongoing	Supplement
Chest x-ray*	07 Jan 2021 (Study Day 130) - 07 Jan 2021 (Study Day 130)	Diagnostic
Ct brain/ head*	07 Jan 2021 (Study Day 130) - 07 Jan 2021 (Study Day 130)	Diagnostic
Ct maxillofacial*	07 Jan 2021 (Study Day 130) - 07 Jan 2021 (Study Day 130)	Adverse Event
Ct scan spine/cervical*	07 Jan 2021 (Study Day 130) - 07 Jan 2021 (Study Day 130)	Adverse Event
Pelvis x-ray*	07 Jan 2021 (Study Day 130) - 07 Jan 2021 (Study Day 130)	Diagnostic
Amoxicillin	08 Jan 2021 (Study Day 131) - 17 Jan 2021 (Study Day 140)	Fracture Orbit Bilateral
Celecoxib	08 Jan 2021 (Study Day 131) - 17 Jan 2021 (Study Day 140)	Fracture Orbit Bilateral
Ct brain/head*	08 Jan 2021 (Study Day 131) - 08 Jan 2021 (Study Day 131)	Adverse Event
Lidocaine	11 Jan 2021 (Study Day 134) - 11 Jan 2021 (Study Day 134)	Foreign Body Right 3rd Finger
Removal foreign body right 3rd finger*	11 Jan 2021 (Study Day 134) - 11 Jan 2021 (Study Day 134)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct brain/head*	25 Feb 2021 (Study Day 179) - 25 Feb 2021 (Study Day 179)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain Lower	Grade 1/mild	Not related	07 Oct 2020 (Study Day 38) - 18 Oct 2020 (Study Day 49)
Subarachnoid Haemorrhage	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 38) - 08 Jan 2021 (Study Day 131)
Foreign Body In Skin Or Subcutaneous Tissue	Grade 2/moderate	Not related	24 Dec 2020 (Study Day 116) - 11 Jan 2021 (Study Day 134)
Facial Bones Fracture	Grade 3/severe	Not related	07 Jan 2021 (Study Day 130) - 25 Feb 2021 (Study Day 179)
Facial Bones Fracture	Grade 3/severe	Not related	07 Jan 2021 (Study Day 130) - 25 Feb 2021 (Study Day 179)
Facial Bones Fracture	Grade 3/severe	Not related	07 Jan 2021 (Study Day 130) - 25 Feb 2021 (Study Day 179)
Fall	Grade 3/severe	Not related	07 Jan 2021 (Study Day 130) - 07 Jan 2021 (Study Day 130)
Subdural Haematoma	Grade 3/severe	Not related	07 Jan 2021 (Study Day 130) - 08 Jan 2021 (Study Day 131)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US301-2329 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	15 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	13 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	COVID-19	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 119) – 25 Jan 2021 (Study Day 133)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US301-2329, a 49-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 11 Jan 2021 (Study Day 119), 118 days after the first dose and 90 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 13 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 13 Jan 2021 (Study Day 121), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 119)	Body Aches	Moderate
11 Jan 2021 (Study Day 119)	Cough	Mild
11 Jan 2021 (Study Day 119)	Headache	Moderate
12 Jan 2021 (Study Day 120)	Body Aches	Moderate
12 Jan 2021 (Study Day 120)	Cough	Mild

Symptom Date	Symptom	Result
12 Jan 2021 (Study Day 120)	Headache	Moderate
13 Jan 2021 (Study Day 121)	Cough	Mild
14 Jan 2021 (Study Day 122)	Body Aches	Mild
14 Jan 2021 (Study Day 122)	Cough	Mild
14 Jan 2021 (Study Day 122)	Difficulty Breathing	Mild
14 Jan 2021 (Study Day 122)	Fatigue	Moderate
14 Jan 2021 (Study Day 122)	Headache	Mild
14 Jan 2021 (Study Day 122)	Sore Throat	Mild
15 Jan 2021 (Study Day 123)	Body Aches	Moderate
15 Jan 2021 (Study Day 123)	Fatigue	Moderate
15 Jan 2021 (Study Day 123)	Headache	Mild
15 Jan 2021 (Study Day 123)	Muscle Aches (Myalgia)	Moderate
15 Jan 2021 (Study Day 123)	Temperature (°F)	101.2
16 Jan 2021 (Study Day 124)	Body Aches	Mild
16 Jan 2021 (Study Day 124)	Cough	Mild
16 Jan 2021 (Study Day 124)	Diarrhea	Moderate
16 Jan 2021 (Study Day 124)	Fatigue	Mild
16 Jan 2021 (Study Day 124)	Headache	Moderate
16 Jan 2021 (Study Day 124)	Muscle Aches (Myalgia)	Mild
16 Jan 2021 (Study Day 124)	Nasal Congestion	Mild
16 Jan 2021 (Study Day 124)	Nausea	Moderate
16 Jan 2021 (Study Day 124)	Temperature (°F)	101
16 Jan 2021 (Study Day 124)	Vomiting	Moderate
17 Jan 2021 (Study Day 125)	Body Aches	Mild
17 Jan 2021 (Study Day 125)	Cough	Mild
17 Jan 2021 (Study Day 125)	Diarrhea	Moderate
17 Jan 2021 (Study Day 125)	Fatigue	Mild
17 Jan 2021 (Study Day 125)	Headache	Mild
17 Jan 2021 (Study Day 125)	Muscle Aches (Myalgia)	Mild
17 Jan 2021 (Study Day 125)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 125)	Nausea	Mild
17 Jan 2021 (Study Day 125)	Vomiting	Moderate
18 Jan 2021 (Study Day 126)	Cough	Mild
18 Jan 2021 (Study Day 126)	Diarrhea	Mild
18 Jan 2021 (Study Day 126)	Fatigue	Mild
18 Jan 2021 (Study Day 126)	Headache	Mild
18 Jan 2021 (Study Day 126)	Nasal Congestion	Mild
18 Jan 2021 (Study Day 126)	Nausea	Mild
18 Jan 2021 (Study Day 126)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 126)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 127)	Body Aches	Mild
19 Jan 2021 (Study Day 127)	Cough	Mild
19 Jan 2021 (Study Day 127)	Difficulty Breathing	Severe

Symptom Date	Symptom	Result
19 Jan 2021 (Study Day 127)	Fatigue	Mild
19 Jan 2021 (Study Day 127)	Headache	Mild
19 Jan 2021 (Study Day 127)	Muscle Aches (Myalgia)	Mild
19 Jan 2021 (Study Day 127)	New Loss of Smell	Moderate
19 Jan 2021 (Study Day 127)	New Loss of Taste	Moderate
19 Jan 2021 (Study Day 127)	O2 Saturation (%)	87
19 Jan 2021 (Study Day 127)	Shortness of Breath	Severe
20 Jan 2021 (Study Day 128)	Cough	Mild
20 Jan 2021 (Study Day 128)	Fatigue	Mild
20 Jan 2021 (Study Day 128)	New Loss of Smell	Moderate
20 Jan 2021 (Study Day 128)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 129)	Cough	Mild
21 Jan 2021 (Study Day 129)	Fatigue	Mild
22 Jan 2021 (Study Day 130)	Cough	Mild
22 Jan 2021 (Study Day 130)	Headache	Mild
22 Jan 2021 (Study Day 130)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 130)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 130)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
19 Jan 2021 (Study Day 127)	Oxygen Saturation	87%
19 Jan 2021 - 22 Jan 2021 (Study Day 127-130)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 25 Jan 2021 (Study Day 133). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004882	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy	1998 - 1998
Uterine leiomyoma	Uterine fibroids	1998 - 1998
Postmenopause	Postmenopausal	1999 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	11 Jan 2021 (Study Day 119) - 12 Jan 2021 (Study Day 120)	Headache, Body Aches (Due To COVID Infection (Ae #1)
Azithromycin	19 Jan 2021 (Study Day 127) - 06 Feb 2021 (Study Day 145)	COVID-19 Infection (Ae #1)
Paracetamol	19 Jan 2021 (Study Day 127) - 06 Feb 2021 (Study Day 145)	COVID-19 Infection (Ae #1)
Prednisone	19 Jan 2021 (Study Day 127) - 24 Jan 2021 (Study Day 132)	COVID-19 Infection (Ae #1)
Benzonatate	25 Jan 2021 (Study Day 133) - 06 Feb 2021 (Study Day 145)	COVID-19 Infection (Ae #2)
Dexamethasone	25 Jan 2021 (Study Day 133) - 06 Feb 2021 (Study Day 145)	COVID-19 Infection (Ae #2)
Ibuprofen	25 Jan 2021 (Study Day 133) - 06 Feb 2021 (Study Day 145)	COVID-19 Infection (Ae #2)
Sulfamethoxazole; trimethoprim	08 Mar 2021 (Study Day 175) - 11 Mar 2021 (Study Day 178)	Urinary Tract Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	11 Jan 2021 (Study Day 119) - 25 Jan 2021 (Study Day 133)
Urinary Tract Infection	Grade 2/moderate	Not related	07 Mar 2021 (Study Day 174) - 11 Mar 2021 (Study Day 178)
Papilloma Viral Infection	Grade 1/mild	Not related	21 Mar 2021 (Study Day 188) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2233 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 36)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 1/mild	Not related	02 Oct 2020 (Study Day 44) – 21 Oct 2020 (Study Day 63)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US302-2233, a 53-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 02 Oct 2020 (Study Day 44), 43 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 36, 24 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 09 Oct 2020 (Study Day 51), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
02 Oct 2020 (Study Day 44)	Headache	Mild
03 Oct 2020 (Study Day 45)	Headache	Mild
04 Oct 2020 (Study Day 46)	Headache	Mild
05 Oct 2020 (Study Day 47)	Headache	Mild
06 Oct 2020 (Study Day 48)	Headache	Mild
06 Oct 2020 (Study Day 48)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
06 Oct 2020 (Study Day 48)	New Loss of Taste	Mild
07 Oct 2020 (Study Day 49)	New Loss of Smell	Mild
07 Oct 2020 (Study Day 49)	New Loss of Taste	Mild
08 Oct 2020 (Study Day 50)	New Loss of Smell	Mild
08 Oct 2020 (Study Day 50)	New Loss of Taste	Mild
09 Oct 2020 (Study Day 51)	New Loss of Smell	Moderate
09 Oct 2020 (Study Day 51)	New Loss of Taste	Moderate
10 Oct 2020 (Study Day 52)	New Loss of Smell	Moderate
10 Oct 2020 (Study Day 52)	New Loss of Taste	Moderate
11 Oct 2020 (Study Day 53)	New Loss of Smell	Moderate
11 Oct 2020 (Study Day 53)	New Loss of Taste	Moderate
12 Oct 2020 (Study Day 54)	New Loss of Smell	Moderate
12 Oct 2020 (Study Day 54)	New Loss of Taste	Moderate
13 Oct 2020 (Study Day 55)	Nausea	Mild
13 Oct 2020 (Study Day 55)	New Loss of Smell	Mild
13 Oct 2020 (Study Day 55)	New Loss of Taste	Mild
14 Oct 2020 (Study Day 56)	Nausea	Mild
14 Oct 2020 (Study Day 56)	New Loss of Smell	Mild
14 Oct 2020 (Study Day 56)	New Loss of Taste	Mild
15 Oct 2020 (Study Day 57)	New Loss of Smell	Mild
15 Oct 2020 (Study Day 57)	New Loss of Taste	Mild
16 Oct 2020 (Study Day 58)	New Loss of Smell	Mild
16 Oct 2020 (Study Day 58)	New Loss of Taste	Mild
17 Oct 2020 (Study Day 59)	New Loss of Smell	Mild
17 Oct 2020 (Study Day 59)	New Loss of Taste	Mild
18 Oct 2020 (Study Day 60)	New Loss of Smell	Mild
18 Oct 2020 (Study Day 60)	New Loss of Taste	Mild
19 Oct 2020 (Study Day 61)	New Loss of Smell	Mild
19 Oct 2020 (Study Day 61)	New Loss of Taste	Mild
21 Oct 2020 (Study Day 63)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
21 Oct 2020 (Study Day 63)	Oxygen Saturation	93%
21 Oct 2020 - 21 Oct 2020 (Study Day 63-63)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 21 Oct 2020 (Study Day 63). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000471	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	2002 - 2002
Drug hypersensitivity	Allergy monocycline	2010 - Ongoing
Eczema	Eczema	2012 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen sodium	02 Oct 2020 (Study Day 44) - 06 Oct 2020 (Study Day 48)	COVID-19
Influenza vaccine	22 Dec 2020 (Study Day 125) - 22 Dec 2020 (Study Day 125)	Influenza Prevention
Amoxicillin	31 Jan 2021 (Study Day 165) - Ongoing	Gum Infection
Diclofenac	20 Feb 2021 (Study Day 185) - 02 Mar 2021 (Study Day 195)	Herpes Zoster
Valaciclovir	20 Feb 2021 (Study Day 185) - 02 Mar 2021 (Study Day 195)	Herpes Zoster

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	02 Oct 2020 (Study Day 44) - 21 Oct 2020 (Study Day 63)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gingivitis	Grade 1/mild	Not related	31 Jan 2021 (Study Day 165) - 24 Feb 2021 (Study Day 189)
Herpes Zoster	Grade 1/mild	Not related	20 Feb 2021 (Study Day 185) - 02 Mar 2021 (Study Day 195)
Lymphadenopathy	Grade 1/mild	Not related	20 Feb 2021 (Study Day 185) - 26 Feb 2021 (Study Day 191)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2110 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 35)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	11 Nov 2020 (Study Day 99) – 01 Dec 2020 (Study Day 119)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US303-2110, a 61-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 11 Nov 2020 (Study Day 99), 98 days after the first dose and 64 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 35, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 19 Nov 2020 (Study Day 107), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
18 Nov 2020 (Study Day 106)	Chills	Moderate
18 Nov 2020 (Study Day 106)	Cough	Moderate
18 Nov 2020 (Study Day 106)	Difficulty Breathing	Moderate
18 Nov 2020 (Study Day 106)	Fatigue	Moderate
18 Nov 2020 (Study Day 106)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 106)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
18 Nov 2020 (Study Day 106)	Shortness of Breath	Moderate
19 Nov 2020 (Study Day 107)	Cough	Mild
19 Nov 2020 (Study Day 107)	Difficulty Breathing	Moderate
19 Nov 2020 (Study Day 107)	Fatigue	Mild
19 Nov 2020 (Study Day 107)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 107)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 107)	Shortness of Breath	Moderate
20 Nov 2020 (Study Day 108)	Cough	Moderate
20 Nov 2020 (Study Day 108)	Diarrhea	Moderate
20 Nov 2020 (Study Day 108)	Difficulty Breathing	Mild
20 Nov 2020 (Study Day 108)	Fatigue	Moderate
20 Nov 2020 (Study Day 108)	Headache	Mild
20 Nov 2020 (Study Day 108)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 108)	O2 Saturation (%)	92
20 Nov 2020 (Study Day 108)	Runny Nose (Rhinorrhea)	Mild
20 Nov 2020 (Study Day 108)	Shortness of Breath	Mild
21 Nov 2020 (Study Day 109)	Cough	Moderate
21 Nov 2020 (Study Day 109)	Diarrhea	Moderate
21 Nov 2020 (Study Day 109)	Difficulty Breathing	Mild
21 Nov 2020 (Study Day 109)	Fatigue	Moderate
21 Nov 2020 (Study Day 109)	Headache	Mild
21 Nov 2020 (Study Day 109)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 109)	Runny Nose (Rhinorrhea)	Mild
21 Nov 2020 (Study Day 109)	Shortness of Breath	Mild
22 Nov 2020 (Study Day 110)	Cough	Mild
22 Nov 2020 (Study Day 110)	Difficulty Breathing	Mild
22 Nov 2020 (Study Day 110)	Fatigue	Moderate
22 Nov 2020 (Study Day 110)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 110)	Shortness of Breath	Mild
23 Nov 2020 (Study Day 111)	Cough	Mild
23 Nov 2020 (Study Day 111)	Difficulty Breathing	Mild
23 Nov 2020 (Study Day 111)	Fatigue	Moderate
23 Nov 2020 (Study Day 111)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 111)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 112)	Cough	Mild
24 Nov 2020 (Study Day 112)	Difficulty Breathing	Mild
24 Nov 2020 (Study Day 112)	Fatigue	Mild
24 Nov 2020 (Study Day 112)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 112)	O2 Saturation (%)	93
24 Nov 2020 (Study Day 112)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 113)	Cough	Mild
25 Nov 2020 (Study Day 113)	Fatigue	Mild
25 Nov 2020 (Study Day 113)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
25 Nov 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
25 Nov 2020 (Study Day 113)	Shortness of Breath	Mild
26 Nov 2020 (Study Day 114)	Cough	Mild
26 Nov 2020 (Study Day 114)	Difficulty Breathing	Mild
26 Nov 2020 (Study Day 114)	Fatigue	Mild
26 Nov 2020 (Study Day 114)	O2 Saturation (%)	93
26 Nov 2020 (Study Day 114)	Runny Nose (Rhinorrhea)	Mild
26 Nov 2020 (Study Day 114)	Shortness of Breath	Mild
27 Nov 2020 (Study Day 115)	Cough	Mild
27 Nov 2020 (Study Day 115)	Difficulty Breathing	Mild
27 Nov 2020 (Study Day 115)	Fatigue	Mild
27 Nov 2020 (Study Day 115)	Runny Nose (Rhinorrhea)	Mild
27 Nov 2020 (Study Day 115)	Shortness of Breath	Mild
28 Nov 2020 (Study Day 116)	Cough	Mild
28 Nov 2020 (Study Day 116)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 117)	Cough	Mild
30 Nov 2020 (Study Day 118)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
20 Nov 2020 (Study Day 108)	Oxygen Saturation	92%
20 Nov 2020 - 26 Nov 2020 (Study Day 108-114)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved on 01 Dec 2020 (Study Day 119). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000847	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	1980 - Ongoing
Menorrhagia	Menorrhagia	1990 - 1998
Hysterectomy	Complete hysterectomy	1998 - 1998
Cholecystectomy	Cholecystectomy	2017 - 2017
Cholecystitis	Cholecystitis	2017 - 2017
Gastrooesophageal reflux disease	Acid reflux	2018 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2019 - Ongoing
Muscle spasms	Muscle spasms of lower back	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2019 - Ongoing	Medical History: Hypercholesterolemia
Levothyroxine	2019 - Ongoing	Medical History: Hypothyroidism
Meloxicam	2019 - Ongoing	Medical History: Muscle Spasms Of Lower Back
Omeprazole	2019 - Ongoing	Medical History: Acid Reflux
Influenza vaccine	24 Sep 2020 (Study Day 51) - 24 Sep 2020 (Study Day 51)	Prevention Of Seasonal Influenza
Dexamethasone	18 Nov 2020 (Study Day 106) - 24 Nov 2020 (Study Day 112)	COVID-19 Infection
Azithromycin	19 Nov 2020 (Study Day 107) - 19 Nov 2020 (Study Day 107)	COVID-19 Infection
Azithromycin	20 Nov 2020 (Study Day 108) - 23 Nov 2020 (Study Day 111)	COVID-19 Infection
Paracetamol	20 Nov 2020 (Study Day 108) - Ongoing	COVID-19 Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	11 Nov 2020 (Study Day 99) - 01 Dec 2020 (Study Day 119)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2047 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 31)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	03 Jan 2021 (Study Day 154) – 02 Feb 2021 (Study Day 184)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US304-2047, a 44-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 03 Jan 2021 (Study Day 154), 153 days after the first dose and 123 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 31, 02 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Jan 2021 (Study Day 162), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 162)	Cough	Mild
11 Jan 2021 (Study Day 162)	Difficulty Breathing	Mild
11 Jan 2021 (Study Day 162)	Fatigue	Mild
11 Jan 2021 (Study Day 162)	Headache	Mild
11 Jan 2021 (Study Day 162)	Nasal Congestion	Mild
11 Jan 2021 (Study Day 162)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 162)	Shortness of Breath	Moderate
12 Jan 2021 (Study Day 163)	Cough	Mild
12 Jan 2021 (Study Day 163)	Difficulty Breathing	Mild
12 Jan 2021 (Study Day 163)	Fatigue	Mild
12 Jan 2021 (Study Day 163)	Headache	Mild
12 Jan 2021 (Study Day 163)	Nasal Congestion	Mild
12 Jan 2021 (Study Day 163)	New Loss of Smell	Severe
12 Jan 2021 (Study Day 163)	Runny Nose (Rhinorrhea)	Mild
12 Jan 2021 (Study Day 163)	Shortness of Breath	Moderate
13 Jan 2021 (Study Day 164)	Cough	Mild
13 Jan 2021 (Study Day 164)	Difficulty Breathing	Mild
13 Jan 2021 (Study Day 164)	Fatigue	Mild
13 Jan 2021 (Study Day 164)	Headache	Mild
13 Jan 2021 (Study Day 164)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 164)	New Loss of Smell	Severe
13 Jan 2021 (Study Day 164)	Runny Nose (Rhinorrhea)	Mild
13 Jan 2021 (Study Day 164)	Shortness of Breath	Mild
14 Jan 2021 (Study Day 165)	Cough	Mild
14 Jan 2021 (Study Day 165)	Difficulty Breathing	Mild
14 Jan 2021 (Study Day 165)	Fatigue	Mild
14 Jan 2021 (Study Day 165)	Headache	Mild
14 Jan 2021 (Study Day 165)	New Loss of Smell	Severe
14 Jan 2021 (Study Day 165)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 166)	Cough	Mild
15 Jan 2021 (Study Day 166)	Difficulty Breathing	Mild
15 Jan 2021 (Study Day 166)	Fatigue	Mild
15 Jan 2021 (Study Day 166)	Headache	Mild
15 Jan 2021 (Study Day 166)	New Loss of Smell	Moderate
15 Jan 2021 (Study Day 166)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 167)	Headache	Mild
16 Jan 2021 (Study Day 167)	New Loss of Smell	Moderate
17 Jan 2021 (Study Day 168)	Headache	Mild
17 Jan 2021 (Study Day 168)	New Loss of Smell	Mild
18 Jan 2021 (Study Day 169)	Headache	Mild
18 Jan 2021 (Study Day 169)	New Loss of Smell	Mild
19 Jan 2021 (Study Day 170)	Headache	Mild
19 Jan 2021 (Study Day 170)	New Loss of Smell	Mild
20 Jan 2021 (Study Day 171)	Headache	Mild
21 Jan 2021 (Study Day 172)	Headache	Mild
22 Jan 2021 (Study Day 173)	Headache	Mild
23 Jan 2021 (Study Day 174)	Headache	Mild
24 Jan 2021 (Study Day 175)	Headache	Mild
25 Jan 2021 (Study Day 176)	Headache	Mild

Symptom Date	Symptom	Result
26 Jan 2021 (Study Day 177)	Headache	Mild
27 Jan 2021 (Study Day 178)	Headache	Mild
28 Jan 2021 (Study Day 179)	Headache	Mild
29 Jan 2021 (Study Day 180)	Headache	Mild
30 Jan 2021 (Study Day 181)	Headache	Mild
31 Jan 2021 (Study Day 182)	Headache	Mild
01 Feb 2021 (Study Day 183)	Headache	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
19 Jan 2021 (Study Day 170)	Heart Rate	130 beats/min
19 Jan 2021 - 19 Jan 2021 (Study Day 170-170)	Heart Rate ≥ 125 per Minute	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 31 days, after which it was considered to be recovered/resolved on 02 Feb 2021 (Study Day 184). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-040460	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	2006 - 2006
Seasonal allergy	Seasonal allergies	2012 - Ongoing
Gout	Right great toe gout	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2012 - Ongoing	Seasonal Allergies
Allopurinol	2015 - Ongoing	Right Great Toe Gout
Indometacin	2015 - Ongoing	Right Great Toe Gout
Other antivirals	07 Jan 2021 (Study Day 158) - 07 Jan 2021 (Study Day 158)	Suspected COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	03 Jan 2021 (Study Day 154) - 02 Feb 2021 (Study Day 184)
Tachycardia	Grade 1/mild	Not related	19 Jan 2021 (Study Day 170) - 19 Jan 2021 (Study Day 170)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2187 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 1/mild	Not related	30 Nov 2020 (Study Day 110) – 13 Jan 2021 (Study Day 154)	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US304-2187, a 59-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 10 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 30 Nov 2020 (Study Day 110), 109 days after the first dose and 81 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 10 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 03 Dec 2020 (Study Day 113), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 113)	Body Aches	Moderate
03 Dec 2020 (Study Day 113)	Chills	Moderate
03 Dec 2020 (Study Day 113)	Cough	Moderate
03 Dec 2020 (Study Day 113)	Diarrhea	Mild
03 Dec 2020 (Study Day 113)	Difficulty Breathing	Moderate
03 Dec 2020 (Study Day 113)	Fatigue	Severe

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 113)	Muscle Aches (Myalgia)	Moderate
03 Dec 2020 (Study Day 113)	O2 Saturation (%)	93
03 Dec 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 113)	Shortness of Breath	Moderate
03 Dec 2020 (Study Day 113)	Sore Throat	Moderate
04 Dec 2020 (Study Day 114)	Body Aches	Mild
04 Dec 2020 (Study Day 114)	Cough	Moderate
04 Dec 2020 (Study Day 114)	Diarrhea	Mild
04 Dec 2020 (Study Day 114)	Difficulty Breathing	Mild
04 Dec 2020 (Study Day 114)	Fatigue	Severe
04 Dec 2020 (Study Day 114)	Muscle Aches (Myalgia)	Mild
04 Dec 2020 (Study Day 114)	O2 Saturation (%)	93
04 Dec 2020 (Study Day 114)	Shortness of Breath	Moderate
04 Dec 2020 (Study Day 114)	Sore Throat	Mild
05 Dec 2020 (Study Day 115)	Body Aches	Mild
05 Dec 2020 (Study Day 115)	Cough	Moderate
05 Dec 2020 (Study Day 115)	Difficulty Breathing	Mild
05 Dec 2020 (Study Day 115)	Fatigue	Severe
05 Dec 2020 (Study Day 115)	Muscle Aches (Myalgia)	Mild
05 Dec 2020 (Study Day 115)	O2 Saturation (%)	93
05 Dec 2020 (Study Day 115)	Shortness of Breath	Moderate
05 Dec 2020 (Study Day 115)	Sore Throat	Mild
06 Dec 2020 (Study Day 116)	Body Aches	Mild
06 Dec 2020 (Study Day 116)	Cough	Moderate
06 Dec 2020 (Study Day 116)	Difficulty Breathing	Mild
06 Dec 2020 (Study Day 116)	Fatigue	Severe
06 Dec 2020 (Study Day 116)	Muscle Aches (Myalgia)	Mild
06 Dec 2020 (Study Day 116)	O2 Saturation (%)	93
06 Dec 2020 (Study Day 116)	Shortness of Breath	Moderate
06 Dec 2020 (Study Day 116)	Sore Throat	Mild
07 Dec 2020 (Study Day 117)	Body Aches	Mild
07 Dec 2020 (Study Day 117)	Cough	Moderate
07 Dec 2020 (Study Day 117)	Difficulty Breathing	Mild
07 Dec 2020 (Study Day 117)	Fatigue	Severe
07 Dec 2020 (Study Day 117)	Muscle Aches (Myalgia)	Mild
07 Dec 2020 (Study Day 117)	Shortness of Breath	Moderate
07 Dec 2020 (Study Day 117)	Sore Throat	Mild
08 Dec 2020 (Study Day 118)	Body Aches	Mild
08 Dec 2020 (Study Day 118)	Cough	Moderate
08 Dec 2020 (Study Day 118)	Difficulty Breathing	Mild
08 Dec 2020 (Study Day 118)	Fatigue	Moderate
08 Dec 2020 (Study Day 118)	Muscle Aches (Myalgia)	Mild
08 Dec 2020 (Study Day 118)	Shortness of Breath	Moderate

Symptom Date	Symptom	Result
08 Dec 2020 (Study Day 118)	Sore Throat	Mild
09 Dec 2020 (Study Day 119)	Body Aches	Mild
09 Dec 2020 (Study Day 119)	Cough	Moderate
09 Dec 2020 (Study Day 119)	Difficulty Breathing	Mild
09 Dec 2020 (Study Day 119)	Fatigue	Moderate
09 Dec 2020 (Study Day 119)	Muscle Aches (Myalgia)	Mild
09 Dec 2020 (Study Day 119)	Shortness of Breath	Moderate
09 Dec 2020 (Study Day 119)	Sore Throat	Mild
10 Dec 2020 (Study Day 120)	Body Aches	Mild
10 Dec 2020 (Study Day 120)	Cough	Moderate
10 Dec 2020 (Study Day 120)	Difficulty Breathing	Mild
10 Dec 2020 (Study Day 120)	Fatigue	Moderate
10 Dec 2020 (Study Day 120)	Muscle Aches (Myalgia)	Mild
10 Dec 2020 (Study Day 120)	Shortness of Breath	Moderate
11 Dec 2020 (Study Day 121)	Body Aches	Mild
11 Dec 2020 (Study Day 121)	Cough	Mild
11 Dec 2020 (Study Day 121)	Difficulty Breathing	Mild
11 Dec 2020 (Study Day 121)	Fatigue	Moderate
11 Dec 2020 (Study Day 121)	Muscle Aches (Myalgia)	Mild
11 Dec 2020 (Study Day 121)	Shortness of Breath	Moderate
12 Dec 2020 (Study Day 122)	Body Aches	Mild
12 Dec 2020 (Study Day 122)	Cough	Mild
12 Dec 2020 (Study Day 122)	Difficulty Breathing	Mild
12 Dec 2020 (Study Day 122)	Fatigue	Moderate
12 Dec 2020 (Study Day 122)	Muscle Aches (Myalgia)	Mild
12 Dec 2020 (Study Day 122)	Shortness of Breath	Moderate
12 Dec 2020 (Study Day 122)	Sore Throat	Mild
13 Dec 2020 (Study Day 123)	Body Aches	Mild
13 Dec 2020 (Study Day 123)	Cough	Mild
13 Dec 2020 (Study Day 123)	Difficulty Breathing	Mild
13 Dec 2020 (Study Day 123)	Fatigue	Moderate
13 Dec 2020 (Study Day 123)	Muscle Aches (Myalgia)	Mild
13 Dec 2020 (Study Day 123)	Shortness of Breath	Moderate
13 Dec 2020 (Study Day 123)	Sore Throat	Mild
14 Dec 2020 (Study Day 124)	Cough	Mild
14 Dec 2020 (Study Day 124)	Difficulty Breathing	Mild
14 Dec 2020 (Study Day 124)	Fatigue	Moderate
14 Dec 2020 (Study Day 124)	Shortness of Breath	Moderate
14 Dec 2020 (Study Day 124)	Sore Throat	Mild
15 Dec 2020 (Study Day 125)	Cough	Mild
15 Dec 2020 (Study Day 125)	Difficulty Breathing	Mild
15 Dec 2020 (Study Day 125)	Fatigue	Moderate
15 Dec 2020 (Study Day 125)	Shortness of Breath	Moderate

Symptom Date	Symptom	Result
16 Dec 2020 (Study Day 126)	Cough	Mild
16 Dec 2020 (Study Day 126)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 126)	Fatigue	Moderate
16 Dec 2020 (Study Day 126)	Shortness of Breath	Moderate
17 Dec 2020 (Study Day 127)	Cough	Mild
17 Dec 2020 (Study Day 127)	Difficulty Breathing	Mild
17 Dec 2020 (Study Day 127)	Fatigue	Moderate
17 Dec 2020 (Study Day 127)	Shortness of Breath	Moderate
18 Dec 2020 (Study Day 128)	Cough	Mild
18 Dec 2020 (Study Day 128)	Difficulty Breathing	Moderate
18 Dec 2020 (Study Day 128)	Fatigue	Moderate
18 Dec 2020 (Study Day 128)	Shortness of Breath	Moderate
19 Dec 2020 (Study Day 129)	Cough	Mild
19 Dec 2020 (Study Day 129)	Difficulty Breathing	Moderate
19 Dec 2020 (Study Day 129)	Fatigue	Moderate
19 Dec 2020 (Study Day 129)	Shortness of Breath	Moderate
20 Dec 2020 (Study Day 130)	Cough	Mild
20 Dec 2020 (Study Day 130)	Difficulty Breathing	Moderate
20 Dec 2020 (Study Day 130)	Fatigue	Moderate
20 Dec 2020 (Study Day 130)	Shortness of Breath	Moderate
21 Dec 2020 (Study Day 131)	Cough	Mild
21 Dec 2020 (Study Day 131)	Difficulty Breathing	Moderate
21 Dec 2020 (Study Day 131)	Fatigue	Moderate
21 Dec 2020 (Study Day 131)	Shortness of Breath	Moderate
22 Dec 2020 (Study Day 132)	Cough	Mild
22 Dec 2020 (Study Day 132)	Difficulty Breathing	Moderate
22 Dec 2020 (Study Day 132)	Fatigue	Moderate
22 Dec 2020 (Study Day 132)	Shortness of Breath	Moderate
23 Dec 2020 (Study Day 133)	Cough	Mild
23 Dec 2020 (Study Day 133)	Difficulty Breathing	Moderate
23 Dec 2020 (Study Day 133)	Shortness of Breath	Moderate
24 Dec 2020 (Study Day 134)	Difficulty Breathing	Mild
24 Dec 2020 (Study Day 134)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 135)	Difficulty Breathing	Mild
25 Dec 2020 (Study Day 135)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 136)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 137)	Difficulty Breathing	Mild
27 Dec 2020 (Study Day 137)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 138)	Difficulty Breathing	Mild
28 Dec 2020 (Study Day 138)	O2 Saturation (%)	92
28 Dec 2020 (Study Day 138)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 139)	Difficulty Breathing	Mild
29 Dec 2020 (Study Day 139)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
22 Dec 2020 (Study Day 132)	Heart Rate	140 beats/min
03 Dec 2020 (Study Day 113)	Oxygen Saturation	92%
03 Dec 2020 - 28 Dec 2020 (Study Day 113-138)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
22 Dec 2020 - 22 Dec 2020 (Study Day 132-132)	Heart Rate ≥ 125 per Minute	Yes
29 Dec 2020 - 29 Dec 2020 (Study Day 139-139)	Clinical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001554	COVID-19

Study Completion/Discontinuation

On 13 Jan 2021 (Study Day 154), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	1980 - Ongoing
Obesity	Obesity	2000 - Ongoing
Postmenopause	Post menopausal	2012 - Ongoing
Arthritis	Bilateral knee arthritis	2016 - Ongoing
Arthritis	Left shoulder arthritis	2016 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1980 - Ongoing	Hypothyroidism
Diclofenac	2018 - Ongoing	Osteoarthritis Pain-Left Knee And Bilateral Shoulder
Lisinopril	2018 - Ongoing	Type 2 Diabetes
Metformin	2018 - Ongoing	Type 2 Diabetes
Hydrocortisone	20 Aug 2020 (Study Day 8) - 20 Aug 2020 (Study Day 8)	Left Shoulder Osteoarthritis
Amoxicillin	25 Nov 2020 (Study Day 105) - Ongoing	Tonsilitis
Other antivirals	02 Dec 2020 (Study Day 112) - 02 Dec 2020 (Study Day 112)	COVID-19
Salbutamol sulfate	10 Dec 2020 (Study Day 120) - 19 Dec 2020 (Study Day 129)	COVID-19 Illness
Azithromycin	14 Dec 2020 (Study Day 124) - Ongoing	Upper Respiratory Illness
Diltiazem	22 Dec 2020 (Study Day 132) - Ongoing	Tachycardia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Musculoskeletal Pain	Grade 1/mild	Related	20 Aug 2020 (Study Day 8) - 20 Aug 2020 (Study Day 8)
Tonsillitis	Grade 1/mild	Not related	25 Nov 2020 (Study Day 105) - Ongoing
COVID-19	Grade 1/mild	Not related	30 Nov 2020 (Study Day 110) - 13 Jan 2021 (Study Day 154)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	14 Dec 2020 (Study Day 124) - Ongoing
Tachycardia	Grade 1/mild	Not related	22 Dec 2020 (Study Day 132) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2241 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	20 Dec 2020 (Study Day 124) – 20 Jan 2021 (Study Day 155)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US304-2241, a 29-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 20 Dec 2020 (Study Day 124), 123 days after the first dose and 95 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 16 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Dec 2020 (Study Day 127), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
27 Sep 2020 (Study Day 40)	Cough	Mild
27 Sep 2020 (Study Day 40)	Fatigue	Mild
27 Sep 2020 (Study Day 40)	Headache	Mild
27 Sep 2020 (Study Day 40)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
27 Sep 2020 (Study Day 40)	Runny Nose (Rhinorrhea)	Mild
27 Sep 2020 (Study Day 40)	Sore Throat	Mild
28 Sep 2020 (Study Day 41)	Cough	Mild
28 Sep 2020 (Study Day 41)	Fatigue	Mild
28 Sep 2020 (Study Day 41)	Headache	Mild
28 Sep 2020 (Study Day 41)	Muscle Aches (Myalgia)	Mild
28 Sep 2020 (Study Day 41)	Runny Nose (Rhinorrhea)	Mild
28 Sep 2020 (Study Day 41)	Sore Throat	Mild
29 Sep 2020 (Study Day 42)	Cough	Mild
29 Sep 2020 (Study Day 42)	Fatigue	Mild
29 Sep 2020 (Study Day 42)	Headache	Mild
29 Sep 2020 (Study Day 42)	Muscle Aches (Myalgia)	Mild
29 Sep 2020 (Study Day 42)	Runny Nose (Rhinorrhea)	Mild
29 Sep 2020 (Study Day 42)	Sore Throat	Mild
30 Sep 2020 (Study Day 43)	Cough	Mild
30 Sep 2020 (Study Day 43)	Fatigue	Mild
30 Sep 2020 (Study Day 43)	Headache	Moderate
30 Sep 2020 (Study Day 43)	Muscle Aches (Myalgia)	Mild
30 Sep 2020 (Study Day 43)	Nasal Congestion	Moderate
30 Sep 2020 (Study Day 43)	Sore Throat	Mild
01 Oct 2020 (Study Day 44)	Cough	Mild
01 Oct 2020 (Study Day 44)	Headache	Moderate
01 Oct 2020 (Study Day 44)	Muscle Aches (Myalgia)	Mild
01 Oct 2020 (Study Day 44)	Nasal Congestion	Moderate
01 Oct 2020 (Study Day 44)	Sore Throat	Mild
02 Oct 2020 (Study Day 45)	Headache	Moderate
02 Oct 2020 (Study Day 45)	Muscle Aches (Myalgia)	Mild
02 Oct 2020 (Study Day 45)	Nasal Congestion	Moderate
02 Oct 2020 (Study Day 45)	Sore Throat	Mild
05 Oct 2020 (Study Day 48)	Headache	Mild
05 Oct 2020 (Study Day 48)	Nasal Congestion	Moderate
23 Dec 2020 (Study Day 127)	Cough	Mild
23 Dec 2020 (Study Day 127)	Difficulty Breathing	Mild
23 Dec 2020 (Study Day 127)	Fatigue	Moderate
23 Dec 2020 (Study Day 127)	Muscle Aches (Myalgia)	Moderate
23 Dec 2020 (Study Day 127)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 127)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 128)	Cough	Mild
24 Dec 2020 (Study Day 128)	Fatigue	Moderate
24 Dec 2020 (Study Day 128)	Muscle Aches (Myalgia)	Mild
24 Dec 2020 (Study Day 128)	Nasal Congestion	Moderate
25 Dec 2020 (Study Day 129)	Cough	Mild
25 Dec 2020 (Study Day 129)	Fatigue	Moderate

Symptom Date	Symptom	Result
25 Dec 2020 (Study Day 129)	Muscle Aches (Myalgia)	Mild
25 Dec 2020 (Study Day 129)	Nasal Congestion	Moderate
26 Dec 2020 (Study Day 130)	Cough	Mild
26 Dec 2020 (Study Day 130)	Fatigue	Moderate
26 Dec 2020 (Study Day 130)	Muscle Aches (Myalgia)	Mild
26 Dec 2020 (Study Day 130)	Nasal Congestion	Moderate
27 Dec 2020 (Study Day 131)	Cough	Mild
27 Dec 2020 (Study Day 131)	Fatigue	Moderate
27 Dec 2020 (Study Day 131)	Muscle Aches (Myalgia)	Mild
27 Dec 2020 (Study Day 131)	Nasal Congestion	Moderate
28 Dec 2020 (Study Day 132)	Cough	Mild
28 Dec 2020 (Study Day 132)	Fatigue	Moderate
28 Dec 2020 (Study Day 132)	Muscle Aches (Myalgia)	Mild
28 Dec 2020 (Study Day 132)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 133)	Cough	Mild
29 Dec 2020 (Study Day 133)	Fatigue	Moderate
29 Dec 2020 (Study Day 133)	Muscle Aches (Myalgia)	Mild
29 Dec 2020 (Study Day 133)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 134)	Cough	Mild
30 Dec 2020 (Study Day 134)	Fatigue	Moderate
30 Dec 2020 (Study Day 134)	Muscle Aches (Myalgia)	Mild
30 Dec 2020 (Study Day 134)	Nasal Congestion	Mild
31 Dec 2020 (Study Day 135)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 136)	Nasal Congestion	Mild
02 Jan 2021 (Study Day 137)	Nasal Congestion	Mild
03 Jan 2021 (Study Day 138)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 139)	Chills	Moderate
04 Jan 2021 (Study Day 139)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 139)	Temperature (°F)	101.0
05 Jan 2021 (Study Day 140)	Chills	Mild
05 Jan 2021 (Study Day 140)	Muscle Aches (Myalgia)	Moderate
05 Jan 2021 (Study Day 140)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 141)	Muscle Aches (Myalgia)	Mild
06 Jan 2021 (Study Day 141)	Nasal Congestion	Mild
07 Jan 2021 (Study Day 142)	Muscle Aches (Myalgia)	Moderate
07 Jan 2021 (Study Day 142)	Nasal Congestion	Mild
08 Jan 2021 (Study Day 143)	Muscle Aches (Myalgia)	Mild
08 Jan 2021 (Study Day 143)	Nasal Congestion	Mild
09 Jan 2021 (Study Day 144)	Muscle Aches (Myalgia)	Mild
09 Jan 2021 (Study Day 144)	Nasal Congestion	Mild
10 Jan 2021 (Study Day 145)	Muscle Aches (Myalgia)	Mild
11 Jan 2021 (Study Day 146)	Muscle Aches (Myalgia)	Mild
12 Jan 2021 (Study Day 147)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
13 Jan 2021 (Study Day 148)	Muscle Aches (Myalgia)	Mild
13 Jan 2021 (Study Day 148)	Shortness of Breath	Mild
14 Jan 2021 (Study Day 149)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 150)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 151)	Shortness of Breath	Mild
17 Jan 2021 (Study Day 152)	Shortness of Breath	Mild
18 Jan 2021 (Study Day 153)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
24 Dec 2020 (Study Day 128)	Heart Rate	137 beats/min
24 Dec 2020 - 24 Dec 2020 (Study Day 128-128)	Heart Rate ≥ 125 per Minute	Yes
06 Jan 2021 - 06 Jan 2021 (Study Day 141-141)	Clinical Evidence of Pneumonia	Yes
06 Jan 2021 - 06 Jan 2021 (Study Day 141-141)	Radiographical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 32 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 155). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001949	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2016 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion	2016 - 26 Dec 2020 (Study Day 130)	Depression
Levonorgestrel	Nov 2016 - Ongoing	Contraception
Atomoxetine hydrochloride	2019 - 26 Dec 2020 (Study Day 130)	Attention Deficit Disorder
Guaifenesin; paracetamol; phenylephrine hydrochloride	27 Sep 2020 (Study Day 40) - 05 Oct 2020 (Study Day 48)	Sore Throat
Influenza vaccine	25 Oct 2020 (Study Day 68) - 25 Oct 2020 (Study Day 68)	Influenza Prevention
Desvenlafaxine	07 Dec 2020 (Study Day 111) - 26 Dec 2020 (Study Day 130)	Worsening Depression
Paracetamol	20 Dec 2020 (Study Day 124) - 20 Jan 2021 (Study Day 155)	COVID Like Symptoms: Muscle Aches
Phenylephrine hydrochloride	20 Dec 2020 (Study Day 124) - 20 Jan 2021 (Study Day 155)	COVID Like Symptoms: Nasal Congestion
Azithromycin	06 Jan 2021 (Study Day 141) - 12 Jan 2021 (Study Day 147)	Pneumonia
Prednisone	06 Jan 2021 (Study Day 141) - 12 Jan 2021 (Study Day 147)	Pneumonia
Budesonide; formoterol fumarate	12 Jan 2021 (Study Day 147) - 20 Jan 2021 (Study Day 155)	Pneumonia
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	13 Feb 2021 (Study Day 179) - Ongoing	Attention Deficit Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Depression	Grade 1/mild	Not related	30 Nov 2020 (Study Day 104) - Ongoing
COVID-19	Grade 1/mild	Not related	20 Dec 2020 (Study Day 124) - 20 Jan 2021 (Study Day 155)
Pneumonia	Grade 1/mild	Not related	06 Jan 2021 (Study Day 141) - 13 Jan 2021 (Study Day 148)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2288 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	SAE, COVID-19	Grade 1/mild	Not related	27 Nov 2020 (Study Day 99) – 22 Dec 2020 (Study Day 124)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US304-2288, a 70-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 27 Nov 2020 (Study Day 99), 98 days after the first dose and 67 days after the second dose of the IP, the participant experienced a Grade 1/Mild serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 32, 21 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 30 Nov 2020 (Study Day 102), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
30 Nov 2020 (Study Day 102)	Body Aches	Moderate
30 Nov 2020 (Study Day 102)	Cough	Moderate
30 Nov 2020 (Study Day 102)	Diarrhea	Moderate
30 Nov 2020 (Study Day 102)	Fatigue	Moderate

Symptom Date	Symptom	Result
30 Nov 2020 (Study Day 102)	Muscle Aches (Myalgia)	Moderate
30 Nov 2020 (Study Day 102)	New Loss of Smell	Mild
30 Nov 2020 (Study Day 102)	New Loss of Taste	Mild
30 Nov 2020 (Study Day 102)	O2 Saturation (%)	93
30 Nov 2020 (Study Day 102)	Shortness of Breath	Moderate
30 Nov 2020 (Study Day 102)	Sore Throat	Mild
01 Dec 2020 (Study Day 103)	Body Aches	Moderate
01 Dec 2020 (Study Day 103)	Cough	Moderate
01 Dec 2020 (Study Day 103)	Diarrhea	Moderate
01 Dec 2020 (Study Day 103)	Fatigue	Moderate
01 Dec 2020 (Study Day 103)	Muscle Aches (Myalgia)	Moderate
01 Dec 2020 (Study Day 103)	New Loss of Smell	Mild
01 Dec 2020 (Study Day 103)	New Loss of Taste	Mild
01 Dec 2020 (Study Day 103)	O2 Saturation (%)	93
01 Dec 2020 (Study Day 103)	Shortness of Breath	Moderate
01 Dec 2020 (Study Day 103)	Sore Throat	Mild
07 Dec 2020 (Study Day 109)	Body Aches	Moderate
07 Dec 2020 (Study Day 109)	Cough	Moderate
07 Dec 2020 (Study Day 109)	Fatigue	Moderate
07 Dec 2020 (Study Day 109)	Muscle Aches (Myalgia)	Moderate
07 Dec 2020 (Study Day 109)	New Loss of Smell	Mild
07 Dec 2020 (Study Day 109)	New Loss of Taste	Mild
07 Dec 2020 (Study Day 109)	Shortness of Breath	Moderate
07 Dec 2020 (Study Day 109)	Sore Throat	Mild
08 Dec 2020 (Study Day 110)	Body Aches	Moderate
08 Dec 2020 (Study Day 110)	Cough	Moderate
08 Dec 2020 (Study Day 110)	Fatigue	Moderate
08 Dec 2020 (Study Day 110)	Muscle Aches (Myalgia)	Moderate
08 Dec 2020 (Study Day 110)	New Loss of Smell	Mild
08 Dec 2020 (Study Day 110)	New Loss of Taste	Mild
08 Dec 2020 (Study Day 110)	Shortness of Breath	Moderate
08 Dec 2020 (Study Day 110)	Sore Throat	Mild
09 Dec 2020 (Study Day 111)	Body Aches	Moderate
09 Dec 2020 (Study Day 111)	Cough	Moderate
09 Dec 2020 (Study Day 111)	Fatigue	Moderate
09 Dec 2020 (Study Day 111)	Muscle Aches (Myalgia)	Moderate
09 Dec 2020 (Study Day 111)	New Loss of Smell	Mild
09 Dec 2020 (Study Day 111)	New Loss of Taste	Mild
09 Dec 2020 (Study Day 111)	O2 Saturation (%)	93
09 Dec 2020 (Study Day 111)	Shortness of Breath	Moderate
10 Dec 2020 (Study Day 112)	Body Aches	Mild
10 Dec 2020 (Study Day 112)	Fatigue	Mild
10 Dec 2020 (Study Day 112)	Muscle Aches (Myalgia)	Mild

Symptom Date	Symptom	Result
10 Dec 2020 (Study Day 112)	Shortness of Breath	Mild
11 Dec 2020 (Study Day 113)	Cough	Mild
11 Dec 2020 (Study Day 113)	Fatigue	Mild
14 Dec 2020 (Study Day 116)	Cough	Mild
14 Dec 2020 (Study Day 116)	Fatigue	Mild
15 Dec 2020 (Study Day 117)	Cough	Mild
15 Dec 2020 (Study Day 117)	Fatigue	Mild
16 Dec 2020 (Study Day 118)	Cough	Mild
16 Dec 2020 (Study Day 118)	Fatigue	Mild
17 Dec 2020 (Study Day 119)	Cough	Mild
17 Dec 2020 (Study Day 119)	Fatigue	Mild
18 Dec 2020 (Study Day 120)	Cough	Mild
18 Dec 2020 (Study Day 120)	Fatigue	Mild
19 Dec 2020 (Study Day 121)	Fatigue	Mild
20 Dec 2020 (Study Day 122)	Fatigue	Mild
21 Dec 2020 (Study Day 123)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
30 Nov 2020 (Study Day 102)	Oxygen Saturation	93%
30 Nov 2020 - 09 Dec 2020 (Study Day 102-111)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
01 Dec 2020 - 05 Dec 2020 (Study Day 103-107)	Admission to an intensive care unit due to SARS-CoV-2	Yes
01 Dec 2020 - 01 Dec 2020 (Study Day 103-103)	Clinical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 26 days, after which it was considered to be recovered/resolved on 22 Dec 2020 (Study Day 124). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001045	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	2003 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	30 Sep 2020 (Study Day 41) - 30 Sep 2020 (Study Day 41)	Influenza Prophylaxis
Paracetamol	27 Nov 2020 (Study Day 99) - 22 Dec 2020 (Study Day 124)	Suspected COVID-19
Ascorbic acid	01 Dec 2020 (Study Day 103) - 18 Dec 2020 (Study Day 120)	COVID-19
Colecalciferol	01 Dec 2020 (Study Day 103) - 18 Dec 2020 (Study Day 120)	COVID-19
Furosemide	01 Dec 2020 (Study Day 103) - 06 Dec 2020 (Study Day 108)	COVID-19
Furosemide	01 Dec 2020 (Study Day 103) - 18 Dec 2020 (Study Day 120)	COVID-19
Remdesivir	01 Dec 2020 (Study Day 103) - 01 Dec 2020 (Study Day 103)	COVID-19
Zinc sulfate	01 Dec 2020 (Study Day 103) - 18 Dec 2020 (Study Day 120)	COVID-19
Remdesivir	02 Dec 2020 (Study Day 104) - 05 Dec 2020 (Study Day 107)	COVID-19
Dexamethasone	06 Dec 2020 (Study Day 108) - 18 Dec 2020 (Study Day 120)	COVID-19
Enoxaparin	06 Dec 2020 (Study Day 108) - 18 Dec 2020 (Study Day 120)	COVID-19
Atorvastatin	27 Jan 2021 (Study Day 160) - Ongoing	Hypercholesteremia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Type 2 Diabetes Mellitus	Grade 1/mild	Not related	01 Dec 2020 (Study Day 103) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypercholesterolaemia	Grade 1/mild	Not related	27 Jan 2021 (Study Day 160) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379211

Participant Number:	US310-2283 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	SAE, COVID-19	Grade 2/ moderate	Not related	09 Nov 2020 (Study Day 75) – 29 Dec 2020 (Study Day 125)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US310-2283, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 09 Nov 2020 (Study Day 75), 74 days after the first dose and 47 days after the second dose of the IP, the participant experienced a Grade 2/Moderate serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 23 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 17 Nov 2020 (Study Day 83), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 75)	Body Aches	Moderate
09 Nov 2020 (Study Day 75)	Fatigue	Moderate
09 Nov 2020 (Study Day 75)	New Loss of Taste	Mild
10 Nov 2020 (Study Day 76)	Body Aches	Moderate
10 Nov 2020 (Study Day 76)	Fatigue	Moderate
10 Nov 2020 (Study Day 76)	New Loss of Taste	Mild

Symptom Date	Symptom	Result
11 Nov 2020 (Study Day 77)	Body Aches	Moderate
11 Nov 2020 (Study Day 77)	Fatigue	Moderate
11 Nov 2020 (Study Day 77)	New Loss of Taste	Mild
12 Nov 2020 (Study Day 78)	Body Aches	Moderate
12 Nov 2020 (Study Day 78)	Diarrhea	Moderate
12 Nov 2020 (Study Day 78)	Fatigue	Moderate
12 Nov 2020 (Study Day 78)	New Loss of Taste	Mild
13 Nov 2020 (Study Day 79)	Body Aches	Moderate
13 Nov 2020 (Study Day 79)	Diarrhea	Moderate
13 Nov 2020 (Study Day 79)	Fatigue	Moderate
13 Nov 2020 (Study Day 79)	Headache	Moderate
13 Nov 2020 (Study Day 79)	New Loss of Taste	Mild
14 Nov 2020 (Study Day 80)	Body Aches	Moderate
14 Nov 2020 (Study Day 80)	Diarrhea	Moderate
14 Nov 2020 (Study Day 80)	Fatigue	Moderate
14 Nov 2020 (Study Day 80)	Headache	Moderate
14 Nov 2020 (Study Day 80)	New Loss of Taste	Mild
15 Nov 2020 (Study Day 81)	Body Aches	Moderate
15 Nov 2020 (Study Day 81)	Cough	Mild
15 Nov 2020 (Study Day 81)	Diarrhea	Moderate
15 Nov 2020 (Study Day 81)	Fatigue	Moderate
15 Nov 2020 (Study Day 81)	New Loss of Taste	Mild
16 Nov 2020 (Study Day 82)	Body Aches	Moderate
16 Nov 2020 (Study Day 82)	Cough	Mild
16 Nov 2020 (Study Day 82)	Fatigue	Moderate
16 Nov 2020 (Study Day 82)	New Loss of Taste	Mild
17 Nov 2020 (Study Day 83)	Body Aches	Moderate
17 Nov 2020 (Study Day 83)	Cough	Mild
17 Nov 2020 (Study Day 83)	Fatigue	Moderate
17 Nov 2020 (Study Day 83)	New Loss of Taste	Mild
18 Nov 2020 (Study Day 84)	Cough	Mild
18 Nov 2020 (Study Day 84)	New Loss of Taste	Mild
19 Nov 2020 (Study Day 85)	Cough	Mild
19 Nov 2020 (Study Day 85)	New Loss of Taste	Mild
20 Nov 2020 (Study Day 86)	Cough	Mild
20 Nov 2020 (Study Day 86)	New Loss of Taste	Mild
21 Nov 2020 (Study Day 87)	Cough	Mild
22 Nov 2020 (Study Day 88)	Cough	Mild
23 Nov 2020 (Study Day 89)	Cough	Mild
26 Dec 2020 (Study Day 122)	Cough	Mild
26 Dec 2020 (Study Day 122)	Runny Nose (Rhinorrhea)	Moderate
26 Dec 2020 (Study Day 122)	Sore Throat	Moderate
27 Dec 2020 (Study Day 123)	Cough	Mild

Symptom Date	Symptom	Result
27 Dec 2020 (Study Day 123)	Runny Nose (Rhinorrhea)	Mild
27 Dec 2020 (Study Day 123)	Sore Throat	Mild
28 Dec 2020 (Study Day 124)	Cough	Mild
28 Dec 2020 (Study Day 124)	Headache	Mild
28 Dec 2020 (Study Day 124)	Nasal Congestion	Mild
28 Dec 2020 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 124)	Sore Throat	Mild
29 Dec 2020 (Study Day 125)	Cough	Mild
29 Dec 2020 (Study Day 125)	Headache	Mild
29 Dec 2020 (Study Day 125)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 125)	Sore Throat	Mild
30 Dec 2020 (Study Day 126)	Cough	Mild
30 Dec 2020 (Study Day 126)	Nasal Congestion	Moderate
31 Dec 2020 (Study Day 127)	Cough	Mild
31 Dec 2020 (Study Day 127)	Nasal Congestion	Moderate
01 Jan 2021 (Study Day 128)	Cough	Mild
02 Jan 2021 (Study Day 129)	Cough	Mild
03 Jan 2021 (Study Day 130)	Cough	Mild
04 Jan 2021 (Study Day 131)	Cough	Mild
05 Jan 2021 (Study Day 132)	Cough	Mild
06 Jan 2021 (Study Day 133)	Cough	Mild
07 Jan 2021 (Study Day 134)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
15 Nov 2020 - 15 Nov 2020 (Study Day 81-81)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 51 days, after which it was considered to be recovered/resolved on 29 Dec 2020 (Study Day 125). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000804	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septum deviation	Deviated septum	Not reported - 1986
Ventricular septal defect	Ventricular septal defect	(b) (6) 1963 (Study Day (b) (6) - 1969
Cardiac ablation	Vsd ablation	1969 - 1969
Cholelithiasis	Gallstones	1975 - 1992
Myopia	Nearsightedness (bilateral eyes)	1983 - 2001
Nasal operation	Nasal airway reconstruction	1986 - 1986
Caesarean section	Cesarean section	1988 - 1988
Gestational diabetes	Gestational diabetes	1988 - 1988
Atrial flutter	Atrial flutter	1990 - Ongoing
Cholecystectomy	Cholecystectomy	1992 - 1992
Mammoplasty	L breast reduction - for breast lift	1992 - 1992
Breast reconstruction	L breast reconstruction	1997 - 1997
Caesarean section	Cesarean section	1997 - 1997
Device breakage	Ruptured l breast implant	1997 - 1997
Female sterilisation	Bilateral tubal ligation	1997 - 1997
Gestational diabetes	Gestational diabetes	1997 - 1997
Glucose tolerance impaired	Borderline diabetes (diet controlled)	1997 - Ongoing
Cardiac ablation	Cardiac ablation	2001 - 2001
Gastrooesophageal reflux disease	Gerd	2001 - Ongoing
Keratomileusis	Laser in situ keratomileusis (bilateral)	2001 - 2001
Postmenopause	Post-menopausal	2002 - Ongoing
Dermatitis contact	Tape allergy	2005 - Ongoing
Botulinum toxin injection	Botox (cosmetic) lips	2008 - 2008
Breast prosthesis user	Breast implant (bilateral)	2008 - 2008
Dermal filler injection	Juvaderm	2008 - 2008
Carpal tunnel syndrome	R carpal tunnel	2014 - 05 Aug 2019 (Study Day -388)
Phyllodes tumour	L breast phyllodes tumor	Apr 2019 - 08 Aug 2019 (Study Day -385)
Carpal tunnel decompression	Capral tunnel surgery (r)	05 Aug 2019 (Study Day -388) - 05 Aug 2019 (Study Day -388)
Breast conserving surgery	Lumpectomy (l)	08 Aug 2019 (Study Day -385) - 08 Aug 2019 (Study Day -385)
Arrhythmia	Arryhthmia (a-fib)	Nov 2019 - Ongoing
Sleep apnoea syndrome	Sleep apnea	Jan 2020 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hepatic steatosis	Fatty liver (diet controlled)	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium carbonate	2001 - Ongoing	Gerd
Apixaban	Nov 2019 - Ongoing	Arrhythmia (A-Fib)
Flecainide	Nov 2019 - 17 Nov 2020 (Study Day 83)	Arrhythmia (A-Fib)
Metoprolol succinate	Nov 2019 - 14 Nov 2020 (Study Day 80)	Arrhythmia (A-Fib)
Ct of head without contrast*	14 Nov 2020 (Study Day 80) - 14 Nov 2020 (Study Day 80)	Diagnostic
Dexamethasone	14 Nov 2020 (Study Day 80) - 17 Nov 2020 (Study Day 83)	Symptomatic COVID-19
Ekg - serial*	14 Nov 2020 (Study Day 80) - 14 Nov 2020 (Study Day 80)	Diagnostic
Paracetamol	14 Nov 2020 (Study Day 80) - 15 Nov 2020 (Study Day 81)	Headache, Body Aches
Sodium chloride	14 Nov 2020 (Study Day 80) - 17 Nov 2020 (Study Day 83)	Iv Flush
Sodium chloride	14 Nov 2020 (Study Day 80) - 17 Nov 2020 (Study Day 83)	Symptomatic COVID-19
Paracetamol	09 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 137)	Headache, Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ageusia	Grade 2/moderate	Not related	09 Nov 2020 (Study Day 75) - 20 Nov 2020 (Study Day 86)
Arthralgia	Grade 1/mild	Not related	09 Nov 2020 (Study Day 75) - 17 Nov 2020 (Study Day 83)
Asthenia	Grade 1/mild	Not related	09 Nov 2020 (Study Day 75) - 14 Nov 2020 (Study Day 80)
Fatigue	Grade 1/mild	Not related	09 Nov 2020 (Study Day 75) - 17 Nov 2020 (Study Day 83)
Diarrhoea	Grade 1/mild	Not related	12 Nov 2020 (Study Day 78) - 15 Nov 2020 (Study Day 81)
Headache	Grade 1/mild	Not related	13 Nov 2020 (Study Day 79) - 14 Nov 2020 (Study Day 80)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dehydration	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 80) - 17 Nov 2020 (Study Day 83)
Dizziness	Grade 1/mild	Not related	14 Nov 2020 (Study Day 80) - 14 Nov 2020 (Study Day 80)
Electrolyte Imbalance	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 80) - 17 Nov 2020 (Study Day 83)
Hypotension	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 84)
Paraesthesia	Grade 1/mild	Not related	14 Nov 2020 (Study Day 80) - 14 Nov 2020 (Study Day 80)
Sinus Bradycardia	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 84)
Syncope	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 80) - 14 Nov 2020 (Study Day 80)
Cough	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 81) - 25 Nov 2020 (Study Day 91)
Sinus Arrest	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 81) - Ongoing
Cough	Grade 1/mild	Not related	26 Dec 2020 (Study Day 122) - Ongoing
Oropharyngeal Pain	Grade 1/mild	Not related	26 Dec 2020 (Study Day 122) - 30 Dec 2020 (Study Day 126)
Rhinorrhoea	Grade 1/mild	Not related	26 Dec 2020 (Study Day 122) - 30 Dec 2020 (Study Day 126)
Nasal Congestion	Grade 1/mild	Not related	27 Dec 2020 (Study Day 123) - 01 Jan 2021 (Study Day 128)
Headache	Grade 1/mild	Not related	28 Dec 2020 (Study Day 124) - 30 Dec 2020 (Study Day 126)
Chills	Grade 1/mild	Related	09 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 137)
Fatigue	Grade 1/mild	Related	09 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 137)
Headache	Grade 1/mild	Related	09 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 137)
Pyrexia	Grade 1/mild	Related	09 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 137)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2219 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 1/mild	Not related	16 Dec 2020 (Study Day 127) – 02 Jan 2021 (Study Day 144)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US311-2219, a 32-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 09 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 16 Dec 2020 (Study Day 127), 126 days after the first dose and 98 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 09 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 16 Dec 2020 (Study Day 127), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
16 Dec 2020 (Study Day 127)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 128)	Chills	Moderate
17 Dec 2020 (Study Day 128)	Cough	Mild
17 Dec 2020 (Study Day 128)	Fatigue	Mild
17 Dec 2020 (Study Day 128)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 128)	O2 Saturation (%)	91

Symptom Date	Symptom	Result
17 Dec 2020 (Study Day 128)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 128)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 128)	Temperature (°F)	100.4
18 Dec 2020 (Study Day 129)	Cough	Mild
18 Dec 2020 (Study Day 129)	Fatigue	Mild
18 Dec 2020 (Study Day 129)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 129)	Runny Nose (Rhinorrhea)	Mild
19 Dec 2020 (Study Day 130)	Headache	Mild
19 Dec 2020 (Study Day 130)	Nasal Congestion	Mild
19 Dec 2020 (Study Day 130)	Nausea	Mild
20 Dec 2020 (Study Day 131)	Fatigue	Mild
20 Dec 2020 (Study Day 131)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 132)	Cough	Mild
21 Dec 2020 (Study Day 132)	Fatigue	Mild
22 Dec 2020 (Study Day 133)	Cough	Mild
22 Dec 2020 (Study Day 133)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 133)	Runny Nose (Rhinorrhea)	Mild
23 Dec 2020 (Study Day 134)	Cough	Mild
23 Dec 2020 (Study Day 134)	Fatigue	Mild
23 Dec 2020 (Study Day 134)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 134)	Runny Nose (Rhinorrhea)	Mild
24 Dec 2020 (Study Day 135)	Cough	Mild
24 Dec 2020 (Study Day 135)	Fatigue	Mild
26 Dec 2020 (Study Day 137)	Cough	Mild
27 Dec 2020 (Study Day 138)	Cough	Mild
27 Dec 2020 (Study Day 138)	Nasal Congestion	Mild
28 Dec 2020 (Study Day 139)	Cough	Mild
30 Dec 2020 (Study Day 141)	Cough	Mild
31 Dec 2020 (Study Day 142)	Cough	Mild
01 Jan 2021 (Study Day 143)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
17 Dec 2020 (Study Day 128)	Oxygen Saturation	91%
17 Dec 2020 - 17 Dec 2020 (Study Day 128-128)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 18 days, after which it was considered to be recovered/resolved on 02 Jan 2021 (Study Day 144). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001219	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1992 - Ongoing
Myopia	Near sighted	1997 - Ongoing
Appendicectomy	Appendectomy	2002 - 2002
Mammoplasty	Breast reduction	2003 - 2003
Obesity	Obesity	2011 - Ongoing
Turbinectomy	Turbinate reduction	2012 - 2012
Goitre	Thyromegaly	2014 - Ongoing
Metabolic surgery	Bariatric surgery	31 Dec 2018 (Study Day -590) - Ongoing
Malnutrition	Nutritional deficiency	2020 - Ongoing
Electrocardiogram J wave	J tube	01 Jul 2020 (Study Day -42) - 09 Oct 2020 (Study Day 59)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
J tube replacement*	09 Oct 2020 (Study Day 59) - 09 Oct 2020 (Study Day 59)	Medical History
Salbutamol	16 Dec 2020 (Study Day 127) - 16 Dec 2020 (Study Day 127)	Sob (COVID-19 Diagnosis)
Azithromycin	17 Dec 2020 (Study Day 128) - 20 Dec 2020 (Study Day 131)	Upper Respiratory Infection (COVID-19 Diagnosis)
Guaifenesin	17 Dec 2020 (Study Day 128) - 31 Dec 2020 (Study Day 142)	Uri (COVID-19 Diagnosis)
Levonorgestrel	02 Feb 2021 (Study Day 175) - Ongoing	Contraception

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	16 Dec 2020 (Study Day 127) - 02 Jan 2021 (Study Day 144)
Photophobia	Grade 1/mild	Not related	27 Dec 2020 (Study Day 138) - 29 Dec 2020 (Study Day 140)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US312-2047 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urticaria/Hypersensitivity Rash - Bilateral Elbows (Macular - Urticarial)	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	04 Aug 2020 (Study Day 9) – 11 Aug 2020 (Study Day 16)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US312-2047, a 28-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 27 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of urticaria. On 23 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of hypersensitivity rash - bilateral elbows (macular - urticarial) lasted for 8 days, after which it was considered to be recovered/resolved on 11 Aug 2020 (Study Day 16). The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Umbilical hernia	Unbilical hernia	(b) (6) 1991 (Study Day (b) (6) - Aug 2017
Seasonal allergy	Seasonal allergies - pollen	1998 - Ongoing
Drug hypersensitivity	Allergy to penicillin	2008 - Ongoing
Inguinal hernia	Inguinal hernia	Jul 2017 - Aug 2017
Inguinal hernia repair	Inguinal hernia repair	Aug 2017 - Aug 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	12 Sep 2020 (Study Day 48) - 12 Sep 2020 (Study Day 48)	Flu Prevention
Bismuth subsalicylate	15 Oct 2020 (Study Day 81) - 18 Oct 2020 (Study Day 84)	Diarrhea
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	19 Oct 2020 (Study Day 85) - 22 Oct 2020 (Study Day 88)	Upper Respiratory Infection
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	19 Oct 2020 (Study Day 85) - 22 Oct 2020 (Study Day 88)	Upper Respiratory Infection
Losartan	03 Nov 2020 (Study Day 100) - Ongoing	Possible Htn
Sertraline hydrochloride	03 Nov 2020 (Study Day 100) - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urticaria	Grade 2/moderate	Related	04 Aug 2020 (Study Day 9) - 11 Aug 2020 (Study Day 16)
Pharyngitis	Grade 1/mild	Not related	14 Oct 2020 (Study Day 80) - 18 Oct 2020 (Study Day 84)
Diarrhoea	Grade 1/mild	Not related	15 Oct 2020 (Study Day 81) - 18 Oct 2020 (Study Day 84)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	15 Oct 2020 (Study Day 81) - 22 Oct 2020 (Study Day 88)
Depression	Grade 1/mild	Not related	03 Nov 2020 (Study Day 100) - Ongoing
Hypertension	Grade 1/mild	Not related	03 Nov 2020 (Study Day 100) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US313-2084 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	19 Oct 2020 (Study Day 27)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID Positive	COVID-19	Grade 2/ moderate	Not related	08 Jan 2021 (Study Day 108) – 20 Jan 2021 (Study Day 120)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US313-2084, a 57-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 23 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 19 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 08 Jan 2021 (Study Day 108), 107 days after the first dose and 81 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID positive.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 27, 19 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 14 Jan 2021 (Study Day 114), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
08 Jan 2021 (Study Day 108)	Cough	Mild
08 Jan 2021 (Study Day 108)	Fatigue	Mild
08 Jan 2021 (Study Day 108)	Nausea	Mild
08 Jan 2021 (Study Day 108)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 109)	Cough	Mild

Symptom Date	Symptom	Result
09 Jan 2021 (Study Day 109)	Fatigue	Mild
09 Jan 2021 (Study Day 109)	Nausea	Mild
09 Jan 2021 (Study Day 109)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 110)	Cough	Mild
10 Jan 2021 (Study Day 110)	Fatigue	Mild
10 Jan 2021 (Study Day 110)	Nausea	Mild
10 Jan 2021 (Study Day 110)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 111)	Cough	Mild
11 Jan 2021 (Study Day 111)	Fatigue	Mild
11 Jan 2021 (Study Day 111)	Nausea	Mild
11 Jan 2021 (Study Day 111)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 112)	Cough	Mild
12 Jan 2021 (Study Day 112)	Fatigue	Mild
12 Jan 2021 (Study Day 112)	Nausea	Mild
12 Jan 2021 (Study Day 112)	Shortness of Breath	Mild
13 Jan 2021 (Study Day 113)	Cough	Mild
13 Jan 2021 (Study Day 113)	Fatigue	Mild
13 Jan 2021 (Study Day 113)	Nausea	Mild
13 Jan 2021 (Study Day 113)	Shortness of Breath	Mild
14 Jan 2021 (Study Day 114)	Body Aches	Severe
14 Jan 2021 (Study Day 114)	Cough	Mild
14 Jan 2021 (Study Day 114)	Diarrhea	Mild
14 Jan 2021 (Study Day 114)	Difficulty Breathing	Severe
14 Jan 2021 (Study Day 114)	Fatigue	Severe
14 Jan 2021 (Study Day 114)	Headache	Mild
14 Jan 2021 (Study Day 114)	Muscle Aches (Myalgia)	Severe
14 Jan 2021 (Study Day 114)	Nasal Congestion	Mild
14 Jan 2021 (Study Day 114)	Nausea	Mild
14 Jan 2021 (Study Day 114)	Runny Nose (Rhinorrhea)	Moderate
14 Jan 2021 (Study Day 114)	Shortness of Breath	Severe
14 Jan 2021 (Study Day 114)	Sore Throat	Severe
15 Jan 2021 (Study Day 115)	Cough	Mild
15 Jan 2021 (Study Day 115)	Difficulty Breathing	Mild
15 Jan 2021 (Study Day 115)	Fatigue	Severe
15 Jan 2021 (Study Day 115)	Headache	Moderate
15 Jan 2021 (Study Day 115)	Nasal Congestion	Mild
15 Jan 2021 (Study Day 115)	Nausea	Mild
15 Jan 2021 (Study Day 115)	Runny Nose (Rhinorrhea)	Mild
15 Jan 2021 (Study Day 115)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 115)	Sore Throat	Mild
16 Jan 2021 (Study Day 116)	Body Aches	Severe
16 Jan 2021 (Study Day 116)	Cough	Mild
16 Jan 2021 (Study Day 116)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
16 Jan 2021 (Study Day 116)	Fatigue	Moderate
16 Jan 2021 (Study Day 116)	Headache	Mild
16 Jan 2021 (Study Day 116)	Muscle Aches (Myalgia)	Severe
16 Jan 2021 (Study Day 116)	Nasal Congestion	Mild
16 Jan 2021 (Study Day 116)	Nausea	Mild
16 Jan 2021 (Study Day 116)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 116)	Sore Throat	Moderate
17 Jan 2021 (Study Day 117)	Body Aches	Moderate
17 Jan 2021 (Study Day 117)	Cough	Moderate
17 Jan 2021 (Study Day 117)	Diarrhea	Mild
17 Jan 2021 (Study Day 117)	Difficulty Breathing	Moderate
17 Jan 2021 (Study Day 117)	Fatigue	Severe
17 Jan 2021 (Study Day 117)	Headache	Moderate
17 Jan 2021 (Study Day 117)	Muscle Aches (Myalgia)	Moderate
17 Jan 2021 (Study Day 117)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 117)	Nausea	Moderate
17 Jan 2021 (Study Day 117)	O2 Saturation (%)	89
17 Jan 2021 (Study Day 117)	Runny Nose (Rhinorrhea)	Mild
17 Jan 2021 (Study Day 117)	Shortness of Breath	Moderate
17 Jan 2021 (Study Day 117)	Sore Throat	Moderate
18 Jan 2021 (Study Day 118)	Difficulty Breathing	Mild
18 Jan 2021 (Study Day 118)	Fatigue	Mild
18 Jan 2021 (Study Day 118)	Headache	Moderate
18 Jan 2021 (Study Day 118)	Nasal Congestion	Moderate
18 Jan 2021 (Study Day 118)	Nausea	Mild
18 Jan 2021 (Study Day 118)	Runny Nose (Rhinorrhea)	Moderate
18 Jan 2021 (Study Day 118)	Shortness of Breath	Mild
18 Jan 2021 (Study Day 118)	Sore Throat	Mild
19 Jan 2021 (Study Day 119)	Sore Throat	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
17 Jan 2021 (Study Day 117)	Oxygen Saturation	89%
17 Jan 2021 - 17 Jan 2021 (Study Day 117-117)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID positive lasted for 13 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 120). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-028583	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1987 - Ongoing
Hypertension	Hypertension	1997 - Ongoing
Bipolar disorder	Bipolar disorder	1998 - Ongoing
Depression	Depression	1998 - Ongoing
Prostatomegaly	Enlarged prostate	1998 - Ongoing
Urinary incontinence	Intermittent urinary incontinence	2006 - Ongoing
Deafness bilateral	Bilateral ear hearing loss	2010 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Fatigue	Fatigue	2015 - Ongoing
Neuropathy peripheral	Bilateral leg neuropathy	2015 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knees	2015 - Ongoing
Renal pain	Kidney pain	2015 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2016 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Helicobacter infection	H pylori	2019 - 2019
Arthralgia	Right knee pain	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Valproate semisodium	2014 - Ongoing	Bipolar Disorder
Metoprolol	2019 - Ongoing	Hypertension
Gabapentin	Oct 2019 - Ongoing	Anxiety
Hydroxyzine	2020 - Ongoing	Anxiety
Meloxicam	Mar 2020 - Ongoing	Right Knee Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion	May 2020 - Ongoing	Bipolar Disorder
Sertraline	May 2020 - Ongoing	Depression
Naproxen sodium	30 Sep 2020 (Study Day 8) - 30 Sep 2020 (Study Day 8)	Headache
Influenza vaccine	04 Nov 2020 (Study Day 43) - 04 Nov 2020 (Study Day 43)	Flu Prophylaxis
Azithromycin	10 Jan 2021 (Study Day 110) - 15 Jan 2021 (Study Day 115)	COVID Symptoms
Tamsulosin hydrochloride	10 Feb 2021 (Study Day 141) - Ongoing	Bph

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphadenopathy	Grade 1/mild	Not related	12 Oct 2020 (Study Day 20) - 15 Oct 2020 (Study Day 23)
COVID-19	Grade 2/moderate	Not related	08 Jan 2021 (Study Day 108) - 20 Jan 2021 (Study Day 120)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US314-2013 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	30 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 62)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	28 Oct 2020 (Study Day 91) – 17 Nov 2020 (Study Day 111)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US314-2013, a 27-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 62). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 28 Oct 2020 (Study Day 91), 90 days after the first dose and 29 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 62, 29 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 30 Oct 2020 (Study Day 93), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
19 Aug 2020 (Study Day 21)	Body Aches	Moderate
19 Aug 2020 (Study Day 21)	Cough	Moderate
19 Aug 2020 (Study Day 21)	Difficulty Breathing	Mild
19 Aug 2020 (Study Day 21)	Fatigue	Moderate
19 Aug 2020 (Study Day 21)	Headache	Moderate
19 Aug 2020 (Study Day 21)	Muscle Aches (Myalgia)	Moderate
19 Aug 2020 (Study Day 21)	Nasal Congestion	Moderate

Symptom Date	Symptom	Result
19 Aug 2020 (Study Day 21)	Nausea	Mild
19 Aug 2020 (Study Day 21)	O2 Saturation (%)	91
19 Aug 2020 (Study Day 21)	Runny Nose (Rhinorrhea)	Moderate
19 Aug 2020 (Study Day 21)	Shortness of Breath	Mild
19 Aug 2020 (Study Day 21)	Sore Throat	Moderate
20 Aug 2020 (Study Day 22)	Body Aches	Moderate
20 Aug 2020 (Study Day 22)	Cough	Moderate
20 Aug 2020 (Study Day 22)	Difficulty Breathing	Mild
20 Aug 2020 (Study Day 22)	Fatigue	Moderate
20 Aug 2020 (Study Day 22)	Headache	Moderate
20 Aug 2020 (Study Day 22)	Muscle Aches (Myalgia)	Moderate
20 Aug 2020 (Study Day 22)	Nasal Congestion	Moderate
20 Aug 2020 (Study Day 22)	Nausea	Mild
20 Aug 2020 (Study Day 22)	Runny Nose (Rhinorrhea)	Moderate
20 Aug 2020 (Study Day 22)	Shortness of Breath	Mild
20 Aug 2020 (Study Day 22)	Sore Throat	Moderate
20 Aug 2020 (Study Day 22)	Vomiting	Mild
21 Aug 2020 (Study Day 23)	Body Aches	Mild
21 Aug 2020 (Study Day 23)	Cough	Moderate
21 Aug 2020 (Study Day 23)	Difficulty Breathing	Mild
21 Aug 2020 (Study Day 23)	Fatigue	Moderate
21 Aug 2020 (Study Day 23)	Headache	Mild
21 Aug 2020 (Study Day 23)	Muscle Aches (Myalgia)	Mild
21 Aug 2020 (Study Day 23)	Nasal Congestion	Moderate
21 Aug 2020 (Study Day 23)	Runny Nose (Rhinorrhea)	Moderate
21 Aug 2020 (Study Day 23)	Shortness of Breath	Mild
21 Aug 2020 (Study Day 23)	Sore Throat	Mild
22 Aug 2020 (Study Day 24)	Body Aches	Mild
22 Aug 2020 (Study Day 24)	Cough	Mild
22 Aug 2020 (Study Day 24)	Fatigue	Moderate
22 Aug 2020 (Study Day 24)	Headache	Mild
22 Aug 2020 (Study Day 24)	Muscle Aches (Myalgia)	Mild
22 Aug 2020 (Study Day 24)	Nasal Congestion	Moderate
22 Aug 2020 (Study Day 24)	Nausea	Mild
22 Aug 2020 (Study Day 24)	Runny Nose (Rhinorrhea)	Mild
22 Aug 2020 (Study Day 24)	Shortness of Breath	Mild
22 Aug 2020 (Study Day 24)	Sore Throat	Moderate
22 Aug 2020 (Study Day 24)	Vomiting	Mild
23 Aug 2020 (Study Day 25)	Body Aches	Mild
23 Aug 2020 (Study Day 25)	Cough	Mild
23 Aug 2020 (Study Day 25)	Fatigue	Mild
23 Aug 2020 (Study Day 25)	Muscle Aches (Myalgia)	Mild
23 Aug 2020 (Study Day 25)	Nasal Congestion	Moderate

Symptom Date	Symptom	Result
23 Aug 2020 (Study Day 25)	Nausea	Mild
23 Aug 2020 (Study Day 25)	Runny Nose (Rhinorrhea)	Mild
23 Aug 2020 (Study Day 25)	Shortness of Breath	Mild
23 Aug 2020 (Study Day 25)	Sore Throat	Mild
23 Aug 2020 (Study Day 25)	Vomiting	Mild
24 Aug 2020 (Study Day 26)	Body Aches	Mild
24 Aug 2020 (Study Day 26)	Cough	Mild
24 Aug 2020 (Study Day 26)	Fatigue	Mild
24 Aug 2020 (Study Day 26)	Headache	Mild
24 Aug 2020 (Study Day 26)	Muscle Aches (Myalgia)	Mild
24 Aug 2020 (Study Day 26)	Nasal Congestion	Mild
24 Aug 2020 (Study Day 26)	Nausea	Mild
24 Aug 2020 (Study Day 26)	Runny Nose (Rhinorrhea)	Mild
24 Aug 2020 (Study Day 26)	Sore Throat	Mild
24 Aug 2020 (Study Day 26)	Vomiting	Mild
30 Oct 2020 (Study Day 93)	Body Aches	Moderate
30 Oct 2020 (Study Day 93)	Chills	Mild
30 Oct 2020 (Study Day 93)	Cough	Mild
30 Oct 2020 (Study Day 93)	Diarrhea	Moderate
30 Oct 2020 (Study Day 93)	Difficulty Breathing	Mild
30 Oct 2020 (Study Day 93)	Fatigue	Mild
30 Oct 2020 (Study Day 93)	Headache	Moderate
30 Oct 2020 (Study Day 93)	Muscle Aches (Myalgia)	Moderate
30 Oct 2020 (Study Day 93)	Nasal Congestion	Mild
30 Oct 2020 (Study Day 93)	New Loss of Smell	Mild
30 Oct 2020 (Study Day 93)	New Loss of Taste	Mild
30 Oct 2020 (Study Day 93)	Shortness of Breath	Mild
30 Oct 2020 (Study Day 93)	Sore Throat	Moderate
01 Nov 2020 (Study Day 95)	Body Aches	Moderate
01 Nov 2020 (Study Day 95)	Chills	Mild
01 Nov 2020 (Study Day 95)	Cough	Mild
01 Nov 2020 (Study Day 95)	Diarrhea	Mild
01 Nov 2020 (Study Day 95)	Difficulty Breathing	Mild
01 Nov 2020 (Study Day 95)	Fatigue	Moderate
01 Nov 2020 (Study Day 95)	Headache	Moderate
01 Nov 2020 (Study Day 95)	Muscle Aches (Myalgia)	Moderate
01 Nov 2020 (Study Day 95)	Nasal Congestion	Mild
01 Nov 2020 (Study Day 95)	New Loss of Smell	Mild
01 Nov 2020 (Study Day 95)	New Loss of Taste	Mild
01 Nov 2020 (Study Day 95)	O2 Saturation (%)	90
01 Nov 2020 (Study Day 95)	Shortness of Breath	Mild
01 Nov 2020 (Study Day 95)	Sore Throat	Moderate
03 Nov 2020 (Study Day 97)	Body Aches	Moderate

Symptom Date	Symptom	Result
03 Nov 2020 (Study Day 97)	Cough	Mild
03 Nov 2020 (Study Day 97)	Difficulty Breathing	Mild
03 Nov 2020 (Study Day 97)	Fatigue	Moderate
03 Nov 2020 (Study Day 97)	Headache	Mild
03 Nov 2020 (Study Day 97)	Muscle Aches (Myalgia)	Moderate
03 Nov 2020 (Study Day 97)	Nasal Congestion	Moderate
03 Nov 2020 (Study Day 97)	New Loss of Smell	Mild
03 Nov 2020 (Study Day 97)	New Loss of Taste	Mild
03 Nov 2020 (Study Day 97)	O2 Saturation (%)	93
03 Nov 2020 (Study Day 97)	Shortness of Breath	Mild
03 Nov 2020 (Study Day 97)	Sore Throat	Mild
04 Nov 2020 (Study Day 98)	Body Aches	Moderate
04 Nov 2020 (Study Day 98)	Cough	Moderate
04 Nov 2020 (Study Day 98)	Difficulty Breathing	Mild
04 Nov 2020 (Study Day 98)	Fatigue	Moderate
04 Nov 2020 (Study Day 98)	Headache	Mild
04 Nov 2020 (Study Day 98)	Muscle Aches (Myalgia)	Moderate
04 Nov 2020 (Study Day 98)	Nasal Congestion	Moderate
04 Nov 2020 (Study Day 98)	New Loss of Smell	Mild
04 Nov 2020 (Study Day 98)	New Loss of Taste	Mild
04 Nov 2020 (Study Day 98)	O2 Saturation (%)	93
04 Nov 2020 (Study Day 98)	Runny Nose (Rhinorrhea)	Mild
04 Nov 2020 (Study Day 98)	Shortness of Breath	Mild
04 Nov 2020 (Study Day 98)	Sore Throat	Mild
05 Nov 2020 (Study Day 99)	Body Aches	Mild
05 Nov 2020 (Study Day 99)	Cough	Moderate
05 Nov 2020 (Study Day 99)	Difficulty Breathing	Mild
05 Nov 2020 (Study Day 99)	Fatigue	Moderate
05 Nov 2020 (Study Day 99)	Muscle Aches (Myalgia)	Mild
05 Nov 2020 (Study Day 99)	Nasal Congestion	Mild
05 Nov 2020 (Study Day 99)	New Loss of Smell	Mild
05 Nov 2020 (Study Day 99)	New Loss of Taste	Mild
05 Nov 2020 (Study Day 99)	Runny Nose (Rhinorrhea)	Mild
05 Nov 2020 (Study Day 99)	Shortness of Breath	Mild
05 Nov 2020 (Study Day 99)	Sore Throat	Mild
06 Nov 2020 (Study Day 100)	Cough	Moderate
06 Nov 2020 (Study Day 100)	Difficulty Breathing	Mild
06 Nov 2020 (Study Day 100)	Fatigue	Moderate
06 Nov 2020 (Study Day 100)	Nasal Congestion	Mild
06 Nov 2020 (Study Day 100)	New Loss of Smell	Mild
06 Nov 2020 (Study Day 100)	New Loss of Taste	Mild
06 Nov 2020 (Study Day 100)	O2 Saturation (%)	93
06 Nov 2020 (Study Day 100)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
10 Nov 2020 (Study Day 104)	Cough	Mild
10 Nov 2020 (Study Day 104)	Fatigue	Mild
10 Nov 2020 (Study Day 104)	Headache	Mild
10 Nov 2020 (Study Day 104)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 104)	New Loss of Smell	Mild
10 Nov 2020 (Study Day 104)	New Loss of Taste	Mild
11 Nov 2020 (Study Day 105)	Cough	Mild
11 Nov 2020 (Study Day 105)	New Loss of Smell	Moderate
11 Nov 2020 (Study Day 105)	Runny Nose (Rhinorrhea)	Moderate
12 Nov 2020 (Study Day 106)	Cough	Mild
12 Nov 2020 (Study Day 106)	Fatigue	Mild
12 Nov 2020 (Study Day 106)	Headache	Mild
12 Nov 2020 (Study Day 106)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 106)	New Loss of Smell	Mild
12 Nov 2020 (Study Day 106)	Runny Nose (Rhinorrhea)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
01 Nov 2020 (Study Day 95)	Oxygen Saturation	90%
01 Nov 2020 - 04 Nov 2020 (Study Day 95-98)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 111). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000761	COVID-19

Study Completion/Discontinuation

On 26 Feb 2021 (Study Day 212), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Urinary tract infection	Intermittent urinary tract infections	1994 - 1999
Seasonal allergy	Seasonal allergies	2005 - Ongoing
Depression	Depression	2006 - Ongoing
Tonsillitis	Tonsillitis	2009 - 2009
Ovarian cyst	Intermittent benign ovarian cysts	2010 - Ongoing
Gallbladder disorder	Gallbladder disease	2013 - 2013
Inguinal hernia	Inginual hernia	2013 - 2013
Drug hypersensitivity	Amoxicillin allergy	2015 - Ongoing
Drug hypersensitivity	Penicillin allergy	2015 - Ongoing
Substance use	Intermittent marijuana user	2015 - Ongoing
Anxiety	Anxiety	2017 - Ongoing
Asthma	Asthma	2017 - Ongoing
Post-traumatic stress disorder	Post-traumatic stress disorder	2019 - Ongoing
Pneumonia	Pneumonia	Sep 2019 - Sep 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide; formoterol fumarate	2018 - Ongoing	Asthma
Montelukast sodium	2018 - Ongoing	Asthma
Hydroxyzine	2019 - Ongoing	Anxiety
Sertraline hydrochloride	2019 - Ongoing	Post Traumatic Stress Disorder
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	30 Sep 2020 (Study Day 63) - 30 Sep 2020 (Study Day 63)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	31 Jul 2020 (Study Day 2) - 08 Aug 2020 (Study Day 10)
Headache	Grade 1/mild	Related	02 Aug 2020 (Study Day 4) - 07 Aug 2020 (Study Day 9)
COVID-19	Grade 2/moderate	Not related	28 Oct 2020 (Study Day 91) - 17 Nov 2020 (Study Day 111)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US314-2034 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	27 Aug 2020 (Study Day 28)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Positive COVID-19 Diagnosis	COVID-19	Grade 2/ moderate	Not related	14 Dec 2020 (Study Day 137) – 28 Dec 2020 (Study Day 151)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US314-2034, a 74-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 27 Aug 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 14 Dec 2020 (Study Day 137), 136 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of positive COVID-19 diagnosis.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 27 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 14 Dec 2020 (Study Day 137), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
10 Dec 2020 (Study Day 133)	Cough	Mild
10 Dec 2020 (Study Day 133)	Fatigue	Mild
10 Dec 2020 (Study Day 133)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 133)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 134)	Cough	Mild
11 Dec 2020 (Study Day 134)	Fatigue	Mild

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 134)	Nasal Congestion	Mild
11 Dec 2020 (Study Day 134)	Runny Nose (Rhinorrhea)	Mild
12 Dec 2020 (Study Day 135)	Cough	Mild
12 Dec 2020 (Study Day 135)	Fatigue	Mild
12 Dec 2020 (Study Day 135)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 135)	Runny Nose (Rhinorrhea)	Mild
13 Dec 2020 (Study Day 136)	Cough	Mild
13 Dec 2020 (Study Day 136)	Fatigue	Mild
13 Dec 2020 (Study Day 136)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 136)	Runny Nose (Rhinorrhea)	Mild
14 Dec 2020 (Study Day 137)	Cough	Mild
14 Dec 2020 (Study Day 137)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 137)	O2 Saturation (%)	93
14 Dec 2020 (Study Day 137)	Runny Nose (Rhinorrhea)	Mild
15 Dec 2020 (Study Day 138)	Cough	Mild
15 Dec 2020 (Study Day 138)	Fatigue	Mild
15 Dec 2020 (Study Day 138)	Headache	Mild
15 Dec 2020 (Study Day 138)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 138)	Runny Nose (Rhinorrhea)	Mild
16 Dec 2020 (Study Day 139)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 139)	O2 Saturation (%)	93
16 Dec 2020 (Study Day 139)	Runny Nose (Rhinorrhea)	Mild
20 Dec 2020 (Study Day 143)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 143)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 144)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 144)	O2 Saturation (%)	93
21 Dec 2020 (Study Day 144)	Runny Nose (Rhinorrhea)	Mild
22 Dec 2020 (Study Day 145)	Fatigue	Mild
22 Dec 2020 (Study Day 145)	Nasal Congestion	Mild
22 Dec 2020 (Study Day 145)	Runny Nose (Rhinorrhea)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
14 Dec 2020 (Study Day 137)	Oxygen Saturation	93%
14 Dec 2020 - 21 Dec 2020 (Study Day 137-144)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of positive COVID-19 diagnosis lasted for 15 days, after which it was considered to be recovered/resolved on 28 Dec 2020 (Study Day 151). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-059163	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Nearsighted bilateral	1966 - Ongoing
Haemorrhoids	Hemorrhoids	1973 - Ongoing
Phlebitis	Phlebitis - unknown location	1974 - 1974
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Hypertonic bladder	Overactive bladder	2000 - Ongoing
Postmenopause	Post-menopausal	2000 - Ongoing
Osteoarthritis	Osteoarthritis in wrists, fingers, shoulders and knees	2006 - Ongoing
Cataract	Cataracts bilateral	2015 - Ongoing
Osteoporosis	Osteoporosis	2015 - Ongoing
Deafness bilateral	Hearing loss bilateral	2018 - Ongoing
Peripheral sensory neuropathy	Neuropathy in both feet - sensory	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2000 - Ongoing	General Health
Diltiazem	2000 - Ongoing	Hypertension
Estradiol	2000 - Ongoing	Menopause
Fish oil	2000 - Ongoing	General Health
Folic acid	2000 - Ongoing	General Health
Lactobacillus acidophilus	2000 - Ongoing	General Health
Lisinopril	2000 - Ongoing	Hypertension
Medroxyprogesterone acetate	2000 - Ongoing	Menopause
Simvastatin	2000 - Ongoing	Hypercholesterolemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b12 nos	2000 - Ongoing	General Health
Calcium	2010 - Ongoing	General Health
Magnesium	2010 - Ongoing	General Health
Calcium citrate	2015 - Ongoing	General Health
Alendronate sodium	2016 - Ongoing	Osteoporosis
Zinc	Mar 2020 - Ongoing	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	14 Dec 2020 (Study Day 137) - 28 Dec 2020 (Study Day 151)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379238

Participant Number:	US314-2043 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 32)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 1/mild	Not related	30 Nov 2020 (Study Day 122) – 12 Dec 2020 (Study Day 134)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US314-2043, a 55-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 01 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 30 Nov 2020 (Study Day 122), 121 days after the first dose and 90 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 32, 01 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 02 Dec 2020 (Study Day 124), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
30 Nov 2020 (Study Day 122)	Fatigue	Moderate
30 Nov 2020 (Study Day 122)	Headache	Mild
30 Nov 2020 (Study Day 122)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 122)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 122)	Sore Throat	Moderate
01 Dec 2020 (Study Day 123)	Fatigue	Moderate

Symptom Date	Symptom	Result
01 Dec 2020 (Study Day 123)	Headache	Mild
01 Dec 2020 (Study Day 123)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 123)	Runny Nose (Rhinorrhea)	Mild
01 Dec 2020 (Study Day 123)	Sore Throat	Moderate
02 Dec 2020 (Study Day 124)	Fatigue	Mild
02 Dec 2020 (Study Day 124)	Headache	Mild
02 Dec 2020 (Study Day 124)	Nasal Congestion	Moderate
02 Dec 2020 (Study Day 124)	O2 Saturation (%)	90
02 Dec 2020 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 125)	Fatigue	Mild
03 Dec 2020 (Study Day 125)	Headache	Mild
03 Dec 2020 (Study Day 125)	Nasal Congestion	Moderate
03 Dec 2020 (Study Day 125)	O2 Saturation (%)	91
03 Dec 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 125)	Sore Throat	Mild
04 Dec 2020 (Study Day 126)	Fatigue	Mild
04 Dec 2020 (Study Day 126)	Nasal Congestion	Moderate
04 Dec 2020 (Study Day 126)	O2 Saturation (%)	92
04 Dec 2020 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
06 Dec 2020 (Study Day 128)	Fatigue	Mild
06 Dec 2020 (Study Day 128)	Headache	Mild
06 Dec 2020 (Study Day 128)	Nasal Congestion	Moderate
06 Dec 2020 (Study Day 128)	O2 Saturation (%)	90
06 Dec 2020 (Study Day 128)	Runny Nose (Rhinorrhea)	Mild
07 Dec 2020 (Study Day 129)	Headache	Mild
07 Dec 2020 (Study Day 129)	Nasal Congestion	Moderate
07 Dec 2020 (Study Day 129)	O2 Saturation (%)	90
07 Dec 2020 (Study Day 129)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 130)	Headache	Mild
08 Dec 2020 (Study Day 130)	Nasal Congestion	Moderate
08 Dec 2020 (Study Day 130)	O2 Saturation (%)	89
08 Dec 2020 (Study Day 130)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 133)	Cough	Mild
11 Dec 2020 (Study Day 133)	O2 Saturation (%)	92
11 Dec 2020 (Study Day 133)	Runny Nose (Rhinorrhea)	Mild
12 Dec 2020 (Study Day 134)	O2 Saturation (%)	91
15 Dec 2020 (Study Day 137)	O2 Saturation (%)	92

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
02 Dec 2020 (Study Day 124)	Oxygen Saturation	90%

Dates	Severity Indication	Result
02 Dec 2020 - 15 Dec 2020 (Study Day 124-137)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 13 days, after which it was considered to be recovered/resolved on 12 Dec 2020 (Study Day 134). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006077	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Astigmatism	Bilateral astigmatism	1969 - Ongoing
Myopia	Bilateral nearsighted	1969 - Ongoing
Seasonal allergy	Seasonal allergies	1984 - Ongoing
Urinary tract infection	Urinary tract infections	1990 - 1990
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Postmenopause	Post menopausal	2010 - Ongoing
Eczema	Eczema	2015 - Ongoing
Herpes zoster	Shingles	2015 - 2015
Basal cell carcinoma	Basal cell cancer	2017 - 2017
Dyspepsia	Heart burn	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Jun 2010 - Ongoing	Hypercholesterolemia
Hydrochlorothiazide	20 Jan 2021 (Study Day 173) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	30 Nov 2020 (Study Day 122) - 12 Dec 2020 (Study Day 134)
Hypertension	Grade 1/mild	Not related	20 Jan 2021 (Study Day 173) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US314-2056 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 30)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	21 Dec 2020 (Study Day 141) – 04 Jan 2021 (Study Day 155)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US314-2056, a 58-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 21 Dec 2020 (Study Day 141), 140 days after the first dose and 111 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 01 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 21 Dec 2020 (Study Day 141), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 99)	Body Aches	Mild
09 Nov 2020 (Study Day 99)	Chills	Mild
09 Nov 2020 (Study Day 99)	Cough	Mild
09 Nov 2020 (Study Day 99)	Muscle Aches (Myalgia)	Mild
09 Nov 2020 (Study Day 99)	Nasal Congestion	Mild
09 Nov 2020 (Study Day 99)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
10 Nov 2020 (Study Day 100)	Body Aches	Mild
10 Nov 2020 (Study Day 100)	Chills	Mild
10 Nov 2020 (Study Day 100)	Cough	Mild
10 Nov 2020 (Study Day 100)	Muscle Aches (Myalgia)	Mild
10 Nov 2020 (Study Day 100)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 100)	Runny Nose (Rhinorrhea)	Mild
11 Nov 2020 (Study Day 101)	Body Aches	Mild
11 Nov 2020 (Study Day 101)	Chills	Mild
11 Nov 2020 (Study Day 101)	Cough	Mild
11 Nov 2020 (Study Day 101)	Muscle Aches (Myalgia)	Mild
11 Nov 2020 (Study Day 101)	Nasal Congestion	Mild
11 Nov 2020 (Study Day 101)	O2 Saturation (%)	92
11 Nov 2020 (Study Day 101)	Runny Nose (Rhinorrhea)	Mild
12 Nov 2020 (Study Day 102)	Cough	Mild
12 Nov 2020 (Study Day 102)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 102)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 137)	Body Aches	Mild
17 Dec 2020 (Study Day 137)	Cough	Moderate
17 Dec 2020 (Study Day 137)	Fatigue	Moderate
17 Dec 2020 (Study Day 137)	Headache	Mild
17 Dec 2020 (Study Day 137)	Muscle Aches (Myalgia)	Mild
17 Dec 2020 (Study Day 137)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 137)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 137)	Shortness of Breath	Mild
18 Dec 2020 (Study Day 138)	Body Aches	Mild
18 Dec 2020 (Study Day 138)	Cough	Moderate
18 Dec 2020 (Study Day 138)	Fatigue	Moderate
18 Dec 2020 (Study Day 138)	Headache	Mild
18 Dec 2020 (Study Day 138)	Muscle Aches (Myalgia)	Mild
18 Dec 2020 (Study Day 138)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 138)	Runny Nose (Rhinorrhea)	Mild
18 Dec 2020 (Study Day 138)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 139)	Body Aches	Mild
19 Dec 2020 (Study Day 139)	Cough	Moderate
19 Dec 2020 (Study Day 139)	Fatigue	Moderate
19 Dec 2020 (Study Day 139)	Headache	Mild
19 Dec 2020 (Study Day 139)	Muscle Aches (Myalgia)	Mild
19 Dec 2020 (Study Day 139)	Nasal Congestion	Mild
19 Dec 2020 (Study Day 139)	Runny Nose (Rhinorrhea)	Mild
19 Dec 2020 (Study Day 139)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 140)	Body Aches	Mild
20 Dec 2020 (Study Day 140)	Cough	Moderate
20 Dec 2020 (Study Day 140)	Fatigue	Moderate

Symptom Date	Symptom	Result
20 Dec 2020 (Study Day 140)	Headache	Mild
20 Dec 2020 (Study Day 140)	Muscle Aches (Myalgia)	Mild
20 Dec 2020 (Study Day 140)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 140)	Runny Nose (Rhinorrhea)	Mild
20 Dec 2020 (Study Day 140)	Shortness of Breath	Mild
21 Dec 2020 (Study Day 141)	Cough	Mild
21 Dec 2020 (Study Day 141)	Fatigue	Mild
21 Dec 2020 (Study Day 141)	Headache	Mild
21 Dec 2020 (Study Day 141)	O2 Saturation (%)	91
22 Dec 2020 (Study Day 142)	Cough	Mild
22 Dec 2020 (Study Day 142)	Fatigue	Mild
22 Dec 2020 (Study Day 142)	Headache	Mild
23 Dec 2020 (Study Day 143)	Cough	Mild
23 Dec 2020 (Study Day 143)	Fatigue	Mild
23 Dec 2020 (Study Day 143)	Headache	Mild
24 Dec 2020 (Study Day 144)	Cough	Mild
24 Dec 2020 (Study Day 144)	Fatigue	Mild
24 Dec 2020 (Study Day 144)	Headache	Mild
25 Dec 2020 (Study Day 145)	Cough	Mild
25 Dec 2020 (Study Day 145)	Fatigue	Mild
25 Dec 2020 (Study Day 145)	Headache	Mild
26 Dec 2020 (Study Day 146)	Cough	Mild
26 Dec 2020 (Study Day 146)	Fatigue	Mild
26 Dec 2020 (Study Day 146)	Headache	Mild
27 Dec 2020 (Study Day 147)	Cough	Mild
27 Dec 2020 (Study Day 147)	Fatigue	Mild
27 Dec 2020 (Study Day 147)	Headache	Mild
28 Dec 2020 (Study Day 148)	Cough	Mild
29 Dec 2020 (Study Day 149)	Cough	Mild
30 Dec 2020 (Study Day 150)	Cough	Mild
31 Dec 2020 (Study Day 151)	Cough	Mild
01 Jan 2021 (Study Day 152)	Cough	Mild
02 Jan 2021 (Study Day 153)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
21 Dec 2020 (Study Day 141)	Oxygen Saturation	91%
21 Dec 2020 - 21 Dec 2020 (Study Day 141-141)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 04 Jan 2021 (Study Day 155). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-060280	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Nearsighted bilateral	1972 - Ongoing
Asthma	Asthma	1974 - Ongoing
Inguinal hernia	Right hernia inguinal	1984 - 1984
Headache	Headaches	1985 - Ongoing
Gastrooesophageal reflux disease	Gerd	2000 - Ongoing
Erectile dysfunction	Erectile dysfunction	2013 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Tooth loss	Tooth loss	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2000 - Ongoing	Heartburn
Ascorbic acid	2017 - Ongoing	General Health
Serenoa repens	2017 - Ongoing	General Health
Vitamin d nos	2017 - Ongoing	General Health
Vitamins nos	2017 - Ongoing	General Eye Health
Vitamins nos	2017 - Ongoing	General Health
Allium sativum extract	2020 - Ongoing	General Health
Paracetamol	05 Aug 2020 (Study Day 3) - 05 Aug 2020 (Study Day 3)	Site Injection Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	21 Dec 2020 (Study Day 141) - 04 Jan 2021 (Study Day 155)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379247

Participant Number:	US314-2100 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 31)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	21 Sep 2020 (Study Day 49) – 23 Nov 2020 (Study Day 112)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US314-2100, a 69-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 21 Sep 2020 (Study Day 49), 48 days after the first dose and 18 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 31, 03 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Sep 2020 (Study Day 51), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
23 Sep 2020 (Study Day 51)	Body Aches	Mild
23 Sep 2020 (Study Day 51)	Cough	Mild
23 Sep 2020 (Study Day 51)	Difficulty Breathing	Mild
23 Sep 2020 (Study Day 51)	Headache	Mild
23 Sep 2020 (Study Day 51)	Muscle Aches (Myalgia)	Mild
23 Sep 2020 (Study Day 51)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
23 Sep 2020 (Study Day 51)	O2 Saturation (%)	93
23 Sep 2020 (Study Day 51)	Shortness of Breath	Mild
24 Sep 2020 (Study Day 52)	Cough	Mild
24 Sep 2020 (Study Day 52)	Fatigue	Mild
25 Sep 2020 (Study Day 53)	Body Aches	Mild
25 Sep 2020 (Study Day 53)	Cough	Mild
25 Sep 2020 (Study Day 53)	Fatigue	Mild
25 Sep 2020 (Study Day 53)	Muscle Aches (Myalgia)	Mild
26 Sep 2020 (Study Day 54)	Body Aches	Mild
26 Sep 2020 (Study Day 54)	Cough	Mild
26 Sep 2020 (Study Day 54)	Fatigue	Mild
26 Sep 2020 (Study Day 54)	Muscle Aches (Myalgia)	Mild
28 Sep 2020 (Study Day 56)	Body Aches	Mild
28 Sep 2020 (Study Day 56)	Cough	Moderate
28 Sep 2020 (Study Day 56)	Fatigue	Moderate
28 Sep 2020 (Study Day 56)	Muscle Aches (Myalgia)	Mild
28 Sep 2020 (Study Day 56)	Nasal Congestion	Mild
28 Sep 2020 (Study Day 56)	Runny Nose (Rhinorrhea)	Mild
29 Sep 2020 (Study Day 57)	Cough	Mild
29 Sep 2020 (Study Day 57)	Fatigue	Mild
29 Sep 2020 (Study Day 57)	Nasal Congestion	Mild
29 Sep 2020 (Study Day 57)	Runny Nose (Rhinorrhea)	Mild
30 Sep 2020 (Study Day 58)	Body Aches	Mild
30 Sep 2020 (Study Day 58)	Cough	Moderate
30 Sep 2020 (Study Day 58)	Fatigue	Mild
30 Sep 2020 (Study Day 58)	Muscle Aches (Myalgia)	Mild
30 Sep 2020 (Study Day 58)	Nasal Congestion	Mild
30 Sep 2020 (Study Day 58)	Runny Nose (Rhinorrhea)	Mild
30 Sep 2020 (Study Day 58)	Temperature (°F)	101
01 Oct 2020 (Study Day 59)	Body Aches	Moderate
01 Oct 2020 (Study Day 59)	Cough	Mild
01 Oct 2020 (Study Day 59)	Fatigue	Moderate
01 Oct 2020 (Study Day 59)	Headache	Mild
01 Oct 2020 (Study Day 59)	Muscle Aches (Myalgia)	Moderate
01 Oct 2020 (Study Day 59)	Nasal Congestion	Mild
01 Oct 2020 (Study Day 59)	O2 Saturation (%)	91
01 Oct 2020 (Study Day 59)	Runny Nose (Rhinorrhea)	Mild
01 Oct 2020 (Study Day 59)	Temperature (°F)	100.9
02 Oct 2020 (Study Day 60)	Body Aches	Mild
02 Oct 2020 (Study Day 60)	Cough	Mild
02 Oct 2020 (Study Day 60)	Fatigue	Moderate
02 Oct 2020 (Study Day 60)	Muscle Aches (Myalgia)	Mild
02 Oct 2020 (Study Day 60)	O2 Saturation (%)	90

Symptom Date	Symptom	Result
02 Oct 2020 (Study Day 60)	Temperature (°F)	102.3
03 Oct 2020 (Study Day 61)	Body Aches	Moderate
03 Oct 2020 (Study Day 61)	Cough	Mild
03 Oct 2020 (Study Day 61)	Fatigue	Moderate
03 Oct 2020 (Study Day 61)	Muscle Aches (Myalgia)	Moderate
03 Oct 2020 (Study Day 61)	O2 Saturation (%)	90
03 Oct 2020 (Study Day 61)	Temperature (°F)	101.4
05 Oct 2020 (Study Day 63)	Cough	Mild
05 Oct 2020 (Study Day 63)	Fatigue	Severe
05 Oct 2020 (Study Day 63)	Headache	Mild
05 Oct 2020 (Study Day 63)	O2 Saturation (%)	90
05 Oct 2020 (Study Day 63)	Temperature (°F)	101.0
06 Oct 2020 (Study Day 64)	Cough	Moderate
06 Oct 2020 (Study Day 64)	Fatigue	Severe
06 Oct 2020 (Study Day 64)	O2 Saturation (%)	93
06 Oct 2020 (Study Day 64)	Temperature (°F)	101.2
14 Oct 2020 (Study Day 72)	Cough	Mild
14 Oct 2020 (Study Day 72)	Fatigue	Moderate
14 Oct 2020 (Study Day 72)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
01 Oct 2020 (Study Day 59)	Oxygen Saturation	90%
01 Oct 2020 - 14 Oct 2020 (Study Day 59-72)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 64 days, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 112). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000384	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillitis	Tonsillitis	1957 - 1957
Corrective lens user	Corrective lens wearer	1962 - Ongoing
Myopia	Nearsighted bilateral	1962 - Ongoing
Oral herpes	Intermittent herpes simplex (cold sores)	1966 - Ongoing
Migraine	Migraines	1967 - 1967
Hypertension	Hypertension	2015 - Ongoing
Dry eye	Chronic dry eyes	2017 - Ongoing
Gout	Gout	2017 - Ongoing
Astigmatism	Astigmatism bilateral	2018 - Ongoing
Deep vein thrombosis	Deep vein thrombosis	2018 - 2018
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Pulmonary embolism	Pulmonary embolism	2018 - 2018
Vitamin D deficiency	Vitamin d deficiency	Mar 2019 - Ongoing
Dental implantation	Dental implant	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Heart Health
Amlodipine	2015 - Ongoing	Hypertension
Allopurinol	2018 - Ongoing	Gout
Atorvastatin	2018 - Ongoing	Hypercholesterolemia
Ciclosporin	2018 - Ongoing	Chronic Dry Eye
Vitamin d nos	2019 - Ongoing	Vitamin D Deficiency
Ibuprofen	27 Sep 2020 (Study Day 55) - 10 Oct 2020 (Study Day 68)	Fever Reduction - COVID 19
Paracetamol	05 Oct 2020 (Study Day 63) - 10 Oct 2020 (Study Day 68)	Fever Reduction - COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	21 Sep 2020 (Study Day 49) - 23 Nov 2020 (Study Day 112)
Alopecia	Grade 1/mild	Not related	01 Dec 2020 (Study Day 120) - 01 Mar 2021 (Study Day 210)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US314-2243 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Lymphadenopathy/Left Armpit Swelling	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	22 Aug 2020 (Study Day 4) – 07 Sep 2020 (Study Day 20)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US314-2243, a 54-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Aug 2020 (Study Day 4), 3 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of lymphadenopathy. On 15 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of left armpit swelling lasted for 17 days, after which it was considered to be recovered/resolved on 07 Sep 2020 (Study Day 20). The investigator assessed the event of lymphadenopathy to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	1985 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Oropharyngeal pain	Scratchy/ sore throat	2008 - Ongoing
Herpes zoster	Shingles	2015 - 2015
Postmenopause	Post menopausal	2016 - Ongoing
Hypermetropia	Farsighted, bilateral	2018 - Ongoing
Myopia	Nearsighted, bilateral	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alprazolam	1985 - Ongoing	Insomnia
Levocetirizine dihydrochloride	2013 - Ongoing	Seasonal Allergies
Trazodone	2015 - Ongoing	Insomnia
Estradiol	2019 - Ongoing	Menopausal
Progesterone	2019 - Ongoing	Menopausal

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Feeling Abnormal	Grade 2/moderate	Related	20 Aug 2020 (Study Day 2) - 29 Aug 2020 (Study Day 11)
Injection Site Pain	Grade 2/moderate	Related	20 Aug 2020 (Study Day 2) - 29 Aug 2020 (Study Day 11)
Lymphadenopathy	Grade 2/moderate	Related	22 Aug 2020 (Study Day 4) - 07 Sep 2020 (Study Day 20)
Fatigue	Grade 3/severe	Related	26 Aug 2020 (Study Day 8) - 07 Sep 2020 (Study Day 20)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US314-2252 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19 Infection	COVID-19	Grade 3/severe	Not related	07 Nov 2020 (Study Day 75) – 01 Dec 2020 (Study Day 99)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US314-2252, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 07 Nov 2020 (Study Day 75), 74 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 22 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Nov 2020 (Study Day 79), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
07 Nov 2020 (Study Day 75)	Fatigue	Severe
07 Nov 2020 (Study Day 75)	Headache	Severe
08 Nov 2020 (Study Day 76)	Body Aches	Severe
08 Nov 2020 (Study Day 76)	Chills	Mild

Symptom Date	Symptom	Result
08 Nov 2020 (Study Day 76)	Diarrhea	Mild
08 Nov 2020 (Study Day 76)	Fatigue	Severe
08 Nov 2020 (Study Day 76)	Headache	Severe
08 Nov 2020 (Study Day 76)	Muscle Aches (Myalgia)	Severe
08 Nov 2020 (Study Day 76)	Nasal Congestion	Mild
08 Nov 2020 (Study Day 76)	New Loss of Smell	Severe
08 Nov 2020 (Study Day 76)	New Loss of Taste	Severe
09 Nov 2020 (Study Day 77)	Body Aches	Severe
09 Nov 2020 (Study Day 77)	Chills	Mild
09 Nov 2020 (Study Day 77)	Cough	Mild
09 Nov 2020 (Study Day 77)	Diarrhea	Mild
09 Nov 2020 (Study Day 77)	Fatigue	Severe
09 Nov 2020 (Study Day 77)	Headache	Severe
09 Nov 2020 (Study Day 77)	Muscle Aches (Myalgia)	Severe
09 Nov 2020 (Study Day 77)	Nasal Congestion	Mild
09 Nov 2020 (Study Day 77)	New Loss of Smell	Severe
09 Nov 2020 (Study Day 77)	New Loss of Taste	Severe
10 Nov 2020 (Study Day 78)	Body Aches	Severe
10 Nov 2020 (Study Day 78)	Chills	Mild
10 Nov 2020 (Study Day 78)	Cough	Mild
10 Nov 2020 (Study Day 78)	Diarrhea	Mild
10 Nov 2020 (Study Day 78)	Fatigue	Severe
10 Nov 2020 (Study Day 78)	Headache	Severe
10 Nov 2020 (Study Day 78)	Muscle Aches (Myalgia)	Severe
10 Nov 2020 (Study Day 78)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 78)	New Loss of Smell	Severe
10 Nov 2020 (Study Day 78)	New Loss of Taste	Severe
11 Nov 2020 (Study Day 79)	Body Aches	Severe
11 Nov 2020 (Study Day 79)	Chills	Mild
11 Nov 2020 (Study Day 79)	Cough	Mild
11 Nov 2020 (Study Day 79)	Diarrhea	Mild
11 Nov 2020 (Study Day 79)	Fatigue	Severe
11 Nov 2020 (Study Day 79)	Headache	Severe
11 Nov 2020 (Study Day 79)	Muscle Aches (Myalgia)	Severe
11 Nov 2020 (Study Day 79)	Nasal Congestion	Mild
11 Nov 2020 (Study Day 79)	New Loss of Smell	Severe
11 Nov 2020 (Study Day 79)	New Loss of Taste	Severe
11 Nov 2020 (Study Day 79)	O2 Saturation (%)	90
12 Nov 2020 (Study Day 80)	Body Aches	Severe
12 Nov 2020 (Study Day 80)	Cough	Mild
12 Nov 2020 (Study Day 80)	Fatigue	Severe
12 Nov 2020 (Study Day 80)	Headache	Severe
12 Nov 2020 (Study Day 80)	Muscle Aches (Myalgia)	Severe

Symptom Date	Symptom	Result
12 Nov 2020 (Study Day 80)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 80)	Nausea	Mild
12 Nov 2020 (Study Day 80)	New Loss of Smell	Severe
12 Nov 2020 (Study Day 80)	New Loss of Taste	Severe
13 Nov 2020 (Study Day 81)	Body Aches	Severe
13 Nov 2020 (Study Day 81)	Cough	Mild
13 Nov 2020 (Study Day 81)	Fatigue	Severe
13 Nov 2020 (Study Day 81)	Headache	Moderate
13 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Severe
13 Nov 2020 (Study Day 81)	Nausea	Mild
13 Nov 2020 (Study Day 81)	New Loss of Smell	Severe
13 Nov 2020 (Study Day 81)	New Loss of Taste	Severe
13 Nov 2020 (Study Day 81)	O2 Saturation (%)	93
14 Nov 2020 (Study Day 82)	Body Aches	Moderate
14 Nov 2020 (Study Day 82)	Cough	Mild
14 Nov 2020 (Study Day 82)	Fatigue	Moderate
14 Nov 2020 (Study Day 82)	Headache	Moderate
14 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
14 Nov 2020 (Study Day 82)	Nausea	Mild
14 Nov 2020 (Study Day 82)	New Loss of Smell	Severe
14 Nov 2020 (Study Day 82)	New Loss of Taste	Moderate
15 Nov 2020 (Study Day 83)	Body Aches	Moderate
15 Nov 2020 (Study Day 83)	Cough	Mild
15 Nov 2020 (Study Day 83)	Fatigue	Moderate
15 Nov 2020 (Study Day 83)	Headache	Mild
15 Nov 2020 (Study Day 83)	Muscle Aches (Myalgia)	Moderate
15 Nov 2020 (Study Day 83)	Nausea	Mild
15 Nov 2020 (Study Day 83)	New Loss of Smell	Severe
15 Nov 2020 (Study Day 83)	New Loss of Taste	Moderate
16 Nov 2020 (Study Day 84)	Body Aches	Moderate
16 Nov 2020 (Study Day 84)	Cough	Mild
16 Nov 2020 (Study Day 84)	Fatigue	Moderate
16 Nov 2020 (Study Day 84)	Headache	Mild
16 Nov 2020 (Study Day 84)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 84)	Nausea	Mild
16 Nov 2020 (Study Day 84)	New Loss of Smell	Severe
16 Nov 2020 (Study Day 84)	New Loss of Taste	Moderate
17 Nov 2020 (Study Day 85)	Body Aches	Moderate
17 Nov 2020 (Study Day 85)	Cough	Mild
17 Nov 2020 (Study Day 85)	Fatigue	Moderate
17 Nov 2020 (Study Day 85)	Headache	Mild
17 Nov 2020 (Study Day 85)	Muscle Aches (Myalgia)	Moderate
17 Nov 2020 (Study Day 85)	Nausea	Mild

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 85)	New Loss of Smell	Severe
17 Nov 2020 (Study Day 85)	New Loss of Taste	Moderate
18 Nov 2020 (Study Day 86)	Body Aches	Mild
18 Nov 2020 (Study Day 86)	Cough	Mild
18 Nov 2020 (Study Day 86)	Fatigue	Moderate
18 Nov 2020 (Study Day 86)	Headache	Mild
18 Nov 2020 (Study Day 86)	Muscle Aches (Myalgia)	Mild
18 Nov 2020 (Study Day 86)	Nausea	Mild
18 Nov 2020 (Study Day 86)	New Loss of Smell	Severe
18 Nov 2020 (Study Day 86)	New Loss of Taste	Moderate
18 Nov 2020 (Study Day 86)	O2 Saturation (%)	93
19 Nov 2020 (Study Day 87)	Body Aches	Mild
19 Nov 2020 (Study Day 87)	Cough	Mild
19 Nov 2020 (Study Day 87)	Fatigue	Mild
19 Nov 2020 (Study Day 87)	Headache	Mild
19 Nov 2020 (Study Day 87)	Muscle Aches (Myalgia)	Mild
19 Nov 2020 (Study Day 87)	Nausea	Mild
19 Nov 2020 (Study Day 87)	New Loss of Smell	Severe
19 Nov 2020 (Study Day 87)	New Loss of Taste	Moderate
19 Nov 2020 (Study Day 87)	O2 Saturation (%)	93
20 Nov 2020 (Study Day 88)	Cough	Mild
20 Nov 2020 (Study Day 88)	Fatigue	Mild
20 Nov 2020 (Study Day 88)	Headache	Mild
20 Nov 2020 (Study Day 88)	New Loss of Smell	Severe
20 Nov 2020 (Study Day 88)	New Loss of Taste	Mild
21 Nov 2020 (Study Day 89)	Cough	Mild
21 Nov 2020 (Study Day 89)	Fatigue	Mild
21 Nov 2020 (Study Day 89)	Headache	Mild
21 Nov 2020 (Study Day 89)	New Loss of Smell	Severe
21 Nov 2020 (Study Day 89)	New Loss of Taste	Mild
22 Nov 2020 (Study Day 90)	Cough	Mild
22 Nov 2020 (Study Day 90)	Fatigue	Mild
22 Nov 2020 (Study Day 90)	Headache	Mild
22 Nov 2020 (Study Day 90)	New Loss of Smell	Severe
22 Nov 2020 (Study Day 90)	New Loss of Taste	Mild
23 Nov 2020 (Study Day 91)	Cough	Mild
23 Nov 2020 (Study Day 91)	Fatigue	Mild
23 Nov 2020 (Study Day 91)	Headache	Mild
23 Nov 2020 (Study Day 91)	New Loss of Smell	Severe
23 Nov 2020 (Study Day 91)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
11 Nov 2020 (Study Day 79)	Oxygen Saturation	90%
11 Nov 2020 - 11 Nov 2020 (Study Day 79-79)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 infection lasted for 25 days, after which it was considered to be recovered/resolved on 01 Dec 2020 (Study Day 99). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000897	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Stomatitis	Intermit tend mouth sores	1972 - Ongoing
Myopia	Bilateral nearsighted	1974 - Ongoing
Hypothyroidism	Hypothyroidism	1984 - Ongoing
Upper-airway cough syndrome	Postnasal drip	1985 - Ongoing
Menopause	Menopause	2015 - Ongoing
Seasonal allergy	Seasonal allergies	Jan 2020 - Ongoing
Tinnitus	Bilateral ringing in ears	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	1984 - Ongoing	Hypothyroidism
Botulinum toxin type a	2019 - 2020	Prevention Of Wrinkles In The Forehead And Between The Eyebrows

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	24 Sep 2020 (Study Day 31) - 25 Sep 2020 (Study Day 32)	Pain After Second Vaccination (Location And Type Of Pain Unknown)
Azithromycin	11 Nov 2020 (Study Day 79) - 11 Nov 2020 (Study Day 79)	COVID-19
Hydroxychloroquine	11 Nov 2020 (Study Day 79) - Ongoing	COVID-19
Azithromycin	12 Nov 2020 (Study Day 80) - 14 Nov 2020 (Study Day 82)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	07 Nov 2020 (Study Day 75) - 01 Dec 2020 (Study Day 99)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US314-2255 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 1/mild	Not related	13 Nov 2020 (Study Day 80) – 17 Dec 2020 (Study Day 114)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US314-2255, a 23-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 13 Nov 2020 (Study Day 80), 79 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 23 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 16 Nov 2020 (Study Day 83), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
13 Nov 2020 (Study Day 80)	Body Aches	Moderate
13 Nov 2020 (Study Day 80)	Fatigue	Mild
13 Nov 2020 (Study Day 80)	Headache	Mild
13 Nov 2020 (Study Day 80)	Muscle Aches (Myalgia)	Moderate
13 Nov 2020 (Study Day 80)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 80)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
13 Nov 2020 (Study Day 80)	New Loss of Taste	Mild
14 Nov 2020 (Study Day 81)	Body Aches	Moderate
14 Nov 2020 (Study Day 81)	Fatigue	Mild
14 Nov 2020 (Study Day 81)	Headache	Mild
14 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Moderate
14 Nov 2020 (Study Day 81)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 81)	New Loss of Smell	Mild
14 Nov 2020 (Study Day 81)	New Loss of Taste	Mild
15 Nov 2020 (Study Day 82)	Body Aches	Moderate
15 Nov 2020 (Study Day 82)	Fatigue	Mild
15 Nov 2020 (Study Day 82)	Headache	Mild
15 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
15 Nov 2020 (Study Day 82)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 82)	New Loss of Smell	Mild
15 Nov 2020 (Study Day 82)	New Loss of Taste	Mild
16 Nov 2020 (Study Day 83)	Body Aches	Mild
16 Nov 2020 (Study Day 83)	Fatigue	Mild
16 Nov 2020 (Study Day 83)	Muscle Aches (Myalgia)	Mild
16 Nov 2020 (Study Day 83)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 83)	New Loss of Smell	Moderate
16 Nov 2020 (Study Day 83)	New Loss of Taste	Moderate
17 Nov 2020 (Study Day 84)	Body Aches	Moderate
17 Nov 2020 (Study Day 84)	Fatigue	Mild
17 Nov 2020 (Study Day 84)	Muscle Aches (Myalgia)	Moderate
17 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
17 Nov 2020 (Study Day 84)	New Loss of Smell	Moderate
17 Nov 2020 (Study Day 84)	New Loss of Taste	Moderate
17 Nov 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
18 Nov 2020 (Study Day 85)	Body Aches	Moderate
18 Nov 2020 (Study Day 85)	Difficulty Breathing	Mild
18 Nov 2020 (Study Day 85)	Fatigue	Moderate
18 Nov 2020 (Study Day 85)	Muscle Aches (Myalgia)	Moderate
18 Nov 2020 (Study Day 85)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 85)	New Loss of Smell	Severe
18 Nov 2020 (Study Day 85)	New Loss of Taste	Severe
18 Nov 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Mild
18 Nov 2020 (Study Day 85)	Shortness of Breath	Mild
19 Nov 2020 (Study Day 86)	Body Aches	Moderate
19 Nov 2020 (Study Day 86)	Difficulty Breathing	Mild
19 Nov 2020 (Study Day 86)	Fatigue	Moderate
19 Nov 2020 (Study Day 86)	Muscle Aches (Myalgia)	Moderate
19 Nov 2020 (Study Day 86)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 86)	New Loss of Smell	Severe

Symptom Date	Symptom	Result
19 Nov 2020 (Study Day 86)	New Loss of Taste	Severe
19 Nov 2020 (Study Day 86)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 86)	Shortness of Breath	Mild
20 Nov 2020 (Study Day 87)	Body Aches	Mild
20 Nov 2020 (Study Day 87)	Cough	Mild
20 Nov 2020 (Study Day 87)	Difficulty Breathing	Mild
20 Nov 2020 (Study Day 87)	Fatigue	Moderate
20 Nov 2020 (Study Day 87)	Headache	Mild
20 Nov 2020 (Study Day 87)	Muscle Aches (Myalgia)	Mild
20 Nov 2020 (Study Day 87)	New Loss of Smell	Severe
20 Nov 2020 (Study Day 87)	New Loss of Taste	Severe
20 Nov 2020 (Study Day 87)	Shortness of Breath	Mild
21 Nov 2020 (Study Day 88)	Body Aches	Mild
21 Nov 2020 (Study Day 88)	Difficulty Breathing	Mild
21 Nov 2020 (Study Day 88)	Fatigue	Mild
21 Nov 2020 (Study Day 88)	Muscle Aches (Myalgia)	Mild
21 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 88)	New Loss of Smell	Severe
21 Nov 2020 (Study Day 88)	New Loss of Taste	Severe
21 Nov 2020 (Study Day 88)	Runny Nose (Rhinorrhea)	Mild
21 Nov 2020 (Study Day 88)	Shortness of Breath	Mild
22 Nov 2020 (Study Day 89)	Body Aches	Mild
22 Nov 2020 (Study Day 89)	Difficulty Breathing	Mild
22 Nov 2020 (Study Day 89)	Fatigue	Mild
22 Nov 2020 (Study Day 89)	Muscle Aches (Myalgia)	Mild
22 Nov 2020 (Study Day 89)	New Loss of Smell	Moderate
22 Nov 2020 (Study Day 89)	New Loss of Taste	Moderate
22 Nov 2020 (Study Day 89)	Shortness of Breath	Mild
23 Nov 2020 (Study Day 90)	Difficulty Breathing	Mild
23 Nov 2020 (Study Day 90)	Fatigue	Mild
23 Nov 2020 (Study Day 90)	Headache	Mild
23 Nov 2020 (Study Day 90)	New Loss of Smell	Moderate
23 Nov 2020 (Study Day 90)	New Loss of Taste	Mild
23 Nov 2020 (Study Day 90)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 91)	Body Aches	Mild
24 Nov 2020 (Study Day 91)	Difficulty Breathing	Mild
24 Nov 2020 (Study Day 91)	Fatigue	Moderate
24 Nov 2020 (Study Day 91)	Muscle Aches (Myalgia)	Mild
24 Nov 2020 (Study Day 91)	New Loss of Smell	Moderate
24 Nov 2020 (Study Day 91)	New Loss of Taste	Mild
24 Nov 2020 (Study Day 91)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 92)	Body Aches	Mild
25 Nov 2020 (Study Day 92)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
25 Nov 2020 (Study Day 92)	Fatigue	Mild
25 Nov 2020 (Study Day 92)	Muscle Aches (Myalgia)	Mild
25 Nov 2020 (Study Day 92)	New Loss of Smell	Moderate
25 Nov 2020 (Study Day 92)	New Loss of Taste	Mild
25 Nov 2020 (Study Day 92)	Shortness of Breath	Mild
28 Nov 2020 (Study Day 95)	Body Aches	Mild
28 Nov 2020 (Study Day 95)	Difficulty Breathing	Mild
28 Nov 2020 (Study Day 95)	Fatigue	Mild
28 Nov 2020 (Study Day 95)	Muscle Aches (Myalgia)	Mild
28 Nov 2020 (Study Day 95)	New Loss of Smell	Mild
28 Nov 2020 (Study Day 95)	Shortness of Breath	Mild

The participant had the following indication of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Date	Severity Indication	Result
16 Nov 2020 - 16 Nov 2020 (Study Day 83-83)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 35 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 114). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000876	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Astigmatism	Astigmatism, bilateral	2018 - Ongoing
Food allergy	Matte tea sensitivity	2018 - Ongoing
Hepatitis C	Hepatitis c	2018 - Feb 2020
Lactose intolerance	Lactose intolerant	2018 - Ongoing
Back pain	Intermittent back pain	Jun 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	23 Sep 2020 (Study Day 29) - 23 Sep 2020 (Study Day 29)	Pain After Second Vaccination (Location And Type Of Pain Unknown)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	13 Nov 2020 (Study Day 80) - 17 Dec 2020 (Study Day 114)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US315-2523 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	18 Nov 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suspected COVID-19/ COVID Like Symptoms	COVID-19	Grade 2/ moderate	Not related	27 Nov 2020 (Study Day 38) – 28 Nov 2020 (Study Day 39)	Recovered/ resolved
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 3/ severe	Not related	01 Jan 2021 (Study Day 73) – 11 Feb 2021 (Study Day 114)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US315-2523, a 71-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 27 Nov 2020 (Study Day 38), 37 days after the first dose and 9 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID like symptoms.

On 01 Jan 2021 (Study Day 73), 72 days after the first dose and 44 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 18 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 05 Jan 2021 (Study Day 77), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
28 Nov 2020 (Study Day 39)	Fatigue	Moderate
28 Nov 2020 (Study Day 39)	Runny Nose (Rhinorrhea)	Moderate
02 Dec 2020 (Study Day 43)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 44)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 44)	Runny Nose (Rhinorrhea)	Mild
04 Dec 2020 (Study Day 45)	Cough	Mild
04 Dec 2020 (Study Day 45)	Nasal Congestion	Mild
04 Dec 2020 (Study Day 45)	Runny Nose (Rhinorrhea)	Moderate
05 Dec 2020 (Study Day 46)	Cough	Mild
05 Dec 2020 (Study Day 46)	Headache	Moderate
05 Dec 2020 (Study Day 46)	Nasal Congestion	Mild
05 Dec 2020 (Study Day 46)	Runny Nose (Rhinorrhea)	Mild
07 Dec 2020 (Study Day 48)	Cough	Mild
07 Dec 2020 (Study Day 48)	Nasal Congestion	Mild
07 Dec 2020 (Study Day 48)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 49)	Nasal Congestion	Mild
08 Dec 2020 (Study Day 49)	Runny Nose (Rhinorrhea)	Mild
04 Jan 2021 (Study Day 76)	Body Aches	Mild
04 Jan 2021 (Study Day 76)	Chills	Mild
04 Jan 2021 (Study Day 76)	Cough	Mild
04 Jan 2021 (Study Day 76)	Diarrhea	Mild
04 Jan 2021 (Study Day 76)	Fatigue	Mild
04 Jan 2021 (Study Day 76)	Headache	Mild
04 Jan 2021 (Study Day 76)	Muscle Aches (Myalgia)	Mild
04 Jan 2021 (Study Day 76)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 76)	Temperature (°F)	100.4
05 Jan 2021 (Study Day 77)	Cough	Mild
05 Jan 2021 (Study Day 77)	Fatigue	Mild
05 Jan 2021 (Study Day 77)	Headache	Mild
05 Jan 2021 (Study Day 77)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 77)	Runny Nose (Rhinorrhea)	Mild
06 Jan 2021 (Study Day 78)	Cough	Mild
06 Jan 2021 (Study Day 78)	Fatigue	Mild
06 Jan 2021 (Study Day 78)	Headache	Mild
06 Jan 2021 (Study Day 78)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 78)	Runny Nose (Rhinorrhea)	Mild
07 Jan 2021 (Study Day 79)	Cough	Mild
07 Jan 2021 (Study Day 79)	Fatigue	Mild
07 Jan 2021 (Study Day 79)	Headache	Mild
07 Jan 2021 (Study Day 79)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
07 Jan 2021 (Study Day 79)	O2 Saturation (%)	93
07 Jan 2021 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild
07 Jan 2021 (Study Day 79)	Temperature (°F)	100.4
08 Jan 2021 (Study Day 80)	Cough	Mild
08 Jan 2021 (Study Day 80)	Fatigue	Moderate
08 Jan 2021 (Study Day 80)	Headache	Moderate
08 Jan 2021 (Study Day 80)	Nasal Congestion	Mild
09 Jan 2021 (Study Day 81)	Cough	Moderate
09 Jan 2021 (Study Day 81)	Fatigue	Moderate
09 Jan 2021 (Study Day 81)	Headache	Moderate
11 Jan 2021 (Study Day 83)	Cough	Mild
11 Jan 2021 (Study Day 83)	Fatigue	Moderate
11 Jan 2021 (Study Day 83)	Headache	Mild
11 Jan 2021 (Study Day 83)	Nasal Congestion	Mild
12 Jan 2021 (Study Day 84)	Cough	Mild
12 Jan 2021 (Study Day 84)	Fatigue	Moderate
12 Jan 2021 (Study Day 84)	Headache	Mild
12 Jan 2021 (Study Day 84)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 85)	Cough	Mild
13 Jan 2021 (Study Day 85)	Fatigue	Moderate
13 Jan 2021 (Study Day 85)	Headache	Mild
13 Jan 2021 (Study Day 85)	New Loss of Smell	Moderate
13 Jan 2021 (Study Day 85)	New Loss of Taste	Moderate
14 Jan 2021 (Study Day 86)	Cough	Mild
14 Jan 2021 (Study Day 86)	Fatigue	Moderate
14 Jan 2021 (Study Day 86)	Headache	Moderate
14 Jan 2021 (Study Day 86)	Nasal Congestion	Mild
14 Jan 2021 (Study Day 86)	New Loss of Smell	Mild
14 Jan 2021 (Study Day 86)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 87)	Cough	Mild
15 Jan 2021 (Study Day 87)	Fatigue	Moderate
15 Jan 2021 (Study Day 87)	Headache	Moderate
15 Jan 2021 (Study Day 87)	Nasal Congestion	Mild
15 Jan 2021 (Study Day 87)	New Loss of Smell	Mild
15 Jan 2021 (Study Day 87)	New Loss of Taste	Mild
16 Jan 2021 (Study Day 88)	Cough	Mild
16 Jan 2021 (Study Day 88)	Fatigue	Moderate
16 Jan 2021 (Study Day 88)	Headache	Mild
16 Jan 2021 (Study Day 88)	Nasal Congestion	Moderate
16 Jan 2021 (Study Day 88)	New Loss of Smell	Moderate
16 Jan 2021 (Study Day 88)	New Loss of Taste	Moderate
18 Jan 2021 (Study Day 90)	Cough	Mild
18 Jan 2021 (Study Day 90)	Fatigue	Mild

Symptom Date	Symptom	Result
18 Jan 2021 (Study Day 90)	Headache	Mild
18 Jan 2021 (Study Day 90)	Nasal Congestion	Mild
18 Jan 2021 (Study Day 90)	New Loss of Smell	Moderate
18 Jan 2021 (Study Day 90)	New Loss of Taste	Moderate
19 Jan 2021 (Study Day 91)	Cough	Mild
19 Jan 2021 (Study Day 91)	Fatigue	Mild
19 Jan 2021 (Study Day 91)	Nasal Congestion	Mild
19 Jan 2021 (Study Day 91)	New Loss of Smell	Moderate
19 Jan 2021 (Study Day 91)	New Loss of Taste	Moderate
20 Jan 2021 (Study Day 92)	Cough	Mild
20 Jan 2021 (Study Day 92)	Fatigue	Moderate
20 Jan 2021 (Study Day 92)	Headache	Mild
20 Jan 2021 (Study Day 92)	New Loss of Smell	Moderate
20 Jan 2021 (Study Day 92)	New Loss of Taste	Moderate
21 Jan 2021 (Study Day 93)	Cough	Mild
21 Jan 2021 (Study Day 93)	Fatigue	Moderate
21 Jan 2021 (Study Day 93)	Headache	Mild
21 Jan 2021 (Study Day 93)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 93)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 93)	Shortness of Breath	Mild
22 Jan 2021 (Study Day 94)	Cough	Mild
22 Jan 2021 (Study Day 94)	Fatigue	Moderate
22 Jan 2021 (Study Day 94)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 94)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 94)	Shortness of Breath	Mild
25 Jan 2021 (Study Day 97)	Cough	Mild
25 Jan 2021 (Study Day 97)	Fatigue	Moderate
25 Jan 2021 (Study Day 97)	Shortness of Breath	Mild
26 Jan 2021 (Study Day 98)	Cough	Mild
26 Jan 2021 (Study Day 98)	Fatigue	Moderate
26 Jan 2021 (Study Day 98)	Shortness of Breath	Mild
27 Jan 2021 (Study Day 99)	Cough	Mild
27 Jan 2021 (Study Day 99)	Fatigue	Moderate
27 Jan 2021 (Study Day 99)	Shortness of Breath	Mild
28 Jan 2021 (Study Day 100)	Cough	Mild
28 Jan 2021 (Study Day 100)	Fatigue	Moderate
28 Jan 2021 (Study Day 100)	Shortness of Breath	Mild
29 Jan 2021 (Study Day 101)	Cough	Mild
29 Jan 2021 (Study Day 101)	Fatigue	Moderate
29 Jan 2021 (Study Day 101)	Shortness of Breath	Mild
30 Jan 2021 (Study Day 102)	Sore Throat	Mild
01 Feb 2021 (Study Day 104)	Cough	Mild
01 Feb 2021 (Study Day 104)	Fatigue	Mild

Symptom Date	Symptom	Result
01 Feb 2021 (Study Day 104)	Runny Nose (Rhinorrhea)	Mild
01 Feb 2021 (Study Day 104)	Shortness of Breath	Mild
02 Feb 2021 (Study Day 105)	Cough	Mild
02 Feb 2021 (Study Day 105)	Fatigue	Moderate
02 Feb 2021 (Study Day 105)	Runny Nose (Rhinorrhea)	Mild
02 Feb 2021 (Study Day 105)	Shortness of Breath	Mild
03 Feb 2021 (Study Day 106)	Cough	Mild
03 Feb 2021 (Study Day 106)	Fatigue	Mild
04 Feb 2021 (Study Day 107)	Fatigue	Mild
04 Feb 2021 (Study Day 107)	Shortness of Breath	Mild
05 Feb 2021 (Study Day 108)	Fatigue	Mild
05 Feb 2021 (Study Day 108)	Shortness of Breath	Mild
08 Feb 2021 (Study Day 111)	Shortness of Breath	Mild
09 Feb 2021 (Study Day 112)	Shortness of Breath	Mild
10 Feb 2021 (Study Day 113)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
07 Jan 2021 (Study Day 79)	Oxygen Saturation	93%
04 Jan 2021 (Study Day 76)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes
07 Jan 2021 - 08 Jan 2021 (Study Day 79-80)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

The IP dose was not changed due to the covid like symptoms. The event of COVID like symptoms lasted for 2 days, after which it was considered to be recovered/resolved on 28 Nov 2020 (Study Day 39). The investigator assessed the event of suspected COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 42 days, after which it was considered to be recovered/resolved on 11 Feb 2021 (Study Day 114). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005775	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dermatitis atopic	Atopic dermatitis	1949 - Ongoing
Rhinitis allergic	Allergic rhinitis	1954 - Ongoing
Asthma	Mild asthma	1973 - Ongoing
Coronary arterial stent insertion	Cardiac stent	2005 - Ongoing
Coronary artery stenosis	Coronary artery stenosis	2005 - 2005
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Myocardial infarction	Myocardial infarction	2005 - 2005
Diverticulum	Diverticulosis	2006 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	2011 - Ongoing
Gout	Gout in right greater toe	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Triamcinolone	1960 - Ongoing	Atopic Dermatitis
Salbutamol	1980 - Ongoing	Mild Asthma
Fluticasone propionate; salmeterol xinafoate	2000 - Ongoing	Mild Asthma
Acetylsalicylic acid	2005 - Ongoing	Cardiac Prophylaxis
Atenolol	2005 - Ongoing	Cardiac Stent
Lisinopril	2005 - Ongoing	Cardiac Stent
Vitamin d nos	2005 - Ongoing	Nutritional Supplement
Tacrolimus	2012 - Ongoing	Atopic Dermatitis
Allopurinol	2014 - Ongoing	Gout
Rosuvastatin	2019 - Ongoing	Hypercholesterolemia
Influenza vaccine	29 Sep 2020 (Study Day -22) - 29 Sep 2020 (Study Day -22)	Prophylaxis For Influenza Virus
Desloratadine	27 Nov 2020 (Study Day 38) - 27 Nov 2020 (Study Day 38)	COVID Like Symptoms
Paracetamol	27 Nov 2020 (Study Day 38) - 28 Nov 2020 (Study Day 39)	COVID Like Symtpoms
Paracetamol	02 Jan 2021 (Study Day 74) - 03 Jan 2021 (Study Day 75)	Upper Respiratory Infection
Paracetamol	07 Jan 2021 (Study Day 79) - 20 Jan 2021 (Study Day 92)	Symptomatic COVID-19
Loratadine	31 Jan 2021 (Study Day 103) - 02 Feb 2021 (Study Day 105)	Symptomatic COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Routine labs*	02 Feb 2021 (Study Day 105) - 02 Feb 2021 (Study Day 105)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 2/moderate	Not related	27 Nov 2020 (Study Day 38) - 28 Nov 2020 (Study Day 39)
COVID-19	Grade 3/severe	Not related	01 Jan 2021 (Study Day 73) - 11 Feb 2021 (Study Day 114)
Liver Function Test Abnormal	Grade 2/moderate	Not related	27 Jan 2021 (Study Day 99) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US316-2006 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	24 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 2/ moderate	Not related	09 Nov 2020 (Study Day 106) – 27 Nov 2020 (Study Day 124)	Recovered/resolved
Acute Kidney Injury/Acute Renal Failure	SAE	Grade 4	Not related	11 Nov 2020 (Study Day 108) – 12 Nov 2020 (Study Day 109)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US316-2006, a 75-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 24 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Nov 2020 (Study Day 108), 107 days after the first dose and 79 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute renal failure lasted for 2 days, after which it was considered to be recovered/resolved on 12 Nov 2020 (Study Day 109). The investigator assessed the event of acute kidney injury to be not related to the IP.

Severe COVID-19 Details

On 09 Nov 2020 (Study Day 106), 105 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 24 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 10 Nov 2020 (Study Day 107), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 106)	Body Aches	Mild
09 Nov 2020 (Study Day 106)	Cough	Moderate
09 Nov 2020 (Study Day 106)	Fatigue	Severe
10 Nov 2020 (Study Day 107)	Body Aches	Mild
10 Nov 2020 (Study Day 107)	Cough	Mild
10 Nov 2020 (Study Day 107)	Fatigue	Moderate
11 Nov 2020 (Study Day 108)	Cough	Moderate
11 Nov 2020 (Study Day 108)	Fatigue	Severe
11 Nov 2020 (Study Day 108)	Shortness of Breath	Mild
12 Nov 2020 (Study Day 109)	Cough	Moderate
12 Nov 2020 (Study Day 109)	Fatigue	Mild
12 Nov 2020 (Study Day 109)	Headache	Mild
13 Nov 2020 (Study Day 110)	Cough	Moderate
13 Nov 2020 (Study Day 110)	Fatigue	Mild
13 Nov 2020 (Study Day 110)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 111)	Cough	Moderate
14 Nov 2020 (Study Day 111)	Fatigue	Mild
14 Nov 2020 (Study Day 111)	Headache	Mild
15 Nov 2020 (Study Day 112)	Cough	Mild
15 Nov 2020 (Study Day 112)	Fatigue	Mild
15 Nov 2020 (Study Day 112)	O2 Saturation (%)	93
16 Nov 2020 (Study Day 113)	Cough	Mild
16 Nov 2020 (Study Day 113)	Fatigue	Mild
16 Nov 2020 (Study Day 113)	Headache	Mild
17 Nov 2020 (Study Day 114)	Cough	Mild
17 Nov 2020 (Study Day 114)	Fatigue	Mild
17 Nov 2020 (Study Day 114)	Headache	Mild
18 Nov 2020 (Study Day 115)	Cough	Mild
18 Nov 2020 (Study Day 115)	Fatigue	Mild
19 Nov 2020 (Study Day 116)	Cough	Mild
19 Nov 2020 (Study Day 116)	Fatigue	Mild
19 Nov 2020 (Study Day 116)	Headache	Mild
20 Nov 2020 (Study Day 117)	Cough	Mild
20 Nov 2020 (Study Day 117)	Diarrhea	Mild
20 Nov 2020 (Study Day 117)	Fatigue	Mild
21 Nov 2020 (Study Day 118)	Cough	Mild
22 Nov 2020 (Study Day 119)	Cough	Mild

Symptom Date	Symptom	Result
22 Nov 2020 (Study Day 119)	Diarrhea	Mild
23 Nov 2020 (Study Day 120)	Cough	Mild
23 Nov 2020 (Study Day 120)	Diarrhea	Mild
24 Nov 2020 (Study Day 121)	Cough	Mild
24 Nov 2020 (Study Day 121)	Diarrhea	Mild
25 Nov 2020 (Study Day 122)	Diarrhea	Mild
26 Nov 2020 (Study Day 123)	Diarrhea	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
15 Nov 2020 (Study Day 112)	Oxygen Saturation	93%
10 Nov 2020 - 03 Feb 2021 (Study Day 107-192)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes
11 Nov 2020 - 11 Nov 2020 (Study Day 108-108)	Acute Renal Dysfunction	Yes
11 Nov 2020 - 11 Nov 2020 (Study Day 108-108)	Neurologic Dysfunction	Yes
15 Nov 2020 - 16 Nov 2020 (Study Day 112-113)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 19 days, after which it was considered to be recovered/resolved on 27 Nov 2020 (Study Day 124). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000748	COVID-19
MOD-2020-000748	Acute kidney injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Restless legs syndrome	Restless leg syndrome, bilateral	1990 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menopause	Natural menopasual	2004 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2014 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Osteoporosis	Osteoporosis	2014 - Ongoing
Sciatica	Sciatica (bilateral legs)	2015 - Ongoing
Gastritis	Gastritis	2019 - Ongoing
Oesophageal spasm	Intermittent esophageal spasm	Oct 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	1990 - Ongoing	Restless Leg Syndrome
Carvedilol	2014 - Ongoing	Hypertension
Ropinirole	2014 - Ongoing	Restless Leg Syndrome
Rosuvastatin	2014 - Ongoing	Hyperlipidemia
Losartan potassium	Oct 2017 - Ongoing	Hypertension
Ascorbic acid	2018 - Ongoing	Nutritional Supplement
Venlafaxine	Apr 2018 - Ongoing	Restless Leg Syndrome
Pantoprazole	2019 - 17 Nov 2020 (Study Day 114)	Gastritis
Acetylsalicylic acid	Sep 2019 - Ongoing	Cardiac Protection
Hydrochlorothiazide	Sep 2019 - 11 Nov 2020 (Study Day 108)	Hypertension
Influenza vaccine	08 Oct 2020 (Study Day 74) - 08 Oct 2020 (Study Day 74)	Influenza Prevention
Varicella zoster vaccine rge (cho)	08 Oct 2020 (Study Day 74) - 08 Oct 2020 (Study Day 74)	Shingles Prevention
Codeine phosphate; guaifenesin	10 Nov 2020 (Study Day 107) - 10 Nov 2020 (Study Day 107)	Symptomatic COVID-19
Ascorbic acid	11 Nov 2020 (Study Day 108) - 12 Nov 2020 (Study Day 109)	Symptomatic COVID-19
Azithromycin	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Symptomatic COVID-19
Ceftriaxone	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Symptomatic COVID-19
Colecalciferol	11 Nov 2020 (Study Day 108) - 12 Nov 2020 (Study Day 109)	Symptomatic COVID-19
Ct scan of head without contrast*	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Adverse Event
Dexamethasone	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Symptomatic COVID-19
Electrocardiogram*	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Heparin	11 Nov 2020 (Study Day 108) - 12 Nov 2020 (Study Day 109)	Clot Prevention
Meclozine	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Lightheadedness
Portable chest xray*	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Adverse Event
Renal ultrasound*	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Adverse Event
Sodium chloride	11 Nov 2020 (Study Day 108) - 11 Nov 2020 (Study Day 108)	Acute Renal Failure
Thiamine	11 Nov 2020 (Study Day 108) - 12 Nov 2020 (Study Day 109)	Nutritional Supplement
Zinc sulfate	11 Nov 2020 (Study Day 108) - 12 Nov 2020 (Study Day 109)	Symptomatic COVID-19
Ascorbic acid	12 Nov 2020 (Study Day 109) - 12 Nov 2020 (Study Day 109)	Symptomatic COVID-19
Paracetamol	12 Nov 2020 (Study Day 109) - 12 Nov 2020 (Study Day 109)	Symptomatic COVID-19
Paracetamol	12 Nov 2020 (Study Day 109) - 19 Nov 2020 (Study Day 116)	Symptomatic COVID-19
Single view chest xray*	12 Nov 2020 (Study Day 109) - 12 Nov 2020 (Study Day 109)	Adverse Event
Ascorbic acid; zinc	21 Nov 2020 (Study Day 118) - Ongoing	COVID Prevention
Captopril	03 Mar 2021 (Study Day 220) - 03 Mar 2021 (Study Day 220)	Worsening Of Hypertension
Clonidine	03 Mar 2021 (Study Day 220) - 03 Mar 2021 (Study Day 220)	Worsening Of Hypertension
Hydrochlorothiazide; triamterene	04 Mar 2021 (Study Day 221) - Ongoing	Worsening Of Hypertension
Pantoprazole	04 Mar 2021 (Study Day 221) - Ongoing	Gastritis
Hydrochlorothiazide; triamterene	12 Mar 2021 (Study Day 229) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	09 Nov 2020 (Study Day 106) - 27 Nov 2020 (Study Day 124)
Dizziness	Grade 3/severe	Not related	10 Nov 2020 (Study Day 107) - 11 Nov 2020 (Study Day 108)
Fall	Grade 1/mild	Not related	10 Nov 2020 (Study Day 107) - 10 Nov 2020 (Study Day 107)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyponatraemia	Grade 1/mild	Not related	11 Nov 2020 (Study Day 108) - 12 Nov 2020 (Study Day 109)
Dizziness	Grade 2/moderate	Not related	19 Nov 2020 (Study Day 116) - 19 Nov 2020 (Study Day 116)
Gastritis	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 190) - Ongoing
Hypertension	Grade 3/severe	Not related	03 Mar 2021 (Study Day 220) - Ongoing
Hypoaesthesia	Grade 1/mild	Not related	15 Mar 2021 (Study Day 232) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US316-2028 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	30 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	27 Aug 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 2/ moderate	Not related	23 Dec 2020 (Study Day 147) – 25 Jan 2021 (Study Day 180)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US316-2028, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 30 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 27 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 23 Dec 2020 (Study Day 147), 146 days after the first dose and 118 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 27 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Dec 2020 (Study Day 152), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
28 Nov 2020 (Study Day 122)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 123)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
01 Dec 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
02 Dec 2020 (Study Day 126)	Nasal Congestion	Mild
02 Dec 2020 (Study Day 126)	New Loss of Smell	Mild
02 Dec 2020 (Study Day 126)	Runny Nose (Rhinorrhea)	Moderate
03 Dec 2020 (Study Day 127)	Runny Nose (Rhinorrhea)	Moderate
23 Dec 2020 (Study Day 147)	Fatigue	Moderate
24 Dec 2020 (Study Day 148)	Body Aches	Mild
24 Dec 2020 (Study Day 148)	Chills	Mild
24 Dec 2020 (Study Day 148)	Fatigue	Mild
25 Dec 2020 (Study Day 149)	Body Aches	Mild
25 Dec 2020 (Study Day 149)	Chills	Mild
25 Dec 2020 (Study Day 149)	Cough	Mild
25 Dec 2020 (Study Day 149)	Fatigue	Mild
25 Dec 2020 (Study Day 149)	Temperature (°F)	100.5
26 Dec 2020 (Study Day 150)	Body Aches	Mild
26 Dec 2020 (Study Day 150)	Chills	Mild
26 Dec 2020 (Study Day 150)	Cough	Mild
26 Dec 2020 (Study Day 150)	Fatigue	Mild
27 Dec 2020 (Study Day 151)	Body Aches	Mild
27 Dec 2020 (Study Day 151)	Chills	Mild
27 Dec 2020 (Study Day 151)	Cough	Mild
27 Dec 2020 (Study Day 151)	Fatigue	Mild
28 Dec 2020 (Study Day 152)	Cough	Mild
28 Dec 2020 (Study Day 152)	Fatigue	Mild
29 Dec 2020 (Study Day 153)	Cough	Mild
29 Dec 2020 (Study Day 153)	Diarrhea	Mild
29 Dec 2020 (Study Day 153)	Fatigue	Mild
30 Dec 2020 (Study Day 154)	Cough	Mild
30 Dec 2020 (Study Day 154)	Fatigue	Mild
31 Dec 2020 (Study Day 155)	Cough	Mild
31 Dec 2020 (Study Day 155)	Diarrhea	Mild
31 Dec 2020 (Study Day 155)	Fatigue	Moderate
01 Jan 2021 (Study Day 156)	Cough	Mild
01 Jan 2021 (Study Day 156)	Fatigue	Moderate
01 Jan 2021 (Study Day 156)	Nausea	Mild
01 Jan 2021 (Study Day 156)	New Loss of Taste	Mild
01 Jan 2021 (Study Day 156)	O2 Saturation (%)	93
02 Jan 2021 (Study Day 157)	Cough	Mild
02 Jan 2021 (Study Day 157)	Fatigue	Mild
02 Jan 2021 (Study Day 157)	New Loss of Taste	Mild
03 Jan 2021 (Study Day 158)	Cough	Moderate
03 Jan 2021 (Study Day 158)	Fatigue	Mild
03 Jan 2021 (Study Day 158)	New Loss of Smell	Mild
03 Jan 2021 (Study Day 158)	New Loss of Taste	Mild

Symptom Date	Symptom	Result
03 Jan 2021 (Study Day 158)	O2 Saturation (%)	93
03 Jan 2021 (Study Day 158)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 159)	Cough	Moderate
04 Jan 2021 (Study Day 159)	Fatigue	Mild
04 Jan 2021 (Study Day 159)	New Loss of Smell	Mild
04 Jan 2021 (Study Day 159)	New Loss of Taste	Mild
04 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 160)	Cough	Moderate
05 Jan 2021 (Study Day 160)	Fatigue	Mild
05 Jan 2021 (Study Day 160)	New Loss of Taste	Mild
05 Jan 2021 (Study Day 160)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 161)	Cough	Mild
06 Jan 2021 (Study Day 161)	Fatigue	Severe
06 Jan 2021 (Study Day 161)	Headache	Mild
06 Jan 2021 (Study Day 161)	New Loss of Taste	Mild
06 Jan 2021 (Study Day 161)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 162)	Cough	Moderate
07 Jan 2021 (Study Day 162)	Fatigue	Moderate
07 Jan 2021 (Study Day 162)	New Loss of Taste	Mild
07 Jan 2021 (Study Day 162)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 163)	Cough	Moderate
08 Jan 2021 (Study Day 163)	Fatigue	Moderate
08 Jan 2021 (Study Day 163)	New Loss of Taste	Mild
08 Jan 2021 (Study Day 163)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 164)	Cough	Moderate
09 Jan 2021 (Study Day 164)	Fatigue	Moderate
09 Jan 2021 (Study Day 164)	New Loss of Taste	Mild
10 Jan 2021 (Study Day 165)	Cough	Mild
10 Jan 2021 (Study Day 165)	Fatigue	Moderate
10 Jan 2021 (Study Day 165)	New Loss of Taste	Mild
10 Jan 2021 (Study Day 165)	O2 Saturation (%)	93
11 Jan 2021 (Study Day 166)	Cough	Mild
11 Jan 2021 (Study Day 166)	Fatigue	Moderate
11 Jan 2021 (Study Day 166)	New Loss of Taste	Mild
11 Jan 2021 (Study Day 166)	O2 Saturation (%)	93
12 Jan 2021 (Study Day 167)	Cough	Mild
12 Jan 2021 (Study Day 167)	Fatigue	Moderate
12 Jan 2021 (Study Day 167)	New Loss of Taste	Mild
12 Jan 2021 (Study Day 167)	O2 Saturation (%)	93
13 Jan 2021 (Study Day 168)	Cough	Moderate
13 Jan 2021 (Study Day 168)	Fatigue	Moderate
13 Jan 2021 (Study Day 168)	New Loss of Taste	Mild
14 Jan 2021 (Study Day 169)	Cough	Mild

Symptom Date	Symptom	Result
14 Jan 2021 (Study Day 169)	Fatigue	Moderate
14 Jan 2021 (Study Day 169)	New Loss of Taste	Mild
14 Jan 2021 (Study Day 169)	O2 Saturation (%)	93
14 Jan 2021 (Study Day 169)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 170)	Cough	Mild
15 Jan 2021 (Study Day 170)	Fatigue	Mild
15 Jan 2021 (Study Day 170)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 170)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 171)	Cough	Mild
16 Jan 2021 (Study Day 171)	Fatigue	Mild
16 Jan 2021 (Study Day 171)	O2 Saturation (%)	93
16 Jan 2021 (Study Day 171)	Shortness of Breath	Mild
17 Jan 2021 (Study Day 172)	Cough	Mild
17 Jan 2021 (Study Day 172)	Fatigue	Moderate
17 Jan 2021 (Study Day 172)	Shortness of Breath	Mild
18 Jan 2021 (Study Day 173)	Cough	Mild
18 Jan 2021 (Study Day 173)	Fatigue	Mild
18 Jan 2021 (Study Day 173)	O2 Saturation (%)	93
18 Jan 2021 (Study Day 173)	Shortness of Breath	Mild
19 Jan 2021 (Study Day 174)	Cough	Mild
19 Jan 2021 (Study Day 174)	Fatigue	Mild
20 Jan 2021 (Study Day 175)	Cough	Mild
20 Jan 2021 (Study Day 175)	Fatigue	Mild
21 Jan 2021 (Study Day 176)	Cough	Mild
21 Jan 2021 (Study Day 176)	Fatigue	Mild
21 Jan 2021 (Study Day 176)	Shortness of Breath	Mild
22 Jan 2021 (Study Day 177)	Fatigue	Mild
22 Jan 2021 (Study Day 177)	Shortness of Breath	Mild
23 Jan 2021 (Study Day 178)	Cough	Mild
23 Jan 2021 (Study Day 178)	Fatigue	Mild
23 Jan 2021 (Study Day 178)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
01 Jan 2021 (Study Day 156)	Oxygen Saturation	93%
01 Jan 2021 - 18 Jan 2021 (Study Day 156-173)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 34 days, after which it was considered to be recovered/resolved on 25 Jan 2021 (Study Day 180). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001594	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillitis	Tonsillitis	1965 - 1966
Tonsillectomy	Tonsillectomy	1966 - 1966
Seasonal allergy	Seasonal allergies	1993 - Ongoing
Menopause	Menopause	2001 - Ongoing
Supraventricular tachycardia	Supraventricular tachycarida	2008 - Ongoing
Pain in extremity	Bilateral hand aches	2010 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Diabetic neuropathy	Diabetic sensory neuropathy bilateral feet	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2017 - Ongoing
Rhinitis perennial	Perennial rhinitis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen sodium	2010 - Ongoing	Bilateral Hand Aches
Acetylsalicylic acid	2013 - Ongoing	Cardiac Prphylaxis
Atenolol	2013 - Ongoing	Supraventricular Tachycardia
Atorvastatin	2015 - Ongoing	Hyperlipidemia
Liraglutide	2017 - Ongoing	Type 2 Diabetes
Lisinopril	2017 - Ongoing	Hypertension
Metformin	2017 - Ongoing	Type 2 Diabetes
Metoprolol tartrate	2017 - Ongoing	Supraventricular Tachycardia
Chlorphenamine maleate	2018 - Ongoing	Seasonal Allergies
Gabapentin	Jan 2019 - Ongoing	Diabetic Sensory Neuropathy Bilateral Feet

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	Jun 2019 - Ongoing	Nutritional Supplement
Calcium citrate; colecalciferol	Jun 2019 - Ongoing	Nutritional Supplement
Vitamin b12 nos	Jun 2019 - Ongoing	Nutritional Supplement
Naproxen sodium	24 Dec 2020 (Study Day 148) - 01 Jan 2021 (Study Day 156)	Symptomatic COVID-19
Ciprofloxacin	12 Jan 2021 (Study Day 167) - 17 Jan 2021 (Study Day 172)	Urinary Tract Infection
Diphenhydramine hydrochloride	17 Jan 2021 (Study Day 172) - 23 Jan 2021 (Study Day 178)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Viral Infection	Grade 1/mild	Not related	28 Nov 2020 (Study Day 122) - 08 Dec 2020 (Study Day 132)
COVID-19	Grade 2/moderate	Not related	23 Dec 2020 (Study Day 147) - 25 Jan 2021 (Study Day 180)
Urinary Tract Infection	Grade 1/mild	Not related	09 Jan 2021 (Study Day 164) - 17 Jan 2021 (Study Day 172)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US316-2078 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19, AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	14 Aug 2020 (Study Day 8) – 03 Sep 2020 (Study Day 28)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US316-2078, a 49-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 14 Aug 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 19 Aug 2020 (Study Day 13), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
19 Aug 2020 (Study Day 13)	Body Aches	Mild
19 Aug 2020 (Study Day 13)	Fatigue	Moderate
19 Aug 2020 (Study Day 13)	Muscle Aches (Myalgia)	Mild
19 Aug 2020 (Study Day 13)	Nasal Congestion	Moderate
19 Aug 2020 (Study Day 13)	New Loss of Smell	Mild
19 Aug 2020 (Study Day 13)	New Loss of Taste	Severe

Symptom Date	Symptom	Result
19 Aug 2020 (Study Day 13)	Runny Nose (Rhinorrhea)	Moderate
20 Aug 2020 (Study Day 14)	Body Aches	Mild
20 Aug 2020 (Study Day 14)	Fatigue	Moderate
20 Aug 2020 (Study Day 14)	Muscle Aches (Myalgia)	Mild
20 Aug 2020 (Study Day 14)	Nasal Congestion	Moderate
20 Aug 2020 (Study Day 14)	New Loss of Smell	Mild
20 Aug 2020 (Study Day 14)	New Loss of Taste	Severe
20 Aug 2020 (Study Day 14)	Runny Nose (Rhinorrhea)	Moderate
21 Aug 2020 (Study Day 15)	Fatigue	Moderate
21 Aug 2020 (Study Day 15)	New Loss of Smell	Moderate
21 Aug 2020 (Study Day 15)	New Loss of Taste	Severe
22 Aug 2020 (Study Day 16)	Fatigue	Moderate
22 Aug 2020 (Study Day 16)	New Loss of Smell	Moderate
22 Aug 2020 (Study Day 16)	New Loss of Taste	Severe
23 Aug 2020 (Study Day 17)	Fatigue	Moderate
23 Aug 2020 (Study Day 17)	New Loss of Smell	Moderate
23 Aug 2020 (Study Day 17)	New Loss of Taste	Severe
24 Aug 2020 (Study Day 18)	Fatigue	Moderate
24 Aug 2020 (Study Day 18)	New Loss of Smell	Moderate
24 Aug 2020 (Study Day 18)	New Loss of Taste	Severe
25 Aug 2020 (Study Day 19)	Fatigue	Moderate
25 Aug 2020 (Study Day 19)	New Loss of Smell	Moderate
25 Aug 2020 (Study Day 19)	New Loss of Taste	Severe
26 Aug 2020 (Study Day 20)	Fatigue	Moderate
26 Aug 2020 (Study Day 20)	New Loss of Smell	Moderate
26 Aug 2020 (Study Day 20)	New Loss of Taste	Severe
27 Aug 2020 (Study Day 21)	Fatigue	Moderate
27 Aug 2020 (Study Day 21)	New Loss of Smell	Moderate
27 Aug 2020 (Study Day 21)	New Loss of Taste	Severe
28 Aug 2020 (Study Day 22)	Fatigue	Mild
28 Aug 2020 (Study Day 22)	New Loss of Smell	Mild
28 Aug 2020 (Study Day 22)	New Loss of Taste	Mild
29 Aug 2020 (Study Day 23)	New Loss of Smell	Mild
29 Aug 2020 (Study Day 23)	New Loss of Taste	Mild
29 Aug 2020 (Study Day 23)	O2 Saturation (%)	93
30 Aug 2020 (Study Day 24)	Fatigue	Mild
30 Aug 2020 (Study Day 24)	Headache	Mild
30 Aug 2020 (Study Day 24)	New Loss of Smell	Moderate
30 Aug 2020 (Study Day 24)	New Loss of Taste	Moderate
31 Aug 2020 (Study Day 25)	Fatigue	Mild
31 Aug 2020 (Study Day 25)	New Loss of Smell	Moderate
31 Aug 2020 (Study Day 25)	New Loss of Taste	Moderate
01 Sep 2020 (Study Day 26)	Fatigue	Mild

Symptom Date	Symptom	Result
01 Sep 2020 (Study Day 26)	New Loss of Smell	Moderate
01 Sep 2020 (Study Day 26)	New Loss of Taste	Moderate
02 Sep 2020 (Study Day 27)	New Loss of Smell	Mild
02 Sep 2020 (Study Day 27)	New Loss of Taste	Mild

The participant had the following indication of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Date	Severity Indication	Result
18 Aug 2020 (Study Day 12)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

On 03 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved on 03 Sep 2020 (Study Day 28). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000222	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	2000 - Ongoing
Seasonal allergy	Intermittent seasonal allergies	2005 - Ongoing
Umbilical hernia	Umbilical hernia	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2000 - Ongoing	Headches
Paracetamol	2005 - Ongoing	Intermittent Seasonal Allergies
Phenylephrine	2005 - Ongoing	Intermittent Seasonal Allergies
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	14 Aug 2020 (Study Day 8) - 18 Aug 2020 (Study Day 12)	COVID-19
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	14 Aug 2020 (Study Day 8) - 18 Aug 2020 (Study Day 12)	COVID-19
Phenylephrine hydrochloride	14 Aug 2020 (Study Day 8) - 15 Aug 2020 (Study Day 9)	COVID-19
Influenza vaccine	10 Nov 2020 (Study Day 96) - 10 Nov 2020 (Study Day 96)	Influenza Prevention
Vitamin d nos	04 Dec 2020 (Study Day 120) - Ongoing	Vitamin D Deficiency

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	14 Aug 2020 (Study Day 8) - 03 Sep 2020 (Study Day 28)
Nasal Discomfort	Grade 1/mild	Not related	26 Aug 2020 (Study Day 20) - 28 Aug 2020 (Study Day 22)
Abdominal Pain Lower	Grade 1/mild	Not related	27 Aug 2020 (Study Day 21) - 28 Aug 2020 (Study Day 22)
Presbyopia	Grade 2/moderate	Not related	11 Sep 2020 (Study Day 36) - 05 Oct 2020 (Study Day 60)
Vitamin D Deficiency	Grade 1/mild	Not related	04 Dec 2020 (Study Day 120) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US316-2159 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19, AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	20 Aug 2020 (Study Day 1) – 03 Sep 2020 (Study Day 15)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US316-2159, a 60-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Severe COVID-19 Details

On 20 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was positive for SARS-CoV-2.

On 20 Aug 2020 (Study Day 1), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

On 27 Aug 2020 (Study Day 8), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
27 Aug 2020 (Study Day 8)	Cough	Mild
27 Aug 2020 (Study Day 8)	Fatigue	Moderate
27 Aug 2020 (Study Day 8)	Headache	Mild

Symptom Date	Symptom	Result
27 Aug 2020 (Study Day 8)	Nasal Congestion	Mild
27 Aug 2020 (Study Day 8)	Nausea	Moderate
27 Aug 2020 (Study Day 8)	New Loss of Smell	Moderate
27 Aug 2020 (Study Day 8)	New Loss of Taste	Moderate
27 Aug 2020 (Study Day 8)	Temperature (°F)	38.2
27 Aug 2020 (Study Day 8)	Vomiting	Moderate
28 Aug 2020 (Study Day 9)	Cough	Mild
28 Aug 2020 (Study Day 9)	Diarrhea	Mild
28 Aug 2020 (Study Day 9)	Fatigue	Mild
28 Aug 2020 (Study Day 9)	Nasal Congestion	Mild
28 Aug 2020 (Study Day 9)	New Loss of Smell	Mild
28 Aug 2020 (Study Day 9)	New Loss of Taste	Mild
29 Aug 2020 (Study Day 10)	Cough	Mild
29 Aug 2020 (Study Day 10)	Diarrhea	Mild
29 Aug 2020 (Study Day 10)	Fatigue	Mild
29 Aug 2020 (Study Day 10)	Nasal Congestion	Mild
29 Aug 2020 (Study Day 10)	New Loss of Smell	Mild
29 Aug 2020 (Study Day 10)	New Loss of Taste	Mild
29 Aug 2020 (Study Day 10)	O2 Saturation (%)	93
30 Aug 2020 (Study Day 11)	Fatigue	Mild
30 Aug 2020 (Study Day 11)	Nasal Congestion	Mild
30 Aug 2020 (Study Day 11)	New Loss of Smell	Mild
30 Aug 2020 (Study Day 11)	New Loss of Taste	Mild
31 Aug 2020 (Study Day 12)	Cough	Mild
31 Aug 2020 (Study Day 12)	Diarrhea	Mild
31 Aug 2020 (Study Day 12)	Nasal Congestion	Mild
31 Aug 2020 (Study Day 12)	New Loss of Smell	Mild
31 Aug 2020 (Study Day 12)	New Loss of Taste	Mild
01 Sep 2020 (Study Day 13)	Cough	Mild
01 Sep 2020 (Study Day 13)	Nasal Congestion	Mild
01 Sep 2020 (Study Day 13)	New Loss of Smell	Mild
01 Sep 2020 (Study Day 13)	New Loss of Taste	Mild
01 Sep 2020 (Study Day 13)	O2 Saturation (%)	93
02 Sep 2020 (Study Day 14)	Cough	Mild
02 Sep 2020 (Study Day 14)	New Loss of Smell	Mild
02 Sep 2020 (Study Day 14)	New Loss of Taste	Mild
04 Sep 2020 (Study Day 16)	O2 Saturation (%)	93
05 Sep 2020 (Study Day 17)	O2 Saturation (%)	93
07 Sep 2020 (Study Day 19)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
29 Aug 2020 (Study Day 10)	Oxygen Saturation	93%
29 Aug 2020 - 08 Sep 2020 (Study Day 10-20)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 03 Sep 2020 (Study Day 15). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000233	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tachycardia	Intermittent tachycardia	2000 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	20 Aug 2020 (Study Day 1) - 03 Sep 2020 (Study Day 15)
Fatigue	Grade 1/mild	Related	21 Aug 2020 (Study Day 2) - 28 Aug 2020 (Study Day 9)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2265 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urticaria/Skin Rash (Consistent With Hives) (Arms, Legs, Chest, And Back)	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	22 Aug 2020 (Study Day 2) – 25 Aug 2020 (Study Day 5)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2265, a 34-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Aug 2020 (Study Day 2), 1 day after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of urticaria. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of skin rash (consistent with hives) (arms, legs, chest, and back) lasted for 4 days, after which it was considered to be recovered/resolved on 25 Aug 2020 (Study Day 5). The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	24 Aug 2020 (Study Day 4) - 24 Aug 2020 (Study Day 4)	Skin Rash (Hives)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urticaria	Grade 1/mild	Related	22 Aug 2020 (Study Day 2) - 25 Aug 2020 (Study Day 5)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2360 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Psoriasis/Psoriasis Flare	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	20 Sep 2020 (Study Day 25) – 17 Nov 2020 (Study Day 83)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2360, a 54-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 27 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Sep 2020 (Study Day 25), 24 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of psoriasis. On 23 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of psoriasis flare lasted for 59 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 83). The investigator assessed the event of psoriasis to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Moderate asthma	1966 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Bilateral myopia / stigmatism	1975 - Ongoing
Alcohol use	Alcohol consumption	1982 - Ongoing
Caffeine consumption	Caffeine consumption	1982 - Ongoing
Tobacco user	Current tobacco user	1982 - Ongoing
Ovarian cyst	Ovarian cysts	1995 - 1995
Anxiety	Anxiety	2007 - Ongoing
Bipolar disorder	Bipolar disorder	2007 - Ongoing
Depression	Depression	2007 - Ongoing
Insomnia	Insomnia	2007 - Ongoing
Pericardial fibrosis	Pericardial sac fibrosis	2011 - 2011
Migraine	Migraine	2014 - Ongoing
Postmenopause	Post-menopausal	2016 - Ongoing
Eczema	Eczema torso upper and lower extremity	2018 - Ongoing
Psoriasis	Upper extremities psoriasis	2018 - Ongoing
Glucose tolerance impaired	Prediabetes	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2000 - Ongoing	Asthma
Alprazolam	2018 - Ongoing	Insomnia
Olanzapine	2018 - Ongoing	Insomnia
Valproate semisodium	2018 - Ongoing	Bipolar
Acetylsalicylic acid	2020 - Ongoing	Migraine
Acetylsalicylic acid; caffeine; paracetamol	2020 - Ongoing	Migraine
Caffeine	2020 - Ongoing	Migraine
Paracetamol	2020 - Ongoing	Migraine
Clobetasol propionate	25 Oct 2020 (Study Day 60) - Ongoing	Psoriasis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Psoriasis	Grade 2/moderate	Related	20 Sep 2020 (Study Day 25) - 17 Nov 2020 (Study Day 83)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2006 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	24 Aug 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	25 Dec 2020 (Study Day 152) – 12 Jan 2021 (Study Day 170)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US318-2006, a 29-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 24 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 25 Dec 2020 (Study Day 152), 151 days after the first dose and 123 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 24 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 30 Dec 2020 (Study Day 157), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
14 Aug 2020 (Study Day 19)	Fatigue	Moderate
15 Aug 2020 (Study Day 20)	Fatigue	Moderate
15 Aug 2020 (Study Day 20)	Muscle Aches (Myalgia)	Moderate
16 Aug 2020 (Study Day 21)	Fatigue	Moderate
16 Aug 2020 (Study Day 21)	Muscle Aches (Myalgia)	Moderate
17 Aug 2020 (Study Day 22)	Fatigue	Moderate
17 Aug 2020 (Study Day 22)	Muscle Aches (Myalgia)	Moderate

Symptom Date	Symptom	Result
18 Aug 2020 (Study Day 23)	Fatigue	Moderate
18 Aug 2020 (Study Day 23)	Muscle Aches (Myalgia)	Moderate
18 Aug 2020 (Study Day 23)	Sore Throat	Mild
19 Aug 2020 (Study Day 24)	Fatigue	Mild
19 Aug 2020 (Study Day 24)	Headache	Mild
19 Aug 2020 (Study Day 24)	O2 Saturation (%)	93
19 Aug 2020 (Study Day 24)	Runny Nose (Rhinorrhea)	Mild
20 Aug 2020 (Study Day 25)	Fatigue	Mild
20 Aug 2020 (Study Day 25)	Headache	Moderate
25 Dec 2020 (Study Day 152)	Body Aches	Mild
25 Dec 2020 (Study Day 152)	Chills	Mild
25 Dec 2020 (Study Day 152)	Fatigue	Moderate
25 Dec 2020 (Study Day 152)	Headache	Mild
25 Dec 2020 (Study Day 152)	Muscle Aches (Myalgia)	Mild
25 Dec 2020 (Study Day 152)	Nasal Congestion	Severe
26 Dec 2020 (Study Day 153)	Body Aches	Mild
26 Dec 2020 (Study Day 153)	Chills	Mild
26 Dec 2020 (Study Day 153)	Fatigue	Moderate
26 Dec 2020 (Study Day 153)	Headache	Mild
26 Dec 2020 (Study Day 153)	Muscle Aches (Myalgia)	Mild
26 Dec 2020 (Study Day 153)	Nasal Congestion	Severe
27 Dec 2020 (Study Day 154)	Fatigue	Moderate
27 Dec 2020 (Study Day 154)	Headache	Mild
27 Dec 2020 (Study Day 154)	Nasal Congestion	Severe
28 Dec 2020 (Study Day 155)	Fatigue	Moderate
28 Dec 2020 (Study Day 155)	Headache	Mild
28 Dec 2020 (Study Day 155)	Nasal Congestion	Severe
29 Dec 2020 (Study Day 156)	Diarrhea	Moderate
29 Dec 2020 (Study Day 156)	Fatigue	Moderate
29 Dec 2020 (Study Day 156)	Headache	Mild
29 Dec 2020 (Study Day 156)	Nasal Congestion	Severe
29 Dec 2020 (Study Day 156)	New Loss of Smell	Mild
29 Dec 2020 (Study Day 156)	New Loss of Taste	Mild
30 Dec 2020 (Study Day 157)	Difficulty Breathing	Mild
30 Dec 2020 (Study Day 157)	Fatigue	Moderate
30 Dec 2020 (Study Day 157)	Headache	Mild
30 Dec 2020 (Study Day 157)	Nasal Congestion	Severe
30 Dec 2020 (Study Day 157)	New Loss of Smell	Mild
30 Dec 2020 (Study Day 157)	New Loss of Taste	Mild
31 Dec 2020 (Study Day 158)	Body Aches	Mild
31 Dec 2020 (Study Day 158)	Diarrhea	Mild
31 Dec 2020 (Study Day 158)	Fatigue	Severe
31 Dec 2020 (Study Day 158)	Headache	Moderate

Symptom Date	Symptom	Result
31 Dec 2020 (Study Day 158)	Muscle Aches (Myalgia)	Mild
31 Dec 2020 (Study Day 158)	Nasal Congestion	Moderate
31 Dec 2020 (Study Day 158)	New Loss of Smell	Severe
31 Dec 2020 (Study Day 158)	New Loss of Taste	Severe
31 Dec 2020 (Study Day 158)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 159)	Diarrhea	Moderate
01 Jan 2021 (Study Day 159)	Difficulty Breathing	Mild
01 Jan 2021 (Study Day 159)	Fatigue	Severe
01 Jan 2021 (Study Day 159)	Headache	Severe
01 Jan 2021 (Study Day 159)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 159)	New Loss of Smell	Severe
01 Jan 2021 (Study Day 159)	New Loss of Taste	Severe
01 Jan 2021 (Study Day 159)	O2 Saturation (%)	93
01 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
02 Jan 2021 (Study Day 160)	Fatigue	Mild
02 Jan 2021 (Study Day 160)	New Loss of Smell	Severe
02 Jan 2021 (Study Day 160)	New Loss of Taste	Severe
03 Jan 2021 (Study Day 161)	Fatigue	Mild
03 Jan 2021 (Study Day 161)	New Loss of Smell	Severe
03 Jan 2021 (Study Day 161)	New Loss of Taste	Severe
04 Jan 2021 (Study Day 162)	Diarrhea	Moderate
04 Jan 2021 (Study Day 162)	Fatigue	Mild
04 Jan 2021 (Study Day 162)	New Loss of Smell	Severe
04 Jan 2021 (Study Day 162)	New Loss of Taste	Severe
05 Jan 2021 (Study Day 163)	Diarrhea	Moderate
05 Jan 2021 (Study Day 163)	Fatigue	Mild
05 Jan 2021 (Study Day 163)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 163)	New Loss of Smell	Severe
05 Jan 2021 (Study Day 163)	New Loss of Taste	Severe
06 Jan 2021 (Study Day 164)	Fatigue	Moderate
06 Jan 2021 (Study Day 164)	Headache	Mild
06 Jan 2021 (Study Day 164)	New Loss of Smell	Severe
06 Jan 2021 (Study Day 164)	New Loss of Taste	Severe
07 Jan 2021 (Study Day 165)	Difficulty Breathing	Mild
07 Jan 2021 (Study Day 165)	Fatigue	Moderate
08 Jan 2021 (Study Day 166)	Fatigue	Mild
08 Jan 2021 (Study Day 166)	New Loss of Smell	Moderate
08 Jan 2021 (Study Day 166)	New Loss of Taste	Severe
09 Jan 2021 (Study Day 167)	New Loss of Smell	Moderate
09 Jan 2021 (Study Day 167)	New Loss of Taste	Moderate
10 Jan 2021 (Study Day 168)	New Loss of Smell	Moderate
10 Jan 2021 (Study Day 168)	New Loss of Taste	Moderate
11 Jan 2021 (Study Day 169)	Fatigue	Mild

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 169)	New Loss of Smell	Moderate
11 Jan 2021 (Study Day 169)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
01 Jan 2021 (Study Day 159)	Oxygen Saturation	93%
01 Jan 2021 - 01 Jan 2021 (Study Day 159-159)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 19 days, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 170). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004664	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septum deviation	Deviated septum	2016 - 11 Mar 2021 (Study Day 228)
Diarrhoea	Intermittent diarrhea	Jan 2020 - Ongoing
Seasonal allergy	Seasonal allergies	Mar 2020 - Ongoing
Abdominal distension	Left upper quadrant fullness/asymmetry	27 Jul 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	Mar 2020 - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ciprofloxacin	30 Jul 2020 (Study Day 4) - 05 Aug 2020 (Study Day 10)	Bladder Infection
Ibuprofen	17 Aug 2020 (Study Day 22) - 19 Aug 2020 (Study Day 24)	Joint Aches
Paracetamol; phenylephrine hydrochloride	25 Dec 2020 (Study Day 152) - 04 Jan 2021 (Study Day 162)	COVID 19
Septoplasty*	11 Mar 2021 (Study Day 228) - 11 Mar 2021 (Study Day 228)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cystitis	Grade 2/moderate	Not related	29 Jul 2020 (Study Day 3) - 05 Aug 2020 (Study Day 10)
COVID-19	Grade 3/severe	Not related	25 Dec 2020 (Study Day 152) - 12 Jan 2021 (Study Day 170)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2012 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	21 Aug 2020 (Study Day 26)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	16 Nov 2020 (Study Day 113) – 20 Feb 2021 (Study Day 209)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US318-2012, a 32-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 21 Aug 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 16 Nov 2020 (Study Day 113), 112 days after the first dose and 87 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 26, 21 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 22 Nov 2020 (Study Day 119), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
05 Jan 2020 (Study Day -204)	Body Aches	Mild
05 Jan 2020 (Study Day -204)	Cough	Mild
05 Jan 2020 (Study Day -204)	Difficulty Breathing	Mild
05 Jan 2020 (Study Day -204)	Fatigue	Moderate
05 Jan 2020 (Study Day -204)	Headache	Mild
05 Jan 2020 (Study Day -204)	Muscle Aches (Myalgia)	Mild
05 Jan 2020 (Study Day -204)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
05 Jan 2020 (Study Day -204)	O2 Saturation (%)	93
05 Jan 2020 (Study Day -204)	Runny Nose (Rhinorrhea)	Mild
05 Jan 2020 (Study Day -204)	Shortness of Breath	Mild
16 Nov 2020 (Study Day 113)	Fatigue	Moderate
16 Nov 2020 (Study Day 113)	Nasal Congestion	Moderate
16 Nov 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Moderate
17 Nov 2020 (Study Day 114)	Fatigue	Moderate
17 Nov 2020 (Study Day 114)	Nasal Congestion	Moderate
17 Nov 2020 (Study Day 114)	Runny Nose (Rhinorrhea)	Moderate
18 Nov 2020 (Study Day 115)	Cough	Mild
18 Nov 2020 (Study Day 115)	Difficulty Breathing	Mild
18 Nov 2020 (Study Day 115)	Fatigue	Moderate
18 Nov 2020 (Study Day 115)	Nasal Congestion	Moderate
18 Nov 2020 (Study Day 115)	Runny Nose (Rhinorrhea)	Moderate
18 Nov 2020 (Study Day 115)	Shortness of Breath	Mild
19 Nov 2020 (Study Day 116)	Body Aches	Moderate
19 Nov 2020 (Study Day 116)	Chills	Moderate
19 Nov 2020 (Study Day 116)	Cough	Mild
19 Nov 2020 (Study Day 116)	Difficulty Breathing	Mild
19 Nov 2020 (Study Day 116)	Fatigue	Moderate
19 Nov 2020 (Study Day 116)	Headache	Mild
19 Nov 2020 (Study Day 116)	Muscle Aches (Myalgia)	Moderate
19 Nov 2020 (Study Day 116)	Nasal Congestion	Moderate
19 Nov 2020 (Study Day 116)	Runny Nose (Rhinorrhea)	Moderate
19 Nov 2020 (Study Day 116)	Shortness of Breath	Mild
19 Nov 2020 (Study Day 116)	Sore Throat	Mild
20 Nov 2020 (Study Day 117)	Body Aches	Moderate
20 Nov 2020 (Study Day 117)	Chills	Moderate
20 Nov 2020 (Study Day 117)	Cough	Mild
20 Nov 2020 (Study Day 117)	Difficulty Breathing	Mild
20 Nov 2020 (Study Day 117)	Fatigue	Moderate
20 Nov 2020 (Study Day 117)	Headache	Mild
20 Nov 2020 (Study Day 117)	Muscle Aches (Myalgia)	Moderate
20 Nov 2020 (Study Day 117)	Nasal Congestion	Moderate
20 Nov 2020 (Study Day 117)	Runny Nose (Rhinorrhea)	Moderate
20 Nov 2020 (Study Day 117)	Shortness of Breath	Mild
20 Nov 2020 (Study Day 117)	Sore Throat	Mild
21 Nov 2020 (Study Day 118)	Body Aches	Moderate
21 Nov 2020 (Study Day 118)	Chills	Mild
21 Nov 2020 (Study Day 118)	Cough	Mild
21 Nov 2020 (Study Day 118)	Difficulty Breathing	Mild
21 Nov 2020 (Study Day 118)	Fatigue	Moderate
21 Nov 2020 (Study Day 118)	Headache	Moderate

Symptom Date	Symptom	Result
21 Nov 2020 (Study Day 118)	Muscle Aches (Myalgia)	Moderate
21 Nov 2020 (Study Day 118)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 118)	Runny Nose (Rhinorrhea)	Mild
21 Nov 2020 (Study Day 118)	Shortness of Breath	Mild
21 Nov 2020 (Study Day 118)	Sore Throat	Mild
22 Nov 2020 (Study Day 119)	Body Aches	Mild
22 Nov 2020 (Study Day 119)	Chills	Moderate
22 Nov 2020 (Study Day 119)	Cough	Mild
22 Nov 2020 (Study Day 119)	Diarrhea	Moderate
22 Nov 2020 (Study Day 119)	Difficulty Breathing	Mild
22 Nov 2020 (Study Day 119)	Fatigue	Moderate
22 Nov 2020 (Study Day 119)	Headache	Moderate
22 Nov 2020 (Study Day 119)	Muscle Aches (Myalgia)	Mild
22 Nov 2020 (Study Day 119)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 119)	O2 Saturation (%)	93
22 Nov 2020 (Study Day 119)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 119)	Shortness of Breath	Mild
22 Nov 2020 (Study Day 119)	Sore Throat	Mild
23 Nov 2020 (Study Day 120)	Body Aches	Moderate
23 Nov 2020 (Study Day 120)	Cough	Moderate
23 Nov 2020 (Study Day 120)	Diarrhea	Moderate
23 Nov 2020 (Study Day 120)	Difficulty Breathing	Moderate
23 Nov 2020 (Study Day 120)	Fatigue	Moderate
23 Nov 2020 (Study Day 120)	Headache	Moderate
23 Nov 2020 (Study Day 120)	Muscle Aches (Myalgia)	Moderate
23 Nov 2020 (Study Day 120)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 120)	O2 Saturation (%)	87
23 Nov 2020 (Study Day 120)	Runny Nose (Rhinorrhea)	Mild
23 Nov 2020 (Study Day 120)	Shortness of Breath	Moderate
23 Nov 2020 (Study Day 120)	Sore Throat	Mild
23 Nov 2020 (Study Day 120)	Temperature (°F)	102.0
24 Nov 2020 (Study Day 121)	Body Aches	Moderate
24 Nov 2020 (Study Day 121)	Chills	Moderate
24 Nov 2020 (Study Day 121)	Cough	Moderate
24 Nov 2020 (Study Day 121)	Diarrhea	Moderate
24 Nov 2020 (Study Day 121)	Difficulty Breathing	Moderate
24 Nov 2020 (Study Day 121)	Fatigue	Moderate
24 Nov 2020 (Study Day 121)	Headache	Moderate
24 Nov 2020 (Study Day 121)	Muscle Aches (Myalgia)	Moderate
24 Nov 2020 (Study Day 121)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 121)	Nausea	Mild
24 Nov 2020 (Study Day 121)	O2 Saturation (%)	88
24 Nov 2020 (Study Day 121)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
24 Nov 2020 (Study Day 121)	Shortness of Breath	Moderate
24 Nov 2020 (Study Day 121)	Sore Throat	Moderate
24 Nov 2020 (Study Day 121)	Temperature (°F)	101.0
24 Nov 2020 (Study Day 121)	Vomiting	Mild
25 Nov 2020 (Study Day 122)	Body Aches	Moderate
25 Nov 2020 (Study Day 122)	Chills	Moderate
25 Nov 2020 (Study Day 122)	Cough	Mild
25 Nov 2020 (Study Day 122)	Diarrhea	Moderate
25 Nov 2020 (Study Day 122)	Difficulty Breathing	Moderate
25 Nov 2020 (Study Day 122)	Fatigue	Moderate
25 Nov 2020 (Study Day 122)	Headache	Moderate
25 Nov 2020 (Study Day 122)	Muscle Aches (Myalgia)	Moderate
25 Nov 2020 (Study Day 122)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 122)	Nausea	Mild
25 Nov 2020 (Study Day 122)	O2 Saturation (%)	85
25 Nov 2020 (Study Day 122)	Runny Nose (Rhinorrhea)	Mild
25 Nov 2020 (Study Day 122)	Shortness of Breath	Moderate
25 Nov 2020 (Study Day 122)	Sore Throat	Moderate
25 Nov 2020 (Study Day 122)	Vomiting	Mild
26 Nov 2020 (Study Day 123)	Body Aches	Moderate
26 Nov 2020 (Study Day 123)	Chills	Moderate
26 Nov 2020 (Study Day 123)	Cough	Mild
26 Nov 2020 (Study Day 123)	Diarrhea	Moderate
26 Nov 2020 (Study Day 123)	Difficulty Breathing	Mild
26 Nov 2020 (Study Day 123)	Fatigue	Moderate
26 Nov 2020 (Study Day 123)	Headache	Mild
26 Nov 2020 (Study Day 123)	Muscle Aches (Myalgia)	Moderate
26 Nov 2020 (Study Day 123)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 123)	Nausea	Mild
26 Nov 2020 (Study Day 123)	O2 Saturation (%)	87
26 Nov 2020 (Study Day 123)	Runny Nose (Rhinorrhea)	Mild
26 Nov 2020 (Study Day 123)	Shortness of Breath	Mild
26 Nov 2020 (Study Day 123)	Sore Throat	Mild
26 Nov 2020 (Study Day 123)	Temperature (°F)	100.8
27 Nov 2020 (Study Day 124)	Body Aches	Moderate
27 Nov 2020 (Study Day 124)	Chills	Mild
27 Nov 2020 (Study Day 124)	Cough	Mild
27 Nov 2020 (Study Day 124)	Diarrhea	Mild
27 Nov 2020 (Study Day 124)	Difficulty Breathing	Mild
27 Nov 2020 (Study Day 124)	Fatigue	Moderate
27 Nov 2020 (Study Day 124)	Headache	Mild
27 Nov 2020 (Study Day 124)	Muscle Aches (Myalgia)	Moderate
27 Nov 2020 (Study Day 124)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
27 Nov 2020 (Study Day 124)	Nausea	Mild
27 Nov 2020 (Study Day 124)	O2 Saturation (%)	89
27 Nov 2020 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
27 Nov 2020 (Study Day 124)	Shortness of Breath	Mild
27 Nov 2020 (Study Day 124)	Sore Throat	Mild
28 Nov 2020 (Study Day 125)	Body Aches	Moderate
28 Nov 2020 (Study Day 125)	Chills	Mild
28 Nov 2020 (Study Day 125)	Cough	Mild
28 Nov 2020 (Study Day 125)	Diarrhea	Mild
28 Nov 2020 (Study Day 125)	Difficulty Breathing	Mild
28 Nov 2020 (Study Day 125)	Fatigue	Moderate
28 Nov 2020 (Study Day 125)	Headache	Moderate
28 Nov 2020 (Study Day 125)	Muscle Aches (Myalgia)	Moderate
28 Nov 2020 (Study Day 125)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 125)	O2 Saturation (%)	91
28 Nov 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
28 Nov 2020 (Study Day 125)	Shortness of Breath	Mild
28 Nov 2020 (Study Day 125)	Sore Throat	Mild
29 Nov 2020 (Study Day 126)	Body Aches	Mild
29 Nov 2020 (Study Day 126)	Chills	Mild
29 Nov 2020 (Study Day 126)	Cough	Mild
29 Nov 2020 (Study Day 126)	Diarrhea	Mild
29 Nov 2020 (Study Day 126)	Difficulty Breathing	Mild
29 Nov 2020 (Study Day 126)	Fatigue	Mild
29 Nov 2020 (Study Day 126)	Headache	Mild
29 Nov 2020 (Study Day 126)	Muscle Aches (Myalgia)	Mild
29 Nov 2020 (Study Day 126)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 126)	New Loss of Smell	Mild
29 Nov 2020 (Study Day 126)	New Loss of Taste	Mild
29 Nov 2020 (Study Day 126)	O2 Saturation (%)	90
29 Nov 2020 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
29 Nov 2020 (Study Day 126)	Shortness of Breath	Mild
29 Nov 2020 (Study Day 126)	Sore Throat	Mild
03 Dec 2020 (Study Day 130)	Body Aches	Moderate
03 Dec 2020 (Study Day 130)	Chills	Moderate
03 Dec 2020 (Study Day 130)	Cough	Moderate
03 Dec 2020 (Study Day 130)	Diarrhea	Mild
03 Dec 2020 (Study Day 130)	Difficulty Breathing	Mild
03 Dec 2020 (Study Day 130)	Fatigue	Moderate
03 Dec 2020 (Study Day 130)	Headache	Mild
03 Dec 2020 (Study Day 130)	Muscle Aches (Myalgia)	Moderate
03 Dec 2020 (Study Day 130)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 130)	Nausea	Mild

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 130)	New Loss of Smell	Mild
03 Dec 2020 (Study Day 130)	New Loss of Taste	Mild
03 Dec 2020 (Study Day 130)	O2 Saturation (%)	90
03 Dec 2020 (Study Day 130)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 130)	Shortness of Breath	Mild
03 Dec 2020 (Study Day 130)	Sore Throat	Mild
04 Dec 2020 (Study Day 131)	Body Aches	Severe
04 Dec 2020 (Study Day 131)	Chills	Moderate
04 Dec 2020 (Study Day 131)	Cough	Moderate
04 Dec 2020 (Study Day 131)	Diarrhea	Severe
04 Dec 2020 (Study Day 131)	Difficulty Breathing	Mild
04 Dec 2020 (Study Day 131)	Fatigue	Severe
04 Dec 2020 (Study Day 131)	Headache	Severe
04 Dec 2020 (Study Day 131)	Muscle Aches (Myalgia)	Severe
04 Dec 2020 (Study Day 131)	Nasal Congestion	Mild
04 Dec 2020 (Study Day 131)	Nausea	Mild
04 Dec 2020 (Study Day 131)	New Loss of Smell	Mild
04 Dec 2020 (Study Day 131)	New Loss of Taste	Mild
04 Dec 2020 (Study Day 131)	Runny Nose (Rhinorrhea)	Mild
04 Dec 2020 (Study Day 131)	Shortness of Breath	Mild
04 Dec 2020 (Study Day 131)	Sore Throat	Mild
04 Dec 2020 (Study Day 131)	Temperature (°F)	102.9
05 Dec 2020 (Study Day 132)	Body Aches	Severe
05 Dec 2020 (Study Day 132)	Chills	Moderate
05 Dec 2020 (Study Day 132)	Cough	Moderate
05 Dec 2020 (Study Day 132)	Diarrhea	Severe
05 Dec 2020 (Study Day 132)	Difficulty Breathing	Moderate
05 Dec 2020 (Study Day 132)	Fatigue	Severe
05 Dec 2020 (Study Day 132)	Headache	Moderate
05 Dec 2020 (Study Day 132)	Muscle Aches (Myalgia)	Severe
05 Dec 2020 (Study Day 132)	Nasal Congestion	Mild
05 Dec 2020 (Study Day 132)	Nausea	Severe
05 Dec 2020 (Study Day 132)	New Loss of Smell	Mild
05 Dec 2020 (Study Day 132)	New Loss of Taste	Mild
05 Dec 2020 (Study Day 132)	O2 Saturation (%)	90
05 Dec 2020 (Study Day 132)	Runny Nose (Rhinorrhea)	Mild
05 Dec 2020 (Study Day 132)	Shortness of Breath	Moderate
05 Dec 2020 (Study Day 132)	Sore Throat	Mild
05 Dec 2020 (Study Day 132)	Temperature (°F)	103.4
05 Dec 2020 (Study Day 132)	Vomiting	Severe
06 Dec 2020 (Study Day 133)	Body Aches	Moderate
06 Dec 2020 (Study Day 133)	Chills	Moderate
06 Dec 2020 (Study Day 133)	Cough	Moderate

Symptom Date	Symptom	Result
06 Dec 2020 (Study Day 133)	Diarrhea	Mild
06 Dec 2020 (Study Day 133)	Difficulty Breathing	Moderate
06 Dec 2020 (Study Day 133)	Fatigue	Moderate
06 Dec 2020 (Study Day 133)	Headache	Moderate
06 Dec 2020 (Study Day 133)	Muscle Aches (Myalgia)	Moderate
06 Dec 2020 (Study Day 133)	Nasal Congestion	Mild
06 Dec 2020 (Study Day 133)	Nausea	Moderate
06 Dec 2020 (Study Day 133)	New Loss of Smell	Mild
06 Dec 2020 (Study Day 133)	New Loss of Taste	Mild
06 Dec 2020 (Study Day 133)	O2 Saturation (%)	89
06 Dec 2020 (Study Day 133)	Runny Nose (Rhinorrhea)	Mild
06 Dec 2020 (Study Day 133)	Shortness of Breath	Moderate
06 Dec 2020 (Study Day 133)	Sore Throat	Mild
06 Dec 2020 (Study Day 133)	Temperature (°F)	102.0
06 Dec 2020 (Study Day 133)	Vomiting	Mild
07 Dec 2020 (Study Day 134)	Body Aches	Moderate
07 Dec 2020 (Study Day 134)	Chills	Moderate
07 Dec 2020 (Study Day 134)	Cough	Moderate
07 Dec 2020 (Study Day 134)	Diarrhea	Mild
07 Dec 2020 (Study Day 134)	Difficulty Breathing	Moderate
07 Dec 2020 (Study Day 134)	Fatigue	Moderate
07 Dec 2020 (Study Day 134)	Headache	Moderate
07 Dec 2020 (Study Day 134)	Muscle Aches (Myalgia)	Moderate
07 Dec 2020 (Study Day 134)	Nasal Congestion	Mild
07 Dec 2020 (Study Day 134)	Nausea	Mild
07 Dec 2020 (Study Day 134)	New Loss of Smell	Mild
07 Dec 2020 (Study Day 134)	New Loss of Taste	Mild
07 Dec 2020 (Study Day 134)	O2 Saturation (%)	93
07 Dec 2020 (Study Day 134)	Runny Nose (Rhinorrhea)	Mild
07 Dec 2020 (Study Day 134)	Shortness of Breath	Moderate
07 Dec 2020 (Study Day 134)	Sore Throat	Mild
07 Dec 2020 (Study Day 134)	Temperature (°F)	101.0
08 Dec 2020 (Study Day 135)	Body Aches	Moderate
08 Dec 2020 (Study Day 135)	Chills	Moderate
08 Dec 2020 (Study Day 135)	Cough	Moderate
08 Dec 2020 (Study Day 135)	Diarrhea	Moderate
08 Dec 2020 (Study Day 135)	Difficulty Breathing	Mild
08 Dec 2020 (Study Day 135)	Fatigue	Severe
08 Dec 2020 (Study Day 135)	Headache	Moderate
08 Dec 2020 (Study Day 135)	Muscle Aches (Myalgia)	Moderate
08 Dec 2020 (Study Day 135)	Nasal Congestion	Mild
08 Dec 2020 (Study Day 135)	Nausea	Moderate
08 Dec 2020 (Study Day 135)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
08 Dec 2020 (Study Day 135)	New Loss of Taste	Mild
08 Dec 2020 (Study Day 135)	O2 Saturation (%)	91
08 Dec 2020 (Study Day 135)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 135)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 135)	Sore Throat	Mild
08 Dec 2020 (Study Day 135)	Temperature (°F)	102.0
09 Dec 2020 (Study Day 136)	Body Aches	Moderate
09 Dec 2020 (Study Day 136)	Chills	Mild
09 Dec 2020 (Study Day 136)	Cough	Moderate
09 Dec 2020 (Study Day 136)	Diarrhea	Mild
09 Dec 2020 (Study Day 136)	Difficulty Breathing	Mild
09 Dec 2020 (Study Day 136)	Fatigue	Severe
09 Dec 2020 (Study Day 136)	Headache	Mild
09 Dec 2020 (Study Day 136)	Muscle Aches (Myalgia)	Moderate
09 Dec 2020 (Study Day 136)	Nasal Congestion	Mild
09 Dec 2020 (Study Day 136)	Nausea	Mild
09 Dec 2020 (Study Day 136)	New Loss of Smell	Mild
09 Dec 2020 (Study Day 136)	New Loss of Taste	Mild
09 Dec 2020 (Study Day 136)	O2 Saturation (%)	91
09 Dec 2020 (Study Day 136)	Runny Nose (Rhinorrhea)	Mild
09 Dec 2020 (Study Day 136)	Shortness of Breath	Mild
09 Dec 2020 (Study Day 136)	Sore Throat	Mild
09 Dec 2020 (Study Day 136)	Temperature (°F)	101.0
10 Dec 2020 (Study Day 137)	Body Aches	Moderate
10 Dec 2020 (Study Day 137)	Chills	Moderate
10 Dec 2020 (Study Day 137)	Cough	Moderate
10 Dec 2020 (Study Day 137)	Diarrhea	Mild
10 Dec 2020 (Study Day 137)	Difficulty Breathing	Mild
10 Dec 2020 (Study Day 137)	Fatigue	Severe
10 Dec 2020 (Study Day 137)	Headache	Mild
10 Dec 2020 (Study Day 137)	Muscle Aches (Myalgia)	Moderate
10 Dec 2020 (Study Day 137)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 137)	Nausea	Mild
10 Dec 2020 (Study Day 137)	New Loss of Smell	Mild
10 Dec 2020 (Study Day 137)	New Loss of Taste	Mild
10 Dec 2020 (Study Day 137)	O2 Saturation (%)	92
10 Dec 2020 (Study Day 137)	Runny Nose (Rhinorrhea)	Mild
10 Dec 2020 (Study Day 137)	Shortness of Breath	Mild
10 Dec 2020 (Study Day 137)	Sore Throat	Mild
10 Dec 2020 (Study Day 137)	Temperature (°F)	102.7
11 Dec 2020 (Study Day 138)	Body Aches	Moderate
11 Dec 2020 (Study Day 138)	Chills	Mild
11 Dec 2020 (Study Day 138)	Cough	Mild

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 138)	Diarrhea	Mild
11 Dec 2020 (Study Day 138)	Difficulty Breathing	Mild
11 Dec 2020 (Study Day 138)	Fatigue	Moderate
11 Dec 2020 (Study Day 138)	Headache	Moderate
11 Dec 2020 (Study Day 138)	Muscle Aches (Myalgia)	Moderate
11 Dec 2020 (Study Day 138)	Nasal Congestion	Mild
11 Dec 2020 (Study Day 138)	Nausea	Mild
11 Dec 2020 (Study Day 138)	New Loss of Smell	Mild
11 Dec 2020 (Study Day 138)	New Loss of Taste	Mild
11 Dec 2020 (Study Day 138)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 138)	Shortness of Breath	Mild
11 Dec 2020 (Study Day 138)	Sore Throat	Mild
11 Dec 2020 (Study Day 138)	Temperature (°F)	101.0
12 Dec 2020 (Study Day 139)	Body Aches	Moderate
12 Dec 2020 (Study Day 139)	Chills	Mild
12 Dec 2020 (Study Day 139)	Cough	Mild
12 Dec 2020 (Study Day 139)	Diarrhea	Mild
12 Dec 2020 (Study Day 139)	Difficulty Breathing	Mild
12 Dec 2020 (Study Day 139)	Fatigue	Moderate
12 Dec 2020 (Study Day 139)	Headache	Mild
12 Dec 2020 (Study Day 139)	Muscle Aches (Myalgia)	Mild
12 Dec 2020 (Study Day 139)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 139)	Nausea	Mild
12 Dec 2020 (Study Day 139)	New Loss of Smell	Mild
12 Dec 2020 (Study Day 139)	New Loss of Taste	Mild
12 Dec 2020 (Study Day 139)	Runny Nose (Rhinorrhea)	Mild
12 Dec 2020 (Study Day 139)	Shortness of Breath	Mild
12 Dec 2020 (Study Day 139)	Sore Throat	Mild
12 Dec 2020 (Study Day 139)	Temperature (°F)	101.0
13 Dec 2020 (Study Day 140)	Body Aches	Moderate
13 Dec 2020 (Study Day 140)	Chills	Mild
13 Dec 2020 (Study Day 140)	Cough	Moderate
13 Dec 2020 (Study Day 140)	Difficulty Breathing	Mild
13 Dec 2020 (Study Day 140)	Fatigue	Moderate
13 Dec 2020 (Study Day 140)	Headache	Mild
13 Dec 2020 (Study Day 140)	Muscle Aches (Myalgia)	Moderate
13 Dec 2020 (Study Day 140)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 140)	New Loss of Smell	Mild
13 Dec 2020 (Study Day 140)	New Loss of Taste	Mild
13 Dec 2020 (Study Day 140)	Runny Nose (Rhinorrhea)	Mild
13 Dec 2020 (Study Day 140)	Shortness of Breath	Mild
13 Dec 2020 (Study Day 140)	Sore Throat	Mild
13 Dec 2020 (Study Day 140)	Temperature (°F)	101.0

Symptom Date	Symptom	Result
14 Dec 2020 (Study Day 141)	Body Aches	Moderate
14 Dec 2020 (Study Day 141)	Chills	Moderate
14 Dec 2020 (Study Day 141)	Cough	Mild
14 Dec 2020 (Study Day 141)	Diarrhea	Mild
14 Dec 2020 (Study Day 141)	Difficulty Breathing	Mild
14 Dec 2020 (Study Day 141)	Fatigue	Moderate
14 Dec 2020 (Study Day 141)	Headache	Moderate
14 Dec 2020 (Study Day 141)	Muscle Aches (Myalgia)	Moderate
14 Dec 2020 (Study Day 141)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 141)	Nausea	Mild
14 Dec 2020 (Study Day 141)	Runny Nose (Rhinorrhea)	Mild
14 Dec 2020 (Study Day 141)	Shortness of Breath	Mild
14 Dec 2020 (Study Day 141)	Sore Throat	Mild
14 Dec 2020 (Study Day 141)	Temperature (°F)	101.0
15 Dec 2020 (Study Day 142)	Body Aches	Moderate
15 Dec 2020 (Study Day 142)	Chills	Moderate
15 Dec 2020 (Study Day 142)	Cough	Moderate
15 Dec 2020 (Study Day 142)	Diarrhea	Mild
15 Dec 2020 (Study Day 142)	Difficulty Breathing	Mild
15 Dec 2020 (Study Day 142)	Fatigue	Moderate
15 Dec 2020 (Study Day 142)	Headache	Mild
15 Dec 2020 (Study Day 142)	Muscle Aches (Myalgia)	Moderate
15 Dec 2020 (Study Day 142)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 142)	Nausea	Mild
15 Dec 2020 (Study Day 142)	New Loss of Smell	Mild
15 Dec 2020 (Study Day 142)	New Loss of Taste	Mild
15 Dec 2020 (Study Day 142)	O2 Saturation (%)	93
15 Dec 2020 (Study Day 142)	Runny Nose (Rhinorrhea)	Mild
15 Dec 2020 (Study Day 142)	Shortness of Breath	Mild
15 Dec 2020 (Study Day 142)	Sore Throat	Mild
15 Dec 2020 (Study Day 142)	Temperature (°F)	101.0
16 Dec 2020 (Study Day 143)	Body Aches	Severe
16 Dec 2020 (Study Day 143)	Chills	Moderate
16 Dec 2020 (Study Day 143)	Cough	Moderate
16 Dec 2020 (Study Day 143)	Diarrhea	Mild
16 Dec 2020 (Study Day 143)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 143)	Fatigue	Severe
16 Dec 2020 (Study Day 143)	Headache	Moderate
16 Dec 2020 (Study Day 143)	Muscle Aches (Myalgia)	Severe
16 Dec 2020 (Study Day 143)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 143)	Nausea	Mild
16 Dec 2020 (Study Day 143)	O2 Saturation (%)	91
16 Dec 2020 (Study Day 143)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
16 Dec 2020 (Study Day 143)	Shortness of Breath	Mild
16 Dec 2020 (Study Day 143)	Sore Throat	Mild
16 Dec 2020 (Study Day 143)	Temperature (°F)	102.0
17 Dec 2020 (Study Day 144)	Body Aches	Moderate
17 Dec 2020 (Study Day 144)	Chills	Moderate
17 Dec 2020 (Study Day 144)	Cough	Moderate
17 Dec 2020 (Study Day 144)	Diarrhea	Mild
17 Dec 2020 (Study Day 144)	Difficulty Breathing	Mild
17 Dec 2020 (Study Day 144)	Fatigue	Moderate
17 Dec 2020 (Study Day 144)	Headache	Mild
17 Dec 2020 (Study Day 144)	Muscle Aches (Myalgia)	Moderate
17 Dec 2020 (Study Day 144)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 144)	Nausea	Mild
17 Dec 2020 (Study Day 144)	O2 Saturation (%)	93
17 Dec 2020 (Study Day 144)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 144)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 144)	Sore Throat	Mild
17 Dec 2020 (Study Day 144)	Temperature (°F)	102.0
18 Dec 2020 (Study Day 145)	Body Aches	Moderate
18 Dec 2020 (Study Day 145)	Chills	Moderate
18 Dec 2020 (Study Day 145)	Cough	Mild
18 Dec 2020 (Study Day 145)	Diarrhea	Mild
18 Dec 2020 (Study Day 145)	Difficulty Breathing	Mild
18 Dec 2020 (Study Day 145)	Fatigue	Moderate
18 Dec 2020 (Study Day 145)	Headache	Mild
18 Dec 2020 (Study Day 145)	Muscle Aches (Myalgia)	Moderate
18 Dec 2020 (Study Day 145)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 145)	Nausea	Mild
18 Dec 2020 (Study Day 145)	O2 Saturation (%)	93
18 Dec 2020 (Study Day 145)	Runny Nose (Rhinorrhea)	Mild
18 Dec 2020 (Study Day 145)	Shortness of Breath	Mild
18 Dec 2020 (Study Day 145)	Temperature (°F)	102.0
19 Dec 2020 (Study Day 146)	Body Aches	Moderate
19 Dec 2020 (Study Day 146)	Chills	Moderate
19 Dec 2020 (Study Day 146)	Cough	Moderate
19 Dec 2020 (Study Day 146)	Diarrhea	Mild
19 Dec 2020 (Study Day 146)	Difficulty Breathing	Mild
19 Dec 2020 (Study Day 146)	Fatigue	Moderate
19 Dec 2020 (Study Day 146)	Headache	Moderate
19 Dec 2020 (Study Day 146)	Muscle Aches (Myalgia)	Moderate
19 Dec 2020 (Study Day 146)	Nasal Congestion	Mild
19 Dec 2020 (Study Day 146)	Nausea	Mild
19 Dec 2020 (Study Day 146)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
19 Dec 2020 (Study Day 146)	New Loss of Taste	Mild
19 Dec 2020 (Study Day 146)	O2 Saturation (%)	92
19 Dec 2020 (Study Day 146)	Runny Nose (Rhinorrhea)	Mild
19 Dec 2020 (Study Day 146)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 146)	Sore Throat	Mild
19 Dec 2020 (Study Day 146)	Temperature (°F)	101.0
20 Dec 2020 (Study Day 147)	Body Aches	Moderate
20 Dec 2020 (Study Day 147)	Chills	Moderate
20 Dec 2020 (Study Day 147)	Cough	Moderate
20 Dec 2020 (Study Day 147)	Diarrhea	Mild
20 Dec 2020 (Study Day 147)	Difficulty Breathing	Mild
20 Dec 2020 (Study Day 147)	Fatigue	Moderate
20 Dec 2020 (Study Day 147)	Headache	Mild
20 Dec 2020 (Study Day 147)	Muscle Aches (Myalgia)	Moderate
20 Dec 2020 (Study Day 147)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 147)	O2 Saturation (%)	92
20 Dec 2020 (Study Day 147)	Runny Nose (Rhinorrhea)	Mild
20 Dec 2020 (Study Day 147)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 147)	Sore Throat	Mild
20 Dec 2020 (Study Day 147)	Temperature (°F)	101.7
21 Dec 2020 (Study Day 148)	Body Aches	Moderate
21 Dec 2020 (Study Day 148)	Chills	Moderate
21 Dec 2020 (Study Day 148)	Cough	Mild
21 Dec 2020 (Study Day 148)	Diarrhea	Mild
21 Dec 2020 (Study Day 148)	Difficulty Breathing	Mild
21 Dec 2020 (Study Day 148)	Fatigue	Moderate
21 Dec 2020 (Study Day 148)	Headache	Moderate
21 Dec 2020 (Study Day 148)	Muscle Aches (Myalgia)	Moderate
21 Dec 2020 (Study Day 148)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 148)	Nausea	Mild
21 Dec 2020 (Study Day 148)	O2 Saturation (%)	93
21 Dec 2020 (Study Day 148)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 148)	Shortness of Breath	Mild
21 Dec 2020 (Study Day 148)	Sore Throat	Mild
21 Dec 2020 (Study Day 148)	Temperature (°F)	100.6
22 Dec 2020 (Study Day 149)	Body Aches	Moderate
22 Dec 2020 (Study Day 149)	Chills	Moderate
22 Dec 2020 (Study Day 149)	Cough	Mild
22 Dec 2020 (Study Day 149)	Difficulty Breathing	Mild
22 Dec 2020 (Study Day 149)	Fatigue	Moderate
22 Dec 2020 (Study Day 149)	Headache	Moderate
22 Dec 2020 (Study Day 149)	Muscle Aches (Myalgia)	Moderate
22 Dec 2020 (Study Day 149)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
22 Dec 2020 (Study Day 149)	Nausea	Mild
22 Dec 2020 (Study Day 149)	Runny Nose (Rhinorrhea)	Mild
22 Dec 2020 (Study Day 149)	Shortness of Breath	Mild
22 Dec 2020 (Study Day 149)	Sore Throat	Mild
22 Dec 2020 (Study Day 149)	Temperature (°F)	102.0
22 Dec 2020 (Study Day 149)	Vomiting	Moderate
23 Dec 2020 (Study Day 150)	Body Aches	Moderate
23 Dec 2020 (Study Day 150)	Chills	Moderate
23 Dec 2020 (Study Day 150)	Cough	Mild
23 Dec 2020 (Study Day 150)	Difficulty Breathing	Mild
23 Dec 2020 (Study Day 150)	Fatigue	Moderate
23 Dec 2020 (Study Day 150)	Headache	Moderate
23 Dec 2020 (Study Day 150)	Muscle Aches (Myalgia)	Moderate
23 Dec 2020 (Study Day 150)	Nasal Congestion	Mild
23 Dec 2020 (Study Day 150)	Nausea	Moderate
23 Dec 2020 (Study Day 150)	New Loss of Smell	Mild
23 Dec 2020 (Study Day 150)	New Loss of Taste	Mild
23 Dec 2020 (Study Day 150)	Runny Nose (Rhinorrhea)	Mild
23 Dec 2020 (Study Day 150)	Shortness of Breath	Mild
23 Dec 2020 (Study Day 150)	Sore Throat	Mild
23 Dec 2020 (Study Day 150)	Temperature (°F)	101.7
23 Dec 2020 (Study Day 150)	Vomiting	Moderate
24 Dec 2020 (Study Day 151)	Body Aches	Moderate
24 Dec 2020 (Study Day 151)	Chills	Mild
24 Dec 2020 (Study Day 151)	Cough	Mild
24 Dec 2020 (Study Day 151)	Difficulty Breathing	Mild
24 Dec 2020 (Study Day 151)	Fatigue	Moderate
24 Dec 2020 (Study Day 151)	Headache	Mild
24 Dec 2020 (Study Day 151)	Muscle Aches (Myalgia)	Moderate
24 Dec 2020 (Study Day 151)	Nasal Congestion	Mild
24 Dec 2020 (Study Day 151)	Nausea	Mild
24 Dec 2020 (Study Day 151)	O2 Saturation (%)	93
24 Dec 2020 (Study Day 151)	Runny Nose (Rhinorrhea)	Mild
24 Dec 2020 (Study Day 151)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 151)	Sore Throat	Mild
25 Dec 2020 (Study Day 152)	Body Aches	Moderate
25 Dec 2020 (Study Day 152)	Chills	Mild
25 Dec 2020 (Study Day 152)	Cough	Mild
25 Dec 2020 (Study Day 152)	Difficulty Breathing	Mild
25 Dec 2020 (Study Day 152)	Fatigue	Moderate
25 Dec 2020 (Study Day 152)	Headache	Moderate
25 Dec 2020 (Study Day 152)	Muscle Aches (Myalgia)	Moderate
25 Dec 2020 (Study Day 152)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
25 Dec 2020 (Study Day 152)	O2 Saturation (%)	92
25 Dec 2020 (Study Day 152)	Runny Nose (Rhinorrhea)	Mild
25 Dec 2020 (Study Day 152)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 152)	Sore Throat	Mild
25 Dec 2020 (Study Day 152)	Temperature (°F)	100.6
26 Dec 2020 (Study Day 153)	Body Aches	Moderate
26 Dec 2020 (Study Day 153)	Chills	Mild
26 Dec 2020 (Study Day 153)	Cough	Mild
26 Dec 2020 (Study Day 153)	Difficulty Breathing	Mild
26 Dec 2020 (Study Day 153)	Fatigue	Moderate
26 Dec 2020 (Study Day 153)	Headache	Moderate
26 Dec 2020 (Study Day 153)	Muscle Aches (Myalgia)	Moderate
26 Dec 2020 (Study Day 153)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 153)	O2 Saturation (%)	93
26 Dec 2020 (Study Day 153)	Runny Nose (Rhinorrhea)	Mild
26 Dec 2020 (Study Day 153)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 154)	Body Aches	Moderate
27 Dec 2020 (Study Day 154)	Chills	Mild
27 Dec 2020 (Study Day 154)	Cough	Mild
27 Dec 2020 (Study Day 154)	Difficulty Breathing	Mild
27 Dec 2020 (Study Day 154)	Fatigue	Moderate
27 Dec 2020 (Study Day 154)	Headache	Moderate
27 Dec 2020 (Study Day 154)	Muscle Aches (Myalgia)	Moderate
27 Dec 2020 (Study Day 154)	Nasal Congestion	Mild
27 Dec 2020 (Study Day 154)	O2 Saturation (%)	93
27 Dec 2020 (Study Day 154)	Runny Nose (Rhinorrhea)	Mild
27 Dec 2020 (Study Day 154)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 154)	Temperature (°F)	100.5
28 Dec 2020 (Study Day 155)	Body Aches	Mild
28 Dec 2020 (Study Day 155)	Chills	Mild
28 Dec 2020 (Study Day 155)	Cough	Mild
28 Dec 2020 (Study Day 155)	Difficulty Breathing	Mild
28 Dec 2020 (Study Day 155)	Fatigue	Moderate
28 Dec 2020 (Study Day 155)	Headache	Mild
28 Dec 2020 (Study Day 155)	Muscle Aches (Myalgia)	Mild
28 Dec 2020 (Study Day 155)	Nasal Congestion	Mild
28 Dec 2020 (Study Day 155)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 155)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 156)	Body Aches	Mild
29 Dec 2020 (Study Day 156)	Chills	Mild
29 Dec 2020 (Study Day 156)	Cough	Mild
29 Dec 2020 (Study Day 156)	Difficulty Breathing	Mild
29 Dec 2020 (Study Day 156)	Fatigue	Moderate

Symptom Date	Symptom	Result
29 Dec 2020 (Study Day 156)	Headache	Mild
29 Dec 2020 (Study Day 156)	Muscle Aches (Myalgia)	Mild
29 Dec 2020 (Study Day 156)	Nasal Congestion	Mild
29 Dec 2020 (Study Day 156)	O2 Saturation (%)	92
29 Dec 2020 (Study Day 156)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 156)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 157)	Body Aches	Mild
30 Dec 2020 (Study Day 157)	Chills	Mild
30 Dec 2020 (Study Day 157)	Cough	Mild
30 Dec 2020 (Study Day 157)	Difficulty Breathing	Mild
30 Dec 2020 (Study Day 157)	Fatigue	Moderate
30 Dec 2020 (Study Day 157)	Headache	Mild
30 Dec 2020 (Study Day 157)	Muscle Aches (Myalgia)	Mild
30 Dec 2020 (Study Day 157)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 157)	O2 Saturation (%)	93
30 Dec 2020 (Study Day 157)	Runny Nose (Rhinorrhea)	Mild
30 Dec 2020 (Study Day 157)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 157)	Sore Throat	Mild
31 Dec 2020 (Study Day 158)	Body Aches	Mild
31 Dec 2020 (Study Day 158)	Chills	Mild
31 Dec 2020 (Study Day 158)	Cough	Mild
31 Dec 2020 (Study Day 158)	Difficulty Breathing	Mild
31 Dec 2020 (Study Day 158)	Fatigue	Mild
31 Dec 2020 (Study Day 158)	Headache	Mild
31 Dec 2020 (Study Day 158)	Muscle Aches (Myalgia)	Mild
31 Dec 2020 (Study Day 158)	Nasal Congestion	Mild
31 Dec 2020 (Study Day 158)	O2 Saturation (%)	92
31 Dec 2020 (Study Day 158)	Runny Nose (Rhinorrhea)	Mild
31 Dec 2020 (Study Day 158)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 159)	Body Aches	Mild
01 Jan 2021 (Study Day 159)	Chills	Mild
01 Jan 2021 (Study Day 159)	Cough	Mild
01 Jan 2021 (Study Day 159)	Difficulty Breathing	Mild
01 Jan 2021 (Study Day 159)	Fatigue	Mild
01 Jan 2021 (Study Day 159)	Headache	Mild
01 Jan 2021 (Study Day 159)	Muscle Aches (Myalgia)	Mild
01 Jan 2021 (Study Day 159)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 159)	O2 Saturation (%)	93
01 Jan 2021 (Study Day 159)	Runny Nose (Rhinorrhea)	Mild
01 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
02 Jan 2021 (Study Day 160)	Body Aches	Mild
02 Jan 2021 (Study Day 160)	Chills	Mild
02 Jan 2021 (Study Day 160)	Cough	Mild

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 160)	Difficulty Breathing	Mild
02 Jan 2021 (Study Day 160)	Fatigue	Mild
02 Jan 2021 (Study Day 160)	Headache	Mild
02 Jan 2021 (Study Day 160)	Muscle Aches (Myalgia)	Mild
02 Jan 2021 (Study Day 160)	Nasal Congestion	Mild
02 Jan 2021 (Study Day 160)	O2 Saturation (%)	93
02 Jan 2021 (Study Day 160)	Runny Nose (Rhinorrhea)	Mild
02 Jan 2021 (Study Day 160)	Shortness of Breath	Mild
03 Jan 2021 (Study Day 161)	Body Aches	Mild
03 Jan 2021 (Study Day 161)	Chills	Mild
03 Jan 2021 (Study Day 161)	Cough	Mild
03 Jan 2021 (Study Day 161)	Difficulty Breathing	Mild
03 Jan 2021 (Study Day 161)	Fatigue	Moderate
03 Jan 2021 (Study Day 161)	Headache	Mild
03 Jan 2021 (Study Day 161)	Muscle Aches (Myalgia)	Mild
03 Jan 2021 (Study Day 161)	Nasal Congestion	Mild
03 Jan 2021 (Study Day 161)	O2 Saturation (%)	93
03 Jan 2021 (Study Day 161)	Runny Nose (Rhinorrhea)	Mild
03 Jan 2021 (Study Day 161)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 162)	Body Aches	Mild
04 Jan 2021 (Study Day 162)	Cough	Mild
04 Jan 2021 (Study Day 162)	Difficulty Breathing	Mild
04 Jan 2021 (Study Day 162)	Fatigue	Mild
04 Jan 2021 (Study Day 162)	Headache	Mild
04 Jan 2021 (Study Day 162)	Muscle Aches (Myalgia)	Mild
04 Jan 2021 (Study Day 162)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 162)	O2 Saturation (%)	90
04 Jan 2021 (Study Day 162)	Runny Nose (Rhinorrhea)	Mild
04 Jan 2021 (Study Day 162)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
22 Nov 2020 (Study Day 119)	Oxygen Saturation	85%
22 Nov 2020 - 05 Jan 2021 (Study Day 119-163)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 97 days, after which it was considered to be recovered/resolved on 20 Feb 2021 (Study Day 209). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001095	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypermetropia	Hyperopia	1990 - Ongoing
Intervertebral disc operation	Herniated disc repair	2013 - 2013
Intervertebral disc protrusion	Herniated disc	2013 - 2013
Polycystic ovaries	Polycystic ovarian syndrome	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	Health Maintenance
Metformin	01 Jan 2018 (Study Day -938) - Ongoing	Polycystic Ovarian Syndrome
Tizanidine	01 Jan 2018 (Study Day -938) - Ongoing	Polycystic Ovarian Syndrome
Levonorgestrel	2019 - Ongoing	Birth Control
Paracetamol	01 Aug 2020 (Study Day 6) - 02 Aug 2020 (Study Day 7)	Headache
Ibuprofen	22 Aug 2020 (Study Day 27) - 22 Aug 2020 (Study Day 27)	Pain At Injection Site
Paracetamol	22 Aug 2020 (Study Day 27) - 22 Aug 2020 (Study Day 27)	Headache
Ibuprofen	16 Nov 2020 (Study Day 113) - 06 Jan 2021 (Study Day 164)	Symptoms Of COVID 19
Azithromycin	02 Dec 2020 (Study Day 129) - 06 Dec 2020 (Study Day 133)	COVID
Chest ct with iv contrast.*	02 Dec 2020 (Study Day 129) - 02 Dec 2020 (Study Day 129)	Adverse Event
Doxycycline	02 Dec 2020 (Study Day 129) - 06 Jan 2021 (Study Day 164)	COVID

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	02 Dec 2020 (Study Day 129) - 06 Jan 2021 (Study Day 164)	COVID
Salbutamol	02 Dec 2020 (Study Day 129) - 06 Jan 2021 (Study Day 164)	COVID

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	16 Nov 2020 (Study Day 113) - 20 Feb 2021 (Study Day 209)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US318-2145 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	21 Dec 2020 (Study Day 140) – 08 Jan 2021 (Study Day 158)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US318-2145, a 51-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 21 Dec 2020 (Study Day 140), 139 days after the first dose and 111 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 01 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 04 Jan 2021 (Study Day 154), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
21 Dec 2020 (Study Day 140)	Cough	Severe
21 Dec 2020 (Study Day 140)	Nasal Congestion	Moderate
22 Dec 2020 (Study Day 141)	Cough	Severe
22 Dec 2020 (Study Day 141)	Headache	Moderate
22 Dec 2020 (Study Day 141)	Nasal Congestion	Moderate
23 Dec 2020 (Study Day 142)	Cough	Severe

Symptom Date	Symptom	Result
23 Dec 2020 (Study Day 142)	Headache	Moderate
23 Dec 2020 (Study Day 142)	Nasal Congestion	Moderate
24 Dec 2020 (Study Day 143)	Cough	Severe
24 Dec 2020 (Study Day 143)	Headache	Moderate
24 Dec 2020 (Study Day 143)	Nasal Congestion	Moderate
25 Dec 2020 (Study Day 144)	Cough	Severe
25 Dec 2020 (Study Day 144)	Headache	Moderate
25 Dec 2020 (Study Day 144)	Nasal Congestion	Moderate
26 Dec 2020 (Study Day 145)	Cough	Severe
26 Dec 2020 (Study Day 145)	Headache	Moderate
26 Dec 2020 (Study Day 145)	Nasal Congestion	Moderate
27 Dec 2020 (Study Day 146)	Cough	Severe
27 Dec 2020 (Study Day 146)	Headache	Moderate
27 Dec 2020 (Study Day 146)	Nasal Congestion	Moderate
28 Dec 2020 (Study Day 147)	Cough	Severe
28 Dec 2020 (Study Day 147)	Headache	Moderate
28 Dec 2020 (Study Day 147)	Nasal Congestion	Moderate
29 Dec 2020 (Study Day 148)	Cough	Severe
29 Dec 2020 (Study Day 148)	Headache	Moderate
29 Dec 2020 (Study Day 148)	Nasal Congestion	Moderate
30 Dec 2020 (Study Day 149)	Cough	Severe
30 Dec 2020 (Study Day 149)	Nasal Congestion	Moderate
31 Dec 2020 (Study Day 150)	Cough	Severe
31 Dec 2020 (Study Day 150)	Nasal Congestion	Moderate
01 Jan 2021 (Study Day 151)	Cough	Severe
01 Jan 2021 (Study Day 151)	Nasal Congestion	Moderate
08 Jan 2021 (Study Day 158)	O2 Saturation (%)	92

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
05 Jan 2021 (Study Day 155)	Oxygen Saturation	92%
05 Jan 2021 - 09 Jan 2021 (Study Day 155-159)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 19 days, after which it was considered to be recovered/resolved on 08 Jan 2021 (Study Day 158). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003264	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Umbilical hernia	Umbilical hernia	2007 - 2007
Umbilical hernia repair	Umbilical hernia repair	2007 - 2007
Osteoarthritis	Osteoarthritis-left knee	2009 - Ongoing
Rotator cuff repair	Left rotator cuff repair	2009 - 2009
Rotator cuff syndrome	Torn left rotator cuff	2009 - 2009
Hypertension	Hypertension	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine hydrochloride	1999 - Ongoing	Seasonal Allergies
Lisinopril	2017 - Ongoing	Hypertension
Ibuprofen	2019 - Ongoing	Left Knee Osteoarthritis Pain
Paracetamol	05 Aug 2020 (Study Day 2) - 05 Aug 2020 (Study Day 2)	Headache
Hydrochlorothiazide	07 Aug 2020 (Study Day 4) - Ongoing	Hypertension
Ibuprofen	22 Dec 2020 (Study Day 141) - 30 Dec 2020 (Study Day 149)	Headache (Secondary To COVID-19)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	21 Dec 2020 (Study Day 140) - 08 Jan 2021 (Study Day 158)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US320-2049 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	SAE, COVID-19	Grade 3/severe	Not related	21 Nov 2020 (Study Day 107) – 11 Dec 2020 (Study Day 127)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US320-2049, a 68-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 03 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 21 Nov 2020 (Study Day 107), 106 days after the first dose and 79 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 03 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 01 Dec 2020 (Study Day 117), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
21 Nov 2020 (Study Day 107)	Body Aches	Mild
21 Nov 2020 (Study Day 107)	Cough	Mild
21 Nov 2020 (Study Day 107)	Fatigue	Mild
21 Nov 2020 (Study Day 107)	Shortness of Breath	Mild
22 Nov 2020 (Study Day 108)	Body Aches	Mild
22 Nov 2020 (Study Day 108)	Chills	Mild

Symptom Date	Symptom	Result
22 Nov 2020 (Study Day 108)	Cough	Mild
22 Nov 2020 (Study Day 108)	Fatigue	Mild
22 Nov 2020 (Study Day 108)	Shortness of Breath	Mild
23 Nov 2020 (Study Day 109)	Body Aches	Mild
23 Nov 2020 (Study Day 109)	Chills	Mild
23 Nov 2020 (Study Day 109)	Cough	Mild
23 Nov 2020 (Study Day 109)	Fatigue	Mild
23 Nov 2020 (Study Day 109)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 110)	Body Aches	Mild
24 Nov 2020 (Study Day 110)	Chills	Mild
24 Nov 2020 (Study Day 110)	Cough	Mild
24 Nov 2020 (Study Day 110)	Fatigue	Mild
24 Nov 2020 (Study Day 110)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 111)	Body Aches	Mild
25 Nov 2020 (Study Day 111)	Cough	Mild
25 Nov 2020 (Study Day 111)	Fatigue	Mild
25 Nov 2020 (Study Day 111)	Shortness of Breath	Mild
26 Nov 2020 (Study Day 112)	Body Aches	Mild
26 Nov 2020 (Study Day 112)	Cough	Mild
26 Nov 2020 (Study Day 112)	Fatigue	Mild
26 Nov 2020 (Study Day 112)	Shortness of Breath	Mild
27 Nov 2020 (Study Day 113)	Body Aches	Mild
27 Nov 2020 (Study Day 113)	Cough	Mild
27 Nov 2020 (Study Day 113)	Fatigue	Mild
27 Nov 2020 (Study Day 113)	Shortness of Breath	Mild
28 Nov 2020 (Study Day 114)	Body Aches	Mild
28 Nov 2020 (Study Day 114)	Cough	Mild
28 Nov 2020 (Study Day 114)	Fatigue	Mild
28 Nov 2020 (Study Day 114)	Shortness of Breath	Mild
29 Nov 2020 (Study Day 115)	Body Aches	Mild
29 Nov 2020 (Study Day 115)	Cough	Mild
29 Nov 2020 (Study Day 115)	Fatigue	Mild
29 Nov 2020 (Study Day 115)	Headache	Mild
29 Nov 2020 (Study Day 115)	Nausea	Mild
29 Nov 2020 (Study Day 115)	Shortness of Breath	Mild
30 Nov 2020 (Study Day 116)	Body Aches	Mild
30 Nov 2020 (Study Day 116)	Cough	Mild
30 Nov 2020 (Study Day 116)	Fatigue	Mild
30 Nov 2020 (Study Day 116)	Headache	Mild
30 Nov 2020 (Study Day 116)	Nausea	Mild
30 Nov 2020 (Study Day 116)	Shortness of Breath	Mild
01 Dec 2020 (Study Day 117)	Body Aches	Mild
01 Dec 2020 (Study Day 117)	Cough	Mild

Symptom Date	Symptom	Result
01 Dec 2020 (Study Day 117)	Fatigue	Mild
01 Dec 2020 (Study Day 117)	Headache	Mild
01 Dec 2020 (Study Day 117)	Nausea	Mild
01 Dec 2020 (Study Day 117)	Shortness of Breath	Mild
02 Dec 2020 (Study Day 118)	Cough	Mild
02 Dec 2020 (Study Day 118)	Fatigue	Mild
02 Dec 2020 (Study Day 118)	Headache	Mild
02 Dec 2020 (Study Day 118)	Shortness of Breath	Mild
02 Dec 2020 (Study Day 118)	Vomiting	Mild
03 Dec 2020 (Study Day 119)	Shortness of Breath	Severe
04 Dec 2020 (Study Day 120)	Shortness of Breath	Severe
07 Dec 2020 (Study Day 123)	Cough	Mild
07 Dec 2020 (Study Day 123)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 124)	Cough	Mild
08 Dec 2020 (Study Day 124)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
03 Dec 2020 (Study Day 119)	Oxygen Saturation	88%
03 Dec 2020 (Study Day 119)	PP Arterial O2/Fraction Inspired O2	271 mmHg
03 Dec 2020 - 03 Dec 2020 (Study Day 119-119)	Clinical Evidence of Pneumonia	Yes
03 Dec 2020 - 06 Dec 2020 (Study Day 119-122)	High-Flow Oxygen	Yes
03 Dec 2020 - 06 Dec 2020 (Study Day 119-122)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes
03 Dec 2020 - 03 Dec 2020 (Study Day 119-119)	PaO2/FIO2 Ratio < 300 mm Hg	Yes
03 Dec 2020 - 03 Dec 2020 (Study Day 119-119)	Radiographical Evidence of Pneumonia	Yes
03 Dec 2020 - 03 Dec 2020 (Study Day 119-119)	Respiratory Failure	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 127). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001009	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Endometriosis	Endometriosis	1980 - 1980
Hysterectomy	Hysterectomy	1980 - 1980
Obesity	Obesity	1990 - Ongoing
Fibromyalgia	Fibromyalgia	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Anxiety	Anxiety	2005 - Ongoing
Bipolar disorder	Bipolar disorder	2005 - Ongoing
Depression	Depression	2005 - Ongoing
Intervertebral disc protrusion	Back pain/bulging discs	2005 - Ongoing
Osteoarthritis	Osteoarthritis- back and neck	2005 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Nonalcoholic fatty liver disease	Nonalcoholic fatty liver disease	2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2019 - Ongoing
Peripheral sensory neuropathy	Idiopathic sensory neuropathy- feet	2019 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2019 - Ongoing	Hypertension
Aripiprazole	2019 - Ongoing	Bipolar Disorder
Buspirone	2019 - Ongoing	Depression
Gabapentin	2019 - Ongoing	Idiopathic Sensory Neuropathy In Feet
Levothyroxine	2019 - Ongoing	Hypothyroidism
Lisinopril	2019 - Ongoing	Hypertension
Oxycodone; paracetamol	2019 - Ongoing	Neck And Back Osteoarthritis
Rosuvastatin calcium	2019 - Ongoing	Hyperlipidemia
Venlafaxine hydrochloride	2019 - Ongoing	Anxiety/Depression
Paracetamol	02 Dec 2020 (Study Day 118) - 02 Dec 2020 (Study Day 118)	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	03 Dec 2020 (Study Day 119) - 03 Dec 2020 (Study Day 119)	COVID-19
Ceftriaxone	03 Dec 2020 (Study Day 119) - 03 Dec 2020 (Study Day 119)	COVID-19
Enoxaparin sodium	03 Dec 2020 (Study Day 119) - 07 Dec 2020 (Study Day 123)	COVID-19
Loperamide hydrochloride	03 Dec 2020 (Study Day 119) - 07 Dec 2020 (Study Day 123)	COVID-19
Ondansetron	03 Dec 2020 (Study Day 119) - 03 Dec 2020 (Study Day 119)	COVID-19
Oxygen	03 Dec 2020 (Study Day 119) - 06 Dec 2020 (Study Day 122)	COVID-19
Paracetamol	03 Dec 2020 (Study Day 119) - 10 Dec 2020 (Study Day 126)	COVID-19
Remdesivir	03 Dec 2020 (Study Day 119) - 03 Dec 2020 (Study Day 119)	COVID-19
Sodium chloride	03 Dec 2020 (Study Day 119) - 03 Dec 2020 (Study Day 119)	COVID-19
Sodium chloride	03 Dec 2020 (Study Day 119) - 07 Dec 2020 (Study Day 123)	COVID-19
Dexamethasone	04 Dec 2020 (Study Day 120) - 07 Dec 2020 (Study Day 123)	COVID-19
Dextromethorphan hydrobromide; guaifenesin	04 Dec 2020 (Study Day 120) - 07 Dec 2020 (Study Day 123)	COVID-19
Famotidine	04 Dec 2020 (Study Day 120) - 07 Dec 2020 (Study Day 123)	COVID-19
Remdesivir	04 Dec 2020 (Study Day 120) - 07 Dec 2020 (Study Day 123)	COVID-19
Specific immunoglobulins	04 Dec 2020 (Study Day 120) - 04 Dec 2020 (Study Day 120)	COVID-19
Azithromycin	07 Dec 2020 (Study Day 123) - 11 Dec 2020 (Study Day 127)	COVID-19
Dexamethasone	07 Dec 2020 (Study Day 123) - 16 Dec 2020 (Study Day 132)	COVID-19
Salbutamol	07 Dec 2020 (Study Day 123) - 11 Dec 2020 (Study Day 127)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US321-2112 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19, AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	14 Oct 2020 (Study Day 66) – 30 Nov 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US321-2112, a 28-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 14 Oct 2020 (Study Day 66), 65 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 29 Oct 2020 (Study Day 81), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
14 Oct 2020 (Study Day 66)	New Loss of Taste	Mild
15 Oct 2020 (Study Day 67)	New Loss of Taste	Mild
16 Oct 2020 (Study Day 68)	Nausea	Mild
17 Oct 2020 (Study Day 69)	Nausea	Mild

Symptom Date	Symptom	Result
19 Oct 2020 (Study Day 71)	Nasal Congestion	Moderate
19 Oct 2020 (Study Day 71)	Temperature (°F)	103.0
20 Oct 2020 (Study Day 72)	Nasal Congestion	Mild
20 Oct 2020 (Study Day 72)	Temperature (°F)	103
21 Oct 2020 (Study Day 73)	Body Aches	Mild
21 Oct 2020 (Study Day 73)	Chills	Mild
21 Oct 2020 (Study Day 73)	Sore Throat	Mild
22 Oct 2020 (Study Day 74)	Sore Throat	Mild
23 Oct 2020 (Study Day 75)	Sore Throat	Mild
24 Oct 2020 (Study Day 76)	Diarrhea	Moderate
24 Oct 2020 (Study Day 76)	Sore Throat	Mild
24 Oct 2020 (Study Day 76)	Vomiting	Moderate
25 Oct 2020 (Study Day 77)	Diarrhea	Moderate
25 Oct 2020 (Study Day 77)	Sore Throat	Mild
25 Oct 2020 (Study Day 77)	Vomiting	Moderate
09 Nov 2020 (Study Day 92)	O2 Saturation (%)	92
10 Nov 2020 (Study Day 93)	O2 Saturation (%)	92
11 Nov 2020 (Study Day 94)	O2 Saturation (%)	90

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
09 Nov 2020 (Study Day 92)	Oxygen Saturation	92%
09 Nov 2020 - 30 Nov 2020 (Study Day 92-113)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

On 06 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of symptomatic COVID-19 lasted for 48 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 113). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000605	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	2014 - 2014
Appendicitis	Appendicitis	2014 - 2014
Nasal septal operation	Septoplasty	2017 - 2017
Nasal septum deviation	Deviated septum	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dietary supplement	2020 - Ongoing	Pre Work Out Supplement
Influenza vaccine	13 Oct 2020 (Study Day 65) - 13 Oct 2020 (Study Day 65)	Prevent Flu
Ascorbic acid	09 Nov 2020 (Study Day 92) - Ongoing	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	14 Oct 2020 (Study Day 66) - 30 Nov 2020 (Study Day 113)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US323-2056 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	02 Jan 2021 (Study Day 139) – 21 Jan 2021 (Study Day 158)	Recovered/ resolved
Atrioventricular Block Complete/Complete Heart Blockage	SAE	Grade 3/severe	Not related	16 Jan 2021 (Study Day 153) – 19 Jan 2021 (Study Day 156)	Recovered/ resolved
Syncope/Syncope	SAE	Grade 3/severe	Not related	16 Jan 2021 (Study Day 153) – 19 Jan 2021 (Study Day 156)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US323-2056, a 72-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Jan 2021 (Study Day 153), 152 days after the first dose and 124 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrioventricular block complete. Action taken with the IP was not applicable. The event of complete heart blockage lasted for 4 days, after which it was considered to be recovered/resolved on 19 Jan 2021 (Study Day 156). The investigator assessed the event of atrioventricular block complete to be not related to the IP.

On 16 Jan 2021 (Study Day 153), 152 days after the first dose and 124 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 4 days, after which it was considered to be recovered/resolved on 19 Jan 2021 (Study Day 156). The investigator assessed the event of syncope to be not related to the IP.

Severe COVID-19 Details

On 02 Jan 2021 (Study Day 139), 138 days after the first dose and 110 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 14 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 08 Jan 2021 (Study Day 145), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 139)	Body Aches	Mild
02 Jan 2021 (Study Day 139)	Cough	Mild
02 Jan 2021 (Study Day 139)	Headache	Mild
03 Jan 2021 (Study Day 140)	Body Aches	Mild
03 Jan 2021 (Study Day 140)	Cough	Mild
03 Jan 2021 (Study Day 140)	Headache	Mild
04 Jan 2021 (Study Day 141)	Body Aches	Mild
04 Jan 2021 (Study Day 141)	Cough	Mild
04 Jan 2021 (Study Day 141)	Headache	Mild
05 Jan 2021 (Study Day 142)	Body Aches	Mild
05 Jan 2021 (Study Day 142)	Cough	Mild
05 Jan 2021 (Study Day 142)	Headache	Mild
06 Jan 2021 (Study Day 143)	Body Aches	Mild
06 Jan 2021 (Study Day 143)	Cough	Mild
06 Jan 2021 (Study Day 143)	Headache	Mild
07 Jan 2021 (Study Day 144)	Body Aches	Mild
07 Jan 2021 (Study Day 144)	Cough	Mild
07 Jan 2021 (Study Day 144)	Headache	Mild
08 Jan 2021 (Study Day 145)	Body Aches	Mild
08 Jan 2021 (Study Day 145)	Cough	Mild
08 Jan 2021 (Study Day 145)	Headache	Mild
09 Jan 2021 (Study Day 146)	Body Aches	Mild
09 Jan 2021 (Study Day 146)	Cough	Mild
09 Jan 2021 (Study Day 146)	Fatigue	Mild
09 Jan 2021 (Study Day 146)	Headache	Moderate
10 Jan 2021 (Study Day 147)	Body Aches	Mild
10 Jan 2021 (Study Day 147)	Cough	Mild
10 Jan 2021 (Study Day 147)	Fatigue	Mild
10 Jan 2021 (Study Day 147)	Headache	Mild
11 Jan 2021 (Study Day 148)	Cough	Mild

Symptom Date	Symptom	Result
11 Jan 2021 (Study Day 148)	Fatigue	Mild
11 Jan 2021 (Study Day 148)	Headache	Mild
12 Jan 2021 (Study Day 149)	Cough	Mild
12 Jan 2021 (Study Day 149)	Fatigue	Mild
12 Jan 2021 (Study Day 149)	Headache	Mild
13 Jan 2021 (Study Day 150)	Cough	Mild
13 Jan 2021 (Study Day 150)	Fatigue	Mild
13 Jan 2021 (Study Day 150)	Headache	Moderate
13 Jan 2021 (Study Day 150)	Nausea	Mild
14 Jan 2021 (Study Day 151)	Headache	Mild
27 Jan 2021 (Study Day 164)	Headache	Mild
27 Jan 2021 (Study Day 164)	O2 Saturation (%)	91
16 Apr 2021 (Study Day 243)	Fatigue	Mild
16 Apr 2021 (Study Day 243)	Headache	Moderate
16 Apr 2021 (Study Day 243)	Nasal Congestion	Moderate
18 Apr 2021 (Study Day 245)	O2 Saturation (%)	91

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
27 Jan 2021 (Study Day 164)	Oxygen Saturation	91%
27 Jan 2021 - 28 Jan 2021 (Study Day 164-165)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 158). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious and serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003140	COVID-19
MOD-2021-003140	Atrioventricular block complete
MOD-2021-003140	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	1956 - Ongoing
Herpes zoster	Shingles	1957 - 2000
Breast cancer	Breast (bilateral) cancer	1990 - 2015
Anaemia	Anemia	1994 - Ongoing
Hysterectomy	Hysterectomy	1997 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2010 - Ongoing
Transfusion	Transfusions	2015 - 2015
Carpal tunnel syndrome	Carpol tunnel syndrome	2017 - Ongoing
Chronic obstructive pulmonary disease	Copd	2017 - Ongoing
Wheezing	Asthma/wheezing	2017 - Ongoing
Cataract	Cataracts	2018 - 2019
Sleep apnoea syndrome	Sleep apnea	2018 - Ongoing
Vitamin B12 deficiency	Vitamin b12 deficiency	2018 - Ongoing
Cardiac failure congestive	Congestive heart failure	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Hypothyroidism	Hypothyroidism	2019 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2019 - Ongoing
Anxiety	Anxiety	02 Mar 2020 (Study Day -168) - Ongoing
Depression	Depression	02 Mar 2020 (Study Day -168) - Ongoing
Tinnitus	Tinnitus	10 Aug 2020 (Study Day -7) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ferrous sulfate	1994 - Ongoing	Anemia
Fluticasone furoate; vilanterol trifenatate	2017 - Ongoing	Asthma/ Copd
Salbutamol	2017 - Ongoing	Asthma
Cyanocobalamin	2018 - Ongoing	B12 Deficiency
Acetylsalicylic acid	2019 - Ongoing	Cardiac Prophylactic
Carvedilol	2019 - Ongoing	Hypertension
Colecalciferol	2019 - Ongoing	General Health
Levothyroxine	2019 - Ongoing	Hypothyroid

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine	12 Mar 2020 (Study Day -158) - Ongoing	Anxiety
Lisinopril	06 Aug 2020 (Study Day -11) - Ongoing	Hypertension
Cefdinir	30 Sep 2020 (Study Day 45) - 10 Oct 2020 (Study Day 55)	Pansinusitis
Ascorbic acid	08 Jan 2021 (Study Day 145) - Ongoing	COVID-19
Azithromycin	08 Jan 2021 (Study Day 145) - 08 Jan 2021 (Study Day 145)	COVID-19
Colecalciferol	08 Jan 2021 (Study Day 145) - Ongoing	COVID-19
Melatonin	08 Jan 2021 (Study Day 145) - Ongoing	COVID-19
Nattokinase	08 Jan 2021 (Study Day 145) - Ongoing	COVID-19
Zinc	08 Jan 2021 (Study Day 145) - Ongoing	COVID-19
Azithromycin	09 Jan 2021 (Study Day 146) - 12 Jan 2021 (Study Day 149)	COVID-19
Caffeine; paracetamol	13 Jan 2021 (Study Day 150) - Ongoing	Headache
Amlodipine	16 Jan 2021 (Study Day 153) - Ongoing	Hypertension
Docusate sodium	16 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 156)	Prophylactic Constipation
Lisinopril	16 Jan 2021 (Study Day 153) - 02 Feb 2021 (Study Day 170)	Hypertension
Naloxone hydrochloride	16 Jan 2021 (Study Day 153) - 16 Jan 2021 (Study Day 153)	Syncope
Ondansetron	16 Jan 2021 (Study Day 153) - 16 Jan 2021 (Study Day 153)	Nausea Prophylaxis
Paracetamol	16 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 156)	Pre/Post Operative Pain (Surgical Site-Pacemaker)
Sodium chloride	16 Jan 2021 (Study Day 153) - 16 Jan 2021 (Study Day 153)	Syncope
Chlorhexidine	17 Jan 2021 (Study Day 154) - 18 Jan 2021 (Study Day 155)	Prophylactic For Infection
Promethazine	17 Jan 2021 (Study Day 154) - 17 Jan 2021 (Study Day 154)	Prophylactic N//V
Pacemaker placement*	18 Jan 2021 (Study Day 155) - 18 Jan 2021 (Study Day 155)	Adverse Event
Doxycycline hyclate	19 Jan 2021 (Study Day 156) - Ongoing	Prophylaxis Bacteria Infection
Ibuprofen	27 Jan 2021 (Study Day 164) - 27 Jan 2021 (Study Day 164)	Headache
Lisinopril	03 Feb 2021 (Study Day 171) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	23 Aug 2020 (Study Day 7) - 28 Aug 2020 (Study Day 12)
Oropharyngeal Pain	Grade 1/mild	Not related	30 Sep 2020 (Study Day 45) - 03 Oct 2020 (Study Day 48)
Sinusitis	Grade 1/mild	Not related	30 Sep 2020 (Study Day 45) - 03 Oct 2020 (Study Day 48)
COVID-19	Grade 3/severe	Not related	02 Jan 2021 (Study Day 139) - 21 Jan 2021 (Study Day 158)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US323-2157 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	06 Jan 2021 (Study Day 120) – 05 Feb 2021 (Study Day 150)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US323-2157, a 62-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 06 Jan 2021 (Study Day 120), 119 days after the first dose and 91 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 07 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 08 Jan 2021 (Study Day 122), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
06 Jan 2021 (Study Day 120)	Cough	Mild
07 Jan 2021 (Study Day 121)	Body Aches	Mild
07 Jan 2021 (Study Day 121)	Chills	Mild
07 Jan 2021 (Study Day 121)	Cough	Mild
08 Jan 2021 (Study Day 122)	Body Aches	Mild
08 Jan 2021 (Study Day 122)	Chills	Mild

Symptom Date	Symptom	Result
08 Jan 2021 (Study Day 122)	Cough	Mild
09 Jan 2021 (Study Day 123)	Body Aches	Severe
09 Jan 2021 (Study Day 123)	Cough	Mild
09 Jan 2021 (Study Day 123)	Fatigue	Severe
09 Jan 2021 (Study Day 123)	Runny Nose (Rhinorrhea)	Mild
10 Jan 2021 (Study Day 124)	Body Aches	Severe
10 Jan 2021 (Study Day 124)	Cough	Mild
10 Jan 2021 (Study Day 124)	Fatigue	Severe
10 Jan 2021 (Study Day 124)	O2 Saturation (%)	92
10 Jan 2021 (Study Day 124)	Runny Nose (Rhinorrhea)	Mild
11 Jan 2021 (Study Day 125)	Cough	Mild
11 Jan 2021 (Study Day 125)	Fatigue	Severe
11 Jan 2021 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
12 Jan 2021 (Study Day 126)	Cough	Mild
12 Jan 2021 (Study Day 126)	Fatigue	Severe
12 Jan 2021 (Study Day 126)	Nausea	Mild
12 Jan 2021 (Study Day 126)	New Loss of Smell	Mild
12 Jan 2021 (Study Day 126)	New Loss of Taste	Mild
12 Jan 2021 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
13 Jan 2021 (Study Day 127)	Cough	Mild
13 Jan 2021 (Study Day 127)	Fatigue	Severe
13 Jan 2021 (Study Day 127)	New Loss of Smell	Moderate
13 Jan 2021 (Study Day 127)	New Loss of Taste	Mild
13 Jan 2021 (Study Day 127)	Runny Nose (Rhinorrhea)	Mild
14 Jan 2021 (Study Day 128)	Cough	Mild
14 Jan 2021 (Study Day 128)	Fatigue	Severe
14 Jan 2021 (Study Day 128)	New Loss of Smell	Severe
14 Jan 2021 (Study Day 128)	New Loss of Taste	Moderate
14 Jan 2021 (Study Day 128)	Runny Nose (Rhinorrhea)	Mild
15 Jan 2021 (Study Day 129)	Cough	Mild
15 Jan 2021 (Study Day 129)	Fatigue	Severe
15 Jan 2021 (Study Day 129)	New Loss of Smell	Severe
15 Jan 2021 (Study Day 129)	New Loss of Taste	Moderate
15 Jan 2021 (Study Day 129)	Runny Nose (Rhinorrhea)	Mild
16 Jan 2021 (Study Day 130)	Cough	Mild
16 Jan 2021 (Study Day 130)	Fatigue	Severe
16 Jan 2021 (Study Day 130)	New Loss of Smell	Severe
16 Jan 2021 (Study Day 130)	New Loss of Taste	Moderate
16 Jan 2021 (Study Day 130)	Runny Nose (Rhinorrhea)	Mild
17 Jan 2021 (Study Day 131)	Cough	Mild
17 Jan 2021 (Study Day 131)	Fatigue	Moderate
17 Jan 2021 (Study Day 131)	New Loss of Smell	Severe
17 Jan 2021 (Study Day 131)	New Loss of Taste	Moderate

Symptom Date	Symptom	Result
17 Jan 2021 (Study Day 131)	Runny Nose (Rhinorrhea)	Mild
18 Jan 2021 (Study Day 132)	Cough	Mild
18 Jan 2021 (Study Day 132)	Fatigue	Moderate
18 Jan 2021 (Study Day 132)	New Loss of Smell	Severe
18 Jan 2021 (Study Day 132)	New Loss of Taste	Moderate
18 Jan 2021 (Study Day 132)	Runny Nose (Rhinorrhea)	Mild
19 Jan 2021 (Study Day 133)	Cough	Mild
19 Jan 2021 (Study Day 133)	Fatigue	Moderate
19 Jan 2021 (Study Day 133)	New Loss of Smell	Severe
19 Jan 2021 (Study Day 133)	New Loss of Taste	Moderate
19 Jan 2021 (Study Day 133)	Runny Nose (Rhinorrhea)	Mild
20 Jan 2021 (Study Day 134)	Cough	Mild
20 Jan 2021 (Study Day 134)	Fatigue	Moderate
20 Jan 2021 (Study Day 134)	New Loss of Smell	Severe
20 Jan 2021 (Study Day 134)	New Loss of Taste	Moderate
20 Jan 2021 (Study Day 134)	Runny Nose (Rhinorrhea)	Mild
21 Jan 2021 (Study Day 135)	Cough	Mild
21 Jan 2021 (Study Day 135)	Fatigue	Moderate
21 Jan 2021 (Study Day 135)	New Loss of Smell	Severe
21 Jan 2021 (Study Day 135)	New Loss of Taste	Moderate
21 Jan 2021 (Study Day 135)	Runny Nose (Rhinorrhea)	Mild
22 Jan 2021 (Study Day 136)	Cough	Mild
22 Jan 2021 (Study Day 136)	Fatigue	Moderate
22 Jan 2021 (Study Day 136)	New Loss of Smell	Severe
22 Jan 2021 (Study Day 136)	New Loss of Taste	Moderate
22 Jan 2021 (Study Day 136)	Runny Nose (Rhinorrhea)	Mild
23 Jan 2021 (Study Day 137)	Cough	Mild
23 Jan 2021 (Study Day 137)	Fatigue	Moderate
23 Jan 2021 (Study Day 137)	New Loss of Smell	Severe
23 Jan 2021 (Study Day 137)	New Loss of Taste	Moderate
23 Jan 2021 (Study Day 137)	Runny Nose (Rhinorrhea)	Mild
24 Jan 2021 (Study Day 138)	Cough	Mild
24 Jan 2021 (Study Day 138)	Fatigue	Moderate
24 Jan 2021 (Study Day 138)	New Loss of Smell	Severe
24 Jan 2021 (Study Day 138)	New Loss of Taste	Moderate
24 Jan 2021 (Study Day 138)	Runny Nose (Rhinorrhea)	Mild
25 Jan 2021 (Study Day 139)	Cough	Mild
25 Jan 2021 (Study Day 139)	Fatigue	Moderate
25 Jan 2021 (Study Day 139)	New Loss of Smell	Moderate
25 Jan 2021 (Study Day 139)	New Loss of Taste	Moderate
26 Jan 2021 (Study Day 140)	Cough	Mild
26 Jan 2021 (Study Day 140)	Fatigue	Moderate
26 Jan 2021 (Study Day 140)	New Loss of Smell	Moderate

Symptom Date	Symptom	Result
26 Jan 2021 (Study Day 140)	New Loss of Taste	Moderate
27 Jan 2021 (Study Day 141)	Cough	Mild
27 Jan 2021 (Study Day 141)	Fatigue	Mild
27 Jan 2021 (Study Day 141)	New Loss of Smell	Moderate
27 Jan 2021 (Study Day 141)	New Loss of Taste	Moderate
28 Jan 2021 (Study Day 142)	Cough	Mild
28 Jan 2021 (Study Day 142)	Fatigue	Mild
28 Jan 2021 (Study Day 142)	New Loss of Smell	Moderate
28 Jan 2021 (Study Day 142)	New Loss of Taste	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
10 Jan 2021 (Study Day 124)	Oxygen Saturation	92%
10 Jan 2021 - 10 Jan 2021 (Study Day 124-124)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 31 days, after which it was considered to be recovered/resolved on 05 Feb 2021 (Study Day 150). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002985	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	1980 - Ongoing
Neck surgery	Cervical surgery	1998 - 1998
Hyperlipidaemia	Hyperlipedemia	2000 - Ongoing
Vision correction operation	Laser vision correction	2005 - 2005

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Herpes simplex	Herpes simplex virus 2 (face)	29 Aug 2013 (Study Day -2568) - Ongoing
Back pain	Recurrent back pain	2016 - Ongoing
Osteoarthritis	Osteoarthritis	2016 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2018 - Ongoing
Cataract	Cataracts	2019 - 2019
Blood donor	Frequent blood donor	15 Mar 2020 (Study Day -178) - 15 Mar 2020 (Study Day -178)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylactic
Atorvastatin	2000 - Ongoing	Hyperlipidemia
Famotidine	2018 - Ongoing	Reflux
Pantoprazole	2018 - Ongoing	Gerd
Valaciclovir	05 Apr 2019 (Study Day -523) - Ongoing	Herpes Simplex Virus 2 (Face)
Ascorbic acid	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19
Azithromycin	08 Jan 2021 (Study Day 122) - 08 Jan 2021 (Study Day 122)	COVID-19
Azithromycin	08 Jan 2021 (Study Day 122) - 12 Jan 2021 (Study Day 126)	COVID-19
Budesonide	08 Jan 2021 (Study Day 122) - Ongoing	Pulmonary Infiltrates
Colecalciferol	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19
Melatonin	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19
Zinc	08 Jan 2021 (Study Day 122) - 22 Jan 2021 (Study Day 136)	COVID-19
Dietary supplement	15 Feb 2021 (Study Day 160) - Ongoing	Gastroenteritis
Simeticone	15 Feb 2021 (Study Day 160) - Ongoing	Gastroenteritis
Naproxen sodium	25 Feb 2021 (Study Day 170) - 10 Mar 2021 (Study Day 183)	Abdominal Pain
Dicycloverine	08 Mar 2021 (Study Day 181) - Ongoing	Gastric Emptying Secondary To Cholangitis
Fentanyl	11 Mar 2021 (Study Day 184) - Ongoing	Abdominal Pain (Pancreatic Mass)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoclopramide	11 Mar 2021 (Study Day 184) - Ongoing	Gastric Empyting Secondary To Cholangitis
Mirtazapine	11 Mar 2021 (Study Day 184) - Ongoing	Insomnia
Tramadol hydrochloride	11 Mar 2021 (Study Day 184) - 11 Mar 2021 (Study Day 184)	Abdominal Pain
Enoxaparin sodium	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Prophylactic Cardiac
Esophagogastroduodenoscopy*	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Adverse Event
Lidocaine hydrochloride	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Pre-Op Egd
Morphine	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Abdominal Pain
Paracetamol	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Fever
Piperacillin; tazobactam	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Cholangitis/Sepsis
Promethazine	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Nausea Secondary To Worsening Gastroesophageal Reflux Disease
Propofol	12 Mar 2021 (Study Day 185) - 12 Mar 2021 (Study Day 185)	Anesthesia Egd Secondary To Abdominal Pain
Sodium chloride	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)	Fluid Resuscitation Secondary To Dehydration
Endoscopic retrograde cholangiopancreatography*	13 Mar 2021 (Study Day 186) - 13 Mar 2021 (Study Day 186)	Adverse Event
Levofloxacin	13 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 196)	Cholangitis/Sepsis
Metronidazole	13 Mar 2021 (Study Day 186) - 23 Mar 2021 (Study Day 196)	Sepsis/Cholangitis
Ondansetron	13 Mar 2021 (Study Day 186) - Ongoing	Nausea Secondary To Worsening Gastroesophageal Reflux Disease
Promethazine	13 Mar 2021 (Study Day 186) - Ongoing	Nausea Secondary To Worsening Gastroesophageal Reflux Disease
Laparoscopic biopsy of peritoneal and omental masses with frozen section and infusaport placement*	25 Mar 2021 (Study Day 198) - 25 Mar 2021 (Study Day 198)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	06 Jan 2021 (Study Day 120) - 05 Feb 2021 (Study Day 150)
Cough	Grade 1/mild	Not related	06 Jan 2021 (Study Day 120) - 05 Feb 2021 (Study Day 150)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lung Infiltration	Grade 2/moderate	Not related	08 Jan 2021 (Study Day 122) - 13 Jan 2021 (Study Day 127)
Gastroenteritis	Grade 2/moderate	Not related	10 Feb 2021 (Study Day 155) - Ongoing
Pancreatic Carcinoma	Grade 3/severe	Not related	26 Feb 2021 (Study Day 171) - Ongoing
Abdominal Pain	Grade 2/moderate	Not related	07 Mar 2021 (Study Day 180) - Ongoing
Insomnia	Grade 2/moderate	Not related	11 Mar 2021 (Study Day 184) - Ongoing
Pyrexia	Grade 2/moderate	Not related	11 Mar 2021 (Study Day 184) - 13 Mar 2021 (Study Day 186)
Bile Duct Obstruction	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Cholangitis	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Early Satiety	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Gastrooesophageal Reflux Disease	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Sepsis	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)
Transaminases Increased	Grade 3/severe	Not related	12 Mar 2021 (Study Day 185) - 13 Mar 2021 (Study Day 186)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2241 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Headache/Occipital Headache	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	20 Aug 2020 (Study Day 1) – 30 Sep 2020 (Study Day 42)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2241, a 67-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of headache. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of occipital headache lasted for 42 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 42). The investigator assessed the event of headache to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

On 31 Dec 2020 (Study Day 134), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mycotic allergy	Seasonal allergies - mold	1959 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies - cedar	1959 - Ongoing
Seasonal allergy	Seasonal allergies - oak	1959 - Ongoing
Food allergy	Food allergy - melon	1960 - Ongoing
Myopia	Myopia	1967 - Ongoing
Uterine leiomyoma	Uterine fibroids	1973 - 2000
Asthma	Asthma	1983 - Ongoing
Delivery	Vaginal delivery	1989 - 1989
Delivery	Vaginal delivery	1991 - 1991
Artificial menopause	Surgical menopause	2000 - Ongoing
Constipation	Constipation	2000 - Ongoing
Drug hypersensitivity	Allergy to sulfa drugs	2000 - Ongoing
Dry eye	Dry eyes	2000 - Ongoing
Hormone replacement therapy	Hormone replacement therapy	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Hysterectomy	Total hysterectomy	2000 - 2000
Rubber sensitivity	Allergy - latex	2000 - Ongoing
Salpingo-oophorectomy bilateral	Bilateral salpingo - oophorectomy	2000 - 2000
Urinary incontinence	Urinary incontinence	2000 - Ongoing
Hyperthyroidism	Hyperthyroidism	2001 - 2001
Hypothyroidism	Hypothyroidism	2001 - Ongoing
Thyroidectomy	Thyroidectomy	2001 - 2001
Cholecystectomy	Cholecystectomy	2003 - 2003
Cholelithiasis	Cholelithiasis	2003 - 2003
Intervertebral disc operation	Discectomy - c5-c6	2007 - 2007
Intervertebral disc protrusion	Bulging disc (c5,c6)	2007 - 2007
Insomnia	Insomnia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1960 - Ongoing	Supplement
Carmellose sodium	2000 - Ongoing	Dry Eyes
Estradiol	2000 - Ongoing	Hormone Replacement
Fibre, dietary	2000 - Ongoing	Constipation
Progesterone	2000 - Ongoing	Hormone Replacement
Quercetin	2000 - Ongoing	Seasonal Allergies
Thyroid	2001 - Ongoing	Hypothyroidism
Triamcinolone acetonide	2010 - Ongoing	Seasonal Allergies
Melatonin	2015 - Ongoing	Insomnia
Prednisolone	2015 - Ongoing	Asthma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Zolpidem	2015 - Ongoing	Insomnia
Montelukast	2017 - Ongoing	Seasonal Allergies
Telmisartan	Jan 2020 - Ongoing	Hypertension
Analgesics	20 Aug 2020 (Study Day 1) - 27 Aug 2020 (Study Day 8)	Headache - Reactogenicity
Paracetamol	20 Aug 2020 (Study Day 1) - 27 Aug 2020 (Study Day 8)	Reactogenicity (Headaches,fatigue)
Clindamycin	22 Sep 2020 (Study Day 34) - 24 Sep 2020 (Study Day 36)	Bilateral Lymphadenitis (Neck)
Influenza vaccine	13 Oct 2020 (Study Day 55) - 13 Oct 2020 (Study Day 55)	Prophylaxis
Punctal plugs*	06 Nov 2020 (Study Day 79) - 06 Nov 2020 (Study Day 79)	Medical History
Amoxicillin; clavulanic acid	27 Nov 2020 (Study Day 100) - 04 Dec 2020 (Study Day 107)	Abdominal Pain
Metronidazole	27 Nov 2020 (Study Day 100) - 04 Dec 2020 (Study Day 107)	Abdominal Pain
Other viral vaccines	24 Dec 2020 (Study Day 127) - 24 Dec 2020 (Study Day 127)	COVID-19 Vaccination

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	20 Aug 2020 (Study Day 1) - 21 Sep 2020 (Study Day 33)
Headache	Grade 2/moderate	Related	20 Aug 2020 (Study Day 1) - 30 Sep 2020 (Study Day 42)
Eye Swelling	Grade 1/mild	Not related	21 Aug 2020 (Study Day 2) - 12 Nov 2020 (Study Day 85)
Lymphadenitis	Grade 2/moderate	Related	21 Aug 2020 (Study Day 2) - 27 Oct 2020 (Study Day 69)
Abdominal Pain	Grade 2/moderate	Not related	24 Nov 2020 (Study Day 97) - 16 Dec 2020 (Study Day 119)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2253 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pleurisy/Idiopathic Pleurisy With Recurrence	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	18 Sep 2020 (Study Day 8) – 19 Oct 2020 (Study Day 39)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2253, a 24-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 11 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Sep 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of pleurisy. On 08 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of idiopathic pleurisy with recurrence lasted for 32 days, after which it was considered to be recovered/resolved on 19 Oct 2020 (Study Day 39). The investigator assessed the event of pleurisy to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pleurisy	Pleurisy	Oct 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine hydrochloride	02 Oct 2020 (Study Day 22) - 19 Oct 2020 (Study Day 39)	Ae Idiopathic Pleurisy With Recurrence
Salbutamol	02 Oct 2020 (Study Day 22) - 19 Oct 2020 (Study Day 39)	Ae Idiopathic Pleurisy With Recurrence
Ibuprofen	08 Oct 2020 (Study Day 28) - 22 Oct 2020 (Study Day 42)	Ae Idiopathic Pleurisy With Recurrence
Influenza vaccine	21 Oct 2020 (Study Day 41) - 21 Oct 2020 (Study Day 41)	Wellness

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pleurisy	Grade 2/moderate	Related	18 Sep 2020 (Study Day 8) - 19 Oct 2020 (Study Day 39)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2023 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Swollen Tongue/Tongue Swelling - Post Injection Allergic Reaction	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	03 Aug 2020 (Study Day 1) – 03 Aug 2020 (Study Day 1)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2023, a 55-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 03 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of swollen tongue. On 30 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of tongue swelling - post injection allergic reaction lasted for 1 days, after which it was considered to be recovered/resolved on 03 Aug 2020 (Study Day 1). The investigator assessed the event of swollen tongue to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dermal filler injection	Cosmetic dermal injection	Not reported
Depression	Depression	2000 - Ongoing
Postmenopause	Post menopausal	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion hydrochloride	2000 - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Swollen Tongue	Grade 2/moderate	Related	03 Aug 2020 (Study Day 1) - 03 Aug 2020 (Study Day 1)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2166 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 4	Not related	24 Nov 2020 (Study Day 100) – 07 Dec 2020 (Study Day 113)	Recovered/resolved
Type 2 Diabetes Mellitus/Worsening Of Diabetes Type 2	SAE	Grade 4	Not related	24 Nov 2020 (Study Day 100) – 07 Dec 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2166, a 65-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Nov 2020 (Study Day 100), 99 days after the first dose and 71 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute kidney injury lasted for 14 days, after which it was considered to be recovered/resolved on 07 Dec 2020 (Study Day 113). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 24 Nov 2020 (Study Day 100), 99 days after the first dose and 71 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of type 2 diabetes mellitus. Action taken with the IP was not applicable. The event of worsening of diabetes type 2 lasted for 14 days, after which it was considered to be recovered/resolved on 07 Dec 2020 (Study Day 113). The investigator assessed the event of type 2 diabetes mellitus to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001104	Acute kidney injury

CIOMS Number	MedDRA Preferred Term
MOD-2020-001104	Type 2 diabetes mellitus

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	1967 - 1967
Hypertension	Hypertension	1990 - Ongoing
Obesity	Obesity	2000 - Ongoing
Pulmonary embolism	Bilateral pulmonary emobolus	2009 - 2009
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Liraglutide	Not reported - May 2020	Diabetes Type Ii
Lisinopril	1990 - Ongoing	Hypertension
Metoprolol	Sep 1990 - Ongoing	Hypertension
Rivaroxaban	2009 - Ongoing	History Of Pulmonary Embolus/ Cardiac Health And Wellness
Insulin glargine	2010 - May 2020	Diabetes Type Ii
Pravastatin	2010 - Ongoing	Hyperlipidemia
Amoxicillin	01 Oct 2020 (Study Day 46) - 08 Oct 2020 (Study Day 53)	Fractured Tooth Resulting In Need For Tooth Extraction.
Hydrocodone bitartrate; paracetamol	01 Oct 2020 (Study Day 46) - Ongoing	Tooth Extraction/ Tooth Cracked
Root canal*	01 Oct 2020 (Study Day 46) - 01 Oct 2020 (Study Day 46)	Adverse Event
Tooth extraction*	01 Oct 2020 (Study Day 46) - 01 Oct 2020 (Study Day 46)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Hyperglycemia
Chemistry panel*	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Diagnostic
Glucagon	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Hyperglycemia
Glucose	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Hyperglycemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin human	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Hyperglycemia
Insulin lispro	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Hyperglycemia
Sodium chloride	24 Nov 2020 (Study Day 100) - 24 Nov 2020 (Study Day 100)	Hyperglycemia/Acute Kidney Injury
Insulin glargine	25 Nov 2020 (Study Day 101) - Ongoing	Diabetes Type Ii
Liraglutide	25 Nov 2020 (Study Day 101) - 01 Dec 2020 (Study Day 107)	Diabetes Mellitus Type Ii
Liraglutide	01 Dec 2020 (Study Day 107) - Ongoing	Diabetes Mellitus
Amlodipine	07 Dec 2020 (Study Day 113) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 1/mild	Not related	24 Aug 2020 (Study Day 8) - 25 Aug 2020 (Study Day 9)
Nausea	Grade 1/mild	Not related	24 Aug 2020 (Study Day 8) - 25 Aug 2020 (Study Day 9)
Hypertension	Grade 2/moderate	Not related	14 Sep 2020 (Study Day 29) - 07 Dec 2020 (Study Day 113)
Tooth Fracture	Grade 2/moderate	Not related	30 Sep 2020 (Study Day 45) - 01 Oct 2020 (Study Day 46)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	28 Nov 2020 (Study Day 104) - 07 Dec 2020 (Study Day 113)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2210 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia Right Lower Lobe	SAE	Grade 3/ severe	Not related	08 Jan 2021 (Study Day 141) – 14 Jan 2021 (Study Day 147)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2210, a 52-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 22 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Jan 2021 (Study Day 141), 140 days after the first dose and 108 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia right lower lobe lasted for 7 days, after which it was considered to be recovered/resolved on 14 Jan 2021 (Study Day 147). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003211	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1969 - Ongoing
Gastrooesophageal reflux disease	Gerd (acid reflux)	2015 - 29 Sep 2020 (Study Day 40)
Barrett's oesophagus	Barrett's esophagus dysplasia	21 Sep 2018 (Study Day -700) - Ongoing
Foot fracture	Right foot fracture	2019 - 2019
Localised infection	Right foot infection	2019 - 2019
Skin graft	Right foot skin graft	2019 - 2019
Hyperlipidaemia	Hyperlipidemia	14 Jun 2019 (Study Day -434) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate; salmeterol	2015 - Ongoing	Asthma
Montelukast	2015 - Ongoing	Asthma
Salbutamol	2015 - Ongoing	Asthma
Pantoprazole	2017 - Ongoing	Gerd (Acid Reflux)
Atorvastatin	2019 - Ongoing	Hyperlipidemia
Ibuprofen	22 Aug 2020 (Study Day 2) - 26 Aug 2020 (Study Day 6)	Upper Respiratory Illness
Azithromycin	08 Jan 2021 (Study Day 141) - 08 Jan 2021 (Study Day 141)	Pneumonia Right Lower Lobe
Calcium chloride; potassium chloride; sodium lactate	08 Jan 2021 (Study Day 141) - 08 Jan 2021 (Study Day 141)	Pneumonia Right Lower Lobe
Ceftriaxone	08 Jan 2021 (Study Day 141) - 08 Jan 2021 (Study Day 141)	Pneumonia Right Lower Lobe
Oxygen	08 Jan 2021 (Study Day 141) - 08 Jan 2021 (Study Day 141)	Pneumonia Right Lower Lobe
Azithromycin	10 Jan 2021 (Study Day 143) - 14 Jan 2021 (Study Day 147)	Pneumonia
Benzonatate	10 Jan 2021 (Study Day 143) - 14 Jan 2021 (Study Day 147)	Pneumonia
Dextromethorphan hydrobromide; guaifenesin	10 Jan 2021 (Study Day 143) - 14 Jan 2021 (Study Day 147)	Pneumonia
Ipratropium; salbutamol	10 Jan 2021 (Study Day 143) - 14 Jan 2021 (Study Day 147)	Pneumonia/Asthma Exacerbation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	22 Aug 2020 (Study Day 2) - 30 Aug 2020 (Study Day 10)
Asthma	Grade 3/severe	Not related	08 Jan 2021 (Study Day 141) - 14 Jan 2021 (Study Day 147)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2222 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Cholecystitis	SAE	Grade 4	Not related	09 Oct 2020 (Study Day 43) – 11 Oct 2020 (Study Day 45)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2222, a 51-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Oct 2020 (Study Day 43), 42 days after the first dose and 7 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 3 days, after which it was considered to be recovered/resolved on 11 Oct 2020 (Study Day 45). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000458	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pseudodementia	Pseudodementia	Not reported - Ongoing
Anxiety	Anxiety	1984 - Ongoing
Depression	Depression	1984 - Ongoing
Migraine	Migraine	1984 - Ongoing
Female sterilisation	Bilateral tubal ligation	2013 - 2013
Asthma	Asthma	2014 - Ongoing
Autoimmune thyroiditis	Hashimoto's thyroiditis	2014 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Anal fissure excision	Anal fissure repair	Jun 2019 - Jun 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion	2010 - Ongoing	Anxiety
Topiramate	2010 - 28 Sep 2020 (Study Day 32)	Migraine
Salbutamol	2014 - Ongoing	Asthma
Sumatriptan	2015 - Ongoing	Migraine
Levothyroxine sodium	Feb 2020 - Ongoing	Hypothyroidism
Duloxetine hydrochloride	08 Sep 2020 (Study Day 12) - 02 Oct 2020 (Study Day 36)	Migraine
Duloxetine hydrochloride	02 Oct 2020 (Study Day 36) - Ongoing	Migraine
Paracetamol	03 Oct 2020 (Study Day 37) - 04 Oct 2020 (Study Day 38)	Headache, Pain At Injection Site, Muscle Aches, Fatigue, To Treat/Prevent Pain/Fever From Occurring/Already Occurred.
Calcium chloride; potassium chloride; sodium lactate	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystectomy
Cholecystectomy*	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Adverse Event
Dexamethasone	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystectomy
Fentanyl	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystectomy
Glycopyrronium	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystectomy
Ketorolac	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystectomy
Lidocaine	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystitis/ Cholecystectomy

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Midazolam	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystitis/ Cholecystectomy
Neostigmine	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystitis/ Cholecystectomy
Ondansetron	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystitis/ Cholecystectomy
Propofol	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystitis/ Cholecystectomy
Rocuronium	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Cholecystitis/ Cholecystectomy
Docusate sodium	11 Oct 2020 (Study Day 45) - Ongoing	Constipation Prevention
Methocarbamol	11 Oct 2020 (Study Day 45) - 17 Oct 2020 (Study Day 51)	Cholecystitis
Ondansetron	11 Oct 2020 (Study Day 45) - 12 Oct 2020 (Study Day 46)	Nausea Prevention
Oxycodone	11 Oct 2020 (Study Day 45) - 12 Oct 2020 (Study Day 46)	Post Operative Pain/Prevention
Ofloxacin	04 Feb 2021 (Study Day 161) - 10 Feb 2021 (Study Day 167)	Ear Infection
Paracetamol	08 Mar 2021 (Study Day 193) - 08 Mar 2021 (Study Day 193)	Migraine
Sumatriptan	08 Mar 2021 (Study Day 193) - 08 Mar 2021 (Study Day 193)	Migraine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	17 Dec 2020 (Study Day 112) - 21 Dec 2020 (Study Day 116)
Otitis Externa	Grade 2/moderate	Not related	04 Feb 2021 (Study Day 161) - 11 Feb 2021 (Study Day 168)
Glucose Tolerance Impaired	Grade 2/moderate	Not related	09 Mar 2021 (Study Day 194) - Ongoing
Lymphadenopathy	Grade 2/moderate	Not related	09 Mar 2021 (Study Day 194) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2244 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthritis/Worsening Of Left Hip Pain/Arthritis	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	08 Sep 2020 (Study Day 16) – 11 Nov 2020 (Study Day 80)	Recovered/resolved
Fracture Nonunion/Worsening Of Anterior Left Pelvic Ring Non-Union	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	09 Sep 2020 (Study Day 17) – 05 Oct 2020 (Study Day 43)	Recovered/resolved
Postoperative Abscess/Post Operative Intra-Abdominal Abscess	SAE	Grade 4	Not related	12 Oct 2020 (Study Day 50) – 13 Oct 2020 (Study Day 51)	Recovered/resolved
Axillary Vein Thrombosis/Right Axillary Deep Vein Thrombosis	SAE	Grade 4	Not related	19 Oct 2020 (Study Day 57) – 05 Nov 2020 (Study Day 74)	Recovered/resolved
Deep Vein Thrombosis/Right Brachial Deep Vein Thrombosis	SAE	Grade 4	Not related	19 Oct 2020 (Study Day 57) – 05 Nov 2020 (Study Day 74)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2244, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of arthritis. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening of left hip pain/arthritis lasted for 65 days, after which it was considered to be recovered/resolved

on 11 Nov 2020 (Study Day 80). The investigator assessed the event of arthritis to be not related to the IP.

On 09 Sep 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of fracture nonunion. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening of anterior left pelvic ring non-union lasted for 27 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 43). The investigator assessed the event of fracture nonunion to be not related to the IP.

On 12 Oct 2020 (Study Day 50), 49 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of postoperative abscess. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of post operative intra-abdominal abscess lasted for 2 days, after which it was considered to be recovered/resolved on 13 Oct 2020 (Study Day 51). The investigator assessed the event of postoperative abscess to be not related to the IP.

On 19 Oct 2020 (Study Day 57), 56 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of axillary vein thrombosis. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of right axillary deep vein thrombosis lasted for 18 days, after which it was considered to be recovered/resolved on 05 Nov 2020 (Study Day 74). The investigator assessed the event of axillary vein thrombosis to be not related to the IP.

On 19 Oct 2020 (Study Day 57), 56 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of deep vein thrombosis. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of right brachial deep vein thrombosis lasted for 18 days, after which it was considered to be recovered/resolved on 05 Nov 2020 (Study Day 74). The investigator assessed the event of deep vein thrombosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious and serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000570	Axillary vein thrombosis
MOD-2020-000570	Deep venous thrombosis arm
MOD-2020-000570	Postoperative abscess
MOD-2020-000592	Fracture nonunion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arrhythmia	Abnormal heart rhythm	Not reported - Ongoing
Postmenopause	Post menopause	Not reported - Ongoing
Thalassaemia alpha	Alpha thalassemia	Not reported - Ongoing
Osteoarthritis	Osteoarthritis bilateral hands	2010 - Ongoing
Osteoporosis	Osteoporosis	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Arthralgia	Left hip pain	Feb 2020 - Ongoing
Pelvic fracture	Fractured pelvis (left pelvic ring non-union)	Feb 2020 - Ongoing
Upper limb fracture	Fractured left elbow	Feb 2020 - Feb 2020
Intervertebral disc degeneration	Degenerative disc disease	27 Apr 2020 (Study Day -119) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2010 - Ongoing	Osteoarthritis
Atorvastatin	2015 - 03 Nov 2020 (Study Day 72)	Hyperlipidemia
Alendronate sodium	2019 - Ongoing	Osteoporosis
Tramadol	Feb 2020 - 03 Nov 2020 (Study Day 72)	Osteoarthritis
Paracetamol	25 Aug 2020 (Study Day 2) - 27 Aug 2020 (Study Day 4)	Osteoarthritis
Gabapentin	09 Sep 2020 (Study Day 17) - 03 Nov 2020 (Study Day 72)	Worsening Of Anterior Left Pelvic Ring Non-Union
Methylprednisolone	09 Sep 2020 (Study Day 17) - 13 Sep 2020 (Study Day 21)	Pain/ Hip Fracture
Bisacodyl	22 Sep 2020 (Study Day 30) - 29 Oct 2020 (Study Day 67)	Help Prevent Constipation From Pain Medication
Hydrocodone bitartrate; paracetamol	22 Sep 2020 (Study Day 30) - 03 Nov 2020 (Study Day 72)	Pain Secondary Worsening Of Anterior Left Pelvic Ring Non-Union
Left pelvic ring fracture nonunion repair*	29 Sep 2020 (Study Day 37) - 29 Sep 2020 (Study Day 37)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium chloride; potassium chloride; sodium lactate	12 Oct 2020 (Study Day 50) - 12 Oct 2020 (Study Day 50)	Iv Hydration Secondary To Post Operative Intra-Abdominal Abscess
Drainage of abscess*	13 Oct 2020 (Study Day 51) - 13 Oct 2020 (Study Day 51)	Adverse Event
Picc line placement right arm*	18 Oct 2020 (Study Day 56) - 18 Oct 2020 (Study Day 56)	Adverse Event
Apixaban	20 Oct 2020 (Study Day 58) - 20 Nov 2020 (Study Day 89)	Right Axillary And Brachial Deep Vein Thrombosis
Cefradine	20 Oct 2020 (Study Day 58) - 03 Nov 2020 (Study Day 72)	Post Operative Intra-Abdominal Abscess
Diclofenac	20 Oct 2020 (Study Day 58) - 03 Nov 2020 (Study Day 72)	Left Hip Pain Due To Worsening Of Anterior Left Pelvic Ring Non-Union
Ferrous sulfate	20 Oct 2020 (Study Day 58) - Ongoing	Alpha Thalassemia
Picc line placement left arm*	20 Oct 2020 (Study Day 58) - 20 Oct 2020 (Study Day 58)	Adverse Event
Rifampicin	20 Oct 2020 (Study Day 58) - 03 Nov 2020 (Study Day 72)	Post Operative Intra-Abdominal Abscess
Linezolid	04 Nov 2020 (Study Day 73) - 13 Nov 2020 (Study Day 82)	Post-Operative Intrabdominal Abscess
Denosumab	05 Nov 2020 (Study Day 74) - 05 Nov 2020 (Study Day 74)	Osteoporosis
Daptomycin	09 Nov 2020 (Study Day 78) - 19 Nov 2020 (Study Day 88)	Post Operative Intrabdominal Abscess
Calcium	13 Nov 2020 (Study Day 82) - Ongoing	Osteoporosis
Doxycycline	24 Nov 2020 (Study Day 93) - Ongoing	Joint Infection Prophylaxis - Suppression Antibiotics

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthritis	Grade 2/moderate	Not related	08 Sep 2020 (Study Day 16) - 11 Nov 2020 (Study Day 80)
Rash Macular	Grade 1/mild	Not related	11 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 26)
Diarrhoea	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 67) - 12 Nov 2020 (Study Day 81)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2285 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	22 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/ Cerebrovascular Accident	SAE	Grade 4	Not related	16 Nov 2020 (Study Day 54) – 18 Nov 2020 (Study Day 56)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2285, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 24 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 22 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Nov 2020 (Study Day 54), 53 days after the first dose and 25 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of cerebrovascular accident lasted for 3 days, after which it was considered to be recovered/resolved on 18 Nov 2020 (Study Day 56). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000873	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Drug allergy - penicillin	1955 - Ongoing
Erectile dysfunction	Erectile disease	2001 - Ongoing
Hypertension	Hypertension	2001 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2001 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Benign prostatic hyperplasia	Benign prostaste hypertrophy	2013 - Ongoing
Drug hypersensitivity	Drug allergy - statins	2014 - Ongoing
Drug hypersensitivity	Drug allergy - clarithromycin	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2018 - Ongoing
Intervertebral disc operation	Lumbar discetomy	2018 - 2018
Polyarthritis	Generalized arthritis	2018 - Ongoing
Vascular stent insertion	Right vascular stent placement	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glipizide	2001 - 2020	Diabetes Type Ii
Hydrochlorothiazide; losartan potassium	2001 - Ongoing	Hypertension
Vardenafil hydrochloride	2001 - Ongoing	Erectile Dysfunction
Omeprazole	2010 - Ongoing	Gastroesophageal Reflux Disease
Finasteride	2013 - Ongoing	Benign Prostate Hypertrophy
Tamsulosin	2013 - Ongoing	Benign Prostate Hypertrophy
Acetylsalicylic acid	2018 - 16 Nov 2020 (Study Day 54)	Cardiac Health
Dulaglutide	2018 - Ongoing	Diabetes Type Ii
Ezetimibe	2018 - Ongoing	Hyperlipidemia
Meloxicam	2018 - 16 Nov 2020 (Study Day 54)	Generalized Arthritis
Empagliflozin	Sep 2020 - Ongoing	Diabetes Type Ii
Influenza vaccine	11 Nov 2020 (Study Day 49) - 11 Nov 2020 (Study Day 49)	Influenza Prevention
Pneumococcal vaccine	11 Nov 2020 (Study Day 49) - 11 Nov 2020 (Study Day 49)	Pneumonia Prevention
Acetylsalicylic acid	16 Nov 2020 (Study Day 54) - 18 Nov 2020 (Study Day 56)	Cerebrovascular Accident
Glimepiride	16 Nov 2020 (Study Day 54) - Mar 2021	Diabetes Type Ii
Clopidogrel	24 Nov 2020 (Study Day 62) - Ongoing	Prevention Of Cerebrovascular Accident

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	15 Dec 2020 (Study Day 83) - Ongoing	Cerebrovascular Accident
Pacemaker*	25 Feb 2021 (Study Day 155) - 25 Feb 2021 (Study Day 155)	Medical History
Vancomycin	25 Feb 2021 (Study Day 155) - 25 Feb 2021 (Study Day 155)	Pre-Op Surgery For Pace Maker Placement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atrioventricular Block	Grade 3/severe	Not related	05 Jan 2021 (Study Day 104) - 25 Feb 2021 (Study Day 155)
Syncope	Grade 3/severe	Not related	05 Jan 2021 (Study Day 104) - 05 Jan 2021 (Study Day 104)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2005 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 43)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hip Fracture/Fractured Left Hip	SAE	Grade 3/ severe	Not related	25 Aug 2020 (Study Day 22) – 26 Aug 2020 (Study Day 23)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2005, a 94-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 15 Sep 2020 (Study Day 43). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Aug 2020 (Study Day 22), 21 days after the first dose and 21 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hip fracture. The IP dose was delayed due to the fractured left hip. The event of fractured left hip lasted for 2 days, after which it was considered to be recovered/resolved on 26 Aug 2020 (Study Day 23). The investigator assessed the event of hip fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000234	Hip fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Inguinal hernia	Inguinal hernia - left	1995 - 1995
Inguinal hernia	Inguinal hernia - right	1995 - 1995
Inguinal hernia repair	Left inguinal herniorrhaphy	1995 - 1995
Inguinal hernia repair	Right inguinal herniorrhaphy	1995 - 1995
Knee arthroplasty	Left knee replacement	2009 - 2009
Osteoarthritis	Osteoarthritis left knee	2009 - 2009
Knee arthroplasty	Right knee replacement	2018 - 2018
Osteoarthritis	Osteoarthritis right knee	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	1990 - Ongoing	Dietary Supplement
Calcium	1990 - Ongoing	Dietary Supplement
Colecalciferol	1990 - Ongoing	Dietary Supplement
Curcuma longa	1990 - Ongoing	Dietary Supplement
Krill oil	1990 - Ongoing	Dietary Supplement
Lycopene	1990 - Ongoing	Dietary Supplement
Lycopene; pinus spp. bark; prunus africana bark; selenium amino acid chelate; serenoa repens fruit; sitosterol; urtica dioica leaf; vitis spp.; zinc	1990 - Ongoing	Dietary Supplement
Magnesium	1990 - Ongoing	Dietary Supplement
Monascus purpureus	1990 - Ongoing	Dietary Supplement
Prasterone	1990 - Ongoing	Dietary Supplement
Ubidecarenone	1990 - Ongoing	Dietary Supplement
Vitamin b complex	1990 - Ongoing	Dietary Supplement
Vitamin b12 nos	1990 - Ongoing	Dietary Supplement
Vitamin k nos	1990 - Ongoing	Dietary Supplement
Vitamins nos	1990 - Ongoing	Dietary Supplement
Xantofyl	1990 - Ongoing	Dietary Supplement
Influenza vaccine	Nov 2019 - Nov 2019	Influenza Prophylaxis/Prevention
Pneumococcal vaccine	Nov 2019 - Nov 2019	Pneumonia Prophylaxis/Prevention
Varicella zoster vaccine	Nov 2019 - Nov 2019	Herpes Zoster Prophylaxis/Prevention
Famotidine	25 Aug 2020 (Study Day 22) - 31 Aug 2020 (Study Day 28)	Gastroesophageal Reflux Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Left hip x-ray*	25 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 22)	Adverse Event
Oxycodone hydrochloride; paracetamol	25 Aug 2020 (Study Day 22) - Ongoing	Left Hip Pain
Left hip hemiarthroplasty*	26 Aug 2020 (Study Day 23) - 26 Aug 2020 (Study Day 23)	Adverse Event
Bisacodyl	28 Aug 2020 (Study Day 25) - Ongoing	Constipation
Paracetamol	28 Aug 2020 (Study Day 25) - Ongoing	Left Hip Pain
Rivaroxaban	28 Aug 2020 (Study Day 25) - 08 Sep 2020 (Study Day 36)	Blood Clot Prevention
Zolpidem	17 Sep 2020 (Study Day 45) - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fall	Grade 2/moderate	Related	25 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 22)
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	25 Aug 2020 (Study Day 22) - 31 Aug 2020 (Study Day 28)
Constipation	Grade 1/mild	Not related	28 Aug 2020 (Study Day 25) - Ongoing
Insomnia	Grade 1/mild	Not related	28 Aug 2020 (Study Day 25) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2060 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Joint Injury/Right Hip Trauma	SAE	Grade 4	Not related	14 Aug 2020 (Study Day 8) – 16 Aug 020 (Study Day 10)	Recovered/resolved
Joint Injury/Right Knee Trauma	SAE	Grade 4	Not related	14 Aug 2020 (Study Day 8) – 04 Sep 2020 (Study Day 29)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2060, a 60-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Aug 2020 (Study Day 8), 7 days after the first dose and 27 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of joint injury. The IP dose was not changed due to the right hip trauma. The event of right hip trauma lasted for 3 days, after which it was considered to be recovered/resolved on 16 Aug 2020 (Study Day 10). The investigator assessed the event of joint injury to be not related to the IP.

On 14 Aug 2020 (Study Day 8), 7 days after the first dose and 27 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of joint injury. Action taken with the IP was not applicable. The event of right knee trauma lasted for 22 days, after which it was considered to be recovered/resolved on 04 Sep 2020 (Study Day 29). The investigator assessed the event of joint injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000406	Joint injury
MOD-2020-000406	Joint injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Knee arthroplasty	Arthroplasty right knee	Apr 1996 - Apr 1996
Meniscus injury	Torn meniscus right knee	Apr 1996 - Apr 1996
Pancreatitis chronic	Chronic pancreatitis	2014 - Ongoing
Coronary angioplasty	Coronary artery angioplasty	Sep 2014 - Sep 2014
Coronary artery disease	Coronary artery disease	Sep 2014 - Sep 2014
Insomnia	Insomnia	2017 - Ongoing
Arthralgia	Bilateral knee pain	2018 - Ongoing
Back pain	Chronic lower back pain	2018 - Ongoing
Head injury	Head trauma	Sep 2018 - Sep 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2016 - Ongoing	Cardiac Prophylaxis
Zolpidem tartrate	2017 - Ongoing	Insomnia
Oxycodone hydrochloride	2018 - Ongoing	Bilateral Knee Pain
Oxycodone hydrochloride	2018 - Ongoing	Lower Back Pain
Trazodone	2019 - Ongoing	Bilateral Knee Pain
Trazodone	2019 - Ongoing	Lower Back Pain
Influenza vaccine	Sep 2019 - Sep 2019	Influenza Prophylaxis/Prevention
Cat scan of the abdomen*	14 Aug 2020 (Study Day 8) - 14 Aug 2020 (Study Day 8)	Adverse Event
Cat scan of the cervical spine*	14 Aug 2020 (Study Day 8) - 14 Aug 2020 (Study Day 8)	Adverse Event
Cefazolin	14 Aug 2020 (Study Day 8) - 14 Aug 2020 (Study Day 8)	Right Knee Laceration
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	14 Aug 2020 (Study Day 8) - 14 Aug 2020 (Study Day 8)	Tetanus Prophylaxis/Prevention
Iopamidol	14 Aug 2020 (Study Day 8) - 14 Aug 2020 (Study Day 8)	Radiopaque Contrast Agent
Oxycodone hydrochloride; paracetamol	14 Aug 2020 (Study Day 8) - 14 Aug 2020 (Study Day 8)	Right Knee Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
X-ray of right knee*	14 Aug 2020 (Study Day 8) - 14 Aug 2020 (Study Day 8)	Adverse Event
Morphine	15 Aug 2020 (Study Day 9) - 15 Aug 2020 (Study Day 9)	Right Knee Pain
Pancrelipase	15 Aug 2020 (Study Day 9) - 16 Aug 2020 (Study Day 10)	Pancreatic Enzyme Replacement
Doxycycline	16 Aug 2020 (Study Day 10) - 26 Aug 2020 (Study Day 20)	Right Knee Trauma Laceration Infection Prevention
Cyclobenzaprine	17 Aug 2020 (Study Day 11) - Ongoing	Right Knee Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US337-2110 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	31 Aug 2020 (Study Day 19) – 14 Sep 2020 (Study Day 33)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2110, a 52-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Aug 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of COVID-19 lasted for 15 days, after which it was considered to be recovered/resolved on 14 Sep 2020 (Study Day 33). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cleft lip	Cleft lip	1970 - 1970
Cleft lip repair	Cleft lip repair	1970 - 1970
Sinuplasty	Sinus ostial dilation	1998 - 1998

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Blood testosterone decreased	Low testosterone	2010 - Ongoing
Chronic sinusitis	Chronic sinusitis	2010 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Sinus polyp	Removal of sinus polyps	2018 - 2018
Sinus polyp	Sinus polyps	2018 - 2018
Hypercholesterolaemia	Hypercholesterolemia	24 Jul 2020 (Study Day -20) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Montelukast sodium	2010 - Ongoing	Chronic Sinusitis
Testosterone	2010 - Ongoing	Low Testosterone
Losartan	2016 - Ongoing	Hypertension
Rosuvastatin	24 Jul 2020 (Study Day -20) - Ongoing	Hypercholesterolemia
Azithromycin	04 Sep 2020 (Study Day 23) - 08 Sep 2020 (Study Day 27)	Sinus Infection
Methylprednisolone	04 Sep 2020 (Study Day 23) - 10 Sep 2020 (Study Day 29)	Acute Sinusitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	31 Aug 2020 (Study Day 19) - 14 Sep 2020 (Study Day 33)
Acute Sinusitis	Grade 1/mild	Not related	04 Sep 2020 (Study Day 23) - 10 Sep 2020 (Study Day 29)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2137 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dizziness/Dizziness	SAE	Grade 3/severe	Not related	19 Jan 2021 (Study Day 159) – 22 Jan 2021 (Study Day 162)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2137, a 73-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Jan 2021 (Study Day 159), 158 days after the first dose and 126 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of dizziness. Action taken with the IP was not applicable. The event of dizziness lasted for 4 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 162). The investigator assessed the event of dizziness to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008634	Dizziness

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy - sulfa	1962 - Ongoing
Basal cell carcinoma	Left ear basal cell carcinoma	1980 - Apr 2019
Basal cell carcinoma	Left leg basal cell carcinoma	1980 - Jan 2020
Basal cell carcinoma	Right upper arm basal cell carcinoma	1980 - Dec 2018
Osteoarthritis	Bilateral knee osteoarthritis	2000 - Ongoing
Postmenopause	Postmenopausal	2002 - Ongoing
Anxiety	Anxiety	2008 - Ongoing
Depression	Depression	2008 - Ongoing
Oedema peripheral	Edema bilateral lower extremities	2010 - Ongoing
Appendicectomy	Appendectomy	Dec 2010 - Dec 2010
Appendicitis	Appendicitis	Dec 2010 - Dec 2010
Dermal filler injection	Juvederm (cosmetic)	2016 - 2016
Electrodesiccation	Right upper arm curettage and electrodesiccation	Dec 2018 - Dec 2018
Uterine dilation and curettage	Dilation and curettage	Jan 2019 - Jan 2019
Uterine polyp	Uterine polyps	Jan 2019 - Jan 2019
Electrodesiccation	Left ear curettage and electrodesiccation	Apr 2019 - Apr 2019
Electrodesiccation	Left leg curettage and electrodesiccation	Jan 2020 - Jan 2020
Umbilical hernia	Umbilical hernia	14 Aug 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram	2008 - Ongoing	Anxiety
Escitalopram	2008 - Ongoing	Depression
Calcium; magnesium	2018 - Ongoing	Dietary Supplement
Colecalciferol	2018 - Ongoing	Dietary Supplement
Influenza vaccine	Oct 2019 - Oct 2019	Influenza Prophylaxis/Prevention
Amoxicillin trihydrate; clavulanate potassium	14 Dec 2020 (Study Day 123) - 24 Dec 2020 (Study Day 133)	Upper Respiratory Infection
Guaifenesin	14 Dec 2020 (Study Day 123) - 21 Dec 2020 (Study Day 130)	Sinus Congestion
Benzonatate	16 Dec 2020 (Study Day 125) - 21 Dec 2020 (Study Day 130)	Cough

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cat head/brain w/o contrast*	19 Jan 2021 (Study Day 159) - 19 Jan 2021 (Study Day 159)	Adverse Event
Chest x-ray*	19 Jan 2021 (Study Day 159) - 19 Jan 2021 (Study Day 159)	Adverse Event
Mri brain*	21 Jan 2021 (Study Day 161) - 21 Jan 2021 (Study Day 161)	Adverse Event
Mri cervical spine*	21 Jan 2021 (Study Day 161) - 21 Jan 2021 (Study Day 161)	Adverse Event
Acetylsalicylic acid	23 Jan 2021 (Study Day 163) - Ongoing	Cardiac Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 2/moderate	Not related	12 Dec 2020 (Study Day 121) - 28 Dec 2020 (Study Day 137)
Headache	Grade 1/mild	Not related	12 Dec 2020 (Study Day 121) - 20 Dec 2020 (Study Day 129)
Sinus Congestion	Grade 1/mild	Not related	12 Dec 2020 (Study Day 121) - 19 Dec 2020 (Study Day 128)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	14 Dec 2020 (Study Day 123) - 24 Dec 2020 (Study Day 133)
Wheezing	Grade 1/mild	Not related	14 Dec 2020 (Study Day 123) - 17 Dec 2020 (Study Day 126)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2184 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/ Appendicitis	SAE	Grade 3/severe	Not related	02 Sep 2020 (Study Day 15) – 02 Sep 2020 (Study Day 15)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2184, a 72-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 22 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Sep 2020 (Study Day 15), 14 days after the first dose and 20 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. The IP dose was not changed due to the appendicitis. The event of appendicitis lasted for 1 day, after which it was considered to be recovered/resolved on 02 Sep 2020 (Study Day 15). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000254	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Genital herpes	Genital herpes	1958 - Ongoing
Hypertension	Hypertension	1970 - Ongoing
Anxiety	Anxiety	1974 - Ongoing
Hypersensitivity	Allergy - environmental	1994 - Ongoing
Sinusitis	Sinusitis	1994 - Ongoing
Osteoarthritis	Generalized osteoarthritis	1995 - Ongoing
Essential tremor	Essential tremors	1997 - Ongoing
Erectile dysfunction	Erectile dysfunction	1999 - Ongoing
Osteopenia	Osteopenia	1999 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Vocal cord polyp	Vocal cord polyps	2005 - 2005
Vocal cord polypectomy	Vocal cord polypectomy	2005 - 2005
Craniotomy	Burr hole	2007 - 2007
Subdural haematoma	Subdural hematoma	2007 - 2007
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2009 - Ongoing
Cataract	Cataracts bilateral	2013 - 2013
Cataract operation	Cataracts surgery bilateral	2013 - 2013
Carpal tunnel syndrome	Carpal tunnel syndrome left wrist	2017 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia (bph)	2019 - Ongoing
Haemorrhoids	Internal hemorrhoids	2019 - Ongoing
Urinary retention	Urinary retention	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1975 - Ongoing	Dietary Supplement
Azelastine	1994 - Ongoing	Sinusitis
Atenolol	1995 - Ongoing	Hypertension
Naproxen	1995 - Ongoing	Generalized Osteoarthritis Pain
Propranolol	1999 - Ongoing	Essential Tremors
Sildenafil	1999 - Ongoing	Erectile Dysfunction
Celecoxib	2002 - Ongoing	Generalized Osteoarthritis Pain
Atorvastatin	2005 - Ongoing	Hypercholesterolemia
Calcium	2009 - Ongoing	Dietary Supplement
Colecalciferol	2009 - Ongoing	Dietary Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famciclovir	2009 - Ongoing	Genital Herpes
Alprazolam	2010 - Ongoing	Anxiety
Diphtheria vaccine toxoid; pertussis vaccine; tetanus vaccine toxoid	2011 - 2011	Diphtheria Tetanus And Acellular Pertussis Prophylaxis/Prevention
Esomeprazole	2012 - Ongoing	Gastroesophageal Reflux Disease
Pneumococcal vaccine	2015 - 2015	Pneumonia Prophylaxis/Prevention
Losartan	2017 - Ongoing	Hypertension
Docusate	2018 - Ongoing	Constipation Prophylaxis/Prevention
Macrogol 3350	2018 - Ongoing	Constipation Prophylaxis/Prevention
Tamsulosin	2019 - Ongoing	Benign Prostatic Hyperplasiia (Bph)
Tamsulosin	2019 - Ongoing	Urinary Retention
Influenza vaccine	Sep 2019 - Sep 2019	Influenza Prophylaxis/Prevention
Varicella zoster vaccine	Sep 2019 - Sep 2019	Herpes Zoster Prophylaxis/Prevention
Corticosteroid nos	Oct 2019 - Oct 2019	Carpal Tunnel Syndrome Left Wrist
Paracetamol	28 Aug 2020 (Study Day 10) - 28 Aug 2020 (Study Day 10)	Right Lower Abdominal Pain
Appendectomy*	02 Sep 2020 (Study Day 15) - 02 Sep 2020 (Study Day 15)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)	Keep Vein Open For Iv Medications
Hydralazine	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)	Hypertension
Morphine	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)	Right Lower Abdominal Pain
Ondansetron	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)	Nausea
Oxycodone hydrochloride; paracetamol	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)	Right Lower Abdominal Pain
Pantoprazole	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)	Gastroesophageal Reflux Disease
Piperacillin; tazobactam	02 Sep 2020 (Study Day 15) - 03 Sep 2020 (Study Day 16)	Appendicitis
Amoxicillin; clavulanic acid	07 Sep 2020 (Study Day 20) - 10 Sep 2020 (Study Day 23)	Post Surgical Infection Prevention
Influenza vaccine	14 Oct 2020 (Study Day 57) - 14 Oct 2020 (Study Day 57)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain Lower	Grade 2/moderate	Not related	28 Aug 2020 (Study Day 10) - 28 Aug 2020 (Study Day 10)
Diarrhoea	Grade 1/mild	Not related	29 Aug 2020 (Study Day 11) - 30 Aug 2020 (Study Day 12)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Not related	02 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 18)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2209 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Atrial Fibrillation	SAE	Grade 4	Not related	16 Dec 2020 (Study Day 118) – 17 Dec 2020 (Study Day 119)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2209, a 73-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 23 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Dec 2020 (Study Day 118), 117 days after the first dose and 84 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of atrial fibrillation lasted for 2 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 119). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001204	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic tonsillitis	Tonsillitis - chronic	1965 - 1965
Tonsillectomy	Tonsillectomy	1965 - 1965
Hypertension	Hypertension	2000 - Ongoing
Cholesteatoma	Right ear cholesteatoma	2004 - 2004
Mastoidectomy	Right ear mastoidectomy	2004 - 2004
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Prostate cancer	Prostate cancer	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	1995 - Ongoing	Dietary Supplement
Fish oil	1995 - Ongoing	Dietary Supplement
Ubidecarenone	1995 - Ongoing	Dietary Supplement
Vitamin b12 nos	1995 - Ongoing	Dietary Supplement
Vitamins nos	1995 - Ongoing	Dietary Supplement
Atenolol	2000 - Ongoing	Hypertension
Atorvastatin	2005 - Ongoing	Hypercholesterolemia
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Magnesium	2015 - Ongoing	Dietary Supplement
Melatonin	2015 - Ongoing	Dietary Supplement
Pneumococcal vaccine	2018 - 2018	Pneumonia Prophylaxis/Prevention
Influenza vaccine	Nov 2019 - Nov 2019	Influenza Prophylaxis/Prevention
Influenza vaccine	08 Sep 2020 (Study Day 19) - 08 Sep 2020 (Study Day 19)	Influenza Prophylaxis/Prevention
Apixaban	16 Dec 2020 (Study Day 118) - Ongoing	Atrial Fibrillation
Cat scan brain*	16 Dec 2020 (Study Day 118) - 16 Dec 2020 (Study Day 118)	Adverse Event
Chest x-ray*	16 Dec 2020 (Study Day 118) - 16 Dec 2020 (Study Day 118)	Adverse Event
Diltiazem	16 Dec 2020 (Study Day 118) - 16 Dec 2020 (Study Day 118)	Atrial Fibrillation
Electrocardiogram*	16 Dec 2020 (Study Day 118) - 16 Dec 2020 (Study Day 118)	Adverse Event
Sodium chloride	16 Dec 2020 (Study Day 118) - 16 Dec 2020 (Study Day 118)	Dehydration

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dehydration	Grade 2/moderate	Not related	16 Dec 2020 (Study Day 118) - 17 Dec 2020 (Study Day 119)
Palpitations	Grade 1/mild	Not related	16 Dec 2020 (Study Day 118) - 16 Dec 2020 (Study Day 118)
Syncope	Grade 2/moderate	Not related	16 Dec 2020 (Study Day 118) - 16 Dec 2020 (Study Day 118)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2274 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarct	SAE	Grade 2/ moderate	Not related	13 Dec 2020 (Study Day 109) – 14 Dec 2020 (Study Day 110)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2274, a 76-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Dec 2020 (Study Day 109), 108 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarct lasted for 2 days, after which it was considered to be recovered/resolved on 14 Dec 2020 (Study Day 110). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001137	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1949 - 1949
Appendicectomy	Appendectomy	1954 - 1954
Appendicitis	Appendicitis	1954 - 1954
Coronary artery bypass	Coronary artery bypass graft - double	1990 - 1990
Coronary artery disease	Coronary artery disease	1990 - 1990
Umbilical hernia	Umbilical hernia	1990 - 1990
Umbilical hernia repair	Umbilical herniorrhaphy	1990 - 1990
Metabolic surgery	Bariatric surgery	2000 - 2000
Obesity	Obesity	2000 - 2000
Hypercholesterolaemia	Hypercholesterolemia	2017 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia (bph)	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2017 - Ongoing	Hypercholesterolemia
Influenza vaccine	2019 - 2019	Influenza Prophylaxis/Prevention
Pneumococcal vaccine polysacch 23v	2019 - 2019	Pneumonia Prophylaxis/Prevention
Varicella zoster vaccine	2019 - 2019	Herpes Zoster Prophylaxis/Prevention
Doxazosin	2020 - 24 Aug 2020 (Study Day -3)	Benign Prostatic Hyperplasia (Bph)
Vitamins nos	2020 - Ongoing	Nutritional Supplement
Alfuzosin	24 Aug 2020 (Study Day -3) - Ongoing	Benign Prostatic Hyperplasia (Bph)
Influenza vaccine	17 Oct 2020 (Study Day 52) - 17 Oct 2020 (Study Day 52)	Influenza Prophylaxis/Prevention
Cat scan thorax*	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)	Adverse Event
Diltiazem	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)	Atrial Fibrillation
Electrocardiogram*	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)	Adverse Event
Glyceryl trinitrate	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)	Atrial Fibrillation
Heparin sodium	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)	Myocardial Infarction
Apixaban	15 Dec 2020 (Study Day 111) - Ongoing	Myocardial Infarct

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Angina Pectoris	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)
Atrial Fibrillation	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)
Pain In Jaw	Grade 2/moderate	Not related	13 Dec 2020 (Study Day 109) - 13 Dec 2020 (Study Day 109)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2394 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arteriosclerosis/Symptomatic Atherosclerotic Disease.	SAE	Grade 2/ moderate	Not related	11 Nov 2020 (Study Day 62) – 03 Dec 2020 (Study Day 84)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2394, a 68-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Nov 2020 (Study Day 62), 61 days after the first dose and 33 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of arteriosclerosis. Action taken with the IP was not applicable. The event of symptomatic atherosclerotic disease. lasted for 23 days, after which it was considered to be recovered/resolved on 03 Dec 2020 (Study Day 84). The investigator assessed the event of arteriosclerosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000795	Arteriosclerosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cholecystectomy	Cholecystectomy	1976 - 1976
Cholelithiasis	Cholelithiasis	1976 - 1976
Pelvic inflammatory disease	Pelvic inflammatory disease	1979 - 1979
Fallopian tube operation	Bilateral cuff tuboplasty	1980 - 1980
Fallopian tube operation	Fallopian tube fimbriae fusion	1980 - 1980
Postmenopause	Postmenopausal	1998 - Ongoing
External fixation of fracture	Surgical reduction of wrist fracture with external fixator	2004 - 2004
Wrist fracture	Fractured right wrist	2004 - 2004
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	2008 - Ongoing
Hip arthroplasty	Total hip replacement left	2009 - 2009
Osteoarthritis	Osteoarthritis of left hip	2009 - 2009
Hypertension	Hypertension	2010 - Ongoing
Hip arthroplasty	Total hip replacement right	2012 - 2012
Osteoarthritis	Osteoarthritis right hip	2012 - 2012

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2008 - 17 Sep 2020 (Study Day 7)	Diabetes Mellitus Type II
Losartan	2010 - Ongoing	Hypertension
Colecalciferol	2016 - Ongoing	Dietary Supplement
Vitamin b12 nos	2016 - Ongoing	Dietary Supplement
Pneumococcal vaccine	26 Apr 2018 (Study Day -869) - 26 Apr 2018 (Study Day -869)	Pneumonia Prophylaxis/Prevention
Varicella zoster vaccine	22 May 2018 (Study Day -843) - 22 May 2018 (Study Day -843)	Herpes Zoster Prophylaxis/Prevention
Varicella zoster vaccine	11 Aug 2018 (Study Day -762) - 11 Aug 2018 (Study Day -762)	Herpes Zoster Prophylaxis/Prevention
Cinnamomum verum	2019 - Ongoing	Dietary Supplement
Simvastatin	Feb 2019 - Ongoing	Hypercholesterolemia
Influenza vaccine	27 Aug 2020 (Study Day -15) - 27 Aug 2020 (Study Day -15)	Influenza Prophylaxis/Prevention
Metformin	05 Oct 2020 (Study Day 25) - Ongoing	Diabetes Mellitus Type IIa
Acetylsalicylic acid	11 Nov 2020 (Study Day 62) - 13 Nov 2020 (Study Day 64)	Cardiac Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cat scan head*	11 Nov 2020 (Study Day 62) - 11 Nov 2020 (Study Day 62)	Diagnostic
Insulin	11 Nov 2020 (Study Day 62) - 11 Nov 2020 (Study Day 62)	Diabetes Mellitus Type II
Mri brain*	11 Nov 2020 (Study Day 62) - 11 Nov 2020 (Study Day 62)	Diagnostic
Clopidogrel	12 Nov 2020 (Study Day 63) - Feb 2021	Cardiac Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

US3382085 Participant Number:	US338-2085 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dermatitis Allergic/Allergic Rash - Unknown Etiology	AE leading to study discontinuation	Grade 2/moderate	Not related	12 Sep 2020 (Study Day 24) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US338-2085, a 41-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of dermatitis allergic. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of allergic rash - unknown etiology was considered to be ongoing. The investigator assessed the event of dermatitis allergic to be not related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

On 25 Sep 2020 (Study Day 37), the participant discontinued from the study due to adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Sulfa allergy	1985 - Ongoing
Knee operation	Left knee scope with meniscal loose body removal	1992 - 1992
Loose body in joint	Meniscal loose body - left knee	1992 - 1992

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	1994 - 1994
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Cholecystectomy	Cholecystectomy	2013 - 2013
Cholelithiasis	Cholelithiasis	2013 - 2013
Anxiety	Anxiety	2014 - Ongoing
Depression	Depression	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; levonorgestrel	1999 - Ongoing	Contraception
Cetirizine hydrochloride	2000 - 08 Sep 2020 (Study Day 20)	Seasonal Allergies
Escitalopram oxalate	2014 - Ongoing	Depression
Lamotrigine	2014 - Ongoing	Depression
Diphenhydramine hydrochloride	13 Sep 2020 (Study Day 25) - 14 Sep 2020 (Study Day 26)	Allergic Rash - Unknown Etiology
Cetirizine hydrochloride	15 Sep 2020 (Study Day 27) - 20 Sep 2020 (Study Day 32)	Allergic Reaction - Unknown Etiology
Methylprednisolone	15 Sep 2020 (Study Day 27) - 15 Sep 2020 (Study Day 27)	Allergic Reaction - Unknown Etiology
Montelukast sodium	15 Sep 2020 (Study Day 27) - 22 Sep 2020 (Study Day 34)	Allergic Rash - Unknown Etiology
Methylprednisolone	16 Sep 2020 (Study Day 28) - 16 Sep 2020 (Study Day 28)	Allergic Reaction - Unknown Etiology
Methylprednisolone	17 Sep 2020 (Study Day 29) - 17 Sep 2020 (Study Day 29)	Allergic Reaction - Unknown Etiology
Methylprednisolone	18 Sep 2020 (Study Day 30) - 18 Sep 2020 (Study Day 30)	Allergic Reaction - Unknown Etiology
Methylprednisolone	19 Sep 2020 (Study Day 31) - 19 Sep 2020 (Study Day 31)	Allergic Reaction - Unknown Etiology
Methylprednisolone	20 Sep 2020 (Study Day 32) - 20 Sep 2020 (Study Day 32)	Allergic Dermatitis Of Unknown Etiology

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dermatitis Allergic	Grade 2/moderate	Not related	12 Sep 2020 (Study Day 24) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US338-2284 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	16 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastric Cancer/Gastric Cancer	SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 2/ moderate	Not related	29 Oct 2020 (Study Day 44) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US338-2284, a 45-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 16 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Oct 2020 (Study Day 44), 43 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of gastric cancer. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of gastric cancer was considered to be ongoing. The investigator assessed the event of gastric cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000690	Gastric cancer

Study Completion/Discontinuation

On 20 Nov 2020 (Study Day 66), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	Oct 2020 - Ongoing	Abdominal Pain/Gastric Cancer
Sucralfate	Oct 2020 - Ongoing	Abdominal Pain/Gastric Cancer
Helicobacter pylori blood test*	12 Oct 2020 (Study Day 27) - 12 Oct 2020 (Study Day 27)	Adverse Event
Endoscopy with biopsies*	29 Oct 2020 (Study Day 44) - 29 Oct 2020 (Study Day 44)	Adverse Event
Ct scan abdomen*	31 Oct 2020 (Study Day 46) - 31 Oct 2020 (Study Day 46)	Adverse Event
Morphine	11 Nov 2020 (Study Day 57) - Ongoing	Gastric Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	23 Sep 2020 (Study Day 8) - 25 Sep 2020 (Study Day 10)
Abdominal Pain	Grade 2/moderate	Not related	06 Oct 2020 (Study Day 21) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US339-2049 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Acute Myocardial Infarction	SAE	Grade 3/ severe	Not related	21 Dec 2020 (Study Day 125) – 23 Dec 2020 (Study Day 127)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2049, a 71-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Dec 2020 (Study Day 125), 124 days after the first dose and 98 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of acute myocardial infarction lasted for 3 days, after which it was considered to be recovered/resolved on 23 Dec 2020 (Study Day 127). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001369	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	May 1997 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	May 1997 - Ongoing
Hypertension	Hypertension	May 1997 - Ongoing
Vascular graft	Bypass surgery	May 1997 - May 1997
Gout	Gout, unspecified	Jun 2004 - Ongoing
Stent placement	Stent placement	May 2007 - May 2007
Prostatomegaly	Enlarged prostate	May 2015 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	Mar 2018 - Ongoing
Osteoarthritis	Osteo arthritis of left foot	May 2018 - Ongoing
Insomnia	Insomnia	Jun 2018 - Ongoing
Cholecystectomy	Cholecystectomy	Apr 2020 - Apr 2020
Cholelithiasis	Gall stones	Apr 2020 - Apr 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rosuvastatin	Mar 1997 - Ongoing	Hypercholesterolemia
Acetylsalicylic acid	May 1997 - Ongoing	Cardiovascular Disease
Folic acid	May 1997 - Ongoing	Worsening Coronary Artery Disease
Metoprolol	May 1997 - Ongoing	Hypertension
Omega-3 fatty acids	May 1997 - Ongoing	Worsening Coronary Arterydisease
Vitamins nos	May 1997 - Ongoing	Worsening Coronary Artery Disease
Indometacin	Jun 2004 - Ongoing	Gout, Unspecified
Tamsulosin	2015 - Ongoing	Enlarged Prostate
Esomeprazole	Mar 2016 - Ongoing	Gastroesophageal Reflux Disease
Potassium citrate	Jun 2017 - Ongoing	Worsening Coronary Artery Disease
Celecoxib	May 2018 - Ongoing	Arthritis, Left Foot
Alprazolam	Jun 2018 - Ongoing	Insomnia
Evolocumab	Jun 2018 - Ongoing	Hypercholesterolemia
Zolpidem	Jun 2018 - Ongoing	Insomnia
Allopurinol	Jan 2019 - Ongoing	Gout, Unspecified
Cardiac catheterization for non-st elevated myocardial infarction*	22 Dec 2020 (Study Day 126) - 22 Dec 2020 (Study Day 126)	Adverse Event
Echocardiogram for non-st elevated myocardial infarction*	23 Dec 2020 (Study Day 127) - 23 Dec 2020 (Study Day 127)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

FDA-CBER-2022-1614-3379397

Participant Number:	US339-2112 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/Small Bowel Obstruction	SAE	Grade 3/severe	Not related	27 Dec 2020 (Study Day 122) – 30 Dec 2020 (Study Day 125)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2112, a 72-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Dec 2020 (Study Day 122), 121 days after the first dose and 96 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of small intestinal obstruction. Action taken with the IP was not applicable. The event of small bowel obstruction lasted for 4 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 125). The investigator assessed the event of small intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001438	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Herpes simplex	Herpes simplex	Mar 1951 - Ongoing
Postmenopause	Post-menopausal	May 2005 - Ongoing
Arthralgia	Knee pain	Aug 2005 - Ongoing
Hypertension	Hypertension	Jan 2010 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	Aug 2015 - Ongoing
Back pain	Back pain	Aug 2017 - Ongoing
Back pain	Lumbar back pain	Aug 2017 - Ongoing
Anaemia	Anemia	Jul 2018 - Ongoing
Fibromyalgia	Fibromyalgia	Jul 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aciclovir	Mar 1951 - Ongoing	Herpes Simplex
Gabapentin	Jun 1982 - Ongoing	Neuropathy
Ibuprofen	Aug 2005 - Ongoing	Knee Pain
Benazepril	Jan 2010 - Ongoing	Hypertension
Pantoprazole	Aug 2015 - Ongoing	Acid Reflux
Methocarbamol	Aug 2017 - Ongoing	Lumbar Back Pain
Ergocalciferol	Jul 2018 - Ongoing	Anemia
Pregabalin	Aug 2019 - Ongoing	Fibromyalgia
Furosemide	Jan 2020 - Ongoing	Hypertension
Potassium chloride	Jan 2020 - Ongoing	Hypertension
Ibuprofen	29 Aug 2020 (Study Day 2) - 29 Aug 2020 (Study Day 2)	Injection Site Pain
Ibuprofen	31 Aug 2020 (Study Day 4) - 02 Sep 2020 (Study Day 6)	Pain At Injection Site, Headache
Ketorolac tromethamine	23 Sep 2020 (Study Day 27) - Ongoing	Knee Pain
Ibuprofen	24 Sep 2020 (Study Day 28) - 24 Sep 2020 (Study Day 28)	Pain At Injection Site, Headache
Metoclopramide hydrochloride	27 Dec 2020 (Study Day 122) - 30 Dec 2020 (Study Day 125)	Small Bowel Obstruction
Ondansetron	27 Dec 2020 (Study Day 122) - 30 Dec 2020 (Study Day 125)	Nausea, Secondary To Small Bowel Obstruction
Sodium chloride	26 Feb 2021 (Study Day 183) - 01 Mar 2021 (Study Day 186)	Acute Kidney Injury

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	24 Sep 2020 (Study Day 28) - 02 Oct 2020 (Study Day 36)
Myalgia	Grade 3/severe	Related	24 Sep 2020 (Study Day 28) - 02 Oct 2020 (Study Day 36)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US339-2120 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	SAE	Grade 3/severe	Not related	24 Oct 2020 (Study Day 55) – 26 Oct 2020 (Study Day 57)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2120, a 63-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 30 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Oct 2020 (Study Day 55), 54 days after the first dose and 24 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 3 days, after which it was considered to be recovered/resolved on 26 Oct 2020 (Study Day 57). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000613	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	Mar 2009 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Mar 2009 - Ongoing
Hypertension	Hypertension	Mar 2009 - Ongoing
Myocardial infarction	Myocardial infarction	Mar 2009 - Mar 2009
Anxiety	Anxiety	Apr 2009 - Ongoing
Depression	Depression	Apr 2009 - Ongoing
Gender dysphoria	Gender dysphoria	Oct 2014 - Ongoing
Urinary retention	Urinary retention	Oct 2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Mar 2009 - Ongoing	Hypercholesterolemia
Metoprolol tartrate	Mar 2009 - Ongoing	Coronary Artery Disease
Escitalopram	Apr 2009 - Ongoing	Anxiety
Estradiol valerate	Oct 2014 - Ongoing	Gender Dysphoria
Finasteride	Oct 2014 - Ongoing	Urinary Retention
Spironolactone	Oct 2014 - Ongoing	Hypertension
Metformin	24 Oct 2020 (Study Day 55) - Ongoing	Type Ii Diabetes
Ticagrelor	24 Oct 2020 (Study Day 55) - Ongoing	Myocardial Infarcation
Percutaneous transluminal coronary angioplasty, right coronary artery*	26 Oct 2020 (Study Day 57) - 26 Oct 2020 (Study Day 57)	Adverse Event
Ticagrelor	28 Oct 2020 (Study Day 59) - 26 Nov 2020 (Study Day 88)	Worsening Of Cardiovascular Disease/Secondary To Myocardial Infarction
Acetylsalicylic acid	29 Oct 2020 (Study Day 60) - Ongoing	Worsening Of Cardiovascular Disease/Secondary To Myocardial Infarction
Gabapentin	10 Mar 2021 (Study Day 192) - Ongoing	Muscle Spasms, Right Leg
Methocarbamol	10 Mar 2021 (Study Day 192) - Ongoing	Muscle Spasms, Right Leg

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Type 2 Diabetes Mellitus	Grade 2/moderate	Not related	24 Oct 2020 (Study Day 55) - Ongoing
Muscle Spasms	Grade 1/mild	Not related	10 Mar 2021 (Study Day 192) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US339-2149 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hepatitis A/Hepatitis A	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	24 Sep 2020 (Study Day 23) – 25 Sep 2020 (Study Day 24)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2149, a 30-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Sep 2020 (Study Day 23), 22 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of hepatitis a. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of hepatitis a lasted for 2 days, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 24). The investigator assessed the event of hepatitis a to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000370	Hepatitis A

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	04 Sep 2020 (Study Day 3) - 05 Sep 2020 (Study Day 4)	Injection Site Pain; Headache
Chemistry labs*	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Adverse Event
Coagulation*	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Adverse Event
Hematology labs*	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Adverse Event
Ondansetron	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Nausea, Secondary To Hepatitis A
Pantoprazole sodium sesquihydrate	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Gastroesophageal Reflux Disease, Secondary To Hepatitis A
Ultrasound*	25 Sep 2020 (Study Day 24) - 25 Sep 2020 (Study Day 24)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US339-2251 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	12 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 4	Not related	20 Oct 2020 (Study Day 39) – 22 Oct 2020 (Study Day 41)	Recovered/resolved
Pyrexia/Fever	SAE	Grade 3/severe	Not related	25 Dec 2020 (Study Day 105) – 28 Dec 2020 (Study Day 108)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US339-2251, a 65-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 12 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Oct 2020 (Study Day 39), 38 days after the first dose and 12 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 3 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 41). The investigator assessed the event of pneumonia to be not related to the IP.

On 25 Dec 2020 (Study Day 105), 104 days after the first dose and 78 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pyrexia. Action taken with the IP was not applicable. The event of fever lasted for 4 days, after which it was considered to be recovered/resolved on 28 Dec 2020 (Study Day 108). The investigator assessed the event of pyrexia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000517	Pneumonia
MOD-2020-001368	Pyrexia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Jan 1970 - Ongoing
Postmenopause	Post-menopausal	Dec 2000 - Ongoing
Diabetes mellitus	Diabetes	Jan 2010 - Ongoing
Hypertension	Hypertension	Jan 2010 - 23 Oct 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	Jan 2010 - Ongoing	Hypertension
Lisinopril	Jan 2010 - Ongoing	Hypertension
Metformin	Jan 2010 - Ongoing	Diabetes
Carvedilol	Jan 2018 - Ongoing	Hypertension
Dulaglutide	Jan 2018 - Ongoing	Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US340-2042 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	25 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Emphysema/ Worsening Of Emphysema	SAE	Grade 2/ moderate	Not related	01 Oct 2020 (Study Day 66) – 17 Oct 2020 (Study Day 82)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2042, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 28 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 25 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Oct 2020 (Study Day 66), 65 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of emphysema. Action taken with the IP was not applicable. The event of worsening of emphysema lasted for 17 days, after which it was considered to be recovered/resolved on 17 Oct 2020 (Study Day 82). The investigator assessed the event of emphysema to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000465	Emphysema

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Urticaria	Uticaria	1967 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1990 - Ongoing
Hiatus hernia	Hiatal hernia	1990 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	1992 - Ongoing
Emphysema	Emphysema	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Depression	Depression	2010 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2010 - Ongoing
Pneumonia	Pneumonia	2016 - 2016
Deep vein thrombosis	Deep vein thrombosis, right leg	2018 - Ongoing
Pulmonary embolism	Pulmonary embolism	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	1990 - Ongoing	Gastroesophageal Reflux Disease
Tamsulosin	1992 - Ongoing	Benign Prostatic Hypertrophy
Bisoprolol	2000 - 17 Oct 2020 (Study Day 82)	Hypertension
Hydrochlorothiazide	2000 - Ongoing	Hypertension
Fluoxetine	2012 - Ongoing	Depression
Roflumilast	2016 - Ongoing	Emphysema
Apixaban	2018 - Ongoing	Deep Vein Thrombosis/ Pulminary Embolism
Formoterol fumarate; glycopyrronium bromide	2018 - Ongoing	Emphysema
Ceftriaxone	01 Oct 2020 (Study Day 66) - 12 Oct 2020 (Study Day 77)	Worsening Emphysema
Doxycycline	01 Oct 2020 (Study Day 66) - 12 Oct 2020 (Study Day 77)	Worsening Of Emphysema
Prednisone	01 Oct 2020 (Study Day 66) - 04 Oct 2020 (Study Day 69)	Worsening Of Emphysema
Prednisone	05 Oct 2020 (Study Day 70) - 06 Oct 2020 (Study Day 71)	Worsening Of Emphysema
Prednisone	07 Oct 2020 (Study Day 72) - 08 Oct 2020 (Study Day 73)	Worsening Of Emphysema
Prednisone	09 Oct 2020 (Study Day 74) - 10 Oct 2020 (Study Day 75)	Worsening Of Emphysema
Apixaban	12 Oct 2020 (Study Day 77) - Ongoing	Worsening Emphysema
Azithromycin	12 Oct 2020 (Study Day 77) - 17 Oct 2020 (Study Day 82)	Worsening Emphysema
Chest xray*	12 Oct 2020 (Study Day 77) - 12 Oct 2020 (Study Day 77)	Adverse Event
Methylprednisolone	12 Oct 2020 (Study Day 77) - Ongoing	Worsening Emphysema

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxygen	12 Oct 2020 (Study Day 77) - 17 Oct 2020 (Study Day 82)	Worsening Emphysema
Cefdinir	17 Oct 2020 (Study Day 82) - Ongoing	Pneumonia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US340-2139 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Left Knee Osteoarthritis	SAE	Grade 2/ moderate	Not related	09 Aug 2020 (Study Day 9) – 14 Oct 2020 (Study Day 75)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2139, a 55-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Aug 2020 (Study Day 9), 8 days after the first dose and 22 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of osteoarthritis. The IP dose was not changed due to the worsening left knee osteoarthritis. The event of worsening left knee osteoarthritis lasted for 67 days, after which it was considered to be recovered/resolved with sequelae on 14 Oct 2020 (Study Day 75). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000549	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	1990 - Ongoing
Osteoarthritis	Osteoarthritis left knee arthritis	2002 - Ongoing
Hypersensitivity	Environmental allergies	2010 - Ongoing
Postmenopause	Post-menopausal	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rizatriptan benzoate	2007 - Ongoing	Migraine Headaches
Levocetirizine	May 2019 - Ongoing	Environmental Allergies
Curcuma longa	Apr 2020 - Ongoing	Nutritional Supplement
Magnesium oxide	Apr 2020 - Ongoing	Nutritional Supplement
Paracetamol	01 Sep 2020 (Study Day 32) - 02 Sep 2020 (Study Day 33)	Mild Pain At Injection Site And Body Aches
Acetylsalicylic acid	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Amoxicillin; clavulanic acid	12 Oct 2020 (Study Day 73) - 22 Oct 2020 (Study Day 83)	Left Knee Replacement (Arthoplasty)
Bisacodyl	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Calcium chloride; potassium chloride; sodium lactate	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Celecoxib	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Famotidine	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Fentanyl	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Ferrous sulfate	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Gabapentin	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Hydrocodone bitartrate; paracetamol	12 Oct 2020 (Study Day 73) - 22 Oct 2020 (Study Day 83)	Left Knee Replacement (Arthroplasty)
Hydroxyzine hydrochloride	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Left knee replacement*	12 Oct 2020 (Study Day 73) - 12 Oct 2020 (Study Day 73)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levofloxacin	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Magnesium hydroxide	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Morphine	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Oxycodone	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Sodium phosphate dibasic; sodium phosphate monobasic	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Zolpidem tartrate	12 Oct 2020 (Study Day 73) - 14 Oct 2020 (Study Day 75)	Worsening Left Knee Arthritis
Complete blood count*	13 Oct 2020 (Study Day 74) - 13 Oct 2020 (Study Day 74)	Adverse Event
Complete blood count*	14 Oct 2020 (Study Day 75) - 14 Oct 2020 (Study Day 75)	Adverse Event
Meloxicam	22 Mar 2021 (Study Day 234) - Ongoing	Left Knee Arthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US340-2211 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intraductal Proliferative Breast Lesion/Ductal Carcinoma Insitu Right Breast	SAE	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 81) – 23 Dec 2020 (Study Day 142)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2211, a 66-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Oct 2020 (Study Day 81), 80 days after the first dose and 52 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of intraductal proliferative breast lesion. Action taken with the IP was not applicable. The event of ductal carcinoma insitu right breast lasted for 62 days, after which it was considered to be recovered/resolved with sequelae on 23 Dec 2020 (Study Day 142). The investigator assessed the event of intraductal proliferative breast lesion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001455	Intraductal proliferative breast lesion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypersensitivity	Environmental allergies	1958 - Ongoing
Seasonal allergy	Seasonal allergies	1958 - Ongoing
Bronchitis chronic	Chronic bronchitis	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2003 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2009 - Ongoing
Osteoporosis	Osteoporosis	2010 - Ongoing
Glaucoma	Glaucoma bilateral	2011 - Ongoing
Postmenopause	Post-menopausal	2011 - Ongoing
Hip fracture	Right hip fracture	2012 - 2013
Cataract	Left cataract	Feb 2015 - Feb 2015
Cataract	Right cataract	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bimatoprost	2011 - Ongoing	Glaucoma Bilateral
Brimonidine tartrate; brinzolamide	2011 - Ongoing	Glaucoma Bilateral
Vitamin d nos	2016 - Ongoing	Supplement
Vitamins nos	2016 - Ongoing	Supplement
Allergens nos	2018 - Ongoing	Environmental Allergies
Influenza vaccine	19 Oct 2020 (Study Day 77) - 19 Oct 2020 (Study Day 77)	Influenza Prophylaxis
Mammogram*	23 Oct 2020 (Study Day 81) - 23 Oct 2020 (Study Day 81)	Diagnostic
Cefalexin	07 Nov 2020 (Study Day 96) - Ongoing	Urinary Tract Infection
Right breast biopsy*	19 Nov 2020 (Study Day 108) - 19 Nov 2020 (Study Day 108)	Adverse Event
Right breast lumpectomy*	23 Dec 2020 (Study Day 142) - 23 Dec 2020 (Study Day 142)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Glycosylated Haemoglobin Increased	Grade 1/mild	Not related	30 Oct 2020 (Study Day 88) - Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 96) - 19 Nov 2020 (Study Day 108)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379416

Participant Number:	US340-2212 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Stenosis/Worsening Spinal Stenosis	SAE	Grade 3/ severe	Not related	23 Aug 2020 (Study Day 20) – 29 Sep 2020 (Study Day 57)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2212, a 79-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Aug 2020 (Study Day 20), 19 days after the first dose and 12 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of spinal stenosis. The IP dose was not changed due to the worsening spinal stenosis. The event of worsening spinal stenosis lasted for 38 days, after which it was considered to be recovered/resolved on 29 Sep 2020 (Study Day 57). The investigator assessed the event of spinal stenosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000221	Spinal stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Moderate obesity	1953 - Ongoing
Postmenopause	Post-menopausal	1980 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2010 - Ongoing
Diabetic neuropathy	Diabetic neuropathy	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Muscle spasms	Back spasms	2015 - Ongoing
Oedema peripheral	Bilateral foot edema	2015 - Ongoing
Osteoarthritis	Degenerative joint disease	2015 - Ongoing
Osteoporosis	Osteoporosis	2015 - Ongoing
Restless legs syndrome	Restless leg syndrome	2015 - Ongoing
Spinal osteoarthritis	Osteoarthritis, spine	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Alendronate sodium	2015 - Ongoing	Osteoporosis
Ascorbic acid	2015 - Ongoing	Dietary Supplement
Carvedilol	2015 - Ongoing	Hypertension
Cinnamomum verum	2015 - Ongoing	Type Ii Diabetes
Colecalciferol	2015 - Ongoing	Supplement
Furosemide	2015 - Ongoing	Edema Bilateral Feet
Gabapentin	2015 - Ongoing	Diabetic Neuropathy
Losartan	2015 - Ongoing	Hypertension
Meloxicam	2015 - Ongoing	Osteoarthritis
Pramipexole	2015 - Ongoing	Restless Leg Syndrome
Semaglutide	2015 - Ongoing	Type Ii Diabetes
Simvastatin	2015 - Ongoing	Hyperlipidemia
Vitamin e nos	2015 - Ongoing	Dietary Supplement
Vitamins nos	2015 - Ongoing	Supplement
Ondansetron	23 Apr 2020 (Study Day -103) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Chest xray*	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Dexamethasone	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Donepezil	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Glucagon	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Type Ii Diabetes
Glucose	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Heparin	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Insulin aspart	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Type Ii Diabetes
Lumbar spine xray*	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Adverse Event
Magnesium hydroxide	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Morphine	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Mri lumbar spine*	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Adverse Event
Oxycodone	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Pain Associated With Worsening Spinal Stenosis
Oxycodone	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Paracetamol	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Potassium chloride	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Valsartan	23 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 22)	Worsening Spinal Stenosis
Complete blood count*	25 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 22)	Adverse Event
Complete metabolic profile*	25 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 22)	Adverse Event
Complete blood count*	22 Sep 2020 (Study Day 50) - 22 Sep 2020 (Study Day 50)	Adverse Event
Left iliac crest bone marrow aspiration and application of 30ml of beta tricalcium phosphate and local autologous bone*	22 Sep 2020 (Study Day 50) - 22 Sep 2020 (Study Day 50)	Adverse Event
Lumbar spine xray*	22 Sep 2020 (Study Day 50) - 22 Sep 2020 (Study Day 50)	Adverse Event
Posterior spinal fusion l2, l3, l4, l5,*	22 Sep 2020 (Study Day 50) - 22 Sep 2020 (Study Day 50)	Adverse Event
Vertebroplasty l2, l3, l4. l5*	22 Sep 2020 (Study Day 50) - 22 Sep 2020 (Study Day 50)	Adverse Event
Wide decompressive laminectomy, bilateral facetectomy l2-l5 with decompression of l 3, l4, l5 nerve root.*	22 Sep 2020 (Study Day 50) - 22 Sep 2020 (Study Day 50)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Complete blood count*	23 Sep 2020 (Study Day 51) - 23 Sep 2020 (Study Day 51)	Adverse Event
Complete blood count*	24 Sep 2020 (Study Day 52) - 24 Sep 2020 (Study Day 52)	Adverse Event
Complete blood count*	25 Sep 2020 (Study Day 53) - 25 Sep 2020 (Study Day 53)	Adverse Event
Chlortalidone	07 Dec 2020 (Study Day 126) - Ongoing	Hypertension
Hydrochlorothiazide	02 Mar 2021 (Study Day 211) - Ongoing	Hypertension
Amoxicillin	16 Mar 2021 (Study Day 225) - 26 Mar 2021 (Study Day 235)	Kidney Stones
Tizanidine	16 Mar 2021 (Study Day 225) - 26 Mar 2021 (Study Day 235)	Kidney Stones

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nephrolithiasis	Grade 2/moderate	Not related	13 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 232)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2284 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Kidney Stone	SAE	Grade 3/ severe	Not related	22 Sep 2020 (Study Day 46) – 23 Sep 2020 (Study Day 47)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2284, a 58-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Sep 2020 (Study Day 46), 45 days after the first dose and 12 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of kidney stone lasted for 2 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 47). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000349	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis left hip	1982 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Gout	Gout (right foot)	2005 - Ongoing
Perthes disease	Perthes disease	2016 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2016 - Ongoing
Cholelithiasis	Gallstones	2018 - 2019
Type 2 diabetes mellitus	Diabetes type 2	2019 - Ongoing
Cholecystectomy	Cholecystectomy	Mar 2019 - Mar 2019
Nerve compression	Pinched nerve left shoulder	Feb 2020 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	1982 - Ongoing	Osteoarthritis Left Hip
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylaxis
Benazepril	2000 - Ongoing	Hypertension
Hydrochlorothiazide	2000 - Ongoing	Hypertension
Vitamins nos	2000 - Ongoing	Dietary Supplement
Allopurinol	2005 - Ongoing	Gout
Fluticasone propionate	2016 - Ongoing	Sleep Apnea
Metoprolol	2017 - Ongoing	Hypertension
Metformin	2019 - Ongoing	Type 2 Diabetes
Cyclobenzaprine	Feb 2020 - Ongoing	Pinched Nerve Left Shoulder
Atorvastatin calcium	May 2020 - Ongoing	Hypercholesterolemia
Ibuprofen	13 Sep 2020 (Study Day 37) - 15 Sep 2020 (Study Day 39)	Headache/Mild Muscle And Joint Aches
Complete blood count*	22 Sep 2020 (Study Day 46) - 22 Sep 2020 (Study Day 46)	Adverse Event
Ct of abdomen and pelvis*	22 Sep 2020 (Study Day 46) - 22 Sep 2020 (Study Day 46)	Adverse Event
Heparin	22 Sep 2020 (Study Day 46) - 23 Sep 2020 (Study Day 47)	Kidney Stone
Ketorolac	22 Sep 2020 (Study Day 46) - 23 Sep 2020 (Study Day 47)	Kidney Stone
Lithotripsy*	22 Sep 2020 (Study Day 46) - 22 Sep 2020 (Study Day 46)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	22 Sep 2020 (Study Day 46) - 23 Sep 2020 (Study Day 47)	Kidney Stones
Ceftriaxone	23 Sep 2020 (Study Day 47) - Ongoing	Kidney Stone
Tamsulosin	23 Sep 2020 (Study Day 47) - Ongoing	Kidney Stone

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	08 Aug 2020 (Study Day 1) - 19 Aug 2020 (Study Day 12)
Fatigue	Grade 1/mild	Related	08 Aug 2020 (Study Day 1) - 21 Aug 2020 (Study Day 14)
Myalgia	Grade 1/mild	Related	08 Aug 2020 (Study Day 1) - 21 Aug 2020 (Study Day 14)
Arthralgia	Grade 1/mild	Related	10 Sep 2020 (Study Day 34) - 27 Sep 2020 (Study Day 51)
Myalgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 35) - 02 Oct 2020 (Study Day 56)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2299 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post Procedural Haemorrhage/Post Operative Bleeding	SAE	Grade 3/severe	Not related	26 Aug 2020 (Study Day 19) – 01 Sep 2020 (Study Day 25)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2299, a 50-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Aug 2020 (Study Day 19), 18 days after the first dose and 15 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of post procedural haemorrhage. The IP dose was delayed due to the post operative bleeding. The event of post operative bleeding lasted for 7 days, after which it was considered to be recovered/resolved on 01 Sep 2020 (Study Day 25). The investigator assessed the event of post procedural haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000253	Post procedural haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine	1988 - Ongoing
Drug hypersensitivity	Allergy to amoxycillan	1990 - Ongoing
Cholecystectomy	Cholecystectomy	Jul 1990 - Jul 1990
Insomnia	Insomnia	2000 - Ongoing
Hysterectomy	Complete hysterectomy	2003 - 2003
Hypothyroidism	Hypothyroidism	2008 - Ongoing
Constipation	Chronic constipation	2010 - Ongoing
Abdominal fat apron	Abnormal pannus. abdominal fat apron	10 Nov 2010 (Study Day -3559) - 26 Aug 2020 (Study Day 19)
Gastric bypass	Gastric bypass roux-en-y	10 Nov 2010 (Study Day -3559) - 10 Nov 2010 (Study Day -3559)
Anxiety	Anxiety	2018 - Ongoing
Depression	Depression	2018 - Ongoing
Wrist fracture	Right wrist fracture	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2008 - Ongoing	Hypothyroidism
Lactulose	2010 - Ongoing	Constipation
Vitamin b12 nos	2010 - Ongoing	Nutritional Supplement
Vitamins nos	2010 - Ongoing	Nutritional Supplement
Ondansetron	10 Nov 2010 (Study Day -3559) – 01 Sep 2020 (Study Day 25)	Idiopathic Abdominal Pannus
Lubiprostone	2011 - Ongoing	Constitpation
Sumatriptan	2016 - Ongoing	Migraines
Trazodone	2016 - Ongoing	Insomnia
Clonazepam	2018 - Ongoing	Anxiety/Depression
Duloxetine	2018 - Ongoing	Depression
Ibuprofen	12 Aug 2020 (Study Day 5) - 15 Aug 2020 (Study Day 8)	Migraine Headaches
Ibuprofen	14 Aug 2020 (Study Day 7) - 15 Aug 2020 (Study Day 8)	Headache After Injection
Metoclopramide hydrochloride	26 Aug 2020 (Study Day 19) - 01 Sep 2020 (Study Day 25)	Pannus Of Abdominal Area
Panniculectomy*	26 Aug 2020 (Study Day 19) - 26 Aug 2020 (Study Day 19)	Other, Planned Procedure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest xray*	27 Aug 2020 (Study Day 20) - 27 Aug 2020 (Study Day 20)	Adverse Event
Complete blood count*	27 Aug 2020 (Study Day 20) - 27 Aug 2020 (Study Day 20)	Adverse Event
Ct abdomen*	27 Aug 2020 (Study Day 20) - 27 Aug 2020 (Study Day 20)	Adverse Event
Ct angrography*	27 Aug 2020 (Study Day 20) - 27 Aug 2020 (Study Day 20)	Adverse Event
Ct pelvis*	27 Aug 2020 (Study Day 20) - 27 Aug 2020 (Study Day 20)	Adverse Event
Post operative bleeding*	28 Aug 2020 (Study Day 21) - 28 Aug 2020 (Study Day 21)	Adverse Event
Red blood cells, concentrated	28 Aug 2020 (Study Day 21) - 29 Aug 2020 (Study Day 22)	Post Operative Bleeding
Influenza vaccine	29 Sep 2020 (Study Day 53) - 29 Sep 2020 (Study Day 53)	Prophylaxis For Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 3/severe	Related	11 Aug 2020 (Study Day 4) - 16 Aug 2020 (Study Day 9)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2300 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Herpes Simplex/ Herpes Simplex	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	13 Aug 2020 (Study Day 6) – 25 Aug 2020 (Study Day 18)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2300, a 44-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 08 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was not reported.

Event Details

On 13 Aug 2020 (Study Day 6), 5 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of herpes simplex. On 04 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of herpes simplex lasted for 13 days, after which it was considered to be recovered/resolved on 25 Aug 2020 (Study Day 18). The investigator assessed the event of herpes simplex to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Factor V Leiden mutation	Factor v leiden	2008 - Ongoing
Otosclerosis	Otosclerosis right ear	2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	09 Aug 2020 (Study Day 2) - 09 Aug 2020 (Study Day 2)	Pain At Injection Site
Valaciclovir hydrochloride	13 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 21)	Herpes Simplex
Tetanus vaccine	25 Sep 2020 (Study Day 49) - 25 Sep 2020 (Study Day 49)	Tetanus Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Simplex	Grade 2/moderate	Not related	13 Aug 2020 (Study Day 6) - 25 Aug 2020 (Study Day 18)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2381 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	16 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE	Grade 2/moderate	Not related	20 Sep 2020 (Study Day 36) – 09 Apr 2021 (Study Day 237)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2381, a 67-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 16 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Sep 2020 (Study Day 36), 35 days after the first dose and 6 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate cancer lasted for 202 days, after which it was considered to be recovered/resolved on 09 Apr 2021 (Study Day 237). The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000707	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Allergy to green peppers	1980 - Ongoing
Food allergy	Raw mushroom allergy	1980 - Ongoing
Abdominal discomfort	Gastric distress	1984 - Ongoing
Back pain	Chronic back pain	1989 - Ongoing
Allergy to arthropod sting	Bee/wasp allergy	1990 - Ongoing
Rubber sensitivity	Latex allergy	2000 - Ongoing
Coronary artery disease	Coronary artery disease	Feb 2009 - Ongoing
Coronary arterial stent insertion	Cardiac stent placement	03 Feb 2009 (Study Day -4212) - 03 Feb 2009 (Study Day -4212)
Myocardial infarction	Myocardial infarction	03 Feb 2009 (Study Day -4212) - 03 Feb 2009 (Study Day -4212)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2009 - Ongoing	Cardiac Prophylaxis
Lisinopril	2009 - Ongoing	Coronary Artery Disease
Metoprolol	2009 - Ongoing	Coronary Artery Disease
Naproxen	2009 - Ongoing	Chronic Back Pain
Atorvastatin	2013 - Ongoing	Coronary Artery Disease
Probiotics nos	2015 - Ongoing	Digestive Distress
Prostate biopsy*	30 Oct 2020 (Study Day 76) - 30 Oct 2020 (Study Day 76)	Adverse Event
Degarelix acetate	05 Nov 2020 (Study Day 82) - 05 Nov 2020 (Study Day 82)	Prostate Cancer
Relugolix	05 Mar 2021 (Study Day 202) - Ongoing	Prostate Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US340-2382 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	16 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/ Atrial Fibrillation	SAE	Grade 3/ severe	Not related	28 Aug 2020 (Study Day 13) – 01 Sep 2020 (Study Day 17)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2382, a 66-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 16 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Aug 2020 (Study Day 13), 12 days after the first dose and 17 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. The IP dose was not changed due to the atrial fibrillation. The event of atrial fibrillation lasted for 5 days, after which it was considered to be recovered/resolved on 01 Sep 2020 (Study Day 17). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000243	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	1995 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Gout	Gout	2008 - Ongoing
Ligament rupture	Torn acl right leg	2008 - Ongoing
Erectile dysfunction	Erectile dysfunction	25 Aug 2008 (Study Day -4374) - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	01 Sep 2017 (Study Day -1080) - Ongoing
Osteoarthritis	Bilateral hip osteoarthritis	25 Apr 2018 (Study Day -844) - Ongoing
Anxiety	Anxiety	05 Nov 2018 (Study Day -650) - Ongoing
Constipation	Constipation	04 Nov 2019 (Study Day -286) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	25 Apr 2008 (Study Day -4496) - Ongoing	Hypertension
Acetylsalicylic acid	25 Aug 2008 (Study Day -4374) - Ongoing	Heart Attack Prevention
Sildenafil	25 Aug 2008 (Study Day -4374) - Ongoing	Erectile Dysfunction
Atorvastatin	10 Feb 2015 (Study Day -2014) - Ongoing	Hyperlipidemia
Empagliflozin	18 Apr 2017 (Study Day -1216) - Ongoing	Diabetes Type 2
Tamsulosin	01 Sep 2017 (Study Day -1080) - Ongoing	Benign Prostatic Hypertrophy
Febuxostat	25 Oct 2017 (Study Day -1026) - Ongoing	Gout
Diclofenac	25 Apr 2018 (Study Day -844) - Ongoing	Osteoarthritis Bilateral Hips
Duloxetine	05 Nov 2018 (Study Day -650) - Ongoing	Anxiety
Semaglutide	05 Nov 2018 (Study Day -650) - Ongoing	Diabetes Type 2
Hydrocodone	31 Oct 2019 (Study Day -290) - Ongoing	Osteoarthritis
Docusate sodium	04 Nov 2019 (Study Day -286) - Ongoing	Constipation
Insulin glargine	04 Nov 2019 (Study Day -286) - Ongoing	Type 2 Diabetes
Glimepiride	21 Jul 2020 (Study Day -26) - Ongoing	Diabetes Type 2
Cefalexin	26 Aug 2020 (Study Day 11) - 06 Sep 2020 (Study Day 22)	Urinary Tract Infection
Apixaban	28 Aug 2020 (Study Day 13) - 01 Sep 2020 (Study Day 17)	Atrial Fibrillation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest xray*	28 Aug 2020 (Study Day 13) - 28 Aug 2020 (Study Day 13)	Adverse Event
Computed tomography head/brain w/o contrast*	28 Aug 2020 (Study Day 13) - 28 Aug 2020 (Study Day 13)	Adverse Event
Levofloxacin	28 Aug 2020 (Study Day 13) - 08 Sep 2020 (Study Day 24)	Urinary Tract Infection Bacteria

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	18 Aug 2020 (Study Day 3) - 24 Aug 2020 (Study Day 9)
Urinary Tract Infection	Grade 2/moderate	Not related	26 Aug 2020 (Study Day 11) - 06 Sep 2020 (Study Day 22)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2425 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/ Pulmonary Embolism	SAE	Grade 3/ severe	Not related	17 Nov 2020 (Study Day 88) – 20 Nov 2020 (Study Day 91)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2425, a 36-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Nov 2020 (Study Day 88), 87 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolism lasted for 4 days, after which it was considered to be recovered/resolved on 20 Nov 2020 (Study Day 91). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000855	Pulmonary embolism

Study Completion/Discontinuation

On 08 Jan 2021 (Study Day 140), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2012 - Ongoing
Rubber sensitivity	Latex allergy	2013 - Ongoing
Polycystic ovaries	Polycystic ovarian syndrome	2014 - Ongoing
Asthma	Mild asthma	2018 - Ongoing
Contraceptive implant	Nexplanon	Aug 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline hydrochloride	2012 - 25 Sep 2020 (Study Day 35)	Depression
Metformin	2014 - Ongoing	Polycystic Ovarian Syndrome
Fluticasone propionate	2018 - Ongoing	Prevent Allergies
Salbutamol	2018 - Ongoing	Mild Asthma
Etonogestrel	Aug 2019 - Ongoing	Birth Control
Sertraline hydrochloride	Sep 2020 - Ongoing	Depression
Aptt*	17 Nov 2020 (Study Day 88) - 17 Nov 2020 (Study Day 88)	Adverse Event
Butalbital; caffeine; paracetamol	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Colecalciferol	17 Nov 2020 (Study Day 88) - Ongoing	Pulmonary Embolism
Complete blood count*	17 Nov 2020 (Study Day 88) - 17 Nov 2020 (Study Day 88)	Adverse Event
Enoxaparin sodium	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Fluticasone	17 Nov 2020 (Study Day 88) - Ongoing	Pulmonary Embolism
Glucagon	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Low Blood Sugar Due To Pulmonary Embolism
Glucose	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Inr*	17 Nov 2020 (Study Day 88) - 17 Nov 2020 (Study Day 88)	Adverse Event
Loratadine	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Magnesium hydroxide	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Ondansetron	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Prothrombin time*	17 Nov 2020 (Study Day 88) - 17 Nov 2020 (Study Day 88)	Adverse Event
Salbutamol	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Sodium chloride	17 Nov 2020 (Study Day 88) - 20 Nov 2020 (Study Day 91)	Pulmonary Embolism
Vitamins nos	17 Nov 2020 (Study Day 88) - Ongoing	Pulmonary Embolism

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bilateral lower exremity ultra sound*	18 Nov 2020 (Study Day 89) - 18 Nov 2020 (Study Day 89)	Adverse Event
Chest x ray*	18 Nov 2020 (Study Day 89) - 18 Nov 2020 (Study Day 89)	Adverse Event
Ct abdomen and pelvis*	18 Nov 2020 (Study Day 89) - 18 Nov 2020 (Study Day 89)	Adverse Event
Ct angigraphy chest*	18 Nov 2020 (Study Day 89) - 18 Nov 2020 (Study Day 89)	Adverse Event
Ct head and neck*	18 Nov 2020 (Study Day 89) - 18 Nov 2020 (Study Day 89)	Adverse Event
Echocardiagram w/ contrast*	18 Nov 2020 (Study Day 89) - 18 Nov 2020 (Study Day 89)	Adverse Event
Apixaban	20 Nov 2020 (Study Day 91) - Ongoing	Pulmonary Embolism/Blood Clot Prevention
Butalbital; caffeine; paracetamol	20 Nov 2020 (Study Day 91) - 04 Dec 2020 (Study Day 105)	Pulmonary Embolism
Diphenhydramine hydrochloride	20 Nov 2020 (Study Day 91) - Ongoing	Pulmonary Embolism
Salbutamol sulfate	20 Nov 2020 (Study Day 91) - Ongoing	Pulmonary Embolism
Nortriptyline	05 Dec 2020 (Study Day 106) - 23 Dec 2020 (Study Day 124)	Migraines
Sumatriptan	05 Dec 2020 (Study Day 106) - 23 Dec 2020 (Study Day 124)	Pulmonary Embolism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US340-2430 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Hypertension	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	14 Sep 2020 (Study Day 24) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2430, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 22 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of hypertension. On 18 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of hypertension was considered to be ongoing. The investigator assessed the event of hypertension to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gastroesaphegeal reflux disease	2010 - Ongoing
Hysterectomy	Total hysterectomy	Jan 2012 - Jan 2012
Postmenopause	Postmenopausal	Jan 2012 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	17 Sep 2020 (Study Day 27) - Ongoing	Hypertension
Lisinopril	20 Sep 2020 (Study Day 30) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Related	14 Sep 2020 (Study Day 24) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2448 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	16 Nov 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Emphysema/Worsening Of Emphysema	SAE	Grade 3/severe	Not related	09 Nov 2020 (Study Day 20) – 11 Nov 2020 (Study Day 22)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US340-2448, a 66-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 16 Nov 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Nov 2020 (Study Day 20), 19 days after the first dose and 7 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of emphysema. The IP dose was not changed due to the worsening of emphysema. The event of worsening of emphysema lasted for 3 days, after which it was considered to be recovered/resolved with sequelae on 11 Nov 2020 (Study Day 22). The investigator assessed the event of emphysema to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000806	Emphysema

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1998 - Ongoing
Hysterectomy	Total hysterectomy (excessive bleeding and cramping)	2001 - 2001
Hypertonic bladder	Overactive bladder	2005 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2006 - Ongoing
Hypercholesterolaemia	Hypercholesterdemia	2006 - Ongoing
Hypertension	Hypertension	2008 - Ongoing
Schizoaffective disorder	Schizoaffective disorder	2010 - Ongoing
Emphysema	Emphysema	2016 - Ongoing
Osteoarthritis	Left knee osteoarthritis	2018 - Ongoing
Arthroscopy	Left knee arthoscopy	Apr 2020 - Apr 2020
Hiatus hernia	Hiatal hernia	May 2020 - 09 Feb 2021 (Study Day 112)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2006 - Ongoing	Hypercholesterdemia
Losartan potassium	2010 - Ongoing	Hypertension
Oxybutynin	2012 - Ongoing	Overactive Bladder
Topiramate	2012 - Ongoing	Schizoaffective Disorder
Olanzapine	2016 - Ongoing	Schizoaffective Disorder
Sertraline	2016 - Ongoing	Depression
Celecoxib	2018 - Ongoing	Left Knee Osteoarthritis
Pantoprazole	2018 - Ongoing	Gastroesophageal Reflux Disease
Oxygen	09 Nov 2020 (Study Day 20) - Ongoing	Worsening Of Emphysema
Hiatal hernia repair*	09 Feb 2021 (Study Day 112) - 09 Feb 2021 (Study Day 112)	Medical History
Tramadol	09 Feb 2021 (Study Day 112) - Ongoing	Pain Control For After Hiatal Hernia Surgery
Amoxicillin	19 Mar 2021 (Study Day 150) - 29 Mar 2021 (Study Day 160)	Sinusitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Sinusitis	Grade 1/mild	Not related	18 Mar 2021 (Study Day 149) - 29 Mar 2021 (Study Day 160)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2013 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	26 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cellulitis/Cellulitis - Left Hand	SAE	Grade 4	Not related	20 Nov 2020 (Study Day 115) – 12 Dec 2020 (Study Day 137)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2013, a 58-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Nov 2020 (Study Day 115), 114 days after the first dose and 86 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cellulitis. Action taken with the IP was not applicable. The event of cellulitis - left hand lasted for 23 days, after which it was considered to be recovered/resolved on 12 Dec 2020 (Study Day 137). The investigator assessed the event of cellulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000875	Cellulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Oral herpes	Fever blisters	1965 - Ongoing
Eczema	Eczema	1995 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2005 - Ongoing
Back pain	Chronic lower back pain	2007 - Ongoing
Autonomic nervous system imbalance	Dysautonomia	2008 - Ongoing
Postmenopause	Post menopausal	2008 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Vertigo	Vertigo	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pregabalin	2008 - Ongoing	Dysautonomia
Atorvastatin	2010 - Ongoing	Hld
Estradiol	2010 - Ongoing	Post-Menopause
Glimepiride	2010 - Ongoing	T2dm
Lisinopril	2010 - 29 Dec 2020 (Study Day 154)	Htn
Omeprazole	2010 - Ongoing	Gerd
Clonazepam	2014 - Ongoing	Anxiety
Meclozine	2015 - Ongoing	Vertigo
Midodrine	2015 - Ongoing	Dysautonomia
Fluocinonide	2016 - Ongoing	Eczema
Hyoscine	2017 - Ongoing	Dysautonomia
Diclofenac	2018 - Ongoing	Chronic Low Back Pain
Famciclovir	2018 - Ongoing	Fever Blisters
Sitagliptin	2019 - Ongoing	T2dm
Vitamin d nos	2019 - Ongoing	General Supplement
Canagliflozin	2020 - 29 Dec 2020 (Study Day 154)	Dmt2
Paracetamol	2020 - Ongoing	Injection Site Pain “solicited Event”
Fluoxetine	15 Sep 2020 (Study Day 49) - Ongoing	Worsening Anxiety
Dextromethorphan hydrobromide; guaifenesin	29 Sep 2020 (Study Day 63) - 02 Oct 2020 (Study Day 66)	Upper Respiratory Infection Ae
Ibuprofen	29 Sep 2020 (Study Day 63) - 24 Oct 2020 (Study Day 88)	Upper Respiratory Infection Ae
Buspirone	04 Nov 2020 (Study Day 99) - Ongoing	Worsening Anxiety
Bacitracin; polymyxin b	21 Nov 2020 (Study Day 116) - 21 Nov 2020 (Study Day 116)	Cellulitis Left Hand

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	21 Nov 2020 (Study Day 116) - 21 Nov 2020 (Study Day 116)	Cellulitis From Cat Bite
Doxycycline	21 Nov 2020 (Study Day 116) - 22 Nov 2020 (Study Day 117)	Cellulitis Left Hand
Fentanyl citrate	21 Nov 2020 (Study Day 116) - 23 Nov 2020 (Study Day 118)	Cellulitis Left Hand
Ibuprofen	21 Nov 2020 (Study Day 116) - 21 Nov 2020 (Study Day 116)	Cellulitis Left Hand
Paracetamol	21 Nov 2020 (Study Day 116) - 21 Nov 2020 (Study Day 116)	Cellulitis Left Hand
X-ray left writs*	21 Nov 2020 (Study Day 116) - 21 Nov 2020 (Study Day 116)	Adverse Event
Bamp*	22 Nov 2020 (Study Day 117) - 22 Nov 2020 (Study Day 117)	Adverse Event
Blood culture*	22 Nov 2020 (Study Day 117) - 22 Nov 2020 (Study Day 117)	Adverse Event
C-reactive protein*	22 Nov 2020 (Study Day 117) - 22 Nov 2020 (Study Day 117)	Adverse Event
Cbc*	22 Nov 2020 (Study Day 117) - 22 Nov 2020 (Study Day 117)	Adverse Event
Clindamycin	22 Nov 2020 (Study Day 117) - 22 Nov 2020 (Study Day 117)	Cellulitis Left Hand
Heparin	22 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 119)	Cellulitis Left Hand
Hydromorphone hydrochloride	22 Nov 2020 (Study Day 117) - 23 Nov 2020 (Study Day 118)	Cellulitis Left Hand
Insulin aspart	22 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 119)	Type 2 Diabetes
Lactate*	22 Nov 2020 (Study Day 117) - 22 Nov 2020 (Study Day 117)	Adverse Event
Meropenem	22 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 119)	Cellulitis Left Hand
Oxycodone	22 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 119)	Cellulitis Left Hand
Sennoside a+b	22 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 119)	Prevention Of Constipation As Side Effect To Meds Given In Hospital
Vancomycin	22 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 119)	Cellulitis (L) Hand
Calcium carbonate	23 Nov 2020 (Study Day 118) - 23 Nov 2020 (Study Day 118)	Gerd
Cbc*	23 Nov 2020 (Study Day 118) - 23 Nov 2020 (Study Day 118)	Adverse Event
Levofloxacin	23 Nov 2020 (Study Day 118) - 23 Nov 2020 (Study Day 118)	Cellulitis Left Hand
Lidocaine	23 Nov 2020 (Study Day 118) - 23 Nov 2020 (Study Day 118)	Cellulitis Left Hand
Wound debridement of left hand*	23 Nov 2020 (Study Day 118) - 23 Nov 2020 (Study Day 118)	Adverse Event
Hba1c*	24 Nov 2020 (Study Day 119) - 24 Nov 2020 (Study Day 119)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	24 Nov 2020 (Study Day 119) - 03 Dec 2020 (Study Day 128)	Cellulitis - Left Hand
Levofloxacin	24 Nov 2020 (Study Day 119) - 03 Dec 2020 (Study Day 128)	Cellulitis- Left Hand
Metronidazole	24 Nov 2020 (Study Day 119) - 03 Dec 2020 (Study Day 128)	Cellulitis - Left Hand
Oxycodone	24 Nov 2020 (Study Day 119) - 29 Nov 2020 (Study Day 124)	Cellulitis - Left Hand5
Empagliflozin	30 Dec 2020 (Study Day 155) - Ongoing	Type 2 Diabetes
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	03 Feb 2021 (Study Day 190) - Ongoing	Attention Deficit Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	15 Sep 2020 (Study Day 49) - 15 Jan 2021 (Study Day 171)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	29 Sep 2020 (Study Day 63) - 16 Dec 2020 (Study Day 141)
Attention Deficit Hyperactivity Disorder	Grade 2/moderate	Not related	03 Feb 2021 (Study Day 190) - Ongoing
Stress Urinary Incontinence	Grade 1/mild	Not related	01 Mar 2021 (Study Day 216) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2016 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	26 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Acute Chest Pain	SAE	Grade 4	Not applicable	02 Dec 2020 (Study Day 127) – 04 Dec 2020 (Study Day 129)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2016, a 58-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 26 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Dec 2020 (Study Day 127), 126 days after the first dose and 98 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of chest pain. Action taken with the IP was not applicable. The event of acute chest pain lasted for 3 days, after which it was considered to be recovered/resolved on 04 Dec 2020 (Study Day 129). The investigator assessed the event of chest pain to be not applicable to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001141	Chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myocardial infarction	Heart attack - myocardial infarction	2000 - 2000
Type 2 diabetes mellitus	Diabetes type 2	2008 - Ongoing
Back pain	Back pain	2010 - Ongoing
Coronary artery disease	Cad	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Insomnia	Insomnia	2012 - Ongoing
Seasonal allergy	Allergic seasonal	2012 - Ongoing
Myocardial infarction	Heart attack - myocardial infarction	2015 - 2015
Stent placement	Stent placement x4	2015 - 2015
Diabetic neuropathy	Diabetic neuropathy	2018 - Ongoing
Essential tremor	Essential tremor	2019 - Ongoing
Rotator cuff repair	Rotator cuff repair	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Heart Attack
Atorvastatin	2010 - Ongoing	Hyperlipidemia
Cyclobenzaprine hydrochloride	2010 - Ongoing	Back Pain
Empagliflozin	2010 - Ongoing	Dm2
Ezetimibe	2010 - Ongoing	Hyperlipidemia
Fenofibrate	2010 - Ongoing	Hyperlipidemia
Glyceryl trinitrate	2010 - Ongoing	Heart Attack
Insulin lispro	2010 - Ongoing	Dm2
Isosorbide dinitrate	2010 - 03 Dec 2020 (Study Day 128)	Heart Attack
Lisinopril	2010 - Ongoing	Hypertension
Metformin	2010 - Ongoing	Dm2
Metoprolol	2010 - Ongoing	Hypertension
Sitagliptin	2010 - 04 Dec 2020 (Study Day 129)	Dm2
Loratadine	2012 - Ongoing	Allergic - Seasonal
Gabapentin	2018 - Ongoing	Diabetic Neuropathy
Primidone	2019 - Ongoing	Essential Tremor
Tramadol	2019 - Ongoing	Back Pain
Olopatadine	Mar 2020 - Ongoing	Seasonal Allergies

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	30 Sep 2020 (Study Day 64) - 30 Sep 2020 (Study Day 64)	General Health
Clopidogrel bisulfate	03 Dec 2020 (Study Day 128) - 03 Dec 2020 (Study Day 128)	Thrombolic Event Prevention
Fentanyl	03 Dec 2020 (Study Day 128) - 03 Dec 2020 (Study Day 128)	Pci
Glyceryl trinitrate	03 Dec 2020 (Study Day 128) - 03 Dec 2020 (Study Day 128)	Acute Chest Pain
Heparin	03 Dec 2020 (Study Day 128) - 03 Dec 2020 (Study Day 128)	Pci
Lidocaine	03 Dec 2020 (Study Day 128) - 03 Dec 2020 (Study Day 128)	Pci
Midazolam hydrochloride	03 Dec 2020 (Study Day 128) - 03 Dec 2020 (Study Day 128)	Pci
Verapamil	03 Dec 2020 (Study Day 128) - 03 Dec 2020 (Study Day 128)	Pci
Insulin aspart	04 Dec 2020 (Study Day 129) - Ongoing	Type 2 Diabetes
Isosorbide dinitrate	04 Dec 2020 (Study Day 129) - Ongoing	Acute Chest Pain
Ranolazine	04 Dec 2020 (Study Day 129) - Ongoing	Acute Chest Pain
Vitamin d nos	04 Dec 2020 (Study Day 129) - Ongoing	General Health
2 coronory artery stents placed for myocardial infarction ae*	09 Dec 2020 (Study Day 134) - 09 Dec 2020 (Study Day 134)	Adverse Event
Acetylsalicylic acid	09 Dec 2020 (Study Day 134) - Ongoing	Stroke Prevention
Metoprolol tartrate	09 Dec 2020 (Study Day 134) - Ongoing	Htn
Zolpidem	09 Dec 2020 (Study Day 134) - Ongoing	Insomnia
Nasopharyngoscopy*	01 Jan 2021 (Study Day 157) - 01 Jan 2021 (Study Day 157)	Adverse Event
Salbutamol	15 Jan 2021 (Study Day 171) - Ongoing	Sob
Echocardiogram*	03 Feb 2021 (Study Day 190) - 03 Feb 2021 (Study Day 190)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Laryngeal Oedema	Grade 2/moderate	Not related	04 Dec 2020 (Study Day 129) - Ongoing
Dyspnoea	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 140) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379448

Participant Number:	US341-2067 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Progressive/ Worsening Osteoarthritis - Back	SAE	Grade 4	Not related	01 Nov 2020 (Study Day 94) – Ongoing	Not recovered/not resolved
Post Procedural Infection/Post-Op Infection	SAE	Grade 4	Not related	02 Feb 2021 (Study Day 187) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2067, a 60-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 94), 93 days after the first dose and 65 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of progressive/worsening osteoarthritis - back was considered to be ongoing. The investigator assessed the event of osteoarthritis to be not related to the IP.

On 02 Feb 2021 (Study Day 187), 186 days after the first dose and 158 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of post procedural infection. Action taken with the IP was not applicable. The event of post-op infection was considered to be ongoing. The investigator assessed the event of post procedural infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011652	Staphylococcal bacteraemia
MOD-2021-011652	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis - bilateral knees, lower back, neck, hands, feet.	2005 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2010 - Ongoing
Knee operation	Right knee septic joint surgery	2015 - 2015
Anxiety	Anxiety	2018 - Ongoing
Depression	Depression	2018 - Ongoing
Benign prostatic hyperplasia	Bph	Mar 2020 - Ongoing
Spinal fusion surgery	Neck surgery - cervical fusion	15 Apr 2020 (Study Day -107) - 15 Apr 2020 (Study Day -107)
Sleep apnoea syndrome	Sleep apnea	31 Jul 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Docusate sodium; sennoside a+b	Not reported - Ongoing	Post Op Infection
Ferrous sulfate	Not reported - Ongoing	Post Op Infection
Gabapentin	Not reported - Ongoing	Post Op Infection
Loratadine	Not reported - Ongoing	Post Op Infection
Methocarbamol	Not reported - Ongoing	Post Op Infection
Ropinirole	Not reported - Ongoing	Post Op Infection
Pioglitazone	2007 - Ongoing	T2dm
Diclofenac	2010 - Ongoing	Oa
Lisinopril	2010 - Ongoing	Htn
Liraglutide	2012 - Ongoing	T2dm
Venlafaxine	2018 - Ongoing	Anxiety/Depression
Cyclobenzaprine	Apr 2020 - Ongoing	Neck Pain
Tamsulosin	Apr 2020 - Ongoing	Bph
Atorvastatin	15 Apr 2020 (Study Day -107) - Ongoing	High Cholesterol
Influenza vaccine	05 Nov 2020 (Study Day 98) - 05 Nov 2020 (Study Day 98)	General Health
Back surgery*	05 Jan 2021 (Study Day 159) - 05 Jan 2021 (Study Day 159)	Adverse Event
Back surgery*	08 Jan 2021 (Study Day 162) - 08 Jan 2021 (Study Day 162)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Heparin	26 Jan 2021 (Study Day 180) - 27 Jan 2021 (Study Day 181)	Post Op Infection
Hydromorphone	26 Jan 2021 (Study Day 180) - 26 Jan 2021 (Study Day 180)	Post Op Infection
Insulin aspart	26 Jan 2021 (Study Day 180) - 06 Feb 2021 (Study Day 191)	Post Op Infection
Ioversol	26 Jan 2021 (Study Day 180) - 26 Jan 2021 (Study Day 180)	Post Op Infection
Paracetamol	26 Jan 2021 (Study Day 180) - 06 Feb 2021 (Study Day 191)	Post Op Infection
Piperacillin; tazobactam	26 Jan 2021 (Study Day 180) - 26 Jan 2021 (Study Day 180)	Post Op Infection
Sodium chloride	26 Jan 2021 (Study Day 180) - 26 Jan 2021 (Study Day 180)	Post Op Infection
Sodium chloride	26 Jan 2021 (Study Day 180) - 06 Feb 2021 (Study Day 191)	Post Op Infection
Vancomycin	26 Jan 2021 (Study Day 180) - 26 Jan 2021 (Study Day 180)	Post Op Infection
Xr chest ap portable*	30 Jan 2021 (Study Day 184) - 30 Jan 2021 (Study Day 184)	Adverse Event
Ct lumbar spine without contrast*	31 Jan 2021 (Study Day 185) - 31 Jan 2021 (Study Day 185)	Adverse Event
Mri lumbar spine w/o contrast*	31 Jan 2021 (Study Day 185) - 31 Jan 2021 (Study Day 185)	Adverse Event
Anesthetics, general	02 Feb 2021 (Study Day 187) - 02 Feb 2021 (Study Day 187)	Post Op Infection
Lumbar wound irrigation and debridement*	02 Feb 2021 (Study Day 187) - 02 Feb 2021 (Study Day 187)	Adverse Event
Ondansetron	02 Feb 2021 (Study Day 187) - 02 Feb 2021 (Study Day 187)	Post Op Infection
Cefazolin	06 Feb 2021 (Study Day 191) - Ongoing	Post Op Infection
Oxycodone	06 Feb 2021 (Study Day 191) - 13 Feb 2021 (Study Day 198)	Post Op Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US341-2081 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Respiratory Failure/Acute Respiratory Failure	SAE	Grade 4	Not related	13 Nov 2020 (Study Day 106) – 26 Nov 2020 (Study Day 119)	Recovered/resolved
Pneumonia Klebsiella/Pneumonia Due To Gram Negative Klebsiella Bacteria	SAE	Grade 4	Not related	13 Nov 2020 (Study Day 106) – 01 Jan 2021 (Study Day 155)	Recovered/resolved
Cholecystitis/Cholecystitis	SAE	Grade 4	Not related	11 Jan 2021 (Study Day 165) – 13 Jan 2021 (Study Day 167)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2081, a 72-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 31 Aug 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Nov 2020 (Study Day 106), 105 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute respiratory failure lasted for 14 days, after which it was considered to be recovered/resolved on 26 Nov 2020 (Study Day 119). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 13 Nov 2020 (Study Day 106), 105 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia klebsiella. Action taken with the IP was not applicable. The event of pneumonia due to gram negative klebsiella bacteria lasted for 50 days, after which it was considered to be recovered/resolved on 01 Jan 2021 (Study Day 155). The investigator assessed the event of pneumonia klebsiella to be not related to the IP.

On 11 Jan 2021 (Study Day 165), 164 days after the first dose and 133 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of cholecystitis lasted for 3 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 167). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000831	Cholecystitis
MOD-2020-000831	Pneumonia klebsiella
MOD-2020-000831	Acute respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ligament operation	Right knee acl repair	1987 - 1987
Ligament operation	Left knee acl repair	1991 - 1991
Inguinal hernia	Left inguinal hernia	1992 - 1992
Inguinal hernia repair	Left inguinal herniorrhaphy	1992 - 1992
Attention deficit hyperactivity disorder	Adhd	2010 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Benign prostatic hyperplasia	Bph	2012 - Ongoing
Osteoarthritis	Osteoarthritis knees, hips, back	2013 - Ongoing
Rotator cuff repair	Right rotator cuff repair	2013 - 2013
Rotator cuff syndrome	Right torn rotator cuff	2013 - 2013
Corneal dystrophy	Fuch's dystrophy	2015 - 2018
Insomnia	Insomnia	2015 - Ongoing
Carpal tunnel syndrome	Carpal tunnel right wrist	2017 - Ongoing
Corneal transplant	Bilateral corneal transplant	2018 - 2018
Type 2 diabetes mellitus	Diabetes - type 2	2019 - Ongoing
Rotator cuff repair	Left rotator cuff repair	Jun 2020 - Jun 2020
Rotator cuff syndrome	Left torn rotator cuff	Jun 2020 - Jun 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin lispro	Not reported - 27 Nov 2020 (Study Day 120)	Diabetes
Omeprazole	2009 - 2018	Gerd
Amfetamine	2010 - Ongoing	Adhd
Hydrochlorothiazide; losartan potassium	2010 - Ongoing	Hypertension
Rosuvastatin	2010 - Ongoing	Hyperlipidemia
Vitamins nos	2010 - Ongoing	General Health
Amlodipine	2012 - Ongoing	Hypertension
Dutasteride	2012 - Ongoing	Bph
Alfuzosin	2013 - Ongoing	Bph
Diclofenac	2013 - Ongoing	Osteoarthritis
Difluprednate	2018 - Ongoing	Post-Op And Corneal Transplant - Anti Rejection. Ocular Inflamation
Omeprazole	2018 - 27 Nov 2020 (Study Day 120)	Gerd
Trazodone	2019 - Ongoing	Insomnia
Hydrocodone bitartrate; paracetamol	18 Aug 2020 (Study Day 19) - 20 Aug 2020 (Study Day 21)	Carpel Tunnel
Influenza vaccine	29 Sep 2020 (Study Day 61) - 29 Sep 2020 (Study Day 61)	General Health Prevention
Influenza vaccine	29 Sep 2020 (Study Day 61) - 29 Sep 2020 (Study Day 61)	Influenza Prophylactic
Ecg*	13 Nov 2020 (Study Day 106) - 13 Nov 2020 (Study Day 106)	Adverse Event
Ctab / pelvis with contrast*	14 Nov 2020 (Study Day 107) - 14 Nov 2020 (Study Day 107)	Adverse Event
Cxr*	14 Nov 2020 (Study Day 107) - 14 Nov 2020 (Study Day 107)	Adverse Event
Ruq ultrasound*	14 Nov 2020 (Study Day 107) - 14 Nov 2020 (Study Day 107)	Adverse Event
Ctab / pelvis w/o contrast*	15 Nov 2020 (Study Day 108) - 15 Nov 2020 (Study Day 108)	Adverse Event
Potassium chloride	17 Nov 2020 (Study Day 110) - Ongoing	Acute Kidney Injury
Ceftriaxone	18 Nov 2020 (Study Day 111) - 19 Nov 2020 (Study Day 112)	Acute Biliary Pacreatitis / Pneumonia / Klebsiella Gram Negative Bacteremia
Metronidazole	18 Nov 2020 (Study Day 111) - 19 Nov 2020 (Study Day 112)	Acute Billary Pacreatitis / Pneumonia / Klebsiella Gram Negative Bacteremia
Mrcp*	18 Nov 2020 (Study Day 111) - 18 Nov 2020 (Study Day 111)	Adverse Event
Ctab with contrast*	19 Nov 2020 (Study Day 112) - 19 Nov 2020 (Study Day 112)	Adverse Event
Cxr*	19 Nov 2020 (Study Day 112) - 19 Nov 2020 (Study Day 112)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fentanyl	19 Nov 2020 (Study Day 112) - 19 Nov 2020 (Study Day 112)	Sedation For Surgical Procedure
Hepatic angio*	19 Nov 2020 (Study Day 112) - 19 Nov 2020 (Study Day 112)	Adverse Event
Hepatic av fistula embolization*	19 Nov 2020 (Study Day 112) - 19 Nov 2020 (Study Day 112)	Adverse Event
Midazolam hydrochloride	19 Nov 2020 (Study Day 112) - 19 Nov 2020 (Study Day 112)	Sedation For Surgical Procedure
Ct guided cholecystostamy drain*	20 Nov 2020 (Study Day 113) - 20 Nov 2020 (Study Day 113)	Adverse Event
Fentanyl	20 Nov 2020 (Study Day 113) - 20 Nov 2020 (Study Day 113)	Sedation For Surgical Procedure
Midazolam hydrochloride	20 Nov 2020 (Study Day 113) - 20 Nov 2020 (Study Day 113)	Sedation For Surgical Procedure
Cta chest*	21 Nov 2020 (Study Day 114) - 21 Nov 2020 (Study Day 114)	Adverse Event
Mri of abd w contrast*	21 Nov 2020 (Study Day 114) - 21 Nov 2020 (Study Day 114)	Adverse Event
Mri of abd w/o contrast*	21 Nov 2020 (Study Day 114) - 21 Nov 2020 (Study Day 114)	Adverse Event
Cardiac echo*	22 Nov 2020 (Study Day 115) - 22 Nov 2020 (Study Day 115)	Adverse Event
Ecg*	22 Nov 2020 (Study Day 115) - 22 Nov 2020 (Study Day 115)	Adverse Event
Ct guided cholecystostamy drain - upsized drain revision*	24 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 117)	Adverse Event
Cta / p / c*	24 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 117)	Adverse Event
Cxr*	24 Nov 2020 (Study Day 117) - 24 Nov 2020 (Study Day 117)	Adverse Event
Magnesium sulfate	25 Nov 2020 (Study Day 118) - 25 Nov 2020 (Study Day 118)	Hypomagnesemia
Piccline*	25 Nov 2020 (Study Day 118) - 25 Nov 2020 (Study Day 118)	Adverse Event
Piperacillin; tazobactam	25 Nov 2020 (Study Day 118) - 26 Nov 2020 (Study Day 119)	Pneumonia / Pancreatitis / Klebsiella Gram Negative Bacteremia
Furosemide	26 Nov 2020 (Study Day 119) - Ongoing	Heart Failure / Hypertension
Oxycodone	26 Nov 2020 (Study Day 119) - 30 Nov 2020 (Study Day 123)	Surgical Pain
Piperacillin sodium; tazobactam sodium	26 Nov 2020 (Study Day 119) - 16 Dec 2020 (Study Day 139)	Acute Billary Pancreatitis
Lidocaine	27 Nov 2020 (Study Day 120) - Ongoing	Surgical Pain
Pantoprazole	27 Nov 2020 (Study Day 120) - Ongoing	Gerd
Bupivacaine; epinephrine	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystitis
Ceftriaxone	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystitis
Cholecytectomy*	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexamethasone	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystitis/Cholecystectomy
Diphenhydramine hydrochloride	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Docusate sodium	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Constipation Prophylaxis
Ephedrine	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Epinephrine	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Fentanyl	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Sedation/Cholecystectomy
Glycopyrronium	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Hydralazine hydrochloride	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Hydromorphone hydrochloride	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Hydromorphone hydrochloride	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Pain, Cholecystectomy
Indocyanine green	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Labetalol	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Lidocaine	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Metoclopramide	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Nausea/Cholecystectomy
Metronidazole	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystitis/ Cholecystectomy
Morphine	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Ondansetron	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Nausea/Cholecystectomy
Oxycodone	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Phenylephrine	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Promethazine	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Nausea/ Cholecystectomy
Propofol	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Sedation/Cholecystectomy
Rocuronium bromide	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Cholecystectomy
Sugammadex sodium	13 Jan 2021 (Study Day 167) - 13 Jan 2021 (Study Day 167)	Anethesia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acute Kidney Injury	Grade 4	Not related	13 Nov 2020 (Study Day 106) - 26 Nov 2020 (Study Day 119)
Cardiac Failure	Grade 4	Not related	13 Nov 2020 (Study Day 106) - Ongoing
Hepatic Haematoma	Grade 4	Not related	13 Nov 2020 (Study Day 106) - Ongoing
Klebsiella Bacteraemia	Grade 4	Not related	13 Nov 2020 (Study Day 106) - Ongoing
Obstructive Pancreatitis	Grade 4	Not related	13 Nov 2020 (Study Day 106) - 10 Dec 2020 (Study Day 133)
Systemic Inflammatory Response Syndrome	Grade 4	Not related	20 Nov 2020 (Study Day 113) - 26 Nov 2020 (Study Day 119)
Hypomagnesaemia	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 118) - 25 Nov 2020 (Study Day 118)
Malignant Melanoma	Grade 2/moderate	Not related	10 Feb 2021 (Study Day 195) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379457

Participant Number:	US341-2118 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Peripheral Artery Occlusion/Right Femoral Artery Occlusion	SAE	Grade 4	Not related	30 Oct 2020 (Study Day 88) – 19 Nov 2020 (Study Day 108)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2118, a 56-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Oct 2020 (Study Day 88), 87 days after the first dose and 59 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of peripheral artery occlusion. Action taken with the IP was not applicable. The event of right femoral artery occlusion lasted for 21 days, after which it was considered to be recovered/resolved on 19 Nov 2020 (Study Day 108). The investigator assessed the event of peripheral artery occlusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000963	Peripheral artery occlusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pain in extremity	Pain in hip and leg	Not reported - Ongoing
Leg amputation	Amputation below right knee	2008 - 2008
Benign prostatic hyperplasia	Bph	2017 - Ongoing
Gastrooesophageal reflux disease	Gerd	2018 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Muscle spasms	Leg cramps (right)	Apr 2020 - Ongoing
Peripheral vascular disorder	Peripheral vascular disease	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2016 - Ongoing	Hip And Leg Pain
Hydrochlorothiazide; losartan potassium	2018 - Ongoing	Htn
Hydrocodone	2018 - 2020	Hip And Leg Pain
Oxycodone hydrochloride; paracetamol	2018 - Ongoing	Hip And Leg Pain
Sodium calcium edetate	2018 - Ongoing	Bone Health
Tamsulosin	2018 - Ongoing	Bph
Temazepam	2018 - Ongoing	Hip And Leg Pain
Pantoprazole	2019 - Ongoing	Gerd
Metoprolol	2020 - Ongoing	Hypertension
Magnesium	Apr 2020 - Ongoing	Leg Cramps
Rosuvastatin calcium	Nov 2020 - Ongoing	Hyperlipidemia
Application of praveena wound vac right groin 13 cm*	19 Nov 2020 (Study Day 108) - 19 Nov 2020 (Study Day 108)	Adverse Event
Colecalciferol	19 Nov 2020 (Study Day 108) - Ongoing	General Health
Pathology report for right femoral lymph node.*	19 Nov 2020 (Study Day 108) - 19 Nov 2020 (Study Day 108)	Diagnostic
Pathology report for right femoral plaque with atheromatous plaque with calcification*	19 Nov 2020 (Study Day 108) - 19 Nov 2020 (Study Day 108)	Diagnostic
Right common femoral endarterectomy with patch angioplasty*	19 Nov 2020 (Study Day 108) - 19 Nov 2020 (Study Day 108)	Adverse Event
Right profunda thrombectomy*	19 Nov 2020 (Study Day 108) - 19 Nov 2020 (Study Day 108)	Adverse Event
Right profundoplasty to the fourth order profunda*	19 Nov 2020 (Study Day 108) - 19 Nov 2020 (Study Day 108)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Grade 1/mild	Not related	15 Oct 2020 (Study Day 73) - Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not related	30 Nov 2020 (Study Day 119) - 04 Dec 2020 (Study Day 123)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2125 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Blood Loss Anaemia/Acute Post Hemorrhagic Anemia	SAE	Grade 4	Not related	08 Sep 2020 (Study Day 36) – Ongoing	Recovering/resolving
Road Traffic Accident/Motor Vehicle Accident	SAE	Grade 4	Not related	08 Sep 2020 (Study Day 36) – 08 Sep 2020 (Study Day 36)	Recovered/resolved
Cervical Vertebral Fracture/Cervical 7 Fracture	SAE	Grade 4	Not related	09 Sep 2020 (Study Day 37) – 09 Dec 2020 (Study Day 128)	Recovered/resolved
Embolic Stroke/Multiple Left Hemisphere Embolic Infarct	SAE	Grade 4	Not related	09 Sep 2020 (Study Day 37) – Ongoing	Not recovered/not resolved
Pneumonia Staphylococcal/Mrsa Pneumonia	SAE	Grade 4	Not related	09 Sep 2020 (Study Day 37) – 29 Sep 2020 (Study Day 57)	Recovered/resolved
Traumatic Liver Injury/Grade Iv Liver Laceration	SAE	Grade 4	Not related	09 Sep 2020 (Study Day 37) – 28 Jan 2021 (Study Day 178)	Recovered/resolved
Acute Myocardial Infarction/Non Stemi	SAE	Grade 4	Not related	13 Sep 2020 (Study Day 41) – 13 Sep 2020 (Study Day 41)	Recovered/resolved
Carotid Artery Thrombosis/Left Intercarotid Artery Dissection With Intraluminal Thrombus	SAE	Grade 4	Not related	13 Sep 2020 (Study Day 41) – Not reported	Unknown
Craniocerebral Injury/Traumatic Brain Injury	SAE	Grade 4	Not related	23 Sep 2020 (Study Day 51) – 01 Oct 2020 (Study Day 59)	Recovered/resolved with sequelae
Subarachnoid Haemorrhage/Subarachnoid Hemhorrage	SAE	Grade 4	Not related	23 Sep 2020 (Study Day 51) – 01 Oct 2020 (Study Day 59)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2125, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 36), 35 days after the first dose and 7 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of blood loss anaemia. Action taken with the IP was not applicable. The event of acute post hemorrhagic anemia was considered to be ongoing. The investigator assessed the event of blood loss anaemia to be not related to the IP.

On 08 Sep 2020 (Study Day 36), 35 days after the first dose and 7 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of road traffic accident. Action taken with the IP was not applicable. The event of motor vehicle accident lasted for 1 day, after which it was considered to be recovered/resolved on 08 Sep 2020 (Study Day 36). The investigator assessed the event of road traffic accident to be not related to the IP.

On 09 Sep 2020 (Study Day 37), 36 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cervical vertebral fracture. Action taken with the IP was not applicable. The event of cervical 7 fracture lasted for 92 days, after which it was considered to be recovered/resolved on 09 Dec 2020 (Study Day 128). The investigator assessed the event of cervical vertebral fracture to be not related to the IP.

On 09 Sep 2020 (Study Day 37), 36 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of embolic stroke. Action taken with the IP was not applicable. The event of multiple left hemisphere embolic infarct was considered to be ongoing. The investigator assessed the event of embolic stroke to be not related to the IP.

On 09 Sep 2020 (Study Day 37), 36 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia staphylococcal. Action taken with the IP was not applicable. The event of mrsa pneumonia lasted for 21 days, after which it was considered to be recovered/resolved on 29 Sep 2020 (Study Day 57). The investigator assessed the event of pneumonia staphylococcal to be not related to the IP.

On 09 Sep 2020 (Study Day 37), 36 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of traumatic liver injury. Action taken with the IP was not applicable. The event of grade iv liver laceration lasted for 142 days, after which it was considered to be recovered/resolved on 28 Jan 2021 (Study Day 178). The investigator assessed the event of traumatic liver injury to be not related to the IP.

On 13 Sep 2020 (Study Day 41), 40 days after the first dose and 12 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of non stemi lasted for 1 days, after which

it was considered to be recovered/resolved on 13 Sep 2020 (Study Day 41). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

On 13 Sep 2020 (Study Day 41), 40 days after the first dose and 12 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of carotid artery thrombosis. Action taken with the IP was not applicable. The outcome of the event was unknown. The investigator assessed the event of carotid artery thrombosis to be not related to the IP.

On 23 Sep 2020 (Study Day 51), 50 days after the first dose and 22 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of craniocerebral injury. Action taken with the IP was not applicable. The event of traumatic brain injury lasted for 9 days, after which it was considered to be recovered/resolved with sequelae on 01 Oct 2020 (Study Day 59). The investigator assessed the event of craniocerebral injury to be not related to the IP.

On 23 Sep 2020 (Study Day 51), 50 days after the first dose and 22 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of subarachnoid haemorrhage. Action taken with the IP was not applicable. The event of subarachnoid hemhorrage lasted for 9 days, after which it was considered to be recovered/resolved on 01 Oct 2020 (Study Day 59). The investigator assessed the event of subarachnoid haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000271	Road traffic accident
MOD-2020-000271	Blood loss anaemia
MOD-2020-000271	Pneumonia staphylococcal
MOD-2020-000271	Cervical vertebral fracture
MOD-2020-000271	Traumatic liver injury
MOD-2020-000271	Embolic stroke
MOD-2020-000271	Acute myocardial infarction
MOD-2020-000271	Carotid artery thrombosis
MOD-2020-000271	Craniocerebral injury
MOD-2020-000271	Subarachnoid haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1963 - 1963
Appendicectomy	Appendectomy	1979 - 1979
Irritable bowel syndrome	Ibs-o	2000 - Ongoing
Otitis media	Non acute serous otitis media (non-infectious) "fluid in ear" (bilateral)	2000 - Ongoing
Postmenopause	Post menopausal	2005 - Ongoing
Back pain	Chronic lower back pain	2009 - Ongoing
Gastrooesophageal reflux disease	Gerd	2009 - Ongoing
Hypothyroidism	Hypothyroid	2009 - Ongoing
Arthralgia	Intermittent joint pain (elbows / ankles, occasional knees / hips)	2010 - Ongoing
Spinal osteoarthritis	Osteoarthritis - back (low back)	2014 - Ongoing
Enterorrhaphy	Ruptured diverticulum repair	2016 - 2016
Ileostomy	Ileostomy	2016 - 2016
Intestinal obstruction	Bowel obstruction	2016 - 2016
Ileostomy	Ileostomy reversal	2017 - 2017
Abdominal hernia repair	Abdominal hernia repair	2018 - 2018
Hypertension	Hypertension	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Enteral nutrition*	Not reported - Not reported	Adverse Event
Head mri*	Not reported - Not reported	Adverse Event
Plantago ovata	Not reported - Ongoing	Ibs
Tte*	Not reported - Not reported	Adverse Event
Dicycloverine hydrochloride	2000 - Ongoing	Irritable Bowel Syndrome-D
Pseudoephedrine	2000 - Ongoing	Serous Otitis Media
Cyclobenzaprine	2009 - Ongoing	Chronic Low Back Pain
Pantoprazole	2009 - 01 Oct 2020 (Study Day 59)	Gerd
Levothyroxine	2010 - 03 Nov 2020 (Study Day 92)	Hypothyroid
Amlodipine	2019 - 19 Nov 2020 (Study Day 108)	Hypertension
Atenolol	2019 - Ongoing	Hypertension
Losartan	2019 - Ongoing	Hypertension
Meloxicam	2019 - Ongoing	Osteoarthritis
Paracetamol	2019 - 01 Oct 2020 (Study Day 59)	Oa

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	05 Aug 2020 (Study Day 2) - Ongoing	General Health
Vitamin d nos	05 Aug 2020 (Study Day 2) - Ongoing	General Health
Metoprolol	Sep 2020 - Oct 2020	Hypertension
Paracetamol	04 Sep 2020 (Study Day 32) - 04 Sep 2020 (Study Day 32)	Injection Site Pain
Ferrous sulfate	08 Sep 2020 (Study Day 36) - Ongoing	Anemia
Fluticasone furoate; vilanterol trifenatate	08 Sep 2020 (Study Day 36) - Ongoing	Cough
Levetiracetam	08 Sep 2020 (Study Day 36) - 15 Nov 2020 (Study Day 104)	Seizure Prevention
Lorazepam	08 Sep 2020 (Study Day 36) - 08 Sep 2020 (Study Day 36)	Seizure
Modafinil	08 Sep 2020 (Study Day 36) - 01 Oct 2020 (Study Day 59)	Promote Wakefulness
Paracetamol	08 Sep 2020 (Study Day 36) - Ongoing	Pain, Motor Vehicle Accident
Cefepime	09 Sep 2020 (Study Day 37) - 29 Sep 2020 (Study Day 57)	Mrsa Pneumonia
Vancomycin	09 Sep 2020 (Study Day 37) - 29 Sep 2020 (Study Day 57)	Mrsa Pneumonia
Placement of extraventricular drains*	10 Sep 2020 (Study Day 38) - 10 Sep 2020 (Study Day 38)	Adverse Event
Closed right tibia-fibula fracture*	13 Sep 2020 (Study Day 41) - 13 Sep 2020 (Study Day 41)	Adverse Event
Head ct*	14 Sep 2020 (Study Day 42) - 14 Sep 2020 (Study Day 42)	Adverse Event
Bronchoscopy*	18 Sep 2020 (Study Day 46) - 18 Sep 2020 (Study Day 46)	Adverse Event
Percutaneous endoscopic gastrostomy tube placement*	18 Sep 2020 (Study Day 46) - 18 Sep 2020 (Study Day 46)	Adverse Event
Trachestomy*	18 Sep 2020 (Study Day 46) - 18 Sep 2020 (Study Day 46)	Adverse Event
Ventilatory support*	18 Sep 2020 (Study Day 46) - 18 Sep 2020 (Study Day 46)	Adverse Event
Blood transfusion*	23 Sep 2020 (Study Day 51) - 23 Sep 2020 (Study Day 51)	Adverse Event
Amantadine hydrochloride	01 Oct 2020 (Study Day 59) - Ongoing	Traumatic Brain Injury
Apixaban	01 Oct 2020 (Study Day 59) - Ongoing	Left Intercarotid Artery Dissection With Ntraluminal Thrombus
Carvedilol	01 Oct 2020 (Study Day 59) - Ongoing	Hypertension
Diclofenac	01 Oct 2020 (Study Day 59) - 09 Dec 2020 (Study Day 128)	Pain, Motor Vehicle Accident
Esomeprazole	01 Oct 2020 (Study Day 59) - Ongoing	Gerd
Heparin	01 Oct 2020 (Study Day 59) - 01 Oct 2020 (Study Day 59)	Embolic Infarct - Multiple Left Hemispheric
Insulin	01 Oct 2020 (Study Day 59) - 09 Dec 2020 (Study Day 128)	Hyperglycemia
Insulin glargine	01 Oct 2020 (Study Day 59) - 09 Dec 2020 (Study Day 128)	Hyperglycemia
Sodium chloride	01 Oct 2020 (Study Day 59) - Ongoing	Hyponatremia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	02 Nov 2020 (Study Day 91) - Ongoing	Thromboembolism Prevention
Bisacodyl	02 Nov 2020 (Study Day 91) - 01 Feb 2021 (Study Day 182)	Constipation Prevention
Clonazepam	02 Nov 2020 (Study Day 91) - Ongoing	Seizures
Glucagon	02 Nov 2020 (Study Day 91) - 09 Dec 2020 (Study Day 128)	Hypoglycemia
Glucose	02 Nov 2020 (Study Day 91) - 09 Dec 2020 (Study Day 128)	Hypoglycemia
Hydralazine hydrochloride	02 Nov 2020 (Study Day 91) - 01 Feb 2021 (Study Day 182)	Hypertension
Hydrocodone bitartrate; paracetamol	02 Nov 2020 (Study Day 91) - Ongoing	Pain, Motor Vehicle Accident
Ipratropium; salbutamol	02 Nov 2020 (Study Day 91) - 09 Dec 2020 (Study Day 128)	Cough
Magnesium oxide	02 Nov 2020 (Study Day 91) - Ongoing	General Health
Melatonin	02 Nov 2020 (Study Day 91) - Ongoing	General Health
Ondansetron hydrochloride	02 Nov 2020 (Study Day 91) - 09 Dec 2020 (Study Day 128)	Nausea
Oxycodone hydrochloride; paracetamol	02 Nov 2020 (Study Day 91) - Ongoing	Pain, Motor Vehicle Accident
Paracetamol	02 Nov 2020 (Study Day 91) - Ongoing	Pain, Motor Vehicle Accident
Paroxetine	02 Nov 2020 (Study Day 91) - 01 Feb 2021 (Study Day 182)	Anxiety
Sodium chloride	02 Nov 2020 (Study Day 91) - Ongoing	Hponatremia
Gabapentin	03 Nov 2020 (Study Day 92) - Ongoing	Motor Vehicle Accident
Levothyroxine	03 Nov 2020 (Study Day 92) - Ongoing	Hypothyroidism
Pantoprazole	03 Nov 2020 (Study Day 92) - Ongoing	Gastroesophageal Reflux Disease
Vitamins nos	03 Nov 2020 (Study Day 92) - Ongoing	Kidney General Health
Ergocalciferol	07 Nov 2020 (Study Day 96) - Ongoing	General Health
Methocarbamol	07 Nov 2020 (Study Day 96) - Ongoing	Muscle Spasms, Motor Vehicle Accident
Diclofenac	13 Nov 2020 (Study Day 102) - Ongoing	Motor Vehicle Accident
Lidocaine	14 Nov 2020 (Study Day 103) - 09 Dec 2020 (Study Day 128)	Pain Due To Motor Vehicle Accident
Amlodipine	20 Nov 2020 (Study Day 109) - 01 Jan 2021 (Study Day 151)	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Seizure	Grade 1/mild	Not related	08 Sep 2020 (Study Day 36) - 08 Sep 2020 (Study Day 36)
Rib Fracture	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 37) - 19 Dec 2020 (Study Day 138)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperglycaemia	Grade 2/moderate	Not related	13 Sep 2020 (Study Day 41) - 09 Dec 2020 (Study Day 128)
Hyponatraemia	Grade 2/moderate	Not related	13 Sep 2020 (Study Day 41) - 09 Dec 2020 (Study Day 128)
Lower Limb Fracture	Grade 2/moderate	Not related	13 Sep 2020 (Study Day 41) - 24 Feb 2021 (Study Day 205)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379467

Participant Number:	US341-2126 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Lung Abscess/Abscess Of Lung	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	22 Aug 2020 (Study Day 19) – 20 Jan 2021 (Study Day 170)	Recovered/resolved
Pneumonia/Pneumonia	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	22 Aug 2020 (Study Day 19) – 20 Jan 2021 (Study Day 170)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2126, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Aug 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of lung abscess. On 31 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of abscess of lung lasted for 152 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 170). The investigator assessed the event of lung abscess to be not related to the IP.

On 22 Aug 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of pneumonia. On 31 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of pneumonia lasted for 152 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 170). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000228	Lung abscess
MOD-2020-000228	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tobacco user	Smoking	1980 - Ongoing
Bronchitis chronic	Chronic bronchitis	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Osteoarthritis	Osteoarthritis hips and shoulders	2010 - Ongoing
Osteoporosis	Osteoperosis	2010 - Ongoing
Postmenopause	Post menopausal	2010 - Ongoing
Anxiety	Anxiety	Mar 2015 - Ongoing
Periarthritis	Frozen shoulder - bilateral	2017 - Ongoing
Seasonal allergy	Allergic rhinitis - seasonal	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tizanidine hydrochloride	2010 - Ongoing	Osteoarthritis
Calcium chloride	2014 - Ongoing	Osteoporosis
Acetylsalicylic acid	2015 - 01 Sep 2020 (Study Day 29)	Hypertension
Citalopram hydrobromide	2015 - Ongoing	Anxiety
Diclofenac	2015 - Ongoing	Osteoarthritis
Furosemide	2015 - Ongoing	Hypertension
Oxycodone hydrochloride; paracetamol	2015 - Ongoing	Osteoarthritis
Potassium chloride	2016 - Ongoing	General Health
Guaifenesin	2017 - Ongoing	Allergic Rhinitis - Seasonal
Denosumab	2018 - Ongoing	Osteoporosis
Mometasone	20 Aug 2019 (Study Day -350) - Ongoing	Seasonal Allergies
Triamcinolone acetonide	08 Oct 2019 (Study Day -301) - Ongoing	Seasonal Allergies
Acetylsalicylic acid	05 Aug 2020 (Study Day 2) - 18 Aug 2020 (Study Day 15)	Uri
Acetylsalicylic acid	08 Aug 2020 (Study Day 5) - 18 Aug 2020 (Study Day 15)	Fever For Uri
Benzonatate	14 Aug 2020 (Study Day 11) - 18 Aug 2020 (Study Day 15)	Uri - Upper Respiratory Infection
Ct pulmonary angiogram*	22 Aug 2020 (Study Day 19) - 22 Aug 2020 (Study Day 19)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	23 Aug 2020 (Study Day 20) - 24 Aug 2020 (Study Day 21)	Pneumonia
Bal cultures and cytology*	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Adverse Event
Ceftriaxone	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Pneumonia
Ecg's daily from 23-aug-2020 to 30-aug-2020*	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Adverse Event
Enoxaparin sodium	23 Aug 2020 (Study Day 20) - 01 Sep 2020 (Study Day 29)	Dvt Prophylaxis
Initial labs showed leucocytosis, blood cx so fard ngtd*	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Adverse Event
Methylprednisolone sodium succinate	23 Aug 2020 (Study Day 20) - 01 Sep 2020 (Study Day 29)	Pneumonia
Morphine	23 Aug 2020 (Study Day 20) - 01 Sep 2020 (Study Day 29)	Rib Pain / Pneumonia
Ondansetron	23 Aug 2020 (Study Day 20) - 01 Sep 2020 (Study Day 29)	Nausea Prophylactic
X-ray chest (pa&lateral)*	23 Aug 2020 (Study Day 20) - 23 Aug 2020 (Study Day 20)	Adverse Event
Bronchoscopy with bal done on 25-aug-2020)*	25 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 22)	Adverse Event
Piperacillin; tazobactam	26 Aug 2020 (Study Day 23) - 22 Sep 2020 (Study Day 50)	Ae - Pneumonia
Picc line insertion*	31 Aug 2020 (Study Day 28) - 31 Aug 2020 (Study Day 28)	Adverse Event
Xray chest (pa&lateral)*	31 Aug 2020 (Study Day 28) - 31 Aug 2020 (Study Day 28)	Adverse Event
Chest ct*	19 Oct 2020 (Study Day 77) - 19 Oct 2020 (Study Day 77)	Adverse Event
Morphine	24 Oct 2020 (Study Day 82) - 24 Oct 2020 (Study Day 82)	Rib Pain
Chest ct*	20 Jan 2021 (Study Day 170) - 20 Jan 2021 (Study Day 170)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not related	05 Aug 2020 (Study Day 2) - 18 Aug 2020 (Study Day 15)
Musculoskeletal Chest Pain	Grade 4	Not related	23 Aug 2020 (Study Day 20) - 22 Sep 2020 (Study Day 50)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2127 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Respiratory Failure/Acute Respiratory Failure	SAE	Grade 4	Not related	14 Aug 2020 (Study Day 10) – 20 Aug 2020 (Study Day 16)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2127, a 42-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Aug 2020 (Study Day 10), 9 days after the first dose and 20 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute respiratory failure. The IP dose was not changed due to the acute respiratory failure. The event of acute respiratory failure lasted for 7 days, after which it was considered to be recovered/resolved on 20 Aug 2020 (Study Day 16). The investigator assessed the event of acute respiratory failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000202	Acute respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2012 - Ongoing
Depression	Depression	2012 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2012 - Ongoing
Post-traumatic stress disorder	Ptsd	2012 - Ongoing
Back pain	Lumbar pain	Jan 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2012 - Ongoing	Hyperlipidemia
Bupropion hydrochloride	2012 - Ongoing	Ptsd
Vortioxetine hydrobromide	2012 - Ongoing	Ptsd
Ibuprofen	06 Aug 2020 (Study Day 2) - 06 Aug 2020 (Study Day 2)	Solicited Pain - Myalgia And Joint Aches
Levofloxacin	16 Aug 2020 (Study Day 12) - 23 Aug 2020 (Study Day 19)	Acute Respiratory Failure
Salbutamol	16 Aug 2020 (Study Day 12) - 19 Aug 2020 (Study Day 15)	Acute Respiratory Failure
Guaifenesin	17 Aug 2020 (Study Day 13) - 24 Aug 2020 (Study Day 20)	Acute Respiratory Failure
Methylprednisolone sodium succinate	17 Aug 2020 (Study Day 13) - 19 Aug 2020 (Study Day 15)	Acute Respiratory Failure
Ondansetron	17 Aug 2020 (Study Day 13) - 19 Aug 2020 (Study Day 15)	Acute Respiratory Failure
Sodium chloride	17 Aug 2020 (Study Day 13) - 19 Aug 2020 (Study Day 15)	Acute Respiratory Failure
Budesonide; formoterol fumarate	20 Aug 2020 (Study Day 16) - 12 Dec 2020 (Study Day 130)	Acute Respiratory Failure
Gabapentin	20 Aug 2020 (Study Day 16) - Ongoing	Lumbar Pain
Prednisone	20 Aug 2020 (Study Day 16) - 24 Aug 2020 (Study Day 20)	Acute Respiratory Failure
Salbutamol	20 Aug 2020 (Study Day 16) - Ongoing	Acute Respiratory Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US341-2184 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intraductal Proliferative Breast Lesion/Right Breast Ductal Carcinoma In Situ	SAE	Grade 2/moderate	Not related	12 Aug 2020 (Study Day 3) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2184, a 73-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Aug 2020 (Study Day 3), 2 days after the first dose and 27 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of intraductal proliferative breast lesion. The IP dose was not changed due to the right breast ductal carcinoma in situ. The event of right breast ductal carcinoma in situ was considered to be ongoing. The investigator assessed the event of intraductal proliferative breast lesion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000203	Intraductal proliferative breast lesion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	1996 - Ongoing
Osteoarthritis	Osteoarthritis bi-lateral knees	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2000 - Ongoing	General Health
Fish oil	2000 - Ongoing	General Health
Vitamins nos	2000 - Ongoing	General Health
Ibuprofen	2010 - Ongoing	Osteoarthritis Of Knee
Ibuprofen	2020 - Ongoing	Oa
Mam sterotactic loc breast biopsy right*	12 Aug 2020 (Study Day 3) - 12 Aug 2020 (Study Day 3)	Diagnostic
Dx bone density axial skeleton*	16 Sep 2020 (Study Day 38) - 16 Sep 2020 (Study Day 38)	Diagnostic
Mri breast bilateral w wo contrast w cad*	17 Sep 2020 (Study Day 39) - 17 Sep 2020 (Study Day 39)	Diagnostic
Anastrozole	03 Nov 2020 (Study Day 86) - Ongoing	Breast Cancer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	05 Jan 2021 (Study Day 149) - 07 Jan 2021 (Study Day 151)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2205 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ovarian Cyst/Ovarian Cyst	SAE	Grade 4	Not related	29 Dec 2020 (Study Day 141) – 04 Feb 2021 (Study Day 178)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2205, a 33-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Dec 2020 (Study Day 141), 140 days after the first dose and 111 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of ovarian cyst. Action taken with the IP was not applicable. The event of ovarian cyst lasted for 38 days, after which it was considered to be recovered/resolved on 04 Feb 2021 (Study Day 178). The investigator assessed the event of ovarian cyst to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-026543	Ovarian cyst

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Tubal ligation	2018 - 2018
Seasonal allergy	Seasonal allergic rhinitis	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen sodium	01 Oct 2020 (Study Day 52) - 03 Oct 2020 (Study Day 54)	Viral Syndrome
Methylprednisolone	09 Nov 2020 (Study Day 91) - 09 Nov 2020 (Study Day 91)	Uri
Methylprednisolone	10 Nov 2020 (Study Day 92) - 10 Nov 2020 (Study Day 92)	Uri
Methylprednisolone	11 Nov 2020 (Study Day 93) - 11 Nov 2020 (Study Day 93)	Uri
Methylprednisolone	12 Nov 2020 (Study Day 94) - 12 Nov 2020 (Study Day 94)	Uri
Methylprednisolone	13 Nov 2020 (Study Day 95) - 13 Nov 2020 (Study Day 95)	Uri
Methylprednisolone	14 Nov 2020 (Study Day 96) - 14 Nov 2020 (Study Day 96)	Uri
Naproxen	26 Dec 2020 (Study Day 138) - Ongoing	Anti Inflammatory Prophylactic
Hysterectomy*	04 Feb 2021 (Study Day 178) - 04 Feb 2021 (Study Day 178)	Adverse Event
Left oopherectomy*	04 Feb 2021 (Study Day 178) - 04 Feb 2021 (Study Day 178)	Adverse Event
Oxycodone hydrochloride; paracetamol	04 Feb 2021 (Study Day 178) - 08 Feb 2021 (Study Day 182)	Ovarian Cyst, Post-Op Pain Relief

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Viral Infection	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 46) - 24 Oct 2020 (Study Day 75)
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 85) - 22 Nov 2020 (Study Day 104)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2240 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intervertebral Disc Protrusion/Cervical Disc Herniation	SAE	Grade 4	Not related	04 Dec 2020 (Study Day 113) – Ongoing	Not recovered/not resolved
Acute Respiratory Failure/Acute Respiratory Failure Due To Hematoma Of Neck	SAE	Grade 4	Not related	07 Dec 2020 (Study Day 116) – 13 Dec 2020 (Study Day 122)	Recovered/resolved
Haematoma/Hematoma Of Neck	SAE	Grade 4	Not related	07 Dec 2020 (Study Day 116) – 08 Dec 2020 (Study Day 117)	Recovered/resolved
Cerebrovascular Accident/Cerebrovascular Accident	SAE	Grade 4	Not related	12 Dec 2020 (Study Day 121) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2240, a 60-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Dec 2020 (Study Day 113), 112 days after the first dose and 84 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of intervertebral disc protrusion. Action taken with the IP was not applicable. The event of cervical disc herniation was considered to be ongoing. The investigator assessed the event of intervertebral disc protrusion to be not related to the IP.

On 07 Dec 2020 (Study Day 116), 115 days after the first dose and 87 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute respiratory failure due to hematoma of neck lasted for 7 days, after which it was considered to be recovered/resolved on 13 Dec 2020 (Study Day 122). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 07 Dec 2020 (Study Day 116), 115 days after the first dose and 87 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of haematoma. Action taken with the IP was not applicable. The event of hematoma of neck lasted for 2 days, after which it was considered to be recovered/resolved on 08 Dec 2020 (Study Day 117). The investigator assessed the event of haematoma to be not related to the IP.

On 12 Dec 2020 (Study Day 121), 120 days after the first dose and 92 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of cerebrovascular accident was considered to be ongoing. The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001059	Radiculopathy
MOD-2020-001059	Spinal stenosis
MOD-2020-001059	Cerebrovascular accident
MOD-2020-001059	Acute respiratory failure
MOD-2020-001059	Hematoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headache	Not reported - Ongoing
Migraine	Migraine	Not reported - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	1969 - Ongoing
Depression	Depression	1974 - Ongoing
Coronary artery disease	Coronary artery disease	1984 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	1989 - Ongoing
Chronic kidney disease	Ckd	2005 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2005 - Ongoing
Fibromyalgia	Fibromyalgia	2007 - Ongoing
Gastric bypass	Gastric bypass	2007 - Ongoing
Gastrooesophageal reflux disease	Gerd	2007 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2007 - Ongoing
Hypertension	Hypertension	2007 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2010 - Ongoing
Narcolepsy	Narcolepsy	2010 - Ongoing
Postmenopause	Post-menapousal	2011 - Ongoing
Osteoarthritis	Osteoarthritis: knees and back	2015 - Ongoing
Muscle spasms	Leg cramps	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine hydrochloride	1997 - Ongoing	Depression
Salbutamol	2006 - Ongoing	Chronic Obstructive Pulmonary Disease
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergic Rhinitis
Dicycloverine	2010 - Ongoing	Post Gastric Bypass
Diphenhydramine hydrochloride	2010 - Ongoing	Seasonal Allergic Rhinitis
Fluticasone propionate	2010 - Ongoing	Seasonal Allergic Rhinitis
Modafinil	2010 - Ongoing	Narcolepsy
Prochlorperazine	2010 - Ongoing	Nausea Secondary To Gastric Bypass
Simeticone	2010 - Ongoing	Post Gastric Bypass
Vitamin d nos	2010 - Ongoing	General Health
Vitamins nos	2010 - Ongoing	General Health
Pregabalin	2014 - Ongoing	Fibromyalgia
Rosuvastatin	2015 - Ongoing	Hyperlipidemia
Atenolol	2017 - Ongoing	Hypertension
Insulin degludec	2017 - Ongoing	Diabetes Type 2
Baclofen	2019 - Ongoing	Leg Cramps Secondary To Statin
Oxycodone	2020 - Ongoing	Fibromyalgia
Famotidine	28 Nov 2020 (Study Day 107) - 02 Dec 2020 (Study Day 111)	Pruritis
Hydrocortisone	28 Nov 2020 (Study Day 107) - 28 Nov 2020 (Study Day 107)	Puritis
Hydroxyzine	28 Nov 2020 (Study Day 107) - Ongoing	Pruritis
Prednisone	02 Dec 2020 (Study Day 111) - 02 Dec 2020 (Study Day 111)	Pruritis
Anterior cervical disc cystectomy and fusion*	05 Dec 2020 (Study Day 114) - 05 Dec 2020 (Study Day 114)	Adverse Event
Buspirone hydrochloride	05 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 133)	Depression
Dexamethasone	05 Dec 2020 (Study Day 114) - 07 Dec 2020 (Study Day 116)	Cervical Spine Stenosis
Insulin glargine	05 Dec 2020 (Study Day 114) - 08 Dec 2020 (Study Day 117)	In Hospital Management Of Type 2 Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	05 Dec 2020 (Study Day 114) - 07 Dec 2020 (Study Day 116)	Pain Management, Cervical Disc Surgery
Sucralfate	05 Dec 2020 (Study Day 114) - 07 Dec 2020 (Study Day 116)	In Hospital Management Of Gerd
Triamcinolone	05 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 133)	Unknown
Ziprasidone	05 Dec 2020 (Study Day 114) - 11 Dec 2020 (Study Day 120)	Depression, Anxiety
Fenofibrate	06 Dec 2020 (Study Day 115) - 24 Dec 2020 (Study Day 133)	Hyperlipidemia
Cefazolin	07 Dec 2020 (Study Day 116) - 13 Dec 2020 (Study Day 122)	Surgical Infection Prevention For Cervical Disc
Epinephrine	07 Dec 2020 (Study Day 116) - 07 Dec 2020 (Study Day 116)	Acute Respiratory Failure
Etomidate	07 Dec 2020 (Study Day 116) - 07 Dec 2020 (Study Day 116)	Cervical Disc Surgery Anesthesia
Fentanyl	07 Dec 2020 (Study Day 116) - 11 Dec 2020 (Study Day 120)	Sedation For Cerebrovascular Accident And Hematoma
Hydromorphone hydrochloride	07 Dec 2020 (Study Day 116) - 07 Dec 2020 (Study Day 116)	Pain, Cerebrovascular Accident, Cervical Disc Surgery
Labetalol	07 Dec 2020 (Study Day 116) - 07 Dec 2020 (Study Day 116)	In Hospital Management Of Hypertension
Propofol	07 Dec 2020 (Study Day 116) - 11 Dec 2020 (Study Day 120)	Sedation (Hospitalization) For Ae Of Acute Respiratory Failure Due To Hematoma Of Neck
Ascorbic acid	08 Dec 2020 (Study Day 117) - 24 Dec 2020 (Study Day 133)	General Health
Budesonide	08 Dec 2020 (Study Day 117) - 15 Dec 2020 (Study Day 124)	Acute Respiratory Failure
Dexamethasone	08 Dec 2020 (Study Day 117) - 08 Dec 2020 (Study Day 117)	Cervical Spinal Stenosis
Diphenhydramine hydrochloride	08 Dec 2020 (Study Day 117) - 08 Dec 2020 (Study Day 117)	Cerebrovascular Accident, Cervical Spinal Stenosis, Hematoma
Drain hematoma*	08 Dec 2020 (Study Day 117) - 08 Dec 2020 (Study Day 117)	Adverse Event
Insulin aspart	08 Dec 2020 (Study Day 117) - 24 Dec 2020 (Study Day 133)	In Hospital Management Of Type 2 Diabetes
Insulin glargine	08 Dec 2020 (Study Day 117) - 08 Dec 2020 (Study Day 117)	In Hospital Management Of Type 2 Diabetes
Ipratropium bromide; salbutamol sulfate	08 Dec 2020 (Study Day 117) - 15 Dec 2020 (Study Day 124)	Acute Respiratory Failure
Pantoprazole	08 Dec 2020 (Study Day 117) - 13 Dec 2020 (Study Day 122)	In Hospital Management Of Gerd
Bisacodyl	09 Dec 2020 (Study Day 118) - 14 Dec 2020 (Study Day 123)	Constipation Prevention, Cerebrovascular Accident, Spinal Stenosis
Diphenhydramine hydrochloride	09 Dec 2020 (Study Day 118) - 18 Dec 2020 (Study Day 127)	Cerebrovascular Accident, Cervical Spinal Stenosis
Magnesium hydroxide	09 Dec 2020 (Study Day 118) - 09 Dec 2020 (Study Day 118)	Constipation Prevention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Albumin human	10 Dec 2020 (Study Day 119) - 10 Dec 2020 (Study Day 119)	Hypoalbuminemia, Cerebrovascular Accident, Cervical Spine Stenosis
Heparin	10 Dec 2020 (Study Day 119) - 14 Dec 2020 (Study Day 123)	Thromboembolism Prevention
Norepinephrine	10 Dec 2020 (Study Day 119) - 10 Dec 2020 (Study Day 119)	Acute Respiratory Failure
Dexamethasone	11 Dec 2020 (Study Day 120) - 11 Dec 2020 (Study Day 120)	Cervical Spinal Stenosis
Acetylsalicylic acid	12 Dec 2020 (Study Day 121) - 24 Dec 2020 (Study Day 133)	General Health
Clopidogrel bisulfate	12 Dec 2020 (Study Day 121) - 24 Dec 2020 (Study Day 133)	Cerebrovascular Accident Prevention
Morphine	13 Dec 2020 (Study Day 122) - 24 Dec 2020 (Study Day 133)	Pain Management, Cervical Disc Surgery
Paracetamol	13 Dec 2020 (Study Day 122) - 22 Dec 2020 (Study Day 131)	Pain, Cervical Spine Stenosis
Enoxaparin sodium	14 Dec 2020 (Study Day 123) - 23 Dec 2020 (Study Day 132)	Dvt Prophylaxis
Pantoprazole	14 Dec 2020 (Study Day 123) - 24 Dec 2020 (Study Day 133)	In Hospital Management Of Gerd
Promethazine	14 Dec 2020 (Study Day 123) - 14 Dec 2020 (Study Day 123)	Nausea
Lisinopril	15 Dec 2020 (Study Day 124) - 24 Dec 2020 (Study Day 133)	In Hospital Management Of Hypertension
Docusate sodium	19 Dec 2020 (Study Day 128) - 24 Dec 2020 (Study Day 133)	Constipation Prevention
Sennoside a+b	19 Dec 2020 (Study Day 128) - 19 Dec 2020 (Study Day 128)	Constipation Prevention
Macrogol 3350	20 Dec 2020 (Study Day 129) - 20 Dec 2020 (Study Day 129)	Constipation Prevention
Diazepam	21 Dec 2020 (Study Day 130) - 21 Dec 2020 (Study Day 130)	Cerebrovascular Accident, Cervical Spinal Stenosis
Methocarbamol	21 Dec 2020 (Study Day 130) - 22 Dec 2020 (Study Day 131)	In Hospital Management Of Leg Cramps
Tramadol	22 Dec 2020 (Study Day 131) - 23 Dec 2020 (Study Day 132)	Pain Management, Cervical Disc Surgery, Hematoma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pruritus	Grade 4	Not related	28 Nov 2020 (Study Day 107) - 29 Nov 2020 (Study Day 108)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2243 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Of Osteoarthritis	SAE	Grade 4	Not related	15 Oct 2020 (Study Day 63) – 18 Mar 2021 (Study Day 217)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2243, a 65-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Oct 2020 (Study Day 63), 62 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening of osteoarthritis lasted for 155 days, after which it was considered to be recovered/resolved on 18 Mar 2021 (Study Day 217). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-034167	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis perennial	Perennial allergic rhinitis	1960 - Ongoing
Asthma	Asthma	1962 - Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Osteoarthritis	Osteoarthritis: elbows, knees	2005 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2012 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2014 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2015 - Ongoing
Glaucoma	Glaucoma	2016 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1975 - Ongoing	Asthma
Cetirizine hydrochloride	2016 - Ongoing	Perennial Allergic Rhinitis
Fluticasone propionate	2016 - Ongoing	Perennial Allergic Rhinitis
Metformin	2016 - Ongoing	Diabetes Type 2
Montelukast sodium	2016 - Ongoing	Asthma
Atorvastatin	2017 - Ongoing	Hyperlipidemia
Omeprazole	2017 - Ongoing	Gastroesophageal Reflux Disease
Left total knee replacement*	13 Jan 2021 (Study Day 153) - 13 Jan 2021 (Study Day 153)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US341-2328 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chest Pain/Atypical Chest Pain	SAE	Grade 4	Not related	17 Sep 2020 (Study Day 23) – 18 Sep 2020 (Study Day 24)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2328, a 64-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Sep 2020 (Study Day 23), 22 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of chest pain. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other (participant decided that they did not want the second dosage). The event of atypical chest pain lasted for 2 days, after which it was considered to be recovered/resolved on 18 Sep 2020 (Study Day 24). The investigator assessed the event of chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000727	Chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Allergic rhinitis - seasonal	1981 - Ongoing
Postmenopause	Post menopausal	2004 - Ongoing
Osteoarthritis	Osteoarthrits - bilateral knees, hand, foot, back	2010 - Ongoing
Atrial fibrillation	Afibrillation - (atrial fibrillation) sympton free since ablation	2015 - 2016
Osteopenia	Osteopenia	2015 - Ongoing
Cardiac ablation	Cardiac ablation	2016 - 2016
Gastrooesophageal reflux disease	Gastroesophogeal reflux disease	2016 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	2010 - Ongoing	General Health
Fluticasone propionate	2010 - Ongoing	Allergic Rhinitis - Seasonal
Vitamin d nos	2010 - Ongoing	General Health
Anesthetics, local	2017 - Ongoing	Pain For Oa Of Foot
Benzoyl peroxide	2017 - Ongoing	General Skin Care
Ethinylestradiol; norethisterone acetate	May 2020 - Ongoing	Osteopenia
Ecg, echocardigram, nuclear stress test, xcr and blood work*	17 Sep 2020 (Study Day 23) - 17 Sep 2020 (Study Day 23)	Other, See Source Notes Dated 30-Dec-2020 For More Information
Influenza vaccine	09 Oct 2020 (Study Day 45) - 09 Oct 2020 (Study Day 45)	General Health
Famotidine	29 Oct 2020 (Study Day 65) - Ongoing	Gerd
Varicella zoster vaccine	29 Oct 2020 (Study Day 65) - 29 Oct 2020 (Study Day 65)	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chest Pain	Grade 3/severe	Not related	05 Sep 2020 (Study Day 11) - 01 Oct 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US342-2135 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Stenosis/Spinal Stenosis	SAE	Grade 3/severe	Not related	06 Oct 2020 (Study Day 40) – 08 Oct 2020 (Study Day 42)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US342-2135, a 67-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Oct 2020 (Study Day 40), 39 days after the first dose and 11 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of spinal stenosis. Action taken with the IP was not applicable. The event of spinal stenosis lasted for 3 days, after which it was considered to be recovered/resolved on 08 Oct 2020 (Study Day 42). The investigator assessed the event of spinal stenosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000450	Spinal stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	1984 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1994 - Ongoing
Hypertension	Hypertension	2003 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2006 - Ongoing
Anxiety	General anxiety	2018 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Sciatica	Sciatica	2019 - Ongoing
Drug hypersensitivity	Allergy alpha-gel	Jun 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1979 - Ongoing	General Health
Levothyroxine	1984 - Ongoing	Hypothyroidism
Simvastatin	1994 - Ongoing	Hypercholesterolemia
Acetylsalicylic acid	2002 - Ongoing	General Health
Metoprolol	2003 - Ongoing	Hypertension
Metformin	2007 - Ongoing	Type Ii Diabetes
Colecalciferol	2015 - Ongoing	General Health
Dulaglutide	2016 - Ongoing	Type Ii Diabetes
Losartan	2016 - Ongoing	Hypertension
Buspirone	2018 - Ongoing	General Anxiety
Fluticasone propionate	2018 - Ongoing	Seasonal Allergies
Montelukast sodium	2018 - Ongoing	Seasonal Allergies
Naproxen	2019 - Ongoing	Sciatica
Albumin human	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Anesthetics	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Spinal Stenosis Repair
Cefazolin	06 Oct 2020 (Study Day 40) - 07 Oct 2020 (Study Day 41)	Surgical Prophylaxis, Spinal Stenosis Repair
Clonidine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Cyclobenzaprine	06 Oct 2020 (Study Day 40) - 20 Oct 2020 (Study Day 54)	Post-Operative Care Pain And Muscle Spasm
Dexamethasone	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Glycopyrronium	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Hydrocodone; paracetamol	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Pain Control, Spinal Stenosis Repair
Hydrocodone; paracetamol	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Post Operative Pain Control
Ibuprofen	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Pain Prevention
Ketamine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Ketorolac	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Pain Control, Spinal Stenosis Repair
Laminectomy with posterolateral fusion*	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Medical History
Lidocaine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Meclozine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Nausea Prevention, Post Operative Care
Methocarbamol	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Midazolam	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Neostigmine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Ondansetron	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Phenylephrine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Povidone-iodine	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Post-Operative Care, Spinal Stenosis Repair
Propofol	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Rocuronium	06 Oct 2020 (Study Day 40) - 06 Oct 2020 (Study Day 40)	Surgical Care, Spinal Stenosis Repair
Hydrocodone; paracetamol	08 Oct 2020 (Study Day 42) - Ongoing	Pain Control
Methylprednisolone	08 Oct 2020 (Study Day 42) - 13 Oct 2020 (Study Day 47)	Post-Operative Care, Pain And Inflammation
Paracetamol	08 Oct 2020 (Study Day 42) - 20 Oct 2020 (Study Day 54)	Post Operative Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US342-2281 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	15 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	14 Oct 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Osteoarthritis	SAE	Grade 3/severe	Not related	27 Oct 2020 (Study Day 43) – 28 Oct 2020 (Study Day 44)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US342-2281, a 65-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 14 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Oct 2020 (Study Day 43), 42 days after the first dose and 13 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening osteoarthritis lasted for 2 days, after which it was considered to be recovered/resolved on 28 Oct 2020 (Study Day 44). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000596	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Calcium deficiency	Calcium deficiency	Not reported - Ongoing
Magnesium deficiency	Magnesium deficiency	Not reported - Ongoing
Menopause	Menopause	2000 - Ongoing
Osteoarthritis	Osteoarthritis, generalized	2000 - Ongoing
Gastrooesophageal reflux disease	Gerd	2008 - Ongoing
Deep vein thrombosis	Deep vein thrombosis	2012 - 2012
Pulmonary embolism	Pulmonary embolus	2012 - 2012
Knee arthroplasty	R knee replacement	May 2020 - May 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2008 - Ongoing	Acid Reflux
Meloxicam	May 2020 - Ongoing	Osteo-Arthritis, Generalized
Biotin	18 May 2020 (Study Day -120) - Ongoing	Health Maintenance
Calcium carbonate	18 May 2020 (Study Day -120) - Ongoing	Gerd (Due To Omeprazole Use), Calcium Deficiency
Magnesium	18 May 2020 (Study Day -120) - Ongoing	Gerd (Due To Omeprazole Use), Magnesium Deficiency
Hydromorphone hydrochloride	27 Oct 2020 (Study Day 43) - 10 Nov 2020 (Study Day 57)	Pain Post Procedure
Primary left total knee arthroplasty*	27 Oct 2020 (Study Day 43) - 27 Oct 2020 (Study Day 43)	Adverse Event
Rivaroxaban	27 Oct 2020 (Study Day 43) - Ongoing	Blood Clot Prevention
Ascorbic acid; bioflavonoids nos	05 Nov 2020 (Study Day 52) - Ongoing	Health Maintenance
Magnesium citrate	05 Nov 2020 (Study Day 52) - 05 Nov 2020 (Study Day 52)	Laxative, (Patient Took For Magnesium Deficiency, But Didn't Mean To Get The Laxative)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US343-2016 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastrooesophageal Reflux Disease/Gerd	SAE	Grade 3/ severe	Not related	22 Oct 2020 (Study Day 79) – 24 Oct 2020 (Study Day 81)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2016, a 76-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Oct 2020 (Study Day 79), 78 days after the first dose and 50 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of gastrooesophageal reflux disease. Action taken with the IP was not applicable. The event of gerd lasted for 3 days, after which it was considered to be recovered/resolved on 24 Oct 2020 (Study Day 81). The investigator assessed the event of gastrooesophageal reflux disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000545	Gastrooesophageal reflux disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Candida infection	Candida albicans	Not reported - Ongoing
Otitis externa	Chronic otitis externa	Not reported - Ongoing
Tonsillectomy	Tonsillectomy	1960 - 1960
Thyroidectomy	Partial thyroidectomy	1995 - 1995
Uvulectomy	Uvula removal	1995 - 1995
Rhinitis allergic	Allergic rhinitis	2000 - Ongoing
Asthma	Asthma	2005 - Ongoing
Hysterectomy	Hysterectomy	2005 - 2005
Postmenopause	Post-menopausal	2005 - Ongoing
Cardiac murmur	Heart murmur	2010 - Ongoing
Chronic obstructive pulmonary disease	Copd	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Urinary bladder suspension	Bladder sling	2010 - 2010
Knee arthroplasty	Knee replacement	2011 - 2011
Osteoarthritis	Osteoarthritis	2011 - Ongoing
Bradycardia	Bradycardia	2012 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2012 - Ongoing
Cataract operation	Cataract surgery	2015 - 2015
Carpal tunnel decompression	Carpal tunnel surgery	2017 - 2017
Hip arthroplasty	Hip replacement	2017 - 2017
Pneumonia	Pneumonia	2017 - 2017
Cholecystectomy	Cholecystectomy	2018 - 2018
Gastrooesophageal reflux disease	Gerd	2018 - Ongoing
Tendon sheath incision	Trigger finger surgery	2018 - 2018
Atrial fibrillation	Atrial fibrillation	2019 - Ongoing
Gluten sensitivity	Gluten sensitivity	2019 - Ongoing
Atrial appendage closure	Watchman procedure for atrial fibrillation	Nov 2019 - Nov 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bacillus coagulans; inulin	Not reported - Ongoing	General Health
Hydrocortisone	Not reported - Ongoing	Chronic Otitis Externa
Macrogol 3350	Not reported - Ongoing	Constipation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid; bromelains; calcium pantothenate; curcuma longa rhizome; cysteine; enzymes nos; magnesium oxide; ruscus aculeatus rhizome; ruscus aculeatus root	2010 - Ongoing	General Health
Ciclosporin	2010 - Ongoing	Dry Eyes
Fluticasone	2010 - Ongoing	Allergic Rhinitis
Fluticasone propionate; salmeterol xinafoate	2010 - 31 Aug 2020 (Study Day 27)	Asthma
Hydrochlorothiazide	2010 - Ongoing	Hypertension
Lisinopril	2010 - Ongoing	Hypertension
Montelukast	2010 - Ongoing	Allergic Rhinitis
Probiotics nos	2010 - Ongoing	General Health
Salbutamol	2010 - Ongoing	Asthma
Unspecified herbal and traditional medicine	2010 - Ongoing	General Health
Vaccinium macrocarpon	2010 - Ongoing	General Health
Amoxicillin	2011 - Ongoing	Dental Prophylaxis
Ibuprofen	2011 - Ongoing	Osteoarthritis
Simvastatin	2012 - Ongoing	Hyperlipidemia
Acetylcysteine	2015 - Ongoing	Mucous Production
Ascorbic acid	2015 - Ongoing	General Health
Vitamins nos	2015 - Ongoing	General Health
Biotin	2017 - Ongoing	General Health
Xantofyl	2018 - Ongoing	General Health
Betamethasone dipropionate; clotrimazole	18 Mar 2018 (Study Day -871) - Ongoing	Chronic Oitis Externa
Acetylsalicylic acid	2019 - Nov 2020	Atrial Fibrillation
Immunotherapy	01 May 2020 (Study Day -96) - Ongoing	Allergic Rhinitis
Ct scan*	24 Aug 2020 (Study Day 20) - 24 Aug 2020 (Study Day 20)	Diagnostic
Breathing test*	27 Aug 2020 (Study Day 23) - 27 Aug 2020 (Study Day 23)	Diagnostic
Fluticasone propionate; salmeterol xinafoate	01 Sep 2020 (Study Day 28) - Ongoing	Asthma
Amoxicillin	09 Sep 2020 (Study Day 36) - 09 Sep 2020 (Study Day 36)	Prophylaxis Dental Procedures
Dental implant*	09 Sep 2020 (Study Day 36) - 09 Sep 2020 (Study Day 36)	Other, Dental Care
Mammogram*	15 Sep 2020 (Study Day 42) - 15 Sep 2020 (Study Day 42)	Diagnostic
Influenza vaccine	17 Sep 2020 (Study Day 44) - 17 Sep 2020 (Study Day 44)	Prophylaxis
Amoxicillin	22 Sep 2020 (Study Day 49) - 22 Sep 2020 (Study Day 49)	Dental Prophylaxis
Dental implant*	22 Sep 2020 (Study Day 49) - 22 Sep 2020 (Study Day 49)	Other, Dental Care

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	23 Oct 2020 (Study Day 80) - 23 Oct 2020 (Study Day 80)	A-Fib
Ondansetron	23 Oct 2020 (Study Day 80) - 23 Oct 2020 (Study Day 80)	Nausea (Gerd)
Paracetamol	24 Oct 2020 (Study Day 81) - 24 Oct 2020 (Study Day 81)	Mild Pain (Gerd)
Lidocaine; triamcinolone	17 Feb 2021 (Study Day 197) - 17 Feb 2021 (Study Day 197)	Trigger Finger

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pyrexia	Grade 1/mild	Related	03 Sep 2020 (Study Day 30) - 04 Sep 2020 (Study Day 31)
Trigger Finger	Grade 1/mild	Not related	10 Feb 2021 (Study Day 190) - 17 Feb 2021 (Study Day 197)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2081 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 3/severe	Not related	20 Jan 2021 (Study Day 164) – 21 Jan 2021 (Study Day 165)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2081, a 28-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Jan 2021 (Study Day 164), 163 days after the first dose and 134 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 2 days, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 165). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-006583	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	2013 - 2013

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levonorgestrel	2019 - Ongoing	Contraception
Naproxen	09 Sep 2020 (Study Day 31) - 09 Sep 2020 (Study Day 31)	Injection Site Pain And Headache
Paracetamol	09 Sep 2020 (Study Day 31) - 09 Sep 2020 (Study Day 31)	Injection Site Pain And Headache
Influenza vaccine	29 Sep 2020 (Study Day 51) - 29 Sep 2020 (Study Day 51)	Influenza Prophylaxis
Appendectomy*	21 Jan 2021 (Study Day 165) - 21 Jan 2021 (Study Day 165)	Adverse Event
Paracetamol	21 Jan 2021 (Study Day 165) - Ongoing	Post-Appendectomy Pain Management

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US343-2094 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Meningioma/Progression Of Meningioma	SAE	Grade 3/ severe	Not related	28 Oct 2020 (Study Day 79) – Ongoing	Not recovered/not resolved
Procedural Haemorrhage/Intra-Operative Medication Induced Hypertensive Intraparenchymal Hemorrhage	SAE	Grade 3/ severe	Not related	23 Nov 2020 (Study Day 105) – Ongoing	Recovering/resolving
Mental Status Changes/Altered Mental Status	SAE	Grade 3/ severe	Not related	27 Dec 2020 (Study Day 139) – 04 Jan 2021 (Study Day 147)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2094, a 76-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 10 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Oct 2020 (Study Day 79), 78 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of meningioma. Action taken with the IP was not applicable. The event of progression of meningioma was considered to be ongoing. The investigator assessed the event of meningioma to be not related to the IP.

On 23 Nov 2020 (Study Day 105), 104 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of procedural haemorrhage. Action taken with the IP was not applicable. The event of intra-operative medication induced hypertensive intraparenchymal hemorrhage was considered to be ongoing. The investigator assessed the event of procedural haemorrhage to be not related to the IP.

On 27 Dec 2020 (Study Day 139), 138 days after the first dose and 108 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of mental status

changes. Action taken with the IP was not applicable. The event of altered mental status lasted for 9 days, after which it was considered to be recovered/resolved on 04 Jan 2021 (Study Day 147). The investigator assessed the event of mental status changes to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000906	Meningioma
MOD-2020-000906	Procedural haemorrhage
MOD-2020-000906	Mental status changes

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Esophageal reflux	1990 - Ongoing
Hypertension	Hypertension	1990 - Ongoing
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Vitamin D decreased	Low vitamin d	1990 - Ongoing
Depression	Depression	2003 - Ongoing
Prostate cancer	Prostate cancer	2003 - 2003
Coronary arterial stent insertion	Coronary stent	Sep 2007 - Sep 2007
Coronary artery disease	Coronary artery disease	Sep 2007 - Ongoing
Leukaemia	History of leukemia	Nov 2011 - 2012
Meningioma	Meningioma	Nov 2011 - Ongoing
Meningioma surgery	Surgical resection for meningioma	2012 - 2012
Atrioventricular block	Heart block	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1990 - Ongoing	Cardiovascular Prophylaxis
Irbesartan	1990 - Ongoing	Hypertension
Levothyroxine	1990 - Ongoing	Pre-Existing Hypothyroidism
Omeprazole	1990 - Ongoing	Esophageal Reflux

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram	2003 - Ongoing	Depression
Bupropion	2015 - Ongoing	Depression
Atorvastatin	Jul 2020 - Ongoing	Coronary Artery Disease
Paracetamol	10 Sep 2020 (Study Day 31) - 12 Sep 2020 (Study Day 33)	Soreness At Injection Site
Mri brain*	28 Oct 2020 (Study Day 79) - 28 Oct 2020 (Study Day 79)	Adverse Event
Bisacodyl	23 Nov 2020 (Study Day 105) - Ongoing	Constipation
Ceftriaxone	23 Nov 2020 (Study Day 105) - 24 Nov 2020 (Study Day 106)	Bacteremia
Craniectomy*	23 Nov 2020 (Study Day 105) - 23 Nov 2020 (Study Day 105)	Medical History
Cranioplasty*	23 Nov 2020 (Study Day 105) - 23 Nov 2020 (Study Day 105)	Medical History
Docusate sodium	23 Nov 2020 (Study Day 105) - Ongoing	Constipation
Esomeprazole	24 Nov 2020 (Study Day 106) - Ongoing	Gastric Reflux
Furosemide	24 Nov 2020 (Study Day 106) - 24 Nov 2020 (Study Day 106)	Fluid Retention Treatment
Paracetamol	24 Nov 2020 (Study Day 106) - Ongoing	Pain After Cranioplasty And Craniectomy
Atropine	25 Nov 2020 (Study Day 107) - Ongoing	Bradycardia
Paracetamol	25 Nov 2020 (Study Day 107) - Ongoing	Pain After Cranioplasty And Craniectomy
Escitalopram oxalate	27 Nov 2020 (Study Day 109) - Ongoing	Anxiety From Surgery
Furosemide	27 Nov 2020 (Study Day 109) - 27 Nov 2020 (Study Day 109)	Fluid Retention Treatment
Hydromorphone hydrochloride	01 Dec 2020 (Study Day 113) - Ongoing	Severe Pain After Cranioplasty And Craniectomy
Hydralazine	03 Dec 2020 (Study Day 115) - Ongoing	High Blood Pressure
Dexamethasone	04 Dec 2020 (Study Day 116) - Ongoing	Inflammation (General)
Heparin	04 Dec 2020 (Study Day 116) - 04 Dec 2020 (Study Day 116)	Anticoagulant
Vancomycin	06 Dec 2020 (Study Day 118) - 04 Jan 2021 (Study Day 147)	Bacteremia
Cefradine	07 Dec 2020 (Study Day 119) - Ongoing	Bacterial Infection Prevention
Heparin	11 Dec 2020 (Study Day 123) - Ongoing	Anticoagulant
Furosemide	15 Dec 2020 (Study Day 127) - 15 Dec 2020 (Study Day 127)	Fluid Retention Treatment
Furosemide	20 Dec 2020 (Study Day 132) - 20 Dec 2020 (Study Day 132)	Fluid Retention Treatment
Bisacodyl	23 Dec 2020 (Study Day 135) - Ongoing	Constipation
Famotidine	23 Dec 2020 (Study Day 135) - Ongoing	Antiacid
Heparin	23 Dec 2020 (Study Day 135) - Ongoing	Coagulant Prophylaxis
Ipratropium bromide; salbutamol sulfate	23 Dec 2020 (Study Day 135) - Ongoing	Shortness Of Breath
Ct scan head*	29 Dec 2020 (Study Day 141) - 29 Dec 2020 (Study Day 141)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ceftriaxone	02 Jan 2021 (Study Day 145) - 03 Feb 2021 (Study Day 177)	Bacteremia
Hydrocortisone	04 Jan 2021 (Study Day 147) - 11 Jan 2021 (Study Day 154)	Adrenal Insufficiency
Hydrocortisone	05 Jan 2021 (Study Day 148) - 05 Jan 2021 (Study Day 148)	Adrenal Insufficiency
Hydrocortisone	06 Jan 2021 (Study Day 149) - 12 Jan 2021 (Study Day 155)	Adrenal Insufficiency
Ct abdomen and pelvis*	02 Feb 2021 (Study Day 176) - 02 Feb 2021 (Study Day 176)	Adverse Event
Macrogol 3350	02 Feb 2021 (Study Day 176) - Ongoing	Constipation
Flexible sigmoidoscopy*	03 Feb 2021 (Study Day 177) - 03 Feb 2021 (Study Day 177)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthropod Bite	Grade 1/mild	Not related	07 Sep 2020 (Study Day 28) - 14 Sep 2020 (Study Day 35)
Lymphadenopathy	Grade 1/mild	Related	10 Sep 2020 (Study Day 31) - 08 Oct 2020 (Study Day 59)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2202 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertensive Urgency/Hypertensive Urgency	SAE	Grade 3/ severe	Not related	25 Sep 2020 (Study Day 38) – 30 Sep 2020 (Study Day 43)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2202, a 77-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 38), 37 days after the first dose and 9 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypertensive urgency. Action taken with the IP was not applicable. The event of hypertensive urgency lasted for 6 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 43). The investigator assessed the event of hypertensive urgency to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000356	Hypertensive urgency

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Exposure keratitis	Exposure keratoconjunctivitis l eye	Not reported
Anxiety	Anxiety	2005 - Ongoing
Blood cholesterol increased	High cholesterol (hld)	2010 - Ongoing
Diabetes mellitus	Diabetes mellitus	2010 - Ongoing
Eyelid retraction	Eyelid retraction l eye	03 Oct 2016 (Study Day -1416) - 03 Oct 2016 (Study Day -1416)
Chorea	Chorea	2017 - Ongoing
Gait disturbance	Gait instability	2017 - Ongoing
Duodenal ulcer	Duodenal ulcer	2019 - Ongoing
Headache	Daily headaches	2019 - Ongoing
Vertebral artery dissection	L vertebral artery dissection	2019 - 2019
Vertigo	Vertigo	2019 - Ongoing
Acute kidney injury	Acute kidney injury	28 Jan 2019 (Study Day -569) - Not reported
Fatigue	Chronic fatigue (being followed by physician)	Nov 2019 - Ongoing
Hypertension	Hypertension	Jan 2020 - Ongoing
Neck pain	Neck pain { being followed by md}	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine hydrochloride	Not reported - Ongoing	Anxiety
Glibenclamide	Not reported - Ongoing	Diabetes Mellitus
Glipizide	Not reported - Ongoing	Diabetes Mellitus
Ibuprofen	Not reported - Ongoing	Unknown
Lorazepam	Not reported - Ongoing	Anxeity
Metformin	Not reported - Ongoing	Dm
Mirtazapine	Not reported - Ongoing	Depression
Nsaids	Not reported - Ongoing	Headache
Pantoprazole	Not reported - Ongoing	Duodenal Ulcer
Simvastatin	Not reported - Ongoing	High Cholesterol
Trazodone	Not reported - Ongoing	Anxiety And Depression
Amlodipine	Jan 2020 - 25 Sep 2020 (Study Day 38)	Htn
Foreign body removal from foot*	20 Aug 2020 (Study Day 2) - 20 Aug 2020 (Study Day 2)	Adverse Event
Ibuprofen	21 Aug 2020 (Study Day 3) - 01 Sep 2020 (Study Day 14)	Foreign Body In Foot
Chest x-ray*	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Adverse Event
Ct head and neck*	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ecg*	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Adverse Event
Hydralazine	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Hypertension
Labetalol	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Hypertension
Mri brain*	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Adverse Event
Paracetamol	25 Sep 2020 (Study Day 38) - 25 Sep 2020 (Study Day 38)	Mild Pain In Hospital (Sae: Hypertensive Urgency)
Sennoside a+b	26 Sep 2020 (Study Day 39) - 30 Sep 2020 (Study Day 43)	Mild Constipation
Lisinopril	27 Sep 2020 (Study Day 40) - Ongoing	Htn
Lisinopril	27 Sep 2020 (Study Day 40) - 30 Sep 2020 (Study Day 43)	Hypertension
Enoxaparin sodium	28 Sep 2020 (Study Day 41) - 30 Sep 2020 (Study Day 43)	Blood Clot Prevention
Ibuprofen	28 Sep 2020 (Study Day 41) - 30 Sep 2020 (Study Day 43)	Mild General Pain While In Hospital (Sae Hypertensive Urgency)
Mri neck*	28 Sep 2020 (Study Day 41) - 28 Sep 2020 (Study Day 41)	Adverse Event
Eeg*	29 Sep 2020 (Study Day 42) - 29 Sep 2020 (Study Day 42)	Adverse Event
Moh’s surgery*	19 Mar 2021 (Study Day 213) - 19 Mar 2021 (Study Day 213)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Foreign Body	Grade 2/moderate	Not related	20 Aug 2020 (Study Day 2) - 02 Sep 2020 (Study Day 15)
Cervical Spinal Stenosis	Grade 3/severe	Not related	02 Oct 2020 (Study Day 45) - 02 Oct 2020 (Study Day 45)
Basal Cell Carcinoma	Grade 2/moderate	Not related	20 Feb 2021 (Study Day 186) - 19 Mar 2021 (Study Day 213)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2208 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Stenosis/Spinal Stenosis	SAE	Grade 3/severe	Not related	07 Sep 2020 (Study Day 19) – 05 Oct 2020 (Study Day 47)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2208, a 54-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 07 Sep 2020 (Study Day 19), 18 days after the first dose and 10 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of spinal stenosis. The IP dose was not changed due to the spinal stenosis. The event of spinal stenosis lasted for 29 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 47). The investigator assessed the event of spinal stenosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000467	Spinal stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2000 - Ongoing
Depression	Depression	2015 - Ongoing
Drug eruption	Ciproflox (rash)	2015 - Ongoing
Drug eruption	Clindamycin allergy (rash)	2015 - Ongoing
Dyspepsia	Dyspepsia	2017 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2018 - Ongoing
Spinal operation	Spine corrective surgery	17 Jun 2019 (Study Day -430) - 17 Jun 2019 (Study Day -430)
Metabolic surgery	Bariatric surgery	31 Oct 2019 (Study Day -294) - 31 Oct 2019 (Study Day -294)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine besilate	2000 - Ongoing	Hypertension
Sertraline	2015 - Ongoing	Depression
Omeprazole	2017 - Ongoing	Dyspepsia
Metformin	2018 - Ongoing	Type Ii Diabetes
Cervical spine mri*	07 Sep 2020 (Study Day 19) - 07 Sep 2020 (Study Day 19)	Adverse Event
Bisacodyl	02 Oct 2020 (Study Day 44) - 06 Oct 2020 (Study Day 48)	Con Medication Related To Procedure For Ae #1 Spinal Stenosis
Discectomy anterior cervical spine fusion*	02 Oct 2020 (Study Day 44) - 02 Oct 2020 (Study Day 44)	Adverse Event
Docusate sodium	02 Oct 2020 (Study Day 44) - Ongoing	Constipation
Hydromorphone	02 Oct 2020 (Study Day 44) - 02 Oct 2020 (Study Day 44)	Pain From Spine Surgery
Ondansetron	02 Oct 2020 (Study Day 44) - 06 Oct 2020 (Study Day 48)	Con Medication Related To Procedure For Ae #1 Spinal Stenosis
Ondansetron	02 Oct 2020 (Study Day 44) - 05 Oct 2020 (Study Day 47)	Nausea
Oxycodone	02 Oct 2020 (Study Day 44) - 04 Oct 2020 (Study Day 46)	Pain From Spine Surgery
Paracetamol	02 Oct 2020 (Study Day 44) - 06 Oct 2020 (Study Day 48)	Con Medication Related To Procedure For Ae #1 Spinal Stenosis
Hydromorphone	04 Oct 2020 (Study Day 46) - 06 Oct 2020 (Study Day 48)	Pain From Spine Surgery
Lidocaine	04 Oct 2020 (Study Day 46) - 06 Oct 2020 (Study Day 48)	Pain From Surgery For Spinal Stenosis
Hydrocodone bitartrate; paracetamol	05 Oct 2020 (Study Day 47) - 14 Oct 2020 (Study Day 56)	Pain From Surgery For Spinal Stenosis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lorazepam	05 Oct 2020 (Study Day 47) - 06 Oct 2020 (Study Day 48)	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Anxiety	Grade 1/mild	Not related	05 Oct 2020 (Study Day 47) - 06 Oct 2020 (Study Day 48)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2229 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intentional Self-Injury/Self- Injurious Behavior	SAE	Grade 3/severe	Not related	17 Oct 2020 (Study Day 58) – 30 Oct 2020 (Study Day 71)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2229, a 24-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Oct 2020 (Study Day 58), 57 days after the first dose and 29 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of intentional self-injury. Action taken with the IP was not applicable. The event of self- injurious behavior lasted for 14 days, after which it was considered to be recovered/resolved on 30 Oct 2020 (Study Day 71). The investigator assessed the event of intentional self-injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000499	Intentional self-injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1998 - Ongoing
Dysmenorrhoea	Dysmenorrhea	2008 - Ongoing
Affective disorder	Mood disorder	2009 - Ongoing
Presyncope	Orthostatic pre-syncopy	2009 - Ongoing
Attention deficit hyperactivity disorder	Adhd	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisdexamfetamine mesilate	2016 - Ongoing	Adhd
Fluticasone propionate	Jun 2019 - Jun 2020	Asthma
Testosterone	Nov 2019 - Ongoing	General Health
Budesonide; formoterol fumarate	Feb 2020 - Ongoing	Asthma
Bupropion hydrochloride	Feb 2020 - Ongoing	Mood Disorder
Salbutamol	21 Aug 2020 (Study Day 1) - Ongoing	Asthma
Meloxicam	22 Aug 2020 (Study Day 2) - 23 Aug 2020 (Study Day 3)	Menstrual Cramps
Sodium chloride	25 Aug 2020 (Study Day 5) - Ongoing	Orthostatic Pre-Syncopy
Meloxicam	27 Aug 2020 (Study Day 7) - 27 Aug 2020 (Study Day 7)	Headache
Meloxicam	28 Aug 2020 (Study Day 8) - 28 Aug 2020 (Study Day 8)	Headache
Ondansetron	04 Sep 2020 (Study Day 15) - 04 Sep 2020 (Study Day 15)	Transient Gastrointestinal Illness
Ibuprofen	19 Sep 2020 (Study Day 30) - 20 Sep 2020 (Study Day 31)	Headaches, Pain At Injection Site, Muscle Aches.
Paracetamol	19 Sep 2020 (Study Day 30) - 20 Sep 2020 (Study Day 31)	Headaches, Pain At Injection Site, Muscle Aches
Rtms (transcranial magnetic stimulation)*	02 Oct 2020 (Study Day 43) - 02 Oct 2020 (Study Day 43)	Medical History
Aripiprazole	24 Oct 2020 (Study Day 65) - 26 Oct 2020 (Study Day 67)	Mood Disorder
Aripiprazole	27 Oct 2020 (Study Day 68) - 14 Nov 2020 (Study Day 86)	Mood Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastrointestinal Disorder	Grade 1/mild	Not related	04 Sep 2020 (Study Day 15) - 05 Sep 2020 (Study Day 16)
Oropharyngeal Pain	Grade 1/mild	Not related	10 Sep 2020 (Study Day 21) - 10 Sep 2020 (Study Day 21)
Hordeolum	Grade 1/mild	Not related	17 Jan 2021 (Study Day 150) - 20 Jan 2021 (Study Day 153)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2242 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Splenic Marginal Zone Lymphoma/Marginal Zone Splenic B-Cell Lymphoma	SAE	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 48) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2242, a 70-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 22 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Oct 2020 (Study Day 48), 47 days after the first dose and 17 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of splenic marginal zone lymphoma. Action taken with the IP was not applicable. The event of marginal zone splenic b-cell lymphoma was considered to be ongoing. The investigator assessed the event of splenic marginal zone lymphoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000484	Splenic marginal zone lymphoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2001 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2014 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Insomnia	Insomnia	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluoxetine	2001 - Ongoing	Anxiety
Atorvastatin	2014 - Ongoing	Hypercholesterolemia
Melatonin	Jul 2020 - Ongoing	Insomnia
Paracetamol	21 Sep 2020 (Study Day 31) - 21 Sep 2020 (Study Day 31)	Fever, Headache
Routine cbc*	28 Sep 2020 (Study Day 38) - 28 Sep 2020 (Study Day 38)	Other, General Health
Blood count repeat*	08 Oct 2020 (Study Day 48) - 08 Oct 2020 (Study Day 48)	Diagnostic
Influenza vaccine	08 Oct 2020 (Study Day 48) - 08 Oct 2020 (Study Day 48)	Influenza Prophylaxis
Flow cytometry*	06 Nov 2020 (Study Day 77) - 06 Nov 2020 (Study Day 77)	Diagnostic
Varicella zoster vaccine rge (cho)	08 Nov 2020 (Study Day 79) - 08 Nov 2020 (Study Day 79)	Prophylaxis
Ct scan (neck to pelvis)*	31 Dec 2020 (Study Day 132) - 31 Dec 2020 (Study Day 132)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US343-2517 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Kidney Stones	SAE	Grade 3/severe	Not related	02 Feb 2021 (Study Day 139) – 03 Feb 2021 (Study Day 140)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2517, a 55-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Feb 2021 (Study Day 139), 138 days after the first dose and 110 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. Action taken with the IP was not applicable. The event of kidney stones lasted for 2 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 140). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012437	Nephrolithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gerd	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	2010 - Ongoing	Generalized Body Aches/Soreness After Running
Calcium carbonate	2015 - Ongoing	Gerd
Colonoscopy*	03 Nov 2020 (Study Day 48) - 03 Nov 2020 (Study Day 48)	Diagnostic
Ct of abdomen/pelvis*	02 Feb 2021 (Study Day 139) - 02 Feb 2021 (Study Day 139)	Adverse Event
Ibuprofen	03 Feb 2021 (Study Day 140) - 07 Feb 2021 (Study Day 144)	Kidney Stones
Tamsulosin hydrochloride	03 Feb 2021 (Study Day 140) - 10 Feb 2021 (Study Day 147)	Kidney Stones

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dizziness	Grade 1/mild	Related	15 Oct 2020 (Study Day 29) - 15 Oct 2020 (Study Day 29)
Myalgia	Grade 1/mild	Related	15 Oct 2020 (Study Day 29) - 23 Oct 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US348-2064 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rash Macular/Non-Urticarial Macular Rash With Blanching Erythema On Left Deltoid	AE leading to withdrawal from study vaccine	Grade 3/ severe	Related	25 Aug 2020 (Study Day 9) – 04 Sep 2020 (Study Day 19)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US348-2064, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of rash macular. On 13 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of non-urticarial macular rash with blanching erythema on left deltoid lasted for 11 days, after which it was considered to be recovered/resolved on 04 Sep 2020 (Study Day 19). The investigator assessed the event of rash macular to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Mammoplasty	Breast implants	Not reported

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Basedow's disease	Graves disease	1968 - 1968
Hypothyroidism	Hypothyroidism	1968 - Ongoing
Adenotonsillectomy	Tonsilectomy and adenoidectomy	1980 - 1980
Postmenopause	Post-menopausal	2004 - Ongoing
Osteoarthritis	Osteoarthitis	2015 - Ongoing
Osteopenia	Osteopenia	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	Dec 1968 - Ongoing	Hypothyroidism
Vitamins nos	2010 - Ongoing	Prophylaxis
Calcium; vitamin d nos	2018 - Ongoing	Osteopenia
Vitamin b12 nos	2019 - Ongoing	Prophylaxis
Diphenhydramine hydrochloride	03 Sep 2020 (Study Day 18) - 03 Sep 2020 (Study Day 18)	Injection Site Redness On Left Arm At Vaccine Site (Non-Urticarial Macular Rash With Blanching Erythema On Left Deltoid)
Influenza vaccine	09 Nov 2020 (Study Day 85) - 09 Nov 2020 (Study Day 85)	Seasonal Flu Prevention
Bilateral explant surgery*	14 Jan 2021 (Study Day 151) - 14 Jan 2021 (Study Day 151)	Other, Elective Surgery
Cefadroxil	14 Jan 2021 (Study Day 151) - 28 Jan 2021 (Study Day 165)	Antibiotic
Fentanyl	14 Jan 2021 (Study Day 151) - 14 Jan 2021 (Study Day 151)	Anesthetic
Hyoscine	14 Jan 2021 (Study Day 151) - 14 Jan 2021 (Study Day 151)	Anti-Nausea
Lidocaine	14 Jan 2021 (Study Day 151) - 14 Jan 2021 (Study Day 151)	Anesthetic
Methocarbamol	14 Jan 2021 (Study Day 151) - 24 Jan 2021 (Study Day 161)	Muscle Relaxer
Ondansetron	14 Jan 2021 (Study Day 151) - 24 Jan 2021 (Study Day 161)	Anti-Nausea
Oxycodone hydrochloride; paracetamol	14 Jan 2021 (Study Day 151) - 15 Jan 2021 (Study Day 152)	Pain Management
Propofol	14 Jan 2021 (Study Day 151) - 14 Jan 2021 (Study Day 151)	Anesthetic
Sevoflurane	14 Jan 2021 (Study Day 151) - 14 Jan 2021 (Study Day 151)	Anesthetic
Paracetamol	15 Jan 2021 (Study Day 152) - Ongoing	Pain Management

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rash Macular	Grade 3/severe	Related	25 Aug 2020 (Study Day 9) - 04 Sep 2020 (Study Day 19)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379516

Participant Number:	US351-2176 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	29 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Headache/Worsening Headache	AE leading to withdrawal from study vaccine	Grade 3/severe	Related	31 Aug 2020 (Study Day 3) – 20 Sep 2020 (Study Day 23)	Recovered/resolved
Urticaria/Intermittent Hives (Face And Neck)	AE leading to withdrawal from study vaccine	Grade 1/mild	Related	31 Aug 2020 (Study Day 3) – 07 Jan 2021 (Study Day 132)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2176, a 71-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Aug 2020 (Study Day 3), 2 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of headache. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening headache lasted for 21 days, after which it was considered to be recovered/resolved on 20 Sep 2020 (Study Day 23). The investigator assessed the event of headache to be related to the IP.

On 31 Aug 2020 (Study Day 3), 2 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of urticaria. On 25 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of intermittent hives (face and neck) lasted for 130 days, after which it was considered to be recovered/resolved on 07 Jan 2021 (Study Day 132). The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1952 - 1952
Tonsillitis	Tonsilitis	1952 - 1952
Appendicectomy	Appendectomy	1959 - 1959
Appendicitis	Appendicitis	1959 - 1959
Headache	Headaches	1960 - Ongoing
Myopia	Nearsighted	1960 - Ongoing
Overweight	Overweight	1960 - Ongoing
Deafness bilateral	Bilateral hearing loss	1964 - Ongoing
Food allergy	Shellfish allergy	1965 - Ongoing
Hypothyroidism	Hypothyroidism	1978 - Ongoing
Perinatal depression	Post-partum depression	1979 - 1980
Hypertension	Hypertension	1980 - Ongoing
Osteoarthritis	Osteoarthritis	1980 - Ongoing
Uterine leiomyoma	Uterine fibroids	1980 - 2017
Anxiety	Anxiety	1981 - Ongoing
Female sterilisation	Tubal ligation	1982 - 1982
Mammoplasty	Breast reduction	1985 - 1985
Fibromyalgia	Fibromyalgia	1991 - Ongoing
Postmenopause	Post-menopausal	1998 - Ongoing
Upper limb fracture	Shattered left elbow	2002 - 2003
Elbow operation	Shattered left elbow repair	2003 - 2003
Gastric bypass	Gastric bypass	2003 - 2003
Upper limb fracture	Broken left elbow	2003 - 2003
Liposuction	Liposuction with full body lift	2004 - 2004
Knee arthroplasty	Left knee replacement	2005 - 2005
Blood triglycerides increased	High triglycerides	2010 - Ongoing
Knee arthroplasty	Right knee replacement	2012 - 2012
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Large intestine polyp	Colon polyps	2016 - 2017
Cerebrovascular accident	Stroke	2017 - 2017
Colectomy	Colon resection	2017 - 2017
Hysterectomy	Hysterectomy	2017 - 2017
Nephrolithiasis	Kidney stones	2017 - 2017
Cataract	Cataracts	2018 - Ongoing
Dyspepsia	Heartburn	2018 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2018 - Ongoing
Peripheral swelling	Swelling in lower extremities	2018 - Ongoing
Vertigo	Vertigo	2018 - Ongoing
Cholecystectomy	Cholecystectomy	2019 - 2019

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cholelithiasis	Gallstones	2019 - 2019
Hip arthroplasty	Left hip replacement	2019 - 2019
Irritable bowel syndrome	Irritable bowl syndrome	Feb 2020 - Ongoing
Allergy to chemicals	Unknown pool chemicals allergy	15 Aug 2020 (Study Day -14) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1978 - Ongoing	Hypothyroidism
Hydrochlorothiazide	1980 - Ongoing	Hypertension
Sertraline hydrochloride	1981 - Ongoing	Anxiety/Fibromyalgia
Ibuprofen	1990 - Ongoing	Headaches
Ferrous fumarate	2003 - Ongoing	Supplement
Fish oil	2010 - Jun 2020	High Triglycerides
Vitamin d nos	2015 - Ongoing	Vitamin D Deficiency
Omeprazole	2018 - 02 Mar 2021 (Study Day 186)	Acid Reflux
Ibuprofen	31 Aug 2020 (Study Day 3) - 20 Sep 2020 (Study Day 23)	Headache
Influenza vaccine	08 Oct 2020 (Study Day 41) - 08 Oct 2020 (Study Day 41)	Seasonal Influenza
Diphenhydramine hydrochloride; zinc acetate	10 Oct 2020 (Study Day 43) - 07 Jan 2021 (Study Day 132)	Intermittent Hives
Paracetamol	14 Oct 2020 (Study Day 47) - 07 Jan 2021 (Study Day 132)	COVID-Like Illness
Prednisone	06 Jan 2021 (Study Day 131) - 07 Jan 2021 (Study Day 132)	Hives
Paracetamol	26 Jan 2021 (Study Day 151) - 26 Jan 2021 (Study Day 151)	Viral Upper Respiratory Infection
Omeprazole	03 Mar 2021 (Study Day 187) - Ongoing	Worsening Acid Reflux
Paracetamol	05 Mar 2021 (Study Day 189) - 06 Mar 2021 (Study Day 190)	Headaches
Ibuprofen	22 Mar 2021 (Study Day 206) - Ongoing	Worsening Osteoarthritis Right Hip

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	30 Aug 2020 (Study Day 2) - 07 Sep 2020 (Study Day 10)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 3/severe	Related	30 Aug 2020 (Study Day 2) - 07 Jan 2021 (Study Day 132)
Myalgia	Grade 1/mild	Related	30 Aug 2020 (Study Day 2) - 09 Sep 2020 (Study Day 12)
Headache	Grade 3/severe	Related	31 Aug 2020 (Study Day 3) - 20 Sep 2020 (Study Day 23)
Urticaria	Grade 1/mild	Related	31 Aug 2020 (Study Day 3) - 07 Jan 2021 (Study Day 132)
Headache	Grade 2/moderate	Related	23 Sep 2020 (Study Day 26) - 23 Nov 2020 (Study Day 87)
Suspected COVID-19	Grade 1/mild	Not related	14 Oct 2020 (Study Day 47) - 07 Jan 2021 (Study Day 132)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 89) - Ongoing
Viral Upper Respiratory Tract Infection	Grade 2/moderate	Related	25 Jan 2021 (Study Day 150) - 28 Jan 2021 (Study Day 153)
Osteoarthritis	Grade 1/mild	Not related	22 Mar 2021 (Study Day 206) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US352-2664 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Injection Site Macule/ Right Deltoid Macular, Non-Urticarial Redness At Injection Site 120mm By 86mm Oblong	AE leading to withdrawal from study vaccine	Grade 3/ severe	Related	23 Sep 2020 (Study Day 13) – 25 Sep 2020 (Study Day 15)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2664, a 62-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 11 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Sep 2020 (Study Day 13), 12 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of injection site macule. On 08 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of right deltoid macular, non-urticarial redness at injection site 120mm by 86mm oblong lasted for 3 days, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 15 The investigator assessed the event of injection site macule to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gerd	Not reported - Ongoing
Botulinum toxin injection	Cosmetic facial botox (forehead and brow)	2016 - 2019
Dermal filler injection	Cosmetic dermal filler (below orbs of the eyes and to creases around the mouth)	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	25 Sep 2020 (Study Day 15) - 25 Sep 2020 (Study Day 15)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Macule	Grade 3/severe	Related	23 Sep 2020 (Study Day 13) - 25 Sep 2020 (Study Day 15)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2020 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ulnar Nerve Injury/Ulnar Nerve Irritation	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	16 Aug 2020 (Study Day 4) – 15 Oct 2020 (Study Day 64)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2020, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Aug 2020 (Study Day 4), 3 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of ulnar nerve injury. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of ulnar nerve irritation lasted for 61 days, after which it was considered to be recovered/resolved on 15 Oct 2020 (Study Day 64). The investigator assessed the event of ulnar nerve injury to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Abdominal distension	Abnominal floating gas	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine with aura	Visual migraines	Not reported - Ongoing
Caesarean section	Caesarean section	1981 - 1981
Osteoarthritis	Osteoarthritis-knees,back and legs	1988 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Rhinoplasty	Rhinoplasty	1996 - 1996
Menopause	Menopause	1999 - Ongoing
Hypothyroidism	Hypothyroidism	2003 - Ongoing
Fungal skin infection	Toe (skin) fungal infection	Dec 2009 - Ongoing
Dermal filler injection	Dermal filler injections	2011 - 2011
Glaucoma	Glaucoma-bilateral	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	Not reported - Ongoing	General Health
Diclofenac	Not reported - Ongoing	Osteoarthritis
Diphenhydramine hydrochloride	Not reported - Ongoing	Seasonal Allergies
Fexofenadine hydrochloride	Not reported - Ongoing	Seasonal Allergies
Steroids	1988 - Ongoing	Osteoarthritis
Levothyroxine	2003 - Ongoing	Hypothyrodism
Calcium carbonate	2005 - Ongoing	Gas
Simeticone	2005 - Ongoing	Gas
Naproxen sodium	2013 - Ongoing	Osteoarthritis
Bimatoprost	2018 - Ongoing	Glaucoma Both Eyes
Magnesium	2019 - Ongoing	General Health
Vitamins nos	2019 - Ongoing	General Health
Antiinflammatory and antirheumatic products	Jun 2020 - Ongoing	Osteoarthritis
Diclofenac	Aug 2020 - 15 Oct 2020 (Study Day 64)	Ulnar Nerve Irritation
Naproxen sodium	13 Aug 2020 (Study Day 1) - 16 Aug 2020 (Study Day 4)	Pain At Injection Site
Mri*	15 Sep 2020 (Study Day 34) - 15 Sep 2020 (Study Day 34)	Adverse Event
Gabapentin	16 Sep 2020 (Study Day 35) - 15 Oct 2020 (Study Day 64)	Ulnar Nerve Irritation
Gabapentin	15 Oct 2020 (Study Day 64) - Ongoing	Osteoarthritis
Influenza vaccine	19 Oct 2020 (Study Day 68) - 19 Oct 2020 (Study Day 68)	Flu Prevention
Corticosteroid nos	11 Mar 2021 (Study Day 211) - 11 Mar 2021 (Study Day 211)	Exacerbation Of Osteoarthritis
Corticosteroids	22 Mar 2021 (Study Day 222) - 22 Mar 2021 (Study Day 222)	Exacerbation Of Osteoarthritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Terbinafine	25 Mar 2021 (Study Day 225) - Ongoing	Worsening Toe Fungal Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ulnar Nerve Injury	Grade 2/moderate	Related	16 Aug 2020 (Study Day 4) - 15 Oct 2020 (Study Day 64)
Osteoarthritis	Grade 2/moderate	Not related	25 Feb 2021 (Study Day 197) - Ongoing
Fungal Skin Infection	Grade 2/moderate	Not related	24 Mar 2021 (Study Day 224) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2087 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/ Worsened Atrial Fibrillation	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	12 Sep 2020 (Study Day 25) – 16 Oct 2020 (Study Day 59)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2087, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Sep 2020 (Study Day 25), 24 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of atrial fibrillation. On 15 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsened atrial fibrillation lasted for 35 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 59). The investigator assessed the event of atrial fibrillation to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Transient ischaemic attack	Transient ischemic attack	Not reported
Atrial fibrillation	Atrial fibrillation	2000 - Ongoing
Basal cell carcinoma	Basal cell cancer	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Retinal tear	Left retinal tear	2018 - 2018
Aortic aneurysm	Aortic aneurysm	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	Health
Apixaban	Jul 2019 - Ongoing	Atrial Fibrillation
Atorvastatin	Feb 2020 - Ongoing	Hypercholesterolemia
Influenza vaccine	01 Oct 2020 (Study Day 44) - 01 Oct 2020 (Study Day 44)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atrial Fibrillation	Grade 2/moderate	Related	12 Sep 2020 (Study Day 25) - 16 Oct 2020 (Study Day 59)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2444 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	16 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/ Worsening Atrial Fibrillation Arrhythmia	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	01 Oct 2020 (Study Day 16) – 16 Oct 2020 (Study Day 31)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2444, a 74-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Oct 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of atrial fibrillation. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening atrial fibrillation arrhythmia lasted for 16 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 31). The investigator assessed the event of atrial fibrillation to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dental caries	Dental decay	Not reported - 13 Oct 2020 (Study Day 28)

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1954 - Ongoing
Chronic sinusitis	Chronic sinusitis	1954 - Ongoing
Seasonal allergy	Seasonal allergies	1954 - Ongoing
Back pain	L4 l5 back pain	1990 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1990 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hypertrophy	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Knee arthroplasty	Left total knee replacement	2010 - 2010
Aortic stenosis	Aortic stenosis	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Inguinal hernia	Right inguinal hernia	2018 - 2018
Atrial fibrillation	Atrial fibrillation	2019 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Skin cancer	Skin cancer	2019 - 2019
Musculoskeletal pain	Left shoulder pain	Jun 2020 - Aug 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate; salmeterol xinafoate	1990 - Ongoing	Asthma
Doxazosin	2000 - Ongoing	Benign Prostatic Hypertrophy
Esomeprazole magnesium	2000 - Ongoing	Gastroesophageal Reflux Disease
Finasteride	2000 - Ongoing	Benign Prostatic Hypertrophy
Loratadine	2000 - Ongoing	Seasonal Allergies
Atenolol	2010 - 11 Oct 2020 (Study Day 26)	Atrial Fibrillation
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Lisinopril	2018 - 07 Oct 2020 (Study Day 22)	Hypertension
Tadalafil	2018 - Ongoing	Benign Prostatic Hypertrophy
Apixaban	2019 - Ongoing	Coagulation Prevention
Melatonin	2019 - Ongoing	Insomnia
Atenolol	12 Oct 2020 (Study Day 27) - Ongoing	Atrial Fibrillation
Cefalexin	13 Oct 2020 (Study Day 28) - Ongoing	Tooth Extraction
Paracetamol	13 Oct 2020 (Study Day 28) - 13 Oct 2020 (Study Day 28)	Tooth Extraction
Tooth extraction*	13 Oct 2020 (Study Day 28) - 13 Oct 2020 (Study Day 28)	Medical History
Influenza vaccine	21 Oct 2020 (Study Day 36) - 21 Oct 2020 (Study Day 36)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atrial Fibrillation	Grade 2/moderate	Related	01 Oct 2020 (Study Day 16) - 16 Oct 2020 (Study Day 31)
Epistaxis	Grade 2/moderate	Not related	11 Oct 2020 (Study Day 26) - 12 Oct 2020 (Study Day 27)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2497 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Injection Site Urticaria/ Urticarial Injection Site Rash To Left Arm	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	03 Oct 2020 (Study Day 8) – 06 Oct 2020 (Study Day 11)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2497, a 22-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 26 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Oct 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of injection site urticaria. On 23 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of urticarial injection site rash to left arm lasted for 4 days, after which it was considered to be recovered/resolved on 06 Oct 2020 (Study Day 11). The investigator assessed the event of injection site urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Childhood asthma	Childhood asthma	2002 - 2006
Autoimmune thyroiditis	Hypothyroidism hashimoto dx	2014 - Mar 2015
Drug hypersensitivity	Allergy to thiamazole	2015 - Ongoing
Thyroidectomy	Thyroidectomy	Mar 2015 - Mar 2015
Hypothyroidism	Hypothyroidism	Aug 2015 - Ongoing
Keloid scar	Keloid lesions on chest	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	2015 - Ongoing	Health Promotion
Levothyroxine	2016 - Ongoing	Hypothyroidism
Levonorgestrel	2017 - Ongoing	Birth Control
Biotin	May 2020 - Ongoing	Health Promotion
Influenza vaccine	13 Oct 2020 (Study Day 18) - 13 Oct 2020 (Study Day 18)	Influenza Prophylaxis
Ibuprofen	21 Jan 2021 (Study Day 118) - 21 Jan 2021 (Study Day 118)	Pain At Injection Site, Fever, Chills, Body Aches

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Urticaria	Grade 1/mild	Related	03 Oct 2020 (Study Day 8) - 06 Oct 2020 (Study Day 11)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US364-2261 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Paraesthesia/Decrease In Sensation And Paresthesia	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	03 Oct 2020 (Study Day 15) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2261, a 70-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Oct 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of paraesthesia. On 16 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of decrease in sensation and paresthesia was considered to be ongoing. The investigator assessed the event of paraesthesia to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 27 Dec 2020 (Study Day 100), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy	1992 - 1992
Gravitational oedema	Dependent edema	2005 - Ongoing
Back pain	Back pain	2017 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	Jul 2019 - Ongoing
Lumbar spinal stenosis	Spinal stenosis of lumbar region with radiculopathy	23 Sep 2019 (Study Day -362) - Ongoing
Arthropathy	Sacroilial joint dysfunction	28 Oct 2019 (Study Day -327) - 21 Jan 2020 (Study Day -242)
Bursitis	Trochanteric bursitis of both hips	28 Oct 2019 (Study Day -327) - 21 Jan 2020 (Study Day -242)
Osteoporosis	Osteoporosis	28 Oct 2019 (Study Day -327) - Ongoing
Constipation	Constipation	22 Apr 2020 (Study Day -150) - Ongoing
Tobacco user	Cigarette smoker	22 Apr 2020 (Study Day -150) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	2017 - Ongoing	Back Pain
Furosemide	23 Feb 2019 (Study Day -574) - Ongoing	Dependent Edema
Colecalciferol	Jul 2019 - Ongoing	Vitamin D Deficiency
Monascus purpureus	Jul 2019 - Ongoing	Supplement For High Cholesterol
Vitamins nos	02 Aug 2019 (Study Day -414) - Ongoing	Supplement
Influenza vaccine	01 Sep 2020 (Study Day -18) - 01 Sep 2020 (Study Day -18)	Prophylaxis For Flu
Varenicline tartrate	17 Oct 2020 (Study Day 29) - 17 Oct 2020 (Study Day 29)	Cigarette Smoker
Methylprednisolone	18 Oct 2020 (Study Day 30) - 23 Oct 2020 (Study Day 35)	Decrease In Sensation And Paresthesia
Other viral vaccines	27 Dec 2020 (Study Day 100) - 27 Dec 2020 (Study Day 100)	COVID-19 Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Paraesthesia	Grade 2/moderate	Related	03 Oct 2020 (Study Day 15) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US364-2268 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Neuropathy Peripheral/Peripheral Neuropathy	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	21 Sep 2020 (Study Day 1) – 04 Nov 2020 (Study Day 45)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2268, a 38-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of neuropathy peripheral. On 18 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of peripheral neuropathy lasted for 45 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 45). The investigator assessed the event of neuropathy peripheral to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Palpitations	Heart palpitations	1983 - 1996
Lyme disease	Lyme disease	1994 - 1994
Prostatitis	Prostatitis	2007 - 2007
Vasectomy	Vasectomy	Dec 2017 - Dec 2017
Wrist fracture	Wrist fracture	Oct 2018 - 18 Oct 2018 (Study Day -704)
Wrist surgery	Wrist surgery	18 Oct 2018 (Study Day -704) - 18 Oct 2018 (Study Day -704)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	22 Sep 2020 (Study Day 2) - 22 Sep 2020 (Study Day 2)	Peripheral Neuropathy
Ibuprofen	Oct 2020 - Oct 2020	Neuropathy
Cefalexin	01 Jan 2021 (Study Day 103) - 13 Jan 2021 (Study Day 115)	Infection Of The Toe
Ibuprofen	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)	Laceration And Dislocation Of Right Toe

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Neuropathy Peripheral	Grade 2/moderate	Related	21 Sep 2020 (Study Day 1) - 04 Nov 2020 (Study Day 45)
Skin Laceration	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 103) - 01 Jan 2021 (Study Day 103)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2092 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Injection Site Erythema/Redness At Injection Site (L)	AE leading to withdrawal from study vaccine	Grade 3/ severe	Related	21 Aug 2020 (Study Day 9) – 27 Aug 2020 (Study Day 15)	Recovered/resolved
Injection Site Swelling/Swelling At Injection Site (L)	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	21 Aug 2020 (Study Day 9) – 27 Aug 2020 (Study Day 15)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2092, a 52-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of injection site erythema. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of redness at injection site (l) lasted for 7 days, after which it was considered to be recovered/resolved on 27 Aug 2020 (Study Day 15). The investigator assessed the event of injection site erythema to be related to the IP.

On 21 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of injection site swelling. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of swelling at injection site (l) lasted for 7 days, after which it was considered to be recovered/resolved on 27 Aug 2020 (Study Day 15). The investigator assessed the event of injection site swelling to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis joint pain	2014 - Ongoing
Postmenopause	Post-menopausal	2018 - Ongoing
Cholecystectomy	Cholecystectomy	Jul 2019 - Jul 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2014 - Ongoing	Osteoarthritis (Joints)
Prednisone	25 Aug 2020 (Study Day 13) - 27 Aug 2020 (Study Day 15)	Redness And Swelling At Injection Site.

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Erythema	Grade 3/severe	Related	21 Aug 2020 (Study Day 9) - 27 Aug 2020 (Study Day 15)
Injection Site Swelling	Grade 2/moderate	Related	21 Aug 2020 (Study Day 9) - 27 Aug 2020 (Study Day 15)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2151 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rash Pruritic/Pruitic Rash Lower Extremities	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	18 Aug 2020 (Study Day 2) – 26 Aug 2020 (Study Day 10)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2151, a 25-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Aug 2020 (Study Day 2), 1 day after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of rash pruritic. On 13 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of pruitic rash lower extremities lasted for 9 days, after which it was considered to be recovered/resolved on 26 Aug 2020 (Study Day 10). The investigator assessed the event of rash pruritic to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 13 Jan 2021 (Study Day 150), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	19 Aug 2020 (Study Day 3) - 21 Aug 2020 (Study Day 5)	Pruritic Rash (Lower Extremities)
Cetirizine hydrochloride	20 Aug 2020 (Study Day 4) - 21 Aug 2020 (Study Day 5)	Pruritic Rash (Lower Extremities)
Influenza vaccine	07 Oct 2020 (Study Day 52) - 07 Oct 2020 (Study Day 52)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rash Pruritic	Grade 2/moderate	Related	18 Aug 2020 (Study Day 2) - 26 Aug 2020 (Study Day 10)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2163 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Induration/Right Arm Induration	AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 2/ moderate	Related	26 Aug 2020 (Study Day 9) – 02 Sep 2020 (Study Day 16)	Recovered/resolved
Urticaria/Right Arm Erythema (Urticarial)	AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 2/ moderate	Related	26 Aug 2020 (Study Day 9) – 01 Oct 2020 (Study Day 45)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2163, a 56-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 18 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of induration. On 14 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of right arm induration lasted for 8 days, after which it was considered to be recovered/resolved on 02 Sep 2020 (Study Day 16). The investigator assessed the event of induration to be related to the IP.

On 26 Aug 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of urticaria. On 14 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of right arm erythema (urticarial) lasted for 37 days, after which it was considered to be recovered/resolved on 01 Oct 2020 (Study Day 45). The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

On 01 Mar 2021 (Study Day 196), the participant discontinued from the study due to adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2016 - Ongoing
Autonomic nervous system imbalance	Vasomotor symptoms	2017 - Ongoing
Cholecystectomy	Cholecystectomy due to gallstones	2018 - 2018
Post procedural diarrhoea	Intermittent post cholecystectomy diarrhea	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	2016 - Ongoing	Seasonal Allergies
Paroxetine	2017 - Ongoing	Vasomotor Symptoms
Colestyramine	2018 - Ongoing	Interrmittent Post - Cholecysterectomy Diarrhea
Influenza vaccine	15 Dec 2020 (Study Day 120) - 15 Dec 2020 (Study Day 120)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Induration	Grade 2/moderate	Related	26 Aug 2020 (Study Day 9) - 02 Sep 2020 (Study Day 16)
Urticaria	Grade 2/moderate	Related	26 Aug 2020 (Study Day 9) - 01 Oct 2020 (Study Day 45)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2251 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Injection Site Erythema/Redness At Injection Site	AE leading to withdrawal from study vaccine	Grade 1/mild	Related	28 Aug 2020 (Study Day 8) – 30 Aug 2020 (Study Day 10)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2251, a 42-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Aug 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of injection site erythema. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of redness at injection site lasted for 3 days, after which it was considered to be recovered/resolved on 30 Aug 2020 (Study Day 10). The investigator assessed the event of injection site erythema to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vitamin B12 deficiency	Vitamin b12 deficient	2016 - Ongoing
Female sterilisation	Tubal ligation	Feb 2016 - Feb 2016
Hypertension	Hypertension	Nov 2019 - Ongoing
Vitamin D deficiency	Vitamin d deficient	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b12 nos	2016 - Ongoing	Vitamin B12 Deficiency
Amlodipine	Nov 2019 - Ongoing	Hypertension
Vitamin d nos	Jan 2020 - Ongoing	Vitamin D Deficiency
Influenza vaccine	10 Oct 2020 (Study Day 51) - 10 Oct 2020 (Study Day 51)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Erythema	Grade 1/mild	Related	28 Aug 2020 (Study Day 8) - 30 Aug 2020 (Study Day 10)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2377 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pruritus/Generalized Pruritis	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	11 Sep 2020 (Study Day 15) – 19 Nov 2020 (Study Day 84)	Recovered/resolved
Angioedema/Angioedema	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	18 Sep 2020 (Study Day 22) – 19 Sep 2020 (Study Day 23)	Recovered/resolved
Urticaria/Worsening Of Uriticaria	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	21 Sep 2020 (Study Day 25) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2377, a 31-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Sep 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of pruritus. On 24 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of generalized pruritis lasted for 70 days, after which it was considered to be recovered/resolved on 19 Nov 2020 (Study Day 84). The investigator assessed the event of pruritus to be related to the IP.

On 18 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of angioedema. On 24 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of angioedema lasted for 2 days, after which it was considered to be recovered/resolved on 19 Sep 2020 (Study Day 23). The investigator assessed the event of angioedema to be related to the IP.

On 21 Sep 2020 (Study Day 25), 24 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of urticaria. On 24 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening of uriticaria was considered to be ongoing. The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Temporomandibular joint syndrome	Temporomandibular joint disorder	2006 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2007 - Ongoing
Mechanical urticaria	Dermatographia	2019 - Ongoing
Pruritus	Pruitis	May 2019 - May 2019
Urticaria	Uriticaria	May 2019 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	2019 - Ongoing	Dermatographia
Omeprazole	2019 - Ongoing	Gerd
Medroxyprogesterone acetate	Oct 2019 - Ongoing	Birth Control
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	11 Aug 2020 (Study Day -17) - Ongoing	Adhd
Acetylsalicylic acid; caffeine; paracetamol	28 Aug 2020 (Study Day 1) - 06 Sep 2020 (Study Day 10)	Headaches
Amoxicillin	09 Sep 2020 (Study Day 13) - 19 Sep 2020 (Study Day 23)	Tooth Infection
Hydrocodone bitartrate; paracetamol	09 Sep 2020 (Study Day 13) - 13 Sep 2020 (Study Day 17)	Tooth Infection
Cetirizine hydrochloride	21 Sep 2020 (Study Day 25) - 04 Nov 2020 (Study Day 69)	Worsening Of Dermatographia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clindamycin	08 Oct 2020 (Study Day 42) - 17 Oct 2020 (Study Day 51)	Tooth Infection
Fexofenadine hydrochloride	19 Oct 2020 (Study Day 53) - Ongoing	Uriticaria
Levocetirizine dihydrochloride	19 Oct 2020 (Study Day 53) - Ongoing	Worsening Of Uriticaria
Hydrocodone bitartrate; paracetamol	16 Mar 2021 (Study Day 201) - 17 Mar 2021 (Study Day 202)	Pain Secondary To Tooth Extraction
Tooth extraction*	16 Mar 2021 (Study Day 201) - 16 Mar 2021 (Study Day 201)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Not related	28 Aug 2020 (Study Day 1) - 06 Sep 2020 (Study Day 10)
Tooth Infection	Grade 1/mild	Not related	09 Sep 2020 (Study Day 13) - 17 Oct 2020 (Study Day 51)
Pruritus	Grade 2/moderate	Related	11 Sep 2020 (Study Day 15) - 19 Nov 2020 (Study Day 84)
Angioedema	Grade 1/mild	Related	18 Sep 2020 (Study Day 22) - 19 Sep 2020 (Study Day 23)
Mechanical Urticaria	Grade 2/moderate	Related	21 Sep 2020 (Study Day 25) - 04 Nov 2020 (Study Day 69)
Urticaria	Grade 2/moderate	Related	21 Sep 2020 (Study Day 25) - Ongoing
Tooth Infection	Grade 2/moderate	Not related	14 Mar 2021 (Study Day 199) - 16 Mar 2021 (Study Day 201)
Procedural Pain	Grade 2/moderate	Not related	16 Mar 2021 (Study Day 201) - 17 Mar 2021 (Study Day 202)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2407 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ventricular Extrasystoles/ Premature Ventricular Contractions	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	07 Sep 2020 (Study Day 5) – 24 Sep 2020 (Study Day 22)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2407, a 41-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 5), 4 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of ventricular extrasystoles. On 30 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of premature ventricular contractions lasted for 18 days, after which it was considered to be recovered/resolved on 24 Sep 2020 (Study Day 22). The investigator assessed the event of ventricular extrasystoles to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Augmentin allergy- nausea	1997 - Ongoing
Genital herpes	Herpes genitalis	17 Jun 2014 (Study Day -2270) - Ongoing
Depression	Depression	2016 - Ongoing
Ventricular extrasystoles	Pvc-premature ventricular contractions	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Valaciclovir hydrochloride	17 Jun 2014 (Study Day -2270) - Ongoing	Mhx: Herpes Genitalis
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2016 - Ongoing	Contraception
Sertraline hydrochloride	2016 - Ongoing	Depression
Vitamin d nos	2020 - 25 Sep 2020 (Study Day 23)	Health Maintenance
Quercetin	Jul 2020 - 25 Sep 2020 (Study Day 23)	Health Management
Influenza vaccine	22 Oct 2020 (Study Day 50) - 22 Oct 2020 (Study Day 50)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ventricular Extrasystoles	Grade 2/moderate	Related	07 Sep 2020 (Study Day 5) - 24 Sep 2020 (Study Day 22)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US368-2040 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Varicella Zoster Virus Infection/Exacerbation Of Varicella Zoster	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	01 Sep 2020 (Study Day 1) – 03 Oct 2020 (Study Day 33)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2040, a 48-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Sep 2020 (Study Day 1), on the day (12 hours 5 minutes following administration) of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of varicella zoster virus infection. On 28 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of exacerbation of varicella zoster lasted for 33 days, after which it was considered to be recovered/resolved on 03 Oct 2020 (Study Day 33). The investigator assessed the event of varicella zoster virus infection to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Intervertebral disc protrusion	Lbp, disc herniation, l4 & l5	01 Sep 2015 (Study Day -1827) - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2016 - Ongoing
Varicella zoster virus infection	Varicella zoster	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	01 Sep 2015 (Study Day -1827) - Ongoing	Lower Back Pain
Methocarbamol	01 Sep 2015 (Study Day -1827) - Ongoing	Lower Back Pain
Nifedipine	2018 - 15 Jan 2021 (Study Day 137)	Hypertension
Paracetamol	15 Sep 2020 (Study Day 15) - 15 Sep 2020 (Study Day 15)	Headache
Paracetamol	22 Nov 2020 (Study Day 83) - 27 Nov 2020 (Study Day 88)	COVID-Like Illness (Body Aches, Headache)
Paracetamol	28 Dec 2020 (Study Day 119) - 31 Dec 2020 (Study Day 122)	Symptomatic COVID19; Headache
Hydrochlorothiazide	15 Jan 2021 (Study Day 137) - 19 Apr 2021 (Study Day 231)	Hypertension
Losartan	15 Jan 2021 (Study Day 137) - 19 Apr 2021 (Study Day 231)	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Varicella Zoster Virus Infection	Grade 2/moderate	Related	01 Sep 2020 (Study Day 1) - 03 Oct 2020 (Study Day 33)
Headache	Grade 2/moderate	Not related	15 Sep 2020 (Study Day 15) - 15 Sep 2020 (Study Day 15)
Suspected COVID-19	Grade 2/moderate	Not related	22 Nov 2020 (Study Day 83) - 26 Nov 2020 (Study Day 87)
COVID-19	Grade 2/moderate	Not related	21 Dec 2020 (Study Day 112) - 01 Jan 2021 (Study Day 123)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US376-2177 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Injection Site Erythema/ Injection Site Redness, Left Arm Non-Urticarial	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	03 Sep 2020 (Study Day 1) – 09 Oct 2020 (Study Day 37)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US376-2177, a 65-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 03 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Sep 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of injection site erythema. On 30 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of injection site redness, left arm non-urticarial lasted for 37 days, after which it was considered to be recovered/resolved on 09 Oct 2020 (Study Day 37). The investigator assessed the event of injection site erythema to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hepatitis A	Hepatitis a	1959 - 1959
Neck pain	Neck pain	1969 - Ongoing
Hypothyroidism	Hypothyroidism	1983 - Ongoing
Depression	Depression	1998 - Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Carpal tunnel syndrome	Carpal tunnel syndrome	2002 - Ongoing
Diverticulitis	Diverticulitis	2002 - Ongoing
Constipation	Frequent constipation	2010 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2010 - Ongoing
Osteoarthritis	Osteoarthritis	2010 - Ongoing
Osteopenia	Osteopenia	2010 - Ongoing
Back pain	Lower back pain	2012 - Ongoing
Botulinum toxin injection	Botox injection cosmetic face	2013 - 2013
Urinary incontinence	Urinary incontinence	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	01 Sep 1983 (Study Day -13517) - Ongoing	Hypothyroid
Bupropion hydrochloride	2000 - Ongoing	Depression
Liothyronine	05 May 2020 (Study Day -121) - Ongoing	Hypothyroid
Paracetamol	05 Sep 2020 (Study Day 3) - 07 Sep 2020 (Study Day 5)	Intermittent Body Aches
Paracetamol	05 Sep 2020 (Study Day 3) - 05 Sep 2020 (Study Day 3)	Muscle Aches
Paracetamol	07 Sep 2020 (Study Day 5) - 07 Sep 2020 (Study Day 5)	Muscle Aches
Loperamide hydrochloride	13 Sep 2020 (Study Day 11) - 14 Sep 2020 (Study Day 12)	Stomach Ache
Omeprazole	13 Sep 2020 (Study Day 11) - 14 Sep 2020 (Study Day 12)	Stomach Ache
Dicycloverine hydrochloride	13 Nov 2020 (Study Day 72) - Ongoing	Ibs

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Erythema	Grade 2/moderate	Related	03 Sep 2020 (Study Day 1) - 09 Oct 2020 (Study Day 37)
Fatigue	Grade 2/moderate	Related	04 Sep 2020 (Study Day 2) - 20 Sep 2020 (Study Day 18)
Pain	Grade 2/moderate	Related	04 Sep 2020 (Study Day 2) - 04 Nov 2020 (Study Day 63)
Abdominal Pain Upper	Grade 2/moderate	Related	13 Sep 2020 (Study Day 11) - 14 Sep 2020 (Study Day 12)
Abdominal Pain Upper	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 55) - Ongoing
Vomiting	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 55) - 27 Oct 2020 (Study Day 55)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379554

Participant Number:	US382-2006 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Eye Swelling/ Swelling Under Eye, Bilateral	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	09 Aug 2020 (Study Day 6) – 21 Sep 2020 (Study Day 49)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2006, a 51-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Aug 2020 (Study Day 6), 5 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of eye swelling. On 31 Aug 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of swelling under eye, bilateral lasted for 44 days, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 49). The investigator assessed the event of eye swelling to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 30 Dec 2020 (Study Day 149), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Psoriasis	Psoriasis	1985 - Ongoing
Oral herpes	Cold sores	1990 - Ongoing
Postmenopause	Post menopausal	2005 - Ongoing
Asthma exercise induced	Exercise induced asthma	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Valaciclovir hydrochloride	2000 - Ongoing	Cold Sores
Vitamins nos	2000 - Ongoing	Supplement
Clobetasol propionate	2010 - Ongoing	Psoriasis
Diphtheria vaccine toxoid; tetanus vaccine toxoid	Jan 2010 - Jan 2010	Vaccine
Influenza vaccine	Sep 2019 - Sep 2019	Vaccine
Salbutamol	2020 - Ongoing	Exercise Induced Asthma
Hyaluronic acid	Jun 2020 - Jun 2020	Cosmetic Enhancement
Doxycycline	14 Aug 2020 (Study Day 11) - 17 Aug 2020 (Study Day 14)	Swelling Under Left Eye
Prednisone	18 Aug 2020 (Study Day 15) - 21 Sep 2020 (Study Day 49)	Inflammation Under Eyes Bilaterally
Hyaluronidase	31 Aug 2020 (Study Day 28) - 03 Sep 2020 (Study Day 31)	Swelling Under Eye, Bilateral

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Eye Swelling	Grade 1/mild	Related	09 Aug 2020 (Study Day 6) - 21 Sep 2020 (Study Day 49)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2175 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rash Pruritic/Rash [erythematous And Pruritic] Of Vaccinated Arm	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	13 Sep 2020 (Study Day 3) – 02 Oct 2020 (Study Day 22)	Recovered/ resolved
Lymphadenopathy/Ipsilateral Axillary Lymphadenopathy	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	16 Sep 2020 (Study Day 6) – 25 Sep 2020 (Study Day 15)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2175, a 51-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Sep 2020 (Study Day 3), 2 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of rash pruritic. On 08 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of rash [erythematous and pruritic] of vaccinated arm lasted for 20 days, after which it was considered to be recovered/resolved on 02 Oct 2020 (Study Day 22). The investigator assessed the event of rash pruritic to be related to the IP.

On 16 Sep 2020 (Study Day 6), 5 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of lymphadenopathy. On 08 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of ipsilateral axillary lymphadenopathy lasted for 10 days, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 15). The investigator assessed the event of lymphadenopathy to be related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Endometriosis	Endometriosis	2008 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2019 - Ongoing
Cervical radiculopathy	Cervical radiculopathy	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2010 - Ongoing	Prophylaxis For General Health
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2011 - Ongoing	Endometriosis
Influenza vaccine	17 Oct 2020 (Study Day 37) - 17 Oct 2020 (Study Day 37)	Influenza Prevention
Diphenhydramine hydrochloride	19 Oct 2020 (Study Day 39) - 24 Oct 2020 (Study Day 44)	Seasonal Allergies
Loratadine	01 Nov 2020 (Study Day 52) - 20 Nov 2020 (Study Day 71)	Seasonal Allergies
Clobetasol	16 Jan 2021 (Study Day 128) - 01 Mar 2021 (Study Day 172)	Chilbains On Index, Middle, Ring Fingers Of Right Hand
Prednisone	16 Jan 2021 (Study Day 128) - 19 Feb 2021 (Study Day 162)	Chilbains On Index, Middle, Ring Fingers Of Right Hand
Prednisone	20 Jan 2021 (Study Day 132) - 25 Jan 2021 (Study Day 137)	Chilbains On Index, Middle, Ring Fingers Of Right Hand
Prednisone	26 Jan 2021 (Study Day 138) - 30 Jan 2021 (Study Day 142)	Chilbains On Index, Middle, Ring Fingers Of Right Hand
Prednisone	31 Jan 2021 (Study Day 143) - 06 Feb 2021 (Study Day 149)	Chilbains On Index, Middle, Ring Fingers Of Right Hand

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rash Pruritic	Grade 1/mild	Related	13 Sep 2020 (Study Day 3) - 02 Oct 2020 (Study Day 22)
Lymphadenopathy	Grade 1/mild	Related	16 Sep 2020 (Study Day 6) - 25 Sep 2020 (Study Day 15)
Seasonal Allergy	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 47) - 20 Nov 2020 (Study Day 71)
Chillblains	Grade 2/moderate	Not related	10 Jan 2021 (Study Day 122) - 01 Mar 2021 (Study Day 172)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2016 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Occlusion/Left Anterior Descending Artery Heart Blockage	SAE	Grade 3/severe	Not related	30 Dec 2020 (Study Day 150) – 02 Jan 2021 (Study Day 153)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2016, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 01 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Dec 2020 (Study Day 150), 149 days after the first dose and 120 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of coronary artery occlusion. Action taken with the IP was not applicable. The event of left anterior descending artery heart blockage lasted for 4 days, after which it was considered to be recovered/resolved on 02 Jan 2021 (Study Day 153). The investigator assessed the event of coronary artery occlusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005755	Coronary artery occlusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Presbyopia	Presbyopia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Angioplasty*	30 Dec 2020 (Study Day 150) - 30 Dec 2020 (Study Day 150)	Adverse Event
Cardiac stent placement in lad*	30 Dec 2020 (Study Day 150) - 30 Dec 2020 (Study Day 150)	Adverse Event
Prasugrel	30 Dec 2020 (Study Day 150) - Ongoing	Heart Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US387-2062 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dehydration/Dehydration (Primary Sae)	SAE	Grade 4	Not related	18 Oct 2020 (Study Day 75) – 23 Oct 2020 (Study Day 80)	Recovered/resolved
Pyelonephritis/ Pyelonephritis	SAE	Grade 3/ severe	Not related	18 Oct 2020 (Study Day 75) – 23 Oct 2020 (Study Day 80)	Recovered/resolved
Sepsis/Septicemia	SAE	Grade 4	Not related	18 Oct 2020 (Study Day 75) – 23 Oct 2020 (Study Day 80)	Recovered/resolved
Urinary Tract Infection/ Urinary Tract Infection	SAE	Grade 4	Not related	18 Oct 2020 (Study Day 75) – 23 Oct 2020 (Study Day 80)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2062, a 61-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Oct 2020 (Study Day 75), 74 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration (primary sae) lasted for 6 days, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 80). The investigator assessed the event of dehydration to be not related to the IP.

On 18 Oct 2020 (Study Day 75), 74 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pyelonephritis. Action taken with the IP was not applicable. The event of pyelonephritis lasted for 6 days, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 80). The investigator assessed the event of pyelonephritis to be not related to the IP.

On 18 Oct 2020 (Study Day 75), 74 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of sepsis. Action taken with the

IP was not applicable. The event of septicemia lasted for 6 days, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 80). The investigator assessed the event of sepsis to be not related to the IP.

On 18 Oct 2020 (Study Day 75), 74 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of urinary tract infection lasted for 6 days, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 80). The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000496	Dehydration
MOD-2020-000496	Pyelonephritis
MOD-2020-000496	Sepsis
MOD-2020-000496	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1970 - 1970
Tonsillitis	Tonsillitis	1970 - 1970
Back pain	Back pain (occasional)	1974 - Ongoing
Gastrooesophageal reflux disease	Gerd	1980 - Ongoing
Migraine	Migraines (occasional)	1980 - Ongoing
Appendicectomy	Appendectomy	1984 - 1984
Appendicitis	Appendicitis	1984 - 1984
Cholecystectomy	Cholecystectomy	1984 - 1984
Cholelithiasis	Gall stones	1984 - 1984
Insomnia	Insomnia	1987 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1988 - Ongoing
Hypertension	Hypertension	1988 - Ongoing
Postmenopause	Post menopausal	2009 - Ongoing
Depression	Intermittent depression	2010 - Ongoing
Gastrectomy	Gastric sleeve	2015 - 2015
Seasonal allergy	Seasonal allergies	2017 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	2018 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diclofenac	1974 - Ongoing	Occasional Back Pain
Pantoprazole	1980 - Ongoing	Gerd
Topiramate	1980 - Ongoing	Migraines
Amitriptyline	1987 - Ongoing	Insomnia
Atorvastatin	1988 - Ongoing	Hyperlipidemia
Lisinopril	1988 - Ongoing	Hypertension
Metoprolol succinate	1988 - Ongoing	Hypertension
Cetirizine	2017 - Ongoing	Seasonal Allergies
Acetylsalicylic acid	2018 - Ongoing	Cardiac Prophylaxis
Ascorbic acid	2018 - Ongoing	Health Maintenance
Calcium carbonate	2018 - Ongoing	Health Maintenance
Magnesium	2018 - Ongoing	Health Maintenance
Metformin hydrochloride	2018 - Ongoing	Type Ii Diabetes
Zinc	2018 - Ongoing	Health Maintenance
Ferrous sulfate	Oct 2019 - 01 Sep 2020 (Study Day 28)	Health Maintenance
Ibuprofen	05 Aug 2020 (Study Day 1) - 05 Aug 2020 (Study Day 1)	Injection Site Pain
Chest xray single view*	17 Oct 2020 (Study Day 74) - 17 Oct 2020 (Study Day 74)	Diagnostic
Electrocardiogram*	17 Oct 2020 (Study Day 74) - 17 Oct 2020 (Study Day 74)	Adverse Event
Sars cov-2 np swab*	17 Oct 2020 (Study Day 74) - 17 Oct 2020 (Study Day 74)	Diagnostic
Sodium chloride	17 Oct 2020 (Study Day 74) - 17 Oct 2020 (Study Day 74)	Dehydration
Urine culture*	17 Oct 2020 (Study Day 74) - 17 Oct 2020 (Study Day 74)	Adverse Event
Acetylsalicylic acid	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Cardiac Prophylaxsis
Amitriptyline	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Insomnia
Atorvastatin	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	High Cholesterol
Butalbital; caffeine; paracetamol	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Migraine Prevention
Citalopram	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Intermitant Depression

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Enoxaparin sodium	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Deep Vein Thrombosis Prophalaxis
Gall bladder ultra sound*	18 Oct 2020 (Study Day 75) - 18 Oct 2020 (Study Day 75)	Diagnostic
Hydralazine	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Hypertension
Insulin aspart	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Type Ii Dabetes
Levothyroxine	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Hypothyroidism
Liver ultrasound*	18 Oct 2020 (Study Day 75) - 18 Oct 2020 (Study Day 75)	Diagnostic
Loratadine	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Seasonal Allergies
Morphine	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Pain
Ondansetron	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Nausea - Symptom Associated To Sae Of Dehydration
Paracetamol	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	For General Pain
Sodium chloride	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Dehydration (Sae)
Topiramate	18 Oct 2020 (Study Day 75) - 23 Oct 2020 (Study Day 80)	Migraine Prevention
2 view chest xray*	19 Oct 2020 (Study Day 76) - 19 Oct 2020 (Study Day 76)	Diagnostic
Renal ultrasound*	19 Oct 2020 (Study Day 76) - 19 Oct 2020 (Study Day 76)	Adverse Event
2 d echo / transthorasic echo*	20 Oct 2020 (Study Day 77) - 20 Oct 2020 (Study Day 77)	Adverse Event
Blood culture ard*	20 Oct 2020 (Study Day 77) - 20 Oct 2020 (Study Day 77)	Adverse Event
Cefepime	20 Oct 2020 (Study Day 77) - 20 Oct 2020 (Study Day 77)	Septacemia
Ceftriaxone	20 Oct 2020 (Study Day 77) - 20 Oct 2020 (Study Day 77)	Septacemia
Ciprofloxacin	23 Oct 2020 (Study Day 80) - 01 Nov 2020 (Study Day 89)	Pneumonia, Sepsis, Uti
Fluconazole	23 Oct 2020 (Study Day 80) - 08 Nov 2020 (Study Day 96)	Yeast Infection
Influenza vaccine	23 Oct 2020 (Study Day 80) - 23 Oct 2020 (Study Day 80)	Prevention Of Influenza Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 2/moderate	Not related	12 Sep 2020 (Study Day 39) - 17 Oct 2020 (Study Day 74)
Injection Site Pain	Grade 1/mild	Related	28 Sep 2020 (Study Day 55) - 01 Oct 2020 (Study Day 58)
Pain	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 67) - 23 Oct 2020 (Study Day 80)
Chills	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 23 Oct 2020 (Study Day 80)
Cough	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 23 Oct 2020 (Study Day 80)
Decreased Appetite	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 30 Oct 2020 (Study Day 87)
Dyspnoea	Grade 1/mild	Not related	12 Oct 2020 (Study Day 69) - 21 Oct 2020 (Study Day 78)
Fatigue	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 02 Dec 2020 (Study Day 120)
Headache	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 22 Oct 2020 (Study Day 79)
Nasal Congestion	Grade 1/mild	Not related	12 Oct 2020 (Study Day 69) - 21 Oct 2020 (Study Day 78)
Nausea	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 71)
Pyrexia	Grade 1/mild	Not related	12 Oct 2020 (Study Day 69) - 23 Oct 2020 (Study Day 80)
Vomiting	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 14 Oct 2020 (Study Day 71)
Troponin Increased	Grade 1/mild	Not related	17 Oct 2020 (Study Day 74) - 18 Oct 2020 (Study Day 75)
Confusional State	Grade 3/severe	Not related	18 Oct 2020 (Study Day 75) - 19 Oct 2020 (Study Day 76)
Hepatic Steatosis	Grade 2/moderate	Not related	18 Oct 2020 (Study Day 75) - Ongoing
Vulvovaginal Mycotic Infection	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 80) - 08 Nov 2020 (Study Day 96)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379566

Participant Number:	US387-2090 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 43)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diarrhoea/Diarrhea Unspecified Type	SAE	Grade 3/ severe	Not related	11 Aug 2020 (Study Day 5) – 14 Sep 2020 (Study Day 39)	Recovered/resolved
Hypoglycaemia/Hypoglycemia (Nondiabetic)	SAE	Grade 4	Not related	25 Nov 2020 (Study Day 111) – 27 Nov 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2090, a 63-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 43). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Aug 2020 (Study Day 5), 4 days after the first dose and 38 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diarrhoea. The IP dose was not changed due to the diarrhea unspecified type. The event of diarrhea unspecified type lasted for 35 days, after which it was considered to be recovered/resolved on 14 Sep 2020 (Study Day 39). The investigator assessed the event of diarrhoea to be not related to the IP.

On 25 Nov 2020 (Study Day 111), 110 days after the first dose and 68 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hypoglycaemia. Action taken with the IP was not applicable. The event of hypoglycemia (nondiabetic) lasted for 3 days, after which it was considered to be recovered/resolved on 27 Nov 2020 (Study Day 113). The investigator assessed the event of hypoglycaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000208	Diarrhoea
MOD-2020-000909	Hypoglycaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nicotine dependence	Nicotine addiction	1987 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin; clavulanic acid	16 Aug 2020 (Study Day 10) - 26 Aug 2020 (Study Day 20)	Diarrhea
Ct abd with contrast*	16 Aug 2020 (Study Day 10) - 16 Aug 2020 (Study Day 10)	Adverse Event
Gall bladder ultrasound*	16 Aug 2020 (Study Day 10) - 16 Aug 2020 (Study Day 10)	Adverse Event
Hydrocodone bitartrate; paracetamol	16 Aug 2020 (Study Day 10) - 22 Aug 2020 (Study Day 16)	Abdominal Pain
Metoclopramide	16 Aug 2020 (Study Day 10) - 29 Sep 2020 (Study Day 54)	Nausea
Ondansetron	16 Aug 2020 (Study Day 10) - 29 Sep 2020 (Study Day 54)	Nausea
Paracetamol	16 Aug 2020 (Study Day 10) - 17 Aug 2020 (Study Day 11)	Headache
Aluminium hydroxide; magnesium hydroxide; simeticone	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Gastric Upset
Ciprofloxacin	18 Aug 2020 (Study Day 12) - 21 Aug 2020 (Study Day 15)	Abdominal Pain And Diarrhea
Hydralazine	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Elevated Blood Pressure
Ipratropium; salbutamol	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Copd
Magnesium sulfate	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Unknown
Metoclopramide	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Nausea
Metronidazole	18 Aug 2020 (Study Day 12) - 21 Aug 2020 (Study Day 15)	Abdominal Pain / Diarrhea
Naproxen	18 Aug 2020 (Study Day 12) - 29 Sep 2020 (Study Day 54)	Abdominal Pain
Nicotine	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Nicotine Addiction

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Nausea
Paracetamol	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Abdominal Pain
Paracetamol	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Fever Or Pain
Potassium chloride	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Dehydration
Sodium chloride	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Hydration
Sodium phosphate	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Unknown
Sodium polystyrene sulfonate	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Dehydration
Temazepam	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)	Insomnia
Colonoscopy*	21 Aug 2020 (Study Day 15) - 21 Aug 2020 (Study Day 15)	Adverse Event
Ibuprofen	22 Aug 2020 (Study Day 16) - 29 Aug 2020 (Study Day 23)	Abdominal Pain
Trazodone	29 Aug 2020 (Study Day 23) - 15 Oct 2020 (Study Day 70)	Insomnia
Ciprofloxacin	22 Sep 2020 (Study Day 47) - 28 Sep 2020 (Study Day 53)	Abdominal Pain
Alprazolam	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown Not Indicated
Aluminium hydroxide; magnesium hydroxide; simeticone	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown Not Indicated
Blood sugar checks (frequent)*	25 Nov 2020 (Study Day 111) - 25 Nov 2020 (Study Day 111)	Adverse Event
Blood work up*	25 Nov 2020 (Study Day 111) - 25 Nov 2020 (Study Day 111)	Adverse Event
Calcium gluconate; sodium chloride	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Chest xray 1 view*	25 Nov 2020 (Study Day 111) - 25 Nov 2020 (Study Day 111)	Adverse Event
Clonidine	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Dextromethorphan; guaifenesin	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Diphenhydramine	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Docusate sodium	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Glucose	25 Nov 2020 (Study Day 111) - 25 Nov 2020 (Study Day 111)	Hypoglycemeia
Hydralazine	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Ipratropium; salbutamol	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Copd

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Magnesium sulfate	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Metoclopramide	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Morphine	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Ondansetron	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Oxycodone hydrochloride; paracetamol	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Paracetamol	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Potassium chloride	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Potassium phosphate monobasic	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Simeticone	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Sodium chloride	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Hydration
Sodium phosphate	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Sodium polystyrene sulfonate	25 Nov 2020 (Study Day 111) - 27 Nov 2020 (Study Day 113)	Unknown
Temazepam	25 Nov 2020 (Study Day 111) - 26 Nov 2020 (Study Day 112)	Insomnia
Urine tox screen*	25 Nov 2020 (Study Day 111) - 25 Nov 2020 (Study Day 111)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Not related	09 Aug 2020 (Study Day 3) - 08 Sep 2020 (Study Day 33)
Enteritis	Grade 3/severe	Not related	11 Aug 2020 (Study Day 5) - 14 Sep 2020 (Study Day 39)
Chills	Grade 2/moderate	Not related	12 Aug 2020 (Study Day 6) - 23 Aug 2020 (Study Day 17)
Nausea	Grade 2/moderate	Not related	12 Aug 2020 (Study Day 6) - 21 Aug 2020 (Study Day 15)
Vomiting	Grade 2/moderate	Not related	12 Aug 2020 (Study Day 6) - 21 Aug 2020 (Study Day 15)
Headache	Grade 2/moderate	Not related	13 Aug 2020 (Study Day 7) - 21 Aug 2020 (Study Day 15)
Chronic Obstructive Pulmonary Disease	Grade 1/mild	Not related	18 Aug 2020 (Study Day 12) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dehydration	Grade 2/moderate	Not related	18 Aug 2020 (Study Day 12) - 22 Aug 2020 (Study Day 16)
Haemangioma Of Liver	Grade 1/mild	Not related	18 Aug 2020 (Study Day 12) - Ongoing
Haemorrhoids	Grade 1/mild	Not related	21 Aug 2020 (Study Day 15) - Ongoing
Insomnia	Grade 2/moderate	Not related	26 Aug 2020 (Study Day 20) - 15 Oct 2020 (Study Day 70)
Insomnia	Grade 2/moderate	Not related	29 Aug 2020 (Study Day 23) - 15 Oct 2020 (Study Day 70)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2118 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholecystitis/Choleystitis	SAE	Grade 3/ severe	Not related	15 Nov 2020 (Study Day 98) – 15 Nov 2020 (Study Day 98)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2118, a 36-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Nov 2020 (Study Day 98), 97 days after the first dose and 68 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cholecystitis. Action taken with the IP was not applicable. The event of choleystitis lasted for 1 days, after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 98). The investigator assessed the event of cholecystitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000799	Cholecystitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Eczema	Eczema bilateral forearms	1989 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder (adhd)	1990 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder (ptsd)	1996 - Ongoing
Anxiety	Anxiety	1999 - Ongoing
Migraine	Migraines	1999 - Ongoing
Gestational diabetes	Gestational diabetes	2002 - 2002
Gastric banding	Lap band surgery	2007 - 2007
Gastrooesophageal reflux disease	Acid reflux	2009 - 01 Apr 2019 (Study Day -497)
Depression	Depression	2013 - Ongoing
Arthritis	Bilateral knee arthritis	2016 - Ongoing
Hypertension	High blood pressure	2018 - 2018
Cholelithiasis	Gall stones	2019 - Ongoing
Gastric banding reversal	Lap band removal	2019 - 2019
Seasonal allergy	Seasonal allergies	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Triamcinolone acetonide	2017 - Ongoing	Eczema
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	2018 - Ongoing	Adhd
Cetirizine	2019 - Ongoing	Seasonal Allergies
Fluticasone propionate	2020 - Ongoing	Seasonal Allergies
Ibuprofen	11 Aug 2020 (Study Day 2) - 11 Aug 2020 (Study Day 2)	Pain At Injection Site
Acetylsalicylic acid; caffeine; paracetamol	09 Sep 2020 (Study Day 31) - 10 Sep 2020 (Study Day 32)	Headache
Guaifenesin	09 Sep 2020 (Study Day 31) - 11 Sep 2020 (Study Day 33)	Fever / Chills
Paracetamol	09 Sep 2020 (Study Day 31) - 10 Sep 2020 (Study Day 32)	Fever And Pain At Injection Site
Aluminium hydroxide; magnesium hydroxide; simeticone	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Indigestion
Amfetamine; dexamfetamine	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Adhd

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium chloride; potassium chloride; sodium lactate	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Fluid Replacement
Cefotetan	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Bacterial Infection (Urine(
Docusate sodium	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Constipation
Ergocalciferol	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Hypercalcemia
Hydralazine	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	High Blood Pressure
Ibuprofen	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Unknown
Indocyanine green cholangiography*	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Adverse Event
Ipratropium bromide; salbutamol sulfate	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Shortness Of Breath
Labetalol	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	High Blood Pressure
Laparoscopic cholecystectomy*	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Adverse Event
Magnesium sulfate	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Unknown
Morphine sulfate	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Mild Abdominal Pain 1-3 Pain Scale
Morphine sulfate	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Severe Abdominal Pain 7-10 Pain Scale
Naloxone	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Opiate Reversal Post Procedure
Ondansetron	15 Nov 2020 (Study Day 98) - 17 Nov 2020 (Study Day 100)	Nausea / Vomiting
Pantoprazole	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)	Acid Reflux
Potassium chloride	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Unknown
Right upper quadrant ultrasound*	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Adverse Event
Sars-cov2-pcr swab*	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Diagnostic
Urine culture*	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)	Adverse Event
Hydrocodone; paracetamol	16 Nov 2020 (Study Day 99) - 20 Nov 2020 (Study Day 103)	Status Post Surgery Pain / Worsening Of Cholelithiasis
Vitamin d nos	16 Nov 2020 (Study Day 99) - Ongoing	Health Maintenace
Guaifenesin	22 Dec 2020 (Study Day 135) - 25 Dec 2020 (Study Day 138)	Nasal Congestion And Cough
Escitalopram oxalate	10 Feb 2021 (Study Day 185) - Ongoing	Depression And Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 2/moderate	Related	11 Aug 2020 (Study Day 2) - 27 Aug 2020 (Study Day 18)
Fatigue	Grade 1/mild	Related	12 Aug 2020 (Study Day 3) - 22 Aug 2020 (Study Day 13)
Lymphadenopathy	Grade 1/mild	Related	14 Aug 2020 (Study Day 5) - 19 Aug 2020 (Study Day 10)
Myalgia	Grade 1/mild	Related	15 Aug 2020 (Study Day 6) - 18 Aug 2020 (Study Day 9)
Nausea	Grade 1/mild	Related	16 Aug 2020 (Study Day 7) - 19 Aug 2020 (Study Day 10)
Vomiting	Grade 1/mild	Related	16 Aug 2020 (Study Day 7) - 19 Aug 2020 (Study Day 10)
Fatigue	Grade 2/moderate	Not related	08 Sep 2020 (Study Day 30) - 22 Sep 2020 (Study Day 44)
Pain	Grade 1/mild	Not related	08 Sep 2020 (Study Day 30) - 22 Sep 2020 (Study Day 44)
Cough	Grade 1/mild	Not related	09 Sep 2020 (Study Day 31) - 22 Sep 2020 (Study Day 44)
Dyspnoea	Grade 1/mild	Not related	09 Sep 2020 (Study Day 31) - 25 Sep 2020 (Study Day 47)
Headache	Grade 1/mild	Not related	09 Sep 2020 (Study Day 31) - 22 Sep 2020 (Study Day 44)
Nasal Congestion	Grade 1/mild	Not related	09 Sep 2020 (Study Day 31) - 22 Sep 2020 (Study Day 44)
Rhinorrhoea	Grade 1/mild	Not related	09 Sep 2020 (Study Day 31) - 22 Sep 2020 (Study Day 44)
Nausea	Grade 1/mild	Related	12 Sep 2020 (Study Day 34) - 22 Sep 2020 (Study Day 44)
Vomiting	Grade 1/mild	Related	12 Sep 2020 (Study Day 34) - 22 Sep 2020 (Study Day 44)
Diarrhoea	Grade 1/mild	Not related	14 Sep 2020 (Study Day 36) - 22 Sep 2020 (Study Day 44)
Cholelithiasis	Grade 3/severe	Not related	15 Nov 2020 (Study Day 98) - 15 Nov 2020 (Study Day 98)
Hypercalcaemia	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)
Hyperglycaemia	Grade 1/mild	Not related	15 Nov 2020 (Study Day 98) - 17 Nov 2020 (Study Day 100)
Hypertension	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)
Thrombocytosis	Grade 1/mild	Not related	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)
Urinary Tract Infection Bacterial	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 98) - 16 Nov 2020 (Study Day 99)
Fatigue	Grade 1/mild	Not related	22 Dec 2020 (Study Day 135) - 27 Dec 2020 (Study Day 140)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 2/moderate	Not related	22 Dec 2020 (Study Day 135) - 25 Dec 2020 (Study Day 138)
Nasal Congestion	Grade 1/mild	Not related	22 Dec 2020 (Study Day 135) - 29 Dec 2020 (Study Day 142)
Pyrexia	Grade 1/mild	Not related	22 Dec 2020 (Study Day 135) - 23 Dec 2020 (Study Day 136)
Cough	Grade 1/mild	Not related	23 Dec 2020 (Study Day 136) - 26 Dec 2020 (Study Day 139)
Myalgia	Grade 1/mild	Not related	23 Dec 2020 (Study Day 136) - 25 Dec 2020 (Study Day 138)
Depression	Grade 2/moderate	Not related	10 Jan 2021 (Study Day 154) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379576

Participant Number:	US387-2173 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Transaminases Increased/Transaminitis	SAE	Grade 3/ severe	Not related	28 Dec 2020 (Study Day 138) – Ongoing	Recovering/resolving
Pyelonephritis/Pyelonephritis	SAE	Grade 3/ severe	Not related	13 Jan 2021 (Study Day 154) – 22 Jan 2021 (Study Day 163)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2173, a 74-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Dec 2020 (Study Day 138), 137 days after the first dose and 104 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of transaminases increased. Action taken with the IP was not applicable. The event of transaminitis was considered to be ongoing. The investigator assessed the event of transaminases increased to be not related to the IP.

On 13 Jan 2021 (Study Day 154), 153 days after the first dose and 120 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pyelonephritis. Action taken with the IP was not applicable. The event of pyelonephritis lasted for 10 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 163). The investigator assessed the event of pyelonephritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009631	Transaminases increased
MOD-2021-009631	Pyelonephritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol use	Occasional etoh (alcohol) use	1960 - Ongoing
Anxiety	Anxiety	1960 - Ongoing
Back pain	Chronic lumbago	1960 - Ongoing
Depression	Depression	1960 - Ongoing
Migraine	Migraines	1960 - Ongoing
Osteoarthritis	Osteoarthritis	1960 - Ongoing
Allergy to arthropod bite	Allergy to mosquito	1961 - Ongoing
Allergy to arthropod sting	Allergy to bee stings	1961 - Ongoing
Food allergy	Allergy to mint	1963 - Ongoing
Asthma	Asthma	1978 - Ongoing
Substance use	Crack cocaine user (2x per month)	1980 - Ongoing
Tobacco user	Cigarette smoker	1980 - Ongoing
Arthralgia	Left knee pain	1985 - 2000
Hysterectomy	Complete hysterectomy	1995 - 1995
Insomnia	Intermittent insomnia	1997 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Knee arthroplasty	Left knee total replacement	2000 - 2000
Drug hypersensitivity	Allergy to bactrim	2010 - Ongoing
Dyspepsia	Heartburn	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1990 - Ongoing	Cardiac Prophylaxis
Echinacea purpurea	1990 - Ongoing	Health Maintenance
Epinephrine	2010 - Ongoing	Allergies To Mosquito Bites Or Bee Stings
Cyclobenzaprine hydrochloride	2018 - 10 Jan 2021 (Study Day 151)	Osteoarthritis
Salbutamol	2019 - Ongoing	Asthma
Paracetamol	Jan 2020 - Ongoing	Osteoarthritis
Acetylsalicylic acid; citric acid; sodium bicarbonate	Feb 2020 - Ongoing	Heartburn

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	12 Oct 2020 (Study Day 61) - 01 Nov 2020 (Study Day 81)	Depression
Trazodone	12 Oct 2020 (Study Day 61) - 01 Nov 2020 (Study Day 81)	Insomnia Intermittent
Influenza vaccine	01 Dec 2020 (Study Day 111) - 01 Dec 2020 (Study Day 111)	Prophylactic Influenza
Tizanidine	01 Dec 2020 (Study Day 111) - 01 Jan 2021 (Study Day 142)	Chronic Lumbago
Nitrofurantoin	28 Dec 2020 (Study Day 138) - 05 Jan 2021 (Study Day 146)	Urinary Tract Infection
Amoxicillin	06 Jan 2021 (Study Day 147) - 13 Jan 2021 (Study Day 154)	Urinary Tract Infection
Ceftriaxone	13 Jan 2021 (Study Day 154) - 13 Jan 2021 (Study Day 154)	Urinary Tract Infection
Ct scan abdomen and pelvis with iv contrast*	13 Jan 2021 (Study Day 154) - 13 Jan 2021 (Study Day 154)	Adverse Event
Fluconazole	13 Jan 2021 (Study Day 154) - 17 Jan 2021 (Study Day 158)	Urinary Tract Infection
Hydrocodone bitartrate; paracetamol	13 Jan 2021 (Study Day 154) - 13 Jan 2021 (Study Day 154)	Flank Pain
Iopamidol	13 Jan 2021 (Study Day 154) - 13 Jan 2021 (Study Day 154)	Flank Pain (Ct Scan Procedure)
Morphine	13 Jan 2021 (Study Day 154) - 17 Jan 2021 (Study Day 158)	Flank Pain
Ondansetron	13 Jan 2021 (Study Day 154) - 15 Jan 2021 (Study Day 156)	Nausea
Paracetamol	13 Jan 2021 (Study Day 154) - 17 Jan 2021 (Study Day 158)	Flank Pain
Trazodone	13 Jan 2021 (Study Day 154) - 17 Jan 2021 (Study Day 158)	Insomnia
Ultrasound abdomen*	13 Jan 2021 (Study Day 154) - 13 Jan 2021 (Study Day 154)	Adverse Event
Potassium chloride	14 Jan 2021 (Study Day 155) - 17 Jan 2021 (Study Day 158)	Hypokalemia
Bisacodyl	15 Jan 2021 (Study Day 156) - 16 Jan 2021 (Study Day 157)	Constipation
Macrogol 3350	15 Jan 2021 (Study Day 156) - 17 Jan 2021 (Study Day 158)	Constipation
Magnesium oxide	15 Jan 2021 (Study Day 156) - 17 Jan 2021 (Study Day 158)	Constipation
Ciprofloxacin	18 Jan 2021 (Study Day 159) - 22 Jan 2021 (Study Day 163)	Pylonephritis
Oxybutynin	17 Mar 2021 (Study Day 217) - Ongoing	Bladder Hyperactivity
Tramadol	17 Mar 2021 (Study Day 217) - Ongoing	Left Knee Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Proteus Infection	Grade 2/moderate	Not related	28 Dec 2020 (Study Day 138) - 22 Jan 2021 (Study Day 163)
Abdominal Wall Cyst	Grade 1/mild	Not related	13 Jan 2021 (Study Day 154) - Ongoing
Diverticulum	Grade 1/mild	Not related	13 Jan 2021 (Study Day 154) - Ongoing
Flank Pain	Grade 3/severe	Not related	13 Jan 2021 (Study Day 154) - 15 Jan 2021 (Study Day 156)
Hyperbilirubinaemia	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 154) - 15 Jan 2021 (Study Day 156)
Hypokalaemia	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 154) - 15 Jan 2021 (Study Day 156)
Nausea	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 154) - 15 Jan 2021 (Study Day 156)
Renal Cyst	Grade 1/mild	Not related	13 Jan 2021 (Study Day 154) - Ongoing
Vomiting	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 154) - 15 Jan 2021 (Study Day 156)
Constipation	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 156) - 18 Jan 2021 (Study Day 159)
Hyperbilirubinaemia	Grade 1/mild	Not related	11 Mar 2021 (Study Day 211) - Ongoing
Hypertonic Bladder	Grade 2/moderate	Not related	11 Mar 2021 (Study Day 211) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2402 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Alcohol Withdrawal Syndrome/Etoh Withdrawl	SAE	Grade 4	Not related	04 Nov 2020 (Study Day 65) – 06 Nov 2020 (Study Day 67)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2402, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Nov 2020 (Study Day 65), 64 days after the first dose and 36 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of alcohol withdrawal syndrome. Action taken with the IP was not applicable. The event of etoh withdrawl lasted for 3 days, after which it was considered to be recovered/resolved on 06 Nov 2020 (Study Day 67). The investigator assessed the event of alcohol withdrawal syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000717	Alcohol withdrawal syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Organ donor	Right kidney donation	1993 - 1993
Depression	Depression	1999 - Ongoing
Postmenopause	Postmenopausal	2001 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Malignant melanoma	Melanoma on face	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Citalopram hydrobromide	2000 - Ongoing	Depression
Botulinum toxin type a	2008 - 2008	Glabellar Lines - Cosmetic Forehead
Amlodipine	2015 - 11 Jan 2021 (Study Day 133)	Hypertension
Olmesartan medoxomil	2015 - 11 Jan 2021 (Study Day 133)	Hypertension
Influenza vaccine	14 Oct 2020 (Study Day 44) - 14 Oct 2020 (Study Day 44)	Flu Prevention
Hydrocodone bitartrate; paracetamol	Nov 2020 - 31 Dec 2020 (Study Day 122)	Right Foot Fracture
Ct head no contrast*	03 Nov 2020 (Study Day 64) - 03 Nov 2020 (Study Day 64)	Adverse Event
X-ray chest*	03 Nov 2020 (Study Day 64) - 03 Nov 2020 (Study Day 64)	Adverse Event
X-ray fibula*	03 Nov 2020 (Study Day 64) - 03 Nov 2020 (Study Day 64)	Adverse Event
X-ray right ankle*	03 Nov 2020 (Study Day 64) - 03 Nov 2020 (Study Day 64)	Adverse Event
X-ray tibia*	03 Nov 2020 (Study Day 64) - 03 Nov 2020 (Study Day 64)	Adverse Event
Clonidine	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Relax Blood Vessels
Cyanocobalamin	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Vitamin B Deficiancy
Folic acid	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Vitamin B Defiancy
Hydrocodone bitartrate; paracetamol	04 Nov 2020 (Study Day 65) - 06 Nov 2020 (Study Day 67)	Pain
Lorazepam	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Alcohol Withdrawal
Lorazepam	04 Nov 2020 (Study Day 65) - 06 Nov 2020 (Study Day 67)	Alcohol Withdrawal

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Meclozine	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Dizziness
Morphine	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Pain
Ondansetron	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Nausea
Sodium chloride	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Dehydration / Hyponatremia
Splinting of right foot*	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)	Adverse Event
Gramicidin; neomycin sulfate; polymyxin b sulfate	06 Nov 2020 (Study Day 67) - 12 Nov 2020 (Study Day 73)	Knee Laceration
Right foot surgery*	16 Nov 2020 (Study Day 77) - 16 Nov 2020 (Study Day 77)	Adverse Event
Hydroxyzine	Dec 2020 - 10 Jan 2021 (Study Day 132)	Insomnia
Olmesartan medoxomil	13 Jan 2021 (Study Day 135) - Ongoing	Hypertension
Trazodone	13 Jan 2021 (Study Day 135) - Ongoing	Insomnia
Mirabegron	15 Feb 2021 (Study Day 168) - Ongoing	Overactive Bladder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	30 Sep 2020 (Study Day 30) - 09 Oct 2020 (Study Day 39)
Foot Fracture	Grade 3/severe	Not related	03 Nov 2020 (Study Day 64) - 06 Jan 2021 (Study Day 128)
Skin Laceration	Grade 1/mild	Not related	03 Nov 2020 (Study Day 64) - 15 Feb 2021 (Study Day 168)
Dizziness	Grade 2/moderate	Not related	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)
Dyspnoea	Grade 1/mild	Not related	04 Nov 2020 (Study Day 65) - 04 Nov 2020 (Study Day 65)
Hyponatraemia	Grade 2/moderate	Not related	04 Nov 2020 (Study Day 65) - 06 Nov 2020 (Study Day 67)
Liver Function Test Increased	Grade 1/mild	Not related	04 Nov 2020 (Study Day 65) - Ongoing
Vitamin B12 Deficiency	Grade 1/mild	Not related	04 Nov 2020 (Study Day 65) - Ongoing
Insomnia	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 92) - Ongoing
Hypertonic Bladder	Grade 2/moderate	Not related	15 Feb 2021 (Study Day 168) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US389-2059 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	05 Oct 2020 (Study Day 28)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19 Pneumonia/ COVID - 19 Pneumonia	COVID-19	Grade 3/ severe	Not related	27 Nov 2020 (Study Day 81) – 03 Jan 2021 (Study Day 118)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US389-2059, a 39-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 27 Nov 2020 (Study Day 81), 80 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID - 19 pneumonia.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 05 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 30 Nov 2020 (Study Day 84), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
28 Nov 2020 (Study Day 82)	Body Aches	Moderate
28 Nov 2020 (Study Day 82)	Chills	Moderate
28 Nov 2020 (Study Day 82)	Cough	Moderate
28 Nov 2020 (Study Day 82)	Difficulty Breathing	Mild
28 Nov 2020 (Study Day 82)	Fatigue	Moderate

Symptom Date	Symptom	Result
28 Nov 2020 (Study Day 82)	Headache	Moderate
28 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
28 Nov 2020 (Study Day 82)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 82)	Shortness of Breath	Moderate
30 Nov 2020 (Study Day 84)	Body Aches	Mild
30 Nov 2020 (Study Day 84)	Chills	Moderate
30 Nov 2020 (Study Day 84)	Cough	Mild
30 Nov 2020 (Study Day 84)	Fatigue	Mild
30 Nov 2020 (Study Day 84)	Headache	Mild
30 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 84)	Shortness of Breath	Mild
01 Dec 2020 (Study Day 85)	Body Aches	Moderate
01 Dec 2020 (Study Day 85)	Chills	Mild
01 Dec 2020 (Study Day 85)	Cough	Moderate
01 Dec 2020 (Study Day 85)	Difficulty Breathing	Moderate
01 Dec 2020 (Study Day 85)	Fatigue	Moderate
01 Dec 2020 (Study Day 85)	Headache	Severe
01 Dec 2020 (Study Day 85)	Muscle Aches (Myalgia)	Moderate
01 Dec 2020 (Study Day 85)	Nasal Congestion	Moderate
01 Dec 2020 (Study Day 85)	Nausea	Moderate
01 Dec 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Mild
01 Dec 2020 (Study Day 85)	Shortness of Breath	Moderate
01 Dec 2020 (Study Day 85)	Sore Throat	Mild
02 Dec 2020 (Study Day 86)	Body Aches	Severe
02 Dec 2020 (Study Day 86)	Chills	Moderate
02 Dec 2020 (Study Day 86)	Cough	Moderate
02 Dec 2020 (Study Day 86)	Difficulty Breathing	Moderate
02 Dec 2020 (Study Day 86)	Fatigue	Severe
02 Dec 2020 (Study Day 86)	Headache	Mild
02 Dec 2020 (Study Day 86)	Muscle Aches (Myalgia)	Moderate
02 Dec 2020 (Study Day 86)	Nasal Congestion	Moderate
02 Dec 2020 (Study Day 86)	Nausea	Moderate
02 Dec 2020 (Study Day 86)	Shortness of Breath	Moderate
02 Dec 2020 (Study Day 86)	Sore Throat	Mild
02 Dec 2020 (Study Day 86)	Temperature (°F)	101.0
03 Dec 2020 (Study Day 87)	Body Aches	Moderate
03 Dec 2020 (Study Day 87)	Chills	Mild
03 Dec 2020 (Study Day 87)	Cough	Severe
03 Dec 2020 (Study Day 87)	Difficulty Breathing	Moderate
03 Dec 2020 (Study Day 87)	Fatigue	Severe
03 Dec 2020 (Study Day 87)	Headache	Mild
03 Dec 2020 (Study Day 87)	Muscle Aches (Myalgia)	Severe
03 Dec 2020 (Study Day 87)	Nasal Congestion	Moderate

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 87)	Nausea	Moderate
03 Dec 2020 (Study Day 87)	O2 Saturation (%)	90
03 Dec 2020 (Study Day 87)	Shortness of Breath	Moderate
03 Dec 2020 (Study Day 87)	Sore Throat	Mild
03 Dec 2020 (Study Day 87)	Temperature (°F)	101.5
04 Dec 2020 (Study Day 88)	Body Aches	Moderate
04 Dec 2020 (Study Day 88)	Chills	Moderate
04 Dec 2020 (Study Day 88)	Cough	Moderate
04 Dec 2020 (Study Day 88)	Difficulty Breathing	Moderate
04 Dec 2020 (Study Day 88)	Fatigue	Severe
04 Dec 2020 (Study Day 88)	Headache	Mild
04 Dec 2020 (Study Day 88)	Muscle Aches (Myalgia)	Moderate
04 Dec 2020 (Study Day 88)	Nasal Congestion	Moderate
04 Dec 2020 (Study Day 88)	Nausea	Moderate
04 Dec 2020 (Study Day 88)	O2 Saturation (%)	92
04 Dec 2020 (Study Day 88)	Shortness of Breath	Moderate
04 Dec 2020 (Study Day 88)	Temperature (°F)	100.6
05 Dec 2020 (Study Day 89)	Body Aches	Moderate
05 Dec 2020 (Study Day 89)	Cough	Moderate
05 Dec 2020 (Study Day 89)	Diarrhea	Moderate
05 Dec 2020 (Study Day 89)	Difficulty Breathing	Moderate
05 Dec 2020 (Study Day 89)	Fatigue	Severe
05 Dec 2020 (Study Day 89)	Headache	Mild
05 Dec 2020 (Study Day 89)	Muscle Aches (Myalgia)	Mild
05 Dec 2020 (Study Day 89)	Nasal Congestion	Moderate
05 Dec 2020 (Study Day 89)	Nausea	Mild
05 Dec 2020 (Study Day 89)	Shortness of Breath	Moderate
06 Dec 2020 (Study Day 90)	Body Aches	Moderate
06 Dec 2020 (Study Day 90)	Chills	Moderate
06 Dec 2020 (Study Day 90)	Cough	Moderate
06 Dec 2020 (Study Day 90)	Diarrhea	Moderate
06 Dec 2020 (Study Day 90)	Difficulty Breathing	Moderate
06 Dec 2020 (Study Day 90)	Fatigue	Severe
06 Dec 2020 (Study Day 90)	Muscle Aches (Myalgia)	Mild
06 Dec 2020 (Study Day 90)	Nasal Congestion	Mild
06 Dec 2020 (Study Day 90)	Nausea	Severe
06 Dec 2020 (Study Day 90)	Runny Nose (Rhinorrhea)	Mild
06 Dec 2020 (Study Day 90)	Shortness of Breath	Severe
06 Dec 2020 (Study Day 90)	Temperature (°F)	102.3
07 Dec 2020 (Study Day 91)	Body Aches	Moderate
07 Dec 2020 (Study Day 91)	Chills	Mild
07 Dec 2020 (Study Day 91)	Cough	Severe
07 Dec 2020 (Study Day 91)	Difficulty Breathing	Severe

Symptom Date	Symptom	Result
07 Dec 2020 (Study Day 91)	Fatigue	Severe
07 Dec 2020 (Study Day 91)	Headache	Mild
07 Dec 2020 (Study Day 91)	Muscle Aches (Myalgia)	Mild
07 Dec 2020 (Study Day 91)	Nasal Congestion	Mild
07 Dec 2020 (Study Day 91)	Nausea	Moderate
07 Dec 2020 (Study Day 91)	O2 Saturation (%)	90
07 Dec 2020 (Study Day 91)	Runny Nose (Rhinorrhea)	Mild
07 Dec 2020 (Study Day 91)	Shortness of Breath	Severe
07 Dec 2020 (Study Day 91)	Temperature (°F)	100.7
08 Dec 2020 (Study Day 92)	Body Aches	Moderate
08 Dec 2020 (Study Day 92)	Chills	Mild
08 Dec 2020 (Study Day 92)	Cough	Severe
08 Dec 2020 (Study Day 92)	Difficulty Breathing	Moderate
08 Dec 2020 (Study Day 92)	Fatigue	Severe
08 Dec 2020 (Study Day 92)	Headache	Moderate
08 Dec 2020 (Study Day 92)	Muscle Aches (Myalgia)	Mild
08 Dec 2020 (Study Day 92)	Nasal Congestion	Mild
08 Dec 2020 (Study Day 92)	Nausea	Mild
08 Dec 2020 (Study Day 92)	Runny Nose (Rhinorrhea)	Mild
08 Dec 2020 (Study Day 92)	Shortness of Breath	Moderate
09 Dec 2020 (Study Day 93)	Body Aches	Moderate
09 Dec 2020 (Study Day 93)	Chills	Mild
09 Dec 2020 (Study Day 93)	Cough	Moderate
09 Dec 2020 (Study Day 93)	Difficulty Breathing	Moderate
09 Dec 2020 (Study Day 93)	Fatigue	Severe
09 Dec 2020 (Study Day 93)	Muscle Aches (Myalgia)	Mild
09 Dec 2020 (Study Day 93)	Nasal Congestion	Mild
09 Dec 2020 (Study Day 93)	Nausea	Mild
09 Dec 2020 (Study Day 93)	O2 Saturation (%)	93
09 Dec 2020 (Study Day 93)	Runny Nose (Rhinorrhea)	Mild
09 Dec 2020 (Study Day 93)	Shortness of Breath	Moderate
10 Dec 2020 (Study Day 94)	Body Aches	Moderate
10 Dec 2020 (Study Day 94)	Chills	Mild
10 Dec 2020 (Study Day 94)	Cough	Moderate
10 Dec 2020 (Study Day 94)	Diarrhea	Mild
10 Dec 2020 (Study Day 94)	Difficulty Breathing	Moderate
10 Dec 2020 (Study Day 94)	Fatigue	Severe
10 Dec 2020 (Study Day 94)	Headache	Mild
10 Dec 2020 (Study Day 94)	Muscle Aches (Myalgia)	Mild
10 Dec 2020 (Study Day 94)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 94)	Nausea	Mild
10 Dec 2020 (Study Day 94)	O2 Saturation (%)	93
10 Dec 2020 (Study Day 94)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
10 Dec 2020 (Study Day 94)	Shortness of Breath	Moderate
10 Dec 2020 (Study Day 94)	Sore Throat	Mild
11 Dec 2020 (Study Day 95)	Body Aches	Moderate
11 Dec 2020 (Study Day 95)	Chills	Mild
11 Dec 2020 (Study Day 95)	Cough	Moderate
11 Dec 2020 (Study Day 95)	Difficulty Breathing	Moderate
11 Dec 2020 (Study Day 95)	Fatigue	Severe
11 Dec 2020 (Study Day 95)	Headache	Moderate
11 Dec 2020 (Study Day 95)	Muscle Aches (Myalgia)	Mild
11 Dec 2020 (Study Day 95)	Nasal Congestion	Mild
11 Dec 2020 (Study Day 95)	Nausea	Moderate
11 Dec 2020 (Study Day 95)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 95)	Shortness of Breath	Moderate
11 Dec 2020 (Study Day 95)	Sore Throat	Mild
12 Dec 2020 (Study Day 96)	Body Aches	Mild
12 Dec 2020 (Study Day 96)	Cough	Moderate
12 Dec 2020 (Study Day 96)	Diarrhea	Mild
12 Dec 2020 (Study Day 96)	Difficulty Breathing	Moderate
12 Dec 2020 (Study Day 96)	Fatigue	Severe
12 Dec 2020 (Study Day 96)	Headache	Moderate
12 Dec 2020 (Study Day 96)	Muscle Aches (Myalgia)	Mild
12 Dec 2020 (Study Day 96)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 96)	Nausea	Moderate
12 Dec 2020 (Study Day 96)	O2 Saturation (%)	92
12 Dec 2020 (Study Day 96)	Runny Nose (Rhinorrhea)	Mild
12 Dec 2020 (Study Day 96)	Shortness of Breath	Moderate
12 Dec 2020 (Study Day 96)	Sore Throat	Mild
13 Dec 2020 (Study Day 97)	Body Aches	Mild
13 Dec 2020 (Study Day 97)	Chills	Mild
13 Dec 2020 (Study Day 97)	Cough	Moderate
13 Dec 2020 (Study Day 97)	Difficulty Breathing	Mild
13 Dec 2020 (Study Day 97)	Fatigue	Severe
13 Dec 2020 (Study Day 97)	Headache	Moderate
13 Dec 2020 (Study Day 97)	Muscle Aches (Myalgia)	Mild
13 Dec 2020 (Study Day 97)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 97)	Nausea	Moderate
13 Dec 2020 (Study Day 97)	Runny Nose (Rhinorrhea)	Mild
13 Dec 2020 (Study Day 97)	Shortness of Breath	Moderate
13 Dec 2020 (Study Day 97)	Sore Throat	Mild
14 Dec 2020 (Study Day 98)	Body Aches	Moderate
14 Dec 2020 (Study Day 98)	Chills	Mild
14 Dec 2020 (Study Day 98)	Cough	Moderate
14 Dec 2020 (Study Day 98)	Difficulty Breathing	Moderate

Symptom Date	Symptom	Result
14 Dec 2020 (Study Day 98)	Fatigue	Severe
14 Dec 2020 (Study Day 98)	Headache	Moderate
14 Dec 2020 (Study Day 98)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 98)	Nausea	Moderate
14 Dec 2020 (Study Day 98)	Runny Nose (Rhinorrhea)	Mild
14 Dec 2020 (Study Day 98)	Shortness of Breath	Moderate
14 Dec 2020 (Study Day 98)	Sore Throat	Mild
15 Dec 2020 (Study Day 99)	Body Aches	Moderate
15 Dec 2020 (Study Day 99)	Chills	Mild
15 Dec 2020 (Study Day 99)	Cough	Mild
15 Dec 2020 (Study Day 99)	Difficulty Breathing	Mild
15 Dec 2020 (Study Day 99)	Fatigue	Severe
15 Dec 2020 (Study Day 99)	Headache	Moderate
15 Dec 2020 (Study Day 99)	Muscle Aches (Myalgia)	Mild
15 Dec 2020 (Study Day 99)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 99)	Nausea	Moderate
15 Dec 2020 (Study Day 99)	Runny Nose (Rhinorrhea)	Mild
15 Dec 2020 (Study Day 99)	Shortness of Breath	Mild
15 Dec 2020 (Study Day 99)	Sore Throat	Mild
16 Dec 2020 (Study Day 100)	Body Aches	Mild
16 Dec 2020 (Study Day 100)	Chills	Mild
16 Dec 2020 (Study Day 100)	Cough	Mild
16 Dec 2020 (Study Day 100)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 100)	Fatigue	Severe
16 Dec 2020 (Study Day 100)	Headache	Mild
16 Dec 2020 (Study Day 100)	Muscle Aches (Myalgia)	Mild
16 Dec 2020 (Study Day 100)	Nausea	Mild
16 Dec 2020 (Study Day 100)	Shortness of Breath	Mild
16 Dec 2020 (Study Day 100)	Sore Throat	Mild
16 Dec 2020 (Study Day 100)	Vomiting	Mild
17 Dec 2020 (Study Day 101)	Body Aches	Mild
17 Dec 2020 (Study Day 101)	Chills	Mild
17 Dec 2020 (Study Day 101)	Cough	Mild
17 Dec 2020 (Study Day 101)	Difficulty Breathing	Moderate
17 Dec 2020 (Study Day 101)	Fatigue	Moderate
17 Dec 2020 (Study Day 101)	Headache	Moderate
17 Dec 2020 (Study Day 101)	Nausea	Mild
17 Dec 2020 (Study Day 101)	Shortness of Breath	Moderate
17 Dec 2020 (Study Day 101)	Sore Throat	Mild
18 Dec 2020 (Study Day 102)	Body Aches	Mild
18 Dec 2020 (Study Day 102)	Chills	Moderate
18 Dec 2020 (Study Day 102)	Cough	Mild
18 Dec 2020 (Study Day 102)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 102)	Fatigue	Severe
18 Dec 2020 (Study Day 102)	Nausea	Moderate
18 Dec 2020 (Study Day 102)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 103)	Body Aches	Mild
19 Dec 2020 (Study Day 103)	Chills	Moderate
19 Dec 2020 (Study Day 103)	Cough	Severe
19 Dec 2020 (Study Day 103)	Fatigue	Moderate
19 Dec 2020 (Study Day 103)	Nausea	Mild
19 Dec 2020 (Study Day 103)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 103)	Sore Throat	Mild
20 Dec 2020 (Study Day 104)	Body Aches	Mild
20 Dec 2020 (Study Day 104)	Chills	Moderate
20 Dec 2020 (Study Day 104)	Cough	Moderate
20 Dec 2020 (Study Day 104)	Diarrhea	Mild
20 Dec 2020 (Study Day 104)	Fatigue	Moderate
20 Dec 2020 (Study Day 104)	Nausea	Mild
20 Dec 2020 (Study Day 104)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 104)	Sore Throat	Mild
21 Dec 2020 (Study Day 105)	Body Aches	Moderate
21 Dec 2020 (Study Day 105)	Chills	Mild
21 Dec 2020 (Study Day 105)	Cough	Mild
21 Dec 2020 (Study Day 105)	Difficulty Breathing	Mild
21 Dec 2020 (Study Day 105)	Fatigue	Moderate
21 Dec 2020 (Study Day 105)	Nausea	Moderate
21 Dec 2020 (Study Day 105)	Shortness of Breath	Mild
22 Dec 2020 (Study Day 106)	Body Aches	Mild
22 Dec 2020 (Study Day 106)	Chills	Mild
22 Dec 2020 (Study Day 106)	Cough	Mild
22 Dec 2020 (Study Day 106)	Difficulty Breathing	Mild
22 Dec 2020 (Study Day 106)	Fatigue	Moderate
22 Dec 2020 (Study Day 106)	Nausea	Moderate
22 Dec 2020 (Study Day 106)	O2 Saturation (%)	92
22 Dec 2020 (Study Day 106)	Shortness of Breath	Mild
23 Dec 2020 (Study Day 107)	Body Aches	Mild
23 Dec 2020 (Study Day 107)	Cough	Mild
23 Dec 2020 (Study Day 107)	Fatigue	Mild
23 Dec 2020 (Study Day 107)	Nausea	Mild
23 Dec 2020 (Study Day 107)	O2 Saturation (%)	92
23 Dec 2020 (Study Day 107)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 108)	Cough	Mild
24 Dec 2020 (Study Day 108)	Fatigue	Mild
24 Dec 2020 (Study Day 108)	Nausea	Mild
24 Dec 2020 (Study Day 108)	O2 Saturation (%)	93

Symptom Date	Symptom	Result
24 Dec 2020 (Study Day 108)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 108)	Vomiting	Mild
25 Dec 2020 (Study Day 109)	Cough	Mild
25 Dec 2020 (Study Day 109)	Fatigue	Mild
25 Dec 2020 (Study Day 109)	Nausea	Mild
25 Dec 2020 (Study Day 109)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 109)	Vomiting	Mild
26 Dec 2020 (Study Day 110)	Chills	Mild
26 Dec 2020 (Study Day 110)	Cough	Mild
26 Dec 2020 (Study Day 110)	Fatigue	Moderate
26 Dec 2020 (Study Day 110)	Nausea	Moderate
26 Dec 2020 (Study Day 110)	O2 Saturation (%)	92
26 Dec 2020 (Study Day 110)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 110)	Vomiting	Mild
27 Dec 2020 (Study Day 111)	Chills	Mild
27 Dec 2020 (Study Day 111)	Cough	Mild
27 Dec 2020 (Study Day 111)	Fatigue	Moderate
27 Dec 2020 (Study Day 111)	Nausea	Moderate
27 Dec 2020 (Study Day 111)	O2 Saturation (%)	92
27 Dec 2020 (Study Day 111)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 112)	Cough	Mild
28 Dec 2020 (Study Day 112)	Diarrhea	Mild
28 Dec 2020 (Study Day 112)	Fatigue	Moderate
28 Dec 2020 (Study Day 112)	Headache	Mild
28 Dec 2020 (Study Day 112)	Nausea	Moderate
28 Dec 2020 (Study Day 112)	Shortness of Breath	Moderate
28 Dec 2020 (Study Day 112)	Vomiting	Mild
28 Feb 2021 (Study Day 174)	Sore Throat	Mild
01 Mar 2021 (Study Day 175)	Sore Throat	Mild
02 Mar 2021 (Study Day 176)	Chills	Mild
02 Mar 2021 (Study Day 176)	Cough	Mild
02 Mar 2021 (Study Day 176)	Sore Throat	Mild
03 Mar 2021 (Study Day 177)	Chills	Mild
03 Mar 2021 (Study Day 177)	Sore Throat	Mild
04 Mar 2021 (Study Day 178)	Chills	Mild
04 Mar 2021 (Study Day 178)	Sore Throat	Mild
06 Mar 2021 (Study Day 180)	O2 Saturation (%)	93
08 Mar 2021 (Study Day 182)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
02 Dec 2020 (Study Day 86)	Heart Rate	125 beats/min
03 Dec 2020 (Study Day 87)	Oxygen Saturation	90%
02 Dec 2020 - 09 Dec 2020 (Study Day 86-93)	Heart Rate ≥ 125 per Minute	Yes
03 Dec 2020 - 27 Dec 2020 (Study Day 87-111)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
07 Dec 2020 - 07 Dec 2020 (Study Day 91-91)	Radiographical Evidence of Pneumonia	Yes
08 Dec 2020 - 08 Dec 2020 (Study Day 92-92)	Clinical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of COVID - 19 pneumonia lasted for 38 days, after which it was considered to be recovered/resolved with sequelae on 03 Jan 2021 (Study Day 118). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001067	COVID-19 pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	2015 - Ongoing
Pain in extremity	Left foot pain	2017 - Ongoing
Dyslipidaemia	Dyslipidemia	08 Sep 2018 (Study Day -731) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2017 - Ongoing	Left Foot Pain
Codeine phosphate; promethazine hydrochloride	29 Nov 2020 (Study Day 83) - 05 Dec 2020 (Study Day 89)	COVID - 19 Pneumonia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	29 Nov 2020 (Study Day 83) - 07 Dec 2020 (Study Day 91)	COVID - 19 Pneumonia
Chest x-ray*	07 Dec 2020 (Study Day 91) - 07 Dec 2020 (Study Day 91)	Adverse Event
Doxycycline	07 Dec 2020 (Study Day 91) - 13 Dec 2020 (Study Day 97)	COVID - 19 Pneumonia
Dextromethorphan hydrobromide	08 Dec 2020 (Study Day 92) - 25 Dec 2020 (Study Day 109)	COVID-19 Pneumonia
Benzonatate	14 Dec 2020 (Study Day 98) - 02 Jan 2021 (Study Day 117)	COVID-19 Pneumonia
Dexamethasone	14 Dec 2020 (Study Day 98) - 24 Dec 2020 (Study Day 108)	COVID-19 Pneumonia
Ibuprofen	04 Jan 2021 (Study Day 119) - Ongoing	Post-COVID Syndrome
Ibuprofen	02 Mar 2021 (Study Day 176) - 03 Mar 2021 (Study Day 177)	Acute Pharyngitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19 Pneumonia	Grade 3/severe	Not related	27 Nov 2020 (Study Day 81) - 03 Jan 2021 (Study Day 118)
Infection	Grade 1/mild	Not related	04 Jan 2021 (Study Day 119) - Ongoing
Conjunctivitis Viral	Grade 2/moderate	Not related	27 Jan 2021 (Study Day 142) - 30 Jan 2021 (Study Day 145)
Pharyngitis	Grade 1/mild	Not related	27 Feb 2021 (Study Day 173) - 05 Mar 2021 (Study Day 179)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US390-2015 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	26 Oct 2020 (Study Day 49) – 10 Nov 2020 (Study Day 64)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US390-2015, a 53-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 26 Oct 2020 (Study Day 49), 48 days after the first dose and 20 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 06 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Oct 2020 (Study Day 51), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
26 Oct 2020 (Study Day 49)	Body Aches	Mild
26 Oct 2020 (Study Day 49)	Chills	Mild
26 Oct 2020 (Study Day 49)	Cough	Mild
26 Oct 2020 (Study Day 49)	Fatigue	Mild
26 Oct 2020 (Study Day 49)	Nasal Congestion	Mild
27 Oct 2020 (Study Day 50)	Body Aches	Mild

Symptom Date	Symptom	Result
27 Oct 2020 (Study Day 50)	Chills	Mild
27 Oct 2020 (Study Day 50)	Cough	Mild
27 Oct 2020 (Study Day 50)	Fatigue	Mild
27 Oct 2020 (Study Day 50)	Nasal Congestion	Mild
28 Oct 2020 (Study Day 51)	Body Aches	Mild
28 Oct 2020 (Study Day 51)	Chills	Mild
28 Oct 2020 (Study Day 51)	Fatigue	Mild
28 Oct 2020 (Study Day 51)	Headache	Mild
28 Oct 2020 (Study Day 51)	Muscle Aches (Myalgia)	Mild
28 Oct 2020 (Study Day 51)	Nasal Congestion	Mild
28 Oct 2020 (Study Day 51)	Runny Nose (Rhinorrhea)	Mild
28 Oct 2020 (Study Day 51)	Sore Throat	Mild
29 Oct 2020 (Study Day 52)	Body Aches	Moderate
29 Oct 2020 (Study Day 52)	Chills	Moderate
29 Oct 2020 (Study Day 52)	Cough	Moderate
29 Oct 2020 (Study Day 52)	Difficulty Breathing	Moderate
29 Oct 2020 (Study Day 52)	Fatigue	Moderate
29 Oct 2020 (Study Day 52)	Headache	Mild
29 Oct 2020 (Study Day 52)	Muscle Aches (Myalgia)	Moderate
29 Oct 2020 (Study Day 52)	Nasal Congestion	Mild
29 Oct 2020 (Study Day 52)	Shortness of Breath	Mild
29 Oct 2020 (Study Day 52)	Temperature (°F)	102.4
30 Oct 2020 (Study Day 53)	Body Aches	Mild
30 Oct 2020 (Study Day 53)	Chills	Mild
30 Oct 2020 (Study Day 53)	Cough	Mild
30 Oct 2020 (Study Day 53)	Difficulty Breathing	Mild
30 Oct 2020 (Study Day 53)	Fatigue	Moderate
30 Oct 2020 (Study Day 53)	Headache	Mild
30 Oct 2020 (Study Day 53)	Muscle Aches (Myalgia)	Moderate
30 Oct 2020 (Study Day 53)	Nasal Congestion	Moderate
30 Oct 2020 (Study Day 53)	Runny Nose (Rhinorrhea)	Mild
30 Oct 2020 (Study Day 53)	Shortness of Breath	Mild
31 Oct 2020 (Study Day 54)	Body Aches	Moderate
31 Oct 2020 (Study Day 54)	Chills	Mild
31 Oct 2020 (Study Day 54)	Cough	Mild
31 Oct 2020 (Study Day 54)	Difficulty Breathing	Mild
31 Oct 2020 (Study Day 54)	Fatigue	Mild
31 Oct 2020 (Study Day 54)	Muscle Aches (Myalgia)	Moderate
31 Oct 2020 (Study Day 54)	Nasal Congestion	Mild
31 Oct 2020 (Study Day 54)	Runny Nose (Rhinorrhea)	Mild
31 Oct 2020 (Study Day 54)	Shortness of Breath	Mild
01 Nov 2020 (Study Day 55)	Body Aches	Mild
01 Nov 2020 (Study Day 55)	Chills	Mild

Symptom Date	Symptom	Result
01 Nov 2020 (Study Day 55)	Cough	Mild
01 Nov 2020 (Study Day 55)	Fatigue	Mild
01 Nov 2020 (Study Day 55)	Muscle Aches (Myalgia)	Mild
01 Nov 2020 (Study Day 55)	Nasal Congestion	Mild
01 Nov 2020 (Study Day 55)	Runny Nose (Rhinorrhea)	Mild
01 Nov 2020 (Study Day 55)	Shortness of Breath	Mild
02 Nov 2020 (Study Day 56)	Body Aches	Mild
02 Nov 2020 (Study Day 56)	Cough	Mild
02 Nov 2020 (Study Day 56)	Fatigue	Mild
02 Nov 2020 (Study Day 56)	Muscle Aches (Myalgia)	Mild
02 Nov 2020 (Study Day 56)	Nasal Congestion	Mild
02 Nov 2020 (Study Day 56)	Runny Nose (Rhinorrhea)	Mild
02 Nov 2020 (Study Day 56)	Shortness of Breath	Mild
03 Nov 2020 (Study Day 57)	Body Aches	Mild
03 Nov 2020 (Study Day 57)	Chills	Mild
03 Nov 2020 (Study Day 57)	Diarrhea	Mild
03 Nov 2020 (Study Day 57)	Difficulty Breathing	Mild
03 Nov 2020 (Study Day 57)	Fatigue	Mild
03 Nov 2020 (Study Day 57)	Headache	Mild
03 Nov 2020 (Study Day 57)	Nausea	Mild
03 Nov 2020 (Study Day 57)	Shortness of Breath	Mild
03 Nov 2020 (Study Day 57)	Temperature (°F)	101.0
04 Nov 2020 (Study Day 58)	Diarrhea	Mild
04 Nov 2020 (Study Day 58)	Fatigue	Mild
04 Nov 2020 (Study Day 58)	Headache	Mild
04 Nov 2020 (Study Day 58)	Muscle Aches (Myalgia)	Mild
04 Nov 2020 (Study Day 58)	Shortness of Breath	Mild
06 Nov 2020 (Study Day 60)	Body Aches	Moderate
06 Nov 2020 (Study Day 60)	Cough	Mild
06 Nov 2020 (Study Day 60)	Difficulty Breathing	Mild
06 Nov 2020 (Study Day 60)	Fatigue	Mild
06 Nov 2020 (Study Day 60)	Headache	Mild
06 Nov 2020 (Study Day 60)	Muscle Aches (Myalgia)	Moderate
06 Nov 2020 (Study Day 60)	O2 Saturation (%)	92
06 Nov 2020 (Study Day 60)	Shortness of Breath	Moderate
07 Nov 2020 (Study Day 61)	Body Aches	Mild
07 Nov 2020 (Study Day 61)	Cough	Mild
07 Nov 2020 (Study Day 61)	Fatigue	Mild
07 Nov 2020 (Study Day 61)	Muscle Aches (Myalgia)	Mild
07 Nov 2020 (Study Day 61)	Shortness of Breath	Mild
08 Nov 2020 (Study Day 62)	Body Aches	Mild
08 Nov 2020 (Study Day 62)	Cough	Mild
08 Nov 2020 (Study Day 62)	Fatigue	Mild

Symptom Date	Symptom	Result
08 Nov 2020 (Study Day 62)	Muscle Aches (Myalgia)	Mild
08 Nov 2020 (Study Day 62)	Shortness of Breath	Mild
09 Nov 2020 (Study Day 63)	Body Aches	Mild
09 Nov 2020 (Study Day 63)	Difficulty Breathing	Mild
09 Nov 2020 (Study Day 63)	Fatigue	Mild
09 Nov 2020 (Study Day 63)	Muscle Aches (Myalgia)	Mild
09 Nov 2020 (Study Day 63)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
06 Nov 2020 (Study Day 60)	Oxygen Saturation	92%
06 Nov 2020 - 06 Nov 2020 (Study Day 60-60)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 16 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 64). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000627	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Morbid obesity	1996 - Ongoing
Back pain	Generalized back pain	2009 - Ongoing
Muscle spasms	Muscle spasms - back	2016 - Ongoing
Peripheral swelling	Bilateral lower leg swelling	2018 - Ongoing
Postmenopause	Postmenopausal	10 Aug 2019 (Study Day -395) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine	2016 - 02 Oct 2020 (Study Day 25)	Muscle Spasms In Back
Meloxicam	2018 - Ongoing	Back Pain
Hydrochlorothiazide	2019 - Ongoing	Bilateral Lower Leg Swelling
Baclofen	03 Oct 2020 (Study Day 26) - Ongoing	Muscle Spasms In Back
Naproxen sodium	27 Oct 2020 (Study Day 50) - 10 Nov 2020 (Study Day 64)	Symptomatic COVID-19
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	02 Nov 2020 (Study Day 56) - 10 Nov 2020 (Study Day 64)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 49) - 10 Nov 2020 (Study Day 64)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US390-2019 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urticaria/Urticarial Rash On Buttocks And Bilateral Axilla	AE leading to withdrawal from study vaccine	Grade 2/moderate	Related	05 Sep 2020 (Study Day 4) – 11 Sep 2020 (Study Day 10)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US390-2019, a 61-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Sep 2020 (Study Day 4), 3 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of urticaria. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of urticarial rash on buttocks and bilateral axilla lasted for 7 days, after which it was considered to be recovered/resolved on 11 Sep 2020 (Study Day 10). The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastric bypass	Gastric bypass	2003 - 2003

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	2003 - Ongoing
Cholecystectomy	Cholecystectomy	2004 - 2004
Cholecystitis	Cholecystitis	2004 - 2004
Intestinal resection	Twisted bowel resection	2004 - 2004
Volvulus	Twisted bowel	2004 - 2004
Botulinum toxin injection	Botox	2014 - 2014
Migraine	Migraines	2014 - 2014
Humerus fracture	Humerus fracture - left	Dec 2015 - Dec 2015
Humerus fracture	Humerus fracture left	Dec 2015 - Dec 2015
Shoulder operation	Left shoulder surgery	Dec 2015 - Dec 2015
Shoulder operation	Left shoulder surgery	Jun 2016 - Jun 2016
Shoulder arthroplasty	Left shoulder replacement	Sep 2016 - Sep 2016
Intestinal perforation	Perforated bowel	Mar 2018 - Mar 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydroxyzine	08 Sep 2020 (Study Day 7) - 11 Sep 2020 (Study Day 10)	Urticarial Rash On Buttocks And Bilateral Axilla
Naproxen	10 Oct 2020 (Study Day 39) - Ongoing	Soreness In Joints - Bilateral Hips
Ascorbic acid; echinacea purpurea; zinc citrate; zinc gluconate	20 Nov 2020 (Study Day 80) - 07 Dec 2020 (Study Day 97)	COVID-19 Symptoms
Paracetamol	20 Nov 2020 (Study Day 80) - 07 Dec 2020 (Study Day 97)	COVID-Like Symptoms
Ibuprofen	23 Nov 2020 (Study Day 83) - 07 Dec 2020 (Study Day 97)	COVID-Like Symptoms
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	24 Nov 2020 (Study Day 84) - 07 Dec 2020 (Study Day 97)	Covd-Like Symptoms
Diphenhydramine hydrochloride	04 Dec 2020 (Study Day 94) - 07 Dec 2020 (Study Day 97)	COVID-Like Symptoms

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urticaria	Grade 2/moderate	Related	05 Sep 2020 (Study Day 4) - 11 Sep 2020 (Study Day 10)
Arthralgia	Grade 1/mild	Related	05 Oct 2020 (Study Day 34) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 2/moderate	Not related	20 Nov 2020 (Study Day 80) - 07 Dec 2020 (Study Day 97)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379601

Participant Number:	US390-2030 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urticaria/Hives	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	05 Sep 2020 (Study Day 3) – 21 Sep 2020 (Study Day 19)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US390-2030, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Sep 2020 (Study Day 3), 2 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of urticaria. On 30 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of hives lasted for 17 days, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 19). The investigator assessed the event of urticaria to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Inguinal hernia	Inguinal hernia	1972 - 1972
Hypertension	Hypertension	2014 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2014 - Ongoing
Osteoarthritis	Osteoarthritis of knees	2015 - Ongoing
Hiatus hernia	Hiatal hernia	2016 - 2019
Cholecystectomy	Cholecystectomy	2017 - 2017
Cholecystitis	Cholecystitis	2017 - 2017
Gastrooesophageal reflux disease	Gastroesophogeal reflux disease	2018 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Knee arthroplasty	Left knee replacement	16 Jan 2020 (Study Day -231) - 16 Jan 2020 (Study Day -231)
Knee arthroplasty	Right knee replacement	16 Jan 2020 (Study Day -231) - 16 Jan 2020 (Study Day -231)
Neuropathy peripheral	Peripheral neuropathy	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2014 - Sep 2020	Hypertension
Metformin hydrochloride	2014 - Ongoing	Diabetes Type Ii
Hydrochlorothiazide	2015 - Ongoing	Hypertension
Lisinopril	2015 - 20 Oct 2020 (Study Day 48)	Hypertension
Empagliflozin	2016 - Ongoing	Diabetes Type Ii
Lovastatin	2018 - Ongoing	Hypercholestrolemia
Insulin human; insulin human injection, isophane	2019 - 20 Oct 2020 (Study Day 48)	Diabetes Type Ii
Omeprazole	Mar 2020 - Ongoing	Gerd
Pregabalin	Mar 2020 - Ongoing	Peripheral Neuropathy
Paracetamol	06 Sep 2020 (Study Day 4) - 08 Sep 2020 (Study Day 6)	Injection Site Pain
Diphenhydramine hydrochloride	09 Sep 2020 (Study Day 7) - 18 Sep 2020 (Study Day 16)	Hives
Insulin human; insulin human injection, isophane	20 Oct 2020 (Study Day 48) - Ongoing	Diabetes Ii
Lisinopril	20 Oct 2020 (Study Day 48) - Ongoing	Hypertension
Hiatal hernia repair*	24 Nov 2020 (Study Day 83) - 24 Nov 2020 (Study Day 83)	Medical History
Amoxicillin	13 Jan 2021 (Study Day 133) - 20 Jan 2021 (Study Day 140)	Ae #4: Upper Respiratory Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lip Swelling	Grade 2/moderate	Related	05 Sep 2020 (Study Day 3) - 08 Sep 2020 (Study Day 6)
Pain In Extremity	Grade 1/mild	Related	05 Sep 2020 (Study Day 3) - 23 Sep 2020 (Study Day 21)
Urticaria	Grade 1/mild	Related	05 Sep 2020 (Study Day 3) - 21 Sep 2020 (Study Day 19)
Arthralgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 9) - 14 Sep 2020 (Study Day 12)
Fatigue	Grade 1/mild	Related	11 Sep 2020 (Study Day 9) - 14 Sep 2020 (Study Day 12)
Injection Site Erythema	Grade 1/mild	Related	11 Sep 2020 (Study Day 9) - 14 Sep 2020 (Study Day 12)
Myalgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 9) - 11 Sep 2020 (Study Day 9)
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 133) - 20 Jan 2021 (Study Day 140)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US391-2114 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Humerus Fracture/ Broken Right Humerus	SAE	Grade 4	Not related	30 Oct 2020 (Study Day 57) – 10 Nov 2020 (Study Day 68)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2114, a 74-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 04 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Oct 2020 (Study Day 57), 56 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of humerus fracture. On 01 Oct 2020 (Study Day 28), the IP dose was discontinued due to protocol deviation. The event of broken right humerus lasted for 12 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 68). The investigator assessed the event of humerus fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000734	Humerus fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug eruption	Penicillin allergy (rash)	1960 - Ongoing
Seasonal allergy	Seasonal allergies (cough, runny nose)	1966 - Ongoing
Drug eruption	Feldene allergy (rash)	1978 - Ongoing
Drug eruption	Lipitor allergy (rash)	1990 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Postmenopause	Post menopausal	2001 - Ongoing
Drug eruption	Gadolinium derivatives (rash)	2003 - Ongoing
Hypothyroidism	Hypothyroidism	2005 - Ongoing
Cataract	Bilateral cataracts	2011 - Aug 2018
Triple negative breast cancer	Triple negative breast cancer left breast	Apr 2011 - Nov 2011
Breast conserving surgery	Lumpectomy left breast	02 May 2011 (Study Day -3413) - 02 May 2020 (Study Day -125)
Cataract operation	Bilateral cataract surgery	Aug 2018 - Aug 2018
Hypertension	Hypertension	Aug 2020 - Ongoing
Pain	Body aches	31 Aug 2020 (Study Day -4) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2005 - Ongoing	Hypothyroidism
Acetylsalicylic acid	2010 - Ongoing	Cardiac
Chondroitin sulfate sodium; glucosamine hydrochloride	2010 - Ongoing	Supplement
Vitamins nos	2010 - Ongoing	Supplement
Calcium; colecalciferol	2011 - Ongoing	Supplement
Vitamin d nos	2011 - Ongoing	Supplement
Fish oil	2017 - Ongoing	Supplement
Rosuvastatin calcium	2018 - Ongoing	Hypercholesterolemia
Biotin	2019 - Ongoing	Supplement
Minoxidil	2019 - Ongoing	Hair Loss
Lisinopril	17 Aug 2020 (Study Day -18) - Ongoing	Hypertension
Ibuprofen	31 Aug 2020 (Study Day -4) - 31 Aug 2020 (Study Day -4)	Body Aches
Acetylsalicylic acid; caffeine; paracetamol	05 Sep 2020 (Study Day 2) - 05 Sep 2020 (Study Day 2)	Headache
Diphenhydramine hydrochloride	13 Sep 2020 (Study Day 10) - 13 Sep 2020 (Study Day 10)	Injection Site Reaction Left Deltoid

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	13 Sep 2020 (Study Day 10) - 14 Sep 2020 (Study Day 11)	Injection Site Reaction Left Deltoid
Influenza vaccine	09 Oct 2020 (Study Day 36) - 09 Oct 2020 (Study Day 36)	Flu Prevention
Hydrocodone bitartrate; paracetamol	30 Oct 2020 (Study Day 57) - 10 Nov 2020 (Study Day 68)	Broken Right Humerus (Related To Fall)
Ibuprofen	30 Oct 2020 (Study Day 57) - 01 Jan 2021 (Study Day 120)	Right Shoulder Pain
Oxycodone	30 Oct 2020 (Study Day 57) - 01 Jan 2021 (Study Day 120)	Right Shoulder Pain
Open reduction internal fixation right humerus*	10 Nov 2020 (Study Day 68) - 10 Nov 2020 (Study Day 68)	Adverse Event
Dexamethasone; tobramycin	20 Feb 2021 (Study Day 170) - 06 Mar 2021 (Study Day 184)	Stye
Doxycycline	20 Feb 2021 (Study Day 170) - 06 Mar 2021 (Study Day 184)	Stye

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 3/severe	Not related	04 Sep 2020 (Study Day 1) - 05 Sep 2020 (Study Day 2)
Injection Site Pruritus	Grade 1/mild	Related	13 Sep 2020 (Study Day 10) - 18 Sep 2020 (Study Day 15)
Seasonal Allergy	Grade 1/mild	Not related	16 Oct 2020 (Study Day 43) - 31 Oct 2020 (Study Day 58)
Hypertension	Grade 3/severe	Not related	30 Oct 2020 (Study Day 57) - 04 Nov 2020 (Study Day 62)
Musculoskeletal Pain	Grade 2/moderate	Not related	30 Oct 2020 (Study Day 57) - 01 Jan 2021 (Study Day 120)
Respiratory Disorder	Grade 1/mild	Not related	30 Oct 2020 (Study Day 57) - 04 Nov 2020 (Study Day 62)
Hordeolum	Grade 2/moderate	Not related	15 Feb 2021 (Study Day 165) - 07 Mar 2021 (Study Day 185)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US391-2163 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	15 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	13 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Nstemi-Non St-Elevation Myocardial Infarction	SAE	Grade 3/severe	Not related	01 Feb 2021 (Study Day 140) – 02 Feb 2021 (Study Day 141)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2163, a 43-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 15 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Feb 2021 (Study Day 140), 139 days after the first dose and 111 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of nstemi-non st-elevation myocardial infarction lasted for 2 days, after which it was considered to be recovered/resolved on 02 Feb 2021 (Study Day 141). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010952	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	Sep 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol tartrate	Sep 2018 - Ongoing	Hypertension
Ascorbic acid	07 Dec 2020 (Study Day 84) - Ongoing	Health Supplement
Azelastine hydrochloride	07 Dec 2020 (Study Day 84) - 21 Dec 2020 (Study Day 98)	Nasal Congestion
Calcium; magnesium; zinc	07 Dec 2020 (Study Day 84) - Ongoing	Health Supplement
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	07 Dec 2020 (Study Day 84) - 21 Dec 2020 (Study Day 98)	Nasal Congestion
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	07 Dec 2020 (Study Day 84) - 08 Dec 2020 (Study Day 85)	Nasal Congestion
Guaifenesin	07 Dec 2020 (Study Day 84) - 10 Dec 2020 (Study Day 87)	Cough
Ibuprofen	07 Dec 2020 (Study Day 84) - 21 Dec 2020 (Study Day 98)	Body Aches
Zinc	07 Dec 2020 (Study Day 84) - Ongoing	Health Supplement
Bismuth subsalicylate	16 Dec 2020 (Study Day 93) - 16 Dec 2020 (Study Day 93)	Diarrhea
Acetylsalicylic acid	01 Feb 2021 (Study Day 140) - Ongoing	Myocardial Infarction
Angioplasty*	01 Feb 2021 (Study Day 140) - 01 Feb 2021 (Study Day 140)	Adverse Event
Glyceryl trinitrate	01 Feb 2021 (Study Day 140) - Ongoing	Myocardial Infarction
Rosuvastatin	01 Feb 2021 (Study Day 140) - Ongoing	Hyperlipidemia
Stent placement*	01 Feb 2021 (Study Day 140) - 01 Feb 2021 (Study Day 140)	Adverse Event
Ticagrelor	01 Feb 2021 (Study Day 140) - Ongoing	Myocardial Infarction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 2/moderate	Related	15 Sep 2020 (Study Day 1) - 16 Sep 2020 (Study Day 2)
Hypertension	Grade 3/severe	Not related	13 Oct 2020 (Study Day 29) - 13 Oct 2020 (Study Day 29)
COVID-19	Grade 1/mild	Not related	04 Dec 2020 (Study Day 81) - 22 Dec 2020 (Study Day 99)
Diarrhoea	Grade 1/mild	Not related	08 Dec 2020 (Study Day 85) - 08 Dec 2020 (Study Day 85)
Hyperlipidaemia	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 140) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2066 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Confirmed COVID 19	COVID-19	Grade 3/severe	Not related	20 Nov 2020 (Study Day 80) – 06 Dec 2020 (Study Day 96)	Recovered/ resolved
Osteoarthritis/Worsening Left Knee Osteoarthritis	SAE	Grade 3/severe	Not related	28 Dec 2020 (Study Day 118) – 16 Feb 2021 (Study Day 168)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US393-2066, a 78-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Dec 2020 (Study Day 118), 117 days after the first dose and 91 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening left knee osteoarthritis lasted for 51 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 168). The investigator assessed the event of osteoarthritis to be not related to the IP.

Severe COVID-19 Details

On 20 Nov 2020 (Study Day 80), 79 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of confirmed COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 27, 28 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Nov 2020 (Study Day 83), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
20 Nov 2020 (Study Day 80)	Body Aches	Mild
20 Nov 2020 (Study Day 80)	Chills	Mild
20 Nov 2020 (Study Day 80)	Fatigue	Mild
20 Nov 2020 (Study Day 80)	Temperature (°F)	102.1
21 Nov 2020 (Study Day 81)	Body Aches	Mild
21 Nov 2020 (Study Day 81)	Chills	Mild
21 Nov 2020 (Study Day 81)	Fatigue	Mild
22 Nov 2020 (Study Day 82)	Fatigue	Mild
23 Nov 2020 (Study Day 83)	Fatigue	Mild
24 Nov 2020 (Study Day 84)	Fatigue	Moderate
24 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 84)	New Loss of Smell	Mild
25 Nov 2020 (Study Day 85)	Fatigue	Moderate
25 Nov 2020 (Study Day 85)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 85)	New Loss of Smell	Mild
27 Nov 2020 (Study Day 87)	Fatigue	Mild
27 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 87)	New Loss of Smell	Mild
28 Nov 2020 (Study Day 88)	Fatigue	Mild
28 Nov 2020 (Study Day 88)	New Loss of Smell	Mild
29 Nov 2020 (Study Day 89)	Fatigue	Mild
29 Nov 2020 (Study Day 89)	New Loss of Smell	Mild
30 Nov 2020 (Study Day 90)	Fatigue	Mild
30 Nov 2020 (Study Day 90)	New Loss of Smell	Mild
01 Dec 2020 (Study Day 91)	Fatigue	Mild
01 Dec 2020 (Study Day 91)	New Loss of Smell	Mild
01 Dec 2020 (Study Day 91)	O2 Saturation (%)	93
02 Dec 2020 (Study Day 92)	Fatigue	Mild
02 Dec 2020 (Study Day 92)	New Loss of Smell	Mild
03 Dec 2020 (Study Day 93)	Fatigue	Mild
03 Dec 2020 (Study Day 93)	New Loss of Smell	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
01 Dec 2020 (Study Day 91)	Oxygen Saturation	93%
01 Dec 2020 - 01 Dec 2020 (Study Day 91-91)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of confirmed COVID 19 lasted for 17 days, after which it was considered to be recovered/resolved on 06 Dec 2020 (Study Day 96). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001244	COVID-19
MOD-2021-014088	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Deafness bilateral	Bilateral hearing loss	Not reported - Ongoing
Drug hypersensitivity	Scopolamine allergy	Not reported - Ongoing
Drug hypersensitivity	Steroid allergy	Not reported - Ongoing
Dry eye	Dry eye	Not reported - Ongoing
Osteoarthritis	Osteoarthritis	Not reported - Ongoing
Neck pain	Neck pain	1959 - Ongoing
Headache	Headache	1965 - Ongoing
Back pain	Back pain	1995 - Ongoing
Upper limb fracture	Rt arm fracture	1995 - 1995
Prostatomegaly	Enlarged prostate	2000 - Ongoing
Pollakiuria	Frequent urination	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Herpes zoster	Shingles	2016 - 2016
Erectile dysfunction	Erectile dysfunction	2018 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Osteoarthritis	Osteoarthritis right hip	2018 - Ongoing
Anxiety	Anxiety	2020 - Ongoing
Depression	Depression	2020 - Ongoing
Asthma	Asthma	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen sodium	2000 - Ongoing	Neck And Back Pain
Montelukast	2015 - Ongoing	Seasonal Allergies
Esomeprazole magnesium	2018 - Ongoing	Gastroesophageal Reflux Disease
Fluticasone furoate; vilanterol trifenatate	Jul 2020 - Ongoing	Asthma
Sertraline	Jul 2020 - Ongoing	Depression
Tamsulosin	Jul 2020 - Ongoing	Enlarged Prostate
Finasteride	Aug 2020 - Ongoing	Enlarged Prostate
Acetylsalicylic acid	12 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 43)	Right Hip Osteoarthritis - Post Surgery
Cefazolin	12 Oct 2020 (Study Day 41) - 13 Oct 2020 (Study Day 42)	Right Hip Osteoarthritis - Post Surgery
Oxycodone	12 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 43)	Right Hip Osteoarthritis - Post Surgery
Paracetamol	12 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 43)	Pain Control -Post Hip Surgery
Pregabalin	12 Oct 2020 (Study Day 41) - 12 Oct 2020 (Study Day 41)	Right Hip Osteoarthritis - Post Surgery
Right hip arthroplasty*	12 Oct 2020 (Study Day 41) - 12 Oct 2020 (Study Day 41)	Adverse Event
Sodium chloride	12 Oct 2020 (Study Day 41) - 12 Oct 2020 (Study Day 41)	Orthostatic Hypotensive Episode
Tramadol	12 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 43)	Right Hip Osteoarthritis - Post Surgery
Pantoprazole sodium sesquihydrate	13 Oct 2020 (Study Day 42) - 14 Oct 2020 (Study Day 43)	Gi Prophylaxis
Zolpidem tartrate	13 Oct 2020 (Study Day 42) - 14 Oct 2020 (Study Day 43)	Right Hip Osteoarthritis - Post Surgery
Docusate	14 Oct 2020 (Study Day 43) - 14 Oct 2020 (Study Day 43)	Constipation Prophylaxis
Sennoside a+b	14 Oct 2020 (Study Day 43) - 14 Oct 2020 (Study Day 43)	Constipation Prophylaxis
Influenza vaccine	20 Oct 2020 (Study Day 49) - 20 Oct 2020 (Study Day 49)	Prophylaxis To Influenza
Tamsulosin hydrochloride	21 Dec 2020 (Study Day 111) - Ongoing	Frequent Urination
Elective total left knee replacement*	10 Feb 2021 (Study Day 162) - 10 Feb 2021 (Study Day 162)	Adverse Event
Acetylsalicylic acid	12 Feb 2021 (Study Day 164) - 09 Mar 2021 (Study Day 189)	Worsening Of Lt Knee Osteoarthritis
Oxycodone	12 Feb 2021 (Study Day 164) - 16 Feb 2021 (Study Day 168)	Worsening Of Lt Knee Osteoarthritis
Paracetamol	12 Feb 2021 (Study Day 164) - 16 Feb 2021 (Study Day 168)	Worsening Of Lt Knee Osteoarthritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tramadol	12 Feb 2021 (Study Day 164) - 19 Feb 2021 (Study Day 171)	Worsening Of Lt Knee Osteoarthritis
Lidocaine	14 Feb 2021 (Study Day 166) - 14 Feb 2021 (Study Day 166)	Worsening Of Neck Pain
Macrogol 3350	14 Feb 2021 (Study Day 166) - Ongoing	Constipation
Sennoside a+b	14 Feb 2021 (Study Day 166) - 15 Feb 2021 (Study Day 167)	Constipation
Physical therapy*	24 Feb 2021 (Study Day 176) - 24 Feb 2021 (Study Day 176)	Other, Follow-Up From Con-Procedure Of Right Hip Arthroplasty

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Orthostatic Hypotension	Grade 1/mild	Not related	12 Oct 2020 (Study Day 41) - 13 Oct 2020 (Study Day 42)
Osteoarthritis	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 43)
COVID-19	Grade 3/severe	Not related	20 Nov 2020 (Study Day 80) - 06 Dec 2020 (Study Day 96)
Constipation	Grade 2/moderate	Not related	14 Feb 2021 (Study Day 166) - Ongoing
Neck Pain	Grade 2/moderate	Not related	14 Feb 2021 (Study Day 166) - 18 Feb 2021 (Study Day 170)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2083 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE, COVID-19	Grade 4	Not related	14 Nov 2020 (Study Day 66) – 11 Jan 2021 (Study Day 124)	Recovered/ resolved
COVID-19 Pneumonia/Pneumonia Due To COVID 19 Positive	SAE	Grade 3/ severe	Not related	14 Nov 2020 (Study Day 66) – 09 Dec 2020 (Study Day 91)	Recovered/ resolved
Renal Impairment/ Decrease In Kidney Function In Relation To COVID-19	SAE	Grade 3/ severe	Not related	18 Nov 2020 (Study Day 70) – 20 Nov 2020 (Study Day 72)	Recovered/ resolved
Coronary Artery Disease/Worsening Coronary Artery Disease	SAE	Grade 3/ severe	Not related	15 Feb 2021 (Study Day 159) – 11 Mar 2021 (Study Day 183)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US393-2083, a 66-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Feb 2021 (Study Day 159), 158 days after the first dose and 130 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of coronary artery disease. Action taken with the IP was not applicable. The event of worsening coronary artery disease lasted for 25 days, after which it was considered to be recovered/resolved with sequelae on 11 Mar 2021 (Study Day 183). The investigator assessed the event of coronary artery disease to be not related to the IP.

Severe COVID-19 Details

On 14 Nov 2020 (Study Day 66), 65 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of COVID-19.

On 14 Nov 2020 (Study Day 66), 65 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of pneumonia due to COVID 19 positive.

On 18 Nov 2020 (Study Day 70), 69 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of decrease in kidney function in relation to COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 08 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 14 Dec 2020 (Study Day 96), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
03 Jan 2020 (Study Day -251)	Difficulty Breathing	Mild
03 Jan 2020 (Study Day -251)	O2 Saturation (%)	93
03 Jan 2020 (Study Day -251)	Shortness of Breath	Mild
18 Nov 2020 (Study Day 70)	Body Aches	Mild
18 Nov 2020 (Study Day 70)	Chills	Mild
18 Nov 2020 (Study Day 70)	Cough	Severe
18 Nov 2020 (Study Day 70)	Difficulty Breathing	Severe
18 Nov 2020 (Study Day 70)	Fatigue	Moderate
18 Nov 2020 (Study Day 70)	Muscle Aches (Myalgia)	Mild
18 Nov 2020 (Study Day 70)	Nasal Congestion	Moderate
18 Nov 2020 (Study Day 70)	New Loss of Smell	Moderate
18 Nov 2020 (Study Day 70)	New Loss of Taste	Moderate
18 Nov 2020 (Study Day 70)	Shortness of Breath	Severe
19 Nov 2020 (Study Day 71)	Body Aches	Mild
19 Nov 2020 (Study Day 71)	Cough	Severe
19 Nov 2020 (Study Day 71)	Difficulty Breathing	Severe
19 Nov 2020 (Study Day 71)	Fatigue	Severe
19 Nov 2020 (Study Day 71)	Muscle Aches (Myalgia)	Mild
19 Nov 2020 (Study Day 71)	New Loss of Smell	Severe
19 Nov 2020 (Study Day 71)	New Loss of Taste	Severe
19 Nov 2020 (Study Day 71)	O2 Saturation (%)	91
19 Nov 2020 (Study Day 71)	Shortness of Breath	Severe

Symptom Date	Symptom	Result
20 Nov 2020 (Study Day 72)	Body Aches	Mild
20 Nov 2020 (Study Day 72)	Cough	Moderate
20 Nov 2020 (Study Day 72)	Difficulty Breathing	Severe
20 Nov 2020 (Study Day 72)	Fatigue	Severe
20 Nov 2020 (Study Day 72)	Muscle Aches (Myalgia)	Mild
20 Nov 2020 (Study Day 72)	New Loss of Smell	Severe
20 Nov 2020 (Study Day 72)	New Loss of Taste	Severe
20 Nov 2020 (Study Day 72)	O2 Saturation (%)	89
20 Nov 2020 (Study Day 72)	Shortness of Breath	Severe
22 Nov 2020 (Study Day 74)	Body Aches	Moderate
22 Nov 2020 (Study Day 74)	Cough	Moderate
22 Nov 2020 (Study Day 74)	Difficulty Breathing	Severe
22 Nov 2020 (Study Day 74)	Fatigue	Severe
22 Nov 2020 (Study Day 74)	Muscle Aches (Myalgia)	Moderate
22 Nov 2020 (Study Day 74)	New Loss of Smell	Severe
22 Nov 2020 (Study Day 74)	New Loss of Taste	Severe
22 Nov 2020 (Study Day 74)	O2 Saturation (%)	83
22 Nov 2020 (Study Day 74)	Shortness of Breath	Severe
29 Nov 2020 (Study Day 81)	Body Aches	Severe
29 Nov 2020 (Study Day 81)	Chills	Severe
29 Nov 2020 (Study Day 81)	Cough	Severe
29 Nov 2020 (Study Day 81)	Difficulty Breathing	Severe
29 Nov 2020 (Study Day 81)	Fatigue	Severe
29 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Severe
29 Nov 2020 (Study Day 81)	New Loss of Smell	Severe
29 Nov 2020 (Study Day 81)	New Loss of Taste	Severe
29 Nov 2020 (Study Day 81)	O2 Saturation (%)	90
29 Nov 2020 (Study Day 81)	Shortness of Breath	Severe
30 Nov 2020 (Study Day 82)	Body Aches	Severe
30 Nov 2020 (Study Day 82)	Chills	Severe
30 Nov 2020 (Study Day 82)	Cough	Severe
30 Nov 2020 (Study Day 82)	Difficulty Breathing	Severe
30 Nov 2020 (Study Day 82)	Fatigue	Severe
30 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Severe
30 Nov 2020 (Study Day 82)	New Loss of Smell	Severe
30 Nov 2020 (Study Day 82)	New Loss of Taste	Severe
30 Nov 2020 (Study Day 82)	Shortness of Breath	Severe
01 Dec 2020 (Study Day 83)	Body Aches	Severe
01 Dec 2020 (Study Day 83)	Chills	Severe
01 Dec 2020 (Study Day 83)	Cough	Severe
01 Dec 2020 (Study Day 83)	Difficulty Breathing	Severe
01 Dec 2020 (Study Day 83)	Fatigue	Severe
01 Dec 2020 (Study Day 83)	Muscle Aches (Myalgia)	Severe

Symptom Date	Symptom	Result
01 Dec 2020 (Study Day 83)	New Loss of Smell	Severe
01 Dec 2020 (Study Day 83)	New Loss of Taste	Severe
01 Dec 2020 (Study Day 83)	Shortness of Breath	Severe
02 Dec 2020 (Study Day 84)	Body Aches	Severe
02 Dec 2020 (Study Day 84)	Cough	Severe
02 Dec 2020 (Study Day 84)	Difficulty Breathing	Severe
02 Dec 2020 (Study Day 84)	Fatigue	Severe
02 Dec 2020 (Study Day 84)	Muscle Aches (Myalgia)	Severe
02 Dec 2020 (Study Day 84)	New Loss of Smell	Severe
02 Dec 2020 (Study Day 84)	New Loss of Taste	Severe
02 Dec 2020 (Study Day 84)	O2 Saturation (%)	93
02 Dec 2020 (Study Day 84)	Shortness of Breath	Severe
06 Dec 2020 (Study Day 88)	Difficulty Breathing	Mild
06 Dec 2020 (Study Day 88)	Fatigue	Moderate
06 Dec 2020 (Study Day 88)	Shortness of Breath	Mild
07 Dec 2020 (Study Day 89)	Difficulty Breathing	Mild
07 Dec 2020 (Study Day 89)	Fatigue	Moderate
07 Dec 2020 (Study Day 89)	New Loss of Smell	Severe
07 Dec 2020 (Study Day 89)	New Loss of Taste	Severe
07 Dec 2020 (Study Day 89)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 90)	Difficulty Breathing	Mild
08 Dec 2020 (Study Day 90)	Fatigue	Moderate
08 Dec 2020 (Study Day 90)	New Loss of Smell	Moderate
08 Dec 2020 (Study Day 90)	New Loss of Taste	Moderate
08 Dec 2020 (Study Day 90)	Shortness of Breath	Mild
10 Dec 2020 (Study Day 92)	Difficulty Breathing	Mild
10 Dec 2020 (Study Day 92)	Fatigue	Moderate
10 Dec 2020 (Study Day 92)	O2 Saturation (%)	92
10 Dec 2020 (Study Day 92)	Shortness of Breath	Mild
12 Dec 2020 (Study Day 94)	Difficulty Breathing	Mild
12 Dec 2020 (Study Day 94)	Fatigue	Mild
12 Dec 2020 (Study Day 94)	New Loss of Smell	Severe
12 Dec 2020 (Study Day 94)	New Loss of Taste	Severe
12 Dec 2020 (Study Day 94)	O2 Saturation (%)	93
12 Dec 2020 (Study Day 94)	Shortness of Breath	Mild
13 Dec 2020 (Study Day 95)	Difficulty Breathing	Mild
13 Dec 2020 (Study Day 95)	Fatigue	Mild
13 Dec 2020 (Study Day 95)	New Loss of Smell	Severe
13 Dec 2020 (Study Day 95)	New Loss of Taste	Severe
13 Dec 2020 (Study Day 95)	O2 Saturation (%)	93
13 Dec 2020 (Study Day 95)	Shortness of Breath	Mild
14 Dec 2020 (Study Day 96)	Difficulty Breathing	Mild
14 Dec 2020 (Study Day 96)	Fatigue	Moderate

Symptom Date	Symptom	Result
14 Dec 2020 (Study Day 96)	Shortness of Breath	Mild
15 Dec 2020 (Study Day 97)	Difficulty Breathing	Mild
15 Dec 2020 (Study Day 97)	Fatigue	Mild
15 Dec 2020 (Study Day 97)	O2 Saturation (%)	92
15 Dec 2020 (Study Day 97)	Shortness of Breath	Mild
16 Dec 2020 (Study Day 98)	Difficulty Breathing	Mild
16 Dec 2020 (Study Day 98)	Fatigue	Moderate
16 Dec 2020 (Study Day 98)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 101)	Difficulty Breathing	Moderate
19 Dec 2020 (Study Day 101)	Fatigue	Moderate
19 Dec 2020 (Study Day 101)	O2 Saturation (%)	92
19 Dec 2020 (Study Day 101)	Shortness of Breath	Moderate
20 Dec 2020 (Study Day 102)	Difficulty Breathing	Mild
20 Dec 2020 (Study Day 102)	Fatigue	Moderate
20 Dec 2020 (Study Day 102)	O2 Saturation (%)	92
20 Dec 2020 (Study Day 102)	Shortness of Breath	Mild
21 Dec 2020 (Study Day 103)	Difficulty Breathing	Mild
21 Dec 2020 (Study Day 103)	O2 Saturation (%)	92
21 Dec 2020 (Study Day 103)	Shortness of Breath	Mild
22 Dec 2020 (Study Day 104)	Difficulty Breathing	Mild
22 Dec 2020 (Study Day 104)	O2 Saturation (%)	93
22 Dec 2020 (Study Day 104)	Shortness of Breath	Mild
23 Dec 2020 (Study Day 105)	Difficulty Breathing	Mild
23 Dec 2020 (Study Day 105)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 107)	Difficulty Breathing	Mild
25 Dec 2020 (Study Day 107)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 109)	Difficulty Breathing	Mild
27 Dec 2020 (Study Day 109)	O2 Saturation (%)	93
27 Dec 2020 (Study Day 109)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 110)	Difficulty Breathing	Mild
28 Dec 2020 (Study Day 110)	O2 Saturation (%)	93
28 Dec 2020 (Study Day 110)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 112)	Difficulty Breathing	Mild
30 Dec 2020 (Study Day 112)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 114)	Difficulty Breathing	Mild
01 Jan 2021 (Study Day 114)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 118)	Difficulty Breathing	Mild
05 Jan 2021 (Study Day 118)	O2 Saturation (%)	93
05 Jan 2021 (Study Day 118)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 119)	Difficulty Breathing	Mild
06 Jan 2021 (Study Day 119)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 120)	Difficulty Breathing	Mild
07 Jan 2021 (Study Day 120)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
08 Jan 2021 (Study Day 121)	Difficulty Breathing	Mild
08 Jan 2021 (Study Day 121)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 122)	Difficulty Breathing	Mild
09 Jan 2021 (Study Day 122)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 123)	Difficulty Breathing	Mild
10 Jan 2021 (Study Day 123)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 124)	Difficulty Breathing	Mild
11 Jan 2021 (Study Day 124)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
16 Nov 2020 (Study Day 68)	Oxygen Saturation	83%
16 Nov 2020 (Study Day 68)	Respiratory Rate	33 breaths/min
16 Nov 2020 - 16 Nov 2020 (Study Day 68-68)	Clinical Evidence of Pneumonia	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 68-68)	High-Flow Oxygen	Yes
16 Nov 2020 - 06 Jan 2021 (Study Day 68-119)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 68-68)	Radiographical Evidence of Pneumonia	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 68-68)	Respiratory Rates ≥ 30 per Minute	Yes
21 Nov 2020 - 29 Nov 2020 (Study Day 73-81)	Admission to an intensive care unit due to SARS-CoV-2	Yes

The IP dose was not changed due to the covid-19. The event of COVID-19 lasted for 59 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 124). The investigator assessed the event of COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of pneumonia due to COVID 19 positive lasted for 26 days, after which it was considered to be recovered/resolved on 09 Dec 2020 (Study Day 91). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Action taken with the IP was not applicable. The event of decrease in kidney function in relation to COVID-19 lasted for 3 days, after which it was considered to be recovered/resolved on 20 Nov 2020 (Study Day 72). The investigator assessed the event of renal impairment to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000821	COVID-19
MOD-2020-000821	COVID-19 pneumonia
MOD-2020-000821	Renal impairment
MOD-2021-040201	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	1983 - Ongoing
Large intestine polyp	Colon polyps - benign	1983 - Ongoing
Benign lung neoplasm	Pulmonary nodules - benign	1990 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1990 - Ongoing
Emphysema	Emphysema	1990 - Ongoing
Fibromyalgia	Fibromyalgia	1990 - Ongoing
Prostatomegaly	Enlarged prostate	2005 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Retinal detachment	Bilateral detached retinas	2013 - Ongoing
Basal cell carcinoma	Basal cell skin cancer	2014 - 2014
Herpes virus infection	Herpes	2016 - Ongoing
Gallbladder polyp	Gallbladder polyps - benign	2018 - Ongoing
Hepatic enzyme increased	Liver enzyme elevation	Aug 2020 - Ongoing
Basal cell carcinoma	Basal cell skin cancer	16 Aug 2020 (Study Day -25) - Ongoing
Coronary artery disease	Coronary artery disease	04 Sep 2020 (Study Day -6) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1985 - Ongoing	Hypothyroidism
Amitriptyline	1990 - Ongoing	Fibromyalgia
Ascorbic acid	2000 - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Biotin; calcium pantothenate; cyanocobalamin; folic acid; nicotinamide; pyridoxine hydrochloride; riboflavin; thiamine mononitrate	2000 - Ongoing	Supplement
Fish oil	2000 - Ongoing	Supplement
Omeprazole	2010 - Ongoing	Gerd
Salbutamol	2015 - Ongoing	Copd
Valaciclovir hydrochloride	2016 - Ongoing	Herpes
Ipratropium bromide; salbutamol sulfate	2018 - Oct 2020	Copd
Umeclidinium; vilanterol	Oct 2020 - Ongoing	Copd
Diclofenac	07 Oct 2020 (Study Day 28) - 07 Oct 2020 (Study Day 28)	Fibromyalgia
Influenza vaccine	29 Oct 2020 (Study Day 50) - 29 Oct 2020 (Study Day 50)	Flu Prophylaxsis
Pneumococcal vaccine polysacch 23v	29 Oct 2020 (Study Day 50) - 29 Oct 2020 (Study Day 50)	Pneumonia Prophylaxsis
Ibuprofen	14 Nov 2020 (Study Day 66) - 16 Nov 2020 (Study Day 68)	COVID Related Pain
Paracetamol	14 Nov 2020 (Study Day 66) - 16 Nov 2020 (Study Day 68)	COVID Related Pain
Prednisone	15 Nov 2020 (Study Day 67) - 16 Nov 2020 (Study Day 68)	COVID Related Muscle Pain
Dexamethasone	16 Nov 2020 (Study Day 68) - 27 Nov 2020 (Study Day 79)	Antibiotics For COVID
Enoxaparin sodium	16 Nov 2020 (Study Day 68) - 18 Nov 2020 (Study Day 70)	Blood Thinner To Prevent Clots Caused By COVID
Plasma	17 Nov 2020 (Study Day 69) - 17 Nov 2020 (Study Day 69)	Treatment Of COVID
Remdesivir	17 Nov 2020 (Study Day 69) - 27 Nov 2020 (Study Day 79)	Anti-Viral For COVID
Heparin	18 Nov 2020 (Study Day 70) - 01 Dec 2020 (Study Day 83)	Prevention Of Blood Clots Due To COVID
Salbutamol	18 Nov 2020 (Study Day 70) - 27 Nov 2020 (Study Day 79)	Treatment Of COVID
Abdominal ultrasound*	19 Nov 2020 (Study Day 71) - 19 Nov 2020 (Study Day 71)	Adverse Event
Echo-cardiogram*	19 Nov 2020 (Study Day 71) - 19 Nov 2020 (Study Day 71)	Adverse Event
Furosemide	19 Nov 2020 (Study Day 71) - 21 Nov 2020 (Study Day 73)	Edema Of Lower Extremities
Ipratropium bromide	19 Nov 2020 (Study Day 71) - 21 Nov 2020 (Study Day 73)	Pneumonia Due To COVID
Levofloxacin	19 Nov 2020 (Study Day 71) - 28 Nov 2020 (Study Day 80)	Pneumonia Due To COVID
Acetylsalicylic acid	20 Nov 2020 (Study Day 72) - Ongoing	Prevention For Heart Conditions
Atovaquone	21 Nov 2020 (Study Day 73) - 26 Dec 2020 (Study Day 108)	Pneumonia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Methylprednisolone	27 Nov 2020 (Study Day 79) - 09 Dec 2020 (Study Day 91)	Treatment Of COVID
Clotrimazole	28 Nov 2020 (Study Day 80) - 09 Dec 2020 (Study Day 91)	Thrush
Enoxaparin sodium	01 Dec 2020 (Study Day 83) - 09 Dec 2020 (Study Day 91)	Blood Thinner For The Treatment Of COVID
Prednisone	01 Dec 2020 (Study Day 83) - 09 Dec 2020 (Study Day 91)	Thrush
Oxygen	05 Dec 2020 (Study Day 87) - Ongoing	Copd
Clotrimazole	09 Dec 2020 (Study Day 91) - 30 Dec 2020 (Study Day 112)	Thrush
Prednisone	09 Dec 2020 (Study Day 91) - 02 Jan 2021 (Study Day 115)	Pneumonia
Apixaban	10 Dec 2020 (Study Day 92) - 26 Dec 2020 (Study Day 108)	Blood Clot Prevention
Prednisone	03 Jan 2021 (Study Day 116) - 08 Jan 2021 (Study Day 121)	Pneumonia
Occupational therapy*	05 Jan 2021 (Study Day 118) - 05 Jan 2021 (Study Day 118)	Adverse Event
Physical therapy*	05 Jan 2021 (Study Day 118) - 05 Jan 2021 (Study Day 118)	Other, Lung Inflammation
Prednisone	15 Jan 2021 (Study Day 128) - 21 Jan 2021 (Study Day 134)	Pneumonia
Prednisone	22 Jan 2021 (Study Day 135) - 28 Feb 2021 (Study Day 172)	Pneumonia
Angiogram*	15 Feb 2021 (Study Day 159) - 15 Feb 2021 (Study Day 159)	Adverse Event
Carvedilol	15 Feb 2021 (Study Day 159) - 04 Mar 2021 (Study Day 176)	Coronary Artery Disease
Echocardiogram*	15 Feb 2021 (Study Day 159) - 15 Feb 2021 (Study Day 159)	Adverse Event
Prednisone	28 Feb 2021 (Study Day 172) - Ongoing	Lung Inflammation
Carvedilol	05 Mar 2021 (Study Day 177) - Ongoing	Coronary Artery Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Not related	11 Sep 2020 (Study Day 2) - 18 Sep 2020 (Study Day 9)
Arthralgia	Grade 1/mild	Not related	12 Oct 2020 (Study Day 33) - 19 Oct 2020 (Study Day 40)
Fatigue	Grade 1/mild	Not related	12 Oct 2020 (Study Day 33) - 19 Oct 2020 (Study Day 40)
Myalgia	Grade 1/mild	Not related	12 Oct 2020 (Study Day 33) - 19 Oct 2020 (Study Day 40)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oedema Peripheral	Grade 2/moderate	Not related	19 Nov 2020 (Study Day 71) - 21 Nov 2020 (Study Day 73)
Oral Candidiasis	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 83) - 19 Jan 2021 (Study Day 132)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2118 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 26)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	01 Jan 2021 (Study Day 112) – 01 Mar 2021 (Study Day 171)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US393-2118, a 49-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 12 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 01 Jan 2021 (Study Day 112), 111 days after the first dose and 86 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 26, 07 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 05 Jan 2021 (Study Day 116), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
01 Jan 2021 (Study Day 112)	Cough	Mild
01 Jan 2021 (Study Day 112)	Fatigue	Mild
01 Jan 2021 (Study Day 112)	Runny Nose (Rhinorrhea)	Mild
02 Jan 2021 (Study Day 113)	Cough	Mild
02 Jan 2021 (Study Day 113)	Fatigue	Mild

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
03 Jan 2021 (Study Day 114)	Cough	Mild
03 Jan 2021 (Study Day 114)	Fatigue	Mild
03 Jan 2021 (Study Day 114)	Runny Nose (Rhinorrhea)	Mild
05 Jan 2021 (Study Day 116)	Cough	Mild
05 Jan 2021 (Study Day 116)	Fatigue	Mild
05 Jan 2021 (Study Day 116)	Runny Nose (Rhinorrhea)	Mild
06 Jan 2021 (Study Day 117)	Cough	Mild
06 Jan 2021 (Study Day 117)	Fatigue	Moderate
06 Jan 2021 (Study Day 117)	Headache	Mild
06 Jan 2021 (Study Day 117)	Runny Nose (Rhinorrhea)	Mild
07 Jan 2021 (Study Day 118)	Cough	Mild
07 Jan 2021 (Study Day 118)	Runny Nose (Rhinorrhea)	Mild
07 Jan 2021 (Study Day 118)	Temperature (°F)	101.0
08 Jan 2021 (Study Day 119)	Cough	Mild
09 Jan 2021 (Study Day 120)	Chills	Moderate
09 Jan 2021 (Study Day 120)	Cough	Mild
09 Jan 2021 (Study Day 120)	Fatigue	Mild
09 Jan 2021 (Study Day 120)	Nasal Congestion	Mild
09 Jan 2021 (Study Day 120)	New Loss of Smell	Moderate
09 Jan 2021 (Study Day 120)	New Loss of Taste	Moderate
09 Jan 2021 (Study Day 120)	Temperature (°F)	100.9
10 Jan 2021 (Study Day 121)	Cough	Moderate
10 Jan 2021 (Study Day 121)	Fatigue	Moderate
10 Jan 2021 (Study Day 121)	Nasal Congestion	Mild
10 Jan 2021 (Study Day 121)	Nausea	Mild
10 Jan 2021 (Study Day 121)	New Loss of Smell	Moderate
10 Jan 2021 (Study Day 121)	New Loss of Taste	Moderate
10 Jan 2021 (Study Day 121)	Vomiting	Moderate
11 Jan 2021 (Study Day 122)	Cough	Moderate
11 Jan 2021 (Study Day 122)	Fatigue	Severe
11 Jan 2021 (Study Day 122)	Nasal Congestion	Mild
11 Jan 2021 (Study Day 122)	New Loss of Smell	Severe
11 Jan 2021 (Study Day 122)	New Loss of Taste	Severe
11 Jan 2021 (Study Day 122)	Vomiting	Moderate
13 Jan 2021 (Study Day 124)	Cough	Severe
13 Jan 2021 (Study Day 124)	Fatigue	Severe
13 Jan 2021 (Study Day 124)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 124)	New Loss of Smell	Severe
13 Jan 2021 (Study Day 124)	New Loss of Taste	Severe
13 Jan 2021 (Study Day 124)	Vomiting	Severe
14 Jan 2021 (Study Day 125)	Cough	Severe
14 Jan 2021 (Study Day 125)	Fatigue	Severe

Symptom Date	Symptom	Result
14 Jan 2021 (Study Day 125)	Nasal Congestion	Mild
14 Jan 2021 (Study Day 125)	New Loss of Smell	Severe
14 Jan 2021 (Study Day 125)	New Loss of Taste	Severe
14 Jan 2021 (Study Day 125)	Vomiting	Moderate
16 Jan 2021 (Study Day 127)	Cough	Moderate
16 Jan 2021 (Study Day 127)	Fatigue	Severe
16 Jan 2021 (Study Day 127)	New Loss of Smell	Severe
16 Jan 2021 (Study Day 127)	New Loss of Taste	Severe
16 Jan 2021 (Study Day 127)	O2 Saturation (%)	93
16 Jan 2021 (Study Day 127)	Vomiting	Mild
17 Jan 2021 (Study Day 128)	Cough	Severe
17 Jan 2021 (Study Day 128)	Fatigue	Severe
17 Jan 2021 (Study Day 128)	New Loss of Smell	Severe
17 Jan 2021 (Study Day 128)	New Loss of Taste	Severe
17 Jan 2021 (Study Day 128)	O2 Saturation (%)	91
17 Jan 2021 (Study Day 128)	Vomiting	Moderate
18 Jan 2021 (Study Day 129)	Cough	Severe
18 Jan 2021 (Study Day 129)	Fatigue	Severe
18 Jan 2021 (Study Day 129)	New Loss of Smell	Severe
18 Jan 2021 (Study Day 129)	New Loss of Taste	Severe
18 Jan 2021 (Study Day 129)	Vomiting	Moderate
19 Jan 2021 (Study Day 130)	Cough	Severe
19 Jan 2021 (Study Day 130)	Fatigue	Moderate
19 Jan 2021 (Study Day 130)	New Loss of Smell	Moderate
19 Jan 2021 (Study Day 130)	New Loss of Taste	Moderate
19 Jan 2021 (Study Day 130)	O2 Saturation (%)	92
21 Jan 2021 (Study Day 132)	Cough	Severe
21 Jan 2021 (Study Day 132)	Fatigue	Moderate
21 Jan 2021 (Study Day 132)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 132)	New Loss of Taste	Mild
21 Jan 2021 (Study Day 132)	Vomiting	Moderate
22 Jan 2021 (Study Day 133)	Cough	Moderate
22 Jan 2021 (Study Day 133)	Fatigue	Mild
22 Jan 2021 (Study Day 133)	Nasal Congestion	Moderate
22 Jan 2021 (Study Day 133)	New Loss of Smell	Mild
22 Jan 2021 (Study Day 133)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 133)	O2 Saturation (%)	92
22 Jan 2021 (Study Day 133)	Vomiting	Moderate
24 Jan 2021 (Study Day 135)	Cough	Moderate
24 Jan 2021 (Study Day 135)	Fatigue	Moderate
24 Jan 2021 (Study Day 135)	New Loss of Smell	Mild
24 Jan 2021 (Study Day 135)	New Loss of Taste	Mild
24 Jan 2021 (Study Day 135)	Vomiting	Moderate

Symptom Date	Symptom	Result
25 Jan 2021 (Study Day 136)	Cough	Moderate
25 Jan 2021 (Study Day 136)	Fatigue	Moderate
25 Jan 2021 (Study Day 136)	O2 Saturation (%)	93
25 Jan 2021 (Study Day 136)	Vomiting	Mild
26 Jan 2021 (Study Day 137)	Cough	Moderate
26 Jan 2021 (Study Day 137)	Fatigue	Mild
26 Jan 2021 (Study Day 137)	O2 Saturation (%)	93
26 Jan 2021 (Study Day 137)	Vomiting	Mild
27 Jan 2021 (Study Day 138)	Cough	Moderate
27 Jan 2021 (Study Day 138)	Fatigue	Moderate
27 Jan 2021 (Study Day 138)	Vomiting	Mild
29 Jan 2021 (Study Day 140)	Cough	Severe
29 Jan 2021 (Study Day 140)	Diarrhea	Mild
29 Jan 2021 (Study Day 140)	Fatigue	Mild
29 Jan 2021 (Study Day 140)	Vomiting	Mild
30 Jan 2021 (Study Day 141)	Cough	Moderate
30 Jan 2021 (Study Day 141)	Nasal Congestion	Moderate
30 Jan 2021 (Study Day 141)	O2 Saturation (%)	93
30 Jan 2021 (Study Day 141)	Vomiting	Mild
31 Jan 2021 (Study Day 142)	Cough	Moderate
31 Jan 2021 (Study Day 142)	Nasal Congestion	Moderate
31 Jan 2021 (Study Day 142)	Vomiting	Mild
01 Feb 2021 (Study Day 143)	Cough	Moderate
01 Feb 2021 (Study Day 143)	Fatigue	Moderate
01 Feb 2021 (Study Day 143)	Nasal Congestion	Moderate
01 Feb 2021 (Study Day 143)	Vomiting	Mild
03 Feb 2021 (Study Day 145)	Cough	Moderate
03 Feb 2021 (Study Day 145)	Fatigue	Severe
03 Feb 2021 (Study Day 145)	Nasal Congestion	Moderate
03 Feb 2021 (Study Day 145)	Vomiting	Mild
04 Feb 2021 (Study Day 146)	Cough	Moderate
04 Feb 2021 (Study Day 146)	Fatigue	Moderate
04 Feb 2021 (Study Day 146)	Nasal Congestion	Mild
04 Feb 2021 (Study Day 146)	Shortness of Breath	Moderate
04 Feb 2021 (Study Day 146)	Vomiting	Mild
05 Feb 2021 (Study Day 147)	Cough	Moderate
05 Feb 2021 (Study Day 147)	Fatigue	Moderate
05 Feb 2021 (Study Day 147)	Nasal Congestion	Mild
05 Feb 2021 (Study Day 147)	O2 Saturation (%)	93
05 Feb 2021 (Study Day 147)	Shortness of Breath	Moderate
05 Feb 2021 (Study Day 147)	Vomiting	Mild
06 Feb 2021 (Study Day 148)	Cough	Moderate
06 Feb 2021 (Study Day 148)	Fatigue	Moderate

Symptom Date	Symptom	Result
06 Feb 2021 (Study Day 148)	Nasal Congestion	Moderate
06 Feb 2021 (Study Day 148)	Shortness of Breath	Moderate
06 Feb 2021 (Study Day 148)	Vomiting	Mild
07 Feb 2021 (Study Day 149)	Cough	Moderate
07 Feb 2021 (Study Day 149)	Fatigue	Moderate
07 Feb 2021 (Study Day 149)	Runny Nose (Rhinorrhea)	Mild
07 Feb 2021 (Study Day 149)	Shortness of Breath	Moderate
07 Feb 2021 (Study Day 149)	Vomiting	Mild
08 Feb 2021 (Study Day 150)	Cough	Moderate
08 Feb 2021 (Study Day 150)	Fatigue	Mild
08 Feb 2021 (Study Day 150)	Nasal Congestion	Mild
08 Feb 2021 (Study Day 150)	Runny Nose (Rhinorrhea)	Mild
08 Feb 2021 (Study Day 150)	Vomiting	Mild
09 Feb 2021 (Study Day 151)	Cough	Mild
09 Feb 2021 (Study Day 151)	Fatigue	Moderate
09 Feb 2021 (Study Day 151)	Nasal Congestion	Moderate
09 Feb 2021 (Study Day 151)	Runny Nose (Rhinorrhea)	Moderate
09 Feb 2021 (Study Day 151)	Vomiting	Mild
10 Feb 2021 (Study Day 152)	Cough	Mild
10 Feb 2021 (Study Day 152)	Fatigue	Mild
10 Feb 2021 (Study Day 152)	Nasal Congestion	Moderate
10 Feb 2021 (Study Day 152)	Runny Nose (Rhinorrhea)	Moderate
10 Feb 2021 (Study Day 152)	Shortness of Breath	Moderate
10 Feb 2021 (Study Day 152)	Vomiting	Mild
11 Feb 2021 (Study Day 153)	Cough	Mild
11 Feb 2021 (Study Day 153)	Fatigue	Mild
11 Feb 2021 (Study Day 153)	Nasal Congestion	Mild
11 Feb 2021 (Study Day 153)	Runny Nose (Rhinorrhea)	Mild
11 Feb 2021 (Study Day 153)	Shortness of Breath	Moderate
11 Feb 2021 (Study Day 153)	Vomiting	Mild
12 Feb 2021 (Study Day 154)	Cough	Moderate
12 Feb 2021 (Study Day 154)	Fatigue	Mild
12 Feb 2021 (Study Day 154)	Nasal Congestion	Mild
12 Feb 2021 (Study Day 154)	Runny Nose (Rhinorrhea)	Mild
12 Feb 2021 (Study Day 154)	Shortness of Breath	Moderate
12 Feb 2021 (Study Day 154)	Vomiting	Mild
13 Feb 2021 (Study Day 155)	Cough	Moderate
13 Feb 2021 (Study Day 155)	Headache	Moderate
13 Feb 2021 (Study Day 155)	Nasal Congestion	Mild
13 Feb 2021 (Study Day 155)	Shortness of Breath	Mild
13 Feb 2021 (Study Day 155)	Vomiting	Mild
14 Feb 2021 (Study Day 156)	Cough	Moderate
14 Feb 2021 (Study Day 156)	Fatigue	Moderate

Symptom Date	Symptom	Result
14 Feb 2021 (Study Day 156)	Nasal Congestion	Moderate
14 Feb 2021 (Study Day 156)	Runny Nose (Rhinorrhea)	Moderate
14 Feb 2021 (Study Day 156)	Shortness of Breath	Moderate
14 Feb 2021 (Study Day 156)	Vomiting	Mild
15 Feb 2021 (Study Day 157)	Cough	Moderate
15 Feb 2021 (Study Day 157)	Fatigue	Moderate
15 Feb 2021 (Study Day 157)	Nasal Congestion	Mild
15 Feb 2021 (Study Day 157)	Runny Nose (Rhinorrhea)	Mild
15 Feb 2021 (Study Day 157)	Shortness of Breath	Mild
15 Feb 2021 (Study Day 157)	Vomiting	Mild
16 Feb 2021 (Study Day 158)	Cough	Moderate
16 Feb 2021 (Study Day 158)	Fatigue	Severe
16 Feb 2021 (Study Day 158)	Nasal Congestion	Mild
16 Feb 2021 (Study Day 158)	Runny Nose (Rhinorrhea)	Mild
16 Feb 2021 (Study Day 158)	Shortness of Breath	Severe
16 Feb 2021 (Study Day 158)	Vomiting	Moderate
17 Feb 2021 (Study Day 159)	Cough	Moderate
17 Feb 2021 (Study Day 159)	Fatigue	Mild
17 Feb 2021 (Study Day 159)	Nasal Congestion	Mild
17 Feb 2021 (Study Day 159)	Runny Nose (Rhinorrhea)	Mild
17 Feb 2021 (Study Day 159)	Shortness of Breath	Moderate
17 Feb 2021 (Study Day 159)	Vomiting	Mild
18 Feb 2021 (Study Day 160)	Cough	Mild
18 Feb 2021 (Study Day 160)	Fatigue	Mild
18 Feb 2021 (Study Day 160)	Nasal Congestion	Mild
18 Feb 2021 (Study Day 160)	Runny Nose (Rhinorrhea)	Mild
18 Feb 2021 (Study Day 160)	Shortness of Breath	Moderate
18 Feb 2021 (Study Day 160)	Vomiting	Mild
19 Feb 2021 (Study Day 161)	Cough	Mild
19 Feb 2021 (Study Day 161)	Fatigue	Mild
19 Feb 2021 (Study Day 161)	Nasal Congestion	Mild
19 Feb 2021 (Study Day 161)	Shortness of Breath	Moderate
19 Feb 2021 (Study Day 161)	Vomiting	Mild
20 Feb 2021 (Study Day 162)	Cough	Mild
20 Feb 2021 (Study Day 162)	Fatigue	Mild
20 Feb 2021 (Study Day 162)	Nasal Congestion	Mild
20 Feb 2021 (Study Day 162)	Runny Nose (Rhinorrhea)	Mild
20 Feb 2021 (Study Day 162)	Shortness of Breath	Mild
20 Feb 2021 (Study Day 162)	Vomiting	Mild
21 Feb 2021 (Study Day 163)	Cough	Mild
21 Feb 2021 (Study Day 163)	Fatigue	Mild
21 Feb 2021 (Study Day 163)	Nasal Congestion	Mild
21 Feb 2021 (Study Day 163)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
22 Feb 2021 (Study Day 164)	Cough	Mild
22 Feb 2021 (Study Day 164)	Fatigue	Mild
22 Feb 2021 (Study Day 164)	Headache	Severe
22 Feb 2021 (Study Day 164)	Nasal Congestion	Mild
22 Feb 2021 (Study Day 164)	Runny Nose (Rhinorrhea)	Mild
23 Feb 2021 (Study Day 165)	Cough	Mild
23 Feb 2021 (Study Day 165)	Fatigue	Mild
23 Feb 2021 (Study Day 165)	Nasal Congestion	Mild
23 Feb 2021 (Study Day 165)	Runny Nose (Rhinorrhea)	Mild
24 Feb 2021 (Study Day 166)	Cough	Mild
24 Feb 2021 (Study Day 166)	Nasal Congestion	Mild
24 Feb 2021 (Study Day 166)	Runny Nose (Rhinorrhea)	Mild
25 Feb 2021 (Study Day 167)	Cough	Mild
25 Feb 2021 (Study Day 167)	Nasal Congestion	Mild
25 Feb 2021 (Study Day 167)	Runny Nose (Rhinorrhea)	Moderate
26 Feb 2021 (Study Day 168)	Cough	Mild
26 Feb 2021 (Study Day 168)	Nasal Congestion	Mild
26 Feb 2021 (Study Day 168)	Runny Nose (Rhinorrhea)	Mild
27 Feb 2021 (Study Day 169)	Cough	Mild
27 Feb 2021 (Study Day 169)	Nasal Congestion	Mild
28 Feb 2021 (Study Day 170)	Cough	Mild
28 Feb 2021 (Study Day 170)	Nasal Congestion	Mild
21 Apr 2021 (Study Day 222)	Diarrhea	Moderate
21 Apr 2021 (Study Day 222)	Temperature (°F)	101
22 Apr 2021 (Study Day 223)	Diarrhea	Moderate
23 Apr 2021 (Study Day 224)	Diarrhea	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
16 Jan 2021 (Study Day 127)	Oxygen Saturation	91%
16 Jan 2021 - 31 Jan 2021 (Study Day 127-142)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 60 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 171). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005706	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	1990 - Ongoing
Migraine	Migraines	1990 - 2017
Depression	Depression	1992 - 2004
Female sterilisation	Bilateral tubal ligation	2005 - 2005
Obesity	Obesity	2010 - Ongoing
Fibromyalgia	Fibromyalgia	2013 - Ongoing
Systemic lupus erythematosus	Systemic lupus erythematosus	2013 - Ongoing
Hypothyroidism	Hypothyroidsm	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2010 - Ongoing	Supplement
Colecalciferol	2010 - Ongoing	Supplement
Acetylsalicylic acid	2014 - Ongoing	Headaches
Vitamin b12 nos	2014 - Ongoing	Supplement
Borago officinalis oil; fish oil; linum usitatissimum oil	2015 - Ongoing	Supplement
Potassium	2015 - Ongoing	Supplement
Botulinum toxin type a	2017 - 2017	Migraines
Hyaluronic acid	2019 - 2019	Anti-Aging Lips
Magnesium	Mar 2020 - Ongoing	Supplement
Zinc	Mar 2020 - Ongoing	Supplement
Phentermine	Jul 2020 - 01 Sep 2020 (Study Day -11)	Obesity
Ibuprofen	Aug 2020 - Ongoing	Headaches
Levothyroxine	Aug 2020 - Ongoing	Hypothyroism

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	07 Oct 2020 (Study Day 26) - 07 Oct 2020 (Study Day 26)	Injection Site Pain
Influenza vaccine	21 Nov 2020 (Study Day 71) - 21 Nov 2020 (Study Day 71)	Flu Prophylaxsis
Anilides	07 Jan 2021 (Study Day 118) - 07 Jan 2021 (Study Day 118)	COVID-19
Paracetamol	07 Jan 2021 (Study Day 118) - 07 Jan 2021 (Study Day 118)	COVID-19 Diagnosis
Paracetamol	09 Jan 2021 (Study Day 120) - 07 Feb 2021 (Study Day 149)	COVID-19
Ibuprofen	11 Jan 2021 (Study Day 122) - 01 Feb 2021 (Study Day 143)	Low Back Pain
Benzonatate	12 Jan 2021 (Study Day 123) - 28 Jan 2021 (Study Day 139)	COVID-19
Salbutamol	12 Jan 2021 (Study Day 123) - 01 Mar 2021 (Study Day 171)	COVID-19
Promethazine	18 Jan 2021 (Study Day 129) - 19 Jan 2021 (Study Day 130)	COVID-19
Dextromethorphan hydrobromide; paracetamol	28 Jan 2021 (Study Day 139) - 27 Feb 2021 (Study Day 169)	COVID- 19 Cough
Amitriptyline	30 Jan 2021 (Study Day 141) - 05 Mar 2021 (Study Day 175)	Panic Attacks
Prednisone	30 Jan 2021 (Study Day 141) - 03 Feb 2021 (Study Day 145)	COVID-19 Diagnosis
Promethazine	30 Jan 2021 (Study Day 141) - 12 Feb 2021 (Study Day 154)	COVID-19 Cough
Mometasone furoate	01 Feb 2021 (Study Day 143) - 01 Mar 2021 (Study Day 171)	COVID -19 Cough
Guaifenesin	11 Feb 2021 (Study Day 153) - 12 Feb 2021 (Study Day 154)	COVID - 19 Cough
Paracetamol	13 Feb 2021 (Study Day 155) - 14 Feb 2021 (Study Day 156)	Headache
Benzonatate	17 Feb 2021 (Study Day 159) - 27 Feb 2021 (Study Day 169)	COVID-19 Cough
Ibuprofen	26 Feb 2021 (Study Day 168) - 26 Feb 2021 (Study Day 168)	Right Ankle Sprain
Paracetamol	26 Feb 2021 (Study Day 168) - 26 Feb 2021 (Study Day 168)	Right Ankle Sprain
Zolpidem	12 Mar 2021 (Study Day 182) - 13 Mar 2021 (Study Day 183)	Panick Attacks
Buspirone	15 Mar 2021 (Study Day 185) - Ongoing	Panic Attacks

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspnoea	Grade 1/mild	Not related	17 Oct 2020 (Study Day 36) - 20 Oct 2020 (Study Day 39)
Headache	Grade 1/mild	Not related	17 Oct 2020 (Study Day 36) - 20 Oct 2020 (Study Day 39)
Myalgia	Grade 1/mild	Not related	17 Oct 2020 (Study Day 36) - 20 Oct 2020 (Study Day 39)
COVID-19	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 112) - 01 Mar 2021 (Study Day 171)
Back Pain	Grade 2/moderate	Not related	09 Jan 2021 (Study Day 120) - 01 Feb 2021 (Study Day 143)
Panic Attack	Grade 2/moderate	Not related	10 Jan 2021 (Study Day 121) - Ongoing
Dizziness	Grade 1/mild	Not related	17 Jan 2021 (Study Day 128) - 26 Jan 2021 (Study Day 137)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2286 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	18 Nov 2020 (Study Day 33)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	SAE, COVID-19	Grade 3/ severe	Not related	20 Nov 2020 (Study Day 35) – 07 Dec 2020 (Study Day 52)	Recovered/resolved
COVID-19 Pneumonia/ Pneumonia Caused By COVID 19	SAE	Grade 4	Not related	20 Nov 2020 (Study Day 35) – 07 Jan 2021 (Study Day 83)	Recovered/resolved
Acute Respiratory Failure/Acute Respiratory Failure	SAE	Grade 3/ severe	Not related	03 Dec 2020 (Study Day 48) – 05 Dec 2020 (Study Day 50)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US393-2286, a 52-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Dec 2020 (Study Day 48), 47 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute respiratory failure lasted for 3 days, after which it was considered to be recovered/resolved on 05 Dec 2020 (Study Day 50). The investigator assessed the event of acute respiratory failure to be not related to the IP.

Severe COVID-19 Details

On 20 Nov 2020 (Study Day 35), 34 days after the first dose and 2 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID 19.

On 20 Nov 2020 (Study Day 35), 34 days after the first dose and 2 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia caused by COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 33, 18 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 01 Dec 2020 (Study Day 46), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
26 Nov 2020 (Study Day 41)	Body Aches	Mild
26 Nov 2020 (Study Day 41)	Chills	Mild
26 Nov 2020 (Study Day 41)	Cough	Mild
26 Nov 2020 (Study Day 41)	Fatigue	Mild
27 Nov 2020 (Study Day 42)	Body Aches	Mild
27 Nov 2020 (Study Day 42)	Chills	Mild
27 Nov 2020 (Study Day 42)	Cough	Mild
27 Nov 2020 (Study Day 42)	Fatigue	Mild
28 Nov 2020 (Study Day 43)	Body Aches	Mild
28 Nov 2020 (Study Day 43)	Chills	Mild
28 Nov 2020 (Study Day 43)	Cough	Mild
28 Nov 2020 (Study Day 43)	Fatigue	Mild
29 Nov 2020 (Study Day 44)	Body Aches	Mild
29 Nov 2020 (Study Day 44)	Chills	Mild
29 Nov 2020 (Study Day 44)	Cough	Mild
29 Nov 2020 (Study Day 44)	Fatigue	Mild
30 Nov 2020 (Study Day 45)	Body Aches	Mild
30 Nov 2020 (Study Day 45)	Chills	Mild
30 Nov 2020 (Study Day 45)	Cough	Mild
30 Nov 2020 (Study Day 45)	Fatigue	Mild
01 Dec 2020 (Study Day 46)	Body Aches	Mild
01 Dec 2020 (Study Day 46)	Cough	Mild
01 Dec 2020 (Study Day 46)	Fatigue	Mild
02 Dec 2020 (Study Day 47)	Body Aches	Mild
02 Dec 2020 (Study Day 47)	Cough	Mild
02 Dec 2020 (Study Day 47)	Fatigue	Mild
03 Dec 2020 (Study Day 48)	Chills	Mild
03 Dec 2020 (Study Day 48)	Cough	Mild
03 Dec 2020 (Study Day 48)	Diarrhea	Mild
03 Dec 2020 (Study Day 48)	Fatigue	Mild
03 Dec 2020 (Study Day 48)	Headache	Mild

Symptom Date	Symptom	Result
03 Dec 2020 (Study Day 48)	Muscle Aches (Myalgia)	Mild
03 Dec 2020 (Study Day 48)	O2 Saturation (%)	90
03 Dec 2020 (Study Day 48)	Shortness of Breath	Mild
05 Dec 2020 (Study Day 50)	Cough	Mild
05 Dec 2020 (Study Day 50)	Diarrhea	Mild
05 Dec 2020 (Study Day 50)	Fatigue	Mild
05 Dec 2020 (Study Day 50)	Shortness of Breath	Mild
06 Dec 2020 (Study Day 51)	Cough	Mild
06 Dec 2020 (Study Day 51)	Shortness of Breath	Mild
07 Dec 2020 (Study Day 52)	Cough	Mild
08 Dec 2020 (Study Day 53)	Cough	Mild
09 Dec 2020 (Study Day 54)	Cough	Mild
10 Dec 2020 (Study Day 55)	Cough	Mild
11 Dec 2020 (Study Day 56)	Cough	Mild
16 Dec 2020 (Study Day 61)	Cough	Mild
17 Dec 2020 (Study Day 62)	Cough	Mild
18 Dec 2020 (Study Day 63)	Cough	Mild
19 Dec 2020 (Study Day 64)	Cough	Mild
20 Dec 2020 (Study Day 65)	Cough	Mild
21 Dec 2020 (Study Day 66)	Cough	Mild
22 Dec 2020 (Study Day 67)	Cough	Mild
23 Dec 2020 (Study Day 68)	Cough	Mild
24 Dec 2020 (Study Day 69)	Cough	Mild
25 Dec 2020 (Study Day 70)	Cough	Mild
26 Dec 2020 (Study Day 71)	Cough	Mild
27 Dec 2020 (Study Day 72)	Cough	Mild
28 Dec 2020 (Study Day 73)	Cough	Mild
29 Dec 2020 (Study Day 74)	Cough	Mild
30 Dec 2020 (Study Day 75)	Cough	Mild
31 Dec 2020 (Study Day 76)	Cough	Mild
01 Jan 2021 (Study Day 77)	Cough	Mild
02 Jan 2021 (Study Day 78)	Cough	Mild
03 Jan 2021 (Study Day 79)	Cough	Mild
04 Jan 2021 (Study Day 80)	Cough	Mild
05 Jan 2021 (Study Day 81)	Cough	Mild
06 Jan 2021 (Study Day 82)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
03 Dec 2020 (Study Day 48)	Oxygen Saturation	90%

Dates	Severity Indication	Result
03 Dec 2020 - 06 Dec 2020 (Study Day 48-51)	Admission to an intensive care unit due to SARS-CoV-2	Yes
03 Dec 2020 - 03 Dec 2020 (Study Day 48-48)	Clinical Evidence of Pneumonia	Yes
03 Dec 2020 - 06 Dec 2020 (Study Day 48-51)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
03 Dec 2020 - 03 Dec 2020 (Study Day 48-48)	Radiographical Evidence of Pneumonia	Yes
06 Dec 2020 - 06 Dec 2020 (Study Day 51-51)	Respiratory Failure	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 18 days, after which it was considered to be recovered/resolved on 07 Dec 2020 (Study Day 52). The investigator assessed the event of COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of pneumonia caused by COVID 19 lasted for 49 days, after which it was considered to be recovered/resolved on 07 Jan 2021 (Study Day 83). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001063	COVID-19
MOD-2020-001063	COVID-19 pneumonia
MOD-2020-001063	Acute respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Large intestine polyp	Colon polyps benign	2018 - 2018
Obesity	Obesity	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2017 - Ongoing	Hyperlipidemia
Liraglutide	Aug 2019 - Ongoing	Obesity
Ibuprofen	20 Nov 2020 (Study Day 35) - 03 Dec 2020 (Study Day 48)	COVID 19
Paracetamol	20 Nov 2020 (Study Day 35) - 03 Dec 2020 (Study Day 48)	COVID 19
Azithromycin	01 Dec 2020 (Study Day 46) - 01 Dec 2020 (Study Day 46)	Pneumonia
Dextromethorphan hydrobromide; guaifenesin	01 Dec 2020 (Study Day 46) - 05 Dec 2020 (Study Day 50)	Pneumonia Caused By COVID
Salbutamol	01 Dec 2020 (Study Day 46) - 06 Dec 2020 (Study Day 51)	Pneumonia Caused By COVID
Azithromycin	02 Dec 2020 (Study Day 47) - 05 Dec 2020 (Study Day 50)	Pneumonia Secondary To COVID 19
Benzonatate	03 Dec 2020 (Study Day 48) - 05 Dec 2020 (Study Day 50)	Pneumonia Secondary To COVID 19
Cefdinir	03 Dec 2020 (Study Day 48) - 13 Dec 2020 (Study Day 58)	Pneumonia Caused By COVID
Chest x ray*	03 Dec 2020 (Study Day 48) - 03 Dec 2020 (Study Day 48)	Adverse Event
Codeine; promethazine	03 Dec 2020 (Study Day 48) - 05 Dec 2020 (Study Day 50)	Pneumonia Caused By COVID
Dexamethasone	03 Dec 2020 (Study Day 48) - 05 Dec 2020 (Study Day 50)	Pneumonia Caused By COVID
Electrocardiogram*	03 Dec 2020 (Study Day 48) - 03 Dec 2020 (Study Day 48)	Adverse Event
Famotidine	03 Dec 2020 (Study Day 48) - 05 Dec 2020 (Study Day 50)	Pneumonia Caused By COVID
Ondansetron	03 Dec 2020 (Study Day 48) - 05 Dec 2020 (Study Day 50)	Pneumonia Secondary To COVID 19
Oxygen	03 Dec 2020 (Study Day 48) - 05 Dec 2020 (Study Day 50)	Acute Respiratory Failure
Dexamethasone	07 Dec 2020 (Study Day 52) - 03 Jan 2021 (Study Day 79)	Pneumonia Caused By COVID
Acetylsalicylic acid	15 Jan 2021 (Study Day 91) - Ongoing	Prophylaxis For Thrombosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US394-2079 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19 Infection	COVID-19, AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	22 Sep 2020 (Study Day 15) – 16 Oct 2020 (Study Day 39)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US394-2079, a 42-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 22 Sep 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 24 Sep 2020 (Study Day 17), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
24 Sep 2020 (Study Day 17)	Cough	Moderate
24 Sep 2020 (Study Day 17)	Headache	Moderate
24 Sep 2020 (Study Day 17)	Nasal Congestion	Moderate
25 Sep 2020 (Study Day 18)	Cough	Mild
28 Sep 2020 (Study Day 21)	Cough	Mild
28 Sep 2020 (Study Day 21)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
29 Sep 2020 (Study Day 22)	Body Aches	Moderate
29 Sep 2020 (Study Day 22)	Cough	Mild
29 Sep 2020 (Study Day 22)	Diarrhea	Mild
29 Sep 2020 (Study Day 22)	Difficulty Breathing	Moderate
29 Sep 2020 (Study Day 22)	Fatigue	Moderate
29 Sep 2020 (Study Day 22)	Muscle Aches (Myalgia)	Moderate
29 Sep 2020 (Study Day 22)	Nasal Congestion	Moderate
29 Sep 2020 (Study Day 22)	New Loss of Smell	Severe
29 Sep 2020 (Study Day 22)	New Loss of Taste	Severe
29 Sep 2020 (Study Day 22)	O2 Saturation (%)	85
29 Sep 2020 (Study Day 22)	Runny Nose (Rhinorrhea)	Moderate
29 Sep 2020 (Study Day 22)	Shortness of Breath	Moderate
30 Sep 2020 (Study Day 23)	Cough	Mild
30 Sep 2020 (Study Day 23)	Diarrhea	Mild
30 Sep 2020 (Study Day 23)	Difficulty Breathing	Moderate
30 Sep 2020 (Study Day 23)	Fatigue	Severe
30 Sep 2020 (Study Day 23)	Nasal Congestion	Mild
30 Sep 2020 (Study Day 23)	New Loss of Smell	Severe
30 Sep 2020 (Study Day 23)	New Loss of Taste	Severe
30 Sep 2020 (Study Day 23)	Shortness of Breath	Moderate
01 Oct 2020 (Study Day 24)	Body Aches	Mild
01 Oct 2020 (Study Day 24)	Cough	Mild
01 Oct 2020 (Study Day 24)	Diarrhea	Mild
01 Oct 2020 (Study Day 24)	Difficulty Breathing	Moderate
01 Oct 2020 (Study Day 24)	Fatigue	Severe
01 Oct 2020 (Study Day 24)	Nasal Congestion	Moderate
01 Oct 2020 (Study Day 24)	New Loss of Smell	Severe
01 Oct 2020 (Study Day 24)	New Loss of Taste	Severe
01 Oct 2020 (Study Day 24)	Shortness of Breath	Moderate
02 Oct 2020 (Study Day 25)	Body Aches	Mild
02 Oct 2020 (Study Day 25)	Cough	Moderate
02 Oct 2020 (Study Day 25)	Difficulty Breathing	Moderate
02 Oct 2020 (Study Day 25)	Fatigue	Moderate
02 Oct 2020 (Study Day 25)	Nasal Congestion	Moderate
02 Oct 2020 (Study Day 25)	Nausea	Mild
02 Oct 2020 (Study Day 25)	New Loss of Smell	Severe
02 Oct 2020 (Study Day 25)	New Loss of Taste	Severe
02 Oct 2020 (Study Day 25)	Shortness of Breath	Moderate
04 Oct 2020 (Study Day 27)	Cough	Mild
04 Oct 2020 (Study Day 27)	Nasal Congestion	Mild
05 Oct 2020 (Study Day 28)	Cough	Mild
05 Oct 2020 (Study Day 28)	Nasal Congestion	Mild
06 Oct 2020 (Study Day 29)	Cough	Mild

Symptom Date	Symptom	Result
06 Oct 2020 (Study Day 29)	Nasal Congestion	Mild
07 Oct 2020 (Study Day 30)	Cough	Mild
07 Oct 2020 (Study Day 30)	Nasal Congestion	Mild
08 Oct 2020 (Study Day 31)	Cough	Mild
08 Oct 2020 (Study Day 31)	Nasal Congestion	Mild
11 Oct 2020 (Study Day 34)	Cough	Mild
12 Oct 2020 (Study Day 35)	Cough	Mild
13 Oct 2020 (Study Day 36)	Cough	Mild
14 Oct 2020 (Study Day 37)	Cough	Mild
15 Oct 2020 (Study Day 38)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
29 Sep 2020 (Study Day 22)	Oxygen Saturation	85%
29 Sep 2020 - 29 Sep 2020 (Study Day 22-22)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

On 05 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 infection lasted for 25 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 39). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000376	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to animal	Pet dander allergy	1981 - Ongoing
Back pain	Chronic back pain	1998 - Ongoing
Headache	Chronic headaches	1998 - Ongoing
Ligament operation	Left acl repair	2001 - 2001

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ligament rupture	Left acl tear	2001 - 2001
Obesity	Morbid obesity	2001 - Ongoing
Intervertebral disc operation	L3-l5 discectomy	2012 - 2012
Laparotomy	L2-l5 laporotomy	2018 - 2018
Factor V Leiden mutation	Factor v leiden	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Laparotomy	L3-l4 laporotomy	2019 - 2019
Pulmonary embolism	Pulmonary embolism	2019 - Sep 2019
Deep vein thrombosis	Left leg deep vein thrombosis	Sep 2019 - Sep 2019
Thrombosis	Hospitalization for multiple blood clots	Sep 2019 - Sep 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Carisoprodol	1998 - Ongoing	Back Pain
Ibuprofen	1998 - Ongoing	Headaches
Apixaban	2019 - Ongoing	Factor IV Ligen
Metoprolol	2019 - Ongoing	Hypertension
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	22 Sep 2020 (Study Day 15) - 09 Oct 2020 (Study Day 32)	COVID-19 Infection
Salbutamol	01 Oct 2020 (Study Day 24) - 06 Oct 2020 (Study Day 29)	COVID-19 Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	22 Sep 2020 (Study Day 15) - 16 Oct 2020 (Study Day 39)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US396-2016 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 35)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 1/mild	Not related	10 Dec 2020 (Study Day 112) – 12 Jan 2021 (Study Day 145)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US396-2016, a 52-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 10 Dec 2020 (Study Day 112), 111 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID -19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 35, 24 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 11 Dec 2020 (Study Day 113), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
10 Dec 2020 (Study Day 112)	Cough	Mild
10 Dec 2020 (Study Day 112)	Headache	Mild
10 Dec 2020 (Study Day 112)	Muscle Aches (Myalgia)	Mild
10 Dec 2020 (Study Day 112)	Nasal Congestion	Mild
10 Dec 2020 (Study Day 112)	Runny Nose (Rhinorrhea)	Mild
10 Dec 2020 (Study Day 112)	Sore Throat	Mild

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 113)	Chills	Moderate
11 Dec 2020 (Study Day 113)	Cough	Mild
11 Dec 2020 (Study Day 113)	Headache	Mild
11 Dec 2020 (Study Day 113)	Nasal Congestion	Mild
11 Dec 2020 (Study Day 113)	Runny Nose (Rhinorrhea)	Mild
11 Dec 2020 (Study Day 113)	Sore Throat	Mild
11 Dec 2020 (Study Day 113)	Temperature (°F)	100.8
12 Dec 2020 (Study Day 114)	Cough	Mild
12 Dec 2020 (Study Day 114)	Headache	Mild
12 Dec 2020 (Study Day 114)	Nasal Congestion	Mild
12 Dec 2020 (Study Day 114)	Nausea	Mild
12 Dec 2020 (Study Day 114)	New Loss of Smell	Mild
12 Dec 2020 (Study Day 114)	Runny Nose (Rhinorrhea)	Mild
12 Dec 2020 (Study Day 114)	Sore Throat	Mild
13 Dec 2020 (Study Day 115)	Cough	Mild
13 Dec 2020 (Study Day 115)	Headache	Mild
13 Dec 2020 (Study Day 115)	Muscle Aches (Myalgia)	Mild
13 Dec 2020 (Study Day 115)	Nasal Congestion	Mild
13 Dec 2020 (Study Day 115)	New Loss of Smell	Severe
13 Dec 2020 (Study Day 115)	Runny Nose (Rhinorrhea)	Mild
14 Dec 2020 (Study Day 116)	Cough	Mild
14 Dec 2020 (Study Day 116)	Headache	Mild
14 Dec 2020 (Study Day 116)	Muscle Aches (Myalgia)	Mild
14 Dec 2020 (Study Day 116)	Nasal Congestion	Mild
14 Dec 2020 (Study Day 116)	New Loss of Smell	Severe
15 Dec 2020 (Study Day 117)	Cough	Mild
15 Dec 2020 (Study Day 117)	Fatigue	Mild
15 Dec 2020 (Study Day 117)	Headache	Mild
15 Dec 2020 (Study Day 117)	Nasal Congestion	Mild
15 Dec 2020 (Study Day 117)	New Loss of Smell	Severe
15 Dec 2020 (Study Day 117)	New Loss of Taste	Moderate
16 Dec 2020 (Study Day 118)	Fatigue	Moderate
16 Dec 2020 (Study Day 118)	Nasal Congestion	Mild
16 Dec 2020 (Study Day 118)	New Loss of Smell	Severe
16 Dec 2020 (Study Day 118)	New Loss of Taste	Moderate
17 Dec 2020 (Study Day 119)	Cough	Mild
17 Dec 2020 (Study Day 119)	Fatigue	Mild
17 Dec 2020 (Study Day 119)	Headache	Mild
17 Dec 2020 (Study Day 119)	Nasal Congestion	Mild
17 Dec 2020 (Study Day 119)	New Loss of Smell	Moderate
17 Dec 2020 (Study Day 119)	New Loss of Taste	Moderate
17 Dec 2020 (Study Day 119)	Runny Nose (Rhinorrhea)	Mild
18 Dec 2020 (Study Day 120)	Cough	Mild

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 120)	Fatigue	Mild
18 Dec 2020 (Study Day 120)	Headache	Mild
18 Dec 2020 (Study Day 120)	Nasal Congestion	Mild
18 Dec 2020 (Study Day 120)	New Loss of Smell	Moderate
18 Dec 2020 (Study Day 120)	New Loss of Taste	Moderate
19 Dec 2020 (Study Day 121)	Body Aches	Moderate
19 Dec 2020 (Study Day 121)	Cough	Mild
19 Dec 2020 (Study Day 121)	Fatigue	Mild
19 Dec 2020 (Study Day 121)	Headache	Mild
19 Dec 2020 (Study Day 121)	New Loss of Smell	Moderate
19 Dec 2020 (Study Day 121)	New Loss of Taste	Moderate
20 Dec 2020 (Study Day 122)	Cough	Mild
20 Dec 2020 (Study Day 122)	Fatigue	Mild
20 Dec 2020 (Study Day 122)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 122)	New Loss of Smell	Moderate
20 Dec 2020 (Study Day 122)	New Loss of Taste	Moderate
20 Dec 2020 (Study Day 122)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 123)	Cough	Mild
21 Dec 2020 (Study Day 123)	Fatigue	Mild
21 Dec 2020 (Study Day 123)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 123)	New Loss of Smell	Severe
21 Dec 2020 (Study Day 123)	New Loss of Taste	Severe
21 Dec 2020 (Study Day 123)	O2 Saturation (%)	93
22 Dec 2020 (Study Day 124)	Fatigue	Mild
22 Dec 2020 (Study Day 124)	New Loss of Smell	Moderate
22 Dec 2020 (Study Day 124)	New Loss of Taste	Moderate
23 Dec 2020 (Study Day 125)	Fatigue	Mild
23 Dec 2020 (Study Day 125)	New Loss of Smell	Moderate
23 Dec 2020 (Study Day 125)	Runny Nose (Rhinorrhea)	Mild
24 Dec 2020 (Study Day 126)	Fatigue	Mild
24 Dec 2020 (Study Day 126)	Nasal Congestion	Mild
24 Dec 2020 (Study Day 126)	New Loss of Smell	Moderate
24 Dec 2020 (Study Day 126)	Runny Nose (Rhinorrhea)	Mild
25 Dec 2020 (Study Day 127)	Fatigue	Mild
25 Dec 2020 (Study Day 127)	Nasal Congestion	Mild
25 Dec 2020 (Study Day 127)	New Loss of Smell	Moderate
26 Dec 2020 (Study Day 128)	Fatigue	Mild
26 Dec 2020 (Study Day 128)	Nasal Congestion	Mild
26 Dec 2020 (Study Day 128)	New Loss of Smell	Moderate
27 Dec 2020 (Study Day 129)	Fatigue	Mild
27 Dec 2020 (Study Day 129)	New Loss of Smell	Moderate
27 Dec 2020 (Study Day 129)	Runny Nose (Rhinorrhea)	Mild
28 Dec 2020 (Study Day 130)	Fatigue	Mild

Symptom Date	Symptom	Result
28 Dec 2020 (Study Day 130)	New Loss of Smell	Moderate
28 Dec 2020 (Study Day 130)	Runny Nose (Rhinorrhea)	Mild
29 Dec 2020 (Study Day 131)	Fatigue	Mild
29 Dec 2020 (Study Day 131)	New Loss of Smell	Moderate
30 Dec 2020 (Study Day 132)	Fatigue	Mild
30 Dec 2020 (Study Day 132)	New Loss of Smell	Moderate
31 Dec 2020 (Study Day 133)	New Loss of Smell	Moderate
01 Jan 2021 (Study Day 134)	New Loss of Smell	Moderate
02 Jan 2021 (Study Day 135)	Fatigue	Mild
02 Jan 2021 (Study Day 135)	New Loss of Smell	Mild
03 Jan 2021 (Study Day 136)	Fatigue	Mild
03 Jan 2021 (Study Day 136)	New Loss of Smell	Mild
04 Jan 2021 (Study Day 137)	Fatigue	Mild
04 Jan 2021 (Study Day 137)	New Loss of Smell	Mild
05 Jan 2021 (Study Day 138)	Fatigue	Mild
05 Jan 2021 (Study Day 138)	New Loss of Smell	Mild
05 Jan 2021 (Study Day 138)	Runny Nose (Rhinorrhea)	Mild
06 Jan 2021 (Study Day 139)	Fatigue	Mild
06 Jan 2021 (Study Day 139)	New Loss of Smell	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
21 Dec 2020 (Study Day 123)	Oxygen Saturation	93%
21 Dec 2020 - 21 Dec 2020 (Study Day 123-123)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID -19 lasted for 34 days, after which it was considered to be recovered/resolved on 12 Jan 2021 (Study Day 145). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001249	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1988 - Ongoing
Osteoarthritis	Left knee osteoarthritis	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Hysterectomy	Total hysterectomy	Sep 2017 - Sep 2017
Uterine leiomyoma	Uterine fibroids	Sep 2017 - Sep 2017
Anxiety	Anxiety	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Doxepin	1995 - Ongoing	Depression
Ibuprofen	2010 - Ongoing	Left Knee Osteoarthritis
Alprazolam	2018 - Ongoing	Anxiety
Ibuprofen	24 Aug 2020 (Study Day 4) - 24 Aug 2020 (Study Day 4)	Headache
Ibuprofen	30 Sep 2020 (Study Day 41) - 02 Oct 2020 (Study Day 43)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	24 Sep 2020 (Study Day 35) - 02 Oct 2020 (Study Day 43)
Headache	Grade 1/mild	Related	24 Sep 2020 (Study Day 35) - 02 Oct 2020 (Study Day 43)
Nausea	Grade 1/mild	Related	30 Sep 2020 (Study Day 41) - 02 Oct 2020 (Study Day 43)
Vomiting	Grade 1/mild	Not related	30 Sep 2020 (Study Day 41) - 02 Oct 2020 (Study Day 43)
COVID-19	Grade 1/mild	Not related	10 Dec 2020 (Study Day 112) - 12 Jan 2021 (Study Day 145)
Haematuria	Grade 1/mild	Not related	11 Jan 2021 (Study Day 144) - 12 Jan 2021 (Study Day 145)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US396-2063 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Tendon Rupture/Torn Tendon Left Ankle	SAE	Grade 4	Not related	02 Oct 2020 (Study Day 30) – 31 Oct 2020 (Study Day 59)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US396-2063, a 57-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 30), 29 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of tendon rupture. Action taken with the IP was not applicable. The event of torn tendon left ankle lasted for 30 days, after which it was considered to be recovered/resolved on 31 Oct 2020 (Study Day 59). The investigator assessed the event of tendon rupture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000621	Tendon rupture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1968 - Ongoing
Anxiety	Anxiety	1972 - Ongoing
Female sterilisation	Bilateral tubal ligation	1990 - 1990
Fibromyalgia	Fibromyalgia	2000 - Ongoing
Spinal fracture	Broken vertebra l5/s1	2000 - 2005
Back pain	Back pain	2004 - Ongoing
Neuropathy peripheral	Peripheral neuropathy	2004 - Ongoing
Hepatitis C	Hepatitis c	2005 - 2006
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Rubber sensitivity	Allergy to latex	2013 - Ongoing
Bipolar disorder	Bipolar disorder	2015 - Ongoing
Dry skin	Dry rough skin (legs)	2015 - Ongoing
Dry skin	Dry rough skin (arms)	2015 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2017 - Ongoing
Parkinson's disease	Parkinson disease	2017 - Ongoing
Insomnia	Insomnia	2018 - Ongoing
Arthralgia	Left ankle pain	May 2020 - Ongoing
Pain in extremity	Left foot pain	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2000 - Ongoing	Fibromyalgia
Ibuprofen	2004 - Ongoing	Back Pain
Loratadine	2004 - Ongoing	Seasonal Allergies
Ammonium lactate	2015 - Ongoing	Barnicles (Rough Dry Skin, Arms And Legs)
Lithium	2015 - 01 Mar 2021 (Study Day 180)	Bi-Polar
Lithium	2015 - 01 Mar 2021 (Study Day 180)	Bipolar
Metformin	2015 - Ongoing	Type Ii Diabetes
Carbidopa	2017 - Ongoing	Parkinson's Disease
Levodopa	2017 - Ongoing	Parkinson's Disease
Levothyroxine	2017 - Ongoing	Hypothyroidism
Lovastatin	2018 - Ongoing	High Cholesterol
Methylphenidate	2018 - Ongoing	Bipolar

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Trazodone	2018 - Ongoing	Insomnia
Ibuprofen	May 2020 - Ongoing	Left Foot And Ankle Pain
Mri left ankle*	26 Sep 2020 (Study Day 24) - 26 Sep 2020 (Study Day 24)	Medical History
Ekg*	26 Oct 2020 (Study Day 54) - 26 Oct 2020 (Study Day 54)	Other, Pre-Surgery Exam
Acetylsalicylic acid	30 Oct 2020 (Study Day 58) - Ongoing	Blood Thinning Following Surgery
Cyclobenzaprine	30 Oct 2020 (Study Day 58) - 06 Nov 2020 (Study Day 65)	Left Ankle Pain
Ondansetron	30 Oct 2020 (Study Day 58) - 06 Nov 2020 (Study Day 65)	Nausea
Oxycodone hydrochloride; paracetamol	30 Oct 2020 (Study Day 58) - 06 Nov 2020 (Study Day 65)	Left Ankle Pain
Surgery to repair torn tendon left ankle*	30 Oct 2020 (Study Day 58) - 30 Oct 2020 (Study Day 58)	Adverse Event
Paracetamol; pseudoephedrine hydrochloride	04 Feb 2021 (Study Day 155) - 07 Feb 2021 (Study Day 158)	Post Nasal Drip - COVID-19 Symptoms
Ibuprofen	16 Feb 2021 (Study Day 167) - 19 Feb 2021 (Study Day 170)	Exacerbation Of Back Pain
Dextromethorphan hydrobromide; guaifenesin	26 Feb 2021 (Study Day 177) - 01 Mar 2021 (Study Day 180)	Post Nasal Drip
Lithium	02 Mar 2021 (Study Day 181) - Ongoing	Elevated Lithium Level - Bipolar

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Not related	30 Oct 2020 (Study Day 58) - 06 Nov 2020 (Study Day 65)
Upper-Airway Cough Syndrome	Grade 1/mild	Not related	15 Jan 2021 (Study Day 135) - 03 Mar 2021 (Study Day 182)
COVID-19	Grade 1/mild	Not related	02 Feb 2021 (Study Day 153) - 03 Mar 2021 (Study Day 182)
Back Pain	Grade 1/mild	Not related	16 Feb 2021 (Study Day 167) - 19 Feb 2021 (Study Day 170)
Antipsychotic Drug Level Increased	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 181) - Ongoing
Neuropathy Peripheral	Grade 2/moderate	Not related	26 Mar 2021 (Study Day 205) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US396-2066 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID - 19	COVID-19	Grade 2/moderate	Not related	16 Jan 2021 (Study Day 136) – 25 Feb 2021 (Study Day 176)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US396-2066, a 60-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 16 Jan 2021 (Study Day 136), 135 days after the first dose and 107 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID - 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 01 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 19 Jan 2021 (Study Day 139), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
16 Jan 2021 (Study Day 136)	Body Aches	Mild
16 Jan 2021 (Study Day 136)	Cough	Moderate
16 Jan 2021 (Study Day 136)	Diarrhea	Mild

Symptom Date	Symptom	Result
16 Jan 2021 (Study Day 136)	Headache	Severe
16 Jan 2021 (Study Day 136)	Nasal Congestion	Mild
16 Jan 2021 (Study Day 136)	New Loss of Smell	Severe
16 Jan 2021 (Study Day 136)	New Loss of Taste	Severe
18 Jan 2021 (Study Day 138)	Body Aches	Mild
18 Jan 2021 (Study Day 138)	Fatigue	Mild
18 Jan 2021 (Study Day 138)	Headache	Mild
18 Jan 2021 (Study Day 138)	Muscle Aches (Myalgia)	Mild
18 Jan 2021 (Study Day 138)	Sore Throat	Mild
19 Jan 2021 (Study Day 139)	Fatigue	Mild
19 Jan 2021 (Study Day 139)	Headache	Mild
19 Jan 2021 (Study Day 139)	New Loss of Smell	Mild
19 Jan 2021 (Study Day 139)	New Loss of Taste	Mild
19 Jan 2021 (Study Day 139)	Runny Nose (Rhinorrhea)	Mild
20 Jan 2021 (Study Day 140)	Body Aches	Mild
20 Jan 2021 (Study Day 140)	Cough	Mild
20 Jan 2021 (Study Day 140)	Diarrhea	Severe
20 Jan 2021 (Study Day 140)	Fatigue	Mild
20 Jan 2021 (Study Day 140)	Headache	Mild
20 Jan 2021 (Study Day 140)	Muscle Aches (Myalgia)	Mild
20 Jan 2021 (Study Day 140)	Nasal Congestion	Severe
20 Jan 2021 (Study Day 140)	New Loss of Smell	Severe
20 Jan 2021 (Study Day 140)	New Loss of Taste	Mild
20 Jan 2021 (Study Day 140)	O2 Saturation (%)	82
20 Jan 2021 (Study Day 140)	Runny Nose (Rhinorrhea)	Severe
21 Jan 2021 (Study Day 141)	Body Aches	Mild
21 Jan 2021 (Study Day 141)	Cough	Mild
21 Jan 2021 (Study Day 141)	Fatigue	Mild
21 Jan 2021 (Study Day 141)	Headache	Severe
21 Jan 2021 (Study Day 141)	Muscle Aches (Myalgia)	Mild
21 Jan 2021 (Study Day 141)	Nausea	Severe
21 Jan 2021 (Study Day 141)	New Loss of Smell	Mild
21 Jan 2021 (Study Day 141)	New Loss of Taste	Mild
22 Jan 2021 (Study Day 142)	Cough	Mild
22 Jan 2021 (Study Day 142)	Difficulty Breathing	Mild
22 Jan 2021 (Study Day 142)	Fatigue	Mild
22 Jan 2021 (Study Day 142)	Headache	Mild
22 Jan 2021 (Study Day 142)	Nasal Congestion	Mild
22 Jan 2021 (Study Day 142)	Nausea	Mild
22 Jan 2021 (Study Day 142)	O2 Saturation (%)	68
22 Jan 2021 (Study Day 142)	Runny Nose (Rhinorrhea)	Mild
22 Jan 2021 (Study Day 142)	Shortness of Breath	Mild
22 Jan 2021 (Study Day 142)	Sore Throat	Mild

Symptom Date	Symptom	Result
23 Jan 2021 (Study Day 143)	Body Aches	Mild
23 Jan 2021 (Study Day 143)	Cough	Mild
23 Jan 2021 (Study Day 143)	Fatigue	Mild
23 Jan 2021 (Study Day 143)	Headache	Mild
23 Jan 2021 (Study Day 143)	Muscle Aches (Myalgia)	Mild
23 Jan 2021 (Study Day 143)	Nausea	Mild
23 Jan 2021 (Study Day 143)	O2 Saturation (%)	92
23 Jan 2021 (Study Day 143)	Shortness of Breath	Mild
25 Jan 2021 (Study Day 145)	Fatigue	Mild
25 Jan 2021 (Study Day 145)	Headache	Mild
25 Jan 2021 (Study Day 145)	Muscle Aches (Myalgia)	Mild
25 Jan 2021 (Study Day 145)	O2 Saturation (%)	93
26 Jan 2021 (Study Day 146)	Body Aches	Mild
26 Jan 2021 (Study Day 146)	Cough	Mild
26 Jan 2021 (Study Day 146)	Fatigue	Mild
26 Jan 2021 (Study Day 146)	Headache	Mild
26 Jan 2021 (Study Day 146)	Muscle Aches (Myalgia)	Mild
27 Jan 2021 (Study Day 147)	Nausea	Mild
27 Jan 2021 (Study Day 147)	O2 Saturation (%)	90
28 Jan 2021 (Study Day 148)	Headache	Mild
29 Jan 2021 (Study Day 149)	Body Aches	Mild
29 Jan 2021 (Study Day 149)	Fatigue	Mild
29 Jan 2021 (Study Day 149)	Muscle Aches (Myalgia)	Mild
30 Jan 2021 (Study Day 150)	Body Aches	Mild
30 Jan 2021 (Study Day 150)	Fatigue	Mild
30 Jan 2021 (Study Day 150)	Muscle Aches (Myalgia)	Mild
31 Jan 2021 (Study Day 151)	Headache	Mild
02 Feb 2021 (Study Day 153)	Fatigue	Mild
02 Feb 2021 (Study Day 153)	Headache	Moderate
14 Feb 2021 (Study Day 165)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
20 Jan 2021 (Study Day 140)	Oxygen Saturation	82%
20 Jan 2021 - 27 Jan 2021 (Study Day 140-147)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID - 19 lasted for 41 days, after which it was considered to be recovered/resolved on 25 Feb 2021 (Study Day 176). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008884	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hysterectomy	Hysterectomy	1982 - 1982
Menorrhagia	Heavy menstrual bleeding	1982 - 1982
Back pain	Back pain	2000 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Asthma	Mild asthma	2010 - Ongoing
Restless legs syndrome	Restless leg syndrome	2010 - Ongoing
Myocardial infarction	Heart attack	2013 - 2013
Hypertension	Hypertension	2014 - Ongoing
Gastrooesophageal reflux disease	Gastro esophageal reflux disease	2015 - Ongoing
Depression	Depression	2018 - Ongoing
Osteoarthritis	Left hip pain - osteroarthritis	2018 - Ongoing
Osteoarthritis	Osteoarthritis left hip	2018 - Ongoing
Osteoarthritis	Osteoarthritis right hip	2018 - Ongoing
Osteoarthritis	Right hip pain - osteroarthritis	2018 - Ongoing
Blood cholesterol increased	High cholesterol	2019 - Ongoing
Migraine	Migraine headaches	2020 - Ongoing
Dizziness	Dizziness	May 2020 - Ongoing
Vision blurred	Blurred vision	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Topiramate	2005 - Ongoing	Migraine Prevention
Amitriptyline	2010 - Ongoing	Anxiety
Hydroxyzine	2010 - Ongoing	Anxiety

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ipratropium bromide; salbutamol sulfate	2010 - Ongoing	Mild Asthma
Ropinirole	2010 - Ongoing	Restless Leg Syndrome
Metoprolol succinate	2014 - Ongoing	Hypertension
Folic acid	2015 - Ongoing	Dietary Supplement
Tizanidine	2015 - Ongoing	Anxiety
Hydrocodone bitartrate; paracetamol	2017 - Ongoing	Back Pain
Mirtazapine	2018 - Ongoing	Depression
Omeprazole	2018 - Ongoing	Gastro Esophageal Reflux Disease
Atorvastatin	2019 - Ongoing	High Cholesterol
Famotidine	2019 - Ongoing	Gastro Esophageal Reflux Disease
Venlafaxine	2019 - 13 Sep 2020 (Study Day 11)	Depression
Venlafaxine	14 Sep 2020 (Study Day 12) - Ongoing	Depression
Bumetanide	30 Sep 2020 (Study Day 28) - Ongoing	Fluid (Edema) Retention Legs
Butalbital; caffeine; paracetamol	28 Oct 2020 (Study Day 56) - Ongoing	Migraine Headaches
Steroids	Nov 2020 - Nov 2020	Right Hip Pain
Influenza vaccine	19 Nov 2020 (Study Day 78) - 19 Nov 2020 (Study Day 78)	Prevention Of Flu
Ondansetron	22 Jan 2021 (Study Day 142) - 27 Jan 2021 (Study Day 147)	Prevent Nausea From COVID - 19
Paracetamol	28 Jan 2021 (Study Day 148) - 28 Jan 2021 (Study Day 148)	Headache
Steroids	23 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 174)	Exacerbation Left Hip Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oedema Peripheral	Grade 1/mild	Not related	30 Sep 2020 (Study Day 28) - Ongoing
Arthralgia	Grade 2/moderate	Not related	28 Oct 2020 (Study Day 56) - 04 Nov 2020 (Study Day 63)
Musculoskeletal Chest Pain	Grade 1/mild	Not related	29 Oct 2020 (Study Day 57) - 30 Oct 2020 (Study Day 58)
Diarrhoea	Grade 1/mild	Not related	21 Dec 2020 (Study Day 110) - 23 Dec 2020 (Study Day 112)
COVID-19	Grade 2/moderate	Not related	16 Jan 2021 (Study Day 136) - 25 Feb 2021 (Study Day 176)
Pain	Grade 2/moderate	Not related	23 Jan 2021 (Study Day 143) - 23 Feb 2021 (Study Day 174)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2213 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Injection Site Swelling/Left Deltoid Injection Site Swelling	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	21 Sep 2020 (Study Day 1) – 06 Oct 2020 (Study Day 16)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2213, a 40-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of injection site swelling. On 18 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of left deltoid injection site swelling lasted for 16 days, after which it was considered to be recovered/resolved on 06 Oct 2020 (Study Day 16). The investigator assessed the event of injection site swelling to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	Cesarean section	25 Oct 1999 (Study Day -7637) - 25 Oct 1999 (Study Day -7637)
Headache	Intermittent headaches	2008 - Ongoing
Caesarean section	Cesarean section	07 Nov 2011 (Study Day -3241) - 07 Nov 2011 (Study Day -3241)
Caesarean section	Cesarean section	11 Mar 2014 (Study Day -2386) - 11 Mar 2014 (Study Day -2386)
Myalgia	Myalgias	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2008 - Ongoing	Headaches
Ibuprofen	26 Sep 2020 (Study Day 6) - 27 Sep 2020 (Study Day 7)	Viral Respiratory Syndrome
Oxycodone hydrochloride; paracetamol	09 Dec 2020 (Study Day 80) - Ongoing	Generalized Body Aches (Back Neck And Legs)
Paracetamol	09 Dec 2020 (Study Day 80) - 09 Dec 2020 (Study Day 80)	Muscle Pain
Physical therapy*	08 Jan 2021 (Study Day 110) - 08 Jan 2021 (Study Day 110)	Adverse Event
Penicillin nos	10 Feb 2021 (Study Day 143) - 10 Feb 2021 (Study Day 143)	COVID Like Symptoms
Penicillin nos	11 Feb 2021 (Study Day 144) - 11 Feb 2021 (Study Day 144)	COVID Like Symptoms

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Erythema	Grade 1/mild	Related	21 Sep 2020 (Study Day 1) - 06 Oct 2020 (Study Day 16)
Injection Site Swelling	Grade 1/mild	Related	21 Sep 2020 (Study Day 1) - 06 Oct 2020 (Study Day 16)
Viral Upper Respiratory Tract Infection	Grade 1/mild	Related	24 Sep 2020 (Study Day 4) - 13 Oct 2020 (Study Day 23)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Not related	27 Oct 2020 (Study Day 37) - Ongoing
Pain	Grade 1/mild	Not related	16 Nov 2020 (Study Day 57) - Ongoing
Viral Upper Respiratory Tract Infection	Grade 2/moderate	Not related	10 Feb 2021 (Study Day 143) - 25 Feb 2021 (Study Day 158)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379660

Participant Number:	US303-2187 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	SAE, COVID-19	Grade 3/severe	Not related	30 Nov 2020 (Study Day 112) – 09 Dec 2020 (Study Day 121)	Recovered/ resolved
Type 2 Diabetes Mellitus/Diabetes Mellitus Type 2	SAE	Grade 3/severe	Not related	03 Dec 2020 (Study Day 115) – 10 Feb 2021 (Study Day 184)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US303-2187, a 49-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Dec 2020 (Study Day 115), 114 days after the first dose and 86 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of type 2 diabetes mellitus. Action taken with the IP was not applicable. The event of diabetes mellitus type 2 lasted for 70 days, after which it was considered to be recovered/resolved on 10 Feb 2021 (Study Day 184). The investigator assessed the event of type 2 diabetes mellitus to be not related to the IP.

Severe COVID-19 Details

On 30 Nov 2020 (Study Day 112), 111 days after the first dose and 83 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 10 Dec 2020 (Study Day 122), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
07 Dec 2020 (Study Day 119)	Body Aches	Moderate
07 Dec 2020 (Study Day 119)	Cough	Mild
07 Dec 2020 (Study Day 119)	Fatigue	Moderate
07 Dec 2020 (Study Day 119)	Headache	Moderate
07 Dec 2020 (Study Day 119)	Muscle Aches (Myalgia)	Moderate
11 Dec 2020 (Study Day 123)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
11 Dec 2020 (Study Day 123)	Oxygen Saturation	93%
11 Dec 2020 - 11 Dec 2020 (Study Day 123-123)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 10 days, after which it was considered to be recovered/resolved on 09 Dec 2020 (Study Day 121). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001056	COVID-19
MOD-2020-001056	Type 2 diabetes mellitus

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	2018 - Ongoing	Seasonal Allergies
Influenza vaccine	25 Oct 2020 (Study Day 76) - 25 Oct 2020 (Study Day 76)	Prophylaxis For Seasonal Influenza
Covid-19 pcr nasal swab*	30 Nov 2020 (Study Day 112) - 30 Nov 2020 (Study Day 112)	Adverse Event
Blood work*	03 Dec 2020 (Study Day 115) - 03 Dec 2020 (Study Day 115)	Adverse Event
Chest x-ray*	03 Dec 2020 (Study Day 115) - 03 Dec 2020 (Study Day 115)	Adverse Event
Ct head without contrast*	03 Dec 2020 (Study Day 115) - 03 Dec 2020 (Study Day 115)	Adverse Event
Dexamethasone	04 Dec 2020 (Study Day 116) - 06 Dec 2020 (Study Day 118)	COVID-19
Insulin aspart	04 Dec 2020 (Study Day 116) - Ongoing	Diabetes Mellitus Type 2
Insulin detemir	04 Dec 2020 (Study Day 116) - Ongoing	Diabetes Mellitus Type 2
Oxygen	04 Dec 2020 (Study Day 116) - 05 Dec 2020 (Study Day 117)	COVID-19
Remdesivir	04 Dec 2020 (Study Day 116) - 04 Dec 2020 (Study Day 116)	COVID-19
Remdesivir	05 Dec 2020 (Study Day 117) - 06 Dec 2020 (Study Day 118)	COVID-19
Acetylsalicylic acid	07 Dec 2020 (Study Day 119) - 09 Dec 2020 (Study Day 121)	COVID-19
Dexamethasone	07 Dec 2020 (Study Day 119) - 17 Dec 2020 (Study Day 129)	COVID-19
Lisinopril	07 Dec 2020 (Study Day 119) - Ongoing	Hypertension
Simvastatin	07 Dec 2020 (Study Day 119) - Ongoing	Hyperlipidemia
Amoxicillin; clavulanate potassium	23 Feb 2021 (Study Day 197) - 01 Mar 2021 (Study Day 203)	Acute Sinusitis
Prednisone	19 Mar 2021 (Study Day 221) - 21 Mar 2021 (Study Day 223)	Sore Throat

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	14 Aug 2020 (Study Day 4) - 23 Aug 2020 (Study Day 13)
Arthralgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 45)
Fatigue	Grade 1/mild	Related	11 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 45)
Myalgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 32) - 24 Sep 2020 (Study Day 45)
Metabolic Encephalopathy	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 115) - 05 Dec 2020 (Study Day 117)
Hyperlipidaemia	Grade 1/mild	Not related	07 Dec 2020 (Study Day 119) - 06 Apr 2021 (Study Day 239)
Hypertension	Grade 1/mild	Not related	07 Dec 2020 (Study Day 119) - 06 Apr 2021 (Study Day 239)
Acute Sinusitis	Grade 1/mild	Not related	23 Feb 2021 (Study Day 197) - 03 Mar 2021 (Study Day 205)
Oropharyngeal Pain	Grade 1/mild	Not related	19 Mar 2021 (Study Day 221) - 21 Mar 2021 (Study Day 223)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US324-2003 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 30)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	09 Jan 2021 (Study Day 157) – 20 Jan 2021 (Study Day 168)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US324-2003, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 09 Jan 2021 (Study Day 157), 156 days after the first dose and 127 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 04 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Jan 2021 (Study Day 171), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
09 Jan 2021 (Study Day 157)	Body Aches	Moderate
09 Jan 2021 (Study Day 157)	Chills	Moderate
09 Jan 2021 (Study Day 157)	Cough	Moderate
09 Jan 2021 (Study Day 157)	Diarrhea	Mild
09 Jan 2021 (Study Day 157)	Difficulty Breathing	Moderate
09 Jan 2021 (Study Day 157)	Fatigue	Moderate

Symptom Date	Symptom	Result
09 Jan 2021 (Study Day 157)	Nausea	Mild
09 Jan 2021 (Study Day 157)	New Loss of Taste	Moderate
09 Jan 2021 (Study Day 157)	Shortness of Breath	Moderate
10 Jan 2021 (Study Day 158)	Body Aches	Moderate
10 Jan 2021 (Study Day 158)	Chills	Moderate
10 Jan 2021 (Study Day 158)	Cough	Moderate
10 Jan 2021 (Study Day 158)	Diarrhea	Mild
10 Jan 2021 (Study Day 158)	Difficulty Breathing	Moderate
10 Jan 2021 (Study Day 158)	Fatigue	Moderate
10 Jan 2021 (Study Day 158)	Headache	Moderate
10 Jan 2021 (Study Day 158)	Muscle Aches (Myalgia)	Moderate
10 Jan 2021 (Study Day 158)	Nausea	Mild
10 Jan 2021 (Study Day 158)	Shortness of Breath	Moderate
11 Jan 2021 (Study Day 159)	Body Aches	Moderate
11 Jan 2021 (Study Day 159)	Chills	Moderate
11 Jan 2021 (Study Day 159)	Cough	Moderate
11 Jan 2021 (Study Day 159)	Diarrhea	Mild
11 Jan 2021 (Study Day 159)	Difficulty Breathing	Moderate
11 Jan 2021 (Study Day 159)	Fatigue	Moderate
11 Jan 2021 (Study Day 159)	Headache	Moderate
11 Jan 2021 (Study Day 159)	Muscle Aches (Myalgia)	Moderate
11 Jan 2021 (Study Day 159)	Nausea	Mild
11 Jan 2021 (Study Day 159)	Shortness of Breath	Moderate
12 Jan 2021 (Study Day 160)	Body Aches	Moderate
12 Jan 2021 (Study Day 160)	Chills	Moderate
12 Jan 2021 (Study Day 160)	Cough	Moderate
12 Jan 2021 (Study Day 160)	Diarrhea	Mild
12 Jan 2021 (Study Day 160)	Difficulty Breathing	Moderate
12 Jan 2021 (Study Day 160)	Fatigue	Moderate
12 Jan 2021 (Study Day 160)	Headache	Moderate
12 Jan 2021 (Study Day 160)	Muscle Aches (Myalgia)	Moderate
12 Jan 2021 (Study Day 160)	Nausea	Mild
12 Jan 2021 (Study Day 160)	Shortness of Breath	Moderate
13 Jan 2021 (Study Day 161)	Body Aches	Moderate
13 Jan 2021 (Study Day 161)	Chills	Moderate
13 Jan 2021 (Study Day 161)	Cough	Moderate
13 Jan 2021 (Study Day 161)	Diarrhea	Mild
13 Jan 2021 (Study Day 161)	Difficulty Breathing	Moderate
13 Jan 2021 (Study Day 161)	Fatigue	Moderate
13 Jan 2021 (Study Day 161)	Headache	Moderate
13 Jan 2021 (Study Day 161)	Muscle Aches (Myalgia)	Moderate
13 Jan 2021 (Study Day 161)	Nausea	Mild
13 Jan 2021 (Study Day 161)	Shortness of Breath	Moderate

Symptom Date	Symptom	Result
14 Jan 2021 (Study Day 162)	Body Aches	Mild
14 Jan 2021 (Study Day 162)	Chills	Mild
14 Jan 2021 (Study Day 162)	Cough	Mild
14 Jan 2021 (Study Day 162)	Diarrhea	Mild
14 Jan 2021 (Study Day 162)	Difficulty Breathing	Mild
14 Jan 2021 (Study Day 162)	Fatigue	Moderate
14 Jan 2021 (Study Day 162)	Headache	Mild
14 Jan 2021 (Study Day 162)	Muscle Aches (Myalgia)	Mild
14 Jan 2021 (Study Day 162)	Nausea	Mild
14 Jan 2021 (Study Day 162)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 163)	Body Aches	Mild
15 Jan 2021 (Study Day 163)	Chills	Mild
15 Jan 2021 (Study Day 163)	Cough	Mild
15 Jan 2021 (Study Day 163)	Diarrhea	Mild
15 Jan 2021 (Study Day 163)	Difficulty Breathing	Mild
15 Jan 2021 (Study Day 163)	Fatigue	Moderate
15 Jan 2021 (Study Day 163)	Headache	Mild
15 Jan 2021 (Study Day 163)	Muscle Aches (Myalgia)	Mild
15 Jan 2021 (Study Day 163)	Nausea	Mild
15 Jan 2021 (Study Day 163)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 164)	Difficulty Breathing	Mild
16 Jan 2021 (Study Day 164)	Fatigue	Mild
16 Jan 2021 (Study Day 164)	Headache	Mild
16 Jan 2021 (Study Day 164)	Nausea	Mild
16 Jan 2021 (Study Day 164)	Shortness of Breath	Mild
17 Jan 2021 (Study Day 165)	Difficulty Breathing	Mild
17 Jan 2021 (Study Day 165)	Fatigue	Mild
17 Jan 2021 (Study Day 165)	Headache	Mild
17 Jan 2021 (Study Day 165)	Nausea	Mild
17 Jan 2021 (Study Day 165)	Shortness of Breath	Mild
18 Jan 2021 (Study Day 166)	Difficulty Breathing	Mild
18 Jan 2021 (Study Day 166)	Fatigue	Mild
18 Jan 2021 (Study Day 166)	Headache	Mild
18 Jan 2021 (Study Day 166)	Nausea	Mild
18 Jan 2021 (Study Day 166)	Shortness of Breath	Mild
19 Jan 2021 (Study Day 167)	Difficulty Breathing	Mild
19 Jan 2021 (Study Day 167)	Fatigue	Mild
19 Jan 2021 (Study Day 167)	Headache	Mild
19 Jan 2021 (Study Day 167)	Nausea	Mild
19 Jan 2021 (Study Day 167)	Shortness of Breath	Mild
28 Jan 2021 (Study Day 176)	O2 Saturation (%)	93

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
28 Jan 2021 (Study Day 176)	Oxygen Saturation	93%
28 Jan 2021 (Study Day 176)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 12 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 168). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010845	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	01 Jan 1999 (Study Day -7888) - Ongoing
Obesity	Obesity	01 Jan 2000 (Study Day -7523) - Ongoing
Deep vein thrombosis	Deep vein thrombosis	01 Jan 2014 (Study Day -2409) - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	01 Jan 2014 (Study Day -2409) - Ongoing
Hypertension	Hypertension	01 Jan 2014 (Study Day -2409) - Ongoing
Osteoporosis	Osteoporosis	01 Jan 2014 (Study Day -2409) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	2014 - Ongoing	Osteoporosis
Fish oil	2014 - Ongoing	Hypercholesterolemia
Lisinopril	01 Jan 2014 (Study Day -2409) - Ongoing	Hypertension
Rivaroxaban	01 Jan 2014 (Study Day -2409) - Ongoing	Deep Vein Thrombosis
Vitamins nos	01 Jan 2014 (Study Day -2409) - Ongoing	Diet Supplement
Paracetamol	09 Jan 2021 (Study Day 157) - 18 Jan 2021 (Study Day 166)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	09 Jan 2021 (Study Day 157) - 20 Jan 2021 (Study Day 168)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379669

Participant Number:	US324-2397 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	27 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	31 Oct 2020 (Study Day 33) – 26 Nov 2020 (Study Day 59)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US324-2397, a 48-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 31 Oct 2020 (Study Day 33), 32 days after the first dose and 4 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 27 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 01 Nov 2020 (Study Day 34), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
03 Oct 2020 (Study Day 5)	Cough	Mild
04 Oct 2020 (Study Day 6)	Cough	Mild
05 Oct 2020 (Study Day 7)	Cough	Mild
06 Oct 2020 (Study Day 8)	Cough	Moderate
06 Oct 2020 (Study Day 8)	Difficulty Breathing	Mild
06 Oct 2020 (Study Day 8)	Fatigue	Moderate

Symptom Date	Symptom	Result
06 Oct 2020 (Study Day 8)	Shortness of Breath	Mild
06 Oct 2020 (Study Day 8)	Sore Throat	Moderate
07 Oct 2020 (Study Day 9)	Body Aches	Moderate
07 Oct 2020 (Study Day 9)	Chills	Moderate
07 Oct 2020 (Study Day 9)	Cough	Severe
07 Oct 2020 (Study Day 9)	Difficulty Breathing	Moderate
07 Oct 2020 (Study Day 9)	Fatigue	Severe
07 Oct 2020 (Study Day 9)	Muscle Aches (Myalgia)	Moderate
07 Oct 2020 (Study Day 9)	Nasal Congestion	Moderate
07 Oct 2020 (Study Day 9)	Nausea	Severe
07 Oct 2020 (Study Day 9)	Runny Nose (Rhinorrhea)	Moderate
07 Oct 2020 (Study Day 9)	Shortness of Breath	Severe
07 Oct 2020 (Study Day 9)	Sore Throat	Moderate
07 Oct 2020 (Study Day 9)	Vomiting	Moderate
08 Oct 2020 (Study Day 10)	Chills	Mild
08 Oct 2020 (Study Day 10)	Cough	Mild
08 Oct 2020 (Study Day 10)	Fatigue	Mild
08 Oct 2020 (Study Day 10)	Nasal Congestion	Mild
08 Oct 2020 (Study Day 10)	Runny Nose (Rhinorrhea)	Mild
08 Oct 2020 (Study Day 10)	Sore Throat	Mild
09 Oct 2020 (Study Day 11)	Body Aches	Moderate
09 Oct 2020 (Study Day 11)	Chills	Moderate
09 Oct 2020 (Study Day 11)	Cough	Mild
09 Oct 2020 (Study Day 11)	Fatigue	Severe
09 Oct 2020 (Study Day 11)	Headache	Moderate
09 Oct 2020 (Study Day 11)	Nasal Congestion	Mild
09 Oct 2020 (Study Day 11)	Runny Nose (Rhinorrhea)	Mild
09 Oct 2020 (Study Day 11)	Sore Throat	Mild
09 Oct 2020 (Study Day 11)	Vomiting	Mild
31 Oct 2020 (Study Day 33)	Body Aches	Mild
31 Oct 2020 (Study Day 33)	Cough	Mild
31 Oct 2020 (Study Day 33)	Fatigue	Mild
31 Oct 2020 (Study Day 33)	Headache	Mild
31 Oct 2020 (Study Day 33)	Shortness of Breath	Mild
01 Nov 2020 (Study Day 34)	Body Aches	Mild
01 Nov 2020 (Study Day 34)	Cough	Mild
01 Nov 2020 (Study Day 34)	Fatigue	Mild
01 Nov 2020 (Study Day 34)	Headache	Mild
01 Nov 2020 (Study Day 34)	Shortness of Breath	Mild
02 Nov 2020 (Study Day 35)	Body Aches	Moderate
02 Nov 2020 (Study Day 35)	Cough	Moderate
02 Nov 2020 (Study Day 35)	Fatigue	Moderate
02 Nov 2020 (Study Day 35)	Headache	Mild

Symptom Date	Symptom	Result
02 Nov 2020 (Study Day 35)	Shortness of Breath	Moderate
05 Nov 2020 (Study Day 38)	Body Aches	Mild
05 Nov 2020 (Study Day 38)	Chills	Mild
05 Nov 2020 (Study Day 38)	Cough	Moderate
05 Nov 2020 (Study Day 38)	Fatigue	Mild
05 Nov 2020 (Study Day 38)	Headache	Moderate
05 Nov 2020 (Study Day 38)	Nasal Congestion	Mild
05 Nov 2020 (Study Day 38)	New Loss of Smell	Mild
05 Nov 2020 (Study Day 38)	New Loss of Taste	Mild
05 Nov 2020 (Study Day 38)	Shortness of Breath	Mild
05 Nov 2020 (Study Day 38)	Sore Throat	Mild
06 Nov 2020 (Study Day 39)	Body Aches	Mild
06 Nov 2020 (Study Day 39)	Cough	Moderate
06 Nov 2020 (Study Day 39)	Headache	Moderate
06 Nov 2020 (Study Day 39)	New Loss of Smell	Mild
06 Nov 2020 (Study Day 39)	New Loss of Taste	Mild
06 Nov 2020 (Study Day 39)	O2 Saturation (%)	68
06 Nov 2020 (Study Day 39)	Shortness of Breath	Moderate
07 Nov 2020 (Study Day 40)	Body Aches	Mild
07 Nov 2020 (Study Day 40)	Chills	Mild
07 Nov 2020 (Study Day 40)	Cough	Mild
07 Nov 2020 (Study Day 40)	Fatigue	Mild
07 Nov 2020 (Study Day 40)	Headache	Mild
07 Nov 2020 (Study Day 40)	New Loss of Smell	Mild
07 Nov 2020 (Study Day 40)	New Loss of Taste	Mild
07 Nov 2020 (Study Day 40)	Sore Throat	Mild
08 Nov 2020 (Study Day 41)	Body Aches	Mild
08 Nov 2020 (Study Day 41)	Cough	Mild
08 Nov 2020 (Study Day 41)	Fatigue	Mild
08 Nov 2020 (Study Day 41)	Headache	Mild
08 Nov 2020 (Study Day 41)	Nasal Congestion	Mild
08 Nov 2020 (Study Day 41)	New Loss of Smell	Mild
08 Nov 2020 (Study Day 41)	New Loss of Taste	Mild
08 Nov 2020 (Study Day 41)	O2 Saturation (%)	92
08 Nov 2020 (Study Day 41)	Runny Nose (Rhinorrhea)	Mild
08 Nov 2020 (Study Day 41)	Sore Throat	Mild
09 Nov 2020 (Study Day 42)	Body Aches	Mild
09 Nov 2020 (Study Day 42)	Chills	Mild
09 Nov 2020 (Study Day 42)	Cough	Mild
09 Nov 2020 (Study Day 42)	Fatigue	Mild
09 Nov 2020 (Study Day 42)	Nasal Congestion	Mild
09 Nov 2020 (Study Day 42)	Runny Nose (Rhinorrhea)	Mild
09 Nov 2020 (Study Day 42)	Sore Throat	Mild

Symptom Date	Symptom	Result
10 Nov 2020 (Study Day 43)	Body Aches	Mild
10 Nov 2020 (Study Day 43)	Chills	Mild
10 Nov 2020 (Study Day 43)	Cough	Mild
10 Nov 2020 (Study Day 43)	Fatigue	Mild
10 Nov 2020 (Study Day 43)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 43)	Runny Nose (Rhinorrhea)	Mild
12 Nov 2020 (Study Day 45)	Cough	Mild
12 Nov 2020 (Study Day 45)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 45)	Runny Nose (Rhinorrhea)	Mild
13 Nov 2020 (Study Day 46)	Cough	Mild
13 Nov 2020 (Study Day 46)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 46)	Runny Nose (Rhinorrhea)	Mild
14 Nov 2020 (Study Day 47)	Cough	Mild
14 Nov 2020 (Study Day 47)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 47)	Runny Nose (Rhinorrhea)	Mild
15 Nov 2020 (Study Day 48)	Cough	Mild
15 Nov 2020 (Study Day 48)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 48)	Runny Nose (Rhinorrhea)	Mild
17 Nov 2020 (Study Day 50)	Cough	Mild
17 Nov 2020 (Study Day 50)	Nasal Congestion	Mild
17 Nov 2020 (Study Day 50)	Runny Nose (Rhinorrhea)	Mild
18 Nov 2020 (Study Day 51)	Cough	Mild
18 Nov 2020 (Study Day 51)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 51)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 52)	Cough	Mild
21 Nov 2020 (Study Day 54)	Cough	Mild
22 Nov 2020 (Study Day 55)	Cough	Mild
23 Nov 2020 (Study Day 56)	Cough	Mild
24 Nov 2020 (Study Day 57)	Cough	Mild
25 Nov 2020 (Study Day 58)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
06 Nov 2020 (Study Day 39)	Oxygen Saturation	68%
06 Nov 2020 - 06 Nov 2020 (Study Day 39-39)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 27 days, after which it was considered to be recovered/resolved on 26 Nov 2020 (Study Day 59). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000608	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Uterine leiomyoma	Uterine fibroids	2011 - 2018
Asthma	Bronchial asthma	2012 - Ongoing
Hysterectomy	Hysterectomy	2018 - 2018
Intervertebral disc protrusion	Herniated disc	2018 - Ongoing
Sciatica	Scatica	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2014 - Ongoing	Bronchial Asthma
Pregabalin	21 Sep 2020 (Study Day -8) - Ongoing	Sciatica
Ibuprofen	06 Oct 2020 (Study Day 8) - Ongoing	Muscle Aches
Ammonium chloride; dextromethorphan hydrobromide; sodium citrate	01 Nov 2020 (Study Day 34) - 24 Nov 2020 (Study Day 57)	COVID-19
Benzonatate	02 Nov 2020 (Study Day 35) - 24 Nov 2020 (Study Day 57)	COVID-19
Dexamethasone	02 Nov 2020 (Study Day 35) - 11 Nov 2020 (Study Day 44)	COVID-19
Salbutamol	02 Nov 2020 (Study Day 35) - 20 Nov 2020 (Study Day 53)	COVID-19
Ibuprofen	09 Nov 2020 (Study Day 42) - 20 Nov 2020 (Study Day 53)	COVID-19
Nitrofurantoin	14 Jan 2021 (Study Day 108) - 18 Jan 2021 (Study Day 112)	Urinary Tract Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 3/severe	Not related	03 Oct 2020 (Study Day 5) - 25 Oct 2020 (Study Day 27)
COVID-19	Grade 3/severe	Not related	31 Oct 2020 (Study Day 33) - 26 Nov 2020 (Study Day 59)
Urinary Tract Infection	Grade 1/mild	Not related	14 Jan 2021 (Study Day 108) - 18 Jan 2021 (Study Day 112)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US326-2007 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	25 Aug 2020 (Study Day 30)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic Rt-Pcr Confirmed COVID Infection	COVID-19	Grade 2/ moderate	Not related	30 Nov 2020 (Study Day 127) – 13 Dec 2020 (Study Day 140)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US326-2007, a 62-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 25 Aug 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 30 Nov 2020 (Study Day 127), 126 days after the first dose and 97 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic rt-pcr confirmed COVID infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 25 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 30 Nov 2020 (Study Day 127), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
30 Nov 2020 (Study Day 127)	Body Aches	Moderate
30 Nov 2020 (Study Day 127)	Chills	Moderate
30 Nov 2020 (Study Day 127)	Cough	Mild
30 Nov 2020 (Study Day 127)	Fatigue	Moderate
30 Nov 2020 (Study Day 127)	Headache	Mild

Symptom Date	Symptom	Result
30 Nov 2020 (Study Day 127)	Muscle Aches (Myalgia)	Moderate
30 Nov 2020 (Study Day 127)	Nausea	Mild
30 Nov 2020 (Study Day 127)	Temperature (°F)	102.0
01 Dec 2020 (Study Day 128)	Body Aches	Mild
01 Dec 2020 (Study Day 128)	Cough	Mild
01 Dec 2020 (Study Day 128)	Fatigue	Mild
01 Dec 2020 (Study Day 128)	Muscle Aches (Myalgia)	Mild
02 Dec 2020 (Study Day 129)	Cough	Mild
03 Dec 2020 (Study Day 130)	Cough	Mild
03 Dec 2020 (Study Day 130)	O2 Saturation (%)	93
03 Dec 2020 (Study Day 130)	Shortness of Breath	Mild
04 Dec 2020 (Study Day 131)	O2 Saturation (%)	93
04 Dec 2020 (Study Day 131)	Shortness of Breath	Mild
05 Dec 2020 (Study Day 132)	O2 Saturation (%)	93
05 Dec 2020 (Study Day 132)	Shortness of Breath	Mild
06 Dec 2020 (Study Day 133)	Shortness of Breath	Mild
07 Dec 2020 (Study Day 134)	Shortness of Breath	Mild
08 Dec 2020 (Study Day 135)	Shortness of Breath	Mild
09 Dec 2020 (Study Day 136)	Shortness of Breath	Mild
10 Dec 2020 (Study Day 137)	Shortness of Breath	Mild
11 Dec 2020 (Study Day 138)	Shortness of Breath	Mild
12 Dec 2020 (Study Day 139)	Shortness of Breath	Mild
13 Dec 2020 (Study Day 140)	Shortness of Breath	Mild
14 Dec 2020 (Study Day 141)	Shortness of Breath	Mild
15 Dec 2020 (Study Day 142)	Shortness of Breath	Mild
16 Dec 2020 (Study Day 143)	Shortness of Breath	Mild
17 Dec 2020 (Study Day 144)	Shortness of Breath	Mild
18 Dec 2020 (Study Day 145)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 146)	Shortness of Breath	Mild
20 Dec 2020 (Study Day 147)	Shortness of Breath	Mild
21 Dec 2020 (Study Day 148)	Shortness of Breath	Mild
22 Dec 2020 (Study Day 149)	Shortness of Breath	Mild
23 Dec 2020 (Study Day 150)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 151)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 152)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 153)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
03 Dec 2020 (Study Day 130)	Oxygen Saturation	93%

Dates	Severity Indication	Result
03 Dec 2020 - 05 Dec 2020 (Study Day 130-132)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic rt-pcr confirmed COVID infection lasted for 14 days, after which it was considered to be recovered/resolved on 13 Dec 2020 (Study Day 140). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000999	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2007 - Ongoing
Hypertension	Hypertension	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2007 - Ongoing	Type 2 Diabetes
Lisinopril	2014 - Ongoing	Hypertension
Dulaglutide	Feb 2020 - 20 Feb 2021 (Study Day 209)	Type 2 Diabetes
Amoxicillin	13 Jan 2021 (Study Day 171) - 20 Jan 2021 (Study Day 178)	Pneumonia
Azithromycin	13 Jan 2021 (Study Day 171) - 18 Jan 2021 (Study Day 176)	Pneumonia
Atorvastatin	Feb 2021 - Ongoing	High Cholesterol Prophylaxis
Dulaglutide	21 Feb 2021 (Study Day 210) - Ongoing	Type Two Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	30 Nov 2020 (Study Day 127) - 13 Dec 2020 (Study Day 140)
Pneumonia	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 171) - 20 Jan 2021 (Study Day 178)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US326-2099 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 30)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic Confirmed COVID Positive Infection	COVID-19	Grade 2/ moderate	Not related	12 Oct 2020 (Study Day 69) – 18 Nov 2020 (Study Day 106)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US326-2099, a 61-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 12 Oct 2020 (Study Day 69), 68 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic confirmed COVID positive infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 03 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 12 Oct 2020 (Study Day 69), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

On 09 Nov 2020 (Study Day 97), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
12 Oct 2020 (Study Day 69)	Body Aches	Moderate

Symptom Date	Symptom	Result
12 Oct 2020 (Study Day 69)	Cough	Moderate
12 Oct 2020 (Study Day 69)	Fatigue	Moderate
12 Oct 2020 (Study Day 69)	Muscle Aches (Myalgia)	Moderate
13 Oct 2020 (Study Day 70)	Body Aches	Moderate
13 Oct 2020 (Study Day 70)	Cough	Moderate
13 Oct 2020 (Study Day 70)	Fatigue	Moderate
13 Oct 2020 (Study Day 70)	Muscle Aches (Myalgia)	Moderate
16 Oct 2020 (Study Day 73)	Body Aches	Moderate
16 Oct 2020 (Study Day 73)	Cough	Moderate
16 Oct 2020 (Study Day 73)	Fatigue	Moderate
16 Oct 2020 (Study Day 73)	Muscle Aches (Myalgia)	Moderate
16 Oct 2020 (Study Day 73)	O2 Saturation (%)	93
17 Oct 2020 (Study Day 74)	Body Aches	Moderate
17 Oct 2020 (Study Day 74)	Cough	Moderate
17 Oct 2020 (Study Day 74)	Fatigue	Moderate
17 Oct 2020 (Study Day 74)	Muscle Aches (Myalgia)	Moderate
18 Oct 2020 (Study Day 75)	Body Aches	Moderate
18 Oct 2020 (Study Day 75)	Cough	Moderate
18 Oct 2020 (Study Day 75)	Fatigue	Moderate
18 Oct 2020 (Study Day 75)	Muscle Aches (Myalgia)	Moderate
19 Oct 2020 (Study Day 76)	Body Aches	Moderate
19 Oct 2020 (Study Day 76)	Cough	Moderate
19 Oct 2020 (Study Day 76)	Fatigue	Moderate
19 Oct 2020 (Study Day 76)	Muscle Aches (Myalgia)	Moderate
20 Oct 2020 (Study Day 77)	Body Aches	Mild
20 Oct 2020 (Study Day 77)	Cough	Moderate
20 Oct 2020 (Study Day 77)	Fatigue	Mild
20 Oct 2020 (Study Day 77)	Muscle Aches (Myalgia)	Mild
21 Oct 2020 (Study Day 78)	Body Aches	Mild
21 Oct 2020 (Study Day 78)	Cough	Moderate
21 Oct 2020 (Study Day 78)	Fatigue	Mild
21 Oct 2020 (Study Day 78)	Muscle Aches (Myalgia)	Mild
22 Oct 2020 (Study Day 79)	Body Aches	Mild
22 Oct 2020 (Study Day 79)	Cough	Moderate
22 Oct 2020 (Study Day 79)	Fatigue	Mild
22 Oct 2020 (Study Day 79)	Muscle Aches (Myalgia)	Mild
23 Oct 2020 (Study Day 80)	Body Aches	Mild
23 Oct 2020 (Study Day 80)	Cough	Moderate
23 Oct 2020 (Study Day 80)	Fatigue	Mild
23 Oct 2020 (Study Day 80)	Muscle Aches (Myalgia)	Mild
23 Oct 2020 (Study Day 80)	O2 Saturation (%)	93
24 Oct 2020 (Study Day 81)	Body Aches	Mild
24 Oct 2020 (Study Day 81)	Cough	Moderate

Symptom Date	Symptom	Result
24 Oct 2020 (Study Day 81)	Fatigue	Mild
24 Oct 2020 (Study Day 81)	Muscle Aches (Myalgia)	Mild
25 Oct 2020 (Study Day 82)	Body Aches	Mild
25 Oct 2020 (Study Day 82)	Cough	Moderate
25 Oct 2020 (Study Day 82)	Fatigue	Mild
25 Oct 2020 (Study Day 82)	Muscle Aches (Myalgia)	Mild
26 Oct 2020 (Study Day 83)	Body Aches	Mild
26 Oct 2020 (Study Day 83)	Cough	Moderate
26 Oct 2020 (Study Day 83)	Fatigue	Mild
26 Oct 2020 (Study Day 83)	Muscle Aches (Myalgia)	Mild
27 Oct 2020 (Study Day 84)	Body Aches	Mild
27 Oct 2020 (Study Day 84)	Cough	Moderate
27 Oct 2020 (Study Day 84)	Fatigue	Mild
27 Oct 2020 (Study Day 84)	Muscle Aches (Myalgia)	Mild
28 Oct 2020 (Study Day 85)	Body Aches	Mild
28 Oct 2020 (Study Day 85)	Cough	Moderate
28 Oct 2020 (Study Day 85)	Fatigue	Mild
28 Oct 2020 (Study Day 85)	Muscle Aches (Myalgia)	Mild
29 Oct 2020 (Study Day 86)	Body Aches	Mild
29 Oct 2020 (Study Day 86)	Cough	Moderate
29 Oct 2020 (Study Day 86)	Fatigue	Mild
29 Oct 2020 (Study Day 86)	Muscle Aches (Myalgia)	Mild
30 Oct 2020 (Study Day 87)	Body Aches	Mild
30 Oct 2020 (Study Day 87)	Cough	Moderate
30 Oct 2020 (Study Day 87)	Fatigue	Mild
30 Oct 2020 (Study Day 87)	Muscle Aches (Myalgia)	Mild
31 Oct 2020 (Study Day 88)	Body Aches	Mild
31 Oct 2020 (Study Day 88)	Cough	Moderate
31 Oct 2020 (Study Day 88)	Fatigue	Mild
31 Oct 2020 (Study Day 88)	Muscle Aches (Myalgia)	Mild
01 Nov 2020 (Study Day 89)	Body Aches	Mild
01 Nov 2020 (Study Day 89)	Cough	Moderate
01 Nov 2020 (Study Day 89)	Fatigue	Mild
01 Nov 2020 (Study Day 89)	Muscle Aches (Myalgia)	Mild
02 Nov 2020 (Study Day 90)	Body Aches	Mild
02 Nov 2020 (Study Day 90)	Cough	Moderate
02 Nov 2020 (Study Day 90)	Fatigue	Mild
02 Nov 2020 (Study Day 90)	Muscle Aches (Myalgia)	Mild
03 Nov 2020 (Study Day 91)	Cough	Moderate
03 Nov 2020 (Study Day 91)	Fatigue	Mild
04 Nov 2020 (Study Day 92)	Cough	Moderate
04 Nov 2020 (Study Day 92)	Fatigue	Mild
05 Nov 2020 (Study Day 93)	Cough	Moderate

Symptom Date	Symptom	Result
05 Nov 2020 (Study Day 93)	Fatigue	Mild
06 Nov 2020 (Study Day 94)	Cough	Moderate
06 Nov 2020 (Study Day 94)	Fatigue	Mild
07 Nov 2020 (Study Day 95)	Cough	Moderate
07 Nov 2020 (Study Day 95)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
16 Oct 2020 (Study Day 73)	Oxygen Saturation	93%
16 Oct 2020 - 23 Oct 2020 (Study Day 73-80)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic confirmed COVID positive infection lasted for 38 days, after which it was considered to be recovered/resolved on 18 Nov 2020 (Study Day 106). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000482	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	1999 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Cough	Chronic intermittent cough	2018 - Ongoing
Obesity	Obesity	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Methylphenidate hydrochloride	1999 - Ongoing	Attention Deficit Hyperactivity Disorder
Losartan	2015 - Ongoing	Hypertension
Nebivolol	2015 - Ongoing	Hypertension
Metformin	2018 - Ongoing	Type Ii Diabetes Prophylaxis
Amlodipine	2019 - Ongoing	Hypertension
Methylprednisolone	20 Oct 2020 (Study Day 77) - 20 Oct 2020 (Study Day 77)	Symptomatic Confirmed COVID Positive Infection
Methylprednisolone	21 Oct 2020 (Study Day 78) - 21 Oct 2020 (Study Day 78)	Symptomatic Confirmed COVID Positive Infection
Methylprednisolone	22 Oct 2020 (Study Day 79) - 22 Oct 2020 (Study Day 79)	Symptomatic Confirmed COVID Positive Infection
Methylprednisolone	23 Oct 2020 (Study Day 80) - 23 Oct 2020 (Study Day 80)	Symptomatic Confirmed COVID Positive Infection
Methylprednisolone	24 Oct 2020 (Study Day 81) - 24 Oct 2020 (Study Day 81)	Symptomatic Confirmed COVID Positive Infection
Methylprednisolone	25 Oct 2020 (Study Day 82) - 25 Oct 2020 (Study Day 82)	Symptomatic Confirmed COVID Positive Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 69) - 18 Nov 2020 (Study Day 106)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US326-2145 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	05 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic Rt-Pcr Conformed COVID19 Infection	SAE, COVID-19	Grade 3/severe	Not related	14 Dec 2020 (Study Day 129) – 29 Dec 2020 (Study Day 144)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US326-2145, a 56-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 05 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 14 Dec 2020 (Study Day 129), 128 days after the first dose and 100 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of symptomatic rt-pcr conformed COVID19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 05 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 14 Dec 2020 (Study Day 129), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
14 Dec 2020 (Study Day 129)	Chills	Moderate
14 Dec 2020 (Study Day 129)	Cough	Mild
14 Dec 2020 (Study Day 129)	Headache	Mild

Symptom Date	Symptom	Result
14 Dec 2020 (Study Day 129)	Temperature (°F)	38.9
15 Dec 2020 (Study Day 130)	Cough	Mild
15 Dec 2020 (Study Day 130)	Headache	Mild
15 Dec 2020 (Study Day 130)	O2 Saturation (%)	93
15 Dec 2020 (Study Day 130)	Temperature (°F)	102.2
16 Dec 2020 (Study Day 131)	Cough	Mild
16 Dec 2020 (Study Day 131)	Headache	Mild
16 Dec 2020 (Study Day 131)	O2 Saturation (%)	93
17 Dec 2020 (Study Day 132)	Cough	Moderate
17 Dec 2020 (Study Day 132)	O2 Saturation (%)	93
17 Dec 2020 (Study Day 132)	Temperature (°F)	100.6
18 Dec 2020 (Study Day 133)	Cough	Moderate
18 Dec 2020 (Study Day 133)	O2 Saturation (%)	93
19 Dec 2020 (Study Day 134)	Cough	Moderate
19 Dec 2020 (Study Day 134)	Difficulty Breathing	Severe
19 Dec 2020 (Study Day 134)	O2 Saturation (%)	91
19 Dec 2020 (Study Day 134)	Shortness of Breath	Severe
19 Dec 2020 (Study Day 134)	Temperature (°F)	101
20 Dec 2020 (Study Day 135)	Cough	Moderate
20 Dec 2020 (Study Day 135)	O2 Saturation (%)	93
20 Dec 2020 (Study Day 135)	Shortness of Breath	Moderate
21 Dec 2020 (Study Day 136)	Cough	Moderate
21 Dec 2020 (Study Day 136)	O2 Saturation (%)	93
21 Dec 2020 (Study Day 136)	Shortness of Breath	Mild
22 Dec 2020 (Study Day 137)	Cough	Moderate
22 Dec 2020 (Study Day 137)	O2 Saturation (%)	92
22 Dec 2020 (Study Day 137)	Shortness of Breath	Mild
23 Dec 2020 (Study Day 138)	Cough	Moderate
23 Dec 2020 (Study Day 138)	O2 Saturation (%)	93
23 Dec 2020 (Study Day 138)	Shortness of Breath	Mild
24 Dec 2020 (Study Day 139)	Cough	Moderate
24 Dec 2020 (Study Day 139)	O2 Saturation (%)	92
25 Dec 2020 (Study Day 140)	Cough	Moderate
25 Dec 2020 (Study Day 140)	O2 Saturation (%)	93
26 Dec 2020 (Study Day 141)	Cough	Moderate
26 Dec 2020 (Study Day 141)	O2 Saturation (%)	93
27 Dec 2020 (Study Day 142)	Cough	Mild
28 Dec 2020 (Study Day 143)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
15 Dec 2020 (Study Day 130)	Oxygen Saturation	91%
15 Dec 2020 - 26 Dec 2020 (Study Day 130-141)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
19 Dec 2020 - 25 Dec 2020 (Study Day 134-140)	High-Flow Oxygen	Yes

Action taken with the IP was not applicable. The event of symptomatic rt-pcr conformed COVID-19 infection lasted for 16 days, after which it was considered to be recovered/resolved on 29 Dec 2020 (Study Day 144). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001221	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dyslipidaemia	Dyslipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Anxiety	Anxiety	2015 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardio Protective
Atorvastatin	2010 - Ongoing	Dyslipidemia
Bupropion	2015 - Ongoing	Anxiety
Metoprolol	2015 - Ongoing	Hypertension
Metformin	2018 - Ongoing	Type 2 Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azithromycin	19 Dec 2019 (Study Day -233) - 24 Dec 2020 (Study Day 139)	Symptomatic Rt Pcr Confirmed COVID 19 Infection
Ceftriaxone	19 Dec 2020 (Study Day 134) - 24 Dec 2020 (Study Day 139)	Symptomatic Rt Pcr Confirmed COVID 19 Infection
Chest ap portable*	19 Dec 2020 (Study Day 134) - 19 Dec 2020 (Study Day 134)	Adverse Event
Oxygen	19 Dec 2020 (Study Day 134) - 24 Dec 2020 (Study Day 139)	Symptomatic Rt Pcr Confirmed COVID19 Infection
Remdesivir	20 Dec 2020 (Study Day 135) - 24 Dec 2020 (Study Day 139)	Severe Symptomatic COVID19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Induration	Grade 1/mild	Related	15 Aug 2020 (Study Day 8) - 16 Aug 2020 (Study Day 9)
Myalgia	Grade 2/moderate	Related	07 Sep 2020 (Study Day 31) - 13 Sep 2020 (Study Day 37)
Fatigue	Grade 1/mild	Not related	12 Sep 2020 (Study Day 36) - 13 Sep 2020 (Study Day 37)
Headache	Grade 1/mild	Not related	12 Sep 2020 (Study Day 36) - 13 Sep 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US326-2275 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	09 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	10 Nov 2020 (Study Day 33)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic Pcr Confirmed COVID Infection	COVID-19	Grade 2/ moderate	Not related	28 Jan 2021 (Study Day 112) – 09 Feb 2021 (Study Day 124)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US326-2275, a 24-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 09 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 10 Nov 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 28 Jan 2021 (Study Day 112), 111 days after the first dose and 79 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic pcr confirmed COVID infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 33, 10 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Jan 2021 (Study Day 112), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
28 Jan 2021 (Study Day 112)	Body Aches	Moderate
28 Jan 2021 (Study Day 112)	Cough	Moderate
28 Jan 2021 (Study Day 112)	Fatigue	Moderate
28 Jan 2021 (Study Day 112)	Headache	Moderate
28 Jan 2021 (Study Day 112)	Muscle Aches (Myalgia)	Moderate

Symptom Date	Symptom	Result
28 Jan 2021 (Study Day 112)	Temperature (°F)	100.7
29 Jan 2021 (Study Day 113)	Cough	Mild
29 Jan 2021 (Study Day 113)	Fatigue	Moderate
29 Jan 2021 (Study Day 113)	Headache	Mild
29 Jan 2021 (Study Day 113)	New Loss of Taste	Moderate
30 Jan 2021 (Study Day 114)	Cough	Mild
30 Jan 2021 (Study Day 114)	Fatigue	Mild
30 Jan 2021 (Study Day 114)	New Loss of Taste	Moderate
31 Jan 2021 (Study Day 115)	Cough	Mild
31 Jan 2021 (Study Day 115)	Fatigue	Mild
31 Jan 2021 (Study Day 115)	New Loss of Taste	Moderate
31 Jan 2021 (Study Day 115)	O2 Saturation (%)	93
01 Feb 2021 (Study Day 116)	Cough	Mild
01 Feb 2021 (Study Day 116)	Fatigue	Mild
01 Feb 2021 (Study Day 116)	New Loss of Taste	Moderate
02 Feb 2021 (Study Day 117)	Body Aches	Moderate
02 Feb 2021 (Study Day 117)	Muscle Aches (Myalgia)	Moderate
02 Feb 2021 (Study Day 117)	New Loss of Taste	Moderate
03 Feb 2021 (Study Day 118)	Body Aches	Moderate
03 Feb 2021 (Study Day 118)	Muscle Aches (Myalgia)	Moderate
03 Feb 2021 (Study Day 118)	New Loss of Taste	Moderate
04 Feb 2021 (Study Day 119)	Body Aches	Moderate
04 Feb 2021 (Study Day 119)	Muscle Aches (Myalgia)	Moderate
04 Feb 2021 (Study Day 119)	New Loss of Taste	Moderate
05 Feb 2021 (Study Day 120)	New Loss of Taste	Moderate
06 Feb 2021 (Study Day 121)	New Loss of Taste	Moderate
07 Feb 2021 (Study Day 122)	New Loss of Taste	Moderate
08 Feb 2021 (Study Day 123)	New Loss of Taste	Moderate
09 Feb 2021 (Study Day 124)	New Loss of Taste	Moderate
10 Feb 2021 (Study Day 125)	New Loss of Taste	Moderate
11 Feb 2021 (Study Day 126)	New Loss of Taste	Moderate
12 Feb 2021 (Study Day 127)	New Loss of Taste	Moderate
13 Feb 2021 (Study Day 128)	New Loss of Taste	Moderate
14 Feb 2021 (Study Day 129)	New Loss of Taste	Moderate
15 Feb 2021 (Study Day 130)	New Loss of Taste	Moderate
16 Feb 2021 (Study Day 131)	New Loss of Taste	Moderate
17 Feb 2021 (Study Day 132)	New Loss of Taste	Moderate
18 Feb 2021 (Study Day 133)	New Loss of Taste	Moderate
19 Feb 2021 (Study Day 134)	New Loss of Taste	Moderate
20 Feb 2021 (Study Day 135)	New Loss of Taste	Moderate
21 Feb 2021 (Study Day 136)	New Loss of Taste	Mild
22 Feb 2021 (Study Day 137)	New Loss of Taste	Mild
23 Feb 2021 (Study Day 138)	New Loss of Taste	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
31 Jan 2021 (Study Day 115)	Oxygen Saturation	93%
31 Jan 2021 - 31 Jan 2021 (Study Day 115-115)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic pcr confirmed COVID infection lasted for 13 days, after which it was considered to be recovered/resolved on 09 Feb 2021 (Study Day 124). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-027069	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Emtricitabine; tenofovir disoproxil	2018 - Ongoing	Prophylaxis For Hiv
Lisinopril	2019 - Ongoing	Hypertension
Ibuprofen	11 Mar 2021 (Study Day 154) - 12 Mar 2021 (Study Day 155)	Headache Body Ache
Ibuprofen	12 Mar 2021 (Study Day 155) - 13 Mar 2021 (Study Day 156)	Headache Body Ache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	28 Jan 2021 (Study Day 112) - 09 Feb 2021 (Study Day 124)
Chills	Grade 2/moderate	Related	10 Mar 2021 (Study Day 153) - 12 Mar 2021 (Study Day 155)
Fatigue	Grade 2/moderate	Related	10 Mar 2021 (Study Day 153) - 12 Mar 2021 (Study Day 155)
Headache	Grade 2/moderate	Related	10 Mar 2021 (Study Day 153) - 12 Mar 2021 (Study Day 155)
Pain	Grade 1/mild	Related	10 Mar 2021 (Study Day 153) - 12 Mar 2021 (Study Day 155)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2026 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 39)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID19	SAE, COVID-19	Grade 4	Not related	08 Nov 2020 (Study Day 100) – 29 Dec 2020 (Study Day 151)	Recovered/ resolved with sequelae
Acute Respiratory Distress Syndrome/ Adult Respiratory Distress Syndrome	SAE	Grade 4	Not related	16 Nov 2020 (Study Day 108) – 20 Jan 2021 (Study Day 173)	Recovered/ resolved with sequelae
Acute Respiratory Failure/ Acute Respiratory Failure	SAE	Grade 4	Not related	16 Nov 2020 (Study Day 108) – 20 Jan 2021 (Study Day 173)	Recovered/ resolved with sequelae
Pneumonia/Multifocal Pneumonia	SAE	Grade 4	Not related	16 Nov 2020 (Study Day 108) – 11 Feb 2021 (Study Day 195)	Recovered/ resolved with sequelae
Cytokine Storm/Cytokine Storm	SAE	Grade 4	Not related	28 Nov 2020 (Study Day 120) – 20 Jan 2021 (Study Day 173)	Recovered/ resolved
Pneumonia Bacterial/ Pseudomonas Aeruginosa, Pneumonia, Bilateral, Ventilator-Associated Pneumonia	SAE	Grade 4	Not related	04 Dec 2020 (Study Day 126) – 23 Dec 2020 (Study Day 145)	Recovered/ resolved
Thrombocytopenia/ Thrombocytopenia	SAE	Grade 4	Not related	09 Dec 2020 (Study Day 131) – 01 Jan 2021 (Study Day 154)	Recovered/ resolved
Enterococcal Bacteraemia/Vancomycin Resistant Enterococcus Bacteremia	SAE	Grade 4	Not related	01 Jan 2021 (Study Day 154) – 19 Jan 2021 (Study Day 172)	Recovered/ resolved
Tracheal Haemorrhage/Tracheal Hemorrhage	SAE	Grade 4	Not related	20 Jan 2021 (Study Day 173) – 21 Jan 2021 (Study Day 174)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US327-2026, a 46-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Aug 2020 (Study Day 1). The second dose was administered in the

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left arm on 08 Sep 2020 (Study Day 39). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Nov 2020 (Study Day 108), 107 days after the first dose and 69 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute respiratory distress syndrome. Action taken with the IP was not applicable. The event of adult respiratory distress syndrome lasted for 66 days, after which it was considered to be recovered/resolved with sequelae on 20 Jan 2021 (Study Day 173). The investigator assessed the event of acute respiratory distress syndrome to be not related to the IP.

On 16 Nov 2020 (Study Day 108), 107 days after the first dose and 69 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute respiratory failure lasted for 66 days, after which it was considered to be recovered/resolved with sequelae on 20 Jan 2021 (Study Day 173). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 16 Nov 2020 (Study Day 108), 107 days after the first dose and 69 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of multifocal pneumonia lasted for 88 days, after which it was considered to be recovered/resolved with sequelae on 11 Feb 2021 (Study Day 195). The investigator assessed the event of pneumonia to be not related to the IP.

On 28 Nov 2020 (Study Day 120), 119 days after the first dose and 81 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cytokine storm. Action taken with the IP was not applicable. The event of cytokine storm lasted for 54 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 173). The investigator assessed the event of cytokine storm to be not related to the IP.

On 04 Dec 2020 (Study Day 126), 125 days after the first dose and 87 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia bacterial. Action taken with the IP was not applicable. The event of pseudomonas aeruginosa, pneumonia, bilateral, ventilator-associated pneumonia lasted for 20 days, after which it was considered to be recovered/resolved on 23 Dec 2020 (Study Day 145). The investigator assessed the event of pneumonia bacterial to be not related to the IP.

On 09 Dec 2020 (Study Day 131), 130 days after the first dose and 92 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of thrombocytopenia. Action taken with the IP was not applicable. The event of thrombocytopenia lasted for 24 days, after which

it was considered to be recovered/resolved on 01 Jan 2021 (Study Day 154). The investigator assessed the event of thrombocytopenia to be not related to the IP.

On 01 Jan 2021 (Study Day 154), 153 days after the first dose and 115 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of enterococcal bacteraemia. Action taken with the IP was not applicable. The event of vancomycin resistant enterococcus bacteremia lasted for 19 days, after which it was considered to be recovered/resolved on 19 Jan 2021 (Study Day 172). The investigator assessed the event of enterococcal bacteraemia to be not related to the IP.

On 20 Jan 2021 (Study Day 173), 172 days after the first dose and 134 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of tracheal haemorrhage. Action taken with the IP was not applicable. The event of tracheal hemorrhage lasted for 2 days, after which it was considered to be recovered/resolved on 21 Jan 2021 (Study Day 174). The investigator assessed the event of tracheal haemorrhage to be not related to the IP.

Severe COVID-19 Details

On 08 Nov 2020 (Study Day 100), 99 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of COVID19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 39, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 12 Nov 2020 (Study Day 104), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
08 Nov 2020 (Study Day 100)	Body Aches	Mild
08 Nov 2020 (Study Day 100)	Chills	Mild
08 Nov 2020 (Study Day 100)	Cough	Mild
08 Nov 2020 (Study Day 100)	Difficulty Breathing	Mild
08 Nov 2020 (Study Day 100)	Headache	Mild
09 Nov 2020 (Study Day 101)	Body Aches	Mild
09 Nov 2020 (Study Day 101)	Chills	Mild
09 Nov 2020 (Study Day 101)	Cough	Mild
09 Nov 2020 (Study Day 101)	Difficulty Breathing	Mild
09 Nov 2020 (Study Day 101)	Headache	Mild
10 Nov 2020 (Study Day 102)	Body Aches	Mild
10 Nov 2020 (Study Day 102)	Chills	Mild
10 Nov 2020 (Study Day 102)	Cough	Mild

Symptom Date	Symptom	Result
10 Nov 2020 (Study Day 102)	Difficulty Breathing	Mild
10 Nov 2020 (Study Day 102)	Headache	Mild
11 Nov 2020 (Study Day 103)	Body Aches	Mild
11 Nov 2020 (Study Day 103)	Chills	Mild
11 Nov 2020 (Study Day 103)	Cough	Mild
11 Nov 2020 (Study Day 103)	Difficulty Breathing	Mild
11 Nov 2020 (Study Day 103)	Headache	Mild
12 Nov 2020 (Study Day 104)	Body Aches	Mild
12 Nov 2020 (Study Day 104)	Chills	Mild
12 Nov 2020 (Study Day 104)	Cough	Moderate
12 Nov 2020 (Study Day 104)	Fatigue	Mild
12 Nov 2020 (Study Day 104)	Headache	Mild
13 Nov 2020 (Study Day 105)	Chills	Mild
13 Nov 2020 (Study Day 105)	Cough	Moderate
13 Nov 2020 (Study Day 105)	Headache	Mild
14 Nov 2020 (Study Day 106)	Chills	Moderate
14 Nov 2020 (Study Day 106)	Cough	Moderate
14 Nov 2020 (Study Day 106)	Shortness of Breath	Mild
14 Nov 2020 (Study Day 106)	Temperature (°F)	101.5
15 Nov 2020 (Study Day 107)	Cough	Moderate
15 Nov 2020 (Study Day 107)	Shortness of Breath	Mild
16 Nov 2020 (Study Day 108)	Body Aches	Moderate
16 Nov 2020 (Study Day 108)	Chills	Severe
16 Nov 2020 (Study Day 108)	Cough	Moderate
16 Nov 2020 (Study Day 108)	Difficulty Breathing	Severe
16 Nov 2020 (Study Day 108)	Fatigue	Severe
16 Nov 2020 (Study Day 108)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 108)	O2 Saturation (%)	80
16 Nov 2020 (Study Day 108)	Shortness of Breath	Severe
16 Nov 2020 (Study Day 108)	Temperature (°F)	103.1
17 Nov 2020 (Study Day 109)	Cough	Moderate
17 Nov 2020 (Study Day 109)	Difficulty Breathing	Severe
17 Nov 2020 (Study Day 109)	Shortness of Breath	Severe
18 Nov 2020 (Study Day 110)	Body Aches	Mild
18 Nov 2020 (Study Day 110)	Chills	Mild
18 Nov 2020 (Study Day 110)	Cough	Moderate
18 Nov 2020 (Study Day 110)	Difficulty Breathing	Moderate
18 Nov 2020 (Study Day 110)	Fatigue	Mild
18 Nov 2020 (Study Day 110)	Muscle Aches (Myalgia)	Mild
18 Nov 2020 (Study Day 110)	Shortness of Breath	Moderate
21 Nov 2020 (Study Day 113)	Body Aches	Mild
21 Nov 2020 (Study Day 113)	Cough	Mild
21 Nov 2020 (Study Day 113)	Difficulty Breathing	Mild

Symptom Date	Symptom	Result
21 Nov 2020 (Study Day 113)	Fatigue	Mild
21 Nov 2020 (Study Day 113)	Headache	Mild
21 Nov 2020 (Study Day 113)	Muscle Aches (Myalgia)	Mild
21 Nov 2020 (Study Day 113)	O2 Saturation (%)	90
21 Nov 2020 (Study Day 113)	Shortness of Breath	Mild
22 Nov 2020 (Study Day 114)	Body Aches	Mild
22 Nov 2020 (Study Day 114)	Cough	Moderate
22 Nov 2020 (Study Day 114)	Difficulty Breathing	Moderate
22 Nov 2020 (Study Day 114)	Fatigue	Mild
22 Nov 2020 (Study Day 114)	Headache	Mild
22 Nov 2020 (Study Day 114)	Muscle Aches (Myalgia)	Mild
22 Nov 2020 (Study Day 114)	O2 Saturation (%)	90
22 Nov 2020 (Study Day 114)	Shortness of Breath	Moderate
23 Nov 2020 (Study Day 115)	Cough	Moderate
23 Nov 2020 (Study Day 115)	Diarrhea	Mild
23 Nov 2020 (Study Day 115)	Difficulty Breathing	Moderate
23 Nov 2020 (Study Day 115)	Fatigue	Moderate
23 Nov 2020 (Study Day 115)	O2 Saturation (%)	68
23 Nov 2020 (Study Day 115)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 116)	Cough	Mild
24 Nov 2020 (Study Day 116)	Diarrhea	Mild
24 Nov 2020 (Study Day 116)	Difficulty Breathing	Mild
24 Nov 2020 (Study Day 116)	Fatigue	Mild
24 Nov 2020 (Study Day 116)	O2 Saturation (%)	90
24 Nov 2020 (Study Day 116)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 117)	Cough	Mild
25 Nov 2020 (Study Day 117)	Difficulty Breathing	Mild
25 Nov 2020 (Study Day 117)	Fatigue	Mild
25 Nov 2020 (Study Day 117)	O2 Saturation (%)	81
25 Nov 2020 (Study Day 117)	Shortness of Breath	Mild
26 Nov 2020 (Study Day 118)	Cough	Moderate
26 Nov 2020 (Study Day 118)	Diarrhea	Mild
26 Nov 2020 (Study Day 118)	Difficulty Breathing	Mild
26 Nov 2020 (Study Day 118)	Fatigue	Moderate
26 Nov 2020 (Study Day 118)	Nasal Congestion	Mild
26 Nov 2020 (Study Day 118)	O2 Saturation (%)	64
26 Nov 2020 (Study Day 118)	Shortness of Breath	Mild
27 Nov 2020 (Study Day 119)	Cough	Moderate
27 Nov 2020 (Study Day 119)	Fatigue	Mild
27 Nov 2020 (Study Day 119)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 119)	O2 Saturation (%)	77
27 Nov 2020 (Study Day 119)	Shortness of Breath	Mild
01 Dec 2020 (Study Day 123)	Body Aches	Mild

Symptom Date	Symptom	Result
01 Dec 2020 (Study Day 123)	Cough	Mild
01 Dec 2020 (Study Day 123)	Difficulty Breathing	Moderate
01 Dec 2020 (Study Day 123)	Fatigue	Mild
01 Dec 2020 (Study Day 123)	Muscle Aches (Myalgia)	Mild
01 Dec 2020 (Study Day 123)	Shortness of Breath	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
16 Nov 2020 (Study Day 108)	Oxygen Saturation	64%
16 Nov 2020 - 16 Nov 2020 (Study Day 108-108)	Acute Renal Dysfunction	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 108-108)	Acute Respiratory Distress Syndrome (ARDS)	Yes
16 Nov 2020 - 12 Feb 2021 (Study Day 108-196)	Admission to an intensive care unit due to SARS-CoV-2	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 108-108)	Clinical Evidence of Pneumonia	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 108-108)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 108-108)	Radiographical Evidence of Pneumonia	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 108-108)	Respiratory Failure	Yes
28 Nov 2020 - 25 Jan 2021 (Study Day 120-178)	Mechanical Ventilation	Yes
30 Nov 2020 - 30 Nov 2020 (Study Day 122-122)	Neurologic Dysfunction	Yes
01 Dec 2020 - 01 Jan 2021 (Study Day 123-154)	ECMO	Yes

Action taken with the IP was not applicable. The event of COVID19 lasted for 52 days, after which it was considered to be recovered/resolved with sequelae on 29 Dec 2020 (Study Day 151). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000812	COVID-19
MOD-2020-000812	Acute respiratory distress syndrome
MOD-2020-000812	Acute respiratory failure
MOD-2020-000812	Pneumonia
MOD-2020-000812	Cytokine storm
MOD-2020-000812	Pneumonia bacterial

CIOMS Number	MedDRA Preferred Term
MOD-2020-000812	Thrombocytopenia
MOD-2020-000812	Enterococcal bacteraemia
MOD-2020-000812	Tracheal haemorrhage

Study Completion/Discontinuation

On 25 Mar 2021 (Study Day 237), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	2002 - 2002
Acrochordon	Bilateral axillary skin tags	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine	2013 - Ongoing	Seasonal Allergies
Azithromycin	16 Nov 2020 (Study Day 108) - 24 Nov 2020 (Study Day 116)	Multifocal Pneumonia
Benzonatate	16 Nov 2020 (Study Day 108) - 20 Jan 2021 (Study Day 173)	COVID-19
Bipap initiated*	16 Nov 2020 (Study Day 108) - 16 Nov 2020 (Study Day 108)	Adverse Event
Codeine; promethazine	16 Nov 2020 (Study Day 108) - 01 Dec 2020 (Study Day 123)	COVID-19
Dexamethasone	16 Nov 2020 (Study Day 108) - 20 Jan 2021 (Study Day 173)	Acute Respiratory Failure
Dexamethasone	16 Nov 2020 (Study Day 108) - Ongoing	COVID-19
Guaifenesin	16 Nov 2020 (Study Day 108) - Ongoing	COVID-19
Ipratropium bromide; salbutamol sulfate	16 Nov 2020 (Study Day 108) - 24 Nov 2020 (Study Day 116)	COVID-19, Acute Respiratory Failure With Hypoxia, Ards, Acute Encephalopathy
Paracetamol	16 Nov 2020 (Study Day 108) - 20 Jan 2021 (Study Day 173)	COVID-19
Piperacillin; tazobactam	16 Nov 2020 (Study Day 108) - 16 Nov 2020 (Study Day 108)	Multifocal Pneumonia
Prednisone	16 Nov 2020 (Study Day 108) - 16 Nov 2020 (Study Day 108)	Multifocal Pneumonia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Remdesivir	16 Nov 2020 (Study Day 108) - 21 Nov 2020 (Study Day 113)	COVID 19
Salbutamol sulfate	16 Nov 2020 (Study Day 108) - Ongoing	COVID-19
Salbutamol sulfate	16 Nov 2020 (Study Day 108) - 20 Jan 2021 (Study Day 173)	COVID-19
Sodium chloride	16 Nov 2020 (Study Day 108) - 17 Nov 2020 (Study Day 109)	Acute Kidney Injury
Specific immunoglobulins	16 Nov 2020 (Study Day 108) - 16 Nov 2020 (Study Day 108)	COVID-19
Ceftriaxone	17 Nov 2020 (Study Day 109) - 24 Nov 2020 (Study Day 116)	Multifocal Pneumonia
Enoxaparin	17 Nov 2020 (Study Day 109) - 01 Dec 2020 (Study Day 123)	Dvt Prophylaxis
Furosemide	17 Nov 2020 (Study Day 109) - 18 Nov 2020 (Study Day 110)	Acute Hypoxic Respiratory Failure Secondary To Ards From COVID 19
Lorazepam	17 Nov 2020 (Study Day 109) - 20 Jan 2021 (Study Day 173)	COVID-19
Midline placement, single lumen*	17 Nov 2020 (Study Day 109) - 17 Nov 2020 (Study Day 109)	Adverse Event
Furosemide	18 Nov 2020 (Study Day 110) - 20 Jan 2021 (Study Day 173)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome, COVID-19
Macrogol	20 Nov 2020 (Study Day 112) - Ongoing	Constipation
Dextromethorphan hydrobromide; guaifenesin	22 Nov 2020 (Study Day 114) - 01 Dec 2020 (Study Day 123)	COVID-19
Fluticasone propionate	22 Nov 2020 (Study Day 114) - 01 Dec 2020 (Study Day 123)	COVID-19
Ruxolitinib phosphate	24 Nov 2020 (Study Day 116) - 01 Dec 2020 (Study Day 123)	COVID 19
Cefepime	25 Nov 2020 (Study Day 117) - 27 Nov 2020 (Study Day 119)	Multifocal Pneumonia
Dexmedetomidine	26 Nov 2020 (Study Day 118) - 13 Jan 2021 (Study Day 166)	COVID-19
Meropenem	26 Nov 2020 (Study Day 118) - 03 Dec 2020 (Study Day 125)	Superimposed Bacterial Infection Secondary To COVID-19
Ascorbic acid	27 Nov 2020 (Study Day 119) - Ongoing	COVID-19
Thiamine	27 Nov 2020 (Study Day 119) - 01 Dec 2020 (Study Day 123)	COVID-19
Vitamin d nos	27 Nov 2020 (Study Day 119) - Ongoing	COVID-19
Zinc sulfate	27 Nov 2020 (Study Day 119) - Ongoing	COVID-19
Arterial line, right arm*	28 Nov 2020 (Study Day 120) - 28 Nov 2020 (Study Day 120)	Adverse Event
Foley catheter placed*	28 Nov 2020 (Study Day 120) - 28 Nov 2020 (Study Day 120)	Adverse Event
Intubated*	28 Nov 2020 (Study Day 120) - 28 Nov 2020 (Study Day 120)	Adverse Event
Meropenem trihydrate	28 Nov 2020 (Study Day 120) - 03 Dec 2020 (Study Day 125)	Adult Respiratory Distress Syndrome
Morphine sulfate	28 Nov 2020 (Study Day 120) - 28 Nov 2020 (Study Day 120)	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Orogastric tube insertion*	28 Nov 2020 (Study Day 120) - 28 Nov 2020 (Study Day 120)	Adverse Event
Paraffin	28 Nov 2020 (Study Day 120) - 20 Jan 2021 (Study Day 173)	COVID-19
Propofol	28 Nov 2020 (Study Day 120) - 20 Jan 2021 (Study Day 173)	COVID-19
Tube feeding*	28 Nov 2020 (Study Day 120) - 28 Nov 2020 (Study Day 120)	Adverse Event
Vancomycin	28 Nov 2020 (Study Day 120) - 29 Dec 2020 (Study Day 151)	Superimposed Bacterial Infection Secondary To COVID-19 Illness
Cisatracurium besilate	29 Nov 2020 (Study Day 121) - 20 Jan 2021 (Study Day 173)	COVID-19
Epoprostenol	29 Nov 2020 (Study Day 121) - 29 Nov 2020 (Study Day 121)	COVID-19
Fentanyl	29 Nov 2020 (Study Day 121) - 20 Jan 2021 (Study Day 173)	COVID-19
Midazolam	29 Nov 2020 (Study Day 121) - 20 Jan 2021 (Study Day 173)	COVID-19
Norepinephrine	29 Nov 2020 (Study Day 121) - 29 Nov 2020 (Study Day 121)	COVID-19
Famotidine	30 Nov 2020 (Study Day 122) - 20 Jan 2021 (Study Day 173)	Gastroesophageal Reflux Disease
Bisacodyl	01 Dec 2020 (Study Day 123) - 20 Jan 2021 (Study Day 173)	Constipation
Chlorhexidine	01 Dec 2020 (Study Day 123) - 28 Jan 2021 (Study Day 181)	Prophylaxis For Prevention Of Oral Candidiasis
Dexamethasone	01 Dec 2020 (Study Day 123) - 11 Dec 2020 (Study Day 133)	Adult Respiratory Distress Syndrome
Docusate	01 Dec 2020 (Study Day 123) - Ongoing	Constipation
Heparin	01 Dec 2020 (Study Day 123) - Ongoing	Dvt Prophylaxis Secondary To Hospitalization Secondary To COVID-19
Hydralazine	01 Dec 2020 (Study Day 123) - 21 Jan 2021 (Study Day 174)	Hypertension
Ipratropium bromide; salbutamol sulfate	01 Dec 2020 (Study Day 123) - 20 Jan 2021 (Study Day 173)	Adult Respiratory Distress Syndrome
Ipratropium bromide; salbutamol sulfate	01 Dec 2020 (Study Day 123) - Ongoing	COVID-19, Adult Respiratory Distress Syndrome
Paracetamol	01 Dec 2020 (Study Day 123) - Ongoing	COVID-19
Albumin human	02 Dec 2020 (Study Day 124) - 31 Dec 2020 (Study Day 153)	Altered Fluid Status Secondary To Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome
Femoral-femoral veno-venous extracorporeal membrane machine catheterization.*	02 Dec 2020 (Study Day 124) - 02 Dec 2020 (Study Day 124)	Adverse Event
Insulin lispro	02 Dec 2020 (Study Day 124) - 28 Dec 2020 (Study Day 150)	Steroid-Induced Hyperglycemia
Nicardipine	02 Dec 2020 (Study Day 124) - 02 Dec 2020 (Study Day 124)	COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bronchoscopy*	04 Dec 2020 (Study Day 126) - 04 Dec 2020 (Study Day 126)	Adverse Event
Fentanyl	05 Dec 2020 (Study Day 127) - 28 Dec 2020 (Study Day 150)	Extracorporeal Membranous Oxygenation
Potassium chloride	05 Dec 2020 (Study Day 127) - 20 Jan 2021 (Study Day 173)	Secondary To Diuretic Usage Secondary To Extracorporeal Membranous Oxygenation Secondary To Adult Respiratory Distress Syndrome
Esmolol	06 Dec 2020 (Study Day 128) - 07 Dec 2020 (Study Day 129)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome
Bronchoscopy*	08 Dec 2020 (Study Day 130) - 08 Dec 2020 (Study Day 130)	Adverse Event
Trazodone	08 Dec 2020 (Study Day 130) - Ongoing	Delirium, Insomnia
Tracheotomy/tracheostomy*	10 Dec 2020 (Study Day 132) - 10 Dec 2020 (Study Day 132)	Adverse Event
Amoxicillin	11 Dec 2020 (Study Day 133) - 13 Dec 2020 (Study Day 135)	Rhino Rocket Packing Prophylaxis
Quetiapine	12 Dec 2020 (Study Day 134) - 20 Jan 2021 (Study Day 173)	Delirium
Quetiapine	12 Dec 2020 (Study Day 134) - 20 Jan 2021 (Study Day 173)	Delirium/Insomnia
Silver nitrate	12 Dec 2020 (Study Day 134) - 12 Dec 2020 (Study Day 134)	Right-Sided Epistaxis
Bronchoscopy*	13 Dec 2020 (Study Day 135) - 13 Dec 2020 (Study Day 135)	Adverse Event
Bronchoscopy*	14 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 136)	Adverse Event
Enema, smog*	14 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 136)	Adverse Event
Extracorporeal membrane oxygenation circuit exchange*	14 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 136)	Adverse Event
Vancomycin	14 Dec 2020 (Study Day 136) - 14 Dec 2020 (Study Day 136)	Multifocal Pneumonia
Cefepime	16 Dec 2020 (Study Day 138) - 22 Dec 2020 (Study Day 144)	Multifocal Pneumonia
Extracorporeal membrane oxygenation circuit exchange*	17 Dec 2020 (Study Day 139) - 17 Dec 2020 (Study Day 139)	Adverse Event
Metronidazole	18 Dec 2020 (Study Day 140) - 22 Dec 2020 (Study Day 144)	Ventilator-Associated Pneumonia, Pseudomonas Bilateral
Prednisolone	18 Dec 2020 (Study Day 140) - 21 Dec 2020 (Study Day 143)	Acute Respiratory Failure
Argatroban	20 Dec 2020 (Study Day 142) - 25 Dec 2020 (Study Day 147)	Extracorporeal Membranous Oxygenation
Hydromorphone hydrochloride	20 Dec 2020 (Study Day 142) - 20 Jan 2021 (Study Day 173)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome
Docusate	21 Dec 2020 (Study Day 143) - 28 Jan 2021 (Study Day 181)	Constipation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rhino rocket procedure*	21 Dec 2020 (Study Day 143) - 21 Dec 2020 (Study Day 143)	Adverse Event
Cefazolin	22 Dec 2020 (Study Day 144) - 23 Dec 2020 (Study Day 145)	Bronchoscopy Prophylaxis
Acetazolamide	23 Dec 2020 (Study Day 145) - 23 Dec 2020 (Study Day 145)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome
Bronchoscopy*	23 Dec 2020 (Study Day 145) - 23 Dec 2020 (Study Day 145)	Adverse Event
Petrolatum	24 Dec 2020 (Study Day 146) - 10 Feb 2021 (Study Day 194)	Pressure Sores, Nose, Bilateral Cheeks, Coccyx
Bacitracin	25 Dec 2020 (Study Day 147) - 09 Feb 2021 (Study Day 193)	Left Posterior Shoulder, Non-Pruritic, Circular Rash
Fentanyl	25 Dec 2020 (Study Day 147) - 17 Jan 2021 (Study Day 170)	Pain, Generalized
Ketamine	25 Dec 2020 (Study Day 147) - 20 Jan 2021 (Study Day 173)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Syndrome, Delirium Secondary To Sedation Secondary To Adult Respiratory Syndrome
Melatonin	25 Dec 2020 (Study Day 147) - Ongoing	Insomnia, Delirium
Methylprednisolone	25 Dec 2020 (Study Day 147) - 03 Jan 2021 (Study Day 156)	Multifocal Pneumonia, Adult Respiratory Distress Syndrome
Metronidazole	25 Dec 2020 (Study Day 147) - 15 Jan 2021 (Study Day 168)	Multifocal Pneumonia
Oxycodone	25 Dec 2020 (Study Day 147) - 09 Jan 2021 (Study Day 162)	Pain, Generalized
Extracorporeal membrane oxygenation circuit exchange*	26 Dec 2020 (Study Day 148) - 26 Dec 2020 (Study Day 148)	Adverse Event
Ampicillin; sulbactam	28 Dec 2020 (Study Day 150) - 29 Dec 2020 (Study Day 151)	Extracorporeal Membrane Oxygenation Circuit Exchange Prophylaxis
Morphine sulfate	28 Dec 2020 (Study Day 150) - 28 Jan 2021 (Study Day 181)	Pain, Generalized
Oxycodone	30 Dec 2020 (Study Day 152) - 28 Jan 2021 (Study Day 181)	Pain, Generalized
Bronchoscopy*	31 Dec 2020 (Study Day 153) - 31 Dec 2020 (Study Day 153)	Adverse Event
Methylprednisolone	31 Dec 2020 (Study Day 153) - 01 Jan 2021 (Study Day 154)	Adult Respiratory Distress Syndrome
Metoprolol tartrate	31 Dec 2020 (Study Day 153) - 20 Jan 2021 (Study Day 173)	Tachycardia
Other viral vaccines	2021 - 2021	COVID Prevention
Femoral-femoral ven-venous extracorporeal membrane machine de-cannulation*	01 Jan 2021 (Study Day 154) - 01 Jan 2021 (Study Day 154)	Adverse Event
Fondaparinux	01 Jan 2021 (Study Day 154) - 07 Jan 2021 (Study Day 160)	Left Lower Leg, Deep Vein Thrombosis
Furosemide	01 Jan 2021 (Study Day 154) - 01 Jan 2021 (Study Day 154)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin glargine	01 Jan 2021 (Study Day 154) - 28 Jan 2021 (Study Day 181)	Steroid-Induced Hyperglycemia
Insulin lispro	01 Jan 2021 (Study Day 154) - 28 Jan 2021 (Study Day 181)	Steroid-Induced Hyperglycemia
Other nasal preparations	01 Jan 2021 (Study Day 154) - 21 Jan 2021 (Study Day 174)	Right-Sided Epistaxis
Sulfamethoxazole; trimethoprim	01 Jan 2021 (Study Day 154) - 06 Feb 2021 (Study Day 190)	Pneumonia Prophylaxis Secondary To Steroids
Linezolid	02 Jan 2021 (Study Day 155) - 02 Jan 2021 (Study Day 155)	Vancomycin-Resistant Enterococcus Septicemia, Ventilator Associated Pneumonia, Pseudomonas Bilateral
Methylprednisolone	02 Jan 2021 (Study Day 155) - 02 Jan 2021 (Study Day 155)	Adult Respiratory Distress Syndrome
Metoprolol tartrate	02 Jan 2021 (Study Day 155) - 20 Jan 2021 (Study Day 173)	Tachycardia
Potassium chloride	02 Jan 2021 (Study Day 155) - 28 Jan 2021 (Study Day 181)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome
Metronidazole	03 Jan 2021 (Study Day 156) - 08 Jan 2021 (Study Day 161)	Ventilator-Associated Pneumonia, Pseudomonas Bilateral
Tobramycin	04 Jan 2021 (Study Day 157) - 12 Jan 2021 (Study Day 165)	Adult Respiratory Distress Syndrome, Vancomycin-Resistant Enterococcus Septicemia
Inferior vena cava filter placement*	06 Jan 2021 (Study Day 159) - 06 Jan 2021 (Study Day 159)	Adverse Event
Acetylsalicylic acid	08 Jan 2021 (Study Day 161) - 12 Jan 2021 (Study Day 165)	Left Lower Leg Deep Vein Thrombosis, Extracorporeal Membrane Oxygenation
Fondaparinux	08 Jan 2021 (Study Day 161) - Ongoing	Left Lower Leg Deep Vein Thrombosis
Prednisone	10 Jan 2021 (Study Day 163) - 16 Jan 2021 (Study Day 169)	Adult Respiratory Distress Syndrome
Acetazolamide	12 Jan 2021 (Study Day 165) - 12 Jan 2021 (Study Day 165)	Extracorporeal Membrane Oxygenation Secondary To Adult Respiratory Distress Syndrome
Hyoscine	12 Jan 2021 (Study Day 165) - 12 Jan 2021 (Study Day 165)	Postoperative Nausea/Vomiting
Fentanyl	17 Jan 2021 (Study Day 170) - 28 Jan 2021 (Study Day 181)	Pain, Generalized
Prednisone	17 Jan 2021 (Study Day 170) - 23 Jan 2021 (Study Day 176)	Adult Respiratory Distress Syndrome
Bronchoscopy*	18 Jan 2021 (Study Day 171) - 18 Jan 2021 (Study Day 171)	Adverse Event
Famotidine	20 Jan 2021 (Study Day 173) - 20 Jan 2021 (Study Day 173)	Gastroesophageal Reflux Disease
Lactobacillus rhamnosus	20 Jan 2021 (Study Day 173) - Ongoing	Multifocal Pneumonia
Miconazole	20 Jan 2021 (Study Day 173) - 05 Feb 2021 (Study Day 189)	Left Posterior Shoulder Non-Pruritic, Non-Urticarial, Circular Rash
Morphine	20 Jan 2021 (Study Day 173) - 28 Jan 2021 (Study Day 181)	Pain, Generalized
Omeprazole	20 Jan 2021 (Study Day 173) - Ongoing	Gastroesophageal Reflux Disease Without Esophagitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Quetiapine	20 Jan 2021 (Study Day 173) - 30 Jan 2021 (Study Day 183)	Delirium
Tramadol	20 Jan 2021 (Study Day 173) - 10 Feb 2021 (Study Day 194)	Pain, Generalized
Amlodipine	21 Jan 2021 (Study Day 174) - Ongoing	Hypertension
Escitalopram oxalate	21 Jan 2021 (Study Day 174) - Ongoing	Anxiety
Metoprolol	21 Jan 2021 (Study Day 174) - Ongoing	Tachycardia
Prednisone	24 Jan 2021 (Study Day 177) - 30 Jan 2021 (Study Day 183)	Adult Respiratory Distress Syndrome
Trachea decannulation*	25 Jan 2021 (Study Day 178) - 25 Jan 2021 (Study Day 178)	Adverse Event
Sodium fluorophosphate	26 Jan 2021 (Study Day 179) - Ongoing	Oral Ulcerations
Influenza vaccine	28 Jan 2021 (Study Day 181) - 28 Jan 2021 (Study Day 181)	Influenza Prophylaxis
Influenza vaccine	28 Jan 2021 (Study Day 181) - 28 Jan 2021 (Study Day 181)	Prophylaxis
Pneumococcal vaccine polysacch 23v	28 Jan 2021 (Study Day 181) - 28 Jan 2021 (Study Day 181)	Prophylaxis
Prednisone	31 Jan 2021 (Study Day 184) - 07 Feb 2021 (Study Day 191)	Adult Respiratory Distress Syndrome
Gabapentin	01 Feb 2021 (Study Day 185) - 05 Feb 2021 (Study Day 189)	Left Lower Leg Parasthesia
Furosemide	03 Feb 2021 (Study Day 187) - 08 Feb 2021 (Study Day 192)	Edema, Bilateral Lower Extremities
Gabapentin	06 Feb 2021 (Study Day 190) - Ongoing	Left Lower Extremity Paresthesia
Potassium chloride	09 Feb 2021 (Study Day 193) - 11 Feb 2021 (Study Day 195)	Hypokalemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acute Kidney Injury	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 108) - 30 Nov 2020 (Study Day 122)
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	18 Nov 2020 (Study Day 110) - 10 Feb 2021 (Study Day 194)
Anxiety	Grade 3/severe	Not related	19 Nov 2020 (Study Day 111) - 11 Feb 2021 (Study Day 195)
Constipation	Grade 2/moderate	Not related	20 Nov 2020 (Study Day 112) - 28 Jan 2021 (Study Day 181)
Pain	Grade 3/severe	Not related	20 Nov 2020 (Study Day 112) - 11 Feb 2021 (Study Day 195)
Hyperglycaemia	Grade 2/moderate	Not related	28 Nov 2020 (Study Day 120) - 28 Jan 2021 (Study Day 181)
Decubitus Ulcer	Grade 1/mild	Not related	01 Dec 2020 (Study Day 123) - 13 Feb 2021 (Study Day 197)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Epistaxis	Grade 3/severe	Not related	02 Dec 2020 (Study Day 124) - 23 Dec 2020 (Study Day 145)
Hypertension	Grade 3/severe	Not related	02 Dec 2020 (Study Day 124) - Ongoing
Deep Vein Thrombosis	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 154) - Ongoing
Tachycardia	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 154) - Ongoing
Mouth Ulceration	Grade 2/moderate	Not related	02 Jan 2021 (Study Day 155) - 10 Feb 2021 (Study Day 194)
Paraesthesia	Grade 3/severe	Not related	10 Jan 2021 (Study Day 163) - Ongoing
Paraesthesia	Grade 3/severe	Not related	10 Jan 2021 (Study Day 163) - Ongoing
Delirium	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 168) - 28 Jan 2021 (Study Day 181)
Insomnia	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 168) - Ongoing
Rash	Grade 1/mild	Not related	17 Jan 2021 (Study Day 170) - 24 Jan 2021 (Study Day 177)
Hypokalaemia	Grade 1/mild	Not related	20 Jan 2021 (Study Day 173) - 16 Feb 2021 (Study Day 200)
Essential Tremor	Grade 1/mild	Not related	28 Jan 2021 (Study Day 181) - 15 Mar 2021 (Study Day 227)
Oedema Peripheral	Grade 1/mild	Not related	03 Feb 2021 (Study Day 187) - 08 Feb 2021 (Study Day 192)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379706

Participant Number:	US327-2104 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suspected COVID-19/ Suspected COVID-19	COVID-19	Grade 1/mild	Not related	20 Oct 2020 (Study Day 71) – 23 Oct 2020 (Study Day 74)	Recovered/ resolved
COVID-19/COVID-19	COVID-19	Grade 2/ moderate	Not related	27 Dec 2020 (Study Day 139) – 24 Jan 2021 (Study Day 167)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US327-2104, a 68-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 20 Oct 2020 (Study Day 71), 70 days after the first dose and 42 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of suspected COVID-19.

On 27 Dec 2020 (Study Day 139), 138 days after the first dose and 110 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 04 Jan 2021 (Study Day 147), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
20 Oct 2020 (Study Day 71)	Body Aches	Mild
20 Oct 2020 (Study Day 71)	Chills	Mild
20 Oct 2020 (Study Day 71)	Cough	Mild
20 Oct 2020 (Study Day 71)	Fatigue	Mild
20 Oct 2020 (Study Day 71)	Headache	Mild
20 Oct 2020 (Study Day 71)	Muscle Aches (Myalgia)	Mild
20 Oct 2020 (Study Day 71)	Sore Throat	Mild
21 Oct 2020 (Study Day 72)	Body Aches	Mild
21 Oct 2020 (Study Day 72)	Chills	Mild
21 Oct 2020 (Study Day 72)	Cough	Mild
21 Oct 2020 (Study Day 72)	Fatigue	Mild
21 Oct 2020 (Study Day 72)	Headache	Mild
21 Oct 2020 (Study Day 72)	Muscle Aches (Myalgia)	Mild
21 Oct 2020 (Study Day 72)	Sore Throat	Mild
21 Oct 2020 (Study Day 72)	Temperature (°F)	38.0
22 Oct 2020 (Study Day 73)	Body Aches	Mild
22 Oct 2020 (Study Day 73)	Chills	Mild
22 Oct 2020 (Study Day 73)	Fatigue	Mild
22 Oct 2020 (Study Day 73)	Headache	Mild
22 Oct 2020 (Study Day 73)	Muscle Aches (Myalgia)	Mild
22 Oct 2020 (Study Day 73)	New Loss of Smell	Mild
22 Oct 2020 (Study Day 73)	New Loss of Taste	Mild
22 Oct 2020 (Study Day 73)	Sore Throat	Mild
23 Oct 2020 (Study Day 74)	Chills	Mild
23 Oct 2020 (Study Day 74)	Diarrhea	Mild
23 Oct 2020 (Study Day 74)	Fatigue	Mild
23 Oct 2020 (Study Day 74)	Sore Throat	Mild
27 Dec 2020 (Study Day 139)	Body Aches	Moderate
27 Dec 2020 (Study Day 139)	Chills	Moderate
27 Dec 2020 (Study Day 139)	Cough	Mild
27 Dec 2020 (Study Day 139)	Diarrhea	Mild
27 Dec 2020 (Study Day 139)	Difficulty Breathing	Mild
27 Dec 2020 (Study Day 139)	Fatigue	Moderate
27 Dec 2020 (Study Day 139)	Headache	Moderate
27 Dec 2020 (Study Day 139)	Muscle Aches (Myalgia)	Moderate
27 Dec 2020 (Study Day 139)	Nasal Congestion	Moderate
27 Dec 2020 (Study Day 139)	Nausea	Moderate
27 Dec 2020 (Study Day 139)	New Loss of Smell	Moderate
27 Dec 2020 (Study Day 139)	New Loss of Taste	Moderate
27 Dec 2020 (Study Day 139)	Runny Nose (Rhinorrhea)	Moderate
27 Dec 2020 (Study Day 139)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 139)	Sore Throat	Mild

Symptom Date	Symptom	Result
28 Dec 2020 (Study Day 140)	Body Aches	Moderate
28 Dec 2020 (Study Day 140)	Chills	Moderate
28 Dec 2020 (Study Day 140)	Cough	Mild
28 Dec 2020 (Study Day 140)	Diarrhea	Mild
28 Dec 2020 (Study Day 140)	Difficulty Breathing	Mild
28 Dec 2020 (Study Day 140)	Fatigue	Moderate
28 Dec 2020 (Study Day 140)	Headache	Moderate
28 Dec 2020 (Study Day 140)	Muscle Aches (Myalgia)	Moderate
28 Dec 2020 (Study Day 140)	Nasal Congestion	Moderate
28 Dec 2020 (Study Day 140)	Nausea	Moderate
28 Dec 2020 (Study Day 140)	New Loss of Smell	Moderate
28 Dec 2020 (Study Day 140)	New Loss of Taste	Moderate
28 Dec 2020 (Study Day 140)	Runny Nose (Rhinorrhea)	Moderate
28 Dec 2020 (Study Day 140)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 140)	Sore Throat	Mild
29 Dec 2020 (Study Day 141)	Body Aches	Moderate
29 Dec 2020 (Study Day 141)	Chills	Moderate
29 Dec 2020 (Study Day 141)	Cough	Mild
29 Dec 2020 (Study Day 141)	Diarrhea	Mild
29 Dec 2020 (Study Day 141)	Difficulty Breathing	Mild
29 Dec 2020 (Study Day 141)	Fatigue	Moderate
29 Dec 2020 (Study Day 141)	Headache	Moderate
29 Dec 2020 (Study Day 141)	Muscle Aches (Myalgia)	Moderate
29 Dec 2020 (Study Day 141)	Nasal Congestion	Moderate
29 Dec 2020 (Study Day 141)	Nausea	Moderate
29 Dec 2020 (Study Day 141)	New Loss of Smell	Moderate
29 Dec 2020 (Study Day 141)	New Loss of Taste	Moderate
29 Dec 2020 (Study Day 141)	Runny Nose (Rhinorrhea)	Moderate
29 Dec 2020 (Study Day 141)	Shortness of Breath	Mild
29 Dec 2020 (Study Day 141)	Sore Throat	Mild
30 Dec 2020 (Study Day 142)	Body Aches	Moderate
30 Dec 2020 (Study Day 142)	Chills	Moderate
30 Dec 2020 (Study Day 142)	Cough	Mild
30 Dec 2020 (Study Day 142)	Diarrhea	Mild
30 Dec 2020 (Study Day 142)	Difficulty Breathing	Mild
30 Dec 2020 (Study Day 142)	Fatigue	Moderate
30 Dec 2020 (Study Day 142)	Headache	Moderate
30 Dec 2020 (Study Day 142)	Muscle Aches (Myalgia)	Moderate
30 Dec 2020 (Study Day 142)	Nasal Congestion	Moderate
30 Dec 2020 (Study Day 142)	Nausea	Moderate
30 Dec 2020 (Study Day 142)	New Loss of Smell	Moderate
30 Dec 2020 (Study Day 142)	New Loss of Taste	Moderate
30 Dec 2020 (Study Day 142)	Runny Nose (Rhinorrhea)	Moderate

Symptom Date	Symptom	Result
30 Dec 2020 (Study Day 142)	Shortness of Breath	Mild
30 Dec 2020 (Study Day 142)	Sore Throat	Mild
31 Dec 2020 (Study Day 143)	Body Aches	Moderate
31 Dec 2020 (Study Day 143)	Chills	Moderate
31 Dec 2020 (Study Day 143)	Cough	Mild
31 Dec 2020 (Study Day 143)	Diarrhea	Mild
31 Dec 2020 (Study Day 143)	Difficulty Breathing	Mild
31 Dec 2020 (Study Day 143)	Fatigue	Moderate
31 Dec 2020 (Study Day 143)	Headache	Moderate
31 Dec 2020 (Study Day 143)	Muscle Aches (Myalgia)	Moderate
31 Dec 2020 (Study Day 143)	Nasal Congestion	Moderate
31 Dec 2020 (Study Day 143)	Nausea	Moderate
31 Dec 2020 (Study Day 143)	New Loss of Smell	Moderate
31 Dec 2020 (Study Day 143)	New Loss of Taste	Moderate
31 Dec 2020 (Study Day 143)	Runny Nose (Rhinorrhea)	Moderate
31 Dec 2020 (Study Day 143)	Shortness of Breath	Mild
31 Dec 2020 (Study Day 143)	Sore Throat	Mild
01 Jan 2021 (Study Day 144)	Body Aches	Moderate
01 Jan 2021 (Study Day 144)	Chills	Moderate
01 Jan 2021 (Study Day 144)	Cough	Mild
01 Jan 2021 (Study Day 144)	Diarrhea	Mild
01 Jan 2021 (Study Day 144)	Difficulty Breathing	Mild
01 Jan 2021 (Study Day 144)	Fatigue	Moderate
01 Jan 2021 (Study Day 144)	Headache	Moderate
01 Jan 2021 (Study Day 144)	Muscle Aches (Myalgia)	Moderate
01 Jan 2021 (Study Day 144)	Nasal Congestion	Moderate
01 Jan 2021 (Study Day 144)	Nausea	Moderate
01 Jan 2021 (Study Day 144)	New Loss of Smell	Moderate
01 Jan 2021 (Study Day 144)	New Loss of Taste	Moderate
01 Jan 2021 (Study Day 144)	Runny Nose (Rhinorrhea)	Moderate
01 Jan 2021 (Study Day 144)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 144)	Sore Throat	Mild
02 Jan 2021 (Study Day 145)	Body Aches	Moderate
02 Jan 2021 (Study Day 145)	Chills	Moderate
02 Jan 2021 (Study Day 145)	Cough	Mild
02 Jan 2021 (Study Day 145)	Diarrhea	Mild
02 Jan 2021 (Study Day 145)	Difficulty Breathing	Mild
02 Jan 2021 (Study Day 145)	Fatigue	Moderate
02 Jan 2021 (Study Day 145)	Headache	Moderate
02 Jan 2021 (Study Day 145)	Muscle Aches (Myalgia)	Moderate
02 Jan 2021 (Study Day 145)	Nasal Congestion	Moderate
02 Jan 2021 (Study Day 145)	Nausea	Moderate
02 Jan 2021 (Study Day 145)	New Loss of Smell	Moderate

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 145)	New Loss of Taste	Moderate
02 Jan 2021 (Study Day 145)	Runny Nose (Rhinorrhea)	Moderate
02 Jan 2021 (Study Day 145)	Shortness of Breath	Mild
02 Jan 2021 (Study Day 145)	Sore Throat	Mild
03 Jan 2021 (Study Day 146)	Body Aches	Moderate
03 Jan 2021 (Study Day 146)	Chills	Moderate
03 Jan 2021 (Study Day 146)	Cough	Mild
03 Jan 2021 (Study Day 146)	Diarrhea	Mild
03 Jan 2021 (Study Day 146)	Difficulty Breathing	Mild
03 Jan 2021 (Study Day 146)	Fatigue	Moderate
03 Jan 2021 (Study Day 146)	Headache	Moderate
03 Jan 2021 (Study Day 146)	Muscle Aches (Myalgia)	Moderate
03 Jan 2021 (Study Day 146)	Nasal Congestion	Moderate
03 Jan 2021 (Study Day 146)	Nausea	Moderate
03 Jan 2021 (Study Day 146)	New Loss of Smell	Moderate
03 Jan 2021 (Study Day 146)	New Loss of Taste	Moderate
03 Jan 2021 (Study Day 146)	Runny Nose (Rhinorrhea)	Moderate
03 Jan 2021 (Study Day 146)	Shortness of Breath	Mild
03 Jan 2021 (Study Day 146)	Sore Throat	Mild
04 Jan 2021 (Study Day 147)	Body Aches	Moderate
04 Jan 2021 (Study Day 147)	Chills	Moderate
04 Jan 2021 (Study Day 147)	Cough	Mild
04 Jan 2021 (Study Day 147)	Diarrhea	Mild
04 Jan 2021 (Study Day 147)	Difficulty Breathing	Mild
04 Jan 2021 (Study Day 147)	Fatigue	Moderate
04 Jan 2021 (Study Day 147)	Headache	Moderate
04 Jan 2021 (Study Day 147)	Muscle Aches (Myalgia)	Moderate
04 Jan 2021 (Study Day 147)	Nasal Congestion	Moderate
04 Jan 2021 (Study Day 147)	Nausea	Moderate
04 Jan 2021 (Study Day 147)	New Loss of Smell	Moderate
04 Jan 2021 (Study Day 147)	New Loss of Taste	Moderate
04 Jan 2021 (Study Day 147)	Runny Nose (Rhinorrhea)	Moderate
04 Jan 2021 (Study Day 147)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 147)	Sore Throat	Mild
05 Jan 2021 (Study Day 148)	Body Aches	Mild
05 Jan 2021 (Study Day 148)	Fatigue	Moderate
05 Jan 2021 (Study Day 148)	Muscle Aches (Myalgia)	Mild
09 Jan 2021 (Study Day 152)	Chills	Moderate
09 Jan 2021 (Study Day 152)	Cough	Mild
09 Jan 2021 (Study Day 152)	Fatigue	Moderate
09 Jan 2021 (Study Day 152)	Nasal Congestion	Mild
09 Jan 2021 (Study Day 152)	O2 Saturation (%)	91
09 Jan 2021 (Study Day 152)	Temperature (°F)	100.7

Symptom Date	Symptom	Result
10 Jan 2021 (Study Day 153)	Body Aches	Mild
10 Jan 2021 (Study Day 153)	Cough	Mild
10 Jan 2021 (Study Day 153)	Difficulty Breathing	Mild
10 Jan 2021 (Study Day 153)	Fatigue	Moderate
10 Jan 2021 (Study Day 153)	Headache	Mild
10 Jan 2021 (Study Day 153)	Muscle Aches (Myalgia)	Mild
10 Jan 2021 (Study Day 153)	Nasal Congestion	Mild
10 Jan 2021 (Study Day 153)	Nausea	Mild
10 Jan 2021 (Study Day 153)	Runny Nose (Rhinorrhea)	Mild
10 Jan 2021 (Study Day 153)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 153)	Sore Throat	Mild
11 Jan 2021 (Study Day 154)	Fatigue	Mild
14 Jan 2021 (Study Day 157)	Cough	Mild
14 Jan 2021 (Study Day 157)	Nasal Congestion	Mild
15 Jan 2021 (Study Day 158)	Cough	Mild
15 Jan 2021 (Study Day 158)	Nasal Congestion	Mild
17 Jan 2021 (Study Day 160)	New Loss of Smell	Moderate
17 Jan 2021 (Study Day 160)	New Loss of Taste	Moderate
17 Jan 2021 (Study Day 160)	Runny Nose (Rhinorrhea)	Mild
18 Jan 2021 (Study Day 161)	New Loss of Smell	Moderate
18 Jan 2021 (Study Day 161)	New Loss of Taste	Moderate
19 Jan 2021 (Study Day 162)	New Loss of Smell	Moderate
19 Jan 2021 (Study Day 162)	New Loss of Taste	Moderate
20 Jan 2021 (Study Day 163)	New Loss of Smell	Moderate
20 Jan 2021 (Study Day 163)	New Loss of Taste	Moderate
21 Jan 2021 (Study Day 164)	New Loss of Smell	Moderate
21 Jan 2021 (Study Day 164)	New Loss of Taste	Moderate
23 Jan 2021 (Study Day 166)	Nasal Congestion	Mild
23 Jan 2021 (Study Day 166)	New Loss of Smell	Severe
23 Jan 2021 (Study Day 166)	New Loss of Taste	Severe
24 Jan 2021 (Study Day 167)	Nasal Congestion	Mild
24 Jan 2021 (Study Day 167)	New Loss of Smell	Moderate
24 Jan 2021 (Study Day 167)	New Loss of Taste	Moderate
27 Jan 2021 (Study Day 170)	Headache	Mild
01 Feb 2021 (Study Day 175)	Fatigue	Mild
01 Feb 2021 (Study Day 175)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
09 Jan 2021 (Study Day 152)	Oxygen Saturation	91%

Dates	Severity Indication	Result
09 Jan 2021 - 09 Jan 2021 (Study Day 152-152)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

The IP dose was not changed due to the suspected covid-19. The event of suspected COVID-19 lasted for 4 days, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 74). The investigator assessed the event of suspected COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of COVID-19 lasted for 29 days, after which it was considered to be recovered/resolved on 24 Jan 2021 (Study Day 167). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002944	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to animal	Allergy to cats	1960 - Ongoing
Angioplasty	Angioplasty	1996 - 1996
Coronary artery disease	Coronary artery disease	1996 - Ongoing
Hypertension	Hypertension	1996 - Ongoing
Asthma	Moderate asthma	2000 - Ongoing
Gout	Bilateral gout in ankles	2000 - Ongoing
Seasonal allergy	Hay fever	2000 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes mellitus	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Depression	Depression	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1996 - Ongoing	Cardiac Prophylaxis
Allopurinol	2000 - Ongoing	Gout In Bilateral Ankles
Glyceryl trinitrate	2000 - Ongoing	Angina
Lisinopril	2000 - Ongoing	Hypertension
Metformin	2000 - Ongoing	Type 2 Diabetes Mellitus
Fluticasone propionate	2005 - Ongoing	Asthma
Amlodipine	2010 - Ongoing	Hypertension
Fluticasone propionate	2010 - Ongoing	Hay Fever
Levothyroxine sodium	2015 - Ongoing	Hypothyroidism
Rosuvastatin calcium	2015 - Ongoing	Hypercholesterolemia
Colecalciferol	2017 - Ongoing	Nutritional Supplement
Insulin glargine	2017 - Ongoing	Type 2 Diabetes Mellitus
Insulin lispro	2017 - Ongoing	Type 2 Diabetes Mellitus
Fenofibrate	2019 - Ongoing	Hypercholesterolemia
Montelukast sodium	2019 - Ongoing	Hay Fever
Carvedilol	Jan 2019 - Ongoing	Hypertension
Empagliflozin	Jun 2019 - Ongoing	Type 2 Diabetes Mellitus
Sertraline	May 2020 - Ongoing	Depression
Paracetamol	20 Oct 2020 (Study Day 71) - Ongoing	Fever
Influenza vaccine	30 Oct 2020 (Study Day 81) - 30 Oct 2020 (Study Day 81)	Influenza
Ibuprofen	27 Dec 2020 (Study Day 139) - 24 Jan 2021 (Study Day 167)	COVID-19
Pseudoephedrine hydrochloride	13 Jan 2021 (Study Day 156) - 24 Jan 2021 (Study Day 167)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 1/mild	Not related	20 Oct 2020 (Study Day 71) - 23 Oct 2020 (Study Day 74)
COVID-19	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 139) - 24 Jan 2021 (Study Day 167)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2144 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	SAE, COVID-19	Grade 4	Not related	02 Nov 2020 (Study Day 81) – 29 Nov 2020 (Study Day 108)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US327-2144, a 29-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 02 Nov 2020 (Study Day 81), 80 days after the first dose and 52 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 11 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 04 Nov 2020 (Study Day 83), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
02 Nov 2020 (Study Day 81)	Body Aches	Mild
02 Nov 2020 (Study Day 81)	Chills	Mild
02 Nov 2020 (Study Day 81)	Diarrhea	Mild
02 Nov 2020 (Study Day 81)	Difficulty Breathing	Mild
02 Nov 2020 (Study Day 81)	Fatigue	Moderate
02 Nov 2020 (Study Day 81)	Headache	Moderate

Symptom Date	Symptom	Result
02 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Moderate
02 Nov 2020 (Study Day 81)	Nasal Congestion	Moderate
02 Nov 2020 (Study Day 81)	Nausea	Mild
02 Nov 2020 (Study Day 81)	New Loss of Smell	Mild
02 Nov 2020 (Study Day 81)	New Loss of Taste	Mild
02 Nov 2020 (Study Day 81)	Shortness of Breath	Mild
03 Nov 2020 (Study Day 82)	Body Aches	Mild
03 Nov 2020 (Study Day 82)	Chills	Mild
03 Nov 2020 (Study Day 82)	Diarrhea	Mild
03 Nov 2020 (Study Day 82)	Difficulty Breathing	Mild
03 Nov 2020 (Study Day 82)	Fatigue	Moderate
03 Nov 2020 (Study Day 82)	Headache	Moderate
03 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
03 Nov 2020 (Study Day 82)	Nasal Congestion	Moderate
03 Nov 2020 (Study Day 82)	Nausea	Mild
03 Nov 2020 (Study Day 82)	New Loss of Smell	Mild
03 Nov 2020 (Study Day 82)	New Loss of Taste	Mild
03 Nov 2020 (Study Day 82)	Shortness of Breath	Mild
04 Nov 2020 (Study Day 83)	Body Aches	Mild
04 Nov 2020 (Study Day 83)	Chills	Mild
04 Nov 2020 (Study Day 83)	Diarrhea	Mild
04 Nov 2020 (Study Day 83)	Difficulty Breathing	Mild
04 Nov 2020 (Study Day 83)	Fatigue	Moderate
04 Nov 2020 (Study Day 83)	Headache	Moderate
04 Nov 2020 (Study Day 83)	Muscle Aches (Myalgia)	Moderate
04 Nov 2020 (Study Day 83)	Nasal Congestion	Moderate
04 Nov 2020 (Study Day 83)	Nausea	Mild
04 Nov 2020 (Study Day 83)	New Loss of Smell	Mild
04 Nov 2020 (Study Day 83)	New Loss of Taste	Mild
04 Nov 2020 (Study Day 83)	Shortness of Breath	Mild
05 Nov 2020 (Study Day 84)	Body Aches	Severe
05 Nov 2020 (Study Day 84)	Chills	Moderate
05 Nov 2020 (Study Day 84)	Cough	Severe
05 Nov 2020 (Study Day 84)	Diarrhea	Moderate
05 Nov 2020 (Study Day 84)	Difficulty Breathing	Mild
05 Nov 2020 (Study Day 84)	Fatigue	Moderate
05 Nov 2020 (Study Day 84)	Headache	Severe
05 Nov 2020 (Study Day 84)	Muscle Aches (Myalgia)	Severe
05 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
05 Nov 2020 (Study Day 84)	Nausea	Mild
05 Nov 2020 (Study Day 84)	Shortness of Breath	Mild
05 Nov 2020 (Study Day 84)	Sore Throat	Mild
06 Nov 2020 (Study Day 85)	Body Aches	Severe

Symptom Date	Symptom	Result
06 Nov 2020 (Study Day 85)	Chills	Moderate
06 Nov 2020 (Study Day 85)	Cough	Severe
06 Nov 2020 (Study Day 85)	Diarrhea	Moderate
06 Nov 2020 (Study Day 85)	Difficulty Breathing	Mild
06 Nov 2020 (Study Day 85)	Fatigue	Moderate
06 Nov 2020 (Study Day 85)	Headache	Severe
06 Nov 2020 (Study Day 85)	Muscle Aches (Myalgia)	Severe
06 Nov 2020 (Study Day 85)	Nasal Congestion	Mild
06 Nov 2020 (Study Day 85)	Nausea	Mild
06 Nov 2020 (Study Day 85)	Shortness of Breath	Mild
06 Nov 2020 (Study Day 85)	Sore Throat	Mild
07 Nov 2020 (Study Day 86)	Body Aches	Moderate
07 Nov 2020 (Study Day 86)	Chills	Mild
07 Nov 2020 (Study Day 86)	Cough	Mild
07 Nov 2020 (Study Day 86)	Diarrhea	Moderate
07 Nov 2020 (Study Day 86)	Difficulty Breathing	Mild
07 Nov 2020 (Study Day 86)	Fatigue	Moderate
07 Nov 2020 (Study Day 86)	Headache	Severe
07 Nov 2020 (Study Day 86)	Muscle Aches (Myalgia)	Moderate
07 Nov 2020 (Study Day 86)	Nasal Congestion	Severe
07 Nov 2020 (Study Day 86)	Shortness of Breath	Mild
07 Nov 2020 (Study Day 86)	Sore Throat	Mild
07 Nov 2020 (Study Day 86)	Temperature (°F)	101.1
08 Nov 2020 (Study Day 87)	Body Aches	Severe
08 Nov 2020 (Study Day 87)	Chills	Severe
08 Nov 2020 (Study Day 87)	Cough	Moderate
08 Nov 2020 (Study Day 87)	Diarrhea	Mild
08 Nov 2020 (Study Day 87)	Difficulty Breathing	Mild
08 Nov 2020 (Study Day 87)	Fatigue	Severe
08 Nov 2020 (Study Day 87)	Headache	Severe
08 Nov 2020 (Study Day 87)	Muscle Aches (Myalgia)	Severe
08 Nov 2020 (Study Day 87)	Nasal Congestion	Severe
08 Nov 2020 (Study Day 87)	Nausea	Moderate
08 Nov 2020 (Study Day 87)	Shortness of Breath	Mild
08 Nov 2020 (Study Day 87)	Sore Throat	Moderate
08 Nov 2020 (Study Day 87)	Temperature (°F)	101.6
09 Nov 2020 (Study Day 88)	Body Aches	Mild
09 Nov 2020 (Study Day 88)	Chills	Moderate
09 Nov 2020 (Study Day 88)	Cough	Moderate
09 Nov 2020 (Study Day 88)	Diarrhea	Moderate
09 Nov 2020 (Study Day 88)	Difficulty Breathing	Mild
09 Nov 2020 (Study Day 88)	Fatigue	Severe
09 Nov 2020 (Study Day 88)	Headache	Severe

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 88)	Muscle Aches (Myalgia)	Mild
09 Nov 2020 (Study Day 88)	Nasal Congestion	Moderate
09 Nov 2020 (Study Day 88)	New Loss of Smell	Moderate
09 Nov 2020 (Study Day 88)	New Loss of Taste	Moderate
09 Nov 2020 (Study Day 88)	Runny Nose (Rhinorrhea)	Mild
09 Nov 2020 (Study Day 88)	Shortness of Breath	Mild
09 Nov 2020 (Study Day 88)	Sore Throat	Moderate
09 Nov 2020 (Study Day 88)	Temperature (°F)	100.6
10 Nov 2020 (Study Day 89)	Body Aches	Mild
10 Nov 2020 (Study Day 89)	Chills	Moderate
10 Nov 2020 (Study Day 89)	Cough	Mild
10 Nov 2020 (Study Day 89)	Diarrhea	Moderate
10 Nov 2020 (Study Day 89)	Difficulty Breathing	Mild
10 Nov 2020 (Study Day 89)	Fatigue	Moderate
10 Nov 2020 (Study Day 89)	Headache	Moderate
10 Nov 2020 (Study Day 89)	Muscle Aches (Myalgia)	Mild
10 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 89)	Nausea	Moderate
10 Nov 2020 (Study Day 89)	New Loss of Smell	Moderate
10 Nov 2020 (Study Day 89)	New Loss of Taste	Moderate
10 Nov 2020 (Study Day 89)	Shortness of Breath	Mild
10 Nov 2020 (Study Day 89)	Sore Throat	Mild
10 Nov 2020 (Study Day 89)	Temperature (°F)	100.6
11 Nov 2020 (Study Day 90)	Body Aches	Mild
11 Nov 2020 (Study Day 90)	Chills	Mild
11 Nov 2020 (Study Day 90)	Cough	Moderate
11 Nov 2020 (Study Day 90)	Diarrhea	Moderate
11 Nov 2020 (Study Day 90)	Difficulty Breathing	Mild
11 Nov 2020 (Study Day 90)	Fatigue	Moderate
11 Nov 2020 (Study Day 90)	Headache	Moderate
11 Nov 2020 (Study Day 90)	Muscle Aches (Myalgia)	Mild
11 Nov 2020 (Study Day 90)	Nasal Congestion	Moderate
11 Nov 2020 (Study Day 90)	Nausea	Moderate
11 Nov 2020 (Study Day 90)	New Loss of Smell	Moderate
11 Nov 2020 (Study Day 90)	New Loss of Taste	Moderate
11 Nov 2020 (Study Day 90)	O2 Saturation (%)	92
11 Nov 2020 (Study Day 90)	Shortness of Breath	Mild
11 Nov 2020 (Study Day 90)	Sore Throat	Moderate
12 Nov 2020 (Study Day 91)	Body Aches	Mild
12 Nov 2020 (Study Day 91)	Cough	Moderate
12 Nov 2020 (Study Day 91)	Diarrhea	Moderate
12 Nov 2020 (Study Day 91)	Difficulty Breathing	Moderate
12 Nov 2020 (Study Day 91)	Fatigue	Moderate

Symptom Date	Symptom	Result
12 Nov 2020 (Study Day 91)	Headache	Severe
12 Nov 2020 (Study Day 91)	Muscle Aches (Myalgia)	Mild
12 Nov 2020 (Study Day 91)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 91)	Nausea	Mild
12 Nov 2020 (Study Day 91)	New Loss of Smell	Severe
12 Nov 2020 (Study Day 91)	New Loss of Taste	Severe
12 Nov 2020 (Study Day 91)	O2 Saturation (%)	92
12 Nov 2020 (Study Day 91)	Shortness of Breath	Mild
12 Nov 2020 (Study Day 91)	Sore Throat	Mild
13 Nov 2020 (Study Day 92)	Chills	Moderate
13 Nov 2020 (Study Day 92)	Cough	Moderate
13 Nov 2020 (Study Day 92)	Diarrhea	Moderate
13 Nov 2020 (Study Day 92)	Fatigue	Mild
13 Nov 2020 (Study Day 92)	Headache	Mild
13 Nov 2020 (Study Day 92)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 92)	New Loss of Smell	Moderate
13 Nov 2020 (Study Day 92)	New Loss of Taste	Moderate
13 Nov 2020 (Study Day 92)	O2 Saturation (%)	93
13 Nov 2020 (Study Day 92)	Shortness of Breath	Mild
13 Nov 2020 (Study Day 92)	Sore Throat	Mild
13 Nov 2020 (Study Day 92)	Temperature (°F)	101.6
14 Nov 2020 (Study Day 93)	Chills	Mild
14 Nov 2020 (Study Day 93)	Cough	Moderate
14 Nov 2020 (Study Day 93)	Diarrhea	Severe
14 Nov 2020 (Study Day 93)	Difficulty Breathing	Mild
14 Nov 2020 (Study Day 93)	Nausea	Mild
14 Nov 2020 (Study Day 93)	New Loss of Smell	Mild
14 Nov 2020 (Study Day 93)	New Loss of Taste	Mild
14 Nov 2020 (Study Day 93)	O2 Saturation (%)	92
14 Nov 2020 (Study Day 93)	Shortness of Breath	Mild
15 Nov 2020 (Study Day 94)	Chills	Mild
15 Nov 2020 (Study Day 94)	Cough	Moderate
15 Nov 2020 (Study Day 94)	Diarrhea	Mild
15 Nov 2020 (Study Day 94)	Difficulty Breathing	Moderate
15 Nov 2020 (Study Day 94)	Fatigue	Severe
15 Nov 2020 (Study Day 94)	Headache	Moderate
15 Nov 2020 (Study Day 94)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 94)	Nausea	Moderate
15 Nov 2020 (Study Day 94)	New Loss of Smell	Mild
15 Nov 2020 (Study Day 94)	New Loss of Taste	Mild
15 Nov 2020 (Study Day 94)	Runny Nose (Rhinorrhea)	Mild
15 Nov 2020 (Study Day 94)	Shortness of Breath	Moderate
16 Nov 2020 (Study Day 95)	Cough	Moderate

Symptom Date	Symptom	Result
16 Nov 2020 (Study Day 95)	Diarrhea	Moderate
16 Nov 2020 (Study Day 95)	Difficulty Breathing	Severe
16 Nov 2020 (Study Day 95)	Fatigue	Moderate
16 Nov 2020 (Study Day 95)	Headache	Moderate
16 Nov 2020 (Study Day 95)	Nasal Congestion	Mild
16 Nov 2020 (Study Day 95)	Nausea	Mild
16 Nov 2020 (Study Day 95)	New Loss of Smell	Mild
16 Nov 2020 (Study Day 95)	New Loss of Taste	Mild
16 Nov 2020 (Study Day 95)	O2 Saturation (%)	91
16 Nov 2020 (Study Day 95)	Runny Nose (Rhinorrhea)	Moderate
16 Nov 2020 (Study Day 95)	Shortness of Breath	Moderate
16 Nov 2020 (Study Day 95)	Sore Throat	Mild
17 Nov 2020 (Study Day 96)	Cough	Mild
17 Nov 2020 (Study Day 96)	Headache	Mild
17 Nov 2020 (Study Day 96)	O2 Saturation (%)	93
18 Nov 2020 (Study Day 97)	Chills	Mild
18 Nov 2020 (Study Day 97)	Cough	Moderate
18 Nov 2020 (Study Day 97)	Diarrhea	Mild
19 Nov 2020 (Study Day 98)	Cough	Mild
19 Nov 2020 (Study Day 98)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 100)	Cough	Mild
21 Nov 2020 (Study Day 100)	Diarrhea	Mild
21 Nov 2020 (Study Day 100)	Headache	Mild
22 Nov 2020 (Study Day 101)	Cough	Mild
22 Nov 2020 (Study Day 101)	Diarrhea	Mild
22 Nov 2020 (Study Day 101)	Headache	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
11 Nov 2020 (Study Day 90)	Oxygen Saturation	92%
11 Nov 2020 - 18 Nov 2020 (Study Day 90-97)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 95-95)	Clinical Evidence of Pneumonia	Yes
16 Nov 2020 - 16 Nov 2020 (Study Day 95-95)	Radiographical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 28 days, after which it was considered to be recovered/resolved on 29 Nov 2020 (Study Day 108). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000759	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1995 - Ongoing
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Haemorrhoids	Hemorrhoids	2013 - 2016
Insomnia	Insomnia	2015 - Ongoing
Allergy to animal	Cat allergy	2016 - Ongoing
Haemorrhoid operation	Hemorrhoidectomy	2016 - 2016
Obesity	Severe obesity	2017 - Ongoing
Food allergy	Wheat allergy	2019 - Ongoing
Vasectomy	Vasectomy	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine	2015 - Ongoing	Seasonal Allergies
Clonazepam	2017 - Ongoing	Insomnia
Vitamins nos	2017 - Ongoing	Nutritional Health
Omeprazole	2019 - Ongoing	Gastroesophageal Reflux Disease
Influenza vaccine	18 Sep 2020 (Study Day 36) - 18 Sep 2020 (Study Day 36)	Influenza Prophylaxis
Paracetamol	02 Nov 2020 (Study Day 81) - Ongoing	COVID 19 Illness
Cetirizine hydrochloride	04 Nov 2020 (Study Day 83) - Ongoing	Cat Allergy
Pseudoephedrine	07 Nov 2020 (Study Day 86) - Ongoing	COVID 19 Illness
Enoxaparin	12 Nov 2020 (Study Day 91) - 13 Nov 2020 (Study Day 92)	Deep Vein Thrombosis 2nd To COVID 19 Illness
Eucalyptus globulus oil; menthol	13 Nov 2020 (Study Day 92) - 29 Jan 2021 (Study Day 169)	COVID 19 Illness

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x-ray*	16 Nov 2020 (Study Day 95) - 16 Nov 2020 (Study Day 95)	Adverse Event
Dexamethasone	16 Nov 2020 (Study Day 95) - 18 Nov 2020 (Study Day 97)	COVID 19
Remdesivir	16 Nov 2020 (Study Day 95) - 16 Nov 2020 (Study Day 95)	COVID 19
Chest x-ray*	17 Nov 2020 (Study Day 96) - 17 Nov 2020 (Study Day 96)	Adverse Event
Dexamethasone	17 Nov 2020 (Study Day 96) - 29 Nov 2020 (Study Day 108)	COVID 19
Lactobacillus acidophilus	17 Nov 2020 (Study Day 96) - 17 Nov 2020 (Study Day 96)	COVID-19
Levofloxacin	17 Nov 2020 (Study Day 96) - 25 Nov 2020 (Study Day 104)	COVID 19, Prevention Of Secondary Pneumonia
Oxygen	17 Nov 2020 (Study Day 96) - 19 Nov 2020 (Study Day 98)	COVID-19
Remdesivir	17 Nov 2020 (Study Day 96) - 18 Nov 2020 (Study Day 97)	COVID 19
Tramadol	17 Nov 2020 (Study Day 96) - 17 Nov 2020 (Study Day 96)	COVID 19
Ascorbic acid	18 Nov 2020 (Study Day 97) - Ongoing	Immune Supplement
Chest x-ray*	18 Nov 2020 (Study Day 97) - 18 Nov 2020 (Study Day 97)	Adverse Event
Colecalciferol	18 Nov 2020 (Study Day 97) - Ongoing	Immune Supplement
Salbutamol	18 Nov 2020 (Study Day 97) - 29 Nov 2020 (Study Day 108)	COVID-19
Zinc sulfate	18 Nov 2020 (Study Day 97) - Ongoing	Immune Supplement
Escitalopram oxalate	25 Nov 2020 (Study Day 104) - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Depression	Grade 1/mild	Not related	20 Nov 2020 (Study Day 99) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2195 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	SAE, COVID-19	Grade 4	Not related	30 Oct 2020 (Study Day 73) – 08 Dec 2020 (Study Day 112)	Recovered/resolved
COVID-19 Pneumonia/ Pneumonia Due To COVID-19 Virus	SAE, COVID-19	Grade 4	Not related	07 Nov 2020 (Study Day 81) – 30 Nov 2020 (Study Day 104)	Recovered/resolved
Hypoxia/Hypoxia	SAE	Grade 3/severe	Not related	07 Nov 2020 (Study Day 81) – 12 Nov 2020 (Study Day 86)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US327-2195, a 44-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Nov 2020 (Study Day 81), 80 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypoxia. Action taken with the IP was not applicable. The event of hypoxia lasted for 6 days, after which it was considered to be recovered/resolved on 12 Nov 2020 (Study Day 86). The investigator assessed the event of hypoxia to be not related to the IP.

Severe COVID-19 Details

On 30 Oct 2020 (Study Day 73), 72 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of COVID-19.

On 07 Nov 2020 (Study Day 81), 80 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia due to COVID-19 virus.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 30, 17 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 02 Nov 2020 (Study Day 76), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
30 Oct 2020 (Study Day 73)	Body Aches	Severe
30 Oct 2020 (Study Day 73)	Fatigue	Severe
31 Oct 2020 (Study Day 74)	Body Aches	Severe
31 Oct 2020 (Study Day 74)	Chills	Severe
31 Oct 2020 (Study Day 74)	Fatigue	Severe
01 Nov 2020 (Study Day 75)	Body Aches	Severe
01 Nov 2020 (Study Day 75)	Chills	Severe
01 Nov 2020 (Study Day 75)	Cough	Mild
01 Nov 2020 (Study Day 75)	Fatigue	Severe
01 Nov 2020 (Study Day 75)	Nasal Congestion	Mild
01 Nov 2020 (Study Day 75)	New Loss of Taste	Mild
01 Nov 2020 (Study Day 75)	Shortness of Breath	Mild
02 Nov 2020 (Study Day 76)	Body Aches	Severe
02 Nov 2020 (Study Day 76)	Chills	Moderate
02 Nov 2020 (Study Day 76)	Cough	Moderate
02 Nov 2020 (Study Day 76)	Fatigue	Severe
02 Nov 2020 (Study Day 76)	Headache	Severe
02 Nov 2020 (Study Day 76)	Nasal Congestion	Moderate
02 Nov 2020 (Study Day 76)	New Loss of Smell	Severe
02 Nov 2020 (Study Day 76)	New Loss of Taste	Severe
03 Nov 2020 (Study Day 77)	Body Aches	Moderate
03 Nov 2020 (Study Day 77)	Chills	Moderate
03 Nov 2020 (Study Day 77)	Cough	Mild
03 Nov 2020 (Study Day 77)	Difficulty Breathing	Mild
03 Nov 2020 (Study Day 77)	Fatigue	Moderate
03 Nov 2020 (Study Day 77)	Muscle Aches (Myalgia)	Moderate
03 Nov 2020 (Study Day 77)	Nasal Congestion	Moderate
03 Nov 2020 (Study Day 77)	New Loss of Smell	Severe
03 Nov 2020 (Study Day 77)	New Loss of Taste	Severe
03 Nov 2020 (Study Day 77)	Temperature (°F)	101.2
04 Nov 2020 (Study Day 78)	Body Aches	Mild

Symptom Date	Symptom	Result
04 Nov 2020 (Study Day 78)	Chills	Moderate
04 Nov 2020 (Study Day 78)	Cough	Moderate
04 Nov 2020 (Study Day 78)	Diarrhea	Moderate
04 Nov 2020 (Study Day 78)	Fatigue	Severe
04 Nov 2020 (Study Day 78)	Headache	Moderate
04 Nov 2020 (Study Day 78)	Muscle Aches (Myalgia)	Mild
04 Nov 2020 (Study Day 78)	Nasal Congestion	Moderate
04 Nov 2020 (Study Day 78)	Nausea	Moderate
04 Nov 2020 (Study Day 78)	New Loss of Smell	Moderate
04 Nov 2020 (Study Day 78)	New Loss of Taste	Moderate
04 Nov 2020 (Study Day 78)	Shortness of Breath	Mild
04 Nov 2020 (Study Day 78)	Temperature (°F)	100.4
05 Nov 2020 (Study Day 79)	Body Aches	Mild
05 Nov 2020 (Study Day 79)	Chills	Moderate
05 Nov 2020 (Study Day 79)	Cough	Moderate
05 Nov 2020 (Study Day 79)	Diarrhea	Moderate
05 Nov 2020 (Study Day 79)	Fatigue	Severe
05 Nov 2020 (Study Day 79)	Headache	Moderate
05 Nov 2020 (Study Day 79)	Muscle Aches (Myalgia)	Mild
05 Nov 2020 (Study Day 79)	Nasal Congestion	Moderate
05 Nov 2020 (Study Day 79)	Nausea	Moderate
05 Nov 2020 (Study Day 79)	New Loss of Smell	Moderate
05 Nov 2020 (Study Day 79)	New Loss of Taste	Moderate
05 Nov 2020 (Study Day 79)	O2 Saturation (%)	92
05 Nov 2020 (Study Day 79)	Shortness of Breath	Mild
05 Nov 2020 (Study Day 79)	Temperature (°F)	100.4
06 Nov 2020 (Study Day 80)	Body Aches	Moderate
06 Nov 2020 (Study Day 80)	Chills	Moderate
06 Nov 2020 (Study Day 80)	Cough	Moderate
06 Nov 2020 (Study Day 80)	Diarrhea	Mild
06 Nov 2020 (Study Day 80)	Difficulty Breathing	Mild
06 Nov 2020 (Study Day 80)	Fatigue	Severe
06 Nov 2020 (Study Day 80)	Headache	Severe
06 Nov 2020 (Study Day 80)	Muscle Aches (Myalgia)	Moderate
06 Nov 2020 (Study Day 80)	Nasal Congestion	Moderate
06 Nov 2020 (Study Day 80)	Nausea	Moderate
06 Nov 2020 (Study Day 80)	New Loss of Smell	Severe
06 Nov 2020 (Study Day 80)	New Loss of Taste	Severe
06 Nov 2020 (Study Day 80)	O2 Saturation (%)	93
06 Nov 2020 (Study Day 80)	Shortness of Breath	Mild
06 Nov 2020 (Study Day 80)	Temperature (°F)	101.0
07 Nov 2020 (Study Day 81)	Body Aches	Mild
07 Nov 2020 (Study Day 81)	Cough	Moderate

Symptom Date	Symptom	Result
07 Nov 2020 (Study Day 81)	Difficulty Breathing	Mild
07 Nov 2020 (Study Day 81)	Fatigue	Moderate
07 Nov 2020 (Study Day 81)	Headache	Mild
07 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Mild
07 Nov 2020 (Study Day 81)	Nasal Congestion	Moderate
07 Nov 2020 (Study Day 81)	Nausea	Mild
07 Nov 2020 (Study Day 81)	New Loss of Smell	Moderate
07 Nov 2020 (Study Day 81)	New Loss of Taste	Moderate
07 Nov 2020 (Study Day 81)	O2 Saturation (%)	87
07 Nov 2020 (Study Day 81)	Shortness of Breath	Mild
08 Nov 2020 (Study Day 82)	Body Aches	Mild
08 Nov 2020 (Study Day 82)	Cough	Moderate
08 Nov 2020 (Study Day 82)	Diarrhea	Mild
08 Nov 2020 (Study Day 82)	Difficulty Breathing	Mild
08 Nov 2020 (Study Day 82)	Fatigue	Mild
08 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Mild
08 Nov 2020 (Study Day 82)	Nasal Congestion	Moderate
08 Nov 2020 (Study Day 82)	New Loss of Smell	Mild
08 Nov 2020 (Study Day 82)	New Loss of Taste	Mild
08 Nov 2020 (Study Day 82)	Shortness of Breath	Mild
09 Nov 2020 (Study Day 83)	Body Aches	Mild
09 Nov 2020 (Study Day 83)	Cough	Severe
09 Nov 2020 (Study Day 83)	Diarrhea	Mild
09 Nov 2020 (Study Day 83)	Difficulty Breathing	Severe
09 Nov 2020 (Study Day 83)	Fatigue	Moderate
09 Nov 2020 (Study Day 83)	Muscle Aches (Myalgia)	Mild
09 Nov 2020 (Study Day 83)	Nasal Congestion	Moderate
09 Nov 2020 (Study Day 83)	New Loss of Smell	Mild
09 Nov 2020 (Study Day 83)	New Loss of Taste	Mild
09 Nov 2020 (Study Day 83)	O2 Saturation (%)	85
09 Nov 2020 (Study Day 83)	Shortness of Breath	Severe
10 Nov 2020 (Study Day 84)	Cough	Moderate
10 Nov 2020 (Study Day 84)	Diarrhea	Mild
10 Nov 2020 (Study Day 84)	Difficulty Breathing	Mild
10 Nov 2020 (Study Day 84)	Fatigue	Mild
10 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
10 Nov 2020 (Study Day 84)	Shortness of Breath	Moderate
11 Nov 2020 (Study Day 85)	Cough	Mild
11 Nov 2020 (Study Day 85)	Diarrhea	Mild
11 Nov 2020 (Study Day 85)	Difficulty Breathing	Mild
11 Nov 2020 (Study Day 85)	Fatigue	Mild
11 Nov 2020 (Study Day 85)	Nasal Congestion	Moderate

Symptom Date	Symptom	Result
11 Nov 2020 (Study Day 85)	Nausea	Mild
11 Nov 2020 (Study Day 85)	O2 Saturation (%)	90
11 Nov 2020 (Study Day 85)	Shortness of Breath	Mild
12 Nov 2020 (Study Day 86)	Cough	Mild
12 Nov 2020 (Study Day 86)	Difficulty Breathing	Mild
12 Nov 2020 (Study Day 86)	Fatigue	Mild
12 Nov 2020 (Study Day 86)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 86)	O2 Saturation (%)	89
12 Nov 2020 (Study Day 86)	Shortness of Breath	Mild
13 Nov 2020 (Study Day 87)	Cough	Mild
13 Nov 2020 (Study Day 87)	Difficulty Breathing	Mild
13 Nov 2020 (Study Day 87)	Fatigue	Mild
13 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 87)	Shortness of Breath	Mild
14 Nov 2020 (Study Day 88)	Cough	Mild
14 Nov 2020 (Study Day 88)	Difficulty Breathing	Mild
14 Nov 2020 (Study Day 88)	Fatigue	Mild
14 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
14 Nov 2020 (Study Day 88)	O2 Saturation (%)	93
14 Nov 2020 (Study Day 88)	Shortness of Breath	Mild
15 Nov 2020 (Study Day 89)	Difficulty Breathing	Mild
15 Nov 2020 (Study Day 89)	Fatigue	Mild
15 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
15 Nov 2020 (Study Day 89)	O2 Saturation (%)	93
15 Nov 2020 (Study Day 89)	Shortness of Breath	Mild
16 Nov 2020 (Study Day 90)	Difficulty Breathing	Mild
16 Nov 2020 (Study Day 90)	Fatigue	Mild
16 Nov 2020 (Study Day 90)	Nasal Congestion	Severe
16 Nov 2020 (Study Day 90)	Runny Nose (Rhinorrhea)	Mild
16 Nov 2020 (Study Day 90)	Shortness of Breath	Mild
17 Nov 2020 (Study Day 91)	Difficulty Breathing	Mild
17 Nov 2020 (Study Day 91)	Fatigue	Mild
17 Nov 2020 (Study Day 91)	Nasal Congestion	Moderate
17 Nov 2020 (Study Day 91)	Runny Nose (Rhinorrhea)	Mild
17 Nov 2020 (Study Day 91)	Shortness of Breath	Mild
18 Nov 2020 (Study Day 92)	Difficulty Breathing	Moderate
18 Nov 2020 (Study Day 92)	Fatigue	Moderate
18 Nov 2020 (Study Day 92)	Nasal Congestion	Moderate
18 Nov 2020 (Study Day 92)	Shortness of Breath	Moderate
19 Nov 2020 (Study Day 93)	Cough	Mild
19 Nov 2020 (Study Day 93)	Difficulty Breathing	Mild
19 Nov 2020 (Study Day 93)	Fatigue	Mild
19 Nov 2020 (Study Day 93)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
19 Nov 2020 (Study Day 93)	Shortness of Breath	Mild
20 Nov 2020 (Study Day 94)	Cough	Mild
20 Nov 2020 (Study Day 94)	Difficulty Breathing	Mild
20 Nov 2020 (Study Day 94)	Fatigue	Mild
20 Nov 2020 (Study Day 94)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 94)	Shortness of Breath	Mild
21 Nov 2020 (Study Day 95)	Cough	Mild
21 Nov 2020 (Study Day 95)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 95)	New Loss of Smell	Mild
21 Nov 2020 (Study Day 95)	New Loss of Taste	Mild
21 Nov 2020 (Study Day 95)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 96)	Cough	Mild
22 Nov 2020 (Study Day 96)	Difficulty Breathing	Mild
22 Nov 2020 (Study Day 96)	Fatigue	Mild
22 Nov 2020 (Study Day 96)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 96)	Shortness of Breath	Mild
23 Nov 2020 (Study Day 97)	Cough	Mild
23 Nov 2020 (Study Day 97)	Nasal Congestion	Mild
23 Nov 2020 (Study Day 97)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 98)	Cough	Mild
24 Nov 2020 (Study Day 98)	Nasal Congestion	Mild
24 Nov 2020 (Study Day 98)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 99)	Cough	Mild
25 Nov 2020 (Study Day 99)	Nasal Congestion	Mild
25 Nov 2020 (Study Day 99)	Shortness of Breath	Mild
26 Nov 2020 (Study Day 100)	Cough	Mild
26 Nov 2020 (Study Day 100)	Nasal Congestion	Mild
27 Nov 2020 (Study Day 101)	Cough	Mild
27 Nov 2020 (Study Day 101)	Nasal Congestion	Mild
28 Nov 2020 (Study Day 102)	Cough	Mild
28 Nov 2020 (Study Day 102)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
05 Nov 2020 (Study Day 79)	Oxygen Saturation	85%
05 Nov 2020 - 15 Nov 2020 (Study Day 79-89)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 40 days, after which it was considered to be recovered/resolved on 08 Dec 2020 (Study Day 112). The investigator assessed the event of COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of pneumonia due to COVID-19 virus lasted for 24 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 104). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000683	COVID-19
MOD-2020-000683	Hypoxia
MOD-2020-000683	COVID-19 pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dyspepsia	Acid indigestion	1992 - Ongoing
Gestational diabetes	Gestational diabetes	2007 - 2007
Seasonal allergy	Seasonal allergies	2007 - Ongoing
Gestational diabetes	Gestational diabetes	2008 - 2008
Sciatica	Sciatica	2017 - Ongoing
Back pain	Generalized lumbar backache	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium carbonate	1992 - Ongoing	Acid Indigestion
Fexofenadine hydrochloride; pseudoephedrine hydrochloride	Apr 2016 - 15 Oct 2020 (Study Day 58)	Seasonal Allergies
Ibuprofen	2019 - Ongoing	Generalized Lumbar Backache
Fluticasone propionate	11 Oct 2020 (Study Day 54) - Ongoing	Seasonal Allergies
Influenza vaccine	15 Oct 2020 (Study Day 58) - 15 Oct 2020 (Study Day 58)	Influenza
Ascorbic acid	30 Oct 2020 (Study Day 73) - Ongoing	Nutritional Supplement
Guaifenesin	30 Oct 2020 (Study Day 73) - 08 Dec 2020 (Study Day 112)	COVID 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sambucus nigra; zinc gluconate	30 Oct 2020 (Study Day 73) - 08 Dec 2020 (Study Day 112)	COVID 19
Vitamin d nos	30 Oct 2020 (Study Day 73) - Ongoing	Nutritional Supplement
Melatonin	02 Nov 2020 (Study Day 76) - Ongoing	COVID 19
Paracetamol	02 Nov 2020 (Study Day 76) - Ongoing	COVID 19
Azithromycin	07 Nov 2020 (Study Day 81) - 11 Nov 2020 (Study Day 85)	Pneumonia Secondary To COVID 19 Positive Illness
Ceftriaxone	07 Nov 2020 (Study Day 81) - Ongoing	Secondary Pneumonia Due To COVID 19 Positive Illness
Chest x-ray*	07 Nov 2020 (Study Day 81) - 07 Nov 2020 (Study Day 81)	Adverse Event
Dexamethasone	07 Nov 2020 (Study Day 81) - 08 Dec 2020 (Study Day 112)	COVID 19
Enoxaparin sodium	07 Nov 2020 (Study Day 81) - 08 Dec 2020 (Study Day 112)	COVID-19
Oxygen	07 Nov 2020 (Study Day 81) - 20 Nov 2020 (Study Day 94)	Hypoxia
Remdesivir	07 Nov 2020 (Study Day 81) - 07 Nov 2020 (Study Day 81)	COVID 19
Remdesivir	08 Nov 2020 (Study Day 82) - 11 Nov 2020 (Study Day 85)	COVID 19
Plasma	09 Nov 2020 (Study Day 83) - 09 Nov 2020 (Study Day 83)	COVID 19
Azithromycin	12 Nov 2020 (Study Day 86) - Ongoing	Pneumonia Secondary To COVID 19 Illness.
Potassium	12 Nov 2020 (Study Day 86) - Ongoing	Hypokalemia
Cetirizine	15 Nov 2020 (Study Day 89) - Ongoing	Nasal Congestion, Allergies - COVID 19
Fluconazole	16 Nov 2020 (Study Day 90) - 16 Nov 2020 (Study Day 90)	Vaginal Candidiasis
Omeprazole	16 Nov 2020 (Study Day 90) - Ongoing	Acid Indigestion
Salbutamol	18 Nov 2020 (Study Day 92) - 08 Dec 2020 (Study Day 112)	COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypokalaemia	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 81) - 20 Nov 2020 (Study Day 94)
Vulvovaginal Candidiasis	Grade 1/mild	Not related	15 Nov 2020 (Study Day 89) - 20 Nov 2020 (Study Day 94)
Dyspepsia	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 90) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2196 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	COVID-19	Grade 1/mild	Not related	05 Nov 2020 (Study Day 79) – 19 Nov 2020 (Study Day 93)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US327-2196, a 59-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 05 Nov 2020 (Study Day 79), 78 days after the first dose and 50 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 16 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 09 Nov 2020 (Study Day 83), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
05 Nov 2020 (Study Day 79)	Body Aches	Moderate
05 Nov 2020 (Study Day 79)	Diarrhea	Moderate
05 Nov 2020 (Study Day 79)	Fatigue	Moderate
05 Nov 2020 (Study Day 79)	Headache	Mild
05 Nov 2020 (Study Day 79)	Muscle Aches (Myalgia)	Moderate
05 Nov 2020 (Study Day 79)	Nausea	Mild

Symptom Date	Symptom	Result
06 Nov 2020 (Study Day 80)	Body Aches	Moderate
06 Nov 2020 (Study Day 80)	Chills	Mild
06 Nov 2020 (Study Day 80)	Diarrhea	Moderate
06 Nov 2020 (Study Day 80)	Fatigue	Moderate
06 Nov 2020 (Study Day 80)	Headache	Mild
06 Nov 2020 (Study Day 80)	Muscle Aches (Myalgia)	Moderate
06 Nov 2020 (Study Day 80)	Nausea	Mild
07 Nov 2020 (Study Day 81)	Body Aches	Moderate
07 Nov 2020 (Study Day 81)	Chills	Mild
07 Nov 2020 (Study Day 81)	Diarrhea	Moderate
07 Nov 2020 (Study Day 81)	Fatigue	Moderate
07 Nov 2020 (Study Day 81)	Headache	Mild
07 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Moderate
07 Nov 2020 (Study Day 81)	Nausea	Mild
07 Nov 2020 (Study Day 81)	New Loss of Smell	Moderate
07 Nov 2020 (Study Day 81)	New Loss of Taste	Moderate
08 Nov 2020 (Study Day 82)	Body Aches	Moderate
08 Nov 2020 (Study Day 82)	Chills	Mild
08 Nov 2020 (Study Day 82)	Diarrhea	Moderate
08 Nov 2020 (Study Day 82)	Fatigue	Moderate
08 Nov 2020 (Study Day 82)	Headache	Mild
08 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
08 Nov 2020 (Study Day 82)	Nausea	Mild
08 Nov 2020 (Study Day 82)	New Loss of Smell	Moderate
08 Nov 2020 (Study Day 82)	New Loss of Taste	Moderate
09 Nov 2020 (Study Day 83)	Body Aches	Moderate
09 Nov 2020 (Study Day 83)	Chills	Mild
09 Nov 2020 (Study Day 83)	Diarrhea	Moderate
09 Nov 2020 (Study Day 83)	Fatigue	Moderate
09 Nov 2020 (Study Day 83)	Headache	Mild
09 Nov 2020 (Study Day 83)	Muscle Aches (Myalgia)	Moderate
09 Nov 2020 (Study Day 83)	Nausea	Mild
09 Nov 2020 (Study Day 83)	New Loss of Smell	Moderate
09 Nov 2020 (Study Day 83)	New Loss of Taste	Moderate
09 Nov 2020 (Study Day 83)	Shortness of Breath	Mild
10 Nov 2020 (Study Day 84)	Body Aches	Moderate
10 Nov 2020 (Study Day 84)	Chills	Mild
10 Nov 2020 (Study Day 84)	Diarrhea	Mild
10 Nov 2020 (Study Day 84)	Fatigue	Mild
10 Nov 2020 (Study Day 84)	Headache	Mild
10 Nov 2020 (Study Day 84)	Muscle Aches (Myalgia)	Moderate
10 Nov 2020 (Study Day 84)	Nasal Congestion	Mild
10 Nov 2020 (Study Day 84)	Nausea	Mild

Symptom Date	Symptom	Result
10 Nov 2020 (Study Day 84)	New Loss of Smell	Mild
10 Nov 2020 (Study Day 84)	New Loss of Taste	Mild
10 Nov 2020 (Study Day 84)	O2 Saturation (%)	92
11 Nov 2020 (Study Day 85)	Body Aches	Moderate
11 Nov 2020 (Study Day 85)	Chills	Moderate
11 Nov 2020 (Study Day 85)	Cough	Mild
11 Nov 2020 (Study Day 85)	Diarrhea	Moderate
11 Nov 2020 (Study Day 85)	Difficulty Breathing	Mild
11 Nov 2020 (Study Day 85)	Fatigue	Moderate
11 Nov 2020 (Study Day 85)	Headache	Moderate
11 Nov 2020 (Study Day 85)	Muscle Aches (Myalgia)	Moderate
11 Nov 2020 (Study Day 85)	Nasal Congestion	Mild
11 Nov 2020 (Study Day 85)	Nausea	Mild
11 Nov 2020 (Study Day 85)	New Loss of Smell	Mild
11 Nov 2020 (Study Day 85)	New Loss of Taste	Mild
11 Nov 2020 (Study Day 85)	O2 Saturation (%)	93
11 Nov 2020 (Study Day 85)	Shortness of Breath	Mild
11 Nov 2020 (Study Day 85)	Temperature (°F)	100.9
11 Nov 2020 (Study Day 85)	Vomiting	Mild
12 Nov 2020 (Study Day 86)	Body Aches	Mild
12 Nov 2020 (Study Day 86)	Chills	Moderate
12 Nov 2020 (Study Day 86)	Cough	Mild
12 Nov 2020 (Study Day 86)	Diarrhea	Moderate
12 Nov 2020 (Study Day 86)	Fatigue	Moderate
12 Nov 2020 (Study Day 86)	Headache	Mild
12 Nov 2020 (Study Day 86)	Muscle Aches (Myalgia)	Mild
12 Nov 2020 (Study Day 86)	Nausea	Mild
12 Nov 2020 (Study Day 86)	New Loss of Smell	Mild
12 Nov 2020 (Study Day 86)	New Loss of Taste	Mild
12 Nov 2020 (Study Day 86)	Shortness of Breath	Mild
13 Nov 2020 (Study Day 87)	Body Aches	Moderate
13 Nov 2020 (Study Day 87)	Chills	Moderate
13 Nov 2020 (Study Day 87)	Cough	Moderate
13 Nov 2020 (Study Day 87)	Diarrhea	Moderate
13 Nov 2020 (Study Day 87)	Difficulty Breathing	Mild
13 Nov 2020 (Study Day 87)	Fatigue	Moderate
13 Nov 2020 (Study Day 87)	Headache	Moderate
13 Nov 2020 (Study Day 87)	Muscle Aches (Myalgia)	Moderate
13 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 87)	Nausea	Moderate
13 Nov 2020 (Study Day 87)	New Loss of Smell	Mild
13 Nov 2020 (Study Day 87)	New Loss of Taste	Mild
13 Nov 2020 (Study Day 87)	O2 Saturation (%)	93

Symptom Date	Symptom	Result
13 Nov 2020 (Study Day 87)	Runny Nose (Rhinorrhea)	Mild
13 Nov 2020 (Study Day 87)	Shortness of Breath	Mild
13 Nov 2020 (Study Day 87)	Temperature (°F)	101.5
14 Nov 2020 (Study Day 88)	Fatigue	Mild
14 Nov 2020 (Study Day 88)	O2 Saturation (%)	93
14 Nov 2020 (Study Day 88)	Shortness of Breath	Mild
15 Nov 2020 (Study Day 89)	Fatigue	Mild
15 Nov 2020 (Study Day 89)	O2 Saturation (%)	93
15 Nov 2020 (Study Day 89)	Shortness of Breath	Mild
16 Nov 2020 (Study Day 90)	Diarrhea	Mild
16 Nov 2020 (Study Day 90)	Fatigue	Mild
16 Nov 2020 (Study Day 90)	O2 Saturation (%)	92
16 Nov 2020 (Study Day 90)	Shortness of Breath	Mild
17 Nov 2020 (Study Day 91)	Diarrhea	Mild
17 Nov 2020 (Study Day 91)	Fatigue	Mild
17 Nov 2020 (Study Day 91)	Shortness of Breath	Mild
18 Nov 2020 (Study Day 92)	Diarrhea	Mild
18 Nov 2020 (Study Day 92)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
10 Nov 2020 (Study Day 84)	Oxygen Saturation	92%
10 Nov 2020 - 16 Nov 2020 (Study Day 84-90)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 15 days, after which it was considered to be recovered/resolved on 19 Nov 2020 (Study Day 93). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000854	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2008 - 2013
Menopause	Menopause	2011 - 2012
Endometrial ablation	Endometrial ablation	2012 - 2016
Postmenopause	Post menopause	2012 - Ongoing
Obesity	Sever obesity	2014 - Ongoing
Knee arthroplasty	Bilateral knee replacement	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	09 Nov 2020 (Study Day 83) - 18 Nov 2020 (Study Day 92)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	05 Nov 2020 (Study Day 79) - 19 Nov 2020 (Study Day 93)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2342 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	23 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 33)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suspected COVID-19/ Suspected COVID-19	COVID-19	Grade 1/mild	Not related	01 Oct 2020 (Study Day 40) – 10 Oct 2020 (Study Day 49)	Recovered /resolved
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	29 Nov 2020 (Study Day 99) – 13 Jan 2021 (Study Day 144)	Recovered /resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US327-2342, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 23 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 01 Oct 2020 (Study Day 40), 39 days after the first dose and 7 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of suspected COVID-19.

On 29 Nov 2020 (Study Day 99), 98 days after the first dose and 66 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 33, 24 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 02 Dec 2020 (Study Day 102), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
01 Oct 2020 (Study Day 40)	Body Aches	Mild
01 Oct 2020 (Study Day 40)	Cough	Mild
01 Oct 2020 (Study Day 40)	Difficulty Breathing	Mild
01 Oct 2020 (Study Day 40)	Fatigue	Severe
01 Oct 2020 (Study Day 40)	Headache	Mild
01 Oct 2020 (Study Day 40)	Muscle Aches (Myalgia)	Mild
01 Oct 2020 (Study Day 40)	Nausea	Mild
01 Oct 2020 (Study Day 40)	New Loss of Smell	Mild
01 Oct 2020 (Study Day 40)	New Loss of Taste	Mild
01 Oct 2020 (Study Day 40)	Runny Nose (Rhinorrhea)	Mild
02 Oct 2020 (Study Day 41)	Body Aches	Mild
02 Oct 2020 (Study Day 41)	Cough	Mild
02 Oct 2020 (Study Day 41)	Difficulty Breathing	Mild
02 Oct 2020 (Study Day 41)	Fatigue	Severe
02 Oct 2020 (Study Day 41)	Headache	Mild
02 Oct 2020 (Study Day 41)	Muscle Aches (Myalgia)	Mild
02 Oct 2020 (Study Day 41)	Nausea	Mild
02 Oct 2020 (Study Day 41)	New Loss of Smell	Mild
02 Oct 2020 (Study Day 41)	New Loss of Taste	Mild
02 Oct 2020 (Study Day 41)	Runny Nose (Rhinorrhea)	Mild
03 Oct 2020 (Study Day 42)	Body Aches	Mild
03 Oct 2020 (Study Day 42)	Cough	Mild
03 Oct 2020 (Study Day 42)	Difficulty Breathing	Mild
03 Oct 2020 (Study Day 42)	Fatigue	Severe
03 Oct 2020 (Study Day 42)	Headache	Mild
03 Oct 2020 (Study Day 42)	Muscle Aches (Myalgia)	Mild
03 Oct 2020 (Study Day 42)	Nausea	Mild
03 Oct 2020 (Study Day 42)	New Loss of Smell	Mild
03 Oct 2020 (Study Day 42)	New Loss of Taste	Mild
03 Oct 2020 (Study Day 42)	Runny Nose (Rhinorrhea)	Mild
04 Oct 2020 (Study Day 43)	Body Aches	Mild
04 Oct 2020 (Study Day 43)	Cough	Mild
04 Oct 2020 (Study Day 43)	Difficulty Breathing	Mild
04 Oct 2020 (Study Day 43)	Fatigue	Severe
04 Oct 2020 (Study Day 43)	Headache	Mild
04 Oct 2020 (Study Day 43)	Muscle Aches (Myalgia)	Mild
04 Oct 2020 (Study Day 43)	Nausea	Mild
04 Oct 2020 (Study Day 43)	New Loss of Smell	Mild
04 Oct 2020 (Study Day 43)	New Loss of Taste	Mild
04 Oct 2020 (Study Day 43)	Runny Nose (Rhinorrhea)	Mild
05 Oct 2020 (Study Day 44)	Body Aches	Mild
05 Oct 2020 (Study Day 44)	Cough	Mild

Symptom Date	Symptom	Result
05 Oct 2020 (Study Day 44)	Difficulty Breathing	Mild
05 Oct 2020 (Study Day 44)	Fatigue	Severe
05 Oct 2020 (Study Day 44)	Headache	Mild
05 Oct 2020 (Study Day 44)	Muscle Aches (Myalgia)	Mild
05 Oct 2020 (Study Day 44)	Nausea	Mild
05 Oct 2020 (Study Day 44)	New Loss of Smell	Mild
05 Oct 2020 (Study Day 44)	New Loss of Taste	Mild
05 Oct 2020 (Study Day 44)	Runny Nose (Rhinorrhea)	Mild
06 Oct 2020 (Study Day 45)	Body Aches	Mild
06 Oct 2020 (Study Day 45)	Cough	Mild
06 Oct 2020 (Study Day 45)	Difficulty Breathing	Mild
06 Oct 2020 (Study Day 45)	Fatigue	Mild
06 Oct 2020 (Study Day 45)	Headache	Mild
06 Oct 2020 (Study Day 45)	Muscle Aches (Myalgia)	Mild
06 Oct 2020 (Study Day 45)	Nausea	Mild
06 Oct 2020 (Study Day 45)	New Loss of Taste	Mild
07 Oct 2020 (Study Day 46)	Body Aches	Mild
07 Oct 2020 (Study Day 46)	Cough	Mild
07 Oct 2020 (Study Day 46)	Difficulty Breathing	Mild
07 Oct 2020 (Study Day 46)	Fatigue	Mild
07 Oct 2020 (Study Day 46)	Headache	Mild
07 Oct 2020 (Study Day 46)	Muscle Aches (Myalgia)	Mild
07 Oct 2020 (Study Day 46)	Nausea	Mild
07 Oct 2020 (Study Day 46)	New Loss of Taste	Mild
08 Oct 2020 (Study Day 47)	Body Aches	Mild
08 Oct 2020 (Study Day 47)	Cough	Mild
08 Oct 2020 (Study Day 47)	Fatigue	Mild
08 Oct 2020 (Study Day 47)	Muscle Aches (Myalgia)	Mild
09 Oct 2020 (Study Day 48)	Body Aches	Mild
09 Oct 2020 (Study Day 48)	Cough	Mild
09 Oct 2020 (Study Day 48)	Fatigue	Mild
09 Oct 2020 (Study Day 48)	Muscle Aches (Myalgia)	Mild
29 Nov 2020 (Study Day 99)	Cough	Mild
29 Nov 2020 (Study Day 99)	Nasal Congestion	Mild
29 Nov 2020 (Study Day 99)	Runny Nose (Rhinorrhea)	Mild
30 Nov 2020 (Study Day 100)	Cough	Mild
30 Nov 2020 (Study Day 100)	Nasal Congestion	Mild
30 Nov 2020 (Study Day 100)	Runny Nose (Rhinorrhea)	Mild
01 Dec 2020 (Study Day 101)	Cough	Mild
01 Dec 2020 (Study Day 101)	Nasal Congestion	Mild
01 Dec 2020 (Study Day 101)	Runny Nose (Rhinorrhea)	Mild
02 Dec 2020 (Study Day 102)	Cough	Mild
02 Dec 2020 (Study Day 102)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
02 Dec 2020 (Study Day 102)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 103)	Chills	Moderate
03 Dec 2020 (Study Day 103)	Cough	Mild
03 Dec 2020 (Study Day 103)	Fatigue	Mild
03 Dec 2020 (Study Day 103)	Headache	Severe
03 Dec 2020 (Study Day 103)	Muscle Aches (Myalgia)	Mild
03 Dec 2020 (Study Day 103)	Nasal Congestion	Mild
03 Dec 2020 (Study Day 103)	Runny Nose (Rhinorrhea)	Mild
03 Dec 2020 (Study Day 103)	Temperature (°F)	100.6
05 Dec 2020 (Study Day 105)	Body Aches	Moderate
05 Dec 2020 (Study Day 105)	Cough	Mild
05 Dec 2020 (Study Day 105)	Diarrhea	Moderate
05 Dec 2020 (Study Day 105)	Fatigue	Moderate
05 Dec 2020 (Study Day 105)	Headache	Moderate
05 Dec 2020 (Study Day 105)	Muscle Aches (Myalgia)	Moderate
05 Dec 2020 (Study Day 105)	Nasal Congestion	Moderate
05 Dec 2020 (Study Day 105)	Nausea	Mild
05 Dec 2020 (Study Day 105)	Temperature (°F)	100.6
06 Dec 2020 (Study Day 106)	Body Aches	Moderate
06 Dec 2020 (Study Day 106)	Chills	Mild
06 Dec 2020 (Study Day 106)	Cough	Mild
06 Dec 2020 (Study Day 106)	Fatigue	Moderate
06 Dec 2020 (Study Day 106)	Headache	Moderate
06 Dec 2020 (Study Day 106)	Muscle Aches (Myalgia)	Moderate
06 Dec 2020 (Study Day 106)	Nasal Congestion	Moderate
06 Dec 2020 (Study Day 106)	Nausea	Mild
06 Dec 2020 (Study Day 106)	O2 Saturation (%)	93
07 Dec 2020 (Study Day 107)	Body Aches	Moderate
07 Dec 2020 (Study Day 107)	Chills	Mild
07 Dec 2020 (Study Day 107)	Cough	Mild
07 Dec 2020 (Study Day 107)	Fatigue	Moderate
07 Dec 2020 (Study Day 107)	Headache	Moderate
07 Dec 2020 (Study Day 107)	Muscle Aches (Myalgia)	Moderate
07 Dec 2020 (Study Day 107)	Nasal Congestion	Moderate
18 Dec 2020 (Study Day 118)	Body Aches	Mild
18 Dec 2020 (Study Day 118)	Fatigue	Moderate
18 Dec 2020 (Study Day 118)	Headache	Severe
18 Dec 2020 (Study Day 118)	Muscle Aches (Myalgia)	Mild
18 Dec 2020 (Study Day 118)	Nasal Congestion	Moderate
18 Dec 2020 (Study Day 118)	Nausea	Moderate
18 Dec 2020 (Study Day 118)	Sore Throat	Mild
18 Dec 2020 (Study Day 118)	Vomiting	Mild
19 Dec 2020 (Study Day 119)	Body Aches	Mild

Symptom Date	Symptom	Result
19 Dec 2020 (Study Day 119)	Chills	Mild
19 Dec 2020 (Study Day 119)	Fatigue	Mild
19 Dec 2020 (Study Day 119)	Headache	Moderate
19 Dec 2020 (Study Day 119)	Muscle Aches (Myalgia)	Mild
19 Dec 2020 (Study Day 119)	Nasal Congestion	Moderate
20 Dec 2020 (Study Day 120)	Body Aches	Mild
20 Dec 2020 (Study Day 120)	Chills	Mild
20 Dec 2020 (Study Day 120)	Fatigue	Mild
20 Dec 2020 (Study Day 120)	Headache	Moderate
20 Dec 2020 (Study Day 120)	Muscle Aches (Myalgia)	Mild
20 Dec 2020 (Study Day 120)	Nasal Congestion	Mild
20 Dec 2020 (Study Day 120)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 121)	Body Aches	Mild
21 Dec 2020 (Study Day 121)	Chills	Mild
21 Dec 2020 (Study Day 121)	Cough	Mild
21 Dec 2020 (Study Day 121)	Fatigue	Mild
21 Dec 2020 (Study Day 121)	Headache	Moderate
21 Dec 2020 (Study Day 121)	Muscle Aches (Myalgia)	Mild
21 Dec 2020 (Study Day 121)	Nasal Congestion	Mild
21 Dec 2020 (Study Day 121)	Runny Nose (Rhinorrhea)	Mild
22 Dec 2020 (Study Day 122)	Body Aches	Mild
22 Dec 2020 (Study Day 122)	Chills	Mild
22 Dec 2020 (Study Day 122)	Fatigue	Mild
22 Dec 2020 (Study Day 122)	Headache	Moderate
22 Dec 2020 (Study Day 122)	Muscle Aches (Myalgia)	Mild
22 Dec 2020 (Study Day 122)	Nasal Congestion	Moderate
23 Dec 2020 (Study Day 123)	Headache	Mild
24 Dec 2020 (Study Day 124)	Headache	Mild
24 Dec 2020 (Study Day 124)	O2 Saturation (%)	87
25 Dec 2020 (Study Day 125)	Chills	Mild
25 Dec 2020 (Study Day 125)	Fatigue	Severe
25 Dec 2020 (Study Day 125)	Headache	Severe
25 Dec 2020 (Study Day 125)	Nasal Congestion	Severe
25 Dec 2020 (Study Day 125)	Nausea	Severe
25 Dec 2020 (Study Day 125)	New Loss of Smell	Severe
25 Dec 2020 (Study Day 125)	New Loss of Taste	Severe
26 Dec 2020 (Study Day 126)	Headache	Mild
27 Dec 2020 (Study Day 127)	Headache	Mild
28 Dec 2020 (Study Day 128)	Headache	Mild
19 Jan 2021 (Study Day 150)	Nasal Congestion	Moderate
19 Jan 2021 (Study Day 150)	Runny Nose (Rhinorrhea)	Moderate
20 Jan 2021 (Study Day 151)	Nasal Congestion	Moderate
20 Jan 2021 (Study Day 151)	Runny Nose (Rhinorrhea)	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
06 Dec 2020 (Study Day 106)	Oxygen Saturation	87%
06 Dec 2020 - 24 Dec 2020 (Study Day 106-124)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

The IP dose was not changed due to the suspected covid-19. The event of suspected COVID-19 lasted for 10 days, after which it was considered to be recovered/resolved on 10 Oct 2020 (Study Day 49). The investigator assessed the event of suspected COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of COVID-19 lasted for 46 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 144). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001181	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Sulfa allergy	1990 - Ongoing
Type 1 diabetes mellitus	Diabetes mellitus type 1	2000 - Ongoing
Depression	Depression	2005 - Ongoing
Menopause	Menopause	2012 - 2013
Postmenopause	Post-menopausal	2013 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Myalgia	Myalgia (lower back)	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	2000 - Ongoing	Diabetes Mellitus Type 1
Insulin degludec	2000 - Ongoing	Diabetes Mellitus Type 1
Metformin	2000 - Ongoing	Diabetes Mellitus Type 1
Levothyroxine	2015 - Ongoing	Hypothyroidism
Acetylsalicylic acid	2019 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2019 - Ongoing	Hypercholesterolemia
Cetirizine	2019 - Ongoing	Seasonal Allergies
Citalopram	2019 - Ongoing	Depression
Lisinopril	2019 - Ongoing	Hypertension
Vitamins nos	2019 - Ongoing	Nutritional Supplement
Gabapentin	Apr 2020 - Ongoing	Myalgia (Lower Back)
Levothyroxine	Jun 2020 - Ongoing	Hypothyroidism
Ubidecarenone	Jun 2020 - Ongoing	Nutritional Supplement
Paracetamol	03 Dec 2020 (Study Day 103) - Ongoing	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 1/mild	Not related	01 Oct 2020 (Study Day 40) - 10 Oct 2020 (Study Day 49)
COVID-19	Grade 3/severe	Not related	29 Nov 2020 (Study Day 99) - 13 Jan 2021 (Study Day 144)
Viral Sinusitis	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 146) - 23 Jan 2021 (Study Day 154)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2357 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	COVID-19	Grade 1/mild	Not related	09 Nov 2020 (Study Day 77) – 08 Dec 2020 (Study Day 106)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US327-2357, a 41-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 09 Nov 2020 (Study Day 77), 76 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 22 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 10 Nov 2020 (Study Day 78), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 77)	Body Aches	Moderate
09 Nov 2020 (Study Day 77)	Cough	Mild
09 Nov 2020 (Study Day 77)	Fatigue	Moderate
09 Nov 2020 (Study Day 77)	Headache	Moderate
09 Nov 2020 (Study Day 77)	Muscle Aches (Myalgia)	Moderate
09 Nov 2020 (Study Day 77)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
09 Nov 2020 (Study Day 77)	Sore Throat	Moderate
10 Nov 2020 (Study Day 78)	Body Aches	Moderate
10 Nov 2020 (Study Day 78)	Cough	Mild
10 Nov 2020 (Study Day 78)	Fatigue	Moderate
10 Nov 2020 (Study Day 78)	Headache	Moderate
10 Nov 2020 (Study Day 78)	Muscle Aches (Myalgia)	Moderate
10 Nov 2020 (Study Day 78)	Shortness of Breath	Mild
10 Nov 2020 (Study Day 78)	Sore Throat	Moderate
11 Nov 2020 (Study Day 79)	Fatigue	Mild
11 Nov 2020 (Study Day 79)	Headache	Mild
11 Nov 2020 (Study Day 79)	Muscle Aches (Myalgia)	Mild
12 Nov 2020 (Study Day 80)	Body Aches	Mild
12 Nov 2020 (Study Day 80)	Cough	Mild
12 Nov 2020 (Study Day 80)	Fatigue	Mild
12 Nov 2020 (Study Day 80)	Headache	Mild
12 Nov 2020 (Study Day 80)	Muscle Aches (Myalgia)	Mild
12 Nov 2020 (Study Day 80)	Nasal Congestion	Mild
12 Nov 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
12 Nov 2020 (Study Day 80)	Sore Throat	Mild
13 Nov 2020 (Study Day 81)	Body Aches	Moderate
13 Nov 2020 (Study Day 81)	Cough	Mild
13 Nov 2020 (Study Day 81)	Fatigue	Moderate
13 Nov 2020 (Study Day 81)	Headache	Mild
13 Nov 2020 (Study Day 81)	Muscle Aches (Myalgia)	Moderate
13 Nov 2020 (Study Day 81)	Nasal Congestion	Mild
13 Nov 2020 (Study Day 81)	Runny Nose (Rhinorrhea)	Mild
14 Nov 2020 (Study Day 82)	Body Aches	Moderate
14 Nov 2020 (Study Day 82)	Chills	Mild
14 Nov 2020 (Study Day 82)	Cough	Mild
14 Nov 2020 (Study Day 82)	Fatigue	Severe
14 Nov 2020 (Study Day 82)	Headache	Mild
14 Nov 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
14 Nov 2020 (Study Day 82)	Nasal Congestion	Moderate
14 Nov 2020 (Study Day 82)	Nausea	Mild
14 Nov 2020 (Study Day 82)	New Loss of Smell	Mild
14 Nov 2020 (Study Day 82)	New Loss of Taste	Mild
14 Nov 2020 (Study Day 82)	Runny Nose (Rhinorrhea)	Moderate
14 Nov 2020 (Study Day 82)	Shortness of Breath	Mild
14 Nov 2020 (Study Day 82)	Temperature (°F)	100.4
15 Nov 2020 (Study Day 83)	Body Aches	Mild
15 Nov 2020 (Study Day 83)	Chills	Mild
15 Nov 2020 (Study Day 83)	Cough	Mild
15 Nov 2020 (Study Day 83)	Fatigue	Mild

Symptom Date	Symptom	Result
15 Nov 2020 (Study Day 83)	Headache	Moderate
15 Nov 2020 (Study Day 83)	Muscle Aches (Myalgia)	Mild
15 Nov 2020 (Study Day 83)	Nasal Congestion	Severe
15 Nov 2020 (Study Day 83)	New Loss of Taste	Mild
15 Nov 2020 (Study Day 83)	Runny Nose (Rhinorrhea)	Severe
15 Nov 2020 (Study Day 83)	Temperature (°F)	101.5
16 Nov 2020 (Study Day 84)	Body Aches	Moderate
16 Nov 2020 (Study Day 84)	Cough	Moderate
16 Nov 2020 (Study Day 84)	Fatigue	Moderate
16 Nov 2020 (Study Day 84)	Headache	Mild
16 Nov 2020 (Study Day 84)	Muscle Aches (Myalgia)	Moderate
16 Nov 2020 (Study Day 84)	Nasal Congestion	Moderate
16 Nov 2020 (Study Day 84)	Nausea	Moderate
16 Nov 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Moderate
17 Nov 2020 (Study Day 85)	Body Aches	Severe
17 Nov 2020 (Study Day 85)	Chills	Moderate
17 Nov 2020 (Study Day 85)	Cough	Moderate
17 Nov 2020 (Study Day 85)	Difficulty Breathing	Moderate
17 Nov 2020 (Study Day 85)	Fatigue	Severe
17 Nov 2020 (Study Day 85)	Headache	Severe
17 Nov 2020 (Study Day 85)	Muscle Aches (Myalgia)	Severe
17 Nov 2020 (Study Day 85)	Nasal Congestion	Moderate
17 Nov 2020 (Study Day 85)	O2 Saturation (%)	89
17 Nov 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Moderate
17 Nov 2020 (Study Day 85)	Shortness of Breath	Moderate
17 Nov 2020 (Study Day 85)	Temperature (°F)	101.9
18 Nov 2020 (Study Day 86)	Cough	Mild
18 Nov 2020 (Study Day 86)	Fatigue	Mild
18 Nov 2020 (Study Day 86)	Muscle Aches (Myalgia)	Mild
18 Nov 2020 (Study Day 86)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 86)	New Loss of Smell	Mild
18 Nov 2020 (Study Day 86)	New Loss of Taste	Mild
19 Nov 2020 (Study Day 87)	Cough	Mild
19 Nov 2020 (Study Day 87)	Fatigue	Mild
19 Nov 2020 (Study Day 87)	Muscle Aches (Myalgia)	Mild
19 Nov 2020 (Study Day 87)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 87)	New Loss of Smell	Mild
19 Nov 2020 (Study Day 87)	New Loss of Taste	Mild
20 Nov 2020 (Study Day 88)	Cough	Mild
20 Nov 2020 (Study Day 88)	Fatigue	Mild
20 Nov 2020 (Study Day 88)	Muscle Aches (Myalgia)	Mild
20 Nov 2020 (Study Day 88)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 88)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
20 Nov 2020 (Study Day 88)	New Loss of Taste	Mild
21 Nov 2020 (Study Day 89)	Cough	Mild
21 Nov 2020 (Study Day 89)	Fatigue	Mild
21 Nov 2020 (Study Day 89)	Headache	Moderate
21 Nov 2020 (Study Day 89)	Nasal Congestion	Mild
21 Nov 2020 (Study Day 89)	New Loss of Smell	Mild
21 Nov 2020 (Study Day 89)	Runny Nose (Rhinorrhea)	Mild
22 Nov 2020 (Study Day 90)	Body Aches	Mild
22 Nov 2020 (Study Day 90)	Cough	Mild
22 Nov 2020 (Study Day 90)	Fatigue	Mild
22 Nov 2020 (Study Day 90)	Headache	Mild
22 Nov 2020 (Study Day 90)	Muscle Aches (Myalgia)	Mild
22 Nov 2020 (Study Day 90)	Nasal Congestion	Mild
22 Nov 2020 (Study Day 90)	New Loss of Smell	Mild
22 Nov 2020 (Study Day 90)	New Loss of Taste	Mild
22 Nov 2020 (Study Day 90)	Runny Nose (Rhinorrhea)	Mild
23 Nov 2020 (Study Day 91)	Body Aches	Mild
23 Nov 2020 (Study Day 91)	Cough	Moderate
23 Nov 2020 (Study Day 91)	Fatigue	Mild
23 Nov 2020 (Study Day 91)	Headache	Moderate
23 Nov 2020 (Study Day 91)	Muscle Aches (Myalgia)	Mild
23 Nov 2020 (Study Day 91)	New Loss of Smell	Moderate
23 Nov 2020 (Study Day 91)	Runny Nose (Rhinorrhea)	Mild
24 Nov 2020 (Study Day 92)	Body Aches	Mild
24 Nov 2020 (Study Day 92)	Cough	Mild
24 Nov 2020 (Study Day 92)	Fatigue	Mild
24 Nov 2020 (Study Day 92)	Muscle Aches (Myalgia)	Mild
24 Nov 2020 (Study Day 92)	Nasal Congestion	Moderate
24 Nov 2020 (Study Day 92)	New Loss of Smell	Moderate
25 Nov 2020 (Study Day 93)	Body Aches	Mild
25 Nov 2020 (Study Day 93)	Cough	Mild
25 Nov 2020 (Study Day 93)	Fatigue	Mild
25 Nov 2020 (Study Day 93)	Muscle Aches (Myalgia)	Mild
25 Nov 2020 (Study Day 93)	New Loss of Smell	Mild
25 Nov 2020 (Study Day 93)	Runny Nose (Rhinorrhea)	Mild
26 Nov 2020 (Study Day 94)	Cough	Mild
26 Nov 2020 (Study Day 94)	Fatigue	Mild
26 Nov 2020 (Study Day 94)	Muscle Aches (Myalgia)	Mild
26 Nov 2020 (Study Day 94)	New Loss of Smell	Mild
27 Nov 2020 (Study Day 95)	Cough	Mild
27 Nov 2020 (Study Day 95)	Fatigue	Mild
27 Nov 2020 (Study Day 95)	Muscle Aches (Myalgia)	Mild
27 Nov 2020 (Study Day 95)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
28 Nov 2020 (Study Day 96)	Muscle Aches (Myalgia)	Mild
28 Nov 2020 (Study Day 96)	New Loss of Smell	Mild
29 Nov 2020 (Study Day 97)	Cough	Mild
29 Nov 2020 (Study Day 97)	Muscle Aches (Myalgia)	Mild
29 Nov 2020 (Study Day 97)	Nasal Congestion	Moderate
30 Nov 2020 (Study Day 98)	Cough	Mild
30 Nov 2020 (Study Day 98)	Fatigue	Mild
30 Nov 2020 (Study Day 98)	Muscle Aches (Myalgia)	Mild
01 Dec 2020 (Study Day 99)	Cough	Moderate
01 Dec 2020 (Study Day 99)	Fatigue	Moderate
01 Dec 2020 (Study Day 99)	Muscle Aches (Myalgia)	Mild
02 Dec 2020 (Study Day 100)	Cough	Mild
02 Dec 2020 (Study Day 100)	Fatigue	Moderate
03 Dec 2020 (Study Day 101)	Cough	Mild
04 Dec 2020 (Study Day 102)	Cough	Mild
05 Dec 2020 (Study Day 103)	Cough	Mild
06 Dec 2020 (Study Day 104)	Cough	Mild
07 Dec 2020 (Study Day 105)	Cough	Mild
08 Dec 2020 (Study Day 106)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
17 Nov 2020 (Study Day 85)	Oxygen Saturation	89%
10 Nov 2020 - 10 Nov 2020 (Study Day 78-78)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes
17 Nov 2020 - 17 Nov 2020 (Study Day 85-85)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 30 days, after which it was considered to be recovered/resolved on 08 Dec 2020 (Study Day 106). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000896	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 1 diabetes mellitus	Diabetes mellitus (type 1)	2009 - Ongoing
Herpes simplex	Herpes simplex virus 1 (lips/mouth)	2017 - Ongoing
Foot deformity	Left foot bunion	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Empagliflozin	2012 - 13 Nov 2020 (Study Day 81)	Type 1 Diabetes Mellitus
Valaciclovir	2017 - Ongoing	Herpes Simplex Virus 1 (Mouth)
Etonogestrel	2019 - Ongoing	Contraception
Insulin lispro	Jan 2020 - Ongoing	Type 1 Diabetes Mellitus
Insulin lispro	Jan 2020 - Ongoing	Type1 Diabetes Mellitus
Paracetamol	28 Aug 2020 (Study Day 4) - 28 Aug 2020 (Study Day 4)	Pain At Injection Site.
Influenza vaccine	17 Oct 2020 (Study Day 54) - 17 Oct 2020 (Study Day 54)	Influenza Prophylaxis
Acetylsalicylic acid	23 Oct 2020 (Study Day 60) - Ongoing	Post-Surgical Prophylaxis
Left foot bunionectomy*	23 Oct 2020 (Study Day 60) - 23 Oct 2020 (Study Day 60)	Medical History
Empagliflozin	19 Nov 2020 (Study Day 87) - Ongoing	Type 1 Diabetes Mellitus
Canagliflozin	01 Feb 2021 (Study Day 161) - Ongoing	Type 1 Diabetes Mellitus

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	01 Sep 2020 (Study Day 8) - 06 Sep 2020 (Study Day 13)
Myalgia	Grade 1/mild	Related	01 Sep 2020 (Study Day 8) - 02 Sep 2020 (Study Day 9)
COVID-19	Grade 1/mild	Not related	09 Nov 2020 (Study Day 77) - 08 Dec 2020 (Study Day 106)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US330-2379 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	SAE, COVID-19	Grade 3/severe	Not related	18 Jan 2021 (Study Day 146) – 07 Feb 2021 (Study Day 166)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US330-2379, a 42-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 18 Jan 2021 (Study Day 146), 145 days after the first dose and 117 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 23 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Jan 2021 (Study Day 151), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
18 Jan 2021 (Study Day 146)	Chills	Moderate
18 Jan 2021 (Study Day 146)	Shortness of Breath	Severe
19 Jan 2021 (Study Day 147)	Chills	Moderate
19 Jan 2021 (Study Day 147)	Shortness of Breath	Severe
20 Jan 2021 (Study Day 148)	Chills	Moderate
20 Jan 2021 (Study Day 148)	Shortness of Breath	Severe

Symptom Date	Symptom	Result
21 Jan 2021 (Study Day 149)	Chills	Moderate
21 Jan 2021 (Study Day 149)	Shortness of Breath	Severe
22 Jan 2021 (Study Day 150)	Chills	Moderate
22 Jan 2021 (Study Day 150)	O2 Saturation (%)	91
22 Jan 2021 (Study Day 150)	Shortness of Breath	Severe
23 Jan 2021 (Study Day 151)	Chills	Mild
23 Jan 2021 (Study Day 151)	O2 Saturation (%)	91
23 Jan 2021 (Study Day 151)	Shortness of Breath	Mild
25 Jan 2021 (Study Day 153)	Shortness of Breath	Moderate
26 Jan 2021 (Study Day 154)	Shortness of Breath	Mild
27 Jan 2021 (Study Day 155)	O2 Saturation (%)	91
27 Jan 2021 (Study Day 155)	Shortness of Breath	Moderate
28 Jan 2021 (Study Day 156)	O2 Saturation (%)	91
29 Jan 2021 (Study Day 157)	Cough	Mild
29 Jan 2021 (Study Day 157)	Shortness of Breath	Mild
30 Jan 2021 (Study Day 158)	Cough	Mild
31 Jan 2021 (Study Day 159)	Cough	Mild
01 Feb 2021 (Study Day 160)	Cough	Mild
02 Feb 2021 (Study Day 161)	Cough	Mild
03 Feb 2021 (Study Day 162)	Cough	Mild
06 Feb 2021 (Study Day 165)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
21 Jan 2021 (Study Day 149)	Oxygen Saturation	91%
21 Jan 2021 - 28 Jan 2021 (Study Day 149-156)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 21 days, after which it was considered to be recovered/resolved on 07 Feb 2021 (Study Day 166). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-007613	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	2009 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2009 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Anxiety	Anxiety	2016 - Ongoing
Insomnia	Insomnia	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glipizide	2013 - Ongoing	Diabetes Mellitus Type 2
Lisinopril	2013 - 21 Jan 2021 (Study Day 149)	Hypertension
Metformin	2013 - Ongoing	Diabetes Mellitus Type 2
Atorvastatin	2015 - Ongoing	Hyperlipidemia
Fluoxetine hydrochloride	2017 - Ongoing	Anxiety
Levonorgestrel	2017 - Ongoing	Birth Control
Lorazepam	2017 - Ongoing	Anxiety
Zolpidem tartrate	2017 - Ongoing	Insomnia
Liraglutide	2019 - Ongoing	Diabetes Mellitus Type 2
Azithromycin	18 Jan 2021 (Study Day 146) - 19 Jan 2021 (Study Day 147)	COVID-19
Ascorbic acid	21 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 157)	COVID-19
Ct scan*	21 Jan 2021 (Study Day 149) - 21 Jan 2021 (Study Day 149)	Adverse Event
Dexamethasone	21 Jan 2021 (Study Day 149) - 21 Jan 2021 (Study Day 149)	COVID-19
Enoxaparin sodium	21 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 157)	Dvt Prophylaxis
Famotidine	21 Jan 2021 (Study Day 149) - 22 Jan 2021 (Study Day 150)	Gerd Prophylaxis
Guaifenesin	21 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 157)	COVID-19
Insulin lispro	21 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 157)	Diabetes Type II
Iopamidol	21 Jan 2021 (Study Day 149) - 21 Jan 2021 (Study Day 149)	Contrast For Ct Scan
Melatonin	21 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 157)	Insomnia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxygen	21 Jan 2021 (Study Day 149) - 03 Feb 2021 (Study Day 162)	COVID-19
Paracetamol	21 Jan 2021 (Study Day 149) - 29 Jan 2021 (Study Day 157)	COVID-19
Potassium chloride	21 Jan 2021 (Study Day 149) - 21 Jan 2021 (Study Day 149)	Supplement
Remdesivir	21 Jan 2021 (Study Day 149) - 21 Jan 2021 (Study Day 149)	COVID-19
Sodium chloride	21 Jan 2021 (Study Day 149) - 21 Jan 2021 (Study Day 149)	COVID-19
Colecalciferol	22 Jan 2021 (Study Day 150) - 29 Jan 2021 (Study Day 157)	COVID-19
Dexamethasone	22 Jan 2021 (Study Day 150) - 22 Jan 2021 (Study Day 150)	COVID-19
Fluoxetine	22 Jan 2021 (Study Day 150) - Ongoing	Anxiety
Fluticasone furoate; vilanterol	22 Jan 2021 (Study Day 150) - 29 Jan 2021 (Study Day 157)	COVID-19
Remdesivir	22 Jan 2021 (Study Day 150) - 29 Jan 2021 (Study Day 157)	COVID-19
Zinc sulfate	22 Jan 2021 (Study Day 150) - 29 Jan 2021 (Study Day 157)	COVID-19
Ascorbic acid	29 Jan 2021 (Study Day 157) - 03 Feb 2021 (Study Day 162)	COVID-19
Insulin glargine	29 Jan 2021 (Study Day 157) - Ongoing	Diabetes Type II
Insulin lispro	29 Jan 2021 (Study Day 157) - Ongoing	Diabetes Type II
Salbutamol	29 Jan 2021 (Study Day 157) - 03 Feb 2021 (Study Day 162)	COVID-19
Thiamine	29 Jan 2021 (Study Day 157) - 03 Feb 2021 (Study Day 162)	COVID-19
Dexamethasone	30 Jan 2021 (Study Day 158) - 03 Feb 2021 (Study Day 162)	COVID-19
Zinc sulfate	30 Jan 2021 (Study Day 158) - 03 Feb 2021 (Study Day 162)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acute Respiratory Failure	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 149) - 07 Feb 2021 (Study Day 166)
Hypoxia	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 149) - 07 Feb 2021 (Study Day 166)
Lung Opacity	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 149) - Ongoing
Pneumonia	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 149) - 07 Feb 2021 (Study Day 166)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tachycardia	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 149) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2330 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 28)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	COVID-19	Grade 1/mild	Not related	24 Dec 2020 (Study Day 120) – 25 Dec 2020 (Study Day 121)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US331-2330, a 53-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 24 Dec 2020 (Study Day 120), 119 days after the first dose and 92 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 28, 23 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 28 Dec 2020 (Study Day 124), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
24 Dec 2020 (Study Day 120)	Body Aches	Mild
24 Dec 2020 (Study Day 120)	Cough	Mild
24 Dec 2020 (Study Day 120)	Fatigue	Mild
24 Dec 2020 (Study Day 120)	Headache	Moderate

Symptom Date	Symptom	Result
24 Dec 2020 (Study Day 120)	Nausea	Mild
25 Dec 2020 (Study Day 121)	Body Aches	Mild
25 Dec 2020 (Study Day 121)	Cough	Mild
25 Dec 2020 (Study Day 121)	Fatigue	Mild
25 Dec 2020 (Study Day 121)	Headache	Moderate
25 Dec 2020 (Study Day 121)	Nausea	Mild
05 Jan 2021 (Study Day 132)	O2 Saturation (%)	93
07 Jan 2021 (Study Day 134)	O2 Saturation (%)	93
13 Jan 2021 (Study Day 140)	O2 Saturation (%)	92
04 Feb 2021 (Study Day 162)	Nasal Congestion	Mild
04 Feb 2021 (Study Day 162)	Sore Throat	Mild
05 Feb 2021 (Study Day 163)	Cough	Mild
05 Feb 2021 (Study Day 163)	Fatigue	Mild
05 Feb 2021 (Study Day 163)	Nasal Congestion	Mild
05 Feb 2021 (Study Day 163)	Sore Throat	Mild
06 Feb 2021 (Study Day 164)	Cough	Mild
06 Feb 2021 (Study Day 164)	Fatigue	Mild
06 Feb 2021 (Study Day 164)	Nasal Congestion	Mild
06 Feb 2021 (Study Day 164)	Runny Nose (Rhinorrhea)	Mild
06 Feb 2021 (Study Day 164)	Sore Throat	Mild
07 Feb 2021 (Study Day 165)	Cough	Mild
07 Feb 2021 (Study Day 165)	Fatigue	Mild
07 Feb 2021 (Study Day 165)	Nasal Congestion	Mild
07 Feb 2021 (Study Day 165)	Runny Nose (Rhinorrhea)	Mild
07 Feb 2021 (Study Day 165)	Sore Throat	Mild
08 Feb 2021 (Study Day 166)	Cough	Mild
08 Feb 2021 (Study Day 166)	Fatigue	Mild
08 Feb 2021 (Study Day 166)	Nasal Congestion	Mild
08 Feb 2021 (Study Day 166)	Runny Nose (Rhinorrhea)	Mild
08 Feb 2021 (Study Day 166)	Sore Throat	Mild
09 Feb 2021 (Study Day 167)	Cough	Mild
09 Feb 2021 (Study Day 167)	Fatigue	Mild
09 Feb 2021 (Study Day 167)	New Loss of Smell	Severe
09 Feb 2021 (Study Day 167)	New Loss of Taste	Severe
10 Feb 2021 (Study Day 168)	Cough	Mild
10 Feb 2021 (Study Day 168)	New Loss of Smell	Severe
10 Feb 2021 (Study Day 168)	New Loss of Taste	Moderate
11 Feb 2021 (Study Day 169)	Cough	Mild
12 Feb 2021 (Study Day 170)	Cough	Mild
12 Feb 2021 (Study Day 170)	Nausea	Mild
13 Feb 2021 (Study Day 171)	Cough	Mild
14 Feb 2021 (Study Day 172)	Cough	Mild
15 Feb 2021 (Study Day 173)	Cough	Mild

Symptom Date	Symptom	Result
16 Feb 2021 (Study Day 174)	Cough	Mild

The participant had no reported indications of Severe COVID-19 infection.

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 2 days, after which it was considered to be recovered/resolved on 25 Dec 2020 (Study Day 121). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001632	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vertigo	Vertigo	2001 - 2001
Female sterilisation	Bilateral tubal ligation	28 Apr 2004 (Study Day -5965) - 28 Apr 2004 (Study Day -5965)
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Postmenopause	Post menopausal	Apr 2016 - Ongoing
Back pain	Occasional low back pain	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2010 - Ongoing	Hypothyroidism
Ibuprofen	Apr 2020 - Ongoing	Occasional Low Back Pain
Ibuprofen	24 Dec 2020 (Study Day 120) - 24 Dec 2020 (Study Day 120)	Symptomatic COVID-19
Guaifenesin	04 Feb 2021 (Study Day 162) - 09 Feb 2021 (Study Day 167)	Upper Respiratory Infection

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Meclozine	04 Feb 2021 (Study Day 162) - 04 Feb 2021 (Study Day 162)	Vertigo
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	06 Feb 2021 (Study Day 164) - 07 Feb 2021 (Study Day 165)	Upper Respiratory Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	24 Dec 2020 (Study Day 120) - 25 Dec 2020 (Study Day 121)
Rhinovirus Infection	Grade 3/severe	Not related	04 Feb 2021 (Study Day 162) - 16 Feb 2021 (Study Day 174)
Vertigo	Grade 2/moderate	Not related	04 Feb 2021 (Study Day 162) - 04 Feb 2021 (Study Day 162)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2605 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID 19	SAE, COVID-19	Grade 3/severe	Not related	19 Oct 2020 (Study Day 40) – 02 Nov 2020 (Study Day 54)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.
The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US331-2605, a 24-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 19 Oct 2020 (Study Day 40), 39 days after the first dose and 11 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of symptomatic COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 08 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 22 Oct 2020 (Study Day 43), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
19 Oct 2020 (Study Day 40)	Body Aches	Severe
19 Oct 2020 (Study Day 40)	Cough	Moderate
19 Oct 2020 (Study Day 40)	Diarrhea	Severe
19 Oct 2020 (Study Day 40)	Fatigue	Severe

Symptom Date	Symptom	Result
19 Oct 2020 (Study Day 40)	Muscle Aches (Myalgia)	Severe
19 Oct 2020 (Study Day 40)	Nausea	Severe
19 Oct 2020 (Study Day 40)	Sore Throat	Severe
19 Oct 2020 (Study Day 40)	Vomiting	Severe
20 Oct 2020 (Study Day 41)	Body Aches	Severe
20 Oct 2020 (Study Day 41)	Cough	Moderate
20 Oct 2020 (Study Day 41)	Diarrhea	Severe
20 Oct 2020 (Study Day 41)	Fatigue	Severe
20 Oct 2020 (Study Day 41)	Headache	Moderate
20 Oct 2020 (Study Day 41)	Muscle Aches (Myalgia)	Severe
20 Oct 2020 (Study Day 41)	Nausea	Severe
20 Oct 2020 (Study Day 41)	Sore Throat	Severe
20 Oct 2020 (Study Day 41)	Vomiting	Severe
21 Oct 2020 (Study Day 42)	Body Aches	Severe
21 Oct 2020 (Study Day 42)	Chills	Moderate
21 Oct 2020 (Study Day 42)	Cough	Moderate
21 Oct 2020 (Study Day 42)	Diarrhea	Severe
21 Oct 2020 (Study Day 42)	Difficulty Breathing	Severe
21 Oct 2020 (Study Day 42)	Fatigue	Severe
21 Oct 2020 (Study Day 42)	Headache	Moderate
21 Oct 2020 (Study Day 42)	Muscle Aches (Myalgia)	Severe
21 Oct 2020 (Study Day 42)	Nasal Congestion	Severe
21 Oct 2020 (Study Day 42)	Nausea	Severe
21 Oct 2020 (Study Day 42)	Shortness of Breath	Severe
21 Oct 2020 (Study Day 42)	Sore Throat	Severe
21 Oct 2020 (Study Day 42)	Vomiting	Severe
22 Oct 2020 (Study Day 43)	Body Aches	Severe
22 Oct 2020 (Study Day 43)	Chills	Moderate
22 Oct 2020 (Study Day 43)	Cough	Moderate
22 Oct 2020 (Study Day 43)	Diarrhea	Severe
22 Oct 2020 (Study Day 43)	Difficulty Breathing	Severe
22 Oct 2020 (Study Day 43)	Fatigue	Severe
22 Oct 2020 (Study Day 43)	Headache	Moderate
22 Oct 2020 (Study Day 43)	Muscle Aches (Myalgia)	Severe
22 Oct 2020 (Study Day 43)	Nasal Congestion	Severe
22 Oct 2020 (Study Day 43)	Nausea	Severe
22 Oct 2020 (Study Day 43)	Shortness of Breath	Severe
22 Oct 2020 (Study Day 43)	Sore Throat	Severe
22 Oct 2020 (Study Day 43)	Vomiting	Severe
23 Oct 2020 (Study Day 44)	Body Aches	Severe
23 Oct 2020 (Study Day 44)	Chills	Moderate
23 Oct 2020 (Study Day 44)	Cough	Moderate
23 Oct 2020 (Study Day 44)	Diarrhea	Severe

Symptom Date	Symptom	Result
23 Oct 2020 (Study Day 44)	Difficulty Breathing	Severe
23 Oct 2020 (Study Day 44)	Fatigue	Severe
23 Oct 2020 (Study Day 44)	Headache	Severe
23 Oct 2020 (Study Day 44)	Muscle Aches (Myalgia)	Severe
23 Oct 2020 (Study Day 44)	Nasal Congestion	Severe
23 Oct 2020 (Study Day 44)	Nausea	Severe
23 Oct 2020 (Study Day 44)	Shortness of Breath	Severe
23 Oct 2020 (Study Day 44)	Sore Throat	Severe
23 Oct 2020 (Study Day 44)	Vomiting	Severe
24 Oct 2020 (Study Day 45)	Body Aches	Severe
24 Oct 2020 (Study Day 45)	Chills	Moderate
24 Oct 2020 (Study Day 45)	Cough	Moderate
24 Oct 2020 (Study Day 45)	Diarrhea	Severe
24 Oct 2020 (Study Day 45)	Difficulty Breathing	Severe
24 Oct 2020 (Study Day 45)	Fatigue	Severe
24 Oct 2020 (Study Day 45)	Headache	Moderate
24 Oct 2020 (Study Day 45)	Muscle Aches (Myalgia)	Severe
24 Oct 2020 (Study Day 45)	Nasal Congestion	Severe
24 Oct 2020 (Study Day 45)	Nausea	Severe
24 Oct 2020 (Study Day 45)	Shortness of Breath	Severe
24 Oct 2020 (Study Day 45)	Sore Throat	Severe
24 Oct 2020 (Study Day 45)	Vomiting	Severe
25 Oct 2020 (Study Day 46)	Body Aches	Severe
25 Oct 2020 (Study Day 46)	Chills	Moderate
25 Oct 2020 (Study Day 46)	Cough	Moderate
25 Oct 2020 (Study Day 46)	Diarrhea	Severe
25 Oct 2020 (Study Day 46)	Difficulty Breathing	Severe
25 Oct 2020 (Study Day 46)	Fatigue	Severe
25 Oct 2020 (Study Day 46)	Headache	Moderate
25 Oct 2020 (Study Day 46)	Muscle Aches (Myalgia)	Severe
25 Oct 2020 (Study Day 46)	Nasal Congestion	Severe
25 Oct 2020 (Study Day 46)	Nausea	Severe
25 Oct 2020 (Study Day 46)	Shortness of Breath	Severe
25 Oct 2020 (Study Day 46)	Sore Throat	Severe
25 Oct 2020 (Study Day 46)	Vomiting	Severe
26 Oct 2020 (Study Day 47)	Body Aches	Severe
26 Oct 2020 (Study Day 47)	Chills	Moderate
26 Oct 2020 (Study Day 47)	Cough	Moderate
26 Oct 2020 (Study Day 47)	Difficulty Breathing	Severe
26 Oct 2020 (Study Day 47)	Fatigue	Severe
26 Oct 2020 (Study Day 47)	Headache	Moderate
26 Oct 2020 (Study Day 47)	Muscle Aches (Myalgia)	Severe
26 Oct 2020 (Study Day 47)	Nasal Congestion	Severe

Symptom Date	Symptom	Result
26 Oct 2020 (Study Day 47)	New Loss of Smell	Severe
26 Oct 2020 (Study Day 47)	New Loss of Taste	Severe
26 Oct 2020 (Study Day 47)	Shortness of Breath	Severe
26 Oct 2020 (Study Day 47)	Sore Throat	Severe
27 Oct 2020 (Study Day 48)	Body Aches	Severe
27 Oct 2020 (Study Day 48)	Chills	Moderate
27 Oct 2020 (Study Day 48)	Cough	Moderate
27 Oct 2020 (Study Day 48)	Difficulty Breathing	Severe
27 Oct 2020 (Study Day 48)	Fatigue	Severe
27 Oct 2020 (Study Day 48)	Headache	Moderate
27 Oct 2020 (Study Day 48)	Muscle Aches (Myalgia)	Severe
27 Oct 2020 (Study Day 48)	Nasal Congestion	Severe
27 Oct 2020 (Study Day 48)	New Loss of Smell	Severe
27 Oct 2020 (Study Day 48)	New Loss of Taste	Severe
27 Oct 2020 (Study Day 48)	Shortness of Breath	Severe
27 Oct 2020 (Study Day 48)	Sore Throat	Severe
28 Oct 2020 (Study Day 49)	Body Aches	Severe
28 Oct 2020 (Study Day 49)	Chills	Moderate
28 Oct 2020 (Study Day 49)	Cough	Moderate
28 Oct 2020 (Study Day 49)	Difficulty Breathing	Severe
28 Oct 2020 (Study Day 49)	Fatigue	Severe
28 Oct 2020 (Study Day 49)	Headache	Moderate
28 Oct 2020 (Study Day 49)	Muscle Aches (Myalgia)	Severe
28 Oct 2020 (Study Day 49)	Nasal Congestion	Severe
28 Oct 2020 (Study Day 49)	New Loss of Smell	Severe
28 Oct 2020 (Study Day 49)	New Loss of Taste	Severe
28 Oct 2020 (Study Day 49)	Shortness of Breath	Severe
28 Oct 2020 (Study Day 49)	Sore Throat	Severe
29 Oct 2020 (Study Day 50)	Body Aches	Severe
29 Oct 2020 (Study Day 50)	Chills	Moderate
29 Oct 2020 (Study Day 50)	Cough	Moderate
29 Oct 2020 (Study Day 50)	Difficulty Breathing	Severe
29 Oct 2020 (Study Day 50)	Fatigue	Severe
29 Oct 2020 (Study Day 50)	Headache	Moderate
29 Oct 2020 (Study Day 50)	Muscle Aches (Myalgia)	Severe
29 Oct 2020 (Study Day 50)	Nasal Congestion	Severe
29 Oct 2020 (Study Day 50)	New Loss of Smell	Severe
29 Oct 2020 (Study Day 50)	New Loss of Taste	Severe
29 Oct 2020 (Study Day 50)	Shortness of Breath	Severe
29 Oct 2020 (Study Day 50)	Sore Throat	Severe
30 Oct 2020 (Study Day 51)	Body Aches	Severe
30 Oct 2020 (Study Day 51)	Chills	Moderate
30 Oct 2020 (Study Day 51)	Cough	Moderate

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Symptom Date	Symptom	Result
30 Oct 2020 (Study Day 51)	Fatigue	Severe
30 Oct 2020 (Study Day 51)	Headache	Moderate
30 Oct 2020 (Study Day 51)	Muscle Aches (Myalgia)	Severe
30 Oct 2020 (Study Day 51)	New Loss of Smell	Severe
30 Oct 2020 (Study Day 51)	New Loss of Taste	Severe
30 Oct 2020 (Study Day 51)	Sore Throat	Severe
01 Nov 2020 (Study Day 53)	New Loss of Smell	Severe
01 Nov 2020 (Study Day 53)	New Loss of Taste	Severe

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
27 Oct 2020 (Study Day 48)	Oxygen Saturation	85%
27 Oct 2020 - 27 Oct 2020 (Study Day 48-48)	Clinical Evidence of Pneumonia	Yes
27 Oct 2020 - 27 Oct 2020 (Study Day 48-48)	Radiographical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID 19 lasted for 15 days, after which it was considered to be recovered/resolved on 02 Nov 2020 (Study Day 54). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000648	COVID-19

Study Completion/Discontinuation

On 16 Nov 2020 (Study Day 68), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillitis	Recurrent tonsillitis	2000 - 2001
Tonsillectomy	Tonsillectomy	2001 - 2001
Facial bones fracture	Nose fracture	2010 - 2010
Headache	Mild occasional headaches	2010 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal operation	Reconstructive nasal surgery	2010 - 2010
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2011 - Ongoing
Anxiety	Anxiety	2016 - Ongoing
Depression	Depression	2016 - Ongoing
Nephrolithiasis	Recurrent nephrolithiasis	2016 - Ongoing
Alopecia	Excessive hair loss	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine	2010 - Ongoing	Seasonal Allergies
Paracetamol	2010 - Ongoing	Mild Occasional Headaches
Amfetamine; dexamfetamine	2011 - Ongoing	Attention Deficit Hyperactivity Disorder
Escitalopram	2016 - Ongoing	Depression And Anxiety
Potassium citrate	2016 - Ongoing	Nephrolithiasis
Finasteride	2019 - Ongoing	Excessive Hair Loss
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	19 Oct 2020 (Study Day 40) - 30 Oct 2020 (Study Day 51)	Symptomatic COVID-19
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	19 Oct 2020 (Study Day 40) - 30 Oct 2020 (Study Day 51)	Symptomatic COVID-19
Ibuprofen	19 Oct 2020 (Study Day 40) - 19 Oct 2020 (Study Day 40)	Symptomatic COVID-19
Paracetamol	19 Oct 2020 (Study Day 40) - 30 Oct 2020 (Study Day 51)	Symptomatic COVID-19
Ascorbic acid	22 Oct 2020 (Study Day 43) - Ongoing	Symptomatic COVID-19
Famotidine	22 Oct 2020 (Study Day 43) - Ongoing	Symptomatic COVID-19
Melatonin	22 Oct 2020 (Study Day 43) - Ongoing	Symptomatic COVID-19
Zinc	22 Oct 2020 (Study Day 43) - Ongoing	Symptomatic COVID-19
Salbutamol	25 Oct 2020 (Study Day 46) - Ongoing	Symptomatic COVID-19
Benzonatate	27 Oct 2020 (Study Day 48) - 29 Oct 2020 (Study Day 50)	Symptomatic COVID-19
Salbutamol	27 Oct 2020 (Study Day 48) - 29 Oct 2020 (Study Day 50)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US332-2006 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID -19	COVID-19, AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	09 Sep 2020 (Study Day 24) – 20 Sep 2020 (Study Day 35)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US332-2006, a 50-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 09 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 14 Sep 2020 (Study Day 29), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

On 08 Oct 2020 (Study Day 53), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
14 Sep 2020 (Study Day 29)	Fatigue	Moderate
14 Sep 2020 (Study Day 29)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
14 Sep 2020 (Study Day 29)	New Loss of Taste	Moderate
14 Sep 2020 (Study Day 29)	Shortness of Breath	Moderate
16 Sep 2020 (Study Day 31)	Cough	Mild
16 Sep 2020 (Study Day 31)	Headache	Moderate
16 Sep 2020 (Study Day 31)	Nasal Congestion	Mild
16 Sep 2020 (Study Day 31)	Runny Nose (Rhinorrhea)	Mild
17 Sep 2020 (Study Day 32)	Cough	Mild
17 Sep 2020 (Study Day 32)	Nasal Congestion	Mild
17 Sep 2020 (Study Day 32)	O2 Saturation (%)	92
17 Sep 2020 (Study Day 32)	Runny Nose (Rhinorrhea)	Mild
18 Sep 2020 (Study Day 33)	Cough	Mild
18 Sep 2020 (Study Day 33)	Nasal Congestion	Mild
18 Sep 2020 (Study Day 33)	O2 Saturation (%)	93
18 Sep 2020 (Study Day 33)	Runny Nose (Rhinorrhea)	Mild
19 Sep 2020 (Study Day 34)	Cough	Mild
20 Sep 2020 (Study Day 35)	Cough	Mild
24 Sep 2020 (Study Day 39)	Headache	Mild
25 Sep 2020 (Study Day 40)	Headache	Mild
26 Sep 2020 (Study Day 41)	Headache	Mild
27 Sep 2020 (Study Day 42)	Headache	Mild
28 Sep 2020 (Study Day 43)	Headache	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
17 Sep 2020 (Study Day 32)	Oxygen Saturation	92%
17 Sep 2020 - 18 Sep 2020 (Study Day 32-33)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

On 13 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID -19 lasted for 12 days, after which it was considered to be recovered/resolved on 20 Sep 2020 (Study Day 35). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000310	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1972 - Ongoing
Tension headache	Intermittent tension headaches	1980 - Ongoing
Migraine	Migraine headaches	1986 - Ongoing
Haemorrhoids	Hemorrhoids	2010 - Ongoing
Asthma	Asthma	2012 - Ongoing
Back pain	Recurrent back pain	2015 - Ongoing
Drug hypersensitivity	Vicodin allergy	2015 - Ongoing
Paraesthesia	Numbness/tingling of hands/feet	2015 - Ongoing
Uterine leiomyoma	Uterine myomas	Jul 2017 - Dec 2017
Hysterectomy	Hysterectomy	Dec 2017 - Dec 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol sulfate	2012 - Ongoing	Asthma
Acetylsalicylic acid; caffeine	2019 - Ongoing	Migraine Headaches
Acetylsalicylic acid; caffeine	Jan 2019 - Ongoing	Intermittent Tension Headaches
Acetylsalicylic acid; caffeine	22 Aug 2020 (Study Day 6) - 23 Aug 2020 (Study Day 7)	Headache
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol; phenylephrine hydrochloride	09 Sep 2020 (Study Day 24) - 18 Sep 2020 (Study Day 33)	Symptomatic COVID-19
Loratadine	28 Sep 2020 (Study Day 43) - Ongoing	Seasonal Allergies
Other ophthalmologicals	28 Sep 2020 (Study Day 43) - Ongoing	Seasonal Allergies
Acetylsalicylic acid; caffeine	06 Feb 2021 (Study Day 174) - 06 Feb 2021 (Study Day 174)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 24) - 20 Sep 2020 (Study Day 35)
Haematochezia	Grade 2/moderate	Not related	28 Sep 2020 (Study Day 43) - Ongoing
Hypertension	Grade 3/severe	Not related	08 Oct 2020 (Study Day 53) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US332-2388 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	26 Oct 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	COVID-19	Grade 2/ moderate	Not related	14 Dec 2020 (Study Day 78) – 02 Jan 2021 (Study Day 97)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US332-2388, a 60-year-old Hispanic or Latino female, received the first dose of placebo in the right arm on 28 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 26 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 14 Dec 2020 (Study Day 78), 77 days after the first dose and 49 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 26 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 21 Dec 2020 (Study Day 85), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
23 Nov 2020 (Study Day 57)	Muscle Aches (Myalgia)	Mild
23 Nov 2020 (Study Day 57)	Nasal Congestion	Moderate
23 Nov 2020 (Study Day 57)	New Loss of Smell	Mild
23 Nov 2020 (Study Day 57)	Sore Throat	Mild

Symptom Date	Symptom	Result
24 Nov 2020 (Study Day 58)	Muscle Aches (Myalgia)	Mild
24 Nov 2020 (Study Day 58)	Nasal Congestion	Moderate
24 Nov 2020 (Study Day 58)	New Loss of Smell	Mild
24 Nov 2020 (Study Day 58)	Sore Throat	Mild
25 Nov 2020 (Study Day 59)	Muscle Aches (Myalgia)	Mild
25 Nov 2020 (Study Day 59)	Nasal Congestion	Moderate
25 Nov 2020 (Study Day 59)	Sore Throat	Mild
26 Nov 2020 (Study Day 60)	Nasal Congestion	Moderate
27 Nov 2020 (Study Day 61)	Nasal Congestion	Moderate
14 Dec 2020 (Study Day 78)	Body Aches	Moderate
14 Dec 2020 (Study Day 78)	Cough	Moderate
14 Dec 2020 (Study Day 78)	Diarrhea	Mild
14 Dec 2020 (Study Day 78)	Fatigue	Moderate
14 Dec 2020 (Study Day 78)	Headache	Mild
14 Dec 2020 (Study Day 78)	Muscle Aches (Myalgia)	Moderate
14 Dec 2020 (Study Day 78)	Nausea	Mild
14 Dec 2020 (Study Day 78)	Runny Nose (Rhinorrhea)	Mild
15 Dec 2020 (Study Day 79)	Body Aches	Moderate
15 Dec 2020 (Study Day 79)	Cough	Moderate
15 Dec 2020 (Study Day 79)	Diarrhea	Mild
15 Dec 2020 (Study Day 79)	Fatigue	Moderate
15 Dec 2020 (Study Day 79)	Headache	Mild
15 Dec 2020 (Study Day 79)	Muscle Aches (Myalgia)	Moderate
15 Dec 2020 (Study Day 79)	Nausea	Mild
15 Dec 2020 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild
16 Dec 2020 (Study Day 80)	Body Aches	Moderate
16 Dec 2020 (Study Day 80)	Cough	Moderate
16 Dec 2020 (Study Day 80)	Diarrhea	Mild
16 Dec 2020 (Study Day 80)	Fatigue	Moderate
16 Dec 2020 (Study Day 80)	Headache	Mild
16 Dec 2020 (Study Day 80)	Muscle Aches (Myalgia)	Moderate
16 Dec 2020 (Study Day 80)	Nausea	Mild
16 Dec 2020 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
17 Dec 2020 (Study Day 81)	Body Aches	Moderate
17 Dec 2020 (Study Day 81)	Cough	Moderate
17 Dec 2020 (Study Day 81)	Diarrhea	Mild
17 Dec 2020 (Study Day 81)	Fatigue	Moderate
17 Dec 2020 (Study Day 81)	Headache	Mild
17 Dec 2020 (Study Day 81)	Muscle Aches (Myalgia)	Moderate
17 Dec 2020 (Study Day 81)	Nausea	Mild
17 Dec 2020 (Study Day 81)	Runny Nose (Rhinorrhea)	Mild
18 Dec 2020 (Study Day 82)	Body Aches	Moderate
18 Dec 2020 (Study Day 82)	Cough	Moderate

Symptom Date	Symptom	Result
18 Dec 2020 (Study Day 82)	Diarrhea	Mild
18 Dec 2020 (Study Day 82)	Fatigue	Moderate
18 Dec 2020 (Study Day 82)	Headache	Mild
18 Dec 2020 (Study Day 82)	Muscle Aches (Myalgia)	Moderate
18 Dec 2020 (Study Day 82)	Nausea	Mild
18 Dec 2020 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
19 Dec 2020 (Study Day 83)	Body Aches	Moderate
19 Dec 2020 (Study Day 83)	Cough	Moderate
19 Dec 2020 (Study Day 83)	Diarrhea	Mild
19 Dec 2020 (Study Day 83)	Fatigue	Moderate
19 Dec 2020 (Study Day 83)	Headache	Mild
19 Dec 2020 (Study Day 83)	Muscle Aches (Myalgia)	Moderate
19 Dec 2020 (Study Day 83)	Nausea	Mild
19 Dec 2020 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
20 Dec 2020 (Study Day 84)	Body Aches	Moderate
20 Dec 2020 (Study Day 84)	Cough	Moderate
20 Dec 2020 (Study Day 84)	Diarrhea	Mild
20 Dec 2020 (Study Day 84)	Fatigue	Moderate
20 Dec 2020 (Study Day 84)	Headache	Mild
20 Dec 2020 (Study Day 84)	Muscle Aches (Myalgia)	Moderate
20 Dec 2020 (Study Day 84)	Nausea	Mild
20 Dec 2020 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
21 Dec 2020 (Study Day 85)	Body Aches	Moderate
21 Dec 2020 (Study Day 85)	Cough	Moderate
21 Dec 2020 (Study Day 85)	Diarrhea	Mild
21 Dec 2020 (Study Day 85)	Fatigue	Moderate
21 Dec 2020 (Study Day 85)	Headache	Mild
21 Dec 2020 (Study Day 85)	Muscle Aches (Myalgia)	Moderate
21 Dec 2020 (Study Day 85)	Nausea	Mild
21 Dec 2020 (Study Day 85)	Runny Nose (Rhinorrhea)	Mild
22 Dec 2020 (Study Day 86)	Body Aches	Moderate
22 Dec 2020 (Study Day 86)	Cough	Moderate
22 Dec 2020 (Study Day 86)	Diarrhea	Mild
22 Dec 2020 (Study Day 86)	Fatigue	Moderate
22 Dec 2020 (Study Day 86)	Headache	Mild
22 Dec 2020 (Study Day 86)	Muscle Aches (Myalgia)	Moderate
22 Dec 2020 (Study Day 86)	Nausea	Mild
22 Dec 2020 (Study Day 86)	O2 Saturation (%)	93
22 Dec 2020 (Study Day 86)	Runny Nose (Rhinorrhea)	Mild
22 Dec 2020 (Study Day 86)	Temperature (°F)	102
23 Dec 2020 (Study Day 87)	Cough	Mild
23 Dec 2020 (Study Day 87)	Headache	Mild
23 Dec 2020 (Study Day 87)	Nausea	Mild

Symptom Date	Symptom	Result
23 Dec 2020 (Study Day 87)	Vomiting	Mild
24 Dec 2020 (Study Day 88)	Cough	Moderate
24 Dec 2020 (Study Day 88)	Headache	Mild
25 Dec 2020 (Study Day 89)	Cough	Moderate
26 Dec 2020 (Study Day 90)	Cough	Mild
26 Dec 2020 (Study Day 90)	Headache	Mild
26 Dec 2020 (Study Day 90)	Shortness of Breath	Moderate
26 Dec 2020 (Study Day 90)	Temperature (°F)	100.4
27 Dec 2020 (Study Day 91)	Cough	Mild
27 Dec 2020 (Study Day 91)	Headache	Mild
27 Dec 2020 (Study Day 91)	Shortness of Breath	Mild
28 Dec 2020 (Study Day 92)	Cough	Mild
29 Dec 2020 (Study Day 93)	Cough	Mild
30 Dec 2020 (Study Day 94)	Cough	Mild
31 Dec 2020 (Study Day 95)	Cough	Mild
31 Dec 2020 (Study Day 95)	Fatigue	Mild
31 Dec 2020 (Study Day 95)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 96)	Fatigue	Mild
01 Jan 2021 (Study Day 96)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 96)	Sore Throat	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
22 Dec 2020 (Study Day 86)	Oxygen Saturation	93%
22 Dec 2020 - 22 Dec 2020 (Study Day 86-86)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 02 Jan 2021 (Study Day 97). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001406	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	Cesarean section	24 Mar 1982 (Study Day -14068) - 24 Mar 1982 (Study Day -14068)
Caesarean section	Cesarean section	11 Jul 1984 (Study Day -13228) - 11 Jul 1984 (Study Day -13228)
Urticaria	Codeine (hives)	1990 - Ongoing
Caesarean section	Cesarean section	21 Sep 1990 (Study Day -10965) - 21 Sep 1990 (Study Day -10965)
Insomnia	Insomnia	2010 - Ongoing
Back pain	Upper and lower back pain	2012 - Ongoing
Hysterectomy	Total hysterectomy due to fibroids	2012 - 2012
Menopause	Menopause	2012 - Ongoing
Obesity	Obesity	2012 - Ongoing
Abdominal hernia repair	Ventral hernia repair	2013 - 2013
Abdominal hernia repair	Ventral hernia repair	2013 - 2013
Anxiety	Anxiety	2015 - Ongoing
Osteoarthritis	Osteoarthritis, bilateral hands and hips	2015 - Ongoing
Urticaria	Naproxen (hives)	2017 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2000 - Ongoing	General Health
Calcium; magnesium; zinc	2000 - Ongoing	General Health
Colecalciferol	2000 - Ongoing	General Health
Magnesium	2000 - Ongoing	General Health
Probiotics nos	2000 - Ongoing	General Health
Vitamins nos	2000 - Ongoing	General Health
Trazodone	2010 - Ongoing	Insomnia
Cyclobenzaprine	2012 - Ongoing	Upper And Lower Back Pain
Estrogens esterified; methyltestosterone	2012 - Ongoing	Postmenopause
Hydroxyzine hydrochloride	2015 - Ongoing	Anxiety
Tramadol	2015 - Ongoing	Osteoarthritis
Topiramate	2018 - Ongoing	Obesity
Famotidine	Jan 2020 - Ongoing	Acid Reflux

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	09 Nov 2020 (Study Day 43) - 09 Nov 2020 (Study Day 43)	Preventative Healthcare
Amoxicillin; clavulanic acid	23 Nov 2020 (Study Day 57) - Ongoing	Human Rhinovirus/Enterovirus Sinusitis
Covid-19 nasal swab (negative result)*	23 Nov 2020 (Study Day 57) - 23 Nov 2020 (Study Day 57)	Diagnostic
Guaifenesin	23 Nov 2020 (Study Day 57) - 28 Nov 2020 (Study Day 62)	Human Rhinovirus/Enterovirus Sinusitis
Covid-19 nasal swab (negative result)*	24 Nov 2020 (Study Day 58) - 24 Nov 2020 (Study Day 58)	Diagnostic
Botulinum toxin type a	13 Dec 2020 (Study Day 77) - 13 Dec 2020 (Study Day 77)	Cosmetic
Loperamide	14 Dec 2020 (Study Day 78) - 14 Dec 2020 (Study Day 78)	Symptomatic COVID-19
Paracetamol	14 Dec 2020 (Study Day 78) - 02 Jan 2021 (Study Day 97)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 2/moderate	Related	29 Sep 2020 (Study Day 2) - 01 Oct 2020 (Study Day 4)
Rhinovirus Infection	Grade 2/moderate	Not related	20 Nov 2020 (Study Day 54) - 03 Dec 2020 (Study Day 67)
Myalgia	Grade 1/mild	Not related	23 Nov 2020 (Study Day 57) - 25 Nov 2020 (Study Day 59)
COVID-19	Grade 2/moderate	Not related	14 Dec 2020 (Study Day 78) - 02 Jan 2021 (Study Day 97)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US333-2001 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 26)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 3/severe	Not related	30 Sep 2020 (Study Day 59) – 02 Oct 2020 (Study Day 61)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US333-2001, a 68-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 30 Sep 2020 (Study Day 59), 58 days after the first dose and 33 days after the second dose of the IP, the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 26, 28 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 30 Sep 2020 (Study Day 59), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
28 Sep 2020 (Study Day 57)	Cough	Moderate
28 Sep 2020 (Study Day 57)	Vomiting	Moderate
29 Sep 2020 (Study Day 58)	Body Aches	Moderate
29 Sep 2020 (Study Day 58)	Cough	Moderate
29 Sep 2020 (Study Day 58)	Fatigue	Severe
29 Sep 2020 (Study Day 58)	Headache	Moderate

Symptom Date	Symptom	Result
29 Sep 2020 (Study Day 58)	Muscle Aches (Myalgia)	Moderate
29 Sep 2020 (Study Day 58)	Sore Throat	Moderate
29 Sep 2020 (Study Day 58)	Temperature (°F)	100.8
01 Oct 2020 (Study Day 60)	Muscle Aches (Myalgia)	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
30 Sep 2020 - 30 Sep 2020 (Study Day 59-59)	Systolic Blood Pressure < 90 mm Hg, Diastolic Blood Pressure < 60 mm Hg	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 3 days, after which it was considered to be recovered/resolved on 02 Oct 2020 (Study Day 61). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000398	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcoholism	Alcoholism	1970 - 2018
Actinic keratosis	Actinic keratosis (facial and bilateral upper extremities)	2000 - Ongoing
Hypothyroidism	Acquired hypothyroidism	2000 - Ongoing
Thyroid cancer	Thyroid cancer	2000 - 2000
Thyroidectomy	Thyroid removal	2000 - 2000
Blood testosterone decreased	Low testosterone	29 Nov 2017 (Study Day -978) - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Insomnia	Insomnia	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sleep apnoea syndrome	Sleep apnea	31 Oct 2018 (Study Day -642) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diclofenac sodium	2000 - Ongoing	Actinic Keratosis
Levothyroxine sodium	2000 - Ongoing	Acquired Hypothyroidism
Alprostadil; papaverine; phentolamine	2017 - Ongoing	Low Testosterone
Testosterone	2017 - Ongoing	Low Testosterone
Enalapril maleate	21 Mar 2018 (Study Day -866) - Ongoing	Hypertension
Alprazolam	26 Nov 2018 (Study Day -616) - Ongoing	Insomnia
Trazodone	26 Nov 2018 (Study Day -616) - Ongoing	Insomnia
Ibuprofen	29 Sep 2020 (Study Day 58) - 29 Sep 2020 (Study Day 58)	Symptomatic COVID-19
Influenza vaccine	10 Oct 2020 (Study Day 69) - 10 Oct 2020 (Study Day 69)	Influenza Prophylaxis
Chest x-ray*	13 Oct 2020 (Study Day 72) - 13 Oct 2020 (Study Day 72)	Adverse Event
Root canal*	17 Nov 2020 (Study Day 107) - 17 Nov 2020 (Study Day 107)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 3/severe	Not related	30 Sep 2020 (Study Day 59) - 02 Oct 2020 (Study Day 61)
Chest Discomfort	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 61) - 20 Oct 2020 (Study Day 79)
Tooth Infection	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 107) - 17 Nov 2020 (Study Day 107)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US333-2101 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	16 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	13 Nov 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	COVID-19	Grade 2/ moderate	Not related	31 Dec 2020 (Study Day 77) – 28 Jan 2021 (Study Day 105)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US333-2101, a 57-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 16 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 13 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 31 Dec 2020 (Study Day 77), 76 days after the first dose and 48 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 13 Nov 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 07 Jan 2021 (Study Day 84), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
31 Dec 2020 (Study Day 77)	Cough	Moderate
31 Dec 2020 (Study Day 77)	Nasal Congestion	Moderate
31 Dec 2020 (Study Day 77)	Runny Nose (Rhinorrhea)	Mild
01 Jan 2021 (Study Day 78)	Cough	Moderate
01 Jan 2021 (Study Day 78)	Nasal Congestion	Moderate
01 Jan 2021 (Study Day 78)	Runny Nose (Rhinorrhea)	Mild
02 Jan 2021 (Study Day 79)	Cough	Moderate

Symptom Date	Symptom	Result
02 Jan 2021 (Study Day 79)	Nasal Congestion	Moderate
02 Jan 2021 (Study Day 79)	Runny Nose (Rhinorrhea)	Mild
03 Jan 2021 (Study Day 80)	Cough	Moderate
03 Jan 2021 (Study Day 80)	Nasal Congestion	Moderate
03 Jan 2021 (Study Day 80)	Runny Nose (Rhinorrhea)	Mild
04 Jan 2021 (Study Day 81)	Cough	Moderate
04 Jan 2021 (Study Day 81)	Nasal Congestion	Moderate
04 Jan 2021 (Study Day 81)	Runny Nose (Rhinorrhea)	Mild
05 Jan 2021 (Study Day 82)	Cough	Moderate
05 Jan 2021 (Study Day 82)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 82)	Runny Nose (Rhinorrhea)	Mild
06 Jan 2021 (Study Day 83)	Cough	Mild
06 Jan 2021 (Study Day 83)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 83)	Runny Nose (Rhinorrhea)	Mild
07 Jan 2021 (Study Day 84)	Runny Nose (Rhinorrhea)	Mild
08 Jan 2021 (Study Day 85)	Nasal Congestion	Mild
09 Jan 2021 (Study Day 86)	Headache	Mild
09 Jan 2021 (Study Day 86)	Nasal Congestion	Mild
10 Jan 2021 (Study Day 87)	Fatigue	Moderate
10 Jan 2021 (Study Day 87)	Headache	Mild
10 Jan 2021 (Study Day 87)	Nasal Congestion	Mild
11 Jan 2021 (Study Day 88)	Fatigue	Moderate
11 Jan 2021 (Study Day 88)	Nasal Congestion	Mild
12 Jan 2021 (Study Day 89)	Fatigue	Moderate
12 Jan 2021 (Study Day 89)	Nasal Congestion	Mild
13 Jan 2021 (Study Day 90)	Fatigue	Moderate
13 Jan 2021 (Study Day 90)	Nasal Congestion	Moderate
14 Jan 2021 (Study Day 91)	Nasal Congestion	Moderate
14 Jan 2021 (Study Day 91)	Runny Nose (Rhinorrhea)	Mild
16 Jan 2021 (Study Day 93)	Nasal Congestion	Moderate
18 Jan 2021 (Study Day 95)	Runny Nose (Rhinorrhea)	Mild
19 Jan 2021 (Study Day 96)	Nasal Congestion	Mild
19 Jan 2021 (Study Day 96)	Runny Nose (Rhinorrhea)	Mild
21 Jan 2021 (Study Day 98)	Nasal Congestion	Mild
22 Jan 2021 (Study Day 99)	Nasal Congestion	Mild
23 Jan 2021 (Study Day 100)	Runny Nose (Rhinorrhea)	Mild
26 Jan 2021 (Study Day 103)	Nasal Congestion	Mild
26 Jan 2021 (Study Day 103)	O2 Saturation (%)	93
27 Jan 2021 (Study Day 104)	Nasal Congestion	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
26 Jan 2021 (Study Day 103)	Oxygen Saturation	93%
26 Jan 2021 - 26 Jan 2021 (Study Day 103-103)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 29 days, after which it was considered to be recovered/resolved on 28 Jan 2021 (Study Day 105). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002822	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2005 - Ongoing
Erectile dysfunction	Impotence	04 Feb 2010 (Study Day -3907) - Ongoing
Arthralgia	Generalized joint pain	2016 - Ongoing
Acrochordon	Skin tag right eye	2018 - Ongoing
Hypothyroidism	Sub-clinical hypothyroidism	06 Oct 2018 (Study Day -741) - Ongoing
Anxiety	Anxiety	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	2005 - Ongoing	Seasonal Allergies
Tadalafil	26 Apr 2010 (Study Day -3826) - Ongoing	Impotence

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	23 May 2016 (Study Day -1607) - Ongoing	Supplement
Glucosamine	09 Oct 2018 (Study Day -738) - Ongoing	Generalized Joint Pain
Herbal preparation	Apr 2020 - Ongoing	Supplement
Naproxen sodium	May 2020 - Ongoing	Generalized Joint Pain
Propranolol	27 Oct 2020 (Study Day 12) - Ongoing	Anxiety
Ramipril	27 Oct 2020 (Study Day 12) - Ongoing	Elevated Blood Pressure
Oxymetazoline	02 Jan 2021 (Study Day 79) - 06 Jan 2021 (Study Day 83)	COVID-19
Diphenhydramine hydrochloride	04 Jan 2021 (Study Day 81) - 05 Jan 2021 (Study Day 82)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Blood Pressure Increased	Grade 1/mild	Not related	16 Oct 2020 (Study Day 1) - Ongoing
Chills	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 17) - 02 Nov 2020 (Study Day 18)
COVID-19	Grade 2/moderate	Not related	31 Dec 2020 (Study Day 77) - 28 Jan 2021 (Study Day 105)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2046 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 35)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19 Infection	COVID-19	Grade 2/ moderate	Not related	17 Nov 2020 (Study Day 97) – 26 Dec 2020 (Study Day 136)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US334-2046, a 41-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 17 Nov 2020 (Study Day 97), 96 days after the first dose and 62 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of symptomatic COVID-19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 35, 16 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 20 Nov 2020 (Study Day 100), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
17 Nov 2020 (Study Day 97)	Cough	Mild
17 Nov 2020 (Study Day 97)	Fatigue	Severe
17 Nov 2020 (Study Day 97)	Nasal Congestion	Mild
17 Nov 2020 (Study Day 97)	Runny Nose (Rhinorrhea)	Mild

Symptom Date	Symptom	Result
18 Nov 2020 (Study Day 98)	Cough	Mild
18 Nov 2020 (Study Day 98)	Fatigue	Severe
18 Nov 2020 (Study Day 98)	Nasal Congestion	Mild
18 Nov 2020 (Study Day 98)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 99)	Body Aches	Moderate
19 Nov 2020 (Study Day 99)	Chills	Moderate
19 Nov 2020 (Study Day 99)	Cough	Mild
19 Nov 2020 (Study Day 99)	Difficulty Breathing	Moderate
19 Nov 2020 (Study Day 99)	Fatigue	Severe
19 Nov 2020 (Study Day 99)	Headache	Moderate
19 Nov 2020 (Study Day 99)	Nasal Congestion	Mild
19 Nov 2020 (Study Day 99)	Runny Nose (Rhinorrhea)	Mild
19 Nov 2020 (Study Day 99)	Shortness of Breath	Moderate
19 Nov 2020 (Study Day 99)	Sore Throat	Mild
20 Nov 2020 (Study Day 100)	Body Aches	Moderate
20 Nov 2020 (Study Day 100)	Chills	Moderate
20 Nov 2020 (Study Day 100)	Cough	Mild
20 Nov 2020 (Study Day 100)	Difficulty Breathing	Moderate
20 Nov 2020 (Study Day 100)	Fatigue	Severe
20 Nov 2020 (Study Day 100)	Headache	Moderate
20 Nov 2020 (Study Day 100)	Nasal Congestion	Mild
20 Nov 2020 (Study Day 100)	Runny Nose (Rhinorrhea)	Mild
20 Nov 2020 (Study Day 100)	Shortness of Breath	Moderate
20 Nov 2020 (Study Day 100)	Sore Throat	Mild
21 Nov 2020 (Study Day 101)	Headache	Mild
21 Nov 2020 (Study Day 101)	Muscle Aches (Myalgia)	Mild
21 Nov 2020 (Study Day 101)	O2 Saturation (%)	93
21 Nov 2020 (Study Day 101)	Shortness of Breath	Moderate
21 Nov 2020 (Study Day 101)	Sore Throat	Mild
22 Nov 2020 (Study Day 102)	Headache	Mild
22 Nov 2020 (Study Day 102)	Muscle Aches (Myalgia)	Mild
22 Nov 2020 (Study Day 102)	Shortness of Breath	Mild
23 Nov 2020 (Study Day 103)	Fatigue	Mild
23 Nov 2020 (Study Day 103)	Headache	Mild
23 Nov 2020 (Study Day 103)	Muscle Aches (Myalgia)	Mild
23 Nov 2020 (Study Day 103)	Shortness of Breath	Mild
24 Nov 2020 (Study Day 104)	Fatigue	Mild
24 Nov 2020 (Study Day 104)	Headache	Mild
24 Nov 2020 (Study Day 104)	Muscle Aches (Myalgia)	Mild
24 Nov 2020 (Study Day 104)	Shortness of Breath	Mild
25 Nov 2020 (Study Day 105)	Body Aches	Moderate
26 Nov 2020 (Study Day 106)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
21 Nov 2020 (Study Day 101)	Oxygen Saturation	93%
21 Nov 2020 - 21 Nov 2020 (Study Day 101-101)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of symptomatic COVID-19 infection lasted for 40 days, after which it was considered to be recovered/resolved on 26 Dec 2020 (Study Day 136). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000940	COVID-19

Study Completion/Discontinuation

On 04 Jan 2021 (Study Day 145), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Intervertebral disc protrusion	Cervical disk herniation	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	2010 - Ongoing	Seasonal Allergies
Fish oil	2015 - Ongoing	Wellness
Vitamins nos	2015 - Ongoing	Wellness
Gabapentin	Feb 2020 - Ongoing	Cervical Disk Herniation
Meloxicam	Feb 2020 - Ongoing	Cervical Disk Herniation
Oxycodone hydrochloride; paracetamol	Feb 2020 - Ongoing	Cervical Disk Herniation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tizanidine	Feb 2020 - Ongoing	Cervical Disc Herniation
Ibuprofen	20 Sep 2020 (Study Day 39) - 20 Sep 2020 (Study Day 39)	Headache (Solicited Ar - Vaccine #2)
Paracetamol	19 Nov 2020 (Study Day 99) - 26 Nov 2020 (Study Day 106)	Symptomatic COVID-19 Infection
Acetylsalicylic acid	21 Nov 2020 (Study Day 101) - Ongoing	Cardiac Prophylaxis
Other viral vaccines	28 Dec 2020 (Study Day 138) - 28 Dec 2020 (Study Day 138)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	19 Sep 2020 (Study Day 38) - 24 Sep 2020 (Study Day 43)
Myalgia	Grade 1/mild	Related	19 Sep 2020 (Study Day 38) - 24 Sep 2020 (Study Day 43)
COVID-19	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 97) - 26 Dec 2020 (Study Day 136)
Blood Pressure Increased	Grade 3/severe	Not related	17 Dec 2020 (Study Day 127) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2182 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 43)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19 Infection	COVID-19	Grade 1/mild	Not related	19 Dec 2020 (Study Day 108) – 05 Feb 2021 (Study Day 156)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US334-2182, a 70-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 15 Oct 2020 (Study Day 43). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 19 Dec 2020 (Study Day 108), 107 days after the first dose and 65 days after the second dose of the IP, the participant experienced a Grade 1/Mild non-serious adverse event of COVID-19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 43, 15 Oct 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 12 Jan 2021 (Study Day 132), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
19 Dec 2020 (Study Day 108)	Headache	Moderate
20 Dec 2020 (Study Day 109)	Headache	Moderate
21 Dec 2020 (Study Day 110)	Headache	Moderate
22 Dec 2020 (Study Day 111)	Headache	Moderate

Symptom Date	Symptom	Result
23 Dec 2020 (Study Day 112)	Diarrhea	Moderate
23 Dec 2020 (Study Day 112)	Headache	Moderate
24 Dec 2020 (Study Day 113)	Diarrhea	Mild
24 Dec 2020 (Study Day 113)	Headache	Mild
04 Jan 2021 (Study Day 124)	Headache	Mild
05 Jan 2021 (Study Day 125)	Cough	Moderate
05 Jan 2021 (Study Day 125)	Headache	Mild
05 Jan 2021 (Study Day 125)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 126)	Body Aches	Moderate
06 Jan 2021 (Study Day 126)	Cough	Moderate
06 Jan 2021 (Study Day 126)	Headache	Mild
06 Jan 2021 (Study Day 126)	Muscle Aches (Myalgia)	Moderate
06 Jan 2021 (Study Day 126)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 126)	Temperature (°F)	100.9
07 Jan 2021 (Study Day 127)	Body Aches	Moderate
07 Jan 2021 (Study Day 127)	Cough	Moderate
07 Jan 2021 (Study Day 127)	Diarrhea	Mild
08 Jan 2021 (Study Day 128)	Body Aches	Mild
08 Jan 2021 (Study Day 128)	Muscle Aches (Myalgia)	Mild
08 Jan 2021 (Study Day 128)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 129)	Cough	Mild
09 Jan 2021 (Study Day 129)	Fatigue	Mild
10 Jan 2021 (Study Day 130)	Body Aches	Moderate
10 Jan 2021 (Study Day 130)	Chills	Moderate
10 Jan 2021 (Study Day 130)	Cough	Moderate
10 Jan 2021 (Study Day 130)	Fatigue	Moderate
10 Jan 2021 (Study Day 130)	Temperature (°F)	101.3
11 Jan 2021 (Study Day 131)	Cough	Moderate
11 Jan 2021 (Study Day 131)	Temperature (°F)	101
12 Jan 2021 (Study Day 132)	Muscle Aches (Myalgia)	Moderate
12 Jan 2021 (Study Day 132)	Temperature (°F)	100.6
15 Jan 2021 (Study Day 135)	Body Aches	Moderate
15 Jan 2021 (Study Day 135)	Chills	Severe
15 Jan 2021 (Study Day 135)	Diarrhea	Moderate
15 Jan 2021 (Study Day 135)	Fatigue	Moderate
15 Jan 2021 (Study Day 135)	Nausea	Mild
15 Jan 2021 (Study Day 135)	New Loss of Taste	Mild
15 Jan 2021 (Study Day 135)	Shortness of Breath	Moderate
15 Jan 2021 (Study Day 135)	Temperature (°F)	100.7
15 Jan 2021 (Study Day 135)	Vomiting	Mild
16 Jan 2021 (Study Day 136)	Body Aches	Moderate
16 Jan 2021 (Study Day 136)	Diarrhea	Moderate
16 Jan 2021 (Study Day 136)	Nausea	Moderate

Symptom Date	Symptom	Result
16 Jan 2021 (Study Day 136)	O2 Saturation (%)	93
17 Jan 2021 (Study Day 137)	Nausea	Mild
17 Jan 2021 (Study Day 137)	Shortness of Breath	Moderate
18 Jan 2021 (Study Day 138)	Cough	Moderate
18 Jan 2021 (Study Day 138)	Fatigue	Mild
18 Jan 2021 (Study Day 138)	Nausea	Moderate
18 Jan 2021 (Study Day 138)	Shortness of Breath	Moderate

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
23 Dec 2020 (Study Day 112)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes
17 Jan 2021 - 17 Jan 2021 (Study Day 137-137)	Clinical Evidence of Pneumonia	Yes
17 Jan 2021 - 17 Jan 2021 (Study Day 137-137)	Radiographical Evidence of Pneumonia	Yes

Action taken with the IP was not applicable. The event of COVID-19 infection lasted for 49 days, after which it was considered to be recovered/resolved on 05 Feb 2021 (Study Day 156). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004629	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1990 - Ongoing
Ovarian cyst	Recurrent bilateral ovarian cysts (benign)	1992 - 1995
Hyperlipidaemia	Hyperlipidemia	1995 - Ongoing
Hysterectomy	Total abdominal hysterectomy	1995 - 1995
Seasonal allergy	Seasonal allergies	1995 - Ongoing
Sinusitis	Recurrent sinus infections	1995 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2000 - Ongoing
Headache	Headaches	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Bronchial hyperreactivity	Reactive airway disease	2010 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2010 - Ongoing
Biopsy thyroid gland	Thyroid biopsy benign	27 Aug 2020 (Study Day -7) - 27 Aug 2020 (Study Day -7)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Headaches
Paracetamol	2000 - Ongoing	Headaches
Citalopram	2010 - 17 Sep 2020 (Study Day 15)	Depression
Guaifenesin	2010 - Ongoing	Seasonal Allergies
Montelukast	2010 - Ongoing	Seasonal Allergies
Vitamin d nos	2010 - Ongoing	Vitamin D Deficiency
Amlodipine	2019 - Ongoing	Hypertension
Fexofenadine hydrochloride	2019 - Ongoing	Seasonal Allergies
Hydrochlorothiazide; triamterene	2019 - Ongoing	Hypertension
Levothyroxine sodium	01 Jun 2020 (Study Day -94) - Ongoing	Hypothyroidisim
Levothyroxine sodium	01 Jun 2020 (Study Day -94) - Ongoing	Hypothyroidism
Escitalopram	18 Sep 2020 (Study Day 16) - 15 Oct 2020 (Study Day 43)	Depression
Citalopram	14 Oct 2020 (Study Day 42) - Ongoing	Depression
Hydrocortisone	21 Oct 2020 (Study Day 49) - 21 Oct 2020 (Study Day 49)	Headache Ae
Alprazolam	26 Oct 2020 (Study Day 54) - Ongoing	Generalized Anxiety Ae
Influenza vaccine	03 Nov 2020 (Study Day 62) - 03 Nov 2020 (Study Day 62)	Influenza Prophylaxis
Ibuprofen	04 Jan 2021 (Study Day 124) - 11 Jan 2021 (Study Day 131)	COVID-19 Infection Ae
Salbutamol	06 Jan 2021 (Study Day 126) - 05 Feb 2021 (Study Day 156)	COVID-19 Infection Ae
Ondansetron	16 Jan 2021 (Study Day 136) - 18 Jan 2021 (Study Day 138)	COVID-19 Infection
Prednisone	16 Jan 2021 (Study Day 136) - 17 Jan 2021 (Study Day 137)	COVID-19 Infection Ae
Azithromycin	17 Jan 2021 (Study Day 137) - 21 Jan 2021 (Study Day 141)	COVID-19 Infection Ae
Prednisone	18 Jan 2021 (Study Day 138) - 20 Jan 2021 (Study Day 140)	COVID-19 Infection Ae

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine hydrochloride	05 Feb 2021 (Study Day 156) - Ongoing	Tension Headaches Ae
Meloxicam	05 Feb 2021 (Study Day 156) - Ongoing	Tension Headaches Ae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Related	03 Sep 2020 (Study Day 1) - 17 Sep 2020 (Study Day 15)
Headache	Grade 1/mild	Not related	18 Sep 2020 (Study Day 16) - 28 Oct 2020 (Study Day 56)
Generalised Anxiety Disorder	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 54) - Ongoing
COVID-19	Grade 1/mild	Not related	19 Dec 2020 (Study Day 108) - 05 Feb 2021 (Study Day 156)
Tension Headache	Grade 2/moderate	Not related	05 Feb 2021 (Study Day 156) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2059 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	SAE, COVID-19	Grade 2/ moderate	Not related	10 Dec 2020 (Study Day 126) – 16 Jan 2021 (Study Day 163)	Recovered/resolved
COVID-19 Pneumonia/COVID 19 Pneumonia	SAE, COVID-19	Grade 3/ severe	Not related	18 Dec 2020 (Study Day 134) – 22 Dec 2020 (Study Day 138)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US337-2059, a 75-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 10 Dec 2020 (Study Day 126), 125 days after the first dose and 93 days after the second dose of the IP, the participant experienced a Grade 2/Moderate serious adverse event of COVID-19.

On 18 Dec 2020 (Study Day 134), 133 days after the first dose and 101 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of COVID-19 pneumonia.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 33, 08 Sep 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 23 Dec 2020 (Study Day 139), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
11 Dec 2020 (Study Day 127)	Chills	Mild
11 Dec 2020 (Study Day 127)	Cough	Mild
11 Dec 2020 (Study Day 127)	Shortness of Breath	Mild
12 Dec 2020 (Study Day 128)	Cough	Mild
12 Dec 2020 (Study Day 128)	Shortness of Breath	Mild
13 Dec 2020 (Study Day 129)	Cough	Mild
13 Dec 2020 (Study Day 129)	Shortness of Breath	Mild
14 Dec 2020 (Study Day 130)	Cough	Mild
14 Dec 2020 (Study Day 130)	Shortness of Breath	Mild
15 Dec 2020 (Study Day 131)	Cough	Mild
15 Dec 2020 (Study Day 131)	Difficulty Breathing	Mild
15 Dec 2020 (Study Day 131)	Shortness of Breath	Mild
16 Dec 2020 (Study Day 132)	Cough	Mild
16 Dec 2020 (Study Day 132)	Difficulty Breathing	Mild
17 Dec 2020 (Study Day 133)	Cough	Mild
17 Dec 2020 (Study Day 133)	Difficulty Breathing	Mild
18 Dec 2020 (Study Day 134)	Cough	Mild
18 Dec 2020 (Study Day 134)	Difficulty Breathing	Mild
18 Dec 2020 (Study Day 134)	O2 Saturation (%)	89
18 Dec 2020 (Study Day 134)	Shortness of Breath	Mild
19 Dec 2020 (Study Day 135)	Cough	Mild
19 Dec 2020 (Study Day 135)	O2 Saturation (%)	93
22 Dec 2020 (Study Day 138)	Cough	Mild
23 Dec 2020 (Study Day 139)	Chills	Mild
23 Dec 2020 (Study Day 139)	Cough	Mild
24 Dec 2020 (Study Day 140)	Cough	Mild
24 Dec 2020 (Study Day 140)	O2 Saturation (%)	92
24 Dec 2020 (Study Day 140)	Shortness of Breath	Mild
25 Dec 2020 (Study Day 141)	Cough	Mild
25 Dec 2020 (Study Day 141)	Shortness of Breath	Mild
26 Dec 2020 (Study Day 142)	Cough	Mild
26 Dec 2020 (Study Day 142)	Shortness of Breath	Mild
27 Dec 2020 (Study Day 143)	Cough	Mild
28 Dec 2020 (Study Day 144)	Cough	Mild
29 Dec 2020 (Study Day 145)	Cough	Mild
30 Dec 2020 (Study Day 146)	Cough	Mild
31 Dec 2020 (Study Day 147)	Cough	Mild
01 Jan 2021 (Study Day 148)	Cough	Mild
02 Jan 2021 (Study Day 149)	Cough	Moderate
02 Jan 2021 (Study Day 149)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
03 Jan 2021 (Study Day 150)	Cough	Moderate
04 Jan 2021 (Study Day 151)	Cough	Moderate
05 Jan 2021 (Study Day 152)	Cough	Moderate
06 Jan 2021 (Study Day 153)	Cough	Moderate
07 Jan 2021 (Study Day 154)	Cough	Mild
08 Jan 2021 (Study Day 155)	Cough	Mild
09 Jan 2021 (Study Day 156)	Cough	Mild
11 Jan 2021 (Study Day 158)	Cough	Mild
12 Jan 2021 (Study Day 159)	Cough	Mild
13 Jan 2021 (Study Day 160)	Cough	Mild
14 Jan 2021 (Study Day 161)	Cough	Mild
15 Jan 2021 (Study Day 162)	Cough	Mild
16 Jan 2021 (Study Day 163)	Cough	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
24 Dec 2020 (Study Day 140)	Oxygen Saturation	92%
19 Dec 2020 - 27 Dec 2020 (Study Day 135-143)	Non-Invasive Ventilation	Yes
24 Dec 2020 - 25 Dec 2020 (Study Day 140-141)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 38 days, after which it was considered to be recovered/resolved on 16 Jan 2021 (Study Day 163). The investigator assessed the event of COVID-19 to be not related to the IP.

Action taken with the IP was not applicable. The event of COVID-19 pneumonia lasted for 5 days, after which it was considered to be recovered/resolved on 22 Dec 2020 (Study Day 138). The investigator assessed the event of COVID-19 pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001187	COVID-19
MOD-2020-001187	COVID-19 pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2003 - Ongoing
Type V hyperlipidaemia	Hyperlipidemia - mixed	2005 - Ongoing
Coronary angioplasty	Coronary artery angioplasty	2008 - 2008
Coronary artery disease	Coronary artery disease	2008 - Ongoing
Inguinal hernia	Inguinal hernia - left	2015 - 2015
Inguinal hernia repair	Inguinal hernia repair left	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; losartan potassium	2003 - Ongoing	Hypertension
Atorvastatin	2005 - Ongoing	Hyperlipidemia - Mixed
Metoprolol	2005 - Ongoing	Hypertension
Clopidogrel bisulfate	2008 - Ongoing	Cardiac Prophylaxis
Ezetimibe	2015 - Ongoing	Hyperlipidemia - Mixed
Colecalciferol	Jan 2019 - Ongoing	Nutritional Supplement
Folic acid	Jan 2019 - Ongoing	Nutritional Supplement
Ubidecarenone	Jan 2019 - Ongoing	Nutritional Supplement
Varicella zoster vaccine	Feb 2019 - Feb 2019	Shingles Prophylaxis/Prevention
Influenza vaccine	Jun 2019 - Jun 2019	Influenza Prophylaxis/Prevention
Influenza vaccine	18 Oct 2020 (Study Day 73) - 18 Oct 2020 (Study Day 73)	Influenza Prophylaxis/Prevention
Prednisone	12 Dec 2020 (Study Day 128) - 16 Dec 2020 (Study Day 132)	Generalized Erythematous Macules
Azithromycin	18 Dec 2020 (Study Day 134) - 18 Dec 2020 (Study Day 134)	COVID 19 Pneumonia
Ceftriaxone	18 Dec 2020 (Study Day 134) - 18 Dec 2020 (Study Day 134)	COVID 19 Pneumonia
Chest x-ray*	18 Dec 2020 (Study Day 134) - 18 Dec 2020 (Study Day 134)	Adverse Event
Dexamethasone	18 Dec 2020 (Study Day 134) - 18 Dec 2020 (Study Day 134)	COVID 19 Pneumonia
Dexamethasone	18 Dec 2020 (Study Day 134) - 22 Dec 2020 (Study Day 138)	COVID 19 Pneumonia
Electrocardiogram*	18 Dec 2020 (Study Day 134) - 18 Dec 2020 (Study Day 134)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Plasma	18 Dec 2020 (Study Day 134) - 18 Dec 2020 (Study Day 134)	COVID 19 Pneumonia
Remdesivir	18 Dec 2020 (Study Day 134) - 18 Dec 2020 (Study Day 134)	COVID 19 Pneumonia
Salbutamol	18 Dec 2020 (Study Day 134) - 22 Dec 2020 (Study Day 138)	COVID 19 Pneumonia
Remdesivir	19 Dec 2020 (Study Day 135) - 22 Dec 2020 (Study Day 138)	COVID 19 Pneumonia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Macule	Grade 2/moderate	Not related	04 Dec 2020 (Study Day 120) - 14 Dec 2020 (Study Day 130)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2284 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE	Grade 1/mild	Not related	30 Nov 2020 (Study Day 95) – 18 Dec 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2284, a 55-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 28 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Nov 2020 (Study Day 95), 94 days after the first dose and 63 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 19 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 113). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001112	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vesicoureteric reflux	Vesicoureteral reflux disease	(b) (6) 1965 (Study Day (b) (6) - 1968
Vesicoureteral reflux surgery	Vesicoureteral reflux disease correction surgery	1968 - 1968
Synovial cyst	Ganglion cyst left wrist	1982 - 1982
Synovial cyst removal	Excision of ganglion cyst of left wrist	1982 - 1982
Myomectomy	Uterine myomectomy	2005 - 2005
Uterine leiomyoma	Uterine fibroids	2005 - 2005
Obesity	Obesity - morbid	2008 - Ongoing
Osteoarthritis	Generalized osteoarthritis	2008 - Ongoing
Postmenopause	Postmenopause	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2008 - Ongoing	Generalized Osteoarthritis
Influenza vaccine	Dec 2019 - Dec 2019	Influenza Prophylaxis/Prevention
Influenza vaccine	27 Oct 2020 (Study Day 61) - 27 Oct 2020 (Study Day 61)	Influenza Prevention
Influenza vaccine	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Influenza Prevention
Paracetamol	06 Dec 2020 (Study Day 101) - 10 Dec 2020 (Study Day 105)	Pyrexia
Dextromethorphan hydrobromide; guaifenesin; phenylpropanolamine hydrochloride	10 Dec 2020 (Study Day 105) - 17 Dec 2020 (Study Day 112)	Cough

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	14 Nov 2020 (Study Day 79) - 18 Dec 2020 (Study Day 113)
Oropharyngeal Pain	Grade 1/mild	Not related	15 Nov 2020 (Study Day 80) - 17 Nov 2020 (Study Day 82)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US340-2029 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	24 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	SAE, COVID-19	Grade 4	Not related	29 Sep 2020 (Study Day 65) – 12 Oct 2020 (Study Day 78)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US340-2029, a 34-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 27 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 24 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 29 Sep 2020 (Study Day 65), 64 days after the first dose and 36 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 24 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 30 Sep 2020 (Study Day 66), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
29 Sep 2020 (Study Day 65)	Chills	Mild
29 Sep 2020 (Study Day 65)	Cough	Mild
29 Sep 2020 (Study Day 65)	Fatigue	Mild
29 Sep 2020 (Study Day 65)	Headache	Mild
29 Sep 2020 (Study Day 65)	Muscle Aches (Myalgia)	Mild
29 Sep 2020 (Study Day 65)	Nasal Congestion	Mild

Symptom Date	Symptom	Result
29 Sep 2020 (Study Day 65)	New Loss of Taste	Mild
29 Sep 2020 (Study Day 65)	Sore Throat	Mild
30 Sep 2020 (Study Day 66)	Chills	Mild
30 Sep 2020 (Study Day 66)	Cough	Mild
30 Sep 2020 (Study Day 66)	Fatigue	Mild
30 Sep 2020 (Study Day 66)	Headache	Mild
30 Sep 2020 (Study Day 66)	Muscle Aches (Myalgia)	Mild
30 Sep 2020 (Study Day 66)	New Loss of Taste	Mild
30 Sep 2020 (Study Day 66)	Sore Throat	Mild
01 Oct 2020 (Study Day 67)	Chills	Mild
01 Oct 2020 (Study Day 67)	Cough	Mild
01 Oct 2020 (Study Day 67)	Fatigue	Mild
01 Oct 2020 (Study Day 67)	Headache	Mild
01 Oct 2020 (Study Day 67)	Nasal Congestion	Mild
01 Oct 2020 (Study Day 67)	New Loss of Smell	Mild
01 Oct 2020 (Study Day 67)	New Loss of Taste	Mild
01 Oct 2020 (Study Day 67)	Temperature (°F)	100.5
02 Oct 2020 (Study Day 68)	Chills	Mild
02 Oct 2020 (Study Day 68)	Cough	Mild
02 Oct 2020 (Study Day 68)	Fatigue	Mild
02 Oct 2020 (Study Day 68)	Headache	Mild
02 Oct 2020 (Study Day 68)	Nasal Congestion	Mild
02 Oct 2020 (Study Day 68)	New Loss of Smell	Mild
02 Oct 2020 (Study Day 68)	New Loss of Taste	Mild
02 Oct 2020 (Study Day 68)	Temperature (°F)	101.0
03 Oct 2020 (Study Day 69)	Chills	Mild
03 Oct 2020 (Study Day 69)	Cough	Mild
03 Oct 2020 (Study Day 69)	Fatigue	Moderate
03 Oct 2020 (Study Day 69)	Headache	Mild
03 Oct 2020 (Study Day 69)	New Loss of Smell	Mild
03 Oct 2020 (Study Day 69)	New Loss of Taste	Mild
03 Oct 2020 (Study Day 69)	Temperature (°F)	102.0
04 Oct 2020 (Study Day 70)	Chills	Mild
04 Oct 2020 (Study Day 70)	Cough	Mild
04 Oct 2020 (Study Day 70)	Diarrhea	Mild
04 Oct 2020 (Study Day 70)	Fatigue	Mild
04 Oct 2020 (Study Day 70)	New Loss of Smell	Mild
04 Oct 2020 (Study Day 70)	New Loss of Taste	Mild
05 Oct 2020 (Study Day 71)	Cough	Mild
05 Oct 2020 (Study Day 71)	Fatigue	Mild
05 Oct 2020 (Study Day 71)	New Loss of Smell	Mild
05 Oct 2020 (Study Day 71)	O2 Saturation (%)	93
06 Oct 2020 (Study Day 72)	Cough	Mild

Symptom Date	Symptom	Result
06 Oct 2020 (Study Day 72)	Fatigue	Mild
06 Oct 2020 (Study Day 72)	New Loss of Smell	Mild
06 Oct 2020 (Study Day 72)	O2 Saturation (%)	92
07 Oct 2020 (Study Day 73)	Cough	Moderate
07 Oct 2020 (Study Day 73)	Fatigue	Mild
07 Oct 2020 (Study Day 73)	New Loss of Smell	Mild
07 Oct 2020 (Study Day 73)	O2 Saturation (%)	88
07 Oct 2020 (Study Day 73)	Shortness of Breath	Moderate
07 Oct 2020 (Study Day 73)	Temperature (°F)	101.0
08 Oct 2020 (Study Day 74)	Cough	Moderate
08 Oct 2020 (Study Day 74)	Fatigue	Moderate
08 Oct 2020 (Study Day 74)	New Loss of Smell	Moderate
08 Oct 2020 (Study Day 74)	O2 Saturation (%)	83
08 Oct 2020 (Study Day 74)	Shortness of Breath	Moderate
08 Oct 2020 (Study Day 74)	Temperature (°F)	101.4
09 Oct 2020 (Study Day 75)	Cough	Mild
09 Oct 2020 (Study Day 75)	O2 Saturation (%)	88
09 Oct 2020 (Study Day 75)	Shortness of Breath	Mild
10 Oct 2020 (Study Day 76)	Cough	Mild
10 Oct 2020 (Study Day 76)	O2 Saturation (%)	92
10 Oct 2020 (Study Day 76)	Shortness of Breath	Mild
11 Oct 2020 (Study Day 77)	Cough	Mild
12 Oct 2020 (Study Day 78)	Fatigue	Mild
12 Oct 2020 (Study Day 78)	O2 Saturation (%)	93
13 Oct 2020 (Study Day 79)	Fatigue	Mild
14 Oct 2020 (Study Day 80)	Fatigue	Mild
16 Oct 2020 (Study Day 82)	Fatigue	Mild
17 Oct 2020 (Study Day 83)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
05 Oct 2020 (Study Day 71)	Oxygen Saturation	83%
05 Oct 2020 - 13 Oct 2020 (Study Day 71-79)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID-19 lasted for 14 days, after which it was considered to be recovered/resolved on 12 Oct 2020 (Study Day 78). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000405	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Severe obesity	2004 - Ongoing
Hypothyroidism	Hypothyroidism	Jul 2004 - Ongoing
Headache	Chronic headaches	2010 - Ongoing
Anxiety	Anxiety	Feb 2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	Jul 2004 - Ongoing	Hypothyroidism
Escitalopram oxalate	Feb 2016 - Ongoing	Anxiety
Paracetamol	01 Oct 2020 (Study Day 67) - 01 Oct 2020 (Study Day 67)	COVID
Guaifenesin	03 Oct 2020 (Study Day 69) - 06 Oct 2020 (Study Day 72)	COVID
Dexamethasone	05 Oct 2020 (Study Day 71) - 17 Oct 2020 (Study Day 83)	COVID
Chest x-ray*	07 Oct 2020 (Study Day 73) - 07 Oct 2020 (Study Day 73)	Adverse Event
Doxycycline	07 Oct 2020 (Study Day 73) - 17 Oct 2020 (Study Day 83)	COVID
Oxygen	07 Oct 2020 (Study Day 73) - 11 Oct 2020 (Study Day 77)	COVID-19
Plasma	07 Oct 2020 (Study Day 73) - 08 Oct 2020 (Study Day 74)	COVID
Remdesivir	07 Oct 2020 (Study Day 73) - 07 Oct 2020 (Study Day 73)	COVID

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Remdesivir	08 Oct 2020 (Study Day 74) - 12 Oct 2020 (Study Day 78)	Sars COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US340-2194 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	02 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE, Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Sars COVID-19	SAE, COVID-19	Grade 3/severe	Not related	06 Nov 2020 (Study Day 97) – 26 Nov 2020 (Study Day 117)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US340-2194, a 57-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 02 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 06 Nov 2020 (Study Day 97), 96 days after the first dose and 65 days after the second dose of the IP, the participant experienced a Grade 3/Severe serious adverse event of sars COVID-19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 13 Nov 2020 (Study Day 104), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
06 Nov 2020 (Study Day 97)	Chills	Mild
06 Nov 2020 (Study Day 97)	Fatigue	Moderate
06 Nov 2020 (Study Day 97)	Headache	Mild
07 Nov 2020 (Study Day 98)	Chills	Mild
07 Nov 2020 (Study Day 98)	Fatigue	Mild
07 Nov 2020 (Study Day 98)	Headache	Mild
08 Nov 2020 (Study Day 99)	Chills	Mild

Symptom Date	Symptom	Result
08 Nov 2020 (Study Day 99)	Fatigue	Mild
08 Nov 2020 (Study Day 99)	Headache	Mild
09 Nov 2020 (Study Day 100)	Chills	Mild
09 Nov 2020 (Study Day 100)	Fatigue	Mild
09 Nov 2020 (Study Day 100)	Headache	Mild
10 Nov 2020 (Study Day 101)	Chills	Mild
10 Nov 2020 (Study Day 101)	Cough	Mild
10 Nov 2020 (Study Day 101)	Diarrhea	Moderate
10 Nov 2020 (Study Day 101)	Fatigue	Mild
10 Nov 2020 (Study Day 101)	Headache	Mild
10 Nov 2020 (Study Day 101)	Nausea	Moderate
10 Nov 2020 (Study Day 101)	Vomiting	Moderate
11 Nov 2020 (Study Day 102)	Chills	Mild
11 Nov 2020 (Study Day 102)	Cough	Mild
11 Nov 2020 (Study Day 102)	Diarrhea	Moderate
11 Nov 2020 (Study Day 102)	Fatigue	Mild
11 Nov 2020 (Study Day 102)	Headache	Mild
11 Nov 2020 (Study Day 102)	Nausea	Moderate
11 Nov 2020 (Study Day 102)	Vomiting	Moderate
12 Nov 2020 (Study Day 103)	Chills	Mild
12 Nov 2020 (Study Day 103)	Cough	Mild
12 Nov 2020 (Study Day 103)	Diarrhea	Moderate
12 Nov 2020 (Study Day 103)	Fatigue	Mild
12 Nov 2020 (Study Day 103)	Headache	Mild
12 Nov 2020 (Study Day 103)	Nausea	Moderate
12 Nov 2020 (Study Day 103)	Vomiting	Moderate
13 Nov 2020 (Study Day 104)	Chills	Mild
13 Nov 2020 (Study Day 104)	Cough	Mild
13 Nov 2020 (Study Day 104)	Diarrhea	Moderate
13 Nov 2020 (Study Day 104)	Fatigue	Mild
13 Nov 2020 (Study Day 104)	Headache	Mild
13 Nov 2020 (Study Day 104)	Nausea	Moderate
13 Nov 2020 (Study Day 104)	Vomiting	Moderate
14 Nov 2020 (Study Day 105)	Chills	Mild
14 Nov 2020 (Study Day 105)	Cough	Mild
14 Nov 2020 (Study Day 105)	Diarrhea	Moderate
14 Nov 2020 (Study Day 105)	Fatigue	Mild
14 Nov 2020 (Study Day 105)	Headache	Mild
14 Nov 2020 (Study Day 105)	Nausea	Moderate
14 Nov 2020 (Study Day 105)	Vomiting	Moderate
15 Nov 2020 (Study Day 106)	Body Aches	Mild
15 Nov 2020 (Study Day 106)	Cough	Mild
15 Nov 2020 (Study Day 106)	Diarrhea	Mild

Symptom Date	Symptom	Result
15 Nov 2020 (Study Day 106)	Fatigue	Mild
15 Nov 2020 (Study Day 106)	Muscle Aches (Myalgia)	Mild
15 Nov 2020 (Study Day 106)	Nausea	Mild
15 Nov 2020 (Study Day 106)	New Loss of Smell	Mild
15 Nov 2020 (Study Day 106)	New Loss of Taste	Mild
15 Nov 2020 (Study Day 106)	Shortness of Breath	Mild
15 Nov 2020 (Study Day 106)	Sore Throat	Mild
15 Nov 2020 (Study Day 106)	Vomiting	Mild
16 Nov 2020 (Study Day 107)	Body Aches	Mild
16 Nov 2020 (Study Day 107)	Cough	Mild
16 Nov 2020 (Study Day 107)	Diarrhea	Mild
16 Nov 2020 (Study Day 107)	Fatigue	Mild
16 Nov 2020 (Study Day 107)	Muscle Aches (Myalgia)	Mild
16 Nov 2020 (Study Day 107)	Nausea	Mild
16 Nov 2020 (Study Day 107)	New Loss of Smell	Mild
16 Nov 2020 (Study Day 107)	New Loss of Taste	Mild
16 Nov 2020 (Study Day 107)	O2 Saturation (%)	83
16 Nov 2020 (Study Day 107)	Shortness of Breath	Mild
16 Nov 2020 (Study Day 107)	Sore Throat	Mild
17 Nov 2020 (Study Day 108)	Body Aches	Mild
17 Nov 2020 (Study Day 108)	Cough	Mild
17 Nov 2020 (Study Day 108)	Diarrhea	Mild
17 Nov 2020 (Study Day 108)	Fatigue	Mild
17 Nov 2020 (Study Day 108)	Muscle Aches (Myalgia)	Mild
17 Nov 2020 (Study Day 108)	Nausea	Mild
17 Nov 2020 (Study Day 108)	New Loss of Smell	Mild
17 Nov 2020 (Study Day 108)	New Loss of Taste	Mild
17 Nov 2020 (Study Day 108)	O2 Saturation (%)	92
17 Nov 2020 (Study Day 108)	Shortness of Breath	Mild
17 Nov 2020 (Study Day 108)	Sore Throat	Mild
22 Nov 2020 (Study Day 113)	O2 Saturation (%)	92
23 Nov 2020 (Study Day 114)	O2 Saturation (%)	92
26 Nov 2020 (Study Day 117)	O2 Saturation (%)	93
30 Nov 2020 (Study Day 121)	Sore Throat	Mild
01 Dec 2020 (Study Day 122)	Cough	Mild
01 Dec 2020 (Study Day 122)	O2 Saturation (%)	90
02 Dec 2020 (Study Day 123)	Cough	Mild
02 Dec 2020 (Study Day 123)	O2 Saturation (%)	91
03 Dec 2020 (Study Day 124)	Fatigue	Mild
03 Dec 2020 (Study Day 124)	O2 Saturation (%)	93
04 Dec 2020 (Study Day 125)	Fatigue	Mild
04 Dec 2020 (Study Day 125)	O2 Saturation (%)	93
05 Dec 2020 (Study Day 126)	Cough	Mild

Symptom Date	Symptom	Result
05 Dec 2020 (Study Day 126)	Fatigue	Mild
06 Dec 2020 (Study Day 127)	Cough	Mild
06 Dec 2020 (Study Day 127)	Fatigue	Mild
07 Dec 2020 (Study Day 128)	Cough	Mild
07 Dec 2020 (Study Day 128)	Fatigue	Mild
08 Dec 2020 (Study Day 129)	Cough	Mild
08 Dec 2020 (Study Day 129)	Fatigue	Mild
09 Dec 2020 (Study Day 130)	Cough	Mild
09 Dec 2020 (Study Day 130)	Fatigue	Mild
11 Dec 2020 (Study Day 132)	Fatigue	Mild
11 Dec 2020 (Study Day 132)	O2 Saturation (%)	92
12 Dec 2020 (Study Day 133)	Fatigue	Mild
13 Dec 2020 (Study Day 134)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
16 Nov 2020 (Study Day 107)	Oxygen Saturation	83%
16 Oct 2020 - 16 Oct 2020 (Study Day 76-76)	High-Flow Oxygen	Yes
16 Nov 2020 - 14 Dec 2020 (Study Day 107-135)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of sars COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved with sequelae on 26 Nov 2020 (Study Day 117). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000815	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 1 diabetes mellitus	Type 1 diabetes	1979 - Ongoing
Coronary artery disease	Coronary artery disease	May 2017 - Ongoing
Peripheral vascular disorder	Peripheral vascular disease	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin lispro	1979 - Ongoing	Type 1 Diabetes
Atorvastatin	May 2017 - Ongoing	Coronary Artery Disease
Lisinopril	May 2017 - Ongoing	Coronary Artery Disease
Ticagrelor	2018 - Ongoing	Peripheral Vascular Disease
Acetylsalicylic acid	16 Nov 2020 (Study Day 107) - 26 Nov 2020 (Study Day 117)	Sars-Cov-2
Ascorbic acid	16 Nov 2020 (Study Day 107) - 17 Nov 2020 (Study Day 108)	Sars-Cov-2
Dexamethasone	16 Nov 2020 (Study Day 107) - 16 Nov 2020 (Study Day 107)	Sars-Cov-2
Furosemide	16 Nov 2020 (Study Day 107) - 26 Nov 2020 (Study Day 117)	Fluid Retension Due To Sars-Cov-2
Glucose	16 Nov 2020 (Study Day 107) - 16 Nov 2020 (Study Day 107)	Fluid Loss Due To Sars-Cov-2
Glucose	16 Nov 2020 (Study Day 107) - 16 Nov 2020 (Study Day 107)	Sars-Cov-2
Glucose	16 Nov 2020 (Study Day 107) - 26 Nov 2020 (Study Day 117)	Type 2 Diabetis With Sars-Cov-2
Heparin	16 Nov 2020 (Study Day 107) - 17 Nov 2020 (Study Day 108)	Sars-Cov-2
Insulin glargine	16 Nov 2020 (Study Day 107) - Ongoing	Diabetes Type 1
Insulin lispro	16 Nov 2020 (Study Day 107) - Ongoing	Diabetes Type 1
Oxygen	16 Nov 2020 (Study Day 107) - 26 Nov 2020 (Study Day 117)	Sars COVID 19
Paracetamol	16 Nov 2020 (Study Day 107) - 16 Nov 2020 (Study Day 107)	Sars-Cov-2
Salbutamol	16 Nov 2020 (Study Day 107) - Ongoing	Sars-Cov-2
Sodium chloride	16 Nov 2020 (Study Day 107) - 26 Nov 2020 (Study Day 117)	Sars-Cov-2
Enoxaparin sodium	17 Nov 2020 (Study Day 108) - 26 Nov 2020 (Study Day 117)	Sars COVID-19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Thiamine	17 Nov 2020 (Study Day 108) - 26 Nov 2020 (Study Day 117)	Sars-Cov-2
Remdesivir	18 Nov 2020 (Study Day 109) - 18 Nov 2020 (Study Day 109)	Sars-Cov-2

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US340-2196 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 29)
Reason for Narrative:	Severe COVID-19

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	COVID-19	Grade 2/ moderate	Not related	17 Dec 2020 (Study Day 137) – 25 Jan 2021 (Study Day 176)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US340-2196, a 72-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Severe COVID-19 Details

On 17 Dec 2020 (Study Day 137), 136 days after the first dose and 108 days after the second dose of the IP, the participant experienced a Grade 2/Moderate non-serious adverse event of COVID 19.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2. On Study Day 29, 31 Aug 2020, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 29 Dec 2020 (Study Day 149), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
17 Dec 2020 (Study Day 137)	Diarrhea	Mild
18 Dec 2020 (Study Day 138)	Diarrhea	Mild
19 Dec 2020 (Study Day 139)	Diarrhea	Mild
20 Dec 2020 (Study Day 140)	Diarrhea	Mild
21 Dec 2020 (Study Day 141)	Diarrhea	Mild
22 Dec 2020 (Study Day 142)	Diarrhea	Mild

Symptom Date	Symptom	Result
23 Dec 2020 (Study Day 143)	Diarrhea	Mild
24 Dec 2020 (Study Day 144)	Diarrhea	Mild
25 Dec 2020 (Study Day 145)	Diarrhea	Mild
26 Dec 2020 (Study Day 146)	Diarrhea	Mild
27 Dec 2020 (Study Day 147)	Diarrhea	Mild
28 Dec 2020 (Study Day 148)	Diarrhea	Mild
29 Dec 2020 (Study Day 149)	Diarrhea	Mild
30 Dec 2020 (Study Day 150)	Body Aches	Mild
30 Dec 2020 (Study Day 150)	Chills	Mild
30 Dec 2020 (Study Day 150)	Cough	Mild
30 Dec 2020 (Study Day 150)	Diarrhea	Mild
30 Dec 2020 (Study Day 150)	Fatigue	Mild
30 Dec 2020 (Study Day 150)	Headache	Mild
30 Dec 2020 (Study Day 150)	Muscle Aches (Myalgia)	Mild
30 Dec 2020 (Study Day 150)	Nasal Congestion	Mild
30 Dec 2020 (Study Day 150)	O2 Saturation (%)	93
30 Dec 2020 (Study Day 150)	Shortness of Breath	Mild
31 Dec 2020 (Study Day 151)	Chills	Mild
31 Dec 2020 (Study Day 151)	Cough	Mild
31 Dec 2020 (Study Day 151)	Diarrhea	Mild
31 Dec 2020 (Study Day 151)	Fatigue	Mild
31 Dec 2020 (Study Day 151)	Headache	Mild
31 Dec 2020 (Study Day 151)	Nasal Congestion	Mild
31 Dec 2020 (Study Day 151)	Runny Nose (Rhinorrhea)	Mild
31 Dec 2020 (Study Day 151)	Shortness of Breath	Mild
01 Jan 2021 (Study Day 152)	Chills	Mild
01 Jan 2021 (Study Day 152)	Cough	Mild
01 Jan 2021 (Study Day 152)	Diarrhea	Mild
01 Jan 2021 (Study Day 152)	Fatigue	Mild
01 Jan 2021 (Study Day 152)	Headache	Mild
01 Jan 2021 (Study Day 152)	Nasal Congestion	Mild
01 Jan 2021 (Study Day 152)	O2 Saturation (%)	93
01 Jan 2021 (Study Day 152)	Runny Nose (Rhinorrhea)	Mild
01 Jan 2021 (Study Day 152)	Shortness of Breath	Moderate
02 Jan 2021 (Study Day 153)	Cough	Mild
02 Jan 2021 (Study Day 153)	Diarrhea	Mild
02 Jan 2021 (Study Day 153)	Fatigue	Mild
02 Jan 2021 (Study Day 153)	Headache	Mild
02 Jan 2021 (Study Day 153)	Nasal Congestion	Mild
02 Jan 2021 (Study Day 153)	O2 Saturation (%)	93
02 Jan 2021 (Study Day 153)	Runny Nose (Rhinorrhea)	Mild
02 Jan 2021 (Study Day 153)	Shortness of Breath	Mild
03 Jan 2021 (Study Day 154)	Cough	Mild

Symptom Date	Symptom	Result
03 Jan 2021 (Study Day 154)	Diarrhea	Mild
03 Jan 2021 (Study Day 154)	Fatigue	Mild
03 Jan 2021 (Study Day 154)	Nasal Congestion	Mild
03 Jan 2021 (Study Day 154)	Shortness of Breath	Mild
04 Jan 2021 (Study Day 155)	Cough	Mild
04 Jan 2021 (Study Day 155)	Diarrhea	Mild
04 Jan 2021 (Study Day 155)	Fatigue	Mild
04 Jan 2021 (Study Day 155)	Nasal Congestion	Mild
04 Jan 2021 (Study Day 155)	Shortness of Breath	Mild
05 Jan 2021 (Study Day 156)	Cough	Mild
05 Jan 2021 (Study Day 156)	Diarrhea	Mild
05 Jan 2021 (Study Day 156)	Nasal Congestion	Mild
05 Jan 2021 (Study Day 156)	Shortness of Breath	Mild
06 Jan 2021 (Study Day 157)	Cough	Mild
06 Jan 2021 (Study Day 157)	Diarrhea	Mild
06 Jan 2021 (Study Day 157)	Nasal Congestion	Mild
06 Jan 2021 (Study Day 157)	Shortness of Breath	Mild
07 Jan 2021 (Study Day 158)	Cough	Mild
07 Jan 2021 (Study Day 158)	Shortness of Breath	Mild
08 Jan 2021 (Study Day 159)	Cough	Mild
08 Jan 2021 (Study Day 159)	Shortness of Breath	Mild
09 Jan 2021 (Study Day 160)	Cough	Mild
09 Jan 2021 (Study Day 160)	Shortness of Breath	Mild
10 Jan 2021 (Study Day 161)	Cough	Mild
10 Jan 2021 (Study Day 161)	Shortness of Breath	Mild
11 Jan 2021 (Study Day 162)	Cough	Mild
11 Jan 2021 (Study Day 162)	Shortness of Breath	Mild
12 Jan 2021 (Study Day 163)	Cough	Mild
12 Jan 2021 (Study Day 163)	Shortness of Breath	Mild
13 Jan 2021 (Study Day 164)	Cough	Mild
13 Jan 2021 (Study Day 164)	Shortness of Breath	Mild
14 Jan 2021 (Study Day 165)	Cough	Mild
14 Jan 2021 (Study Day 165)	Shortness of Breath	Mild
15 Jan 2021 (Study Day 166)	Cough	Mild
15 Jan 2021 (Study Day 166)	Shortness of Breath	Mild
16 Jan 2021 (Study Day 167)	Cough	Mild
16 Jan 2021 (Study Day 167)	Shortness of Breath	Mild
17 Jan 2021 (Study Day 168)	Cough	Mild
17 Jan 2021 (Study Day 168)	Shortness of Breath	Mild
18 Jan 2021 (Study Day 169)	Cough	Mild
18 Jan 2021 (Study Day 169)	Shortness of Breath	Mild
19 Jan 2021 (Study Day 170)	Cough	Mild
19 Jan 2021 (Study Day 170)	Shortness of Breath	Mild

Symptom Date	Symptom	Result
20 Jan 2021 (Study Day 171)	Cough	Mild
20 Jan 2021 (Study Day 171)	Shortness of Breath	Mild
21 Jan 2021 (Study Day 172)	Cough	Mild
21 Jan 2021 (Study Day 172)	Shortness of Breath	Mild
22 Jan 2021 (Study Day 173)	Cough	Mild
22 Jan 2021 (Study Day 173)	Shortness of Breath	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
30 Dec 2020 (Study Day 150)	Oxygen Saturation	93%
30 Dec 2020 - 02 Jan 2021 (Study Day 150-153)	Oxygen Saturation of SpO2 ≤93% on room air at sea level	Yes

Action taken with the IP was not applicable. The event of COVID 19 lasted for 40 days, after which it was considered to be recovered/resolved on 25 Jan 2021 (Study Day 176). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001910	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	1990 - Ongoing
Hypertension	Hypertension	1990 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	2017 - Ongoing	Hypertension
Valsartan	2017 - Ongoing	Hypertension
Amoxicillin	26 Dec 2020 (Study Day 146) - 05 Jan 2021 (Study Day 156)	Abcessed Tooth
Prednisone	30 Dec 2020 (Study Day 150) - 08 Jan 2021 (Study Day 159)	Sars COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	17 Dec 2020 (Study Day 137) - 25 Jan 2021 (Study Day 176)
Tooth Abscess	Grade 2/moderate	Not related	26 Dec 2020 (Study Day 146) - 06 Jan 2021 (Study Day 157)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379812

Participant Number:	US344-2024 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Of Right Hip Osteoarthritis	SAE	Grade 3/ severe	Not related	07 Dec 2020 (Study Day 112) – 08 Dec 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2024, a 69-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 17 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Dec 2020 (Study Day 112), 111 days after the first dose and 81 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening of right hip osteoarthritis lasted for 2 days, after which it was considered to be recovered/resolved on 08 Dec 2020 (Study Day 113). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001123	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1956 - 1956
Tonsillitis	Tonsillitis	1956 - 1956
Rhinitis allergic	Allergic rhinitis	1970 - Ongoing
Panic attack	Panic attacks	1978 - Ongoing
Anxiety	Anxiety	1980 - Ongoing
Dyspepsia	Heartburn	1990 - Ongoing
Gastrooesophageal reflux disease	Gerd	1990 - Ongoing
Diabetes mellitus	Diabetes mellitus	1998 - Ongoing
Depression	Mild depression	2000 - Ongoing
Blood cholesterol increased	High cholesterol	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Insomnia	Insomnia	2012 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2012 - Ongoing
Osteoarthritis	Osteoarthritis: back, right hip, right knee	2015 - Ongoing
Back pain	Lumbar back pain	2016 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	Aug 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	1998 - Ongoing	Dm 2
Lisinopril	2005 - Ongoing	Hypertension
Simvastatin	2005 - 07 Dec 2020 (Study Day 112)	High Cholesterol
Insulin detemir	2008 - 07 Dec 2020 (Study Day 112)	Dm 2
Glipizide	2012 - Ongoing	Dm 2
Pioglitazone	2016 - Ongoing	Dm 2
Empagliflozin	2018 - Ongoing	Dm 2
Naproxen sodium	Feb 2019 - 30 Jan 2021 (Study Day 166)	Osteoarthritis
Meloxicam	10 Sep 2020 (Study Day 24) - 07 Dec 2020 (Study Day 112)	Osteoarthritis
Paracetamol	10 Sep 2020 (Study Day 24) - 07 Dec 2020 (Study Day 112)	Osteoarthritis
Influenza vaccine inact split 4v	17 Oct 2020 (Study Day 61) - 17 Oct 2020 (Study Day 61)	Influenza
Acetylsalicylic acid	07 Dec 2020 (Study Day 112) - Ongoing	Dvt

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium chloride; potassium chloride; sodium lactate	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Dexamethasone	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Diazepam	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Famotidine	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Fentanyl	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Glycopyrronium bromide	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Hydromorphone hydrochloride	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Pain During Hip Surgery
Insulin detemir	07 Dec 2020 (Study Day 112) - Ongoing	Type 2 Diabetes (Dm Ii)
Lidocaine	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Lidocaine	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Pain During Hip Surgery
Macrogol	07 Dec 2020 (Study Day 112) - Ongoing	Stool Softener
Morphine	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip Surgery
Neostigmine	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Ondansetron	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Oxycodone hydrochloride; paracetamol	07 Dec 2020 (Study Day 112) - 06 Jan 2021 (Study Day 142)	Pain In Right Hip Due To Hip Replacement Surgery
Propofol	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Rocuronium	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery
Simvastatin	07 Dec 2020 (Study Day 112) - Ongoing	Hypercholesterolemia
Sodium chloride	07 Dec 2020 (Study Day 112) - 08 Dec 2020 (Study Day 113)	Right Hip Replacement
Total hip arthroplasty on the right*	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Adverse Event
Tranexamic acid	07 Dec 2020 (Study Day 112) - 07 Dec 2020 (Study Day 112)	Iv Drip For Surgery

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	07 Dec 2020 (Study Day 112) - 28 Feb 2021 (Study Day 195)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US344-2031 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deep Vein Thrombosis/Deep Vein Thrombosis (Left Leg)	SAE	Grade 3/ severe	Not related	03 Nov 2020 (Study Day 78) – 04 Nov 2020 (Study Day 79)	Recovered/resolved
Pulmonary Embolism/Pulmonary Embolism	SAE	Grade 3/ severe	Not related	03 Nov 2020 (Study Day 78) – 04 Nov 2020 (Study Day 79)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2031, a 55-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 21 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Nov 2020 (Study Day 78), 77 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of deep vein thrombosis. Action taken with the IP was not applicable. The event of deep vein thrombosis (left leg) lasted for 2 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 79). The investigator assessed the event of deep vein thrombosis to be not related to the IP.

On 03 Nov 2020 (Study Day 78), 77 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolism lasted for 2 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 79). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000687	Deep vein thrombosis
MOD-2020-000687	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Recurrent kidney stones	1982 - Ongoing
Obesity	Obesity	1990 - 2012
Drug hypersensitivity	Morphine allergy (itching and crawling feeling)	1992 - Ongoing
Pulmonary embolism	Multiple pulmonary embolisms	2007 - 2007
Thrombosis	Thrombus	Nov 2007 - Nov 2008
Hypercoagulation	Thrombophillia	21 Nov 2008 (Study Day -4288) - Ongoing
Appendicectomy	Appendectomy	2010 - 2010
Appendicitis	Appendicitis	2010 - 2010
Postmenopause	Post-menopausal	2010 - Ongoing
Gastrectomy	Gastric sleeve	2012 - 2012
Cholecystectomy	Cholecystectomy	2013 - 2013
Cholelithiasis	Cholelithiasis	2013 - 2013
Abdominoplasty	Abdominoplasty	2015 - 2015
Mammoplasty	Breast augmentation	2015 - 2015
Anxiety	Anxiety	2016 - Ongoing
Dyspepsia	Heartburn	2016 - Ongoing
Hypothyroidism	Hypothyroidism	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Amitriptyline	2016 - Ongoing	Anxiety
Pantoprazole sodium sesquihydrate	2016 - Ongoing	Acid Reflux
Levothyroxine	2017 - Ongoing	Hypothyroidism
Sertraline	2017 - Ongoing	Anxiety
Paracetamol	19 Aug 2020 (Study Day 2) - 20 Aug 2020 (Study Day 3)	Injection Site Pain
Ondansetron	26 Aug 2020 (Study Day 9) - 27 Aug 2020 (Study Day 10)	Nausea

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	22 Sep 2020 (Study Day 36) - 24 Sep 2020 (Study Day 38)	Elevated Temperature, Body Aches, Fatigue
Acetylsalicylic acid	03 Nov 2020 (Study Day 78) - 03 Nov 2020 (Study Day 78)	Pulmonary Embolism
Acetylsalicylic acid	03 Nov 2020 (Study Day 78) - 04 Nov 2020 (Study Day 79)	Pulmonary Embolism
Chest x-ray*	03 Nov 2020 (Study Day 78) - 03 Nov 2020 (Study Day 78)	Diagnostic
Ct scan - angio chest w&wo cont*	03 Nov 2020 (Study Day 78) - 03 Nov 2020 (Study Day 78)	Diagnostic
Ecg*	03 Nov 2020 (Study Day 78) - 03 Nov 2020 (Study Day 78)	Diagnostic
Ketorolac tromethamine	03 Nov 2020 (Study Day 78) - 04 Nov 2020 (Study Day 79)	Pulmonary Embolism
Sodium chloride	03 Nov 2020 (Study Day 78) - 04 Nov 2020 (Study Day 79)	Deep Venous Thrombosis (Prophylaxis)
Ultra sound*	03 Nov 2020 (Study Day 78) - 03 Nov 2020 (Study Day 78)	Diagnostic
Aluminium hydroxide; magnesium hydroxide; simeticone	04 Nov 2020 (Study Day 79) - 04 Dec 2020 (Study Day 109)	Gastrointestinal Prophylaxis
Apixaban	04 Nov 2020 (Study Day 79) - 11 Nov 2020 (Study Day 86)	Pulmonary Embolism
Enoxaparin sodium	04 Nov 2020 (Study Day 79) - 04 Nov 2020 (Study Day 79)	Pulmonary Embolism
Magnesium hydroxide	04 Nov 2020 (Study Day 79) - 04 Dec 2020 (Study Day 109)	Gastrointestinal Prophylaxis
Ondansetron hydrochloride	04 Nov 2020 (Study Day 79) - 04 Nov 2020 (Study Day 79)	Gastrointestinal Prophylaxis
Paracetamol	04 Nov 2020 (Study Day 79) - 04 Nov 2020 (Study Day 79)	Pulmonary Embolism
Tramadol	04 Nov 2020 (Study Day 79) - 12 Nov 2020 (Study Day 87)	Left Calf Pain (Secondary To Deep Vein Thrombosis)
Apixaban	12 Nov 2020 (Study Day 87) - Ongoing	Pulmonary Embolism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Warmth	Grade 1/mild	Related	26 Aug 2020 (Study Day 9) - 29 Aug 2020 (Study Day 12)
Lymphadenopathy	Grade 1/mild	Related	26 Aug 2020 (Study Day 9) - 29 Aug 2020 (Study Day 12)
Nausea	Grade 1/mild	Related	26 Aug 2020 (Study Day 9) - 27 Aug 2020 (Study Day 10)
Dyspnoea	Grade 3/severe	Not related	04 Nov 2020 (Study Day 79) - 12 Nov 2020 (Study Day 87)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US344-2051 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	SAE	Grade 3/severe	Not related	09 Jan 2021 (Study Day 143) – 29 Jan 2021 (Study Day 163)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2051, a 42-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Jan 2021 (Study Day 143), 142 days after the first dose and 114 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved on 29 Jan 2021 (Study Day 163). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004672	COVID-19
MOD-2020-000723	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1988 - 1988
Tonsillitis	Tonsillitis	1988 - 1988
Gastrooesophageal reflux disease	Gerd	1990 - Ongoing
Oesophagogastric fundoplasty	Fundoplication of stomach	2013 - 2015
Hiatus hernia	Hiatal hernia	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	23 Sep 2020 (Study Day 35) - 23 Sep 2020 (Study Day 35)	Left Periobital Soreness
Paracetamol	23 Sep 2020 (Study Day 35) - 23 Sep 2020 (Study Day 35)	Left Periobital Soreness
Paracetamol	09 Jan 2021 (Study Day 143) - 12 Feb 2021 (Study Day 177)	COVID-19
Azithromycin	17 Jan 2021 (Study Day 151) - 19 Jan 2021 (Study Day 153)	COVID - 19
Benzonatate	17 Jan 2021 (Study Day 151) - 19 Jan 2021 (Study Day 153)	COVID - 19
Dexamethasone	17 Jan 2021 (Study Day 151) - 19 Jan 2021 (Study Day 153)	COVID - 19
Promethazine	17 Jan 2021 (Study Day 151) - 19 Jan 2021 (Study Day 153)	COVID - 19
Azithromycin	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID - 19
Ceftriaxone	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID - 19
Ct chest w/o contrast*	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	Adverse Event
Dexamethasone sodium phosphate	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID - 19
Enoxaparin	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID-19
Famotidine	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID - 19
Ondansetron hydrochloride	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID - 19
Salbutamol	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID - 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	19 Jan 2021 (Study Day 153) - 19 Jan 2021 (Study Day 153)	COVID - 19
Ekg*	20 Jan 2021 (Study Day 154) - 20 Jan 2021 (Study Day 154)	Adverse Event
Brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride	21 Jan 2021 (Study Day 155) - 28 Jan 2021 (Study Day 162)	COVID - 19
Doxycycline monohydrate	21 Jan 2021 (Study Day 155) - 28 Jan 2021 (Study Day 162)	COVID - 19
Montelukast sodium	21 Jan 2021 (Study Day 155) - 28 Jan 2021 (Study Day 162)	COVID - 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Periorbital Pain	Grade 1/mild	Related	22 Sep 2020 (Study Day 34) - 24 Sep 2020 (Study Day 36)
COVID-19	Grade 2/moderate	Not related	21 Oct 2020 (Study Day 63) - 25 Oct 2020 (Study Day 67)
Rash	Grade 1/mild	Not related	17 Jan 2021 (Study Day 151) - 21 Jan 2021 (Study Day 155)
Headache	Grade 2/moderate	Not related	09 Mar 2021 (Study Day 202) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US344-2060 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Of Left Knee Osteoarthritis	SAE	Grade 3/ severe	Not related	18 Nov 2020 (Study Day 90) – 11 Feb 2021 (Study Day 175)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2060, a 75-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 21 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Nov 2020 (Study Day 90), 89 days after the first dose and 58 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening of left knee osteoarthritis lasted for 86 days, after which it was considered to be recovered/resolved on 11 Feb 2021 (Study Day 175). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-028061	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	1994 - Ongoing
Neck surgery	Neck surgery	1998 - 1998
Spinal osteoarthritis	Osteoarthritis: neck	1998 - Ongoing
Neck surgery	Neck surgey	2006 - 2006
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Neck surgery	Neck surgery	2013 - 2013
Osteoarthritis	Osteoarthritis: left knee	2013 - Ongoing
Anaemia	Anemia	2016 - Ongoing
Bone density decreased	Low bone density	Aug 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine besilate	2010 - Ongoing	Hypertension
Losartan	2010 - Dec 2020	Hypertension
Simvastatin	2010 - Ongoing	High Cholesterol
Acetylsalicylic acid	2015 - 04 Feb 2021 (Study Day 168)	Cardiac Prophylaxis
Ascorbic acid; zinc	2015 - Ongoing	Nutritional Supplement
Calcium	2015 - Ongoing	Nutritional Supplement
Chondroitin; glucosamine	2015 - Ongoing	Nutritional Supplement
Cinnamomum verum	2015 - Ongoing	Supplement
Colecalciferol	2015 - Ongoing	Nutritional Supplement
Curcuma longa	2015 - Ongoing	Nutritional Supplement
Fish oil	2015 - Ongoing	Nutritional Supplement
Iron	2015 - Ongoing	Nutritional Supplement
Magnesium	2015 - Ongoing	Nutritional Supplemnent
Probiotics nos	2015 - Ongoing	Nutritional Supplement
Vitamins nos	2015 - Ongoing	Nutritional Supplement
Alendronate sodium	Aug 2019 - Ongoing	Low Bone Density
Meloxicam	Feb 2020 - 04 Feb 2021 (Study Day 168)	Osteoarthritis: Left Knee And Neck
Influenza vaccine inact split 4v	02 Nov 2020 (Study Day 74) - 02 Nov 2020 (Study Day 74)	Influenza
Dexamethasone	18 Nov 2020 (Study Day 90) - 18 Nov 2020 (Study Day 90)	Worsening Of Left Knee Osteoarthritis
Bevacizumab	14 Dec 2020 (Study Day 116) - Ongoing	Hypertensive Retinopathy (Left)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	17 Dec 2020 (Study Day 119) - Ongoing	Hypertension
Chest pa lateral*	11 Feb 2021 (Study Day 175) - 11 Feb 2021 (Study Day 175)	Adverse Event
Ekg*	11 Feb 2021 (Study Day 175) - 11 Feb 2021 (Study Day 175)	Adverse Event
Left total knee arthoroplasty*	11 Feb 2021 (Study Day 175) - 11 Feb 2021 (Study Day 175)	Medical History
Radiology - left knee portable 2 views*	11 Feb 2021 (Study Day 175) - 11 Feb 2021 (Study Day 175)	Adverse Event
Acetylsalicylic acid	12 Feb 2021 (Study Day 176) - Ongoing	Cardiac Prophylaxis
Meloxicam	12 Feb 2021 (Study Day 176) - Ongoing	Arthritis Left Neck And Knee
Hydrocodone bitartrate; paracetamol	13 Feb 2021 (Study Day 177) - Ongoing	Knee Pain (Left) Secondary To Left Knee Replacement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Retinopathy Hypertensive	Grade 1/mild	Not related	14 Dec 2020 (Study Day 116) - Ongoing
Hypertension	Grade 2/moderate	Not related	17 Dec 2020 (Study Day 119) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US344-2068 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Osteoarthritis/ Cervical Spondylosis With Radiculopathy	SAE	Grade 3/ severe	Not related	30 Dec 2020 (Study Day 132) – 30 Dec 2020 (Study Day 132)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2068, a 59-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Dec 2020 (Study Day 132), 131 days after the first dose and 99 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of spinal osteoarthritis. Action taken with the IP was not applicable. The event of cervical spondylosis with radiculopathy lasted for 1 day, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 132). The investigator assessed the event of spinal osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005524	Spinal osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Intervertebral disc degeneration	Two degenerative cervical discs	2004 - 30 Dec 2020 (Study Day 132)
Neuropathy peripheral	Neuropathy in the left arm	2009 - Ongoing
Osteoarthritis	Osteoathritis (bilateral knees and shoulders, neck)	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2012 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2015 - Ongoing
Anxiety	Anxiety	2019 - Ongoing
Depression	Mild depression	2019 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2019 - Ongoing
Migraine	Migraines	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2015 - Ongoing	Hypercholesterolemia
Empagliflozin	2015 - Ongoing	Type 2 Diabetes
Citalopram	2019 - Ongoing	Depression/Anxiety
Colecalciferol	2019 - Ongoing	Supplement
Fenofibrate	2019 - Ongoing	Hypercholesterolemia
Gabapentin	2019 - Ongoing	Neuropathy: Left Arm
Hydrochlorothiazide	2019 - Ongoing	Hypertension
Ibuprofen	2019 - 23 Dec 2020 (Study Day 125)	Osteoarthritis: Neck, Bilaterally Shoulders And Knees
Metformin	2019 - Ongoing	Type 2 Diabetes
Pantoprazole	2019 - Ongoing	Acid Reflux
Sumatriptan	2019 - Ongoing	Migraines
Topiramate	2019 - Ongoing	Migraines
Cervical replacement and fusion two degenerative cervical disc*	30 Dec 2020 (Study Day 132) - 30 Dec 2020 (Study Day 132)	Adverse Event
Codeine; paracetamol	30 Dec 2020 (Study Day 132) - Ongoing	Appendicitis
Cyclobenzaprine	30 Dec 2020 (Study Day 132) - Ongoing	Cervical Replacement And Fusion
Methylprednisolone	30 Dec 2020 (Study Day 132) - Ongoing	Appendicitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US344-2113 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Acute Appendicitis	SAE	Grade 3/severe	Not related	02 Sep 2020 (Study Day 2) – 04 Sep 2020 (Study Day 4)	Recovered/resolved
Peritonitis/Localized Peritonitis	SAE	Grade 3/severe	Not related	02 Sep 2020 (Study Day 2) – 03 Sep 2020 (Study Day 3)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US344-2113, a 71-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Sep 2020 (Study Day 2), 1 day after the first dose and 27 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. The IP dose was not changed due to the acute appendicitis. The event of acute appendicitis lasted for 3 days, after which it was considered to be recovered/resolved on 04 Sep 2020 (Study Day 4). The investigator assessed the event of appendicitis to be not related to the IP.

On 02 Sep 2020 (Study Day 2), 1 day after the first dose and 27 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of peritonitis. The IP dose was not changed due to the localized peritonitis. The event of localized peritonitis lasted for 2 days, after which it was considered to be recovered/resolved on 03 Sep 2020 (Study Day 3). The investigator assessed the event of peritonitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000261	Peritonitis
MOD-2020-000261	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal polypectomy	Nasal polyp surgery	1995 - 1995
Neck injury	Neck injury c6 c7	1998 - 1998
Spinal fusion surgery	C6,c7 fusion	1998 - 1998
Basedow's disease	Graves disease	2002 - Ongoing
Endocrine ophthalmopathy	Graves ophthalmopathy	2002 - Ongoing
Nasal polypectomy	Nasal polyp surgery	2003 - 2003
Nasal polypectomy	Nasal polyp surgery	2007 - 2007
Foot deformity	Hammertoe: right foot 2nd and 3rd toes	2009 - 2014
Hypothyroidism	Hypothyroidism	2009 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Erectile dysfunction	Erectile dysfunction	2011 - Ongoing
Meniscus injury	Torn meniscus bl	2011 - 2011
Meniscus operation	Bl meniscus repair	2011 - 2011
Asthma	Asthma	2012 - Ongoing
Nasal polyps	Benign nasal polyps	2014 - 2014
Toe operation	Hammertoe surgery: right foot 2nd and 3rd toe	2014 - 2014
Gastrooesophageal reflux disease	Gerd	2015 - Ongoing
Sleep apnoea syndrome	Sleep apnea	Feb 2015 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2018 - Ongoing
Diplopia	Diplopia	2019 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Myalgia	General myalgias	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2010 - Ongoing	Hypothyroidism
Montelukast sodium	2010 - Ongoing	Seasonal Allergies
Budesonide; formoterol fumarate	2012 - Ongoing	Asthma
Fluticasone propionate	2012 - Ongoing	Seasonal Allergies
Omeprazole	2015 - Ongoing	Gerd
Omeprazole	2015 - Ongoing	Seasonal Allergies
Tamsulosin	2018 - Ongoing	Benign Prostatic Hyperplasia
Amlodipine	2019 - Ongoing	Hypertension
Atorvastatin	2019 - Ongoing	Hypercholesterolemia
Benralizumab	2019 - Ongoing	Seasonal Allergies
Naproxen	2019 - Ongoing	General Myalgias
Ramipril	2019 - Ongoing	Hypertension
Selenium	2019 - Ongoing	Diplopia
Trazodone	2019 - Ongoing	Insomnia
Zolpidem tartrate	2019 - Ongoing	Insomnia
Cetirizine hydrochloride	Mar 2020 - Ongoing	Seasonal Allergies
Calcium chloride; potassium chloride; sodium lactate	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Hydration
Ct scan abdominal*	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Diagnostic
Hydrocodone bitartrate; paracetamol	03 Sep 2020 (Study Day 3) - 04 Sep 2020 (Study Day 4)	Mild Pain / Appendicitis
Hydromorphone	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Severe Pain / Appendicitis
Iopamidol	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Ct Scan Prep
Laparoscopic appendectomy*	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Adverse Event
Morphine	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Appendicitis
Ondansetron	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Appendicitis
Piperacillin; tazobactam	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Appendicitis
Piperacillin; tazobactam	03 Sep 2020 (Study Day 3) - 04 Sep 2020 (Study Day 4)	Appendicitis
Sodium chloride	03 Sep 2020 (Study Day 3) - 03 Sep 2020 (Study Day 3)	Hydration
Sodium chloride	03 Sep 2020 (Study Day 3) - 04 Sep 2020 (Study Day 4)	Iv Flush
Hydrocodone bitartrate; paracetamol	04 Sep 2020 (Study Day 4) - 09 Sep 2020 (Study Day 9)	Pain (Secondary 2 Appendectomy)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	04 Sep 2020 (Study Day 4) - 10 Sep 2020 (Study Day 10)	Appendectomy
Zolpidem tartrate	04 Sep 2020 (Study Day 4) - 04 Sep 2020 (Study Day 4)	Insomnia
Influenza vaccine inact sag 3v	15 Oct 2020 (Study Day 45) - 15 Oct 2020 (Study Day 45)	Flu Vaccine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	04 Sep 2020 (Study Day 4) - 09 Sep 2020 (Study Day 9)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US346-2091 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Neck Pain/Neck Pain	SAE	Grade 4	Not related	09 Oct 2020 (Study Day 61) – 29 Dec 2020 (Study Day 142)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2091, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Oct 2020 (Study Day 61), 60 days after the first dose and 31 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of neck pain. Action taken with the IP was not applicable. The event of neck pain lasted for 82 days, after which it was considered to be recovered/resolved on 29 Dec 2020 (Study Day 142). The investigator assessed the event of neck pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000493	Neck pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract	Right eye cataract	(b) (6) 1953 - Ongoing
Intervertebral disc protrusion	Lower back ruptured discs	2004 - Ongoing
Joint injury	Bilateral knee damage	2007 - Ongoing
Cardiac failure congestive	Congestive heart failure	2008 - Ongoing
Cholelithiasis	Gall bladder stones	2008 - Ongoing
Oedema peripheral	Bilateral leg edema	2008 - Ongoing
Cataract	Left eye cataract	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2010 - Ongoing
Limb injury	Left shoulder damage	2013 - 2013
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2015 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease exacerbation	24 Jun 2020 (Study Day -47) - 29 Jun 2020 (Study Day -42)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2008 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2008 - Ongoing	Congestive Heart Failure
Losartan	2008 - Ongoing	Congestive Heart Failure
Potassium	2008 - Ongoing	Supplement
Torasemide	2008 - Ongoing	Bilateral Leg Edema
Metformin	2010 - Ongoing	Type Ii Diabetes
Beclometasone dipropionate	2015 - Ongoing	Chronic Obstructive Pulminary Disease
Olodaterol hydrochloride; tiotropium bromide monohydrate	2015 - Ongoing	Chronic Obstructive Pulminary Disease
Arformoterol tartrate	May 2020 - Ongoing	Chronic Obstructive Pulminary Disease
Prednisone	24 Jun 2020 (Study Day -47) - 26 Jun 2020 (Study Day -45)	Chronic Obstructive Pulmnary Disease Exacerbation
Prednisone	27 Jun 2020 (Study Day -44) - 29 Jun 2020 (Study Day -42)	Chronic Obstructive Pulminary Disease Exacerbation
Empagliflozin	10 Jul 2020 (Study Day -31) - Ongoing	Congestive Heart Failure
Antibiotics	09 Oct 2020 (Study Day 61) - 15 Oct 2020 (Study Day 67)	Neck Pain
Ecoli test*	09 Oct 2020 (Study Day 61) - 09 Oct 2020 (Study Day 61)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Electrocardiogram*	09 Oct 2020 (Study Day 61) - 09 Oct 2020 (Study Day 61)	Adverse Event
Iv fluids*	09 Oct 2020 (Study Day 61) - 09 Oct 2020 (Study Day 61)	Adverse Event
Morphine	09 Oct 2020 (Study Day 61) - 10 Oct 2020 (Study Day 62)	Neck Pain
Muscle relaxants	09 Oct 2020 (Study Day 61) - 29 Dec 2020 (Study Day 142)	Neck Pain
Nasal swab*	09 Oct 2020 (Study Day 61) - 09 Oct 2020 (Study Day 61)	Adverse Event
Paracetamol	09 Oct 2020 (Study Day 61) - 29 Dec 2020 (Study Day 142)	Neck Pain
Spinal tap*	09 Oct 2020 (Study Day 61) - 09 Oct 2020 (Study Day 61)	Adverse Event
Spinal tap*	10 Oct 2020 (Study Day 62) - 10 Oct 2020 (Study Day 62)	Adverse Event
Oxycodone	11 Oct 2020 (Study Day 63) - 16 Oct 2020 (Study Day 68)	Neck Pain
Prednisone	08 Mar 2021 (Study Day 211) - 15 Mar 2021 (Study Day 218)	Pneumonia
Azithromycin	09 Mar 2021 (Study Day 212) - 15 Mar 2021 (Study Day 218)	Pneumonia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pneumonia	Grade 3/severe	Not related	06 Feb 2021 (Study Day 181) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US346-2101 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Transient Ischaemic Attack/Transient Ischemic Attack	SAE	Grade 4	Not related	25 Sep 2020 (Study Day 47) – 25 Sep 2020 (Study Day 47)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2101, a 45-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 10 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 47), 46 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of transient ischaemic attack. Action taken with the IP was not applicable. The event of transient ischemic attack lasted for 1 day, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 47). The investigator assessed the event of transient ischaemic attack to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000430	Transient ischaemic attack

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1992 - Ongoing
Bipolar disorder	Bipolar disorder	1992 - Ongoing
Arthritis	Bilateral hip arthritis	2016 - Ongoing
Exostosis	Bone spurs in both femurs	2016 - Ongoing
Scleroderma	Sub dermal sclerosis in both femurs	2016 - Ongoing
Gastrooesophageal reflux disease	Gerd	01 Jun 2019 (Study Day -436) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	1992 - Ongoing	Anxiety
Nortriptyline hydrochloride	1998 - Ongoing	Anxiety
Lamotrigine	2002 - Ongoing	Bipolar
Vitamins nos	2010 - Ongoing	Supplementation
Calcium carbonate	2012 - Ongoing	Supplementation
Colecalciferol	2012 - Ongoing	Supplements
Omeprazole	2019 - Ongoing	Gerd
Vitamin b12 nos	2019 - Ongoing	Supplementation
Ibuprofen	11 Sep 2020 (Study Day 33) - 11 Sep 2020 (Study Day 33)	Pain Around Vaccine Site
Ct head wo*	25 Sep 2020 (Study Day 47) - 25 Sep 2020 (Study Day 47)	Diagnostic
Cta head neck*	25 Sep 2020 (Study Day 47) - 25 Sep 2020 (Study Day 47)	Diagnostic
Acetylsalicylic acid	26 Sep 2020 (Study Day 48) - Ongoing	Prophylaxis For Tia
Atorvastatin	26 Sep 2020 (Study Day 48) - Ongoing	Prophylaxis For Tia/Hyperlipidemia
Ecg*	26 Sep 2020 (Study Day 48) - 26 Sep 2020 (Study Day 48)	Diagnostic
Echo 2d complete doppler*	26 Sep 2020 (Study Day 48) - 26 Sep 2020 (Study Day 48)	Diagnostic
Mri brain wo*	26 Sep 2020 (Study Day 48) - 26 Sep 2020 (Study Day 48)	Adverse Event
Influenza vaccine	06 Oct 2020 (Study Day 58) - 06 Oct 2020 (Study Day 58)	Annual Prophylaxis
Influenza vaccine	06 Nov 2020 (Study Day 89) - 06 Nov 2020 (Study Day 89)	Immunization

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Grade 1/mild	Not related	26 Sep 2020 (Study Day 48) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379837

Participant Number:	US346-2111 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Laryngeal Oedema/Laryngeal Edema	SAE	Grade 4	Not related	19 Sep 2020 (Study Day 40) – 24 Sep 2020 (Study Day 45)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2111, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Sep 2020 (Study Day 40), 39 days after the first dose and 4 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of laryngeal oedema. Action taken with the IP was not applicable. The event of laryngeal edema lasted for 6 days, after which it was considered to be recovered/resolved on 24 Sep 2020 (Study Day 45). The investigator assessed the event of laryngeal oedema to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000350	Laryngeal oedema

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	(b) (6) 1962 - Ongoing
Headache	Occasional headaches	1985 - Ongoing
Urticaria	Sulfa allergy (hives)	1985 - Ongoing
Oophorectomy	Oophorectomy left	2009 - 2009
Ovarian cyst	Left ovarian cyst	2009 - 2009
Rib fracture	Right fractured ribs	2011 - 2011
Hypertension	Hypertension	2015 - Ongoing
Postmenopause	Post menopausal	Feb 2017 - Feb 2017
Cyst removal	Cyst removal (back) benign	28 Feb 2020 (Study Day -165) - 28 Feb 2020 (Study Day -165)
Insomnia	Occasional insomnia	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1982 - Ongoing	Asthma
Biotin	2011 - Ongoing	Supplement
Colecalciferol	2011 - Ongoing	Supplement
Magnesium	2011 - Ongoing	Supplement
Vitamin b12 nos	2011 - Ongoing	Supplement
Ibuprofen	2012 - Ongoing	Occasional Headaches
Lisinopril	Sep 2018 - 19 Sep 2020 (Study Day 40)	Hypertension
Fluticasone propionate; salmeterol xinafoate	27 Nov 2018 (Study Day -623) - Ongoing	Asthma
Cimicifuga racemosa	11 Apr 2019 (Study Day -488) - Ongoing	Supplement
Diphenhydramine hydrochloride; paracetamol	Apr 2020 - Ongoing	Occasional Insomnia
Prednisone	19 Sep 2020 (Study Day 40) - 24 Sep 2020 (Study Day 45)	Laryngeal Edema
Olmesartan	22 Sep 2020 (Study Day 43) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US346-2116 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/Congestive Heart Failure	SAE	Grade 4	Not related	03 Sep 2020 (Study Day 24) – 09 Sep 2020 (Study Day 30)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2116, a 43-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 14 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Sep 2020 (Study Day 24), 23 days after the first dose and 11 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of cardiac failure congestive. The IP dose was not changed due to the congestive heart failure. The event of congestive heart failure lasted for 7 days, after which it was considered to be recovered/resolved on 09 Sep 2020 (Study Day 30). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000281	Cardiac failure congestive

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1981 - 1981
Tonsillitis	Tonsillitis	1981 - 1981
Intervertebral disc operation	Lumbar discectomy	1991 - 1991
Intervertebral disc protrusion	Ruptured l5	1991 - 1991
Drug abuse	Methamphetamine abuse 1993-2003	1993 - 2003
Osteoarthritis	Right ankle arthritis	1997 - 2006
Headache	Occasional headaches	2000 - Ongoing
Hodgkin's disease	Hodgkins lymphoma	2003 - 2004
Bronchospasm	Exertional bronchospasm	2004 - Ongoing
Hypothyroidism	Hypothyroidism	2004 - Ongoing
Female sterilisation	Tubal ligation	Nov 2005 - Nov 2005
Intervertebral disc operation	Lumbar disectomy	2006 - 2006
Intervertebral disc protrusion	Ruptured l6	2006 - 2006
Restless legs syndrome	Restless leg syndrome	2006 - Ongoing
Ankle operation	Right ankle joint fusion	2016 - 2016
Pain in extremity	Chronic foot pain bilateral	2016 - Ongoing
Diabetic neuropathy	Sensory diabetic neuropathy bilateral feet	2019 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2019 - Ongoing
Cardiomyopathy	Familial cardiomyopathy	2020 - Ongoing
Diabetic ulcer	Diabetic ulcers	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Occasional Headache
Levothyroxine sodium	2005 - Ongoing	Hypothyroidism
Ropinirole hydrochloride	2007 - Ongoing	Restless Leg Syndrome
Salbutamol	2018 - Ongoing	Exertional Bronchospasm
Insulin glargine	2019 - Ongoing	Type Ii Diabetes
Insulin lispro	2019 - Ongoing	Type Ii Diabetes
Chest x-ray*	04 Sep 2020 (Study Day 25) - 04 Sep 2020 (Study Day 25)	Adverse Event
Cat scan*	05 Sep 2020 (Study Day 26) - 05 Sep 2020 (Study Day 26)	Adverse Event
Echocardiogram*	05 Sep 2020 (Study Day 26) - 05 Sep 2020 (Study Day 26)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Angiogram*	08 Sep 2020 (Study Day 29) - 08 Sep 2020 (Study Day 29)	Adverse Event
Atorvastatin	08 Sep 2020 (Study Day 29) - Ongoing	Familial Cardiomyopathy/ Congestive Heart Failure
Acetylsalicylic acid	09 Sep 2020 (Study Day 30) - Ongoing	Cardiac Prophylaxis
Carvedilol	09 Sep 2020 (Study Day 30) - Ongoing	Familial Cardiomyopathy/ Congestive Heart Failure
Furosemide	10 Sep 2020 (Study Day 31) - Ongoing	Familial Cardiomyopathy/ Congestive Heart Failure
Lisinopril	10 Sep 2020 (Study Day 31) - Ongoing	Familial Cardiomyopathy/ Congestive Heart Failure
Spironolactone	10 Sep 2020 (Study Day 31) - Ongoing	Familial Cardiomyopathy/ Congestive Heart Failure
Hydrocodone bitartrate; paracetamol	01 Mar 2021 (Study Day 203) - 14 Mar 2021 (Study Day 216)	Bilateral Chronic Foot Pain
Methocarbamol	01 Mar 2021 (Study Day 203) - 14 Mar 2021 (Study Day 216)	Bilateral Chronic Foot Pain
Anesthetics, general	15 Mar 2021 (Study Day 217) - 15 Mar 2021 (Study Day 217)	L Below The Knee Amputation
Enoxaparin sodium	15 Mar 2021 (Study Day 217) - 07 Apr 2021 (Study Day 240)	Cardiac Prophylaxis
Hydrocodone bitartrate; paracetamol	15 Mar 2021 (Study Day 217) - Ongoing	Post-Surgical Pain
L below the knee amputation*	15 Mar 2021 (Study Day 217) - 15 Mar 2021 (Study Day 217)	Medical History
Methocarbamol	15 Mar 2021 (Study Day 217) - Ongoing	Post-Surgical Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cardiomyopathy	Grade 2/moderate	Not related	05 Sep 2020 (Study Day 26) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379842

Participant Number:	US346-2133 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Seizure/Generalized Seizures	SAE	Grade 4	Not related	23 Aug 2020 (Study Day 12) – 26 Aug 2020 (Study Day 15)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2133, a 61-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Aug 2020 (Study Day 12), 11 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of seizure. On 08 Sep 2020 (Study Day 28), the IP dose was discontinued due to withdrawal of consent by participant. The event of generalized seizures lasted for 4 days, after which it was considered to be recovered/resolved on 26 Aug 2020 (Study Day 15). The investigator assessed the event of seizure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000238	Seizure

Study Completion/Discontinuation

On 14 Sep 2020 (Study Day 34), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis perennial	Perennial allergic rhinitis	1978 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	1978 - Ongoing
Back pain	Back pain	2000 - Ongoing
Drug hypersensitivity	Morphine allergy	2000 - Ongoing
Headache	Occasional headaches	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Neck pain	Neck pain	2000 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	2006 - Ongoing
Postmenopause	Post-menopausal	2010 - Ongoing
Seizure	Occasional seizures	Oct 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Back Pain
Atenolol	2015 - 23 Aug 2020 (Study Day 12)	Hypertension
Vitamins nos	2019 - Ongoing	Supplement
Atorvastatin	23 Aug 2020 (Study Day 12) - Ongoing	Heart Failure
Ct head without contrast*	23 Aug 2020 (Study Day 12) - 23 Aug 2020 (Study Day 12)	Adverse Event
Labs*	23 Aug 2020 (Study Day 12) - 23 Aug 2020 (Study Day 12)	Adverse Event
Levetiracetam	23 Aug 2020 (Study Day 12) - 26 Aug 2020 (Study Day 15)	Generalized Seizures
Lisinopril	23 Aug 2020 (Study Day 12) - 26 Aug 2020 (Study Day 15)	Hypertension
Metoprolol	23 Aug 2020 (Study Day 12) - Ongoing	Hypertension
Ct angiogram head*	24 Aug 2020 (Study Day 13) - 24 Aug 2020 (Study Day 13)	Adverse Event
Ct angiogram neck*	24 Aug 2020 (Study Day 13) - 24 Aug 2020 (Study Day 13)	Adverse Event
Echo 2d complete doppler color flow*	25 Aug 2020 (Study Day 14) - 25 Aug 2020 (Study Day 14)	Adverse Event
Mri brain with and without contrast*	25 Aug 2020 (Study Day 14) - 25 Aug 2020 (Study Day 14)	Adverse Event
Disulfiram	26 Aug 2020 (Study Day 15) - Ongoing	Alcohol Cessation
Nicotine	26 Aug 2020 (Study Day 15) - Ongoing	Smoking Cessation
Ondansetron	26 Aug 2020 (Study Day 15) - 02 Sep 2020 (Study Day 22)	Heart Failure
Acetylsalicylic acid	27 Aug 2020 (Study Day 16) - Ongoing	Cardiac Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cardiac Failure	Grade 2/moderate	Not related	23 Aug 2020 (Study Day 12) - Ongoing
Cerebrovascular Accident	Grade 2/moderate	Not related	23 Aug 2020 (Study Day 12) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US346-2213 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 45)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Optic Neuritis/Nonarteritic Ischemic Optic Nerve Neuritis (Right Eye)	SAE	Grade 4	Not related	15 Dec 2020 (Study Day 121) – 27 Jan 2021 (Study Day 164)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2213, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 45). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Dec 2020 (Study Day 121), 120 days after the first dose and 76 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of optic neuritis. Action taken with the IP was not applicable. The event of nonarteritic ischemic optic nerve neuritis (right eye) lasted for 44 days, after which it was considered to be recovered/resolved with sequelae on 27 Jan 2021 (Study Day 164). The investigator assessed the event of optic neuritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002167	Optic neuritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Occasional headaches	1980 - Ongoing
Appendicectomy	Appendectomy	1986 - 1986
Appendicitis	Appendicitis	1986 - 1986
Iodine allergy	Injected iodine allergy	1986 - Ongoing
Urticaria	Sulfa allergy (hives)	1987 - Ongoing
Back pain	Occasional back pain	1989 - Ongoing
Anxiety	Anxiety	1994 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1995 - Ongoing
Asthma	Asthma (moderate)	1998 - Ongoing
Female sterilisation	Tubal ligation	1998 - 1998
Rhinitis perennial	Perennial allergic rhinitis	1998 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	1998 - Ongoing
Constipation	Occasional constipation	1999 - Ongoing
Depression	Depression	2003 - 2007
Uterine leiomyoma	Uterine fibroids	2005 - 2010
Irritable bowel syndrome	Irritable bowel syndrome	2007 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	Oct 2007 - Ongoing
Intervertebral disc protrusion	Lumbar disc bulge	2008 - Ongoing
Osteoporosis	Osteoporosis	2008 - Ongoing
Cholelithiasis	Gallstones	2009 - 2009
Type 2 diabetes mellitus	Diabetes ii (diet controlled)	Apr 2009 - Ongoing
Benign abdominal neoplasm	Benign fatty abdominal tumor	2010 - 2012
Cholecystectomy	Cholecystectomy	Dec 2010 - Dec 2010
Hysterectomy	Hysterectomy	Dec 2010 - Dec 2010
Postmenopause	Post menopausal	Dec 2010 - Dec 2010
Arthralgia	Left knee pain	2012 - Ongoing
Lipoma excision	Abdominial fatty tumor removed	2012 - 2012
Goitre	Hyperplastic thyroid nodule	Jan 2012 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Breast mass	Left breast nodule	Jan 2016 - Oct 2019
Hypertension	Hypertension	Nov 2017 - Ongoing
Herpes zoster	Shingles	29 May 2019 (Study Day -446) - 04 Jun 2019 (Study Day -440)
Breast conserving surgery	Right breast lumpectomy	Oct 2019 - Oct 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1998 - Ongoing	Asthma
Naproxen sodium	2002 - Ongoing	Occasional Headaches
Omeprazole	2005 - Ongoing	Gastroesophageal Reflux Disease
Cetirizine hydrochloride	2006 - Ongoing	Seasonal And Perennial Allergic Rhinitis
Colecalciferol	2006 - Ongoing	Supplement
Macrogol 3350	2006 - Ongoing	Occasional Constipation
Calcium	Jun 2006 - Ongoing	Supplemen T
Montelukast sodium	2010 - Ongoing	Asthma
Lidocaine	2011 - Ongoing	Occasional Back Pain
Budesonide; formoterol fumarate	2012 - Ongoing	Asthma
Algeldrate; sodium alginate	Nov 2017 - Ongoing	Gastroesophageal Reflux Disease
Amlodipine besilate	Nov 2017 - Ongoing	Hypertension
Hydrochlorothiazide; triamterene	Nov 2017 - Ongoing	Hypertension
Meloxicam	Nov 2017 - Ongoing	Occasional Back Pain
Fluticasone propionate	Dec 2017 - Ongoing	Seasonal And Perennial Allergic Rhinitis
Influenza vaccine	17 Sep 2020 (Study Day 32) - 17 Sep 2020 (Study Day 32)	Flu Prophylaxis
Influenza vaccine	17 Sep 2020 (Study Day 32) - 17 Sep 2020 (Study Day 32)	Influenza Prophylaxis
Prednisolone	15 Dec 2020 (Study Day 121) - 28 Dec 2020 (Study Day 134)	Right Eye Swollen Optic Nerve
Brain magnetic resonance imaging*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Computed tomography of head*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Methylprednisolone sodium succinate	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Right Eye Nonarteritic Ischemic Optic Nerve Neuritis
Methylprednisolone sodium succinate	04 Jan 2021 (Study Day 141) - 09 Jan 2021 (Study Day 146)	Right Eye Nonarteritic Ischemic Optic Nerve Neuritis
Complete echocardiagram*	05 Jan 2021 (Study Day 142) - 05 Jan 2021 (Study Day 142)	Adverse Event
Visual analog scale: carotid duplex bilateral*	05 Jan 2021 (Study Day 142) - 05 Jan 2021 (Study Day 142)	Adverse Event
Visual analog scale: temporal arteries*	05 Jan 2021 (Study Day 142) - 05 Jan 2021 (Study Day 142)	Adverse Event
Cerebral angiogram*	07 Jan 2021 (Study Day 144) - 07 Jan 2021 (Study Day 144)	Adverse Event
Atorvastatin	09 Jan 2021 (Study Day 146) - Ongoing	Hypercholesterolemia
Prednisone	09 Jan 2021 (Study Day 146) - 12 Jan 2021 (Study Day 149)	Right Eye Nonarteritic Ischemic Optic Nerve Neuritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	13 Jan 2021 (Study Day 150) - 17 Jan 2021 (Study Day 154)	Right Eye Nonarteritic Ischemic Optic Nerve Neuritis
Prednisone	18 Jan 2021 (Study Day 155) - 22 Jan 2021 (Study Day 159)	Right Eye Nonarteritic Ischemic Optic Nerve Neuritis
Prednisone	23 Jan 2021 (Study Day 160) - 27 Jan 2021 (Study Day 164)	Right Eye Nonarteritic Ischemic Optic Nerve Neuritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Laryngitis	Grade 1/mild	Not related	10 Sep 2020 (Study Day 25) - 25 Oct 2020 (Study Day 70)
Papilloedema	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 121) - 04 Jan 2021 (Study Day 141)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US346-2255 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaemia/Anemia	SAE	Grade 4	Not related	09 Oct 2020 (Study Day 52) – Ongoing	Recovering/resolving
Dehydration/Dehydration	SAE	Grade 4	Not related	09 Oct 2020 (Study Day 52) – 17 Oct 2020 (Study Day 60)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2255, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Oct 2020 (Study Day 52), 51 days after the first dose and 23 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of anaemia. Action taken with the IP was not applicable. The event of anaemia was considered to be ongoing. The investigator assessed the event of anaemia to be not related to the IP.

On 09 Oct 2020 (Study Day 52), 51 days after the first dose and 23 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration lasted for 9 days, after which it was considered to be recovered/resolved on 17 Oct 2020 (Study Day 60). The investigator assessed the event of dehydration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000510	Dehydration
MOD-2020-000510	Anaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergic rhinitis / perennial allergic rhinitis	1980 - Ongoing
Caesarean section	Cesarean section	1982 - 1982
Carpal tunnel syndrome	Bilateral carpel tunnel	1985 - 1988
Caesarean section	Cesarean section	1988 - 1988
Carpal tunnel decompression	Bilateral carpel tunnel repair	1988 - 1988
Gastrooesophageal reflux disease	Gastroesophogeal reflux disease	1995 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Tachycardia	Occasional tachycardia	2000 - Ongoing
Osteoarthritis	Osteoarthritis (bilateral knees)	2005 - Ongoing
Meniscus injury	Torn right lateral meniscus	2008 - 2009
Meniscus operation	Right lateral meniscus repair	2009 - 2009
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Obesity	Mild obestiy	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus (type 2)	2011 - Ongoing
Back pain	Lower back pain	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1995 - Ongoing	Cardiac Risk
Omeprazole	1995 - Ongoing	Gerd
Duloxetine	2000 - Ongoing	Anxiety
Hydrochlorothiazide	2000 - Ongoing	Hypertension
Metoprolol	2000 - Ongoing	Occasional Tachycardia
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Cetirizine hydrochloride	2015 - Ongoing	Seasonal Allergic Rhinitis / Perennial Allergic Rhinitis
Metformin	2017 - Ongoing	Type Ii Diabetes
Other dermatologicals	2018 - 2018	Cosmetic
Meloxicam	2019 - Ongoing	Osteoarthritis
Glipizide	Jan 2020 - Ongoing	Type Ii Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	Feb 2020 - Ongoing	Type 2 Diabetes
Gabapentin	May 2020 - Ongoing	Bilateral Knee Arthritis
Cyclobenzaprine	29 Jul 2020 (Study Day -21) - Ongoing	Lower Back Pain
Gastric bypass surgery*	02 Oct 2020 (Study Day 45) - 02 Oct 2020 (Study Day 45)	Medical History
Hydrocodone bitartrate; paracetamol	02 Oct 2020 (Study Day 45) - 03 Oct 2020 (Study Day 46)	Post Gastric Bypass Surgery Pain
Iron	16 Oct 2020 (Study Day 59) - Ongoing	Anemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US346-2388 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	12 Oct 2020 (Study Day 43)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Joint Stiffness/Severe Arthrosclerosis	SAE	Grade 4	Not related	25 Sep 2020 (Study Day 26) – 11 Dec 2020 (Study Day 103)	Recovered/resolved
Myocardial Infarction/Myocardial Infarction	SAE	Grade 4	Not related	25 Sep 2020 (Study Day 26) – 25 Sep 2020 (Study Day 26)	Recovered/resolved
Pneumonia Aspiration/Aspiration Pneumonia	SAE	Grade 4	Not related	25 Sep 2020 (Study Day 26) – 04 Oct 2020 (Study Day 35)	Recovered/resolved
Pericarditis/Post Surgical Pericarditis Secondary To Coronary Bypass Surgery	SAE	Grade 4	Not related	28 Dec 2020 (Study Day 120) – 30 Dec 2020 (Study Day 122)	Recovered/resolved
Pleural Effusion/Post Surgical Pleural Effusion	SAE	Grade 4	Not related	28 Dec 2020 (Study Day 120) – 30 Dec 2020 (Study Day 122)	Recovered/resolved
Pericarditis/Post-Surgical Pericarditis Secondary To Coronary Bypass Surgery	SAE	Grade 4	Not related	14 Jan 2021 (Study Day 137) – 20 Jan 2021 (Study Day 143)	Recovered/resolved
Pericarditis/Post Surgical Pericarditis Secondary To Coronary Bypass Surgery	SAE	Grade 4	Not related	26 Jan 2021 (Study Day 149) – 30 Jan 2021 (Study Day 153)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US346-2388, a 46-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 12 Oct 2020 (Study Day 43). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 26), 25 days after the first dose and 17 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of joint stiffness. The IP dose

was not changed due to the severe arthrosclerosis. The event of severe arthrosclerosis lasted for 78 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 103). The investigator assessed the event of joint stiffness to be not related to the IP.

On 25 Sep 2020 (Study Day 26), 25 days after the first dose and 17 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of myocardial infarction. The IP dose was not changed due to the myocardial infarction. The event of myocardial infarction lasted for 1 day, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 26). The investigator assessed the event of myocardial infarction to be not related to the IP.

On 25 Sep 2020 (Study Day 26), 25 days after the first dose and 17 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia aspiration. The IP dose was not changed due to the aspiration pneumonia. The event of aspiration pneumonia lasted for 10 days, after which it was considered to be recovered/resolved on 04 Oct 2020 (Study Day 35). The investigator assessed the event of pneumonia aspiration to be not related to the IP.

On 28 Dec 2020 (Study Day 120), 119 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pericarditis. Action taken with the IP was not applicable. The event of post surgical pericarditis secondary to coronary bypass surgery lasted for 3 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 122). The investigator assessed the event of pericarditis to be not related to the IP.

On 28 Dec 2020 (Study Day 120), 119 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pleural effusion. Action taken with the IP was not applicable. The event of post surgical pleural effusion lasted for 3 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 122). The investigator assessed the event of pleural effusion to be not related to the IP.

On 14 Jan 2021 (Study Day 137), 136 days after the first dose and 94 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pericarditis. Action taken with the IP was not applicable. The event of post surgical pericarditis secondary to coronary bypass surgery lasted for 7 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 143). The investigator assessed the event of pericarditis to be not related to the IP.

On 26 Jan 2021 (Study Day 149), 148 days after the first dose and 106 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pericarditis. Action taken with the IP was not applicable. The event of post surgical pericarditis secondary to coronary bypass surgery lasted for 5 days, after which it was considered to be recovered/resolved on 30 Jan 2021 (Study Day 153). The investigator assessed the event of pericarditis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000429	Pneumonia aspiration
MOD-2020-000429	Myocardial infarction
MOD-2020-000429	Joint stiffness
MOD-2020-000429	Pericarditis
MOD-2020-000429	Pleural effusion
MOD-2020-000429	Pericarditis
MOD-2020-000429	Pericarditis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tourette's disorder	Touretts syndrome	1990 - Ongoing
Constipation	Occasional constipation	2005 - Ongoing
Drug hypersensitivity	Antiinflamatory allergy (stomach ache)	2005 - Ongoing
Gastrooesophageal reflux disease	Occasional acid reflux	2005 - Ongoing
Psoriasis	Psoriasis (feet)	2005 - Ongoing
Ankle fracture	Right ankle break with surgical repair	2011 - 2011
Back pain	Lower back pain	2015 - Ongoing
Depression	Depression	2015 - Ongoing
Spinal fusion surgery	Low back fusion	2017 - 2017
Spinal fusion surgery	Neck fusion	2018 - 2018
Hypercholesterolaemia	Hypercholesterolemia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline hydrochloride	2015 - Ongoing	Depression
Gabapentin	2017 - Ongoing	Touretts Syndrome
Atorvastatin	2019 - Ongoing	Hypercholesterolemia
Esomeprazole magnesium	2019 - Ongoing	Occasional Acid Reflux
Diazepam	Mar 2020 - Ongoing	Tourettes Syndrome

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocodone bitartrate; paracetamol	Mar 2020 - Ongoing	Lower Back Pain
Angiogram*	02 Dec 2020 (Study Day 94) - 02 Dec 2020 (Study Day 94)	Adverse Event
Single bypass surgery*	11 Dec 2020 (Study Day 103) - 11 Dec 2020 (Study Day 103)	Adverse Event
Fluid draining from heart and lungs*	26 Jan 2021 (Study Day 149) - 26 Jan 2021 (Study Day 149)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US347-2013 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atelectasis/Atelectasis	SAE	Grade 4	Not related	21 Sep 2020 (Study Day 20) – 24 Sep 2020 (Study Day 23)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US347-2013, a 59-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 20), 19 days after the first dose and 7 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of atelectasis. The IP dose was not changed due to the atelectasis. The event of atelectasis lasted for 4 days, after which it was considered to be recovered/resolved on 24 Sep 2020 (Study Day 23). The investigator assessed the event of atelectasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000346	Atelectasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Moderate asthma	1968 - Ongoing
Depression	Depression	1996 - Ongoing
Sleep disorder	Sleep disorder	2002 - Ongoing
Obesity	Morbid obesity	31 May 2006 (Study Day -5208) - Ongoing
Dermal filler injection	Dermal injection, unknown type, forehead	2015 - 2015
Renal cell carcinoma	Renal cell cancer	07 Aug 2017 (Study Day -1122) - 14 Aug 2017 (Study Day -1115)
Bursitis	Mild left greater trochanter bursitis	18 Oct 2018 (Study Day -685) - Ongoing
Tendon rupture	Interstitial tearing of the left gluteus medius and minimus tendons	18 Oct 2018 (Study Day -685) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	1996 - Ongoing	Depression
Methylphenidate hydrochloride	1998 - Ongoing	Depression
Trazodone	2002 - Ongoing	Sleep Disturbance
Omalizumab	10 Feb 2020 (Study Day -205) - Ongoing	Asthma
Paracetamol	02 Sep 2020 (Study Day 1) - 05 Sep 2020 (Study Day 4)	Injection Site Pain
Codeine; paracetamol	21 Sep 2020 (Study Day 20) - 25 Sep 2020 (Study Day 24)	Postoperative Pain
Gastric band surgery*	21 Sep 2020 (Study Day 20) - 21 Sep 2020 (Study Day 20)	Medical History
Omeprazole	21 Sep 2020 (Study Day 20) - 21 Oct 2020 (Study Day 50)	Prophylaxis For Gerd Following Gastric Band
Paracetamol	21 Sep 2020 (Study Day 20) - 25 Sep 2020 (Study Day 24)	Postoperative Pain
Enoxaparin	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Postoperative Prophylaxis For Dvt
Left gluteus medius tendon repair and reconstruction*	01 Oct 2020 (Study Day 30) - 01 Oct 2020 (Study Day 30)	Medical History
Oxycodone	01 Oct 2020 (Study Day 30) - 04 Oct 2020 (Study Day 33)	Postoperative Pain
Apixaban	02 Oct 2020 (Study Day 31) - Ongoing	Postoperative Prophylaxis For Dvt
Influenza vaccine	16 Oct 2020 (Study Day 45) - 16 Oct 2020 (Study Day 45)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oesophagitis	Grade 1/mild	Not related	21 Sep 2020 (Study Day 20) - 01 Oct 2020 (Study Day 30)
Meniscus Injury	Grade 2/moderate	Not related	12 Mar 2021 (Study Day 192) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US348-2023 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain Upper/Epigastric Pain	SAE	Grade 4	Not related	04 Nov 2020 (Study Day 73) – 05 Nov 2020 (Study Day 74)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US348-2023, a 70-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 24 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Nov 2020 (Study Day 73), 72 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of abdominal pain upper. Action taken with the IP was not applicable. The event of epigastric pain lasted for 2 days, after which it was considered to be recovered/resolved on 05 Nov 2020 (Study Day 74). The investigator assessed the event of abdominal pain upper to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000785	Abdominal pain upper

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Endometriosis	Endometriosis	1970 - 1994
Hysterectomy	Hysterectomy	1994 - 1994
Botulinum toxin injection	Botox for cosmetic reasons	2000 - 2000
Hypertension	Hypertension	Jan 2008 - Ongoing
Iliotibial band syndrome	Lateral iliotibial band syndrome	Jan 2015 - Ongoing
Cataract operation	R and l cataract surgery	Jul 2020 - Jul 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	Not reported - Ongoing	Nutritional Supplement
Vitamin d nos	Jan 2009 - Ongoing	Supplement
Duloxetine hydrochloride	Jan 2015 - Ongoing	Lateral Iliotibial Band Syndrome
Curcuma longa	Jan 2019 - Ongoing	Nutritional Supplement
Probiotics nos	2020 - Ongoing	Nutritional Supplment
Losartan	Feb 2020 - Ongoing	Hypertension
Zinc	Mar 2020 - Ongoing	Nutritional Supplement
Phentermine hydrochloride	Jun 2020 - 06 Jul 2020 (Study Day -49)	Weight Control
Unspecified herbal and traditional medicine	Jun 2020 - Ongoing	Nutritional Supplement
Besifloxacin hydrochloride	06 Jul 2020 (Study Day -49) - 12 Aug 2020 (Study Day -12)	Cataract Surgery
Bromfenac sodium	16 Jul 2020 (Study Day -39) - 12 Aug 2020 (Study Day -12)	Cataract Surgery
Loteprednol etabonate	30 Jul 2020 (Study Day -25) - 12 Aug 2020 (Study Day -12)	Post Cataract Surgery
Influenza vaccine	11 Oct 2020 (Study Day 49) - 11 Oct 2020 (Study Day 49)	Health Maintenance
Enoxaparin	04 Nov 2020 (Study Day 73) - 05 Nov 2020 (Study Day 74)	Dvt Prophylaxis
Hydromorphone hydrochloride	04 Nov 2020 (Study Day 73) - 05 Nov 2020 (Study Day 74)	Epigastric Pain Management
Pantoprazole sodium sesquihydrate	04 Nov 2020 (Study Day 73) - 05 Nov 2020 (Study Day 74)	Epigastric Pain Management
Gallbladder removal*	09 Feb 2021 (Study Day 170) - 09 Feb 2021 (Study Day 170)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

FDA-CBER-2022-1614-3379862

Participant Number:	US348-2145 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure/Acute Cardiac Heart Failure Exacerbation	SAE	Grade 4	Not related	02 Sep 2020 (Study Day 8) – 13 Sep 2020 (Study Day 19)	Recovered/resolved
Streptococcal Sepsis/Sepsis Related To Streptococcus Bacteremia	SAE	Grade 4	Not related	02 Sep 2020 (Study Day 8) – 13 Sep 2020 (Study Day 19)	Recovered/resolved
Chronic Kidney Disease/Acute Exacerbation Of Chronic Kidney Disease Stage Iii	SAE	Grade 3/severe	Not related	26 Sep 2020 (Study Day 32) – 30 Sep 2020 (Study Day 36)	Recovered/resolved
Gout/Gout Exacerbation In Right Knee	SAE	Grade 3/severe	Not related	26 Sep 2020 (Study Day 32) – 30 Sep 2020 (Study Day 36)	Recovered/resolved
Anaemia/Exacerbation Of Anemia	SAE	Grade 3/severe	Not related	21 Oct 2020 (Study Day 57) – 26 Oct 2020 (Study Day 62)	Recovered/resolved
Cardiac Failure Acute/Worsening Of Acute Decompensated Heart Failure	SAE	Grade 4	Not related	09 Nov 2020 (Study Day 76) – 10 Nov 2020 (Study Day 77)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US348-2145, a 66-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Sep 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of cardiac failure. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of acute cardiac heart failure exacerbation lasted for 12 days, after which it was considered to be recovered/resolved on 13 Sep 2020 (Study Day 19). The investigator assessed the event of cardiac failure to be not related to the IP.

On 02 Sep 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of streptococcal sepsis. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of sepsis related to streptococcus bacteremia lasted for 12 days, after which it was considered to be recovered/resolved on 13 Sep 2020 (Study Day 19). The investigator assessed the event of streptococcal sepsis to be not related to the IP.

On 26 Sep 2020 (Study Day 32), 31 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of chronic kidney disease. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of acute exacerbation of chronic kidney disease stage iii lasted for 5 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 36). The investigator assessed the event of chronic kidney disease to be not related to the IP.

On 26 Sep 2020 (Study Day 32), 31 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of gout. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of gout exacerbation in right knee lasted for 5 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 36). The investigator assessed the event of gout to be not related to the IP.

On 21 Oct 2020 (Study Day 57), 56 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of anaemia. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of exacerbation of anemia lasted for 6 days, after which it was considered to be recovered/resolved on 26 Oct 2020 (Study Day 62). The investigator assessed the event of anaemia to be not related to the IP.

On 09 Nov 2020 (Study Day 76), 75 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of cardiac failure acute. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of worsening of acute decompensated heart failure lasted for 2 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 77). The investigator assessed the event of cardiac failure acute to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000288	Cardiac failure
MOD-2020-000288	Streptococcal sepsis
MOD-2021-166152	Anemia
MOD-2020-000805	Cardiac failure acute
MOD-2020-000808	Gout

CIOMS Number	MedDRA Preferred Term
MOD-2020-000808	Chronic kidney disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anaemia macrocytic	Macrocytic anemia	Not reported - Ongoing
Chronic kidney disease	Chronic kidney disease stage iii	Not reported - Ongoing
Chronic left ventricular failure	Chronic systolic heart failure.	Not reported - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Heart valve replacement	Metallic prosthetic heart valve placement	Not reported
Thrombocytopenia	Mild thrombocytopenia	Not reported
Rheumatic fever	Rheumatic fever atrial fibrillation. details: hospitalized at engleston- 1964	1964 - Ongoing
Fluid retention	Water retention in feet related to gout.	2015 - Ongoing
Gout	Gout in bilateral knees	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2019 - Ongoing
Joint injury	Right knee injury. details: wears a knee brace at home and uses a cane while walking.	Feb 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Health Maintenance
Carvedilol	Not reported - Ongoing	Chronic Systolic Heart Failure
Ceftriaxone	Not reported - 13 Sep 2020 (Study Day 19)	Sepsis Due To Beta Hemolytic Streptoccocus Bacteremia
Ferrous sulfate	Not reported - Ongoing	Macrocytic Anemia
Fluticasone; salmeterol	Not reported - Ongoing	Chronic Obstructive Pulmonary Disease
Heparin	Not reported - Ongoing	Deep Vein Thrombosis Prophylaxis
Paracetamol	Not reported - Ongoing	Analgesia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	Not reported - Ongoing	Chronic Obstructive Pulmonary Disease
Colchicine	2015 - Ongoing	Gout In Both Knees
Furosemide	2015 - Ongoing	Water Retention In Feet Related To Gout
Lisinopril	2015 - 2020	Hypertention
Atorvastatin calcium	2019 - Ongoing	Hyperlipidemia
Vitamins nos	26 Aug 2020 (Study Day 1) - Ongoing	Health Maintenance
Blood culture*	02 Sep 2020 (Study Day 8) - 02 Sep 2020 (Study Day 8)	Adverse Event
Blood workup*	02 Sep 2020 (Study Day 8) - 02 Sep 2020 (Study Day 8)	Adverse Event
Urine culture*	02 Sep 2020 (Study Day 8) - 02 Sep 2020 (Study Day 8)	Adverse Event
Ampicillin; sulbactam	03 Sep 2020 (Study Day 9) - 04 Sep 2020 (Study Day 10)	Sepsis Due To Beta Hemolytic Streptococcus Bacteremia
Furosemide	03 Sep 2020 (Study Day 9) - 04 Sep 2020 (Study Day 10)	Chronic Systolic Heart Failure
Thiamine	03 Sep 2020 (Study Day 9) - 03 Sep 2020 (Study Day 9)	Chronic Systolic Heart Failure
Pantoprazole	05 Sep 2020 (Study Day 11) - Ongoing	Ulcer Prophylaxis
Potassium chloride	05 Sep 2020 (Study Day 11) - 06 Sep 2020 (Study Day 12)	Electrolyte Replacement Related To Chronic Systolic Heart Failure
Echocardiogrophay*	11 Sep 2020 (Study Day 17) - 11 Sep 2020 (Study Day 17)	Diagnostic
Levofloxacin	13 Sep 2020 (Study Day 19) - 16 Sep 2020 (Study Day 22)	Sepsis Due To Beta Hemolytic Streptoccocus Bactermeia
Calcium gluconate	26 Sep 2020 (Study Day 32) - 26 Sep 2020 (Study Day 32)	Acute Exacerbation Of Chronic Kidney Disease Stage Iii
Glucose	26 Sep 2020 (Study Day 32) - 26 Sep 2020 (Study Day 32)	Hyperkalemia Related To Acute Exacerbation Of Chronic Kidney Disease Stage Iii
Insulin	26 Sep 2020 (Study Day 32) - 26 Sep 2020 (Study Day 32)	Hyperkalemia Related To Acute Exacerbation Of Chronic Kidney Disease Stage Iii
Lidocaine	26 Sep 2020 (Study Day 32) - 30 Sep 2020 (Study Day 36)	Gout Exacerbation In Right Knee
Prednisone	26 Sep 2020 (Study Day 32) - 02 Oct 2020 (Study Day 38)	Gout Exacerbation In Right Knee
Sodium polystyrene sulfonate	27 Sep 2020 (Study Day 33) - 27 Sep 2020 (Study Day 33)	Hyperkalemia Related To Acute Exacerbation Of Chronic Kidney Disease Stage Iii
Sodium bicarbonate	29 Sep 2020 (Study Day 35) - 30 Sep 2020 (Study Day 36)	Acidosis Related To Acute Exacerbation Of Chronic Kidney Disease Stage Iii
Influenza vaccine	30 Sep 2020 (Study Day 36) - 30 Sep 2020 (Study Day 36)	Influenza Prophylaxis
Blood workup*	21 Oct 2020 (Study Day 57) - 21 Oct 2020 (Study Day 57)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x-ray*	21 Oct 2020 (Study Day 57) - 21 Oct 2020 (Study Day 57)	Adverse Event
Ekg*	21 Oct 2020 (Study Day 57) - 21 Oct 2020 (Study Day 57)	Adverse Event
Omeprazole	21 Oct 2020 (Study Day 57) - 21 Oct 2020 (Study Day 57)	Ae#3: Exacerbation Of Anemia
Blood workup*	22 Oct 2020 (Study Day 58) - 22 Oct 2020 (Study Day 58)	Adverse Event
Red blood cells, concentrated	22 Oct 2020 (Study Day 58) - 22 Oct 2020 (Study Day 58)	Sae: Exacerbation Of Anemia
Diagnostic colonoscopy*	23 Oct 2020 (Study Day 59) - 23 Oct 2020 (Study Day 59)	Adverse Event
Furosemide	09 Nov 2020 (Study Day 76) - 10 Nov 2020 (Study Day 77)	Shortness Of Breath Due To Acute Decompensated Heart Failure
Iron	09 Nov 2020 (Study Day 76) - 09 Nov 2020 (Study Day 76)	Acute Decompensated Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US348-2267 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/Acute Pulmonary Emboli	SAE	Grade 4	Not related	18 Dec 2020 (Study Day 100) – 13 Jan 2021 (Study Day 126)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US348-2267, a 78-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Dec 2020 (Study Day 100), 99 days after the first dose and 71 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of acute pulmonary emboli lasted for 27 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 126). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001222	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthrosis involving lower legs	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Postmenopause	Post-menopausal	1998 - Ongoing
Glucose tolerance impaired	Pre diabetes	1999 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Depression	Depression	2005 - Ongoing
Restless legs syndrome	Restless leg syndrome	2009 - Ongoing
Glaucoma	Glaucoma	2010 - Ongoing
Cough	Dry chronic cough, unknown etiology	2015 - Ongoing
Asthma	Moderate asthma	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	Not reported - Ongoing	Seasonal Allergies
Terbinafine hydrochloride	Not reported - Ongoing	Rash On Bilateral Hands (Ae #4)
Simvastatin	2001 - Ongoing	Heart Health
Clonazepam	2006 - Ongoing	Anxiety
Acetylsalicylic acid	2010 - Ongoing	Coronary Artery Disease Prevention
Pramipexole	2010 - Ongoing	Restless Leg Syndrome
Alendronate sodium	2015 - Ongoing	Osteoporosis
Brinzolamide	2015 - Ongoing	Glaucoma
Diclofenac	2015 - Ongoing	Bilateral Knee Pain Associated With Osteoarthrosis
Fluticasone propionate	2015 - Ongoing	Seasonal Allergies
Latanoprost	2015 - Ongoing	Glaucoma
Budesonide; formoterol fumarate	2016 - Ongoing	Asthma
Salbutamol	2016 - Ongoing	Asthma
Escitalopram	2018 - Ongoing	Depression
Lisinopril	2018 - 20 Dec 2020 (Study Day 102)	Hypertension
Cardiac stress test*	23 Sep 2020 (Study Day 14) - 23 Sep 2020 (Study Day 14)	Medical History
Loratadine	01 Oct 2020 (Study Day 22) - Ongoing	Seasonal Allergies
Influenza vaccine	02 Nov 2020 (Study Day 54) - 02 Nov 2020 (Study Day 54)	Influenza Prevention
Diphenhydramine hydrochloride	10 Dec 2020 (Study Day 92) - Ongoing	Itching In Hands Related To Rash (Ae #4)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	13 Dec 2020 (Study Day 95) - 13 Dec 2020 (Study Day 95)	Common Cold
Naproxen sodium	13 Dec 2020 (Study Day 95) - 13 Dec 2020 (Study Day 95)	Headache Associated With Ae #6
Chest ct*	18 Dec 2020 (Study Day 100) - 18 Dec 2020 (Study Day 100)	Adverse Event
Heparin	18 Dec 2020 (Study Day 100) - 18 Dec 2020 (Study Day 100)	Pulmonary Emboli
Heparin	18 Dec 2020 (Study Day 100) - 20 Dec 2020 (Study Day 102)	Pulmonary Emboli
Paracetamol	19 Dec 2020 (Study Day 101) - 20 Dec 2020 (Study Day 102)	Pain During Hospital Admission (Ae #5)
Apixaban	20 Dec 2020 (Study Day 102) - 26 Dec 2020 (Study Day 108)	Acute Pulmonary Embolism
Lisinopril	21 Dec 2020 (Study Day 103) - Ongoing	Hyypertension
Potassium chloride	21 Dec 2020 (Study Day 103) - 21 Dec 2020 (Study Day 103)	Supplementation (Associated With Ae #5)
Paracetamol	22 Dec 2020 (Study Day 104) - Ongoing	Knee Pain
Apixaban	27 Dec 2020 (Study Day 109) - Ongoing	Acute Pulmonary Embolism
Fluocinonide	15 Feb 2021 (Study Day 159) - 20 Feb 2021 (Study Day 164)	Ae #4 Rash

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Bruising	Grade 1/mild	Not related	10 Sep 2020 (Study Day 1) - 10 Sep 2020 (Study Day 1)
Presyncope	Grade 3/severe	Not related	08 Oct 2020 (Study Day 29) - 08 Oct 2020 (Study Day 29)
Tremor	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 33) - Ongoing
Rash Macular	Grade 2/moderate	Not related	30 Nov 2020 (Study Day 82) - 20 Feb 2021 (Study Day 164)
Nasopharyngitis	Grade 2/moderate	Not related	10 Dec 2020 (Study Day 92) - 13 Jan 2021 (Study Day 126)
Osteoarthritis	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 97) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US348-2284 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	16 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea/Shortness Of Breath, Worsening	SAE	Grade 4	Not related	28 Oct 2020 (Study Day 13) – 20 Dec 2020 (Study Day 66)	Recovered/resolved
Myocardial Infarction/Myocardial Infarction	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	28 Oct 2020 (Study Day 13) – 31 Oct 2020 (Study Day 16)	Recovered/resolved with sequelae
Acute Left Ventricular Failure/Acute On Chronic Systolic Heart Failure	SAE	Grade 4	Not related	05 Nov 2020 (Study Day 21) – 04 Jan 2021 (Study Day 81)	Recovered/resolved with sequelae
Atrial Flutter/Paroxysmal Atrial Flutter	SAE	Grade 3/severe	Not related	05 Nov 2020 (Study Day 21) – 14 Jan 2021 (Study Day 91)	Recovered/resolved with sequelae
Acute Coronary Syndrome/Acute Coronary Syndrome, Exacerbation	SAE	Grade 4	Not related	16 Nov 2020 (Study Day 32) – 20 Nov 2020 (Study Day 36)	Recovered/resolved
Atrial Fibrillation/Atrial Fibrillation With Rapid Ventricular Response	SAE	Grade 4	Not related	16 Nov 2020 (Study Day 32) – 14 Jan 2021 (Study Day 91)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US348-2284, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 16 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Oct 2020 (Study Day 13), 12 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of dyspnoea. On 12 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of shortness of breath, worsening lasted for 54 days, after which it was considered to be recovered/resolved on

20 Dec 2020 (Study Day 66). The investigator assessed the event of dyspnoea to be not related to the IP.

On 28 Oct 2020 (Study Day 13), 12 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of myocardial infarction. On 12 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of myocardial infarction lasted for 4 days, after which it was considered to be recovered/resolved with sequelae on 31 Oct 2020 (Study Day 16). The investigator assessed the event of myocardial infarction to be not related to the IP.

On 05 Nov 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of acute left ventricular failure. On 12 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute on chronic systolic heart failure lasted for 61 days, after which it was considered to be recovered/resolved with sequelae on 04 Jan 2021 (Study Day 81). The investigator assessed the event of acute left ventricular failure to be not related to the IP.

On 05 Nov 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of atrial flutter. On 12 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of paroxysmal atrial flutter lasted for 71 days, after which it was considered to be recovered/resolved with sequelae on 14 Jan 2021 (Study Day 91). The investigator assessed the event of atrial flutter to be not related to the IP.

On 16 Nov 2020 (Study Day 32), 31 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of acute coronary syndrome. On 12 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute coronary syndrome, exacerbation lasted for 5 days, after which it was considered to be recovered/resolved on 20 Nov 2020 (Study Day 36). The investigator assessed the event of acute coronary syndrome to be not related to the IP.

On 16 Nov 2020 (Study Day 32), 31 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of atrial fibrillation. On 12 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of atrial fibrillation with rapid ventricular response lasted for 60 days, after which it was considered to be recovered/resolved with sequelae on 14 Jan 2021 (Study Day 91). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000597	Myocardial infarction
MOD-2020-000597	Acute left ventricular failure
MOD-2020-000597	Atrial fibrillation
MOD-2020-000597	Acute coronary syndrome
MOD-2020-000597	Atrial flutter
MOD-2020-000597	Dyspnoea

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial septal defect repair	Atrial septal defect, with repairs in 1986 & 1997	Not reported - 1998
Chronic kidney disease	Chronic kidney disease stage iiia	Not reported - Ongoing
Osteoarthritis	Osteoarthritis (multiple joints, multiple surgeries)	Not reported - Ongoing
Cardiac murmur	Heart murmur	1988 - Ongoing
Heart rate irregular	Irregular heart rhythm	1995 - Ongoing
Herpes simplex	Herpes simplex 2 infection	2002 - Ongoing
Bipolar disorder	Bipolar disorder	2006 - Ongoing
Erectile dysfunction	Erectile dysfunction	2008 - Ongoing
Prostate cancer	Prostate cancer	2008 - 2008
Drug hypersensitivity	Ace inhibitor allergy	2009 - Ongoing
Elbow operation	Orthopedic repair, left elbow	2010 - 2010
Hip arthroplasty	Dvt left leg (post l hip arthroplasty)	2012 - 2012
Hip arthroplasty	Hip arthroplasty, left	2012 - 2012
Hip arthroplasty	Hip arthroplasty, right	2014 - 2014
Hypertension	Hypertension	2014 - Ongoing
Elbow operation	Orthopedic repair, r elbow	2016 - 2016
Prophylaxis against HIV infection	Hiv prophylaxis	2016 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2018 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	Jan 2019 - Ongoing
Gout	Gout, l toe	Dec 2019 - Ongoing
Arteriosclerosis coronary artery	Coronary artery disease with calcified lesion	Jan 2020 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rotator cuff repair	Rotator cuff surgery, left	20 Feb 2020 (Study Day -239) - 20 Feb 2020 (Study Day -239)
Tendon rupture	Torn tendon, left shoulder	20 Feb 2020 (Study Day -239) - 20 Feb 2020 (Study Day -239)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Quetiapine fumarate	Not reported - 30 Oct 2020 (Study Day 15)	Insomnia And Bipolar Disorder
Amlodipine	2015 - 05 Nov 2020 (Study Day 21)	Hypertension
Hydrochlorothiazide; triamterene	2015 - 05 Nov 2020 (Study Day 21)	Hypertension
Losartan	2015 - Ongoing	Hypertension
Metoprolol	2015 - Ongoing	Hypertension
Botulinum toxin type a	May 2017 - May 2017	Cosmetic
Acetylsalicylic acid	2018 - Ongoing	Heart Health
Atorvastatin	2018 - 30 Oct 2020 (Study Day 15)	Hyperlipidemia
Emtricitabine; tenofovir alafenamide fumarate	2018 - Ongoing	Hiv Prophylaxis
Quetiapine	2018 - Nov 2020	Bipoloar Disorder
Zolpidem	2019 - Ongoing	Insomnia
Andrographis paniculata; echinacea purpurea root; olea europaea leaf	Mar 2020 - Ongoing	Health Maintenance
Herbal antiobesity preparations	Mar 2020 - 10 Oct 2020 (Study Day -6)	Weight Loss
Acetylsalicylic acid	29 Oct 2020 (Study Day 14) - 29 Oct 2020 (Study Day 14)	Ae#1 (Myocardial Infarction)
Cardiac catheterization with angiography and percutaneous coronary intervention*	29 Oct 2020 (Study Day 14) - 29 Oct 2020 (Study Day 14)	Adverse Event
Chest xray*	29 Oct 2020 (Study Day 14) - 29 Oct 2020 (Study Day 14)	Adverse Event
Electrocardiogram*	29 Oct 2020 (Study Day 14) - 29 Oct 2020 (Study Day 14)	Adverse Event
Eptifibatide	29 Oct 2020 (Study Day 14) - 31 Oct 2020 (Study Day 16)	Myocardial Infarction
Glyceryl trinitrate	29 Oct 2020 (Study Day 14) - 29 Oct 2020 (Study Day 14)	Chest Pain - Associated With Ae #1
Heparin	29 Oct 2020 (Study Day 14) - 29 Oct 2020 (Study Day 14)	Treatment Of Clot - Associated With Ae #1
Standard of care blood work for chest pain protocol*	29 Oct 2020 (Study Day 14) - 29 Oct 2020 (Study Day 14)	Adverse Event
Atorvastatin	30 Oct 2020 (Study Day 15) - Ongoing	Hyperlipidemia - Associated With Ae #1
Clopidogrel	30 Oct 2020 (Study Day 15) - Ongoing	Ae#1 (Myocardial Infarction)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glyceryl trinitrate	31 Oct 2020 (Study Day 16) - Ongoing	Chest Pain - Associated With Ae #1
Quetiapine fumarate	31 Oct 2020 (Study Day 16) - Ongoing	Insomnia
Acetylsalicylic acid	05 Nov 2020 (Study Day 21) - 05 Nov 2020 (Study Day 21)	Shortness Of Breath, Worsening
Ceftriaxone	05 Nov 2020 (Study Day 21) - 07 Nov 2020 (Study Day 23)	Suspected Pneumonia - Associated With Ae #3
Doxycycline	05 Nov 2020 (Study Day 21) - 07 Nov 2020 (Study Day 23)	Suspected Pneumonia - Associated With Ae #3
Electrocardiogram*	05 Nov 2020 (Study Day 21) - 05 Nov 2020 (Study Day 21)	Adverse Event
Furosemide	05 Nov 2020 (Study Day 21) - 06 Nov 2020 (Study Day 22)	Shortness Of Breath, Worsening
Heparin	05 Nov 2020 (Study Day 21) - 05 Nov 2020 (Study Day 21)	Shortness Of Breath, Worsening
Echocardiogram*	06 Nov 2020 (Study Day 22) - 06 Nov 2020 (Study Day 22)	Adverse Event
Heparin	06 Nov 2020 (Study Day 22) - 06 Nov 2020 (Study Day 22)	Clot Prevention - Associated With Ae #3
Rivaroxaban	06 Nov 2020 (Study Day 22) - Ongoing	Clot Prevention - Associated With Ae #3
Acetylsalicylic acid	16 Nov 2020 (Study Day 32) - 16 Nov 2020 (Study Day 32)	Chest Pain Protocol - Associated With Ae #4
Blood cultures*	16 Nov 2020 (Study Day 32) - 16 Nov 2020 (Study Day 32)	Adverse Event
Digoxin	16 Nov 2020 (Study Day 32) - 16 Nov 2020 (Study Day 32)	Atrial Flutter/Fibrillation Associated With Ae #5
Furosemide	16 Nov 2020 (Study Day 32) - 19 Nov 2020 (Study Day 35)	Diuretic - Associated With Ae #4
Glyceryl trinitrate	16 Nov 2020 (Study Day 32) - 17 Nov 2020 (Study Day 33)	Chest Pain Related To Acs Associated With Ae #4
Heparin	16 Nov 2020 (Study Day 32) - 19 Nov 2020 (Study Day 35)	Clot Prevention Associated With Ae #5
Magnesium sulfate	16 Nov 2020 (Study Day 32) - 18 Nov 2020 (Study Day 34)	Hypertension Associated With Ae #4
Metoprolol	16 Nov 2020 (Study Day 32) - 16 Nov 2020 (Study Day 32)	Hypertension Associated With Ae #4
Ceftriaxone sodium	17 Nov 2020 (Study Day 33) - 18 Nov 2020 (Study Day 34)	Suspected Pneumonia Associated With Ae #4
Echocardiogram*	17 Nov 2020 (Study Day 33) - 17 Nov 2020 (Study Day 33)	Adverse Event
Famotidine	17 Nov 2020 (Study Day 33) - 20 Nov 2020 (Study Day 36)	To Prevent Gi Upset Related To Medication Administration - Associated With Ae #4
Hydralazine	17 Nov 2020 (Study Day 33) - 20 Nov 2020 (Study Day 36)	Hypertension Associated With Ae #4
Metoprolol	17 Nov 2020 (Study Day 33) - 17 Nov 2020 (Study Day 33)	Hypertension Associated With Ae #4
Potassium chloride	18 Nov 2020 (Study Day 34) - 20 Nov 2020 (Study Day 36)	Hypokalemia Related To Lasix Administration Associated With Ae #4

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Adenosine	19 Nov 2020 (Study Day 35) - 19 Nov 2020 (Study Day 35)	Atrial Flutter/Fibrillation - Associated With Ae #5
Amiodarone	19 Nov 2020 (Study Day 35) - 08 Dec 2020 (Study Day 54)	Atrial Flutter/Fibrillation - Associated With Ae #5
Cardiovascular mri*	19 Nov 2020 (Study Day 35) - 19 Nov 2020 (Study Day 35)	Adverse Event
Furosemide	20 Nov 2020 (Study Day 36) - 29 Nov 2020 (Study Day 45)	Diuretic - Associated With Ae #4
Ondansetron	20 Nov 2020 (Study Day 36) - 20 Nov 2020 (Study Day 36)	Nausea - Associated With Ae #4
Furosemide	29 Nov 2020 (Study Day 45) - 14 Dec 2020 (Study Day 60)	Diuretic - Associated With Ae #3
Amiodarone	08 Dec 2020 (Study Day 54) - Ongoing	Atrial Flutter
Furosemide	03 Feb 2021 (Study Day 111) - Ongoing	Acute On Chronic Systolic Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US349-2064 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cerebrovascular Accident/Cerebrovascular Accident	SAE	Grade 3/severe	Not related	30 Oct 2020 (Study Day 57) – 11 Nov 2020 (Study Day 69)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2064, a 59-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Oct 2020 (Study Day 57), 56 days after the first dose and 28 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cerebrovascular accident. Action taken with the IP was not applicable. The event of cerebrovascular accident lasted for 13 days, after which it was considered to be recovered/resolved with sequelae on 11 Nov 2020 (Study Day 69). The investigator assessed the event of cerebrovascular accident to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000615	Cerebrovascular accident

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Muscular weakness	Right lower extremity weakness	2017 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2020 - Ongoing
Corneal abrasion	Corneal abrasion	May 2020 - Ongoing
Benign prostatic hyperplasia	Bph	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2017 - Ongoing	Supplement
Vitamin b12 nos	2017 - Ongoing	Supplement
Metformin	02 Oct 2019 (Study Day -338) - Ongoing	Diabetes
Erythromycin	12 Aug 2020 (Study Day -23) - 31 Oct 2020 (Study Day 58)	Runny Eye Issue Due To Corneal Abrasion
Tamsulosin	Sep 2020 - Ongoing	Bph
Atorvastatin	03 Sep 2020 (Study Day -1) - 31 Oct 2020 (Study Day 58)	Cholesterol - Hyperlipidemia
Influenza vaccine	29 Oct 2020 (Study Day 56) - 29 Oct 2020 (Study Day 56)	Prevent Influenza
Varicella zoster vaccine	29 Oct 2020 (Study Day 56) - 29 Oct 2020 (Study Day 56)	Prevent Shingles
Acetylsalicylic acid	31 Oct 2020 (Study Day 58) - Ongoing	Ascvd Prophylaxis
Atorvastatin	31 Oct 2020 (Study Day 58) - Ongoing	Hyperlipidemia
Heparin	31 Oct 2020 (Study Day 58) - 11 Nov 2020 (Study Day 69)	Thrombus Prophylaxis
Macrogol 3350	31 Oct 2020 (Study Day 58) - 11 Nov 2020 (Study Day 69)	Prevent Constipation
Sennoside a+b	31 Oct 2020 (Study Day 58) - 11 Nov 2020 (Study Day 69)	Prevent Constipation
Clopidogrel	20 Nov 2020 (Study Day 78) - 29 Nov 2020 (Study Day 87)	Ascvd Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

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Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 2/moderate	Not related	05 Sep 2020 (Study Day 2) - Ongoing
Myalgia	Grade 1/mild	Related	05 Sep 2020 (Study Day 2) - 23 Sep 2020 (Study Day 20)
Myalgia	Grade 1/mild	Not related	03 Oct 2020 (Study Day 30) - 17 Oct 2020 (Study Day 44)
Asymptomatic COVID-19	Grade 1/mild	Not related	31 Oct 2020 (Study Day 58) - 11 Nov 2020 (Study Day 69)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2078 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	05 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Haematoma/Hematoma Of The R Leg	SAE	Grade 3/severe	Not related	03 Nov 2020 (Study Day 60) – 13 Nov 2020 (Study Day 70)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2078, a 93-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Nov 2020 (Study Day 60), 59 days after the first dose and 32 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of haematoma. Action taken with the IP was not applicable. The event of hematoma of the r leg lasted for 11 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 70). The investigator assessed the event of haematoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000868	Haematoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1932 - 1932
Tonsillitis	Tonsillitis	1932 - 1932
Cardiac arrest	S/p cardiac arrest with resuscitation	1973 - 1973
Prostate cancer	Prostate cancer	1998 - 1998
Prostatectomy	Prostatectomy	1998 - 1998
Coronary artery bypass	Coronary artery bypass graft	2003 - 2003
Coronary artery disease	Coronary artery disease	2003 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2003 - Ongoing
Oedema peripheral	Right lower extremity edema	2003 - Ongoing
Nephrectomy	Left nephrectomy for kidney cancer	2013 - 2013
Atrial fibrillation	Atrial fibrillation	2015 - Ongoing
Cardiac failure congestive	Congestive heart failure	2015 - Ongoing
Cerebrovascular accident	S/p cva	2015 - 2015
Cerebrovascular accident	S/p cva	2017 - 2017
Depression	Depression	2017 - Ongoing
Skin neoplasm excision	S/p resection of basal cell cancer	2018 - 2018
Cerebrovascular accident	S/p cva with residual right lower extremity weakness and ataxia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2003 - Ongoing	Hyperlipidemia
Metoprolol	2016 - 17 Nov 2020 (Study Day 74)	Atrial Fibrillation
Sertraline	2017 - Ongoing	Depression
Apixaban	2018 - 10 Nov 2020 (Study Day 67)	S/P History Of Multiple Cva's
Furosemide	2018 - Ongoing	Congestive Heart Failure
Acetylsalicylic acid	2019 - 10 Nov 2020 (Study Day 67)	Coronary Artery Disease
3 units of prbc infusion*	10 Nov 2020 (Study Day 67) - 10 Nov 2020 (Study Day 67)	Adverse Event
Colonoscopy*	11 Nov 2020 (Study Day 68) - 11 Nov 2020 (Study Day 68)	Adverse Event
Ct right lower extremity*	11 Nov 2020 (Study Day 68) - 11 Nov 2020 (Study Day 68)	Adverse Event
Iron	11 Nov 2020 (Study Day 68) - Ongoing	Low Hemogloblin
Arterial angiogram with embolization*	13 Nov 2020 (Study Day 70) - 13 Nov 2020 (Study Day 70)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	16 Nov 2020 (Study Day 73) - Ongoing	Cerebrovascular Disease And Atrial Fibrillation
Metoprolol	18 Nov 2020 (Study Day 75) - 01 Mar 2021 (Study Day 178)	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	05 Sep 2020 (Study Day 1) - 07 Sep 2020 (Study Day 3)
Diarrhoea	Grade 1/mild	Not related	07 Nov 2020 (Study Day 64) - 18 Nov 2020 (Study Day 75)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2085 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	05 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain Lower/Right Lower Quadrant Pain	SAE	Grade 2/ moderate	Not related	26 Nov 2020 (Study Day 80) – 25 Dec 2020 (Study Day 109)	Recovered/resolved
Ovarian Cyst/Benign Right Ovarian Cyst	SAE	Grade 4	Not related	26 Nov 2020 (Study Day 80) – 25 Dec 2020 (Study Day 109)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2085, a 29-year-old Hispanic or Latino female, received the first dose of placebo in the right arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 05 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Nov 2020 (Study Day 80), 79 days after the first dose and 52 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of abdominal pain lower. Action taken with the IP was not applicable. The event of right lower quadrant pain lasted for 30 days, after which it was considered to be recovered/resolved on 25 Dec 2020 (Study Day 109). The investigator assessed the event of abdominal pain lower to be not related to the IP.

On 26 Nov 2020 (Study Day 80), 79 days after the first dose and 52 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of ovarian cyst. Action taken with the IP was not applicable. The event of benign right ovarian cyst lasted for 30 days, after which it was considered to be recovered/resolved on 25 Dec 2020 (Study Day 109). The investigator assessed the event of ovarian cyst to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001007	Ovarian cyst
MOD-2020-001007	Abdominal pain lower

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Fibromyalgia	Fibromyalgia	2008 - Ongoing
Anxiety	Anxiety	2009 - Ongoing
Depression	Depression	2009 - Ongoing
Migraine	History of migraines	2009 - 2013
Gastrooesophageal reflux disease	Gerd	2012 - Ongoing
Cholecystectomy	Cholecystectomy	2013 - 2013
Coeliac disease	Celiac disease	2013 - Ongoing
Asthma	Asthma - mild, intermittent	2014 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Eczema	Eczema	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	2012 - Ongoing	Gerd
Salbutamol	2014 - Ongoing	Mild Asthma
Biotin	2015 - Ongoing	General Health
Vitamin d nos	2015 - Ongoing	General Health
Vitamins nos	2015 - Ongoing	General Health
Levonorgestrel	2018 - Ongoing	Contraception
Loratadine	2018 - Ongoing	Seasonal Allergies
Emtricitabine; tenofovir disoproxil fumarate	2019 - Oct 2020	Prep
Methocarbamol	2020 - Ongoing	Fibromyalgia
Ibuprofen	20 Sep 2020 (Study Day 13) - 22 Sep 2020 (Study Day 15)	Generalized Muscle Soreness From Exercising

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amoxicillin	26 Sep 2020 (Study Day 19) - 02 Oct 2020 (Study Day 25)	Strep Throat
Lidocaine	26 Sep 2020 (Study Day 19) - 28 Sep 2020 (Study Day 21)	Pain Relief Of Sore Throat
Amoxicillin; clavulanic acid	03 Oct 2020 (Study Day 26) - 09 Oct 2020 (Study Day 32)	Strep Throat
Clindamycin	12 Oct 2020 (Study Day 35) - 17 Oct 2020 (Study Day 40)	Strep Throat
Vancomycin	17 Oct 2020 (Study Day 40) - 27 Oct 2020 (Study Day 50)	Strep Throat
Influenza vaccine	27 Oct 2020 (Study Day 50) - 27 Oct 2020 (Study Day 50)	Influenza Prevention
Ibuprofen	28 Nov 2020 (Study Day 82) - 25 Dec 2020 (Study Day 109)	Benign Right Ovarian Cyst Pain
Hydrocodone; paracetamol	02 Dec 2020 (Study Day 86) - 25 Dec 2020 (Study Day 109)	Right Ovarian Cyst Pain
Ultrasound*	02 Dec 2020 (Study Day 86) - 02 Dec 2020 (Study Day 86)	Adverse Event
Right ovarian cyst removal*	10 Dec 2020 (Study Day 94) - 10 Dec 2020 (Study Day 94)	Adverse Event
Cefdinir	24 Mar 2021 (Study Day 198) - Ongoing	Tonsilitis
Probiotics nos	24 Mar 2021 (Study Day 198) - Ongoing	Prevent Diarrhea From Antibiotic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Myalgia	Grade 1/mild	Not related	20 Sep 2020 (Study Day 13) - 22 Sep 2020 (Study Day 15)
Fibromyalgia	Grade 2/moderate	Not related	24 Sep 2020 (Study Day 17) - 28 Sep 2020 (Study Day 21)
Pharyngitis Streptococcal	Grade 3/severe	Not related	24 Sep 2020 (Study Day 17) - 25 Oct 2020 (Study Day 48)
Diarrhoea	Grade 1/mild	Not related	11 Oct 2020 (Study Day 34) - 24 Oct 2020 (Study Day 47)
Myalgia	Grade 1/mild	Related	11 Oct 2020 (Study Day 34) - 13 Oct 2020 (Study Day 36)
Tonsillitis	Grade 3/severe	Not related	14 Mar 2021 (Study Day 188) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

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Participant Number:	US349-2178 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis Perforated/ Appendicitis/Perforated Appendix, S/P Appendectomy	SAE	Grade 3/ severe	Not related	04 Jan 2021 (Study Day 110) – 11 Jan 2021 (Study Day 117)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2178, a 68-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Jan 2021 (Study Day 110), 109 days after the first dose and 81 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis perforated. Action taken with the IP was not applicable. The event of appendicitis/perforated appendix, s/p appendectomy lasted for 8 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 117). The investigator assessed the event of appendicitis perforated to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002636	Appendicitis perforated

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

FDA-CBER-2022-1614-3379886

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Postmenopause	Post-menopausal	2001 - Ongoing
Hepatic steatosis	Fatty liver	2015 - 2018
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Restless legs syndrome	Restless legs syndrome	2017 - Ongoing
Osteoarthritis	Osteoarthritis of the foot	2018 - Ongoing
Vitamin D deficiency	Vitamin d3 deficiency	2019 - Ongoing
Foot deformity	Right foot bunion	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2017 - Ongoing	Restless Leg Syndrome
Magnesium	2018 - Ongoing	Restless Leg Syndrome
Paracetamol	2018 - Ongoing	Osteoarthritis Of The Foot
Vitamins nos	2018 - 15 Jan 2021 (Study Day 121)	Health Maintenance
Fexofenadine hydrochloride	2019 - Ongoing	Seasonal Allergies
Colecalciferol	2020 - Ongoing	Vitamin D3 Deficiency
Collagen	2020 - Ongoing	Health Maintenance
Monascus purpureus	2020 - 24 Sep 2020 (Study Day 8)	Hyperlipidemia
Naproxen	2020 - Ongoing	Right Foot Bunion
Melatonin	01 Oct 2020 (Study Day 15) - Ongoing	General Restlessness
Cannabidiol	Nov 2020 - Ongoing	Osteoarthritis Of The Foot
Ct of abdomen*	07 Jan 2021 (Study Day 113) - 07 Jan 2021 (Study Day 113)	Adverse Event
Laparoscopic appendectomy*	07 Jan 2021 (Study Day 113) - 07 Jan 2021 (Study Day 113)	Adverse Event
Hydrocodone	11 Jan 2021 (Study Day 117) - 21 Jan 2021 (Study Day 127)	Post Surgical Pain Appendectomy
Amoxicillin; clavulanic acid	12 Jan 2021 (Study Day 118) - 21 Jan 2021 (Study Day 127)	Post Appendicitis (Perforated Appendix), S/P Appendectomy
Ibuprofen	15 Jan 2021 (Study Day 121) - 15 Jan 2021 (Study Day 121)	Pain In Side Post Appendectomy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Foot Deformity	Grade 3/severe	Not related	17 Sep 2020 (Study Day 1) - 18 Sep 2020 (Study Day 2)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3379888

Participant Number:	US349-2243 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	21 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE	Grade 1/mild	Not related	07 Nov 2020 (Study Day 46) – 19 Nov 2020 (Study Day 58)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2243, a 50-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 23 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 21 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Nov 2020 (Study Day 46), 45 days after the first dose and 17 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 13 days, after which it was considered to be recovered/resolved on 19 Nov 2020 (Study Day 58). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000839	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	21 Oct 2020 (Study Day 29) - 22 Oct 2020 (Study Day 30)	Headache And Injection Site Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Myalgia	Grade 1/mild	Not related	09 Oct 2020 (Study Day 17) - 14 Oct 2020 (Study Day 22)
Fatigue	Grade 1/mild	Related	22 Oct 2020 (Study Day 30) - 06 Nov 2020 (Study Day 45)
Fatigue	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 40) - 03 Nov 2020 (Study Day 42)
Myalgia	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 40) - 03 Nov 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2273 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	30 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ventricular Extrasystoles/ Chest Pressure - Respiratory/ Shortness Of Breath - Cardiac Related From Pvcs	SAE	Grade 4	Not related	30 Dec 2020 (Study Day 92) – 30 Dec 2020 (Study Day 92)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2273, a 65-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 30 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Dec 2020 (Study Day 92), 91 days after the first dose and 63 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of ventricular extrasystoles. Action taken with the IP was not applicable. The event of chest pressure - respiratory/shortness of breath - cardiac related from pvcs lasted for 1 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 92). The investigator assessed the event of ventricular extrasystoles to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001710	Angina pectoris

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Coronary artery disease	Coronary artery disease	Not reported
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Intervertebral disc protrusion	Lumbar spine bulging disc	Not reported - Ongoing
Pituitary tumour benign	Benign pituitary gland tumor	Not reported - 1978
Nephrolithiasis	Kidney stones	1989 - Ongoing
Arthritis	Arthritis of the right knee	2010 - Ongoing
Pollakiuria	Urinary frequency of unknown origin	2014 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017 - Ongoing
Myocardial infarction	Myocardial infarction	Mar 2019 - Mar 2019
Hypertension	Hypertension	Aug 2020 - Ongoing
Rotator cuff syndrome	Left shoulder rotator tear	12 Aug 2020 (Study Day -49) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2019 - Ongoing	Health Maintenance
Cyclobenzaprine	2020 - Ongoing	Pain From Left Shoulder Rotator Tear
Diclofenac	2020 - Ongoing	Pain From Arthritis To Right Knee
Lisinopril	2020 - Ongoing	Hypertension
Pneumococcal vaccine polysacch 23v	01 Sep 2020 (Study Day -29) - 01 Sep 2020 (Study Day -29)	Preventative Care
Varicella zoster vaccine rge (cho)	01 Sep 2020 (Study Day -29) - 01 Sep 2020 (Study Day -29)	Preventative Care
Amoxicillin	09 Oct 2020 (Study Day 10) - 09 Oct 2020 (Study Day 10)	Prior To Dental Work
Tamsulosin	14 Nov 2020 (Study Day 46) - Ongoing	Benign Prostatic Hyperplasia
Influenza vaccine	23 Nov 2020 (Study Day 55) - 23 Nov 2020 (Study Day 55)	Prevent Influenza
Varicella zoster vaccine	23 Nov 2020 (Study Day 55) - 23 Nov 2020 (Study Day 55)	Prevent Shingles
Tamsulosin hydrochloride	25 Nov 2020 (Study Day 57) - Ongoing	Urinary Frequecny Of Unknown Origin
Acs rule out with troponin negative x3*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event
Chest x-ray 1 view*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ekg*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event
Exercise stress echo*	30 Dec 2020 (Study Day 92) - 30 Dec 2020 (Study Day 92)	Adverse Event
Metoprolol succinate	31 Dec 2020 (Study Day 93) - Ongoing	Premature Ventricular Contractions - In Relation To Chest Pressure Ae
Angiogram with stent placement*	18 Jan 2021 (Study Day 111) - 18 Jan 2021 (Study Day 111)	Medical History
Clopidogrel bisulfate	18 Jan 2021 (Study Day 111) - Ongoing	Post-Procedure Stent
Rosuvastatin calcium	18 Jan 2021 (Study Day 111) - Ongoing	Hyperlipidemia
Blood cultures*	30 Jan 2021 (Study Day 123) - 30 Jan 2021 (Study Day 123)	Adverse Event
Appendectomy*	01 Feb 2021 (Study Day 125) - 01 Feb 2021 (Study Day 125)	Adverse Event
Piperacillin; tazobactam	01 Feb 2021 (Study Day 125) - 05 Feb 2021 (Study Day 129)	Streptococcal Anginosus Blood Stream Infection
Amoxicillin; clavulanic acid	05 Feb 2021 (Study Day 129) - 13 Feb 2021 (Study Day 137)	Post-Appendectomy Antibiotic Coverage
Docusate sodium	05 Feb 2021 (Study Day 129) - Ongoing	Stool Softener
Paracetamol	05 Feb 2021 (Study Day 129) - Ongoing	Post-Operative Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Post-Traumatic Pain	Grade 1/mild	Not related	06 Oct 2020 (Study Day 7) - 07 Oct 2020 (Study Day 8)
Road Traffic Accident	Grade 1/mild	Not related	06 Oct 2020 (Study Day 7) - 06 Oct 2020 (Study Day 7)
Nocturia	Grade 1/mild	Not related	13 Nov 2020 (Study Day 45) - 18 Nov 2020 (Study Day 50)
Nocturia	Grade 1/mild	Not related	13 Nov 2020 (Study Day 45) - 18 Nov 2020 (Study Day 50)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2281 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	29 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Tendon Rupture/Torn Tendon In Left Wrist	SAE	Grade 2/ moderate	Not related	21 Dec 2020 (Study Day 82) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2281, a 42-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 29 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Dec 2020 (Study Day 82), 81 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of tendon rupture. Action taken with the IP was not applicable. The event of torn tendon in left wrist was considered to be ongoing. The investigator assessed the event of tendon rupture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012366	Tendon rupture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Muscle operation	Major pectoralis surgical repair	2008 - 2008
Muscle rupture	Major pectoralis tear	2008 - 2008

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hordeolum	Recurrent bilateral styes	2014 - Jun 2020
Alopecia	Hair loss	2017 - Ongoing
Fracture treatment	Left ulnar fracture with surgical repair	2017 - 2017
Dermal filler injection	Cosmetic skin procedure to bilateral cheeks with juvederm	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Doxycycline	2014 - Jun 2020	Bilateral Recurrent Styes
Finasteride	2017 - Ongoing	Hair Loss
Emtricitabine; tenofovir disoproxil fumarate	2020 - Ongoing	Prep
Cyclobenzaprine	23 Dec 2020 (Study Day 84) - Ongoing	Torn Tendon Left Wrist
Diclofenac	23 Dec 2020 (Study Day 84) - Ongoing	Torn Tendon Left Wrist
Lidocaine	23 Dec 2020 (Study Day 84) - Ongoing	Torn Tendon Left Wrist
Menthol; methyl salicylate	23 Dec 2020 (Study Day 84) - Ongoing	Torn Tendon Left Wrist
Naproxen	23 Dec 2020 (Study Day 84) - Ongoing	Torn Tendon Left Wrist
Physical therapy for torn tendon in left wrist*	04 Jan 2021 (Study Day 96) - 04 Jan 2021 (Study Day 96)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Oropharyngeal Pain	Grade 1/mild	Not related	03 Oct 2020 (Study Day 3) - 04 Oct 2020 (Study Day 4)
Rhinorrhoea	Grade 1/mild	Not related	03 Oct 2020 (Study Day 3) - 04 Oct 2020 (Study Day 4)
Nasal Congestion	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 134) - 15 Feb 2021 (Study Day 138)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US350-2045 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Migraine/Migraine Exacerbation	SAE	Grade 3/ severe	Not related	16 Sep 2020 (Study Day 20) – 23 Sep 2020 (Study Day 27)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US350-2045, a 55-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 20), 19 days after the first dose and 9 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of migraine. The IP dose was not changed due to the migraine exacerbation. The event of migraine exacerbation lasted for 8 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 27). The investigator assessed the event of migraine to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000345	Migraine

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1970 - Ongoing
Blood cholesterol increased	High cholesterol	1998 - Ongoing
Migraine	Migraines	2006 - Ongoing
Asthma	Asthma	2010 - Ongoing
Postmenopause	Post-menopausal	2018 - Ongoing
Osteoarthritis	Arthritis (osteoarthritis) - bilateral hands and feet	Apr 2018 - Ongoing
Muscle spasms	Muscle spasms - low back	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Magnesium	2005 - Ongoing	General Wellness
Naltrexone	2005 - Ongoing	Migraine Prevention
Ubidecarenone	2005 - Ongoing	General Wellness
Topiramate	2007 - Ongoing	Migraine Prevention
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Biotin	2017 - Ongoing	General Wellness
Fluticasone propionate	2017 - Ongoing	Asthma
Rosuvastatin	2017 - Ongoing	High Cholesterol
Salbutamol	2017 - Ongoing	Asthma
Sertraline	2017 - Ongoing	Migraine Prevention
Promethazine	2019 - Ongoing	Migraine Related Nausea Prevention
Lasmiditan succinate	2020 - Ongoing	Migraine Prevention
Dexamethasone	16 Sep 2020 (Study Day 20) - 16 Sep 2020 (Study Day 20)	Treatment Of Acute Migraine
Diphenhydramine	16 Sep 2020 (Study Day 20) - 16 Sep 2020 (Study Day 20)	Treatment Of Acute Migraine
Magnesium sulfate	16 Sep 2020 (Study Day 20) - 16 Sep 2020 (Study Day 20)	Treatment Of Acute Migraine
Prochlorperazine	16 Sep 2020 (Study Day 20) - 16 Sep 2020 (Study Day 20)	Treatment Of Acute Migraine
Promethazine	16 Sep 2020 (Study Day 20) - 16 Sep 2020 (Study Day 20)	Treatment Of Acute Migraine
Sodium chloride	16 Sep 2020 (Study Day 20) - 16 Sep 2020 (Study Day 20)	Treatment Of Acute Migraine
Valproate sodium	16 Sep 2020 (Study Day 20) - 16 Sep 2020 (Study Day 20)	Treatment Of Acute Migraine

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Treatment Of Migraine
Ketorolac tromethamine	22 Sep 2020 (Study Day 26) - 23 Sep 2020 (Study Day 27)	Treatment Of Migraine
Lorazepam	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Treatment Of Migraine
Magnesium sulfate	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Treatment Of Migraine
Mri of brain*	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Adverse Event
Paracetamol	22 Sep 2020 (Study Day 26) - 23 Sep 2020 (Study Day 27)	Treatment Of Migraine
Prochlorperazine	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Treatment Of Migraine
Sodium chloride	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Treatment Of Migraine
Cyclobenzaprine	23 Sep 2020 (Study Day 27) - 23 Sep 2020 (Study Day 27)	Muscle Spasms - Low Back
Influenza vaccine	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Flu Prophylaxis
Fluticasone propionate	15 Oct 2020 (Study Day 49) - Ongoing	Seasonal Allergy Exacerbation
Ketotifen	15 Oct 2020 (Study Day 49) - Ongoing	Seasonal Allergy Exacerbation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Related	01 Sep 2020 (Study Day 5) - 05 Sep 2020 (Study Day 9)
Fatigue	Grade 1/mild	Related	02 Sep 2020 (Study Day 6) - 06 Sep 2020 (Study Day 10)
Milk Allergy	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 46) - 21 Nov 2020 (Study Day 86)
Seasonal Allergy	Grade 1/mild	Not related	15 Oct 2020 (Study Day 49) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US350-2142 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Multiple Sclerosis/Multiple Sclerosis	SAE	Grade 4	Not related	12 Nov 2020 (Study Day 63) – 23 Nov 2020 (Study Day 74)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US350-2142, a 45-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Nov 2020 (Study Day 63), 62 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of multiple sclerosis. Action taken with the IP was not applicable. The event of multiple sclerosis lasted for 12 days, after which it was considered to be recovered/resolved with sequelae on 23 Nov 2020 (Study Day 74). The investigator assessed the event of multiple sclerosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000751	Multiple sclerosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy	1980 - Ongoing
Endometriosis	Endometriosis	2010 - 2010
Oophorectomy	Oophorectemy	2010 - 2010
Hot flush	Hot flashes	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Venlafaxine	2016 - Ongoing	Hot Flashes
Influenza vaccine	26 Oct 2020 (Study Day 46) - 26 Oct 2020 (Study Day 46)	Flu Prevention
Ergocalciferol	12 Nov 2020 (Study Day 63) - Ongoing	Vitamin D Deficiency
Methylprednisolone sodium succinate	12 Nov 2020 (Study Day 63) - 13 Nov 2020 (Study Day 64)	Multiple Sclerosis
Mri on brain*	12 Nov 2020 (Study Day 63) - 12 Nov 2020 (Study Day 63)	Adverse Event
Omeprazole	12 Nov 2020 (Study Day 63) - Ongoing	Prevent Steroid Induced Ulcers
Calcium	14 Nov 2020 (Study Day 65) - Ongoing	Vitamin D Deficiency
Methylprednisolone sodium succinate	14 Nov 2020 (Study Day 65) - 16 Nov 2020 (Study Day 67)	Multiple Sclerosis
Vitamin d nos	14 Nov 2020 (Study Day 65) - Ongoing	Vitamin D Deficiency
Lumbar puncture*	23 Nov 2020 (Study Day 74) - 23 Nov 2020 (Study Day 74)	Adverse Event
Varicella zoster vaccine rge (cho)	14 Dec 2020 (Study Day 95) - 14 Dec 2020 (Study Day 95)	Shingles Prevention
Varicella zoster vaccine rge (cho)	09 Mar 2021 (Study Day 180) - 09 Mar 2021 (Study Day 180)	Shingles Prevention
Diroximel fumarate	23 Mar 2021 (Study Day 194) - Ongoing	Multiple Sclerosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vitamin D Deficiency	Grade 2/moderate	Not related	12 Nov 2020 (Study Day 63) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US351-2036 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Venous Thrombosis Limb/Venous Thrombosis Of Right Lower Extremity	SAE	Grade 4	Not related	02 Dec 2020 (Study Day 113) – 13 Dec 2020 (Study Day 124)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2036, a 43-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 12 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Dec 2020 (Study Day 113), 112 days after the first dose and 84 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of venous thrombosis limb. Action taken with the IP was not applicable. The event of venous thrombosis of right lower extremity lasted for 12 days, after which it was considered to be recovered/resolved with sequelae on 13 Dec 2020 (Study Day 124). The investigator assessed the event of venous thrombosis limb to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001158	Venous thrombosis limb

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Substance use	Former recreational drug use	Not reported - 2017
Fallot's tetralogy	Tetarology of fallout	(b) (6) 1976 (Study Day (b) (6) - 1978
Nasal septum deviation	Deviated septum	(b) (6) 1976 (Study Day (b) (6)) - Ongoing
Seasonal allergy	Ragweed allergy	1977 - Ongoing
Tetralogy of Fallot repair	Tetarology of fallout repair	1978 - 1978
Seasonal allergy	Seasonal allergies	1986 - Ongoing
Acne	Acne face and back	1988 - 1999
Folliculitis	Folliculitis of face	1988 - 1999
Myopia	Nearsighted bilateral	1988 - Ongoing
Nasal septal operation	Sinus surgery deviated septum	1991 - 1991
Tympanic membrane perforation	Perforated left eardrum	1991 - 1996
Tympanoplasty	Perforated left eardrum repair	1991 - 1991
Nasal septal operation	Sinus surgery deviated septum	1994 - 1994
Nasal septal operation	Sinus surgery deviated septum	1995 - 1995
Tinnitus	Left ear tinnitus	1996 - Ongoing
Peripheral swelling	Swelling in bilateral legs and feet	2000 - Ongoing
Poor peripheral circulation	Poor circulation in bilateral legs	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2001 - Ongoing
Overweight	Overweight	2001 - Ongoing
Restless legs syndrome	Restless leg syndrome	2001 - Ongoing
Spinal osteoarthritis	Osteoarthritis lower back	2001 - Ongoing
Spinal osteoarthritis	Osteoarthritis of the neck	2001 - Ongoing
Thyroid cancer	Thyroid cancer	2001 - 2001
Thyroidectomy	Thyroidectomy	2001 - 2001
Hypertension	Hypertension	2002 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2002 - Ongoing
Intermittent explosive disorder	Intermittent explosive disorder	2003 - Ongoing
Back pain	Back pain	2005 - Ongoing
Intervertebral disc operation	L4-l5 discectomy	2008 - 2008
Atrial fibrillation	Atrial fibrillation	2010 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Deep vein thrombosis	Deep vein thrombosis of lower extremity	2012 - 2012
Gastric ulcer	Gastric ulcer	2012 - 2012
Pulmonary valve replacement	Pulmonary valve replacement	Sep 2012 - Sep 2012
Clostridium difficile infection	C. diff infection	2015 - 2015
Gout	Gout bilateral feet	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2001 - Ongoing	Hypothyroidism
Fluticasone propionate	2010 - Ongoing	Seasonal Allergies
Omeprazole	2011 - 26 Jan 2021 (Study Day 168)	Acid Reflux
Benazepril	2012 - Ongoing	Hypertension
Hydrochlorothiazide	2012 - Ongoing	Hypertension
Cetirizine hydrochloride	2014 - Ongoing	Seasonal Allergies
Allopurinol	2016 - Ongoing	Gout Bilateral Feet
Gabapentin	2016 - Ongoing	Osteoarthritis Neck/Back Pain/Restless Leg Syndrome
Aripiprazole	2017 - Ongoing	Intermittent Explosive Disorder
Ibuprofen	2018 - 14 Dec 2020 (Study Day 125)	Back Pain
Ibuprofen	07 Sep 2020 (Study Day 27) - 10 Sep 2020 (Study Day 30)	Left Shoulder Nerve Impingement
Glucose; heparin sodium	11 Dec 2020 (Study Day 122) - 13 Dec 2020 (Study Day 124)	Venous Thrombosis Of Right Lower Extremity
Heparin	11 Dec 2020 (Study Day 122) - 11 Dec 2020 (Study Day 122)	Venous Thrombosis Of Right Lower Extremity
Paracetamol	11 Dec 2020 (Study Day 122) - 13 Dec 2020 (Study Day 124)	Venous Thrombosis Of Right Lower Extremity
Potassium chloride	11 Dec 2020 (Study Day 122) - 11 Dec 2020 (Study Day 122)	Hypokalemia
Apixaban	14 Dec 2020 (Study Day 125) - 20 Dec 2020 (Study Day 131)	Venous Thrombosis Of Right Lower Extremity
Apixaban	21 Dec 2020 (Study Day 132) - Ongoing	Venous Thrombosis Of Right Lower Extremity
Omeprazole	27 Jan 2021 (Study Day 169) - Ongoing	Worsening Acid Reflux

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rotator Cuff Syndrome	Grade 2/moderate	Not related	27 Aug 2020 (Study Day 16) - Ongoing
Hypokalaemia	Grade 2/moderate	Not related	11 Dec 2020 (Study Day 122) - Ongoing
Cholelithiasis	Grade 1/mild	Not related	13 Dec 2020 (Study Day 124) - Ongoing
Diverticulum Intestinal	Grade 1/mild	Not related	13 Dec 2020 (Study Day 124) - Ongoing
Deep Vein Thrombosis	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 155) - Ongoing
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	27 Jan 2021 (Study Day 169) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US351-2193 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Atrial Fibrillation	SAE	Grade 3/severe	Not related	27 Oct 2020 (Study Day 56) – 06 Nov 2020 (Study Day 66)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2193, a 77-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 02 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Oct 2020 (Study Day 56), 55 days after the first dose and 25 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of atrial fibrillation lasted for 11 days, after which it was considered to be recovered/resolved with sequelae on 06 Nov 2020 (Study Day 66). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000580	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Constipation	Constipation	1950 - Ongoing
Hypermetropia	Farsighted	1953 - Ongoing
Myopia	Nearsighted	1953 - Ongoing
Acne	Acne	1960 - Ongoing
Ex-tobacco user	Former tobacco use	1960 - 1964
Bipolar disorder	Bipolar disorder	1969 - 2015
Depression	Depression	1969 - Ongoing
Migraine	Migraines	1973 - Ongoing
Breast cancer	Cancer of the left breast	1990 - 1990
Female sterilisation	Bilateral tubal ligation	1990 - 1990
Hypothyroidism	Hypothyroidism	1990 - Ongoing
Lymphadenectomy	Left underarm lymph node removal	1990 - 1990
Mastectomy	Bilateral mastectomy	1990 - 1990
Peripheral vascular disorder	Bilateral peripheral vascular disease	1993 - Ongoing
Retinal operation	Bilateral retinal repair	1998 - 1998
Retinal tear	Bilateral retinal tears	1998 - 1998
Dupuytren's contracture	Duputren's contracture bilateral hands	2000 - Ongoing
Cataract	Bilateral cataracts	2002 - 2002
Cataract operation	Bilateral cataracts removal	2002 - 2002
Back pain	Back pain	2010 - 2016
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2010 - Ongoing
Haemorrhoids	Hemorrhoids	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Asthma exercise induced	Exercise induced asthma	2013 - Ongoing
Osteoarthritis	Osteoarthritis of bilateral hands and knees	2013 - Ongoing
Osteoporosis	Osteoporosis	2013 - Ongoing
Basal cell carcinoma	Basal cell skin cancer face	2014 - 2014
Glaucoma	Glaucoma	2014 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Sinusitis	Sinusitis	2015 - Ongoing
Urinary tract infection	Intermittent urinary tract infections	2015 - Ongoing
Spinal fusion surgery	Spinal fusion	2016 - 2016
Spinal laminectomy	Spinal laminectomy	2016 - 2016
Squamous cell carcinoma of skin	Squamous cell skin cancer	2016 - 2016
Varicose vein operation	Varicose vein ablation x3	2016 - 2016
Macular degeneration	Macular degeneration	2017 - Ongoing
Gastritis	Gastritis	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Oesophagitis	Esophagitis	2018 - Ongoing
Muscle operation	Left bicep repair	18 Dec 2018 (Study Day -624) - 18 Dec 2018 (Study Day -624)
Rotator cuff repair	Left rotator cuff repair	18 Dec 2018 (Study Day -624) - 18 Dec 2018 (Study Day -624)
Hyponatraemia	Hyponatremia	Jan 2020 - Ongoing
Botulinum toxin injection	Botox facial injection	Mar 2020 - Mar 2020
Dermatitis contact	Contact dermatitis bilateral arms	Mar 2020 - Ongoing
Eczema	Eczema	May 2020 - Ongoing
Perichondritis	Chondrodermatitis nodularis helicis	25 Aug 2020 (Study Day -8) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1990 - Ongoing	Hypothyroidism
Sumatriptan	2000 - Ongoing	Migraines
Naproxen sodium	2013 - Ongoing	Osteoarthritis
Lisinopril	2014 - Ongoing	Hypertension
Calcium; vitamin d nos	2015 - Ongoing	Supplement
Colecalciferol	2015 - Ongoing	Supplement
Fluticasone	2015 - Ongoing	Sinusitis
Guaifenesin	2015 - Ongoing	Sinusitis
Macrogol 3350	2015 - Ongoing	Constipation
Omega-3 nos	2015 - Ongoing	Supplement
Other ophthalmologicals	2015 - Ongoing	Glaucoma/Macular Degeneration
Resveratrol	2015 - Ongoing	Supplement
Vitamin b complex	2015 - Ongoing	Supplement
Vitamins nos	2015 - Ongoing	Supplement
Liothyronine	2017 - Ongoing	Hypothyroidism
Triamcinolone	02 Mar 2020 (Study Day -184) - Ongoing	Contact Dermatitis Bilateral Arm
Ascorbic acid	15 Aug 2020 (Study Day -18) - Ongoing	Supplement
Ciprofloxacin	Sep 2020 - 04 Oct 2020 (Study Day 33)	Intermittent Urinary Tract Infection
Influenza vaccine	19 Oct 2020 (Study Day 48) - 19 Oct 2020 (Study Day 48)	Prophylaxis For Seasonal Influenza
Naproxen sodium	22 Oct 2020 (Study Day 51) - 28 Oct 2020 (Study Day 57)	Upper Respiratory Infection
Echocardiogram*	28 Oct 2020 (Study Day 57) - 28 Oct 2020 (Study Day 57)	Adverse Event
Cardioversion*	29 Oct 2020 (Study Day 58) - 29 Oct 2020 (Study Day 58)	Adverse Event
Apixaban	30 Oct 2020 (Study Day 59) - Ongoing	Atrial Fibrillation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	30 Oct 2020 (Study Day 59) - 06 Nov 2020 (Study Day 66)	Atrial Fibrillation
Doxycycline	02 Nov 2020 (Study Day 62) - 11 Nov 2020 (Study Day 71)	Sinusitis
Prednisone	02 Nov 2020 (Study Day 62) - 06 Nov 2020 (Study Day 66)	Sinusitis
Sotalol	06 Nov 2020 (Study Day 66) - 03 Dec 2020 (Study Day 93)	Atrial Fibrillation
Cardioversion*	13 Nov 2020 (Study Day 73) - 13 Nov 2020 (Study Day 73)	Adverse Event
Cryoballoon ablation*	09 Dec 2020 (Study Day 99) - 09 Dec 2020 (Study Day 99)	Adverse Event
Cryotherapy*	23 Feb 2021 (Study Day 175) - 23 Feb 2021 (Study Day 175)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	21 Oct 2020 (Study Day 50) - 05 Nov 2020 (Study Day 65)
Fatigue	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 52) - Ongoing
Sinusitis	Grade 2/moderate	Not related	02 Nov 2020 (Study Day 62) - 05 Nov 2020 (Study Day 65)
Atrial Fibrillation	Grade 3/severe	Not related	07 Nov 2020 (Study Day 67) - 09 Dec 2020 (Study Day 99)
Foot Fracture	Grade 2/moderate	Not related	26 Nov 2020 (Study Day 86) - 26 Dec 2020 (Study Day 116)
Actinic Keratosis	Grade 1/mild	Not related	23 Feb 2021 (Study Day 175) - 23 Feb 2021 (Study Day 175)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US351-2217 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Syncope/Syncopal Episode	SAE	Grade 4	Not related	31 Dec 2020 (Study Day 119) – 31 Dec 2020 (Study Day 119)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2217, a 64-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Dec 2020 (Study Day 119), 118 days after the first dose and 90 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncopal episode lasted for 1 day, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 119). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001875	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Congenital aortic valve incompetence	Congenital aortic valve insufficiency	(b) (6) 1956 (Study Day (b) (6) - Ongoing
Medical device implantation	Titanium screw inserted left arm	1985 - 1985
Upper limb fracture	Broken left arm	1985 - 1985
Gastrooesophageal reflux disease	Acid reflux	1990 - Ongoing
Myocardial infarction	Myocardial infarction	2005 - 2005
Coronary artery disease	Coronary artery disease	2008 - Ongoing
Hypertension	Hypertension	2009 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Myopia	Nearsighted	2013 - Ongoing
Hepatitis C	Hepatitis c	2014 - 2016
Porphyria non-acute	Porphyria cutanae tarda	2014 - Ongoing
Aortic valve stenosis	Moderate aortic valve stenosis	24 Jul 2019 (Study Day -408) - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Jul 2020 - Ongoing
Peripheral swelling	Bilateral lower leg swelling	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2009 - Ongoing	Hypertension
Nifedipine	2009 - 04 Jan 2021 (Study Day 123)	Hypertension
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Finasteride	Jul 2020 - 18 Feb 2021 (Study Day 168)	Benign Prostatic Hyperplasia
Furosemide	Jul 2020 - 18 Feb 2021 (Study Day 168)	Bilateral Lower Leg Swelling
Ibuprofen	16 Sep 2020 (Study Day 13) - 26 Sep 2020 (Study Day 23)	Low Back Pain
Hydrocodone bitartrate; paracetamol	31 Dec 2020 (Study Day 119) - 31 Dec 2020 (Study Day 119)	Neck And Right Shoulder Injury
Sodium chloride	31 Dec 2020 (Study Day 119) - 31 Dec 2020 (Study Day 119)	Syncopal Episode
Heparin sodium	01 Jan 2021 (Study Day 120) - 01 Jan 2021 (Study Day 120)	Dvt Prophylaxis
Heparin sodium	01 Jan 2021 (Study Day 120) - 01 Jan 2021 (Study Day 120)	Prophylaxis Deep Vein Thrombosis
Influenza vaccine	04 Jan 2021 (Study Day 123) - 04 Jan 2021 (Study Day 123)	Seasonal Flu Prophylaxis
Bupropion	07 Jan 2021 (Study Day 126) - 15 Mar 2021 (Study Day 193)	Smoking Cessation
Ergocalciferol	18 Feb 2021 (Study Day 168) - Ongoing	Low Vitamin D Prophylaxis
Varenicline tartrate	19 Mar 2021 (Study Day 197) - 25 Mar 2021 (Study Day 203)	Smoking Cessation
Varenicline tartrate	26 Mar 2021 (Study Day 204) - Ongoing	Smoking Cessation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Back Pain	Grade 2/moderate	Not related	16 Sep 2020 (Study Day 13) - 26 Sep 2020 (Study Day 23)
Limb Injury	Grade 2/moderate	Not related	31 Dec 2020 (Study Day 119) - 04 Feb 2021 (Study Day 154)
Neck Injury	Grade 2/moderate	Not related	31 Dec 2020 (Study Day 119) - 04 Feb 2021 (Study Day 154)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US352-2077 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/Pulmonary Embolisms (Right Main Pulmonary Artery, Lefts Lower Lobar Branch)	SAE	Grade 4	Not related	15 Oct 2020 (Study Day 66) – 19 Oct 2020 (Study Day 70)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2077, a 62-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Oct 2020 (Study Day 66), 65 days after the first dose and 35 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolisms (right main pulmonary artery, lefts lower lobar branch) lasted for 5 days, after which it was considered to be recovered/resolved on 19 Oct 2020 (Study Day 70). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000560	Pulmonary embolism

Study Completion/Discontinuation

On 29 Dec 2020 (Study Day 141), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Migraine	Migraines	Not reported - Ongoing
Nephrolithiasis	Nephrolithiasis	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Evolocumab	Not reported - Ongoing	Hyperlipidemia
Gabapentin	Not reported - 17 Oct 2020 (Study Day 68)	Migraines
Verapamil	Not reported - Ongoing	Migraines
Ct chest with iv contrast-pe*	17 Oct 2020 (Study Day 68) - 17 Oct 2020 (Study Day 68)	Diagnostic
Enoxaparin	17 Oct 2020 (Study Day 68) - 19 Oct 2020 (Study Day 70)	Pulmonary Embolisms
Gabapentin	17 Oct 2020 (Study Day 68) - 18 Oct 2020 (Study Day 69)	Pulmonary Embolism
Heparin	17 Oct 2020 (Study Day 68) - 17 Oct 2020 (Study Day 68)	Pulmonary Embolism
Morphine	17 Oct 2020 (Study Day 68) - 18 Oct 2020 (Study Day 69)	Pulmonary Embolism
Moxifloxacin hydrochloride	17 Oct 2020 (Study Day 68) - 17 Oct 2020 (Study Day 68)	Pulmonary Embolism
Bilateral venous doppler (lower extremities)*	18 Oct 2020 (Study Day 69) - 18 Oct 2020 (Study Day 69)	Diagnostic
Influenza vaccine rha 3v (baculovirus)	18 Oct 2020 (Study Day 69) - 18 Oct 2020 (Study Day 69)	Prevention Of Influenza
Paracetamol	18 Oct 2020 (Study Day 69) - 19 Oct 2020 (Study Day 70)	Pulmonary Embolisms
Apixaban	19 Oct 2020 (Study Day 70) - Ongoing	Pulmonary Embolisms
Gabapentin	19 Oct 2020 (Study Day 70) - Ongoing	Migraine
Other viral vaccines	29 Dec 2020 (Study Day 141) - 29 Dec 2020 (Study Day 141)	Prevention Of COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US352-2128 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Flutter/Atrial Flutter With Rapid Ventricular Response	SAE	Grade 4	Not related	25 Sep 2020 (Study Day 43) – 27 Sep 2020 (Study Day 45)	Recovered/ resolved
Pneumonia/Multifocal Pneumonia In Both Lungs	SAE	Grade 4	Not related	08 Oct 2020 (Study Day 56) – 18 Oct 2020 (Study Day 66)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2128, a 70-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 43), 42 days after the first dose and 14 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of atrial flutter. Action taken with the IP was not applicable. The event of atrial flutter with rapid ventricular response lasted for 3 days, after which it was considered to be recovered/resolved on 27 Sep 2020 (Study Day 45). The investigator assessed the event of atrial flutter to be not related to the IP.

On 08 Oct 2020 (Study Day 56), 55 days after the first dose and 27 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of multifocal pneumonia in both lungs lasted for 11 days, after which it was considered to be recovered/resolved on 18 Oct 2020 (Study Day 66). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000400	Atrial flutter

CIOMS Number	MedDRA Preferred Term
MOD-2020-000400	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial fibrillation	Afib	Not reported - Ongoing
Cardiac failure congestive	Chf	Not reported - Ongoing
Cardiomyopathy	Cardiomyopathy	Not reported - Ongoing
Cerebrovascular accident	Past of stroke	Not reported
Chronic kidney disease	Ckd stage 3	Not reported - Ongoing
Coronary artery disease	Cad	Not reported - Ongoing
Diabetic autonomic neuropathy	Diabetic autonomic neuropathy associated with type 2 diabetes mellitus- generalized peripheral pain and numbness	Not reported - Ongoing
Gout	Gout (flairs in left knee and right elbow)	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hyperparathyroidism	Hyperparathyroidism	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hyperlipidemia
Diltiazem	Not reported - Ongoing	Afib
Furosemide	Not reported - 26 Sep 2020 (Study Day 44)	Chf
Gabapentin	Not reported - 14 Oct 2020 (Study Day 62)	Neuropothy
Metformin	Not reported - Ongoing	Type Two Diabetes
Metoprolol	Not reported - 26 Sep 2017 (Study Day -1053)	Hypertension / Afib
Warfarin	Not reported - 11 Oct 2020 (Study Day 59)	Afib
Potassium chloride	24 Apr 2020 (Study Day -112) - 07 Apr 2021 (Study Day 237)	Chronic Systolic Heart Failure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cardioversion*	29 Aug 2020 (Study Day 16) - 29 Aug 2020 (Study Day 16)	Medical History
Digoxin	25 Sep 2020 (Study Day 43) - 25 Sep 2020 (Study Day 43)	Atrial Flutter With Rvr
Metoprolol	26 Sep 2020 (Study Day 44) - Ongoing	Hypertension/Afib
Furosemide	27 Sep 2020 (Study Day 45) - 07 Apr 2021 (Study Day 237)	Chf
Digoxin	28 Sep 2020 (Study Day 46) - 12 Oct 2020 (Study Day 60)	Atrial Fibrillation
Cardiac profile (blood draw)*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Ct chest*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Electrophysiology study*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Emergency department ultrasound cardiac*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Piperacillin sodium; tazobactam sodium	08 Oct 2020 (Study Day 56) - 11 Oct 2020 (Study Day 59)	Multifocal Pneumonia In Both Lungs
Protime with inr (blood draw)*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Vancomycin	08 Oct 2020 (Study Day 56) - 09 Oct 2020 (Study Day 57)	Multifocal Pneumonia In Both Lungs
Xray chest portable 1 view*	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Adverse Event
Blood culture*	09 Oct 2020 (Study Day 57) - 09 Oct 2020 (Study Day 57)	Adverse Event
Heated high flow nasal cannula*	09 Oct 2020 (Study Day 57) - 09 Oct 2020 (Study Day 57)	Adverse Event
Sputum culture*	09 Oct 2020 (Study Day 57) - 09 Oct 2020 (Study Day 57)	Adverse Event
Vancomycin	09 Oct 2020 (Study Day 57) - 11 Oct 2020 (Study Day 59)	Multifocal Pneumonia In Both Lungs
Anakinra	10 Oct 2020 (Study Day 58) - 12 Oct 2020 (Study Day 60)	Gout Flair
Levofloxacin	11 Oct 2020 (Study Day 59) - 14 Oct 2020 (Study Day 62)	Multifocal Pneumonia In Both Lungs
Metronidazole	11 Oct 2020 (Study Day 59) - 14 Oct 2020 (Study Day 62)	Multifocal Pneumonia In Both Lungs
Ekg 12 lead*	12 Oct 2020 (Study Day 60) - 12 Oct 2020 (Study Day 60)	Adverse Event
Elective ablation in heart for afib*	12 Oct 2020 (Study Day 60) - 12 Oct 2020 (Study Day 60)	Medical History
Prednisone	12 Oct 2020 (Study Day 60) - Ongoing	Gout / Gout Flair
Apixaban	13 Oct 2020 (Study Day 61) - 16 Oct 2020 (Study Day 64)	Atrial Fibrillation
Apixaban	18 Oct 2020 (Study Day 66) - Ongoing	A-Fib

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Related	14 Aug 2020 (Study Day 1) - 15 Aug 2020 (Study Day 2)
Atrial Fibrillation	Grade 2/moderate	Not related	27 Aug 2020 (Study Day 14) - 27 Aug 2020 (Study Day 14)
Gout	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 58) - 11 Oct 2020 (Study Day 59)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US352-2200 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Papillary Thyroid Cancer/Papillary Thyroid Cancer	SAE	Grade 3/severe	Not related	01 Dec 2020 (Study Day 105) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2200, a 29-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Dec 2020 (Study Day 105), 104 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of papillary thyroid cancer. Action taken with the IP was not applicable. The event of papillary thyroid cancer was considered to be ongoing. The investigator assessed the event of papillary thyroid cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001028	Papillary thyroid cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Adjustment disorder with anxiety	Adjustment disorder with anxiety	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; norethisterone acetate	Apr 2019 - Ongoing	Birth Control
Naproxen sodium	19 Aug 2020 (Study Day 1) - 19 Aug 2020 (Study Day 1)	Pain At Injection/Blood Draw Site
Influenza vaccine	02 Oct 2020 (Study Day 45) - 02 Oct 2020 (Study Day 45)	14 Days Post 2nd Ip
Paroxetine hydrochloride	19 Oct 2020 (Study Day 62) - Ongoing	Adjustment Disorder With Anxiety
Thyroid fna biopsy*	24 Nov 2020 (Study Day 98) - 24 Nov 2020 (Study Day 98)	Diagnostic
Thyroid ultrasound*	24 Nov 2020 (Study Day 98) - 24 Nov 2020 (Study Day 98)	Diagnostic
Topiramate	04 Dec 2020 (Study Day 108) - 05 Dec 2020 (Study Day 109)	Not Clearly Known By Participant
Propranolol	05 Dec 2020 (Study Day 109) - Ongoing	Papillary Thyroid Cancer
Thyroidectomy*	15 Jan 2021 (Study Day 150) - 15 Jan 2021 (Study Day 150)	Adverse Event
Liothyronine	18 Jan 2021 (Study Day 153) - 13 Feb 2021 (Study Day 179)	Hypo-Thyroid
Radioactive iodine treatment*	11 Feb 2021 (Study Day 177) - 11 Feb 2021 (Study Day 177)	Adverse Event
Liothyronine	13 Feb 2021 (Study Day 179) - Ongoing	Hypothyroidism Post Thyroidectomy
Central compartment lymph node dissection*	16 Feb 2021 (Study Day 182) - 16 Feb 2021 (Study Day 182)	Adverse Event
Left modified radical neck dissection.*	16 Feb 2021 (Study Day 182) - 16 Feb 2021 (Study Day 182)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US352-2227 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Atrial Fibrillation Exacerbation	SAE	Grade 2/ moderate	Not related	06 Jan 2021 (Study Day 141) – 07 Jan 2021 (Study Day 142)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2227, a 67-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Jan 2021 (Study Day 141), 140 days after the first dose and 111 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of atrial fibrillation exacerbation lasted for 2 days, after which it was considered to be recovered/resolved on 07 Jan 2021 (Study Day 142). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002625	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Atrial fibrillation	Atrial fibrillation	Not reported - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Not reported - Ongoing
Cardiomyopathy	Cardiomyopathy	Not reported - Ongoing
Chronic obstructive pulmonary disease	Copd	Not reported - Ongoing
Depression	Depression	Not reported - Ongoing
Gastrooesophageal reflux disease	Gerd	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Hypertonic bladder	Overactive bladder	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Implantable defibrillator insertion	Implantable cardioverter-defibrillator	Not reported
Migraine	Migraines	Not reported - Ongoing
Obesity	Morbid obesity	Not reported - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide; formoterol fumarate	Not reported - Ongoing	Copd
Butalbital; caffeine; paracetamol	Not reported - Ongoing	Migraines
Diazepam	Not reported - Ongoing	Migraines
Dofetilide	Not reported - Ongoing	Atrial Fibrillation
Finasteride	Not reported - Ongoing	Bph
Hydrocodone bitartrate; paracetamol	Not reported - Ongoing	Migraines
Levothyroxine sodium	Not reported - Ongoing	Hypothyroidism
Metformin	Not reported - Aug 2020	Morbid Obesity/Weight Loss
Metoprolol tartrate	Not reported - Ongoing	High Blood Pressure
Oxybutynin hydrochloride	Not reported - Ongoing	Overactive Bladder
Pantoprazole	Not reported - Ongoing	Gerd
Rivaroxaban	Not reported - Ongoing	Atrial Fibrillation
Salbutamol	Not reported - Ongoing	Copd
Simvastatin	Not reported - Ongoing	Hyperlipidemia
Tamsulosin hydrochloride	Not reported - Ongoing	Bph
Tiotropium bromide	Not reported - Ongoing	Copd
Influenza vaccine	07 Oct 2020 (Study Day 50) - 07 Oct 2020 (Study Day 50)	Annual Vaccine

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	08 Oct 2020 (Study Day 51) - 08 Oct 2020 (Study Day 51)	Flu
Ct heart*	06 Jan 2021 (Study Day 141) - 06 Jan 2021 (Study Day 141)	Adverse Event
Electrocardiography*	06 Jan 2021 (Study Day 141) - 06 Jan 2021 (Study Day 141)	Adverse Event
Nuclear stress test*	06 Jan 2021 (Study Day 141) - 06 Jan 2021 (Study Day 141)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US352-2269 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nausea/Nausea	SAE	Grade 4	Not related	07 Sep 2020 (Study Day 18) – 15 Sep 2020 (Study Day 26)	Recovered/resolved
Abdominal Pain/Abdominal Pain	SAE	Grade 4	Not related	08 Sep 2020 (Study Day 19) – 15 Sep 2020 (Study Day 26)	Recovered/resolved
Vomiting/Vomiting	SAE	Grade 4	Not related	08 Sep 2020 (Study Day 19) – 15 Sep 2020 (Study Day 26)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2269, a 44-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 18), 17 days after the first dose and 15 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of nausea. The IP dose was not changed due to the nausea. The event of nausea lasted for 9 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 26). The investigator assessed the event of nausea to be not related to the IP.

On 08 Sep 2020 (Study Day 19), 18 days after the first dose and 14 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of abdominal pain. The IP dose was not changed due to the abdominal pain. The event of abdominal pain lasted for 8 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 26). The investigator assessed the event of abdominal pain to be not related to the IP.

On 08 Sep 2020 (Study Day 19), 18 days after the first dose and 14 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of vomiting. The IP dose was not changed due to the vomiting. The event of vomiting lasted for 8 days, after which it was

considered to be recovered/resolved on 15 Sep 2020 (Study Day 26). The investigator assessed the event of vomiting to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000328	Nausea
MOD-2020-000328	Abdominal pain
MOD-2020-000328	Vomiting

Study Completion/Discontinuation

On 13 Oct 2020 (Study Day 54), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Abdomina ultrasound*	11 Sep 2020 (Study Day 22) - 11 Sep 2020 (Study Day 22)	Adverse Event
Magnesium	12 Sep 2020 (Study Day 23) - 13 Sep 2020 (Study Day 24)	Electrolyte Replacement For Vomiting
Morphine	12 Sep 2020 (Study Day 23) - 13 Sep 2020 (Study Day 24)	Abdominal Pain
Ondansetron	12 Sep 2020 (Study Day 23) - 14 Sep 2020 (Study Day 25)	Nausea
Pantoprazole	12 Sep 2020 (Study Day 23) - 16 Sep 2020 (Study Day 27)	Nausea
Potassium	12 Sep 2020 (Study Day 23) - 13 Sep 2020 (Study Day 24)	Electrolyte Replacement For Vomiting
Calcium	14 Sep 2020 (Study Day 25) - 16 Sep 2020 (Study Day 27)	Electrolyte Replacement For Vomiting
Influenza vaccine	05 Oct 2020 (Study Day 46) - 05 Oct 2020 (Study Day 46)	Flu Vaccination

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US352-2513 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Joint Injury/Right Knee Injury	SAE	Grade 3/severe	Not related	11 Dec 2020 (Study Day 101) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2513, a 46-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Dec 2020 (Study Day 101), 100 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of joint injury. Action taken with the IP was not applicable. The event of right knee injury was considered to be ongoing. The investigator assessed the event of joint injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-097263	Joint injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign neoplasm of thyroid gland	Benign right-sided thyroid nodule	Not reported - Ongoing
Genital herpes	Genital herpes	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Spondylitis	Cervical arthritis	Not reported - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	Not reported - Ongoing
Hysterectomy	Hysterectomy	01 May 2002 (Study Day -6699) - 01 May 2002 (Study Day -6699)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hyperlipidemia
Methocarbamol	Not reported - Ongoing	Cervical Arthritis
Valaciclovir	Not reported - Ongoing	Genital Herpes
Paracetamol	03 Sep 2020 (Study Day 2) - 04 Sep 2020 (Study Day 3)	Pain At Injection Site
Right-sided thyroid nodule fna biopsy*	30 Nov 2020 (Study Day 90) - 30 Nov 2020 (Study Day 90)	Medical History
Hydrocodone bitartrate; paracetamol	24 Dec 2020 (Study Day 114) - 30 Dec 2020 (Study Day 120)	Right Knee Injury
Right knee brace*	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Adverse Event
Right-sided thyroid nodule fna biopsy*	05 Jan 2021 (Study Day 126) - 05 Jan 2021 (Study Day 126)	Medical History
Hydrocodone bitartrate; paracetamol	05 Feb 2021 (Study Day 157) - 09 Feb 2021 (Study Day 161)	Right Knee Injury
Acetylsalicylic acid	24 Mar 2021 (Study Day 204) - 21 Apr 2021 (Study Day 232)	Prevention Of Blood Clots Post-Right Total Knee Replacement
Arthroplasty robot-assisted right total knee*	24 Mar 2021 (Study Day 204) - 24 Mar 2021 (Study Day 204)	Adverse Event
Celecoxib	24 Mar 2021 (Study Day 204) - 31 Mar 2021 (Study Day 211)	Pain Post Right Total Knee Replacement
Gabapentin	24 Mar 2021 (Study Day 204) - Ongoing	Pain Post Total Right Knee Replacement
Oxycodone	24 Mar 2021 (Study Day 204) - Ongoing	Pain Post Right Total Knee Replacement
Paracetamol	24 Mar 2021 (Study Day 204) - Ongoing	Pain Post- Right Total Knee Replacement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US352-2529 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Intervertebral Disc Protrusion/Herniated Disc	SAE	Grade 4	Not related	21 Sep 2020 (Study Day 20) – 23 Sep 2020 (Study Day 22)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2529, a 44-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 20), 19 days after the first dose and 16 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of intervertebral disc protrusion. The IP dose was not changed due to the herniated disc. The event of herniated disc lasted for 3 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 22). The investigator assessed the event of intervertebral disc protrusion to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000340	Intervertebral disc protrusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Not reported - Ongoing	Migraines/Headaches/ Generalized Pain
Zolmitriptan	Not reported - Ongoing	Migraines
Botulinum toxin type a	24 Jan 2019 (Study Day -587) - Ongoing	Migraines
Calcium gluconate	21 Sep 2020 (Study Day 20) - 21 Sep 2020 (Study Day 20)	Presumed Electrolyte Imbalance
Lab work including phlebotomy.*	21 Sep 2020 (Study Day 20) - 21 Sep 2020 (Study Day 20)	Diagnostic
Magnesium sulfate	21 Sep 2020 (Study Day 20) - 21 Sep 2020 (Study Day 20)	Presumed Electrolyte Imbalance
Potassium chloride	21 Sep 2020 (Study Day 20) - 21 Sep 2020 (Study Day 20)	Presumed Electrolyte Imbalance
Potassium chloride	21 Sep 2020 (Study Day 20) - 22 Sep 2020 (Study Day 21)	Presumed Electrolyte Imbalance
Methocarbamol	23 Sep 2020 (Study Day 22) - 25 Sep 2020 (Study Day 24)	Herniated Disc
Prednisone	23 Sep 2020 (Study Day 22) - 27 Sep 2020 (Study Day 26)	Herniated Disc
Tramadol	23 Sep 2020 (Study Day 22) - 25 Sep 2020 (Study Day 24)	Herniated Disc
Ibuprofen	07 Oct 2020 (Study Day 36) - 12 Oct 2020 (Study Day 41)	Headache, Muscle Ache, Joint Pain
Influenza vaccine	04 Nov 2020 (Study Day 64) - 04 Nov 2020 (Study Day 64)	Influenza
Tizanidine hydrochloride	10 Mar 2021 (Study Day 190) - Ongoing	Migraines

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	08 Sep 2020 (Study Day 7) - 10 Sep 2020 (Study Day 9)
Headache	Grade 2/moderate	Related	09 Sep 2020 (Study Day 8) - 10 Sep 2020 (Study Day 9)
Headache	Grade 1/mild	Related	10 Sep 2020 (Study Day 9) - 10 Sep 2020 (Study Day 9)
Electrolyte Imbalance	Grade 2/moderate	Not related	21 Sep 2020 (Study Day 20) - 21 Sep 2020 (Study Day 20)
Fatigue	Grade 1/mild	Related	13 Oct 2020 (Study Day 42) - 16 Oct 2020 (Study Day 45)
Myalgia	Grade 1/mild	Related	14 Oct 2020 (Study Day 43) - 28 Oct 2020 (Study Day 57)
Headache	Grade 1/mild	Related	15 Oct 2020 (Study Day 44) - 15 Oct 2020 (Study Day 44)
Fatigue	Grade 1/mild	Not related	15 Nov 2020 (Study Day 75) - 16 Nov 2020 (Study Day 76)
Nasal Congestion	Grade 1/mild	Not related	15 Nov 2020 (Study Day 75) - 16 Nov 2020 (Study Day 76)
Oropharyngeal Pain	Grade 1/mild	Not related	15 Nov 2020 (Study Day 75) - 17 Nov 2020 (Study Day 77)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2002 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Pain/Worsening Back Pain	SAE	Grade 4	Not related	08 Sep 2020 (Study Day 29) – 14 Oct 2020 (Study Day 65)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2002, a 63-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 29), 28 days after the first dose and on the day of the second dose of the IP, the participant experienced a Grade 4 serious adverse event of back pain. Action taken with the IP was not applicable. The event of worsening back pain lasted for 37 days, after which it was considered to be recovered/resolved on 14 Oct 2020 (Study Day 65). The investigator assessed the event of back pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000335	Back pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cartilage injury	Torn cartilage in right knee	Not reported - 1984
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Femur fracture	Right broken femur	1976 - Not reported
Glaucoma	Bilateral glaucoma	1977 - Ongoing
Gout	Gout	1980 - Ongoing
Arthroscopy	Right knee scope	1984 - 1984
Blood cholesterol increased	Elevated cholesterol	1990 - Ongoing
Hypertension	Hypertension	1990 - Ongoing
Vasectomy	Vasectomy	1996 - 1996
Bone operation	Right femur lengthening surgery	1997 - 1997
Rotator cuff syndrome	Right rotator cuff tear	2004 - 2005
Rotator cuff repair	Right rotator cuff repair	2005 - 2005
Rosacea	Rosacea	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2012 - Ongoing
Cataract	Bilateral cataracts	2018 - Sep 2018
Cataract operation	Bilateral cataract surgeries	Sep 2018 - Sep 2018
Intervertebral disc degeneration	Degenerative disk disease of back	Nov 2019 - Ongoing
Spinal laminectomy	Back surgery lumbar laminectomy	Dec 2019 - Dec 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	Not reported - Ongoing	Hypertension
Carvedilol	Not reported - 12 Feb 2021 (Study Day 186)	Hypertension
Fenofibrate	Not reported - Ongoing	Elevated Cholesterol
Losartan	Not reported - Ongoing	Hypertension
Rosuvastatin	Not reported - Ongoing	Elevated Cholesterol
Levothyroxine	1985 - 12 Feb 2021 (Study Day 186)	Hypothyroidism
Acetylsalicylic acid	2016 - Ongoing	General Heart Health
Metformin	2016 - Ongoing	Type 2 Diabetes
Semaglutide	2019 - Ongoing	Type 2 Diabetes
Methocarbamol	Aug 2020 - 14 Oct 2020 (Study Day 65)	Worsening Back Pain
Ibuprofen	10 Sep 2020 (Study Day 31) - 10 Sep 2020 (Study Day 31)	Headache
Transforaminal lumbar interbody fusion*	16 Sep 2020 (Study Day 37) - 16 Sep 2020 (Study Day 37)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone; paracetamol	17 Sep 2020 (Study Day 38) - 29 Sep 2020 (Study Day 50)	Worsening Back Pain
Influenza vaccine	10 Nov 2020 (Study Day 92) - 10 Nov 2020 (Study Day 92)	Annual Vaccine
Reoccurring physical therapy*	10 Nov 2020 (Study Day 92) - 10 Nov 2020 (Study Day 92)	Other, Related To Recent Back Surgery
Doxycycline	08 Dec 2020 (Study Day 120) - 07 Jan 2021 (Study Day 150)	Worsening Rosacea
Squamous cell removal*	29 Dec 2020 (Study Day 141) - 29 Dec 2020 (Study Day 141)	Adverse Event
Carvedilol	12 Feb 2021 (Study Day 186) - Ongoing	Worsening Hypertension
Levothyroxine	12 Feb 2021 (Study Day 186) - Ongoing	Worsening Hypothyroidism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Back Pain	Grade 2/moderate	Not related	20 Aug 2020 (Study Day 10) - 05 Sep 2020 (Study Day 26)
Rosacea	Grade 2/moderate	Not related	15 Nov 2020 (Study Day 97) - 15 Dec 2020 (Study Day 127)
Squamous Cell Carcinoma	Grade 2/moderate	Not related	08 Dec 2020 (Study Day 120) - 29 Dec 2020 (Study Day 141)
Hypertension	Grade 2/moderate	Not related	12 Feb 2021 (Study Day 186) - Ongoing
Hypothyroidism	Grade 2/moderate	Not related	12 Feb 2021 (Study Day 186) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2063 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Femur Fracture/Fractured Left Femur	SAE	Grade 4	Not related	28 Oct 2020 (Study Day 72) – 27 Jan 2021 (Study Day 163)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2063, a 70-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Oct 2020 (Study Day 72), 71 days after the first dose and 42 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of femur fracture. Action taken with the IP was not applicable. The event of fractured left femur lasted for 92 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 163). The investigator assessed the event of femur fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000631	Femur fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Synovial cyst	Ganglion cyst	Not reported - 1978
Menopause	Menopause	2000 - Ongoing
Osteoarthritis	Osteoarthritis neck and legs	2000 - Ongoing
Rubber sensitivity	Latex allergy	2000 - Ongoing
Benign breast neoplasm	Breast node - benign	2010 - 2010
Cyst	Cyst on neck benign	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	Not reported - Ongoing	Health
Chondroitin; glucosamine	Not reported - 30 Nov 2020 (Study Day 105)	Health
Colecalciferol	Not reported - Ongoing	Health
Curcuma longa	Not reported - 30 Nov 2020 (Study Day 105)	Health
Omega-3 nos	Not reported - 30 Nov 2020 (Study Day 105)	Health
Vitamin b complex	Not reported - Ongoing	Health
Vitamin e nos	Not reported - 30 Nov 2020 (Study Day 105)	Health
Vitamins nos	Not reported - 30 Nov 2020 (Study Day 105)	Health
Influenza vaccine	07 Oct 2020 (Study Day 51) - 07 Oct 2020 (Study Day 51)	Annual Flu Vaccine
Xray of hips and pelvis*	28 Oct 2020 (Study Day 72) - 28 Oct 2020 (Study Day 72)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Cefradine	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Dexamethasone	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Ephedrine	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Fentanyl	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lidocaine	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Midazolam	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Morphine	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Ondansetron	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Propofol	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Rocuronium	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Sodium chloride	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Sugammadex sodium	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Concomitant Procedure # 1. Surgical Repair Of L Femoral Fracture
Surgical repair of left fractured femur*	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Adverse Event
Xray of hip and pelvis*	29 Oct 2020 (Study Day 73) - 29 Oct 2020 (Study Day 73)	Adverse Event
Apixaban	01 Nov 2020 (Study Day 76) - 16 Dec 2020 (Study Day 121)	Post Surgical Dvt Prophylaxis
Cyclobenzaprine hydrochloride	01 Nov 2020 (Study Day 76) - 16 Dec 2020 (Study Day 121)	Post Surgical Muscle Leg Spasms Following Repair Of Fractured Femur
Docusate sodium	01 Nov 2020 (Study Day 76) - 16 Dec 2020 (Study Day 121)	Post Surgical Constipation
Ondansetron	01 Nov 2020 (Study Day 76) - 11 Nov 2020 (Study Day 86)	Post Surgical Nausea
Oxycodone hydrochloride; paracetamol	01 Nov 2020 (Study Day 76) - 11 Nov 2020 (Study Day 86)	Postsurgical Leg Pain - Following Repair Of Fractured Femur
Physical therapy*	01 Dec 2020 (Study Day 106) - 01 Dec 2020 (Study Day 106)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 3/severe	Not related	29 Oct 2020 (Study Day 73) - 11 Nov 2020 (Study Day 86)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2170 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Acute Myocardial Infartion	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	07 Sep 2020 (Study Day 12) – 06 Oct 2020 (Study Day 41)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2170, a 66-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 12), 11 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of acute myocardial infarction. On 23 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute myocardial infartion lasted for 30 days, after which it was considered to be recovered/resolved with sequelae on 06 Oct 2020 (Study Day 41). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000299	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myalgia	Generalized muscle aches	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Encephalitis viral	Viral encephalitis	1975 - Ongoing
Hypothyroidism	Hypothyroidism	1985 - Ongoing
Gastrooesophageal reflux disease	Gerd	1995 - Ongoing
Cataract operation	Bilateral cataract surgery	2002 - 2002
Menopause	Menopause	2008 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Osteoarthritis	Basillar thrumb osteoarthritis	2016 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2016 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2017 - Ongoing
Plantar fasciitis	Plantar fasciitis	2018 - Ongoing
Limb operation	Thumb surgery	25 Nov 2019 (Study Day -276) - 25 Nov 2019 (Study Day -276)
Vitamin D decreased	Low vitamin d level	18 Feb 2020 (Study Day -191) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	Not reported - Ongoing	Generalized Muscle Aches
Levothyroxine	1985 - Ongoing	Hypothyroidism
Vitamins nos	1985 - Sep 2020	General Health
Lisinopril	2015 - 30 Sep 2020 (Study Day 35)	Hypertension
Metformin	2016 - Ongoing	Type Ii Diabetes
Insulin glargine	16 Feb 2020 (Study Day -193) - 12 Oct 2020 (Study Day 47)	Type Ii Diabetes
Vitamin d nos	18 Feb 2020 (Study Day -191) - Ongoing	General Health
Paracetamol	28 Aug 2020 (Study Day 2) - 28 Aug 2020 (Study Day 2)	Headache
Guaifenesin	Sep 2020 - 29 Sep 2020 (Study Day 34)	Myocardial Infarction Post Cabg Treatment Protocol
Cabg x 2*	08 Sep 2020 (Study Day 13) - 08 Sep 2020 (Study Day 13)	Adverse Event
Amiodarone	12 Sep 2020 (Study Day 17) - 01 Jan 2021 (Study Day 128)	Myocardial Infarction Post Cabg Treatment Protocol
Ferrous sulfate	12 Sep 2020 (Study Day 17) - 12 Oct 2020 (Study Day 47)	Myocardial Infarction Post Cabg Treatment Protocol
Hydrocodone; paracetamol	12 Sep 2020 (Study Day 17) - 19 Sep 2020 (Study Day 24)	Myocardial Infarction- Post Cabg Treatment Protocol
Insulin lispro	12 Sep 2020 (Study Day 17) - Ongoing	Type Ii Diabetes
Metoprolol tartrate	12 Sep 2020 (Study Day 17) - 14 Jan 2021 (Study Day 141)	Myocardial Infarction Post Cabg Treatment Protocol

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Milrinone	12 Sep 2020 (Study Day 17) - 14 Sep 2020 (Study Day 19)	Myocardial Infarction
Morphine	12 Sep 2020 (Study Day 17) - 13 Sep 2020 (Study Day 18)	Myocardial Infarction
Ondansetron	12 Sep 2020 (Study Day 17) - 09 Oct 2020 (Study Day 44)	Nausea
Pantoprazole	12 Sep 2020 (Study Day 17) - Nov 2020	Gerd
Sennoside a+b	12 Sep 2020 (Study Day 17) - Ongoing	Myocardial Infarctin Post Cabg Treatment Protocol
Acetylsalicylic acid	13 Sep 2020 (Study Day 18) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Ascorbic acid	13 Sep 2020 (Study Day 18) - Nov 2020	General Health
Hydralazine	13 Sep 2020 (Study Day 18) - 13 Sep 2020 (Study Day 18)	Hypertension
Atorvastatin	14 Sep 2020 (Study Day 19) - 28 Jan 2021 (Study Day 155)	Myocardial Infarction Post Cabg Treatment Protocol
Docusate sodium	14 Sep 2020 (Study Day 19) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Enoxaparin	14 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 23)	Myocardial Infarction
Furosemide	14 Sep 2020 (Study Day 19) - 01 Jan 2021 (Study Day 128)	Myocardial Infarction Post Cabg Treatment Protocol
Ipratropium	14 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 23)	Wheezing
Myroxylon balsamum var. pereirae; ricinus communis oil	14 Sep 2020 (Study Day 19) - 12 Oct 2020 (Study Day 47)	Myocardial Infarction Post Cabg Treatment Protocol
Potassium chloride	14 Sep 2020 (Study Day 19) - 28 Oct 2020 (Study Day 63)	Myocardial Infarction Post Cabg Treatment Protocol
Salbutamol	14 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 23)	Wheezing
Macrogol	15 Sep 2020 (Study Day 20) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Bisacodyl	16 Sep 2020 (Study Day 21) - 12 Oct 2020 (Study Day 47)	Myocardial Infarction Post Cabg Treatment Protocol
Influenza vaccine	04 Oct 2020 (Study Day 39) - 04 Oct 2020 (Study Day 39)	Influenza
Doxycycline	06 Oct 2020 (Study Day 41) - 08 Oct 2020 (Study Day 43)	Myocardial Infarction Post Cabg Treatment Protocol
Gabapentin	06 Oct 2020 (Study Day 41) - Ongoing	Myocardial Infarction Post Cabg Treatment Protocol
Magnesium oxide	06 Oct 2020 (Study Day 41) - 19 Nov 2020 (Study Day 85)	Myocardial Infarction Post Cabg Treatment Protocol
Sertraline	06 Oct 2020 (Study Day 41) - 14 Jan 2021 (Study Day 141)	Anxiety Post Cabg
Empagliflozin	12 Oct 2020 (Study Day 47) - Ongoing	Type Ii Diabetes
Promethazine	20 Oct 2020 (Study Day 55) - Ongoing	Nausea
Ampicillin	13 Nov 2020 (Study Day 79) - 27 Nov 2020 (Study Day 93)	Infected Wound- Bedsore
Event monitor (wore for 2 weeks)*	19 Nov 2020 (Study Day 85) - 19 Nov 2020 (Study Day 85)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Echocardiogram*	20 Nov 2020 (Study Day 86) - 20 Nov 2020 (Study Day 86)	Adverse Event
Bedsore wound debridement*	27 Nov 2020 (Study Day 93) - 27 Nov 2020 (Study Day 93)	Adverse Event
Lisinopril	10 Dec 2020 (Study Day 106) - Ongoing	Hypertension
Bupropion hydrochloride	14 Jan 2021 (Study Day 141) - Ongoing	Anxiety Post Cabag
Furosemide	14 Jan 2021 (Study Day 141) - Ongoing	Bilateral Leg Swelling
Metoprolol succinate	14 Jan 2021 (Study Day 141) - 16 Apr 2021 (Study Day 233)	Hypertension
Wound vac placment*	20 Jan 2021 (Study Day 147) - 20 Jan 2021 (Study Day 147)	Adverse Event
Glipizide	28 Jan 2021 (Study Day 155) - Ongoing	Type Ii Diabetes
Rosuvastatin calcium	28 Jan 2021 (Study Day 155) - Ongoing	Hyperlipidemia
Ceftriaxone	19 Feb 2021 (Study Day 177) - 23 Feb 2021 (Study Day 181)	Wound Infection Left Buttock/Sepsis
Ct of abd and pelvis with contrast*	19 Feb 2021 (Study Day 177) - 19 Feb 2021 (Study Day 177)	Adverse Event
Hematology draw*	19 Feb 2021 (Study Day 177) - 19 Feb 2021 (Study Day 177)	Adverse Event
Metronidazole	19 Feb 2021 (Study Day 177) - 20 Feb 2021 (Study Day 178)	Sepsis/Wound Infection Left Buttock
Vancomycin	19 Feb 2021 (Study Day 177) - 19 Feb 2021 (Study Day 177)	Sepsis/Wound Infection Left Buttock
Hematology draw*	20 Feb 2021 (Study Day 178) - 20 Feb 2021 (Study Day 178)	Adverse Event
Blood culture*	21 Feb 2021 (Study Day 179) - 21 Feb 2021 (Study Day 179)	Adverse Event
Vancomycin	21 Feb 2021 (Study Day 179) - 24 Feb 2021 (Study Day 182)	Sepsis/Wound Infection Left Buttock
Amoxicillin; clavulanic acid	24 Feb 2021 (Study Day 182) - 10 Mar 2021 (Study Day 196)	Wound Infection- Left Buttock

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ventricular Fibrillation	Grade 3/severe	Not related	08 Sep 2020 (Study Day 13) - Ongoing
Nausea	Grade 3/severe	Not related	12 Sep 2020 (Study Day 17) - 09 Oct 2020 (Study Day 44)
Wheezing	Grade 2/moderate	Not related	14 Sep 2020 (Study Day 19) - 18 Sep 2020 (Study Day 23)
Procedural Anxiety	Grade 2/moderate	Not related	06 Oct 2020 (Study Day 41) - Ongoing
Decubitus Ulcer	Grade 2/moderate	Not related	13 Nov 2020 (Study Day 79) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspnoea	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 97) - 01 Dec 2020 (Study Day 97)
Peripheral Swelling	Grade 2/moderate	Not related	14 Jan 2021 (Study Day 141) - Ongoing
Syncope	Grade 3/severe	Not related	14 Jan 2021 (Study Day 141) - 14 Jan 2021 (Study Day 141)
Intention Tremor	Grade 1/mild	Not related	28 Jan 2021 (Study Day 155) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2192 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 37)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Clear Cell Renal Cell Carcinoma/Kidney Cancer, Right Kidney Clear Cell Renal Cell Carcinoma, Who/Isup Grade 3	SAE	Grade 3/severe	Not related	09 Nov 2020 (Study Day 71) – 23 Nov 2020 (Study Day 85)	Recovered/resolved
Retroperitoneal Haemorrhage/Retroperitoneal Bleed	SAE	Grade 4	Not related	18 Nov 2020 (Study Day 80) – 20 Nov 2020 (Study Day 82)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2192, a 38-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 37). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Nov 2020 (Study Day 71), 70 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of clear cell renal cell carcinoma. Action taken with the IP was not applicable. The event of kidney cancer, right kidney clear cell renal cell carcinoma, who/isup grade 3 lasted for 15 days, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 85). The investigator assessed the event of clear cell renal cell carcinoma to be not related to the IP.

On 18 Nov 2020 (Study Day 80), 79 days after the first dose and 43 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of retroperitoneal haemorrhage. Action taken with the IP was not applicable. The event of retroperitoneal bleed lasted for 3 days, after which it was considered to be recovered/resolved on 20 Nov 2020 (Study Day 82). The investigator assessed the event of retroperitoneal haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000756	Clear cell renal cell carcinoma
MOD-2020-000756	Retroperitoneal haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic kidney disease	Chronic kidney failure	2014 - Ongoing
Epistaxis	Intermittent nosebleeds	2014 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Dialysis	Dialysis	2018 - Ongoing
Hypokalaemia	Hypokalemia	2018 - Ongoing
Cardiac failure congestive	Congestive heart failure	2019 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2014 - Ongoing	Hypertension
Carvedilol	2014 - 23 Nov 2020 (Study Day 85)	Hypertension
Hydralazine	2014 - Ongoing	Hypertension
Isosorbide	2014 - Ongoing	Hypertension
Vitamins nos	2014 - Ongoing	General Health
Calcium carbonate	2017 - Ongoing	Chronic Kidney Failure
Furosemide	2018 - Ongoing	Chronic Kidney Failure
Potassium	2018 - 23 Nov 2020 (Study Day 85)	Hypokalemia
Calcium	2019 - Ongoing	Chronic Kidney Failure
Lisinopril	2019 - Ongoing	Hypertension
Cefazolin	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Desmopressin	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Electrolytes nos	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fentanyl	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Hydromorphone	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Lidocaine	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Magnesium sulfate	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Midazolam	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Naloxone	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Ondansetron	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Paracetamol	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kideny Cancer
Paracetamol	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Propofol	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Right radical nephrectomy*	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Adverse Event
Rocuronium	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Sugammadex	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Vecuronium	18 Nov 2020 (Study Day 80) - 18 Nov 2020 (Study Day 80)	Kidney Cancer
Calcium chloride; potassium chloride; sodium lactate	19 Nov 2020 (Study Day 81) - 19 Nov 2020 (Study Day 81)	Kidney Cancer
Epinephrine; lidocaine	19 Nov 2020 (Study Day 81) - 19 Nov 2020 (Study Day 81)	Kidney Cancer
Calcium gluconate	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Cefazolin	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Desmopressin	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Electrolytes nos	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Exploratory lap: evacuation of hematoma, clip placement near renal hilum*	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Adverse Event
Fentanyl	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Glucose	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Hydralazine	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Hydromorphone	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Lidocaine	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Midazolam	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Norepinephrine	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Propofol	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Rocuronium	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Sodium bicarbonate	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Sodium chloride	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Sugammadex	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Retroperitoneal Bleed
Transfusion of plasma*	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Adverse Event
Transfusion of rbc's*	20 Nov 2020 (Study Day 82) - 20 Nov 2020 (Study Day 82)	Adverse Event
Bisacodyl	23 Nov 2020 (Study Day 85) - 23 Nov 2020 (Study Day 85)	Kidney Cancer
Carvedilol	23 Nov 2020 (Study Day 85) - Ongoing	Hypertension
Macrogol 3350	23 Nov 2020 (Study Day 85) - 01 Dec 2020 (Study Day 93)	Kidney Cancer
Oxycodone	23 Nov 2020 (Study Day 85) - 30 Nov 2020 (Study Day 92)	Kidney Cancer
Potassium	23 Nov 2020 (Study Day 85) - Ongoing	Hypokalemia
Colecalciferol	05 Jan 2021 (Study Day 128) - Ongoing	General Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Epistaxis	Grade 1/mild	Not related	19 Oct 2020 (Study Day 50) - 20 Oct 2020 (Study Day 51)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2212 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Back Pain/Worsening Back Pain	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	25 Sep 2020 (Study Day 24) – 17 Nov 2020 (Study Day 77)	Not recovered/not resolved
Spinal Stenosis/Spinal Stenosis	SAE	Grade 4	Not related	17 Nov 2020 (Study Day 77) – 19 Nov 2020 (Study Day 79)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2212, a 61-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of back pain. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening back pain lasted for 54 days, after which it was considered to be not recovered/not resolved on 17 Nov 2020 (Study Day 77). The investigator assessed the event of back pain to be not related to the IP.

On 17 Nov 2020 (Study Day 77), 76 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of spinal stenosis. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of spinal stenosis lasted for 3 days, after which it was considered to be recovered/resolved on 19 Nov 2020 (Study Day 79). The investigator assessed the event of spinal stenosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009184	Spinal stenosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Knee pain -obesity	Not reported - 2018
Drug hypersensitivity	Allergy to penicillin	1960 - Ongoing
Drug hypersensitivity	Allergy to sulfa drugs	1960 - Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Brachial plexus injury	Brachial plexus injury	1982 - 1982
Joint dislocation	Dislocated ball joint -left shoulder	1982 - 2009
Peripheral nerve operation	Brachial plexus surgery	1982 - 1982
Deafness	Hearing loss	1985 - Ongoing
Back pain	Lower back pain	1990 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	1995 - Ongoing
Carpal tunnel syndrome	Carpal tunnel	2005 - Ongoing
Osteoarthritis	Osteoarthritis	2005 - Ongoing
Sciatica	Sciatica	2005 - Ongoing
Shoulder arthroplasty	Left shoulder ball joint replacement	2009 - 2009
Anxiety	Anxiety	2010 - Ongoing
Depression	Depression	2010 - Ongoing
Benign prostatic hyperplasia	Bph	2018 - Ongoing
Erectile dysfunction	Erectile dysfunction	2018 - Ongoing
Knee arthroplasty	Knee replacement	2018 - 2018
Hypothyroidism	Hypothyroidism	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2005 - Ongoing	Osteo Arthritis
Alprazolam	2010 - Ongoing	Anxiety
Bupropion	2010 - Ongoing	Depression
Diclofenac	2010 - Dec 2020	Osteoarthritis
Ibuprofen	2010 - Ongoing	Seasonal Allergies
Cyanocobalamin	Jan 2010 - Ongoing	General Health
Famotidine	2012 - Ongoing	Acid Reflux
Gabapentin	2017 - 25 Sep 2020 (Study Day 24)	Sciatica

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Finasteride	2018 - Ongoing	Bph
Tadalafil	2018 - Ongoing	Erectile Dysfunction
Levothyroxine	Jan 2020 - Ongoing	Hypothyroidism
Mri spine*	02 Sep 2020 (Study Day 1) - 02 Sep 2020 (Study Day 1)	Medical History
Gabapentin	25 Sep 2020 (Study Day 24) - Jan 2021	Worsening Back Pain - Ae# 1 And 4
Corticosteroid nos	01 Oct 2020 (Study Day 30) - 01 Oct 2020 (Study Day 30)	Ae 4 Worsening Back Pain
Epidural-back*	01 Oct 2020 (Study Day 30) - 01 Oct 2020 (Study Day 30)	Adverse Event
X-ray (spinal)*	02 Nov 2020 (Study Day 62) - 02 Nov 2020 (Study Day 62)	Adverse Event
L1-l5 decompression surgery*	17 Nov 2020 (Study Day 77) - 17 Nov 2020 (Study Day 77)	Adverse Event
Tramadol	17 Nov 2020 (Study Day 77) - 20 Nov 2020 (Study Day 80)	Pain After Spinal Stenosis Surgery
Paracetamol	19 Nov 2020 (Study Day 79) - Ongoing	Back Surgery Pain Ae 1
Diclofenac	Dec 2020 - Ongoing	Osteoarthritis
Carpal tunnel surgery*	18 Dec 2020 (Study Day 108) - 18 Dec 2020 (Study Day 108)	Adverse Event
Trigger finger surgery*	18 Dec 2020 (Study Day 108) - 18 Dec 2020 (Study Day 108)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Back Pain	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 24) - 17 Nov 2020 (Study Day 77)
Carpal Tunnel Syndrome	Grade 2/moderate	Not related	18 Dec 2020 (Study Day 108) - 18 Dec 2020 (Study Day 108)
Trigger Finger	Grade 2/moderate	Not related	18 Dec 2020 (Study Day 108) - 18 Dec 2020 (Study Day 108)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2231 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Community Acquired Pneumonia	SAE	Grade 4	Not related	10 Oct 2020 (Study Day 38) – 16 Oct 2020 (Study Day 44)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2231, a 76-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Oct 2020 (Study Day 38), 37 days after the first dose and 9 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of community acquired pneumonia lasted for 7 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 44). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000447	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Sinusitis	Frequent sinus infections	Not reported - 1988
Anxiety	Anxiety	1952 - Ongoing
Osteoarthritis	Osteoarthritis	1968 - Ongoing
Haemorrhoids	Hemorrhoids	1986 - Ongoing
Sinus operation	Sinus surgery (to correct frequent sinus infections)	1988 - 1988
Prostatomegaly	Enlarged prostate	1990 - Ongoing
Bundle branch block left	Left bundle branch block	1995 - Ongoing
Hernia repair	Hernia repair	1995 - 1995
Gastrooesophageal reflux disease	Gerd	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Sciatica	Sciatica	2005 - Ongoing
Trigeminal neuralgia	Trigeminal neuralgia	2005 - Ongoing
Depression	Depression	2010 - Ongoing
Blood cholesterol increased	High cholesterol	2013 - Ongoing
Rotator cuff syndrome	Torn rotator cuff	2014 - Ongoing
Deafness	Hearing loss	2015 - Ongoing
Erectile dysfunction	Erectile dysfunction	2015 - Ongoing
Cardiac ablation	Cardiac ablation	2016 - 2016
Supraventricular tachycardia	Av nodal re-entry tachycardia	2016 - Ongoing
Supraventricular tachycardia	Paroxysmal svt	2016 - Ongoing
Ventricular extrasystoles	Premature ventricular contractions	2016 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	2017 - Ongoing
Cataract	Cataracts	2018 - 2018
Cataract operation	Cataract surgery-both eyes	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Not reported - Ongoing	Muscle Aches And General Pain
Paracetamol	Not reported - Ongoing	Muscle Aches And General Pains
Fluvoxamine	2010 - Ongoing	Heart Arrythmia Depression
Atorvastatin	2013 - 16 Oct 2020 (Study Day 44)	High Cholesterol
Famotidine	2013 - Ongoing	Gerd
Losartan	2013 - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2015 - Ongoing	Heart Health
Nebivolol hydrochloride	2016 - Ongoing	Heart Arrythmia
Bupropion hydrochloride	2019 - Ongoing	Depression
Colecalciferol	2019 - Ongoing	General Health
Fluticasone propionate	25 Sep 2020 (Study Day 23) - Ongoing	Seasonal Allergies
Ceftriaxone	Oct 2020 - Oct 2020	Pneumonia
Ibuprofen	08 Oct 2020 (Study Day 36) - 08 Oct 2020 (Study Day 36)	Joint Pain/Fever
Paracetamol	08 Oct 2020 (Study Day 36) - 08 Oct 2020 (Study Day 36)	Joint Pain/Fever
Azithromycin	10 Oct 2020 (Study Day 38) - 12 Oct 2020 (Study Day 40)	Pneumonia
Bacterial study*	10 Oct 2020 (Study Day 38) - 10 Oct 2020 (Study Day 38)	Adverse Event
Chest x-ray*	10 Oct 2020 (Study Day 38) - 10 Oct 2020 (Study Day 38)	Adverse Event
Enoxaparin	10 Oct 2020 (Study Day 38) - 16 Oct 2020 (Study Day 44)	Prevention Of Dvt
Metoprolol	10 Oct 2020 (Study Day 38) - 16 Oct 2020 (Study Day 44)	Hypertension
Ondansetron	10 Oct 2020 (Study Day 38) - 16 Oct 2020 (Study Day 44)	Nausea And Vomiting
Paracetamol	10 Oct 2020 (Study Day 38) - 16 Oct 2020 (Study Day 44)	General Pain
Viral studies*	10 Oct 2020 (Study Day 38) - 10 Oct 2020 (Study Day 38)	Adverse Event
Valsartan	11 Oct 2020 (Study Day 39) - 16 Oct 2020 (Study Day 44)	Hypertension
Vitamin b12 nos	11 Oct 2020 (Study Day 39) - 11 Oct 2020 (Study Day 39)	General Health
Cefdinir	12 Oct 2020 (Study Day 40) - Oct 2020	Community Acquired Pneumonia
Abdominal ultrasound*	14 Oct 2020 (Study Day 42) - 14 Oct 2020 (Study Day 42)	Adverse Event
Ipratropium	16 Oct 2020 (Study Day 44) - Ongoing	Seasonal Allergies
Vitamin b12 nos	16 Oct 2020 (Study Day 44) - Ongoing	General Health
Varicella zoster vaccine rge (cho)	18 Jan 2021 (Study Day 138) - 18 Jan 2021 (Study Day 138)	Prevent Shingles

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	17 Sep 2020 (Study Day 15) - 19 Sep 2020 (Study Day 17)
Hepatic Steatosis	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 38) - 16 Oct 2020 (Study Day 44)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Toxic Encephalopathy	Grade 4	Not related	10 Oct 2020 (Study Day 38) - 16 Oct 2020 (Study Day 44)
Respiratory Disorder	Grade 2/moderate	Not related	04 Nov 2020 (Study Day 63) - 09 Nov 2020 (Study Day 68)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2279 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	04 Oct 2020 (Study Day 25) – 26 Oct 2020 (Study Day 47)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2279, a 66-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Oct 2020 (Study Day 25), 24 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of covid-19. On 07 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of COVID-19 lasted for 23 days, after which it was considered to be recovered/resolved on 26 Oct 2020 (Study Day 47). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000461	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Menopause	Menopause	2003 - Ongoing
Dermal filler injection	Dermal filler injection	2014 - 2014
Basal cell carcinoma	Basal cell carcinoma	2016 - 2016
Skin neoplasm excision	Basal cell carcinoma removal	2016 - 2016

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	Not reported - Ongoing	General Health
Ibuprofen; pseudoephedrine hydrochloride	2015 - Ongoing	Seasonal Allergies
Ibuprofen; pseudoephedrine hydrochloride	08 Oct 2020 (Study Day 29) - 15 Oct 2020 (Study Day 36)	COVID Symptoms: Sore Throat, Cough, Nasal Congestion
Ibuprofen	03 Mar 2021 (Study Day 175) - 25 Mar 2021 (Study Day 197)	Rib Chest Pain And Foot Pain
X-ray of neck and r foot*	04 Mar 2021 (Study Day 176) - 04 Mar 2021 (Study Day 176)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	04 Oct 2020 (Study Day 25) - 26 Oct 2020 (Study Day 47)
Musculoskeletal Chest Pain	Grade 2/moderate	Not related	03 Mar 2021 (Study Day 175) - 25 Mar 2021 (Study Day 197)
Pain In Extremity	Grade 2/moderate	Not related	03 Mar 2021 (Study Day 175) - 25 Mar 2021 (Study Day 197)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US353-2281 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Of Osteoarthritis	SAE	Grade 4	Not related	23 Oct 2020 (Study Day 44) – 25 Oct 2020 (Study Day 46)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US353-2281, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Oct 2020 (Study Day 44), 43 days after the first dose and 17 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening of osteoarthritis lasted for 3 days, after which it was considered to be recovered/resolved on 25 Oct 2020 (Study Day 46). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000561	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Knee arthroplasty	Meniscus transplant	1994 - 1994
Osteotomy	Femoral osteotomy	1994 - 1994
Depression	Depression	2005 - Ongoing
Osteoarthritis	Osteoarthritis	2005 - Ongoing
Blood testosterone decreased	Low testosterone	2010 - Ongoing
Knee arthroplasty	Knee replacement - right knee	2010 - 2010
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2012 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Deafness	Hearing loss	2014 - Ongoing
Dermal filler injection	Dermal filler injection	2015 - 2015
Erectile dysfunction	Erectile dysfunction	2017 - Ongoing
Spinal operation	Revision surgery (back surgery)	01 Jan 2018 (Study Day -983) - 01 Jan 2018 (Study Day -983)
Seasonal allergy	Season allergies	2019 - Ongoing
Spinal fusion surgery	Back fusion surgery	2019 - 2019
Foot fracture	Fifth meditarsal break	31 Aug 2020 (Study Day -10) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Not reported - Ongoing	Osteoarthritis
Venlafaxine	2005 - Ongoing	Depression
Testosterone cipionate	2010 - Ongoing	Low Testosterone
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	2012 - Ongoing	Adhd
Spironolactone	2016 - Ongoing	Hypertension
Telmisartan	2016 - Ongoing	Hypertension
Tadalafil	2017 - Ongoing	Erectile Dysfunction
Fluticasone propionate	2019 - Ongoing	Seasonal Allergies
Vitamins nos	2019 - Ongoing	General Health
Ibuprofen	07 Oct 2020 (Study Day 28) - 07 Oct 2020 (Study Day 28)	Body Aches
Paracetamol	07 Oct 2020 (Study Day 28) - 08 Oct 2020 (Study Day 29)	Fever (Documented In Ediary Post 2nd Dose

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	23 Oct 2020 (Study Day 44) - Ongoing	Dvt Prevention After Ankle Surgery
Left total ankle arthroplasty*	23 Oct 2020 (Study Day 44) - 23 Oct 2020 (Study Day 44)	Medical History
Oxycodone	23 Oct 2020 (Study Day 44) - 29 Oct 2020 (Study Day 50)	Pain From Ankle Surgery
Paracetamol	23 Oct 2020 (Study Day 44) - 03 Nov 2020 (Study Day 55)	Pain From Ankle Surgery
Macrogol	25 Oct 2020 (Study Day 46) - 28 Oct 2020 (Study Day 49)	Bowel Management -Prevention Of Constipation Caused By Pain Medication

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Epistaxis	Grade 1/mild	Not related	10 Oct 2020 (Study Day 31) - 10 Oct 2020 (Study Day 31)
Procedural Pain	Grade 2/moderate	Not related	23 Oct 2020 (Study Day 44) - 03 Nov 2020 (Study Day 55)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US354-2090 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthralgia/Polyarthralgias	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	03 Sep 2020 (Study Day 7) – 15 Jan 2021 (Study Day 141)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2090, a 65-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 28 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of arthralgia. On 24 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of polyarthralgias lasted for 135 days, after which it was considered to be recovered/resolved on 15 Jan 2021 (Study Day 141). The investigator assessed the event of arthralgia to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 10 Mar 2021 (Study Day 195), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Prostatectomy	Prostatectomy (secondary to prostate cancer)	Aug 2011 - Aug 2011
Erectile dysfunction	Erectile dysfunction	2012 - Ongoing
Spinal fusion surgery	Spinal surgery (l5-s1 fusion)	Nov 2015 - Nov 2015
Sleep apnoea syndrome	Sleep apnea	Aug 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sildenafil	Jul 2012 - Ongoing	Erectile Dysfunction
Allium sativum	Aug 2019 - Ongoing	General Health Prophylaxis
Ascorbic acid	Aug 2019 - Ongoing	General Health Prophylaxis
Fish oil	Aug 2019 - Ongoing	General Health Prophylaxis
Vitamin d nos	Aug 2019 - Ongoing	General Health Prophylaxis
Vitamins nos	Aug 2019 - Ongoing	General Health Prophylaxis
Cyclobenzaprine	13 Oct 2020 (Study Day 47) - 15 Jan 2021 (Study Day 141)	Polyarthralgias
Naproxen	13 Oct 2020 (Study Day 47) - 15 Jan 2021 (Study Day 141)	Polyarthralgias
Ibuprofen	17 Oct 2020 (Study Day 51) - 17 Oct 2020 (Study Day 51)	Polyarthralgia
Influenza vaccine	02 Nov 2020 (Study Day 67) - 02 Nov 2020 (Study Day 67)	Flu Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 7) - 15 Jan 2021 (Study Day 141)
Groin Pain	Grade 1/mild	Not related	04 Sep 2020 (Study Day 8) - 04 Sep 2020 (Study Day 8)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US354-2168 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anxiety/Anxiety Exacerbation	SAE	Grade 4	Not related	10 Sep 2020 (Study Day 7) – 18 Sep 2020 (Study Day 15)	Recovered/resolved
Anxiety/Anxiety Exacerbation	SAE, AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	19 Sep 2020 (Study Day 16) – 23 Sep 2020 (Study Day 20)	Recovered/resolved
Depression/Depression Exacerbation	SAE	Grade 3/severe	Not related	19 Sep 2020 (Study Day 16) – 23 Sep 2020 (Study Day 20)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2168, a 54-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 04 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of anxiety. On 01 Oct 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of anxiety exacerbation lasted for 9 days, after which it was considered to be recovered/resolved on 18 Sep 2020 (Study Day 15). The investigator assessed the event of anxiety to be not related to the IP.

On 19 Sep 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of anxiety. On 01 Oct 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of anxiety exacerbation lasted for 5 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 20). The investigator assessed the event of anxiety to be not related to the IP.

On 19 Sep 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of depression. On 01 Oct 2020

(Study Day 28), the IP dose was discontinued due to physician decision. The event of depression exacerbation lasted for 5 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 20). The investigator assessed the event of depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000312	Anxiety
MOD-2020-000312	Anxiety
MOD-2020-000312	Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sickle cell disease	Sickle cell disease	(b) (6) 1966 - Ongoing
Skin graft	Skin grafts for burn	1992 - 1992
Anxiety disorder	Anxiety disorder	2000 - Ongoing
Borderline personality disorder	Borderline personality disorder	2000 - Ongoing
Depression	Depression	2000 - Ongoing
Generalised anxiety disorder	Generalized anxiety disorder	2000 - Ongoing
Post-traumatic stress disorder	Ptsd	2000 - Ongoing
Hypertension	Hypertension	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2018 - Ongoing	Hypertension
Mirtazapine	2019 - 10 Sep 2020 (Study Day 7)	Generalized Anxiety Disorder
Hydroxycarbamide	May 2020 - Ongoing	Sickle Cell Disease
Oxycodone	Aug 2020 - Ongoing	Sickle Cell Disease
Mirtazapine	10 Sep 2020 (Study Day 7) - Ongoing	Generalized Anxiety Disorder Exacerbation
Diphenhydramine hydrochloride	19 Sep 2020 (Study Day 16) - 19 Sep 2020 (Study Day 16)	Lower Leg Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydromorphone hydrochloride	19 Sep 2020 (Study Day 16) - 19 Sep 2020 (Study Day 16)	Lower Leg Pain
Morphine	19 Sep 2020 (Study Day 16) - 19 Sep 2020 (Study Day 16)	Lower Leg Pain
Lithium	20 Sep 2020 (Study Day 17) - Ongoing	Depression And Anxiety Exacerbation
Mirtazapine	20 Sep 2020 (Study Day 17) - Ongoing	Depression Exacerbation
Prazosin	20 Sep 2020 (Study Day 17) - Ongoing	Ptsd
Acetylsalicylic acid	23 Oct 2020 (Study Day 50) - 25 Oct 2020 (Study Day 52)	Headache
Ibuprofen	10 Nov 2020 (Study Day 68) - Ongoing	Right Trapezius Strain.

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain In Extremity	Grade 2/moderate	Not related	18 Sep 2020 (Study Day 15) - 19 Sep 2020 (Study Day 16)
Headache	Grade 1/mild	Not related	21 Oct 2020 (Study Day 48) - 23 Oct 2020 (Study Day 50)
Rhinorrhoea	Grade 1/mild	Not related	21 Oct 2020 (Study Day 48) - 23 Oct 2020 (Study Day 50)
Muscle Strain	Grade 1/mild	Not related	10 Nov 2020 (Study Day 68) - 22 Dec 2020 (Study Day 110)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US354-2199 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Renal Cell Carcinoma/Renal Cell Carcinoma	SAE	Grade 2/ moderate	Not related	02 Oct 2020 (Study Day 23) – 29 Oct 2020 (Study Day 50)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2199, a 66-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 23), 22 days after the first dose and 6 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of renal cell carcinoma. The IP dose was not changed due to the renal cell carcinoma. The event of renal cell carcinoma lasted for 28 days, after which it was considered to be recovered/resolved on 29 Oct 2020 (Study Day 50). The investigator assessed the event of renal cell carcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-037763	Renal cell carcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1960 - Ongoing
Hypertrophic cardiomyopathy	Hypertrophic cardiomyopathy	2004 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2004 - 20 Oct 2020 (Study Day 41)	Cardiomyopathy
Atenolol	2004 - Ongoing	Cardiomyopathy
Rosuvastatin	2004 - Ongoing	Cardiomyopathy
Azelastine	2015 - Ongoing	Seasonal Allergies
Fexofenadine	2015 - Ongoing	Seasonal Allergies
Olopatadine	2015 - Ongoing	Seasonal Allergies
Vitamin d nos	2015 - Ongoing	General Health
Influenza vaccine inact sag 3v	22 Oct 2020 (Study Day 43) - 22 Oct 2020 (Study Day 43)	Influenza Prophylaxis
Cefazolin	27 Oct 2020 (Study Day 48) - 29 Oct 2020 (Study Day 50)	Partial Nephrectomy
Docusate	27 Oct 2020 (Study Day 48) - 01 Nov 2020 (Study Day 53)	Left Partial Nephrectomy
Heparin	27 Oct 2020 (Study Day 48) - 29 Oct 2020 (Study Day 50)	Partial Nephrectomy
Hydromorphone hydrochloride	27 Oct 2020 (Study Day 48) - 28 Oct 2020 (Study Day 49)	Partial Nephrectomy
Ketorolac tromethamine	27 Oct 2020 (Study Day 48) - 29 Oct 2020 (Study Day 50)	Partial Nephrectomy
Left partial nephrectomy*	27 Oct 2020 (Study Day 48) - 27 Oct 2020 (Study Day 48)	Adverse Event
Left ureteral catheter placement*	27 Oct 2020 (Study Day 48) - 27 Oct 2020 (Study Day 48)	Adverse Event
Ondansetron	27 Oct 2020 (Study Day 48) - 27 Oct 2020 (Study Day 48)	Left Partial Nephrectomy
Paracetamol	27 Oct 2020 (Study Day 48) - 01 Nov 2020 (Study Day 53)	Left Partial Nephrectomy
Acetylsalicylic acid	31 Oct 2020 (Study Day 52) - Ongoing	Cardiomyopathy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US354-2309 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	28 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Subarachnoid Haemorrhage/Subarachnoid Hemorrhage	SAE	Grade 3/ severe	Not related	13 Nov 2020 (Study Day 44) – 11 Dec 2020 (Study Day 72)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2309, a 57-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 28 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Nov 2020 (Study Day 44), 43 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of subarachnoid haemorrhage. Action taken with the IP was not applicable. The event of subarachnoid hemorrhage lasted for 29 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 72). The investigator assessed the event of subarachnoid haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000833	Subarachnoid haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Umbilical hernia repair	Umbilical hernia repair	1966 - 1966
Iron deficiency anaemia	Anemia (iron deficiency)	1970 - Ongoing
Brain neoplasm benign	Benign brain tumor	1999 - 1999
Hypersensitivity	Allergies (environmental)	2018 - Ongoing
Hysterectomy	Hysterectomy	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	2018 - Ongoing	Allergies (Environmental)
Paracetamol	29 Oct 2020 (Study Day 29) - 29 Oct 2020 (Study Day 29)	Headache
Ct head & cervical spine*	13 Nov 2020 (Study Day 44) - 13 Nov 2020 (Study Day 44)	Adverse Event
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	13 Nov 2020 (Study Day 44) - 13 Nov 2020 (Study Day 44)	Tetanus Prophylaxis
Enoxaparin	13 Nov 2020 (Study Day 44) - 15 Nov 2020 (Study Day 46)	Dvt Prohylaxis
Lidocaine	13 Nov 2020 (Study Day 44) - 13 Nov 2020 (Study Day 44)	Posterior Scalp Laceration
Ocrilate	13 Nov 2020 (Study Day 44) - 13 Nov 2020 (Study Day 44)	Posterior Scalp Laceration
Posterior scalp laceration repair*	13 Nov 2020 (Study Day 44) - 13 Nov 2020 (Study Day 44)	Adverse Event
Carotid ultrasound, bilateral*	14 Nov 2020 (Study Day 45) - 14 Nov 2020 (Study Day 45)	Adverse Event
Ibuprofen	14 Nov 2020 (Study Day 45) - Ongoing	Subarachnoid Hemorrhage
Levetiracetam	14 Nov 2020 (Study Day 45) - Ongoing	Subarachnoid Hemorrhage
Paracetamol	14 Nov 2020 (Study Day 45) - Ongoing	Subarachnoid Hemorrhage
Transthoracic echocardiogram with doppler*	15 Nov 2020 (Study Day 46) - 15 Nov 2020 (Study Day 46)	Adverse Event
Mri brain*	11 Dec 2020 (Study Day 72) - 11 Dec 2020 (Study Day 72)	Adverse Event
Trazodone	20 Feb 2021 (Study Day 143) - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Related	29 Oct 2020 (Study Day 29) - 29 Oct 2020 (Study Day 29)
Arnold-Chiari Malformation	Grade 1/mild	Not related	13 Nov 2020 (Study Day 44) - Ongoing
Skin Laceration	Grade 2/moderate	Not related	13 Nov 2020 (Study Day 44) - 17 Dec 2020 (Study Day 78)
Syncope	Grade 3/severe	Not related	13 Nov 2020 (Study Day 44) - 13 Nov 2020 (Study Day 44)
Insomnia	Grade 1/mild	Not related	15 Feb 2021 (Study Day 138) - Ongoing
Herpes Zoster	Grade 2/moderate	Not related	25 Feb 2021 (Study Day 148) - 07 Mar 2021 (Study Day 158)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US354-2332 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Seizure/Exacerbation Of Seizure Disorder	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	07 Nov 2020 (Study Day 30) – 09 Nov 2020 (Study Day 32)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2332, a 56-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 09 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Nov 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of seizure. On 05 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of exacerbation of seizure disorder lasted for 3 days, after which it was considered to be recovered/resolved on 09 Nov 2020 (Study Day 32). The investigator assessed the event of seizure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000714	Seizure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seizure	Seizure disorder	Feb 1998 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Blood cholesterol increased	High cholesterol	2015 - Ongoing
Osteoarthritis	Righ hand osteoarthritis	2015 - Ongoing
Cerebrovascular accident	Cva	Jan 2019 - Jan 2019
Hemiparesis	L sided weakness secondary to cva	Jan 2019 - Ongoing
Implantable cardiac monitor insertion	Implanted cardiac monitor to detect arrhythmias	Jan 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2014 - Ongoing	Seizure Disorder
Levetiracetam	2014 - 06 Nov 2020 (Study Day 29)	Seizure Disorder
Lisinopril	2014 - Ongoing	Hypertension
Acetylsalicylic acid	2018 - Ongoing	Stroke Prevention
Simvastatin	2018 - Ongoing	High Cholesterol
Apixaban	Jan 2020 - Ongoing	Stroke Prevention
Zonisamide	Feb 2020 - Ongoing	Seizure Disorder
Influenza vaccine	04 Nov 2020 (Study Day 27) - 04 Nov 2020 (Study Day 27)	Influenza Prevention
Levetiracetam	07 Nov 2020 (Study Day 30) - 09 Nov 2020 (Study Day 32)	Seizure Disorder
Levetiracetam	07 Nov 2020 (Study Day 30) - 07 Nov 2020 (Study Day 30)	Worsening Seizure Disorder (Loading Dose)
Lorazepam	07 Nov 2020 (Study Day 30) - 07 Nov 2020 (Study Day 30)	Worsening Seizure Disorder
Paracetamol	07 Nov 2020 (Study Day 30) - 09 Nov 2020 (Study Day 32)	Right Hand Osteoarthritis
Vitamins nos	07 Nov 2020 (Study Day 30) - 09 Nov 2020 (Study Day 32)	Health Maintenance
Carbamazepine	08 Nov 2020 (Study Day 31) - Ongoing	Seizure Disorder
Carbamazepine	09 Nov 2020 (Study Day 32) - 09 Nov 2020 (Study Day 32)	Worsening Seizure Disorder
Ibuprofen	09 Nov 2020 (Study Day 32) - Ongoing	Right Hand Osteoarthritis
Levetiracetam	09 Nov 2020 (Study Day 32) - Ongoing	Seizure Disorder
Levetiracetam	21 Jan 2021 (Study Day 105) - 21 Jan 2021 (Study Day 105)	Breakthrough Seizure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct head*	02 Mar 2021 (Study Day 145) - 02 Mar 2021 (Study Day 145)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Seizure	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 105) - 21 Jan 2021 (Study Day 105)
Dizziness	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 145) - 02 Mar 2021 (Study Day 145)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2024 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Non-Cardiac Chest Pain/Non-Cardiac Chest Pain, Non-Specified	SAE	Grade 3/severe	Not related	24 Aug 2020 (Study Day 12) – 11 Sep 2020 (Study Day 30)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2024, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Aug 2020 (Study Day 12), 11 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of non-cardiac chest pain. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of non-cardiac chest pain, non-specified lasted for 19 days, after which it was considered to be recovered/resolved on 11 Sep 2020 (Study Day 30). The investigator assessed the event of non-cardiac chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000252	Non-cardiac chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Glaucoma	Bilateral glaucoma	1999 - Ongoing
Hypertension	Hypertension	Jun 1999 - Ongoing
Hyperlipidaemia	Hyperlipidemia	11 Jun 2009 (Study Day -4081) - Ongoing
Cataract	Cataract right eye	Dec 2017 - Dec 2017
Eye laser surgery	R eye laser surgery for cataract	Dec 2017 - Dec 2017
Intraocular lens implant	Cataract lens implant in right eye	Dec 2017 - Dec 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Timolol maleate	2009 - Ongoing	Glaucoma
Losartan	Jun 2009 - Ongoing	Hypertension
Amlodipine	2015 - Jul 2020	Hypertension
Amlodipine	Jul 2020 - Ongoing	Hypertension
Influenza vaccine	08 Oct 2020 (Study Day 57) - 08 Oct 2020 (Study Day 57)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Seasonal Allergy	Grade 1/mild	Not related	18 Aug 2020 (Study Day 6) - 21 Sep 2020 (Study Day 40)
Vaccination Site Pain	Grade 1/mild	Related	21 Jan 2021 (Study Day 162) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2035 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Herpes Zoster/Shingles	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	04 Sep 2020 (Study Day 22) – 21 Sep 2020 (Study Day 39)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2035, a 55-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of herpes zoster. On 10 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of shingles lasted for 18 days, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 39). The investigator assessed the event of herpes zoster to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1998 - 1999
Intervertebral disc degeneration	L4-l5 degenerative disk	2001 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2004 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2005 - Ongoing
Seasonal allergy	Seasonal allergies	2006 - Ongoing
Barrett's oesophagus	Barretts esophagust	2010 - Ongoing
Gastrooesophageal reflux disease	Reflux disease	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Back pain	Back pain	Oct 2017 - Ongoing
Herpes zoster	Shingles	Oct 2017 - Nov 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	2004 - Ongoing	Anxiety
Methylphenidate	2005 - Ongoing	Attention Deficit Disorder
Omeprazole	2010 - Ongoing	Reflux Disease
Naproxen	11 Aug 2020 (Study Day -3) - Ongoing	Back Pain
Eszopiclone	13 Aug 2020 (Study Day -1) - Ongoing	Insomnia
Prednisone	04 Sep 2020 (Study Day 22) - 09 Sep 2020 (Study Day 27)	Shingles
Valaciclovir	04 Sep 2020 (Study Day 22) - 14 Sep 2020 (Study Day 32)	Shingles

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Zoster	Grade 1/mild	Not related	04 Sep 2020 (Study Day 22) - 21 Sep 2020 (Study Day 39)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2103 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression/Worsening Depression	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	03 Sep 2020 (Study Day 15) – 12 Oct 2020 (Study Day 54)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2103, a 51-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Sep 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of depression. On 16 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening depression lasted for 40 days, after which it was considered to be recovered/resolved on 12 Oct 2020 (Study Day 54). The investigator assessed the event of depression to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Intervertebral disc degeneration	Degenerative disc disease	Not reported - Ongoing
Headache	Headaches	1980 - Ongoing
Female sterilisation	Tubal ligation	Dec 1994 - Dec 1994
Depression	Depression	2001 - Ongoing
Drug hypersensitivity	Allergy to morphine	2003 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2006 - Ongoing
Hysterectomy	Hysterectomy	Aug 2008 - Aug 2008
Seasonal allergy	Seasonal allergies	2012 - Ongoing
Anxiety	Anxiety with heights	2017 - Ongoing
Gastrooesophageal reflux disease	Bile reflux	2017 - Ongoing
Intervertebral disc operation	Cervical discs replaced	2018 - May 2019
Irritable bowel syndrome	Irritable bowel syndrome	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion hydrochloride	2004 - Ongoing	Depression
Salbutamol	2012 - Ongoing	Seasonal Allergies
Triamcinolone acetonide	2012 - Ongoing	Seasonal Allergies
Vitamin b nos	2016 - Ongoing	Health Promotion
Lorazepam	2017 - Ongoing	Anxiety With Heights
Dicycloverine	2018 - Ongoing	Irritable Bowel Syndrome
Paracetamol	19 Aug 2020 (Study Day -1) - Ongoing	Headaches And Degenerative Disc Disease
Sertraline hydrochloride	28 Sep 2020 (Study Day 40) - Ongoing	Depression
Famotidine	05 Oct 2020 (Study Day 47) - Ongoing	Bile Reflux
Levothyroxine	27 Oct 2020 (Study Day 69) - Ongoing	Hypothyroidism
Influenza vaccine	28 Oct 2020 (Study Day 70) - 28 Oct 2020 (Study Day 70)	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Depression	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 15) - 12 Oct 2020 (Study Day 54)
Vitreous Floaters	Grade 2/moderate	Not related	08 Jan 2021 (Study Day 142) - 12 Feb 2021 (Study Day 177)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2140 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Retinal Detachment/Retinal Detachment Of Left Eye	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	08 Sep 2020 (Study Day 18) – 12 Sep 2020 (Study Day 22)	Recovered/resolved
Retinal Tear/Horseshoe Tear Of Right Eye	SAE	Grade 3/ severe	Not related	01 Oct 2020 (Study Day 41) – 06 Oct 2020 (Study Day 46)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2140, a 59-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 22 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 18), 17 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of retinal detachment. On 18 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of retinal detachment of left eye lasted for 5 days, after which it was considered to be recovered/resolved on 12 Sep 2020 (Study Day 22). The investigator assessed the event of retinal detachment to be not related to the IP.

On 01 Oct 2020 (Study Day 41), 40 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of retinal tear. On 18 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of horseshoe tear of right eye lasted for 6 days, after which it was considered to be recovered/resolved on 06 Oct 2020 (Study Day 46). The investigator assessed the event of retinal tear to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000277	Retinal detachment
MOD-2020-000407	Retinal tear

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract	Left eye cataract	Not reported - Ongoing
Cholelithiasis	Cholelithiasis	Not reported - 1999
Intervertebral disc protrusion	Herniated discs l3-l5	Not reported - Jan 2019
Anaemia	Borderline anemia	1979 - Ongoing
Corneal implant	Bilateral corneal intacs	1994 - Ongoing
Cholecystectomy	Cholestectomy	1999 - 1999
Gastric bypass	Elective gastric bypass surgery	2000 - 2000
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Sjogren's syndrome	Sjogren's syndrome	2004 - Ongoing
Mixed connective tissue disease	Mixed connective disease	Sep 2004 - Ongoing
Raynaud's phenomenon	Raynaud's disease	Sep 2004 - Ongoing
Fibromyalgia	Fibromyelgia	2008 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Oedema	Bilateral pitting edema	2012 - Ongoing
Menopause	Menopause	2013 - 2013
Insomnia	Insomnia	2015 - Ongoing
Rheumatoid arthritis	Generalized rheumatoid arthritis	2015 - Ongoing
Knee arthroplasty	Left knee replacement secondary to rheumatoid arthritis	2018 - 2018
Thrombophlebitis	Thrombophlebitis	2018 - 2019
Spinal fusion surgery	Spinal fusion	Jan 2019 - Jan 2019
Anxiety	Anxiety	Apr 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	Not reported - Ongoing	Hypertension
Diphenhydramine hydrochloride	2000 - Ongoing	Seasonal Allergies
Vitamins nos	2000 - Ongoing	Health Promotion
Pilocarpine	2004 - Ongoing	Sjogren's Syndome
Milnacipran hydrochloride	2008 - Ongoing	Fibromyalgia
Cyclobenzaprine	2010 - Ongoing	Muscle Pain Due To Fibromyalgia
Bumetanide	2012 - Ongoing	Hypertension
Nifedipine	2013 - Ongoing	Hypertension
Celecoxib	2015 - Ongoing	Rheumatoid
Zolpidem	2015 - Ongoing	Insomnia
Bupropion hydrochloride	09 Sep 2020 (Study Day 19) - Ongoing	Anxiety
Left eye vitrectomy membranectomy [retinal detachment repair]*	11 Sep 2020 (Study Day 21) - 11 Sep 2020 (Study Day 21)	Adverse Event
Moxifloxacin	11 Sep 2020 (Study Day 21) - 18 Sep 2020 (Study Day 28)	Retinal Detachment
Prednisolone acetate	11 Sep 2020 (Study Day 21) - Ongoing	Retinal Detachment
Cyclopentolate	12 Sep 2020 (Study Day 22) - Ongoing	Retinal Detachment
Ibuprofen	01 Oct 2020 (Study Day 41) - 02 Oct 2020 (Study Day 42)	Eye Pain Related To Eye Procedure
Laser photocoagulation repair of right retinal horseshoe tear*	01 Oct 2020 (Study Day 41) - 01 Oct 2020 (Study Day 41)	Adverse Event
Cryotherapy of right eye*	06 Oct 2020 (Study Day 46) - 06 Oct 2020 (Study Day 46)	Adverse Event
Cyclopentolate	06 Oct 2020 (Study Day 46) - 06 Oct 2020 (Study Day 46)	Cryotherapy Of Right Eye
Phenylephrine	06 Oct 2020 (Study Day 46) - 06 Oct 2020 (Study Day 46)	Cryotherapy Of Right Eye
Tropicamide	06 Oct 2020 (Study Day 46) - 06 Oct 2020 (Study Day 46)	Cryotherapy Of Right Eye
Influenza vaccine	17 Nov 2020 (Study Day 88) - 17 Nov 2020 (Study Day 88)	Influenza Prophylaxis
Leflunomide	19 Nov 2020 (Study Day 90) - Ongoing	Rheumatoid Arthritis
Prednisone	26 Nov 2020 (Study Day 97) - 02 Dec 2020 (Study Day 103)	Fibromyalgia
Prednisone	04 Dec 2020 (Study Day 105) - 09 Dec 2020 (Study Day 110)	Fibromyalgia
Prednisone	10 Dec 2020 (Study Day 111) - 16 Dec 2020 (Study Day 117)	Fibromyalgia
Prednisone	17 Dec 2020 (Study Day 118) - 23 Dec 2020 (Study Day 124)	Fibromyalgia
Diclofenac	24 Dec 2020 (Study Day 125) - 12 Jan 2021 (Study Day 144)	Lower Back Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone hydrochloride; paracetamol	24 Dec 2020 (Study Day 125) - 27 Dec 2020 (Study Day 128)	Lower Back Pain
Codeine phosphate; paracetamol	26 Jan 2021 (Study Day 158) - 27 Jan 2021 (Study Day 159)	Intraocular Silicone Implant Removal - Left Eye
Intraocular silicone implant removal - left eye*	26 Jan 2021 (Study Day 158) - 26 Jan 2021 (Study Day 158)	Adverse Event
Left eye cataract implant*	26 Mar 2021 (Study Day 217) - 26 Mar 2021 (Study Day 217)	Medical History
Meloxicam	26 Mar 2021 (Study Day 217) - Ongoing	Left Eye Cataract Implant
Nepafenac	26 Mar 2021 (Study Day 217) - Ongoing	Left Eye Cataract Implant
Prednisone	26 Mar 2021 (Study Day 217) - Ongoing	Left Eye Cataract Implant

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fibromyalgia	Grade 2/moderate	Not related	26 Nov 2020 (Study Day 97) - 04 Jan 2021 (Study Day 136)
Back Pain	Grade 2/moderate	Not related	24 Dec 2020 (Study Day 125) - 04 Jan 2021 (Study Day 136)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2189 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cauda Equina Syndrome/ Cauda Equina Syndrome	SAE	Grade 4	Not related	20 Dec 2020 (Study Day 117) – 24 Dec 2020 (Study Day 121)	Recovered/resolved
Wound Dehiscence/ Laminectomy Wound Dehiscence	SAE	Grade 4	Not related	26 Jan 2021 (Study Day 154) – 27 Jan 2021 (Study Day 155)	Recovered/resolved
Spinal Cord Compression/ Spinal Compression L5/S1	SAE	Grade 4	Not related	04 Feb 2021 (Study Day 163) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2189, a 21-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Dec 2020 (Study Day 117), 116 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of cauda equina syndrome. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of cauda equina syndrome lasted for 5 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 121). The investigator assessed the event of cauda equina syndrome to be not related to the IP.

On 26 Jan 2021 (Study Day 154), 153 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of wound dehiscence. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of laminectomy wound dehiscence lasted for 2 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 155). The investigator assessed the event of wound dehiscence to be not related to the IP.

On 04 Feb 2021 (Study Day 163), 162 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of spinal cord

compression. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of spinal compression l5/s1 was considered to be ongoing. The investigator assessed the event of spinal cord compression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001247	Cauda equina syndrome
MOD-2021-010325	Spinal cord compression
MOD-2021-010325	Wound dehiscence
MOD-2021-010325	Urinary incontinence

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Dysmenorrhoea	Dysmenorrhea	Not reported - Ongoing
Rubber sensitivity	Latex allergy	(b) (6) 1999 (Study Day(b) (6) - Ongoing
Asthma	Asthma	2002 - Ongoing
Migraine	Migraines	2004 - Ongoing
Eczema	Eczema	2007 - 2015
Depression	Depression	2010 - Ongoing
Cholecystitis	Cholecystitis	2017 - 2019
Anaemia	Anemia	2018 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Sinus operation	Sinus surgery	2018 - 2018
Concussion	Concussion	Jul 2018 - Jul 2018
Kidney infection	Kidney infection	Oct 2019 - Oct 2019
Obesity	Severe obesity	2020 - Ongoing
Cholecystectomy	Cholecystectomy	Mar 2020 - Mar 2020
Drug hypersensitivity	Nsaids allergy	Mar 2020 - Ongoing
Gastric bypass	Gastric bypass surgery	Mar 2020 - Mar 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ipratropium bromide; salbutamol sulfate	Not reported - Ongoing	Asthma
Loratadine	Not reported - Ongoing	Asthma
Salbutamol sulfate	2002 - Ongoing	Asthma
Colecalciferol	2013 - 26 Jan 2021 (Study Day 154)	Health
Bupropion hydrochloride	2016 - Ongoing	Depression
Fremanezumab	2018 - 26 Jan 2021 (Study Day 154)	Migraines
Lorazepam	2018 - Ongoing	Anxiety
Topiramate	2018 - 26 Jan 2021 (Study Day 154)	Migraines
Iron	2019 - 26 Jan 2021 (Study Day 154)	Anemia
Calcium	Mar 2020 - 26 Jan 2021 (Study Day 154)	Health
Vitamins nos	Mar 2020 - 26 Jan 2021 (Study Day 154)	Health
Ethinylestradiol; norgestimate	May 2020 - Ongoing	Birth Control Pills
Paracetamol	27 Aug 2020 (Study Day 2) - 01 Sep 2020 (Study Day 7)	Temperature Of 99.1-99.9, Pain At Injection Site, Headache
Paracetamol	02 Sep 2020 (Study Day 8) - 02 Oct 2020 (Study Day 38)	Headache, Ipsilateral Axillary Lymphadenopathy, Body Aches
Levofloxacin	09 Sep 2020 (Study Day 15) - 15 Sep 2020 (Study Day 21)	Sinus Infection
Guaifenesin	01 Oct 2020 (Study Day 37) - 02 Oct 2020 (Study Day 38)	Nasal Congestion
Prednisone	02 Oct 2020 (Study Day 38) - 04 Oct 2020 (Study Day 40)	Nasal Congestion
Bisacodyl	06 Oct 2020 (Study Day 42) - 07 Oct 2020 (Study Day 43)	Constirpation
Macrogol 3350	06 Oct 2020 (Study Day 42) - 07 Oct 2020 (Study Day 43)	Constipation
Ondansetron	07 Oct 2020 (Study Day 43) - 24 Dec 2020 (Study Day 121)	Nausea
Nitrofurantoin	19 Oct 2020 (Study Day 55) - 28 Oct 2020 (Study Day 64)	Urinary Tract Infection
Hydrocodone bitartrate; paracetamol	05 Nov 2020 (Study Day 72) - 26 Jan 2021 (Study Day 154)	Left Meniscus Tear Repair
Left knee meniscus tear repair*	05 Nov 2020 (Study Day 72) - 05 Nov 2020 (Study Day 72)	Adverse Event
Tramadol	05 Nov 2020 (Study Day 72) - 26 Jan 2021 (Study Day 154)	Left Meniscus Tear Repair
Gabapentin	15 Nov 2020 (Study Day 82) - Ongoing	Left Meniscus Tear Repair And Back Injury L5, Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Influenza vaccine	19 Nov 2020 (Study Day 86) - 19 Nov 2020 (Study Day 86)	Influenza Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocortisone	23 Nov 2020 (Study Day 90) - 23 Nov 2020 (Study Day 90)	L5 Back Injury
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	27 Nov 2020 (Study Day 94) - 13 Dec 2020 (Study Day 110)	Rhinorrhea, Headache
Guaifenesin	27 Nov 2020 (Study Day 94) - 12 Dec 2020 (Study Day 109)	Cough
Hydrocortisone	07 Dec 2020 (Study Day 104) - 07 Dec 2020 (Study Day 104)	L5 Back Injury
Laminectomy (l5, s1, partial s2)*	21 Dec 2020 (Study Day 118) - 21 Dec 2020 (Study Day 118)	Adverse Event
Amitriptyline	24 Dec 2020 (Study Day 121) - 27 Jan 2021 (Study Day 155)	Laminectomy, Laminectomy Wound Dehiscence
Benzoyl peroxide; clindamycin	24 Dec 2020 (Study Day 121) - Ongoing	Laminectomy, Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Bisacodyl	24 Dec 2020 (Study Day 121) - Ongoing	Laminectomy, Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Clindamycin	24 Dec 2020 (Study Day 121) - 31 Dec 2020 (Study Day 128)	Laminectomy, Bacterial Vaginosis
Cyclobenzaprine	24 Dec 2020 (Study Day 121) - Ongoing	Laminectomy, Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Dicycloverine	24 Dec 2020 (Study Day 121) - Ongoing	Laminectomy, Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Docusate; senna alexandrina	24 Dec 2020 (Study Day 121) - Ongoing	Laminectomy, Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Enoxaparin sodium	24 Dec 2020 (Study Day 121) - 22 Feb 2021 (Study Day 181)	Thrombosis Prophylaxis
Ondansetron	24 Dec 2020 (Study Day 121) - Ongoing	Laminectomy, Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Oxycodone hydrochloride	24 Dec 2020 (Study Day 121) - 26 Jan 2021 (Study Day 154)	Laminectomy
Paracetamol	24 Dec 2020 (Study Day 121) - 26 Jan 2021 (Study Day 154)	Laminectomy
Sucralfate	24 Dec 2020 (Study Day 121) - Ongoing	Ulcer Prophylaxis
Laminectomy wound debridement and irrigation*	27 Jan 2021 (Study Day 155) - 27 Jan 2021 (Study Day 155)	Adverse Event
Laminectomy wound vacuum*	27 Jan 2021 (Study Day 155) - 27 Jan 2021 (Study Day 155)	Adverse Event
Picc [peripherally inserted central catheter] line*	27 Jan 2021 (Study Day 155) - 27 Jan 2021 (Study Day 155)	Adverse Event
Vancomycin	27 Jan 2021 (Study Day 155) - 04 Feb 2021 (Study Day 163)	Laminectomy Wound Dehiscence
Baclofen	01 Feb 2021 (Study Day 160) - 12 Feb 2021 (Study Day 171)	Laminectomy Wound Dehiscence, Spinal Decompression L5/S1

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bethanechol	01 Feb 2021 (Study Day 160) - 08 Feb 2021 (Study Day 167)	Laminectomy Wound Dehiscence
Calcium carbonate	01 Feb 2021 (Study Day 160) - Ongoing	Health
Ferrous sulfate	01 Feb 2021 (Study Day 160) - Ongoing	Health
Fremanezumab	01 Feb 2021 (Study Day 160) - Ongoing	Migraines
Heparin	01 Feb 2021 (Study Day 160) - 23 Feb 2021 (Study Day 182)	Picc [peripherally Inserted Central Catheter] Line
Iron; vitamins nos	01 Feb 2021 (Study Day 160) - Ongoing	Health
Macrogol 3350	01 Feb 2021 (Study Day 160) - Ongoing	Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Pantoprazole sodium sesquihydrate	01 Feb 2021 (Study Day 160) - Ongoing	Ulcer Prophylaxis
Paracetamol	01 Feb 2021 (Study Day 160) - Ongoing	Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Sodium chloride	01 Feb 2021 (Study Day 160) - 23 Feb 2021 (Study Day 182)	Picc [peripherally Inserted Central Catheter] Line
Tamsulosin	01 Feb 2021 (Study Day 160) - 08 Feb 2021 (Study Day 167)	Laminectomy Wound Dehiscence
Topiramate	01 Feb 2021 (Study Day 160) - Ongoing	Migraines
Triamcinolone acetonide	01 Feb 2021 (Study Day 160) - Ongoing	Laminectomy Wound Dehiscence, Spinal Decompression L5/S1
Vitamin d nos	01 Feb 2021 (Study Day 160) - Ongoing	Health
Cyanocobalamin	02 Feb 2021 (Study Day 161) - Ongoing	Health
Hemovac placement*	05 Feb 2021 (Study Day 164) - 05 Feb 2021 (Study Day 164)	Adverse Event
L5/s1 wound vacuum*	05 Feb 2021 (Study Day 164) - 05 Feb 2021 (Study Day 164)	Adverse Event
Spinal decompression l5/s1*	05 Feb 2021 (Study Day 164) - 05 Feb 2021 (Study Day 164)	Adverse Event
Bethanechol	09 Feb 2021 (Study Day 168) - 15 Feb 2021 (Study Day 174)	Spinal Compression L5/S1
Iron; vitamins nos	09 Feb 2021 (Study Day 168) - Ongoing	Health
Tamsulosin	09 Feb 2021 (Study Day 168) - 15 Feb 2021 (Study Day 174)	Spinal Compression L5/S1
Tramadol	09 Feb 2021 (Study Day 168) - Ongoing	Spinal Decompression L5/S1
Vancomycin	09 Feb 2021 (Study Day 168) - 23 Feb 2021 (Study Day 182)	Spinal Decompression L5/S1
Doxycycline	23 Feb 2021 (Study Day 182) - 31 Mar 2021 (Study Day 218)	Spinal Decompression L5/S1
Picc [peripherally inserted central catheter] removal*	23 Feb 2021 (Study Day 182) - 23 Feb 2021 (Study Day 182)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	27 Aug 2020 (Study Day 2) - 15 Sep 2020 (Study Day 21)
Headache	Grade 2/moderate	Related	27 Aug 2020 (Study Day 2) - 17 Sep 2020 (Study Day 23)
Myalgia	Grade 1/mild	Related	27 Aug 2020 (Study Day 2) - 15 Sep 2020 (Study Day 21)
Lymphadenopathy	Grade 1/mild	Related	28 Aug 2020 (Study Day 3) - 05 Sep 2020 (Study Day 11)
Chills	Grade 1/mild	Related	01 Sep 2020 (Study Day 7) - 06 Sep 2020 (Study Day 12)
Chest Discomfort	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 9) - 07 Sep 2020 (Study Day 13)
Dyspnoea	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 9) - 07 Sep 2020 (Study Day 13)
Sinusitis	Grade 2/moderate	Not related	05 Sep 2020 (Study Day 11) - 15 Sep 2020 (Study Day 21)
Cough	Grade 1/mild	Not related	07 Sep 2020 (Study Day 13) - 07 Sep 2020 (Study Day 13)
Pain	Grade 1/mild	Not related	07 Sep 2020 (Study Day 13) - 07 Sep 2020 (Study Day 13)
Constipation	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 28) - 07 Oct 2020 (Study Day 43)
Cough	Grade 1/mild	Not related	25 Sep 2020 (Study Day 31) - 01 Oct 2020 (Study Day 37)
Headache	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 31) - 06 Oct 2020 (Study Day 42)
Nasal Congestion	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 31) - 07 Oct 2020 (Study Day 43)
Oropharyngeal Pain	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 31) - 02 Oct 2020 (Study Day 38)
Pain	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 31) - 10 Oct 2020 (Study Day 46)
Rhinorrhoea	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 31) - 07 Oct 2020 (Study Day 43)
Concussion	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 43) - 01 Apr 2021 (Study Day 219)
Dizziness	Grade 1/mild	Not related	07 Oct 2020 (Study Day 43) - 01 Apr 2021 (Study Day 219)
Nausea	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 43) - 01 Apr 2021 (Study Day 219)
Urinary Tract Infection	Grade 2/moderate	Not related	16 Oct 2020 (Study Day 52) - 28 Oct 2020 (Study Day 64)
Meniscus Injury	Grade 3/severe	Not related	27 Oct 2020 (Study Day 63) - 05 Nov 2020 (Study Day 72)
Spinal Column Injury	Grade 2/moderate	Not related	05 Nov 2020 (Study Day 72) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 2/moderate	Not related	27 Nov 2020 (Study Day 94) - 13 Dec 2020 (Study Day 110)
Fatigue	Grade 1/mild	Not related	27 Nov 2020 (Study Day 94) - 29 Dec 2020 (Study Day 126)
Headache	Grade 2/moderate	Not related	27 Nov 2020 (Study Day 94) - 13 Dec 2020 (Study Day 110)
Rhinorrhoea	Grade 1/mild	Not related	27 Nov 2020 (Study Day 94) - 29 Dec 2020 (Study Day 126)
Myalgia	Grade 1/mild	Not related	06 Dec 2020 (Study Day 103) - 15 Dec 2020 (Study Day 112)
Pain	Grade 1/mild	Not related	06 Dec 2020 (Study Day 103) - 15 Dec 2020 (Study Day 112)
Urinary Incontinence	Grade 3/severe	Not applicable	19 Dec 2020 (Study Day 116) - 24 Dec 2020 (Study Day 121)
Bacterial Vaginosis	Grade 2/moderate	Not applicable	20 Dec 2020 (Study Day 117) - 24 Dec 2020 (Study Day 121)
Urinary Retention	Grade 3/severe	Not related	04 Feb 2021 (Study Day 163) - 09 Feb 2021 (Study Day 168)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2273 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Worsening Hypertension	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	01 Sep 2020 (Study Day 1) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2273, a 52-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Sep 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of hypertension. On 28 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening hypertension was considered to be ongoing. The investigator assessed the event of hypertension to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 01 Mar 2021 (Study Day 182), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1990 - Ongoing
Bronchitis	Bronchitis	2000 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Generalised anxiety disorder	General anxiety disorder	2000 - Ongoing
Lithotripsy	Lithotripsy	2003 - 2003
Nephrolithiasis	Renal calculi	2003 - 2003
Sleep apnoea syndrome	Sleep apnea	Apr 2009 - Apr 2009
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; lisinopril	1990 - Ongoing	Hypertension
Alprazolam	2000 - Ongoing	Anxiety And Tachycardia And Worsening Hypertension
Emtricitabine; tenofovir alafenamide fumarate	2019 - Ongoing	Hiv Prophylaxis
Omeprazole	2019 - Ongoing	Gastroesophageal Reflux Disease
Vitamins nos	Mar 2020 - Ongoing	Health Promotion
Influenza vaccine	16 Oct 2020 (Study Day 46) - 16 Oct 2020 (Study Day 46)	Influenza Prophylaxis
Metronidazole	10 Feb 2021 (Study Day 163) - 14 Feb 2021 (Study Day 167)	Diarrhea
Other viral vaccines	01 Mar 2021 (Study Day 182) - 01 Mar 2021 (Study Day 182)	COVID-19 Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 3/severe	Not related	01 Sep 2020 (Study Day 1) - Ongoing
Tachycardia	Grade 1/mild	Not related	01 Sep 2020 (Study Day 1) - Ongoing
Diarrhoea	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 161) - 14 Feb 2021 (Study Day 167)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US355-2331 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression/Worsening Depression	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	14 Sep 2020 (Study Day 11) – 01 Oct 2020 (Study Day 28)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2331, a 44-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Sep 2020 (Study Day 11), 10 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of depression. On 01 Oct 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of worsening depression lasted for 18 days, after which it was considered to be recovered/resolved on 01 Oct 2020 (Study Day 28). The investigator assessed the event of depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000318	Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eczema	Eczema	1981 - Ongoing
Drug hypersensitivity	Augmentin allergy	1989 - Ongoing
Headache	Headache	1996 - Ongoing
Seasonal allergy	Seasonal allergy	2001 - Ongoing
Anxiety	Airplane flight anxiety	2006 - Ongoing
Depression	Depression	2008 - Ongoing
Obesity	Obesity	2008 - 2009
Gastrectomy	Gastric sleeve	2009 - 2009
Menorrhagia	Menorrhagia	Jan 2018 - Jun 2019
Endometrial ablation	Uterine ablation	Jun 2019 - Jun 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	01 Jun 2018 (Study Day -826) - Ongoing	Health Promotion
Magnesium	01 Jun 2018 (Study Day -826) - Ongoing	Health Promotion
Potassium	01 Jun 2018 (Study Day -826) - Ongoing	Health Promotion
Vitamins nos	01 Jun 2018 (Study Day -826) - Ongoing	Health Promotion
Drospirenone; ethinylestradiol	01 Jun 2019 (Study Day -461) - Ongoing	Birth Control
Trazodone	14 Sep 2020 (Study Day 11) - 14 Sep 2020 (Study Day 11)	Worsening Depression
Escitalopram oxalate	16 Sep 2020 (Study Day 13) - 21 Sep 2020 (Study Day 18)	Worsening Depression
Venlafaxine hydrochloride	24 Sep 2020 (Study Day 21) - Ongoing	Worsening Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US355-2371 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hepatic Enzyme Increased/ Elevated Liver Enzymes	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	16 Sep 2020 (Study Day 9) – 17 Dec 2020 (Study Day 101)	Recovered/resolved
Renal Cell Carcinoma/ Right Kidney Renal Cell Carcinoma	SAE	Grade 4	Not related	08 Oct 2020 (Study Day 31) – 13 Nov 2020 (Study Day 67)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2371, a 56-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of hepatic enzyme increased. On 05 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of elevated liver enzymes lasted for 93 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 101). The investigator assessed the event of hepatic enzyme increased to be not related to the IP.

On 08 Oct 2020 (Study Day 31), 30 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of renal cell carcinoma. On 05 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of right kidney renal cell carcinoma lasted for 37 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 67). The investigator assessed the event of renal cell carcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000842	Renal cell carcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pain in jaw	Temporomandipular jaw pain, left jaw	1982 - Ongoing
Mitral valve incompetence	Mitral regurgitation	1995 - Apr 1995
Mitral valve repair	Mitral valve repair	Apr 1995 - Apr 1995
Autoimmune thyroiditis	Hypothyroid/hashimotos	May 1995 - Ongoing
Drug hypersensitivity	Sulfa allergy	2001 - Ongoing
Myalgia	Generalized muscle soreness	2012 - Ongoing
Seasonal allergy	Seasonal allergies	2012 - Ongoing
Menopause	Menopause	2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Oct 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	1995 - 05 Sep 2020 (Study Day -3)	Muscle Soreness
Levothyroxine	May 1995 - Ongoing	Hypothyroid
Colecalciferol	Sep 2017 - Ongoing	Health Promotion
Magnesium	Sep 2017 - Ongoing	Health Promotion
Zinc	Sep 2017 - Ongoing	Health Promotion
Calcium	2018 - 21 Sep 2020 (Study Day 14)	Health
Atorvastatin	Oct 2018 - 24 Sep 2020 (Study Day 17)	Hyperlipidemia
Gabapentin	16 Sep 2020 (Study Day 9) - 21 Sep 2020 (Study Day 14)	Fractured Ankle
Oxycodone hydrochloride; paracetamol	16 Sep 2020 (Study Day 9) - 21 Sep 2020 (Study Day 14)	Fractured Ankle
Abdominal ultrasound*	08 Oct 2020 (Study Day 31) - 08 Oct 2020 (Study Day 31)	Adverse Event
Escitalopram oxalate	22 Oct 2020 (Study Day 45) - Ongoing	Anxiety

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	22 Oct 2020 (Study Day 45) - 22 Oct 2020 (Study Day 45)	Influenza Prophylaxis
Electrolytes nos	12 Nov 2020 (Study Day 66) - 13 Nov 2020 (Study Day 67)	Partial Nephrectomy
Morphine	12 Nov 2020 (Study Day 66) - 13 Nov 2020 (Study Day 67)	Partial Nephrectomy Pain
Partial nephrectomy of right kidney*	12 Nov 2020 (Study Day 66) - 12 Nov 2020 (Study Day 66)	Adverse Event
Oxycodone hydrochloride; paracetamol	13 Nov 2020 (Study Day 67) - 17 Nov 2020 (Study Day 71)	Partial Nephrectomy
Amoxicillin	11 Jan 2021 (Study Day 126) - 11 Jan 2021 (Study Day 126)	Dental Procedure Prophylaxis
Dental procedure*	11 Jan 2021 (Study Day 126) - 11 Jan 2021 (Study Day 126)	Other, Routine Dental Cleaning

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Ankle Fracture	Grade 3/severe	Not related	16 Sep 2020 (Study Day 9) - 19 Nov 2020 (Study Day 73)
Hepatic Enzyme Increased	Grade 3/severe	Not related	16 Sep 2020 (Study Day 9) - 17 Dec 2020 (Study Day 101)
Anxiety	Grade 1/mild	Not related	22 Oct 2020 (Study Day 45) - 29 Oct 2020 (Study Day 52)

Preferred terms are coded using MedDRA version 23.0.

vParticipant Number:	US355-2473 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	19 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	14 Oct 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Perirectal Abscess/Perirectal Abscess	SAE	Grade 4	Not related	22 Nov 2020 (Study Day 65) – 01 Dec 2020 (Study Day 74)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2473, a 53-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Nov 2020 (Study Day 65), 64 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of perirectal abscess. Action taken with the IP was not applicable. The event of perirectal abscess lasted for 10 days, after which it was considered to be recovered/resolved on 01 Dec 2020 (Study Day 74). The investigator assessed the event of perirectal abscess to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001030	Perirectal abscess

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	Not reported - Ongoing
Gonorrhoea	Gonorrhea	Not reported
Syphilis	Syphillis	Not reported
Drug hypersensitivity	Allergy to codeine	1985 - Ongoing
Anxiety	Anxiety	1996 - Ongoing
Major depression	Major clinical depression	1996 - Ongoing
HIV infection	Human immunodificiency virus	1997 - Ongoing
Hepatitis C	Hepatitis c	1997 - 2010
Hepatic enzyme increased	Elevated liver enzymes	2010 - Ongoing
Hypersensitivity	Indoor allergies	2010 - Ongoing
Periorbital cellulitis	Bilateral periorbital cellutlitis	Jan 2013 - 2013
Mastoiditis	Bilateral mastoiditis	Nov 2018 - Nov 2018
Pulmonary embolism	Pulmonary embolus	Nov 2018 - Nov 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	1995 - Ongoing	Health Promotion
Vitamins nos	1995 - Ongoing	Health Promotion
Bupropion	2014 - Ongoing	Major Clinical Depression
Clonazepam	2014 - Ongoing	Anxiety
Ibuprofen	2015 - Ongoing	Generalized Aches
Bictegravir sodium; emtricitabine; tenofovir alafenamide fumarate	2017 - Ongoing	Human Immunodeficiency Virus
Bupropion	Feb 2020 - Ongoing	Anxiety
Tiotropium	13 Oct 2020 (Study Day 25) - Ongoing	Chronic Obstructive Pulmonary Disease
Varenicline	14 Oct 2020 (Study Day 26) - 28 Oct 2020 (Study Day 40)	Smoking Cessation
Influenza vaccine	30 Oct 2020 (Study Day 42) - 30 Oct 2020 (Study Day 42)	Influenza Prophylactic
Calcium chloride; potassium chloride; sodium lactate	24 Nov 2020 (Study Day 67) - 25 Nov 2020 (Study Day 68)	Perirectal Abscess
Ceftriaxone	24 Nov 2020 (Study Day 67) - 24 Nov 2020 (Study Day 67)	Perirectal Abscess
Morphine	24 Nov 2020 (Study Day 67) - 25 Nov 2020 (Study Day 68)	Perirectal Abscess

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Piperacillin sodium; tazobactam sodium	24 Nov 2020 (Study Day 67) - 24 Nov 2020 (Study Day 67)	Perirectal Abscess
Ciprofloxacin	25 Nov 2020 (Study Day 68) - 01 Dec 2020 (Study Day 74)	Perirectal Abscess
Incision and drainage of perirectal abscess*	25 Nov 2020 (Study Day 68) - 25 Nov 2020 (Study Day 68)	Adverse Event
Metronidazole	25 Nov 2020 (Study Day 68) - 01 Dec 2020 (Study Day 74)	Perirectal Abscess
Amantadine hydrochloride	25 Mar 2021 (Study Day 188) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US355-2499 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Oesophageal Spasm/Non-Cardiac Chest Pain Related To Esophageal Spasm	SAE	Grade 4	Not related	06 Dec 2020 (Study Day 72) – 07 Dec 2020 (Study Day 73)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US355-2499, a 73-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 26 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Dec 2020 (Study Day 72), 71 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of oesophageal spasm. On 23 Oct 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of non-cardiac chest pain related to esophageal spasm lasted for 2 days, after which it was considered to be recovered/resolved on 07 Dec 2020 (Study Day 73). The investigator assessed the event of oesophageal spasm to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001046	Oesophageal spasm

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy	1957 - Ongoing
Depression	Depression	1985 - Ongoing
Postmenopause	Post menopausal	1986 - Ongoing
Nephrolithiasis	Kidney stone	2006 - 2006
Gastrooesophageal reflux disease	Gastric reflux	2013 - Ongoing
Arteriosclerosis	Arteriosclerosis	2018 - Ongoing
Drug hypersensitivity	Steroid allergy	2018 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Sinusitis	Sinus infection	Feb 2018 - Feb 2018
Deafness bilateral	Bilateral hearing loss	Nov 2018 - Ongoing
Headache	Headaches	Aug 2020 - Ongoing
Pain in extremity	Right leg pain	17 Sep 2020 (Study Day -9) - 17 Sep 2020 (Study Day -9)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Coagulation Prophylaxis
Ascorbic acid	2010 - Ongoing	Health Promotion
Colecalciferol	2010 - Ongoing	Health Promotion
Herbal pollen nos	2010 - Ongoing	Health Promotion
Omega-3 nos	2010 - Ongoing	Health Promotion
Probiotics nos	2010 - Ongoing	Health Promotion
Selenium	2010 - Ongoing	Health Promotion
Ubidecarenone	2010 - Ongoing	Health Promotion
Vitamin b complex	2010 - Ongoing	Health Promotion
Vitamin e nos	2010 - Ongoing	Health Promotion
Vitamins nos	2010 - Ongoing	Health Promotion
Zinc	2010 - Ongoing	Health Promotion
Ketorolac tromethamine	17 Sep 2020 (Study Day -9) - 17 Sep 2020 (Study Day -9)	Right Leg Pain
Famotidine	07 Dec 2020 (Study Day 73) - 21 Dec 2020 (Study Day 87)	Non Cardiac Chest Pain Related To Esophageal Spasm

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	27 Sep 2020 (Study Day 2) - 07 Oct 2020 (Study Day 12)
Fatigue	Grade 1/mild	Related	27 Sep 2020 (Study Day 2) - 06 Oct 2020 (Study Day 11)
Myalgia	Grade 1/mild	Related	27 Sep 2020 (Study Day 2) - 10 Oct 2020 (Study Day 15)
Pain In Extremity	Grade 2/moderate	Not related	21 Oct 2020 (Study Day 26) - 01 Dec 2020 (Study Day 67)
Fatigue	Grade 2/moderate	Related	22 Jan 2021 (Study Day 119) - Ongoing
Nausea	Grade 1/mild	Related	22 Jan 2021 (Study Day 119) - 31 Jan 2021 (Study Day 128)
Somnolence	Grade 1/mild	Related	22 Jan 2021 (Study Day 119) - 31 Jan 2021 (Study Day 128)
Cough	Grade 1/mild	Not related	29 Jan 2021 (Study Day 126) - 30 Jan 2021 (Study Day 127)
Myalgia	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 126) - 31 Jan 2021 (Study Day 128)
Nasal Congestion	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 126) - 31 Jan 2021 (Study Day 128)
Pain	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 126) - 31 Jan 2021 (Study Day 128)
Rhinorrhoea	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 126) - 31 Jan 2021 (Study Day 128)
Headache	Grade 2/moderate	Not related	30 Jan 2021 (Study Day 127) - 31 Jan 2021 (Study Day 128)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US356-2157 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	14 Oct 2020 (Study Day 34)
Reason for Narrative:	SAE, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colorectal Cancer/Colorectal Cancer	SAE, AE leading to study discontinuation	Grade 4	Not related	04 Nov 2020 (Study Day 55) – Ongoing	Not recovered/not resolved
Pelvic Neoplasm/Pelvic Cancer	SAE	Grade 4	Not related	04 Nov 2020 (Study Day 55) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US356-2157, a 62-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Nov 2020 (Study Day 55), 54 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of colorectal cancer. The IP dose was withdrawn due to the colorectal cancer. The event of colorectal cancer was considered to be ongoing. The investigator assessed the event of colorectal cancer to be not related to the IP.

On 04 Nov 2020 (Study Day 55), 54 days after the first dose and 21 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pelvic neoplasm. Action taken with the IP was not applicable. The event of pelvic cancer was considered to be ongoing. The investigator assessed the event of pelvic neoplasm to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000671	Pelvic neoplasm
MOD-2020-000671	Colorectal cancer

Study Completion/Discontinuation

On 02 Dec 2020 (Study Day 83), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	2008 - Ongoing
Migraine	Migraine headaches	2008 - Ongoing
Postmenopause	Post menopause	2008 - Ongoing
Menopausal symptoms	Post menopause syndrome	2010 - Ongoing
Osteoporosis	Osteoporosis	2015 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Folate deficiency	Folic acid deficiency	2019 - Ongoing
Abdominal pain lower	Right lower abdomen pain	Jan 2019 - Ongoing
Pelvic pain	Pelvic pain	Dec 2019 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Jun 2020 - Ongoing
Ovarian cyst	Benign bilateral ovarian complex cyst	27 Aug 2020 (Study Day -15) - Ongoing
Uterine leiomyoma	Fibroid uterus	27 Aug 2020 (Study Day -15) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	2008 - Ongoing	Insomnia
Melatonin	2008 - Ongoing	Insominia
Sumatriptan	2015 - Ongoing	Migraine
Alendronate sodium	2019 - Ongoing	Osteoporosis
Colecalciferol	2019 - Ongoing	Osteoporosis
Estradiol	2019 - Ongoing	Post Menopause Syndrome
Folic acid	2019 - Ongoing	Folic Acid Deficiency
Vitamin b12 nos	2019 - Ongoing	Nutritional Supplement
Paracetamol	12 Sep 2020 (Study Day 2) - 12 Sep 2020 (Study Day 2)	Headache
Progesterone	14 Sep 2020 (Study Day 4) - Ongoing	Post Menopause Syndrome
Aciclovir	28 Sep 2020 (Study Day 18) - 07 Oct 2020 (Study Day 27)	Shingles
Lidocaine	30 Sep 2020 (Study Day 20) - 05 Oct 2020 (Study Day 25)	Shingles

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	23 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 43)	Injection Site Pain
Influenza vaccine	30 Oct 2020 (Study Day 50) - 30 Oct 2020 (Study Day 50)	Flu Prophylaxis
Diagnostic laparoscopy*	04 Nov 2020 (Study Day 55) - 04 Nov 2020 (Study Day 55)	Adverse Event
Peritoneal wash*	04 Nov 2020 (Study Day 55) - 04 Nov 2020 (Study Day 55)	Adverse Event
Ct of abdomen with contrast*	05 Nov 2020 (Study Day 56) - 05 Nov 2020 (Study Day 56)	Adverse Event
Colorectal cytology*	06 Nov 2020 (Study Day 57) - 06 Nov 2020 (Study Day 57)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Zoster	Grade 2/moderate	Not related	17 Sep 2020 (Study Day 7) - 07 Oct 2020 (Study Day 27)
Injection Site Pain	Grade 1/mild	Related	23 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 43)
Atelectasis	Grade 2/moderate	Not related	05 Nov 2020 (Study Day 56) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US356-2205 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	01 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	29 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/Worsening Of Diverticulitis	SAE	Grade 4	Not related	20 Jan 2021 (Study Day 112) – 04 Feb 2021 (Study Day 127)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US356-2205, a 53-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 01 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 29 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Jan 2021 (Study Day 112), 111 days after the first dose and 83 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of diverticulitis. Action taken with the IP was not applicable. The event of worsening of diverticulitis lasted for 16 days, after which it was considered to be recovered/resolved on 04 Feb 2021 (Study Day 127). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-008079	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1970 - Ongoing
Endometrial ablation	Uterine ablation	2001 - 2004
Vaginal haemorrhage	Accessibe vaginal bleeding	2004 - 2004
Abdominal pain	Abdominal cramp pain	2010 - Ongoing
Constipation	Chronic constipation	2013 - Ongoing
Diverticulitis	Diverticulitis	2013 - Ongoing
Hypothyroidism	Hypothyroidism	2013 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2013 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2015 - Ongoing
Anxiety	Anxiety	2016 - Ongoing
Drug withdrawal headache	Headaches caffiene withdrawal	2017 - Ongoing
Ear infection	Left ear infection	07 Sep 2020 (Study Day -24) - 15 Sep 2020 (Study Day -16)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ergocalciferol	2013 - Ongoing	Vitamin D Deficiency
Levothyroxine	2013 - Ongoing	Hypothyroidism
Levothyroxine sodium	2014 - Ongoing	Hypothyroidism
Liothyronine	2014 - Ongoing	Hypothyroidism
Naproxen	2017 - Ongoing	Headache Caffeine Withdrawal
Cetirizine hydrochloride	2018 - Ongoing	Seasonal Allergies
Linaclotide	Jan 2020 - Ongoing	Chronic Consipation
Naproxen	Jan 2020 - Ongoing	Abdominal Cramp Pain
Alprazolam	Feb 2020 - Ongoing	Anxiety
Ibuprofen	Mar 2020 - Ongoing	Abdominal Cramp Pain
Ciprofloxacin	09 Sep 2020 (Study Day -22) - 15 Sep 2020 (Study Day -16)	Left Ear Infection
Influenza vaccine	15 Sep 2020 (Study Day -16) - 15 Sep 2020 (Study Day -16)	Flu Prophylaxis
Naproxen	01 Nov 2020 (Study Day 32) - 01 Nov 2020 (Study Day 32)	Body Aches
Naproxen	01 Nov 2020 (Study Day 32) - 01 Nov 2020 (Study Day 32)	Low Grade Fever/Fatigue/Injection Arm Pain
Ct scan*	21 Jan 2021 (Study Day 113) - 21 Jan 2021 (Study Day 113)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Abdominal x ray view*	22 Jan 2021 (Study Day 114) - 22 Jan 2021 (Study Day 114)	Adverse Event
Ciprofloxacin	22 Jan 2021 (Study Day 114) - 04 Feb 2021 (Study Day 127)	Worsening Diverticulitis
Metronidazole	22 Jan 2021 (Study Day 114) - 04 Feb 2021 (Study Day 127)	Worsening Of Diverticulitis
Amoxicillin	12 Mar 2021 (Study Day 163) - 26 Mar 2021 (Study Day 177)	Worsening Diverticulitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diverticulitis	Grade 2/moderate	Not related	19 Mar 2021 (Study Day 170) - 26 Mar 2021 (Study Day 177)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US356-2230 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	15 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Liver Abscess/Liver Abcess	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	07 Nov 2020 (Study Day 24) – 17 Nov 2020 (Study Day 34)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US356-2230, a 45-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 15 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Nov 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of liver abscess. On 11 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of liver abcess lasted for 11 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 34). The investigator assessed the event of liver abscess to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000710	Liver abscess

Study Completion/Discontinuation

On 20 Nov 2020 (Study Day 37), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1995 - Ongoing
Insomnia	Insomnia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine	2015 - Ongoing	Insomnia
Heparin	07 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 34)	Blood Clots Prophylaxis
Hydralazine	07 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 34)	Blood Pressure Prophylaxis
Influenza vaccine	07 Nov 2020 (Study Day 24) - 07 Nov 2020 (Study Day 24)	Flu Prophylaxis
Ondansetron	07 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 34)	Nausea Prophylaxis
Vancomycin	07 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 34)	Liver Abcess

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 1/mild	Not related	22 Oct 2020 (Study Day 8) - 23 Oct 2020 (Study Day 9)
Abdominal Pain	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 18) - 07 Nov 2020 (Study Day 24)
Pyrexia	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 18) - 07 Nov 2020 (Study Day 24)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US357-2116 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suicide Attempt/Suicide Attempt	SAE	Grade 4	Not related	19 Apr 2021 (Study Day 236) – 23 Apr 2021 (Study Day 240)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2116, a 18-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Apr 2021 (Study Day 236), 235 days after the first dose and 206 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of suicide attempt. Action taken with the IP was not applicable. The event of suicide attempt lasted for 5 days, after which it was considered to be recovered/resolved on 23 Apr 2021 (Study Day 240). The investigator assessed the event of suicide attempt to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-090633	Suicide attempt

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anaemia	Anemia	2014 - Ongoing
Bipolar disorder	Bipolar disorder	2016 - 2017
Oral pain	Oral pain	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Not reported - 10 Sep 2020 (Study Day 15)	Headache
Melatonin	Not reported - Ongoing	Sleep
Benzocaine	2019 - Ongoing	Oral Pain
Sertraline	15 Dec 2020 (Study Day 111) - Ongoing	Depression

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Depression	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 97) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US357-2125 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Alcohol Withdrawal Syndrome/Alcohol Withdrawals	SAE	Grade 2/moderate	Not related	10 Jan 2021 (Study Day 130) – 13 Jan 2021 (Study Day 133)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2125, a 41-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Jan 2021 (Study Day 130), 129 days after the first dose and 100 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of alcohol withdrawal syndrome. Action taken with the IP was not applicable. The event of alcohol withdrawals lasted for 4 days, after which it was considered to be recovered/resolved on 13 Jan 2021 (Study Day 133). The investigator assessed the event of alcohol withdrawal syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011008	Alcohol withdrawal syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Congenital renal disorder	One kidney birth defect	(b) (6) 1978 (Study Day(b) (6) - Ongoing
Psoriasis	Psoriasis	2000 - Ongoing
Herpes simplex	Herpes simplex ii	2013 - Ongoing
Rhinitis allergic	Allergic rhinitis	2013 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2015 - Ongoing
Insomnia	Insomnia	2015 - Ongoing
Alcoholism	Alcoholism	2018 - Ongoing
Blood testosterone decreased	Low testosterone	Jul 2020 - Ongoing
Dandruff	Dandruff	Jul 2020 - Ongoing
Papilloma excision	Subject realized they had a wart on their foot. on 08 Sep 2020, they had it removed per doctors recommendation	01 Aug 2020 (Study Day -33) - 08 Sep 2020 (Study Day 6)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine	01 Jan 2013 (Study Day -2802) - Ongoing	Allergic Rhinitis
Valaciclovir	01 Jan 2013 (Study Day -2802) - Ongoing	Herpes Simplex Ii
Trazodone	01 Jan 2015 (Study Day -2072) - 03 Mar 2021 (Study Day 182)	Insomnia
Vitamins nos	01 Jan 2017 (Study Day -1341) - Ongoing	Dietary Supplement
Ketoconazole	01 Jul 2020 (Study Day -64) - Ongoing	Dandruff
Testosterone cipionate	01 Jul 2020 (Study Day -64) - 14 Jan 2021 (Study Day 134)	Low Testosterone
Azelastine hydrochloride	01 Aug 2020 (Study Day -33) - Ongoing	Allergic Rhinitis
Famotidine	01 Aug 2020 (Study Day -33) - Ongoing	Gerd
Fluticasone	01 Aug 2020 (Study Day -33) - Ongoing	Allergic Rhinitis
Wart removal- dermatology*	08 Sep 2020 (Study Day 6) - 08 Sep 2020 (Study Day 6)	Other, Scheduled Previously
Acetylsalicylic acid	03 Oct 2020 (Study Day 31) - 04 Oct 2020 (Study Day 32)	Fever, Pain (Headache And General Joint Ache)
Valaciclovir hydrochloride	10 Oct 2020 (Study Day 38) - 21 Oct 2020 (Study Day 49)	Herpes Simplex Flare Up
Hpv vaccine	09 Dec 2020 (Study Day 98) - 09 Dec 2020 (Study Day 98)	Herpes Simplex Prevention
Valaciclovir hydrochloride	10 Dec 2020 (Study Day 99) - 18 Dec 2020 (Study Day 107)	Herpes Simplex Flare Up

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chlordiazepoxide	10 Jan 2021 (Study Day 130) - 13 Jan 2021 (Study Day 133)	Alcohol Withdraws
I.v. solutions	10 Jan 2021 (Study Day 130) - 13 Jan 2021 (Study Day 133)	Alcohol Withdraws
Vitamins nos	10 Jan 2021 (Study Day 130) - 13 Jan 2021 (Study Day 133)	Alcohol Withdraws
Chlordiazepoxide	13 Jan 2021 (Study Day 133) - 18 Jan 2021 (Study Day 138)	Alcohol Withdraws
Testosterone	14 Jan 2021 (Study Day 134) - 12 Mar 2021 (Study Day 191)	Low Testosterone
Hpv vaccine	18 Jan 2021 (Study Day 138) - 18 Jan 2021 (Study Day 138)	Hpv Prevention
Cetirizine hydrochloride; pseudoephedrine hydrochloride	25 Feb 2021 (Study Day 176) - 03 Mar 2021 (Study Day 182)	Allergic Rhinitis
Levocetirizine dihydrochloride	03 Mar 2021 (Study Day 182) - Ongoing	Allergic Rhinitis
Trazodone	03 Mar 2021 (Study Day 182) - Ongoing	Insomnia
Testosterone	12 Mar 2021 (Study Day 191) - Ongoing	Low Testosterone

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Simplex	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 38) - 21 Oct 2020 (Study Day 49)
Herpes Simplex	Grade 1/mild	Not related	10 Dec 2020 (Study Day 99) - 17 Dec 2020 (Study Day 106)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US357-2134 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaemia Macrocytic/Macrocytic Anemia	SAE	Grade 3/severe	Not related	08 Nov 2020 (Study Day 73) – Ongoing	Not recovered/not resolved
Fall/Fall	SAE	Grade 3/severe	Not related	08 Nov 2020 (Study Day 73) – 08 Nov 2020 (Study Day 73)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2134, a 48-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Nov 2020 (Study Day 73), 72 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of anaemia macrocytic. Action taken with the IP was not applicable. The event of macrocytic anemia was considered to be ongoing. The investigator assessed the event of anaemia macrocytic to be not related to the IP.

On 08 Nov 2020 (Study Day 73), 72 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of fall. Action taken with the IP was not applicable. The event of fall lasted for 1 day, after which it was considered to be recovered/resolved on 08 Nov 2020 (Study Day 73). The investigator assessed the event of fall to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000711	Anaemia macrocytic
MOD-2020-000711	Fall

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcoholism	Alcoholism	Not reported - Ongoing
Dizziness	Dizziness	Not reported - Ongoing
Fall	Frequent falls	Not reported - Ongoing
Hepatic steatosis	Fatty liver	Not reported - Ongoing
Hypoacusis	Hard of hearing	Not reported - Ongoing
Obesity	Obesity	Not reported - Ongoing
Gastric bypass	Gastric bypass	Jan 2004 - Jan 2004
Seizure	Seizures	2015 - Ongoing
Insomnia	Insomnia	2017 - Ongoing
Anxiety	Anxiety	Aug 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levetiracetam	2015 - Ongoing	Seizures
Gabapentin	2017 - Ongoing	Insomnia
Alprazolam	Aug 2019 - Ongoing	Anxiety
Acetylsalicylic acid; caffeine; paracetamol	17 Sep 2020 (Study Day 21) - 17 Sep 2020 (Study Day 21)	Headache
Ct (computed tomography) abdomen pelvis w*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Ct head or brain wo*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Hydrocodone bitartrate; paracetamol	08 Nov 2020 (Study Day 73) - Ongoing	Pain Due To Fall
Paracetamol	08 Nov 2020 (Study Day 73) - Ongoing	Pain Due To Fall
Xr humerus min 2 v right dr, xr forearm 2 v right dr, xr shoulder complete min 2 v right dr*	08 Nov 2020 (Study Day 73) - 08 Nov 2020 (Study Day 73)	Adverse Event
Abdomen ultrasound*	09 Nov 2020 (Study Day 74) - 09 Nov 2020 (Study Day 74)	Medical History
Ni echo transthoracic echocardiogram (tte) 2d*	09 Nov 2020 (Study Day 74) - 09 Nov 2020 (Study Day 74)	Adverse Event
Nm myocardial perfusion stress multi*	09 Nov 2020 (Study Day 74) - 09 Nov 2020 (Study Day 74)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 1/mild	Not related	17 Sep 2020 (Study Day 21) - 17 Sep 2020 (Study Day 21)
Headache	Grade 1/mild	Related	17 Sep 2020 (Study Day 21) - 17 Sep 2020 (Study Day 21)
Nausea	Grade 1/mild	Not related	17 Sep 2020 (Study Day 21) - 17 Sep 2020 (Study Day 21)
Vomiting	Grade 1/mild	Not related	17 Sep 2020 (Study Day 21) - 17 Sep 2020 (Study Day 21)
Nausea	Grade 1/mild	Related	29 Sep 2020 (Study Day 33) - 26 Oct 2020 (Study Day 60)
Diarrhoea	Grade 1/mild	Not related	02 Oct 2020 (Study Day 36) - 05 Oct 2020 (Study Day 39)
Nausea	Grade 1/mild	Not related	05 Nov 2020 (Study Day 70) - 05 Feb 2021 (Study Day 162)
Spinal Pain	Grade 2/moderate	Not applicable	01 Dec 2020 (Study Day 96) - Ongoing
Diarrhoea	Grade 2/moderate	Not related	17 Mar 2021 (Study Day 202) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US357-2181 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post Procedural Fever/Fever Post Hysterectomy	SAE	Grade 2/ moderate	Not related	27 Jan 2021 (Study Day 147) – 30 Jan 2021 (Study Day 150)	Recovered/resolved
Uterine Leiomyoma/Multiple Fibroids	SAE	Grade 3/ severe	Not related	27 Jan 2021 (Study Day 147) – 27 Jan 2021 (Study Day 147)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2181, a 44-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Jan 2021 (Study Day 147), 146 days after the first dose and 117 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of post procedural fever. Action taken with the IP was not applicable. The event of fever post hysterectomy lasted for 4 days, after which it was considered to be recovered/resolved on 30 Jan 2021 (Study Day 150). The investigator assessed the event of post procedural fever to be not related to the IP.

On 27 Jan 2021 (Study Day 147), 146 days after the first dose and 117 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of uterine leiomyoma. Action taken with the IP was not applicable. The event of multiple fibroids lasted for 1 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 147). The investigator assessed the event of uterine leiomyoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010302	Post procedural fever
MOD-2021-010302	Uterine leiomyoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	C-section	05 Jun 2004 (Study Day -5934) - 05 Jun 2004 (Study Day -5934)
Caesarean section	C-section	12 Sep 2007 (Study Day -4740) - 12 Sep 2007 (Study Day -4740)
Female sterilisation	Bilateral tubal ligation	12 Sep 2007 (Study Day -4740) - 12 Sep 2007 (Study Day -4740)
Hypertension	Hypertension	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2017 - Ongoing	Hypertension
Influenza vaccine	16 Oct 2020 (Study Day 44) - 16 Oct 2020 (Study Day 44)	Flu Prevention
Biopsy of cervix*	02 Dec 2020 (Study Day 91) - 02 Dec 2020 (Study Day 91)	Diagnostic
Hysterectomy*	27 Jan 2021 (Study Day 147) - 27 Jan 2021 (Study Day 147)	Adverse Event
Ibuprofen	27 Jan 2021 (Study Day 147) - Ongoing	Pain At Injection Site
Hydrochlorothiazide	25 Feb 2021 (Study Day 176) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 1) - 03 Sep 2020 (Study Day 1)
Vaginal Haemorrhage	Grade 2/moderate	Not related	21 Oct 2020 (Study Day 49) - 30 Nov 2020 (Study Day 89)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US357-2199 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	05 Oct 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colitis/Worsening Of Colitis	SAE	Grade 2/moderate	Not related	12 Dec 2020 (Study Day 100) – 11 Jan 2021 (Study Day 130)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2199, a 35-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Dec 2020 (Study Day 100), 99 days after the first dose and 68 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of colitis. Action taken with the IP was not applicable. The event of worsening of colitis lasted for 31 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 130). The investigator assessed the event of colitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001485	Colitis
MOD-2020-001485	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Colitis ulcerative	Ulcerative colitis	2011 - Ongoing
Female sterilisation	Bilateral tubal ligation	09 Jan 2015 (Study Day -2065) - 09 Jan 2015 (Study Day -2065)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2017 - Ongoing	Supplement
Escitalopram	24 Sep 2020 (Study Day 21) - Ongoing	Anxiety
Gentamicin	02 Oct 2020 (Study Day 29) - 12 Oct 2020 (Study Day 39)	Scratch To Right Eye
Loperamide	19 Dec 2020 (Study Day 107) - Ongoing	Acute Hemorrhagic Colitis
Levofloxacin	24 Dec 2020 (Study Day 112) - 30 Dec 2020 (Study Day 118)	COVID-19 Positive
Metronidazole	24 Dec 2020 (Study Day 112) - 29 Dec 2020 (Study Day 117)	Colitis/Diarrhea

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Superficial Injury Of Eye	Grade 1/mild	Not related	02 Oct 2020 (Study Day 29) - 12 Oct 2020 (Study Day 39)
COVID-19	Grade 3/severe	Not related	19 Dec 2020 (Study Day 107) - 07 Jan 2021 (Study Day 126)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2111 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	07 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticular Perforation/Perforated Diverticulitis	SAE	Grade 2/ moderate	Not related	03 Nov 2020 (Study Day 86) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US359-2111, a 73-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 07 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Nov 2020 (Study Day 86), 85 days after the first dose and 57 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of diverticular perforation. Action taken with the IP was not applicable. The event of perforated diverticulitis was considered to be ongoing. The investigator assessed the event of diverticular perforation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000704	Diverticular perforation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Myopia bilateral	1955 - Ongoing
Cough	Chronic cough	1988 - Ongoing
Postmenopause	Postmenopausal	1997 - Ongoing
Fibrocystic breast disease	Fibrocystic breast disease	2002 - Ongoing
Hypermetropia	Hyperopia bilateral	2007 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Deafness bilateral	Hearing loss bilateral	2014 - Ongoing
Hypothyroidism	Hypothyroidism	2014 - Ongoing
Osteoarthritis	Osteoarthritis left knee	Dec 2014 - Ongoing
Skin cosmetic procedure	Restylane refyne dermal filler 1 ml	21 Jul 2020 (Study Day -20) - 21 Jul 2020 (Study Day -20)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	2005 - Ongoing	Nutritional Supplement
Vitamin d nos	2005 - Ongoing	Nutritional Supplement
Vitamins nos	2005 - Ongoing	Nutritional Supplement
Fexofenadine	2011 - Ongoing	Chronic Cough Secondary To Post Nasal Drainage
Phenylephrine	2011 - Ongoing	Chronic Cough Secondary To Post Nasal Drainage
Levothyroxine	2014 - Ongoing	Hypothyroidism
Telmisartan	2018 - Ongoing	Hypertension
Liothyronine	01 May 2020 (Study Day -101) - Ongoing	Hypothyroidism
Influenza vaccine	26 Sep 2020 (Study Day 48) - 26 Sep 2020 (Study Day 48)	Influenza Prophylaxis
Ct abdomen and pelvis*	03 Nov 2020 (Study Day 86) - 03 Nov 2020 (Study Day 86)	Adverse Event
Ceftriaxone	05 Nov 2020 (Study Day 88) - 15 Nov 2020 (Study Day 98)	Colon Abscess
Ct abdomen and pelvis*	05 Nov 2020 (Study Day 88) - 05 Nov 2020 (Study Day 88)	Adverse Event
Hydromorphone	05 Nov 2020 (Study Day 88) - 15 Nov 2020 (Study Day 98)	Abdominal Pain
Macrogol 3350	05 Nov 2020 (Study Day 88) - 15 Nov 2020 (Study Day 98)	Constipation

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metronidazole	05 Nov 2020 (Study Day 88) - 15 Nov 2020 (Study Day 98)	Perforated Diverticulitis
Ondansetron	05 Nov 2020 (Study Day 88) - 15 Nov 2020 (Study Day 98)	Nausea
Ondansetron	05 Nov 2020 (Study Day 88) - 30 Nov 2020 (Study Day 113)	Nausea
Oxycodone hydrochloride	05 Nov 2020 (Study Day 88) - 15 Nov 2020 (Study Day 98)	Abdominal Pain
Paracetamol	05 Nov 2020 (Study Day 88) - Ongoing	Abdominal Pain
Ct guided wound drain placement*	10 Nov 2020 (Study Day 93) - 10 Nov 2020 (Study Day 93)	Adverse Event
Ct abdomen and pelvis*	12 Nov 2020 (Study Day 95) - 12 Nov 2020 (Study Day 95)	Adverse Event
Oxycodone; paracetamol	15 Nov 2020 (Study Day 98) - 22 Nov 2020 (Study Day 105)	Adbominal Pain
Sulfamethoxazole; trimethoprim	15 Nov 2020 (Study Day 98) - 18 Nov 2020 (Study Day 101)	Colon Abscess
Amoxicillin; clavulanic acid	18 Nov 2020 (Study Day 101) - 23 Nov 2020 (Study Day 106)	Colon Abscess
Fluconazole	19 Nov 2020 (Study Day 102) - 25 Nov 2020 (Study Day 108)	Oral Candidiasis Secondary To Iv Antibiotic Use
Probiotics nos	19 Nov 2020 (Study Day 102) - Ongoing	Dietary Supplement
Placement of wound drain*	02 Dec 2020 (Study Day 115) - 02 Dec 2020 (Study Day 115)	Adverse Event
Computed tomography scan*	03 Dec 2020 (Study Day 116) - 03 Dec 2020 (Study Day 116)	Adverse Event
Magnesium citrate	03 Dec 2020 (Study Day 116) - 03 Dec 2020 (Study Day 116)	Constipation
Drain removal*	04 Dec 2020 (Study Day 117) - 04 Dec 2020 (Study Day 117)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain	Grade 2/moderate	Not related	03 Nov 2020 (Study Day 86) - 30 Jan 2021 (Study Day 174)
Constipation	Grade 1/mild	Not related	03 Nov 2020 (Study Day 86) - 03 Dec 2020 (Study Day 116)
Colonic Abscess	Grade 2/moderate	Not related	05 Nov 2020 (Study Day 88) - Ongoing
Nausea	Grade 1/mild	Not related	05 Nov 2020 (Study Day 88) - 30 Nov 2020 (Study Day 113)
Cholelithiasis	Grade 1/mild	Not related	12 Nov 2020 (Study Day 95) - Ongoing
Pleural Effusion	Grade 1/mild	Not related	12 Nov 2020 (Study Day 95) - Ongoing
Oral Candidiasis	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 101) - 25 Nov 2020 (Study Day 108)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2226 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Cord Abscess/Spinal Cord Abscess	SAE	Grade 4	Not related	17 Dec 2020 (Study Day 122) – 22 Jan 2021 (Study Day 158)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US359-2226, a 34-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Dec 2020 (Study Day 122), 121 days after the first dose and 93 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of spinal cord abscess. Action taken with the IP was not applicable. The event of spinal cord abscess lasted for 37 days, after which it was considered to be recovered/resolved on 22 Jan 2021 (Study Day 158). The investigator assessed the event of spinal cord abscess to be not related to the IP.

Additional Information From the Safety Database

No additional details for the serious event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to ceclor	(b) (6) 1986 - Ongoing
Hypertension	Hypertension	2009 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Chronic back pain	2010 - Ongoing
Vasectomy	Vasectomy	2012 - 2012

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2010 - Ongoing	Chronic Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	28 Sep 2020 (Study Day 42) - 30 Sep 2020 (Study Day 44)
Oropharyngeal Pain	Grade 1/mild	Not related	28 Sep 2020 (Study Day 42) - 30 Sep 2020 (Study Day 44)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2229 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Endometrial Hyperplasia/Atypical Complex Hyperplasia	SAE	Grade 3/ severe	Not related	19 Nov 2020 (Study Day 94) – 16 Mar 2021 (Study Day 211)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US359-2229, a 52-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Nov 2020 (Study Day 94), 93 days after the first dose and 65 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of endometrial hyperplasia. Action taken with the IP was not applicable. The event of atypical complex hyperplasia lasted for 118 days, after which it was considered to be recovered/resolved on 16 Mar 2021 (Study Day 211). The investigator assessed the event of endometrial hyperplasia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-05275	Endometrial adenocarcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	Mar 1988 - Ongoing
Rhinitis allergic	Allergic rhinitis	Mar 1988 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Jan 2008 - Ongoing
Attention deficit hyperactivity disorder	Attention deficiency disorder	Mar 2014 - Ongoing
Gastrooesophageal reflux disease	Gastroesophogeal reflux disease	Mar 2014 - Ongoing
Depression	Depression	Mar 2016 - Ongoing
Insomnia	Insomnia	Mar 2016 - Ongoing
Postmenopause	Postmenopausal	Jan 2018 - Ongoing
Gastrointestinal endoscopic therapy	Endoscopic dilation	Mar 2018 - Mar 2018
Laryngeal stenosis	Subglottic stenosis	Mar 2018 - Mar 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Simvastatin	Jan 2014 - Ongoing	Hypercholesterolemia
Amfetamine	Mar 2014 - Ongoing	Attention Deficiency Disorder
Dexamfetamine sulfate	Mar 2014 - Ongoing	Attention Deficiency Disorder
Hydrochlorothiazide; irbesartan	Jan 2017 - 05 Nov 2020 (Study Day 80)	Hypertension
Paroxetine	Jan 2017 - Ongoing	Depression
Pantoprazole	Mar 2018 - Ongoing	Gastroesophageal Reflux Disease
Ibuprofen	22 Aug 2020 (Study Day 5) - 22 Aug 2020 (Study Day 5)	Pain, Fever
Nitrofurantoin	22 Aug 2020 (Study Day 5) - 26 Aug 2020 (Study Day 9)	Urinary Tract Infection
Influenza vaccine	15 Oct 2020 (Study Day 59) - 15 Oct 2020 (Study Day 59)	Influenza Prophylaxis
Hydrochlorothiazide; irbesartan	06 Nov 2020 (Study Day 81) - Ongoing	Hypertension
Hydrocodone bitartrate; paracetamol	16 Mar 2021 (Study Day 211) - 18 Mar 2021 (Study Day 213)	Atypical Complex Hyperplasia
Hysterectomy*	16 Mar 2021 (Study Day 211) - 16 Mar 2021 (Study Day 211)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	22 Aug 2020 (Study Day 5) - 26 Aug 2020 (Study Day 9)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2232 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Femoral Neck Fracture/Right Subcapital Femoral Neck Fracture, Displaced Garden Iii	SAE	Grade 3/ severe	Not related	25 Aug 2020 (Study Day 6) – 05 Oct 2020 (Study Day 47)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US359-2232, a 79-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Aug 2020 (Study Day 6), 5 days after the first dose and 27 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of femoral neck fracture. The IP dose was not changed due to the right subcapital femoral neck fracture, displaced garden iii. The event of right subcapital femoral neck fracture, displaced garden iii lasted for 42 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 47). The investigator assessed the event of femoral neck fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000230	Femoral neck fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Astigmatism	Astigmatism bilateral	1990 - Ongoing
Postmenopause	Postmenopausal	1990 - Ongoing
Hysterectomy	Hysterectomy	1998 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Osteoporosis	Osteoporosis	2005 - Ongoing
Neuropathy peripheral	Pedal neuropathy bilateral	2010 - Ongoing
Cataract	Cataract right eye	2012 - Ongoing
Urinary tract infection	Frequent urinary tract infections	2013 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2018 - Ongoing
Bladder prolapse	Bladder prolapse	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2007 - Ongoing	Nutritional Supplement
Amlodipine	Oct 2007 - Ongoing	Hypertension
Lisinopril	Oct 2007 - Ongoing	Hypertension
Trazodone	2018 - Ongoing	Anxiety
Omeprazole	Apr 2018 - Ongoing	Gastroesophageal Reflux Disease
Alendronate sodium	Jul 2019 - Ongoing	Osteoporosis
Nitrofurantoin	20 Aug 2020 (Study Day 1) - 25 Aug 2020 (Study Day 6)	Frequent Urinary Tract Infections
Cefazolin sodium	25 Aug 2020 (Study Day 6) - 26 Aug 2020 (Study Day 7)	Preoperative - Hip Surgery
Fentanyl citrate	25 Aug 2020 (Study Day 6) - 25 Aug 2020 (Study Day 6)	Right Hip Pain, Chest Wall Pain
Magnetic resonance imaging*	25 Aug 2020 (Study Day 6) - 25 Aug 2020 (Study Day 6)	Adverse Event
Paracetamol	25 Aug 2020 (Study Day 6) - 28 Aug 2020 (Study Day 9)	Right Hip Pain
Right femoral neck open reduction internal fixation*	26 Aug 2020 (Study Day 7) - 26 Aug 2020 (Study Day 7)	Adverse Event
Docusate sodium	27 Aug 2020 (Study Day 8) - 03 Sep 2020 (Study Day 15)	Right Subcapital Femoral Neck Fracture, Displaced Garden Iii
Macrogol 3350	27 Aug 2020 (Study Day 8) - 03 Sep 2020 (Study Day 15)	Right Subcapital Femoral Neck Fracture, Displaced Garden Iii
Paracetamol	27 Aug 2020 (Study Day 8) - Ongoing	Right Hip Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Tamsulosin	27 Aug 2020 (Study Day 8) - Ongoing	Urinary Retention
Acetylsalicylic acid	01 Sep 2020 (Study Day 13) - Ongoing	Deep Vein Thrombosis Prophylaxis
Apixaban	28 Sep 2020 (Study Day 40) - Ongoing	Deep Vein Thrombosis Prophylaxis
Thyroid sonogram*	12 Oct 2020 (Study Day 54) - 12 Oct 2020 (Study Day 54)	Diagnostic
Influenza vaccine	20 Oct 2020 (Study Day 62) - 20 Oct 2020 (Study Day 62)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 4	Not related	25 Aug 2020 (Study Day 6) - 01 Oct 2020 (Study Day 43)
Benign Neoplasm Of Thyroid Gland	Grade 1/mild	Not related	25 Aug 2020 (Study Day 6) - Ongoing
Fall	Grade 1/mild	Not related	25 Aug 2020 (Study Day 6) - 25 Aug 2020 (Study Day 6)
Post-Traumatic Pain	Grade 2/moderate	Not related	25 Aug 2020 (Study Day 6) - 26 Aug 2020 (Study Day 7)
Leukocytosis	Grade 1/mild	Not related	27 Aug 2020 (Study Day 8) - 28 Aug 2020 (Study Day 9)
Urinary Retention	Grade 1/mild	Not related	27 Aug 2020 (Study Day 8) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2247 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	29 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	26 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bradycardia/Bradycardia	SAE	Grade 4	Not related	10 Nov 2020 (Study Day 74) – 16 Nov 2020 (Study Day 80)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US359-2247, a 87-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 26 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Nov 2020 (Study Day 74), 73 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of bradycardia. Action taken with the IP was not applicable. The event of bradycardia lasted for 7 days, after which it was considered to be recovered/resolved on 16 Nov 2020 (Study Day 80). The investigator assessed the event of bradycardia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000765	Bradycardia

Study Completion/Discontinuation

On 19 Jan 2021 (Study Day 144), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Myopia	1947 - Ongoing
Hypertension	Hypertension	1987 - Ongoing
Postmenopause	Postmenopausal	01 Jan 1987 (Study Day -12294) - Ongoing
Arthritis	Arthritis hands	1995 - Ongoing
Spondylitis	Arthritis lower back	1995 - Ongoing
Drug hypersensitivity	Neurontin allergy	2009 - Ongoing
Spinal stenosis	Spinal stenosis	2009 - Ongoing
Cataract	Cataract right eye	2010 - Ongoing
Hypertriglyceridaemia	Hypertrigluycerdemia	2016 - Ongoing
Osteoporosis	Osteoporosis	2019 - Ongoing
Scoliosis	Scoliosis	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1990 - Ongoing	Nutritional Supplement
Ibuprofen	1995 - Ongoing	Arthritis Hand
Paracetamol	1995 - Ongoing	Arthritis Hand
Hydrochlorothiazide; triamterene	2001 - Ongoing	Hypertension
Hydrocodone bitartrate; paracetamol	2009 - Ongoing	Spinal Stenosis
Gemfibrozil	2016 - Ongoing	Hypertriglyceridemia
Carvedilol	2019 - 16 Nov 2020 (Study Day 80)	Hypertension
Denosumab	01 Feb 2019 (Study Day -575) - Ongoing	Osteoporosis
Influenza vaccine	19 Oct 2020 (Study Day 52) - 19 Oct 2020 (Study Day 52)	Influenza Prophylaxis
Chest x-ray*	10 Nov 2020 (Study Day 74) - 10 Nov 2020 (Study Day 74)	Adverse Event
Ct abdomen/pelvis*	10 Nov 2020 (Study Day 74) - 10 Nov 2020 (Study Day 74)	Adverse Event
Echocardiogram*	10 Nov 2020 (Study Day 74) - 10 Nov 2020 (Study Day 74)	Adverse Event
Echocardiogram*	11 Nov 2020 (Study Day 75) - 11 Nov 2020 (Study Day 75)	Adverse Event
Ertapenem	11 Nov 2020 (Study Day 75) - 12 Jan 2021 (Study Day 137)	Abdominal Abscess
Fexofenadine	11 Nov 2020 (Study Day 75) - Ongoing	Seasonal Allergies
Echocardiogram*	12 Nov 2020 (Study Day 76) - 12 Nov 2020 (Study Day 76)	Adverse Event
Ct guided abdominal abscess drainage*	13 Nov 2020 (Study Day 77) - 13 Nov 2020 (Study Day 77)	Adverse Event
Amoxicillin; clavulanic acid	14 Nov 2020 (Study Day 78) - Ongoing	Abdominal Abscess

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amiodarone	16 Nov 2020 (Study Day 80) - 22 Nov 2020 (Study Day 86)	Atrial Fibrillation
Amiodarone	23 Nov 2020 (Study Day 87) - Ongoing	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Abscess	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 74) - Ongoing
Cholelithiasis	Grade 1/mild	Not related	10 Nov 2020 (Study Day 74) - Ongoing
Hypokalaemia	Grade 1/mild	Not related	10 Nov 2020 (Study Day 74) - Ongoing
Seasonal Allergy	Grade 1/mild	Not related	10 Nov 2020 (Study Day 74) - Ongoing
Vertigo	Grade 3/severe	Not related	10 Nov 2020 (Study Day 74) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US360-2004 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/Nstemi (Non-St Segment Elevation Myocardial Infarction)	SAE	Grade 3/severe	Not related	03 Jan 2021 (Study Day 124) – 04 Jan 2021 (Study Day 125)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US360-2004, a 57-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Jan 2021 (Study Day 124), 123 days after the first dose and 97 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute myocardial infarction. Action taken with the IP was not applicable. The event of nstemi (non-st segment elevation myocardial infarction) lasted for 2 days, after which it was considered to be recovered/resolved on 04 Jan 2021 (Study Day 125). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-023120	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1980 - 1980
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Diabetes mellitus	Diabetes	2005 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	2009 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Myocardial infarction	Myocardial infarction	2010 - 2010
Restless legs syndrome	Restless leg syndrome	2010 - Ongoing
Presyncope	Vasovagal episode	2011 - 2011
Menopause	Menopausal	2012 - Ongoing
Presyncope	Vasovagal episode	2012 - 2012
Gastrooesophageal reflux disease	Gastroesophageal reflux disorder (gerd) (self-diagnosed)	2017 - Ongoing
Insomnia	Insomnia (self-diagnosed)	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Not reported - Ongoing	Hypercholesterolemia
Berberine	Not reported - Ongoing	Glycemic Control
Empagliflozin	Not reported - Ongoing	Iddm
Gabapentin	Not reported - Ongoing	Restless Leg Syndrome
Loratadine	Not reported - Ongoing	Seasonal Allergies
Metformin	Not reported - Ongoing	Iddm
Unspecified herbal and traditional medicine	Not reported - Ongoing	Anti-Reflux (For Self-Diagnosed Gerd)
Ibuprofen	2000 - Ongoing	Oral Pain
Cannabis sativa	Jul 2020 - Ongoing	Sleep Aide (For Self-Diagnosed Insomnia)
Ibuprofen	02 Sep 2020 (Study Day 1) - 07 Sep 2020 (Study Day 6)	Pain At Injection Site
Ibuprofen	04 Dec 2020 (Study Day 94) - 09 Dec 2020 (Study Day 99)	Headache And Congestion
Fluticasone propionate	10 Dec 2020 (Study Day 100) - 10 Dec 2020 (Study Day 100)	Upper Respiratory Tract Infection
Pseudoephedrine hydrochloride	10 Dec 2020 (Study Day 100) - 10 Dec 2020 (Study Day 100)	Upper Respiratory Tract Infection
Salbutamol	03 Jan 2021 (Study Day 124) - 03 Jan 2021 (Study Day 124)	Shortness Of Breath

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	04 Jan 2021 (Study Day 125) - Ongoing	Nstemi (Non-St Segment Elevated Myocardial Infarction)
Blood work-up*	04 Jan 2021 (Study Day 125) - 04 Jan 2021 (Study Day 125)	Diagnostic
Ekg*	04 Jan 2021 (Study Day 125) - 04 Jan 2021 (Study Day 125)	Adverse Event
Glyceryl trinitrate	04 Jan 2021 (Study Day 125) - 04 Jan 2021 (Study Day 125)	Nstemi (Non-St Segment Elevation Myocardial Infarction)
Left heart catheterization*	04 Jan 2021 (Study Day 125) - 04 Jan 2021 (Study Day 125)	Adverse Event
Metoprolol tartrate	04 Jan 2021 (Study Day 125) - 04 Jan 2021 (Study Day 125)	Nstemi (Non-St Segment Elevation Myocardial Infarction)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Sinus Congestion	Grade 2/moderate	Not related	04 Dec 2020 (Study Day 94) - 11 Dec 2020 (Study Day 101)
Upper Respiratory Tract Infection	Grade 1/mild	Not related	04 Dec 2020 (Study Day 94) - 10 Dec 2020 (Study Day 100)
Chest Discomfort	Grade 1/mild	Not related	08 Dec 2020 (Study Day 98) - 08 Dec 2020 (Study Day 98)
Dyspnoea	Grade 2/moderate	Not related	03 Jan 2021 (Study Day 124) - 04 Jan 2021 (Study Day 125)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US360-2008 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Immunisation Anxiety Related Reaction/Anxiety Due The Side Effects Of The First Ip	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	08 Sep 2020 (Study Day 7) – 30 Sep 2020 (Study Day 29)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US360-2008, a 62-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of immunisation anxiety related reaction. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of anxiety due the side effects of the first ip lasted for 23 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 29). The investigator assessed the event of immunisation anxiety related reaction to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Arthralgias of bilateral hands and fingers	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia (hl)	Not reported - Ongoing
Hypertension	Hypertension (htn)	Not reported - Ongoing
Diabetes mellitus	Dm - 2010 - controlled with medications	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	Not reported - Ongoing	Nutritional Needs/Dietary Supplement
Ramipril	Not reported - Ongoing	For Hypertension
Rosuvastatin calcium	Not reported - Ongoing	For Hyperlipidemia
Vitamin b12 nos	Not reported - Ongoing	Nutritional Needs/Dietary Supplement
Metformin hydrochloride; sitagliptin	2010 - Ongoing	Diabetes Mellitus
Celecoxib	23 Sep 2020 (Study Day 22) - 30 Sep 2020 (Study Day 29)	To Treat A.E- Worsening Joint Aches Or Pain Located In Bilateral Shoulder And Hands Reported On Day 21 On 9/23

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Immunisation Anxiety Related Reaction	Grade 1/mild	Not related	08 Sep 2020 (Study Day 7) - 30 Sep 2020 (Study Day 29)
Arthralgia	Grade 2/moderate	Related	09 Sep 2020 (Study Day 8) - 23 Sep 2020 (Study Day 22)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US361-2010 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Aortic Aneurysm/ Abdominal Aortic Aneurysm (3cm)	SAE	Grade 1/mild	Not related	16 Oct 2020 (Study Day 46) – 21 Oct 2020 (Study Day 51)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US361-2010, a 67-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Oct 2020 (Study Day 46), 45 days after the first dose and 16 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of aortic aneurysm. Action taken with the IP was not applicable. The event of abdominal aortic aneurysm (3cm) lasted for 6 days, after which it was considered to be recovered/resolved with sequelae on 21 Oct 2020 (Study Day 51). The investigator assessed the event of aortic aneurysm to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000681	Aortic aneurysm

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Peripheral arterial occlusive disease	Peripheral artery disease	Not reported - Ongoing
Tobacco user	Heavy smoker	1965 - Ongoing
Blood cholesterol increased	High cholesterol	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Coronary artery disease	Coronary artery disease	2006 - Ongoing
Catheterisation cardiac	Cardiac catherization	2007 - 2007
Pulmonary mass	Benign pulmonary nodules in right upper lobe	13 May 2016 (Study Day -1572) - Ongoing
Atrial fibrillation	Atrial fibrillation	2018 - Ongoing
Emphysema	Emphysema	08 May 2018 (Study Day -847) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2005 - Ongoing	High Cholesterol
Lisinopril	2005 - Ongoing	Hypertension
Metoprolol	2005 - Ongoing	Hypertension
Lung ct scan*	16 Oct 2020 (Study Day 46) - 16 Oct 2020 (Study Day 46)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyponatraemia	Grade 1/mild	Not related	21 Oct 2020 (Study Day 51) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US362-2012 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anxiety/Anxiety	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	29 Aug 2020 (Study Day 19) – 04 Sep 2020 (Study Day 25)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2012, a 23-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Aug 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of anxiety. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of anxiety lasted for 7 days, after which it was considered to be recovered/resolved on 04 Sep 2020 (Study Day 25). The investigator assessed the event of anxiety to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 13 Nov 2020 (Study Day 95), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Occasional headaches	01 Aug 2020 (Study Day -10) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	01 Aug 2020 (Study Day -10) - Ongoing	Occasional Headache
Paracetamol	01 Aug 2020 (Study Day -10) - Ongoing	Occasional Headache
Alprazolam	29 Aug 2020 (Study Day 19) - Ongoing	Anxiety
Hydroxyzine	29 Aug 2020 (Study Day 19) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 3/severe	Not related	29 Aug 2020 (Study Day 19) - 04 Sep 2020 (Study Day 25)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US362-2116 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain Lower/Right Lower Quadrant Abdominal Pain	SAE	Grade 4	Not related	29 Nov 2020 (Study Day 91) – 16 Dec 2020 (Study Day 108)	Recovered/ resolved
Loss Of Consciousness/Loss Of Consciousness	SAE	Grade 4	Not related	29 Nov 2020 (Study Day 91) – 29 Nov 2020 (Study Day 91)	Recovered/ resolved
Nausea/Nausea	SAE	Grade 4	Not related	29 Nov 2020 (Study Day 91) – 03 Dec 2020 (Study Day 95)	Recovered/ resolved
Vomiting/Vomiting	SAE	Grade 4	Not related	29 Nov 2020 (Study Day 91) – 03 Dec 2020 (Study Day 95)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2116, a 55-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Nov 2020 (Study Day 91), 90 days after the first dose and 62 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of abdominal pain lower. Action taken with the IP was not applicable. The event of right lower quadrant abdominal pain lasted for 18 days, after which it was considered to be recovered/resolved on 16 Dec 2020 (Study Day 108). The investigator assessed the event of abdominal pain lower to be not related to the IP.

On 29 Nov 2020 (Study Day 91), 90 days after the first dose and 62 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of loss of consciousness. Action taken with the IP was not applicable. The event of loss of consciousness lasted for 1 days, after which it was considered to be recovered/resolved on 29 Nov 2020 (Study Day 91). The investigator assessed the event of loss of consciousness to be not related to the IP.

On 29 Nov 2020 (Study Day 91), 90 days after the first dose and 62 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of nausea. Action taken with

the IP was not applicable. The event of nausea lasted for 5 days, after which it was considered to be recovered/resolved on 03 Dec 2020 (Study Day 95). The investigator assessed the event of nausea to be not related to the IP.

On 29 Nov 2020 (Study Day 91), 90 days after the first dose and 62 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of vomiting. Action taken with the IP was not applicable. The event of vomiting lasted for 5 days, after which it was considered to be recovered/resolved on 03 Dec 2020 (Study Day 95). The investigator assessed the event of vomiting to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000976	Abdominal pain lower
MOD-2020-000976	Loss of consciousness
MOD-2020-000976	Nausea
MOD-2020-000976	Vomiting

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Diverticulitis	Diverticulitis	Not reported - Ongoing
Blood cholesterol increased	High cholesterol	2019 - Ongoing
Abdominal hernia	Abdominal hernia	Jun 2020 - 16 Mar 2021 (Study Day 198)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omega-3 nos	1980 - Ongoing	Prophylaxis
Vitamins nos	1980 - Ongoing	Supplement
Ascorbic acid	2019 - Ongoing	Supplement Vitamin
Colecalciferol	2019 - Ongoing	Supplement Vitamin
Pitavastatin calcium	15 Sep 2020 (Study Day 16) - 12 Jan 2021 (Study Day 135)	Hypercholesterolemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	25 Oct 2020 (Study Day 56) - 25 Oct 2020 (Study Day 56)	Prophylaxis For Flu
Chest x-ray*	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)	Diagnostic
Ct abdomen and pelvis with and without contrast*	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)	Diagnostic
Famotidine	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)	Gerd
Iopamidol	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)	Radiopaque Contrast Agent
Liver ultrasound*	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)	Diagnostic
Morphine	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)	Abdominal Pain (Right Lower Quadrant)
Ondansetron	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)	Nausea, Vomiting
Atorvastatin	19 Jan 2021 (Study Day 142) - Ongoing	Hypercholesterolemia
Colonoscopy*	22 Feb 2021 (Study Day 176) - 22 Feb 2021 (Study Day 176)	Diagnostic
Abdominal hernia repair*	16 Mar 2021 (Study Day 198) - 16 Mar 2021 (Study Day 198)	Medical History
Celecoxib	16 Mar 2021 (Study Day 198) - 22 Mar 2021 (Study Day 204)	Abdominal Hernia Repair
Oxycodone hydrochloride; paracetamol	16 Mar 2021 (Study Day 198) - 18 Mar 2021 (Study Day 200)	Abdominal Hernia Repair

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Not related	18 Sep 2020 (Study Day 19) - 24 Nov 2020 (Study Day 86)
Insomnia	Grade 1/mild	Not related	24 Sep 2020 (Study Day 25) - Ongoing
Myalgia	Grade 1/mild	Not related	30 Sep 2020 (Study Day 31) - 28 Dec 2020 (Study Day 120)
Constipation	Grade 1/mild	Not related	29 Nov 2020 (Study Day 91) - 03 Dec 2020 (Study Day 95)
Flatulence	Grade 1/mild	Not related	29 Nov 2020 (Study Day 91) - 03 Dec 2020 (Study Day 95)
Hepatic Cyst	Grade 3/severe	Not related	29 Nov 2020 (Study Day 91) - Ongoing
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 93) - 01 Dec 2020 (Study Day 93)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US362-2197 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaemia/Worsening Anemia	SAE	Grade 4	Not related	12 Jan 2021 (Study Day 118) – 15 Jan 2021 (Study Day 121)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2197, a 56-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Jan 2021 (Study Day 118), 117 days after the first dose and 89 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of anaemia. Action taken with the IP was not applicable. The event of worsening anemia lasted for 4 days, after which it was considered to be recovered/resolved on 15 Jan 2021 (Study Day 121). The investigator assessed the event of anaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003469	Anaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1990 - Ongoing
Hysterotomy	Partial hysterotomy	2008 - 2008
Vaginal haemorrhage	Abnormal virginial bleeding	2008 - 2008
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2010 - Ongoing
Sciatica	Sciatica	2010 - Ongoing
Depression	Depression	2013 - Ongoing
Obesity	Severe obesity	2015 - Ongoing
Anaemia	Anemia	2016 - Ongoing
Cholelithiasis	Gall stones	2016 - Ongoing
Insomnia	Insomnia	2017 - Ongoing
Migraine	Migraine	2018 - Ongoing
Abdominal hernia	Abdominal hernia	2020 - Ongoing
Tendonitis	Bilateral foot tendonitis	2020 - 2020
Gastrointestinal haemorrhage	Gi bleed	Jun 2020 - Jun 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2020 - Ongoing	Hypertension
Ferrous sulfate	2020 - Ongoing	Anemia
Vitamin b12 nos	2020 - Ongoing	Prophylaxis Supplement
Vitamin d nos	2020 - Ongoing	Prophylaxis Supplement
Influenza vaccine	01 Sep 2020 (Study Day -16) - 01 Sep 2020 (Study Day -16)	Prophylaxis For Flu
Cbc lab*	12 Jan 2021 (Study Day 118) - 12 Jan 2021 (Study Day 118)	Diagnostic
Chest x-ray*	12 Jan 2021 (Study Day 118) - 12 Jan 2021 (Study Day 118)	Diagnostic
Ekg*	12 Jan 2021 (Study Day 118) - 12 Jan 2021 (Study Day 118)	Diagnostic
Fobt*	12 Jan 2021 (Study Day 118) - 12 Jan 2021 (Study Day 118)	Diagnostic
Iron lab*	12 Jan 2021 (Study Day 118) - 12 Jan 2021 (Study Day 118)	Diagnostic
Iron saturation lab*	12 Jan 2021 (Study Day 118) - 12 Jan 2021 (Study Day 118)	Diagnostic
Pantoprazole sodium sesquihydrate	12 Jan 2021 (Study Day 118) - 15 Jan 2021 (Study Day 121)	Prevent Gerd

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	12 Jan 2021 (Study Day 118) - 15 Jan 2021 (Study Day 121)	Prevention Of Fever
Saccharated iron oxide	12 Jan 2021 (Study Day 118) - 15 Jan 2021 (Study Day 121)	Anemia
Sodium chloride	12 Jan 2021 (Study Day 118) - 15 Jan 2021 (Study Day 121)	Anemia
Tibc lab*	12 Jan 2021 (Study Day 118) - 12 Jan 2021 (Study Day 118)	Diagnostic
Vitamin b12 nos	12 Jan 2021 (Study Day 118) - 15 Jan 2021 (Study Day 121)	Anemia
Blood transfusion (2 units of prbs's)*	13 Jan 2021 (Study Day 119) - 13 Jan 2021 (Study Day 119)	Adverse Event
Lorazepam	13 Jan 2021 (Study Day 119) - 13 Jan 2021 (Study Day 119)	Insomnia
Blood transfusion (1 unit of prbc)*	15 Jan 2021 (Study Day 121) - 15 Jan 2021 (Study Day 121)	Adverse Event
Melatonin	25 Jan 2021 (Study Day 131) - Ongoing	Insomnia
Ibuprofen	24 Feb 2021 (Study Day 161) - 24 Feb 2021 (Study Day 161)	Rib Cage Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Musculoskeletal Chest Pain	Grade 3/severe	Not related	22 Feb 2021 (Study Day 159) - 06 Mar 2021 (Study Day 171)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US362-2211 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	19 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Encephalopathy/ Encephalopathy	SAE	Grade 4	Not related	01 Jan 2021 (Study Day 103) – 02 Jan 2021 (Study Day 104)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2211, a 56-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 19 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Jan 2021 (Study Day 103), 102 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of encephalopathy. Action taken with the IP was not applicable. The event of encephalopathy lasted for 2 days, after which it was considered to be recovered/resolved on 02 Jan 2021 (Study Day 104). The investigator assessed the event of encephalopathy to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002639	Encephalopathy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Prostatomegaly	Enlarged prostate	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Finasteride	Apr 2020 - 09 Oct 2020 (Study Day 19)	Enlarge Prostate
Acetylsalicylic acid	01 Jan 2021 (Study Day 103) - 11 Jan 2021 (Study Day 113)	Prevention Of Blood Clot
Atorvastatin	01 Jan 2021 (Study Day 103) - 11 Jan 2021 (Study Day 113)	Hypercholesterolemia
Bisacodyl	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)	Prevention Of Constipation
Brain ct wo contrast*	01 Jan 2021 (Study Day 103) - 01 Jan 2021 (Study Day 103)	Diagnostic
Chest single view x-ray*	01 Jan 2021 (Study Day 103) - 01 Jan 2021 (Study Day 103)	Diagnostic
Ct chest wo contrast*	01 Jan 2021 (Study Day 103) - 01 Jan 2021 (Study Day 103)	Diagnostic
Ekg*	01 Jan 2021 (Study Day 103) - 01 Jan 2021 (Study Day 103)	Diagnostic
Heparin	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)	Prevention Of Blood Clots
Labetalol hydrochloride	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)	Hypertension
Macrogol 3350	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)	Prevention Of Constipation
Sennoside a+b	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)	Prevention Of Constipation
Brain mri wo contrast*	02 Jan 2021 (Study Day 104) - 02 Jan 2021 (Study Day 104)	Diagnostic
Carotid duplex*	02 Jan 2021 (Study Day 104) - 02 Jan 2021 (Study Day 104)	Diagnostic
Echocardiogram*	02 Jan 2021 (Study Day 104) - 02 Jan 2021 (Study Day 104)	Diagnostic
Head mra wo contrast*	02 Jan 2021 (Study Day 104) - 02 Jan 2021 (Study Day 104)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arachnoid Cyst	Grade 1/mild	Not related	01 Jan 2021 (Study Day 103) - Ongoing
Diastolic Dysfunction	Grade 1/mild	Not related	01 Jan 2021 (Study Day 103) - Ongoing
Hypercholesterolaemia	Grade 1/mild	Not related	01 Jan 2021 (Study Day 103) - 11 Jan 2021 (Study Day 113)
Hypertension	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 103) - Ongoing
Lung Infiltration	Grade 1/mild	Not related	01 Jan 2021 (Study Day 103) - Ongoing
Mastoiditis	Grade 1/mild	Not related	01 Jan 2021 (Study Day 103) - Ongoing
Sinus Tachycardia	Grade 1/mild	Not related	01 Jan 2021 (Study Day 103) - Ongoing
Transient Global Amnesia	Grade 3/severe	Not related	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)
Transient Ischaemic Attack	Grade 3/severe	Not related	01 Jan 2021 (Study Day 103) - 02 Jan 2021 (Study Day 104)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US362-2282 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypotension/Hypotension (1st Episode)	SAE	Grade 3/ severe	Not related	06 Nov 2020 (Study Day 17) – 13 Nov 2020 (Study Day 24)	Recovered/ resolved
Sepsis/Sepsis	SAE	Grade 4	Not related	06 Nov 2020 (Study Day 17) – 26 Nov 2020 (Study Day 37)	Recovered/ resolved
Mental Status Changes/Altered Mental Status (Prolongation Of Hospitalization)	SAE	Grade 4	Not related	10 Nov 2020 (Study Day 21) – 25 Nov 2020 (Study Day 36)	Recovered/ resolved
Hypotension/Hypotension (2nd Episode)	SAE	Grade 3/ severe	Not related	21 Nov 2020 (Study Day 32) – 23 Nov 2020 (Study Day 34)	Recovered/ resolved
Sepsis/Sepsis	SAE	Grade 4	Not related	25 Jan 2021 (Study Day 97) – 31 Jan 2021 (Study Day 103)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US362-2282, a 51-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Nov 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of hypotension. On 17 Nov 2020 (Study Day 28), the IP dose was discontinued due to other. The event of hypotension (1st episode) lasted for 8 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 24). The investigator assessed the event of hypotension to be not related to the IP.

On 06 Nov 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of sepsis. On 17 Nov 2020 (Study Day 28), the IP dose was discontinued due to other. The event of sepsis lasted for 21 days, after which it was considered to be recovered/resolved on 26 Nov 2020 (Study Day 37). The investigator assessed the event of sepsis to be not related to the IP.

On 10 Nov 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of mental status changes. On 17 Nov 2020 (Study Day 28), the IP dose was discontinued due to other. The event of altered mental status (prolongation of hospitalization) lasted for 16 days, after which it was considered to be recovered/resolved on 25 Nov 2020 (Study Day 36). The investigator assessed the event of mental status changes to be not related to the IP.

On 21 Nov 2020 (Study Day 32), 31 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of hypotension. On 17 Nov 2020 (Study Day 28), the IP dose was discontinued due to other. The event of hypotension (2nd episode) lasted for 3 days, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 34). The investigator assessed the event of hypotension to be not related to the IP.

On 25 Jan 2021 (Study Day 97), 96 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of sepsis. On 17 Nov 2020 (Study Day 28), the IP dose was discontinued due to other. The event of sepsis lasted for 7 days, after which it was considered to be recovered/resolved on 31 Jan 2021 (Study Day 103). The investigator assessed the event of sepsis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000832	Sepsis
MOD-2020-000832	Sepsis
MOD-2020-000832	Mental status changes
MOD-2020-000832	Hypotension
MOD-2020-000832	Hypotension

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	Not reported - Ongoing
Diabetes mellitus	Diabetes	Not reported - Ongoing
Seizure	Seizures	Not reported - Ongoing
Tobacco user	Smoker	Not reported - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma (severe)	1971 - Ongoing
Anxiety	Anxiety	1985 - Ongoing
Bipolar disorder	Bipolar disorder	1985 - Ongoing
Paranoia	Paranoia	1985 - Ongoing
Post-traumatic stress disorder	Post-traumatic stress disorder	1985 - Ongoing
HIV infection	Hiv infection	1997 - Ongoing
Schizophrenia	Schizophrenia	2000 - Ongoing
Nerve injury	Nerve damage (neuropathy)	2001 - Ongoing
Postmenopause	Post menopause	2013 - Ongoing
Deep vein thrombosis	Deep vein thrombosis (site unknown)	2019 - Not reported
Ankle fracture	Right ankle fracture	Sep 2020 - 03 Oct 2020 (Study Day -18)
Arthralgia	Right ankle pain	Sep 2020 - Ongoing
Infection	Right ankle infection	Oct 2020 - Ongoing
Ankle operation	Right ankle surgery	03 Oct 2020 (Study Day -18) - 03 Oct 2020 (Study Day -18)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide	Not reported - Ongoing	Asthma
Montelukast	2000 - Ongoing	Asthma, Chronic Obstructive Pulmonary Disease
Quetiapine fumarate	2000 - 11 Nov 2020 (Study Day 22)	Paranoia
Valproate semisodium	2000 - 06 Nov 2020 (Study Day 17)	Anxiety, Schizophrenia, Seizures
Salbutamol sulfate	2005 - Ongoing	Asthma
Abacavir sulfate; dolutegravir sodium; lamivudine	2010 - 06 Nov 2020 (Study Day 17)	Hiv
Pregabalin	2010 - Ongoing	Nerve Damage
Ipratropium bromide	2011 - Ongoing	Asthma
Ipratropium bromide; salbutamol sulfate	2015 - 06 Nov 2020 (Study Day 17)	Asthma
Salbutamol	2015 - 06 Nov 2020 (Study Day 17)	Asthma
Rivaroxaban	2017 - 13 Nov 2020 (Study Day 24)	Prophylaxis For Dvt
Lurasidone hydrochloride	2020 - 06 Nov 2020 (Study Day 17)	Bipolar Disorder
Paracetamol	Oct 2020 - Ongoing	Right Ankle Pain
Bacitracin; neomycin sulfate; polymyxin b sulfate	03 Oct 2020 (Study Day -18) - 06 Nov 2020 (Study Day 17)	Right Ankle Infection
Ibuprofen	03 Oct 2020 (Study Day -18) - 06 Nov 2020 (Study Day 17)	Right Ankle Pain
Paracetamol	21 Oct 2020 (Study Day 1) - 22 Oct 2020 (Study Day 2)	Fever

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	21 Oct 2020 (Study Day 1) - 22 Oct 2020 (Study Day 2)	Headaches, Muscle Aches, Joint Aches, Chills, Fever
Alprazolam	06 Nov 2020 (Study Day 17) - 10 Nov 2020 (Study Day 21)	Anxiety
Arterial blood gases*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Blood culture*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Budesonide	06 Nov 2020 (Study Day 17) - 25 Nov 2020 (Study Day 36)	Asthma/Intermittent Wheezing
C-reactive protein*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Cefepime	06 Nov 2020 (Study Day 17) - 09 Nov 2020 (Study Day 20)	Right Ankle Cellulitis/Sepsis/Uti
Chest x ray*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Clindamycin	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Right Ankle Cellulitis/Sepsis
Complete blood count and differential*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Complete metabolic panel*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Ct tib-fib right with iv contrast*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Electrocardiogram (ekg)*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Insulin lispro	06 Nov 2020 (Study Day 17) - Ongoing	Diabetes
Iohexol	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Iv Contrast (Right Leg Ct Scan)
Ketorolac	06 Nov 2020 (Study Day 17) - 10 Nov 2020 (Study Day 21)	Right Leg Pain - Cellulitis
Naloxone hydrochloride	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Lethargy - Suspected Opioid Abuse
Oxygen	06 Nov 2020 (Study Day 17) - 26 Nov 2020 (Study Day 37)	Unknown
Pantoprazole	06 Nov 2020 (Study Day 17) - 25 Nov 2020 (Study Day 36)	Prophylaxis For Gastrointestinal (Gi) Bleed
Paracetamol	06 Nov 2020 (Study Day 17) - 25 Nov 2020 (Study Day 36)	Pain Right Ankle
Right ankle x ray*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Right foot x ray*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Ultrasound bilateral upper extremities*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Urinalysis*	06 Nov 2020 (Study Day 17) - 06 Nov 2020 (Study Day 17)	Diagnostic
Valproate semisodium	06 Nov 2020 (Study Day 17) - 17 Nov 2020 (Study Day 28)	Seizures

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vancomycin	06 Nov 2020 (Study Day 17) - 08 Nov 2020 (Study Day 19)	Right Ankle Cellulitis/Sepsis/Uti
Vancomycin	08 Nov 2020 (Study Day 19) - 11 Nov 2020 (Study Day 22)	Right Ankle Cellulitis/Sepsis
Calcium chloride; potassium chloride; sodium lactate	10 Nov 2020 (Study Day 21) - 18 Nov 2020 (Study Day 29)	Blood Pressure Support - Hypotension
Calcium chloride; potassium chloride; sodium lactate	10 Nov 2020 (Study Day 21) - 11 Nov 2020 (Study Day 22)	Hypotension
Ct brain without iv contrast*	10 Nov 2020 (Study Day 21) - 10 Nov 2020 (Study Day 21)	Diagnostic
Mri brain without iv contrast*	10 Nov 2020 (Study Day 21) - 10 Nov 2020 (Study Day 21)	Diagnostic
Naloxone hydrochloride	10 Nov 2020 (Study Day 21) - 10 Nov 2020 (Study Day 21)	Lethargy - Suspected Opioid Abuse
Nicotine	10 Nov 2020 (Study Day 21) - 25 Nov 2020 (Study Day 36)	Smoking Cessation
Sodium chloride	10 Nov 2020 (Study Day 21) - 13 Nov 2020 (Study Day 24)	Hypotension
Sodium chloride	10 Nov 2020 (Study Day 21) - 22 Nov 2020 (Study Day 33)	Hypotension (1st Episode) And Hypotension (2nd Episode)
Ampicillin; sulbactam	11 Nov 2020 (Study Day 22) - 13 Nov 2020 (Study Day 24)	Right Ankle Cellulitis/Sepsis
Bedside eeg monitoring continuous*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Ct abd/pelvis without iv contrast*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Ipratropium bromide; salbutamol	11 Nov 2020 (Study Day 22) - 24 Nov 2020 (Study Day 35)	Asthma - Intermittent Wheezing, Atelectasis
Mid line insertion - ultrasound guided*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Adverse Event
Portable eeg*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Transthoracic echo*	11 Nov 2020 (Study Day 22) - 11 Nov 2020 (Study Day 22)	Diagnostic
Valproate semisodium	11 Nov 2020 (Study Day 22) - 17 Nov 2020 (Study Day 28)	Seizures
Vancomycin	11 Nov 2020 (Study Day 22) - 15 Nov 2020 (Study Day 26)	Right Ankle Cellulitis/Sepsis
Calcium gluconate	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Hypocalcemia (2nd Episode)
Chest x ray*	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Diagnostic
Electrolytes nos	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Electrolyte Imbalance
Magnesium bloodwork*	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Diagnostic
Magnesium sulfate	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Hypomagnesemia
Piperacillin sodium; tazobactam sodium	12 Nov 2020 (Study Day 23) - 12 Nov 2020 (Study Day 23)	Right Ankle Cellulitis/Sepsis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Abacavir	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Hiv
Dolutegravir	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Hiv
Lamivudine	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Hiv
Sulfamethoxazole; trimethoprim	13 Nov 2020 (Study Day 24) - 17 Nov 2020 (Study Day 28)	Prophylaxis For Pcp
Aciclovir	14 Nov 2020 (Study Day 25) - 16 Nov 2020 (Study Day 27)	Potential Cns Infection
Ampicillin	14 Nov 2020 (Study Day 25) - 16 Nov 2020 (Study Day 27)	Right Ankle Cellulitis/Sepsis
Cefepime	14 Nov 2020 (Study Day 25) - 16 Nov 2020 (Study Day 27)	Potential Cns Infection
Haloperidol	14 Nov 2020 (Study Day 25) - 18 Nov 2020 (Study Day 29)	Episodes Of Agitation
Lidocaine	15 Nov 2020 (Study Day 26) - 15 Nov 2020 (Study Day 26)	Lumbar Puncture
Lumbar puncture*	15 Nov 2020 (Study Day 26) - 15 Nov 2020 (Study Day 26)	Diagnostic
Vancomycin	15 Nov 2020 (Study Day 26) - 16 Nov 2020 (Study Day 27)	Potential Cns Infection
Chest x ray*	16 Nov 2020 (Study Day 27) - 16 Nov 2020 (Study Day 27)	Diagnostic
Glucose	16 Nov 2020 (Study Day 27) - 18 Nov 2020 (Study Day 29)	Hypoglycemia
Lorazepam	16 Nov 2020 (Study Day 27) - 16 Nov 2020 (Study Day 27)	Episodes Of Agitation
Magnesium bloodwork*	16 Nov 2020 (Study Day 27) - 16 Nov 2020 (Study Day 27)	Diagnostic
Rivaroxaban	16 Nov 2020 (Study Day 27) - 17 Nov 2020 (Study Day 28)	Dvt Prophylaxis
Complete metabolic panel*	17 Nov 2020 (Study Day 28) - 17 Nov 2020 (Study Day 28)	Diagnostic
Ct brain without iv contrast*	17 Nov 2020 (Study Day 28) - 17 Nov 2020 (Study Day 28)	Diagnostic
Quetiapine	17 Nov 2020 (Study Day 28) - 25 Nov 2020 (Study Day 36)	Paranoia
Calcium alginate	18 Nov 2020 (Study Day 29) - 24 Nov 2020 (Study Day 35)	Right Ankle Wound Care
Enoxaparin	18 Nov 2020 (Study Day 29) - 25 Nov 2020 (Study Day 36)	Deep Vein Thrombosis Prophylaxis
Miconazole	18 Nov 2020 (Study Day 29) - Ongoing	Bilateral Inguinal Areas And Pannus Fold
Potassium chloride	18 Nov 2020 (Study Day 29) - 19 Nov 2020 (Study Day 30)	Hypokalemia
Valproate sodium	18 Nov 2020 (Study Day 29) - 25 Nov 2020 (Study Day 36)	Seizures
Zinc oxide	18 Nov 2020 (Study Day 29) - Ongoing	Intergluteal Fold Fissure Wound Care

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glucose; sodium chloride	19 Nov 2020 (Study Day 30) - 24 Nov 2020 (Study Day 35)	Unknown
Magnesium sulfate	19 Nov 2020 (Study Day 30) - 19 Nov 2020 (Study Day 30)	Hypomagnesemia
Ampicillin; sulbactam	20 Nov 2020 (Study Day 31) - 23 Nov 2020 (Study Day 34)	Sepsis
Hydromorphone	20 Nov 2020 (Study Day 31) - 21 Nov 2020 (Study Day 32)	Right Ankle Pain
Chest x ray*	21 Nov 2020 (Study Day 32) - 21 Nov 2020 (Study Day 32)	Diagnostic
Magnesium sulfate	21 Nov 2020 (Study Day 32) - 21 Nov 2020 (Study Day 32)	Hypomagnesemia (2nd Episode)
Abacavir	22 Nov 2020 (Study Day 33) - 25 Nov 2020 (Study Day 36)	Hiv
Chest x ray*	22 Nov 2020 (Study Day 33) - 22 Nov 2020 (Study Day 33)	Diagnostic
Dolutegravir	22 Nov 2020 (Study Day 33) - 25 Nov 2020 (Study Day 36)	Hiv
Lamivudine	22 Nov 2020 (Study Day 33) - 25 Nov 2020 (Study Day 36)	Hiv
Magnesium sulfate	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Hypomagnesemia (2nd Episode)
Potassium chloride	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Hypokalemia (3rd Episode)
Potassium; sodium phosphate	23 Nov 2020 (Study Day 34) - 23 Nov 2020 (Study Day 34)	Hypokalemia (3rd Episode)
Docusate sodium; sennoside a+b	24 Nov 2020 (Study Day 35) - 25 Nov 2020 (Study Day 36)	Constipation
Lidocaine	24 Nov 2020 (Study Day 35) - 25 Nov 2020 (Study Day 36)	Right Ankle Pain
Macrogol	24 Nov 2020 (Study Day 35) - 25 Nov 2020 (Study Day 36)	Constipation
Meglumine gadoterate	24 Nov 2020 (Study Day 35) - 24 Nov 2020 (Study Day 35)	Mri Right Ankle With And Without Contrast
Mri right ankle with and without iv contrast*	24 Nov 2020 (Study Day 35) - 24 Nov 2020 (Study Day 35)	Diagnostic
Us dvt lower bilateral extremities*	25 Nov 2020 (Study Day 36) - 25 Nov 2020 (Study Day 36)	Diagnostic
Us dvt upper bilateral extremities*	25 Nov 2020 (Study Day 36) - 25 Nov 2020 (Study Day 36)	Diagnostic
Abacavir sulfate; dolutegravir sodium; lamivudine	26 Nov 2020 (Study Day 37) - Ongoing	Hiv
Ibuprofen	26 Nov 2020 (Study Day 37) - Ongoing	Right Foot Pain
Quetiapine fumarate	26 Nov 2020 (Study Day 37) - Ongoing	Paranoia
Rivaroxaban	26 Nov 2020 (Study Day 37) - Ongoing	Prophylaxis For Deep Vein Thrombosis
Valproate semisodium	26 Nov 2020 (Study Day 37) - Ongoing	Anxiety
Amoxicillin trihydrate; clavulanate potassium	25 Jan 2021 (Study Day 97) - 03 Feb 2021 (Study Day 106)	Right Ankle Cellulitis
Alprazolam	Feb 2021 - Ongoing	Anxiety

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	Feb 2021 - Ongoing	Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 3/severe	Not related	27 Oct 2020 (Study Day 7) - Ongoing
Cystitis	Grade 2/moderate	Not related	04 Nov 2020 (Study Day 15) - 13 Nov 2020 (Study Day 24)
Atelectasis	Grade 2/moderate	Not related	06 Nov 2020 (Study Day 17) - Ongoing
Cellulitis	Grade 3/severe	Not related	06 Nov 2020 (Study Day 17) - Ongoing
Electrolyte Imbalance	Grade 2/moderate	Not related	06 Nov 2020 (Study Day 17) - 26 Nov 2020 (Study Day 37)
Hypocalcaemia	Grade 1/mild	Not related	06 Nov 2020 (Study Day 17) - 09 Nov 2020 (Study Day 20)
Lethargy	Grade 2/moderate	Not related	06 Nov 2020 (Study Day 17) - 13 Nov 2020 (Study Day 24)
Osteonecrosis	Grade 2/moderate	Not related	06 Nov 2020 (Study Day 17) - Ongoing
Wheezing	Grade 2/moderate	Not related	06 Nov 2020 (Study Day 17) - 25 Nov 2020 (Study Day 36)
Hypocalcaemia	Grade 1/mild	Not related	10 Nov 2020 (Study Day 21) - 14 Nov 2020 (Study Day 25)
Encephalopathy	Grade 3/severe	Not related	11 Nov 2020 (Study Day 22) - 25 Nov 2020 (Study Day 36)
Hypomagnesaemia	Grade 1/mild	Not related	12 Nov 2020 (Study Day 23) - 13 Nov 2020 (Study Day 24)
Agitation	Grade 2/moderate	Not related	14 Nov 2020 (Study Day 25) - 18 Nov 2020 (Study Day 29)
Dysphagia	Grade 3/severe	Not related	16 Nov 2020 (Study Day 27) - 22 Nov 2020 (Study Day 33)
Hypoglycaemia	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 27) - 18 Nov 2020 (Study Day 29)
Hypomagnesaemia	Grade 1/mild	Not related	16 Nov 2020 (Study Day 27) - 24 Nov 2020 (Study Day 35)
Hypokalaemia	Grade 1/mild	Not related	17 Nov 2020 (Study Day 28) - 18 Nov 2020 (Study Day 29)
Fungal Skin Infection	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 29) - 12 Apr 2021 (Study Day 174)
Fungal Skin Infection	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 29) - 12 Apr 2021 (Study Day 174)
Right Hemisphere Deficit Syndrome	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 29) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Skin Fissures	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 29) - 12 Apr 2021 (Study Day 174)
Hypocalcaemia	Grade 1/mild	Not related	23 Nov 2020 (Study Day 34) - 24 Nov 2020 (Study Day 35)
Hypokalaemia	Grade 1/mild	Not related	23 Nov 2020 (Study Day 34) - 26 Nov 2020 (Study Day 37)
Constipation	Grade 1/mild	Not related	24 Nov 2020 (Study Day 35) - 26 Nov 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US363-2022 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Leiomyosarcoma Metastatic/ Metastatic, Recurrent, Stage 4 Leiomyosarcoma	SAE	Grade 4	Not related	20 Nov 2020 (Study Day 85) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US363-2022, a 68-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Nov 2020 (Study Day 85), 84 days after the first dose and 56 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of leiomyosarcoma metastatic. Action taken with the IP was not applicable. The event of metastatic, recurrent, stage 4 leiomyosarcoma was considered to be ongoing. The investigator assessed the event of leiomyosarcoma metastatic to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000891	Leiomyosarcoma metastatic

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1978 - 1978
Postmenopause	Postmenopausal	2003 - Ongoing
Osteopenia	Osteopenia	2010 - 01 Jul 2020 (Study Day -58)
Leiomyosarcoma recurrent	Leiomyosarcoma (diagnosed in 2017 and had a polyp removed from nasal cavity and then in july 2020 there was a 2nd surgery which was a skull based resection)	2017 - 01 Nov 2017 (Study Day -1031)
Anxiety	Anxiety	01 Dec 2017 (Study Day -1001) - Ongoing
Insomnia	Insomnia	01 Dec 2017 (Study Day -1001) - Ongoing
Osteonecrosis	Avascular necrosis in right hip	2018 - 01 Apr 2018 (Study Day -880)
Hip arthroplasty	Hip replacement (right)	01 Apr 2018 (Study Day -880) - 01 Apr 2018 (Study Day -880)
Osteoporosis	Osteoporosis	2020 - Ongoing
Skin operation	Partial scalp removal	01 Jul 2020 (Study Day -58) - 01 Jul 2020 (Study Day -58)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	Not reported - Ongoing	Osteoarthririts
Calcium carbonate; ergocalciferol	2010 - Ongoing	Osteoporosis & Osteopenia
Vitamins nos	2010 - Ongoing	General Health
Escitalopram oxalate	2017 - Ongoing	Anxiety
Zolpidem	2017 - Ongoing	Insomnia
Mri on abdomen*	19 Nov 2020 (Study Day 84) - 19 Nov 2020 (Study Day 84)	Diagnostic
Liver biopsy*	16 Dec 2020 (Study Day 111) - 16 Dec 2020 (Study Day 111)	Diagnostic
Pet scan*	23 Dec 2020 (Study Day 118) - 23 Dec 2020 (Study Day 118)	Diagnostic
Gemcitabine	07 Jan 2021 (Study Day 133) - Ongoing	Metastatic Leiomyosarcoma
Vinorelbine	07 Jan 2021 (Study Day 133) - Ongoing	Metastatic Leiomyosarcoma
Radiotherapy	15 Mar 2021 (Study Day 200) - 24 Mar 2021 (Study Day 209)	Leiomyosarcoma (Ae)
Sbrt radiation to sternum*	15 Mar 2021 (Study Day 200) - 15 Mar 2021 (Study Day 200)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

FDA-CBER-2022-1614-3380062

Participant Number:	US363-2032 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	16 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertensive Emergency/ Hypertensive Emergency	SAE	Grade 4	Not related	16 Sep 2020 (Study Day 1) – 18 Sep 2020 (Study Day 3)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US363-2032, a 55-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of hypertensive emergency. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to withdrawal of consent by participant. The event of hypertensive emergency lasted for 3 days, after which it was considered to be recovered/resolved on 18 Sep 2020 (Study Day 3). The investigator assessed the event of hypertensive emergency to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000301	Hypertensive emergency

Study Completion/Discontinuation

On 19 Oct 2020 (Study Day 34), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Severe obesity	Not reported - Ongoing
Seasonal allergy	Allergies (pollen/hay fever)	Not reported - Ongoing
Salpingo-oophorectomy unilateral	Right ovary and tube removed	01 Apr 1993 (Study Day -10030) - 01 Apr 1993 (Study Day -10030)
Arthroscopy	Right knee arthroscopy	01 Jun 1995 (Study Day -9239) - 01 Oct 1997 (Study Day -8386)
Atrial fibrillation	Atrial fibrillation	01 Jan 1996 (Study Day -9025) - Ongoing
Hypertension	Hypertension	01 Jan 1996 (Study Day -9025) - Ongoing
Cholecystectomy	Gallbladder removed	01 Jan 1998 (Study Day -8294) - 01 Jan 1998 (Study Day -8294)
Asthma	Mild asthma (on inhaler as needed rarely needed)	01 Jan 2000 (Study Day -7564) - Ongoing
Anaemia	Anemia (low-grade) (two low to be treatable)	01 Jan 2010 (Study Day -3911) - Ongoing
Cardiac ablation	Cardiac ablation	01 Oct 2012 (Study Day -2907) - 01 Apr 2013 (Study Day -2725)
Gastrectomy	Sleeve gastrectomy	01 Oct 2013 (Study Day -2542) - 01 Oct 2013 (Study Day -2542)
Menopause	Menopause	01 Jan 2019 (Study Day -624) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	1996 - 05 Oct 2020 (Study Day 20)	Atrial Fibrillation
Lisinopril	2000 - 16 Sep 2020 (Study Day 1)	Hypertension
Levosalbutamol hydrochloride	2010 - Ongoing	Mild Asthma
Ipratropium bromide; salbutamol sulfate	2019 - Ongoing	Asthma Exacerbation
Flecainide	01 Apr 2019 (Study Day -534) - Ongoing	Atrial Fibrillation
Cetirizine	01 Apr 2020 (Study Day -168) - Ongoing	Pollen/Hay Fever Allergies
Lisinopril	16 Sep 2020 (Study Day 1) - Ongoing	Hypertension
Paracetamol	04 Oct 2020 (Study Day 19) - 04 Oct 2020 (Study Day 19)	Migraine
Metoprolol	06 Oct 2020 (Study Day 21) - Ongoing	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Atrial Fibrillation	Grade 2/moderate	Not related	01 Oct 2020 (Study Day 16) - Ongoing
Migraine	Grade 1/mild	Not related	04 Oct 2020 (Study Day 19) - 04 Oct 2020 (Study Day 19)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US363-2064 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Transient Ischaemic Attack/Transient Ischemic Attack	SAE	Grade 4	Not related	31 Dec 2020 (Study Day 114) – 04 Jan 2021 (Study Day 118)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US363-2064, a 75-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Dec 2020 (Study Day 114), 113 days after the first dose and 85 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of transient ischaemic attack. Action taken with the IP was not applicable. The event of transient ischemic attack lasted for 5 days, after which it was considered to be recovered/resolved with sequelae on 04 Jan 2021 (Study Day 118). The investigator assessed the event of transient ischaemic attack to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001558	Transient ischaemic attack

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rosacea	Rosacea	1990 - Ongoing
Skin cancer	Skin cancer- monitored every 6 months	1990 - Ongoing
Skin neoplasm excision	Skin cancer cells have been removed- 6 different procedures in 30 years period (2 were melanoma and the rest were bcc)	1990 - Not reported
Blood cholesterol increased	High cholesterol	1995 - Ongoing
Hypertension	High blood pressure	1995 - Ongoing
Thyroid mass	Thyroid nodules (resulted in a partial thyroid removal)	2015 - 2015
Thyroidectomy	Thyroid gland removed (partial removal)	2015 - 2015
Benign prostatic hyperplasia	Benign prostatic hyperplasia (bph	2018 - Ongoing
Parkinson's disease	Parkinson's disease (slow progression)	2019 - Ongoing
Obesity	Severe obesity with a bmi over 40	2020 - Ongoing
Basal cell carcinoma	Basal cell carcinoma (skin cancer)	01 Jul 2020 (Study Day -70) - 01 Jul 2020 (Study Day -70)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Doxycycline hyclate	2000 - Ongoing	Rosacea
Amlodipine	2010 - Ongoing	High Blood Pressure
Acetylsalicylic acid	31 Aug 2010 (Study Day -3662) - Ongoing	General Health
Vitamin b12 nos	17 Jul 2013 (Study Day -2611) - Ongoing	General Health
Calcium; vitamin d nos	27 Aug 2014 (Study Day -2205) - Ongoing	General Health
Hydrochlorothiazide	2015 - Ongoing	High Blood Pressure
Irbesartan	2015 - Ongoing	High Blood Pressure
Metoprolol	2015 - Ongoing	High Blood Pressure
Pravastatin	2015 - 04 Jan 2021 (Study Day 118)	High Cholesterol
Vitamin d nos	2015 - Ongoing	General Health
Finasteride	2018 - Ongoing	Prostate And Bladder Issues
Tamsulosin	2018 - Ongoing	Prostate And Bladder Issues
Carbidopa; levodopa	02 Dec 2019 (Study Day -282) - Ongoing	Parkinson's Disease
Mirabegron	14 Jul 2020 (Study Day -57) - Ongoing	Prostate And Bladder Issues
Clopidogrel bisulfate	31 Dec 2020 (Study Day 114) - 31 Dec 2020 (Study Day 114)	Transient Ischemic Attack
Atorvastatin	03 Jan 2021 (Study Day 117) - Ongoing	High Cholesterol
Clopidogrel bisulfate	03 Jan 2021 (Study Day 117) - Ongoing	Tia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Mri*	03 Jan 2021 (Study Day 117) - 03 Jan 2021 (Study Day 117)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US363-2127 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	13 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	11 Nov 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sexual Abuse/Sexual Assault	SAE	Grade 4	Not related	07 Nov 2020 (Study Day 26) – 07 Nov 2020 (Study Day 26)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US363-2127, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 13 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 11 Nov 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Nov 2020 (Study Day 26), 25 days after the first dose and 4 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of sexual abuse. The IP dose was not changed due to the sexual assault. The event of sexual assault lasted for 1 day, after which it was considered to be recovered/resolved on 07 Nov 2020 (Study Day 26). The investigator assessed the event of sexual abuse to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000722	Sexual abuse

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Severe obesity (bmi 42.13479)	Not reported - Ongoing
Anaphylactic reaction	Geodon allergy (anaphylaxis)	1993 - Ongoing
Constipation	Constipation	1994 - Ongoing
Small intestine operation	Small bowel surgery	1994 - 1994
Osteoarthritis	Osteoarthritis	2003 - Ongoing
Postmenopause	Post menopausal	2006 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Herpes simplex	Herpes simplex virus	2012 - Ongoing
Small intestinal resection	Small bowel repair due to blockage	2013 - 2013
Rheumatoid arthritis	Rheumatoid arthritis (both ankles)	2016 - Ongoing
Blood cholesterol increased	Elevated cholesterol	Feb 2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Naproxen	2005 - Ongoing	Osteoarthritis & Rheumatoid Arthritis
Vaccinium macrocarpon	2005 - Ongoing	General Health
Acetylsalicylic acid	2010 - Ongoing	Heart Attack Prevention
Curcuma longa	2010 - Ongoing	Osteoarthritis
Fish oil	2010 - Ongoing	Hypertension
Hydrochlorothiazide; lisinopril	2010 - Ongoing	Hyptertension
Probiotics nos	2015 - Ongoing	General Health
Malus spp. vinegar extract	2018 - Ongoing	General Health
Diclofenac sodium	2019 - Ongoing	Rheumatoid Arthritis
Ascorbic acid; rosa canina; sodium ascorbate	01 Feb 2020 (Study Day -255) - Ongoing	General Health
Magnesium	01 Apr 2020 (Study Day -195) - Ongoing	Constipation
Potassium	01 Apr 2020 (Study Day -195) - Ongoing	Hypertension
Colecalciferol	01 May 2020 (Study Day -165) - 2021	To Help With Bone Health
Sambucus nigra	01 Sep 2020 (Study Day -42) - Ongoing	General Health
Naproxen	13 Oct 2020 (Study Day 1) - 13 Oct 2020 (Study Day 1)	Osteoarthritis/Rheumatoid Arthritis
Pravastatin	19 Oct 2020 (Study Day 7) - Ongoing	Slightly Elevated Cholesterol
Azithromycin	07 Nov 2020 (Study Day 26) - 07 Nov 2020 (Study Day 26)	Sexual Assault (Ae)- Presumptive Treatment Of Sti's
Ceftriaxone	07 Nov 2020 (Study Day 26) - 07 Nov 2020 (Study Day 26)	Sexual Assault (Ae)- Presumptive Treatment Of Sti's

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metronidazole	07 Nov 2020 (Study Day 26) - 07 Nov 2020 (Study Day 26)	Sexual Assault (Ae)- Presumptive Treatment Of Sti's
Naproxen	07 Nov 2020 (Study Day 26) - 15 Dec 2020 (Study Day 64)	Fractured Toe (Ae)
Dolutegravir sodium	12 Nov 2020 (Study Day 31) - 20 Nov 2020 (Study Day 39)	Sexual Assault (Ae #1)
Emtricitabine; tenofovir disoproxil fumarate	12 Nov 2020 (Study Day 31) - 20 Nov 2020 (Study Day 39)	Sexual Assault
Colecalciferol	2021 - Ongoing	General Bone Health
Paracetamol	15 Jan 2021 (Study Day 95) - 15 Jan 2021 (Study Day 95)	Arm Soreness After Ol Vaccination
Naproxen	16 Jan 2021 (Study Day 96) - 16 Jan 2021 (Study Day 96)	Pain In Arm After Ol Vaccination
Hydrocodone	17 Jan 2021 (Study Day 97) - 17 Jan 2021 (Study Day 97)	Left Arm Pain After Ol Vaccine
Phentermine	05 Feb 2021 (Study Day 116) - 13 Feb 2021 (Study Day 124)	Severe Obesity
Fluconazole	25 Feb 2021 (Study Day 136) - 26 Feb 2021 (Study Day 137)	Urinary Tract Infection
Nitrofurantoin	25 Feb 2021 (Study Day 136) - 01 Mar 2021 (Study Day 140)	Urinary Tract Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Foot Fracture	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 26) - 15 Dec 2020 (Study Day 64)
Muscle Spasms	Grade 3/severe	Not related	06 Dec 2020 (Study Day 55) - 06 Dec 2020 (Study Day 55)
Cough	Grade 1/mild	Not related	03 Jan 2021 (Study Day 83) - 13 Jan 2021 (Study Day 93)
Urinary Tract Infection	Grade 1/mild	Not related	19 Feb 2021 (Study Day 130) - 03 Mar 2021 (Study Day 142)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US364-2024 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rib Fracture/Closed Fracture Of Multiple Ribs	SAE	Grade 3/ severe	Not related	25 Sep 2020 (Study Day 30) – 11 Jan 2021 (Study Day 138)	Recovered/resolved
Traumatic Haemothorax/Hemopneumothorax Right Side	SAE	Grade 4	Not related	25 Sep 2020 (Study Day 30) – 30 Sep 2020 (Study Day 35)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2024, a 70-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 30), 29 days after the first dose and 6 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of rib fracture. Action taken with the IP was not applicable. The event of closed fracture of multiple ribs lasted for 109 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 138). The investigator assessed the event of rib fracture to be not related to the IP.

On 25 Sep 2020 (Study Day 30), 29 days after the first dose and 6 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of traumatic haemothorax. Action taken with the IP was not applicable. The event of hemopneumothorax right side lasted for 6 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 35). The investigator assessed the event of traumatic haemothorax to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-074277	Hemopneumothorax
MOD-2021-074277	Closed fracture of multiple ribs, unspecified

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety disorder	Anxiety disorder	Not reported - Ongoing
Back pain	Back pain	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Depression	Depression	2005 - Ongoing
Osteoporosis	Osteoporosis	28 Mar 2007 (Study Day -4901) - Ongoing
Prostate cancer	Prostate cancer	2010 - 2010
Insomnia	Insomnia	02 May 2015 (Study Day -1944) - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	17 Oct 2017 (Study Day -1045) - Ongoing
Supraventricular extrasystoles	Atrial ectopy	25 Feb 2019 (Study Day -549) - Ongoing
Dandruff	Dandruff	24 Jan 2020 (Study Day -216) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Quetiapine fumarate	02 May 2015 (Study Day -1944) - Ongoing	Insomnia
Venlafaxine hydrochloride	14 May 2015 (Study Day -1932) - Ongoing	Anxiety Disorder
Atorvastatin	25 Oct 2019 (Study Day -307) - Ongoing	Hyperlipidemia
Ketoconazole	24 Jul 2020 (Study Day -34) - Ongoing	Dandruff
Cyclobenzaprine hydrochloride	05 Aug 2020 (Study Day -22) - Ongoing	Back Pain
Meloxicam	05 Aug 2020 (Study Day -22) - 12 Aug 2020 (Study Day -15)	Back Pain
Meclofenamate sodium	12 Aug 2020 (Study Day -15) - Ongoing	Back Pain
Tizanidine hydrochloride	12 Aug 2020 (Study Day -15) - Ongoing	Back Pain
Calcium chloride; potassium chloride; sodium lactate	25 Sep 2020 (Study Day 30) - 26 Sep 2020 (Study Day 31)	Hemopneumothorax, Rib Fracture, Scapula Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest x-ray*	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Diagnostic
Ct chest, absomen, pelvis*	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Diagnostic
Ipratropium; salbutamol	25 Sep 2020 (Study Day 30) - 29 Sep 2020 (Study Day 34)	Hemopneumothorax
Lidocaine	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Closed Fracture Of Multiple Ribs
Morphine	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Morphine	25 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 32)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Ondansetron	25 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 32)	Nausea
Oxycodone	25 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 32)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Oxycodone	25 Sep 2020 (Study Day 30) - 28 Sep 2020 (Study Day 33)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Paracetamol	25 Sep 2020 (Study Day 30) - 30 Sep 2020 (Study Day 35)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Bisacodyl	26 Sep 2020 (Study Day 31) - 26 Sep 2020 (Study Day 31)	Prophylaxis For Constipation
Celecoxib	26 Sep 2020 (Study Day 31) - 30 Sep 2020 (Study Day 35)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Chest x-ray*	26 Sep 2020 (Study Day 31) - 26 Sep 2020 (Study Day 31)	Diagnostic
Docusate sodium; senna alexandrina	26 Sep 2020 (Study Day 31) - 30 Sep 2020 (Study Day 35)	No Bowel Movment For 3 Days
Gabapentin	26 Sep 2020 (Study Day 31) - 30 Sep 2020 (Study Day 35)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Lidocaine	26 Sep 2020 (Study Day 31) - 27 Sep 2020 (Study Day 32)	Closed Fracture Of Multiple Ribs
Sodium chloride	26 Sep 2020 (Study Day 31) - 28 Sep 2020 (Study Day 33)	Hemopneumothorax, Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Vascular ult venous duplex lower extremeity complete bilateral*	26 Sep 2020 (Study Day 31) - 26 Sep 2020 (Study Day 31)	Diagnostic
Calcium chloride; potassium chloride; sodium lactate	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cefazolin	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Chest x-ray*	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Diagnostic
Dexamethasone	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Evacuation of retained hemothorax*	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Adverse Event
Hydromorphone	27 Sep 2020 (Study Day 32) - 28 Sep 2020 (Study Day 33)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Lidocaine	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Magnesium sulfate	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Magnesium Deficiency
Metoclopramide	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Ondansetron	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Oxycodone	27 Sep 2020 (Study Day 32) - 29 Sep 2020 (Study Day 34)	Closed Fracture Of Multiple Ribs, Closed Fracture Of Body Of Right Scapula
Phenylephrine	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Plating of right ribs 3-7 fractures*	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Propofol	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Right chest tube placement*	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Adverse Event
Rocuronium	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Sodium chloride	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Sugammadex	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Plating Of Right Ribs 3-7 Fractures, Right Chest Tube Placement, Evacuation Of Retained Hemothorax, Video-Assisted Thoracoscopic Surgery Cryoablation Of Right Paraspinal Nerves 3-9
Video-assisted thoracoscopic surgery cryoablation of right paraspinal nerves 3-9*	27 Sep 2020 (Study Day 32) - 27 Sep 2020 (Study Day 32)	Adverse Event
Chest x-ray*	28 Sep 2020 (Study Day 33) - 28 Sep 2020 (Study Day 33)	Diagnostic
Heparin	28 Sep 2020 (Study Day 33) - 29 Sep 2020 (Study Day 34)	Prophylaxis For Blood Clot
Lidocaine	28 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 35)	Closed Fracture Of Multiple Ribs
Macrogol 3350	28 Sep 2020 (Study Day 33) - 30 Sep 2020 (Study Day 35)	No Bowel Movment For 3 Days
Sodium chloride	28 Sep 2020 (Study Day 33) - 29 Sep 2020 (Study Day 34)	Hemopneumothorax
Chest x-ray*	29 Sep 2020 (Study Day 34) - 29 Sep 2020 (Study Day 34)	Diagnostic
Lactulose	29 Sep 2020 (Study Day 34) - 30 Sep 2020 (Study Day 35)	No Bowel Movement For 3 Days
Chest x-ray*	30 Sep 2020 (Study Day 35) - 30 Sep 2020 (Study Day 35)	Diagnostic
Magnesium citrate	30 Sep 2020 (Study Day 35) - 30 Sep 2020 (Study Day 35)	Magnesium Deficiency

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chronic Kidney Disease	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 30) - Ongoing
Nausea	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 30) - 27 Sep 2020 (Study Day 32)
Road Traffic Accident	Grade 3/severe	Not related	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)
Scapula Fracture	Grade 3/severe	Not related	25 Sep 2020 (Study Day 30) - 11 Jan 2021 (Study Day 138)
Skin Abrasion	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 30) - 08 Oct 2020 (Study Day 43)
Magnesium Deficiency	Grade 2/moderate	Not related	27 Sep 2020 (Study Day 32) - 30 Sep 2020 (Study Day 35)
Constipation	Grade 2/moderate	Not related	29 Sep 2020 (Study Day 34) - 30 Sep 2020 (Study Day 35)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US364-2035 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Osteoarthritis Left Hip	SAE	Grade 3/severe	Not related	10 Sep 2020 (Study Day 14) – 12 Oct 2020 (Study Day 46)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2035, a 71-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Sep 2020 (Study Day 14), 13 days after the first dose and 15 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening osteoarthritis left hip lasted for 33 days, after which it was considered to be recovered/resolved on 12 Oct 2020 (Study Day 46). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001195	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1980 - Ongoing
Postmenopause	Postmenopausal	1999 - Ongoing
Atrial fibrillation	Atrial fibrilation	May 2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	May 2018 - Ongoing
Osteoarthritis	Osteoarthritis	Nov 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Celecoxib	Not reported - 12 Oct 2020 (Study Day 46)	Osteoarthritis
Paracetamol	Not reported - Ongoing	Osteoarthritis
Sumatriptan	2000 - Ongoing	Migraines
Glucosamine sulfate	2005 - Ongoing	Supplement
Vitamins nos	2005 - Ongoing	Supplement
Calcium; vitamin d nos	2010 - 10 Oct 2020 (Study Day 44)	Supplement
Colecalciferol	2010 - Ongoing	Supplement
Apixaban	May 2018 - Ongoing	Atrial Fibrilation
Atorvastatin	May 2018 - Ongoing	Hyperlipidemia
Metoprolol	May 2018 - Ongoing	Atrial Fibrilation, Hypertension
Palmidrol	2019 - Ongoing	Osteoarthritis
Chest xray*	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Diagnostic
Cta abdomen and pelvis*	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Diagnostic
Cta chest*	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Diagnostic
Diazepam	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Muscle Spasm
Ekg*	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Diagnostic
Fentanyl citrate	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Pain (Left Flank)
Iohexol	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Contrast For Chest Ct (Ae Log Line 1)
Ketorolac tromethamine	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Pain Left Flank
Lidocaine	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Pain Left Flank
Ondansetron hydrochloride	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Nausea
Promethazine	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Nausea

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)	Dehydration
Gabapentin	01 Sep 2020 (Study Day 5) - 01 Sep 2020 (Study Day 5)	Pain Left Flank
Hydrocodone; paracetamol	01 Sep 2020 (Study Day 5) - 01 Sep 2020 (Study Day 5)	Pain Left Flank
Alendronate sodium	03 Sep 2020 (Study Day 7) - Ongoing	Osteopenia
Calcium; vitamin d nos	10 Oct 2020 (Study Day 44) - Ongoing	Supplement
Influenza vaccine	10 Oct 2020 (Study Day 44) - 10 Oct 2020 (Study Day 44)	Prophylaxis For Flu
Calcium chloride; potassium chloride; sodium lactate	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Left Total Hip Replacment
Cefazolin	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Intra-Op Infection Prophylaxis
Dexamethasone	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Hip Surgery
Dexamethasone	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Docusate sodium; senna alexandrina	12 Oct 2020 (Study Day 46) - Ongoing	Prophylaxis For Constipation D/T Opiod Prescription
Docusate sodium; senna alexandrina	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Prophylaxis For Stool Softening During Opiod Use
Famotidine	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Hip Surgery
Fentanyl	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacment
Glucose; sodium chloride	12 Oct 2020 (Study Day 46) - 13 Oct 2020 (Study Day 47)	Hip Surgery
Hydromorphone	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Hip Surgery, Pain
Hydromorphone	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Lidocaine	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Ondansetron	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Oxycodone	12 Oct 2020 (Study Day 46) - Ongoing	Osteoarthritis Left Hip
Oxycodone	12 Oct 2020 (Study Day 46) - Ongoing	Post Operative Pain, Hip
Paracetamol	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Hip Surgery - Pain
Paracetamol	12 Oct 2020 (Study Day 46) - 13 Oct 2020 (Study Day 47)	Hip Surgery, Pain
Paracetamol	12 Oct 2020 (Study Day 46) - Ongoing	Post Operative Pain, Hip
Phenylephrine	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Propofol	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Rocuronium	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sugammadex	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Total hip replacement, left*	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Adverse Event
Tranexamic acid	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Total Left Hip Replacement
Dexamethasone	13 Oct 2020 (Study Day 47) - 13 Oct 2020 (Study Day 47)	Post Operative Pain, Hip
Oxycodone	13 Oct 2020 (Study Day 47) - 13 Oct 2020 (Study Day 47)	Post Operative Pain, Hip
Dexamethasone	14 Oct 2020 (Study Day 48) - 14 Oct 2020 (Study Day 48)	Post Operative Pain, Hip

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dehydration	Grade 2/moderate	Not related	31 Aug 2020 (Study Day 4) - 31 Aug 2020 (Study Day 4)
Flank Pain	Grade 2/moderate	Not related	31 Aug 2020 (Study Day 4) - 03 Sep 2020 (Study Day 7)
Muscle Spasms	Grade 2/moderate	Not related	31 Aug 2020 (Study Day 4) - 03 Sep 2020 (Study Day 7)
Nausea	Grade 2/moderate	Not related	31 Aug 2020 (Study Day 4) - 03 Sep 2020 (Study Day 7)
Osteopenia	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 7) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US364-2072 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Fall/Fall (Accidental)	SAE	Grade 3/severe	Not related	27 Nov 2020 (Study Day 88) – 27 Nov 2020 (Study Day 88)	Recovered/resolved
Hip Fracture/Hip Fracture S/P Fall	SAE	Grade 3/severe	Not related	27 Nov 2020 (Study Day 88) – 30 Nov 2020 (Study Day 91)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2072, a 79-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Nov 2020 (Study Day 88), 87 days after the first dose and 59 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of fall. Action taken with the IP was not applicable. The event of fall (accidental) lasted for 1 days, after which it was considered to be recovered/resolved on 27 Nov 2020 (Study Day 88). The investigator assessed the event of fall to be not related to the IP.

On 27 Nov 2020 (Study Day 88), 87 days after the first dose and 59 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hip fracture. Action taken with the IP was not applicable. The event of hip fracture s/p fall lasted for 4 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 91). The investigator assessed the event of hip fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000987	Fall

CIOMS Number	MedDRA Preferred Term
MOD-2020-000987	Hip fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post-menopausal	Not reported - Ongoing
Migraine	Migraines	1980 - Ongoing
Hypercholesterolaemia	Hyper cholesterol	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Hypothyroidism	Hypothyroidism	2017 - Ongoing
Bone pain	Bone pain (back)	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2017 - Ongoing	High Cholesterol
Levothyroxine	2017 - Ongoing	Hypothyroidism
Losartan	2017 - Ongoing	Hypertension
Methocarbamol	2018 - Ongoing	Bone Pain
Sumatriptan	2018 - Ongoing	Migraines
Influenza vaccine	23 Oct 2020 (Study Day 53) - 23 Oct 2020 (Study Day 53)	Prophylaxis For Flu
Acetylsalicylic acid	28 Nov 2020 (Study Day 89) - Ongoing	Dvt Prophylaxis
Left hip replacement*	28 Nov 2020 (Study Day 89) - 28 Nov 2020 (Study Day 89)	Adverse Event
Oxycodone	28 Nov 2020 (Study Day 89) - 02 Mar 2021 (Study Day 183)	Hip Fracture S/P Fall
Oxycodone hydrochloride	29 Nov 2020 (Study Day 90) - 02 Mar 2021 (Study Day 183)	Left Hip Replacement Surgery
Fluorouracil	04 Mar 2021 (Study Day 185) - 16 Mar 2021 (Study Day 197)	Pre-Basal Cell Carcinoma Skin Lesion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Precancerous Skin Lesion	Grade 2/moderate	Not related	04 Mar 2021 (Study Day 185) - 16 Mar 2021 (Study Day 197)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US364-2333 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	18 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID19	SAE	Grade 4	Not related	19 Dec 2020 (Study Day 60) – 04 Feb 2021 (Study Day 107)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US364-2333, a 72-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 21 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 18 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Dec 2020 (Study Day 60), 59 days after the first dose and 31 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID19 lasted for 48 days, after which it was considered to be recovered/resolved on 04 Feb 2021 (Study Day 107). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001519	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	May 2000 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	May 2000 - Ongoing	Diabetes Type Ii

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US365-2039 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 (Sars-Cov-2 Confirmed 10/27/2020)	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	25 Oct 2020 (Study Day 27) – 03 Nov 2020 (Study Day 36)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US365-2039, a 33-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 29 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Oct 2020 (Study Day 27), 26 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 26 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of COVID-19 (sars-cov-2 confirmed 10/27/2020) lasted for 10 days, after which it was considered to be recovered/resolved on 03 Nov 2020 (Study Day 36). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000624	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Presyncope	Vasovagal response	29 Sep 2020 (Study Day 1) - 29 Sep 2020 (Study Day 1)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	Not reported - Ongoing	Supplement
Ibuprofen	01 Oct 2020 (Study Day 3) - 01 Oct 2020 (Study Day 3)	Headache Pain (Ediary Symptoms)
Ibuprofen	16 Oct 2020 (Study Day 18) - 16 Oct 2020 (Study Day 18)	Headache
Ibuprofen	25 Oct 2020 (Study Day 27) - 27 Oct 2020 (Study Day 29)	COVID-19 Symptoms
Paracetamol	25 Oct 2020 (Study Day 27) - 27 Oct 2020 (Study Day 29)	COVID-19 Symptoms
Paracetamol	28 Oct 2020 (Study Day 30) - Ongoing	COVID-19 Symptoms (Sore Throat)
Ibuprofen	29 Oct 2020 (Study Day 31) - 29 Oct 2020 (Study Day 31)	COVID-19 Symptoms
Ibuprofen	30 Oct 2020 (Study Day 32) - Ongoing	COVID-19 Symptoms (Sore Throat)
Finasteride	10 Nov 2020 (Study Day 43) - Ongoing	Hair Loss
Influenza vaccine	10 Nov 2020 (Study Day 43) - 10 Nov 2020 (Study Day 43)	Influenza Prophylaxis
Ibuprofen	13 Jan 2021 (Study Day 107) - 14 Jan 2021 (Study Day 108)	Muscle Ache (Post Ol Ae)
Paracetamol	13 Jan 2021 (Study Day 107) - 14 Jan 2021 (Study Day 108)	Fever (Post Ol Ae)
Paracetamol	10 Feb 2021 (Study Day 135) - 11 Feb 2021 (Study Day 136)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Not related	16 Oct 2020 (Study Day 18) - 16 Oct 2020 (Study Day 18)
COVID-19	Grade 1/mild	Not related	25 Oct 2020 (Study Day 27) - 03 Nov 2020 (Study Day 36)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chills	Grade 2/moderate	Related	13 Jan 2021 (Study Day 107) - 14 Jan 2021 (Study Day 108)
Fatigue	Grade 2/moderate	Related	13 Jan 2021 (Study Day 107) - 14 Jan 2021 (Study Day 108)
Headache	Grade 1/mild	Related	13 Jan 2021 (Study Day 107) - 14 Jan 2021 (Study Day 108)
Injection Site Pain	Grade 1/mild	Related	13 Jan 2021 (Study Day 107) - 15 Jan 2021 (Study Day 109)
Myalgia	Grade 2/moderate	Related	13 Jan 2021 (Study Day 107) - 14 Jan 2021 (Study Day 108)
Pyrexia	Grade 2/moderate	Related	13 Jan 2021 (Study Day 107) - 14 Jan 2021 (Study Day 108)
Lip Swelling	Grade 1/mild	Related	13 Jan 2021 (Study Day 107) - 13 Jan 2021 (Study Day 107)
Dyspnoea	Grade 1/mild	Related	14 Jan 2021 (Study Day 108) - 19 Jan 2021 (Study Day 113)
Oropharyngeal Pain	Grade 1/mild	Not related	15 Jan 2021 (Study Day 109) - 16 Jan 2021 (Study Day 110)
Lip Swelling	Grade 1/mild	Related	10 Feb 2021 (Study Day 135) - Ongoing
Fatigue	Grade 1/mild	Related	10 Feb 2021 (Study Day 135) - 11 Feb 2021 (Study Day 136)
Headache	Grade 1/mild	Related	10 Feb 2021 (Study Day 135) - 11 Feb 2021 (Study Day 136)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US366-2033 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abdominal Pain/ Abdominal Pain	SAE	Grade 3/ severe	Not related	08 Sep 2020 (Study Day 8) – 10 Sep 2020 (Study Day 10)	Recovered/resolved
Appendicitis/Acute Appendicitis	SAE	Grade 3/ severe	Not related	08 Sep 2020 (Study Day 8) – 09 Sep 2020 (Study Day 9)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US366-2033, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 8), 7 days after the first dose and 21 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of abdominal pain. The IP dose was not changed due to the abdominal pain. The event of abdominal pain lasted for 3 days, after which it was considered to be recovered/resolved on 10 Sep 2020 (Study Day 10). The investigator assessed the event of abdominal pain to be not related to the IP.

On 08 Sep 2020 (Study Day 8), 7 days after the first dose and 21 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. The IP dose was not changed due to the acute appendicitis. The event of acute appendicitis lasted for 2 days, after which it was considered to be recovered/resolved on 09 Sep 2020 (Study Day 9). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000276	Abdominal pain
MOD-2020-000276	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Other and unspecified osteoarthritis	01 Jan 1990 (Study Day -11201) - Ongoing
Postmenopause	Post menopausal	01 Jul 2005 (Study Day -5541) - Ongoing
Atrial fibrillation	Paroxysmal atrial fibrillation	01 Jan 2010 (Study Day -3896) - Ongoing
Hypertension	Hypertension nec	01 Jan 2010 (Study Day -3896) - Ongoing
Anxiety	Anxiety state, unspecified	01 Jan 2016 (Study Day -1705) - Ongoing
Arthralgia	Generalized joint pain	01 Jan 2019 (Study Day -609) - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	01 Jan 2019 (Study Day -609) - Ongoing
Vitamin D deficiency	Unspecified vitamin d deficiency	23 Apr 2019 (Study Day -497) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	01 Jan 2010 (Study Day -3896) - Ongoing	Hypertension
Metoprolol	01 Jan 2010 (Study Day -3896) - Ongoing	Hypertension
Sertraline	01 Jan 2016 (Study Day -1705) - Ongoing	Anxiety
Apixaban	07 Aug 2017 (Study Day -1121) - Ongoing	Paroxysmal Atrial Fibrillation
Vitamin d nos	23 Apr 2019 (Study Day -497) - Ongoing	Vitamin D Deficiency
Flecainide acetate	20 May 2019 (Study Day -470) - Ongoing	Paroxysmal Atrial Fibrillation
Olodaterol hydrochloride; tiotropium bromide monohydrate	01 Jul 2019 (Study Day -428) - Ongoing	Copd
Paracetamol	02 Sep 2020 (Study Day 2) - Ongoing	Generalized Joint Pain
Paracetamol	07 Sep 2020 (Study Day 7) - 07 Sep 2020 (Study Day 7)	Fever/Abdominal Pain
Ct abdomen and pelvis with contrast*	08 Sep 2020 (Study Day 8) - 08 Sep 2020 (Study Day 8)	Adverse Event
Hydromorphone hydrochloride	08 Sep 2020 (Study Day 8) - 08 Sep 2020 (Study Day 8)	Abdominal Pain
Iohexol	08 Sep 2020 (Study Day 8) - 08 Sep 2020 (Study Day 8)	Ct Contrast/Procedure
Famotidine	09 Sep 2020 (Study Day 9) - 09 Sep 2020 (Study Day 9)	Pre-Op
Fentanyl	09 Sep 2020 (Study Day 9) - 09 Sep 2020 (Study Day 9)	Post Op Abdominal Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Laparoscopic appendectomy*	09 Sep 2020 (Study Day 9) - 09 Sep 2020 (Study Day 9)	Adverse Event
Metronidazole	09 Sep 2020 (Study Day 9) - 12 Sep 2020 (Study Day 12)	Appendicitis
Ondansetron	09 Sep 2020 (Study Day 9) - 09 Sep 2020 (Study Day 9)	Pre-Op
Salbutamol	09 Sep 2020 (Study Day 9) - 09 Sep 2020 (Study Day 9)	Copd
Bifidobacterium infantis	10 Sep 2020 (Study Day 10) - 27 Sep 2020 (Study Day 27)	Digestive Support
Ceftriaxone sodium	10 Sep 2020 (Study Day 10) - 10 Sep 2020 (Study Day 10)	Appendicitis
Cefuroxime	10 Sep 2020 (Study Day 10) - 12 Sep 2020 (Study Day 12)	Appendicitis
Ketorolac tromethamine	10 Sep 2020 (Study Day 10) - 10 Sep 2020 (Study Day 10)	Abdominal Pain
Oxycodone hydrochloride	10 Sep 2020 (Study Day 10) - 13 Sep 2020 (Study Day 13)	Post-Op Abdominal Pain
Piperacillin sodium	10 Sep 2020 (Study Day 10) - 10 Sep 2020 (Study Day 10)	Appendicitis
Senna alexandrina extract	19 Sep 2020 (Study Day 19) - 27 Sep 2020 (Study Day 27)	Prophylaxis
Paracetamol	29 Sep 2020 (Study Day 29) - 01 Oct 2020 (Study Day 31)	Muscle Aches
Paracetamol	03 Oct 2020 (Study Day 33) - 03 Oct 2020 (Study Day 33)	Muscle Aches
Loratadine	08 Oct 2020 (Study Day 38) - 12 Oct 2020 (Study Day 42)	Sinus Congestion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 7) - 08 Sep 2020 (Study Day 8)
Pyrexia	Grade 1/mild	Not related	07 Sep 2020 (Study Day 7) - 10 Sep 2020 (Study Day 10)
Fatigue	Grade 1/mild	Not related	10 Sep 2020 (Study Day 10) - 07 Oct 2020 (Study Day 37)
Procedural Pain	Grade 2/moderate	Not related	11 Sep 2020 (Study Day 11) - 17 Sep 2020 (Study Day 17)
Myalgia	Grade 2/moderate	Related	29 Sep 2020 (Study Day 29) - 01 Oct 2020 (Study Day 31)
Myalgia	Grade 2/moderate	Related	03 Oct 2020 (Study Day 33) - 03 Oct 2020 (Study Day 33)
Sinus Congestion	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 38) - 12 Oct 2020 (Study Day 42)
Upper-Airway Cough Syndrome	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 38) - 12 Oct 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US366-2181 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	19 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Schizoaffective Disorder/ Schizoaffective Disorders, Worsening	SAE	Grade 3/severe	Not related	26 Oct 2020 (Study Day 5) – 30 Oct 2020 (Study Day 9)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US366-2181, a 61-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 22 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 19 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Oct 2020 (Study Day 5), 4 days after the first dose and 24 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of schizoaffective disorder. The IP dose was not changed due to the schizoaffective disorders, worsening. The event of schizoaffective disorders, worsening lasted for 5 days, after which it was considered to be recovered/resolved on 30 Oct 2020 (Study Day 9). The investigator assessed the event of schizoaffective disorder to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000620	Schizoaffective disorder

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Bipolar disorder	Bipolar affective disorder unspecified	15 Jul 1974 (Study Day -16901) - Ongoing
Generalised anxiety disorder	Generalized anxiety disorder	15 Jul 1974 (Study Day -16901) - Ongoing
Major depression	Major depressive disorder recur epis mild	15 Jul 1974 (Study Day -16901) - Ongoing
Schizoaffective disorder	Schizo-affect shizo unspecified condition	15 Jul 1974 (Study Day -16901) - Ongoing
Hyperparathyroidism	Hyperparathyroidism	15 Jul 1980 (Study Day -14709) - Ongoing
Brain neoplasm benign	Benign neoplasm of brain	15 Jul 1993 (Study Day -9961) - Ongoing
Seizure	Other convulsions	15 Jul 1993 (Study Day -9961) - Ongoing
Glaucoma	Unspecified glaucoma	15 Jul 2000 (Study Day -7404) - Ongoing
Urinary retention	Unspecified retention of urine	22 Jun 2006 (Study Day -5236) - Ongoing
Hypertension	Hypertension nec	15 Jul 2014 (Study Day -2291) - Ongoing
Anaemia	Unspecified anemia	15 Jul 2015 (Study Day -1926) - Ongoing
Chronic kidney disease	Chronic kidney disease stg. iv	15 Jul 2015 (Study Day -1926) - Ongoing
Hyperlipidaemia	Hyperlipidemia, unspecified	15 Jul 2015 (Study Day -1926) - Ongoing
Von Willebrand's disease	Low von willebrand factor	15 Jul 2015 (Study Day -1926) - Ongoing
Suicidal ideation	Suicidal ideation	10 Feb 2020 (Study Day -255) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Timolol maleate	15 Jul 2010 (Study Day -3752) - Ongoing	Glaucoma
Asenapine maleate	15 Jul 2013 (Study Day -2656) - Ongoing	Bipolar Disorder
Amlodipine besilate	15 Jul 2014 (Study Day -2291) - Ongoing	Hypertension
Vitamin e nos	15 Jul 2014 (Study Day -2291) - Ongoing	Supplement
Atorvastatin	15 Jul 2015 (Study Day -1926) - Ongoing	Hyperlipidemia
Sodium bicarbonate	15 Jul 2015 (Study Day -1926) - Ongoing	Unspecified Acute Renal Failure
Unspecified herbal and traditional medicine	15 Jul 2015 (Study Day -1926) - Ongoing	Supplement
Vitamin b complex	15 Jul 2015 (Study Day -1926) - Ongoing	Supplement
Acetylsalicylic acid	15 Jul 2018 (Study Day -830) - Ongoing	Heart Health Preventive Measure
Escitalopram	15 Sep 2020 (Study Day -37) - Ongoing	Depression
Hydroxyzine	15 Sep 2020 (Study Day -37) - Ongoing	Anxiety
Lumateperone tosylate	15 Sep 2020 (Study Day -37) - Ongoing	Bipolar Disorder
Risperidone	28 Oct 2020 (Study Day 7) - 30 Oct 2020 (Study Day 9)	Schizoaffective Disorder, Worsening
Risperidone	04 Nov 2020 (Study Day 14) - 30 Nov 2020 (Study Day 40)	Schizoaffective Disorder, Worsening

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lamotrigine	30 Nov 2020 (Study Day 40) - 14 Dec 2020 (Study Day 54)	Bipolar Disorder
Lamotrigine	15 Dec 2020 (Study Day 55) - Ongoing	Bi Polar Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US367-2097 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	07 Sep 2020 (Study Day 26) – 13 Oct 2020 (Study Day 62)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2097, a 38-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 26), 25 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of COVID-19 lasted for 37 days, after which it was considered to be recovered/resolved on 13 Oct 2020 (Study Day 62). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000309	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2017 - Ongoing	Chronic Disease Prophylaxis
Probiotics nos	May 2020 - Ongoing	Chronic Disease Prophylaxis
Ibuprofen	16 Aug 2020 (Study Day 4) - 16 Aug 2020 (Study Day 4)	Headache
Ibuprofen	19 Aug 2020 (Study Day 7) - 19 Aug 2020 (Study Day 7)	Headache
Ibuprofen	07 Sep 2020 (Study Day 26) - 13 Oct 2020 (Study Day 62)	COVID
Ibuprofen	13 Sep 2020 (Study Day 32) - 13 Sep 2020 (Study Day 32)	COVID-19
Ibuprofen	16 Sep 2020 (Study Day 35) - 16 Sep 2020 (Study Day 35)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	14 Aug 2020 (Study Day 2) - 23 Aug 2020 (Study Day 11)
COVID-19	Grade 1/mild	Not related	07 Sep 2020 (Study Day 26) - 13 Oct 2020 (Study Day 62)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2187 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Blood Pressure Diastolic Increased/Elevated Diastolic Blood Pressure	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	21 Sep 2020 (Study Day 34) – 17 Oct 2020 (Study Day 60)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2187, a 72-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 34), 33 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of blood pressure diastolic increased. On 15 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of elevated diastolic blood pressure lasted for 27 days, after which it was considered to be recovered/resolved on 17 Oct 2020 (Study Day 60). The investigator assessed the event of blood pressure diastolic increased to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2018 - Ongoing	Cardiac Prophylaxis
Atorvastatin	26 Sep 2020 (Study Day 39) - Ongoing	Hypertension
Cefdinir	06 Mar 2021 (Study Day 200) - 07 Mar 2021 (Study Day 201)	Pneumonia Right Lung

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Blood Pressure Diastolic Increased	Grade 3/severe	Not related	21 Sep 2020 (Study Day 34) - 17 Oct 2020 (Study Day 60)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2199 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Post Procedural Haematoma/Hematoma R Groin Following Angioplasty	SAE	Grade 3/severe	Not related	06 Oct 2020 (Study Day 49) – 08 Oct 2020 (Study Day 51)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2199, a 71-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 18 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Oct 2020 (Study Day 49), 48 days after the first dose and 18 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of post procedural haematoma. Action taken with the IP was not applicable. The event of hematoma r groin following angioplasty lasted for 3 days, after which it was considered to be recovered/resolved on 08 Oct 2020 (Study Day 51). The investigator assessed the event of post procedural haematoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000454	Post procedural haematoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cataract	Bilateral cataracts	Not reported - Apr 2019
Benign prostatic hyperplasia	Bph	2010 - Ongoing
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Glucose tolerance impaired	Pre diabeties	2010 - Nov 2016
Gout	Gout	2010 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Obesity	Obesity	2010 - Ongoing
Pain in extremity	B/l toe pain	2010 - Ongoing
Peripheral vascular disorder	Peripheral vascular disease	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	Nov 2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiovascular Disease Prophylaxis
Atorvastatin	2010 - Ongoing	Hld
Ezetimibe	2010 - Ongoing	Hld
Hydrochlorothiazide	2010 - Ongoing	Hypertension
Meloxicam	2010 - Ongoing	B/L Toe Pain
Metformin	2010 - Ongoing	Prediabestes
Metoprolol tartrate	2010 - Ongoing	Htn
Tamsulosin	2010 - 01 Sep 2020 (Study Day 14)	Bph
Tamsulosin	02 Sep 2020 (Study Day 15) - Ongoing	Bph
Angioplasty surgery*	06 Oct 2020 (Study Day 49) - 06 Oct 2020 (Study Day 49)	Medical History
I.v. solutions	06 Oct 2020 (Study Day 49) - 06 Oct 2020 (Study Day 49)	Post Angioplasty Infection Prevention
Piperacillin sodium; tazobactam sodium	06 Oct 2020 (Study Day 49) - 06 Oct 2020 (Study Day 49)	Post Angioplasty Infection Prevention
Ciprofloxacin	08 Oct 2020 (Study Day 51) - Ongoing	Infection Prophylaxis
Metronidazole	08 Oct 2020 (Study Day 51) - Ongoing	Infection Prophylaxis
Amoxicillin	03 Mar 2021 (Study Day 197) - 10 Mar 2021 (Study Day 204)	Skin Ulcer Right Great Toe
Sulfamethoxazole; trimethoprim	16 Mar 2021 (Study Day 210) - Ongoing	Skin Ulcer Left Heel

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chest Discomfort	Grade 1/mild	Not related	20 Aug 2020 (Study Day 2) - 22 Aug 2020 (Study Day 4)
Skin Ulcer	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 105) - Ongoing
Skin Ulcer	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 105) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2278 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Ischaemic Stroke/ Ischemic Stroke (Frontal Lobe)	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	10 Sep 2020 (Study Day 11) – 11 Sep 2020 (Study Day 12)	Recovered/resolved with sequelae
Speech Disorder/Speech Deficit	SAE, AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	10 Sep 2020 (Study Day 11) – 26 Jan 2021 (Study Day 149)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2278, a 78-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Sep 2020 (Study Day 11), 10 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of ischaemic stroke. On 27 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of ischemic stroke (frontal lobe) lasted for 2 days, after which it was considered to be recovered/resolved with sequelae on 11 Sep 2020 (Study Day 12). The investigator assessed the event of ischaemic stroke to be not related to the IP.

On 10 Sep 2020 (Study Day 11), 10 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of speech disorder. On 27 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of speech deficit lasted for 139 days, after which it was considered to be recovered/resolved on 26 Jan 2021 (Study Day 149). The investigator assessed the event of speech disorder to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000286	Ischemic stroke
MOD-2020-000286	Speech disorder

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	Not reported - Ongoing
Myocardial infarction	Myocardial infarction	1989 - 1989
Rhinitis allergic	Allergic rhinitis	1989 - Ongoing
Muscle spasms	Leg cramps	1990 - Ongoing
Cerebrovascular disorder	Cerebral vascular disease	2002 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2014 - Ongoing
Cardiac failure congestive	Congestive heart failure	Dec 2019 - Ongoing
Coronary artery disease	Coronary artery disease	Dec 2019 - Ongoing
Implantable defibrillator insertion	Defibrillator implant	Dec 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Furosemide	1989 - Ongoing	Mycardial Infarction
Losartan	1989 - 10 Sep 2020 (Study Day 11)	Myocardial Infaraction
Metoprolol	1989 - Ongoing	Myocardial Infarction
Diphenhydramine hydrochloride	1990 - Ongoing	Leg Cramps (Bilateral)
Loratadine	2000 - Ongoing	Allergic Rhinitis
Glipizide	2014 - Ongoing	Type Ii Diabetes
Metformin	2014 - Ongoing	Type 2 Dm
Spironolactone	2019 - Ongoing	Myocardial Infarction
Pravastatin	Apr 2020 - Ongoing	Frontal Lobe Stroke
Acetylsalicylic acid	10 Sep 2020 (Study Day 11) - 10 Sep 2020 (Study Day 11)	Frontal Lobe Stroke
Carotid duplex*	10 Sep 2020 (Study Day 11) - 10 Sep 2020 (Study Day 11)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct head stroke protocol w/o contrast*	10 Sep 2020 (Study Day 11) - 10 Sep 2020 (Study Day 11)	Adverse Event
Diagnostic lab testing*	10 Sep 2020 (Study Day 11) - 10 Sep 2020 (Study Day 11)	Adverse Event
Diphenhydramine	10 Sep 2020 (Study Day 11) - Ongoing	Obstructive Sleep Apnea
Speech therapy*	10 Sep 2020 (Study Day 11) - 10 Sep 2020 (Study Day 11)	Adverse Event
Clopidogrel bisulfate	11 Sep 2020 (Study Day 12) - Ongoing	Frontal Lobe Stroke
Losartan	11 Sep 2020 (Study Day 12) - Ongoing	Myocardial Infarction (Prevention)
Metformin	Oct 2020 - Ongoing	Type 2 Diabetes
Influenza vaccine	04 Oct 2020 (Study Day 35) - 04 Oct 2020 (Study Day 35)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US367-2333 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Upper Respiratory Tract Infection/Upper Respiratory Infection (Uri)	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	24 Sep 2020 (Study Day 30) – 30 Sep 2020 (Study Day 36)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2333, a 19-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Sep 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of upper respiratory tract infection. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of upper respiratory infection (uri) lasted for 7 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 36). The investigator assessed the event of upper respiratory tract infection to be not related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Adhd attention deficit hyperactivity disorder	2006 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Etonogestrel	26 Nov 2018 (Study Day -639) - Ongoing	Contraception
Influenza vaccine	09 Nov 2020 (Study Day 76) - 09 Nov 2020 (Study Day 76)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphadenopathy	Grade 1/mild	Related	07 Sep 2020 (Study Day 13) - 18 Sep 2020 (Study Day 24)
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	24 Sep 2020 (Study Day 30) - 30 Sep 2020 (Study Day 36)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US367-2388 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/Recurrent Small Bowel Obstruction	SAE	Grade 3/severe	Not related	01 Nov 2020 (Study Day 63) – 04 Nov 2020 (Study Day 66)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US367-2388, a 70-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 63), 62 days after the first dose and 34 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of small intestinal obstruction. Action taken with the IP was not applicable. The event of recurrent small bowel obstruction lasted for 4 days, after which it was considered to be recovered/resolved on 04 Nov 2020 (Study Day 66). The investigator assessed the event of small intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005914	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	Jun 1995 - Ongoing
Constipation	Chronic constipation	2000 - 2001
Colectomy	Colectomy	2001 - 2001
Oedema peripheral	Lower extremity edema	2001 - Ongoing
Small intestinal obstruction	History of multiple small bowel obstructions	2001 - Ongoing
Botulinum toxin injection	Cosmetic botox injections	2011 - Ongoing
Dermal filler injection	Dermal filler injections	2011 - Ongoing
Insomnia	Difficulty sleeping	Nov 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; triamterene	2001 - Ongoing	Lower Extremity Edema
Clonazepam	Oct 2020 - Ongoing	Difficulty Sleeping
Influenza vaccine	Oct 2020 - Oct 2020	Influenza Prophylaxis
Ct scan (without contrast)*	01 Nov 2020 (Study Day 63) - 01 Nov 2020 (Study Day 63)	Adverse Event
Ct scan (with contrast)*	02 Nov 2020 (Study Day 64) - 02 Nov 2020 (Study Day 64)	Adverse Event
Iopamidol	02 Nov 2020 (Study Day 64) - 02 Nov 2020 (Study Day 64)	Recurrent Small Bowel Obstruction
Nasogastric tube*	02 Nov 2020 (Study Day 64) - 02 Nov 2020 (Study Day 64)	Adverse Event
Morphine	03 Nov 2020 (Study Day 65) - 03 Nov 2020 (Study Day 65)	Recurrent Small Bowel Obstruction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	Not reported - Not reported

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US368-2001 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	18 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Of Osteoarthritis R Knee	SAE	Grade 4	Not related	17 Sep 2020 (Study Day 28) – 30 Nov 2020 (Study Day 102)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2001, a 58-year-old Hispanic or Latino female, received the first dose of placebo in the right arm on 21 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 18 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Sep 2020 (Study Day 28), 27 days after the first dose and 1 day before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of osteoarthritis. The IP dose was not changed due to the worsening of osteoarthritis r knee. The event of worsening of osteoarthritis r knee lasted for 75 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 102). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000996	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Mammoplasty	Breast augmentation surgery	2002 - 2002
Ovarian cystectomy	L ovarian cyst, removed, benign	Apr 2009 - Apr 2009
Drug hypersensitivity	Allergic to sulfa drugs	2010 - Ongoing
Asthma	Asthma, moderate,	01 Apr 2010 (Study Day -3795) - Ongoing
Steatohepatitis	Early steatohepatitis. controlled with diet	2012 - Ongoing
Ankle fracture	L ankle fracture	Oct 2014 - Nov 2014
Deep vein thrombosis	Dvt - deep venous thrombosis	Dec 2014 - Mar 2015
Osteoarthritis	Osteoarthritis	2015 - Ongoing
Postmenopause	Post menopausal	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium	Not reported - Ongoing	Osteoarthritis
Colecalciferol	Not reported - Ongoing	General Health
Glutathione; phosphatidyl choline	Not reported - 04 Sep 2020 (Study Day 15)	Early Steatohepatitis
Herbal preparation	Not reported - Ongoing	Early Steatohepatitis
Levosalbutamol hydrochloride	Not reported - Ongoing	Asthma Exacerbation
Magnesium glycinate	Not reported - Ongoing	General Health
Monascus purpureus	Not reported - Ongoing	Hyperlipidemia
Nicotinic acid	Not reported - Ongoing	Hyperlipidemia
Omega-3 fatty acids	Not reported - Ongoing	Hyperlipidemia
Probiotics nos	Not reported - Ongoing	General Health
Ubidecarenone	Not reported - 05 Oct 2020 (Study Day 46)	General Health
Vitamin b complex	Not reported - Ongoing	General Health
Vitamins nos	Not reported - Ongoing	General Health
Beclometasone dipropionate	2010 - Ongoing	Asthma
Astragalus propinquus	25 Aug 2020 (Study Day 5) - 25 Aug 2020 (Study Day 5)	Headache
Naproxen sodium	25 Aug 2020 (Study Day 5) - 26 Aug 2020 (Study Day 6)	Headache
Naproxen	03 Oct 2020 (Study Day 44) - 04 Oct 2020 (Study Day 45)	Headache/Lymphadenopathy, Cervical, Bilateral
Total right knee replacement*	30 Nov 2020 (Study Day 102) - 30 Nov 2020 (Study Day 102)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	01 Dec 2020 (Study Day 103) - 21 Dec 2020 (Study Day 123)	Deep Vein Thrombosis Prophylaxis
Diphenhydramine hydrochloride; paracetamol	01 Dec 2020 (Study Day 103) - 26 Dec 2020 (Study Day 128)	Pain Related To Right Total Knee Arthroplasty
Oxycodone	01 Dec 2020 (Study Day 103) - 06 Dec 2020 (Study Day 108)	Pain Related To Right Total Knee Arthroplasty
Pantoprazole	01 Dec 2020 (Study Day 103) - 21 Dec 2020 (Study Day 123)	Gastroesophageal Reflux Disease Prophylaxis
Paracetamol	01 Dec 2020 (Study Day 103) - 26 Dec 2020 (Study Day 128)	Pain Related To Right Total Knee Arthroplasty
Bisacodyl	02 Dec 2020 (Study Day 104) - 03 Dec 2020 (Study Day 105)	Constipation Related To Right Total Knee Arthroplasty And Associated Medications
Dexamethasone	03 Dec 2020 (Study Day 105) - 05 Dec 2020 (Study Day 107)	Pain And Inflammation Secondary To Right Total Knee Arthroplasty
Tramadol	16 Dec 2020 (Study Day 118) - 09 Jan 2021 (Study Day 142)	Post Op Pain R Knee Replacement
Naproxen	27 Dec 2020 (Study Day 129) - 16 Mar 2021 (Study Day 208)	Pain Related To Right Total Knee Arthroplasty

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 2/moderate	Not related	03 Oct 2020 (Study Day 44) - 04 Oct 2020 (Study Day 45)
Lymphadenopathy	Grade 2/moderate	Not related	03 Oct 2020 (Study Day 44) - 04 Oct 2020 (Study Day 45)
Hypoaesthesia	Grade 1/mild	Not related	16 Oct 2020 (Study Day 57) - 16 Oct 2020 (Study Day 57)
Procedural Pain	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 103) - Ongoing
Post Procedural Constipation	Grade 2/moderate	Not related	02 Dec 2020 (Study Day 104) - 03 Dec 2020 (Study Day 105)
Procedural Nausea	Grade 2/moderate	Not related	07 Dec 2020 (Study Day 109) - 21 Dec 2020 (Study Day 123)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US368-2017 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Superficial Injury Of Eye/Scratched Cornea - L Eye	SAE	Grade 3/severe	Not related	11 Nov 2020 (Study Day 78) – 01 Dec 2020 (Study Day 98)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2017, a 41-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 26 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Nov 2020 (Study Day 78), 77 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of superficial injury of eye. On 22 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of scratched cornea - l eye lasted for 21 days, after which it was considered to be recovered/resolved on 01 Dec 2020 (Study Day 98). The investigator assessed the event of superficial injury of eye to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001058	Superficial injury of eye
MOD-2020-001135	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
HIV infection	Hiv	Apr 2005 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sulfamethoxazole; trimethoprim	Apr 2005 - Ongoing	Pneumocystis Prophylaxis
Cobicistat; darunavir ethanolate; emtricitabine; tenofovir alafenamide fumarate	Jan 2020 - Ongoing	Hiv
Hydrocodone bitartrate; paracetamol	03 Oct 2020 (Study Day 39) - 03 Oct 2020 (Study Day 39)	Abdominal Pain - Due To Colitis And Pancreatitis
Levofloxacin	03 Oct 2020 (Study Day 39) - 13 Oct 2020 (Study Day 49)	Colitis And Pancreatitis
Metronidazole	03 Oct 2020 (Study Day 39) - 13 Oct 2020 (Study Day 49)	Colitis, Pancreatitis
Corneal transplant - left eye*	01 Dec 2020 (Study Day 98) - 01 Dec 2020 (Study Day 98)	Adverse Event
Ciprofloxacin	02 Dec 2020 (Study Day 99) - Ongoing	Cornea Transplant
Dolutegravir	02 Dec 2020 (Study Day 99) - 10 Dec 2020 (Study Day 107)	Corneal Transplant
Prednisolone	02 Dec 2020 (Study Day 99) - 06 Dec 2020 (Study Day 103)	Cornea Transplant
Tobramycin	02 Dec 2020 (Study Day 99) - Ongoing	Cornea Transplant
Vancomycin	02 Dec 2020 (Study Day 99) - 06 Dec 2020 (Study Day 103)	Cornea Transplant
Vancomycin	07 Dec 2020 (Study Day 104) - 13 Dec 2020 (Study Day 110)	Cornea Transplant
Atropine	14 Dec 2020 (Study Day 111) - Ongoing	Cornea Transplant
Prednisolone	14 Dec 2020 (Study Day 111) - Ongoing	Cornea Transplant
Vancomycin	14 Dec 2020 (Study Day 111) - Ongoing	Cornea Transplant
Bacitracin	18 Dec 2020 (Study Day 115) - Ongoing	Cornea Transplant
Measles vaccine; mumps vaccine; rubella vaccine	23 Jan 2021 (Study Day 151) - 23 Jan 2021 (Study Day 151)	Measles, Mumps, And Rubella Prevention
Diphenhydramine; paracetamol; phenylephrine	07 Feb 2021 (Study Day 166) - 08 Feb 2021 (Study Day 167)	COVID-Like Illness (Nasal Congestion, Runny Nose, Chills)
Ibuprofen	07 Feb 2021 (Study Day 166) - Ongoing	COVID-Like Illness (Muscles Aches, Body Aches, And Headache)
Paracetamol	09 Feb 2021 (Study Day 168) - Ongoing	COVID-Like Illness (Muscle Aches)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	27 Aug 2020 (Study Day 2) - 04 Sep 2020 (Study Day 10)
Myalgia	Grade 1/mild	Related	30 Aug 2020 (Study Day 5) - 04 Sep 2020 (Study Day 10)
Arthralgia	Grade 1/mild	Related	31 Aug 2020 (Study Day 6) - 04 Sep 2020 (Study Day 10)
Suspected COVID-19	Grade 2/moderate	Not related	14 Sep 2020 (Study Day 20) - 03 Oct 2020 (Study Day 39)
Colitis	Grade 3/severe	Not related	21 Sep 2020 (Study Day 27) - 13 Oct 2020 (Study Day 49)
Pancreatitis	Grade 3/severe	Not related	21 Sep 2020 (Study Day 27) - 13 Oct 2020 (Study Day 49)
Suspected COVID-19	Grade 2/moderate	Not related	06 Feb 2021 (Study Day 165) - 13 Feb 2021 (Study Day 172)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US368-2134 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Syncope/Syncope, Worsened From Baseline	SAE	Grade 4	Not related	21 Sep 2020 (Study Day 5) – 21 Sep 2020 (Study Day 5)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US368-2134, a 46-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 5), 4 days after the first dose and 24 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of syncope. The IP dose was not changed due to the syncope, worsened from baseline. The event of syncope, worsened from baseline lasted for 1 days, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 5). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000354	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Pain	Generalized chronic pain	2008 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus, type ii	2008 - Ongoing
Leg amputation	Right below knee amputation	2010 - 2010
Staphylococcal infection	Mrsa infection of right lower extremity	2010 - 2010
Hypertension	Hypertension	2011 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Syncope	Recurrent syncope	2018 - Ongoing
Skin ulcer	Left foot open ulcer	Mar 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amitriptyline	2008 - Ongoing	Chronic Pain - Generalized
Insulin glargine	2008 - Ongoing	Diabetes Mellitus Type II
Insulin lispro	2008 - Ongoing	Diabetes Mellitus Type II
Linagliptin	2008 - Ongoing	Diabetes Mellitus Type II
Liraglutide	2008 - Ongoing	Diabetes Mellitus Type II
Metformin	2008 - Ongoing	Diabetes Mellitus Type II
Tizanidine	2010 - Ongoing	Chronic Pain - Generalized
Tramadol	2010 - Ongoing	Generalized Chronic Pain
Carvedilol	2011 - Ongoing	Hypertension
Diltiazem	2011 - Ongoing	Hypertension
Omeprazole	2015 - Ongoing	Heartburn Prevention
Pravastatin	2015 - Ongoing	Hyperlipidemia
Ct of the head and cervical spine*	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Adverse Event
Electrocardiogram*	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Adverse Event
Piperacillin sodium; tazobactam sodium	21 Sep 2020 (Study Day 5) - 24 Sep 2020 (Study Day 8)	Cellulitis/Osteomyelitis Of Left Â foot
Vancomycin	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Cellulitis/Osteomyelitis Of Left Foot
X-ray of the chest, left shoulder, left foot*	21 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 5)	Adverse Event
Mri of the left foot*	22 Sep 2020 (Study Day 6) - 22 Sep 2020 (Study Day 6)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Transthoracic echocardiogram*	22 Sep 2020 (Study Day 6) - 22 Sep 2020 (Study Day 6)	Adverse Event
Ibuprofen	24 Sep 2020 (Study Day 8) - 04 Oct 2020 (Study Day 18)	Headaches As A Result Of A Concussion
Sulfamethoxazole; trimethoprim	24 Sep 2020 (Study Day 8) - 06 Oct 2020 (Study Day 20)	Cellulitis/Osteomyelitis Of Left Foot
Angioplasty of left lower extremity*	22 Feb 2021 (Study Day 159) - 22 Feb 2021 (Study Day 159)	Adverse Event
Acetylsalicylic acid	02 Mar 2021 (Study Day 167) - Ongoing	Cardiovascular Health
Electrocardiogram*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
Piperacillin sodium; tazobactam sodium	02 Mar 2021 (Study Day 167) - 06 Mar 2021 (Study Day 171)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Ultrasound of bilateral lower extremities*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
Vancomycin	02 Mar 2021 (Study Day 167) - 06 Mar 2021 (Study Day 171)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
X-ray of chest*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
X-ray of left tibia/fibula*	02 Mar 2021 (Study Day 167) - 02 Mar 2021 (Study Day 167)	Adverse Event
Continuous cardiac monitor*	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Adverse Event
Insulin	03 Mar 2021 (Study Day 168) - 08 Mar 2021 (Study Day 173)	Diabetic Ketoacidosis
Magnesium oxide	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Diabetic Ketoacidosis
Magnesium sulfate	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Diabetic Ketoacidosis
Potassium chloride; sodium chloride	03 Mar 2021 (Study Day 168) - 09 Mar 2021 (Study Day 174)	Diabetic Ketoacidosis
Potassium phosphate dibasic	03 Mar 2021 (Study Day 168) - 03 Mar 2021 (Study Day 168)	Diabetic Ketoacidosis
Mri of left foot and left ankle*	04 Mar 2021 (Study Day 169) - 04 Mar 2021 (Study Day 169)	Adverse Event
Staged deep incision and drainage with fasciotomy through multiple layers with excisional debidment of all non-viable tissue and 3rd metatarsal resection, left foot.*	04 Mar 2021 (Study Day 169) - 04 Mar 2021 (Study Day 169)	Adverse Event
X-ray of left foot and left ankle*	04 Mar 2021 (Study Day 169) - 04 Mar 2021 (Study Day 169)	Adverse Event
Ceftriaxone	06 Mar 2021 (Study Day 171) - 09 Mar 2021 (Study Day 174)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Clindamycin	06 Mar 2021 (Study Day 171) - 09 Mar 2021 (Study Day 174)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Ciprofloxacin	08 Mar 2021 (Study Day 173) - 07 Apr 2021 (Study Day 203)	Osteomyelitis Of Left Foot, Necrotizing Fasciitis Of Left Foot
Cefazolin	09 Mar 2021 (Study Day 174) - 13 Apr 2021 (Study Day 209)	Osteomyelitis Of The Left Foot, Necrotizing Fasciitis Of Left Foot

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insertion of left peripherally inserted central catheter*	09 Mar 2021 (Study Day 174) - 09 Mar 2021 (Study Day 174)	Adverse Event
Clopidogrel	10 Mar 2021 (Study Day 175) - Ongoing	Peripheral Vascular Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cellulitis	Grade 2/moderate	Not related	21 Sep 2020 (Study Day 5) - Ongoing
Osteomyelitis	Grade 2/moderate	Not related	21 Sep 2020 (Study Day 5) - 06 Oct 2020 (Study Day 20)
Concussion	Grade 2/moderate	Not related	24 Sep 2020 (Study Day 8) - 04 Oct 2020 (Study Day 18)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US369-2001 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastric Ulcer Haemorrhage/Bleeding Gastric Ulcer	SAE	Grade 3/severe	Not related	14 Dec 2020 (Study Day 111) – 16 Dec 2020 (Study Day 113)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US369-2001, a 56-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Dec 2020 (Study Day 111), 110 days after the first dose and 82 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of gastric ulcer haemorrhage. Action taken with the IP was not applicable. The event of bleeding gastric ulcer lasted for 3 days, after which it was considered to be recovered/resolved on 16 Dec 2020 (Study Day 113). The investigator assessed the event of gastric ulcer haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001199	Gastric ulcer haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Blood testosterone decreased	Low testosterone	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Gastrooesophageal reflux disease	Gerd (gastroesophageal reflux disease)	Jan 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Simvastatin	2016 - Ongoing	Hyperlipidemia
Testosterone cipionate	2016 - Ongoing	Low Testosterone
Calcium carbonate	Jan 2018 - 16 Dec 2020 (Study Day 113)	Gerd
Influenza vaccine	Nov 2020 - Nov 2020	Prophylaxis For Flu
Acetylsalicylic acid	11 Dec 2020 (Study Day 108) - 11 Dec 2020 (Study Day 108)	Headache
Esophagogastroduodenoscopy (egd)*	14 Dec 2020 (Study Day 111) - 14 Dec 2020 (Study Day 111)	Adverse Event
Ondansetron	14 Dec 2020 (Study Day 111) - 15 Dec 2020 (Study Day 112)	Gastric Ulcer
Sodium chloride	14 Dec 2020 (Study Day 111) - 15 Dec 2020 (Study Day 112)	Gastric Ulcer
Omeprazole	16 Dec 2020 (Study Day 113) - 18 Jan 2021 (Study Day 146)	Gastric Ulcer
Pantoprazole	16 Dec 2020 (Study Day 113) - 04 Jan 2021 (Study Day 132)	Gastric Ulcer/Eosinophilic Esophagitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tachypnoea	Grade 1/mild	Not related	26 Aug 2020 (Study Day 1) - 23 Oct 2020 (Study Day 59)
Sinus Congestion	Grade 1/mild	Not related	28 Aug 2020 (Study Day 3) - 01 Sep 2020 (Study Day 7)
Sneezing	Grade 1/mild	Not related	28 Aug 2020 (Study Day 3) - 01 Sep 2020 (Study Day 7)
Headache	Grade 1/mild	Not related	11 Dec 2020 (Study Day 108) - 11 Dec 2020 (Study Day 108)
Eosinophilic Oesophagitis	Grade 2/moderate	Not related	14 Dec 2020 (Study Day 111) - 18 Jan 2021 (Study Day 146)
Tachypnoea	Grade 1/mild	Not related	08 Feb 2021 (Study Day 167) - 19 Mar 2021 (Study Day 206)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US369-2016 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Peripheral Artery Aneurysm/Iliac Artery Aneurysm	SAE	Grade 2/ moderate	Not related	01 Nov 2020 (Study Day 65) – 02 Nov 2020 (Study Day 66)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US369-2016, a 55-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 29 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 65), 64 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of peripheral artery aneurysm. Action taken with the IP was not applicable. The event of iliac artery aneurysm lasted for 2 days, after which it was considered to be recovered/resolved on 02 Nov 2020 (Study Day 66). The investigator assessed the event of peripheral artery aneurysm to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000616	Peripheral artery aneurysm

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Erectile dysfunction	Erectile dysfunction	Not reported - Ongoing
Bronchial hyperreactivity	Reactive airway disease	2000 - Ongoing
Folliculitis	Folliculitis	2005 - Ongoing
Peripheral artery aneurysm	Iliac artery aneurysm	2016 - Ongoing
Hypersensitivity	Environmental allergies (dog hair, ragweed)	2017 - Ongoing
Hypertension	Hypertension	2019 - Ongoing
Arteriosclerosis	Slow progression of athersclerosis	Jun 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide	2000 - Ongoing	Reactive Airway Disease
Clindamycin	2005 - Ongoing	Folliculitis
Sodium fluoride	2005 - Ongoing	Oral Hygiene
Atenolol	2006 - Ongoing	Reactive Airway Disease/Environmental Allergies
Allium sativum	2010 - Ongoing	Heart Health
Calcium citrate; colecalciferol	2010 - Ongoing	Bone Health
Chondroitin; glucosamine	2010 - Ongoing	Joint Health
Curcuma longa	2010 - Ongoing	Joint Health
Fish oil	2010 - Ongoing	Health Promotion
Tadalafil	2010 - Ongoing	Erectile Dysfunction
Ubidecarenone	2010 - Ongoing	Heart Health
Vitamins nos	2010 - Ongoing	Health Promotion
Zingiber officinale	2010 - Ongoing	Heart Health
Acetylsalicylic acid	2017 - Ongoing	Heart Health
Ezetimibe	2017 - Ongoing	Secondary Prevention For Cardiovascular Disease
Montelukast sodium	2017 - Ongoing	Reactive-Airway Disease
Rosuvastatin	Jun 2019 - 12 Oct 2020 (Study Day 45)	Slow Progression Of Atherosclerosis
Lisinopril	21 Sep 2020 (Study Day 24) - Ongoing	Hypertension
Rosuvastatin	12 Oct 2020 (Study Day 45) - Ongoing	Hperlipidemia
Open iliac artery repair*	02 Nov 2020 (Study Day 66) - 02 Nov 2020 (Study Day 66)	Medical History
Docusate sodium	08 Nov 2020 (Study Day 72) - 08 Nov 2020 (Study Day 72)	Stool Softener Following Iliac Artery Aneurysm Procedure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydromorphone hydrochloride	08 Nov 2020 (Study Day 72) - 13 Nov 2020 (Study Day 77)	Pain (Post Bilateral Iliac Aneurysm Repair)
Paracetamol	08 Nov 2020 (Study Day 72) - 31 Dec 2020 (Study Day 125)	Pain (Post-Bilateral Iliac Aneurysm Repair)
Sennoside a+b	08 Nov 2020 (Study Day 72) - 08 Nov 2020 (Study Day 72)	Stimulant Laxative - Following Iliac Artery Aneurysm Procedure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tachypnoea	Grade 1/mild	Not related	23 Sep 2020 (Study Day 26) - 23 Oct 2020 (Study Day 56)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US369-2141 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	19 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anaphylactic Reaction/Anaphylaxis	SAE	Grade 4	Not related	30 Sep 2020 (Study Day 10) – 30 Sep 2020 (Study Day 10)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US369-2141, a 20-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 19 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Sep 2020 (Study Day 10), 9 days after the first dose and 19 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of anaphylactic reaction. The IP dose was not changed due to the anaphylaxis. The event of anaphylaxis lasted for 1 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 10). The investigator assessed the event of anaphylactic reaction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001210	Anaphylactic reaction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	Not reported - Ongoing
Attention deficit hyperactivity disorder	Attention-deficit/hyperactivity disorder	Not reported - Ongoing
Borderline personality disorder	Borderline personality disorder	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Depression	Depression	Aug 2019 - Ongoing
Implant site haemorrhage	Bleeding at implant insertion site	Aug 2019 - Ongoing
Post-traumatic stress disorder	Post-traumatic stress disorder	Aug 2019 - Ongoing
Dermatitis contact	Allergy to dove soap	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Etonogestrel	Aug 2019 - Ongoing	Birth Control
Fluoxetine	Aug 2019 - Ongoing	Depression
Ibuprofen	Sep 2019 - Ongoing	Pain And Bleeding At Implant Site
Diphenhydramine hydrochloride	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Anaphylaxis
Epinephrine	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Anaphylaxis
Famotidine	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Anaphylaxis
Methylprednisolone sodium succinate	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Anaphylaxis
Ibuprofen	21 Oct 2020 (Study Day 31) - 21 Oct 2020 (Study Day 31)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tachypnoea	Grade 1/mild	Not related	21 Sep 2020 (Study Day 1) – 16 Nov 2020 (Study Day 57)
Ovarian Cyst	Grade 1/mild	Not related	16 Mar 2021 (Study Day 177) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US371-2013 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	05 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 2/ moderate	Not related	18 Sep 2020 (Study Day 11) – 05 Oct 2020 (Study Day 28)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2013, a 71-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Sep 2020 (Study Day 11), 10 days after the first dose and 17 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pneumonia. The IP dose was not changed due to the pneumonia. The event of pneumonia lasted for 18 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 28). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-033943	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Myopia	1958 - Ongoing
Seasonal allergy	Seasonal allergies	1979 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	1990 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1995 - Ongoing
Ventricular extrasystoles	Premature ventricular complexes	2013 - Ongoing
Insomnia	Insomnia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium carbonate	1990 - Ongoing	Acid Reflux
Colecalciferol	2010 - Ongoing	Supplement
Fish oil	2010 - Ongoing	Supplement
Folic acid	2010 - Ongoing	Supplement
Nicotinic acid	2010 - Ongoing	Supplement
Vitamin b12 nos	2010 - Ongoing	Supplement
Famotidine	2015 - Ongoing	Acid Reflux
Fluticasone propionate	2016 - Ongoing	Seasonal Allergies
Pantoprazole	2016 - Ongoing	Acid Reflux
Diphenhydramine hydrochloride	2019 - Ongoing	Insomnia
Fexofenadine hydrochloride	2019 - Ongoing	Seasonal Allergies
Famotidine	21 Sep 2020 (Study Day 14) - 22 Sep 2020 (Study Day 15)	Pneumonia Inpatient Treatment
Fexofenadine	21 Sep 2020 (Study Day 14) - 22 Sep 2020 (Study Day 15)	Pneumonia Inpatient Treatment
Levofloxacin	21 Sep 2020 (Study Day 14) - 22 Sep 2020 (Study Day 15)	Pneumonia Inpatient Treatment
Melatonin	21 Sep 2020 (Study Day 14) - 22 Sep 2020 (Study Day 15)	Pneumonia Inpatient Treatment
Ondansetron	21 Sep 2020 (Study Day 14) - 22 Sep 2020 (Study Day 15)	Pneumonia Inpatient Treatment
Paracetamol	21 Sep 2020 (Study Day 14) - 22 Sep 2020 (Study Day 15)	Pneumonia Inpatient Treatment
Sildenafil citrate	21 Sep 2020 (Study Day 14) - 22 Sep 2020 (Study Day 15)	Pneumonia Inpatient Treatment
Acetylsalicylic acid	22 Sep 2020 (Study Day 15) - 22 Sep 2020 (Study Day 15)	Generalized Non-Cardiac Chest Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cefdinir	22 Sep 2020 (Study Day 15) - 25 Sep 2020 (Study Day 18)	Pneumonia
Ceftriaxone	22 Sep 2020 (Study Day 15) - 22 Sep 2020 (Study Day 15)	Pneumonia
Doxycycline	22 Sep 2020 (Study Day 15) - 25 Sep 2020 (Study Day 18)	Pneumonia
Sodium chloride	22 Sep 2020 (Study Day 15) - 22 Sep 2020 (Study Day 15)	Pneumonia
Cetirizine hydrochloride	15 Oct 2020 (Study Day 38) - Ongoing	Seasonal Allergies
Influenza vaccine	22 Oct 2020 (Study Day 45) - 22 Oct 2020 (Study Day 45)	Influenza Preventive
Acetylsalicylic acid	15 Nov 2020 (Study Day 69) - Ongoing	Cardiac Prophylaxis
Atorvastatin	15 Nov 2020 (Study Day 69) - Ongoing	Hyperlipidemia
Melatonin	31 Dec 2020 (Study Day 115) - Ongoing	Insomnia
Diphtheria vaccine toxoid; pertussis vaccine; tetanus vaccine toxoid	11 Mar 2021 (Study Day 185) - 11 Mar 2021 (Study Day 185)	Tetanus Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US371-2032 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Non-Hodgkin's Lymphoma/Non-Hodgkin's Lymphoma	SAE	Grade 2/moderate	Not related	18 Dec 2020 (Study Day 100) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2032, a 64-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 07 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Dec 2020 (Study Day 100), 99 days after the first dose and 72 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of non-hodgkin's lymphoma. Action taken with the IP was not applicable. The event of non-hodgkin's lymphoma was considered to be ongoing. The investigator assessed the event of non-hodgkin's lymphoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015383	Non-Hodgkin's Lymphoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	1978 - 1978
Drug hypersensitivity	Allergy to penicillin	1980 - Ongoing
Cholecystectomy	Cholecystectomy	1985 - 1985
Cholecystitis	Cholecystitis	1985 - 1985
Myopia	Myopia	1990 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Dysmenorrhoea	Dysmenorrhea	2001 - 2001
Endometrial ablation	Uterine ablation	2001 - 2001
Depression	Depression	2005 - Ongoing
Hip arthroplasty	Partial left hip replacement	2009 - 2009
Osteoarthritis	Left hip, ball and socket was bone on bone	2009 - 2009
Sleep apnoea syndrome	Obstructive sleep apnea	2010 - Ongoing
Varicose vein	Varicose veins (bilateral)	2010 - Ongoing
Anxiety	Anxiety	2012 - Ongoing
Inguinal hernia	Inguinal hernia	Sep 2018 - Sep 2018
Inguinal hernia repair	Inguinal hernia repair	Sep 2018 - Sep 2018
Pulmonary embolism	Saddle block pulmonary embolus	2019 - 2019
Eczema	Eczema	Mar 2019 - Ongoing
Chest tube insertion	Thoracostomy	May 2019 - May 2019
Thrombosis	Bilateral blood clots	May 2019 - May 2019
Umbilical hernia repair	Umbilical hernia repair	Sep 2019 - Sep 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Triamterene	2000 - Ongoing	Hypertension
Citalopram	2005 - Ongoing	Depression
Vitamins nos	2010 - Ongoing	Supplement
Magnesium	2014 - Ongoing	Supplement
Acetylsalicylic acid	2018 - Ongoing	Cardiac Prophylaxis
Atorvastatin	Jun 2019 - Ongoing	Hyperlipidemia
Paracetamol	08 Oct 2020 (Study Day 29) - 09 Oct 2020 (Study Day 30)	Body Aches, Sore Throat, Headache, And Fatigue

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	27 Oct 2020 (Study Day 48) - 27 Oct 2020 (Study Day 48)	Preventive Health
Right leg vein ablation*	02 Nov 2020 (Study Day 54) - 02 Nov 2020 (Study Day 54)	Adverse Event
Varicella zoster vaccine	02 Nov 2020 (Study Day 54) - 02 Nov 2020 (Study Day 54)	Prevention Health
Ct abdomen/pelvis*	15 Dec 2020 (Study Day 97) - 15 Dec 2020 (Study Day 97)	Adverse Event
Retroperitoneal needle biopsy*	18 Dec 2020 (Study Day 100) - 18 Dec 2020 (Study Day 100)	Adverse Event
Us lower extremities*	18 Dec 2020 (Study Day 100) - 18 Dec 2020 (Study Day 100)	Adverse Event
Allopurinol	23 Dec 2020 (Study Day 105) - Ongoing	Non-Hodgkin's Lymphoma
Apixaban	23 Dec 2020 (Study Day 105) - Ongoing	Non-Hodgkin's Lymphoma
Diphenhydramine hydrochloride; hydrocortisone; nystatin	23 Dec 2020 (Study Day 105) - Ongoing	Non-Hodgkin's Lymphoma
Valsartan	01 Jan 2021 (Study Day 114) - Ongoing	Hypertension
Chest xray*	04 Jan 2021 (Study Day 117) - 04 Jan 2021 (Study Day 117)	Adverse Event
Levofloxacin	04 Jan 2021 (Study Day 117) - 05 Jan 2021 (Study Day 118)	Port Placement
Port placement*	04 Jan 2021 (Study Day 117) - 04 Jan 2021 (Study Day 117)	Adverse Event
Pet ct*	06 Jan 2021 (Study Day 119) - 06 Jan 2021 (Study Day 119)	Adverse Event
Bendamustine	13 Jan 2021 (Study Day 126) - Ongoing	Non-Hodgkin's Lymphoma
Lidocaine; prilocaine	13 Jan 2021 (Study Day 126) - Ongoing	Chemo Therapy Prophylaxis
Prochlorperazine maleate	13 Jan 2021 (Study Day 126) - Ongoing	Non-Hodgkin's Lymphoma
Rituximab	13 Jan 2021 (Study Day 126) - 13 Jan 2021 (Study Day 126)	Non-Hodgkin's Lymphoma
Bendamustine	14 Jan 2021 (Study Day 127) - 14 Jan 2021 (Study Day 127)	Non-Hodgkin's Lymphoma
Bone marrow aspiration and biopsy*	20 Jan 2021 (Study Day 133) - 20 Jan 2021 (Study Day 133)	Adverse Event
Rituximab	11 Mar 2021 (Study Day 183) - 11 Mar 2021 (Study Day 183)	Chemotherapy Non-Hodgkin's Lymphoma

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Varicose Vein	Grade 2/moderate	Not related	02 Nov 2020 (Study Day 54) - 02 Nov 2020 (Study Day 54)
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	01 Dec 2020 (Study Day 83) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hydronephrosis	Grade 2/moderate	Not related	18 Dec 2020 (Study Day 100) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US371-2035 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Upper Limb Fracture/ Worsening Of Left Shoulder Acromial Fracture	SAE	Grade 2/ moderate	Not related	22 Oct 2020 (Study Day 43) – 23 Oct 2020 (Study Day 44)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2035, a 80-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 07 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Oct 2020 (Study Day 43), 42 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of upper limb fracture. Action taken with the IP was not applicable. The event of worsening of left shoulder acromial fracture lasted for 2 days, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 44). The investigator assessed the event of upper limb fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001156	Upper limb fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1945 - 1945
Tonsillitis	Tonsillitis	1945 - 1945
Presbyopia	Presbyopia	1950 - Ongoing
Varicocele	Varicocele	1972 - 1972
Varicocele repair	Varicocele repair	1972 - 1972
Hyperkeratosis	Keratosis	1995 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2000 - Ongoing
Gastrooesophageal reflux disease	Acid relfux	2000 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2000 - Ongoing
Inguinal hernia	Inguinal hernia	2010 - 2010
Inguinal hernia repair	Inguinal hernia repair	2010 - 2010
Spinal osteoarthritis	Cervical spondylosis	2010 - Ongoing
Umbilical hernia	Umbilical hernia	2010 - 2010
Umbilical hernia repair	Umbilical hernia repair	2010 - 2010
Insomnia	Insomnia	2012 - Ongoing
Osteoarthritis	Osteoarthritis (hands, shoulder, right knee)	2013 - Ongoing
Cataract operation	Cataract surgery	2015 - 2015
Fracture treatment	Nondisplaced fracture of left acromion process repair	2015 - 2015
Neuropathic arthropathy	Charcot joint of right shoulder	2015 - 2015
Scapula fracture	Nondisplaced fracture of left acromion process	2015 - 2015
Rotator cuff repair	Nontraumatic complete tear of left rotator cuff repair	17 Dec 2015 (Study Day -1729) - 17 Dec 2015 (Study Day -1729)
Rotator cuff syndrome	Nontraumatic complete tear of left rotator cuff	17 Dec 2015 (Study Day -1729) - 17 Dec 2015 (Study Day -1729)
Anxiety	Anxiety	2018 - Ongoing
Coronary artery disease	Coronary artery disease	Jun 2018 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	Feb 2019 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Aug 2019 - Ongoing
Tooth impacted	Wisdom teeth impaction	Jul 2020 - Jul 2020
Wisdom teeth removal	Wisdom teeth extraction	Jul 2020 - Jul 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	2000 - Ongoing	Gastroesophageal Reflux Disease
Finasteride	2000 - Ongoing	Benign Prostatic Hyperplasia
Glucosamine	2000 - Ongoing	Supplement
Omeprazole	2000 - Ongoing	Acid Reflux
Trazodone	2012 - Ongoing	Insomnia
Cefazolin	22 Oct 2012 (Study Day -2880) - 23 Oct 2020 (Study Day 44)	Prevention Of Infection Due To Surgical Intervention During Hospitalization
Colecalciferol	2015 - Ongoing	Supplement
Vitamin b complex	2015 - Ongoing	Supplement
Escitalopram	2018 - Ongoing	Anxiety
Cetirizine hydrochloride	Feb 2019 - Ongoing	Seasonal Allergic Rhinitis
Acetylsalicylic acid	Aug 2019 - Ongoing	Cardiac Prophylaxis
Fenofibrate	Aug 2019 - Ongoing	Hypercholesterolemia
Rosuvastatin	Aug 2019 - Ongoing	Hypercholesterolemia
Ubiquinol	Dec 2019 - Ongoing	Supplement
Melatonin	Jul 2020 - Ongoing	Insomnia
Ascorbic acid; iron	01 Sep 2020 (Study Day -9) - Ongoing	Supplement
Ascorbic acid; ferrous fumarate	28 Sep 2020 (Study Day 19) - Ongoing	Mild Anemia
Ibuprofen	08 Oct 2020 (Study Day 29) - 08 Oct 2020 (Study Day 29)	Fever
Acetylsalicylic acid	22 Oct 2020 (Study Day 43) - 28 Oct 2020 (Study Day 49)	Pre And Post Op Blood Clot Prophylaxis
Ascorbic acid; ferrous fumarate	22 Oct 2020 (Study Day 43) - Ongoing	Dietary Supplement
Atorvastatin	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Prevention Of Hyperlipidemia During Hospitalization
Bisacodyl	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Prevention Of Constipation Due To Pain Medication During Hospitalization
Calcium chloride; potassium chloride; sodium lactate	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Electrolyte And Fluid Replacement Due To Surgery During Hospitalization
Ct scan*	22 Oct 2020 (Study Day 43) - 22 Oct 2020 (Study Day 43)	Adverse Event
Left shoulder, reverse arthroplasty*	22 Oct 2020 (Study Day 43) - 22 Oct 2020 (Study Day 43)	Adverse Event
Loratadine	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Prevention Of Seasonal Allergies During Hospitalization
Morphine	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Prevention Of Pain Due To Surgery During Hospitalization
Mri of left rotators cuff*	22 Oct 2020 (Study Day 43) - 22 Oct 2020 (Study Day 43)	Adverse Event
Naproxen	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Prevention Of Pain Due To Surgery During Hospitalization

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxycodone	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Prevention Of Pain Due To Surgery During Hospitalization
Oxycodone	22 Oct 2020 (Study Day 43) - 24 Oct 2020 (Study Day 45)	Prevention Of Pain Due To Surgery During Hospitalization
Ranitidine	22 Oct 2020 (Study Day 43) - 23 Oct 2020 (Study Day 44)	Prevention Of Gastroesophageal Reflux Disease During Hospitalization
Vancomycin	22 Oct 2020 (Study Day 43) - 22 Oct 2020 (Study Day 43)	Prevention Of Infection Due To Surgery During Hospitalization
X-ray of left shoulder*	22 Oct 2020 (Study Day 43) - 22 Oct 2020 (Study Day 43)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anaemia	Grade 1/mild	Not related	28 Sep 2020 (Study Day 19) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US371-2064 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	18 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	16 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Left Hip Degenerative Joint Disease With Arthritis	SAE	Grade 2/ moderate	Not related	12 Jan 2021 (Study Day 117) – 05 Feb 2021 (Study Day 141)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2064, a 74-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 18 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 16 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Jan 2021 (Study Day 117), 116 days after the first dose and 88 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of left hip degenerative joint disease with arthritis lasted for 25 days, after which it was considered to be recovered/resolved on 05 Feb 2021 (Study Day 141). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-015319	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypermetropia	Hyperopia	1949 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	1998 - Ongoing
Prostate cancer	Prostate cancer	2005 - 2005
Radical prostatectomy	Radical prostatectomy	2005 - 2005
Hypertension	Hypertension	2009 - Ongoing
Osteoarthritis	Bilateral knees osteoarthritis	2010 - Ongoing
Large intestine polyp	Colon polyps (benign)	2012 - Ongoing
Bladder cancer	Bladder cancer	2014 - 2014
Cystoscopy	Cystoscopy of the bladder	2014 - 2014
Attention deficit hyperactivity disorder	Adult attention deficit disorder	2015 - Ongoing
Purpura senile	Senile purpura	2015 - Ongoing
Sciatica	Sciatica	Dec 2015 - Ongoing
Drug hypersensitivity	Allergy to lovenox	Jun 2019 - Ongoing
Hip arthroplasty	Total hip arthroplasty	Jun 2019 - Jun 2019
Osteoarthritis	Osteoarthritis in right hip	Jun 2019 - Jun 2019
Inguinal hernia	Left inguinal hernia	13 May 2020 (Study Day -128) - 13 May 2020 (Study Day -128)
Inguinal hernia repair	Left inguinal hernia repair	13 May 2020 (Study Day -128) - 13 May 2020 (Study Day -128)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide	2009 - Ongoing	Hypertension
Ibuprofen	2010 - Ongoing	Osteoarthritis
Colecalciferol	2011 - Ongoing	Supplement
Methylphenidate hydrochloride	2015 - Ongoing	Adult Add
Influenza vaccine	02 Nov 2020 (Study Day 46) - 02 Nov 2020 (Study Day 46)	Preventive Health
Left hip x-ray*	12 Jan 2021 (Study Day 117) - 12 Jan 2021 (Study Day 117)	Adverse Event
Tramadol	22 Jan 2021 (Study Day 127) - 27 Jan 2021 (Study Day 132)	Left Hip Pain
Apixaban	04 Feb 2021 (Study Day 140) - 11 Mar 2021 (Study Day 175)	Left Hip Replacement
Bisacodyl	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Constipation During Hospitalization

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium carbonate	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Acid Reflux During Hospitalized
Cefazolin sodium	04 Feb 2021 (Study Day 140) - 04 Feb 2021 (Study Day 140)	Left Hip Replacement
Cefazolin sodium	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Left Hip Replacement
Colecalciferol	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Supplement
Diphenhydramine	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Of Allergic Reaction While Hospitalized
Docusate	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Constipation While Hospitalized
Glucose	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Left Hip Replacement
Hydrocodone bitartrate; paracetamol	04 Feb 2021 (Study Day 140) - 07 Feb 2021 (Study Day 143)	Left Hip Replacement
Left hip replacement*	04 Feb 2021 (Study Day 140) - 04 Feb 2021 (Study Day 140)	Adverse Event
Magnesium oxide	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Supplement
Methylphenidate	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Left Hip Replacement
Ondansetron	04 Feb 2021 (Study Day 140) - 07 Feb 2021 (Study Day 143)	Left Hip Replacement
Ondansetron	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Nausea While Hospitalized
Paracetamol	04 Feb 2021 (Study Day 140) - 10 Feb 2021 (Study Day 146)	Left Hip Replacement
Paracetamol	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Pain During Hospitalization
Promethazine	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Nausea During Hospitalization
Sennoside a+b	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Constipation While Hospitalized
Simeticone	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Pain While Hospitalized
Sodium chloride	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Flush Of Iv While Hospitalization
Sodium chloride	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Dehydration During Hospitalization
Sodium chloride	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Prevention Of Iv Clotting While Hospitalized
Vitamin d nos	04 Feb 2021 (Study Day 140) - 05 Feb 2021 (Study Day 141)	Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 89) - 05 Feb 2021 (Study Day 141)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US371-2094 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	19 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 2/ moderate	Not related	20 Dec 2020 (Study Day 91) – 22 Dec 2020 (Study Day 93)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2094, a 41-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 19 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Dec 2020 (Study Day 91), 90 days after the first dose and 62 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 3 days, after which it was considered to be recovered/resolved on 22 Dec 2020 (Study Day 93). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-020659	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tooth impacted	Wisdom teeth impaction	2000 - 2000
Wisdom teeth removal	Wisdom teeth extraction	2000 - 2000
Mammoplasty	Breast implants	2007 - 2007
Bipolar II disorder	Bipolar disorder type ii	2012 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2015 - Ongoing	Bipolar Disorder Type Ii
Oxcarbazepine	2015 - Ongoing	Bipolar Disorder Type Ii
Venlafaxine	2016 - Ongoing	Bipolar Disorder Type Ii
Quetiapine fumarate	Sep 2017 - Ongoing	Bipolar Disorder Type Ii
Intrauterine contraceptive device	2018 - Ongoing	Contraception
Influenza vaccine	09 Nov 2020 (Study Day 50) - 09 Nov 2020 (Study Day 50)	Influenza Vaccine
Appendectomy*	21 Dec 2020 (Study Day 92) - 21 Dec 2020 (Study Day 92)	Adverse Event
Ondansetron	22 Dec 2020 (Study Day 93) - 22 Dec 2020 (Study Day 93)	Nausea (Appendicitis)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Uterine Leiomyoma	Grade 1/mild	Not related	21 Dec 2020 (Study Day 92) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US371-2114 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	22 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/ Progression Prostate Cancer	SAE	Grade 3/ severe	Not related	01 Oct 2020 (Study Day 8) – 13 Nov 2020 (Study Day 51)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US371-2114, a 70-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 24 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 22 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Oct 2020 (Study Day 8), 7 days after the first dose and 21 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of progression prostate cancer lasted for 44 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 51). The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014524	Prostate Cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to penicillin	1956 - Ongoing
Drug hypersensitivity	Allergy to sulfa	1958 - Ongoing
Immunoglobulins	Antitetanic immunoglobulins from animal origin	1958 - Ongoing
Anisometropia	Anisometropia	1964 - Ongoing
Skull fracture	Left skull fracture	1969 - 1969
Tooth impacted	Wisdom teeth impaction	1972 - 1972
Wisdom teeth removal	Wisdom teeth extraction	1972 - 1972
Haematoma	Hematoma left ankle	1973 - 1973
Haematoma evacuation	Hematoma left ankle removed	1973 - 1973
Skull fracture	Left skull fracture	1975 - 1975
Tonsillectomy	Tonsillectomy	1975 - 1975
Tonsillitis	Tonsillitis	1975 - 1975
Nasal septum deviation	Nasal septum deviation	1980 - 1980
Diabetic neuropathy	Diabetic neuropathy bilateral	1989 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1989 - Ongoing
Hypertension	Hypertension	1989 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	1989 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2000 - Ongoing
Sarcoidosis	Sarcoidosis	2002 - Ongoing
Basal cell carcinoma	Basal cell carcinoma bilateral shoulders	2012 - 2012
Basal cell carcinoma	Basal cell carcinoma lower back	2012 - 2012
Skin neoplasm excision	Basal cell carcinoma removal bilateral shoulders	2012 - 2012
Skin neoplasm excision	Basal cell carcinoma removal lower back	2012 - 2012
Elbow operation	Left elbow surgical repair	2018 - 2018
Upper limb fracture	Left elbow fracture	2018 - 2018
Seasonal allergy	Seasonal allergies	2019 - Ongoing
Prostate cancer	Prostate cancer	14 Jul 2020 (Study Day -72) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	1989 - Ongoing	Hyperlipidemia
Empagliflozin; linagliptin	1989 - Ongoing	Type 2 Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	1989 - Ongoing	Hypertension
Metformin	1989 - Ongoing	Type 2 Diabetes
Esomeprazole magnesium	2000 - Ongoing	Gastroesophageal Reflux Disease
Colecalciferol	2015 - Ongoing	Supplement
Gabapentin	2015 - Ongoing	Diabetic Neuropathy
Vitamins nos	2015 - Ongoing	Supplement
Iron	2018 - Ongoing	Supplement
Dextromethorphan hydrobromide; guaifenesin	2019 - Ongoing	Seasonal Allergies
Insulin degludec	2019 - Ongoing	Type 2 Diabetes
Krill oil	01 Jan 2020 (Study Day -267) - Ongoing	Supplement
Loratadine	01 Jan 2020 (Study Day -267) - Ongoing	Seasonal Allergies
Ciprofloxacin	13 Nov 2020 (Study Day 51) - 13 Nov 2020 (Study Day 51)	Prevention Of Infection After Surgery While Hospitalized
Heparin	13 Nov 2020 (Study Day 51) - 14 Nov 2020 (Study Day 52)	Prevention Of Deep Vein Thrombosis While Hospitalized
Ondansetron	13 Nov 2020 (Study Day 51) - 14 Nov 2020 (Study Day 52)	Prevention Of Nausea While Hospitalized
Oxybutynin	13 Nov 2020 (Study Day 51) - 14 Nov 2020 (Study Day 52)	Prevention Of Bladder Spasms After Surgery While Hospitalized
Oxycodone	13 Nov 2020 (Study Day 51) - 14 Nov 2020 (Study Day 52)	Prevention Of Pain After Surgery While Hospitalized
Paracetamol	13 Nov 2020 (Study Day 51) - 13 Nov 2020 (Study Day 51)	Prevention Of Pain After Surgery While Hospitalized
Paracetamol	13 Nov 2020 (Study Day 51) - 14 Nov 2020 (Study Day 52)	Prevention Of Pain After Surgery While Hospitalized
Phenazopyridine	13 Nov 2020 (Study Day 51) - 13 Nov 2020 (Study Day 51)	Prevention Of Painful Urination After Surgery While Hospitalized
Robotic assisted laparoscopic radial prostatectomy with bilateral pelvic lymph node dissection*	13 Nov 2020 (Study Day 51) - 13 Nov 2020 (Study Day 51)	Adverse Event
Sodium chloride	13 Nov 2020 (Study Day 51) - 13 Nov 2020 (Study Day 51)	Prevention Of Dehydration While Hospitalized
Colecalciferol	14 Nov 2020 (Study Day 52) - 14 Nov 2020 (Study Day 52)	Supplement
Insulin lispro	14 Nov 2020 (Study Day 52) - 14 Nov 2020 (Study Day 52)	Type 2 Diabetes
Pantoprazole sodium sesquihydrate	14 Nov 2020 (Study Day 52) - 14 Nov 2020 (Study Day 52)	Prevention Of Gastroesophageal Reflux Disease While Hospitalized

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US372-2034 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	02 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	31 Aug 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer Metastatic/ Metastatic Castrate Sensitive Prostrate Cancer With Metastases	SAE	Grade 3/severe	Not related	01 Sep 2020 (Study Day 31) – 24 Feb 2021 (Study Day 207)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2034, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 31 Aug 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Sep 2020 (Study Day 31), 30 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer metastatic. Action taken with the IP was not applicable. The event of metastatic castrate sensitive prostrate cancer with metastases lasted for 177 days, after which it was considered to be recovered/resolved with sequelae on 24 Feb 2021 (Study Day 207). The investigator assessed the event of prostate cancer metastatic to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000416	Prostate Cancer Metastatic

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Claustrophobia	Claustrophobia	2017 - Ongoing
Prostate cancer	Prostate cancer	2017 - Ongoing
Gynaecomastia	Gynecomastia, male	Feb 2017 - Oct 2020
Orchidectomy	Bilateral orchiectomy for surgical castration due to prostate cancer	Feb 2017 - Feb 2017
Intervertebral disc degeneration	Degenerative disc disease worse at l4-l5	2019 - Ongoing
Diverticulitis	Diverticulitis	Jun 2020 - Ongoing
Arthralgia	Right hip pain	Jul 2020 - Ongoing
Insomnia	Insomnia	Jul 2020 - 02 Nov 2020 (Study Day 93)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Iopamidol	Not reported - 2020	Abdominal And Pelvic Ct
Enzalutamide	2018 - Oct 2019	Prostate Cancer
Tramadol	Jun 2020 - Oct 2020	Generalized Pain
Naproxen	Jul 2020 - Ongoing	Hip Pain
Magnesium citrate	Sep 2020 - Sep 2020	Constipation/Generalized Pain
Tamsulosin hydrochloride	Sep 2020 - Ongoing	Benign Prostatic Hyperplasia
Colonoscopy with polyps removal*	01 Sep 2020 (Study Day 31) - 01 Sep 2020 (Study Day 31)	Adverse Event
X-ray of the abdomen*	01 Sep 2020 (Study Day 31) - 01 Sep 2020 (Study Day 31)	Adverse Event
Cervical xray*	03 Sep 2020 (Study Day 33) - 03 Sep 2020 (Study Day 33)	Adverse Event
Meloxicam	09 Sep 2020 (Study Day 39) - Ongoing	Back Pain Related To Metastatic Castrate Sensitive Prostrate Cancer With Metastases
Ct chest with contrast*	18 Sep 2020 (Study Day 48) - 18 Sep 2020 (Study Day 48)	Adverse Event
Hydrocodone bitartrate; paracetamol	23 Sep 2020 (Study Day 53) - Ongoing	Metastatic Castrate Sensitive Prostrate Cancer With Metastases
Lorazepam	25 Sep 2020 (Study Day 55) - Ongoing	Anxiety
Ct of abdomen*	19 Oct 2020 (Study Day 79) - 19 Oct 2020 (Study Day 79)	Adverse Event
Nuclear medicine bone scan*	19 Oct 2020 (Study Day 79) - 19 Oct 2020 (Study Day 79)	Adverse Event
Bupivacaine	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium chloride; potassium chloride; sodium lactate	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Worsening Of Prostate Cancer
Diphenhydramine hydrochloride	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer
Flumazenil	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer
Heparin porcine	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer
Hydrocodone bitartrate; paracetamol	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer
Hydromorphone	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer
Promethazine	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer
Sodium chloride	29 Oct 2020 (Study Day 89) - 02 Nov 2020 (Study Day 93)	Prostate Cancer
Carboplatin	03 Nov 2020 (Study Day 94) - 03 Nov 2020 (Study Day 94)	Prostate Cancer
Etoposide	03 Nov 2020 (Study Day 94) - 03 Nov 2020 (Study Day 94)	Prostate Cancer
Ct abdomen and pelvis*	04 Nov 2020 (Study Day 95) - 04 Nov 2020 (Study Day 95)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Constipation	Grade 2/moderate	Not related	01 Sep 2020 (Study Day 31) - Ongoing
Insomnia	Grade 1/mild	Not related	01 Sep 2020 (Study Day 31) - 02 Nov 2020 (Study Day 93)
Intervertebral Disc Degeneration	Grade 2/moderate	Not related	01 Sep 2020 (Study Day 31) - Ongoing
Large Intestine Polyp	Grade 1/mild	Not related	01 Sep 2020 (Study Day 31) - 01 Sep 2020 (Study Day 31)
Neck Pain	Grade 1/mild	Not related	01 Sep 2020 (Study Day 31) - 04 Sep 2020 (Study Day 34)
Blood Iron Decreased	Grade 2/moderate	Not related	04 Sep 2020 (Study Day 34) - Ongoing
Anxiety	Grade 1/mild	Not applicable	25 Sep 2020 (Study Day 55) - Ongoing
Cervical Vertebral Fracture	Grade 1/mild	Not related	01 Oct 2020 (Study Day 61) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US372-2338 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Incarcerated Hernia/ Acute Incarcerated Left Hernia Lower Quadrant	SAE	Grade 3/severe	Not related	12 Oct 2020 (Study Day 54) – 21 Oct 2020 (Study Day 63)	Recovered/resolved
Urinary Retention/Acute Urinary Retention	SAE	Grade 3/severe	Not related	14 Oct 2020 (Study Day 56) – 26 Oct 2020 (Study Day 68)	Recovered/resolved
Pulmonary Embolism/Pulmonary Embolism	SAE	Grade 3/severe	Not related	26 Oct 2020 (Study Day 68) – 28 Oct 2020 (Study Day 70)	Recovered/resolved
Urinary Tract Infection/ Urinary Tract Infection	SAE	Grade 3/severe	Not related	26 Oct 2020 (Study Day 68) – 10 Nov 2020 (Study Day 83)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2338, a 73-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Oct 2020 (Study Day 54), 53 days after the first dose and 25 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of incarcerated hernia. Action taken with the IP was not applicable. The event of acute incarcerated left hernia lower quadrant lasted for 10 days, after which it was considered to be recovered/resolved on 21 Oct 2020 (Study Day 63). The investigator assessed the event of incarcerated hernia to be not related to the IP.

On 14 Oct 2020 (Study Day 56), 55 days after the first dose and 27 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of urinary retention. Action taken with the IP was not applicable. The event of acute urinary retention lasted for 13

days, after which it was considered to be recovered/resolved on 26 Oct 2020 (Study Day 68). The investigator assessed the event of urinary retention to be not related to the IP.

On 26 Oct 2020 (Study Day 68), 67 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of pulmonary embolism lasted for 3 days, after which it was considered to be recovered/resolved on 28 Oct 2020 (Study Day 70). The investigator assessed the event of pulmonary embolism to be not related to the IP.

On 26 Oct 2020 (Study Day 68), 67 days after the first dose and 39 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of urinary tract infection lasted for 16 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 83). The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000524	Incarcerated hernia
MOD-2020-000524	Urinary retention
MOD-2021-004897	Pulmonary embolism
MOD-2021-004897	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes 2	1990 - Ongoing
Abdominal hernia	Hernia left lower quadrant	2003 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Insomnia	Insomnia	2015 - Ongoing
Osteoarthritis	Osteoarthritis arthritis in bilateral knees	2015 - Ongoing
Dyspnoea	Dyspnea	2016 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Seasonal allergy	Seasonal allergies	2016 - Ongoing
Varicose vein	Varicose veins	2016 - Ongoing
Anaemia	Chronic anemia	2018 - Ongoing
Thrombophlebitis superficial	Superficial thrombophlebitis	2018 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypoalbuminaemia	Chronic hypoalbuminemia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin glargine	1993 - Ongoing	Diabetes 2
Insulin lispro	1994 - Ongoing	Diabetes 2
Insulin aspart	03 Mar 2016 (Study Day -1631) - Ongoing	Diabetes 2
Salbutamol sulfate	03 Mar 2016 (Study Day -1631) - Ongoing	Shortness Of Breath
Fluticasone	28 Oct 2016 (Study Day -1392) - Ongoing	Seasonal Allergies
Lisinopril	2017 - Ongoing	Hypertension
Pravastatin	2017 - Ongoing	Hyperlipidemia
Empagliflozin; metformin hydrochloride	2018 - Ongoing	Diabetes 2
Clonazepam	17 Mar 2020 (Study Day -156) - Ongoing	Anxiety
Acetylsalicylic acid	19 Sep 2020 (Study Day 31) - 23 Sep 2020 (Study Day 35)	Left Arm Pain And Swelling
Ibuprofen	19 Sep 2020 (Study Day 31) - 23 Sep 2020 (Study Day 35)	Left Arm Pain And Swelling
Rivaroxaban	02 Oct 2020 (Study Day 44) - Ongoing	Left Sided Dvt
Fentanyl	12 Oct 2020 (Study Day 54) - 21 Oct 2020 (Study Day 63)	Pain Related To Acute Incarcerated Left Hernia Repair With Mesh
Hernia repair*	12 Oct 2020 (Study Day 54) - 12 Oct 2020 (Study Day 54)	Adverse Event
Colecalciferol	13 Oct 2020 (Study Day 55) - Ongoing	Supplement
Zinc	13 Oct 2020 (Study Day 55) - Ongoing	Supplement
Coude foley catheter placement*	14 Oct 2020 (Study Day 56) - 14 Oct 2020 (Study Day 56)	Adverse Event
Paracetamol	14 Oct 2020 (Study Day 56) - 31 Oct 2020 (Study Day 73)	Pain Related To Acute Incarcerated Left Hernia Repair With Mesh
Finasteride	21 Oct 2020 (Study Day 63) - 21 Oct 2020 (Study Day 63)	Acute Urinary Retention Requiring Foley Catheter
Levofloxacin	21 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 70)	Left Hernia Repair With Mesh
Tramadol	21 Oct 2020 (Study Day 63) - 28 Oct 2020 (Study Day 70)	Pain Related To Acute Incarcerated Left Hernia Repair With Mesh
Ceftriaxone	26 Oct 2020 (Study Day 68) - 28 Oct 2020 (Study Day 70)	Urinary Tract Infection
Coude foley catheter replacement*	26 Oct 2020 (Study Day 68) - 26 Oct 2020 (Study Day 68)	Adverse Event
Ondansetron	26 Oct 2020 (Study Day 68) - 28 Oct 2020 (Study Day 70)	Urinary Tract Infection
Oxygen	26 Oct 2020 (Study Day 68) - 28 Oct 2020 (Study Day 70)	Acute Hypoxemic Respiratory Failure

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydromorphone hydrochloride	28 Oct 2020 (Study Day 70) - 03 Nov 2020 (Study Day 76)	Pain Related To Acute Incarcerated Left Hernia Repair With Mesh

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 2/moderate	Related	19 Sep 2020 (Study Day 31) - 23 Sep 2020 (Study Day 35)
Injection Site Swelling	Grade 2/moderate	Related	19 Sep 2020 (Study Day 31) - 23 Sep 2020 (Study Day 35)
Deep Vein Thrombosis	Not reported	Not applicable	02 Oct 2020 (Study Day 44) - Ongoing
Hypoxia	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 68) - 28 Oct 2020 (Study Day 70)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US372-2406 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Benign Prostatic Hyperplasia/ Worsening Benign Prostate Hyperplasia	SAE	Grade 2/ moderate	Not related	08 Oct 2020 (Study Day 42) – 14 Oct 2020 (Study Day 48)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US372-2406, a 63-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Oct 2020 (Study Day 42), 41 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of benign prostatic hyperplasia. Action taken with the IP was not applicable. The event of worsening benign prostate hyperplasia lasted for 7 days, after which it was considered to be recovered/resolved on 14 Oct 2020 (Study Day 48). The investigator assessed the event of benign prostatic hyperplasia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000775	Benign prostatic hyperplasia

Study Completion/Discontinuation

On 04 Jan 2021 (Study Day 130), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2012 - Ongoing
Erectile dysfunction	Erectile dysfunction	2017 - Ongoing
Benign prostatic hyperplasia	Benign prostate hyperplasia	2019 - Ongoing
Dizziness	Dizziness	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Other viral vaccines	Not reported - 2021	Vaccine
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Fluticasone propionate	2010 - Ongoing	Seasonal Allergies
Tadalafil	2017 - Ongoing	Ed
Meclozine hydrochloride	2019 - Ongoing	Dizziness
Ct head with contrast*	07 Oct 2020 (Study Day 41) - 07 Oct 2020 (Study Day 41)	Adverse Event
Echo*	07 Oct 2020 (Study Day 41) - 07 Oct 2020 (Study Day 41)	Adverse Event
French foley catheter placement*	07 Oct 2020 (Study Day 41) - 07 Oct 2020 (Study Day 41)	Medical History
Ascorbic acid	08 Oct 2020 (Study Day 42) - Ongoing	Supplement
Hydrocodone bitartrate; paracetamol	08 Oct 2020 (Study Day 42) - 26 Oct 2020 (Study Day 60)	Bladder Spasms
Hyoscyamine sulfate	08 Oct 2020 (Study Day 42) - 26 Oct 2020 (Study Day 60)	Bladder Spasms
Vitamin b complex	08 Oct 2020 (Study Day 42) - Ongoing	Supplement
Turp*	13 Oct 2020 (Study Day 47) - 13 Oct 2020 (Study Day 47)	Adverse Event
Foley catheter replaced*	25 Oct 2020 (Study Day 59) - 25 Oct 2020 (Study Day 59)	Adverse Event
Lidocaine	25 Oct 2020 (Study Day 59) - 25 Oct 2020 (Study Day 59)	Bhp
Cystoscopy for clot evacuation*	26 Oct 2020 (Study Day 60) - 26 Oct 2020 (Study Day 60)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Haemorrhage Urinary Tract	Grade 1/mild	Not applicable	07 Oct 2020 (Study Day 41) - 14 Oct 2020 (Study Day 48)
Bladder Spasm	Grade 2/moderate	Not applicable	08 Oct 2020 (Study Day 42) - 26 Oct 2020 (Study Day 60)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Constipation	Grade 2/moderate	Not related	24 Oct 2020 (Study Day 58) - 27 Oct 2020 (Study Day 61)
Haematuria	Grade 2/moderate	Not related	25 Oct 2020 (Study Day 59) - 26 Oct 2020 (Study Day 60)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2094 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Supraventricular Tachycardia/ Supraventricular Tachycardia	SAE	Grade 3/severe	Not related	24 Dec 2020 (Study Day 128) – 25 Dec 2020 (Study Day 129)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2094, a 69-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Dec 2020 (Study Day 128), 127 days after the first dose and 99 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of supraventricular tachycardia. Action taken with the IP was not applicable. The event of supraventricular tachycardia lasted for 2 days, after which it was considered to be recovered/resolved on 25 Dec 2020 (Study Day 129). The investigator assessed the event of supraventricular tachycardia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004755	Supraventricular tachycardia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol use	Alcohol use	1968 - Ongoing
Substance use	Marijuana use - inhalation	1968 - 1968
Synovial cyst	Ganglion cyst - left foot	1980 - 1980
Synovial cyst removal	Ganglion cyst left foot removal	1980 - 1980
Drug hypersensitivity	Cipro drug allergy	1990 - Ongoing
Headache	Non-migraine headaches	1990 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	1990 - Ongoing
Abdominal hernia	Abdominal hernia	1995 - 1995
Abdominal hernia repair	Abdominal hernia repair	1995 - 1995
Presbyopia	Presbyopia	2010 - Ongoing
Deafness bilateral	Bilateral hearing loss	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Prostate cancer	Prostate cancer	2015 - Ongoing
Insomnia	Insomnia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	1990 - Ongoing	Non-Migraine Headaches
Acetylsalicylic acid	2011 - Ongoing	General Health
Amlodipine besilate	2011 - 27 Jan 2021 (Study Day 162)	Hypertension
Losartan	2015 - Ongoing	Hypertension
Simvastatin	2015 - 27 Jan 2021 (Study Day 162)	Hypercholesterolemia
Eszopiclone	2019 - 27 Jan 2021 (Study Day 162)	Insomnia
Trazodone hydrochloride	2019 - Ongoing	Insomnia
Chest x-ray*	24 Dec 2020 (Study Day 128) - 24 Dec 2020 (Study Day 128)	Diagnostic
Ecg*	24 Dec 2020 (Study Day 128) - 24 Dec 2020 (Study Day 128)	Diagnostic
Head and neck cta*	24 Dec 2020 (Study Day 128) - 24 Dec 2020 (Study Day 128)	Diagnostic
Metoprolol	24 Dec 2020 (Study Day 128) - 24 Dec 2020 (Study Day 128)	Supraventricular Tachycardia
Ecg*	25 Dec 2020 (Study Day 129) - 25 Dec 2020 (Study Day 129)	Diagnostic
Echocardiogram*	25 Dec 2020 (Study Day 129) - 25 Dec 2020 (Study Day 129)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol	25 Dec 2020 (Study Day 129) - Ongoing	Supraventricular Tachycardia
Simvastatin	27 Jan 2021 (Study Day 162) - Ongoing	Hypercholesterolemia
Bilateral total thyroidectomy*	25 Feb 2021 (Study Day 191) - 25 Feb 2021 (Study Day 191)	Adverse Event
Liothyronine sodium	26 Feb 2021 (Study Day 192) - 13 Mar 2021 (Study Day 207)	Thyroid Cancer
Levothyroxine	13 Mar 2021 (Study Day 207) - Ongoing	Thyroid Hormone Therapy Status Post Total Thyroidectomy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Papillary Thyroid Cancer	Grade 3/severe	Not related	15 Jan 2021 (Study Day 150) - 26 Feb 2021 (Study Day 192)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2182 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	20 Oct 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cervical Spinal Stenosis/C5-C6 Severe Left Canal Stenosis	SAE	Grade 3/ severe	Not related	22 Oct 2020 (Study Day 29) – 17 Nov 2020 (Study Day 55)	Recovered/ resolved
Lung Adenocarcinoma/ Right Lung Adenocarcinoma	SAE	Grade 3/ severe	Not related	28 Oct 2020 (Study Day 35) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2182, a 62-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 20 Oct 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Oct 2020 (Study Day 29), 28 days after the first dose and 2 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cervical spinal stenosis. Action taken with the IP was not applicable. The event of c5-c6 severe left canal stenosis lasted for 27 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 55). The investigator assessed the event of cervical spinal stenosis to be not related to the IP.

On 28 Oct 2020 (Study Day 35), 34 days after the first dose and 8 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of lung adenocarcinoma. Action taken with the IP was not applicable. The event of right lung adenocarcinoma was considered to be ongoing. The investigator assessed the event of lung adenocarcinoma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000594	Cervical spinal stenosis
MOD-2021-028098	Lung adenocarcinoma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Chronic kidney disease	Stage 4 kidney disease	Not reported - Ongoing
Drug hypersensitivity	Penicillin allergy	1968 - Ongoing
Tonsillitis	Tonsillitis	1968 - 1968
Endometriosis	Endometriosis	1979 - 2006
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Postmenopause	Post menopausal	2001 - Ongoing
Ovarian cyst	Ovarian cysts	2003 - 2006
Hysterectomy	Hysterectomy	2006 - 2006
Lumbar spinal stenosis	Lumbar canal stenosis	2013 - Ongoing
Coronary artery disease	Cornonary artery disease	2019 - Ongoing
Insomnia	Insomnia	2019 - Ongoing
Paraesthesia	Lower extremity paresthesis	Aug 2020 - 05 Oct 2020 (Study Day 12)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2018 - Ongoing	Hypertension
Atorvastatin	2018 - Ongoing	High Cholesterol
Hydralazine	2018 - Ongoing	Hypertension
Hydroxyzine	2018 - Ongoing	Insomnia
Lisinopril	2018 - Ongoing	Hypertension
Acetylsalicylic acid	2019 - Ongoing	Cardiac Prophylaxis
Clopidogrel	2019 - Ongoing	Coronary Artery Disease
Isosorbide	Aug 2020 - Ongoing	Cad
Varenicline tartrate	Aug 2020 - Ongoing	Smoking Cessation
Colecalciferol	Sep 2020 - Ongoing	Vitamin Supplement
Gabapentin	Sep 2020 - 28 Sep 2020 (Study Day 5)	Lumbar Canal Stenosis
Gabapentin	28 Sep 2020 (Study Day 5) - 22 Mar 2021 (Study Day 180)	Lumbar Canal Stenosis
Ct c-spine without contrast*	22 Oct 2020 (Study Day 29) - 22 Oct 2020 (Study Day 29)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Brain ct without contrast*	23 Oct 2020 (Study Day 30) - 23 Oct 2020 (Study Day 30)	Adverse Event
Chest ct without contrast*	26 Oct 2020 (Study Day 33) - 26 Oct 2020 (Study Day 33)	Adverse Event
Ct t-spine without contrast*	26 Oct 2020 (Study Day 33) - 26 Oct 2020 (Study Day 33)	Adverse Event
Mri l-spine without contrast*	26 Oct 2020 (Study Day 33) - 26 Oct 2020 (Study Day 33)	Adverse Event
X-ray c-spine*	26 Oct 2020 (Study Day 33) - 26 Oct 2020 (Study Day 33)	Adverse Event
Transthoracic echocardiogram*	28 Oct 2020 (Study Day 35) - 28 Oct 2020 (Study Day 35)	Medical History
Methocarbamol	13 Nov 2020 (Study Day 51) - Ongoing	Lumbar Canal Stenosis
Oxycodone	13 Nov 2020 (Study Day 51) - Ongoing	Lumbar Canal Stenosis
Influenza vaccine	20 Nov 2020 (Study Day 58) - 20 Nov 2020 (Study Day 58)	Flu Prophylaxis
Glyceryl trinitrate	Dec 2020 - Ongoing	Cardiac Related Chest Pain
Tizanidine	Dec 2020 - Ongoing	Cardiac Related Chest Pain And Neuropathy In Bilateral Legs
Radiation therapy*	15 Mar 2021 (Study Day 173) - 15 Mar 2021 (Study Day 173)	Adverse Event
Radiotherapy	15 Mar 2021 (Study Day 173) - 19 Mar 2021 (Study Day 177)	Right Lung Adenocarcinoma
Chest x-ray*	16 Mar 2021 (Study Day 174) - 16 Mar 2021 (Study Day 174)	Adverse Event
Ecg*	16 Mar 2021 (Study Day 174) - 16 Mar 2021 (Study Day 174)	Adverse Event
Gabapentin	22 Mar 2021 (Study Day 180) - Ongoing	Lumbar Canal Stenosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Neuropathy Peripheral	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 55) - Ongoing
Chest Pain	Grade 2/moderate	Not related	20 Dec 2020 (Study Day 88) - Ongoing
Radiation Associated Pain	Grade 2/moderate	Not related	16 Mar 2021 (Study Day 174) - 17 Mar 2021 (Study Day 175)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2192 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	27 Oct 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Systemic Inflammatory Response Syndrome/Sirs (Systemic Inflammatory Response Syndrome)	SAE	Grade 4	Not related	11 Mar 2021 (Study Day 167) – 16 Mar 2021 (Study Day 172)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2192, a 35-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 26 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 27 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Mar 2021 (Study Day 167), 166 days after the first dose and 135 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of systemic inflammatory response syndrome. Action taken with the IP was not applicable. The event of sirs (systemic inflammatory response syndrome) lasted for 6 days, after which it was considered to be recovered/resolved on 16 Mar 2021 (Study Day 172). The investigator assessed the event of systemic inflammatory response syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-045330	Systemic inflammatory response syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthritis	Arthritis - back	1998 - Ongoing
Exostosis	Bone spurs - neck	1998 - Ongoing
Scoliosis	Scoliosis	1998 - Ongoing
Hepatic steatosis	Hepatic steatosis	2000 - Ongoing
Female sterilisation	Tubal ligation	2009 - 2009
Hepatic enzyme increased	Liver enzyme elevation	2009 - Ongoing
Irritable bowel syndrome	Irritable bowel syndrom	2009 - 2009
Goodpasture's syndrome	Goodpasture syndrome	2011 - 2012
Drug intolerance	Iodine intolerance	2012 - Ongoing
Drug intolerance	Tylenol intolerance	2012 - Ongoing
Drug intolerance	Zofran intolerance	2013 - Ongoing
Nephrolithiasis	Kidney stones	2016 - 2016
Migraine	Migraines - intermittent	2017 - Ongoing
Cholecystectomy	Cholecystectomy	2018 - 2018
Hysterectomy	Hysterectomy	2018 - 2018
Menorrhagia	Menorrhagia	2018 - 2018
Postmenopause	Post menopausal	2018 - Ongoing
Gastrooesophageal reflux disease	Gastroesophagel reflux disease	2019 - 2019
Impaired gastric emptying	Gastroparesis	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cannabis sativa	2018 - Ongoing	Back Pain
Estradiol	2018 - Ongoing	Post Menopausal Hormone Replacement
Ibuprofen	2018 - Ongoing	Arthritis - Back Pain
Gastric pacemaker*	18 Nov 2020 (Study Day 54) - 18 Nov 2020 (Study Day 54)	Medical History
Oxycodone	18 Nov 2020 (Study Day 54) - Ongoing	Post Procedure Gastric Pacemaker Pain
Benzonatate	12 Mar 2021 (Study Day 168) - 16 Mar 2021 (Study Day 172)	Systemic Inflammatory Response Syndrome
Salbutamol	12 Mar 2021 (Study Day 168) - 16 Mar 2021 (Study Day 172)	Systemic Inflammatory Response Syndrome

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US393-2206 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	05 Nov 2020 (Study Day 39)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Non-Cardiac Chest Pain/ Non-Cardiac Chest Pain (General Pain And Discomfort)	SAE	Grade 3/ severe	Not related	31 Jan 2021 (Study Day 126) – 01 Mar 2021 (Study Day 155)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2206, a 56-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Nov 2020 (Study Day 39). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Jan 2021 (Study Day 126), 125 days after the first dose and 87 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of non-cardiac chest pain. Action taken with the IP was not applicable. The event of non-cardiac chest pain (general pain and discomfort) lasted for 30 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 155). The investigator assessed the event of non-cardiac chest pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014170	Non-cardiac chest pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1975 - Ongoing
Anxiety	Anxiety	1991 - Ongoing
Depression	Depression	1991 - Ongoing
Hypertension	Hypertension	1995 - Ongoing
Osteoarthritis	Osteoarthritis	1995 - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	1998 - Ongoing
Vertigo	Vertigo	1998 - Ongoing
Back pain	Back pain	2000 - Ongoing
Insomnia	Insomnia	2000 - Ongoing
Carpal tunnel syndrome	Carpal tunnel (both wrists)	2005 - Ongoing
Fibromyalgia	Fibromyalgia	2005 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2005 - Ongoing
Aortic aneurysm	Aortic aneurysm	Sep 2005 - Sep 2005
Eczema	Eczema	2008 - Ongoing
Muscle spasms	Generalized muscle spasms	2008 - Ongoing
Seasonal allergy	Seasonal allergies	2008 - Ongoing
Gastrectomy	Gastric sleeve	2011 - 2011
Obesity	Obesity	2011 - 2011
Postmenopause	Post-menopausal	2013 - Ongoing
Large intestine polyp	Benign colon polyps	2014 - 2014
Transient ischaemic attack	Transient ischemic attack	2014 - 2014
Endometrial ablation	Uterine ablation	2016 - 2016
Constipation	Constipation	2018 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2018 - Ongoing
Cataract	Left eye cataract	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	1995 - Ongoing	Hypertension
Metoprolol	1995 - Ongoing	Hypertension
Amlodipine	1998 - Ongoing	Hypertension
Meclozine	1998 - 07 Dec 2020 (Study Day 71)	Vertigo
Fluticasone propionate; salmeterol xinafoate	2000 - Ongoing	Asthma
Salbutamol sulfate	2000 - Ongoing	Asthma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	2005 - Oct 2020	Acid Reflux
Diphenhydramine hydrochloride	2008 - Ongoing	Seasonal Allergies
Oxycodone hydrochloride; paracetamol	2008 - Ongoing	Back Pain
Venlafaxine	2009 - Ongoing	Depression
Venlafaxine	2009 - Ongoing	Fibromyalgia
Buspirone	2011 - Ongoing	Anxiety
Atorvastatin	2018 - Ongoing	Hypercholesterol
Linaclotide	2018 - Ongoing	Constipation
Spironolactone	2018 - Ongoing	Hypertension
Trazodone	2018 - Oct 2020	Insomnia
Tizanidine	2019 - Ongoing	Generalized Muscle Spasms
Paracetamol	30 Sep 2020 (Study Day 3) - 01 Oct 2020 (Study Day 4)	Treat Fever/Pain Ae Diary 1
Influenza vaccine	19 Nov 2020 (Study Day 53) - 19 Nov 2020 (Study Day 53)	Influenza Prophylaxis
Acetylsalicylic acid	04 Feb 2021 (Study Day 130) - 05 Feb 2021 (Study Day 131)	Chest Pain (Non-Cardiac)
Chest xray*	04 Feb 2021 (Study Day 130) - 04 Feb 2021 (Study Day 130)	Adverse Event
Cyclobenzaprine	04 Feb 2021 (Study Day 130) - 04 Feb 2021 (Study Day 130)	Muscle Spasms (Generalized)
Ecg*	04 Feb 2021 (Study Day 130) - 04 Feb 2021 (Study Day 130)	Adverse Event
Enoxaparin	04 Feb 2021 (Study Day 130) - 04 Feb 2021 (Study Day 130)	Prophylaxis For Dvt
Glyceryl trinitrate	04 Feb 2021 (Study Day 130) - 05 Feb 2021 (Study Day 131)	Chest Pain (Non-Cardiac)
Labetalol	04 Feb 2021 (Study Day 130) - 04 Feb 2021 (Study Day 130)	Hypertension
Morphine	04 Feb 2021 (Study Day 130) - 04 Feb 2021 (Study Day 130)	Chest Pain (Non-Cardiac)
Morphine	04 Feb 2021 (Study Day 130) - 05 Feb 2021 (Study Day 131)	Chest Pain (Non-Cardiac)
Pantoprazole	04 Feb 2021 (Study Day 130) - 05 Feb 2021 (Study Day 131)	Acid Reflux
Paracetamol	04 Feb 2021 (Study Day 130) - 05 Feb 2021 (Study Day 131)	Chest Pain (Non-Cardiac)
Omeprazole	16 Feb 2021 (Study Day 142) - Ongoing	Worsening Acid Reflux
Ct angiogram - chest, abdomen & pelvis*	26 Feb 2021 (Study Day 152) - 26 Feb 2021 (Study Day 152)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	28 Dec 2020 (Study Day 92) - 07 Jan 2021 (Study Day 102)
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	22 Jan 2021 (Study Day 117) - 28 Jan 2021 (Study Day 123)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 142) - 24 Feb 2021 (Study Day 150)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2215 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	30 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Oct 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colitis/Colitis	SAE	Grade 3/ severe	Not related	28 Jan 2021 (Study Day 121) – 22 Mar 2021 (Study Day 174)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2215, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 30 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Jan 2021 (Study Day 121), 120 days after the first dose and 91 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of colitis. Action taken with the IP was not applicable. The event of colitis lasted for 54 days, after which it was considered to be recovered/resolved on 22 Mar 2021 (Study Day 174). The investigator assessed the event of colitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009255	Colitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicitis	Appendicitis	1967 - 1967
Joint dislocation	Dislocated left shoulder	1976 - Ongoing
Nerve compression	Pinched nerve in left dislocated shoulder	1976 - Ongoing
Ulcer haemorrhage	Bleeding ulcer	2015 - 2015
Cataract	Bilateral cataracts	2018 - 2019
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2019 - Ongoing
Hepatitis C	Hepatitis c	Feb 2020 - Ongoing
Peripheral swelling	Left lower leg swelling	30 Sep 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2019 - 23 Mar 2021 (Study Day 175)	Chronic Obstructive Pulmonary Disease
Sofosbuvir; velpatasvir	May 2020 - Aug 2020	Hepatitis C
Gabapentin	Aug 2020 - Ongoing	Pinched Nerve In Left Dislocated Shoulder
Paracetamol	30 Oct 2020 (Study Day 31) - 30 Oct 2020 (Study Day 31)	Injection Site Pain
Colonoscopy*	29 Jan 2021 (Study Day 122) - 29 Jan 2021 (Study Day 122)	Adverse Event
Acetylsalicylic acid	01 Feb 2021 (Study Day 125) - 22 Mar 2021 (Study Day 174)	Colitis
Atorvastatin	03 Feb 2021 (Study Day 127) - 03 Mar 2021 (Study Day 155)	Colitis
Umeclidinium bromide; vilanterol trifenatate	24 Mar 2021 (Study Day 176) - Ongoing	Chronic Obstructive Pulmonary Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US393-2296 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	22 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	19 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypoglycaemia/ Hypoglycemia	SAE	Grade 3/severe	Not related	21 Jan 2021 (Study Day 92) – 03 Feb 2021 (Study Day 105)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2296, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 22 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 19 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Jan 2021 (Study Day 92), 91 days after the first dose and 63 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypoglycaemia. Action taken with the IP was not applicable. The event of hypoglycemia lasted for 14 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 105). The investigator assessed the event of hypoglycaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-011634	Hypoglycaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Asthma	Asthma	1991 - Ongoing
Hypertension	Hypertension	1991 - Ongoing
Rubber sensitivity	Latex allergy	1993 - Ongoing
Meniscus injury	Right knee torn meniscus	1995 - 1995
Cardiac failure congestive	Congestive heart failure	2004 - Ongoing
Cardiomyopathy	Cardiomyopathy	2004 - Ongoing
Erectile dysfunction	Erectile dysfunction	2004 - Ongoing
Hyperthyroidism	Hyperthyroidism	2004 - Ongoing
Neuropathy peripheral	Peripheral neuropathy	2004 - Ongoing
Oedema peripheral	Bilateral lower extremity edema	2004 - Ongoing
Transient ischaemic attack	Transient ischemia attack	2004 - 2004
Type 2 diabetes mellitus	Type 2 diabetes	2004 - Ongoing
Cataract	Bilateral cataracts	2012 - 2015
Cardiac pacemaker insertion	Pacemaker	2015 - Ongoing
Hand fracture	Right hand pinky fracture	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	1991 - Ongoing	Seasonal Allergies
Salbutamol	1991 - Ongoing	Asthma
Acetylsalicylic acid	2004 - Ongoing	Prophylaxis For Chronic Heart Failure
Insulin glargine	2004 - 31 Jan 2021 (Study Day 102)	Type 2 Diabetes
Insulin lispro	2004 - 31 Jan 2021 (Study Day 102)	Type 2 Diabetes
Levothyroxine sodium	2004 - 02 Feb 2021 (Study Day 104)	Hypothyroidism
Losartan	2004 - 15 Feb 2021 (Study Day 117)	Hypertension
Carvedilol	2013 - 02 Feb 2021 (Study Day 104)	Hypertension
Furosemide	2015 - 15 Feb 2021 (Study Day 117)	Congestive Heart Failure
Spironolactone	2017 - Ongoing	Chronic Heart Failure
Chest x-ray*	31 Jan 2021 (Study Day 102) - 31 Jan 2021 (Study Day 102)	Adverse Event
Ct head and cervical spine without contrast*	31 Jan 2021 (Study Day 102) - 31 Jan 2021 (Study Day 102)	Adverse Event
Enoxaparin sodium	31 Jan 2021 (Study Day 102) - 03 Feb 2021 (Study Day 105)	Cardiac Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin lispro	31 Jan 2021 (Study Day 102) - 31 Jan 2021 (Study Day 102)	Hypoglycemia
Ultrasound of abdomen*	31 Jan 2021 (Study Day 102) - 31 Jan 2021 (Study Day 102)	Adverse Event
Chest x-ray*	01 Feb 2021 (Study Day 103) - 01 Feb 2021 (Study Day 103)	Adverse Event
Echocardiogram*	01 Feb 2021 (Study Day 103) - 01 Feb 2021 (Study Day 103)	Adverse Event
Furosemide	01 Feb 2021 (Study Day 103) - 02 Feb 2021 (Study Day 104)	Shortness Of Breath
Insulin lispro	01 Feb 2021 (Study Day 103) - 01 Feb 2021 (Study Day 103)	Hypoglycemia
Insulin lispro	02 Feb 2021 (Study Day 104) - 02 Feb 2021 (Study Day 104)	Hypoglycemia
Carvedilol	03 Feb 2021 (Study Day 105) - Ongoing	Hypertension
Dapagliflozin propanediol monohydrate	03 Feb 2021 (Study Day 105) - Ongoing	Type 2 Diabetes
Insulin glargine	03 Feb 2021 (Study Day 105) - Ongoing	Type 2 Diabetes
Furosemide	16 Feb 2021 (Study Day 118) - Ongoing	Chronic Heart Failure
Levothyroxine sodium	17 Mar 2021 (Study Day 147) - Ongoing	Hypothyroidism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspnoea	Grade 2/moderate	Not related	31 Jan 2021 (Study Day 102) - 03 Feb 2021 (Study Day 105)
Hepatic Enzyme Abnormal	Grade 2/moderate	Not related	31 Jan 2021 (Study Day 102) - Ongoing
Injury	Grade 2/moderate	Not related	31 Jan 2021 (Study Day 102) - 03 Feb 2021 (Study Day 105)
Hyponatraemia	Grade 2/moderate	Not related	02 Feb 2021 (Study Day 104) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US394-2001 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥ 65 Years
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE	Grade 3/severe	Not related	13 Oct 2020 (Study Day 55) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2001, a 68-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Oct 2020 (Study Day 55), 54 days after the first dose and 19 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. Action taken with the IP was not applicable. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001231	Prostate cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asbestosis	Asbestosis	1994 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis generalized	2000 - Ongoing
Pleural effusion	Pleural effusion	2004 - 2004
Pleural effusion	Pulmonary effusion	2004 - 2004
Thoracotomy	Thoracotomy	2004 - 2004
Nephrolithiasis	Nephrolithiasis	2008 - 2008
Ureteral stent insertion	Right ureteral stent	Dec 2008 - Dec 2008
Hypertension	Hypertension	2011 - Ongoing
Atrial fibrillation	Atrial fibrillation	27 Sep 2011 (Study Day -3250) - Ongoing
Cardiac ablation	Cardiac ablasion	May 2012 - May 2012
Knee arthroplasty	Left knee replacement	10 Jun 2015 (Study Day -1898) - 10 Jun 2015 (Study Day -1898)
Drug hypersensitivity	Striptomycin allergy	2016 - Ongoing
Cataract	Bilateral cataracts	2017 - May 2017
Rotator cuff syndrome	Left rotator cuff tear	2017 - 02 Aug 2017 (Study Day -1114)
Cataract operation	Bilateral cataracts removal	May 2017 - May 2017
Rotator cuff repair	Left rotator cuff repair	02 Aug 2017 (Study Day -1114) - 02 Aug 2017 (Study Day -1114)
Blood cholesterol increased	High cholesterol	2018 - Ongoing
Cardiac ablation	Cardiac ablation	12 Feb 2019 (Study Day -555) - 12 Feb 2019 (Study Day -555)
Atrial flutter	Atrial flutter	May 2019 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	27 Jun 2019 (Study Day -420) - Ongoing
Knee arthroplasty	Right knee replacement	12 Feb 2020 (Study Day -190) - 12 Feb 2020 (Study Day -190)
Nocturia	Nocturia	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2015 - 18 Feb 2021 (Study Day 183)	Hypertension
Acetylsalicylic acid	2018 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2018 - Ongoing	High Cholsterol
Diclofenac	2018 - Dec 2020	Osteoarthritis Generalized
Celecoxib	20 Aug 2020 (Study Day 1) - Dec 2020	Osteoarthritis Generalized
Influenza vaccine	13 Oct 2020 (Study Day 55) - 13 Oct 2020 (Study Day 55)	Preventative
Amoxicillin; clavulanic acid	15 Dec 2020 (Study Day 118) - 19 Dec 2020 (Study Day 122)	Elevated Psa (Prostate Cancer)
Prostate biopsy*	15 Dec 2020 (Study Day 118) - 15 Dec 2020 (Study Day 118)	Adverse Event
Celecoxib	19 Feb 2021 (Study Day 184) - Ongoing	Osteoarthritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrochlorothiazide; telmisartan	19 Feb 2021 (Study Day 184) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US394-2021 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Road Traffic Accident/Motor Vehicle Accident Trauma	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	06 Sep 2020 (Study Day 10) – 01 Oct 2020 (Study Day 35)	Recovered/ resolved
Substance Abuse/Polysubstance Abuse	AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 2/ moderate	Not related	06 Sep 2020 (Study Day 10) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2021, a 49-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Sep 2020 (Study Day 10), 9 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of road traffic accident. On 24 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of motor vehicle accident trauma lasted for 26 days, after which it was considered to be recovered/resolved on 01 Oct 2020 (Study Day 35). The investigator assessed the event of road traffic accident to be not related to the IP.

On 06 Sep 2020 (Study Day 10), 9 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of substance abuse. On 24 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of polysubstance abuse was considered to be ongoing. The investigator assessed the event of substance abuse to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000409	Road traffic accident

Study Completion/Discontinuation

On 08 Oct 2020 (Study Day 42), the participant discontinued from the study due to the adverse event of substance abuse.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	1981 - Ongoing
Uterine leiomyoma	Uterine fibroids	2012 - 22 Mar 2016 (Study Day -1620)
Hysterectomy	Hysterectomy	22 Mar 2016 (Study Day -1620) - 22 Mar 2016 (Study Day -1620)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amitriptyline	Feb 2020 - Ongoing	Migraine Headaches
Topiramate	Feb 2020 - Ongoing	Migraine Headaches
Phenylephrine	06 Aug 2020 (Study Day -22) - 11 Sep 2020 (Study Day 15)	Motor Vehicle Accident Trauma
Bilateral femur xray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Chest x-ray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Ct abdomen/pelvis with contrast*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Ct angio of neck*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Ct chest with contrast*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Ct chest without contrast*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Ct right knee without contrast*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Electrocardiogram*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glucose	06 Sep 2020 (Study Day 10) - 09 Sep 2020 (Study Day 13)	Supplement/Hydration
Iohexol	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Ct Chest, Ct Angio Neck, Ct Abdomen/Pelvis
Left knee xray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Left wrist xray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Pelvis x-ray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Right ankle xray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Right femur xray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Right knee xray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Right tibula and fibula xray*	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Adverse Event
Sodium chloride	06 Sep 2020 (Study Day 10) - 06 Sep 2020 (Study Day 10)	Motor Vehicle Accident Trauma
Chest xray*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
Spinal cord decompression*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T5-6 posterior arthrodesis*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T6-7 anterior arthrodesis*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T6-7 facetectomy*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T6-7 laminectomy*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T6-7 posterior arthrodesis*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T7-8 anterior arthrodesis*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T7-8 facetectomy*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T7-8 posterior arthrodesis*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
T8-9 posterior arthrodesis*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
Transpedicular screw fixation t6-9*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
Ultrasound of b/l lower extremity*	07 Sep 2020 (Study Day 11) - 07 Sep 2020 (Study Day 11)	Adverse Event
Ct chest with contrast*	08 Sep 2020 (Study Day 12) - 08 Sep 2020 (Study Day 12)	Adverse Event
Iohexol	08 Sep 2020 (Study Day 12) - 08 Sep 2020 (Study Day 12)	Ct Chest

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chest xray*	09 Sep 2020 (Study Day 13) - 09 Sep 2020 (Study Day 13)	Adverse Event
Left thoracostomy tube placement*	09 Sep 2020 (Study Day 13) - 09 Sep 2020 (Study Day 13)	Adverse Event
Open reduction and internal fixation of sternal fracture*	09 Sep 2020 (Study Day 13) - 09 Sep 2020 (Study Day 13)	Adverse Event
Chest xray*	10 Sep 2020 (Study Day 14) - 10 Sep 2020 (Study Day 14)	Adverse Event
Ct angio chest*	10 Sep 2020 (Study Day 14) - 10 Sep 2020 (Study Day 14)	Adverse Event
Iohexol	10 Sep 2020 (Study Day 14) - 10 Sep 2020 (Study Day 14)	Ct Angio Chest
Chest x ray*	11 Sep 2020 (Study Day 15) - 11 Sep 2020 (Study Day 15)	Adverse Event
Electrocardiogram*	11 Sep 2020 (Study Day 15) - 11 Sep 2020 (Study Day 15)	Adverse Event
Ultrasound of b/l lower extremity*	11 Sep 2020 (Study Day 15) - 11 Sep 2020 (Study Day 15)	Adverse Event
Chest xray*	12 Sep 2020 (Study Day 16) - 12 Sep 2020 (Study Day 16)	Adverse Event
Left thoracostomy tube removal*	12 Sep 2020 (Study Day 16) - 12 Sep 2020 (Study Day 16)	Adverse Event
Right knee xray*	14 Sep 2020 (Study Day 18) - 14 Sep 2020 (Study Day 18)	Adverse Event
Right ankle xray*	21 Sep 2020 (Study Day 25) - 21 Sep 2020 (Study Day 25)	Adverse Event
Right knee xray*	21 Sep 2020 (Study Day 25) - 21 Sep 2020 (Study Day 25)	Adverse Event
Alprazolam	22 Sep 2020 (Study Day 26) - 30 Sep 2020 (Study Day 34)	Motor Vehicle Accident Trauma
Amitriptyline hydrochloride	22 Sep 2020 (Study Day 26) - 30 Sep 2020 (Study Day 34)	Motor Vehicle Accident Trauma
Ascorbic acid	22 Sep 2020 (Study Day 26) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Baclofen	22 Sep 2020 (Study Day 26) - 27 Sep 2020 (Study Day 31)	Motor Vehicle Accident Trauma
Chest xray*	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Adverse Event
Docusate	22 Sep 2020 (Study Day 26) - 22 Sep 2020 (Study Day 26)	Motor Vehicle Accident Trauma
Enoxaparin	22 Sep 2020 (Study Day 26) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Famotidine	22 Sep 2020 (Study Day 26) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Hydrocodone; paracetamol	22 Sep 2020 (Study Day 26) - Ongoing	Motor Vehicle Accident Trauma
Ibuprofen	22 Sep 2020 (Study Day 26) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Lidocaine	22 Sep 2020 (Study Day 26) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prazosin	22 Sep 2020 (Study Day 26) - 30 Sep 2020 (Study Day 34)	Motor Vehicle Accident Trauma
Topiramate	22 Sep 2020 (Study Day 26) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Magnesium oxide	23 Sep 2020 (Study Day 27) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Nicotine	23 Sep 2020 (Study Day 27) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Vitamins nos	23 Sep 2020 (Study Day 27) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Melatonin	24 Sep 2020 (Study Day 28) - 30 Sep 2020 (Study Day 34)	Motor Vehicle Accident Trauma
Xray right knee*	29 Sep 2020 (Study Day 33) - 29 Sep 2020 (Study Day 33)	Adverse Event
Pregabalin	30 Sep 2020 (Study Day 34) - 01 Oct 2020 (Study Day 35)	Motor Vehicle Accident Trauma
Xray of right knee*	30 Sep 2020 (Study Day 34) - 30 Sep 2020 (Study Day 34)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pleural Effusion	Grade 2/moderate	Not related	06 Sep 2020 (Study Day 10) - Ongoing
Substance Abuse	Grade 2/moderate	Not related	06 Sep 2020 (Study Day 10) - Ongoing
Respiratory Distress	Grade 1/mild	Not related	09 Sep 2020 (Study Day 13) - 01 Oct 2020 (Study Day 35)
Insomnia	Grade 1/mild	Not related	13 Sep 2020 (Study Day 17) - Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	13 Sep 2020 (Study Day 17) - 08 Oct 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US394-2036 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Sepsis/Sepsis	SAE	Grade 3/ severe	Not related	12 Dec 2020 (Study Day 104) – 24 Dec 2020 (Study Day 116)	Recovered/ resolved
Type 2 Diabetes Mellitus/Worsening Of Diabetes Mellitus Ii	SAE	Grade 3/ severe	Not related	12 Dec 2020 (Study Day 104) – 24 Dec 2020 (Study Day 116)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2036, a 45-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Dec 2020 (Study Day 104), 103 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis lasted for 13 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 116). The investigator assessed the event of sepsis to be not related to the IP.

On 12 Dec 2020 (Study Day 104), 103 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of type 2 diabetes mellitus. Action taken with the IP was not applicable. The event of worsening of diabetes mellitus ii lasted for 13 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 116). The investigator assessed the event of type 2 diabetes mellitus to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001169	Sepsis
MOD-2020-001169	Type 2 diabetes mellitus

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes mellitus ii	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin glargine	2014 - Ongoing	Diabetes Mellitus Ii
Abdomen/pelvis ct*	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Adverse Event
Buttock ultrasound*	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	13 Dec 2020 (Study Day 105) - 20 Dec 2020 (Study Day 112)	Sepsis
Cefepime	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Perineal Abcess
Chest x-ray*	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Adverse Event
Docusate	13 Dec 2020 (Study Day 105) - 24 Dec 2020 (Study Day 116)	Sepsis
Glucose; sodium chloride	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Sepsis
Insulin	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Diabetes Mellitis Ii
Insulin aspart	13 Dec 2020 (Study Day 105) - 24 Dec 2020 (Study Day 116)	Diabetes Mellitus Ii
Magnesium sulfate	13 Dec 2020 (Study Day 105) - 15 Dec 2020 (Study Day 107)	Sepsis
Morphine	13 Dec 2020 (Study Day 105) - 20 Dec 2020 (Study Day 112)	Perineal Abscess

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Sepsis
Oxycodone	13 Dec 2020 (Study Day 105) - 24 Dec 2020 (Study Day 116)	Perineal Abscess
Paracetamol	13 Dec 2020 (Study Day 105) - 24 Dec 2020 (Study Day 116)	Perineal Abscess
Piperacillin; tazobactam	13 Dec 2020 (Study Day 105) - 20 Dec 2020 (Study Day 112)	Sepsis
Potassium chloride	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Sepsis
Potassium phosphate dibasic	13 Dec 2020 (Study Day 105) - 15 Dec 2020 (Study Day 107)	Sepsis
Sodium chloride	13 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 105)	Diabetes Mellitis Ii
Vancomycin	13 Dec 2020 (Study Day 105) - 20 Dec 2020 (Study Day 112)	Perineal Abcess
Insulin glargine	14 Dec 2020 (Study Day 106) - 16 Dec 2020 (Study Day 108)	Worsening Of Diabetes Mellitus Ii
Oxycodone	14 Dec 2020 (Study Day 106) - 24 Dec 2020 (Study Day 116)	Perineal Abscess
Hydrocodone bitartrate; paracetamol	15 Dec 2020 (Study Day 107) - 21 Dec 2020 (Study Day 113)	Perineal Abscess
Hydromorphone	15 Dec 2020 (Study Day 107) - 21 Dec 2020 (Study Day 113)	Sepsis
Naproxen	15 Dec 2020 (Study Day 107) - 18 Dec 2020 (Study Day 110)	Perineal Abscess
Pelvic ultrasound*	15 Dec 2020 (Study Day 107) - 15 Dec 2020 (Study Day 107)	Adverse Event
Right thigh wound debridement*	16 Dec 2020 (Study Day 108) - 16 Dec 2020 (Study Day 108)	Adverse Event
Scrotum ultrasound*	16 Dec 2020 (Study Day 108) - 16 Dec 2020 (Study Day 108)	Adverse Event
Clindamycin	17 Dec 2020 (Study Day 109) - 23 Dec 2020 (Study Day 115)	Perineal Abscess
Insulin glargine	17 Dec 2020 (Study Day 109) - 19 Dec 2020 (Study Day 111)	Worsening Of Diabetes Mellitus Ii
Fentanyl	18 Dec 2020 (Study Day 110) - 18 Dec 2020 (Study Day 110)	Perineal Abscess
Insulin glargine	20 Dec 2020 (Study Day 112) - 20 Dec 2020 (Study Day 112)	Worsening Of Diabetes Mellitus Ii
Macrogol 3350	20 Dec 2020 (Study Day 112) - 24 Dec 2020 (Study Day 116)	Sepsis
Sodium hypochlorite	20 Dec 2020 (Study Day 112) - 31 Dec 2020 (Study Day 123)	Perineal Abcess
Insulin glargine	21 Dec 2020 (Study Day 113) - 21 Dec 2020 (Study Day 113)	Worsening Of Diabetes Mellitus Ii
Glucose	22 Dec 2020 (Study Day 114) - 24 Jan 2021 (Study Day 147)	Worsening Of Diabetes Mellitus Ii
Insulin glargine	22 Dec 2020 (Study Day 114) - 22 Dec 2020 (Study Day 114)	Worsening Of Diabetes Mellitus Ii

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clindamycin	24 Dec 2020 (Study Day 116) - Ongoing	Perineal Abcess
Ibuprofen	24 Dec 2020 (Study Day 116) - Ongoing	Diabetic Sore
Insulin aspart	24 Dec 2020 (Study Day 116) - Ongoing	Diabetes Mellitis Ii
Insulin glargine	24 Dec 2020 (Study Day 116) - Ongoing	Diabetes Mellitis Ii
Oxycodone	24 Dec 2020 (Study Day 116) - Ongoing	Diabetic Sore
Oxycodone	24 Dec 2020 (Study Day 116) - 31 Dec 2020 (Study Day 123)	Perineal Abcess

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Perineal Abscess	Grade 3/severe	Not related	12 Dec 2020 (Study Day 104) - 31 Dec 2020 (Study Day 123)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US394-2151 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	12 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Femur Fracture/Left Femur Fracture	SAE, AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	13 Oct 2020 (Study Day 2) – 22 Nov 2020 (Study Day 42)	Recovered/ resolved
Joint Injury/Right Knee Injury	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	13 Oct 2020 (Study Day 2) – 22 Nov 2020 (Study Day 42)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2151, a 54-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 12 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Oct 2020 (Study Day 2), 1 day after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild serious adverse event of femur fracture. On 08 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of left femur fracture lasted for 41 days, after which it was considered to be recovered/resolved on 22 Nov 2020 (Study Day 42). The investigator assessed the event of femur fracture to be not related to the IP.

On 13 Oct 2020 (Study Day 2), 1 day after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of joint injury. On 08 Nov 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of right knee injury lasted for 41 days, after which it was considered to be recovered/resolved on 22 Nov 2020 (Study Day 42). The investigator assessed the event of joint injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000548	Femur fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1975 - Ongoing
Tonsillar hypertrophy	Tonsil enlargement	1979 - 1979
Tonsillectomy	Tonsilectomy	1979 - 1979
Caesarean section	Cesarean section	24 Sep 1985 (Study Day -12802) - 24 Sep 1985 (Study Day -12802)
Facial bones fracture	Multiple facial fractures	1991 - 1991
Facial operation	Facial repair	1991 - 1991
Hip fracture	Rt hip fracture	1992 - 1992
Hip surgery	Rt hip repair	1992 - 1992
Joint arthroplasty	Rt arm, elbow and wrist repair	1992 - 1992
Limb operation	Right leg repair	1992 - 1992
Lower limb fracture	Rt leg fracture	1992 - 1992
Upper limb fracture	Rt arm fracture	1992 - 1992
Upper limb fracture	Rt elbow fracture	1992 - 1992
Wrist fracture	Rt wrist fracture	1992 - 1992
Cholecystectomy	Cholecystectomy	1993 - 1993
Cholelithiasis	Gall stones	1993 - 1993
Ankle fracture	Left ankle fracture	1996 - 1996
Ankle operation	Lft ankle repair	1996 - 1996
Depression	Depression/anxiety	2000 - Ongoing
Neuropathy peripheral	Neuropathy	2000 - Ongoing
Oedema peripheral	Edema in lower limbs	2000 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus ii	2000 - Ongoing
Pain	Chronic pain	2009 - Ongoing
Drug hypersensitivity	Diflucan allergy	2012 - Ongoing
Bipolar disorder	Bipolar disorder	2013 - Ongoing
Drug hypersensitivity	Januvia allergy	2014 - Ongoing
Gastrooesophageal reflux disease	Gastroesophogeal reflux disease	2014 - Ongoing
Hypokalaemia	Hypokalemia	2014 - Ongoing
Seasonal allergy	Seasonal allergies	2014 - Ongoing
Osteoarthritis	Osteoarthritis of the right knee	2015 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2016 - Ongoing
Osteoarthritis	Degenerative joint disease pelvis	12 Jan 2016 (Study Day -1735) - Ongoing
Rotator cuff syndrome	Impingement syndrome shoulder	12 Jan 2016 (Study Day -1735) - Ongoing
Breast mass	Nodule of breast skin unspecified site	29 Jan 2016 (Study Day -1718) - Ongoing
Breast mass	Breast lump unspecified location	09 Feb 2016 (Study Day -1707) - Ongoing
Bronchitis	Bronchitis	19 Jun 2016 (Study Day -1576) - Not reported
Upper respiratory tract infection	Upper respiratory infection	19 Jun 2016 (Study Day -1576) - Not reported
Diarrhoea	Diarrhea	23 Jun 2016 (Study Day -1572) - Ongoing
Anaemia	Anemia	2017 - Ongoing
Hyperlipidaemia	Hyperlipidimia	2017 - Ongoing
Osteoarthritis	Osteoarthritis of the left knee	2017 - 24 Feb 2020 (Study Day -231)
Diabetic retinopathy	Mild non-proliferative diabetic retinopathy	28 Aug 2017 (Study Day -1141) - Ongoing
Upper respiratory tract infection	Acute upper respiratory infection	20 Sep 2017 (Study Day -1118) - 30 Sep 2017 (Study Day -1108)
Ear pain	Bilateral earache	31 Oct 2017 (Study Day -1077) - Nov 2017
Hypoglycaemia	Hypoglycemia	2018 - Ongoing
Postmenopause	Post menopausal	Oct 2018 - Ongoing
Postmenopause	Post menopausal	Oct 2018 - Ongoing
Nail dystrophy	Dystrophia unguium	13 Dec 2018 (Study Day -669) - Ongoing
Dental caries	Tooth decay	2019 - 25 Aug 2020 (Study Day -48)
Onycholysis	Onycholysis	19 Jun 2019 (Study Day -481) - Jul 2019
Osteopenia	Osteopenia	23 Jun 2019 (Study Day -477) - Ongoing
Knee arthroplasty	Left knee arthroplasty/ total replacement	24 Feb 2020 (Study Day -231) - 24 Feb 2020 (Study Day -231)
Nasal congestion	Nasal congestion	20 Aug 2020 (Study Day -53) - Ongoing
Oral surgery	Oral surgery for implants	25 Aug 2020 (Study Day -48) - 25 Aug 2020 (Study Day -48)
Knee arthroplasty	Rt knee arthroplasty/ total replacement	05 Oct 2020 (Study Day -7) - 05 Oct 2020 (Study Day -7)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion hydrochloride	2000 - Ongoing	Depression
Furosemide	2000 - Ongoing	Edema, Lower Limbs
Gabapentin	2000 - Ongoing	Neuropathy
Glipizide	2000 - Ongoing	Diabetes Mellitus Ii
Metformin	2000 - Ongoing	Diabetes Mellitus Ii
Citalopram hydrobromide	2009 - Ongoing	Depression/Anxiety
Meloxicam	2009 - Ongoing	Chronic Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Topiramate	2013 - Ongoing	Depression/Anxiety
Omeprazole	2014 - 17 Oct 2020 (Study Day 6)	Gastroesophageal Reflux Disease
Potassium	2014 - Ongoing	Hypokalemia
Losartan	2016 - Ongoing	Hypertension
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
Canagliflozin	2017 - Ongoing	Diabetes Mellitus Ii
Iron	2017 - 17 Oct 2020 (Study Day 6)	Anemia
Montelukast sodium	2017 - Ongoing	Seasonal Allergies
Pravastatin	2017 - 17 Oct 2020 (Study Day 6)	Hyperlipidemia
Doxepin	2018 - Ongoing	Depression/Anxiety
Liraglutide	2018 - Ongoing	Diabetes Mellitus Ii
Tramadol	2018 - Ongoing	Chronic Pain
Ibuprofen	05 Oct 2020 (Study Day -7) - Ongoing	Knee Pain, Osteoarthritis
Paracetamol	05 Oct 2020 (Study Day -7) - 17 Oct 2020 (Study Day 6)	Knee Pain, Osteoarthritis
Oxycodone	10 Oct 2020 (Study Day -2) - 01 Nov 2020 (Study Day 21)	Knee Pain, Osteoarthritis; Left Femur Injury
Left femur xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Left hip xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Left knee xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Pelvis xray*	17 Oct 2020 (Study Day 6) - 17 Oct 2020 (Study Day 6)	Adverse Event
Ascorbic acid	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Supplement
Atorvastatin	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Hyperlipidemia
Ct left knee without contrast*	18 Oct 2020 (Study Day 7) - 18 Oct 2020 (Study Day 7)	Adverse Event
Ferrous sulfate	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Supplement
Gabapentin	18 Oct 2020 (Study Day 7) - 19 Oct 2020 (Study Day 8)	Neuropathy
Hydromorphone	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Fracture
Insulin	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Diabetes Mellitus Ii
Loperamide hydrochloride	18 Oct 2020 (Study Day 7) - 18 Oct 2020 (Study Day 7)	Diarrhea
Oxycodone	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Fracture
Pantoprazole	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Gastroesphageal Reflux Disease
Paracetamol	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pramipexole	18 Oct 2020 (Study Day 7) - 22 Oct 2020 (Study Day 11)	Left Femur Injury
Blood transfusion (6 units)*	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Adverse Event
Calcium chloride; potassium chloride; sodium lactate	19 Oct 2020 (Study Day 8) - 20 Oct 2020 (Study Day 9)	Nutritional Supplement
Fentanyl	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Left Femur Fracture
Left distal femur replacement*	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Adverse Event
Left femur xray*	19 Oct 2020 (Study Day 8) - 19 Oct 2020 (Study Day 8)	Adverse Event
Gabapentin	20 Oct 2020 (Study Day 9) - 22 Oct 2020 (Study Day 11)	Neuropathy

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Joint Injury	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 2) - 22 Nov 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US395-2004 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spondylolisthesis/Worsening Of Degenerative Spondylolithesis	SAE	Grade 3/ severe	Not related	22 Nov 2020 (Study Day 80) – 24 Dec 2020 (Study Day 112)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2004, a 69-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Nov 2020 (Study Day 80), 79 days after the first dose and 47 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of spondylolisthesis. Action taken with the IP was not applicable. The event of worsening of degenerative spondylolithesis lasted for 33 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 112). The investigator assessed the event of spondylolisthesis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-012108	Spondylolisthesis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1956 - Ongoing
Menopause	Menopause	1990 - Ongoing
Glaucoma	Glaucoma	2000 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Intervertebral disc protrusion	Herniated lumbar disks	2010 - Ongoing
Osteoarthritis	Osteoarthritis	2010 - Ongoing
Spondylolisthesis	Degenerative spondylolisthesis	2010 - Ongoing
Cataract	Right eye cataract	2015 - 2015
Cataract operation	Right eye cataract surgery	2015 - 2015
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Depression	Depression	2017 - Ongoing
Rosacea	Rosacea	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Betaxolol hydrochloride	2000 - Ongoing	Glaucoma
Montelukast	2010 - Ongoing	Seasonal Allergies
Acetylsalicylic acid	2015 - Ongoing	Cardiac Prophylaxis
Azelastine hydrochloride; fluticasone propionate	2015 - Ongoing	Seasonal Allergies
Famotidine	2015 - Ongoing	Gerd
Rosuvastatin	2015 - Ongoing	Hyperlipidemia
Escitalopram oxalate	2017 - Ongoing	Depression
Amlodipine	Sep 2019 - 19 Oct 2020 (Study Day 46)	Hypertension
Gabapentin	22 Feb 2020 (Study Day -195) - 24 Dec 2020 (Study Day 112)	Post-Op Pain
Diclofenac	May 2020 - 16 Oct 2020 (Study Day 43)	Herniated Lumbar Disks
Steroids	12 Jun 2020 (Study Day -84) - Ongoing	Herniated Lumbar Disks
Doxycycline	04 Sep 2020 (Study Day 1) - 22 Sep 2020 (Study Day 19)	Rosacea
Metronidazole	04 Sep 2020 (Study Day 1) - Ongoing	Rosacea
Pimecrolimus	04 Sep 2020 (Study Day 1) - Ongoing	Rosacea
Sulfacetamide	04 Sep 2020 (Study Day 1) - Ongoing	Rosacea
Amlodipine	19 Oct 2020 (Study Day 46) - Ongoing	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	26 Oct 2020 (Study Day 53) - 26 Oct 2020 (Study Day 53)	Influenza Prevention
Betaxolol	22 Dec 2020 (Study Day 110) - 24 Dec 2020 (Study Day 112)	Glaucoma
Calcium chloride; potassium chloride; sodium lactate	22 Dec 2020 (Study Day 110) - 23 Dec 2020 (Study Day 111)	Post-Op Fluids
Cefazolin sodium	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Prophylaxis
Dexamethasone	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Pain
Gabapentin	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post Op Pain
Gentamicin	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Prophylaxis
Hydromorphone hydrochloride	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Pain
Lumbar fusion; lumbar laminectomy*	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Adverse Event
Magnesium sulfate	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Pain
Oxycodone	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Pain
Paracetamol	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Pain
Sennoside a+b	22 Dec 2020 (Study Day 110) - 23 Dec 2020 (Study Day 111)	Constipation
Tranexamic acid	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Post-Op Bleeding
Xr l spine 1 vw*	22 Dec 2020 (Study Day 110) - 22 Dec 2020 (Study Day 110)	Other, Intraoperative Imaging
Dexamethasone	23 Dec 2020 (Study Day 111) - 23 Dec 2020 (Study Day 111)	Post-Op Pain
Ondansetron	23 Dec 2020 (Study Day 111) - 23 Dec 2020 (Study Day 111)	Post-Op Nausea
Paracetamol	23 Dec 2020 (Study Day 111) - 24 Dec 2020 (Study Day 112)	Post-Op Pain
Hydrocodone	27 Dec 2020 (Study Day 115) - 02 Jan 2021 (Study Day 121)	Post-Op Pain
Paracetamol	27 Dec 2020 (Study Day 115) - 02 Jan 2021 (Study Day 121)	Post-Op Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US395-2052 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	13 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Giardiasis/Diarrhea From Giardia	SAE	Grade 3/severe	Not related	09 Feb 2021 (Study Day 155) – 12 Mar 2021 (Study Day 186)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2052, a 74-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Feb 2021 (Study Day 155), 154 days after the first dose and 119 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of giardiasis. Action taken with the IP was not applicable. The event of diarrhea from giardia lasted for 32 days, after which it was considered to be recovered/resolved on 12 Mar 2021 (Study Day 186). The investigator assessed the event of giardiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-040015	Giardiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsillectomy	1947 - 1947
Wisdom teeth removal	Wisdom teeth removal	1963 - 1963
Basal cell carcinoma	Basal cell skin cancer	1975 - 2015
Keratotomy	Radial keratotomy	1982 - 1982
Keratotomy	Radial keratotomy	1984 - 1984
Obesity	Obesity	1994 - Ongoing
Hysterectomy	Complete hysterectomy	1998 - 1998
Hyperlipidaemia	Hyperlipidemia	2012 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2012 - Ongoing
Cataract operation	Bilateral cataract surgery	2015 - 2015
Rotator cuff repair	Bilateral rotator cuff repair	2017 - 2017
Retinal tear	Right torn retina	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2005 - Ongoing	Cardiac Prophylaxis
Exenatide	2012 - Ongoing	Type Ii Diabetes
Metformin	2012 - 19 Jan 2021 (Study Day 134)	Type Ii Diabetes
Glipizide	2018 - 15 Oct 2020 (Study Day 38)	Type Ii Diabetes
Pneumococcal vaccine polysacch 23v	03 Feb 2020 (Study Day -218) - 03 Feb 2020 (Study Day -218)	Pneumonia Vaccine
Influenza vaccine	24 Aug 2020 (Study Day -15) - 24 Aug 2020 (Study Day -15)	Influenza Vaccine
Fenofibrate	Dec 2020 - Ongoing	Hyperlipidemia
Metformin	20 Jan 2021 (Study Day 135) - 09 Feb 2021 (Study Day 155)	Type Ii Diabetes
Metformin	09 Feb 2021 (Study Day 155) - Ongoing	Type Ii Diabetes
Azithromycin	24 Feb 2021 (Study Day 170) - 26 Feb 2021 (Study Day 172)	Traveler's Diarrhea
Glipizide	24 Feb 2021 (Study Day 170) - Ongoing	Type Ii Diabetes
Enoxaparin sodium	06 Mar 2021 (Study Day 180) - 13 Mar 2021 (Study Day 187)	Right Pulmonary Embolism
Metronidazole	08 Mar 2021 (Study Day 182) - 12 Mar 2021 (Study Day 186)	Diarrhea From Giardia
Dabigatran etexilate mesilate	14 Mar 2021 (Study Day 188) - Ongoing	Right Pulmonary Embolism

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US395-2104 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hip Fracture/Hip Fracture	SAE, AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	05 Oct 2020 (Study Day 19) – 08 Oct 2020 (Study Day 22)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2104, a 67-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Oct 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of hip fracture. On 14 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of hip fracture lasted for 4 days, after which it was considered to be recovered/resolved on 08 Oct 2020 (Study Day 22). The investigator assessed the event of hip fracture to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000494	Hip fracture

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1957 - Ongoing
Lower limb fracture	Broken leg	07 Dec 2002 (Study Day -6494) - 07 Dec 2002 (Study Day -6494)
Prostatomegaly	Enlarged prostate	2014 - Ongoing
Oedema peripheral	Bilateral lower extremity edema	2019 - Ongoing
Seasonal allergy	Seasonal allergies	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Boron; chromium; copper; germanium; iodine; manganese; molybdenum; selenium; silicon; sitosterol; vanadium; vitamin d nos; zinc	2014 - Ongoing	Enlarged Prostate
Diphenhydramine hydrochloride	2020 - Ongoing	Seasonal Allergies
Pneumococcal vaccine polysacch 23v	Apr 2020 - Apr 2020	Pneumonia Vaccine
Calcium chloride; potassium chloride; sodium lactate	07 Oct 2020 (Study Day 21) - 08 Oct 2020 (Study Day 22)	Hip Fracture
Enoxaparin sodium	07 Oct 2020 (Study Day 21) - 12 Oct 2020 (Study Day 26)	Hip Fracture
Sennoside a+b	07 Oct 2020 (Study Day 21) - 11 Oct 2020 (Study Day 25)	Constipation Prevention
Sodium chloride	07 Oct 2020 (Study Day 21) - 07 Oct 2020 (Study Day 21)	Hip Fracture
Cefazolin	08 Oct 2020 (Study Day 22) - 08 Oct 2020 (Study Day 22)	Hip Fracture
Left trochanteric nailing*	08 Oct 2020 (Study Day 22) - 08 Oct 2020 (Study Day 22)	Adverse Event
Morphine	08 Oct 2020 (Study Day 22) - 08 Oct 2020 (Study Day 22)	Hip Fracture
Ondansetron	08 Oct 2020 (Study Day 22) - 08 Oct 2020 (Study Day 22)	Nausea Prevention
Paracetamol	08 Oct 2020 (Study Day 22) - 08 Oct 2020 (Study Day 22)	Hip Fracture
Calcium citrate	09 Oct 2020 (Study Day 23) - 12 Oct 2020 (Study Day 26)	Hip Fracture
Colecalciferol	09 Oct 2020 (Study Day 23) - 12 Oct 2020 (Study Day 26)	Hip Fracture
Paracetamol	09 Oct 2020 (Study Day 23) - 11 Oct 2020 (Study Day 25)	Hip Fracture

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	10 Oct 2020 (Study Day 24) - Ongoing	Deep Vein Thrombosis Prophylaxis
Macrogol 3350	11 Oct 2020 (Study Day 25) - 12 Oct 2020 (Study Day 26)	Constipation Prevention
Continued physical therapy for fractured left hip*	12 Oct 2020 (Study Day 26) - 12 Oct 2020 (Study Day 26)	Adverse Event
Calcium citrate	01 Nov 2020 (Study Day 46) - Ongoing	Prophylaxis/Bone Health [secondary To Hip Fracture]
Colecalciferol	01 Nov 2020 (Study Day 46) - 21 Nov 2020 (Study Day 66)	Prophylaxis/Bone Health [secondary To Hip Fracture]

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US395-2116 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	18 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Blood Pressure Increased/Worsening Of Baseline Elevated Grade 3 Blood Pressure	AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	23 Oct 2020 (Study Day 36) – 23 Oct 2020 (Study Day 36)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2116, a 75-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 18 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Oct 2020 (Study Day 36), 35 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of blood pressure increased. On 15 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of worsening of baseline elevated grade 3 blood pressure lasted for 1 day, after which it was considered to be recovered/resolved on 23 Oct 2020 (Study Day 36). The investigator assessed the event of blood pressure increased to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	1959 - Ongoing
Gout	Gout [bilateral feet]	1995 - Ongoing
Diabetes mellitus	Diabetes	2007 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2007 - Ongoing
Hypertension	Hypertension	2012 - Ongoing
Erectile dysfunction	Erectile dysfunction	2013 - Ongoing
Musculoskeletal pain	Shoulder pain	2013 - Ongoing
Neck pain	Neck pain	2013 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2015 - Ongoing
Osteoarthritis	Osteoarthritis of hip	2020 - Ongoing
Spinal osteoarthritis	Osteoarthritis of back	2020 - Ongoing
Tooth infection	Dental infection	06 Aug 2020 (Study Day -43) - 07 Sep 2020 (Study Day -11)
Cardiac murmur	Cardiac murmur	18 Sep 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Allopurinol	1997 - Ongoing	Gout [bilateral Feet]
Colchicine	1997 - Ongoing	Gout [bilateral Feet]
Metformin	2007 - Ongoing	Diabetes
Lisinopril	2015 - 22 Oct 2020 (Study Day 35)	Hypertension
Sildenafil	2017 - Ongoing	Erectile Dysfunction
Tramadol	Mar 2020 - Ongoing	Osteoarthritis
Pantoprazole	Aug 2020 - Ongoing	Acid Reflux
Amoxicillin	06 Aug 2020 (Study Day -43) - 07 Sep 2020 (Study Day -11)	Dental Infection
Ibuprofen	23 Sep 2020 (Study Day 6) - 22 Oct 2020 (Study Day 35)	Osteoarthritis
Atorvastatin calcium	06 Oct 2020 (Study Day 19) - Ongoing	Hyperlipidemia
Sodium chloride	22 Oct 2020 (Study Day 35) - 23 Oct 2020 (Study Day 36)	Dehydration
Tramadol	14 Jan 2021 (Study Day 119) - Ongoing	Neck/Shoulder Pain
Diphenhydramine hydrochloride	18 Feb 2021 (Study Day 154) - Ongoing	Allergic Rhinitis
Fluocinonide	18 Feb 2021 (Study Day 154) - Ongoing	Xerosis
Loratadine	18 Feb 2021 (Study Day 154) - Ongoing	Allergic Rhinitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dehydration	Grade 2/moderate	Not related	22 Oct 2020 (Study Day 35) - 23 Oct 2020 (Study Day 36)
Blood Pressure Increased	Grade 3/severe	Not related	23 Oct 2020 (Study Day 36) - 23 Oct 2020 (Study Day 36)
Xerosis	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 152) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US395-2141 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Spinal Osteoarthritis/ Worsening Of Lumbar Spondylosis	SAE	Grade 3/severe	Not related	04 Feb 2021 (Study Day 135) – 10 Mar 2021 (Study Day 169)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2141, a 63-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 23 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 28 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Feb 2021 (Study Day 135), 134 days after the first dose and 99 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of spinal osteoarthritis. Action taken with the IP was not applicable. The event of worsening of lumbar spondylosis lasted for 35 days, after which it was considered to be recovered/resolved on 10 Mar 2021 (Study Day 169). The investigator assessed the event of spinal osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-059047	Spinal osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Sulfa allergy	1975 - Ongoing
Rubber sensitivity	Latex allergy	1975 - Ongoing
Headache	Headaches	1978 - Ongoing
Postmenopause	Postmenopausal	2009 - Ongoing
Sinus headache	Sinus headaches	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Spinal osteoarthritis	Lumbar spondylosis	Jun 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	Feb 2019 - Ongoing	Seasonal Allergies
Influenza vaccine	Sep 2019 - Sep 2019	Influenza Prevention
Naproxen sodium	Aug 2020 - Ongoing	Headaches
Vitamin d nos	23 Jan 2021 (Study Day 123) - Ongoing	Vitamin D Deficiency
Gabapentin	04 Feb 2021 (Study Day 135) - Ongoing	Worsening Lumbar Spondylosis
Cefazolin sodium	10 Mar 2021 (Study Day 169) - 15 Mar 2021 (Study Day 174)	Preventative Antibiotic
Cyclobenzaprine	10 Mar 2021 (Study Day 169) - 11 Mar 2021 (Study Day 170)	Worsening Lubar Spondylosis
Docusate	10 Mar 2021 (Study Day 169) - Ongoing	Constipation
Hydromorphone hydrochloride	10 Mar 2021 (Study Day 169) - 10 Mar 2021 (Study Day 169)	Post Op Pain
Lumbar 4-5 spinal fusion [lumbar spondylolisthesis, l5-s1 stenosis, radiculopathy, and back pain]*	10 Mar 2021 (Study Day 169) - 10 Mar 2021 (Study Day 169)	Adverse Event
Ondansetron	10 Mar 2021 (Study Day 169) - 10 Mar 2021 (Study Day 169)	Nausea
Oxycodone	10 Mar 2021 (Study Day 169) - Ongoing	Worsening Lubar Spondylosis
Benzocaine; menthol	11 Mar 2021 (Study Day 170) - 11 Mar 2021 (Study Day 170)	Topical Anesthesia
Lidocaine	11 Mar 2021 (Study Day 170) - 16 Mar 2021 (Study Day 175)	Worsening Lubar Spondylosis
Lumbar spine ct w/o contrast for lumbar spondylosis*	11 Mar 2021 (Study Day 170) - 11 Mar 2021 (Study Day 170)	Adverse Event
Methocarbamol	11 Mar 2021 (Study Day 170) - Ongoing	Worsening Lubar Spondylosis
Oxycodone	11 Mar 2021 (Study Day 170) - Ongoing	Worsening Lubar Spondylosis
Paracetamol	11 Mar 2021 (Study Day 170) - Ongoing	Worsening Lubar Spondylosis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lactulose	12 Mar 2021 (Study Day 171) - 12 Mar 2021 (Study Day 171)	Constipation
Magnesium citrate	12 Mar 2021 (Study Day 171) - 12 Mar 2021 (Study Day 171)	Constipation
Oxycodone	12 Mar 2021 (Study Day 171) - 16 Mar 2021 (Study Day 175)	Worsening Lubar Spondylosis
Lumbar spine ct w/o contrast for lumbar spondylosis*	13 Mar 2021 (Study Day 172) - 13 Mar 2021 (Study Day 172)	Adverse Event
Sodium phosphate dibasic; sodium phosphate monobasic	13 Mar 2021 (Study Day 172) - 13 Mar 2021 (Study Day 172)	Constipation
Diphenhydramine	15 Mar 2021 (Study Day 174) - 15 Mar 2021 (Study Day 174)	Seasonal Allergies
Insulin aspart	15 Mar 2021 (Study Day 174) - 15 Mar 2021 (Study Day 174)	Post Op Bg Control
Lactulose	15 Mar 2021 (Study Day 174) - 15 Mar 2021 (Study Day 174)	Constipation
Mri spine w/o contrast for lumbar spondylosis*	15 Mar 2021 (Study Day 174) - 15 Mar 2021 (Study Day 174)	Adverse Event
Salbutamol	16 Mar 2021 (Study Day 175) - Ongoing	Seasonal Allergies

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious event is presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vitamin D Deficiency	Grade 2/moderate	Not related	15 Jan 2021 (Study Day 115) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US395-2158 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Blood Pressure Diastolic Increased/Elevated Diastolic Blood Pressure	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	26 Oct 2020 (Study Day 29) – 23 Nov 2020 (Study Day 57)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2158, a 41-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 28 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Oct 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of blood pressure diastolic increased. On 25 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of elevated diastolic blood pressure lasted for 29 days, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 57). The investigator assessed the event of blood pressure diastolic increased to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2011 - 2011

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	14 Dec 2020 (Study Day 78) - Ongoing	Tooth Ache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Blood Pressure Diastolic Increased	Grade 3/severe	Not related	26 Oct 2020 (Study Day 29) - 23 Nov 2020 (Study Day 57)
Toothache	Grade 1/mild	Not related	14 Dec 2020 (Study Day 78) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US395-2216 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Hypertension	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	06 Nov 2020 (Study Day 29) – 02 Dec 2020 (Study Day 55)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US395-2216, a 31-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 09 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Nov 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of hypertension. On 05 Nov 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of hypertension lasted for 27 days, after which it was considered to be recovered/resolved on 02 Dec 2020 (Study Day 55). The investigator assessed the event of hypertension to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	1995 - Ongoing
Obesity	Obesity	2014 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicitis	Appendicitis	30 Sep 2019 (Study Day -375) - 03 Oct 2019 (Study Day -372)
Appendicectomy	Appendectomy	03 Oct 2019 (Study Day -372) - 03 Oct 2019 (Study Day -372)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	1996 - Ongoing	Attention Deficit Hyperactivity Disorder
Etonogestrel	2015 - Ongoing	Contraception
Lisinopril	17 Oct 2020 (Study Day 9) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	16 Oct 2020 (Study Day 8) – 06 Nov 2020 (Study Day 29)
Hypertension	Grade 3/severe	Not related	06 Nov 2020 (Study Day 29) - 02 Dec 2020 (Study Day 55)
Cough	Grade 2/moderate	Not related	06 Feb 2021 (Study Day 121) - 25 Feb 2021 (Study Day 140)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US396-2042 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cellulitis/Cellulitis - Right Upper Arm	SAE	Grade 3/ severe	Not related	18 Feb 2021 (Study Day 172) – 08 Mar 2021 (Study Day 190)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US396-2042, a 57-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Feb 2021 (Study Day 172), 171 days after the first dose and 143 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cellulitis. Action taken with the IP was not applicable. The event of cellulitis - right upper arm lasted for 19 days, after which it was considered to be recovered/resolved on 08 Mar 2021 (Study Day 190). The investigator assessed the event of cellulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-022085	Cellulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2000 - Ongoing
Migraine	Migraine headaches	2005 - Ongoing
Anxiety	Anxiety	2010 - Ongoing
Back pain	Chronic pain back	2010 - Ongoing
Depression	Depression	2010 - Ongoing
Joint range of motion decreased	Decreased range of motion neck	2010 - Ongoing
Neck pain	Chronic pain neck	2010 - Ongoing
Pain in extremity	Chronic pain left arm	2010 - Ongoing
Postmenopause	Post-menopausal	2015 - Ongoing
Intervertebral disc protrusion	Herniated disc back	Feb 2018 - Feb 2018
Shoulder operation	Right shoulder surgery	Feb 2020 - Feb 2020
Upper limb fracture	Fractured right shoulder	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - Ongoing	Cardiac Prophylaxis
Fluoxetine	2010 - Ongoing	Depression
Gabapentin	2010 - Ongoing	Chronic Pain Of Neck, Back And Left Arm
Iron	2010 - Ongoing	Dietary Supplement
Mirtazapine	2010 - Ongoing	Depression And Anxiety
Vitamins nos	2010 - Ongoing	Dietary Supplement
Metoprolol succinate	2015 - Ongoing	Hypertension
Oxycodone hydrochloride; paracetamol	2015 - Ongoing	Chronic Pain Of Neck, Back And Left Arm
Lamotrigine	2019 - Ongoing	Depression
Erenumab	2020 - Ongoing	Migraine Headaches
Hydroxyzine hydrochloride	2020 - Ongoing	Anxiety
Cefalexin	18 Feb 2021 (Study Day 172) - 19 Feb 2021 (Study Day 173)	Cellulitis Right Upper Arm
Sulfamethoxazole; trimethoprim	18 Feb 2021 (Study Day 172) - 19 Feb 2021 (Study Day 173)	Cellulitis Right Upper Arm
Cefadroxil	23 Feb 2021 (Study Day 177) - 05 Mar 2021 (Study Day 187)	Cellulitis Right Upper Arm

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US397-2049 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/Acute Renal Failure	SAE	Grade 2/ moderate	Not related	15 Nov 2020 (Study Day 81) – 17 Nov 2020 (Study Day 83)	Recovered/ resolved
Septic Shock/Septic Shock	SAE	Grade 3/ severe	Not related	15 Nov 2020 (Study Day 81) – 04 Dec 2020 (Study Day 100)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2049, a 57-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 29 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Nov 2020 (Study Day 81), 80 days after the first dose and 47 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute renal failure lasted for 3 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 83). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 15 Nov 2020 (Study Day 81), 80 days after the first dose and 47 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of septic shock. Action taken with the IP was not applicable. The event of septic shock lasted for 20 days, after which it was considered to be recovered/resolved on 04 Dec 2020 (Study Day 100). The investigator assessed the event of septic shock to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000856	Acute kidney injury
MOD-2020-000856	Septic shock

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1983 - Ongoing
Urinary tract infection	Urinary tract infection (recurring)	1983 - Ongoing
Autonomic dysreflexia	Dysreflexia	May 1983 - Ongoing
Bladder catheterisation	Suprapubic catheterization	May 1983 - Ongoing
Neurogenic bladder	Neurogenic bladder	May 1983 - Ongoing
Spinal cord injury cervical	Spinal cord injury (c5,c6) quadriplegic	May 1983 - Ongoing
Deep vein thrombosis	Deep vein thrombosis	1993 - 1993
Pneumonia	Pneumonia	Jan 2019 - Jan 2019
Cardiac arrest	Cardiac arrest	07 Feb 2019 (Study Day -567) - 07 Feb 2019 (Study Day -567)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	May 1983 - Ongoing	Neurogenic Bladder
Diazepam	May 1983 - Ongoing	Neurogenic Bladder
Oxybutynin	May 1983 - 14 Nov 2020 (Study Day 80)	Neurogenic Bladder
Ascorbic acid	Jun 2010 - Ongoing	General Health Supplement
Vitamin d nos	Jun 2010 - Ongoing	General Health Supplement
Zinc	Aug 2017 - Ongoing	General Health Supplement
D-mannose	Sep 2017 - Ongoing	General Health Supplement
Cefepime	15 Nov 2020 (Study Day 81) - 20 Nov 2020 (Study Day 86)	Septic Shock
Norepinephrine	15 Nov 2020 (Study Day 81) - 17 Nov 2020 (Study Day 83)	Septic Shock
Oxybutynin	15 Nov 2020 (Study Day 81) - Ongoing	Neurogenic Bladder
Salbutamol	15 Nov 2020 (Study Day 81) - Ongoing	Wheezing
Vancomycin	15 Nov 2020 (Study Day 81) - 15 Nov 2020 (Study Day 81)	Septic Shock
Piperacillin sodium; tazobactam sodium	16 Nov 2020 (Study Day 82) - 19 Nov 2020 (Study Day 85)	Septic Shock
Replacement of suprapubic catheter*	16 Nov 2020 (Study Day 82) - 16 Nov 2020 (Study Day 82)	Medical History
Paracetamol	17 Nov 2020 (Study Day 83) - Ongoing	Fever, Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	17 Nov 2020 (Study Day 83) - 24 Feb 2021 (Study Day 182)	Sepsis/Prophylaxis
Amikacin	19 Nov 2020 (Study Day 85) - 19 Nov 2020 (Study Day 85)	Septic Shock
Amoxicillin	20 Nov 2020 (Study Day 86) - 04 Dec 2020 (Study Day 100)	Septic Shock
Heparin	15 Jan 2021 (Study Day 142) - 22 Feb 2021 (Study Day 180)	Vte Prophylaxis
Docusate sodium	08 Feb 2021 (Study Day 166) - Ongoing	Constipation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US397-2064 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure Congestive/ Congestive Heart Failure Exacerbation	SAE	Grade 2/ moderate	Not related	02 Sep 2020 (Study Day 3) – 05 Sep 2020 (Study Day 6)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2064, a 69-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 30 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Sep 2020 (Study Day 3), 2 days after the first dose and 28 days before the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of cardiac failure congestive. The IP dose was not changed due to the congestive heart failure exacerbation. The event of congestive heart failure exacerbation lasted for 4 days, after which it was considered to be recovered/resolved on 05 Sep 2020 (Study Day 6). The investigator assessed the event of cardiac failure congestive to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000260	Congestive heart failure aggravated

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acute myocardial infarction	Nstemi type ii	Not reported
Aortic valve incompetence	Severe aortic insufficiency	Not reported - Ongoing
Systemic lupus erythematosus	Systemic lupus erythematosus	Not reported - Ongoing
Drug hypersensitivity	Allergy to penicillin	2000 - Ongoing
Transient ischaemic attack	Transient ischemic attack	2000 - 2000
Peripheral arterial occlusive disease	Peripheral arterial disease l leg	2010 - 2011
Postmenopause	Post menopausal	2010 - Ongoing
Cardiac failure	Heart failure with preserved ejection fraction	2014 - Ongoing
Fibromyalgia	Fibromylagia	2014 - Ongoing
Blood cholesterol increased	High cholesterol	2017 - Ongoing
Drug hypersensitivity	Allergy to sulfa drug	2017 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Seasonal allergy	Seasonal allergy	2018 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2018 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease (copd)	2019 - Ongoing
Coronary artery disease	Non obstructive cad	Oct 2019 - Ongoing
Constipation	Constipation	08 Oct 2019 (Study Day -328) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2012 - Ongoing	Prevention Of Heart Failure
Carvedilol	2014 - Ongoing	Heart Failure With Preserved Ejection Fraction
Tramadol	2014 - Ongoing	Fibromyalgia
Rosuvastatin	2017 - Ongoing	Hypercholesterolemia
Ergocalciferol	2018 - Ongoing	Vitamin D Deficiency
Fluticasone propionate	2018 - Ongoing	Seasonal Allergies
Salbutamol	2019 - Ongoing	Copd
Tiotropium bromide	2019 - Ongoing	Copd
Losartan	Oct 2019 - 17 Sep 2020 (Study Day 18)	Hypertension
Macrogol 3350	08 Oct 2019 (Study Day -328) - Ongoing	Constipation
Bumetanide	Jan 2020 - Ongoing	Heart Failure With Preserved Ejection Fraction

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bumetanide	02 Sep 2020 (Study Day 3) - 02 Sep 2020 (Study Day 3)	Congestive Heart Failure
Losartan	18 Sep 2020 (Study Day 19) - 19 Nov 2020 (Study Day 81)	Hypertension
Benign polypectomy*	06 Oct 2020 (Study Day 37) - 06 Oct 2020 (Study Day 37)	Diagnostic
Routine colonoscopy*	06 Oct 2020 (Study Day 37) - 06 Oct 2020 (Study Day 37)	Diagnostic
Amlodipine	19 Nov 2020 (Study Day 81) - Ongoing	Hypertension
Influenza vaccine	19 Nov 2020 (Study Day 81) - 19 Nov 2020 (Study Day 81)	Flu Prevention
Pneumococcal vaccine	19 Nov 2020 (Study Day 81) - 19 Nov 2020 (Study Day 81)	Pneumonia Prevention
Computed tomography (ct scan) of chest*	30 Nov 2020 (Study Day 92) - 30 Nov 2020 (Study Day 92)	Medical History
Clindamycin	31 Dec 2020 (Study Day 123) - 07 Jan 2021 (Study Day 130)	Tooth Infection (Third Top Molar Abscess)
Diphenhydramine hydrochloride	31 Dec 2020 (Study Day 123) - 07 Jan 2021 (Study Day 130)	Suspected Allergic Reaction To Clindamycin. Per M.D At V4 - Not Determined To Be An Allergic Reaction
Annual mammograms*	13 Jan 2021 (Study Day 136) - 13 Jan 2021 (Study Day 136)	Other, Routine

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Large Intestine Polyp	Grade 1/mild	Not related	06 Oct 2020 (Study Day 37) - 07 Oct 2020 (Study Day 38)
Tooth Abscess	Grade 2/moderate	Not related	29 Dec 2020 (Study Day 121) - Ongoing
Dermatitis	Grade 1/mild	Not related	31 Dec 2020 (Study Day 123) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US397-2097 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertensive Urgency/ Hypertensive Urgency	SAE	Grade 3/ severe	Not related	08 Jan 2021 (Study Day 128) – 10 Jan 2021 (Study Day 130)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2097, a 67-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Jan 2021 (Study Day 128), 127 days after the first dose and 99 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypertensive urgency. Action taken with the IP was not applicable. The event of hypertensive urgency lasted for 3 days, after which it was considered to be recovered/resolved on 10 Jan 2021 (Study Day 130). The investigator assessed the event of hypertensive urgency to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003115	Hypertensive urgency

Study Completion/Discontinuation

On 29 Jan 2021 (Study Day 149), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Lactose intolerance	Lactose intolerance	(b) (6) 1952 (Study Day(b) (6)) - Ongoing
Hypertension	Hypertension	1971 - Ongoing
Cataract	Cataracts bilateral	1980 - Sep 2019
Hypercholesterolaemia	Hypercholesterolemia	1980 - Ongoing
Transient ischaemic attack	History of t.i.a (transient ischemic attack)	2000 - 2008
Myocardial infarction	History of heart attack	2002 - 2013
Cerebrovascular accident	History of strokes	2004 - 2010
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Asthma	Mild asthma	2015 - Ongoing
Sleep apnoea syndrome	Sleep apnea	Sep 2019 - Ongoing
Prostatomegaly	Enlarged prostate	Jun 2020 - Ongoing
Hemiparesis	Hemiparesis, secondary to cva	03 Sep 2020 (Study Day 1) - Ongoing
Oedema peripheral	Bilateral edema of ankles	03 Sep 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	1971 - Ongoing	Hypertension
Acetylsalicylic acid	1980 - Ongoing	Blood Clot Prophylaxis
Atorvastatin	1980 - 05 Jan 2021 (Study Day 125)	Hyperlipidemia
Carvedilol	1980 - Ongoing	Hypertension
Clopidogrel	2013 - Ongoing	Prophylaxis For Heart Attacks
Nifedipine	2013 - 05 Jan 2021 (Study Day 125)	Heart Stent
Sildenafil	2015 - Ongoing	Erectile Dysfunction
Eplerenone	2019 - Ongoing	Hypertension
Ascorbic acid; betacarotene; cupric oxide; tocopheryl acetate; zinc oxide	Sep 2019 - Ongoing	Post Op Eye Recover
Fluticasone propionate	Sep 2019 - Ongoing	Asthma
Ascorbic acid; betacarotene; biotin; calcium carbonate; calcium pantothenate; chromic chloride; colecalciferol; cupric oxide; cyanocobalamin; dl-alpha tocopheryl acetate; folic acid; lycopene; magnesi	01 Jan 2020 (Study Day -246) - Ongoing	General Health
Vitamin b12 nos	Mar 2020 - Ongoing	General Health
Tamsulosin	Jun 2020 - Ongoing	Enlarged Prostate
Ipratropium; salbutamol	05 Aug 2020 (Study Day -29) - Ongoing	Asthma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin calcium	05 Jan 2021 (Study Day 125) - Ongoing	Hypercholesterolemia
Nifedipine	05 Jan 2021 (Study Day 125) - Ongoing	Hypertension
Other viral vaccines	27 Jan 2021 (Study Day 147) - 27 Jan 2021 (Study Day 147)	COVID-19 Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US397-2104 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Vomiting/Intractable Vomiting	SAE	Grade 3/ severe	Not related	28 Mar 2021 (Study Day 207) – 29 Mar 2021 (Study Day 208)	Recovered/ resolved
Depression/Depession	SAE	Grade 3/ severe	Not related	08 Apr 2021 (Study Day 218) – 13 Apr 2021 (Study Day 223)	Recovered/ resolved
Substance-Induced Mood Disorder/Substance Induced Mood Disorder, Alcohol Use Disorder Severe-Withdrawal,hyperglycemia Sleeplessnes	SAE	Grade 3/ severe	Not related	08 Apr 2021 (Study Day 218) – 13 Apr 2021 (Study Day 223)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2104, a 55-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Mar 2021 (Study Day 207), 206 days after the first dose and 178 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of vomiting. Action taken with the IP was not applicable. The event of intractable vomiting lasted for 2 days, after which it was considered to be recovered/resolved on 29 Mar 2021 (Study Day 208). The investigator assessed the event of vomiting to be not related to the IP.

On 08 Apr 2021 (Study Day 218), 217 days after the first dose and 189 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of depression. The IP dose was not changed due to the depression. The event of depression lasted for 6 days, after which it was considered to be recovered/resolved on 13 Apr 2021 (Study Day 223). The investigator assessed the event of depression to be not related to the IP.

On 08 Apr 2021 (Study Day 218), 217 days after the first dose and 189 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of substance-induced mood disorder. Action taken with the IP was not applicable. The event of substance induced mood disorder, alcohol use disorder severe-withdrawal, hyperglycemia sleeplessness lasted for 6 days, after which it was considered to be recovered/resolved on 13 Apr 2021 The investigator assessed the event of substance-induced mood disorder to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-061289	Vomiting
MOD-2021-080860	Substance-induced mood disorder
MOD-2021-080860	Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Neuropathy peripheral	Neuropathy on both feet	08 Feb 2019 (Study Day -573) - Ongoing
Hypertension	Hypertension	Mar 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	08 Feb 2019 (Study Day -573) - Ongoing	Neuropathy Both Feet
Lisinopril	Mar 2019 - Ongoing	Hypertension
Vitamin b nos	Mar 2019 - Ongoing	General Health
Paracetamol	01 Oct 2020 (Study Day 29) - 03 Oct 2020 (Study Day 31)	Mild Pain In Injection Site

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Decreased Appetite	Grade 1/mild	Not related	15 Feb 2021 (Study Day 166) - Ongoing
Dyspnoea	Grade 1/mild	Not related	15 Feb 2021 (Study Day 166) - Ongoing
Fatigue	Grade 1/mild	Not related	15 Feb 2021 (Study Day 166) - Ongoing
Nausea	Grade 1/mild	Not related	15 Feb 2021 (Study Day 166) - Ongoing
Vomiting	Grade 1/mild	Not related	15 Feb 2021 (Study Day 166) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US397-2116 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dyspnoea/Shortness Of Breath Possible Fluid In The Lungs	SAE	Grade 3/ severe	Not related	28 Dec 2020 (Study Day 116) – 30 Dec 2020 (Study Day 118)	Recovered/resolved
Pneumonia/Pneumonia	SAE	Grade 2/ moderate	Not related	06 Feb 2021 (Study Day 156) – 16 Feb 2021 (Study Day 166)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2116, a 64-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Dec 2020 (Study Day 116), 115 days after the first dose and 87 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of dyspnoea. Action taken with the IP was not applicable. The event of shortness of breath possible fluid in the lungs lasted for 3 days, after which it was considered to be recovered/resolved on 30 Dec 2020 (Study Day 118). The investigator assessed the event of dyspnoea to be not related to the IP.

On 06 Feb 2021 (Study Day 156), 155 days after the first dose and 127 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 11 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 166). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001563	Dyspnoea
MOD-2021-014129	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
HIV infection	Hiv	1992 - Ongoing
Skin cancer	Cancerous tumor, left inguinal	Jan 1999 - Sep 2004
Uterine cancer	Uterine cancer	Jan 1999 - Sep 2004
Postmenopause	Post menopausal	Feb 1999 - Ongoing
Osteoarthritis	Osteoarthritis (bilateral knees & shoulders) secondary to radiation	Sep 2004 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	Sep 2004 - Ongoing	Osteoarthritis
Paracetamol	Sep 2004 - Ongoing	Osteoarthritis
Cobicistat; darunavir ethanolate	2008 - Ongoing	Hiv
Dolutegravir sodium	2008 - Ongoing	Hiv
Emtricitabine; tenofovir alafenamide fumarate	2008 - Ongoing	Hiv
Enalapril	2018 - Ongoing	Hypertension
Insulin glargine	2018 - Ongoing	Diabetes Type Ii
Metformin	2018 - Ongoing	Diabetes Type Ii
Influenza vaccine	21 Oct 2020 (Study Day 48) - 21 Oct 2020 (Study Day 48)	Prevention Of Flu
Ct scan chest*	28 Dec 2020 (Study Day 116) - 28 Dec 2020 (Study Day 116)	Adverse Event
Furosemide	28 Dec 2020 (Study Day 116) - Ongoing	Shortness Of Breath Possible Fluid In The Lungs

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin	28 Dec 2020 (Study Day 116) - 28 Dec 2020 (Study Day 116)	Type Ii Diabetes Mellitus
Apixaban	31 Dec 2020 (Study Day 119) - 11 Jan 2021 (Study Day 130)	Prevention Of Blood Clot
Losartan	Feb 2021 - Ongoing	High Blood Pressure & Pt Was Put On Medication When Pt Had Pneumonia
Metoprolol	Feb 2021 - Ongoing	High Blood Pressure & While Experiencing Pneumonia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US398-2022 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Tooth Socket Haemorrhage/ Hemorrhage From Wisdom Tooth Extraction #32	SAE	Grade 3/ severe	Not related	15 Jan 2021 (Study Day 142) – 18 Jan 2021 (Study Day 145)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2022, a 67-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Jan 2021 (Study Day 142), 141 days after the first dose and 112 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of tooth socket haemorrhage. Action taken with the IP was not applicable. The event of hemorrhage from wisdom tooth extraction #32 lasted for 4 days, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 145). The investigator assessed the event of tooth socket haemorrhage to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004543	Tooth socket hemorrhage

Study Completion/Discontinuation

On 20 Jan 2021 (Study Day 147), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Aortic valve disease	Damaged aortic valve	Jul 2008 - Sep 2008
Endocarditis	Endocarditis	06 Aug 2008 (Study Day -4404) - 12 Sep 2008 (Study Day -4367)
Aortic valve replacement	Mechanical aortic valve placement	Sep 2008 - Sep 2008
Artificial heart implant	Mechanical heart valve	Sep 2008 - Ongoing
Insomnia	Insomnia	2011 - Ongoing
Knee arthroplasty	Left knee replacement	2016 - 2016
Meniscus injury	Knee tear	2016 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2019 - Ongoing
Hypertension	Hypertension	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Warfarin	Sep 2008 - 15 Jan 2021 (Study Day 142)	Mechanical Heart Valve
Hydrochlorothiazide	12 Sep 2008 (Study Day -4367) - Ongoing	Hypertension
Zolpidem	2011 - Ongoing	Insomnia
Ubidecarenone	2014 - Ongoing	Muscle Supplement
Acetylsalicylic acid	2015 - Ongoing	Cardiac Prophylaxis
Potassium	2015 - Ongoing	Muscle Supplement
Atorvastatin	2019 - Ongoing	Hyperlipidemia
Losartan	2019 - Ongoing	Hypertension
Omeprazole	2019 - Ongoing	Gastroesophageal Reflux Disease
Influenza vaccine	11 Aug 2020 (Study Day -16) - 11 Aug 2020 (Study Day -16)	Prophylaxis
Amoxicillin	19 Dec 2020 (Study Day 115) - 23 Dec 2020 (Study Day 119)	Tooth Abscess
Tooth # 32 extraction*	19 Dec 2020 (Study Day 115) - 19 Dec 2020 (Study Day 115)	Adverse Event
Other viral vaccines	05 Jan 2021 (Study Day 132) - 05 Jan 2021 (Study Day 132)	Vs. COVID 19
Epinephrine; lidocaine	15 Jan 2021 (Study Day 142) - 15 Jan 2021 (Study Day 142)	Hemorrhage
Thrombin	15 Jan 2021 (Study Day 142) - 15 Jan 2021 (Study Day 142)	Hemorrhage
Tranexamic acid	15 Jan 2021 (Study Day 142) - 15 Jan 2021 (Study Day 142)	Hemorrhage

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Heparin	16 Jan 2021 (Study Day 143) - 18 Jan 2021 (Study Day 145)	Mechanical Heart Valve
Packing and suturing extraction site # 32*	16 Jan 2021 (Study Day 143) - 16 Jan 2021 (Study Day 143)	Adverse Event
Phytomenadione	16 Jan 2021 (Study Day 143) - 16 Jan 2021 (Study Day 143)	Hemorrhage (Anticoagulation Reversal)
Plasma	16 Jan 2021 (Study Day 143) - 16 Jan 2021 (Study Day 143)	Hemorrhage From Wisdom Tooth Extraction
Enoxaparin sodium	18 Jan 2021 (Study Day 145) - Ongoing	Mechanical Heart Valve
Warfarin	18 Jan 2021 (Study Day 145) - Ongoing	Mechanical Heart Valve

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tooth Abscess	Grade 2/moderate	Not related	19 Dec 2020 (Study Day 115) - 23 Dec 2020 (Study Day 119)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2031 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Coronary Artery Disease/ Coronary Artery Disease	SAE	Grade 3/ severe	Not related	10 Sep 2020 (Study Day 15) – 26 Sep 2020 (Study Day 31)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2031, a 86-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Sep 2020 (Study Day 15), 14 days after the first dose and 21 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of coronary artery disease. The IP dose was not changed due to the coronary artery disease. The event of coronary artery disease lasted for 17 days, after which it was considered to be recovered/resolved on 26 Sep 2020 (Study Day 31). The investigator assessed the event of coronary artery disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000381	Coronary artery disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1970 - Ongoing
Hysterectomy	Hysterectomy	1980 - 1980
Postmenopause	Post menopausal	1980 - Ongoing
Uterine enlargement	Enlarged uterus	1980 - 1980
Intestinal obstruction	Bowel obstruction	1988 - 1988
Sigmoidectomy	Sigmoid resection	1988 - 1988
Food allergy	Allergy to shellfish (anaphylaxis)	1990 - Ongoing
Hypertension	High blood pressure	1995 - Ongoing
Tendon operation	Right dequervain's tenosynovitis surgery	1995 - 1995
Tenosynovitis stenosans	Right dequervain's tenosynovitis	1995 - 1995
Tenolysis	Left dequervain's tenosynovitis surgery	2000 - 2000
Tenosynovitis stenosans	Left dequervain's tenosynovitis	2000 - 2000
Cataract	Left eye cataract	Nov 2003 - 16 Dec 2003 (Study Day -6099)
Cataract	Right eye cataract	Nov 2003 - 02 Dec 2003 (Study Day -6113)
Cataract operation	Right eye cataract surgery	02 Dec 2003 (Study Day -6113) - 02 Dec 2003 (Study Day -6113)
Cataract operation	Left eye cataract surgery	16 Dec 2003 (Study Day -6099) - 16 Dec 2003 (Study Day -6099)
Medical device implantation	Back surgery metal implants l4-l5	2017 - 2017
Spinal stenosis	Spinal stenosis	2017 - 2017
Urticaria	Allergy to penicillin (hives)	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Immunotherapy	1970 - Ongoing	Seasonal Allergies
Estradiol	2015 - Ongoing	Post Menopausal
Torasemide	Jun 2020 - 24 Sep 2020 (Study Day 29)	High Blood Pressure
Nuclear gxt*	24 Sep 2020 (Study Day 29) - 24 Sep 2020 (Study Day 29)	Adverse Event
Spect, myocardial perfusion*	24 Sep 2020 (Study Day 29) - 24 Sep 2020 (Study Day 29)	Adverse Event
Cardiac catheterization with stent placement*	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Adverse Event
Acetylsalicylic acid	26 Sep 2020 (Study Day 31) - 26 Apr 2021 (Study Day 243)	Coronary Artery Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	26 Sep 2020 (Study Day 31) - 21 Jan 2021 (Study Day 148)	High Blood Pressure
Rosuvastatin	26 Sep 2020 (Study Day 31) - Ongoing	Coronary Artery Disease
Ticagrelor	26 Sep 2020 (Study Day 31) - 26 Apr 2021 (Study Day 243)	Coronary Artery Disease
Electrocardiogram*	08 Oct 2020 (Study Day 43) - 08 Oct 2020 (Study Day 43)	Adverse Event
Influenza vaccine	16 Oct 2020 (Study Day 51) - 16 Oct 2020 (Study Day 51)	Flu Prevention
Lisinopril	22 Jan 2021 (Study Day 149) - 18 Feb 2021 (Study Day 176)	Hypertension
Lisinopril	18 Feb 2021 (Study Day 176) - Ongoing	High Blood Pressure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	27 Aug 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2050 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastroenteritis Viral/ Viral Gastroenteritis	SAE	Grade 2/moderate	Not related	02 Mar 2021 (Study Day 184) – 07 Mar 2021 (Study Day 189)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2050, a 34-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the right arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Mar 2021 (Study Day 184), 183 days after the first dose and 158 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of gastroenteritis viral. Action taken with the IP was not applicable. The event of viral gastroenteritis lasted for 6 days, after which it was considered to be recovered/resolved on 07 Mar 2021 (Study Day 189). The investigator assessed the event of gastroenteritis viral to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-037917	Gastroenteritis viral

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 1 diabetes mellitus	Diabetes type 1	1998 - Ongoing
Hidradenitis	Hidradenitis suppurativa	2005 - Ongoing
Epilepsy	Epilepsy (stable on dilantin)	2011 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	1998 - Ongoing	Diabetes Type 1
Phenytoin	Nov 2011 - Ongoing	Epilepsy
Naproxen	04 Sep 2020 (Study Day 5) - 05 Sep 2020 (Study Day 6)	Injection Site Pain
Naproxen sodium	26 Sep 2020 (Study Day 27) - 27 Sep 2020 (Study Day 28)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hidradenitis	Grade 1/mild	Not related	10 Sep 2020 (Study Day 11) - 25 Sep 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2069 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening R Knee Osteo Arthritis	SAE	Grade 3/ severe	Not related	29 Dec 2020 (Study Day 120) – 30 Dec 2020 (Study Day 121)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2069, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 30 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Dec 2020 (Study Day 120), 119 days after the first dose and 90 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening r knee osteo arthritis lasted for 2 days, after which it was considered to be recovered/resolved with sequelae on 30 Dec 2020 (Study Day 121). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001523	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	(b) (6) 1954 (Study Day (b) (6) - Ongoing
Tonsillitis	Tonsillitis	1971 - 1976
Tonsillectomy	Tonsil surgery	1976 - 1976
Benign breast neoplasm	Bening mass (right breast)	1985 - 1990
Benign breast lump removal	Lumpectomy right breast (benign)	Aug 1989 - Aug 1989
Osteoarthritis	Osteoarthritis (generalized)	1990 - Ongoing
Female sterilisation	Tubal ligation (sterilization)	20 Apr 1990 (Study Day -11092) - 20 Apr 1990 (Study Day -11092)
Sleep disorder	Sleeping problems	2000 - Ongoing
Diverticulitis	Diverticulitis	Jan 2015 - May 2015
Colectomy	Colon resection	May 2015 - May 2015
Thoracic vertebral fracture	Back injury (t12 fracture)	Oct 2017 - Nov 2017
Vertebroplasty	Kyphoplasty	Nov 2017 - Nov 2017
Back pain	Back pain (lower)	Jan 2018 - Ongoing
Knee arthroplasty	Joint replacement knee (left)	06 May 2019 (Study Day -484) - 06 May 2019 (Study Day -484)
Seasonal allergy	Seasonal allergies	Aug 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1954 - Ongoing	Asthma
Chondroitin; glucosamine	1990 - Ongoing	Osteoarhtritis (Generalized)
Diphenhydramine hydrochloride	2000 - Ongoing	Sleeping Probelms
Calcium	2010 - Ongoing	Dietary Supplement
Colecalciferol	2010 - Ongoing	Dietary Supplement
Fish oil	2010 - Ongoing	Dietary Supplement
Magnesium	2010 - Ongoing	Dietary Supplement
Melatonin	2010 - Ongoing	Sleeping Problems
Diclofenac	2015 - Ongoing	Osteoarthritis (Generalized)
Fibre, dietary	Jun 2015 - Ongoing	Dietary Supplement
Probiotics nos	Jun 2015 - Ongoing	Dietary Supplement
Hydrocodone bitartrate; paracetamol	Nov 2018 - 20 Dec 2020 (Study Day 111)	Back Pain (Low)
Tizanidine	2019 - Ongoing	Back Pain (Low)
Loratadine; pseudoephedrine sulfate	Aug 2019 - Ongoing	Seasonal Allergies
Vitamins nos	Mar 2020 - Ongoing	Dietary Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone furoate; vilanterol trifenatate	Apr 2020 - 30 Sep 2020 (Study Day 30)	Asthma
Fluticasone propionate; salmeterol	01 Oct 2020 (Study Day 31) - Ongoing	Asthma
Influenza vaccine	20 Oct 2020 (Study Day 50) - 20 Oct 2020 (Study Day 50)	Flu Prophylaxis
Ciprofloxacin	24 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 88)	Uti
Gabapentin	29 Dec 2020 (Study Day 120) - 24 Mar 2021 (Study Day 205)	Total Knee Replacment Surgery Post Op Pain
Right total knee replacement*	29 Dec 2020 (Study Day 120) - 29 Dec 2020 (Study Day 120)	Other, Osteoartritis
Acetylsalicylic acid	30 Dec 2020 (Study Day 121) - Ongoing	Cardiac Prophylaxis
Oxycodone hydrochloride; paracetamol	30 Dec 2020 (Study Day 121) - 07 Jan 2021 (Study Day 129)	Post Op Pain (Lower Back)
Hydrocodone bitartrate; paracetamol	07 Jan 2021 (Study Day 129) - 24 Feb 2021 (Study Day 177)	Lower Back Pain
Hydrocodone bitartrate; paracetamol	24 Feb 2021 (Study Day 177) - Ongoing	Lower Back Pain
Gabapentin	24 Mar 2021 (Study Day 205) - Ongoing	Pain From Knee Replacement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	20 Nov 2020 (Study Day 81) - 27 Nov 2020 (Study Day 88)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2088 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Muscular Weakness/ Diffuse Muscle Weakness	SAE	Grade 3/severe	Not related	30 Nov 2020 (Study Day 90) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2088, a 62-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Nov 2020 (Study Day 90), 89 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of muscular weakness. Action taken with the IP was not applicable. The event of diffuse muscle weakness was considered to be ongoing. The investigator assessed the event of muscular weakness to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014642	Muscular weakness

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Naproxen allergy	1977 - Ongoing
Endometrial ablation	Uterine ablation	1996 - 1996
Menorrhagia	Menorrhagia	1996 - 29 Sep 1997 (Study Day -8374)
Hysterectomy	Hysterectomy	29 Sep 1997 (Study Day -8374) - 29 Sep 1997 (Study Day -8374)
Postmenopause	Postmenopausal	29 Sep 1997 (Study Day -8374) - Ongoing
Arthroscopy	Arthroscopy right	2002 - 2002
Meniscus injury	Torn meniscus right	2002 - 2002
Irritable bowel syndrome	Irritable bowel syndrome	2005 - Ongoing
Anxiety	Anxiety	2006 - Ongoing
Depression	Depression	2006 - Ongoing
Arthroscopy	Arthroscopy left	2007 - 2007
Ligament rupture	Anterior cruciate ligament injury left	2007 - 2007
Rhinitis allergic	Allergic rhinitis	2007 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2010 - Ongoing
Otitis media acute	Acute otitis media bilateral	31 Aug 2020 (Study Day -2) - 07 Sep 2020 (Study Day 6)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clonazepam	2007 - Ongoing	Anxiety And Depression
Vortioxetine hydrobromide	2007 - Ongoing	Depression
Pantoprazole	2009 - Ongoing	Irritable Bowel Syndrome
Topiramate	2009 - Ongoing	Anxiety And Depression
Pravastatin	2010 - Ongoing	Hyperlipidemia
Ascorbic acid	2018 - Ongoing	Health Supplement
Vitamin b12 nos	2018 - Ongoing	Health Supplement
Colecalciferol	2019 - Ongoing	Health Supplement
Famotidine	2019 - 08 Sep 2020 (Study Day 7)	Irritable Bowel Syndrome
Fluticasone	2019 - Ongoing	Allergic Rhinitis
Montelukast	2019 - 08 Sep 2020 (Study Day 7)	Allergic Rhinitis
Ofloxacin	02 Sep 2020 (Study Day 1) - 07 Sep 2020 (Study Day 6)	Acute Otitis Media
Influenza vaccine	05 Nov 2020 (Study Day 65) - 05 Nov 2020 (Study Day 65)	Flu Prophylaxis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	23 Nov 2020 (Study Day 83) - 28 Nov 2020 (Study Day 88)	Nausea

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 77) - 28 Nov 2020 (Study Day 88)
Vomiting	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 77) - 28 Nov 2020 (Study Day 88)
Fatigue	Grade 1/mild	Not related	24 Nov 2020 (Study Day 84) - 28 Nov 2020 (Study Day 88)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2125 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diabetic Foot Infection/ Diabetic Foot Infection Left Foot	SAE	Grade 3/ severe	Not related	24 Jan 2021 (Study Day 140) – 18 Mar 2021 (Study Day 193)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2125, a 50-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Jan 2021 (Study Day 140), 139 days after the first dose and 107 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diabetic foot infection. Action taken with the IP was not applicable. The event of diabetic foot infection left foot lasted for 54 days, after which it was considered to be recovered/resolved on 18 Mar 2021 (Study Day 193). The investigator assessed the event of diabetic foot infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009172	Diabetic foot infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	2000 - Ongoing
Osteomyelitis	Osteomyelitis right foot	2011 - Dec 2019
Coronary arterial stent insertion	2 cardiac stents	2015 - 2015
Myocardial infarction	Heart attack	2015 - 2015
Arteriosclerosis	Arteriosclerosis iliac arteries	2019 - Ongoing
Venous stent insertion	4 iliac vein stents	Sep 2019 - Sep 2019
Leg amputation	Right leg amputation (under the knee)	Dec 2019 - Dec 2019
Hypertension	High blood pressure	Jun 2020 - Ongoing
Blood cholesterol increased	High cholesterol	05 Aug 2020 (Study Day -33) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	Jun 2019 - Ongoing	Diabetes Type Ii
Acetylsalicylic acid	Oct 2019 - Ongoing	Cardiac Stents
Clopidogrel bisulfate	Oct 2019 - Ongoing	Arteriosclerosis Iliac Arteries
Vitamins nos	Apr 2020 - Ongoing	Supplement
Amlodipine	Jun 2020 - Ongoing	High Blood Pressure
Rosuvastatin calcium	05 Aug 2020 (Study Day -33) - Ongoing	High Cholesterol
Influenza vaccine	26 Oct 2020 (Study Day 50) - 26 Oct 2020 (Study Day 50)	Prophylaxis
Cefalexin	26 Jan 2021 (Study Day 142) - 26 Jan 2021 (Study Day 142)	Diabetic Foot Infection (Left)
Ceftriaxone	26 Jan 2021 (Study Day 142) - 28 Jan 2021 (Study Day 144)	Diabetic Foot Infection (Left)
Sulfamethoxazole; trimethoprim	26 Jan 2021 (Study Day 142) - 26 Jan 2021 (Study Day 142)	Diabetic Foot Infection (Left)
Cefalexin	31 Jan 2021 (Study Day 147) - 13 Feb 2021 (Study Day 160)	Left Foot Diabetic Infection
Debridement and bone biopsy left foot*	07 Feb 2021 (Study Day 154) - 07 Feb 2021 (Study Day 154)	Adverse Event
Ciprofloxacin	10 Feb 2021 (Study Day 157) - 15 Feb 2021 (Study Day 162)	Left Foot Diabetic Infection
Doxycycline	10 Feb 2021 (Study Day 157) - 15 Feb 2021 (Study Day 162)	Left Foot Diabetic Infection
Losartan	06 Mar 2021 (Study Day 181) - Ongoing	High Blood Pressure
Rivaroxaban	06 Mar 2021 (Study Day 181) - Ongoing	Cardiac Stents

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ciprofloxacin	16 Mar 2021 (Study Day 191) - 18 Mar 2021 (Study Day 193)	Diabetic Foot Infection (Left)
Doxycycline	16 Mar 2021 (Study Day 191) - 21 Mar 2021 (Study Day 196)	Diabetic Foot Infection (Left)
Excisional debridement and skin graft placement left foot*	17 Mar 2021 (Study Day 192) - 17 Mar 2021 (Study Day 192)	Adverse Event
Ciprofloxacin	18 Mar 2021 (Study Day 193) - 21 Mar 2021 (Study Day 196)	Diabetic Foot Infection (Left)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diabetic Mononeuropathy	Grade 1/mild	Not related	16 Nov 2020 (Study Day 71) - 15 Jan 2021 (Study Day 131)
Diplopia	Grade 1/mild	Not related	16 Nov 2020 (Study Day 71) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2144 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	14 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pancreatitis/Pancreatitis	SAE	Grade 2/ moderate	Not related	14 Feb 2021 (Study Day 151) – 21 Feb 2021 (Study Day 158)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2144, a 43-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 14 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Feb 2021 (Study Day 151), 150 days after the first dose and 123 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of pancreatitis. Action taken with the IP was not applicable. The event of pancreatitis lasted for 8 days, after which it was considered to be recovered/resolved on 21 Feb 2021 (Study Day 158). The investigator assessed the event of pancreatitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-016729	Pancreatitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Allergy to vaccine	Tetanus allergy	1982 - Ongoing
Drug hypersensitivity	Penicillin allergy	1982 - Ongoing
Seasonal allergy	Seasonal allergies	1985 - Ongoing
Back pain	Chronic low back pain	1998 - Ongoing
Anxiety	Anxiety	2004 - Ongoing
Depression	Depression	2004 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2004 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2004 - Ongoing
Hypertension	Hypertension	2004 - Ongoing
Hypertriglyceridaemia	Hypertriglyceridemia	2004 - Ongoing
Hypothyroidism	Hypothyroidism	2004 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitius type 2	2004 - Ongoing
Drug hypersensitivity	Niacin allergy	2005 - Ongoing
Eczema	Eczema	2010 - Ongoing
Cartilage injury	Torn labrum left shoulder	2011 - 2011
Cartilage operation	Torn labrum left shoulder surgery	2011 - 2011
Sleep apnoea syndrome	Sleep apnea	2011 - Ongoing
Ketoacidosis	Ketoacidosis hospitalization	Feb 2019 - Feb 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	1996 - Ongoing	Seasonal Allergies
Atorvastatin	2004 - 14 Feb 2021 (Study Day 151)	Hypercholesterolemia
Fenofibrate	2004 - 14 Feb 2021 (Study Day 151)	Hypertriglyceridemia
Hydrochlorothiazide; lisinopril	Jul 2004 - Ongoing	Hypertension
Levothyroxine	Jul 2004 - Ongoing	Hypothyroidism
Metformin	Jul 2004 - Ongoing	Diabetes Mellitus Type 2
Morphine	2011 - Ongoing	Chronic Low Back Pain
Oxycodone	2011 - Ongoing	Chronic Low Back Pain
Omeprazole	Jul 2011 - Ongoing	Acid Reflux
Bupropion	Jul 2012 - Ongoing	Depression
Buspirone	Jul 2012 - Ongoing	Anxiety
Duloxetine	Jul 2012 - Ongoing	Anxiety And Depression
Folic acid	Jul 2012 - Ongoing	Nutritional Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Empagliflozin; linagliptin	Jan 2020 - Ongoing	Diabetes Mellitus Type 2
Insulin	Jul 2020 - Ongoing	Diabetes Mellitus Type 2
Verapamil	Jul 2020 - Ongoing	Hypertension
Influenza vaccine	02 Sep 2020 (Study Day -15) - 02 Sep 2020 (Study Day -15)	Prophylaxis
Ketoconazole	08 Sep 2020 (Study Day -9) - Ongoing	Eczema
Lorazepam	13 Oct 2020 (Study Day 27) - Ongoing	Anxiety
Eicosapentaenoic acid ethyl ester	14 Oct 2020 (Study Day 28) - Ongoing	Hypertriglyceridemia
Naproxen	11 Jan 2021 (Study Day 117) - Ongoing	Viral Syndrome
Atorvastatin	14 Feb 2021 (Study Day 151) - Ongoing	Hypercholesterolemia
Empagliflozin	14 Feb 2021 (Study Day 151) - Ongoing	Diabetes Mellitus 2
Fenofibrate	14 Feb 2021 (Study Day 151) - Ongoing	Hypertriglyceridemia
Ondansetron	18 Feb 2021 (Study Day 155) - 20 Feb 2021 (Study Day 157)	Pancreatitis
Pantoprazole	18 Feb 2021 (Study Day 155) - 20 Feb 2021 (Study Day 157)	Pancreatitis
Sodium chloride	18 Feb 2021 (Study Day 155) - 20 Feb 2021 (Study Day 157)	Pancreatitis
Tizanidine	18 Feb 2021 (Study Day 155) - 20 Feb 2021 (Study Day 157)	Chronic Low Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Not related	20 Sep 2020 (Study Day 4) - 02 Oct 2020 (Study Day 16)
Headache	Grade 2/moderate	Not related	20 Sep 2020 (Study Day 4) - 25 Sep 2020 (Study Day 9)
Myalgia	Grade 1/mild	Not related	21 Sep 2020 (Study Day 5) - 02 Oct 2020 (Study Day 16)
Fatigue	Grade 2/moderate	Not related	24 Sep 2020 (Study Day 8) - 02 Oct 2020 (Study Day 16)
Viral Infection	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 107) - 16 Jan 2021 (Study Day 122)
Diarrhoea	Grade 1/mild	Not related	19 Jan 2021 (Study Day 125) - 20 Jan 2021 (Study Day 126)
Rhinitis Allergic	Grade 2/moderate	Not related	21 Jan 2021 (Study Day 127) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2151 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastritis/Acute Gastritis Without Bleeding	SAE	Grade 3/ severe	Not related	26 Dec 2020 (Study Day 108) – 31 Dec 2020 (Study Day 113)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2151, a 60-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Dec 2020 (Study Day 108), 107 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of gastritis. On 07 Oct 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of acute gastritis without bleeding lasted for 6 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 113). The investigator assessed the event of gastritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001720	Gastritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	1974 - Ongoing
Hypertension	Hypertension	1976 - Ongoing
Migraine	Migraines	1976 - Ongoing
Back pain	Chronic back pain	1991 - Ongoing
Constipation	Constipation, probably opioid induced	1994 - Ongoing
Cerebrovascular accident	Stroke	2001 - 2001
Craniotomy	Craniotomy	2001 - 2001
Epilepsy	Seizures (epilepsy)	2001 - Ongoing
Postmenopause	Post-menopausal	2005 - Ongoing
Depression	Depression	2012 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2013 - Ongoing
Heart valve replacement	Heart valve replacement	Dec 2013 - Dec 2013
Myocardial infarction	Myocardial infarction	Dec 2013 - Dec 2013
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2020 - Ongoing
Osteoporosis	Osteoporosis	2020 - Ongoing
Restless legs syndrome	Restless leg syndrome	2020 - Ongoing
Gastric ulcer	Stomach ulcer	Apr 2020 - 29 Dec 2020 (Study Day 111)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1978 - Ongoing	Supplement
Docusate sodium	1994 - Ongoing	Prevent Constipation Due To Medication
Hydrocodone bitartrate; paracetamol	1994 - Ongoing	Chronic Back Pain
Metoprolol	2001 - 30 Sep 2020 (Study Day 21)	Hypertension
Atorvastatin	2013 - Ongoing	Hyperlipidemia
Gabapentin	2018 - Ongoing	Migraine
Levetiracetam	2018 - Ongoing	Seizures/Epilepsy
Topiramate	2018 - Ongoing	Seizures/Epilepsy
Trazodone	2018 - Ongoing	Depression
Famotidine	2020 - 25 Sep 2020 (Study Day 16)	Stomach Ulcer
Fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	2020 - Ongoing	Chronic Obstructive Pulmonary Disease
Omeprazole	2020 - 25 Sep 2020 (Study Day 16)	Stomach Ulcer

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Quetiapine	2020 - Ongoing	Depression
Ropinirole hydrochloride	2020 - 15 Oct 2020 (Study Day 36)	Restless Leg Syndrome
Sucralfate	2020 - 25 Sep 2020 (Study Day 16)	Stomach Ulcer
Vortioxetine hydrobromide	2020 - Ongoing	Depression
Ondansetron	Sep 2020 - Ongoing	Gastroparesis
Famotidine	26 Sep 2020 (Study Day 17) - 12 Oct 2020 (Study Day 33)	Stomach Ulcer
Omeprazole	26 Sep 2020 (Study Day 17) - 12 Oct 2020 (Study Day 33)	Stomach Ulcer
Sucralfate	26 Sep 2020 (Study Day 17) - 12 Oct 2020 (Study Day 33)	Stomach Ulcer
Famotidine	13 Oct 2020 (Study Day 34) - 30 Dec 2020 (Study Day 112)	Stomach Ulcer
Diltiazem	15 Oct 2020 (Study Day 36) - Ongoing	Hypertension
Ropinirole	15 Oct 2020 (Study Day 36) - Ongoing	Restless Leg Syndrome
Diphenhydramine hydrochloride	17 Nov 2020 (Study Day 69) - 28 Nov 2020 (Study Day 80)	Allergic Reaction (Flu Vaccine)
Influenza vaccine	17 Nov 2020 (Study Day 69) - 17 Nov 2020 (Study Day 69)	Prophylaxis Flu
Salbutamol	17 Nov 2020 (Study Day 69) - 28 Nov 2020 (Study Day 80)	Allergic Reaction (Flu Vaccine)
Ct abd/ pelvis*	21 Dec 2020 (Study Day 103) - 21 Dec 2020 (Study Day 103)	Adverse Event
Gi cocktail	26 Dec 2020 (Study Day 108) - 26 Dec 2020 (Study Day 108)	Stomach Ulcer
Ct angio chest*	27 Dec 2020 (Study Day 109) - 27 Dec 2020 (Study Day 109)	Medical History
Echocardiogram*	28 Dec 2020 (Study Day 110) - 28 Dec 2020 (Study Day 110)	Medical History
Endoscopy (egd-upper)*	29 Dec 2020 (Study Day 111) - 29 Dec 2020 (Study Day 111)	Adverse Event
Famotidine	31 Dec 2020 (Study Day 113) - Ongoing	Stomach Ulcer
Gabapentin	31 Dec 2020 (Study Day 113) - Ongoing	Chronic Lbp
Hydrocodone bitartrate; paracetamol	31 Dec 2020 (Study Day 113) - Ongoing	Chronic Lbp
Sucralfate	31 Dec 2020 (Study Day 113) - Ongoing	Stomach Ulcer
Macrogol 3350	04 Jan 2021 (Study Day 117) - Ongoing	Constipation
Pantoprazole	04 Jan 2021 (Study Day 117) - Ongoing	Stomach Ulcer
Salbutamol	04 Jan 2021 (Study Day 117) - Ongoing	Copd
Domperidone	02 Mar 2021 (Study Day 174) - Ongoing	Gastroparesis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastric Ulcer	Grade 2/moderate	Not related	30 Sep 2020 (Study Day 21) - 15 Oct 2020 (Study Day 36)
Pruritus	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 69) - 22 Nov 2020 (Study Day 74)
Impaired Gastric Emptying	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 152) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2169 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	14 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Localised Infection/Left Anterior Lower Leg Infection	SAE	Grade 2/ moderate	Not related	30 Dec 2020 (Study Day 108) – 01 Mar 2021 (Study Day 169)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2169, an 81-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Dec 2020 (Study Day 108), 107 days after the first dose and 82 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of localised infection. Action taken with the IP was not applicable. The event of left anterior lower leg infection lasted for 62 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 169). The investigator assessed the event of localised infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-010869	Localised infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Renal stone	Not reported - Ongoing
Inguinal hernia	(r) groin hernia	1995 - 1995
Inguinal hernia repair	(r) groin hernia repair	1995 - 1995
Inguinal hernia	(l) groin hernia	2000 - 2000
Inguinal hernia repair	(l) groin hernia repair	2000 - 2000
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Umbilical hernia	Umbilical hernia	2005 - 2005
Umbilical hernia repair	Umbilical hernia repair	2005 - 2005
Cataract	Cataracts (bilateral)	2010 - 2010
Cataract operation	Bilateral cateract surgery	2010 - 2010
Erectile dysfunction	Erectile dysfunction	2010 - Ongoing
Syncope	Syncope	2016 - 2016
Balance disorder	Balance issue	2017 - Ongoing
Osteoarthritis	Arthritis (osteoarthritis)	2017 - Ongoing
Peripheral arterial occlusive disease	Peripheral artery disease (legs)	2018 - Ongoing
Deafness	Hearing loss (mild)	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2005 - Ongoing	Hyperlipidemia
Acetylcysteine; calcium mefolinate; mecobalamin	2015 - Ongoing	To Prevent Memory Loss
Acetylsalicylic acid	2015 - Ongoing	To Prevent Blood Clots
Bisoprolol	2015 - Ongoing	To Prevent Hypertension
Vitamins nos	2015 - Ongoing	Supplement
Vitamin d nos	2017 - Ongoing	Supplement
Vitamins nos	2017 - Ongoing	Supplement
Minocycline	30 Dec 2020 (Study Day 108) - 13 Jan 2021 (Study Day 122)	Left Leg Anterior Infection
Cefdinir	23 Jan 2021 (Study Day 132) - 02 Feb 2021 (Study Day 142)	Left Anterior Leg Infection
Metronidazole	23 Jan 2021 (Study Day 132) - 02 Feb 2021 (Study Day 142)	Left Anterior Leg Infection
Lithotripsy for renal stones*	06 Feb 2021 (Study Day 146) - 06 Feb 2021 (Study Day 146)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 1/mild	Not related	03 Dec 2020 (Study Day 81) - 04 Dec 2020 (Study Day 82)
Limb Injury	Grade 2/moderate	Not related	18 Dec 2020 (Study Day 96) - 18 Dec 2020 (Study Day 96)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2244 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hemiparesis/Right Sided Hemiparesis	SAE	Grade 3/ severe	Not related	03 Feb 2021 (Study Day 129) – Ongoing	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2244, a 59-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Feb 2021 (Study Day 129), 128 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of hemiparesis. On 25 Oct 2020 (Study Day 28), the IP dose was discontinued due to protocol deviation. The event of right sided hemiparesis was considered to be ongoing. The investigator assessed the event of hemiparesis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-020919	Gastrointestinal haemorrhage

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	Cesarean section	1980 - 1980
Caesarean section	Cesarean section	1982 - 1982
Caesarean section	Cesarean section	1987 - 1987
Postmenopause	Post-menopausal	2018 - Ongoing
Coronary arterial stent insertion	Coronary artery and stent surgery	Feb 2020 - Feb 2020
Hyperlipidaemia	Hyperlipidemia	Feb 2020 - Ongoing
Hypertension	Hypertension	Feb 2020 - Ongoing
Myocardial infarction	Myocardial infarction	Feb 2020 - Feb 2020
Type 2 diabetes mellitus	Diabetes type 2	Feb 2020 - Ongoing
Embolism	Embolus (arterial)	Jun 2020 - Ongoing
Paraesthesia	Hands tingling	Jun 2020 - Ongoing
Transient ischaemic attack	Transient ischemic attack	Jun 2020 - Jun 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	Feb 2020 - Ongoing	Hyperlipidemia
Carvedilol	Feb 2020 - Ongoing	Hypertension
Insulin glargine; lixisenatide	Feb 2020 - 24 Dec 2020 (Study Day 88)	Diabetes Type 2
Isosorbide mononitrate	Feb 2020 - Ongoing	Myocardial Infarction Prevention
Torasemide	Feb 2020 - Ongoing	Hypertension
Acetylsalicylic acid	Jun 2020 - Ongoing	Arterial Embolus
Clopidogrel	Jun 2020 - Ongoing	Arterial Embolus
Potassium chloride	Jun 2020 - Ongoing	Transient Ischemic Attack
Warfarin	Jun 2020 - 09 Mar 2021 (Study Day 163)	Arterial Embolus
Influenza vaccine	23 Oct 2020 (Study Day 26) - 23 Oct 2020 (Study Day 26)	Flu Prevention
Metformin	25 Dec 2020 (Study Day 89) - Ongoing	Diabetes Type Ii
Saxagliptin	25 Dec 2020 (Study Day 89) - Ongoing	Diabetes Type Ii
Apixaban	06 Mar 2021 (Study Day 160) - Ongoing	Prophylaxis For Cerebrovascular Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US398-2246 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	28 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	26 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bronchitis/Acute Bronchitis	SAE	Grade 2/ moderate	Not related	28 Nov 2020 (Study Day 62) – 15 Dec 2020 (Study Day 79)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2246, a 76-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 26 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Nov 2020 (Study Day 62), 61 days after the first dose and 33 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of bronchitis. Action taken with the IP was not applicable. The event of acute bronchitis lasted for 18 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 79). The investigator assessed the event of bronchitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001054	Bronchitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Tonsillectomy	Tonsillectomy	1959 - 1959
Tonsillitis	Tonsillitis	1959 - 1959
Back pain	Lower back pain	1976 - Ongoing
Hysterectomy	Hysterectomy	1996 - 1996
Smear cervix abnormal	Abnormal cervix cells	1996 - 1996
Botulinum toxin injection	Botox injection-lips	Jun 2009 - Jun 2009
Glaucoma	Bilateral glaucoma	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2012 - Ongoing
Neuropathy peripheral	Neuropathy bilateral feet	2012 - Ongoing
Pollakiuria	Urinary frequency	2017 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Spinal fusion surgery	Spinal lumbar fusion	17 Jun 2019 (Study Day -469) - 17 Jun 2019 (Study Day -469)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2012 - Ongoing	Neuropathy
Latanoprost	04 Feb 2014 (Study Day -2428) - Ongoing	Bilateral Glaucoma
Timolol	04 Feb 2014 (Study Day -2428) - Ongoing	Bilateral Glaucoma
Ascorbic acid	2015 - Ongoing	Supplement
Vitamin a nos	2015 - Ongoing	Supplement
Vitamin b12 nos	2015 - Ongoing	Supplement
Levothyroxine	01 May 2015 (Study Day -1977) - Ongoing	Hypothyroidism
Gabapentin	2018 - Ongoing	Lower Back Pain
Lisinopril	05 Oct 2018 (Study Day -724) - Ongoing	Hypertension
Diclofenac sodium	18 Sep 2020 (Study Day -10) - Ongoing	Lower Back Pain
Alprazolam	04 Oct 2020 (Study Day 7) - Ongoing	Hypertension And Anxiety
Oxybutynin	29 Oct 2020 (Study Day 32) - Ongoing	Urinary Frequency
Erythromycin	07 Nov 2020 (Study Day 41) - 11 Nov 2020 (Study Day 45)	Right Ear Infection
Prednisone	07 Nov 2020 (Study Day 41) - 11 Nov 2020 (Study Day 45)	Right Ear Infection
Amlodipine	28 Nov 2020 (Study Day 62) - Ongoing	Hypertension
Ceftriaxone	29 Nov 2020 (Study Day 63) - 30 Nov 2020 (Study Day 64)	Acute Bronchitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levofloxacin	01 Dec 2020 (Study Day 65) - 15 Dec 2020 (Study Day 79)	Bronchitis
Benzonatate	08 Dec 2020 (Study Day 72) - 15 Dec 2020 (Study Day 79)	Bronchitis
Codeine; promethazine	08 Dec 2020 (Study Day 72) - 15 Dec 2020 (Study Day 79)	Bronchitis
Ibuprofen	29 Jan 2021 (Study Day 124) - Ongoing	Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	04 Oct 2020 (Study Day 7) - Ongoing
Cough	Grade 1/mild	Not related	04 Oct 2020 (Study Day 7) - 05 Oct 2020 (Study Day 8)
Ear Infection	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 41) - 11 Nov 2020 (Study Day 45)
Back Pain	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 59) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2256 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	30 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	28 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	SAE	Grade 2/ moderate	Not related	23 Nov 2020 (Study Day 55) – 11 Dec 2020 (Study Day 73)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2256, a 46-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 30 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 28 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Nov 2020 (Study Day 55), 54 days after the first dose and 26 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of covid-19. Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 19 days, after which it was considered to be recovered/resolved on 11 Dec 2020 (Study Day 73). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001031	COVID-19

Study Completion/Discontinuation

On 13 Feb 2021 (Study Day 137), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Lactose intolerance	Lactose intolerant	2012 - Ongoing
Headache	Headaches (at night)	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	Jun 2020 - Ongoing	Supplement
Calcium	Jun 2020 - Ongoing	Supplement
Colecalciferol	Jun 2020 - Ongoing	Supplement
Iron	Jun 2020 - Ongoing	Supplement
Magnesium	Jun 2020 - Ongoing	Supplement
Omega-3 nos	Jun 2020 - 04 Nov 2020 (Study Day 36)	Supplement
Potassium	Jun 2020 - Ongoing	Supplement
Vitamin b complex	Jun 2020 - Ongoing	Supplement
Xantofyl	Jun 2020 - Ongoing	Supplement
Zinc	Jun 2020 - Ongoing	Supplement
Paracetamol	17 Oct 2020 (Study Day 18) - Ongoing	Headache
Omega-3 nos	04 Nov 2020 (Study Day 36) - Ongoing	Supplement
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol; phenylephrine hydrochloride	28 Nov 2020 (Study Day 60) - 11 Dec 2020 (Study Day 73)	Symptomatic COVID 19
Dextromethorphan; paracetamol; phenylephrine	28 Nov 2020 (Study Day 60) - 11 Dec 2020 (Study Day 73)	Symptomatic COVID-19
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	02 Dec 2020 (Study Day 64) - 11 Dec 2020 (Study Day 73)	Symptomatic COVID 19
Diphenhydramine; paracetamol; phenylephrine	02 Dec 2020 (Study Day 64) - 11 Dec 2020 (Study Day 73)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US398-2269 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	09 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	06 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Fall/Fall	SAE	Grade 2/moderate	Not related	02 Dec 2020 (Study Day 55) – 02 Dec 2020 (Study Day 55)	Recovered/ resolved
Transient Ischaemic Attack/ Transient Ischemic Attack Vs Slurred Speech 2nd Medication Use	SAE	Grade 2/moderate	Not related	02 Dec 2020 (Study Day 55) – 05 Dec 2020 (Study Day 58)	Recovered/ resolved
Hypoglycaemia/Hypoglycemia	SAE	Grade 3/severe	Not related	05 Feb 2021 (Study Day 120) – 05 Feb 2021 (Study Day 120)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2269, a 58-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 09 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 06 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Dec 2020 (Study Day 55), 54 days after the first dose and 26 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of fall. Action taken with the IP was not applicable. The event of fall lasted for 1 day, after which it was considered to be recovered/resolved on 02 Dec 2020 (Study Day 55). The investigator assessed the event of fall to be not related to the IP.

On 02 Dec 2020 (Study Day 55), 54 days after the first dose and 26 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of transient ischaemic attack. Action taken with the IP was not applicable. The event of transient ischemic attack vs slurred speech 2nd medication use lasted for 4 days, after which it was considered to be recovered/resolved on 05 Dec 2020 (Study Day 58). The investigator assessed the event of transient ischaemic attack to be not related to the IP.

On 05 Feb 2021 (Study Day 120), 119 days after the first dose and 91 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypoglycaemia. Action taken with the IP was not applicable. The event of hypoglycemia lasted for 1 day, after which it was considered to be recovered/resolved on 05 Feb 2021 (Study Day 120). The investigator assessed the event of hypoglycaemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001229	Fall
MOD-2020-001229	Transient ischaemic attack
MOD-2021-011815	Hypoglycaemia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Irritable bowel syndrome	Irritable bowel syndrome	Not reported - Ongoing
Obesity	Obesity	Not reported - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	07 Jul 1990 (Study Day -11052) - Ongoing
Deafness bilateral	Hearing loss bilateral	Jun 2000 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2013 - Ongoing
Intervertebral disc degeneration	Lumbar disk degeneration	2015 - Ongoing
Osteoarthritis	Osteoarthritis right knee	15 Jul 2015 (Study Day -1913) - Ongoing
Blood cholesterol increased	High cholesterol	28 Jun 2016 (Study Day -1564) - Ongoing
Hypertension	Hypertension	28 Jun 2016 (Study Day -1564) - Ongoing
Transient ischaemic attack	Transient ischemic attack	15 Jul 2016 (Study Day -1547) - 15 Jul 2016 (Study Day -1547)
Nausea	Nausea intermittent	2017 - Ongoing
Postmenopause	Post menopausal	2017 - Ongoing
Seasonal allergy	Seasonal allergies	2017 - Ongoing
Neuropathy peripheral	Peripheral neuropathy	2018 - Ongoing
Spinal fusion surgery	Spinal fusion	2018 - 2018
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2019 - Ongoing
Hypertonic bladder	Overactive bladder	09 Oct 2019 (Study Day -366) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cyclobenzaprine	Not reported - Ongoing	Lumbar Disc Degenerations
Insulin human	1990 - Ongoing	Type 2 Diabetes
Insulin lispro	1990 - 03 Dec 2020 (Study Day 56)	Type 2 Diabetes
Glipizide	25 Jul 1990 (Study Day -11034) - 02 Dec 2020 (Study Day 55)	Type 2 Diabetes
Acetylsalicylic acid	2017 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2017 - Ongoing	High Cholesterol
Lisinopril	2017 - Ongoing	Hypertension
Loratadine	2017 - Ongoing	Seasonal Allergies
Ondansetron	2017 - Ongoing	Intermittent Nausea
Pantoprazole	2017 - Ongoing	Acid Reflux
Baclofen	2018 - Ongoing	Neuropathy
Duloxetine	2018 - 17 Dec 2020 (Study Day 70)	Neuropathy
Gabapentin	Jun 2018 - Ongoing	Neuropathy
Salbutamol	2019 - Ongoing	Chronic Obstructive Pulmonary Disease
Oxybutynin	Oct 2019 - Ongoing	Overactive Bladder
Ct brain perfusion scan*	02 Dec 2020 (Study Day 55) - 02 Dec 2020 (Study Day 55)	Adverse Event
Ct brain*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
Cta brain*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
Ecg*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
X-ray chest*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
X-ray hip*	03 Dec 2020 (Study Day 56) - 03 Dec 2020 (Study Day 56)	Adverse Event
Mri brain*	05 Dec 2020 (Study Day 58) - 05 Dec 2020 (Study Day 58)	Adverse Event
Amlodipine	17 Dec 2020 (Study Day 70) - Ongoing	Hypertension
Carvedilol	17 Dec 2020 (Study Day 70) - Ongoing	Hypertension
Dicycloverine	17 Dec 2020 (Study Day 70) - Ongoing	Irritable Bowel Syndrome
Metformin	Feb 2021 - Ongoing	Diabetes Mellitus 2
Ceftriaxone	05 Feb 2021 (Study Day 120) - 07 Feb 2021 (Study Day 122)	Cystitis Acute
Glucose	05 Feb 2021 (Study Day 120) - 05 Feb 2021 (Study Day 120)	Hypoglycemia
Insulin glargine	05 Feb 2021 (Study Day 120) - 08 Mar 2021 (Study Day 151)	Type Two Diabetes
Insulin lispro	05 Feb 2021 (Study Day 120) - Ongoing	Type Two Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	05 Feb 2021 (Study Day 120) - 05 Feb 2021 (Study Day 120)	Hypoglycemia
Cefdinir	08 Feb 2021 (Study Day 123) - 10 Feb 2021 (Study Day 125)	Cystitis Acute
Fluconazole	08 Feb 2021 (Study Day 123) - 08 Feb 2021 (Study Day 123)	Prophylaxis For Cystitis Acute
Occupational therapy*	03 Mar 2021 (Study Day 146) - 03 Mar 2021 (Study Day 146)	Other, Motility Dysfunctional
Physical therapy*	03 Mar 2021 (Study Day 146) - 03 Mar 2021 (Study Day 146)	Other, Motility Dysfunctional
Meropenem	04 Mar 2021 (Study Day 147) - 07 Mar 2021 (Study Day 150)	Urinary Tract Infection
Cefdinir	06 Mar 2021 (Study Day 149) - 16 Mar 2021 (Study Day 159)	Bilateral Pneumonia
Fluconazole	06 Mar 2021 (Study Day 149) - 12 Mar 2021 (Study Day 155)	Vaginal Candidiasis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperglycaemia	Grade 2/moderate	Not applicable	05 Jan 2021 (Study Day 89) - 06 Jan 2021 (Study Day 90)
Urinary Tract Infection	Grade 1/mild	Not related	05 Jan 2021 (Study Day 89) - 15 Jan 2021 (Study Day 99)
Cystitis	Grade 2/moderate	Not related	05 Feb 2021 (Study Day 120) - 10 Feb 2021 (Study Day 125)
Vulvovaginal Candidiasis	Grade 2/moderate	Not related	06 Mar 2021 (Study Day 149) - 12 Mar 2021 (Study Day 155)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2272 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	13 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	10 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Atrial Fibrillation With Rapid Ventricular Rate, New Onset	SAE	Grade 3/ severe	Not related	19 Oct 2020 (Study Day 7) – 20 Oct 2020 (Study Day 8)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2272, a 69-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 13 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 10 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Oct 2020 (Study Day 7), 6 days after the first dose and 22 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. The IP dose was not changed due to the atrial fibrillation with rapid ventricular rate, new onset. The event of atrial fibrillation with rapid ventricular rate, new onset lasted for 2 days, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 8). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000505	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Shellfish allergy	Not reported - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	Not reported - Ongoing
Obesity	Obesity	Not reported - Ongoing
Osteoarthritis	Right knee joint osteoarthritis	Not reported - 2012
Varicose vein	Varicose veins	Not reported - Ongoing
Back pain	Lower back pain (intermittent)	1961 - Ongoing
Musculoskeletal pain	Right shoulder pain	1961 - Ongoing
Bronchial hyperreactivity	Reactive airway disease	2001 - Ongoing
Oophorectomy	Left oophorectomy	2001 - 2001
Postmenopause	Post menopausal	2002 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Pollakiuria	Urinary frequency	2005 - Ongoing
Osteoarthritis	Left knee osteoarthritis	2010 - Ongoing
Osteopenia	Osteopenia	2010 - Ongoing
Knee arthroplasty	Right knee joint replacement	2012 - 2012
Arteriosclerosis coronary artery	Coronary artery atherosclerosis, mild	30 Dec 2015 (Study Day -1749) - Ongoing
X-ray limb	Right shoulder x-ray	2020 - 2020
Sleep apnoea syndrome	Obstructive sleep apnea	12 Oct 2020 (Study Day -1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Lower Back Pain And Right Shoulder Pain
Methocarbamol	2000 - Ongoing	Lower Back Pain And Right Shoulder Pain
Acetylsalicylic acid	2005 - Ongoing	Prophylaxis
Budesonide	2005 - Ongoing	Reactive Airway Disease
Colecalciferol	2005 - Ongoing	Supplement
Olmesartan	2005 - Ongoing	Hypertension
Rosuvastatin	2005 - Ongoing	Hyperhcolesterolemia
Salbutamol	2005 - Ongoing	Reactive Airway Disease
Ascorbic acid; betacarotene; cupric oxide; tocopheryl acetate; zinc oxide	2019 - Ongoing	Supplement
Curcuma longa	2019 - Ongoing	Prophylaxis For Osteoarthritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ubidecarenone	2019 - Ongoing	Supplement
Chest xray*	20 Oct 2020 (Study Day 8) - 20 Oct 2020 (Study Day 8)	Adverse Event
Diltiazem	20 Oct 2020 (Study Day 8) - 21 Oct 2020 (Study Day 9)	Atrial Fibrillation With Rapid Ventricular Response
Diltiazem	20 Oct 2020 (Study Day 8) - 20 Oct 2020 (Study Day 8)	Atril Fibrillation With Rapid Ventricular Rate
Electrocardiogram*	20 Oct 2020 (Study Day 8) - 20 Oct 2020 (Study Day 8)	Adverse Event
Simeticone	20 Oct 2020 (Study Day 8) - 20 Oct 2020 (Study Day 8)	Abdominal Gas Feeling
Apixaban	21 Oct 2020 (Study Day 9) - Ongoing	Atrial Fibrillation
Diltiazem	21 Oct 2020 (Study Day 9) - Ongoing	Atrial Fibrillation
Echocardiogram*	21 Oct 2020 (Study Day 9) - 21 Oct 2020 (Study Day 9)	Adverse Event
Cpap... continuous psotive airway pressure*	05 Nov 2020 (Study Day 24) - 05 Nov 2020 (Study Day 24)	Medical History
Paracetamol	11 Nov 2020 (Study Day 30) - 13 Nov 2020 (Study Day 32)	Injection Site
Cefalexin	02 Feb 2021 (Study Day 113) - 07 Feb 2021 (Study Day 118)	Urinary Frequency (Increased)
Amoxicillin; clavulanic acid	07 Feb 2021 (Study Day 118) - 13 Feb 2021 (Study Day 124)	Urinary Frequency (Increased)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Flatulence	Grade 2/moderate	Not related	20 Oct 2020 (Study Day 8) - 20 Oct 2020 (Study Day 8)
Cystitis	Grade 1/mild	Not related	04 Feb 2021 (Study Day 115) - 13 Feb 2021 (Study Day 124)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US325-2516 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	21 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	20 Oct 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pleural Effusion/Small Bilateral Pleural Effusions	SAE	Grade 3/severe	Not related	30 Sep 2020 (Study Day 10) – 10 Oct 2020 (Study Day 20)	Recovered/resolved
Pneumonia Mycoplasmal/Bilateral Multifocal Pneumonia Right Greater Than Left Due To Mycoplasma Pneumonia	SAE	Grade 3/severe	Not related	30 Sep 2020 (Study Day 10) – 20 Oct 2020 (Study Day 30)	Recovered/resolved
Respiratory Failure/Hypoxemia Respiratory Failure On Admission, Resolved	SAE	Grade 3/severe	Not related	30 Sep 2020 (Study Day 10) – 10 Oct 2020 (Study Day 20)	Recovered/resolved
Colitis/Acute Colitis	SAE	Grade 3/severe	Not related	30 Sep 2020 (Study Day 10) – 20 Oct 2020 (Study Day 30)	Recovered/resolved
Heart Rate Irregular/ Irregular Heart Beat	SAE	Grade 3/severe	Not related	01 Apr 2021 (Study Day 193) – Ongoing	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2516, a 40-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 20 Oct 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Sep 2020 (Study Day 10), 9 days after the first dose and 20 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pleural effusion. The IP dose was not changed due to the small bilateral pleural effusions. The event of small bilateral pleural effusions lasted for 11 days, after which it was considered to be recovered/resolved on 10 Oct 2020 (Study Day 20). The investigator assessed the event of pleural effusion to be not related to the IP.

On 30 Sep 2020 (Study Day 10), 9 days after the first dose and 20 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia

mycoplasmal. The IP dose was not changed due to the bilateral multifocal pneumonia right greater than left due to mycoplasma pneumonia. The event of bilateral multifocal pneumonia right greater than left due to mycoplasma pneumonia lasted for 21 days, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 30) The investigator assessed the event of pneumonia mycoplasmal to be not related to the IP.

On 30 Sep 2020 (Study Day 10), 9 days after the first dose and 20 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of respiratory failure. Action taken with the IP was not applicable. The event of hypoxemia respiratory failure on admission, resolved lasted for 11 days, after which it was considered to be recovered/resolved on 10 Oct 2020 (Study Day 20). The investigator assessed the event of respiratory failure to be not related to the IP.

On 30 Sep 2020 (Study Day 10), 9 days after the first dose and 20 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of colitis. The IP dose was not changed due to the acute colitis. The event of acute colitis lasted for 21 days, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 30). The investigator assessed the event of colitis to be not related to the IP.

On 01 Apr 2021 (Study Day 193), 192 days after the first dose and 163 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of heart rate irregular. Action taken with the IP was not applicable. The event of heart beat irregular lasted for an unreported number of days, after which it was considered to be recovered/resolved on an unreported date. The investigator assessed the event of heart rate irregular to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000455	Pneumonia mycoplasmal
MOD-2020-000455	Respiratory failure
MOD-2020-000455	Colitis
MOD-2020-000455	Pleural effusion

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cirrhosis alcoholic	Alcoholic liver cirrhosis	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Type II diabetes mellitus	2010 - Ongoing
Insomnia	Insomnia	Apr 2010 - Ongoing
Seizure	Seizure disorder	2012 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Propranolol	2010 - Ongoing	Hypertension
Sitagliptin	2010 - Ongoing	Type II Diabetes Mellitus
Trazodone	Apr 2010 - 10 Oct 2020 (Study Day 20)	Insomnia
Levetiracetam	30 Sep 2014 (Study Day -2183) - Ongoing	Seizures
Tramadol	30 Sep 2016 (Study Day -1452) - Ongoing	Generalized Pain
Trazodone	14 Apr 2020 (Study Day -160) - Ongoing	Insomnia
Pantoprazole sodium sesquihydrate	16 Apr 2020 (Study Day -158) - Ongoing	Gastroesophageal Reflux Disease
Abdominal ultrasound*	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Adverse Event
Azithromycin	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Bilateral Multifocal Pneumonia Right Greater Than Left Due To Mycoplasma Pneumonia
Chest x-ray*	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Adverse Event
Chlordiazepoxide	30 Sep 2020 (Study Day 10) - Ongoing	Alcohol Withdrawal Symptoms
Dextromethorphan hydrobromide; guaifenesin	30 Sep 2020 (Study Day 10) - 10 Oct 2020 (Study Day 20)	Cough
Furosemide	30 Sep 2020 (Study Day 10) - 30 Oct 2020 (Study Day 40)	Hypertension
Insulin glargine	30 Sep 2020 (Study Day 10) - 10 Oct 2020 (Study Day 20)	Type 2 Diabetes Mellitus
Salbutamol sulfate	30 Sep 2020 (Study Day 10) - 10 Oct 2020 (Study Day 20)	Shortness Of Breath
Spironolactone	30 Sep 2020 (Study Day 10) - 30 Oct 2020 (Study Day 40)	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Thiamine hydrochloride	30 Sep 2020 (Study Day 10) - 30 Jan 2021 (Study Day 132)	Thiamin Deficiency
Ultrasound of the kidneys and urinary bladder*	30 Sep 2020 (Study Day 10) - 30 Sep 2020 (Study Day 10)	Adverse Event
Azithromycin	01 Oct 2020 (Study Day 11) - 04 Oct 2020 (Study Day 14)	Bilateral Multifocal Pneumonia Right Greater Than Left Due To Mycoplasma Pneumonia
Computed tomography angiogram chest with iv contrast*	01 Oct 2020 (Study Day 11) - 01 Oct 2020 (Study Day 11)	Adverse Event
Dexamethasone	01 Oct 2020 (Study Day 11) - 10 Oct 2020 (Study Day 20)	Bilateral Multifocal Pneumonia Right Greater Than Left Due To Mycoplasma Pneumonia
Famotidine	01 Oct 2020 (Study Day 11) - 10 Oct 2020 (Study Day 20)	Gastroesophageal Reflux Disease
Transthoracic echocardiogram*	02 Oct 2020 (Study Day 12) - 02 Oct 2020 (Study Day 12)	Adverse Event
Chest x-ray*	04 Oct 2020 (Study Day 14) - 04 Oct 2020 (Study Day 14)	Adverse Event
Computed tomography of the abdomen/pelvis w/o contrast*	04 Oct 2020 (Study Day 14) - 04 Oct 2020 (Study Day 14)	Adverse Event
Abdominal x-ray*	05 Oct 2020 (Study Day 15) - 05 Oct 2020 (Study Day 15)	Adverse Event
Ultrasound paracentesis with image*	05 Oct 2020 (Study Day 15) - 05 Oct 2020 (Study Day 15)	Adverse Event
Colonoscopy*	06 Oct 2020 (Study Day 16) - 06 Oct 2020 (Study Day 16)	Adverse Event
Left colon biopsy*	06 Oct 2020 (Study Day 16) - 06 Oct 2020 (Study Day 16)	Adverse Event
Right colon biopsy*	06 Oct 2020 (Study Day 16) - 06 Oct 2020 (Study Day 16)	Adverse Event
Abdominal x-ray*	07 Oct 2020 (Study Day 17) - 07 Oct 2020 (Study Day 17)	Adverse Event
Levofloxacin	11 Oct 2020 (Study Day 21) - 20 Oct 2020 (Study Day 30)	Colitis,pneumonia
Metronidazole	11 Oct 2020 (Study Day 21) - 20 Oct 2020 (Study Day 30)	Colitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US357-2120 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colitis/Acute Colitis	SAE	Grade 3/severe	Not related	14 Dec 2020 (Study Day 110) – 14 Jan 2021 (Study Day 141)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US357-2120, a 59-year-old Hispanic or Latino male, received the first dose of placebo in the right arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Dec 2020 (Study Day 110), 109 days after the first dose and 80 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of colitis. Action taken with the IP was not applicable. The event of acute colitis lasted for 32 days, after which it was considered to be recovered/resolved on 14 Jan 2021 (Study Day 141). The investigator assessed the event of colitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005912	Colitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes type II	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loperamide	24 Dec 2020 (Study Day 120) - 08 Jan 2021 (Study Day 135)	Diarrhea
Mesalazine	11 Feb 2021 (Study Day 169) - Ongoing	Colitis
Trimebutine	11 Feb 2021 (Study Day 169) - Ongoing	Colitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Colitis	Grade 2/moderate	Not related	11 Feb 2021 (Study Day 169) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2235 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	SAE, COVID-19	Grade 2/ moderate	Not related	31 Dec 2020 (Study Day 123) – 26 Jan 2021 (Study Day 149)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2235, a 86-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Dec 2020 (Study Day 123), 122 days after the first dose and 94 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of covid-19. Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 27 days, after which it was considered to be recovered/resolved on 26 Jan 2021 (Study Day 149). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005758	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Adenoidectomy	Adenoidectomy	1936 - 1936
Adenoiditis	Adenoiditis	1936 - 1936
Mastoidectomy	Unilateral mastoidectomy	1936 - 1936
Mastoiditis	Mastoiditis	1936 - 1936
Tonsillectomy	Tonsillectomy	1936 - 1936
Tonsillitis	Tonsillitis	1936 - 1936
Uterine prolapse	Uterine prolapse	1971 - Nov 1976
Nerve root injury cervical	Cervical spine nerve impairment	1975 - 1975
Spinal laminectomy	Cervical spine laminectomy	1975 - 1975
Hysterectomy	Total hysterectomy	1976 - 1976
Postmenopause	Postmenopausal	1976 - Ongoing
Spinal osteoarthritis	Osteoarthritis lumbar spine	1980 - Ongoing
Osteoarthritis	Left knee osteoarthritis	2010 - 2017
Type 2 diabetes mellitus	T2dm	2011 - Ongoing
Atrial fibrillation	Atrial fibrillation	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2015 - Ongoing
Knee arthroplasty	Left knee arthroplasty	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estradiol	1976 - Ongoing	Post-Menopausal
Chondroitin; glucosamine	2010 - Ongoing	Vitamin Deficiency
Plantago ovata	2010 - Ongoing	Constipation
Vitamins nos	2010 - Ongoing	Vitamin Deficiency
Diltiazem hydrochloride	2015 - Ongoing	Atrial Fibrillation
Rosuvastatin	2015 - Ongoing	Hyperlipidemia
Dabigatran etexilate mesilate	2019 - Ongoing	Atrial Fibrillation
Unspecified herbal and traditional medicine	2019 - Ongoing	Malnutrition
Zinc	01 Jan 2021 (Study Day 124) - Ongoing	Vitammin Deficiency
Azithromycin	02 Jan 2021 (Study Day 125) - 02 Jan 2021 (Study Day 125)	Symptomatic COVID 19
Azithromycin	03 Jan 2021 (Study Day 126) - 04 Feb 2021 (Study Day 158)	Symptomatic COVID 19
Azithromycin	05 Jan 2021 (Study Day 128) - 06 Jan 2021 (Study Day 129)	Symptomatic COVID 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	15 Jan 2021 (Study Day 138) - Ongoing	T2dm
Doxycycline	04 Feb 2021 (Study Day 158) - 09 Feb 2021 (Study Day 163)	L Lower Leg Spider Bite

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthropod Bite	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 107) - 09 Feb 2021 (Study Day 163)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2249 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deep Vein Thrombosis/ Deep Vein Thrombosis - Right Leg	SAE	Grade 3/severe	Not related	15 Jan 2021 (Study Day 137) – Ongoing	Recovering/resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2249, an 80-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Jan 2021 (Study Day 137), 136 days after the first dose and 108 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of deep vein thrombosis. Action taken with the IP was not applicable. The event of deep vein thrombosis - right leg was considered to be ongoing. The investigator assessed the event of deep vein thrombosis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009707	Deep vein thrombosis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tobacco user	Tobacco use	1959 - 1966
Alcohol use	Alcohol use	1965 - Ongoing
Cataract	Bilateral eyes cataracts	2007 - 2008
Cataract operation	Bilateral eyes cataract lens surgery	2008 - 2008
Prostate cancer	Prostate cancer	2008 - 2008
Prostatectomy	Prostectomy	Jan 2008 - Jan 2008
Pulmonary embolism	Pulmonary embolism	Jan 2008 - Jan 2008
Actinic keratosis	Actinic keratosis - face and scalp	2010 - Ongoing
Drug hypersensitivity	Allergy to cipro	2010 - Ongoing
Herpes zoster	Shingles	2010 - 2010
Cancer surgery	Squamous cell carcinoma removal surgery - right ear	2016 - 2016
Squamous cell carcinoma	Squamous cell carcinoma - right ear	2016 - 2016
Basal cell carcinoma	Basal cell carcinoma - back of the neck	2018 - 2018
Micrographic skin surgery	Moh's surgery - neck	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Warfarin	2008 - 29 Jan 2021 (Study Day 151)	Pulmonary Embolism
Calcium	2010 - Ongoing	Vitamin Deficiency
Vitamin d nos	2010 - Ongoing	Vitamin Deficiency
Simeticone	22 Oct 2020 (Study Day 52) - 26 Oct 2020 (Study Day 56)	Loose Stools
Bilateral duplex lower extremity ultrasound*	29 Jan 2021 (Study Day 151) - 29 Jan 2021 (Study Day 151)	Diagnostic
Enoxaparin sodium	29 Jan 2021 (Study Day 151) - 31 Jan 2021 (Study Day 153)	Dvt Right Leg
Famotidine	29 Jan 2021 (Study Day 151) - 31 Jan 2021 (Study Day 153)	Gi Prophylaxis
Echocardiogram*	30 Jan 2021 (Study Day 152) - 30 Jan 2021 (Study Day 152)	Diagnostic
Apixaban	31 Jan 2021 (Study Day 153) - Ongoing	Dvt Right Leg

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 2/moderate	Not related	22 Oct 2020 (Study Day 52) - 27 Oct 2020 (Study Day 57)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2262 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	06 Sep 2020 (Study Day 5) – 19 Sep 2020 (Study Day 18)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2262, a 37-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 06 Sep 2020 (Study Day 5), 4 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of symptomatic COVID-19 lasted for 14 days, after which it was considered to be recovered/resolved on 19 Sep 2020 (Study Day 18). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000270	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Constipation	Constipation	1989 - Ongoing
Astigmatism	Astigmatism	1996 - 2010
Hypersensitivity	Environmental allergies	1996 - Ongoing
Myopia	Myopia	1996 - 2010
Iron deficiency anaemia	Iron deficiency anemia	1998 - 1999
Keratomileusis	Lasik	2010 - 2010
Rosacea	Rosacea - facial	2013 - Ongoing
Anxiety	Anxiety	2014 - Ongoing
Dysmenorrhoea	Menstrual cramps	2014 - Ongoing
Hypertension	Hypertension	2014 - Ongoing
Perinatal depression	Post-partum depression	2014 - 2014
Urinary tract infection	Uncomplicated urinary tract infection	2014 - 2014
Migraine	Migraine headaches	2017 - Ongoing
Papilloma viral infection	Human papillomavirus	2019 - Ongoing
Ligament sprain	Left sprained ankle	Mar 2020 - Ongoing
Substance use	Marijuana use - oral	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	2014 - Ongoing	Menstrual Cramps
Ibuprofen	2017 - Ongoing	Migraine Headaches
Ibuprofen	Mar 2020 - Ongoing	Left Sprained Ankle
Losartan	Jun 2020 - Ongoing	Hypertension
Paracetamol	04 Sep 2020 (Study Day 3) - 04 Sep 2020 (Study Day 3)	E-Diary Pain - Headache
Paracetamol	12 Sep 2020 (Study Day 11) - 19 Sep 2020 (Study Day 18)	Symptomatic COVID-19
Influenza vaccine	16 Oct 2020 (Study Day 45) - 16 Oct 2020 (Study Day 45)	Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	06 Sep 2020 (Study Day 5) - 19 Sep 2020 (Study Day 18)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2304 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	07 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/Bilateral Pulmonary Embolism	SAE	Grade 3/severe	Not related	25 Oct 2020 (Study Day 47) – 15 Apr 2021 (Study Day 219)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2304, a 55-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 09 Sep 2020 (Study Day 1). The second dose was administered in the right arm on 07 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Oct 2020 (Study Day 47), 46 days after the first dose and 18 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pulmonary embolism. Action taken with the IP was not applicable. The event of bilateral pulmonary embolism lasted for 173 days, after which it was considered to be recovered/resolved with sequelae on 15 Apr 2021 (Study Day 219). The investigator assessed the event of pulmonary embolism to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000628	Pulmonary embolism

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypersensitivity	Environmental allergies	1965 - Ongoing
Asthma	Asthma	1974 - Ongoing
Myopia	Myopia bilateral	1974 - Ongoing
Allergy to animal	Allergy to pet dander	1978 - Ongoing
Carpal tunnel syndrome	Right carpal tunnel	1994 - 12 Jun 2020 (Study Day -89)
Depression	Depression	1996 - Ongoing
Insomnia	Insomnia	1996 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1998 - Ongoing
Back pain	Chronic back pain	2010 - Ongoing
Neck pain	Chronic neck pain	2010 - Ongoing
Cystocele	Cystocele	16 Nov 2013 (Study Day -2489) - 16 Nov 2013 (Study Day -2489)
Cystocele repair	Cystocele surgery	16 Nov 2013 (Study Day -2489) - 16 Nov 2013 (Study Day -2489)
Urinary tract infection	Frequent urinary tract infections	2015 - Ongoing
Cystocele	Cystocele	17 Aug 2015 (Study Day -1850) - 17 Aug 2015 (Study Day -1850)
Cystocele repair	Cystocele surgery	17 Aug 2015 (Study Day -1850) - 17 Aug 2015 (Study Day -1850)
Menopause	Peri menopause	2017 - Ongoing
Carpal tunnel decompression	Right carpal tunnel release	12 Jun 2020 (Study Day -89) - 12 Jun 2020 (Study Day -89)
Tendon sheath incision	Right trigger finger release	12 Jun 2020 (Study Day -89) - 12 Jun 2020 (Study Day -89)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1974 - Ongoing	Asthma
Cetirizine hydrochloride	1978 - Ongoing	Pet Dander And Environmental Allergies
Amitriptyline	1996 - Ongoing	Depression / Insomnia
Bupropion hydrochloride	1996 - Ongoing	Depression
Fluoxetine	1996 - Ongoing	Depression
Colecalciferol	1998 - Ongoing	Vitamin Deficiency
Magnesium	1998 - Ongoing	Vitamin Deficiency
Pantoprazole	1998 - Ongoing	Gastroesophageal Reflux Disease

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1998 - Ongoing	Vitamin Deficiency
Zinc	1998 - Ongoing	Vitamin Deficiency
Gabapentin	2010 - Ongoing	Chronic Back Pain
Hydrocodone bitartrate; paracetamol	2010 - Ongoing	Post Surgical Pain
Naproxen	2010 - 29 Oct 2020 (Study Day 51)	Chronic Back Pain
Estradiol	2017 - Ongoing	Peri-Menopause
Ethinylestradiol; etonogestrel	2018 - 11 Nov 2020 (Study Day 64)	Pregnancy
Chest x-ray*	29 Oct 2020 (Study Day 51) - 29 Oct 2020 (Study Day 51)	Diagnostic
Cta pulmonary embolus*	29 Oct 2020 (Study Day 51) - 29 Oct 2020 (Study Day 51)	Diagnostic
Heparin	29 Oct 2020 (Study Day 51) - 03 Nov 2020 (Study Day 56)	Bilateral Pulmonary Embolism
Bilateral venous duplex lower extremity ultrasound*	30 Oct 2020 (Study Day 52) - 30 Oct 2020 (Study Day 52)	Diagnostic
Chest x-ray*	02 Nov 2020 (Study Day 55) - 02 Nov 2020 (Study Day 55)	Diagnostic
Apixaban	03 Nov 2020 (Study Day 56) - Ongoing	Sae- Bilateral Pulmonary Embolism
Cyclobenzaprine	22 Feb 2021 (Study Day 167) - Ongoing	Chronic Back Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	08 Oct 2020 (Study Day 30) - 18 Oct 2020 (Study Day 40)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US373-2311 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Device Dislocation/Displaced Left Breast Silicone Implant	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	29 Sep 2020 (Study Day 20) – 05 Oct 2020 (Study Day 26)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2311, a 32-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Sep 2020 (Study Day 20), 19 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of device dislocation. On 07 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of displaced left breast silicone implant lasted for 7 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 26). The investigator assessed the event of device dislocation to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	1995 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Substance use	Marijuana use	2015 - Ongoing
Mammoplasty	Bilateral breast augmentation surgery	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fish oil	2010 - Ongoing	Malnutrition
Vitamins nos	2010 - Ongoing	Vitamin Deficiency
Quetiapine	2019 - Ongoing	Insomnia
Ibuprofen	18 Sep 2020 (Study Day 9) - 22 Oct 2020 (Study Day 43)	Left Axillary Lymphadenopathy
Bilateral breast implant removal and left pectoral muscle repair*	05 Oct 2020 (Study Day 26) - 05 Oct 2020 (Study Day 26)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Lymphadenopathy	Grade 1/mild	Related	18 Sep 2020 (Study Day 9) - 22 Oct 2020 (Study Day 43)
Device Dislocation	Grade 2/moderate	Not related	29 Sep 2020 (Study Day 20) - 05 Oct 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2022 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ COVID 19	SAE	Grade 1/mild	Not related	24 Nov 2020 (Study Day 98) – 15 Dec 2020 (Study Day 119)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2022, a 38-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 19 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Nov 2020 (Study Day 98), 97 days after the first dose and 69 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID 19 lasted for 22 days, after which it was considered to be recovered/resolved on 15 Dec 2020 (Study Day 119). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001076	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Asthma	Asthma [mild]	1989 - Ongoing
Endometriosis	Endometriosis	1997 - Ongoing
Eczema	Generalized eczema	2010 - Ongoing
Generalised anxiety disorder	Generalized anxiety disorder	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2015 - Ongoing
Depression	Depression	2018 - Ongoing
Arthralgia	Hip pain	Aug 2020 - Ongoing
Back pain	Back pain	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	2010 - Ongoing	Supplement
Diazepam	2010 - Ongoing	Generalized Anxiety Disorder
Fluocinonide	2010 - Ongoing	Eczema
Levosalbutamol	2010 - Ongoing	Asthma
Loratadine	2010 - Ongoing	Seasonal Allergies
Vitamins nos	2010 - Ongoing	Supplement
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	2015 - Ongoing	Attention Defecit Disorder
Fluticasone	2015 - Ongoing	Nasal Allergies
Montelukast	2015 - Ongoing	Seasonal Allergies/ Asthma
Citalopram	2018 - Ongoing	Depression
Ethinylestradiol; etonogestrel	2018 - Ongoing	Contraception
Probiotics nos	2019 - Ongoing	Supplement
Colecalciferol	2020 - Oct 2020	Supplement
Linum usitatissimum seed	2020 - Ongoing	Supplement
Ibuprofen	26 Aug 2020 (Study Day 8) - Ongoing	Seasonal Allergies
Oxymetazoline hydrochloride	31 Aug 2020 (Study Day 13) - 02 Sep 2020 (Study Day 15)	Seasonal Allergies
Colecalciferol	Oct 2020 - Ongoing	Supplement
Influenza vaccine	03 Oct 2020 (Study Day 46) - 03 Oct 2020 (Study Day 46)	Prophylaxis Seasonal Flu Vaccine
Meloxicam	15 Oct 2020 (Study Day 58) - Ongoing	Hip And Back Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Doxycycline	24 Nov 2020 (Study Day 98) - 11 Dec 2020 (Study Day 115)	Sinus Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Back Pain	Grade 1/mild	Not related	24 Aug 2020 (Study Day 6) - 24 Aug 2020 (Study Day 6)
Injection Site Pain	Grade 1/mild	Not related	03 Oct 2020 (Study Day 46) - 07 Oct 2020 (Study Day 50)
Diarrhoea	Grade 1/mild	Not related	04 Oct 2020 (Study Day 47) - 04 Oct 2020 (Study Day 47)
Diarrhoea	Grade 1/mild	Not related	18 Nov 2020 (Study Day 92) - 18 Nov 2020 (Study Day 92)
Sinusitis	Grade 2/moderate	Not related	18 Nov 2020 (Study Day 92) - 11 Dec 2020 (Study Day 115)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2076 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	22 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Osteoarthritis/Worsening Osteoarthritis	SAE	Grade 2/moderate	Not related	12 Jan 2021 (Study Day 141) – 04 Mar 2021 (Study Day 192)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2076, a 76-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 22 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Jan 2021 (Study Day 141), 140 days after the first dose and 112 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of osteoarthritis. Action taken with the IP was not applicable. The event of worsening osteoarthritis lasted for 52 days, after which it was considered to be recovered/resolved on 04 Mar 2021 (Study Day 192). The investigator assessed the event of osteoarthritis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005459	Osteoarthritis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Menopause	Menopause	Jun 1990 - Ongoing
Drug hypersensitivity	Neosporin allergy	2000 - Ongoing
Hypothyroidism	Hypothyroidism	2000 - Ongoing
Osteoarthritis	Osteoarthritis	2000 - Ongoing
Coronary artery disease	Coronary artery disease	2017 - Ongoing
Blood cholesterol increased	High cholesterol	Mar 2017 - Ongoing
Hypertension	Hypertension	Mar 2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2000 - Ongoing	Osteoarthritis
Levothyroxine	2000 - Ongoing	Hypothyroidism
Acetylsalicylic acid	Mar 2017 - Ongoing	Prophylaxis Coronary Artery Disease
Atorvastatin	Mar 2017 - Ongoing	High Cholesterol
Metoprolol	Mar 2017 - Ongoing	Hypertension
Influenza vaccine	10 Oct 2020 (Study Day 47) - 10 Oct 2020 (Study Day 47)	Flu Prevention
Cefazolin	12 Jan 2021 (Study Day 141) - 14 Jan 2021 (Study Day 143)	Post Op Prophylaxis
Fentanyl	12 Jan 2021 (Study Day 141) - 13 Jan 2021 (Study Day 142)	Post Op Pain
Paracetamol	12 Jan 2021 (Study Day 141) - Ongoing	Post Operative Right Shoulder Pain
Right should replacement for worsening osteoarthritis*	12 Jan 2021 (Study Day 141) - 12 Jan 2021 (Study Day 141)	Adverse Event
Amlodipine	14 Jan 2021 (Study Day 143) - Ongoing	Worsening Htn
Oxycodone	14 Jan 2021 (Study Day 143) - 16 Jan 2021 (Study Day 145)	Post Op Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	12 Jan 2021 (Study Day 141) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2132 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pelvic Pain/Left Side Pelvic Pain	SAE	Grade 3/severe	Not related	10 Jan 2021 (Study Day 136) – 11 Jan 2021 (Study Day 137)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2132, a 28-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 25 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Jan 2021 (Study Day 136), 135 days after the first dose and 107 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pelvic pain. Action taken with the IP was not applicable. The event of left side pelvic pain lasted for 2 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 137). The investigator assessed the event of pelvic pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-018733	Pelvic pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to cefaclor	1995 - Ongoing
Adenoidectomy	Adenoidectomy	1999 - 1999
Drug hypersensitivity	Allergy bactrim	10 Jan 2010 (Study Day -3883) - Ongoing
Adnexal torsion	Right ovarian torsion	Feb 2020 - Feb 2020
Ovarian cyst	Right ovarian cyst	Feb 2020 - Feb 2020
Ovarian cystectomy	Laparoscopic ovarian cystectomy	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Botulinum toxin type a	25 Sep 2020 (Study Day 29) - 25 Sep 2020 (Study Day 29)	Cosmetic To Forehead Wrinkles
Paracetamol	25 Sep 2020 (Study Day 29) - 28 Sep 2020 (Study Day 32)	Pain And Fever
Influenza vaccine	12 Oct 2020 (Study Day 46) - 12 Oct 2020 (Study Day 46)	Flu Prophylaxis
Doppler ultrasound*	10 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 136)	Adverse Event
Ibuprofen	10 Jan 2021 (Study Day 136) - 11 Jan 2021 (Study Day 137)	Left-Sided Pelvic Pain
Oxycodone	10 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 136)	Left-Sided Pelvic Pain
Paracetamol	10 Jan 2021 (Study Day 136) - 11 Jan 2021 (Study Day 137)	Left-Sided Pelvic Pain
Pelvic ultrasound*	10 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 136)	Adverse Event
Transvaginal uhaa sound*	10 Jan 2021 (Study Day 136) - 10 Jan 2021 (Study Day 136)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphadenopathy	Grade 1/mild	Related	01 Sep 2020 (Study Day 5) - 04 Sep 2020 (Study Day 8)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Viral Infection	Grade 1/mild	Not related	18 Oct 2020 (Study Day 52) - 25 Oct 2020 (Study Day 59)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3380297

Participant Number:	US374-2330 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Respiratory Failure/Acute Hypoxemic Respiratory Failure	SAE	Grade 3/severe	Not related	28 Nov 2020 (Study Day 79) – 03 Dec 2020 (Study Day 84)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2330, a 74-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Nov 2020 (Study Day 79), 78 days after the first dose and 50 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute hypoxemic respiratory failure lasted for 6 days, after which it was considered to be recovered/resolved on 03 Dec 2020 (Study Day 84). The investigator assessed the event of acute respiratory failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000955	Acute Respiratory Failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Menopause	Menopause	2000 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Nephrectomy	Nephrectomy (r)	2006 - Ongoing
Renal failure	Stage 2 renal insufficiency	2006 - Ongoing
Fluid retention	Fluid retention	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Sinus congestion	Sinus congestion	2010 - Ongoing
Osteoarthritis	Osteoarthritis - bilateral knees	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	1985 - 29 Nov 2020 (Study Day 80)	Cardiac
Amlodipine	2005 - Ongoing	Hypertension
Metoprolol	2005 - Ongoing	Hypertension
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Fexofenadine hydrochloride	2010 - Oct 2020	Sinus Congestion
Furosemide	05 Aug 2020 (Study Day -37) - 29 Nov 2020 (Study Day 80)	Fluid Retention
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	22 Sep 2020 (Study Day 12) - Ongoing	Nasal Congestion
Ibuprofen	22 Sep 2020 (Study Day 12) - 07 Oct 2020 (Study Day 27)	Sinus Headache
Paracetamol	09 Oct 2020 (Study Day 29) - 09 Oct 2020 (Study Day 29)	Sinus Headache
Losartan	19 Oct 2020 (Study Day 39) - Ongoing	Renal Insufficiency
Influenza vaccine	27 Oct 2020 (Study Day 47) - 27 Oct 2020 (Study Day 47)	Influenza Prophylaxis
Paracetamol	27 Oct 2020 (Study Day 47) - 27 Oct 2020 (Study Day 47)	Left Arm Pain From Seasonal Influenza Vaccine
Dabigatran	30 Nov 2020 (Study Day 81) - Ongoing	Atrial Fibrillation
Furosemide	30 Nov 2020 (Study Day 81) - 03 Dec 2020 (Study Day 84)	Acute Hypoxemic Respiratory Failure
Furosemide	30 Nov 2020 (Study Day 81) - Ongoing	Fluid Retention
Spironolactone	30 Nov 2020 (Study Day 81) - 19 Feb 2021 (Study Day 162)	Fluid Retention

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Oxygen	03 Dec 2020 (Study Day 84) - 09 Feb 2021 (Study Day 152)	Acute Hypoxemic Respiratory Failure
Chest ct for evaulation of chf*	29 Dec 2020 (Study Day 110) - 29 Dec 2020 (Study Day 110)	Adverse Event
Fluticasone propionate	30 Dec 2020 (Study Day 111) - Ongoing	Sinus Congestion
Corticosteroid nos	06 Jan 2021 (Study Day 118) - 06 Jan 2021 (Study Day 118)	Ostearthritis
Corticosteroid nos	06 Jan 2021 (Study Day 118) - 06 Jan 2021 (Study Day 118)	Osteoarthritis
Spironolactone	19 Feb 2021 (Study Day 162) - Ongoing	Fluid Retention
Sleep study*	25 Feb 2021 (Study Day 168) - 25 Feb 2021 (Study Day 168)	Other, Rule Out Sleep Apnea

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Sinus Headache	Grade 1/mild	Not related	22 Sep 2020 (Study Day 12) - 29 Sep 2020 (Study Day 19)
Cough	Grade 1/mild	Not related	23 Sep 2020 (Study Day 13) - 28 Sep 2020 (Study Day 18)
Nasal Congestion	Grade 1/mild	Not related	23 Sep 2020 (Study Day 13) - 28 Sep 2020 (Study Day 18)
Injection Site Pain	Grade 1/mild	Not related	27 Oct 2020 (Study Day 47) - 27 Oct 2020 (Study Day 47)
Cardiac Failure Congestive	Grade 3/severe	Not related	26 Nov 2020 (Study Day 77) - Ongoing
Arteriosclerosis	Grade 2/moderate	Not related	29 Nov 2020 (Study Day 80) - Ongoing
Atrial Fibrillation	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 84) - Ongoing
Chronic Kidney Disease	Grade 2/moderate	Not related	03 Dec 2020 (Study Day 84) - 27 Jan 2021 (Study Day 139)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2342 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Major Depression/Major Depressive Disorder Without Psychotic Features	SAE	Grade 3/severe	Not related	16 Sep 2020 (Study Day 6) – 17 Sep 2020 (Study Day 7)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2342, a 18-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 6), 5 days after the first dose and 23 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of major depression. The IP dose was not changed due to the major depressive disorder without psychotic features. The event of major depressive disorder without psychotic features lasted for 2 days, after which it was considered to be recovered/resolved on 17 Sep 2020 (Study Day 7). The investigator assessed the event of major depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000313	Major Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Childhood asthma	Childhood asthma	2008 - 2013
Depression	Depression	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atomoxetine hydrochloride	14 Jan 2019 (Study Day -606) - Ongoing	Depression
Ethinylestradiol; levonorgestrel	May 2019 - Ongoing	Birth Control
Sertraline hydrochloride	19 Sep 2020 (Study Day 9) - Oct 2020	Depression
Sertraline hydrochloride	Oct 2020 - Ongoing	Depression
Influenza vaccine	21 Oct 2020 (Study Day 41) - 21 Oct 2020 (Study Day 41)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US374-2364 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	15 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Syncope/Syncope	SAE	Grade 3/severe	Not related	10 Jan 2021 (Study Day 116) – 11 Jan 2021 (Study Day 117)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2364, a 64-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 15 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Jan 2021 (Study Day 116), 115 days after the first dose and 87 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncope lasted for 2 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 117). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005513	Syncope

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1990 - Ongoing
HIV infection	Hiv	1990 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2000 - Ongoing
Deep vein thrombosis	Deep vein thrombosis	2016 - Ongoing
Myocardial infarction	Myocardial infarction 1	2017 - 2017
Cardiac pacemaker insertion	Placement of pacemaker	04 Aug 2017 (Study Day -1140) - 04 Aug 2017 (Study Day -1140)
Myocardial infarction	Myocardial infarction 2	2018 - 2018
Anxiety	Anxiety	15 Apr 2020 (Study Day -155) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2017 - Ongoing	Leg Pain From Hx Of Deep Vein Thrombosis
Atorvastatin	2018 - Ongoing	Cardiac Prophylaxis
Dolutegravir sodium	2018 - Ongoing	Hiv
Emtricitabine; tenofovir alafenamide fumarate	2018 - Ongoing	Hiv
Metoprolol	2018 - Ongoing	Cardiac Prophylaxis
Mometasone furoate	2018 - Ongoing	Sleep Apnea
Apixaban	2019 - Ongoing	Deep Vein Thrombosis
Clonazepam	Apr 2020 - Ongoing	Anxiety
Escitalopram	May 2020 - 11 Nov 2020 (Study Day 56)	Anxiety
Gabapentin	May 2020 - Ongoing	Anxiety
Paracetamol	28 Sep 2020 (Study Day 12) - 29 Sep 2020 (Study Day 13)	Viral Illness Unspecified
Lorazepam	04 Oct 2020 (Study Day 18) - 04 Oct 2020 (Study Day 18)	Anxiety
Influenza vaccine	05 Nov 2020 (Study Day 50) - 05 Nov 2020 (Study Day 50)	Prophylaxis Flu Vaccine
Pneumococcal vaccine polysacch 23v	05 Nov 2020 (Study Day 50) - 05 Nov 2020 (Study Day 50)	Prophylaxis Pneumonia Vaccine
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	06 Nov 2020 (Study Day 51) - 06 Nov 2020 (Study Day 51)	Viral Illness Unspecified
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	06 Nov 2020 (Study Day 51) - 09 Nov 2020 (Study Day 54)	Viral Illness Unspecified

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sulfamethoxazole; trimethoprim	06 Nov 2020 (Study Day 51) - 10 Nov 2020 (Study Day 55)	Viral Illness Unspecified (Cough)
Ultrasound on left calf for dvt*	11 Nov 2020 (Study Day 56) - 11 Nov 2020 (Study Day 56)	Diagnostic
Benzonatate	14 Nov 2020 (Study Day 59) - Ongoing	Anxiety
Escitalopram	14 Nov 2020 (Study Day 59) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Not related	22 Sep 2020 (Study Day 6) - 02 Oct 2020 (Study Day 16)
Chills	Grade 1/mild	Not related	23 Sep 2020 (Study Day 7) - 02 Oct 2020 (Study Day 16)
Viral Infection	Grade 2/moderate	Not related	27 Sep 2020 (Study Day 11) - 08 Oct 2020 (Study Day 22)
Pain In Extremity	Grade 2/moderate	Not related	01 Oct 2020 (Study Day 15) - 05 Oct 2020 (Study Day 19)
Peripheral Swelling	Grade 1/mild	Not related	01 Oct 2020 (Study Day 15) - 05 Oct 2020 (Study Day 19)
Pain In Extremity	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 43) - 23 Nov 2020 (Study Day 68)
Peripheral Swelling	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 43) - 23 Nov 2020 (Study Day 68)
Viral Infection	Grade 2/moderate	Not related	05 Nov 2020 (Study Day 50) - 19 Nov 2020 (Study Day 64)
Anxiety	Grade 2/moderate	Not related	08 Jan 2021 (Study Day 114) - Ongoing
Musculoskeletal Pain	Grade 2/moderate	Not related	01 Mar 2021 (Study Day 166) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2384 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	16 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	13 Oct 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diverticulitis/Diverticulitis	SAE	Grade 3/severe	Not related	01 Nov 2020 (Study Day 47) – 09 Nov 2020 (Study Day 55)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2384, a 40-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 47), 46 days after the first dose and 19 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diverticulitis. Action taken with the IP was not applicable. The event of diverticulitis lasted for 9 days, after which it was considered to be recovered/resolved with sequelae on 09 Nov 2020 (Study Day 55). The investigator assessed the event of diverticulitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000625	Diverticulitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Pneumonia	Pneumonia	Not reported
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Hypertension	Hypertension	30 Jun 2017 (Study Day -1174) - Ongoing
Sarcoidosis	Sarcoidosis	2019 - Ongoing
Pneumonia	Pneumonia	Apr 2019 - Apr 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2015 - Ongoing	Vitamin D Deficiency
Varenicline tartrate	12 Dec 2016 (Study Day -1374) - Ongoing	Smoking Cessation
Hydrochlorothiazide	30 Jun 2017 (Study Day -1174) - Ongoing	Hypertension
Losartan	30 Jun 2017 (Study Day -1174) - Ongoing	Hypertension
Chromium nicotinate; nicotinic acid	Jan 2018 - Ongoing	Supplement Prophylaxis
Fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	2019 - Ongoing	Sarcoidosis
Prednisone	Jul 2019 - Ongoing	Sarcoidosis
Choline; inositol; methionine	02 Oct 2020 (Study Day 17) - Ongoing	Obesity
Vitamin b12 nos	02 Oct 2020 (Study Day 17) - Ongoing	Obesity
Metronidazole	08 Oct 2020 (Study Day 23) - 15 Oct 2020 (Study Day 30)	Bacterial Vaginosis
Acetylsalicylic acid; caffeine	13 Oct 2020 (Study Day 28) - 13 Oct 2020 (Study Day 28)	Headache
Ibuprofen	13 Oct 2020 (Study Day 28) - 17 Oct 2020 (Study Day 32)	Headache
Influenza vaccine	28 Oct 2020 (Study Day 43) - 28 Oct 2020 (Study Day 43)	Influenza Prophylaxis
Levofloxacin	01 Nov 2020 (Study Day 47) - 09 Nov 2020 (Study Day 55)	Thrombus Prophylaxis
Ondansetron	01 Nov 2020 (Study Day 47) - 09 Nov 2020 (Study Day 55)	Nausea/Diverticulitis
Piperacillin; tazobactam	01 Nov 2020 (Study Day 47) - 09 Nov 2020 (Study Day 55)	Diverticulitis
Ketorolac	02 Nov 2020 (Study Day 48) - 09 Nov 2020 (Study Day 55)	Diverticulitis
Labetalol	02 Nov 2020 (Study Day 48) - 09 Nov 2020 (Study Day 55)	Hypertension
Hartman’s procedure*	05 Nov 2020 (Study Day 51) - 05 Nov 2020 (Study Day 51)	Adverse Event
Levofloxacin	10 Nov 2020 (Study Day 56) - 17 Nov 2020 (Study Day 63)	Pneumonia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metronidazole	10 Nov 2020 (Study Day 56) - 17 Nov 2020 (Study Day 63)	Diverticulitis
Oxycodone hydrochloride; paracetamol	10 Nov 2020 (Study Day 56) - 25 Nov 2020 (Study Day 71)	Post-Op Pain
Potassium chloride	10 Nov 2020 (Study Day 56) - 13 Nov 2020 (Study Day 59)	Hypokalemia
Hydrocodone bitartrate; paracetamol	27 Nov 2020 (Study Day 73) - 15 Dec 2020 (Study Day 91)	Post-Op Pain
Cyclobenzaprine hydrochloride	15 Dec 2020 (Study Day 91) - 30 Dec 2020 (Study Day 106)	Lower Back Muscle Strain
Zolpidem tartrate	15 Dec 2020 (Study Day 91) - 04 Jan 2021 (Study Day 111)	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Bacterial Vaginosis	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 22) - 15 Oct 2020 (Study Day 30)
Headache	Grade 1/mild	Not related	13 Oct 2020 (Study Day 28) - 13 Oct 2020 (Study Day 28)
Pneumonia	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 56) - Ongoing
Insomnia	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 91) - 04 Jan 2021 (Study Day 111)
Muscle Strain	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 91) - 30 Dec 2020 (Study Day 106)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2395 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Deep Vein Thrombosis/Deep Vein Thrombosis	AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	25 Sep 2020 (Study Day 9) – 15 Feb 2021 (Study Day 152)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2395, a 61-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of deep vein thrombosis. On 14 Oct 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of deep vein thrombosis lasted for 144 days, after which it was considered to be recovered/resolved with sequelae on 15 Feb 2021 (Study Day 152). The investigator assessed the event of deep vein thrombosis to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to penicillin	1970 - Ongoing
Contrast media allergy	Allergy to contrast dye	1982 - Ongoing
HIV infection	Human immunodeficiency virus (hiv)	1988 - Ongoing
Deep vein thrombosis	Deep vein thrombosis	Feb 2019 - Feb 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bictegravir sodium; emtricitabine; tenofovir alafenamide fumarate	2018 - Ongoing	Human Immunodeficiency Virus
Enoxaparin	25 Sep 2020 (Study Day 9) - 04 Nov 2020 (Study Day 49)	Deep Vein Thrombosis
Influenza vaccine	06 Oct 2020 (Study Day 20) - 06 Oct 2020 (Study Day 20)	Influenza Prophylaxis
Apixaban	05 Nov 2020 (Study Day 50) - Ongoing	Deep Vein Thrombosis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Deep Vein Thrombosis	Grade 3/severe	Not related	25 Sep 2020 (Study Day 9) - 15 Feb 2021 (Study Day 152)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2129 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Papillary Thyroid Cancer/Papillary Thyroid Carcinoma Exacerbation	SAE	Grade 4	Not related	01 Oct 2020 (Study Day 45) – 02 Oct 2020 (Study Day 46)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2129, a 46-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Oct 2020 (Study Day 45), 44 days after the first dose and 10 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of papillary thyroid cancer. Action taken with the IP was not applicable. The event of papillary thyroid carcinoma exacerbation lasted for 2 days, after which it was considered to be recovered/resolved on 02 Oct 2020 (Study Day 46). The investigator assessed the event of papillary thyroid cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000702	Papillary Thyroid Cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Thyroid cancer	Thyroid carcinoma	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levonorgestrel	2019 - 2019	Contraceptive
Left thyroid fine needle aspiration with biopsy*	28 Aug 2020 (Study Day 11) - 28 Aug 2020 (Study Day 11)	Medical History
Naproxen sodium	22 Sep 2020 (Study Day 36) - 22 Sep 2020 (Study Day 36)	Injection Site Pain
Calcium carbonate; colecalciferol	02 Oct 2020 (Study Day 46) - Ongoing	Hypocalcemia
Doxycycline	02 Oct 2020 (Study Day 46) - 07 Oct 2020 (Study Day 51)	Post Procedure Infection Prophylaxis
Total thyroidectomy*	02 Oct 2020 (Study Day 46) - 02 Oct 2020 (Study Day 46)	Adverse Event
Influenza vaccine	21 Oct 2020 (Study Day 65) - 21 Oct 2020 (Study Day 65)	Influenza Prophylaxis
Thyroid cancer ablation with i-131*	22 Oct 2020 (Study Day 66) - 22 Oct 2020 (Study Day 66)	Adverse Event
Levothyroxine sodium	26 Oct 2020 (Study Day 70) - Ongoing	Hypothyroidism Due To Thyroid Cancer
Total body iodine scan*	04 Nov 2020 (Study Day 79) - 04 Nov 2020 (Study Day 79)	Adverse Event
Botulinum toxin type a	12 Feb 2021 (Study Day 179) - 12 Feb 2021 (Study Day 179)	Cosmetic Elective
Tetanus vaccine	15 Mar 2021 (Study Day 210) - 15 Mar 2021 (Study Day 210)	Tetanus Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 2/moderate	Related	21 Sep 2020 (Study Day 35) - 02 Oct 2020 (Study Day 46)
Hypocalcaemia	Grade 1/mild	Not related	02 Oct 2020 (Study Day 46) - 20 Jan 2021 (Study Day 156)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2245 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 43)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Facial Paralysis/Bell's Palsy	SAE	Grade 3/severe	Not related	06 Nov 2020 (Study Day 74) – 29 Dec 2020 (Study Day 127)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2245, a 67-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 43). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Nov 2020 (Study Day 74), 73 days after the first dose and 31 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of facial paralysis. Action taken with the IP was not applicable. The event of bell's palsy lasted for 54 days, after which it was considered to be recovered/resolved on 29 Dec 2020 (Study Day 127). The investigator assessed the event of facial paralysis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000678	Bell's palsy

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arthralgia	Joint pain (location and associated medical condition unknown)	Not reported - Ongoing
Cerebrovascular accident	Previous cerebrovascular accident	Not reported
Drug hypersensitivity	Naproxen allergy	Not reported - Ongoing
Drug hypersensitivity	Penicillin allergy	Not reported - Ongoing
Rubber sensitivity	Latex allergy	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Tonsillectomy	Tonsillectomy	1974 - 1974
Female sterilisation	Tubal ligation	1979 - 1979
Biopsy breast	Breast biopsy (unknown if benign or malignant)	1994 - 1994
Colonoscopy	Colonoscopy	2003 - 2003
Biopsy breast	Breast biopsy (unknown if benign or malignant)	2004 - 2004
Urinary incontinence	Urinary incontinence	2004 - Ongoing
Depression	Depression	2010 - Ongoing
Appendicectomy	Appendectomy	2017 - 2017
Colonoscopy	Colonoscopy	2017 - 2017
Sleep apnoea syndrome	Obstructive sleep apnea	2017 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type ii	2017 - Ongoing
Asthma	Asthma	2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2018 - Ongoing
Tendonitis	Tendinitis bilateral wrists	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram oxalate	2010 - Ongoing	Depression
Cannabidiol	2017 - Ongoing	Supplement
Cetirizine hydrochloride	2017 - Ongoing	Seasonal Allergies
Cinnamomum verum	2017 - Ongoing	Supplement
Curcumin	2017 - Ongoing	Supplement
Fexofenadine	2017 - Ongoing	Seasonal Allergies
Fish oil	2017 - Ongoing	Supplement
Meloxicam	2017 - Ongoing	Joint Pain (Type And Locaton Unknown)
Nicotinic acid	2017 - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2017 - Ongoing	Supplement
Fenofibrate	2018 - Ongoing	Hyperlipidemia
Rosuvastatin	2018 - Ongoing	Hyperlipidemia
Metformin	2019 - Ongoing	Type Ii Diabetes Mellitus
Azelastine	2020 - Ongoing	Seasonal Allergies
Curcuma longa	2020 - Ongoing	Supplement
Ibuprofen	2020 - Ongoing	Supplement
Ibuprofen; paracetamol	2020 - Ongoing	General Pain Relief
Salbutamol	2020 - Ongoing	Asthma
Vitamin b complex	2020 - Ongoing	Supplement
Ibuprofen	01 Oct 2020 (Study Day 38) - Ongoing	Tendinitis Bilateral Wrists
Corticosteroid nos	06 Oct 2020 (Study Day 43) - 06 Oct 2020 (Study Day 43)	Tendinitis Bilateral Wrists
Influenza vaccine	20 Oct 2020 (Study Day 57) - 20 Oct 2020 (Study Day 57)	Prevention Of Seasonal Influenza
Chest x-ray*	06 Nov 2020 (Study Day 74) - 06 Nov 2020 (Study Day 74)	Adverse Event
Ct w/o contrast*	06 Nov 2020 (Study Day 74) - 06 Nov 2020 (Study Day 74)	Diagnostic
Enoxaparin sodium	06 Nov 2020 (Study Day 74) - 07 Nov 2020 (Study Day 75)	Stroke Prevention
Mri*	06 Nov 2020 (Study Day 74) - 06 Nov 2020 (Study Day 74)	Adverse Event
Clopidogrel bisulfate	08 Nov 2020 (Study Day 76) - 11 Nov 2020 (Study Day 79)	Prevention Of Stroke
Valaciclovir	08 Nov 2020 (Study Day 76) - 18 Nov 2020 (Study Day 86)	Treatment Of Bell’s Palsy
Methylprednisolone	11 Nov 2020 (Study Day 79) - 11 Nov 2020 (Study Day 79)	Treatment Of Bell’s Palsy
Prednisone	16 Nov 2020 (Study Day 84) - 22 Nov 2020 (Study Day 90)	Treatment Of Bell’s Palsy
Pseudoephedrine hydrochloride	10 Dec 2020 (Study Day 108) - 13 Dec 2020 (Study Day 111)	Nasal Congestion
Carotid artery doppler*	15 Mar 2021 (Study Day 203) - 15 Mar 2021 (Study Day 203)	Adverse Event
Acetylsalicylic acid	22 Mar 2021 (Study Day 210) - Ongoing	Thrombolytic Prophylaxis
Mri w/ contrast*	25 Mar 2021 (Study Day 213) - 25 Mar 2021 (Study Day 213)	Adverse Event
Mri w/o contrast*	25 Mar 2021 (Study Day 213) - 25 Mar 2021 (Study Day 213)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nasal Congestion	Grade 1/mild	Not related	07 Dec 2020 (Study Day 105) - 15 Dec 2020 (Study Day 113)
Oropharyngeal Pain	Grade 1/mild	Not related	07 Dec 2020 (Study Day 105) - 13 Dec 2020 (Study Day 111)
Rhinorrhoea	Grade 1/mild	Not related	07 Dec 2020 (Study Day 105) - 15 Dec 2020 (Study Day 113)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2259 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	23 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/Simultaneous Occurrence Of Atrial Fibrillation	SAE	Grade 4	Not related	20 Dec 2020 (Study Day 117) – 21 Dec 2020 (Study Day 118)	Recovered/ resolved
Atrial Flutter/Simultaneous Occurrence Of Atrial Flutter	SAE	Grade 4	Not related	20 Dec 2020 (Study Day 117) – 21 Dec 2020 (Study Day 118)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2259, a 74-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 23 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Dec 2020 (Study Day 117), 116 days after the first dose and 88 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of simultaneous occurrence of atrial fibrillation lasted for 2 days, after which it was considered to be recovered/resolved on 21 Dec 2020 (Study Day 118). The investigator assessed the event of atrial fibrillation to be not related to the IP.

On 20 Dec 2020 (Study Day 117), 116 days after the first dose and 88 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of atrial flutter. Action taken with the IP was not applicable. The event of simultaneous occurrence of atrial flutter lasted for 2 days, after which it was considered to be recovered/resolved with sequelae on 21 Dec 2020 (Study Day 118). The investigator assessed the event of atrial flutter to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Terms
MOD-2020-001228	Atrial fibrillation
MOD-2020-001228	Atrial flutter

Study Completion/Discontinuation

On 03 Feb 2021 (Study Day 162), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Adenoidectomy	Adenoidectomy	Not reported
Aortic valve replacement	Aortic valve replacement	Not reported
Coronary artery bypass	Coronary artery bypass graft	Not reported
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Inguinal hernia repair	Inguinal hernia surgery times 3	Not reported
Lipoma excision	Lipoma removal right neck	Not reported
Tonsillectomy	Tonsillectomy	Not reported
Eyeglasses therapy	Glasses (unknown associated condition/diagnosis)	1960 - Ongoing
Vasectomy	Vasectomy	1976 - 1976
Nephrolithiasis	Kidney stones	1980 - Ongoing
Osteoarthritis	Osteoarthritis (unknown site)	1990 - Ongoing
Deafness	Hearing loss	2010 - Ongoing
Eczema	Eczema	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Type V hyperlipidaemia	Mixed hyperlipidemia	2010 - Ongoing
Cardiac murmur	Cardiac murmur due to coronary artery bypass grafting and aortic valve replacement	2012 - Ongoing
Colitis ulcerative	Ulcerative colitis history	2015 - 2019
Macular degeneration	Macular degeneration	2015 - Ongoing
Pneumonia	Pneumonia	2015 - 2015
Muscle spasms	Muscle spasms	2017 - Ongoing
Glucose tolerance impaired	Prediabetic	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2010 - 21 Dec 2020 (Study Day 118)	Heart Health
Magnesium	2010 - Ongoing	Heart Health
Silybum marianum	2010 - Ongoing	Liver Health
Thiamine	2010 - Ongoing	Supplement
Vitamins nos	2010 - Ongoing	General Health Supplement
Ascorbic acid; betacarotene; cupric oxide; tocopheryl acetate; zinc oxide	2015 - Ongoing	Dry Eyes
Tizanidine	2017 - Ongoing	Muscle Relaxant For Muscle Spasms
Atenolol	14 May 2018 (Study Day -835) - Ongoing	Heart Health
Meloxicam	2019 - Ongoing	Osteoarthritis (Upper And Lower Extremities)
Metoprolol	2019 - 21 Dec 2020 (Study Day 118)	Hypertension
Simvastatin	2019 - 21 Dec 2020 (Study Day 118)	Hypercholesterolemia
Mesalazine	2020 - Ongoing	Ulcerative Colitis
Cetirizine	07 May 2020 (Study Day -111) - Ongoing	Seasonal Allergies
Influenza vaccine	14 Oct 2020 (Study Day 50) - 14 Oct 2020 (Study Day 50)	Prophylaxis For Seasonal Influenza
Amiodarone	20 Dec 2020 (Study Day 117) - Ongoing	Atrial Flutter
Apixaban	20 Dec 2020 (Study Day 117) - Ongoing	Stroke/Blood Clot Prophylaxis
Atorvastatin	20 Dec 2020 (Study Day 117) - Ongoing	Mixed Hyperlipidemia
Diltiazem	20 Dec 2020 (Study Day 117) - 21 Dec 2020 (Study Day 118)	Atrial Flutter
Echo tte*	20 Dec 2020 (Study Day 117) - 20 Dec 2020 (Study Day 117)	Adverse Event
Enoxaparin	20 Dec 2020 (Study Day 117) - 21 Dec 2020 (Study Day 118)	Blood Clot Prevention
Heparin	20 Dec 2020 (Study Day 117) - 21 Dec 2020 (Study Day 118)	Blood Clot Prevention
Ep-cardioversion with transesophageal echo*	21 Dec 2020 (Study Day 118) - 21 Dec 2020 (Study Day 118)	Adverse Event
Metoprolol succinate	22 Dec 2020 (Study Day 119) - Ongoing	Essential Hypertension
Other viral vaccines	12 Jan 2021 (Study Day 140) - 12 Jan 2021 (Study Day 140)	COVID Prevention
Apixaban	20 Jan 2021 (Study Day 148) - Ongoing	Atrial Flutter
Other viral vaccines	02 Feb 2021 (Study Day 161) - 02 Feb 2021 (Study Day 161)	COVID Preventative

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US376-2161 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dehydration/[diarrhea With] Dehydration	SAE	Grade 2/ moderate	Not related	09 Nov 2020 (Study Day 69) – 15 Nov 2020 (Study Day 75)	Recovered/ resolved
Diarrhoea/Diarrhea	SAE	Grade 3/ severe	Not related	09 Nov 2020 (Study Day 69) – 15 Nov 2020 (Study Day 75)	Recovered/ resolved
Acute Kidney Injury/Acute Kidney Injury	SAE	Grade 3/ severe	Not related	10 Nov 2020 (Study Day 70) – 11 Nov 2020 (Study Day 71)	Recovered/ resolved
Hypokalaemia/Hypokalemia	SAE	Grade 1/ mild	Not related	10 Nov 2020 (Study Day 70) – 15 Nov 2020 (Study Day 75)	Recovered/ resolved
Hyponatraemia/Acute Hyponatremia	SAE	Grade 1/ mild	Not related	10 Nov 2020 (Study Day 70) – 15 Nov 2020 (Study Day 75)	Recovered/ resolved
Pneumonia/Left Upper Lobe Pneumonia	SAE	Grade 3/ severe	Not related	10 Nov 2020 (Study Day 70) – 18 Nov 2020 (Study Day 78)	Recovered/ resolved
Sepsis/Sepsis	SAE	Grade 3/ severe	Not related	10 Nov 2020 (Study Day 70) – 20 Nov 2020 (Study Day 80)	Recovered/ resolved
Urinary Tract Infection/Urinary Tract Infection	SAE	Grade 3/ severe	Not related	24 Dec 2020 (Study Day 114) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US376-2161, a 74-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of dehydration. Action taken with the IP was not applicable. The event of [diarrhea with] dehydration lasted for 7 days,

after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 75). The investigator assessed the event of dehydration to be not related to the IP.

On 09 Nov 2020 (Study Day 69), 68 days after the first dose and 40 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of diarrhoea. Action taken with the IP was not applicable. The event of diarrhea lasted for 7 days, after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 75). The investigator assessed the event of diarrhoea to be not related to the IP.

On 10 Nov 2020 (Study Day 70), 69 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute kidney injury lasted for 2 days, after which it was considered to be recovered/resolved on 11 Nov 2020 (Study Day 71). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 10 Nov 2020 (Study Day 70), 69 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of hypokalaemia. Action taken with the IP was not applicable. The event of hypokalemia lasted for 6 days, after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 75). The investigator assessed the event of hypokalaemia to be not related to the IP.

On 10 Nov 2020 (Study Day 70), 69 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of hyponatraemia. Action taken with the IP was not applicable. The event of acute hyponatremia lasted for 6 days, after which it was considered to be recovered/resolved on 15 Nov 2020 (Study Day 75). The investigator assessed the event of hyponatraemia to be not related to the IP.

On 10 Nov 2020 (Study Day 70), 69 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of left upper lobe pneumonia lasted for 9 days, after which it was considered to be recovered/resolved on 18 Nov 2020 (Study Day 78). The investigator assessed the event of pneumonia to be not related to the IP.

On 10 Nov 2020 (Study Day 70), 69 days after the first dose and 41 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of sepsis. Action taken with the IP was not applicable. The event of sepsis lasted for 11 days, after which it was considered to be recovered/resolved on 20 Nov 2020 (Study Day 80). The investigator assessed the event of sepsis to be not related to the IP.

On 24 Dec 2020 (Study Day 114), 113 days after the first dose and 85 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of urinary tract infection was

considered to be ongoing. The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000729	Dehydration
MOD-2020-000729	Diarrhoea
MOD-2020-000729	Acute kidney injury
MOD-2020-000729	Hypokalaemia
MOD-2020-000729	Hyponatraemia
MOD-2020-000729	Pneumonia
MOD-2020-000729	Sepsis
MOD-2020-001373	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Vasectomy	Vasectomy	1981 - 1981
Nephrolithiasis	Kidney stones	1995 - Ongoing
Diabetes mellitus	Diabetes	1998 - Ongoing
Diabetic neuropathy	Diabetic neuropathy in feet and lower legs	1998 - Ongoing
Blood cholesterol increased	High cholesterol	2000 - Ongoing
Hypertension	Hypertension	Aug 2000 - Ongoing
Cerebrovascular accident	Stroke - cerebellum	2006 - 2006
Coronary artery bypass	Cardiovascular arterial bypass graph	2007 - 2007
Myocardial infarction	Heart attack	2007 - 2007
Hypoaesthesia	Numbness in feet	2010 - Ongoing
Tremor	Tremors	2011 - Ongoing
Cataract	Cataracts - bilateral	2016 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin lispro	1998 - Ongoing	Type Ii Diabetes
Lisinopril	Aug 2000 - Ongoing	Hypertension
Acetylsalicylic acid	2005 - Ongoing	Heart Health
Insulin detemir	2007 - Ongoing	Type Ii Diabetes
Atorvastatin	Feb 2007 - Ongoing	High Cholesterol
Metformin	Feb 2007 - Ongoing	Type Ii Diabetes
Gabapentin	2010 - 24 Dec 2020 (Study Day 114)	Polyneuropathy In Feet
Ct chest scan without contrast*	10 Nov 2020 (Study Day 70) - 10 Nov 2020 (Study Day 70)	Adverse Event
Ondansetron	10 Nov 2020 (Study Day 70) - 10 Nov 2020 (Study Day 70)	Nausea
Paracetamol	10 Nov 2020 (Study Day 70) - 10 Nov 2020 (Study Day 70)	Headache
Sodium chloride	10 Nov 2020 (Study Day 70) - 11 Nov 2020 (Study Day 71)	Dehydration, Hyponatremia, And Acute Kidney Injury
Piperacillin; tazobactam	12 Nov 2020 (Study Day 72) - 15 Nov 2020 (Study Day 75)	Pneumonia
Vancomycin	13 Nov 2020 (Study Day 73) - 15 Nov 2020 (Study Day 75)	Pneumonia
Cefdinir	15 Nov 2020 (Study Day 75) - 18 Nov 2020 (Study Day 78)	Pneumonia And Sepsis
Doxycycline hyclate	15 Nov 2020 (Study Day 75) - 18 Nov 2020 (Study Day 78)	Pneumonia And Sepsis
Gentamicin	15 Dec 2020 (Study Day 105) - 15 Dec 2020 (Study Day 105)	Kidney Stone
Kidney stone removal*	15 Dec 2020 (Study Day 105) - 15 Dec 2020 (Study Day 105)	Medical History
Right ureteral stent*	15 Dec 2020 (Study Day 105) - 15 Dec 2020 (Study Day 105)	Medical History
Tramadol	15 Dec 2020 (Study Day 105) - 20 Dec 2020 (Study Day 110)	Kidney Stone
Tamsulosin hydrochloride	18 Dec 2020 (Study Day 108) - Ongoing	Kidney Stones
Azithromycin	19 Dec 2020 (Study Day 109) - 20 Dec 2020 (Study Day 110)	Kidney Stone
Gabapentin	24 Dec 2020 (Study Day 114) - Ongoing	Neuropathy
Ultrasound of urinary/renal system*	24 Dec 2020 (Study Day 114) - 24 Dec 2020 (Study Day 114)	Adverse Event
Cefdinir	26 Dec 2020 (Study Day 116) - 31 Dec 2020 (Study Day 121)	Urinary Tract Infection
Right ureteral stent removal*	28 Dec 2020 (Study Day 118) - 28 Dec 2020 (Study Day 118)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 3/severe	Not related	05 Nov 2020 (Study Day 65) - 10 Nov 2020 (Study Day 70)
Cough	Grade 1/mild	Not related	09 Nov 2020 (Study Day 69) - 10 Nov 2020 (Study Day 70)
Fatigue	Grade 3/severe	Not related	09 Nov 2020 (Study Day 69) - 11 Nov 2020 (Study Day 71)
Pain	Grade 2/moderate	Not related	09 Nov 2020 (Study Day 69) - 10 Nov 2020 (Study Day 70)
Faeces Discoloured	Grade 3/severe	Not related	10 Nov 2020 (Study Day 70) - 11 Nov 2020 (Study Day 71)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US376-2175 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Muscular Weakness/Bilateral Lower Extremity Weakness	SAE	Grade 3/ severe	Not related	15 Dec 2020 (Study Day 104) – 18 Dec 2020 (Study Day 107)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US376-2175, an 81-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Dec 2020 (Study Day 104), 103 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of muscular weakness. Action taken with the IP was not applicable. The event of bilateral lower extremity weakness lasted for 4 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 107). The investigator assessed the event of muscular weakness to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001248	Muscular weakness

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tinnitus	Tinnitus	1957 - Ongoing
Deafness	Hearing loss	1961 - Ongoing
Drug hypersensitivity	Talwin allergy	1968 - Ongoing
Blood cholesterol increased	High cholesterol	1988 - Ongoing
Blood triglycerides increased	High triglycerides	1988 - Ongoing
Arthritis	Arthritis	1999 - Ongoing
Back pain	Chronic back pain	1999 - Ongoing
Erectile dysfunction	Erectile dysfunction	1999 - Ongoing
Libido decreased	Decreased libido	1999 - Ongoing
Osteoarthritis	Osteoarthritis	1999 - Ongoing
Depression	Depression	2000 - Ongoing
Gait disturbance	Unsteady gait	2000 - Ongoing
Herpes zoster	Shingles	2000 - 2000
Nocturia	Frequent nighttime urination	2000 - Ongoing
Peripheral vascular disorder	Peripheral vascular disease in left leg	2000 - Ongoing
Malignant melanoma	Melanoma in right eye	2014 - 2014
Gastritis	Gastritis	2016 - Ongoing
Glaucoma	Glaucoma	2016 - Ongoing
Hypermetropia	Farsighted	2016 - Ongoing
Hypertension	Hypertension	2016 - Ongoing
Retinopathy	Retinopothy in right eye	2016 - Ongoing
Rotator cuff repair	Right rotator cuff repair	2018 - 2018
Arthralgia	Recurremt joint pain	2019 - Ongoing
Drug hypersensitivity	Clindamycin allergy	2019 - Ongoing
Pneumonia	Pneumonia	2019 - 2019
Tenoplasty	Left rotator cuff/biceps tendon repair	2019 - 2019
Cataract	Cataracts	01 Feb 2020 (Study Day -215) - 01 Feb 2020 (Study Day -215)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Pvd
Colecalciferol	Not reported - Ongoing	Supplement
Omega 9 fatty acids; omega-3 fatty acids; omega-6 fatty acids	Not reported - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b12 nos	Not reported - Ongoing	Supplement
Vitamin e nos	Not reported - Ongoing	Supplement
Vitex agnus-castus extract	Not reported - Ongoing	Eye Health
Simvastatin	1988 - 2020	High Cholesterol
Bupivacaine hydrochloride	1999 - Ongoing	Chronic Back Pain
Clonidine	1999 - Ongoing	Chronic Back Pain
Morphine sulfate	1999 - Ongoing	Chronic Back Pain
Desvenlafaxine	2000 - Ongoing	Depression
Furosemide	2000 - Ongoing	Edema Legs
Triazolam	01 Sep 2000 (Study Day -7307) - Ongoing	Depression
Amlodipine	2016 - Ongoing	High Blood Pressure
Calcium carbonate	2016 - Ongoing	Osteoarthritis
Cilostazol	2016 - Ongoing	Pvd
Gabapentin	2016 - 14 Jan 2021 (Study Day 134)	Pvd
Omeprazole	2016 - 2020	Gastritis
Cyclobenzaprine	Aug 2019 - Ongoing	Chronic Back Pain
Pantoprazole	2020 - Ongoing	Gastritis
Pravastatin	2020 - 18 Dec 2020 (Study Day 107)	High Cholesterol
Central nervous system inplant / pvd*	14 Jan 2021 (Study Day 134) - 14 Jan 2021 (Study Day 134)	Medical History
Gabapentin	14 Jan 2021 (Study Day 134) - Ongoing	Pvd
“nevro” - permanent wires / pvd*	04 Feb 2021 (Study Day 155) - 04 Feb 2021 (Study Day 155)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Lymphadenopathy	Grade 1/mild	Related	04 Sep 2020 (Study Day 2) - 05 Sep 2020 (Study Day 3)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US377-2051 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	12 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP, AE leading to study discontinuation

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Incarcerated Hernia/Acute Incarcerated Ventral Hernia	SAE, AE leading to withdrawal from study vaccine, AE leading to study discontinuation	Grade 3/ severe	Not related	04 Sep 2020 (Study Day 24) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US377-2051, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 12 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of incarcerated hernia. On 08 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of acute incarcerated ventral hernia was considered to be ongoing. The investigator assessed the event of incarcerated hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000296	Incarcerated Hernia

Study Completion/Discontinuation

On 28 Sep 2020 (Study Day 48), the participant discontinued from the study due to serious adverse event.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	2000 - Ongoing
Depression	Depression	2004 - Ongoing
Hypertension	Hypertension	2004 - Ongoing
Obesity	Obesity	2005 - Ongoing
Fibromyalgia	Fibromyalgia	2006 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylaxis
Amlodipine besilate; benazepril hydrochloride	2004 - Ongoing	Hypertension
Duloxetine	2004 - Ongoing	Depression
Cyclobenzaprine	2006 - Ongoing	Fibromyalgia
Exploratory laparotomy with repair of incarcerated recurrent ventral hernia with phasix mesh enterectomy with anastomosis*	10 Sep 2020 (Study Day 30) - 10 Sep 2020 (Study Day 30)	Adverse Event
Oxycodone; paracetamol	14 Sep 2020 (Study Day 34) - Ongoing	Acute Incarcerated Ventral Hernia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Acute Kidney Injury	Grade 3/severe	Not related	05 Sep 2020 (Study Day 25) - 14 Sep 2020 (Study Day 34)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US377-2103 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	20 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Colitis/Acute Colitis Of Sigmoid And Descending Colon	SAE	Grade 4	Not related	30 Dec 2020 (Study Day 133) – 14 Jan 2021 (Study Day 148)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US377-2103, a 53-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 20 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 24 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Dec 2020 (Study Day 133), 132 days after the first dose and 97 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of colitis. Action taken with the IP was not applicable. The event of acute colitis of sigmoid and descending colon lasted for 16 days, after which it was considered to be recovered/resolved on 14 Jan 2021 (Study Day 148). The investigator assessed the event of colitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001855	Colitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1977 - Ongoing
Erectile dysfunction	Erectile dysfunction	2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sumatriptan	1990 - Ongoing	Migraine
Testosterone	2008 - Ongoing	Erectile Dysfunction
Hydrochlorothiazide; lisinopril	23 Aug 2020 (Study Day 4) - Ongoing	Hypertension
Cefalexin	01 Sep 2020 (Study Day 13) - 07 Sep 2020 (Study Day 19)	Dog Bite
Duloxetine	13 Nov 2020 (Study Day 86) - 30 Dec 2020 (Study Day 133)	Depression
Influenza vaccine	02 Jan 2021 (Study Day 136) - 02 Jan 2021 (Study Day 136)	Influenza Prophylaxis
Ciprofloxacin	03 Jan 2021 (Study Day 137) - 07 Jan 2021 (Study Day 141)	Acute Colitis Of Sigmoid And Descending Colon.
Metronidazole	03 Jan 2021 (Study Day 137) - 09 Jan 2021 (Study Day 143)	Acute Colitis Of Sigmoid And Descending Colon.

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 1/mild	Not related	23 Aug 2020 (Study Day 4) - Ongoing
Animal Bite	Grade 1/mild	Not related	01 Sep 2020 (Study Day 13) - 01 Sep 2020 (Study Day 13)
Depression	Grade 1/mild	Not related	13 Nov 2020 (Study Day 86) - 30 Dec 2020 (Study Day 133)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US377-2187 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 3/ severe	Not related	07 Dec 2020 (Study Day 99) – 07 Dec 2020 (Study Day 99)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US377-2187, a 37-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Dec 2020 (Study Day 99), 98 days after the first dose and 68 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 1 day, after which it was considered to be recovered/resolved on 07 Dec 2020 (Study Day 99). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001053	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Palpitations	Palpitations	2000 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	01 Sep 2020 (Study Day 2) - 01 Sep 2020 (Study Day 2)	Pain At The Injection Site
Ibuprofen	02 Oct 2020 (Study Day 33) - 02 Oct 2020 (Study Day 33)	Headache
Paracetamol	01 Dec 2020 (Study Day 93) - 02 Dec 2020 (Study Day 94)	Myalgia Abdominal Obliques
Abscess drainage*	07 Dec 2020 (Study Day 99) - 07 Dec 2020 (Study Day 99)	Adverse Event
Appendectomy*	07 Dec 2020 (Study Day 99) - 07 Dec 2020 (Study Day 99)	Adverse Event
Hydrocodone bitartrate; paracetamol	08 Dec 2020 (Study Day 100) - 20 Dec 2020 (Study Day 112)	Post Appendectomy
Piperacillin sodium; tazobactam sodium	08 Dec 2020 (Study Day 100) - 11 Dec 2020 (Study Day 103)	Post Appendectomy Infection Prophylaxis
Ciprofloxacin	10 Dec 2020 (Study Day 102) - 20 Dec 2020 (Study Day 112)	Post Appendectomy Infection Prophylaxis
Metronidazole	10 Dec 2020 (Study Day 102) - 20 Dec 2020 (Study Day 112)	Post Appendectomy Infection Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Appendiceal Abscess	Grade 3/severe	Not related	07 Dec 2020 (Study Day 99) - 07 Dec 2020 (Study Day 99)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US378-2073 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angioedema/Angiodema	AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	28 Aug 2020 (Study Day 5) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2073, a 56-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Aug 2020 (Study Day 5), 4 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of angioedema. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of angiodema was considered to be ongoing. The investigator assessed the event of angioedema to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 24 Dec 2020 (Study Day 123), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Psoriasis	Scalp psoriasis	1995 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2000 - Ongoing	General Health
Ethinylestradiol; norethisterone acetate	Oct 2010 - Ongoing	Contraception
Diphenhydramine hydrochloride	28 Aug 2020 (Study Day 5) - 28 Aug 2020 (Study Day 5)	Angioedema
Famotidine	28 Aug 2020 (Study Day 5) - 28 Aug 2020 (Study Day 5)	Angioedema
Naproxen	28 Aug 2020 (Study Day 5) - 28 Aug 2020 (Study Day 5)	Malaise
Naproxen	29 Aug 2020 (Study Day 6) - 29 Aug 2020 (Study Day 6)	Angioedema
Famotidine	12 Sep 2020 (Study Day 20) - 12 Sep 2020 (Study Day 20)	Angioedema
Fexofenadine hydrochloride	18 Sep 2020 (Study Day 26) - 18 Sep 2020 (Study Day 26)	Angioedema
Influenza vaccine	05 Oct 2020 (Study Day 43) - 05 Oct 2020 (Study Day 43)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Angioedema	Grade 3/severe	Not related	28 Aug 2020 (Study Day 5) - Ongoing
Malaise	Grade 1/mild	Related	28 Aug 2020 (Study Day 5) - 28 Aug 2020 (Study Day 5)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US378-2100 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/ Small Bowel Obstruction	SAE	Grade 4	Not related	29 Nov 2020 (Study Day 95) – 02 Dec 2020 (Study Day 98)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2100, a 76-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Nov 2020 (Study Day 95), 94 days after the first dose and 66 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of small intestinal obstruction. Action taken with the IP was not applicable. The event of small bowel obstruction lasted for 4 days, after which it was considered to be recovered/resolved on 02 Dec 2020 (Study Day 98). The investigator assessed the event of small intestinal obstruction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001021	Small intestinal obstruction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendecotmy	1970 - 1970
Hysterectomy	Hysterectomy	Sep 2000 - Sep 2000
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Muscle spasms	Leg spasms	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rosuvastatin	2015 - Ongoing	Hypercholesterolemia
Biotin	2016 - Ongoing	General Health
Vitamin d nos	2016 - Ongoing	General Health
Magnesium	Jan 2020 - Ongoing	Leg Spasms
Glucosamine	15 Oct 2020 (Study Day 50) - Ongoing	Leg Spasms
Influenza vaccine	17 Oct 2020 (Study Day 52) - 17 Oct 2020 (Study Day 52)	Influenza Prophylaxis
Pneumococcal vaccine polysacch 23v	17 Oct 2020 (Study Day 52) - 17 Oct 2020 (Study Day 52)	Pneumococcal Prophylaxis
Ondansetron	30 Nov 2020 (Study Day 96) - 30 Nov 2020 (Study Day 96)	Small Bowel Obstruction
Anesthetics, general	02 Dec 2020 (Study Day 98) - 02 Dec 2020 (Study Day 98)	Small Bowel Obstruction
Enoxaparin sodium	02 Dec 2020 (Study Day 98) - 04 Dec 2020 (Study Day 100)	Deep Vein Thrombosis Prophylaxis
Laparoscopic removal of abdominal adhesions*	02 Dec 2020 (Study Day 98) - 02 Dec 2020 (Study Day 98)	Adverse Event
Anesthetics, general	11 Feb 2021 (Study Day 169) - 11 Feb 2021 (Study Day 169)	Neck Lift
Clindamycin	11 Feb 2021 (Study Day 169) - 16 Feb 2021 (Study Day 174)	Infection Prophylaxis Post Neck Lift
Hydrocodone bitartrate; paracetamol	11 Feb 2021 (Study Day 169) - 16 Feb 2021 (Study Day 174)	Post-Op Pain Neck Lift
Neck lift*	11 Feb 2021 (Study Day 169) - 11 Feb 2021 (Study Day 169)	Other, Elective Cosmetic
Paracetamol	15 Feb 2021 (Study Day 173) - 15 Feb 2021 (Study Day 173)	Post-Op Pain Neck Lift

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US378-2153 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Appendicitis/Appendicitis	SAE	Grade 4	Not related	26 Nov 2020 (Study Day 84) – 27 Nov 2020 (Study Day 85)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2153, a 65-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Nov 2020 (Study Day 84), 83 days after the first dose and 51 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of appendicitis. Action taken with the IP was not applicable. The event of appendicitis lasted for 2 days, after which it was considered to be recovered/resolved on 27 Nov 2020 (Study Day 85). The investigator assessed the event of appendicitis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000915	Appendicitis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2000 - Ongoing
Gastrooesophageal reflux disease	Gerd	2006 - Ongoing
Hysterosalpingo-oophorectomy	Bilateral oophorectomy + hysterectomy	Apr 2008 - Apr 2008
Rhinitis allergic	Allergic rhinitis	2009 - Ongoing
Depression	Depression	2016 - Ongoing
Anxiety	Anxiety	Apr 2017 - Ongoing
Osteoporosis	Osteoporosis	Jan 2018 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Sep 2018 - Ongoing
Dermatitis contact	Generalized contact dermatitis	24 Aug 2020 (Study Day -11) - 24 Aug 2020 (Study Day -11)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol succinate	2006 - Ongoing	Hypertension
Omeprazole	2006 - Ongoing	Gerd
Cetirizine	2009 - Ongoing	Allergic Rhinitis
Amlodipine	2012 - Ongoing	Hypertension
Losartan	May 2012 - Ongoing	Hypertension
Bupropion	2016 - Ongoing	Depression
Acetylsalicylic acid	Oct 2016 - Ongoing	Cardiovascular Prophylaxis
Lorazepam	Apr 2017 - Ongoing	Anxiety
Rosuvastatin	Sep 2018 - Ongoing	Hypercholesterolemia
Dexamethasone	24 Aug 2020 (Study Day -11) - 24 Aug 2020 (Study Day -11)	Generalized Contact Dermatitis
Prednisone	24 Aug 2020 (Study Day -11) - 29 Aug 2020 (Study Day -6)	Generalized Contact Dermatitis
Triamcinolone	24 Aug 2020 (Study Day -11) - 24 Aug 2020 (Study Day -11)	Generalized Contact Dermatitis
Zoledronic acid	18 Sep 2020 (Study Day 15) - 18 Sep 2020 (Study Day 15)	Osteoporosis
Influenza vaccine	21 Sep 2020 (Study Day 18) - 21 Sep 2020 (Study Day 18)	Influenza Prophylaxis
Appendectomy*	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Adverse Event
Ceftriaxone	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fentanyl	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Lidocaine	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Morphine sulfate	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Ondansetron	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Oxycodone	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Oxycodone	27 Nov 2020 (Study Day 85) - 30 Nov 2020 (Study Day 88)	Appendicitis (Post-Op Pain)
Phenylephrine	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Propofol	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Rocuronium	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Sugammadex	27 Nov 2020 (Study Day 85) - 27 Nov 2020 (Study Day 85)	Appendicitis
Paracetamol	30 Nov 2020 (Study Day 88) - 14 Dec 2020 (Study Day 102)	Appendicitis (Post-Op Pain)
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	04 Jan 2021 (Study Day 123) - 04 Jan 2021 (Study Day 123)	Diphtheria, Tetanus, Pertussis Prophylaxis
Pneumococcal vaccine conj 7v (crm197)	04 Jan 2021 (Study Day 123) - 04 Jan 2021 (Study Day 123)	Pneumococcal Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US378-2162 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	09 Oct 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Coronary Syndrome/Acute Coronary Syndrome	SAE	Grade 4	Not related	21 Sep 2020 (Study Day 14) – 21 Sep 2020 (Study Day 14)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2162, a 78-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 09 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 21 Sep 2020 (Study Day 14), 13 days after the first dose and 18 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute coronary syndrome. The IP dose was not changed due to the acute coronary syndrome. The event of acute coronary syndrome lasted for 1 day, after which it was considered to be recovered/resolved on 21 Sep 2020 (Study Day 14). The investigator assessed the event of acute coronary syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000444	Acute Coronary Syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Constipation	Constipation	Not reported - Ongoing
Coronary artery disease	Coronary artery disease	Not reported - Ongoing
Deafness neurosensory	Sensory hearing loss	Not reported - Ongoing
Essential tremor	Essential tremor	Not reported - Ongoing
Gastrooesophageal reflux disease	Gerd	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Benign prostatic hyperplasia	Bph	2015 - Ongoing
Back pain	Back pain	2017 - Ongoing
Angina pectoris	Angina	30 Oct 2017 (Study Day -1044) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Cad
Atorvastatin	Not reported - Ongoing	Hyperlipidemia
Carbidopa; levodopa	Not reported - Ongoing	Tremors
Losartan	Not reported - Ongoing	Hypertension
Macrogol 3350	Not reported - Ongoing	Constipation
Omeprazole	Not reported - Ongoing	Gerd
Primidone	Not reported - Ongoing	Tremor
Tamsulosin hydrochloride	Not reported - Ongoing	Bph
Vitamins nos	2000 - Ongoing	General Health
Finasteride	2015 - Ongoing	Bph
Gabapentin	2017 - 22 Oct 2020 (Study Day 45)	Back Pain
Paracetamol	2017 - Ongoing	Back Pain
Vitamin d nos	08 Sep 2020 (Study Day 1) - Ongoing	General Health
Nuclear stress test*	22 Sep 2020 (Study Day 15) - 22 Sep 2020 (Study Day 15)	Adverse Event
Left heart catheterization*	23 Sep 2020 (Study Day 16) - 23 Sep 2020 (Study Day 16)	Adverse Event
Metoprolol	24 Sep 2020 (Study Day 17) - 27 Oct 2020 (Study Day 50)	Coronary Artery Disease
Paracetamol	09 Oct 2020 (Study Day 32) - 09 Oct 2020 (Study Day 32)	Post-Vaccination Symptom Prophylaxis
Glyceryl trinitrate	14 Oct 2020 (Study Day 37) - 14 Oct 2020 (Study Day 37)	Cardiac Chest Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colonoscopy*	22 Oct 2020 (Study Day 45) - 22 Oct 2020 (Study Day 45)	Other, Routine
Influenza vaccine	26 Oct 2020 (Study Day 49) - 26 Oct 2020 (Study Day 49)	Influenza Prophylaxis
Metoprolol	28 Oct 2020 (Study Day 51) - Ongoing	Cornary Artery Disease
Investigational drug	20 Jan 2021 (Study Day 135) - 20 Jan 2021 (Study Day 135)	Fracture Prophylaxis
Glyceryl trinitrate	21 Jan 2021 (Study Day 136) - Ongoing	Chest Pain (Cardiac)
Isosorbide mononitrate	23 Jan 2021 (Study Day 138) - Ongoing	Angina
Ranolazine	23 Jan 2021 (Study Day 138) - Ongoing	Angina
Skin biopsy right arm*	12 Mar 2021 (Study Day 186) - 12 Mar 2021 (Study Day 186)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Angina Pectoris	Grade 2/moderate	Not related	14 Oct 2020 (Study Day 37) - 14 Oct 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US379-2080 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	30 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	04 Nov 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE	Grade 1/ mild	Not related	03 Dec 2020 (Study Day 65) – 31 Dec 2020 (Study Day 93)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US379-2080, a 42-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 30 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 04 Nov 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Dec 2020 (Study Day 65), 64 days after the first dose and 29 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 29 days, after which it was considered to be recovered/resolved on 31 Dec 2020 (Study Day 93). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001122	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	1990 - Ongoing
Drug hypersensitivity	Allergy to sulfa	1998 - Ongoing
Seasonal allergy	Seasonal allergies	1999 - Ongoing
Asthma	Seasonal asthma	2010 - Ongoing
Female sterilisation	Tuballigation	2014 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2010 - Ongoing	Seasonal Asthma
Vitamin b12 nos	2017 - Ongoing	Vitamin B Deficiency Prophylaxis
Vitamin d nos	2017 - Ongoing	Vitamin D Deficiency Prophylaxis
Fexofenadine hydrochloride	2019 - Ongoing	Seasonal Allergies
Guaifenesin	2019 - Ongoing	Seasonal Allergies
Sertraline	Mar 2020 - Ongoing	Depression
Influenza vaccine	15 Oct 2020 (Study Day 16) - 15 Oct 2020 (Study Day 16)	Influenza Prophylaxis
Dextromethorphan hydrobromide; paracetamol	29 Oct 2020 (Study Day 30) - 30 Oct 2020 (Study Day 31)	Common Cold
Dextromethorphan hydrobromide; paracetamol	03 Dec 2020 (Study Day 65) - 04 Dec 2020 (Study Day 66)	COVID 19
Ibuprofen	05 Dec 2020 (Study Day 67) - 21 Dec 2020 (Study Day 83)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Not related	07 Oct 2020 (Study Day 8) – 10 Oct 2020 (Study Day 11)
Nasopharyngitis	Grade 1/mild	Not related	29 Oct 2020 (Study Day 30) - 30 Oct 2020 (Study Day 31)
Aphthous Ulcer	Grade 1/mild	Related	28 Dec 2020 (Study Day 90) - 31 Dec 2020 (Study Day 93)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US379-2090 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	05 Nov 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	SAE	Grade 1/ mild	Not related	12 Dec 2020 (Study Day 67) – 29 Dec 2020 (Study Day 84)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US379-2090, a 24-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 05 Nov 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Dec 2020 (Study Day 67), 66 days after the first dose and 37 days after the second dose of the IP, the participant experienced a Grade 1/mild serious adverse event of covid-19. Action taken with the IP was not applicable. The event of COVID 19 lasted for 18 days, after which it was considered to be recovered/resolved on 29 Dec 2020 (Study Day 84). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001182	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2001 - Ongoing
Musculoskeletal pain	Left shoulder pain	2017 - Ongoing
Arthralgia	Right ankle joint pain	2018 - Ongoing
Arthralgia	Right knee joint pain	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	13 Dec 2020 (Study Day 68) - 23 Dec 2020 (Study Day 78)	COVID-19 Symptom

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US379-2094 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	09 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	06 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Kidney Injury/ Acute Kidney Injury	SAE	Grade 4	Not related	20 Oct 2020 (Study Day 12) – 22 Oct 2020 (Study Day 14)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US379-2094, a 66-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 09 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 06 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Oct 2020 (Study Day 12), 11 days after the first dose and 17 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of acute kidney injury. The IP dose was not changed due to the acute kidney injury. The event of acute kidney injury lasted for 3 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 14). The investigator assessed the event of acute kidney injury to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000543	Acute Kidney Injury

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	1972 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1975 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus, type 2	2001 - Ongoing
Osteoarthritis	Left shoulder osteoarthritis	2005 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2008 - Ongoing
Tinnitus	Tinnitus	2009 - Ongoing
Gout	Gout	2010 - Ongoing
Insomnia	Insomnia	2010 - Ongoing
Diabetic neuropathy	Diabetic neuropathy	2011 - Ongoing
Carpal tunnel syndrome	Carpal tunnel syndrome, bilateral	2014 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2015 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2015 - Ongoing
Hypertension	Hpertension	2015 - Ongoing
Diabetic retinopathy	Diabetic retinopathy of both eyes	18 Jun 2020 (Study Day -113) - Ongoing
Foot fracture	Closed fracture of phalanx of left 3rd toe	01 Sep 2020 (Study Day -38) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Insulin aspart	2008 - Ongoing	Diabetes Mellitus Type 2
Pantoprazole	2008 - Ongoing	Acid Reflux
Melatonin	2010 - Ongoing	Insomnia
Carvedilol	2015 - Ongoing	Hypertension
Eicosapentaenoic acid ethyl ester	2015 - Ongoing	Hyperholesterolemia
Insulin glargine	2015 - 28 Oct 2020 (Study Day 20)	Diabetes Mellitus Type 2
Losartan potassium	2015 - 20 Oct 2020 (Study Day 12)	Renal Prophylaxis
Salbutamol	2015 - Ongoing	Copd
Tamsulosin	2015 - Ongoing	Benign Prostatic Hyperplasia
Ibuprofen	2017 - 01 Mar 2021 (Study Day 144)	Bilateral Carpal Tunnel Syndrome, Left Shoulder Osteoarthritis
Acetylsalicylic acid	2018 - Ongoing	Cardiac Prophyaxis
Duloxetine	2018 - Ongoing	Diabetic Neuropathy
Empagliflozin	2018 - Ongoing	Diabetes Mellitus, Type 2
Fluticasone furoate; vilanterol trifenatate	2018 - Ongoing	Copd

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pregabalin	2018 - Ongoing	Diabetic Neuropathy
Furosemide	20 Oct 2020 (Study Day 12) - 22 Oct 2020 (Study Day 14)	Acute Kidney Injury
Glyceryl trinitrate	20 Oct 2020 (Study Day 12) - 20 Oct 2020 (Study Day 12)	Acute Kidney Injury
Insulin lispro	20 Oct 2020 (Study Day 12) - 22 Oct 2020 (Study Day 14)	Elevated Blood Glucose
Oxycodone; paracetamol	20 Oct 2020 (Study Day 12) - 22 Oct 2020 (Study Day 14)	Acute Kidney Injury
Trazodone	21 Oct 2020 (Study Day 13) - 21 Oct 2020 (Study Day 13)	Insomnia
Chest x-ray*	22 Oct 2020 (Study Day 14) - 22 Oct 2020 (Study Day 14)	Adverse Event
Echocardiogram*	22 Oct 2020 (Study Day 14) - 22 Oct 2020 (Study Day 14)	Adverse Event
Furosemide	22 Oct 2020 (Study Day 14) - 05 Nov 2020 (Study Day 28)	Acute Kidney Injury
Renal ultrasound*	22 Oct 2020 (Study Day 14) - 22 Oct 2020 (Study Day 14)	Adverse Event
Insulin glargine	29 Oct 2020 (Study Day 21) - Ongoing	Elevated Blood Glucose
Influenza vaccine	15 Dec 2020 (Study Day 68) - 15 Dec 2020 (Study Day 68)	Influenza Prophylaxis
Tramadol	12 Jan 2021 (Study Day 96) - 13 Jan 2021 (Study Day 97)	Right Great Toenail Injury
Azithromycin	30 Jan 2021 (Study Day 114) - 05 Feb 2021 (Study Day 120)	Upper Respiratory Infection
Dextromethorphan hydrobromide; promethazine hydrochloride	30 Jan 2021 (Study Day 114) - 05 Feb 2021 (Study Day 120)	Upper Respiratory Infection
Prednisone	30 Jan 2021 (Study Day 114) - 04 Feb 2021 (Study Day 119)	Upper Respiratory Infection
Paracetamol	04 Mar 2021 (Study Day 147) - Ongoing	Bilateral Carpal Tunnel Syndrome, Left Shoulder Osteoarthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diabetes Mellitus	Grade 2/moderate	Not related	20 Oct 2020 (Study Day 12) - 11 Feb 2021 (Study Day 126)
Renal Cyst	Grade 1/mild	Not related	20 Oct 2020 (Study Day 12) - Ongoing
Renal Impairment	Grade 1/mild	Not related	22 Oct 2020 (Study Day 14) - Ongoing
Nail Injury	Grade 2/moderate	Not related	12 Jan 2021 (Study Day 96) - 26 Feb 2021 (Study Day 141)
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	29 Jan 2021 (Study Day 113) - 06 Feb 2021 (Study Day 121)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US380-2149 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	07 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID 19	SAE	Grade 2/ moderate	Not related	23 Nov 2020 (Study Day 78) – 01 Feb 2021 (Study Day 148)	Recovered/resolved with sequelae
Thrombophlebitis Superficial/Superficial Venous Thrombosis	SAE	Grade 2/ moderate	Not related	01 Dec 2020 (Study Day 86) – 03 Dec 2020 (Study Day 88)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US380-2149, a 64-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Nov 2020 (Study Day 78), 77 days after the first dose and 46 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of covid-19. Action taken with the IP was not applicable. The event of symptomatic COVID 19 lasted for 71 days, after which it was considered to be recovered/resolved with sequelae on 01 Feb 2021 (Study Day 148). The investigator assessed the event of covid-19 to be not related to the IP.

On 01 Dec 2020 (Study Day 86), 85 days after the first dose and 54 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of thrombophlebitis superficial. Action taken with the IP was not applicable. The event of superficial venous thrombosis lasted for 3 days, after which it was considered to be recovered/resolved on 03 Dec 2020 (Study Day 88). The investigator assessed the event of thrombophlebitis superficial to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000954	COVID-19
MOD-2020-000954	Thrombophlebitis Superficial

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arteriosclerosis coronary artery	Arteriosclerotic heart disease	2008 - Ongoing
Drug hypersensitivity	Sulfa-drug allergy	2008 - Ongoing
Hypertension	Hypertension	2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid; dextromethorphan hydrobromide; doxylamine succinate; phenylephrine bitartrate	Not reported - Ongoing	COVID-19
Paracetamol	Not reported - Ongoing	COVID-19
Paracetamol	Not reported - 03 Dec 2020 (Study Day 88)	Cardiac Chest Pain
Acetylsalicylic acid	2008 - Ongoing	Hypertension
Amlodipine	2008 - Ongoing	Hypertension
Atorvastatin	2008 - Ongoing	Arteriosclerotic Heart Disease
Carvedilol	2008 - 31 Dec 2020 (Study Day 116)	Hypertension
Losartan	2008 - Ongoing	Hypertension
Influenza vaccine	27 Oct 2020 (Study Day 51) - 27 Oct 2020 (Study Day 51)	Prevent Influenza Infection
Enoxaparin sodium	01 Dec 2020 (Study Day 86) - 02 Dec 2020 (Study Day 87)	Superficial Venous Thrombosis
Ibuprofen	02 Dec 2020 (Study Day 87) - 03 Dec 2020 (Study Day 88)	Cardiac Chest Pain
Fluticasone propionate	14 Dec 2020 (Study Day 99) - Ongoing	COVID 19
Rivaroxaban	21 Dec 2020 (Study Day 106) - Ongoing	Arteriosclerotic Heart Disease
Clopidogrel bisulfate	30 Dec 2020 (Study Day 115) - Ongoing	Stent Placement
Carvedilol	31 Dec 2020 (Study Day 116) - Jan 2021	Hypertension

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Carvedilol	Jan 2021 - Ongoing	Hypertension
Cardiac catheterizaation with stent placement*	01 Jan 2021 (Study Day 117) - 01 Jan 2021 (Study Day 117)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Angina Pectoris	Grade 2/moderate	Not related	01 Dec 2020 (Study Day 86) - 03 Dec 2020 (Study Day 88)
Extrasystoles	Grade 1/mild	Not related	01 Dec 2020 (Study Day 86) - Ongoing
Hypertension	Grade 2/moderate	Not related	31 Dec 2020 (Study Day 116) - Ongoing
Arteriosclerosis Coronary Artery	Grade 2/moderate	Not related	01 Jan 2021 (Study Day 117) - 01 Jan 2021 (Study Day 117)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US380-2218 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	13 Oct 2020 (Study Day 33)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hiatus Hernia/ Paraesophogeal Hiatal Hernia Worsening	SAE	Grade 2/ moderate	Not related	28 Oct 2020 (Study Day 48) – 05 Nov 2020 (Study Day 56)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US380-2218, a 64-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 13 Oct 2020 (Study Day 33). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Oct 2020 (Study Day 48), 47 days after the first dose and 15 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of hiatus hernia. Action taken with the IP was not applicable. The event of paraesophogeal hiatal hernia worsening lasted for 9 days, after which it was considered to be recovered/resolved on 05 Nov 2020 (Study Day 56). The investigator assessed the event of hiatus hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000612	Hiatus Hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	Not reported - Ongoing
Blood cholesterol increased	High choloesterol	Not reported - Ongoing
Dust allergy	Dust allergy	Not reported - Ongoing
Hiatus hernia	Hiatal hernia	Not reported - Ongoing
Hypersensitivity	Enrionmental allergies	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Hypertriglyceridaemia	Hypertriglycerides	Not reported - Ongoing
Prostatomegaly	Enlarged prostate	Not reported - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	Not reported - Ongoing
Rash	Generalized rash	2015 - Ongoing
HIV infection	Hiv	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Heart Health
Atorvastatin	Not reported - Ongoing	High Cholesterol
Fenofibrate	Not reported - Ongoing	Hypertriglycerides
Glimepiride	Not reported - Ongoing	Diabetes Type 2
Lisinopril	Not reported - Ongoing	Hypertension
Colecalciferol	2015 - Ongoing	Supplement
Levocetirizine	2015 - Ongoing	Dust Allergies
Abacavir sulfate; dolutegravir sodium; lamivudine	2016 - Ongoing	Hiv
Venlafaxine	2016 - Ongoing	Anxiety
Tamsulosin	2017 - Ongoing	Enlarged Prostate
Triamcinolone acetonide	2017 - Ongoing	Generalized Rash
Cxr*	28 Oct 2020 (Study Day 48) - 28 Oct 2020 (Study Day 48)	Adverse Event
Heparin	29 Oct 2020 (Study Day 49) - 05 Nov 2020 (Study Day 56)	Clot Prevention
Left pigtail catheter*	30 Oct 2020 (Study Day 50) - 30 Oct 2020 (Study Day 50)	Adverse Event
Paraesophagealâ hernia repair*	30 Oct 2020 (Study Day 50) - 30 Oct 2020 (Study Day 50)	Adverse Event
Cxr*	31 Oct 2020 (Study Day 51) - 31 Oct 2020 (Study Day 51)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	06 Nov 2020 (Study Day 57) - 06 Nov 2020 (Study Day 57)	Prevent Influenza Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US381-2010 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 26)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Angina Unstable/Unstable Angina	SAE	Grade 3/ severe	Not related	23 Dec 2020 (Study Day 143) – 04 Jan 2021 (Study Day 155)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2010, a 71-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 26). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Dec 2020 (Study Day 143), 142 days after the first dose and 117 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of angina unstable. Action taken with the IP was not applicable. The event of unstable angina lasted for 13 days, after which it was considered to be recovered/resolved on 04 Jan 2021 (Study Day 155). The investigator assessed the event of angina unstable to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001430	Angina Unstable

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gerd	1977 - Ongoing
Deafness bilateral	Bilateral hearing loss	1995 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2000 - Ongoing
Blood cholesterol increased	Elevated cholesterol	2001 - Ongoing
Rotator cuff syndrome	Left rotator cuff strain	2004 - 2005
Rotator cuff repair	Left rotator cuff repair	2005 - 2005
Arthralgia	Bilateral knee pain	2007 - 2013
Hepatic steatosis	Fatty liver	2010 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2010 - Ongoing
Meniscus injury	Bilateral meniscus tear	2013 - 2013
Meniscus operation	Bilateral meniscus repair	2013 - 2013
Osteoarthritis	Bilateral knee osteoarthritis	2014 - Ongoing
Osteoarthritis	Bilateral shoulder osteoarthritis	2014 - Ongoing
Benign prostatic hyperplasia	Bph	2019 - Ongoing
Diabetic neuropathy	Bilateral lower extremity sensory diabetic neuropathy	2019 - Ongoing
Diverticulitis	Recurrent diverticulitis	2019 - 2019
Tobacco user	Weekly cigar smoker	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	1977 - 15 Feb 2021 (Study Day 197)	Gastroesophageal Reflux Disease
Simvastatin	2001 - 28 Dec 2020 (Study Day 148)	Elevated Cholesterol
Metformin	2019 - 28 Dec 2020 (Study Day 148)	Diabetes Mellitus Type 2
Tamsulosin	2019 - Ongoing	Benign Prostatic Hyperplasia
Ibuprofen	28 Aug 2020 (Study Day 26) - 30 Aug 2020 (Study Day 28)	Muscle Ache, Joint Aches, Headache, Fever, & Injection Site Pain
Chest, abdominal, and pelvic computerized tomography angiography*	26 Dec 2020 (Study Day 146) - 26 Dec 2020 (Study Day 146)	Adverse Event
Ecg*	26 Dec 2020 (Study Day 146) - 26 Dec 2020 (Study Day 146)	Adverse Event
Resting echocardiography*	26 Dec 2020 (Study Day 146) - 26 Dec 2020 (Study Day 146)	Adverse Event
Stress echocardiogram*	26 Dec 2020 (Study Day 146) - 26 Dec 2020 (Study Day 146)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	28 Dec 2020 (Study Day 148) - Ongoing	Unstable Angina And Cad
Atorvastatin	28 Dec 2020 (Study Day 148) - Ongoing	Unstable Angina And Cad
Carvedilol	28 Dec 2020 (Study Day 148) - Ongoing	Unstable Angina And Cad
Clopidogrel bisulfate	28 Dec 2020 (Study Day 148) - Ongoing	Unstable Angina And Cad
Isosorbide mononitrate	28 Dec 2020 (Study Day 148) - Ongoing	Unstable Angina And Cad
Chest x-ray*	29 Dec 2020 (Study Day 149) - 29 Dec 2020 (Study Day 149)	Adverse Event
Cardiac echocardiogram*	04 Jan 2021 (Study Day 155) - 04 Jan 2021 (Study Day 155)	Adverse Event
Left coronary angiography*	04 Jan 2021 (Study Day 155) - 04 Jan 2021 (Study Day 155)	Adverse Event
Lisinopril	04 Jan 2021 (Study Day 155) - 15 Feb 2021 (Study Day 197)	Hypertension
Percutaneous intervention with a drug eluting stent*	04 Jan 2021 (Study Day 155) - 04 Jan 2021 (Study Day 155)	Adverse Event
Right coronary angiography*	04 Jan 2021 (Study Day 155) - 04 Jan 2021 (Study Day 155)	Adverse Event
Losartan	15 Feb 2021 (Study Day 197) - Ongoing	Hypertension
Pantoprazole	15 Feb 2021 (Study Day 197) - Ongoing	Worsening Gastroesophageal Reflux Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Neck Pain	Grade 1/mild	Not related	12 Aug 2020 (Study Day 10) - 14 Aug 2020 (Study Day 12)
Rash Maculo-Papular	Grade 2/moderate	Related	12 Aug 2020 (Study Day 10) - 14 Aug 2020 (Study Day 12)
Ear Pain	Grade 1/mild	Not related	16 Nov 2020 (Study Day 106) - 04 Dec 2020 (Study Day 124)
Coronary Artery Disease	Grade 2/moderate	Not related	04 Jan 2021 (Study Day 155) - Ongoing
Hypertension	Grade 1/mild	Not related	04 Jan 2021 (Study Day 155) - Ongoing
Drug Hypersensitivity	Grade 2/moderate	Not related	15 Feb 2021 (Study Day 197) - Ongoing
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	15 Feb 2021 (Study Day 197) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2059 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 27)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Anxiety Disorder/Anxiety Disorder	SAE	Grade 4	Not related	24 Oct 2020 (Study Day 80) – 10 Nov 2020 (Study Day 97)	Recovered/resolved
Major Depression/Severe Episode Of Recurrent Major Depressive Disorder	SAE	Grade 4	Not related	29 Oct 2020 (Study Day 85) – 10 Nov 2020 (Study Day 97)	Recovered/resolved
Major Depression/Severe Episode Of Recurrent Major Depressive Disorder	SAE	Grade 4	Not related	18 Nov 2020 (Study Day 105) – 30 Nov 2020 (Study Day 117)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2059, a 20-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 27). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Oct 2020 (Study Day 80), 79 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of anxiety disorder. Action taken with the IP was not applicable. The event of anxiety disorder lasted for 18 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 97). The investigator assessed the event of anxiety disorder to be not related to the IP.

On 29 Oct 2020 (Study Day 85), 84 days after the first dose and 58 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of major depression. Action taken with the IP was not applicable. The event of severe episode of recurrent major depressive disorder lasted for 13 days, after which it was considered to be recovered/resolved on 10 Nov 2020 (Study Day 97). The investigator assessed the event of major depression to be not related to the IP.

On 18 Nov 2020 (Study Day 105), 104 days after the first dose and 78 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of major depression. Action taken with the IP was not applicable. The event of severe episode of recurrent major depressive

disorder lasted for 13 days, after which it was considered to be recovered/resolved on 30 Nov 2020 (Study Day 117). The investigator assessed the event of major depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000573	Anxiety disorder
MOD-2020-000573	Major depression
MOD-2020-000858	Major depression

Study Completion/Discontinuation

On 23 Mar 2021 (Study Day 230), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Eyelid retraction	(b) eyelid retraction	Not reported - Ongoing
Drug hypersensitivity	Atropine allergy	(b) (6) 1999 (Study Day (b) (6) - Ongoing
Eye operation	Left eye shunt revision x18	(b) (6) 1999 (Study Day (b) (6) - 2013
Glaucoma	Left eye glaucoma	(b) (6) 1999 (Study Day (b) (6) - Ongoing
Headache	Frequent headaches	2008 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Depression	Depression	2018 - Ongoing
Electronic cigarette user	Vape smoker	2018 - Ongoing
Drug abuse	Marijuana abuse	Feb 2019 - Ongoing
Alcohol use disorder	Alcohol use disorder	Jan 2020 - Ongoing
Major depression	Recurrent major depressive disorder	Jan 2020 - Ongoing
Nicotine dependence	Nicotine addiction	Jan 2020 - Ongoing
Post-traumatic stress disorder	Post traumatic stress disorder	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Substance abuse treatment program*	Not reported - Not reported	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dorzolamide hydrochloride; timolol maleate	01 May 2018 (Study Day -828) - Ongoing	Glaucoma
Travoprost	01 May 2018 (Study Day -828) - 30 Oct 2020 (Study Day 86)	Glaucoma
Sertraline	20 Dec 2019 (Study Day -230) - 24 Oct 2020 (Study Day 80)	Depression/Anxiety
Ethinylestradiol; etonogestrel	Jun 2020 - Ongoing	Pregnancy Prevention/ Birth Control
Brimonidine tartrate	24 Aug 2020 (Study Day 19) - 30 Oct 2020 (Study Day 86)	Glaucoma
Ibuprofen	08 Oct 2020 (Study Day 64) - 13 Oct 2020 (Study Day 69)	COVID-Like Illness
Sertraline	24 Oct 2020 (Study Day 80) - 26 Oct 2020 (Study Day 82)	Depression/Anxeity
Hydroxyzine	26 Oct 2020 (Study Day 82) - 26 Oct 2020 (Study Day 82)	Anxiety Disorder
Urine drug screen*	26 Oct 2020 (Study Day 82) - 26 Oct 2020 (Study Day 82)	Adverse Event
Bupropion	27 Oct 2020 (Study Day 83) - Ongoing	Anxiety Disorder
Nicotine	27 Oct 2020 (Study Day 83) - Ongoing	Worsening Nicotine Addiction
Nicotine polacrilex	27 Oct 2020 (Study Day 83) - Ongoing	Worsening Nicotine Addiction
Clonazepam	30 Oct 2020 (Study Day 86) - Ongoing	Major Depressive Disorder
Diphenhydramine	30 Oct 2020 (Study Day 86) - 30 Oct 2020 (Study Day 86)	Major Depressive Disorder
Trazodone	30 Oct 2020 (Study Day 86) - Ongoing	Major Depressive Disorder
Hydroxyzine hydrochloride	31 Oct 2020 (Study Day 87) - Ongoing	Major Depressive Disorder
Latanoprost	31 Oct 2020 (Study Day 87) - Ongoing	Glaucoma
Nicotine polacrilex	31 Oct 2020 (Study Day 87) - 08 Nov 2020 (Study Day 95)	Nicotine Addiction
Prazosin	31 Oct 2020 (Study Day 87) - Ongoing	Major Depressive Disorder
Quetiapine	31 Oct 2020 (Study Day 87) - 03 Nov 2020 (Study Day 90)	Major Depressive Disorder
Dorzolamide; timolol	01 Nov 2020 (Study Day 88) - Ongoing	Glaucoma
Quetiapine	03 Nov 2020 (Study Day 90) - Ongoing	Major Depressive Disorder
Chlorpromazine	06 Nov 2020 (Study Day 93) - Ongoing	Major Depressive Disorder
Dorzolamide hydrochloride; timolol maleate	18 Nov 2020 (Study Day 105) - 18 Nov 2020 (Study Day 105)	Glaucoma
Lorazepam	18 Nov 2020 (Study Day 105) - 18 Nov 2020 (Study Day 105)	Severe Episode Of Recurrent Major Deppressive Disorder
Olanzapine	18 Nov 2020 (Study Day 105) - 18 Nov 2020 (Study Day 105)	Severe Episode Of Recurrent Major Deppressive Disorder
Quetiapine	18 Nov 2020 (Study Day 105) - 18 Nov 2020 (Study Day 105)	Severe Episode Of Recurrent Major Deppressive Disorder
Brimonidine tartrate	19 Nov 2020 (Study Day 106) - 19 Nov 2020 (Study Day 106)	Glaucoma
Hydroxyzine	19 Nov 2020 (Study Day 106) - 19 Nov 2020 (Study Day 106)	Severe Episode Of Recurrent Major Deppressive Disorder
Trazodone	19 Nov 2020 (Study Day 106) - 19 Nov 2020 (Study Day 106)	Severe Episode Of Recurrent Major Deppressive Disorder

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Brimonidine tartrate	30 Nov 2020 (Study Day 117) - Ongoing	Glaucoma
Clonazepam	30 Nov 2020 (Study Day 117) - Ongoing	Severe Episode Of Recurrent Major Deppressive Disorder
Lurasidone	30 Nov 2020 (Study Day 117) - Ongoing	Severe Episode Of Recurrent Major Deppressive Disorder

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Nausea	Grade 1/mild	Not related	23 Sep 2020 (Study Day 49) - 23 Sep 2020 (Study Day 49)
Vomiting	Grade 1/mild	Not related	23 Sep 2020 (Study Day 49) - 23 Sep 2020 (Study Day 49)
Suspected COVID-19	Grade 2/moderate	Not related	08 Oct 2020 (Study Day 64) - 13 Oct 2020 (Study Day 69)
Nicotine Dependence	Grade 2/moderate	Not related	27 Oct 2020 (Study Day 83) - Ongoing
Dissociative Disorder	Grade 4	Not related	29 Oct 2020 (Study Day 85) - 10 Nov 2020 (Study Day 97)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2062 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hyponatraemia/Worsening Hyponatremia	SAE	Grade 4	Not related	16 Jan 2021 (Study Day 164) – 20 Jan 2021 (Study Day 168)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2062, a 55-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Jan 2021 (Study Day 164), 163 days after the first dose and 134 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of hyponatraemia. Action taken with the IP was not applicable. The event of worsening hyponatremia lasted for 5 days, after which it was considered to be recovered/resolved on 20 Jan 2021 (Study Day 168). The investigator assessed the event of hyponatraemia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-004902	Hyponatremia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	1972 - Ongoing
Substance use	Occasional marijuana use	1975 - Ongoing
Visual impairment	Bilateral vision impairment	1975 - Ongoing
Nicotine dependence	Nicotine addiction	1983 - Ongoing
Alcohol abuse	Alcohol abuse	1986 - 1988
Caesarean section	Caesarean section	21 Mar 1989 (Study Day -11461) - 21 Mar 1989 (Study Day -11461)
Anxiety	Anxiety	1998 - Ongoing
Bipolar disorder	Bipolar	1998 - Ongoing
Depression	Depression	1998 - Ongoing
Migraine	Migraines	1998 - Ongoing
Craniotomy	Craniotomy	Nov 1998 - Nov 1998
Intra-cerebral aneurysm operation	Brain aneurysm clipping	Nov 1998 - Nov 1998
Intracranial aneurysm	Brain aneurysm	Nov 1998 - Nov 1998
Medical device implantation	Skull steel plate placement	Nov 1998 - Nov 1998
Generalised tonic-clonic seizure	Grandmal seizure	2012 - 2012
Hypokalaemia	Hypokalemia	2012 - 11 Jul 2019 (Study Day -392)
Hyponatraemia	Hyponatremia	2012 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	2012 - Ongoing
Back pain	Chronic back pain	2013 - Ongoing
Skin discolouration	Bilateral upper extremity discoloration	May 2015 - Ongoing
Postmenopause	Post menopausal	2017 - Ongoing
Hypertension	Hypertension	Jul 2017 - Ongoing
Osteoarthritis	Bilateral hand osteoarthritis	2018 - Ongoing
Osteopenia	Osteopenia	2019 - Ongoing
Osteoporosis	Osteoporosis	2019 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2019 - Ongoing
Fibrocystic breast disease	Bilateral fibrocystic breast	Feb 2019 - Ongoing
Blood cholesterol increased	High cholesterol	Feb 2020 - Ongoing
Bursitis	Right elbow bursitis	01 May 2020 (Study Day -97) - Ongoing
Cellulitis	Right elbow cellulitis	01 May 2020 (Study Day -97) - 01 Jun 2020 (Study Day -66)
Cellulitis	Right elbow cellulitis	24 Jun 2020 (Study Day -43) - Jul 2020
Rash	Abdominal rash	Jul 2020 - Jul 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2013 - 05 Aug 2020 (Study Day -1)	Chronic Back Pain
Fluoxetine hydrochloride	Jul 2017 - Ongoing	Bipolar
Hydrochlorothiazide; lisinopril	Jul 2017 - 20 Jan 2021 (Study Day 168)	Hypertension
Hydroxyzine	Jul 2017 - Ongoing	Anxiety
Metoprolol tartrate	Jul 2017 - 12 Nov 2020 (Study Day 99)	Hypertension
Olanzapine	Jul 2017 - Ongoing	Bipolar
Ergocalciferol	2019 - Ongoing	Vitamin D Deficiency
Meloxicam	2019 - Ongoing	Chronic Back Pain
Methocarbamol	2019 - Ongoing	Chronic Back Pain
Atorvastatin	Feb 2020 - Ongoing	High Cholesterol
Pneumococcal vaccine	10 Jul 2020 (Study Day -27) - 10 Jul 2020 (Study Day -27)	Pneumonia Prevention
Ibuprofen	07 Aug 2020 (Study Day 2) - 08 Aug 2020 (Study Day 3)	Chronic Back Pain
Ibuprofen	25 Aug 2020 (Study Day 20) - 25 Aug 2020 (Study Day 20)	Chronic Back Pain
Paracetamol	04 Sep 2020 (Study Day 30) - 04 Sep 2020 (Study Day 30)	Pain At Injection Site
Influenza vaccine	16 Oct 2020 (Study Day 72) - 16 Oct 2020 (Study Day 72)	Influenza Prevention
Chest x-ray*	16 Jan 2021 (Study Day 164) - 16 Jan 2021 (Study Day 164)	Adverse Event
Ct head without contrast*	16 Jan 2021 (Study Day 164) - 16 Jan 2021 (Study Day 164)	Adverse Event
Ekg 12-lead*	16 Jan 2021 (Study Day 164) - 16 Jan 2021 (Study Day 164)	Adverse Event
Magnesium sulfate	16 Jan 2021 (Study Day 164) - 16 Jan 2021 (Study Day 164)	Hyponatremia
Nicotine	16 Jan 2021 (Study Day 164) - Ongoing	Nicotine Addiction
Potassium chloride	16 Jan 2021 (Study Day 164) - 16 Jan 2021 (Study Day 164)	Hypokalemia
Sodium chloride	16 Jan 2021 (Study Day 164) - 16 Jan 2021 (Study Day 164)	Hyponatremia
Ekg 12 lead*	17 Jan 2021 (Study Day 165) - 17 Jan 2021 (Study Day 165)	Adverse Event
Echo*	19 Jan 2021 (Study Day 167) - 19 Jan 2021 (Study Day 167)	Adverse Event
Us carotid doppler*	19 Jan 2021 (Study Day 167) - 19 Jan 2021 (Study Day 167)	Adverse Event
Amlodipine	20 Jan 2021 (Study Day 168) - 20 Feb 2021 (Study Day 199)	Hyponatremia
Metoprolol	20 Jan 2021 (Study Day 168) - Ongoing	Hyponatremia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	20 Jan 2021 (Study Day 168) - 27 Jan 2021 (Study Day 175)	Hyponatremia
Vitamin b1 nos	20 Jan 2021 (Study Day 168) - 20 Feb 2021 (Study Day 199)	Hyponatremia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fall	Grade 2/moderate	Not related	14 Jan 2021 (Study Day 162) - 14 Jan 2021 (Study Day 162)
Cerebral Atrophy	Grade 1/mild	Not related	16 Jan 2021 (Study Day 164) - Ongoing
Electrocardiogram Qt Prolonged	Grade 1/mild	Not related	16 Jan 2021 (Study Day 164) - Ongoing
Hypokalaemia	Grade 3/severe	Not related	16 Jan 2021 (Study Day 164) - 20 Jan 2021 (Study Day 168)
Liver Function Test Increased	Grade 1/mild	Not related	16 Jan 2021 (Study Day 164) - Ongoing
Troponin Increased	Grade 1/mild	Not related	16 Jan 2021 (Study Day 164) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2098 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	10 Sep 2020 (Study Day 32)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Prostate Cancer/Prostate Cancer	SAE	Grade 3/ severe	Not related	28 Aug 2020 (Study Day 19) – Ongoing	Not recovered/ not resolved
Plasma Cell Myeloma/Multiple Myeloma	SAE	Grade 3/ severe	Not related	24 Nov 2020 (Study Day 107) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2098, a 67-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 10 Sep 2020 (Study Day 32). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Aug 2020 (Study Day 19), 18 days after the first dose and 13 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of prostate cancer. The IP dose was not changed due to the prostate cancer. The event of prostate cancer was considered to be ongoing. The investigator assessed the event of prostate cancer to be not related to the IP.

On 24 Nov 2020 (Study Day 107), 106 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of plasma cell myeloma. Action taken with the IP was not applicable. The event of multiple myeloma was considered to be ongoing. The investigator assessed the event of plasma cell myeloma to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000469	Prostate cancer
MOD-2020-001071	Plasma cell myeloma

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anosmia	Anosmia	1985 - Ongoing
Craniofacial fracture	Craniofacial separation	1985 - 1985
Cranioplasty	Craniofacial reconstruction	1985 - 1985
Eye prosthesis user	Dependency of right eye prosthetic	1985 - Ongoing
Road traffic accident	History of motor vehicle accident	03 Nov 1985 (Study Day -12699) - 03 Nov 1985 (Study Day -12699)
Alcohol use	Alcohol use-16 oz of wine/day	2000 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Vasectomy	Vasectomy	2008 - 2008
Inguinal hernia	(r) inguinal hernia	2009 - 2009
Inguinal hernia repair	(r) inguinal hernia repair	2009 - 2009
Drug hypersensitivity	Sulfa allergy	2015 - Ongoing
Food allergy	Shrimp allergy	2015 - Ongoing
Sensation of foreign body	Globus sensation	2019 - Ongoing
Vitamin B12 deficiency	Vitamin b12-deficiency	2019 - Ongoing
Microalbuminuria	Microalbumuinuria	Jun 2019 - Ongoing
Cataract	(l) cataract	Feb 2020 - Ongoing
Thyroid mass	Thyroid nodules	09 Mar 2020 (Study Day -154) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ubidecarenone	2010 - Ongoing	General Health
Vitamin b12 nos	2019 - Ongoing	B-12 Deficiency
Paracetamol	10 Sep 2020 (Study Day 32) - 11 Sep 2020 (Study Day 33)	Pain At Injection Site
Acetylsalicylic acid	24 Sep 2020 (Study Day 46) - 24 Sep 2020 (Study Day 46)	Bilateral Hip Pain And Neck Pain
Paracetamol	24 Sep 2020 (Study Day 46) - 24 Sep 2020 (Study Day 46)	Bilateral Hip Pain And Neck Pain
Ascorbic acid	Oct 2020 - 04 Dec 2020 (Study Day 117)	Prostate Cancer And Multiple Myeloma
Cannabidiol	Oct 2020 - Ongoing	Prostate Cancer And Multiple Myeloma
Colecalciferol	Oct 2020 - 04 Dec 2020 (Study Day 117)	Prostate Cancer And Multiple Myeloma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fish oil	Oct 2020 - Ongoing	Prostate Cancer And Multiple Myeloma
Biopsy of prostate*	02 Oct 2020 (Study Day 54) - 02 Oct 2020 (Study Day 54)	Adverse Event
Ceftriaxone	02 Oct 2020 (Study Day 54) - 02 Oct 2020 (Study Day 54)	Prostate Biopsy
Left cataract removal*	15 Oct 2020 (Study Day 67) - 15 Oct 2020 (Study Day 67)	Adverse Event
Pneumococcal vaccine polysacch 23v	04 Nov 2020 (Study Day 87) - 04 Nov 2020 (Study Day 87)	Immunization
Prednisone	04 Nov 2020 (Study Day 87) - 13 Nov 2020 (Study Day 96)	Bilateral Hip Pain
Ct pet scan*	17 Nov 2020 (Study Day 100) - 17 Nov 2020 (Study Day 100)	Adverse Event
Tizanidine hydrochloride	20 Nov 2020 (Study Day 103) - 02 Dec 2020 (Study Day 115)	Multiple Myeloma
Bone marrow aspirate*	02 Dec 2020 (Study Day 115) - 02 Dec 2020 (Study Day 115)	Adverse Event
Peripheral blood smear*	02 Dec 2020 (Study Day 115) - 02 Dec 2020 (Study Day 115)	Adverse Event
Tramadol	02 Dec 2020 (Study Day 115) - Ongoing	Multiple Myeloma
Lenalidomide	04 Dec 2020 (Study Day 117) - 08 Dec 2020 (Study Day 121)	Prostate Cancer
Acetylsalicylic acid	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Aciclovir	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Bortezomib	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Denosumab	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Dexamethasone	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Famotidine	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Hydrocodone bitartrate; paracetamol	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Lenalidomide	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Prochlorperazine	08 Dec 2020 (Study Day 121) - Ongoing	Multiple Myeloma
Lidocaine	22 Dec 2020 (Study Day 135) - Ongoing	Multiple Myeloma
Escitalopram oxalate	05 Jan 2021 (Study Day 149) - Ongoing	Worsening Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Neck Pain	Grade 1/mild	Not related	22 Sep 2020 (Study Day 44) - 30 Nov 2020 (Study Day 113)
Arthralgia	Grade 1/mild	Not related	24 Sep 2020 (Study Day 46) - 11 Dec 2020 (Study Day 124)
Cataract	Grade 2/moderate	Not related	15 Oct 2020 (Study Day 67) - 15 Oct 2020 (Study Day 67)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	05 Jan 2021 (Study Day 149) - 05 Feb 2021 (Study Day 180)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2132 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	08 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Obesity/Worsening Obesity	SAE	Grade 3/ severe	Not related	24 Dec 2020 (Study Day 136) – 26 Dec 2020 (Study Day 138)	Recovered/resolved
Postoperative Abscess/ Abscess (Post Surgical Abdominal)	SAE	Grade 4	Not related	29 Jan 2021 (Study Day 172) – 06 Feb 2021 (Study Day 180)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2132, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 11 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 08 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Dec 2020 (Study Day 136), 135 days after the first dose and 107 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of obesity. Action taken with the IP was not applicable. The event of worsening obesity lasted for 3 days, after which it was considered to be recovered/resolved on 26 Dec 2020 (Study Day 138). The investigator assessed the event of obesity to be not related to the IP.

On 29 Jan 2021 (Study Day 172), 171 days after the first dose and 143 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of postoperative abscess. Action taken with the IP was not applicable. The event of abscess (post surgical abdominal) lasted for 9 days, after which it was considered to be recovered/resolved on 06 Feb 2021 (Study Day 180). The investigator assessed the event of postoperative abscess to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003686	Obesity
MOD-2021-012044	Postoperative abscess

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sinusitis	Sinusitis	1965 - Ongoing
Fracture treatment	Left broken hand surgery	1968 - 1968
Hand fracture	Left broken hand	1968 - 1968
Anaphylactic reaction	Penicillin allergy (anaphylactic)	1975 - Ongoing
Drug hypersensitivity	Sulfa allergy	1975 - Ongoing
Ex-tobacco user	Past smoker	1975 - 1980
Asthma	Moderate persistent asthma with acute exacerbation	1990 - Ongoing
Hypersensitivity	Environmental allergies	1990 - Ongoing
Insomnia	Insomnia	1990 - Ongoing
Ligament operation	Left cruciate ligament torn-repair	1999 - 1999
Ligament rupture	Left torn cruciate ligament	1999 - 1999
Ankle fracture	Left ankle break	2007 - 2007
Ankle operation	Left ankle surgery	2007 - 2007
Sinus operation	Sinus surgery	2007 - 2007
Depression	Depression	25 Aug 2011 (Study Day -3274) - Ongoing
Hypertension	Hypertension	25 Aug 2011 (Study Day -3274) - Ongoing
Testicular failure	Testicular hypofunction	25 Aug 2011 (Study Day -3274) - Ongoing
Osteoarthritis	Osteoarthritis bilateral hands	2013 - Ongoing
Anxiety	Anxiety	2015 - Ongoing
Polycythaemia	Erythrocytosis	03 Feb 2015 (Study Day -2016) - Ongoing
Vitamin D deficiency	Vitamin d deficiency	03 Feb 2015 (Study Day -2016) - Ongoing
Cholecystectomy	Gallbladder removal	2018 - 2018
Cholecystitis	Gallbladder inflammation	2018 - 2018
Obesity	Obesity	11 Jan 2018 (Study Day -943) - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	21 Aug 2018 (Study Day -721) - Ongoing
Gastrooesophageal reflux disease	Gerd	2019 - Ongoing
Restless legs syndrome	Bilateral restless legs syndrome	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Budesonide; formoterol fumarate	1990 - 26 Oct 2020 (Study Day 77)	Asthma
Fluticasone propionate	1990 - Ongoing	Environmental Allergies
Salbutamol	1990 - Ongoing	Asthma
Testosterone	Aug 2011 - Ongoing	Testicular Hypofunction
Trazodone	2014 - Ongoing	Insomnia
Alprazolam	2015 - 26 Oct 2020 (Study Day 77)	Anxiety
Hydrochlorothiazide	2015 - 20 Feb 2021 (Study Day 194)	Hypertension
Levocetirizine dihydrochloride	2015 - Ongoing	Environmental Allergies
Azelastine	2016 - Ongoing	Environmental Allergies
Celecoxib	2016 - Ongoing	Osteoarthritis In Both Hands
Tamsulosin	2016 - Ongoing	Preventative Prostate Health
Epinephrine	2017 - Ongoing	Penicillin Allergy
Vitamins nos	2017 - Ongoing	Vitamin D Deficiency
Bupropion	2018 - Ongoing	Depression
Metoprolol	2018 - Ongoing	Hypertension
Quercetin	2018 - Ongoing	General Health
Iron	2019 - 20 Feb 2021 (Study Day 194)	General Health
Rotigotine	2019 - 24 Feb 2021 (Study Day 198)	Restless Leg Syndrome
Vitamins nos	2019 - 24 Dec 2020 (Study Day 136)	General Health
Buspirone	27 Aug 2020 (Study Day 17) - 08 Sep 2020 (Study Day 29)	Worsening Anxiety
Omeprazole	27 Aug 2020 (Study Day 17) - Ongoing	Worsening Gerd
Paracetamol	09 Sep 2020 (Study Day 30) - 11 Sep 2020 (Study Day 32)	Headache And Pain At Injection Site
Alprazolam	26 Oct 2020 (Study Day 77) - 01 Jan 2021 (Study Day 144)	Worsening Anxiety
Buspirone	26 Oct 2020 (Study Day 77) - 01 Jan 2021 (Study Day 144)	Worsening Anxiety
Umeclidinium bromide; vilanterol trifenatate	26 Oct 2020 (Study Day 77) - Ongoing	Bronchitis
Gastric sleeve surgery*	24 Dec 2020 (Study Day 136) - 24 Dec 2020 (Study Day 136)	Adverse Event
Vitamins nos	26 Dec 2020 (Study Day 138) - Ongoing	Supplement
Alprazolam	01 Jan 2021 (Study Day 144) - Ongoing	Anxiety
Buspirone	01 Jan 2021 (Study Day 144) - Ongoing	Anxiety
Abscess drain*	30 Jan 2021 (Study Day 173) - 30 Jan 2021 (Study Day 173)	Adverse Event
Linezolid	06 Feb 2021 (Study Day 180) - 12 Feb 2021 (Study Day 186)	Abscess
Losartan	20 Feb 2021 (Study Day 194) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	27 Aug 2020 (Study Day 17) - 08 Sep 2020 (Study Day 29)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	27 Aug 2020 (Study Day 17) - 08 Sep 2020 (Study Day 29)
Dermatitis	Grade 3/severe	Related	09 Sep 2020 (Study Day 30) - 17 Sep 2020 (Study Day 38)
Anxiety	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 77) - 01 Nov 2020 (Study Day 83)
Bronchitis	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 77) - 31 Oct 2020 (Study Day 82)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2169 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	11 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Fall/Multiple Falls	SAE	Grade 4	Not related	17 Dec 2020 (Study Day 126) – 21 Dec 2020 (Study Day 130)	Recovered/resolved
Urinary Tract Infection/Urinary Tract Infection	SAE	Grade 4	Not related	21 Dec 2020 (Study Day 130) – 28 Dec 2020 (Study Day 137)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2169, a 67-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 11 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Dec 2020 (Study Day 126), 125 days after the first dose and 97 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of fall. Action taken with the IP was not applicable. The event of multiple falls lasted for 5 days, after which it was considered to be recovered/resolved on 21 Dec 2020 (Study Day 130). The investigator assessed the event of fall to be not related to the IP.

On 21 Dec 2020 (Study Day 130), 129 days after the first dose and 101 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of urinary tract infection. Action taken with the IP was not applicable. The event of urinary tract infection lasted for 8 days, after which it was considered to be recovered/resolved on 28 Dec 2020 (Study Day 137). The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002878	Fall
MOD-2021-002878	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Iron deficiency anaemia	Iron deficiency induced anemia	1974 - 20 Mar 1982 (Study Day -14027)
Substance use	Recreational marijuana use	1982 - Ongoing
Female sterilisation	Tubal ligation	20 Mar 1982 (Study Day -14027) - 20 Mar 1982 (Study Day -14027)
Urticaria	Flagyl allergy (hives)	1998 - Ongoing
Neuropathy peripheral	Unilateral peripheral neuropathy (right side only, sensory or motor in nature unknown)	2000 - Ongoing
Postmenopause	Post menopausal	15 May 2005 (Study Day -5570) - Ongoing
Constipation	Chronic constipation	2010 - Ongoing
Arthralgia	(r) hip pain	2011 - Ongoing
Osteoarthritis	Osteoarthritis bilateral knee	11 Aug 2011 (Study Day -3291) - Ongoing
Peroneal nerve palsy	Left foot drop	2013 - Ongoing
Insomnia	Insomnia	2016 - Ongoing
Headache	Headaches	Jan 2017 - Ongoing
Hypertonic bladder	Overactive bladder	Nov 2019 - Ongoing
Influenza	Influenza strain b	06 Jan 2020 (Study Day -221) - 15 Jan 2020 (Study Day -212)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Butalbital; paracetamol	Jan 2017 - Ongoing	Headaches
Tramadol	2018 - Ongoing	Osteoarthritis Bilateral Knee
Zolpidem	2018 - Ongoing	Insomnia
Mirabegron	Nov 2019 - Ongoing	Overactive Bladder
Gabapentin	Jun 2020 - Ongoing	Right Sided Unilateral Peripheral (Both Limbs) Neuropathy
Nitrofurantoin	27 Aug 2020 (Study Day 14) - 03 Sep 2020 (Study Day 21)	Urinary Tract Infection
Influenza vaccine	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Flu Prophalactic
Right total knee replacement*	04 Dec 2020 (Study Day 113) - 04 Dec 2020 (Study Day 113)	Medical History

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	05 Dec 2020 (Study Day 114) - 19 Dec 2020 (Study Day 128)	Post Op Pain-Right Total Knee Replacement
Celecoxib	05 Dec 2020 (Study Day 114) - 11 Dec 2020 (Study Day 120)	Post Op Pain Right Total Knee Replacement
Oxycodone; paracetamol	05 Dec 2020 (Study Day 114) - 21 Dec 2020 (Study Day 130)	Post-Op Pain (Right Total Knee Replacement)
Sennoside a+b	05 Dec 2020 (Study Day 114) - 09 Dec 2020 (Study Day 118)	Opioid Induced Constipation
Ct of head*	21 Dec 2020 (Study Day 130) - 21 Dec 2020 (Study Day 130)	Adverse Event
Ultrasound of right lower extremity*	21 Dec 2020 (Study Day 130) - 21 Dec 2020 (Study Day 130)	Adverse Event
Ct of pelvis*	22 Dec 2020 (Study Day 131) - 22 Dec 2020 (Study Day 131)	Adverse Event
Nitrofurantoin	22 Dec 2020 (Study Day 131) - 28 Dec 2020 (Study Day 137)	Uti
Hydrocodone bitartrate; paracetamol	28 Dec 2020 (Study Day 137) - 12 Jan 2021 (Study Day 152)	Post-Op Pain Right Total Knee Replacement
Nitrofurantoin	18 Feb 2021 (Study Day 189) - 25 Feb 2021 (Study Day 196)	Urinary Tract Infection
Scarring debridement*	03 Mar 2021 (Study Day 202) - 03 Mar 2021 (Study Day 202)	Adverse Event
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	20 Mar 2021 (Study Day 219) - 20 Mar 2021 (Study Day 219)	Nasal Congestion
Pseudoephedrine hydrochloride	21 Mar 2021 (Study Day 220) - 21 Mar 2021 (Study Day 220)	Nasal Congestion
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	22 Mar 2021 (Study Day 221) - 22 Mar 2021 (Study Day 221)	Nasal Congestion
Pseudoephedrine hydrochloride	23 Mar 2021 (Study Day 222) - 23 Mar 2021 (Study Day 222)	Nasal Congestion

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 1/mild	Not related	27 Aug 2020 (Study Day 14) - 03 Sep 2020 (Study Day 21)
Procedural Pain	Grade 2/moderate	Not related	05 Dec 2020 (Study Day 114) - Ongoing
Sciatica	Grade 3/severe	Not related	21 Dec 2020 (Study Day 130) - 30 Dec 2020 (Study Day 139)
Urinary Tract Infection	Grade 1/mild	Not related	11 Feb 2021 (Study Day 182) - 25 Feb 2021 (Study Day 196)
Joint Range Of Motion Decreased	Grade 2/moderate	Not related	25 Feb 2021 (Study Day 196) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rhinovirus Infection	Grade 1/mild	Not related	18 Mar 2021 (Study Day 217) - 01 Apr 2021 (Study Day 231)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2270 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Diabetes Mellitus/Diabetes Mellitus	SAE	Grade 4	Not related	08 Jan 2021 (Study Day 136) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2270, a 40-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Jan 2021 (Study Day 136), 135 days after the first dose and 106 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of diabetes mellitus. Action taken with the IP was not applicable. The event of diabetes mellitus was considered to be ongoing. The investigator assessed the event of diabetes mellitus to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-002629	Type 2 diabetes mellitus
MOD-2020-001035	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tobacco user	Smoker - cigarettes 3x day	1980 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Arthralgia	Left elbow pain	01 Aug 2020 (Study Day -25) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fexofenadine hydrochloride	Jan 2020 - Feb 2020	Seasonal Allergies
Mentha x piperita oil	10 Sep 2020 (Study Day 16) - 13 Sep 2020 (Study Day 19)	Constipation
Mentha x piperita oil	13 Sep 2020 (Study Day 19) - 03 Oct 2020 (Study Day 39)	Digestive Health
Influenza vaccine	17 Oct 2020 (Study Day 53) - 17 Oct 2020 (Study Day 53)	Prophalactic
Ketoconazole	09 Nov 2020 (Study Day 76) - 15 Nov 2020 (Study Day 82)	Tinea Pedis
Paracetamol	29 Nov 2020 (Study Day 96) - 29 Nov 2020 (Study Day 96)	Headache
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	03 Dec 2020 (Study Day 100) - 03 Dec 2020 (Study Day 100)	Fever (100.4)
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	04 Dec 2020 (Study Day 101) - 06 Dec 2020 (Study Day 103)	Symptomatic COVID 19
Azithromycin	07 Dec 2020 (Study Day 104) - 07 Dec 2020 (Study Day 104)	Stmptomatic COVID 19
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol; phenylephrine hydrochloride	07 Dec 2020 (Study Day 104) - 10 Dec 2020 (Study Day 107)	Symptomatic COVID19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	07 Dec 2020 (Study Day 104) - 10 Dec 2020 (Study Day 107)	Symptomatic COVID 19
Ibuprofen	07 Dec 2020 (Study Day 104) - 07 Dec 2020 (Study Day 104)	Symptomatic COVID 19
Menthol	07 Dec 2020 (Study Day 104) - 08 Dec 2020 (Study Day 105)	Symptomatic COVID 19
Azithromycin	08 Dec 2020 (Study Day 105) - 11 Dec 2020 (Study Day 108)	Symptomatic COVID 19
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	11 Dec 2020 (Study Day 108) - 17 Dec 2020 (Study Day 114)	Symptomatic COVID 19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	11 Dec 2020 (Study Day 108) - 11 Dec 2020 (Study Day 108)	Symptomatic COVID 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	12 Dec 2020 (Study Day 109) - 14 Dec 2020 (Study Day 111)	Symptomatic COVID 19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	16 Dec 2020 (Study Day 113) - 17 Dec 2020 (Study Day 114)	Symptomatic COVID 19
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol; phenylephrine hydrochloride	19 Dec 2020 (Study Day 116) - 19 Dec 2020 (Study Day 116)	Symptomatic COVID-19
Cymbopogon schoenanthus	20 Dec 2020 (Study Day 117) - 20 Dec 2020 (Study Day 117)	Symptomatic COVID-19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	20 Dec 2020 (Study Day 117) - 20 Dec 2020 (Study Day 117)	Symptomatic COVID-19
Eucalyptus globulus oil; menthol	20 Dec 2020 (Study Day 117) - 21 Dec 2020 (Study Day 118)	Symptomatic COVID-19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	29 Dec 2020 (Study Day 126) - 29 Dec 2020 (Study Day 126)	Symptomatic COVID-19
Eucalyptus globulus oil; menthol	29 Dec 2020 (Study Day 126) - 29 Dec 2020 (Study Day 126)	Symptomatic COVID-19
Blood culture*	08 Jan 2021 (Study Day 136) - 08 Jan 2021 (Study Day 136)	Adverse Event
Blood glucose level*	08 Jan 2021 (Study Day 136) - 08 Jan 2021 (Study Day 136)	Adverse Event
Chest x-ray*	08 Jan 2021 (Study Day 136) - 08 Jan 2021 (Study Day 136)	Adverse Event
Ekg*	08 Jan 2021 (Study Day 136) - 08 Jan 2021 (Study Day 136)	Adverse Event
Urinalysis*	08 Jan 2021 (Study Day 136) - 08 Jan 2021 (Study Day 136)	Adverse Event
Glipizide	10 Jan 2021 (Study Day 138) - 27 Jan 2021 (Study Day 155)	Type II Diabetes
Metformin	10 Jan 2021 (Study Day 138) - 27 Jan 2021 (Study Day 155)	Type II Diabetes
Insulin glargine	14 Jan 2021 (Study Day 142) - 18 Feb 2021 (Study Day 177)	Type II Diabetes
Insulin aspart	18 Jan 2021 (Study Day 146) - Ongoing	Type II Diabetes
Triamcinolone	21 Jan 2021 (Study Day 149) - Ongoing	Pruitis-Bilateral Feet
Fexofenadine hydrochloride	30 Jan 2021 (Study Day 158) - Ongoing	Seasonal Allergies
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	31 Jan 2021 (Study Day 159) - 31 Jan 2021 (Study Day 159)	Symptomatic COVID-19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	01 Feb 2021 (Study Day 160) - 01 Feb 2021 (Study Day 160)	Symptomatic COVID-19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	03 Feb 2021 (Study Day 162) - 03 Feb 2021 (Study Day 162)	Symptomatic COVID-19
Paracetamol	03 Feb 2021 (Study Day 162) - 03 Feb 2021 (Study Day 162)	Tooth Pain

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	04 Feb 2021 (Study Day 163) - 04 Feb 2021 (Study Day 163)	Symptomatic COVID-19
Paracetamol	04 Feb 2021 (Study Day 163) - 04 Feb 2021 (Study Day 163)	Tooth Pain
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	05 Feb 2021 (Study Day 164) - 05 Feb 2021 (Study Day 164)	Symptomatic COVID-19
Dextromethorphan hydrobromide; guaifenesin; paracetamol; phenylephrine hydrochloride	07 Feb 2021 (Study Day 166) - 07 Feb 2021 (Study Day 166)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Constipation	Grade 1/mild	Not related	07 Sep 2020 (Study Day 13) - 13 Sep 2020 (Study Day 19)
Temperature Intolerance	Grade 1/mild	Not related	07 Oct 2020 (Study Day 43) - 08 Oct 2020 (Study Day 44)
Erythema	Grade 1/mild	Not related	01 Nov 2020 (Study Day 68) - 29 Dec 2020 (Study Day 126)
Skin Abrasion	Grade 1/mild	Not related	01 Nov 2020 (Study Day 68) - 29 Dec 2020 (Study Day 126)
Tinea Pedis	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 68) - 21 Jan 2021 (Study Day 149)
COVID-19	Grade 2/moderate	Not related	29 Nov 2020 (Study Day 96) - 07 Feb 2021 (Study Day 166)
Abnormal Loss Of Weight	Grade 1/mild	Not related	21 Dec 2020 (Study Day 118) - 17 Feb 2021 (Study Day 176)
Tachycardia	Grade 1/mild	Not related	22 Dec 2020 (Study Day 119) - 28 Dec 2020 (Study Day 125)
Pruritus	Grade 1/mild	Not related	21 Jan 2021 (Study Day 149) - Ongoing
Vision Blurred	Grade 1/mild	Not related	23 Jan 2021 (Study Day 151) - 01 Feb 2021 (Study Day 160)
Toothache	Grade 1/mild	Not related	03 Feb 2021 (Study Day 162) - 06 Feb 2021 (Study Day 165)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2280 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression Suicidal/Major Depressive Disorder With Suicidal Ideation	SAE	Grade 4	Not related	12 Nov 2020 (Study Day 78) – 17 Nov 2020 (Study Day 83)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2280, a 29-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Nov 2020 (Study Day 78), 77 days after the first dose and 49 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of depression suicidal. Action taken with the IP was not applicable. The event of major depressive disorder with suicidal ideation lasted for 6 days, after which it was considered to be recovered/resolved on 17 Nov 2020 (Study Day 83). The investigator assessed the event of depression suicidal to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000796	Depression suicidal

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to sulfa	1995 - Ongoing
Anxiety	Anxiety	1998 - Ongoing
Depression	Depression	1998 - Ongoing
Suicidal ideation	Recurrent suicidal ideation	1998 - 2018
Dizziness	Intermittent dizziness	2000 - Ongoing
Hypersensitivity	Environmental allergies	2000 - Ongoing
Back pain	Back pain	2001 - Ongoing
Fatigue	Fatigue	2001 - Ongoing
Scoliosis	Scoliosis	2001 - Ongoing
Anaemia	Anemia	2002 - Ongoing
Seizure	Seizure	2002 - 2002
Migraine	Migraines	2006 - Ongoing
Gastrooesophageal reflux disease	Gerd	2010 - Ongoing
Cholecystectomy	Cholecystectomy	Apr 2014 - Apr 2014
Cholecystitis	Cholecystitis	Apr 2014 - Apr 2014
Cervix carcinoma stage 0	Stage 0 cervical ca	Aug 2014 - Aug 2014
Loop electrosurgical excision procedure	Leep procedure (loop electrosurgical excision procedure)	Aug 2014 - Aug 2014
Hallucination, auditory	Auditory hallucinations	2016 - Ongoing
Visual impairment	Bilateral vision impairment	2017 - Ongoing
Autism spectrum disorder	Autism spectrum disorder	2018 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Dec 2019 - Ongoing
Peripheral swelling	Bilateral le swelling	Dec 2019 - Ongoing
Polycystic ovaries	Polycystic ovarian syndrome	Dec 2019 - Ongoing
Sinus arrhythmia	Sinus arrhythmia	27 Aug 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2010 - Ongoing	Gerd
Bupropion hydrochloride	Aug 2016 - 19 Oct 2020 (Study Day 54)	Depression
Spironolactone	Dec 2019 - Ongoing	Bilateral Le Swelling
Vitamins nos	Dec 2019 - Ongoing	General Health
Cetirizine hydrochloride	Mar 2020 - 19 Oct 2020 (Study Day 54)	Environmental Allergies
Intrauterine contraceptive device	14 Aug 2020 (Study Day -13) - Ongoing	Contraception

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Headache
Naproxen	25 Sep 2020 (Study Day 30) - 25 Sep 2020 (Study Day 30)	Headache
Ibuprofen	16 Oct 2020 (Study Day 51) - 24 Oct 2020 (Study Day 59)	COVID Like Illness
Ibuprofen	16 Oct 2020 (Study Day 51) - 25 Oct 2020 (Study Day 60)	COVID Like Illness
Ascorbic acid	20 Oct 2020 (Study Day 55) - Ongoing	General Health
Bupropion hydrochloride	20 Oct 2020 (Study Day 55) - Ongoing	Depression
Cetirizine hydrochloride	20 Oct 2020 (Study Day 55) - Ongoing	Environmental Allergies
Colecalciferol	20 Oct 2020 (Study Day 55) - Ongoing	General Health
Nitrofurantoin	20 Oct 2020 (Study Day 55) - 25 Oct 2020 (Study Day 60)	Urinary Tract Infection
Benzocaine; dextromethorphan hydrobromide	23 Oct 2020 (Study Day 58) - 23 Oct 2020 (Study Day 58)	COVID Like Illness
Caffeine; paracetamol	23 Oct 2020 (Study Day 58) - 23 Oct 2020 (Study Day 58)	COVID Like Illness
Caffeine; paracetamol	25 Oct 2020 (Study Day 60) - 25 Oct 2020 (Study Day 60)	COVID Like Illness
Urine drug screen*	13 Nov 2020 (Study Day 79) - 13 Nov 2020 (Study Day 79)	Adverse Event
Aripiprazole	17 Nov 2020 (Study Day 83) - Ongoing	Major Depressive Disorder
Calcium carbonate	17 Nov 2020 (Study Day 83) - Ongoing	Gerd Exacerbation
Paracetamol	17 Nov 2020 (Study Day 83) - 30 Nov 2020 (Study Day 96)	Headache And Upper Respiratory Illness
Ibuprofen	21 Nov 2020 (Study Day 87) - 21 Nov 2020 (Study Day 87)	Headache
Potassium	09 Feb 2021 (Study Day 167) - Ongoing	Bilateral Le Cramping

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	26 Sep 2020 (Study Day 31) - 17 Nov 2020 (Study Day 83)
Depression	Grade 2/moderate	Not related	05 Oct 2020 (Study Day 40) - 27 Oct 2020 (Study Day 62)
Suspected COVID-19	Grade 2/moderate	Not related	16 Oct 2020 (Study Day 51) - 25 Oct 2020 (Study Day 60)
Urinary Tract Infection	Grade 1/mild	Not related	19 Oct 2020 (Study Day 54) - 25 Oct 2020 (Study Day 60)
Suspected COVID-19	Grade 2/moderate	Not related	13 Nov 2020 (Study Day 79) - 01 Feb 2021 (Study Day 159)
Upper Respiratory Tract Infection	Grade 2/moderate	Not related	13 Nov 2020 (Study Day 79) - 01 Feb 2021 (Study Day 159)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Muscle Spasms	Grade 1/mild	Not related	23 Jan 2021 (Study Day 150) - 19 Feb 2021 (Study Day 177)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US382-2003 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	01 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	SAE	Grade 3/severe	Not related	24 Oct 2020 (Study Day 82) – 27 Oct 2020 (Study Day 85)	Recovered/ resolved
Pericarditis/Acute Pericarditis	SAE	Grade 4	Not related	12 Nov 2020 (Study Day 101) – 13 Nov 2020 (Study Day 102)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2003, a 65-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 01 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Oct 2020 (Study Day 82), 81 days after the first dose and 53 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 4 days, after which it was considered to be recovered/resolved on 27 Oct 2020 (Study Day 85). The investigator assessed the event of myocardial infarction to be not related to the IP.

On 12 Nov 2020 (Study Day 101), 100 days after the first dose and 72 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pericarditis. Action taken with the IP was not applicable. The event of acute pericarditis lasted for 2 days, after which it was considered to be recovered/resolved on 13 Nov 2020 (Study Day 102). The investigator assessed the event of pericarditis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000566	Myocardial infarction
MOD-2020-000811	Pericarditis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficient hyperactivity disorder	1990 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2017 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	08 Jan 2019 (Study Day -574) - Ongoing
Hiatus hernia	Hiatal hernia	17 Jul 2019 (Study Day -384) - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type II	Jan 2020 - Ongoing
Bursitis	Bursitis of olecranon of right elbow	07 May 2020 (Study Day -89) - Ongoing
Dermatitis contact	Contact dermatatis - sea life, snorkling	02 Jul 2020 (Study Day -33) - 09 Jul 2020 (Study Day -26)
Benign prostatic hyperplasia	Benign prostatic hypertrophy with outflow obstruction	17 Jul 2020 (Study Day -18) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	12 Apr 2016 (Study Day -1575) - 12 Apr 2016 (Study Day -1575)	Vaccine
Pneumococcal vaccine	10 Sep 2016 (Study Day -1424) - 10 Sep 2016 (Study Day -1424)	Vaccine
Influenza vaccine	01 Oct 2018 (Study Day -673) - 01 Oct 2018 (Study Day -673)	Vaccine
Simvastatin	03 Dec 2018 (Study Day -610) - Ongoing	Hypercholesterolemia
Influenza vaccine	16 Oct 2019 (Study Day -293) - 16 Oct 2019 (Study Day -293)	Vaccine
Varicella zoster vaccine	05 Dec 2019 (Study Day -243) - 05 Dec 2019 (Study Day -243)	Vaccine
Metformin	28 Jan 2020 (Study Day -189) - Ongoing	Diabetes Mellitus Ii
Varicella zoster vaccine	03 Mar 2020 (Study Day -154) - 03 Mar 2020 (Study Day -154)	Vaccine
Paracetamol	01 Sep 2020 (Study Day 29) - 02 Sep 2020 (Study Day 30)	Injection Site Pain, Headache, Swelling At Injection Site, Chills, Fatigue
Methylprednisolone	16 Sep 2020 (Study Day 44) - 22 Sep 2020 (Study Day 50)	Urticarial Rash (Right Arm)

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	24 Oct 2020 (Study Day 82) - Ongoing	Myocardial Infarction, Coronary Artery Disease
Atorvastatin	24 Oct 2020 (Study Day 82) - Ongoing	Myocardial Infarction, Coronary Artery Disease
Heart cath*	24 Oct 2020 (Study Day 82) - 24 Oct 2020 (Study Day 82)	Adverse Event
Metoprolol succinate	24 Oct 2020 (Study Day 82) - Ongoing	Myocardial Infarction, Coronary Artery Disease
Cardiac stent*	25 Oct 2020 (Study Day 83) - 25 Oct 2020 (Study Day 83)	Adverse Event
Lisinopril	25 Oct 2020 (Study Day 83) - Ongoing	Myocardial Infarction
Prasugrel	25 Oct 2020 (Study Day 83) - Ongoing	Myocardial Infarction
Cardiac lab work*	12 Nov 2020 (Study Day 101) - 12 Nov 2020 (Study Day 101)	Adverse Event
Chest x-ray*	12 Nov 2020 (Study Day 101) - 12 Nov 2020 (Study Day 101)	Adverse Event
Colchicine	12 Nov 2020 (Study Day 101) - 13 Nov 2020 (Study Day 102)	Acute Pericarditis
Echocardiogram*	12 Nov 2020 (Study Day 101) - 12 Nov 2020 (Study Day 101)	Adverse Event
Ibuprofen	12 Nov 2020 (Study Day 101) - 13 Nov 2020 (Study Day 102)	Acute Pericarditis
Pantoprazole	12 Nov 2020 (Study Day 101) - 13 Nov 2020 (Study Day 102)	Acute Pericarditis
Electrocardiogram*	18 Nov 2020 (Study Day 107) - 18 Nov 2020 (Study Day 107)	Diagnostic

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Salivary Hypersecretion	Grade 1/mild	Not related	04 Aug 2020 (Study Day 1) - 04 Aug 2020 (Study Day 1)
Urticaria	Grade 2/moderate	Not related	16 Sep 2020 (Study Day 44) - 30 Sep 2020 (Study Day 58)
Coronary Artery Disease	Grade 2/moderate	Not related	24 Oct 2020 (Study Day 82) - Ongoing
Angina Pectoris	Grade 2/moderate	Not related	10 Nov 2020 (Study Day 99) - 12 Nov 2020 (Study Day 101)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US382-2015 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cardiac Failure/Heart Failure	SAE	Grade 3/severe	Not related	09 Sep 2020 (Study Day 36) – 12 Sep 2020 (Study Day 39)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2015, an 83-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 05 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Sep 2020 (Study Day 36), 35 days after the first dose and 6 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cardiac failure. Action taken with the IP was not applicable. The event of heart failure lasted for 4 days, after which it was considered to be recovered/resolved with sequelae on 12 Sep 2020 (Study Day 39). The investigator assessed the event of cardiac failure to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000284	Cardiac failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Heart murmur	Not reported - Ongoing
Purpura senile	Senile purpura left arm	Not reported - Ongoing
Atrial fibrillation	Atrial fibrillation	2018 - Ongoing
Hypertension	Hypertension	2018 - Ongoing
Hypogonadism	Hypogonadism	2018 - Ongoing
Neuropathy peripheral	Peripheral nerve disease	Nov 2018 - Ongoing
Restless legs syndrome	Restless leg syndrome	Nov 2018 - Ongoing
Rhinitis allergic	Allergic rhinitis	16 Nov 2018 (Study Day -628) - Ongoing
Benign prostatic hyperplasia	Benign prostaic hyperplasia	27 Nov 2018 (Study Day -617) - Ongoing
Mitral valve incompetence	Mitral valve regurgitation	03 Dec 2018 (Study Day -611) - Ongoing
Tricuspid valve incompetence	Tricuspid valve regurgitation	03 Dec 2018 (Study Day -611) - Ongoing
Ventricular extrasystoles	Ventricular premature beats	2019 - Ongoing
Cardiac pacemaker insertion	Biotrink pacemaker insertion	01 Apr 2019 (Study Day -492) - Ongoing
Chronotropic incompetence	Chronotropic incompentence	01 Apr 2019 (Study Day -492) - Ongoing
Pulmonary valve incompetence	Pulmonic valve regurgitation	01 Apr 2019 (Study Day -492) - Ongoing
Sinus node dysfunction	Sinus node dysfunction	01 Apr 2019 (Study Day -492) - Ongoing
Insomnia	Insomnia	Sep 2019 - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	Sep 2019 - Ongoing
Aortic valve incompetence	Aortic valve regurgitation	27 Dec 2019 (Study Day -222) - Ongoing
Hypercoagulation	Hypercoagulabity state	27 Dec 2019 (Study Day -222) - Ongoing
Depression	Depressive disorder	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pneumococcal vaccine polysacch 23v	07 Apr 2015 (Study Day -1947) - 07 Apr 2015 (Study Day -1947)	Vaccine
Pneumococcal vaccine 13v	04 May 2016 (Study Day -1554) - 04 May 2016 (Study Day -1554)	Vaccine
Amlodipine	2018 - Ongoing	Hypertension
Fluticasone propionate	2018 - Ongoing	Allergic Rhinitis
Gabapentin	2018 - Ongoing	Peripheral Nerve Disease
Lisinopril	2018 - Ongoing	Hyptertension
Metoprolol succinate	2018 - Ongoing	Paroxysmal Atrial Fibrillation
Tamsulosin	2018 - Ongoing	Benign Prostatic Hyperplasia
Testosterone cipionate	2018 - Ongoing	Hypogonadism

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Varicella zoster vaccine	Oct 2018 - Oct 2018	Vaccine
Diphenhydramine hydrochloride; paracetamol	2019 - Ongoing	Obstructive Sleep Apnea
Influenza vaccine	Sep 2019 - Sep 2019	Vaccine
Apixaban	Dec 2019 - Ongoing	Cardiac Health
Paracetamol	2020 - Ongoing	Unknown
Cardiac ablation*	09 Sep 2020 (Study Day 36) - 09 Sep 2020 (Study Day 36)	Adverse Event
Metoprolol succinate	09 Sep 2020 (Study Day 36) - Ongoing	Atrial Fibrillation
Omeprazole	09 Sep 2020 (Study Day 36) - Ongoing	Gi Prophyaxis
Chest x-ray 1 view*	10 Sep 2020 (Study Day 37) - 10 Sep 2020 (Study Day 37)	Diagnostic
Echocardiogram*	10 Sep 2020 (Study Day 37) - 10 Sep 2020 (Study Day 37)	Adverse Event
Furosemide	10 Sep 2020 (Study Day 37) - 12 Sep 2020 (Study Day 39)	Bilateral Edema, Extremities (Arms/Legs)
Oxygen	10 Sep 2020 (Study Day 37) - 12 Sep 2020 (Study Day 39)	Heart Failure
Ct angiography coronary artery scan*	11 Sep 2020 (Study Day 38) - 11 Sep 2020 (Study Day 38)	Diagnostic
Ct coronary chest noncardiac with contrast*	11 Sep 2020 (Study Day 38) - 11 Sep 2020 (Study Day 38)	Diagnostic
Incentive spirometer*	11 Sep 2020 (Study Day 38) - 11 Sep 2020 (Study Day 38)	Other, Prophylaxis
Chest x-ray 2 views*	12 Sep 2020 (Study Day 39) - 12 Sep 2020 (Study Day 39)	Diagnostic
Amiodarone	10 Dec 2020 (Study Day 128) - 27 Feb 2021 (Study Day 207)	Atrial Fibrillation
Cardioversion*	29 Jan 2021 (Study Day 178) - 29 Jan 2021 (Study Day 178)	Adverse Event
Furosemide	09 Feb 2021 (Study Day 189) - Ongoing	Heart Failure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Phrenic Nerve Injury	Grade 3/severe	Not related	09 Sep 2020 (Study Day 36) - Ongoing
Oedema Peripheral	Grade 1/mild	Not related	10 Sep 2020 (Study Day 37) - 12 Sep 2020 (Study Day 39)
Pleural Effusion	Grade 1/mild	Not related	11 Sep 2020 (Study Day 38) - 12 Sep 2020 (Study Day 39)
Oedema Peripheral	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 181) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US382-2119 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	17 Sep 2020 (Study Day 36)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urinary Tract Infection/Urinary Tract Infection	SAE	Grade 3/severe	Not related	03 Sep 2020 (Study Day 22) – 06 Sep 2020 (Study Day 25)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2119, a 73-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 17 Sep 2020 (Study Day 36). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Sep 2020 (Study Day 22), 21 days after the first dose and 14 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of urinary tract infection. The IP dose was delayed due to the urinary tract infection. The event of urinary tract infection lasted for 4 days, after which it was considered to be recovered/resolved on 06 Sep 2020 (Study Day 25). The investigator assessed the event of urinary tract infection to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000280	Urinary tract infection

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Affective disorder	Mood disorder	Not reported - Ongoing
Arthralgia	Hip pain	Not reported - Ongoing
Blood cholesterol increased	High cholesterol	Not reported - Ongoing
Diarrhoea	Chronic diarrhea	Not reported - Ongoing
Gastrooesophageal reflux disease	Gerd	Not reported - Ongoing
Gastrooesophageal reflux disease	Gerd	Not reported - Ongoing
Hypertonic bladder	Overactive bladder	Not reported - Ongoing
Hypothyroidism	Hypothyroid	Not reported - Ongoing
Iron deficiency anaemia	Iron deficiency anemia	Not reported - Ongoing
Macular degeneration	Macular degeneration	Not reported - Ongoing
Osteopenia	Osteopenia	Not reported - Ongoing
Systemic lupus erythematosus	Systemic lupus	1987 - Ongoing
Hysterectomy	Total hysterectomy	1988 - 1988
Crohn's disease	Crohn's disease	1990 - Ongoing
Seasonal allergy	Seasonal allergies	1990 - Ongoing
Hypothyroidism	Hypothyrodism	2003 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid; betacarotene; cupric oxide; tocopheryl acetate; zinc oxide	Not reported - Ongoing	Eye Health
Atropine; diphenoxylate	Not reported - Ongoing	Frequent Diarrhea
Budesonide	Not reported - Ongoing	Crohn's
Calcium; colecalciferol	Not reported - Ongoing	Supplement
Gabapentin	Not reported - Ongoing	Unk
Glucosamine sulfate	Not reported - Ongoing	Supplement
Levocetirizine	Not reported - Ongoing	Seasonal Allergies
Levothyroxine	Not reported - Ongoing	Hypothyrodism
Magnesium	Not reported - Ongoing	Supplement
Omeprazole	Not reported - Ongoing	Acid Reflux/Gerd
Potassium	Not reported - Ongoing	Supplement
Probiotics nos	Not reported - Ongoing	Supplement
Pyridoxine hydrochloride	Not reported - Ongoing	Supplement
Sertraline	Not reported - Ongoing	Unk
Solifenacin succinate	Not reported - Ongoing	Overactive Bladder

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b12 nos	Not reported - Ongoing	Supplement
Vitamin e nos	Not reported - Ongoing	Supplement
Measles vaccine; mumps vaccine; rubella vaccine	1953 - 1953	Vaccine
Polio vaccine	1953 - 1953	Vaccine
Varicella zoster vaccine	1953 - 1953	Vaccine
Influenza vaccine	Sep 2019 - Sep 2019	Vaccine
Paracetamol	17 Aug 2020 (Study Day 5) - 23 Aug 2020 (Study Day 11)	Tooth Pain
Levofloxacin	07 Sep 2020 (Study Day 26) - 11 Sep 2020 (Study Day 30)	Urinary Tract Infection
Ibuprofen	28 Sep 2020 (Study Day 47) - Ongoing	Hip Pain
Umeclidinium bromide; vilanterol trifenatate	20 Oct 2020 (Study Day 69) - Ongoing	Asthma, Copd

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Toothache	Grade 2/moderate	Not related	17 Aug 2020 (Study Day 5) - 22 Aug 2020 (Study Day 10)
Mental Status Changes	Grade 1/mild	Not related	04 Sep 2020 (Study Day 23) - 06 Sep 2020 (Study Day 25)
Sepsis	Grade 2/moderate	Not related	04 Sep 2020 (Study Day 23) - 06 Sep 2020 (Study Day 25)
Asthma	Grade 1/mild	Not related	19 Oct 2020 (Study Day 68) - Ongoing
Chronic Obstructive Pulmonary Disease	Grade 1/mild	Not related	19 Oct 2020 (Study Day 68) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US382-2154 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	SAE	Grade 3/severe	Not related	28 Dec 2020 (Study Day 134) – 09 Jan 2021 (Study Day 146)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2154, a 63-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Dec 2020 (Study Day 134), 133 days after the first dose and 105 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 13 days, after which it was considered to be recovered/resolved on 09 Jan 2021 (Study Day 146). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-001526	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Herpes simplex	Herpes simplex	1987 - Ongoing
Blood testosterone decreased	Decreased testosterone	1992 - Ongoing
Depression	Depression	2000 - Ongoing
Headache	Headaches	2000 - Ongoing
Erectile dysfunction	Erectile dysfunction	2005 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2010 - Ongoing
Anxiety	Anxiety	2013 - Ongoing
Acne	Acne	2015 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2016 - Ongoing
Pollakiuria	Frequent urination	2016 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Seasonal allergy	Seasonal allergies	2018 - Ongoing
Hypertension	Hypertension	14 Nov 2018 (Study Day -642) - Ongoing
Insomnia	Chronic insomnia	14 Nov 2018 (Study Day -642) - Ongoing
Type V hyperlipidaemia	Mixed hyperlipidemia	14 Nov 2018 (Study Day -642) - Ongoing
Labile hypertension	Labile hypertension	06 May 2019 (Study Day -469) - Ongoing
Botulinum toxin injection	Botox injection	Sep 2019 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	11 May 2020 (Study Day -98) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	Not reported - Ongoing	Seasonal Allergies
Valaciclovir	1987 - Ongoing	Hsv
Testosterone cipionate	1992 - Ongoing	Low Testosterone
Acetylsalicylic acid; caffeine; paracetamol	2000 - Ongoing	Headaches
Bupropion hydrochloride	2000 - Ongoing	Depression
Tadalafil	2005 - Ongoing	Ed
Eszopiclone	2010 - Ongoing	Sleep Apnea
Alprazolam	2013 - Ongoing	Anxiety
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	01 May 2014 (Study Day -2300) - 01 May 2014 (Study Day -2300)	Vaccine
Acetylsalicylic acid	2015 - Ongoing	Supplement - Heart Health
Alpha-amylase swine pancreas; cellulase; lipase; protease nos	2015 - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Anastrozole	2015 - Ongoing	Low Testosterone
Ascorbic acid	2015 - Ongoing	Supplement
Chondroitin; glucosamine	2015 - Ongoing	Supplement
Colecalciferol	2015 - Ongoing	Supplement
Fibre, dietary	2015 - Ongoing	Supplement
Ginkgo biloba	2015 - Ongoing	Supplement
Keratin	2015 - Ongoing	Supplement
Menaquinone-7	2015 - Ongoing	Supplement
Probiotics nos	2015 - Ongoing	Supplement
Unspecified herbal and traditional medicine	2015 - Ongoing	Supplement
Zinc	2015 - Ongoing	Supplement
Alfuzosin	2016 - Ongoing	Frequent Urination
Allergens nos	2018 - Ongoing	Allergies
Montelukast	2018 - Ongoing	Seasonal Allergies
Triamcinolone acetonide	2018 - Ongoing	Seasonal Allergies
Influenza vaccine	13 Feb 2020 (Study Day -186) - 13 Feb 2020 (Study Day -186)	Vaccine
Varicella zoster vaccine	01 Apr 2020 (Study Day -138) - 01 Apr 2020 (Study Day -138)	Vaccine
Efinaconazole	Jun 2020 - Ongoing	Supplement
Naproxen sodium	14 Sep 2020 (Study Day 29) - 15 Sep 2020 (Study Day 30)	Muscle Aches, Headache
Salbutamol	Nov 2020 - Ongoing	More Frequent Coughing And Asthmatic Symptoms
Amlodipine	24 Dec 2020 (Study Day 130) - Ongoing	Hypertension
Heart cath*	29 Dec 2020 (Study Day 135) - 29 Dec 2020 (Study Day 135)	Adverse Event
Implantable cardioverter defibrillator*	08 Jan 2021 (Study Day 145) - 08 Jan 2021 (Study Day 145)	Adverse Event
Amiodarone	09 Jan 2021 (Study Day 146) - Ongoing	Heart Attack
Apixaban	09 Jan 2021 (Study Day 146) - Ongoing	Heart Attack
Carvedilol	09 Jan 2021 (Study Day 146) - Ongoing	Heart Attack

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	14 Sep 2020 (Study Day 29) - 25 Sep 2020 (Study Day 40)
Injection Site Joint Pain	Grade 1/mild	Related	14 Sep 2020 (Study Day 29) - 22 Sep 2020 (Study Day 37)
Asthma	Grade 2/moderate	Not related	27 Nov 2020 (Study Day 103) - Ongoing

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	25 Dec 2020 (Study Day 131) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US382-2278 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	26 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	25 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Dehydration/Dehydration	SAE	Grade 2/ moderate	Not related	26 Sep 2020 (Study Day 32) – 28 Sep 2020 (Study Day 34)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US382-2278, a 69-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the right arm on 26 Aug 2020 (Study Day 1). The second dose was administered in the right arm on 25 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Sep 2020 (Study Day 32), 31 days after the first dose and 1 day after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of dehydration. Action taken with the IP was not applicable. The event of dehydration lasted for 3 days, after which it was considered to be recovered/resolved on 28 Sep 2020 (Study Day 34). The investigator assessed the event of dehydration to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000367	Dehydration

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Arteriosclerosis	Atherosclerosis	Not reported - Ongoing
Asthma	Asthma	Not reported - Ongoing
Blood triglycerides increased	High triglycerides	Not reported - Ongoing
Diabetes mellitus	Diabetes	Not reported - Ongoing
Gastrooesophageal reflux disease	Acid reflux	Not reported - Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing
Postmenopause	Post menopausal	Jan 2005 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	Not reported - Ongoing	Atherosclerosis Of Aorta
Calcium	Not reported - Ongoing	Supplement
Cetirizine hydrochloride	Not reported - Ongoing	Seasonal Allergies
Chondroitin; glucosamine	Not reported - Ongoing	Supplement
Clopidogrel	Not reported - Ongoing	Stroke Prevention
Fish oil	Not reported - Ongoing	Supplement
Fluticasone	Not reported - Ongoing	Seasonal Allergies
Fluticasone propionate; salmeterol xinafoate	Not reported - Ongoing	Asthma
Levocetirizine dihydrochloride	Not reported - Ongoing	Seasonal Allergies
Levothyroxine sodium	Not reported - Ongoing	Hypothyroidism
Losartan	Not reported - Ongoing	Hbp
Metformin hydrochloride; sitagliptin	Not reported - Ongoing	Diabetes
Methylcellulose	Not reported - Ongoing	Supplement
Omega-3-acid ethyl ester	Not reported - Ongoing	Unk
Omeprazole	Not reported - Ongoing	Reflux
Rosuvastatin	Not reported - Ongoing	High Triglycerides
Vaccinium macrocarpon	Not reported - Ongoing	Supplement
Venlafaxine hydrochloride	Not reported - Ongoing	Hormone Replacement Therapy - Post Menopausal
Vitamin b complex	Not reported - Ongoing	Supplement
Influenza vaccine	01 Sep 2019 (Study Day -360) - 01 Sep 2019 (Study Day -360)	Vaccine

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Nitrofurantoin	09 Sep 2020 (Study Day 15) - Ongoing	Uti
Lumbar puncture*	27 Sep 2020 (Study Day 33) - 27 Sep 2020 (Study Day 33)	Diagnostic
Magnesium; sodium chloride	27 Sep 2020 (Study Day 33) - 29 Sep 2020 (Study Day 35)	Dehydration - Sae
Pregabalin	05 Jan 2021 (Study Day 133) - Ongoing	Neuropathy
Zinc acetate; zinc gluconate	19 Jan 2021 (Study Day 147) - Ongoing	Common Cold

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Not related	26 Sep 2020 (Study Day 32) - 28 Sep 2020 (Study Day 34)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US383-2014 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertensive Emergency/ Hypertensive Emergency	SAE	Grade 3/ severe	Not related	31 Aug 2020 (Study Day 32) – 02 Sep 2020 (Study Day 34)	Recovered/ resolved
Sinus Tachycardia/Sinus Tachycardia	SAE	Grade 2/ moderate	Not related	31 Aug 2020 (Study Day 32) – 02 Sep 2020 (Study Day 34)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2014, a 56-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the right arm on 28 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 31 Aug 2020 (Study Day 32), 31 days after the first dose and 3 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hypertensive emergency. Action taken with the IP was not applicable. The event of hypertensive emergency lasted for 3 days, after which it was considered to be recovered/resolved on 02 Sep 2020 (Study Day 34). The investigator assessed the event of hypertensive emergency to be not related to the IP.

On 31 Aug 2020 (Study Day 32), 31 days after the first dose and 3 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of sinus tachycardia. Action taken with the IP was not applicable. The event of sinus tachycardia lasted for 3 days, after which it was considered to be recovered/resolved on 02 Sep 2020 (Study Day 34). The investigator assessed the event of sinus tachycardia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000307	Hypertensive emergency
MOD-2020-000307	Sinus tachycardia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Benign breast neoplasm	Benign left breast mass	1981 - 1981
Benign neoplasm of skin	Benign tumor right arm	1981 - 1981
Appendicitis	Appendicitis	1992 - 1992
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	1999 - Ongoing
Hysterectomy	Complete hysteretomy	2000 - 2000
Menorrhagia	Menorrhagia	2000 - 2000
Ankle fracture	Broken left ankle	2001 - 2001
Anxiety	Anxiety	2010 - Ongoing
Cough	Chronic cough	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Pleurisy	Pleurisy	2010 - Ongoing
Muscle spasms	Muscle spasms	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clonidine	2010 - Ongoing	Hypertension
Homatropine methylbromide; hydrocodone bitartrate	2010 - Ongoing	Chronic Obstructive Pulmonary Disease
Oxycodone hydrochloride; paracetamol	2010 - Ongoing	Chronic Obstructive Pulmonary Disease
Fluticasone propionate	2013 - Ongoing	Chronic Obstructive Pulmonary Disease
Ipratropium bromide; salbutamol sulfate	2013 - Ongoing	Chronic Obstructive Pulmonary Disease
Levosalbutamol hydrochloride	2013 - Ongoing	Chronic Obstructive Pulmonary Disease
Tiotropium bromide	2013 - Ongoing	Copd- Chronic Obstructive Pulmonary Disease
Tizanidine	2013 - Ongoing	Muscle Spasms In The Lower Back
Ct scan of head*	31 Aug 2020 (Study Day 32) - 31 Aug 2020 (Study Day 32)	Adverse Event
Ct scan of pelvis and abdomen*	31 Aug 2020 (Study Day 32) - 31 Aug 2020 (Study Day 32)	Adverse Event
Echocardiogram*	31 Aug 2020 (Study Day 32) - 31 Aug 2020 (Study Day 32)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aluminium hydroxide; magnesium hydroxide; simeticone	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Reflux Prophylaxis
Insulin lispro	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Hyperglycemia
Lorazepam	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Hypertensive Emergency
Macrogol 3350	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Constipation Prophylaxis
Melatonin	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Hypertensive Emergency
Morphine sulfate	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Abdominal Pain
Nicardipine hydrochloride	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Hypertensive Emergency
Ondansetron	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Nausea Prophylaxis
Oxycodone hydrochloride; paracetamol	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Abdominal Pain
Pantoprazole sodium sesquihydrate	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Acid Reflux Prophylaxis
Paracetamol	01 Sep 2020 (Study Day 33) - 01 Sep 2020 (Study Day 33)	Hypertensive Emergency

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Abdominal Pain	Grade 1/mild	Not related	31 Aug 2020 (Study Day 32) - 02 Sep 2020 (Study Day 34)
Back Pain	Grade 1/mild	Not related	31 Aug 2020 (Study Day 32) - 02 Sep 2020 (Study Day 34)
Brain Natriuretic Peptide Increased	Grade 1/mild	Not related	31 Aug 2020 (Study Day 32) - 02 Sep 2020 (Study Day 34)
Hyperglycaemia	Grade 1/mild	Not related	31 Aug 2020 (Study Day 32) - 02 Sep 2020 (Study Day 34)
Mental Status Changes	Grade 1/mild	Not related	31 Aug 2020 (Study Day 32) - 02 Sep 2020 (Study Day 34)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US383-2043 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	04 Sep 2020 (Study Day 34)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Toxic Shock Syndrome/ Suspected Toxic Shock Syndrome	SAE	Grade 3/ severe	Not related	23 Aug 2020 (Study Day 22) – 25 Aug 2020 (Study Day 24)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2043, a 29-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 04 Sep 2020 (Study Day 34). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Aug 2020 (Study Day 22), 21 days after the first dose and 12 days before the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of toxic shock syndrome. The IP dose was not changed due to the suspected toxic shock syndrome. The event of suspected toxic shock syndrome lasted for 3 days, after which it was considered to be recovered/resolved on 25 Aug 2020 (Study Day 24). The investigator assessed the event of toxic shock syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000259	Toxic shock syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tooth impacted	Wisdom teeth impaction	2014 - 2014
Wisdom teeth removal	Wisdom teeth removal	2014 - 2014

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2015 - Ongoing	Seasonal Allergies
Chest x-ray*	23 Aug 2020 (Study Day 22) - 23 Aug 2020 (Study Day 22)	Adverse Event
Clindamycin	23 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 24)	Suspected Toxic Shock Syndrome
Famotidine	23 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 24)	Gastrointestinal Prophylaxis
Piperacillin sodium; tazobactam sodium	23 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 24)	Suspected Toxic Shock Syndrome
Vancomycin	23 Aug 2020 (Study Day 22) - 25 Aug 2020 (Study Day 24)	Suspected Toxic Shock Syndrome
Abdominal ct scan*	24 Aug 2020 (Study Day 23) - 24 Aug 2020 (Study Day 23)	Adverse Event
Amoxicillin; clavulanic acid	25 Aug 2020 (Study Day 24) - 30 Aug 2020 (Study Day 29)	Urinary Tract Infection
Ibuprofen	05 Sep 2020 (Study Day 35) - 05 Sep 2020 (Study Day 35)	Ar - Headache, Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	23 Aug 2020 (Study Day 22) - 30 Aug 2020 (Study Day 29)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US383-2055 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 38)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Syncope/Syncopal Episode	SAE	Grade 3/severe	Not related	20 Sep 2020 (Study Day 49) – 23 Sep 2020 (Study Day 52)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2055, a 71-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 38). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Sep 2020 (Study Day 49), 48 days after the first dose and 11 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of syncope. Action taken with the IP was not applicable. The event of syncopal episode lasted for 4 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 52). The investigator assessed the event of syncope to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000339	Syncopal attack

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Intermittent headaches	1990 - Ongoing
Intervertebral disc degeneration	Degenerative disc disease	1999 - Ongoing
Rhinitis allergic	Allergic rhinitis	2000 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Nasal septum deviation	Deviated septum	2018 - Dec 2019
Paranasal cyst	Maxillary sinus cyst (benign)	2019 - Dec 2019
Cholecystitis	Cholecystitis	May 2019 - May 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2000 - Ongoing	Allergic Rhinitis
Thyroid	2015 - Ongoing	Hypothyroidism
Oxycodone	2016 - Ongoing	Degenerative Disc Disease
Amlodipine	2018 - 20 Sep 2020 (Study Day 49)	Hypertension
Nebivolol hydrochloride	Jan 2020 - Ongoing	Hypertension
Ct scan of neck and spine*	20 Aug 2020 (Study Day 18) - 20 Aug 2020 (Study Day 18)	Adverse Event
Ekg*	20 Aug 2020 (Study Day 18) - 20 Aug 2020 (Study Day 18)	Adverse Event
Influenza vaccine	25 Aug 2020 (Study Day 23) - 25 Aug 2020 (Study Day 23)	Vaccination
Ct of facial bones*	20 Sep 2020 (Study Day 49) - 20 Sep 2020 (Study Day 49)	Adverse Event
Hyponatremia chloride levels*	20 Sep 2020 (Study Day 49) - 20 Sep 2020 (Study Day 49)	Adverse Event
Hyponatremia chloride levels*	21 Sep 2020 (Study Day 50) - 21 Sep 2020 (Study Day 50)	Adverse Event
Oxycodone hydrochloride; paracetamol	21 Sep 2020 (Study Day 50) - 29 Sep 2020 (Study Day 58)	Post Surgical Pain
Tolvaptan	21 Sep 2020 (Study Day 50) - 21 Sep 2020 (Study Day 50)	Ae- Hyponatremia
Hyponatremia chloride levels*	22 Sep 2020 (Study Day 51) - 22 Sep 2020 (Study Day 51)	Adverse Event
Open reduction, internal fixation of the right zygomaticomaxillary complex fracture.*	22 Sep 2020 (Study Day 51) - 22 Sep 2020 (Study Day 51)	Adverse Event
Lisinopril	24 Sep 2020 (Study Day 53) - Ongoing	Ae-Syncopal Episode
Sodium chloride	24 Sep 2020 (Study Day 53) - Ongoing	Ae-Hyponatremia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Facial Bones Fracture	Grade 2/moderate	Not related	20 Sep 2020 (Study Day 49) - 23 Sep 2020 (Study Day 52)
Hyponatraemia	Grade 2/moderate	Not related	20 Sep 2020 (Study Day 49) - 23 Sep 2020 (Study Day 52)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US383-2074 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Myocardial Infarction/St Elevation Myocardial Infarction (Unspecified Artery)	SAE	Grade 3/severe	Not related	16 Sep 2020 (Study Day 44) – 18 Sep 2020 (Study Day 46)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2074, an 82-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 44), 43 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of acute myocardial infarction. On 31 Aug 2020 (Study Day 28), the IP dose was discontinued due to other (participant did not withdraw consent for the study but did not wish to receive second IP dose). The event of st elevation myocardial infarction (unspecified artery) lasted for 3 days, after which it was considered to be recovered/resolved on 18 Sep 2020 (Study Day 46). The investigator assessed the event of acute myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000311	Acute myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Tubal ligation	1970 - 1970
Back pain	Intermittent back pain	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Hypertension	Hypertension	2005 - Ongoing
Hysterectomy	Hysterectomy	2005 - 2005
Menorrhagia	Menorrhagia	2005 - 2005

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	Not reported - Ongoing	Acid Reflux
Lisinopril	2005 - Ongoing	Hypertension
Simvastatin	2005 - 16 Sep 2020 (Study Day 44)	Hyperlipidemia
Diphenhydramine hydrochloride	2010 - Ongoing	Sleep Aid
Naproxen sodium	07 Sep 2020 (Study Day 35) - 08 Sep 2020 (Study Day 36)	Lumbar Back Pain
Cardiac echo: noted low normal left ventricle systolic function, grade 1 left ventricular diastolic dysfunction*	16 Sep 2020 (Study Day 44) - 16 Sep 2020 (Study Day 44)	Adverse Event
Chest x-ray*	16 Sep 2020 (Study Day 44) - 16 Sep 2020 (Study Day 44)	Adverse Event
Labs obtained all noted within normal limits with the exception of glucose noted at 144*	16 Sep 2020 (Study Day 44) - 16 Sep 2020 (Study Day 44)	Adverse Event
Lch- attempted pci to rca unsuccessful*	16 Sep 2020 (Study Day 44) - 16 Sep 2020 (Study Day 44)	Adverse Event
Clopidogrel	17 Sep 2020 (Study Day 45) - Ongoing	Ae - Myocardial Infarction
Glyceryl trinitrate	17 Sep 2020 (Study Day 45) - Ongoing	Ae - Myocardial Infarction
Heart catherization*	17 Sep 2020 (Study Day 45) - 17 Sep 2020 (Study Day 45)	Adverse Event
Isosorbide mononitrate	17 Sep 2020 (Study Day 45) - Ongoing	Ae - Myocardial Infarction
Metoprolol tartrate	17 Sep 2020 (Study Day 45) - Ongoing	Myocardial Infarction
Rosuvastatin	17 Sep 2020 (Study Day 45) - Ongoing	Adverse Event - Myocardial Infarction
Acetylsalicylic acid	19 Sep 2020 (Study Day 47) - Ongoing	Cardiac Prophylaxis
Rosuvastatin calcium	19 Sep 2020 (Study Day 47) - Ongoing	Dyslipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Back Pain	Grade 1/mild	Not related	07 Sep 2020 (Study Day 35) - 08 Sep 2020 (Study Day 36)
Wrist Fracture	Grade 2/moderate	Not applicable	15 Mar 2021 (Study Day 224) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US383-2150 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	09 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Endometrial Cancer/ Endometrioid Carcinoma	SAE	Grade 3/ severe	Not related	Not reported – 18 Jan 2021 (Study Day 162)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2150, a 61-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 09 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On an unknown date (Study Day not reported), the participant experienced a Grade 3/severe serious adverse event of endometrial cancer. Action taken with the IP was not applicable. The event of endometrioid carcinoma lasted for an unreported duration, after which it was considered to be recovered/resolved on 18 Jan 2021 (Study Day 162). The investigator assessed the event of endometrial cancer to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-009642	Endometrial cancer

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Ovarian cyst	Ovarian cyst	1986 - 1987
Appendicectomy	Appendectomy	1987 - 1987
Appendicitis	Appendicitis	1987 - 1987
Oophorectomy	Oophorectomy	1987 - 1987
Postmenopause	Post menopausal	2008 - Ongoing
Anxiety	Anxiety	2009 - Ongoing
Insomnia	Insomnia	2009 - Ongoing
Aortic valve replacement	Aortic valve replacement	2012 - 2012
Heart valve incompetence	Leaky aortic valve	2012 - Ongoing
Bronchiectasis	Bronchiectasis	2016 - Ongoing
Colitis	Colitis	2018 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dilation and curettage*	Not reported - Not reported	Adverse Event
Endometrial biopsy*	Not reported - Not reported	Diagnostic
Vaginal ultrasound*	Not reported - Not reported	Adverse Event
Clonazepam	2009 - Ongoing	Insomnia
Sertraline	2009 - Ongoing	Anxiety
Acetylsalicylic acid	2012 - Ongoing	Cardiac Prophylaxis
Diphenhydramine hydrochloride	2018 - Ongoing	Seasonal Allergic Rhinitis
Eluxadoline	2018 - Ongoing	Colitis
Formoterol fumarate; mometasone furoate	2018 - Ongoing	Bronchiectasis
Salbutamol sulfate	2018 - Ongoing	Bronchiectasis
Total abdominal hysterectomy and bilateral salpingo oophorectomy*	18 Jan 2021 (Study Day 162) - 18 Jan 2021 (Study Day 162)	Adverse Event
Pet ct of skull and mid thigh*	03 Feb 2021 (Study Day 178) - 03 Feb 2021 (Study Day 178)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Postmenopausal Haemorrhage	Grade 2/moderate	Not related	Not reported - 18 Jan 2021 (Study Day 162)
Viral Infection	Grade 1/mild	Not related	11 Nov 2020 (Study Day 94) - 13 Nov 2020 (Study Day 96)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US383-2211 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	15 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Chronic Obstructive Pulmonary Disease/Copd Exacerbation	SAE	Grade 3/ severe	Not related	08 Oct 2020 (Study Day 52) – 16 Oct 2020 (Study Day 60)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US383-2211, a 76-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 18 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 15 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Oct 2020 (Study Day 52), 51 days after the first dose and 23 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of chronic obstructive pulmonary disease. Action taken with the IP was not applicable. The event of copd exacerbation lasted for 9 days, after which it was considered to be recovered/resolved on 16 Oct 2020 (Study Day 60). The investigator assessed the event of chronic obstructive pulmonary disease to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000466	Chronic obstructive pulmonary disease

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Angina pectoris	Angina pectoris	2000 - Ongoing
Type 2 diabetes mellitus	Diabetes ii	2004 - Ongoing
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	2005 - Ongoing
Pain	Chronic pain	2005 - Ongoing
Insomnia	Insomnia	2006 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2006 - Ongoing
Atrial fibrillation	Atrial fibrillation	2010 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Neuropathy peripheral	Neuropathy	2011 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2012 - Ongoing
Hypothyroidism	Hypothyroidism	2014 - Ongoing
Restless legs syndrome	Restless leg syndrome	2017 - Ongoing
Osteoarthritis	Osteoarthritis bilateral extremities	Dec 2017 - Ongoing
Depression	Depression	Jan 2020 - Ongoing
Rhinitis allergic	Allergic rhinitis	Jan 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glyceryl trinitrate	2010 - Ongoing	Angina
Gabapentin	2011 - Ongoing	Neuropathy
Atorvastatin	2012 - Ongoing	Hyperlipidemia
Budesonide; formoterol fumarate	2014 - Ongoing	Chronic Obstructive Pulmonary Disease
Insulin lispro	2015 - Ongoing	Diabetes Type Ii
Ipratropium bromide; salbutamol sulfate	2015 - Ongoing	Chronic Obstructive Pulmonary Disease
Levothyroxine	2016 - Ongoing	Hypothyroidism
Tamsulosin	2016 - Ongoing	Benign Prostatic Hyperplasia
Carvedilol	2017 - Ongoing	Hypertension
Meloxicam	2017 - Ongoing	Osteoarthritis Bilateral Extremities
Ropinirole	2017 - Ongoing	Restless Leg Syndrome
Finasteride	2018 - Ongoing	Benign Prostatic Hyperplasion
Apixaban	2019 - Ongoing	Atrial Fibrillation
Trazodone	2019 - Ongoing	Insomnia
Colecalciferol	2020 - Ongoing	Supplement

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline	2020 - Ongoing	Depression
Hydrocodone; paracetamol	Jan 2020 - Ongoing	Chronic Pain
Montelukast	May 2020 - Ongoing	Allergic Rhinitis
Salbutamol sulfate	Jun 2020 - Ongoing	Chronic Obstructive Pulmonary Disease
Chest x-ray(wnl)*	08 Oct 2020 (Study Day 52) - 08 Oct 2020 (Study Day 52)	Adverse Event
Covid 19 test (negative)*	08 Oct 2020 (Study Day 52) - 08 Oct 2020 (Study Day 52)	Adverse Event
Influenza a and b testing (negative)*	08 Oct 2020 (Study Day 52) - 08 Oct 2020 (Study Day 52)	Adverse Event
Oxygen	08 Oct 2020 (Study Day 52) - 08 Oct 2020 (Study Day 52)	Copd Exacerbation
Prednisone	08 Oct 2020 (Study Day 52) - 10 Oct 2020 (Study Day 54)	Copd Exacerbation
Benzonatate	09 Oct 2020 (Study Day 53) - 16 Oct 2020 (Study Day 60)	Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation
Doxycycline	09 Oct 2020 (Study Day 53) - 16 Oct 2020 (Study Day 60)	Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation
Guaifenesin	09 Oct 2020 (Study Day 53) - 16 Oct 2020 (Study Day 60)	Chronic Obstructive Pulmonary Disease Exacerbation
Ipratropium bromide; salbutamol sulfate	09 Oct 2020 (Study Day 53) - Ongoing	Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation
Prednisone	11 Oct 2020 (Study Day 55) - 13 Oct 2020 (Study Day 57)	Copd Exacerbation
Prednisone	14 Oct 2020 (Study Day 58) - 14 Oct 2020 (Study Day 58)	Copd Exacerbation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US384-2027 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	08 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute Respiratory Failure/Acute Hypoxemia Respiratory Failure (Worsening)	SAE	Grade 3/ severe	Not related	19 Dec 2020 (Study Day 101) – 23 Dec 2020 (Study Day 105)	Recovered/resolved
Pneumothorax/Worsening Left Pneumothorax	SAE	Grade 3/ severe	Not related	19 Dec 2020 (Study Day 101) – 23 Dec 2020 (Study Day 105)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US384-2027, a 81-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 08 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Dec 2020 (Study Day 101), 100 days after the first dose and 72 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute hypoxemia respiratory failure (worsening) lasted for 5 days, after which it was considered to be recovered/resolved on 23 Dec 2020 (Study Day 105). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 19 Dec 2020 (Study Day 101), 100 days after the first dose and 72 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumothorax. Action taken with the IP was not applicable. The event of worsening left pneumothorax lasted for 5 days, after which it was considered to be recovered/resolved on 23 Dec 2020 (Study Day 105). The investigator assessed the event of pneumothorax to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001230	Pneumothorax
MOD-2020-001230	Respiratory failure

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acute respiratory failure	Acute hypoxemic respiratory failure (secondary to recurrent left pneumothorax)	Not reported - Ongoing
Asthma	Asthma	Not reported - Ongoing
Atrial fibrillation	Atrial fibrillation	Not reported - Ongoing
Benign prostatic hyperplasia	Benign prostate hyperplasia	Not reported - Ongoing
Benign prostatic hyperplasia	Â€œbenign prostatic hyperplasia,	Not reported - Ongoing
Constipation	Constipation	Not reported - Ongoing
Ileostomy	Ileostomy	Not reported - Ongoing
Lymphadenopathy	Distant lung lymphadenopathy benign	Not reported
Oedema peripheral	Chronic bilateral lower extremity edema (secondary to venous insufficiency)	Not reported - Ongoing
Pulmonary mass	Pulmonary nodules	Not reported
Type 2 diabetes mellitus	Type ii diabetes (insulin dependent)	1980 - Ongoing
Blood pressure increased	Elevated blood pressure	1990 - Ongoing
Prostate cancer	Prostate cancer	2008 - 2013
Sleep apnoea syndrome	Sleep apneia	2010 - Ongoing
Tremor	Tremors, hands	2010 - Ongoing
Colon cancer	Colon cancer	2012 - 2012
Lung neoplasm malignant	Lung cancer	2013 - 2013
Heart valve replacement	Heart valve tavr replacement	2016 - 2016
Cataract operation	Cataract surgery	2019 - 2019
Chronic obstructive pulmonary disease	Copd (chronic obstructive pulmonary disease)	May 2020 - Ongoing
Pneumothorax	Left pneumothorax	03 May 2020 (Study Day -130) - 09 May 2020 (Study Day -124)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ipratropium bromide	Not reported - Ongoing	Asthma
Metoprolol tartrate	Not reported - Ongoing	Atrial Fibrilation
Salbutamol sulfate	Not reported - Ongoing	Asthma
Insulin detemir	1980 - 23 Dec 2020 (Study Day 105)	Type Ii Diabetes
Insulin lispro	1980 - 23 Dec 2020 (Study Day 105)	Type Ii Diabetes
Vitamins nos	1980 - Ongoing	Nutritional Supplement
Acetylsalicylic acid	1990 - Ongoing	Heart Health
Torasemide	1990 - Ongoing	Elevated Blood Pressure
Potassium	1995 - Ongoing	Nutritional Supplement
Finasteride	2008 - Ongoing	Prostate Cancer
Tamsulosin	2008 - Ongoing	Prostate Cancer
Topiramate	2010 - Ongoing	Tremors
Influenza vaccine	20 Aug 2020 (Study Day -21) - 20 Aug 2020 (Study Day -21)	Vaccine
Budesonide; formoterol fumarate dihydrate	Dec 2020 - Ongoing	Copd Worsened
Enoxaparin	19 Dec 2020 (Study Day 101) - 23 Dec 2020 (Study Day 105)	Dvt Prevention
Oxygen	19 Dec 2020 (Study Day 101) - 19 Dec 2020 (Study Day 101)	Oxygen Saturation 92%
Bullectomy*	21 Dec 2020 (Study Day 103) - 21 Dec 2020 (Study Day 103)	Adverse Event
Left video assisted thoracoscopic surgery (lvats)*	21 Dec 2020 (Study Day 103) - 21 Dec 2020 (Study Day 103)	Adverse Event
Talc pleurodesis*	21 Dec 2020 (Study Day 103) - 21 Dec 2020 (Study Day 103)	Adverse Event
Docusate sodium	23 Dec 2020 (Study Day 105) - Ongoing	Constipation
Insulin detemir	23 Dec 2020 (Study Day 105) - Ongoing	Diabetes Ii
Insulin lispro	23 Dec 2020 (Study Day 105) - Ongoing	Diabetes Ii
Paracetamol; tramadol hydrochloride	23 Dec 2020 (Study Day 105) - 13 Jan 2021 (Study Day 126)	Pain, Left Rib Cage S/P Surgery, Discharge To Home
Topiramate	23 Dec 2020 (Study Day 105) - Ongoing	Hand Tremors Worsening

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Chronic Obstructive Pulmonary Disease	Grade 1/mild	Not related	01 Dec 2020 (Study Day 83) - 13 Jan 2021 (Study Day 126)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Procedural Pain	Grade 2/moderate	Not related	23 Dec 2020 (Study Day 105) - 13 Jan 2021 (Study Day 126)
Tremor	Grade 2/moderate	Not related	23 Dec 2020 (Study Day 105) - 13 Jan 2021 (Study Day 126)
Fatigue	Grade 2/moderate	Not related	29 Dec 2020 (Study Day 111) - 13 Jan 2021 (Study Day 126)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US385-2200 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nephrolithiasis/Kidney Stones	SAE	Grade 3/ severe	Not related	23 Nov 2020 (Study Day 33) – 29 Nov 2020 (Study Day 39)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US385-2200, a 53-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 22 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Nov 2020 (Study Day 33), 32 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of nephrolithiasis. On 18 Nov 2020 (Study Day 28), the IP dose was discontinued due to lost to follow-up. The event of kidney stones lasted for 7 days, after which it was considered to be recovered/resolved on 29 Nov 2020 (Study Day 39). The investigator assessed the event of nephrolithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000911	Nephrolithiasis

Study Completion/Discontinuation

On 18 Dec 2020 (Study Day 58), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	06 Nov 2020 (Study Day 16) - 06 Nov 2020 (Study Day 16)	Prophylaxis For Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US386-2020 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	16 Sep 2020 (Study Day 31)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Adenocarcinoma Gastric/Medullary Gastric Adenocarcinoma Stage III	SAE	Grade 2/moderate	Not related	04 Jan 2021 (Study Day 141) – Ongoing	Not recovered/not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2020, a 61-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 16 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Jan 2021 (Study Day 141), 140 days after the first dose and 110 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of adenocarcinoma gastric. Action taken with the IP was not applicable. The event of medullary gastric adenocarcinoma stage III was considered to be ongoing. The investigator assessed the event of adenocarcinoma gastric to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005895	Adenocarcinoma gastric

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2010 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2018 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	Mar 2020 - Ongoing
Hyperlipidaemia	Hyperlipidemia	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin	2018 - Ongoing	Diabetes Mellitus Type 2
Gabapentin	Jun 2019 - Jun 2019	Peripheral Neuropathy
Atorvastatin	Mar 2020 - 15 Feb 2021 (Study Day 183)	Hyperlipidemia
Glipizide	Mar 2020 - 12 Jan 2021 (Study Day 149)	Diabetes Mellitus Type 2
Lisinopril	Mar 2020 - 15 Feb 2021 (Study Day 183)	Hypertension
Tamsulosin hydrochloride	Mar 2020 - Ongoing	Benign Prostatic Hyperplasia
Iron	30 Oct 2020 (Study Day 75) - Ongoing	Iron Deficiency Anemia
Macrogol; potassium chloride; sodium bicarbonate; sodium chloride; sodium sulfate	03 Jan 2021 (Study Day 140) - 03 Jan 2021 (Study Day 140)	Colonoscopy
Colonoscopy with biopsy*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Esophagogastroduodenoscopy with biopsy*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Fentanyl	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Colonoscopy
Fentanyl	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Endoscopy
Midazolam hydrochloride	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Colonoscopy
Midazolam hydrochloride	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Endoscopy
Moderate sedation*	04 Jan 2021 (Study Day 141) - 04 Jan 2021 (Study Day 141)	Adverse Event
Ferric carboxymaltose	13 Jan 2021 (Study Day 150) - 13 Jan 2021 (Study Day 150)	Iron Deficiency Anemia
Glipizide	13 Jan 2021 (Study Day 150) - Ongoing	Uncontrolled Type 2 Diabetes Mellitis
Vitamins nos	13 Jan 2021 (Study Day 150) - Ongoing	Anemia
Red blood cells, concentrated	19 Jan 2021 (Study Day 156) - 19 Jan 2021 (Study Day 156)	Iron Deficiency Anemia
Ct of chest, abdomen and pelvis*	22 Jan 2021 (Study Day 159) - 22 Jan 2021 (Study Day 159)	Adverse Event
Gastric biopsy*	04 Feb 2021 (Study Day 172) - 04 Feb 2021 (Study Day 172)	Adverse Event
Upper endoscopy*	04 Feb 2021 (Study Day 172) - 04 Feb 2021 (Study Day 172)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diagnostic laparoscopy*	19 Feb 2021 (Study Day 187) - 19 Feb 2021 (Study Day 187)	Adverse Event
Paracetamol	19 Feb 2021 (Study Day 187) - 23 Feb 2021 (Study Day 191)	Pain Post Portha Cath Insertion
Port placement*	19 Feb 2021 (Study Day 187) - 19 Feb 2021 (Study Day 187)	Adverse Event
Mri abdomen*	20 Feb 2021 (Study Day 188) - 20 Feb 2021 (Study Day 188)	Adverse Event
Lidocaine; prilocaine	22 Feb 2021 (Study Day 190) - 22 Feb 2021 (Study Day 190)	Porth-A-Cath Access
Ondansetron	22 Feb 2021 (Study Day 190) - Ongoing	Chemotherapy Induced-Nausea
Pet/ct scan skull base to mid thigh*	22 Feb 2021 (Study Day 190) - 22 Feb 2021 (Study Day 190)	Adverse Event
Prochlorperazine	22 Feb 2021 (Study Day 190) - Ongoing	Chemotherapy Induced-Nausea
Pantoprazole	17 Mar 2021 (Study Day 213) - Ongoing	Prophylaxis For Heartburn

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	07 Sep 2020 (Study Day 22) - 07 Sep 2020 (Study Day 22)
Non-Cardiac Chest Pain	Grade 1/mild	Not related	08 Sep 2020 (Study Day 23) - 30 Sep 2020 (Study Day 45)
Iron Deficiency Anaemia	Grade 1/mild	Not related	30 Oct 2020 (Study Day 75) - Ongoing
Diabetes Mellitus Inadequate Control	Grade 2/moderate	Not related	13 Jan 2021 (Study Day 150) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2021 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	14 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/ Inferolateral Stemi	SAE	Grade 4	Not related	04 Oct 2020 (Study Day 49) – 07 Oct 2020 (Study Day 52)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2021, a 55-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 17 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 14 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Oct 2020 (Study Day 49), 48 days after the first dose and 20 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of inferolateral stemi lasted for 4 days, after which it was considered to be recovered/resolved on 07 Oct 2020 (Study Day 52). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000421	Myocardial Infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Sulfa allergy	Not reported - Ongoing
Rhabdomyolysis	Statin intolerant (rhabdomyolysis)	Not reported - Ongoing
Hyperthyroidism	Hyperthyroidism	2008 - 2008
Hypothyroidism	Hypothyroidism	2008 - Ongoing
Radioactive iodine therapy	Thyroid i131 ablation	2008 - 2008
Type 2 diabetes mellitus	Diabetes mellitus type 2	21 May 2010 (Study Day -3741) - Ongoing
Hypertension	Hypertension	May 2011 - Ongoing
Seasonal allergy	Seasonal allergies	2014 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	2015 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Benign prostatic hyperplasia	Benign prostatic hyperplasia	2017 - Ongoing
Drug hypersensitivity	Bactrim allergy	2018 - Ongoing
Coronary artery disease	Coronary artery disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine sodium	2008 - 09 Feb 2021 (Study Day 177)	Hypothroidism
Metoprolol succinate	2008 - 05 Oct 2020 (Study Day 50)	Hypertension
Acetylsalicylic acid	2010 - 03 Oct 2020 (Study Day 48)	Coronary Artery Disease
Vitamin d nos	2015 - 06 Oct 2020 (Study Day 51)	Vitamin D Deficiency
Ezetimibe	2016 - 09 Feb 2021 (Study Day 177)	Hyperlipidemia
Insulin aspart	2016 - 10 Oct 2020 (Study Day 55)	Diabetes Mellitus Type 2
Liothyronine sodium	2017 - Ongoing	Hypothryoidism
Liothyronine sodium	2017 - Ongoing	Hypothyroidism
Tamsulosin hydrochloride	2017 - Ongoing	Benign Prostatic Hyperplasia
Isosorbide mononitrate	2019 - 04 Oct 2020 (Study Day 49)	Coronary Artery Disease
Amlodipine besilate	Jun 2019 - 05 Oct 2020 (Study Day 50)	Hypertension
Hydrochlorothiazide; olmesartan	2020 - Ongoing	Hypertension
Measles vaccine live (enders-edmonston); mumps vaccine live (jeryl lynn); rubella vaccine live (wistar ra 27/3)	12 Aug 2020 (Study Day -5) - 12 Aug 2020 (Study Day -5)	Prevention Of Mumps, Measles, Rubella
Diphenhydramine hydrochloride	14 Sep 2020 (Study Day 29) - 15 Sep 2020 (Study Day 30)	Injection Site Swelling

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	15 Sep 2020 (Study Day 30) - 16 Sep 2020 (Study Day 31)	Fever And Injection Site Pain
Acetylsalicylic acid	04 Oct 2020 (Study Day 49) - Ongoing	Coronary Artery Disease
Acetylsalicylic acid	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Inferolateral Stemi
Adenosine	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	During Pci For Inferolateral Stemi
Carvedilol	04 Oct 2020 (Study Day 49) - 17 Oct 2020 (Study Day 62)	Hypertension
Chest x ray*	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Adverse Event
Contrast media	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	During Pci
Docusate sodium	04 Oct 2020 (Study Day 49) - 07 Oct 2020 (Study Day 52)	Prophylaxis For Constipation During Hospitalization For Inferolateral Stemi
Ekg*	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Adverse Event
Enoxaparin	04 Oct 2020 (Study Day 49) - 07 Oct 2020 (Study Day 52)	Prophylaxis For Deep Vein Thrombosis
Eptifibatide	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Inferolateral Stemi
Fentanyl	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Inferolateral Stemi
Heparin	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Inferolateral Stemi
Influenza vaccine	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Influenza
Intravascular ultrasound (iv us)*	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Adverse Event
Left heart catherization*	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Adverse Event
Lisinopril	04 Oct 2020 (Study Day 49) - 17 Oct 2020 (Study Day 62)	Hypertension
Morphine sulfate	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Inferolateral Stemi
Nicotinic acid	04 Oct 2020 (Study Day 49) - Ongoing	Hyperlipidemia
Pantoprazole	04 Oct 2020 (Study Day 49) - Ongoing	Prophylaxis For Gerd
Percutaneous coronary intervention (pci)*	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Adverse Event
Selective coronary angiogram*	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Adverse Event
Sennoside a+b	04 Oct 2020 (Study Day 49) - 07 Oct 2020 (Study Day 52)	Prophylaxis For Constipation During Hospitalization For Inferolateral Stem
Sodium chloride	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	During Pci For Inferolateral Stemi
Sodium chloride	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	For Iv Flush

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sodium chloride	04 Oct 2020 (Study Day 49) - 07 Oct 2020 (Study Day 52)	Hydration During Hospitalization For Inferolateral Stemi
Ticagrelor	04 Oct 2020 (Study Day 49) - Ongoing	Cardiovascular Event Prevention
Ticagrelor	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Inferolateral Stemi
Ultrasound guided access through right femoral artery*	04 Oct 2020 (Study Day 49) - 04 Oct 2020 (Study Day 49)	Adverse Event
Transthoracic echocardiogram with doppler*	05 Oct 2020 (Study Day 50) - 05 Oct 2020 (Study Day 50)	Adverse Event
Vitamin d nos	07 Oct 2020 (Study Day 52) - Ongoing	Vitamin D Deficiency
Alirocumab	16 Oct 2020 (Study Day 61) - Ongoing	Hyperlipidemia
Amlodipine besilate	17 Oct 2020 (Study Day 62) - Ongoing	Hypertension
Metoprolol succinate	17 Oct 2020 (Study Day 62) - Ongoing	Hypertension
Diltiazem	22 Oct 2020 (Study Day 67) - Ongoing	Coronary Artery Disease
Diphtheria vaccine toxoid; pertussis vaccine acellular; tetanus vaccine toxoid	09 Nov 2020 (Study Day 85) - 09 Nov 2020 (Study Day 85)	Prevention Of Tetanus And Difteria
Dulaglutide	14 Dec 2020 (Study Day 120) - Ongoing	Type 2 Diabetes Mellitus
Levothyroxine sodium	10 Feb 2021 (Study Day 178) - Ongoing	Hypothyroidism
Hydrocortisone	04 Mar 2021 (Study Day 200) - Ongoing	Low Cortisol Level

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diabetes Mellitus Inadequate Control	Grade 2/moderate	Not related	14 Dec 2020 (Study Day 120) - Ongoing
Cortisol Decreased	Grade 1/mild	Not related	04 Mar 2021 (Study Day 200) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2044 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Heart Rate Irregular/Irregular Heart Beat	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	10 Sep 2020 (Study Day 21) – 10 Sep 2020 (Study Day 21)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2044, a 52-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Sep 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of heart rate irregular. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of irregular heart beat lasted for 1 day, after which it was considered to be recovered/resolved on 10 Sep 2020 (Study Day 21). The investigator assessed the event of heart rate irregular to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 15 Dec 2020 (Study Day 117), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	2017 - Ongoing	Vitamin Supplement
Vitamin e nos	2017 - Ongoing	Vitamin Supplement
Ascorbic acid	2019 - Ongoing	Vitamin Supplement
Pantoprazole	2019 - Ongoing	Gerd
Influenza vaccine	10 Oct 2020 (Study Day 51) - 10 Oct 2020 (Study Day 51)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Heart Rate Irregular	Grade 1/mild	Not related	10 Sep 2020 (Study Day 21) - 10 Sep 2020 (Study Day 21)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2050 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	29 Aug 2020 (Study Day 6) – 11 Sep 2020 (Study Day 19)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2050, a 50-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Aug 2020 (Study Day 6), 5 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of covid-19. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of symptomatic COVID-19 lasted for 14 days, after which it was considered to be recovered/resolved on 11 Sep 2020 (Study Day 19). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000269	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	Jan 2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Famotidine	Jan 2020 - Ongoing	Gerd
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	29 Aug 2020 (Study Day 6) - 29 Aug 2020 (Study Day 6)	Symptomatic COVID 19
Paracetamol	29 Aug 2020 (Study Day 6) - 30 Aug 2020 (Study Day 7)	Symptomatic COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	29 Aug 2020 (Study Day 6) - 11 Sep 2020 (Study Day 19)
Fatigue	Grade 1/mild	Related	31 Aug 2020 (Study Day 8) - 01 Sep 2020 (Study Day 9)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2053 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	SAE	Grade 2/ moderate	Not related	16 Oct 2020 (Study Day 54) – 21 Dec 2020 (Study Day 120)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2053, a 74-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Oct 2020 (Study Day 54), 53 days after the first dose and 25 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of covid-19. Action taken with the IP was not applicable. The event of symptomatic COVID-19 lasted for 67 days, after which it was considered to be recovered/resolved on 21 Dec 2020 (Study Day 120). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000502	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1990 - Ongoing
Hyperlipidaemia	Hyperlipidemia	1996 - Ongoing
Hypertension	Hypertension	1996 - Ongoing
Postmenopause	Post menopausal	1996 - Ongoing
Gastrooesophageal reflux disease	Gerd	2000 - Ongoing
Uterine leiomyoma	Uterine fibroid	09 Oct 2019 (Study Day -320) - Ongoing
Postmenopausal haemorrhage	Post menopausal bleeding	Apr 2020 - May 2020
Sinusitis	Sinusitis	13 Aug 2020 (Study Day -11) - 23 Aug 2020 (Study Day -1)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2005 - Ongoing	Prophylaxis For Coronary Artery Disease
Atorvastatin	2005 - Ongoing	Hyperlipidemia
Hydrochlorothiazide	2005 - Ongoing	Hypertension
Levocetirizine	2012 - Ongoing	Seasonal Allergies
Montelukast	2012 - Ongoing	Seasonal Allergies
Azelastine	2015 - Ongoing	Seasonal Allergies
Nifedipine	2017 - Ongoing	Hypertension
Vitamins nos	2019 - Ongoing	Vitamin Supplement
Naproxen sodium	23 Sep 2020 (Study Day 31) - 23 Sep 2020 (Study Day 31)	Leg Pain
Melatonin	27 Sep 2020 (Study Day 35) - 27 Sep 2020 (Study Day 35)	Insomnia
Paracetamol	17 Oct 2020 (Study Day 55) - 21 Dec 2020 (Study Day 120)	Symptomatic COVID 19
Aluminium hydroxide; magnesium carbonate	20 Oct 2020 (Study Day 58) - 21 Dec 2020 (Study Day 120)	Symptomatic COVID-19
Calcium chloride; potassium chloride; sodium lactate	23 Oct 2020 (Study Day 61) - 23 Oct 2020 (Study Day 61)	Dehydration Associated With Symptomatic COVID 19
Benzonatate	31 Oct 2020 (Study Day 69) - 21 Dec 2020 (Study Day 120)	Symptomatic COVID-19
Ergocalciferol	31 Oct 2020 (Study Day 69) - Ongoing	Prophylaxis Vitamin D Deficiency
Azithromycin	10 Nov 2020 (Study Day 79) - 10 Nov 2020 (Study Day 79)	Symptomatic COVID 19

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Codeine; guaifenesin	10 Nov 2020 (Study Day 79) - 21 Dec 2020 (Study Day 120)	Symptomatic COVID 19
Salbutamol	10 Nov 2020 (Study Day 79) - 21 Dec 2020 (Study Day 120)	Symptomatic COVID 19
Azithromycin	11 Nov 2020 (Study Day 80) - 21 Nov 2020 (Study Day 90)	Symptomatic COVID 19
Fluticasone	14 Nov 2020 (Study Day 83) - 21 Dec 2020 (Study Day 120)	Symptomatic COVID 19
Pantoprazole	09 Dec 2020 (Study Day 108) - 13 Dec 2020 (Study Day 112)	Exacerbation Of Gastroesophageal Reflux Disease

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pain In Extremity	Grade 1/mild	Not related	23 Sep 2020 (Study Day 31) - 23 Sep 2020 (Study Day 31)
Insomnia	Grade 1/mild	Not related	27 Sep 2020 (Study Day 35) - Ongoing
Abnormal Loss Of Weight	Grade 1/mild	Not related	18 Nov 2020 (Study Day 87) - Ongoing
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	05 Dec 2020 (Study Day 104) - 13 Dec 2020 (Study Day 112)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2098 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Hypertension	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	29 Sep 2020 (Study Day 30) – 15 Oct 2020 (Study Day 46)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2098, a 45-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Sep 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of hypertension. On 27 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of hypertension lasted for 17 days, after which it was considered to be recovered/resolved on 15 Oct 2020 (Study Day 46). The investigator assessed the event of hypertension to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	2014 - Ongoing
Supraventricular tachycardia	Supraventricular tachycardia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fish oil	2015 - Ongoing	Supplement
Metoprolol	2015 - Ongoing	Svt
Vitamins nos	2018 - Ongoing	Supplement
Melatonin	Feb 2020 - Ongoing	Prophylaxis For Insomnia
Losartan	01 Oct 2020 (Study Day 32) - 19 Apr 2021 (Study Day 232)	Hypertension
Ubidecarenone	23 Dec 2020 (Study Day 115) - Ongoing	General Well-Being

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 3/severe	Not related	29 Sep 2020 (Study Day 30) - 15 Oct 2020 (Study Day 46)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2099 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	28 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Flank Pain/Left Flank Pain	SAE	Grade 3/severe	Not related	30 Dec 2020 (Study Day 122) – 11 Apr 2021 (Study Day 224)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2099, a 51-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 28 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Dec 2020 (Study Day 122), 121 days after the first dose and 93 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of flank pain. Action taken with the IP was not applicable. The event of left flank pain lasted for 103 days, after which it was considered to be recovered/resolved on 11 Apr 2021 (Study Day 224). The investigator assessed the event of flank pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-048696	Flank pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pain	General body aches	2000 - Ongoing
Chronic hepatitis B	Chronic hepatitis b	Feb 2005 - Ongoing
HIV infection	Hiv	Dec 2018 - Ongoing
Glucose tolerance impaired	Prediabetes	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Entecavir	Feb 2005 - Ongoing	Hepatitis B
Cobicistat; darunavir ethanolate	Dec 2018 - Ongoing	Hiv
Doravirine	Dec 2018 - Ongoing	Hiv
Ibuprofen	2020 - Ongoing	General Pain
Ibuprofen	04 Oct 2020 (Study Day 35) - 04 Oct 2020 (Study Day 35)	General Pain Post Vaccination Reactogenicity Symptoms
Camphor; eucalyptus spp. oil; menthol	19 Oct 2020 (Study Day 50) - 19 Oct 2020 (Study Day 50)	Forehead Pain
Influenza vaccine	21 Oct 2020 (Study Day 52) - 21 Oct 2020 (Study Day 52)	Influenza
Ibuprofen	12 Feb 2021 (Study Day 166) - 12 Feb 2021 (Study Day 166)	Prophylaxis Post Vaccine Reactogenicity Symptoms
Calcium chloride dihydrate; potassium chloride; sodium chloride; sodium lactate	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Docusate sodium; sennoside a+b	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Morphine	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Phenazopyridine hydrochloride	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Sodium chloride	13 Mar 2021 (Study Day 195) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Cystoscopy*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event
Laser lithotripsy*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Macrogol 3350	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Tamsulosin	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Left Proximal And Distal Ureteral Calculi Non Obstructing Left Nephrolithiasis
Ureteral stent placement*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event
Ureteroscopy*	14 Mar 2021 (Study Day 196) - 14 Mar 2021 (Study Day 196)	Adverse Event
Azithromycin	15 Mar 2021 (Study Day 197) - Ongoing	Prophylaxis For Pain Post Laparoscopic Surgery (Due To Nephrolithiasis)
Cefuroxime axetil	15 Mar 2021 (Study Day 197) - 21 Mar 2021 (Study Day 203)	Prophylaxis For Infection Post Laparoscopic Surgery Due To Nephrolithiasis
Hydrocodone bitartrate; paracetamol	15 Mar 2021 (Study Day 197) - Ongoing	Prophylaxis For Pain Post Laparoscopic Surgery(Due To Nephrolithiasis)
Tolterodine	22 Mar 2021 (Study Day 204) - Ongoing	Prophylaxis For Urinary Spasm

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tinnitus	Grade 1/mild	Not related	12 Oct 2020 (Study Day 43) - 19 Oct 2020 (Study Day 50)
Headache	Grade 1/mild	Not related	19 Oct 2020 (Study Day 50) - 19 Oct 2020 (Study Day 50)
Dysuria	Grade 2/moderate	Not related	04 Jan 2021 (Study Day 127) - 19 Apr 2021 (Study Day 232)
Haematuria	Grade 2/moderate	Not related	04 Jan 2021 (Study Day 127) - 19 Apr 2021 (Study Day 232)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2119 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	01 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Atrial Fibrillation/ Worsening Of Paroxysmal Atrial Fibrillation	SAE	Grade 2/ moderate	Not related	01 Dec 2020 (Study Day 90) – 24 Feb 2021 (Study Day 175)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2119, a 68-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 01 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Dec 2020 (Study Day 90), 89 days after the first dose and 61 days after the second dose of the IP, the participant experienced a Grade 2/moderate serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of worsening of paroxysmal atrial fibrillation lasted for 86 days, after which it was considered to be recovered/resolved on 24 Feb 2021 (Study Day 175). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-023562	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1958 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Atrial fibrillation	Paroxysmal atrial fibriliation	2015 - Ongoing
Cardiac failure congestive	Congestive heart failure	2015 - Ongoing
Ischaemic cardiomyopathy	Ischemic cardiomyopathy	2015 - Ongoing
Myocardial infarction	Myocardial infarction	2015 - 2015
Coronary artery bypass	Coronary artery bypass graft surgery	23 Feb 2015 (Study Day -2019) - 23 Feb 2015 (Study Day -2019)
Coronary artery disease	Coronary artery disease	23 Feb 2015 (Study Day -2019) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine hydrochloride	2010 - Ongoing	Seasonal Allergies
Vitamins nos	2010 - Ongoing	Prophylaxis For General Health
Atorvastatin	2015 - Ongoing	Coronary Artery Disease
Losartan	2015 - Ongoing	Hypertension
Rivaroxaban	2015 - Ongoing	Atrial Fibrillation
Sotalol	2015 - 04 Feb 2021 (Study Day 155)	Paroxysmal Atrial Fibrillation
Vitamin b12 nos	2015 - Ongoing	Prophylaxis For General Health
Paracetamol	Sep 2020 - Ongoing	Prophylaxis For Toothache
Loperamide hydrochloride	03 Sep 2020 (Study Day 1) - 03 Sep 2020 (Study Day 1)	Diarrhea
Paracetamol	01 Oct 2020 (Study Day 29) - 03 Oct 2020 (Study Day 31)	Pain On Injection Site Post Vaccination
Influenza vaccine	16 Oct 2020 (Study Day 44) - 16 Oct 2020 (Study Day 44)	Influenza
Levofloxacin	24 Oct 2020 (Study Day 52) - 31 Oct 2020 (Study Day 59)	Gum Infection Right Upper Quadrant Gum Area
Benzocaine	Nov 2020 - Ongoing	Gum Infection Right Upper Quadrant Gum Area
Colonoscopy*	16 Nov 2020 (Study Day 75) - 16 Nov 2020 (Study Day 75)	Other, Routine Screening
Sotalol	01 Dec 2020 (Study Day 90) - 04 Feb 2021 (Study Day 155)	Worsening Of Paroxysmal Atrial Fibrillation
Bismuth subsalicylate	24 Dec 2020 (Study Day 113) - 24 Dec 2020 (Study Day 113)	Diarrhea

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loperamide hydrochloride	24 Dec 2020 (Study Day 113) - 24 Dec 2020 (Study Day 113)	Diarrhea
Acetylsalicylic acid	18 Jan 2021 (Study Day 138) - Ongoing	Prophylaxis For Thromboembolic Event
Holter monitor*	18 Jan 2021 (Study Day 138) - 18 Jan 2021 (Study Day 138)	Adverse Event
Cardiac mri*	20 Jan 2021 (Study Day 140) - 20 Jan 2021 (Study Day 140)	Adverse Event
Carvedilol	04 Feb 2021 (Study Day 155) - 07 Feb 2021 (Study Day 158)	Paroxysmal Atrial Fibrillation
Metoprolol	08 Feb 2021 (Study Day 159) - Ongoing	Paroxymal Atrial Fibrilation
Ceftriaxone	23 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 174)	Dual Chamber Defribilator Implantation
Etomidate	23 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 174)	Implantation Of Dual Chamber Icd
Fentanyl	23 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 174)	Implantation Of Dual Chamber Icd
Implantation of dual chamber implantable cardioverter defibrillator (icd)*	23 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 174)	Adverse Event
Midazolam hydrochloride	23 Feb 2021 (Study Day 174) - 23 Feb 2021 (Study Day 174)	Implantation Of Dual Chamber Icd
Minocycline	24 Feb 2021 (Study Day 175) - 28 Feb 2021 (Study Day 179)	Prophylaxis For Icd Implantation Site Infection
Tramadol hydrochloride	26 Feb 2021 (Study Day 177) - 07 Mar 2021 (Study Day 186)	Pain On Left Upper Anterior Chest Area (Icd Implantation Site)
Paracetamol	28 Feb 2021 (Study Day 179) - 28 Feb 2021 (Study Day 179)	Low Grade Fever

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 1/mild	Not related	03 Sep 2020 (Study Day 1) – 03 Sep 2020 (Study Day 1)
Gingivitis	Grade 1/mild	Not related	16 Oct 2020 (Study Day 44) - 15 Jan 2021 (Study Day 135)
Haemorrhoids	Grade 1/mild	Not related	01 Nov 2020 (Study Day 60) - Ongoing
Dizziness	Grade 1/mild	Not related	16 Nov 2020 (Study Day 75) - Ongoing
Diarrhoea	Grade 1/mild	Related	24 Dec 2020 (Study Day 113) - 24 Dec 2020 (Study Day 113)
Ventricular Extrasystoles	Grade 1/mild	Not related	18 Jan 2021 (Study Day 138) - Ongoing
Haematuria	Grade 2/moderate	Not related	06 Feb 2021 (Study Day 157) - 07 Feb 2021 (Study Day 158)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Medical Device Site Pain	Grade 2/moderate	Not related	24 Feb 2021 (Study Day 175) - Ongoing
Pyrexia	Grade 1/mild	Not related	28 Feb 2021 (Study Day 179) - 28 Feb 2021 (Study Day 179)
Dysuria	Grade 1/mild	Not related	23 Mar 2021 (Study Day 202) - Ongoing
Haematuria	Grade 1/mild	Not related	23 Mar 2021 (Study Day 202) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US386-2286 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	16 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Viral Infection/Viral Like Illness	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	01 Nov 2020 (Study Day 17) – 11 Nov 2020 (Study Day 27)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US386-2286, a 54-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 16 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Nov 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of viral infection. On 12 Nov 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of viral like illness lasted for 11 days, after which it was considered to be recovered/resolved on 11 Nov 2020 (Study Day 27). The investigator assessed the event of viral infection to be not related to the IP.

Additional Information From the Safety Database

No additional details for the events are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Psoriasis	Psoriasis intermittent	1976 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1976 - Ongoing
Malignant melanoma	Melanoma right hip stage 1	2011 - 2011
Basal cell carcinoma	Basal cell carcinoma suprasternal notch	2014 - 2014
Benign neoplasm of thyroid gland	Benign thyroid nodule	2015 - 2015
Hypothyroidism	Hypothyroidism	2015 - Ongoing
Thyroidectomy	S/p left thyroidectomy	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ascorbic acid	1985 - Ongoing	Prophylaxis For General
Vitamins nos	1985 - Ongoing	Prophylaxis For General Health
Acetylsalicylic acid	2010 - Ongoing	Melanoma
Fluticasone propionate	2014 - Ongoing	Seasonal Allergies
Levothyroxine	2015 - Ongoing	Hypothyroidism
Paracetamol	01 Nov 2020 (Study Day 17) - 10 Nov 2020 (Study Day 26)	Viral Like Illness
Ibuprofen	03 Nov 2020 (Study Day 19) - 10 Nov 2020 (Study Day 26)	Viral Like Illness
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	05 Nov 2020 (Study Day 21) - 10 Nov 2020 (Study Day 26)	Viral Like Illness
Azithromycin	06 Nov 2020 (Study Day 22) - 06 Nov 2020 (Study Day 22)	Viral Like Illness
Azithromycin	06 Nov 2020 (Study Day 22) - 10 Nov 2020 (Study Day 26)	Viral Like Illness
Ondansetron	06 Nov 2020 (Study Day 22) - 09 Nov 2020 (Study Day 25)	Viral Like Illness

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Viral Infection	Grade 2/moderate	Not related	01 Nov 2020 (Study Day 17) - 11 Nov 2020 (Study Day 27)
Viral Upper Respiratory Tract Infection	Grade 1/mild	Not related	09 Dec 2020 (Study Day 55) - 19 Dec 2020 (Study Day 65)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2001 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	28 Aug 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Rib Fracture/Right Rib Fractures (#9-#11)	SAE	Grade 3/severe	Not related	30 Nov 2020 (Study Day 123) – 24 Dec 2020 (Study Day 147)	Recovered/resolved
Acute Respiratory Failure/Acute Respiratory Failure	SAE	Grade 3/severe	Not related	02 Dec 2020 (Study Day 125) – 17 Dec 2020 (Study Day 140)	Recovered/resolved
Pneumonia/Pneumonia (Bilateral)	SAE	Grade 3/severe	Not related	06 Dec 2020 (Study Day 129) – 06 Jan 2021 (Study Day 160)	Recovered/resolved
Failure To Thrive/Failure To Thrive	SAE	Grade 4	Not related	24 Dec 2020 (Study Day 147) – 06 Jan 2021 (Study Day 160)	Recovered/resolved
Duodenal Ulcer Perforation/Perforated Duodenal Ulcer	SAE	Grade 4	Not related	25 Jan 2021 (Study Day 179) – 25 Jan 2021 (Study Day 179)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2001, a 72-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 31 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 28 Aug 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Nov 2020 (Study Day 123), 122 days after the first dose and 94 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of rib fracture. Action taken with the IP was not applicable. The event of right rib fractures (#9-#11) lasted for 25 days, after which it was considered to be recovered/resolved on 24 Dec 2020 (Study Day 147). The investigator assessed the event of rib fracture to be not related to the IP.

On 02 Dec 2020 (Study Day 125), 124 days after the first dose and 96 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute respiratory failure. Action taken with the IP was not applicable. The event of acute respiratory failure lasted

for 16 days, after which it was considered to be recovered/resolved on 17 Dec 2020 (Study Day 140). The investigator assessed the event of acute respiratory failure to be not related to the IP.

On 06 Dec 2020 (Study Day 129), 128 days after the first dose and 100 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia (bilateral) lasted for 32 days, after which it was considered to be recovered/resolved on 06 Jan 2021 (Study Day 160). The investigator assessed the event of pneumonia to be not related to the IP.

On 24 Dec 2020 (Study Day 147), 146 days after the first dose and 118 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of failure to thrive. Action taken with the IP was not applicable. The event of failure to thrive lasted for 14 days, after which it was considered to be recovered/resolved on 06 Jan 2021 (Study Day 160). The investigator assessed the event of failure to thrive to be not related to the IP.

On 25 Jan 2021 (Study Day 179), 178 days after the first dose and 150 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of duodenal ulcer perforation. Action taken with the IP was not applicable. The event of perforated duodenal ulcer lasted for 1 day, after which it was considered to be recovered/resolved on 25 Jan 2021 (Study Day 179). The investigator assessed the event of duodenal ulcer perforation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001364	Rib fracture
MOD-2020-001364	Acute respiratory failure
MOD-2020-001364	Pneumonia
MOD-2020-001364	Failure to thrive
MOD-2021-008566	Duodenal ulcer perforation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Nearsighted	1960 - Ongoing
Rotator cuff repair	Right rotator cuff tear repair	1990 - 1990
Rotator cuff syndrome	Right rotator cuff tear	1990 - 1990

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Insomnia	Insomnia	2000 - Ongoing
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2010 - Ongoing
Back pain	Low back pain	2015 - Ongoing
Constipation	Opiate induced constipation	2015 - Ongoing
Sinus tachycardia	Sinus tachycardia	2017 - Ongoing
Arthralgia	Joint aches(generalized)	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Glimepiride	Not reported - Ongoing	Type II Dm
Metoprolol tartrate	Not reported - Ongoing	Type II Dm
Rosuvastatin calcium	Not reported - Ongoing	Elevated Cholesterol
Vitamins nos	1980 - Ongoing	Health Maintenance
Metformin	2010 - Ongoing	Type 2 Diabetes
Simvastatin	2010 - Ongoing	Hypercholesterolemia
Oxycodone hydrochloride; paracetamol	2015 - Ongoing	Low Back Pain
Quetiapine fumarate	2015 - 03 Dec 2020 (Study Day 126)	Insomnia
Atenolol	2017 - Ongoing	Sinus Tachycardia
In dwelling catheter placement*	01 Dec 2020 (Study Day 124) - 01 Dec 2020 (Study Day 124)	Adverse Event
Pa chest and right ribs 3 views*	01 Dec 2020 (Study Day 124) - 01 Dec 2020 (Study Day 124)	Adverse Event
Xray ribs with pa right chest*	01 Dec 2020 (Study Day 124) - 01 Dec 2020 (Study Day 124)	Adverse Event
Xray chest 1 vew frontal*	02 Dec 2020 (Study Day 125) - 02 Dec 2020 (Study Day 125)	Adverse Event
Acetylcysteine	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Pneumonia
Atenolol	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Sinus Tachycordia
Atorvastatin	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	High Cholesterol
Furosemide	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Pleurol Effusion
Glimepiride	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Type II Diabetes
Glucagon	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Type II Diabetes
Glucose	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Type II Diabetes

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Heparin	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Throboembolism Phrophylaxis
Influenza vaccine	03 Dec 2020 (Study Day 126) - 03 Dec 2020 (Study Day 126)	Flu Prevention
Insulin aspart	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Type II Diabetes
Iopamidol	03 Dec 2020 (Study Day 126) - 03 Dec 2020 (Study Day 126)	Iv Contrast
Ipratropium bromide; salbutamol sulfate	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Pneumonia
Lisinopril	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Hypertension Secondary To Pain
Lisinopril	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Hypertension Secondary To Pain Of Rib Fractures
Macrogol 3350	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Constipation Opiate Induced
Naloxone	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Opiate Reversal
Nicotine	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Nicotine Addiction
Nystatin; zinc oxide	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Staphaureus Prevention (Nasal)
Ondansetron	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Nausea Due To Pain
Oxycodone hydrochloride; paracetamol	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Generalized Pain
Pantoprazole	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Acid Reducer
Paracetamol	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Generalized Body Pain Associated With Broken Ribs/ Fall
Potassium chloride	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Hypokalemia
Potassium citrate	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Hypokalemia
Quetiapine	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Insomnia
Ramelteon	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Insomnia
Ranitidine	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Stomach Acid Reducer
Simvastatin	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	High Cholesterol
Sulfadiazine silver	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Right Knee Abrasion
Tamsulosin	03 Dec 2020 (Study Day 126) - 17 Dec 2020 (Study Day 140)	Benign Prostatic Hyperplaia
Xray chest 1 view frontal*	04 Dec 2020 (Study Day 127) - 04 Dec 2020 (Study Day 127)	Adverse Event
Ct angio chest with contrast*	05 Dec 2020 (Study Day 128) - 05 Dec 2020 (Study Day 128)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Endotracheal intubation*	05 Dec 2020 (Study Day 128) - 05 Dec 2020 (Study Day 128)	Adverse Event
Nasogastric tube placement*	05 Dec 2020 (Study Day 128) - 05 Dec 2020 (Study Day 128)	Adverse Event
Sequential compression device applied bilaterally to legs*	05 Dec 2020 (Study Day 128) - 05 Dec 2020 (Study Day 128)	Other, Deep Vein Thrombosis Prevention Due To Bed Bound.
Xray chest 1 view frontal*	05 Dec 2020 (Study Day 128) - 05 Dec 2020 (Study Day 128)	Adverse Event
Echocardiogram*	06 Dec 2020 (Study Day 129) - 06 Dec 2020 (Study Day 129)	Adverse Event
Xray chest 1 view frontal*	06 Dec 2020 (Study Day 129) - 06 Dec 2020 (Study Day 129)	Adverse Event
Echocardiogram*	07 Dec 2020 (Study Day 130) - 07 Dec 2020 (Study Day 130)	Adverse Event
Xray chest 1 view frontal*	07 Dec 2020 (Study Day 130) - 07 Dec 2020 (Study Day 130)	Adverse Event
Xray chest 1 view frontal*	08 Dec 2020 (Study Day 131) - 08 Dec 2020 (Study Day 131)	Adverse Event
Endotracheal extubation*	09 Dec 2020 (Study Day 132) - 09 Dec 2020 (Study Day 132)	Adverse Event
Nasogastric tube removal*	09 Dec 2020 (Study Day 132) - 09 Dec 2020 (Study Day 132)	Adverse Event
Xray chest 1 view frontal*	09 Dec 2020 (Study Day 132) - 09 Dec 2020 (Study Day 132)	Adverse Event
Cta thorax*	10 Dec 2020 (Study Day 133) - 10 Dec 2020 (Study Day 133)	Adverse Event
Xray chest 1 view frontal*	10 Dec 2020 (Study Day 133) - 10 Dec 2020 (Study Day 133)	Adverse Event
Xray chest 1 view frontal*	11 Dec 2020 (Study Day 134) - 11 Dec 2020 (Study Day 134)	Adverse Event
Cefepime hydrochloride	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	B/L Pneumonia
Citric acid; potassium bicarbonate	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Hypokalcemia
Electrolyte solutions [umbrella term]	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Hypokalcemia
Glucose	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Type II Diabetes
Glucose; magnesium sulfate	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Low Magnesium
Insulin	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Type II Diabetes
Iopamidol	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Contrast Media For Ct
Lactulose	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Constipation
Magnesium oxide	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Low Magnesium
Magnesium sulfate	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Low Magnesium

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metoprolol tartrate	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Sinus Tochycardio
Metronidazole	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Infection Suspected With Shock
Mupirocin	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Staphylococcus Aureus Prevention
Norepinephrine bitartrate	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Shock Hypotemcon
Oxycodone; paracetamol	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Low Back Pain
Pantoprazole sodium sesquihydrate	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Acid Reflux
Paracetamol	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Generalized Pain
Phenylephrine hydrochloride	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Shock Hypotemcon
Phosphorus	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Low Phosphorus
Phytomenadione	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Failure To Thrive/ Vitamin Deficiency / Bleeding Prop
Piperacillin sodium	24 Dec 2020 (Study Day 147) - 24 Dec 2020 (Study Day 147)	Septic Shock Of Unknown Etiology
Potassium chloride	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Hypokalcemia
Quetiapine fumarate	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Insomnia
Sodium chloride	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Hyponatremia / Carrier For Antibiotic
Sodium chloride	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Iv Hyprotion
Sodium chloride	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Ivpb
Sodium chloride	24 Dec 2020 (Study Day 147) - 24 Dec 2020 (Study Day 147)	Septic Shock Of Unknown Etiology
Solutions for parenteral nutrition	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Hypokalcemia
Tazobactam sodium	24 Dec 2020 (Study Day 147) - 24 Dec 2020 (Study Day 147)	Septic Shock Of Unknown Etiology
Trazodone	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Insomnia
Vancomycin hydrochloride	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	B/L
Vancomycin hydrochloride	24 Dec 2020 (Study Day 147) - 24 Dec 2020 (Study Day 147)	Bilateral Pneumonia
Vasopressin	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)	Shock Hypotemcon
Quetiapine	30 Dec 2020 (Study Day 153) - Ongoing	Insomnia
Ct abd w/o contrast*	25 Jan 2021 (Study Day 179) - 25 Jan 2021 (Study Day 179)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Insomnia
Enoxaparin sodium	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Dvt Prophylaxis
Famotidine	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Acid Reducer For Ulcer Hx
Glucagon	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Type II Diabetes
Glucose	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Type II Diabetes
Grahm patch*	25 Jan 2021 (Study Day 179) - 25 Jan 2021 (Study Day 179)	Adverse Event
Hydrocodone bitartrate; paracetamol	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Low Back Pain
Hydroxyzine hydrochloride	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Insomnia
Insulin aspart	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Type II Dm
Lapartomoy exploratory*	25 Jan 2021 (Study Day 179) - 25 Jan 2021 (Study Day 179)	Adverse Event
Morphine	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Status Post Surgical Pain
Myroxylon balsamum var. pereirae; ricinus communis oil	25 Jan 2021 (Study Day 179) - 15 Mar 2021 (Study Day 228)	Left Knee Abrasion
Nicotine	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Nicotine Patch
Ondansetron	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Nausea 2 To Duodenal Ucler
Pantoprazole	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Acid Reducer For Ulcer Hx
Paracetamol	25 Jan 2021 (Study Day 179) - 08 Feb 2021 (Study Day 193)	Generalized Joint Pain
Omeprazole	26 Jan 2021 (Study Day 180) - Ongoing	Acid Reducer
Ondansetron	05 Mar 2021 (Study Day 218) - Ongoing	Nausea Secondary To Duodenal Ulcer (Sae)
Ondansetron	05 Mar 2021 (Study Day 218) - Ongoing	Nausea Secondary To Status Post Duodenal Ulcer

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Skin Abrasion	Grade 1/mild	Not related	30 Nov 2020 (Study Day 123) - 15 Mar 2021 (Study Day 228)
Hypertension	Grade 1/mild	Not related	16 Dec 2020 (Study Day 139) - 17 Dec 2020 (Study Day 140)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Septic Shock	Grade 3/severe	Not related	24 Dec 2020 (Study Day 147) - 06 Jan 2021 (Study Day 160)
C-Reactive Protein Increased	Grade 2/moderate	Not related	25 Dec 2020 (Study Day 148) - 06 Jan 2021 (Study Day 160)
Faecaloma	Grade 1/mild	Not related	25 Dec 2020 (Study Day 148) - 26 Dec 2020 (Study Day 149)
Leukocytosis	Grade 3/severe	Not related	25 Dec 2020 (Study Day 148) - 25 Jan 2021 (Study Day 179)
Fatigue	Grade 1/mild	Not related	09 Feb 2021 (Study Day 194) - 28 Mar 2021 (Study Day 241)
Pain	Grade 2/moderate	Not related	09 Feb 2021 (Study Day 194) - 02 Apr 2021 (Study Day 246)
Nausea	Grade 2/moderate	Not related	05 Mar 2021 (Study Day 218) - 26 Mar 2021 (Study Day 239)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US390-2020 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	30 Sep 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Myocardial Infarction/Myocardial Infarction	SAE	Grade 3/severe	Not related	15 Feb 2021 (Study Day 167) – 16 Feb 2021 (Study Day 168)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US390-2020, a 57-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 30 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Feb 2021 (Study Day 167), 166 days after the first dose and 138 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of myocardial infarction. Action taken with the IP was not applicable. The event of myocardial infarction lasted for 2 days, after which it was considered to be recovered/resolved on 16 Feb 2021 (Study Day 168). The investigator assessed the event of myocardial infarction to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-023125	Myocardial infarction

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Morbid obesity	2000 - Ongoing
Sciatica	Sciatica	2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	19 Feb 2021 (Study Day 171) - Ongoing	Hyperlipedemia
Levofloxacin	19 Feb 2021 (Study Day 171) - 24 Feb 2021 (Study Day 176)	Infection (Lower Lobes Of Lungs)
Lisinopril	19 Feb 2021 (Study Day 171) - Ongoing	Hypertension
Metoprolol	19 Feb 2021 (Study Day 171) - Ongoing	Hypertension
Ticagrelor	19 Feb 2021 (Study Day 171) - Ongoing	Hyperlipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperlipidaemia	Grade 1/mild	Not related	15 Feb 2021 (Study Day 167) - Ongoing
Hypertension	Grade 1/mild	Not related	16 Feb 2021 (Study Day 168) - Ongoing
Pneumonia	Grade 2/moderate	Not related	16 Feb 2021 (Study Day 168) - 24 Feb 2021 (Study Day 176)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US390-2021 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	29 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Cholelithiasis/Cholelithiasis	SAE	Grade 3/ severe	Not related	22 Feb 2021 (Study Day 174) – 01 Mar 2021 (Study Day 181)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US390-2021, a 38-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 29 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Feb 2021 (Study Day 174), 173 days after the first dose and 146 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of cholelithiasis. Action taken with the IP was not applicable. The event of cholelithiasis lasted for 8 days, after which it was considered to be recovered/resolved on 01 Mar 2021 (Study Day 181). The investigator assessed the event of cholelithiasis to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-027979	Cholelithiasis

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	30 Sep 2020 (Study Day 29) - 10 Oct 2020 (Study Day 39)	Headache
Cholecystectomy*	23 Feb 2021 (Study Day 175) - 23 Feb 2021 (Study Day 175)	Adverse Event
Amoxicillin; clavulanate potassium	25 Feb 2021 (Study Day 177) - Ongoing	Cholelithiasis
Oxycodone; paracetamol	25 Feb 2021 (Study Day 177) - Ongoing	Cholelithiasis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	11 Sep 2020 (Study Day 10) - 11 Sep 2020 (Study Day 10)
Headache	Grade 1/mild	Related	07 Oct 2020 (Study Day 36) - 10 Oct 2020 (Study Day 39)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US391-2121 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	06 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Small Intestinal Obstruction/Small Bowel Obstruction	SAE	Grade 4	Not related	17 Dec 2020 (Study Day 101) – 18 Dec 2020 (Study Day 102)	Recovered/resolved
Atrial Fibrillation/ Paroxysmal Atrial Fibrillation	SAE	Grade 3/ severe	Not related	20 Dec 2020 (Study Day 104) – 25 Dec 2020 (Study Day 109)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2121, a 73-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 06 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Dec 2020 (Study Day 101), 100 days after the first dose and 72 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of small intestinal obstruction. Action taken with the IP was not applicable. The event of small bowel obstruction lasted for 2 days, after which it was considered to be recovered/resolved on 18 Dec 2020 (Study Day 102). The investigator assessed the event of small intestinal obstruction to be not related to the IP.

On 20 Dec 2020 (Study Day 104), 103 days after the first dose and 75 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of atrial fibrillation. Action taken with the IP was not applicable. The event of paroxysmal atrial fibrillation lasted for 6 days, after which it was considered to be recovered/resolved on 25 Dec 2020 (Study Day 109). The investigator assessed the event of atrial fibrillation to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-001186	Small intestinal obstruction
MOD-2020-001186	Atrial fibrillation

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardioversion	Direct current cardioversion	1st in Feb 2012; 2nd May 2012
Endometriosis	Endometriosis	1972 - 1984
Benign neoplasm of thyroid gland	Benign thyroid nodules	1982 - 1984
Drug hypersensitivity	Sulfa allergy-hives	1984 - Ongoing
Hysterectomy	Total abdominal hysterectomy	1984 - 1984
Post procedural hypothyroidism	Hypothyroidism (post-surgical)	1984 - Ongoing
Thyroidectomy	Thyroidectomy	1984 - 1984
Drug hypersensitivity	Penicillin allergy	1990 - Ongoing
Cholelithiasis	Gall stones	1994 - 1995
Cholecystectomy	Gallbladder removal	1995 - 1995
Drug hypersensitivity	Demerol allergy-vomiting	1995 - Ongoing
Arthritis	Arthritis	2009 - Ongoing
Knee arthroplasty	Left knee replacement (secondary to arthritis)	2009 - 2009
Hip arthroplasty	Left hip replacement (secondary to arthritis)	2010 - 2010
Atrial fibrillation	Atrial fibrillation	2011 - Ongoing
Cardiac ablation	Heart ablation	May 2012 - May 2012
Drug hypersensitivity	Zofran allergy-vomiting	2014 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Knee arthroplasty	Right knee replacement (secondary to arthritis)	2015 - 2015
Limb injury	Fall-shoulder injury (right)	2017 - 2017
Shoulder arthroplasty	Right shoulder replacement	2017 - 2017
Drug eruption	Prednisone allergy-rash	2018 - Ongoing
Facial paralysis	Bell's palsy	2018 - 2019
Cataract	Cataracts-bilateral	Feb 2020 - May 2020
Cataract operation	Cataract surgery-left	Feb 2020 - Feb 2020
Cataract operation	Cataract surgery-right	May 2020 - May 2020

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Degenerative joint disease, right hip	Jun 2020 - Ongoing
Joint range of motion decreased	Decreased range of motion right hip	08 Sep 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Estrogens conjugated	1984 - Ongoing	Hormone Replacement
Levothyroxine sodium	1984 - Ongoing	Hypothypoidism
Apixaban	2011 - Ongoing	Atrial Fibrillation
Sotalol	2011 - 28 Dec 2020 (Study Day 112)	Atrial Fibrillation
Amlodipine	2015 - 28 Dec 2020 (Study Day 112)	Hypertension
Paracetamol	2015 - Ongoing	Arthritis
Influenza vaccine	21 Oct 2020 (Study Day 44) - 21 Oct 2020 (Study Day 44)	Flu Prevention
Bowel resection*	18 Dec 2020 (Study Day 102) - 18 Dec 2020 (Study Day 102)	Adverse Event
Cefepime	18 Dec 2020 (Study Day 102) - 18 Dec 2020 (Study Day 102)	Infection Prophylaxis
Ct abdomen/pelvis with contrast*	18 Dec 2020 (Study Day 102) - 18 Dec 2020 (Study Day 102)	Diagnostic
Diltiazem	18 Dec 2020 (Study Day 102) - 19 Dec 2020 (Study Day 103)	Hypertension
Electrocardiogram*	18 Dec 2020 (Study Day 102) - 18 Dec 2020 (Study Day 102)	Diagnostic
Metoprolol	18 Dec 2020 (Study Day 102) - 22 Dec 2020 (Study Day 106)	Paroxysmal A-Fib
Morphine	18 Dec 2020 (Study Day 102) - 25 Dec 2020 (Study Day 109)	Small Bowel Obstruction
Promethazine	18 Dec 2020 (Study Day 102) - 25 Dec 2020 (Study Day 109)	Small Bowl Obstruction
X-ray chest*	18 Dec 2020 (Study Day 102) - 18 Dec 2020 (Study Day 102)	Diagnostic
Digoxin	19 Dec 2020 (Study Day 103) - 19 Dec 2020 (Study Day 103)	Paroxysmal A-Fib
Potassium chloride	19 Dec 2020 (Study Day 103) - 27 Dec 2020 (Study Day 111)	Hyperkalemia
Cefepime	20 Dec 2020 (Study Day 104) - 25 Dec 2020 (Study Day 109)	Prophylaxis For Small Bowel Obstruction
Esmolol	20 Dec 2020 (Study Day 104) - 25 Dec 2020 (Study Day 109)	Paroxysmal A-Fib
Melatonin	20 Dec 2020 (Study Day 104) - 26 Dec 2020 (Study Day 110)	Insomnia
Trazodone	20 Dec 2020 (Study Day 104) - 27 Dec 2020 (Study Day 111)	Insomnia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amino acids nos; glucose; lipids nos	21 Dec 2020 (Study Day 105) - 28 Dec 2020 (Study Day 112)	Nutritional Support
Amiodarone	21 Dec 2020 (Study Day 105) - 27 Dec 2020 (Study Day 111)	Paroxysmal A-Fib
Digoxin	21 Dec 2020 (Study Day 105) - 25 Dec 2020 (Study Day 109)	Paroxysmal A-Fib
Enoxaparin sodium	21 Dec 2020 (Study Day 105) - 27 Dec 2020 (Study Day 111)	Clot Prevention
Olanzapine	21 Dec 2020 (Study Day 105) - 21 Dec 2020 (Study Day 105)	Post-Op Altered Mental Status
Transthoracic echocardiogram*	21 Dec 2020 (Study Day 105) - 21 Dec 2020 (Study Day 105)	Diagnostic
Furosemide	22 Dec 2020 (Study Day 106) - 24 Dec 2020 (Study Day 108)	Small Bowel Obstruction
Levothyroxine	23 Dec 2020 (Study Day 107) - 27 Dec 2020 (Study Day 111)	Hypothyroidism Post Thyroidectomy
Paracetamol	26 Dec 2020 (Study Day 110) - 26 Dec 2020 (Study Day 110)	Post Surgery - Small Bowel Obstruction
Amiodarone	27 Dec 2020 (Study Day 111) - Ongoing	Paroxysmal A-Fib
Amlodipine	27 Jan 2021 (Study Day 142) - Ongoing	Hypertension
Sotalol	27 Jan 2021 (Study Day 142) - Ongoing	Atrial Fibrillation

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Pleural Effusion	Grade 1/mild	Not related	18 Dec 2020 (Study Day 102) - 21 Dec 2020 (Study Day 105)
Left Atrial Enlargement	Grade 1/mild	Not related	21 Dec 2020 (Study Day 105) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US391-2241 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pulmonary Embolism/Pulmonary Embolism, Lll	SAE, AE leading to withdrawal from study vaccine	Grade 4	Not related	03 Nov 2020 (Study Day 23) – 09 Nov 2020 (Study Day 29)	Recovered/ resolved
Schizophrenia/Worsening Of Schizophrenia Psychotic Disorder	SAE	Grade 3/ severe	Not related	01 Dec 2020 (Study Day 51) – 04 Dec 2020 (Study Day 54)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US391-2241, a 59-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 12 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Nov 2020 (Study Day 23), 22 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 4 serious adverse event of pulmonary embolism. On 08 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event of pulmonary embolism. The event of pulmonary embolism, lll lasted for 7 days, after which it was considered to be recovered/resolved on 09 Nov 2020 (Study Day 29). The investigator assessed the event of pulmonary embolism to be not related to the IP.

On 01 Dec 2020 (Study Day 51), 50 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of schizophrenia. On 08 Nov 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event of pulmonary embolism. The event of worsening of schizophrenia psychotic disorder lasted for 4 days, after which it was considered to be recovered/resolved on 04 Dec 2020 (Study Day 54). The investigator assessed the event of schizophrenia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000646	Pulmonary embolism
MOD-2020-001041	Schizophrenia

Study Completion/Discontinuation

On 04 Feb 2021 (Study Day 116), the participant discontinued from the study due to physician decision (participant was withdrawn due to his refusal to medically manage his mental health (schizophrenia); realizing that this condition will likely worsen without treatment, participant withdrawn.).

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Food allergy	Allergy to oranges- itchy all over	Not reported - Ongoing
Pruritus allergic	Allergy to tomatoes- itchy all over	Not reported - Ongoing
Pain	General body aches	2000 - Ongoing
Schizophrenia	Schizophrenia psychotic disorder	2006 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Generalized Body Aches
Chest x-ray*	04 Nov 2020 (Study Day 24) - 04 Nov 2020 (Study Day 24)	Diagnostic
Doppler ultrasound*	04 Nov 2020 (Study Day 24) - 04 Nov 2020 (Study Day 24)	Diagnostic
Electrocardiogram*	04 Nov 2020 (Study Day 24) - 04 Nov 2020 (Study Day 24)	Diagnostic
Enoxaparin sodium	04 Nov 2020 (Study Day 24) - 05 Nov 2020 (Study Day 25)	Pulmonary Embolism
Iopamidol	04 Nov 2020 (Study Day 24) - 04 Nov 2020 (Study Day 24)	Diagnostic Agent For Cta
Ketorolac tromethamine	04 Nov 2020 (Study Day 24) - 04 Nov 2020 (Study Day 24)	Chest Pain
Transthoracic echocardiography*	04 Nov 2020 (Study Day 24) - 04 Nov 2020 (Study Day 24)	Diagnostic

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Apixaban	05 Nov 2020 (Study Day 25) - Ongoing	Pulmonary Embolism
Codeine phosphate; paracetamol	05 Nov 2020 (Study Day 25) - 05 Nov 2020 (Study Day 25)	Chest Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asthenia	Grade 4	Related	03 Nov 2020 (Study Day 23) - 06 Nov 2020 (Study Day 26)
Pleuritic Pain	Grade 1/mild	Related	03 Nov 2020 (Study Day 23) - 05 Nov 2020 (Study Day 25)
Dry Skin	Grade 1/mild	Not related	21 Nov 2020 (Study Day 41) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US392-2067 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Confusional State/Confusion	SAE, AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	07 Sep 2020 (Study Day 7) – 09 Sep 2020 (Study Day 9)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US392-2067, a 77-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 01 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of confusional state. On 28 Sep 2020 (Study Day 28), the IP dose was discontinued due to serious adverse event. The event of confusion lasted for 3 days, after which it was considered to be recovered/resolved on 09 Sep 2020 (Study Day 9). The investigator assessed the event of confusional state to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000273	Confusional state

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to penicillin	1950 - 2000
Tonsillectomy	Tonsillectomy	Dec 1953 - Dec 1953
Tonsillitis	Tonsillitis	Dec 1953 - Dec 1953
Female sterilisation	Tubal ligation	Jun 1973 - Jun 1973
Breast cyst excision	Right breast cyst removal benign	1975 - 1975
Caffeine allergy	Allergy of caffeine	1980 - Ongoing
Menorrhagia	Menorrhagia	1982 - 1982
Hysterectomy	Hysterectomy	12 Mar 1982 (Study Day -14053) - 12 Mar 1982 (Study Day -14053)
Drug hypersensitivity	Allergy to erythromycin	1997 - Ongoing
Allergy to chemicals	Chronic allergies (chemical)	1998 - Ongoing
Urinary incontinence	Urinary incontinence	2001 - 2001
Urinary bladder suspension	Bladder suspension	05 Sep 2001 (Study Day -6936) - 05 Sep 2001 (Study Day -6936)
Hypercholesterolaemia	Hypercholesterolemia	2003 - Ongoing
Breast cancer	Left breast cancer	2004 - 21 Jan 2005 (Study Day -5702)
Drug hypersensitivity	Allergy to nitrofurantoin	2005 - Ongoing
Breast conserving surgery	Lumpectomy left breast(cancerous)	21 Jan 2005 (Study Day -5702) - 21 Jan 2005 (Study Day -5702)
Sleep apnoea syndrome	Sleep apnea	2008 - Ongoing
Cataract	Bilateral cataracts	2010 - 2010
Cataract operation	Bilateral cataract surgery	2010 - 2010
Drug hypersensitivity	Allergy to ciprofloxacin	2010 - Ongoing
Drug hypersensitivity	Allergy to septra	2010 - Ongoing
Hypothyroidism	Hypothyroidism	2010 - Ongoing
Urinary tract infection	Chronic recurrent uti's	2010 - Ongoing
Musculoskeletal pain	Left shoulder pain	2011 - 09 Sep 2011 (Study Day -3280)
Musculoskeletal pain	Right shoulder pain	2011 - 30 Dec 2011 (Study Day -3168)
Shoulder arthroplasty	Left shoulder replacement	09 Sep 2011 (Study Day -3280) - 09 Sep 2011 (Study Day -3280)
Shoulder arthroplasty	Right shoulder replacement	30 Dec 2011 (Study Day -3168) - 30 Dec 2011 (Study Day -3168)
Dizziness	Dizziness	2013 - Ongoing
Atrial fibrillation	Atrial fibrillation	2015 - Ongoing
Osteoarthritis	Osteoarthritis bilateral hands	2015 - Ongoing
Dyspnoea	Chronic shortness of breath	2017 - Ongoing
Arthralgia	Left knee pain	2018 - 2018
Fatigue	Fatigue	2018 - Ongoing
Knee arthroplasty	Left knee replacement	07 Jun 2018 (Study Day -817) - 07 Jun 2018 (Study Day -817)
Dysphagia	Dysphagia	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Colecalciferol	2010 - Ongoing	Supplement
Fallopia japonica; vitis vinifera seed	2010 - Ongoing	Supplement
Levothyroxine sodium	2010 - Ongoing	Hypothyroidism
Omega-3 nos	2010 - Ongoing	Supplement
Ubidecarenone	2010 - Ongoing	Supplement
Vaccinium macrocarpon	2010 - Ongoing	Supplement
Apixaban	2015 - Ongoing	Atrial Fibrillation
Atorvastatin	2015 - Ongoing	Hypercholesterolemia
Azelastine hydrochloride; fluticasone propionate	2017 - Ongoing	Chronic Allergies (Chemical)
Ct chest*	07 Sep 2020 (Study Day 7) - 07 Sep 2020 (Study Day 7)	Adverse Event
Ct scan of head*	07 Sep 2020 (Study Day 7) - 07 Sep 2020 (Study Day 7)	Adverse Event
Eeg*	08 Sep 2020 (Study Day 8) - 08 Sep 2020 (Study Day 8)	Adverse Event
Mri head*	08 Sep 2020 (Study Day 8) - 08 Sep 2020 (Study Day 8)	Adverse Event
Echocardiogram*	09 Sep 2020 (Study Day 9) - 09 Sep 2020 (Study Day 9)	Adverse Event
Influenza vaccine	14 Sep 2020 (Study Day 14) - 14 Sep 2020 (Study Day 14)	Flu Prophylaxis
Eeg(72 hours)*	27 Sep 2020 (Study Day 27) - 27 Sep 2020 (Study Day 27)	Adverse Event
Nitrofurantoin	27 Dec 2020 (Study Day 118) - 05 Jan 2021 (Study Day 127)	Ae#6 Worsening Chronic Recurrent Urinary Tract Infections
Ceftriaxone	28 Dec 2020 (Study Day 119) - 28 Dec 2020 (Study Day 119)	Ae#6 Worsening Of Chronic Recurrent Urinary Tract Infections
I.v. solutions	28 Dec 2020 (Study Day 119) - 28 Dec 2020 (Study Day 119)	Nausea/Vomiting/Diarrhea(Ae 4,5,6)
Ondansetron hydrochloride	28 Dec 2020 (Study Day 119) - 28 Dec 2020 (Study Day 119)	Nausea/Vomiting (Ae 4/5)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Not related	28 Sep 2020 (Study Day 28) - 29 Sep 2020 (Study Day 29)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Diarrhoea	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 118) - 28 Dec 2020 (Study Day 119)
Nausea	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 118) - 28 Dec 2020 (Study Day 119)
Urinary Tract Infection	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 118) - 04 Jan 2021 (Study Day 126)
Vomiting	Grade 2/moderate	Not related	27 Dec 2020 (Study Day 118) - 28 Dec 2020 (Study Day 119)
Dacryostenosis Acquired	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 154) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US392-2080 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hypertension/Worsening Of Hypertension	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	02 Oct 2020 (Study Day 30) – 24 Feb 2021 (Study Day 175)	Recovered/ resolved
Septic Shock/Septic Shock	SAE	Grade 3/ severe	Not related	03 Feb 2021 (Study Day 154) – 07 Feb 2021 (Study Day 158)	Recovered/ resolved
Polyarteritis Nodosa/Polyarteritis Nodosa	SAE	Grade 3/ severe	Not related	10 Feb 2021 (Study Day 161) – Ongoing	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US392-2080, a 46-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 02 Oct 2020 (Study Day 30), 29 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of hypertension. On 30 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event of hypertension. The event of worsening of hypertension lasted for 146 days, after which it was considered to be recovered/resolved on 24 Feb 2021 (Study Day 175). The investigator assessed the event of hypertension to be not related to the IP.

On 03 Feb 2021 (Study Day 154), 153 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of septic shock. On 30 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event of hypertension. The event of septic shock lasted for 5 days, after which it was considered to be recovered/resolved on 07 Feb 2021 (Study Day 158). The investigator assessed the event of septic shock to be not related to the IP.

On 10 Feb 2021 (Study Day 161), 160 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of polyarteritis nodosa. On 30 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event of hypertension. The outcome of the event was unknown. The investigator assessed the event of polyarteritis nodosa to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-033666	Septic shock
MOD-2021-033666	Polyarteritis nodosa

Study Completion/Discontinuation

On 25 Feb 2021 (Study Day 176), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Alcohol abuse	Alcohol abuse	Not reported - Ongoing
Anxiety	Anxiety	Not reported - Ongoing
Cardiac failure chronic	Chronic heart failure	Not reported - Ongoing
Chlamydial infection	Chlamydia	Not reported
Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease	Not reported - Ongoing
Drug abuse	Cocaine abuse	Not reported - Ongoing
Gonococcal infection	Gonococcal infection	Not reported
Herpes simplex	Herpes simplex	Not reported
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Oedema peripheral	Peripheral edema	Not reported - Ongoing
Sleep apnoea syndrome	Obstructive sleep apnea	Not reported - Ongoing
Syphilis	Syphilis infection	Not reported
Uterine haemorrhage	Abnormal uterine bleeding	Not reported
Chronic hepatitis B	Chronic hepatitis b	1993 - Ongoing
Depression	Depression	1993 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	1993 - Ongoing
Headache	Headaches	1993 - Ongoing
Hepatic cirrhosis	Cirrhosis	1993 - Ongoing
Schizoaffective disorder	Schizo affective disorder	1993 - Ongoing
Uterine leiomyoma	Uterine fibroids	1993 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	20 Jun 1993 (Study Day -9937) - Ongoing
Caesarean section	Caesarean section	1995 - 1995
Knee operation	Knee surgery right	1995 - 1995
Female sterilisation	Tubal ligation	1997 - 1997
Joint dislocation	Patella dislocated right	1997 - 1997
Joint dislocation reduction	Reconstruction of dislocated patella right	1997 - 1997
Caesarean section	Cesarean section	21 Jan 1997 (Study Day -8626) - 21 Jan 1997 (Study Day -8626)
Obesity	Obesity	2010 - Ongoing
Menorrhagia	Menorrhagia	2012 - Sep 2014
Hysterectomy	Hysterectomy	Sep 2014 - Sep 2014

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	30 Jun 1993 (Study Day -9927) - 09 Sep 2020 (Study Day 7)	Hypertension
Amlodipine	09 Sep 2020 (Study Day 7) - 20 Oct 2020 (Study Day 48)	Hypertension
Amlodipine	21 Oct 2020 (Study Day 49) - Ongoing	Worsening Hypertension(Ae #1)
Losartan	21 Oct 2020 (Study Day 49) - Ongoing	Worsening Hypertension(Ae #1)
Acetylsalicylic acid	2021 - Ongoing	Sae#3 Polyarteritis Nodosa
Albumin nos	2021 - 2021	Acute Renal Failure
Amiodarone	2021 - 05 Feb 2021 (Study Day 156)	Atrial Fibrillation
Aripiprazole	2021 - Ongoing	Schizo Affective Disorder
Atorvastatin	2021 - Ongoing	Hyperlipidemia
Buspirone	2021 - Ongoing	Anxiety
Calcium chloride; potassium chloride; sodium lactate	2021 - Ongoing	Hydration
Carvedilol	2021 - Ongoing	Hypertension
Ceftriaxone	2021 - Ongoing	Sae#1(Septic Shock)
Chlorhexidine gluconate	2021 - Ongoing	Ae#10 (Left Dorsal Tongue Ulcerative Lesion)
Chlortalidone	2021 - Ongoing	Hypertension
Diclofenac	2021 - Ongoing	Pain
Diltiazem	2021 - Ongoing	Atrial Fibrillation
Duloxetine	2021 - Ongoing	Neuropathy Pain
Famotidine	2021 - Ongoing	Gerd
Fentanyl	2021 - Ongoing	Pain
Fluoxetine	2021 - Ongoing	Depression

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone	2021 - Ongoing	Chronic Obstructive Pulmonary Disease
Folic acid	2021 - Ongoing	Anemia
Furosemide	2021 - 07 Feb 2021 (Study Day 158)	Acute Renal Failure
Gabapentin	2021 - Ongoing	Neuropathy Pain
Gabapentin	2021 - Ongoing	Sae#3 (Polyarteritis Nodosa)
Hydrochlorothiazide; losartan potassium	2021 - Ongoing	Hypertension
Hydrocodone bitartrate; paracetamol	2021 - Ongoing	Sae#3 (Polyarteritis Nodosa)
Hydromorphone hydrochloride	2021 - Ongoing	Pain
Ipratropium bromide	2021 - Ongoing	Chronic Obstructive Pulmonary Disease
Ketorolac tromethamine	2021 - Ongoing	Pain
Lidocaine	2021 - Ongoing	Ae#10(Left Dorsal Tongue Ulcerative Lesion)
Lidocaine	2021 - Ongoing	Pain
Lorazepam	2021 - Ongoing	Anxiety
Macrogol	2021 - Ongoing	Constipation
Methocarbamol	2021 - Ongoing	Sae#3(Polyarteritis Nodosa)
Metoprolol	2021 - Ongoing	Hypertension
Norepinephrine bitartrate	2021 - Ongoing	Sae#1(Septic Shock)
Nystatin	2021 - Ongoing	Sae#3(Polyarteritis Nodosa)
Ondansetron	2021 - Ongoing	Nausea/Vomiting
Piperacillin	2021 - Ongoing	Sae#1 (Septic Shock)
Salbutamol	2021 - Ongoing	Chronic Obstructive Pulmonary Disease
Sennoside a+b	2021 - Ongoing	Constipation
Thiamine	2021 - Ongoing	Supplement
Tiotropium bromide	2021 - Ongoing	Chronic Obstructive Pulmonary Disease
Tramadol	2021 - Ongoing	Pain
Trazodone	2021 - Ongoing	Insomnia
Urea	2021 - Ongoing	Myxedema Of Hands
Vitamins nos	2021 - Ongoing	Supplement
Xr chest, 1 view*	03 Feb 2021 (Study Day 154) - 03 Feb 2021 (Study Day 154)	Adverse Event
Ct brain w/o iv contrast*	04 Feb 2021 (Study Day 155) - 04 Feb 2021 (Study Day 155)	Adverse Event
Xr left hand, 3 or more views*	04 Feb 2021 (Study Day 155) - 04 Feb 2021 (Study Day 155)	Adverse Event
Xr right hand, 3 or more views*	04 Feb 2021 (Study Day 155) - 04 Feb 2021 (Study Day 155)	Adverse Event
Ct abdomen/pelvis, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Ct cervical spine, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ct chest, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Ct lower extremity left, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Ct lower extremity right, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Ct lumbar spine, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Ct thoracic spine, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Ct upper extremity left, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Ct upper extremity right, w/o iv contrast*	05 Feb 2021 (Study Day 156) - 05 Feb 2021 (Study Day 156)	Adverse Event
Maxiillofacial ct, w/o iv contrast*	07 Feb 2021 (Study Day 158) - 07 Feb 2021 (Study Day 158)	Adverse Event
Xr chest 1 view*	07 Feb 2021 (Study Day 158) - 07 Feb 2021 (Study Day 158)	Adverse Event
Biopsy left dorsal tongue ulcerative lesion*	08 Feb 2021 (Study Day 159) - 08 Feb 2021 (Study Day 159)	Diagnostic
Lidocaine	08 Feb 2021 (Study Day 159) - 08 Feb 2021 (Study Day 159)	Tongue Lesion Biopsy
Us doppler venous dvt lower extremity bilateral*	08 Feb 2021 (Study Day 159) - 08 Feb 2021 (Study Day 159)	Adverse Event
Us doppler venous dvt upper extremity right*	08 Feb 2021 (Study Day 159) - 08 Feb 2021 (Study Day 159)	Adverse Event
Cefepime	10 Feb 2021 (Study Day 161) - Ongoing	Sae#1 Septic Shock
Vancomycin	10 Feb 2021 (Study Day 161) - Ongoing	Sae#1 Septic Shock
Xr chest 1 view*	10 Feb 2021 (Study Day 161) - 10 Feb 2021 (Study Day 161)	Adverse Event
Rivaroxaban	15 Feb 2021 (Study Day 166) - 17 Feb 2021 (Study Day 168)	Ae# 11 Uti
Enoxaparin sodium	17 Feb 2021 (Study Day 168) - Ongoing	Ae# 11 Uti
‘xr right ankle, 2 views’*	20 Feb 2021 (Study Day 171) - 20 Feb 2021 (Study Day 171)	Adverse Event
Xr left ankle, 2 views*	20 Feb 2021 (Study Day 171) - 20 Feb 2021 (Study Day 171)	Adverse Event
Xr right knee, 2 or less views*	20 Feb 2021 (Study Day 171) - 20 Feb 2021 (Study Day 171)	Adverse Event
Xr tibia fibula right, 2 views*	20 Feb 2021 (Study Day 171) - 20 Feb 2021 (Study Day 171)	Adverse Event
Xr chest, 1 view*	21 Feb 2021 (Study Day 172) - 21 Feb 2021 (Study Day 172)	Adverse Event
Fluconazole	22 Feb 2021 (Study Day 173) - 08 Mar 2021 (Study Day 187)	Ae#11(Urinary Tract Infection
Fluconazole	22 Feb 2021 (Study Day 173) - Ongoing	Unknown
Naproxen	24 Feb 2021 (Study Day 175) - Ongoing	Pain
Sulfamethoxazole; trimethoprim	24 Feb 2021 (Study Day 175) - 01 Mar 2021 (Study Day 180)	Ae#5 (Cystitis)
Entecavir	25 Feb 2021 (Study Day 176) - Ongoing	Hepatitis B

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Meropenem	25 Feb 2021 (Study Day 176) - 01 Mar 2021 (Study Day 180)	Ae#11 (Urinary Tract Infection)
Prednisone	03 Mar 2021 (Study Day 182) - 11 Mar 2021 (Study Day 190)	Sae#3 (Polyarteritis Nodosa)
Prednisone	12 Mar 2021 (Study Day 191) - 16 Mar 2021 (Study Day 195)	Sae#3 (Polyarteritis Nodosa)
Prednisone	17 Mar 2021 (Study Day 196) - Ongoing	Sae#3 (Polyarteritis Nodosa)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hypertension	Grade 2/moderate	Not related	02 Oct 2020 (Study Day 30) - 24 Feb 2021 (Study Day 175)
Tongue Ulceration	Grade 2/moderate	Not related	09 Jan 2021 (Study Day 129) - Ongoing
Cystitis	Grade 2/moderate	Not related	03 Feb 2021 (Study Day 154) - 01 Mar 2021 (Study Day 180)
Hyponatraemia	Grade 1/mild	Not related	03 Feb 2021 (Study Day 154) - 24 Feb 2021 (Study Day 175)
Left Ventricular Hypertrophy	Grade 3/severe	Not related	03 Feb 2021 (Study Day 154) - Ongoing
Normocytic Anaemia	Grade 2/moderate	Not related	03 Feb 2021 (Study Day 154) - Ongoing
Osteoarthritis	Grade 2/moderate	Not related	03 Feb 2021 (Study Day 154) - Ongoing
Thrombophlebitis Superficial	Grade 1/mild	Not related	08 Feb 2021 (Study Day 159) - Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	24 Feb 2021 (Study Day 175) - 01 Mar 2021 (Study Day 180)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2003 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Amnesia/Intermittent Memory Loss	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	09 Sep 2020 (Study Day 16) – 11 Sep 2020 (Study Day 18)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2003, a 72-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Sep 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of amnesia. On 21 Sep 2020 (Study Day 28), the IP dose was discontinued due to adverse event. The event of intermittent memory loss lasted for 3 days, after which it was considered to be recovered/resolved on 11 Sep 2020 (Study Day 18). The investigator assessed the event of amnesia to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hiatus hernia	Hiatal hernia	1962 - Ongoing
Drug hypersensitivity	Drug allergy - sulfa drugs	1980 - Ongoing
Drug hypersensitivity	Drug allergy -penicillin	1980 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephritis	Nephritis	1982 - 1982
Urinary tract infection	Urinary tract infection	1986 - 1986
Breast cancer	Breast cancer	2004 - 2004
Mitral valve incompetence	Mitral valve insufficieny	2004 - Ongoing
Postmenopause	Post-menopausal	2004 - Ongoing
Migraine	Migraines (light and noise)	2007 - Ongoing
Nausea	Nausea	2015 - Ongoing
Photopsia	Flashing lights in eyes bilateral	2019 - Ongoing
Sinus node dysfunction	Sick sinus syndrome	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Calcium citrate; vitamin d nos	2018 - Ongoing	Nutritional Supplement
Vitamin d nos	01 Jan 2021 (Study Day 130) - Ongoing	Nutritional Supplement
Ciprofloxacin	17 Mar 2021 (Study Day 205) - 24 Mar 2021 (Study Day 212)	Urinary Tract Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Amnesia	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 16) - 11 Sep 2020 (Study Day 18)
Fatigue	Grade 1/mild	Related	09 Sep 2020 (Study Day 16) - 20 Sep 2020 (Study Day 27)
Nausea	Grade 2/moderate	Related	09 Sep 2020 (Study Day 16) - 20 Sep 2020 (Study Day 27)
Pyrexia	Grade 1/mild	Related	09 Sep 2020 (Study Day 16) - 16 Sep 2020 (Study Day 23)
Arthralgia	Grade 2/moderate	Not related	29 Oct 2020 (Study Day 66) - 20 Nov 2020 (Study Day 88)
Photopsia	Grade 1/mild	Not related	23 Dec 2020 (Study Day 121) - Ongoing
Urinary Tract Infection	Grade 2/moderate	Not related	17 Mar 2021 (Study Day 205) - 24 Mar 2021 (Study Day 212)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2005 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	21 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Hiatus Hernia/Hiatal Hernia	SAE	Grade 3/severe	Not related	20 Oct 2020 (Study Day 57) – 22 Oct 2020 (Study Day 59)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2005, a 79-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 21 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Oct 2020 (Study Day 57), 56 days after the first dose and 29 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of hiatus hernia. Action taken with the IP was not applicable. The event of hiatal hernia lasted for 3 days, after which it was considered to be recovered/resolved with sequelae on 22 Oct 2020 (Study Day 59). The investigator assessed the event of hiatus hernia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000552	Hiatus hernia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Blood cholesterol increased	High cholesterol	Not reported - Ongoing
Constipation	Chronic constipation	Not reported - Ongoing
Deafness	Hearing loss	Not reported - Ongoing
Depression	Depression	Not reported - Ongoing
Diarrhoea	Diarrhea - intermittent	Not reported - Ongoing
Dyshidrotic eczema	Dyshydrosis	Not reported - Ongoing
Herpes zoster	Shingles	Not reported
Hypertension	High blood pressure	Not reported - Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing
Osteoporosis	Osteoporosis	Not reported - Ongoing
Urinary incontinence	Incontinence - urinary	Not reported - Ongoing
Type 2 diabetes mellitus	Diabetes type ii	1960 - Ongoing
Hysterectomy	Hysterectomy	1969 - 1969
Cholelithiasis	Gallstones	1976 - 1976
Carpal tunnel syndrome	Carpal tunnel right hand	2015 - Ongoing
Dry eye	Dry eyes	2017 - Ongoing
Gastrooesophageal reflux disease	Gerd	2018 - Ongoing
Osteoarthritis	Osteoarthritis right thumb	21 Jan 2020 (Study Day -217) - Ongoing
Dyshidrotic eczema	Dyshyrodrotic eczema b/l hands	May 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2005 - Ongoing	Hypertension
Duloxetine	2007 - Ongoing	Depression
Insulin glargine	2010 - Ongoing	Diabetes Type 2
Insulin lispro	2010 - Ongoing	Diabetes Type 2
Calcium	2013 - Ongoing	Nutritional Supplement
Colecalciferol	2013 - Ongoing	Nutritional Supplement
Vitamin e nos	2013 - Ongoing	Nutritional Supplement
Omeprazole	2015 - 09 Oct 2020 (Study Day 46)	Gerd
Alendronate sodium	2017 - Ongoing	Osteoporosis
Atorvastatin	2017 - Ongoing	Dyslipidemia
Carmellose sodium	2017 - Ongoing	Dry Eye
Metoprolol	2017 - Ongoing	Hypertension
Acetylsalicylic acid	2018 - Ongoing	Cardiac Protection
Levothyroxine sodium	2018 - Ongoing	Hypothyroidism
Oxybutynin	2019 - Ongoing	Incontinence - Urinary
Colestipol	Mar 2020 - Ongoing	Dyslipidemia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Hydrocortisone	May 2020 - 15 Nov 2020 (Study Day 83)	Dyshydrotic Eczema B/L Hands
Ranitidine	07 Sep 2020 (Study Day 14) - Ongoing	Gerd
Paracetamol	14 Sep 2020 (Study Day 21) - 15 Sep 2020 (Study Day 22)	Right Hip Joint Ache
Omeprazole	09 Oct 2020 (Study Day 46) - 20 Oct 2020 (Study Day 57)	Gerd
Bisacodyl	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Constipation
Ct neck without contrast*	20 Oct 2020 (Study Day 57) - 20 Oct 2020 (Study Day 57)	Adverse Event
Ct scan thorax without contrast*	20 Oct 2020 (Study Day 57) - 20 Oct 2020 (Study Day 57)	Adverse Event
Electrocardiogram*	20 Oct 2020 (Study Day 57) - 20 Oct 2020 (Study Day 57)	Adverse Event
Glucose	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Diabetes Mellitus Ii
Morphine	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Hiatal Hernia
Ondansetron	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Nausea/Vomiting
Pantoprazole	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Gerd
Paracetamol	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Hiatal Hernia
Promethazine	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Vomiting Secondary To Hiatal Hernia
Sodium chloride	20 Oct 2020 (Study Day 57) - 22 Oct 2020 (Study Day 59)	Hiatal Hernia
Chest x-ray*	21 Oct 2020 (Study Day 58) - 21 Oct 2020 (Study Day 58)	Adverse Event
Upper gi endoscopy*	21 Oct 2020 (Study Day 58) - 21 Oct 2020 (Study Day 58)	Adverse Event
Acetylsalicylic acid	19 Jan 2021 (Study Day 148) - 20 Jan 2021 (Study Day 149)	Bruised Knees Due To Fall
Paracetamol	20 Jan 2021 (Study Day 149) - 20 Jan 2021 (Study Day 149)	Bruised Knees Due To Fall
Paracetamol	04 Mar 2021 (Study Day 192) - 04 Mar 2021 (Study Day 192)	Injection Site Pain
Right hand x-ray*	08 Mar 2021 (Study Day 196) - 08 Mar 2021 (Study Day 196)	Adverse Event
Surgery on right eye tear duct*	11 Mar 2021 (Study Day 199) - 11 Mar 2021 (Study Day 199)	Adverse Event
Neomycin; polymyxin b	13 Mar 2021 (Study Day 201) - Ongoing	Nasolacrimal Stenosis Of Right Eye

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Injection Site Pain	Grade 1/mild	Related	01 Sep 2020 (Study Day 8) - 06 Sep 2020 (Study Day 13)
Gastrooesophageal Reflux Disease	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 14) - 17 Oct 2020 (Study Day 54)
Vomiting	Grade 1/mild	Not related	12 Sep 2020 (Study Day 19) - 14 Sep 2020 (Study Day 21)
Arthralgia	Grade 1/mild	Not related	14 Sep 2020 (Study Day 21) - 15 Sep 2020 (Study Day 22)
Dysphagia	Grade 2/moderate	Not related	01 Oct 2020 (Study Day 38) - 22 Oct 2020 (Study Day 59)
Nausea	Grade 2/moderate	Not related	01 Oct 2020 (Study Day 38) - 22 Oct 2020 (Study Day 59)
Vomiting	Grade 2/moderate	Not related	01 Oct 2020 (Study Day 38) - 22 Oct 2020 (Study Day 59)
Weight Decreased	Grade 1/mild	Not related	01 Oct 2020 (Study Day 38) - 31 Oct 2020 (Study Day 68)
Vomiting	Grade 1/mild	Not related	09 Oct 2020 (Study Day 46) - 17 Oct 2020 (Study Day 54)
Dehydration	Grade 2/moderate	Not related	20 Oct 2020 (Study Day 57) - 20 Oct 2020 (Study Day 57)
Dacryostenosis Acquired	Grade 2/moderate	Not related	18 Feb 2021 (Study Day 178) - Ongoing
Fall	Grade 2/moderate	Not related	06 Mar 2021 (Study Day 194) - 06 Mar 2021 (Study Day 194)
Peripheral Swelling	Grade 2/moderate	Not related	06 Mar 2021 (Study Day 194) - 01 Apr 2021 (Study Day 220)
Glaucoma	Grade 2/moderate	Not related	24 Mar 2021 (Study Day 212) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2018 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 28)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Drug Withdrawal Syndrome/Suboxone Withdrawal	SAE	Grade 3/severe	Not related	04 Jan 2021 (Study Day 130) – 18 Mar 2021 (Study Day 203)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2018, a 47-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 28). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Jan 2021 (Study Day 130), 129 days after the first dose and 102 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of drug withdrawal syndrome. Action taken with the IP was not applicable. The event of suboxone withdrawal lasted for 74 days, after which it was considered to be recovered/resolved on 18 Mar 2021 (Study Day 203). The investigator assessed the event of drug withdrawal syndrome to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005904	Drug withdrawal syndrome

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug abuse	Drug abuse	1995 - 2015
Ex-drug abuser	Ex heroin user	1995 - 2015
Anxiety	Anxiety	2000 - Ongoing
Depression	Depression	2000 - Ongoing
Gastrooesophageal reflux disease	Gerd	2005 - Ongoing
Arthralgia	Knee pain	2012 - Ongoing
Back pain	Back pain	2012 - Ongoing
Myalgia	Muscle aches	2012 - Ongoing
Neuralgia	Neuropathy related to back pain	2012 - Ongoing
Pain in extremity	Leg pain	2012 - Ongoing
Hepatitis C	Hepatitis c	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2012 - Ongoing	Gerd
Gabapentin	2017 - Ongoing	Neuropathy Related To Back Pain
Ibuprofen	2017 - Ongoing	Back/ Knee Pain
Buprenorphine hydrochloride; naloxone hydrochloride	Jul 2020 - Jan 2021	Opioid Dependence
Cefalexin	13 Oct 2020 (Study Day 47) - 09 Nov 2020 (Study Day 74)	Rash On Bilateral Legs Urticaria
Gi cocktail	27 Oct 2020 (Study Day 61) - 27 Oct 2020 (Study Day 61)	Abdominal Pain
Ondansetron	27 Oct 2020 (Study Day 61) - 27 Oct 2020 (Study Day 61)	Abdominal Pain
Pantoprazole	27 Oct 2020 (Study Day 61) - 27 Oct 2020 (Study Day 61)	Abdominal Pain
Aluminium hydroxide; magnesium hydroxide	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Suboxone Withdrawal
Baclofen	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Suboxone Withdrawal
Dicycloverine	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Suboxone Withdrawal
Folic acid	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Nutritional Supplement
Hydroxyzine embonate	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Anxiety

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Suboxone Withdrawal
Paracetamol	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Neuropathy Pain
Thiamine	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Nutritional Supplement
Vitamins nos	05 Mar 2021 (Study Day 190) - 15 Mar 2021 (Study Day 200)	Nutritional Supplement
Olanzapine	15 Mar 2021 (Study Day 200) - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	28 Aug 2020 (Study Day 1) - 23 Sep 2020 (Study Day 27)
Fatigue	Grade 1/mild	Related	28 Aug 2020 (Study Day 1) - 05 Sep 2020 (Study Day 9)
Arthralgia	Grade 1/mild	Related	24 Sep 2020 (Study Day 28) - 06 Oct 2020 (Study Day 40)
Myalgia	Grade 1/mild	Related	24 Sep 2020 (Study Day 28) - 06 Oct 2020 (Study Day 40)
Fatigue	Grade 1/mild	Related	24 Sep 2020 (Study Day 28) - 06 Oct 2020 (Study Day 40)
Urticaria	Grade 2/moderate	Not related	10 Oct 2020 (Study Day 44) - 24 Oct 2020 (Study Day 58)
Abdominal Pain	Grade 2/moderate	Not related	26 Oct 2020 (Study Day 60) - 28 Oct 2020 (Study Day 62)
Insomnia	Grade 2/moderate	Not related	05 Jan 2021 (Study Day 131) - Ongoing
Abscess Limb	Grade 2/moderate	Not related	08 Feb 2021 (Study Day 165) - 08 Mar 2021 (Study Day 193)
Dry Skin	Grade 1/mild	Not related	15 Feb 2021 (Study Day 172) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2051 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	01 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	05 Oct 2020 (Study Day 35)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 4	Not related	19 Nov 2020 (Study Day 80) – 23 Dec 2020 (Study Day 114)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2051, a 57-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 01 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 05 Oct 2020 (Study Day 35). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Nov 2020 (Study Day 80), 79 days after the first dose and 45 days after the second dose of the IP, the participant experienced a Grade 4 serious adverse event of pneumonia. Action taken with the IP was not applicable. The event of pneumonia lasted for 35 days, after which it was considered to be recovered/resolved on 23 Dec 2020 (Study Day 114). The investigator assessed the event of pneumonia to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000982	Pneumonia

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nephrolithiasis	Kidney stones	2007 - 2007
Hypertension	Hypertension	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2013 - Ongoing	Hypertension
Vitamins nos	2014 - Ongoing	Nutritional Supplement
Ascorbic acid	Jun 2020 - Ongoing	Nutritional Supplement
Omeprazole	03 Sep 2020 (Study Day 3) - 19 Nov 2020 (Study Day 80)	Acid Indigestion
Amoxicillin	19 Nov 2020 (Study Day 80) - 24 Nov 2020 (Study Day 85)	Pneumonia
Azithromycin	19 Nov 2020 (Study Day 80) - 23 Nov 2020 (Study Day 84)	Pneumonia
Computerized tomography of chest*	20 Nov 2020 (Study Day 81) - 20 Nov 2020 (Study Day 81)	Adverse Event
Levofloxacin	23 Nov 2020 (Study Day 84) - 14 Dec 2020 (Study Day 105)	Pneumonia
Levofloxacin	23 Nov 2020 (Study Day 84) - 14 Dec 2020 (Study Day 105)	Valley Fever
Fluconazole	24 Dec 2020 (Study Day 115) - Ongoing	Valley Fever
Branch retinal vein occlusion with retinal neovascularization*	05 Jan 2021 (Study Day 127) - 05 Jan 2021 (Study Day 127)	Adverse Event
Endoscopy*	12 Feb 2021 (Study Day 165) - 12 Feb 2021 (Study Day 165)	Adverse Event
Omeprazole	23 Feb 2021 (Study Day 176) - Ongoing	Acid Indigestion
Bismuth subsalicylate	16 Mar 2021 (Study Day 197) - Ongoing	H. Pylori Infection
Doxycycline	16 Mar 2021 (Study Day 197) - Ongoing	H. Pylori Infection
Metronidazole	16 Mar 2021 (Study Day 197) - Ongoing	H. Pylori Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Dyspepsia	Grade 2/moderate	Not related	03 Sep 2020 (Study Day 3) - 19 Nov 2020 (Study Day 80)
Mass	Grade 2/moderate	Not related	19 Nov 2020 (Study Day 80) - Ongoing
Coccidioidomycosis	Grade 2/moderate	Not related	12 Dec 2020 (Study Day 103) - Ongoing
Eye Haemorrhage	Grade 2/moderate	Not related	05 Jan 2021 (Study Day 127) - 12 Jan 2021 (Study Day 134)
Helicobacter Gastritis	Grade 2/moderate	Not related	12 Feb 2021 (Study Day 165) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2077 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastritis/Gastritis	SAE	Grade 3/severe	Not related	06 Nov 2020 (Study Day 64) – Ongoing	Not recovered/ not resolved
Nausea/Intermittent Nausea	SAE	Grade 3/severe	Not related	06 Nov 2020 (Study Day 64) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2077, a 29-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 04 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Nov 2020 (Study Day 64), 63 days after the first dose and 35 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of gastritis. Action taken with the IP was not applicable. The event of gastritis was considered to be ongoing. The investigator assessed the event of gastritis to be not related to the IP.

On 06 Nov 2020 (Study Day 64), 63 days after the first dose and 35 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of nausea. Action taken with the IP was not applicable. The event of intermittent nausea was considered to be ongoing. The investigator assessed the event of nausea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000774	Gastritis
MOD-2020-000774	Nausea

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicectomy	Appendectomy	1994 - 1994
Appendicitis	Appendicitis	1994 - 1994
Aspiration pleural cavity	Right thoracentesis	2008 - 2008
Pneumonia	Pneumonia	2008 - 2008
Fibula fracture	Broken fibula	Nov 2019 - Nov 2019
Fibula fracture	Broken tibula	Nov 2019 - Nov 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	04 Sep 2020 (Study Day 1) - 04 Oct 2020 (Study Day 31)	Injection Site Pain
Paracetamol	05 Sep 2020 (Study Day 2) - 05 Sep 2020 (Study Day 2)	Pain At Injection Site
Melatonin	Oct 2020 - Ongoing	Nutritional Supplement
Paracetamol	03 Oct 2020 (Study Day 30) - 05 Oct 2020 (Study Day 32)	Headache, Body Aches, Fever
Gamma-aminobutyric acid; theanine	14 Oct 2020 (Study Day 41) - Ongoing	Anxiety
Vitamins nos	17 Oct 2020 (Study Day 44) - Ongoing	Vitamin Supplement
Bismuth subsalicylate	07 Nov 2020 (Study Day 65) - 09 Nov 2020 (Study Day 67)	Intermittent Nausea
Dicycloverine hydrochloride	11 Nov 2020 (Study Day 69) - 12 Nov 2020 (Study Day 70)	Nausea
Morphine	11 Nov 2020 (Study Day 69) - 12 Nov 2020 (Study Day 70)	Gastric Pain
Ondansetron	11 Nov 2020 (Study Day 69) - 12 Nov 2020 (Study Day 70)	Gastritis
Oxycodone hydrochloride; paracetamol	11 Nov 2020 (Study Day 69) - 12 Nov 2020 (Study Day 70)	Gastritis Stomach Pain
Pantoprazole sodium sesquihydrate	11 Nov 2020 (Study Day 69) - 12 Nov 2020 (Study Day 70)	Gastritis
Right upper quadrant ultrasound*	11 Nov 2020 (Study Day 69) - 11 Nov 2020 (Study Day 69)	Adverse Event
Upper gastric body biopsies*	12 Nov 2020 (Study Day 70) - 12 Nov 2020 (Study Day 70)	Adverse Event
Upper gi endoscopy*	12 Nov 2020 (Study Day 70) - 12 Nov 2020 (Study Day 70)	Adverse Event
Dicycloverine	13 Nov 2020 (Study Day 71) - 19 Dec 2020 (Study Day 107)	Gastritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole	13 Nov 2020 (Study Day 71) - 19 Dec 2020 (Study Day 107)	Gastritis
Sucralfate	13 Nov 2020 (Study Day 71) - 19 Dec 2020 (Study Day 107)	Gastritis
Ondansetron	15 Nov 2020 (Study Day 73) - Ongoing	Nausea
Promethazine	15 Nov 2020 (Study Day 73) - Ongoing	Nausea
Ascorbic acid	17 Nov 2020 (Study Day 75) - Ongoing	Nutritional Supplement
Colecalciferol	17 Nov 2020 (Study Day 75) - Ongoing	Nutritional Supplement
Folic acid; pyridoxine hydrochloride; vitamin b12 nos	17 Nov 2020 (Study Day 75) - Ongoing	Nutritional Supplement
Oxycodone hydrochloride; paracetamol	05 Jan 2021 (Study Day 124) - Ongoing	Leg Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Anxiety	Grade 2/moderate	Not related	14 Oct 2020 (Study Day 41) - Ongoing
Pain In Extremity	Grade 2/moderate	Not related	05 Jan 2021 (Study Day 124) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2151 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	23 Oct 2020 (Study Day 37)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Depression/Worsening Depression	SAE	Grade 3/ severe	Not related	08 Jan 2021 (Study Day 114) – 02 Feb 2021 (Study Day 139)	Recovered/resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2151, a 19-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 23 Oct 2020 (Study Day 37). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Jan 2021 (Study Day 114), 113 days after the first dose and 77 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of depression. Action taken with the IP was not applicable. The event of worsening depression lasted for 26 days, after which it was considered to be recovered/resolved with sequelae on 02 Feb 2021 (Study Day 139). The investigator assessed the event of depression to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-005624	Depression

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Acne	Acne	2013 - Ongoing
Bipolar disorder	Bipolar disorder	2013 - Ongoing
Depression	Depression	2013 - Ongoing
Insomnia	Insomnia	2013 - Ongoing
Anxiety	Anxiety	2015 - Ongoing
Headache	Headache	2019 - Ongoing
Myalgia	Muscle ache	Apr 2020 - Ongoing
Seasonal allergy	Seasonal allergies	Jun 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Melatonin	2018 - Sep 2020	Insomnia
Diphenhydramine	Sep 2020 - 06 Oct 2020 (Study Day 20)	Worsening Insomnia
Ibuprofen	Sep 2020 - Ongoing	Muscle Aches
Melatonin	Sep 2020 - 06 Oct 2020 (Study Day 20)	Insomnia
Fluoxetine	06 Oct 2020 (Study Day 20) - 15 Oct 2020 (Study Day 29)	Depression
Hydroxyzine	06 Oct 2020 (Study Day 20) - 05 Nov 2020 (Study Day 50)	Anxiety
Fluoxetine	16 Oct 2020 (Study Day 30) - 07 Jan 2021 (Study Day 113)	Depression
Ibuprofen	24 Oct 2020 (Study Day 38) - 29 Oct 2020 (Study Day 43)	Worsening Headache
Trazodone	27 Oct 2020 (Study Day 41) - 07 Jan 2021 (Study Day 113)	Depression
Fish oil	24 Nov 2020 (Study Day 69) - Ongoing	Supplement
Vitamins nos	24 Nov 2020 (Study Day 69) - Ongoing	Supplement
Fluoxetine	08 Jan 2021 (Study Day 114) - Ongoing	Worsening Depression
Olanzapine	08 Jan 2021 (Study Day 114) - 20 Feb 2021 (Study Day 157)	Worsening Depression
Trazodone	08 Jan 2021 (Study Day 114) - Ongoing	Worsening Depression
Chemistry panel*	09 Jan 2021 (Study Day 115) - 09 Jan 2021 (Study Day 115)	Adverse Event
Hematology*	09 Jan 2021 (Study Day 115) - 09 Jan 2021 (Study Day 115)	Adverse Event
Lipid panel*	09 Jan 2021 (Study Day 115) - 09 Jan 2021 (Study Day 115)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Urinalysis*	09 Jan 2021 (Study Day 115) - 09 Jan 2021 (Study Day 115)	Adverse Event
Cbc*	11 Jan 2021 (Study Day 117) - 11 Jan 2021 (Study Day 117)	Adverse Event
Olanzapine	13 Jan 2021 (Study Day 119) - 23 Jan 2021 (Study Day 129)	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US395-2033 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, Severe COVID-19, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Gastritis/Gastritis W/ Intractable Vomiting	SAE	Grade 3/severe	Not related	23 Sep 2020 (Study Day 22) – 30 Sep 2020 (Study Day 29)	Recovered/resolved
COVID-19/COVID-19 Infection	COVID-19, AE leading to withdrawal from study vaccine	Grade 3/severe	Not related	06 Oct 2020 (Study Day 35) – 25 Oct 2020 (Study Day 54)	Recovered/resolved
Pericarditis/Pericarditis	SAE	Grade 3/severe	Not related	31 Oct 2020 (Study Day 60) – 03 Nov 2020 (Study Day 63)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0. The severity was based on investigator assessment, but severe COVID-19 narratives were adjudicated as severe by the adjudication committee.

Participant US395-2033, a 52-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Sep 2020 (Study Day 22), 21 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of gastritis. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of gastritis w/ intractable vomiting lasted for 8 days, after which it was considered to be recovered/resolved on 30 Sep 2020 (Study Day 29). The investigator assessed the event of gastritis to be not related to the IP.

On 31 Oct 2020 (Study Day 60), 59 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe serious adverse event of pericarditis. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of pericarditis lasted for 4 days, after which it was considered to be recovered/resolved on 03 Nov 2020 (Study Day 63). The investigator assessed the event of pericarditis to be not related to the IP.

Severe COVID-19 Details

On 06 Oct 2020 (Study Day 35), 34 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/Severe non-serious adverse event of COVID-19 infection.

On Study Day 1, a nasal swab tested by RT-PCR was negative for SARS-CoV-2.

On 08 Oct 2020 (Study Day 37), the participant was tested for SARS-CoV-2 with the following results: Coronavirus SARS-CoV-2 RT-PCR (Study Qualitative): positive.

The participant experienced the following symptoms:

COVID-19 Symptom Log:

Symptom Date	Symptom	Result
03 Oct 2020 (Study Day 32)	Body Aches	Mild
03 Oct 2020 (Study Day 32)	Headache	Mild
03 Oct 2020 (Study Day 32)	Temperature (°F)	101.3
04 Oct 2020 (Study Day 33)	Body Aches	Mild
04 Oct 2020 (Study Day 33)	Muscle Aches (Myalgia)	Mild
07 Oct 2020 (Study Day 36)	Temperature (°F)	101.9
08 Oct 2020 (Study Day 37)	Body Aches	Mild
08 Oct 2020 (Study Day 37)	Cough	Mild
08 Oct 2020 (Study Day 37)	Difficulty Breathing	Mild
08 Oct 2020 (Study Day 37)	Fatigue	Mild
08 Oct 2020 (Study Day 37)	Headache	Mild
08 Oct 2020 (Study Day 37)	Muscle Aches (Myalgia)	Mild
08 Oct 2020 (Study Day 37)	New Loss of Smell	Mild
08 Oct 2020 (Study Day 37)	New Loss of Taste	Mild
08 Oct 2020 (Study Day 37)	Shortness of Breath	Mild
08 Oct 2020 (Study Day 37)	Sore Throat	Mild
08 Oct 2020 (Study Day 37)	Temperature (°F)	102.2
09 Oct 2020 (Study Day 38)	Chills	Moderate
09 Oct 2020 (Study Day 38)	Cough	Moderate
09 Oct 2020 (Study Day 38)	Difficulty Breathing	Severe
09 Oct 2020 (Study Day 38)	Fatigue	Severe
09 Oct 2020 (Study Day 38)	Headache	Mild
09 Oct 2020 (Study Day 38)	Nausea	Mild
09 Oct 2020 (Study Day 38)	New Loss of Smell	Mild
09 Oct 2020 (Study Day 38)	New Loss of Taste	Mild
09 Oct 2020 (Study Day 38)	O2 Saturation (%)	92
09 Oct 2020 (Study Day 38)	Shortness of Breath	Severe
09 Oct 2020 (Study Day 38)	Sore Throat	Mild
09 Oct 2020 (Study Day 38)	Temperature (°F)	103.1
10 Oct 2020 (Study Day 39)	Chills	Mild
10 Oct 2020 (Study Day 39)	Cough	Mild

Symptom Date	Symptom	Result
10 Oct 2020 (Study Day 39)	Fatigue	Moderate
10 Oct 2020 (Study Day 39)	Headache	Moderate
10 Oct 2020 (Study Day 39)	New Loss of Smell	Mild
10 Oct 2020 (Study Day 39)	New Loss of Taste	Mild
10 Oct 2020 (Study Day 39)	O2 Saturation (%)	93
10 Oct 2020 (Study Day 39)	Shortness of Breath	Moderate
10 Oct 2020 (Study Day 39)	Temperature (°F)	103.7
11 Oct 2020 (Study Day 40)	Chills	Moderate
11 Oct 2020 (Study Day 40)	Cough	Moderate
11 Oct 2020 (Study Day 40)	Difficulty Breathing	Severe
11 Oct 2020 (Study Day 40)	Fatigue	Severe
11 Oct 2020 (Study Day 40)	Headache	Severe
11 Oct 2020 (Study Day 40)	Nausea	Mild
11 Oct 2020 (Study Day 40)	New Loss of Smell	Moderate
11 Oct 2020 (Study Day 40)	New Loss of Taste	Moderate
11 Oct 2020 (Study Day 40)	O2 Saturation (%)	89
11 Oct 2020 (Study Day 40)	Shortness of Breath	Severe
11 Oct 2020 (Study Day 40)	Temperature (°F)	101.9
12 Oct 2020 (Study Day 41)	Chills	Mild
12 Oct 2020 (Study Day 41)	Cough	Mild
12 Oct 2020 (Study Day 41)	Fatigue	Mild
12 Oct 2020 (Study Day 41)	Headache	Moderate
12 Oct 2020 (Study Day 41)	Nausea	Moderate
12 Oct 2020 (Study Day 41)	New Loss of Smell	Mild
12 Oct 2020 (Study Day 41)	New Loss of Taste	Mild
12 Oct 2020 (Study Day 41)	Shortness of Breath	Mild
12 Oct 2020 (Study Day 41)	Temperature (°F)	102.7
12 Oct 2020 (Study Day 41)	Vomiting	Moderate
13 Oct 2020 (Study Day 42)	Chills	Mild
13 Oct 2020 (Study Day 42)	Cough	Moderate
13 Oct 2020 (Study Day 42)	Fatigue	Moderate
13 Oct 2020 (Study Day 42)	Headache	Mild
13 Oct 2020 (Study Day 42)	Nausea	Mild
13 Oct 2020 (Study Day 42)	New Loss of Smell	Mild
13 Oct 2020 (Study Day 42)	New Loss of Taste	Mild
13 Oct 2020 (Study Day 42)	Shortness of Breath	Mild
13 Oct 2020 (Study Day 42)	Temperature (°F)	102.1
14 Oct 2020 (Study Day 43)	Cough	Mild
14 Oct 2020 (Study Day 43)	Diarrhea	Mild
14 Oct 2020 (Study Day 43)	Fatigue	Moderate
14 Oct 2020 (Study Day 43)	Headache	Mild
14 Oct 2020 (Study Day 43)	Nausea	Mild
14 Oct 2020 (Study Day 43)	New Loss of Smell	Mild

Symptom Date	Symptom	Result
14 Oct 2020 (Study Day 43)	New Loss of Taste	Mild
14 Oct 2020 (Study Day 43)	Shortness of Breath	Mild
15 Oct 2020 (Study Day 44)	Chills	Mild
15 Oct 2020 (Study Day 44)	Cough	Mild
15 Oct 2020 (Study Day 44)	Fatigue	Moderate
15 Oct 2020 (Study Day 44)	Nausea	Mild
15 Oct 2020 (Study Day 44)	New Loss of Smell	Mild
15 Oct 2020 (Study Day 44)	New Loss of Taste	Mild
16 Oct 2020 (Study Day 45)	Chills	Mild
16 Oct 2020 (Study Day 45)	Cough	Mild
16 Oct 2020 (Study Day 45)	Diarrhea	Mild
16 Oct 2020 (Study Day 45)	Fatigue	Moderate
16 Oct 2020 (Study Day 45)	Headache	Mild
16 Oct 2020 (Study Day 45)	Nausea	Mild
16 Oct 2020 (Study Day 45)	Shortness of Breath	Mild
17 Oct 2020 (Study Day 46)	Cough	Mild
17 Oct 2020 (Study Day 46)	Diarrhea	Mild
17 Oct 2020 (Study Day 46)	Fatigue	Moderate
17 Oct 2020 (Study Day 46)	Nausea	Mild
18 Oct 2020 (Study Day 47)	Cough	Mild
18 Oct 2020 (Study Day 47)	Diarrhea	Mild
18 Oct 2020 (Study Day 47)	Fatigue	Moderate
18 Oct 2020 (Study Day 47)	Nausea	Mild
19 Oct 2020 (Study Day 48)	Cough	Mild
19 Oct 2020 (Study Day 48)	Diarrhea	Mild
19 Oct 2020 (Study Day 48)	Fatigue	Moderate
19 Oct 2020 (Study Day 48)	Nausea	Mild
20 Oct 2020 (Study Day 49)	Cough	Mild
20 Oct 2020 (Study Day 49)	Diarrhea	Mild
20 Oct 2020 (Study Day 49)	Fatigue	Mild
20 Oct 2020 (Study Day 49)	Nausea	Mild
21 Oct 2020 (Study Day 50)	Cough	Mild
21 Oct 2020 (Study Day 50)	Fatigue	Mild
22 Oct 2020 (Study Day 51)	Fatigue	Mild
22 Oct 2020 (Study Day 51)	Nausea	Mild
23 Oct 2020 (Study Day 52)	Diarrhea	Mild
23 Oct 2020 (Study Day 52)	Fatigue	Mild
24 Oct 2020 (Study Day 53)	Diarrhea	Mild
24 Oct 2020 (Study Day 53)	Fatigue	Mild

The participant had the following indications of severe COVID-19 infection:

Severe COVID-19 Indication Log:

Dates	Severity Indication	Result
09 Oct 2020 (Study Day 38)	Oxygen Saturation	89%
09 Oct 2020 - 11 Oct 2020 (Study Day 38-40)	Oxygen Saturation of SpO2 ≤ 93% on room air at sea level	Yes

On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 infection lasted for 20 days, after which it was considered to be recovered/resolved on 25 Oct 2020 (Study Day 54). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious and nonserious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000371	Gastritis
MOD-2020-000994	COVID-19
MOD-2020-000643	Pericarditis

Study Completion/Discontinuation

On 20 Jan 2021 (Study Day 141), the participant discontinued from the study due to physician decision (not medically stable to proceed to open label vaccine. will get outside eua leading to withdraw).

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Herpes simplex	Herpes simplex I	1976 - Ongoing
Chronic sinusitis	Chronic sinusitis	1992 - Ongoing
Osteoarthritis	Osteoarthritis	1995 - Ongoing
Depression	Depression	1996 - Ongoing
Ankle arthroplasty	Left ankle reconstruction	2000 - 2000
Obesity	Severe obesity	2005 - Ongoing
Rheumatoid arthritis	Rheumatoid arthritis	2006 - Ongoing
Hysterectomy	Hysterectomy	2009 - 2009
Uterine leiomyoma	Uterine fibroids	2009 - 2009
Anxiety	Anxiety	2010 - Ongoing
Antiphospholipid syndrome	Antiphospholipid syndrome	2011 - Ongoing
Knee arthroplasty	Right total knee arthroplasty	2011 - 2011

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pain	Chronic pain syndrome	2014 - Ongoing
Knee arthroplasty	Left total knee arthroplasty	2015 - 2015
Rheumatoid arthritis	Rhuematoid arthritis flare	Mar 2020 - Apr 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paroxetine hydrochloride	1996 - 03 Oct 2020 (Study Day 32)	Depression
Fondaparinux sodium	2011 - Ongoing	Antiphospholipid Syndrome
Hydrocodone bitartrate; paracetamol	2014 - Ongoing	Chronic Pain Syndrome
Oxycodone	2014 - Ongoing	Chronic Pain Syndrome
Melatonin	08 Jun 2020 (Study Day -86) - Ongoing	Insomnia
Abatacept	10 Jun 2020 (Study Day -84) - Ongoing	Rheumatoid Arthritis
Barium sulfate	05 Aug 2020 (Study Day -28) - 03 Nov 2020 (Study Day 63)	Imaging (Barium Swallow)
Paracetamol	05 Sep 2020 (Study Day 4) - 12 Sep 2020 (Study Day 11)	Myalgia
Paracetamol	06 Sep 2020 (Study Day 5) - 12 Sep 2020 (Study Day 11)	COVID 19
Aciclovir	08 Sep 2020 (Study Day 7) - 14 Sep 2020 (Study Day 13)	Herpes Simplex I
Ondansetron	11 Sep 2020 (Study Day 10) - 11 Oct 2020 (Study Day 40)	Nausea
Fluoxetine	23 Sep 2020 (Study Day 22) - Ongoing	Depression
Gluconate sodium; magnesium chloride hexahydrate; potassium chloride; sodium acetate trihydrate; sodium chloride	23 Sep 2020 (Study Day 22) - 23 Sep 2020 (Study Day 22)	Gastritis
Morphine	23 Sep 2020 (Study Day 22) - 24 Sep 2020 (Study Day 23)	Gastritis
Ondansetron	23 Sep 2020 (Study Day 22) - 23 Sep 2020 (Study Day 22)	Gastritis
Paracetamol	23 Sep 2020 (Study Day 22) - 23 Sep 2020 (Study Day 22)	Gastritis
Prochlorperazine	23 Sep 2020 (Study Day 22) - 26 Sep 2020 (Study Day 25)	Gastritis
Ciprofloxacin	24 Sep 2020 (Study Day 23) - 25 Sep 2020 (Study Day 24)	Antibiotic
Metronidazole	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Gastritis
Metronidazole	24 Sep 2020 (Study Day 23) - 25 Sep 2020 (Study Day 24)	Gastritis
Morphine	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Pain Secondary To Gastritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ondansetron	24 Sep 2020 (Study Day 23) - 27 Sep 2020 (Study Day 26)	Gastritis
Ondansetron	24 Sep 2020 (Study Day 23) - 26 Sep 2020 (Study Day 25)	Nausea Secondary To Gastritis
Paracetamol	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Pain Secondary To Gastritis
Prochlorperazine	24 Sep 2020 (Study Day 23) - 24 Sep 2020 (Study Day 23)	Nausea Secondary To Gastritis
Prochlorperazine	24 Sep 2020 (Study Day 23) - 25 Sep 2020 (Study Day 24)	Nausea Secondary To Gastritis
Ciprofloxacin	25 Sep 2020 (Study Day 24) - 25 Sep 2020 (Study Day 24)	Gastritis
Metronidazole	25 Sep 2020 (Study Day 24) - 25 Sep 2020 (Study Day 24)	Gastritis
Morphine	25 Sep 2020 (Study Day 24) - 27 Sep 2020 (Study Day 26)	Pain Secondary To Gastritis
Glucose; sodium chloride	26 Sep 2020 (Study Day 25) - 26 Sep 2020 (Study Day 25)	Fluids
Melatonin	26 Sep 2020 (Study Day 25) - 30 Sep 2020 (Study Day 29)	Insomnia
Paracetamol	26 Sep 2020 (Study Day 25) - 30 Sep 2020 (Study Day 29)	Headache
Paracetamol	26 Sep 2020 (Study Day 25) - 26 Sep 2020 (Study Day 25)	Pain Secondary To Gastritis
Paroxetine	26 Sep 2020 (Study Day 25) - Ongoing	Depression
Sodium chloride	26 Sep 2020 (Study Day 25) - 30 Sep 2020 (Study Day 29)	Prophylaxis Fluids
Fondaparinux	27 Sep 2020 (Study Day 26) - 30 Sep 2020 (Study Day 29)	Prophylaxis Dvt
Morphine	27 Sep 2020 (Study Day 26) - 29 Sep 2020 (Study Day 28)	Pain Secondary To Gastritis
Prochlorperazine	27 Sep 2020 (Study Day 26) - 30 Sep 2020 (Study Day 29)	Nausea
Esophagogastroduodenoscopy for gastritis*	28 Sep 2020 (Study Day 27) - 28 Sep 2020 (Study Day 27)	Adverse Event
Omeprazole	28 Sep 2020 (Study Day 27) - 28 Sep 2020 (Study Day 27)	Nausea Secondary To Gastritis
Oxycodone	28 Sep 2020 (Study Day 27) - 29 Sep 2020 (Study Day 28)	Pain Secondary Gastritis
Pantoprazole	28 Sep 2020 (Study Day 27) - 30 Sep 2020 (Study Day 29)	Gastritis
Moxifloxacin	29 Sep 2020 (Study Day 28) - 30 Sep 2020 (Study Day 29)	Cellulitis
Oxycodone	29 Sep 2020 (Study Day 28) - 30 Sep 2020 (Study Day 29)	Pain Secondary To Gastritis
Oxymetazoline	29 Sep 2020 (Study Day 28) - 30 Sep 2020 (Study Day 29)	Seasonal Allergies
Oxycodone	30 Sep 2020 (Study Day 29) - 30 Sep 2020 (Study Day 29)	Pain Secondary To Gastritis
Pantoprazole	30 Sep 2020 (Study Day 29) - Ongoing	Gastritis

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prochlorperazine	30 Sep 2020 (Study Day 29) - 30 Oct 2020 (Study Day 59)	Gastritis
Vancomycin	30 Sep 2020 (Study Day 29) - 10 Oct 2020 (Study Day 39)	C Diff
Moxifloxacin	01 Oct 2020 (Study Day 30) - 08 Oct 2020 (Study Day 37)	Cellulitis
Doxycycline	06 Oct 2020 (Study Day 35) - 05 Nov 2020 (Study Day 65)	COVID-19
Fluticasone propionate	06 Oct 2020 (Study Day 35) - 05 Nov 2020 (Study Day 65)	Seasonal Allergies
Lactobacillus acidophilus	06 Oct 2020 (Study Day 35) - 05 Nov 2020 (Study Day 65)	Prophylactic
Paracetamol	06 Oct 2020 (Study Day 35) - 13 Oct 2020 (Study Day 42)	COVID-19 Positive
Pantoprazole	20 Oct 2020 (Study Day 49) - Ongoing	Gastritis
12 lead ekg for pericarditis*	31 Oct 2020 (Study Day 60) - 31 Oct 2020 (Study Day 60)	Adverse Event
Cta pe protocol w wo iv contrast for pericarditis*	31 Oct 2020 (Study Day 60) - 31 Oct 2020 (Study Day 60)	Adverse Event
Fondaparinux	31 Oct 2020 (Study Day 60) - 31 Oct 2020 (Study Day 60)	Deep Vein Thrombosis
Glyceryl trinitrate	31 Oct 2020 (Study Day 60) - 31 Oct 2020 (Study Day 60)	Pericarditis
Morphine	31 Oct 2020 (Study Day 60) - 31 Oct 2020 (Study Day 60)	Pericarditis
Ondansetron	31 Oct 2020 (Study Day 60) - 31 Oct 2020 (Study Day 60)	Nausea
Oxycodone	31 Oct 2020 (Study Day 60) - 01 Nov 2020 (Study Day 61)	Chronic Pain Syndrome
Paracetamol	31 Oct 2020 (Study Day 60) - 01 Nov 2020 (Study Day 61)	Pericarditis
Sodium chloride	31 Oct 2020 (Study Day 60) - 01 Nov 2020 (Study Day 61)	Pericarditis
Clonazepam	01 Nov 2020 (Study Day 61) - 02 Nov 2020 (Study Day 62)	Anxiety
Ct of the head without contrast for pericarditis*	01 Nov 2020 (Study Day 61) - 01 Nov 2020 (Study Day 61)	Adverse Event
Ct of the sinus without contrast for pericarditis*	01 Nov 2020 (Study Day 61) - 01 Nov 2020 (Study Day 61)	Adverse Event
Fluoxetine	01 Nov 2020 (Study Day 61) - 03 Nov 2020 (Study Day 63)	Depression
Hydrocodone bitartrate; paracetamol	01 Nov 2020 (Study Day 61) - 03 Nov 2020 (Study Day 63)	Pericarditis
Lorazepam	01 Nov 2020 (Study Day 61) - 02 Nov 2020 (Study Day 62)	Anxiety
Morphine	01 Nov 2020 (Study Day 61) - 01 Nov 2020 (Study Day 61)	Pericarditis
Mri of the brain without contrast for pericarditis*	01 Nov 2020 (Study Day 61) - 01 Nov 2020 (Study Day 61)	Adverse Event

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Pantoprazole sodium sesquihydrate	01 Nov 2020 (Study Day 61) - 01 Nov 2020 (Study Day 61)	Gastroesophageal Reflux Disease
Pantoprazole sodium sesquihydrate	01 Nov 2020 (Study Day 61) - 03 Nov 2020 (Study Day 63)	Gastroesophageal Reflux Disease
Pharmacological nuclear cardiac stress test for pericarditis*	01 Nov 2020 (Study Day 61) - 01 Nov 2020 (Study Day 61)	Adverse Event
Sodium chloride	01 Nov 2020 (Study Day 61) - 02 Nov 2020 (Study Day 62)	Pericarditis
Colchicine	02 Nov 2020 (Study Day 62) - Ongoing	Pericarditis
Potassium chloride	02 Nov 2020 (Study Day 62) - 02 Nov 2020 (Study Day 62)	Pericarditis
Transthoracic echo report (2d with doppler and color flow)*	02 Nov 2020 (Study Day 62) - 02 Nov 2020 (Study Day 62)	Adverse Event
Clonazepam	03 Nov 2020 (Study Day 63) - Ongoing	Anxiety
Prednisone	11 Jan 2021 (Study Day 132) - 17 Jan 2021 (Study Day 138)	Rheumatoid Arthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Herpes Simplex	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 6) - 14 Sep 2020 (Study Day 13)
Lymphadenopathy	Grade 2/moderate	Related	09 Sep 2020 (Study Day 8) - 16 Sep 2020 (Study Day 15)
COVID-19	Grade 3/severe	Not related	06 Oct 2020 (Study Day 35) - 25 Oct 2020 (Study Day 54)
Blood Pressure Increased	Grade 3/severe	Not related	14 Jan 2021 (Study Day 135) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US300-2031 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	28 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	SAE, AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia/Pneumonia	SAE	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 44) – 12 Sep 2020 (Study Day 47)	Recovered/resolved
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	18 Sep 2020 (Study Day 53) – 22 Oct 2020 (Study Day 87)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2031, a 25-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 28 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Sep 2020 (Study Day 44), 43 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate serious adverse event of pneumonia. On 24 Aug 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of pneumonia lasted for 4 days, after which it was considered to be recovered/resolved on 12 Sep 2020 (Study Day 47). The investigator assessed the event of pneumonia to be not related to the IP.

On 18 Sep 2020 (Study Day 53), 52 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild nonserious adverse event of COVID-19. On 24 Aug 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 35 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 87). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious and serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000379	Pneumonia
MOD-2020-000379	COVID-19

Study Completion/Discontinuation

On 26 Feb 2021 (Study Day 214), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild intermittent asthma	1995 - 2010
Obesity	Obesity	2000 - Ongoing
Fibromyalgia	Fibromialgia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	28 Jul 2020 (Study Day 1) - 05 Aug 2020 (Study Day 9)	Suspected COVID 19
Ibuprofen	29 Jul 2020 (Study Day 2) - 29 Jul 2020 (Study Day 2)	Muscle Aches All Over Body
Ibuprofen	30 Jul 2020 (Study Day 3) - 03 Aug 2020 (Study Day 7)	Headache
Ibuprofen	27 Aug 2020 (Study Day 31) - 27 Aug 2020 (Study Day 31)	Suspected COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 1/mild	Not related	28 Jul 2020 (Study Day 1) - 14 Aug 2020 (Study Day 18)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Headache	Grade 1/mild	Related	29 Jul 2020 (Study Day 2) - 06 Aug 2020 (Study Day 10)
Myalgia	Grade 1/mild	Related	29 Jul 2020 (Study Day 2) - 07 Aug 2020 (Study Day 11)
Fatigue	Grade 1/mild	Related	30 Jul 2020 (Study Day 3) - 05 Aug 2020 (Study Day 9)
Suspected COVID-19	Grade 1/mild	Not related	21 Aug 2020 (Study Day 25) - 01 Sep 2020 (Study Day 36)
COVID-19	Grade 1/mild	Not related	18 Sep 2020 (Study Day 53) - 22 Oct 2020 (Study Day 87)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US300-2302 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	15 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	07 Oct 2020 (Study Day 23) – 17 Oct 2020 (Study Day 33)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US300-2302, a 50-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 15 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Oct 2020 (Study Day 23), 22 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 12 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 11 days, after which it was considered to be recovered/resolved on 17 Oct 2020 (Study Day 33). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000472	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	1999 - 1999
Obesity	Obesity	2000 - Ongoing
Menorrhagia	Menorrhagia	2011 - 2012
Ankle fracture	Right malleolar fracture	2015 - Ongoing
Osteoarthritis	Generalized osteoarthritis	2015 - Ongoing
Arthralgia	Right chronic ankle pain	May 2015 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Esomeprazole magnesium	2019 - Ongoing	Gastroesophageal Reflux Disease
Acetylsalicylic acid	May 2020 - Ongoing	Right Chronic Ankle Pain/Generalize Osteoarthritis
Phenylephrine hydrochloride	08 Oct 2020 (Study Day 24) - 08 Oct 2020 (Study Day 24)	COVID-19
Root canal*	27 Oct 2020 (Study Day 43) - 27 Oct 2020 (Study Day 43)	Adverse Event
Medroxyprogesterone	01 Feb 2021 (Study Day 140) - Ongoing	Endometrial Hyperplasia Prophylaxis
Iud removal surgery*	12 Mar 2021 (Study Day 179) - 12 Mar 2021 (Study Day 179)	Adverse Event

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Tooth Abscess	Grade 2/moderate	Not related	20 Sep 2020 (Study Day 6) – 27 Oct 2020 (Study Day 43)
COVID-19	Grade 1/mild	Not related	07 Oct 2020 (Study Day 23) - 17 Oct 2020 (Study Day 33)
Uterine Perforation	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 140) - 12 Mar 2021 (Study Day 179)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2012 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	27 Jul 2020 (Study Day 1) – 15 Sep 2020 (Study Day 51)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2012, a 35-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 27 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 27 Jul 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of covid-19. On 23 Aug 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 51 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 51). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000229	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	28 Jul 2020 (Study Day 2) - 01 Aug 2020 (Study Day 6)	Possible COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	27 Jul 2020 (Study Day 1) - 15 Sep 2020 (Study Day 51)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US302-2063 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	27 Aug 2020 (Study Day 30)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Breast Pain/Worsening Of Bilateral Large Painful Breast	SAE	Grade 4	Not related	16 Aug 2020 (Study Day 19) – 22 Oct 2020 (Study Day 86)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US302-2063, a 58-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose was administered in the left arm on 27 Aug 2020 (Study Day 30). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Aug 2020 (Study Day 19), 18 days after the first dose and 11 days before the second dose of the IP, the participant experienced a Grade 4 serious adverse event of breast pain. Action taken with the IP was not applicable. The event of worsening of bilateral large painful breast lasted for 68 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 86). The investigator assessed the event of breast pain to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-003399	Breast pain

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	1980 - Ongoing
Drug hypersensitivity	Imitrex allergy	1990 - Ongoing
Drug hypersensitivity	Toradol allergy	2000 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2000 - Ongoing
Breast pain	Bilateral large painful breast	2004 - 22 Oct 2020 (Study Day 86)
Drug hypersensitivity	Morphine allergy	2005 - Ongoing
Postmenopause	Post menopausal	2010 - Ongoing
Inguinal hernia	Inguinal hernia	Mar 2010 - 22 Oct 2020 (Study Day 86)
Obesity	Obesity	29 Jul 2020 (Study Day 1) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2000 - Ongoing	Cardiac Prophylaxis
Atorvastatin	2001 - Ongoing	Hypercholesterolemia
Ibuprofen	Jan 2020 - Ongoing	Migraines
Breast reduction surgery*	21 Oct 2020 (Study Day 85) - 21 Oct 2020 (Study Day 85)	Medical History
Panniculectomy*	21 Oct 2020 (Study Day 85) - 21 Oct 2020 (Study Day 85)	Medical History
Worsening of inguinal hernia repair*	21 Oct 2020 (Study Day 85) - 21 Oct 2020 (Study Day 85)	Medical History

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US303-2171 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	05 Sep 2020 (Study Day 27) – 24 Sep 2020 (Study Day 46)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2171, a 52-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 05 Sep 2020 (Study Day 27), 26 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of covid-19. On 06 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 24 Sep 2020 (Study Day 46). The investigator assessed the event of covid-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000320	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anaphylactic reaction	Penicillin allergy-anaphylaxis	1978 - Ongoing
Drug hypersensitivity	Azithromycin allergy	1989 - Ongoing
Asthma exercise induced	Exercise-induced asthma	2010 - Ongoing
Oestrogen deficiency	Estrogen defiency	2018 - Ongoing
Postmenopause	Postmenopausal	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2010 - Ongoing	Medical History: Exercise-Induced Asthma
Montelukast sodium	2010 - Ongoing	Medical History: Exercise-Induced Asthma
Salbutamol	2010 - Ongoing	Medical History: Exercise-Induced Asthma
Estrogens conjugated; medroxyprogesterone acetate	May 2020 - Ongoing	Medical History: Estrogen Hormone Defiency
Prednisone	14 Sep 2020 (Study Day 36) - 17 Sep 2020 (Study Day 39)	Adverse Event: Generalized Urticaria
Prednisone	18 Sep 2020 (Study Day 40) - 22 Sep 2020 (Study Day 44)	Adverse Event: Generalized Urticaria
Prednisone	23 Sep 2020 (Study Day 45) - 28 Sep 2020 (Study Day 50)	Adverse Event: Generalized Urticaria
Prednisone	29 Sep 2020 (Study Day 51) - 05 Oct 2020 (Study Day 57)	Adverse Event: Generalized Urticaria
Influenza vaccine	07 Oct 2020 (Study Day 59) - 07 Oct 2020 (Study Day 59)	Prophylaxis For Seasonal Influenza
Ibuprofen	17 Mar 2021 (Study Day 220) - Ongoing	Right Hip Pain

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	05 Sep 2020 (Study Day 27) - 24 Sep 2020 (Study Day 46)
Urticaria	Grade 2/moderate	Not related	13 Sep 2020 (Study Day 35) - 24 Sep 2020 (Study Day 46)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2172 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	01 Sep 2020 (Study Day 23) – 08 Sep 2020 (Study Day 30)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2172, a 57-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 10 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 01 Sep 2020 (Study Day 23), 22 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 06 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID 19 lasted for 8 days, after which it was considered to be recovered/resolved on 08 Sep 2020 (Study Day 30). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000268	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Pruritus	Chronic itching- bilateral hands	2009 - Ongoing
Arthralgia	Arthralgia- bilateral knees	2010 - Ongoing
Seasonal allergy	Seasonal allergies	2010 - Ongoing
Blood testosterone decreased	Low testosterone	2014 - Ongoing
Bronchogenic cyst	Benign bronchial cleft cyst	2018 - 2018
Lung cyst removal	Bronchial left cyst removal	2018 - 2018

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Gabapentin	2009 - Ongoing	Medical History: Chronic Itching Bilateral Hands
Triamcinolone acetonide	2009 - Ongoing	Medical History: Chronic Itching Bilateral Hands
Loratadine	2010 - Ongoing	Medical History: Seasonal Allergies
Meloxicam	2010 - Ongoing	Medical History: Arthralgia-Bilateral Knees, Hips, And Shoulders
Testosterone	2014 - Ongoing	Medical History: Low Testosterone
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	02 Sep 2020 (Study Day 24) - 15 Sep 2020 (Study Day 37)	Adverse Event: Sars-Cov-2 Infection
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	02 Sep 2020 (Study Day 24) - 15 Sep 2020 (Study Day 37)	Adverse Event: Sars-Cov-2 Infection
Paracetamol	02 Sep 2020 (Study Day 24) - 15 Sep 2020 (Study Day 37)	Adverse Event: Sars-Cov-2 Infection
Influenza vaccine	09 Oct 2020 (Study Day 61) - 09 Oct 2020 (Study Day 61)	Prophylaxis For Seasonal Influenza
Testosterone	16 Nov 2020 (Study Day 99) - 16 Nov 2020 (Study Day 99)	Hypogonadism
Lisinopril	03 Dec 2020 (Study Day 116) - Ongoing	Hypertension Secondary To Hypogonadism
Omeprazole	16 Mar 2021 (Study Day 219) - Ongoing	Acid Reflux

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Upper Respiratory Tract Infection	Grade 1/mild	Not applicable	31 Aug 2020 (Study Day 22) - 08 Sep 2020 (Study Day 30)
COVID-19	Grade 1/mild	Not related	01 Sep 2020 (Study Day 23) - 08 Sep 2020 (Study Day 30)
Hypogonadism	Grade 1/mild	Not related	16 Nov 2020 (Study Day 99) - Ongoing
Secondary Hypertension	Grade 1/mild	Not related	03 Dec 2020 (Study Day 116) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3380521

Participant Number:	US303-2211 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	18 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/SARS-Cov-2 Infection	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not applicable	18 Aug 2020 (Study Day 1) – 18 Aug 2020 (Study Day 1)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2211, a 43-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 18 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 18 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 14 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of SARS-CoV-2 infection lasted for 1 day, after which it was considered to be recovered/resolved on 18 Aug 2020 (Study Day 1). The investigator assessed the event of COVID-19 to be not applicable to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1980 - Ongoing
Depression	Depression	2018 - Ongoing
Hypothyroidism	Hypothyroidism	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	2018 - Ongoing	Medical History: Hypothyroidism
Sertraline	2018 - Ongoing	Medical History: Depression
Influenza vaccine	02 Oct 2020 (Study Day 46) - 02 Oct 2020 (Study Day 46)	Prevention Of Seasonal Flu

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not applicable	18 Aug 2020 (Study Day 1) - 18 Aug 2020 (Study Day 1)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2305 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Infection	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	08 Sep 2020 (Study Day 19) – 08 Sep 2020 (Study Day 19)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2305, a 71-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 infection lasted for 1 day, after which it was considered to be recovered/resolved on 08 Sep 2020 (Study Day 19). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Postmenopausal	1985 - Ongoing
Hypothyroidism	Hypothyroidism	2009 - Ongoing
Gastrooesophageal reflux disease	Acid reflux	2010 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Osteoarthritis	Osteoarthritis in bilateral hands	2010 - Ongoing
Osteopenia	Osteopenia	2016 - Ongoing
Restless legs syndrome	Restless leg syndrome	2018 - Ongoing
Arrhythmia supraventricular	Supraventricular arrhythmias	Feb 2020 - Ongoing
Pulmonary embolism	Bilateral pulmonary embolism	Feb 2020 - Feb 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Omeprazole	2010 - Ongoing	Medical History: Acid Reflux
Levothyroxine	2011 - Ongoing	Medical History: Hypothyroidism
Calcium; vitamin d nos	2016 - Ongoing	Medical History: Osteopenia
Atorvastatin	2017 - Ongoing	Medical History: Hypercholesterolemia
Ropinirole	2018 - Ongoing	Medical History: Restless Leg Syndrome
Apixaban	Feb 2020 - 26 Aug 2020 (Study Day 6)	Medical History: Pulmonary Embolism Prophylaxis
Metoprolol	Feb 2020 - Ongoing	Medical History: Supraventricular Arrhythmia
Apixaban	26 Aug 2020 (Study Day 6) - Ongoing	Pulmonary Embolism Prophylaxis
Influenza vaccine	10 Oct 2020 (Study Day 51) - 10 Oct 2020 (Study Day 51)	Seasonal Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	08 Sep 2020 (Study Day 19) - 08 Sep 2020 (Study Day 19)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US303-2320 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Sars-Cov-2 Infection	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	22 Aug 2020 (Study Day 1) – 22 Aug 2020 (Study Day 1)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US303-2320, a 61-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 22 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 22 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 18 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of sars-cov-2 infection lasted for 1 day, after which it was considered to be recovered/resolved on 22 Aug 2020 (Study Day 1). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 07 Jan 2021 (Study Day 139), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Deafness bilateral	Bilateral hearing loss	1980 - Ongoing
Nasal septal operation	Deviated septum repair	Oct 1994 - Oct 1994

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septum deviation	Deviated septum	Oct 1994 - Oct 1994
Seasonal allergy	Seasonal allergies	2000 - Ongoing
Cholecystectomy	Cholecystectomy	2006 - 2006
Cholelithiasis	Gall stones	2006 - 2006
Asthma	Asthma	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	1990 - Ongoing	Nutritional Supplement
Pseudoephedrine hydrochloride	2000 - Ongoing	Medical History: Seasonal Allergies
Fluticasone furoate; vilanterol trifenatate	2018 - Ongoing	Medical History: Asthma (Mild)
Fluticasone propionate	Jan 2019 - Ongoing	Medical History: Seasonal Allergies
Guaifenesin	Jan 2020 - Ongoing	Medical History: Seasonal Allergies
Other viral vaccines	07 Jan 2021 (Study Day 139) - 07 Jan 2021 (Study Day 139)	Prophylaxis Against COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	22 Aug 2020 (Study Day 1) - 22 Aug 2020 (Study Day 1)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US304-2209 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	08 Sep 2020 (Study Day 26) – 06 Oct 2020 (Study Day 54)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US304-2209, a 30-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 08 Sep 2020 (Study Day 26), 25 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of covid-19. On 10 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 29 days, after which it was considered to be recovered/resolved on 06 Oct 2020 (Study Day 54). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000300	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	2013 - Ongoing
Type 2 diabetes mellitus	Diabetes type 2	2013 - Ongoing
Anxiety	Anxiety	2018 - Ongoing
Obesity	Obesity	Apr 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Metformin hydrochloride	2013 - 22 Sep 2020 (Study Day 40)	Diabetes Type 2
Escitalopram	2018 - Ongoing	Anxiety
Empagliflozin	2019 - 22 Sep 2020 (Study Day 40)	Diabetes Type 2
Glimepiride	2019 - Ongoing	Diabetes Type 2
Propranolol	2019 - Ongoing	Migraine Headaches
Rizatriptan	Jan 2020 - Ongoing	Migraine Headaches
Ethinylestradiol; ferrous fumarate; norethisterone acetate	Apr 2020 - Ongoing	Contraception
Phentermine	Apr 2020 - Ongoing	Obesity
Amoxicillin; clavulanic acid	18 Sep 2020 (Study Day 36) - 28 Sep 2020 (Study Day 46)	Acute Bacterial Sinusitis
Semaglutide	23 Sep 2020 (Study Day 41) - Ongoing	Diabetes Type 2
Influenza vaccine	08 Oct 2020 (Study Day 56) - 08 Oct 2020 (Study Day 56)	Influenza Prophylaxis
Methocarbamol	01 Dec 2020 (Study Day 110) - 16 Dec 2020 (Study Day 125)	Left Shoulder Soft Tissue Injury
Tramadol	01 Dec 2020 (Study Day 110) - 16 Dec 2020 (Study Day 125)	Left Shoulder Soft Tissue Injury

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	08 Sep 2020 (Study Day 26) - 06 Oct 2020 (Study Day 54)
Sinusitis Bacterial	Grade 1/mild	Not related	18 Sep 2020 (Study Day 36) - 28 Sep 2020 (Study Day 46)
Limb Injury	Grade 1/mild	Not related	01 Dec 2020 (Study Day 110) - 09 Dec 2020 (Study Day 118)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US308-2247 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	16 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	13 Oct 2020 (Study Day 28) – 22 Oct 2020 (Study Day 37)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US308-2247, a 41-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 16 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Oct 2020 (Study Day 28), 27 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of covid-19. On 13 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID 19 lasted for 10 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 37). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000485	COVID-19

Study Completion/Discontinuation

On 15 Mar 2021 (Study Day 181), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2016 - Ongoing	Nutrtional Supplement
Ethinylestradiol; etonogestrel	2019 - Ongoing	Birth Control
Ibuprofen	14 Oct 2020 (Study Day 29) - 22 Oct 2020 (Study Day 37)	COVID 19
Paracetamol	14 Oct 2020 (Study Day 29) - 22 Oct 2020 (Study Day 37)	COVID 19
Ascorbic acid	16 Oct 2020 (Study Day 31) - 22 Oct 2020 (Study Day 37)	Nutritional Supplement
Oxymetazoline hydrochloride	16 Oct 2020 (Study Day 31) - 22 Oct 2020 (Study Day 37)	COVID-19 Symptom Relief
Influenza vaccine	29 Oct 2020 (Study Day 44) - 29 Oct 2020 (Study Day 44)	Annual Flu Preventative

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US311-2266 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Diagnosis	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	06 Sep 2020 (Study Day 24) – 26 Sep 2020 (Study Day 44)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2266, a 28-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 10 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 diagnosis lasted for 21 days, after which it was considered to be recovered/resolved on 26 Sep 2020 (Study Day 44). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000394	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraines	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid; caffeine; paracetamol	18 Sep 2020 (Study Day 36) - 18 Sep 2020 (Study Day 36)	Migraine/Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	06 Sep 2020 (Study Day 24) - 26 Sep 2020 (Study Day 44)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US311-2267 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Diagnosis	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	06 Sep 2020 (Study Day 24) – 17 Sep 2020 (Study Day 35)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US311-2267, a 27-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 06 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 10 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 diagnosis lasted for 12 days, after which it was considered to be recovered/resolved on 17 Sep 2020 (Study Day 35). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000375	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	06 Sep 2020 (Study Day 24) - 17 Sep 2020 (Study Day 35)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US315-2025 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Jul 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	14 Aug 2020 (Study Day 17) – 27 Aug 2020 (Study Day 30)	Recovered/ resolved with sequelae

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US315-2025, a 39-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Jul 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Aug 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 25 Aug 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 14 days, after which it was considered to be recovered/resolved with sequelae on 27 Aug 2020 (Study Day 30). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000223	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Premenstrual pain	Premenstrual cramps	2001 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2008 - Ongoing	Premenstrual Cramps
Ibuprofen	14 Aug 2020 (Study Day 17) - 14 Aug 2020 (Study Day 17)	COVID 19
Ibuprofen	16 Aug 2020 (Study Day 19) - 16 Aug 2020 (Study Day 19)	COVID 19
Paracetamol	17 Aug 2020 (Study Day 20) - 30 Aug 2020 (Study Day 33)	COVID 19
Paracetamol	01 Sep 2020 (Study Day 35) - 01 Sep 2020 (Study Day 35)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	14 Aug 2020 (Study Day 17) - 27 Aug 2020 (Study Day 30)
Vision Blurred	Grade 1/mild	Not related	14 Aug 2020 (Study Day 17) - 18 Sep 2020 (Study Day 52)
Hyperhidrosis	Grade 1/mild	Not related	19 Aug 2020 (Study Day 22) - 23 Aug 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US317-2467 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID 19 Symptomatic	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	29 Oct 2020 (Study Day 9) – 07 Nov 2020 (Study Day 18)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US317-2467, a 55-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 21 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 29 Oct 2020 (Study Day 9), 8 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 17 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID 19 symptomatic lasted for 10 days, after which it was considered to be recovered/resolved on 07 Nov 2020 (Study Day 18). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000665	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Glaucoma	Left eye glaucoma	1998 - Ongoing
Presbyopia	Presbyopia	2010 - Ongoing
Hand fracture	Right scaphoide fracture (right hand)	2011 - 2011
Epistaxis	Occasional nose bleeds	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	29 Oct 2020 (Study Day 9) - 05 Nov 2020 (Study Day 16)	COVID Symptoms - Fever
Azithromycin	30 Oct 2020 (Study Day 10) - 05 Nov 2020 (Study Day 16)	COVID 19
Cefalexin	19 Nov 2020 (Study Day 30) - 02 Dec 2020 (Study Day 43)	Neck Hairline Folliculitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US318-2292 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	23 Aug 2020 (Study Day 13) – 28 Aug 2020 (Study Day 18)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US318-2292, a 19-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 23 Aug 2020 (Study Day 13), 12 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 6 days, after which it was considered to be recovered/resolved on 28 Aug 2020 (Study Day 18). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000240	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Colitis	Colitis	2003 - Ongoing
Crohn's disease	Crohns disease	2003 - Ongoing
Fracture treatment	Right arm fracture surgically repaired	May 2006 - May 2006
Upper limb fracture	Right arm fracture	May 2006 - Jul 2006
Fracture treatment	Right arm fracture surgical repair	May 2020 - May 2020
Upper limb fracture	Right arm fracture	May 2020 - May 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	26 Aug 2020 (Study Day 16) - 28 Aug 2020 (Study Day 18)	Positive COVID Pcr

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	23 Aug 2020 (Study Day 13) - 28 Aug 2020 (Study Day 18)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US319-2086 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	03 Sep 2020 (Study Day 29)
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Suspected COVID-19/ COVID-Like Illness	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	30 Oct 2020 (Study Day 86) – 07 Nov 2020 (Study Day 94)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US319-2086, a 23-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 06 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 03 Sep 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 30 Oct 2020 (Study Day 86), 85 days after the first dose and 57 days after the second dose of the IP, the participant experienced a Grade 1/mild non-serious adverse event of suspected COVID-19. The IP dose was withdrawn due to the COVID-like illness. The event of COVID-like illness lasted for 9 days, after which it was considered to be recovered/resolved on 07 Nov 2020 (Study Day 94). The investigator assessed the event of suspected COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Nasal septal operation	Deviated septum repair	1998 - 1998
Bipolar disorder	Bipolar	2016 - Ongoing
Depression	Depression	2016 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Escitalopram	2016 - Ongoing	Depression
Lamotrigine	2016 - Ongoing	Bipolar/ Mood Stabilizer
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	2019 - 07 Apr 2021 (Study Day 245)	Attention Deficit Hyperactivity Disorder
Ibuprofen	03 Sep 2020 (Study Day 29) - 05 Sep 2020 (Study Day 31)	Fever/Headache/Pain At Injection Site
Paracetamol	03 Sep 2020 (Study Day 29) - 05 Sep 2020 (Study Day 31)	Fever/Headache/Pain At Injection Site
Ibuprofen	30 Oct 2020 (Study Day 86) - 31 Oct 2020 (Study Day 87)	COVID-Like Illness
Paracetamol	30 Oct 2020 (Study Day 86) - 01 Nov 2020 (Study Day 88)	COVID-Like Illness
Iron	02 Nov 2020 (Study Day 89) - Ongoing	Supplement
Paracetamol	02 Nov 2020 (Study Day 89) - 02 Nov 2020 (Study Day 89)	COVID-Like Illness
Iron	04 Feb 2021 (Study Day 183) - Ongoing	Supplement

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Suspected COVID-19	Grade 1/mild	Not related	30 Oct 2020 (Study Day 86) - 07 Nov 2020 (Study Day 94)
Anaemia	Grade 1/mild	Not related	02 Nov 2020 (Study Day 89) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US321-2066 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	09 Aug 2020 (Study Day 4) – 25 Aug 2020 (Study Day 20)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US321-2066, a 43-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 09 Aug 2020 (Study Day 4), 3 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 02 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 25 Aug 2020 (Study Day 20). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Female sterilisation	Bilateral tubal ligation	Not reported
Menorrhagia	Menorrhagia	2011 - 2017
Hypertension	Hypertension	2015 - Ongoing
Endometrial ablation	Uterine ablation	2017 - 2017
Headache	Headaches	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2015 - Ongoing	Hypertension
Propranolol	2018 - Ongoing	Headaches
Sumatriptan	07 Aug 2020 (Study Day 2) - Ongoing	Migraine Headaches
Paracetamol	09 Aug 2020 (Study Day 4) - Ongoing	Headache
Paracetamol	09 Aug 2020 (Study Day 4) - Ongoing	Headaches
Prednisone	10 Aug 2020 (Study Day 5) - 15 Aug 2020 (Study Day 10)	COVID-19
Topiramate	29 Sep 2020 (Study Day 55) - Ongoing	Migraine Headaches
Influenza vaccine	06 Nov 2020 (Study Day 93) - 06 Nov 2020 (Study Day 93)	Immunization
Azithromycin	28 Dec 2020 (Study Day 145) - 02 Jan 2021 (Study Day 150)	Acute Sinusitis
Prednisone	28 Dec 2020 (Study Day 145) - 29 Dec 2020 (Study Day 146)	Acute Sinusitis
Prednisone	30 Dec 2020 (Study Day 147) - 02 Jan 2021 (Study Day 150)	Acute Sinusitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 2/moderate	Related	07 Aug 2020 (Study Day 2) - 16 Aug 2020 (Study Day 11)
COVID-19	Grade 2/moderate	Not related	09 Aug 2020 (Study Day 4) - 25 Aug 2020 (Study Day 20)
Rhinovirus Infection	Grade 1/mild	Not related	24 Dec 2020 (Study Day 141) - 02 Jan 2021 (Study Day 150)
Acute Sinusitis	Grade 2/moderate	Not related	28 Dec 2020 (Study Day 145) - 02 Jan 2021 (Study Day 150)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US322-2424 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	31 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/SARS COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	10 Sep 2020 (Study Day 11) – 05 Oct 2020 (Study Day 36)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US322-2424, a 65-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 31 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Sep 2020 (Study Day 11), 10 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 27 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of SARS COVID-19 lasted for 26 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 36). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000324	COVID-19

Study Completion/Discontinuation

On 07 Nov 2020 (Study Day 69), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1991 - Ongoing	Hypothyroid

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US323-2021 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arthralgia/Worsening Upper Extremities Arthralgia	AE leading to withdrawal from study vaccine	Grade 1/ mild	Related	25 Aug 2020 (Study Day 16) – Not reported	Recovering/ resolving

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US323-2021, a 47-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 10 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Aug 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of arthralgia. On 06 Sep 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of worsening upper extremities arthralgia was considered to be ongoing. The investigator assessed the event of arthralgia to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 28 Sep 2020 (Study Day 50), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tobacco user	Past tobacco use, cigarettes, 5 per day	Not reported - 2000
Anxiety	Anxiety	2008 - Ongoing
Vitamin D deficiency	Vitamin d deficiency	May 2018 - Ongoing
Osteoarthritis	Osteoarthritis	Oct 2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Sertraline hydrochloride	2013 - Ongoing	Anxiety
Colecalciferol	May 2018 - Ongoing	Vitamin D Deficiency
Vitamins nos	2020 - Ongoing	Maintenance
Ibuprofen	11 Aug 2020 (Study Day 2) - 11 Aug 2020 (Study Day 2)	Injection Site Pain
Ibuprofen	25 Aug 2020 (Study Day 16) - Ongoing	Upper Extremity Arthralgia
Celecoxib	16 Sep 2020 (Study Day 38) - Ongoing	Upper Extremity Arthralgia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US324-2002 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	09 Aug 2020 (Study Day 4) – 02 Sep 2020 (Study Day 28)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2002, a 35-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Aug 2020 (Study Day 4), 3 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 02 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 25 days, after which it was considered to be recovered/resolved on 02 Sep 2020 (Study Day 28). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000210	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	Jan 1985 - Ongoing
Drug hypersensitivity	Drug allergy-erythromycin	Jan 1985 - Ongoing
Seasonal allergy	Seasonal allergic rhinitis	Jan 1985 - Ongoing
Obesity	Obesity	Aug 2010 - Ongoing
Drug hypersensitivity	Drug allergy-aspirin	Jan 2014 - Ongoing
Drug hypersensitivity	Drug allergy-ibuprofen	Jan 2014 - Ongoing
Insomnia	Insomnia	2015 - Ongoing
Anxiety	Anxiety	Jan 2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	Jan 1990 - Ongoing	Asthma
Loratadine	01 Jan 1990 (Study Day -11175) - Ongoing	Seasonal Allergic Rhinitis
Medroxyprogesterone acetate	01 Oct 2012 (Study Day -2866) - Ongoing	Birth Control
Sertraline	Jan 2015 - Ongoing	Anxiety
Trazodone	Jan 2015 - Ongoing	Insomnia
Fluticasone propionate	2019 - Ongoing	Asthma
Paracetamol	10 Aug 2020 (Study Day 5) - 11 Aug 2020 (Study Day 6)	COVID-19 (Symptoms)
Sulfamethoxazole; trimethoprim	13 Aug 2020 (Study Day 8) - 19 Aug 2020 (Study Day 14)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	09 Aug 2020 (Study Day 4) - 02 Sep 2020 (Study Day 28)
Sneezing	Grade 1/mild	Not related	09 Aug 2020 (Study Day 4) - 11 Aug 2020 (Study Day 6)
Fatigue	Grade 1/mild	Not related	13 Aug 2020 (Study Day 8) - 13 Aug 2020 (Study Day 8)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US324-2288 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	03 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/SARS-CoV-2	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	09 Sep 2020 (Study Day 7) – 23 Sep 2020 (Study Day 21)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US324-2288, a 58-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 03 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 30 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of SARS-CoV-2 lasted for 15 days, after which it was considered to be recovered/resolved on 23 Sep 2020 (Study Day 21). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000294	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2000 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2005 - Ongoing
Bradycardia	Bradycardia	2010 - Ongoing
Obesity	Obesity	2015 - Ongoing
Postmenopause	Postmenopausal	2016 - Ongoing
Gastrectomy	Gastric sleeve	2017 - 2017
Breast hyperplasia	Hyperplasia bilateral breast	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Clonidine	2000 - Ongoing	Hypertension
Simvastatin	2005 - 28 Sep 2020 (Study Day 26)	Hyperlipidemia
Botulinum toxin type a	2014 - 2014	Cosmetic
Anastrozole	Aug 2020 - Ongoing	Hyperplasia In Breast Tissue, Bilateral
Dextromethorphan hydrobromide; paracetamol; phenylephrine hydrochloride	10 Sep 2020 (Study Day 8) - 24 Sep 2020 (Study Day 22)	Fever And Congestion (COVID-19 Symptoms)
Paracetamol	10 Sep 2020 (Study Day 8) - 23 Sep 2020 (Study Day 21)	Fever(COVID-19 Symptoms)
Rosuvastatin calcium	29 Sep 2020 (Study Day 27) - Ongoing	Hyperlipidemia
Influenza vaccine	12 Oct 2020 (Study Day 40) - 12 Oct 2020 (Study Day 40)	Prophylaxis For Influenza
Monascus purpureus	26 Oct 2020 (Study Day 54) - 26 Oct 2020 (Study Day 54)	Supplement For Hyperlipidemia
Varicella zoster vaccine rge (cho)	26 Oct 2020 (Study Day 54) - 26 Oct 2020 (Study Day 54)	Prophylaxis For Shingles
Acetylsalicylic acid	09 Nov 2020 (Study Day 68) - Ongoing	Heart Health

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	09 Sep 2020 (Study Day 7) - 23 Sep 2020 (Study Day 21)
Hyperlipidaemia	Grade 2/moderate	Not related	29 Sep 2020 (Study Day 27) - 05 Mar 2021 (Study Day 184)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US325-2020 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	04 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Infection	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	13 Aug 2020 (Study Day 10) – 30 Aug 2020 (Study Day 27)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2020, a 24-year-old race not reported male, received the first dose of placebo in the left arm on 04 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 13 Aug 2020 (Study Day 10), 9 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 31 Aug 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 infection lasted for 18 days, after which it was considered to be recovered/resolved on 30 Aug 2020 (Study Day 27). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000432	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	17 Aug 2020 (Study Day 14) - 22 Aug 2020 (Study Day 19)	COVID +
Azithromycin	17 Aug 2020 (Study Day 14) - 22 Aug 2020 (Study Day 19)	COVID +
Brompheniramine maleate; dextromethorphan hydrobromide; pseudoephedrine hydrochloride	17 Aug 2020 (Study Day 14) - 31 Aug 2020 (Study Day 28)	COVID +

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	13 Aug 2020 (Study Day 10) - 30 Aug 2020 (Study Day 27)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US325-2075 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	13 Aug 2020 (Study Day 7) – 21 Aug 2020 (Study Day 15)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US325-2075, a 67-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 07 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 13 Aug 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 03 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 9 days, after which it was considered to be recovered/resolved on 21 Aug 2020 (Study Day 15).

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000212	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hip arthroplasty	Right hip replacement	Jan 2016 - Jan 2016
Type 2 diabetes mellitus	Type 2 diabetes	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	13 Aug 2020 (Study Day 7) - 19 Aug 2020 (Study Day 13)	COVID Positive
Azithromycin	13 Aug 2020 (Study Day 7) - 13 Aug 2020 (Study Day 7)	COVID Positive
Loratadine	13 Aug 2020 (Study Day 7) - 19 Aug 2020 (Study Day 13)	COVID Positive
Paracetamol	13 Aug 2020 (Study Day 7) - 15 Aug 2020 (Study Day 9)	COVID Positive
Azithromycin	14 Aug 2020 (Study Day 8) - 19 Aug 2020 (Study Day 13)	COVID Positive

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	13 Aug 2020 (Study Day 7) - 21 Aug 2020 (Study Day 15)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US327-2260 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID- 19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	26 Aug 2020 (Study Day 5) – 29 Aug 2020 (Study Day 8)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US327-2260, a 30-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 22 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 26 Aug 2020 (Study Day 5), 4 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 18 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 4 days, after which it was considered to be recovered/resolved on 29 Aug 2020 (Study Day 8). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000857	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma exercise induced	Exercise induced asthma	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	29 Sep 2020 (Study Day 39) - 29 Sep 2020 (Study Day 39)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	26 Aug 2020 (Study Day 5) - 29 Aug 2020 (Study Day 8)
Nasal Congestion	Grade 1/mild	Not related	26 Aug 2020 (Study Day 5) - 29 Aug 2020 (Study Day 8)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US329-2412 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	24 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	25 Sep 2020 (Study Day 2) – 11 Jan 2021 (Study Day 110)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US329-2412, a 42-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 24 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 25 Sep 2020 (Study Day 2), 1 day after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 21 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 109 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 110). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000357	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Myopia	Myopia	1988 - Ongoing
Polycystic ovaries	Polycystic ovarian syndrome - pcos	1995 - Ongoing
Anxiety	Anxiety	2000 - Ongoing
Depression	Depression	2000 - Ongoing
Allergy to arthropod sting	Allergies to bees	2003 - Ongoing
Female sterilisation	Tubal ligation - bilateral	2004 - 2004
Bunion operation	Bunionectomy	2008 - 2008
Foot deformity	Bunions	2008 - 2008
Hypertension	Hypertension	2012 - Ongoing
Hypothyroidism	Hypothyroid	2012 - Ongoing
Rhinitis allergic	Allergic rhinitis	2012 - Ongoing
Seasonal allergy	Seasonal allergies	2012 - Ongoing
Gastrooesophageal reflux disease	Gastroesophageal reflux disease - gerd	2013 - Ongoing
Type 2 diabetes mellitus	Type ii diabetes	2014 - Ongoing
Cholecystectomy	Cholecystectomy	2016 - 2016
Cholelithiasis	Gall stones	2016 - 2016
Non-alcoholic steatohepatitis	Nonalcoholic steatohepatitis - nash	2016 - Ongoing
Hysterectomy	Partial hysterectomy	Apr 2016 - Apr 2016
Asthma	Asthma	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2012 - Ongoing	Hypertension
Cetirizine hydrochloride	2012 - Ongoing	Seasonal Allergies
Levothyroxine	2012 - Ongoing	Hypothyroid
Losartan	2012 - Ongoing	Hypertension
Dexlansoprazole	2013 - Ongoing	Gerd
Liraglutide	2014 - Ongoing	Type Ii Diabetes
Colecalciferol	Jan 2016 - Ongoing	Supplement
Iron	Jan 2016 - Ongoing	Supplement
Vitamin b complex	Jan 2016 - Ongoing	Supplement
Spironolactone	2017 - Ongoing	Polycystic Ovary Syndrome
Fluticasone	2018 - Ongoing	Seasonal Allergies
Fluticasone propionate; salmeterol xinafoate	2018 - Ongoing	Asthma

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Montelukast	2018 - Ongoing	Seasonal Allergies
Salbutamol	2018 - Ongoing	Asthma
Escitalopram oxalate	Jun 2018 - Ongoing	Depression/Anxiety
Paracetamol	25 Sep 2020 (Study Day 2) - 11 Jan 2021 (Study Day 110)	COVID Generalized Pain/Fever
Azithromycin	30 Sep 2020 (Study Day 7) - 03 Oct 2020 (Study Day 10)	Prevention Of Phneumonia
Azithromycin	30 Oct 2020 (Study Day 37) - 03 Nov 2020 (Study Day 41)	Prevention Of Pneumonia
Glimepiride	07 Jan 2021 (Study Day 106) - Ongoing	Type 2 Diabetes
Metformin	07 Jan 2021 (Study Day 106) - Ongoing	Type 2 Diabetes

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	24 Sep 2020 (Study Day 1) - 07 Oct 2020 (Study Day 14)
Headache	Grade 1/mild	Related	24 Sep 2020 (Study Day 1) - 07 Oct 2020 (Study Day 14)
Myalgia	Grade 1/mild	Related	24 Sep 2020 (Study Day 1) - 05 Oct 2020 (Study Day 12)
COVID-19	Grade 2/moderate	Not related	25 Sep 2020 (Study Day 2) - 11 Jan 2021 (Study Day 110)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2068 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	17 Aug 2020 (Study Day 5) – 28 Aug 2020 (Study Day 16)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2068, a 21-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 17 Aug 2020 (Study Day 5), 4 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 12 days, after which it was considered to be recovered/resolved on 28 Aug 2020 (Study Day 16). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000242	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; ferrous fumarate; norethisterone acetate	Aug 2019 - Ongoing	Birth Control
Ibuprofen	18 Aug 2020 (Study Day 6) - 19 Aug 2020 (Study Day 7)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	17 Aug 2020 (Study Day 5) - 28 Aug 2020 (Study Day 16)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2548 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	08 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	03 Oct 2020 (Study Day 26) – 15 Oct 2020 (Study Day 38)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2548, a 65-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 08 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Oct 2020 (Study Day 26), 25 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 05 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 13 days, after which it was considered to be recovered/resolved on 15 Oct 2020 (Study Day 38). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000457	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Attention deficit hyperactivity disorder	Attention deficit disorder	2000 - Ongoing
Rotator cuff syndrome	Left rotator cuff tear	2002 - 2012
Meniscus injury	Right knee meniscus tear	2009 - 2017
Hypercholesterolaemia	Hypercholesterolemia	2010 - Ongoing
Osteoarthritis	Bilateral knee osteoarthritis	2010 - Ongoing
Rotator cuff repair	Left rotator cuff repair	2012 - 2012
Sleep apnoea syndrome	Obstructive sleep apnea	2014 - Ongoing
Hypertension	Hypertension	2017 - Ongoing
Meniscus operation	Right knee meniscus tear repair	2017 - 2017
Deafness bilateral	Bilateral hearing loss	2018 - Ongoing
Ligament sprain	Left elbow strain	Jan 2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Methylphenidate	2005 - 16 Oct 2020 (Study Day 39)	Attention Deficit Disorder
Acetylsalicylic acid	2012 - Ongoing	Health Maintenance
Fish oil	2012 - Ongoing	Prophylaxis
Oxygen	2014 - Ongoing	Obstructive Sleep Apnea
Lisinopril	2017 - 16 Oct 2020 (Study Day 39)	Hypertension
Rosuvastatin	2017 - Ongoing	Hypercholesterolemia
Alirocumab	Jan 2020 - Ongoing	Hypercholesterolemia
Paracetamol; phenylephrine hydrochloride	03 Oct 2020 (Study Day 26) - 07 Oct 2020 (Study Day 30)	Symptomatic COVID-19
Hydrochlorothiazide; lisinopril	17 Oct 2020 (Study Day 40) - Ongoing	Exacerbation Of Hypertension
Cardiac stress test*	22 Oct 2020 (Study Day 45) - 22 Oct 2020 (Study Day 45)	Diagnostic
Ferric citrate	14 Dec 2020 (Study Day 98) - Ongoing	Osteoarthritis
Left knee arthroplasty*	14 Dec 2020 (Study Day 98) - 14 Dec 2020 (Study Day 98)	Medical History
Meloxicam	14 Dec 2020 (Study Day 98) - Ongoing	Osteoarthritis
Paracetamol	14 Dec 2020 (Study Day 98) - Ongoing	Osteoarthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	03 Oct 2020 (Study Day 26) - 15 Oct 2020 (Study Day 38)
Hypertension	Grade 3/severe	Not related	07 Oct 2020 (Study Day 30) - 03 Nov 2020 (Study Day 57)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US331-2587 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	09 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	03 Oct 2020 (Study Day 25) – 20 Oct 2020 (Study Day 42)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US331-2587, a 27-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 09 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 03 Oct 2020 (Study Day 25), 24 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 06 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 18 days, after which it was considered to be recovered/resolved on 20 Oct 2020 (Study Day 42). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000459	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Occasional migraine	2003 - Ongoing
Carpal tunnel syndrome	Right carpal tunnel	2010 - Ongoing
Anxiety	Anxiety	2014 - Ongoing
Attention deficit hyperactivity disorder	Attention deficit hyperactivity disorder	2014 - Ongoing
Depression	Depression	2014 - Ongoing
Fallopian tube cyst	Cyst on fallopian tube	2014 - 2014
Salpingectomy	Unilateral salpingectomy	2014 - 2014
Hypothyroidism	Hypothyroidism	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid; caffeine; paracetamol	2003 - Ongoing	Occasional Migraine
Sumatriptan	2003 - Ongoing	Occasional Migraine
Naproxen sodium	2010 - Ongoing	Right Carpal Tunnel
Amfetamine aspartate; amfetamine sulfate; dexamfetamine saccharate; dexamfetamine sulfate	2014 - Ongoing	Attention Deficit Hyperactivity Disorder
Ethinylestradiol; ferrous fumarate; norethisterone acetate	2015 - 21 Dec 2020 (Study Day 104)	Birth Control
Levothyroxine	2016 - Ongoing	Hypothyroidism
Acetylsalicylic acid; caffeine; paracetamol	05 Oct 2020 (Study Day 27) - 19 Oct 2020 (Study Day 41)	Symptomatic COVID-19
Ibuprofen	08 Oct 2020 (Study Day 30) - 13 Oct 2020 (Study Day 35)	Symptomatic COVID 19
Phenylephrine hydrochloride	08 Oct 2020 (Study Day 30) - 13 Oct 2020 (Study Day 35)	Symptomatic COVID 19
Triamcinolone acetonide	11 Oct 2020 (Study Day 33) - 20 Oct 2020 (Study Day 42)	Symptomatic COVID 19
Influenza vaccine	23 Oct 2020 (Study Day 45) - 23 Oct 2020 (Study Day 45)	Influenza Prophylaxis
Tuberculosis skin test*	23 Oct 2020 (Study Day 45) - 23 Oct 2020 (Study Day 45)	Diagnostic
Ethinylestradiol; etonogestrel	21 Dec 2020 (Study Day 104) - Ongoing	Birth Control

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	03 Oct 2020 (Study Day 25) - 20 Oct 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US332-2061 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	07 Sep 2020 (Study Day 18) – 15 Sep 2020 (Study Day 26)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US332-2061, a 57-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 18), 17 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 9 days, after which it was considered to be recovered/resolved on 15 Sep 2020 (Study Day 26). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000303	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Penicillin allergy	1967 - Ongoing
Food allergy	Shellfish allergy	1990 - Ongoing
Arthroscopy	Left knee arthroscopy	1992 - 1992
Meniscus injury	Left knee torn meniscus	1992 - 1992
Migraine	Migraine	1994 - Ongoing
Caesarean section	Cesarean section	1999 - 1999
Caesarean section	Cesarean section	2001 - 2001
Dermatitis contact	Band-aids allergy	2001 - Ongoing
Female sterilisation	Bilateral tubal ligation	2001 - 2001
Abdominoplasty	Abdominoplasty, elective	2004 - 2004
Mammoplasty	Breast augmentation	2004 - 2004
Hot flush	Hot flashes	2008 - Ongoing
Postmenopause	Post-menopausal	2008 - Ongoing
Mammoplasty	Breast augmentation	2010 - 2010

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	Jan 2010 - Ongoing	Supplements
Venlafaxine hydrochloride	Jun 2020 - 03 Sep 2020 (Study Day 14)	Hot Flashes
Influenza vaccine	Sep 2020 - Sep 2020	Prophylaxis
Paracetamol	07 Sep 2020 (Study Day 18) - 15 Sep 2020 (Study Day 26)	Symptomatic COVID-19
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	10 Sep 2020 (Study Day 21) - 15 Sep 2020 (Study Day 26)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	07 Sep 2020 (Study Day 18) - 15 Sep 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US333-2060 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	24 Sep 2020 (Study Day 31)
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Migraine/Worsening Of Migrianes	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	25 Aug 2020 (Study Day 1) – 27 Aug 2020 (Study Day 3)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US333-2060, a 43-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 25 Aug 2020 (Study Day 1). The second dose was administered in the left arm on 24 Sep 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Aug 2020 (Study Day 1), on the day of the first dose and 30 days before the second dose of the IP, the participant experienced a Grade 2/moderate non-serious adverse event of migraine. The IP dose was withdrawn due to the worsening of migrianes. The event of worsening of migrianes lasted for 3 days, after which it was considered to be recovered/resolved on 27 Aug 2020 (Study Day 3). The investigator assessed the event of migraine to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Astigmatism	Astigmatism	1991 - 18 Dec 2020 (Study Day 116)
Hypotension	Hypotension	1997 - Ongoing
Migraine	Migranes	2000 - Ongoing
Depression	Depression	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ethinylestradiol; levonorgestrel	2020 - Ongoing	Pregnancy Prophylaxis
Acetylsalicylic acid	25 Aug 2020 (Study Day 1) - 27 Aug 2020 (Study Day 3)	Worsening Of Migraines
Ubrogepant	25 Aug 2020 (Study Day 1) - 25 Aug 2020 (Study Day 1)	Worsening Of Migraines
Ibuprofen	27 Aug 2020 (Study Day 3) - 27 Aug 2020 (Study Day 3)	Headache
Acetylsalicylic acid	26 Sep 2020 (Study Day 33) - 26 Sep 2020 (Study Day 33)	Headache
Influenza vaccine	09 Oct 2020 (Study Day 46) - 09 Oct 2020 (Study Day 46)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Migraine	Grade 2/moderate	Related	25 Aug 2020 (Study Day 1) - 27 Aug 2020 (Study Day 3)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US333-2089 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	18 Sep 2020 (Study Day 2) – 09 Oct 2020 (Study Day 23)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US333-2089, a 42-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 17 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Sep 2020 (Study Day 2), 1 day after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 14 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 22 days, after which it was considered to be recovered/resolved on 09 Oct 2020 (Study Day 23). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000377	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Depression	Depression	2002 - Ongoing
Arthralgia	Bilateral knee pain	2012 - Ongoing
Insomnia	Insomnia	2018 - Ongoing
Umbilical hernia	Umbillical hernia	May 2020 - 04 Aug 2020 (Study Day -44)
Umbilical hernia repair	Umbillical hernia repair	04 Aug 2020 (Study Day -44) - 04 Aug 2020 (Study Day -44)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Bupropion	2005 - Ongoing	Depression
Glucosamine	2012 - Ongoing	Bilateral Knee Pain
Duloxetine	2015 - Ongoing	Depression
Levonorgestrel	Jul 2016 - Ongoing	Pregnancy Prophylaxis
Hydrocodone bitartrate; paracetamol	18 Sep 2020 (Study Day 2) - 18 Sep 2020 (Study Day 2)	Injection Site Pain
Paracetamol	18 Sep 2020 (Study Day 2) - 26 Sep 2020 (Study Day 10)	Injection Site Pain, Muscle Aches
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	24 Sep 2020 (Study Day 8) - 26 Sep 2020 (Study Day 10)	Symptomatic COVID-19
Paracetamol	24 Sep 2020 (Study Day 8) - 05 Oct 2020 (Study Day 19)	Symptomatic COVID-19
Caffeine; mepyramine maleate; paracetamol	30 Sep 2020 (Study Day 14) - 02 Oct 2020 (Study Day 16)	Stomach Pain
Oxycodone	03 Oct 2020 (Study Day 17) - 03 Oct 2020 (Study Day 17)	Symptomatic COVID-19
Escitalopram oxalate	12 Feb 2021 (Study Day 149) - Ongoing	Depression
Zolpidem tartrate	12 Feb 2021 (Study Day 149) - Ongoing	Insomnia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	18 Sep 2020 (Study Day 2) - 09 Oct 2020 (Study Day 23)
Abdominal Pain Upper	Grade 2/moderate	Not related	30 Sep 2020 (Study Day 14) - 02 Oct 2020 (Study Day 16)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US334-2323 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	15 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	11 Nov 2020 (Study Day 28) – 05 Dec 2020 (Study Day 52)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US334-2323, a 26-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 15 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Nov 2020 (Study Day 28), 27 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 11 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 25 days, after which it was considered to be recovered/resolved on 05 Dec 2020 (Study Day 52). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious events are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000938	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches	2013 - Ongoing
Ovarian cyst	Benign ovarian cyst (r)	2015 - Ongoing
Attention deficit hyperactivity disorder	Adhd	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2013 - Ongoing	Headaches
Amfetamine sulfate	2019 - Ongoing	Adhd
Levonorgestrel	Mar 2019 - Ongoing	Contraception
Influenza vaccine	09 Sep 2020 (Study Day -36) - 09 Sep 2020 (Study Day -36)	Influenza Prophylaxis
Doxycycline	04 Oct 2020 (Study Day -11) - 08 Oct 2020 (Study Day -7)	Ovarian Cyst Infection Prophylaxis
Dextromethorphan	16 Nov 2020 (Study Day 33) - 26 Nov 2020 (Study Day 43)	Symptomatic COVID-19 Infection Ae
Paracetamol	17 Nov 2020 (Study Day 34) - 22 Nov 2020 (Study Day 39)	Symptomatic COVID-19 Infection Ae

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US335-2072 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	19 Aug 2020 (Study Day 7) – 08 Sep 2020 (Study Day 27)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US335-2072, a 63-year-old Hispanic or Latino female, received the first dose of placebo in the right arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Aug 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved on 08 Sep 2020 (Study Day 27). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000224	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Caesarean section	C-section	1979 - 1979
Presbyopia	Presbyopia	1997 - Ongoing
Abdominoplasty	Tummy tuck	2000 - 2000
Postmenopause	Postmenopausal	2007 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	19 Aug 2020 (Study Day 7) - 28 Aug 2020 (Study Day 16)	Body Aches (Due To COVID-19)
Paracetamol	19 Aug 2020 (Study Day 7) - 28 Aug 2020 (Study Day 16)	Headache
Guaifenesin	27 Aug 2020 (Study Day 15) - 31 Aug 2020 (Study Day 19)	Cough (Due To COVID-19)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	19 Aug 2020 (Study Day 7) - 08 Sep 2020 (Study Day 27)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2083 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	08 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	28 Aug 2020 (Study Day 21) – 06 Sep 2020 (Study Day 30)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2083, a 18-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 08 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 28 Aug 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 04 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 10 days, after which it was considered to be recovered/resolved on 06 Sep 2020 (Study Day 30). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000263	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	29 Aug 2020 (Study Day 22) - 31 Aug 2020 (Study Day 24)	COVID-19
Zinc	29 Aug 2020 (Study Day 22) - 05 Sep 2020 (Study Day 29)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	28 Aug 2020 (Study Day 21) - 06 Sep 2020 (Study Day 30)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US336-2124 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	18 Aug 2020 (Study Day 6) – 18 Sep 2020 (Study Day 37)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US336-2124, a 20-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 13 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Aug 2020 (Study Day 6), 5 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 09 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 32 days, after which it was considered to be recovered/resolved on 18 Sep 2020 (Study Day 37). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000226	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fluticasone propionate	2019 - Ongoing	Allergic Rhinitis
Famotidine; ibuprofen	21 Aug 2020 (Study Day 9) - 21 Aug 2020 (Study Day 9)	Sars-Cov 2 Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Arthralgia	Grade 1/mild	Related	14 Aug 2020 (Study Day 2) - 23 Aug 2020 (Study Day 11)
COVID-19	Grade 1/mild	Not related	18 Aug 2020 (Study Day 6) - 18 Sep 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US337-2092 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	19 Aug 2020 (Study Day 1) – 31 Aug 2020 (Study Day 13)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US337-2092, a 68-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 19 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 19 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 15 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 13 days, after which it was considered to be recovered/resolved on 31 Aug 2020 (Study Day 13). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2021-050658	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypercholesterolaemia	Hypercholesterolemia	2005 - Ongoing
Hypertension	Hypertension	2015 - Ongoing
Varicose vein	Varicose veins left leg	06 Jan 2020 (Study Day -226) - 06 Jan 2020 (Study Day -226)
Varicose vein	Varicose veins right leg	06 Jan 2020 (Study Day -226) - 06 Jan 2020 (Study Day -226)
Varicose vein operation	Varicose removal left leg	06 Jan 2020 (Study Day -226) - 06 Jan 2020 (Study Day -226)
Varicose vein operation	Varicose vein removal right leg	06 Jan 2020 (Study Day -226) - 06 Jan 2020 (Study Day -226)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Lisinopril	2005 - 2005	Hypertension
Atorvastatin	2010 - Ongoing	Hypercholesterolemia
Tetanus vaccine	20 Sep 2011 (Study Day -3256) - 20 Sep 2011 (Study Day -3256)	Infection Prophylaxis/Prevention
Ubidecarenone	2017 - Ongoing	Dietary Supplement
Pneumococcal vaccine	09 Aug 2017 (Study Day -1106) - 09 Aug 2017 (Study Day -1106)	Pneumonia Prophylaxis/Prevention
Colecalciferol	Aug 2018 - Ongoing	Dietary Supplement
Influenza vaccine	Oct 2019 - Oct 2019	Influenza Prophylaxis/Prevention
Metoprolol	Jan 2020 - Ongoing	Hypertension
Varicella zoster vaccine rge (cho)	10 Jul 2020 (Study Day -40) - 10 Jul 2020 (Study Day -40)	Herpes Zoster Prophylaxis/Prevention
Influenza vaccine	30 Oct 2020 (Study Day 73) - 30 Oct 2020 (Study Day 73)	Influenza Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	19 Aug 2020 (Study Day 1) - 31 Aug 2020 (Study Day 13)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US338-2035 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 [positive Test]	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	14 Aug 2020 (Study Day 1) – 26 Aug 2020 (Study Day 13)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US338-2035, a 32-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 14 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 10 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 [positive test] lasted for 13 days, after which it was considered to be recovered/resolved on 26 Aug 2020 (Study Day 13). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	2002 - Ongoing
Seasonal allergy	Seasonal allergies	2012 - Ongoing
Herpes simplex	Herpes simplex virus 2	2014 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Anxiety	Anxiety	2016 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Caffeine; paracetamol	2002 - Ongoing	Migraine Headaches
Chondroitin; glucosamine	2012 - Ongoing	Nutritional Supplement
Colecalciferol	2012 - Ongoing	Nutritional Supplement
Vitamin b12 nos	2012 - Ongoing	Nutritional Supplement
Fexofenadine hydrochloride	2014 - Ongoing	Seasonal Allergies
Valaciclovir hydrochloride	2014 - Ongoing	Herpes Simplex Virus 2
Emtricitabine; tenofovir disoproxil fumarate	2015 - Ongoing	Prophylaxis For Hiv
Acetylsalicylic acid	2020 - Ongoing	Prophylaxis For Blood Clots Related To COVID-19
Sertraline hydrochloride	2020 - Ongoing	Anxiety
Zinc	2020 - Ongoing	Nutritional Supplement
Covid pcr test*	14 Aug 2020 (Study Day 1) - 14 Aug 2020 (Study Day 1)	Diagnostic
Influenza vaccine	19 Sep 2020 (Study Day 37) - 19 Sep 2020 (Study Day 37)	Flu
Paracetamol	29 Jan 2021 (Study Day 169) - 29 Jan 2021 (Study Day 169)	Pain At Injection Site
Benzonatate	12 Feb 2021 (Study Day 183) - 15 Feb 2021 (Study Day 186)	Productive Cough
Paracetamol	26 Feb 2021 (Study Day 197) - 26 Feb 2021 (Study Day 197)	Solicited Symptoms Of Injection Site Soreness And Headache
Paracetamol	27 Feb 2021 (Study Day 198) - 27 Feb 2021 (Study Day 198)	Solicited Symptoms Of Injection Site Soreness And Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	14 Aug 2020 (Study Day 1) - 26 Aug 2020 (Study Day 13)
Injection Site Pain	Grade 1/mild	Related	16 Aug 2020 (Study Day 3) - 23 Aug 2020 (Study Day 10)
Lymphadenopathy	Grade 1/mild	Related	16 Aug 2020 (Study Day 3) - 23 Aug 2020 (Study Day 10)
Myalgia	Grade 1/mild	Related	19 Aug 2020 (Study Day 6) - 23 Aug 2020 (Study Day 10)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US341-2129 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	05 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	12 Aug 2020 (Study Day 8) – 19 Sep 2020 (Study Day 46)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US341-2129, a 37-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 05 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 12 Aug 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 01 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 39 days, after which it was considered to be recovered/resolved on 19 Sep 2020 (Study Day 46). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000227	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diphenhydramine hydrochloride; ibuprofen	12 Aug 2020 (Study Day 8) - 12 Aug 2020 (Study Day 8)	Headache
Dextromethorphan; doxylamine; paracetamol	13 Aug 2020 (Study Day 9) - 17 Aug 2020 (Study Day 13)	COVID-19
Ibuprofen	13 Aug 2020 (Study Day 9) - 17 Aug 2020 (Study Day 13)	COVID-19
Acetylsalicylic acid	14 Aug 2020 (Study Day 10) - 17 Aug 2020 (Study Day 13)	COVID-19
Ibuprofen	01 Feb 2021 (Study Day 181) - 01 Feb 2021 (Study Day 181)	Headache - Solicited Adverse Reaction

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	12 Aug 2020 (Study Day 8) - 19 Sep 2020 (Study Day 46)
Headache	Grade 1/mild	Related	12 Aug 2020 (Study Day 8) - 12 Aug 2020 (Study Day 8)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US343-2334 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	28 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asymptomatic COVID-19/SARS-Cov-2 Infection (Asymptomatic)	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	16 Sep 2020 (Study Day 20) – 26 Sep 2020 (Study Day 30)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US343-2334, a 29-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 28 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 16 Sep 2020 (Study Day 20), 19 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of asymptomatic COVID-19. On 24 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of SARS-CoV-2 infection (asymptomatic) lasted for 11 days, after which it was considered to be recovered/resolved on 26 Sep 2020 (Study Day 30). The investigator assessed the event of asymptomatic COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 29 Dec 2020 (Study Day 124), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	2018 - Ongoing	Asthma
Hepatitis b vaccine	05 Oct 2020 (Study Day 39) - 05 Oct 2020 (Study Day 39)	Hepatitis B Prophylaxis
Influenza vaccine	05 Oct 2020 (Study Day 39) - 05 Oct 2020 (Study Day 39)	Flu Prophylaxis
Other viral vaccines	17 Dec 2020 (Study Day 112) - 17 Dec 2020 (Study Day 112)	COVID-19 Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asymptomatic COVID-19	Grade 1/mild	Not related	16 Sep 2020 (Study Day 20) - 26 Sep 2020 (Study Day 30)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US345-2295 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	06 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not applicable	06 Aug 2020 (Study Day 1) – 25 Aug 2020 (Study Day 20)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US345-2295, a 62-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 06 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 06 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 02 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 20 days, after which it was considered to be recovered/resolved on 25 Aug 2020 (Study Day 20). The investigator assessed the event of COVID-19 to be not applicable to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000205	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Reaction to food additive	Allergy to saccharin	1975 - Ongoing
Chronic sinusitis	Chronic sinusitis	1977 - Ongoing
Drug hypersensitivity	Allergy to sulfa	1995 - Ongoing
Sinus operation	Sinus surgery	1995 - 1995
Dyspepsia	Heartburn	2010 - Ongoing
Hypertension	High blood pressure	2015 - Ongoing
Seasonal allergy	Seasonal allergies	2015 - Ongoing
Blood testosterone decreased	Low testosterone	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Cetirizine	2015 - Ongoing	Seasonal Allergies
Lisinopril	2015 - Ongoing	High Blood Pressure
Omeprazole	2015 - Ongoing	Heartburn
Ascorbic acid	07 Aug 2020 (Study Day 2) - Ongoing	Immune Boost
Docosahexaenoic acid; eicosapentaenoic acid	07 Aug 2020 (Study Day 2) - Ongoing	Immune Health
Famotidine	07 Aug 2020 (Study Day 2) - Ongoing	Stomach Coating/Acid Reflux
Fluticasone propionate	07 Aug 2020 (Study Day 2) - Ongoing	Sinus Congestion/ COVID 19
Salbutamol	07 Aug 2020 (Study Day 2) - 13 Sep 2020 (Study Day 39)	Chest Congestion/ COVID 19
Vitamins nos	07 Aug 2020 (Study Day 2) - Ongoing	Supplement
Zinc acetate; zinc gluconate	07 Aug 2020 (Study Day 2) - 13 Aug 2020 (Study Day 8)	COVID-19
Benzonatate	10 Aug 2020 (Study Day 5) - 03 Sep 2020 (Study Day 29)	COVID-19
Amoxicillin; clavulanic acid	03 Sep 2020 (Study Day 29) - 13 Sep 2020 (Study Day 39)	Worsening Of Chronic Sinusitis
Amoxicillin; clavulanic acid	02 Oct 2020 (Study Day 58) - 23 Oct 2020 (Study Day 79)	Worsening Of Sinusitis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not applicable	06 Aug 2020 (Study Day 1) - 25 Aug 2020 (Study Day 20)
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	07 Aug 2020 (Study Day 2) - 13 Aug 2020 (Study Day 8)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3380597

Participant Number:	US347-2096 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	09 Nov 2020 (Study Day 34) – 29 Nov 2020 (Study Day 54)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US347-2096, a 42-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 07 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Nov 2020 (Study Day 34), 33 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 03 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 21 days, after which it was considered to be recovered/resolved on 29 Nov 2020 (Study Day 54). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000786	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergic rhinitis	1996 - Ongoing
Borderline personality disorder	Borderline personality disorder	Jan 2000 - Ongoing
Intervertebral disc protrusion	Herniated disc, l5-s1	2005 - Sep 2005
Seborrhoeic dermatitis	Seborrheic dermititis, perioral	2017 - Ongoing
Cholecystitis	Cholecystitis	Sep 2019 - Oct 2019
Cholecystectomy	Cholecystectomy	Oct 2019 - Oct 2019
Obesity	Obesity	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azelastine hydrochloride; fluticasone propionate	2000 - Ongoing	Allergic Rhinitis
Carbamazepine	2000 - Ongoing	Bpd
Ibuprofen	2000 - Ongoing	Generalized Pain
Allergens nos	2016 - Ongoing	Allergic Rhinitis
Ketoconazole	2017 - Ongoing	Seborrheic Dermititis
Sertraline hydrochloride	01 Sep 2020 (Study Day -36) - Ongoing	Bpd
Influenza vaccine	21 Oct 2020 (Study Day 15) - 21 Oct 2020 (Study Day 15)	Influenza Prophylaxis
Ascorbic acid	10 Nov 2020 (Study Day 35) - Ongoing	Supplement
Colecalciferol	10 Nov 2020 (Study Day 35) - Ongoing	Supplement
Zinc	10 Nov 2020 (Study Day 35) - Ongoing	Supplement
Azithromycin	12 Nov 2020 (Study Day 37) - 12 Nov 2020 (Study Day 37)	COVID-19
Salbutamol	12 Nov 2020 (Study Day 37) - 29 Nov 2020 (Study Day 54)	COVID-19
Paracetamol	06 Feb 2021 (Study Day 123) - 06 Feb 2021 (Study Day 123)	Pain At Injection Site
Lisinopril	18 Mar 2021 (Study Day 163) - Ongoing	Elevated Blood Pressure

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	09 Nov 2020 (Study Day 34) - 29 Nov 2020 (Study Day 54)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US348-2302 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	19 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	16 Nov 2020 (Study Day 29)
Reason for Narrative:	SAE

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	SAE	Grade 3/ severe	Not related	11 Jan 2021 (Study Day 85) – 27 Jan 2021 (Study Day 101)	Recovered/resolved
Acute Kidney Injury/Acute Renal Failure Superimposed On Chronic Kidney Disease	SAE	Grade 3/ severe	Not related	29 Jan 2021 (Study Day 103) – 03 Feb 2021 (Study Day 108)	Recovered/resolved
Nausea/Intractable Nausea	SAE	Grade 3/ severe	Not related	29 Jan 2021 (Study Day 103) – 03 Feb 2021 (Study Day 108)	Recovered/resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US348-2302, a 73-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 19 Oct 2020 (Study Day 1). The second dose was administered in the left arm on 16 Nov 2020 (Study Day 29). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 11 Jan 2021 (Study Day 85), 84 days after the first dose and 57 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of COVID-19. Action taken with the IP was not applicable. The event of COVID-19 lasted for 17 days, after which it was considered to be recovered/resolved on 27 Jan 2021 (Study Day 101). The investigator assessed the event of COVID-19 to be not related to the IP.

On 29 Jan 2021 (Study Day 103), 102 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of acute kidney injury. Action taken with the IP was not applicable. The event of acute renal failure superimposed on chronic kidney disease lasted for 6 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 108). The investigator assessed the event of acute kidney injury to be not related to the IP.

On 29 Jan 2021 (Study Day 103), 102 days after the first dose and 74 days after the second dose of the IP, the participant experienced a Grade 3/severe serious adverse event of nausea. Action taken with the IP was not applicable. The event of intractable nausea lasted for 6 days, after which it was considered to be recovered/resolved on 03 Feb 2021 (Study Day 108). The investigator assessed the event of nausea to be not related to the IP.

Additional Information From the Safety Database

Additional details for the serious events are available in the following CIOMS reports:

CIOMS Number	MedDRA Preferred Term
MOD-2021-014606	Acute kidney injury
MOD-2021-014606	Nausea
MOD-2021-006694	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	1996 - Ongoing
Arthritis	Arthritis in right knee	2012 - Ongoing
Chronic kidney disease	Chronic kidney disease stage 3	2014 - Ongoing
Cataract	Cataract	2017 - Ongoing
Glaucoma	Glaucoma	2017 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	2014 - Ongoing	Hypertension
Metoprolol	2014 - Ongoing	Hypertension
Diclofenac	2016 - Ongoing	Arthritis In Knee
Dorzolamide; timolol	2017 - Ongoing	Glaucoma
Latanoprost	2017 - Ongoing	Glaucoma
Azithromycin	21 Jan 2021 (Study Day 95) - 25 Jan 2021 (Study Day 99)	COVID 19
Ceftriaxone	21 Jan 2021 (Study Day 95) - 24 Jan 2021 (Study Day 98)	COVID 19 Related Pneumonia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Dexamethasone	21 Jan 2021 (Study Day 95) - 21 Jan 2021 (Study Day 95)	COVID 19
Paracetamol	21 Jan 2021 (Study Day 95) - 25 Jan 2021 (Study Day 99)	Fever
Supplemental oxygen*	21 Jan 2021 (Study Day 95) - 21 Jan 2021 (Study Day 95)	Adverse Event
X-ray chest*	21 Jan 2021 (Study Day 95) - 21 Jan 2021 (Study Day 95)	Diagnostic
Ascorbic acid	22 Jan 2021 (Study Day 96) - 30 Jan 2021 (Study Day 104)	COVID 19
Convalescent plasma infusion*	22 Jan 2021 (Study Day 96) - 22 Jan 2021 (Study Day 96)	Adverse Event
Dexamethasone	22 Jan 2021 (Study Day 96) - 01 Feb 2021 (Study Day 106)	COVID 19
Enoxaparin	22 Jan 2021 (Study Day 96) - 25 Jan 2021 (Study Day 99)	Vte Prophylaxis
Famotidine	22 Jan 2021 (Study Day 96) - 24 Jan 2021 (Study Day 98)	Peptic Ulcer Disease Prophylaxis
Lung perfusion scan*	22 Jan 2021 (Study Day 96) - 22 Jan 2021 (Study Day 96)	Diagnostic
Remdesivir	22 Jan 2021 (Study Day 96) - 25 Jan 2021 (Study Day 99)	COVID 19
Zinc sulfate	22 Jan 2021 (Study Day 96) - 30 Jan 2021 (Study Day 104)	COVID 19
Enoxaparin	01 Feb 2021 (Study Day 106) - 03 Feb 2021 (Study Day 108)	Vte Prophylaxis
Insulin lispro	01 Feb 2021 (Study Day 106) - 03 Feb 2021 (Study Day 108)	Hyperglycemia From Newly Diagnosed Diabetes Type Ii
Sodium chloride	02 Feb 2021 (Study Day 107) - 03 Feb 2021 (Study Day 108)	Hyponatremia
Metformin	03 Feb 2021 (Study Day 108) - Ongoing	Hyperglycemia From Newly Diagnosed Diabetes Type Ii
Omeprazole	04 Feb 2021 (Study Day 109) - Ongoing	Gerd Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Hyperkalaemia	Grade 1/mild	Not related	01 Feb 2021 (Study Day 106) - 02 Feb 2021 (Study Day 107)
Hypermagnesaemia	Grade 1/mild	Not related	01 Feb 2021 (Study Day 106) - 03 Feb 2021 (Study Day 108)
Hyponatraemia	Grade 2/moderate	Not related	01 Feb 2021 (Study Day 106) - 03 Feb 2021 (Study Day 108)
Type 2 Diabetes Mellitus	Grade 3/severe	Not related	01 Feb 2021 (Study Day 106) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2117 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19, Confirmed	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	22 Sep 2020 (Study Day 13) – 05 Oct 2020 (Study Day 26)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2117, a 61-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Sep 2020 (Study Day 13), 12 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 07 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19, confirmed lasted for 14 days, after which it was considered to be recovered/resolved on 05 Oct 2020 (Study Day 26). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000361	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Postmenopause	Post menopausal	2007 - Ongoing
Hyperlipidaemia	Hyperlipidemia	2016 - Ongoing
Dermal filler injection	Dermal filler injection	2018 - 2019
Skin cosmetic procedure	Skin cosmetic procedure	2018 - 2019

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin d nos	2015 - Ongoing	Supplement
Vitamins nos	2015 - Ongoing	Supplement
Zinc	2015 - Ongoing	Supplement
Hydrocodone bitartrate; paracetamol	22 Sep 2020 (Study Day 13) - 22 Sep 2020 (Study Day 13)	Myalgias
Ibuprofen	23 Sep 2020 (Study Day 14) - 27 Sep 2020 (Study Day 18)	Coivd-19 (Confirmed) - Myalgias, Fever
Paracetamol	24 Sep 2020 (Study Day 15) - 24 Sep 2020 (Study Day 15)	Fever, Myalgias And Headache
Pseudoephedrine	01 Oct 2020 (Study Day 22) - 01 Oct 2020 (Study Day 22)	Sinus Congestion From COVID-19 Infection
Colesevelam	23 Dec 2020 (Study Day 105) - Ongoing	Hyperlipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 13) - 05 Oct 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2237 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	22 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Infection	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	22 Sep 2020 (Study Day 1) – 09 Oct 2020 (Study Day 18)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2237, a 60-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 22 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 22 Sep 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 19 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 infection lasted for 18 days, after which it was considered to be recovered/resolved on 09 Oct 2020 (Study Day 18). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000397	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	Not reported - Ongoing
Asthma	Asthma-mild	1966 - Ongoing
Gastrooesophageal reflux disease	Gastro-esophageal reflux disease	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Azelastine	Not reported - Ongoing	Allergic Rhinitis
Fluticasone	Not reported - Ongoing	Allergic Rhinitis
Fluticasone propionate; salmeterol xinafoate	Not reported - Ongoing	Asthma
Montelukast	Not reported - Ongoing	Asthma
Pantoprazole	01 Jan 2018 (Study Day -995) - Ongoing	Gerd
Naproxen	24 Sep 2020 (Study Day 3) - 27 Sep 2020 (Study Day 6)	Myalgias, Arthralgias Associated With COVID Infection
Paracetamol	27 Sep 2020 (Study Day 6) - 01 Oct 2020 (Study Day 10)	Fever Associated With COVID Infection
Azithromycin	05 Oct 2020 (Study Day 14) - 09 Oct 2020 (Study Day 18)	Cough From COVID
Varicella zoster vaccine	10 Nov 2020 (Study Day 50) - 10 Nov 2020 (Study Day 50)	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Not related	22 Sep 2020 (Study Day 1) - 10 Oct 2020 (Study Day 19)
COVID-19	Grade 2/moderate	Not related	22 Sep 2020 (Study Day 1) - 09 Oct 2020 (Study Day 18)
Chills	Grade 1/mild	Not related	24 Sep 2020 (Study Day 3) - 06 Oct 2020 (Study Day 15)
Headache	Grade 2/moderate	Not related	24 Sep 2020 (Study Day 3) - 30 Sep 2020 (Study Day 9)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2242 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	23 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Infection	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	29 Sep 2020 (Study Day 7) – 22 Oct 2020 (Study Day 30)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2242, a 29-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 23 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 29 Sep 2020 (Study Day 7), 6 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 20 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 infection lasted for 24 days, after which it was considered to be recovered/resolved on 22 Oct 2020 (Study Day 30). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000403	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Sleep apnoea syndrome	Sleep apnea	2016 - Ongoing
Hypertension	Hypertension	2018 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Losartan	2019 - Ongoing	Hypertension
Diphenhydramine hydrochloride; paracetamol; phenylephrine hydrochloride	29 Sep 2020 (Study Day 7) - Ongoing	Cough Later Found To Be Related To COVID-19
Dextromethorphan hydrobromide; doxylamine succinate; paracetamol	04 Oct 2020 (Study Day 12) - 07 Oct 2020 (Study Day 15)	Cough, Related To COVID 19 Infection
Dextromethorphan hydrobromide; guaifenesin	07 Oct 2020 (Study Day 15) - 14 Oct 2020 (Study Day 22)	Cough, Related To COVID 19 Infection
Metoprolol	22 Nov 2020 (Study Day 61) - 06 Mar 2021 (Study Day 165)	Worsening Hypertension
Metoprolol	06 Mar 2021 (Study Day 165) - Ongoing	Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	29 Sep 2020 (Study Day 7) - 22 Oct 2020 (Study Day 30)
Hypertension	Grade 2/moderate	Not related	22 Nov 2020 (Study Day 61) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US349-2299 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	13 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	10 Nov 2020 (Study Day 29) – Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US349-2299, a 55-year-old Hispanic or Latino male, received the first dose of placebo in the left arm on 13 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 10 Nov 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 09 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 was considered to be ongoing. The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000962	COVID-19

Study Completion/Discontinuation

On 20 Jan 2021 (Study Day 100), the participant discontinued from the study due to lost to follow-up.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1966 - Ongoing
Hypogonadism	Low testosterone - hypogonadism	2005 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Chorionic gonadotrophin	2010 - Ongoing	Hypogonadism
Loratadine	2010 - Ongoing	Seasonal Allergies
Testosterone cipionate	2012 - Ongoing	Hypogonadism
Paracetamol	20 Nov 2020 (Study Day 39) - Ongoing	Fevers - COVID 19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US351-2199 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asymptomatic COVID-19/Asymptomatic COVID-19 Infection	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	02 Sep 2020 (Study Day 1) – 12 Sep 2020 (Study Day 11)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US351-2199, a 59-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 02 Sep 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of asymptomatic COVID-19. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of asymptomatic COVID-19 infection lasted for 11 days, after which it was considered to be recovered/resolved on 12 Sep 2020 (Study Day 11). The investigator assessed the event of asymptomatic COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	(b) (6) 1961 (Study Day (b) (6) - Ongoing
Insomnia	Insomnia	1966 - Ongoing
Tobacco user	Current tobacco use	1990 - Ongoing
Intraventricular haemorrhage	Intraventricular brain bleed	2008 - 2008
Retinal detachment	Left retinal detachment	2008 - 2008
Blood cholesterol increased	High cholesterol	2010 - Ongoing
Blood triglycerides increased	High triglycerides	2010 - Ongoing
Hypertension	Hypertension	2010 - Ongoing
Type 2 diabetes mellitus	Type 2 diabetes	2010 - Ongoing
Hypermetropia	Farsighted bilateral	2018 - Ongoing
Musculoskeletal pain	Right shoulder pain	2018 - Ongoing
Skin laceration	Cut on left knee	25 Jun 2020 (Study Day -69) - 25 Jun 2020 (Study Day -69)
Suture insertion	One stitch placed from left knee cut	25 Jun 2020 (Study Day -69) - 25 Jun 2020 (Study Day -69)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Fenofibric acid	2010 - Ongoing	High Triglycerides
Levothyroxine	2010 - Ongoing	Hypothyroidism
Metformin	2010 - Ongoing	Type 2 Diabetes
Metoprolol	2010 - Ongoing	Hypertension
Nicardipine	2010 - Ongoing	Hypertension
Pitavastatin calcium	2010 - Ongoing	High Cholesterol
Acetylsalicylic acid	2015 - Ongoing	Prophylaxis For Coronary Artery Disease
Zolpidem	2016 - Ongoing	Insomnia
Naproxen sodium	2018 - Ongoing	Right Shoulder Pain
Amlodipine	2019 - Ongoing	Hypertension
Dulaglutide	01 May 2020 (Study Day -124) - Ongoing	Type 2 Diabetes
Glimepiride	01 Sep 2020 (Study Day -1) - Ongoing	Type 2 Diabetes
Naproxen sodium	08 Sep 2020 (Study Day 7) - 08 Sep 2020 (Study Day 7)	Worsening Right Shoulder Soreness Secondary To Yard Work
Influenza vaccine	16 Sep 2020 (Study Day 15) - 16 Sep 2020 (Study Day 15)	Seasonal Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asymptomatic COVID-19	Grade 1/mild	Not related	02 Sep 2020 (Study Day 1) - 12 Sep 2020 (Study Day 11)
Musculoskeletal Pain	Grade 1/mild	Not related	08 Sep 2020 (Study Day 7) - 08 Sep 2020 (Study Day 7)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US352-2042 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	07 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	22 Aug 2020 (Study Day 16) – 30 Aug 2020 (Study Day 24)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2042, a 34-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 07 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 22 Aug 2020 (Study Day 16), 15 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 03 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 9 days, after which it was considered to be recovered/resolved on 30 Aug 2020 (Study Day 24). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000215	COVID-19

Study Completion/Discontinuation

On 24 Dec 2020 (Study Day 140), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	Not reported - Ongoing
Seasonal allergy	Seasonal allergies	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Loratadine	Not reported - Ongoing	Seasonal Allergies
Hydrochlorothiazide	2012 - Ongoing	Hypertension
Paracetamol	23 Aug 2020 (Study Day 17) - 24 Aug 2020 (Study Day 18)	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	22 Aug 2020 (Study Day 16) - 30 Aug 2020 (Study Day 24)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US352-2297 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19 Infection	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	18 Sep 2020 (Study Day 29) – 26 Sep 2020 (Study Day 37)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US352-2297, a 63-year-old race unknown male, received the first dose of placebo in the left arm on 21 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 18 Sep 2020 (Study Day 29), 28 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 17 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 infection lasted for 9 days, after which it was considered to be recovered/resolved on 26 Sep 2020 (Study Day 37). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000327	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No prior or concomitant medications or procedures were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	22 Aug 2020 (Study Day 2) - 23 Aug 2020 (Study Day 3)	Joint Aches In Several Joints
Acetylsalicylic acid	18 Sep 2020 (Study Day 29) - 26 Sep 2020 (Study Day 37)	Symptomatic COVID-19 Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	18 Sep 2020 (Study Day 29) - 26 Sep 2020 (Study Day 37)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US354-2043 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	24 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	07 Sep 2020 (Study Day 15) – 14 Sep 2020 (Study Day 22)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US354-2043, a 26-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 24 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Sep 2020 (Study Day 15), 14 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 20 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 8 days, after which it was considered to be recovered/resolved on 14 Sep 2020 (Study Day 22). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000378	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Systolic murmur	2008 - Ongoing
Migraine	Migraines	2011 - Ongoing
Allergy to animal	Allergies (dogs)	Jul 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levonorgestrel	Feb 2016 - 03 Nov 2020 (Study Day 72)	Contraception
Topiramate	Mar 2019 - Ongoing	Migraine
Cetirizine hydrochloride	Jul 2020 - Ongoing	Dog Allergy
Phenylephrine	08 Sep 2020 (Study Day 16) - 11 Sep 2020 (Study Day 19)	Symptomatic COVID-19
Colposcopy*	03 Nov 2020 (Study Day 72) - 03 Nov 2020 (Study Day 72)	Diagnostic
Amoxicillin	27 Dec 2020 (Study Day 126) - 03 Jan 2021 (Study Day 133)	Dog Bite To The Face

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	07 Sep 2020 (Study Day 15) - 14 Sep 2020 (Study Day 22)
Cervical Dysplasia	Grade 1/mild	Not related	06 Oct 2020 (Study Day 44) - Ongoing
Animal Bite	Grade 2/moderate	Not related	24 Dec 2020 (Study Day 123) - 31 Dec 2020 (Study Day 130)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US359-2196 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	16 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asymptomatic COVID-19/ Asymptomatic COVID-19 Positive	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not applicable	16 Aug 2020 (Study Day 1) – 28 Aug 2020 (Study Day 13)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US359-2196, a 69-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 16 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 16 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of asymptomatic COVID-19. On 12 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of asymptomatic COVID-19 positive lasted for 13 days, after which it was considered to be recovered/resolved on 28 Aug 2020 (Study Day 13). The investigator assessed the event of asymptomatic COVID-19 to be not applicable to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Headache	Headaches occasionally	1957 - Ongoing
Drug hypersensitivity	Penicillin allergy	1969 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypothyroidism	Hypothyroidism	1969 - Ongoing
Osteoarthritis	Osteoarthritis general	1990 - Ongoing
Seasonal allergy	Seasonal allergies	1990 - Ongoing
Nausea	Nausea	1991 - Ongoing
Fibromyalgia	Fibromyalgia	1993 - Ongoing
Constipation	Constipation	2000 - Ongoing
Nocturia	Nocturia	2000 - Ongoing
Postmenopause	Postmenopausal	2000 - Ongoing
Deafness bilateral	Bilateral hearing loss	2010 - Ongoing
Dry eye	Dry eye, bilateral	2010 - Ongoing
Flatulence	Occasional excess stomach gas	2010 - Ongoing
Hypokalaemia	Hypokalemia	2015 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1970 - Ongoing	Hypothyroidism
Diphenhydramine	1990 - Ongoing	Seasonal Allergies
Naproxen sodium	1990 - Ongoing	Osteoarthritis
Pseudoephedrine	1990 - Ongoing	Seasonal Allergies
Ondansetron	1993 - Ongoing	Nausea
Ascorbic acid	2000 - Ongoing	Nutritional Supplement
Calcium citrate; colecalciferol	2000 - Ongoing	Nutritional Supplement
Chondroitin; glucosamine	2000 - Ongoing	Osteoarthritis
Colecalciferol	2000 - Ongoing	Nutritional Supplement
Docusate sodium	2000 - Ongoing	Constipation
Estradiol	2000 - Ongoing	Post Menopausal
Medroxyprogesterone	2000 - Ongoing	Post Menopausal
Melatonin	2000 - Ongoing	Nutritional Supplement
Solifenacin	2000 - Ongoing	Nocturia
Vitamins nos	2000 - Ongoing	Nutritional Supplement
Ciclosporin	2010 - Ongoing	Dry Eye
Lysine	2010 - Ongoing	Cold Sores Prophylaxis
Simeticone	2010 - Ongoing	Excess Stomach Gas
Potassium chloride	2015 - Ongoing	Hypokalemia
Methocarbamol	Jan 2020 - Ongoing	Fibromyalgia
Naproxen	20 Aug 2020 (Study Day 5) - 20 Aug 2020 (Study Day 5)	Muscle Aches
Naproxen	22 Aug 2020 (Study Day 7) - 22 Aug 2020 (Study Day 7)	Headache

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Influenza vaccine	16 Sep 2020 (Study Day 32) - 16 Sep 2020 (Study Day 32)	Influenza Prophylaxis
Famotidine	08 Oct 2020 (Study Day 54) - Ongoing	Acid Reflux
Hydrocortisone	28 Jan 2021 (Study Day 166) - Ongoing	Osteoarthritis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asymptomatic COVID-19	Grade 1/mild	Not applicable	16 Aug 2020 (Study Day 1) - 28 Aug 2020 (Study Day 13)
Gastrooesophageal Reflux Disease	Grade 1/mild	Not related	08 Oct 2020 (Study Day 54) - 03 Nov 2020 (Study Day 80)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US360-2111 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	29 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	24 Oct 2020 (Study Day 26) – 23 Nov 2020 (Study Day 56)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US360-2111, a 36-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 29 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Oct 2020 (Study Day 26), 25 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 26 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 31 days, after which it was considered to be recovered/resolved on 23 Nov 2020 (Study Day 56). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000662	COVID-19

Study Completion/Discontinuation

On 06 Feb 2021 (Study Day 131), the participant discontinued from the study due to protocol deviation.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Asthma	1993 - Ongoing
Female sterilisation	Bilateral tubal ligation	2015 - 2015
Abdominoplasty	Abdominoplasty	2017 - 2017

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Salbutamol	1993 - Ongoing	Asthma
Vitamins nos	2018 - Ongoing	Dietary Supplement
Ibuprofen	24 Oct 2020 (Study Day 26) - 24 Oct 2020 (Study Day 26)	Fever
Ibuprofen	25 Oct 2020 (Study Day 27) - 28 Oct 2020 (Study Day 30)	Fever
Ibuprofen	29 Oct 2020 (Study Day 31) - 31 Oct 2020 (Study Day 33)	Headache
Ibuprofen	01 Nov 2020 (Study Day 34) - 01 Nov 2020 (Study Day 34)	Headache
Other viral vaccines	13 Jan 2021 (Study Day 107) - 13 Jan 2021 (Study Day 107)	COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US373-2207 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	27 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	14 Sep 2020 (Study Day 19) – Ongoing	Unknown

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US373-2207, a 30-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 27 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Sep 2020 (Study Day 19), 18 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 23 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The outcome of the event was unknown. The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000334	COVID-19

Study Completion/Discontinuation

On 24 Sep 2020 (Study Day 29), the participant discontinued from the study due to withdrawal of consent by participant.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Migraine	Migraine headaches	2008 - Ongoing
Anxiety	Anxiety	Nov 2010 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Erenumab	2008 - Ongoing	Migraine Headaches
Lorazepam	2010 - Ongoing	Anxiety
Ibuprofen	15 Sep 2020 (Study Day 20) - Ongoing	Symptomatic COVID-19
Paracetamol	17 Sep 2020 (Study Day 22) - Ongoing	Symptomatic COVID-19

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

Participant Number:	US374-2253 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	04 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	20 Sep 2020 (Study Day 17) – 29 Sep 2020 (Study Day 26)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2253, a 44-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 04 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 20 Sep 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 01 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 10 days, after which it was considered to be recovered/resolved on 29 Sep 2020 (Study Day 26). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the nonserious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000464	COVID-19

Study Completion/Discontinuation

On 07 Jan 2021 (Study Day 126), the participant discontinued from the study due to other.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Drug hypersensitivity	Allergy to penicillin	1976 - Ongoing
Vitiligo	Vitiligo	1985 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	28 Sep 2020 (Study Day 25) - 23 Oct 2020 (Study Day 50)	Prophylaxis Of COVID-Related Hypercoagulability
Ascorbic acid	28 Sep 2020 (Study Day 25) - 23 Oct 2020 (Study Day 50)	Health Maintenance Prophylaxis
Influenza vaccine	07 Nov 2020 (Study Day 65) - 07 Nov 2020 (Study Day 65)	Influenza Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	20 Sep 2020 (Study Day 17) - 29 Sep 2020 (Study Day 26)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US374-2477 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	01 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	14 Oct 2020 (Study Day 14) – 31 Oct 2020 (Study Day 31)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US374-2477, a 49-year-old Hispanic or Latino female, received the first dose of placebo in the left arm on 01 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Oct 2020 (Study Day 14), 13 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 28 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 18 days, after which it was considered to be recovered/resolved on 31 Oct 2020 (Study Day 31). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000538	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Obesity	Not reported - Ongoing
Cyst removal	Cyst removal(left hand)	1995 - 1995
Female sterilisation	Tubal ligation	06 Mar 1998 (Study Day -8245) - 06 Mar 1998 (Study Day -8245)
Knee arthroplasty	Left knee replacement	Dec 2016 - Dec 2016
Osteoarthritis	Osteoarthritis	Dec 2016 - Ongoing
Asthma	Asthma moderate	Apr 2017 - Ongoing
Constipation	Constipation	Aug 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Diclofenac	Not reported - Ongoing	Osteoarthritis, Knee Pain, Joint Pain
Beclometasone dipropionate	Apr 2017 - Ongoing	Asthma
Protein	May 2020 - Ongoing	Supplement
Herbal preparation	Aug 2020 - Ongoing	Constipation
Mineral supplements	Sep 2020 - Ongoing	Supplement
Ibuprofen	05 Oct 2020 (Study Day 5) - 07 Oct 2020 (Study Day 7)	Muscle Aches
Dextromethorphan hydrobromide; paracetamol; phenylephrine	07 Oct 2020 (Study Day 7) - 07 Oct 2020 (Study Day 7)	Rhinorrhea And Nasal Congestion
Paracetamol	15 Oct 2020 (Study Day 15) - 30 Oct 2020 (Study Day 30)	Symptomatic COVID-19
Ibuprofen	23 Oct 2020 (Study Day 23) - 25 Oct 2020 (Study Day 25)	Symptomatic COVID-19
Acetylsalicylic acid	29 Oct 2020 (Study Day 29) - 01 Nov 2020 (Study Day 32)	Thrombosis Prevention

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	07 Oct 2020 (Study Day 7) - 09 Oct 2020 (Study Day 9)
Nasal Congestion	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 7) - 08 Oct 2020 (Study Day 8)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Rhinorrhoea	Grade 2/moderate	Not related	07 Oct 2020 (Study Day 7) - 07 Oct 2020 (Study Day 7)
Arthralgia	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 13) - 26 Oct 2020 (Study Day 26)
Musculoskeletal Pain	Grade 2/moderate	Not related	13 Oct 2020 (Study Day 13) - 26 Oct 2020 (Study Day 26)
COVID-19	Grade 2/moderate	Not related	14 Oct 2020 (Study Day 14) - 31 Oct 2020 (Study Day 31)
Arthralgia	Grade 2/moderate	Not related	16 Nov 2020 (Study Day 47) - 19 Feb 2021 (Study Day 142)
Pain In Extremity	Grade 1/mild	Not related	16 Nov 2020 (Study Day 47) - Ongoing
Breast Mass	Grade 2/moderate	Not related	14 Dec 2020 (Study Day 75) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US375-2366 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	04 Sep 2020 (Study Day 3) – 16 Sep 2020 (Study Day 15)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US375-2366, a 49-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 04 Sep 2020 (Study Day 3), 2 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 13 days, after which it was considered to be recovered/resolved on 16 Sep 2020 (Study Day 15). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000283	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cardiac murmur	Grade i cardiac murmur (final diagnosis unknown)	Not reported - Ongoing
Keratomileusis	Lasik eye surgery	Not reported
Rotator cuff repair	Decompression left subacromial arthroscopy	Not reported
Conjunctivitis allergic	Allergic conjunctivitis	1990 - Not reported
Rhinitis allergic	Allergic rhinitis	1990 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamins nos	2019 - Ongoing	Supplement
Paracetamol	06 Sep 2020 (Study Day 5) - 06 Sep 2020 (Study Day 5)	Symptomatic COVID-19
Influenza vaccine	05 Oct 2020 (Study Day 34) - 05 Oct 2020 (Study Day 34)	Prophylaxis For Seasonal Influenza

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	04 Sep 2020 (Study Day 3) - 16 Sep 2020 (Study Day 15)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US378-2198 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	23 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Psoriasis/Exacerbation Psoriasis	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	09 Nov 2020 (Study Day 18) – 05 Dec 2020 (Study Day 44)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US378-2198, a 30-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 23 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 09 Nov 2020 (Study Day 18), 17 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of psoriasis. On 19 Nov 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of exacerbation psoriasis lasted for 27 days, after which it was considered to be recovered/resolved on 05 Dec 2020 (Study Day 44). The investigator assessed the event of psoriasis to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Back pain	Occasional back pain	2006 - Ongoing
Anxiety	Anxiety	2008 - Ongoing

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Psoriasis	Psoriasis	2018 - Ongoing
Pharyngitis streptococcal	Strep pharyngitis	17 Oct 2020 (Study Day -6) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Ibuprofen	2006 - Ongoing	Occasional Back Pain
Amoxicillin	17 Oct 2020 (Study Day -6) - 26 Oct 2020 (Study Day 4)	Strep Pharyngitis
Clobetasol propionate	20 Nov 2020 (Study Day 29) - Ongoing	Excacerbation Psoriasis
Diphenhydramine hydrochloride	26 Nov 2020 (Study Day 35) - 02 Dec 2020 (Study Day 41)	Exacerbation Psoriasis
Betamethasone dipropionate; calcipotriol monohydrate	02 Dec 2020 (Study Day 41) - 14 Dec 2020 (Study Day 53)	Exacerbation Proriasis
Ceftriaxone	02 Dec 2020 (Study Day 41) - 02 Dec 2020 (Study Day 41)	Exacerbation Psoriasis
Fludroxycortide	02 Dec 2020 (Study Day 41) - 19 Dec 2020 (Study Day 58)	Exacerbation Proriasis
Methylphenidate	18 Jan 2021 (Study Day 88) - Ongoing	Anxiety

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Psoriasis	Grade 2/moderate	Not related	09 Nov 2020 (Study Day 18) - 05 Dec 2020 (Study Day 44)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2174 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	14 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	14 Aug 2020 (Study Day 1) – 26 Sep 2020 (Study Day 44)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2174, a 18-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 14 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 10 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 44 days, after which it was considered to be recovered/resolved on 26 Sep 2020 (Study Day 44). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000291	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Asthma	Mild asthma	2007 - 2014
Amnesia	Mild short term memory loss	2010 - Ongoing
Concussion	Concussion	2010 - 2010
Obesity	Obesity	2010 - Ongoing
Hypersensitivity	Environmental allergies	2019 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	14 Aug 2020 (Study Day 1) - 26 Sep 2020 (Study Day 44)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2197 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	17 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/ Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	24 Aug 2020 (Study Day 8) – 28 Aug 2020 (Study Day 12)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2197, a 38-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 17 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 24 Aug 2020 (Study Day 8), 7 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 13 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID-19 lasted for 5 days, after which it was considered to be recovered/resolved on 28 Aug 2020 (Study Day 12). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000239	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Seasonal allergy	Seasonal allergies	1998 - Ongoing
Finger repair operation	Right ring finger repair	2000 - 2000
Hand fracture	Right broken ring finger	2000 - 2000
Hiatus hernia	Hiatal hernia	2000 - 2000

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

No prior or concomitant medications or procedures were reported.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	24 Aug 2020 (Study Day 8) - 28 Aug 2020 (Study Day 12)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US381-2257 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	25 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19 Infection	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	25 Aug 2020 (Study Day 1) – 11 Jan 2021 (Study Day 140)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US381-2257, a 52-year-old not Hispanic or Latino male, received the first dose of placebo in the right arm on 25 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 25 Aug 2020 (Study Day 1), on the day of the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 21 Sep 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 infection lasted for 140 days, after which it was considered to be recovered/resolved on 11 Jan 2021 (Study Day 140). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Visual impairment	Bilateral impaired vision	1972 - Ongoing
Food allergy	Coconut allergy	1977 - Ongoing
Hypersensitivity	Environmental allergies	1977 - Ongoing
Alcohol use	Alcohol consumption 1-2 times per week	1988 - Ongoing
Continuous positive airway pressure	Cpap usage	2005 - Ongoing
Gout	Gout bilateral feet and knees	2005 - Ongoing
Sleep apnoea syndrome	Sleep apnea	2005 - Ongoing
Hypertension	Hypertension	Jun 2005 - Ongoing
Carpal tunnel syndrome	Left carpel tunnel	2010 - Mar 2020
Obesity	Obesity	2010 - Ongoing
Cardiac failure congestive	Congestive heart failure	Aug 2012 - Ongoing
Contrast media allergy	Lipid microsphere allergy	Aug 2012 - Ongoing
Hypercholesterolaemia	Hypercholesterolemia	Aug 2012 - Ongoing
Hypokalaemia	Potassium deficiency	Aug 2012 - Ongoing
Myocardial infarction	Myocardial infarction	Aug 2012 - Aug 2012
Gastric bypass	Gastric bypass	Dec 2018 - Dec 2018
Carpal tunnel decompression	Left carpel tunnel repair	Mar 2020 - Mar 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Amlodipine	Jun 2005 - Ongoing	Hypertension
Carvedilol	Jun 2005 - Ongoing	Hypertension
Cetirizine hydrochloride	2010 - Ongoing	Seasonal/Environmental Allergies
Acetylsalicylic acid	Aug 2012 - Ongoing	Cardiac Health
Allopurinol	Aug 2012 - Ongoing	Gout Bilateral Feet And Knees
Atorvastatin	Aug 2012 - Ongoing	Hypercholesterolemia
Furosemide	Aug 2012 - Ongoing	Hypertension
Losartan	Aug 2012 - Ongoing	Hypertension
Potassium	Aug 2012 - Ongoing	Potassium Deficiency
Influenza vaccine	29 Oct 2020 (Study Day 66) - 29 Oct 2020 (Study Day 66)	Flu Prevention
Amoxicillin	30 Dec 2020 (Study Day 128) - 15 Jan 2021 (Study Day 144)	Bilateral Otitis Media

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Prednisone	01 Jan 2021 (Study Day 130) - 06 Jan 2021 (Study Day 135)	Bilateral Otitis Media

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	25 Aug 2020 (Study Day 1) - 11 Jan 2021 (Study Day 140)
Diplacusis	Grade 1/mild	Not related	30 Dec 2020 (Study Day 128) - 15 Jan 2021 (Study Day 144)
Otitis Media	Grade 1/mild	Not related	30 Dec 2020 (Study Day 128) - 15 Jan 2021 (Study Day 144)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US384-2060 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	21 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asymptomatic COVID-19/A-Symptomatic COVID-19	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	26 Oct 2020 (Study Day 6) – 29 Oct 2020 (Study Day 9)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US384-2060, a 57-year-old Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 21 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 26 Oct 2020 (Study Day 6), 5 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of asymptomatic COVID-19. On 17 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of a-symptomatic COVID-19 lasted for 4 days, after which it was considered to be recovered/resolved on 29 Oct 2020 (Study Day 9). The investigator assessed the event of asymptomatic COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rotator cuff repair	Right rotator cuff surgery	2008 - 2008
Intervertebral disc protrusion	Chronic leg weakness (both) herniated disk	2010 - Ongoing
Peripheral sensory neuropathy	Neuropathy, right side of face (sensory)	2010 - Ongoing
Intervertebral disc protrusion	Herniated disk t10 t11	2020 - Ongoing
Seasonal allergy	Seasonal rhinitis (allergic)	2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Vitamin b12 nos	2016 - Ongoing	Nutritional Supplement
Botulinum toxin type a	2019 - Ongoing	Neuropathy, Face (Right Side)
Simvastatin	2019 - Ongoing	Reduce Risk Of Mi Or Brain Attack
Vitamin d nos	Sep 2020 - Ongoing	Nutritional Supplement
Diazepam	17 Nov 2020 (Study Day 28) - 17 Nov 2020 (Study Day 28)	Anxiety Related To Mri Induced Claustrophobia
Zinc	Dec 2020 - Ongoing	Nutritional Supplement
Botox administration to face every 90 days*	13 Jan 2021 (Study Day 85) - 13 Jan 2021 (Study Day 85)	Other, Neuropathy, Right Side Of Face

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asymptomatic COVID-19	Grade 1/mild	Not related	26 Oct 2020 (Study Day 6) - 29 Oct 2020 (Study Day 9)
Anxiety	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 28) - 17 Nov 2020 (Study Day 28)
Claustrophobia	Grade 2/moderate	Not related	17 Nov 2020 (Study Day 28) - 17 Nov 2020 (Study Day 28)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US387-2138 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥65 Years
First Dose of Vaccine:	11 Aug 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Urinary Tract Infection/Urinary Tract Infection	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	27 Aug 2020 (Study Day 17) – 08 Sep 2020 (Study Day 29)	Recovered/ resolved
Retching/Dry Heaves	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	31 Aug 2020 (Study Day 21) – 31 Aug 2020 (Study Day 21)	Recovered/ resolved
Vertigo/Vertigo	AE leading to withdrawal from study vaccine	Grade 3/ severe	Not related	31 Aug 2020 (Study Day 21) – 31 Aug 2020 (Study Day 21)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2138, a 73-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 11 Aug 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 27 Aug 2020 (Study Day 17), 16 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of urinary tract infection. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of urinary tract infection lasted for 13 days, after which it was considered to be recovered/resolved on 08 Sep 2020 (Study Day 29). The investigator assessed the event of urinary tract infection to be not related to the IP.

On 31 Aug 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of retching. On 07 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of dry heaves lasted for 1 day, after which it was considered to be recovered/resolved on 31 Aug 2020 (Study Day 21). The investigator assessed the event of retching to be not related to the IP.

On 31 Aug 2020 (Study Day 21), 20 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 3/severe non-serious adverse event of vertigo. On 07 Sep 2020

(Study Day 28), the IP dose was discontinued due to other. The event of vertigo lasted for 1 day, after which it was considered to be recovered/resolved on 31 Aug 2020 (Study Day 21). The investigator assessed the event of vertigo to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Cholelithiasis	Gallstones	1968 - 1968
Presbyopia	Presbyopia	1975 - Ongoing
Hysterectomy	Complete hysterectomy	1984 - 1984
Uterine leiomyoma	Uterine fibroids	1984 - 1984
Intervertebral disc protrusion	Herniated l4-5 disc	1986 - 1986
Hypertension	Hypertension	2005 - Ongoing
Cataract	Bilateral cataracts	2013 - 2013
Increased tendency to bruise	Easy bruising	2013 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Valsartan	2005 - Ongoing	Hypertension
Amoxicillin; clavulanic acid	30 Aug 2020 (Study Day 20) - 30 Aug 2020 (Study Day 20)	Urinary Tract Infection
Sulfamethoxazole; trimethoprim	31 Aug 2020 (Study Day 21) - 06 Sep 2020 (Study Day 27)	Urinary Tract Infection
Influenza vaccine	13 Oct 2020 (Study Day 64) - 13 Oct 2020 (Study Day 64)	Flu Prevetion
Ibuprofen	09 Dec 2020 (Study Day 121) - 10 Dec 2020 (Study Day 122)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Urinary Tract Infection	Grade 3/severe	Not related	27 Aug 2020 (Study Day 17) - 08 Sep 2020 (Study Day 29)
Retching	Grade 3/severe	Not related	31 Aug 2020 (Study Day 21) - 31 Aug 2020 (Study Day 21)
Vertigo	Grade 3/severe	Not related	31 Aug 2020 (Study Day 21) - 31 Aug 2020 (Study Day 21)
Cough	Grade 2/moderate	Not related	09 Dec 2020 (Study Day 121) - 10 Dec 2020 (Study Day 122)
Headache	Grade 1/mild	Not related	09 Dec 2020 (Study Day 121) - 10 Dec 2020 (Study Day 122)
Diarrhoea	Grade 2/moderate	Not related	20 Dec 2020 (Study Day 132) - 22 Dec 2020 (Study Day 134)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3380648

Participant Number:	US387-2501 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Asymptomatic COVID-19/COVID-19 (Asymptomatic)	AE leading to withdrawal from study vaccine	Grade 1/ mild	Not related	19 Sep 2020 (Study Day 10) – 24 Oct 2020 (Study Day 45)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US387-2501, a 62-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 10 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was positive.

Event Details

On 19 Sep 2020 (Study Day 10), 9 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of asymptomatic COVID-19. On 07 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 (asymptomatic) lasted for 36 days, after which it was considered to be recovered/resolved on 24 Oct 2020 (Study Day 45). The investigator assessed the event of asymptomatic COVID-19 to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Hypertension	Hypertension	2005 - Ongoing
Osteoarthritis	Osteoarthritis (hands, knees and hip	2005 - Ongoing
Drug hypersensitivity	Allergic to lisinopril	2008 - Ongoing
Type 2 diabetes mellitus	Diabetes mellitus type 2	2008 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Acetylsalicylic acid	2012 - Ongoing	Cardiac Prophylaxis
Hydrochlorothiazide	2012 - Ongoing	Hypertension
Metformin	2013 - Ongoing	Diabetes Mellitus Type 2
Amlodipine	2015 - Ongoing	Hypertension
Metoprolol	2015 - Ongoing	Hypertension
Naproxen	2015 - Ongoing	Osteoarthritis
Influenza vaccine	20 Oct 2020 (Study Day 41) - 20 Oct 2020 (Study Day 41)	Influenza Prevention
Tetanus vaccine	20 Oct 2020 (Study Day 41) - 20 Oct 2020 (Study Day 41)	Prophylaxis

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Asymptomatic COVID-19	Grade 1/mild	Not related	19 Sep 2020 (Study Day 10) - 24 Oct 2020 (Study Day 45)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US388-2049 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥65 Years
First Dose of Vaccine:	23 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	25 Nov 2020 (Study Day 34) – 03 Dec 2020 (Study Day 42)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US388-2049, a 66-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 23 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Nov 2020 (Study Day 34), 33 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 19 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 9 days, after which it was considered to be recovered/resolved on 03 Dec 2020 (Study Day 42). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000953	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Glucose tolerance impaired	Pre-diabetes	Not reported - Ongoing
Hyperlipidaemia	Hyperlipidemia	Not reported - Ongoing
Malignant melanoma	Malignant melanoma	Not reported - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Rosuvastatin	Not reported - Ongoing	Hyperlipidemia

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	25 Nov 2020 (Study Day 34) - 03 Dec 2020 (Study Day 42)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US390-2064 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	10 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	15 Sep 2020 (Study Day 6) – 25 Sep 2020 (Study Day 16)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US390-2064, a 50-year-old not Hispanic or Latino female, received the first dose of placebo in the left arm on 10 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Sep 2020 (Study Day 6), 5 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 07 Oct 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 11 days, after which it was considered to be recovered/resolved on 25 Sep 2020 (Study Day 16). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000344	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Tonsillectomy	Tonsilectomy	1986 - 1986
Tonsillitis	Tonsillitis	1986 - 1986
Hysterectomy	Hysterectomy	2000 - 2000
Uterine leiomyoma	Uterine fibroids	2000 - 2000
Hypothyroidism	Hypothyroidism	Mar 2020 - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	Mar 2020 - Ongoing	Hypothyroidism
Naproxen sodium	15 Sep 2020 (Study Day 6) - Oct 2020	COVID-19
Paracetamol	15 Sep 2020 (Study Day 6) - Oct 2020	COVID-19
Azithromycin	17 Sep 2020 (Study Day 8) - 21 Sep 2020 (Study Day 12)	COVID-19
Oxymetazoline hydrochloride	17 Sep 2020 (Study Day 8) - Oct 2020	COVID-19
Cyclobenzaprine hydrochloride	19 Oct 2020 (Study Day 40) - Ongoing	Back Pain
Propranolol	06 Nov 2020 (Study Day 58) - Ongoing	Ae: Hypertension

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 2/moderate	Not related	15 Sep 2020 (Study Day 6) - 25 Sep 2020 (Study Day 16)
Eye Swelling	Grade 1/mild	Not related	18 Sep 2020 (Study Day 9) - 25 Sep 2020 (Study Day 16)
Hypertension	Grade 3/severe	Not related	18 Sep 2020 (Study Day 9) - Ongoing
Ear Pain	Grade 1/mild	Not related	26 Sep 2020 (Study Day 17) - Ongoing
Back Pain	Grade 2/moderate	Not related	12 Oct 2020 (Study Day 33) - Ongoing
Dizziness	Grade 1/mild	Not related	12 Oct 2020 (Study Day 33) - Ongoing
Fatigue	Grade 1/mild	Not related	28 Oct 2020 (Study Day 49) - 06 Nov 2020 (Study Day 58)

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Feeling Abnormal	Grade 1/mild	Not related	28 Oct 2020 (Study Day 49) - 06 Nov 2020 (Study Day 58)
Malaise	Grade 1/mild	Not related	28 Oct 2020 (Study Day 49) - 06 Nov 2020 (Study Day 58)
Myalgia	Grade 1/mild	Not related	28 Oct 2020 (Study Day 49) - 06 Nov 2020 (Study Day 58)
Pain	Grade 1/mild	Not related	29 Oct 2020 (Study Day 50) - 06 Nov 2020 (Study Day 58)
Nausea	Grade 1/mild	Not related	01 Nov 2020 (Study Day 53) - 06 Nov 2020 (Study Day 58)
Dyspnoea	Grade 1/mild	Not related	02 Nov 2020 (Study Day 54) - 06 Nov 2020 (Study Day 58)

Preferred terms are coded using MedDRA version 23.0.

FDA-CBER-2022-1614-3380655

Participant Number:	US392-2074 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	02 Oct 2020 (Study Day 31)
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bipolar Disorder/Bipolar Disorder	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	19 Jan 2021 (Study Day 140) –Ongoing	Not recovered/ not resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US392-2074, a 50-year-old not Hispanic or Latino male, received the first dose of mRNA-1273 in the left arm on 02 Sep 2020 (Study Day 1). The second dose was administered in the left arm on 02 Oct 2020 (Study Day 31). The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 19 Jan 2021 (Study Day 140), 139 days after the first dose and 109 days after the second dose of the IP, the participant experienced a Grade 2/moderate non-serious adverse event of bipolar disorder. The IP dose was withdrawn due to the bipolar disorder. The event of bipolar disorder was considered to be ongoing. The investigator assessed the event of bipolar disorder to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Rhinitis allergic	Allergic rhinitis	1996 - Ongoing
Appendicectomy	Appendectomy	1997 - 1997

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Appendicitis	Appendicitis	1997 - 1997
Ligament operation	Acl reconstruction l knee	2002 - 2002
Ligament rupture	Torn acl l knee	2002 - 2002
Intervertebral disc degeneration	Degenerative disc disease l5-s1	2005 - 2005
Spinal fusion surgery	Lumbar fusion l5-s1	2005 - 2005
Sleep apnoea syndrome	Obstructive sleep apnea	2008 - Ongoing
Dyspepsia	Heartburn	2013 - Ongoing
Hypertension	Hypertension	2013 - Ongoing
Blood testosterone decreased	Low testosterone	2016 - Ongoing
Cervical radiculopathy	Cervical radiculopathy (nerve pain in neck)	2019 - Ongoing
Headache	Headache	2019 - Ongoing
Depression	Depression	15 Mar 2020 (Study Day -171) - Ongoing
Large intestine polyp	Colon polyp (benign)	19 Aug 2020 (Study Day -14) - 26 Aug 2020 (Study Day -7)
Large intestinal polypectomy	Colon polypectomy (benign)	26 Aug 2020 (Study Day -7) - 26 Aug 2020 (Study Day -7)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atorvastatin	2012 - Ongoing	Hyperlipidemnia
Losartan	2013 - Ongoing	Hypertension
Pantoprazole	2013 - Ongoing	Heartburn
Lamotrigine	01 Jan 2014 (Study Day -2436) - Ongoing	Depression
Hydroxyzine	2015 - Ongoing	Seasonal Allergies
Testosterone cipionate	2016 - Ongoing	Low Testosterone
Methocarbamol	2019 - 25 Nov 2020 (Study Day 85)	Cervical Radiculopathy
Indometacin	Oct 2019 - Ongoing	Intermittent Headache
Oxcarbazepine	Jul 2020 - 23 Mar 2021 (Study Day 203)	Bipolar Depression
Paracetamol	04 Oct 2020 (Study Day 33) - 04 Oct 2020 (Study Day 33)	Pain At Injection Site
Influenza vaccine	29 Oct 2020 (Study Day 58) - 29 Oct 2020 (Study Day 58)	Flu Prophylaxis
Gabapentin	03 Nov 2020 (Study Day 63) - 25 Nov 2020 (Study Day 85)	Cervical Radiculopathy
Aripiprazole	15 Dec 2020 (Study Day 105) - Ongoing	Ae#2 (Worsening Of Depression)
Fluticasone propionate	11 Jan 2021 (Study Day 132) - Ongoing	Ae #4 (Right Sided Partial Hearing Loss) And Ae #5 (Right Sided Tinnitus)
Lurasidone hydrochloride	20 Jan 2021 (Study Day 141) - Ongoing	Ae# 3 Bipolar Disorder
Eszopiclone	15 Feb 2021 (Study Day 167) - Ongoing	Ae#6 Insomnia

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Aripiprazole	20 Feb 2021 (Study Day 172) - Ongoing	Ae #2 (Worsening Depression)
Quetiapine fumarate	23 Mar 2021 (Study Day 203) - Ongoing	Ae #6 (Insomnia)

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Fatigue	Grade 1/mild	Related	09 Sep 2020 (Study Day 8) – 10 Sep 2020 (Study Day 9)
Cervical Radiculopathy	Grade 2/moderate	Not related	04 Oct 2020 (Study Day 33) - 25 Nov 2020 (Study Day 85)
Hypoacusis	Grade 1/mild	Not related	12 Dec 2020 (Study Day 102) - Ongoing
Tinnitus	Grade 1/mild	Not related	12 Dec 2020 (Study Day 102) - 19 Mar 2021 (Study Day 199)
Depression	Grade 2/moderate	Not related	15 Dec 2020 (Study Day 105) - Ongoing
Bipolar Disorder	Grade 2/moderate	Not related	19 Jan 2021 (Study Day 140) - Ongoing

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US393-2238 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	13 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/COVID-19	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Not related	07 Nov 2020 (Study Day 26) – 09 Dec 2020 (Study Day 58)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US393-2238, a 59-year-old not Hispanic or Latino female, received the first dose of placebo in the right arm on 13 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 07 Nov 2020 (Study Day 26), 25 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of COVID-19. On 09 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of COVID-19 lasted for 33 days, after which it was considered to be recovered/resolved on 09 Dec 2020 (Study Day 58). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000837	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Single functional kidney	Solitary rt kidney	23 Oct 1966 (Study Day -19714) - Ongoing
Hypothyroidism	Hypothyroidism	1995 - Ongoing
Diverticulitis	Diverticulitis	2001 - 2001
Hypertension	Hypertension	2012 - Ongoing
Lumbar vertebral fracture	Lumbar spine fracture	2012 - 2012
Type 2 diabetes mellitus	Diabetes type 2	2013 - Ongoing
Hypercholesterolaemia	Hypecholesterolemia	2014 - Ongoing
Foot fracture	Lt foot fracture	2017 - 2017
Lower limb fracture	Rt knee fracture	May 2018 - Aug 2018
Foot fracture	Rt toe fracture	2020 - 2020

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Levothyroxine	1995 - Ongoing	Hypothyroidism
Lisinopril	2012 - Ongoing	High Blood Pressure
Dapagliflozin propanediol monohydrate	2013 - Ongoing	Diabetes Type 2
Atorvastatin	2014 - Ongoing	High Cholesterol
Dulaglutide	2017 - Ongoing	Diabetes Type 2
Calcium; vitamin d nos	Sep 2020 - Ongoing	Vitamin Supplement
Influenza vaccine	07 Sep 2020 (Study Day -36) - 07 Sep 2020 (Study Day -36)	Influenza Prophylaxis
Calcium; vitamin d nos	22 Oct 2020 (Study Day 10) - 26 Dec 2020 (Study Day 75)	Vitamin D Deficiency
Botulinum toxin type a	07 Jan 2021 (Study Day 87) - 07 Jan 2021 (Study Day 87)	Antiaging
Paracetamol	24 Feb 2021 (Study Day 135) - 24 Feb 2021 (Study Day 135)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Vitamin D Deficiency	Grade 2/moderate	Not related	22 Oct 2020 (Study Day 10) - 26 Dec 2020 (Study Day 75)
COVID-19	Grade 2/moderate	Not related	07 Nov 2020 (Study Day 26) - 09 Dec 2020 (Study Day 58)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US394-2044 (Part A)
Vaccination Group:	Placebo
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	02 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Headache/Headache	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	25 Sep 2020 (Study Day 24) – 14 Oct 2020 (Study Day 43)	Recovered/ resolved
Oropharyngeal Pain/Sore Throat	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	25 Sep 2020 (Study Day 24) – 14 Oct 2020 (Study Day 43)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US394-2044, a 39-year-old not Hispanic or Latino male, received the first dose of placebo in the left arm on 02 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 25 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of headache. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of headache lasted for 20 days, after which it was considered to be recovered/resolved on 14 Oct 2020 (Study Day 43). The investigator assessed the event of headache to be not related to the IP.

On 25 Sep 2020 (Study Day 24), 23 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of oropharyngeal pain. On 29 Sep 2020 (Study Day 28), the IP dose was discontinued due to other. The event of sore throat lasted for 20 days, after which it was considered to be recovered/resolved on 14 Oct 2020 (Study Day 43). The investigator assessed the event of oropharyngeal pain to be not related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

No medical history or ongoing medical conditions were reported.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Paracetamol	25 Sep 2020 (Study Day 24) - 14 Oct 2020 (Study Day 43)	Headache

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
Cough	Grade 1/mild	Not related	25 Sep 2020 (Study Day 24) - 14 Oct 2020 (Study Day 43)
Fatigue	Grade 1/mild	Not related	25 Sep 2020 (Study Day 24) - 14 Oct 2020 (Study Day 43)
Headache	Grade 1/mild	Not related	25 Sep 2020 (Study Day 24) - 14 Oct 2020 (Study Day 43)
Oropharyngeal Pain	Grade 1/mild	Not related	25 Sep 2020 (Study Day 24) - 14 Oct 2020 (Study Day 43)
Rhinorrhoea	Grade 1/mild	Not related	25 Sep 2020 (Study Day 24) - 14 Oct 2020 (Study Day 43)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US397-2225 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and Not at Risk
First Dose of Vaccine:	12 Oct 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19/Symptomatic COVID 19	AE leading to withdrawal from study vaccine	Grade 1/mild	Not related	15 Oct 2020 (Study Day 4) – 16 Nov 2020 (Study Day 36)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US397-2225, a 22-year-old Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 12 Oct 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 15 Oct 2020 (Study Day 4), 3 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 1/mild non-serious adverse event of COVID-19. On 08 Nov 2020 (Study Day 28), the IP dose was discontinued due to SARS-CoV-2. The event of symptomatic COVID 19 lasted for 33 days, after which it was considered to be recovered/resolved on 16 Nov 2020 (Study Day 36). The investigator assessed the event of COVID-19 to be not related to the IP.

Additional Information From the Safety Database

Additional details for the non-serious event are available in the following CIOMS report:

CIOMS Number	MedDRA Preferred Term
MOD-2020-000732	COVID-19

Study Completion/Discontinuation

At the time of last contact, the participant was continuing in the study.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Leukaemia	Leukemia	2006 - 2008
Bacterial infection	Bacterial infection on right hand	2007 - 2007
Sinusitis	Sinusitis	2007 - 2007
Tonsillitis	Tonsillitis	2009 - 2009
Anxiety	Anxiety	2012 - Ongoing
Eczema	Eczema	2013 - Ongoing
Cholelithiasis	Gall stones	2015 - 2015

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Alprazolam	2014 - Ongoing	Anxiety
Dienogest; ethinylestradiol	2014 - Ongoing	Pregnancy Prevention
Sertraline	2014 - Ongoing	Anxiety
Betamethasone dipropionate; clotrimazole	2015 - Ongoing	Eczema
Ibuprofen	14 Oct 2020 (Study Day 3) - 18 Oct 2020 (Study Day 7)	Headache
Azithromycin	18 Oct 2020 (Study Day 7) - 23 Oct 2020 (Study Day 12)	COVID-19 Infection
Paracetamol	18 Oct 2020 (Study Day 7) - 25 Oct 2020 (Study Day 14)	Headache
Salbutamol	18 Oct 2020 (Study Day 7) - 23 Oct 2020 (Study Day 12)	COVID-19 Infection

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

The unsolicited nonserious events are presented in the following table:

Preferred Term	Severity	Relationship to IP	Start Date – Stop Date/Ongoing
COVID-19	Grade 1/mild	Not related	15 Oct 2020 (Study Day 4) - 16 Nov 2020 (Study Day 36)

Preferred terms are coded using MedDRA version 23.0.

Participant Number:	US398-2158 (Part A)
Vaccination Group:	mRNA-1273
Randomization Strata:	≥18 and <65 Years and at Risk
First Dose of Vaccine:	11 Sep 2020 (Study Day 1)
Second Dose of Vaccine:	Not Administered
Reason for Narrative:	AE leading to withdrawal from IP

Narrative Overview

MedDRA Preferred Term/ Verbatim Term	Event Category	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Idiopathic Intracranial Hypertension/Worsening Pseudotumor Cerebri	AE leading to withdrawal from study vaccine	Grade 2/ moderate	Related	14 Sep 2020 (Study Day 4) – 01 Oct 2020 (Study Day 21)	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities version 23.0.

Participant US398-2158, a 52-year-old not Hispanic or Latino female, received the first dose of mRNA-1273 in the left arm on 11 Sep 2020 (Study Day 1). The second dose on Study Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Event Details

On 14 Sep 2020 (Study Day 4), 3 days after the first dose of the IP (second dose not applicable), the participant experienced a Grade 2/moderate non-serious adverse event of idiopathic intracranial hypertension. On 08 Oct 2020 (Study Day 28), the IP dose was discontinued due to physician decision. The event of worsening pseudotumor cerebri lasted for 18 days, after which it was considered to be recovered/resolved on 01 Oct 2020 (Study Day 21). The investigator assessed the event of idiopathic intracranial hypertension to be related to the IP.

Additional Information From the Safety Database

No additional details for the event are available.

Study Completion/Discontinuation

On 16 Oct 2020 (Study Day 36), the participant discontinued from the study due to protocol deviation.

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Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions are presented in the following table:

Preferred Term	Condition	Start Date – Stop Date/Ongoing
Obesity	Severe obesity	Not reported - Ongoing
Hypertension	Hypertension	2000 - Ongoing
Menorrhagia	Menorrhagia	2000 - 02 Dec 2018 (Study Day -649)
Idiopathic intracranial hypertension	Pseudotumor cerebri	2006 - Ongoing
Hysterectomy	Hysterectomy	02 Dec 2018 (Study Day -649) - 02 Dec 2018 (Study Day -649)
Salpingo-oophorectomy bilateral	Bilateral salpingo oophorectomy	02 Dec 2018 (Study Day -649) - 02 Dec 2018 (Study Day -649)

Preferred terms are coded using MedDRA version 23.0.

Prior/Concomitant Medications and Procedures

The participant was taking the prior and/or concomitant medications and underwent the concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Atenolol	2000 - Ongoing	Hypertension
Lisinopril	2000 - Ongoing	Hypertension
Acetylsalicylic acid	15 Sep 2020 (Study Day 5) - 21 Sep 2020 (Study Day 11)	Headache
Butalbital; caffeine; paracetamol	16 Sep 2020 (Study Day 6) - 21 Sep 2020 (Study Day 11)	Headache
Dextromethorphan; paracetamol; phenylephrine	17 Sep 2020 (Study Day 7) - Ongoing	Headache
Acetazolamide	18 Sep 2020 (Study Day 8) - 01 Oct 2020 (Study Day 21)	Worsening Pseudotumor Cerebri

Medications are coded using WHO Drug Dictionary version Mar 2020. Concomitant procedures are denoted by *.

Unsolicited Nonserious Adverse Events

No unsolicited nonserious events were reported.

16 APPENDICES

16.1 Study Information

16.1.1 Protocol and Protocol Amendments
16.1.2 Sample Case Report Form (Unique Pages Only)
16.1.3 List of IECs and IRBs (Plus the Name of the Committee Chair if Required by the Regulatory Authority) and Representative Written Information for Participant and Sample Consent Forms
16.1.4 List and Description of Investigators and Other Important Participants in the Study, Including Brief (One Page) Curricula Vitae or Equivalent Summaries of Training and Experience Relevant to the Performance of the Study
16.1.5 Signatures of Principal or Coordinating Investigator(s) and Sponsor's Responsible Medical Officer, Depending on the Regulatory Authority's Requirement, and Signature of Responsible Biostatistician
16.1.6 Listing of Participants Receiving Investigational Product/Investigational Product(s) From Specific Batches, Where More Than One Batch Was Used
16.1.7 Randomization Scheme and Codes (Participant Identification and Treatment Assigned)
16.1.8 Audit Certificates (if available)
16.1.9 Documentation of Statistical Methods
16.1.10 Documentation of Interlaboratory Standardization Methods and Quality Assurance Procedures if Used
16.1.11 Publications Based on the Study
16.1.12 Important Publications Referenced in the Report
16.1.13 Optional Appendix

16.2 Participant Data Listings

16.2.1 Discontinued Participants
16.2.2 Protocol Deviations
16.2.3 Participants Excluded From the Efficacy Analysis
16.2.4 Demographic Data
16.2.5 Compliance or Drug Concentration Data (or both, if available)
16.2.6 Individual Efficacy Response Data
16.2.7 Adverse Event Listings (Each Participant)
16.2.8 Listing of Individual Laboratory Measurements by Participant, When Required by Regulatory Authorities

16.3 Case Report Forms (CRFs)

16.3.1 CRFs for Deaths, Serious Adverse Events, and Withdrawals for Adverse Events

16.3.2 Other CRFs Submitted (only if applicable)

16.4 Individual Participant Data Listings

16.5 Genotyping Report

16.6 Summary of Biomarker Assays Used in the mRNA-1273 Program

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